Health Facilities Scotland

NHS National Services Scotland

Scottish Health Technical Memorandum 01-06

Decontamination of thermolabile flexible endoscopes and Transoesophageal echocardiograph (TOE) ultrasound probes in Endoscope Decontamination Units.

Part D: Automated endoscope washer disinfectors

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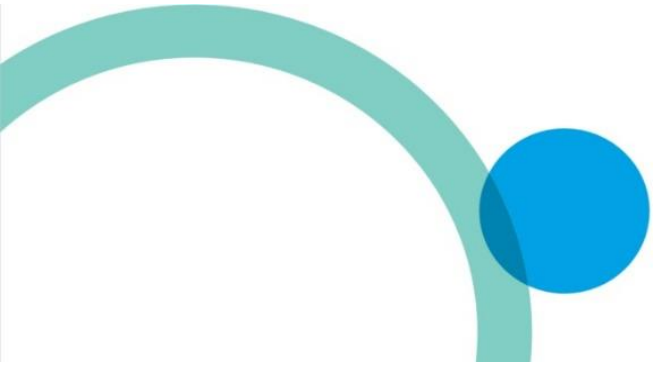

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1. Introduction

1.1 Scottish Health Technical Memorandum (SHTM) 01-06 Part D presents best practice guidance on automated cleaning and disinfection using Endoscope Washer Disinfectors (EWDs) as defined in Part A of SHTM 01-06 located within Endoscope Decontamination Units (EDUs).

1.2 The standards BS EN 15883 Part 1:2009+A1: 2014, Part :4: 2018, and BS EN 15883 Part 5: 2021 specify performance requirements, mechanical and process requirements, and conformity tests for EWDs. Standard BS EN IEC 61010-2-040: 2021 sets general safety requirements for electrical equipment. These standards are addressed in this guidance.

Note 1.1: Standard BS EN 15883 Part 1:2009+A1: 2014 and Standard BS EN 15883 Part 4: 2018 use the term Washer-disinfector throughout. The term Endoscope Washer Disinfector (EWD) was introduced in HFS guidance, planning note SHPN 13 Part 3 v1 published 2010 and used in the HFS compliance document for Endoscope Decontamination Units GUID 5013 published 2014. Therefore, the term Endoscope Washer Disinfector is used to describe a washer-disinfector employing chemical disinfection for thermolabile endoscopes throughout SHTM 01-06.

1.3 Stages within the EWD cycle may include leak testing, cleaning, disinfection, rinsing and purging/drying. The standard on processing healthcare products BS EN 17664 Part 1: 2021 defines:

- cleaning as ‘removal of contaminants to the extent necessary for further processing or for intended use and’;
- disinfection as ‘the process to reduce the number of viable microorganisms to a level previously specified as being appropriate for a defined purpose’.

Where an EWD is used these processes are described In BS EN 17664 Part 1: 2021 as automated cleaning and automated disinfection.

1.4 SHTM 01-06 Part D is intended as a guide for management, technical personnel with appropriate training and experience and Users responsible for the operational management of decontamination equipment. It will also be of interest to microbiologists, infection control managers, estates managers, supplies officers, and others in both the public and private sectors.

Note 1.2: Scottish Health Planning Note (SHPN13) Part 3 Decontamination facilities: Endoscope Decontamination Units: 2010 is applicable to new builds or upgrades of EDUs. A room data sheet for a general plant room (which may house any water treatment plant that supplies the EWD) is also included. Planning involving installation of EWDs should take account of the need to maintain the integrity/performance of the EDU rooms.

Scope of SHTM 01- 06 Part D

1.5 This guidance covers automated EWDs, their accessories and the quality of water required when processing:

- thermolabile flexible endoscopes;
- Transoesophageal echocardiograph (TOE) ultrasound probes (recommended to be processed in an EWD by the TOE ultrasound probe manufacturer). The TOE ultrasound probe may also be thermolabile.

Note 1.3: Part A (of SHTM 01-06) defines thermolabile as 'readily damaged by heat'.

Exclusions

1.6 This guidance does not cover:

- decontamination equipment located out with an EDU, with the exception of endoscope storage cabinets;
- decontamination of devices such as rigid endoscopes, surgical instruments or robotic instruments that are not recommended by the IFU (in full);
- decontamination of ultrasound probes other than TOE ultrasound probes unless approved by the manufacturer for processing in an EWD.

2. Pre-purchase considerations

General

2.1 This section of SHTM01-06-Part D discusses technical specifications and operational requirements to be considered when inviting tenders and issuing a contract for EWDs and associated equipment. Where possible Health Boards (HB) should procure new EWDs under the terms of the NP143 framework for decontamination equipment, accessories and maintenance

2.2 It is essential that any purchase of an item of decontamination equipment is planned to ensure that the User's predefined requirements are met. An overview of points to consider can be found in Part A and general requirements applicable to all decontamination equipment can be found in Part B of this SHTM 01-06 series.

2.3 Where possible the NP187 framework for decontamination equipment and consumables, should be considered as the first option. when considering the purchase of process chemicals. This framework includes EWDs and process chemicals reviewed by HFS and Health Board technical staff, as part of a National Procurement tendering exercise.

Workload and throughput requirements

2.4 The throughput requirements of the EDU should be based on the number and type of endoscopes required by the clinical services supplied. The capacity of the EWD should be assessed on the number of endoscopes or TOE ultrasound probes that can be processed in a single load and the EWD cycle time. Further guidance on the planning and selection of equipment and facilities can be found in Scottish Health Planning Note (SHPN) 13 Part 3: 2010 'Decontamination Facilities: Endoscope Decontamination Units'.

Note 2.1: As turnaround times can fluctuate based on the demand placed on the service, the period of maximum demand should be used to calculate the capacity requirements or unacceptable delays could result.

2.5 During planning and prior to purchase make allowance for downtime, including testing, maintenance, and servicing. Where possible any additional future service requirements should also be included in the calculations.

Note 2.2: In the event of a breakdown, periodic testing or other issues that may halt normal production, the loss of an EWD can have a large impact on throughput and service provision. Therefore, contingency arrangements should be in place. Any contingency plan should allow for catastrophic failure of facilities, equipment or critical services.

Specifications

2.6 It is essential that the procurement specification is prepared by a team of qualified and competent staff and the Authorised Person (Decontamination) (AP(D)), and Authorising Engineer (Decontamination) (AE(D)) may be consulted. Endoscope

Washer Disinfectors should be compliant with the requirements specified in GUID 5013 v2: 2014, 'Requirements for compliant Endoscope Decontamination Units'. Compliance with relevant parts of standards BS EN 15883 part 1:2009+A1:2014, BS EN 15883 Part 4:2018 and BS EN 15883 Part 5: 2021 is also required.

Configuration and load handling

2.7 Endoscope Washer Disinfectors of various sizes and configurations are available on the market. Wherever possible the use of a pass through EWD is advised. This will allow segregation of dirty and clean areas within the EDU as shown in the model EDU layouts for two or more rooms found in SHPN 13 Part 3: 2010.

2.8 Prior to purchase of an EWD several factors should be considered, including:

- the number and type of endoscopes to be processed;
- if there is a requirement to process TOE ultrasound probes;
- the size of the EDU;
- the size of the EWD;
- engineering service provision including the type and location of any water treatment facilities;
- maximum and minimum operational temperatures;
- process chemical type and concentration;
- required pump pressure;
- water flow volume, rate and pressure;
- water quality (chemical and microbial);
- air temperature;
- air-flow rate;
- loading pattern;
- tracking and traceability of operational staff and endoscopes.

2.9 The above factors may vary depending on the make model and design of the EWD. The Authorised Person (Decontamination) AP(D) and the Authorising Engineer (Decontamination) (AE(D)) may be consulted to ensure all factors are identified.

Image 2.1: an example of a TOE ultrasound probe in a protective case

Note 2.3: Where an EWD is being considered for decontamination of TOE probes an additional means of protecting the electrical components will be required (Image 2.1) due to the construction of TOE ultrasound probes. The manufacturer of the TOE ultrasound probe and Endoscope Washer Disinfector (EWD) should be consulted on the suitability and compatibility prior to purchase. TOE ultrasound probe manufacturers' decontamination instructions should be followed.

Note 2.4: Where technological advances provide new dedicated equipment, designed to clean and disinfect TOE probes to the same standard of cleanliness and microbiocidal impacts as EN 15883:1, 4 and 5 these may be considered as an alternative to EWDs.

Operational and performance requirements

2.10 The choice of EWD should be determined by several operational and performance requirements compliant with BS EN 15883 Part 4: 2018 and relevant parts of BS EN 15883 Part 1:2009+A1: 2014 and using test methods described in BS EN 15883 Part 5:2021. EWD operating cycles should include:

- leak testing of endoscopes;
- a cleaning stage that includes pre-cleaning, washing and rinsing;
- a chemical disinfection stage;
- post disinfect final rinse;
- drying (purging) stage;
- an EWD self-disinfection cycle (thermal disinfection is the preferred method).

The duration of each process stage should be defined, repeatable and recorded, to ensure all cycle parameters for each consecutive operating cycle have the same efficacy.

2.11 An independent process verification system (commonly known as the independent Monitoring System (IMS) is also required. This system should monitor all critical process variables, have separate sensors and be independent of the EWD process controller. This will enable verification that the EWD consistently achieves the required specified parameters. A fault indication system should be included and activate if any of the critical parameters described in section 4 validation and BS EN 15883 Part 4: 2018 are out with the specified limits.

Note 2.5: When additional monitoring is required, a separate test connection should be provided for each test sensor. This will permit periodic verification of the installed system by comparison with an independent calibrated process verification system test sensor.

2.12 The EWD chamber should be designed to withstand no less than 10,000 cycles as recommended in BS EN 15883 Part 1: 2014 clause 5.1.3 when operated and maintained in accordance with the EWD manufacturer's instructions.

2.13 It should be a requirement for the lid or door to lock before the EWD cycle can begin.

Instrumentation and controls

2.14 Instruments and controls should be designed, positioned and protected as specified in BS EN 15883 Part 1:2009+A1:2014, and BS EN 15883 Part 4:2018.

2.15 The following indicators for the process should be displayed or available to the user and located at the loading end of the EWD:

- in-process;
- fault;
- hours run meter or cycle counter (that cannot be re-set by the user);
- cycle complete;
- insufficient process chemicals to complete cycle;
- a temperature indicator showing the temperature attained at a reference point within the EWD during the cleaning, disinfection and drying stages of the cycle.

On double ended (pass through) EWDs, the following indicators should also be located at the unloading end:

- in-process;
- cycle complete
- fault.

Where a fault occurs during an operating cycle, or where a cycle has been aborted this information should be clearly displayed and an audible alarm, capable of being muted, activated. The EWD should be fitted with an emergency stop system that can be activated from both sides of the EWD if it is necessary to abort the cycle, or, if the machine becomes isolated from any essential services (e.g. Electricity or compressed air supply).

The Automatic controller

2.16 An automatic control system should regulate all essential parameters (e.g. time/temperature relationship, chemical concentration etc.) of the EWD and verify that process conditions specified by the endoscope and EWD manufacturer were attained.

2.17 The temperature of any process fluids (e.g. detergent and disinfectant solutions) should be maintained within the range specified by the process chemical manufacturer and below the maximum temperature advised by the endoscope manufacturer. Time/temperature relationships, including self-disinfect cycle parameters and chemical concentrations should be monitored and controlled by the automatic controller and verified during validation.

2.18 It is desirable for the EWD automatic controller to be adjustable for a range of endoscope connection types. Any adjustment should be a programmable option.

Note 2.6: Endoscopes should not be used without confirmation of a successfully completed cycle. Any endoscopes removed from a failed cycle should be fully reprocessed prior to use.

Irrigation systems

2.19 Endoscope Washer Disinfectors should be fitted with rotating spray arms (with rotation detection sensors) or water jets to ensure a uniform external wash action. Dedicated connection points for the irrigation of all possible endoscope channels should also be provided. The suitability of the design of connectors from endoscope lumens to the EWD should have been demonstrated during type testing.

2.20 The EWD irrigation systems should be protected by filters to prevent the passage of particles that may block spray arms, nozzles or endoscope channels. Where fitted the EWD should also have removable nozzles designed with:

- bayonet, screws or other suitable removable fittings that can be easily cleaned inside and outside;
- a means of identifying they have been installed in their correct position;
- the ability to withstand a minimum of 250 matings.

2.21 All working channels must be clearly identified and specific dedicated connection points and connectors for each channel provided by the EWD manufacturer. All connectors/hubs etc. should also have endoscope connection points as shown in image 2.2, that prevent incorrect connection of endoscope channels to the EWD. Consult the EWD and endoscope manufacturer's instructions. The AE(D) may advise.

Image 2.2 EWD interior showings dedicated endoscope conectors

2.22 Many endoscopes have multiple narrow working channels. EWD should be designed to ensure that fluids flow freely though the endoscope channels/lumen(s) during all stages of the cleaning process.

Load carriers

2.23 All load carriers (e.g. hook-ups, hubs, trays or baskets see Image 2.3) for supporting endoscopes or TOE ultrasound probes during the cycle, or, when transferring the load into and out of the chamber should be operated in accordance with the manufacturer's instructions.

Image:2.3 an example of an EWD load carrier for connection and support of endoscopes during processing.

The manufacturer should provide evidence from the type test data that load carriers:

- are designed and constructed from durable, corrosion-resistant materials able to withstand the environment within the chamber;
- do not cause damage wear and tear or excessive stress on the load carrier (e.g. point loadings) or the chamber;
- ensure adequate spacing and orientation of all endoscope or TOE ultrasound probe surfaces results in exposure to the process fluids;
- prevent incorrect positioning of the endoscopes that could restrict the penetration of air, water, detergent and disinfectant solutions into the endoscope lumens or, the free drainage of water from the load;
- protect the endoscopes from mechanical damage during the EWD process.

Note 2.7: Ensure any device used for the protection of non-immersible parts of TOE ultrasound probes are compatible with the EWD.

2.24 Where Load carriers include irrigation pipework, a way of connecting test equipment should be provided for use during testing. Further guidance on the use of test equipment including data loggers can be found in SHTM 01-06 Part B.

Automatic leak testing

2.25 It is a requirement that the EWD includes a pre-cycle leak test before the load contacts with process fluids. It is also desirable for the EWD to perform an additional leak check at the end of the cycle, to ensure no damage has occurred during processing. The effectiveness of any leak test should demonstrate compliance with BS EN 15883 Part 4: 2018 clause 6.5 when tested as described in Appendix 3 of this guidance document.

2.26 It should be confirmed that the EWD can meet the endoscope manufacturers requirements for the intensity and duration of pressurisation and any pressure drop and/or air flow change required to indicate a leak test failure. Where critical to the sensitivity of the leak test, the permitted temperature range should also be stated.

2.27 A pressure regulating valve should be provided to prevent over pressurisation of the endoscope in the event of a system failure. In addition, the pressure inside the EWD should be independent of the pressure control used to perform the endoscope leak test via a pressure transducer.

2.28 Where a failure is detected (a leak) or where a leak test connector is not connected at the start of the EWD cycle, the automatic controller should initiate an audible and visible alarm indicating a 'leak test failure' and prevent the continuation of the operating cycle.

2.29 Connectors for joining endoscope working channel(s) to the EWD should not be able to connect to the endoscope leak test connection port and leak testing connectors should not fit other working channels.

Cleaning performance

2.30 The efficacy of the endoscope cleaning stage of the EWD cycle is crucial to the successful outcome of the disinfection stage and is dependent on a range of variables for each stage of the process, including:

- water quality;
- flow/pressure;
- temperature;
- time;
- process chemicals (pH, concentration etc.).

Enzymatic cleaners

2.31 A considerable proportion of the soiling found on thermolabile flexible endoscopes contains proteins which can bind onto surfaces acting as a focal point for particulates and microbial contamination. Therefore, enzymatic cleaning solutions are recommended for use in the EWD washing stage, as they help breakdown proteins enabling their removal from endoscope surfaces.

Note 2.8: As enzymes are not cleansing agents it is essential that balanced solutions that include a combination of enzymes and detergents are used to clean endoscopes.

2.32 Enzymatic detergent activity is temperature and time dependent therefore, it should be used at the temperature and for the duration recommended by the chemical manufacturer.

2.33 Enzymatic cleaning solutions also have an optimum pH at which the enzyme has the greatest activity. Therefore, any enzymatic detergent in use should include buffering agents to maintain the pH within the recommended range.

2.34 During manufacturers type testing (and operational testing on site) the EWD should have been shown to remove contamination (e.g. test soils as described in BS EN 15883 Part 5:2021) from the endoscope and EWD basin with the disinfection stage disabled. Test soil formulations should be based on and representative of the worst

case soiling found after clinical use. Test requirements from BS EN 15883 Part 5:2021 clause 4.3 include detection of protein and one other analyte from:

- total organic Carbon;
- carbohydrate;
- haemoglobin;
- ATP;
- Endotoxin.

This should demonstrate that the recommended detergent achieves the level of cleanliness required. That is:

- test pieces (surrogates or endoscopes) that are visibly free from the test soil with no test soil having been transferred to the chamber walls or load carrier.
- no visible soil remains on the exterior of the test pieces or within channels when checked visually the method in Appendix 3, 3.44;
- protein detection levels below:
  - alert level ≥ to 3µg/cm^2;
  - action level ≥ 6 µg/cm^2.

As specified in BS EN 15883 Part 5:2021.

2.35 Local water quality can also affect EWD cleaning efficacy therefore the incoming water supply should be of a quality that will not contaminate the EWD (including the internal pipe work) and endoscopes with micro-organisms. The use of internal storage tanks for storing EWD process water is not recommended. Further guidance on water quality can be found in Section 3 and Appendix 4 of this guidance document.

2.36 Cleaning efficacy tests should be repeated on site during Performance Qualification (PQ). Further details of the tests and methodology required for compliance with the above standards can be found in Section 4 and Appendix 4.

2.37 Process chemicals should also be validated in the EDU during Operational Qualification (OQ) and Performance Qualification (PQ) testing.

2.38 When considering the introduction of any new detergents review the instructions for use and consult with the:

- EWD manufacturer;
- Detergent manufacturer;
- Endoscope manufacturer.

Chemical compatibility

2.39 All process chemicals should be appropriate for their intended purpose, (cleaning and disinfecting flexible endoscopes). The results of biocompatibility studies should

be provided by the chemical manufacturer and show that the chemical formula is safe to use. Additionally process chemicals for use in EWDs should be:

- compatible with the quality of water available;
- compatible with any other additives to be used in the EWD process;
- non-abrasive;
- low foaming;
- free rinsing;
- biodegradable;
- liquid (to facilitate accurate dispensing);
- readily removed from the load items by rinsing with water;
- compatible with any subsequent decontamination process such as low temperature sterilization or packing systems that dose chemicals.

Note 2.9: To ensure compatibility with the decontamination process and equipment only process chemicals (detergents and disinfectants) validated and approved by the EWD manufacturer and endoscope manufacturer should be used. It is not sufficient to only determine the compatibility of the principal active ingredients in a process chemical, as the precise formulation will affect its compatibility.

Note 2.10: Where a change to the process chemical in use is being considered the proposed process chemicals will require validation and formal confirmation from the EWD manufacturer that it is compatible with their equipment, compatible with the endoscopes in use and is effective.

2.40 Suppliers should provide product data sheets and material safety data sheets for the products supplied. Reference should be made to local COSHH provisions.

Note 2.11: Process chemicals used in the EWDs can be irritant. An emergency eye wash station, suitable Personal Protective Equipment (PPE) and an appropriate spillage kit should be available in any area where process chemicals are stored or used.

The safe use of these chemicals by EDU staff is covered by the Control of Substances Hazardous to Health (COSHH) Regulations: 2002 (as amended).

2.41 It is advisable that all staff working in the EDU are trained in emergency spill procedures. Staff should manage any chemical spills as per local policy with reference to local COSHH provision.

2.42 To prevent the incorrect chemical being delivered during the EWD cycle, the dosing system should have dedicated non interchangeable connectors for each chemical in use.

2.43 During the cleaning stage(s) of the EWD cycle, water, and aqueous solutions in contact with the endoscope should be controlled within the temperature range stated by the detergent manufacturer and specified by the endoscope manufacturer's instructions.

Note 2.12: Water and detergent solutions used for flushing/cleaning of endoscopes should not be reused for later stages that is, detergent and disinfectant solutions should be used once and then discarded.

Note 2.13: Water and chemical solutions from all stages of the process should discharge to the drain prior to the next stage of the EWD cycle. Requirements for drainage systems can be found in Section 3.9 of this guidance document.

Note 2.14: Process chemicals should be stored in a dedicated cabinet, in a secure location with controlled entry. Refer to SHPN 13 Part 3: 2010. Only validated, in date process chemicals should be kept in the operational location. New chemicals being trialled should be stored securely away from the operational storage area to prevent accidental use. A change management process should be in place (see SHTM 01–06-Part B section 3.9 management.

2.44 Lubricants should only be used as required by the EWD manufacturers' instructions for use.

Post wash rinsing

2.45 It is desirable that EWDs are capable of rinsing between each stage of the cycle to remove residual soil and prevent interaction between the process chemicals (detergents and disinfectants) in use. Where an EWD does not rinse between each stage of the process the manufacturer is required to demonstrate that:

- there is no adverse reaction between process chemicals being used for each of these stages;
- there is no adverse reaction between suspended or residual soiling and the disinfectant that can compromise the disinfection stage (BS EN 15883 Part 4:2018. clause 4.3.4.)

Note 2.15: Detergent residue can reduce the efficacy of the chemical disinfectant required for high level endoscope disinfection and disinfectant residue could result in harm to the patient during clinical procedures It should be noted that disinfection stage/final rinse and purging ultimately also impact on residue levels on the endoscope.

Disinfection performance

2.46 Disinfection is the process used to reduce the number of viable microorganisms (bioburden) to a level that makes the endoscope safe for further handling or use. As thermolabile flexible endoscopes processed in EDUs are not heat tolerant and cannot be thermally disinfected low temperature chemical disinfection is undertaken. Each disinfectant used should be specified and accepted by both the EWD and endoscope manufacturers, as being appropriate and effective before being introduced.

2.47 The process chemical manufacturer/supplier of any new process chemicals should demonstrate that the disinfectant activity levels are in line with relevant published standards on chemical disinfectants e.g. BS EN 12353: 2013, BS EN 13624, BS EN 13727, BS EN 14348, BS EN 14476, BS EN 14561, BS EN 14562, BS EN 14885 and BS EN 14563. Disinfectant dosing systems should also be accurate,

reproducible and meet the requirements of both BS EN 15883 Part 1:2009+A1:2014 and BS EN 15883 Part 4:2018 as applicable.

2.48 The EWD manufacturer/supplier should also provide evidence that during type testing for chemical disinfection of the load a range of organisms representative of the organisms found on the device after use and most resistant to the disinfectant were used. Annex B of BS EN 15883 Part 4: 2018 suggests the use of:

- Pseudomonas aeruginosa;
- Serratia marcescens;
- Staphylococcus aureus;
- Enterococcus faecium;
- Enterococcus hirae;
- Mycobacterium terrae;
- Mycobacterium avium;
- Candida albicans;
- Aspergillus (spores) brasiliensis;
- Adenovirus type 5 Adenoid 75;
- Poliovirus Type 1 LSc-2ab, or suitable surrogate;
- Bovine parvovirus strain Haden or Murine parvovirus strain Crawford following species;
- Murine norovirus strain (S99)2), or suitable surrogate;
- endospores of Clostridium difficile (NCTC3) 13366);
- endospores of Geobacillus stearothermophilus;
- endospores of Bacillus subtilis/atropheus.

These organisms should be defined strains from a type culture collection, for example The American Type Culture Collection or identical strains from another recognised culture collection.

2.49 The minimum log10 reduction obtained after a complete standard cycle for the selected microorganism(s) should comply with the BS EN 15883 Part 4: 2018 Performance requirement 4.1.3. shown in table 2.1.

Table 2.1: log reduction requirements for disinfection efficacy during type testing

Microorganism	Log reduction
Vegetative bacteria;	— 9 log10
Fungal spores;	— 6 log10
Mycobacteria;	— 6 log10
Bacterial endospores	— 4 log10

2.50 This should be confirmed during type testing and PQ testing. Additional information for test requirements and methods can be found in Section 4 and Appendix 3.

2.51 The biocompatibility data provided by the chemical manufacturer should include a safe limit of disinfectant residue shown to prevent harm to patients. This should have been demonstrated during EWD type testing.

Note 2.16: Where further processing (e.g. low temperature sterilization or packing systems employing chemical dosing) of the endoscope is required after processing in the EWD verify with the equipment manufacturer or service provider that the level of residual disinfectant on the endoscope will not impact the efficacy of their sterilization or packaging process. Additional information on the requirements for low temperature sterilization and packing systems employing chemical dosing can be found in SHTM 01-01 Part E and SHTM 01-06 Part E respectively.

2.52 The disinfectant manufacturer should provide a validated neutralization method for the specific disinfectant to be used during testing. This will prevent any continued reduction in the microbial population after sampling and before analysis.

2.53 The automatic controller should include a means of verification that the process conditions (disinfectant concentration, temperature and contact time) specified by the EWD manufacturer for disinfection to take place were attained.

2.54 EWDs should be fitted with a system that indicates when there is insufficient chemical(s) available for the next operating cycle and prevent the cycle from starting until the chemicals have been replaced.

Final rinse water

2.55 The EWD manufacturer should specify the chemical and microbial quality of incoming water required based on their type test data. Operational qualification testing at the EDU should include chemical and microbial testing of the final rinse water. These tests should demonstrate that the final rinse water is:

- free of pathogenic microorganisms, including Pseudomonas aeruginosa, Mycobacterium sp. and Legionella sp. with a TVC of <10 cfu per 100ml at the point of use.
- the chemical purity, and bacterial endotoxin levels should comply with BS EN 15883 Part 1, Clause 6.4.2. Further details of the acceptance criteria and associated test methods can be found in section 3 and Appendix 4 of this guidance document.

2.56 Additional external water treatment (e.g. Reverse Osmosis (RO)) systems may needed to meet the specified water quality.

Note 2.17 BS EN 15883 Part 4: 2018 Clause 4.5.3 states depending upon the intended site of use of the endoscope (e.g. sterile body site) the level of bacterial endotoxins in the final rinse water should be controlled and monitored. However, no limits are stated for chemical purity or bacterial endotoxin levels.

Therefore, where used for invasive procedures or with susceptible patients the total dose of endotoxin on the endoscope surface in contact with the patients' tissue should be considered for possible adverse impact. Table A4.1 in Appendix 4 of this guidance (01-06 Part D) sets chemical limits and endotoxin levels for final rinse water quality.

2.57 Tests for other microorganisms that can be of clinical significance may also need to be carried out. (e.g. gram-negative Enterobacteriaceae) the Microbiologist (Decontamination) should be consulted.

Note 2.18: Where a disinfected endoscope is to be stored in a storage cabinet or to be packed by a packing system consult SHTM 01-06 Part E to determine the required level of dryness of the endoscopes on removal from the EWD.

Self-disinfection cycle

2.58 EWDs should include a self-disinfection cycle to prevent build-up of micro-organisms within the EWD. The EWD manufacturer should specify a validated method of disinfecting the EWD each day. Thermal disinfection is the preferred option for EWD self-disinfect cycles as it has been proven to be:

- the most effective method of killing a wide range of micro-organisms including some spores;
- is reliable;
- reproducible;
- free from toxic residues;
- capable of physical monitoring and recording.

2.59 All parts of the EWD heating system and the associated pipework, (including any internal EWD water tank) should be subject to a thermal self-disinfection cycle of 80°C for 10 minutes or equivalent and achieve an A_0 value of at least 600 seconds (see Table 2.2). Any pre-set combination of time and temperature should be demonstrated by the manufacturer and satisfy the requirements of BS EN 15883 Part 1:2009+A1:2014 Annex B.3. The combination of time and temperature used to achieve the A_0 of 600 may be decided by the User in the light of operational requirements.

Table 2.2: Time/temperatures meeting the requirements of an acceptable A_0 of 600 for thermal disinfection of EWDs

Exposure Time	Disinfection Temperature (°C)	A_0 Value
100 minutes (6000s)	70	600
10 minutes (600s)	80	600
1 minute (60)	90	600

3. Engineering services for EWDs

3.1 Any new EWD will require connection to a range of services (e.g. water, gases, electricity, compressed air, drainage and ventilation including air extraction). To ensure the appropriate services are available in the correct location prior to delivery. The EWD manufacturer or supplier should specify the building services required (BS EN 15883 Part 1:2009+A1: 2014 clause 8.2). The manufacturer appointed CP(D) should also validate all ancillary equipment in co-operation with the EWD contractor.

Water supply

3.2 Scottish Water are responsible for the water supply network and have the statutory power to make and enforce bylaws to prevent waste, excessive consumption, misuse or contamination of the water supplied by them. Endoscope washer Disinfectors should be installed, operated and maintained in accordance with the requirements of the relevant by-laws, see 'The Water Supply (Water Fittings) (Scotland) Byelaws 2014' and SHPN 13 Part 3 2010. All fixtures and fittings should comply with the 'Water Fittings and materials Directory' published by the Water Regulations Advisory Scheme (WRAS). Consult Scottish Health Technical Memorandum 04-01: Water safety for healthcare premises Part A: Design, installation and testing: 2014.

3.3 The pipework used to supply decontamination equipment should be appropriate to the quality of water carried and manufactured from material known to minimise the growth of bacteria. The use of flexible hoses should be avoided where practically possible. An audit should be carried out to ascertain the water supply system design from the point where potable water enters the healthcare facility premises to the point of use. The use of intermediate storage tanks and inappropriate pipework can lead to a deterioration in quality.

3.4 All pipework should be:

- run with a continuous fall to the discharge point;
- be free draining and as far as possible;
- free from dead ends and other areas where water can become stagnant and become a focal point for microbial growth and biofilm formation.

Note 3.1: Draw-off points may be installed at convenient locations within the system to enable water samples to be obtained; these should be installed as close to the EWD and treatment plant as possible and designed to minimise dead ends and stagnant areas.

3.5 Storage cisterns should be fitted with warning pipes and an overflow which should not comprise of, or be connected to, a flexible hose.

3.6 A 'Type A' air gap is required at the point of use or an interposed cistern. This applies to all EWDs and water softening treatment plant, unless regenerated by sodium chloride solutions, which should be protected by a 'Type B' air gap.

3.7 The 'Public water supplies (Scotland) Regulations 2014' lists the parameters expected for potable water quality. Water pre-treatment equipment (filtration, water softening, and Reverse Osmosis (RO) equipment) may be required to achieve a suitable quality of water for use in the EWD process. Details on water quality requirements test methods and acceptance criteria can be found in Sections, 4.11 and table 4.1 and Appendix 4 of this guidance document.

3.8 Where Water Treatment Equipment (WTE) is needed and installed a Service level agreement (SLA) should be in place and stipulate where responsibility lies for each part of the equipment and associated pipe work. This applies whether the water treatment is a part of the EWD or a separate system provided by a third party. Water quality for EWD feed water should also be specified and comply with the requirements in section 3 of this guidance document. Details of the EDU specifications for building services can be found in the SHPN 13 Part 3: 2010.

Temperature requirement

3.9 Endoscope Washer Disinfectors can be supplied with both hot and cold water. The water temperature for each stage of the process has a major effect on the efficacy of the process. Water above 45°C can lead to the coagulation and fixing of proteinaceous soil to endoscope surfaces. Therefore, water for the initial rinse and wash stages should be supplied from a cold supply. When hot water is required as part of the operating cycle, it may be advantageous to supply hot water to the EWD rather than heat cold water within it.

3.10 When water is to be heated, the heat source should be controlled by a thermostat and meet with the process requirements. The heating method should be specified by the purchaser and be removable for replacement or maintenance purposes. Where the water heating is integral to the EWD the heat control should have been assessed at type testing and verified during validation. Some designs of EWDs incorporate holding tanks that pre-heat the water supply for the relevant phase of operating cycle allowing the temperature of the hot water to be more readily controlled and maintained at a temperature that prevents microbial growth.

Note 3.2: The precise temperature settings of the EWD will be dependent on the type of process chemical used. Ensure that the optimum temperature range specified by the detergent and disinfectant manufacturer is maintained. Where water is heated for the wash stage, the EWD operating cycle should be configured to add the process chemical when the optimal temperature has been reached.

Feed water quality

3.11 The quality of water used at all stages in the decontamination process is critical to the successful outcome of the process and should be compatible with:

- the materials of construction of the EWD;
- the flexible endoscopes to be processed;
- the process chemicals used;
- the process requirements of each stage.

3.12 The key factors to be considered in the feed water quality are:

- temperature;
- pH;
- Chemical composition including ionic contaminants, for example, heavy metals, halides, phosphates and silicates;
- microbial population;
- bacterial endotoxins;
- hardness.

Note 3.3: The maximum temperature of rinse water should be compatible with the flexible endoscopes being processed.

Microbial quality

3.13 While potable water from the public supply has a low microbial content and should be free from pathogenic organisms, this can increase considerably when stored in tanks or cisterns. Therefore, additional measures are frequently required to maintain the microbial quality of water during storage and distribution.

3.14 The 'Health and Safety Executive guidance 'Control of legionella bacteria in water systems Approved Code of Practice '(ACOP) L18: 2013 and SHTM 04-01 include detailed guidance on the requirements. i.e., water in intercepting tanks should be stored below 25°C or above 60°C'. Water stored at 60°C or above may be assumed not to have a proliferating microbial population.

3.15 The water used at each stage of the EWD operating cycle should not increase the bioburden of the load items. Appropriate water treatment to control or reduce the microbial contamination in water may be required e.g., the installation of a 2µm filter with ultraviolet light treatment or Reverse Osmosis (RO) of incoming water. When water is treated by filtration rigorous controls are needed to ensure that the system works effectively. These should include:

- monitoring of the pressure drop across the filter throughout its working life;
- a continuous recirculation system so that the filter is not left wet in static water;
- treatment of the circulating water either by use of elevated temperature (>60ºC) or the use of UV irradiation (wavelength 260 nm ± 10nm; >2 Jm^{-2}) to ensure that proliferation of microbial contamination is inhibited;
- verification of purification by filtration should be made by relevant Total Viable Count (TVC) tests and achieve levels of <10cfu/100ml* and absence of Pseudomonas aeruginosa and (atypical) Mycobacterium sp.

Concentration of bacterial endotoxins

3.16 Bacterial endotoxins (measured in Endotoxin Units (EU)) are thermostable compounds derived from the cell walls of bacteria which, when introduced into the human body, can cause a fever-like reaction and other adverse effects. They are not readily inactivated at the temperatures used for disinfection of endoscopes. The

frequency of routine testing may be established based on risk assessment using trend analysis.

3.17 Where RO systems are in use the endotoxin levels of water produced for use in the final rinse stages of the EWD operating cycle, should not contain endotoxin at more than 0.25 EU ml^{-1} as Table 4.1 and Appendix 4 of this guidance.

Water treatment

3.18 Water treatment may be required to varying levels (dependent on the quality of local water supplies) to provide the required quality for wash and rinse stages of the EWD cycle. Two types of water treatment are recommended in this guidance:

- water softeners for waters with a hardness of >125mgl-^{1} of $CaCO_3$;
- Reverse Osmosis (RO) for final rinse water.

Water hardness

3.19 Any deposition of lime scale (Calcium carbonate $CaCO_3$) within the EWD will seriously impair the EWD performance, (Image 3.1) and may impair the effectiveness of the process chemicals in use.

Image 3.1: An example of lime scale build-up within a washer disinfector

3.20 The fouling of electrical heating elements or heat exchange components by hard water can reduce the heat-transfer efficiency and can lead to an increase in heating costs. Using hard water in the EWD operating cycle is one major cause of white powdery deposits on load items and should be avoided. These deposits impair endoscope optical systems.

3.21 Water of various levels of calcium carbonate can be used in various stages of the EWD cycle. Table 3.1 shows the water quality requirements for each EWD stage.

Table 3.1: Examples of water quality requirements for EWD process stages

Quality of water	EWD Cycle stage
Potable Cold water	Flushing

Quality of water	EWD Cycle stage
Soft potable water (<50mgl-1 CaCO3)	Flushing, Cleaning with process chemicals i.e. detergent or enzymatic cleaners
Reverse Osmosis	Final rinse water in all EWDs Thermal disinfection in all EWDs

Water softeners

3.22 Where required the size and type of water softeners should be chosen based on the total demand of softened water in the EDU, including provision for manual washing facilities and other plant and the level of $CaCO_3$ reduction required. Some EWDs are available with built in base-exchange water softeners.

3.23 Water softeners, or 'base-exchange' softeners, consist of an ion-exchange column containing a strong cation resin in the sodium form. Calcium and magnesium ions in the water are replaced by sodium ions. The process is simple to operate and an automated in-line system, will handle water with varying levels of hardness, and is simple and safe to regenerate. If the water softener is integral to the EWD then this will have been tested during type testing and detailed in the EWD manufacturer's instructions for use including maintenance requirements.

3.24 The column may be regenerated by treatment with a solution of common salt (sodium chloride). However, after regeneration, high levels of chloride ions (Cl^-) may be present in the initial output from the softener, which should be run to waste.

Note 3.4: If not installed, configured and maintained according to the manufacturers' instructions, base-exchange softeners can cause a significant increase in the microbial content of the water.

3.25 In common with other water treatment systems, the base-exchange softener should run to a minimum volume of out-flow to achieve the required water quality. This volume should be specified by the manufacturer of the treatment plant. The output from the softener should be to a water tank and the volume demanded each time additional water is fed to the tank should exceed the minimum flow.

Ionic Contaminants

3.26 Chlorine and chloramine are widely used disinfectants in supplies of potable water. While this can reduce the microbial load of the supply water and help prevent membrane fouling, free Chlorine in the water can also damage some RO membranes.

3.26 As Chlorine concentrations greater than 240 mgl^{-1} Cl^- can cause pitting of stainless steel components to occur water used for cleaning stainless steel components of endoscopes should have a chloride concentration less than 120 mgl^{-1} and for final rinse/disinfection, less than 10 mgl^{-1} Chloride (Cl^-).

Reverse osmosis

3.27 As RO units supply moderate volumes of water over a long period and EWDs need large volumes of water quickly, multiple RO units may be required to guarantee the water demand from multiple EWDs can be met.

Note 3.5: Hot and cold RO systems require different maintenance programmes.

3.28 Reverse Osmosis (RO) treatment plants remove bacteria, endotoxins and approximately 95% of chemical contaminants; by passing water, under pressure, through a semi-permeable membrane against an osmotic gradient. Some RO units are also fitted with a final 0.2 µm filter to further control bacterial numbers. The process will also remove a high proportion of organic material.

3.29 Factors to be considered prior to installing an RO system include:

- thermal self-disinfection of the RO system (the preferred method);
- if the system is maintained above 20°C but below 60°C the system and associated pipework need to be sanitised regularly and routine maintenance and membrane replacement is essential to maintain the required water quality;
- a carbon filter should be fitted ahead of the RO unit to remove traces of chlorine from the water supply;
- if the supply water is hard (i.e. >125mg/l of $CaCO_3$), a softening system will be required ahead of the RO unit;
- adequate space and provision for a plant room to house the equipment is required;
- downtime required for the maintenance activities as per the manufacturer's instructions.

3.30 Where the RO unit is an integral part of the EWD all of the above should still apply. These RO units will require careful management.

Compressed air supply

3.31 Endoscope Washer Disinfectors may need a supply of compressed air for the operation of valves and powered door systems and/or during any drying stage of the operating cycle. The quality of air contacting endoscopes should be oil free and filtered as specified in BS EN 15883 Part 4: 2018.

3.32 If air is supplied by pipeline from a central air compressor system, a Bourdon-type pressure gauge conforming to BS EN 837-1: 1998 should be fitted on the supply line to the EWD via an isolation valve.

Note 3.6: The use of medical gas (medical air) lines may be prohibited. The AP or AE (Medical Gases) should be consulted when considering connection to any central air supply.

3.33 A reducing valve, or other automatic device, should be fitted to ensure the pressure of air delivered to the EWD does not exceed the maximum supply pressure specified by the EWD manufacturer. A pressure relief valve may also be required.

3.34 Components of the compressed air system that require servicing and maintenance, such as dryers and filters, should be located where they are readily accessible for service or exchange. These should be isolatable so that maintenance can take place without depressurising the whole supply system.

Ventilation

3.35 Endoscope EWDs should be connected to a dedicated air extraction system. The extract system should be constructed of corrosion resistant material that can withstand temperatures greater than the maximum temperature of effluent gases specified by the manufacturer (typically greater than 105°C). Extraction systems should also be resistant to chemical vapours generated from the disinfectant solutions.

3.36 Where multiple EWDs are connected to a common air extraction system a method of preventing cross contamination should be provided. Additional guidance is given in EDU planning guidance SHPN 13 Part 3: 2010.

Drainage

3.37 All EWDs and associated equipment should be connected to the main drain in a manner that provides backflow protection. All connections should be consistent with Building (Scotland) Regulations 2004 and Sewerage (Scotland) Act 1968 (as amended 2002).

3.38 The drainage system for the EDU should be trapped and designed to pass the flow rate of water, air and condensate for the total number of EWDs during the period of maximum use.

3.39 Effluent from EWDs should pass via an air break into a tundish or tank before being discharged to drain. The air break should be preserved at all times to prevent the EWD and its associated pipework being contaminated by reverse flow from the drainage system.

3.40 The drainage system for each EWD should also be designed to:

- take account of the peak water use and output period during the operating cycle;
- pass and maintain in suspension, the maximum expected quantity of solids to be removed from the load during the process;
- ensure the minimum diameter of the drainage system should be greater than the maximum diameter of the most restricted section of the discharge from the EWD chamber.

Note 3.7: A means of diluting/reducing any high temperature effluent may be required to ensure the maximum accessible surface temperature of any pipes or surfaces will not exceed 43°C.

4. Validation and verification

Test programmes

4.1 Endoscope Washer Disinfectors (EWDs) require validation to demonstrate they will consistently clean and disinfect thermolabile flexible endoscopes prior to use or further processing use. The EWD manufacturer's instructions for testing and maintenance should be followed. Service Level Agreements for testing should be in place.

Testing for Conformity

4.2 The EWD performance requirements are specific to the cleaning and chemical disinfection of thermolabile flexible endoscopes and TOE ultrasound probes. The effectiveness of the process can be dependent on several factors, including:

- the type of the item(s) processed;
- the disinfection efficacy;
- the nature level of the contamination to be removed;
- the type and extent of any pre-treatment (e.g. manual brushing, and flushing);
- the temperature;
- any physical cleaning (of endoscope surface by spray or jet power);
- the type of detergent system;
- the level of process residues considered safe in use.

4.3 The manufacturer will carry out 'type tests' on representative samples of EWDs in serial production to demonstrate compliance of the design with the type testing specified in EN ISO 15883 Part 1: 2009 A+: 2014 and EN ISO15883 Part 4:2018, clause 6.11 and Annex B and H. The test methods, instrumentation and instructions required for validation, routine control and monitoring, and requalification of EWDs periodically and after essential repairs, are also specified.

Note 4.1: Works test/factory acceptance testing where requested by the User are conducted by the EWD manufacturer at their facilities, prior to delivery of the EWD to the EDU.

During type testing manufacturers must evaluate both surrogate devices and inoculated endoscopes to demonstrate the cleaning and disinfection efficacy of the EWD. During installation and where required periodic testing BS EN 15883- Part 4: 2018 advises the use of surrogate devices during OQ testing to ensure the EWD operates to the required parameters.

Note 4.2: Some tests specified in earlier versions of EN ISO 15883 Part 4:2018 are no longer recommended or are optional during OQ, PQ and routine testing (Appendix 5 table A5.7 and A5.8). Where verification of this type test data is required during validation, the test methods used to demonstrate compliance, or an equivalent modified operational test should be obtained from the EWD manufacturer.

4.4 During PQ and routine testing the standard recommends verification by sampling inoculated endoscopes or devices previously used during clinical procedures (live endoscopes). It is recognised in the standard that testing inoculated endoscopes may not be in line with national requirements or, may not be practical due to limited availability of some endoscopes. In these cases, a surrogate device can be used to simulate load items. Therefore, this guidance specifies that periodic testing should be conducted as shown in section 4 30 and tables 4.2 to 4.5 using surrogate devices of a design recommended by the EWD manufacturer.

Note 4.3: To ensure OQ, PQ and quarterly tests are comparable with the type test data the manufacturer should provide specific design requirements for surrogate devices compliant with Annex H of BS EN 15883 Part 4:2018 to be used during EWD validation. A detailed list of the requirements with relevant standard subclauses and tests from the BS EN 15883 series are given in Appendix 5 tables 1.1 to 1.3 and 1.5 to 1.9.

Information to be received prior to delivery

4.5 The EWD manufacturer should provide the purchaser with the following information prior to delivery of the EWD:

- installation instructions, as described in BS EN 15883 Part 1:2009+A1: 2014 clause 8.2) and BS EN 15883 Part 4: 2018 clause 8;
- operating instructions and short form of manual; available in waterproof material;
- user instructions with at least details of the maximum operating temperature and time for each stage;
- information on process security details (e.g. door interlocking mechanism);
- maintenance manual;
- documented evidence of compliance with BS EN 15883 Part 1:2009+A1: 2014;
- the facsimile of the marking on the vessel).

A detailed list of the information that should be included in the above manufactures' documents can be found in Appendix 6.

Installation qualification

4.6 Prior to carrying out OQ or PQ tests the installation safety checks and tests listed in IEC 61010-2-040:2021, should be carried out to ensure that all necessary services have been correctly supplied, connected and that the EWD is safe to operate (Clause 6.1.3.2 Installation qualification of BS EN 15883 Part 1: 2009+A1: 2014).

4.7 After the equipment has been installed, check that the following conditions are met:

- all supports, bases and fixings are secure and without imposed strain from service connections;
- thermal insulation is in a satisfactory condition and securely attached for all relevant services;

- security settings of door safety switches are compliant with data supplied by the manufacturer;
- each machine has been supplied with the unique keys, codes or tools needed to enable the CP(D) to calibrate sensors, adjust chemical dosing systems, control over-rides etc. as required. Check that they operate correctly, and only operate the control for which they are intended; and cannot unlock controls on other machines in the vicinity;
- load carrier's/baskets/hubs are effective and safe in use;
- checks on emergency stops and other safety devices required to ensure the safety of staff and prevent damage to equipment have been completed. Advice can be sought from the local Health and Safety advisor;
- check that all specified data systems are functioning correctly including automatic downloading of data from the EWD and process verification recorder to a computer network, or track and trace system. Any electronic track and trace system load scanners should also be checked to ensure endoscope and staff identification tags are captured;
- as applicable check that the room pressure differentials are maintained as specified in SHPN 13 Part 3: 2010;
- confirm that access for maintenance and servicing of the EWD services is safe;
- confirm that any additional operating cycles requested by the User are as specified;
- confirm a means of positioning temperature sensors has been provided for test purpose.

Ancillary equipment and engineering services testing during installation

4.8 Inspection and testing of ancillary equipment and engineering services (as described in section 3 and Appendix 3, 7 to A3, 13) should be carried out before OQ testing of the EWD begins. A Competent Person (Decontamination) CP(D) should validate all ancillary equipment in co-operation with the EWD contractor.

4.9 Inspection of the engineering services should ensure there are no leaks, they can meet the maximum demands for the number of EWDs being installed and that all necessary isolating valves/switches and test points are in place.

4.10 Drains should be checked to ensure the effective removal of the maximum volume of effluent from all equipment in the vicinity, including when all decontamination equipment is operating at full capacity (Appendix 3, 3.12).

4.11 Any exhaust ventilation and/or condenser unit to be fitted to the EWD should be adequate to remove the hot humid air, evolved from the cleaning stages, at thermal self-disinfection and any drying stages (Appendix 3, 3.9).

4.12 Ensure that no defects are apparent from a visual inspection of the equipment.

4.13 Check that all electrical equipment is correctly connected to the electrical service and carry out the following electrical tests:

- insulation resistance;

- phase sequence (for three-phase installations);
- polarity;
- bonding and earth continuity;
- emergency stop.

4.14 Ensure all equipment has been supplied in accordance with the contract and that the manufacturer has supplied all required documentation including verification certificates for the calibration of measuring instruments and controller(s) on the EWD.

Water treatment equipment

4.15 Prior to instillation of the EWD the water quality required should be specified and the ability of any Water Treatment Equipment (WTE) to consistently achieve this standard demonstrated. This may require multiple repeat water samples to ensure levels are consistent.

4.16 Confirm that where installed external WTE operates correctly including confirmation of flow rates, pressure, and temperature etc as per table 4.1. Any water economy system (if fitted) should not impact on water quality. Where the WTE is internal the manufacturer of the EWD should confirm that the supply quality meets the purchasers' specifications. Section 3 includes detailed water quality specifications and Annex 4 gives test methods and acceptance criteria while table A4.1 lists the maximum permitted values where applicable.

Table 4.1: List of water treatment equipment parameters to be checked prior to installation and delivery of the EWD with reference section for requirements and test methods in SHTM 01-06

Water treatment equipment-parameter checks	SHTM01-06 Requirements	Test Method
Water supply pressure	As per EWD manufacturers type test data and Table A4.1	A4 13 and
Volume of water generated	As required in the purchase specification.	Optional OQ test
Appearance	As per EWD manufacturers type test data and A4 5 and Table A4.1	A4 14
Degree of acidity (pH)	As per EWD manufacturers type test data and A4 5 and Table A4.1	A4 15
Water supply temperature	Section 3.9 and 3.10	A4 12
Water Quality (Hardness) (as CaCO3)	Section 3.19 and Appendix 4 Table A4.1	A4 19
Conductivity (	Appendix 4 table A4.1	A4 16

Water treatment equipment-parameter checks	SHTM01-06 Requirements	Test Method
Total Dissolved Solids (TDS)	Appendix 4 table A4.1	A4 17
Chemical purity including Heavy metals determined as Lead (Pb) mgl^{-1}	Appendix 4 table A4.1	A4 21 to A4 25
Total Viable Count (TVC)-cfu/100ml. Microbiological testing of final rinse source water (e.g. RO systems) for absence of *Pseudomonas species, Mycobacterium sp.* and *Legionella sp.*	Section 2 table 2.1, sections 3.13 to 3.15 and Appendix 4 table A4.1.	A4 10
Bacterial endotoxin levels $EUml^{-1}$	Section 3.16 and 3.17 and Appendix 4 table A4.1	A4 11

Disinfection of water treatment equipment

4.17 Manufacturers or contractors of WTE should provide a validated method and required frequency for periodic disinfection of their equipment. The WTE disinfection procedure can be approved when tested in accordance with the methods given in section 6.12.4 of EN ISO 15883 Part 4: 2018.

4.18 Where the equipment is part of the EWD it should be possible to disinfect the system daily to maintain the required water quality. This can be confirmed by water sample test results of less than 10 CFU of micro-organisms recovered with no pathogenic organisms present from each of two 100ml final rinse water samples (Section 5 and Appendix 4, 10).

Note 4.4: When establishing the frequency of any disinfection protocol the possible impact of seasonal variations in the quality of the incoming water supply should be considered.

Safety checks and safe working

4.19 Safety checks are undertaken throughout the operational lifetime of the EWD including at validation. Specific safety tests should be carried out prior to or as part of a test schedule. Refer to standard BS EN IEC 61010-2-040: 2021 ‘Safety requirements for electrical equipment for measurement, control, and laboratory use Part 2-040 Requirements for sterilizers and washer-disinfectors used to treat medical materials’ and the EWD manufacturer’s instructions. If required, the AE(D) may advise on the documented programme of safety checks necessary for the EWD(s) in use.

4.20 These safety checks should include inspection of the EWD door seal(s) and the performance and security of door safety interlocks and devices (A3 14 to A3 19).

4.22 For equipment that includes compressed air, all requirements of the ‘The Pressure Systems Safety Regulations: 2000’ should be met. A schedule for testing any pressure vessels must be compiled by a Competent Person (Pressure Systems)

(CP(PS)). Any tests should then be carried out by staff qualified and experienced in the testing of pressure vessels.

4.23 A permit-to-work system as outlined in SHTM 01-06 Part B should be followed prior to servicing or maintenance activities and before returning the equipment to service.

4.24 The calibration of controls and instrumentation should be verified, and the equipment should have undergone an approved maintenance programme prior to periodic testing. Additional information on the development of a planned maintenance program is given in Part B of SHTM 01-06. Reference should be made to the EWD manufacturer's maintenance schedules.

4.25 A method for recording and storage of test results should be in place. This could be an electronic system or logbooks may be used. The data generated by IQ, OQ and PQ tests should be kept for comparison with subsequent quarterly, yearly and routine tests to verify the EWD continues to meet the stated performance requirements.

Sequence of testing

4.26 The sequence of testing required to validate an Endoscope Washer Disinfector (EWD) after installation should include:

- three sequential qualification stages;
  - the Installation Qualification (IQ) described in section 4.6 and 4.7;
  - the Operational Qualification (OQ); described in section 4.31 to 4.35 and table 4.3;
  - the Performance Qualification (PQ) 4.36 to 4.39 and table 4.4;
- routine (periodic) and maintenance checks (once the EWD is operational) 4.56 and table 4.5;
- re-qualification (yearly) 4.28 and table 4.2.

Note 4.5: *As stated in section Note box 4.1 and to ensure consistency OQ, PQ and periodic (Quarterly) testing should be carried out using surrogate devices and test methods designed as recommended by the EWD manufacturer and inoculated with test soil as specified for use during initial validation in BS EN 15883 Part 5:2021.

a) May be undertaken at the same time as the previous test

b) Calibration, limits and function, including fault/alarm, of the independent monitoring system should be checked during quarterly and annual tests.

c) Commonly used alternative test name given in brackets.

d) Testing of the self-disinfection of the EWD during OQ and routine testing is not recommended in the 15883 Part 4:2018 and clause 6.12.3.2 recommends that testing the final rinse water in line with Clause 6.3 is sufficient to verify the self-disinfection cycle.

In order to detect any biofilm, within the EWD it may be necessary to leave the EWD unused for more than six hours after completion of the self-disinfection cycle before taking final rinse water samples.

Certification of validation the IQ, OQ and PQ reports should be prepared and signed by persons designated as responsible for preparing, reviewing and accepting the reports the as BS EN 15883 Part 1: 2009+A1: 2014.

Operational qualification of EWD

4.31 Operational Qualification (OQ) tests should include verification that, all variables controlling the EWD cycle are within the limits established during type testing.

4.32 Operational Qualification (OQ) requirements from 15883 Part 1: 2014 and 4: 2018 of the BS EN 15883 series are summarised in table 4.2. These tests should be conducted during an operating cycle.

Table 4.2: Operational qualification (OQ) checks/tests –CP(D) (may be the contractors CP(D))

OQ - Performance mechanical	Process requirements	SHTM 01-06 Part D Section reference for test
Safety Checks	As per BS EN IEC 61010-2-040: 2021 and manufacturers instruction.	Section 4.19 to 4.25
EWD Instrumentation	Verification of calibration and legibility- Section 4.30	Visual check
	Calibration	Appendix 3, 32
Leak Test	Testing the pressure relief device	Appendix 3, 21
	Leak tester fault and pass conditions	Appendix 3, 22
	Leak test non connection	Appendix 3, 23
Thermal self -disinfection of the EWD	Chamber walls temperature and Load carrier (if present). Final rinse water tank. (optional)	Appendix 3, 36
Automatic control test	Check all parameters for complete cycle	Section 4.34 and A3, 47
Independent Monitoring System:	Including calibration Limits and trip points Alarm actions	Appendix 3, 28 A3, 35 A3, 36 and A3, 37
Door seals and interlocks	Leak tightness of doors	Appendix 3 24
	Door opening force.	Appendix 3 25
Door interlock:	Operating cycle start interlock: in-cycle interlock. loading unloading (double ended (pass-through) door opening) Section 4.35	Appendix 3, 14, A 15, 16 and 17
On door sensor failure	On fault condition	Appendix 3, 18
	Failed cycle fault indication	Appendix 3, 19
Load carriers' alignment and operation	Visual check during an operational cycle	Appendix 3, 26
Operational cycle	Spray system-spray arm rotation/jet wash Section 4.35	Appendix 3, 27

OQ - Performance mechanical	Process requirements	SHTM 01-06 Part D Section reference for test
	Fault indication (if blockage and sensor fitted)	Appendix 3, 27
	Automatic control fault indication on sensor failure	Appendix 3, 28
Leak tightness of Doors (Water vapour/fluid emissions test)	Chamber leak proof	Appendix 3, 24
	Door seals - Safety check section 4.19	Appendix 3,14
Process chemical dosing tests	Accuracy and repeatability of volume admitted	Appendix 3, 29 and A3, 30
	Indication of insufficient process chemicals (low level indicator)	Appendix 3, 31
	Residual process chemicals	Appendix 3, 38
Free draining tanks, chamber and pipework	Free draining (optional test)	Appendix 3, 12
	Dead volume (optional test).	Appendix 3, 7
	Water seal	Appendix 3, 8
	Condenser drain seal	Appendix 3, 11
	Blocked drain protection	Appendix 3, 10
	Purging of trap	Appendix 3, 13
Temperature control tests throughout the process for	Temperature limits	Appendix 3, 34, and A3, 35
	Over temperature cut out Only recommended where the EWD stage is not thermostatically regulated.	Appendix 3 37
Channel non connection test-all channels	Test Load: using *surrogate devices with leak tester disconnected.	Appendix 3 41
Channel non obstruction test-all channels	Test Load: using *surrogate devices with a means of obstructing each channel in turn.	Appendix 3 42
Test of disinfection efficacy	Establish that the levels of all controlling variables that affect the disinfection of the load are within the limits for chemical concentration, temperature, time and pH established during type testing using a *surrogate device recommended by the EWD manufacturer.	Appendix 3 45
Ventilation/Venting System	EWD Air Filter Quality test load contamination from ductwork (if fitted)	Appendix 3 17
Cleaning efficacy	Chamber and Load carrier	Appendix 3 43
	Test Load: using *surrogate devices and test soil (on the cleaning stage alone) using the biofilm test pieces as specified in ISO 15883 Part 5: 2021.	Appendix 3 44
Quality of final rinse water	Tested for microbiological quality Sections 3.13 to 5.15	Appendix 4 10 and table 4.1
	Total viable count	Appendix 4 10

OQ - Performance mechanical	Process requirements	SHTM 01-06 Part D Section reference for test
	Absece of *Pseudomonas .a* and *Mycobacterium sp.*	Appendix 4, 10
	Appearance	Appendix 4, 14
	Chemical purity	Appendix 4, 22 to 25
	Conductivity	Appendix 4, 16
	pH	Appendix 4, 15
	Bacterial endotoxins. 3.16 and 3.17	Appendix 4, 11
Load dryness test	Reference load	Appendix 3, 39
	HEPA air filter for purging/drying	Appendix 3, 40

Note 4.6: *As stated in section Note box 4.1 and to ensure consistency OQ, PQ and periodic (Quarterly) testing should be carried out using surrogate devices and test methods designed as recommended by the EWD manufacturer and inoculated with test soil as specified for use during initial validation in BS EN 15883 Part 5: 2021.

a) May be undertaken at the same time as the previous test

b) Calibration, limits and function, including fault/alarm, of the independent monitoring system should be checked during quarterly and annual tests.

c) Commonly used alternative test name given in brackets.

d) Testing of the self-disinfection of the EWD during OQ and routine testing is not recommended in the 15883 Part 4:2018 and clause 6.12.3.2 recommends that testing the final rinse water in line with Clause 6.3 is sufficient to verify the self-disinfection cycle.

In order to detect any biofilm, within the EWD it may be necessary to leaving the EWD unused for more than six hours after completion of the self-disinfection cycle before taking final rinse water samples.

4.33 Ensure the selection of automatic or manual control is by key code or tool and the selection of one control mode inactivates the other control mode. In addition, confirm that:

- under automatic control, water, compressed air or process chemicals cannot be admitted into the chamber, and the operating cycle cannot start until the door is closed (locked and sealed);
- under manual control the operator can only advance the operating cycle sequentially through each stage. Any stages designed to remove process chemicals from the chamber and load cannot be circumvented;
- throughout the operating cycle the indicated and recorded values of critical variables are within the limits specified by the manufacturer and within the limits required by EN ISO 15883 Part 1:2009 A+: 2014 or EN ISO 15883 Part 4: 2018;
- throughout the operating cycle there are no leaks of water, process chemicals, aerosols, air, or effluent;

- there is no evidence of interference to or from other equipment connected to the same services;
- there is no evidence of electromagnetic interference to or from other equipment;
- operation and readability of all instruments are satisfactory;
- the temperature of surfaces routinely handled by the operator does not exceed 43°C as specified in the HSE publication ‘Managing the risks from hot water and surfaces in health and social care’;
- the door cannot be opened until the operating cycle has been completed without causing the cycle to abort and a fault/incomplete alert produced, that is, the automatic controller has operated in accordance with its specification;
- the door interlock system is either fail-safe or is fitted with at least two independent interlocks;
- failure of one interlock, or any one service, does not allow the door to open when conditions within the chamber would cause a hazard (for example, unacceptable level of chemical vapours);
- the automatic controller has operated in accordance with the parameter values determined at type testing;
- confirm that all data from all sensors is present and correlated and that all data from the Information Management System (IMS) and EWD are downloaded correctly;
- if a spray arm rotation detection system is fitted check that it functions correctly and that any anomalies are resolved e.g. variable pump pressure.

4.34 The EWD should also be tested to ensure it reacts correctly and safely when exposed to external fault conditions. During each stage of an operating cycle, the following faults (as appropriate to the type of machine) should be simulated:

- operation of the emergency stop button;
- power failure;
- leak test failure;
- water pressure too low;
- water pressure too high;
- compressed air pressure too low;
- compressed air pressure too high;
- failure of process chemical supply (detergent or disinfectant);
- failure of extract ventilation;
- channel partial obstruction test for each available channel;
- channel non connection test (each channel is disconnected separately, and a fault should be indicated);
- communication systems failure;
- blocked drain failure;

- spray arm failure (if sensor fitted).

The EWD should not show a satisfactorily completed operating cycle when a fault is present.

4.35 The detailed OQ requirements from each of the BS EN 15883 series of standards including information from sections 4 ‘mechanical requirements’ and section 5 ‘process requirement’ are given in Appendix 5, tables 5.4 and 5.5. Several cycles may be necessary to complete all OQ tests and checks.

Performance Qualification

4.36 Performance Qualification (PQ) testing is the process of obtaining and documenting evidence that the EWD will consistently give reproducible results and will produce clean and disinfect endoscopes. PQ tests are conducted by the CP(D). A list of PQ tests is shown table 4.3.

4.37 In principle, validation is not complete until a PQ test has been performed for each combination of endoscopes or TOE ultrasound probes (including any load carriers, used within the chamber) to be processed. For example, a load comprising of four non-lumen endoscopes constitutes a different loading condition from one endoscope with multiple channels. Therefore, each loading condition to be used for PQ testing should be specified by the User.

4.38 Users should adopt the following process. Establish a list of endoscopes processed and group into potential product families based on their channel configuration and number of auxiliary channels:

- identify the corresponding test type group;
- establish a list of the different loading conditions used to process each load in the EWD. Each production load should correspond to one of the listed loading conditions;
- select the surrogate device(s) that represents the loading conditions that present the greatest challenge as advised by the EWD manufacturer.

Table 4.3: Performance qualification (PQ) tests for EWD’s

PQ - Performance mechanical	Process requirements	SHTM 01-06 Part D Section reference for test
Cleaning efficacy	[a]Chamber walls and load carriers (optional)	Appendix 3, A 43
	Test Load using *surrogate devices during cleaning stage only	Appendix 3, A 45
Leak tightness of doors	Visual check during an operating cycle	Appendix 3, A 24
Leak test-failures	Testing the pressure relief valve Fault and pass conditions Non connection test	Appendix 3, A 20 to A3, 21 and A3, 23
Thermometric tests	[a]Temperature limits for Chamber walls Temperature control – Reproducibility of on process temperature control limits Rate of rise	Appendix 3, 35

PQ - Performance mechanical	Process requirements	SHTM 01-06 Part D Section reference for test
	Flushing stage Washing stage	
	EWD – self disinfection	Appendix 3, 36
	Over temperature cut out	Appendix 3, A 37
Chemical disinfection	Chamber walls and load carrier (optional)	Appendix 3, A 46
	Load	Appendix 3, A 46
Load carrier alignment	Automatic control test On sensor failure	Appendix 3, A26
Operating cycle	Spray arm Reproducibility (optional)	Appendix 3, A 48
	Load dryness test	Appendix 3, A 82-83
Water quality	Microbial quality- Section 5.11 to 5.13	Appendix 4, table 4.1
	Total Viable Count	Appendix 4, 10
	Absence of *Pseudomonas .a* and *Mycobacterium sp*.	Appendix 4, 10
	Endotoxin level Section 5.14 and 5.15	Appendix 4, 11

Note 4.7: *As stated in section Note box 4.1 and to ensure consistency OQ, PQ and periodic (Quarterly) testing should be carried out using surrogate devices and test methods designed as recommended by the EWD manufacturer and inoculated with test soil as specified for use during initial validation in BS EN 15883 Part 5:2021.

a) May be undertaken at the same time as the previous test

b) Calibration, limits and function, including fault/alarm, of the independent monitoring system should be checked during quarterly and annual tests.

4.39 Additional PQ tests are required for EWDs during their operational lifetime where there have been changes to:

- the quality of the water supply, due to a change in source or interruption of supply;
- the process chemicals used in the process;
- a new model of endoscope is introduced which is not included in the manufacturers type test data. Settings for new (and existing) endoscopes should be checked to ensure all channels are irrigated and correct patency/ disconnect parameters set, and that correct connectors are available;
- when extensive maintenance of critical components or a major repair had been undertaken.

Cleaning efficacy

4.40 Cleaning efficacy tests are intended to demonstrate the ability of the EWD to remove or reduce, soiling and contamination that occurs during normal use of an endoscope

to acceptable levels. Cleaning efficacy tests should be carried out at the end of the cleaning and rinsing stages i.e. prior to the release of any disinfectant solution.

4.41 Any surrogate device used during testing should be designed as advised by the EWD manufacturer, present the greatest challenge to the process and be compliant with the requirements of Annex H of BS EN 15883 Part 4:2018.

4.42 The surrogate device should also be constructed to incorporate:

- residual test soil or survivors from a microbial challenge;
- sensors for thermometric tests;
- method of initiating a channel obstruction tests.

4.43 Test soils specified in BS EN 15883 Part 5: 2021, Annex F should be used to ensure the EWD is able to achieve the required cleaning and disinfection levels for all types of endoscope in use. The use of any test soil should be agreed with the User (and if required the AE(D)).

4.44 Alternatively cleaning efficacy tests performed as part of the performance PQ testing can be carried out using endoscopes that represent the product families in use and the worst-case soiling after clinical use (EN ISO 15883 Part 4:2018 clause 4.4.1). Where live endoscopes are used for testing it is recommended that this is only carried out after OQ testing has verified the efficacy of the EWD and a risk assessment is carried out. A validated method of sampling is required (Annex E of BS EN 15883 Part 4: 2018 gives guidance on this process) and the analysis should be made after the post disinfection rinsing stage but before drying. EN ISO 15883 Part 4: 2018 section 6.11.

Process residues

4.45 The process chemicals used during the decontamination process i.e. detergents, and disinfectants, can cause significant harm to patients if not completely removed by the rinsing process. The tolerable residual level is dependent on the nature of the chemical and the intended use of the medical device.

4.46 The supplier of any process chemical is obliged to provide data on the chemical composition, the biocompatibility of its components and the method of detection. This will allow tests of the EWD to be carried out (Annex A) to determine if processed flexible endoscopes are free from residuals at the specified levels and are safe to use.

PQ – Endoscope Disinfection

4.47 Due to the thermolabile nature of the materials used to manufacturer flexible endoscopes a range of chemical manufacturers have developed specific detergent and disinfectant solutions for their decontamination.

4.48 Verification of disinfectant efficacy is required prior to type testing of the EWD. The strain of organisms should be selected from B.2.1.1 in Annex B of EN ISO 15883 Part 4: 2018 and have been proven to be the most resistant to the disinfectant used by a validated test method. A list of the recommended strains is given in section 2.40 of this document. As a minimum these tests should include the use of, inoculated carriers incorporating Gram-positive and Gram-negative vegetative bacteria, the

strain of *Mycobacterium sp*., deemed most resistant to the disinfectant, enveloped and non-enveloped viruses, fungi, and bacterial endospores. A validated method of counting the test organisms is required.

Note 4.8: During type testing the EWD manufacturer will have validated that the EWD can achieve the required levels of cleaning and disinfection using the recommended range of chemicals. If specific chemical disinfectants are required by the endoscope manufacturer, then the user should advise the EWD manufacturer of this and request factory acceptance tests (works tests) prior to purchase. During Product Qualification the CP(D) should check the EWD parameters for chemical dosing, holding time, temperature, and the concentration of the disinfectant solution.

Thermal self-disinfect cycle

4.49 The requirements for thermal self-disinfection are defined in EN ISO 15883 Part 1: 2014 (clause 6.8) and in section 2 of this guidance.

4.50 Thermal disinfection conditions are specified either by an A_0 value to be achieved throughout the chamber, or by a disinfection temperature band with defined minimum and maximum allowable time/temperatures.

4.51 Other validated time/temperature relationships may be used where an equivalent A_0 value has been shown to be achieved. As shown in Table 2.2: in section 2 of this document. The higher the disinfection temperature, the shorter the holding time needed to achieve the same level of disinfection.

Note 4.9: Microbiological testing is not recommended for the thermal disinfection stage in the decontamination process.

PQ - Load dryness tests

4.52 Most EWDs purge channels with medical grade air to clear them visually of residual water. Some EWDs will dry the endoscope at the end of the cycle but this will extend the cycle time substantially.

4.53 Where a drying stage is programmed, the dryness of the load should be evaluated visually according to the method in clause 6.8 of the standard and Appendix 3, 39 and Appendix 3, 40 of this guidance.

Note 4.10: Special care is required to ensure the product family representing the greatest challenge to the process (e.g. colonoscopes and enteroscopes) and those with fine lumens such as duodenoscopes with elevator channels are selected for testing.

4.54 Re-qualification should be carried out annually, or at the intervals defined by the manufacture, the User or where requested the AE(D) (BS EN 15883 Part 1: 2009+A1: 2014 clause 6.1.5). Requalification should also be carried out when:

- changes to critical engineering equipment are made that could affect the performance of the EWD;
- a review of EWD performance records indicates unacceptable deviation(s) from the data obtained during initial validation;

- the EWD performance is seen to deteriorate;
- process conditions (e.g. process chemicals) are changed.

4.55 Completion of the annual test schedule is required for revalidation of the EWD and contains the tests recommended for re-qualification of the performance of the equipment.

4.56 The results of periodic tests should be recorded, documented and filed securely, in electronic or paper format. All process records should be kept for at least 13 years to allow tracking and tracing of thermolabile flexible endoscopes in the event of an adverse event and in compliance with the Scottish Government Records Management NHS Code of Practice (Scotland):2010.

Periodic checks and testing

4.57 Periodic testing may comprise of tests and checks. These tests and checks are carried out at daily, weekly, quarterly and yearly intervals. It is recommended that periodic testing is performed as defined, in section 4.30 see. The test methods and acceptance criteria are included in appendices 3 and 4 of this guidance document. Minimum requirements for periodic testing and checks are defined in EN ISO 15883-1:2009+A12014 and EN ISO 15883 Part 4: 2018. An overview of these requirements can be found in Appendix 5.

4.58 Periodic tests should only be undertaken after completion of the planned maintenance tasks as described in Part B of this SHTM.

4.59 All periodic tests should be carried out with the machine at normal working temperature, which may require a warm-up run before commencement of testing. The recommended tests can be conducted concurrently on the same operating cycle.

4.60 An overview of the recommended checks and tests for EWD validation to be conducted during periodic (daily, weekly, quarterly yearly) testing is given below:

- Daily checks -User to complete:
  - Check that a successful self-disinfect cycle has been carried out within a 24 hour period;
  - Check spray arm(s) for rotation/free movement and blockages;
  - Remove and clean strainers and filters, etc;
  - Chemical dispensing check - Ensure sufficient process chemicals are available and that dosing system is functioning;
  - Check condition of connectors-no holes in tubing and wear on connectors;
  - Check door seals for wear / tears;
  - Process challenge device test (optional);
  - Any other daily checks recommended by the manufacturer.
- Weekly checks -User to complete:
  - Carry out daily checks;

- Weekly safety checks;
- Visibility of any displays or indicators and check for any damage to screens etc.
- Automatic control test checked for cycle stages, temperature and time;
- Water quality tests for final rinse water

  Total viable count (TVC) and Absence of *Pseudomonas sp*

  Frequency of routine water testing may be reduced based on risk assessment using trend analysis.

- Quarterly checks -CP(D) to complete:
  - Weekly safety checks and functional check of engineering services;
  - Carry out daily checks and weekly tests;
  - Verification of calibration of EWD instrumentation;
  - Thermometric tests of the chamber;
  - Leak test;
  - Doors and door interlocks

    Cycle start;

    In-cycle interlock;

    Double door checks;

    Fault indication on sensor failure.
  - Chemical dosage checks - Process chemical dosing tests (for single use per dose)

    Reproducibility of volume admitted;

    Insufficient/low level alarm test.
  - Calibration, limits and function, including fault/alarm, of the independent monitoring [b]system;
  - Channel non obstruction test (Channel Patency tests) using *surrogate devices as using recommended by the EWD manufacturer;
  - Performance qualification of the whole cycle using *surrogate devices;
- Yearly checks -User to complete:
  - All Daily and weekly checks;
  - Annual Safety checks and verify the adequacy/safe connection of all engineering services;
  - Automatic control test for each cycle;
  - Verification of calibration of EWD instruments (including all independent process verification system instruments);
  - Water system

    Chemical purity;

    Hardness and conductivity;

Bacterial endotoxins;

Total viable count;

Absence of Psudomonas sp.and Mycobacterium sp.

- Drainage

  Free draining;
- Fault indication activated on sensor failure;
- Water vapour emissions test;
- Process chemical dosing tests;

  Reproducibility of volume admitted;

  Insufficient/low level alarm test;
- Load carriers;
- Carriages; hubs; hook-ups; baskets alignment check;
- Channel non obstruction test (Channel Patency);
- Cleaning efficacy test: using endoscope surrogates*;
- Chemical disinfection of the load (Disinfection efficacy test): using endoscope surrogates*;
- Thermometric tests

  over temperature cut-out test (if fitted);

  load carrier temperature test;

  load dryness temperature test if applicable.
- Performance qualification of the whole cycle using *surrogate devices.

5. Operational management

Product release after processing through the EWD

5.1 It is important that all EWDs are effective in achieving the performance required to produce a clean and disinfected endoscope. Each stage of the EWD cycle should be checked to confirm it is satisfactory before the endoscopes are released for use.

5.2 The cleanliness and microbial safety of all endoscopes processed in a EWD ultimately depends upon the care taken in following all validated processes and procedures. See SHTM 01-06 Part A for guidance on improving the cleaning performance of EWDs. Failure to achieve the required standard of cleanliness may impair the capability of the process to achieve disinfection and when necessary subsequent sterilization.

5.3 A documented process should be in place and verify that all stages of the decontamination process have been completed successfully, prior to releasing a processed endoscope for further processing or use. This should include confirmation that:

- the endoscope has been leak tested appropriately (wet/dry);
- a manual clean has been carried out;
- the EWD display/print out indicates a passed cycle;
- the EWD cycle shows all required conditions were met;
- all endoscope channels were identified, connected and monitored during the EWD decontamination cycle;
- the endoscope was inspected for damage, contamination and dryness.

Investigating a failed EWD operating cycle

5.4 The following points should be considered when investigating a failed EWD operating cycle including:

- failure to correctly carry out the manual cleaning step(s) prior to loading the endoscope in the EWD;
- failure to load the endoscope in the EWD correctly;
- failure to follow standard operating procedures for EWD operation;
- the use of non-validated process chemicals;
- failure of a water treatment plant;
- underestimating the cleaning or disinfection challenge of a given endoscope design, unsatisfactory validation of the EWD prior to it being put into use;
- validation of the EWD using a surrogate device not representative of the endoscopes in use;
- failure of the EWD to maintain the cycle parameters, temperature, concentration time for each stage in the process.

Routine maintenance

5.5 Certain maintenance tasks should be carried out by the AP(D), the User, or by the Operator under the User's supervision. All maintenance tasks and the person carrying out the task should be recorded in the EWD logbook.

5.6 An EWD maintenance manual should be suppled by the manufacturer and should include:

- required maintenance tests and the frequency that they should be carried out;
- electrical diagrams and circuits;
- hydraulic plans and circuits;
- the dead volume of pipework;
- the recommended method of cleaning all injection lines and valves;
- actions required to produce test conditions specified in Clause 6 (of BS EN 15883 Part 1: 2014);
- a complete spare parts list;
- a list of the special tools necessary for maintaining and testing;
- type of guarantee offered;
- list of service stations;
- guidance on tracing and rectifying causes of malfunction.

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 384: 2015 Laboratory glass and plastics ware. Principles of design and construction of volumetric instruments. CEN.

BS 853-1: 1990+A3:2011. Specification for vessels for use in heating systems. Calorifiers and storage vessels for central heating and hot water supply.

BS 1427: 2009. Guide to on-site test methods for the analysis of waters.

BS 1704: 1985, ISO 1770: 1981. Specification for solid-stem general purpose thermometers.

BS 1752:1983, ISO 4793: 1980. Specification for laboratory sintered or fitted filters including porosity grading.

BS 2690-104: 1983. Methods of testing water used in industry. Silica: reactive, total and suspended.

BS 3928: 1969. Method for sodium flame test for air filters (other than for air supply to I.C. engines and compressors).

BS 6068-2.29: 1987. Water quality. Physical, chemical and biochemical methods. Determination of cobalt, nickel, copper, zinc, cadmium and lead: flame atomic absorption spectrometric methods.

BS 6068-2.29:1987. Water quality. Physical, chemical and biochemical methods. Determination of cobalt, nickel, copper, zinc, cadmium and lead: flame atomic absorption spectrometric methods

BS 6068-2.2: 1983, ISO 6332-1982. Water quality. Physical, chemical and biochemical methods. Determination of iron: 1,10-phenanthroline photometric method.

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

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

BS EN 55014-1: 2017+A11:2020. Electromagnetic compatibility. Requirements for household appliances, electric tools and similar apparatus. Emission. CEN.

BS EN 61000-4-3: 2006+A2: 2010. Electromagnetic compatibility (EMC). Testing and measurement techniques. Radiated, radio-frequency, electromagnetic field immunity test. CENELEC.

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

BS EN 61000-6-3: 2007+A:2011. Electromagnetic compatibility (EMC). Generic standards. Emission standard for residential, commercial and light-industrial environments. CENELEC.

BS EN 61010-1: 2010+A1:2019. Safety requirements for electrical equipment for measurement, control, and laboratory use. General requirements. CENELEC.

BS EN IEC 61010-2-040: 2021 Safety requirements for electrical equipment for measurement, control, and laboratory use Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials.

BS EN ISO 3746: 2010. Acoustics. Determination of sound power levels and sound energy levels of noise sources using sound pressure. Survey method using an enveloping measurement surface over a reflecting plane. CEN.

BS EN ISO 4788: 2005. Laboratory glassware. Graduated measuring cylinder. CEN.

BS EN ISO 6878: 2004, BS 6068-2.28: 2004. Water quality. Determination of phosphorus. Ammonium molybdate spectrometric method. CEN.

BS EN 14971: 2019, Medical devices Application of risk management to medical devices.

BS EN 12353: 2013, Chemical disinfectants and antiseptics, Preservation of test organisms used for the determination of bactericidal (including Legionella), mycobactericidal, sporicidal, fungicidal and virucidal (including bacteriophages) activity.

BS EN 13727:2012+A2: 2015, Chemical disinfectants and antiseptic. Quantitative suspension test for the evaluation of bactericidal activity in the medical area Test method and requirements (phase 2, step 1).

BS EN 15883 Part 1: 2009+A1: 2014 Washer disinfectors. General requirements, terms and definitions and tests. CEN.

BS EN 15883 Part 4: 2018 Washer-disinfectors. Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes.

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

BS EN 17664 Part 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. CEN.

BS EN IEC 61010 Part 2-120:2018 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-120: Particular safety requirements for machinery aspects of equipment. CENELEC.

BS EN 1822 Part 1:2019 High efficiency air filters (EPA, HEPA and ULPA) Part 1: Classification, performance testing, marking.

Test specification/published documents

PD 5500: 2018+A20:19. Specification for unfired fusion welded pressure vessels.

Healthcare Facilities Scotland publications

Scottish Health Planning Note 13 Part 3: 2010. Decontamination Facilities - Endoscope Decontamination Unit.

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

Scottish Health Technical Memorandum (SHTM) 01-06: 2022 Decontamination of Thermolabile flexible endoscopes in an Endoscope Decontamination Unit, Part A: Management.

Scottish Health Technical Memorandum (SHTM) 01-06: 2022 Decontamination of Thermolabile flexible endoscopes in an Endoscope Decontamination Unit, Part B.

Scottish Health Technical Memorandum (SHTM) 01-06: 2022 Decontamination of Thermolabile flexible endoscopes in an Endoscope Decontamination Unit, Part C.

Scottish Health Technical Memorandum (SHTM) 01-06: 2022 Decontamination of Thermolabile flexible endoscopes in an Endoscope Decontamination Unit, Part E.

Scottish Health Technical Memorandum (SHTM) 01-01 E: 2018 Sterilization by Hydrogen Peroxide or Ethylene Oxide.

Scottish Health Technical Memorandum 04-01: 2014 Water safety for healthcare premises Part A: Design, installation and testing.

Legislation

Medicines and Medical Devices Act 2021.

Medical Device Regulations 2002.

Control of substances hazardous to health (COSHH) Regulations: 2002.

Electromagnetic Compatibility Regulations: 1992.

Pressure Equipment Regulations: 1999.

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).

Workplace (Health, Safety and Welfare) Regulations: 1992.

The Public Water Supplies (Scotland) Regulations 2014.

Water Supply (Water Fittings) (Scotland) Byelaws 2014.

Other Guidance

Health Protection Scotland, NHS Scotland Guidance for the interpretation and clinical management of endoscopy final rinse water v1.0:2019.

NHS Scotland Guidance for Decontamination of Semi-Critical Ultrasound Probes; Semi-invasive and Non-invasive Ultrasound Probes HPS/HFS 2017.

Approved Code of Practice ‘(ACOP) L18: 2013.

Appendix 2: Glossary

Terms and conditions from standards - Part 1: 2014, Part 4: 2018 and Part 5: 2021 of the BS EN 15883 series.

Automatic controller - BS EN 15883 Part 1: 2009+A1: 2014 Terms and definitions – clause 3.2. Device that, in response to pre-determined cycle variables, operates the apparatus sequentially through the required stages of the process or processes.

Endoscope connector - BS EN 15883 Part 4: 2018 Terms and definitions clause 3.8. Device to interface with the fluid entry port of a channel of an endoscope that, where applicable, includes the tubing connected to the channel irrigation system of the washer-disinfector.

Endoscope leak test - BS EN 15883 Part 4: 2018 Terms and definitions clause 3.9. Set of actions to identify a loss of integrity Note 1 to entry: The test is intended to establish that the surface covering the device and/or lining a device channel is intact to the extent necessary to maintain a slightly positive pressure.

Endoscope port - BS EN 15883 Part 4: 2018 Terms and definitions clause 3.10. Part of an endoscope to which the irrigation system of the washer-disinfector is connected to irrigate all or part of a channel.

Liquid transport systems - BS EN 15883 Part 4: 2018 Terms and definitions clause 3.16. <washer-disinfector> components of equipment used to store, pump or transport water and/or solutions, excluding pipework before the air break.

Process verification recorder - BS EN 15883 Part 1: 2009+A1: 2014 Terms and definitions - clause 3.46. Device that, independently of the automatic controller, records values obtained for some, or all, of the control variables.

Routine test - BS EN 15883 Part 1: 2009+A1: 2014 Terms and definitions - clause 3.50. Periodic checking and testing carried out to establish that the operational performance of the washer disinfector remains within the limits established during validation.

Self-disinfection cycle - BS EN 15883 Part 4: 2018 Terms and definitions clause 3.24. Operating cycle intended to disinfect all liquid transport systems' piping, chamber(s), tanks and other components which come into contact with the water and/or solutions used for cleaning, disinfecting and rinsing the load.

Note 1 to entry: The self-disinfection cycle is used without a load in a washer-disinfector.

Endoscope surrogate device - BS EN 15883 Part 4: 2018 Terms and definitions - clause 3.12. Item designed to represent construction elements of endoscope specific characteristics affecting the flow conditions in endoscope channels.

Note 1 to entry: Elements can include channel length and diameter, connectors, channel separators, port closures, return valves, etc.

Surrogate product - BS EN 15883 Part 5: 2021 Terms and definitions clause 3.11. Item designed to represent product in process simulations and which is comparable with the actual product.

Appendix 3: Test methods for EWDs

A3 1 This section gives detailed methodology for tests required during type testing, the Installation Qualification (IQ), Operational Qualification (OQ), Performance Qualification (PQ) and periodic (routine) testing of EWDs used in an EDU as described in BS EN 15883 Part 1:2009+A1:2014 and BS EN 15883 Part 4:2018.

Note A3.1: Where technological advances in test equipment can be shown to have equal or better efficacy than current approved methods of testing, they may be adopted in place of the equipment and/or test methods described in SHTM01-06 Part D.

Prior to undertaking operational and performance tests on an installed EWD the , installation tests included in Section 4 should be carried out to ensure that all necessary services have been correctly supplied and connected and that the EWD is safe for use.

Type tests and works tests (factory acceptance tests)

A3 2 The manufacturer will carry out type tests on representative samples of EWDs in serial production to demonstrate compliance of the EWD design requirements of BS EN 15883 Part 1: 2009 +A1: 2014 and BS EN 15883 Part 4: 2018, clause 6.11 Annex B and H and BS EN 15883 Part 5:2021.

A3.3 The results of any type test and factory acceptance tests (work tests) 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 the AE(D) may be sought.

Test descriptions

Sound pressure test

A3.4 The sound pressure test described in BS EN 15883 Part 1:2009+A1: 2014 should be carried out as part of the manufacturers' type testing. It is neither necessary nor practicable to repeat the test as part of periodic testing. Standard BS EN IEC 61010-2-040: 2021 Safety requirements for electrical equipment for measurement, control, and laboratory use Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials, discusses sound level protection.

Note A3.2: The perceived level of noise in the immediate vicinity of the equipment during operation may, give cause for concern. The perceived noise level depends not only upon the sound power level of the equipment but also on the acoustic properties of the environment and other sources of noise.

If ambient noise levels are of concern, they should be determined with the EWD installed and working normally.

The peak ‘A-weighted’ ambient noise level in both the ‘Wash Room’ and the ‘ISD Room’ unloading area should not exceed the reported mean ‘A-weighted’ surface sound pressure level by more than 15 dBA.

Electromagnetic compatibility

A3 5 Standard BS EN 15883 Part 4: 2018 for EWDs specifies that:

- when tested by one of the methods in EN 61000 Part 4-3: 2010, the functioning of the automatic controller and the instrumentation should be unaffected by electromagnetic interference (EMI) of severity level 3;
- when tested in accordance with EN 55014 Part 1: 2017, any EMI interference generated by the EWD should not exceed the limits specified.

Volume of water used per stage

A3 6 During type testing, manufacturers’ are required to determine the volume of water used during each stage of the operating cycle. This data is used in later calculations of the service requirements and must be accounted for in equipment procurement specifications.

Equipment:

- a water flow meter (or volumetric measuring equipment) should be used;
- there are three methods that may be used for determining the volume of water required. The method should have been chosen based on which is most convenient for the installation.

Methods:

- a water flow meter should have been fitted in each of the water supply pipes, consecutively or concurrently, following the water meter manufacturer’s instructions for installation. Particular attention should have been paid to the length of uninterrupted straight pipe required on either side of the meter. The EWD is then operated with the chamber empty and the following tests performed:
  - the volume of water used by comparison of the readings before and after each stage of the process operating cycle is determined;
  - where the EWD water is supplied from a readily accessible tanked supply the water supply to the tank should have been interrupted and the water level marked. An operating cycle is then run and a measured volume of water is added until the water level in the tank is restored to its original level;
  - for EWDs which discharge all the water from the chamber at the end of each stage, an estimate of the volume used can be calculated from the volume of water discharged into the drain.

Acceptance criteria:

- the volume of water used for each stage of the operating cycle should be within ±5% of the volume specified by the manufacturer.

Estimation of dead volume of pipework

A3 7 Residual water that does not drain from the internal pipework of the EWD may provide an environment for microbial growth; this can lead to colonisation of the EWD pipe work and lead to cross-contamination of the load.

Note A3.3: This test is intended primarily as a type test but is also of value when investigating microbial contamination occurring in a EWD. The test should only be carried out once the checks for free draining (tanks, chamber, load carriers and pipe work) have been satisfactorily completed.

Equipment:

- volumetric measuring vessels of an appropriate size should be used.

Method:

- flush with a known volume of water, simulating the flow that would occur in normal use;
- either following disassembly and reassembly or by purging with dry compressed air for not less than 30 min;
- measure the volume of water discharged and subtract from the known volume flushed. The difference is an estimate of the dead volume (i.e., volume retained);
- when the EWD has two or more entirely separate pipe work systems e.g., for flushing water, wash water, rinse water or detergent solution, each system should be tested separately.

Acceptance criteria:

- the volume of retained water should be less than 1% of the volume of water used and there is no visible liquid in the pipe work of the EWD.

Water seal

A3 8 To establish that the seal integrity is maintained under normal operating conditions the following tests should be undertaken. During type testing this is carried out with a test trap, of the same type and dimensions as normally fitted, but manufactured from a transparent material. OQ testing requires:

Equipment:

- a full load of surrogate devices of the type the EWD is designed to process;
- a calibrated measuring device (dipstick).

Method:

- carry out the test on the installed EWD with all services connected;
- verify that the trap is charged with water to the normal working level;
- close the door and start the operating cycle;

- at the end of the operating cycle, examine the water level in the trap. This can be done visually during type testing, or by using a calibrated measuring stick (dipstick);
- repeat the procedure for five consecutive cycles observing the trap between each cycle.

Acceptance criteria:

- the water seal should remain intact with no obvious damage;

Load contamination from extractor ductwork.

A3 9 The evolution of water vapour from the chamber during the EWD operating cycle can result in condensation occurring in ductwork. The ducting is commonly arranged to allow this condensate to drain back into the chamber. This test is designed to establish that any condensate draining back into the chamber will not contact the load. This test is intended for use as an IQ test.

Note A3.4: It may be impractical to carry out this test as specified in an operational environment. Where this applies the CP(D) may be able to adapt other test methods to visually inspect the load for contamination.

Equipment:

- a measuring vessel of not less than 500 ml capacity having a discharge port at its base connected to a flexible tube fitted with an on/off valve and a flow control valve;
- stopwatch;
- load carrier and full load for the EWD;
- paper towels.

Note A3.5: If it is not possible to disconnect the ducting at this position it should be disconnected at the chamber and an additional 1 m length of ducting should be connected to the chamber.

Method:

- disconnect the external ducting to the EWD 1 m above the chamber;
- with the on/off valve closed, fill the vessel with 200 mls ± 20 mls of cold water. Open and adjust the flow control valve so that the contents of the vessel are discharged to waste in 1 min ± 5 sec;
- position the measuring vessel above the disconnected section of ducting. Refill the vessel with 200 mls ± 20 mls of cold water. Feed the flexible tube into the ducting so that the open end of the flexible tube is 600–800 mm above the top of the chamber;
- load the chamber with a full load of dry load items following the manufacturer's instructions. Close the chamber door and then open the on/off valve. Record the time required for the vessel to empty;

- within one minute of the vessel emptying, open the chamber door and remove the load and any removable load containers. Place all the load items on absorbent paper, examine all surfaces of the load and the absorbent paper for traces of water;
- repeat the above procedure for the full range of load carriers that the EWD is designed to process.

Acceptance criteria:

- there should be no visible water on the load or load carriers, basins or baths.

Drainage

Blocked drain protection

A3 10 This test is intended for use both as a type test and as an Installation Qualification test and where possible should be repeated during annual testing. The purpose of blocked drain protection is to prevent spillage and minimise the risk of cross-infection.

Method:

- deliberately block the basin drain and run successive operating cycles until the water level rises to sensor level.

Acceptance criteria:

- an alert or alarm should be indicated before the water level reaches the door seal. ‘EN ISO 15883 Part 1:2009+A1:2014 (clause 6.3.8).

Condenser drain seal integrity

A3 11 When the EWD has been vented via a condenser there is a danger that any restricted flow within this system can produce a back pressure in the EWD chamber. If the back pressure is excessive the water seal between the chamber and drain may be broken.

During type testing this is carried out with a test trap, of the same type and dimensions as normally fitted, but manufactured from a transparent material. To establish that the seal integrity is maintained under normal operating conditions during OQ testing requires:

Equipment:

- a full load of surrogate devices of the type the EWD is designed to process;
- a calibrated measuring device (dipstick}.

Method:

- carry out the test on the installed EWD with all services connected;
- verify that the trap is charged with water to the normal working level;

- close the door and start the operating cycle. At the end of the operating cycle, examine the water level in the trap. This can be done visually during type testing, or by using a calibrated measuring stick (dipstick);
- repeat the procedure for five consecutive cycles observing the trap between each cycle.

Acceptance criteria:

- the water seal should remain intact with no obvious damage.

Free draining (tanks, chamber and pipework during OQ testing)

A3 12 Residual water that does not drain from the internal pipework of the EWD can provide an environment for microbial growth. This may colonise the EWD posing an infection risk. The following checks should be carried out during type-testing, works testing (commissioning) and OQ and quarterly to verify that the EWD will effectively discharge all the water from the system.

Method:

- at the end of the operating cycle check the free draining of the chamber, and all tanks by examining to ensure no solution remains after draining;
- visually inspect the pipework flow to the discharge point for signs of fluid retention, including the use of a spirit level when necessary.

Acceptance criteria:

- the pipework should be free of water.

Purging of the trap: efficacy of discharge through the trap.

A3 13 This test is intended to verify that the operating cycle is effective in purging the trap of all waste and soil. The test can be carried out as part of the cleaning efficacy test during OQ testing.

Equipment:

- test soil appropriate to the type of EWD being tested;
- sampling tube of sufficient length to reach the water trap in the drain of the EWD and a sampling pump, for example, a pipette pump or syringe.

Method:

- on completion of an operating cycle with a full load contaminated with an appropriate test soil, place the sampling tube into the water trap and remove a sample;
- examine the water sample from the trap for residual test soil using the detection method appropriate to the test soil used.

Acceptance criteria:

- the water in the trap should be free from residual soil to the same level of detection as specified for the load items. Any residual soil found in the trap can indicate an infection or recontamination hazard.

Doors seals and interlock tests

A3 14 Security and settings of door safety switches and interlocks should be checked quarterly. Maintenance and inspection of door safety devices and door interlocking and chamber sealing systems should be carried out at least quarterly or in accordance with the manufacturer's instructions for use. The setting should be within the limits specified by the manufacturer.

The interlocks on door(s) of the EWD are intended to:

- prevent the operator gaining access to the load during processing;
- prevent both the loading and unloading doors being open at the same time on 'pass-through' EWDs;
- prevent the operator within the ISD room gaining direct access to a load that has not been satisfactorily processed.

Operating cycle start interlock

A3 15 The interlock should prevent an operating cycle from starting with the door open.

Method:

- ensure that all services are connected;
- leave the doors open and unlocked and attempt to initiate an operating cycle;
- close and lock the doors and make a further attempt to initiate an operating cycle.

Acceptance criteria:

- at the start of an operating cycle it should only be possible to initiate an operating cycle when all door(s) are closed.

In-cycle interlock

A3 16 An interlock is required to ensure the door(s) cannot be deliberately or inadvertently opened while the EWD is in operation.

Method:

- close and lock the door(s) and start the operating cycle;
- where practicable, visually inspect the interlocks to verify engagement before attempting to open the door;
- while the operating cycle is in progress attempt to unlock each of the doors.

Acceptance criteria:

- during a cycle It should not be possible to unlock any of the doors;

Double-ended EWD doors opening test

A3 17 For EWDs with separate loading and unloading sides the following checks should be made.

Method:

- during the operating cycle and on completion of the operating cycle attempt to open both the loading and unloading doors as described below.

Acceptance criteria:

- after initiation of an operating cycle:
  - it should not be possible to open either door until the operating cycle has been satisfactorily completed, or a cycle has failed;
  - it should not be possible to open the unloading door until a cycle has been completed satisfactorily;
  - it should not be possible for both doors (loading & unloading) to be opened at the same time.

On door sensor failure

A3 18 Used to check the door open sensor is functioning correctly.

Method:

- disable each fault sensor in turn and attempt to open each of the door(s). Where practicable, avoid undertaking these checks during an operating cycle.

Acceptance criteria:

- when the sensors are disabled it should not be possible to open the door(s).

Failed cycle door interlock

A3 19 The failed cycle interlock should prevent the Operator from unloading without using a special key, code or tool.

Method:

- during an operating cycle interrupt one, or more, of the services to the EWD to cause a cycle failure.

Acceptance criteria:

- a fault should be indicated. It should not be possible to open the unloading door in the ISD room. It should only be possible to open the Wash-room loading door by using of a key, code or tool.

Leak test failure alarm

A3 20 The following test should be used to check all EWD leak test channels quarterly. Ensure:

- the pressure applied during an automated leak test is within the endoscope manufacturers specified pressure range;
- that where a leak occurs in an endoscope the EWD detects the failure and alerts the operator to the leak;
- to ensure if a Leak test connector is disconnected the EWD will not start the cycle and will alert the operator to the error.

Equipment:

- a test piece, consisting of a length of tubing terminated at one end with a connector for connection to the EWD and at the other end a flow control valve. The internal volume of the tube should be within ± 10 % of the internal volume of the largest endoscope that the EWD is intended to process.
- a pressure transducer (sensor), capable of reading to ± 1 mbar (±0,1 kPa) over the range of the system's operating pressure.

Testing the leak tester fault and pass conditions

A3 21 This test should be conducted Quarterly.

Method:

- connect the test piece to the leak tester and activate the leak test procedure in order to reach the leak test pressure level (p1);
- open the flow control valve on the test piece in order to allow the pressure to drop to a level of $\Delta p > 0{,}8\ (p2 - p3)$ in the leak test period $(t3 - t2)$;
- connect the test piece to the leak tester and activate the leak test procedure to reach the leak test pressure level ($p1$);
- open the flow control valve on the test piece to allow the pressure to drop to a level of $\Delta p \leq 0{,}8\ (p2 - p3)$ in the leak test period $(t3 - t2)$.

Acceptance criteria:

- verify that the pressure (p) does not exceed the endoscope manufacturers specified maximum pressure ($p$max);
- verify from EWD readings taken from the pressure transducer that a fault or pass condition has been indicated as appropriate.

Testing the pressure relief device

A3 22 This test can be carred out at the same time as the 'leak tester fault and pass conditions test' above.

Method:

- connect the test piece to the EWD with the flow control valve fully closed. The pressure regulation system should be disabled;
- initiate the leak test;
- record the pressure at which the pressure relief system operates $p$max.

Leak test non-connection

A3 23 This test should be conducted quarterly as described below.

Method:

- connect an endoscope/ surrogate device to the WD, except for the leak test connector;
- initiate an operating cycle.

Acceptance criteria:

- verify that the EWD indicates that the leak test has failed via an audible/visual alarm, and an operational cycle has not been initiated.

Leak tightness of doors

A3 24 The door(s) of the EWD are intended to prevent the escape of fluids into the surrounding environment and to ensure freedom from aerosols that may be potentially infectious.

Damaged door seals are the major potential source of leaks and should receive careful attention as advised by the manufacturer. Excessive and persistent leakage also carries the risk of scalding the operator and causing deterioration of walls and their surface finishes. The working life of door seals can be prolonged by regular cleaning.

Equipment:

- absorbent paper wipes (of a type which change colour density when damp);
- one or more mirrors 50 mm x 50 mm or larger.

Method:

- load the EWD, close the door and wipe the joints between the door and the door surround to remove any moisture. Start an operating cycle;
- throughout the operating cycle use the mirror(s) to check if water vapour escapes from the door seal or condenser, if fitted;
- at the end of the operating cycle, with the door still closed, use the absorbent wipes to wipe the joints between the door and the door surround as close as possible to the door seal. Examine the wipes for dampness.

Acceptance criteria:

- door leak test;
  - there should be no misting of the mirror(s), which would be evidence of vapour emission, and no dampness of the absorbent wipes, which would be evidence of vapour or liquid emission.

Door opening force

A3 25 The mechanism for opening the EWD door should not require the use of excessive force. This test need only be conducted during installation qualification or in the event of operational concerns. Measurement of the force needed to initiate and sustain the movement of the door opening mechanism.

Equipment:

- spring balance calibrated in kilograms with a range including 0–250 kg and with an accuracy of ±1 kg over the range 0–250 kg;
- non-extensible means of attachment of the spring balance to the door mechanism.

Method:

- attach a spring balance, aligned with an axis or centre line common with the direction of movement of the door opening mechanism (co-axially), between the operator and the mechanism;
- attach the spring balance to the door opening mechanism. Open the door, record the force required to initiate and sustain the movement.

Acceptance criteria:

- door opening force;
  - the measured value required to initiate or sustain the movement of the door opening mechanism should not exceed 250 Newtons (i.e. a mass of 25 kg).

Load carriers

A3 26 The correct functioning of load carriers is essential to the successful outcome of an EWD operating cycle. It is important that they cannot easily be misaligned, that they function correctly and when applicable, they fully connect with service supply points in the chamber and with load items. Load carriers come in a variety of forms including:

- carriages;
- hubs;
- hook-ups;
- baskets.

Method:

- verify the alignment of load carriers, by observing their connection to water, air or the process chemical(s) supply within the chamber and any connection to all working channels of the endoscopes;
- check load carriers with rotary spray arms to ensure the spray arms are free to rotate, both when the load carrier is empty and when fully loaded.

Water sprays and jets

A3 27 The correct flow and distribution of water and process chemicals throughout the chamber and load are essential to the correct functioning of an EWD. The spray system should be checked daily as part of the routine housekeeping tasks carried out by the User or operator.

In addition, maintenance staff should also check the system at least weekly and confirm:

- that the rotating spray arms, both installed within the chamber and located on load carriers, are free to rotate;
- that nozzles are not blocked; clean and/or replace if necessary;
- inspection for wear in bearings of rotating parts; replace any worn parts as necessary;
- ensuring that the mating of any necessary connection between the load carrier and the water supply to the chamber.

Automatic controller fault indication on sensor failure

A3 28 A failure of any sensor used as part of the control system of the EWD should cause a fault to be indicated by the automatic controller.

Note A3.6: This test should only be carried out during routine testing where practical disablement of each sensor is possible. If in doubt consult the manufacturer for the most appropriate method.

Method:

- start an operating cycle;
- immediately before the stage of the cycle where the sensor provides information to the automatic controller disable each sensor in turn;
- establish that a fault is indicated.

Acceptance criteria:

- confirm each sensor disabled produces a fault condition;
- a fault should be indicated during or at the end of the cycle;
- it should not be possible to open the unloading door of the EWD without a key or code.

Chemical dosing systems

A3 29 The correct amount of process chemical should be delivered at the right time in the operating cycle to ensure the correct functioning of a EWD. The process chemical dosing system should be subjected to daily inspection, maintenance and testing. This should include:

- ensurance that sufficient process chemicals are available and are being dosed;

- visual inspection of all piping/tubing to ensure there are no leaks;
- that neither the delivery or pick-up piping/tubing is not restricted or blocked by coagulated or hardened process chemical (many of the process chemicals used are a viscous suspension), followed by cleaning or replacing piping as necessary;
- lubrication of the pinch tubing on peristaltic pumps in accordance with the manufacturers' instructions.

Reproducibility of the process chemical volume dispensed

A3 30 This test is intended to verify the settings for the volume of process chemical(s) dispensed is reproducible and within defined limits recommended by the manufacturer. The test should be carried out as part of the OQ and during quarterly and annual tests for each chemical dosing system on the EWD.

Note A3.7: As concentrates used can be an irritant, care should be taken, when process chemicals are dispensed into measuring cylinders.

Unless advised by the process chemical manufacturer, water should not be used as a substitute as potential differences in density or viscosity can affect the volume dispensed.

Two methods can be used to measure the quantity of dispensed chemicals. Either method is suitable, the choice will be dependent on the equipment available.

Equipment 1:

- two measuring cylinders that conform to standard EN 384: 2015/ EN ISO 4788: 2005 should be used. The size of measuring cylinder should be appropriate to the volume of process chemical to be dispensed.

Method 1:

- disconnect the chamber supply line as close as possible to its discharge point into the chamber or water circulation system;
- place a measured volume of process chemical into two measuring cylinders;
- actuate a normal cycle and at the end of the dosing stage, top up the first cylinder to the original mark from the second cylinder. Disregard the result of the first test;
- calculate the detergent added from the second cylinder;
- repeat the test three more times; record the volume added on each test.

Equipment 2:

- a set of laboratory grade balances or scales and a two measuring cylinders conforming to EN 384: 2015/EN ISO 4788: 2005 as described above.

Method 2:

- weigh one empty measuring cylinder and record the weight or zero the scales;

- disconnect the chamber supply line as close as possible to its discharge point into the chamber or water circulation system and place into the weighed cylinder;
- place twice the manufactures specified volume of process chemical into the measuring cylinder;
- actuate a normal cycle and at the end of the dosing stage record the weight of any remaining process chemical.

Acceptance criteria:

- the mean collected volume from the final three tests should be within ±10% of the nominal dispensed volume.

Indication of insufficient process chemicals

A3 31 All EWDs should be equipped with a method of preventing a cycle from starting when there are insufficient process chemicals in the reservoir to complete the cycle, or if the float switch fails. The volume of process chemicals recommended by the manufacturers for the correct functioning of the EWD should be used.

This test should be carried out for each chemical dosing system on the EWD during OQ and quarterly testing.

Method:

- fill an empty measuring cylinder or beaker with sufficient chemical for more than three cycles but less than four operational cycles;
- run the EWD for four consecutive cycles;
- estimate the volume remaining at the end of each cycle by recording the level on a pre-marked container, measuring the depth with a dipstick or by recording the weight).

Acceptance criteria:

- testing for insufficient process chemical to complete a cycle. At the start of the fourth cycle the EWD should indicate that there is insufficient chemical to complete a cycle.

Instrumentation fitted to an EWD

Verification of calibration

A3 32 The calibration of instrumentation and any independent monitor fitted to the EWD should be verified by comparison with calibrated test instruments during steady state conditions. This test should be carried out during OQ and quarterly testing and comply with ‘EN ISO 15883 Part 1:2009+A1:2014 clause 5.12–5.17. SHTM 01-06 Part B should be consulted for calibration requirements for test equipment.

Where adjustments of calibration are carried out on the EWD, the measured results and corrections should be clearly identified in the validation or service reports. Values should be recorded before and after any adjustment.

Method:

- Instruments accuracy should be verified and if necessary adjusted to an accuracy of;
  - 1°C for temperature measurements at the wash and disinfection stage temperatures);
  - 0.05 Bar (50millibars) for operating pressure (where specified);
  - ± 5 % of reading or ± 0.1 µS/cm whichever is greater. (Conductivity measurement).
- This may be carried out concurrently with other testing, for example, during the automatic control test during quarterly periodic testing.

Thermometric tests

A3 33 Thermometric tests are conducted to verify the attainment of the specified conditions throughout the chamber and load during the operating cycle. Thermometric tests should be used for all stages where temperature is a critical parameter. For thermal self-disinfection processes the time/temperature relationships giving an A_0 of 600 are defined in 'EN ISO 15883 Part 1:2009+A1:2014 and EN ISO 15883 Part 2:2009' can be found in section 2, Table 2.2.

Note A3.8: Biological indicators should not be used as a substitute for thermometric testing.

Note A3.9: During validation and periodic testing the use of self-contained data loggers is recommended (see Part B of this SHTM). Care is required when selecting units to ensure they are capable of withstanding disinfectant solutions with high pH and the high temperatures used during thermal self-disinfect test cycles. Those housed in protective cases rated at IP68 (as defined in EN 60529: 1992+A2: 2013) are suitable for use.

The equipment specifications for temperature measurement systems (thermocouples and data loggers) are given in SHTM 01-06 Part B.

The use of recorders with fixed sensors may be impractical due to the configuration of the EWD chamber. In these instances, self-contained data loggers that can be processed through the EWD should be used.

Chamber wall temperature and load carrier testing

A3 34 EWD chambers may be tested consecutively or concurrently. In the latter case eight sensors should be used for each chamber. The EWD should be operated empty except for, load carriers.

Method:

- locate thermocouples as follows;
  - two diagonally opposite in the chamber;
  - one in the centre of the door or lid;

  - one in the centre of the two side walls;
  - one adjacent to each automatic control temperature sensor;
  - one adjacent to the process recorder temperature sensor;
- the sensors should be in direct contact with the items or sensor and placed as far as possible on or in the part of the chamber that is slowest to heat up;
- measure the temperature attained throughout the EWD chamber during three operating cycles. The first of these tests should be carried out from a cold start (at least 60 min since the machine was last used). The remaining three tests should be carried out with no more than a 15 min interval between cycles (a hot start).

Acceptance criteria:

- the results should be as follows;
  - the temperatures recorded on the surface of the chamber should be within the range 0 to 5°C of the disinfection temperature throughout the holding period for the disinfection stage;
  - the temperatures recorded on the surface of the chamber should be within ±5°C of the set temperature for the relevant stage and throughout the holding period for each of the other stages;
  - the temperature indicated/recorded by the EWD instruments should be within ±2°C of that recorded by the test instrument from the sensor adjacent to the reference sensor throughout the holding period for the disinfection stage;
  - the temperature profile obtained for the operating cycle should be consistent within ±2°C for the last three test cycles.

Operating cycle temperature limits on washing and chemical disinfection stages

A3 35 This test is only recommended where the WD washing and/or disinfection stage is not thermostatically regulated.

Equipment:

- surrogate device as specified by the EWD manufacturer and compliant with BS EN 15883 Part 4:2021, Annex H.

Method:

- locate the temperature sensors as specified in A33;
- in addition place one sensor in at least one channel of the surrogate device to a depth of not less than 100 mm and one sensor on the outer surface of the surrogate tubing;
- run a cycle. Supply the detergent and/or disinfectant solution at a temperature 2 °C to 4 °C below the minimum temperature specified for the washing/disinfection stage;

- run a second cycle. Supply the detergent and/or disinfectant solution at a temperature 2 °C to 4 °C above the minimum temperature specified for the washing/disinfection stage.

Acceptance criteria:

- record the minimum temperature attained by the load and chamber surface during the washing and/or disinfection stage and whether or not a fault was indicated by the automatic controller.

Thermometric test for thermal self-disinfection

A3 36 Temperature monitoring of the chamber should be used to determine the attainment of the required time-temperature conditions. The test should be performed in triplicate for OQ and commissioning tests and once during periodic testing quarterly and yearly tests.

EWDs may be tested using thermocouples passed through the entry port into the chamber, or independent data-loggers or a combination of both. Independent data-loggers located within the load items can be used where it is impractical to test the load using thermocouple cables for example where they may be damaged by movement.

During thermometric tests for the thermal self-disinfection stage, where necessary any the washing stages should be disabled, or the controlled temperature reduced to 20°C ± 5°C to avoid pre-heating. Reducing the wash temperature to 20°C creates the worst-case conditions which the self-disinfection stage would be expected to cope with.

Equipment:

- temperature measuring equipment, see SHTM 01-06 Part B.

Method:

- if required disable or reduce any washing stage controlled temperature to 20°C ± 5°C. Place temperature sensors in the following positions;
  - at least one at each level in the load carrier (up to a maximum of three) if the load carrier accommodates load items on more than one level;
  - one on in the region known to attain the disinfection temperature in the longest time;
  - one in the region known to attain the disinfection temperature in the shortest time;
  - one adjacent to the automatic control temperature sensor;
  - one adjacent to the process recorder sensor, if fitted, in each chamber or compartment;
  - one on each door of a double-ended EWD.

Note A3.10: The position of thermocouples or data loggers should be specified by the manufacturer and supported by data from type tests. If these data are not available from the manufacturer preliminary tests to map the temperature throughout

the load will be necessary. The sensors should be in direct contact with the item or the installed sensor they are monitoring.

Acceptance criteria:

- the test should be considered satisfactory if the following requirements are met;
  - the indicated and recorded chamber temperatures are within 2°C of the temperature measured at the automatic control sensor;
  - during the holding time the measured temperatures are within the disinfection temperature band recommended for the operating cycle and comply with, the requirements to give an A_0 of 600 as defined in EN ISO 15883 Part 1: 2009+A:2014;
  - the temperature (see Table 2 for required temperature bands) measured on the chamber surface does not fluctuate by more than ±2°C and does not differ from the temperature of other load items by more than 4°C;
  - at the end of the cycle, the temperature sensors have remained in position.

Over-temperature cut-out

A3 37 The EWD is fitted with an over temperature cut-out to control the temperature in the EWD. This prevents the temperature from rising to a level that would damage the load in the event of the automatic control failing. The manufacturers' procedure for testing the over-temperature cut-out should be followed during OQ testing to avoid potential damage to the washer disinfector.

Equipment:

- temperature measuring equipment, according to SHTM 01-06 Part B. No less than four sensors should be used or three independent self-contained data loggers and a temperature recorder having at least one sensor may be used as an alternative.

Method:

- locate temperature sensors at two diagonally opposite corners of any load carrier, in the centre of the load carrier and adjacent to the temperature sensor used as the reference sensor for chamber temperature;
- operate the EWD on a normal operating cycle, empty except for the load carrier. For multi-cycle machines test the two cycles with the highest and lowest operating temperatures;
- during the stage of the cycle when the maximum temperature is attained, disable the temperature control system.

Acceptance Criteria:

- testing the over-temperature cut-out - the over-temperature cut-out should operate at a temperature not more than 5ºC higher than that provided by any temperature control or temperature limiting device.

Residual process chemicals

A3 38 Process chemicals used during the decontamination process, detergents, etc., should be reduced during rinsing to the level set by the EWD manufacturer. The process chemical manufacturer should provide evidence of the maximum level of residual chemicals found not to cause harm to the staff or patients at the end of the final rinse stage. Where required the concentration of any chemical residue can be tested as detailed.

Method:

- the sampling and analytical methods used should be capable of determining the presence of the process chemical at concentrations below the maximum acceptable level;
- test the efficacy of the rinse process by using the upper limit of the normal dose of the process chemical(s) on a normal operating cycle using a test load;
- take a sample of the rinse water and send for testing.

Acceptance Criteria:

- the concentration should be lower than the manufacturer specified maximum acceptable level. Where residual limits are not specified and/or no analytical method is available, biocompatibility testing to ISO 10993 can be used to meet the requirements.

Load dryness

A3 39 If the EWD includes a drying stage, a drying efficacy test should be carried out.

Equipment:

- crepe paper and/or a mirror;
- medical grade compressed air.

Method:

- from a cold start run a normal cycle. Within five minutes of the end of the cycle;
  - place the load on a sheet of coloured crepe paper;
  - observe any water emanating from the load and carriage and examine the crepe paper for any staining of residual water from the load;
  - test pieces or endoscopes with lumens should be examined by blowing medical grade dry compressed air through the lumen onto a mirror surface or crepe paper.

Acceptance Criteria

- no residual water from the load should be observed on the crepe paper or, where relevant, on the mirror surface.

Washer disinfector fitted with HEPA air filters (for purging/drying)

A3 40 Some EWDs are fitted with High Efficiency Particulate Air (HEPA) filters (for example, class H 13 as EN 1822 Part 1: 2019) to remove bacterial contamination from the air supplied to the purging/drying stage. When they are used as general particulate filters, performance tests for the filter or the filter housing are not necessary. The method specified in EN ISO 14644 Part 1: 2015 and SHTM 01-06 Part B should be followed.

Method:

- a challenge aerosol of inert particles of the type produced by a dispersed oil particle generator, should be introduced into the air upstream of the filter. The downstream face of the filter and its housing should then be scanned for leakage using a photometer.

Acceptance Criteria:

- the reading on the photometer should be steady and repeatable and should not exceed 0.01% of the upstream reading.

Channel non connection test

A3 41 All channels of a surrogate device or an endoscope from a model representative of each endoscope type test group are connected to the channel irrigation system of the WD.

Equipment:

- test using a surrogate device designed to connect to all channels of the EWD irrigation system as advised by the EWD manufacturer.

Method:

- place the surrogate device into the EWD and connect all channels to the channel irrigation system;
- disconnect one channel and start the operating cycle;
- repeat for all available channels.

Acceptance criteria:

- a fault should be indicated for each channel when it was not connected.

Note A3.11: if the automatic controller is not able to detect a specific non-connection then this should be indicated within the instructions for use with reference to the applicable endoscope(s

Channel non obstruction test

A3 42 This test is suitable for EWDs with an automatic controller can monitor and detect obstructed channels run the operating cycle with the surrogate device while

obstructing one channel until the minimum flow specified by the manufacturer is reached.

Equipment:

- this test should be performed with a surrogate device designed as advised by the EWD manufacturer;
- repeat for each available channel in turn.

Acceptance criteria:

- a fault is indicated when each channel was obstructed.

Cleaning efficacy tests

Chamber walls and load carriers

A3 43 This test is carried out during OQ testing and is optional as a quarterly or routine test.

Method:

- contaminate the chamber walls and load carrier with the test soil following the manufacturers' instructions, including the specified quantities to be used and any drying stage;
- run a normal wash cycle;
- after completion of the wash and rinse stage but before the disinfection stage, (except where this is combined with the rinse stage), abort the cycle;
- for OQ tests, carry out the test in duplicate for each type of operating cycle available on the EWD;
- when used as a periodic test, carry out the test once for each available operating cycle.

Acceptance Criteria:

- the chamber walls and load carrier should be visibly free from the test soil;
- the test load should be visibly free from the test soil and no test soil should have been transferred to the chamber walls or load carrier.

Cleaning efficacy of the load - OQ testing

A3 44 During validation the type test methods used by the manufacturer or an equivalent modified operational test that demonstrates compliance should be obtained from the EWD manufacturer.

Equipment:

- at least one surrogate device designed to the specifications of the EWD manufacturer, representative of the most difficult to clean endoscope in use and compliant with the requirement specified in Annex H of EN ISO15883 Part 4:2018 is required;

- test soil formulations should be based on and representative of the worst case soiling found after clinical use. Detection of protein and one other analyte from the list given in BS EN 15883 Part 5:2021 clause 4.4.3. is required;
  - total organic Carbon;
  - carbohydrate;
  - haemoglobin;
  - ATP;
  - Endotoxin.

Method:

- the method of application and any required conditioning (e.g. drying) should represent the worst-case conditions (e.g. an endoscope used out of hours and stored prior to cleaning).
- consideration should also be given to the method of transport, dwell time and environmental conditions (e.g. temperature, time, humidity) from point of use until reprocessing, and any pre-treatment if applicable. Negative and positive controls should be used to exclude interference of process conditions.
- cleaning test stages should be conducted in duplicate under defined process conditions.

The level of detection will be dependent on the analytes tested. Where possible direct measurement can be made for some parameters will require extraction by a UKAS accredited laboratory.

Equipment:

- the following equipment is required;
  - paintbrush, 25 mm in width, soft;
  - disposable gloves;
  - drainage tray;
  - surrogate device;
  - syringe for injecting test soil into lumens;
  - test soil based on BS EN 15883 Part 5:2021 biofilm test soil for endoscopes;
  - quantitative test for protein residue;
  - quantitative test for protein residue.

Application of the test soil:

- don the protective gloves;
- apply an even coat of soil using the paint brush;
- allow excess soil to drain from the items, dry at room temperature (15ºC to 25ºC). For lumened surrogate devices a known quantity of test soil should be injected into each channel;

- allow the test soil to dry for between 30 minutes and 2 hours. The specified quantities should be used and drying of the test soil carried out in strict accordance with the instructions.

Method for test loads:

- contaminate the test load with the test soil in accordance with BS EN 15883 Part 5:2021 Annex A Table A1;
- run a normal operating cycle for the type of load under test;
- abort the cycle after completion of the wash stage, and before the disinfection stage, except where this is combined with the rinse stage. Examine the test load, chamber walls and load carrier for the presence of residual soil;
- for OQ tests, carry out the test in duplicate for each type of operating cycle available.

Acceptance Criteria:

- the surrogates should be visibly free from the test soil and no test soil should have been transferred to the chamber walls or load carrier;
- the exterior of the surrogates should be checked visually to ensure no visible soil remains;
- channels should be checked visually using a method compatible with the surrogate device;
- protein detection levels should be below limits specified in BS EN 15883 Part 5:2021 for action and alert levels shown below;
  - alert level ≥ to 3µg/cm^2;
  - action level ≥ 6 µg/cm$^{2.}$

Note A3.12: Additional methods may comprise swabbing of channels for protein/soil residuals, sections of transparent tubing which can be checked visually, soil test strips designed to be used with the surrogate or a combination of these methods.

PQ cleaning efficacy tests

A3 45 The requirement for PQ testing of the load in BS EN 15883 Part 4: 2018 is that inoculated endoscopes or those contaminated by clinical use should be used to test the cleaning efficacy of the EWD. It is recognised in the standard that testing inoculated endoscopes may not be in line with national requirements or, may not be practical due to limited availability of some endoscopes. In these cases, a surrogate device can be used to simulate load items. Therefore, periodic testing should be conducted using surrogate devices of a design recommended by the EWD manufacturer and inoculated with test soil approved by the Microbiologist (Decontamination) and compliant with BS EN 15883 Part 5:2021.

Method:

- a validated sampling process for surrogate devices as advised by the EWD manufacturer and approved by the Microbiologist (Decontamination) should be used;
- cleaning test stages should be conducted in duplicate under defined process conditions;
- the level of cleanliness should be determined by visual examination and by the use of protein detection methods listed in NP187;
- protein detection levels should be below limits specified in BS EN 15883 Part 5:2021 for action and alert levels shown above in section A 3.44;

Tests of chemical disinfection efficacy

A3 46 The disinfectant in use should comply with the requirements specified in section 2 and have been validated by the EWD manufacturer to achieve the required microbial reduction during type testing.

Chemical disinfection efficacy test of the load should be carried out using surrogate devices of a design recommended by the EWD manufacturer and inoculated with test soil as specified in BS EN 15883 Part 5: 2021. The Microbiologist (Disinfection) should be consulted before introducing any inoculated surrogate devices into the EWD.

Equipment:

- the surrogate device should be made from polytetrafluoroethylene (PTFE) tubing, of at least 150 mm in length and of the same diameter as the channels of the endoscope they are representing;
- a known microbiological challenge (The inoculum) should be applied in advance of the test. The inoculum should contain not less than 108 CFU/ml of the test organisms with the population in the original inoculum and deposited on the test piece for exposure to the disinfection process;
- BS EN 15883 Part 4: 2018, Annex B clause B.2.1.1. gives a list of organisms considered to be a suitable challenge. As a minimum, the test organisms should include Gram-positive and Gram-negative vegetative bacteria, Mycobacterium sp. enveloped and non-enveloped viruses, fungi, and bacterial endospores. A validated method of counting the test organisms is required;

Method:

- place the surrogate devices inoculated with test organism into the EWD and run the disinfection stage of the EWD cycle;
- carry out all tests in duplicate during installation and once during routine testing;
- apply the recommended neutralizing agent at the end of the test to prevent further disinfection activity.

Detection of test organisms

After testing the surrogate device should be sent for microbiological assessment at a UKAS accredited laboratory for TVC and the absence of Pseudomonas a. and

Mycobacteria spec. The culture method used to enumerate the number of surviving microorganisms after exposure to the disinfectant should be validated. The culture method must be capable of recovering a low number (approximately 10 CFU) of the organisms.

Acceptance criteria:

- the disinfection stage of the process should achieve a Log reduction of;
  - vegetative bacteria;— 9 log10;
  - fungal spores; — 6 log10;
  - mycobacteria; — 6 log10;
  - bacterial endospores — 4 log10.

Note A3.13: If required a method for sampling of endoscopes prior to the EWD cycle is included in BS EN 15883 Part 4: 2018 any sampling method should be based on this process.

EWD Periodic tests

Automatic control test

A3 47 The Automatic Control Test (ACT) is designed to show that the operating cycle functions correctly and that the EWD indicated and recorded values are within the validated parameters/consistent with annual tests. The Automatic controller data should be checked daily to confirm the recorded values are present and within the original specifications. A full ACT test as described below should be carried out weekly.

Method:

- place the test load within any load furniture normally used and place in the chamber;
- for EWDs equipped with multiple cycle capability select the operating cycle to be tested. Start the cycle;
- using a calibrated time piece- observe the elapsed times for each stage of the cycle;
- observe and note the elapsed time indicated chamber temperatures and flow rates etc. at all significant points of the operating cycle, for example the beginning and ending of each stage or sub-stage and the maximum values during the holding time;
- each stage should be independently timed and the indicated and recorded temperature(s) logged;
- ensure that an individual process record is made by the recording instrument fitted to the machine.

Acceptance Criteria:

- the test should be considered satisfactory if;
  - a visual display indicates ‘cycle complete’;
  - during the whole of the operational cycle the values of the cycle variables, as recorded by the EWD systems and any independent monitor are within the limits established by the manufacturer during type testing and performance qualification testing;
  - during the disinfection stage the EWD record, and any independent monitoring system are within the disinfection temperature and hold period requirement defined in EN ISO 15883 Parts 1: 2009 + A1 2014 and Part 4: 2018, and the performance qualification tests;
  - the person conducting the test does not observe any mechanical or other anomaly.

Additional PQ tests of cleaning efficacy

A3 48 PQ tests of cleaning efficacy are necessary during validation or when some of the items or loads to be processed are:

- not a member of the type test groups, or product families used during type testing or EWD validation;
- when any of the essential parameters of the EWD have changed (e.g. water quality, chemistries in use or a new medical device to be processed).

Method:

- repeat the tests described above for surrogate devices from the in section A 44.

Process Challenge Device (PCD) test for cleaning efficacy?

A3 49 Commercial PCDs are being developed whose challenge simulates the attachment of prion protein to instruments and whose analysis is quantitative. When these become available and have been validated, EDUs should carry out evaluation for their performance before considering their use.

Where local policy recommends the use of PCDs they should be correlated with and indicate the performance of EWDs in reducing the protein level.

Method:

- one PCD should be used per chamber as part of the automatic control test. It should be placed within a standard operational load;
- the position in the chamber, batch number of the indicator and expiry date should be recorded along with the result;
- several tests may be required initially to establish the position that represents the worst-case scenario within the wash chamber.

Appendix 4: Water quality tests methods

Introduction

A4 1 A continuous supply of water of the specified chemical and microbial quality is essential to the correct functioning of all EWDs. Washer disinfector standard BS EN 15883 Part 1: 2009+A1: 2014 specifies requirements for water quality for all WDs unless modified by BS EN 15883 Part 4: 2018 which specifies requirements for EWD final rinse water quality in clause 6.3.1 with limits given. No limit is specified for levels of endotoxin.

A4.2 Many of the test methods recommended here are intended to be suitable for onsite use and a range of test systems are available commercially. Where technological advances allow alternative methods of analysis that can be shown to have the same or greater accuracy these alternative methods can be used in place of the tests listed below.

Note A4.1: It is, essential that personnel receive appropriate training before attempting to carry out this work. Where analysis with a high level of accuracy is required for the detection of low concentrations of chemical contaminants described in A4 22 to A4 25, the use of a laboratory accredited to EN ISO/IEC 17025:2017 for the tests requested is recommended. Recourse to more precise independent analysis may also be needed in the event of a dispute between two parties.

A4 3 The recommend analytical methods used to determine the various biological, physical and chemical properties of water samples for the various qualities of feedwater to the EWD are detailed in this section. Before adopting one of these methods care should be taken to ensure the test(s) provides results of sufficient accuracy and sensitivity. For any given test there may be several suitable methods for the range of chemical analysis of interest.

A4 4 All EWD water samples should be drawn from a water source within the chamber or as close as practically possible to the point of entry to the EWD or water treatment equipment. Water samples should be collected in an aseptic manner to minimise microbial contamination of the sample using the type of collection container listed in the methods section below.

A4 5 When trying to identify the cause of a non-conformity additional samples from additional points in the supply system may be required. Therefore, additional draw-off points should be installed at convenient locations e.g. pre and post pre filtration, pre and post water treatment system. Requirements for water quality: final rinse and process water are detailed, see Table A4.1.

Table A4.1: Requirements for water quality

Parameter	Maximum permitted values - Final rinse	Maximum permitted values - Other stages
Appearance	Clear and colourless	N/A
Degree of acidity (pH)	5.5 to 8	N/A
Conductivity at 25°C (µScm-1)	30 µScm-1	N/A

Parameter	Maximum permitted values - Final rinse	Maximum permitted values - Other stages
Total dissolved solids (mg/100 mL)	4mg/100ml	N/A
Total hardness CaCO3	50mgl-1	210 mgl-1
Chloride mgl-1	10 mgl-1	120 mgl-1
Heavy metals, determined as Lead, Pb (mgl-1)	10 mgl-1	N/A
Iron, Fe	2 mgl-1	N/A
Phosphate, P2O5	0.2 mgl-1	N/A
Silica, SiO2	0.2 mgl-1	2 mgl-1
TVC cfu/100 ml	<10cfu/100ml*	N/A
Endotoxin Units EUml-1	0.25 EUml-1	N/A

Note A4.2:<10cfuml^{-1} value is the test limit for periodic testing of final rinse water for validation purposes Absence of *Pseudomonas aeruginosa* and (atypical) *Mycobacterium sp* should be confirmed.

A4 6 Further guidance on appropriate on-site test methods for the analysis of water may be obtained from BS 1427: 2009.

Test methods for on-site use

A4 7 Tests methods suitable for on-site use fall into three main categories:

- instrumental tests using portable equipment designed for on-site use, for example, portable pH meters, conductivity meters and ion selective electrodes;
- spectrophotometric tests based on measurement of the absorbance of a colour change during a reaction. Measurements can be visual or photometric and can be against a pre-calibrated coloured disc or standard reference solutions. Manufacturers usually supply a complete test system, including reagents;
- titrimetric tests may be carried out using standard laboratory equipment or with commercially available equipment designed for field use; the latter is usually simpler to use.

A4 8 To ensure compatibility and maintenance of the manufacturer's claimed sensitivity and accuracy for the method, any kit specified by the manufacturer should not be substituted.

A4 9 All variables for which instrumental methods are recommended are temperature dependent and equipment should be allowed sufficient time to equilibrate to the local ambient temperature on site, prior to use. All monitoring equipment must be calibrated in line with EN ISO/IEC 17025: 2017 and manufacturers' instructions.

Specific types of sampling containers must be used for specific tests as listed below.

Cations

1 Litre acid-washed borosilicate bottles.

Anions

1 Litre polypropylene bottles.

pH and conductivity

100 ml high-density polyethylene bottles.

Microbiological testing of final rinse water

Total Viable Count (TVC)

A4 10 If the operating cycle of the EWD requires that the medical device is rinsed after the disinfection stage the rinse water should be free from microbial contamination which could compromise the intended use of the load. A total viable count should be made on the final rinse water.

Water samples should be collected using an aseptic technique to prevent accidental contamination of the sample.

Method:

- the first 50 mls of sample taken at each sampling point should be run to waste;
- all samples should be taken in duplicate;
- samples should be tested within 4 hours of collection or if necessary stored at 2–4°C immediately after collection for no more than 24 hours. If samples are stored for more than 24 hours' fresh samples should be obtained;
- packaged in an insulated container with ice packs prior to dispatch.

Laboratory test methods:

- make a total viable count by membrane filtration of not less than 100 ml final rinse water sample;
- place the filter on R2A-medium or other suitable low nutrient medium and incubate at 28°C to 32°C for a minimum of 5 days to determine the aerobic mesophilic viable count.

Note A4.3: Other methods, including rapid methods such as ATP bioluminescence, that have been validated to be at least equivalent to the above method in terms of both specificity and sensitivity can also be used. Refer to EN ISO 15883 Part 1:2009+A1:2014 (clause 6.4.2.4 and Annex E of BS EN15883 Part 4:2018).

Acceptance criteria:

- Water services supplied to EWDs should have less than 10 cfu/100 mL of water (determined as the mean of the duplicate tests);
- The TVC of EWD final rinse water should be less than 10 CFU per 100ml and have no pathogenic microorganisms present.

Bacterial endotoxins

A4 11 Water samples for bacterial endotoxins should be collected in pyrogen free containers using an aseptic technique to prevent a false positive results.

Equipment:

- for sampling - 250 ml sterile pyrogen-free single-use containers for determination of bacterial endotoxin levels.

Method:

- use the same technique as for TVC collect the samples and dispatch.

Acceptance criteria:

- for final rinse water or RO water samples should contain no more than 0.25 $EUml^{-1}$.

Note A4.4: HPS Guidance document 'NHSScotland Guidance for the interpretation and clinical management of endoscope final rinse water' gives a value for the alert level as 10 cfu/ml^{-1} or greater as unfit for some uses. Where results show levels greater than 100cfu/ml the EWDs are deemed as unacceptable for clinical use and should not be used until remedial action is taken.

Physical and chemical properties

Water supply temperature

A4 12 The water supplied to the various stages of the EWD operating cycle should be at the temperature recommended by the EWD and endoscope manufacturer. If the temperature of the water supplied to the flushing stage is too high (>45°C) there is a risk of coagulating proteinaceous soiling, which inhibits the cleaning process.

If the temperature of water supplied to the washing, rinsing and disinfection stages is too low, the EWD cycle time may be extended, while the water is heated to the required temperature.

Water supplied in the temperature range 25°C to 60°C presents a serious risk of microbial contamination of the system. The test should be carried out as an installation and/or operational test and repeated when any change is made to the water services supplying the EWD, including the connection or removal of additional machines.

Equipment:

- an indicating or recording thermometer should be used.

Method:

- measure the temperature of the water supply from a sampling point as close to the EWD hot water storage system as possible;

- place the temperature sensor in the middle of the flowing stream. Allow the water to flow for at least one minute before the temperature is read;
- measure the surface temperature of pipes to the EWD using a sensor designed for the purpose and follow the manufacturer's instructions for ensuring thermal contact with the surface;
- Record or note the temperature during a normal operating cycle not less than 30 seconds after the start of water flow through the pipe to the EWD.

Acceptance criteria:

- feed water supply - the noted value should be within the temperature range specified at installation. The result should be recorded and documented for audit purposes.

Water supply pressure

A4 13 If the water supply pressure to the EWD is below the minimum specified by the manufacturer, the performance and productivity of the EWD will be adversely affected. If the pressure of the water supply to the EWD is above the maximum pressure specified by the manufacturer, the capacity of any overflow may be inadequate. The designed performance characteristics of valves, etc., may be exceeded and in extreme cases there may be the risk of damage to components of the EWD or to any endoscopes being processed.

Note A4.5: It is engineering best practice to install appropriate pressure gauges at strategic points on the distribution systems of each water supply.

Equipment:

- a pressure indicator or recorder covering 0 to 10 bar should be used.

Method:

- connect the pressure sensor to each of the EWD water supply pipes on the supply side of the EWD isolating valve as close as practicable;
- observe and record the static pressure when the valve is closed and the pressure indicated throughout a normal operating cycle;
- when the water service also supplies other equipment on the same supply line, run the test with the other equipment operating throughout the test period where possible. If it is not possible to run other equipment during the test period, their operation should be simulated by an appropriate discharge to waste.

Acceptance criteria:

- the water pressure should remain within the supply pressure limits specified by the EWD manufacturer.

Water Appearance

A4 14 All the water supplied to the EWD should be clean, colourless and free from particulate matter when assessed visually.

Equipment:

- the following equipment should be used;
  - a clean, clear glass bottle with stopper;
  - filter paper (qualitative grade 1), filter funnel and holder.

Method:

- transfer an aliquot to a clear colourless glass bottle, which should then be tightly closed with its stopper;
- shake the bottle vigorously and then examine against a white background, under good quality lighting;
- if the sample is turbid;
  - filter through the qualitative grade filter paper (grade 1) described above;
  - examine the filter paper for evidence of colloidal material;
  - record a description of any retained material including colour and intensity.

Acceptance criteria:

- all the samples tested should be clear, bright and colourless.

Note A4.6: Action is required if the sample is discoloured. Check and replace filters, carry out thermal disinfection of the washer as necessary. The AP(D) and AE(D) should advise.

Measurement of pH

A4 15 Portable pH meters with built-in temperature compensation provide suitable accuracy for most general applications.

Colourimetric tests for pH are widely used for field tests in various disciplines. While the accuracy can be limited and discrimination may not be better than 0.2 pH units this is, suitable for field tests.

Note A4.7: Colourimetric tests should not be used to measure pH of distilled and RO water due to the low ionic strength of water of high purity. Only those pH meters specifically designed for the measurement of low ionic strength solutions should be used for determining the pH of RO water.

Narrow range indicators, for use on successive samples, should be chosen to cover the range of pH 4 to pH 10.

Colourimeters that cover a range of 2 or 3 pH units should not be used due to their poor discrimination. Photometric equipment with greater discrimination are commercially available.

Equipment:

- portable pH meter or:

- colourimetric tests;
- colour disc comparator.

Method:

- operate the test kit in accordance with the manufacturers' instructions. Pay particular attention to using accurate volumes of both sample and reagent and monitoring both temperature and reaction time;
  - verify the calibration using standard buffer solutions made up in advance and kept in capped bottles until required. The buffer solutions should be chosen to have a pH in the midpoint of range of the calibrated colour discs to be used in the determination;
  - match the colour of the reacted sample against the calibrated colour disc when viewed through a blank sample. Read off the value in pH units directly from the disc.

Acceptance criteria:

- the indicated pH value should be in the range 5.5 to 8.0.

Electrical conductivity

A4 16 There is a wide variety of portable conductivity meters available. Conductivity meters should be calibrated in ranges of µS cm^{-1}.

The meter or meters used should cover the ranges shown in Table 19 and be temperature-compensated over the range 0 to 40°C. A comprehensive range of standard conductivity reference solutions, including pure water standards, are available commercially, standardized at 25°C and traceable to national standard reference materials.

Table A4.2: Range, resolution, and accuracy of the conductivity meter

Range	Resolution	Accuracy
0–199 µS cm–1	0.1 µS cm–1	±1% full scale
10–1990 µS cm–1	1 µS cm–1	±1.5% full scale

Equipment:

- conductivity meter;
- standard conductivity reference solutions;
- for high purity waters, flow-through cells are recommended to minimize absorption of gases which will modify the electrical conductivity. Where it is necessary to sample high purity waters separately, this should be done with minimum agitation to minimize absorption of gases.

Method:

- use the following method for electrical conductivity calibration;
  - verify the calibration of the meter against 0.001 molar (M) and 0.0005 M reference standard solutions of potassium chloride (KCl) and pure water as

working standards (Water for injection). These give conductivities at 25ºC of 141 µS cm^{-1} and 84 µS cm^{-1} and 0.06µS cm^{-1} respectively;

- prepare the potassium chloride solutions by dilution of a 0.1 molar solution with distilled water;
- after calibration rinse the sample cup or immersion probe thoroughly with pure water;
- collect the sample in a high-density polyethylene bottle and test as soon as practicable;
- pour an aliquot of the sample into the sample cup of the conductivity meter or, for meters with an immersion probe, into the clean beaker. Follow the meter manufacturer's instructions for making the measurement; this will usually require a short stabilization period before noting the reading.

Acceptance criteria:

- the conductivity at 25°C should not exceed the specified limits provided by the EWD Manufacturer and that given in table 18.

Total Dissolved Solids (TDS)

A4 17 The laboratory test for the determination of dissolved solids is a gravimetric method. This involves determining the weight of the residue obtained by evaporating a known sample volume to dryness.

TDS method 1

Equipment:

- silica or borosilicate dish or beaker of >150 ml capacity;
- oven set to 110ºC ± 2°C;
- boiling water bath or heating mantle set to 100ºC ± 2°C;
- 1 Litre polypropylene bottle;
- balance weighing to 0.1 mg;
- 100 ml pipette or measuring cylinder.

Method:

- collect a 1 Litre water sample;
- take the silica dish (or equivalent), dry for 2 hours in the oven set to 100°C ± 2°C and then cool to ambient temperature, and weigh to the nearest 0.1 mg;
- dispense 100 ml of the sample into the weighed dish and evaporate it over the boiling water bath until visibly dry. Evaporate two further 100 ml aliquots of the sample in the same dish in the same manner;
- dry the dish in the oven to constant weight to an accuracy of 0.1 mg;
- calculate the mass of residue in the dish and hence calculate the mass of residue per 100 ml of water.

Acceptance criteria:

- TDS expressed as the evaporative residue should not exceed 4 mg 100 ml^{-1} for purified water (RO).

TDS Method 2

A4 18 Alternatively, when a water sample contains predominantly ionisable solids, and the composition of the various constituents is reasonably constant, an estimate of the total dissolved solids can be obtained from the electrical conductivity of the sample which can be used to determine concentrations up to 10,000 mg/L total dissolved solids.

The electrical conductivity should be measured as described in A4 16 and expressed in micro-siemens per centimetre (µS/cm) at 25°C. This is then multiplied by an experimentally derived conversion factor in the range 0.55 to 0.8 to give the concentration of total ionisable dissolved solids in milligrams per litre (mg/L). The conversion factor can be derived experimentally for waters of consistent ionic composition by making direct comparison of the measured mass of total dissolved solids by gravimetric methods and the electrical conductivity on a test sample.

Conversion factor = TDS (in mg/L) / conductivity (in µS/cm at 25°C).

Alternatively, an arbitrary factor can be used. The one most commonly chosen is based on sodium sulphate as the ionic species giving an arbitrary factor of 6.7 for most waters. Where conductivity is expressed in other units or recorded at a different temperature this value may not apply.

Note A4.8: When purchasing commercially available conductivity meters that are scaled directly in milligrams per litre of total dissolved solids TDS mg/L care should be taken to ensure that the conversion factor used is appropriate; as different models may have variable conversion factors. Therefore, it is advisable to check such meters with test solutions of known TDS concentration prior to use.

Ready-to-use standard salt solutions traceable to National Institute of Standards and Technology (NIST) standard reference materials are available commercially. A TDS standard solution such as NaCl 1382 ppm, in a tenfold dilution can be used to verify the calibration.

Equipment:

- conductivity meter;
- phenolphthalein indicator;
- 5% w/w acetic acid solution; or
- 5% w/w sodium hydroxide solution as dictated by the pH of the sample.

Method:

- measure the pH of the sample;

- using phenolphthalein as the indicator neutralize the test sample, by drop-wise addition of 5% w/w sodium hydroxide solution or 5% w/w acetic acid solution depending on the initial pH of the sample;
- measure the conductivity of the sample and multiply by the conversion factor to give an estimate of the TDS in mg/L.

Acceptance criteria:

- the estimate of total dissolved solids should not exceed 4 mg 100 mL^{-1} for purified water (RO or DI).

Hardness (as $CaCO_3$)

A4 19 Hardness of water is due to the presence of dissolved salts of the alkaline earth metals, calcium, magnesium and strontium. Their presence causes limescale formation from heated or evaporated water, can inactivate process chemicals and causes scaling on load items.

The calcium selective electrodes available have a Nernstian response for concentrations from 1M down to approximately 5 x 10^{-6}M and a selectivity ratio of better than 2000 against magnesium. This range is suitable for analysis of softened water and purified water (RO). The electrodes are free from any major interference except zinc ions. They are, however, poisoned by a number of biological fluids.

Equipment:

- Ion-Selective Electrodes (ISE) are available for calcium and also for divalent cations (total hardness). Ion-selective electrodes do not directly measure the concentration of a specific ion in solution but provide a potentiometric response to the activity of the ions in solution. The activity is proportional to the concentration for determinations carried out in solutions of the same ionic strength.

Method:

- ensure the pH of the sample is within the optimum working range of pH 4 to 9;
- adjust the sample and calibration standard solution to the same ionic strength. An adjustment buffer of 4M potassium Chloride (KCl^-) solution is often used;
- the calcium electrode requires a single junction reference electrode. Calibration is made against two or more standard solutions. These are commercially available;
- adjust both analyte and calibration standard solutions to the same ionic strength;
- using a high impedance milli-voltmeter measure the potential between the ion selective electrode and a suitable reference electrode. The measured potential is proportional to the logarithm of the concentration of the ion(s) in solution.

Note A4.9: Phosphate buffers should not be used since the calcium activity will be lowered by the formation of complexes or precipitation.

Titrimetric method

A4 20 Commercially available kits for the titrimetric determination of both total hardness and calcium hardness are available. The test reagents are specific to each kit. The manufacturer's instructions should be followed.

Most test kits are based on the same reaction in which divalent cations are complexed with the disodium salt of Ethylene Diamine Tetra-Acetic acid (EDTA). When the reaction is carried out, at pH 10 to 11, with Eriochrome black as the complexometric indicator, all the calcium and magnesium ions are chelated by the EDTA. The absence of free calcium and magnesium ions causes a definite colour change in the indicator.

At pH values above 12, magnesium ions are precipitated as the hydroxide and do not react with the EDTA. Under these conditions calcium hardness can be determined using 'Patton and Reeders' indicator powder as the complexometric indicator.

Range: determinations within the range 5 to 400 mg/L can be made.

Note A4.10: This method is not suitable for purified water or condensate from clean or pure steam, which should have calcium concentrations well below the range for accurate determination.

Acceptance criteria:

- water with values >210 mg/L should be regarded as unsuitable for use in EWDs without pre-treatment;
- the hardness expressed as mg/L $CaCO_3$ should not exceed 50 mg/L for softened water.

Chloride

A4 21 The presence of significant levels of chloride ions (Cl^-) in water supplied to EWDs may cause pitting and corrosion in metallic parts of the load (including stainless steel). Significant levels of chloride can be present in untreated mains water supplies. High chloride concentrations are also associated with breakthrough from defective, or incorrectly operated, water softening or deionising equipment.

This method is not quantitative for purified water, which should have chloride concentrations well below the range for accurate determinations; it can be used, however, as a limit test. The BP limit test, based on comparison of the turbidity obtained from a known chloride concentration, can also be used.

Equipment:

- using Ion Selective Electrodes (ISE);
  - commercially available chloride selective electrodes have a working range from 1 M to 10^{-5} and work over the pH range 3 -10. If required ionic strength of the sample can be adjusted using an adjustment buffer of 5 M $NaNO_3$ solution;
  - the electrodes show poor selectivity against other halides and cyanide ions. Sulphide ions should be absent;

  - the chloride electrode requires a double junction 0.1 M $NaNO_3$ reference electrode;
  - conduct the calibration against two or more commercially available standard solutions.

Equipment:

- using silver nitrate titration kits;
  - commercial titrimetric kits are available that are based on the method described in BS 6068- 2.37: 1990, ISO 9297: 1989.

Method:

- titrate the sample at pH 5 to pH 9 with silver nitrate using a potassium chromate indicator solution;
- the analytical range is 5 –150 mg/L.

Acceptance criteria:

- the chloride concentration in final rinse water for EWDs processing metal items should not exceed 10 mg/L;
- the chloride concentration in other water supplies for EWDs processing metal items should not exceed 120 mg/L.

Laboratory Tests

Heavy metals (expressed as Lead)

A4 22 Heavy metals are generally toxic in low concentrations and, as far as possible, should be absent from potable water used to process endoscopes.

Method:

- determine the total concentration of heavy metals using the BP limit test or see also BS 6068-2.29: 1987 on determination of lead using flame atomic absorption spectrometric methods and ISO 8288-1986.

Acceptance criteria:

- the total concentration of heavy metals should not exceed 10 mg/L determined as lead.

Iron

A4 23 The presence of significant concentrations of iron in water used to process endoscopes can promotes corrosion of stainless-steel components and exacerbates the effect of any chloride ions that may be present.

One of the commercially available colour disk comparator kits should be used for this test. Typically, these are based on the reference method described in standard ‘BS 6068-2.2:1983, ISO 6332-1982’.

The reaction of iron (II) with '1, 10 phenanthroline' in solution yields a red complex with peak absorption at around 510nm. Most commercial test kits include methods and reagents for pre-treatment to reduce any iron (III) compounds to the iron (II) form in which they can be analysed.

This method is generally suitable for determination of the concentration of iron in untreated water but is not sufficiently exact for determination of the concentration specified for steam condensate which at ≤0.1 mg/l is at the limit of discrimination of most systems.

Equipment:

- colour disc comparator kit;
- reagents;
- a standard 0.702 g/l iron(II) ammonium sulphate $(NH_4)_2Fe(SO4)_2\,6H_2O$) solution;
- a mercury in glass thermometer graduated in 0.5°C steps conforming to BS 1704: 1985 and ISO 1770: 1981.

Note A4.11: On test equipment:

The analytical range depends on the calibrated colour disc supplied with the chosen test kit. A range of 0-5 mg/l is commercially available and provides adequate precision. The pre-packaged reagents available from the comparator manufacturer should be used.

Discs offering extended ranges should not be used as the discrimination of intermediate concentrations becomes unacceptably poor.

Method:

- prepare a standard 0.702 g/l iron (II) ammonium sulphate $(NH_4)_2Fe(SO_4)_2$ solution which provides a standard solution of 100 mg/l iron;
- prepare the solution as required and do not store. Prepare working standards spanning the usable range of the colour disc comparator by appropriate dilution;
- measure the sample temperature before commencing the analysis;
- after the kit manufacturer's specified reaction time has elapsed use the colour intensity of the sample to estimate the concentration of iron in the sample;
- for details of the colorimetric method, see the method for the determination of silicate.

Acceptance criteria:

- untreated and softened water should have less than 2 mg/l iron present.

Phosphate

A4 24 This test method measures only orthophosphate. Pre-treatment to convert other forms of phosphate to orthophosphate should be used if appropriate. Some other

phosphates such as condensed phosphates and labile organic phosphates are slowly hydrolysed under the acidic conditions used for the test.

The method depends on the reaction of phosphate in acidic solution with molybdate and antimony ions to form an antimony phosphomolybdate complex, which on reduction with ascorbic acid forms a blue coloured complex having maximum absorbance at 882 nm.

Phosphate is readily absorbed onto many plastic surfaces. When polypropylene bottles are used as sample containers the sample for phosphate analysis should be transferred immediately to a borosilicate glass container and assayed as soon as possible.

This glassware should have been subjected to acid hardening, that is, cleaned and allowed to stand overnight, filled with sulphuric acid, then rinsed several times and stored filled with water, in the dark at 0 to 4°C until required for use. The glassware should not be allowed to come into contact with detergents or alkaline liquids.

Commercially available test kits are generally based on the reference method described in EN ISO 6878: 2004 and BS 6068 Part 2.28: 2004.

The calibrated phosphate colour disc should be calibrated in P_2O_5 mg/l. A sensitivity range of 0–5 mg/l is commercially available and provides adequate precision. Discs offering extended ranges should not be used as the discrimination of intermediate concentrations becomes unacceptably poor.

Note A4.12: Only the pre-packaged reagents available from the manufacturer of the comparator should be used.

Commercially available comparators that work at 700 nm is less sensitive and should not be used.

The presence of oxidising agents and sulphides will interfere with the reaction. Otherwise, there are no particularly sensitive interferences.

Equipment:

- colour disc comparator kit;
- reagents;
- sample container;
- glassware;
- a standardised solution containing 100 mg/l potassium dihydrogen orthophosphate for preparation of calibration standards.

Method:

- follow the manufacturer’s instructions;
- react the sample in acidic solution with antimony and molybdate ions to form an antimony phosphomolybdate complex. Reduce with ascorbic acid to form a molybdenum blue complex;

- prepare a stock standard solution containing 100mg/l potassium dihydrogen orthophosphate and dilute to provide suitable working standards for calibration verification. The concentrated stock solution is stable for several weeks;
- test the samples as soon as possible after sampling. If sampling will be delayed by more than 4 hours store the sample(s) in suitable glass bottles at 2 to 5°C for up to 24 hours;
- for details of the colorimetric method, see the description given in the method for the determination of silicate;
- the temperature has a significant effect on reaction time; at 20°C the reaction is typically completed within 3 to 4 minutes. Before making the measurement ensure that the reaction is complete but avoid excessive delays, which can cause errors from hydrolysis of other phosphates. Read the measurement at 10 to 15 minutes after the start of the reaction.

Acceptance criteria:

- the phosphate concentration of rinse water used for metal load items should not exceed 0.2 mg/L expressed as P_2O_5.

Silicate

A4 25 Silicate reacts with metal items, including stainless steel, causing discoloration. This is accentuated at elevated temperatures.

This method is based on the use of one of the commercially available colour disc comparator kits. Typically, these are based on the analytical method described in BS 2690-104: 1983, which is a recognised reference method. Reactive silica is reacted with ammonium molybdate under acidic conditions to form molybdosilicic acid which is then reduced to molybdenum blue.

The analytical range depends on the calibrated colour disc supplied with the chosen test kit. A range of 0 to 5 mg/L is commercially available and provides adequate precision. Discs offering extended ranges should not be used as the discrimination of intermediate concentrations becomes unacceptably poor.

The method is generally suitable for determination of SiO_2 levels in softened and untreated water but is only sufficiently sensitive to act as a limit test for purified (RO) water.

Equipment:

- colour disc comparator kit;
- reagents;
- a standard 3.132 g/L disodium hexafluorosilicate (Na_2SiF_6) solution;
- a mercury-in-glass thermometer graduated in 0.5°C steps conforming to BS 1704: 1985 and ISO 1770: 1981.

Note A4.13: Only the pre-packaged reagents available from the manufacturer of the comparator should be used.

Note A4.14: For most kits the temperature should be at least 15°C to ensure that the reaction will go to completion. If the sample temperature is below this, or the minimum temperature specified by the manufacturer, the sample should be warmed.

Method:

- prepare a standard 3.132 gl^{-1} disodium hexafluorosilicate (Na_2SiF_6) solution, providing a stock standard solution of 1000 mgl^{-1} as SiO_2. The solution is stable for several months after preparation stored in a sealed polyethylene bottle. Working standards spanning the usable range of the colour disc comparator can be prepared by appropriate dilution;
- measure the sample temperature before commencing the analysis using the mercury-in- glass thermometer then;
  - after the kit manufacturer's specified reaction time has elapsed use the colour intensity of the sample to estimate the concentration of silicate in the sample;
  - with the calibrated colour disc for silica in the comparator, an untreated water sample in the blank cuvette and the reacted sample in the sample cuvette;
  - placed in the comparator cell holder;
  - visually match the colour density developed in the sample against the calibrated colour disc viewed through the untreated sample;
  - read off the displayed value of SiO_2 concentration from the calibrated disc;
- Serial dilutions of the standard solution may be used to verify the calibration of the comparator disc.

Acceptance Criteria:

- Untreated and softened water should have less than 2 mgl^{-1} silicate expressed as SiO_2, determined as reactive silica, present;
- Purified (RO) water should have not more than 0.2 mgl^{-1} silicate expressed as SiO_2, determined as reactive silica, present.

Appendix 5:-Tests for conformity overview

An overview of Tests for conformity from relevant parts of the BS EN 15883

A5.1 Endoscope Washer disinfectors must demonstrate compliance with the relevant performance requirements, mechanical & process requirements, and conformity tests for EWDs as outlined in the Washer-disinfector standards BS EN 15883 Part 1: 2009 +A1: 2014, BS EN 15883 Part 4: 2018, and BS EN 15883 Part 5: 2021. The EWD manufacturer should have carried out type tests to demonstrate that the EWD fulfils the above requirements.

A5.2 Standard BS EN 15883 Part 1:2009+A1: 2014 specifies performance requirements, and mechanical & process requirements applicable to all washer disinfectors. Part 1 subclause 4.3.1 (specification for thermal disinfection of the load carrier and chamber walls during a standard cleaning and disinfection cycle) and subclause 6.5.6 (test for chamber venting to prevent pressurization by steam) are not applicable to EWDs. In addition some tests included in Part 1 are modified by BS EN 15883 Part 4: 2018 Part 4: subclauses, as listed below:

- Part 1 subclause 4.2.3 (washing stage), is modified by 4.3.3 of Part 4);
- Part 1 subclause 4.3.3 (chemical and thermal disinfection, modified by 5.4);
- Part 1 subclause 5.3.2.5 (microbial quality of final rinse water, modified by 4.5 Part 4);
- Part 1 subclause 5.11.4 (process verification, modified by 5.6);
- Part 1 subclause 6.4.2.1 (test for quality of final rinse water – sampling, modified by 6.3 and Annex E);
- Part 1 subclause 6.8.2 (load temperature test, modified by 6.9.1);
- Part 1 subclause 6.8.3 (chamber wall temperature test, replaced by 6.9.1);
- Part 1 subclause 6.10.2 (cleaning efficacy test 1; modified by 6.11).

A5 3 To confirm that the EWD is operating to the original specification after installation OQ and PQ testing is carried out. Tables A5.1-A5.9 are provided below to give an overview of these requirements as specified in the standards.

Note A5.1 Where a reference to a specific clause or annex is given in the overview table A2-1.8 this refers to the annex or clause in the referenced standard not in SHTM01-06.

A5 4 Many of the tests carried out at these times are repeated in a simplified form during routine testing after installation and during the life of the equipment as discussed in section 4 of this guidance document.

A5 5 Table A5.1 outlines requirements from the Operational Qualifications requirements in BS EN 15883 Part 1+A1 2009: 2014. Consult the standards for full details.

Table A5.1: Outlines requirements from the Operational Qualifications requirements in BS EN 15883 Part 1+A1:2009: 2014

Brief description of test– Table A.1 Operational Qualification Requirement subclause no.	Outline of requirement
Cleaning efficacy (chamber, load carrier and load)	Not applicable Replaced by BS EN 15883-4: 2018 OQ requirements
Thermometric 2.1 Thermal disinfection Optional -4.3.1.2, 4.3.1.3, Chamber walls Optional -4.3.3 Thermal and chemical disinfection	The temperatures recorded on the surface of the chamber wall should be within −0 °C and +5 °C of the disinfection temperature throughout the time specified for disinfection when this has been specified as a time/temperature relationship (see 6.8.3) d) the temperature profile obtained for the temperature-controlled stages of the operating cycle are consistent within ± 2,5 °C for the last three of four test cycles (see 6.8.3.2).
5.9.2	When tested in accordance with 6.8.3 the temperatures attained on the chamber walls throughout the process should meet the following requirements: a) the temperatures recorded on the surface of the chamber throughout the holding period for the disinfection stage are within − 0 °C and + 5 °C of the disinfection temperature; b) the temperatures recorded on the surface of the chamber throughout the holding period for each of the stages, other than the disinfection stage (see above) are within ± 5 °C of the set temperature for the relevant stage; c) the temperature indicated/recorded by the EWD instruments are within ± 2 °C of that recorded by the test instrument from the sensor adjacent to the reference sensor throughout the holding period for the disinfection stage;

A5 6 Table A5.2 outlines requirements from the Operational Qualifications requirements in BS EN 15883 Part 4: 2018 Normative Annex C Table C.2. These are in addition to the requirements in BS EN 15883 Part 1. Others tests given in table C.2 of BS EN 15883 Part 4: 2018 are not included as these are stated as “not recommended” for OQ testing. Requirement clauses from section 4 are performance requirements and those from section 5 are mechanical and process requirements (of the standard BS EN 15883-4: 2018). Consult the standards for full details.

Table A5.2- Operational Qualification requirements outlined in ‘BS EN 15883 Part 4: 2018 Normative Annex C Table C.2 – in addition to that in BS EN 15883 Part 1’. 1009

Brief description of BS EN 15883-4: 2018 Annex C Table Operational Qualification Requirement subclause no	Outline requirements
Leak test failure alarm 4.2.3	For EWD having an automatic leak test, the automatic controller should prevent the continuation of the operating cycle and operate an audible and visible alarm indicating a leak test failure if a leak is detected in an endoscope. Variations in temperature that might adversely affect the sensitivity of the leak test and the temperature range permitted in the EWD during the automatic leak test, if fitted, should be stated [see 8 g)]. NOTE 1 A leak test failure indicates that the device is likely to be damaged by further processing. However, a satisfactory leak test does not provide absolute assurance that the device will not be damaged by further processing.

Brief description of BS EN 15883-4: 2018 Annex C Table Operational Qualification Requirement subclause no	Outline requirements
	NOTE 2 An automatic leak test which maintains a positive pressure throughout the cycle can provide an additional safety level.
Cleaning efficacy 4.3.5	Determination of cleaning efficacy Cleaning efficacy should be determined in accordance with 6.11.
Complete process 4.1.3 (test clause 6.12.6.2)	Demonstration of the capability of the complete cycle efficacy should be provided during additional type testing by employing a modification of the methods described in Annex B with added test soil and/or as standard BS EN 15883-5:2021, using the organism(s) previously established during *in vitro* tests as most resistant to the disinfectant under in-use conditions and on endoscopes that are representative for each relevant endoscope type test group. According to the nature of the most resistant microorganism selected the minimum log10 reduction obtained after a complete standard cycle for that microorganism(s) should be: — 9 log10 for vegetative bacteria; — 6 log10 for fungal spores; — 6 log10 for mycobacteria; or — 4 log10 for bacterial endospores. In order to limit the work load the type tests can be performed on representative endoscopes from endoscope type test groups (see Annex H to establish relevant
	The efficacy of the process (including cleaning and disinfection) depends on a number of factors which include: Endoscope type test groups). a) the nature (characteristics) of the device being processed; b) the extent and nature of the soiling to be removed; c) the temperature of the process; d) the mechanical energy (type, output); e) purging to remove rinse water; f) the detergent system; g) the nature, volume, concentration and temperature of the cleaning and disinfectant solutions and their ability to wet the surfaces to be cleaned and disinfected; h) the duration of the various process stages; i) the removal of suspended soil. (outline test clause 6.12.6.3)
	When required by national regulation, a surrogate device should be used to simulate the load items. Inoculated carriers shall be incorporated as part of the surrogate device to monitor the efficacy of the disinfection stage (see 6.12.6.1).
	Local and national requirements can specify the interpretation of microbiological test results and when the samples for routine testing are taken after a defined time period, e.g. at least 12 h after the operating cycle. Microorganisms incorporated into test soils can be used instead of, or as well as, the use of inoculated carriers (see standard BS EN 15883-5: 2021). Endoscopes can be selected by the User according to Annex I.
	Where the disinfection of the water supplied to the EWD is performed by adding a low dosage of a disinfectant to the water, compliance with the standard should be demonstrated with and without the water disinfectant. Any variation in water disinfectant

Brief description of BS EN 15883-4: 2018 Annex C Table Operational Qualification Requirement subclause no	Outline requirements
	concentration due to local environmental conditions that might change the result of the test should be taken into account.
Drying 4.7-4.7.1	Where the EWD has no drying stage or has a user selectable drying stage: The instructions for use should indicate that the device and the channels of the device should be dried prior to storage in accordance with 8 k), 2).
4.7.2	The quality of air used during the drying stage should be at least that defined in 4.6.2.
4.7.3	When tested in accordance with 6.8 there should be no visible droplets of moisture.
Disinfection of liquid transport system*4.8 - 4.8.5	The self-disinfection cycle should ensure that an EWD that has become contaminated through failure of the water treatment equipment can be effectively disinfected. Compliance should be verified by testing in accordance with 6.12.5. After carrying out a self-disinfection cycle, the performance should be deemed to be satisfactory if the final microbial count is 10 CFU/100 ml or fewer, and free from *Pseudomonas aeruginosa* in 100 ml, and if required for operational and routine testing, the sample is free from (atypical) *Mycobacterium* sp. in 100 ml (see 6.12.5). Methods for microbiological evaluation of disinfection of the liquid transport system are specified in Annex D.
Self disinfection 4.8.7	For chemical disinfection systems a microbiological test should be required. The test should be designed to ensure that the self-disinfection cycle will disinfect contaminated tubing by evaluating the effect of the cycle against a biofilm containing *Pseudomonas aeruginosa* (see standard BS EN 15883-5: 2021).
Disinfection of water treatment equipment 4.9 4.9.2 - Optional Water treatment equipment -4.9.2.1	When the water treatment equipment is a part of the EWD, the former should be designed and constructed so that it can be periodically submitted to a disinfection procedure. Guidance on the minimum frequency with which the equipment should be disinfected should be stated according to the information supplied by the purchaser for the quality of the water supply and the manufacturer of the water treatment equipment [see 8 i)].
	The disinfection of the water treatment equipment can be carried out during a self-disinfection cycle. The actual frequency should be specified based on, e.g. seasonal variations in the quality of water supplied to the EWD and the operational history of the water treatment equipment.
	The disinfection method should not cause any damage to, nor impair the efficacy of, the treatment equipment. The efficacy of the water treatment equipment disinfection procedure to provide self-disinfection should be deemed to have been established when tested in accordance with the methods given in 6.12.4 and 6.12.5.. There should be less than 10 CFU recovered from each of the two 100 ml samples and other controlling parameters should be achieved
4.9.2.2	If the water treatment equipment is not part of the EWD, then the requirements for water supplied to the EWD should be specified. This should include specification of the permissible microbial contamination of the water supply [see 4.3.4 and 8 p)]. To meet the specification of the permissible microbial contamination of the water supply, it can be necessary to make provision for maintenance of the external water treatment equipment (e.g.

Brief description of BS EN 15883-4: 2018 Annex C Table Operational Qualification Requirement subclause no	Outline requirements
	filter replacement, disinfection, ultraviolet sources, calibration of dosing system).
Incoming water used for the final rinse. 4.9.2.3	Means should be provided to disinfect incoming water used for the final rinse. The disinfection process should ensure that: a) there are less than 10 CFU/100 ml sample of final rinse water when tested in accordance with E.3.2 and; b) the water is free from *Pseudomonas aeruginosa* in 100 ml, and (atypical) *Mycobacterium* sp. in 100 ml when tested in accordance with E.3.3 (see 6.3).
	The following methods can be suitable for control of the microbial contamination of rinse water. The rinse water will be: a) maintained in a dedicated reservoir at a temperature not less than 65 °C for the time demonstrated to achieve disinfection of the incoming supply; or b) disinfected immediately prior to use; or c) filtered to remove suspended particles of a size greater than 0,2 µm; or d) sterile, in a closed container, with a connection to the EWD designed and constructed to provide aseptic transfer.
4.9.2.4	The connection between the water supply, which has been treated to remove microbial contamination, and the circulation system for rinsing the endoscope, should be designed and constructed to prevent recontamination of the water. Provision should be made for disinfection of this connection to be made periodically. The frequency and method of carrying out this disinfection should be specified [see 8 h) and 8 i)].
4.9.2.5	If the water treatment equipment is part of the EWD, then where possible, the final rinse water treatment used to fulfil the requirements of 4.5 should be monitored by the EWD automatic controller to verify that the parameters affecting the efficacy of the water treatment equipment remain within specification. If the monitoring cannot be done by the automatic controller, then all the parameters to be verified during validation and routine monitoring should be specified [see 8 s)].
Final rinse water treatment-micro quality 4.5 - Final rinsing 4.5.2	The final rinse water should meet the requirements for microbiological quality as given in 4.9.2.3.
Temperature throughout process -Temperature 4.4.3 The temperature of the disinfecting agent	The temperature of the disinfecting agent throughout the disinfection stage should be monitored to ensure that it remains within the specified limits of the disinfectant and be compatible with the temperature limits for the device(s) to be processed. This should be achieved either by controlling the temperature of the disinfectant solution or, where appropriate, by operating the EWD at ambient temperature with means to prevent operation of the EWD when the disinfectant temperature is outside the specified temperature range.
Temperature control of the washing stage 5.4.2	Throughout the washing stage, when tested as described in 6.9.1, the temperature recorded on the surface of the chamber and on all surfaces of the device being processed should be within the specified washing temperature band. If the temperature band is wider than 5 °C, the efficacy of the washing stage should be demonstrated during type testing at the minimum and maximum temperature of the specified washing stage temperature band.

Brief description of BS EN 15883-4: 2018 Annex C Table Operational Qualification Requirement subclause no	Outline requirements
	The temperature during washing stage should be within the limits specified for the detergent(s) and compatible endoscopes.
Temperature control of the disinfection stage 5.4.3	Throughout the disinfection stage, when tested as described in 6.9.1, the temperature recorded on the surface of the chamber and on all surfaces of the device being processed should be within the specified disinfection temperature band. If the temperature band is wider than 5 °C, the efficacy of the disinfection stage shall be demonstrated during type testing at the minimum and maximum temperature of the specified disinfection stage temperature band. The temperature during the disinfection stage should be within the limits specified for the disinfectant(s) and compatible endoscopes.
Minimum process temperature test 5.4.4 - EWD with a minimum operating temperature for the washing and/or disinfection stage	Throughout the washing and/or disinfection stage, when tested as described in 6.9.2, a fault should be indicated when: the temperature on the surface of the chamber and of the liquid process medium are below the minimum temperature specified for the device.
Water quality 4.5.2 - The final rinse water	The final rinse water should meet the requirements for microbiological quality as given in 4.9.2.3.
Chemical dosing test (single dose container) 5.7	For those EWD in which the required dose of process chemical is contained in a single-dose container which is replaced before each cycle, means should be provided to ensure that the intended volume has been dispensed. When tested in accordance with 6.10 there should be an indication of a fault. For EWD in which process chemicals are supplied in multi-dose containers, ISO 15883-1:2006+Amd 1:2014, 5.7 Dosing systems applies.

A5 7 Table A5.3 gives the combined subject list of PQ requirement tests as per the BS EN 15883 series of Part 1: 2014, Part 4: 2018 and Part 5: 2021

Table A5.3 Combined subject list of PQ requirement tests as per the BS EN 15883 series of Part 1: 2014, Part 4: 2018 and Part 5: 2021

PQ Tests	BS EN 15883-series
Cleaning efficacy – load Thermometric- Thermal disinfection - Chamber walls Thermometric- Thermal disinfection - Load [a]Chemical disinfection — Chamber walls and load carrier [a]Chemical disinfection — Calorifier and tanks [a]Chemical disinfection — Load Load dryness process residuals Load carriers – internal- Alignment Operating cycle -Spray system Operating cycle -Reproducibility – optional	Part 1: 2014
Leak test non-connection test Cleaning efficacy Complete process Channels non-obstruction test Channels non-connection test Temperature throughout process	Part 4: 2018

PQ Tests	BS EN 15883-series
Minimum process temperature test Water quality	
Cleaning performance qualification test (5.4 of Part 5: 2021) Process residuals (5.5 of Part 5: 2021)	Part 5: 2021
[a] Applied only to WDs employing chemical disinfection with controlled temperatures	[a] Chemical disinfection Applied only to EWDs employing chemical disinfection with controlled temperatures

A5 8 Table A5.4 gives the outline PQ requirements for the EWD (from BS EN 15883 Part 1+A1:2009: 2014 – Table A.1 Part 1: 2014). Consult the standard for full details.

Table A5.4 – Outline of BS EN 15883 Part 1+A1:2009: 2014 – Table A.1 Performance Qualification Requirements

PQ test requirements Requirement subclause no	Outline requirements
1 Cleaning efficacy -1.3 load 4.2.1.1 (test subclauses 6.10.3 test 1, visual and annex C).	Cleaning should have been achieved if the acceptance criteria for the test method in 6.10 and the relevant subsequent parts of BS EN 15883 -4 have been met. The test method for type testing and operational testing (6.10.2) should employ one of the nationally published. Refer to standard BS EN 15883-5: 2021. Additional verification of attainment of the required cleaning efficacy during operational testing can be provided by the use of one of the methods for the detection and assessment of residual protein given in 6.10.3 and Annex C. A test for residual protein is performed for determining cleaning efficacy on used medical devices but can also be used with proteinaceous test soil. described in 6.10.3 and should include the use of one of the methods for the detection and assessment of residual proteinaceous contamination given in Annex C. The test method for performance qualification of cleaning efficacy is The three test methods for protein residue testing in Annex C are not equally sensitive. The ninhydrin method (C.1) and biuret method (C.3) have similar sensitivities but are regarded as a limit test and a semi-quantitative test respectively. The OPA method (C.2) is more sensitive but requires the use of laboratory facilities. Both the ninhydrin and OPA methods react with α- and ε-amino groups of proteins; other amino compounds can give false positives. Cleaning efficacy test 2 - 6.10.3 6.10.3.1 - General. This test is undertaken following satisfactory completion of cleaning efficacy test 1 and the thermometric tests (see 6.8). The EWD should be tested using actual loads contaminated by normal use, specified by the User as being representative of loads it is intended to process. 6.10.3.2 Procedure Operate no less than three cycles using actual loads contaminated by normal use of the type that it is intended to process. Visually assess the cleanliness of the processed items. When the items are visually clean, one of the methods given in Annex C should be used to detect the presence of residual proteinaceous contamination. When other methods will be used routinely for assessing the

PQ test requirements Requirement subclause no	Outline requirements
	acceptability of items processed through the EWD, the test method to be used should be agreed between the user and the manufacturer. Other types of contamination e.g. non-proteinaceous can require other test methods. 6.10.3.3 Results Report the composition of the test load, the method(s) used to assess the cleanliness of the load and whether all parts of the load were found to be free from residual contamination by the test method used.
Thermal and chemical disinfection 4.3.1 **2** Thermometric tests 2.1 Thermal disinfection -Optional - 4.3.1.1, 4.3.1.3, 4.3.3.1 and 4.3.3.2 5.9.1 Thermal disinfection -Chamber walls and load carrier	The temperature should be continuously maintained within the specified disinfection temperature band for the specified disinfection time. Thermal disinfection can be achieved by exposure to hot water, steam or a combination of the two. The temperature on all surfaces of the load and load carrier should be within −0 °C and +5 °C of the disinfection temperature throughout the time specified for disinfection when this has been specified as a time/temperature relationship (see 6.8.2). a) the temperatures recorded on the surface of the load and load carrier are within − 0 °C and + 5 °C of the disinfection temperature throughout the holding period for the disinfection stage; b) the temperatures recorded on the surface of the load and load carrier are within ± 5 °C of the set temperature for the relevant stage throughout the holding period for each of the other stages; c) the temperature profile obtained for the temperature controlled stages of the operating cycle should be consistent within ± 2,5 °C for the last three of four test cycles (see 6.8.2.3); d) the holding time, as determined from the measured temperatures on the surface of the load items, is not less than that specified for the disinfection stage (or the specified A_0 value has been obtained); e) during the holding time the measured temperatures on the surface of the load and load carriers are within the disinfection temperature band specified for the operating cycle (or the specified A_0 value has been obtained); f) the temperatures shown on the chamber temperature indicator and/or recorder are within ± 2 °C of the temperature measured at the automatic control sensor; g) the temperature measured on the surface of each load item does not fluctuate by more than ± 2 °C and does not differ from that in other load items by more than 4 °C; h) at the end of the cycle the temperature sensors are found to have remained in position.
5.9.2	When tested in accordance with 6.8.3 the temperatures attained on the chamber walls throughout the process should meet the following requirements: a) the temperatures recorded on the surface of the chamber throughout The holding period for the disinfection stage are within − 0 °C and + 5 °C of the disinfection temperature; b) the temperatures recorded on the surface of the chamber throughout the holding period for each of the stages, other than the disinfection stage (see above) are within ± 5 °C of the set temperature for the relevant stage;

PQ test requirements Requirement subclause no	Outline requirements
	c) the temperature indicated/recorded by the EWD instruments are within ± 2 °C of that recorded by the test instrument from the sensor adjacent to the reference sensor throughout the holding period for the disinfection stage; d) the temperature profile obtained for the temperature-controlled stages of the operating cycle are consistent within ± 2,5 °C for the last three of four test cycles (see 6.8.3.2).
2.4 [a]Chemical disinfection - Of Chamber walls and load carrier 4.3.2, 4.3.2.2, 4.3.2.3 and 4.3.2.4 the load 4.3.2.,	Chemical disinfection of the chamber walls and load carriers should have been achieved when the specified conditions of chemical disinfectant concentration, temperature and contact time have been attained on all chamber walls and load carriers. The conditions of time, temperature and chemical disinfectant concentration should be those specified, under the conditions of use, by the disinfectant manufacturer. The temperatures recorded on the surface of the chamber wall should be within −0 °C and +5 °C of the disinfection temperature throughout the time specified for disinfection when this has been specified as a time/temperature relationship (see 6.8.3). Alternatively, a party other than the disinfectant manufacturer should determine the conditions of time, The temperature and chemical disinfectant concentration that provide the required microbial reduction factor (see 4.1.5). Appropriate additional testing (e.g. load compatibility, environmental safety, disinfectant stability) should have been performed also. Microbiological testing should be performed (see BS EN 15883-4: 2018).
[a]Chemical disinfection - Of the load 4.3.2., 4.3.2.1-	Chemical disinfection of the load should have been achieved when all load surfaces have been exposed to the specified conditions of chemical disinfectant concentration and temperature for the required contact time. The temperature on all surfaces of the load and load carrier should be within −0 °C and +5 °C of the disinfection temperature throughout the time specified for disinfection when this has been specified as a time/temperature relationship (see 6.8.2). Appropriate additional testing (e.g. load compatibility, environmental safety, disinfectant stability) should have been performed also.
[a]Chemical disinfection - Of Calorifier and tanks 5.3. and 4.3.3 Tanks	5.3.2 Tanks – 5.3.2.3 When water is to be heated, the temperature to which it is heated should be controlled within the limits specified for the process. 4.3.3 Thermal and chemical disinfection 4.3.3.1 The temperature on all surfaces of the load and load carrier should be within −0 °C and +5 °C of the disinfection temperature throughout the time specified for disinfection when this has been specified as a time/temperature relationship (see 6.8.2). 4.3.3.2 The temperatures recorded on the surface of the chamber wall should be within −0 °C and +5 °C of the disinfection temperature throughout the time specified for disinfection when this has been specified as a time/temperature relationship (see 6.8.3).
3 Load dryness Drying 4.5 - 4.5.1,and 4.5.2	The EWD should, unless otherwise specified, be provided with a drying stage which removes surface moisture from the load. Drying of the load should have been achieved if, when tested in accordance with 6.12 and the relevant

PQ test requirements Requirement subclause no	Outline requirements
	subsequent parts of BS EN 15883, no residual water is detected at the end of the drying stage.
6 Process residuals 4.4	Rinsing 4.4 - 4.4.1 The EWD should be provided with a rinsing stage which reduces the concentration of process chemicals on the load to a level not exceeding that specified by the manufacturer, or supplier, of the process chemical(s) as safe in the context of the intended use of the load. 4.4.2 Rinsing should have been achieved if, when tested in accordance with 6.10.4 and with the relevant subsequent parts of ISO 15883, the reduction of process chemicals has been determined and been shown to have been sufficient for the subsequent intended use of the load.
12 Load carriers - Internal 12.2 Alignment	5.1 Materials, design, and manufacture/construction. 5.1.10The construction of the load carriers should be such that these are cleaned and disinfected during the normal operating cycle and do not obstruct the free flow of water to the drain [see 5.9.1 a), b) and e)]. Compliance should be checked by testing in accordance with 6.5.2, 6.5.4, 6.8.2 and 6.10.2.
14 Operating cycle 14.1 spray system	Spray systems 5.6 5.6.1 Spray nozzles should be positioned to ensure complete contact of the spray with all parts of the load together with the appropriate load carrier when loaded in accordance with the manufacturer's instructions. 5.6.2 Nozzles should be protected from blockage by the passage of particles, e.g. by the provision of a filter upstream of the nozzle which will remove particles of a size which could block the nozzles. All nozzles should be designed to minimize the possibility of blockage. 5.6.3 All pipes containing nozzles should be demountable, complete with bayonet, screw or other fittings. With all inside and outside surfaces being cleanable. 5.6.4 All nozzles, which are intended to be removable by the user, should be designed to be suitable for a minimum of 250 matings. Compliance should be established by review of the design verification data. Removable nozzles should have a means of identifying that they have been installed in their correct position. All fittings shall be designed to prevent misalignment when nozzles and associated systems are assembled or reassembled. 5.6.5 It should be possible to check that the spray nozzles are not blocked and that the spray arms are free to move to the extent specified by the EWD manufacturer. The method to be used should be specified in the instructions for use [see 8.3 b)]. 5.6.6 and 5.6.7 Fixed irrigation nozzles should be designed and constructed to provide a similar flow of water from all nozzles of the same type intended for the same application. It should be possible to check that fixed nozzles intended to provide fluids for the irrigation of the internal channels of hollow instruments provide the specified flow of water and/or aqueous solutions. The method to be used should be specified in the instructions for use [see 8.3 b)].
14 Operating cycle 14.2-Reproducibility -Optional	5.9 Process temperature control limits. 5.9.1(c) When tested in accordance with 6.8.2, the process should meet the following requirements: c) the temperature profile

PQ test requirements Requirement subclause no	Outline requirements
	obtained for the temperature controlled stages of the operating cycle should be consistent within ± 2,5 °C for the last three of four test cycles (see 6.8.2.3). Chamber walls 5.9.2 (d) When tested in accordance with 6.8.3 the temperatures attained on the chamber walls throughout the process should meet the following requirements: d) the temperature profile obtained for the temperature controlled stages of the operating cycle are consistent within ± 2,5 °C for the last three of four test cycles (see 6.8.3.2).
[a] Chemical disinfection Applied only to EWDs employing chemical disinfection with controlled temperatures	

A5 9 Table A5.5 outlines the PQ requirements from BS EN 15883 Part 4: 2018 Normative Annex C Table C.2 – PQ requirements in addition to that in BS EN 15883 Part 1. Others tests in the table C.2 of the standard are not included as these are stated as “not recommended” for PQ in the standard. Consult the standard for full details.

Table A5.5 – Outline of BS EN 15883 Part 4: 2018 Normative Annex C Table C.2 – PQ requirements in addition to that in BS EN 15883 Part 1.

BS EN 15883-4: 2018 PQ Requirement Subclause no.	Outline of requirements
Leak test 4.2.4	4.2.4 In EWD provided with an automatic leak test: a) the EWD should be designed so that the connectors provided for irrigation of the endoscope channel(s) cannot be connected to the endoscope leak test connection port on the endoscope; b) the connection system between the endoscope and the EWD should be designed so that the leak test connector on the EWD cannot be connected to the endoscope channel(s) to be irrigated; c) the means used to monitor the pressure inside the device (e.g. pressure transducer) should be independent from the means used to control the pressure applied to the endoscope to perform the leak test (e.g. pressure regulating valve); d) the system used to pressurize the device during each leak test should be provided with a means of preventing over-pressurization of the device in the event of failure of the pressure control system; e) the extent and duration of pressurization and the pressure drop or air flow which will be used to indicate a failure should be either in accordance with the device manufacturer’s instructions for the devices that the EWD is intended to process, or independently verified.
Non-connection test 4.2.5	For EWD with an automatic leak test, means should be provided to automatically warn the user with an audible and/or visible alarm after the initiation of the operating cycle if the leak test connectors are not connected to the endoscopes.
Cleaning efficacy 4.3.5	Determination of cleaning efficacy. Cleaning efficacy should be determined in accordance with 6.11.
Complete process 4.1.3 (test clause 6.12.6.3)	4.1.3 After the complete process in the EWD the endoscope should be safe for its intended use. The combination of the cleaning, disinfection and rinsing process should be designed to achieve this condition, recognizing the high level of microbial and other contamination that might exist. It should be necessary to take into account other factors such as the design of

BS EN 15883-4: 2018 PQ Requirement Subclause no.	Outline of requirements
	connectors. This capability should be demonstrated during type testing for endoscopes that the EWD is designed to process [see also 8 a), 8 b) and 8 c)]. Where the disinfection of the water supplied to the EWD is performed by adding a low dosage of a disinfectant to the water, compliance with this document should be demonstrated with and without the water disinfectant. Any variation in water disinfectant concentration due to local environmental conditions that might change the result of the test should be taken into account. Demonstration of the capability of the complete cycle efficacy should be provided during additional type testing by employing a modification of the methods described in Annex B with added test soil and/or standard BS EN 15883 5:2021, , using the organism(s) previously established during in vitro tests as most resistant to the disinfectant under in-use conditions and on endoscopes that are representative for each relevant endoscope type test group [see 8 a) and Annex H]. According to the nature of the most resistant microorganism selected the minimum log10 reduction obtained after a complete standard cycle for that microorganism(s) should be: — 9 log10 for vegetative bacteria; — 6 log10 for fungal spores; — 6 log10 for mycobacteria; or — 4 log10 for bacterial endospores. In order to limit the work load the type tests can be performed on representative endoscopes from endoscope type test groups (see Annex H to establish relevant endoscope type test groups). The efficacy of the process (including cleaning and disinfection) depends on a number of factors which include: a) the nature (characteristics) of the device being processed; b) the extent and nature of the soiling to be removed; c) the temperature of the process; d) the mechanical energy (type, output); e) purging to remove rinse water; f) the detergent system; g) the nature, volume, concentration and temperature of the cleaning and disinfectant solutions and their ability to wet the surfaces to be cleaned and disinfected; h) the duration of the various process stages; i) the removal of suspended soil. (test clause 6.12.6.3) For performance qualification and routine tests the process should be verified by sampling endoscopes that have been used on patients after processing. The post-disinfection microbial contamination should be estimated by analysis of samples taken immediately after the post-disinfection rinsing stage but without the drying stage. Sufficient samples for each test should be used to provide assurance of disinfection of the processed endoscopes. When required by national regulation, a surrogate device should be used to simulate the load items. Inoculated carriers shall be incorporated as part of the surrogate device to monitor the efficacy of the disinfection stage (see 6.12.6.1). Microorganisms incorporated into test soils can be used instead of, or as well as, the use of inoculated carriers (see BS EN 15883 5: 2021). Endoscopes can be selected by the user according to Annex I. Local and national requirements can specify the interpretation of microbiological test results and when the samples for routine

BS EN 15883-4: 2018 PQ Requirement Subclause no.	Outline of requirements
	testing are taken after a defined time period, e.g. at least 12 h after the operating cycle. When required by national regulation, a surrogate device should be used to simulate the load items. Microorganisms incorporated into test soils can be used instead of, or as well as, the use of inoculated carriers (see BS EN 15883-5: 2021). Endoscopes can be selected by the user according to Annex I. Local and national requirements can specify the interpretation of microbiological test results and when the samples for routine testing are taken after a defined time period, e.g. at least 12 h after the operating cycle.
Channels non-obstruction test 5.2.2.1	The maximum extent of flow reduction permissible (e.g. change in flow volumes, pressures, rates) that will not impair the efficacy of the process for each channel or channel systems should be specified [see 8 e)]. To enable determination of the flow that will occur through the unobstructed channels of the medical device, relevant data should be obtained, e.g. dimensions of connectors, internal dimensions of channels, and maximum pressures to which channels may be subjected. When one or more channels of the device are obstructed to an extent that would impair the efficacy of the process, the automatic controller should cause a fault to be indicated. Compliance with this requirement should be demonstrated by testing in accordance with 6.6. With some designs of endoscope a blockage in one channel could cause the flow to be diverted to another channel or endoscope port. Under these circumstances detection of an obstruction by the automatic controller might not be reliable. The user might need to refer to the device manufacturer's instructions for the method to be used to verify that all channels are free from obstructions.
Channels non-connection test 5.2.2.2	When one or more channels of the device are not connected to the EWD, the automatic controller should cause a fault to be indicated. Compliance with this requirement should be demonstrated by testing in accordance with 6.7.
Temperature throughout process 4.4.3 (also 5.4.2 and 5.4.3)	The temperature of the disinfecting agent throughout the disinfection stage should be monitored to ensure that it remains within the specified limits of the disinfectant and be compatible with the temperature limits for the device(s) to be processed. This should be achieved either by controlling the temperature of the disinfectant solution or, where appropriate, by operating the EWD at ambient temperature with means to prevent operation of the EWD when the disinfectant temperature is outside the specified temperature range.
Temperature throughout process 4.4.3 and Temperature control of the washing stage, 5.4.2, and disinfection stage 5.4.3	Throughout the washing and/or disinfection stage, when tested as described in 6.9.2, a fault should be indicated when the temperature on the surface of the chamber and of the liquid process medium are below the minimum temperature specified for the device. This should be achieved either by controlling the temperature of the disinfectant solution or, where appropriate, by operating the EWD at ambient temperature with means to prevent operation of the EWD when the disinfectant temperature is outside the specified temperature range. 5.4.2 Temperature control of the washing stage 5.4.3 Temperature control of the disinfection stage
Minimum process temperature test 5.4.4	Throughout the washing and/or disinfection stage, when tested as described in 6.9.2, a fault should be indicated when the temperature on the surface of the chamber and of the liquid

BS EN 15883-4: 2018 PQ Requirement Subclause no.	Outline of requirements
	process medium are below the minimum temperature specified for the device.
Water quality 4.5.2 (also 4.9.2.3 a and b)	The final rinse water should meet the requirements for microbiological quality as given in 4.9.2.3. Means should be provided to disinfect incoming water used for the final rinse. The disinfection process shall ensure that: a) there are less than 10 CFU/100 ml sample of final rinse water when tested in accordance with E.3.2; and b) the water is free from *Pseudomonas aeruginosa* in 100 ml, and (atypical) *Mycobacterium* sp. in 100 ml when tested in accordance with E.3.3 (see 6.3). NOTE: The following methods can be suitable for control of the microbial contamination of rinse water. The rinse water will be: — maintained in a dedicated reservoir at a temperature not less than 65 °C for the time demonstrated to achieve disinfection of the incoming supply; or disinfected immediately prior to use; or filtered to remove suspended particles of a size greater than 0,2 µm; or Sterile, in a closed container, with a connection to the EWD designed and constructed to provide aseptic transfer.

A5 10 Table C1.6 gives the outline requirements from BS EN 15883 Part 5: 2021 for the PQ as applicable to cleaning performance and process residuals. Consult the standard for full details.

Table A5.6– Outline of BS EN 15883 Part 5: 2021 PQ requirements for cleaning performance and process residuals

Test requirement subclause	Outline of requirements
5 Testing for conformity 5.2 Washer-disinfector requirements	5.2.1. The cleaning tests should be performed on the defined EWD loads. The worst-case load shall include representative product and specified load carrier(s). Each type of load carrier with representative product shall be tested separately unless a justification is provided to do otherwise. 5.2.2 The EWD cleaning stage(s) parameters and cleaning process chemicals should be specified. Type testing should be conducted under the specified worst-case parameters (e.g. temperature, time, process chemical concentration, services, pressure, and flow rate). Services can include electricity, water, air, and steam supplies. 5.2.3 Cleaning validation should be tested without any disinfection or drying stage (see BS EN 15883-1:2014, 6.10).
Cleaning performance qualification test 5.4	Where practicable, cleaning efficacy should conform with the alert levels in 4.4.3 for the test load. Visual examination may be sufficient for chamber walls and load carrier (see 4.4.2). Photographic records can assist by capturing visual examination outcomes.
Process residuals 5.5 General	5.5.1 The acceptable amount of process residuals should be specified as part of risk analysis and cytotoxicity testing as part of type testing. Performance qualification requires periodic sampling of the product for process residuals (see BS EN 15883-1: 2014, Table A.1). In the case of a change to the process or the process chemicals, type testing and performance qualification should be repeated. Compliance with this requirement should be verified for all process chemicals intended to be used inside the EWD. 5.5.2 Risk analysis. A risk analysis should be documented,

Test requirement subclause	Outline of requirements
	demonstrating that the risk of process residuals has been reduced to below harmful levels. The risk analysis shall consider the requirements of BS EN 10993-1. 5.5.3 Cytotoxicity A sampling method for extraction of process residuals from the load and analytical method for detection of process residuals in the samples should be specified. 5.5. These methods should be capable of determining the presence of process chemical(s) at concentrations below that specified as potentially harmful, i.e. as the maximum acceptable (see BS EN 15883-1:2014, 6.10.4). Sampling should be done at the end of the complete EWD process. 5.5.5 Acceptance criteria Based on the risk analysis or cytotoxicity test results, an action and alert level should be specified.

A5 11 Table A5.7 summarises the list of routine tests as specified in standard BS EN 15883 Part 1: 2014, Part 4: 2018 and Part 5: 2021.

Table A5.7 – Subject list of routine testing requirements including frequency, as BS EN 15883 series Part 1: 2014, Part 4: 2018 and Part 5: 2021

BS EN 15883 series	Title of routine tests	Frequency of routine testing
Part 4:2018	Leak test failure alarm	Quarterly
	Leak test non-connection test	Quarterly
	Cleaning efficacy	Quarterly
	Complete process	Quarterly
	Drying	No frequency given
	Disinfection of liquid transport system (single-dose container)	No frequency given
	Self-disinfection test	No frequency given
	Channels non-obstruction test	Quarterly
	Channels non- connection test	Quarterly
	Temperature throughout process	Quarterly
	Minimum process temperature test	Quarterly
	Water quality	Weekly until established consistency then Quarterly 6.6.3
	Chemical dosing test	Optional test
Part 1: 2014	Cleaning efficacy 1.3 Load	Daily/Quarterly and optional
	Thermometric Thermal disinfection - Chamber walls, Load carrier and Final rinse water tank	all optional
	Thermometric Thermal disinfection — Load	Quarterly
	Temperature control — Rate of rise, Flushing stage and Washing stage	All quarterly
	Chemical disinfection[a] — Chamber walls and load Carrier	Optiona
	Chemical disinfection[a] — Load	Quarterly]
	Load dryness	Optional
	Chemical dosing- Accuracy and repeatability/ Low level indicator	All quarterly

BS EN 15883 series	Title of routine tests	Frequency of routine testing
	Water quality/Rinse water	Both optional
	Air quality	Optional
	Instrumentation- Calibration	Quarterly
	Doors and interlocks - Cycle start and Loading/unloading	All quarterly
	Doors and interlocks - On fault condition and door interlock-	All optional
	Operating cycle- Spray system, Reproducibility and Fault indication	All optional
Part 5: 2021	4.4 Cleaning efficacy test criteria criteria given in 4.4.3.	
	4.4.1 General - A validated qualitative method can be used for routine testing when the detection level of this method is below the alert level assay	
	Annex C – C.1 General - The initial examination of cleaning efficacy during type testing (as well as performance qualification and routine testing) is carried out by visual inspection.	

A5 12 Table A5.8 gives a list of Routine testing requirements showing the relevant subclause, test sub cause and frequency from BS EN 15883-1+A1:2009: 2014 – Table A.1

Table A5.8: Routine testing requirements as BS EN 15883 Part 1:2009+A1: 2014 Table A.1

Routine testing requirements	Requirement subclause	Test subclause and frequency
Cleaning efficacy 1.3 Load	4.2.1.1	6.10.2 – Quarterly 6.10.3 (visual) – Daily 6.10.3 (Annex C) - Optional
2 Thermometric 2.1 Thermal disinfection — Chamber walls	4.3.1.2, 4.3.1.3, 4.3.3.2 and 5.9.2	Optional
2 Thermometric 2.1 Thermal disinfection — Load carrier	4.3.1.1, 4.3.1.3	Optional
2 Thermometric 2.1 Thermal disinfection — Final rinse water tank	5.3.2.5	Optional
2 Thermometric 2.1 Thermal disinfection — Load	4.3.1.1, 4.3.1.3, 4.3.3.1, 5.9.1	Quarterly
2.2 Temperature control — Rate of rise	4.1.4	Quarterly
2.2 Temperature control — Flushing stage	4.2.2	Quarterly

Routine testing requirements	Requirement subclause	Test subclause and frequency
2.2 Temperature control — Washing stage	4.2.3	Quarterly
2.4 Chemical disinfection[a] — Chamber walls and load Carrier	4.3.2	Optional
2.4 Chemical disinfection[a] — Load	5.3.2.3 4.3.2, 4.3.3	Quarterly Quarterly [a] Applied only to EWDs employing chemical disinfection with controlled temperatures.
3 Load dryness	4.5.1, 4.5.2	Optional
5 Doors and interlocks 5.1 Cycle start	5.4.1.8	Quarterly
5 Doors and interlocks 5.2 Loading/unloading	5.4.3.1 5.4.3.3 5.4.1.4	Quarterly Quarterly Quarterly
5 Doors and interlocks 5.3 On fault condition — Door interlock	 5.4.1.5 5.22 5.4.3.2	 Optional Optional Optional
7 Chemical dosing 7.1 Accuracy and repeatability	5.7.5	Quarterly
7 Chemical dosing 7.2 Low level indicator	 5.7.6	 Quarterly
5 Doors and interlocks 5.2 Loading/unloading	5.4.3.1 5.4.3.3 5.4.1.4	Quarterly Quarterly Quarterly
8 Water quality	4.4.1	Optional
8.1 Rinse water	4.4.2, 4.4.3	Optional
9 Air quality	4.5.3, 4.5.4	Optional
11 Instrumentation 11.2 Calibration	5.11 5.14 5.15	Quarterly verification calibration Quarterly verification calibration
14 Operating cycle 14.1 Spray system	5.6	
14 Operating cycle 14.2 Reproducibility	5.9.1 c) 5.9.2 d)	Optional Optional
14 Operating cycle 14.3 Fault indication	5.22.1	Optional

A5 13 Table A5.9 outlines the additional routine testing requirements for EWDs as BS EN 15883 Part 4: 2018 Table C.2. Consult the standard for full details.

Table A5.9 – outline of routine testing requirements as BS EN 15883 Part 4: 2018 in addition to BS EN 15883 Part 1:2009+Amd 1:2014

Brief description BS EN 15883-4:2018 Table C.2 Routine test clause	Outline of requirements -Table C.2
1 Leak tests failure alarm 4.2.3	Quarterly test subclause 6.5.3.3-
	4.2.3 For EWD having an automatic leak test, the automatic controller should prevent the continuation of the operating cycle and operate an audible and visible alarm indicating a leak test failure if a leak is detected in an endoscope. Variations in temperature that might adversely affect the sensitivity of the leak test and the temperature range permitted in the EWD during the automatic leak test, if fitted, should be stated [see 8 g)].
	A leak test failure indicates that the device is likely to be damaged by further processing. However, a satisfactory leak test does not provide absolute assurance that the device will not be damaged by further processing.
2. Leak test non-connection test 4.2.4	Quarterly 6.5.3.4- In an EWD provided with an automatic leak test. The EWD should be designed so that: a) the connectors provided for irrigation of the endoscope channel(s) cannot be connected to the endoscope leak test connection port on the endoscope;. b) the connection system between the endoscope and the EWD should be designed so that: the leak test connector on the EWD cannot be connected to the endoscope channel(s) to be irrigated; c) the means used to monitor the pressure inside the device (e.g. pressure transducer) should be independent from the means used to control the pressure applied to the endoscope to perform the leak test (e.g. pressure regulating valve); d) the system used to pressurize the device during each leak test should be provided with a means of preventing over-pressurization of the device in the event of failure of the pressure control system; e) the extent and duration of pressurization and the pressure drop or air flow which will be used to indicate a failure should be: either in accordance with the device manufacturer's instructions for the devices that the EWD is intended to process, or independently verified. 4.2.5 A means should be provided to automatically warn the user with an audible and/or visible alarm after the initiation of the operating cycle if: the leak test connectors are not connected to the endoscopes.
4. Cleaning efficacy Tests of cleaning efficacy 4.3.5 determined in accordance with 6.11.	Quarterly Test subclause 6.11.1 6.11.1 General Cleaning efficacy testing should follow the requirements of BS EN 15883-1:2006+Amd 1:2014, 6.10 with the exception of 6.10.2 (replaced by 6.11 in 15883-4: 2018 but including 6.10.3. 6.11.2 Principal To claim that particular device(s) can be processed in the EWD, data should be required to establish that the particular device(s) can be effectively cleaned in the EWD. The test procedure and test loads described below are designed to demonstrate compliance with the requirements of cleaning efficacy in accordance with BS EN 15883 1:2006+Amd 1:2014, 6.10 but take into consideration the complex nature of the endoscope. The measurement of cleaning efficacy shall be made on the cleaning stage alone. This shall include any stages that take place in the EWD prior to admission of the disinfectant. Cleaning efficacy tests should be carried out on the surrogate devices that are representative for each relevant endoscope type test group (see 6.6.2) and on endoscopes of each relevant endoscope type test group as defined according to Annex H.

Brief description BS EN 15883-4:2018 Table C.2 Routine test clause	Outline of requirements -Table C.2
	These tests provide a basic assessment of the cleaning efficacy of the process. It might be inappropriate to include bacteria in some test soils while performing tests on installed, operational EWD. Where the EWD manufacturer's instructions for use with a particular endoscope requires a pre-treatment, e.g. manual cleaning of a particular component or channel, that pre-treatment can be included as part of the test procedure. 6.11.3 Material 6.11.3.1 Load carrier The load carrier chosen for the test load should be of the type recommended for the device to be processed. 6.11.3.2 Test loads The type test should be done: a) on at least one surrogate device specified according to Annex H and including at least block B2 [see Figure 2 b)]; the test pieces should be the biofilm test pieces as specified in BS EN 15883 5:2021, Annex F incorporated into the surrogate device; the test pieces shall be placed at the same locations as the blockages indicated in Figure 2; b) on surrogate devices of each relevant endoscope type test group as defined according to Annex H using test pieces contaminated with clinically relevant thermolabile (flexible) endoscope test soil(s) (see 6.11.3.3); c) in addition, test loads composed of endoscopes from the relevant endoscope type test groups, according to Annex H, contaminated (internal and external surfaces) with the appropriate test soil (see 6.11.3.3), shall be used. Under no circumstances shall the test pieces be installed in such a way that they unduly influence the correct flow of process fluids inside the channels. To minimize the possibility of damaging an endoscope it might be prudent to establish the efficacy of the process using a surrogate device before using an endoscope to verify the cleaning process. For operational qualification testing, a surrogate device defined according to Annex H should be used. The appropriate surrogate device shall be specified. Alternatively, endoscopes can be selected according to Annex I. 6.11.3.3 Test soils Devices to constitute a test load shall be contaminated with one or more test soils that simulate the use of thermolabile (flexible) endoscopes. BS EN 15883 -.5: 2021 specifies examples of test soils. The attention of manufacturers is drawn to the user's choice of test soil(s) and method(s) for operational testing. This can indicate a need to carry out similar testing before the EWD is supplied. The test soil(s) used for the load, chamber wall and load carriers may be the same or different. Where different test soils are used the rationale for the choice of each test soil should be documented. The choice of test soil(s), its method of application, and conditioning (e.g. drying) should simulate the worst-case clinical conditions of actual use of the devices. The method of test soil recovery (sampling/extraction from devices) and detection of analytes should be validated. 6.11.4 Procedure Place the test load contaminated with the test soil in the chamber. Connect the endoscope ports to the channel irrigation devices in accordance with the EWD manufacturer's instructions and process. Tests using contaminated

Brief description BS EN 15883-4:2018 Table C.2 Routine test clause	Outline of requirements -Table C.2
	devices should only be carried out after satisfactory completion of the tests using the surrogate device. NOTE The use of endoscopes that are in clinical use for any testing that includes the application of test soils and/or test contamination can represent a risk in further use of the endoscope. Start a normal operating cycle for the load type under test. Interrupt the cycle just prior to the start of the disinfection stage. Then examine the test load for the presence of residual soil.
7. Complete process 4.1.3 Operational and performance qualification	Quarterly - Test subclause 6.12.6.3 4.1.3 After the complete process in the EWD the endoscope should be safe for its intended use. The combination of the cleaning, disinfection and rinsing process shall be designed to achieve this condition, recognizing the high level of microbial and other contamination that might exist. It should be necessary to take into account other factors such as the design of connectors. This capability should be demonstrated during type testing for endoscopes that the EWD is designed to process [see also 8 a), 8 b) and 8 c)]. Where the disinfection of the water supplied to the EWD is performed by adding a low dosage of a disinfectant to the water, compliance with this document should be demonstrated with and without the water disinfectant. Any variation in water disinfectant concentration due to local environmental conditions that might change the result of the test should be taken into account. Demonstration of the capability of the complete cycle efficacy shall be provided during additional type testing by employing a modification of the methods described in Annex B with added test soil and/or BS EN 15883 5:2021, Annex I, using the organism(s) previously established during in vitro tests as most resistant to the disinfectant under in-use conditions and on endoscopes that are representative for each relevant endoscope type test group [see 8 a) and Annex H]. According to the nature of the most resistant microorganism selected the minimum log10 reduction obtained after a complete standard cycle for that microorganism(s) should be: — 9 log10 for vegetative bacteria; — 6 log10 for fungal spores; — 6 log10 for mycobacteria; or — 4 log10 for bacterial endospores. In order to limit the work load the type tests can be performed on representative endoscopes from endoscope type test groups (see Annex H to establish relevant endoscope type test groups). The efficacy of the process (including cleaning and disinfection) depends on a number of factors which include: a) the nature (characteristics) of the device being processed; b) the extent and nature of the soiling to be removed; c) the temperature of the process; d) the mechanical energy (type, output); e) purging to remove rinse water; f) the detergent system; g) the nature, volume, concentration and temperature of the cleaning and disinfectant solutions and their ability to wet the surfaces to be cleaned and disinfected; h) the duration of the various process stages; i) the removal of suspended soil.
8. Drying 4.7	Test subclause 6.8.

Brief description BS EN 15883-4:2018 Table C.2 Routine test clause	Outline of requirements -Table C.2
	4.7.1 Drying Where the EWD has no drying stage or has a user selectable drying stage, the instructions for use should indicate that the device and the channels of the device should be dried prior to storage in accordance with 8 k), 2). Automatic cycles in which the device is not dried are intended for use on devices which will be used without storage. Purging with 0,2 µm filtered alcohol (e.g. 70 % isopropanol) can be used to aid drying, if compatible with the medical device. 4.7.2 The quality of air used during the drying stage shall be at least that defined in 4.6.2. 4.7.3 When tested in accordance with 6.8 there shall be no visible droplets of moisture.
10 Disinfection of liquid transport system 4.8.5 Operational qualification and routine test	Test subclause 6.12.5.2 4.8.5 The self-disinfection cycle shall ensure that an EWD that has become contaminated through failure of the water treatment equipment can be effectively disinfected. Compliance should be verified by testing in accordance with 6.12.5. After carrying out a self-disinfection cycle, the performance should be deemed to be satisfactory if the final microbial count is 10 CFU/100 ml or fewer, and free from Pseudomonas aeruginosa in 100 ml, and if required for operational and routine testing, the sample is free from (atypical) Mycobacterium sp. in 100 ml (see 6.12.5). NOTE Methods for microbiological evaluation of disinfection of the liquid transport system are specified in Annex D.
12. Self-disinfection test - Operational qualification and routine test 4.7	Test subclause 6.12.3.2 4.8.7A For chemical disinfection systems microbiological test shall be required. The test should be designed to ensure that the self-disinfection cycle will disinfect contaminated tubing by evaluating the effect of the cycle against a biofilm containing Pseudomonas aeruginosa (see BS EN 15883-5:2021). The capability of the EWD to provide self-disinfection should be deemed to have been established if, when tested in accordance with 6.12.3, the required microbial reduction factor has been achieved.
15. Channels non-obstruction test 5.2.2.	Quarterly 5.2.2 Test subclause 6.6 5.2.2.1 Verification of device channel irrigation by the automatic controller The maximum extent of flow reduction permissible (e.g. change in flow volumes, pressures, rates) that will not impair the efficacy of the process for each channel or channel systems should be specified [see 8e)]. To enable determination of the flow that will occur through the unobstructed channels of the medical device, relevant data should be obtained, e.g. dimensions of connectors, internal dimensions of channels, and maximum pressures to which channels may be subjected. Compliance with this requirement should be demonstrated by testing in accordance with 6.6. When one or more channels of the device are obstructed to an extent that would impair the efficacy of the process, the automatic controller should cause a fault to be indicated. With some designs of endoscope a blockage in one channel could cause the flow to be diverted to another channel or endoscope port. Under these circumstances detection of an obstruction by the automatic controller might not be reliable. The user might need to refer to the device manufacturer's instructions for the method to be used to verify that all channels are free from obstructions.
16. Channels non-connection test	Quarterly Test subclause 6.7 5.2.2.2 When one or more channels of the device are not connected to the EWD, the automatic controller should cause a fault to be indicated. Compliance with this requirement should be demonstrated by testing in accordance with 6.7.

Brief description BS EN 15883-4:2018 Table C.2 Routine test clause	Outline of requirements -Table C.2
17. Temperature Throughout process Disinfection stage	Quarterly Test subclause 6.9 4.4.3 Temperature The temperature of the disinfecting agent throughout the disinfection stage should be monitored to ensure that it remains within the specified limits of the disinfectant and be compatible with the temperature limits for the device(s) to be processed. This shall be achieved either by controlling the temperature of the disinfectant solution or, where appropriate, by operating the EWD at ambient temperature with means to prevent operation of the EWD when the disinfectant temperature is outside the specified temperature range. 5.4.2 Temperature control of the washing stage Throughout the washing stage, when tested as described in 6.9.1, the temperature recorded on the surface of the chamber and on all surfaces of the device being processed should be within the specified washing temperature band. If the temperature band is wider than 5 °C, the efficacy of the washing stage should be demonstrated during type testing at the minimum and maximum temperature of the specified washing stage temperature band. The temperature during washing stage should be within the limits specified for the detergent(s) and compatible endoscopes. 5.4.3 Temperature control of the disinfection stage Throughout the disinfection stage, when tested as described in 6.9.1, the temperature recorded on the surface of the chamber and on all surfaces of the device being processed should be within the specified disinfection temperature band. If the temperature band is wider than 5 °C, the efficacy of the disinfection stage should be demonstrated during type testing at the minimum and maximum temperature of the specified disinfection stage temperature band. The temperature during the disinfection stage should be within the limits specified for the disinfectant(s) and compatible endoscopes.
18. Minimum process temperature test 5.4.4	Quarterly - Test subclause 6.9.2 5.4.4. EWD with a minimum operating temperature for the washing and/or disinfection stage Throughout the washing and/or disinfection stage, when tested as described in 6.9.2, a fault should be indicated when the temperature on the surface of the chamber and of the liquid process medium are below the minimum temperature specified for the device.
19. Water quality Final rinsing Principle 4.5	Weekly - Test subclause 6.3 6.3 Water used for final rinsing 6.3.1 Principal The water used for final (post-disinfection) rinsing should conform to 4.9.2.3 and E.3.2. In addition, any growth shall be characterized. 6.3.2 Material/procedure The water should be tested for total viable count, and the presence of Pseudomonas aeruginosa and (atypical) Mycobacterium sp. at the point of discharge into the EWD chamber in accordance with Annex E. Tests for other microorganisms that can be of clinical significance might also need to be performed. (e.g. gram-negative Enterobacteriaceae, Legionella sp). Where residual detergent or disinfectant is present it is necessary to use a neutralization method to eliminate any antimicrobial activity (see 5.5). 6.3.3 Results/acceptance criteria Results should be recorded as the number of colony forming units per 100 ml of water for the total viable count and the presence or absence of Pseudomonas aeruginosa in 100 ml, and (atypical) Mycobacterium spp. in 100 ml.

Brief description BS EN 15883-4:2018 Table C.2 Routine test clause	Outline of requirements -Table C.2
	It is recommended that the tests be carried out after installation and at regular intervals thereafter. Until it has been established that the water supply is consistently within specification, these tests may be performed approximately weekly, then at less frequent intervals thereafter. Quarterly 4.5 Final rinsing - 4.5.2 The final rinse water should meet the requirements for microbiological quality as given in 4.9.2.3. 4.9.2 Disinfection of water treatment equipment 4.9.2.3 Means should be provided to disinfect incoming water used for the final rinse. The disinfection process should ensure that: a) there are less than 10 CFU/100 ml sample of final rinse water when tested in accordance with E.3.2; and b) the water is free from Pseudomonas aeruginosa in 100 ml, and (atypical) Mycobacterium sp. in 100 ml when tested in accordance with E.3.3 (see 6.3). The following methods can be suitable for control of the microbial contamination of rinse water. The rinse water will be: — maintained in a dedicated reservoir at a temperature not less than 65 °C for the time demonstrated to achieve disinfection of the incoming supply; or — disinfected immediately prior to use; or — filtered to remove suspended particles of a size greater than 0,2 µm; or — sterile, in a closed container, with a connection to the EWD designed and constructed to provide aseptic transfer.
20. Chemical dosing test (Single-dose container) 5.7	Optional Test subclause 6.10 5.7 Dosing systems For those EWD in which the required dose of process chemical is contained in a single-dose container which is replaced before each cycle, means should be provided to ensure that the intended volume has been dispensed. When tested in accordance with 6.10 there should be an indication of a fault. For EWD in which process chemicals are supplied in multi-dose containers, BS EN 15883-1:2006+Amd 1:2014, 5.7 applies.

A5 14 The recommended minimum frequency for routine testing is as table A5.9 (which is as per clause 6.1.6 of BS EN 15883 Part 1:2009+A12014).

Appendix 6: Information requirements for Manufacturers instructions

A6.1 Information to be included in the manufacturer's instillation instructions as required in as BS EN 15883 Part 1:2009+A1: 2014 clause 8.2);

- the overall dimensions and overall mass of the EWD;
- the floor loading at each support when the EWD is filled with water;
- the clearance required for access and the masses of the principal heavy components;
- details of the services required including the maximum demand and the minimum and maximum values for the correct functioning of the EWD;
- for each validated process, and each water connection;
- the volume of water used per cycle and for each process stage, with tolerances;
- the maximum flow of water and condensed steam to the drain;
- the maximum temperature of effluent that may be discharged from the machine during normal operation and in a single fault condition;
- the maximum hardness, the range for pH and the conductivity of the water;
- maximum total heat in watts transmitted to the surrounding air when the EWD is operated in an ambient temperature of (23 ± 2) °C in still air;
- maximum heat in watts transmitted from the fascia when the EWD is operated in an ambient temperature of (23 ± 2) °C in the working area;
- mean and peak sound power levels generated by the EWD, expressed as an A-weighted sound power;
- type of doors and information on the necessary space required for the movement of the door(s);
- suitable process chemicals for each stage of the process where these are required;
- details of any supplied materials or necessary materials (detergents, chemical disinfectants, etc.) used for the correct functioning of the EWD and subject to control under national guidelines for the safe handling of chemicals or have environmental limits set;
- the chemical constituents (active ingredients) should be listed and any national guidance on exposure limits [e.g. the time weighted average (TWA) and 10 min short-term exposure levels (STEL)] provided;
- details of the independent body where complete programme and "software" are lodged, when this is required by the purchaser;
- maximum deviation from a plane horizontal surface that can be accommodated;
- declaration with which parts of ISO 15883 the EWD complies.

A6 2 Information to be received on delivery of the EWD:

- evidence that the specific make and model of endoscopes and TOE probes to be used can be processed satisfactorily (i.e. during type testing the EWD was validated using equivalent type test groups);
- any precautions necessary for particular devices (e.g. protection for non-immersible parts of TOE probes) or operational conditions;
- for each device listed verification of device channel irrigation by the automatic controller and/or the leak test system function;
- for each device, a description of the number and type of connections required for channel irrigation;
- the minimum and maximum flow and the maximum pressure of fluids which may be delivered to each channel during processing in the EWD;
- the maximum permissible restriction of flow through each channel before the automatic controller will indicate a fault;
- the maximum temperature of any process fluid in contact with the device during processing in the EWD;
- the maximum temperature variation permissible during the automatic leak test, if fitted;
- details of which parts of the EWD are subjected to disinfection during the self-disinfection cycle;
- guidance on the frequency at which any water treatment equipment that is part of the EWD should be disinfected;
- diagram of the circulation of fluids in the EWD used to irrigate channels in the device(s);
- locations of temperature sensors being representative of the lowest temperatures on the systems;
- the detergent(s) and disinfectant(s) type tested with the EWD;
- the method for monitoring the disinfectant concentration provided by the disinfectant manufacturer, e.g. an indicator test strip, specific for the disinfectant to show that the disinfectant is at or above the manufacturers recommended concentration (MRC);
- if the water treatment equipment is not part of the EWD, the quality requirements for water supplied to the EWD including the requirement to control the microbial contamination of the water supply;
- quality of the rinse water to be used for post-washing rinsing;
- details on how, the EWD endoscope ports are connected to the endoscope channels;
- if water treatment is part of the EWD and the parameters affecting the water treatment are not monitored by the automatic controller, then all parameters should be specified to be verified by the user.

A6 3 Operational instructions should include:

- range of application;

- type of load;
- load configuration;
- correct loading procedure;
- total chamber volume;
- design pressure, allowable working pressure and allowable temperature;
- description of the available operating (cleaning and disinfection) cycles;
- description of controls and indicating devices;
- description and setting of safety devices;
- instructions for malfunctions;
- instructions for purging and disinfecting the EWD;
- instructions for cleaning the panelling;
- instructions for checking that spray nozzles are not blocked;
- instructions for checking that spray arms are free to move;

A6 4 Maintenance Information should include:

- maintenance tests and the frequency that they should be carried out;
- electrical diagrams and circuits;
- hydraulic plans and circuits;
- a complete spare parts list;
- a list of the special tools necessary for maintaining and testing;
- type of guarantee offered;
- list of service stations;
- guidance on tracing and rectifying causes of malfunction;

A6 5 The EWD instructions for use should also include:

- the recommendation to use thermal disinfection for heat stable endoscopic accessories for medical devices;
- guidance on the need for drying devices which are to be stored before use;
- a means to verify the flow of process fluids through each channel;
- the method and frequency of self-disinfection;
- the method and frequency for disinfection of the connection between the EWD and the water supply for final rinse water;
- the method to be used for collecting samples of final rinse water from the chamber;
- any pre-treatment recommended to ensure effective and safe processing of the endoscope and its accessories.

Note A6.1: While 15883 Part 4:2021 state that ‘for EWDs not provided with an automatic leak test, the information that a manual leak test is required prior to processing’ the purchase of an EWD without an initial leak is not recommended as stated in Section 2.