Washer-disinfectors

Validation and verification

Health Technical Memorandum 2030

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Health Technical Memoranda (HTMs) give comprehensive advice and guidance on the design, installation and operation of specialised building and engineering technology used for the delivery of healthcare.

They are applicable to new and existing sites, and are for use at various stages during the inception, design, construction, refurbishment and maintenance of a building.

Health Technical Memorandum 2030 is being published in three volumes.

**Operational management** is a summary of the information required by personnel responsible for the management of facilities in which washer-disinfectors are used. It discusses the various types of washer-disinfectors, for both clinical and laboratory use, and also contains guidance on legal and policy matters, and on the appointment and responsibilities of personnel. It covers all aspects of routine operation and maintenance stressing the need for a planned maintenance programme along with the type of records to be kept. Advice on the safe and efficient operation of washer-disinfectors is given, as well as procedures for reporting defects and accidents. It should be read by anyone consulting this memorandum for the first time;

**Design considerations** contains information relevant to the specification and installation of new washer-disinfectors. It discusses the requirements for each type of washer-disinfector and outlines the specifications to be included in any contract. Practical considerations for the installation of washer-disinfectors are discussed including siting, heat emission, ventilation, noise and vibration, and mains services with an emphasis on steam quality;

**Validation and verification** covers all aspects of validation and periodic testing of washer-disinfectors. It includes detailed schedules and procedures for tests and checks to be carried out for commissioning and performance qualification and for subsequent periodic testing.
Executive summary

HTM 2030 gives guidance on the choice, specification, purchase, installation, validation, periodic testing, operation and maintenance of washer disinfectors (WDs) in use in the National Health Service for processing medical devices, laboratory ware and sanitary products. No guidance is given on WDs intended for use in processing textiles or for dishwashers in general catering applications.

This volume is intended as a guide for technical personnel with appropriate training and experience and also for users responsible for the day to day running of WDs. It will also be of interest to architects, planners, estates managers, supplies officers, and others in both the public and private sectors.

Detailed information on the planning and design of a sterile services department, including the provision of WDs, is given in Health Building Note 13 – ‘Sterile services department’. (Scottish Hospital Planning Note 13 applies to the NHS in Scotland.) Guidance for laboratory installations can be found in Health Building Note 15 – ‘Accommodation for pathology services’ (Scottish Hospital Planning Note 15 applies to the NHS in Scotland).

Although this edition of HTM 2030 reflects current WD technology it is recognised that considerable scope exists for improvements in the operational and management technology used with WDs.

The current British Standards for WDs, although only in force since 1993, are expected to be replaced by European Standards within the next two to three years. These Standards include consideration of the requirements arising as a result of European Union Directives on medical devices which are of concern for WDs in two ways; firstly, some WDs will themselves be considered to be medical devices and therefore must meet the relevant requirements of the Medical Devices Directive and secondly, the manufacturer of a medical device which is intended to be reprocessed is required to specify the method to be used for reprocessing which will include any necessary washing and disinfecting stage.

When practicable the information in this HTM has been aligned with existing or anticipated Standards and advice is offered when no standard has yet been formulated.

The WDs described in this HTM may not be suitable, without modification, for safely processing articles contaminated with either Hazard Group 4 pathogens or with agents which are unusually resistant to disinfection.

The guidance previously given in ‘Management policy’ has been incorporated into ‘Operational management’.
About this publication

Executive summary

1.0 General  page 5
1.1 Introduction
1.4 Legal framework for washing and disinfection
1.7 Medicinal products
1.11 Medicinal devices
1.16 Published Standards
1.22 Personnel
1.39 Water supply
1.40 Safety
1.41 Chemical additives
1.45 Infectious materials

2.0 Testing of washer-disinfectors  page 10
2.1 Introduction
2.11 Responsibilities
2.12 Purchaser
2.16 Manufacturer
2.18 Contractor
2.20 Validation
2.21 Works test
2.24 Commissioning
2.26 Installation tests
2.31 Operational tests
2.33 Performance qualification
2.36 Documentation
2.37 Summary sheets
2.40 Validation reports
2.46 Periodic tests
2.50 Revalidation
2.53 Repeat validation
2.56 Types of test
2.58 Procedure on failure of a test
2.63 Inter-relationship of test programmes

3.0 Schedule of type tests and works tests  page 19
3.1 Introduction
Table 1: Summary of manufacturer’s test programmes for WDs

4.0 Schedule of installation tests  page 21
4.1 Introduction
4.6 Checks on ancillary equipment
4.9 Engineering services
4.10 Additional checks for WDs using a chemical disinfectant
4.14 Checks on the WD

4.14 Preliminary checks
4.16 Functional checks
4.18 Response to external faults

5.0 Schedule of operational tests  page 25
5.1 Introduction
Table 2a: WDs for human-waste containers
Table 2b: WDs for surgical instruments
Table 2c: WDs for hollowware
Table 2d: WDs for anaesthetic accessories
Table 2e: WDs for endoscopes
Table 2f: WDs for laboratory use
Table 2g: Ultrasonic cleaners

6.0 Schedule of performance qualification tests  page 33
6.1 Introduction
6.14 Loading conditions
6.19 Surrogate devices
6.24 Cleaning efficacy tests
6.24 Native soiling
6.29 Test soils
6.34 Standard test soils
6.36 Process residues
6.40 Disinfection
6.40 Thermometric tests
6.42 Microbiological tests
Table 3: Thermal disinfection temperature bands
6.44 Load dryness tests
6.46 PQ report
6.49 Master Process Record
6.54 Tests for performance requalification
Table 4a: WDs for human-waste containers
Table 4b: WDs for surgical instruments
Table 4c: WDs for hollowware
Table 4d WDs for anaesthetic accessories
Table 4e: WDs for endoscopes
Table 4f: WDs for laboratory use
Table 4g: Ultrasonic cleaners

7.1 Introduction  page 42
7.8 Weekly safety checks
7.10 Yearly safety checks
Table 5a: WDs for human-waste containers
Table 5b: WDs for surgical instruments
Table 5c: WDs for hollowware
Table 5d WDs for anaesthetic accessories
Table 5e: WDs for endoscopes
Table 5f: WDs for laboratory use
Table 5g: Ultrasonic cleaners
8.0 Test equipment and materials  page 53
8.1 Introduction
8.6 Calibration and sources of error
8.11 Recorders
8.18 Temperature measurement
  8.18 Temperature sensors
  8.21 Thermometric recording instrument(s)
  8.26 Use of sensors
  8.31 Calibration
  8.35 Self-contained systems
8.42 Pressure measurement
  8.43 Transducers
  8.44 Gauges
8.50 Flow measurement
  8.50 Water
  8.55 Chemical additives
8.61 Volume measurement
8.66 Humidity measurement
8.68 Other instruments
  8.68 Sound level meter
  8.69 Balance
  8.71 Gas monitoring equipment
  8.74 Aerosol generator
  8.76 Particle counting photometer
Table 6: Requirements for pressure measurement
8.79 Volume measurement
9.0 Testing methods  page 64
9.2 Terminology
  9.3 Cycle variables
  9.8 Disinfection conditions
9.17 Drainage
  9.17 Drain seal integrity
  9.25 Blocked drain protection
  9.38 Free draining
  9.40 Purging of the trap
  9.43 Efficacy of discharge through the trap
  9.49 Estimation of dead volume of pipework
9.57 Venting system
  9.57 Steam venting
  9.61 Load contamination from ductwork
9.69 Water system
  9.89 Water supply temperature
  9.94 Water supply pressure
  9.100 Appearance
  9.106 pH
  9.112 Electrical conductivity
  9.123 Total dissolved solids
  9.140 Hardness
  9.153 Chloride
  9.164 Heavy metals
  9.167 Iron
  9.176 Phosphate
  9.188 Silicate
  9.201 Bacterial endotoxins
  9.213 Total viable count
  9.227 Environmental mycobacteria
9.237 Overflow test
9.245 Volume of water used per stage
9.253 Doors and door interlocks
  9.253 Cycle start interlock
  9.257 In-cycle interlock
  9.260 Double ended WDs
  9.264 On sensor failure
  9.266 Door opening force
  9.271 Failed cycle interlock
  9.274 Fault indication on sensor failure
9.279 Chemical dosing
  9.279 Reproducibility of volume admitted
  9.285 Indication of insufficient chemical additives
9.290 Emissions
  9.290 Water vapour emission
  9.298 Aerosol emissions
  9.308 Chemical vapour emission
9.311 Instrumentation fitted to WD
9.313 Load carriers
9.316 Thermometric tests
  9.317 Chamber wall temperature
  9.323 Load carrier temperature
  9.330 Over-temperature cut-out
9.336 Load dryness
9.343 Residual chemical additives
9.349 Air quality
9.353 Sound pressure test
9.360 Electromagnetic compatibility
10.0 Cleaning efficacy tests  page 106
10.1 Introduction
10.2 Type tests
10.7 Operational tests
  10.9 Test soil
  10.14 Test loads
  10.16 Procedure for chamber walls and load carriers
10.25 Performance qualification tests
10.37 Periodic tests
  10.37 Tests for residual soil: the ninhydrin method
10.50 Visual inspection
11.0 Disinfection efficacy tests  page 112
11.1 Introduction
11.2 Test for thermal disinfection
11.4 Thermometric test for disinfection
11.12 Microbiological test for performance qualification
12.0 Automatic control test  page 119
12.1 Introduction
12.4 Test procedure
13.0 Specific tests for WDs for human-waste containers  page 121
13.1 Introduction
13.4 Test for flushing of toilet tissues
13.15 Test for flushing of non-absorbent materials
13.21 Test for safety of loading and/or emptying of containers
13.26 Reference test loads
13.29 Test soil
  13.29 Bedpan soil
  13.36 Urine bottle soil
13.43 Performance qualification tests

14.0 Specific tests for WDs for surgical instruments  
page 127
14.1 Introduction
14.5 Water quality
14.8 Reference test loads
14.12 Test soil
14.19 Performance qualification tests

15.0 Specific tests for WDs for hollowware  
page 130
15.1 Introduction
15.4 Reference test loads
15.6 Test soil
15.13 Performance qualification tests

16.0 Specific tests for WDs for anaesthetic accessories  
page 133
16.1 Introduction
16.5 Reference test loads
16.6 Test soil
16.14 Performance qualification tests

17.0 Specific tests for WDs for endoscopes  
page 136
17.1 Introduction
17.3 WD self-disinfection test
17.16 Final rinse decontamination test
17.19 Channel patency detection test
17.23 Disinfectant concentration test
17.33 Reference test loads
17.34 Test soil
17.41 Microbiological test of disinfection efficacy
17.43 Performance qualification tests

18.0 Specific tests for WDs for laboratory use  
page 143
18.1 Introduction
18.3 Reference test loads
18.4 Test soil
18.11 Performance qualification tests

19.0 Specific tests for ultrasonic cleaners  
page 145
19.1 Introduction
19.3 Test for ultrasonic activity
19.18 Reference test loads
19.22 Test soil
19.29 Performance qualification tests

Appendix I: Glossary  page 149

Appendix II: Abbreviations  page 152
Appendix III: Useful addresses  page 154
References  page 156
About NHS Estates  page 163
1.0 General

Introduction

1.1 This volume of HTM 2030 covers the validation and periodic testing of the various types of washer disinfectors (WDs) used in hospitals, laboratories and other healthcare facilities.

1.2 Terminology used in washing and disinfection has long been inconsistent and this has often led to ambiguities. This HTM introduces a set of terms which, it is hoped, will provide workers in the field with a vocabulary that will be consistent with the European Union (EU) Standards that are to be introduced in the near future. The glossary provides a definition of terms referred to in this volume of HTM 2030.

1.3 References for all the documents referred to in this volume and other selected documents that provide additional information of which the reader should be aware are contained at the end of this volume.

Legal framework for washing and disinfection

1.4 WDs are used in relation to both medical devices and medicinal products as well as for sanitary equipment, laboratory equipment and cutlery/crockery.

1.5 They may be used for reprocessing, within their intended use, medical devices, sanitary equipment, laboratory equipment, manufacturing equipment (for use in the manufacture of medicinal products or medical devices) or cutlery and crockery.

1.6 They may also be used as part of the manufacturing process for medical devices, medicinal products, in vitro diagnostics or laboratory products in processing ‘single-use’ products or components such as bottles and vials.

Medicinal products

1.7 The manufacture and supply of medicinal products are controlled by extensive legislation based on EU Directives on medicinal products and enacted in the UK by the Medicines Act and a number of Regulations.

1.8 The requirements for the manufacture and supply of medicinal products are set out in the ‘Guide to good manufacturing practice for medicinal products’ (GGMP) published in Volume IV of ‘The rules governing medicinal products in the European Community’.

1.9 The GGMP contains guidance on cleaning of components and manufacturing equipment which have implications for the design, installation and operation of WDs. When a WD is to be installed for processing containers, components or manufacturing equipment for use with medicinal products the GGMP should be consulted at an early stage.
1.10 Guidance on the application of medicines legislation to particular cases is beyond the scope of this HTM and advice should be sought from the Medicines Control Agency (MCA) when necessary.

Medical devices

1.11 HTM 2030 ‘Operational management’ refers to the three European Directives on the manufacture and supply of medical devices and in vitro diagnostics.

1.12 Whether, and if so under what circumstances, the Medical Devices Directive applies to medical devices which are being reprocessed for further use, either within a particular healthcare facility or externally under a service contract, is a complex issue beyond the scope of this HTM. If necessary, further guidance is given in the MDA Directives Bulletin 18.

1.13 The essential requirements of the Medical Devices Directive require, inter alia:

- that devices and manufacturing processes be designed to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties (Annex I, paragraph 8.1)
- that devices must be designed manufactured and packed in such a way as to minimise the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients (Annex I, paragraph 7.2)

1.14 There is no direct equivalent of the GGMP for medical devices. The same role is fulfilled by general Quality System Standards (the BS EN ISO 9000 series), supplemented by Standards tailoring the requirements specified in the general standard for medical devices (BS EN 46001 and BS EN 46002) and Standards providing guidance on compliance with these Standards (EN 724 and EN 50103).

1.15 These are mandated Standards and as such compliance with them affords the presumption of conformance with the relevant essential requirements of the Directive.

Published Standards


1.17 There are no European Standards, as yet, for WDs. CEN Technical Committee TC102 is developing a series of mandated Standards relevant to the Medical Devices Directive for WDs. There are four parts with the working titles ‘General Requirements’, ‘Washer-disinfectors for human-waste containers’, ‘Washer-disinfectors for medical devices and surgical instruments’ and ‘Washer-disinfectors for thermolabile medical devices (for example endoscopes)’.

1.18 IEC Technical Committee TC66 is developing Standards for ‘Safety requirements for washer-disinfectors’.
1.19 When published, compliance with these Standards may be used to give a presumption of conformance to the relevant requirements of the Medical Devices Directive.

1.20 This edition of HTM 2030 has been written while the new Standards are in the course of development. The guidance given here is designed to be broadly consistent with the emerging Standards but HTM 2030 should not be regarded as a substitute for the Standards themselves when ascertaining compliance with the EU Directives and the UK Regulations that implement them.

1.21 If the WD is purchased with the intention of processing both medical devices and components, or equipment for use in the manufacture of medical products, purchasers should ensure that the requirements for both types of load are met.

Personnel

1.22 The following personnel are referred to in this volume of HTM 2030. Further information, including qualifications and areas of responsibility, can be found in HTM 2030 ‘Operational management’ and in Part 1 of HTM 2010.

1.23 Management is defined as the owner, occupier, employer, general manager, chief executive or other person of similar authority who is ultimately accountable for the operation of the premises. Depending on the nature of the organisation, this role may be filled by the general manager, chief executive, laboratory director or other person of similar authority. In small autonomous units the user may take on this function.

1.24 The User is defined as the person designated by management to be responsible for the management of the WD. In a hospital the user could be a sterile services manager, theatre manager, endoscopy clinic manager, ward manager or laboratory manager; in primary care he or she could be a general practitioner, dentist or other health professional. When a WD is used to process equipment or containers for use in the preparation of medicinal products the user is normally the production manager in charge of the manufacturing process.

1.25 The Competent Person (Pressure Vessels) is defined as a person or organisation designated by management to exercise certain legal responsibilities with regard to the written scheme of examination of any pressure vessel associated with a WD described in the ‘Pressure Systems and Transportable Gas Containers Regulations 1989’. The shorter term ‘competent person’ is used in this HTM.

1.26 The Authorised Person (Sterilizers) is defined as a person designated by management to provide independent auditing and advice on sterilizers and sterilization and to review and witness validation. (see HTM 2010 Part 1 for a full definition of the responsibilities of the Authorised Person (Sterilizers) with respect to sterilizers and the qualifications and experience required). Authorised Persons (Sterilizers) are also able to provide independent auditing and advice on washing and disinfection and WDs and to review and witness validation of these processes and machines. The abbreviation AP(S) is used in this HTM.
1.27 At the discretion of management the function of the AP(S) may be carried out by an independent person, not registered as an AP(S), but who can demonstrate, to the satisfaction of management, previous training and experience appropriate to carry out the designated tasks in respect of WDs.

1.28 The Test Person (Sterilizers) is defined as a person designated by management to carry out validation and periodic testing of sterilizers. (see HTM 2010 Part 1 for a full definition of the responsibilities of the Test Person (Sterilizers) with respect to sterilizers and the qualification and experience required). Test Persons (Sterilizers) who have received appropriate training should be designated to carry out validation and periodic testing of WDs. The abbreviation TP(S) is used in this HTM.

1.29 The Maintenance Person (Sterilizers) is defined as a person designated by management to carry out maintenance and periodic testing on sterilizers. (see HTM 2010 Part 1 for a full definition of the responsibilities of the Maintenance Person (Sterilizers) with respect to sterilizers and the qualifications and experience required). Maintenance Persons (Sterilizers) who have received appropriate training should be designated to carry out validation and periodic testing of WDs. The abbreviation MP(S) is used in this HTM.

1.30 The Microbiologist (Sterilizers) is defined as a person designated by management to be responsible for advising the user on microbiological aspects of the sterilization of non-medicinal products. They should also be defined as the persons responsible for advising the user on the microbiological aspects of handling, washing and disinfecting used medical devices. The shorter term ‘microbiologist’ is used in this HTM.

1.31 The Control of Infection Officer is defined as the person designated by management to be responsible for advising the user on all infection control aspects.

1.32 The Production Manager is defined as a person designated by management to be responsible for the production of medicinal products or medical devices.

1.33 The Quality Controller is defined as a person designated by management to be responsible for quality control of medicinal products and/or medical devices with the authority to establish, verify and implement all quality control and quality assurance procedures.

1.34 The Laboratory Safety Officer is defined as a person designated by management to be responsible for all aspects of laboratory safety including equipment, personnel and training relating to safety matters, and ensuring compliance with safety legislation and guidelines.

1.35 An Operator is defined as any person with the authority to operate a WD. Their duties may include the noting of WD instrument readings, replenishment of consumable items such as detergent, and simple housekeeping duties.

1.36 The Manufacturer is defined as the person or organisation responsible for the manufacture of a WD.

1.37 The Contractor is defined as a person or organisation designated by management to be responsible for the supply and installation of the WD, and for carrying out the installation checks and tests. The contractor is usually the manufacturer of the WD.
1.38 The Purchaser is defined as the person or organisation who orders the WD and is responsible or paying for it.

Water supply

1.39 All the organisations responsible for water supply have the statutory power to make and enforce byelaws to prevent waste, excessive consumption, misuse or contamination of the water supply. The Model Water Byelaws form the basis of such byelaws. WDs must be designed, constructed, installed, operated and maintained in accordance with the requirements of the relevant byelaws.

Safety

1.40 Guidance on the safe operation of the various types of WD is given in HTM 2030 ‘Operational management’. As far as testing is concerned, normal safety precautions are adequate except in the case of WDs using liquid chemical germicides. In this case users are recommended to operate a permit-to-work system to ensure that such WDs are declared safe to work on, and that personnel working on them have documented authority to do so.

Chemical additives

1.41 Many of the chemical additives used in WDs and their associated ancillary equipment, for example water treatment plant, are corrosive, toxic or otherwise hazardous and require special provision for their storage and use.

1.42 The ‘Control of Substances Hazardous to Health (COSHH) Regulations’ place upon management an obligation to ensure that suitable measures are adopted to protect their staff and others affected by the work activity. These methods may include both safe systems of work and the provision of a special ventilation system.

1.43 Some of the substances which may be used in WDs, in particular those employing chemical disinfection or sterilization, have Occupational Exposure Limits (OEL) set out in Guidance Note EH40 published annually by the Health and Safety Executive. These limits are statutory maxima but should not be regarded as representing a safe working exposure. Employers have a legal obligation to ensure that exposure is reduced as far as reasonably practicable.

1.44 The WD, including any special ventilation equipment necessary for its safe operation will be subject to the COSHH Regulations. These Regulations introduced controls on biological agents which are of relevance to purchasers of WDs. Detailed guidance on ventilation systems is provided in HTM 2025.

Infectious materials

1.45 All WDs have the potential to process infectious materials. The user should therefore ensure that personnel working on WDs wear appropriate protective clothing and are fully informed of any hazards that may be present. In case of doubt the microbiologist should be consulted.
2.0 Testing of washer-disinfectors

Introduction

2.1 WDs are used to carry out the processes of cleaning and disinfection consecutively.

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 have to be validated before use, the performance of the process monitored during routine use, the calibration of controls and instrumentation verified, and the equipment subjected to a suitable maintenance programme.

2.5 The control protocols described in this volume of HTM 2030 provide the means for ensuring that the WD is fit for its intended purpose and includes tests and checks carried out during manufacture, after delivery, during validation and periodically thereafter. Tests are also required before a WD is returned to service after repairs that affect one or more components which influence the attainment of critical process control variables or after modification.

2.6 The control protocol is based on four key aspects to ensure that the required standards of performance and safety are met and sustained:
   a. all WDs are subjected to a planned programme of tests to validate their performance, that is, to provide experimental evidence that, when operated under the specified conditions, the WD will reliably produce cleaned and disinfected items to the standard required;
   b. all WDs are subjected to a planned programme of tests to monitor their performance;
   c. all WDs are operated in accordance with an agreed procedure by staff trained in the use of the WD;
   d. all WDs are subjected to a planned programme of preventive maintenance irrespective of whether a preventive maintenance scheme is operated on the premises.

2.7 Expertise on all aspects of the operation and testing of WDs should be available on two levels: the Authorised Person (Sterilizers) (AP(S)) and the Test Person (Sterilizers) (TP(S)).

2.8 The scheduled test programmes include simple tasks to be undertaken by the user as well as more complex tests undertaken by the TP(S).
2.9 Schedules for pre-delivery works tests (when necessary), installation checks, validation tests and periodic tests are presented in Chapters 3, 4, 5 and 6 of this document, and discussed below. When appropriate, the schedules refer to detailed test procedures described in later chapters.

2.10 Maintenance of WDs is dealt with in HTM 2030 ‘Operational management’.

Responsibilities

2.11 WDs should be subjected to a planned programme of testing both before delivery and on-site. The on-site testing should be carried out using the procedures described in this HTM and should include installation qualification, operational qualification and process qualification. The purchaser, manufacturer and contractor have distinct responsibilities.

Purchaser

2.12 Management should nominate, when necessary, an AP(S) to provide advice on validation and a TP(S) to carry out the checks and tests required.

2.13 The AP(S) should review the results of pre-delivery works tests carried out by the manufacturer, and review the test instruments provided by either or both the contractor (see paragraph 1.37) and the TP(S) to ensure that their accuracy, calibration and condition meet the standards for test instruments described in Chapter 8.

2.14 The TP(S) should witness the installation checks and tests carried out by the contractor, including ensuring that the calibration of each test instrument provided by the contractor has been checked on site and is satisfactory and arrange for test loads to be supplied as required.

2.15 The TP(S) should carry out the operational qualification and performance qualification tests.

Manufacturer

2.16 The manufacturer should ensure that the WD is designed, manufactured and tested within a quality system complying with the requirements of BS EN ISO 9001 or BS EN ISO 9002.

2.17 The manufacturer should carry out pre-delivery works testing. The extent of testing will depend on whether the product is in serial production or a ‘one off’ and, for machines in serial production, whether the manufacturer has obtained a certificate of compliance to a relevant British or European Standard by means of a type test for the particular type and size of WD.

Contractor

2.18 The contractor, who may also be the manufacturer, should complete the installation checks and tests specified in Chapter 4 to the satisfaction of the TP(S) before the WD can be accepted for use in accordance with the contract.
2.19 The contractor should provide the test instruments and equipment (but, unless otherwise specified in the contract, should not be expected to provide the test loads). The test instruments provided should meet the standards for test instruments described in Chapter 8.

Validation

2.20 Validation is the documented procedure required for obtaining, recording and interpreting the results needed to show that a process will consistently yield a product complying with a pre-determined specification. Validation is a total process beginning with a review of the specification against which the equipment is purchased. This is to ensure that it will meet the user’s specified production needs including installation qualification, operational qualification and performance qualification. Installation qualification and operational qualification are sometimes referred to jointly as ‘commissioning’.

![Validation Process Diagram]

Figure 1 The validation process

Works tests

2.21 Before delivery of the WD, the manufacturer should subject the machine to a programme of factory tests. The extent of these tests will depend on whether the WD is in serial production or is a unique design (a ‘one-off’). For machines in serial production the works tests are intended to verify that, in respect of various critical attributes, the WD performs in conformity with the results obtained from type testing. It is rarely necessary to attend the factory to witness works tests but the manufacturer should make the results of these tests available on or before delivery of the WD.

2.22 For ‘one-off’ designs a more extensive programme of works tests, similar to the programme of type tests for machines in serial production, is required and the purchaser may wish to arrange for their representative (either the AP(S) or TP(S)) to attend the factory to witness these tests before accepting delivery of the WD.

2.23 The schedule for type test and works tests is set out in Chapter 3.
**Commissioning**

2.24 Commissioning is defined as the process of obtaining and documenting evidence that the equipment has been provided and installed within the agreed purchase specification, and that it functions within pre-determined limits when operated in accordance with the manufacturer’s instructions.

2.25 Commissioning consists of a series of installation tests to be carried out by the contractor and operational tests to be carried out by the TP(S).

**Installation tests**

2.26 The contractor should carry out the required installation checks on delivery of the WD, to ensure that the WD has been supplied and installed correctly, is safe to operate, has been provided with satisfactory services that do not impair the performance of the WD, and that in operation the WD does not interfere with other equipment.

2.27 Ancillary equipment such as service supplies and ventilation systems should checked by the contractor responsible for their installation.

2.28 When these checks have been completed and found satisfactory the contractor should carry out the installation tests necessary to demonstrate that the WD is working satisfactorily. The contractor is not required to carry out any thermometric tests unless these were specified in the purchase contract. Any assistance required from the purchaser should be agreed as part of the purchase contract.

2.29 If any modification, maintenance or repair work is carried out on the steam, water, compressed air ventilation or drainage systems after the installation tests have been completed, the relevant installation tests should be repeated before the operational tests are undertaken.

2.30 The schedule for installation checks and tests is set out in Chapter 4.

**Operational tests**

2.31 When the WD has been installed and accepted the TP(S) should carry out a sequence of operational performance tests to evaluate the basic performance and safety of the WD. Some of these tests are identical to those specified as installation tests and need not be repeated if operational testing follows within ten working days of the completion of the installation tests.

2.32 The schedule for operational tests is set out in Chapter 5.

**Performance qualification**

2.33 Performance qualification is defined as the process of obtaining documented evidence that the equipment, as commissioned, will produce an acceptable product when operated in accordance with the specification.
2.34 Performance qualification consists of tests designed to show that:

a. soil removal and cleaning have been effective throughout the load and the WD chamber, and the products are of the required standard of cleanliness, free from process residues (when applicable);

b. disinfection conditions have been attained throughout the load and the WD chamber, and to the required standard for the type of load being processed. A thermometric test is sufficient for WDs employing a thermal disinfection process. Additional microbiological tests will be required for WDs that use chemical disinfectants and may be necessary for WDs where the nature of the load or loading conditions do not permit thermometric monitoring which accurately reflects the conditions pertaining in the load.

2.35 In principle, it might be argued that a performance qualification test is required for each loading condition that a WD is required to process. In practice, it is possible to identify reference loads and reference loading conditions which present an equal or greater challenge to the process than the loads which may be encountered in normal use.

Documentation

2.36 Accurate and efficient record keeping is an essential part of the management of a WD. The extent and nature of the records that are necessary varies with the type of WD and the use to which it is put. Guidance is given in HTM 2030 ‘Operational management’.

Summary sheets

2.37 On completion of the validation process, and before leaving the premises, the TP(S) should prepare a summary report containing the results of the commissioning and performance qualification tests and essential working data.

2.38 The summary report should be signed by the TP(S) and countersigned by the user to certify that the WD is fit for use.

2.39 Summary reports should be securely retained by the user and be available for ready reference.

Validation report

2.40 Within one month of the completion of the validation process the TP(S) should prepare a full validation report which should include:

a. all the data supplied by the contractor, collected during the installation checks and tests with written confirmation that they meet the manufacturer’s specification;

b. written confirmation that the calibration of all measuring instruments fitted to the WD have been verified;

c. all the data collected during the commissioning tests, with written confirmation that they meet the specified requirements;

d. data showing the correlation between the performance of the measuring instruments fitted to the WD and the test instruments used during commissioning and performance qualification;
e. reports containing all the data collected during the performance qualification tests with written confirmation from the TP(S) and the user of the loading conditions and types of load (including when necessary reference to specific individual items) which may be satisfactorily processed in the WD.

2.41 When data is in the form of electronic data files, the report should include copies of disks or tapes containing the data in a format agreed with the user and a print out of the directory of each, annotated to show where the data for each test is to be found.

2.42 The TP(S) should certify that all necessary tests have been carried out and that the results were satisfactory.

2.43 The records of any microbiological tests should be signed by the microbiologist.

2.44 The AP(S) should review and countersign the completed validation report.

2.45 The validation report should be retained by the User. Copies may be retained as necessary by the TP(S), the AP(S), the microbiologist and, where applicable, the quality controller.

**Periodic tests**

2.46 After validation and when the WD is passed into service, it should be subject to a schedule of periodic tests at daily, weekly, quarterly and yearly intervals.

2.47 The user and the TP(S) are responsible for the periodic tests.

2.48 The daily, weekly and quarterly test schedules provide evidence that the WD continues to operate within the limits established during commissioning.

2.49 The yearly test schedule is a revalidation procedure and provides a more comprehensive test programme than the other periodic tests; it serves to demonstrate that data collected during commissioning and the performance qualification remain valid.

**Revalidation**

2.50 In addition to annual revalidation, revalidation is required under the following circumstances:

a. when the WD is to be returned to service after repair or component replacement of part of the systems which affect satisfactory attainment of the pre-set variables of the operating cycle;

b. when the pre-set values of the cycle variables have been modified;

c. when the software in a programmable electronic system (PES), used for control of the process, has been modified;

d. whenever the user or AP(S) advises that revalidation is necessary;
2.0 Testing of washer-disinfectors

2.51 The full revalidation procedure is identical to that specified for the yearly test. See Chapter 7.

2.52 It will not always be necessary to carry out a full revalidation and the advice of the AP(S) should be sought on which tests are required following any particular event.

Repeat validation

2.53 Revalidation and periodic tests are designed to establish the continued conformance of the equipment and its performance with data established during the original validation study.

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

2.55 Repeat validation will be necessary:
   a. when the WD is modified to such an extent that it must be presumed that the original data is no longer valid;
   b. when a WD, other than a table top machine, has been moved and installed at a new site;
   c. when the WD has been dismantled or extensively overhauled;
   d. whenever the user or AP(S) advises that repeat validation is necessary;
   e. whenever it is required by an authorised inspectorate or licensing authority;
   f. whenever revalidation fails to confirm compliance with the original data and no cause for the discrepancy can be found.

It will not always be necessary to carry out a full repeat validation and the advice of the AP(S) should be sought as to which tests are required following any particular event.

Types of test

2.56 The tests listed in the schedules fall into the following categories.

   a. Automatic control tests which are designed to verify the correct functioning of the operating cycle from the readings obtained from the instruments fitted to the WD.

   b. Thermometric tests which are designed to provide assurance that the temperature requirements for disinfection are met by using accurate measuring equipment, independent of the instruments fitted to the WD to monitor the temperatures attained within the chamber and reference loads.

   c. Microbiological tests which are designed to show that disinfection (sterilization) conditions are attained when thermometric methods alone are inadequate for this purpose.
2.0 Testing of washer-disinfectors

d. **Cleaning efficacy tests** which are designed to show, by monitoring the removal of a test soil, that the process will effectively clean products of the type to be processed.

2.57 Other performance tests specific to certain types of WD are designed to provide assurance that the WD will perform correctly under the anticipated conditions of use.

**Procedure on failure of a test**

2.58 There should be no difficulty in ensuring that a correctly installed and maintained WD will comply with both the validation tests and periodic tests described.

2.59 Failure of a test generally indicates that a WD is not working to specification and it should be withdrawn from service and the failure investigated.

2.60 In practice the action to be taken is a matter of judgement and will depend on the nature of the failure and the use to which the WD is being put. It may be acceptable for the WD to continue operating under carefully defined restrictions until the cause of the failure can be established and rectified.

2.61 The AP(S) and the user should agree the course of action to be taken.

2.62 The user has the ultimate responsibility for certifying that the WD is fit for use.

**Inter-relationship of test programmes**

2.63 The tests described in this volume of HTM 2030 are intended for use in type tests, works tests, commissioning (installation and operational tests), and performance qualification (thermometric tests, microbiological tests, cleaning efficacy tests and load dryness tests), and routine periodic tests.

2.64 The inter-relationship 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.

2.65 The circumstances under which each of the test schedules should be applied is given in Table 1 ‘Summary of test programmes for washer-disinfectors’.

2.66 The programmes of tests should be applied to all WDs where relevant. Details are given under the test schedules for particular types of WD.
## 2.0 Testing of washer-disinfector

*Figure 2 Inter-relation of test programmes*

<table>
<thead>
<tr>
<th>Location</th>
<th>Production of WD</th>
<th>Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Factory</td>
<td>Serial Production → 'One-off' WD</td>
<td></td>
</tr>
<tr>
<td></td>
<td>INSTALLATION</td>
<td>Manufacturer</td>
</tr>
<tr>
<td></td>
<td>OPERATIONAL</td>
<td></td>
</tr>
<tr>
<td></td>
<td>PERFORMANCE QUALIFICATION</td>
<td>User</td>
</tr>
<tr>
<td>On-Site</td>
<td>PERIODIC ROUTINE TESTS</td>
<td></td>
</tr>
<tr>
<td></td>
<td>ANNUAL REVALIDATION TESTS</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Commissioning Checks &amp; Tests</td>
<td></td>
</tr>
</tbody>
</table>
3.0 Schedule of type tests and works tests

Introduction

3.1 The manufacturer carries out type tests on representative samples of WDs in serial production to demonstrate compliance of the WD design with its specification and/or published Standards as appropriate.

3.2 The manufacturer carries out works tests on each WD before it leaves the manufacturing site to ensure that each WD meets specification.

3.3 For WDs in serial production the programme of tests required for the works test is usually a reduced set of the tests in the schedule for type testing.

3.4 For WDs of ‘one-off’ design the schedule of works tests would necessarily be the same as the schedule for type testing.

3.5 Type tests, and more rarely works tests on one-off designs, may be carried out or witnessed by a third party to allow certification of the product to a relevant standard eg BS 2745 Part 2 or Part 3. The product certification scheme run by BSI leads to the award of the ‘kitemark’ for certified products. A similar scheme is operated through CEN for products complying with European Standards and compliant products may carry the CEN ‘keymark’. Those clinical WDs which are classified as medical devices and are supplied on, or after, the 14 June 1998 will be required to bear the CEN marking.

3.6 The manufacturer should make available to the purchaser the results of type tests and works tests on or before delivery of the WD.

3.7 It will rarely be necessary for the purchaser, or their representative, to visit the manufacturer’s works to witness works testing except, perhaps, in the case of ‘one-off’ machines. The advice of the AP(S) should be sought.

3.8 A summary of the tests which should be included in a programme of type tests and works tests is shown in Table 1.
### Table 1  Summary of manufacturer’s test programmes for WDs

<table>
<thead>
<tr>
<th>Test</th>
<th>Type Test</th>
<th>Works Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Cleaning efficacy</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Chamber</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Load</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Load carrier</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>2. Thermometric</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Thermal disinfection</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Temperature control</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Over-temperature cut-outs</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Chemical disinfection</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Thermal insulation</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>3. Microbiological</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Disinfection</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>4. Load dryness</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>5. Fluid emission</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chamber leak proof</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Door seal</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Vapour emission</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>6. Sound power</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>7. Electromagnetic interference</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>8. Doors &amp; interlocks</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cycle start</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Loading/unloading</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Opening force</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>With services</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>On fault condition</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>9. Process residuals</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>10. Chemical dosing</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Accuracy and repeatability</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Low level indicator</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>11. Water quality</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Rinse water</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>In relation to performance testing</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Water volume</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>12. Air quality</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>13. Pipework</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Dead volume</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Free draining</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Venting system</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>14. Instrumentation</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Legibility</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Calibration</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>15. Load carriers</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Fitting</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Stability</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Alignment</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Force to move</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Effect in cycle</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>16. Operating cycle</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Spray system</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Reproducibility</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Fault indication</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>
4.0 Schedule of installation tests

Introduction

4.1 On delivery of the WD the contractor should carry out the installation checks included in the contract and as set out in this chapter to establish that:
   a. the WD has been provided and installed correctly;
   b. the WD is safe to operate;
   c. the WD does not interfere with other equipment;
   d. all connected services are satisfactory and do not prevent attainment of the designed cleaning and disinfection performance of the WD.

4.2 The contractor responsible for installing the WD should carry out installation checks on services and other ancillary equipment. These checks should be completed and all services and ancillary equipment found to be satisfactory before carrying out installation checks on the WD itself.

4.3 The contractor responsible for installing the WD should carry out any additional checks specified by the manufacturer.

4.4 The TP(S) should be carry out any checks specified in this chapter which were not included in the purchase contract for the WD.

4.5 As a safety precaution, checks on chemical dosing systems (for chemical additives such as detergents, disinfectants etc) should be carried out using water. Checks on fume extract systems designed to eliminate personnel exposure to hazardous chemicals (for example glutaraldehyde) should be carried out using a non-hazardous substitute or a smoke test.

Checks on ancillary equipment

4.6 Ancillary equipment should, whenever practicable, be installed and commissioned before validation of the WD begins.

4.7 When the checks on ancillary equipment require the WD to be in operation, the TP(S) should carry them out in cooperation with the contractor for the WD.

4.8 The contractor for the WD is not responsible for the correct functioning of services and ancillary equipment unless this was agreed in the purchase contract.
Engineering services

4.9 Check that the following requirements are met.

a. The engineering services have been installed correctly, they are adequate to meet the demands of the WD, they do not leak and all necessary isolating valves/switches and test points have been installed.

b. Drains remove effluent effectively when all plant in the vicinity, including the WD, is connected and operating.

c. The water treatment plant (if fitted) operates correctly and the quality of water supplied for each stage of the process is in accordance with the specification.

d. The provision for storage, handling and connection to the WD for all process chemicals, meets the requirements for safe handling of potentially hazardous chemicals.

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

f. For WDs employing volatile process chemicals, the exhaust ventilation maintains the environmental concentration below any limit specified for occupational exposure and that the discharge is to a safe place.

Additional checks for WDs using a chemical disinfectant

4.10 WDs using chemical disinfectants require further tests to the ventilation and safety systems because of the possible emission of toxic gases or vapours.

4.11 For WDs using a chemical disinfectant check that the ventilation system within the loading (or unloading) area of the WD, the plant room (if applicable) and the storage area for the disinfectant meet the specified requirements. Particular attention should be paid to the following:

a. the installation meets the manufacturer’s specifications;

b. air flow is from the operator towards the WD and air does not flow from the plant room (if applicable) or disinfectant storage area into the loading (or unloading) area;

c. exhaust systems are non-recirculating and their discharges comply with relevant safety Regulations.

4.12 Check that local exhaust ventilation incorporated in the WD or installed as a dedicated accessory meets the specified requirements. Particular attention should be paid to the following:

a. air flow is from the operator towards the WD;

b. the rate of flow complies with the specified requirements;

c. the exhaust discharge complies with safety Regulations.

4.13 When the disinfectant solution is intended to be discharged to drain ensure that the drainage system is trapped, sealed and vented to a safe position. The drainage system should be checked to ensure that it is not possible for toxic materials to be vented into any other part of the building.
Checks on the WD

Preliminary checks

4.14 Check that the electrical equipment on the WD is correctly connected to the electrical service. Carry out the following electrical tests:
   a. insulation resistance
   b. phase sequence (for 3 phase installations)
   c. polarity
   d. bonding and earth continuity
   e. emergency stop

4.15 After the WD has been installed, check that the following requirements are met:
   a. the manufacturer has supplied all the documents specified in the contract;
   b. the WD has been supplied and installed in accordance with the contract;
   c. calibration verification certificates for the measuring instruments and controller(s) on the WD have been supplied;
   d. no defects are apparent from a visual inspection of the WD;
   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;
   j. loading conveyors and trolleys, load carriers and load baskets are effective and safe in use.

Functional checks

4.16 During an operating cycle, with an empty chamber, check that the following requirements are met (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.
   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 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.

j. The temperature of surfaces routinely handled by the operator does not exceed those specified in HTM 2030 'Design considerations'.

k. The effluent temperature does not exceed that specified in HTM 2030 'Design considerations'.

4.17 At the end of the cycle check that the following requirements are met.

a. The door opening system cannot be opened until the cycle has been completed, 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;
   (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.

Response to external faults

4.18 It is necessary to check that the WD 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.

4.19 During each stage of an operating cycle, check the response of the WD to the following simulated faults (as appropriate to the type of WD):

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;

j. failure of chemical additive supply (detergent, rinse aid, disinfectant etc);

k. failure of extract ventilation.
5.0 Schedule of operational tests

Introduction

5.1 To demonstrate compliance with specifications the contractor should carry out installation checks and tests before operational tests are carried (see Chapter 4); these may be repeated by the TP(S) if required.

5.2 Operational tests and performance qualification (see Chapter 6) tests are carried out by the TP(S).

5.3 The schedules for the tests are set out for each type of WD in Tables 2a to 2g inclusive.

5.4 Each test is cross-referenced to a detailed description of the test procedure in Chapter 9. Unless otherwise specified in Chapter 9 the tests should be carried out with the WD at normal working temperature, which may require a ‘warm-up’ run to be carried out before commencement of testing.

5.5 A number of the tests required can be carried out concurrently on the same operating cycle and this is also indicated in Chapter 9.

5.6 The calibration of test equipment should be checked before and after use as described in Chapter 9.

5.7 In principle, performance qualification tests should be carried out after operational tests have been completed. However, for WDs employing a thermal disinfection stage the performance qualification tests may be performed while the temperature sensors used in the commissioning tests are still in place.
Table 2a. WDs for human-waste containers: Type 1 (single chamber)

<table>
<thead>
<tr>
<th>Installation tests – contractor</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Verification of calibration of WD instruments</td>
<td>9.311 to 9.312</td>
</tr>
<tr>
<td>2. Automatic control test</td>
<td>12.4 to 12.8</td>
</tr>
<tr>
<td>4. Water supply temperature</td>
<td>9.89 to 9.93</td>
</tr>
<tr>
<td>5. Water supply pressure</td>
<td>9.94 to 9.99</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Operational tests – TP(S)</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Weekly safety checks</td>
<td>7.8 to 7.9</td>
</tr>
<tr>
<td>2. Automatic control test</td>
<td>12.4 to 12.8</td>
</tr>
<tr>
<td>3. Verification of calibration of WD instruments</td>
<td>9.311 to 9.312</td>
</tr>
<tr>
<td>(Temperature recorder, temperature indicator and/or disinfection temperature attained indicator)</td>
<td></td>
</tr>
<tr>
<td>4. Water system</td>
<td></td>
</tr>
<tr>
<td>– overflow test</td>
<td>9.237 to 9.244</td>
</tr>
<tr>
<td>– volume used per stage</td>
<td>9.245 to 9.252</td>
</tr>
<tr>
<td>5. Drainage</td>
<td></td>
</tr>
<tr>
<td>– drain seal integrity</td>
<td>9.17 to 9.24</td>
</tr>
<tr>
<td>– blocked drain protection</td>
<td>9.25 to 9.37</td>
</tr>
<tr>
<td>– free draining</td>
<td>9.38 to 9.39</td>
</tr>
<tr>
<td>– efficacy of discharge</td>
<td>9.40 to 9.42</td>
</tr>
<tr>
<td>6. Venting system</td>
<td></td>
</tr>
<tr>
<td>– steam venting</td>
<td>9.57 to 9.60</td>
</tr>
<tr>
<td>– load contamination</td>
<td>9.61 to 9.68</td>
</tr>
<tr>
<td>7. Doors and Door interlocks</td>
<td></td>
</tr>
<tr>
<td>– Cycle start</td>
<td>9.253 to 9.256</td>
</tr>
<tr>
<td>– In-cycle</td>
<td>9.257 to 9.259</td>
</tr>
<tr>
<td>– On sensor failure</td>
<td>9.264 to 9.265</td>
</tr>
<tr>
<td>– Opening force</td>
<td>9.266 to 9.270</td>
</tr>
<tr>
<td>– Failed cycle</td>
<td>9.271 to 9.273</td>
</tr>
<tr>
<td>8. Fault interlock</td>
<td>9.274 to 9.278</td>
</tr>
<tr>
<td>10. Aerosol discharge test</td>
<td>9.298 to 9.307</td>
</tr>
<tr>
<td>11. Chemical additive dosing tests</td>
<td></td>
</tr>
<tr>
<td>– reproducibility</td>
<td>9.279 to 9.284</td>
</tr>
<tr>
<td>– low level detection</td>
<td>9.285 to 9.289</td>
</tr>
<tr>
<td>12. Test for flushing toilet tissues</td>
<td>13.4 to 13.14</td>
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<td>13. Test for flushing non-absorbent material</td>
<td>13.15 to 13.20</td>
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<tr>
<td>14. Test for safe loading and emptying of containers</td>
<td>13.21 to 13.25</td>
</tr>
<tr>
<td>15. Cleaning efficacy test</td>
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</tr>
<tr>
<td>– test soil</td>
<td>10.7 to 10.24</td>
</tr>
<tr>
<td>– reference load</td>
<td>13.29 to 13.42</td>
</tr>
<tr>
<td>16. Chamber wall temperature test</td>
<td>13.26 to 13.28</td>
</tr>
<tr>
<td>17. Load carrier temperature test</td>
<td>9.317 to 9.322</td>
</tr>
<tr>
<td>19. Thermometric test for thermal disinfection</td>
<td></td>
</tr>
<tr>
<td>– reference load</td>
<td>9.330 to 9.335</td>
</tr>
<tr>
<td>20. Load dryness test</td>
<td>11.4 to 11.11</td>
</tr>
<tr>
<td>– reference load</td>
<td>13.26 to 13.28</td>
</tr>
<tr>
<td>– reference load</td>
<td>13.26 to 13.28</td>
</tr>
<tr>
<td>– test soil</td>
<td>9.53 to 9.59</td>
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</table>
Table 2b. WDs for surgical instruments: Type 1 (single chamber), and Type 2 (multiple chamber or conveyor)

<table>
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<th>Test Description</th>
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<tr>
<td>1. Verification of calibration of WD instruments</td>
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</tr>
<tr>
<td>2. Automatic control test</td>
<td>12.4 to 12.8</td>
</tr>
<tr>
<td>4. Water supply temperature</td>
<td>9.89 to 9.93</td>
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<tr>
<td>5. Water supply pressure</td>
<td>9.94 to 9.99</td>
</tr>
<tr>
<td><strong>Operational tests – TP(S)</strong></td>
<td></td>
</tr>
<tr>
<td>1. Weekly safety checks</td>
<td>7.8 to 7.9</td>
</tr>
<tr>
<td>2. Automatic control test</td>
<td>12.4 to 12.8</td>
</tr>
<tr>
<td>3. Verification of calibration of WD instruments</td>
<td>9.311 to 9.312</td>
</tr>
<tr>
<td>4. Water system</td>
<td></td>
</tr>
<tr>
<td>5. Drainage</td>
<td></td>
</tr>
<tr>
<td>6. Venting system</td>
<td></td>
</tr>
<tr>
<td>7. Doors and door interlocks</td>
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</tr>
<tr>
<td>8. Fault interlock</td>
<td>9.274 to 9.278</td>
</tr>
<tr>
<td>10. Aerosol discharge test</td>
<td>9.298 to 9.307</td>
</tr>
<tr>
<td>11. Chemical additive dosing tests</td>
<td></td>
</tr>
<tr>
<td>12. Load carriers</td>
<td>9.313 to 9.315</td>
</tr>
<tr>
<td>13. Test for air quality</td>
<td>9.349 to 9.352</td>
</tr>
<tr>
<td>14. Cleaning efficacy test</td>
<td>10.7 to 10.24</td>
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<tr>
<td>15. Chamber wall temperature test</td>
<td>9.317 to 9.322</td>
</tr>
<tr>
<td>16. Load carrier temperature test</td>
<td>9.323 to 9.329</td>
</tr>
<tr>
<td>18. Thermometric test for thermal disinfection</td>
<td>11.4 to 11.11</td>
</tr>
<tr>
<td>19. Load dryness test</td>
<td>9.326 to 9.342</td>
</tr>
<tr>
<td>20. Sound pressure</td>
<td>9.52 to 9.59</td>
</tr>
</tbody>
</table>

1 Additional test loads and alternative test soils may be required for WDs which are also intended for use with hollowware and/or anaesthetic accessories (see Tables 2c, 2d, 3c, 3d, 4c and 4d and Chapters 15 and 16). The additional testing should also include tests on the load carriers that will be used with these additional loads (9.313 to 9.315).
Table 2c: WDs for hollowware: Type 1 (single chamber), Type 2 (multiple chamber or conveyor)

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<thead>
<tr>
<th>Installation tests – contractor</th>
<th>Reference</th>
</tr>
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<tr>
<td>1. Verification of calibration of WD instruments</td>
<td>9.311 to 9.312</td>
</tr>
<tr>
<td>2. Automatic control test</td>
<td>12.4 to 12.8</td>
</tr>
<tr>
<td>4. Water supply temperature</td>
<td>9.89 to 9.93</td>
</tr>
<tr>
<td>5. Water supply pressure</td>
<td>9.94 to 9.99</td>
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<table>
<thead>
<tr>
<th>Operational tests – TP(S)</th>
<th>Reference</th>
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<td>1. Weekly safety checks</td>
<td>7.8 to 7.9</td>
</tr>
<tr>
<td>2. Automatic control test</td>
<td>12.4 to 12.8</td>
</tr>
<tr>
<td>3. Verification of calibration of WD instruments</td>
<td>9.311 to 9.312</td>
</tr>
<tr>
<td>4. Water system</td>
<td>9.237 to 9.244</td>
</tr>
<tr>
<td>– overflow test</td>
<td>9.245 to 9.252</td>
</tr>
<tr>
<td>– volume used per stage</td>
<td></td>
</tr>
<tr>
<td>5. Drainage</td>
<td>9.17 to 9.24</td>
</tr>
<tr>
<td>– drain seal integrity</td>
<td>9.25 to 9.37</td>
</tr>
<tr>
<td>– blocked drain protection</td>
<td>9.38 to 9.39</td>
</tr>
<tr>
<td>– free draining</td>
<td>9.40 to 9.42</td>
</tr>
<tr>
<td>– efficacy of discharge</td>
<td></td>
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<tr>
<td>6. Venting system</td>
<td>9.57 to 9.60</td>
</tr>
<tr>
<td>– steam venting</td>
<td>9.61 to 9.68</td>
</tr>
<tr>
<td>– load contamination</td>
<td></td>
</tr>
<tr>
<td>7. Doors and door interlocks</td>
<td>9.253 to 9.256</td>
</tr>
<tr>
<td>– Cycle start</td>
<td>9.257 to 9.259</td>
</tr>
<tr>
<td>– In-cycle</td>
<td>9.264 to 9.265</td>
</tr>
<tr>
<td>– On sensor failure</td>
<td>9.266 to 9.270</td>
</tr>
<tr>
<td>– Opening force</td>
<td>9.271 to 9.273</td>
</tr>
<tr>
<td>– Failed cycle</td>
<td></td>
</tr>
<tr>
<td>8. Fault interlock</td>
<td>9.274 to 9.278</td>
</tr>
<tr>
<td>10. Aerosol discharge test</td>
<td>9.298 to 9.307</td>
</tr>
<tr>
<td>11. Chemical additive dosing tests</td>
<td>9.279 to 9.284</td>
</tr>
<tr>
<td>– reproducibility</td>
<td>9.285 to 9.289</td>
</tr>
<tr>
<td>– low level detection</td>
<td></td>
</tr>
<tr>
<td>12. Cleaning efficacy test</td>
<td>10.7 to 10.24</td>
</tr>
<tr>
<td>– test soil</td>
<td>15.6 to 15.12</td>
</tr>
<tr>
<td>– reference load</td>
<td>15.4 to 15.5</td>
</tr>
<tr>
<td>13. Chamber wall temperature test</td>
<td>9.317 to 9.322</td>
</tr>
<tr>
<td>16. Thermometric test for thermal disinfection</td>
<td>11.4 to 11.11</td>
</tr>
<tr>
<td>– reference load</td>
<td>15.4 to 15.5</td>
</tr>
<tr>
<td>17. Load dryness test</td>
<td>9.336 to 9.342</td>
</tr>
<tr>
<td>– reference load</td>
<td>15.4 to 15.5</td>
</tr>
<tr>
<td>18. Sound pressure</td>
<td>9.53 to 9.59</td>
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### Table 2d. WDs for anaesthetic accessories: Type 1, Type 2 (multiple chamber or conveyor)

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<tr>
<td>1. Verification of calibration of WD instruments</td>
<td>9.311 to 9.312</td>
</tr>
<tr>
<td>2. Automatic control test</td>
<td>12.4 to 12.8</td>
</tr>
<tr>
<td>4. Water supply temperature</td>
<td>9.89 to 9.93</td>
</tr>
<tr>
<td>5. Water supply pressure</td>
<td>9.94 to 9.99</td>
</tr>
<tr>
<td><strong>Operational tests – TP(S)</strong></td>
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<td>1. Weekly safety checks</td>
<td>7.8 to 7.9</td>
</tr>
<tr>
<td>2. Automatic control test</td>
<td>12.4 to 12.8</td>
</tr>
<tr>
<td>3. Verification of calibration of WD instruments</td>
<td>9.311 to 9.312</td>
</tr>
<tr>
<td>4. Water system</td>
<td></td>
</tr>
<tr>
<td>– overflow test</td>
<td>9.237 to 9.244</td>
</tr>
<tr>
<td>– volume used per stage</td>
<td>9.245 to 9.252</td>
</tr>
<tr>
<td>5. Drainage</td>
<td></td>
</tr>
<tr>
<td>– drain seal integrity</td>
<td>9.17 to 9.24</td>
</tr>
<tr>
<td>– blocked drain protection</td>
<td>9.25 to 9.37</td>
</tr>
<tr>
<td>– free draining</td>
<td>9.38 to 9.39</td>
</tr>
<tr>
<td>– efficacy of discharge</td>
<td>9.40 to 9.42</td>
</tr>
<tr>
<td>6. Venting system</td>
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</tr>
<tr>
<td>– steam venting</td>
<td>9.57 to 9.60</td>
</tr>
<tr>
<td>– load contamination</td>
<td>9.61 to 9.68</td>
</tr>
<tr>
<td>7. Doors and door interlocks</td>
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<tr>
<td>– Cycle start</td>
<td>9.253 to 9.256</td>
</tr>
<tr>
<td>– In-cycle</td>
<td>9.257 to 9.259</td>
</tr>
<tr>
<td>– On sensor failure</td>
<td>9.264 to 9.265</td>
</tr>
<tr>
<td>– Opening force</td>
<td>9.266 to 9.270</td>
</tr>
<tr>
<td>– Failed cycle</td>
<td>9.271 to 9.273</td>
</tr>
<tr>
<td>8. Fault interlock</td>
<td>9.274 to 9.278</td>
</tr>
<tr>
<td>10. Aerosol discharge test</td>
<td>9.298 to 9.307</td>
</tr>
<tr>
<td>11. Chemical additive dosing tests</td>
<td></td>
</tr>
<tr>
<td>– reproducibility</td>
<td>9.279 to 9.284</td>
</tr>
<tr>
<td>– low level detection</td>
<td>9.285 to 9.289</td>
</tr>
<tr>
<td>12. Cleaning efficacy test</td>
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</tr>
<tr>
<td>– test soil</td>
<td>10.7 to 10.24</td>
</tr>
<tr>
<td>– reference load</td>
<td>16.6 to 16.13</td>
</tr>
<tr>
<td>13. Chamber wall temperature test</td>
<td>16.5</td>
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<tr>
<td>16. Thermometric test for thermal disinfection</td>
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</tr>
<tr>
<td>– reference load</td>
<td>9.330 to 9.335</td>
</tr>
<tr>
<td>– 11.4 to 11.11</td>
<td></td>
</tr>
<tr>
<td>17. Load dryness test</td>
<td>16.5</td>
</tr>
<tr>
<td>– reference load</td>
<td>9.336 to 9.342</td>
</tr>
<tr>
<td>18. Sound pressure</td>
<td>16.5</td>
</tr>
<tr>
<td>19. Water vapour discharge test</td>
<td>9.53 to 9.59</td>
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### Table 2e. WDs for endoscopes: Type 1

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<th>Reference</th>
<th>Operational tests – TP(S)</th>
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<tr>
<td>7.8 to 7.9</td>
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</tr>
<tr>
<td>12.4 to 12.8</td>
<td>Automatic control test</td>
</tr>
<tr>
<td>9.311 to 9.312</td>
<td>Verification of calibration of WD instruments</td>
</tr>
<tr>
<td>9.237 to 9.244</td>
<td>Water system – overflow test</td>
</tr>
<tr>
<td>9.245 to 9.252</td>
<td>Water system – volume used per stage</td>
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<tr>
<td>9.100 to 9.200</td>
<td>Water system – chemical purity</td>
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<td>9.201 to 9.212</td>
<td>Water system – bacterial endotoxins</td>
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<td>9.213 to 9.226</td>
<td>Water system – Total viable count</td>
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<tr>
<td>9.227 to 9.236</td>
<td>Water system – Environmental mycobacteria</td>
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<td>9.25 to 9.37</td>
<td>Drainage – blocked drain protection</td>
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<tr>
<td>9.38 to 9.39</td>
<td>Drainage – free draining</td>
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<tr>
<td>9.49 to 9.56</td>
<td>Drainage – pipework residual volume</td>
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<td>9.61 to 9.68</td>
<td>Venting system – load contamination</td>
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<tr>
<td>9.253 to 9.256</td>
<td>Doors and door interlocks – Cycle start</td>
</tr>
<tr>
<td>9.257 to 9.259</td>
<td>Doors and door interlocks – In-cycle</td>
</tr>
<tr>
<td>9.264 to 9.265</td>
<td>Doors and door interlocks – On sensor failure</td>
</tr>
<tr>
<td>9.266 to 9.270</td>
<td>Doors and door interlocks – Opening force</td>
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<tr>
<td>9.271 to 9.273</td>
<td>Doors and door interlocks – Failed cycle</td>
</tr>
<tr>
<td>9.274 to 9.278</td>
<td>Fault interlock</td>
</tr>
<tr>
<td>9.308 to 9.310</td>
<td>Chemical vapour discharge test</td>
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<tr>
<td>9.279 to 9.284</td>
<td>Chemical additive dosing tests – reproducibility</td>
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<td>Chemical additive dosing tests – low level detection</td>
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<td>9.313 to 9.315</td>
<td>Load carriers</td>
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<td>17.3 to 17.15</td>
<td>WD self-disinfection test</td>
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<td>Final rinse decontamination test</td>
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<td>Channel patency test</td>
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<td>17.23 to 17.32</td>
<td>Disinfectant concentration test</td>
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<td>10.7 to 10.24</td>
<td>Cleaning efficacy test – test soil</td>
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<tr>
<td>17.33</td>
<td>Cleaning efficacy test – reference load</td>
</tr>
<tr>
<td>9.317 to 9.322</td>
<td>Chamber wall temperature test</td>
</tr>
<tr>
<td>9.323 to 9.329</td>
<td>Load carrier temperature test</td>
</tr>
<tr>
<td>9.330 to 9.335</td>
<td>Over-temperature cut-out test</td>
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<td>11.4 to 11.11</td>
<td>Thermometric test for disinfection stage – reference load</td>
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<td>17.33</td>
<td>Microbiological test of disinfection efficacy</td>
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<td>17.41 to 17.42</td>
<td>Load dryness test</td>
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<tr>
<td>9.349 to 9.352</td>
<td>Test for air quality</td>
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<td>9.53 to 9.59</td>
<td>Sound pressure</td>
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### Table 2f. WDs for laboratory use: Type 1

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<td>1. Verification of calibration of WD instruments</td>
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<tr>
<td>2. Automatic control test</td>
<td>12.4 to 12.8</td>
</tr>
<tr>
<td>4. Water supply temperature</td>
<td>9.89 to 9.93</td>
</tr>
<tr>
<td>5. Water supply pressure</td>
<td>9.94 to 9.99</td>
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<th>Reference</th>
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<tr>
<td>2. Automatic control test</td>
<td>12.4 to 12.8</td>
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<td>3. Verification of calibration of WD instruments</td>
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</tr>
<tr>
<td>4. Water system</td>
<td>9.237 to 9.244</td>
</tr>
<tr>
<td>– overflow test</td>
<td>9.245 to 9.252</td>
</tr>
<tr>
<td>– volume used per stage</td>
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</tr>
<tr>
<td>5. Drainage</td>
<td>9.17 to 9.24</td>
</tr>
<tr>
<td>– drain seal integrity</td>
<td>9.25 to 9.37</td>
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<tr>
<td>– blocked drain protection</td>
<td>9.38 to 9.39</td>
</tr>
<tr>
<td>– free draining</td>
<td>9.40 to 9.42</td>
</tr>
<tr>
<td>6. Venting system</td>
<td>9.57 to 9.60</td>
</tr>
<tr>
<td>– steam venting</td>
<td>9.61 to 9.68</td>
</tr>
<tr>
<td>– load contamination</td>
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<tr>
<td>7. Doors and door interlocks</td>
<td>9.253 to 9.256</td>
</tr>
<tr>
<td>– Cycle start</td>
<td>9.257 to 9.259</td>
</tr>
<tr>
<td>– In-cycle</td>
<td>9.264 to 9.265</td>
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<tr>
<td>– On sensor failure</td>
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</tr>
<tr>
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<td>9.271 to 9.273</td>
</tr>
<tr>
<td>– Failed cycle</td>
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<tr>
<td>8. Fault interlock</td>
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<td>10. Aerosol discharge test</td>
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<tr>
<td>11. Chemical additive dosing tests</td>
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<tr>
<td>– reproducibility</td>
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<tr>
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</tr>
<tr>
<td>– test soil</td>
<td>18.4 to 18.10</td>
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<td>– reference load</td>
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<tr>
<td>13. Chamber wall temperature test</td>
<td>9.317 to 9.322</td>
</tr>
<tr>
<td>16. Thermometric test for thermal disinfection</td>
<td>11.4 to 11.11</td>
</tr>
<tr>
<td>– reference load</td>
<td>18.3</td>
</tr>
<tr>
<td>17. Load dryness test</td>
<td>9.336 to 9.342</td>
</tr>
<tr>
<td>– reference load</td>
<td>18.3</td>
</tr>
<tr>
<td>18. Sound pressure</td>
<td>9.53 to 9.59</td>
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</table>
### Table 2g. Ultrasonic cleaners: Type 1 – Free standing Ultrasonic cleaners: Type 2 – Section of multiple chamber/conveyor WD

<table>
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<th>Reference</th>
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<td>1. Verification of calibration of WD instruments</td>
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<td>12.4 to 12.8</td>
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<tr>
<td>4. Water supply temperature</td>
<td>9.89 to 9.93</td>
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<th>Operational tests – TP(S)</th>
<th>Reference</th>
</tr>
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<tr>
<td>1. Weekly safety checks</td>
<td>7.8 to 7.9</td>
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<tr>
<td>2. Automatic control test</td>
<td>12.4 to 12.8</td>
</tr>
<tr>
<td>3. Verification of calibration of WD instruments</td>
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</tr>
<tr>
<td>4. Water system</td>
<td></td>
</tr>
<tr>
<td>   – overflow test</td>
<td>9.237 to 9.244</td>
</tr>
<tr>
<td>   – volume used per stage</td>
<td>9.245 to 9.252</td>
</tr>
<tr>
<td>5. Drainage</td>
<td>9.38 to 9.39</td>
</tr>
<tr>
<td>6. Doors and door interlocks</td>
<td></td>
</tr>
<tr>
<td>   – Cycle start</td>
<td>9.253 to 9.256</td>
</tr>
<tr>
<td>   – In-cycle</td>
<td>9.257 to 9.259</td>
</tr>
<tr>
<td>   – Opening force</td>
<td>9.266 to 9.270</td>
</tr>
<tr>
<td>7. Fault interlock</td>
<td>9.274 to 9.278</td>
</tr>
<tr>
<td>8. Aerosol discharge test</td>
<td>9.298 to 9.307</td>
</tr>
<tr>
<td>9. Chemical additive dosing tests</td>
<td></td>
</tr>
<tr>
<td>   – reproducibility</td>
<td>9.279 to 9.284</td>
</tr>
<tr>
<td>   – low level detection</td>
<td>9.285 to 9.289&lt;sup&gt;1&lt;/sup&gt;</td>
</tr>
<tr>
<td>10. Cleaning efficacy test</td>
<td></td>
</tr>
<tr>
<td>   – test soil</td>
<td>10.7 to 10.24</td>
</tr>
<tr>
<td>   – reference load</td>
<td>19.22 to 19.31</td>
</tr>
<tr>
<td>    </td>
<td>19.18 to 19.21</td>
</tr>
<tr>
<td>11. Chamber wall temperature test</td>
<td>9.317 to 9.322&lt;sup&gt;2&lt;/sup&gt;</td>
</tr>
<tr>
<td>12. Load carrier temperature test</td>
<td>9.323 to 9.329&lt;sup&gt;2&lt;/sup&gt;</td>
</tr>
<tr>
<td>14. Thermometric test for thermal disinfection</td>
<td></td>
</tr>
<tr>
<td>   – reference load</td>
<td>11.4 to 11.11</td>
</tr>
<tr>
<td>    </td>
<td>19.18 to 19.21&lt;sup&gt;2&lt;/sup&gt;</td>
</tr>
<tr>
<td>15. Load dryness test</td>
<td>9.336 to 9.342</td>
</tr>
<tr>
<td>   – reference load</td>
<td>18.3&lt;sup&gt;3&lt;/sup&gt;</td>
</tr>
<tr>
<td>16. Test for ultrasonic activity</td>
<td>19.3 to 19.17</td>
</tr>
<tr>
<td>17. Sound pressure</td>
<td>9.53 to 9.59</td>
</tr>
</tbody>
</table>

<sup>1</sup> Only required for WDs with automatic chemical dosing
<sup>2</sup> Only required for WDs with a thermal disinfection stage
<sup>3</sup> Only required for WDs with a drying stage
Introduction

6.1 Performance qualification (PQ) is the procedure for obtaining documented evidence that the WD, as commissioned, will produce cleaned and/or disinfected goods of the standard required when operated in accordance with the operational instructions.

6.2 PQ tests are performed as part of the initial validation procedure, as part of any repeat validation procedure and whenever the user, acting on the advice of the AP(S), judges that new loading or operating conditions require a new PQ test.

6.3 Circumstances that may lead to new PQ tests would include changes to the quality of the water supply, changes to the chemical additives used in the cleaning and disinfection process, changes to the loading system or the requirement to process a new type of product.

6.4 Performance qualification should not be undertaken on any WD until the requirements of the installation and operational tests specified in Chapters 4 and 5 have been met.

6.5 Soil removal efficacy tests are required for all WDs as part of the performance qualification (see Chapter 10).

6.6 Performance qualification tests are carried out by the TP(S).

6.7 The schedules for the tests are set out for each type of WD in Tables 4a to 4g inclusive.

6.8 Each test is cross-referenced to a detailed description of the test procedure. Unless otherwise specified, the tests should be carried out with the WD at normal working temperature, which may require a ‘warm-up’ run to be carried out before commencement of the tests.

6.9 Test data obtained from the PQ tests should be recorded in a written PQ report which clearly identifies the loading conditions, the operating cycles, the chemical additives and the water quality used at each stage of the cycle.

6.10 The user should employ the PQ report to confirm the suitability of the process for loads which are to be processed. It should be used by the TP(S) and AP(S) as the basis for comparison with subsequent performance requalification tests.

6.11 Performance requalification (PRQ) is the process of confirming that the WD continues to meet the performance standards established during PQ and that the working data established during PQ tests remain valid.

6.12 Performance requalification is carried out annually as part of the yearly test schedule, as part of any revalidation or repeat validation study, or whenever the user requests such confirmation.
6.13 Before undertaking performance requalification tests the TP(S) should confirm, either by testing or by reference to current test records, that the WD meets the requirements of the installation and operational tests.

Loading conditions

6.14 A loading condition is a specified combination of the nature and number of load items, the items of chamber furniture, and their distribution within the chamber. For example, a load placed on the topmost level of a four level load carrier constitutes a different loading condition from the same load placed on the lowest level.

6.15 In principle, validation is not complete until a PQ test has been performed for each loading condition that the WD is expected to process.

6.16 In practice, the loading conditions specified in the tests to be carried out during commissioning are designed to represent the nature of production loads and to present a greater challenge to the process than production loads. In these cases further PQ tests will not be required; the data obtained from the commissioning tests will be sufficient.

6.17 PQ tests are required under the following conditions:
   a. when the proposed production loading condition presents a greater challenge to the process than that presented by the commissioning tests; for example, WDs for surgical instruments will require PQ tests if the mass of metal instruments to be processed exceeds that of the standard test load or if it is intended to process instruments with narrow lumens;
   b. when the nature of the load is not represented by the commissioning tests; for example, WDs for surgical instruments will require PQ tests if it is intended to process instruments with narrow lumens such as endoscopes.

6.18 When PQ tests are required it is often possible to select a production load that is known to be a greater challenge to the process than any of the others. This reference load can then serve as a ‘worst case’ and allow one PQ test to be valid for a range of less demanding conditions.

Surrogate devices

6.19 Many of the devices that constitute the most difficult loads to process in a WD, which therefore require PQ, are difficult to monitor either thermometrically or microbiologically, are in short supply and are extremely expensive; examples include fibre-optic endoscopes, videoscopes etc.

6.20 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.

6.21 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 may be separated into sections to facilitate the evaluation of residual test soil or survivors from a microbial challenge.
6.22 The surrogate device should have similar geometry and thermal mass and, as far as may be practicable, should be constructed of the same materials and with the same surface finishes as the device it is designed to emulate.

6.23 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

Native soiling

6.24 Cleaning efficacy tests are intended to demonstrate the ability of the WD to remove or reduce to acceptable levels, soiling and contamination which occurs during normal use of re-usable items.

6.25 Naturally occurring contamination shows considerable variation both in the nature and proportion of constituents and also in the extent of soiling which may occur during use.

6.26 Test methods based on the detection of naturally occurring soiling are difficult to standardise and show poor reproducibility due to:

- the variation in the composition of the soiling which may affect the ease with which soiling is removed;
- the changes in sensitivity of detection which may occur due to variation in composition of the soiling;
- the variation in the extent of soiling.

6.27 A number of methods exist for estimating (both qualitatively and quantitatively) the residual levels of some important soils or components of soils. These include detection of blood (Hydrogen peroxide test, Kastle-Meyer test), protein (ninhydrin test, Biuret test) or bacterial endotoxins (LAL test).

6.28 Common practice in the past has been to rely solely upon visual inspection to detect unacceptable levels of residual soiling. This method 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

6.29 Artificial test soils are designed to simulate the nature of native soiling and to be equally, or more difficult to remove.

6.30 By incorporating appropriate marker substances, they can provide improved sensitivity of detection.

6.31 Test soils can be used to give a quantified loading level, quantified detection and hence a quantified estimate of the soil removal which has occurred.

6.32 Test soils avoid any hazard which may be associated with native soiling (for example blood borne viruses) which may be of particular concern with the more extensive handling necessary for test work.
Worldwide, many different test soils have been specified for testing WDs 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, wall paper 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;
- validated 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

Current proposals for the European standard for WDs are to specify a test method for the validation of test soils. This would allow acceptance of the use of any test soil which meets the defined criteria and is validated as equivalent to a particular native soil or soils.

The test soils described in this HTM are those specified in BS 2745. It is apparent that they do not meet the criteria given above but, nevertheless, when used in conjunction with the test for residual soiling, they should be able to demonstrate that an acceptable level of soil removal has been obtained.

Process residues

The nature of process residues and the level of such residues that may be 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.

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

The water used for the process may give rise also 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 mammalian body. Items intended for surgically invasive use or for the preparation or administration of parenteral fluids should be free from, or have suitably low levels of, bacterial endotoxins.

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

Thermometric tests

6.40 Thermometric tests are required for both thermal disinfection processes and chemical disinfection processes.

6.41 For thermal disinfection processes the time temperature relationships which are generally regarded as acceptable are shown in Table 3.

Table 3 Thermal disinfection temperature bands

<table>
<thead>
<tr>
<th>Disinfection temperature (°C)a</th>
<th>Minimum exposure time (minutes)</th>
<th>Maximum allowable temperature (°C)</th>
</tr>
</thead>
<tbody>
<tr>
<td>65</td>
<td>10</td>
<td>70</td>
</tr>
<tr>
<td>73</td>
<td>3</td>
<td>78</td>
</tr>
<tr>
<td>80</td>
<td>1</td>
<td>85</td>
</tr>
<tr>
<td>90</td>
<td>0.2b</td>
<td>95</td>
</tr>
<tr>
<td>93c</td>
<td>10</td>
<td>98</td>
</tr>
</tbody>
</table>

Note:

a. The disinfection temperature is measured at the surface to be disinfected.
b. The exposure time of 1 second (as specified in BS 2745 Part 1) is too short for reliable measurement and a minimum time of 12 seconds (0.2 min) should be used.
c. This time/temperature relationship is only used for items known to be contaminated with large amounts of pathogenic organisms, for example in laboratories.

Microbiological tests

6.42 A microbiological PQ test is required, in addition to the thermometric test, for WDs in which disinfection is carried out using a chemical germicidal agent (see Chapter 11).

6.43 Normally, microbiological testing is not required for thermal disinfection processes. If particular circumstances make such testing necessary or desirable the advice of the microbiologist should be sought. Direct evaluation of microbial efficacy within the WD is difficult. Whenever practicable, microbiological testing should be carried out by:

   a. undertaking a laboratory investigation of the inactivation characteristics of the micro-organisms of interest (that is, by determination of the D value and z value over the range 65°C to 95°C);

   b. calculating from these data the exposure conditions necessary to give the required assurance of disinfection;

   c. determining attainment of the required exposure conditions in the WD by physical measurement (temperature, time etc).

Load dryness tests

6.44 The presence of residual water on cleaned and disinfected items is undesirable since it may interfere with the correct functioning of the item, promote re-contamination and microbial growth, or prevent attainment of sterilizing conditions.
The ability of the WD to dry the load may be evaluated either visually, when appropriate, or by drying to constant weight and determining the mass of residual water present at the end of the WD process cycle (see paragraphs 9.336 to 9.342).

**PQ report**

All the data collected during PQ tests should be filed in a PQ report, a copy of which should be kept with the plant history file.

The PQ report should contain or refer to the complete specification for the washing/disinfection process. The specification should be sufficiently detailed to allow the loading condition and the operating cycle (including the type and volume of all chemical additives and the water quality) to be replicated on any future occasion.

The report should include the following:

- a specification of the loading condition defined by the nature and number of the load items, items of chamber furniture and their distribution within the chamber; photographs taken of the load are valuable for future reference and can minimise the need for extensive descriptive text;
- a specification of the operating cycle, defined by the settings for the cycle variables; for microprocessor based control systems a copy of the program held independently on electro-magnetic storage media is suitable also;
- a specification of the service supply, defined by reference to the nature and volume of all chemical additives and the quality of the water service(s);
- a specification of any pre-test operation of the WD, for example a warm-up cycle;
- a specification of any pre-treatment of the test load, for example manual cleaning, ultrasonic cleaning etc;
- all the indicated, recorded and measured data from the test; these should be annotated with the target values and permitted tolerances of elapsed time and other cycle variables at all significant points of the operating cycle, for example at the beginning and end of each stage or sub-stage;
- for WDs equipped with process recording, the original of the process record derived from the test should also form part of the record.

**Master process record**

A master process record (MPR) is a record of the values and permitted tolerances of cycle variables for a correctly functioning operational cycle against which test and production cycles can be checked.

It is derived from the process records obtained during a PQ test, or during commissioning when no PQ test was required.

The MPR may be a 1:1 copy of the process record from a chart recorder, a template derived from the process record or data stored in a
computer system and compared automatically with the data from each production run.

6.52 An MPR is intended to facilitate production control on WDs when the attainment of the validated standards of cleanliness and disinfection are critical to the safe subsequent use of the product.

6.53 When a number of different processes and different loading conditions are to be used for production it will be necessary to prepare an MPR for each operational condition.

Tests for performance requalification

6.54 Performance requalification (PRQ) tests are performed once a year to ensure that the established criteria for cleaning and disinfection are still being met. The PRQ tests should follow the yearly schedule of tests and checks listed in Chapter 7.

6.55 For a given operating cycle it is necessary to perform the PRQ tests only for those reference loads for which a PQ test was performed and reported.

6.56 The need for additional PQ tests in the light of changes in the nature of loads being processed should be agreed between the user and the TP(S).

6.57 The procedure for the PRQ test is essentially the same as that used for the corresponding PQ test. The operating cycle and the loading conditions used should be identical with those used previously for the PQ test.

6.58 The PRQ test should be considered satisfactory if the values of the measured variables are within the tolerances stated in the PQ report.

6.59 The results of the PRQ tests should be linked with the relevant PQ report and retained securely.

6.60 The PRQ test should meet the specified requirements without difficulty for a WD which has passed the yearly test programme. If the PRQ test is not satisfactory the advice of the AP(S) and/or the WD manufacturer should be sought.

Table 4a. WDs for human-waste containers: Type 1

<table>
<thead>
<tr>
<th>Reference</th>
<th>Operational tests – TP(S)</th>
</tr>
</thead>
<tbody>
<tr>
<td>See Chapter 4</td>
<td>See Table 2a</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Performance qualification tests</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Installation tests – contractor</td>
<td></td>
</tr>
<tr>
<td>1. Thermometric test for a full load of particular items not represented adequately by the reference load.</td>
<td>11.4 to 11.11</td>
</tr>
<tr>
<td>2. Cleaning efficacy test for a full load of particular items not represented adequately by the reference load.</td>
<td>10.7 to 10.24</td>
</tr>
<tr>
<td>– test soil</td>
<td>13.29 to 13.42</td>
</tr>
<tr>
<td>3. Load dryness test for a full load of particular items not represented adequately by the reference load.</td>
<td>9.336 to 9.342</td>
</tr>
</tbody>
</table>
### Table 4b. WDs for surgical instruments: Type 1, Type 2 (multiple chamber or conveyor)

<table>
<thead>
<tr>
<th>Installation tests – contractor</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>See Chapter 4</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Operational tests – TP(S)</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>See Table 2b</td>
<td></td>
</tr>
</tbody>
</table>

**Performance qualification tests**

1. Thermometric test for a full load of particular items not represented adequately by the reference load.  
   11.4 to 11.11
2. Cleaning efficacy test for a full load of particular items not represented adequately by the reference load.  
   – test soil  
   10.7 to 10.24  
   13.29 to 13.42
3. Load dryness test for a full load of particular items not represented adequately by the reference load.  
   9.336 to 9.342  
   9.343 to 9.348
4. Process residues – chemical additives  
   9.343 to 9.348

### Table 4c. WDs for hollowware: Type 1, Type 2 (multiple chamber or conveyor)

<table>
<thead>
<tr>
<th>Installation tests – contractor</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>See Chapter 4</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Operational tests – TP(S)</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>See Table 2c</td>
<td></td>
</tr>
</tbody>
</table>

**Performance qualification tests**

1. Thermometric test for a full load of particular items not represented adequately by the reference load.  
   11.4 to 11.11
2. Cleaning efficacy test for a full load of particular items not represented adequately by the reference load.  
   – test soil  
   10.7 to 10.24  
   13.29 to 13.42
3. Load dryness test for a full load of particular items not represented adequately by the reference load.  
   9.336 to 9.342  
   9.343 to 9.348
4. Process residues – chemical additives  
   9.343 to 9.348

### Table 4d. WDs for anaesthetic accessories: Type 1, Type 2 (multiple chamber or conveyor)

<table>
<thead>
<tr>
<th>Installation tests – contractor</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>See Chapter 4</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Operational tests – TP(S)</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>See Table 2d</td>
<td></td>
</tr>
</tbody>
</table>

**Performance qualification tests**

1. Thermometric test for a full load of particular items not represented adequately by the reference load.  
   11.4 to 11.11
2. Cleaning efficacy test for a full load of particular items not represented adequately by the reference load.  
   – test soil  
   10.7 to 10.24  
   13.29 to 13.42
3. Load dryness test for a full load of particular items not represented adequately by the reference load.  
   9.336 to 9.342  
   9.343 to 9.348
4. Process residues – chemical additives  
   9.343 to 9.348
Table 4e. WDs for endoscopes: Type 1

<table>
<thead>
<tr>
<th>Performance qualification</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Thermometric test for a full load of particular items not represented adequately by the reference load.</td>
<td>11.4 to 11.11</td>
</tr>
<tr>
<td>2. Cleaning efficacy test for a full load of particular items not represented adequately by the reference load.</td>
<td>10.7 to 10.24</td>
</tr>
<tr>
<td>– test soil</td>
<td>13.29 to 13.42</td>
</tr>
<tr>
<td>3. Load dryness test for a full load of particular items not represented adequately by the reference load.</td>
<td>9.336 to 9.342</td>
</tr>
<tr>
<td>4. Microbiological tests for efficacy of chemical disinfection for a full load of particular items not represented adequately by the reference load.</td>
<td></td>
</tr>
<tr>
<td>5. Process residues – chemical additives.</td>
<td>9.343 to 9.348</td>
</tr>
</tbody>
</table>

1 No test method is specified for microbiological tests on endoscopes in normal use; if required by the user the advice of the microbiologist should be sought.

Table 4f. WDs for laboratory use: Type 1

<table>
<thead>
<tr>
<th>Performance qualification</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Thermometric test for a full load of particular items not represented adequately by the reference load.</td>
<td>11.4 to 11.11</td>
</tr>
<tr>
<td>2. Cleaning efficacy test for a full load of particular items not represented adequately by the reference load.</td>
<td>10.7 to 10.24</td>
</tr>
<tr>
<td>– test soil</td>
<td>13.29 to 13.42</td>
</tr>
<tr>
<td>3. Load dryness test for a full load of particular items not represented adequately by the reference load.</td>
<td>9.336 to 9.342</td>
</tr>
</tbody>
</table>

Table 4g. Ultrasonic cleaners: Type 1 – Free standing Ultrasonic cleaners: Type 2 – Section of multiple chamber/conveyor WD

<table>
<thead>
<tr>
<th>Performance qualification</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Cleaning efficacy test for a full load of particular items not represented adequately by the reference load.</td>
<td>10.7 to 10.24</td>
</tr>
<tr>
<td>– test soil</td>
<td>13.29 to 13.42</td>
</tr>
<tr>
<td>2. Load dryness test for a full load of particular items not represented adequately by the reference load.</td>
<td>9.336 to 9.342</td>
</tr>
</tbody>
</table>
7.0 Schedule of periodic tests

Introduction

7.1 Periodic tests are carried out at daily, weekly, quarterly and yearly intervals. They are the shared responsibility of the TP(S) and the user.

7.2 The yearly test schedule is identical to that required for revalidation. It contains the tests required for re-commissioning and for re-qualification of the performance of the WD.

7.3 Tests should only be undertaken after completion of the planned maintenance tasks described in HTM 2030 ‘Operational management’.

7.4 The schedules for the tests are set out for each type of WD in Tables 5a to 5g inclusive.

7.5 Each test is cross-referenced to a detailed description of the test procedure in Chapter 9. Unless otherwise specified in Chapter 9 the tests should be carried out with the WD at normal working temperature, which may require a ‘warm-up’ run to be carried out before commencement of testing.

7.6 A number of the tests required can be carried out concurrently on the same operating cycle and this is also indicated in Chapter 9.

7.7 The results of periodic tests, whether carried out by the user or by the TP(S) should be filed securely, for example in the plant history file.

Weekly safety checks

7.8 The TP(S) 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.

7.9 For WDs which include 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. make any other checks required by the competent person in connection with the written scheme of examination for the pressure vessel.

Yearly safety checks

7.10 In order to ensure the continued safe functioning of the WD the TP(S) should conduct a series of safety checks before starting the yearly tests.

7.11 The AP(S) should draw up a documented programme of the yearly safety checks necessary for a particular installation.
7.12 The original installation checks and tests may be used as a basis for the yearly safety checks paying particular attention to those factors which affect safety and especially to those which may have changed since the previous annual safety check (or installation test).

7.13 The adequacy and safe connection of all engineering services should be verified.
## 7.0 Schedule of periodic tests

### Table 5a. WDs for human-waste containers: Type 1

<table>
<thead>
<tr>
<th>Daily tests – user</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Automatic control test</td>
<td>12.4 to 12.8</td>
</tr>
<tr>
<td>2. Check spray arm rotation for free movement</td>
<td></td>
</tr>
<tr>
<td>3. Check spray nozzles for blockage</td>
<td></td>
</tr>
<tr>
<td>4. Remove and clean strainers and filters etc</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Weekly tests – user or TP(S)</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Weekly safety checks</td>
<td>7.8 to 7.9</td>
</tr>
<tr>
<td>2. Carry out daily tests</td>
<td></td>
</tr>
<tr>
<td>3. Visual inspection of water system and drainage system for leaks</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Quarterly tests – TP(S)</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Weekly safety checks</td>
<td>7.8 to 7.9</td>
</tr>
<tr>
<td>2. Automatic control test</td>
<td>12.4 to 12.8</td>
</tr>
<tr>
<td>3. Verification of calibration of WD instruments</td>
<td>9.311 to 9.312</td>
</tr>
<tr>
<td>(Temperature recorder, temperature indicator and/or disinfection temperature attained indicator)</td>
<td></td>
</tr>
<tr>
<td>4. Thermometric test for thermal disinfection</td>
<td>11.4 to 11.11</td>
</tr>
<tr>
<td>– reference load</td>
<td>13.26 to 13.28</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Yearly and revalidation tests – TP(S)</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Yearly safety checks</td>
<td>7.10 to 7.13</td>
</tr>
<tr>
<td>2. Water quality tests – hardness</td>
<td>9.140 to 9.152</td>
</tr>
<tr>
<td>3. Water supply temperature</td>
<td>9.89 to 9.93</td>
</tr>
<tr>
<td>5. Automatic control test</td>
<td>12.4 to 12.8</td>
</tr>
<tr>
<td>6. Verification of calibration of WD instruments</td>
<td>9.311 to 9.312</td>
</tr>
<tr>
<td>(Temperature recorder, temperature indicator and/or disinfection temperature attained indicator)</td>
<td></td>
</tr>
<tr>
<td>7. Doors and door interlocks</td>
<td></td>
</tr>
<tr>
<td>– Cycle start</td>
<td>9.253 to 9.256</td>
</tr>
<tr>
<td>– In-cycle</td>
<td>9.257 to 9.259</td>
</tr>
<tr>
<td>– On sensor failure</td>
<td>9.264 to 9.265</td>
</tr>
<tr>
<td>– Opening force</td>
<td>9.266 to 9.270</td>
</tr>
<tr>
<td>– Failed cycle</td>
<td>9.271 to 9.273</td>
</tr>
<tr>
<td>8. Fault interlock</td>
<td>9.274 to 9.278</td>
</tr>
<tr>
<td>10. Aerosol discharge test</td>
<td>9.298 to 9.307</td>
</tr>
<tr>
<td>11. Chemical additive dosing tests</td>
<td></td>
</tr>
<tr>
<td>– reproducibility</td>
<td>9.279 to 9.284</td>
</tr>
<tr>
<td>12. Thermometric test for thermal disinfection</td>
<td>11.4 to 11.11</td>
</tr>
<tr>
<td>– reference load</td>
<td>13.26 to 13.28</td>
</tr>
<tr>
<td>13. Cleaning efficacy test</td>
<td></td>
</tr>
<tr>
<td>– reference load</td>
<td>10.7 to 10.24</td>
</tr>
<tr>
<td>– test soil</td>
<td>13.26 to 13.28</td>
</tr>
<tr>
<td>14. Load dryness test</td>
<td></td>
</tr>
<tr>
<td>– reference load</td>
<td>13.26 to 13.28</td>
</tr>
</tbody>
</table>
Table 5b. WDs for surgical instruments: Type 1, Type 2 (multiple chamber or conveyor)

<table>
<thead>
<tr>
<th>Daily tests – user</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Automatic control test</td>
<td>12.4 to 12.8</td>
</tr>
<tr>
<td>2. Check spray arm rotation for free movement</td>
<td></td>
</tr>
<tr>
<td>3. Check spray nozzles for blockage</td>
<td></td>
</tr>
<tr>
<td>4. Remove and clean strainers and filters</td>
<td></td>
</tr>
</tbody>
</table>

Weekly tests – user or TP(S)
| 1. Weekly safety checks | 7.8 to 7.9 |
| 2. Carry out Daily tests | |
| 3. Water hardness (all process stages) | 9.140 to 9.152 |
| 4. Water conductivity (final rinse stage) | 9.112 to 9.122 |
| 5. Cleaning efficacy test by residual soil detection | 10.37 to 10.49 |

Quarterly tests – TP(S)
| 1. Weekly safety checks | 7.8 to 7.9 |
| 2. Automatic control test | 12.4 to 12.8 |
| 3. Verification of calibration of WD instruments | 9.311 to 9.312 |
| 4. Thermometric test for thermal disinfection | 11.4 to 11.11 |
| 5. Cleaning efficacy test | 10.7 to 10.24 |
| – reference load¹ | |
| General instruments | 14.8 |
| Endoscopic/MAT instruments | 14.9 to 14.11 |
| – test soil | 14.12 to 14.18 |

Yearly and revalidation tests – TP(S)
| 1. Yearly safety checks | 7.10 to 7.13 |
| 2. Automatic control test | 12.4 to 12.8 |
| 3. Verification of calibration of WD instruments | 9.311 to 9.312 |
| 4. Water system | |
| – chemical purity | 9.100 to 9.200 |
| – bacterial endotoxins | 9.201 to 9.212 |
| 5. Drainage | |
| – free draining | 9.38 to 9.39 |
| – efficacy of discharge | 9.40 to 9.42 |
| 6. Doors and door interlocks | |
| – Cycle start | 9.253 to 9.256 |
| – In-cycle | 9.257 to 9.259 |
| – On sensor failure | 9.264 to 9.265 |
| – Failed cycle | 9.271 to 9.273 |
| 7. Fault interlock | 9.274 to 9.278 |
| 10. Chemical additive dosing tests | |
| – reproducibility | 9.279 to 9.284 |
| – low level detection | 9.285 to 9.289 |
| 11. Load carriers | 9.313 to 9.315 |
| 12. Test for air quality | 9.349 to 9.352 |
| 13. Cleaning efficacy test | 10.7 to 10.24 |
| – test soil | 14.12 to 14.18 |
| – reference load¹ | |
| General instruments | 14.8 |
| Endoscopic/MAT instruments | 14.9 to 14.11 |

continues ...
### 7.0 Schedule of periodic tests

<table>
<thead>
<tr>
<th>Test Description</th>
<th>Reference Numbers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endoscopic/MAT instruments</td>
<td>14.9 to 14.11</td>
</tr>
<tr>
<td>16. Load dryness test</td>
<td>9.336 to 9.342</td>
</tr>
<tr>
<td>– reference load&lt;sup&gt;1&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>General instruments</td>
<td>14.8</td>
</tr>
<tr>
<td>Endoscopic/MAT instruments</td>
<td>14.9 to 14.11</td>
</tr>
<tr>
<td>17. Process residues – chemical additives</td>
<td>9.343 to 9.348</td>
</tr>
</tbody>
</table>

<sup>1</sup> Additional test loads and alternative test soils may be required for WDs which are also intended for use with hollowware and/or anaesthetic accessories (see Tables 2c, 2d, 3c, 3d, 4c and 4d and Chapters 15 and 16). The additional testing should also include tests on the load carriers that will be used with these additional loads (9.313 to 9.315).
Table 5c. WDs for hollowware: Type 1, Type 2 (multiple chamber or conveyor)

<table>
<thead>
<tr>
<th>Tests</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Daily tests – user</strong></td>
<td></td>
</tr>
<tr>
<td>1. Automatic control test</td>
<td>12.4 to 12.8</td>
</tr>
<tr>
<td>2. Check spray arm rotation for free movement</td>
<td></td>
</tr>
<tr>
<td>3. Check spray nozzles for blockage</td>
<td></td>
</tr>
<tr>
<td>4. Remove and clean strainers and filters</td>
<td></td>
</tr>
<tr>
<td><strong>Weekly tests – user or TP(S)</strong></td>
<td></td>
</tr>
<tr>
<td>1. Weekly safety checks</td>
<td>7.8 to 7.9</td>
</tr>
<tr>
<td>2. Carry out daily tests</td>
<td></td>
</tr>
<tr>
<td>3. Water hardness (all process stages)</td>
<td>9.140 to 9.152</td>
</tr>
<tr>
<td>4. Water conductivity (final rinse stage)</td>
<td>9.112 to 9.122</td>
</tr>
<tr>
<td>5. Cleaning efficacy test by residual soil detection</td>
<td>10.37 to 10.49</td>
</tr>
<tr>
<td><strong>Quarterly tests – TP(S)</strong></td>
<td></td>
</tr>
<tr>
<td>1. Weekly safety checks</td>
<td>7.8 to 7.9</td>
</tr>
<tr>
<td>2. Automatic control test</td>
<td>12.4 to 12.8</td>
</tr>
<tr>
<td>3. Verification of calibration of WD instruments</td>
<td>9.311 to 9.312</td>
</tr>
<tr>
<td>4. Thermometric test for thermal disinfection</td>
<td>11.4 to 11.11</td>
</tr>
<tr>
<td>5. Cleaning efficacy test</td>
<td>10.7 to 10.24</td>
</tr>
<tr>
<td>– test soil</td>
<td>15.6 to 15.12</td>
</tr>
<tr>
<td>– reference load</td>
<td>15.4 to 15.5</td>
</tr>
<tr>
<td><strong>Yearly and revalidation tests – TP(S)</strong></td>
<td></td>
</tr>
<tr>
<td>1. Yearly safety checks</td>
<td>7.10 to 7.13</td>
</tr>
<tr>
<td>2. Automatic control test</td>
<td>12.4 to 12.8</td>
</tr>
<tr>
<td>3. Verification of calibration of WD instruments</td>
<td>9.311 to 9.312</td>
</tr>
<tr>
<td>5. Drainage</td>
<td></td>
</tr>
<tr>
<td>– free draining</td>
<td>9.38 to 9.39</td>
</tr>
<tr>
<td>– efficacy of discharge</td>
<td>9.40 to 9.42</td>
</tr>
<tr>
<td>6. Doors and door interlocks</td>
<td></td>
</tr>
<tr>
<td>– Cycle start</td>
<td>9.253 to 9.256</td>
</tr>
<tr>
<td>– In-cycle</td>
<td>9.257 to 9.259</td>
</tr>
<tr>
<td>– On sensor failure</td>
<td>9.264 to 9.265</td>
</tr>
<tr>
<td>– Failed cycle</td>
<td>9.271 to 9.273</td>
</tr>
<tr>
<td>7. Fault interlock</td>
<td>9.274 to 9.278</td>
</tr>
<tr>
<td>10. Chemical additive dosing tests</td>
<td></td>
</tr>
<tr>
<td>– reproducibility</td>
<td>9.279 to 9.284</td>
</tr>
<tr>
<td>– low level detection</td>
<td>9.285 to 9.289</td>
</tr>
<tr>
<td>11. Load carriers</td>
<td>9.313 to 9.315</td>
</tr>
<tr>
<td>12. Test for air quality</td>
<td>9.349 to 9.352</td>
</tr>
<tr>
<td>13. Cleaning efficacy test</td>
<td>10.7 to 10.24</td>
</tr>
<tr>
<td>– test soil</td>
<td>15.6 to 15.12</td>
</tr>
<tr>
<td>– reference load</td>
<td>15.4 to 15.5</td>
</tr>
<tr>
<td>15. Thermometric test for thermal disinfection</td>
<td></td>
</tr>
<tr>
<td>– reference load</td>
<td>15.4 to 15.5</td>
</tr>
<tr>
<td>16. Load dryness test</td>
<td>9.336 to 9.342</td>
</tr>
<tr>
<td>– reference load</td>
<td>15.4 to 15.5</td>
</tr>
<tr>
<td>17. Process residues – chemical additives</td>
<td></td>
</tr>
<tr>
<td>18. Performance qualification tests</td>
<td>9.343 to 9.348</td>
</tr>
</tbody>
</table>
### Table 5d. WDs for anaesthetic accessories: Type 1, Type 2 (multiple chamber or conveyor)

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Test Description</th>
<th>Reference</th>
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<tr>
<td><strong>Daily tests – user</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.</td>
<td>Automatic control test</td>
<td>12.4 to 12.8</td>
</tr>
<tr>
<td>2.</td>
<td>Check spray arm rotation for free movement</td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>Check spray nozzles for blockage</td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>Remove and clean strainers and filters</td>
<td></td>
</tr>
<tr>
<td><strong>Weekly tests – user or TP(S)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.</td>
<td>Weekly safety checks</td>
<td>7.8 to 7.9</td>
</tr>
<tr>
<td>2.</td>
<td>Carry out daily tests</td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>Water hardness (all process stages)</td>
<td>9.140 to 9.152</td>
</tr>
<tr>
<td>4.</td>
<td>Water conductivity (final rinse stage)</td>
<td>9.112 to 9.122</td>
</tr>
<tr>
<td>5.</td>
<td>Cleaning efficacy test by residual soil detection</td>
<td>10.37 to 10.49</td>
</tr>
<tr>
<td><strong>Quarterly tests – TP(S)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.</td>
<td>Weekly safety checks</td>
<td>7.8 to 7.9</td>
</tr>
<tr>
<td>2.</td>
<td>Automatic control test</td>
<td>12.4 to 12.8</td>
</tr>
<tr>
<td>3.</td>
<td>Verification of calibration of WD instruments</td>
<td>9.311 to 9.312</td>
</tr>
<tr>
<td>4.</td>
<td>Thermometric test for thermal disinfection</td>
<td>11.4 to 11.11</td>
</tr>
<tr>
<td>5.</td>
<td>Cleaning efficacy test</td>
<td>10.7 to 10.24</td>
</tr>
<tr>
<td></td>
<td>– test soil</td>
<td>16.6 to 16.13</td>
</tr>
<tr>
<td></td>
<td>– reference load</td>
<td>16.5</td>
</tr>
<tr>
<td><strong>Yearly and revalidation tests – TP(S)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.</td>
<td>Yearly safety checks</td>
<td>7.10 to 7.13</td>
</tr>
<tr>
<td>2.</td>
<td>Automatic control test</td>
<td>12.4 to 12.8</td>
</tr>
<tr>
<td>3.</td>
<td>Verification of calibration of WD instruments</td>
<td>9.311 to 9.312</td>
</tr>
<tr>
<td>4.</td>
<td>Water hardness</td>
<td>9.140 to 9.152</td>
</tr>
<tr>
<td>5.</td>
<td>Drainage</td>
<td>9.38 to 9.39</td>
</tr>
<tr>
<td></td>
<td>– free draining</td>
<td>9.40 to 9.42</td>
</tr>
<tr>
<td></td>
<td>– efficacy of discharge</td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td>Doors and door interlocks</td>
<td>9.253 to 9.256</td>
</tr>
<tr>
<td></td>
<td>– Cycle start</td>
<td>9.257 to 9.259</td>
</tr>
<tr>
<td></td>
<td>– In-cycle</td>
<td>9.264 to 9.265</td>
</tr>
<tr>
<td></td>
<td>– On sensor failure</td>
<td>9.271 to 9.273</td>
</tr>
<tr>
<td></td>
<td>– Failed cycle</td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td>Fault interlock</td>
<td>9.274 to 9.278</td>
</tr>
<tr>
<td>10.</td>
<td>Chemical additive dosing tests</td>
<td>9.279 to 9.284</td>
</tr>
<tr>
<td></td>
<td>– reproducibility</td>
<td>9.285 to 9.289</td>
</tr>
<tr>
<td></td>
<td>– low level detection</td>
<td></td>
</tr>
<tr>
<td>11.</td>
<td>Load carriers</td>
<td>9.313 to 9.315</td>
</tr>
<tr>
<td>12.</td>
<td>Test for air quality</td>
<td>9.349 to 9.352</td>
</tr>
<tr>
<td>13.</td>
<td>Cleaning efficacy test</td>
<td>10.7 to 10.24</td>
</tr>
<tr>
<td></td>
<td>– test soil</td>
<td>16.6 to 16.13</td>
</tr>
<tr>
<td></td>
<td>– reference load</td>
<td>16.5</td>
</tr>
<tr>
<td>15.</td>
<td>Thermometric test for thermal disinfection</td>
<td>11.4 to 11.11</td>
</tr>
<tr>
<td></td>
<td>– reference load</td>
<td>16.5</td>
</tr>
<tr>
<td>16.</td>
<td>Load dryness test</td>
<td>9.336 to 9.342</td>
</tr>
<tr>
<td></td>
<td>– reference load</td>
<td>16.5</td>
</tr>
<tr>
<td>17.</td>
<td>Process residues – chemical additives</td>
<td>9.343 to 9.348</td>
</tr>
<tr>
<td>18.</td>
<td>Performance qualification tests</td>
<td></td>
</tr>
</tbody>
</table>
**Table 5e. WDs for endoscopes: Type 1**

<table>
<thead>
<tr>
<th>Daily tests – user</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Automatic control test</td>
<td>12.4 to 12.8</td>
</tr>
<tr>
<td>2. Remove and clean strainers and filters</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Weekly tests – user or TP(S)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Weekly safety checks</td>
<td>7.8 to 7.9</td>
</tr>
<tr>
<td>2. Carry out daily tests</td>
<td></td>
</tr>
<tr>
<td>3. Water hardness (all process stages)</td>
<td>9.140 to 9.152</td>
</tr>
<tr>
<td>4. Water conductivity (final rinse stage)</td>
<td>9.112 to 9.122</td>
</tr>
<tr>
<td>5. Cleaning efficacy test by residual soil detection</td>
<td>10.37 to 10.49</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Quarterly tests – TP(S)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Weekly safety checks</td>
<td>7.8 to 7.9</td>
</tr>
<tr>
<td>2. Automatic control test</td>
<td>12.4 to 12.8</td>
</tr>
<tr>
<td>3. Verification of calibration of WD instruments</td>
<td>9.311 to 9.312</td>
</tr>
<tr>
<td>4. Thermometric test for disinfection stage</td>
<td>11.4 to 11.11</td>
</tr>
<tr>
<td>5. Cleaning efficacy test</td>
<td>10.7 to 10.24</td>
</tr>
<tr>
<td></td>
<td>– reference load</td>
</tr>
<tr>
<td></td>
<td>– test soil</td>
</tr>
</tbody>
</table>

| 6. Channel patency test     |              |

<table>
<thead>
<tr>
<th>Yearly and revalidation tests – TP(S)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Weekly safety checks</td>
<td>7.8 to 7.9</td>
</tr>
<tr>
<td>2. Automatic control test</td>
<td>12.4 to 12.8</td>
</tr>
<tr>
<td>3. Verification of calibration of WD instruments</td>
<td>9.311 to 9.312</td>
</tr>
<tr>
<td>4. Water system</td>
<td></td>
</tr>
<tr>
<td>– chemical purity</td>
<td>9.100 to 9.200</td>
</tr>
<tr>
<td>– bacterial endotoxins</td>
<td>9.201 to 9.212</td>
</tr>
<tr>
<td>– Total viable count</td>
<td>9.213 to 9.226</td>
</tr>
<tr>
<td>– Environmental mycobacteria</td>
<td>9.227 to 9.236</td>
</tr>
<tr>
<td>5. Drainage</td>
<td></td>
</tr>
<tr>
<td>– blocked drain protection</td>
<td>9.25 to 9.37</td>
</tr>
<tr>
<td>– free draining</td>
<td>9.38 to 9.39</td>
</tr>
<tr>
<td>– pipework residual volume</td>
<td>9.49 to 9.56</td>
</tr>
<tr>
<td>6. Venting system</td>
<td></td>
</tr>
<tr>
<td>– load contamination</td>
<td>9.61 to 9.68</td>
</tr>
<tr>
<td>7. Doors and door interlocks</td>
<td></td>
</tr>
<tr>
<td>– Cycle start</td>
<td>9.253 to 9.256</td>
</tr>
<tr>
<td>– In-cycle</td>
<td>9.257 to 9.259</td>
</tr>
<tr>
<td>– On sensor failure</td>
<td>9.264 to 9.265</td>
</tr>
<tr>
<td>– Opening force</td>
<td>9.266 to 9.270</td>
</tr>
<tr>
<td>– Failed cycle</td>
<td>9.271 to 9.273</td>
</tr>
<tr>
<td>8. Fault interlock</td>
<td></td>
</tr>
<tr>
<td>10. Chemical additive dosing tests</td>
<td></td>
</tr>
<tr>
<td>– reproducibility</td>
<td>9.279 to 9.284</td>
</tr>
<tr>
<td>– low level detection</td>
<td>9.285 to 9.289</td>
</tr>
<tr>
<td>11. Load carriers</td>
<td>9.313 to 9.315</td>
</tr>
<tr>
<td>12. WD self-disinfection test</td>
<td>17.3 to 17.15</td>
</tr>
<tr>
<td>13. Final rinse decontamination test</td>
<td>17.16 to 17.18</td>
</tr>
<tr>
<td>14. Channel patency test</td>
<td>17.19 to 17.22</td>
</tr>
<tr>
<td>15. Disinfectant concentration test</td>
<td>17.23 to 17.32</td>
</tr>
<tr>
<td>16. Cleaning efficacy test</td>
<td></td>
</tr>
<tr>
<td>– test soil</td>
<td>17.34 to 17.40</td>
</tr>
<tr>
<td>– reference load</td>
<td>17.33</td>
</tr>
<tr>
<td>17. Chamber wall temperature test</td>
<td>9.317 to 9.322</td>
</tr>
</tbody>
</table>
## 7.0 Schedule of periodic tests

<table>
<thead>
<tr>
<th>Test Description</th>
<th>Reference Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Load carrier temperature test</td>
<td>9.323 to 9.329</td>
</tr>
<tr>
<td>Over-temperature cut-out test</td>
<td>9.330 to 9.335</td>
</tr>
<tr>
<td>Thermometric test for disinfection stage</td>
<td>11.4 to 11.11</td>
</tr>
<tr>
<td>– reference load</td>
<td>17.33</td>
</tr>
<tr>
<td>Microbiological test of disinfection efficacy</td>
<td>17.41 to 17.42</td>
</tr>
<tr>
<td>Load dryness test</td>
<td>9.336 to 9.342</td>
</tr>
<tr>
<td>Test for air quality</td>
<td>9.349 to 9.352</td>
</tr>
<tr>
<td>Sound pressure</td>
<td>9.53 to 9.59</td>
</tr>
</tbody>
</table>
Table 5f  WDs for laboratory use: Type 1

<table>
<thead>
<tr>
<th>Daily tests – user</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Automatic control test</td>
<td>12.4 to 12.8</td>
</tr>
<tr>
<td>2. Check spray arm rotation for free movement</td>
<td></td>
</tr>
<tr>
<td>3. Check spray nozzles for blockage</td>
<td></td>
</tr>
<tr>
<td>4. Remove and clean strainers and filters</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Weekly tests – user or TP(S)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Weekly safety checks</td>
<td>7.8 to 7.9</td>
</tr>
<tr>
<td>2. Carry out Daily tests</td>
<td></td>
</tr>
<tr>
<td>3. Water hardness (all process stages)</td>
<td>9.140 to 9.152</td>
</tr>
<tr>
<td>4. Water conductivity (final rinse stage)</td>
<td>9.112 to 9.122</td>
</tr>
<tr>
<td>5. Cleaning efficacy test by residual soil detection</td>
<td>10.37 to 10.49</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Quarterly tests – TP(S)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Weekly safety checks</td>
<td>7.8 to 7.9</td>
</tr>
<tr>
<td>2. Automatic control test</td>
<td>12.4 to 12.8</td>
</tr>
<tr>
<td>3. Verification of calibration of WD instruments</td>
<td>9.311 to 9.312</td>
</tr>
<tr>
<td>4. Thermometric test for thermal disinfection</td>
<td>11.4 to 11.11</td>
</tr>
<tr>
<td>5. Cleaning efficacy test</td>
<td></td>
</tr>
<tr>
<td>– test soil</td>
<td>10.7 to 10.24</td>
</tr>
<tr>
<td>– reference load</td>
<td>18.4 to 18.10</td>
</tr>
<tr>
<td>– test soil</td>
<td>18.3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Yearly and revalidation tests – TP(S)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Yearly safety checks</td>
<td>7.10 to 7.13</td>
</tr>
<tr>
<td>2. Automatic control test</td>
<td>12.4 to 12.8</td>
</tr>
<tr>
<td>3. Verification of calibration of WD instruments</td>
<td>9.311 to 9.312</td>
</tr>
<tr>
<td>5. Drainage</td>
<td></td>
</tr>
<tr>
<td>– free draining</td>
<td>9.38 to 9.39</td>
</tr>
<tr>
<td>– efficacy of discharge</td>
<td>9.40 to 9.42</td>
</tr>
<tr>
<td>6. Doors and door interlocks</td>
<td></td>
</tr>
<tr>
<td>– Cycle start</td>
<td>9.253 to 9.256</td>
</tr>
<tr>
<td>– In-cycle</td>
<td>9.257 to 9.259</td>
</tr>
<tr>
<td>– On sensor failure</td>
<td>9.264 to 9.265</td>
</tr>
<tr>
<td>– Failed cycle</td>
<td>9.271 to 9.273</td>
</tr>
<tr>
<td>7. Fault interlock</td>
<td>9.274 to 9.278</td>
</tr>
<tr>
<td>10. Chemical additive dosing tests</td>
<td></td>
</tr>
<tr>
<td>– reproducibility</td>
<td>9.279 to 9.284</td>
</tr>
<tr>
<td>– low level detection</td>
<td>9.285 to 9.289</td>
</tr>
<tr>
<td>11. Load carriers</td>
<td>9.313 to 9.315</td>
</tr>
<tr>
<td>12. Test for air quality</td>
<td>9.349 to 9.352</td>
</tr>
<tr>
<td>13. Cleaning efficacy test</td>
<td></td>
</tr>
<tr>
<td>– test soil</td>
<td>10.7 to 10.24</td>
</tr>
<tr>
<td>– reference load</td>
<td>18.4 to 18.10</td>
</tr>
<tr>
<td>– test soil</td>
<td>18.3</td>
</tr>
<tr>
<td>15. Thermometric test for thermal disinfection</td>
<td></td>
</tr>
<tr>
<td>– reference load</td>
<td>11.4 to 11.11</td>
</tr>
<tr>
<td>– reference load</td>
<td>18.3</td>
</tr>
<tr>
<td>16. Load dryness test</td>
<td>9.336 to 9.342</td>
</tr>
<tr>
<td>– reference load</td>
<td>18.3</td>
</tr>
<tr>
<td>17. Process residues – chemical additives</td>
<td>9.343 to 9.348</td>
</tr>
<tr>
<td>18. Performance qualification tests</td>
<td></td>
</tr>
</tbody>
</table>

Note: for some applications more stringent testing may be required, see chemical purity 9.100 to 9.200; bacterial endotoxins 9.201 to 9.212; total viable count 9.213 to 9.226; environmental bacteria 9.227 to 9.236.
<table>
<thead>
<tr>
<th>Schedule of periodic tests</th>
</tr>
</thead>
</table>

**Table 5g. Ultrasonic cleaners: Type 1 – Free-standing Ultrasonic cleaners: Type 2 – Section of multiple chamber/conveyor WD**

<table>
<thead>
<tr>
<th>Daily tests – user</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Automatic control test</td>
<td>12.4 to 12.8</td>
</tr>
<tr>
<td>2. Remove and clean strainers and filters</td>
<td>12.4 to 12.8</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Weekly tests – user or TP(S)</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Weekly safety checks</td>
<td>7.8 to 7.9</td>
</tr>
<tr>
<td>2. Carry out Daily tests</td>
<td>7.8 to 7.9</td>
</tr>
<tr>
<td>3. Cleaning efficacy test by residual soil detection</td>
<td>10.37 to 10.49</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Quarterly tests – TP(S)</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Weekly safety checks</td>
<td>7.8 to 7.9</td>
</tr>
<tr>
<td>2. Automatic control test</td>
<td>12.4 to 12.8</td>
</tr>
<tr>
<td>3. Verification of calibration of WD instruments</td>
<td>9.311 to 9.312</td>
</tr>
<tr>
<td>4. Test for ultrasonic activity</td>
<td>19.3 to 19.17</td>
</tr>
<tr>
<td>5. Cleaning efficacy test</td>
<td>10.7 to 10.24</td>
</tr>
<tr>
<td>– test soil</td>
<td>18.4 to 18.10</td>
</tr>
<tr>
<td>– reference load</td>
<td>18.3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Yearly and revalidation tests – TP(S)</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Weekly safety checks</td>
<td>7.8 to 7.9</td>
</tr>
<tr>
<td>2. Automatic control test</td>
<td>12.4 to 12.8</td>
</tr>
<tr>
<td>3. Verification of calibration of WD instruments</td>
<td>9.311 to 9.312</td>
</tr>
<tr>
<td>4. Water system</td>
<td>9.237 to 9.244</td>
</tr>
<tr>
<td>– overflow test</td>
<td>9.245 to 9.252</td>
</tr>
<tr>
<td>– volume used per stage</td>
<td>9.140 to 9.152</td>
</tr>
<tr>
<td>– hardness</td>
<td>9.89 to 9.93</td>
</tr>
<tr>
<td>5. Drainage</td>
<td>9.237 to 9.244</td>
</tr>
<tr>
<td>– free draining</td>
<td>9.245 to 9.252</td>
</tr>
<tr>
<td>6. Doors and door interlocks</td>
<td>9.253 to 9.256</td>
</tr>
<tr>
<td>– Cycle start</td>
<td>9.257 to 9.259</td>
</tr>
<tr>
<td>– In-cycle</td>
<td>9.266 to 9.270</td>
</tr>
<tr>
<td>– Opening force</td>
<td>9.274 to 9.278</td>
</tr>
<tr>
<td>7. Fault interlock</td>
<td>9.298 to 9.307</td>
</tr>
<tr>
<td>8. Aerosol discharge test</td>
<td>9.274 to 9.278</td>
</tr>
<tr>
<td>9. Chemical additive dosing tests</td>
<td>9.279 to 9.284</td>
</tr>
<tr>
<td>– reproducibility</td>
<td>9.285 to 9.289</td>
</tr>
<tr>
<td>– low level detection</td>
<td>9.285 to 9.289</td>
</tr>
<tr>
<td>10. Cleaning efficacy test</td>
<td>10.7 to 10.24</td>
</tr>
<tr>
<td>– test soil</td>
<td>19.22 to 19.31</td>
</tr>
<tr>
<td>– reference load</td>
<td>19.18 to 19.21</td>
</tr>
<tr>
<td>11. Chamber wall temperature test</td>
<td>9.317 to 9.322</td>
</tr>
<tr>
<td>12. Load carrier temperature test</td>
<td>9.323 to 9.329</td>
</tr>
<tr>
<td>14. Thermometric test for thermal disinfection 1</td>
<td>11.4 to 11.11</td>
</tr>
<tr>
<td>– reference load</td>
<td>19.18 to 19.21</td>
</tr>
<tr>
<td>15. Load dryness test</td>
<td>9.336 to 9.342</td>
</tr>
<tr>
<td>– reference load</td>
<td>18.3</td>
</tr>
<tr>
<td>16. Test for ultrasonic activity</td>
<td>19.3 to 19.17</td>
</tr>
<tr>
<td>17. Sound pressure</td>
<td>9.53 to 9.59</td>
</tr>
</tbody>
</table>

---

1. Only required for WDs with automatic chemical dosing
2. Only required for WDs with a thermal disinfection stage
3. Only required for WDs with a drying stage
8.0 Test equipment and materials

Introduction

8.1 This chapter reviews the major items of portable test equipment necessary to carry out the test procedures described in this HTM. Specifications for instruments fitted permanently to WDs are given in the relevant British Standards and will be included in the forthcoming European Standards; they are discussed in HTM 2030 ‘Operational management’.

8.2 Instrumentation technology continues to advance rapidly making it increasingly difficult and undesirable to provide detailed specifications for the equipment to be used in testing WDs. There is a clear trend towards computer controlled data loggers with software which enables the system to verify attainment of the required conditions and then to produce a detailed written report accompanied by tabulated or graphed data. Although these new systems may offer advantages in clarity of presentation, as well as reduced operator time, the traditional instruments, such as chart recorders, remain equally acceptable.

8.3 The objectives of this chapter are both to ensure that traditional measurement methods are supported adequately and to define clearly the essential requirements that apply to the test equipment whether it is a traditional system or the latest technology.

8.4 When it is proposed to use measurement and/or recording techniques that are not covered in this HTM the advice of the AP(S) should be sought.

8.5 It has been assumed also that there will be ready access to standard laboratory equipment and supplies.

Calibration and sources of error

8.6 Errors of measurement occur for a number of reasons. These include inherent factors such as the design of the measuring equipment and other problems such as loose or imperfect connections and change in environmental temperature around the instrument. Variations in the sensors themselves, the method of introducing the sensors into the WD and their location within the load may add to the error in the temperature measurement. Changes in conditions other than the one being sensed may also lead to errors, for example temperature fluctuations within pressure sensing elements may lead to errors in pressure measurement.

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

8.8 Instruments should be subjected to a planned maintenance and calibration programme in accordance with the instrument manufacturers recommendations. Each instrument should be labelled with a calibration date and a reference from which its current calibration status may be traced.
8.9 The calibration of all test instruments should be verified yearly by using reference instruments with a valid certificate of calibration traceable to a national standard. A history record should be kept for each instrument.

8.10 In use all electronic test instruments should be located in a position protected from draughts and not subjected to rapid temperature variations. Test instruments should be allowed a period of time to stabilise within the environment of the test site. The manufacturer’s instructions should be followed.

Recorders

8.11 Test recorders are required to measure temperature in all types of WD and may also be required for the measurement of pressure, flow rates and humidity. They should be designed for use with the appropriate sensors, independent of those fitted to the WD, as described later in this HTM. Most of the tests described in this HTM may be conducted with a single recorder combining both temperature and pressure functions showing both records on the same chart or print-out. For WDs incorporating humidity control or humidity monitoring of a hot air drying stage, the measurement of humidity is desirable but not essential.

8.12 Analogue recorders should comply with the display requirements of BS 3693. Recorders using a potentiometric system should comply with BS 5164.

8.13 Digital recorders (data loggers) have many advantages over traditional pen recorders. Data may be presented graphically or as a listing of numerical values or as a combination of both. In many cases parts of the operating cycle can be expanded and replotted for closer examination.

8.14 Digital recorders should have the facility to copy data onto tape or disk which can then be removed for secure storage. Software used with digital recorders should be developed under a quality system (such as BS EN ISO 9001).

8.15 The detailed specification for a test recorder will depend upon the range of WDs with which it is to be used. The measurement system (recorder and sensors) should be capable of measuring cycle variables to an accuracy equal to, or greater than, the instruments fitted to the WD.

8.16 The accuracy with which a variable can be read from the recorder will be affected not only by the sources of error discussed above but also by the precision of the calibration, the scale range, the integration time, the sampling interval and the intrinsic accuracy of the recorder. Digital instruments may register measurements with a precision greater than the accuracy of the system as a whole and care needs to be taken with the interpretation of such measurements.

8.17 The accuracies quoted by recorder manufacturers are measured under controlled reference conditions and do not include the errors from connected sensors. Temperature measurement errors due to ambient temperature changes should not exceed 0.04°C per °C rise.
Temperature measurement

Temperature sensors

8.18 Temperature sensors should be used to sense the temperature in locations specified in the tests described in this HTM. The sensors should be either platinum resistance elements and comply with IEC 751 Class A or thermocouples and comply with the relevant international table specified in IEC 584 Tolerance Class 1.

8.19 The performance characteristics of the temperature sensor should not be adversely affected by the environment in which it is placed, eg pressure, hot detergent solution etc.

8.20 In order to avoid undue disturbance of the system being measured the major diameter of the temperature sensors and their connecting leads which will be located within the WD should not exceed 2 mm.

Thermometric recording instrument(s)

8.21 One or more thermometric recording instruments should be used in conjunction with the temperature sensors to record the temperatures measured in the locations specified in the tests described in this HTM. They may also be used to verify the readings obtained from instruments fitted to the WD.

8.22 The recording instrument(s) should record the temperature from a minimum of three temperature sensors. The channels may be multiplexed or independent of one another. The data recording rate for each channel should not exceed 2.5 s. All data sampled should be used for the interpretation of results.

8.23 The scale range should include the expected maximum and minimum values of the cycle variables throughout the operating cycle with sufficient allowance for any deviations resulting from a malfunctioning WD. This should normally include at least the range 10ºC to 110ºC.

8.24 In some WDs the air temperature close to the heater bank during the drying stage may considerably exceed the upper limit of the air drying temperature.
**Figure 3:** A method of introducing temperature sensors into a WD chamber

The illustration shows a fitting designed for a WD chamber having a male gland and an ‘O’ ring seal. When the gland is a female thread an adaptor will be required (F).

Other methods of introducing temperature sensors into a WD chamber, which guarantee a water-tight seal, are equally acceptable.
8.25 The most critical stage of the WD operating cycle is the disinfection stage. It is during this period that the values of the cycle variables are at their most critical and the recorder should be capable of measuring them to sufficient accuracy to confirm that the disinfection conditions have been attained. The criteria are as follows.

a. For digital recorders, the sampling interval should be short enough for the holding time to contain at least five independent measurements in each recording channel.

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

c. The recorder must be accurate enough to show clearly whether the measured temperatures are within the disinfection temperature band. The repeatability of the recorder should be ± 0.5ºC or better and the limit of error of the complete measurement system including sensors should be no more than 1.0ºC when tested in an ambient temperature of 20ºC ± 3K. The additional error due to changes in environmental temperature should not exceed 0.04 K/K.

d. For analogue instruments the minor mark interval should not exceed 1K and the chart speed should be not less than 10 mm per minute. The resolution should be not less than 0.5 K. Digital instruments should register and record in increments of not more than 0.1 K.

Use of sensors

8.26 WDs conforming to BS 2745 are equipped with thermocouple entry glands of the same type as those used on sterilizer chambers. A typical method of introducing sensors into the chamber is shown in Figure 3.

8.27 In older machines, having no dedicated entry port, entry may be made via a tee which can usually be inserted into a service entry pipe to the chamber (for example the water supply pipe). Sensors should not be introduced through a door seal.

8.28 Many of the tests require a sensor to be placed at the reference point specified by the manufacturer as representative of the conditions prevailing throughout the chamber and load. This will usually be in the drain or sump of the chamber and will often be adjacent to the sensor used for the automatic controller.

8.29 The sensors may often be placed in positions where they are submerged for most of the cycle. Under these conditions water may migrate along the wire between the cores and the outer insulation sheath. To prevent damage to the recorder the outer sheath should either be punctured or stripped back a few centimetres from the end connected to the recorder to allow droplets of water to fall clear of the recorder.

8.30 Sensors used to monitor the temperature of load items and the chamber walls should be held securely in good thermal contact with the region to be monitored using high temperature masking tape or autoclave indicator tape.
8.0 Test equipment and materials

Calibration

8.31 Calibration should be carried out in accordance with the instrument manufacturers instructions by a validated method using a working or reference standard which is traceable to a national standard.

8.32 The instrument should have a valid test certificate and the calibration data should include a temperature within the disinfection temperature band.

8.33 Before and after each series of tests on a WD the temperature recording system should be verified by comparison with an independent temperature reference source at a temperature within the disinfection temperature band.

8.34 The temperature measured by all temperature sensors when immersed in a temperature source at a temperature known within ± 0.1K and within the disinfection temperature band should not differ by more than 0.5K after calibration and adjustment.

Self-contained systems

8.35 Temperature measuring systems involving the use of leads from the sensing point within the load to an external measuring instrument are difficult or impractical to use within several designs of WD, for example continuous process machines consisting of several interconnecting cabins which are separated by intermediate doors during processing.

8.36 A number of different designs of small self-contained single channel data loggers for the measurement of temperature are commercially available. They are independently powered, may be programmed to take readings at the required rate for the required duration and are downloaded onto a personal computer on completion of the data logging period. Those housed in protective cases rated at IP68 are suitable for inclusion in washing machines.

8.37 Care needs to be taken in selecting units which are capable of withstanding the high temperature which may be found during the thermal disinfection stage (≥ 90°C) and drying stage (≥ 105°C) of the cycle since many of these devices are powered by batteries which will not withstand temperatures above approximately 75°C.

8.38 Data loggers with an external probe may be housed in an insulated waterproof container through which the lead to the sensor passes by means of a leak tight gland. A 25 mm thick layer of mineral wool insulation on all surfaces of a datalogger contained within a 1000 ml screw top polypropylene jar has proved suitable.

8.39 The accuracy obtainable from these units is rarely to the standard specified for conventional temperature recorders but the limit of error should not exceed ± 0.8°C when tested over the range 0°C to 100°C at an ambient temperature of 20°C ± 3K. The additional error due to changes in environmental temperature should not exceed 0.04 K/K instruments should register and record in increments of not more than 1K.

8.40 The device should be capable of recording the sensed temperature at least every 1 second and should be capable of storing not less than 1800 records.
8.41 For continuous process WDs not less than three such devices will be needed together with a conventional temperature recorder.

Pressure measurement

8.42 Pressure may be required to be measured over the range from atmospheric to 10 bar (for example for the water supply pressure). Differential pressure of 1 –100 hectoPascals may be required to be measured (for example for the determination of the pressure drop across filters).

Transducers

8.43 Transducers for use with pressure recorders should conform with BS 6447, be suitable for the purpose and be of an accuracy equal to, or better than, the gauges specified below. The natural frequency of the sensor and connected tubing should be not less than 10Hz and the time constant for rising pressure (0–63%) should be not greater than 0.04 seconds.

Gauges

8.44 Pressure gauges are required when the pressure recorder is unsuitable or for verifying the calibration of pressure instruments fitted to the WD.

8.45 Three gauges will normally be required to cover the whole pressure range for all WDs and these are shown in Table 6.

8.46 Pressure gauges should be temperature compensated and except for the differential pressure gauge be Bourdon-tube gauges conforming to BS 837 Part 1 of nominal size 150 mm and accuracy class 0.25 (that is, the air should not exceed 0.25% FSD).

Table 6 Requirements for pressure measurement

<table>
<thead>
<tr>
<th>Scale range</th>
<th>Mark interval</th>
<th>Calibration</th>
<th>Application</th>
</tr>
</thead>
<tbody>
<tr>
<td>0–100 kPa</td>
<td>1 kPa</td>
<td>Liquid</td>
<td>Differential pressure across water filters</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Flow through endoscopes</td>
</tr>
<tr>
<td>0–1000 kPA</td>
<td>5 kPa</td>
<td>Liquid</td>
<td>Water supply pressure</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Recirculating pump pressure</td>
</tr>
<tr>
<td>0–50 kPa</td>
<td>1 kPa</td>
<td>Air</td>
<td>Differential pressure across air filter</td>
</tr>
</tbody>
</table>

8.47 Gauges should be tested yearly by a recognised testing laboratory as described in paragraph 5.2.1 of BS 1780.

8.48 The measurement of differential pressure across air filters may be made with an inclined water manometer.
8.49 The recorder for pressure measurement should have an overall limit of error no more than 1% of the maximum specified operating pressure.

**Flow measurement**

**Water**

8.50 The volume of water used for each stage of the operating cycle may be measured using a water meter complying with ISO 4064 Part 1 Class A.

8.51 The meter should be designed to operate at temperatures up to 90°C with a supply pressure up to 16 bar.

8.52 The meter should have a minimum scale division of 0.1 litres or less and be designed to measure flow rates over the range 1 litre per minute to 25 litres per minute.

8.53 A single jet turbine system is sufficiently accurate for the purpose. Other systems such as multi-jet turbine or semi-positive displacement systems complying with ISO 4064 Part 1 Class B or Class C, or BS 5728 Class D, may also be used.

8.54 The calibration of the meter should be verified by determining the indicated volume flowing to a collecting vessel and comparing this with the collected volume which may be determined by gravimetric or volumetric measurement.

**Chemical additives**

8.55 The volume of chemical additive used for each stage of the operating cycle may be measured using a flow meter. There are a number of commercially available flow sensors designed to monitor flows in the range 0 to 2 litres/minute which are suitable for interfacing to a recorder or datalogger.

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

8.57 The sensor should be designed to operate at temperatures up to 70°C with a supply pressure up to 10 bar.

8.58 The meter/recorder should have a minimum scale division of 10 millilitres or less and be designed to measure flow rates over the range 50 ml/min to 1500 ml/min.

8.59 The system should have an accuracy of ± 2.5% of full scale or better.

8.60 The calibration of the meter should be verified by determining the indicated volume flowing to a collecting vessel and comparing this with the collected volume determined by gravimetric or volumetric measurement.
Volume measurement

8.61 The volume of chemical additives and the volume of water used in each stage are critical variables in the control of the washing-disinfecting process.

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

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

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


Humidity measurement

8.66 Humidity is one of the cycle variables that may be used to control the drying stage on WDs of various types. The level of humidity in the chamber and load at the end of the drying stage is ideally measured during validation by test instruments calibrated for relative humidity (RH) at atmospheric pressure. The accuracy of measurement should not be less than ± 10% RH over the range 30 to 80% RH.

8.67 There is no British Standard for humidity sensors but it is recommended that the test sensors should function at temperatures of 10ºC to 100ºC and at pressures up to 2 bar absolute.

Other instruments

Sound level meter

8.68 An integrating sound level meter is required for the sound pressure test. It should comply with Type 2 of BS 6698 (BS EN 60804: 1994 specification for integrating-averaging sound level meters). Ten microphones are required for the test on a single WD.

Balance

8.69 A laboratory balance may be required for load dryness tests and for calibration of flow meters (for measuring the flow of water and/or chemical additives). It should be capable of measuring the mass of loads up to 4 kg to an accuracy of 0.1 g and up to 400 g to an accuracy of 0.01 g.

8.70 An analytical balance is required for determination of the Total Dissolved Solids (Evaporative residue) in feed water. It should be capable of measuring a mass of up to 100 g with an accuracy of 0.1 mg.
8.0 Test equipment and materials

Gas monitoring equipment

8.71 A gas monitoring instrument is required for tests on WDs using chemical additives which have a significant vapour pressure and are a potential risk.

8.72 The nature of the instrument will depend on the substance to be monitored. In case of doubt advice should be sought from the manufacturer of the chemical additive or the AP(S).

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

Aerosol generator

8.74 An aerosol generator is required for tests on WDs incorporating air filters intended to deliver air free from micro-organisms.

8.75 The device should be capable of generating a polydisperse aerosol with particles having the size distribution shown in Table 7.

Particle counting photometer

8.76 A particle counter is required for tests on WDs incorporating air filters intended to deliver air free from micro-organisms. The device should be suitable for estimation for comparison of mass concentration of airborne particles as defined in Table 7.

8.77 It should have an accuracy of better than ±5% over the range of a five-expandable, six-decade resolution (that is 0.01% to 100% of the test cloud) as specified in Appendix C of BS 5295 Part 1.

8.78 The photometer should have a minimum threshold sensitivity of 0.0001 µg.l⁻¹ and should be capable of measuring aerosol concentration in the range 80-120 µg.l⁻¹.

8.79 The sampling flow rate should be 0.40 ± 0.05 l s⁻¹ and sampling should be via a suitable probe.
Table 7 Particle size distribution for aerosol generator

<table>
<thead>
<tr>
<th>Particle size µm</th>
<th>Fraction % by mass</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 0.5</td>
<td>&gt; 20</td>
</tr>
<tr>
<td>&lt; 0.7</td>
<td>&gt; 50</td>
</tr>
<tr>
<td>&lt; 1.0</td>
<td>&gt; 75</td>
</tr>
</tbody>
</table>

Source: BS 5295 Part 1
9.0 Testing methods

9.1 This chapter discusses general principles and methods that are used in the tests described in this HTM.

Terminology

9.2 For the purposes of this HTM the following definitions have been adopted.

Cycle variables

9.3 The cycle variables are the physical and chemical properties such as time, temperature, pressure, flow rate, concentration, chemical composition that influence the efficacy of the cleaning and disinfection processes. Many of the test described in this HTM require the values of cycle variables to be determined experimentally and then compared with specified or standard values.

9.4 An indicated value is that shown by a visual display fitted to the WD.

9.5 A recorded value is that shown on the output of a recording instrument fitted permanently to the WD.

9.6 A measured value is that shown on a test instrument, for example a temperature recorder attached to the WD for test purposes.

9.7 A noted value is that written down following personal observation of an indicated, recorded or measured value.

Disinfection conditions

9.8 Most operating cycles have a stage in which the load is exposed to the disinfection conditions for a specified length of time. This period is known as the holding time.

9.9 The disinfection conditions are the ranges of the cycle variables which may prevail throughout the chamber and load during the holding time.

9.10 The holding time is preceded by a period in which the disinfection conditions are present in the chamber but have yet to be attained throughout the load. This is known as the equilibration time.

9.11 Together the equilibration time and the holding time constitute the plateau period. The plateau period can always be determined from the indicated or recorded temperature in the chamber during each cycle. The equilibration and holding times cannot be ascertained unless the temperature in that part of the load which is slowest to reach temperature is also being measured.
9.12 For thermal (moist heat) disinfection the disinfection conditions are specified by a 
\textbf{disinfection temperature band}, defined by a minimum acceptable temperature, known as the 
\textbf{disinfection temperature}, and a \textbf{maximum allowable temperature}.

9.13 The higher the disinfection temperature the shorter the holding time which will be required to achieve the same level of disinfection (see Table 3).

9.14 For liquid chemical disinfection, the disinfection conditions are specified by a 
\textbf{disinfection temperature band} and a \textbf{disinfectant contact concentration range}. The disinfection temperature band is defined by a minimum acceptable temperature, known as the disinfection temperature and a maximum allowable temperature. The disinfectant contact concentration is specified by the minimum acceptable concentration in contact with the load to be disinfected and the maximum allowable concentration.

9.15 For those WDs in which the chemical disinfection stage is thermostatically controlled at elevated temperature, the duration of the exposure to chemical germicide may be determined thermometrically. In most cases, investigation of the performance of chemical disinfection processes can only be carried out successfully using microbiological test methods in conjunction with physical testing.

9.16 The disinfection temperature band may also be quoted for liquid chemical disinfection/sterilization processes but is not a complete specification of the disinfection conditions since the efficacy of such processes depends also on the concentration of the chemical agent.

\textbf{Drainage}

\textbf{Drain seal integrity}

\textit{Introduction}

9.17 When it is impractical to vent the WD externally a condenser may be used to allow venting into the workspace without discharging hot, humid air. The restricted flow associated with this system may produce a back pressure in the chamber. If the back pressure is excessive the water seal between the chamber and drain may be broken.

9.18 The 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 2745: Part 2: 1993, Annex B) and as an operational or installation test.

\textit{Equipment}

9.19 The following equipment is necessary:
- a full load of the type the WD is designed to process;
- a test trap, of the same type and dimensions as normally fitted, but manufactured from a transparent material (Type test only).
**Method for Type test**

9.20 The transparent tap is fitted in place of the normal trap and connected to a suitable outlet. Sufficient water is poured into the chamber to charge the trap to the normal level. Verify that there are no leaks.

9.21 A full load is placed in the chamber, the door closed and an operating cycle initiated. Without opening the door between cycles a further four cycles are run. During each operating cycle observe the trap and establish whether the water seal in the trap has been broken.

**Method for operational test**

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

9.23 A full load is placed in the chamber, the door closed and an operating cycle initiated. 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.

**Results**

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

**Blocked drain protection**

**Introduction**

9.25 In the event that the drain from the chamber of the WD became blocked continued operation of the WD would allow water and suspended soil to be discharged onto the floor either during the operating cycle or, for cabinet type WDs with sealed door(s), by sudden discharge when the door is opened at the end of the cycle.

9.26 The purpose of blocked drain protection is to prevent unacceptable spillage and minimise the risk of cross-infection.

9.27 In the test the drain is deliberately blocked and successive operating cycles are run until the water level is above the level of the door seal. The test is intended for use both as a type test (and as such is a requirement of BS 2745 Part 2 1993) and as an operational or installation test.

**Equipment and materials**

9.28 A solid metal sphere of diameter 10% to 15% greater than the internal diameter of the trap or similar means of obstructing the discharge from the drain is necessary.
Method for WDs with sealed doors

9.29 Introduce the metal sphere (or equivalent device) to block the drain.

9.30 Close the door and start the operating cycle. On completion of the operating cycle attempt to open the WD door using the normal release procedure.

9.31 If the door opens and the water level is below the door seal close the door and start another operating cycle.

9.32 Repeat the operating cycle as many times as necessary for either the water level at the end of the cycle to be above the level of the door seal or for a fault to be indicated.

Method for WDs without sealed doors

9.33 Introduce the metal sphere (or equivalent device) to block the drain.

9.34 Start the operating cycle. On completion of the operating cycle if no water has been spilled from the WD and no fault has been indicated start another operating cycle.

9.35 Repeat the operating cycle as many times as necessary for either water to be spilled from the WD or for a fault to be indicated.

Results for WDs with sealed doors

9.36 A fault should be indicated on, or before, the water level in the chamber reaching the level of the door seal. The door should not be capable of being opened by the normal release procedure; a tool, key or code should be required.

Results for WDs without sealed doors

9.37 A fault should be indicated before water is spilled from the WD and the operating cycle should be stopped preventing further inflow of water. A tool, key or code should be required to restart the WD.

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

Introduction

9.38 Residual water that does not drain from the internal pipework of the WD may provide an environment for microbial growth; these micro-organisms may then be available to re-contaminate the disinfected load.

9.39 The following checks should be carried out during Type testing, works testing and Installation testing to verify that as designed, built and installed the WD will effectively discharge all the water from the system.

(i) Free draining of chamber and load carriers
   – test by visual observation at end of the cycle;

(ii) Free draining of tanks
   – test by visual observation on draining the tanks;
9.0 Testing methods

(iii) Pipework flow to discharge point
– test by visual observation including use, when necessary, of a spirit level.

Purging of the trap (Type test only)

Introduction

9.40 The British Standard for WDs for human-waste containers requires that the mean volume of water discharged in each operating cycle shall exceed 15 litres and that on completion of the washing stage of the operating cycle the trap shall be clear of waste and soil.

9.41 The test method for determination of the volume of water discharged is described in BS 2745: Part 2: 1993 Annex D.

9.42 An alternative test method, applicable to all types of WD, is described in paragraphs 9.43 to 9.48.

Efficacy of discharge through the trap

Introduction

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

Equipment and materials

9.44 The following equipment and materials are necessary.
   a. test soil appropriate to the type of WD being tested (see Chapter 10);
   b. sampling tube of sufficient length to reach the water trap in the drain of the WD and a sampling pump (for example a pipette pump or syringe).

Method

9.45 The test may be carried out as part of the cleaning efficacy test during operational testing.

9.46 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.

9.47 Examine the water sample from the trap for residual test soil using the detection method appropriate to the test soil.

Results

9.48 The water in the trap should be free from residual soil at the same level of detection as that specified for the load items.

In other European countries great emphasis is placed on minimising the volume of water used and it is unlikely that this requirement will be included in a European standard for WDs for human-waste containers.

Residual soil in the trap may present an infection or recontamination hazard.
Estimation of dead volume of pipework

Introduction

9.49 Residual water that does not drain from the internal pipework of the WD may provide an environment for microbial growth; these micro-organisms may then be available to re-contaminate the disinfected load.

9.50 The test is intended primarily as a Type test but may also be of value as an operational test or when investigating microbial contamination occurring in a WD.

9.51 The test should only be carried out after completion of the checks for free drainage described in paragraphs 9.38 to 9.39 have been satisfactorily completed.

Equipment

9.52 Volumetric measuring vessels of appropriate size are necessary.

Method

9.53 The pipework of the WD which is known to be dry (either following disassembly and re-assembly or purging with dry compressed air for not less than 30 minutes) is flushed with a known volume of water (simulating the flow that would occur in normal use).

9.54 The volume of water flushed through the system should be twice that determined as the volume used per operating cycle (see paragraphs 9.201 to 9.212) The volume of water discharged is measured and the dead volume, estimated as the volume retained, calculated from the difference between the two values.

9.55 When the WD has two or more pipework systems which are entirely separate (for example for flushing water, wash water, rinse water, chemical disinfectant solution) each system may be tested separately.

Results

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

Venting system

Steam venting

Introduction

9.57 For WDs in which the load is heated and/or 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.

For WDs with chemical disinfection systems the retained volume in the pipework providing the final rinse volume should be, as nearly as possible, zero.
9.0 Testing methods

Equipment

9.58 A pressure gauge is necessary (if the WD chamber is not already equipped with a pressure gauge in a known state of calibration).

Method

9.59 Close and seal the chamber of the WD in the manner specified by the manufacturer and start an operating cycle. Over-ride the automatic controller to allow the continuous admission of steam to the chamber. Observe where steam is vented. Note the maximum value obtained on the pressure gauge.

Results

9.60 Steam discharge should occur solely through the vent. The noted 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 mbar (gage).

Load contamination from ductwork

Introduction

9.61 The evolution of water vapour from the chamber during the washing stage, thermal disinfection stage and drying stage may 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 2745) and as an installation or operational test.

Equipment and materials

9.62 The following equipment and materials are necessary.

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 WD;

d. paper towels.

Method

9.63 Disconnect the external ducting to the WD 1 metre above the chamber. (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.

9.64 Position the vessel approximately 1 m above the level of the chamber discharge to the vent.
With the on/off valve closed, fill the vessel with 200 ml ± 20 ml of cold water. Open the valve and adjust the flow control valve so that the contents of the vessel are discharged in 1 min ± 5 sec.

Refill the vessel with 200 ml ± 20 ml of cold water. Feed the flexible tube into the ducting so that the open end of the flexible tube is 600 mm to 800 mm above the top of the chamber.

9.65 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.

9.66 Within 1 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.

9.67 Repeat the above procedure for the full range of load carriers which the WD is designed to process.

Results

9.68 There should be no visible water on the load or load carriers

Water system

Introduction

9.69 A continuous supply of water of the specified chemical and microbial quality is essential to the correct functioning of all WDs. Water which is too hard or has too high a concentration of dissolved solids may impair the activity of detergents (or require the use of increased quantities of chemical additives) and cause deposits, scaling or corrosion of items being processed.

9.70 Water containing high numbers of micro-organisms may recontaminate disinfected items. For all these tests the water should be sampled from the water supply pipe to each WD. Additional samples may need to be taken from any water treatment plant when trying to identify the cause of a non-conformity.

Water samples

9.71 Water samples should be obtained from draw-off points installed at convenient locations within the system.

9.72 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.

9.73 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 litre acid washed, borosilicate bottles, 
   (for determination of cations);

c. 1 litre polypropylene bottles, 
   (for determination of anions, total dissolved solids);

d. 100 ml high density polyethylene bottles 
   (for determination of pH, conductivity).

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

9.75 All samples should be taken in duplicate.

9.76 Samples should be tested within four hours of collection or stored at 
   2°C to 5°C and tested within 48 hours of collection.

Water quality tests

9.77 The following sections describe analytical methods which may be used 
   to determine the various biological, physical and chemical properties of water 
   samples for the various qualities of feedwater to the WD.

9.78 The methods of analysis required 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. 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.

9.79 This HTM contains detailed procedures for tests which may be carried 
   out on-site or with very simple laboratory equipment at, or shortly after, the 
   time of sampling.

9.80 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. 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

9.81 For any given determinand there will usually be several methods which 
   are suitable and cover the range of concentrations of interest. The methods 
   given below are intended to be representative of those which may be suitable. 
   They are chosen as examples of tests which may conveniently be carried out 
   on site.

9.82 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.

9.83 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.
9.84 It is apparent that many contaminants will 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.

9.85 Further guidance on appropriate test methods may be obtained from BS 1427: 1993.

9.86 Tests suitable for use on-site fall into three main categories:

a. **instrumental tests** using portable instruments designed for on-site use for example portable pH meters, ion selective electrodes etc;

b. **spectrophotometric tests** based on measurement of the absorbance of a coloured reaction product; measurement may be visual or photometric and may be against a precalibrated coloured disc or against standard reference solutions;

c. **titrimetric tests** these 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.

9.87 For all the instrumental methods described there is commercially available equipment specifically intended for field use. All the variables for which instrumental methods are described 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.

9.88 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 manufacturers claimed sensitivity and accuracy for the method, the kit specified by the manufacturer should not be substituted.

**Water supply temperature**

*Introduction*

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

*Equipment*

9.90 An indicating or recording thermometer is necessary.

*Method*

9.91 The temperature of the water supply should be measured from a
sampling point as close to the WD 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)

9.92 When it is not convenient, or practicable, to run the water to waste from a sampling point close to the WD the water temperature may be estimated by measurement of the temperature of the outer surface of the supply pipe. When it is intended to use 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. The surface temperature should be measured using a sensor designed for the purpose and the manufacturers instructions for ensuring good thermal contact with the surface should be followed. The temperature should be noted or recorded during a normal operating cycle not less than 30 seconds after the start of water flow through the pipe to the WD.

Results

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

Water supply pressure

Introduction

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

9.95 If the pressure of the water supply to the WD 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 WD or to products being processed. (For example many flexible endoscopes are likely to be damaged if subjected to internal pressures greater than 35 kPa.)

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

Equipment

9.97 Pressure indicator or recorder 0–10 bar is necessary.

Method

9.98 The pressure sensor should be connected to each of the water supply pipes to the WD, as close to the WD as may be practicable, on the supply side of the WD isolating valve for that supply. The static pressure when the valve is closed and the pressure indicated throughout a normal operating cycle should be recorded or observed and noted. When the water service also supplies
other equipment on the same supply line, the test should be run 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

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

Appearance

Introduction

9.100 All the water supplied to the WD should be clean, colourless and free
from visible particulate matter. The appearance of the sample is assessed
visually.

Equipment

9.101 The following equipment is necessary:
   a. clean, clear glass bottle and stopper;
   b. filter paper (qualitative grade), filter funnel and holder.

Method

9.102 An aliquot should be transferred to a clear colourless glass bottle
which should then be tightly stoppered. The sample should be shaken well
and examined visually against a white background, preferably in a north light.

9.103 If the sample is turbid it should be filtered through a qualitative grade
filter paper. The filter paper should be examined and a description of the
retained material reported. The filtrate should then be visually examined as
previously described.

9.104 The appearance should be reported in terms of both colour and the
intensity of any colour. If the sample is coloured it should be examined
carefully to see if there is visible evidence of colloidal material present.

Results

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

pH

Introduction

9.106 Two suitable methods for on-site measurement of pH are available; the
colour disc comparator and portable pH meter.
Equipment

9.107 The following equipment is necessary.

a. pH meter
   (i) There are several commercially available small, portable, pH meters which cost only a few pounds. A number of these include built in temperature compensation. Although they provide suitable accuracy for most general applications they are not well suited to measurement of pH in solutions of low ionic strength. Their use for the determination of pH in water of high purity may 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.
   (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 8. 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

9.108 The test kit should be operated in accordance with the manufacturers instructions. Particular attention should be paid to using accurate volumes of both sample and reagent, and monitoring both temperature and reaction time.

9.109 The colour of the reacted sample is matched against the calibrated colour disc viewed through a blank sample. The value in pH units is read off directly from the disc.

9.110 The calibration should be verified 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

9.111 The indicated value should be in the range 5.5 to 8.0.
Electrical conductivity

Equipment and materials

9.112 There is a wide variety of portable conductivity meters available. The unit chosen should meet the performance criteria given below which will allow its use for measuring conductivity of very pure water through to boiler water containing in excess of 5,000 ppm TDS.

9.113 Meters are available to cover the range 0.1 mS.m\(^{-1}\) to 20,000 mS.m\(^{-1}\) at 25ºC. Conductivity meters may also be calibrated in µS.cm\(^{-1}\) The meter, or meters, used should cover the following ranges:

<table>
<thead>
<tr>
<th>Range</th>
<th>Resolution</th>
<th>Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.0 to 199 µS.cm(^{-1})</td>
<td>0.1 µS.cm(^{-1})</td>
<td>± 1 % full scale</td>
</tr>
<tr>
<td>10 to 1990 µS.cm(^{-1})</td>
<td>1 µS.cm(^{-1})</td>
<td>± 1.5 % full scale</td>
</tr>
<tr>
<td>100 to 19,900 µS.cm(^{-1})</td>
<td>10 µS.cm(^{-1})</td>
<td>± 1.5 % full scale</td>
</tr>
</tbody>
</table>

and should be temperature compensated over the range 0ºC to 40ºC.

Method

9.114 The following method is used for electrical conductivity calibration.

9.115 The calibration of the meter should be verified against 0.001 molar and 0.0005 molar solutions of potassium chloride and pure water as working standards. These give conductivities at 25ºC of 14.7 mS.m\(^{-1}\) and 84 µS.cm\(^{-1}\) and < 0.06 µS.cm\(^{-1}\).

9.116 The potassium chloride solutions may be prepared by dilution of a 0.1 molar solution.

9.117 The working standards are stable for up to 1 week when stored in cool conditions, in a well stoppered container.

9.118 A comprehensive range of standard conductivity reference solutions, including pure water standards (also known as absolute water) are available commercially, standardised at 25ºC and traceable to national standard reference materials.

9.119 After calibration the sample cup, or immersion probe, should be thoroughly rinsed with pure water.

9.120 The sample should be collected in a high density polyethylene bottle and tested as soon as practicable.

9.121 An aliquot of the sample should be poured into the sample cup of the conductivity meter or, for meters with an immersion probe, into the clean beaker. The meter manufacturers instructions for making the measurement should be followed; this will usually require a short stabilisation period before noting the reading.
**Results**

9.122 The conductivity at 25ºC should not exceed:
- 10 µS.cm⁻¹ for Reverse Osmosis water
- 30 µS.cm⁻¹ for De-ionised water
- 300 µS.cm⁻¹ for Softened or mains water

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

**Total dissolved solids**

**Introduction**

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

9.124 When a water sample contains predominantly ionizable solids in solution, and the composition of the various constituents is reasonably constant, a good estimate of the total dissolved solids may be obtained from the electrical conductivity of the sample which may be used to determine concentrations up to 10 000 mg/l total dissolved solids.

**Method a: conductivity method**

9.125 The following equipment and materials are necessary:
   - conductivity meter (see paragraphs 9.112 to 9.122);
   - phenolphthalein indicator;
   - 5% w/w acetic acid solution;
   - 5% w/w sodium hydroxide solution.

9.126 The test sample should be neutralised, using phenolphthalein as the indicator, by dropwise addition of 5% w/w sodium hydroxide solution or 5% w/w acetic acid solution. The conductivity of the sample should be measured (see paragraphs 9.112 to 9.122) and multiplied by the conversion factor to give an estimate of the TDS in mg/l.

9.127 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.

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

9.129 For conductivity at 25ºC measured in mS.m⁻¹ then,

\[ \text{TDS mg/l} = \text{electrical conductivity mS.m}^{-1} \times 6.7. \]

**Calibration**

9.130 Conductivity meters calibrated in TDS mg/l are also available. Care should be taken to ensure that the conversion factor used is appropriate.
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, may be used to verify the calibration.

Results

The estimate of total dissolved solids should not exceed 4 mg/100 ml for purified water (RO or DI).

Method b: evaporative residue method

The following equipment and materials are necessary

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

Collect a 1 litre sample.

Take the silica dish (or equivalent), dried for 2 hours in the oven set to 100ºC ± 2ºC and then cooled to ambient temperature and weigh it to the nearest 0.1 mg.

Dispense 100 ml of the sample into the weighed dish and evaporate it over the boiling water bath until visibly dry. Evaporate two further 100 ml aliquots of the sample in the same dish in the same manner.

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

Calculate the mass of residue in the dish and hence calculate the mass of residue per 100 ml of water.

Results

The evaporative residue should not exceed 4 mg/100 ml for purified water (RO or DI).

Hardness (as CaCO₃)

Introduction

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, may inactivate detergents and disinfectants and causes scaling on load items.
9.0 Testing methods

Method a: ISE method

9.141 Ion selective electrodes are available for calcium and also for divalent cations (total hardness). Ion selective electrodes are not specific for a particular ion but have a relative selectivity for a particular ion or group of ions. They are sensors which 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.

9.142 Both analyte and calibration standard solutions must be adjusted to the same ionic strength. To make the measurement a high impedance millivoltmeter is used 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.

9.143 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 must not be used since the calcium activity will be lowered by complexation or precipitation.

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

9.145 The calcium electrode requires a single junction reference electrode. Calibration is made against two or more standard solutions. These are commercially available.

Range

9.146 The calcium selective electrodes which are available have a Nernstian response for concentrations from 1 M down to about 5 x 10^-6M 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).

Method b: titrimetric method

9.147 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 ethylenediaminetetra-acetic acid (EDTA). When the reaction is carried out, at pH 10 to 11, with Eriochrome Black as the complexiometric indicator, all the calcium and magnesium ions are chelated by the EDTA and the absence of free calcium and magnesium ions causes a colour change in the indicator.

9.148 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 Reeder indicator powder as a complexiometric indicator.

9.149 The commercially available kits often use novel titration methods instead of burettes. The test reagents are specific to each kit. The manufacturers instructions should be followed.

9.150 Range: determinations within the range 5 mg/l to 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

9.151 The hardness expressed as mg/l CaCO₃ should not exceed:
- mg/l for softened water
- mg/l for water used in the flushing stage (or all stages of a Bedpan WD)
- mg/l for water used for Bedpan WDs (this will typically require the use of a descaler)

9.152 Water with values > 210 mg/l should be regarded as unsuitable for use in WDs without treatment.

Chloride

Introduction

9.153 The presence of significant levels of chloride ions in water supplied to WDs will 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 are often associated with ‘breakthrough’ from a defective, or incorrectly operated, water softener or de-ioniser.

Method a: Ion selective electrode method

9.154 The commercially available chloride selective electrodes have a working range from 1M to 10⁻⁵M. They work over the pH range 3–10 and the sample should be adjusted for ionic strength using an adjustment buffer consisting of 5M NaNO₃ solution.

9.155 The electrodes show poor selectivity against other halides and cyanide ions. Sulphide ions should be absent.

9.156 The chloride electrode requires a double junction 0.1M NaNO₃ reference electrode.

9.157 Calibration is made against two or more standard solutions. These are commercially available.

Method b: Silver nitrate titration

9.158 Commercial titrimetric kits based on the method described in BS 6068 Section 2.37 are available.

9.159 The method employs the titration of the sample at pH 5 to pH 9 with silver nitrate using a potassium chromate indicator solution.

9.160 The analytical range extends from 5 mg/l to 150 mg/l.

9.161 The method is not quantitative for purified water which should have chloride concentrations well below the range for accurate determinations; it may be used however as a limit test.
9.0  Testing methods

Results

9.162 The chloride concentration in final rinse water for WDs processing metal items should not exceed 10 mg/l.

9.163 The chloride concentration in other water supplies for WDs processing metal items should not exceed 120 mg/l.

Heavy metals

Introduction

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

Method

9.165 These may be determined using the limit test described in the British Pharmacopoeia. See also ISO 8288.

Results

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

Iron

Introduction

9.167 The presence of significant concentrations of iron in water used to process stainless steel items will promote corrosion of those items and will exacerbate the effect of any chloride ions which may be present.

Equipment and materials

9.168 The following equipment and materials are necessary.

a. colour disc comparator kit;
   (The analytical range depends on the calibrated colour disc supplied with the chosen test kit. A range of 0 to 5 mg/l is commercially available and provides adequate precision. Discs offering extended ranges are also available but the discrimination of intermediate concentrations becomes unacceptably poor.)

b. reagents;
   (The prepackaged reagents available from the manufacturer of the comparator should be used.)

c. a standard 0.702 g/l iron (II) ammonium sulphate solution \((\text{NH}_4)_2\text{Fe(SO}_4)_2\);

d. a mercury in glass thermometer graduated in 0.5°C steps conforming to BS 1704: 1985.
Method

9.169 The recommended method is the use of one of the commercially available colour disc comparator kits. Typically these are based on the reference method described in BS 6068 Section 2.2. 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 pretreatment to reduce any iron (III) compounds to the iron (II) form in which they can be analysed.

9.170 The 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.

9.171 A standard 0.702 g/l iron (II) ammonium sulphate solution \((\text{NH}_4)_2\text{Fe(SO}_4\text{)}_2\) provides a standard solution of 100 mg/l iron. The solution should be prepared as required and not stored. Working standards spanning the usable range of the colour disc comparator can be prepared by appropriate dilution.

9.172 It is important to measure the sample temperature before commencing the analysis.

9.173 After the kit manufacturer’s specified reaction time has elapsed the colour intensity of the sample is used to estimate the concentration of iron in the sample.

9.174 For details of the colorimetric method see the description given in the method for the determination of silicate.

Results

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

Phosphate

Equipment and materials

9.176 The following equipment and materials are necessary.

a. Colour disc comparator kit
   (The calibrated phosphate colour disc should be calibrated in \(\text{P}_2\text{O}_5\) mg/l. A sensitivity range of 0 to 5 mg/l is commercially available and provides adequate precision. Discs offering extended ranges are also available but the discrimination of intermediate concentrations becomes unacceptably poor.)

b. Reagents
   (The prepackaged reagents available from the manufacturer of the comparator should be used.)

c. Sample container
   (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.)
9.0 Testing methods

d. Glassware
   (This must be borosilicate which has been subject to acid hardening, ie cleaned and allowed to stand overnight filled with sulphuric acid (d<sub>20</sub>1.84) then rinsed several times and stored filled with water, in the dark at 0–4ºC until required for use. The glassware should not be allowed to come into contact with detergents or alkaline liquids.)

e. A standardised solution containing 100 mg/l Potassium dihydrogen orthophosphate for preparation of calibration standards.

Method

9.177 Commercially available kits are generally based on the reference method described in BS 6068 Section 2.28. The sample is reacted in acidic solution with antimony and molybdate ions to form an antimony phosphomolybdate complex. This is reduced with ascorbic acid to form a molybdenum blue complex.

9.178 The test method measures only orthophosphate and pre-treatment would be necessary if it was required to convert other forms of phosphate to orthophosphate. (Some other phosphates such as condensed phosphates and labile organic phosphates are slowly hydrolysed under the acidic conditions used for the test. Undue delay in reading the test may result in a gradual increase in phosphate concentration as hydrolysis proceeds).


9.180 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.)

9.181 A stock standard solution containing 100 mg/l Potassium dihydrogen orthophosphate may be prepared and diluted to provide suitable working standards for calibration verification. The concentrated stock solution is stable for several weeks.

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

9.183 Samples should be tested as soon as possible after sampling. If sampling will be delayed by more than 4 hours the sample(s) should be stored in suitable glass bottles at 2ºC to 5ºC for up to 48 hours.

9.184 The manufacturer’s instructions should be followed precisely.

9.185 For details of the colorimetric method see the description given in the method for the determination of silicate.

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

9.187 The phosphate concentration of rinse water used for metal load items should not exceed 0.2 mg/l expressed as P$_2$O$_5$.

Silicate

Introduction

9.188 Silicate will react with metal items, including stainless steel, causing corrosion and discolouration. This is accentuated at elevated temperatures.

Equipment and materials

9.189 The following equipment and materials are necessary.

- a. colour disc comparator kit;
- b. reagents (The prepackaged reagents available from the manufacturer of the comparator should be used.);
- c. a standard 3.132 g/l disodium hexafluorosilicate solution (Na$_2$SiF$_6$);
- d. a mercury in glass thermometer graduated in 0.5ºC steps conforming to BS 1704: 1985.

Method

9.190 The 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 part 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.

9.191 The analytical range depends on the calibrated colour disc supplied with the chosen test kit. A range of 0 to 5 mg/l is commercially available and provides adequate precision. Discs offering extended ranges are also available but the discrimination of intermediate concentrations becomes unacceptably poor.

9.192 The method is generally suitable for determination of SiO$_2$ level in softened and untreated water but is only sufficiently sensitive to act as a limit test for purified (RO or DI) water.

9.193 A standard 3.132 g/l disodium hexafluorosilicate solution (Na$_2$SiF$_6$) provides a stock standard solution of 1000 mg/l as SiO$_2$.

The solution is stable for several months after preparation stored in a sealed polyethylene bottle. Working standards spanning the usable range of the colour disc comparator can be prepared by appropriate dilution.

9.194 It is important to measure the sample temperature before commencing the analysis. A mercury in glass thermometer graduated in 0.5ºC steps conforming to BS 1704: 1985 is suitable for the purpose.

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

9.196 After the kit manufacturer’s specified reaction time has elapsed the colour intensity of the sample is used to estimate the concentration of silicate in the sample.

9.197 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, the colour density developed in the sample is visually matched against the calibrated colour disc viewed through the untreated sample. The displayed value of SiO₂ concentration is read off from the calibrated disc.

9.198 Serial dilutions of the standard solution may be used to verify the calibration of the comparator disc.

Results

9.199 Untreated and softened water should have less than 2 mg/l silicate expressed as SiO₂, determined as reactive silica, present.

9.200 Purified (DI or RO) water should have not more than 0.2 mg/l silicate expressed as SiO₂, determined as reactive silica, present.

Bacterial endotoxins

Introduction

9.201 When the intended use of the WD is for products that will be used invasively eg surgical instruments the water used for final rinsing should be tested for bacterial endotoxins (Limulus amoebocyte lysate (LAL) test).

9.202 The method describes the detection of bacterial endotoxin by the Limulus Amoebocyte Lysate (LAL) gel formation method. Other LAL methods (Chromogenic, Turbidimetric or Kinetic Turbidimetric) are equally suitable.

9.203 The water sample is incubated, in a test tube, with an equal volume of lysate for 1 hour at 37°C and examined for the formation of a solid clot which holds upon inversion of the test tube. The lysate, reconstituted from lyophilised Limulus amoebocyte lysate, 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.

Equipment and materials

9.204 The following equipment and materials are necessary.

a. pyrogen free water;
b. LAL reagent (reconstituted Limulus amoebocyte lysate).
c. standard endotoxin;
d. reaction tubes;
e. dilution tubes;
f. hot air oven;
g. pipettes;
Method

9.205 Sample collection and preservation:
- All apparatus used for collecting samples must be pyrogen free; metal components may be depyrogenated by dry heat. Samples should be collected in single-use sterile, apyrogenic polystyrene containers.
- Samples should be tested within four hours of collection. When this is not practicable, samples should be stored at 2°C to 5°C for not more than 48 hours before testing.

9.206 Sample pre-treatment:
- The pH of the reaction mixture (sample + lysate) should be 6 to 8.

9.207 Reconstitution of the freeze dried reagent:
The LAL reagent should be selected for the required sensitivity to endotoxin; 0.125 EU/ml is used to test for compliance with a maximum permitted endotoxin level of 0.25 EU/ml.

a. After gently tapping the vial to ensure that all the white powder is at the bottom of the vial, remove the crimp cap and rubber stopper from the vial and discard them.

b. Add the required quantity of pyrogen free water (usually 5 ml), allow several minutes for the lyophilised reagent to go into solution and the mix by gentle agitation and store on ice until used.

c. Re-seal the tube using paraffin wax film. Only the side in contact with the paper backing should be regarded as pyrogen free.

d. If not all the reagent will be used immediately it may be subdivided into suitable aliquots which may be frozen and stored at −20°C, or below, for up to 3 months. Note: frozen reagent should only be thawed once.

e. Before use mix the contents of the vial gently to ensure homogeneity. Note: vigorous mixing may cause foaming and loss of sensitivity.
9.208 Reconstitution of the Control Standard Endotoxin:

- Using a similar procedure to that described for the LAL reagent reconstitute a vial of freeze dried Control Standard Endotoxin, mix by repeated vortexing and prepare working standards by serial dilution using pyrogen free water and pyrogen free dilution tubes.

9.209 Analytical procedure:

a. Dispense 0.1 ml of LAL reagent into each of six reaction tubes.

b. Add 0.1 ml of sample to each of two of these tubes. (duplicate determination).

c. Add 0.1 ml of pyrogen free water to each of two of these tubes. (negative controls).

d. Add 0.1 ml of the working dilution of Control Standard Endotoxin to each of two of these tubes. (positive controls).

e. Incubate for 1 hour at 37°C.

f. After 1 hour carefully remove each tube and invert slowly. If a firm clot has formed which does not move the sample contains at least 0.125 EU/ml endotoxin.

9.210 Sources of error:

a. The various commercially available LAL reagents differ in their tolerance of interfering substances, their inhibition endpoints and in their buffer capacity. There may also be some lot to lot variation within supplies from any one manufacturer. Revalidation is therefore necessary for each change of lot and/or manufacturer and for water supply system.

b. Turbidity can be confused with initial stages of gelation. It is essential that all apparent gel formation is verified by demonstrating a stable gel on inversion through 180°.

c. Vibration during the incubation period can prevent stable gel formation. An unstirred water bath should be used since the vibration from the stirrer motor may be sufficient to interfere with the reaction.

d. Different surfaces have different affinities for endotoxin. New borosilicate glass test tubes have a relatively high affinity for endotoxin in aqueous solution and may give rise to artificially low readings if used to make dilutions of endotoxin. Strict adherence to the reagent manufacturer’s recommendations for choice and preparation of test equipment is necessary.

e. Standard deviation/Precision: for a given batch of LAL of calibrated sensitivity EU, a positive result indicates the presence of endotoxin within the range 0.5λ to 2λ EU.

f. Limit of detection: a limit of detection of 0.03 EU/ml is achievable using the gel formation method. (0.01 EU/ml and 0.001 EU/ml are achievable for Chromogenic and Kinetic Turbidimetric methods respectively).

9.211 Safety information:

a. No hazardous component has been identified in commercially produced Limulus Amoebocyte Lysate. However, since it contains proteinaceous material (including human serum albumin) the possibility of allergic reaction, especially after prolonged or repeated exposure, should be considered.
b. Other reagents, although sterile and pyrogen free, are not intended for administration to animals or humans.

c. The lyophilised endotoxin which is used to prepare reference standards has a threshold limit value of 5 EU/kg/hour. Over exposure may result in fever, nausea, shock. It is important to avoid inhalation of the powder and parenteral injection of the reconstituted solution.

d. **Emergency first aid procedures.** If endotoxin solution has been injected treat the patient as for endotoxin shock, if the lyophilised endotoxin has been inhaled, remove the patient to fresh air and treat as for endotoxin shock.

**Results**

9.212 The endotoxin concentration in final rinse water for items intended for invasive use, parenteral administration or the preparation of parenterals should not exceed 0.25 EU/ml.

**Total viable count**

**Introduction**

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

9.214 The following test will only detect the presence of mesophyllic aerobic bacteria which do not have specialised nutritional requirements. If particular micro-organisms are of concern other recovery conditions (growth medium, incubation temperature etc) should be used as appropriate (see also paragraphs 9.227 to 9.236). The advice of the microbiologist should be sought.

9.215 The following test should be carried out as an installation or operational test and as a weekly periodic test for endoscope WDs.

9.216 For other WDs the test should be carried out when requested by the user as an installation test and repeated annually thereafter.

9.217 The following test should be carried out by the microbiologist.

**Equipment and materials**

9.218 The following equipment and materials are necessary:

a. 250 ml sterile single use containers;

b. sterile filter membranes (47 mm diameter, ≥ 0.45 µm pore size);

c. suction filtration apparatus;

d. incubator set at 35ºC ± 2ºC;

e. tryptone soya agar plates;
   (The medium should have been demonstrated as capable of recovering an inoculum of 10–100 cells of *Pseudomonas aeruginosa*);

f. 70% isopropanol and non-woven wipes.
Method: Sample collection

9.219 Wipe the discharge surfaces of the sampling point thoroughly with 70% isopropanol and allow to evaporate to dryness.

9.220 Run off not less than 50 ml through the sampling point and discard.

9.221 Using aseptic handling techniques collect not less than 200 ml of sample in the sterile container and close the lid securely. Label the container with details of the sampling point and the time and date the sample was collected.

9.222 The sample should be transferred to the laboratory and tested within 4 hours; if this is not possible the sample should be stored at 2°C to 5°C for not more than 48 hours before testing.

Method: Testing

9.223 Filter a 100 ml aliquot of the sample through a 0.45 µm filter. Aseptically transfer the filter to the surface of a TSA plate and incubate at 35°C ± 2°C for 48 to 72 hours. Carry out the test in duplicate.

9.224 Examine the filters daily and record the number of colony forming units which are visible.

Results

9.225 For WDs in which the product is rinsed after the disinfection stage there should be no recovery of micro-organisms from the rinse water.

9.226 All other water services supplied to WDs should have less than 100 cfu/100 ml of water (determined as the mean of the duplicate tests).

Environmental mycobacteria

Introduction

9.227 Environmental, non-pathogenic, mycobacteria present a particular problem when they occur in the final rinse water of some instruments used for diagnosis. Cells of the environmental mycobacteria are easily confused, on initial detection, with pathogenic mycobacteria and may lead to mis-diagnosis. Other mycobacteria which occur in water, for example M. kansasii and M. chelonei, are opportunistic pathogens. The test is intended as a performance qualification test and periodic test on WDs for endoscopes. The test should be carried out by the microbiologist.

Equipment and materials

9.228 The following equipment and materials are necessary:
   a. 250 ml sterile single use containers;
   b. sterile filter membranes (47 mm diameter, ø 0.45 µm pore size);
   c. suction filtration apparatus;
   d. incubator set at 30°C ± 2°C;

The sample should be taken downstream of any filter or other device or equipment intended to remove or control microbial contamination in the water supply.
e. Middlebrook 7H10 plates;
   (The medium should have been demonstrated as capable of recovering an inoculum of 10–100 cells of M. gordonae.)

f. 70% isopropanol and non-woven wipes.

Method: Sample collection

9.229 Wipe the discharge surfaces of the sampling point thoroughly with 70% isopropanol and allow to evaporate to dryness.

9.230 Run off not less than 50 ml through the sampling point and discard.

9.231 Using aseptic handling techniques collect not less than 200 ml of sample in the sterile container and close the lid securely. Label the container with details of the sampling point and the time and date the sample was collected.

9.232 The sample should be transferred to the laboratory and tested within 4 hours; if this is not possible the sample should be stored at 2ºC to 5ºC for not more than 48 hours before testing.

Method: Testing

9.233 Filter a 100 ml aliquot of the sample through a 0.45 µm filter. Aseptically transfer the filter to the surface of a Middlebrook 7H10 plate and incubate at 35ºC ± 2ºC for 28 days. Carry out the test in duplicate.

9.234 Examine the cultures weekly and record the number of colony forming units which are visible.

9.235 If growth is observed the cultures should be transferred to a laboratory with established expertise in Mycobacterial identification for identification of the strains isolated.

Results

9.236 For endoscope WDs, in which the product is rinsed after the disinfection stage there should be no recovery of mycobacteria from the rinse water.

Overflow test

Introduction

9.237 For WDs which incorporate one or more water storage tanks within the WD the capacity of the overflow(s) to discharge all excess water, as intended, without spillage into the WD or working area should be verified.

Method a: Type test or Works test

9.238 The WD should be connected to all necessary services and the water supply pressure adjusted to not less than 6 bar under the conditions of flow which prevail with the supply valve(s) fully open.

9.239 Fully open the supply valve(s).
9.0 Testing methods

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

Method b. Installation test

9.241 The WD should be connected to all necessary services.

9.242 Fully open the supply valve(s).

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

Results

9.244 The WD 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

Introduction

9.245 During type testing the manufacture 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 requirement (see HTM 2030 ‘Design considerations’).

9.246 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 may be adversely affected. If the volume is greater than that specified an unexpected heavy demand may be placed upon the water supply.

Equipment and materials

9.247 A water flow meter (or volumetric measuring equipment) is necessary.

Method

9.248 Three methods are available for determining the volume of water used. The method chosen will depend upon which is most convenient for the particular installation.

9.249 A water flow meter may be fitted in each of the water supply pipes, consecutively or concurrently, and the volume used determined by comparison of the reading before and after each stage of the process cycle. The WD should be operated with the chamber empty apart from the chamber furniture. The water meter manufacturers instructions for installation should be followed. Particular attention needs to be paid to the length of uninterrupted straight pipe required on either side of the meter.

9.250 When the WD is supplied from a readily accessible tanked supply the make-up to the tank may be interrupted and the water level marked. The volume of water required to restore the level after an operating cycle stage may then be determined by the addition of a measured volume of water.
For those WDs which discharge all the water from each stage at the end of each stage a suitable estimate of the volume used may be obtained by volumetric measurement of the discharge from the drain.

Results

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

Doors and door interlocks

Cycle start interlock

Introduction

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

Method

Testing should be carried out as follows. The doors should be left open and unlocked. All services should be connected. An attempt should be made to initiate an operating cycle.

The doors should then be closed and locked and a further attempt made to initiate an operating cycle.

Results

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

Introduction

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

Method

The door(s) should be closed and locked and the operating cycle started. While the operating cycle is in progress an attempt should be made to unlock each of the doors.

Results

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

When practicable, the interlocks should be visually inspected to verify engagement before attempting to open the door.
Double-ended WDs

Method

9.260 Both during and between cycles attempts should be made to open either or both the loading door and unloading door of the double ended WD.

Results

9.261 It should not be possible to open the unloading door after initiation of a cycle until a cycle has been completed satisfactorily.

9.262 It should not be possible for both doors to be opened at the same time.

9.263 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

9.264 Each sensor should be disabled in turn and an attempt made to open each of the door(s).

Results

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

Door opening force

Introduction

9.266 The mechanism for opening the WD door should not require the use of excessive force.

Equipment

9.267 The following equipment is necessary:

a. spring balance calibrated in kilograms with a range including 0 to 250 kg and with an accuracy of ± 1 kg over the range 0 to 250 kg;

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

Method

9.268 The force required to initiate and sustain the movement of the door opening mechanism is measured by interposing a spring balance, aligned co-axially with the direction of movement of the door opening mechanism, between the operator and the mechanism.
9.269 Attach the spring balance to the door opening mechanism. Open the door, note the force required to initiate the movement and to sustain the movement.

Results

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

Failed cycle interlock

Introduction

9.271 The interlock should prevent an operator from removing a load in the normal manner at the end of a cycle which failed.

Method

9.272 During an operating cycle one, or more, of the services to the WD should be interrupted sufficiently to cause a cycle failure.

Results

9.273 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

Introduction

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

Method

9.275 Each sensor providing information to the automatic controller is disabled in turn to establish that a fault is indicated.

9.276 Testing of each sensor should be carried out as follows. An operating cycle should be started. 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 the sensor should be disabled.

9.277 Each sensor should be tested in both ‘open circuit’ and ‘short circuit’ failure modes.

Result

9.278 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 WD or the unloading door of a double-ended WD.
9.0 Testing methods

**Chemical dosing**

**Reproducibility of volume admitted**

*Introduction*

9.279 The 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 WD.

*Equipment*

9.280 A measuring cylinder to BS 604: 1982 (1993) is necessary [or BS 5404: Part 2: 1977 (1994) when compatibility with the chemical additive to be measured has been established]. The size of measuring cylinder should be appropriate to the volume of chemical additive to be dispensed.

9.281 Alternatively a flow meter of appropriate range may be used.

*Method*

9.282 Testing should be carried out as follows:

a. Disconnect the supply line to the chamber as close as possible to its discharge point into the chamber or water circulation system.

b. Actuate the dosing system and collect the discharged volume of the chemical solution in the measuring cylinder.

c. Repeat the test three more times. Record the volume dispensed on each test.

*Results*

9.283 Ignore the result of the first test.

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

**Indication of insufficient chemical additives**

*Introduction*

9.285 The use of the correct volume of chemical additive(s) is necessary for the correct functioning of the WD. The WD 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.

9.286 The test should be carried out for each chemical dosing system on the WD.

*Method*

9.287 A low level of additives is placed in the dispenser reservoir and repeated cycles are run.
9.288 Fill an otherwise empty container with sufficient chemical for more than 2 but less than 4 operational cycles. Run the WD on 3 consecutive cycles. Estimate the volume remaining at the end of each cycle (pre-marked container, dipstick, or weight).

Results

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

Emissions

Water vapour emission

Introduction

9.290 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 WD.

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

Equipment

9.292 The following equipment is necessary:

a. absorbent paper wipes (of a type which change colour density when damp);

b. one or more mirrors 50 mm x 50 mm or larger.

Method

9.293 Load the WD, close the door and wipe the joints between the door and the door surround to remove any moisture. Carry out an operating cycle.

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

9.295 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.

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

Results

9.297 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.
Aerosol emissions

Introduction

9.298 Emissions of aerosols and water droplets presents a high risk of transmitting infection from contaminated load items. The test is designed to be carried out as an operational test.

Equipment and materials

9.299 The following equipment and materials are necessary:

a. one or more sheets of white paper, saturated with cobalt chloride solution, dried to an even white and kept under desiccation until required;

b. one x 5 magnifying glass.

Method

9.300 This test should not be carried out until the WD has passed the vapour emission test.

9.301 The WD should be operated with the chamber empty except for any chamber furniture (for example load carrier).

9.302 Any chemical additives used should be replaced with water.

9.303 Close the door of the WD.

9.304 The cobalt chloride paper(s) of appropriate size and shape to cover the joint between the door and its surround to 75 mm either side of the door edge, should be placed at a distance of 50 mm to 100 mm from the door.

9.305 Initiate an operating cycle.

9.306 At the end of the cycle the paper should be carefully removed and examined with a x5 magnifying glass for bright pink spots.

Result

9.307 There should be no bright pink spots visible. A bright pink spot indicates the discharge of a water droplet.

Chemical vapour emission

Introduction

9.308 When a WD employs chemical additives for which there are specified exposure limits (usually disinfectants) under the COSHH Regulations it is necessary to determine that the emissions from the WD do not cause personal exposure to exceed the legal limits.
### Method

**9.309** The method of sampling for airborne emissions and the method of analysis or detection will be specific to the chemical additive(s) being used. Advice should be sought from the WD manufacturer, the supplier of the chemical additive(s) and/or HSE in order to determine an appropriate test method.

### Results

**9.310** Emissions from the WD during normal operation and maintenance, including when opening the WD at the end of the cycle or when changing or re-filling chemical additive reservoirs, should not expose personnel to concentrations in excess of the legal maxima.

### Instrumentation fitted to WD

**Verification of calibration**

**9.311** The calibration of instrumentation fitted to the WD should be verified by comparison with calibrated test instruments during steady state conditions eg the temperature during the disinfection hold period.

**9.312** This may be carried out concurrently with other testing, for example during the automatic control test during quarterly periodic testing (see Chapter 12).

### Load carriers

**Introduction**

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

**Method**

**9.314** 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 eg cannulated instruments (when applicable) should be verified by visual observation.

**9.315** Load carriers with rotary spray arms should be checked to ensure that the spray arms are free to rotate, both when the load carrier is empty and when fully loaded.
Thermometric tests

9.316 Thermometric tests are carried out to verify the attainment of the specified conditions throughout the chamber and load during the operating cycle. Continuous process WDs and multichamber WDs 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 WD. The use of biological indicators as a substitute for thermometric testing is not acceptable.

Chamber wall temperature

Equipment and materials

9.317 A temperature recorder complying with the requirements specified in Chapter 8 and having not less than 8 sensors is necessary.

Method

9.318 Thermocouples should be located 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.

9.319 The temperature attained should be measured 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’).

9.320 The WD should be operated empty except for chamber furniture (for example load carriers).

9.321 Multi-chamber WDs may be tested with each chamber tested consecutively or concurrently. In the latter case eight sensors will be required for each chamber.

Results

9.322 The results should be the following:

a. The temperatures recorded on the surface of the chamber should be within the range 0°C to 5°C of the disinfection temperature throughout the holding period for the disinfection stage.

b. The temperatures recorded on the surface of the chamber should be within ±5°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 WD instruments should be within ±2°C of that recorded by the test instrument from the sensor adjacent to the reference sensor throughout the holding period for the disinfection stage.

d. The temperature profile obtained for the operating cycle should be consistent within ±2°C for the last three test cycles.
Load carrier temperature

Equipment and materials

9.323 A temperature recorder complying with the requirements specified in Chapter 8 and having not fewer than four sensors is necessary.

Method

9.324 Temperature sensors should be located 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.

9.325 The temperature attained should be measured 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’). The WD should be operated empty except for chamber furniture (for example load carriers).

9.326 The load carrier should be replaced between cycles with a load carrier at ambient temperature.

9.327 Multi-chamber WDs may be tested with each chamber tested consecutively using independent data loggers to record the temperature of the load carrier. A temperature recorder with fixed sensors may be used to record the temperature adjacent to the reference sensor.

9.328 This test may be run simultaneously with the chamber wall temperature test.

Results

9.329 The results should be the following.

a. The temperatures recorded on the surface of the load carrier should be within the range 0°C to 5°C of the disinfection temperature throughout the holding period for the disinfection stage.

b. The temperatures recorded on the surface of the load carrier should be within ± 5°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 WD instruments should be within ± 2°C of that recorded by the test instrument from the sensor adjacent to the reference sensor throughout the holding period for the disinfection stage.

d. The temperature profile obtained for the operating cycle should be consistent within ± 2°C for the last three test cycles.
9.0 Testing methods

Over-temperature cut-out

Introduction

9.330 The WD 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 WD, the temperature will not rise to a level which would damage the load in the WD.

Equipment and materials

9.331 A temperature recorder complying with the requirements specified in Chapter 8 and having not less than 4 sensors is necessary.

Method

9.332 Temperature sensors should be located 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.

9.333 The WD, empty except for the load carrier, should be operated on a normal operating cycle. For multi-cycle machines the two cycles that have the highest and lowest operating temperatures should be tested.

9.334 During the stage of the cycle when the maximum temperature is attained, the temperature control system should be disabled.

Results

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

Load dryness

Introduction

9.336 The presence of residual water on cleaned and disinfected items may interfere with the correct functioning of the item, promote re-contamination and microbial growth or prevent attainment of sterilizing conditions.

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

9.338 The dryness of most items may be evaluated visually. The dryness of the internal surface of lengths of tubing may be tested by blowing through with dry compressed air onto a mirror; misting of the mirror will indicate residual internal moisture.

9.339 Drying to constant weight should be used to evaluate the drying performance of the WD with cannulated instruments with narrow lumens and similar items which are difficult to assess visually.

Three independent data loggers and a temperature recorder having at least one sensor may be used as an alternative.
Equipment and materials

9.340 The following equipment and materials are necessary:
   a. balance weighing to 0.1 mg or better;
   b. oven with recirculating and fan controlled at 110°C ± 2°C.

Method

9.341 At the end of the WD cycle the load item to be tested should be removed and weighed. Record the weight and transfer the item to the oven and dry at 110°C ± 2°C for not less than 30 minutes. Remove from the oven and allow to cool to ambient temperature. Weigh and record the weight.

Results

9.342 The difference in weight of the instrument before and after drying in the oven should not exceed 0.1 mg.

Residual chemical additives

Introduction

9.343 The nature of the residues and the level of such residues which may be of concern depend on the chemical additives used during the process and the intended use of the washed and disinfected product.

9.344 The chemical additives used during the process (detergents, rinse aids etc) may not be completely removed by the rinsing process.

9.345 The residual level which may be tolerated will depend upon the nature of the chemical and the intended use of the product. The supplier of any chemical agent used should provide data on the chemical composition of the chemical agent and the biocompatibility of the components of the chemical agent. The supplier should also provide details of the method of detection which may be used to determine that processed items are free from residuals at the specified levels.

9.346 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 ie as the maximum acceptable level.

Method

9.347 The efficacy of the rinse process should be tested by using twice the normal dose of the chemical additive on a normal operating cycle using a test load of the simulated product. Analysis, by the method recommended by the manufacturer, should be carried out on the final rinse water and on the simulated product.

Results

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

This method is not suitable for heat sensitive items which would be damaged by heating to 112°C
Air quality

Introduction

9.349 Many WDs 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 will not normally be required for the filter or the filter housing. The filter and filter housing should be tested when the intention is to provide air free from bacterial contamination when the load is intended for use without further processing (for example sterilization).

9.350 Microbial sampling will not normally be required for either system unless otherwise specified.

Method

9.351 The complete installation should be tested using the method described in BS 5295: Part 1 Appendix C: 'Method of testing for the determination of filter installation leaks'. 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

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

Sound pressure test

Introduction

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

9.354 The perceived level of noise in the immediate vicinity of the WD 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 must necessarily be determined with the WD installed and working normally.

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

9.356 Information about sound reducing measures may be found in HTM 2030 ‘Design considerations’. 

9.357 The sound pressure test should be carried out in accordance with the detailed instructions given in BS 4196 Part 6 by suitably trained and
experienced personnel. The information given below is intended only for additional guidance and is not the complete test method.

Test procedure

9.358 Using the procedure described in clause 8.1 of BS 4196 Part 6, for both the loading and unloading area if these are not common, determine the following:
   a. the mean A-weighted surface sound pressure level;
   b. the peak A-weighted surface sound pressure level.

Results

9.359 The test should be considered satisfactory if the following requirements are met:
   a. the mean A-weighted surface sound pressure level does not exceed:
      (i) 55 dBA for a WD installed in an operating suite, ward, treatment room or other noise sensitive area;
      (ii) 70 dBA for a WD 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

9.360 The British Standard for WDs requires that:
   • when tested by one of the methods in BS 6667: Part 3: 1985 the functioning of the automatic controller and the instrumentation shall be unaffected by electromagnetic interference of severity level 3 as specified in BS 6667: Part 3: 1985;
   • when tested in accordance with BS 800: 1988 any RF interference generated by the WD shall not exceed the limits specified in BS 800: 1988.

9.361 The current proposal within the CEN TC102 committee preparing Standards for WDs would require compliance with the corresponding European Standards, EN 50081 and 50082.
10.0 Cleaning efficacy tests

Introduction

10.1 Cleaning efficacy tests are used to demonstrate the ability of the WD to remove or reduce to acceptable levels, soiling and contamination which occurs during normal use of re-usable items. Test soils are used to simulate naturally occurring contamination since the latter shows considerable variation and is therefore more difficult to use for standardised testing.

Type tests

10.2 The cleaning efficacy should be determined using the relevant test soil applied to a reference load or simulated product of demonstrated relevance (see Chapters 13 to 19 or as specified in the relevant part of the British or (when published) European standard).

10.3 The test should be carried out using alternately purified water (DI or RO) and WHO water of standard hardness (see BS 6734 paragraph 5.2) with detergents of the type recommended by the WD manufacturer. The detergents should be selected by the machine manufacturer and should include a choice of at least two from different suppliers (one of which may be the WD manufacturer). All tests should be run in triplicate and for each series of tests each of the three tests should meet or exceed the minimum acceptance criteria.

10.4 The manufacturer should establish ‘worst case’ conditions of temperature, detergent concentration and water pressure/flow rate for use during testing.

10.5 By analysing the fraction of soil removed during the cleaning process when operated for various time periods shorter than those which will normally be used a quantitative comparison of cleaning efficacy can be made.

10.6 The recommended minimum operating conditions given by the manufacturer should be based on these data which should be made available to the user.

Operational tests

10.7 During operational tests of cleaning efficacy with test soils the thermal disinfection stage should be disabled. During thermal disinfection the action of hot water and/or steam may also reduce the concentration of residual test soil.

10.8 The drying stage may also be disabled if this is necessary to facilitate the detection of residual soil.
Test soil

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

10.10 Numerous test soil formulations are in use in various European countries including those specified in the various British Standards.

10.11 None are entirely satisfactory since they do not meet all the requirements for an ideal test soil. The committee drafting the European standard is currently proposing a laboratory method against which test soils may be validated; this would then allow the use of any formulation that met the required performance criteria.

10.12 These performance criteria include the following.

a. The test soil formulation should be validated as being of equal or greater difficulty to remove than the naturally occurring soils which it is intended to simulate.

b. The method of application to give a level of soiling which is reproducible within specified limits should be validated and documented.

c. The method of detection of residual soil should be quantitative, visual assessment alone should not be regarded as satisfactory.

d. The limit of sensitivity of the detection method employed should be established and stated.

e. For tests on the chamber walls and load carrier, the detection method shall include a validated method for quantitative detection of the residual soil in situ or a validated method of removal eg by swabbing, for subsequent evaluation.

10.13 In the interim the test soil formulations given in the British Standard should be used; details are given in Chapters 13 to 19 for tests on specific types of WDs.

Test loads

10.14 The test load should consist of items of similar size, mass and materials of construction to the range of products the WD is intended to process.

10.15 Details of suitable reference loads are given in Chapters 13 to 19 for tests on specific types of WDs.

Procedure for chamber walls and load carriers

10.16 The chamber walls and load carrier should be contaminated with the test soil in accordance with the instructions for the test soil.

10.17 A normal operating cycle should be run.

10.18 After completion of the wash cycle, and before the disinfection stage (except where this is combined with the rinse stage) the cycle should be aborted. The chamber walls and load carrier should be examined for the presence of residual soil by the method prescribed for the particular test soil.
10.19 The test should be carried out in duplicate for each type of operating cycle available on the WD.

Procedure for reference loads

10.20 This test should be run only after satisfactory completion of the test for the efficacy of soil removal from chamber walls and load carriers. The test load should be contaminated with the test soil in accordance with the instructions for the test soil.

10.21 A normal operating cycle for the load type under test should be run.

10.22 After completion of the wash cycle, and before the disinfection stage (except where this is combined with the rinse stage) the cycle should be aborted. The test load, chamber walls and load carrier should be examined for the presence of residual soil.

Results

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

10.24 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.

Performance qualification tests

Introduction

10.25 Performance qualification 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

10.26 The tests described above for reference loads should be repeated with actual loads to be processed specified by the user as being representative of the items or loads intended to be processed.

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

10.28 The test load should be contaminated with the test soil in accordance with the instructions for the test soil.

10.29 A normal operating cycle for the load type under test should be run.

10.30 After completion of the wash cycle, and before the disinfection stage (except where this is combined with the rinse stage) the cycle should be aborted. The test load should be removed and examined for the presence of residual soil. These test should be run in duplicate.
10.31 On satisfactory completion of this part of the test a further 3 cycles should be operated with actual loads, of the type intended to be processed, contaminated with natural soiling ‘in-use’.

10.32 A normal operating cycle for the load type under test should be run.

10.33 After completion of the complete operating cycle the test load should be removed and examined for cleanliness.

10.34 The cleanliness of the processed items should be assessed visually or by such other means as will be routinely used for acceptance testing (see paragraphs 10.37 to 10.49).

Results

10.35 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.

10.36 The cleanliness of the processed items should be acceptable by the means which will be used routinely for acceptance testing (see Periodic testing below).

Periodic tests

Tests for residual soil: the ninhydrin method

Equipment and materials

10.37 The following equipment and materials are required:

a. sterile purified water;

b. ninhydrin reagent (0.30 g ninhydrin in 100 ml 70% v/v isopropanol);

c. cotton swabs (plastic handles not wooden);

(Alternatively a small quantity of cotton wool held in the jaws of clean forceps may be used.)

d. glass microscope slide 25 mm x 75 mm;

e. oven set at 110°C ± 2°C;

f. 0.5 g/l arginine solution.

Method

10.38 The ninhydrin method utilises the reaction of amino acids, peptides and proteins, with 1,2,3-indantrione monohydrate. (Chemical Abstracts Service Reference Number 485-47-2)

10.39 The method will detect a broad spectrum of substances which may occur as residuals from body fluids and from microbiological studies and is thus suitable for detecting residuals in many of the applications for which WDs are employed. Because only the cotton swab moistened with sterile distilled water comes into contact with the item being tested the item may be used after testing if necessary.

The swabs used for sampling should not have a wooden handle since the wood may interfere with the reaction giving a false positive.
10.40 A defined area of the surface to be examined should be swabbed with a sterile cotton swab moistened with sterile water.

10.41 The swab may then be air dried and transferred to the laboratory for examination or if suitable facilities exist on-site it may be examined on site.

10.42 The swab is tested for the presence of residual protein by adding a drop of ninhydrin reagent to the swab and heating the swab at 110ºC for 30 minutes. After heating the swab is examined for a purple colour.

10.43 Instruments with a lumen may be tested by using a ‘pipe-cleaner’ style cleaning brush instead of the swab.

10.44 Each test, or series of tests, should be accompanied by a negative control. A cotton swab of the same batch is moistened with sterile water of the same batch and then immediately tested using the ninhydrin reagent.

10.45 A positive control may also be carried out to establish the sensitivity of the test method. A microscope slide should be prepared by thorough cleaning, tested using the method and demonstrated to be negative. The surface should then be inoculated with four 25 µl drops of a 0.5 g/l arginine solution, air dried and used as a positive control test surface.

Results

10.46 A purple discolouration on the swab will indicate the presence of amino acid, peptide or protein residues.

10.47 The limit of detection for the method is equivalent to 2 mg.m–2 determined as arginine, or better.

10.48 There should be no purple discolouration on clean items.

Tests for residual soil: alternative methods

10.49 There are three alternative methods to the ninhydrin method:

a. Biuret test: commonly used as a test for the presence of proteins and detects the presence of two or more adjacent peptide bonds. A violet colour appears when a protein or tri-peptide is treated with sodium hydroxide and copper (II) sulphate solutions.

The reagent solution may be flushed through the channels of instruments with a long narrow lumen to detect residuals within the instrument. After testing the item should be cleaned to remove any residual reagent before it is used.

b. A 2% v/v hydrogen peroxide solution may be used to verify the absence of blood and high levels of haemoglobin.

The solution should be applied dropwise to the surface to be tested and is then observed for the evolution of bubbles.

The presence of bubbles indicates the presence of significant levels of protein or residual blood. The method is at least one hundred-fold less sensitive than the ninhydrin method.
c. Ortho phthallic dialdehyde may be used, in the presence of a thiol compound, to detect $\alpha$ and $\epsilon$ terminal amino groups of human blood proteins by formation of a fluorescent compound detectable at 360 nm in picomole quantities. The method is only applicable where there is a suitably equipped laboratory available. The sensitivity is similar to that provided by the ninhydrin method.


**Visual inspection**

10.50 High levels of residual soil, process chemical residues and residues from poor quality water may be detected by visual inspection of the items which have been cleaned.

10.51 This should be done by unaided normal, or corrected, vision under suitable illumination (not less than 400 lux at the work surface).
11.0 Disinfection efficacy tests

Introduction

11.1 Thermometric tests are required for both thermal disinfection processes and chemical disinfection processes. For thermal disinfection processes the time temperature relationships which are generally regarded as acceptable are shown in Table 3. Microbiological testing is only required for chemical disinfection processes.

Test for thermal disinfection

11.2 During thermometric tests for thermal disinfection, the washing stages should be disabled or the controlled temperature reduced to ambient (20°C ± 5°C) in order to avoid pre-heating the load.

11.3 Temperature monitoring of the load should be used to determine the attainment of the required time-temperature conditions. Reducing the wash temperature to 20°C creates the ‘worst case’ conditions with which the disinfection stage may be expected to cope and ensures that disinfection conditions will be attained in the event of a failure of the washing stage.

Thermometric test for disinfection

11.4 This test is suitable for all WDs and should be used to established the adequacy of temperature control during chemical disinfection as well as for verifying attainment of thermal disinfection conditions.

11.5 The load under test will consist of a reference load (see Chapters 13 to 19) or a performance qualification load of discrete items of the type which the WD under test is intended to process, or of surrogate devices used to simulate such load items.
1. For type 1 machines and type 2 machines without physical separation of compartments (Conveyor WDs) sensors may be passed into the chamber through the thermocouple entry port into the chamber.

2. For type 2 (conveyor WDs) the sensors to fixed positions may be passed into the chamber(s) through the thermocouple entry port; the sensors on the load may have to be fed in from one end and, when the load exits at other end, detached and withdrawn the back through the WD. Care should be taken to ensure that there is sufficient length of cable for this to happen.

*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.

Method

11.7 Temperature sensors should be placed 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.

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

11.9 The test should be performed in triplicate.
11.0 Disinfection efficacy tests

Results

11.10 The test should be considered satisfactory if the following requirements are met:

a. the requirements of the automatic control test are met;

b. the holding time, as determined from the measured temperatures on the surface of the load items, is not less than that specified for the appropriate disinfection temperature band in Table 3;

c. during the holding time the measured temperatures are within the disinfection temperature band specified for the operating cycle;

the indicated and recorded chamber temperatures are within 2ºC of the temperature measured at the automatic control sensor;

the temperature measured on the surface of each load item does not fluctuate by more than ± 2ºC and does not differ from that in other load items by more than 4ºC;

d. at the end of the cycle:

the temperature sensors have remained in position.

11.11 If having completed the commissioning tests based on a reference load the WD fails to meet the above requirements for the specific performance qualification load then it is possible that the WD is not capable of processing loads of the type intended. Advice should be sought from the AP(S).

Microbiological test for performance qualification

Introduction

11.12 Microbiological testing is only required for WDs employing a chemical disinfection stage.

11.13 There are a number of difficulties associated with microbiological monitoring of the disinfection process in a WD. These include, but are not limited to, the following.

a. The end-point which is desired in practice (no survivors) does not allow quantitative interpretation of the results and does not provide assurance that the recovery method used would detect surviving organisms.

b. Artificial inoculation of surfaces to be disinfected may not adequately simulate the naturally occurring microflora because both the resistance of the organisms and the adhesion of the organisms to the surface may be changed by in-vitro culture and preparative methods (harvesting, cleaning, inoculation etc).

c. ‘Worst-case’ conditions may be created by the use of high numbers which are also necessary to give quantifiable results. However these may not be representative of naturally occurring populations due to clumping etc.

d. The addition of organic material (usually serum or blood) and/or inorganic material (usually the mineral salts causing hardness of water) may be used to simulate soiling but there are few data to support the correlation of these artificial soils with naturally occurring soiling.
e. The organisms which are normally of interest are pathogens (both obligate and facultative (or opportunistic)) but the use of non-pathogenic strains is necessary for test purposes. In many cases the evidence correlating the behaviour and resistance of the different species and strains is scant or absent.

f. The surfaces of particular interest are frequently the internal surfaces of devices with long narrow lumens. Their inaccessibility makes quantitative inoculation and recovery more difficult.

11.14 During normal processing the cleaning and rinsing stages of a WD cycle are designed to remove surface soiling and should therefore remove most of the contaminating micro-organisms.

11.15 In carrying out tests to verify the efficacy of the disinfection process it is therefore necessary either:

a. to evaluate the removal of micro-organisms which occurs during the cleaning and rinsing stages and demonstrate that this removal efficacy is reproducible within acceptable limits (ie such that for a known initial contaminating population there will be a known residual population present at the start of the disinfection stage), or

b. to eliminate the cleaning and rinsing stages of the cycle during the test runs for evaluation of chemical disinfection efficacy.

11.16 In either case the exposure to disinfectant solution and then its removal with rinse water will also cause the physical removal of micro-organisms and the extent to which this occurs should be evaluated as part of the validation of the test method.

11.17 Validation of the test method should demonstrate the following.

a. The ability to produce a reproducible population of micro-organisms (on the surface to be disinfected) by the chosen inoculation method. This should include determination of the loss of viable organisms as the inoculum dries onto the surface.

This may be undertaken by:

a. preparing a solution of surfactant and estimating its antimicrobial activity against the test organisms using an in vitro suspension test;

b. evaluating and comparing the extent of removal with water and with a surfactant solution (after correction for the ‘error’ caused by the previously determined inactivation effect);

c. the ability to neutralise the disinfectant. The neutraliser solution will then be used instead of water for the post-disinfection rinse. (the extent to which organisms are physically removed by the neutralising rinse will also need to be evaluated);

d. the extent to which the remaining micro-organisms are detected (or removed) by the recovery method.
b. The extent to which these organisms are lost from the surface by the physical action of the disinfection and post-disinfection rinsing process. During evaluation of this effect it is necessary to ensure that any surfactants/detergents normally present in the germicide formulation, or any similar effect of the germicidal moiety, are evaluated.

Microbiological test method

11.18 The method uses a surrogate device to simulate the load items and inoculated carriers are incorporated as part of the surrogate device to monitor the efficacy of the disinfection process. A range of micro-organisms is suggested but others may be used at the discretion of the microbiologist, or at the request of the user.

Test organisms

11.19 The following are the preferred species and the alternative species to be used for test organisms.

<table>
<thead>
<tr>
<th>Preferred species</th>
<th>Alternatives</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pseudomonas aeruginosa</td>
<td>Serratia marcescens</td>
</tr>
<tr>
<td>Staphylococcus aureus</td>
<td>E coli K12</td>
</tr>
<tr>
<td>Mycobacterium terrae</td>
<td>Mycobacterium gordonae</td>
</tr>
<tr>
<td>Candida albicans</td>
<td>Aspergillus (spores) not fumigatus which is thermophilic</td>
</tr>
<tr>
<td>Bacillus stearothermophilus</td>
<td></td>
</tr>
</tbody>
</table>

Methods in which suspensions of micro-organisms are flushed through the lumen of a device and are assumed to adhere in large numbers; are then exposed to liquid disinfectants flushed through the lumen which it is assumed do not physically remove any of the deposited micro-organisms; are then evaluated for the lethal effect of the disinfectant by flushing the lumen with an eluate solution which it is assumed removes close to 100% of the surviving population are unacceptable in the absence of systematic validation and justification for each of the assumptions made.

Elimination of bacterial spores is not expected from a disinfection process. The low level of activity against spores compared with vegetative cells makes the spores a useful indicator of the extent of removal compared with kill. The use of a thermophilic spore facilitates recovery without interference from mesophyllic micro-organisms which are also present.

Before undertaking this test, it should be established that an alternative disinfection method (for example moist heat) is available and could be used to decontaminate the WD in the event of a failure of the chemical disinfection process.

Preparation of inoculum

11.20 Culture conditions:

a. The test organisms should be obtained from a 48 hour culture at 35 ± 2°C on solid media for the vegetative bacteria (Tryptone Soya Agar) and fungi (Mycological Agar).

b. For the mycobacteria a 14 to 21 day culture in Middlebrook 7H9 broth should be used.

c. Bacterial spores are commercially available as aqueous suspensions. Bacillus stearothermophilus may be grown on nutrient agar,
supplemented with 10 mg/l Manganese sulphate, for 72 to 96 hours at 56ºC ± 2ºC. The spores should be harvested in sterile distilled water and separated from vegetative cells and sporangial debris by repeated centrifugation and water washing.

11.21 Suspending menstruum:
   a. Bacterial spores should be suspended in sterile distilled water.
   b. The other test organisms should be suspended in peptone water with 10% w/v sodium glutamate.

11.22 Inoculum:
   • The inoculum should contain known high numbers of the test organism. The population in the original inoculum and deposited on the test piece for exposure to the disinfection process should be counted. The inoculum should contain not less than 106 cfu per ml. If the suspension has a lower count than this the cells should be concentrated by centrifugation and resuspension in a smaller volume.
   • A number of counting methods are available. Direct counting using a Helber bacterial counting chamber and phase contrast microscopy with the numbers confirmed by a viable plate count (by the spread plate or pour plate method) is preferred.
   • Nephelometry or McFarland Barium Sulphate Standards may also be used for a more rapid assessment of numbers.
   • Spectrophotometry is less accurate than nephelometry and generally should not be used.

Test pieces

11.23 A surrogate device for investigation of cleaning and disinfection may be constructed from two lengths of 2 mm ID teflon (polytetrafluorethylene) tube and one length of 1 mm ID teflon tube. These should be bound together with adhesive tape at intervals of approximately 15 cm.

11.24 Test pieces for inoculation may be formed from 150 mm lengths of the same diameters of tubing. These may then be positioned at each end and in the middle of the long lengths of tubing. They should be held in position with a sleeve made from a short length of tube of greater diameter. The overall length of each tube, including the three test pieces, should be not less than 1.5 metres.

Inoculation method

11.25 A microsyringe should be used to dispense 25 l aliquots into each of the 150 mm long test pieces. These should then be rotated until visibly dry and the procedure repeated three more times.

Recovery method

11.26 The test piece should be transferred to a sterile isotonic solution containing a suitable neutraliser for the disinfectant. The tube should be removed after 5 minutes. The 150 mm length of tube should be cut in half and one half slit lengthwise with a sterile scalpel. The split halves should be
transferred to 20 ml of ¼ strength Ringers solution containing 0.05% polysorbate 80 in a thin walled glass universal and ultrasonicated for 10 minutes at 45 MHz. The eluate should be used to prepare a dilution series from which a viable count should be determined.

11.27 The other half of the test piece should be transferred to recovery medium (growth/no growth test).

**Test method**

11.28 **Evaluation of initial inoculum:** Test pieces prepared as described above should be tested by the recovery method to establish the population of each test organism which can be recovered from the inoculum (Note. There will be some loss of viability during the drying down process).

11.29 **Evaluation of physical removal:** Surrogate devices incorporating test pieces inoculated with Bacillus spores should be exposed to the WD process and recovered by the method described.

11.30 A parallel study should be undertaken in which test pieces prepared in the same manner are exposed to the disinfectant in the laboratory by immersion in disinfectant solution of the same concentration, followed by recovery in the manner described above. The difference in population between the two groups of test pieces is a measure of the extent to which test organisms are physically removed by the WD process.

11.31 There should be no significant reduction in the inoculum of the laboratory exposed test pieces and not less than $10^5$ spores remaining on each of the test pieces exposed to the WD process.

11.32 If there is significant sporicidal activity from the disinfectant it will be necessary to evaluate the physical removal of test organisms by repeating the study in the WD with Bacillus spores but with the disinfectant solution replaced by water.

11.33 If, due to physical removal, there are less than $10^5$ spores remaining on the test piece the tests should be repeated without the initial washing and/or rinsing stage.

11.34 **Evaluation of disinfection efficacy:** The surrogate devices incorporating test pieces inoculated with test organism should be exposed to the WD process and recovered by the method described. Duplicate tests should be carried out for each test organism. The tests using mycobacteria should not be undertaken until satisfactory results have been obtained from the other test organisms.

**Results**

11.35 There should be not less than a $10^5$ reduction for each of the vegetative test organisms.

11.36 Organisms should be recovered from at least three of the tests carried out on vegetative organisms. If there was no recovery of vegetative organisms the test should be repeated with reduced exposure time to the disinfectant until at least three of the tests carried out show recovery of vegetative organisms.
12.0 Automatic control test

Introduction

12.1 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 WD.

12.2 It is carried out once a week on most WDs and is the main test for ensuring that the WD continues to function correctly.

12.3 During the commissioning, yearly and quarterly test programmes the temperature 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 may be checked during periods of stable temperature in the automatic control test.

Test procedure

12.4 Place the test load appropriate to the type of WD, contained within any load furniture normally used, in the chamber.

12.5 For WDs equipped with multiple cycle capability select the operating cycle to be tested. Start the cycle.

12.6 Ensure that a batch process record is made by the recording instrument fitted to the WD. If the WD 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.

12.7 At the approximate mid-point of the disinfection hold time, note the elapsed time and the indicated chamber temperature.

12.8 The test should be considered satisfactory if the following requirements are met:
   a. a visual display indicating ‘cycle complete’ occurs;
   b. during the whole of the operational cycle the values of the cycle variables as indicated by the instruments on the WD 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 and recorded chamber temperatures are within the appropriate disinfection temperature band specified in Table 3;
(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 band for the time specified in Table 3;

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.
13.0 Specific tests for WDs for human-waste containers

Introduction

13.1 WDs for human-waste containers are used to process bedpans, commode bowls, vomitus bowls, urine bottles, suction bottles, kidney dishes and sputum cups etc. The WD is usually a dedicated machine intended solely for human-waste containers.

13.2 WDs for human-waste containers (Bedpan WDs) are Type 1 machines only. The following tests are specific to WDs for human-waste containers.

13.3 Thermal disinfection should be verified by thermometric measurement; the use of biological indicators for assessment of thermal disinfection is not a satisfactory alternative.

Test for flushing of toilet tissues

Introduction

13.4 This test is intended to be carried out as a type test (and as such is a requirement of BS 2745: Part 2: 1993, Annex F) and as an operational test. It is based on a similar test for WC pans described in Appendix A of BS 5503: Part 3: 1990. The test assesses the capability of the WD to flush away toilet tissue sheets.

Equipment and materials

13.5 The following equipment and materials are necessary:

a. thermometer capable of measuring temperatures including the range 7ºC to 20ºC to within ± 1ºC;

b. solids catchment sieve (type test only);

c. 100 mm diameter drainpipe 2 m long (type test only);

d. toilet tissue sheets with an absorbency conforming to A.2.1 of BS 5503: Part 3: 1990.

Method for Type test

13.6 The WD is mounted in an elevated position with connected to a 2 m long 100 mm diameter drainage discharge system so arranged that the discharge passes through a solids catchment sieve. All services except the hot water supply are connected to the WD. Verify that the trap is charged with water to the normal working level and that the temperature is between 7ºC and 20ºC.

13.7 For each bedpan that can be processed simultaneously in the WD take twelve toilet tissue sheets. Crumple each sheet and drop it into the chamber of the WD. Close the door and start the cycle.
13.8 At the end of the wash stage of the cycle record the number of sheets of toilet tissue discharged from the WD into the sieve. Repeat the test a further four times.

Method for operational test

13.9 The test is carried out on the installed WD with all services connected; the hot water supply to the WD should be isolated. Verify that the trap is charged with water to the normal working level and that the temperature is between 7ºC and 20ºC.

13.10 For each bedpan that can be processed simultaneously in the WD take twelve toilet tissue sheets. Crumple each sheet and drop it into the chamber of the WD. Close the door and start the cycle.

13.11 At the end of the wash stage of the cycle use the override facility to abort the cycle, open the door and examine the number of sheets of toilet tissue remaining within the chamber and/or trap.

13.12 Repeat the test a further four times.

Results

13.14 All the sheets of toilet tissue should be discharged from the chamber and trap into the drainage system.

Test for flushing of non-absorbent materials

Introduction

13.15 The test is designed to assess the effectiveness of flushing of non-absorbent materials. It is intended to be carried out as a type test (and as such is a requirement of BS 2745: Part 2: 1993, Annex F).

13.16 When necessary it may be carried out as an operational test but the discharge from the WD must be disconnected from the building drainage system.

Equipment and materials

13.17 The following equipment and materials are necessary:

a. non-absorbent test spheres (relative density 1.075 to 1.080, diameter 43 ± 0.5 mm);

b. a solids catchment sieve.

Method

13.18 Drop one non-absorbent test sphere (relative density 1.075 to 1.080, diameter 43 ± 0.5 mm) into the chamber for each bedpan that the WD is intended to process, close the door and start the WD. At the end of the cleaning (washing) stage and before the disinfection stage, stop the machine and examine the trap and the solids catchment sieve.
13.19 Carry out the test in triplicate.

**Results**

13.20 All test spheres should be discharged from the chamber and the trap on each cycle.

**Test for safety of loading and/or emptying of containers**

**Introduction**

13.21 The test is intended to ensure that containers can be emptied without spillage or splashing which would cause a hazard to the operator. The WD should be tested for either manual or automatic emptying.

**Equipment and materials**

13.22 A full load of each type of container which the WD is intended to process is necessary.

**Method: manual emptying**

13.23 Each type of container which the WD is designed to process should be tested. Fill each container to not less than 75% of its brim full capacity and empty it and locate it in the load carrier in accordance with the manufacturers instructions. Load the chamber to the maximum recommended capacity. Close the door. Observe whether any liquid is spilled or splashed. Carry out the test in triplicate on each type of container.

**Method: automatic emptying**

13.24 Each type of container which the WD is designed to process should be tested. Fill each container to 75% ± 5% of its brim full capacity and locate it in the load carrier in accordance with the manufacturers instructions. Load the chamber to the maximum recommended capacity. Close the door. Observe whether any liquid is spilled or splashed. Carry out the test in triplicate on each type of container.

**Results**

13.25 There should be no spillage or splashing of the contents of the containers during the emptying process.

**Reference test loads**

13.26 The reference test load(s), for both cleaning efficacy and disinfection efficacy tests, should consist of a full load (as specified by the WD manufacturer) of each of the containers that the WD is intended to process. When the WD is designed to process mixed loads the composition of the mixed load should be determined by a preliminary study to establish the ‘worst-case’ combination.
13.27 During operational testing new containers should be used in order to obtain reproducible results. Performance qualification may need to be carried out with used containers since surface damage may affect the ease with which soil can be removed.

13.28 These should include as appropriate:
   a. bedpans (conforming to BS 2588:Part 1: 1992, or of the type specified by the user);
   b. commode pans (conforming to BS 2588:Part 1: 1992);
   c. urine bottles (polypropylene, polycarbonate, glass or porcelain, conforming to BS 3215:1995);
   d. suction bottles (polypropylene, polycarbonate or glass);
   e. supports for disposable bedpans;
   f. other hollowware which it is intended to process.

Test soil

Bedpan soil

Constituents

13.29 The following ingredients are required:
   a. 30 g unbleached plain wheat flour;
   b. 15 g water soluble wallpaper adhesive powder (to BS 3046:1981 (1991));
   c. 1 hen’s egg (size 3);
   d. 10 ml black ink (water tolerant/permanent to BS EN 26461 Part 1 1993);
   e. 240 ml water (to BS EN ISO 3696 Type 1).

Preparation and storage

13.30 Mix all the ingredients together and agitate in a stomacher to blend them and give a uniform thick paste.

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

Application and use

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

13.33 Apparatus required:
   a. paintbrush, 25 mm in width, soft;
   b. disposable gloves, for example latex.
13.34 Method of application:
   a. Clean and dry the bedpan thoroughly and warm it to a temperature of 20 to 35°C.
   b. Don the protective gloves. Apply 200 g of the test soil, using the paintbrush, to all areas of the bedpan which are likely to be in contact with human waste or with the skin. This should include the whole of the inner surface, and when it is intended to process the perfection style bed pan, up under the rim.
   c. The base should be covered by an homogenous layer which may be up to approximately 20 mm deep in places; the other surfaces should be covered by an even layer not more than approximately 2 mm deep.
   d. Rest the bedpan on its base and leave it to dry at room temperature (15°C to 25°C) for 30 to 35 minutes. Use the soil coated bedpan for the cleaning efficacy test within the next 30 minutes.
   e. The same soil may be used for other containers eg kidney bowls. The quantity of soil used should be adjusted to give approximately the same quantity per unit area of surface.

Method of detection

13.35 Detection is by visual examination only.

Urine bottle soil

Constituents

13.36 The following ingredients are required:
   • 10 ml defibrinated blood (horse or sheep’s);
   • 5 g water soluble wallpaper adhesive powder (to BS 3046:1981 (1991));
   • 1 hen’s egg (size 3);
   • 15 ml black ink (water tolerant/permanent to BS EN 26461 Part 1: 1993);
   • 200 ml water (to BS EN ISO 3696 Type 1).

Preparation and storage

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

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

Application and use

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

13.40 Apparatus required:
   a. syringe of capacity 20 ml or greater with graduations at 5 ml intervals;
b. disposable gloves, for example latex.

13.41 Method of application:

a. Don the protective gloves. Using the syringe discharge 15 ml of the test soil into a urine bottle. Shake and rotate the bottle to ensure that the test soil is distributed evenly on all the inner surface of the bottle. This should include the neck region of the bottle where, during use, the surface is likely to be in contact with the skin.

b. Use the coated bottle within 5 minutes; do not leave the soil to dry.

Method of detection

13.42 Detection is by visual examination only.

Performance qualification tests

13.43 For most applications the reference load tests will be sufficient. However, when extensive use is made of worn containers, particularly those made of plastic, the tests for cleaning efficacy may need to be repeated with worn containers. If the results are unsatisfactory every effort should be made to persuade the user to replace badly worn containers.
14.0 Specific tests for WDs for surgical instruments

Introduction

14.1 WDs for surgical instruments may be Type 1 (double or single door) or Type 2 (multiple cabinet or conveyor).

14.2 ‘WDs for surgical instruments’ is a description often given to a WD for general purposes which is used for other specific applications by using suitable load carriers (for example hollowware, anaesthetic accessories, laboratory ware). The tests described for WDs for each of these specific purposes (see Chapters 15, 16 and 18) should be carried out in addition to the test described in this Chapter, when relevant.

14.3 WDs for surgical instruments are used also to process those rigid endoscopes which are able to withstand thermal disinfection. Specific tests for WDs used for this purpose are considered in this category.

14.4 Thermal disinfection should be verified by thermometric measurement; the use of biological indicators for assessment of thermal disinfection is not a satisfactory alternative.

Water quality

14.5 Water which is too hard or has too high a concentration of dissolved solids may impair the activity of detergents (or require the use of increased quantities of chemical additives) and cause deposits, scaling or corrosion of items being processed. Water for washing and subsequent stages of the process should be tested to ensure that it is not hard (see paragraphs 9.140 to 9.152).

14.6 Trace elements in the water supply may cause corrosion of surgical instruments. The water supplied for the final rinse stage should be of high purity and this should be confirmed by testing (see paragraphs 9.100 to 9.200).

14.7 Bacterial endotoxins are undesirable on items which are to be used in invasive procedures, and for this reason are monitored in steam used for sterilization. For the same reasons the water used for the final rinse should be tested to verify that it is free from bacterial endotoxins (see paragraphs 9.201 to 9.212).

Reference test loads

14.8 The following general equipment is required:

a. 3 cuscoe speculae;

b. 3 artery forceps (Crile, Kelly or Spencer Wells) with box joints;

c. 3 No 3 scalpel handles;
d. 3 Yankauers or Pooles suction tubes;
e. sufficient additional instruments to make up a full load.

14.9 The following endoscope/MAT instruments are required:
   a. 2 Trochar and Cannulae;
   b. 2 MAT forceps;
   c. 2 surrogate endoscopes (see below);
   d. sufficient additional instruments to make up a full load.

14.10 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.

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

Test soil

Constituents

14.12 The following ingredients are required:
   a. fresh egg yolk 100 ml;
   b. defibrinated blood, 100 ml (horse or sheep’s);
   c. dehydrated hog mucin 2g.

Preparation and storage

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

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

Application and use

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

14.16 The following apparatus is required:
   • paintbrush, 25 mm in width, soft;
   • disposable gloves, for example latex;
   • drainage tray.

14.17 Method of application:
   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 (15ºC to 25ºC) for not less than 30 minutes and not more than 2 hours.

Method of detection

**14.18** Detection is by visual examination.

Performance qualification tests

Cleaning efficacy – hollow instruments, endoscopes

**14.19** The inner surfaces of hollow instruments are often those for which successful cleaning and disinfection are most critical. Performance qualification tests, in addition to the operational tests specified may be required for all aspects of the process. The use of surrogate devices may be advantageous.

Load dryness – hollow instruments and endoscopes

**14.20** Items which are left warm and damp after an ineffective drying stage will rapidly become recontaminated with micro-organisms. The presence of droplets of water within an instrument may seriously impair the efficacy of some sterilization processes (for example gas plasma processes)

**14.21** The adequacy of the drying stage may be determined by drying the test pieces to constant weight. A balance accurate to 0.1 mg should be used.

**14.22** After removal from the WD the load item should be weighed and then returned for further drying (not less than 30 minutes) and re-weighed. This process should be continued until there is no further loss in weight between consecutive weighings. The mass of residual water left after processing is the difference between the first weighing and the final weighing.

Chemical additive compatibility with instruments

**14.23** While most surgical instruments are constructed from stainless steel a number are constructed from other materials which may be adversely affected by various chemical additives. For example Auroscopes and other instruments with blackened, non-reflective surfaces, may have the surface treatment removed by exposure to strongly alkaline detergents. The instruments to be processed should be reviewed and the manufacturers advice sought when necessary.
15.0 Specific tests for WDs for hollowware

Introduction

15.1 WDs for hollowware are used to process bowls, receivers, instrument trays, containers and lids etc. The WD may be a dedicated machine intended solely for hollowware or a WD for surgical instruments with an appropriate load carrier and operating cycle. In the latter case the tests and reference loads described in this chapter should also be applied to the WD for surgical instruments (see Chapter 14).

15.2 WDs for hollowware may be Type 1 (single or double door) or Type 2 (multiple chamber or conveyor).

15.3 Thermal disinfection should be verified by thermometric measurement; the use of biological indicators for assessment of thermal disinfection is not a satisfactory alternative.

Reference test loads

15.4 Metal and plastic hollowware has significantly different drying characteristics and may also have different carrier requirements since plastic containers are easily ‘flipped over’ and may then become filled with water. When this happens, not only are the containers impossible to dry but also, there may be a serious risk of scalding when unloading the WD. Plastic items are usually more difficult to dry and are therefore chosen for the standard test load.

15.5 The standard test load for hollowware should consist of items conforming to BS 5452: 1977 (1989) as follows:

a. 1 instrument tray 200 mm x 150 mm;
b. 1 instrument tray 300 mm x 250 mm;
c. 1 compartmented instrument tray 270 mm x 180 mm;
d. 1 kidney dish of 150 mm x 300 mm;
e. 1 wash bowl of 350 mm x 135 mm;
f. 1 lotion bowl of 100 mm x 45 mm;
g. 1 lotion bowl of 250 mm x 110 mm;
h. 1 gallipot of 40 mm (30 ml to 60 ml);
j. 1 gallipot of 80 mm (250 ml to 280 ml);
k. sufficient additional items of the same type to form a full load.
Test soil

Constituents

15.6 The following ingredients are required:
   a. fresh egg yolk 100 ml;
   b. defibrinated blood, 100 ml (horse or sheep);
   c. dehydrated hog mucin 2 g.

Preparation and storage

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

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

Application and use

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

15.10 The following apparatus is required:
   a. paintbrush, 25 mm in width, soft;
   b. disposable gloves, for example latex;
   c. drainage tray.

15.11 Method of application:
   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

15.12 Detection is by visual examination.

Performance qualification tests

15.13 Additional tests are unlikely to be required for particular load items other than for WDs which are used to clean and disinfect re-usable containers for sterile products (see EN 868 Part 8 – Publication expected late 1997).

15.14 A test load consisting of the following should be used:
   • 1 full size container (600 mm x 300 mm x 300 mm);
   • 1 half height container (600 mm x 300 mm x 150 mm);
   • 2 half-size half-height containers (300 mm x 300 mm x 150 mm).
15.15 Further tests may be necessary also for particular loading configurations. When load carriers are heavily loaded there may be 'shadowing' of some parts of the load causing inefficient cleaning and/or failure to achieve disinfection conditions throughout the load.
16.0 Specific tests for WDs for anaesthetic accessories

Introduction

16.1 WDs for anaesthetic accessories are used to process breathing tubes, reservoir bags, connectors, endotracheal tubes, tracheostomy tubes, face masks and similar items. The WD may be a dedicated machine intended solely for anaesthetic accessories or a WD for surgical instruments with an appropriate load carrier and operating cycle. In the latter case the tests and reference loads described in this chapter should be applied also to the WD for surgical instruments (see Chapter 14).

16.2 WDs for anaesthetic accessories may be Type 1 (single or double door) or Type 2 (multiple chamber or conveyor).

16.3 Long lengths of tubing are difficult to clean internally and the attainment of cleanliness is difficult to verify. Anaesthetic tubing is also difficult to dry; this is particularly the case for plastic tubing which cannot withstand high (100°C+) drying temperatures.

16.4 Thermal disinfection should be verified by thermometric measurement; the use of biological indicators for assessment of thermal disinfection is not a satisfactory alternative.

Reference test loads

16.5 A test load consisting of the following should be used:

a. 2 Breathing tubes > 600 mm in length (conforming to BS 6151: 1992) (transparent/translucent tubing should be used);

b. 1 anaesthetic reservoir bag of 15 mm, 1.5 litre capacity (conforming to BS 3353: 1987);

c. 1 anaesthetic reservoir bag of 22 mm, 1.5 litre capacity (conforming to BS 3353: 1987);

d. 2 dis-assembled conical connectors of 15 mm, screw threaded with cone and socket joints (conforming to BS 3849);

e. 2 dis-assembled conical connectors of 22 mm, screw threaded with cone and socket joints (conforming to BS 3849);

f. tracheostomy tube and connector of 11 mm size (conforming to BS 6149);

g. endotracheal tube connector of 11 mm size (conforming to BS 6546: 1984);

h. 4 face masks.
Test soil

Constituents

16.6 The following ingredients are necessary:
- a. water 50 ml (conforming to BS EN ISO 3696 Type 1);
- b. glycerol 30 ml (conforming to BS 2621-5 :1979 (1994) chemically pure glycerol);
- c. horse serum 30 ml;
- d. dehydrated hog mucin 5 g;
- e. unbleached plain flour 2 g;
- f. 2% m/m aq safranine solution 1 ml.

Preparation and storage

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

16.8 Use immediately or store in an air-tight container at 2ºC to 5ºC for not more than one month.

Application and use

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

16.10 The following apparatus is required:
- a. paintbrush, 25 mm in width, soft;
- b. disposable gloves, for example latex;
- c. drainage tray;
- d. syringe of capacity 20 ml or greater with graduations at 5 ml intervals.

16.11 Method of application:
- a. Don the protective gloves. Apply the soil to the inner surface of the larger test pieces (breathing tubes and reservoir bags) by pouring the soil into the items; lay the items on a horizontal surface and roll the items to distribute the soil over the inner surface.
- b. Hold the item vertically to allow excess soil to drain away. Then apply an even coat of soil to the outer surface using the paint brush. Allow excess soil to drain from the items and allow them to dry at room temperature (15ºC to 25ºC) for not less than 30 minutes and not more than 2 hours.

16.12 Smaller items such as endotracheal tubes should be treated similarly but it may be necessary to use the syringe to introduce the test soil into the lumen.
Method of detection

16.13 Detection is by visual examination.

Performance qualification tests

Cleaning and disinfection

16.14 The inner surfaces of anaesthetic accessories are often those for which successful cleaning and disinfection are most critical. Some items may be used after disinfection without further decontamination (for example sterilization). Performance qualification tests, in addition to the operational tests specified may be required for all aspects of the process. The use of surrogate devices may be advantageous.

Drying

16.15 Items which are left warm and damp after an ineffective drying stage will rapidly become recontaminated with micro-organisms. The adequacy of the drying stage may be determined by drying the test pieces to constant weight. A balance accurate to 0.1 mg should be used.

16.16 After removal from the WD the load item should be weighed and then returned for further drying (not less than 30 minutes) and re-weighed. This process should be continued until there is no further loss in weight between consecutive weighings. The mass of residual water left after processing is the difference between the first weighing and the final weighing.
17.0 Specific tests for WDs for endoscopes

Introduction

17.1 WDs for flexible thermolabile endoscopes are machines of Type 1 only. (Rigid endoscopes able to tolerate terminal steam sterilization are considered under WDs for surgical instruments.)

17.2 These WDs are characterised by a chemical disinfection stage because the products which are intended to be processed will not withstand the high temperatures required for thermal disinfection. It is necessary to ensure that the disinfectant is removed from the endoscope before it is used on a patient; this is achieved by a post-disinfection rinsing stage. It is apparent that the microbiological control of this stage is of critical importance to the microbial status of the processed item. A number of additional tests are required to ensure that this aspect of the process is properly controlled.

WD self-disinfection test

Introduction

17.3 To verify that the WD ‘machine disinfection’ mode will disinfect those parts of the WD which come into contact with fluids which are intended to, or may, contact the load.

17.4 The process is intended to deal with the situation where WD has become contaminated. The piping used to convey rinse water to the endoscope, if contaminated, may easily develop a layer of biofilm containing many micro-organisms in a state which is highly resistant to chemical disinfection. This tubing should normally be replaced at the interval specified by the manufacturer. Normally this should not exceed 500 operating cycle or 3 months.

17.5 Thermal disinfection systems should be evaluated by thermometric monitoring of the system with sensors placed at the parts of the system most remote from the heat source. The entire system should attain the required disinfection temperature (see Table 3).

17.6 For chemical disinfection systems a microbiological test will be required. The test is designed to ensure that the self disinfection cycle will disinfect contaminated tubing by evaluating the effect of the cycle against a biofilm containing Pseudomonas aeruginosa.

Production of biofilm test pieces

Equipment and materials

17.7 The following equipment and materials are necessary:

   a. peristaltic pump;
b. incubator at 30°C ± 2°C;
c. 1 litre conical flask fitted with rubber bung, air vent and two glass tubes;
d. connecting tubing;
e. 1.5 metre length of 6 mm ID Teflon tubing;
f. nutrient agar supplemented with 1 g/l sodium desoxycholate;
g. 0.025 g/l of 2,4,4'-trichlor-2'-hydroxydiphenylether;
h. pseudomonas aeruginosa ATCC 25619;
i. liquid growth medium: phosphate buffer (containing 1.2 g/l sodium phosphate, dibasic and 0.5 g/l potassium phosphate, monobasic)
j. containing 0.25 g/l sodium glutamate and 0.1 g/l citric acid.

Method

17.8 A petri dish containing supplemented nutrient agar should be inoculated with Pseudomonas aeruginosa ATCC 25619 and incubated at 30°C ± 2°C for 36 to 48 hours.

17.9 A 1 litre conical flask containing 500 ml of the sterile liquid growth medium is inoculated with mucoid colonies of Pseudomonas aeruginosa from the agar plate and incubated at 30°C ± 2°C for 18 to 24 hours. The flask is then fitted with a bung through which passes an air vent, filtered to 0.22 m, and two glass tubes one of which reaches to the bottom of the flask and one of which terminates above the level of liquid in the flask.

17.10 The glass tubes are connected, via a peristaltic pump and short lengths of flexible tubing, to a 1.5 to 2.0 metre length of 6 mm ID PTFE tubing. The culture is pumped round the tubing system at 50–75 ml/min throughout the incubation period. The system is maintained in an incubator at 30°C ± 2°C for 72 to 96 hours.

Evaluation of the self-disinfection cycle

17.11 A 30 cm section of the tubing suitably identified (for example T1) prepared with biofilm is subjected to the recovery procedure described below.

a. A section of the piping in the endoscope channel irrigation system of the WD is removed and replaced with the test system. The test system consists of two 30 cm lengths of the biofilm test piece tubing connected via isolating valves and ‘Y’ piece connectors in place of the removed section of pipework.

b. With the valves open the WD is set to operate a ‘self-disinfect’ cycle.

c. At the end of any wash stage, and immediately before the start of the chemical disinfection stage, close the valves isolating one of the test pieces (T2). On completion of the disinfection stage and any subsequent rinse stage remove both test pieces (T2 and T3) and carry out the recovery procedure described below.

d. Replace the test pieces with two more sections of the tubing with biofilm and carry out a further self-disinfect cycle. Isolate one of the test pieces (T4) at the end of the disinfection stage and before any rinsing process. On completion of the cycle remove both test pieces (T4 and T5) and carry out the recovery procedure described below.
Recovery procedure

17.12 The 30 cm length of tube should be cut into 6 portions each of approximately 5 cm length. Three of these should be transferred into individual universal containers containing nutrient broth and incubated at 30°C ± 2°C.

17.13 The remaining 3 sections should be cut in half longitudinally and each pair transferred to 10 ml of ¼ strength ringers solution containing 0.05% Polysorbate 80 in a thin walled universal container. The container should be ultrasonicated for 10 minutes at 45 MHz. Tenfold serial dilutions should be prepared of the eluate obtained and these should be used for enumeration of the surviving organisms by the spread plate technique. All determinations should be carried out in duplicate.

Results

17.14 The data obtained give the following information:

- T1 – recoverable population on the original test piece;
- T2 – recoverable population after the washing stage;
- T3 – recoverable population after wash, disinfect and rinse stages;
- T4 – recoverable population after wash and disinfect stage;
- T5 – recoverable population after wash, disinfect and rinse stages
- T3 and T5 should have the same population within the limits of experimental error; the difference between them is a measure of the reproducibility of the system;
- T1 – T2 is the loss during the washing stage;
- T3 – T4 and T5 – T4 are the loss during the post-disinfection rinse;
- T2 – T4 is the loss due to the disinfection process.

17.15 On testing the full self-disinfect cycle there should be no recovery of organisms from T3, T4 and T5. When this is the case the test should be repeated with the exposure time reduced to half the normal value. The reduced exposure time should give a reduction of at least $10^3$ in the number of recoverable micro-organisms ($T2 – T4 \geq 10^3$).

Final rinse decontamination test

17.16 Various methods are used to ensure that the final rinse water is decontaminated before use. The test should verify the performance of the particular system by the method specified by the manufacturer.

17.17 This may include:

a. verification of filter performance by a bubble point test or by measuring the differential pressure drop across the filter;

b. verification of thermal disinfection by thermometric testing;

c. verification of UV activity by confirmation that the illumination is at the wavelength and intensity specified by the manufacturer and that the residence time is also as specified.
**Microbiological test**

17.18 In each case the decontamination system also should be challenged by inoculation with a test organism (E coli K12 is a suitable test organism) upstream of the decontamination system. The inoculum should be sufficient to produce a population of 10⁶ organisms per ml in the final rinse water if there was no effect from the decontamination system. A 220 ml sample of the final rinse water should be collected during an operating cycle and analysed for the number of remaining organisms by the filtration method (see paragraphs 9.213 to 9.226). There should be less than 10 cfu of the test organism recovered from a 100 ml sample.

**Channel patency detection test**

17.19 WDs for endoscopes should be fitted with means to ensure that each of the channels is patent so that germicidal and rinse solutions will flow through each channel.

17.20 A surrogate device should be used to demonstrate that the system for determining the patency of each channel is function correctly. The surrogate device may be constructed by using a 1.5 metre length of 1 mm ID PTFE tubing.

17.21 For each channel (air/water, biopsy, elevator as relevant) connect a 1.5 metre length of tubing of the appropriate diameter and run an operating cycle. On completion of the cycle replace one of the tubes with a similar tube which has a 100 mm long 1.1 mm OD 0.5 mm ID melting point tube (Borosilicate glass) inserted and secured in the distal end and run another operating cycle. Repeat the test changing the position of the partially obstructed tube on each test.

17.22 The WD should indicate a fault for any channel to which the partially obstructed surrogate device is fitted.

**Disinfectant concentration test**

17.23 WDs employing a chemical disinfection stage may re-use the chemical germicide a number of times (see HTM 2030 ‘Operational management’).

17.24 When such a system is employed the WD should be equipped with means to establish that the concentration of the active ingredient(s) in the germicide is above the concentration specified as the minimum acceptable. (This may be in the form of a test kit to be employed by the user)

17.25 The disinfectant concentration test is carried out to establish that the means provided is effective.

17.26 The full strength solution, unused (and if necessary freshly prepared or activated), should be prepared according to the manufacturers instructions. When this requires the addition of water only distilled or purified water should be used.

17.27 A dilution series should be prepared using distilled or purified water.
17.28 When the concentration of fresh disinfectant is $C_1$ and the minimum concentration of usable disinfectant is $C_2$.

17.29 The following dilutions should be prepared:
   a. $C_2 + \frac{(C_1 - C_2)}{10}$
   b. $C_2$
   c. $C_2 - \frac{(C_1 - C_2)}{10}$

17.30 For WDs with an automated detection system the test should be carried out by transferring the dilute disinfectant to the disinfectant reservoir and attempting to start an operating cycle. The WD should indicate when the concentration is insufficient.

17.31 For WDs in which the disinfectant concentration is intended to be determined by the user testing a sample from the WD reservoir the tests should be carried out outside the WD.

17.32 The automated system or the user test should indicate an unsuitable disinfectant concentration for dilution c. and a satisfactory disinfectant concentration for dilution a.

Reference test loads

17.33 A surrogate device for investigation of cleaning and disinfection may be constructed from two 1.5 metre lengths of 2mm ID teflon (polytetrafluorethylene) tube and one 1.5 metre length of 1 mm ID teflon tube. These should be bound together with adhesive tape at intervals of approximately 15 cm.

Test soil

Constituents

17.34 The following ingredients are necessary:
   a. water 50 ml;
   b. glycerol 30 ml;
   c. horse serum 30 ml;
   d. dehydrated hog mucin 5 g;
   f. unbleached plain flour 2 g;
   g. 2% m/m aq safranine solution 1 ml.

Preparation and storage

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

17.36 Use immediately or store in an air-tight container at 2°C to 5°C for not more than one month.
Application and use

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

17.38 The following apparatus is necessary:
   a. disposable gloves, for example latex;
   b. drainage tray;
   c. syringe of capacity 20 ml or greater with graduations at 5 ml intervals.

17.39 Method of application:
   a. Don the protective gloves. Apply the soil to the inner surface of the test pieces by injecting the soil into the tubes of the surrogate device (approximately 5 ml into the 1 mm ID tube and 20 ml into each of the 2 mm ID tubes; lay the tubes on a horizontal surface and roll them to distribute the soil over the inner surface.
   b. Hold them vertically to allow excess soil to drain away. Then apply an even coat of soil to the outer surface using the paint brush. Allow excess soil to drain from the items and allow them to dry at room temperature (15ºC to 25ºC) for not less than 30 minutes and not more than 2 hours.

Method of detection

17.40 Detection is by visual examination.

Microbiological test of disinfection efficacy

17.41 Disinfection efficacy should be verified using the test described in paragraphs 11.12 to 11.36. The test should not be carried out until the adequacy of the WD self disinfection cycle has been established (see above).

17.42 The thermometric test for assessment of temperature control throughout the disinfection stage (see paragraphs 11.4 to 11.11) should be completed satisfactorily before commence microbiological tests.

Performance qualification tests

Cleaning

17.43 The soil removal efficacy is tested with a surrogate device. When necessary the adequacy of the cleaning process on a load item may be verified by using a modification of the tests for residual soil described in paragraphs 10.37 to 10.49.

17.44 The endoscope should be brushed through with a disposable cleaning brush and then tested for traces of residual protein using the ninhydrin method (see paragraphs 10.37 to 10.48).
Disinfection

**17.45** The disinfection efficacy has been tested during operational testing with a surrogate device (see paragraphs 17.41 to 17.42 and Chapter 11). When necessary the adequacy of the disinfection process may be verified by using the method given below.

**17.46** The endoscope should be brushed through with a sterile disposable cleaning brush. The brush end should be aseptically cut from the handle and aseptically transferred to 10 ml of sterile peptone water containing 0.05% polysorbate 80 and ultrasonicated at 40 MHz for 10 minutes. The eluate should then be filtered through a 47 mm diameter 0.45 μm filter and then tested as described in paragraphs 9.213 to 9.226.
18.0 Specific tests for WDs for laboratory use

Introduction

18.1 WDs for laboratory use are generally of Type 1 only. Their major use is for cleaning laboratory glassware and this is reflected in the reference load specified. However, there is a wide range of possible loads and load carriers adapted for particular purposes and specific performance qualification tests may therefore be required.

18.2 The disinfection stage may not be required for many laboratory applications.

Reference test loads

18.3 The reference test load to be used in tests for cleaning efficacy, thermal disinfection efficacy and (when applicable) load dryness consists of a full load of glassware. This should contain:
   a. 100 rimless test tubes of 16 mm x 150 mm with 1.2 mm wall thickness (conforming to BS 3218:1982);
   b. 24 low form beakers, 1000 ml volume, 106 mm diameter by 145 mm high (conforming to BS 6523:1984);
   c. additional items as may be required to fully load the chamber of the WD.

Test soil

Constituents

18.4 The following ingredients are necessary:
   a. fresh egg yolk 100 ml;
   b. defibrinated blood, 100 ml (horse or sheep’s);
   c. dehydrated hog mucin 2g.

Preparation and storage

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

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

Application and use

18.7 If the soil has been stored allow it to equilibrate to room temperature before use.
18.8 The following apparatus is necessary:
   a. paintbrush, 25 mm in width, soft;
   b. disposable gloves, for example latex;
   c. drainage tray.

18.9 Method of application:
   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

18.10 Detection is by visual examination.

Performance qualification tests

Load items

18.11 For laboratory items other than general purpose glassware of the type included in the reference load, or of other items (for example holloware) for which standard reference loads have been defined it will be necessary to review 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 which will be used further tests should be carried out using loads composed of items which will be in normal production loads.

Nature of soiling

18.12 Laboratory items may be subjected to soiling of a variety of types many of which are very difficult to remove. The test soil for operational testing is chosen to represent biological fluids which may be present. If other types of soiling will be encountered tests should be conducted using items soiled in the manner which will occur for normal production loads.

Process residue tests

18.13 In many cases there will be a need for laboratory items to be free from residues of chemical additives used during the cycle since these may interfere with the subsequent use of the load items. The manufacturer(s) of the chemical additives which it is intended to use should be asked to provide appropriate test methods for the determination of residual levels.
19.0 Specific tests for ultrasonic cleaners

Introduction

19.1 Ultrasonic cleaners may be of the ‘stand-alone’ ultrasonic bath type or may be WDs of Type 1 or Type 2 (multiple chamber or conveyor) or they may be one stage of a Type 2 WD. Many Type 1 ultrasonic cleaners do not incorporate a disinfection stage and are intended for use as a pre-cleaning process before final cleaning and disinfection in a WD for surgical instruments (see Chapter 13).

19.2 Some ultrasonic cleaners are equipped with means to irrigate hollow instruments such as endoscopes. These WDs should be tested both with the general reference load and the endoscope/MAT reference load (see below).

Test for ultrasonic activity

Introduction

19.3 The activity of an ultrasonic cleaner may be investigated by the erosion pattern which is created on aluminium foil exposed in the bath for a short period. The activity will not be 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.

19.4 The exposure time will 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.

Equipment and materials

19.5 The following equipment and materials are necessary:

a. aluminium foil of nominal thickness 0.015 mm to 0.025 mm (sold as an aluminium foil wrap for cooking);

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

19.6 Measure the depth of the bath from the level of the lid to the bottom of the bath. Let the depth be D mm.

19.7 Cut strips of aluminium foil 15 mm to 20 mm wide and (D + 120) mm.
19.8 Carry out the manufacturer’s recommended start-up procedure; this will normally include a period of operation to eliminate dissolved gases from the solution in the bath (the de-gassing procedure).

19.9 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.

19.10 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 x 3 grid.

19.11 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.

19.12 Operate the bath for the predetermined exposure time. This may vary typically between 30 seconds for a watt density of 20 watt.dm\(^{-3}\) and 10 minutes for a watt density of 5 w.dm\(^{-3}\).

19.13 Remove the strips from the bath, blot dry and examine.

19.14 The strips may be filed conveniently by sticking them to an A4 sheet of plain paper using a transparent adhesive tape.

19.15 Drain the bath and clean to remove debris of eroded aluminium foil.

Results

19.16 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).

19.17 On re-testing the extent of erosion and the erosion pattern should have remained consistent with those originally determined during commissioning.

Reference test loads

19.18 The test load should contain the following general equipment:
   a. 3 cuscoe speculae;
   b. 3 artery forceps (Crile, Kelly or Spencer Wells) with box joints;
   c. 3 No 3 Scalpel handles;
   d. 3 Yankauers or Pooles suction tubes;
   e. sufficient additional instruments to make up a full load.

19.19 The test load should contain the following endoscope/MAT instruments:
   a. 2 Trochar and Cannulae;
   b. 2 MAT forceps;
   c. 2 surrogate endoscopes (see below);
   d. sufficient additional instruments to make up a full load.

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.
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.

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

**Test soil**

*Constituents*

The following ingredients are necessary:

a. fresh egg yolk 100 ml;

b. defibrinated blood, 100 ml (horse or sheep's);

c. dehydrated hog mucin 2g.

*Preparation and storage*

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

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

*Application and use*

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

The following apparatus is required:

a. paintbrush, 25 mm in width, soft;

b. disposable gloves, for example latex;

c. drainage tray.

Method of application:

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*

Detection is by visual examination.
Performance qualification tests

Load items

19.29 For ‘difficult to clean’ laboratory items other than those of the type included in the reference load, or of other items (for example holloware) for which standard reference loads have been defined it will be necessary to review 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 which will be used further tests should be carried out using loads composed of items which will be in normal production loads.

Nature of soiling

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

19.31 The test soil for operational testing is chosen to represent biological fluids which may 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 which will occur for normal production loads.
Appendix I: Glossary

**Automatic controller:** Device that, in response to pre-determined cycle variables, operates the WD sequentially through the required stages of the cycle(s)/process.

**Calibration:** The set of operations that establish, under specified conditions, the relationship between values of a quantity indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realised by standards.

**Chamber:** That part of the WD in which the load is processed.

**Chemical additive:** one or more chemicals added to the chamber and load of a WD during one or more stages of the process

**Chemical disinfection:** disinfection achieved by the action of one or more chemicals the primary purpose of which is to be microbicidal.

**Commissioning:** obtaining and documenting evidence that equipment has been provided and installed in accordance with its specifications and that it functions within pre-determined limits when operated in accordance with operational instructions

**Cycle variables:** The physical and chemical properties (eg times, temperatures, disinfectant concentration, pressures and flows) that influence the efficacy of the washing and processes.

**D value:** for a microbiological process the extent of exposure under defined conditions which cause a 90% decrease in the viable population of a specified micro-organism.

**Decontamination:** the combination of processes, including cleaning and disinfection and/or sterilization, used to render a re-usable item safe for further use.

**Disinfection:** the reduction of the number of viable micro-organisms on a product to a level previously specified as appropriate for its intended further handling or use.

**Door:** Device provided as a means of closing and sealing the chamber.

**Fail safe:** Attribute of WD design, component or its associated services that minimises a possible safety hazard.

**Fault:** Recognition by the automatic controller that the pre-set cycle variables for the WD cycle have not been attained.

**Installation qualification:** see commissioning

**Installation test:** series of checks and tests performed after installation of the WD in the place of use

*The chamber does not include steam generators, pipework and fittings from which it can be isolated.*
Load: A collective term used to describe all the goods equipment and materials that are put into a WD at any one time for the purpose of processing it by an operating cycle.

Medical device: see EN 46001: 1997.

Monitoring: the measurement of physical variables, such as the function of the automatic controller to check the attainment, or otherwise, of the pre-set cycle variables essential to the efficacy of the operating cycle.

Operating cycle: The complete set of stages of the process that is carried out in the sequence as regulated by the automatic controller.

Performance qualification: obtaining and documenting evidence that the equipment as commissioned will produce acceptable product when operated in accordance with the process specification.

Product compatibility: ability of the WD operational cycle to achieve the intended results without detrimental effect on the product or its intended use.

Reference load: specified load made up to represent the most difficult combination of items to be processed in a particular WD operational cycle.

Routine test: series of tests intended to be performed by the user, or their representative, at various pre-determined intervals to demonstrate that the performance of the WD remains within the limits established during type/works/installation and validation testing.

Steam generator: vessel designed to contain water and a heating system (eg a steam coil or a fully immersed electric element) which is used to heat water to its vapour state.

Sterile: see EN 556.

Sterilization: process used to render a product sterile.

Surrogate device: a test piece designed and constructed to emulate those characteristics of a device which influence the facility with which it may be cleaned and disinfected.

Tank: A process vessel, integral to the WD, designed to hold solutions during processing.

Test soil: substance used to test the washing efficacy of WDs.

Thermal disinfection: disinfection achieved by the action of moist or dry heat.

Type test: series of tests to establish the working data for a WD type.

Validation: documented procedure for obtaining, recording and interpreting data to show that a process will consistently produce product complying with pre-determined specifications.

Viable micro-organism: micro-organisms, including viruses, which are capable of multiplication under specified culture conditions.
This type of machine does not include those designed specifically to wash linen or clothing.

**Washer-disinfector (WD):** Machine intended to clean and disinfect medical devices and other articles used in the context of medical, dental, pharmaceutical and veterinary practice.

**Works test:** series of tests performed at the manufacturer’s works to demonstrate compliance of each WD with its specification

**Z value:** for a thermal microbicidal process the change in temperature required to cause a tenfold change in D value.
Appendix II: Abbreviations

AP(S)  Authorised Person (Sterilizers)
BP    British Pharmacopoeia
BS    British Standard
C     degrees Celsius
CEN   Committee European de Normalisation
cfu   colony forming unit
COSHH Control of Substances Hazardous to Health
DI    De-ionised
EMC   Electro-magnetic compatibility
EN    European Norm
EU    European Union or Endotoxin Unit
HBN   Health Building Note
HEPA  High Efficiency Particulate Arrestance
HSE   Health and Safety Executive
HTM   Health Technical Memorandum
ID    Internal Diameter
IEC   International Electrotechnical Commission
ISE   Iron selective electrodes
ISO   International Standards Organisation
K     degrees Kelvin
LAL   Limulus Amoebocyte Lysate
MAT   Minimal Access Therapy
MCA   Medicines Control Agency
MDA   Medical Devices Agency
MPR   Master Process Record
MP(S) Maintenance Person (Sterilizers)
OD    Outside diameter
OEL   Occupational exposure limit
PES   Programmable Electronic System
pH    The inverse of the logarithm to base 10 of the hydrogen ion activity of a solution. (Solutions with pH values less than 7 are acidic and those with pH values greater than 7 are alkaline.)
PQ    Performance qualification
### Appendix II: Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRQ</td>
<td>Performance re-qualification</td>
</tr>
<tr>
<td>RO</td>
<td>Reverse Osmosis</td>
</tr>
<tr>
<td>TC</td>
<td>Technical committee</td>
</tr>
<tr>
<td>TDS</td>
<td>Total Dissolved Solids</td>
</tr>
<tr>
<td>TP(S)</td>
<td>Test Person (Sterilizers)</td>
</tr>
<tr>
<td>TVC</td>
<td>Total viable count</td>
</tr>
<tr>
<td>WD</td>
<td>washer-disinfector</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organisation</td>
</tr>
</tbody>
</table>
Appendix III: Useful addresses

UK health agencies

NHS Estates,
1 Trevelyan Square, Boar Lane,
Leeds LS1 6AE
Tel 01132 547000

Medical Devices Agency (MDA)
Hannibal House, Elephant and Castle,
London, SE1 6TQ
Tel 0171 972 8000

Medicines Control Agency (MCA)
Market Towers,
1 Nine Elms Lane,
London SW8 5NQ
Tel 0171 273 3000

NHS in Scotland Management Executive,
St Andrews House,
Edinburgh EH1 3DG
Tel 0131 556 8400

NHS in Scotland
Healthcare Engineering and Environment Unit,
University of Strathclyde, Graham Hills Building,
50 George Street Glasgow G1 1QE
Tel 0141 548 3446

Scottish Healthcare Supplies,
Trinity Park House, South Trinity Road,
Edinburgh, EH4 2RQ
Tel 0131 552 6255

Welsh Office,
Cathays Park, Cardiff CF1 3NQ
Tel 01222 825111

Estate Policy, Health Estates,
Stoney Road, Dundonald,
Belfast BT16 0US
Tel 01232 520025
Fax 01232 523900

Health and Safety
Health and Safety Executive,
Broad Lane,
Sheffield S3 7HQ,
Tel. 0114-289 2345

Note. Addresses of HSE area offices may be found in the local telephone directory
Standards organisations

British Standards Institution
British Standards House,
389 Chiswick High Road,
London W4 4AL
Tel 0181 996 9000

European Committee for Standardisation
rue de Stassart 36,
B-1050 Brussels

Other organisations

Institute of Healthcare Engineering and Estates Management.
2 Abingdon House,
Cumberland Business Centre,
Northumberland Road,
Portsmouth PO5 1DS.
Tel. 01705 823186
References

**Acts and Regulations**


**European Union (EC) Directives**


**British Standards**

- **BS EN 55014: 1993 Limits and methods of measurement of radio disturbance characteristics of electrical motor-operated and thermal appliances for household and similar purposes, electronic tools and similar electric apparatus.**
- **BS 837: 1939 (withdrawn) Steel-cored copper conductors for overhead transmission purposes.**
- **BS 853: 1990 Specification for vessels for use in heating systems.**
- **BS 1427: 1993 Guide to field and on-site test methods for the analysis of waters.**
- **BS 1449 Steel plate, sheet and strip.**
- **BS 1704: 1985 (1992) Specification for solid-stem general purposes thermometers.**
- **BS 1780: 1985 (1992) Specification for bourdon tube pressure and vacuum gauges.**
- **BS 2588 Portable sanitary pans for use in healthcare establishments.**
- **BS 2745 Washer-disinfectors for medical purposes.**
- **BS 3693: 1992 Recommendations for design of scales and indexes on analogue indicating instruments.**
- **BS 3849 Conical connectors for anaesthetic and respiratory equipment.**
- **BS 4196 Sound power levels of noise sources.**
- **BS EN ISO 3746: 1996 Acoustics. Determination of sound power levels of noise sources using sound...**
pressure. Survey method using an enveloping measurement surface over a reflecting plane.


BS 5295 Environmental cleanliness in enclosed spaces.

BS 5404 Specification for plastics laboratory ware.


BS 5503 Vitreous china washdown WC pans with horizontal outlet.
   Part 3: 1990 Specification for WC pans with horizontal outlet for use with 7.5L maximum flush capacity cisterns.

BS 5728 Measurement of flow of cold potable water in closed circuits.


BS 6068 Water quality.
   Part 2 Physical, chemical and biochemical methods.


   Part 6 Sampling.

   Section 6.5: 1991 Guidance on sampling of drinking water and water used for food and beverage processing.

BS EN 25667 Water quality. Sampling.


BS EN ISO 5667 Water quality. Sampling.

BS EN ISO 5667-3: 1996 Guidance on the preservation and handling of samples.

BS 6149 Tracheostomy tubes.


BS 6667 Electromagnetic compatibility for industrial-process measurement and control equipment.


BS 1139 Metal scaffolding.
   Part 2 Couplers.


EN 50103: 1996 Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for the active (including active implantable) medical device industry.

BS EN ISO 9001: 1994 Quality systems. Model for quality assurance in design, development, production, installation and servicing.


BS EN 50081 Electromagnetic compatibility. Generic emission standard.

EN 58001-1: 1992 Residential, commercial and light industry.


EN 50082 Electromagnetic compatibility. Generic immunity standard.

EN 58002-1: 1992 Residential, commercial and light industry.

EN 58002-2: (Draft) Industrial environment.

EN 61010: Safety requirements for electrical equipment for measurement, control and laboratory use.

EN 61010-1: 1993 General requirements.

EN 61010-2-045 (Draft) Particular requirements for washer disinfectors and other equipment incorporating washing equipment for the treatment of medical materials and for laboratory processes.


BS EN 26461 Water quality. Detection and enumeration of the spores of sulfice-reducing anaerobes (Clostridia).


IEC 751/BS EN 60751: 1996 Industrial platinum resistance thermometer sensors.


Part 1 Specifications.


EN (Draft)Washer-disinfectors.

Part 1: 1997 (Draft) General requirements and tests.

Part 2: 1997 (Draft) Requirements and tests before washer-disinfectors for surgical instruments and trays, anaesthetic equipment, hailer and glassware.


Part 4: 1997 (Provisional) Requirements and tests washer-disinfectors for thermolabile reusable instruments including endoscope.

NHS Estates publications


Concode


Health Building Note (HBNs)


Health Technical Memoranda (HTMs)


Firecode

Health Technical Memoranda (HTMs)


Scottish Office publications

Scottish Hospital Planning Notes (SHPNs)


Firecode


Department of Health publications

Sterilization, disinfection and cleaning of medical equipment, guidance on decontamination from the Microbiology Advisory Committee to the Department of Health Medical Devices Directorate. Microbiology Advisory Committee, Department of Health, 1993.


Health and Safety Executive publications


Miscellaneous publications


About NHS Estates

NHS Estates is an Executive Agency of the Department of Health and is involved with all aspects of health estate management, development and maintenance. The Agency has a dynamic fund of knowledge which it has acquired during over 30 years of working in the field. Using this knowledge NHS Estates has developed products which are unique in range and depth. These are described below. NHS Estates also makes its experience available to the field through its consultancy services.

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1 Trevelyan Square, Boar Lane, Leeds LS1 6AE.
Telephone 0113 254 7000.
http://www.nhsestates.gov.uk

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**Design Guides** – complementary to Health Building Notes, Design Guides provide advice for planners and designers about subjects not appropriate to the Health Building Notes series. **SO**

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**Concode** – outlines proven methods of selecting contracts and commissioning consultants. Reflects official policy on contract procedures. **SO**

**Works Information Management System** – a computerised information system for estate management tasks, enabling tangible assets to be put into the context of servicing requirements. **NHS Estates**

**Health Building Notes** – advice for project teams procuring new buildings and adapting or extending existing buildings. **SO**

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**Health Facilities Notes** – debate current and topical issues of concern across all areas of healthcare provision. **SO**

**Encode** – shows how to plan and implement a policy of energy efficiency in a building. **SO**

**Firecode** – for policy, technical guidance and specialist aspects of fire precautions. **SO**

**Capital Investment Manual Database** – software support for managing the capital programme. Compatible with Capital Investment Manual. **NHS Estates**

**Model Engineering Specifications** – comprehensive advice used in briefing consultants, contractors and suppliers of healthcare engineering services to meet Departmental policy and best practice guidance. **NHS Estates**

**Quarterly Briefing** – gives a regular overview on the construction industry and an outlook on how this may affect building projects in the health sector, in particular the impact on business prices. Also provides information on new and revised cost allowances for health buildings. Published four times a year; available on subscription direct from NHS Estates. **NHS Estates**

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