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WHTM 01-01



Welsh Health Technical Memorandum
**Decontamination
of surgical instruments
(medical devices)
used in acute care**
Part D: Washer-disinfectors

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It replaces WHTM 01-01:2013 *Decontamination of medical devices within acute services. Part D: Washers-disinfectors*

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Welsh Health Technical Memorandum 01-01

Decontamination of surgical instruments (medical devices) used in acute care

Part D: Washer-disinfectors

Overview

Welsh Health Technical Memorandum (WHTM) 01-01 gives guidance on the whole decontamination cycle in the management and decontamination of surgical instruments used in acute care.

Part A covers the policy, management approach and choices available in the formulation of a locally developed, risk-controlled operational environment. The technical concepts are based on British (BS), European (EN) and International (ISO) Standards used alongside policy and broad guidance. In addition to the prevention of transmission of conventional pathogens, precautionary policies in respect of human prion diseases including variant Creutzfeldt-Jakob disease (vCJD) are clearly stated. Advice is also given on surgical instrument management related to surgical care efficiencies and contingency against perioperative non-availability of instruments.

The management of decontamination equipment is a critical engineering service.

WHTM 01-01 Part A provides a description of the overall structure of the guidance and the rationale behind the following:

- the regulatory framework;
- roles of key personnel;
- procedures for the reporting of adverse incidents and defective equipment;
- local reprocessing (decontamination in primary care, and local decontamination);
- the management of instruments potentially contaminated with transmissible spongiform encephalopathy (TSE) infectivity.

Part B covers common elements that apply to all methods of surgical instrument reprocessing such as:

- test equipment and materials;
- design and pre-purchase considerations;
- validation and verification.

Part C covers standards, technical guidance, operational requirements, and testing and validation protocols when using steam for sterilisation within the acute care setting.

Part D covers standards, technical guidance, operational requirements, and testing and validation protocols when using washer-disinfectors as part of the decontamination cycle within the acute care setting.

Part E covers non-steam sterilisation processes (such as the use of vapourised hydrogen peroxide gas plasmas and ethylene oxide exposure.) for sterilisation for decontamination providers for the acute care setting.

WHTM 01-01 Part A supersedes Welsh Health Technical Memorandum 01-01 Part A (2013 edition)

WHTM 01-01 Part D supersedes Welsh Health Technical Memorandum 01/01 Part D (2013 edition)

Why has the guidance been updated?

WHTM 01-01 has been updated to take account of recent changes identified within the advisory Committee on Dangerous Pathogens' Transmissible Spongiform Encephalopathies (ACDP-TSE) Subgroup's Annex C: General principles of decontamination. In relation to the decontamination of surgical instruments, this principally relates to paragraphs C21 and C22:

Protein detection

C21. Work commissioned by the Department of Health indicates the upper limit of acceptable protein contamination after processing in $\leq 5\mu\text{g}$ BSA equivalent per instrument side. A lower level necessary for neurosurgical instruments.

C22. It is necessary to use protein detection methods to check for the efficient removal of protein from surgical instruments after processing. Protein levels are used as an indication of the amount of prion protein contamination. Ninhydrin swab kits are commonly used for this purpose, but recent evidence shows that ninhydrin is insensitive. Furthermore, proteins are poorly desorbed from instruments by swabbing.

Reference HTM 01-01 part A

Note:

The figure $\leq 5\mu\text{g}$ of protein has been shown to be achievable by effective cleaning processes. There is currently no definitive evidence base to link this with the absence of prion transmission risk, which is why lower levels for instruments making contact with high risk tissues (see ACDP-TSE's Annex J) is necessary.

What SSDs can do to ensure implementation of the ACDP-TSE Subgroup's recommendations

Because of the risks of prion transmission, there is a need to optimise the whole of the decontamination pathway of surgical instruments.

Reducing the time from close of procedure to reprocessing

Prions are easier to remove if they have not dried on the surface of an instrument. To enable efficient prion removal, theatre and SSD staff should ensure that instruments are transported to the SSD immediately after the close of the procedure, for cleaning and reprocessing as soon as practically possible.

This will make the cleaning process more effective, hence reducing the risks to the patients and staff handling the devices. If devices cannot be returned in a timely manner, it is important that the instruments are kept moist using appropriate methods approved and verified by the SSD.

Cleaning validation and continuous monitoring

Traditionally, cleaning validation has been about removing visible soiling. Now the emphasis is on removing proteins to very low levels. To be able to have a greater chance of removing these proteins, there needs to be as efficient a cleaning process as possible – therefore SSDs need to both optimise the cleaning performance of washer-disinfectors and remain within the validation parameters (such parameters will be determined during type testing and/or performance qualification).

Note:

Manufacturers must ensure the WD's are configured with operational capabilities of achieving the performance required in this revised WHTM. NWSSP-SES will provide advice and guidance on the verification required to achieve the expected standards.

Results should be recorded and monitored in accordance with WHTM 01/01 part D. Appropriate actions should be taken based on these results. SSDs should undertake:

- daily testing using process challenge devices* (along with the standard periodic tests);
- a schedule of weekly residual protein testing
- Priority for cleaning validation and continuous monitoring should be given to instruments that have contact with high-prion-risk tissues as defined by ACDP-TSE (see Table A1 in ACDP- TSE's guidance Annex A1).

* Commercial process challenge devices 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, SSDs are advised to consider their use in addition to process challenge devices based on soils in BS EN 15883-5 Annex N.

Methods for detecting residual protein

Any method used to detect residual protein, should be validated as being able to detect protein equivalent to ≤ 5 μg of BSA in situ on the surface of an instrument (shape of instrument may influence most effective method of detection). Methods that do not have protein as their target, such as ATP assays, cannot be used as a substitute for residual protein detection.

The use of 'in-situ' protein detection fluorescent technologies support the safe processing of reusable medical devices, and has application in situations where the design of the instrument is small enough to fit into the detection area of commercially available protein detection devices, and where those devices do not have internal lumens, non-line of sight areas or incompatible surface materials such as some plastics. There are many

devices, however, where such 'in-situ' technologies are unable to assess protein residuals due to size, design and material of construction.

The implementation of methods for residual protein detection is a local choice, provided that these methods are validated as being capable of detection of $\leq 5\mu\text{g}$ of protein on reusable medical devices; for higher-risk neurosurgical devices, these methods must be of a greater sensitivity.

Organisations should develop a schedule of testing and monitoring for residual proteins. The level of instruments tested will be dependent on the following considerations;

- Numbers of instrument sets being processed per day/week by the SSD;
- Types of surgical procedures, especially neurology, dentistry, ophthalmology etc.
- The instruments tested should be identified as those in use operationally as a 'live' set and not those unused or dedicated for test purposes only;
- The numbers of instruments tested will be determined by the decontamination team to provide evidence of monitoring of process over each quarterly period.

If the results are improving and consistent, the frequency and numbers tested maybe reduced in number. However, if high levels become evident as the norm, testing may need to be increased to investigate the problem, and then reduced again when the issue is under control.

Note:

A combination of different methods of fluorescent and alternative validated systems may provide a balanced solution to obtaining a complete residual protein picture for the full range of devices processed through decontamination facilities, resulting in cleaner surgical instruments and subsequently safer surgical procedures for patients. Any decision on test regimes should be based upon localised choice, considering clinical procedures and risks undertaken within the healthcare facility.

Note:

A number of new technologies are being developed to detect proteins and residual proteins and these can be assessed upon release into the market.

Continuous improvement plans

SSDs should have in place a plan of continuous process improvement. This plan should be carried out as part of a risk management plan (see BS EN ISO 14971 on medical device risk management). There should also be a specific record that relates to residual protein trend analysis (e.g a weekly record).

Urgent action points to develop are:

The need to remove ninhydrin and replace with cleaning efficacy testing methods proven to be more sensitive, such methods may include proven swabbing technologies and/or florescent technology [depending on local surgical requirements] with declared sensitivity to measure protein to meet standard of $\leq 5 \mu\text{g}$ /instrument surface.

The concerns expressed over lack of sensitivity of swabbing methods principally relate to detection based on ninhydrin reagent and do not relate to all current swab technologies.

The choice of analytical technique should take into consideration a variety of factors, such as:

- Specificity & Sensitivity
- Reproducibility and repeatability
- Instrument accuracy and bias
- Sources of error (false positives and false negatives)
- Training requirements
- Uncertainty of measurement of the technique
- Suitability for the intended purpose
- Impact on the department's efficiency and effectiveness.

The following actions should be considered as critical objectives, alongside the need to monitor of protein remaining on medical devices:

- Keep the lag time between use and reprocessing to a minimum (e.g not exceeding 24 hour maximum).
- Instrument set retention within moist environments, using systems designed appropriate for purpose.
- Examine improvement opportunities in the cleaning performance of washer- disinfectors through the optimisation of detergents, wash times, wash temperatures etc.
- Ensure the validation of washer disinfectors is based on the worst load scenario, including the loading patterns, quantity and type of load.
- Cleaning efficacy tests carried out during periodic testing and validation should meet the criteria of acceptance.
- The loading pattern and cycle operation of the WD should be in accordance with validation/PQ testing.
- Instrumentation to be reprocessed should be prepared for the WD, to maximise the exposure to the wash process and there should be minimal shadowing of devices (use of disposable bowls, receivers, gallipots prevent shadowing when reprocessing instrument sets).
- Manual pre-cleaning should target areas with accumulated and/or baked soiling. Old medical devices that have been used and reprocessed may contain soiling that cannot be easily removed using a WD only.
- Use of pre-cleaning technologies such as Ultrasonic bath/irrigators to aid the process, in particular assisting the cleaning cannulated and lumened devices.
- Constantly investigate and improve, to keep the time lapse to a minimum for used surgical instrumentation to return to the wash process. Regular audits can assist in this management area of the process.

List of major changes to Part D since the 2013 edition

- New guidance included on how to ensure implementation of the ACDP TSE's Subgroup's recommendations.
- New examples of periodic in-use test included for residual protein including flowchart.
- New text on process challenge devices inserted and now added as a daily test.
- Previous tests for residual soil using ninhydrin and alternative methods now removed as they are no longer applicable.

Who should use WHTM 01-01 Part D

Part D is intended as a technical guide for management, for technical personnel with appropriate training and experience, and for users responsible for the procurement, maintenance, validation and operational management of washer/disinfectors used as part of the decontamination cycle of re-usable medical devices within the healthcare environment. It will also be of interest to microbiologists, infection control officers, architects, planners, estates managers, supplies officers, and others in both the public and private sectors.

Scope of Welsh Health Technical Memorandum 01-01 Parts A to E

WHTM 01/01 part D is part of a suite of evidence-based policy and guidance documents on the management and decontamination of reusable medical devices designed to reflect the need to continuously improve outcomes in terms of:

- patient safety;
- clinical effectiveness;
- patient experience.

It is also designed to reflect the need to ensure the environment in which decontamination procedures are carried out is fit for purpose.

Acknowledgements

This guidance is based on HTM 01-01:2016 *Management and decontamination of surgical instruments (medical devices) used in acute care. Part D: Washer-disinfectors* published by the Department of Health in 2016. NHS Wales Shared Services Partnership – Specialist Estates Services is grateful to the Department of Health for its permission to adapt the original guidance for application in Wales.

The contents of the original document were reviewed by NHS Wales Shared Services Partnership – Specialist Estates Services and decontamination representatives from NHS Wales, Welsh Government and the All Wales Decontamination Group.

Abbreviations

ACDP: Advisory Committee on Dangerous Pathogens

ACDP TSE (Subgroup): Advisory Committee on Dangerous Pathogens – Transmissible Spongiform Encephalopathies (Subgroup)

AE(D): Authorising Engineer (Decontamination)

AP(D): Authorised Person (Decontamination)

BS: British Standard

CJD: Creutzfeldt-Jakob disease

DH: Department of Health

EN: European norm

HCAI: healthcare associated infections

HIW: Health Inspectorate Wales

ISO: International Standards Organisation

MHRA: Medicines and Healthcare products Regulatory Agency

NWSSP-SES: NHS Wales Shared Services Partnership / Specialist Estate Services

sCJD: sporadic Creutzfeldt-Jakob disease

SSD's: sterile service department

TSEs: transmissible spongiform encephalopathies

vCJD: variant Creutzfeldt-Jakob disease

WD: Washer-disinfectors

WHTM: Welsh Health Technical Memorandum

Contents

Preface	2
Overview	3
Acknowledgements	10
Abbreviations	11
Chapter 1 Design and pre-purchase considerations	20
Purpose of washer-disinfectors	20
Categorisation of washer-disinfectors by nature of load to be processed	21
Categorisation of washer-disinfectors by configuration/load handling type	21
When is a washer-disinfector required?	23
Choice of washer-disinfector	24
Assessment of workload and throughput	25
Rigid endoscopes	25
Powered devices	26
Specification and contract	26
Introduction	26
CE marking	26
Preparing a specification	27
Construction materials	28
Integral air compressors	28
Integral calorifiers and tanks	28
Dosing systems	28
Door controls	29
Cleaning the washer-disinfector	31
Engineering Service Requirements	32
Steam	32
Steam for indirect heating	32
Integral steam generators	33
Condensate recovery	33
Compressed air	33
Drainage	34
Hazardous effluents	36
Machine ventilation	36
Chemical additives: storage	37
Chemical additives	37
Introduction	37
Compatibility with the materials of construction of the washer-disinfector	38
Compatibility with the process	38

Compatibility with the items to be processed	39
Compatibility with the quality of water	39
Compatibility with other chemical additives	39
Compatibility with subsequent decontamination process	39
Detergents	40
Enzymatic cleaners	41
Cleaning additives for ultrasonic cleaners	41
Rinse aids	42
Lubricants	42
Disinfectants	42
Choice of disinfection method	42
Materials compatibility	42
Safety of disinfectants	43
Washer-disinfectors for surgical instruments and associated equipment	43
Single-chamber machines	43
Multi-chamber machines	44
Standard specifications	44
Load-handling equipment	44
Test connections	45
Ultrasonic cleaners	45
Applications	46
Standard specifications	46
Additional specifications	46
Wash cycle	47
Type 1 ultrasonicators	48
Type 2 (continuous process) ultrasonicators	48
Chapter 2 Validation and verification	49
Testing of washer-disinfectors	49
Interrelation of test programmes	49
Schedule of type tests and work tests	50
Schedule of installation tests	51
Checks on ancillary equipment	51
Engineering services	51
Checks on washer-disinfectors	52
Preliminary checks	52
Functional checks	53
Response to external faults	54
Schedule of operational tests	55

Performance Qualification tests	57
Surrogate devices	57
Cleaning efficacy test	57
Representative soiling	57
Test soils	58
Standard test soils	59
Typical test soils	59
Constituents	59
Preparation and storage	59
Application and use	60
Method of application	60
Method of detection	60
Process residues	60
Disinfection	61
Thermometric tests	61
Load dryness tests	61
Schedule of periodic tests	62
Weekly safety checks	63
Yearly safety checks	66
Test methods	66
Drainage	67
Drain seal integrity	67
Apparatus	67
Method for type test	67
Method for operational test	67
Results	68
Method	68
Apparatus	68
Method	69
Results	69
Apparatus	69
Method	69
Result	70
Venting system	70
Apparatus	70
Method	70
Results	70
Apparatus	71
Method	71
Results	72

Type/works test method	72
Installation test	72
Results	72
Apparatus	73
Method	73
Results	73
Door and door interlocks	73
Method	74
Results	74
Method	74
Results	74
Double-door washer-disinfectors	74
Method	74
Results	74
On sensor failure	75
Method	75
Results	75
Door opening force	75
Apparatus	75
Method	75
Results	75
Failed cycle interlock	76
Method	76
Results	76
Fault indication on sensor failure	76
Method	76
Results	76
Chemical dosing	76
Reproducibility of volume admitted	76
Apparatus	77
Method	77
Results	77
Indication of insufficient chemical additives	77
Method	78
Results	78
Water vapour emissions	78
Apparatus	78
Method	79
Results	79
Instrumentation fitted to a washer-disinfector	79
Verification of calibration	79

Load carriers	79
Method	79
Thermometric tests	80
Chamber wall temperature	80
Apparatus	80
Method	80
Results	80
Load carrier temperature	81
Apparatus	81
Method	81
Results	82
Over-temperature cut-out	82
Apparatus	82
Method	83
Results	83
Load dryness	83
Results	83
Residual chemical additives	84
Method	84
Results	84
Air quality	84
Method	85
Results	85
Sound pressure test	85
Method	85
Results	86
Electromagnetic compatibility	86
Cleaning efficacy tests	87
Method for chamber walls and load carriers	88
Method for reference loads	88
Results	88
PQ tests	89
Method	89
Results	89
Periodic tests	90
Tests for residual soils	90
Method	90
Monitoring for residual protein	90
Method	92
Results	93

Disinfection efficacy tests	95
Thermal disinfection test	95
Thermometric test for disinfection	96
Apparatus	96
Method	97
Results	97
Automatic control test	98
Method	98
Results	99
Validation and periodic tests for ultrasonic cleaners	100
Test for ultrasonic activity	100
Apparatus	102
Method	102
Results	103
Reference test loads	103
PQ test	104
Load items	104
Nature of soiling	104
Chapter 3 Water supply	105
Water hardness	106
Ionic contaminants	107
Microbial population	107
Concentration of bacterial endotoxins	108
Water treatment	108
Chemical purity	109
Water softeners	109
Integral water softeners	109
Deionisers	110
Reverse osmosis (RO)	110
Microbial purity	111
Pipework	112
Water supply-by-laws	112
Water system tests	113
Water samples	113
Water quality tests	115
Choice of method	115
Water supply temperature	116
Apparatus	117
Method	117
Alternative method (for periodic testing)	117

Results	117
Water supply pressure	117
Apparatus	118
Method	118
Results	118
Appearance	118
Apparatus	118
Method	119
Results	119
pH	119
Apparatus	119
Method	120
Results	120
Electrical conductivity	120
Equipment and materials	120
Method	121
Results	122
Hardness as (CaCO ₃)	122
Ion-selective electrodes (ISE) method	122
Titrimetric method	123
Results	123
Chloride	123
Ion selective electrode (ISE) method	124
Silver nitrate titration method	124
Results	124
Bacterial endotoxins	125
Total viable count	125
Chapter 4 Operational management	126
Introduction	126
Equipment damage	127
Maintenance	127
Introduction	127
Planned maintenance programme	128
Design of a PM programme	128
Warranty period	129
Review of the PM programme	130
Modifications	130
Routine housekeeping	130
Pressure Systems Safety Regulations	131
Features requiring special attention	131

	Leak tightness of doors	131
	Doors interlocks	131
	Chemical dosing systems	132
	Water sprays and jets	132
	Ultrasonic transducers	133
	Ventilation plant	133
	Returning a washer-disinfector to service	134
	Troubleshooting	134
Appendix 1	Further information on the testing methodology for water quality used within washer disinfectors	136
	Total dissolved solids	136
	Conductivity method	137
	Results	137
	Evaporative residue method	138
	Results	138
	Heavy metals	138
	Method	139
	Results	139
	Iron	139
	Apparatus	139
	Method	140
	Results	140
	Phosphate	140
	Apparatus	141
	Method	142
	Results	142
	Silicate	142
	Apparatus	143
	Results	144
Appendix 2	Technical Specification template (TST) for the purchase of washer-disinfectors for surgical instruments	145
References		172



Design and pre-purchase considerations

Chapter 1

Design and pre-purchase considerations

Purpose of washer-disinfectors

1.1 Washer-disinfectors are used to clean and disinfect items intended for re-use. They may be used in relation to both medical devices and medicinal products as well as other items.

Washer-disinfectors for surgical instruments and associated equipment should conform to EN ISO 15883 Parts 1 and 2 and the safety specifications in EN 61010-2-040.

1.2 The cleaning and disinfection process is intended to:

- make the item safe for staff to handle;
- make the item safe for use on a patient (after any necessary additional processing such as a terminal sterilisation process), including, if appropriate, ensuring freedom from contamination that could lead to an erroneous diagnosis.

1.3 When items being cleaned and disinfected by a washer-disinfector are intended to be used again without further treatment (such as a terminal sterilisation process), before being reused the washer-disinfector should produce an item that is microbiologically safe for its intended use.

1.4 When the items being cleaned/disinfected by a washer-disinfector are intended to be subjected to further processing (such as a terminal sterilisation process) before being re-used the disinfection stage in the washer-disinfector should produce an item that is microbiologically safe to be handled during preparation for subsequent processing.

1.5 Washer-disinfector processing involves two distinct stages: cleaning and microbial inactivation. The latter can be achieved by disinfection, sterilisation or both (disinfection followed by sterilisation). Washer-disinfectors are used to decontaminate items intended for re-use by subjecting the items to an automated process of cleaning and disinfection. This is shown in [Figure 1](#).

1.6 The efficacy of the cleaning stage of the process is of crucial importance to the successful outcome of the disinfection stage.



Design and pre-purchase considerations

General washer disinfecter cycles should include, as a minimum, 5 distinct stages:

- pre-wash – Rinse <45°C
- wash – with a validated detergent at the appropriate dilution and control temperature
- rinse;
- disinfection;
- drying.

Washer disinfectors are required to be effective in achieving the performance required to produce a clean and disinfected product. Failure to achieve the required standard of cleanliness may also impair the capability of the process to achieve disinfection and subsequent sterilisation.

Categorisation of washer-disinfectors by nature of load to be processed

- 1.7 Washer-disinfectors may be categorised according to their intended use, i.e. the nature of the load they are intended to process.
- 1.8 Washer-disinfectors may be further defined both by their configuration/load handling system and by the nature of the operational process.
- 1.9 Washer-disinfectors may be used for processing a wide range of products used in clinical practice. Loads will include surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils and glassware. Further information, including validation protocols can be found in BS EN ISO 15883.

Categorisation of washer-disinfectors by configuration/load handling type

- 1.10 Washer-disinfectors may also be categorised by their construction and the manner in which the load is processed through the machine.

1

Design and pre-purchase considerations

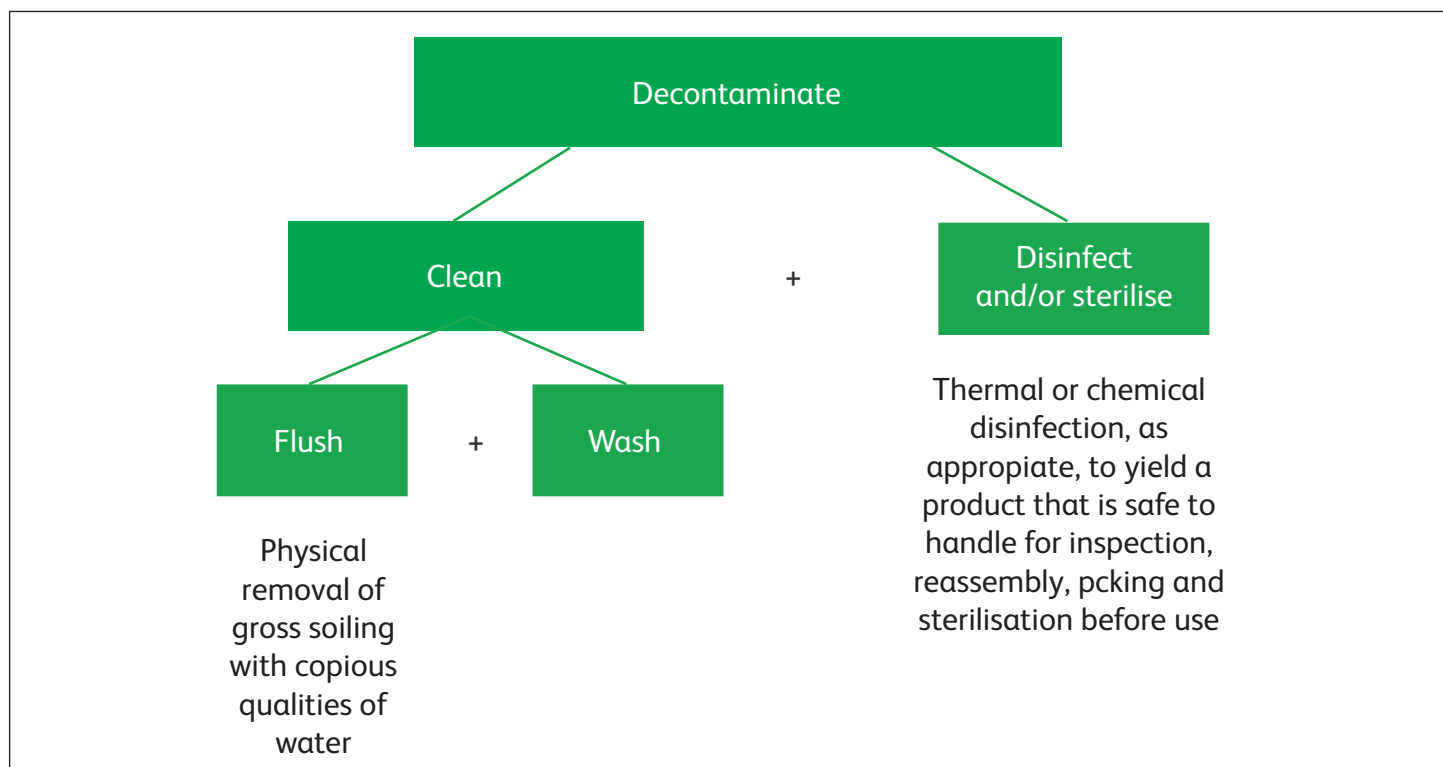


Figure 1 Elements of the decontamination process

Single-chamber machines

1.11 Single-chamber machines have one chamber in which the full range of process stages are carried out. They are machines in which all stages of the cycle are completed on one chamber load before another load can be processed in that chamber.

1.12 These might have either a single door through which both loading and unloading takes place or double doors with one door being used for loading and the other for unloading.

Multi-chamber machines

1.13 Multi-chamber machines have more than one chamber where separate stages of the cycle are performed in each chamber. The full range of process stages is only completed when the load is delivered from the final chamber. The segregation of cycle stages may be determined by specific User requirements but, typically, the chambers will be dedicated to cleaning, disinfection and drying. Different loads may be processed concurrently. An extra chamber for ultrasonic cleaning may also be included. These machines will have doors at either end and at intermediate positions between chambers.

Conveyor machines

1.14 Washer-disinfectors of this type may find it difficult to meet the requirements of some validation and periodic tests and are thus not recommended. Current machines of this type should be replaced.

1

Design and pre-purchase considerations

Thermal disinfection

- 1.15 In this process disinfection is achieved by the action of moist heat maintained on the surface to be disinfected at a particular temperature for a particular time. The combination of time and temperature should satisfy the A_0 requirement of BS EN ISO 15883-1 for disinfection to be achieved.
- 1.16 The A_0 concept is defined in BS EN ISO 15883-1. It is defined as the disinfection effect resulting from an exposure to 80°C for a period of 1 s for an organism with a z-value of 10°C.

Time/temperature bands meeting the requirements of an acceptable A_0 of 600 are as follows:

Disinfection temperature (°C)	Maximum allowable temperature	Exposure time period
70	75	100 minutes
80	85	10 minutes
90	95	1 minute

Drying

- 1.17 Drying can be an integral part of the cycle, usually by the circulation of hot air over the product, or provided as a separate drying cabinet. For some products, for example corrugated anaesthetic tubing, prolonged drying times are recommended and a separate drying cabinet can improve the productivity of the washer-disinfector.
- 1.18 A dry product can also be obtained by the flash evaporation of residual moisture from product items that are hot following a high temperature thermal disinfection stage.

When is a washer-disinfector required?

- 1.19 For many products used in healthcare practice there are two choices available:
 - products intended for re-use after they have been decontaminated and subjected to any necessary reprocessing (for example terminal sterilisation);
 - single-use products, that is, to be discarded after use.

1

Design and pre-purchase considerations

- 1.20 Products that are intended to be re-used should be decontaminated, in accordance with the manufacturer's instructions, in one of the following ways:
- manual cleaning followed by disinfection and sterilisation;
 - machine cleaning followed by disinfection and sterilisation;
 - automated machine decontamination incorporating cleaning.
- 1.21 See MHRA's Device Bulletin MDA DB 2006(04) – 'Single use medical devices: implications and consequence of reuse'.

Note:

HSC 1999(178) – 'Variant Creutzfeldt-Jakob disease (vCJD): minimising the risk of transmission' states that "medical devices designated as single-use should never be re-used".

Choice of washer-disinfector

- 1.22 The choice of washer-disinfector should be determined by the nature of the loads to be cleaned and disinfected.
- 1.23 Purchasers should be aware that items suitable for a particular type of washer- disinfector might still require different operating cycles, which need to be specified before purchase.
- 1.24 Guidance on the modification of operating cycles to suit different loads is given in [Chapter 4](#), 'Operational management'. Advice on individual cases should be sought, if necessary, from the AE(D) before any decision is made. Use should be made of the 'Technical specification' for washer-disinfectors see [appendix 2](#).
- 1.25 Once the type of washer-disinfector has been decided, preliminary enquiries should be made with a number of manufacturers. The use of a standard specification (as shown in appendices of this WHTM) will enable data provided by the tenderer on technical points, as well as financial data to be compared. Not only will this enable the purchaser to confirm the acceptability of current services, spatial requirements and portorage but it will enable a like-for-like tender analysis to be made. Tender analysis will be best achieved by formalising tender comparison with respect to performance and cost in all key areas. Qualifying statements by the tenderer should be taken into account and their effect on tender content or eligibility should be made prior to a choice being made.
- 1.26 The dispensed volume of the chemical additives (e.g. detergents), including the accuracy and reproducibility of the dosing system(s), should be specified.



Design and pre-purchase considerations

- 1.27 For washer-disinfectors employing jet-washing systems, the pump pressure and water flow are also critical variables. Water quality will also be a critical variable where water is used for cleaning or disinfection. Where drying is performed air temperature and air-flow rate are critical variables.
- 1.28 For ultrasonic cleaners, the frequency, amplitude and power are critical variables. For cleaning efficacy the following parameters may also be included: water temperature, detergent type and detergent concentration.
- 1.29 In all cases, the duration of each process stage should be determined with sufficient accuracy to ensure that consecutive cycles have the same efficacy.

In Summary:

Critical variables that are key to optimum cleaning performance and should be set up as part of a validated process.

Cycle Time – should not be compromised and should be configured in line with local variables at point of use (e.g water, steam pressures).

Detergent – must be validated for the W/D, to determine concentration, exposure time and optimum control temperature.

Water Quality – At point of use.

Mechanical Wash action – to include pump pressure, jet wash systems, spray arm rotation.

Loading Pattern – to include control of shadowing and preparation of load prior to insertion into the WD.

Drying of the load – removal of all surface moisture.

Assessment of workload and throughput

- 1.30 Advice on equipment numbers and instrument throughput is included within Health Building Note 13 – ‘Sterile services department’.

Rigid endoscopes

- 1.31 Many rigid endoscopes and most of the reusable surgical accessories used for minimal access therapy (MAT) can withstand steam sterilisation and may be processed through washer-disinfectors employing a thermal disinfection stage to make them safe to handle during packing etc.



Design and pre-purchase considerations

- 1.32 The washer-disinfector should be designed or adapted to ensure that during the flushing, cleaning, disinfecting and drying stages, process fluids (including drying) flow through the lumen(s) of the device.
- 1.33 Many washer-disinfectors can be equipped with dedicated load carriers to process rigid endoscopes, gas cannulae etc. There are also a number of dedicated endoscope cleaners including ultrasonic cleaners.
- 1.34 The capacity of the washer-disinfector should be assessed on the number of items of each type that can be processed in a single load.

Powered devices

- 1.35 Some powered devices rely on the flow of a pressurised fluid or compressed air for operation (for example, dental handpieces, phaco handpieces, orthopaedic saws and drills). If such devices are to be processed through a washer-disinfector and the internal surfaces are to be flushed, they should be connected via dedicated connectors to ensure that process fluids flow through the lumen(s) of the device during the flushing, cleaning and disinfection stages. Flow and pressure through lumens should be in line with the manufacturer's recommendations for the device. Specialist filtration of process fluids passed through fine lumens and powered devices may be necessary to avoid adverse effects on their performance.

Specification and contract

Introduction

- 1.36 This section discusses general specifications for washer-disinfectors and the steps to be taken in inviting tenders and issuing a contract.

CE marking

- 1.37 Washer-disinfectors are covered by a number of European Directives and are thus required to be in conformance. Relevant Directives include but are not restricted to: Medical Device Directive (93/42/EEC and 2007/47/EEC) Class II a, Electromagnetic Compatibility Directive (2004/108/EEC), Low-voltage Directive (2006/95/EC), Pressure Equipment Directive (97/23/EEC) and the Machinery Directive (98/37/EEC and 2006/42/EEC).

1

Design and pre-purchase considerations

Preparing a specification

- 1.38 It is essential that the preparation of procurement specifications be carried out by a qualified and competent person. The purchaser should use the services of NWSSP/SES for assistance compiling the specification. A national specification is available and can be obtained through NWSSP/SES.
- 1.39 Purchasers should refer to BS EN ISO 15883 Parts 1 and 2, WHTM 01-01 Part B and the 'Particular specification' for washer-disinfectors included on page 147 when preparing a specification for a washer-disinfector.

Key Considerations Preparing a Specification:

- What are the User requirements?
 - number and type of MEDICAL DEVICE being processed;
 - turnaround time;
 - future capacity requirements;
- What is the budget available?
- What is the quality of the water supplying the SSD?
- What space is available?
- Where will the machines be located?
- What services are currently available?
- What model and design is most appropriate?
- What chemical solutions (detergents etc.) can be used and are they compatible with the devices to be processed?
- What are the revenue implications of the different options available?
- What warranty conditions are required?
- The need to continually monitor performance of WD and service response under the warranty period (KPI assessment)

1

Design and pre-purchase considerations

- Ongoing service needs
- Estates support and communication with supplier

Construction materials

1.40 Materials of construction should comply with the requirements of BS EN ISO 15883.

Integral air compressors

- 1.41 Washer-disinfectors might require a supply of compressed air for either the operation of valves and powered door systems and/or during the drying stage of the cycle.
- 1.42 When compressed air is intended to come into contact with the washed and disinfected product the compressed air supplied should be “medical grade”, i.e. it should be oil and particulate free (see HTM 02-01 – ‘Medical gas pipeline systems’).
- 1.43 Built-in air compressors should be suitable for the duty imposed upon them.

Integral calorifiers and tanks

- 1.44 All integral calorifiers should conform to BS 853-1, and should be designed and constructed to allow thermal disinfection to be achieved throughout the calorifier and associated pipework before water/steam can be supplied to the washer-disinfector during the thermal disinfection and subsequent stages.
- 1.45 Water tanks within the washer-disinfector should be self-draining and located so that they are cleanable by the Operator and fitted with a drain down system which either works automatically when the machine is switched off or which is accessible to the User.
- 1.46 All tanks should be fitted with an overflow (see the Water Supply (Water Fittings) Regulations 1999).
- 1.47 When water is to be heated the heat source should be controlled by a thermostat and it should employ a heating medium as specified by the purchaser. The heat sources should be removable for replacement or maintenance purposes.

Dosing systems

- 1.48 The washer-disinfector should be fitted with not less than two systems for controlling the admission of chemicals (detergents, additives etc) and should be provided with the facility for at least one additional dosing system to be fitted.



Design and pre-purchase considerations

- 1.49 Each dosing system should be provided with means to adjust the volume admitted. Access to the means of adjustment should require the use of a key, code or tool. The means of adjustment can be manual or automatic.
- 1.50 The stage(s) in the process cycle at which each dosing system admits chemical to the washer-disinfector should be under the control of the automatic controller.
- 1.51 Each dosing system should be provided with means to determine the volume admitted and the time within the operational cycle when the admission occurred. This data should be available to the operator.
- 1.52 Failure to admit the specified minimum volume should cause a fault to be indicated and a failure indication raised.
- 1.53 The accuracy and reproducibility of chemical dosing systems should meet the requirements of BS EN ISO 15883-2.
- 1.54 The washer-disinfector should be fitted with a system that will indicate when there is insufficient chemical(s) available for the next cycle and that cycle should not be allowed to start.

Chemical dilution rates, configured as part of operational/performance qualification, should not be adjusted unless as part of a validated process and additionally after consultation with the AE(D) or DE(W).

Door controls

Control of manually operated doors

- 1.55 An explanation of the manual action required to lock the door should be provided for the Operator. In addition, if the unlocking procedure is not the reverse of the locking procedure, there should be an indication to the Operator of the manual action required to unlock the door. The indication should be clearly displayed either on the door or on its handle or handwheel. Explicit instructions should be displayed on the facing panel adjacent to the door or on the Operator's control panel.
- 1.56 The door mechanism should be such that the force to be applied by an Operator in order to either lock or unlock the door does not exceed 250 N at the intended point of grip.

Control of doors in a double-door washer-disinfector

- 1.57 In double-door washer-disinfectors, the control initiating the automatic cycle should be at one end only. When the loading door is closed and locked, it should not be possible to open the unloading door until the washer- disinfector has completed a successful operating cycle, i.e. without showing a fault.
- 1.58 If a fault develops, it should only be possible to open the loading door.



Design and pre-purchase considerations

- 1.59 It should not be possible for an Operator to open or close a door at the opposite end of the washer-disinfector or for more than one door to be open at one time.
- 1.60 A visual display should be provided at both ends of the washer-disinfector to indicate when the cycle is in progress.
- 1.61 The indication “cycle complete”, or an equivalent indication, should be cancelled when the unloading door is unlocked, and the loading door should remain locked until the unloading door has been locked again.

Loading systems

- 1.62 The washer-disinfector should be provided with carriers to locate the load during the washing and disinfection process. When interchangeable load carriers and baskets are provided, each load carrier should be capable of being fitted and removed without the use of tools. Washer-disinfector loading systems should be designed with regard to the Manual Handling Operations Regulations 1992 (as amended).
- 1.63 When the washer-disinfector is supplied with a system for supporting the load/transferring the load into and out of the chamber, the following should apply:
- the load should be wholly supported and retained within the usable chamber space for the duration of the operating cycle;
 - the force required by the Operator, either directly or by the application of a mechanical device supplied with the equipment, to remove the whole, or part, of the load from the chamber should not exceed 250 N when loaded and operated in accordance with the manufacturer’s instructions;
 - the load carrier should either be retained in the chamber by a mechanism which is only released when the transfer system is in place, or remain stable when withdrawn for a distance equal to two-thirds of the chamber length, and be fitted with a retaining device, which has to be released if the load is to be withdrawn further.
- 1.64 Means should be provided such that the transfer of the load into and out of the chamber does not cause damage and wear to the chamber.
- 1.65 Systems which cause high levels of local stress, e.g. point loadings, might also initiate corrosion in stainless steel materials.
- 1.66 The system used to support the load should be constructed from durable, corrosion-resistant materials and should withstand, without damage, the environment within the chamber.



Design and pre-purchase considerations

- 1.67 The system used should neither prevent the attainment of the pre-set cycle variables nor the free drainage of water from the load and the penetration of water/steam into the load. The load carrier(s) should be designed so that they cannot be mis-positioned in a manner that will prevent such attainment.
- 1.68 Any accessory used for handling the load which can be used outside the washer- disinfecter (e.g. a trolley) should remain stable when it is supporting its maximum design load and a force of 250 N is applied horizontally in any direction to the highest point of the load or accessory.
- 1.69 The trolley should be designed to allow the operator to align the trolley with the washer-disinfecter for ease of loading and unloading.
- 1.70 The trolley should be provided with means to collect liquid residues from the load to prevent these from dripping onto the floor. The means provided should be detachable for cleaning and disinfection in a washer-disinfecter or, where necessary sterilisation at 134–137°C in a porous-load steriliser.
- 1.71 The trolley should be provided with swivel wheels to facilitate manoeuvring.
- 1.72 The trolley should be provided with a parking brake.
- 1.73 The trolley 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.
- 1.74 Trolleys intended for use with single door machines should be designed and constructed to facilitate cleaning and disinfection of the trolley between use for dirty and clean loads.
- 1.75 Load conveyors outside the washer- disinfecter that are intended to, or might reasonably be expected to, come into contact with soiled/contaminated goods should be designed and constructed to be easy to clean and disinfect.

Cleaning the washer-disinfecter

- 1.76 The design, construction and operation of the washer-disinfecter should ensure that during the process the surfaces of the chamber and the load carrier presented to the operator are cleaned and disinfected.
- 1.77 For manually filled and emptied cleaning machines with no disinfection cycle, for example stand-alone ultrasonic cleaners, the manufacturer should advise on the cleaning/ disinfection method.



Design and pre-purchase considerations

Engineering Service Requirements:

Steam

- 1.78 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 a washer-disinfector operating cycle.
- 1.79 Steam may also be used to heat process water directly, or to heat the load directly during the thermal disinfection stage, and for this purpose may be supplied either with an integral steam generator or from an external (mains) supply.

Steam for indirect heating

- 1.80 Steam heat exchangers used for heating water or air may be of the shell, tube or plate design. In all cases, the steam supplied should be substantially free from non-condensable gases and free from oil since these contaminants seriously impair the efficiency of the heating process. The effect of thin films of air on the surface of the heat exchanger may increase heating costs by 25% or more.
- 1.81 The steam service should be designed to meet the maximum demand of the washer-disinfector, or bank of washer-disinfectors, while keeping the fall in pressure before the final pressure reducing system to no more than 10%. Tests should be carried out as part of the installation/operational qualification to verify that steam demand is sufficient to service all washer disinfectors when they are at the stage of the operating cycle with the greatest steam demand.
- 1.82 Except for vertical rises between floors or at intermediate points on long runs, the pipework should have a continuous fall such that any condensate flows by gravity in the same direction as the steam. Air vents and steam traps should be fitted at each vertical rise.
- 1.83 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 water logging the heat exchanger.
- 1.84 When the steam supply pressure at the inlet to the washer-disinfector exceeds the maximum value specified by the manufacturer, a pressure reducing valve should be fitted to the supply pipe at least 3 m from the washer-disinfector.
- 1.85 Careful attention should be paid to the appropriate control of incoming steam pressure to ensure that the washer-disinfector is properly protected. Installation of pressure reducing/relief valves must be appropriate in line with manufacturers recommendations and pressure systems safety regulations.



Design and pre-purchase considerations

- 1.86 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. The discharge pipe should terminate in a safe position outside the building.
- 1.87 Steel and copper piping traditionally used for steam supply are acceptable for this application.
- 1.88 Excessive moisture in the steam supply will impair the heating efficiency of the heat exchanger and so should be avoided.

Integral steam generators

- 1.89 Some washer-disinfectors are equipped with small electrically heated steam generators to raise steam to heat the load directly for thermal disinfection.
- 1.90 They may be of the open-boiler type, which are so designed and constructed that they are unable to generate an internal pressure above atmospheric pressure. The design should ensure that, under a single fault condition, for example obstruction of the steam discharge port, the boiler cannot become pressurised.
- 1.91 Integral steam generators which are pressure vessels should be in accordance with PD 5500.

Condensate recovery

- 1.92 Condensate from steam heating systems (calorifiers, dryers) and steam traps on the pipeline is suitable for recovery and should be returned to the steam generating plant when recovery is economically justifiable. It should not be possible to contaminate instruments if a failure of the heating coil occurs.

To ensure the condensate recovery system is operating as designed, routine monitoring and maintenance is essential and key components, such as steam traps and filters, should be inspected or replaced at pre-determined intervals or whenever they are defective.

Compressed air

- 1.93 A compressed air supply might be required for the operation of controls and air-drying. If the washer-disinfector does not contain an integral air compressor, the air may be supplied from a piped service (mains supply) or from a local compressor.

Mains supply

- 1.94 If air is supplied by pipeline from a central air-compressor system, a Bourdon-type pressure gauge conformant to BS EN 837 should be fitted on the supply line to the washer-disinfector via an isolation valve.



Design and pre-purchase considerations

- 1.95 A reducing valve, or other automatic device, should be fitted to reduce the pressure of air delivered to the washer-disinfector to no more than the maximum supply pressure specified by the manufacturer. A pressure relief valve will normally be required.

Local compressor

- 1.96 When it is not practical to obtain compressed air from a mains supply, a dedicated compressed air system should be installed to supply the washer-disinfectors.
- 1.97 The compressors might be too noisy to install with the washer-disinfector and might need to be located in a dedicated location away from noise sensitive areas.
- 1.98 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.

Air quality

- 1.99 The quality of air can be critical for some applications and some washer-disinfectors will incorporate appropriate filters. When the purchaser is to be responsible for the provision of filtered air the CP(D) should ensure that the quality of air available meets the washer-disinfector manufacturer's specification or the requirements given below.
- 1.100 Air that could come into direct contact with the load, such as air used for drying the load or testing the free-passage of lumens, should be:
- oil-free (i.e. should have no more than 0.5 mg of oil per cubic metre of free air measured at 1013 mbar and 20°C; see ISO 554);
 - filtered to an efficiency of at least 95 % when tested in accordance with BS 3928; and
 - free of bacteria (see HTM 02-01).
- 1.101 Air for control purposes should be free of liquid water, filtered to 25 µm (5 µm for precision controls) and lubricated with micro-fog oil particles of 2 µm or less.

Drainage

- 1.102 All effluent from a washer-disinfector is potentially contaminated and should be disposed of to the main drain. All washer-disinfector and associated equipment should be connected to the drain in a manner that provides backflow protection and complies with local regulations.
- 1.103 Effluent can originate from each of the stages of the process, which may include:

1

Design and pre-purchase considerations

Stage	Purpose	Effluent type
Flushing	Removal of gross contamination.	Organic contaminants, potentially infectious microorganisms.
Washing with detergent	Removal of remaining soil.	Some organic contaminants and potentially infectious microorganisms and high concentrations of process chemicals.
Rinsing, with or without the addition of a neutralizer	Removal of residual soil and process chemicals.	Some microorganisms and high concentrations of process chemicals.
Thermal disinfection	Reduction of microbiological load.	High temperatures discharge water(90°C–100°C).
Drying	Drying the load	Drying particles

- 1.104 Effluent from early stages (a) and (b) of the process might contain significant concentrations of organic contaminants and potentially infectious microorganisms. Effluent from the middle stages (b), (c) and (d) can contain some organic contaminants and potentially infectious microorganisms and high concentrations of process chemicals. Effluent from the latter stages (d), (e) and (f) can be at high temperatures (90°C–100°C).
- 1.105 Effluent from washer-disinfectors 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 washer-disinfector and its associated pipework being contaminated by reverse flow from the drainage system.
- 1.106 Where a tank supplies water to a pump on the washer-disinfector, the overflow discharge from the tank should also include an air break.
- 1.107 The drainage system from the installation 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 during the operating cycle.
- 1.108 The drainage system should be designed to pass and maintain in suspension the solids 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 washer-disinfector chamber.
- 1.109 Means should be provided to prevent, as far as possible, flash steam being liberated into the atmosphere or causing condensation on electrical equipment.



Design and pre-purchase considerations

- 1.110 The discharge temperature from a washer-disinfector may be as high as 95°C.
- 1.111 The materials used for the construction of the discharge system should be chosen to withstand temperatures up to 100°C. Materials used for the construction of the discharge system should be chosen to withstand temperatures up to 100°C. A means of diluting/reducing any high temperature effluent to <60 °C is required prior to discharge into any water company common drains.

Hazardous effluents

- 1.112 The discharge of soil from washer-disinfectors should be regarded as being no more, but no less, hazardous than the discharge from any other sanitary appliance, e.g. a WC.
- 1.113 The discharge of process chemicals, including detergents and microbicides, may require special attention. The local sewerage undertaker should be consulted before such chemicals are discharged into the drainage system, as it may be necessary to neutralise or inactivate them before discharge (see HTM 07- 01 – ‘Safe management of healthcare waste’).
- 1.114 A sealed and vented drain should be used for the discharge of chemicals with a significant vapour pressure, determined at the maximum attainable temperature of effluent in the drain, which may be hazardous to health or a nuisance. Possible backflow from the drain should be prevented by the inclusion of a check valve and a vacuum breaker.

Machine ventilation

- 1.115 Washer-disinfectors are often run under a slight negative pressure to minimise the potential for the discharge of aerosols into the environment.
- 1.116 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 noncorrosive material that can withstand temperatures greater than 105°C. The advice of NWSSP/SES should be sought during the design stage.
- 1.117 Additional guidance is given in Part B of Health Technical Memorandum 03-01 – ‘Specialised ventilation systems in healthcare’.



Design and pre-purchase considerations

Chemical additives: storage

- 1.118 Safe storage provision, using dedicated cabinets appropriately ventilated if required, is needed for containers of chemical additives used in the washer-disinfector. These chemicals are frequently corrosive, irritant and toxic and provision should be made in, or adjacent to, the storage area for an emergency eye wash station and a source of running water to dilute any spillage. Reference should be made to local COSHH (Control of Substances Hazardous to Health) provisions.
- 1.119 In large installations with two or more machines, as might often be required in SSDs, bulk storage tanks for chemical additives required for the process might be preferred with a piped distribution system to each washer-disinfector.
- 1.120 For each chemical additive to be used, there should be two storage tanks in parallel (one of which might be a small reserve tank):
- to permit cleaning and maintenance of the of the large tank without interrupting the use of the washer-disinfectors;
 - to facilitate segregation between separate batches of chemical additive; and
 - to allow for an orderly change to a different formulation if required.
- 1.121 The liquid concentrates are often viscous and chemically aggressive. The pipework, valves etc used for the distribution of these chemicals will need to withstand the corrosive effects of these materials. Advice should be sought from the manufacturer of the chemical additives on suitable materials, construction and pumping systems for the distribution system.

Each chemical formulation used should be clearly labelled for the appropriate chemical supplied. If chemicals are positioned within the WD, there should be protection systems in place to prevent inadvertent misconnections. Process chemicals should be stored in dedicated cabinets in line with suppliers recommendations.

Chemical additives

Introduction

- 1.122 Chemical additives are not necessary for all applications; while they can enhance the removal efficacy it is then necessary to remove them during the rinsing stage. For applications in the laboratory and in the preparation of components and equipment used in manufacturing medical devices and medicinal products, chemical additives should be avoided if their use is not essential.



Design and pre-purchase considerations

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.

1.123 In choosing the various chemical additives for effective cleaning and disinfection, the formulation of each chemical additive should be compatible with:

- the materials of construction of the washer-disinfector;
- the process being operated in the washer-disinfector;
- the quality of water available;
- the items to be processed and their intended use;
- any other additives to be used in the washer-disinfector process;
- any intended subsequent decontamination process (e.g. sterilisation).

1.124 The required concentration should be accurately and reproducibly generated by the dosing system(s) on the washer-disinfector.

1.125 It is not sufficient to determine only the compatibility of the principal active constituents, as the precise formulation of the chemical additive will affect its compatibility.

Chemical additive's should not be changed with consultation prior consultation with NWSSP/SES, additionally any changes need to accompanied by an agreed validation procedure.

Compatibility with the materials of construction of the washer-disinfector

1.126 The cleaning formulation should have no long-term effects on the components of the washer-disinfector.

1.127 Chemical additives that can be absorbed into, or adsorbed onto, surfaces of the washer-disinfector (e.g. plastic pipework) may be carried over into subsequent stages of the process (see also [next section](#) and [paragraph 1.134](#), 'Compatibility with subsequent decontamination processes').

Compatibility with the process

1.128 The performance of the additive should be matched to the physical characteristics of the operating cycle (e.g. jet-washing action systems require low foam detergents), if the washing action is not to be impaired.



Design and pre-purchase considerations

Compatibility with the items to be processed

- 1.129 The chemical additives used should be compatible with the materials of which the load items are constructed and should not cause chemical or physical damage, e.g. phenolic compounds used in detergents and disinfectants might cause material changes in rubber and plastics, while the anodic coating on the surface of anodized aluminium is removed by strongly acid or strongly alkaline compounds. Use of a rinse-free cycle for laryngeal masks may be considered.
- 1.130 The chemical additives used should be readily removed from the load items by rinsing with water and should be biologically compatible with the intended use of the load items. Chemical additives that are intended to persist on the surface of items processed through the washer-disinfector (e.g. lubricants) should be biologically compatible with the intended use of the load items.

Compatibility with the quality of water

- 1.131 The activity of many detergents and disinfectants are seriously impaired by hard water.
- 1.132 Detergent formulations intended for use only with soft water might give rise to precipitation if used with hard water, particularly at elevated temperatures. Once this precipitation has occurred on the surfaces of the washer-disinfector or the load it is particularly difficult to remove (see [paragraph 1.129](#), 'Compatibility with the items to be processed').

Compatibility with other chemical additives

- 1.133 The additives used should be both compatible with other chemicals used in the same process stage and, as far as may be practicable, with those used in preceding and subsequent stages to minimize the adverse effect of any carryover.

Compatibility with subsequent decontamination process

- 1.134 Chemical additives that might persist on the surface of items processed through the washer-disinfector should be compatible with any subsequent decontamination process that might be required, such as terminal sterilisation. An in-process instrument lubricant that deposits a lubricant film on all surfaces of the instrument should only be used if it has been demonstrated to be compatible with any subsequent sterilisation process.
- 1.135 The specified concentration of chemical additives should be attained in order to ensure effective processing. Too little will impair the process, while too much is wasteful, might impair the process and might contribute to unacceptably high residual levels.



Design and pre-purchase considerations

- 1.136 Suppliers of chemical additives 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.
- 1.137 Suppliers of chemical additives normally provide details of the analytical methods that can be used to detect residual concentrations of product. The sensitivity of the method should be sufficient to determine the presence of the compound below the level at which any adverse biological reaction would be determined.

Detergents

- 1.138 For most applications, where compatible, alkaline detergents in the pH range 8.0–11.0 are preferred. However device manufacturers recommendations may add the need to consider chemicals compatible with devices, a localised risk assessment in line with advice from NWSSP/SES should assess the most appropriate choice of chemistry.
- 1.139 Cleaning agents for use in washer- disinfectors should be:
- liquid (to facilitate accurate dispensing);
 - non-abrasive;
 - low foaming;
 - free rinsing;
 - biodegradable.
- 1.140 Detergents should not contain:
- artificial colouring agents;
 - optical brighteners;
 - perfumes;
 - halides at an in-use concentration greater than 120 mg/L;
 - fatty soaps, glycerine or lanolin;
 - toxic residue.



Design and pre-purchase considerations

Enzymatic cleaners

- 1.141 Enzymes are biological catalysts through which the metabolism of most living organisms takes place. Although produced by living organisms, they are not themselves alive. They are large molecules whose steric configuration (shape) affords them the ability to catalyse many reactions in the living cell.
- 1.142 Enzymes are classified into groups depending on the nature of the chemical reaction that they catalyse. Generally the enzymes used in enzymatic cleaners are hydrolases, i.e. they promote the hydrolysis of the substrate with which they interact.
- 1.143 Enzymatic cleaners are themselves proteins and can be sensitising or allergenic agents.
- 1.144 A considerable proportion of the soiling found on medical items contains proteins that act as binding agents. Particulate dirt can be bound by the coagulation of these proteins on the surface.
- 1.145 If the binder proteins can be broken down into smaller molecules, this binding action is destroyed and the bound soil, as well as the protein, can be released from the surface.
- 1.146 Formulations will often include buffering agents to maintain the pH within the preferred range. For example, the proteolytic hydrolase derived from *Bacillus subtilis*, subtilisin A, withstands temperatures up to 76°C and has optimum activity at pH 9.4.
- 1.147 The importance of the enzymatic solution being at the correct temperature and pH, as well as being used for the specified contact time, cannot be too strongly emphasised.
- 1.148 Enzymes are not themselves cleansing agents. A properly balanced surfactant might still be needed to remove the simpler molecular forms resulting from the enzymatic action.
- 1.149 Enzymatic formulations for cleaning solid surfaces are available in two forms:
- a pre-soak formulation which is used to digest soil and is followed by normal washing process using detergent;
 - a combination of enzymes along with detergent formulation.

Cleaning additives for ultrasonic cleaners

- 1.150 Only detergents specifically intended for use in ultrasonic cleaners should be used. The use of other detergents can impair rather than enhance the cleaning process.



Design and pre-purchase considerations

Rinse aids

1.151 Rinse aids are generally formulated from surfactants and are designed to make the water more free rinsing.

Lubricants

1.152 The addition of oil-based compounds to the cleaning process is wrong in principle, as they cause contamination over the entire cleaned surface. Only the water-soluble type should be used. Mineral oils have poor biocompatibility and can inhibit the penetration of steam or sterilant gases on terminally sterilised product.

1.153 Lubrication should only be applied to those areas where it is required during the inspection/packing process after thorough cleaning of the instrument.

Disinfectants

Choice of disinfection method

1.154 Thermal disinfection using moist heat is the preferred method and should be used whenever it is compatible with the load to be processed.

1.155 Temperatures in excess of 65°C and up to 95°C (or in some cases 100°C) can be used for disinfection; the lower the temperature the longer the exposure time in order to obtain the same reduction in microbial population. The thermal disinfection process is reliable, reproducible, free from toxic residues and capable of easy and economical physical monitoring and recording.

1.156 Chemical disinfection should only be used for products that cannot be treated using thermal disinfection methods.

Materials compatibility

1.157 The disinfectant should not cause damage to either load items or the washer- disinfectant in which it is used. Damage that may occur with incompatible disinfectants includes corrosion, embrittlement or swelling of plastics, degradation of lens cement in optical systems, etc.

1.158 The potential for electrolytic attack to occur as a result of different metals in the load and the washer-disinfectant coming into contact, via a powerful electrolyte, should not be overlooked.

1.159 The material of construction of the washer-disinfectant and of the items in the load should not inhibit the disinfectant.



Design and pre-purchase considerations

Safety of disinfectants

1.160 Many of the compounds that are most effective as disinfectants are potentially human health hazards. Employers are required by law to do everything that is 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 (as amended). It should be noted that some disinfectants require dilution or activation before use.

Washer-disinfectors for surgical instruments and associated equipment

1.161 This section gives recommendations for washer-disinfectors used for cleaning and disinfecting surgical instruments and associated equipment including anaesthetic accessories, bowls, dishes, receivers, utensils and glassware.

1.162 The guidance given here assumes that the washer-disinfector is to be used during decontamination of medical devices and that the essential requirements of the EU directives are met. Further information and requirements can be found in BS EN ISO 15883 Parts 1 and 2.

Single-chamber machines

1.163 Single-chamber cabinet washers for surgical instruments and associated equipment may be designed to accept interchangeable load carriers, typically with rotating spray arms or other devices to ensure a uniform wash action with several layers of load items.

1.164 The spacing between layers should be designed to accommodate a number of wire mesh baskets full of instruments or should be more widely spaced to accept and correctly position large bowls, instrument trays, reusable rigid containers and similar items. Spacing should also allow for anaesthetic accessories to be located and processed, as well as specialist carriers with connections for particular instruments such as rigid endoscopes, MAT instruments, lumen devices and powered devices.

1.165 Since all stages of the cycle take place in the same chamber, it is not possible to get physical separation between the dirty and clean stages of the cycle. 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 washer- disinfector as well as the load.



Design and pre-purchase considerations

Multi-chamber machines

- 1.166 Continuous process washers, other than those designed as automatic ultrasonic cleaners only, are usually designed to accept interchangeable load carriers (see [paragraph 1.163](#), ‘Single-chamber machines’). Where the first chamber is used for first (that is, cold) wash only there may be a build-up of deposits, which will require additional cleaning at set intervals.
- 1.167 Compared with single-chamber machines they have a higher throughput and, for a similar process, achieve some decrease in overall cycle time.
- 1.168 Since the load is moved through the machine as the cleaning and disinfection cycles proceed it is possible to get excellent physical separation between dirty and clean load items.
- 1.169 There may be some loss of operational flexibility when this type of machine is used for several applications at a time; for example, if it is used to process anaesthetic accessories, the increased drying time, necessary for this application, will slow the passage of other loads passing through the washer-disinfector.
- 1.170 Washer-disinfectors of this type are large, expensive pieces of equipment and they should only be used in centralized production units.

Standard specifications

- 1.171 Washer-disinfectors for surgical instruments and associated equipment should conform to BS EN ISO 15883 Parts 1 and 2 and the safety specifications in BS EN 61010-1.
- 1.172 Use should be made of the ‘Particular specification’ for washer-disinfectors on page 146. It is recommended NWSSP/SES are contacted to supply the latest version of the specification.

Load-handling equipment

- 1.173 A number of different types of carrier should be used to accommodate the range of items to be processed. The range of carriers that might be necessary for an SSD include:
- a multi-layer carrier for instruments in wire mesh baskets (wire-mesh baskets to include a number with retaining systems for small instruments);
 - a two layer carrier for small hollowware and instrument trays;
 - a single layer carrier for large bowls, Edinburgh trays etc;
 - a rigid endoscope/MAT instrument/lumen device carrier;



Design and pre-purchase considerations

- an anaesthetic accessories carrier;
- sterilisation containers;
- carrier with dedicated connectors for powered devices.

1.174 The load carriers should protect instruments from mechanical damage during the wash process and should also orientate the instruments to facilitate proper cleaning providing, when necessary, a direct connection between the water flow and the lumen of the load item.

1.175 The specification for load handling equipment should include the provision of appropriate tabling to permit sorting of instruments and loading of load carriers and, after processing, the unloading of load carriers.

1.176 When double-door washer-disinfectors are used, means should be provided to return load carriers from the unloading to the loading end. Where this passes through the wall between the packing room and decontamination room, there should be a pass-through hatch with interlocked doors.

Test connections

1.177 Test connections should be provided to permit the connection of thermocouples and pressure transducers to be used during validation and periodic testing.

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

Ultrasonic cleaners

1.179 The guidance given here assumes that the washer-disinfector is to be used to clean and disinfect medical devices and that the essential requirements of the EU directives are to be met.

1.180 Ultrasonic cleaners may be Type 1 or Type 2 machines (ultrasonication may be integrated into a Type 2 washer-disinfector). They are mainly used as a preliminary cleaning stage prior to processing through a washer-disinfector.



Design and pre-purchase considerations

1.181 Ultrasonic cleaners work by exposing the items to be cleaned to high frequency sound waves in the liquid cleaning medium. The high frequency sound waves are generated within the liquid by the vibration of one or more surfaces of the bath, which is caused by one or more transducers bonded to the outer surface(s). The transducers convert electrical power into vibrations of the required frequency and amplitude. The highly effective cleaning action occurs as a result of the penetrative agitation caused by cavitation, the rapid formation and collapse of tiny bubbles within the liquid, which are generated by the high frequency sound waves.

Applications

- 1.182 Ultrasonic treatment is particularly suitable for cleaning instruments of high-grade steel. Delicate instruments such as micro-surgery instruments and dental instruments can be effectively cleaned with little risk of damage.
- 1.183 Ultrasonic treatment is also particularly effective for cleaning instruments that have deep interstices that may be contaminated with body tissues, for example reamers, drills and burrs.
- 1.184 When combined with appropriate connection to an irrigation or flushing system, ultrasonicators are also effective for cleaning internal and external surfaces of cannulated instruments.
- 1.185 Ultrasonic cleaners are less effective when used to clean plastic and similar readily compressible materials since they absorb much of the ultrasonic energy.

Within SSD's ultrasonic cleaners are mainly used for pre-cleaning activities, prior to decontamination in a validated washer-disinfector. They can provide extra assurance of optimum cleaning of devices known to be difficult to clean.

Additionally they should be used when specified in manufacturers instructions.

Validation requirements can be assessed between User/AP(D) and AE(D) if the Ultrasonic is used for pre-clean activities only.

Standard specifications

1.186 Safety specifications for ultrasonic cleaners are included in BS EN 61010-1.

Additional specifications

1.187 The ultrasonic cleaner should be fitted with means to drain the tank with the cleaner in situ. The tank should be free draining so that no pools of water are left in the tank after draining.



Design and pre-purchase considerations

- 1.188 The tank should be heated electrically and the heaters should be thermostatically controlled.
- 1.189 The ultrasonic cleaner should be fitted with a timer to control the duration of exposure.
- 1.190 The ultrasonic cleaner should have a lid; the lid should be interlocked with the operating system to prevent normal operation if the lid is open and should fit securely to prevent the emission of aerosols when the cleaner is in operation.
- 1.191 The lid interlock should ensure that no part of the Operator's body can be immersed in the ultrasonic cleaner during operation.
- 1.192 The ultrasonic cleaner should be effectively insulated to prevent high frequency sound transmission at a power that could cause a health hazard. The casing and lid should provide adequate sound proofing so that harmonic frequencies within the audible range are not obtrusive.
- 1.193 The manufacturer will normally recommend the chemical additives (detergents/ enzymatic cleaners) that are compatible with the process. Low foaming detergents should be used. Liquid detergents used for washing dishes ("washing-up liquid") are not suitable.
- 1.194 The manufacturer is obliged to specify how the cleaner may be disinfected. This might be by the provision of a high-temperature (for example 80°C) cycle option, or by means of a suitable disinfectant solution. In the absence of guidance the Microbiologist should be asked to advise on a suitable procedure.
- 1.195 The manufacturer is also obliged to specify the degassing time(s) to be used on start-up and, when necessary, between each load of instruments processed.

Wash cycle

- 1.196 The ultrasonic frequency used should be within the range 35 kHz \pm 5 kHz and the energy input used may range from 5 W L⁻¹ to 20 W L⁻¹.
- 1.197 Ultrasonic cleaners can be designed to operate at a single frequency, across a frequency range, or with a feedback control system claimed to adjust the frequency in response to the loading conditions.
- 1.198 For medical applications aqueous solutions should be used. Although ultrasonic cleaners containing aqueous solutions can be effective at temperatures up to 90°C it is normal practice to operate those for medical applications at temperatures between ambient and 40°C. This minimizes the rate of coagulation of proteinaceous material in the soiling and is compatible with the use of enzymatic cleaners, many of which are rapidly destroyed at higher temperatures.



Design and pre-purchase considerations

Type 1 and Type 2 ultrasonicators

Type 1 ultrasonicators

- 1.199 A mechanical lifting device should be used when the ultrasonicator is intended to process heavy sets of instruments.
- 1.200 The load container, usually a wire mesh basket, should be of appropriate size for the longest instrument to be processed.
- 1.201 When it is intended to process micro- surgical instruments or instruments with fine points the load handling equipment should provide means of retaining these in position so that the points are not blunted by the impacts resulting from fine mechanical shaking.

Type 2 (continuous process) ultrasonicators

- 1.202 Continuous process washer-disinfectors may incorporate an ultrasonic cleaning stage within the cycle programme.
- 1.203 Ultrasonic cleaners are also available in continuous process format with a thermal disinfection stage and with the option to provide a hot air drying stage.
- 1.204 If complex tabling or conveyors are required these should be specified, and preferably illustrated with a sketch plan, when seeking tenders.
- 1.205 When it is intended to process micro-surgical instruments or instruments with fine points the load handling equipment should provide means of retaining these in position so that the points are not blunted by the impacts resulting from fine mechanical shaking.
- 1.206 The ultrasonic cleaner should be fitted with a temperature indicator; provision should be made for a recorder to be fitted if requested by the purchaser.
- 1.207 The ultrasonic cleaner should be fitted with an indicator to show the power consumption (in watts), or electrical demand (in amps) of the ultrasonic transducers; provision should be made for a recorder to be fitted if requested by the purchaser.

Chapter 2

Validation and verification

Testing of washer-disinfectors

2.1 Washer-disinfectors are used to carry out the processes of cleaning and disinfection consecutively. These processes require validation to demonstrate they will consistently clean and disinfect all instrument scenarios likely to be presented including those most difficult to clean and disinfect. Choice of test loads and dryness of soils need careful consideration to ensure that this objective is met.

Validation - A documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications.

- 2.2 In some instances a visual inspection for residual contamination may be considered sufficient for monitoring the adequacy of the cleaning process before use. However, this is not true in all cases; for example, visual inspection will not detect soiling on the internal surfaces of instruments with lumens and will not detect low, but potentially significant, concentrations of soiling (for example proteins) or residual chemical additives from the WD remaining on load items.
- 2.3 There is no simple method to verify by inspection or test the efficacy of the disinfection process on product prior to use.
- 2.4 In consequence, cleaning and disinfection processes should be validated before use, the performance of the process should be monitored during routine use, the calibration of controls and instrumentation should be verified, and the equipment should be subjected to a suitable maintenance programme.
- 2.5 The control protocols recommended in this section provide the means for ensuring that the washer-disinfectors are fit for their intended purpose and includes tests and checks carried out during manufacture, after delivery, during validation and periodically thereafter. Tests are also recommended before a washer-disinfectors is returned to service after repairs that affect one or more components which influence the attainment of critical process control variables or after modification.

Interrelation of test programmes

- 2.6 The tests recommended in this section are intended for use in type tests, works tests, commissioning (installation and operational tests), PQ (thermometric tests, microbiological tests, cleaning efficacy tests and load dryness tests) and routine periodic tests.
- 2.7 The interrelationship of the various test programmes, the place where they would usually be conducted and the responsibility for conducting the tests are shown in [Figure 2](#).
- 2.8 The programmes of tests should be applied to all washer-disinfectors where relevant. Details are given under the test schedules for particular types of washer-disinfectors.

2

Validation and verification

Schedule of type tests and work tests

2.9 The manufacturer will carry out type tests on representative samples of washer- disinfectors in serial production to demonstrate compliance of the washer-disinfector design with BS EN ISO 15883 Parts 1 and 2.

Location	Production of EWD	Responsibility for conducting the test
Factory	Type tests and Works tests	Manufacturer/AE(D)
On site	<div style="border: 1px solid black; padding: 5px; display: inline-block;"> Commissioning Checks and Tests </div> <div style="display: inline-block; vertical-align: middle; margin-left: 10px;"> ↘ ↙ </div> <div style="display: inline-block; vertical-align: middle; margin-left: 10px;"> INSTALLATION OPERATIONAL </div>	Manufacturer/AE(D)
	Performance Qualification	User
	Periodic Routine Tests Annual Revalidation	

Figure 2 Interrelationship of test programmes

- 2.10 The manufacturer will carry out works tests on each washer-disinfector before it leaves the manufacturing site to ensure that each washer-disinfector meets the specification. These tests should be as given in BS EN ISO 15883 Parts 1 and 2 including any additional tests required by the User and AE(D).
- 2.11 The manufacturer should make the results of type tests and works tests available to the purchaser on or before delivery of the washer-disinfector.
- 2.12 It may be necessary for the purchaser, or their representative, to visit the manufacturer’s works to witness works testing. The advice of the AE(D) should be sought.



Validation and verification

Schedule of installation tests

Checks on ancillary equipment

- 2.13 Ancillary equipment should, whenever practicable, be installed and commissioned before validation of the equipment begins.
- 2.14 When the checks on ancillary equipment require the washer-disinfector to be in operation, the washer/disinfector manufacturer/installer should carry them out in co-operation with the CP(D) or NWSSP/SES.
- 2.15 The contractor for the equipment is not responsible for the correct functioning of services and ancillary equipment unless this was agreed in the purchase contract. The correct functioning and supply of services and ancillary equipment should be the responsibility of local Estates/contract organisations unless alternative arrangements were agreed in the purchase contract. Correct service assessments should be carried out prior to the agreement of contract.

Engineering services

- 2.16 Checks should be made for the following services:
 - a. the engineering services should be installed correctly, should be adequate to meet the demands of the decontamination equipment, should not leak and all necessary isolating valves/ switches and test points should be installed;
 - b. the drains should remove effluent effectively when all plant in the vicinity, including the decontamination equipment, is connected and operating;
 - c. the 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;
 - d. the water economy system (if fitted) should operate correctly;
 - e. the provision for storage, handling and connection to the washer-disinfector for all process chemicals should meet the requirements for safe handling of potentially hazardous chemicals;
 - f. the exhaust ventilation and/or condenser unit fitted to the washer-disinfector should be adequate to remove the hot, humid air evolved from the washing, thermal disinfection and drying and unloading processes;
 - g. for washer-disinfectors employing volatile process chemicals, the exhaust ventilation should maintain the environmental concentration below any limit specified for occupational exposure and the discharge should be to a safe place.



Validation and verification

Checks on washer-disinfectors

Preliminary checks

2.17 Check that the electrical equipment on the equipment is correctly connected to the electrical service. Carry out the following electrical tests:

- a. insulation resistance;
- b. phase sequence (for three-phase installations);
- c. polarity;
- d. bonding and earth continuity;
- e. emergency stop.

2.18 After the equipment has been installed, check that the following recommendations are met:

- a. the manufacturer has supplied all the documents specified in the contract;
- b. the equipment has been supplied and installed in accordance with the contract;
- c. calibration verification certificates for the measuring instruments and controller(s) on the equipment have been supplied;
- d. no defects are apparent from a visual inspection of the equipment; all supports, bases and fixings are secure and without imposed strain from service connections;
- e. all supports, bases and fixings are secure and without imposed strain from service connections;
- f. thermal insulation is in good condition and securely attached;
- g. security and settings of door safety switches are in compliance with data supplied by the manufacturer;
- h. keys, codes or tools required to operate locked controls and control over-rides have been supplied, operate correctly and only operate the control for which it is intended; and cannot unlock controls on other machines in the vicinity;
- i. loading conveyors and trolleys, load carriers and load baskets are effective and safe in use;
- j. all appropriate connections for irrigation are available.

Functional checks

- 2.19 During an operating cycle, with an empty chamber, check that the following recommendations are followed (several cycles may be necessary to complete all the checks):
- a. The selection of automatic or manual control is by key code or tool. The selection of one control mode inactivates the other control mode.
 - b. Under automatic control, water, steam, compressed air or chemical additives cannot be admitted into the chamber, and the operating cycle cannot start until the door is closed (locked and sealed).
 - c. Under manual control the operator can advance the cycle only sequentially through each stage. Any stages designed to remove chemical additives from the chamber and load cannot be circumvented.
 - d. Throughout the cycle the indicated and recorded values of cycle variables are within the limits specified by the manufacturer.
 - e. Throughout the cycle there are no leaks of water, steam aerosols, toxic chemicals, air, gas or effluent.
 - f. There is no evidence of interference to or from other equipment connected to the same services.
 - g. There is no evidence of electromagnetic interference to or from other equipment.
 - h. Operation and reading of all instruments appear to be satisfactory.
 - i. The temperature of surfaces routinely handled by the operator does not exceed those specified in **Chapter 1**, 'Design and pre-purchase considerations'.
 - j. The effluent temperature does not exceed that specified in **Chapter 1**.
- 2.20 At the end of the cycle check that the following recommendations are followed.
- a. The door opening system cannot be opened until the cycle has been completed without causing the cycle to abort and a fault/incomplete cycle indication produced, that is, the automatic controller has operated in accordance with its specification.
 - b. For systems incorporating one or more cycle stages at pressures 200 mbar above or below atmospheric pressure:
 - (i) the door opening system cannot be operated until the chamber has been vented to atmosphere and the chamber pressure is within 200 mbar of atmospheric pressure;

2

Validation and verification

- (ii) the door retaining parts cannot be released until the seal between the door and chamber has been broken, and the chamber is effectively vented to atmospheric pressure.
- c. 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 be opened when conditions within the chamber would cause a hazard (for example, pressure in excess of 200 mbar or unacceptable level of chemical vapours).
- d. The automatic controller has operated in accordance with the parameter values determined at validation.

Response to external faults

- 2.21 The decontamination equipment should be checked to ensure it reacts correctly and safely when exposed to a number of external fault conditions; that is, a safety hazard is not created and a false indication of satisfactory completion of a cycle is not obtained.
- 2.22 During each stage of an operating cycle, check the response of the decontamination equipment to the following simulated faults (as appropriate to the type of machine):
- a. operation of the emergency stop button;
 - b. power failure;
 - c. water pressure too low;
 - d. water pressure too high;
 - e. steam pressure too low;
 - f. steam pressure too high;
 - g. compressed air pressure too low;
 - h. compressed air pressure too high;
 - i. failure of chemical additive supply (detergent, sterilant, disinfectant etc);
 - j. failure of extract ventilation.



Validation and verification

Schedule of operational tests

2.23 Full testing protocols for washer-disinfectors for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils and glassware can be found in BS EN ISO 15883 Parts 1 and 2.

2.24 Protocols for washer-disinfectors are shown in **Table 1**.

Table 1 Testing protocols for washer-disinfectors

Installation tests – contractor
1. Verification of calibration of WD instruments
2. Automatic control test
3. Water quality tests – hardness
4. Water supply temperature
5. Water supply pressure

Operational tests – CP(D)
1. Weekly safety checks
2. Automatic control test
3. Verification of calibration of WD instruments
4. Water system: <ul style="list-style-type: none"> – overflow test – volume of water used per stage – chemical purity – bacterial endotoxins
5. Drainage: <ul style="list-style-type: none"> – drain seal integrity – free draining – efficacy of discharge – pipework residual volume
6. Venting system: <ul style="list-style-type: none"> – steam venting – load contamination from ductwork

2

Validation and verification

7. Doors and door interlocks <ul style="list-style-type: none"> – In-cycle interlock – Double-door WDs – On sensor failure – Door opening force – Failed cycle interlock – Fault indication on sensor failure
8. Water vapour discharge test
9. Chemical additive dosing tests: <ul style="list-style-type: none"> – reproducibility of volume admitted – low level detection¹
10. Load carriers
11. Air quality
12. Cleaning efficacy test: <ul style="list-style-type: none"> – test soil – reference load
13. Chamber wall temperature test ²
14. Load carrier temperature test ²
15. Over-temperature cut-out test ²
16. Thermometric test for disinfection reference load ²
17. Load dryness test reference load ³
18. Test for ultrasonic activity
19. Process residue test
20. Independent Monitoring System: Calibration, fault recognition, dosing measurement, alarm actions.

¹ Only required for WDs with automatic chemical dosing ²Only required for WDs with a thermal disinfection stage ³Only required for WDs with a drying stage

Note: Checks are also required on the independent monitoring system, including calibration, limits and trip points/alarm actions

Performance Qualification tests

Performance Qualification (PQ) tests is the process of obtaining and documenting evidence that the washer-disinfector will consistently give reproducible results when operated in accordance with the pre-defined acceptance criteria within the process specification. The extent of the PQ tests required will depend on the type of washer-disinfector and the nature of the load.

Surrogate devices

- 2.25 Many of the devices that constitute the most difficult loads to process in a washer- disinfector, which therefore require PQ, are difficult to monitor either thermometrically or microbiologically, and are in short supply and are extremely expensive; examples include fibre-optic endoscopes, videoscopes etc.
- 2.26 A surrogate device is a test piece designed and constructed to emulate the characteristics of a device to facilitate appropriate monitoring of the cleaning and disinfecting processes.
- 2.27 An example of a surrogate device might be a rigid endoscope emulated by a similar length of stainless steel tube of appropriate diameter and bore. The surrogate device can be constructed to incorporate the appropriate temperature sensors and so that it can be separated into sections to facilitate the evaluation of residual test soil or survivors from a microbial challenge.
- 2.28 The surrogate device should have similar geometry and thermal mass and, as far as practicable, should be constructed of the same materials and with the same surface finishes as the device it is designed to emulate.
- 2.29 When an instrument presents particular problems in validation the manufacturer of the instrument should be requested to provide details of the method by which they recommend that PQ studies should be performed.

Cleaning efficacy tests

Representative soiling

- 2.30 Cleaning efficacy tests are intended to demonstrate the ability of the washer-disinfector to remove or reduce, soiling and contamination that occurs during normal use of reusable items to acceptable levels.
- variation in the composition of the soiling, which can affect the ease with which soiling is removed;
 - changes in sensitivity of detection that can occur due to variation in composition of the soiling;
 - variation in the extent of soiling.

2

Validation and verification

In addition, the ACDP requirement that the washer disinfectant in use should be able to reduce protein levels $\leq 5 \mu\text{g}$ per instrument side/surface and a lower level for medical devices contacting high CJD risk tissue. Further information on suitable methods for protein testing are included in [section 2.274](#).

- 2.31 Naturally occurring contamination shows considerable variation both in the nature and proportion of constituents and in the extent of soiling which can occur during use.
- 2.32 Test methods based on the detection of naturally occurring soiling are difficult to standardise and show poor reproducibility due to:
- variation in the composition of the soiling, which can affect the ease with which soiling is removed;
 - changes in sensitivity of detection that can occur due to variation in composition of the soiling;
 - variation in the extent of soiling.
- 2.33 A number of methods exist for estimating the residual levels of proteins on surgical instruments.

A number of methods are being developed for measuring the residual levels of proteins on stainless steel instruments, great care should be undertaken when investigating their methodology, practical implementation, repeatability, uncertainties of measurement process, accuracy and levels of attainment with evidential information available.

- 2.34 Common practice in the past has been to rely solely upon visual inspection to detect unacceptable levels of residual soiling. This method should not be used, as it has poor sensitivity, is very subjective and can be greatly influenced by a number of factors including the intensity and nature of the illumination in the inspection area.

Test soils

- 2.35 Artificial test soils are designed to simulate the nature of native soiling and to be equally or more difficult to remove.
- 2.36 Appropriate marker substances should be incorporated to provide improved sensitivity of detection.
- 2.37 Soil tests may be used to aid determination of loading levels.
- 2.38 Test soils avoid any hazard that might be associated with native soiling (for example blood-borne viruses), which can be of particular concern with the more extensive handling necessary for test work.



Validation and verification

2.39 Worldwide, many different test soils have been specified for testing washer-disinfectors but they generally fail to meet the key criteria necessary for a test soil. These criteria include:

- a chemically defined formulation (the traditional soils use substances such as flour, wallpaper paste, fresh egg yolk, horse blood etc which introduce a significant variability);
- a quantitative method of applying the test soil to the surfaces of all types of item to be processed;
- a quantitative method of detection of soiling remaining after the washing–disinfection process;
- validation with a known relationship to native soiling for ease of removal, relevant residual levels etc;
- safe to handle, easy and economical to use.

Standard test soils

2.40 Test soils are defined in ISO/TS 15883-5 as follows:

Instrument type	ISO/TS 15883-5 Annex reference
Surgical instruments	Annex N – see description below
Anaesthetic accessories	Annex O

2.41 The typical procedures for manufacturing soils within the UK are described as follows:

Typical test soils

Constituents

2.42 The following ingredients are required:

- a) fresh egg yolk 100mL is
- b) defibrinated blood, 10mL
- c) dehydrated hog mucin 2 g

Preparation and storage

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

2.44 Use immediately or store in an air-tight container at 2°C to 5°C for not more than one week.



Validation and verification

Application and use

2.45 If the soil has been stored, allow it to equilibrate to room temperature before use.

2.46 The following apparatus is required:

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

Method of application

2.47 The method is:

- a. Don the protective gloves. Apply the soil to the test pieces by fully immersing the items in the soil or, for larger items, applying an even coat of soil using the paint brush.
- b. Allow excess soil to drain from the items and allow them to dry at room temperature (15°C to 25°C) for not less than 30 minutes and not more than 2 hours.

Method of detection

2.48 Visual examination. There are alternatives available. The advice of the AE(D) should be sought.

Process residues

2.49 The nature and level of process residues that are of concern depend on the chemical additives and quality of water used during the process and the intended use of the washed and disinfected product.

2.50 The water used for the process can give rise to a number of chemical residues on processed items. The most obvious of these is limescale from hard water.

2.51 The water used for the process might also give rise to contaminants of microbial origin. Bacterial endotoxins, primarily derived from the cell wall of Gram-negative bacteria, may give rise to adverse (pyrogenic) reactions when introduced into the body.

2.52 Items intended for surgically invasive use or for the preparation or administration of parenteral fluids should have suitably low levels of bacterial endotoxins.



Validation and verification

- 2.53 The chemical additives used during the process (detergents, rinse aids etc) might not be completely removed by the rinsing process. The residual level that may be tolerated depends upon the nature of the chemical and the intended use of the product. The supplier of any chemical agent used will normally provide data on the chemical composition of the chemical agent and the biocompatibility of the components of the chemical agent. The supplier will also normally provide details of the method of detection, which can be used to determine whether processed items are free from residuals at the specified levels.

Disinfection

Thermometric tests

- 2.54 Thermometric tests should be carried out for both thermal disinfection processes and chemical disinfection processes.
- 2.55 The requirements for thermal disinfection are defined in BS EN ISO 15883 parts 1 and 2.
- 2.56 Normally, microbiological testing is not recommended for thermal disinfection processes.

Load dryness tests

- 2.57 The presence of residual water on cleaned and disinfected items should be avoided as it can interfere with the correct functioning of the item, promote re-contamination and microbial growth, or prevent attainment of sterilising conditions. In many cases these data will already be available from the published literature.
- 2.58 The ability of the washer-disinfector 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 washer-disinfector process cycle.
- 2.59 Performance qualification tests are shown in [Table 2](#).



Validation and verification

Table 2 Performance qualification tests for washer-disinfectors (carried out by the CP(D))

Cleaning efficacy test for a full load of particular items not represented adequately by the reference load: – test soil
Load dryness test for a full load of particular items not represented adequately by the reference load
Process residues: chemical additives
For temperature of internal surfaces of processed devices (e.g. anaesthetic and respiratory tubing, lumen devices and powered devices), see BS EN ISO 15883-2 clauses 4.4 and 6.3.3
For cleaning efficacy test for internal surfaces of processed devices (e.g. anaesthetic and respiratory tubing, lumen devices and powered devices), see BS EN ISO 15883-2 clause 4.4 and 6.2
For verification of flow through lumen and powered devices, see BS EN ISO 15883-2 clauses 4.4, 5.1.1, 5.1.2 and 6.3.3

Where PQ tests have been undertaken as part of the installation tests and no separate PQ report will be created, the AE(D) should satisfy himself/herself that the range of installation, operational and periodic tests undertaken during commissioning is representative of the range of loads and product families processed by that particular washer-disinfector. This should be documented.

New PQ tests may be required for WDs during their operational lifetime where there have been changes to the quality of the water supply, changes to the chemical additives used in the cleaning process, changes to the loading system or the requirement to process a new type of medical device.

Schedule of periodic tests

Introduction

- 2.60 Periodic tests are carried out at daily, weekly, quarterly and yearly intervals. Whilst protocols are defined in BS EN ISO 15883 Parts 1 and 2, it is recommended that periodic testing is performed as defined in **Table 3**.
- 2.61 The yearly test schedule is identical to that required for revalidation. It contains the tests recommended for re-commissioning and for re-qualification of the performance of the equipment.
- 2.62 Tests should only be undertaken after completion of the planned maintenance tasks described in **Chapter 4**, 'Operational management'.



Validation and verification

- 2.63 Each test is cross-referenced to a detailed description of the test procedure in paragraph 2.72ff, ‘Test methods’. Unless otherwise specified in ‘Test methods’, the tests should be carried out with the machine at normal working temperature, which might require a warm-up run to be carried out before commencement of testing.
- 2.64 A number of the tests recommended can be carried out concurrently on the same operating cycle and this is also indicated in ‘Test methods’.
- 2.65 The results of periodic tests should be filed securely, for example in electronic or paper format. All process records should be kept for at least 11 years to allow tracking and tracing of surgical instruments in the event of an adverse event and in compliance with the “Consumer Protection Act”.

Weekly safety checks

- 2.66 The CP(D) should make the following safety checks before starting the sequence of weekly tests:
 - a. examine the door seal(s);
 - b. check the security and performance of door safety devices.
- 2.67 For equipment that includes a pressure vessel or pressure system (for example steam or compressed air) the following checks should be made:
 - a. that safety valves or other pressure limiting devices are free to operate;
 - b. any other checks required by the CP(PS) in connection with the written scheme of examination for the pressure vessel.

Table 3

Daily tests – User	
1.	Check spray arm rotation for free movement
2.	Check spray nozzles for blockage (paying particular attention to those fitted to carriages for cannulated instruments)
3.	Remove and clean strainers and filters etc
4.	Ensure sufficient additives available and that dosing system is functioning
5.	Process challenge device cleaning efficacy test



Validation and verification

Weekly tests – User or CP(D)
1. Weekly safety checks
2. Carry out daily tests
3. Water hardness (all process stages)
4. Water conductivity (final rinse stage)
5. Automatic control test
6. Residual protein testing

Quarterly tests – CP(D)
1. Weekly safety checks
2. Automatic control test
3. Verification of calibration of WD instruments
4. Thermometric test for thermal disinfection
5. Cleaning efficacy test: – reference load ¹ general instruments rigid endoscopic/MAT instruments
6. Cleaning efficacy test by residual soil detection
Periodic monitoring by the User (see paragraph 2.269): Residual protein detection test (to be carried out by nominated individual(s))

Yearly and revalidation tests – CP(D)
1. Yearly safety checks
2. Automatic control test
3. Verification of calibration of WD instruments
4. Water system: – chemical purity – bacterial endotoxins



Validation and verification

5. Drainage: – free draining – efficacy of discharge
6. Doors and door interlocks: – Cycle start interlock – In-cycle interlock – Failed cycle interlock
7. Fault indication on sensor failure
8. Water vapour discharge test
9. Chemical additive dosing tests: – reproducibility of volume admitted – low level detection
10. Load carriers
11. Air quality
12. Cleaning efficacy test: – test soil – reference load ¹ general instruments endoscopic/MAT instruments
13. Over temperature cut-out test
14. Thermometric test for thermal disinfection – reference load ¹
15. Load dryness test – reference load ¹
16. Process residue test

Notes:

¹ Additional test loads and alternative test soils may be required for WDs 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.

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

If the User is to undertake part of the testing e.g daily and weekly, they should receive appropriate training and be deemed competent prior to undertaking the tests.



Validation and verification

Yearly safety checks

- 2.68 In order to ensure the continued safe functioning of decontamination equipment the CP(D) should conduct a series of safety checks before starting the yearly tests.
- 2.69 NWSSP/SES undertake the programme of the yearly safety checks necessary for a particular installation with input, if required, from the AE(D). Reference should be made to the manufacturer’s maintenance schedules.
- 2.70 The original installation checks and tests can be used as a basis for the yearly safety checks paying particular attention to those factors that affect safety and especially to those that might have changed since the previous annual safety check (or installation test).
- 2.71 The adequacy and safe connection of all engineering services should be verified.

Test methods

- 2.72 Test methods, equipment and requirements are detailed in WHTM 01/01 part B and BS EN ISO 15883 parts 1 and 2. The following information, where relevant, will apply to those washer-disinfectors not covered by this Standard. For thermal (moist heat) disinfection the disinfection conditions are specified either by an A_0 value to be achieved throughout the load or by a disinfection temperature band, defined by a minimum acceptable temperature, known as the disinfection temperature, and a maximum allowable temperature. Time/temperature bands meeting the requirements of an acceptable A_0 of 600 are as follows:

Disinfection temperature (°C)	Maximum allowable temperature (°C)	Exposure time period
70	75	100 minutes
80	85	10 minutes
90	95	1 minute

- 2.73 Other time/temperature relationships may be used as long as achievement of the acceptable A_0 has been validated to be achieved.
- 2.74 The higher the disinfection temperature, the shorter the holding time that should be used to achieve the same level of disinfection.



Validation and verification

Drainage

Drain seal integrity

- 2.75 When it is impractical to vent the washer-disinfector externally a condenser can be used to allow venting into the workspace without discharging hot, humid air. The restricted flow associated with this system can produce a back pressure in the chamber. If the back pressure is excessive the water seal between the chamber and drain might be broken.
- 2.76 This test is designed to establish that the seal integrity is maintained under normal operating conditions. The test is intended for use both as a type test (and as such is a requirement of BS EN ISO 15883-1) and as an operational or installation test.

Apparatus

- 2.77 The following equipment should be used:
- a full load of the type the washer- disinfector 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).

Method for type test

- 2.78 Fit the transparent trap in place of the normal trap and connect it to a suitable outlet. Pour sufficient water into the chamber to charge the trap to the normal level. Verify that there are no leaks.
- 2.79 Place a full load in the chamber, close the door and initiate an operating cycle. Without opening the door between cycles run a further four cycles. During each operating cycle observe the trap and establish whether the water seal in the trap has been broken.

Method for operational test

- 2.80 Carry out the test on the installed washer- disinfector with all services connected. Verify that the trap is charged with water to the normal working level.
- 2.81 Place a full load in the chamber, close the door and initiate the operating cycle. At the end of the cycle, remove the load and examine the water level in the trap. This may be done either visually or using a dipstick as appropriate. Without any delay (which would allow the chamber or load to cool), reload the machine with the same full load and run a further cycle. Repeat the same procedure until five consecutive cycles have been run. After each operating cycle, observe the trap and establish whether the water seal in the trap has been broken.



Validation and verification

Results

2.82 The water seal should not be broken during the test.

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

2.83 Residual water that does not drain from the internal pipework of the washer-disinfector can provide an environment for microbial growth; these microorganisms might then be available to recontaminate the disinfected load.

2.84 The following checks should be carried out during type-testing, works testing and installation testing to verify that as designed, built and installed the washer-disinfector will effectively discharge all the water from the system.

Method

2.85 Test the free draining of chamber and load carriers by visual observation at end of the cycle.

2.86 Test the free draining of tanks by visual observation on draining the tanks.

2.87 Test the pipework flow to discharge point by visual observation including use, when necessary, of a spirit level.

Purging of the trap (type test only): efficacy of discharge through the trap

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

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

Apparatus

2.90 The following apparatus should be used:

- test soil appropriate to the type of washer-disinfector being tested (see [paragraph 2.268](#), 'Periodic tests');
- sampling tube of sufficient length to reach the water trap in the drain of the washer-disinfector and a sampling pump (for example a pipette pump or syringe).



Validation and verification

Method

- 2.91 On completion of an operating cycle to test the cleaning efficacy by processing a full load contaminated with an appropriate test soil, place the sampling tube into the water trap and remove a sample for examination.
- 2.92 Examine the water sample from the trap for residual test soil using the detection method appropriate to the test soil.

Results

- 2.93 The water in the trap should be free from residual soil at the same level of detection as that specified for the load items. Residual soil in the trap can present an infection or recontamination hazard.

Estimation of dead volume of pipework

- 2.94 Residual water that does not drain from the internal pipework of the washer-disinfector might provide an environment for microbial growth; these microorganisms might then be available to re-contaminate the disinfected load.
- 2.95 This test is intended primarily as a type test but might also be of value as an operational test or when investigating microbial contamination occurring in a washer-disinfector.
- 2.96 The test should only be carried out once the checks for free drainage recommended in [paragraph 2.83](#), 'Free draining (tanks, chamber, load carriers, pipework)' have been satisfactorily completed.

Apparatus

- 2.97 Volumetric measuring vessels of appropriate size should be used.

Method

- 2.98 Ensure that the pipework of the washer- disinfector is dry (either following disassembly and re-assembly or purging with dry compressed air for not less than 30 min), then flush with a known volume of water (simulating the flow that would occur in normal use).
- 2.99 Measure the volume of water discharged and the dead volume, estimated as the volume retained, calculated from the difference between the two values.
- 2.100 When the washer-disinfector has two or more pipework systems that are entirely separate (e.g. for flushing water, wash water, rinse water or chemical disinfectant solution) each system may be tested separately.



Validation and verification

Result

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

Venting system

Steam venting

2.102 For washer-disinfectors in which the load is heated/thermally disinfected by steam heating the chamber should be protected against a rise in pressure above the designed working pressure of the chamber and any discharge of steam should be only from the vent provided.

Apparatus

2.103 A pressure gauge should be used (if the washer-disinfector chamber is not already equipped with a pressure gauge in a known state of calibration).

Method

2.104 Close and seal the chamber of the washer-disinfector in the manner specified by the manufacturer and start an operating cycle. Override the automatic controller to allow the continuous admission of steam to the chamber. Observe where steam is vented. Record the maximum value obtained on the pressure gauge.

Results

2.105 Steam discharge should occur solely through the vent. The recorded value for the pressure within the chamber should not exceed the specified working pressure or, for a chamber designed to work at atmospheric pressure, 200 mbarg.

Load contamination from ductwork

2.106 The evolution of water vapour from the chamber during the washing stage, thermal disinfection stage and drying stage can result in condensation occurring in the ductwork and in the condenser (if fitted). The ducting is commonly arranged to allow this condensate to drain back into the chamber. Should this condensate become contaminated there is a risk that it could contaminate the load. The test is designed to establish that any condensate draining back into the chamber will not contact the load. The test is intended for use both as a type test (and as such is a requirement of BS EN ISO 15883-2) and as an installation or operational test.

2

Validation and verification

Apparatus

2.107 The following apparatus should be used:

- a. 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;
- b. stopwatch;
- c. load carrier and full load for the washer-disinfector;
- d. paper towels.

Method

2.108 Disconnect the external ducting to the washer-disinfector 1 m above the chamber.

Note:

If it is not possible to disconnect the ducting at this position the ducting should be disconnected at the chamber and a spare 1 m length of ducting should be connected to the chamber.

2.109 Position the vessel approximately 1 m above the level of the chamber discharge to the vent.

2.110 With the on/off valve closed, fill the vessel with $200 \text{ mL} \pm 20 \text{ mL}$ of cold water. Open the valve and adjust the flow control valve so that the contents of the vessel are discharged in $1 \text{ min} \pm 5 \text{ s}$.

2.111 Refill the vessel with $200 \text{ mL} \pm 20 \text{ mL}$ 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.

2.112 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.

2.113 Within ONE minute of the vessel emptying open the chamber door and remove the load and any removable load containers. Place all the removed items on absorbent paper and examine all surfaces of the load and the absorbent paper for traces of water.

2.114 Repeat the above procedure for the full range of load carriers that the washer- disinfector is designed to process.



Validation and verification

Results

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

Overflow test

2.116 For washer-disinfectors that incorporate one or more water storage tanks within the washer-disinfector, the capacity of the overflow(s) to discharge all excess water, as intended, without spillage into the washer- disinfector or working area should be verified.

Type/works test method

2.117 Ensure that the washer-disinfector is connected to all necessary services and the water supply pressure adjusted to not less than 6 barg under the conditions of flow that prevail with the supply valve(s) fully open.

2.118 Fully open the supply valve(s).

2.119 Observe the level of water in each tank or cistern until this has been unchanged for not less than 2 min.

Installation test

2.120 The washer-disinfector should be connected to all necessary services.

2.121 Fully open the supply valve(s).

2.122 Observe the level of water in each tank or cistern until this has been unchanged for not less than 2 min.

Results

2.123 The washer-disinfector and 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.

Volume of water used per stage

2.124 During type-testing, the manufacturer should be required to determine the volume of water used during each stage of the cycle. These data are used in calculations of the service requirements.



Validation and verification

- 2.125 In addition, during installation or operational testing, the volume of water used for each stage of should be verified. If the volume of water used is insufficient the efficacy of the cleaning and disinfection process might be adversely affected. If the volume is greater than that specified an unexpectedly heavy demand might be placed upon the water supply.
- 2.126 There are three methods that may be used for determining the volume of water used. The method should be chosen on the basis of which is most convenient for the particular installation.

Apparatus

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

Method

- 2.128 Fit a water flow meter in each of the water supply pipes, consecutively or concurrently, and determine the volume used by comparison of the reading before and after each stage of the process cycle. Operate the washer-disinfector with the chamber empty, apart from the chamber furniture. 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.
- 2.129 When the washer-disinfector is supplied from a readily accessible tanked supply interrupt the make-up to the tank and mark the water level. Determine the volume of water required to restore the level after an operating cycle stage by the addition of a measured volume of water.
- 2.130 For those washer-disinfectors which discharge all the water from each stage at the end of each stage, obtain a suitable estimate of the volume used by volumetric measurement of the discharge from the drain.

Results

- 2.131 The volume of water used for each stage of the cycle should be within $\pm 5\%$ of the volume specified by the manufacturer.

Doors and door interlocks

Cycle start interlock

- 2.132 The interlock should prevent a cycle being started with the door open.



Validation and verification

Method

- 2.133 Leave the doors open and unlocked. Ensure that all services are connected. Make an attempt to initiate an operating cycle.
- 2.134 Close and lock the doors and make a further attempt to initiate an operating cycle.

Results

- 2.135 It should not be possible to initiate a cycle with the door(s) left open. With the door(s) closed it should be possible to initiate an operating cycle.

In-cycle interlock

- 2.136 An interlock is required to ensure that the door(s) cannot be deliberately or inadvertently opened while the washer-disinfector is in operation.

Method

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

Results

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

Double-door washer-disinfectors

Method

- 2.139 Both during and between cycles, make attempts to open either or both the loading door and unloading door of the double-door washer-disinfector.

Results

- 2.140 It should not be possible to open the unloading door after initiation of a cycle until a cycle has been completed satisfactorily.
- 2.141 It should not be possible for both doors to be opened at the same time.



Validation and verification

2.142 It should not be possible to open the loading door until a cycle has been satisfactorily completed and the unloading door has been opened and closed.

On sensor failure

Method

2.143 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

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

Door opening force

2.145 The mechanism for opening the washer- disinfector door should not require the use of excessive force.

Apparatus

2.146 The following equipment should be used:

- a. 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;
- b. non-extensible means of attachment of the spring balance to the door mechanism.

Method

2.147 Measure the force required to initiate and sustain the movement of the door opening mechanism by interposing a spring balance, aligned co-axially with the direction of movement of the door opening mechanism, between the operator and the mechanism.

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

Results

The indicated value required to initiate or sustain the movement of the door opening mechanism should not exceed 25 kg.



Validation and verification

Failed cycle interlock

2.149 The interlock should prevent the Operator from removing a load in the normal manner at the end of a cycle that failed.

Method

2.150 During an operating cycle interrupt one, or more, of the services to the washer- disinfecter sufficiently to cause a cycle failure.

Results

2.151 A fault should be indicated. It should not be possible to open the unloading door (if fitted); it should only be possible to open the loading and/or unloading door by means of a special key, code or tool.

Fault indication on sensor failure

2.152 A failure of any sensor used as part of the control system of the washer-disinfecter should cause a fault to be indicated by the automatic controller.

Method

2.153 Disable each sensor providing information to the automatic controller in turn to establish that a fault is indicated.

2.154 Test each sensor as follows. Start an operating cycle. During, or before, the stage of the cycle at which the sensor is intended to provide data used to determine the control of the cycle, disable the sensor.

2.155 Test each sensor in both “open circuit” and “short circuit” failure modes.

Results

2.156 A fault should be indicated during or at the end of the cycle. It should not be possible to open the door on a single-ended washer-disinfecter or the unloading door of a double- door washer-disinfecter.

Chemical dosing

Reproducibility of volume admitted

2.157 This test is intended to verify the setting for the dispensed volume of chemical additive(s) and to ensure that it is reproducible within defined limits. The test should be carried out for each chemical dosing system on the washer-disinfecter.



Validation and verification

Note:

Actual chemical dosed should be recorded and verified as part of cycle data recorded for product release.

Apparatus

2.158 Two measuring cylinders that conform to BS EN ISO 4788 should be used. The size of measuring cylinder should be appropriate to the volume of chemical additive to be dispensed.

Note:

When compatibility with the chemical additive to be measured has been established, conformity to BS 5404-2 is sufficient.

Method

2.159 Disconnect the supply line to the chamber as close as possible to its discharge point into the chamber or water circulation system in order to discharge into the measuring cylinder.

2.160 Place detergent in the first cylinder to a known mark. Place detergent to a known mark in the second cylinder.

2.161 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.

2.162 Repeat the test three more times; record the volume added on each test.

2.163 Care should be taken since many of the concentrates used are irritant or corrosive. Water might not be an acceptable substitute because, for many dosing systems, differences in viscosity can affect the dispensed volume.

Results

2.164 The result of the first test should be ignored.

2.165 The mean collected volume from the final three tests should be within $\pm 10\%$ of the nominal dispensed volume.

Indication of insufficient chemical additives

2.166 The correct volume of chemical additive(s) for the correct functioning of the washer-disinfector should be used. The washer-disinfector should be equipped with means to ensure that a cycle is not initiated when there is insufficient chemical additive remaining in the reservoir to complete a cycle.



Validation and verification

2.167 The test should be carried out for each chemical dosing system on the washer-disinfector.

Method

2.168 Place a low level of additives in the dispenser reservoir and run repeated cycles.

2.169 Fill an otherwise empty container with sufficient chemical for more than two but less than four operational cycles. Run the washer- disinfector on three consecutive cycles. Estimate the volume remaining at the end of each cycle (pre-marked container, dipstick, or weight).

Results

2.170 The washer-disinfector should indicate at the beginning of the third or fourth cycle that there is insufficient chemical remaining to complete a cycle.

Water vapour emissions

2.171 Faulty or damaged door seals, or faulty condensers, can give rise to vapour emission into the working area and the leakage of potentially infectious material from the washer-disinfector.

2.172 Excessive and persistent leakage carries the risk of scalding the operator and causing deterioration of walls and their surface finishes.

Apparatus

2.173 The following equipment should be used:

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

Method

2.174 Load the washer-disinfector, close the door and wipe the joints between the door and the door surround to remove any moisture. Carry out an operating cycle.

2.175 Throughout the operating cycle use the mirror(s) to check if water vapour escapes from the door seal or from the condenser (if fitted).

2

Validation and verification

- 2.176 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.
- 2.177 A further four operating cycles should be run with the checks described above being carried out on the final cycle.

Results

- 2.178 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.

Instrumentation fitted to a washer-disinfector

Verification of calibration

- 2.179 The calibration of instrumentation and any independent monitor fitted to the washer- disinfector should be verified by comparison with calibrated test instruments during steady state conditions, for example the temperature during the disinfection hold period. Compliance to BS EN ISO 15883-1 clause 5.12–17 should be met.

Where adjustments of calibration are carried out against appropriately certificated test equipment, the measured results, known errors and corrections should be clearly identified in a service report, test report or any other formal method of documentation submitted to the management responsible.

- 2.180 This may be carried out concurrently with other testing, for example during the automatic control test during quarterly periodic testing (see [paragraph 2.924](#), 'Automatic control test').

Load carriers

- 2.181 Load carriers come in a variety of forms including trolleys, carriages and baskets. Their correct functioning is essential to the successful outcome of a washer-disinfector operating cycle. It is important that they cannot easily be misaligned, that they function correctly and that, when applicable, they make good connection with service supply points in the chamber and with load items (when necessary).

Method

- 2.182 Verify by visual observation the alignment of load carriers, their connection to water, air or chemical additive supply in the chamber (when applicable) and their connection to load items, for example cannulated instruments (when applicable).



Validation and verification

- 2.183 Check load carriers with rotary spray arms to ensure that the spray arms are free to rotate, both when the load carrier is empty and when fully loaded.

Thermometric tests

- 2.184 Thermometric tests are carried out to verify the attainment of the specified conditions throughout the chamber and load during the operating cycle. Continuous process washer-disinfectors and multi-chamber washer- disinfectors in which the use of recorders with fixed sensors is impractical should be tested using single channel data loggers that can be processed through the washer-disinfector. Biological indicators should not be used as a substitute for thermometric testing.

Chamber wall temperature

Apparatus

- 2.185 A temperature recorder, according to the recommendations given in the ‘Decontamination equipment: test equipment and materials’ section of CFPP 01-01 Part B, with not less than 12 sensors should be used.

Method

- 2.186 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.
- 2.187 Measure the temperature attained throughout four operating cycles, the first of which should be at least 60 min since the machine was last used (a cold start) and the final three with not more than a 15 min interval between cycles (a hot start).
- 2.188 The washer-disinfector should be operated empty except for chamber furniture (for example load carriers).
- 2.189 Multi-chamber washer-disinfectors may be tested with each chamber tested consecutively or concurrently. In the latter case eight sensors should be used for each chamber.

Results

- 2.190 The results should be as follows:
- The temperatures recorded on the surface of the chamber should be within the range 0–5°C of the disinfection temperature throughout the holding period for the disinfection stage.



Validation and verification

- b. The temperatures recorded on the surface of the chamber should be within $\pm 5^{\circ}\text{C}$ of the set temperature for the relevant stage throughout the holding period for each of the other stages.
- c. The temperature indicated/recorded by the washer-disinfector instruments should be within $\pm 2^{\circ}\text{C}$ of that recorded by the test instrument from the sensor adjacent to the reference sensor throughout the holding period for the disinfection stage.
- d. The temperature profile obtained for the operating cycle should be consistent within $\pm 2^{\circ}\text{C}$ for the last three test cycles.

Load carrier temperature

Apparatus

- 2.191 A temperature recorder (according to the recommendations given in the 'Decontamination equipment: test equipment and materials' section of WHTM 01-01 Part B) with not fewer than twelve sensors should be used.
- 2.192 Data loggers at strategic positions and a temperature recorder having at least one sensor may be used as an alternative. Discussions with NWSSP/SES need to clarify exact testing regimes prior to commencement.

Method

- 2.193 Locate temperature sensors at two diagonally opposite corners of the load carrier, in the approximate geometric centre of the load carrier and adjacent to the temperature sensor used as the reference sensor for chamber temperature.
- 2.194 Measure the temperature attained throughout four operating cycles, the first of which should be at least 60 minutes since the machine was last used (a cold start) and the final three with not more than a 15-minute interval between cycles (a hot start). Ensure that the washer-disinfector is empty except for chamber furniture (for example load carriers).
- 2.195 Replace the load carrier between cycles with a load carrier at ambient temperature.
- 2.196 Test each chamber of multi-chamber washer-disinfectors consecutively using independent data loggers to record the temperature of the load carrier. Use a temperature recorder with fixed sensors to record the temperature adjacent to the reference sensor.

2

Validation and verification

- 2.197 Keep the washer-disinfector in continuous operation, with not more than 15 minutes between cycles, when the length of cycle/the number of dataloggers available precludes re-use of the dataloggers, so that when the second and subsequent tests are initiated not more than 15 minutes has elapsed since the first chamber completed a cycle.
- 2.198 This test may be run simultaneously with the chamber wall temperature test.

Results

- 2.199 The results should be as follows:
- The temperatures recorded on the surface of the load carrier should be within the range 0–5°C of the disinfection temperature throughout the holding period for the disinfection stage.
 - The temperatures recorded on the surface of the load carrier should be within $\pm 5^\circ\text{C}$ of the set temperature for the relevant stage throughout the holding period for each of the other stages.
 - The temperature indicated/recorded by the washer-disinfector instruments should be within $\pm 2^\circ\text{C}$ of that recorded by the test instrument from the sensor adjacent to the reference sensor throughout the holding period for the disinfection stage.
 - The temperature profile obtained for the operating cycle should be consistent within $\pm 2^\circ\text{C}$ for the last three test cycles.

Over-temperature cut-out

- 2.200 The washer-disinfector is fitted with an over-temperature cut-out to ensure that, in the event of the automatic control failing to control the temperature in the washer-disinfector, the temperature will not rise to a level that would damage the load in the washer-disinfector.

If there are concerns, consult with manufacturer to confirm whether this test is safe to undertake routinely on a particular design of W/D. Discuss with NWSSP/SES the appropriate risks before a decision is made to undertake this test operationally on W/D's installed.

Apparatus

- 2.201 A temperature recorder, according to the recommendations given in the 'Decontamination equipment: test equipment and materials' section of CFPP 01-01 Part B, with not less than four sensors should be used.
- 2.202 Three independent data loggers and a temperature recorder having at least one sensor may be used as an alternative.



Validation and verification

Method

- 2.203 Locate temperature sensors at two diagonally opposite corners of the load carrier, in the approximate geometric centre of the load carrier and adjacent to the temperature sensor used as the reference sensor for chamber temperature.
- 2.204 Operate the washer-disinfector on a normal operating cycle, empty except for the load carrier. For multi-cycle machines test the two cycles that have the highest and lowest operating temperatures.
- 2.205 During the stage of the cycle when the maximum temperature is attained, disable the temperature control system.

Results

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

Load dryness

- 2.207 If the washer-disinfector includes a drying stage, the drying efficacy should be tested on a test load as follows:
- Within five minutes of the end of a normal cycle initiated from cold, place the load on a sheet of coloured crepe paper.
 - Observe any water emanating from the load and carriage, and examine the crepe paper from any residual water from the load staining it.
 - Lumen instruments should be examined by blowing dry compressed air through the lumen onto a mirror surface.

Results

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



Validation and verification

Residual chemical additives

- 2.209 The nature of the residues and the level of such residues that might be of concern depend on the chemical additives used during the process and the intended use of the washed and disinfected product.
- 2.210 The chemical additives used during the process (detergents, rinse aids etc) might not be completely removed by the rinsing process.
- 2.211 The residual level that should be tolerated depends on the nature of the chemical and the intended use of the product. The supplier of any chemical agent used will normally provide data on the chemical composition of the chemical agent and the biocompatibility of the components of the chemical agent. The supplier will also normally provide details of the method of detection that may be used to determine that processed items are free from residuals at the specified levels.
- 2.212 The sampling method and analytical method should be capable of determining the presence of the chemical additive at concentrations below that specified as potentially harmful, i.e. as the maximum acceptable level.

Method

- 2.213 Test the efficacy of the rinse process by using twice the normal dose of the chemical additive on a normal operating cycle using a test load of the simulated product. Analyse the final rinse water and the simulated product using the method recommended by the manufacturer.

Results

- 2.214 The concentration on the simulated product should be lower than the specified maximum acceptable level.

Air quality

- 2.215 Many washer-disinfectors are fitted with air filters to remove particulate material from the air supplied to the drying stage. These filters are often HEPA filters (for example, EU 12/13) of the type used to remove bacterial contamination from the air supply. When they are used as general particulate filters, performance tests for the filter or the filter housing are not necessary, except when the intention is to provide air free from bacterial contamination when the load is intended for use without further processing (for example sterilisation).
- 2.216 Microbial sampling is not necessary for either system unless otherwise specified.



Validation and verification

Method

2.217 The complete installation should be tested using the method specified in BS EN ISO 14644-1. Additional reference should be made to BS EN ISO 14644-1 for test procedures. 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

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

Sound pressure test

2.219 The British Standard requires the manufacturer to carry out a sound power test as a type test for decontamination equipment. This test measures the total sound power radiated from the machine and should be performed in a specially designed and equipped test room. It is neither necessary nor practicable to repeat the test on an installed machine.

2.220 The perceived level of noise in the immediate vicinity of the equipment during operation is, however, of 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. It should necessarily be determined with the washer-disinfector installed and working normally.

2.221 A failure of the sound pressure test need not be an indication that the machine is faulty. The problem might lie in the acoustic properties of the room in which the machine is installed.

2.222 The sound pressure test should be carried out in accordance with BS EN ISO 3746 by suitably trained and experienced personnel. The guidelines given in the following two paragraphs are intended only for additional guidance and are not the complete test method.

Method

2.223 Use the procedure specified in BS EN ISO 3746 for both the loading and unloading area if these are not common (and plantroom if present), to determine the following:

- a. the mean A-weighted surface sound pressure level;
- b. the peak A-weighted surface sound pressure level.



Validation and verification

Results

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

- a. the mean A-weighted surface sound pressure level does not exceed:
 - (i) 55 dBA for decontamination equipment installed in an operating suite, ward, treatment room or other noise sensitive area;
 - (ii) 70 dBA for decontamination equipment installed in a sterile services department, laboratory or pharmacy production area;
- b. in both the loading and 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

2.225 The British Standard for washer-disinfectors specifies that:

- when tested by one of the methods in BS EN 61000-4-3, the functioning of the automatic controller and the instrumentation should be unaffected by electromagnetic interference of severity level 3 as specified in BS EN 61000-4-3;
- when tested in accordance with BS EN 55014-1, any RF interference generated by the washer-disinfector should not exceed the limits specified in BS EN 55014-1.

2.226 The current proposal within the CEN TC102 committee preparing standards for washer-disinfectors is to specify compliance with BS EN 61000-6-3 and BS EN 61000-6-1.

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

2.228 Since June 1993, washer-disinfectors classified as medical devices have been required to carry the CE marking. Under the Medical Devices Directive, any washer-disinfector which bears CE marking solely under the Electromagnetic Compatibility Directive should have the CE marking identified as being applied under the EMC Directive.



Validation and verification

Cleaning efficacy tests

- 2.229 Cleaning efficacy tests are used to demonstrate the ability of the washer-disinfector to remove or reduce to acceptable levels, soiling and contamination that occurs during normal use of reusable items.
- 2.230 Test soils are used to simulate naturally occurring contamination since the latter shows considerable variation and is therefore more difficult to use for standardized testing.

Type tests

- 2.231 The cleaning efficacy should be determined using the relevant test soil applied to a reference load or simulated product of demonstrated relevance.
- 2.232 The manufacturer will normally establish worst-case conditions of temperature, detergent concentration, water hardness and water pressure/flow rate for use during testing.
- 2.233 By analysing the fraction of soil removed during the cleaning process when operated for various time periods shorter than those that will normally be used a quantitative comparison of cleaning efficacy can be made.
- 2.234 The recommended minimum operating conditions given by the manufacturer should be based on these data that should be made available to the User.

Operational tests

- 2.235 During operational tests of cleaning efficacy with test soils the thermal disinfection stage should be disabled.
- 2.236 During thermal disinfection the action of hot water/steam can also reduce the concentration of residual test soil.
- 2.237 The drying stage may also be disabled if this is necessary to facilitate the detection of residual soil.

Test soil

- 2.238 The choice of test soil to be used should be based on the intended use of the washer- disinfector and should be formulated to simulate the soiling which will be encountered in practice and which would be most difficult to remove.

Test loads

- 2.239 The test load should consist of items of similar size, mass and materials of construction to the range of products the washer-disinfector is intended to process. Care is needed if loads are mixed or lacking in uniformity.



Validation and verification

Method for chamber walls and load carriers

- 2.240 Contaminate the chamber walls and load carrier with the test soil in accordance with the manufacturer's instructions for the test soil including the specified quantities to be used and any drying stage.
- 2.241 Run a normal operating cycle.
- 2.242 After completion of the wash cycle, and before the disinfection stage (except where this is combined with the rinse stage) abort the cycle.
- 2.243 For operational tests, carry out the test in duplicate for each type of operating cycle available on the washer-disinfector.
- 2.244 When used as a periodic test, carry out the test only once for each type of operating cycle available.

Method for reference loads

- 2.245 This test should be run only after satisfactory completion of the test for the efficacy of soil removal from chamber walls and load carriers.
- 2.246 Contaminate the test load with the test soil in accordance with the manufacturer's instructions for the test soil.
- 2.247 The specified quantities should be used and any drying stage should be carried out in strict accordance with the instructions.
- 2.248 Run a normal operating cycle for the load type under test.
- 2.249 Abort the cycle after completion of the wash cycle, 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.
- 2.250 For operational tests, carry out the test in duplicate for each type of operating cycle available.
- 2.251 When used as a periodic test, carry out the test only once for each type of operating cycle available.

Results

- 2.252 The chamber walls and load carrier should be free from the test soil to the extent specified for the test soil employed.

2

Validation and verification

2.253 The test load should be free from the test soil to the extent specified for the test soil employed and no test soil should have been transferred to the chamber walls or load carrier.

PQ tests

2.254 PQ tests of cleaning efficacy are necessary only when some of the items, or some of the loads, to be processed are more difficult to clean than the reference load.

Method

2.255 Repeat the tests described above for reference loads with actual loads to be processed specified by the user as being representative of the items or loads intended to be processed.

Note:

The items to be processed might need to be replaced by surrogate devices when the design of the actual item makes subsequent examination for residual soil impractical.

2.256 Contaminate the test load with the test soil in accordance with the instructions for the test soil.

2.257 The specified quantities should be used and any drying stage should be carried out in strict accordance with the instructions.

2.258 Run a normal operating cycle for the load type under test.

2.259 Abort the cycle after completion of the wash cycle, and before the disinfection stage (except where this is combined with the rinse stage). Remove the test load and examine for the presence of residual soil. Run these tests in duplicate.

2.260 On satisfactory completion of this part of the test, run a further three cycles with actual loads, of the type intended to be processed, contaminated with natural soiling in-use.

2.261 Run a normal operating cycle for the load type under test.

2.262 After completion of the complete operating cycle remove the test load and examine for cleanliness.

2.263 Assess the cleanliness of the processed items visually or by such other means as will be routinely used for acceptance testing (see [paragraph 2.266](#), 'Tests for residual soil').

Results

2.264 The test loads should be free from the test soil to the extent specified for the test soil employed and no test soil should have been transferred to the chamber walls or load carrier.



Validation and verification

2.265 The cleanliness of the processed items should be acceptable by the means that will be used routinely for acceptance testing as per **paragraphs 2.266-2.267**

Periodic tests

Tests for residual soils

2.266 A visual check for cleanliness and dryness should be made for all items washed as part of the decontamination process.

2.267 Any visually soiled instruments should be recorded. Identify the machine, the type of instrument, the time of day, the cycle time and the position in the machine. The tray should then be returned to the wash area for appropriate cleaning before continuing through to packaging and sterilisation.

Method

2.268 This should be performed visually using suitable illumination and magnification where appropriate, for example microsurgical or ophthalmic surgical instruments (see also HBN 13 – ‘Sterile services departments’).

Monitoring for residual protein

2.269 One of the purposes of cleaning surgical instruments is the removal of prion proteins, which are infectious by contact. Analytical methods used should therefore have been validated to demonstrate they can detect dry residual proteins that may be firmly attached to the surfaces of stainless steel instruments.

This section of the guidance is aimed to provide a pragmatic approach to the ACDP guidance.

2

Validation and verification

The following actions should be considered as critical objectives, alongside the need to monitor of protein remaining on medical devices:

- Keep the lag time between use and reprocessing to a minimum (e.g not exceeding 24 hour maximum).
- Instrument set retention within moist environments, using systems designed appropriate for purpose.
- Examine improvement opportunities in the cleaning performance of washer- disinfectors through the optimisation of detergents, wash times, wash temperatures etc.
- Ensure the validation of washer disinfectors is based on the worst load scenario, including the loading patterns, quantity and type of load.
- Cleaning efficacy tests carried out during periodic testing and validation should meet the criteria of acceptance.
- The loading pattern and cycle operation of the WD should be in accordance with validation/PQ testing.
- Instrumentation to be reprocessed should be prepared for the WD, to maximise the exposure to the wash process and there should be minimal shadowing of devices (use of disposable bowls, receivers, gallipots prevent shadowing when reprocessing instrument sets)
- Manual pre-cleaning should target areas with accumulated and/or baked soiling. Old medical devices that have been used and reprocessed may contain soiling that cannot be easily removed using a WD only.
- Use of pre-cleaning technologies such as Ultrasonic bath/irrigators to aid the process, in particular assisting the cleaning cannulated and lumened devices.
- *Constantly investigate and improve, to keep the time lapse to a minimum for used surgical instrumentation to return to the wash process. Regular audits can assist in this management area of the process.*

Note: Any changes in the decontamination process, as a result of anomalies highlighted as part of such trend analysis should be clearly logged and recoded. No changes to the WD configuration should be carried unless there is full consultation between AE(D), NESSP/SES, the User and AP(D).

2

Validation and verification

Method

2.270 **Figure 3** shows a flowchart that may be used as a basis for identifying trends and continuously monitoring residual protein on surgical instruments (see also the example sampling strategy in the overview of WHTM 01-01 Part A of WHTM 01-01 Part A).

Note

This test should be conducted by a nominated person who has been trained in the test methods used at individual sites.

- 2.271 Instruments representative of those that are difficult to clean (e.g. those with box joints, hinges, textured surfaces, serrations, interfaces between material types, complex retractors and the difficult-to-clean medical devices etc) that have been used on patients should be selected for testing after being processed in a WD. The medical devices stated above should reflect those used to develop the benchmark.
- 2.272 Systems used should be capable of detection of at least 5µg of protein (bovine serum albumin (BSA) equivalent) equivalent per instrument surface.
- 2.273 Any equipment used should be maintained and calibrated according to manufacturers' instructions, and operators should be trained in the analytical method and their competency assessed on a regular basis. Records of both should be maintained.
- 2.274 When introducing this test, priority should be given to instruments used on high- prion-risk tissues as defined by ACDP (see Annex J of ACDP TSE's guidelines).
- medical devices should be tested promptly after removal from the WD and handled with protein-free gloves (e.g. nitrile) to prevent cross contamination of protein from other sources;
 - a side of medical devices estimated to be the largest surface areas and/or most challenging configuration is selected for residual protein testing;
 - if a swabbing technique is used, the swabbing should include the crevices, hinges and other areas accessible for the swab head to access;
 - any equipment/system/chemicals used should be maintained, calibrated (if applicable), stored, and used in according to manufacturers' instructions. The results should be interpreted in accordance with the manufacturer instructions and criteria of acceptance.

Types of systems used to test maybe quantitative (using fluorescent systems), semi-quantitative or qualitative. Choice will be determined at local level, based upon clinical activity undertaken on the site and documented risk to patient.

2 Validation and verification

Results

2.275 For surface protein residual, there should be $\leq 5 \mu\text{g}$ of protein per side/surface of instrument or less for neurosurgical instruments.

2.276 After testing, the whole medical devices set should re-enter the decontamination route process according to local protocols.

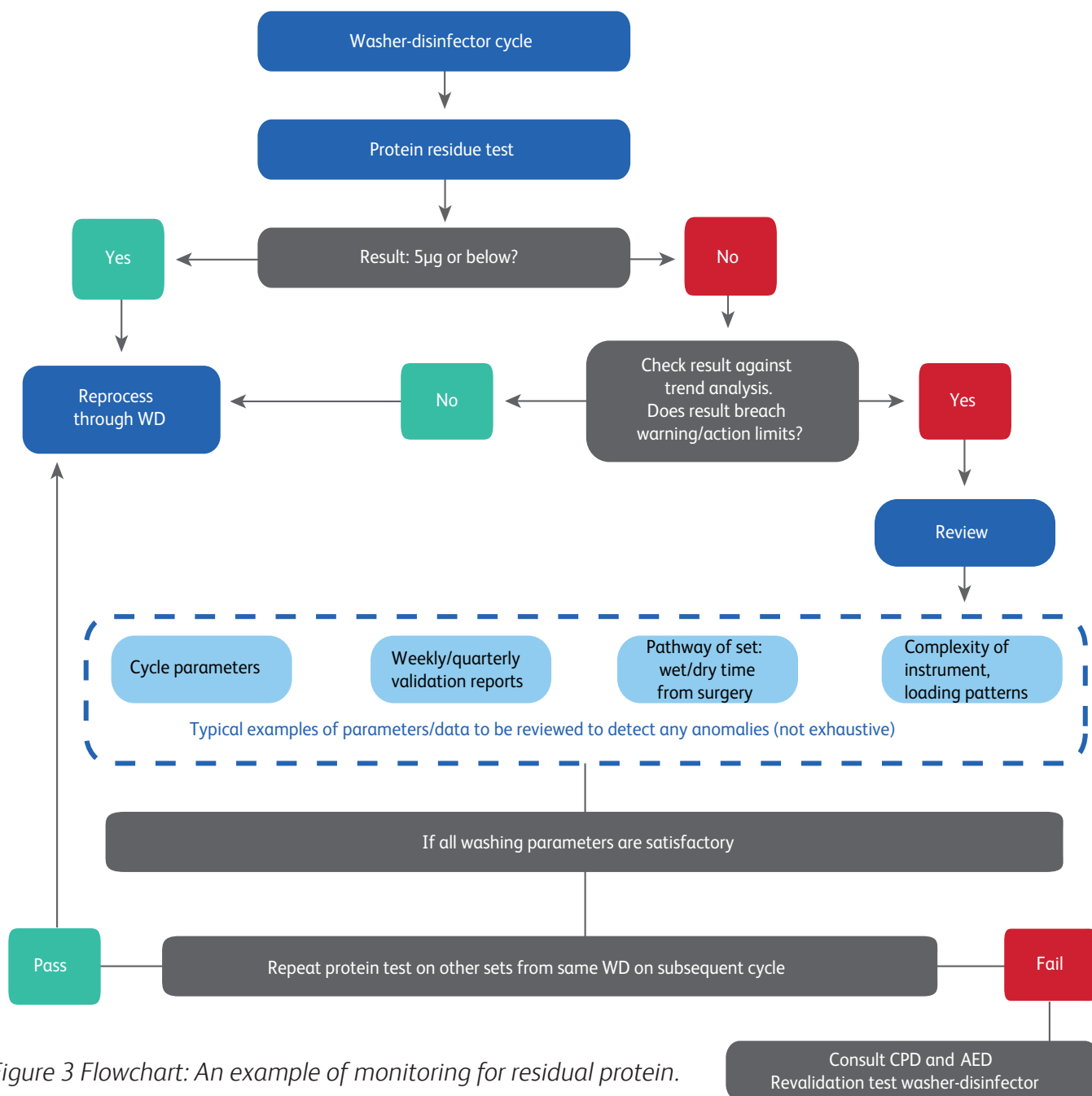


Figure 3 Flowchart: An example of monitoring for residual protein.

2

Validation and verification

Organisations should develop a schedule of testing and monitoring for residual proteins. The level of instruments tested will be dependent on the following considerations;

- Numbers of instrument sets being processed per day/week by the SSD
- Types of surgical procedures, especially neurology, dentistry, ophthalmology etc.
- The instruments tested should be identified as those in use operationally as a 'live' set and not those unused or dedicated for test purposes only
- The numbers of instruments tested will be determined by the decontamination team to provide evidence of monitoring of process over each quarterly period.

If the results are improving and consistent, the frequency and numbers tested maybe reduced in number. However, if high levels become evident as the norm, testing may need to be increased to investigate the problem, and then reduced again when the issue is under control.

2.277 This is intended to assess the complete pathway from instrument point of use until after removal from the WD and to monitor any trends. It does not relate to the specific instruments tested. Results should be recorded and compared with previous results to identify specific factors that may lead to failure and to determine actions to improve cleaning.

2.278 If reagents are added to instruments, the whole instrument set should re-enter the decontamination route process according to local protocols.

Process challenge device (PCD)

2.279 PCDs are based on traditional test soils predating current concerns with prion transmissibility. They do not assess the removal of hydrophobic proteins such as prions. The aim of using these devices is to improve and assure the wash process relevant to the removal of prion transmissibility. If such PCDs are used regularly, soil tests could become optional.



Validation and verification

Note

Use of PCD's provides a clear indication of effectiveness of cleaning efficacy and should be carried out as part of daily procedures.

There are numerous commercial types of PCD's available for use, either manufactured to be soil based or with defined protein challenge that provide a measured quantitative result after the test.

The type and design will be decided by the User with advice from the AE(D)/AP(D) and systems should be reviewed as technology improves.

The position of the PCD[s] should be determined as part of initial validation to establish the position that represents the worst case scenario within the wash chamber. (WD manufacturer can provide advice, based upon type test data)

- During the validation tests, place a PCD in each corner of the chamber on the loading carriage at both high and low levels, plus the geometric centre of the chamber.
- Utilize the various loading carriages to determine if they change the performance testing of cleaning the PCD.
- If the different loading carriages in use in that particular WD produce various results, it is recommended that the carriages are rotated for the daily tests to ensure the performance of the WD.
- As part of the daily test, one device should be used per chamber as part of the automatic control test,
- The position in the chamber, batch number of the indicator and expiry date should be recorded along with the result.

Disinfection efficacy tests

2.280 Thermometric tests should be used for both thermal disinfection processes and chemical disinfection processes where temperature is a critical parameter. For thermal disinfection processes the time temperature relationships are defined in BS EN ISO 15883 Parts 1 and 2.

Thermal disinfection test

2.281 During thermometric tests for thermal disinfection, the washing stages should be disabled or the controlled temperature reduced to ambient ($20^{\circ}\text{C} \pm 5^{\circ}\text{C}$) in order to avoid pre- heating the load. Reducing the wash temperature to 20°C creates the worst-case conditions with which the disinfection stage might be expected to cope and ensures that disinfection conditions will be attained in the event of a failure of the washing stage. Temperature monitoring of the load should be used to determine the attainment of the required time-temperature conditions.



Validation and verification

Thermometric test for disinfection

- 2.282 This test is suitable for all washer- disinfectors and should be used to established the adequacy of temperature control during chemical disinfection, as well as for verifying attainment of thermal disinfection conditions.
- 2.283 The load under test will consist of a reference load or a PQ load of discrete items of the type that the washer-disinfector under test is intended to process, or of surrogate devices used to simulate such load items.

Apparatus

- 2.284 The following equipment should be used:
- a. temperature recorder (see the ‘Decontamination equipment: test equipment and materials’ section in WHTM 01-01 Part B);
 - b. thermocouples or self-contained data loggers (see the ‘Decontamination equipment: test equipment and materials’ section in WHTM 01-01 Part B).
- 2.285 For type 1 machines and type 2 machines without physical separation of compartments (conveyor washer-disinfectors) sensors may be passed into the chamber through the thermocouple entry port into the chamber.
- 2.286 For type 2 (conveyor washer-disinfectors) the sensors to fixed positions may be passed into the chamber(s) through the thermocouple entry port; the sensors on the load might have to be fed in from one end and, when the load exits at the other end, detached and withdrawn from the back through the washer-disinfector. Care should be taken to ensure that there is sufficient length of cable for this to happen.
- 2.287 When this is not possible the method used for type 2 (multiple cabinet) washer-disinfectors should be adopted.
- 2.288 For type 2 (multiple cabinet) washer-disinfectors the sensors to fixed positions may be passed into the chambers through the thermocouple entry port; the sensors on the load should be provided from self-contained data loggers within the load.



Validation and verification

Method

2.289 Place temperature sensors in the following positions:

- at least one on an 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 an item in the region known to be slowest to attain the
- disinfection temperature*;
- one on an item in the region known to be fastest to attain the disinfection temperature*;
- one adjacent to the automatic control temperature sensor;
- one adjacent to the process recorder sensor (if fitted) in each chamber or compartment;
- three on the load carrier as follows: two at two diagonally opposite corners and one in the approximate geometric centre.

* 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.

2.290 The sensors should be in good thermal contact with the item or installed sensor that they are monitoring and placed, if possible, in or on the part of the item that will be slowest to heat up.

2.291 The test should be performed in triplicate for PQ and commissioning tests but once for periodic testing.

Results

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

- a. the recommendations of the automatic control test are followed;
- b. the holding time, as determined from the measured temperatures on the surface of the load items, is not less than that recommended to give an A0 of 600 as defined in BS EN ISO 15883-1;
- c. during the holding time the measured temperatures are within the disinfection temperature band recommended for the operating cycle;

2

Validation and verification

- d. the indicated and recorded chamber temperatures are within 2°C of the temperature measured at the automatic control sensor;
- e. the temperature measured on the surface of each load item does not fluctuate by more than $\pm 2^{\circ}\text{C}$ and does not differ from that in other load items by more than 4°C;
- f. at the end of the cycle: the temperature sensors have remained in position.

2.293 If having completed the commissioning tests based on a reference load the washer- disinfecter fails to follow the above recommendations for the specific PQ load then it is possible that the washer-disinfecter is not capable of processing loads of the type intended. Advice should be sought from the AE(D).

Automatic control test

2.294 The automatic control test is designed to show that the operating cycle functions correctly as shown by the values of the cycle variables indicated and recorded by the instruments fitted to the decontamination equipment.

2.295 It should be carried out once a week on most machines and is the main test for ensuring that the equipment continues to function correctly.

2.296 During the commissioning, yearly and quarterly test programmes the temperature (and for sterilisers, pressure) sensors for subsequent thermometric tests will be connected to the chamber during this test. If a sensor is placed adjacent to each of the sensors connected to the installed temperature measuring instruments the calibration of these instruments can be checked during periods of stable temperature in the automatic control test.

Independent monitoring systems should be in place to electronically store data for comparison and should be reviewed as part of weekly test.

The use of dataloggers can assist the ACT process and provide a calibrated comparison of WD performance.

Method

2.297 Place the test load appropriate to the type of washer-disinfecter, contained within any load furniture normally used, in the chamber.

2.298 For washer-disinfectors equipped with multiple cycle capability select the operating cycle to be tested. Start the cycle.



Validation and verification

- 2.299 Ensure that a BPR 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.
- 2.300 Each stage should be independently timed and the indicated and recorded temperature during these stages logged.

Results

- 2.301 The test should be considered satisfactory if the following recommendations are followed:
- a. a visual display indicates “cycle complete”;
 - b. during the whole of the operational cycle the values of the cycle variables, as indicated by the instruments on the washer-disinfector and any independent monitor or shown on the batch process record, are within the limits established as giving satisfactory results either by the manufacturer or during performance qualification;
 - c. during the disinfection hold period determined from the indicated and/or recorded chamber temperature:
 - (i) the indicated, recorded and any independent monitor chamber temperatures are within the disinfection temperature requirement defined in BS EN ISO 15883 Parts 1 and 2;
 - (ii) the time for which the disinfection temperature is maintained is not less than that previously established, by either the manufacturer or performance qualification tests, as necessary to ensure that the load is maintained at temperatures within the disinfection temperature requirement defined in BS EN ISO 15883 Parts 1 and 2;
 - d. the door cannot be opened until the cycle is complete;
 - e. the person conducting the test does not observe any mechanical or other anomaly.
- 2.302 Where an independent monitoring system is used which has the necessary data- processing capability, process variability may be monitored automatically through presentation of suitable control charts displaying critical process data. Under these conditions, the need for automatic control tests may be restricted to quarterly, annual and revalidation testing.



Validation and verification

Validation and periodic tests for ultrasonic cleaners

Introduction

- 2.303 Ultrasonic cleaners are of the stand- alone ultrasonic bath type, or included as a separate dedicated chamber in a multi- chamber machine. Many ultrasonic cleaners do not incorporate a disinfection stage and are intended for use as an initial cleaning process before cleaning and disinfection in a washer- disinfectant for surgical instruments.
- 2.304 Some ultrasonic cleaners are equipped with means to irrigate hollow instruments such as endoscopes. These washer-disinfectors should be tested both with the general reference load and the endoscope/ MAT reference loads. A testing protocol is shown in [Table 4](#).

Test for ultrasonic activity

- 2.305 The activity of an ultrasonic cleaner can be investigated by the erosion pattern that is 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 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.
- 2.306 The exposure time should depend on the thickness of the foil, the hardness of the foil, the operating frequency, the watt density and the temperature of the ultrasonic bath.



Validation and verification

Table 4 Schedule of testing for ultrasonic cleaners

Test	IQ	OQ	PQ	Periodic
Automatic control test	X	X	X	W Q Y
Chamber wall		X	X	Y
Chemical additive(s): low level detection		X	X	
Chemical additive(s):			X	
Chemical: reproducibility		X	X	Y
Cleaning efficacy by residual soil		X	X	W
Cleaning efficacy with test soil		X	X	Q Y
Doors: in-cycle interlock		X	X	Y
Doors: cycle start interlock		X	X	Y
Doors: door-opening force		X	X	Y
Drainage: free drainage		X	X	Y
Fault interlock		X	X	Y
Load carrier temperature test	X	X		
Load carriers				Y
Load dryness test		X	X	Y
Over-temperature cut out test		X	X	Y
Remove and clean strainers				D W
Weekly safety checks		X	X	W Q
Sound pressure test		X	X	Y
Test for ultrasonic		X	X	Y
Thermometric test for disinfection		X	X	Y
Verification of calibration	X	X	X	Q Y
Water: hardness	X			Y
Water: overflow test		X	X	Y

2

Validation and verification

Water supply temperature	X			Y
Volume of water used per stage		X	X	Y
IQ = installation qualification OQ = operational qualification PQ = performance qualification W = weekly Q = quarterly Y = yearly				

Frequency of testing maybe extended to longer periods for ultrasonic equipment used as pre-cleaners only. Such frequencies can be determined after consultation between User and AE(D), based upon a number of factors.

- Design of equipment
- Clinical risks
- Devices to be reprocessed within the Ultrasonic cleaner
- Volume of use

Apparatus

2.307 The following apparatus should be used:

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

Method

2.308 Measure the depth of the bath from the level of the lid to the bottom of the bath. Let the depth be D mm. 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 (the de-gassing procedure).

2.309 Ensure that the water in the tank is at the required level, that the required amount of any chemical additive specified by the manufacturer has been added and that the water in the tank is at the specified operating temperature.



Validation and verification

- 2.310 Using strips of autoclave indicator tape across the top of the bath suspend nine strips of the prepared foil in the bath in a 3 × 3 grid.
- 2.311 The rolled end of each foil strip acts as a sinker weight to maintain the foil in an approximately vertical position. The sinker weight should be not more than 10 mm above, but not touching, the bottom of the bath.
- 2.312 Operate the bath for the predetermined exposure time. This can vary typically between 30 s for a watt density of 20 W dm⁻³ and 10 min for a watt density of 5 W dm⁻³.
- 2.313 Remove the strips from the bath, blot dry and examine.
- 2.314 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.
- 2.315 Drain the bath and clean to remove debris of eroded aluminium foil.

Results

- 2.316 The zones of maximum erosion should be at similar positions on all nine foils and each should be eroded to a similar extent (by visual inspection). For precise evaluation the foils should be weighed before and after exposure to ultrasonication and the loss in weight recorded. The variation in loss of weight should be such that the weight of any one foil is within ±20% of the mean loss of weight.
- 2.317 On re-testing, the extent of erosion and the erosion pattern should have remained consistent with those originally determined during commissioning.

Reference test loads

- 2.318 The test load should 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.



Validation and verification

2.319 The test load should contain the following endoscope/MAT instruments:

- a. 2 Trochar and Cannulae;
- b. 2 MAT forceps;
- c. 2 surrogate endoscopes (see next paragraph);
- d. sufficient additional instruments to make up a full load.

2.320 The surrogate endoscope should be constructed from 6 mm OD/4 mm ID stainless steel tubing. The overall length should be 450 mm. At the midpoint of the tube should be a 50 mm length of tubing connected to the tubing on either side with compression fittings.

2.321 The 50 mm demountable length can be used to provide a more readily visible section for determination of cleaning efficacy.

PQ tests

Load items

2.322 Difficult to clean laboratory items, other than those of the type included in the reference load, or other items (for example hollowware) for which standard reference loads have been defined, should be reviewed to determine how well they are represented by the items of which the reference loads are composed. If the reference loads do not adequately represent the loads to be used further tests should be carried out using loads composed of items which will be in normal production loads.

Nature of soiling

2.323 Ultrasonic cleaners are often used for items that are contaminated with soiling which is difficult to remove by other cleaning processes.

2.324 The test soil for operational testing should be chosen to represent biological fluids that might be present. If other types of soiling will be encountered (for example orthopaedic bone cement) tests should be conducted using items soiled in the manner that occurs for normal production loads.

3 Water supply

Chapter 3

Water supply

Introduction

- 3.1 All the organisations responsible for water supply have the statutory power to make and enforce bylaws to prevent waste, excessive consumption, misuse or contamination of the water supply. Washer-disinfectors should be designed, constructed, installed, operated and maintained in accordance with the requirements of the relevant by-laws.
- 3.2 The number, nature and quality of water supplies required are dependent on the size and type of washer-disinfector and method of decontamination.
- 3.3 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 washer-disinfector rather than heat cold water for certain phases of the cycle at the required temperature within the washer-disinfector. Many designs of washer-disinfectors now incorporate holding tanks that pre-heat the water supply for the relevant phase of cycle.
- 3.4 The quality of water used at all stages in the decontamination process is critical to the successful outcome of the process.
- 3.5 At each stage the water quality should be compatible with:
- the materials of construction of the washer-disinfector;
 - the load items to be processed;
 - the chemical additive used;
 - the process requirements of that particular stage.
- 3.6 The key factors to be considered are:
- hardness;
 - temperature;
 - ionic contaminants, for example, heavy metals, halides, phosphates and silicates;
 - microbial population;
 - bacterial endotoxins.



Water supply

Water hardness

- 3.7 Hard water is caused by the presence of dissolved salts of the alkaline earth metals (calcium, magnesium and strontium), which come out of solution and deposit as hard mineral layers (limescale) when water is heated or evaporated.
- 3.8 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 %.
- 3.9 The deposition of limescale within the chamber, piped supplies and around the edges of spray nozzles can seriously impair the performance of a washer-disinfector. Hard water will cause scaling on the edges of spray nozzles even when fed with only cold water.
- 3.10 The presence of hardness in water seriously impairs the efficiency of most detergents and disinfectants. If the use of hard water is unavoidable process chemicals containing sequestering agents should be used. This adds considerably to the cost of the process.
- 3.11 Using hard water in the thermal disinfection and final rinse stages of the washer-disinfector cycle is one of the major causes of white powdery deposits on load items. These are not only unsightly and an unwelcome contaminant but act as a focus for soiling and recontamination of the item in use. In some applications, for example, with optical systems, such deposits can seriously impair the utility of the item.
- 3.12 For the cleaning – that is, flushing and washing – stages most washer-disinfectors will operate with water hardness values up to 125 mg/L CaCO₃ but are more effective and cheaper to operate when the hardness of the water is consistent and has a mean value of 50 mg/L CaCO₃. Accepted limits can be assessed upon local conditions, devices to be reprocessed, design of washer-disinfectors and properties of process chemicals used. NWSSP-SES can provide advice and guidance where required.
- 3.13 Some washer-disinfectors are fitted with integral water treatment systems; however, such systems are known to promote microbial growth if not used effectively and maintained to the correct levels.
- 3.14 The temperature at which water is supplied to each stage of the process has a major effect on the efficacy of the process:
- Water at too high a temperature during the flushing, i.e. the initial cleaning stage, stage can lead to the coagulation of proteins and thus serve to “fix” proteinaceous soil to the surface of the load items. It is recommended that the initial temperature should not exceed 45°C. Traditionally the flushing stage has been supplied with water from a cold supply and, providing there is sufficient mechanical action, this has proved an effective first stage of the cycle;

3

Water supply

- Water at too low a temperature during the washing stage, i.e. heated cleaning stage, of the cycle will often impair the ability of detergents used to remove soils composed largely of fats, oils or grease. The manufacturer of the chemicals should state optimum conditions for most effective detergent action of solution. This should be verified as part of validation procedure.
- 3.15 When enzymatic cleaners are used the water temperature should be maintained close to the optimum temperature specified by the manufacturer; too high a temperature will inactivate the enzymes.
- 3.16 When chemical disinfectants are used, the rate of activity generally increases with increased temperature. Too low a temperature will cause failure to attain the required microbial activation. However, too high a temperature with particular compounds can lead to degradation of the active components, evolution of toxic vapours or adverse reactions with the load items being processed.
- 3.17 The maximum temperature of rinsing water should be compatible with the items being processed; many items used in medical practice are temperature sensitive or might be damaged by thermal shock.

Ionic contaminants

- 3.18 To avoid the risk of corrosion, 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 50 mg/L Cl⁻. Chloride concentrations greater than 240 mg/L Cl⁻ cause pitting to occur. Irrespective of known limits, it is important to visually inspect devices prior to packaging and terminal sterilisation to ensure they are fit for purpose and further re-use.
- 3.19 Tarnishing of stainless steel instruments, shown by blue, brown or iridescent surface coloration, occurs when heavy metal ions, such as iron, are present in the process water. In hot water, over 75°C, magnesium ions and silicates can cause similar discoloration.

Microbial population

- 3.20 The purpose of the cleaning and disinfection process is to remove soiling and reduce the microbial contamination to an acceptable level for the intended use of the items to be processed. The water used at each stage of the washer-disinfector process cycle should not increase the bioburden of the load items.
- 3.21 For terminal disinfection, where items are intended to be used without further decontamination processing, the nature and extent of the microbial population in the final rinse or disinfection water should not present a potential hazard to the patient, either through infection or by leading to an erroneous diagnosis. Appropriate treatment to control or reduce the microbial contamination in water might be required.

Concentration of bacterial endotoxins

- 3.22 Bacterial endotoxins (see [paragraph 3.141](#)) 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 sterilisation.
- 3.23 Traditional guidance states that water used for the final stages of processing in a washer-disinfector, where there is a significant risk of residual water remaining on the load items should not contain more than 0.25 EU mL⁻¹ when the washer- disinfector is being used to process surgically invasive items or those which are intended to come into contact with parenteral solutions. However, measurement of endotoxin levels on instruments addresses concerns that users have with regards to patient safety rather than endotoxin levels in rinse water, which have been shown to be unrelated. Therefore the recommendation is that endotoxin levels per device should not exceed 20EU/ml, rather than identified levels in the supply. Further information can be found in the 'Water quality requirements for surgical instrument testing' series of documents on the SMTL website.

Water treatment

- 3.24 Despite the cost involved in treating water from the public supply, treatment systems can be cost-effective and may have benefits in certain circumstances. The use of an individual type of water treatment system should only be considered where it is deemed there is an actual need, e.g. where inconsistent variables from the local water supply are identified. A decision should be made at local level based upon clinical concerns and historic knowledge of public supply in the region.

Note

NHS Wales, through the All Wales Decontamination Group has taken the view that water of potable quality is the base standard for final rinse supply used in the decontamination of medical devices.

In general, direct mains feed is the most consistent method of supplying water of potable quality.

The installation of any treatment systems should be based on localised knowledge where technical issues present a clear benefit for the capital and revenue costs of installing such equipment.

Any such systems installed should be maintained in accordance with manufacturers' specification.



Water supply

Chemical purity

3.25 There are generally three methods of water treatment available for use on water supplies to be used in washer-disinfectors:

- water softeners;
- water deionisers;
- reverse osmosis (RO).

Water softeners

3.26 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 column may be regenerated by treatment with a solution of common salt (sodium chloride). If not installed, configured, maintained or tested according to the manufacturers’ specification, base-exchange softeners can cause a significant increase in the microbial content of the water.

3.27 The concentration of total dissolved solids in the water is not reduced by this process. The sodium salts that remain do not readily form hard deposits to foul heat exchangers or spray nozzles but if used as the final rinse or disinfection will leave white deposits on the load items as they dry.

3.28 The process is simple to operate with an automated in-line system, will handle water with varying levels of hardness, and is simple and safe to regenerate. After regeneration, however, high levels of chloride ions might be present in the initial output from the softener, which should be run to waste.

3.29 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.

Integral water softeners

3.30 Some washer-disinfectors are available with built in base-exchange water softeners although these are generally laboratory washer-disinfectors.

3.31 Water softeners should be chosen based on the total demand of softened water in the unit, e.g. SSD, including when necessary provision for manual washing facilities and other plant.



Water supply

Deionisers

- 3.32 Deionisation or demineralisation systems can remove virtually all the dissolved ionic material by ion-exchange using a combination of cation and anion exchange resins either in a single column (mixed bed) or in a separate column.
- 3.33 Operating costs of mixed bed deionisers are usually higher than for two-stage systems.
- 3.34 Routine maintenance (regeneration) of deionisation and demineralisation systems requires the use of a strong acid (hydrochloric acid) and a strong alkali (sodium hydroxide). For most types of installation, an exchange column service is available from the water treatment suppliers. The maintenance of these systems in line with manufacturers' requirements is essential to safeguard output quality.
- 3.35 Deionised water may become contaminated with microorganisms and the resin column colonised. Deionised water should not be used for the final rinse of products intended for invasive use without further decontamination processing by heating, filtration, etc. It is essential that your risk assessment in this area and related local policy establish safe water supply appropriate for each stage of the process.
- 3.36 Systems are available in a range of sizes from small wall-mounted units in which ion exchange resins are contained in disposable cartridges to large industrial units. Regeneration requires the use of strong acid (hydrochloric acid) and strong alkali (sodium hydroxide). For most types of installation an exchange column service is available from the water treatment suppliers.
- 3.37 For a given output volume, the initial cost of providing deionisation equipment will be lower than for reverse osmosis (RO). However, the inconvenience and cost of the regeneration process for deionisers, and the better microbial quality of the RO process, makes RO the preferred option.

Reverse osmosis (RO)

- 3.38 RO treatment plants remove almost all dissolved inorganic contaminants by passing the water, under pressure, through a semi-permeable membrane against an osmotic gradient. The process will also remove a high proportion of organic material, bacterial endotoxins and microorganisms. Some RO units are fitted with a final 0.2 µm filter to control bacterial numbers.
- 3.39 The initial capital cost of an RO plant is generally higher than for a deionisation system supplying a similar volume of water, but operational costs are lower. The water has a low microbial population. Measures are required to maintain the microbial quality of water during storage and distribution. The retention of this water quality requires a high level of understanding, maintenance and testing.
- 3.40 The wastewater produced by properly RO plant may be designated as grey and reused appropriately.



Water supply

3.41 Issues to be considered if a decision is made on installing RO systems include:

- An RO system removes bacteria, endotoxins and approximately 95 % of chemical contaminants;
- The system and associated pipework need to be sanitised regularly;
- The system provides processed water over a long period with minimal maintenance;
- Routine maintenance and membrane replacement are very important;
- The system usually requires a carbon filter to be fitted ahead of the RO unit to remove traces of chlorine from the water supply;
- RO units use large volumes of water, much going to waste, which can be used as grey water;
- Selecting an RO system will depend on the geographical area of the water source and its quality;
- If the supply water is hard, a softening system will be required ahead of the RO unit;
- Adequate space and provision for a plant room to house the equipment.

3.42 Water storage is required, as RO units supply moderate volumes of water over a long period. Washer-disinfectors need large volumes of water quickly during various stages of the cycle.

Microbial purity

3.43 Potable water from the public supply has a low microbial content and should be free from pathogenic organisms, other than those that might cause opportunistic infections in immunologically compromised patients.

3.44 If stored in tanks or cisterns, the microbial content can increase considerably.

3.45 Attention is drawn to the requirement under the code of practice for control of legionella that water in intercepting tanks should be stored below 20°C or above 55°C.

3.46 The extent and nature of microbial contamination in the water supplied to a washer-disinfector will depend on the stage in the process cycle at which it is to be used and the intended use of the decontaminated load at the end of the process.

3.47 Water stored at 60°C or above may be assumed not to have a proliferating microbial population.

3

Water supply

- 3.48 When water is treated by filtration, for example, through a 0.22 mm filter to remove microbial contaminants, rigorous controls are needed to ensure that the system works effectively. These should include:
- either maintaining the pressure drop across the filter throughout its working life, a decrease in differential pressure being cause for rejection of the process cycle and a change of filter, or, a bubble point test before and after each process cycle, see BS 1752, ISO 4793;
 - a continuous recirculation system so that the filter is not left wet in static water;
 - treatment of the circulating water to ensure that proliferation of microbial contamination is inhibited either by use of elevated temperature (for example $>60^{\circ}\text{C}$) or by the use of UV irradiation (wavelength $260\text{ nm} \pm 10\text{ nm}$; $>2\text{ J m}^{-2}$).
- 3.49 Verification of purification by filtration should be made by relevant TVC (total viable count) tests.

Pipework

- 3.50 The pipework used to supply the grades of water should be appropriate to the quality of water carried and be manufactured from material known to minimise the growth of bacteria, e.g. copper. The use of flexible hoses should be avoided where practically possible; however, the difficulty in access may result in it being necessary to employ hoses for final connection. In such cases, the hoses used should comply with the requirements of application and be manufactured in alignment with recognised standards, e.g. Water Regulations Advisory Scheme.
- 3.51 All pipework should be run with a continuous fall to the discharge point so that it is free draining. It should be free from dead ends and other areas where water can become stagnant.

Water supply-by-laws

- 3.52 All the organisations responsible for water supply within the UK have the statutory power to make, and the duty to enforce, by-laws for the prevention of waste, undue consumption, misuse or contamination of the water supplied by them, (see the Water Supply (Water Fittings) Regulations 1999).
- 3.53 By-laws 38 to 41 require storage cisterns to be fitted with warning pipes (and an overflow if in excess of 1000 L capacity).
- 3.54 The warning pipe and overflow should not comprise, or have connected to it, a flexible hose.
- 3.55 By-law 25 Schedule A gives examples of points of use or delivery of water where backflow is, or is likely to be, harmful to health due to a substance continuously or frequently present (By-law 25 (1) (a)).



Water supply

- 3.56 This schedule also lists water softening treatment plant, bedpan washers, bottle washers, dishwashers and disinfection equipment and clearly applies to all washer-disinfectors.
- 3.57 The required protection is a Type A air gap at the point of use or an interposed cistern.
- 3.58 Water softeners, regenerated only by means of sodium chloride solutions, need only be protected by a Type B air gap.

Water system tests

- 3.59 A continuous supply of water of the specified chemical and microbial quality is essential to the correct functioning of all washer-disinfectors.
- 3.60 Water that is too hard or has too high a concentration of dissolved solids can impair the activity of detergents, or require the use of increased quantities of chemical additives, and cause deposits, scaling or corrosion of the washer/disinfecter and items being processed.
- 3.61 Water containing high numbers of microorganisms may re-contaminate disinfected items. For all these tests the water should be sampled from a water source either within the chamber or as close as practically possible to the point of entry to the washer-disinfecter. Samples may need to be taken from additional points in the supply when trying to identify the cause of a non-conformity.

Water samples

- 3.62 The sampling procedure should be suitable for all the physical, chemical, and biological determinands of interest. It may be used for water samples throughout the water distribution system.
- 3.63 The sampling containers used should be specific for the determinands of interest. This should include, as appropriate:
 - a. 250 mL sterile pyrogen-free single-use containers (for determination of bacterial endotoxin levels and/or total viable count);
 - b. 1 L acid-washed borosilicate bottles (for determination of cations);
 - c. 1 L polypropylene bottles (for determination of anions, total dissolved solids);
 - d. 100 mL high-density polyethylene bottles (for determination of pH, conductivity).



Water supply

3.64 The first 50 mL of sample taken at each sampling point should be run to waste.

3.65 All samples should be taken in duplicate.

3.66 Samples should be stored at 2–5°C and tested within 4h of collection.

Parameter	Guidance on recommended values	Note
pH	5.5 to 8	
Conductivity uS/cm	300	Conductivity is a simple test that can be carried out regularly and can be helpful in identifying unusual trends. Unexpected results indicate that other parameters should be investigated.
Hardness CaCO ₃ (mg/L)	<210	To be assessed locally both through test results and visual assessment of washer-disinfector chamber/ devices reprocessed.
Chloride mg/L	50	
TVC cfu/100 ml	5000	Level determined as a result of terminal sterilisation process undergone by these instruments reprocessed within the washer-disinfector's.
Endotoxin Units EU/device	<20 EU	Limit based upon risk to patient safety of endotoxins on device rather than in rinse water.

Table 5 Requirements for water quality: final rinse and process water
(See [Appendix 1](#) for additional tests that may be necessary in certain circumstances)



Water supply

Water quality tests

- 3.67 The following clauses recommend analytical methods to determine the various biological, physical and chemical properties of water samples for the various qualities of feedwater to the washer-disinfector. A list of acceptable results for the analysis is provided in **Table 5**. It should be noted that these levels are a guide and further testing to include additional variables maybe required where problems are identified, either through visual inspection or analytical testing.
- 3.68 The methods of analysis recommended to detect chemical contaminants at low concentrations with a high level of accuracy require the use of a laboratory with appropriate expertise, facilities and experience.
- 3.69 Other tests can be carried out on-site or with very simple laboratory facilities; these lack the precision and sensitivity of the laboratory tests but are sufficient for most purposes.
- 3.70 The following clauses contain detailed procedures for tests that may be carried out on-site or with very simple laboratory equipment at, or shortly after, the time of sampling.
- 3.71 The precision, accuracy, sensitivity and limits of detection of these methods are usually inferior to those of laboratory methods. They are useful, however, in that they provide evidence of any gross failure and the results are available straightaway making them of diagnostic value during a fault- finding exercise.
- 3.72 They are generally economical compared with more sophisticated laboratory analysis and can be carried out by non-specialist personnel after thorough, but limited, training. The results should not, however, be used as evidence in cases of dispute.

Choice of method

- 3.73 For any given determinand there will usually be several methods that are suitable and cover the range of concentrations of interest. The methods recommended here are intended to be representative of those that might be suitable. They are chosen as examples of tests which can conveniently be carried out on site.
- 3.74 A number of test systems are available commercially. Before adopting one of these methods care should be taken to ensure that the test(s) provides results of sufficient accuracy and sensitivity.
- 3.75 It is not necessary to use experienced chemical analysts to undertake the on-site analysis of water samples described. It is, however, essential that personnel receive appropriate training before attempting to carry out this work. Recourse to more precise analysis might be needed in the event of a dispute between two parties.

- 3.76 Many contaminants can be detected by two or more of the determinations normally carried out for laboratory analysis. For example, an increase in one or other of the ionic species present will cause an increase in electrical conductivity and an increase in the evaporative residue as well as showing an increase in the concentration of that particular ion.
- 3.77 Further guidance on appropriate test methods may be obtained from BS 1427.
- 3.78 Tests suitable for use on-site fall into three main categories:
- instrumental tests using portable instruments designed for on-site use, for example, portable pH meters, ion selective electrodes;
 - spectrophotometric tests based on measurement of the absorbance of a coloured reaction product; measurement can be visual or photometric and can be against a precalibrated coloured disc or against standard reference solutions;
 - titrimetric tests may be carried out using standard laboratory equipment or with commercially available apparatus designed for field use; the latter is usually much simpler to use.
- 3.79 For all the instrumental methods recommended there is commercially available equipment specifically intended for field use. All the variables for which instrumental methods are recommended are temperature dependent. The equipment used should be temperature compensated. Also the equipment should be allowed sufficient time on site, before it is put into use, to equilibrate to the local ambient temperature.
- 3.80 Commercially available test kits based on visual or photometric comparison with coloured discs have become an accepted standard for on-site analysis. Manufacturers usually supply a complete test system, including kits of reagents. To ensure compatibility and maintenance of the manufacturer's claimed sensitivity and accuracy for the method, the kit specified by the manufacturer should not be substituted.

Water supply temperature

- 3.81 The water supplied to the various stages of the washer-disinfector operating cycle should be at an appropriate temperature. If the temperature of the water supplied to the flushing stage is too high (>45°C) there is a risk of coagulating proteinaceous soiling, which inhibits the cleaning process. If the temperature of water supplied to the washing, rinsing and disinfection stages is too low, the washer-disinfector cycle can be greatly extended, with a significant reduction in throughput, while the water is heated to the required temperature within the washer- disinfector. Water supplied in the temperature range 25–40°C presents a serious risk of microbial contamination of the system.



Water supply

Apparatus

3.82 An indicating or recording thermometer should be used.

Method

3.83 Measure the temperature of the water supply from a sampling point as close to the washer-disinfector as possible. Place the temperature sensor in the middle of the flowing stream as close as practicable to the sampling point. Allow the water to flow for at least a minute before the temperature is read.

Alternative method (for periodic testing)

3.84 When it is not convenient, or practicable, to run the water to waste from a sampling point close to the washer-disinfector the water temperature can be estimated by measurement of the temperature of the outer surface of the supply pipe. For this method the correlation between the temperature of the water flowing out of the pipe and the surface temperature of the pipe at a particular point should be established during installation testing.

3.85 Measure the surface temperature using a sensor designed for the purpose and follow the manufacturer's instructions for ensuring good thermal contact with the surface. Record or note the temperature during a normal operating cycle not less than 30 s after the start of water flow through the pipe to the washer-disinfector.

Results

3.86 The noted value should be within the temperature range specified for the installation.

Water supply pressure

3.87 If the pressure of the water supply to the washer- disinfector is below the minimum pressure specified by the manufacturer, the performance and productivity of the washer-disinfector will be affected adversely.

3.88 If the pressure of the water supply to the washer- disinfector is above the maximum pressure specified by the manufacturer the capacity of overflow devices 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 washer- disinfector or to products being processed.

3.89 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 washer-disinfector, including the connection or removal of additional machines.



Water supply

Note:

It is good engineering practice to install appropriate pressure gauges as strategic points on the distribution systems of each water supply.

Apparatus

3.90 A pressure indicator or recorder 0–10 barg should be used.

Method

3.91 Connect the pressure sensor to each of the water supply pipes to the washer-disinfector, as close to the washer-disinfector as practicable, on the supply side of the washer-disinfector isolating valve for that supply. 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 both with the other equipment operating throughout the test, or their operation simulated by an appropriate discharge to waste, and with no other equipment operating.

Results

3.92 The water pressure should remain within the supply pressure limits specified by the washer- disinfector manufacturer.

Appearance

3.93 All the water supplied to the washer-disinfector should be clean, colourless and free from visible particulate matter. The appearance of the sample should be assessed visually.

Apparatus

3.94 The following equipment should be used:

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



Water supply

Method

- 3.95 Transfer an aliquot to a clear colourless glass bottle, which should then be tightly stoppered. Shake the sample well and examine visually against a white background, preferably in a north light.
- 3.96 If the sample is turbid, filter through a qualitative grade filter paper. Examine the filter paper and report a description of the retained material. Visually examine the filtrate as previously described.
- 3.97 Report the appearance in terms of both colour and the intensity of any colour. If the sample is coloured, examine it carefully to see whether visible evidence of colloidal material is present.

Results

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

pH

- 3.99 All the water supplied to the washer-disinfector should be clean, colourless and free from visible particulate matter. The appearance of the sample should be assessed visually.

Apparatus

- 3.100 The following equipment should be used:

- a. pH meter:

- (i) Several commercially available small portable pH meters are available. A number of these include built-in temperature compensation. These should not be used to measure pH solutions of low ionic strength, although they provide suitable accuracy for most general applications. Their use for the determination of pH in water of high purity might give unstable or unreliable readings;
- (ii) Only those pH meters specifically designed for the measurement of low ionic strength solutions should be used for determining the pH of DI or RO water.

- b. Colour disc comparator:

- (i) Colorimetric tests for pH are suitable for high purity, low conductivity, water samples of the type required to be tested;



Water supply

- (ii) Since colorimeter methods are being used for other field tests this may be the more appropriate method;
- (iii) The accuracy is limited and discrimination may not be better than 0.2 pH units. This is, however, quite suitable for field tests;
- (iv) Colour, turbidity or strong oxidants in the sample all interfere with the test;
- (v) A narrow range indicator, or two for use on successive samples, should be chosen to cover the required range of pH 4 to pH 1. Manufacturers of colorimeters usually provide indicators to cover a range of 2 or 3 pH units. Wide-range indicators should not be used because of their poor discrimination.

Method

- 3.101 Operate the test kit in accordance with the manufacturer's instructions. Pay particular attention to using accurate volumes of both sample and reagent and monitoring both temperature and reaction time.
- 3.102 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.
- 3.103 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.

Results

- 3.104 The indicated value should be in the range 5.5 to 8.0. Photometric apparatus with somewhat better discrimination is also commercially available.

Electrical conductivity

Equipment and materials

- 3.105 There is a wide variety of portable conductivity meters available. The unit chosen should meet the performance criteria given in this clause, which will allow its use for measuring conductivity of very pure water through to boiler water containing in excess of 5000 ppm TDS.
- 3.106 Meters are available to cover the range 0.1–20,000 mS m⁻¹ at 25°C. Conductivity meters may also be calibrated in μS cm⁻¹. The meter, or meters, used should cover the following ranges:



Water supply

Range	Resolution	Accuracy
0–199 $\mu\text{S cm}^{-1}$	0.1 $\mu\text{S cm}^{-1}$	$\pm 1\%$ full scale
10–1990 $\mu\text{S cm}^{-1}$	1 $\mu\text{S cm}^{-1}$	$\pm 1.5\%$ full scale

3.107 They should also be temperature-compensated over the range 0–40°C.

Method

3.108 Use the following method for electrical conductivity calibration.

3.109 Verify the calibration of the meter against 0.001 molar and 0.0005 molar solutions of potassium chloride and pure water as working standards. These give conductivities at 25°C of 14.7 mS m^{-1} and 84 $\mu\text{S cm}^{-1}$ and $<0.06 \mu\text{S cm}^{-1}$.

3.110 Prepare the potassium chloride solutions by dilution of a 0.1 molar solution.

3.111 The working standards are stable for up to one week when stored in cool conditions, in a well stoppered container.

3.112 A comprehensive range of standard conductivity reference solutions, including pure water standards, also known as absolute water, are available commercially, standardized at 25°C and traceable to national standard reference materials.

3.113 After calibration rinse the sample cup or immersion probe thoroughly with pure water.

3.114 Collect the sample in a high-density polyethylene bottle and test as soon as practicable.

3.115 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.

3

Water supply

Results

3.116 The conductivity at 25°C should not exceed:

- 30 $\mu\text{S cm}^{-1}$ for reverse osmosis water;
- 30 $\mu\text{S cm}^{-1}$ for deionised water;
- 300 $\mu\text{S cm}^{-1}$ for softened or mains water.

Note

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

Hardness as (CaCO_3)

3.117 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 detergents and disinfectants and causes scaling on load items.

Ion-selective electrodes (ISE) method

- 3.118 Ion-selective electrodes are available for calcium and also for divalent cations (total hardness). Ionselective electrodes are not specific for a particular ion but have a relative selectivity for a particular ion or group of ions. They are sensors that 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.
- 3.119 Adjust both analyte and calibration standard solutions to the same ionic strength. Use a high impedance millivoltmeter to 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.
- 3.120 The optimum working pH range is 4 to 9 and the ionic strength of the sample should be adjusted for ionic strength. An adjustment buffer consisting of 4M KCl solution is often used. Phosphate buffers should not be used since the calcium activity will be lowered by complexation or precipitation.
- 3.121 The electrodes are free from any major interference except zinc ions. They are, however, poisoned by a number of biological fluids.



Water supply

- 3.122 The calcium electrode requires a single junction reference electrode. Calibration is made against two or more standard solutions. These are commercially available.
- 3.123 The calcium selective electrodes that are available have a Nernstian response for concentrations from 1 M down to about 5×10^{-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 or DI).

Titrimetric method

- 3.124 Commercially available kits for the titrimetric determination of both total hardness and calcium hardness are available. They are based on the same reaction in which divalent cations are complexed with the disodium salt of ethylenediaminetetraacetic acid (EDTA). When the reaction is carried out, at pH 10 to 11, with eriochrome black as the complexometric indicator, all the calcium and magnesium ions are chelated by the EDTA and the absence of free calcium and magnesium ions causes a colour change in the indicator.
- 3.125 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 complexometric indicator.
- 3.126 The commercially available kits often use novel titration methods instead of burettes. The test reagents are specific to each kit. The manufacturer's instructions should be followed.
- 3.127 Range: determinations within the range 5–400 mg/L can be made. The method is not applicable to purified water or condensate from clean or pure steam, which should have calcium concentrations well below the range for accurate determinations.

Results

- 3.128 The hardness expressed as mg/L CaCO₃ should not exceed 50 mg/L for softened water.
- 3.129 Water with values >210 mg/L should be regarded as unsuitable for use in washer-disinfectors without treatment.

Chloride

- 3.130 The presence of significant levels of chloride ions in water supplied to washer-disinfectors may cause pitting and corrosion in metallic items in the load (including stainless steel). Significant levels of chloride are present in untreated mains water supplies to which it is added for its anti-microbial activity. High chloride concentrations can be associated with breakthrough from a defective, or incorrectly operated, water softener or deioniser.



Water supply

Ion selective electrode (ISE) method

- 3.131 The commercially available chloride selective electrodes have a working range from 1 M to 10⁻⁵ M. They work over the pH range 3–10; adjust the sample for ionic strength using an adjustment buffer consisting of 5 M NaNO₃ solution.
- 3.132 The electrodes show poor selectivity against other halides and cyanide ions. Sulphide ions should be absent.
- 3.133 The chloride electrode requires a double junction 0.1 M NaNO₃ reference electrode.
- 3.134 Conduct the calibration against two or more standard solutions.

Note

These are commercially available.

Silver nitrate titration method

- 3.135 Commercial titrimetric kits are available that are based on the method described in BS 6068- 2.37:1990, ISO 9297:1989.
- 3.136 Titrate the sample at pH 5 to pH 9 with silver nitrate using a potassium chromate indicator solution.
- 3.137 The analytical range is 5–150 mg/L.
- 3.138 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.

Results

- 3.139 The chloride concentration in final rinse water for washer-disinfectors processing metal items should not exceed 50 mg/L.
- 3.140 The chloride concentration in other water supplies for washer-disinfectors processing metal items should not exceed 120 mg/L.



Water supply

Bacterial endotoxins

- 3.141 When the intended use of the washer-disinfector is for products that will be used invasively, for example, surgical instruments, the water used for final rinsing can be tested for bacterial endotoxins (limulus amoebocyte lysate (LAL) test). It is recommended that this test need only be carried out where there are documented concerns with water supply for decontamination process. Where this test is deemed necessary, quantified results are needed to determine the levels of endotoxin present.
- 3.142 The method describes the detection of bacterial endotoxin by the limulus amoebocyte lysate (LAL) gel formation method.
- 3.143 Other LAL methods (chromogenic, turbidimetric or kinetic turbidimetric) are equally suitable.
- 3.144 The water sample is incubated, in a test tube, with an equal volume of lysate for 1 h at 37°C 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 to be tested and by the use of lysates with different levels of sensitivity.

Total viable count

- 3.145 When the operating cycle of the washer-disinfector requires that the product is rinsed after the disinfection stage the rinse water should be consistent and not present a risk of microbial contamination to devices used for clinical activity patients, which could compromise the intended use of the load. A total viable count should be made on the final rinse water.
- 3.146 The test method, as described in BS EN ISO 15883 Part 1, sets out a particular test method with set culture media and incubation times/temperatures. 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.
- 3.147 A test can be carried out pre-installation or operational test to determine the water quality and an assessment for any treatment that may be necessary.
- 3.148 For other washer-disinfectors the test should be carried out when requested by the User as an installation test and repeated annually thereafter.



Chapter 4

Operational management

Introduction

- 4.1 This chapter covers the maintenance and operation of the various types of washer-disinfectors used in healthcare facilities.
- 4.2 Terminology used in decontamination has long been inconsistent and this has often led to ambiguities. European and International Standards adopt a common set of definitions for terms relating to decontamination. Reference should be made to these documents for definitions.
- 4.3 The testing, maintenance and reporting procedures recommended in this section are based upon good practice in both the United Kingdom and the rest of Europe, as formalised in new European Standards designed to support the new EU Directives. They are designed to prevent the possibility of gross failure and serious incident.
- 4.4 Good staff morale is important. Anomalous behaviour that may foreshadow a malfunction of a washer-disinfector is often first noticed by an alert operator or other relatively junior employee. It is vital that staff report such observations promptly to management, and that appropriate remedial action is taken.
- 4.5 It is important that all washer-disinfectors are effective in achieving the performance required to produce a clean and disinfected product, and that they are safe in operation.
- 4.6 Failure to achieve the required standard of cleanliness might also impair the capability of the process to achieve disinfection/subsequent sterilisation.
- 4.7 The cleanliness and microbial safety of all products processed in a washer-disinfector ultimately depends upon the care taken by the personnel responsible for its design, manufacture, installation, operation, test and maintenance.
- 4.8 Cleaning and disinfection might appear to be relatively simple processes, but considerable care is needed to consistently achieve satisfactory results.
- 4.9 Responsibility for assurance on these points rests variously with NWSSP/SES, AP(D), CP(D), the Microbiologist, the Control of Infection Officer and the User.
- 4.10 A permit to work system should be utilised for all maintenance activities as given in Section 6 of WHTM 01-01 Part A.



Operational management

Permits to Work should be managed by an AP(D) or a Responsible Engineer at each site, in conjunction with CP(D) and the User. Such a system provides the organisation the appropriate safe control of contractors (internal and external) and should be in place to manage any engineering activity that will compromise the integrity of the safe operation of the unit.

NWSSP/SES will audit the use of PTW as part of annual AP(D) assessments and can provide advice and guidance where required.

Equipment damage

- 4.11 The User should ensure that chemical additives used in the decontamination process are compatible with the materials of which the washer-disinfector is constructed and also with the items to be processed. No changes to process chemicals should be instigated without consultation with the AE(D) and as part of a formally agreed validation process.
- 4.12 Most washer-disinfectors are made partly or wholly of stainless steel; the water supplied to the chamber, and the detergent and other chemical additives used, should have a low chloride content to minimise the risk of corrosion.
- 4.13 Lubricants, if installed, for squeeze tubes on peristaltic pumps and other dispensing devices should be chosen and used in accordance with the manufacturer's instructions.
- 4.14 Care should be taken to ensure that the walls of ultrasonic tanks are not scratched as this can cause serious cavitation erosion.
- 4.15 Operators should be instructed never to drop or rest load items directly on the bottom of an ultrasonic tank.

Maintenance

Introduction

- 4.16 Decontamination is a set of processes, the efficacy of which cannot be verified retrospectively by inspection or testing of the product before use. For this reason decontamination processes (cleaning and disinfection and/or sterilisation) have to be validated before use, the performance of the process routinely monitored, and the equipment maintained.

- 4.17 Means of ensuring that a washer-disinfector is fit for its intended purpose will include the validation and testing programme recommended in **Chapter 2**, 'Validation and verification', and also the programme of planned maintenance recommended in this section.

It is essential maintenance is carried out at periods specified by the manufacturer. CP(D)'s undertaking maintenance activity, should be trained appropriately and the AP(D) within the organisation should have documented evidence of relevant training.

- 4.18 The philosophy of maintenance and testing embodies two main principles to ensure that the required standards of performance and safety are met and maintained:
- all washer-disinfectors are subject to a carefully planned programme of tests to monitor their performance;
 - all washer-disinfectors are subjected to a planned programme of preventive maintenance.
- 4.19 Expertise on the maintenance of washer- disinfectors is available at three levels: the CP(D), AP(D) and NWSSP-SES. The roles and responsibilities of all the responsible engineering staff are defined in the 'Functional Responsibilities' section of WHTM 01-01 Part A.
- 4.20 Recommendations for testing of washer- disinfectors are given in **Chapter 2**, 'Validation and verification'.

Planned maintenance programme

- 4.21 The planned maintenance (PM) programme should be designed according to the manufacturers instructions and based upon the risk of malfunction, severity of malfunction, legal requirements, e.g. pressure systems safety regulations, practicalities of maintenance provision and ability to maintain an effective and reliable operation of equipment. All parts of the control system vital to the correct functioning or safety of the washer-disinfector should be tested at pre-determined intervals (weekly, quarterly, bi-annually, annually) as recommended by the manufacturer.

Design of a PM programme

- 4.22 The PM programme recommended by the manufacturer should be supplied and should be used. The maintenance programme may be modified subsequently to take account of equipment use, equipment history and local conditions after a suitable period of operational experience.
- 4.23 The manufacturer's schedule may be modified if necessary but only after discussion with the NWSSP-SES, AP(D) and User.



Operational management

- 4.24 Although the manufacturer might carry out certain inspection and maintenance procedures under the terms of its guarantee, these might not constitute a full PM programme. The User should therefore ensure that the complete PM programme is carried out by the CP(D), who may be an employee of the manufacturer, during the guarantee period. The User should also implement any reasonable instructions given by the manufacturer during this period. Failure to carry out maintenance tasks and periodic tests could affect safety. It could also allow a contractor to place some, if not all of his liability on to the management. Where maintenance is carried out under lump sum term contract (see Chapter 1, ‘Design and pre-purchase considerations’) such failure is tantamount to breach of contract and can give the contractor cause to terminate the contract if it so wishes.
- 4.25 A set of procedures should be developed for each model of washer-disinfector, each containing full instructions for a particular maintenance task.
- 4.26 The frequency with which each task will need to be carried out will depend, in part, on the usage level for the washer-disinfector and on the quality of the water/steam supplied to the washer- disinfector. It might be necessary to adjust the programme so that work is carried out more frequently on machines that are heavily used/supplied with hard water.
- 4.27 It is important that maintenance is planned so that the washer-disinfector is out of service as little as possible. Maintenance should, where practicable, be scheduled to immediately precede the periodic tests as specified in **Chapter 2**, ‘Validation and verification’.
- 4.28 Systematic records should be kept of all maintenance work undertaken both to demonstrate that the work has been carried out and also to facilitate periodic review of the PM programme.
- 4.29 Spare and new components used for WD’s should be constructed of sufficient quality and be fit for purpose.
- 4.30 Log books and maintenance files should be maintained for each item of equipment either as electronic or paper records.

Warranty period

- 4.31 After the purchase of a new washer-disinfector the manufacturer might carry out certain inspection and maintenance procedures under the terms of the warranty. This might not be a full PM programme. The User should ensure that the complete PM programme is carried out as specified by the manufacturer during the warranty period.

It is essential, that the machine performance is monitored during the warranty period. Periodic meetings should be held to assess reliability and anomalies documented as part of official procurement agreement.



Operational management

4.32 The User should comply with any reasonable instructions from the manufacturer during the warranty period.

Review of the PM programme

- 4.33 The PM programme should be reviewed at least annually to ensure that the equipment is being fully maintained but without any unnecessary maintenance activity. The review should aim to identify:
- a. the adequacy of maintenance records and compliance with the PM programme;
 - b. any emerging defects;
 - c. any changes required to the PM programme;
 - d. any changes required to any maintenance procedure;
 - e. any additional training required by maintenance personnel;
 - f. any external advice such as that provided by NWSSP-FS, based upon experience of similar equipment on other sites.
- 4.34 Proposed changes to the PM programme should be made in consultation with the NWSSP/SES or manufacturer whenever possible.

Modifications

4.35 Occasionally, modifications to the washer- disinfecter might be recommended by the manufacturer or by NWSSP-SES 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.

Routine housekeeping

- 4.36 Certain maintenance tasks may be carried out by the User, or by the Operator under the User's supervision, and should be recorded in the washer-disinfecter log. Examples of such tasks include:
- a. checking that the rotating spray arms are free to rotate;
 - b. checking that nozzles are not blocked;
 - c. removal, cleaning and replacement of strainers and filters;
 - d. checking that the supply of chemical additives is sufficient for the day's use and replenishing if necessary;



Operational management

- e. cleaning the inside of the chamber;
- f. cleaning the external surfaces of the washer- disinfectors;
- g. washing of loading side conveyors and trolleys;
- h. for washer-disinfectors with a built-in water softener, checking the level of salt in the regeneration tank and replenishing if necessary.

Pressure Systems Safety Regulations

4.37 Requirements of the Pressure Systems Safety Regulations shall be met following advice from the CP(PS).

Features requiring special attention

Leak tightness of doors

- 4.38 The door(s) of the washer-disinfectors are intended to prevent the escape of fluids into the surrounding environment, to ensure freedom from aerosols that might be potentially infectious.
- 4.39 Damaged door seals are the major potential source of leaks and should receive careful attention as advised by the manufacturer.
- 4.40 The working life of door seals can be prolonged by regular cleaning.
- 4.41 Door seals should be renewed with spares provided, or approved, by the manufacturer at recommended intervals or when there is any sign of damage/deterioration.

Doors interlocks

- 4.42 The interlocks on door(s) of the washer-disinfectors are intended to:
 - a. prevent the operator gaining access to the load during processing;
 - b. prevent both the loading and unloading doors being open at the same time on “pass-through” washer-disinfectors;
 - c. prevent the operator gaining direct access to a load that has not been satisfactorily processed.
- 4.43 Maintenance and inspection of door safety devices and door interlocking and chamber sealing systems should be carried out in accordance with the manufacturer’s written instructions.



Operational management

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

Chemical dosing systems

4.45 The correct amount of chemical additive should be administered at the right time in the operating cycle to ensure the correct functioning of a washer-disinfector.

4.46 The chemical additive dosing system shall be subjected to regular (at least daily) inspection, maintenance and test. This should include:

- a. visual inspection of all piping to ensure freedom from leaks;
- b. visual inspection/testing to ensure that neither the delivery or pick-up piping is blocked by coagulated or hardened chemical additive (many of the chemical additives used are a viscous suspension), followed by cleaning or replacing piping as necessary;
- c. lubrication of the pinch tubing on peristaltic pumps in accordance with the manufacturer's instructions;
- d. ensuring that there is sufficient additives(s) available and that it (they) are being dosed;
- e. Care should be taken when changing chemical containers to avoid misconnection of process chemicals. Clear labelling of each dosing system should be in place, preferably dedicated connections to ensure there is no potential for error.

Water sprays and jets

4.47 The correct flow and distribution of water and aqueous solutions throughout the chamber and load are essential to the correct functioning of a washer-disinfector. The spray system should be checked on a daily basis as part of the routine housekeeping tasks carried out by the User.

4.48 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.



Operational management

Ultrasonic transducers

- 4.49 Many ultrasonic cleaners are not fitted with means to provide continuous monitoring of performance. Transducers can fail or become detached from the ultrasonic tank without being noticed by the Operator, other than by the deterioration in the cleaning performance.
- 4.50 Periodic functional testing of ultrasonic cleaners is defined in this WHTM.
- 4.51 The tank of the ultrasonic cleaner should be cleaned with a suitable neutral detergent and soft brush at least weekly.

Ventilation plant

- 4.52 Correct operation of ventilation plant used in decontamination area's essential to ensure:
- the safe operation of washer-disinfectors that include interlocking systems to ensure that there is correct operation of both the room ventilation system and the process specific extraction system. Such systems should be balanced on installation and routinely checked thereafter;
 - the efficient operation of the drying stage, where this is included to remove the high levels of moisture present post process;
 - the maintenance of a comfortable working environment for staff working within the area wearing appropriate forms of personal protective equipment.

See HBN 13 for the environmental and ventilation requirements for SSD's.

- 4.53 All ventilation systems associated with a washer- disinfectors should be inspected, serviced and maintained at least every six months. Guidance on maintenance is given in HTM 03-01 Part B. Washer-disinfectors are often designed to be connected to extraction systems to create a slight negative pressure to minimise the potential for discharge of aerosols into the environment.
- 4.54 Washer-disinfectors that include a chemical disinfection stage should have the associated ventilation system examined and tested annually.
- 4.55 Before undertaking maintenance work on the machine covering/fascia, or its associated ventilation system, it may need to be decontaminated and the advice of the designated safety officer should be sought. A permit-to-work system should be in operation.

A permit to work should be implemented as specified in WHTM 01/01 part A (chapter 8.0)



Operational management

Returning a washer-disinfector to service

4.56 Whenever any work has been carried out on a washer-disinfector, whether or not this was part of the PM programme, the user should be satisfied that it is fit for use. Following major repairs, overhauls, etc. which might affect the performance of the washer-disinfector, the User and AP(D) with assistance from the NWSSP-SES, should draw up a schedule of checks and tests to be carried out before the washer-disinfector is returned to service. This should include some or all of the recommissioning (yearly) tests specified in **Chapter 2**, 'Validation and verification'. See also guidance on the permit to work system given in the 'General' section of WHTM 01-01 Part A.

Troubleshooting

4.57 A failure to clean all the items processed in a load through a washer-disinfector is the most frequently observed fault. The most common causes of this type of failure, and thus those that should be considered first in any investigation, are:

- a. incorrect loading:
 - (i) items that are not correctly located in an appropriate load carrier will not be subjected to the intended washing process;
 - (ii) overloaded baskets and load carriers allow some load items to shield others from spray jets, etc.;
 - (iii) hinged instruments that are not opened prior to washing will not be effectively cleaned;
- b. blocked spray jets, spray arms that are not free to rotate or a blocked strainer in the chamber base;
- c. soiled instruments which have been stored for prolonged periods before decontamination: blood and protein will coagulate if stored for more than 8 h making this hard to remove (the sooner devices are reprocessed the easier it is to clean to the required standard);
- d. soiled instruments subjected to heat treatment before decontamination: this will lead to coagulation of blood and protein making this hard to remove;
- e. incorrect choice or quantity of detergent:
 - (i) the detergent chosen should be compatible with the loads to be processed, the soil to be removed and the quality of water supplied;
 - (ii) malfunction of the dosing system may cause the wrong quantity of chemical additive to be used: too little will not provide the detergency required but too much may also impair cleaning by causing excessive foaming, etc.;



Operational management

f. Inappropriate water quality:

- (i) initial flush with water that is too hot will lead to coagulation of blood and protein making this hard to remove;
- (ii) the hardness of water used during washing should be compatible with the detergent chosen;
- (iii) hard water used in the final rinse can leave deposits on the surface of instruments.

4.58 The choice of detergent should be based upon a number of factors. These include:

- a. the quality of water available;
- b. the nature of the load;
- c. the nature of the soiling to be removed;
- d. the nature of the washing process.

4.59 Advice should be sought from both the washer- disinfectant and detergent manufacturers.

4.60 The quality of water used for the final rinse stage is important in ensuring freedom from scaling, process residuals, etc.



Appendix 1

Further information on the testing methodology for water quality used within washer disinfectors

Certain chemical purity tests were identified as periodic tests in HTM 2030. However, evidence based research produced in the 'Water quality requirements for surgical instrument reprocessing', carried out by SMTL on behalf of the All Wales Decontamination Group, indicates that the variables listed do not normally affect the decontamination process and it is deemed to be unnecessary to test routinely. These variables may need to be tested and assessed where there are operational problems or disputes with any part of the decontamination process for medical devices.

The variables in question are:

- Total Dissolved Solids;
- Heavy Metals;
- Iron;
- Silicates;
- Phosphate.

Total dissolved solids

- A.1 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. It is recommended that this test need only carried be out where there are documented concerns with water supply for decontamination process.
- A.2 When a water sample contains predominantly ionisable solids in solution, and the composition of the various constituents is reasonably constant, a good 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.

Conductivity method

A.3 The following apparatus should be used:

- a. conductivity meter (see paragraph 3.105, 'Electrical conductivity');
- b. phenolphthalein indicator;
- c. 5% w/w acetic acid solution;
- d. 5% w/w sodium hydroxide solution.

A.4 Neutralize the test sample, using phenolphthalein as the indicator, by drop-wise addition of 5% w/w sodium hydroxide solution or 5% w/w acetic acid solution. Measure the conductivity of the sample (see 'Electrical conductivity') and multiply by the conversion factor to give an estimate of the TDS in mg/L.

A.5 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 and the electrical conductivity.

A.6 Alternatively, an arbitrary factor can be used. The one most commonly chosen is based on sodium sulphate being the ionic species.

A.7 For conductivity at 25°C measured in mS m^{-1} : $\text{TDS mg/L} = \text{electrical conductivity mS m}^{-1} \times 1.6$.

A.8 Conductivity meters calibrated in TDS mg/L are also available. Care should be taken to ensure that the conversion factor used is appropriate.

A.9 Standard salt solutions are available commercially as ready-to-use standard solutions traceable to NIST standard reference materials. A TDS standard solution such as 1382 ppm NaCl, and a tenfold dilution of it, can be used to verify the calibration.

Results

A.10 The estimate of total dissolved solids should not exceed $4 \text{ mg } 100 \text{ mL}^{-1}$ for purified water (RO or DI).



Appendix 1 Further information on the testing methodology

Evaporative residue method

A.11 The following apparatus should be used:

- a. silica or borosilicate dish or beaker of >150 mL capacity;
- b. oven set to $110^{\circ}\text{C} \pm 2^{\circ}\text{C}$;
- c. boiling water bath or heating mantle set to $100^{\circ}\text{C} \pm 2^{\circ}\text{C}$;
- d. 1 L polypropylene bottle;
- e. balance weighing to 0.1 mg;
- f. 100 mL pipette or measuring cylinder.

A.12 Collect a 1 L sample.

A.13 Take the silica dish (or equivalent), dried for 2 h in the oven set to $100^{\circ}\text{C} \pm 2^{\circ}\text{C}$ and then cooled to ambient temperature, and weigh it to the nearest 0.1 mg.

A.14 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.

A.15 Dry the dish in the oven to constant weight to an accuracy of 0.1 mg.

A.16 Calculate the mass of residue in the dish and hence calculate the mass of residue per 100 mL of water.

Results

A.17 The evaporative residue should not exceed $4 \text{ mg } 100 \text{ mL}^{-1}$ for purified water (RO or DI).

Heavy metals

A.18 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. It is recommended that this test need only be carried out where there are documented concerns with water supply for the decontamination process.

Method

- A.19 Determine the total concentration of heavy metals using the limit test described in the British Pharmacopoeia, see also BS 6068-2.29:1987, ISO 8288-1986.

Results

- A.20 The total concentration of heavy metals should not exceed 10 mg/L determined as lead.

Iron

- A.21 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 might be present. It is recommended that a test for this variable need only be carried out where there are documented concerns with water supply for the decontamination process.
- A.22 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 BS 6068-2.2:1983, ISO 6332-1982.

The reaction of iron (II) with 1,10 phenanthroline in solution yields a red complex with peak absorption at around 510 nm. Most 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.

- A.23 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.

Apparatus

- A.24 The following apparatus should be used:

- a. colour disc comparator kit;

Note:

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

A1

Appendix 1 Further information on the testing methodology

b. Reagents;

Note:

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

- c. a standard 0.702 g/L iron (II) ammonium sulphate solution $(\text{NH}_4)_2\text{Fe}(\text{SO}_4)_2$;
- d. a mercury in glass thermometer graduated in 0.5°C steps conforming to BS 1704:1985, ISO 1770:1981.

Method

- A.25 Prepare a standard 0.702 g/L iron (II) ammonium sulphate solution $(\text{NH}_4)_2\text{Fe}(\text{SO}_4)_2$ 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.
- A.26 Measure the sample temperature before commencing the analysis.
- A.27 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.
- A.28 For details of the colorimetric method, see the method for the determination of silicate.

Results

- A.29 Untreated and softened water should have less than 2 mg/L iron present.

Phosphate

- A.30 The 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. It is recommended that a test for this variable need only be carried out where there are documented concerns with water supply for the decontamination process.
- A.31 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.

Note

Some commercially available comparators work at 700 nm but this is less sensitive and should not be used.

A.32 The presence of oxidising agents and sulphides will interfere with the reaction. Otherwise there are no particularly sensitive interferences.

Apparatus

A.33 The following apparatus should be used:

a. colour disc comparator kit;

Note

The calibrated phosphate colour disc should be calibrated in P2O5 mg/L. A sensitivity range of 0–adequate precision. Discs offering extended ranges should not be used as the discrimination of intermediate concentrations becomes unacceptably poor.

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

b. reagents;

Note

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

c. sample container;

Note

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 glass container and assayed as soon as possible.

d. glassware;

Note

This should be borosilicate which has been subject to acid hardening, that is, cleaned and allowed to stand overnight, filled with sulphuric acid (d201.84), then rinsed several times and stored filled with water, in the dark at 0–4°C until required for use. The glassware should not be allowed to come into contact with detergents or alkaline liquids.

- e. a standardised solution containing 100mg/L potassium dihydrogen orthophosphate for preparation of calibration standards.

Method

- A.34 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.
- A.35 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.
- A.36 Test the samples as soon as possible after sampling. If sampling will be delayed by more than 4 h store the sample(s) in suitable glass bottles at 2–5°C for up to 24 h.
- A.37 Follow the manufacturer's instructions precisely.
- A.38 For details of the colorimetric method, see the description given in the method for the determination of silicate.
- A.39 The temperature has a significant effect on reaction time, at 20°C the reaction is typically completed within 3–4 min. 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 10–15 min after the start of the reaction.

Results

- A.40 The phosphate concentration of rinse water used for metal load items should not exceed 0.2 mg/L expressed as P₂O₅.

Silicate

- A.41 Silicate reacts with metal items, including stainless steel, causing corrosion and discoloration. This is accentuated at elevated temperatures. It is recommended that a test for this variable need only be carried out where there are documented concerns with water supply for the decontamination process.
- A.42 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, 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.

A1

Appendix 1 Further information on the testing methodology

- A.43 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. Discs offering extended ranges should not be used as the discrimination of intermediate concentrations becomes unacceptably poor.
- A.44 The method is generally suitable for determination of SiO₂ level in softened and untreated water but is only sufficiently sensitive to act as a limit test for purified (RO or DI) water.

Apparatus

- A.45 The following apparatus should be used:
- colour disc comparator kit;
 - reagents;
 - a standard 3.132 g/L disodium hexafluorosilicate solution (Na₂SiF₆);
 - a mercury-in-glass thermometer graduated in 0.5°C steps conforming to BS 1704:1985, ISO 1770:1981.
 - a standard 3.132 g/L disodium hexafluorosilicate solution (Na₂SiF₆);
 - a mercury-in-glass thermometer graduated in 0.5°C steps conforming to BS 1704:1985, ISO 1770:1981.

Measure the sample temperature before commencing the analysis using the mercury-in-glass thermometer.

Note:

The prepackaged reagents available from the manufacturer of the comparator should be used.

- A.46 Prepare a standard 3.132 g/L disodium hexafluorosilicate solution (Na₂SiF₆), providing a stock standard solution of 1000 mg/L as SiO₂. 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.
- A.47 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.

A1

Appendix 1 Further information on the testing methodology

- A.48 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 alibrated colour disc viewed through the untreated sample. Read off the displayed value of SiO₂ concentration from the calibrated disc.

Note

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

- A.49 Serial dilutions of the standard solution may be used to verify the calibration of the comparator disc.

Results

- A.50 Untreated and softened water should have less than 2 mg/L silicate expressed as SiO₂, determined as reactive silica, present.
- A.51 Purified (DI or RO) water should have not more than 0.2 mg/L silicate expressed as SiO₂, determined as reactive silica, present.

A2

Appendix 2 Technical Specification template (TST)

Appendix 2

Technical Specification template (TST) for the purchase of washer-disinfectors for surgical instruments

Note

This example of the TST is for reference purpose; amended versions are available from NWSSP-SES upon request. It is essential this is completed as part of formal procurement contract when purchasing new washer disinfectors.

The User, AE(D), AP(D) and Procurement representative should be consulted as part of the completion process of the TST.



Appendix 2 **Technical Specification template (TST)**



Technical Specification Template for the purchase washer disinfectors for surgical instruments

Reference document in support of WHTM 01.01

Name of Health Board	Details
Purchaser	
Hospital site	
Department	
Name of SSD Manager and contact details	
Name of Estates contact and details	
Technical support	NHS Wales Shared Services Partnership – Specialist Estates Services (NWSSP-SES) Telephone: 029 20904 097 This includes the services of the Decontamination Engineers (DE(W)) and the Authorising Engineer (Decontamination) (AE(D))

The machine(s) are to be supplied under the agreement of NHS Wales Shared Services Partnership - Procurement Services and the NHS Supply Chain framework agreement.

Site visit(s) are required by the Supplier to ensure that the machine(s) will fit correctly, and no problems will be encountered during the delivery process. All engineering systems and services must be surveyed during the visit(s).



Appendix 2 Technical Specification template (TST)

The machine(s) are to be supplied under the agreement of NHS Wales Shared Services Partnership – Procurement Services and the NHS Supply Chain framework agreement.

Technical support is provided by NHS Wales Shared Services Partnership – Specialist Estates Services. Site visit(s) are required by the Supplier to ensure that the machine(s) will fit correctly and no problems will be encountered during the delivery process. All engineering systems and services must be surveyed during the visit(s).

All equipment suppliers must ensure that all items listed in this template are essential requirements and not optional – the Supplier must make clear to the Client any further available options for a final decision and agree the specification before agreements are made on the contract price.

Note: It is a requirement that where service arrangements are taken in conjunction with the manufacturer and in alignment with maintenance schedules, a guarantee of 95 % uptime is underwritten, providing that the operation of the washer-disinfector is completed as per the manufacturer’s training and errors are not proved to be as a result of external factors, e.g. water supply, operator errors.



Appendix 2 **Technical Specification template (TST)**

1 Washer disinfectant selection details

Total number of machines required as below

Washer disinfectant type -	Type A Standard cabinet Pass through double interlocked doors	Type B Cabinet single door	Type C Multi chamber design
Numbers of machines			
Chamber capacity- size (nominal)			
Special requirements			
Door movement preferred (Upward closing, drop down door, etc.)			

Surgical specialties of department (optional details)

Types of surgery	Daily throughput	Loading system	General comments

Surgical specialties of department (optional details)

Type C

Multi chamber design and sections required

Chamber function				



Appendix 2 **Technical Specification template (TST)**

2 Washer disinfectant cycles requirements

Cycles	Required Yes or No	Options and comments



Appendix 2 **Technical Specification template (TST)**

3 Washer disinfectant process chemical(s) – options

Chemistry used within operating cycles	Required Yes or No	Options and comments

4 Details of delivery/installation requirements

- 4.1 Any comments on any interim storage and/or installation for the delivered equipment prior to final installation.
- 4.2 It is the responsibility of the Supplier to establish the site access, route and requirements of delivery of the equipment to the final installation site.

General comments:

5 Delivery details of packing methods

- Select
- Standard packing for basic weather protection - A
 - Good weather covering to protect machines under delivery - B
 - Dust proof packing and wrapping for further storage needs - C
 - Dust proof packing and timber casing - D





6 Removal and disposal of existing plant, equipment and services

Costs and any remedial work in this area must be clear to all parties at the time of tendering.

<p>Details:</p> <p>Plant:</p> <p>Services:</p>

7 Drawings

- 7.1 Layout drawings must be submitted to the Client prior to tender to view the details of the installation.
- 7.2 Any drawings such as engineering services supplied or required by the Supplier and the Client must be clearly agreed and defined during the tender process.
- 7.3 All service(s) and connections must be agreed by the Supplier and Client (or their representative) during the tender process. These connections will then be clearly illustrated on the drawings as submitted with the tender.

Note: All Schematic drawings have to be supplied to Estates and HSDU (including Electrical and Mechanical drawings)

8 Documentation

- 8.1 Machine manuals must be supplied with the washer disinfectors on site delivery.
- 8.2 Pressure vessel certificates are to be supplied on machine delivery if required.

Note: All Engineering manuals/User manuals have to be supplied to Estates and HSDU.

9 Air supply (if required)

- 9.1 Compressed air maybe required for process control or for the drying.



Appendix 2 **Technical Specification template (TST)**

9.2 It must be agreed at the tender how the air will be supplied to the washer disinfectors(s). Select. (One or more)

- A Individual machine compressors
- B Common supply
- C Air compressors paired up per two machines
- D None supplied with tender
- E Spare compressors supplied
- F Other
- G N/A

Comments and details:

10 Heating medium

10.1 The washer disinfectors may be steam or electrically heated in the various stages.

10.2 Medium choice will effect the cycle time.

10.3 The Supplier must discuss the options available and services required with the user.

Stages	Steam - yes or no	Electric - yes or no
Washing		
Thermal disinfection		
Drying		
Or ALL stages		



11 Steam

- 11.1 The installation of a pressure reducing valve should be fitted in the steam line from the mains supply to the machine(s) to protect any direct acting valves on the machines from damage and to ensure a steady and safer supply pressure for the process.
- 11.2 Steam may be supplied indirectly to heat the water/air to the relevant control temperatures during the cycles through suitably manufactured heat exchangers.

Further details:

12 Electrical supply

- 12.1 It must be agreed at the tender stage what is the electrical loading /demand for the installation.
- 12.2 Discussions must be held with the relevant Estates department officers and the Suppliers to determine the supplies in general and if single or three phase is available or required.

Further details as required:

13 Water supply

- 13.1 An assessment should be carried out on the supply water used in all phases to the washer disinfectors prior to the procurement process.
- 13.2 A decision on whether further treatment is required can be assessed in conjunction with the Manager, AE(D) and Infection Control Officers and DE(W) at NWSSP-SES.
- 13.3 The Supplier to provide advice on the minimum supply pressure(s) required at each stage of the process(s).



Appendix 2 **Technical Specification template (TST)**

Further details as required:

14 Washer disinfectant monitoring

- 14.1 It is a requirement of NWSSP-SES that cycle independent monitoring is installed to each washer disinfectant, in compliance with EN ISO 15883 parta 1 and 2. Options should be provided to the client.
- 14.2 Monitoring could be a built in supervisor system, electronic independent system or data recorder as agreed with NWSSP/SES and the client.
- 14.3 It is a requirement that the instrumentation is connected to the Hospital IT server and system.

Details:

15 Consumables

- 15.1 At the time of delivery of the washer disinfectant(s), consumables such as printer roles and cartridges **MUST** be supplied to the unit for a minimum three month operating period of constant use.
- 15.2 Detergents, rinse aids and other solutions must be supplied by the Manufacturer at the time of installation for at least three months operation.
- 15.3 Discussions must be made by the supplier with the SSD manager or representative prior to tender to discuss the solution options available with machines.
- 15.4 Rinse aid selection or requirements for final disinfection stage,
- 15.5 Consumables required to be supplied with the machines.



Appendix 2 **Technical Specification template (TST)**

<p>Comments, if required:</p> <p>Detergent (s) required (make/type):</p> <p>Details of general consumables required by the user:</p>

16 Chamber furniture required

<p>Numbers and types of loading trolleys:</p> <p>Numbers and types of loading carriages (internal):</p>

<p>Further comments for loading equipment</p>
--

17 Testing and validation

- 17.1 Factory testing is not normally carried out, but if there is a requirement to carry out this function, the costs will have to be built into the tender.
- 17.2 *Validation testing will be carried out by the Supplier, with NWSSP/SES witnessing on behalf of the client.*
- 17.3 The AE(D) will be monitor and audit all test results.
- 17.4 The Supplier will consult with the client and NWSSP-SES for any technical advice required.



Appendix 2 **Technical Specification template (TST)**

Further comments/requirements:

Testing and maintenance contracts are to be quoted by the Manufacturer during the tender for the costs to be analyzed by the client for machine care after the warranty period

18 Service response times and costs

Details and client response time(s) requirements:

Breakdown advice time required:

Site attendance time required:

Spares availability in delivery to

19 Fascia and panelling

Details of panelling required – Panel work to be agreed to ensure maintenance access is optimised.

20 Training requirements

- 20.1 Staff training is required before the machine(s) can be put into service.
- 20.2 The training will include the monitoring system and logging requirements.
- 20.3 Factory testing can be arranged with prior agreement with the manufacturer.



Appendix 2 **Technical Specification template (TST)**

20.4 Training is required for both Estates and Operational tests.

20.5 Full operational training for SSD staff will cover all staff who will be required to work on the machines.

20.6 Estates staff training will be required to cover:

- Cycle control
- Machine controls and operating procedures
- Door operations
- Loading equipment
- Monitoring equipment
- Fault finding
- Repair/dismantle main components
- Cycle operation via the valves and operation components
- Basic cycle programming and fault analysis
- Demonstration of the maintenance manual

20.7 Numbers of staff required for training

Operational staff	Estates staff
Details of shift times	Details of shift times



21 Warranties

Details should be quoted and agreed with the client and the date from which it will commence.
Costs in **Section 2**

- The agreement must be clear before the purchase is made.
- Extended warranty options can be quoted and discussed with the Client to cover both maintenance and testing as required.
- Number of visits per year.
- Cost of each visit.

Commencement and completion dates for warranty period should be clearly documented as part of procurement contract.

22 Contract testing/maintenance

Contracts can be built into the tender with full consultation with the client

- Quarterly testing contracts.
- Breakdown call outs.
- Response times.
- Maintenance contracts as required.
- Availability of spares.

Details to be given in Section 2 by the Supplier

Note: Communication has to be in place with Estates to deal with first line response to breakdown situation.



23 Gauges fitted for the Washer Disinfectors

(Select as required)

Gauge	Yes	No
Steam supply pressure – main		
Reduced steam supply pressure at machine		
Water supply pressure		
Air supply pressure		
Door seal pressure if active seal fitted		
Pump pressure		
Mains water supply temperature		
Tank water temperature		
Hot water service temperature		
Other		

24 Ventilation requirements of the washer disinfectors

- 24.1 Individual machines are or can be ventilated independently or linked into a common extract. The Supplier should clearly indicate at the tendering stage what details they are required to supply or what are to be fitted by the Hospital unit.
- 24.2 Drawings and air duties must be supplied with the tender documents.
- 24.3 The Supplier must inform the purchaser if the fan(s) are required as part of the machine as supplied.
- 24.4 The Supplier must inform the purchaser if a complete system is required and where it will be terminated under the supply contract, i.e. for others to design and extend the system to a safe extract position outside the building.
- 24.5 The system must be constructed to allow correct drainage of possible condensate forming in the duct to drain as per the WHTM. It can be constructed or manufactured of non-corrosive materials and heat recovery systems can be considered.



Appendix 2 **Technical Specification template (TST)**

24.6 The supplier must ensure that the Estates Department is fully consulted in the early stages of procurement so that appropriate designs can be drawn up with the client. This will include drawings for consultation.

Additional notes or comments for consideration for the tender



Section 2

This section is a guide for the type of information and energy duties that are required by the Client for a good and effective installation.

INFORMATION TO BE COMPLETED BY SUPPLIER

Details of Microprocessor Control System

The following information shall be provided by the Supplier:

- Details of independent body where complete program and software are lodged.
- Details of interface and file protocol requirements for transfer of data in the storage device to an external computer.
- Details of diagnostic checks incorporated in the system.
- Details (including cost) of the data storage device.
- Maximum ambient temperature within the protective case °C
- With an ambient temperature of °C

Interim Storage Requirements

Suppliers are required to advise of the storage conditions required if different from final installed location. If interim storage is needed state storage conditions required.

Details:

Warranty Details

Length of standard/free warranty period offered:

Number of included service visits during warranty period:



Conditions of Warranty

Projected mean time between failures:

Guaranteed up-time:

Please state definition of up-time:

.....

.....

.....

.....

Please state remedy available to purchaser if guaranteed up-time is not achieved:

.....

.....

.....

.....

.....



Extended warranty options for service and maintenance

Please complete the following schedule for a planned preventative maintenance and emergency call out contract to cover all items shown in the individual site schedule and to commence 12 / 24 / 36* months after acceptance, if required by the purchaser:

Number of service visits per annum

Duration of service visits hours per machine Normal working hours are 0800-1800 unless otherwise stated: All emergency call-outs included: YES / NO*

Price for emergency call-out during normal working hours, if not included: £ per hour
All out of hours working included: YES / NO*

**Delete as applicable*

Price for Saturday working £per hour

Price for Sunday working £ per hour

Price for evening working£ per hour

Price for bank holiday working £ per hour

Response time to emergency call-outs (engineer on site) hours

Latest time on a working day to guarantee engineer on site same day

Base of engineer to service this site

How many other sites does he/she service

Number of engineers available to service this site

All spare parts included YES / NO*

**Delete as applicable*



Appendix 2 **Technical Specification template (TST)**

Please list any parts that are not included that appear on the following lists:

Ten most used commodities by volume

Description, Part No., Delivery lead time, Price (exc. VAT)

1.
2.
3.
4.
5.
6.
7.
8.
9.
10.

Most used commodities by value:

Description, Part No., Delivery lead time, Price (exc. VAT)

1.
2.
3.
4.
5.
6.



Appendix 2 **Technical Specification template (TST)**

Location of spare parts

Delivery lead time for spare parts

*Is Remote Maintenance and Diagnosis via modem available: YES / NO**

Price for supply and installation: £

*Software Upgrades (during warranty or maintenance contract period): Safety / Defect Upgrades
Free of charge / At cost**

*New Applications Free of charge / At cost**

**Delete as applicable*

Annual maintenance contract costs including validation to the latest WHTM

Contract price for one year £ exc.VAT

Five year maintenance contract £ exc. VAT

Annual maintenance contract costs excluding validation:

Contract price for one year £ exc. VAT

Five year maintenance contract £ exc. VAT

Contract price for five years paid annually (including warranty)

The maintenance contract will be at this price with no price increases. These costs are not to form part of the total costs but are to be provided as options for considerations.



Appendix 2 **Technical Specification template (TST)**

Service Requirements

The following information shall be provided by the Supplier for each type of machine supplied (Based on a standard cycle being processed).

Service Requirements

Machine number

Water flow rate

Water supply pressure

Water consumption per cycle

Drain flow rate

Drain size

Drain type

Drain vent size and type

Compressed air flow rate

Compressed air supply pressure

Compressed air consumption per cycle

Electricity voltage

Electricity current

Electricity maximum power kW

Air filter (air removal) expected life

Test procedure(s) for filter integrity



Appendix 2 **Technical Specification template (TST)**

If steam heating is used:

Steam flow rate – average

Steam flow rate – maximum

Steam consumption per cycle

Steam supply pressure

Safety valve outlet size

Condensate flow rate

Sound power per washer-disinfector

Total sound power all specified washer-disinfector(s)

Process chemical cost per cycle:

Other

Cost per cycle

Total energy cost per cycle (please specify cycle type)

Overall Washer Disinfector Dimensions

The following information shall be provided by the Supplier.

M/C no

Internal chamber dimensions (H x W x L) mm

Max floor area

Height

Max floor

Loading

Force kN/m²



Appendix 2 **Technical Specification template (TST)**

Max fascia opening

Porterage details

Total cost of processing a typical operational cycle to the requirements identified in WHTM 01-01 Part D, on a configuration suitable for typical devices reprocessed within the departmental (including energy and process chemical costs:

Energy cost basis:

Mains cold water £ /m³

Hot water £ /m³

Electricity p/kWh

Steam £ /1000kg

Other

Overall Cycle(s) Time(s)

Note: For continuous process machines this should be expressed as the time from the first basket in to the last basket exit for a production load.

The following information shall be provided by the Supplier:

Load (including number of baskets) Maximum Cycle Time

Details (including weight and dimensions)

Heat Emission

The following information shall be provided by the Supplier.

Heat emission during normal operation at ambient temperature of

25°C: to fascia - with door(s) closed W

to plant area W



Appendix 2 **Technical Specification template (TST)**

Contract Completion

The following information shall be provided by the Supplier.

Time required from receipt of order in works weeks

Time required for installation andweeks

Pre-commissioning on site

Time required for commissioning on siteweeks

Detailed Cost Breakdown

The following information shall be provided by the Supplier.

Item Washer Disinfector Type Model

Name/No

No. of **Agreed NHS Supply Chain contract prices**

Discount % Unit total Price

Chamber Furniture

Trolleys £ Numbers of

Carriages £ Numbers of

Total costs£

WD 1 £

WD 2 £

WD 3 £

WD 4 £

WD 5 £

WD 6 £

Total costs£



Summary of Tender

The following information shall be provided by the Supplier.

Supply (Nos. of) washer disinfectors(s) ex works

Delivery, offloading & positioning of WD(s)

Installation of WD(s)

Supply and installation of services

Supply and installation of fascia panelling

Site commissioning, i.e. installation checks and tests

Test equipment, test loads and materials (if required)

12 months service including 4 off quarterly visits

Staff training, consisting of days

Supply chamber furniture type

Costs of consumables

Costs of cleaning solutions, detergents, etc.

Monitoring equipment

Supply set(s) of recommended service spares

Contingency - to be set by Purchaser

Sub-Total **VAT @** %



Appendix 2 **Technical Specification template (TST)**

Hospital:

Site:

Department:

Total £

Comments:

.....

.....

.....

.....

.....

Date of tender:



References

Acts and Regulations

All the acts and regulations shown below can be accessed from the www.legislation.gov.uk/ website

Control of Substances Hazardous to Health Regulations (COSHH)

Electromagnetic Compatibility Regulations Machinery Regulations

Manual Handling Operations Regulations Medical Devices Regulations

Pressure Equipment Regulations Pressure Systems Safety Regulations

Water Supply (Water Fittings) Regulations

British Pharmacopoeia

<http://www.pharmacopoeia.co.uk/>

British Standards Institution

<http://shop.bsigroup.com/en/>

BS 853-1 Specification for vessels for use in heating systems Calorifiers and storage vessels for central heating and hot water supply

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

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

BS 1752, ISO 4793 Specification for laboratory sintered or fritted filters including porosity grading

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

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

BS 5404-2 Specification for plastics laboratory ware Graduated measuring cylinders

BS 6068-2.29:1987, ISO 8288-1986 Water quality. Physical, chemical and biochemical methods Determination of cobalt, nickel, copper, zinc, cadmium and lead: flame atomic absorption spectrometric methods

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

BS EN 55014-1 Electromagnetic compatibility. Requirements for household appliances, electric tools and similar apparatus Emission

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



References

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

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

BS EN 61010-1 Safety requirements for electrical equipment for measurement, control, and laboratory use
General requirements

BS EN 61010-2-040:2005 Safety requirements for electrical equipment for measurement, control and laboratory use Particular requirements for sterilisers and washer-disinfectors used to treat medical materials
Replaces IEC 61010-2-045

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

BS EN ISO 4788 Laboratory glassware. Graduated measuring cylinders

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

BS EN ISO 14644-1:2015 Cleanrooms and associated controlled environments. Classification of air cleanliness

BS EN ISO 15883-1 Washer-disinfectors. General requirements, terms and definitions and tests

BS EN ISO 15883-2 Washer-disinfectors. Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.
ISO/TS 15883-5 ISO/TS15883-5:2005 Washer-disinfectors Part 5: Test soils and methods for demonstrating cleaning efficacy

Health & Safety Executive
www.hse.gov.uk/index.htm

Control of Substances Hazardous to Health (COSHH). <http://www.hse.gov.uk/coshh/>



References

Healthcare guidance and publications

The publications below are available from the NHS Wales Shared Services Partnership - Facilities Services websites Intranet : howis.wales.nhs.uk/whe

Internet: www.wales.nhs.uk/whe

Health Building Note 13 – Sterile services department

Welsh Health Technical Memorandum 02-01 ‘Medical gas pipeline systems’

Health Technical Memorandum 03-01 Part B ‘Specialised ventilation systems in healthcare’

International Standards

http://www.iso.org/iso/home/store/catalogue_ics.htm

ISO 554 - Standard atmospheres for conditioning and/or testing – Specifications
Medicines and Healthcare Products Regulatory Agency (MHRA)

www.mhra.gov.uk

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