Scottish Health Technical Memorandum 2030

(Part 1 of 3)

Design considerations

Washer-disinfectors

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Executive summary

SHTM 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 SHTM 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.

Detailed information on the planning and design of a sterile services department, including the provision of WDs, is given in Scottish Hospital Planning Note 13; *Sterile Services Department* and Health Building Note 13 Supplement 1 *'Ethylene oxide sterilization'* section. Guidance for Laboratory installations can be found in Scottish Hospital Planning Note 15; *Accommodation for pathology services*.

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

NOTE: The term washer-disinfector is abbreviated to WD throughout this publication.

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 SHTM has been aligned with existing or anticipated Standards and advice is offered when no Standard has yet been formulated.

The WDs described in this SHTM 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 HTM 2030 ‘Management policy’ has been incorporated into SHTM 2030 ‘Operational management’. HTM 2030 is superseded.

Contents

1. General

Introduction

1.1 This part of SHTM 2030 covers the specification, purchase and installation 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 SHTM 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 part of SHTM 2030.

1.3 Full references for all the documents referred to in this volume and for selected documents providing additional information of which the reader should be aware are listed at the end of this part.

Purpose of washer-disinfectors

1.4 WDs are used to decontaminate items intended for re-use. They may be used in relation to both medical devices and medicinal products as well as other items. For example, 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.

1.5 The decontamination process is intended to:

a. make the item safe for staff to handle;

b. make the item safe for use on a patient (after any necessary additional processing) – including when relevant ensuring freedom from contamination that could lead to an erroneous diagnosis.

1.6 WDs 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.

1.7 When items being decontaminated by a WD are intended to be used again without further treatment (such as a terminal sterilization process) before being re-used, the disinfection process in the WD must produce an item which is microbiologically safe for its intended use.

1.8 When the items being decontaminated by a WD are intended to be subjected to further processing (such as a terminal sterilization process) before being re-used, the disinfection stage must produce an item which is microbiologically safe to be handled during preparation for subsequent processing.

1.9 The decontamination process involves two distinct stages: cleaning and microbial inactivation (disinfection). WDs are used to decontaminate items intended for re-use by subjecting the items to an automated process of cleaning and disinfection.

1.10 The efficacy of the cleaning stage of the process is of crucial importance to the successful outcome of the disinfection stage. This is especially relevant in the circumstances when a liquid chemical disinfection or sterilization process has to be used.

Legal framework for washing and disinfection

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

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

1.13 WDs 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

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

1.15 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’.

1.16 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.

1.17 Guidance on the application of medicines legislation to particular cases is beyond the scope of this SHTM and advice should be sought from the Medicines Control Agency (MCA) when necessary.

Medical devices

1.18 SHTM 2030 Part 2, 'Operational management' refers to the three EU Directives on the manufacture and supply of medical devices and in-vitro diagnostics.

1.19 Whether, and if so in what circumstances, the Medical Devices Directive (93/42/EEC) 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 SHTM. Guidance is given in the Medical Devices Agency (MDA) Directives Bulletin 18. If necessary further advice should be sought from the MDA.

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

a. 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);

b. that devices must be designed, manufactured and packed in such a way as to minimise the risk posed by contaminants and residues, to persons involved in the transport, storage and use of the devices and to patients (annex I, paragraph 7.2).

1.21 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 (BS EN 724 and BS EN 50103).

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

Published Standards

1.23 British Standard 2745: 1993 specifies requirements for WDs for medical purposes. The standard is in three parts: Part 1: 'Specification for general requirements'; Part 2: 'Specification for human-waste container washer disinfectors'; and Part 3: 'Specification for washer-disinfectors except those used for processing human-waste containers and laundry'.

1.24 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 thermo-labile medical devices (for example endoscopes)'.

1.25 IEC Technical Committee TC66 is developing Standards for 'Safety requirements for washer-disinfectors'.

1.26 When published, compliance with these Standards may be used to give a presumption of conformance to the relevant requirements of the Medical Devices Directive.

1.27 This edition of SHTM 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 SHTM 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.

1.27 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.

Washer-disinfectors as medical devices

1.28 The Medical Devices Directive (93/42/EEC) Annex IX, Classification Criteria, Rule 15 classifies as medical devices "all devices intended specifically to be used for disinfecting medical devices" and places them in Class IIa for conformity assessment purposes. It specifically excludes products that are intended to clean medical devices, other than contact lenses, by means of physical action.

1.29 WDs for cleaning and disinfecting medical devices are thus covered by the medical devices legislation and those supplied on or after 14 June 1998 will have to bear the CE marking in accordance with the provisions of the Medical Devices Directive.

This will apply to many of the WDs described in this SHTM.

1.30 Detailed guidance on the application of medical devices legislation to particular cases is beyond the scope of this SHTM and advice should be sought from the Medical Devices Agency.

Key Personnel

1.31 The following personnel are referred to in this part of SHTM 2030.

Management

1.32 Management is defined as the owner, occupier employer, general manager, chief executive or other person who is ultimately accountable for the operation of the premises.

1.33 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.

User

1.34 The user is defined as the person designated by management to be responsible for the management of a WD.

1.35 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/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.

1.36 The principle responsibilities of the user are as follows:

a. to certify that the WD is fit for use;

b. to hold all documentation relating to the WD;

c. to ensure that the WD is subject to periodic testing and maintenance;

d. to appoint operators where required and ensure that they are adequately trained;

e. to maintain production records.

Competent Person (Pressure vessels)

1.37 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 Safety Regulations 2000’. The shorter term “competent person” is used in this SHTM.

1.38 The following guidance on the qualifications for the competent person is based on the HSC Approved Code of Practice, Safety of Pressure Systems:

a. where required to draw up or certify schemes of examination, the competent person should be qualified at least to technician engineer level, with adequate relevant experience and knowledge of the law, codes of practice, examination and inspection techniques and understanding of the effects of operation of the pressure vessel concerned. He or she must have established access to basic design and plant operation advice, materials engineering and non-destructive testing (NDT) facilities. The competent person must have sufficient organisation to ensure a reasonable data storage and retrieval system with ready access to relevant laws, technical standards and codes;

b. where required to carry out examinations, the competent person should have sufficient practical and theoretical knowledge and actual experience of the type of pressure vessel which is to be examined to enable defects or weaknesses to be detected and their importance in relation to the integrity and safety of the WD to be assessed.

1.33 The principle duties of the competent person under the Regulations are as follows (they need not all be exercised by the same individual):

a. advising on the scope of the written scheme of examination;

b. drawing up the written scheme of examination or certifying the scheme as being suitable;

c. carrying out examinations in accordance with the written scheme, assessing the results and reviewing the written scheme for its suitability.

1.34 Most insurance companies maintain a technical division able to advise on appointing a competent person. Advice may also be obtained from Scottish Healthcare Supplies, Trinity Park House, Edinburgh.

Test Person (Washer-disinfectors)

1.39 The test person (washer-disinfectors) is defined as a person designated by management to carry out validation of washer-disinfectors and to provide advice on testing, maintenance and procedures. The shorter terms test person or TP are used in this SHTM. The test person should either:

a. be a Test Person (Sterilizers) (see SHTM 2010 for a definition of this role);

b. be qualified to at least HNC level in engineering or relevant sciences and have at least two years experience in the validation of washer-disinfector processes; or

c. have at least five years experience in the testing of washer-disinfector processes.

1.40 The principle responsibilities of the TP are as follows:

a. to advise on programmes of periodic testing and periodic maintenance of WDs;

b. to advise on operational procedures for routine production;

c. to conduct the validation test specified in SHTM 2030 Part 3, 'Validation and verification' and to prepare the validation report;

d. to conduct the periodic tests specified in SHTM 2030 Part 3, 'Validation and verification' and to prepare reports as required by the user;

e. to conduct any additional tests at the request of the user.

Maintenance Person (Washer-disinfectors)

1.41 The Maintenance Person (washer-disinfectors) is defined as a person designated by management to carry out maintenance duties on washer-disinfectors. The shorter terms maintenance person or MP are used in this SHTM.

1.42 The Maintenance Person should be a fitter or electrician with documentary evidence to demonstrate competence in the maintenance of one or more types of washer-disinfector. He or she should be in a position to deal with any breakdown in an emergency and have the ability to diagnose faults and carry out repairs or to arrange for repairs to be carried out by others.

1.43 The principle responsibilities of the Maintenance Person are as follows:

a. to carry out the maintenance tasks outlined in SHTM 2030 Part 2, 'Operational management';

b. to carry out additional maintenance and repair work at the request of the user.

1.44 A Maintenance Person who has a minimum of 5 years experience in the maintenance of washer-disinfectors may, by agreement, perform the duties of the Test Person for the daily, weekly and quarterly tests described in SHTM 2030 Part 3, 'Validation and verification'.

Microbiologist

1.45 The microbiologist is defined as a person designated by management to be responsible for advising the user on microbiological aspects of disinfection.

1.46 The microbiologist should have a degree in microbiology and will normally be a member of the hospital staff.

1.47 The principle responsibilities of the microbiologist are as follows:

a. to provide general and impartial advice on all matters concerned with washing and disinfection;

b. to advise the user on the microbiological aspects of all disinfection procedures;

c. to arrange for the culturing of biological indicators used in microbiological tests;

d. to audit the documentation from all washer-disinfectors which have been tested by microbiological methods.

Control of Infection Officer

1.48 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.

Production Manager

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

Quality Controller

1.50 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.

Laboratory Safety Officer

1.51 The Laboratory Safety Officer is defined as a person designated by management to be responsible for all aspects of laboratory safety in respect of equipment, maintenance, personnel and training relating to safety issues, and to ensure compliance with safety legislation and guidelines.

Operator

1.52 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.

Manufacturer

1.53 The manufacturer is defined as a person or organisation responsible for the manufacture of a WD.

Contractor

1.54 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.

Purchaser

1.55 The purchaser is defined as the person or organisation who orders the WD and is responsible for paying for it.

Authorised Person (Sterilizers)

1.56 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 SHTM 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). AP(S) are also able to provide independent auditing and advice on washing/disinfection and WDs and to review and witness validation of these processes and machines.

Independent Advisor

1.57 The Independent Advisor is defined as a person who may or may not be registered as an AP(sterilizers), but can demonstrate to the satisfaction of management previous training and experience appropriate to carry out the designated tasks in respect of WDs as the AP(S) would carry out in respect of sterilizers. AP(S) is a suitable person to carry out the functions of an Independent Advisor.

Water supply

1.58 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 for such byelaws. WDs must be designed, constructed, installed, operated and maintained in accordance with the requirements of the relevant byelaws.

Safety

1.59 Guidance on the safe operation of the various types of WD is given in SHTM 2030 Part 2; ‘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

1.60 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.

1.61 The 'Control of Substances Hazardous to Health (COSHH) Regulations 1999' 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.

1.62 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 and to carry out regular Occupational Health review of "at risk" staff..

1.63 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 SHTM 2025.

Infectious materials

1.64 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. Procurement of a washer-disinfector – an overview

Introduction

2.1 This chapter gives a short synopsis of the steps involved in purchasing a WD. More detailed information, including information relevant to specific types of WDs, is given in subsequent chapters.

Purchasing a washer-disinfector

2.2 The first step is to form a consultative group which could consist of User, Control of Infection Officer, Maintenance Person and Independent Adviser.

2.3 The purchase of a WD can be broken down into a stepwise sequence of decisions. These are summarised in the following paragraphs (see also Table 1).

What type of load is to be processed?

2.4 A knowledge of the load(s) which will be processed by the WD is an essential pre-requisite in making the correct decision about which WD to purchase; the difficulty in obtaining a clean product, the standard of cleanliness and the disinfection required vary for different product types. For example, some products with intricate interstices or long narrow lumens require specific provision if they are to be cleaned satisfactorily.

Purchasers should be aware of the need to specify all the items requiring processing to allow the tenderer to offer the most appropriate machine and accessories.

What suitable washing-disinfection processes are available?

2.5 In this SHTM, WDs are classified by:

a. the product range which they are intended to process;

b. their configuration and load handling type;

c. the nature of the cleaning and disinfection process.

Eight product-specific categories are recognised but, in many cases, WDs are available in which a single machine is designed to process two or more of these product categories. Guidance on the selection of a WD is given in Chapter 3.

What models are available?

2.6 Once the type of WD which will be required has been agreed sales literature and product data sheets should be sought from a number of manufacturers. The development of EU Standards on WDs should widen the choice open to purchasers. Guidance on the information which should be sought is given in Chapter 4.

Where will the washer-disinfector be sited?

2.7 The location available for the WD will have a significant influence on the type of machine which can be used. Many of the larger continuous process machines require considerable space. Guidance on siting is given in Chapter 5.

What services are available?

2.8 A WD will require one or more of the following services: electricity, water, steam, compressed air, drainage, ventilation and chemical additive (detergent, rinse aid etc.) supply. The manufacturer's product data sheets will show which services are required for each model. Determine which of these are available at the proposed site and the capacities of each service. It may be necessary to plan for a new service which would add significantly to the cost of the installation. Further information about services is to be found in Chapter 6. Water supply is crucial and is discussed in detail in Chapter 7.

Who will operate the equipment?

2.9 If the equipment is to be sited in a general area, eg. a ward sluice room, intended for use by a wide range of ancillary and nursing staff the machine should be simple to operate and as foolproof as possible.

Conversely, a machine which will be located in a centralised processing unit under the care of specially trained staff – whose sole or principle activity will be the operation of the WD – may be a more complex machine offering a number of different operational cycles and loading systems to optimise the washing and disinfection of diverse products.

What capacity is required?

2.10 Establish the likely daily and weekly work load, and the peak hourly work load, that the WD will have to process. Calculate the number of WDs required to process the workload. Throughput figures for different manufacturer's machines and different models within any given range vary considerably. For continuous process machines a distinction must be made between the time required to process one load and the total number of loads which may be processed in a period of one hour. Further guidance is given in Chapter 3.

What ancillary equipment is required?

2.11 A WD may require ancillary equipment such as water softeners, de-ionisation or reverse osmosis (RO) water treatment plant, steam generators, air compressors, extract ventilation (with or without condensers), bulk storage and dispensing facilities for process chemicals.

2.12 In addition some WDs will require load staging facilities, before and after processing, purpose-built load carriers for different categories of product and means for returning load carriers from the unloading side of the WD back to the loading side.

What Standards or published specifications are relevant?

2.13 Most WDs for clinical applications (see Chapter 3) should have been constructed to British and EU Standards. In some cases, eg. for endoscopes, there are no published British or European Standards and additional specifications will be required. Advice on preparing a detailed specification for the WD is given in Chapter 4.

What sort of contract?

2.14 Once the specification has been completed a contract should be drawn up for the supply and installation of the WD. Chapter 4 gives guidance on suitable forms of contract.

Which manufacturer?

2.15 Two or more manufacturers should be invited to tender for the supply of the WD. While no manufacturer should be excluded unnecessarily from the tendering process they should not be invited to tender unless there is a realistic prospect of their being awarded the contract. Guidance on tendering is given in Chapter 4.

What installation and commissioning arrangements?

2.16 Chapter 4 contains advice on the documentation that the manufacturer should provide with the WD. After delivery and installation, the WD should be subjected to a formal documented programme of installation, commissioning checks and validation testing. This is discussed in detail in SHTM 2030, Part 3 ‘Validation and verification’.

What arrangements for service and repair?

2.17 It is common practice for the initial purchase contract to include all service and repair costs for the first year after installation, ie. during the warranty period. A number of manufacturers also offer an “extended warranty” facility which, for an additional fee, provides an all-inclusive service and repair option.

What are the likely running costs?

2.18 Advice should be sought at the time of tender on the operational costs of the various machines which would be suitable. The operational costs should include the anticipated requirements for services (water, electricity, steam etc.), consumable items (detergents, rinse aids etc.) and maintenance. This data should be used in the evaluation of the tender bids.

3. Choice of washer-disinfector

Introduction

3.1 This chapter contains information relevant to the choice of a new WD. It discusses the different types of WD and the way in which they are classified in this SHTM. It summarises the loads for which each type is suitable and gives guidance on choosing the size and number of WDs required for a given application.

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

3.2 This SHTM groups WDs into two broad categories according to their intended use, ie. the nature of the load which they are intended to process:

a. clinical WDs are designed to process medical devices which may be intended for use without further processing or may be subjected to a terminal sterilization process before further use.

b. laboratory WDs are designed to process equipment for use in the manufacture of medical devices and medicinal products, or to process laboratory goods that are neither medical devices nor medicinal products and are not intended for use in the clinical care of patients.

3.3 WDs can be further classified both by their configuration/load handling system and by the nature of the operational process.

Clinical washer-disinfectors

Human waste containers

3.4 These are intended for use in emptying, cleaning and disinfecting bed pans, urinals, suction bottles and similar containers, and for the rigid supports used to hold disposable bedpans.

3.5 They may have a large volume or mass of material to be removed (faeces, urine, blood, serum, mucous) and many of these materials have a high biomass of potentially infective organisms.

3.6 The processed product will usually be used without further treatment.

Surgical instruments and associated products

3.7 These are intended for processing a wide range of products used in clinical practice. WDs may be dedicated for use with one particular category of products or may be intended for use with a range of products, often by the use of dedicated load carriers for each product type.

Surgical instruments

3.8 This includes the whole range of surgical instruments but some particular instruments, such as those with long narrow lumens or intricate interstices, may require disassembly and/or specific adapters if they are to be cleaned effectively.

Anaesthetic accessories

3.9 This includes tubing, face masks and re-breathing bags for both anaesthetic use and for respiratory therapy and diagnosis.

Bowls and utensils (hollowware)

3.10 This includes instrument trays and containers, receivers, gallipots, specula etc.

Endoscopes

3.11 Endoscopes may be considered in two categories based on the method of construction of the endoscope. This will often determine which of the available washing-disinfection processes is suitable. However, in all cases, users should seek advice from the manufacturer of the endoscope on the most suitable method of decontamination.

3.12 Rigid endoscopes and their accessories may often be processed through conventional WDs used for surgical instruments – provided the WD is fitted with appropriate load carriers which direct water and wash solutions through the lumen(s).

3.13 Flexible endoscopes are often unsuitable for processing through a conventional WD – parts of the endoscope may not withstand immersion and valved channels may not be accessible unless the valve is open during the cleaning process. In addition, most flexible endoscopes will not withstand the elevated temperatures used during thermal disinfection and drying in a conventional WD.

3.14 Dedicated WDs are available which are intended specifically for processing endoscopes. These may incorporate a chemical disinfection or sterilization stage or may require that, after processing in the WD, the endoscope is terminally sterilized using a suitable low temperature sterilization process.

Dishwashers

3.15 Dishwashers in general are not covered by this SHTM. However there is an occasional need for the crockery and cutlery used by immunologically compromised patients to be disinfected to a higher standard than is found in standard commercial or domestic dishwashers. Consideration should be given to using a terminal steam sterilization process for items processed through a standard dishwasher or to specifying a dishwasher with a thermal disinfection process as shown in Table 2.

3.16 In the latter case the WD should be fitted with a temperature indicating instrument to show the temperature attained during the disinfection stage.

Laboratory washer-disinfectors

Laboratory equipment

3.17 Laboratory washers are available to process a range of laboratory items. These items may include bottles and vials – either new or after previous use – intended for containing reagents, culture media, etc. and other laboratory equipment, predominantly glassware. Most do not include a disinfection stage except when the WD has been designed for a particular application, eg. animal cage washing and disinfection.

Pharmaceutical equipment

3.18 Laboratory washers specifically intended for processing equipment and containers for use in the manufacture of pharmaceutical or in-vitro diagnostic products may be configured for a single product or family of products, eg. vials, or may be required to process a range of items.

3.19 The process specification may include high requirements for cleaning efficacy and levels of process residuals. This may incorporate a disinfection stage for items to be used without further treatment in the preparation of a non-sterile product.

Classification of washer-disinfectors by configuration/load handling type:

3.20 WDs can also be classified by the construction of the WD and the manner in which the load is processed through the machine.

Cabinet (single chamber) machines (Type 1)

Installed machines

3.21 Type 1 machines have a single chamber in which the full range of process stages are carried out. Type 1 machines may have more than one chamber but the full range of process stages are carried out in each chamber. They are batch process machines in which all stages of the cycle are completed on one chamber load before another load can be processed in that chamber.

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

"Table top" machines

3.23 These are a particular category of Type 1 machines which have only a single door and are distinguished by their small size – having a chamber which will not accommodate two standard sterilization modules (SSMs) each of 600 mm x 300 mm x 300 mm dimensions – and by their limited requirements for connected services. These machines can be operated by connecting to a single phase outlet (normally drawing 20 Amps or less at 230 V), a potable water supply and discharging into a domestic drain or sink.

NOTE: They may be intended to be floor standing or may be placed on a work surface to provide a convenient loading height.

Continuous process machines (Type 2)

Sequential chamber machines

3.24 These all have double doors, ie. a loading door at one end of the machine and an unloading door at the other end of the machine, and also have doors or some other means of segregation between adjacent chambers.

3.25 Sequential chamber machines have two or more chambers through which the load is moved in sequence. Each chamber is employed for one, or more, different stages in the process. Two or more loads may be processed simultaneously, with the loads at different stages in the cycle at any one time. Adjacent chambers are separated by an intervening door.

Conveyor machines

3.26 These may be equipped with double doors, air-flow baffles at each end, or a door at one end and an air-flow baffle at the other.

3.27 Conveyor machines have a continuously, or intermittently, moving load carrier which progresses the load through a series of tanks, chambers or zones – in each of which one stage of the process takes place. Two or more loads may be processed simultaneously, with the loads at different stages in

the cycle at any one time. The separation between adjacent stages may be spatial only or there may be baffles (eg. strip curtains) interposed.

Classification of washer-disinfectors by the nature of the process

3.28 WDs can be further classified by the nature of the process employed in each of the three principle processing stages: cleaning, disinfection and drying. A limited range of WDs also provide a chemical sterilization facility.

Cleaning

Flushing machines

3.29 Cleaning is achieved by flushing with water; no detergents are employed.

Washing machines

3.30 Water and detergents are used to clean the product. Detergents act both as wetting agents – in which the reduction of surface tension allows contact with all surfaces – and also as a solvent and/or dispersant of soil. Enzymatic detergent systems are intended to work by converting insoluble soil into a water-soluble form.

3.31 The mass of water and the force with which the water comes into contact with the surface to be cleaned plays a significant part in the soil removal process.

Ultrasonic machines

3.32 Ultrasound energy is used to effect the mechanical removal of soil from the surface of the product.

Solvent cleaning machines

3.33 These machines use cleaning processes which employ specific solvents in which the particular soils to be removed are soluble. An example of this type of process is the de-greasing systems which employ organic solvents to remove mineral oils. These processes are not commonly used in reprocessing healthcare products and are not covered by this SHTM.

Disinfection

Thermal disinfection

3.35 In this process disinfection is achieved by the action of moist heat maintained on the surface to be disinfected at a particular temperature for a particular time (see Table 2) or some other time-temperature relationship of demonstrated equivalence.

Chemical disinfection

3.36 Disinfection is achieved by the action of a solution of a microbicidal chemical maintained on the surface to be disinfected at a particular concentration for a particular time at, or above, a specified temperature.

3.37 The removal of the chemical disinfectant after the disinfection stage is of importance also and must be achieved without compromising the microbial quality of the product.

Drying

3.38 Drying may be an integral part of the cycle, usually by the circulation of hot air over the product, or may be provided as a separate drying cabinet. Some products, eg. corrugated anaesthetic tubing, require prolonged drying times and a separate drying cabinet can improve the productivity of the WD.

3.39 Solvent drying systems have also been used but their relevance is limited to specific applications.

3.40 A dry product can also be obtained by the flash evaporation of residual moisture from product items which are hot following a high temperature thermal disinfection stage. This method is often employed in low cost machines, eg. bed pan washers.

Liquid chemical sterilization

3.41 Sterilization by means of solutions of microbicidal chemicals is also employed for a limited range of products which, although required to be sterile for their intended use, cannot be sterilized through conventional terminal sterilization processes (see SHTM 2010; *Sterilization*).

3.42 Key factors in determining the efficacy of the process include:

a. the concentration of the chemical sterilant;

b. the temperature at which it is used;

c. the contact time with the product;

d. the absence of inhibitory materials, such as residual soiling.

3.43 The removal of the chemical sterilant after the sterilization stage is of importance and must be achieved without compromising the microbial quality of the product. The control of the microbial quality of the rinse water is critical in this respect.

3.44 The sterile product obtained from a liquid chemical sterilization process is not usually packaged for transport and may not have been dried. Under these circumstances the product is only suitable for immediate use and the machine must be installed close to the point of use. Prolonged storage (eg. for more than two or three hours) may permit contamination to occur followed by the growth of a large microbial population. The storage conditions are also important determinants of contamination.

NOTE: The microbicidal chemicals used for disinfection and sterilization are usually toxic and may also be sensitisers in low concentrations. Many have defined exposure limits (see HSE guidance on occupational exposure). Control of environmental emissions and personnel exposure are important considerations in the design and operation of the processing equipment and in the siting of such equipment. Specific ventilation provision may be required.

When is a washer-disinfector required?

3.45 For many products used in healthcare practice there are two choices available:

a. products which are intended to be re-used after they have been decontaminated and subjected to any necessary reprocessing (eg. terminal sterilization);

b. single-use products – ie. those which are intended to be discarded after use.

3.46 Products which are intended to be re-used may be decontaminated, in accordance with the manufacturer's instructions, by:

a. manual cleaning followed by disinfection and/or sterilization;

b. machine cleaning followed by disinfection and/or sterilization;

c. automated machine decontamination incorporating cleaning and disinfection (or more rarely sterilization).

For further guidance, see Device Bulletin 9501 'The re-use of medical devices supplied for single-use only' published by the Medical Devices Agency.

NOTE: The decontamination and subsequent re-use of items intended for single-use requires extensive technical investigation to establish the compatibility of the process and that the performance of the item has not been impaired. To undertake such studies is beyond the competence and expertise of hospital departments and routine laboratories and is rarely justified on economic terms. There are also serious legal implications for both management and user.

3.47 When both re-usable and single-use devices are available a choice may need to be made based on several considerations including: clinical acceptability; economics; local constraints, such as the storage space needed for single-use items or engineering services (electricity, water, drainage) required for a WD processing re-usable devices.

This situation is most relevant in the disposal of human excreta from bed-dependent patients and is discussed in more detail in Chapter 9.

Choice of washer-disinfector

3.48 The choice of WD will be governed by the nature of the loads required to be cleaned and disinfected. Detailed guidance on appropriate processes for different load items can be found in a number of documents: 'Sterilization, disinfection and cleaning of medical equipment: Part 1 Principles' published by the Medical Devices Agency; 'Sterilization and disinfection of thermo-heat labile equipment'; 'Bed pan washers' published by the Central Sterilising Club; and in SHTM 2030 Part 2, 'Operational management'.

3.49 Purchasers should be aware that items suitable for a particular type of WD may still require different operating cycles, which need to be specified before purchase.

Guidance on the modification of operating cycles to suit different loads is given in SHTM 2030, Part 2 'Operational management'.

More information about the different types of WD is given in Chapters 10 to 14.

Advice on individual cases should be sought, if necessary, from the AP(S) before any decision is made. When a chemical disinfection process is being considered the microbiologist should also be consulted.

3.50 Once the type of WD has been decided, preliminary enquiries should be made with a number of manufacturers to obtain specifications and price lists. Table 1 indicates some of the information that will be useful for planning purposes and which should be obtained at this stage.

Table 1: Information to be obtained before inviting tenders

Information required	Objectives
The standards to which the WD is designed and constructed and a statement of compliance.	To confirm that the WD meets recognised specifications for design, construction, safety and performance.
Installation data including the overall dimensions and the mass of the WD (fully loaded, the number of supports), floor loading at each. The clearance space required for installation access. The mass of the principle components. Access space required for maintenance. Doors and necessary space for movement of the doors.	To enable the user to establish whether the proposed location is suitable for the WD and the extent of any site improvement work required (see chapter 5).
The usable chamber space expressed as volume, the principle internal dimensions, and the number of standard load carriers or load items which can be accommodated.	To enable the user to determine the capacity of the WD for the load which it is intended.
Specifications for each of the engineering services required by the WD.	To enable the user to establish that the required quality and quantity of each utility required is present or can be provided, and to assess operational costs.
The mean and peak sound power levels generated by the WD (see BS 2745: Part1).	To enable the contractor to confirm that the sound power level after installation will not exceed that specified for the location (see Chapter 5).
A description of the operating cycle including overall cycle time(s) for classes of goods to be processed, length of individual stages: cleaning, disinfection, drying.	To enable the user to determine the throughput of the WD and hence calculate the number of WDs required for the anticipated workload.
The maximum temperature which may be attained during each stage, the range within which cycle variables can be adjusted, the nature and quality of chemical additives required.	To enable the user to assess their compatibility with the load.

Cycle variables

3.51 For the purposes of this SHTM the following definitions have been adopted.

3.52 The **Cycle Variables** are the physical factors – such as time, temperature, water volume, flow rate, pressure, detergent concentration – that influence the efficacy of the cleaning and disinfection processes.

3.53 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** (see Table 2).

3.54 The **Disinfection Conditions** are the range of conditions that may prevail throughout the chamber and load during the holding time.

3.55 The holding time may be preceded by a period in which the disinfection conditions are present in the chamber but not yet present on all surfaces of the load which are to be disinfected. This period is the **Equilibration Time**.

3.56 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 the disinfection temperature is also being recorded or measured.

3.57 For thermal (moist heat) disinfection the disinfection conditions are specified by a **Disinfection Temperature Band**, defined by a minimum acceptable temperature, known as the **Disinfection Temperature**, and a maximum allowable temperature.

3.58 The higher the disinfection temperature the shorter the holding time which will be required to achieve the same level of disinfection.

3.59 For liquid chemical disinfection/sterilization processes the plateau period is equivalent to the **Disinfectant/Sterilant Exposure Time**. The holding time can only be determined by thermometry when the chemical agent is supplied at an elevated temperature to a load which was not pre-heated to the required temperature.

3.60 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.

Table 2: Thermal disinfection temperature bands

Disinfection[a] temperature (°C)	Minimum exposure time (minutes)	Maximum allowable temperature (°C)
65	10	70
73	3	78
80	1	85
90	0.2[b]	95
93[c]	10	98

Notes.

a. The disinfection temperature is measured at the surface to be disinfected.

b. The exposure time of 1 second (as specified in BS 2745 Part1) 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.

3.61 The dispensed volume of the chemical additives (eg. detergents), including the accuracy and reproducibility of the dosing system(s), should be specified.

3.62 For WDs employing jet washing systems, the pump pressure and water flow are also critical variables.

3.63 For ultrasonic cleaners, the frequency, amplitude and power density (Watts/litre of usable chamber space) are critical variables.

3.64 In all cases, the duration of each process stage must be determined with sufficient accuracy to ensure that consecutive cycles have the same efficacy.

Sizes and numbers

3.65 Precise information on the sizes and numbers of WDs required for particular applications is difficult to give since there are considerable variations in patterns of use. The number of WDs required will depend on the cycle time and the loading capacity of the machine and in some circumstances on the flexibility of operation that may be required, eg. whether items to be processed can wait until there is a full load for the WD or need to be processed immediately. Within the clinical applications for WDs, the size and number will also depend on the configuration and load handling type and the operational type. Guidance on calculating the size and number of WDs required for a particular application is given later.

3.66 The methods which may be used to estimate the size and number of WDs varies with the application for which the WD is to be purchased. A detailed description of two approaches is given for WDs intended to be used to process surgical instruments and associated products with brief complementary notes for WDs for other applications. The cycle times quoted by manufacturers of WDs will usually be based on the assumption that the water supply is no less than the mid-point of the specified range for an

acceptable supply. It should be noted that lower pressures may significantly extend cycle times.

Assessment of workload and throughput

3.67 A combination of different types of WD and cleaning processes will often be required to deal with the extensive range of instruments to be processed, eg. in an SSD. This needs to be taken into account in calculating the capacity (size and number) of WDs required.

3.68 The provision of separate drying facilities for items which are difficult to dry (eg. corrugated tubing for anaesthetic and respiratory use) can dramatically increase throughput by reducing overall cycle times.

3.69 Bowls and receivers occupy a large volume but are relatively easy to clean. For a large SSD, consideration needs to be given to using a relatively simple washer to process bowls and receivers rather than occupying space in a more sophisticated machine which is better utilised processing more complex instruments.

3.70 Two distinct methods of assessment should be considered:

a. aggregated workload and throughput capacity;

b. throughput time.

Aggregated workload and throughput capacity

3.71 For items in sufficiently plentiful supply, minimising the turn-round time (the time between receipt of the used item and its having been reprocessed and made available for further use) is not a priority. An assessment based on the weekly workload generated by users is appropriate.

Throughput capacity

3.72 Throughput capacity is affected by a number of variables.

These include:

a. The number of operational hours per week for the department in which the WD is located.

b. The machine utilisation factor expressed as a percentage of the number of operational hours. This will be influenced by several factors including:

   (i) delivery schedules from clinical areas;

   (ii) staff availability for loading and unloading (meal and comfort breaks may total one hour/day);

   (iii) start-up and shut-down time each day (approx. one hour/day);

   (iv) planned and breakdown maintenance time (approx four hours/week);

(v) routine, periodic and annual testing.

3.73 Precise estimations are difficult to make and may have limited value due to continually changing and developing clinical workloads. SHPN 13 recommends an assumed utilisation factor of 60% for most types of WDs and in practice this is reputed to be appropriate.

Throughput time

3.74 Throughput time may be the controlling factor:

a. for items, usually sophisticated and expensive devices such as endoscopes, where the shortest practicable turn-round time may be required in order to maintain an effective clinical service;

b. for items where anything more than a short delay in initiating processing would be unacceptable (eg. human-waste containers).

3.75 Throughput time is affected by three key factors:

a. cycle time;

b. machine capacity;

c. machine availability.

Sizing calculation

Cycle time

3.76 The processing time varies depending upon:

a. the number and the duration of the flushing and washing stages;

b. the disinfection time;

c. the drying time.

With modern microprocessor-based control systems, several cycle options may be programmed into the same machine.

NOTE: The cycle time may be adversely affected by inadequate services such as low water pressure and low water temperature.

3.77 Some WDs now include a load identification system which reads a label attached to a load carrier in order to identify the nature of the load. The machine then automatically switches to the required process cycle.

3.78 The cycle time may be determined from the WD manufacturer's specification either for the particular item to be processed or for the "worst case" load for which the cycle time will equal or exceed that required for the products to be processed.

Machine capacity

3.79 The machine capacity, specified by the manufacturer, will normally be stated in terms of the number of “baskets” or “trays” that can be accommodated in one load.

The EU standard on sterilizers BS EN 285 has standardised 600 mm x 300 mm x 300 mm as a single sterilization module. Rigid re-usable containers for use in sterilizers are also standardised to fit either singly, or in multiples, within the modular unit. Current proposals in the committee draft for the EU Standards on WDs have adopted this size as the basic module for WDs also. However, until these standards are finalised it will be necessary to determine the size of the baskets referred to by the manufacturer.

Aggregated workload for theatres

3.80 An approximate assessment of the workload can be determined from the total actual, or the expected, case load on a weekly basis.

3.81 Each case may be assumed to require the use of at least two baskets in the WD load carrier; one for the instruments and one for the Edinburgh tray, instrument orientation tray or re-usable container used to package the instrument set. Large instrument sets will often require additional baskets – eg. for orthopaedic, cardio-thoracic or large abdominal sets – and careful notes should be made of which specialities may be served by the installation.

3.82 Dedicated load carriers or separate provision (eg. ultrasonics) will be required for particular items eg. micro-surgical instruments, laparoscopes and their accessories.

Workload estimate

3.83 The workload should be estimated from historical records of operational activity or based on proposed work loads.

Theatre case load per week = C_S[1]

Number of acute beds = C_A

Average number of machine baskets:

– per theatre case = B_S[1]

– per acute bed/week = B_A[2]

Workload: W_{TOTAL} (= number of baskets to be processed/week)

$W_{TOTAL} = (C_S \times B_S) + (C_A \times B_A)$

1. It may be necessary to carry out this assessment on the sum of several subsets when there are a number of operating theatres with diverse instrument demands per case.
2. This assessment should be based on the total number of acute beds, including maternity and geriatric, but excluding mental health. If a factor of approximately 0.2 baskets per acute bed is assumed, this should be sufficient to allow for demands from other areas with lower volume requirements such as A&E, community, etc.

Throughput estimate

3.84 The following data are required to estimate the throughput

Machine baskets per load B_N

Machine cycle time (in hrs)[1] C_T

Number of operational cycles per week H

Machine utilisation (%)[2] A

1. If a number of different operating cycles are to be run with widely differing cycle times, it may be advisable to calculate the workload and throughput separately for each category of instruments/process cycle and sum the individual components. Alternatively, a weighted mean cycle time may be calculated from the proportion of each cycle that is expected to be required.
2. An assumption of 60% utilisation is appropriate in most cases (see also SHPN 13).

Then the throughput $T_{TOTAL} = \frac{B_N \times H \times A}{CT}$ baskets per week

Number of machines required

3.85 The number of machines required may be calculated as follows:

W_{TOTAL} : Workload as machine baskets per week

T_{TOTAL} : Throughput as machine baskets/week/machine

No. of machines required =

$$\frac{[W_{TOTAL}]}{[T_{TOTAL}]}$$

Worked example

If W_{TOTAL} = 1400 baskets/week

and T_{TOTAL} = 1600 baskets/week/machine

then no. of machines required =

$$\frac{[1400]}{[1600]}$$

= [0.875]

i.e. 1 machine

Clinical washer-disinfectors for surgical instruments and associated products

3.86 WDs for this application present the greatest diversity of operational, configuration and load handling types. They range from small table-top models suitable for use in general practice to large, fully automated continuous process models capable of processing the full range of surgical instruments, utensils, containers and anaesthetic accessories with high throughput rates.

3.87 WDs for small units where a single, low volume WD is adequate are considered under WDs for use in general practice.

3.88 Most WDs for surgical instruments and associated products, other than flexible endoscopes, are located in centralised units such as sterile service departments (SSDs).

Clinical washer-disinfectors for human-waste containers

3.89 These machines are equipped with load carriers built to accept standard numbers and/or patterns of specified containers including bedpans, urine bottles, suction bottles and bedpan carriers (for use with disposable bedpans), raised toilet seats, commode bowls, enema and emesis containers.

3.90 The workload will depend on the number of beds to be served, the bed-dependency of the patients in these beds and the nature of the medical or surgical speciality – for example an orthopaedic ward may be expected to have a high level of bed-dependency.

3.91 Human-waste containers need to be processed as soon as possible after use if they are not to become offensive or a potential infection hazard. The peak workload and the maximum throughput are factors that need to be considered. A high proportion of bed-dependent patients may be expected to use a bedpan in the hour following breakfast and the capacity of the WD should be sufficient to process this within an hour.

3.92 Two capacities of WD are widely available: one that will process one bed pan or two urine bottles per cycle; and one that will process two bed pans or four urine bottles. The latter affords more flexibility at times of peak demand.

Clinical washer-disinfectors for anaesthetic accessories

3.93 Many WDs for surgical instruments and associated products can be adapted to process anaesthetic accessories, eg. corrugated tubing, face masks, airways – usually by the provision of a dedicated, interchangeable load carrier.

There are also dedicated WDs intended solely, or principally, for processing anaesthetic accessories.

NOTE: Simple deluge washers (normally used for bowls and utensils) and ultrasonic washers cannot usually deal with anaesthetic accessories or other tubing.

3.94 Current clinical practice makes frequent use of single-use items and/or protects patient connected circuitry from contamination by the use of filters. These have dramatically reduced the throughput of such items. In many SSDs only those items used in respiratory diagnosis, where filters cannot be used, are sent for reprocessing.

3.95 When the projected throughput is low the use of a WD for surgical instruments with a suitable load carrier is to be recommended. However, the drying stage will necessarily be greatly extended beyond that required for surgical instruments leading to a longer cycle time.

3.96 When a higher throughput is anticipated but where it is still not economical to provide a dedicated WD for anaesthetic accessories, consideration should be given to the provision of a separate drying cabinet.

3.97 Capacity should be assessed based on the number of items of each type that can be processed in a single load.

Clinical washer-disinfectors for endoscopes

3.98 Users are reminded that they should seek advice from the manufacturer of the endoscope as to the most suitable method of decontamination.

Rigid endoscopes

3.99 Many rigid endoscopes and most of the re-usable surgical accessories used for minimal access therapy (MAT) can withstand steam sterilization and may be processed through WDs employing a thermal disinfection stage to make them safe to handle during packing, etc.

3.100 It is essential that the WD is designed or adapted to ensure that during the flushing, cleaning and disinfecting stages water flows though the lumen(s) of the device.

3.101 Many cabinet WDs and continuous process WDs of the discrete chamber type can be equipped with dedicated load carriers to process rigid endoscopes, gas cannulae, etc. There are also a number of dedicated endoscope cleaners including ultrasonic cleaners.

3.102 The capacity of the WD should be assessed on the number of items of each type that can be processed in a single load.

Flexible endoscopes

3.103 Most fibre-optic endoscopes cannot be processed in conventional WDs used for surgical instruments. Fibre-optic endoscopes are unable to withstand the high pressures generated during the cleaning process or the high temperatures attained during the disinfection process. Dedicated endoscope WDs are available.

NOTE: Many fibre-optic endoscopes are stated by the manufacturer to be incompatible with ultrasonic cleaning.

3.104 In general, the re-usable accessories, biopsy forceps, etc. can be processed through a WD for surgical instruments.

3.105 For most fibre-optic endoscopes, the throughput time is the critical factor. Most endoscope WDs will only accept one endoscope per cycle. Those which will take two endoscopes or more may be of little benefit in reducing

throughput time unless each endoscope is accommodated in a separate chamber and cycles can be run independently.

3.106 The disinfection stage of WDs for fibre-optic endoscopes is also critical since there are few suitable terminal sterilization processes with sufficiently rapid cycle times.

Clinical washer-disinfectors for use in general practice

3.107 These are generally small machines, eg. “table-top” cabinet washers, intended for use in dental, medical or veterinary general practice, clinics, mortuaries, etc. where there is a low level demand for thorough cleaning and disinfection of surgical instruments and utensils such as bowls and receivers.

3.108 The maximum anticipated demand and required turn-round time will usually be readily identified by the user for comparison with the loading capacity and cycle times specified for the WD.

3.109 Purchasers should note the importance of the effect of low water supply pressure and, where a hot water supply is required, the effect of low feed water temperature on process cycle times.

Laboratory washer-disinfectors

3.110 Laboratory WDs, whether intended for use in a clinical laboratory or in the laboratory of a manufacturer of a medical device or medicinal product, are equipped with one or more load carriers specific to the nature of the items to be processed.

3.111 The number of each type of item that can be accommodated and the length of the operating cycle may then be used to estimate throughput by comparison with anticipated workload. This can be used to calculate the size and number of machines required.

4. Specification and contract

Introduction

4.1 This chapter discusses general specifications for WDs and the steps to be taken in inviting tenders and issuing a contract. The validation procedure which begins on installation of the WD is discussed in detail in SHTM 2030 Part 3, 'Validation and verification'.

Preparing a specification

4.2 Purchasers are strongly recommended to seek assistance from the Independent Advisor when preparing a specification for a WD.

4.3 Standards and other specification documents are continually being updated and purchasers should ensure that they consult the latest editions of such documents, including any amendments issued after publication, to keep abreast of changing requirements. Advice should be sought from the Independent Advisor on this.

4.4 Most WDs are constructed to British Standards or the standards of another European country, eg. the German Standards Authority (DIN). In some cases the Standards specification may not be adequate for WDs to be used in the public service. In these cases additional specifications are listed below for general design considerations and, where appropriate, under an additional specification heading in each chapter.

4.5 Details of the proposed location of the WD should be stated clearly in the specification sent to suppliers.

4.6 Purchasers should specify all of the items requiring to be processed through the WD to allow the tenderer to offer the most appropriate machine and accessories.

4.7 Except where the manufacturer is responsible for installation of the machine the type and standard of packing and delivery of the WD should be specified. When site conditions are likely to be poor and damage could occur a substantial dust proof transit case may be necessary.

General design considerations

4.8 The following design considerations are applicable to all or most types of WD, but are not necessarily required by the current standards. When applicable they should be included in the specification for any WD to be operated in the NHS.

4.9 All WDs and associated equipment are classed as “work equipment” and should comply with the ‘Provision and Use of Work Equipment Regulations 1998’. Purchasers are reminded that under the Regulations it is the responsibility of the employer, not the manufacturer, to provide a WD that is “suitable for the purpose that it is used or provided”.

4.10 All WDs made or sold in the UK from the 1 January 1996 should conform to the emission and immunity requirements of the ‘Electromagnetic Compatibility Regulations 1992 (as amended)’. This may be achieved by compliance with BS EN 50081 (Emission) and BS EN 50082 (Immunity). The manufacturer should be informed of any local sources of electrical magnetic disturbance which may effect the operation of the WD.

4.11 For maintenance purposes one or more panels of free standing WDs should be easily removable and replaceable.

4.12 Special foundations are not normally required. The weight of the WD, which can be as much as 2500kg for a large continuous process WD when fully loaded, should be borne by at least four pads each measuring at least 150 mm x 50 mm. Floor mountings should be designed to minimise vibration.

Safety features

4.13 Safety features should be designed in accordance with the Standard PD 5304: 2000 and the standard for the ‘Safety of electrical equipment BS EN 61010’.

4.14 The design of the control system should ensure that the door can not be opened until the cycle is complete. When a fault is indicated the door should only be able to be opened by a key code, or tool, when the WD is returned to a safe condition.

4.15 The manufacturer should provide a list of all safety devices together with their settings and methods of adjustment.

4.16 All safety devices should be designed to fail in a manner which does not cause a safety hazard to personnel.

4.17 A safety hazard should not be caused by an error in the control or indication system.

Over pressure protection

4.18 Over pressure safety valves should be fitted to protect components that may be damaged by inadvertent high pressures. This includes any pressure vessel, eg. the steam generator or compressed air reservoir, used within the machine. The discharge from safety valves should be terminated in a safe position.

Instrumentation

4.19 The WD should be fitted with means to verify and/or record the attainment of the specified process conditions. The nature and extent of monitoring should be commensurate with the intended use of the load and the risk arising from the inadvertent use of an improperly cleaned or disinfected load. Particular requirements for different types of WD are described in subsequent chapters.

A "cycle control" recorder may be of value in fault diagnosis but does not provide verification of attainment of the specified operating conditions.

NOTE: WDs may be fitted with either, or both, of two separate recording systems. A "cycle control" recorder which records the values of control variables as seen by the controller; or a "process verification" recorder which, independently of the controller and its sensors, records the values attained for some or all of the critical variables which determine the adequacy of the process.

4.20 Within this SHTM, three levels of process verification are identified:

a. Verification by the operator of the attainment of disinfection conditions – the WD is equipped with a temperature indicator, independent from the controller, to allow the operator to verify attainment of the programmed disinfection temperature.

   This may be used when, because of the intended use of the load, the risk arising from use of the product after an unsatisfactory disinfection process is low. This may include, for example, WDs for human-waste containers.

b. Verification by process record, independent from the controller, of the attainment of disinfection conditions – the WD is equipped with a temperature recorder, with sensors and signal processing independent from the controller, to record the attainment of the programmed disinfection conditions.

   This may be used when, because of the intended use of the load, it is necessary to provide confirmatory evidence that the disinfection process has taken place within the limits established during validation.

c. Verification by process record, independent from the controller, of the attainment of process variables affecting both the cleaning and disinfection processes – the WD is equipped with a multi-channel recorder, with sensors and signal processing independent from the controller, to record the process variables which were determined during validation studies to be critical to the satisfactory outcome of the cleaning and disinfection processes.

   This may be used when, because of the intended use of the load, it is necessary to provide confirmatory evidence that both the cleaning and disinfection processes have taken place within the limits established

during validation. This may include WDs for products which will be used without further processing and where the risks arising from an unsatisfactory cleaning and/or disinfection process are unacceptable.

4.21 A temperature indicator, independent of the controller, should be fitted to all WDs having a chemical disinfection stage to enable the user to verify the attainment of the specified disinfection temperature.

4.22 WDs used in SSDs and other similar production environments should be fitted with recorders to record process temperatures and the values of other key variables, eg. volume of chemical additive admitted.

NOTE: The use of recording devices may be required for compliance with the various quality systems under which the WD may be operated but in addition may be cost effective in producing the information to optimise the decontamination process.

4.23 When an instrument has a facility to allow it to be adjusted the adjustment should require the use of a key code, or tool, which is not available to the operator.

4.24 When a fault is indicated in the form of an error message shown on a visual display unit, it should be clearly distinguishable from the normal messages – for example, by use of a different colour or larger size of text. The indicator should remain displayed until cancelled by the operator.

4.25 The contractor should be required to carry out adjustments to the instruments on site so that the accuracy specified at the disinfection temperature can be met with the plant running and under the conditions normally prevailing on site.

4.26 An indicator should show which stage of the operating cycle is in progress and indicate “cycle complete” at the end of the cycle. For continuous process machines, separate indication of the operational status should be provided for each chamber or section.

4.27 A five digit counter should be provided to indicate the cumulative number of cycles started. The counter should be non re-settable, tamper evident or sealed. For continuous process machines the counter should indicate the number of loads which have entered the WD.

4.28 Provision should be made for the attachment of the test instruments required for the tests specified in SHTM 2030 Part 3, ‘Validation and verification’.

For temperature testing – a connection should be provided to permit the entry of sensors into the chamber, as described in BS 2745 Part 1. A suitable form of temperature connection is described in BS EN 285.

For pressure or flow testing – test tees and valve cocks with sealing plugs should be fitted to permit connection of test instruments for the verification

and calibration of all pressure and flow instruments permanently fitted to the WD.

When the WD is provided with instruments to monitor other variables – such as electrical conductivity of water supply or ion selective electrodes (ISE) for the determination of detergent concentration – means should be provided to enable test instruments to be connected to verify the readings obtained from the installed sensors.

Programmable electronic systems

4.29 Modern WDs frequently use programmable electronic systems (PES) for control and data recording. Such systems should be designed in accordance with the principles set out in the two parts of the HSE document 'Programmable electronic systems in safety related applications'.

4.30 When a PES is used to control or monitor the process, the values of cycle variables critical to process performance and determined during validation should be documented in the validation report regardless of whether or not they are held in the PES memory.

4.31 The version number of the software used in the PES should be available for display when required.

4.32 Combined control and instrumentation systems that are wholly operated by means of a PES should incorporate at least two timing systems independent of each other. When one timing system is used to control the holding time during the disinfection stage it is verified by the other timer.

Steam supply

4.33 When the WD is fitted with a steam supply, the steam pipework should include a pressure reducing system with a separator on the high pressure side. The system should be fitted with a strainer and trap to prevent condensate accumulating in the system.

Doors

4.34 WDs may have a single door or a door at each end (double door or pass through machines). Double door machines are preferred since they allow full physical segregation of clean disinfected items from dirty contaminated items. However, the increased complexity of a two door system may present additional maintenance requirements. Without special provision these may be inadequate for effective use of the WD as a "pass-through" machine from a "dirty" to a "clean" area since they allow a continuous, large, loss of air from the clean area.

NOTE: Some continuous process machines are fitted only with baffle stops at each end of the machine, and in some cases between sections of the machine.

4.35 Other continuous process machines may be in the form of a series of tanks into which the load is moved by an overhead conveyor. Each tank is protected by horizontally hinged spring loaded flaps which are pushed open by the load as it is lowered into, or raised from, the tank.

4.36 Discrete chamber or cabinet type machines (Type 1) may be fitted with manual or power operated doors whereas continuous process machines (Type 2) are normally fitted with power operated doors. Power operated doors will usually be vertical sliding doors. When manually operated doors are used they may be either vertically hinged or horizontally hinged. Horizontally hinged doors which fold down may offer the additional benefit of providing a loading and/or unloading platform.

4.37 The choice of design for any particular installation will depend on the workload, space restriction, price and ease of maintenance. If hinged doors are specified it should be clearly stated whether they are to be hinged on the left hand side, the right hand side or horizontally hinged.

4.38 It should be possible to clean the contact surfaces of the door seal without removing parts of the WD.

Materials of construction

4.39 Those parts of the WD which come into contact with the load should be manufactured from materials which have corrosion and abrasion resistant properties equal to or better than stainless steel.

4.40 The wet and chemically aggressive environment within the WD will cause corrosion and galvanic attack when dissimilar metals come into contact –a fact which should be taken into account when choosing the materials of construction.

4.41 The chamber should be designed to withstand 25,000/T operating cycles where T is the minimum operating cycle time in hours, specified by the manufacturer.

4.42 The method of construction of the chamber should ensure that it is self draining and free from sharp internal corners which cannot be cleaned during the normal cleaning cycle.

4.43 Floor mounted WDs shall be fitted with adjustable feet to compensate for irregular surfaces.

Integral steam generators designed to operate at pressures exceeding 200 mbar gauge

4.44 Steam generators fitted to WDs should be designed and manufactured to conform to BS 5500: 2000.

4.45 The integral steam generator should be equipped with blow down facilities to enable sludge to be expelled.

Integral air compressors

4.46 WDs may require a supply of compressed air for either the operation of valves and powered door systems and/or during the drying stage of the cycle.

4.47 When compressed air is intended to come into contact with the washed and disinfected product the compressed air supplied should be “medical grade” ie. it should be oil and particulate free (see SHTM 2022).

4.48 Built-in air compressors should be suitable for the duty imposed upon them. Current experience suggests that certain small compressors of the type fitted to domestic refrigerators are not suitable for use in WDs. Without meticulous maintenance a small air leak can cause them to run continuously thus causing carbonisation of the oil and a consequent failure of the WD pneumatic system.

Integral calorifiers and tanks

4.49 All integral calorifiers should conform to BS 853: 1996 and should be designed and constructed to allow thermal disinfection to be achieved throughout the calorifier and associated pipework before water and/or steam can be supplied to the WD during the thermal disinfection and subsequent stages.

4.50 Water tanks within the WD should be self draining and located so that they are cleanable by the operator and fitted with a drain down system which either works automatically when the machine is switched off or which is accessible to the user.

4.51 All tanks should be fitted with an overflow (see Water Bye-laws 1989).

When water is to be heated the heat source should be controlled by a thermostat and it should employ a heating medium as specified by the purchaser. The heat sources should be removable for replacement or maintenance purposes.

Dosing systems

4.52 The WD should be fitted with not less than two systems for controlling the admission of chemicals (detergents, disinfectants, rinse aids, lubricants etc.) and should be provided with the facility for at least one additional dosing system to be fitted.

NOTE: This requirement does not apply to WDs for human-waste containers.

4.53 Each dosing system should be provided with means to adjust the volume admitted. Access to the means of adjustment should require the use of a key, code or tool.

NOTE: The means of adjustment can be manual or automatic.

4.54 The stage(s) in the process cycle at which each dosing system admits chemical to the WD should be under the control of the automatic controller.

4.55 Each dosing system should be provided with means to determine the volume admitted and the time within the operational cycle when the admission occurred. This data should be available to the operator.

Failure to admit the specified minimum volume should cause a fault to be indicated.

4.56 The manufacturer should specify the accuracy and reproducibility of the control of volume admitted for each of the dosing systems used (detergents, disinfectants, rinse aids, lubricants) per cycle.

4.57 The WD should be fitted with a system that will indicate when there is insufficient chemical(s) available for the next cycle.

Door controls

Control of manually operated doors

4.58 An explanation of the manual action required to lock the door should be provided for the operator. In addition, if the unlocking procedure is not the reverse of the locking procedure, there should be an indication to the operator of the manual action required to unlock the door.

The indication should be clearly displayed either on the door or on its handle or handwheel. Explicit instructions should be displayed on the facing panel adjacent to the door or on the operator's control panel.

4.59 The door mechanism should be such that the force to be applied by an operator in order to either lock or unlock the door does not exceed 250N at the intended point of grip.

Control of doors of a double-ended WD

4.60 In double-ended WDs the control initiating the automatic cycle should be at one end only. When the loading door is closed and locked, it should not be possible to open the unloading door until the WD has completed a successful operating cycle – ie. without showing a fault.

4.61 If a fault develops, it should only be possible to open the loading door.

4.62 It should not be possible for an operator to open or close a door at the opposite end of the WD or for more than one door to be open at one time.

4.63 A visual display should be provided at both ends of the WD to indicate when the cycle is in progress.

4.64 The indication “cycle complete”, or an equivalent indication, should be cancelled when the unloading door is unlocked, and the loading door should remain locked until the unloading door has been locked again.

Internal doors and access ports

4.65 Doors between consecutive sections of a multi-section machine and access ports fitted to the outside of the machine for maintenance purposes.

Loading systems

4.66 The WD should be provided with carriers to locate the load during the washing and disinfection process. When interchangeable load carriers and baskets are provided each load carrier should be capable of being fitted and removed without the use of tools.

WD loading systems should be designed with regard to the Manual Handling Operations Regulations 1992. Reference should be made to the Lifting Operations and Lifting Equipment Regulations 1998 (LOLER).

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

a. the load should be wholly supported and retained within the usable chamber space for the duration of the operating cycle;

b. the force required by the operator, either directly or by the application of a mechanical device supplied with the equipment, to remove the whole, or part, of the load from the chamber should not exceed 250N when loaded and operated in accordance with the manufacturer’s instructions;

c. the load carrier should either be retained in the chamber by a mechanism which is only released when the transfer system is in place, or remain stable when withdrawn for a distance equal to two-thirds of the chamber length, and be fitted with a retaining device, which has to be released if the load is to be withdrawn further.

4.68 Means should be provided such that the transfer of the load into and out of the chamber does not cause damage and wear to the chamber.

NOTE: Systems which cause high levels of local stress, eg. point loadings, may also initiate corrosion in stainless steel materials.

4.69 The system used to support the load should be constructed from durable, corrosion-resistant materials and should withstand, without damage, the environment within the chamber.

4.70 The system used should neither prevent the attainment of the pre-set cycle variables nor the free drainage of water from the load and the penetration of water and/or steam into the load.

The load carrier(s) should be designed so that they cannot be mis-positioned in a manner which will prevent such attainment.

4.71 Any accessory used for handling the load which can be used outside the WD (eg. a trolley) should remain stable when it is supporting its maximum design load and a force of 250N is applied horizontally in any direction to the highest point of the load or accessory.

4.72 The trolley should be designed to allow the operator to align the trolley with the WD for ease of loading and unloading.

4.73 The trolley should be provided with means to collect liquid residues from the load to prevent these from dripping onto the floor. The means provided should be detachable for cleaning and for sterilization at 134–137°C in a porous load sterilizer.

4.74 The trolley should be provided with swivel wheels to facilitate manoeuvring.

4.75 The trolley should be provided with a parking brake.

4.76 The trolley should be designed to secure the load carriers on the trolley during loading and unloading, and while traversing a gradient at a slope of up to one in 20.

4.77 Trolleys intended for use with single door machines should be designed and constructed to facilitate cleaning and disinfection of the trolley between use for dirty and clean loads.

4.78 Load conveyors outside the WD which are intended to, or may reasonably be expected to come into contact with, soiled/contaminated goods should be designed and constructed to be easy to clean and disinfect. When practicable the load conveyors should be demountable and be able to be sterilized at 134–137°C in a porous load sterilizer.

Cleaning the washer-disinfector

4.79 The design, construction and operation of the WD should ensure that during the process the surfaces of the chamber and the load carrier presented to the operator are cleaned and disinfected.

4.80 For manually filled and emptied cleaning machines with no disinfection cycle, eg. stand alone ultrasonic cleaners, the manufacturer should advise on the cleaning/disinfection method.

Invitation to tender

4.81 Once detailed specifications have been drawn up, manufacturers should be invited to tender for the supply and, if required, installation of the WD.

4.82 When inviting tenders purchasers should follow the principles described in Scottish Capital Investment Manual and Scotconcode.

4.83 The purchasers should specify that the WD manufacturer operates a quality system in accordance with the principles described in the BS EN ISO 9000 series and, when applicable, the BS EN 46000 series.

If the manufacturer has both designed and manufactured the WD the quality system should conform with BS EN ISO 9001/BS EN 46001.

If the WD has been manufactured to a design supplied by a third party the manufacturer's quality system should conform to BS EN ISO 9002/BS EN 46002.

In either case the manufacturer should ensure that each supplier of accessories, fittings and other materials also operates an appropriate quality system.

4.84 Prospective contractors should be given the following information:

a. that each WD will be subject to a validation process as described in SHTM 2030 Part 3, 'Validation and verification';
b. unless otherwise specified, that the installation checks and test specified in the validation process must be satisfactorily completed before the WD can be accepted;
c. whether the installation checks and tests are to be witnessed by the purchasers representative (normally the TP);
d. the date by which all services will be available;
e. the date by which the validation process is expected to be completed.

4.85 Under the Public Supply Contract Regulations an exceptionally low offer may only be rejected after the contracting authority has requested and taken into account any explanation given by the supplier in writing (Statutory Instrument 1995 No 201 Part V 21/71).

Contract

4.86 For procurement of WDs reference should be made to the latest issue of PROCODE and the procedures advised in the Scottish Capital Investment Manual.

Guidance on the various contract types is available from the Property and Environment Forum Executive.

4.87 Consideration may also be given to the use of alternative forms of contract, for example MF/1 (available from the Institution of Electrical Engineers, the Institution of Mechanical Engineers or the Association of Consulting Engineers) or the Joint Contracts Tribunal (JCT) suite of documents (available from RIBA publications) or the New Engineering Contract issued by the Institution of Civil Engineers. Addresses are given in Appendix III.

4.88 Purchasers using other forms of contract are strongly advised to seek legal advice especially where a contract proposed by the prospective contractor is being considered.

4.89 Other contracts – notably for the authorised person, test person, maintenance person, competent person, and microbiologist – may need to be considered at this time (see SHTM 2030 Part 2, 'Operational management' and Part 1 of SHTM 2010).

4.90 In awarding these contracts purchasers should ensure that there is no conflict of interest that would compromise the validation process as set out in SHTM 2030 Part 3, 'Validation and verification'.

Delivery

4.91 On or before delivery of the WD the manufacturer should provide the purchaser with the information specified in Appendix 4. WDs for a particular scheme should not be ordered and stored on site for long periods prior to installation and validation. Disregard of this recommendation may invalidate the manufacturer's warranty and cause deterioration of the WD prior to installation.

5. Siting

Introduction

5.1 This chapter sets out some of the considerations to be taken into account when siting a WD. WDs are commonly installed in sterile service departments (SSDs), operating departments, wards and laboratories. A comprehensive review of the requirements for SSDs is given in SHPN 13 and for operating departments in SHPN 26.

5.2 The room in which a WD is installed and operated should meet the requirements of the Workplace (Health, Safety and Welfare) Regulations 1992. These Regulations have considerable implications for the design of accommodation for WDs.

5.3 Fire safety precautions should comply with NHSScotland Firecode.

Operating department dirty utility room

5.4 This area should be equipped for the storage, preparation for use, and disposal of contents after use, of human-waste containers including vomit bowls, bedpans and urine bottles. Specific guidance is given in SHPN 26.

Endoscope cleaning room

5.5 Provision may be made within the operating department for an endoscope cleaning room to provide facilities for cleaning and disinfection or sterilization of those endoscopes which cannot be returned to the central SSD or TSSU for reprocessing. When practicable this is best provided by means of an automated endoscope WD. Manual cleaning facilities will also be required.

5.6 A toxic vapour extract system at bench level to exclude all possibility of inhalation should be installed whenever a liquid chemical microbicide is to be used other than in an enclosed ventilated automatic WD.

5.7 The same area may also be used to accommodate an automated WD for emptying, cleaning and disinfecting suction bottles.

Specific guidance is given in SHPN 26 Operating Department.

Sterile services department

Decontamination area

5.8 A soiled returns hold area, where collection trolleys containing soiled returns can be marshalled, is normally located adjacent to or within the washing area and adjacent, or with easy access to, the hospital corridor or loading bay.

5.9 The washing area provides space to:

a. off-load soiled returns from trolleys;

b. sort items for disposal or appropriate cleaning and disinfection;

c. clean and disinfect reprocessable items;

d. transfer cleaned and disinfected items to the packing room.

When the transfer is automatic (ie. from an automatic WD) means should be provided to allow for the return of items which, when inspected in the packing room, are found not to have been properly cleaned.

5.10 The necessary cleaning and disinfection processes for the routine range of items to be processed may require several different types of WD. These may include, for example:

a. Single door cabinet WDs which may be used with a pass through hatch to the packing room.

When a hot air drying cabinet is used this should be of the pass through type with interlocking doors for transferring items from the washing area to the packing area.

b. Continuous process “pass through” WDs which will usually be equipped with a conveyor system to return the load carriers from the packing room to the decontamination room.

The conveyors should be designed and constructed to be easy to clean and disinfect (see also paragraph 4.78).

The decontamination room should provide a facility for cleaning trolleys used to transport returned items for decontamination and a suitable holding space for the number of trolleys which will be in use.

The room should also provide sorting benches with sufficient space for unloading trays from the trolleys and transferring items to WD baskets/load carriers.

Proper insulation of WD and exposed pipework from services is essential, together with appropriate ventilation, in order to maintain a comfortable working environment.

5.11 Manual cleaning facilities may also be required. A stainless steel double sink, double drainer and water gun unit (hot and cold water) should be provided. The manual cleaning area should be provided with a hood and extract ventilation (to microbiological safety cabinet Class 1 – 0.7m/sec face velocity) to protect the operator from aerosols created during the cleaning process.

6. Engineering services

Introduction

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

6.2 The manufacturer should make clear at an early stage which services will be needed and give detailed requirements for each service (see Table 3).

6.3 For most WDs the water and drainage services are the most critical although for user comfort, especially in the case of WDs using chemical disinfectant/sterilant, the ventilation and extraction system are also of importance.

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

Electrical services

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

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

a. for small WDs and table top WDs with a maximum current demand not exceeding 13A on a single phase supply, isolation may be provided by a simple plug and socket connection using a correctly fused plug and a switched socket-outlet;

b. when a three phase and neutral supply is required or when the maximum demand from a single phase supply is more than 13A, the WD should be wired directly to the isolator. The switch should isolate all poles simultaneously and each pole should be fused separately. The cable from isolator to WD should be fixed and protected from the effects of heat and water.

Table 3: Information on services to be obtained from the washer-disinfector manufacturer

Steam	a) acceptable range of supply pressures; b) maximum flow and usage rates; c) usage per operating cycle d) when steam is generated within the WD, the acceptable limits for hardness, pH and conductivity of feed water.
Electricity	a) type of supply eg. a.c. or d.c; b) number of phases (normally one or three) and whether neutral is required for a three – phase supply; c) supply voltage and frequency including nominal and acceptable minimum and maximum values; d) maximum continuous power demand in kW or kVA.
Compressed air	a) acceptable range of supply pressures; b) the flow required at minimum pressure; c) the volume of air used for each cycle; d) the quality or quantity of air required including dew point, maximum size and concentration of particulate material, oil content, and microbial contamination level as relevant.
Water	For each grade of water required, a) the acceptable range of supply pressures; b) the flow at minimum pressure; c) the volume used per cycle; d) the acceptable temperature range for incoming water; e) the quality of water required when relevant: - the maximum permissible hardness expressed as mg/l $CaCO_3$; - the acceptable range of pH; - the maximum permissible conductivity; - the limiting concentration of heavy metals, halides, phosphates and nitrates; - the maximum acceptable microbial population.
Drainage	a) the maximum flow of effluent to the drain; b) the maximum temperature of the effluent on leaving the WD; c) the maximum effective diameter of the discharge orifice from the WD chamber; d) requirement for sealed drainage system if hazardous fumes or gases are produced from chemicals used in the process.
Ventilation	a) the peak value during a cycle and the average value throughout a cycle of the heat in Watts transmitted to the environment when the WD is operated in still air at an ambient temperature of $23 \pm 2\ ^{o}C$; b) the heat in watts transmitted by a full load being unloaded from the WD into still air at an ambient temperature of $23 \pm 2\ ^{o}C$; c) the maximum flow of air extracted from the environment of the WD as exhaust ventilation; d) ventilation requirements for removal of fumes or gases from hazardous chemicals used in the process.
Process chemicals	Details of all process chemicals required (eg. detergents, rinse aids, sequestering agents, descalers, microbicides) for the regeneration of integral water treatment system), the quantity required per cycle, the nature and size of containers in which they are supplied, the necessary storage conditions for safe handling.

6.7 Within the loading area an additional switch should be provided so that the operator can electrically isolate the WD or group of WDs in the event of an

emergency. The switch should be placed between the normal operating position and the exit door.

6.8 It is not normally necessary for WDs to be connected to the essential supplies circuit, when this is available. Exceptions might include the decision to ensure that a limited number of WDs within the SSD remains on the essential supplies circuit. Guidance on the supply of electricity in the event of failure of the normal supply is given in SHTM 2011; *Emergency electrical services*.

6.9 All electrical installations should conform to IEE Regulations contained in BS 7671. Further guidance is given in SHTM 2007; *Electrical services: supply and distribution* and SHTM 2020; *Electrical safety code for low voltage systems (Escode–LV)*.

Steam

6.10 Steam may be used to supply a heat exchanger as a source of indirect heating for water or air to be used in the cleaning, disinfection or drying stages of a WD operating cycle.

6.11 Steam may also be used to heat process water directly, or to heat the load directly during the thermal disinfection stage, and for this purpose may be supplied either with an integral steam generator or from an external ("mains") supply.

Steam for indirect heating

6.12 Steam heat exchangers used for heating water or air may be of the shell, tube or plate design. In all cases, the steam supplied should be substantially free from non-condensable gases and free from oil since these contaminants will seriously impair the efficiency of the heating process. The effect of thin films of air on the surface of the heat exchanger may increase heating costs by 25% or more.

6.13 Suitable steam may be available from the high-pressure hot water systems used in some hospitals.

6.14 The steam service should be designed to meet the maximum demand of the WD, while keeping the fall in pressure before the final pressure reducing system to no more than 10%.

6.15 Except for vertical rises between floors or at intermediate points on long runs, the pipework should have a continuous fall such that any condensate flows by gravity in the same direction as the steam. Air vents and steam traps should be fitted at each vertical rise.

6.16 The condensate discharge system should be sized to ensure that the high volume of condensate found during the initial stages of heating can be discharged without "water-logging" the heat exchanger.

6.17 When the steam supply pressure at the inlet to the WD exceeds the maximum value specified by the manufacturer, a pressure reducing valve should be fitted to the supply pipe at least 3 m from the WD (this may be supplied by the manufacturer and be integral to the WD).

6.18 Careful attention should be paid to the siting of all pressure relief valves to ensure that the WD is properly protected.

6.19 Relief valves and their discharge pipes should be large enough to prevent the pressure in the supply pipes rising to more than 10% above the design pressure for the heat exchanger. The discharge pipe should terminate in a safe position outside the building.

6.20 Steel and copper piping traditionally used for steam supply are acceptable for this application.

6.21 Excessive moisture in the steam supply will impair the heating efficiency of the heat exchanger.

Steam for direct heating

6.22 Steam for direct heating should meet the requirements described above but should also be of an appropriate chemical and microbiological quality.

6.23 Any contaminants carried with the steam supply will be transferred to the load being processed either through contact with water which was steam heated or heated directly.

6.24 Filming amines or similar volatile corrosion inhibitors used to prevent corrosion in condensate return pipes should not be employed in steam used for direct heating.

6.25 The quality of steam required will depend on the nature of the load to be processed and, in particular, on the intended use of the load items. In heating for loads intended for use in surgically invasive procedures, the condensed steam should meet the chemical purity Standards specified for Water for Irrigation EP and should contain no more than 0.25 Endotoxin units/ml. Detailed guidance is given in SHTM 2031; *Clean steam for sterilization* and the same Standards are applicable.

6.26 When direct heating of the load by steam is used, the design of the WD should include adequate venting to the chamber to ensure that there is no possibility of pressurisation during a single fault condition.

Integral steam generators

6.27 Some WDs are equipped with small electrically heated steam generators to raise steam to heat the load directly by thermal disinfection.

6.28 They may be of the “open-boiler” type which are so designed and constructed that they are unable to generate an internal pressure above atmospheric pressure. The design should ensure that, under a single fault condition eg. obstruction of the steam discharge port, the boiler cannot become pressurised.

6.29 Integral steam generators which are pressure vessels should comply with the requirements of BS 5500: 2000.

Condensate recovery

6.30 Condensate from steam heating systems (calorifiers, dryers) and steam traps on the pipeline is suitable for recovery and should be returned to the steam generating plant when recovery is economically justifiable.

Compressed air

6.31 A compressed air supply may be required for the operation of controls and also for air drying. When the WD does not contain an integral air compressor (see paragraph 4.45) the air may be supplied from a piped service (mains supply) or from a local compressor.

Mains supply

6.32 If air is supplied by pipeline from a central air-compressor system a pressure gauge of the Bourdon type, complying with BS EN 837, should be fitted on the supply line to the WD via an isolation valve.

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

Local compressor

6.34 When it is not practical to obtain compressed air from a mains supply, a dedicated compressed air system should be installed to supply the WDs.

6.35 The compressors may be too noisy to install with the WD and may need to be located in a dedicated location away from noise sensitive areas.

6.36 Components of the compressed air system which require servicing and maintenance, such as dryers and filters, should be located where they are readily accessible for service or exchange.

Air quality

6.37 The quality of air may be critical for some applications and some WDs will incorporate appropriate filters. When the purchaser is to be responsible for the provision of filtered air the TP should ensure that the quality of air available meets the WD manufacturer's specification or the requirements given below.

6.38 Air that could come into direct contact with the load, such as air used for drying the load or testing the free-passage of lumens, should be oil-free (ie. should have no more than 0.5mg of oil per cubic metre of free air measured at 1013 mbar and 20°C; see BS EN 554), be filtered to an efficiency of at least 95% when tested in accordance with BS 3928 and be free of bacteria (see SHTM 2022, *Medical gas pipeline systems*).

6.39 Air for control purposes should be free of liquid water, filtered to 25 µm (5 µm for precision controls) and lubricated with micro-fog oil particles of 2 µm or less.

Drainage

6.40 All effluent from a WD is potentially contaminated and should be disposed of to the main drain.

6.41 Effluent may originate from each of the stages of the process which may include:

a. flushing to remove gross contamination;
b. washing with detergent and/or enzymatic cleaners;
c. rinsing, with or without the addition of a neutraliser, rinse aid or instrument lubricant;
d. chemical disinfection or thermal disinfection;
e. post-disinfection rinsing;
f. drying.

6.42 Effluent from the initial stages [(a) and (b) above] of the process may contain significant concentrations of organic contaminants and potentially infective micro-organisms. Effluent from the middle stages [(b), (c) and (d) above] may contain some organic contaminants and potentially infective micro-organisms and high concentrations of process chemicals. Effluent from the latter stages [(d), (e) and (f) above] may be at high temperatures (90–100°C).

6.43 Effluent from WDs (other than WDs for human-waste containers) should pass via an air break into a tundish or tank before being discharged to drain. The air break should be preserved at all times to prevent the WD and its associated pipework being contaminated by reverse flow from the drainage system.

NOTE: WDs for human-waste containers are connected directly to a soil pipe but are tested to ensure that back siphoning cannot occur under severe operating pressure.

6.44 When a tank supplies water to a pump on the WD, the overflow discharge from the tank should also include an air break.

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

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

6.47 Means shall be provided to prevent, as far as possible, flash steam being liberated into the atmosphere or causing condensation on electrical equipment.

6.48 The discharge temperature from a WD may be as high as 95°C. The materials used for the construction of the discharge system should be chosen to withstand temperatures up to 100°C.

6.49 Attention is drawn to the legal requirement (Public Health (Scotland) Act) that the maximum temperature of any liquid to be emptied into the public sewer or communicating drain is 43°C. This should be interpreted as referring to the main building connection to the sewer and not to the internal building drain.

Hazardous effluents

6.50 The discharge of soil from WDs should be regarded as being no more, but no less, hazardous than the discharge from any other sanitary appliance eg. a WC.

6.51 The discharge of process chemicals, including detergents and microbicides, may require special attention. The local water undertaking should be consulted before such chemicals are discharged into the drainage system as it may be necessary to neutralise or inactivate them before discharge.

6.52 A sealed and vented drain should be used for the discharge of chemicals with a significant vapour pressure – determined at the maximum attainable temperature of effluent in the drain – which may be hazardous to health or a nuisance. Possible backflow from the drain should be prevented by the inclusion of a check valve and a vacuum breaker.

6.53 WDs should not be used to process items known to be contaminated with high titre pathogens in Hazard Group 3, eg. arising from research activities, or any pathogens in Hazard Group 4 unless the items have been sterilized

by an appropriate steam sterilization cycle in a laboratory sterilizer designed and operated for the purpose (Further guidance is given in SHTM 2010 and advice should also be sought from the HSE).

Ventilation

6.54 Ventilation of the area near WDs may be needed to remove excessive heat and humidity, and also vapours from disinfectants such as glutaraldehyde.

6.55 General room ventilation will be sufficient for most WDs, but local exhaust ventilation may be required for chemical disinfection/sterilization systems.

6.56 Electrical systems used in ventilation systems should take account of the high levels of humidity that may be discharged and the potential for this to condense within the ventilation system.

6.57 All ventilation systems should meet the ventilation requirements of the Workplace (Health, Safety and Welfare) Regulations 1992.

6.58 Further guidance on ventilation systems may be found in SHTM 2025; *Ventilation in healthcare premises*.

General room ventilation

6.59 WDs for most healthcare applications do not require a filtered air supply in the room in which they are located unless there is no physical segregation between this area and the packing/sterilizing area.

6.60 The ventilation system in the area of a WD used to decontaminate used items should be a “full fresh air” system without recirculation. In designing the ventilation system reference should be made to SHTM 2025 ‘Ventilation in healthcare premises – Design considerations’.

6.61 Decontamination areas should generally be at a pressure below atmospheric; a 5-10Pa pressure difference is sufficient to minimise the dispersion of potentially infective aerosols into adjacent areas.

6.62 In designing the ventilation system two factors are of particular importance:

a. the provision of adequate cooling so that working conditions remain comfortable for staff;

b. correct sizing of the room ventilation system and/or interlocking with operation of both the room ventilation system and the machine/process specific extraction system(s) when extraction fans on WDs and/or extraction hoods are in operation.

6.63 WDs, particularly those employing thermal disinfection processes and a drying stage, may discharge significant heat energy to the surrounding environment. In designing a ventilation system for single ended WDs,

account should also be taken of the heat emitted from the load after it has been removed from the WD.

6.64 Current experience suggests that a 250 litre capacity cabinet WD, with a thermal disinfection stage and hot air drying installed as a free standing unit with the door closed and the machine operating, will release by radiation and convection heat energy at the rate of approximately 1.0 kW. A full load of processed items being removed from the WD will release energy at a declining rate but having a peak rate of approximately 0.5 kW immediately upon removal from the WD. Large multi-cabinet machines can release by radiation and convection energy over their operating cycles at rates up to 4 or 5 kW.

Machine ventilation

6.65 WDs are often run under a slight negative pressure to minimise the potential for the discharge of aerosols into the environment.

6.66 WDs not equipped with an air extract system may require siting under an extraction hood. The capture velocity in the vicinity of the process should be within the range 0.25–0.5m/s to ensure adequate extraction of steam and water vapour.

6.67 The extracted air from WDs is discharged into the atmosphere. In large installations significant quantities of useful energy may be discharged as a result. A heat recovery system may be economically viable and a full assessment of the benefits and costs should be carried out. Additional guidance is given in SHTM 2025 Part 2 ‘Ventilation in healthcare premises – Design considerations’.

6.68 The air extracted from WDs, both during the washing and the drying phases of an operating cycle, will normally have a high moisture level. The extraction system should, therefore, be equipped with a drain to discharge the condensate and should be designed and constructed so that it may be cleaned periodically. The drainage system should be constructed with a continuous fall to discharge, without any upstand at the point of connection to the ventilation system to prevent pooling.

6.69 The extraction system should be constructed from corrosion resistant materials. The discharge from some WD dryer systems is at high temperature (105°C) which is sufficient to melt or distort some lightweight plastic ducting materials. Typical worst case values are temperatures >105°C and 100% saturation.

6.70 Current experience suggests that flow rates for built-in extraction systems are in the order of 100 m^3/hr for a single cabinet 250 litre capacity machine, and up to 800 m^3/hr for a multi-cabinet continuous process machine of 1500 litre total capacity (ie. three 500 litre chambers).

6.71 The output from the extraction system should be considered as potentially containing infective aerosols and should, therefore, be discharged away from

opened windows, air intake systems or where down draughts occur. It is important that adequate dispersal is achieved and roof-level discharge is preferred.

6.72 The extraction ductwork connected to the WD is an efficient transmission system for noise originating within either the WD or extraction plant. Care is needed in the design and construction of the ducting to ensure that noise does not become a problem. This may require the use of sound attenuators as part of the ductwork design. Additional guidance is given in SHTM 2025 Part 2 'Ventilation in healthcare premises – Design considerations'.

6.73 Extraction hoods to protect operators against aerosol dispersion of potentially infective material, eg. over a manual washing sink or an unlidded ultrasonic bath, should have extraction velocities at working level of no less than 0.7–1.0 m/s.

NOTE: Although higher velocities will not impair extraction they are wasteful of energy.

6.74 Extraction systems, eg. bench extraction ventilation designed to protect operators against contact with vapours or gases such as those arising from chemical microbicides including glutaraldehyde, should have extraction velocities of 5.0–6 0 m/s.

6.75 Extraction hoods should be provided with local controls, or a control system interlocked with the equipment with which they are intended to work, so that they may be shut down when not required.

6.76 Purpose built work stations for glutaraldehyde disinfection/sterilization with built-in ventilation systems are also available. These are generally installed in a similar manner to laboratory fume cupboards (see BS 5728: 1990).

6.77 Extract from WDs and extraction hoods should not be discharged through general ventilation extraction systems. The extract from two or more WDs and/or extraction hoods should not use common ducting unless provision is made to ensure that there is no risk of contamination of a disinfected load from the cross-connection.

Chemical additives

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

6.79 In large installations with two or more Type 2 machines, as may often be required in SSDs, bulk storage tanks for chemical additives required for the process may be preferred with a piped distribution system to each WD.

6.80 For each chemical additive to be used there should be two storage tanks in parallel, one of which may be a small reserve tank, to permit cleaning and maintenance of the system without interrupting the use of the WDs, to facilitate segregation between separate batches of chemical additive and to allow for an orderly change to a different formulation if required.

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

7. Water supply

7.1 The number, nature and quality of water supplies required are dependent on the size and type of WD.

7.2 WDs may be supplied with both hot and cold water. When hot water is required as part of the operating cycle, it is generally advantageous to supply hot water to the WD rather than heat cold water to the required temperature within the WD.

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

7.4 At each stage the water quality should be compatible with:

a. the materials of construction of the WD;
b. the load items to be processed;
c. the chemical additive used;
d. the process requirements of that particular stage.

7.5 The key factors are:

a. hardness;
b. temperature;
c. ionic contaminants (eg. heavy metals, halides, phosphates and silicates);
d. microbial population;
e. bacterial endotoxins.

Water hardness

7.6 Hard water is caused by the presence of dissolved salts of the alkaline earth (calcium, magnesium and strontium) which come out of solution and deposit as hard mineral layers (lime-scale) when water is heated or evaporated.

7.7 The fouling of electrical heating elements or heat exchange components by hard water dramatically reduces the heat-transfer efficiency and can quickly lead to an increase in heating costs of 50–100%.

7.8 The deposition of lime-scale within pipes and around the edges of spray nozzles will seriously impair the performance of a WD. Hard water will cause scaling on the edges of spray nozzles even when fed with only cold water.

7.9 The presence of hardness in water seriously impairs the efficiency of most detergents and disinfectants. If the use of hard water is unavoidable it will be

essential to use process chemicals that contain sequestering agents. This adds considerably to the cost of the process.

7.10 Using hard water in the thermal disinfection and final rinse stages of the WD cycle is one of the major causes of white powdery deposits on load items. These are not only unsightly and an unwelcome contaminant but act as a focus for soiling and recontamination of the item in use. In some applications (eg. with optical systems) such deposits may seriously impair the utility of the item.

7.11 Most WDs will operate with water of hardness values up to 125mg/l $CaCO_3$ but are more effective and cheaper to operate when the hardness of the water does not exceed 50 mg/l $CaCO_3$

7.12 Some WDs are fitted with integral water treatment systems (see paragraphs 7.31 to 7.33).

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

7.14 Water at too high a temperature during the initial flushing stage may lead to the coagulation of proteins and thus serve to “fix” proteinaceous soil to the surface of the load items. The British Standard (BS 2745) recommends that the initial temperature should not exceed 35°C. The initial flushing stage should be supplied with water from a cold supply.

7.15 Water at too low a temperature during the washing stage of the cycle will often impair the ability of detergents used to remove soils composed largely of fats, oils or grease.

7.16 When enzymic cleaners are used the water temperature must be maintained close to the optimum temperature specified by the manufacturer; too high a temperature will inactivate the enzymes.

7.17 When chemical disinfectants are used the rate of activity generally increases with increased temperature. Too low a temperature will cause failure to attain the required microbial activation. However, too high a temperature with particular compounds can lead to degradation of the active components, evolution of toxic vapours or adverse reactions with the load items being processed.

7.18 The maximum temperature of rinsing water must be compatible with the items being processed; many items used in medical practice are temperature sensitive or may be damaged by thermal shock.

Ionic contaminants

7.19 Water used in the cleaning and disinfection of stainless steel instruments should have a chloride concentration between 0 and 120 mg/l Cl – to avoid the risk of corrosion. Chloride concentrations greater than 240 mg/l Cl – cause pitting to occur.

7.20 Tarnishing of stainless steel instruments, shown by blue, brown or iridescent surface colouration, occurs when heavy metal ions – such as iron, manganese or copper – are present in the process water. In hot water (over 75°C) magnesium ions and silicates can cause similar discolouration.

Microbial population

7.21 The purpose of the decontamination process is to remove soiling and reduce the microbial contamination to an acceptable level for the intended use of the items to be processed. The water used at each stage of the WD process cycle should not increase the bioburden of the load items.

7.22 For items which are intended to be used without further decontamination processing (eg. terminal sterilization) the nature and extent of the microbial population in the final rinse water should not present a potential hazard to the patient, either through infection or by leading to a erroneous diagnosis. Appropriate treatment to control or reduce the microbial contamination in water may be required.

Bacterial endotoxins

7.23 Bacterial endotoxins are thermostable compounds derived from the cell walls of bacteria which, when introduced into the human body, can cause a fever-like reaction and other adverse effects (for a more detailed explanation see SHTM 2010 *Sterilization*, part 5). They are not readily inactivated at the temperatures used for disinfection or sterilization.

7.24 Water used for the final stages of processing in a WD, where there is a significant risk of residual water remaining on the load items, should not contain more than 0.25EU/ml when the WD is being used to process surgically invasive items or those which are intended to come into contact with parenteral solutions.

Water treatment

7.25 Despite the cost involved in treating water from the public supply to provide the optimum quality for use at each stage in the WD process cycle, this is usually cost-effective.

Chemical purity

7.26 There are generally four methods of water treatment available for use on water supplies to be used in WDs:

a. water softeners;

b. water de-ionisers;

c. distillation;

d. reverse osmosis.

Water softeners

7.27 Water softeners, or "base-exchange" softeners, consist of an ion-exchange column containing a strong cation resin in the sodium form. Calcium and magnesium ions in the water are replaced by sodium ions. The column may be regenerated by treatment with a solution of common salt (sodium chloride).

Table 4: Use to which water of various qualities may be put

Types of water	Application
Cold water	Flushing ie. removal of gross soiling
Potable water	Flushing/cleaning
-soft eg. <50 mg/l $CaCo_3$	Cleaning with detergents or enzymatic cleaners Thermal disinfection in WCs for human-waste containers Final rinse water in WDs for human-waste containers
-hard eg. >125 mg/l $CaCo_3$	Flushing for WDs for human-waste containers will require use of descalers
Softened water -base exchange softener	Desirable in all water >50 mg/l $CaCO_3$ Essential in all water >125 mg/l $CaCO_3$ for use in WDs
Purified water	Final rinse water for laboratory WDs
De-ionised water	Thermal disinfection in all WDs Final rinse water
Reverse osmosis	Diluent for chemical disinfection Final rinse water
RO/0.22μm filtered recirculated, heated and or UV disinfected	Post-disinfection/sterilization rinsing of products intended for immediate use in critical applications eg. fibre-optic endoscopes
Sterile purified water	Post-disinfection/sterilization rinsing of products intended for immediate use in critical applications eg. fibre-optic endoscopes

Note: The above table shows suitable applications for the various qualities of water commonly available. Although water of lower quality may be used, this will normally require additional chemical additives and may entail some impairment of the WD performance.

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

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

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

Integral water softener

7.31 WDs are available with built in base-exchange water softeners although these are generally laboratory WDs.

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

7.33 Base-exchange softeners may cause a significant increase in the microbial content of the water.

De-ionisers

7.34 De-ionisation or demineralisation systems can remove virtually all the dissolved ionic material by ion-exchange using a combination of cation and anion exchange resins either in a single column (mixed bed) or in a separate column.

7.35 Operating costs of mixed bed de-ionisers are usually higher than for two-stage systems.

7.36 Systems are available in a range of sizes from small wall-mounted units in which ion-exchange resins are contained in disposable cartridges to large industrial units. Regeneration requires the use of strong acid (hydrochloric acid) and strong alkali (sodium hydroxide). For most types of installation an exchange column service is available from the water treatment suppliers.

7.37 De-ionised water may be heavily contaminated with micro-organisms and de-ionised water will be colonised rapidly because the chloride ions normally present to control microbial growth have been removed. De-ionised water should not be used for the final rinse of products intended for invasive use without further decontamination processing by heating, filtration etc. (see below).

7.38 For a given output volume, the initial cost of providing de-ionisation equipment will be lower than for reverse osmosis (RO). However, the inconvenience and cost of the regeneration process for de-ionisers, and the better microbial quality of the RO process, makes RO the preferred option.

Reverse osmosis (RO)

7.39 RO treatment plants remove dissolved contaminants from water by passing the water, under pressure, through a semi-permeable membrane against an osmotic gradient. The process will remove organic material, bacterial endotoxins and micro-organisms, as well as ionic species.

7.40 The initial capital cost of an RO plant is generally higher than for a de-ionisation system supplying a similar volume of water but operational costs are generally lower. When appropriate measures are taken to maintain the microbial quality of the water during storage and distribution, the water is endotoxin-free and has a negligible microbial population.

Distilled water

7.41 Distilled water may equal or exceed the purity of RO water but, despite the relatively low capital cost of the necessary plant, is very expensive to produce due to the high energy usage.

7.42 Distilled water is only used in laboratory WDs and RO is usually an acceptable alternative.

7.43 When indirect steam heating of WD water tanks and air dryers takes place, the condensate formed may provide an acceptable quality of water for use instead of distilled water.

Microbial purity

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

7.45 On storage in tanks and cisterns, the microbial content may increase considerably.

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

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

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

7.49 When sterile water is required for final rinsing in critical applications, eg. WDs for endoscopes, this should be provided by using a single-use container of sterile water for each cycle whenever practicable. The pipework, valves and pumps through which the water will pass should be subjected to an appropriate sterilization/disinfection process.

7.50 When water is treated by filtration, eg. through a 0.22 μm filter to remove microbial contaminants, rigorous controls are needed to ensure that the system works effectively. This should include:

a. either maintaining the pressure drop across the filter throughout its working life – a decrease in differential pressure being cause for rejection of the process cycle and a change of filter – or, a bubble point test before and after each process cycle (see BS 1752);

b. a continuous recirculation system so that the filter is not left wet in static water;

c. treatment of the circulating water to ensure that proliferation of microbial contamination is inhibited either by use of elevated temperature (eg. >60°C) or by the use of UV irradiation (wavelength 260 ± 10nm; >2J.m^{-2}). (See also report of the Expert Advisory Committee on biocides).

Pipework

7.51 The pipework used to supply the various grades of water should be appropriate to the quality of water carried. Sterilized uPVC or stainless steel pipes are preferred for all qualities of purified water.

7.52 All pipework should be run with a continuous fall to the discharge point so that it is free draining. It should be free from dead ends and other areas where water may become stagnant.

Water supply byelaws

7.53 All the organisations responsible for water supply within the UK have the statutory power to make, and the duty to enforce, byelaws for the prevention of waste, undue consumption, misuse or contamination of the water supplied by them.

7.54 Attention is drawn to the following points:

a. Bye-laws 38 to 41 require storage cisterns to be fitted with warning pipes (and an overflow if in excess of 1000 litre capacity). The warning pipe and overflow should not comprise, or have connected to it, a flexible hose.

b. Byelaw 25 Schedule A gives examples of points of use or delivery of water where backflow is, or is likely to be, harmful to health owing to a substance continuously or frequently present (Byelaw 25 (1)(a)).

c. This schedule lists amongst other things water softening treatment plant, bedpan washers, bottle washers, dishwashers and disinfection equipment and clearly applies to all WDs.

d. The required protection is a Type A air gap at the point of use or an interposed cistern.

e. Water softeners, regenerated only by means of sodium chloride solutions, need only be protected by a Type B air gap.

8. Chemical additives (detergents, enzymic cleaners, rinse aids, lubricants and disinfectants)

Introduction

8.1 Chemical additives are not necessary for all applications while they may enhance the removal efficacy they then in turn have to be removed during the rinsing stage. For applications in the laboratory and in the preparation of components and equipment used in manufacturing medical devices and medicinal products, it may be better not to use chemical additives when their use is not essential. Further guidance is given in the chapter on each type of WD.

8.2 In choosing the various chemical additives which may be required for effective cleaning and disinfection, it is important to ensure that the formulation of each chemical additive is compatible with:

a. the materials of construction of the WD;

b. the process being operated in the WD;

c. the quality of water available;

d. the items to be processed and their intended use;

e. any other additives to be used in the WD process;

f. any intended subsequent decontamination process (eg. sterilization).

It is also important that the required concentration can be accurately and reproducibly generated by the dosing system(s) on the WD.

Compatibility with the materials of construction of the washer-disinfector

8.3 The pH, redox potential and ionic nature of the chemical additive is important in determining whether it will cause corrosion or electrolytic attack (either between different materials in the WD or between the WD and items in the load).

8.4 Chemical additives which can be absorbed into, or adsorbed onto, surfaces of the WD (eg. plastic pipework) may be carried over into subsequent stages of the process (see also paragraphs 8.7 and 8.15).

Compatibility with the process

8.5 The performance of the additive must be matched to the physical characteristics of the operating cycle, eg. jet washing action systems require low foam detergents, if the washing action is not to be impaired.

Compatibility with the items to be processed

8.6 The chemical additives used must be compatible with the materials of which the load items are constructed and should not cause chemical or physical damage – eg. phenolic compounds used in detergents and disinfectants may cause material changes in rubber and plastics, while the anodic coating on the surface of anodised aluminium is removed by strongly acid or strongly alkaline compounds. The precise formulation of the chemical additive will affect its compatibility. It is not sufficient to determine only the compatibility of the principle active constituents.

8.7 The chemical additives used must be readily removed from the load items by rinsing with water and should be biologically compatible with the intended use of the load items. Chemical additives which are intended to persist on the surface of items processed through the WD (eg. lubricants) should be biologically compatible with the intended use of the load items.

Compatibility with the quality of water

8.8 Many detergents and disinfectants are seriously impaired in their activity by hard water. If only hard water is available formulations should be sought which are intended for use with water of that quality.

8.9 Detergent formulations intended for use only with soft water may give rise to precipitation if used with hard water, particularly at elevated temperatures. Once this precipitation has occurred on the surfaces of the WD or the load it is particularly difficult to remove (see paragraph 8.7).

Compatibility with other chemical additives

8.10 Many of the chemical additives which might be used are incompatible with one another – eg. quaternary ammonium compounds which are often used as surfactants will rapidly destroy the activity of enzymic cleaners, while many detergents will inactivate chemical disinfectants.

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

Compatibility with subsequent decontamination processes

8.12 Chemical additives which may persist on the surface of items processed through the WD should be compatible with any subsequent decontamination process which may be required, such as terminal sterilization. An in-process instrument lubricant which deposits a lubricant film on all surfaces of the instrument should only be used if it has been demonstrated to be compatible with any subsequent sterilization process.

General

8.13 In almost all cases, attainment of the specified concentration of chemical additives is essential to effective processing. The addition of too little will impair the process while too much is wasteful, may also impair the process and may contribute to unacceptably high residual levels.

8.14 Suppliers of chemical additives should provide product data sheets and material safety data sheets for the products supplied. These should include details of biocompatibility studies.

8.15 Suppliers of chemical additives should provide details of the analytical methods which may be use to detect residual concentrations of product. The sensitivity of the method should be sufficient to determine the presence of the compound below the level at which any adverse biological reaction may be determined.

Detergents

8.16 For most applications, mild alkaline detergents in the pH range 8.0–11.0 are preferred. Alkalinity improves the efficacy of detergents both by enhancing their inherent cleaning capabilities – neutralising and helping to remove acid soils, emulsifying oils and fats and peptidising proteins – and by synergistic action with other detergent compounds. Many surfactants work better in the presence of alkaline “builders” such as sodium tripolyphosphate (STPP).

8.17 Alkaline detergents inhibit the growth of most micro-organisms. Alkaline detergent residues are readily detected by pH measurement.

8.18 Acid-based detergents should only be used for stainless steel surfaces and then only for limited applications, eg. for de-scaling instruments that have been processed in hard water.

8.19 Cleaning agents for use in WDs should be:

a. liquid – to facilitate accurate dispensing;

b. non-abrasive;

c. low foaming;

d. free rinsing;

e. biodegradable.

8.20 Cleaning agents should not contain:

a. artificial colouring agents;

b. optical brighteners;

c. perfumes;

d. halides at an in-use concentration greater than 120mg/l;

e. fatty soaps, glycerine or lanolin.

Enzymic cleaners

8.21 Enzymes are organic catalysts through which the normal metabolism of most living organisms takes place. Although produced by living organisms they are not themselves alive. Enzymes are large organic molecules whose steric configuration (shape) affords them the ability to catalyse many reactions in the living cell.

8.22 Enzymes are classified into groups depending on the nature of the chemical reaction that they catalyse. Generally the enzymes used in enzymic cleaners are hydrolases ie. they promote the hydrolysis of the substrate with which they interact.

8.23 Enzymic cleaners are themselves proteins (often derived from the bacteria B subtilis and B stearothermophilus) and may be sensitising or allergenic agents. A similar adverse reaction is allegedly produced in some people by domestic biological washing powders.

8.24 Many of the developments in enzymic cleaners originated with the pre-soak cleaners and subsequently the biological washing powders used in domestic laundry applications.

8.25 A considerable proportion of the soiling found on medical items contains proteins which act as binding agents. Particulate dirt can be bound by the coagulation of these proteins on the surface.

8.26 If the binder proteins can be broken down into a simpler molecular form this binding action is destroyed and the bound soil, as well as the protein, can be released from the surface.

8.27 Formulations will often include buffering agents to maintain the pH within the preferred range. Most enzymes have an optimum pH at which their activity is greatest and a pH at which the enzyme itself is most resistant to thermal degradation, although these two values are not necessarily the same.

8.28 For example the proteolytic hydrolase derived from B subtilis, subtilisin A, withstands temperatures up to 60°C and displays its greater stability at pH 9.4.

8.29 The importance of the enzymic solution being at the correct temperature and pH, as well as being used for the specified contact time, cannot be too strongly emphasised.

8.30 Enzymes are not themselves cleansing agents. A properly balanced detergent may still be needed to remove the simpler molecular forms resulting from the enzymic action.

8.31 It is important to ensure that any detergents used are compatible with the enzymes – quaternary ammonium compounds (QACs) deactivate many of these enzymes (the deactivation of enzymes in the bacterial cell is one of the proposed mechanisms of action for the microbicidal action of QACs).

8.32 Enzymic formulations for cleaning solid surfaces are available in two forms:

a. a pre-soak formulation which is used to digest proteinaceous soil and is then followed by normal washing process using detergent;

b. a combined enzyme and detergent formulation.

Cleaning additives for ultrasonic cleaners

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

Rinse aids

8.34 Rinse aids are generally formulated from surfactants and are designed to make the water more free rinsing. They are often at low pH in order to remove deposited salts arising from the use of hard water.

Lubricants

8.35 The addition of oil-based compounds to the cleaning process is wrong in principle. They deliberately cause contamination over the entire cleaned surface. If they are to be used the water-soluble type should be used. Mineral oils have poor biocompatibility and may inhibit the penetration of steam or sterilant gases on terminally sterilized product.

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

Disinfectants and/or sterilants

Choice of disinfection method

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

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

8.39 Chemical disinfection should only be used for products which cannot be treated using thermal disinfection methods.

Criteria for selecting a chemical disinfectant

8.40 Chemical disinfectants differ in their ability to kill micro-organisms.

8.41 In order to choose a disinfectant for a particular application it is necessary to know the microbicidal activity required – both the number and types of organisms that may be encountered and the assurance that may be required that they have been inactivated. The technical information from the manufacturer of disinfectants should provide the required information about the activity of the product.

8.42 The major application for chemical disinfection is in processing for re-use thermo-abile equipment such as fibre-optic endoscopes. Two distinct standards are applicable: for those instruments that will only come in contact with intact mucosa; and for those that will invade a sterile body space. While the same or similar disinfectant formulations may be used for both applications the operational controls required may be different. This is addressed in Chapter 12. Further guidance is given also in SHTM 2030 Part 3, ‘Validation and verification’.

8.43 Although there are numerous disinfectant formulations available on the market, there are relatively few generic types of disinfectant suitable for chemical disinfection in WDs.

8.44 A solution containing 2% glutaraldehyde is the most commonly used disinfectant. Other aldehydes, quaternary ammonium compounds, hydrogen peroxide, peracetic acid, chlorine dioxide and alcohol solutions have also been recommended by various workers and may have particular benefits in certain applications.

8.45 The guidelines from various professional bodies are not in agreement as to the disinfectant contact time to be used and few recognise the need to specify the temperature or minimum concentration. Furthermore, these guidelines may not be in accord with the recommendations from the manufacturer of the item to be sterilized or from the manufacturer of the disinfectant.

8.46 Current guidelines from the UK Departments of Health are given in Health Circular HC (91)33. These recommend:

a. a freshly activated solution containing 2% glutaraldehyde at room temperature for 30 minutes for dealing with contamination with HIV or HBV;

b. a 2% solution of glutaraldehyde for 60 minutes if mycobacterial contamination is suspected.

8.47 'Guidance for Clinical Health Care Workers: Protection against infection from HIV and hepatitis virus' produced by the Expert Advisory Group on AIDS also recommends "endoscopes which will enter sterile body cavities must be immersed for a minimum of three hours".

8.48 While these times may be reduced if the items are processed in a validated automatic WD with appropriate routine monitoring, the exposure time should in all cases be at least that specified by the disinfectant manufacturer. More detailed information is provided in SHTM 2030, 'Validation and verification'.

8.49 Instructions for use supplied with the disinfectant should include:

a. the quality of water with which the product should be diluted;

b. the **storage life** – the life before dilution or activation (or before use if supplied at the required concentration for use);

c. the **use-life** – the storage life after dilution and storage under stated conditions within which the unused disinfectant will retain activity at, or above, the minimum specified by the manufacturer;

d. the **re-use life** – the extent to which the disinfectant may be re-used. This may be specified as time, the number of load items processed or the number of disinfection cycles.

NOTE: This is event related not time related but when a manufacturer specifies a "use-life" this should be based on simulated "worst case" use conditions. Whenever possible, a single use is preferred since it avoids the many problems associated with control of re-use.

Materials compatibility

8.50 The disinfectant should not cause damage to either load items or the WD in which it is used. Damage which may occur with incompatible disinfectants includes corrosion, embrittlement or swelling of plastics, degradation of lens cement in optical systems etc. The potential for electrolytic attack to occur as a result of different metals in the load and the WD coming into contact, via a powerful electrolyte, should not be overlooked.

8.51 The material of construction of the WD and of the items in the load should not inhibit the disinfectant.

Safety of disinfectants

8.52 Many of the compounds which are most effective as disinfectants are potentially human health hazards. Employers are required by law to do everything that is reasonably practicable to protect the health of their workers. The safe use of these compounds is covered by the COSHH Regulations.

8.53 Glutaraldehyde has an occupational exposure standard of 0.2 ppm over a 15 minute reference period. This should not be regarded as a permissible limit but as a maximum which should not be exceeded. Further guidance is given in SHTM 2030 Part 3, ‘Validation and verification’.

9. Washer-disinfectors for human-waste containers

Introduction

9.1 This chapter discusses specifications for WDs intended for emptying, cleaning and disinfecting human-waste containers.

9.2 WDs for human-waste containers are all Type 1 machines.

9.3 Human-waste containers include bed pans, urine bottles, commode bowls, enema and emesis containers, and suction bottles.

9.4 WDs currently available may be divided into two groups: flusher-disinfectors in which there is no detergent wash stage – all soil removal is accomplished by the physical action of water; and washer-disinfectors in which there is a wash stage after the initial flushing stage to remove gross soiling. While the former may be less expensive, the latter design may be used to process a wider range of items such as support frames for disposable bedpans, raised toilet seats, jugs and bowls etc.

Choice

9.5 WDs for human-waste containers are one of two available systems for providing for the needs of bed-dependent patients. The alternative system uses disposable containers, made of cellulose pulp, which are disposed of, complete with their contents, using a macerator. When properly installed, maintained and operated either system can provide a satisfactory solution for the provision of human-waste containers.

9.6 Factors to be considered in making the choice include:

a. the relative capital and running costs;

b. the storage space required for an appropriate working stock of disposables;

c. the peak throughput required;

d. the need to provide for the cleaning and disinfection of support frames used with disposable bedpans;

e. whether the flexibility to clean and decontaminate other sanitary items is required, and so on.

A review of these factors was published in 1991 (Rollnick) and should be consulted for further information.

Load handling equipment

9.7 The load handling equipment may be specific for the containers to be processed or may be designed to accommodate a range of different containers without the need to change load carriers.

9.8 When a range of items is to be processed eg. raised toilet seats, jugs, bowls, disposable bedpan support frames, as well as bedpans and urine bottles, the load carrier should be designed to accept these without the need to change carriers or add accessories. This reduces the operator time, the storage space required and the risk of loading errors. When it is necessary to change carriers or add accessories this should be a simple operation not requiring the use of tools.

9.9 The loading capacities from currently available machines are either one bedpan/two urine bottles per cycle or two bedpans/four urine bottles per cycle. The higher capacity machine is the preferred option in most cases because of its increased capability to deal with peak demands. For certain applications (eg. GU wards) designs capable of carrying up to eight urine bottles per cycle are available.

Standard specifications

9.10 WDs for human-waste containers should conform to the specifications in BS 2745: Part 1: 1993 and BS 2745: Part 2: 1993 and the safety specifications in BS EN 61010: Part 1.

Additional specifications

9.11 The WD should be equipped to provide automatic emptying of human-waste containers. Manual emptying prior to, or during, the loading of containers into the WD should not be required.

9.12 When a cold water rinse is used after the disinfection cycle, the water used shall not have been stored in a tank or cistern within the WD at a temperature above 20°C or below 60°C for more than four hours.

9.13 Consideration should be given to specifying an in-built condenser system to obviate the need for an external ventilation connection.

9.14 When required for connection to a hard water supply, a dispensing system should be specified to add detergent-descaler to the water during the washing stage of the process.

9.15 The WD should flush the residual soil from the emptied containers with a discharge volume of no less than 15 litres to ensure adequate clearance of solids from the drainage system. The total volume of water used per cycle may be significantly greater than this value and the volume of water required per load item processed should be a consideration when choosing a WD.

Operating cycle

9.16 The WD should perform the following operational stages in each cycle:

a. emptying – this should take place automatically and is usually effected and controlled by closing the door; Some WDs are provided with two chemical additive dispensing systems as standard giving the option to add a detergent wash stage for processing specific items;

b. flushing – removing residual soil from the containers with water at no more than 35°C;

c. washing – removing any remaining soil by washing with water, water and detergent, or water and detergent/descaler;

d. rinsing – removing any residual detergent or detergent/descaler;

e. thermal disinfection – raising the temperature of the load to the preset temperature (using hot water or steam) and maintaining the temperature for the required disinfection holding time.

The following stages may be included if required by the user:

a. cooling – rinsing the hot load with cold water to reduce the temperature of the load;

b. drying – purging the load and chamber with heated air to remove residual moisture.

Disinfection requirements

9.17 Thermal disinfection using moist heat is the preferred method; none of the equipment intended to be processed in this type of WD is unable to withstand thermal disinfection within the specified temperature range and there is no justification for the use of chemical disinfection.

9.18 The WD should be programmable to provide a thermal disinfection process within the temperature range 65-90°C for disinfection times between 10 minutes and one second respectively. The preferred disinfection process is 80°C for one minute.

9.19 A post-disinfection cold water rinse is available on some WDs. This is intended to cool the load so that it can be handled, and/or used, immediately at the end of the cycle. However, the advantage in shortening the time before the item can be re-used is minimal and, since the final product is wet, it has to be dried manually – eg. using paper towels.

9.20 When thermal disinfection is the final stage of the cycle, the hot load at the end of the cycle dries rapidly as the water evaporates from the surface – cooling the load at the same time.

Drying stage

9.21 Although a hot air drying stage is available on many current models, drying by evaporation after the hot disinfection/rinse stage is sufficient in most cases.

9.22 A hot air drying stage should be specified if the WD is to be used to process a range of other items.

Instrumentation/recorders

9.23 The WD should be fitted with a chamber temperature indicating instrument to show the temperature attained during the disinfection stage.

10. Washer-disinfectors for surgical instruments and associated equipment

Introduction

10.1 This chapter discusses specifications for WDs intended to be used for cleaning and disinfecting surgical instruments and associated equipment including instrument trays (eg.: Edinburgh trays), bowls and hollowware.

10.2 The guidance given here assumes that the WD is to be used to decontaminate medical devices and that the essential requirements of the EU Directives discussed in Chapter 1 must be met.

10.3 WDs for this purpose may be Type 1 or Type 2 machines.

Type 1 machines

10.4 Single chamber cabinet washers for surgical instruments and associated equipment may be either:

a. simple “deluge” washers primarily intended for bowls and hollowware but also suitable for dealing with simple easy to clean instruments;

b. designed to accept inter-changeable load carriers, typically with rotating spray arms or other devices to ensure a uniform wash action with several layers of load items.

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

10.5 Since all stages of the cycle take place in the same chamber, it is not possible to get physical separation between the dirty and clean stages of the cycle. Assurance that the load will not be recontaminated is dependent upon the efficacy of the cleaning and disinfecting stages in decontaminating the interior of the WD as well as the load.

Type 2 machines

10.6 Continuous process washers, other than those designed as automatic ultrasonic cleaners only, are usually designed to accept inter-changeable load carriers (see above).

10.7 Compared with Type 1 machines they have a higher throughput and, for a similar process, achieve some decrease in overall cycle time.

10.8 Since the load is moved through the machine as the cleaning and disinfection cycles proceed it is possible to get excellent physical separation between dirty and clean load items.

10.9 There may be some loss of operational flexibility when this type of machine is used for several applications at a time, eg. if it is used to process anaesthetic accessories the increased drying time, necessary for this application, will slow the passage of other loads passing through the WD.

10.10 WDs of this type are large, expensive pieces of equipment and their use is only justified in centralised production units.

Standard specifications

10.11 WDs for surgical instruments and associated equipment should conform to the specifications in BS 2745: Part 1: 1993 and BS 2745: Part 3: 1993 and the safety specifications in BS EN 61010: Part 1.

10.12 An EU standard is in preparation for WDs for surgical instruments and associated equipment and for specific safety requirements for WDs.

Additional specifications

10.13 The automatic controller of Type 2 machines should prevent initiation of any further operating cycles if there is an inadequate supply of the chemical additives required for the next cycle.

10.14 Whenever practicable the WD should be of the double-ended pass through type to facilitate physical segregation of dirty and decontaminated items.

10.15 The design should permit installation through the wall between the decontamination area and the clean area with effective sealing to prevent either passage of air from dirty to clean areas or excessive air loss from the clean area (normally maintained at a pressure above atmospheric).

Load handling equipment

10.16 A number of different types of carrier may be required to accommodate the range of items to be processed. The range of carriers required in an SSD may include:

a. a multi-layer carrier for instruments in wire mesh baskets (wire mesh baskets to include a number with retaining systems for small instruments);

b. a two layer carrier for small hollowware and instrument trays;

c. a single layer carrier for large bowls, Edinburgh trays etc;

d. a rigid endoscope/MAT instrument carrier;

e. an anaesthetic accessories carrier.

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

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

10.19 When double-ended WDs are specified a conveyor will normally be required to return load carriers from the unloading to the loading end. Where this passes through the wall between the packing room and decontamination room there should be a pass through hatch with interlocked doors.

Operating cycle

10.20 The WD should perform the following operational stages in each cycle:

a. flushing – removing gross contamination from the items in the load with water at a temperature not exceeding 35°C;

b. washing – removing any remaining soil by washing with water, water and detergent, or water and enzymic cleaner. Several sub-stages may be used consecutively to provide a combination of treatments; physical removal of the soil may be by the impingement of water jets or by ultrasonication or both consecutively;

c. rinsing – removing any residual detergent or enzymic cleaner. This stage may be combined with the thermal disinfection stage which follows;

d. thermal disinfection – raising the temperature of the load to the preset temperature (using hot water or steam) and maintaining the temperature for the required disinfection holding time;

e. drying – purging the load and chamber with heated air to remove residual moisture.

Disinfection requirements

10.21 The load, the load carriers and the internal surfaces of the WD chamber should be subjected to a thermal disinfection cycle. This should ensure that all surfaces to be disinfected are exposed to moist heat for a period and at a temperature not less than specified in Table 2.

Drying stage

10.22 The drying of the load is greatly facilitated by the thermal disinfection/hot rinse stage. In Type 1 machines with a low throughput drying by flash evaporation from the hot load may be sufficient. Individual items for which drying is more critical may be transferred to a separate drying cabinet.

10.23 For more critical applications and in Type 2 machines it is normal practice to include a hot air drying stage.

10.24 Thorough drying is of great importance. Products which are to be sterilized must be thoroughly dry as should products which are to be used without further treatment if there is not to be a significant risk of recontamination by, and growth of, micro-organisms.

The drying stage may be omitted on Type 1 machines particularly for small “table-top” machines. Additional chemical treatments may also be included if required by the user.

The addition of “rinse-aids” may be required to assist drying and to minimise “spotting” (deposits of waterborne salts) if purified water is not used for the final rinse.

The addition of instrument lubricants during the final rinse should be avoided whenever possible.

Instrumentation/recorders

10.25 The extent of necessary monitoring depends on the particular application. As a minimum for the thermal disinfection stage the attainment of the required temperature should be monitored independently of the cycle controller, displayed on a temperature indicator or recorder, and recorded.

10.26 When the WD is to be used to decontaminate medical devices – and the technical Standards described in the essential requirements of the EU Directives discussed in Chapter 1 must be met – additional monitoring facilities will be required.

10.27 The WD should be equipped with monitoring and recording devices to monitor the critical variables which affect the outcome of the cleaning and disinfection processes. This may include some, or all, of the following:

a. pump pressure, water flow and temperature at each process stage;
b. the flow or volume admitted of each chemical additive used (or, when applicable, by direct measurement of the concentration);
c. the chemical purity of the final rinse (by measurement of electrical conductivity);
d. the flow and temperature of the hot air used for drying.

NOTE: Visual inspection following the decontamination process is not of itself sufficient to determine whether the process was successful. The decontamination process must be subject to validation and then routinely monitored to ensure that the process remains within the validated limits. Further guidance is given in SHTM 2030 Part 2, 'Operational management' and Part 3, 'Validation and verification'.

Test connections

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

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

11. Washer-disinfectors for anaesthetic accessories

Introduction

11.1 This chapter discusses specifications for WDs intended for use in cleaning and disinfecting anaesthetic accessories. These items are often intended for use without further reprocessing.

11.2 The guidance given here assumes that the WD is to be used to decontaminate medical devices and that the essential requirements of the EU Directives discussed in Chapter 1 must be met.

11.3 Dedicated equipment for anaesthetic equipment would usually only be justified when there is a particularly heavy demand; most anaesthetic departments now use single use and/or filter protected patient circuitry.

11.4 Although dedicated WDs for anaesthetic equipment are commercially available their use is declining due to the changing pattern of equipment and accessories used in anaesthetic departments.

11.5 There is still a requirement for this type of equipment to be decontaminated because of its use in respiratory monitoring where the use of filters may not be practicable.

11.6 Dedicated anaesthetic WDs are usually Type 1 machines but when this facility is provided as an option with WDs for surgical instruments they may be Type 1 or Type 2 machines (see Chapter 10).

Load handling equipment

11.7 WDs for surgical instruments which can accept inter-changeable loading racks may be adapted to deal with anaesthetic accessories using a loading rack designed to hold anaesthetic breathing circuits, rebreathing bags and self-inflating resuscitator sets, face masks etc.

11.8 The design of load carrier should ensure that each hollow or tubular item can be connected to a spigot through which flushing, washing solutions and the water for rinsing and thermal disinfection can be directed into the lumen of the load item.

11.9 Whenever practicable the WD should be of the double-ended pass through type to facilitate physical segregation of dirty and decontaminated items.

11.10 The design should permit installation through the wall between the decontamination area and the clean area with effective sealing to prevent either passage of air from dirty to clean areas or excessive air loss from the clean area (normally maintained at a pressure above atmospheric).

Standard specifications

11.11 WDs for anaesthetic accessories should conform to the specifications in BS 2745: Part 1: 1993 and BS 2745: Part 3: 1993 and the safety specifications in BS EN 61010: Part 1.

11.12 An EU standard is in preparation for WDs for surgical instruments and associated equipment and for specific safety requirements for WDs.

Operating cycle

11.13 The WD should perform the following operational stages in each cycle:

a. flushing – removing gross contamination from the items in the load with water at less than 35°C;

b. washing – removing any remaining soil using water and detergent or water and enzymic cleaner. Several sub-stages may be used consecutively to provide a combination of treatments; physical removal of the soil should be by flushing through lumens and by the impingement of water jets on external surfaces of load items. Ultrasonication is not effective for items made from flexible rubber or plastic;

c. rinsing – removing any residual detergent. This stage may be combined with the thermal disinfection stage which follows;

d. thermal disinfection – raising the temperature of the load to the preset temperature (using hot water or steam) and maintaining the temperature for the required disinfection holding time;

e. drying – purging the load and chamber with heated air to remove residual moisture.

The drying stage may be omitted if a separate drying cabinet is to be provided. No additional chemical treatments should be necessary.

Disinfection requirements

11.14 Many anaesthetic accessories will be used without further decontamination treatment.

11.15 The load, the load carriers and the internal surfaces of the WD chamber should be subjected to a thermal disinfection cycle. This should ensure that all surfaces to be disinfected are exposed to moist heat for a period and at a temperature not less than one of those specified in Table 2.

11.16 The use of chemical disinfection is particularly contra-indicated because of the possibility of residuals being absorbed into the polymeric materials, of which the anaesthetic accessories are made, and then being evolved as irritant or toxic gases during use.

Drying stage

11.17 Thorough drying of anaesthetic tubing and other accessories is essential whether or not they are to be subjected to a further decontamination process, eg. sterilization.

11.18 Because of the thermal characteristics of the materials and the structural complexity of the items, drying with a current of warm air is a relatively slow process and may take more than twice as long as an equivalent sized load carrier filled with steel instruments. It is, for example, very difficult to remove the residual water from inside long lengths of corrugated tubing.

11.19 When anaesthetic accessories are processed through a WD for surgical instruments the extended hot air drying stage required will significantly reduce the throughput; if significant quantities of anaesthetic accessories are to be decontaminated consideration may need to be given to the provision of a separate drying cabinet.

11.20 Whether within the machine, or within drying cabinet, the flow of warm dry air should be directed through and over the items to be dried.

Instrumentation/recorders

11.21 The extent of necessary monitoring depends on the particular application. As a minimum for the thermal disinfection stage the attainment of the required temperature should be monitored independently of the cycle controller, displayed on a temperature indicator or recorder, and recorded.

12. Washer-disinfectors for endoscopes

Introduction

12.1 This chapter discusses specifications for WDs intended for cleaning and disinfection of flexible endoscopes (fibre-optic or video) and rigid endoscopes and their accessories.

12.2 The guidance given here assumes that the WD is to be used to decontaminate medical devices and that the essential requirements of the EU Directives discussed in Chapter 1 must be met.

12.3 WDs for flexible fibre-optic endoscopes are all Type 1 machines; the form of the chamber is often complex and sculpted to provide appropriate support to the endoscope(s) being processed. WDs for rigid endoscopes may be Type 1 or Type 2 machines.

12.4 Disinfection may be achieved:

a. for most rigid endoscopes and other items which are not heat sensitive, by direct contact of the load items with moist heat at a temperature in excess of 65°C and below 95°C. The preferred temperature is 80°C for no less than one minute;

b. for fibre-optic and other heat sensitive equipment, by direct contact of the load items with a chemical disinfectant.

NOTE: Users should seek advice from the manufacturer of the endoscope as to the most suitable method of disinfection and the limiting values of process variables (eg. temperature) for particular endoscopes.

12.5 Automated WDs for endoscopes are preferred to manual cleaning, whether followed by a manual or automated disinfection procedure. This is both for the safety of the user and also because it provides a more consistent, validated process with a higher level of assurance of attaining the required standards than can be achieved with manual cleaning.

Standard specifications

12.6 WDs for rigid endoscopes which can withstand thermal disinfection and steam sterilization are similar to WDs for surgical instruments and associated equipment and should conform to the specifications in BS 2745: Part 1: 1993 and BS 2745: Part 3: 1993 and the safety specifications in BS EN 61010: Part 1.

12.7 An EU standard is in preparation for WDs for surgical instruments and associated equipment and for specific safety requirements for WDs.

12.8 There are currently no British Standards for WDs intended for use with thermo-labile endoscopes. An EU standard for WDs for thermo-labile equipment including fibre-optic endoscopes and videoscopes is in preparation.

Additional specifications

12.9 WDs for endoscopes which employ a thermal disinfection stage should meet all the requirements specified for WDs for surgical instruments (see Chapter 10).

WDs with a chemical disinfection stage

12.10 The WD should be an enclosed system. It should be a requirement for the lid to be locked before it is possible to start a cycle, and it should not be possible for the operator to interrupt a cycle before completion.

12.11 The control system should permit regulation of pump pressure and inlet pressure to the various connections to allow the WD to be adjusted for particular types of instrument. It is desirable that this should be a programmable option on the automatic controller.

12.12 The WD should discharge solutions of cleaning agents to drain after each operating cycle unless the WD is equipped with means to verify the concentration of the chemical additive which remains active in the solution. (For some cleaning agents this may be achieved by continuous monitoring of in-use concentration using an appropriate ion selective electrode (ISE).)

12.13 The disinfectant solution should be used once and discarded. Alternatively, when systems which re-use disinfectant solutions for a number of cycles are employed, means should be incorporated to ensure that the automatic cycle will not start when the disinfectant concentration has fallen to, or below, the minimum recommended by the manufacturer or established by independent testing – eg. for a 2% solution of glutaraldehyde a limiting concentration of 1.5% would be recommended (Babb et al 1992).

NOTE: Re-use of the same disinfectant solutions for several operating cycles is often justified on grounds of economy. This may be a false economy if second and subsequent processes with the same batch of disinfectant solution are not subject to the same control as the initial use.

12.14 The rinsing stage should be carried out with water of a quality that does not lead to recontamination of the endoscope with micro-organisms coming from the incoming water supply reservoirs, including pipework within the machine.

12.15 The rinse water from one process should not be retained and used in subsequent cycles but should be discharged to drain.

12.16 There should be no static water stored within the WD at a temperature above 10°C or below 55°C for more than four hours if it is intended to come into contact with the load. This should be controlled and monitored by the automatic controller of the WD.

12.17 WDs should be designed and constructed such that they are able to be drained and dried when not in use.

12.18 The available operating cycles on the automatic control system should provide for a WD decontamination cycle to ensure that all pipework, tanks, pumps, water filtration systems and other fittings which are used to carry aqueous solutions intended to come into direct contact with the product are cleaned and disinfected. The decontamination cycle shall be user selectable.

12.19 The automatic controller should control the temperature of the disinfectant solution or monitor the temperature to ensure that it is above a value previously determined during validation studies (see SHTM 2030, 'Validation and verification' for more information).

12.20 The WD should be equipped with a recorder or data logger to record the attainment of the specified value of critical cycle variables throughout the cycle.

12.21 The WD should be equipped with means to contain or vent fumes and gases from the disinfectant solution to ensure that operators are not exposed to hazardous concentrations of the chemicals used. The WD should be provided with means to vent fumes from the chamber before allowing access to the operator.

Load handling equipment

12.22 The loading system should be appropriate to the range of endoscopes which it is intended to process.

12.23 Some endoscopes are not designed to be completely immersed in liquid and the operating head must remain above the liquid level.

NOTE: Endoscopes of this type are being phased out of service.

Some endoscopes require protective caps to be fitted to sensitive components before they can be decontaminated in an automated WD, eg. videoscopes need a protective cap on the video plug.

12.24 The load carrier needs to provide connection to the various channels within the endoscope to allow the cleaning and disinfection solutions to flow through the channels and may need to provide holders for disassembled components, valves etc.

Compatibility with items to be processed

12.25 Attention is drawn to the need to ensure that for any particular load item that all cleaning and decontamination processes are carried out in strict accordance with the manufacturer's instructions. All endoscopes, but particularly those incorporating fibre-optic systems, are easily damaged.

12.26 If the process conditions recommended by the manufacturer, including maximum temperatures, internal pressures, nature of any physical treatment such as ultrasonication, and limitations on the chemical additives which may be used, are ignored serious damage can be caused to these expensive instruments.

Disinfection requirements

12.27 The standard of disinfection required should be defined by the user in consultation with the control of infection officer.

12.28 In general:

a. endoscopes which, in use, are passed into sterile body cavities are considered to be invasive and must be sterilized;

b. endoscopes which, in use, come into contact with mucous membranes but do not invade sterile body cavities are non-invasive and can be decontaminated using high-level disinfection.

12.29 The choice of disinfectant should be based on the rigours of the disinfection procedure required, and on the compatibility with the endoscope and WD and the constructional materials of both.

NOTE: There is a potential for electrolytic action between different materials even when one material is part of the load and the other is part of the WD. This may result in corrosion of the load items and/or the WD.

Guidance on suitable disinfectants and exposure times is given in SHTM 2030 Part 3, 'Validation and verification' and in the MDA Bulletin on 'Decontamination of endoscopes and their accessories'.

Rinse water: quality requirements

12.30 For invasive endoscopes the final rinse water should be sterile and for non-invasive endoscopes it is preferable that it is sterile.

12.31 The most reliable method of providing water of the quality required for the final rinse is to use sterile “bottled” water.

12.32 Alternatively it is possible to produce water of appropriate quality by treatment of the local piped water supply. This may be provided adjacent to, or within, the WD.

12.33 The nature and extent of treatment will depend in part on the quality of the local water supply but normally should include at least the following steps:

a. pre-filtration to remove suspended particulate matter (this may require one or two filtration stages but the final stage should be with a filter that will retain particles of 5 µm or larger);

b. filtration through a bacteria retentive filter (0.22 µm).

The operating system should include:

a. means to monitor the integrity of the filter or warn of failure;

b. means to disinfect or sterilize the filter and the downstream water distribution system between uses or at four hourly intervals. This should preferably be by exposure to moist heat but a chemical disinfection process may also be used. A demountable system which allows the filter and downstream distribution system to be removed, dried and steam sterilized between sessions provides an acceptable alternative;

c. means to maintain the filter with a constant flow of water (not left wet in static water);

d. means to inhibit microbial growth in water in the storage and distribution system downstream

e. of the filter. This may be achieved by recirculation through an appropriate UV light disinfection system or by maintaining the water at elevated temperature eg. >80°C.

12.34 The design of the pipework, tanks, valves and pumps to avoid dead legs and areas where microbial growth may proliferate is critical to the maintenance of the system from microbial contamination. All fittings and pipe connections should be pharmaceutical grade sanitary fittings.

NOTE: If heated storage is used it will be necessary to cool the water supplied to the WD to ensure that the endoscope(s) are not damaged by exposure to too high a temperature.

Operating cycle requirements

12.35 The following operating cycle presents a general specification which may need to be adapted for particular instruments. It assumes that immediately after use, and before transfer to decontamination, the insertion tube will have

been wiped clean and that all channels will have been flushed through to remove gross contamination and ensure that they are free from blockages.

12.36 It is also assumed that any manual dismantling required (including removal of single use items, separation of accessories, removal of valves and covers, and disassembly) has taken place before the instruments are placed into the WD.

12.37 The operating cycle should include:

a. a **leak test** to verify that the endoscope is undamaged and will not suffer irreparable damage during exposure to the cleaning and disinfection process. (This should be a user selectable option);

b. **flushing** with water at a temperature not exceeding 35°C (this maximum temperature is necessary to minimise the coagulation of protein and consequent fixing of the soiling);

c. a **flow test** to ensure that all channels which should be irrigated with cleaning solution and disinfectant solutions are not blocked;

NOTE: Although this should have been verified before the instrument was placed in the WD, blockage can occur during processing when soiling dislodged from one place becomes trapped in a more restricted part of the instrument.

d. **washing** with an aqueous solution of detergent or an enzymic cleaner; when detergent solutions are used this may be at elevated temperature but should not exceed 60°C (see paragraphs 12.25 and 12.26).

The efficacy of chemical cleaning agents (detergents and enzymic cleaners) is affected by concentration, temperature, contact time and the presence or absence of materials/chemicals which will react with, and therefore inactivate, the chemical cleaning agent. The WD should provide means to control all these factors to the extent necessary to obtain satisfactory and reproducible cleaning.

For most rigid endoscopes ultrasonication may be used except for the telescope; ultrasonication generally is not suitable for use with optical or fibre-optic systems.

The pressure at which fluids are pumped through the internal channels of the endoscope should be controlled and maintained within the limits specified by the endoscope manufacturer;

e. **rinsing** to remove chemical additives used during the cleaning process;

NOTE: The rinse stage between cleaning and disinfection may be omitted if the disinfectant and cleaning agents are known to be compatible and the disinfectant preparation is used only for a single cycle.

f. **drying** to remove excess water before transferring to the disinfection stage where residual water can cause serious dilution of the disinfectant. This stage may be optional unless the load has to be manually transferred to an automatic disinfector;

g. **disinfection**. For rigid endoscopes thermal disinfection may be practicable (see endoscope manufacturer's instructions) and if so should be used. For fibre-optic endoscopes there is usually an upper temperature limit of 60°C for processing conditions; thermal disinfection is impracticable and chemical disinfection should be used.

   The efficacy of chemical disinfectants is affected by concentration, temperature, contact time and the presence or absence of materials/chemicals which will react with, and therefore inactivate, the disinfectant. The WD should provide means to control all these factors to the extent necessary to obtain satisfactory and reproducible disinfection;

h. **rinsing** to remove disinfectant. After an effective cleaning and disinfection process the microbial quality of the final rinse water will determine the microbial contamination which may be present on the endoscope;

i. **drying**.

Drying stage

12.38 Drying may be achieved by purging with heated dry air; means should be provided to ensure that the temperature of the endoscope is not raised above the maximum specified by the endoscope manufacturer. The quality of air used should not contribute to physical, chemical or microbial recontamination of the decontaminated item.

12.39 Drying may also be accomplished by purging the decontaminated item with 70% alcohol and allowing this to evaporate. The quality of the alcohol used should not contribute to physical, chemical or microbial recontamination of the decontaminated item. In particular spore-free alcohol should be used.

NOTE: Most endoscope manufacturers advise that the lens system should not be exposed to alcohol for prolonged periods, although normally two to five minutes exposure will cause no damage.

Decontamination of the washer-disinfector

12.40 Automatic WDs for endoscopes may themselves act as a source of contamination for the decontaminated items.

12.41 The design, installation and operation of the WD, including the quality of connected services, may contribute to the problem.

12.42 The WD should include a flushing stage for the WD pipework after each cleaning cycle to remove dislodged debris, biofilm etc. so that these cannot initiate a contamination problem.

12.43 All tanks used for the storage of water or aqueous solutions should be designed and constructed to ensure that they are free draining and cleanable.

NOTE: The use of hard water, water of inadequate microbiological quality or water stored in tanks at ambient temperatures for prolonged periods will promote contamination and the formation of biofilms within the machine.

12.44 The use of soft water can help alleviate this problem but it should be noted that base exchange softeners, and also de-ionisers, may themselves be a source of microbial contamination and can lead to high microbial counts of water borne organisms. These organisms are typically of species adapted to develop biofilms and the extracellular layers present in these biofilms provide good protection against microbicides.

12.45 Microbial colonisation of pipework may occur if the system is not disinfected regularly or if there is inappropriate cleaning and maintenance of the machine.

12.46 The WD manufacturer should provide information on cleaning and disinfection procedures and compatible chemicals for these purposes.

Requirements for control of the disinfection stage

12.47 The chemical disinfection system must:

a. ensure that the disinfectant solution temperature is either controlled at a pre-set temperature or is above a specified minimum temperature on which the exposure time was based;

b. ensure that all parts of load items to be disinfected are in contact with the disinfectant. This should include means to ensure the elimination of air bubbles etc;

c. avoid the risk of recontamination with micro-organisms from the WD, other load items or the connected services.

NOTE: Some disinfectant formulations have an upper temperature limit beyond which the disinfectant or its adjuvants in the formulation are decomposed or inactive.

Recontamination could lead to transfer of infection or inaccurate diagnosis if the contaminant is erroneously assumed to have come from the patient.

Instrumentation/recorders

12.48 The extent of necessary monitoring depends on the particular application. As a minimum for the thermal disinfection stage the attainment of the required temperature should be monitored independently of the cycle controller, displayed on a temperature indicator or recorder, and recorded.

12.49 When the WD is to be used to decontaminate medical devices and the technical Standards described in the essential requirements of the EU Directives discussed in Chapter 1 must be met additional monitoring facilities will be required.

12.50 The WD should be equipped with monitoring and recording devices to monitor the pump pressure (or water flow) and temperature at each process stage, the flow or volume admitted of each chemical additive used (or, when applicable, by direct measurement of the concentration), the chemical purity of the final rinse (by measurement of electrical conductivity), and the flow and temperature of the hot air used for drying.

Test connections

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

12.52 When additional monitoring is provided (see above) a separate test connection should be provided for each sensor to permit periodic verification of calibration of the installed system by comparison with a calibrated test sensor.

NOTE: Visual inspection following the decontamination process is not of itself sufficient to determine whether the process was successful. The decontamination process must be subject to validation and then routinely monitored to ensure that the process remains within the validated limits. Further guidance is given in SHTM 2030 Part 2, ‘Operational management’ and Part 3, ‘Validation and verification’.

13. Laboratory washer-disinfectors

Introduction

13.1 This chapter discusses specifications for laboratory WDs.

13.2 Laboratory WDs may be used to process components or equipment for use in the manufacture of medical devices or medicinal products or they may be used to process apparatus and equipment for use in clinical, or other, laboratories.

13.3 When used to process components or equipment for use in the manufacture of medical devices or medicinal products the design, construction, validation, operation and maintenance of these WDs will need to meet the requirements of the relevant EU Directives for medical devices or medicinal products (see Chapter 1).

13.4 WDs for both these applications may be machines of Type 1 or Type 2.

13.5 Commercially available machines offer a similar range of options to those WDs intended for the decontamination of surgical instruments and associated equipment (see Chapter 10).

Load handling equipment

13.6 The load handling equipment must be specific for the load items to be processed to ensure both that the load items are retained in the load carrier and that the external and any internal surfaces of the load items are reached effectively by the cleaning and disinfecting liquids throughout the cycle.

Standard specifications

13.7 There are no standard performance specifications specifically for laboratory WDs. For most applications the WD should conform to the relevant parts of the specifications in BS 2745: Part 1: 1993 and BS 2745: Part 3: 1993 which includes, for example, specific requirements for WDs used for the decontamination of glassware.

13.8 Laboratory WDs should conform to the safety specifications given in BS EN 61010: Part 1.

Operating cycle

13.9 The WD should perform the following stages in each cycle:

a. flushing – removing gross contamination from the items in the load with water at a temperature not exceeding 35°C;

b. washing – removing any remaining soil by washing with water, water and detergent, or water and enzymic cleaner. Several sub-stages may be used consecutively to provide a combination of treatments; physical removal of the soil may be by the impingement of water jets or by ultrasonication or both consecutively;

c. rinsing – removing any residual detergent or enzymic cleaner. This stage may be combined with the thermal disinfection stage which follows and normally requires the use of purified (DI, RO or distilled) water;

d. thermal disinfection – raising the temperature of the load to the preset temperature (using hot water or steam) and maintaining the temperature for the required disinfection holding time;

e. drying – purging the load and chamber with heated air to remove residual moisture.

For many applications in laboratories the drying stage may be omitted.

NOTE: Laboratory WDs incorporating a solvent wash stage are also available but are beyond the scope of this SHTM.

Choice of detergent/cleaning agent

13.10 The cleaning agent(s) to be used should be chosen to be appropriate to the materials of the load items, the soiling to be removed, the intended end use of the load items and compatible with the WD. In many cases there are highly specific requirements and a specific formulation is required.

13.11 The use of detergent and other chemical additives may not be appropriate in all cases. For example in the preparation of single-use glass containers for pharmaceutical applications the process is required to remove dust and similar debris which have contaminated the containers during distribution and storage, rather than strongly adherent soiling, and vigorous washing with water alone may be sufficient. Furthermore, if detergents and/or other chemical additives are to be used the process must be designed and operated to ensure that the concentration of residual detergent is reduced to a level where it will not have an adverse effect on the product.

Disinfection requirements

13.12 Disinfection is achieved by direct contact of the load items with moist heat at a temperature in excess of 65°C and below 95°C (see Table 2). The preferred temperature is 80°C for not less than one minute.

Drying stage

13.13 Drying is greatly facilitated by the final hot rinse. In general laboratory applications drying by flash evaporation from the hot load may be sufficient with individual items for which drying is more critical being transferred to a separate drying cabinet. For more critical applications, eg. containers for parenteral products where residual moisture may permit recontamination and unacceptable microbial growth, drying is important. Drying is also important for those products which are to be sterilized subsequently since this will require that the item is thoroughly dry.

Instrumentation/recorders

13.14 The extent of necessary monitoring depends on the particular application. As a minimum when thermal disinfection is required the attainment of the required temperature should be monitored independently of the cycle controller and displayed on a temperature indicator or recorder.

13.15 For critical applications, eg. the preparation of pharmaceutical containers for parenteral products, all key variables of the process should be independently monitored. The WD should be equipped with monitoring and recording devices to monitor the pump pressure, water flow and temperature at each process stage, the flow or volume admitted of each chemical additive used (or, when applicable, by direct measurement of the concentration), the chemical purity of the final rinse (by measurement of electrical conductivity), and the flow and temperature of the hot air used for drying.

NOTE: Visual inspection following the decontamination process is not of itself sufficient to determine whether the process was successful. The decontamination process must be subject to validation and then routinely monitored to ensure that the process remains within the validated limits. Further guidance is given in SHTM 2030 Part 2, ‘Operational management’ and Part 3, ‘Validation and verification’.

Test connections

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

13.17 When additional monitoring is provided (see above) a separate test connection should be provided for each sensor to permit periodic verification of calibration of the installed system by comparison with a calibrated test sensor.

14. Ultrasonic cleaners

Introduction

14.1 This chapter discusses specifications for ultrasonic cleaners.

14.2 The guidance given here assumes that the WD is to be used to decontaminate medical devices and that the essential requirements of the EU Directives discussed in Chapter 1 must be met.

14.3 Ultrasonic cleaners may be Type 1 or Type 2 machines.

14.4 Ultrasonic cleaners work by exposing the items to be cleaned to high frequency sound waves in the liquid cleaning medium.

14.5 The high frequency sound waves are generated within the liquid by the vibration of one or more surfaces of the bath; the surface(s) of the bath being caused to vibrate by one or more transducers bonded to the outer surface(s). The transducers convert electrical energy into vibrations of the required frequency and amplitude.

14.6 The highly effective cleaning action occurs as a result of the penetrative agitation caused by cavitation; the rapid formation and collapse of tiny bubbles within the liquid which are generated by the high frequency sound waves.

Applications

14.7 Ultrasonic cleaners are used in a wide range of industries including engineering, jewellery etc.

14.8 Ultrasonic treatment is particularly suitable for cleaning instruments of high grade steel. Delicate instruments such as micro-surgery instruments and dental instruments can be effectively cleaned with little risk of damage.

14.9 Ultrasonic treatment is also particularly effective for cleaning instruments that have deep interstices that may be contaminated with body tissues, eg. reamers, drills and burrs.

14.10 When combined with appropriate connection to an irrigation or flushing system ultrasonicators are also effective for cleaning cannulated instruments.

14.11 Ultrasonic cleaners are less effective when used to clean plastic and similar readily compressible materials since they absorb much of the ultrasonic energy.

Standard specifications

14.12 Ultrasonic cleaners, whether designed as stand alone units or incorporated into continuous process machines, should comply with the requirements of BS 2745: Part 3: 1993 and the safety specifications in BS EN 61010: Part 1.

Additional specifications

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

14.14 The tank should be heated electrically and the heaters should be thermostatically controlled.

14.15 The ultrasonic cleaner should be fitted with a timer to control the duration of exposure.

14.16 The ultrasonic cleaner should have a lid; the lid should be interlocked with the operating system to prevent normal operation if the lid is open and should fit securely to prevent the emission of aerosols when the cleaner is in operation.

NOTE: The lid interlock should ensure that no part of the operator's body can be immersed in the ultrasonic cleaner during operation; long term direct exposure to ultrasound is suspected of causing arthritic conditions.

14.17 The ultrasonic cleaner should be effectively insulated to prevent high frequency sound transmission at a power which could cause a health hazard. (Note: High frequency sound is suspected of causing damage to hearing). The casing and lid should provide adequate sound proofing so that harmonic frequencies within the audible range are not obtrusive.

14.18 The manufacturer should specify the chemical additives (detergents and/or enzymic cleaners) which are required and which are compatible with the process.

NOTE: Low foaming detergents are required; liquid detergents used for washing dishes ("washing-up liquid") are generally not suitable. Although an ultrasonicator will work without detergent/cleaner the cleaning action is much less effective.

14.19 The manufacturer should specify the means by which the cleaner may be disinfected. This may be by the provision of a high-temperature, eg. 80°C cycle option, or by means of a suitable disinfectant solution. In the absence of guidance the microbiologist should be asked to advise on a suitable procedure.

14.20 The manufacturer should specify the de-gassing time(s) which should be used on start-up and, when necessary, between each load of instruments processed.

Wash cycle

14.21 The ultrasonic frequency used is typically within the range 35 ± 5 kHz and the energy input used may range from 5.0 to 20.0 Watts/litre.

14.22 Ultrasonic cleaners may be designed to operate at a single frequency, across a frequency range, or with a feedback control system claimed to adjust the frequency in response to the loading conditions.

14.23 For medical applications aqueous solutions are used. Although ultrasonic cleaners containing aqueous solutions may be effective at temperatures up to 90°C it is normal practice to operate those for medical applications at temperatures between ambient and 40°C. This minimises the rate of coagulation of proteinaceous material in the soiling and is compatible with the use of enzymatic cleaners, many of which are rapidly destroyed at higher temperatures.

Type 1 ultrasonicators

Load handling equipment

14.24 A mechanical lifting device should be specified when the ultrasonicator is intended to process heavy sets of instruments.

14.25 The load container, usually a wire mesh basket, should be of appropriate size for the longest instrument to be processed.

14.26 When it is intended to process micro-surgical instruments or instruments with fine points the load handling equipment should provide means of retaining these in position so that the points are not blunted by the impacts resulting from fine mechanical shaking.

Type 2 (continuous process) ultrasonicators

14.27 Continuous process WDs may incorporate an ultrasonic cleaning stage within the cycle programme.

14.28 Ultrasonic cleaners are also available in continuous process format with a thermal disinfection stage and with the option to provide a hot air drying stage.

14.29 Ultrasonic cleaners with a solvent drying stage are no longer commercially available since the solvents used were CFCs which are now prohibited under the Montreal Protocol.

Load handling equipment

14.30 If complex tabling or conveyors are required these should be specified, and preferably illustrated with a sketch plan, when seeking tenders.

14.31 When it is intended to process micro-surgical instruments or instruments with fine points the load handling equipment should provide means of retaining these in position so that the points are not blunted by the impacts resulting from fine mechanical shaking.

Instrumentation/recorders

14.32 The ultrasonic cleaner should be fitted with a temperature indicator; provision should be made for a recorder to be fitted if requested by the purchaser.

14.33 The ultrasonic cleaner should be fitted with an indicator to show the power consumption (in Watts), or electrical demand (in Amps) of the ultrasonic transducers; provision should be made for a recorder to be fitted if requested by the purchaser.

Appendix 1: Glossary of terms

Automatic controller: Device that, in response to pre-determined cycle variables, operates the WD sequentially through the required stages of the cycle(s)/process.

Biological indicator: See BS EN 866-1:1997 ‘ Biological systems for testing sterilizers and sterilization processes: General requirements’.

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.

Calorifier: A closed vessel in which water is indirectly heated under a pressure greater than atmospheric.

Chamber: That part of the WD in which the load is processed.

NOTE: The chamber does not include steam generators, pipework and fittings from which it can be isolated.

Chemical disinfection: Disinfection achieved by the action of one or more chemicals; the primary purpose of which is to be microbicidal.

Continuous process machine: A machine which automatically transports the load through each stage of the operating cycle.

Chemical additive: A formulation of chemical compounds intended for use in a WD.

Cycle complete: Indication that the washing and disinfection cycle has been satisfactorily completed and that the disinfected load is ready for removal from the chamber.

Cycle variables: The physical and chemical properties (eg. times, temperatures, disinfectant concentration, pressures and flows) that influence the efficacy of the washing and processes.

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.

Disinfection temperature: The minimum temperature of the disinfection temperature band.

Disinfection temperature band: The range of temperatures, expressed as the disinfection temperature and the maximum allowable temperature which may prevail throughout the load during the disinfection time.

Disinfection time: The time period at which the cycle variable (eg. temperature of the load, disinfectant concentration in the chamber) is maintained at or above the value specified for disinfection.

NOTE: This includes detergents, surfactants, rinse aids, disinfectants, and enzymatic cleaners.

Door: Device provided as a means of closing and sealing the chamber.

Double-ended washer-disinfector: A WD incorporating separate doors for loading and unloading.

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.

Holding time: the time period for which the cycle variables are maintained at or above the value specified for disinfection.

Hysteresis: The lagging of effect behind cause.

Inoculated carrier: See BS EN 866-1:1997 ‘ Biological systems for testing sterilizers and sterilization processes: General requirements’.

Installation test: Series of checks and tests performed after installation of the WD in the place of use.

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.

Loading door: Door in a double-ended WD through which the load is put into the WD prior to processing.

Loading height: The minimum height to which the underside of the load or load container has to be raised for it to enter the loading door.

Medical device: See BS EN 46001: 1997 ‘Specification for applications of EN ISO 9001 to the manufacture of medical devices’.

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.

Operating pressure: The gauge pressure at which the vessel is operated during normal use.

Override: The system by which the operating cycle can be interrupted or modified as necessary.

Safety hazard: Potential detrimental effect on persons arising from the load.

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 BS EN 556 'Sterilization of medical devices. Requirements for terminally sterilized devices to be labelled 'Sterile''.

Sterilization: Process used to render a product sterile (35).

Tank: A process vessel, integral to the WD, designed to hold solutions during processing.

Test organism: See BS EN 866-1:1997 ' Biological systems for testing sterilizers and sterilization processes: General requirements'.

Test soil: Substance used to test the washing efficacy of a WD.

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.

Unloading door: Door in a double ended WD through which the load is removed after an operating cycle.

Usable space: Space inside the chamber which is not restricted by fixed parts and which is consequently available to accept the load.

Validation: See BS EN 554 'Sterilization of medical devices. Validation of and routine control of sterilization by moist heat'.

Viable micro-organism: Micro-organisms, including viruses, which are capable of multiplication under specified culture conditions.

Warning pipe: Overflow pipe so fitted that its outlet, whether inside or outside the building, is in a conspicuous position, where the discharge of water can be readily seen.

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.

NOTE: This type of machine does not include those designed specifically to wash linen or clothing.

Waste outlet: The point from which the chamber discharges the waste fluids.

Works test: Series of tests performed at the manufacturer's works to demonstrate compliance of each WD with its specification.

Appendix 2: Abbreviations

A	Amperes
a.c.	Alternating Current
A & E	Accident and Emergency
AP(s)	Authorised Person (Sterilizers)
BS	British Standard
°C	Degrees Celsius
$CaCO_3$	Calcium Carbonate
CE	Council of Europe
CEN	Committee European de Normalisation
CFCs	Chlorofluorocarbons (refrigerants)
Cl	Chlorine
COSHH	Control of Substances Hazardous to Health
d.c.	Direct current
D.I.	De-ionised (referring to water)
EEC	European Economic Community
EMC	Electro magnetic compatibility
EN	European Norm
EU	European Union
	Endotoxin unit
EU/ml	Endotoxin units/millilitre
GGMP	Guide to Good Manufacturing Practice…….etc.
GU	Genito Urinary
HBV	Hepatitis B Virus
HIV	Human Immunodeficiency Virus
HMSO	Her Majesty's Stationary Office
HSE	Health and Safety Executive
IEC	International Electro Technical Commission
IEE	Institution of Electrical Engineers
ISE	Ion selective electrode
ISO	International Standards Organisation
Jm^2	Joules/square metre
kg	Kilogram
kHz	Kilo Hertz
kVA	Kilo Volt amp
kW	Kilo Watt
m	metre
MAT	Minimum access therapy
mbar	Millibar
MCA	Medical Control Agency
MDA	Medical Devices Agency
mg	Milligram
mg/l	Milligram/litre
ml	millilitre
mm	millimetre

MP	Maintenance person
m/s	metre/second
m^3/hr	cubic metres/hour
N	Newton
NHS	National Health Service
nm	nanometre
No.	number
OEL	Occupational exposure limit
PA	Pascal
P&EF	Property and Environment Forum
P&EFEx	Property and Environment Forum Executive
PES	Programmable electronic system
pH	measure of acidity or alkalinity of a solution
ppm	parts per million
QAC	Quaterrary ammonium compound
RO	Reverse osmosis – a method of water treatment
Sec	Second
SHTM	Scottish Health Technical Memorandum
SHPN	Scottish Health Planning Note
SSD	Sterile services department
SSM	Standard sterilization modules (600 mm x 300 mm x 300 mm)
TC	Technical committee
TP	Test person
TSSU	Theatre sterile supplies unit
UK	United Kingdom
UV	Ultra violet
uPVC	Unplasticised polyvinyl chloride (plastic)
V	Volts
WC	water closet
WD	Washer disinfector
µm	micron (a unit of length equal to one millionth of a metre)
<	less than
>	greater than

Appendix 3: Useful addresses

UK health agencies

NHSScotland
Property and Environment Forum Executive
4th Floor, St Andrew House
141 West Nile Street
Glasgow G1 2RN

NHS Estates
1 Trevelyan Square
Boar Lane
Leeds, LS1 6AE
Tel. 0113 254 7000

Medical Devices Agency (MDA)
Hannibal House,
Elephant and Castle, London, SE1 6TQ
Tel. 0171 972 8000

Scottish Healthcare Supplies
Trinity Park House
South Trinity Road
Edinburgh
EH4 2RQ
Tel. 0131 552 6255

Medicines Control Agency (MCA)
Market Towers,
1 Nine Elms Lane, London SW8 5NQ
Tel. 0171 273 3000

Scottish Executive Health Department,
St Andrews House,
Edinburgh EH1 3DG
Tel. 0131 556 8400

Health and Safety

Health and Safety Executive
375 West George Street
Glasgow
G2 4LW
Tel. 0141 275 3000

Belford House
59 Belford Road
Edinburgh
EH4 3UE
Tel. 0131 247 2000

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. 02392 823 186

Appendix 4: Information to be supplied by the manufacturer

A2.1 The following information should be supplied by the manufacturer of the WD at or before the time the WD is delivered.

Standards

A2.2 Statements of, and documentary evidence to substantiate, compliance with relevant British and EU Standards.

Instruction manual

A2.3 The manual should contain complete instructions including:

a. simplified operating instructions in a durable form suitable for fixing next to the WD;

b. guidance on the types of load that may be processed in the WD and the recommended loading patterns/load carriers to be used;

c. operational limits including the maximum working temperature which may be attained within the WD chamber or chambers, and the maximum pressure that may be applied to the lumen of cannulated instruments.

A2.4 When the WD incorporates a pressure vessel (eg. an integral steam generator) the operational limits of the pressure vessel including design pressure, maximum permissible working pressure and maximum permissible working temperature in accordance with the 'Pressure systems regulations'. A valid test certificate should be provided by the manufacturer for all pressure vessels supplied.

Instruments and controls

A2.5 The manual should include a description of each instrument and control fitted to the WD including:

a. the scale ranges of each and the limits of accuracy;

b. evidence that the calibration of each instrument has been verified and that the instrument is reading correctly within its limits of accuracy.

Operating cycles

A2.6 The manual should give a description of each operating cycle available on the sterilizer.

Services

A2.7 The manual should give a description of all the engineering services required by the WD, specifying:

a. values of the fluctuating demands placed on each service during the course of a normal operating cycle;

b. the maximum and minimum safe supply pressures, temperatures and voltages.

This should also include specification of the minimum acceptable water quality for each stage in the process (defined as pH, total dissolved solids, redox potential, electrical conductivity).

Safety

A2.8 Safety information should include:

a. description of any safety hazard that may arise in the normal operation of the WD and recommended precautions to avoid them;

b. description of all safety devices including their recommended settings and any means provided to override and reset them;

c. description of the chemical additives with which the WD is intended to be used.

Machine characteristics

A2.9 The manual should include a description of the machine, specifying the total volume of the chamber: This should include the following information:

a. dimensions of the usable space and its capacity expressed either as an integral number of load baskets based on the standard sterilization module (SSM) or as a specific number of identified load items eg. the number of bed pans;

b. parts of the usable chamber space which are fastest and slowest to attain the disinfection temperature, and those parts which are hottest and coolest during the disinfection holding time.

Maintenance manual

A2.10 Two copies should be provided. The manual should include:

a. a planned preventive maintenance programme, consistent with the principles outlined in SHTM 2030 Part 2, 'Operational management', together with detailed instructions for the procedures contained within it;

b. a list of any special tools and equipment required for periodic maintenance and testing;

c. diagrams of all electrical, steam, compressed air, water, chemical additive dosing systems, and ventilation and drainage connections;

d. a complete list of all spare parts, indicating all parts which should be held in stock and that may require replacement during the normal working life of the WD together with their usage rates;

e. guidance on tracing and correcting likely causes of malfunction;

f. method of adjusting and calibrating the pressure, temperature and flow rate indicating or recording systems;

g. Specification and source of supply for suitable flexible ducting to enable extracts from WDs to be conveyed to atmosphere.

References

NOTE:
Where there is a requirement to address a listed reference, care should be taken to ensure that all amendments following the date of issue are included.

Publication ID	*Title*	*Publisher*	*Date*	*Notes*
Acts and Regulations				
	Building (Scotland) Act	HMSO	1959	
	Clean Air Act	HMSO	1993	
	Consumer Protection Act	HMSO	1987	
	Electricity Act	HMSO	1989	
	Health and Medicines Act	HMSO	1988	
	Health and Safety at Work Act	HMSO	1974	
	Public Health (Scotland) Act	HMSO	1988	
	The Water (Scotland) Act	HMSO	1980	
SI 2179	Building Standards (Scotland) Regulations (as amended)	HMSO	1990	
	Building Standards (Scotland) Regulations: Technical Standards Guidance	HMSO	1998	
SI 437	Control of Substances Hazardous to Health Regulations (COSHH)	HMSO	1999	
SI 3140	Construction (Design and Management) Regulations	HMSO	1994	
SI 635	Electricity at Work Regulations	HMSO	1989	
SI 1057	Electricity Supply Regulations (as amended)	HMSO	1988 (amd. 1994)	
SI 2372	Electromagnetic Compatibility Regulations (as amended)	HMSO	1992	
SI 2451	Gas Safety (Installation and Use) Regulations	HMSO	1998	
SI 2792	Health and Safety (Display Screen Equipment) Regulations	HMSO	1992	
SI 917	Health and Safety (First Aid) Regulations	HMSO	1981	
SI 682	Health and Safety (Information for Employees) Regulations	HMSO	1989	

Publication ID	*Title*	*Publisher*	*Date*	*Notes*
SI 341	Health and Safety (Safety Signs and Signals) Regulations	HMSO	1996	
SI 1380	Health and Safety (Training for Employment) Regulations	HMSO	1994	
SI 2037	Lifting Operations and Lifting Equipment Regulations	HMSO	1998	
SI 2865	Management of Health and Safety at Work Regulations	HMSO	1999	
SI 2793	Manual Handling Operations Regulations	HMSO	1992	
SI 3017	Medical Devices Regulation	HMSO	1994	
SI 2169	Medicines (Standard Provisions of Licences and Certificates) Amendment (No 3) Regulations	HMSO	1977 1992	
SI 1790	Noise at Work Regulations	HMSO	1989	
SI 2966	Personal Protective Equipment at Work (PPE) Regulations	HMSO	1992	
SI 2966	Personal Protective Equipment (EC Directive) Regulations (as amended)	HMSO	1992	
SI 128	Pressure Systems Safety Regulations (PSSR)	HMSO	2000	
SI 2306	Provision and Use of Work Equipment Regulations (PUWER)	HMSO	1998	
SI 201	Public supply contracts regulations	HMSO	1995	
SI 2023	Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR)	HMSO	1995	
SI 119	Water Supply (Water Quality) (Scotland) Regulations	HMSO	1990	
SI 3004	Workplace (Health, Safety and Welfare) Regulations	HMSO	1992	
British Standards				
BS 853	**Specification for vessels for use in heating systems** **Part 1:** Calorifiers and storage vessels for central heating and hot water supply **Part 2:** Tubular heat exchangers and storage vessels for building and industrial services	BSI Standards	1996 1996	
BS 1427	**Guide to field and on-site test methods for the analysis of waters**	BSI Standards	1993	

Publication ID	*Title*	*Publisher*	*Date*	*Notes*
BS 1752	**Specification for laboratory sintered or fritted filters including porosity grading**	BSI Standards	1983	
BS 2745	**Washer disinfectors for medical purposes** **Part 1:** Specification for general requirements **Part 2:** Specification for human-waste container washer-disinfectors **Part 3:** Specification for washer-disinfectors except those used for processing human-waste containers and laundry	BSI Standards	 1993 1993 1993	
BS 3218	**Specification for test tubes and boiling tubes**	BSI Standards	1982	
BS 3693	**Recommendations for design of scales and indexes on analogue indicating instruments**	BSI Standards	1992	
BS 3849-4	**Concial connectors for anaesthetic and respiratory equipment. Specification for 8.5 mm cones and sockets**	BSI Standards	1990	
BS 3928	**Method for sodium flame test for air filters (other than air supply to IC engines and compressors)**	BSI Standards	1969	
BS 5164	**Specification for indirect-acting electrical indicating and recording instruments and their accessories**	BSI Standards	1975	
BS 5295	**Environmental cleanliness in enclosed spaces**	BSI Standards	1989	
BS 5452	**Specification for hospital hollow-ware made of plastics material**	BSI Standards	1977	
BS 5500	**Specification for unfired fusion welded pressure vessels**	BSI Standards	2000	
BS 5728	**Measurement of flow of cold potable water in closed conduits** **Parts 2, 3, 5, 6,and 7**	BSI Standards	1980 - 1987	
BS 6253	**Specification for glass beakers for laboratory use**	BSI Standards	1984	
BS 6447	**Specification for absolute and gauge pressure transmitters with electrical outputs**	BSI Standards	1984	
BS 7320	**Specification for sharps containers**	BSI Standards	1990	
BS EN 285	**Sterilisation. Steam sterilizers. Large sterilizer**	BSI Standards	1997	

Publication ID	*Title*	*Publisher*	*Date*	*Notes*
BS EN 554	**Sterilization of medical devices. Validation of and routine control of sterilization by moist heat**	BSI Standards	1994	
BS EN 556	**Sterilization of medical devices. Requirements for terminally sterilized devices to be labelled 'Sterile'**	BSI Standards	1995	
BS EN 724	**Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for non-active medical devices**	BSI Standards	1995	
BS EN 837	**Pressure gauges** **Part 1:** Bourdon tube pressure gauges. Dimensions, metrology, requirements and testing **Part 2:** Pressure gauges. Selection and installation recommendations for pressure gauges **Part 3:** Diaphragm and capsule pressure gauges. Dimensions, metrology, requirements and testing	BSI Standards	1998 1998 1998	
BS EN 866	**Biological systems for testing sterilizers and sterilisation processes** **Part 1:** General requirements **Part 2:** Particular systems for use in ethylene oxide sterlizers **Part 3:** Particular systems for use in moist heat sterlizers	BSI Standards	1997 1998 1997	
BS EN 1281	**Anaesthetic and Respiratory equipment** **Part 1:** Conical connectors	BSI Standards	1997	
BS EN 1282	**Anaesthetic and respiratory equipment** **Part 1:** Tracheostomy tubes: Tubes for use in adults	BSI Standards	1997	
BS EN 1782	**Tracheal tubes and connectors**	BSI Standards	1998	
BS EN 1820	**Anaesthetic reservoir bags**	BSI Standards	1997	
BS EN 6001	**Application of EN ISO 9001 to the manufacture of medical devices**	BSI Standards	1997	
BS EN 6002	**Application of EN ISO 9002 to the manufacture of medical devices**	BSI Standards	1997	

Publication ID	*Title*	*Publisher*	*Date*	*Notes*
BS EN 12342	**Breathing tubes intended for use with anaesthetic apparatus and ventilators**	BSI Standards	1998	
BS EN 46001	**Specification for application of EN ISO 9001 to the manufacture of medical devices**	BSI Standards	1997	
BS EN 46002	**Specification for application of EN ISO 9002 to the manufacture of medical devices**	BSI Standards	1997	
BS EN 50081	**Electromagnetic compatibility. Generic emission standard** **Part 1:** Residential, commercial and light industry **Part 2:** Industrial environment	BSI Standards	 1992 1994	
BS EN 50082	**Electromagnetic compatibility. Generic immunity standard** **Part 1:** Residential, commercial and light industry **Part 2:** Industrial environment	BSI Standards	 1998 1995	
BS EN 50103	**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**	BSI Standards	1996	
BS EN 60584	**Thermocouples** **Part 1:** Reference tables	BSI Standards	1996	
BS EN 60751	**Industrial platinum resistance thermometer sensors**	BSI Standards	1996	
BS EN 61010	**Safety requirements for electrical equipment for measurement, control and laboratory use** **Part 1:** General requirements	BSI Standards	1993	
BS EN ISO 14644-1	**Cleanrooms and associated controlled environments. Classification of air cleanliness**	BSI Standards	1999	
BS EN ISO 9000	**Quality management and quality assurance standards.**	BSI Standards	2000	
BS EN ISO 9001	**Quality systems. Model for quality assurance in design, development, production, installation and servicing.**	BSI Standards	1994/ 2000	
BS EN ISO 9002	**Quality assurance. Model for quality assurance in production, installation and servicing**	BSI Standards	1994	

Publication ID	*Title*	*Publisher*	*Date*	*Notes*
PD 5304	**Safe use of machinery**	BSI Standards	2000	
European Union (EC) Directives				
90/385/EEC	Active Implantable Medical Devices Directive Note: the Directive was adopted by the EC Council of Ministers on 20 June 1990 and came into effect in the UK on 1 January 1993 as the Active Implantable Devices Regulations 1992	Official Journal of the European Communities (OJEC)		
91/356/EEC	Council Directive laying down the principle and guidelines of good manufacturing practice for medicinal products for human use	Official Journal of the European Communities (OJEC), L193, 17.7.91, p30		
93/42/EEC	Council Directive concerning medical devices	Official Journal of the European Communities (OJEC), L169, 12.7.93, p1		
80/778/EEC	Council Directive relating to the quality of water intended for human consumption	Official Journal of the European Communities (OJEC)		
93/94/EEC	Medical Devices Directive. Note: The Directive was adopted by the EC Council of Ministers on 14 June 1993 and came into effect in the UK on 1 January 1995 as the Medical Devices Regulations	Official Journal of the European Communities (OJEC), L319, 17.11.81, p19		
Scottish Health Technical Guidance				
SHTM 2007	Electrical Services Supply & Distribution	P&EFEx	2001	CD-ROM
SHTM 2010	Sterilization	P&EFEx	2001	CD-ROM
SHTM 2011	Emergency electrical services	P&EFEx	2001	CD-ROM
SHTM 2020	Electrical safety code for low voltage systems (Escode – LV)	P&EFEx	2001	CD-ROM
SHTM 2022	Medical gas pipeline systems Supplement 1: Dental compressed air and vacuum systems Supplement 2: Piped medical gases in ambulance vehicles	P&EFEx	2001	CD-ROM
SHTM 2025	Ventilation in healthcare premises	P&EFEx	2001	CD-ROM
SHTM 2027	Hot and cold water supply, storage and mains services	P&EFEx	2001	CD-ROM
SHTM 2031	Clean steam for sterilization	P&EFEx	2001	CD-ROM

Publication ID	*Title*	*Publisher*	*Date*	*Notes*
SHTM 2040	Control of legionellae in healthcare premises – a code of practice	P&EFEx	2001	CD-ROM
SHPN 1	Health service building in Scotland	HMSO	1991	
SHPN 2	Hospital briefing and operational policy	HMSO	1993	
SHPN 13	Sterile services department	Scottish Office	1994	
SHPN 15	Accommodation for pathology service	Scottish Office	1994	
SHPN 26	Operating department	Scottish Office	1992	
SHPN 26 Supp.1	Operating department activity space data sheets	Scottish Office	1993	
HBN 13 Supp 1	Oxide sterilization section			
	NHS in Scotland PROCODE	P&EFEx	2001	Version 1.1
NHS in Scotland Firecode				
SHTM 81	Fire precautions in new hospitals	P&EFEx	1999	CD-ROM
SHTM 82	Alarm and detection systems	P&EFEx	1999	CD-ROM
SHTM 83	Fire safety in healthcare premises	P&EFEx	1999	CD-ROM
SHTM 84	Fire safety in NHS residential care properties	P&EFEx	1999	CD-ROM
SHTM 85	Fire precautions in existing hospitals	P&EFEx	1999	CD-ROM
SHTM 86	Fire risk assessment in hospitals	P&EFEx	1999	CD-ROM
SHTM 87	Textiles and furniture	P&EFEx	1999	CD-ROM
SFPN 3	Escape bed lifts	P&EFEx	1999	CD-ROM
SFPN 4	Hospital main kitchens	P&EFEx	1999	CD-ROM
SFPN 5	Commercial enterprises on hospital premises	P&EFEx	1999	CD-ROM
SFPN 6	Arson prevention and control in NHS healthcare premises	P&EFEx	1999	CD-ROM
SFPN 7	Fire precautions in patient hotels	P&EFEx	1999	CD-ROM
SFPN 10	Laboratories on hospital premises	P&EFEx	1998	CD-ROM
Health and Safety Publications				
(MDA SN 9619)	Compatibility of medical devices and their accessories and reprocessing units with cleaning, disinfecting and sterilizing agents. Medical Devices Agency	Dept. of Health	1996	

Publication ID	Title	Publisher	Date	Notes
(L5)	Control and substances hazardous to health and control of carcinogenic substances: Control of substances hazardous to health regulations 1999: approved code of practice. Health and Safety Executive	HSE Books	1999	3rd Edition
(HC(79)3)	Code of practice for the prevention of infection in clinical laboratories and post-mortem rooms	Dept of Health	1979	
(H(91)33)	Decontamination of equipment, linen or other surfaces contaminated with hepatitis B and/or human immunodeficiency viruses	Dept. of Health	1991	
(SAB(93)32)	Endoscope washer/disinfectors: recontamination of equipment	Dept of Health	1993	
	Microbiological safety cabinets: recommendations concerning their choice, installation, routine maintenance and use (Health Equipment Information No 86) Medical Devices Agency	Dept. of Health	1980	
	Scottish Infection Manual 1998 – guidance on core Standards for the Control of Infection in Hospitals, Healthcare premises and at the Community Interface	Scottish Office	1998	
	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	Dept. of Health	1993	
(L23)	Manual handling: Manual handling operations regulations 1992: guidance on regulations. Health and Safety Executive	HSE Books	1992	
(EH40)	Occupational exposure limits. Health and Safety Executive	HSE Books		Issued annually
	Programmable electronic systems in safety related applications: an introductory guide. Health and Safety Executive	HSE Books	1987	
MDA DB 9501	Re-use of medical devices supplied for single use only	HMSO	1995	
	Safety in health service laboratories: safe working and the prevention of infection in clinical laboratories. Advisory Committee/Health and Safety Executive	HSE Books	1991	

Publication ID	Title	Publisher	Date	Notes
	Safe working and the prevention of infection in the mortuary and post-mortem room. Health and Safety Executive			
(L22)	Work equipment. Provision and use of work equipment regulations 1998. Guidance on regulations. Health and Safety Executive	HSE Books	1998	
(L24)	Workplace health, safety and welfare. Workplace (Health, Safety and Welfare) Regulations 1992: approved code of practice and guidance. Health and Safety Commission	HSE Books	1992	
Miscellaneous References				
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	Rollnick M, *How You Spend Your Pennies*	Health Estate Journal	1991	May, p12-15
	Dawson M, Novitsky T J, Gould M J. *Microbes, endotoxin and water*	Pharm Eng	1988	Mar/Apr vol 8, no2
	Twohy C W, Nierman ML, Duran A P *et al*, *Comparison of limulus amoebocyte lysates from different manufacturers*	Journal of Parent Science & Tech	1983	May/Jun vol 37, no3, p93-96
	Bacterial endotoxin test USP 8th Supp. Pharmacopoeial Convention		1993	Mar XXII NF XVII, p3349-3350
	Chloride in waters, sewage and effluent. Methods for the examination of waters and associated materials	DOE/Nat. Water St. Committee	1981	
	Determination of pH in low ionic strength waters	DOE/Nat Water St Committee	1988	
	Determination of alkalinity and acidity in water	DOE/Nat Water St Committee	1981	
	Deprygogenation by dry heat. Technical report no 7. Parental Drug Association			Ch12, p101-108
	Dry heat destruction of lipo-polysaccharide. Applied Environmental Microbiology		1997	Vol 36 p715

Publication ID	Title	Publisher	Date	Notes
	General principles of sampling and accuracy of results	DOE/Nat Water St Committee		
	Guidelines on the validation of the Limulus Amoebocyte Lysate test as an end product Endotoxin test for human and animal parenteal drugs, biological products and medical devices	US Food and Drug Administration	1987	
	Guide to contract procedures	NHS Estates	1998	
	International standards for drinking water	WHO	1971	
	Iron in raw and potable waters by spectrophotometry. Methods for the examination of waters and associated materials	DOE/Nat Water St. Committee	1977	
	Measurements of Electrical conductivity and the laboratory determination of the pH value of natural, treated and waste waters	DOE/Nat Water St Committee	1981	
	Model Engineering Specifications	NHS Estates, HMSO	1998	Issued in 4 volumes
	Model Water Byelaws: Dept. of the Environment	HMSO	1986	
	Ninhydrin test	Analytical Bio-chemistry	1993	Vol 211, p240-242
	Phosphorus and silicon in waters, effluent and sludges	DOE/Nat Water St Committee	1992	
	Rules governing medicinal products in the European Community. Vol IV Good manufacturing practice for medicinal products. Commissions of the European Communities		1992	
	Scottish Capital Investment Manual	Scottish Office		
	Sterilization and disinfection of heat-labile equipment: report of a working Party on sterilization and disinfection of heat-labile equipment. Hospital Infection Research Laboratory		1986	

Publication ID	Title	Publisher	Date	Notes
	Total hardness, calcium hardness and magnesium hardness in raw and potable waters	DOE/Nat Water St Committee	1981	
	Water Supply Byelaws Guide. Water Byelaws Advisory Service Water Research Centre		1989	2nd Edition