NHS National Services Scotland

Management, equipment, and process of the decontamination of dental instruments in a Local Decontamination Unit (LDU) in NHSScotland

Scottish Health Technical Memorandum 01-05

SHTM 01-05 part B

part B - Decontamination equipment/ test methods

Version 1 - April 2024

Contents

1. Introduction

1.1. This part of the Scottish Health Technical Memorandum (SHTM) 01-05 details the decontamination equipment used to carry out the processing of dental instruments. Following the initial validation and commissioning requirements as per this document, the Chief Dental Officer (CDO) letter (2010) details the subsequent maintenance, and periodic testing requirements for decontamination equipment in line with current guidance.

1.2. The CDO letter through Scottish Government Health Department (SGHD)/ CDO (2010) 'Decontamination - Testing, Maintenance and Revalidation of Equipment' states "… *Scottish Ministers are of the opinion that following validation on installation, the testing, maintenance and revalidation of equipment in compliance with the manufacturer's instructions will allow practitioners to meet their obligations to provide proper, sufficient and safe decontamination standards as set out in the NHS (General Dental Services) (Scotland) Regulations 2010, Schedule 1 paragraph 42*".

1.3. Furthermore, "*Scottish Ministers continue to keep the decontamination matters in general under review and as further evidence emerges reserve the right to issue further guidance on this interpretation*."

1.4. Due to variances between manufacturer's recommended testing regimes, SHTM 01-05 part B presents best practice guidance for implementing and using decontamination equipment in a Local Decontamination Unit (LDU).

1.5. SHTM 01-05 part A - Management and SHTM 01-05 part C - Process should be used in conjunction with this guidance, with part C expanding on the decontamination processes such as cleaning, disinfection, and sterilizing.

Note 1: The type of instruments included in this document are dental instruments that are intended for reuse and require processing to take them from their state after clinical use to the state of being cleaned, disinfected, and sterilized, ready for their next use. Most dental instruments will be sterilized but not sterile when used. In all cases manufacturers' instructions should be followed.

Note 2: The term "medical devices" as stated in the glossary refers to dental instruments as listed throughout the SHTM 01-05 series of documents.

Scope of SHTM 01-05 part B

1.6. SHTM 01-05 part B 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, contractors, suppliers, and others in both the public and private sectors.

1.7. This guidance covers Ultrasonic cleaners (UCs), Automated Washer Disinfectors (WDs), Sterilizers (Type N, B and S), lubricators and their accessories used for processing medical devices in an LDU.

Note 3: Scottish Health Planning Note (SHPN) 13 Part 2 ‘Decontamination facilities: Local Decontamination Units', 2008 applies to new builds or upgrades of LDUs with single and two room layouts. Room layout diagrams for single and two room configurations are included with room data sheets for areas such as for the two-room configuration Washroom and the Sterilizer room between which the WD is located.

1.8. Additional room data sheets provide guidance on room design, finishes, mechanical and electrical and equipment/ furniture/ fittings. Planning involving the LDU should consider the need to not compromise the requirements for air changes per hour (AC/hr).

2. Maintenance and periodic testing

Maintenance and servicing

2.1. A programme of Planned Preventative Maintenance (PPM) should be in place for all decontamination equipment to ensure the required standards of performance and safety are met and maintained. Instructions for use (IFU) should be followed in accordance with the Chief Dental Officer (CDO) letter Scottish Government Health Department (SGHD)/ CDO (2010).

> Note 4: For PPM and following any modification to the washer disinfector (WD), ultrasonic cleaner (UC) or sterilizer including software upgrades, operating cycle parameters or process chemicals in use, technical expertise should be sought. Relevant roles and responsibilities such as Authorising Engineer (Decontamination) (AE(D)) is defined in Scottish Health Technical Memorandum (SHTM) 01-05 part A.

2.2. The PPM programme recommended by the manufacturer should be supplied and used.

2.3. If no PPM programme is available from the manufacturer, a maintenance programme should be drawn up in consultation with the AE(D), the Approved Person (Decontamination) (AP(D)) and Competent Person (Decontamination) (CP(D)).

2.4. During the warranty/ guarantee period, the supplier should carry out a full PPM programme, else the warranty may be forfeit. Afterwards the supplier may carry out certain inspection and maintenance procedures, however, these may not constitute a full PPM programme. The User should therefore ensure that the complete PPM programme is carried out after this period.

2.5. Maintenance should be carried out under the Local Decontamination Unit (LDU) quality management system (QMS) and any Original Equipment Manufacturer (OEM) parts/ spares fitted to decontamination equipment (for example WDs and sterilizers) should be sourced from manufacturer authorised agents.

2.6. All parts of any LDU decontamination equipment such as WD, UC, or sterilizers vital to correct functioning or safety should be subject to a PPM programme designed according to the manufacturer's instructions for use.

2.7. Occasionally, modifications to the decontamination equipment may be recommended by the manufacturer for reasons of efficacy and safety. The User should arrange for such modifications to be carried out within a reasonable period, normally coinciding with a scheduled maintenance/ validation session, and controlled through the LDU's quality management system.

2.8. The frequency with which each task is carried out will depend, in part, on the usage level for the equipment and on the quality of the services supplied, for example water/ steam. It may

be necessary to increase the frequency of the maintenance programme for machines that are heavily used or supplied with hard water.

2.9. It is important that maintenance is planned so that the equipment is out of service for the minimum time possible. Maintenance should, where practicable, be scheduled to immediately precede the periodic tests as specified in this section.

2.10. The maintenance programme may be modified in agreement with the manufacturer and/ or AE(D) to take account of equipment use, equipment history and local conditions after a suitable period of operational experience. Any alternative protocols of maintenance that deviate from the manufacturer's recommendations should be equal to, or exceed, the manufacturer's specification and must be justified. Supportive documentation of any additional actions taken, and rationale should be recorded.

2.11. All maintenance, servicing and testing of equipment should be carried out by suitably qualified competent persons. All Staff and CP(D) undertaking these duties should be knowledgeable in the correct use and wearing of personal protective equipment (PPE) as outlined in the National Infection Prevention and Control Manual (NIPCM).

Review of PPM programme

2.12. The PPM programme should be reviewed at least annually to ensure the equipment is being fully maintained but with no unnecessary maintenance activity. The review should aim to identify:

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

2.13. In a healthcare setting, proposed changes to the PPM programme should be made in consultation with the AE(D) and manufacturer.

Returning decontamination equipment to service

2.14. Whenever any work has been carried out on decontamination equipment, such as major repairs, overhauls, and so on, which may affect its performance, the User and AP(D) with assistance from the AE(D), should draw up a schedule of checks and tests. These should be carried out before the equipment is returned to service. One such method for doing this is a "Permit to Work "system which may also be used whenever periodic testing is being carried out.

2.15. The schedule of checks or tests completed may include some or all the re-commissioning (annual) tests.

2.16. Decontamination equipment may have inherent dangers when handed over to the CP(D) for repair, fault-finding, or testing. These dangers will include burns and scalds, pressure, and electrical energy with possible microbiological and or chemical contamination. These dangers will require the CP(D) to take appropriate precautions, for example, the use of PPE.

2.17. The use of the permit to work or an equivalent documented system will enable the User to become more aware of when equipment is inoperable, that personnel working on them have the documented authority to do so, and to enable a safe place of work for the department and operators for the period(s) when out of use.

2.18. The CP(D) will sign the permit to work or equivalent system to declare the work is completed, at which point the User will then sign the equipment back into use declaring it fit for purpose.

2.19. In line with the dental department quality management system, a set of procedures should be in place for all decontamination equipment containing full instructions for the required maintenance tasks.

Warranty period

2.20. After the purchase of any new decontamination equipment such as WD, the manufacturer may carry out certain inspection and maintenance procedures under the terms of the warranty. The User should comply with any reasonable instructions from the manufacturer during the warranty period. Failure to do so could allow the manufacturer or supplier to pass some, if not all, of its liability on to the organisation.

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

Validation and periodic testing

2.22. Validation is required for new equipment at installation with additional periodic monitoring thereafter (daily, weekly, quarterly, and annually - see Table 4.4) to ensure all decontamination equipment is fit for purpose It will also be necessary to re-validate equipment after any major repairs have been carried out.

Note 5: Definition of validation - validation is a documented procedure used to show that the decontamination process will repeatedly and consistently take place to a satisfactory standard when defined operating conditions are used. Validation comprises a series of specified checks and tests that are performed by a CP(D) as specified in SHTM 01-05 part A. These checks and tests are carried out after installation of new equipment as part of commissioning. Thereafter, validation checks and tests are carried out at least annually, which is referred to as revalidation.

2.23. Installation and validation tests must follow current guidance included within SHTM 01-05 part B, which is aligned with the standards and guidance for benchtop sterilizers British Standards (BS) EN 13060:2014 + A1 2018, and for WDs BS EN ISO 15883 Parts 1, 2 and 5.

2.24. For equipment not covered by the standards, such as lubricators, manufacturer's guidance should be followed at installation.

2.25. Annual revalidation and periodic testing requirements are to be in line with the CDO letter SGHD/ CDO (2010) requiring that the manufacturer's instructions be followed. LDU owners/ managers have the responsibility to risk assess the suitability of the manufacturer's instructions for their decontamination equipment to ensure they meet the required quality standard and are compatible with the devices and decontamination process.

2.26. In the absence of manufacturer's instructions or where there are inadequate or unclear manufacturer instructions, the frequency, methods, and outcomes of tests must follow the relevant equipment sections and appendices within this document and the appropriate BS, and those European Union (EU) Standards adopted into law before May 2021.

2.27. For equipment that includes a pressure vessel or pressure system, for example, steam or compressed air, all requirements of the 'The Pressure Systems Safety Regulations (PSSR): 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. Refer to SHTM 01-05 part A: 'Functional responsibilities - roles and responsibilities'.

2.28. A testing protocol should be agreed in advance prior to purchase and included in the procurement contract. The responsibility for performing works tests will normally rest with the manufacturer. The responsibility for testing once installed on site is dependent upon contractual agreements and/ or purchaser preferences.

2.29. Failure to employ testing protocols or retain evidence of their performance may indicate non-compliance of the decontamination process.

2.30. All validation and periodic testing should be carried out by a qualified competent person in decontamination CP(D). Daily and weekly testing may be carried out by appointed personnel within the LDU that are adequately trained, and competency assessed by the User.

2.31. Within one month of the completion of the validation process, the CP(D) should submit a full validation report to the User to clearly show the test methods and standards that have been applied with all results and recommendations. The CP(D) must provide an interim certificate to the User to declare equipment is fit for use until full validation report is provided.

2.32. Protocols should be in place such that any issues highlighted during testing by the CP(D) or User during daily or weekly tests that would compromise the ability of the decontamination equipment to function as originally installed should be resolved prior to the equipment going back into service.

2.33. Advice in the Health Board setting can be sought from an AE(D) with respect to the status of the test procedures described in this guidance.

Decommissioning of decontamination equipment

2.34. Disposal of decontamination equipment should be in accordance with the Health Facilities Scotland (HFS) guidance: Scottish Health Technical Memorandum (SHTN) 03-01 published 2023.

Documentation and logbooks

2.35. Systematic records should be kept of all maintenance and service work undertaken and Logbooks and maintenance files should be maintained for each item of equipment. This should show that the work has been carried out and facilitate periodic review of the PPM programme. These records can be stored as electronic or paper records and should be kept for audit and inspection. Refer to SHTM 01-05 part A, Section 7 ‘Documentation and traceability for record retention’.

2.36. Logbooks for decontamination equipment may be provided by the manufacturer or downloaded from the NSS website.

2.37. The Scottish Dental Clinical Effectiveness Programme (SDCEP) also provides online documents via SDCEP’s Practice Support Manual that may be relevant.

2.38. Documentation and signatures provide the only evidence of completed work. Absence of documentation for any work item will indicate the omission of that item. It is important that all documentation relating to decontamination equipment is up-to-date and is kept locally for audit and inspection purposes.

2.39. The following documentation should be kept for the equipment and be readily available at any time:

- specification(s) of purchased equipment
- validation report(s)

- test results and performance qualification details, loading patterns, and required parameter values. These results for both the WD(s) and sterilizer(s)
- logbook(s) of periodic testing for both WD(s) and sterilizer(s)
- logbook(s) of plant history, component replacement, and so on
- process log of items being reprocessed
- training and competency records of staff operating the decontamination equipment
- documentation for PSSR including written scheme of examination and examination reports
- list of all named designated Responsible Persons
- other relevant documentation and records on the decontamination equipment

3. Test equipment and consumables

3.1. This section covers test equipment/ methods and consumables that are used to test and calibrate decontamination process equipment such as ultrasonic cleaners (UC), thermal washer disinfectors (WDs), and sterilizers.

3.2. This section primarily is intended for decontamination test engineers and manufacturers/ suppliers that will carry out periodic test and maintenance of the decontamination equipment.

Parameters tested and equipment used

3.3. The test equipment/ methods are primarily concerned with directly testing decontamination process equipment to verify that the process equipment is fit for purpose in producing safe product. Other tests include where product is tested to confirm satisfactory performance of the process equipment and health and safety tests related to staff safety as opposed to product quality.

3.4. A broad range of parameters (see Table 3.1) are required to be measured by test equipment.

Table 3.1: Parameters to be measured by test equipment

Parameter tested	Test equipment	SHTM 01-05 reference paragraph	Application
Temperature	Dataloggers with platinum sensors or thermocouples	Appendix A.34 - A.41	Thermometric test for thermal disinfection and sterilization.
Pressure	Pressure gauge with required scale and resolution for the application	Appendix A.42 - A.48	Vacuum leak testing, steam sterilizers, water supply pressure, diff pressure across air and water filters
Volume	Graduated vessel (British Standards (BS) EN ISO 384:2015)	Appendix A.49 - A.53	Recording of process chemicals in WD cycle.
Weight	Laboratory balance/ analytical balance	Appendix A.54 - A.56	Load dryness test, calibration of flowmeters. total dissolved solids (TDS) in feedwater. Weighing of standard test pack and metal load.

Parameter tested	Test equipment	SHTM 01-05 reference paragraph	Application
Time	Calibrated time piece	Appendix A.57	Measurement of stage times for automatic control tests (ACTs), verification of chart recorder time base.
Relative humidity	Calibrated humidity meter	Appendix A.58	Measuring relative humidity in sterilizer standard test pack as BS EN 13060:2014 + A1 2018.
Conductivity	Calibrated conductivity meter	Appendix A.59	Water quality testing of conductivity.
Residual protein on a medical device	In-situ testing equipment (such as incubator) or use of swabs	Appendix A.60 - A.63	Monitoring protein levels on medical devices.
Ultrasonic activity	Aluminium foil/ Ultrasonic energy meter	Appendix A.64 - A.65	Monitoring of ultrasonic operating frequency and efficiency
Steam penetration	Helix or Bowie Dick test pack	Appendix A.66 - A.67	Monitoring of steam penetration in sterilizing chamber

3.5. Specifications for instruments fitted permanently to decontamination equipment are given in the relevant European and international standards.

3.6. Instrumentation technology continues to advance rapidly, making it increasingly difficult to provide detailed specifications for the equipment to be used in testing WDs and sterilizers, and so on. Computer-controlled data recorders with software, which enables the system to verify attainment of the required conditions and then to produce a detailed written report accompanied by tabulated or graphed data are now commonplace. These systems offer advantages in clarity of presentation, as well as reduced operator time. However, traditional instruments, such as chart recorders, remain equally acceptable where they meet the accuracy defined in this section of Scottish Health Technical Memorandum (SHTM) 01-05.

Note 6: Retention of data for long-term use is important. Where modern technology/ data-recording equipment is used, it should be equipped with memory devices that enable data to be retrieved later to allow final data storage at a secure and accessible location.

3.7. Some test equipment traditionally consisted of separate instruments (a data recorder) and sensors but is increasingly supplied as combined units where the sensor is integrated into a self-contained datalogger. The objectives of this section are to ensure that both these new and traditional measurement methods are supported adequately and to clearly define the

essential requirements that apply to the test equipment, whether it is based upon the latest technology or a traditional system.

Note 7: The Competent Person (Decontamination) (CP(D) should ensure that all test equipment is clean and free from risk of environmental contamination between machine testing and different sites/ departments.

3.8. When it is proposed to use measurement and/ or recording techniques that are not covered in this guidance, the advice of an Authorising Engineer (Decontamination) (AE(D)) should be sought throughout the assessment.

3.9. All test equipment should be calibrated by an accredited laboratory in accordance with BS EN ISO/IEC 17025: 2017.

Measurement errors

3.10. Errors of measurement occur for several reasons. These include:

- inherent factors, such as the design of the measuring instrument
- common problems with sensors (such as loose or imperfect connections)
- damaged insulation and broken conductors, combined with changes in the environmental temperature around the instrument
- variations in the sensors themselves, the method of introducing the sensors into the machine and their location within the load may add to the error in the temperature measurement
- changes in conditions other than the one being sensed may also lead to errors. For example, temperature fluctuations within pressure-sensing elements may lead to errors in pressure measurement
- the integrity of the measuring system is essential to obtain meaningful results
- significant errors can arise through improper use of test equipment and calibration instruments, and it is therefore important that staff are trained and skilled in their use with competency assessed
- two types of errors exist: Intrinsic and Introduced. Intrinsic errors relate mainly to the instrument's best capability and usually cannot be improved upon without modification. Introduced errors may be very small or great, depending upon the skill of the person used in the process

3.11. Careful attention to detail including the location of the test equipment, effective maintenance and the skill of personnel trained in the application, handling and use of the test equipment are required to eliminate or minimise these errors. Systematic errors can be reduced by careful calibration.

3.12. Appendix A details more information on the use of test equipment and the test methods for which these are used.

4. Washer disinfector

4.1. The washer disinfector (WD) is a machine used to carry out the cleaning, disinfection and drying of re-usable dental instruments. Cleaning is an essential prerequisite before sterilization to remove soiling, allowing steam to penetrate the devices. Disinfection will reduce the number of viable micro-organisms (bioburden) and render the instruments safe for handling and inspection. Drying removes moisture to reduce recontamination.

4.2. Scottish Health Technical Memorandum (SHTM) 01-05 part C further explains the process of manual and automated cleaning and disinfection in more detail.

Washer disinfector stages

4.3. All WD cycles for instruments include the following five distinct stages designed to achieve the relevant intent for each stage:

- **pre-wash** - removes “difficult” gross contamination, including blood, tissue debris, bone fragments and other fluid and solid debris. The latest standards indicate that a water temperature of less than 45ºC prevents protein coagulation and fixing of soil to the instrument

Note 8: Additional pre-treatment may be required to remove hardened contamination such as cement.

- **wash** - mechanical and chemical processes loosen and break up contamination to remove soil adhering to the instrument surface remaining after pre-wash stage. Detergents used in this process must be specified by the manufacturer as suitable for use in a WD. They should also be compatible with the instruments being processed and supplied to perform correctly and avoid instrument degradation, including discoloration, staining, corrosion, and pitting
- **rinse** - removes detergent used during the cleaning process. This stage can contain several sub-stages. The quality of the water used for this stage is an important consideration in ensuring a clean, unmarked product after sterilization and should meet manufacturer requirements. Potable water direct from the mains supply that meets the Public Water Supplies (Scotland) Regulations 2014 requirements is unlikely to harm health in this application. However, where the local potable water is unsatisfactory for processing, (such as it contains high levels of ionic contaminants such as silicates), not compatible with process chemicals or spotting is observed on instruments, then final stage purification systems should be considered to improve the process, such as reverse osmosis (RO)

Note 9: Annual testing of potable water will verify quality. See Table 4.4 Periodic testing of WD.

- **thermal disinfection** - the temperature of the load is raised and held at the pre-set disinfection temperature for the required disinfection holding time, for example, 80ºC for 10 minutes; or for 90ºC for 1 minute

- **drying** - purges the load and chamber with filtrated heated air to remove residual moisture

Types of automated washer disinfector

4.4. The WDs found in Local Decontamination Units (LDUs) are single cabinet machines which carry out the full range of process stages.

4.5. There can be three models of WDs found in an LDU - Stand-alone, under-bench or benchtop, with either single door through which both loading and unloading takes place, or pass-through double doors with one door being used for loading and the other for unloading into a clean room area.

4.6. The choice and number of WDs required is determined by throughput and performance requirements.

Washer disinfector specification

4.7. Refer to the SHTM 01-05 part A Appendix 2 ‘Procurement of equipment’ which includes a specification preparation and an overview of points to consider.

4.8. Manufacturers should provide certification to the purchaser that the particular design of the equipment is manufactured in conformity with all relevant British Standards (BS), national guidance, and regulations.

4.9. WDs for medical devices and associated equipment should conform to BS EN ISO 15883-1 :2009 + A1 2014 and BS EN ISO 15883-2: 2009 and the safety requirements for electrical equipment BS EN IEC 61010-2-040: 2021.

4.10. WDs are also covered by several other European Regulations/ Directives and are thus required to be in conformance. Relevant Regulations/ Directives included but are not restricted to:

- Medical Device Regulations 2002
- Electromagnetic Compatibility Directive (2014/30/EU)
- Low voltage Directive (2014/35/EU)
- Machinery Directive (2006/42/E)

4.11. After a fault has been indicated, the automatic controller shall allow the WD operating cycle to be terminated without causing a safety hazard. Any user intervention shall require the use of a special key, code, or tool. A visual display of fault shall continue at least until the door-locking mechanism is released by the use of a special key, code, or tool (BS EN ISO 15883-1 :2009 + A1 2014, 5.22.3).

Performance requirements of the washer disinfector

4.12. The following performance requirements should be considered:

- cleaning performance should be verified before buying/ installing. The cleaning performance of WDs should be optimised by considering a range of parameters including water, process chemicals, cycle time, and so on

Note 10: The standard BS EN ISO 15883-1: 2014 - 'Washer disinfectors Part 1: General requirements, terms and definitions and tests' defines cleaning as "*removal of contamination from an item to the extent necessary for its further processing and its intended subsequent use.*" When defining the cleanliness state of invasive medical devices, there must be a link between performance requirements and test method criteria for determining cleaning efficacy in WDs (EN ISO 15883 series) and pass/fail criteria for reprocessed medical devices. Failure to link these two processes will lead to operational difficulties in achieving medical device cleanliness outcomes. This link should be established during the commissioning process of the washer disinfector and followed through to performance qualification and subsequent periodic testing.

- thermal disinfection is the preferred option (as stated in Health Facilities Scotland (HFS) guidance GUID 5005 'Compliant Dental Local Decontamination Units in Scotland': 2019) for processing medical devices in LDUs. Disinfection is achieved by the action of moist heat maintained on the surface to be disinfected at a particular temperature for a particular time as defined in BS EN ISO 15883-1 :2009 + A1 2014, Annex 2
- drying - method employed should be rapid and reliable and should not contaminate the medical device with chemical, microbial, or particulate contaminants. Medical devices should be dry at the end of the WD cycle prior to sterilization
- cycle time - in all cases, the duration of each process stage should be determined with sufficient accuracy to ensure all cycle parameters are defined, repeatable and recorded for each operating cycle used to ensure consecutive cycles have the same efficacy

4.13. Temperatures more than 65ºC and up to 95ºC can be used for disinfection. The lower the temperature, the longer the exposure time needed to obtain the same reduction in microbial population, see Table 4.1.

Note 11: A_0 is defined in BS EN ISO 15883-1 :2009 + A1 2014, as the equivalent time in seconds at 80°C, delivered by the disinfection process, with reference to a microorganism with a z value of 10 K.

4.14. An A_0 of 600 may be achieved by 10 minute (600 s) at 80°C or by 1 minute at 90°C, or by 100 minutes at 70°C and so on. The combination of time and temperature to be used to achieve the A_0 of 600 may be decided by the User in the light of operational requirements. While the combination of time and temperature should satisfy the requirements of BS EN ISO 15883-2: 2009 (clause 4.3) for an A_0 disinfection value of 600 an operational temperature band with a minimum temperature can be used, see Table 4.1.

Table 4.1 - Time/ temperature bands meeting the requirements of an acceptable A_0 of 600 for thermal disinfection of medical device

Exposure time	Disinfection temperature band (°C)	A_0 value
100 minutes (6000s)	70 - 75	600
10 minutes (600s)	80 - 85	600
1 minute (60s)	90 - 95	600

Design consideration for dental handpiece/ implant instruments

4.15. Check with the handpiece/ implant surgery instrument kits manufacturer that a WD can be used to clean them.

4.16. Certain types of WDs can be adapted using specific load carriers to clean some handpieces/ implant instruments, and these can be validated independently as being effective. It is recommended that handpieces bought can be processed via the WD. Manufacturer's instructions should be referred to for reprocessing.

4.17. Where a handpiece manufacturer does not recommend a WD for cleaning, manufacturers may recommend dedicated handpiece-cleaning machines. These are not included within the scope of this document.

4.18. Always consult the WD manufacturer for operating details (for example, whether filters are required when processing dental handpieces, and how often these need to be replaced) along with running costs before purchase.

Note 12: Some WDs that have a handpiece irrigation system require that a special filter be fitted to protect the internal mechanism of the handpiece from extraneous debris during the operating cycle. These filters need to be replaced at regular intervals in accordance with the manufacturer's instructions. Failure to maintain/ replace filters as per manufacturer's instructions may result in damage to dental handpieces internal components.

Note 13: There are certain commercial products that claim to sterilize as well as wash and disinfect dental handpieces. Please seek advice from the Authorising Engineer (Decontamination) (AE(D)) and/ or Decontamination Lead, or your local infection prevention and control team prior to purchase.

Note 14: Always follow manufacturer's instructions for processing handpieces and implant instruments/ kits. To achieve the required cleanliness, instruments may need to be removed from tray sets and reassembled as required.

Utilities

4.19. A WD installation will require external service connections. These may include water (of various qualities), electricity, compressed air, drainage, ventilation, and supplies of process chemicals.

4.20. The manufacturer should make clear at an early stage which, services will be needed and give detailed requirements for each service (see Table 4.2 below).

Table 4.2 - Information on services to be obtained from the WD manufacturer

Service	Criteria
Electricity	a. type of supply such as alternating current (AC) or direct current (DC) b. number of phases (normally one or three) and whether neutral is required for a three-phase supply c. supply voltage and frequency including nominal and acceptable minimum and maximum values d. maximum continuous power demand in kilowatt (kW) or kilovolt-ampere (kVA)
Compressed air	a. acceptable range of supply pressures b. the flow required at minimum pressure c. the volume of air used for each cycle d. the quality or quantity of air required, including dew point, maximum size and concentration of particulate material, oil content and microbial contamination level
Water (for each grade of water required)	a. the acceptable range of supply pressures b. the flow at minimum pressure c. the volume used per cycle d. the acceptable temperature range for incoming water e. the quality of water required when relevant: • The maximum permissible hardness expressed as mg/l $CaCO_3$ • The acceptable range of potential of hydrogen (pH) • The maximum permissible conductivity • The limiting concentration of heavy metals, halides, • phosphates and nitrates • The maximum acceptable microbial population
Drainage	a. the maximum flow of effluent to the drain b. the maximum temperature of the effluent on leaving the WD

Service	Criteria
	c. the maximum effective diameter of the discharge orifice from the WD chamber d. requirement for sealed drainage system if hazardous fumes or gases are produced from chemicals used in the process
Ventilation	a. the peak value during a cycle and the average value throughout a cycle of the heat in watts transmitted to the environment when the WD is operated in still air at an ambient temperature of 23 ± 2°C b. the heat in watts transmitted by a full load being unloaded from the WD into still air at an ambient c. temperature of 23 ± 2°C d. the maximum flow of air extracted from the environment of the WD as exhaust ventilation e. ventilation requirements for removal of fumes or gases from hazardous chemicals used in the process

4.21. For most WDs the water and drainage services are the most critical, although for user comfort, the ventilation and extraction system are also of importance.

4.22. If the services are to be installed by a contractor, other than the contractor installing the WD, care must be taken to ensure that the size and location of terminations are agreed before the contracts are placed.

Electrical services

4.23. The electrical power requirements will depend on several factors, such as the type of WD and the method used to heat water, hot air dryers, and so on. Some WDs will need a three-phase supply. The manufacturer should provide details of the type of supply (AC or DC), number of phases, frequency, and voltage, with tolerances and loading.

4.24. Each WD should be connected via an isolator. The type of isolator will depend on the nature of the supply:

- for small WDs and tabletop WDs with a maximum current demand not exceeding 13A on a single-phase supply, isolation may be provided by a simple plug and socket connection using a correctly fused plug and a switched socket-outlet
- when a three phase and neutral supply is required or when the maximum demand from a single-phase supply is more than 13A, the WD should be wired directly to the isolator
- the switch should isolate all poles simultaneously and each pole should be fused separately. The cable from isolator to WD should be fixed and protected from the effects of heat and water

4.25. Within the loading area, an additional switch should be provided so that the operator can electrically isolate the WD or group of WDs in the event of an emergency. The switch should be placed between the normal operating position and the exit door.

4.26. All electrical installations should conform to IEE Regulations in BS 7671:2018+A1:2022. Further guidance is given in SHTM 06-01 ‘Electrical services: supply and distribution’.

Compressed air

4.27. WD may require a supply of compressed air for either the operation of valves and/ or, powered door systems at varying stages of the operating cycle.

4.28. 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 WD via an isolation valve.

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

4.30. Air compressors may exceed permitted noise levels and may need to be sited in a dedicated location away from noise sensitive areas.

4.31. 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.

Drainage

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

4.33. Effluent from WDs should pass via an air break into a tundish or tank before being discharged to drain. The air break should be always preserved to prevent the WD and its associated pipework being contaminated by reverse flow from the drainage system.

4.34. Where a storage tank supplies water to a pump on the WD, the overflow discharge from the storage tank should also discharge to the drain and include an air break.

4.35. The drainage system should be trapped and designed to pass the flow rate of water, air and condensed steam specified by the manufacturer, with account taken of the peak output period during the operating cycle.

4.36. The drainage system should be designed to pass and maintain in suspension the maximum expected quantity of solids to be removed from the load during the flushing process. The minimum diameter of the drainage system should be greater than the maximum diameter of the most restricted section of the discharge from the WD chamber.

4.37. The discharge temperature from a WD may be as high as 95ºC. Therefore, the materials used for the construction of the discharge system should be chosen to withstand temperatures up to 100ºC. A means of diluting/ reducing any high temperature effluent should be provided to ensure the maximum accessible surface temperature of any pipes or surfaces should not exceed 43°C where this would cause an issue.

Ventilation

4.38. General room ventilation may be sufficient for most WDs; however, consideration should be given whether WDs should be connected to a suitable air extraction system dedicated for purpose. The extract system should be constructed of corrosion resistant material that can withstand temperatures greater than 105ºC. Where multiple WDs are connected to a common air extraction system, a means should be provided to prevent contamination. Local exhaust ventilation may be required for chemical disinfection/ sterilization systems.

4.39. Means should be provided to prevent, as far as possible, flash steam being liberated into the atmosphere or causing condensation on electrical equipment. Additional guidance is given in planning guidance Scottish Health Planning Note (SHPN) 13 part 2 ‘Decontamination Facilities: Local Decontamination Units’, 2008 and SHTM 03-01 ‘Ventilation for healthcare premises'.

Water supply

4.40. 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. WDs should be designed, constructed, installed, operated and maintained in accordance with the requirements of the relevant by-laws, see ‘The Water Supply (Water Fittings) (Scotland) Byelaws, 2014 and SHTM 04-01 ‘Water safety for healthcare premises part A: Design, installation and testing’, 2014 and SHPN 13 part 2 ‘Decontamination Facilities: Local Decontamination Unit,’ 2008. All fixtures and fittings should comply with the ‘Water Fittings and materials Directory’ published by the Water Regulations Advisory Scheme (WRAS). Consult SHTM 04-01: ‘Water safety for healthcare premises part A: Design, installation and testing’.

4.41. 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.

4.42. 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. 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 WD as possible and designed to minimise dead ends and stagnant areas.

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

4.44. A 'Type A' air gap is required at the point of use or an interposed cistern. This applies to all WDs and water softening treatment plant, other than those regenerated only by means of sodium chloride solutions, which should be protected by a 'Type B' air gap.

4.45. The 'Public water supplies (Scotland) Regulations 2014' lists the parameters expected for potable water quality. Water pre-treatment (water softening equipment, reverse osmosis equipment) may be required to achieve a suitable quality of water for later stages in the WD process. Further details on water quality requirements and testing can be found in Section 7 of this guidance document.

4.46. WDs can be supplied with both hot and cold water. When hot water is required as part of the operating cycle, it can be advantageous to supply hot water to the WD rather than heat cold water. Many designs of WDs now incorporate holding tanks that pre-heat the water supply for the relevant phase of the operating cycle.

4.47. The quality of water used at all stages in the decontamination process is critical to the successful outcome of the process. The incoming water quality should be specified by the manufacturer.

4.48. At each stage the feed water quality should be compatible with:

- the materials of construction of the WD
- the medical devices to be processed
- the process chemicals used
- the particular process requirements of each stage

Feed water quality

4.49. The number, nature and quality of water supplies required are dependent on the size and type of WD. The key factors to be considered in the feed water quality are specified by the manufacturer and may include:

- temperature
- ionic contaminants, for example - heavy metals, halides, phosphates, and silicates
- microbial population
- hardness

Note 15: Types of water application - potable cold water flushing soft potable water (<50mg/L/$CaCO_3$) flushing, cleaning with process chemicals for instance detergent or enzymatic cleaners softened water - based exchange softener desirable in all water >50mg/l/$CaCO_3$ water softening essential in all water >125mg/l/$CaCO_3$ for use in WDs.

Water temperature requirement

4.50. The temperature at which water is supplied to each stage of the process has a major effect on the efficacy of the process.

4.51. Water above 45ºC can lead to the coagulation and fixing of proteinaceous soil on the surface of the load items. Therefore, water for the initial rinse and wash stages should be supplied from a cold supply.

4.52. The temperature settings of the WD will be dependent on the type of process chemical used, and to ensure their effectiveness the optimum temperature range specified by the detergent manufacturer should be maintained.

4.53. Where water is heated for the wash stage, the WD operating cycle should be configured to add the process chemical when the optimal temperature has been reached.

4.54. Water storage tanks within the WD should be self-draining and fitted with a drain down system and an overflow which works automatically when the machine is switched off, 'Water Supply (Water Fittings) (Scotland) Byelaws 2014'.

4.55. 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.

Ionic contaminants

4.56. Water used in the cleaning of stainless-steel instruments should have a chloride concentration less than 120 mg/l and for final rinse/ disinfection, less than 10 mg/l Chloride (Cl). Concentrations greater than 240 mg/l Cl cause pitting to occur.

4.57. Tarnishing of stainless-steel instruments, shown by blue, brown or iridescent surface colouration, occur when heavy metal ions, such as iron, are present in the process water. In water, over 75ºC, magnesium ions and silicates can cause similar discolouration.

Microbial quality of water

4.58. The water used at each stage of the WD operating cycle should not increase the bioburden of the load items. Appropriate treatment to control or reduce the microbial contamination in water may be required.

4.59. Potable water from the public supply has a low microbial content and should be free from pathogenic organisms, (other than those that may cause opportunistic infections in immunologically compromised patients). If stored in tanks or cisterns, the microbial content can increase considerably.

4.60. The requirement of the Health and Safety Executive (HSE) approved code of practice for control of legionella states, "*water in intercepting tanks should be stored below 20ºC or above 60ºC*". Water stored at 60ºC or above may be assumed not to have a proliferating microbial population.

4.61. When water is treated by filtration, for example, through a filter to remove microbial contaminants, 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 using UV irradiation (wavelength 260 nm ± 10nm; >2 J m–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

Water hardness

4.62. The deposition of limescale (Calcium carbonate $CaCO_3$) deposits within the chamber, piped supplies and around the edges of spray nozzles will seriously impair the performance of a WD, see Figure 4.1. It may also impair the efficiency of process chemicals.

4.63. Hard water will cause scaling on the edges of spray nozzles even when fed with only cold water. The fouling of electrical heating elements or heat exchange components by hard water dramatically reduces the heat-transfer efficiency and can quickly lead to an increase in heating costs of 50-100%.

4.64. Using hard water in the thermal disinfection and final rinse stages of the WD operating cycle is one of the major causes of white powdery deposits on load items acting as a focus for soiling and recontamination of the item. In some applications, for example, optical systems, such deposits can seriously impair the utility of the item.

4.65. Where the local water supply is >125mg/l of $CaCO_3$, some form of water treatment system may be required.

Figure 4.1 - An example of limescale build-up within a WD

Water quality for cleaning and final rinse

4.66. The efficacy of cleaning will also depend on the relationship between potable water quality and detergent performance. The detergent should be chosen not only for its cleaning efficacy but also for its compatibility with the potable water quality and parameters of its use.

4.67. Periodic testing of the water is optional as per European standard; however, it is recommended that water quality tests such as conductivity and hardness are carried out as recommended by the manufacturer or at a minimum on an annual basis to ensure they are within the levels required. Appendix B includes details on water quality test methods for conductivity, hardness, and total dissolved solids (TDS) should the dental department wish to incorporate these tests.

4.68. If the input water quality, for example, hardness, is higher than recommended levels, then the following water treatment methods may be considered as an option:

- 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
- 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

Chemical additives

4.69. The type of detergent used, the dosage, and temperature range within the WD should be specified by the manufacturer as suitable for use and compatible with the instruments being processed.

4.70. When considering the purchase of process chemicals and accessories, the 'NP187 framework for Decontamination consumables', should be considered as the first option. This framework includes process chemicals reviewed by HFS and Health Board technical staff as part of a National Procurement (NP) tendering exercise and is accessible to NHS managed dental practices. However, it is still essential to validate these chemicals for each WD on-site using the most challenging loads, as the performance can be affected by water quality, configuration of WD, loads, temperature, and so on.

4.71. The performance qualification includes the testing of cleaning efficacy and process residues which relate to the process chemicals in use, see periodic testing Table 4.4.

4.72. Changing process chemicals would require the performance qualification to be revisited. This would include confirmation from both the WD manufacturer and the process chemical manufacturer/ supplier that introducing the new process chemicals would provide a satisfactory process.

4.73. Chemical dosing systems should be accurate, reproducible, and meet the requirements of BS EN ISO 15883-2: 2009 clause 4.1.6. This should be confirmed by validation of the process at the initial installation Qualification of the WD as local water quality can affect cleaning efficacy.

4.74. WDs should be fitted with a system that will indicate when there is insufficient chemical(s) available for the next operating cycle, and if so, the cycle should not be allowed to start.

Note 16: Ensure the process chemical in use is compatible with the feed water quality. Formulations intended for use only with soft water may give rise to precipitation if used with hard water, particularly at elevated temperatures. Once this precipitation has occurred on the surfaces of the WD or the load it is particularly difficult to remove.

4.75. Suppliers of process chemicals should provide product data sheets and material safety data sheets for the products supplied. These should include details of biocompatibility studies. Reference should be made to local Control of Substances Hazardous to Health (COSHH) Regulations 2002 provisions:

- The Control of Substances Hazardous to Health Regulations 2002 (legislation.gov.uk)

4.76. Safe storage provision is needed for containers of chemical additives used in the WD. These chemicals can be corrosive, irritant, and toxic and provision should be made, in or adjacent to, the storage area for an emergency eyewash station and a source of running water to dilute any spillage:

- Detergents: Great Britain (hse.gov.uk)

- EUR-Lex - l32025 - EN - EUR-Lex (europa.eu)

4.77. The liquid concentrates are often viscous and chemically aggressive. The pipework, valves etc. used for the distribution of these chemicals will need to withstand the corrosive effects of these materials. Advice should be sought from the manufacturer of the chemical additives on suitable materials, construction, and pumping systems for the distribution system.

Validation and periodic testing schedules

Initial validation

4.78. This part of SHTM 01-05 details the requirements for what guidance the WD testing regime is based upon.

4.79. Table 4.3 below illustrates the sequence of testing required for a WD and supporting equipment/ services required to validate the WD for initial use in production at the LDU as per BS EN ISO 15883 Parts 1 and 2.

4.80. Test methods for performing each of the tests included in Table 4.3 and are detailed in Appendix B.

Table 4.3 - Initial installation and validation tests - performed by manufacturer CP(D)

Test	Description	SHTM 01-05 Pt B Ref
Water supply pressure/ temperature	Within range as specified by manufacturer	Appendix B: B.3 - B.14B.13
Volume of water	Check water level is within manufacturer levels	Appendix B: B.15 - B.18
Water system	Samples taken to confirm water quality is within manufacturers recommended levels such as conductivity and hardness	Appendix B: B.131 – B.168B.117B.145
Faults/ Fails	Specified by manufacturer and can include but not inclusive of power fail, water pressure too low/ high, and so on	Appendix B: B.19 - B.20 B.17
Safety checks	Inspection of door seal, performance of door safety devices or other checks as per manufacturer Instructions for use (IFU)	Paragraph 4.92
Drainage tests	Includes a check for blocked drain and ensures free-flowing drainage	Appendix B.21 - B.37

Test	Description	SHTM 01-05 Pt B Ref
Water vapour emission	Confirms door-seal prevents contamination to surroundings	Appendix B.38 - B.42
Doors and door interlocks	Confirms safety to operator and exposure to complete cycle only	Appendix B: B.43 - B.62
Detergent dosing test	Confirms repeatable detergent addition and low dosage	Appendix B: B.63 - B.73
Cleaning efficacy test	Using an artificial soil to clean a worst-case load, chamber walls and load carriers to confirm the exposure to cleaning parameters is sufficient to remove soil	Appendix B: B.74 – B.89
Verification of calibration	The accuracy of indicating and recording instruments is checked against certificated source instruments	Appendix B: B.90 - B.93
Automatic control test (ACT)	The values of cycle time and temperature are noted at relevant stages of the cycle so that a fingerprint of the automatic cycle can be made	Appendix B: B.119 - B.123
Thermometric test	Thermocouples are attached to worst-case load, chamber walls and load carriers to confirm that disinfection parameters are acceptable	Appendix B: B.94- B.104
Load carriers	Confirms mechanical alignment of all load carriers	Appendix B: B.109 - B.110
Over temperature cut-out	To check the WD aborts for excessive temperature rises	Appendix B: B.105 - B.108
Load dryness test	To check that no residual water remains in the load at cycle completion	Appendix B: B.111 - B.114
WD fitted with HEPA air filters (for drying)	To check High Efficiency Particulate Air (HEPA) filter is functioning correctly	Appendix B: B.115 - B.118
Residual process chemicals	To check the rinse system is sufficient to remove chemicals used at cycle completion	Appendix B: B.127 - B.130
Ventilation system	To check ventilation system is functioning adequately	Appendix B: B.124 - B.126

Periodic testing - daily, weekly, quarterly and annually

4.81. As per Section 2, manufacturer's IFU should be followed, however periodic testing protocols will vary between manufacturers and therefore a risk assessment should be taken to assess if the testing being carried out is adequate. For example, if the manufacturers recommended testing frequency is inadequate to highlight a potential issue, then the recommended tests below should be considered.

4.82. In the absence of manufacturer's instructions or where there are inadequate or unclear manufacturer's instructions, the frequency, methods, and outcomes of tests must follow current guidance and the appropriate BS.

4.83. Minimum requirements for periodic tests are defined in BS EN ISO 15883 Parts 1 and 2. These tests are carried out at daily, weekly, quarterly, and annual intervals. It is recommended that periodic testing is performed as defined in Table 4.4 below. Any additional tests defined by the manufacturer should also be performed.

4.84. Tests should only be undertaken after completion of the planned maintenance tasks described in Section 2.

4.85. All periodic tests should be carried out with the machine at normal working temperature, which may require a warm-up run to be carried out before commencement of testing.

4.86. The results of periodic tests should be recorded, documented, and filed securely, in electronic or paper format. See SHTM 01-05 part A Section 7 for Documentation and traceability.

Table 4.4 - Periodic test schedule

Daily tests - performed by User or be delegation, Operator	Description	Reference
Remove and clean strainers and filters	Ensure filters and strainers are clean	Paragraph 4.89 – 4.91
Check spray arms/ nozzles	Ensure these are clear from obstruction and free to rotate	Paragraph 4.89 – 4.91
Detergent levels	Ensure adequate detergent is available	Paragraph 4.89 – 4.91

Weekly tests - performed by User or be delegation, Operator (includes daily tests above)	Description	Reference
Safety checks	Check condition of the door seal	Paragraph 4.92
Protein residue test	Confirms that the cleaning process retains the capability of removing protein	Paragraph 4.93 and Appendix A: A.60 - A.63
Automatic Control Test (ACT)	This test is designed to show the operating cycle functions properly and that the disinfection temperature / time are within the original specification (Weekly – full cycle noted)	Paragraph 4.93 and Appendix B: B.119 - B.123

Quarterly tests - performed by CP(D) (Includes weekly tests above)	Description	Reference
Safety checks	Check safe operation of doors and door interlocks	Paragraph 4.92
Load Carriers	Confirms mechanical alignment of all load carriers	Appendix B: B.109 - B.110

Quarterly tests - performed by CP(D) (Includes weekly tests above)	Description	Reference
ACT	This test is designed to show the operating cycle functions properly and that the whole cycle including disinfection temperature/ time are within the original specification	Appendix B: B.119 - B.123
Cleaning Efficacy test	Application of test soil onto a full worst-case load to check that the cleaning process is adequate for removing protein	Appendix B: B.74 - B.89
Chemical Dosing	Confirm delivery of detergent (and any other additives) is repeatable and the machine reacts correctly to low levels	Appendix B: B.63 - B.73
Verification of calibration	The accuracy of indicating and recording instruments is checked against certificated source instruments	Appendix B: B.90 - B.93
Thermometric test for disinfection	Use of thermocouples on worst-case load to confirm disinfection parameters are acceptable	Appendix B: B.94 - B.104

Annual tests - performed by CP(D) (Includes quarterly tests above)	Description	Reference
Water system	Samples taken to confirm water quality is within manufacturer's recommended levels such as conductivity and hardness	Appendix B: B.131 - B.168
Over temperature cut-out	To check the WD aborts for excessive temperature rises	Appendix B: B.105 - B.108

4.87. The testing protocols recommended in the tables within this section provide the means for ensuring that the WD is fit for its intended purpose. Tests are also recommended before a washer is returned to service, after repairs that affect one or more components, which influence the attainment of critical process control parameters.

4.88. The testing methods and protocols are detailed in Appendix B.

Daily and weekly testing

4.89. Manufacturer's IFUs should always be followed for daily/ weekly testing that involves certain maintenance tasks that should be carried out by the User, or by the Operator under the Users supervision and should be recorded in the WD logbook.

Routine maintenance

4.90. The correct flow and distribution of water and process chemicals throughout the chamber and load are essential to the correct functioning of a WD. The spray system should be checked daily as part of the routine maintenance tasks carried out by the User or operator.

4.91. Regular daily maintenance tasks should include:

- removal of strainers and filters for cleaning then replace back into position
- checking that the rotating spray arms, both installed within the chamber and located on load carriers, are free to rotate
- checking that nozzles are not blocked; clean and/or replace if necessary
- checking for wear in bearings of rotating parts; replace any worn parts as necessary
- checking the mating of any necessary connection between the load carrier and the water supply in the chamber
- checking that the supply of process chemicals is in date and sufficient for the day's use and replenished as necessary
- cleaning of the external surfaces of the WD

Safety checks

4.92. Safety checks are undertaken throughout the lifetime of the WD. Initially at the validation stage prior to use and subsequently during the periodic testing when the WD is operational. Certain specific weekly safety tests should be carried out as part of the periodic test schedule. These safety checks should include:

- inspection of the WD door seal(s)
- the performance and security of door safety devices
- operation of the automatic load carrier safety mechanism (if fitted)

4.93. Additional weekly checks involve:

- ACT - the test is carried out to show the operating cycle functions correctly and is consistent. See Appendix B: B.117 - B.123 for details. The test can be carried out by checking the WD printout if relevant data is present, for example disinfection hold time and temperature
- protein residue test - to confirm the WD is cleaning satisfactory. This can be achieved by using a protein detection method as detailed in Appendix A: A.60 - A.63. Manufacturer's instructions for the protein detection method should be followed to determine a pass or fail result

5. Ultrasonic cleaner

5.1. An Ultrasonic Cleaner (UC) within a Local Decontamination Unit (LDU) environment is usually a stand-alone ultrasonic bath. A UC is not an essential requirement and is not intended for routine use. In exceptional circumstances, such as in the event of washer disinfector (WD) failure, a UC may be used as a backup automated cleaning process. It is essential that UCs are shown to be effective through regular routine testing, maintenance, and revalidation.

Note 17: UCs do not usually incorporate a disinfection stage, which would render instruments safe to handle. Therefore, personal protective equipment (PPE) is required.

5.2. Ultrasonic cleaning in a well-maintained machine can be useful for removal of debris prior to processing in a WD, particularly from instruments with hinges and/or intricate parts and aid in cleaning instruments that may be contaminated with body tissues, for example drills and burrs.

5.3. UCs are less effective when used to clean plastic and similar readily compressible materials as they absorb much of the ultrasonic energy.

5.4. When using these UCs, it is essential that the water is changed when it becomes visibly contaminated or otherwise every at the end of each morning and afternoon session. The build-up of debris will reduce the UC effectiveness.

5.5. Manufacturer's instructions should always be followed for the operation, use and maintenance of an UC. Scottish Health Technical Memorandum (SHTM) 01-05 part C further explains the use of an UC within the LDU environment.

Ultrasonic cleaner specification

5.6. UCs work by exposing items to high frequency sound waves in a liquid cleaning medium. The high frequency sound waves are generated within the liquid by the vibration of one or more transducers bound to the outer surfaces of the bath. The transducers convert electrical power into vibrations of the required frequency and amplitude. This results in a highly effective cleaning action occurring because of the penetrative agitation caused by cavitation; the rapid formation and collapse of tiny bubbles within the liquid which are generated by the high frequency sound waves.

5.7. As many UCs are not fitted with a means of continuously monitoring performance, if transducers fail or become detached from the ultrasonic tank, it may only be noticed by deterioration in the cleaning performance.

Note 18: Medical Device Regulations 2002 and United Kingdom Conformity Assessed (UKCA) marked applies as a critical medical device for decontamination. Safety specifications for UCs are included in British Standard (BS) EN 61010-1: 2010: A1:2019 and BS EN IEC 61010-2-040: 2021.

5.8. The UC should:

- be fitted with means to drain the tank so that no pools of liquid are left in the tank
- be heated with an electric thermostat
- be fitted with an over temperature sensor, with automatic cut-off and warning indication
- be fitted with a timer to control the duration of operation
- have maximum/ minimum fluid levels clearly visible to the user marked on the chamber/ reservoir
- have a chamber of polished stainless-steel construction with internal rounded edges and corners to aid in the cleaning process
- have an integral purpose built holding basket, which enables all equipment to be held within the ultrasonic bath in the optimum position, so that micro-dental instruments or instruments with fine points are not blunted by the impacts resulting from fine mechanical shaking; have a hinged auto-locking lid that fits securely to prevent the emission of aerosols, interaction with the load when in use, and protect the operator from harm during operation
- have a lock or sensor that prevents normal operation if the lid is open should also be present. The body and lid of the UC should be effectively insulated to prevent high frequency sound transmission that could exceed the recommended levels for safe working within the Washroom (refer to ‘The Control of Noise at Work Regulations’ 2005 and Scottish Health Planning Note (SHPN) 13 part 2: ‘Decontamination Facilities: Local Decontamination Units’ 2008)
- have a visual display on the unit for displaying the following but not inclusive of:
    - time/ date
    - elapsed cycle time
    - max/ min temperatures
    - cycle process steps, for example ultrasonic activity
    - cycle failure indications
    - have an automatic printer and data logger whether integrated or externally linked to record the following:
        - serial number
        - time and date
        - cycle type/ programme and unique cycle number
        - cycle parameters such as max/ min temperatures, stage times and cycle duration
        - ultrasonic activity

- cycle failure details (if fault occurs).

5.9. The UC manufacturer should recommend the process chemicals (detergents/ enzymatic cleaners) that are compatible with their equipment and have a means to control the dosage and concentration of the chemical.

5.10. Confirm with the UC manufacturer whether any degassing time(s) is required on start-up or between each load of medical devices processed.

5.11. The ultrasonic frequency used should be within the range 35 kHz ± 5 kHz and the energy input used may range from 5 to 20 Watts per litre (WL^{-1}).

5.12. For dental instrument applications, aqueous solutions should be used at temperatures recommended by the process chemical manufacturer's instructions (normally between 21ºC and 45ºC) to ensure compatibility with the use of enzymatic cleaners, many of which are rapidly degraded at higher temperatures. Maintaining water temperatures in this range will also minimise the rate of coagulation of proteinaceous material in any soil.

5.13. For manually filled and emptied UCs, with no disinfection cycle built in, the UC manufacturer should advise on the required cleaning/ disinfection method for their equipment.

5.14. The manufacturer should supply an operating, maintenance, and technical manual with the UC that details how the user can ensure continued fit for purpose use of the UC for reprocessing medical instruments.

Validation and periodic testing for ultrasonic cleaners

5.15. Manufacturer's protocols should be followed for validation and periodic testing (daily, weekly, quarterly, and annual) of an UC. A risk assessment should be carried out to assess if the testing is adequate.

5.16. Section 2 provides details on who should perform validation and periodic testing.

5.17. A recommended testing schedule for UCs is provided, see Table 5.1 below.

5.18. The testing protocols recommended in the table provide the means for ensuring that the UC is fit for its intended purpose. Tests are also recommended before an UC is returned to service, after repairs that affect one or more components, which influence the attainment of critical process control parameters.

5.19. Testing methods and protocols mentioned in the Table 5.1 below are detailed in the various sections and appendices as indicated.

Table 5.1 - Schedule of periodic testing for UCs

Daily tests - performed by User or be delegation, Operator	**Description**	**Reference**
Remove and clean strainers and filters	Ensure filters and strainers are clean	Paragraph 5.22
Drain machine periodically - at the end of morning and afternoon sessions.	Ensure contaminated water is not stored in tank	Paragraph 5.22
Detergent levels	Ensure adequate detergent is available (may be in sachet form)	Paragraph 5.22

Weekly tests - performed by User or by delegation, Operator (includes daily tests above)	**Description**	**Reference**
Safety checks	Check condition of the door seal and safe operation of doors and door interlocks	Paragraph 5.23
Protein residue test	Confirms that the cleaning process retains the capability of removing protein	Appendix A: A.60 - A.63
Automatic Control Test (ACT)	This test is designed to show the operating cycle functions properly and that the disinfection temperature/ time are within the original specification	Appendix B: B.119 - B.123

Quarterly tests - performed by CP(D) (includes weekly tests above)	**Description**	**Reference**
Cleaning Efficacy test	Application of test soil onto a full worst-case load to check that the cleaning process is adequate for removing protein	Appendix B: B.74 – B.89

Quarterly tests - performed by CP(D) (includes weekly tests above)	**Description**	**Reference**
Ultrasonic activity	Test to check for a uniform ultrasonic activity throughout the bath	Appendix C: C.1 - C.6
Drainage - Free drainage	To check that no residual water remains in the load at cycle completion	Appendix B: B.21 - B.37
Verification of calibration	The accuracy of indicating and recording instruments is checked against certificated source instruments	Appendix B: B.90 - B.93

Annual tests - performed by CP(D) (includes Quarterly tests above)	**Description**	**Reference**
Water system	Water quality should remain within manufacturer's recommended levels such as chemical purity, hardness.	Appendix B: B.131 - B.168

Daily/ Weekly testing

5.20. Manufacturer's IFUs should always be followed for daily/ weekly testing that involves certain maintenance tasks that should be carried out by the User, or by the Operator under the User's supervision and should be recorded in the UC logbook.

5.21. The daily/ weekly tests schedule listed in Table 5.1 are suggested checks to be carried out. The manufacturer may have additional checks to be completed.

Routine Maintenance

5.22. Regular daily maintenance tasks should include:

- removal of strainers and filters for cleaning then replace back into position
- draining the chamber bath at the end of each morning and afternoon session to ensure contaminated water is not stored in the bath. The period of changing the water may vary depending on loads processed, such as when water is visibly contaminated
- checking that the supply of process chemicals is in date and sufficient for the day's use and replenished, as necessary. This may be in tablet/ sachet form or distributed from a container
- cleaning of the internal/ external surfaces of the UC

Safety Checks

5.23. Safety checks are undertaken throughout the lifetime of the UC. Initially at the validation stage prior to use and subsequently during the periodic testing when the UC is operational. Certain specific weekly safety tests should be carried out as part of the periodic test schedule. These safety checks should include:

- inspection of the UC door seal(s) to ensure no wear and tear is found
- the performance and security of door safety devices to ensure the door locks when in use

5.24. Additional weekly checks involve:

- automatic control test (ACT) - this test is carried out to show the operating cycle functions correctly and is consistent. See Appendix B: B.119 - B.123 for details. The test can be carried out by checking the WD printout if relevant data is present, for example disinfection hold time and temperature. If not, a stopwatch should be used
- protein residue test - to confirm the WD is cleaning satisfactory. This can be achieved by using a protein detection method, as detailed in Appendix A: A.60 - A.63. Manufacturer's instructions for the protein detection method should be followed

6. Lubricators and Heat sealers

6.1. Lubricators are mainly used during the reprocessing of dental handpieces. All lubricators should comply with Medical Device Regulations 2002, as a critical medical device for decontamination.

6.2. Refer to manufacturer instructions for the type of lubrication required for a dental handpiece and the point(s) at which lubrication should be applied. For example, washer disinfectors (WDs) might remove lubrication during the cleaning cycle; therefore, the handpiece may require further lubrication.

6.3. Manufacturer's recommendations for lubrication should always be followed. See also Scottish Health Technical Memorandum (SHTM) 01-05 part C for more information on lubrication.

Types of lubricators

6.4. There are several varying types of lubricators on the market available that will provide automatic instrument maintenance. This is the preferred method to provide a repeatable process to ensure the correct functioning and long working life of dental instruments, for example handpieces.

6.5. Lubricators currently obtainable have various capabilities with some offering automatic lubrication, whilst others state both an automated cleaning and lubrication system. However, unlike a washer disinfector, depending on the type of lubricator used, it may not disinfect or clean. Whatever lubricator is used, it should comply with manufacturer's instructions for the device processed, such as dental handpiece.

Note 19: Lubricators that include a cleaning stage are not within the scope of this document.

6.6. Where cleaning agents are required follow the manufacturer's recommended guidance for compatible detergents that are suitable for medical devices.

Maintenance and testing of lubricators

6.7. Manufacturer's instruction should always be followed for content and frequency and may vary with different products. The following are suggested checks:

- cleaning of external surfaces, cover, and waste disposal trays
- check filling level displays
- o-ring checks for damage or potential leaks
- function checks

- filter checks for contamination on suction and air filters

General information on lubricants

6.8. Lubricants, usually in aerosol form, are often used during the decontamination and preparation process. This is often required by the manufacturer to lengthen the working life of some instruments. Manufacturer's instructions should be followed. Any doubts about the relevance of these instructions should be checked and confirmed in writing by the manufacturer.

6.9. It should be noted that using lubricants will inevitably introduce oils into a process designed to remove contamination. Where water is reused in the sterilizer, this contamination may build up within the reservoir and the sterilizer chamber. However, this effect will be limited if water is changed at least daily.

6.10. There is a limited conflict between decontamination and the use of lubricant. If lubrication is practiced in accordance with manufacturer's instructions, the consequence of this recontamination should be assessed. This assessment will require consultation with the equipment manufacturer or service agent, who should be asked to approve the choice of lubricant used.

6.11. Lubricants used in conjunction with automated equipment should be as recommended by the manufacturer and compatible with the devices to be lubricated.

Note 20: Manufacturers may advise additional lubrication of handpieces post sterilization. A separate lubricator should be in place for this purpose to avoid re-contamination from the lubricator used at the wash stage.

Heat sealers

6.12. Local Decontamination Units (LDUs) may use self-seal pouches for vacuum sterilizers to ensure dental instruments remain sterile after sterilization. However, there is also the option to use bags or pouches with a heat sealer.

6.13. Heat sealers are machines or devices that are used to seal a wide variety of materials to suit many applications.

6.14. Bags or pouches when put through the heat sealer will be hermetically sealed, ensuring that the dental instruments inside remain sterile after completion of a satisfactory vacuum steam sterilization cycle.

6.15. The method of sealing should ensure that the microbial barrier properties are preserved and that the pack can be opened aseptically.

6.16. Heat seals are dependent for their success on the performance of the heat sealer used.

6.17. The seal integrity and strength are affected by the temperature, pressure, and dwell time of the heat-sealing equipment. The design of many heat sealers makes effective monitoring, calibration, and adjustment of the operating conditions difficult.

Maintenance and validation requirements for heat sealers

6.18. Any heat sealer which is to be used for sealing packs for sterilization should be maintained and monitored regularly for the controlling variable of temperature, pressure, and dwell time. Machines which cannot be independently tested should not be used.

6.19. Regular maintenance as per manufacturer's instructions should be followed to ensure ongoing seals are fit for purpose.

6.20. The heat sealer should be validated at installation and be subject to routine periodic validation in line with the heat sealer manufacturer's instructions for use and completed by a suitably qualified Competent Person (Decontamination) (CP(D)).

6.21. Clause 3.3.2.7 of technical specification PD CEN ISO/TS 16775: 2021 provides guidance on validation of heat sealers.

6.22. Typical quarterly and yearly periodic tests that may be performed as per manufacturer IFUs on a heat sealer are specified below see Table 6.1.

6.23. Three batches or sets of sealed sterile barrier systems should be made; these batches should encompass the potential significant sources of variation such as operator, time of day, material (size, source, and lot), sterile barrier system contents. Package contents that present the greatest challenge (worst-case) should be included.

Table 6.1 - Heat sealer quarterly and yearly periodic tests

Test	Frequency
Recording of key critical variables including temperature, temperature uniformity, pressure, pressure uniformity, dwell time.	Quarterly and yearly
Verification of calibration (using the procedure and tolerances recommended by the manufacturer of the sealing machine).	Quarterly and yearly
Thermometric measurement of actual seal temperature (using thermometric measuring equipment specified in Section 3 of this SHTM)	Yearly
Visual test of seal integrity • intact seal for a specified seal width • no channels or open seals, no bubbles	Quarterly and yearly
Visual test of package integrity - No punctures or tears	Quarterly and yearly

Test	Frequency
Seal strength (tested according to Annex D of *BS EN 868-5:2018. EN 868-5 indicates a minimum reference value of 1.5 N per 15 mm for steam sterilization processes and 1.2 N per 15 mm for other sterilization processes)	Yearly
Peelability (tested according to Annex E of BS EN 868-5:2018)	Yearly

Operation of heat-sealing equipment

6.24. Heat sealing machines must be in good condition, properly set and maintained to the manufacturer's specification, and closing and sealing operations should be under constant supervision.

6.25. For heat sealing operations the critical variables of temperature, temperature uniformity, pressure, pressure uniformity, dwell time, and the characteristics of the packaging materials, for example, the type, thickness, and uniformity of the heat seal adhesive, should, ideally, be verified at regular intervals.

6.26. The efficacy of the seals should be tested and proved on a regular basis, not less than daily for each heat sealer when in use.

6.27. As a minimum, daily heat-sealing records should be kept, and these should be reviewed quarterly; there should also be a quarterly check on the temperature control of each heat sealer.

6.28. Several methods for testing heat seals are available. For daily production checks, a dye penetration test or a test using a commercially available seal indicator paper can be performed.

7. Sterilizer

7.1. Steam sterilizers are used to sterilize dental instruments via direct contact of the load items with good quality saturated steam at a defined temperature and time to render them free from viable microorganisms.

7.2. Saturated steam under pressure delivered at the highest temperature compatible with the product is the preferred method for the sterilization of most instruments used in the clinical setting.

7.3. High temperature steam inactivates pathogens by a combination of moisture and heat; water molecules combine with proteins and genetic material, which are then susceptible to thermal disruption. The process is well understood, and the attainment of sterilization conditions can normally be confirmed by simple physical measurements.

7.4. Many high temperature steam sterilizers are large machines requiring permanently installed engineering services (including good quality steam) and purpose-built accommodation. Most Local Decontamination Units (LDU) environments use smaller models which are transportable and generate steam from an internal water reservoir. To facilitate sterilization; load items should first be thoroughly cleaned (and disinfected where a washer disinfector (WD) has been used).

7.5. The operating cycles are designed to cope with the differing properties of the diverse types of loads, and it is essential that a sterilizer is used only for the type of load for which it is designed.

Types of sterilizers

7.6. The majority of steam sterilizers within the LDU setting are transportable benchtop models which are electrically heated, requiring only a 13A socket and no piped services.

7.7. Steam is generated within the sterilizer chamber and a supply of distilled, de-ionised, or reverse osmosis (RO) water is required. Tap water should not be used as it may cause scaling and chlorine dissolved in the water may corrode the chamber.

Note 21: Freshly distilled/ deionised water from distilling/deionising units may be produced for immediate use but not stored. If using bottled deionised water remaining contents must be discharged at end of session once opened.

7.8. Most steam sterilizers used in LDUs will have a chamber volume of less than 60 L and thus are considered to be small devices within the standards applied by national and international bodies.

7.9. BS EN 13060:2014 + A1 2018 describes three types of small sterilizer used within the healthcare setting:

- **type N**: air removal in type N sterilizers is achieved by passive displacement with steam. They are non-vacuum sterilizers designed for non-wrapped solid instruments. These sterilizers are not designed for reprocessing instruments with a lumen
- **type B (vacuum)**: type B sterilizers incorporate a vacuum stage and are designed to reprocess load types such as hollow, air-retentive, and packaged loads. Several different cycles may be provided. Each cycle should be fully validated and used in accordance with instructions provided by both the sterilizer and the instrument manufacturer. Users should be aware that type B benchtop sterilizers can incur financial implications in comparison with a type N design, as the technical nature of design will require additional maintenance, and require an in-depth validation regime in accordance with current guidance to include regular steam penetration and air testing
- **type S**: these sterilizers are specially designed to reprocess specific load types. The manufacturer of the sterilizer will define exactly which load, or instrument, types are compatible. These sterilizers should be used strictly in accordance with these instructions.

7.10. Types B and N sterilizers are most frequently used in dental practices.

7.11. Where a sterilizer is installed with multiple cycle options, it is important to note that all the cycles configured within the control memory require periodic validation to current guidance. If there are cycle options that are configured and not used, they should be deleted or disabled to prevent unauthorised use. Single cycle options are preferred where benchtop sterilizers are used.

Note 22: All cycles to be used on the sterilizer must be validated and periodically tested, with written reports and charts for audit.

7.12. In each case, practice staff should consult with the manufacturer and supplier of the sterilizer to ascertain the status of the machine in respect of validation and verification and the recording of parameters achieved during sterilization cycles.

Air removal

7.13. The presence of air in the load can impede the penetration of steam and drastically reduce the effectiveness of the sterilization process. Type N sterilizers remove air through passive displacement. Type B and S benchtop sterilizers have an active air removal system in which air is replaced with steam by a series of vacuum and pressure changes. A sterilizer conforming to BS EN 13060:2014 + A1 2018 in conjunction with air detection tests included in this guidance, which is validated according to the schedule set out in this section should be capable of removing sufficient air from the chamber.

Sterilizer conditions and time

7.14. The time–temperature relationships for sterilization by steam is defined for two ranges, see Table 7.1.

Table 7.1 - Time-temperature relationship for sterilization by steam

Sterilization parameters for saturated steam	121°C cycle	134°C cycle
Minimum temperature [°C]*	121	134
Maximum temperature [°C]	124	137
Minimum holding time [min]	15	3

* The temperature setting on the automatic controller will not generally be the sterilization temperature, but a higher temperature within the sterilization temperature band.

7.15. The time required to complete an operating cycle depends both on the design and configuration of the sterilizer (especially the methods used to remove air from the chamber and to heat and cool the load) and on the type and size of load to be processed.

Sterilizer specifications

7.16. The National Procurement (NP) framework NP143 for decontamination equipment should be used as the basis for selection of suitable equipment suppliers. It is essential that Health Boards and General dental practitioners (GDPs) fully explore their individual requirements and draft a detailed user/ site specific specification for the equipment being procured as prerequisite to a mini competition. This should enable comparison to be made between suppliers on a like-for-like basis. Refer to Scottish Health Technical Memorandum (SHTM) 01-05 part A Appendix 2 ‘Procurement of Equipment’ for guidance.

7.17. Sterilizers should conform to the specifications of British Standards (BS) EN 13060:2014 + A1 2018 and BS EN IEC 61010-2-040: 2021. Purchasers should refer to Scottish Health Planning Note (SHPN) 13 part 2 Decontamination Facilities: Local Decontamination Units, 2008, when preparing a specification for a sterilizer. The definition for sterilization can be found in BS EN 556-1: 2001 and monitoring of steam sterilization in BS EN ISO 17665-1:2006.

7.18. Manufacturers should provide certification to the purchaser that the particular design of the equipment is manufactured in conformity with all relevant UK and European Union (EU) standards, national guidance, and regulations. Sterilizers are covered by several European Regulations/ Directives and are thus required to be in conformance. Relevant directives include but are not restricted to:

- Medical Device Regulation 2002
- Electromagnetic Compatibility Directive (2014/30/EU)
- Low voltage Directive (2014/35/EU)
- Pressure Equipment Directive (2014/68/EU)
- Machinery Directive (2006/42/EC)

Pressure systems safety regulations

7.19. All steam sterilizers are subject to the Pressure Systems Safety Regulations (PSSR) and must be examined periodically by a Competent Person (Pressure Systems) (CP(PS) as per the written scheme schedule.

7.20. Requirements of the PSSR 2000 (amended) should be met. Advice should be sought from the CP(PS). The CP(PS) has three principal duties under the Regulations:

- advising on the scope of the written scheme of examination for each pressure vessel
- drawing up the written scheme of examination or certifying the scheme as being suitable
- carrying out examinations in accordance with the written scheme, assessing the results and reviewing the written scheme for its suitability

7.21. The User and Approved Person (Decontamination) (AP(D)) should co-operate closely with the CP(PS) to ensure that the written scheme of examination is accommodated within the maintenance and testing programmes. The written scheme may require certain examinations to be carried out more frequently than recommended by the manufacturer. Each scheme should include detailed procedures and frequency of examination and be regularly reviewed and updated.

Using a small steam sterilizer

7.22. Each sterilizer will have a reservoir chamber from which the water is delivered for steam generation; this should be filled daily using water of a suitable quality. A practical approach should be adopted using good operational practice.

- the quality of water used should meet the requirements for sterile water for irrigation as per pharmacopoeia. Sterile water for irrigation is non-pyrogenic distilled water that has been sterilized. It has an endotoxin level less than 0.25Eu/ml and as an option is readily available from pharmacies for bulk supply
- alternative water supplies can be distilled/ deionised or RO if there is a problem sourcing water of the required standard (see Section 4 - water supply for more information). The use of water for irrigation is preferable to distilled water, as the quality of distilled water cannot be guaranteed
- at the end of the day or whenever the sterilizer is to be unused for several hours, the chamber should be drained after the water has cooled and all internal surfaces that are accessible should be rinsed with suitable quality water, dried, and left empty with the door kept open
- for single-shot types, which does not store water between cycles of use, these rules still apply in terms of the water quality to be used when the sterilizer reservoir is to be replenished, it should be refilled with suitable water quality to the level recommended by the manufacturer

Note 23: The NHSScotland sustainability policy and any other local sustainable policies should be considered when deciding on method used to supply the correct quality of water for irrigation.

A policy for NHSScotland on the climate emergency and sustainable development

Validation and periodic testing schedules

Initial validation

7.23. Sterilization is a process whose efficacy cannot be verified retrospectively by inspection or testing of the product. For this reason, sterilization processes should be validated before use. The performance of the process should be monitored routinely, and the sterilization equipment should be maintained in accordance with the manufacturer's instructions for use, see section 2 for maintenance, validation, and periodic testing requirements.

7.24. Validation is necessary to demonstrate that the physical conditions required for sterilization (temperature, pressure, and time) are achieved. Consultation with appropriately qualified engineers through the Health Board or commercial arrangements will be necessary in this area. A qualified Competent Person (Decontamination) (CP(D)) will be able to ensure that validation is achieved, and that the instrumentation used for parametric release is functioning and calibrated appropriately. The CP(D) will be needed to validate or revalidate the equipment.

Note 24: Parametric release is defined as the release of a batch of sterilized items based on data from the sterilization process. All parameters within the process must be met before the batch can be released for use. It is important that regular monitoring, testing and validation is carried out to ensure confidence in the parametric release method.

7.25. Testing is an integral part of ensuring that a small sterilizer consistently performs to operating parameters set during the machine's commissioning. Failure to carry out routine periodic tests and maintenance tasks could compromise safety and have legal and insurance-related implications for the User (see SHTM 01-05 part A).

7.26. Table 7.2 below illustrates the sequence of testing required for a sterilizer and supporting equipment/services required to validate it for initial use in production at the LDU as per BS EN 13060:2014 + A1 2018 with additional air detection tests.

Note 25: Not all vacuum sterilizers may have an air detector (A/D) fitted and therefore the A/D performance and functions tests may be omitted from initial validation and periodic tests.

7.27. Test methods for performing each of the tests included in the table are detailed in Appendix D.

Table 7.2 - Initial installation and validation tests - performed by manufacturer CP(D)

Test	Description	SHTM 01-05 pt B Ref
Safety checks	As per manufacturer instructions - check door seal, door safety devices and other safety checks required as per written scheme of examination for the pressure vessel, such as chamber safety valve	Paragraph 7.38 - 7.47
Automatic Control Test (ACT)	This test is designed to show the operating cycle functions properly and that the whole cycle including sterilizing temperature/ time are within the original specification	Appendix D: D.21 - D.31
Bowie and Dick or Helix test (Type B/S sterilizers only)	Check for steam penetration NB: This test can be combined with the ACT	Appendix D: D.4 – D.20
Air leakage test (Type B/S sterilizers only)	Check for excessive air in chamber (Sensors connected and removed)	Appendix D: D.32 - D.41
Verification of calibration	The accuracy of indicating and recording instruments is checked against certificated source instruments	Appendix D: D.62 - D.65
Thermometric test - small load (Porous load)	Check to measure temperature spread throughout the test load and chamber	Appendix D: D.78 - D.84
Thermometric test - full load (Porous load - Type B/S sterilizers only)	Check to measure temperature spread throughout the test load and chamber	Appendix D: D.85 - D.94
Thermometric test - small load (Solid load)	Check to measure temperature spread throughout the test load and chamber	Appendix D: D.66 – D.71
Thermometric test - full load (Solid load)	Check to measure temperature spread throughout the test load and chamber	Appendix D: D.72 - D.77

Test	Description	SHTM 01-05 pt B Ref
A/D performance test - small load (Type B/S sterilizers only)	To determine the A/D setting for a small load	Appendix D: D.42 - D.61
A/D performance test - full load (Type B/S sterilizers only)	To determine the A/D setting for a full load	Appendix D: D.42 - D.61
Performance Requalification Test (PRQ)	Additional tests that may be required as per initial validation and as specified by User, including Narrow Lumen test D.133-139, Simple hollow test D.140-143	Appendix D: D.119 D.119 - D.126
Load dryness (Solid (Type N) and Porous load (Type B/S sterilizers only))	Check metal and porous load dryness - NB: This test can be combined with the Thermometric full load test	Appendix D: D.110 - D.118 (Can be combined with relevant thermometric tests above)
A/D function test (Type B/S sterilizers only)	Check sterilizer fails with air leak	Appendix D: D.42 - D.61
Overheat cut-out	To ensure sterilizer cut-out operates to prevent temperature from exceeding manufacturers upper limit	Appendix D: D.106 - D.109
Microbiological tests for Performance Qualification (PQ)	Additional biological tests to confirm sterility assurance levels are met	Appendix D: D.127 - D.132
Narrow lumen test (Type B/S sterilizers only)	Additional test to demonstrate a basic minimum level of steam penetration in a narrow lumen	Appendix D: D.133– D.139
Simple hollow item test (Type B/S sterilizers only)	Additional test to demonstrate a basic minimum level of steam penetration in a single ended hollow device	Appendix D: D.140– D.143

Periodic testing - daily, weekly, quarterly and annually

7.28. As per Section 2, manufacturer's Instructions for use (IFU) should be followed for periodic testing after the initial validation has been completed. However, periodic testing protocols will vary between manufacturers and therefore a risk assessment should be taken to assess if the testing being carried out is adequate. If the manufacturer's recommended testing schedule is inadequate to highlight a potential issue, then the recommended tests below should be considered.

7.29. In the absence of manufacturer's instructions or where there are inadequate or unclear manufacturer instructions, the frequency, methods, and outcomes of tests must follow current guidance and the appropriate British Standard (BS).

7.30. Recommendations for periodic tests are defined in BS EN 13060 :2014 + A1 2018 including additional air detection tests as best practice guidance. These tests are carried out at daily, weekly, quarterly, and annual intervals. It is recommended that periodic testing is performed as defined in Table 7.3 below. Any additional tests defined by the manufacturer should also be performed.

7.31. Tests should only be undertaken after completion of the planned maintenance tasks described in Section 2.

7.32. All periodic tests should be carried out with the machine at normal working temperature, which may require a warm-up run to be carried out before commencement of testing. The manufacturer's instruction manual should be consulted to find out whether this is the case.

7.33. The results of periodic tests should be recorded, documented, and filed securely, in electronic or paper format. See SHTM 01-05 part A Section 7 'Documentation and Traceability' for record retention.

Table 7.3 - Periodic tests for Type N,B and S sterilizers

Daily tests - performed by User or be delegation, Operator	**Description**	**Reference**
Bowie and Dick or Helix test (Type B/S sterilizers only)	Check for steam penetration	Appendix D: D.4 – D.20

Weekly tests - performed by User or by delegation, Operator (includes daily tests above)	**Description**	**Reference**
Safety checks	Check condition of the door seal and safe operation of doors and door interlocks	Paragraph 7.40 - 7.44
Automatic control test (ACT)	This test is designed to show the operating cycle functions properly and that the sterilizing temperature/ time are within the original specification	Appendix D: D.21 - D.31 (Sterilizing hold time checked via printout - Can be combined with Bowie and Dick, or Helix, steam penetration test if required)
Air leakage test (Type B/S sterilizers only)	Check for excessive air leakage into the chamber	Appendix D: D.32 - D.41
A/D function test (Type B/S sterilizers only)	Check sterilizer fails with air leaks	Appendix D: D.42 - D.61

Quarterly tests - performed by CP(D) (includes weekly tests above)	**Description**	**Reference**
Automatic Control Test (ACT)	This test is designed to show the operating cycle functions properly and that the whole cycle including sterilizing temperature/ time are within the original specification	Appendix D: D.21 - D.31 (Full cycle checked - can be combined with Bowie and Dick steam penetration test if required)
Air leakage test (Type B/S sterilizers only)	Check for excessive air in chamber (Sensors connected and removed)	Appendix D: D.32 - D.41 (Additional checks to be made with test equipment attached and removed when tests completed)
Verification of calibration	The accuracy of indicating and recording instruments is checked against certificated source instruments	Appendix D: D.62 - D.65
Thermometric test for small load (Type-N sterilizer)	Check to measure temperature spread throughout the test load and chamber	Appendix D: D.66 - D.71
Thermometric test for small load (Type-B sterilizer)	Check to measure temperature spread throughout the test load and chamber	Appendix D: D.78– D.84

Annual tests - performed by CP(D) (includes Quarterly tests above)	**Description**	**Reference**
Yearly safety checks	As per manufacturer instructions which may include power, water supply, door checks, chamber safety valve	Paragraph 7.45 - 7.47
A/D performance test - small load (Type B/S sterilizers only)	To determine the A/D setting for a small load	Appendix D: D.42 - D.61

Annual tests - performed by CP(D) (includes Quarterly tests above)	**Description**	**Reference**
A/D performance test - full load (Type B/S sterilizers only)	To determine the A/D setting for a full load	Appendix D: D.42 - D.61
Thermometric test - full load (Solid load)	Check to measure temperature spread throughout the test load and chamber	Appendix D: D.72 - D.77
Thermometric test - full load (Porous load - Type B/S sterilizers only)	Check to measure temperature spread throughout the test load and chamber	Appendix D: D.85 - D.94
Load dryness (Solid (Type N) and Porous load (Type B/S sterilizers only))	Check moisture content has not increased in load	Appendix D: D.110 - D.118
Overheat cut-out	Check sterilizer aborts under fail condition (Can be combined with relevant thermometric tests above)	Appendix D: D.106 - D.109
PRQ test	Additional tests that may be required as per initial validation and as specified by User	Appendix D: D.119– D.126
Microbiological tests for Performance Qualification (PQ)	Additional biological tests to confirm sterility assurance levels are met	Appendix D: D.127 - D.132
Narrow lumen test (Type B/S sterilizers only)	Additional test to demonstrate a basic minimum level of steam penetration in a narrow lumen	Appendix D: D.133– D.139
Simple hollow item test (Type B/S sterilizers only)	Additional test to demonstrate a basic minimum level of steam penetration in a single ended hollow device	Appendix D: D.140– D.143

Daily testing and maintenance tasks

7.34. Before carrying out the daily tests, the user should:

- clean the rubber door seal with a clean, damp, non-linting cloth
- check the chamber and shelves for cleanliness and debris
- fill the reservoir with water of a suitable quality (for example water for irrigation) or RO if no alternative is available
- turn the power source on

7.35. The daily tests should be performed by the operator or User and will normally consist of:

- a steam penetration test - Helix or Bowie and Dick tests for type B or S vacuum sterilizers only

7.36. Sterilizers should not be used until the daily tests and maintenance tasks have been carried out and the results found to be satisfactory. Correct loading of instruments and equipment is essential to ensure effective sterilization. Reference should be made to the instructions and illustrations included in the manufacturer's handbook to ensure correct loading every time.

7.37. If the sterilizer fails to meet any of the test requirements, it must be withdrawn from service and advice should be sought from the manufacturer or maintenance contractor. Any instruments processed in an unsuccessful cycle must not be used.

Weekly tests

7.38. In addition to the daily test, the following weekly checks should be made in accordance with manufacturer's instructions. See Table 7.3 for a schedule of periodic tests, including daily/ weekly tasks.

7.39. The tests should be performed by a qualified CP(D), but the user may perform them if suitably trained.

7.40. The User should perform the following weekly checks:

- examine the door seal for signs of deterioration or leaks
- check the security and performance of door safety devices
- an ACT for all small sterilizers in line with manufacturer's instructions

Note 26: **Warning - do not attempt to open the door while the chamber is pressurized. Any defects must be corrected before attempting the weekly tests or before using the sterilizer.**

7.41. The sterilizer hold times and temperature found during the ACT should be recorded in a logbook together with the date and signature of the operator.

7.42. The ACT and steam penetration tests may be carried out at the same time. See Appendix D for further details on the ACT and steam penetration tests.

7.43. An air leakage test is relevant for type B/S sterilizers only and is intended to check that air will not leak into the sterilizer during periods of vacuum, at a rate that is greater than that specified by the sterilizer manufacturer. See Appendix D for details.

7.44. Air leaking into the chamber can:

- impair steam penetration into the load and prevent sterilization
- re-contaminate the damp load during the drying phase

Yearly safety checks

7.45. In order to ensure the safe functioning of the sterilizer, the CP(D) should conduct a sequence of safety checks before starting the yearly tests.

7.46. Initial validation test safety checks and manufacturer's recommendations should a basis for these. In selecting which checks to include in the yearly schedule, consideration should be given to conditions which affect safety and to those which may have changed over time, such as chamber safety valve.

7.47. It will not be necessary, for example, to check again that the sterilizer has been supplied in accordance with specification, but it will be necessary to check that the engineering services remain adequate and are connected safely.

Note 27: All gauges fitted to the sterilizer should be checked for correct functioning

Records

7.48. Each sterilizer should have an automatic printer. The printout should be kept or copied to a permanent record. The User will also manually record the following information in the process log/ equipment logbook as part of daily/ weekly periodic testing:

- date
- satisfactory completion of the cycle (absence of fault recognition indicator)
- temperature/ pressure achieved
- signature of the operator

7.49. With newer machines, the parameters monitored for each cycle of use will be stored and/or available as a downloadable file or a print-out to provide a short-term record.

7.50. The use of automated dataloggers or interfaced small computer-based recording systems is acceptable provided the records are kept securely on a reliable network and replicated.

Appendix A Test equipment use, test methods and consumables

Test equipment calibration

A.1 Test equipment should be subject to a planned maintenance and calibration programme, in accordance with the manufacturer's recommendations, occurring at least annually. The drift status of test equipment should be monitored to ensure that they remain within their intrinsic specification. The stability of the equipment should be reviewed to ensure the maximum calibration interval of 1 year is satisfactory. If not, the interval may require shortening. Each instrument or piece of test equipment should be labelled with a unique identifier, calibration date and a reference from which its current calibration status may be traced.

A.2 Calibration of the test equipment should be carried out in accordance with the equipment manufacturer's instructions by a validated method, using a reference standard of suitable accuracy that has been certified within the previous 12 months by a British Standard (BS) EN ISO/IEC 17025: 2017 accredited test laboratory. The calibration laboratory should be instructed to adjust the test equipment under the test to read true values, and to report before and after calibration results so that instrument drift can be monitored. A full history record, including all maintenance and calibration details, should be kept for each test instrument. A written procedure that describes the calibration method should be prepared and made available for the Authorising Engineer (Decontamination) (AE(D)) to review. Be aware of the difference between a calibration check and a calibration.

A.3 The test equipment should have a valid calibration test certificate. The calibration data should cover the range of measurement required for the parameter being tested and include at least one measurement within the process operating band. Examples would include:

- a temperature within the disinfection temperature band
- a pressure within the operating range of the water pump during the wash stage for washer disinfector (WD) and a pressure under vacuum in sterilizer cycle used for drying stage
- a temperature within the sterilizing temperature band and a pressure within the equivalent sterilization pressure range

A.4 In use, all test equipment instruments, where applicable, should be in a position protected from draughts and not subjected to rapid temperature variations. Test equipment instruments, where applicable, should be allowed a period of time to stabilise within the environment of the test site. The manufacturer's instructions should be followed.

Self-contained measurement and recording systems

A.5 Several different designs of small self-contained single or multi-channel data loggers for the measurement of temperature and pressure are commercially available. They are independently powered, may be programmed to take readings at the required rate for the required duration, and may either transmit data wirelessly in real time or require it to be downloaded.

A.6 These can be used for most temperature and pressure measurements but are especially useful where it is impractical to insert sensor leads into processing equipment. In some cases, where either real time data transmission is not required or the wireless system has sufficient power to transmit the data through the sterilizer chamber wall, the chamber integrity does not need to be disturbed to undertake testing of a sterilizer. This can lead to a considerable reduction in time associated with leak testing after insertion and removal of sensors.

A.7 Care needs to be taken in selecting units that can withstand the high temperatures found in sterilizers and WDs. Those housed in protective cases rated at IP68 (as defined in BS EN 60529:1992+A2:2013) are suitable for inclusion in WDs.

A.8 The accuracy, resolution and sampling rate requirements should be as detailed in Test equipment specification. Self-contained measurement and recording systems should comply with the requirements of BS EN 13060:2014 + A1 2018 or BS EN ISO 15883-1 :2009 + A1 2014, and BS EN ISO 15883-2:2009.

A.9 They should be capable of measuring the temperature of the test load items described in this part of Scottish Health Technical Memorandum (SHTM) 01-05 and not only the temperature of the datalogger (such as within the jaws of an instrument or the surface of a chamber). This will necessitate the use of loggers with flying leads.

A.10 The temperature sensors contained within these devices are usually platinum resistance thermometers. These do not suffer from short term calibration drift to the extent that thermocouple-based system does. Therefore, if short term drift of the device can be demonstrated to be negligible between annual calibration intervals, the requirements of the test equipment verification section do not apply. However, if this cannot be demonstrated to the satisfaction of the AE(D) with calibration data, it is not acceptable to undertake testing using self-contained data loggers without undertaking test equipment verification of calibration. This will necessitate the use of loggers with flying leads for temperature measurement that can be immersed in an independent temperature reference source. Pressure measurement data loggers will need to allow connection to a pressure calibrator for the same reason.

A.11 Where two or more data loggers are used together on the same process; the time bases of the instruments should be synchronised. For presentation of results, it must be possible to show the graphical representation of all the loggers used during a particular test onto the same chart.

A.12 Sufficient data loggers to meet the testing requirements of the SHTM 01-05, BS EN ISO 15883-1 :2009 + A1 2014, BS EN ISO 15883-2:2009 and BS EN 13060:2014 + A1 2018 will be needed.

Data recorders with separate sensors

A.13 Data recorders are required to measure temperature and pressure in all types of decontamination equipment and may also be required for the measurement of flow rates and other critical parameters. They should be designed for use with the appropriate sensors, independent of those fitted to the machine.

A.14 Sufficient input channels and connections to meet the testing requirements of the SHTM 01-05, BS EN ISO 15883-1 :2009 + A1 2014, BS EN ISO 15883-2:2009 and BS EN 13060:2014 + A1 2018 should be provided.

A.15 The accuracy, resolution and sampling rate requirements should be as detailed in the test equipment specification section. Data recorders should comply with the requirements of BS EN 13060:2014 + A1 2018 or BS EN ISO 15883-1 :2009 + A1 2014, and BS EN ISO 15883-2:2009.

A.16 The accuracies quoted by data recorder manufacturers are measured under controlled reference conditions and do not include the errors from connected sensors. The entire system should be calibrated.

Test equipment specification

A.17 Data from digital test equipment can be presented graphically or as a listing of numerical values, or as a combination of both. In many cases, parts of the operating cycle can be expanded and re-plotted for closer examination.

A.18 They should have the facility to record data immediately that can then be removed for secure storage. Alternatively, the digital test equipment may be connected to a central computer and the data recorded to the hard drive. Software used with digital test equipment should be developed and validated under a recognised quality system (such as BS EN ISO 9000: 2015 or if appropriate BS EN ISO 13485: 2016: +A11: 2021).

A.19 The detailed specification will depend upon the range of equipment with which it is to be used. The complete measurement system (both recorder and sensors in the case of data recorders) should be capable of measuring cycle variables to the required accuracy of the instruments fitted to the machine.

A.20 The accuracy with which a variable can be read will be affected not only by the sources of error discussed above but also by the precision of the calibration, the scale range, the integration time, the sampling interval, and the intrinsic accuracy of the test equipment. Digital instruments may display measured values with a greater level of discrimination than

the accuracy of the system as a whole: care needs to be taken with the configuration of outputs and the interpretation of the measured values. The scale ranges should include the expected maximum and minimum values of the cycle variables throughout the operating cycle, with sufficient leeway to accommodate any deviations resulting from a malfunctioning machine.

A.21 At all stages of the WD or sterilizer operating cycle, the values of the variables are critical, and the equipment should be capable of measuring them to sufficient accuracy to confirm that the process conditions have been attained.

A.22 For digital test equipment, the sampling interval should not exceed 1 second per channel and be short enough for the holding time to contain at least five independent measurements in each recording channel. For pen recorders, the chart speed should be fast enough to allow fluctuations on that scale to be clearly resolved. The duration of the holding time should be measurable to within 1%.

A.23 The integration time of the system (the response time) should be short enough to enable the output to follow significant fluctuations in the cycle variables and to ensure that successive measurements are independent of each other. It should not be longer than the sampling interval.

A.24 It should be accurate enough to show clearly whether the measured temperatures are within the band or not. For all the types of equipment covered by this guidance, the repeatability of the temperature measurements should be ± 0.25°C or better, and the uncertainty of measurement of the complete measurement system including sensors should be no more than ± 0.5°C taking all component errors into consideration. Temperature measurement errors due to ambient temperature changes should not exceed 0.04°C per °C rise.

A.25 For analogue instruments the minor mark interval for temperature should not exceed 0.5°C and the chart speed should be not less than 10 mm per minute/600 mm per hour. The resolution should be not less than 0.5°C.

A.26 Digital instruments should register and record in increments of not more than 0.1°C for temperature.

A.27 For pressure measurement, the uncertainty of measurement should be no more than 0.5% of the absolute pressure during the plateau period.

A.28 Attention should also be paid to the accuracy of the time base of the recording system, particularly on longer cycles where any error will become more obvious. This can be by means of a calibrated timepiece against a calibrated time signal.

A.29 The scale range for each variable to be measured should be optimised to cover all values occurring during the process. As well as having calibration certificates for each item of the measuring chain, the complete system should be verified in the working environment (for example, the Local Decontamination Unit (LDU)).

Test equipment verification

A.30 The test equipment should be calibrated and/ or adjusted in a controlled environment or laboratory with relevant BS EN ISO/IEC 17025: 2017 certification and traceable laboratory references. However, before and after each series of tests on any item of decontamination equipment, the measured temperature and pressure test equipment should be verified by comparison with an independent reference source at the process temperatures and pressures. The exception being for self-contained measurement and recording systems discussed earlier.

A.31 The heat source should be of a design that meets the recommendations of publication EURAMET cg-13 Version 3 (previously EA-10.13) 'Calibration of temperature block calibrators'. Precautions regarding temperature block calibrators should be adhered to. Procedures used when applying comparison calibrations should also be in accordance with these guidelines. The comparison reference sources used, such as a digital thermometer and digital or analogue pressure gauge should be traceable to BS EN ISO/IEC 17025: 2017 calibration standards. No adjustment to the test instrumentation should be made on site in an uncontrolled environment unless the test contractor or organisation holds a site calibration procedure and BS EN ISO/IEC 17025: 2017 certification. This includes adjustment which should be available for inspection or audit. Any adjustments made to test instrumentation should be recorded and included within the test report.

A.32 The temperature measured by all temperature sensors when immersed in a temperature source at a temperature known within ±0.1^{o}C and within the process temperature band should not differ by more than 0.5^{o}C. Consider the error of the whole system.

A.33 The pressure measured by all pressure sensors when compared to a pressure reference standard and within the process pressure band should not differ by more than 50mBar.

Temperature measurement

Temperature sensors

A.34 Unless self-contained measurement and recording systems are used, temperature sensors should be used to sense the temperature in locations specified in the tests described in this guidance. The sensors should be either platinum resistance elements and comply with class A (of BS EN 60751:2008 Table 3) or thermocouples and comply with Tolerance Class 1 (of BS EN 60584-1:2013 Table 12). Other sensors of demonstrated equivalence can be used.

A.35 Thermocouple wire should be single strand, not exceeding 0.7 mm diameter over the covering of one core of a twin cable. The width of the cable should not exceed 2 mm. If thicker cable is used, the tracking of steam along the outside of the cable may invalidate certain tests, such as those which require temperatures to be measured in the centre of a standard test pack (the standard test pack is described in BS EN 13060:2014 + A1 2018).

The cross-sectional area of any part of the probe for testing and its connecting wires within the usable space should not exceed 3.1mm^2.

A.36 Thermocouples may be argon arc-welded or micro-welded. However, experience has shown that, provided the wires are cleaned, they may be satisfactorily twisted together to form the hot junction. Brazing, silver brazing and welding with filler rods is no more reliable in respect of accuracy than freshly twisted wires and is therefore discouraged. Thermocouples should not be fitted with a heat sink.

A.37 The performance characteristics of the temperature sensor should not be adversely affected by the environment in which it is placed, for example, pressure, hot detergent solution etc. Certain environments in which thermocouples may be used may be corrosive to certain metals. Thermocouple junctions should be regularly inspected for corrosion, remade, and recalibrated, as necessary.

Thermometric recording instrument(s)

A.38 Thermometric recording instruments should be used in conjunction with the temperature sensors to record the temperatures measured in the locations specified in the tests described in this guidance.

A.39 Guidance on test apparatus designed to introduce thermometric measuring equipment into the sterilizer chamber and WD chamber is provided in BS EN 13060:2014 + A1 2018, BS EN ISO 15883-1 :2009 + A1 2014, and BS EN ISO 15883-2:2009, respectively. Other methods of introducing temperature sensors into a chamber, which guarantee a watertight or gas-tight seal, are equally acceptable.

A.40 All reporting software should be validated, backed-up (with backed-up data being kept in a secure location off-site) and secure to ensure no unauthorised access.

Use of temperature sensors

A.41 Guidance on use of sensors for sterilizers and WDs is provided in BS EN 13060:2014 + A1 2018, BS EN ISO 15883-1 :2009 + A1 2014, and BS EN ISO 15883-2:2009.

Pressure measurement

Measurement ranges

A.42 Pressure measurement ranges for WDs should be up to 1000 kPa [10 bar] (for example, for the water supply pressure). Differential pressures of 0.1 - 10 kPa [1-100 mbar] may need to be measured (for example, for the determination of the pressure drop across filters).

A.43 Pressure measurement ranges for steam sterilizers may be from 3 to 10 kPa [30-100mbar] (in vacuum leak testing) to typically 400 kPa [4000mbar] at the working pressure of a high-temperature steam sterilizer.

Pressure sensors and gauges

A.44 Pressure sensors should be used in the tests described in this guidance and EN 837-2: 1998 Pressure gauges. Selection and installation recommendations for pressure gauges should be consulted.

A.45 The performance characteristics of the pressure sensor should not be adversely affected by the environment in which it is placed (for example, temperature, hot detergent solution and so on). Certain environments in which sensors may be used may be corrosive to certain materials. Compatibility should be confirmed with manufacturer's instructions.

A.46 The scale range requirements for gauges required for testing decontamination equipment vary dependent on the application (see Table A.1).

A.47 Pressure gauges should be temperature compensated and, except for the differential pressure gauge, be Bourdon-tube gauges conforming to BS EN 837-1: 1998 of nominal size 150mm and accuracy class 0.25 (that is, the error should not exceed 0.25% of full-scale deflection).

Table A.1 - Scale range requirements for pressure measurements

Scale range	Mark interval	Calibration	Application
0 to 16 kPa [0 to 160 mbar]	0.1 kPa 0.2 [1 mbar]	Gas	Vacuum leak- testing
0 to 100 kPa [0 to 1 bar]	1 kPa [10 mbar]	Liquid	Differential pressure across water filters
0 to 500 kPa [0 to 5 bar]	5 kPa [50 mbar]	Liquid	Steam sterilizers
0 to 1000 kPa [0 to 10 bar]	5 kPa [50 mbar]	Liquid	Water supply pressure. Recirculating pump pressure
0 to 50 kPa [0 to 500 mbar]	1 kPa [10 mbar]	Air	Differential pressure across air filter

A.48 Gauges not designed for direct connection to steam at 380 kPa [3.8 bar absolute] should be connected via a siphon or similar device to ensure that the accuracy of the gauge is maintained over the temperature range associated with changing steam pressure. If the low-pressure gauge used for vacuum leak testing cannot withstand the pressure in the chamber during sterilization, an automatic valve should be provided to protect it.

Volume measurement

A.49 The volume of process chemicals and the volume of water used in each stage are critical variables in the control of the washing disinfecting process.

A.50 The volume used may be measured directly by collection in a graduated vessel of appropriate size.

A.51 Alternatively, for liquids of known density, the volume may be determined by collection in an appropriate size vessel of known mass (empty), determination of the mass of the vessel and contents, calculation of the mass of the liquid and hence (by dividing this volume by the density) calculating the volume of liquid.

A.52 Whichever method is used, the accuracy should be such that the error is less than ± 2%.

A.53 Volumetric measuring containers complying with BS EN ISO 384: 2015 are suitable.

Balance for measuring weight

A.54 A laboratory balance is required for steam dryness tests, load dryness tests, calibration of flow meters (for measuring the flow of water and/ or process chemicals) and coolant quality tests. It should be capable of measuring the mass of loads up to 4 kg to an accuracy of 0.1g and up to 400g to an accuracy of 0.01g.

Note 28: all balances should be sited in a level manner prior to measurement.

A.55 An analytical balance is required for determination of the Total Dissolve Solids (TDS) (evaporative residue) in feed water. It should be capable of measuring a mass of up to 100g with an accuracy of 0.1mg.

A.56 A balance is also required for weighing the standard small load test pack (900g) and the metal load (6kg) to a 10g resolution.

Timepiece for measuring time

A.57 Measuring time using a calibrated time piece is required. Examples of applications included measurement of stage times for automatic control test, verification of chart recorder time base which is often overlooked as a measurement.

Relative humidity measurement

A.58 Measurement of relative humidity using a calibrated probe is required. Applications include BS EN 13060:2014 + A1 2018 for sterilizer standard test pack using calibrated temp/humidity meter ‘sword hygrometer’.

Conductivity measurement

A.59 Measuring conductivity using a calibrated probe is a requirement. This may be used as part of a series of water quality tests. Be aware that the ambient temperature variation can affect the conductivity measurement.

Methods to measure residual protein on medical devices

A.60 The protein detection test systems listed in the National Procurement (NP) 187 Framework for decontamination consumables should be used. Each test system used should follow manufacturer's instructions, including the use of personal protective equipment (PPE) where required. Research on test systems was carried out in 2016 and reported by Holmes et al., 2017 (A Comparative Study of the Sensitivity of Protein Detection Test Systems for Surgical Instruments | Request PDF (researchgate.net)).

A.61 If a swabbing technique is used, the swabbing should include the crevices, hinges, and other areas accessible for the swab head to access.

A.62 If reagents are added to instruments; the whole medical devices set should re-enter the decontamination route process according to local protocols.

A.63 Any equipment/ system/ chemicals used should be maintained, calibrated (if applicable), stored and used in according to manufacturer's instructions. The results should be interpreted in accordance with the manufacturer's instructions.

Note 29: Interpretation of the results should take account of the possibility of false negative and false positive results.

Note 30: Adherence to the relevant test SOP (Standard Operating Procedures), which will take account of the test equipment manufacturer's instructions, is required to avoid inaccurate results. This includes sample incubation, time, amount of reagent and technique.

Ultrasonic activity

A.64 Aluminium foil of normal thickness 0.015mm to 0.025mm can be cut into strips and used to detect ultrasonic activity patterns throughout the ultrasonic bath chamber. Refer to NP187 contract for decontamination consumables that should be used.

A.65 Ultrasonic energy wand meters are also available to monitor the efficiency and operating frequency of ultrasonic baths and should typically be capable of measuring a range of 35 kHz with an energy input of 5-20 Watts per litre.

Steam penetration

A.66 Bowie and Dick test packs for small steam sterilizers are commercially available for conducting tests. Refer to NP187 contract for decontamination consumables that should be used.

A.67 Manufacturer’s instructions for both usage and storage of the Bowie and Dick test packs should be followed.

Appendix B WD test methods

B.1 This section of gives detailed method for tests required during the initial installation and periodic testing of thermal washer disinfectors (WDs) used in a Local Decontamination Unit (LDU) as described in British Standard (BS) EN ISO 15883 parts 1: 2014 and BS EN ISO 15883-2: 2009. Test equipment calibration methods are detailed in Scottish Health Technical Memorandum (SHTM) 01-05 part B, Appendix A.

B.2 The schedule of tests is listed in Section 4, see Table 4.3 and Table 4.4.

Water supply temperature

B.3 The test should be carried out as an installation and/ or operational test. The test should be repeated when any change is made to the water services supplying the WD, including the connection or removal of additional machines.

Note 31: The water supplied to the various stages of the WD operating cycle should be at an appropriate temperature. If the temperature of the water supplied to the flushing stage is too high (>45ºC) there is a risk of coagulating proteinaceous soiling, which inhibits the cleaning process.

B.4 If the temperature of water supplied to the washing, rinsing and disinfection stages is too low, the WD cycle can be greatly extended, with a significant reduction in throughput, while the water is heated to the required temperature.

B.5 Water supplied in the temperature range 25 to 40ºC presents a serious risk of microbial contamination of the system, for example legionella.

Equipment

B.6 An indicating or recording thermometer should be used.

Method

B.7 Use the following method:

- measure the temperature of the water supply from a sampling point as close to the WD 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 WD 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 WD

Results of testing the water supply temperature

B.8 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

B.9 The test should be carried out as an installation and/ or operational test. The test should be repeated when any change is made to the water services supplying the WD, including the connection or removal of additional machines.

B.10 If the water supply pressure to the WD is below the minimum pressure specified by the manufacturer, the performance and productivity of the WD will be adversely affected.

B.11 If the pressure of the water supply to the WD is above the maximum pressure specified by the manufacturer, the capacity of any overflow may be inadequate. The designed performance characteristics of valves, and so on, may be exceeded and in extreme cases there may be the risk of damage to components of the WD or to medical devices being processed.

Note 32: It is engineering best practice to install pressure gauges at strategic points on the distribution systems of each water supply.

Equipment

B.12 A pressure indicator or recorder covering 0 to 10 bar should be used.

Method

B.13 Use the following method:

- connect the pressure sensor to each of the water supply pipes to the WD, as close to the WD as practicable, on the supply side of the WD isolating valve
- record or observe and note 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

Results of water supply pressure measurement

B.14 The water pressure should remain within the supply pressure limits specified by the WD manufacturer.

Volume of water used per stage

B.15 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 during equipment procurement specifications. In addition, in the event of concerns with WD performance during installation and operational testing, the volume of water used for each stage should be verified.

Equipment

B.16 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 be chosen based on which is most convenient for the particular installation.

Method

B.17 Use the following method:

- fit a water flow meter in each of the water supply pipes, consecutively or concurrently. Follow the water meter manufacturer's instructions for installation. Pay particular attention to the length of uninterrupted straight pipe required on either side of the meter
- measure the volume of water used at each stage of the operating cycle using suitable volumetric measuring vessels. The accuracy of the vessels shall be equal to, or better than, 1% of the volume to be measured, as specified by the manufacturer
- operate the WD with the chamber empty, apart from the chamber furniture. Determine the volume used by comparison of the readings before and after each stage of the process operating cycle
- when the WD is supplied from a readily accessible tanked supply, interrupt the water supply to the tank and mark the water level. Run an operating cycle. Determine the volume of water required to restore the water level in the tank by the addition of a measured volume of water
- for WDs which discharge all the water from the chamber at the end of each stage, obtain an estimate of the volume used by measurement of the discharge from the drain

Results of water used for each stage of the operating cycle

B.18 The volume of water used for each stage of the operating cycle should be within ±5% of the volume specified by the manufacturer.

Fault indication on sensor failure

B.19 A failure of any sensor used as part of the control system of the WD should cause a fault to be indicated by the automatic controller.

Note 33: 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

B.20 Use the following 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
- test each sensor in both ‘open circuit’ and ‘short circuit’ failure modes

Result from testing the automatic controller when a sensor fails

A fault should be indicated during or at the end of the cycle. It should not be possible to open the door the unloading door of a double-door WD without a key or code.

Drainage

Blocked drain protection

B.21 The purpose of blocked drain protection is to prevent spillage and minimise the risk of cross-infection. This test is intended for use both as a type test and as an installation test.

B.22 In the test, the drain is deliberately blocked and successive operating cycles are run until the water level rises to sensor level. The water level should not rise to the door seal.

B.23 A suitable test method is described in BS EN ISO 15883 part 1: 2014 (clause 6.3.8).

Free draining (tanks, chamber, load carriers, pipework)

B.24 Residual water that does not drain from the internal pipework of the WD can provide an environment for microbial growth. This may then colonise the WD posing an infection risk.

B.25 The following checks should be carried out during, works testing (commissioning) and periodic testing to verify that the WD will effectively discharge all the water from the system.

Method

B.26 At the end of the operating cycle check the free draining of the chamber, load carriers and all tanks by examining to ensure no solution remains after draining.

B.27 Visually inspect the pipework flow to the discharge point for signs of fluid retention, including the use of a spirit level when necessary.

Purging of the trap: efficacy of discharge through the trap

B.28 This test is intended to verify that the operating cycle is effective in purging the trap of all waste and soil.

B.29 The test can be carried out as part of the cleaning efficacy test during operational testing.

Equipment

B.30 The following equipment should be used:

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

Method

B.31 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.

Results of checking the trap

B.32 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.

Estimation of dead volume of pipework (type test)

B.33 Residual water that does not drain from the internal pipework of the WD may provide an environment for microbial growth; this can lead to colonisation of the WD pipe work and lead to cross-contamination of the load.

B.34 This test is intended primarily as a type test but is also of value as an installation test or when investigating microbial contamination occurring in a WD. 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

B.35 Volumetric measuring vessels of appropriate size should be used.

Method

B.36 Use the following method:

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

Results of testing the dead volume of pipework

B.37 The volume of retained water should be less than 1% of the volume of water used.

Leak tightness of doors

B.38 The door(s) of the WD are intended to prevent the escape of fluids into the surrounding environment and to ensure freedom from aerosols that may be potentially infectious.

B.39 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

B.40 The following equipment should be used:

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

Method

B.41 Use the following method:

- load the WD, close the door and wipe the joints between the door and the door surround to remove any moisture. Carry out 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
- a further four operating cycles should be run with the checks described above being carried out on the final cycle

Results of the door leak test

B.42 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.

Doors interlock tests

B.43 Security and settings of door safety switches and interlocks should be checked at least quarterly. The setting should be within the limits specified by the manufacturer.

B.44 Maintenance and inspection of door safety devices and door interlocking and chamber sealing systems should be carried out in accordance with the manufacturer's instructions for use.

B.45 The interlocks on door(s) of the WD 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' WDs
- prevent the operator within the IAP room gaining direct access to a load that has not been satisfactorily processed

Operating cycle start interlock

B.46 The interlock should prevent an operating cycle from starting with the door open.

Method

B.47 Use the following 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

Results of testing the door interlock at the start of an operating cycle

B.48 It should not be possible to initiate an operating cycle with the door(s) open. With the door(s) closed it should be possible to initiate an operating cycle.

In-cycle interlock

B.49 An interlock is required to ensure that the door(s) cannot be deliberately or inadvertently opened while the WD is in operation.

Method

B.50 Use the following 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

Results of checking the door interlock during a cycle

B.51 In these circumstances it should not be possible to unlock any of the doors.

Double-door washer disinfectors

Method

B.52 Both during and between operating cycles, attempt to open both the loading and unloading doors both during the operating cycle and on completion of the operating cycle.

Results of the WD double door opening test

B.53 After initiation of an operating cycle:

- it should not be possible to open the loading door until the operating cycle has been satisfactorily completed, the unloading door has been opened and closed, 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 to be opened at the same time

On sensor failure

Method

B.54 Disable each sensor in turn and attempt to open each of the door(s). Where practicable, avoid the undertaking of checks during an operating cycle.

Results of testing when the sensors are disabled

- In each case it should not be possible to open the door(s)

Failed cycle interlock

B.55 The failed cycle interlock should prevent the Operator from removing a load without using a special key, code, or tool.

Method

B.56 During an operating cycle interrupt one, or more, of the services to the WD to cause a cycle failure.

Results of testing the failed cycle door interlock

B.57 A fault should be indicated. It should not be possible to open the unloading door; without the use of a key, code, or tool.

Door opening force

B.58 The mechanism for opening the WD door should not require the use of excessive force. This test need only be carried out during installation qualification or in the event of operational concerns. Measurement of the force required to initiate and sustain the movement of the door opening mechanism.

Equipment

B.59 The following equipment should be used:

- 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

B.60 Attaching 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.

B.61 Attach the spring balance to the door opening mechanism. Open the door, record the force required to initiate and sustain the movement.

Results of testing the door opening force

B.62 The measured value required to initiate or sustain the movement of the door opening mechanism should not exceed 250 Newton’s (for instance a mass of 25 kg).

Chemical dosing systems

B.63 The correct amount of process chemical should be delivered at the right time in the operating cycle to ensure the correct functioning of a WD.

B.64 The process chemical dosing system should be subjected to daily inspection, maintenance, and testing.

B.65 This should include:

- visual inspection of all piping to ensure freedom from leaks
- visual inspection/ testing to ensure that neither the delivery or pick-up piping is 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 manufacturer's instructions
- ensuring sufficient process chemicals are available and are being dosed

Reproducibility of the process chemical volume dispensed

B.66 This test is intended to verify the settings for the volume of process chemical(s) dispensed and ensure that it is reproducible and within defined limits recommended by the manufacturer. The test should be carried out as part of the installation tests, quarterly and yearly tests for each chemical dosing system on the WD.

Note 34: 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 because as potential differences in density or viscosity can affect the volume dispensed.

Equipment

B.67 Two measuring cylinders that conform to standard BS EN 384: 2015/ BS 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

B.68 Use the following method:

- the result of the first test should be disregarded
- 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. Calculate the detergent added from the second cylinder
- repeat the test three more times; record the volume added on each test

Results of checking the reproducibility of process chemicals dispensed

B.69 The mean collected volume from the final three tests should be within ±10% of the nominal dispensed volume.

Indication of insufficient process chemicals

B.70 All WDs should be equipped with a method of ensuring that a cycle is not initiated when there are insufficient process chemicals in the reservoir to complete a cycle, or if the float switch fails. The volume of process chemicals recommended by the manufacturers for the correct functioning of the WD should be used.

B.71 This test should be carried out for each chemical dosing system on the WD.

Method

B.72 Fill an empty container with sufficient chemical for more than three cycles but less than four operational cycles. Run the WD on four consecutive cycles. Estimate the volume remaining at the end of each cycle by pre-marked container, dipstick, or weight).

Results of testing for insufficient process chemical to complete a cycle

B.73 The WD should indicate at the beginning of the fourth cycle that there is insufficient chemical remaining to complete a cycle.

Cleaning efficacy tests

B.74 Type tests for cleaning efficacy should be determined using the test soil requested by the customer or an agreed equivalent. The test soil should be applied to a reference load or agreed surrogate medical device. The reference load(s) should be representative of the load(s) to be processed during normal production. The manufacturer will normally establish worst-case conditions of temperature, detergent concentration, water hardness and water pressure/flow rate for use during testing.

B.75 By analysing the fraction of soil removed during the cleaning process, when operated for various time periods (including those shorter than the normal cycle time) a quantitative comparison of cleaning efficacy can be made. The recommended minimum operating conditions given by the manufacturer should be based on this data. All results should be made available to the User for review.

B.76 During the validation process cleaning efficacy tests using test soils, the thermal disinfection stage of the WD should be disabled to prevent any hot water or steam generated from reducing the concentration of any remaining residual test soil. The choice of test soil should be based on the intended use of the WD and formulated to simulate the soiling encountered in practice and which would be most difficult to remove.

Test specification BS EN ISO 15883-5:2021 gives the recommended constituents and procedure for production of test soil as listed below.

Ingredients required for test soil

- fresh egg yolk 100 mL
- defibrinated blood, 10 mL (horse or sheep)
- dehydrated hog mucin 2 g

Preparation and storage of test soil

B.77 Mix all the constituents together and agitate in a stomacher to give a liquid of uniform consistency.

B.78 Use immediately or store in an air-tight container at 2ºC to 5ºC for not more than one week. If the soil has been stored, allow it to equilibrate to room temperature before use.

B.79 The following equipment is required:

- paintbrush, 25 mm in width, soft
- disposable gloves
- drainage tray

Method of application of the test soil

B.80 Don the protective gloves. Apply the soil to the test pieces by fully immersing the items in the soil. For larger items, 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 not less than 30 minutes and not more than 2 hours.

Method for chamber walls and load carriers

B.81 Use the following method:

- contaminate the chamber walls and load carrier with the test soil in accordance with the manufacturer's 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 Operational Qualification (OQ) tests, carry out the test in duplicate for each type of operating cycle available on the WD
- when used as a periodic test, carry out the test once for each type of operating cycle available

B.82 This test should be run after satisfactory completion of the test for the efficacy of soil removal from chamber walls and load carriers.

B.83 The test load(s) should consist of items of equivalent size, mass, and materials of construction for the range of medical devices the WD is intended to process. Care is needed if loads are mixed or lacking in uniformity.

Method for test loads

B.84 Use the following method:

- contaminate the test load with the test soil in accordance with the manufacturer's instructions
- the specified quantities should be used and drying of the test soil carried out in strict accordance with the instructions
- run a normal operating cycle for the load type 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 operational tests, carry out the test in duplicate for each type of operating cycle available
- when used as a periodic test, carry out the test only once for each type of operating cycle available

Results of soil tests for both chamber walls/ load carriers and test loads

B.85 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.

Monitoring of residual protein on medical devices

B.86 The standard BS EN ISO 15883-1 :2009 + A1 2014 - 'Washer disinfectors part 1: General requirements, terms and definitions and tests' defines cleaning as "*removal of contamination from an item to the extent necessary for its further processing and its intended subsequent use.*" When defining the cleanliness state of invasive medical devices, there must be a link between performance requirements and test method criteria for determining cleaning efficacy in WDs (BS EN ISO 15883 series) and pass/ fail criteria for reprocessed medical devices. Failure to link these two processes will lead to operational difficulties in achieving medical device cleanliness outcomes. This link should be established during the commissioning process of the WD and followed through to performance qualification and subsequent periodic testing.

B.87 While current cleaning efficacy tests depend on visual inspection of medical devices post the WD cleaning cycle it is hoped that greater assurance of the cleaning efficacy of the

process can be achieved by using one of the protein detection methods listed in the NP187 framework. The relevant standard operating procedure for a given test method should be followed.

B.88 Validation of the WD should aim to achieve a lower level of protein on the processed medical devices and when testing cleaning efficacy should consider the worst-case scenario as regards the load placed in the WD and its configuration.

B.89 Once validation of the WD is complete, the use of the WD in production cycles should be in compliance with those validated load conditions. The WD load conditions in production should not be a greater challenge than that validated.

Instrumentation fitted to a WD

Verification of calibration

B.90 The calibration of instrumentation and any independent monitor fitted to the WD should be verified by comparison with calibrated test instruments during steady state conditions. Compliance to BS EN ISO 15883-1 :2009 + A1 2014 clause 5.12–5.17 should be met and SHTM 01-05 part B Section 3 should be consulted for calibration requirements for test equipment.

B.91 Where adjustments of calibration are carried out, the measured results and corrections should be clearly identified in the validation or service report. Values should be recorded before and after any adjustment.

Method

B.92 Instruments should be adjusted to an accuracy of:

- 1°C for temperature measurements at the disinfection temperature (or wash temperature for machines without a disinfection stage)
- 0.05 Bar (50millibars) for pressure measurements at the operating pressure
- ± 5% of reading or ± 0.1µS/cm whichever is greater

B.93 This may be carried out concurrently with other testing, for example, during the automatic control test during quarterly periodic testing.

Thermometric tests

B.94 Thermometric tests are carried out 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 disinfection processes the time/temperature relationships giving an A_0 of 600 are defined in BS EN ISO

15883 -1:2009: A1 2014 and BS EN ISO 15883-2: 2009 and can be found in Section 4, Table 4.1.

Note 35: Biological indicators should not be used as a substitute for thermometric testing.

B.95 The equipment specifications for temperature measurement systems (thermocouples and data loggers) are given in Section 3.

Chamber wall temperature testing

B.96 The WD should be operated empty except for chamber furniture, for example, load carriers.

Method

B.97 Eight sensors should be used. Locate thermocouples as follows:

- One in each corner of the chamber, one in the centre of the two side walls, one in the centre of the roof of the chamber and one adjacent to the temperature sensor used as the reference sensor for chamber temperature
- Measure the temperature attained throughout the WD chamber during four operating cycles. The first of these tests should be carried out from a cold start (at least 60 minutes since the machine was last used). The remaining three tests should be carried out with no more than a 15-minute interval between cycles (a hot start)

Results of the temperature measurement of the chamber surface

B.98 The results should be as follows:

- the temperatures recorded on the surface of the chamber should be within the range 0 to 5ºC of the disinfection temperature throughout the holding period for the disinfection stage
- the temperatures recorded on the surface of the chamber should be within ±5ºC 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 WD instruments should be within ±2ºC 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 ±2ºC for the last three test cycles

Thermometric test for thermal disinfection

B.99 Any test load will consist of a reference load or a specific Performance Qualification (PQ) load representative of the load that the WD under test is intended to process. Sometimes, a surrogate device may be used to simulate load items.

B.100 Temperature monitoring of the load should be used to determine the attainment of the required time-temperature conditions. The test should be performed in triplicate for PQ and commissioning tests and once during periodic testing, quarterly and yearly tests.

B.101 WDs may be tested using thermocouples passed through the entry port into the chamber, alternatively with independent data-loggers or a combination thereof.

B.102 During thermometric tests for the thermal disinfection stage, the washing stages should be disabled, or the controlled temperature reduced to 20ºC ± 5ºC to avoid pre-heating the load. Reducing the wash temperature to 20ºC creates the worst-case conditions with which the disinfection stage may be expected to cope.

Equipment

Temperature measuring equipment, see the 'test equipment' Appendix A.

Method

B.103 Use the following method:

- disable the washing stages or reduce the controlled temperature to 20ºC ± 5ºC
- place temperature sensors in the following positions:
    - at least one on a load item at each level in the load carrier (up to a maximum of three) if the load carrier accommodates load items at more than one level
    - one on a load item in the region known to attain the disinfection temperature in the longest time
    - one on an item 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 double door cabinet WD

Note 36: These positions 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 installed sensor they are monitoring.

Results of thermometric testing for thermal disinfection

B.104 The test should be considered satisfactory if the following requirements are met:

- the indicated and recorded chamber temperatures are within 2ºC 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 BS EN ISO 15883-1 :2009 + A1 2014 on the surface of the load items

- the temperature (see Table 4.1 for required temperature bands) measured on the surface of each load item does not fluctuate by more than ±2ºC and does not differ from that in other load items by more than 4ºC
- at the end of the cycle, the temperature sensors have remained in position

Note 37: If commissioning tests are based on a reference load and the WD fails to achieve the above recommendations for the specific PQ load, it is possible that the WD cannot process loads of this type.

Over-temperature cut-out

B.105 The WD is fitted with an over temperature cut-out to control the temperature in the WD. This prevents the temperature from rising to a level that would damage the load in the event of the automatic control failing. The manufacturer's procedure for testing the over-temperature cut-out should be followed to avoid potential damage to the WD.

Equipment

B.106 Temperature measuring equipment, according to Section 2 and Appendix A of this part of SHTM 01-05 should be used. 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

B.107 Use the following method:

- locate temperature sensors at two diagonally opposite corners of the 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 WD 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

Results of testing the over-temperature cut-out

B.108 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.

Load carriers

B.109 Load carriers correct functioning is essential to the successful outcome of a WD 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.

Method

B.110 Use the following 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 load items, for example, dental handpieces if required by manufacturer
- 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

Load dryness

B.111 If the WD includes a drying stage, a drying efficacy test should be carried out.

Equipment

B.112 Use the following method:

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

Method

B.113 Use the following 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
- surrogate devices for medical devices with lumens should be examined by blowing medical grade dry compressed air through the lumen onto a mirror surface or crepe paper

Results of testing the load dryness

B.114 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 drying)

B.115 Many WDs are fitted with High Efficiency Particulate Air (HEPA) filters (for example, class H 13 as BS EN 1822-1 :2019) to remove bacterial contamination from the air supplied to the drying stage. When they are used as general particulate filters, performance tests for the filter or the filter housing are not necessary.

Note 38: Class E 12 would be an Efficient Particulate Air (EPA) filter as BS EN 1822-1 :2019

B.116 When the load is intended for use without further processing, for example sterilization, the full requirements of the method specified in BS EN ISO 14644-1: 2015 and Appendix A should be followed.

Method

B.117 The complete installation should be tested, and the method specified in BS EN ISO 14644-1:2015 followed. 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.

Results of testing the air filter

B.118 The reading on the photometer should be steady and repeatable and should not exceed 0.01% of the upstream reading.

Automatic control test

B.119 The Automatic Control Test (ACT) is designed to show that the operating cycle functions correctly and that the WD indicated and recorded values are within the original specification. It should be carried out daily on most machines.

Method

B.120 Use the following method:

- place the test load within any load furniture normally used and place in the chamber
- for WDs equipped with multiple cycle capability select the operating cycle to be tested. Start the cycle
- ensure that an individual process record is made by the recording instrument fitted to the machine. If the machine does not have a recorder, observe and note the elapsed time indicated chamber temperatures and pressures 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

Results of the automatic control test

B.121 The test should be considered satisfactory if the following recommendations are followed:

- any visual display indicates ‘cycle complete’

- during the whole of the operational cycle the values of the cycle variables, as recorded by the WD systems and any independent monitor, are within the limits established by the manufacturer during the performance qualification testing
- during the disinfection stage the WD record, and any independent monitoring system are within the disinfection temperature and hold period requirement defined in BS EN ISO 15883 -1:2009+A1 2014 and BS EN ISO 15883-2: 2009, and the performance qualification tests
- the door cannot be opened until the cycle is complete
- the person conducting the test does not observe any mechanical or other anomaly

B.122 Where an independent monitoring system is used process variability may be monitored automatically through presentation of suitable control charts displaying critical process data. Under these conditions, the need for the above automatic control tests may be restricted to quarterly, annual and revalidation testing.

B.123 For weekly checks this can be monitored via batch number printouts if the available data is included for example disinfection hold time and temperature. Otherwise, this can be confirmed using a timepiece.

Ventilation plant

B.124 Consult Scottish Health Planning Note (SHPN) 13 part 2: 2008 Decontamination Facilities: Local Decontamination Unit. Correct operation of ventilation plant is essential to ensure:

- the safe operation of WDs, that includes interlocking systems, to ensure that there is correct operation of both the room ventilation system and the process specific extraction system
- the efficient operation of the drying stage
- the maintenance of a comfortable working environment

B.125 All ventilation systems associated with the WD should be inspected, serviced, and maintained at least every six months or in line with manufacturer's instructions for use. Guidance on extraction ventilation plant maintenance is given in SHTM 03-01 Ventilation for healthcare premises.

B.126 Before undertaking maintenance work on the machine covering/ fascia, or its associated ventilation system, it may require to be decontaminated. The advice of the designated safety officer should be sought.

Residual process chemicals

B.127 Process chemicals used during the decontamination process, detergents, and so on. may not be completely removed by the rinsing process. Depending on the intended use of the washed and disinfected medical device, the level of any residues may be of concern. The

process chemical supplier should provide details of the method used to determine that processed medical devices are free from residuals at the specified levels.

Method

B.128 The sampling and analytical methods used should be capable of determining the presence of the process chemical at concentrations below the maximum acceptable level.

B.129 Test the efficacy of the rinse process by using twice the normal dose of the process chemical(s) on a normal operating cycle using a test load. Analyse the final rinse water and the test load using the method recommended by the manufacturer.

Results of testing for residual process chemicals

B.130 The concentration on the test load should be lower than the specified maximum acceptable level.

Water System

B.131 A continuous supply of water of the specified chemical and microbial quality is essential to the correct functioning of all WDs.

B.132 The test methods recommended here are intended to be suitable for onsite use. Several test systems are available commercially, but the results should not be used as evidence in cases of dispute. Where analysis with a high level of accuracy is required for the detection of low concentrations of chemical contaminants, the use of a laboratory accredited to BS EN ISO/IEC 17025: 2017 for the tests requested is recommended.

Note 39: It is not necessary to use experienced chemical analysts to undertake the on-site analysis of water samples as described. It is, however, essential that personnel receive appropriate training before attempting to carry out this work. Recourse to more precise independent analysis may be needed in the event of a dispute between two parties.

B.133 The recommend analytical methods to determine the various biological, physical, and chemical properties of water samples for the various qualities of feedwater to the WD are detailed in this section. Before adopting one of these methods, care should be taken to ensure that 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.

B.134 All WD 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 WD in an aseptic manner to minimise microbial contamination of the sample. 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 such as pre and post pre filtration, pre and post water treatment system.

B.135 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

B.136 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 against 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

B.137 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.

B.138 All variables for which instrumental methods are recommended are temperature dependent and equipment should be allowed sufficient time on site, to equilibrate to the local ambient temperature prior to use. All monitoring equipment must be calibrated in line with BS EN ISO/IEC 17025: 2017 and manufacturers' instructions.

Equipment

Note 40: Specific types of sampling containers must be used for specific tests as listed below.

B.139 Samples for the determination of:

- total dissolved solids - 1 Litre polypropylene bottles
- conductivity and hardness - 100 ml high-density polyethylene bottles

Method

B.140 Use the following method:

- the first 50mls of sample taken at each sampling point should be run to waste
- all samples should be taken in duplicate
- samples should be collected using an aseptic technique to prevent accidental contamination of the sample
- samples should be tested within 4 hours of collection or if necessary stored at 2-4ºC immediately after collection and for no more than 24 hours. If samples are stored for more than 24 hours, fresh samples should be obtained

Electrical conductivity

B.141 There is a wide variety of portable conductivity meters available. Conductivity meters should be calibrated in ranges of µScm-1.

B.142 The meter or meters used should cover the ranges shown in Table B.1 and be temperature-compensated over the range 0 to 40ºC. A comprehensive range of standard conductivity reference solutions, including pure water standards, are available commercially, standardized at 25ºC and traceable to national standard reference materials.

Table B.1 - Range, resolution, and accuracy of the conductivity meter

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

Equipment

B.143 The following equipment should be used:

- conductivity meter
- standard conductivity reference solutions

Method

B.144 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 0.06 µS 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

Results of conductivity measurement

B.145 The conductivity at 25ºC should not exceed:

- 30 µS cm^{-1} for reverse osmosis water
- 300 µS cm^{-1} for softened or mains water

Note 41: Conductivity levels in excess of this value are indicative of a high concentration of dissolved solids.

B.146 The working standard solutions are stable for up to one week when stored in cool conditions, in a sealed container.

B.147 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.

Total dissolved solids (TDS) for RO / purified water only

B.148 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.

B.149 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.

B.150 The electrical conductivity should be measured as described previously and expressed in microsiemens per centimetre (μS cm^{-1}) at 25 °C. This is then multiplied by is an experimentally derived conversion factor which lies 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.

B.151 Conversion factor = TDS (in mg/L)/ conductivity (in μS cm^{-1} at 25 ºC).

B.152 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 42: 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.

B.153 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.

TDS determined by the conductivity method

Equipment

B.154 The following equipment should be used:

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

Method

B.155 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.

B.156 Measure the conductivity of the sample and multiply by the conversion factor to give an estimate of the TDS in mg/L.

Results for TDS using the conductivity method

B.157 The estimate of total dissolved solids should not exceed 4 mg 100 mL^{-1} for purified water (RO or deionised (DI)).

TDS determined by the evaporative residue method

Equipment

B.158 The following equipment should be used:

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

Method

B.159 Use the following method:

- collect a 1 Litre sample

- take the silica dish (or equivalent), dry for 2 hours in the oven set to 100ºC ± 2ºC 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

Results for TDS by the evaporative residue method

B.160 TDS expressed as the evaporative residue should not exceed 4 mg 100 ml^{-1} for purified water, for example reverse osmosis (RO).

Water Hardness (as $CaCO_3$)

B.161 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.

B.162 The calcium selective electrodes available have a Nernstian response for concentrations from 1M down to about 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, for example RO.

B.163 The electrodes are free from any major interference except zinc ions. They are, however, poisoned by a number of biological fluids.

Equipment

B.164 The following equipment should be used:

- Ion-Selective Electrodes (ISE) are available for calcium and for divalent cations (total hardness). Ion-selective electrodes are not specific for a particular ion 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

B.165 Use the following 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 millivoltmeter 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 43: Phosphate buffers should not be used since the calcium activity will be lowered by the formation of complexes or precipitation

Titrimetric method

B.166 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. They 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 complexiometric indicator, all the calcium and magnesium ions are chelated by the EDTA. The absence of free calcium and magnesium ions causes a colour change in the indicator.

B.167 At pH values above 12, magnesium ions are precipitated as the hydroxide and do not react with the EDTA. Calcium hardness can be determined using Patton and Reeders indicator powder as a complexiometric indicator.

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

Note 44: 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

Results of hardness measurement

B.168 Water with values >210 mg/L should be regarded as unsuitable for use in WDs without pre-treatment.

Appendix C Ultrasonic cleaner test methods

Test for ultrasonic activity

C.1 The activity of an ultrasonic cleaner (UC) can be investigated by the erosion pattern created on aluminium foil exposed in the bath for a short period. The activity is not uniform throughout the ultrasonic bath. Tests carried out during initial validation are intended to establish the variation in activity at various positions and levels within the bath and the time required to obtain a characteristic erosion pattern.

C.2 The exposure time is dependent on the thickness and hardness of the foil, the operating frequency, the watt density and the temperature of the ultrasonic bath.

Equipment

The following equipment should be used:

- aluminium foil, nominal thickness 0.015–0.025 mm
- autoclave indicator tape
- timepiece, graduated in 0.2 s and with an accuracy over a period of 15 min of ± 0.5 s, or better
- ruler/ tape measure graduated in mm

Method

C.3 Measure the depth of the bath (D measured in millimetres) from the level of the lid to the bottom of the bath. Cut strips of aluminium foil, 15–20 mm wide and (D + 120) mm. Carry out the manufacturer's recommended start-up procedure.

Note 45: This will normally include a period of operation to eliminate dissolved gases from the solution in the bath (known as de-gassing).

- ensure that the water in the tank is at the required level and the amount of any process chemicals specified by the manufacturer have been added and the solution has reached the specified operating temperature
- using strips of autoclave indicator tape across the top of the bath suspend nine strips of prepared foil in the bath in a 3 x 3 grid
- roll one end of each foil strip to acts as a sinker weight to maintain the foil in an approximately vertical position. The sinker weight should be no more than 10 mm above, but not touching, the bottom of the bath
- operate the UC for the predetermined exposure time. This can vary according to the between watt density of the ultrasonic bath
- 30 s for a 20 W dm^{-3} and 10 min for a watt density of 5 W dm^{-3}
- remove the strips from the bath, blot dry and examine

- file the strips by sticking them to an A4 sheet of plain paper using a transparent adhesive tape or by lamination in a clear pocket
- drain the bath and clean to remove debris of eroded aluminium foil

Results of testing ultrasonic activity

C.4 For precise evaluation of the foils should be weighed before and after exposure to ultrasonication and the loss in weight recorded. The mean weight loss should then be calculated; all test foils should be within ±20% of the mean loss of weight.

C.5 When examined, the zones of maximum erosion should be at similar positions on all nine foils, and each should be eroded to a similar extent. On re-testing, the results should have remained consistent with those originally determined during commissioning.

C.6 Where validated and shown to be equivalent or better to the erosion pattern method, commercially available cavitation meters can be used to test the activity of the UC. Manufacturers' instructions for use should be followed.

Appendix D Sterilizer test methods

D.1 This section of gives detailed methodology for tests required during the initial validation and periodic testing of sterilizers used in a Local Decontamination Unit (LDU) as described in British Standards (BS) EN 13060:2014 + A1 2018 in conjunction with additional air detection tests as required included in this section. Test equipment calibration methods are detailed in this part of Scottish Health Technical Memorandum (SHTM) 01-05, section 3 and Appendix A.

D.2 The schedule of tests is listed in Section 7, see Table 7.2 and Table 7.3.

D.3 Bowie and Dick test for steam penetration - type B and S only

D.4 The Bowie and Dick test was conceived as a test for successful air removal for porous load sterilizers. A successful Bowie and Dick test indicates rapid and even penetration of steam into the test pack. It does not confirm that the sterilizing conditions have been achieved within the load.

D.5 A Bowie and Dick test should be carried out at the start of each day and production for Type B and S cycles should not begin until the test has been shown to be satisfactory.

D.6 For convenience it is common to use an Alternative Porous Indicator System (APIS) which is a commercially produced Bowie and Dick test pack or device for conducting the daily test. Manufacturers' instructions should be followed. Alternatively, a reference porous device (RPD) for example, a Helix Challenge Device, or standard test pack as described in section D.95 may be used with a Class 2 chemical indicator inserted into the middle.

Principle of the test

D.7 The Bowie and Dick test is referred to in the BS EN 13060:2014 + A1 2018 and involves a test in which a pre-printed Class 2 chemical indicator sheet complying with BS EN ISO 11140-3: 2009 is used in conjunction with a standard test pack. Alternative indicators for use in the Bowie and Dick type tests are specified in BS EN ISO 11140-4: 2007. These indicator systems are designed to show a failure when, at the start of the holding time, the temperature at the centre of the test pack is 2ºC or more below the temperature in the active chamber discharge caused by the presence of residual air. Manufacturer's instructions should always be followed.

Bowie and Dick test procedure

D.8 The Bowie and Dick test is normally preceded by a warm-up cycle to ensure the effectiveness of air removal which is dependent on all parts of the sterilizer being at working temperature. Conducting a warm-up run will also clear the steam supply system of any non-condensable gases that have accumulated during periods when the sterilizer is unused.

D.9 If using a standard test pack, place an indicator sheet compliant with BS EN ISO 11140-3 in the centre of the pack. Reassemble and secure the pack.

D.10 Alternatively, prepare the commercially produced Bowie and Dick test pack/ device as directed by the manufacturer's instructions.

D.11 Place the test pack in the position which the sterilizer manufacturer identifies as being the most difficult from which to remove air from the load.

D.12 Select the standard cycle or specific Bowie and Dick test cycle if available. The range of acceptable hold time and temperature should be specified for the chemical indicator, and be suitable for the cycle selected, see Table D.1. Start the operating cycle. (The test should be performed always using the same cycle).

Table D.1 - Holding time range for the Bowie and Dick test cycle

Sterilization holding time temperature (°C)	Minimum (minutes)	Maximum (minutes)
134	3.3	3.5

D.13 When the cycle is complete, remove the indicator paper from the test pack and record the result according to the manufacturer's instructions.

D.14 The test should be considered satisfactory if the following requirements are met:

- there is a uniform colour change throughout the indicator sheet
- the automatic controller indicates that the Bowie and Dick test cycle has just been completed satisfactory

D.15 For printed indicator sheets, it is important to compare the colour of the indicator at the corners of the paper with that at the centre so that any difference can be clearly seen. If there is any discernible difference, the test should be recorded as failed, and the paper marked accordingly. A large area of unchanged indicator points to a gross failure.

D.16 The result of the Bowie and Dick test should be recorded in process records. The indicator paper may be marked with the result and kept for reference; however, in some cases the chemical reaction giving rise to the colour change may continue during storage, giving rise to a change in appearance. Process records are legal documents and should be kept for a period of time consistent with local policies and procedures.

D.17 An unsatisfactory Bowie and Dick test result indicates that the sterilizer should not be used until the fault has been identified and rectified. It is important to realise that if a sterilizer fails the Bowie and Dick test, it cannot be made safe simply by increasing the holding time until an acceptable result is produced. A failed sterilizer is in urgent need of skilled engineering attention.

Reasons for Bowie and Dick test failure

D.18 Several factors may inhibit steam penetration and cause the Bowie and Dick test to fail. Common causes of failure include the following:

- an inefficient air removal stage due to, for example, a pressure sensor going out of calibration and misreporting the actual pressure attained
- an air leak during the air removal stage due to, for example, a damaged door seal, poor valve seats, porous fittings, and damaged condenser

D.19 The failure of a Bowie and Dick test will require corrective action. It is common to conduct a series of tests to identify the cause of the failed process:

- an air leak test to identify any chamber leaks
- calibration checks on pressure sensors to identify calibration errors or faulty probes
- a check of all the chamber fittings, valves, and connections

D.20 A thermometric test for a small load will also provide information to help diagnose the cause(s) of failure:

- If the test reveals a temperature depression at the centre of the test pack, the problem is likely to be inefficient air removal or an air leak into the chamber. Air remaining in the centre of the test pack is inhibiting the penetration of steam and the correct temperature is not being attained. The sterilizer should not be returned to service until it has been subjected to a vacuum leak test and an air detector (A/D) function test
- If the test fails to reveal a temperature depression, the problem is almost certainly air or other non-condensable gases in the steam supply. In this case the correct temperature is being attained, but the steam is diluted, and insufficient moisture is present to change the indicator. The sterilizer should not be returned to service until the steam supply has been tested for the presence of non-condensable gases

Automatic control test - Type N, B and S

D.21 The automatic control test (ACT) is designed to show that the operating cycle functions correctly as shown by the cycle variables indicated and recorded by the instruments fitted to the sterilizer.

Note 46: For daily test ACT it can be carried out by visually observing and noting the reading of the sterilizer hold time and temperature from the sterilizer printout and observations recorded in the sterilizer logbook.

D.22 The ACT is one of the tests for ensuring that the sterilizer continues to function correctly.

D.23 During the initial validation, periodic quarterly and yearly test programmes the temperature and pressure sensors for subsequent thermometric tests should be connected to the chamber during this test. If a sensor is placed adjacent to each of the sensors connected to the installed temperature measuring instruments, the calibration of these instruments may be checked during periods of stable temperature in the automatic control test.

Method

D.24 Place the test load, as defined in BS EN 13060 :2014 + A1 2018 appropriate to the cycle to be tested and the load to be processed in the chamber.

D.25 Select the operating cycle to be tested. This should normally be the highest temperature compatible with the load. Start the cycle.

D.26 Ensure that a Batch Processing Record (BPR) is made by the recording instrument fitted to the machine. For daily tests, if a process-data recording is not made by the machine, the elapsed time, chamber temperatures and pressures at all significant stages of the cycle should be observed and noted.

D.27 For validation, quarterly and annual tests at the approximate mid-point of the sterilizing hold time note the elapsed time and indicated critical parameters.

Results

D.28 The test should be considered satisfactory if the following requirements are met:

- a visual display indicating “cycle complete” occurs
- during the whole cycle, the values of the cycle variables, as indicated by the instruments on the machine or shown on the BPR, are within the limits established as giving satisfactory results either by the manufacturer or during the whole of the operational cycle

D.29 During the plateau period determined from the recorded chamber temperature:

- the indicated and recorded chamber temperatures are within the appropriate sterilization temperature band specified in Table 7.1
- the difference between the indicated, recorded and any other independent monitor chamber temperature does not exceed 2ºC
- the difference between the indicated, recorded and any other independent monitor chamber pressure does not exceed 0.1 bar
- during the holding time, any temperatures recorded in the load are within the appropriate sterilization temperature band specified in Table 7.1
- the door cannot be opened until the cycle is complete
- the person conducting the test does not observe any mechanical or other anomaly

D.30 The sterilization conditions are specified by a sterilization temperature band, defined by a minimum acceptable temperature (sterilization temperature) and a maximum allowable temperature. These are listed in Table 7.1.

D.31 Where an independent monitoring system is employed that has the necessary data-processing capability, process variability may be monitored automatically through presentation of suitable control charts displaying critical process data (for example, vacuum

and pressure set points on each pulse, and average, minimum and maximum temperatures and pressures during the sterilization hold phase).

Air leakage test - Type B and S only

D.32 The air leakage test is applicable to any sterilizer that employs vacuum to remove air from the load.

D.33 Leakage of air into the chamber at a rate greater than that specified by the sterilizer manufacturer is unacceptable because:

- the presence of air may inhibit the penetration of steam into the load and prevent sterilization
- air leaking into the chamber during the drying stages will not have passed through the bacterial retentive filter and there is a risk of re-contaminating the load

D.34 This test may be carried out weekly in accordance with BS EN 13060:2014 + A1 2018 clause 10.2 using an automatic cycle incorporated into the sterilizer as per manufacturer's Instructions for use (IFU); or the test can be operated under manual control by an engineer to establish criteria of the test or for investigations of the sterilizer.

D.35 This test is also commonly referred to as the 'vacuum leak test' or 'leak rate test'.

D.36 The test is designed to establish the air tightness of the chamber and that permissible limits are not exceeded. If the sterilizer is not fitted with an instrument to measure the air leakage, connect a 0-160 mbar absolute gauge to a chamber port with an isolation valve.

D.37 For the test to be satisfactory the chamber temperature should be stable; hence the air leakage test should be preceded by a warmup cycle.

D.38 Select the correct cycle and start the test. Under the cycle, the chamber pressure is evacuated to a predetermined level, which is equal to or lower than the level set for the cycle, during the air removal and steam penetration stage.

D.39 When the set point is reached, the machine will stop the vacuum pump and close the appropriate chamber valves: a predetermined 5-minute stabilization period begins following which readings are taken.

D.40 The predetermined hold stage is measured at the start and finish of the subsequent 10-minute period. Once the 10 minutes is complete, the chamber is vented to atmospheric pressure.

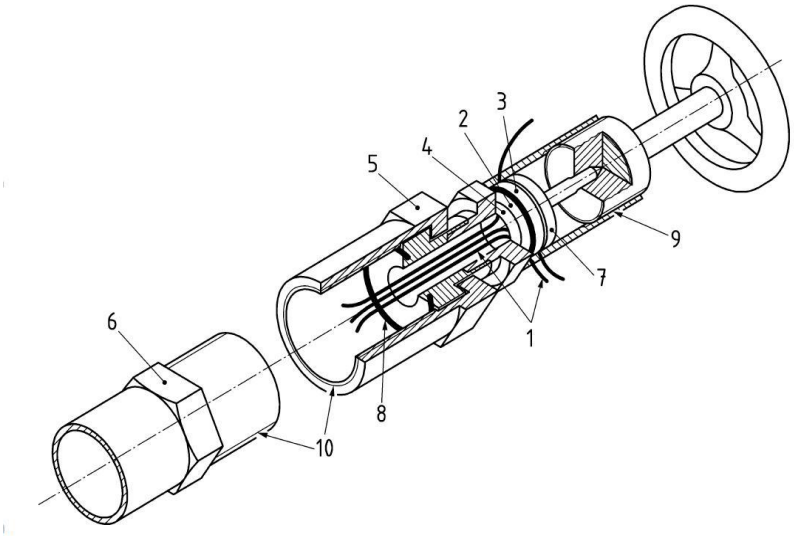
D.41 The test is deemed a pass if the pressure increase does not exceed 13mbar (1.3kPa) in the 10-minute hold period.

Note 47: If using sensors that require a through chamber connection and/or a pressure sensing device that requires a connection to the chamber, they should be introduced into the chamber via a purpose designed entry gland and suitable fittings. A typical sensor entry gland is shown, see Figure D.1 (Appendix A provides the requirements for test equipment, including sensors).

Note 48: This gland is fitted after the initial air leakage test and the air leakage test should be undertaken again after the gland and sensors have been fitted to the chamber port. Figure D.1 shows a fitting designed for a sterilizing chamber having a male gland and an 'O' ring seal, see key 8 in Figure D.1. When the gland is a female thread an adaptor, see key 6 in Figure D.1, will be required.

Note 49: Other methods of introducing temperature sensors into a sterilizer chamber and which guarantee a gas-tight seal are equally acceptable. Care should be taken with the sensors so that they are not damaged when fitted.

Figure D.1: Typical sensor entry gland



Key

1	temperature probes wire	6	adaptor
2	silicon rubber washer	7	metal thrust spigot
3, 4	metal thrust washer	8	O-ring
5	metal body	9	castellated to permit entry of leads
		10	pipe thread ISO 228-G1 A

A/D function test and performance tests - Type B and S

D.42 The continued correct functioning of the air detection system must be tested weekly, quarterly, and annually.

D.43 An A/D is used to determine whether any air or non-condensable gas (ncg) present in the chamber is sufficient to impair the sterilizing process. If the sterilizer is fitted with an A/D, the method specified here for the A/D function test should be followed.

D.44 For weekly tests the sterilizer may be equipped with an automatic test cycle, however the test method should be specified by the manufacturer. The test should be performed by a

Competent Person (Decontamination) (CP(D)) but, if the sterilizer is equipped with an automatic test cycle, the User may perform the weekly test with the appropriate training.

D.45 As there is unlikely to be a standard air detection system; each sterilizer manufacturer must specify the test method to demonstrate that the automatic air detection system is functioning correctly. The test pack shall represent the maximum density of porous load material that the sterilizer is capable of processing.

D.46 Although the test methods may differ, in all cases the A/D should cause a fault to be indicated if the amount of air or gas in the chamber at the start of the plateau period is sufficient to depress the temperature in the centre of the load by more than 2ºC below the temperature in the active chamber discharge.

D.47 The tests can be divided into two types:

- the A/D performance test, used to set up and check the continued suitability of the A/D settings
- the A/D function test used to check correct functioning of the A/D once it is correctly adjusted

D.48 Several repeat tests may be required to establish the air leakage rate required. The maximum leak used should be as per manufacturer's instructions, such as 10 ± 1 mbar/min (1.0 ± 0.1 kPa/min for small and full load A/D tests).

D.49 During validation testing, the manufacturer should advise on the initial air leakage value and set points for the A/D.

D.50 Once a satisfactory result for a small load is achieved, the large load should be tested. This will ensure that the A/D will fail a cycle under normal operational conditions from the small load to a full production load, yet still be sterilizing the medical devices in the chamber.

D.51 The A/D function test shall use the same induced leak and set point as determined at initial validation.

D.52 All results must be recorded. This will include depression results, set points and the induced leak applied to the chamber.

D.53 An air flow metering device such as a needle valve capable of controlling the flow of air into an evacuated chamber is required. Its position and the alarm settings should be recorded in the validation/periodic test report for future reference.

D.54 Small or full load performance tests are carried out on the pre-set and validated porous load cycle. If any significant parameters are changed to improve the air removal, tests should be repeated until a satisfactory performance is reached.

D.55 A small load test is carried out with a single test pack in the chamber.

D.56 Full load performance tests use a standard test pack as per BS EN 13060:2014 + A1 2018 (clause 8.6.2) and fill the remaining space with identical test packs as described in BS EN 13060:2014 + A1 2018 (clause 8.6.6).

D.57 The air is admitted into the chamber via the needle valve(s) at the pre-determined induced leak rate. This may be performed automatically by a pre-determined cycle or by a manual means.

D.58 If a separate automatic cycle is used for the A/D performance or function tests, then all cycle parameters must be identical to those used for the production cycle, except for operation of the air metering device and associated vacuum measurement system.

Method

D.59 Start the correct cycle for the test. If a manual test is being performed, open the needle valve or metering device at the pre-set value and air will be admitted into the chamber during the air removal stage. On some types of sterilizers, the A/D may need to be switched off for this test.

D.60 The test for A/D performance small and full load tests are satisfactory if, at the start of the plateau period, the lowest temperature measured in the test pack is not more than 2ºC lower than the temperature measured at the reference measurement point (usually the drain sensor).

D.61 The A/D function test is deemed satisfactory if the sterilizer fails the cycle and a fail result is shown on the printout.

Verification of calibration

D.62 The calibration of instrumentation and any independent monitor fitted to the sterilizer should be verified by comparison with calibrated test instruments during steady-state conditions. Compliance to BS EN 13060:2014 + A1 2018 clause 5.3, 5.4.2. 10.4 should be met and Section 3 should be consulted for calibration requirements for test equipment.

D.63 Where adjustments of calibration are carried out, the measured results and corrections should be clearly identified in the validation or service report. Values should be recorded before and after any adjustment.

Method

D.64 Instruments should be adjusted to an accuracy of:

- 1°C for temperature measurements at the sterilizing temperature
- 0.05 Bar (50millibars) for pressure measurements at the operating pressure
- ± 5 % of reading or ± 0.1 µS cm^{-1} whichever is greater

D.65 This may be carried out concurrently with other testing, for example, during the automatic control test during quarterly periodic testing.

Thermometric test for a small load - Type N, unwrapped instruments cycle

D.66 Temperatures and pressures should be recorded by independent measuring equipment as described in Section 3.

D.67 Place a pair of forceps (for example, 5-inch artery forceps) in the approximate centre of the chamber.

D.68 Place four temperature sensors in the following positions:

- one in an active chamber discharge (drain or vent)
- one trapped between the jaws of the forceps
- where steam is supplied from outside the chamber, one in the upper third
- of the free chamber space
- where steam is generated within the chamber, one either in the reservoir or, if water is retained in the chamber, in the water

D.69 Connect a pressure recorder (or test gauge) to the chamber.

D.70 Select and start the operating cycle.

D.71 The test should be considered satisfactory if the following requirements are met:

- the requirements of the automatic control test (see paragraph appendix D.29 - D.29) are met
- during the first minute of the plateau period the temperature measured in the chamber free space does not exceed the temperature measured in the active chamber discharge by more than 5°C
- after the first minute of the plateau period:
    - the temperature measured in the chamber free space does not exceed the temperature measured in the active chamber discharge by more than 2°C
    - the temperature measured in the jaws of the forceps is within 1°C of the temperature measured in the active chamber discharge
- the holding time determined from the measured temperatures is not less than that specified in Table 7.1
- during the holding time:
    - the measured temperatures are within the appropriate sterilization temperature band specified in Table 7.1
    - the indicated and recorded chamber temperatures are within 1°C of the temperature measured in the active chamber discharge
    - the indicated and recorded chamber pressures are within 0.05 bar of the measured chamber pressure
- at the end of the cycle, the temperature of any water left in the chamber or in the reservoir is less than the boiling point of water at local atmospheric pressure

Thermometric test for a full load - Type N, unwrapped instruments

D.72 Temperatures and pressures should be recorded by independent measuring equipment as per Section 3.

D.73 Place a pair of forceps as for the small-load test in the approximate centre of the chamber and add further instruments and utensils up to the maximum total mass which the sterilizer is designed to process.

D.74 Place four temperature sensors in the following positions:

- one in an active chamber discharge (drain or vent)
- one trapped between the jaws of the forceps
- where steam is supplied from outside the chamber, one in the free space
- between the load items or where steam is generated within the chamber, one either in the reservoir or, if water is retained in the chamber, in the water

D.75 Connect a pressure recorder (or test gauge) to the chamber.

D.76 Select and start the operating cycle.

D.77 The test should be considered satisfactory if the requirements as stated for the small load test are met, and the total cycle time is within the performance class stated by the manufacturer.

Thermometric test for small porous load - Type B and S

D.78 This test is used to demonstrate that after the air removal stage of the operating cycle, sterilizing conditions are obtained within the chamber and standard test pack. The more air there is to remove, the more exacting will be the test; that is why the pack is used by itself in an otherwise empty chamber.

D.79 Temperatures and pressures should be recorded by independent measuring equipment as described in Section 2.

D.80 Use a RPD - standard test pack conforming to D.94. Place a total of seven temperature sensors at each of the following positions:

- the defined reference point within the chamber to measure the chamber reference temperature
- the approximate geometric centre of the test pack, carefully arranging the wire so that steam does not track along it and place the assembly in the position identified by the sterilizer manufacturer as the most difficult to sterilize
- three sensors 20mm below the centre of the pack at 45mm diameter spacing

Note 50: As the coolest location within the standard test pack will not be predictably at the exact geometric centre, the additional temperature sensors in the standard test pack are used to improve the reproducibility of the test results.

- 30mm below the centre of the pack
- the free space above the approximate geometrical centre of the pack at a height of 50mm

D.81 Connect a pressure recorder (or test gauge) to the chamber.

D.82 Start the operating cycle, with standard drying time, and take readings as described for the automatic control test (see paragraph D.21 - D.31).

D.83 If a test gauge is being used, measure the chamber pressure at the approximate mid-point of the holding time.

D.84 The test should be considered satisfactory if the following requirements are met:

- the requirements of the automatic control test (see paragraph D.28 - D.29) are met
- during the plateau period the temperature measured above the test pack does not exceed the temperature measured in the active chamber discharge by more than 5°C for the first 60 s and 2°C for the remaining period
- the equilibration time determined from the measured temperatures does not exceed 15 seconds for chambers less than 60 l

Note 51: An equilibration time not exceeding 30 sec is acceptable if:

a. the rise of the theoretical steam temperature during the last 10 K of the heating stage is less than 8 K/min but greater than 1 K/min

b. during the last 10 K of the heating stage all temperatures measured in the chamber and the load as well as the theoretical steam temperature do not differ from one another by more than 2 K

- the holding time determined from the measured temperatures is not less than that specified in Table 7.1
- during the holding time the temperatures measured in the active chamber discharge and in the centre of the test pack:
    - are within the appropriate sterilization temperature band specified in Table 7.1
    - do not fluctuate by more than ± 1°C
    - do not differ from one another by more than 2°C
- during the holding time:
    - the indicated and recorded chamber temperatures are within 1°C of the temperature measured in the active chamber discharge
    - the indicated and recorded chamber pressures are within 0.05 bar of the measured pressure

- at the end of the cycle, the sheets are sensibly dry

Thermometric test for a full load

D.85 The full-load test is designed to demonstrate that, at the levels at which cycle variables are set, rapid and even penetration of steam into the centre of a load occurs, and the sterilizing condition is achieved in a test load of specified maximum mass and of sufficient size to fill the usable chamber space.

D.86 Temperatures and pressures should be recorded by independent measuring equipment as described in Section 3.

D.87 The load is made up of a reference porous device (standard test pack) (see paragraph D.95) and additional folded sheets designed to represent the maximum mass of textiles which may be processed in the sterilizer as per D.103. Each sheet should contain at least 50% m/m of cotton fibre and have a surface density of approximately 200 g m^{-2}. They should be washed and aired as for the standard test pack (see paragraphs D.98 - D.100). After airing, the standard pack should be folded to approximately 11 cm x 15 cm and laid one on top of the other to form stacks of mass 900 ± 30g.

D.88 Place the standard test pack within the chamber in a position identified by the manufacturer as the most difficult to sterilize. This will normally be in the approximate centre of the chamber.

D.89 Place a total of seven temperature sensors in the following positions:

- the defined reference point within the chamber to measure the chamber reference temperature
- the approximate geometric centre of the test pack, carefully arranging the wire so that steam does not track along it and place the assembly in the position identified by the sterilizer manufacturer as the most difficult to sterilize
- three sensors 20mm below the centre of the pack at 45mm diameter spacing

Note 52: As the coolest location within the standard test pack will not be predictably at the exact geometric centre, the additional temperature sensors in the standard test pack are used to improve the reproducibility of the test results.

- 30mm below the centre of the pack
- the free space above the approximate geometrical centre of the pack at a height of 50mm

D.90 Load the rest of the usable chamber space with similar stacks of sheets to fill 90% of usable space.

D.91 Connect a pressure recorder (or test gauge) to the chamber.

D.92 Start the operating cycle, with standard drying time, and take readings as described for the automatic control test (see paragraph D.21).

D.93 If a test gauge is being used, measure the chamber pressure at the approximate mid-point of the holding time.

D.94 The test should be considered satisfactory if the following requirements are met:

- the requirements of the automatic control test (see paragraph D.29 - D.29) are met
- the equilibration time determined from the measured temperatures does not exceed 15 s for LDU sterilizers; see note below

Note 53: An equilibration time not exceeding 30 sec is acceptable if:

a. the rise of the theoretical steam temperature during the last 10 K of the heating stage is less than 8 K/min but greater than 1 K/min

b. during the last 10 K of the heating stage all temperatures measured in the chamber and the load as well as the theoretical steam temperature do not differ from one another by more than 2 K

- the holding time determined from the measured temperatures is not less than that specified in Table 7.1
- during the holding time:
    - the measured temperatures are within the appropriate sterilization temperature band specified in Table 7.1
    - the measured temperatures do not fluctuate by more than ± 1°C
    - the measured temperatures do not differ from one another by more than 2°C
    - the indicated and recorded chamber temperatures are within 1°C of the temperature measured in the active chamber discharge
    - the indicated and recorded chamber pressures are within 0.05 bar of the measured pressure
    - the total cycle time is within the performance class stated by the manufacturer
    - at the end of the cycle, the sheets are sensibly dry

Reference porous device - standard test pack for small and full load tests

D.95 This is intended for use in small porous load sterilizers with chamber volumes between 10 and 54 litres and with an internal diameter (or, for rectangular vessels, an inscribed circle) greater than 180 mm.

D.96 The pack shall be constructed from plain cotton sheets complying with BS 5815-1:2005, bleached to a good white, and each having an approximate size of 450mm x 300mm. The number of threads per centimetre in the warp shall be (30 ± 6) and the number of threads per centimetre in the weft shall be (27 ± 5).

D.97 The mass per unit area of the sheets shall be approximately 185 ±5 g m2

D.98 The sheets shall be washed when new and when soiled. During the washing process the sheets shall not be subjected to any fabric conditioning agent.

Note 54: Washing includes adequate rinsing to remove bleach and detergent residues.

D.99 After washing, the sheets shall be dried and aired, but not ironed or calendered.

D.100 Before use, the sheets shall be stored, unfolded, and well separated, for at least 1 hour at a temperature between 20°C and 30°C and at a relative humidity (RH) of 40% to 60%.

D.101 After equilibration, the sheets shall be folded to approximately 110mm x 150mm and stacked to a height of approximately 120mm after compressing by hand. The pack shall be wrapped in a single sheet of the same fabric and secured with a tape not exceeding 19mm in width. The total mass of the pack shall be 900g±30g.

D.102 This standard test pack which should take up 20 ± 5% of the chamber volume should be used for a small porous load test.

D.103 For a full load, the same standard test pack would be used. In addition, the remaining usable chamber space should be filled with identical test packs or sheets to fill 90 ± 10% of the usable chamber space.

Note 55: When forming the pack, consecutive sheets should be stacked with the folded side alternating to ensure an even stack.

Note 56: Packs which are not used within one hour of preparation may be stored until required, providing the environmental conditions are maintained within the limits specified above.

Note 57: With repeated use, the sheets will become compressed. When the mass of sheets used to form a stack 120mm high exceeds 930g, the sheets should be discarded.

Note 58: The standard test pack should not be used if its volume is more than one fifth of the usable chamber space (20 ± 5%); in such cases, a smaller version of the pack may be used. This should be of cuboid form and its volume should be about one fifth of the usable chamber volume. It may be made from a different material, and be of different size and weight, from the standard test pack, provided its performance can be demonstrated to be equivalent to that of the standard test pack in each test for which it is to be used.

Note 59: The cotton test sheets should be stored at a RH of between 45% and 55% as sheets which have been stored outside these limits (but within the limits 30% to 70% RH) have been found to give variable and misleading results in thermometric testing. Paper test packs, however, appear to give results which are less dependent on the RH of the storage conditions.

Note 60: Cotton sheets having the recommended RH may be obtained by storing the sheets above a saturated solution of magnesium nitrate in a sealed container for at least 12 hours before use. Sheets that have been conditioned may be stored in a hermetically sealed container (such as for transportation to site) where they will retain the correct humidity for 24 hours.

Solid Load

D.104 The solid load shall be composed of metal bolts. The metal bolts shall:

- be austenitic stainless steel, according to EN 10088-1
- be hexagon head bolts BS EN ISO 4017:2022 - M12 × 100
- be cleaned, degreased, and dried before use

D.105 Several bolts shall be used which represent as specified the maximum weight of unwrapped solid instruments which can be processed.

Chamber overheat cut-out test

D.106 This test applies only to sterilizers where the steam is generated within the chamber. The test is done with an empty chamber and with insufficient water charge for a complete cycle. Temperatures should be recorded by independent measuring equipment as described in Section 3.

D.107 Attach a temperature sensor to the chamber wall in a position identified by the manufacturer as attaining the highest temperature.

D.108 Select the operating cycle with the highest sterilization temperature. (Only one cycle is normally provided). Start the cycle.

D.109 The test should be considered satisfactory if the following requirements are met:

- a boil-dry condition occurs before the end of the cycle
- the overheat cut-out operates, and the heaters are isolated from the electricity supply
- the chamber wall temperature does not exceed the temperature specified by the manufacturer

Load dryness test

D.110 This test is used to demonstrate that the operating cycle will not cause an increase in moisture in a solid or porous production load sufficient for there to be uncertainty about the dryness of loads routinely processed. This test should be carried out yearly or where problems are experienced with the condition of the load.

Solid Load dryness

D.111 Select the cycle to be tested and, if required, carry out a sterilization cycle with the sterilizer chamber empty. Place the test load in the usable chamber space supported by the chamber furniture in a position such that it will acquire the maximum moisture. Immediately start the sterilization cycle. Upon completion of the sterilization cycle, remove the test load from the sterilizer chamber and visually inspect.

D.112 In case of doubt, perform the test as specified in BS EN 13060:2014 + A1 2018 paragraph 10.11 by weighing the test load before starting the cycle and within 2 minutes after cycle completion and calculate the change in moisture content.

D.113 For a solid load, the moisture content shall not exceed 0.2 %.

Porous Load dryness

D.114 Select the cycle to be tested and carry out a sterilization cycle with the sterilizer chamber empty. Place the test load in the usable chamber space supported by the chamber furniture in a position which will cause the maximum moisture. Immediately start the sterilization cycle. Upon completion of the sterilization cycle, remove the test load from the sterilizer chamber. Check the test load by visual inspection. No moisture spots shall be visible on the test load or the wrapping material. In case of doubt, perform the test as specified for the type test.

D.115 In case of doubt, perform the test as specified in BS EN 13060:2014 + A1 2018 paragraph 10.12 by weighing the test load before starting the cycle and within 2 minutes after cycle completion and calculate the change in moisture content.

D.116 For a porous load, the moisture content shall not exceed 1.0 %.

Production load dryness test

D.117 Process a production load that is known to present the greatest challenge to the operating cycle.

D.118 The check should be considered satisfactory if a 'cycle complete' indication is obtained, and the load is sensibly dry.

Performance qualification tests

D.119 Performance Qualification (PQ) is the process of obtaining and documenting evidence that the sterilizer will consistently provide reproducible results when operated in accordance with the pre-defined acceptance criteria within the process specification. PQ tests should be performed as part of the validation procedure, as part of any repeat validation procedure, and whenever the User judges that a new loading condition calls for a new PQ test. It is the responsibility of the User to set the acceptance criteria to allow the sterilizer to be validated during PQ testing. Standard BS EN ISO 17665-1:2006 and technical specification DD CEN ISO/TS 17665-2:2009 describe how this should be carried out.

D.120 PQ tests collect three distinct types of data, indicated, recorded, and measured. The three sets of data serve different purposes and may require different tolerances:

- indicated data (electronic displays and so on) are available as a general guide to the user for monitoring production cycles during operation on all types of sterilizers
- recorded data are available to the user for production cycles on most types of sterilizers and can be regarded as definitive proof for routine production control and product release
- measured data obtained during Operational Qualification (OQ) and PQ testing is regarded as definitive proof of sterilizer efficacy for the purposes of validation, as they are more reliable than indicated or recorded values. The permitted tolerances should reflect this

D.121 PQ data can be generated for single load conditions or conditions representative of pre-determined product families. Where the PQ data is to be used for loads requiring specific conditions (such as dental instruments that would be damaged if the limits were broader) any recorded variation between cycles should be small and due to the performance limits of the sterilizer) and the permitted tolerances should be tight. Replicated thermometric PQ tests should give some indication of acceptable variation.

D.122 Where the PQ data for a single loading condition is judged to be valid for a range of loading conditions (such as for a product family), the variation between cycles will contain a systematic variation related to the differing loading conditions, and the permitted tolerances will be greater. The choice of loading conditions for which the data is valid should consider whether this greater tolerance is acceptable.

D.123 The extent of the PQ required will depend on the type of sterilizer and the nature of the load. The initial PQ load should be accurately documented to enable replication at yearly revalidation. Where a new load is not covered by an existing PQ report, full PQ tests should be conducted.

D.124 Users should adopt the following procedure for every sterilizer:

- establish a list of potential product families and their relationship to the validation loads (see DD CEN ISO/TS 17665-2: 2009 Sections 6 and 9 and PD ISO/TS 17665-3:2013)
- establish a list of the different loading conditions to be processed in the sterilizer. Each production load should correspond to one of the listed loading conditions
- determine whether each loading condition presents a greater or lesser challenge to the process than the small and full loads used in the thermometric tests carried out during validation
- where the loading condition is a lesser challenge than the validation loads, the results of the validation tests may be used as PQ data
- where the loading condition is a greater challenge than the validation loads, additional PQ tests should be carried out

D.125 When designing a new loading condition, it is important that the correct packaging is specified with the load. The packaging specification and materials should be to the appropriate standards and not altered without repeating the PQ procedure unless the loading condition with new packaging can be demonstrated to be covered by an existing PQ report.

D.126 Additional PQ tests may include a narrow lumen test (D.139) or a simple hollow item test (D.140 - D.143).

Microbiological test for PQ

D.127 The microbiological test should ideally follow a satisfactory thermometric test, using the identical loading condition and operating cycle. This test is designed to be used in exceptional circumstances as an additional PQ test for steam sterilizers. There may be situations where thermometric tests are not possible, for example, with medical devices with narrow lumens, where it is not physically possible to place a thermocouple or temperature sensor into the lumen without altering the nature of the load. Reference should be made to BS EN 556-1: 2001 for sterility assurance requirements.

Result

D.128 The test should be considered satisfactory if the following requirements are met:

- during the whole of the cycle the values of the cycle variables as shown on the BPR are within the permitted tolerances marked on the master processing record (MPR) established during the thermometric PQ test
- the requirements for microbiological tests are met

Use of biological indicators

D.129 Biological indicators are designed to show whether specified sterilization conditions have been attained by the survival of test microorganisms. However, they should not be used for routine monitoring of steam sterilization processes. In exceptional circumstances where the use of biological monitors could be considered, advice should be sought from the Microbiologist (Decontamination).

D.130 When biological indicators are required, those specified in BS EN ISO 11138-3: 2017 should be used. These will usually be Geobacillus stearothermophilus. Advice on selection, use and interpretation of results when using biological indicators can be found in BS EN ISO 11138-7: 2019.

D.131 After use, the biological indicators should be recovered according to the manufacturer's instructions.

D.132 Biological indicators should be cultured in accordance with the manufacturer's instructions for use.

Narrow lumen test (reference hollow device (RHD))

D.133 A process challenge device (PCD) and chemical indicator that complies with BS EN ISO 11140-6:2022 should be used for this test. (See BS EN 13060:2014 + A1 2018 Annex G for examples of a PCD for narrow hollow items or BS EN ISO 11140-6:2022 Annex E).

D.134 This test device for narrow lumen shall comply with BS EN ISO 11140-6:2022.

D.135 This process challenge device is used solely to demonstrate a basic minimum level of steam penetration. It is not intended to provide assurance that any particular medical device may be satisfactorily sterilized by the process.

D.136 The chemical indicator to be used in the process challenge device shall comply with BS EN ISO 11140-1:2014 and BS EN ISO 11140-6:2022.

D.137 Allow the process challenge device to reach ambient temperature and make sure that the internal parts are dry before using it.

D.138 Carry out a sterilization cycle with the sterilizer chamber empty. Place the chemical indicator into the indicator holding device. Close and seal the capsule. Check that the

plateau period does not exceed the endpoint of the chemical indicator (if necessary, reduce the plateau period). Place the process challenge device into the usable chamber space according to the user instructions provided with the sterilizer, using the sterilizer furniture. The sterilizer chamber shall be empty except for the sterilizer furniture. Immediately start the sterilization cycle. At the end of the sterilization cycle, remove the process challenge device from the chamber. Remove the chemical indicator from the indicator holding device.

D.139 A satisfactory test should comply with Table 7.1.

Simple Hollow Item test

D.140 A PCD and chemical indicator that complies with BS EN ISO 11140-6:2022 as per BS EN 13060:2014 + A1 2018 8.11 should be used for this test.

D.141 Allow the receptacles to reach ambient temperature before using them and make sure that the internal parts are dry.

D.142 Connect the equipment as specified in BS EN 13060:2014 + A1 2018 paragraph 10.11. Distribute the temperature sensors throughout the usable chamber space. Place one of these temperature sensors in the test receptacle shown to be the most critical during the type test. Locate another temperature sensor at the position shown to be the most critical during the empty chamber test. Place the load into the usable chamber space according to the user instructions provided with the sterilizer, using the sterilizer furniture. Immediately start the sterilization cycle.

D.143 A satisfactory test should comply with Table 7.1.

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Glossary (specific to Part B)

Absolute pressure - pressure for which the zero value is associated with absolute vacuum. [SOURCE: BS EN ISO 11139: 2018 section 3 definitions]

Accessory for a medical device - means an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s). [SOURCE: Regulation (European Union (EU)) 2017/745 article 2 - (2)]

Active ingredient - chemical or biological component that is included in the formulation of a health care product to achieve the intended purpose. [SOURCE: BS EN ISO 11139: 2018 section 3 definitions]

Aeration - part of the sterilization cycle during which the sterilizing agent and/or its reaction products desorb from the health care product until predetermined levels are reached. [SOURCE: BS EN ISO 11139: 2018 section 3 definitions]

Air detector (A/D) - device designed to detect the presence of non-condensable gases in the chamber or in a stream of steam and condensate. [SOURCE: BS EN ISO 11139: 2018 section 3 definitions]

Alternative hollow device (AHD) - equivalent in performance to the Reference hollow device (RHD) such as an alternative hollow device, usually commercially manufactured, of any design [SOURCE: BS EN ISO 11140-6: 2022]

Alternative porous indicator system (APIS) - an alternative porous chemical indicator system equivalent in performance to the Reference porous device (RPD), usually commercially manufactured, of any design [SOURCE: BS EN ISO 11140-6: 2022]

Aseptic presentation - transfer of the sterile contents from its sterile barrier system using conditions and procedures that minimize the risk of microbial contamination. [SOURCE: BS EN ISO 11139: 2018 section 3 definitions]

Automatic controller - device that directs the equipment sequentially through required stages of the cycle in response to programmed cycle parameters. [SOURCE: BS EN ISO 11139: 2018 section 3 definitions]

A_0 - measure of microbiological lethality delivered by a moist heat disinfection process expressed in terms of the equivalent time in seconds at 80°C with reference to a microorganism with a z value of 10 K. [SOURCE: BS EN ISO 11139: 2018 section 3 definitions]

Bioburden - population of viable microorganisms on or in a product and/or sterile barrier system. [SOURCE: BS EN ISO 11737-1: 2018 section 3 definitions]

Biological indicator - test system containing viable microorganisms providing a defined resistance to a specified sterilization process. [SOURCE: BS EN ISO 11138-1: 2017 section 3 definitions]

Clean - visually free of soil and below specified levels of analytes. [SOURCE: BS EN ISO 11139: 2018 section 3 definitions]

Cleaning - removal of contaminants to the extent necessary for further processing or for intended use. Note 1 to entry: Cleaning consists of the removal of adherent soil (such as blood, protein substances and other debris) from the surfaces, crevices, serrations, joints, and lumens of a medical device by a manual or automated process that prepares the items for safe handling and/or further processing. [SOURCE: BS EN ISO 17664-1: 2021 section 3 definitions]

Cleaning agent - physical or chemical entity, or combination of entities, having activity to render an item clean. [SOURCE: BS EN ISO 11139: 2018 section 3 definitions]

Chemical indicator non-biological indicator - test system that reveals change in one or more pre-defined process variables based on a chemical or physical change resulting from exposure to a process [SOURCE: EN ISO 17665: 2006 section 3 definitions]

Conditioning - treatment of product prior to the exposure phase to attain a specified temperature, relative humidity, or other process variable throughout the load. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

Cycle complete - message from the automatic controller that the operating cycle has ended successfully. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

Decontamination – refer to definitions for “processing” and “reprocessing”.

Disinfection - process to reduce the number of viable microorganisms to a level previously specified as being appropriate for a defined purpose. [SOURCE: BS EN ISO 17664-1: 2021 section 3 definitions]

Implantable medical device - medical device which can only be removed by medical or surgical intervention, and which is intended to:

- be totally or partially introduced into the human body or a natural orifice
- replace an epithelial surface or the surface of the eye
- remain after the procedure for at least 30 days

[SOURCE: BS EN ISO 13485: 2016: +A11:2021 section 3 definitions]

Installation Qualification (IQ) - is the process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification. [SOURCE: BS EN ISO 17665-1:2006]

Instructions for use (IFU) - means the information provided by the manufacturer to inform the user of a device's intended purpose and proper use and of any precautions to be taken. [SOURCE: Regulation (EU) 2017/745 article 2 – (14)]

Invasive device - means any device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body. [SOURCE: Regulation (EU) 2017/745 article 2 – (6)]

Labelling - label, instructions for use, and any other information that is related to identification, technical description, intended purpose and proper use of the medical device, but excluding shipping documents. [SOURCE: BS EN ISO 13485: 2016: +A11:2021 section 3 definitions]

Life-cycle - all phases in the life of a medical device, from the initial conception to final decommissioning and disposal. [SOURCE: BS EN ISO 13485: 2016: +A11:2021 section 3 definitions]

Load - product, equipment, or materials to be processed together within an operating cycle. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

Load configuration - distribution and orientation of a load. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

Lumen device - item that consists of tube(s) or pipe(s). [SOURCE: EN ISO 11139: 2018 section 3 definitions]

Manual cleaning - Manual cleaning -removal of contaminants from an item to the extent necessary for further processing or for intended use without the use of an automated process. [SOURCE: BS EN ISO 17664-1: 2021 section 3 definitions]

Medical device - means any instrument, apparatus, appliance, software, implant, reagent, material, or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment, or alleviation of disease
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability
- investigation, replacement, or modification of the anatomy or of a physiological or pathological process or state
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood, and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological, or metabolic means, in or on the human body, but which may be assisted in its function by such means. definitions]

The following products shall also be deemed to be medical devices:

- devices for the control or support of conception

- products specifically intended for the cleaning, disinfection or sterilization of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point. [SOURCE: Regulation (EU) 2017/745 article 2 – (1)]

Note 61: The term medical device as used in the SHTM 01-05 series only applies to dental instruments processed through a Local Decontamination Unit (LDU).

Microbial barrier - property of a sterile barrier system to minimize the risk of ingress of microorganisms. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

Microbial contamination - presence of unintended bacteria, fungi, protozoa, or viruses. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

Moist heat - thermal energy in the presence of moisture released by gaseous or liquid water. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

Operating cycle - complete set of stages of a process that is carried out, in a specified sequence. Note 1 to entry: Loading and unloading are not part of the operating cycle. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

Operational Qualification (OQ) - is the process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures. [SOURCE: BS EN ISO 17665-1:2006]

Original Equipment Manufacturer (OEM) – is a company that produces components for itself, or for use by another company (sometimes referred to as a VAR, for instance, value-added reseller) to sell or incorporate into another product for resale. A component can be a part or finished product depending on the needs and specifications of the reseller. [SOURCE: https://www.bmpmedical.com/blog/what-is-a-medical-device-oem/]

Overkill approach - method of defining a sterilization process that achieves a maximal sterility assurance level (SAL) for product substantially less than 10−6. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

Packaging system – combination of the sterile barrier system and protective packaging. [SOURCE: EN 11607-1: 2017]

Performance Qualification (PQ) - is defined as the process of obtaining and documenting PQ evidence that the equipment, as installed and operated in accordance with operational procedures, consistently performs in accordance with predetermined criteria and thereby yields products meeting its specification.

Periodic testing - is a series of tests carried out at daily, weekly, quarterly, and yearly intervals.

Process chemical - formulation of chemical compounds intended for use in a washer-disinfector.

Note 62: Process chemicals include for example detergents, surfactants, rinse aids, disinfectants, enzymatic cleaners. [SOURCE: BS EN ISO 15883-1 :2009 + A1 2014, section 3 definitions]

Processing - activity to prepare a new or used healthcare product for its intended use. Note processing includes cleaning, disinfection, and sterilization (if necessary and applicable). A healthcare product refers to a medical device. [SOURCE: BS EN ISO 17664-1: 2021 section 3 definitions]

Processor - organization and/ or individual with the responsibility for carrying out actions necessary to prepare a new or reusable healthcare product for its intended use. Note a healthcare product refers to a medical device. [SOURCE: BS EN ISO 17664-1: 2021 section 3 definitions]

Process challenge device (PCD) - item designed to constitute a defined resistance to a sterilization process and used to assess performance of the process. [SOURCE: EN ISO 11138-1: 2017 section 3 definitions]

Product family - group or subgroup of product characterized by similar attributes determined to be equivalent for evaluation and processing purposes. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

Protective packaging – configuration of materials designed to prevent damage to the sterile barrier system and its contents from the time of assembly until the point of use. [SOURCE: EN 11607-1: 2017]

Reference porous device (RPD) - a reference device by which alternative porous indicator systems (APISs) can be shown to be equivalent in performance according to this document, i.e., a textile test pack in which steam penetration is judged by thermometric means [SOURCE: BS EN ISO 11140-6: 2022]

Reference hollow device (RHD) - used as a reference device in this document, for instance, a lumened device with attached capsule in which steam penetration is judged by inactivation or survival of a specified biological indicator [SOURCE: BS EN ISO 11140-6: 2022]

Reference load - specified load created to represent combinations of items that provide defined challenge(s) to a process. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

Relative humidity - measure of water vapour in the air expressed as a percentage of the maximum for a given temperature. Note 1 to entry: It is expressed as a percent. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

Reprocessing - means a process carried out on a used device in order to allow its safe reuse including cleaning, disinfection, sterilization, and related procedures, as well as testing and restoring the technical and functional safety of the used device. [SOURCE: Regulation (EU) 2017/745 article 2 – (39)]

Reusable medical device - medical device designated or intended by the manufacturer as suitable for processing and reuse. Note: This is not a medical device that is designated or intended by the manufacturer for single-use only. [SOURCE: BS EN ISO 17664-1: 2021 section 3 definitions]

Reusable surgical instrument - means an instrument intended for surgical use in cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, w manufacturer to be reused after appropriate procedures such as cleaning, disinfection and sterilization have been carried out. [SOURCE: Regulation (EU) 2017/745 Annex VIII chapter 1, paragraph 2.3]

Seal - <packaging> result of joining surfaces together by fusion to form a microbial barrier. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

Seal integrity - <packaging> characteristics of a seal to minimize the risk of ingress of microorganisms. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

Self-contained biological indicator - biological indicator presented in such a way that the primary package, intended for incubation, contains the incubation medium required for recovery of the test organism [SOURCE: EN ISO 11138-1: 2017 section 3 definitions]

Service life - number of processing cycles and/or lifetime that a medical device can be subjected to and remain suitable and safe for its intended use. [SOURCE: BS EN ISO 17664-1: 2021 section 3 definitions]

Single-use medical device - medical device designated or intended by the manufacturer for one-time use only. Note: A single-use medical device is not intended to be further processed and used again. [SOURCE: BS EN ISO 17664-1: 2021 section 3 definitions]

Single-use device - means a device that is intended to be used on one individual during a single procedure. [SOURCE: Regulation (EU) 2017/745 article 2 – (8)]

Single patient use - means the medical device may be used for more than one episode of use on one patient only; the device may undergo some form of reprocessing between each use. [SOURCE: Ref Page 14 – MHRA Single-use medical devices: implications and consequences of reuse December 2013]

Sterilant - chemical or combination of chemicals used to generate a sterilizing agent. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

Sterile - free from viable microorganisms. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

Sterile barrier system - minimum package that minimizes the risk of ingress of microorganisms and allows aseptic presentation of the sterile product at the point of use. [SOURCE: EN ISO 11737-1: 2018 section 3 definitions]

Sterile field - area created by sterile surgical drape material where aseptic technique is practised NOTE A sterile field can be practised such as., on a back table. [SOURCE: EN ISO 13795: 2013 section 3 definitions]

Sterile medical device - medical device intended to meet the requirements for sterility. [SOURCE: BS EN ISO 13485: 2016: +A11:2021 section 3 definitions]

Sterility assurance level (SAL) - probability of a single viable microorganism occurring on an item after sterilization. Note 1 to entry: It is expressed as the negative exponent to the base 10. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

Sterilization - process used to render product free from viable microorganisms.

Note 63:to entry: In a sterilization process, the nature of microbial inactivation is exponential and thus the survival of a microorganism on an individual item can be expressed in terms of probability. While this probability can be reduced to a very low number, it can never be reduced to zero [SOURCE: BS EN ISO 17664-1: 2021 section 3 definitions]

Sterilized – condition of a product that has been exposed to a sterilization process in its sterilized barrier system [SOURCE: EN ISO 11139: 2018 section 3 definitions]

Unique Device Identifier (UDI) - means a series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market. [SOURCE: Regulation (EU) 2017/745 article 2 – (15)]

Usable chamber space - specified geometry within the chamber that is available to accept the load. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

Validation - is the documented procedure required for obtaining, recording, and interpreting the results needed to show that a process will consistently yield a product complying with a predetermined specification.

Washing - removal of adherent contamination from surfaces to be cleaned by means of an aqueous medium, with or without process chemicals, as necessary [SOURCE: BS EN ISO 15883-1 :2009 + A1 2014, section 3 definitions].

Washer-disinfector WD - equipment designed to clean and disinfect product. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

Works tests - series of tests performed during or after manufacture to demonstrate compliance of each equipment with the requirements of the test specified [SOURCE: BS EN 13060 :2014 + A1 2018].

Abbreviations (used in SHTM 01-05)

AC:	alternating current
ACDP:	Advisory Committee on Dangerous Pathogens
AC/hr:	Air Changes/per hour
ACoP:	Approved Code of Practice
ACT:	Automatic Control Test
A/D:	Air Detector
ADR:	Agreement concerning the international carriage of Dangerous goods by Road
AE(D):	Authorising Engineer (Decontamination)
AHD:	Alternative hollow device
AP(D):	Authorized Person (Decontamination)
APIS:	Alternative Porous Indicator System
ARHAI:	Antimicrobial Resistance and Healthcare Associated Infection
BPR:	Batch Processing Record
BS:	British Standard
$CaCO_3$:	Calcium Carbonate
CDO:	Chief Dental Officer
CE:	Conformité Européene
CEL:	Chief Executive Letter
CJD:	Creutzfeldt Jakob Disease
Cl:	Chloride
CMO:	Chief Medical Officer
COSHH:	Control of Substances Hazardous to Health
CPD:	Continuing Professional Development
CP(D):	Competent Person (Decontamination)
CPI:	Combined Practice Inspection
CP(PS):	Competent Person (Pressure Systems)
DB:	Device Bulletin

DC:	Direct Current
DI:	Deionised
DoH	Department of Health
EDTA:	Ethylene Diamine Tetra-Acetic acid
EFA:	Estates and Facilities Alerts
EPA:	Efficient Particulate Air
EU:	European Union
GDC:	General Dental Council
GDP:	General dental practitioners
HAI:	Healthcare Associated Infection
HDL:	Health Department Letter
HEPA:	High Efficiency Particulate Air
HFS:	Health Facilities Scotland
HIS:	Healthcare Improvement Scotland
HoC:	Hierarchy of Controls
HSE:	Health and Safety Executive
HTM:	Health Technical Memorandum, Department of Health, England
IFU:	Instructions for Use
IHEEM:	Institute of Healthcare Engineering and Estate Management
IPC:	Infection, Prevention and Control
IQ:	Installation Qualification
IRIC:	Incident Reporting Investigation Centre
ISE:	Ion-Selective Electrodes
kVA:	kilovolt-ampere
kW:	kilowatt
LDU:	Local Decontamination Unit
MDA:	Medical Device Alerts
MDDP:	Managing Decontamination in Dental Practice
MDR:	Medical Device Regulations

MHRA:	Medicines and Healthcare products Regulatory Agency
mg/L:	milligrams per litre
MPR:	Master Processing Record
ncg:	non-condensable gas
NES:	NHS Education for Scotland
NIPCM:	National Infection Prevention and Control Manual
NIST:	National Institute of Standards and Technology
NP:	National Procurement
NSS:	National Services Scotland
OEM:	Original equipment manufacturer
OQ:	Operational Qualification
PCD:	Process Challenge Device
PDP:	Personal Development Plan
PES:	Programmable Electronic Systems
pH:	potential of Hydrogen
PPE:	Personal Protective Equipment
ppm:	parts per million
PPM:	Planned Preventative Maintenance
PQ:	Performance Qualification
PRQ:	Performance Requalification Test
PSM:	Practice Support Manual
PSSR:	Pressure Systems Safety Regulations
QIiPT:	Quality Improvement in-Practice Training
QMS:	Quality Management System
RH:	Relative Humidity
RHD:	Reference Hollow Device
RIDDOR:	Reporting of Injuries, Diseases and Dangerous Occurrences Regulations
RMD:	Reusable Medical Device
RO:	Reverse Osmosis

RPD:	Reference Porous Device
SAL:	Sterility Assurance Level
SAN:	Safety Action Notice
SBS:	sterile barrier systems
SDCEP:	Scottish Dental Clinical Effectiveness Programme
SEHD:	Scottish Executive Health Department
SGHD:	Scottish Government Health Department
SHPN:	Scottish Health Planning Note
SHTG:	Scottish Health Technologies Group
SHTM:	Scottish Health Technical Memorandum
SHTN:	Scottish Health Technical Note
SICPs:	Standard Infection Control Precautions
SOP:	Standard Operating Procedure
TBP:	Transmission Based Precautions
TDS:	Total Dissolved Solids
TSE:	Transmissible Spongiform Encephalopathy
TVC:	Total Viable Count
UC:	Ultrasonic Cleaner
UDI:	Unique Device Identifier
UKCA:	United Kingdom Conformity Assessed
vCJD:	variant Creutzfeldt Jakob Disease
WD:	Washer Disinfector
WRAS:	Water Regulations Advisory Scheme
ºC:	Degrees Celsius
µS/cm:	microsiemens per centimetre