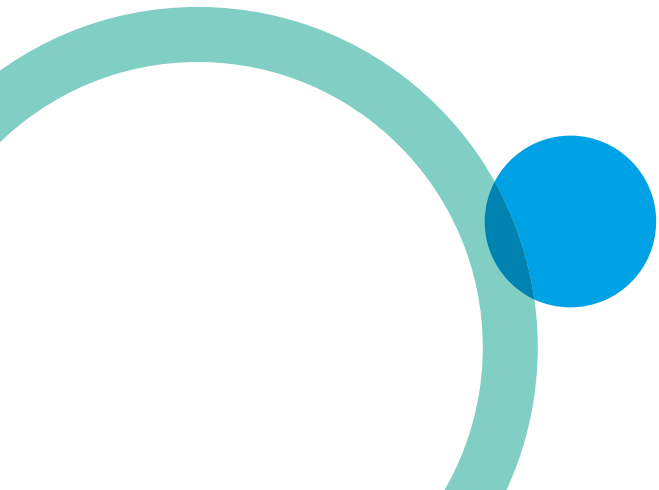
NSS Health Facilities Scotland

Scottish Health Technical Memorandum 01-01

Decontamination of medical devices in a Central Decontamination Unit

Part D:

Automated cleaning and disinfection equipment



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1. Introduction

1.1 Scottish Health Technical Memorandum (SHTM) 01-01 Part D presents best practice guidance on automated cleaning and disinfection equipment in a Central Decontamination Unit (CDU). SHTM 01-01 Part A 'Management': 2018 should be used in conjunction with this guidance. A glossary is contained in SHTM 01-01 Part A.

Note: For the purposes of this series 'medical device' is taken to mean as applicable both a reusable medical device and a single use medical device that is supplied non sterile to the CDU for processing once prior to use. The term medical device as used in the SHTM 01-01 series only applies to those processed through a CDU.

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

Note: Scottish Health Planning Note (SHPN13) Part 1 Decontamination facilities: CDUs 2011 is applicable to new builds or upgrades of CDUs and provides room data sheets for areas such as the Wash Room and the Inspection Assembly and Packing (IAP) Room between which the Washer Disinfector (WD) is located. A room data sheet for a general plant room (which may house the water treatment plant that supplies the WD) is also included.

These room data sheets provide guidance on room design, finishes, mechanical & electrical and equipment/furniture/fittings. Planning involving the WD should take account of the need to not compromise the integrity/performance of the IAP Room which is a 'cleanroom' as defined in standard EN 14644-1: 2016.

Scope of SHTM 01-01 Part D

1.3 This guidance covers thermal Washer Disinfectors (WDs), Ultrasonic Cleaners (UCs) and their accessories used for processing medical devices in a Central Decontamination Unit. All references to WDs refer to thermal Washer Disinfectors.

Exclusions

1.4 This guidance does not cover the decontamination of medical devices that are not processed through a CDU or decontamination equipment that is not located within a CDU.

2. Design and pre-purchase considerations

2.1 SHTM 01-01 Part A should be consulted for guidance on the specification, purchase and installation of equipment used for the decontamination of medical devices in Central Decontamination Units. It provides an overview of points to consider during procurement. Health Boards should use the NP143 framework for Decontamination equipment, accessories and maintenance when purchasing Ultrasonic Cleaners (UC) and Washer-Disinfectors (WD).

2.2 It is essential that the purchase of an item of decontamination equipment is planned correctly in order that the User's predefined requirements are met.

Washer disinfector specification

2.3 This section discusses general specifications for WDs and the steps to be taken in inviting tenders and issuing a contract. Refer to the section 'Procurement of equipment' with SHTM 01-01 Part A which includes specification preparation and an overview of points to consider.

2.4 A specification should be completed as part of the procurement process and submitted as part of a legal contract between the purchaser and the manufacturer. It is essential that the procurement specification is prepared by a team of qualified and competent staff and that the AP(D) and AE(D) are consulted during this process.

2.5 Purchasers should refer to EN ISO 15883 Parts 1 and 2: 2014 when preparing a specification for washer disinfectors. Manufacturers should provide certification to the purchaser that the particular design of the equipment is manufactured in conformity with all relevant EU standards, national guidance and regulations.

2.6 Washer Disinfectors are covered by a number of European Regulations/Directives and are thus required to be in conformance. Relevant Regulation/Directives include but are not restricted to:

- Regulation (EU) 2017/745 on medical devices;
- Electromagnetic Compatibility Directive (2014/30/EU);
- Low voltage Directive (2014/35/EU)Pressure Equipment Directive (2014/68/EU);
- Machinery Directive (2006/42/E).

2.7 To ensure the safety of technical and maintenance staff the design and construction of a WD should ensure that:

- where a failure occurs during the cleaning stage of the WD operating cycle the surfaces of the chamber and the load carrier presented to the operator are clean and disinfected. This is especially important during loading and unloading of a multi chamber WD;
- each wet chamber has the capability of being thermally disinfected;
- for a drying only chamber a manual cleaning regime is provided and followed.

- any recommended cleaning solutions are not detrimental to the material of the WD surfaces. Consult with the WD manufacturer and review their WD instructions for use when considering the introduction of any new cleaning solutions;
- if the WD contains an ultrasonication stage confirm the cleaning and disinfection instructions are provided by the WD manufacturer.

Refer to SHTM 01-01 Part A with regard to the permit-to-work system.

2.8 Washer disinfectors for medical devices and associated equipment should conform to EN ISO 15883 Parts1: 2014 and 2: 2009 and the safety requirements for electrical equipment EN 61010-2-040: 2015.

All washer disinfector operating cycles should include five distinct stages:

- pre-wash;
- wash;
- rinse;
- disinfection;
- drying.

2.9 The choice of WD is determined by a number of performance requirements.

Cleaning performance requirements

2.10 Cleaning of the medical device removes contamination to the extent necessary for further processing. The Advisory Committee on Dangerous Pathogens Transmissible Spongiform Encephalopathy (ACDP-TSE) 2015 Annex C guidance states 'the upper limit of acceptable protein contamination after processing is 5 µg BSA equivalent per instrument side. A lower level is necessary for neurosurgical instruments'. Detailed information on the recommended equipment and method to show compliance with this limit is given in Section 4 of this guidance and in SHTM01-01 part A. Requirements concerning process chemicals are given, see 2.66.

2.11 SHTM 01-01 Part A states 'Ensure that during procurement the washer disinfectors requested are specified to deliver the required cleaning level to meet the ACDP guidance on prion proteins. The washer disinfector performance should be verified before buying/installing.' The cleaning performance of washer disinfectors should be optimised by considering a range of parameters including water, process chemicals, cycle time etc. It should be noted that research undertaken by Lee Palmer titled 'Optimising the efficacy of the prewash stage' published 2015 demonstrated the impact of water temperature at the prewash stage on the cleaning performance of the WD. The research indicated there was an optimal range in the pre-wash stage temperature.

Disinfection performance requirements

2.12 Disinfection is the process used to reduce the number of viable microorganisms (bioburden) on the medical device to a level as appropriate for its further handling.

2.13 Thermal disinfection is the preferred option (as stated in HFS guidance GUID 5014 'Requirements for compliant CDUs': 2016) for processing medical devices in CDUs. 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 EN 15883-1 Annex 2: 2014.

2.14 Temperatures in excess of 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 1. A_0 is defined in EN 15883-1: 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.

2.15 An A_0 of 600 may be achieved by 10 min (600 s) at 80 °C or by 1 min at 90 °C, or by 100 min 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 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 1.

Exposure Time	Disinfection Temperature band (ºC)	A_0 Value
100 minutes (6000s)	70 - 75	600
10 minutes (600s)	80 - 85	600
1 minute (60s)	90 - 95	600

Table 1: Time/temperature bands meeting the requirements of an acceptable A_0 of 600 for thermal disinfection of medical devices

Drying requirements

2.16 Medical devices must be dried, before being placed in a sterile barrier package. The drying method employed should be rapid and reliable and should not contaminate the medical device with chemical, microbial or particulate contaminants. Generally medical devices should be dried at the end of the washer disinfector cycle.

Cycle time

2.17 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 in use to ensure consecutive cycles have the same efficacy.

Type of load, workload and throughput requirements

2.18 As the efficacy of the cleaning stage of the process is of crucial importance to the successful outcome of the disinfection stage, ensure the WD selected is compatible and validated for all medical devices to be processed. Many medical devices including rigid endoscopes can withstand steam sterilization and may be processed through WDs employing a thermal disinfection stage. Medical devices with narrow working channels or lumens will require specific connectors to the WDs to ensure cleaning efficacy. The WD should be designed to ensure that during all stages of the process that process fluids (including air) flow though the lumen(s) of the medical device. Filtration of process fluids passed through fine lumens of medical devices may be necessary to avoid adverse effects on medical device performance. Consult the medical device manufacturer and AE(D) to ensure compatibility prior to purchase. There are also a number of dedicated WDs that include ultrasonic cleaners for complex medical devices including those with lumens. Some powered medical devices require electrical connectors or compressed air for operation, for example, phaco handpieces, orthopaedic saws and drills. These medical devices should be connected to the WD via dedicated connectors.

2.19 The capacity of the WD should be assessed on the number of medical devices of each type that can be processed in a single load and the required throughput time. Prior to purchase ensure the capacity requirements make allowance for downtime maintenance and servicing and any possible additional future service requirements. Further guidance on the planning and selection of equipment and facilities for CDUs can be found in Scottish Health Planning Note(SHPN) 13 part 1: 2011- 'Decontamination Facilities: Central Decontamination Units'. This should be used for WD sizing requirements. Consideration should also be given to contingency plans for machine usage, and sufficient time included for testing, maintenance and servicing. Any contingency plan should also allow for any catastrophic failure of equipment or services. Reliance on a single item of equipment is not advisable. It should also be noted that the turnaround times can fluctuate based on the demand placed on the service.

2.20 Further guidance on the planning and selection of equipment and facilities for CDUs can be found in 'SHPN 13 part 1: 2011- Decontamination Facilities: Central Decontamination Units' should be used for WD sizing requirements.

Selection of configuration/load handling

2.21 Washer Disinfectors of various sizes and configurations (single chamber, multi chamber machines) are available on the market and suitable for use.

Single-chamber WD requirements

2.22 As all stages of the single-chamber WD operating cycle take place in the same chamber, it is not possible to get physical separation between the dirty and clean stages. Therefore assurance that the load will not be re-contaminated is dependent upon the efficacy of the cleaning and disinfecting stages in decontaminating the interior of the WD as well as the load. Also consider:

- the costs of the water, heating and process chemicals;
- the possible disruption to production during a failure;
- decontamination of the chamber.

Multi-chamber WD requirements

2.23 Multi-chamber WDs have more than one chamber where separate stages of the operating cycle are performed. Typically the chambers will be dedicated to cleaning, disinfection and drying. Alternative operating cycle stage segregation may be determined by specific User requirements as part of the WD specification.

2.24 This configuration allows different loads to be processed concurrently. Multi-chamber WDs, other than those designed as automatic ultrasonic cleaners, are usually designed to accept interchangeable load carriers. When compared with single-chamber machines they have a higher throughput and may achieve some decrease in overall operating cycle time.

2.25 As the load moves through the machine during the operating cycle, these WDs provide excellent physical separation between dirty and clean load items. Multi chamber WDs doors are located at either end and at intermediate positions between chambers.

2.26 For multi chamber WDs the ultrasonication may take place in a separate chamber. Additional considerations should include:

- the costs of the water, heating and process chemicals;
- possible disruption to production during a failure;
- racks not requiring ultrasonication should pass through the chamber without being lowered into the tank;
- decontamination of the chamber will be required.

2.27 The manufacturer should specify how their ultrasonic WD is to be disinfected. This may be by the provision of a high-temperature self disinfect (for example 80ºC) cycle or by a suitable disinfectant solution.

Note: In the event of a breakdown, periodic testing or other issues that may halt normal production, the loss of a multi-chamber WD can have a large impact on throughput. Therefore when installing this type of WD, contingency arrangements should be considered and consideration given to the installation of a number of single chamber pass through WDs in parallel. Refer to planning guidance SHPN 13 Part 1: 2011.

Type of load carriers

2.28 Washer Disinfectors for medical devices and associated equipment can be designed to accept interchangeable load carriers They are typically fitted with rotating spray arms (with rotation detection sensors) or other devices to ensure a uniform wash action throughout the load items. Additional requirements for load carriers can be found under ‘Associated load-handling equipment for WDs’ later in this section.

2.29 The WD design should ensure spacing between layers can accommodate a range of tray or basket sizes and include an adjustable multi-layer carrier for 3, 4 or 5 layers as required and a method to accommodate large bowls, instrument trays, reusable rigid containers etc. Consideration should also be given to specialist carriers for particular medical devices such as anaesthetic accessories, rigid endoscopes, minimally invasive surgical instruments (MIS), lumen and powered devices.

2.30 Washer Disinfector (WD) loading systems should be designed with regard to the 'Manual Handling Operations Regulations: 1992' (as amended). When interchangeable load carriers and baskets are provided, each load carrier should be capable of being fitted and removed without the use of additional tools.

2.31 A number of different types of load carriers can be used to accommodate the range of medical devices to be processed. The range of carriers that may be necessary for a CDU includes:

- an adjustable multi-layer carrier for 3, 4 or 5 layers;
- a rigid endoscope/MIS instrument/lumen device carrier;
- an anaesthetic accessories carrier;
- sterilization containers;
- specific carriers for complex medical devices e.g. robotic surgery;
- power tool carriers.

2.32 Load carriers should protect medical devices from mechanical damage during the wash process and orientate them to facilitate proper cleaning. When necessary, a direct connection between the water flow and any lumen of the load item should be present.

2.33 The use of self contained data loggers is recommended during validation and periodic testing. A connection should be provided on racks for attachment to allow monitoring of water pressure within the rack irrigation pipe work. This is especially recommended for multi chamber WDs. Care needs to be taken in selecting units that are capable of withstanding the high temperatures found in washer-disinfectors. Those housed in protective cases rated at IP68 (as defined in EN 60529: 1992+A2: 2013) are suitable for use. Further guidance on the use of Data loggers can be found in SHTM 01-01 Part B.

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

2.35 When the WD is supplied with a system for supporting and/or transferring the load into and out of the chamber, the following should apply:

- the force required by the Operator, to unload the system should not exceed the limits set within local manual handling policy. This limit applies whether force is applied directly or indirectly;
- the load carrier should be stable when withdrawn for a distance equal to two-thirds of the chamber length, or if the load is to be withdrawn further a retaining device should be fitted. This may include application of a mechanical device supplied with the equipment;
- all load carriers should be operated in accordance with the manufacturer's instructions.

2.36 The system used to support the load should be constructed from durable, corrosion-resistant materials able to withstand, the environment within the chamber.

2.37 A means should be provided to prevent damage wear and tear or excessive stress (e.g. point loadings) that could initiate corrosion in stainless steel materials or to the chamber, during transfer of the load into and out of the WD.

2.38 The load carriers used should be designed in a manner that prevents incorrect positioning that could prevent the attainment of the pre-set operating cycle variables i.e. the penetration of water into the load or the free drainage of water from the load.

2.39 Automatic loading equipment is also available for some WDs and a decision regarding the benefit of these systems should be based upon space available in loading/unloading areas, manual handling assessments and the numbers and design of the WDs in use.

2.40 Dedicated trolleys should be used in the 'Wash Room' and the 'IAP Room' as stated in SHPN 13 Part 1: 2011 and a process should be in place for the cleaning and disinfection of trolleys between uses.

2.41 The trolley should be designed to:

- allow the operator to align the trolley with the washer disinfector for ease of loading and unloading;
- should be provided with means to collect liquid residues from the load to prevent dripping onto the floor;
- should be provided with swivel wheels to facilitate manoeuvring;
- should be provided with a parking brake;
- should be designed to secure the load carriers on the trolley during loading and unloading, and while traversing a gradient at a slope of up to 1 in 20.

Additional factors to consider

2.42 Prior to purchase or use of a washer disinfector a number of factors should be considered. These include:

- temperature;
- process chemical type and concentration;
- wash racks;
- required pump pressure;
- water flow volume and rate;
- water quality;
- air temperature;
- air-flow rate;
- loading pattern.

2.43 The above factors may also vary depending on the make model and design of the WD. The User, Authorised Person (Decontamination) AP(D) and the Authorising

Engineer (Decontamination) (AE(D)) should be consulted to ensure all factors are identified.

Washer Disinfector engineering service requirements

Steam supply

2.44 Within thermal washer disinfectors steam may be used in a heat exchanger, as a source of indirect heating for water or air to be used in the cleaning, disinfection or drying stages of the operating cycle. Steam used to heat process water, may be supplied from an external (mains) supply. Requirements for steam quality can be found in Part C of SHTM 01-01.

Note: Consult HFS guidance Scottish Health Planning Note (SHPN13) Part 1 Decontamination facilities: CDUs 2011 for guidance on Engineering services. This should be done in conjunction with the Room Data Sheet (no. 27) for the 'Wash Room' provided in the guidance.

2.45 Excessive moisture or Non Condensable Gases (NCGs) in the steam supply will also impair the heating efficiency of the heat exchanger and so should be avoided.

2.46 Tests should be carried out during the Installation Qualification (IQ) and Operational Qualification (OQ) tests (see Section 3) to verify that the steam supply is sufficient for all WDs under conditions of greatest steam demand.

2.47 Vertical rises between floors or at intermediate points of the pipework should be kept to the minimum and have a continuous fall to allow any condensate to flow by gravity in the same direction as the steam. Air vents and steam traps should be fitted at each vertical rise.

2.48 The condensate discharge system should be sized to ensure that the high volume of condensate found during the initial stages of heating can be discharged without causing 'waterlogging' of the heat exchanger.

2.49 When the steam supply pressure at the inlet to the WD exceeds the maximum value specified by the manufacturer, a pressure reducing valve should be fitted to the supply pipe at least 3m from the WD. Careful attention should be paid to the siting of all pressure relief valves to ensure that the WD is properly protected.

2.50 Relief valves and their discharge pipes should be large enough to prevent the pressure in the supply pipes rising to more than 10% above the design pressure for the heat exchanger.

2.51 The discharge pipe should terminate in a safe position outside the building. Steel and copper piping traditionally used for steam supply are acceptable for this application.

Condensate recovery

2.52 Condensate from calorifiers, dryers and steam traps suitable for recovery, should be returned to the steam generating plant when economically justifiable.

Compressed air

2.53 Washer disinfectors may require a supply of compressed air for either the operation of valves and powered door systems and/or during the drying stage of the operating cycle. The quality of air can be critical for example for drying, if the load is to be released without subsequent sterilization.

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

2.55 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.

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

2.57 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.

Washer disinfector ventilation

2.58 Washer Disinfectors should be connected to a suitable air extraction system dedicated for purpose and not connected to the general ventilation extraction system. 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.

2.59 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 SHPN 13 part 1: 2011 and Scottish Health Technical Memorandum 03-01 ‘Ventilation for healthcare premises'.

Drainage

2.60 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).

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

2.62 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.

2.63 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.

2.64 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.

2.65 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 to ensure the maximum accessible surface temperature of any pipes or surfaces should not exceed 43 °C.

Process chemicals for medical device cleaning

2.66 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 tendering exercise. 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 etc. The cleaning performance requirements of the WD are addressed in Section 2.10. This includes the requirement to meet the Advisory Committee on Dangerous Pathogens Transmissible Spongiform Encephalopathy (ACDP-TSE) 2015 Annex C guidance. The performance qualification includes the testing of cleaning efficacy and process residues which relate to the process chemicals in use, see Table 5. 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.

2.67 Chemical dosing systems should be accurate, reproducible and meet the requirements of EN ISO 15883-2: 2009 clause 4.1.6. This should be confirmed by validation of the process at Installation Qualification (IQ) Operational Qualification (OQ) and Performance Qualification (PQ) of the WD as local water quality can affect cleaning efficacy.

2.68 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: Ensure the process chemical in use is compatible with the feedwater 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.

2.69 Employers are required by law to do everything reasonably practicable to protect the health of their workers. The safe use of these compounds is covered by the 'Control of Substances Hazardous to Health (COSHH) Regulations: 2002 (as amended)'.

Enzymatic cleaners

2.70 A considerable proportion of the soiling found on medical devices contains proteins that can bind onto surfaces and act as a focal point for particulates. Enzymatic cleaning solutions help breakdown proteins enabling bound soil to be released from the medical device surface.

2.71 Enzymes are not themselves cleansing agents therefore a properly balanced surfactant may still be required to remove the resulting organic residues and other molecules such as fats.

Formulations for cleaning medical devices are available in two forms:

- initial soaking solutions used to digest proteinaceous soil, followed by the normal washing process using detergent;
- a combination solution of enzymes and detergent formulation.

Note: Enzymatic cleaning solutions used in manual cleaning processes require a risk assessment to be carried out in accordance with the Health and Safety Executive guidance:

http://www.hse.gov.uk/research/rrpdf/rr972.pdf

https://www.aise.eu/our-activities/standards-and-industry-guidelines/safe-handling-of-enzymes.aspx

2.72 Any enzymatic detergent activity is temperature and time dependant and should be used at the temperature and for the duration recommended by the manufacturer. Enzymatic cleaning solutions also have an optimum pH at which their activity is greatest and the enzyme is most resistant to thermal degradation, therefore, they should include buffering agents to maintain the pH within the preferred range.

Compatibility considerations

2.73 The process chemicals used should be appropriate for their intended purpose of cleaning and have no long term effects on the components of the WD or the medical devices to be processed. Confirm with the WD manufacturer that the process chemical is compatible with their WD. This includes the circumstances where a change to existing process chemical in use is being considered. It is not sufficient to determine only the compatibility of the principal active constituents, as the precise formulation of the process chemical will affect its compatibility. The process chemicals used can be viscous and chemically aggressive. As pipe work, 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 process chemicals. The use by date for all process chemicals should be checked prior to use and the lot number and expiry date recorded.

2.74 Lubricants should be applied as required by the medical device manufacturers' instructions for use. Where possible this should be carried out during the inspection/packing process after thorough cleaning of the medical device. Refer to SHTM 01-01 Part F for further guidance.

Compatibility with the process

2.75 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 COSHH provisions.

http://www.hse.gov.uk/detergents/detergents-guidance-document.htm

http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:l32025

2.76 The process chemicals used should be compatible with the construction materials of the load and should not cause chemical or physical damage.

2.77 The process chemicals used should be readily removed from the load items by rinsing with water.

2.78 For most applications, where compatible, alkaline detergents in the pH range 8.0 to 11.0 are preferred. Process chemicals for use in washer disinfectors should be:

- compatible with medical devices to be processed and their intended use (i.e. biocompatible);
- compatible with any subsequent decontamination process such as terminal sterilization, e.g. low temperature sterilization processes;
- compatible with the materials of construction of the WD;
- compatible with the quality of water available;
- compatible any other additives to be used in the WD process;
- non-abrasive;
- low foaming;
- free rinsing;
- biodegradable;
- liquid (to facilitate accurate dispensing).

2.79 Process chemicals used in the WDs can be an irritant. Provision should be made for safe storage in a dedicated locked chemical store cabinet. Refer to HFS planning guidance SHPN 13 Part 1: 2011. Only validated chemicals should be available for use. Any change to the process chemicals in use should follow a change management process to prevent the use of un-validated process chemicals.

2.80 An emergency eye wash station, suitable Personal Protective Equipment (PPE) and an appropriate spillage kit should also be available in any area where process chemicals are stored or used.

Note: Only staff trained in emergency spill procedures as per local policy should manage any chemical spill. Reference should be made to local Control of Substances Hazardous to Health (COSHH) provisions.

Storage and dispensing systems for process chemicals

2.81 In large installations, bulk storage tanks of process chemicals, piped to the WD may be required to meet the demands of the CDU. Each dosing system and associated chemical containers should be clearly labelled for the appropriate chemical supplied.

Note: Process chemicals should be stored in a secure location with controlled entry and only validated in date process chemicals should be kept in this location. New process chemicals being trialled should be stored elsewhere to prevent mix up.

Where bulk storage tanks are installed, there should be two storage tanks in parallel for each process chemical to be used (one of which may be a small reserve tank):

- to permit cleaning and maintenance of the large tank without interrupting the use of the washer disinfectors;
- to facilitate segregation between separate batches of chemical additive;
- to allow for an orderly change to a different formulation if required.

Stand alone ultrasonic cleaner specification

Note: Ultrasonic Cleaners (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. Ultrasonic cleaners are particularly suitable for cleaning medical devices of high-grade steel and are effective for cleaning instruments that have deep interstices that may be contaminated with body tissues, for example reamers, drills and burrs. Ultrasonic cleaners are less effective when used to clean plastic and similar readily compressible materials as they absorb much of the ultrasonic energy.

2.82 Where stated by the medical device manufacturer's instruction for use e.g. for some robotic systems, UCs can be used as an initial cleaning method with or without disinfection followed by processing through a validated WD.

2.83 UCs can be a stand-alone ultrasonic bath or included as a separate dedicated chamber in a multi-chamber machine. Many UCs do not incorporate a disinfection stage and are intended for use as an initial cleaning process before cleaning and disinfection in a WD for medical devices. As many ultrasonic cleaners 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.

2.84 When combined with appropriate connection to an irrigation or flushing system, UCs are effective for cleaning internal and external surfaces of cannulated medical devices such as robotic devices.

Note: Safety specifications for ultrasonic cleaners are included in EN 61010-1: 2010 and EN 61010-2-040: 2015.

2.85 The ultrasonic cleaner should be:

- fitted with means to drain the tank so that no pools of liquid are left in the tan;
- heated with an electric thermostat;
- fitted with a timer to control the duration of operation.

2.86 The UC should have a lid that fits securely to prevent the emission of aerosols and protect the operator from harm during operation. 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 Wash Room (refer to 'The Control of Noise at Work Regulations 2005' and SHPN 13 Part 1: 2011).

2.87 The UC manufacturer should recommend the process chemicals (detergents/enzymatic cleaners) that are compatible with their equipment.

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

2.89 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}).

2.90 For medical device applications, aqueous solutions should be used at temperatures recommended by the process chemical manufacturers' 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 minimizes the rate of coagulation of proteinaceous material in any soil.

2.91 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.

3. Validation and verification of washer disinfectors

3.1 The sequence of testing required for a Washer Disinfector (WD) and supporting equipment/services required to validate the WD for initial use in production at the Central Decontamination Unit (CDU) and thereafter monitoring by periodic testing in routine use comprises of:

- type testing by the WD manufacturer at their facilities prior to delivery to the CDU, see Section 3.8;
- testing of ancillary equipment and engineering services at the CDU prior to delivery of the WD, see Section 3.11;
- validation of the WD and associated load handling equipment comprising of three sequential qualification stages namely:
  - the Installation Qualification (IQ), see Section 3.22;
  - the Operational Qualification (OQ), see Section 3.23 and;
  - the Performance Qualification (PQ), see Section 3.26;
- periodic testing of the WD, see Section 3.47.

3.2 The interrelationship of the various test programmes, where they would usually be conducted and the WD manufacturer and User responsibilities for conducting the tests are shown, see Figure 1.

3.3 Washer Disinfectors (WD) are used to carry out cleaning, disinfection and drying of medical devices. These processes require validation to demonstrate they will consistently clean and disinfect the medical devices to be processed. For additional information for the management of the validation process, refer to SHTM 01-01 Part A section 4 ‘validation/periodic testing of equipment used in the decontamination process’ and section 14 on ‘procurement of equipment’.

3.4 The calibration of controls and instrumentation should be verified and the equipment should be subjected to a suitable maintenance programme, see Section 9. Reference should be made to the WD manufacturer’s maintenance schedules.

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

Safety checks and safe working

3.6 The AE(D) should advise on the documented programme of safety checks necessary for each WD(s) in use. 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. See SHTM 01-01 Part A section 11 with regard to the permit-to-work system that should be followed. Certain specific safety tests should be carried out prior to or 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).

3.7 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: 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 01-01 Part A: 'Functional roles and responsibilities'. Also refer to the permit-to-work system outlined in SHTM 01-01 Part A.

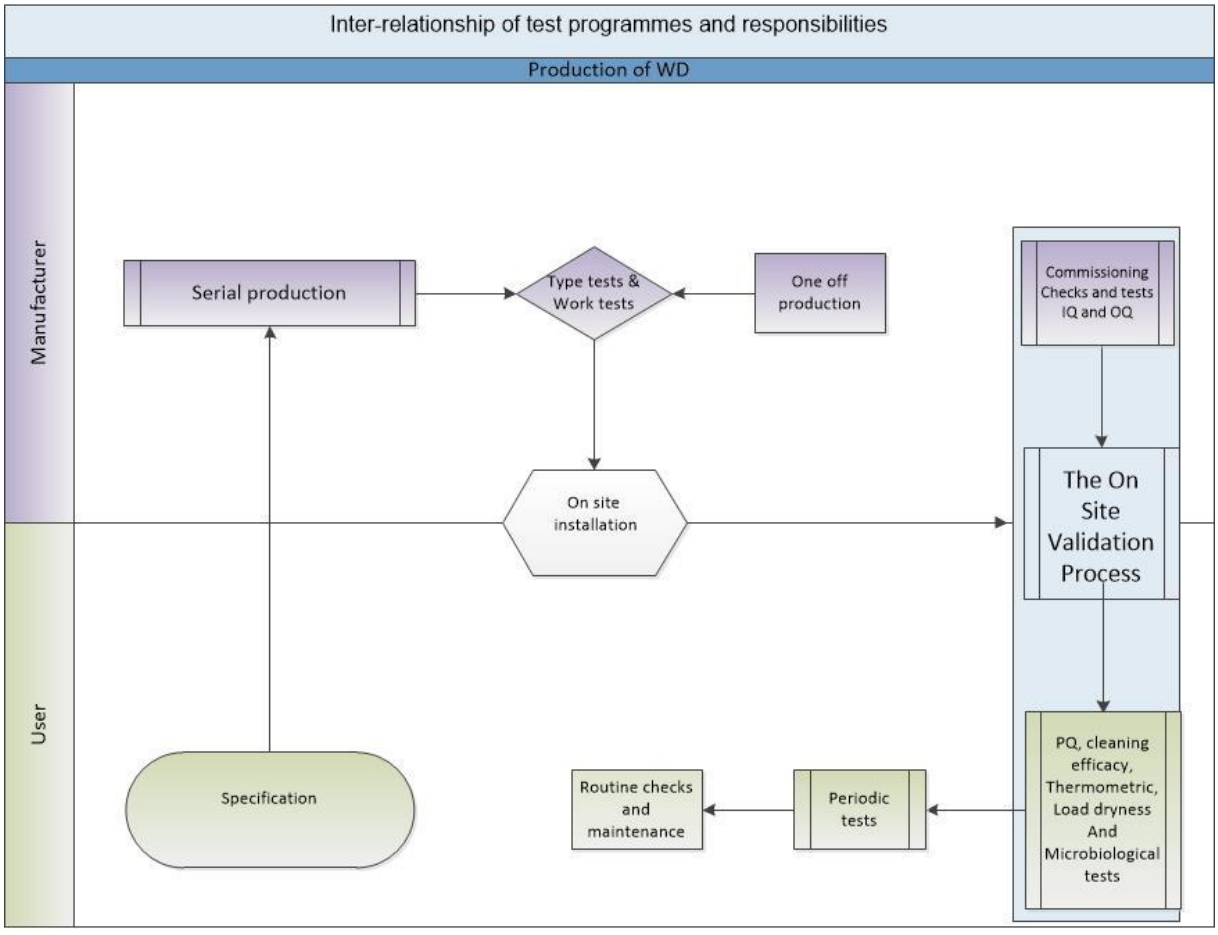

Figure 1: Interrelationship of tests showing responsibilities of User and manufacturer

Type tests and works tests – at the WD manufacturer's facility

3.8 The manufacturer will carry out 'type tests' on representative samples of washer disinfectors in serial production to demonstrate compliance of the WD design with EN ISO 15883 Parts 1: 2014 and 2: 2009.

3.9 Where the customer has specified additional requirements the manufacturer will carry out 'works tests' on each WD before it leaves the manufacturing site to ensure that each WD meets the required specification. These tests should comply with the EN ISO 15883 series and include any additional tests required by the User, AP(D) and AE(D).

3.10 The results of any type test and works tests can be requested by the purchaser as part of the specification for tender or purchase. It may be necessary for the purchaser, or their representative, to visit the manufacturer's premises to witness works testing. The advice of the AE(D) should be sought. The manufacturer should make the results of type tests and works tests available to the purchaser on, or before, delivery of the WD. Post installation of the WD, further testing may be required by the WD manufacturer in the event of new process chemicals being considered.

Testing ancillary equipment and engineering services at the CDU prior to delivery of the WD

3.11 Testing ancillary equipment and engineering services should, whenever practicable, be carried out before testing of the WD begins.

3.12 Ancillary equipment required for operation of the WD should be further tested with the WD in operation. The CP(D) should validate all ancillary equipment in co-operation with the contractor for the WD.

3.13 The WD and ancillary equipment manufacturer or installation contractor(s) are not responsible for the correct functioning of services and ancillary equipment unless this was agreed in the purchase contract.

3.14 Inspection of the engineering services should be made to ensure they have been installed correctly, are adequate to meet the demands of the decontamination equipment, there are no leaks and all necessary isolating valves/switches and test points are installed.

3.15 Drains should be checked to ensure the effective removal of the maximum volume of effluent from all plant in the vicinity, including when the decontamination equipment is operating at full capacity.

3.16 Any water treatment plant (if fitted) should operate correctly and the quality of water supplied for each stage of the process should be in accordance with the specification, including the required pressure and temperature, see Table 2.

Checks – User/CP(D)
Water Quality (Hardness) (as $CaCO_3$)
Water supply temperature
Volume of water used per stage
Water supply pressure

Table 2: Water checks at the CDU prior to the delivery of the WD

3.17 The water economy system (if fitted) should operate correctly.

3.18 The provision for storage, handling and connection to the WD for all process chemicals should meet the COSHH requirements for safe handling of potentially hazardous chemicals.

3.19 The exhaust ventilation and/or condenser unit fitted to the WD should be adequate to remove the hot, humid air evolved from the washing, thermal disinfection and drying and unloading processes.

3.20 Ensure all equipment has been supplied in accordance with the contract and that the manufacturer has supplied all required documentation. Ensure verification certificates for calibration of measuring instruments and controller(s) on the WD have been supplied and that no defects are apparent from a visual inspection of the equipment.

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

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

Installation qualification of WD and associated load handling equipment

3.22 After the equipment has been installed, check that the following recommendations are met and see the testing detailed in Table 3:

- all supports, bases and fixings are secure and without imposed strain from service connections;
- thermal insulation is in satisfactory condition and securely attached for all relevant services;
- security settings of door safety switches are in compliance with data supplied by the manufacturer;
- each machine has been supplied with the unique keys, codes or tools required to operate locked controls, control over-rides and that they operate correctly, that is, only operate the control for which it is intended; and cannot unlock controls on other machines in the vicinity;
- loading conveyors and trolleys, load carriers and load baskets are effective and safe in use;
- check (if applicable) that any automatic load/unload systems function correctly and safely, including checks on emergency stops and other safety devices required to ensure the safety of staff and prevent damage to equipment. Advice can be sought from the local Health and Safety advisor;
- check that all specified data systems are functioning correctly. This may include automatic download of the machine and IMS operating cycle data to a computer or network, download of data to a track and trace system, the function of rack ID systems and load scanners etc;

- check that the room pressure differential is maintained between the 'Wash Room' and the 'IAP Room' as specified in SHPN 13 Part 1: 2011;
- confirm that access for maintenance and servicing of the WD services is safe;
- confirm that any additional operating cycles requested for the WD by the User are as per specification.

Installation qualification tests – contractor	SHTM 01-01 Part D Section reference for the test
Water supply pressure	7.14
Verification of calibration	4.67
Automatic control test	4.97
Blocked drain protection	4.12
Estimation of dead volume of pipework	4.7
Efficacy of drainage discharge	4.25
Equipment overflow test	4.32

Table 3: Contractor IQ tests

Operational qualification of WD and associated load handling equipment

3.23 During an operating cycle, with an empty chamber, verify the following (several cycles may be necessary to complete all the checks) and see the range of Operational Qualification (OQ) testing outlined in Table 4:

- the selection of automatic or manual control is by key code or tool. The selection of one control mode inactivates the other control mode;
- under automatic control, water, steam, compressed air or process chemicals cannot be admitted into the chamber, and the operating cycle cannot start until the door is closed (locked and sealed);
- under manual control the operator can only advance the operating cycle sequentially through each stage. Any stages designed to remove process chemicals from the chamber and load cannot be circumvented;
- throughout the operating cycle the indicated and recorded values of critical variables are within the limits specified by the manufacturer and within the limits required by EN 15883-1: 2014;
- throughout the operating cycle there are no leaks of water, steam aerosols, air, or effluent;
- there is no evidence of interference to or from other equipment connected to the same services;
- there is no evidence of electromagnetic interference to or from other equipment;
- operation and reading of all instruments are satisfactory;
- the temperature of surfaces routinely handled by the operator does not exceed 43^{o}C as specified in the HSE publication 'Managing the risks from hot water and surfaces in health and social care';

- the effluent temperature does not exceed 43^{o}C as specified in section 2 ‘drainage’ and depending on the location of the CDU any hot water discharge may require dilution with other cold waste water prior to discharge;
- the door cannot be opened until the operating cycle has been completed without causing the cycle to abort and a fault/incomplete alert produced, that is, the automatic controller has operated in accordance with its specification;
- the door interlock system is either fail-safe or is fitted with at least two independent interlocks;
- failure of one interlock, or any one service, does not allow the door to open when conditions within the chamber would cause a hazard (for example, pressure in excess of 200 mbar or unacceptable level of steam or chemical vapours);
- the automatic controller has operated in accordance with the parameter values determined at validation;
- confirm that all data from all sensors is present and correlated and that all data from the IMS and WD are downloaded correctly;
- if a spray arm rotation detection system is fitted check that it functions correctly and that any anomalies are resolved e.g. variable pump pressure.

3.24 The decontamination equipment should be tested to ensure it reacts correctly and safely when exposed to a number of external fault conditions. A false indication of a satisfactorily completed operating cycle should not be obtained when a fault is present.

3.25 During each stage of an operating cycle, the following faults (as appropriate to the type of machine) should be simulated:

- operation of the emergency stop button;
- power failure;
- water pressure too low;
- water pressure too high;
- steam pressure too low;
- steam pressure too high;
- compressed air pressure too low;
- compressed air pressure too high;
- failure of process chemical supply (detergent, etc.);
- failure of extract ventilation;
- communication systems failure.

Operational qualification tests – CP(D) (may be the contractors CP(D))	SHTM 01-01 Part D Section reference for the test
Safety checks	3.6
Automatic control test (each cycle)	4.97
Verification of calibration	4.67
Water system: – chemical purity – conductivity – bacterial endotoxins – total viable count	Section 7
Doors and door interlocks: – cycle start – in-cycle interlock – loading unloading (double door/pass-through WDs) – fault indication on sensor failure	 4.37 4.38 4.40 4.42
Water vapour/fluid emissions test: – Chamber leakproof – Door seals	 4.47
Process chemical dosing tests: – reproducibility of volume admitted – indication of insufficient process chemicals (low level detection)	 4.61 4.63
Load carriers alignment and operation: – spray arm rotation blockage test if sensor fitted	 4.54
Channel Patency (if using channel irrigation system)	
Ultrasonic activity (If the WD has an ultrasonic stage or process)	
Cleaning efficacy test: using test soil Chamber Load carrier – reference load of general instruments – rigid endoscopic/MIS instruments/surrogates	4.100
Thermometric tests	4.71
Load carrier temperature test	
Over-temperature protection test (if fitted)	4.83
Final rinse water tank	
Thermometric test for:	
– thermal disinfection – reference load – chamber walls – final rinse water tank	4.76
Temperature control tests	
Rate of rise	
During –Flushing stage, washing stage	
Over temperature cut-out	4.83
Load dryness test: – reference load	4.90

Ventilation/Venting System –	
WD Air Filter Quality test	4.93
load contamination from ductwork (if fitted)	4.9
Chamber Wall test	
Sound pressure test	4.2
Independent monitoring system:	4.99
– including calibration	
– limits and trip points	
– alarm actions	

Table 4: OQ tests

Performance Qualification

3.26 Performance Qualification (PQ) testing is the process of obtaining and documenting evidence that the WD will consistently give reproducible results when operated in accordance with the pre-defined acceptance criteria within the process specification.

3.27 The extent of the PQ tests required will depend on the type of WD and the nature of the load. PQ tests are carried out by the CP(D). A list of PQ tests is shown, see Table 5.

PQ tests	SHTM 01-01 Part D Section reference for the test
Cleaning efficacy tests using test soil	4.100
Cleaning efficacy test for a full load of particular items not represented adequately by the reference load.	
Cleaning efficacy test for internal surfaces of processed medical devices, e.g. anaesthetic and respiratory tubing, lumen devices and powered devices, or agreed surrogates (see EN ISO 15883-2: 2009 clauses 4.4 and 6).	4.109
Cleaning efficacy testing to be compliant with the ACDP-TSE Annex C 2015 guidance which stated 'the upper limit of acceptable protein contamination after processing is 5 µg BSA equivalent per instrument side. A lower level is necessary for neurosurgical instruments'.	4.114
Load dryness test for a full load of particular items not represented adequately by the reference load	4.90
Process residues: Process chemicals	4.86
Thermometric Tests	4.71
Chamber walls	4.74
Load - For temperature of internal surfaces of processed medical devices (e.g. anaesthetic and respiratory tubing, lumen devices and powered devices), see EN ISO 15883- 2: 2009 clauses 4.4 and 6.3.3.	4.76
Load carrier alignment	
For verification of flow through lumen and powered devices, see EN ISO 15883-2: 2009 clauses 4.4,	4.54

5.1.1, 5.1.2 and 6.3.3.	
Additional optional tests	
Reproducibility requirement on process temperature control limits see EN ISO 15883-1: 2014 clauses 5.9.1c and 5.9.2 d.	

Table 5: Performance qualification tests for washer disinfectors (carried out by the CP(D))

3.28 In principle, validation is not complete until a PQ test has been performed for each loading condition that the WD is expected to process. A loading condition is a specified combination of the nature and number of load items, the chamber furniture, and their distribution within the chamber. For example, a load placed on the top level of a four level load carrier constitutes a different loading condition from the same load placed on the lowest level.

3.29 Users should adopt the following procedure for every WD:

- establish a list of potential product families and their relationship to the validation loads;
- establish a list of the different loading conditions used to process each load in the equipment;
- 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 test loads used in the cleaning efficacy and thermometric tests carried out during validation.

3.30 In practice, where the loading conditions used during OQ testing are designed to represent the actual production loads or present a greater challenge to the process, the data obtained during OQ tests is sufficient.

3.31 Additional PQ tests will be required if:

- the mass of metal medical devices to be processed exceeds that of the standard test load used during validation;
- medical devices with narrow lumens will be processed;
- when the loading condition is a greater challenge than previous validation loads;
- when extensive maintenance of critical components or a major repair had been undertaken.

3.32 Where PQ tests have been undertaken as part of the installation tests and no separate PQ report will be created, the AE(D) should be satisfied that the range of installation, operational and performance qualification tests undertaken is representative of the range of loads and product families processed by that particular WD. This should be documented.

3.33 New PQ tests may be required for WDs during their operational lifetime where there have been changes to:

- the quality of the water supply;
- the process chemicals used in the cleaning process;

- the loading system or the requirement to process a new type of medical device;
- optimise the process or if advised by an AE(D). E.g. if the results of cleaning efficacy testing are not compliant with the ACDP-TSE Annex C 2015 guidance and the point in the process outlined in Figure 2 is reached which indicates revalidation should be considered;
- Surrogate devices for use in the PQ.

3.34 Many of the most difficult loads to process in a WD that require PQ testing, are also difficult to monitor either thermometrically or microbiologically, are in short supply or may be extremely expensive; examples include, ophthalmic handpieces and robotic systems.

3.35 In these cases a surrogate device designed and constructed to emulate the characteristics of the medical device can be used to monitor the cleaning and disinfection processes.

3.36 The surrogate device should have similar geometry, thermal mass, surface finishes and as far as practicable, be constructed of the same materials as the medical device it is designed to represent. An example of a surrogate device for a rigid endoscope could be a similar length of stainless steel tube of the appropriate diameter and bore. The surrogate device should also be constructed to incorporate the appropriate temperature sensors and to facilitate the evaluation of residual test soil or survivors from a microbial challenge.

PQ - Cleaning efficacy

3.37 Cleaning efficacy tests are intended to demonstrate the ability of the WD to remove or reduce, soiling and contamination that occurs during normal use of a medical device from the device and the WD to acceptable levels. Information on the methodology for protein monitoring for compliance with ACDP TSE Annex C 2015 guidance is included in SHTM 01-01 Part A section 12. Improving the cleaning performance of existing WDs is also addressed.

3.38 Natural soiling varies in, the extent of soiling that can occur during use and the nature of constituent parts. This can affect the ease with which soiling is removed and makes test methods based on the detection of naturally occurring soil difficult to standardise and reproduce. Changes in the sensitivity of soil detection can also occur due to variation in soil composition.

3.39 Artificial test soils are designed to simulate the nature of native soiling and to be equally or more difficult to remove. Artificial test soil composition can vary in both consistency and colour. Therefore the same test soil should be used for all testing on a specific machine to obtain reproducible results. Careful consideration should be given to the test loads used and degree of soiling applied to ensure the instruments that represent the greatest cleaning challenge to the WD and are cleaned to the required level of cleanliness.

Note: The recommended test soil for use can be found in ISO/TS 15883-5: 2005, ‘Annex N’ for surgical instruments and ‘Annex O’ for Anaesthetic accessories. The ingredients and method of use are included in section 4 of this guidance document.

3.40 While test soils avoid any hazard associated with handling of medical devices contaminated with pathogens they have several limitations which include:

- there is no chemically defined formulation (the traditional soils use substances such as flour, wallpaper paste, fresh egg yolk, horse blood, which introduce significant variability);
- there is no agreed quantitative method of applying the test soil to the surfaces of the medical device to be processed;
- there is no agreed quantitative method of detection for soil remaining after the processing in the washer–disinfector;
- there is no known relationship between test soils and native soiling with regard to ease of removal or relevant residual levels etc.

PQ - Process residues

3.41 The process chemicals used during the decontamination process, i.e. detergents, etc., may not be completely removed by the rinsing process. The tolerable residual level is dependent on the nature of the chemical and the intended use of the medical device.

The supplier of any process chemicals in use is obliged to provide data on the chemical composition of the chemical the biocompatibility of its components and the method of detection, to determine whether processed medical devices are free from residuals at the specified levels.

PQ - Disinfection

3.42 The requirements for thermal disinfection are defined in EN ISO 15883 Part 1: 2014 (clause 6.8) and Part 2: 2009 (clause 6.3) and in section 2 of this guidance.

For thermal WDs, disinfection is achieved by moist heat. The disinfection conditions are specified either by an A_0 value to be achieved throughout the load, or by a disinfection temperature band with defined minimum and maximum allowable temperatures. Time/temperature bands meeting the requirements of an acceptable A_0 of 600 as stated in Table 1.

3.43 Other validated time/temperature relationships may be used as long as an equivalent A_0 value has been demonstrated as being achieved. The higher the disinfection temperature, the shorter the holding time needed to achieve the same level of disinfection. The choice of A_0 and disinfection temperature will depend upon the:

- intended use of the medical devices;
- materials of which the medical devices are made;
- nature and extent of expected bioburden on the medical devices.

3.44 Microbiological testing is not recommended for a thermal disinfection process.

PQ - Load dryness tests

3.45 The presence of residual water on cleaned, disinfected medical devices should be avoided as it can interfere with its functionality, promote re-contamination and microbial growth or prevent attainment of sterilizing conditions.

3.46 The ability of the WD to dry the load can be evaluated either visually, when appropriate, or by drying to constant weight and determining the mass of residual water present at the end of the WD operating cycle.

Periodic testing

3.47 Minimal requirements for periodic tests are defined in EN ISO 15883 Parts 1 and 2. These tests are carried out at daily, weekly, quarterly and annual intervals. However it is recommended that periodic testing is performed as defined, see Table 6.

3.48 Tests should only be undertaken after completion of the planned maintenance tasks described in section 9 ‘Planned preventative maintenance programme’.

3.49 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 recommended tests can be carried out concurrently on the same operating cycle.

3.50 The results of periodic tests should be recorded, documented and filed securely, in electronic or paper format. All process records should be kept for at least 13 years to allow tracking and tracing of medical devices in the event of an adverse event and in compliance with the ‘Consumer Protection Act Scotland (2006)’.

Daily tests – User
Check spray arm for rotation/free movement and blockages
Check spray nozzles for blockage (paying particular attention to those fitted to carriages for cannulated instruments)
Remove and clean strainers and filters, etc.
Ensure sufficient additives available and that dosing system is functioning
Automatic control test (rotate cycles)
check grommets / seals holding control probes etc for deterioration due to chemicals used
door seals for any wear / tears
Process challenge device test (optional)[1]
Weekly tests – User or CP(D)
Weekly safety checks
Carry out daily tests
Water hardness (all process stages)
Water conductivity (final rinse stage)
Cleaning efficacy test by residual soil detection
Quarterly tests – CP(D)
Weekly safety checks and functional check of engineering services
Carry out daily and weekly tests
Verification of calibration
Thermometric tests for disinfection
Cleaning efficacy test: Using test soil – reference load[2] – general instruments endoscopic/MIS instruments
Doors and door interlocks: – cycle start – in-cycle interlock – double-door washer disinfectors – fault indication on sensor failure
Chemical dosage check - ensure parameter remains within tolerance
Calibration, limits and function, including fault/alarm, of the independent monitoring system[3]
Annual and revalidation tests – CP(D)
Safety checks and verify the adequacy/safe connection of all engineering services
Automatic control test for each cycle
Verification of calibration of WD instruments (including all IMS system instruments)
Water system: – chemical purity – hardness and conductivity – bacterial endotoxins – total viable count
Drainage: – free draining
Fault indication on sensor failure
Water vapour emissions test
Process chemical dosing tests: – reproducibility of volume admitted

– low level detection
Load carriers
Channel Patency (if using channel irrigation system)
Ultrasonic activity (If the WD has an ultrasonic stage or process)
Cleaning efficacy test: – test soil – reference load[2] – general instruments – endoscopic/MIS instruments
Over temperature cut-out test (if fitted)
Load carrier temperature test
Load dryness test – reference load[2]
Water vapour emissions test – type test
Performance Qualification Tests (if required)
Notes: 1. May be undertaken at the same time as the previous test 2. Additional test loads and alternative test soils may be required for washer disinfectors that are also intended for use with hollowware and/or anaesthetic accessories. The additional testing should also include tests on the load carriers that will be used with these additional loads. 3. Calibration, limits and function, including fault/alarm, of the independent monitoring system should be checked during quarterly and annual tests.

Table 6: Schedule of periodic tests – daily, weekly, quarterly and annual

3.51 Completion of the annual test schedule is required for revalidation of the WD and contains the tests recommended for requalification of the performance of the equipment.

4. Test methods for washer disinfectors

Introduction

4.1 This section of gives detailed methodology for tests required during type testing, the Installation Qualification (IQ), Operational Qualification (OQ), Performance Qualification (PQ) and periodic testing of thermal washer disinfectors used in a CDU as described in EN ISO 15883 Parts 1: 2014 and 2: 2009. Test equipment calibration methods are detailed in SHTM 01-01 Part B. The tests are listed below, see Table 7, in alphabetical order with the corresponding paragraph reference number.

Table 7: Alphabetical list of the test methods

Test	SHTM 01-01 Part D section reference
Additional PQ tests of cleaning efficacy	4.109
Additional Process Challenge Device (PCD) test	4.111
Automatic control test (inc IMS)	4.97
Blocked drain protection	4.12
Chamber wall temperature testing	4.74
Chemical dosing systems	4.59
Cleaning efficacy tests	4.100
Condenser drain seal integrity	4.15
Door opening force	4.50
Doors seals and interlock tests	4.34
Double-door washer disinfectors	4.40
Electromagnetic compatibility	4.3
Equipment Overflow test	4.32
Estimation of dead volume of pipework (type test)	4.7
Failed cycle interlock	4.44
Fault indication on sensor failure	4.57
Free draining (tanks, chamber, load carriers & pipework)	4.22
In-cycle interlock	4.38
Indication of insufficient process chemicals	4.63
Leak tightness of doors	4.47
Load carriers	4.54
Load contamination from ductwork	4.9
Load dryness	4.90
Method for chamber walls and load carriers	4.106
Method for test loads:	4.107
Monitoring of residual protein on medical devices	4.114
On sensor failure	4.42
Operating cycle start interlock	4.37
Over-temperature cut-out	4.83
Purging of the trap: efficacy of discharge through the trap	4.25
Reproducibility of the process chemical volume dispensed	4.61

Residual process chemicals	4.86
Sound pressure test	4.2
Thermometric test for thermal disinfection	4.76
Thermometric tests	4.71
Ventilation plant	4.29
Verification of calibration	4.67
Volume of water used per stage (type test)	4.6
Washer disinfector fitted with HEPA air filters (for drying)	4.93
Water sprays and jets	4.55

Table 7 Cont'd: Alphabetical list of the test methods

Sound pressure test

4.2 The sound pressure test is carried out as part of the IQ tests. It is neither necessary nor practicable to repeat the test as part of periodic testing.

Method

The sound pressure test should be carried out in accordance with EN ISO 3746 by suitably trained and experienced personnel.

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

IEC 61010-2-120: 2016 requires the manufacturer of equipment to carry out a sound power test as part of their type testing if the noise it produces is at a level which could cause a hazard. This test measures the total sound power radiated from the machine and should be performed in a specially designed and equipped test room.

Results of sound pressure test

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

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

- the mean A-weighted surface sound pressure level does not exceed;
- 70 dBA for decontamination equipment installed in the CDU ;
- in both the 'Wash Room' and the 'IAP Room' unloading area the peak 'A-weighted' surface sound pressure does not exceed the mean 'A-weighted' surface sound pressure level by more than 15 dBA.

Electromagnetic compatibility

4.3 These tests are applicable as type tests or works tests only.

4.4 Since June 1993, washer disinfectors classified as medical devices have been required to carry the CE marking. Any WD which bears CE marking solely under the 'Electromagnetic Compatibility Directive' should have the CE marking identified as being applied under the Directive.

4.5 The standard for washer disinfectors EN 15883 specifies that:

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

Volume of water used per stage (type test)

4.6 During type-testing, manufacturers' are required to determine the volume of water used during each stage of the operating cycle. This data is used in later calculations of the service requirements and must be accounted for during equipment procurement specifications. In addition, in the event of concerns with WD performance during installation or operational testing, the volume of water used for each stage should be verified.

Equipment

A water flow meter (or volumetric measuring equipment) should be used.

There are three methods that may be used for determining the volume of water required. The method should be chosen on the basis of which is most convenient for the particular installation.

Methods:

- 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;
- 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

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

Estimation of dead volume of pipework (type test)

4.7 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.

4.8 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

Volumetric measuring vessels of appropriate size should be used.

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 (i.e. volume retained);
- when the WD has two or more entirely separate pipe work systems e.g. for flushing water, wash water, rinse water or detergent solution, each system should be tested separately.

Results of testing the dead volume of pipework

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

Load contamination from ductwork

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

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

Equipment

4.10 The following equipment should be used:

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

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

Method:

- disconnect the external ducting to the WD 1 m above the chamber;
- with the on/off valve closed, fill the vessel with 200 mls ± 20 mls of cold water. Open and adjust the flow control valve so that the contents of the vessel are discharged to waste in 1 min ± 5 sec;
- position the measuring vessel above the disconnected section of ducting. Refill the vessel with 200 mls ± 20 mls of cold water. Feed the flexible tube into the ducting so that the open end of the flexible tube is 600–800 mm above the top of the chamber;
- load the chamber with a full load of dry load items in accordance with the manufacturer's instructions. Close the chamber door and then open the on/off valve. Record the time required for the vessel to empty;
- within one minute of the vessel emptying, open the chamber door and remove the load and any removable load containers. Place all the load items on absorbent paper, examine all surfaces of the load and the absorbent paper for traces of water;
- repeat the above procedure for the full range of load carriers that the WD is designed to process.

Results of checking for load contamination from ductwork

4.11 There should be no visible water on the load or load carriers.

Drainage

Blocked drain protection

4.12 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.

4.13 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.

4.14 A suitable test method is described in EN ISO 15883 Part 1: 2014 (clause 6.3.8).

Condenser drain seal integrity

4.15 When it is impractical to vent the WD externally the WD can be vented via a condenser preventing the discharge of hot, humid air into the surrounding environment.

4.16 There is a danger that any restricted flow within this system can produce a back pressure in the WD chamber. If the back pressure is excessive the water seal between the chamber and drain may be broken.

4.17 To establish that the seal integrity is maintained under normal operating conditions the following tests should be undertaken.

Equipment

A full load of the type the WD is designed to process;

- a test trap, of the same type and dimensions as normally fitted, but manufactured from a transparent material (type test only);
- a dipstick.

Method

4.18 Carry out the test on the installed WD with all services connected. Verify that the trap is charged with water to the normal working level.

4.19 Place a full load in the chamber, close the door and initiate the operating cycle. At the end of the operating cycle, remove the load and examine the water level in the trap. This may be done either visually or using a dipstick.

4.20 Immediately reload the machine with the same full load and repeat the procedure for five consecutive cycles observing the trap between each cycle to establish whether the water seal in the trap has been broken.

Results of checking the drain seal integrity

4.21 The water seal should remain intact with no obvious damage.

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

4.22 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.

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

Method

4.24 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.

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

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

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

Equipment:

- 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

4.27 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

4.28 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.

Ventilation plant

4.29 Consult SHPN13 Part 1: 2011. Correct operation of ventilation plant is essential to ensure:

- the safe operation of WDs, that include 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.

4.30 All ventilation systems associated with the WD should be inspected, serviced and maintained at least every six months or in line with manufacturers' instructions for use. Guidance on extraction ventilation plant maintenance is given in Scottish Health Technical Memorandum 03-01 Ventilation for healthcare premises.

4.31 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. A permit-to-work system should be in operation.

Equipment Overflow test

4.32 For washer disinfectors that incorporate one or more water storage tanks within the WD, verify the capacity of the overflow(s) is adequate to discharge all excess water, without spillage into the WD or work area.

Method:

- ensure that the WD is connected to all necessary services and the water supply pressure adjusted to not less than 6 bar;
- fully open the supply valve(s);
- observe the level of water in each tank or cistern until this has been unchanged for not less than 2 min.

Result of the equipment overflow test

4.33 The WD and overflow installation should be regarded as satisfactory when equilibrium conditions have been attained within the tank(s) without discharge of water other than by the intended (piped) overflow.

Doors seals and interlock tests

4.34 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.

4.35 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.

4.36 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' washer disinfectors;
- prevent the operator within the IAP room gaining direct access to a load that has not been satisfactorily processed.

Operating cycle start interlock

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

Method:

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

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

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

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

Method:

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

Results of checking the door interlock during a cycle

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

Double-door washer disinfectors

Method

4.40 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

4.41 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

4.42 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

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

Failed cycle interlock

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

Method

4.45 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

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

Leak tightness of doors

4.47 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.

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

Equipment:

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

Method:

- load the 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

4.49 There should be no misting of the mirror(s), which would be evidence of vapour emission, and no dampness of the absorbent wipes, which would be evidence of vapour or liquid emission.

Door opening force

4.50 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

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

4.51 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.

4.52 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

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

Load carriers

4.54 Load carriers come in a variety of forms including trolleys, carriages and baskets. Their 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 of checking load carriers:

- 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, cannulated medical devices;
- check load carriers with rotary spray arms to ensure the spray arms are free to rotate, both when the load carrier is empty and when fully loaded.

Water sprays and jets

4.55 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 on a daily basis as part of the routine housekeeping tasks carried out by the User or operator.

4.56 In addition, maintenance staff should also check the system at least weekly; this should include:

- 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.

Fault indication on sensor failure

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

Method:

- start an operating cycle. Immediately before the stage of the cycle where the sensor provides information to the automatic controller disable each sensor in turn. Establish that a fault is indicated;
- test each sensor in both 'open circuit' and 'short circuit' failure modes.

Result from testing the automatic controller when a sensor fails

4.58 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.

Chemical dosing systems

4.59 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.

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

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

4.61 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 OQ and yearly tests for each chemical dosing system on the WD.

Note: 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

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

Method:

- 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

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

Indication of insufficient process chemicals

4.63 All WDs should be equipped with a method of ensuring that a cycle is not initiated when there is 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.

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

Method

4.65 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

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

Instrumentation fitted to a WD

Verification of calibration

4.67 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 EN ISO 15883-1: 2014 clause 5.12–5.17 should be met and SHTM 01-01 Part B should be consulted for calibration requirements for test equipment.

4.68 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

4.69 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 ± 0.1 µS/cm whichever is greater.

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

Thermometric tests

4.71 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 EN ISO 15883 Parts 1: 2014 and 2: 2009 and can be found in Table 1.

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

4.72 The equipment specifications for temperature measurement systems (thermocouples and data loggers) are given in SHTM 01-01 Part B section 2 ‘Decontamination test equipment’

4.73 For multichamber washer disinfectors the use of recorders with fixed sensors may be impractical. In these instances self contained data loggers that can be processed through the WD should be used.

Chamber wall temperature testing

4.74 For multi-chamber washer disinfectors each chamber may be tested consecutively or concurrently. In the latter case eight sensors should be used for each chamber. The WD should be operated empty except for chamber furniture, for example, load carriers.

Method

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 min since the machine was last used). The remaining three tests should be carried out with no more than a 15 min interval between cycles (a hot start).

Results of the temperature measurement of the chamber surface

4.75 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

4.76 Any test load will consist of a reference load or a specific PQ load representative of the load that the WD under test is intended to process. In some cases a surrogate device may be used to simulate load items. If required seek advice from an AE(D).

4.77 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.

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

4.79 Multi chamber WDs may be tested using a combination of thermocouples passed through the entry port into the chamber and located at fixed positions (e.g. adjacent to fixed control/monitoring sensors). Independent data-loggers located within the load items can be used where it is impractical to test the load using thermocouple cables which may be damaged by movement of the loading cart between successive chambers of the WD.

4.80 During thermometric tests for the thermal disinfection stage, the washing stages should be disabled or the controlled temperature reduced to 20ºC ± 5ºC in order 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

4.81 Temperature measuring equipment, see the 'Decontamination test equipment' section in SHTM 01-01 Part B section 2 should be used.

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 on 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:__ 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

4.82 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 EN ISO 15883-1: 2014 on the surface of the load items;

- the temperature (see Table 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: 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 is not capable of processing loads of this type. Advice should be sought from the AE(D).

Over-temperature cut-out

4.83 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 washer disinfector.

Equipment

4.84 Temperature measuring equipment, according to the 'Decontamination test equipment' section of SHTM 01-01 Part B section 2 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:

- 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

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

Residual process chemicals

4.86 Process chemicals used during the decontamination process, detergents, etc., 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

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

4.88 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

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

Load dryness

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

Equipment:

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

Method

4.91 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

4.92 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)

4.93 Many washer disinfectors are fitted with High Efficiency Particulate Air (HEPA) filters (for example, class H 13 as EN 1822-1: 2009) 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: class E 12 would be an Efficient Particulate Air (EPA) filter as EN 1822-1.

4.94 When the load is intended for use without further processing, for example sterilization, the full requirements of the method specified in EN ISO 14644-1: 2015 and SHTM 01-01 Part B should be followed.

Method

4.95 The complete installation should be tested, and the method specified in EN ISO 14644-1 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

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

Periodic tests

Automatic control test

4.97 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:

- place the test load within any load furniture normally used and place in the chamber;
- for washer disinfectors 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

4.98 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 EN ISO 15883 Parts 1: 2014 and 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.

4.99 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. For daily and weekly checks this should be confirmed by the use of a timepiece.

Cleaning efficacy tests

4.100 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.

4.101 By analysing the fraction of soil removed during the cleaning process, when operated for various time periods (including those shorter than the normally 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.

4.102 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 ISO/TS 15883: 2005 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

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

4.104 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.

4.105 The following equipment is required:

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

Method of application of the test soil

4.106 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:

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

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

The test load(s) should consist of items of similar 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:

- 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

4.108 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.

Additional PQ tests of cleaning efficacy

4.109 Additional PQ tests of cleaning efficacy are necessary when some of the items or loads to be processed, are:

- more difficult to clean than the recommended reference load;
- when any of the essential parameters of the WD have changed (e.g. water quality, chemistries in use or a new medical device to be processed).

Method

4.110 Repeat the tests described above for reference loads with actual loads to be processed as specified by the User.

Note: The medical devices to be processed may need to be replaced by surrogate devices when the design of the actual item makes subsequent examination for residual soil impractical.

Additional Process Challenge Device (PCD) test

4.111 PCDs are based on traditional test soils based on test specification ISO/TS 15883-5 Annex N: 2005. As this test specification predated concerns with prion transmissibility it does not assess the removal of hydrophobic proteins such as prions.

4.112 Commercial PCDs are being developed whose challenge simulates the attachment of prion protein to instruments and whose analysis is quantitative. When these become available and have been validated, CDUs should carry out evaluation for their performance before considering their use. The use of a PCD should be correlated with and indicate the performance of WDs in reducing the protein level.

4.113 Where local policy recommends the use of PCDs one should be used per chamber as part of the automatic control test. It should be placed within a standard operational load in a wash basket. The position in the chamber, batch number of the indicator and expiry date should be recorded along with the result. Several tests may be required initially to establish the position that represents the worst case scenario within the wash chamber.

Monitoring of residual protein on medical devices

4.114 The standard EN 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 cleanliness states of invasive medical devices, there must be a link between performance requirements and test method criteria for determining cleaning efficacy in washer disinfectors (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 commencing with witnessed type testing and followed through to performance qualification and subsequent periodic testing.

4.115 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.

4.116 The ACDP-TSE Annex C 2015 guidance indicates 'the upper limit of acceptable protein contamination after processing is 5 µg BSA equivalent per instrument side. A lower level is necessary for neurosurgical instruments'. Their rationale for this is given in section 12 of part SHTM 01-01 Part A. Definitions are given as below:

- '**after processing**' in this occasion only is deemed to be after disinfection and not after sterilization of the medical device;
- '**per instrument side**' is deemed to be a single side of the medical device;
- '**instrument side**' is deemed to be the exposed surface of the medical device when looking down from above when the medical device is placed on a horizontal surface.

4.117 Validation of the WD should aim to achieve a lower level of protein on the processed medical devices meeting the requirements set in the ACDP TSE 2015 Annex C guidance.

4.118 Validation of the WD should consider the worst case scenario as regards the load placed in the WD and its configuration.

4.119 The method of detection of residual protein should be a test method that makes use of products on the NP187 contract. The relevant standard operating procedure for a given test method should be followed.

4.120 Cleaning efficacy is determined by visual examination and by the use of protein detection methods listed in NP187.

4.121 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.

Quality Assurance exercise for testing the protein levels on RMDs

Sampling

4.122 This single test exercise requires a minimum of triplicate testing of the medical devices to demonstrate consistency. Test requirement - Sample 50 medical devices per washer disinfector in a quarter (13 week period). Repeat this twice more over the year giving a total of 150 medical devices tested per washer disinfector. The protein testing of medical devices may be carried out weekly over a 13 week period (totalling 50 medical devices) to give a better understanding of the ongoing washer disinfector performance. The test process (see Figure 2) should be carried out using a protein detection test in NP 187 on medical devices with the most challenging surfaces i.e. those with crevices, hinges or large surface areas etc.

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4.123 Standard Operating Procedures (SOP) will be published for each test method. Adherence to SOP and staff competency will influence the results of the test.

Reporting results

4.124 On completion of the exercise a report should be prepared indicating that the all test samples have met the ACDP target level.

Mitigating actions in the event of protein levels exceeding the target level

4.125 Consult the flow chart, see Figure 2 for the steps to be taken in the case where test samples results do not meeting the target level. The corrective actions should be noted along with any repeat test sample results.

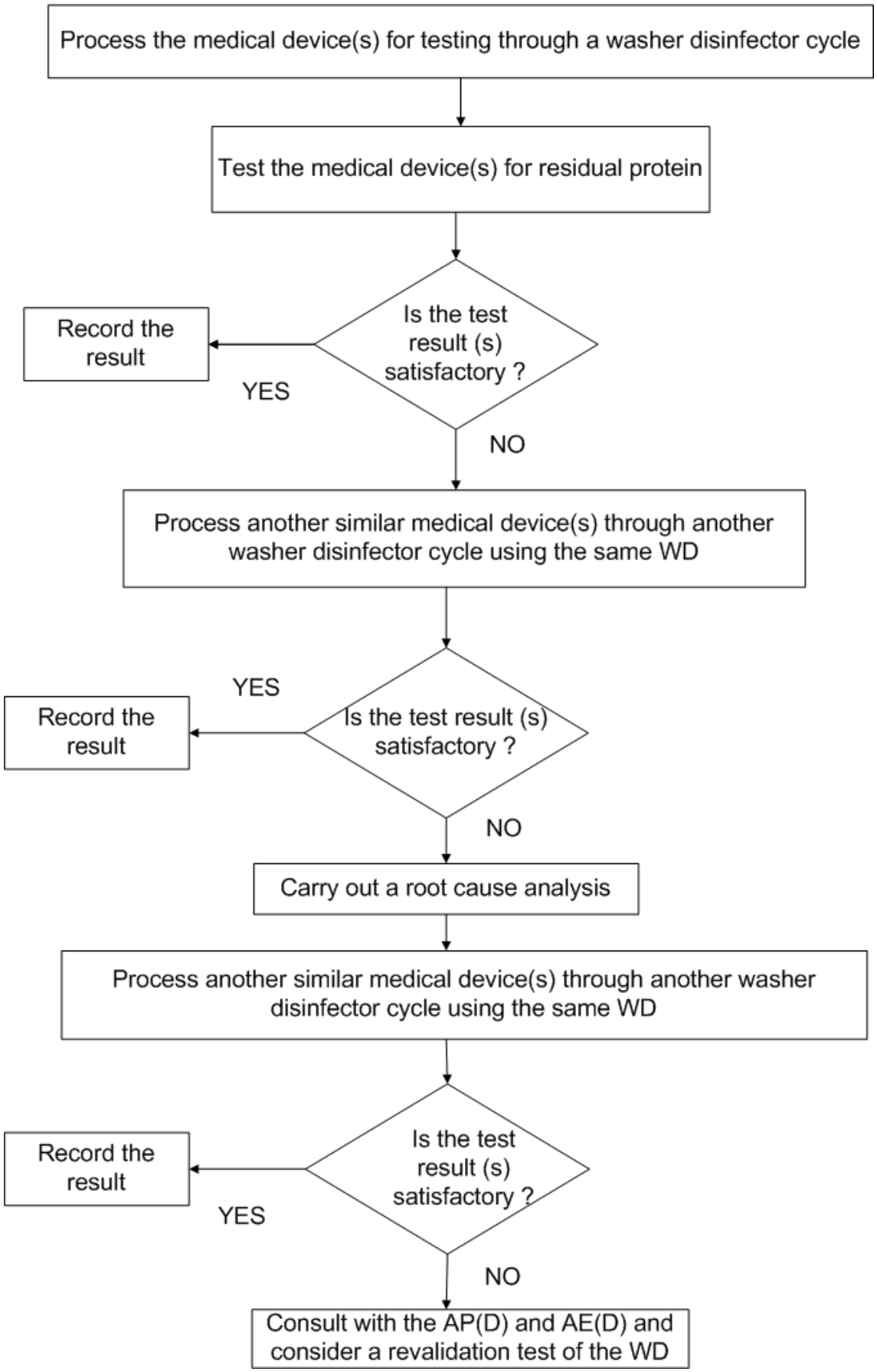

Figure 2: Test process method when measuring residual protein

5. Validation and periodic tests for ultrasonic cleaners

5.1 A testing schedule for Ultrasonic Cleaners (UCs) is shown, see Table 8. This covers the Installation Qualification (IQ), the Operational Qualification (OQ), the Performance Qualification (PQ) and periodic testing.

Test	IQ	OQ	PQ	Periodic
Automatic control test	*X*	*X*		*WQY*
Chamber wall temperature		*X*		*Y*
Chemical additive(s): low level detection		*X*		
Chemical additive(s): process residue			*X*	
Chemical: reproducibility		*X*		*QY*
Cleaning efficacy by residual soil		*X*	*X*	*W*
Cleaning efficacy with test soil		*X*	*X*	*QY*
Doors: in-cycle interlock		*X*		*Y*
Doors: cycle start interlock		*X*		*Y*
Drainage: free drainage		*X*		*Y*
Fault interlock		*X*		*Y*
Load carriers				*Y*
Over-temperature cut out test		*X*		*Y*
Remove and clean strainers or filters				*DW*
Weekly safety checks		*X*		*WQ*
Sound pressure test		*X*		
Test for ultrasonic activity		*X*		*QY*
Water: hardness	*X*			*Y*
Water: overflow test		*X*		*Y*
Water supply temperature	*X*			*Y*
	X = applicable test for each qualification stage			D = daily W = weekly Q = quarterly Y = annual

Table 8: Schedule of validation and periodic testing for ultrasonic cleaners

Test for ultrasonic activity

5.2 The activity of an ultrasonic cleaner 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 commissioning (IQ/OQ) are intended to establish the variation in activity at different positions and levels within the bath and the time required to obtain a characteristic erosion pattern.

5.3 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

5.4 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: 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 bath 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

5.5 For precise evaluation 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.

5.6 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.

5.7 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 ultrasonic cleaner. Manufacturers' instructions for use should be followed.

PQ tests for ultrasonic cleaners

Load items

5.8 Test reference loads for ultrasonic cleaners should be representative of the most difficult to clean items and medical devices. If the reference loads do not adequately represent the range of loads to be processed, further tests should be carried out using items from normal production loads.

5.9 Ultrasonic cleaners equipped with a means to irrigate medical devices with lumens, such as rigid endoscopes, should be tested with the general reference load and the endoscope/MIS reference loads as required.

Nature of soiling

5.10 Ultrasonic cleaners are often used for initial treatment of items contaminated with soiling that is difficult to remove by other cleaning processes. Therefore the test soil used should be chosen to represent the contamination present, for example, orthopaedic bone cement. Tests items should be items soiled in a way that is representative of the greatest challenge expected on production loads.

Reference test loads

5.11 The test loads for ultrasonic cleaners can contain the following general equipment:

- 3 cuscoe speculae;
- 3 artery forceps (Crile, Kelly or Spencer Wells) with box joints;
- 3 No. 3 Scalpel handles;
- 3 Yankauers or Pooles suction tubes;
- sufficient additional instruments to make up a full load.

5.12 The test load can contain the following ridged endoscope/MIS instruments:

- 2 Trochar and Cannulae;
- 2 MIS forceps;
- 2 surrogate endoscopes;
- sufficient additional instruments to make up a full load.

The surrogate endoscope should be constructed from 6 mm outer diameter and 4 mm internal diameter stainless steel tubing. The overall length should be 450 mm. At the midpoint of this tubing an additional 50 mm length of tubing should be connected to the tubing on either side with compression fittings. The 50 mm demountable length can be used to provide a more readily visible section for determination of cleaning efficacy.

6. Water supply

Introduction

6.1 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. Washer disinfectors 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: 2014 and SHPN 13 Part 1: 2011. All fixtures and fittings should comply with the 'Water Fittings and materials Directory' published by the Water Regulations Advisory Scheme (WRAS). Consult Scottish Health Technical Memorandum 04-01: Water safety for healthcare premises Part A: Design, installation and testing: 2014.

6.2 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.

6.3 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.

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

6.5 A 'Type A' air gap is required at the point of use or an interposed cistern. This applies to all washer disinfectors 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.

6.6 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.

6.7 Washer disinfectors 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 washer disinfectors now incorporate holding tanks that pre-heat the water supply for the relevant phase of operating cycle.

6.8 The quality of water used at all stages in the decontamination process is critical to the successful outcome of the process.

6.9 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

6.10 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:

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

Note: The maximum temperature of rinse water should be compatible with the medical devices being processed; some items used in surgical practice are temperature sensitive or may be damaged by thermal shock. Any heat labile items should not be processed in a thermal WD.

Temperature requirement

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

6.12 Water above 45^{o}C 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.

6.13 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.

6.14 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.

6.15 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'.

6.16 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

6.17 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.

6.18 Tarnishing of stainless steel instruments, shown by blue, brown or iridescent surface coloration, 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 discoloration.

Microbial quality

6.19 The purpose of the cleaning and disinfection process is to:

- remove soiling;
- reduce the microbial contamination to a level for safe handling by staff;
- to prepare the medical devices for the next stage in the decontamination process (sterilization).

6.20 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.

6.21 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.

6.22 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.

6.23 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 by the use of UV irradiation (wavelength 260 nm ± 10nm; >2 Jm^{-2}) to ensure that proliferation of microbial contamination is inhibited;
- verification of purification by filtration should be made by relevant TVC (total viable count) tests.

Concentration of bacterial endotoxins

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

devices. Rinse water used in the final wet stages of the WD operating cycle to process surgically invasive medical devices should not contain more than 0.25 EU ml^{-1}.

Water hardness

6.25 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 3. It may also impair the efficiency of process chemicals.

6.26 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%.

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.

6.27 Where the local water supply is >125mg/l of $CaCO_3$ a water softening system should be used.

Figure 3: An example of lime scale build up within a washer disinfector

Water treatment

6.28 Despite the cost involved in treating water from the public supply, to provide the optimum quality for use at each stage in the WD operating cycle, treatment is usually

cost-effective. There are two types of water treatment recommended in this guidance:

- water softeners;
- Reverse Osmosis (RO) as required by HFS guidance - GUID 5014 'Requirements for compliant CDUs: 2016'.

The use to which water of various qualities should be put is shown, see Table 9.

Types of water	Application
Potable Cold water	Flushing
Soft potable water (<50mg/L/$CaCO_3$)	Flushing, Cleaning with process chemicals i.e. 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	
Reverse osmosis	Final rinse water in all WDs
	Thermal disinfection in all WDs

Table 9: Water quality requirements for process stages water chemistry

Water softeners

6.29 The size and type of water softeners should be chosen based on the total demand of softened water in the CDU, including when necessary provision for manual washing facilities and other plant. Some washer disinfectors are available with built in base-exchange water softeners.

6.30 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.

6.31 The column may be regenerated by treatment with a solution of common salt (sodium chloride). However, after regeneration, high levels of chloride ions (Cl^-) may be present in the initial output from the softener, which should be run to waste. While the remaining sodium salts do not readily form hard deposits if used as the final rinse or as source water for disinfection, white deposits may be left on the load items as they dry this while unsightly does not have a detrimental effect on the processed medical device.

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

6.32 In common with other water treatment systems, the base-exchange softener should run to a minimum volume of out-flow if the required water quality is to be achieved.

This volume should be specified by the manufacturer of the treatment plant. The output from the softener should be to a water tank and the volume demanded each time additional water is fed to the tank should exceed the minimum flow.

Reverse osmosis

6.33 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.

6.34 The wastewater produced by a properly managed RO plant may be designated as grey water and reused appropriately.

6.35 As RO units supply moderate volumes of water over a long period and washer disinfectors need large volumes of water quickly, water storage may be required during various stages of the WD operating cycle. Additional measures are required to maintain the microbial quality of water during storage and distribution. Take note that hot and cold RO systems may require different maintenance programmes.

6.36 Factors to be considered prior to installing an RO systems include:

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

7. Water quality and tests methods

Introduction

7.1 A continuous supply of water of the specified chemical and microbial quality is essential to the correct functioning of all washer disinfectors.

7.2 The test methods recommended here are intended to be suitable for onsite use. A number of 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 EN ISO/IEC 17025: 2005 for the tests requested is recommended. The tests are listed below, see Table 10.

Test	SHTM 01-01 Part D section reference
Appearance	7.19
Bacterial endotoxins	7.71
Chloride	7.45
Electrical conductivity	7.26
Hardness (as $CaCO_3$)	7.39
Heavy metals (expressed as Lead)	7.48
Iron	7.51
Measurement of pH	7.22
Phosphate	7.56
Silicate	7.65
Test methods for on-site use	7.6
Total Dissolved Solids (TDS)	7.30
Total Viable Count (TVC)	7.74
Water supply pressure	7.14
Water supply temperature	7.10

Table 10: Alphabetical list of water quality tests

Note: 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.

7.3 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.

7.4 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 e.g. pre and post pre filtration, pre and post water treatment system. Requirements for water quality: final rinse and process water are detailed, see Table 11.

Parameter	Maximum permitted values - Final rinse	Maximum permitted values - Other stages
Appearance	Clear and colourless	-
Degree of acidity (pH)	5.5 to 8	-
Conductivity at 25°C (µS/cm)	30	
Total dissolved solids (mg/100 mL)	4	-
Total hardness $CaCO_3$(mg/L)	50	210
Chloride mg/L	10	120
Heavy metals, determined as Lead, Pb (mg/L)	10	-
Iron, Fe (mg/L)	2	-
Phosphate, P_2O_5 (mg/L)	0.2	-
Silica, SiO_2 (mg/L)	0.2	2
TVC cfu/100 ml	100	-
Endotoxin Units EU/ml	0.25	-

Table 11: Requirements for water quality: final rinse and process water

7.5 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

7.6 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.

7.7 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.

7.8 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 EN ISO/IEC 17025: 2017 and manufacturers' instructions.

Equipment

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

7.9 Samples for the determination of:

Bacterial endotoxins and Total Viable Count (TVCs)

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

Cations

1 Litre acid-washed borosilicate bottles.

Anions and total dissolved solids

1 Litre polypropylene bottles.

pH and conductivity

100 ml high-density polyethylene bottles.

Method:

- the first 50 mls of sample taken at each sampling point should be run to waste;
- all samples should be taken in duplicate;
- samples should be 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.

Water supply temperature

7.10 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.

7.11 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.

7.12 Water supplied in the temperature range 25 to 40ºC presents a serious risk of microbial contamination of the system.

Equipment

An indicating or recording thermometer should be used.

Method:

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

7.13 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

7.14 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.

7.15 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.

7.16 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, etc., 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: It is engineering best practice to install appropriate pressure gauges at strategic points on the distribution systems of each water supply.

Equipment

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

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

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

Appearance

7.19 All the water supplied to the WD should be clean, colourless and free from particulate matter when assessed visually.

Equipment

7.20 The following equipment should be used:

- a clean, clear glass bottle with stopper;
- filter paper (qualitative grade 1), filter funnel and holder.

Method:

- transfer an aliquot to a clear colourless glass bottle, which should then be tightly closed with its stopper;
- shake the bottle vigorously and then examine against a white background, under good quality lighting.

If the sample is turbid:

- filter through the qualitative grade filter paper (grade 1) described above;
- examine the filter paper for evidence of colloidal material;
- record a description of any retained material including colour and intensity.

Results of the appearance test

All the samples tested should be clear, bright and colourless.

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

Measurement of pH

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

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

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

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

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

Equipment

Portable pH meter or:

- Colorimetric tests;
- Colour disc comparator.

Method

7.25 Operate the test kit in accordance with the manufacturers' instructions. Pay particular attention to using accurate volumes of both sample and reagent and monitoring both temperature and reaction time:

- verify the calibration using standard buffer solutions made up in advance and kept in capped bottles until required. The buffer solutions should be chosen to have a pH in the midpoint of range of the calibrated colour discs to be used in the determination;
- match the colour of the reacted sample against the calibrated colour disc viewed through a blank sample. Read off the value in pH units directly from the disc.

Results of pH measurement

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

Electrical conductivity

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

7.27 The meter or meters used should cover the ranges shown in Table 12 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.

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

Table 12: Range, resolution and accuracy of the conductivity meter

Equipment

Conductivity meter.

Standard conductivity reference solutions.

Method

7.28 Use the following method for electrical conductivity calibration:

- verify the calibration of the meter against 0.001 molar (M) and 0.0005 M reference standard solutions of potassium chloride (KCl) and pure water as working standards (Water for injection). These give conductivities at 25ºC of 141 µS cm^{-1} and 84 µS cm^{-1} and 0.06µS cm^{-1} respectively;
- prepare the potassium chloride solutions by dilution of a 0.1 molar solution with distilled water;
- after calibration rinse the sample cup or immersion probe thoroughly with pure water;
- collect the sample in a high-density polyethylene bottle and test as soon as practicable;
- pour an aliquot of the sample into the sample cup of the conductivity meter or, for meters with an immersion probe, into the clean beaker. Follow the meter manufacturer's instructions for making the measurement; this will usually require a short stabilization period before noting the reading.

Results of conductivity measurement

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

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

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)

7.30 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.

7.31 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.

7.32 The electrical conductivity should be measured as described previously and expressed in microsiemens per centimetre (µS/cm) 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.

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

7.33 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: 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.

7.34 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

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

Method

7.35 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.

7.36 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

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

TDS determined by the evaporative residue method

Equipment:

- 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:

- 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

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

Hardness (as $CaCO_3$)

7.39 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.

7.40 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 (RO).

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

Equipment

7.42 Ion-Selective Electrodes (ISE) are available for calcium and also 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:

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

Titrimetric method

7.43 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.

7.44 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: 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:

- water with values >210 mg/L should be regarded as unsuitable for use in washer disinfectors without pre-treatment;

- the hardness expressed as mg/L $CaCO_3$ should not exceed 50 mg/L for softened water.

Chloride

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

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

Equipment – using Ion Selective Electrodes (ISE)

- commercially available chloride selective electrodes have a working range from 1 M to 10^{-5} and work over the pH range 3–10. If required ionic strength of the sample can be adjusted using an adjustment buffer of 5 M $NaNO_3$ solution.
- the electrodes show poor selectivity against other halides and cyanide ions. Sulphide ions should be absent.
- the chloride electrode requires a double junction 0.1 M $NaNO_3$ reference electrode.
- conduct the calibration against two or more commercially available standard solutions.

Equipment – using silver nitrate titration kits

7.47 Commercial titrimetric kits are available that are based on the method described in BS 6068- 2.37: 1990, ISO 9297: 1989.

Method

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

Results of chloride measurement

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

Laboratory Tests

Heavy metals (expressed as Lead)

7.48 Heavy metals are generally toxic in low concentrations and, as far as possible, should be absent from water used to process items that will be used invasively.

Method:

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

Results of heavy metals (Lead) test as measured in a laboratory

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

Iron

7.51 The presence of significant concentrations of iron in water used to process stainless steel items promotes corrosion of those items and exacerbates the effect of any chloride ions that may be present.

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

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

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

Equipment

The following equipment should be used:

- colour disc comparator kit;
- reagents;
- a standard 0.702 g/l iron(II) ammonium sulphate $(NH_4)_2Fe(SO_4)_2$ solution;
- a mercury in glass thermometer graduated in 0.5ºC steps conforming to BS 1704: 1985 and ISO 1770: 1981.

Notes: on the test equipment:

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

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

Method:

- prepare a standard 0.702 g/l iron (II) ammonium sulphate $(NH4)_2Fe(SO_4)_2$ solution which provides a standard solution of 100 mg/l iron. Prepare the solution as required and do not store. Prepare working standards spanning the usable range of the colour disc comparator by appropriate dilution;
- measure the sample temperature before commencing the analysis;
- after the kit manufacturer's specified reaction time has elapsed use the colour intensity of the sample to estimate the concentration of iron in the sample;
- for details of the colorimetric method, see the method for the determination of silicate.

Results of Iron test as measured in a laboratory

7.55 Untreated and softened water should have less than 2 mg/l iron present.

Phosphate

7.56 This test method measures only orthophosphate. Pre-treatment to convert other forms of phosphate to orthophosphate should be used if appropriate. Some other phosphates such as condensed phosphates and labile organic phosphates are slowly hydrolysed under the acidic conditions used for the test.

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

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

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

7.60 The pre-packaged reagents available from the manufacturer of the comparator should be used.

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

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

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

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

Equipment

The following Equipment should be used:

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

Method:

- follow the manufacturer's instructions;
- react the sample in acidic solution with antimony and molybdate ions to form an antimony phosphomolybdate complex. Reduce with ascorbic acid to form a molybdenum blue complex;
- prepare a stock standard solution containing 100mg/l potassium dihydrogen orthophosphate and dilute to provide suitable working standards for calibration verification. The concentrated stock solution is stable for several weeks;
- test the samples as soon as possible after sampling. If sampling will be delayed by more than 4 hours store the sample(s) in suitable glass bottles at 2 to 5ºC for up to 24 hours;
- for details of the colorimetric method, see the description given in the method for the determination of silicate.

7.64 The temperature has a significant effect on reaction time; at 20ºC the reaction is typically completed within 3 to 4 minutes. Before making the measurement ensure that the reaction is complete but avoid excessive delays, which can cause errors from hydrolysis of other phosphates. Read the measurement at 10 to 15 minutes after the start of the reaction.

Results of the phosphate test as measured in a laboratory

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

Silicate

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

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

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

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

Equipment:

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

Notes on the test Equipment:

The pre-packaged reagents available from the manufacturer of the comparator should be used.

For most kits the temperature should be 15ºC to ensure that the reaction will go to completion. If the sample temperature is below this, or the minimum temperature specified by the manufacturer, the sample should be warmed.

Method:

- prepare a standard 3.132 g/L disodium hexafluorosilicate (Na_2SiF_6) solution, providing a stock standard solution of 1000 mg/L as SiO_2. The solution is stable for several months after preparation stored in a sealed polyethylene bottle. Working standards spanning the usable range of the colour disc comparator can be prepared by appropriate dilution;
- measure the sample temperature before commencing the analysis using the mercury-in- glass thermometer;
- after the kit manufacturer's specified reaction time has elapsed use the colour intensity of the sample to estimate the concentration of silicate in the sample;
- with the calibrated colour disc for silica in the comparator, an untreated water sample in the blank cuvette and the reacted sample in the sample cuvette, placed

in the comparator cell holder, visually match the colour density developed in the sample against the calibrated colour disc viewed through the untreated sample. Read off the displayed value of SiO_2 concentration from the calibrated disc;

- serial dilutions of the standard solution may be used to verify the calibration of the comparator disc.

Results of the silicate test as measured in a laboratory

7.69 Untreated and softened water should have less than 2 mg/L silicate expressed as SiO_2, determined as reactive silica, present.

7.70 Purified (RO) water should have not more than 0.2 mg/L silicate expressed as SiO_2, determined as reactive silica, present.

Bacterial endotoxins

7.71 When the intended use of the WD is for medical devices to be used invasively, for example, surgical instruments, the water used for final rinsing should be tested for bacterial endotoxins (using the limulus amoebocyte lysate (LAL) gel formation method).

7.72 The method described in the European pharmacopeia is recommended. Other LAL methods (chromogenic, turbidimetric or kinetic turbidimetric) are equally suitable.

7.73 The water sample is incubated, in a test tube, with an equal volume of lysate for 1 hour at 37ºC and examined for the formation of a solid clot that holds upon inversion of the test tube. The lysate, reconstituted from lyophilised LAL, is selected with the required level of sensitivity. Semi-quantitative results may be obtained by testing dilutions of the sample and by the use of lysates with different levels of sensitivity.

Results of endotoxin testing as measured in a laboratory

The acceptable level of endotoxin is 0.25 EU/ml.

Total Viable Count (TVC)

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

7.75 Refer to EN ISO 15883 Part 1: 2014 (clause 6.4.2.4 and Annex D). Make a total viable count by membrane filtration of not less than 100 ml final rinse water sample. Place the filter on R_2A-medium or other suitable low nutrient medium and incubate at 28 °C to 32 °C for a minimum of 5 days to determine the aerobic mesophillic viable count. Other methods, including rapid methods such as ATP bioluminescence, that have been validated to be at least equivalent to the above method in terms of both specificity and sensitivity can also be used. If particular microorganisms are of concern, other recovery conditions (growth medium, incubation temperature, etc.) should be used as appropriate. The advice of the microbiologist should be sought.

7.76 The test should be carried out annually.

Results of the TVC test measured in a laboratory:

- water services supplied to WDs should have less than 100 cfu/100 mL of water (determined as the mean of the duplicate tests).

Note: For WDs in which the medical device is rinsed after the disinfection stage there should be no recovery of microorganisms from the rinse water.

8. Operational management

8.1 Central Decontamination Units require to be managed in line with the Quality Management System (QMS) standard EN ISO 13485: 2016. The standard is titled 'Medical devices – Quality Management systems – Requirements for regulatory purposes'. The 2007government letter (ref F750497) Ross Scott to NHS Board Chief Executives titled Central Decontamination Unit – Accreditation, stated that CDUs should be accredited to the standard using a Notified Body.

8.2 Within the quality system there will be management of production activities as well as periodic testing and maintenance/breakdown activities. These will all apply to the automated cleaning and disinfection equipment.

8.3 The Washer Disinfectors (WDs) are used to clean and disinfect medical devices (intended for re-use or further processing (e.g. terminal sterilization)) and are intended to:

- remove soil (by cleaning);
- reduce microbial contamination to a predetermined limit (by disinfection);
- make the item safe for staff to handle;

8.4 Initial treatment by use of an Ultrasonic Cleaner (UC) should only be used where instructed by the medical device manufacturer's instructions for use. Each UC cycle run in production should be checked to confirm it is satisfactory before the medical devices continue on to the next stage of the decontamination process. Further guidance on the requirements for UCs can be found in Section 2 of this guidance.

8.5 SHTM 01-01 Part A section 3 outlines all the process stages in the decontamination process applicable to a CDU. This includes the elements that are relevant to both a WD and an UC.

8.6 WDs are used to process a wide range of medical devices and can be categorised according to their intended use, the nature of the load they are intended to process, the configuration of the load handling system and their method of disinfection.

Note: When medical devices being cleaned and disinfected by a WD are intended to be used again without terminal sterilization, the WD should produce an item that is safe for its intended use.

Further information on WD validation protocols can be found in the EN ISO 15883 Parts 1 and 2: 2014.

8.7 Thermal disinfection is the preferred option (as stated in HFS guidance GUID 5014 'Requirements for compliant CDUs':2016) for processing medical devices in CDUs. 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 EN 15883-1 Annex 2: 2014.

8.8 Thermal disinfection is reliable, reproducible, free from toxic residues and capable of physical monitoring and recording. Thermal disinfection should be used whenever it is compatible with the load to be processed unless the manufacturers'

decontamination instructions for use prohibit its use (e.g. some anaesthetic equipment).

8.9 Temperatures in excess of 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 1. A_0 is defined in EN 15883-1: 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.

8.10 An A_0 of 600 may be achieved by 10 min (600 s) at 80 °C, or by 1 min at 90 °C, or by 100 min 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 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 1.

Note: Chemical disinfection should only be used for medical devices that cannot be treated using thermal disinfection methods and only when stated in the medical device manufacturer's instructions for use.

8.11 Decontamination is comprised of a set of processes, the efficacy of which cannot easily be verified retrospectively by testing of the processed product, or by inspection before use. For this reason decontamination processes (cleaning, disinfection and sterilization) and equipment require validation before use. SHTM 01-01 Part A outlines the medical device decontamination process applicable to the CDU.

8.12 Initial cleaning (manual or by ultrasonic cleaner) may be required as specified by the manufacturers' instructions for use and or where indicated by quality assurance issues e.g. where a large number of a specific medical device is rejected during inspection in the IAP room. Water in the ultrasonic tank should be changed at least every 3 hours or when visibly contaminated. Where manufacturers of medical devices used in microsurgery specify the use of UCs, special measures may be needed to prevent damage to these delicate instruments. Manufacturer's instructions for use should be followed.

8.13 A means of ensuring that a WD is fit for its intended purpose should be put in place and include:

- design and pre-purchase considerations including capacity requirements;
- satisfactory completion of the Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ) exercises ;
- periodic testing requirements;
- a planned maintenance programme;
- operation and loading in accordance with PQ tests.

8.14 Requirements for test equipment can be found in SHTM 01-01 part B.

8.15 It is important that all WDs are effective in achieving the performance required to produce a clean and disinfected medical device. Each WD cycle run in production

should be checked to confirm it is satisfactory before the medical devices continue on to the next stage of the decontamination process. Failure to achieve the required standard of cleanliness may impair the capability of the process to achieve disinfection and subsequent sterilization.

8.16 The cleanliness and microbial safety of all medical devices processed in a WD ultimately depends upon the care taken by the decontamination personnel.

See SHTM 01-01 Part A section 12 for guidance on:

- improving the cleaning performance of existing washer disinfectors;
- the QA exercise for testing the protein levels on medical devices with respect to the Advisory Committee on Dangerous Pathogens (ACDP) Transmissible Spongiform Encephalopathy (TSE) 2015 annex C requirements.

Investigating a failed WD operating cycle

8.17 A number of points to consider when investigating a failed WD operating cycle are addressed here. These include underestimating the challenge to cleaning presented by the design of a given medical device, unsatisfactory validation of the medical device(s) prior to it being put into use or failure to follow standard operating procedures in production.

8.18 A failure to satisfactorily clean all the medical devices processed through a WD cycle is one reported fault. Causes of this type of failure include:

- incorrect loading; medical devices that are not correctly located in an appropriate load carrier will not be subjected to the intended washing process;
- overloaded baskets and load carriers can cause some medical devices to be shadowed by others in the load from the spray jets;
- the manufacturer's Instructions for Use (IFU) have not been followed. For example the medical devices may not have been disassembled or irrigated as required by the manufacturer IFU. This could be hinged medical devices that require to be opened when loaded into the WD;
- issues with the WD such as blocked strainers in the chamber base, blocked spray jets or spray arms that are not free to rotate;
- elevated water temperature in the initial flushing/rinsing stages of the WD cycle leading to coagulation of blood and protein thus providing a greater challenge to the cleaning stage of the WD;
- medical devices that have not been through performance qualification tests at validation of the WD. For example the medical devices may not be suitable for the cycles or loadcarriers available;
- inadequate cycle parameters such as the pre-wash or wash cycle hold times are insufficient or the temperature is not suitable for the process chemical in use.

8.19 The incorrect choice or quantity of process chemical is another factor that may produce a failed cycle. The choice of process chemical should be based upon a number of factors. These include:

- the quality of water available. The hardness of water used during washing should be compatible with the process chemical chosen. Hard water used in the final rinse can leave deposits on the surface of medical devices;
- the nature of the load;
- the nature of the soiling to be removed;
- the nature of the washing process.

8.20 Advice should be sought from both the WD and process chemical manufacturers. Malfunction of the dosing system may cause the wrong quantity of process chemical to be used - for example; an insufficient quantity of process chemical may result in inadequate cleaning or an excessive quantity may impair cleaning by causing excessive foaming.

8.21 The quality of water used for the final rinse stage is critical in ensuring the prevention of scaling and excess process residues.

Routine housekeeping

8.22 Certain maintenance tasks should be carried out by the User, or by the Operator under the User's supervision and should be recorded in the WD logbook. Examples of such tasks include:

- checking that the rotating spray arms are free to rotate;
- checking that spray nozzles are not blocked;
- removal, cleaning and replacement of strainers and filters;
- 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;
- washing of the loading side conveyors and trolleys;
- for washer disinfectors with a built-in water softener, checking the level of salt in the regeneration tank and replenishing as necessary.

9. Planned preventative maintenance programme

Introduction

9.1 A programme of Planned Preventative Maintenance (PPM) should be in place to ensure the required standards of performance and safety are met and maintained. Expertise is available at three levels, 'The Competent Person (Decontamination) (CP(D)), Authorised Person (Decontamination) (AP(D)) and the Authorising Engineer (Decontamination) (AE(D))'. These roles are defined in the 'Staffing roles and responsibilities' in SHTM 01-01 Part A. Following any modification to the Washer Disinfector (WD) or Ultrasonic Cleaner (UC) including software upgrades, operating cycle parameters or process chemicals in use, the AE(D) should be consulted to advise on any re-validation tests necessary.

9.2 The PPM programme recommended by the manufacturer should be supplied and used. The maintenance programme may be modified to take account of equipment use, equipment history and local conditions after a suitable period of operational experience.

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

9.4 Maintenance should be carried out under the CDUs quality management system and any spares fitted to washer- disinfectors should be sourced from approved suppliers.

9.5 All parts of the WD or the UC vital to correct functioning or safety should be subject to a PPM programme designed according to the manufacturers' instructions for use.

9.6 Occasionally, modifications to the WD or UC 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 CDU's quality management system.

9.7 The frequency with which each task is carried out will depend, in part, on the usage level for the WD or UC and on the quality of the water/steam supplied. It may be necessary to increase the frequency of the maintenance programmes for machines that are heavily used or supplied with hard water.

9.8 It is important that maintenance is planned so that the WD or UC is out of service for the minimum time possible. Maintenance should, where practicable, be scheduled to immediately precede the periodic tests as specified in the chapter 'Validation and verification' in this guidance.

Review of PPM programme

9.9 The PPM programme should be reviewed at least annually to ensure the equipment is being fully maintained but without any 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.

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

Returning a WD to service

9.11 Whenever any work has been carried out on a WD e.g. major repairs, overhauls, etc. which may affect the performance of the WD, 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 WD is returned to service. This may include some or all of the re-commissioning (annual) tests. See guidance on the permit to work system given in SHTM 01-01 Part A.

9.12 Systematic records should be kept of all maintenance work undertaken and Log books and maintenance files should be maintained for each item of equipment. This should demonstrate that the work has been carried out and facilitate periodic review of the PPM programme. These records can be stored as electronic or paper records. Health Facilities Scotland has published a thermal washer disinfector logbook which includes templates for maintenance records.

9.13 In line with the CDU's quality management system a set of procedures should be in place for each model of WD containing full instructions for the required maintenance tasks.

Warranty period

9.14 After the purchase of a new WD or UC 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 Health Board.

9.15 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.

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