HEALTH TECHNICAL MEMORANDUM 2030
Washer disinfectors: Operational management
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Operational management

Health Technical Memorandum 2030

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We look forward to hearing from you.
Health Technical Memoranda (HTMs) give comprehensive advice and guidance on the design, installation and operation of specialised building and engineering technology used for the delivery of healthcare.

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

Health Technical Memorandum 2030 is being published in three volumes.

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

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

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

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

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

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

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

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

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

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

The guidance previously given in ‘Management policy’ has been incorporated into this volume.

\[1\] The term washer-disinfector is abbreviated to ‘WD’ throughout this publication.
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1.0 Disinfection in healthcare: an overview

1.1 Contamination by washing and disinfection is a complex and subtle process. The testing, maintenance and reporting procedures described in this HTM may seem excessive, but they are based upon good practice in both the UK and Europe, as formalised in European Standards designed to support the EC Directives.

1.2 The main purpose of washing and disinfection is to eliminate the hazard of contamination and infection.

1.3 Disinfection is 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.

1.4 The lethality of the process is less than that of sterilization but eliminates virtually all recognised pathogenic organisms, although not necessarily all microbial forms, for example bacterial endospores. Disinfection is adequate for the preparation of many items intended for use in patient care, but should not be used as a substitute for sterilization.

1.5 The hospital infection committee should prepare and implement a disinfection policy. This requires consultation between the microbiologist, infection control officer, engineer, pharmacist, supplies officer and representatives of medical, nursing and domestic staff.

1.6 The use of chemical disinfectants should be avoided when heat can be reasonably used as an alternative, for example in thermal disinfection or sterilization.
2.0 Washer-disinfectors and the role of management

Introduction

2.1 This volume of HTM 2030 covers the maintenance and operation of the various types of WDs used in hospitals, laboratories and other healthcare facilities.

2.2 Terminology used in washing and disinfection has long been inconsistent and this has often lead to ambiguities. This HTM introduces a set of terms which, it is hoped, will provide workers in this field with a standard vocabulary and will also be consistent with the EU Standards which are to be introduced in the near future. The glossary contains defined terms referred to in this volume of HTM 2030.

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

2.4 The NHS is no longer protected by Crown immunity and is now subject to the full force of the law, notably in health and safety, medicinal products and consumer legislation. Tighter statutory control, brought in by new European Union Directives, will extend to almost every aspect of disinfection, and practices which were common a few years ago will no longer be acceptable.

2.5 The test, maintenance and reporting procedures described in this HTM are based upon good practice in both the United Kingdom and the rest of Europe, as formalised in new European Standards designed to support the new EU Directives, and are designed to prevent the possibility of gross failure and serious incident.

2.6 Good staff morale is important. Anomalous behaviour which may foreshadow a malfunction of a WD is often first noticed by an alert operator or other relatively junior employee. It is vital that staff feel free to report such observations promptly, and that appropriate remedial action is taken. “Untiring vigilance” demands no less.

Legal framework for washing and disinfection

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

2.8 They may be used for reprocessing, within their intended use, medical devices, sanitary equipment, laboratory equipment, manufacturing equipment and components (for use in the manufacture of medicinal products or medical devices) or cutlery and crockery.
2.9 Users must be clear as to whether the load items they intend to process in a WD are classified as medicinal products or medical devices. While the practical requirements are very similar their implementation is covered by different legislation.

2.10 For the guidance given in this HTM the various types of WDs are presumed to be used primarily as follows:
   a. for medicinal products – laboratory WDs;
   b. for medical devices, WDs for human-waste containers, surgical instruments and utensils, for anaesthetic equipment, for heat labile medical equipment eg endoscopes.

2.11 When a WD is purchased with the intention of processing both medicinal products and medical devices purchasers should ensure that the requirements for both types of product are met.

Medicinal products

2.12 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.


2.14 The GGMP contains guidance on cleaning of components and manufacturing equipment which has implications for the 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.

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

Medical devices

2.16 This volume refers to three EU Directives on the manufacture and supply of medical devices and in vitro diagnostics:
   a. the Active Implantable Medical Devices Directive (Council Directive 90/385/EEC) covers all powered implants or partial implants that are left in the human body. (Heart pacemakers are the most common example of powered implants.) 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 (see paragraph 4.29);
   b. the Medical Devices Directive (Council Directive 93/94/EEC) covers most other medical devices ranging from first aid bandages and tongue depressors through to hip prostheses and will therefore have a wide impact on disinfection. The Directive was adopted by the EU Council on 14 June 1993 and came into effect in the UK on 1 January 1995 as the Medical Devices Regulations;
2.0 Washer-disinfectors and the role of management

c. the In-Vitro Diagnostic Medical Devices Directive will cover any medical
device, reagent product, kit, instrument, apparatus or system which is
intended to be used in vitro for the examination of substances derived
from the human body. Some examples of in-vitro diagnostic devices
are blood grouping reagents, pregnancy test kits, and hepatitis B test
kits.

2.17 Whether, and if so under 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 HTM. Guidance
is given in the MDA Directives Bulletin 18. If necessary advice should be sought
from the Medical Devices Agency (MDA).

2.18 The relevant essential requirements of the Medical Devices Directive
are, inter alia:

- that devices and manufacturing processes be designed to eliminate or
  reduce as far as possible the risk of infection to the patient, user and
  third parties (Appendix 1, paragraph 8.1);
- that devices must be designed, manufactured and packed in such a way
  as to minimise the risk posed by contaminants and residues to the
  persons involved in the transport, storage and use of the devices and to
  the patients (Appendix 1, paragraph 7.2).

2.19 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 Standards for medical devices (BS EN 46001 and BS EN 46002) and
Standards providing guidance on compliance with these Standards (EN 724
and EN 50103).

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

Published Standards

2.21 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 washer-disinfectors for human-waste
containers’ and Part 3 ‘Specification for washer-disinfectors except those used
for processing human-waste containers and laundry’.

2.22 There are no EU Standards, as yet, for WDs. CEN Technical Committee
TC 102 is developing a series of mandated Standards relevant to the Medical
Devices Directive for WDs. There are four parts with the working titles ‘General
requirements’, ‘Washer-disinfectors for human-waste containers’, ‘Washer-
disinfectors for medical devices and surgical instruments’ and ‘Washer-
disinfectors for thermolabile medical devices (eg endoscopes)’. IEC Technical
Committee TC66 is developing Standards for ‘Safety requirements for washer-
disinfectors’.

2.23 When published compliance with these Standards may be used to give
a presumption of conformance to the relevant requirements of the Medical
Devices Directive.
2.24 This edition of HTM 2030 has been written while the new Standards are in the course of development. The guidance given here is designed to be broadly consistent with the emerging Standards but HTM 2030 should not be regarded as a substitute for the Standards themselves when ascertaining compliance with the EU Directives and the UK Regulations that implement them.

2.25 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

2.26 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.

2.27 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 HTM.

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

Water supply

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

Safety

2.30 Extensive guidance on the safe operation of various types of WDs is given within this HTM (Chapters 5 to 11), while guidance on safety practice of testing WDs in given in HTM 2030 ‘Validation and verification’.

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

2.32 The ‘Control of Substances Hazardous to Health (COSHH) Regulations’ place an obligation upon management to ensure that suitable measures are in place 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.

2.33 Some of the substances that may be used in WDs, in particular those employing chemical disinfection or sterilization, have Occupational Exposure Limits (OEL) set out in Guidance Note EH 40 published annually by the Health and Safety Executive. These limits are a statutory maxima and 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.

2.34 The WD, including any special ventilation equipment necessary for its safe operation, will be subject to the COSHH Regulations. These Regulations also include control of biological agents. This is of particular relevance to the operation of WDs which are commonly used to process items that may be heavily contaminated with pathogenic micro-organisms.

Summary of management responsibilities

2.35 HTM 2030 will assist managers and other personnel to ensure that WDs are operated safely and effectively and in compliance with existing and anticipated legislation and Standards. To this end, the major responsibilities of management can be summarised as follows:

a. to ensure that washing and disinfection are carried out in compliance with the law and with the policy of the UK health departments;

b. to ensure that all personnel connected with washing and disinfection, whether NHS employees or contract personnel, are suitably qualified and trained for their responsibilities;

c. to ensure that purchased WDs conform to legal requirements, the minimum specifications set out in British and European Standards and any additional requirements of the UK health departments;

d. to ensure that WDs are installed correctly and safely with regard to proper functioning, safety of personnel and environmental protection;

e. to ensure that newly installed WDs are subject to a documented scheme of validation comprising installation checks and tests, commissioning tests and performance qualification tests before they are put into services;

f. to ensure that WDs are subject to a documented scheme of periodic tests at yearly, quarterly, weekly and (in some cases) daily intervals;

g. to ensure that WDs are subject to a documented scheme of preventative maintenance;

h. to ensure that procedures for production, quality control and safe working are documented and adhered to in the light of statutory requirements and accepted best practice;

j. to ensure that procedures for dealing with malfunctions, accidents and dangerous occurrences are documented and adhered to.
3.0 Statutory requirements

Introduction

3.1 So far as washing and disinfection is concerned, the chief areas of legislation with which managers should be familiar are health and safety, medicinal products and consumer protection including the medical devices regulations.

Health and safety

3.2 The largest body of law with which managers need to be familiar concerns health and safety, in particular the Health and Safety at Work etc Act 1974 (the HSW Act) and its various Regulations.

3.3 The HSW Act and its Regulations require employers to assess the risks to their employees. Attention is drawn to the following hazards which are implicit in the practice of washing and disinfection:

a. the hazard of scalding from escaping steam or water vapour;
b. the high temperatures (up to 100°C) at which WDs are operated;
c. the toxic properties of chemicals used in certain WDs;
d. the infection hazard associated with the microbial pathogens that may be handled by personnel using certain laboratory WDs;
e. the hazard of infection to patients and staff by the inadvertent release of an infected load due to the failure of a disinfection and quality control process;
f. the hazards associated with the handling of heavy and hot loads while loading and unloading WDs;
g. the hazards associated with high pressure leaks from piping used for transfer of water or chemical agents.

3.4 The guidance given throughout this HTM is designed to ensure that these hazards are minimised and that washing and disinfection procedures comply with the relevant legislation and established good practice.

Health and Safety at Work etc Act 1974

3.5 The HSW Act sets out the basic legal responsibilities of employers and employees with regard to health and safety at work.

Management of Health and Safety at Work Regulations 1992

3.7 The core of the Regulations is a requirement of employers to make a systematic assessment of the risks to health and safety of their employees and others arising from work activities.

**Workplace (Health and Safety and Welfare) Regulations 1992**

3.8 The Workplace (Health and Safety and Welfare) Regulations 1992 (SI 1992/3004) are designed to ensure that workplaces meet the health, safety and welfare needs of each member of the workforce, including people with disabilities.

3.9 Most of the Regulations deal with the physical requirements of the workplace. Managers concerned with the operation of WDs should pay particular attention to the Regulations on maintenance, ventilation, temperature, lighting, cleanliness, room dimensions and space, floors, doors, and traffic routes.

**Provision of Use of Work Equipment Regulations 1992**

3.10 The Provision and Use of Work Equipment Regulations 1992 (SI 1992/2932) aim to ensure the provision of safe work equipment and its safe use.

3.11 Work equipment, defined to include “any machinery, appliance, apparatus or tool”, clearly covers WDs and associated equipment. The requirements are numerous, and managers should ensure that all equipment complies with them.

**Pressure Systems and Transportable Gas Containers Regulations 1989**

3.12 These Regulations apply to steam and compressed air services supplying WDs and to those WDs with a pressurised chamber.

3.13 The Regulations define the duties of the competent person: a person or organisation responsible in law for advising on the scope of a written scheme of examination of a pressure system, drawing up the scheme, certifying the scheme as being suitable, and carrying out examination under the scheme.

**Control of Substances Hazardous to Health Regulations 1994**

3.14 The Control of Substances Hazardous to Health (COSHH) Regulations list a number of substances hazardous to health and specify a maximum exposure limit for inhalation, eg glutaraldehyde.

3.15 The Health and Safety Executive (HSE) publishes an annually updated guidance note on current exposure limits – ‘Occupational Exposure Limits (EH40)’.
Table 1 Maximum exposure for glutaraldehyde-based disinfectant

<table>
<thead>
<tr>
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<th>Short-term exposure limit ppm</th>
<th>Long-term exposure limit ppm</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>mg/m³</td>
<td>mg/m³</td>
</tr>
<tr>
<td>Gas</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Glutaraldehyde</td>
<td>0.2</td>
<td>0.7</td>
</tr>
</tbody>
</table>

Notes: The short-term exposure limit is the average exposure over any 15-min period. The long-term exposure limit (LTEL) is the average exposure over any 24-hour period expressed as a single uniform exposure over an 8-hour period. Source: HSE Guidance Note EH40 (1995)

3.16 Users of WDs should note that a “substance hazardous to health” may include a micro-organism which creates a hazard to the health of any person. Suitable precautions are required when handling items that may be contaminated with pathogenic micro-organisms.

Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1985

3.17 Commonly known as RIDDOR, these Regulations impose duties on persons responsible for the activities of persons at work, and on self-employed persons, to report accidents resulting in death or major injury arising out of or in connection with work, and to report specified dangerous occurrences. They also require certain particulars of accidents at work to be reported both to the Department of Health and also to the Health and Safety Executive, and require records to be kept.

3.18 Some WDs may contain pressure vessels as defined under Part 1 of Schedule 1 (see paragraph 3.12).

3.19 Poisoning by chemical agents, eg disinfectants, is a reportable disease listed under Schedule 2.

Manual Handling Operations Regulations 1992

3.20 These Regulations require employers to make an ergonomic assessment of all manual handling operations which involve a risk of injury and to reduce the risk as far as is reasonably practicable. Factors to be assessed include the nature of the task, the load, the working environment and individual capability.

3.21 Managers should assess the risks associated with loading and unloading WDs, whether by loading trolleys or by hand. Top-loading WDs can be especially hazardous if lifting equipment is not available. The mass of the load is not the only source of risk; the temperature and other factors should be taken into account. Risks associated with maintenance and overhauling should also be assessed.

Personal Protective Equipment at Work Regulations 1992

3.22 Managers should assess whether the risks associated with washing and disinfection require the use of personal protective equipment (PPE). Some examples include heat-resistant gloves for use when hot loads are removed from WDs, protective gloves for use when loading contaminated material into WDs, eye or face protection when testing WDs containing pumped fluids and chemical agents, and foot protection for operators loading and unloading WDs.
3.0 Statutory requirements

Consumer protection

3.23 In recent years new legislation has been introduced affording protection to persons who may be harmed by unsafe goods supplied to them. In certain circumstances this may include products from WDs.

Consumer Protection Act 1987

3.24 Part 1 implements EU Council Directive 85/374/EEC (the Product Liability Directive) providing for compensation to be paid to persons injured by a defective product. Under the Act a product is defective “if the safety of the products is not such as persons generally are entitled to expect”, taking the circumstances into account. It is likely that civil action for damages could be taken against a hospital for supplying, for example, “disinfected” products that were not in fact disinfected and caused the infection of a patient.


Electromagnetic Compatibility Regulations 1992

3.26 The Electromagnetic Compatibility Regulations (SI 1992/2372) (the EMC Regulations) impose requirements concerning the electromagnetic compatibility of most types of electrical and electronic apparatus which must be complied with when such apparatus is to be supplied or taken into service.

3.27 A WD (and any ancillary equipment) is a “relevant apparatus” within the terms of the Regulations, and will have to meet Standards for emission of and immunity to electromagnetic disturbance. Note that it is an offence not only to supply but also to “take into service” a WD that does not conform to the Regulations.

3.28 The Regulations do not apply to any WD supplied or taken into service in the EU before 28 October 1992. A WD supplied or taken into service in the UK on or before 31 December 1995 is not required to comply with the Regulations provided it complies with the requirements of the Wireless Telegraphy Acts listed in Schedule 1 of the Regulations.

4.0 Personnel

Introduction

4.1 This chapter introduces the personnel who share the responsibility for the safe and efficient operation of WDs. It gives guidance on qualifications and training and summarises areas of responsibility.

Training

4.2 It is essential that personnel at all levels should have a sound general knowledge of the principles, design and functions of WDs. They should be trained on those types and models of WD with which they are concerned. They should have some knowledge of the basic elements of microbiology in order to ensure personal safety, safety of others and general safety. Training given to individuals should be recorded and reviewed regularly.

4.3 Users working in relative isolation should take care to ensure not only that they are trained in the use of WDs in their charge, but also that they are aware of the changing requirements of the law and good practice as outlined in this HTM.

4.4 Further information is available from NHS Estates and the authorised person (sterilizers).

4.5 Detailed training on a particular model of WD is usually available from the manufacturer, either on site (such as during validation) or by courses at their premises.

Functional responsibility

4.6 There have been profound changes in the management philosophy of the NHS over recent years. With the wide range of circumstances in which a WD may be employed, from a busy sterile services department in a major general hospital to a small clinic, it is not possible to prescribe a universally applicable management structure for washing and disinfection.

4.7 The approach chosen for this HTM is to identify the distinct functions that need to be exercised and the responsibilities that go with them. The titles given are therefore generic; they describe the individual’s role in connection with washing and disinfection but are not intended to be prescriptive job titles for terms of employment. Indeed, many of the personnel referred to may not be resident staff but employed by outside bodies and working on contract. Some of them will have other responsibilities unconnected with washing and disinfection and in some cases the same individual may take on more than one role.

4.8 In every case, however, it is possible to identify a user who is responsible for the day-to-day management of the WD. The philosophy of this HTM is to invest the user with the responsibility for seeing that the WD is operated safely and efficiently.
4.0 Personnel

4.9 In cases where steam is generated in a pressure vessel within the WD, the law requires that a competent person (pressure vessels), who is not the user, be designated to exercise certain responsibilities of inspection (see paragraph 4.17).

4.10 For small installations where the user is qualified to perform all required test and maintenance functions, no other personnel may be necessary. However, the Department strongly recommends that in all cases the user receives professional advice from a microbiologist.

Key personnel

4.11 The following personnel are referred to in this part of HTM 2030. Further information including qualifications and areas of responsibility can be found in Volume 1 of HTM 2010.

Management

4.12 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.

4.13 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

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

4.15 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 equipment in use of medical products the user is normally the production manager in charge of the manufacturing process.

4.16 The principal 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)

4.17 The competent person (pressure vessels) is defined as a person or organisation designed by management to exercise certain legal responsibilities with regard to the written scheme of examination of any pressure vessel associated with a WD described in the ‘Pressure Systems and Transportable Gas Containers Regulations (Northern Ireland) 1991’ apply in Northern Ireland.
Transportable Gas Containers Regulations 1989’. The shorter term “competent person” is used in this HTM.

4.18 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 low, 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.

4.19 The principal 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.

4.20 Most insurance companies are able to advise on appointing a competent person. The authorised person (sterilizers) will also be able to provide advice.

4.21 Further information about the written scheme of examination will be found elsewhere in this HTM.

Authorised Person (Sterilizers)

4.22 The Authorised Person (Sterilizers) is defined as a person designated by management to provide independent auditing and advice on sterilizers and sterilization and to review and witness validation (see HTM 2010 Volume 1 for a full definition of the responsibilities of the Authorised Person (Sterilizers) with respect to sterilizers and the qualifications and experience required). The Authorised Person (Sterilizers) is also able to provide independent auditing and advice on washing/disinfection and WDs and to review and witness validation processes of these machines. The abbreviation AP(S) is used in this HTM.

4.23 At the discretion of the management the function of the AP(S) may be carried out by an independent person, not registered as an AP(S), but who can demonstrate, to the satisfaction of management, previous training and experience appropriate to carry out the designated tasks in respect of WDs.

4.24 The principal responsibilities of the AP(S) are as follows:

a. to provide general and impartial advice on all matters concerned with sterilization;
4.0 Personnel

b. to advise on programmes of validation;

c. to audit reports on validation, revalidation and yearly tests prepared by the test person;

d. to advise on programmes of periodic tests and periodic maintenance;

e. to advise on operational procedures for routine production.

Test Person (Sterilizers)

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

4.26 The principal responsibilities of the TP(S) 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 liaise as necessary with the authorised person (sterilizers);

d. to conduct the validation test specified in HTM 2030 ‘Validation and verification’ and to prepare the validation report;

e. to conduct the periodic test specified in HTM 2030 ‘Validation and verification’ and to prepare reports as required by the user;

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

Maintenance Person (Sterilizers)

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

4.28 The principal responsibilities of the MP(S) are as follows:

a. to carry out the maintenance tasks outlined in this volume;

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

4.29 A maintenance person who has a minimum of five years’ experience in the maintenance of WDs may, following suitable training and by agreement with the authorised person, perform the duties of the test person for the daily, weekly and quarterly tests described in the ‘Validation and verification’ volume of this HTM.
Microbiologist (Sterilizers)

4.30 The Microbiologist (Sterilizers) is defined as a person designated by management to be responsible for advising the user on microbiological aspects of washing and disinfecting non-medicinal products. The shorter term “microbiologist” is used in this HTM.

4.31 The principal 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 WDs which have been tested by microbiological methods.

Control of Infection Officer

4.32 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

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

Quality Controller

4.34 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

4.35 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

4.36 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.
4.0 Personnel

Manufacturer

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

Contractor

4.38 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

4.39 The purchaser is defined as the person or organisation who orders the WD and is responsible for paying for it.
5.0  Operational management: an overview

Introduction

5.1  It is important that all WDs are effective in achieving the performance required to produce a clean and disinfected product, and that they are safe in operation.

5.2  Failure to achieve the required standard of cleanliness may also impair the capability of the process to achieve disinfection and/or subsequent sterilization.

5.3  The cleanliness and microbial safety of all products processed in a WD is ultimately dependent upon the care taken by the personnel responsible for its design, manufacture, installation, operation, test and maintenance.

5.4  Washing and disinfection may appear to be relatively simple processes, but considerable care is needed to consistently achieve satisfactory results. The quality and safety of the product obtained from a WD ultimately depends upon the vigilance of skilful personnel fully trained in the operation of WDs.

5.5  Responsibility for assurance on these points rests variously with the AP(S), the TP(S), the MP(S), the microbiologist, the control of infection officer, and the user.

Maintenance

5.6  Decontamination processes are among those processes which have to be validated before use. In consequence the performance of the process has to be routinely monitored (see HTM 2030 'Validation and verification') and the equipment has to be maintained in good working order.

5.7  The maintenance of WDs should, therefore, meet the following requirements:

   a.  preventive maintenance should be planned and performed in accordance with documented procedures;

   b.  the procedure for each planned task, and the frequency at which it is carried out, should be specified and documented;

   c.  the WD should not be used to process contaminated loads until all maintenance tasks have been satisfactorily completed and recorded;

   d.  records of maintenance should be retained as specified in BS EN ISO 9001:1994 or BS EN ISO 9002:1994;

   e.  the maintenance scheme, maintenance procedures and maintenance records should be reviewed periodically by a designated person who should be appropriately qualified and experienced.
Safety precautions

5.8 Whether products which have been processed in a WD are safe to handle and/or use, as appropriate, is ultimately dependent on the vigilance of all personnel responsible for its operation.

5.9 Effective decontamination necessitates, in many cases, complex operating cycles. Protection is provided, in the first instance, by fail-safe design principles some of which also serve to protect the product by indicating when an ineffective operating cycle has occurred.

5.10 However fool-proof the design, any safety device can be defeated ultimately, either wantonly or accidentally. To ensure that this does not occur requires the continuing vigilance of skilful personnel fully trained in the operation of WDs.

5.11 Some WDs are only intended to perform an initial step in the reprocessing of soiled re-usable items. Care should be taken to ensure that items which have been cleaned and disinfected in a WD are, when necessary, subjected to terminal sterilization prior to their use on patients.

5.12 To prevent the hazard of burning or scalding the door should be interlocked to prevent it being opened in mid-cycle. In the event of a fault there may be an escape of hot water vapour when the door is opened or hot water (up to 93°C) may be retained within the chamber and load.

5.13 Washing is a wet process and water dropping on to the floor can create a serious hazard of slipping and falling for personnel. Any leaks should receive urgent attention from maintenance staff and any spillages should be cleaned up as soon as possible.

Management should have a safety policy to deal with spillages which considers both the chemical and microbiological hazards that may be posed.

A copy of the documented procedures to deal with spillages should be available in the vicinity of each WD. The user, and all operators who may use the WD, should be trained in the implementation of these procedures.

5.14 Overloading load baskets, and/or load carriers, can cause a hazard and will also impair the efficacy of the disinfection process. Operators and maintenance personnel should ensure that the loading does not exceed the manufacturer’s stated capacity for the loading accessories in use.

5.15 Detergents and other additives are, or may be, caustic and can cause adverse effects to exposed tissues; operators and maintenance personnel should wear protective gloves, a face shield and water-proof clothing whenever handling chemical additives or servicing the injection pumps or pipework. Contact with the eyes and skin or ingestion of chemical additives should be avoided.

5.16 Operators and maintenance personnel should read and follow the precautions and instructions given in the material safety data sheet and on the label prior to handling any chemical additive, refilling the container or servicing the injection pump and pipework.

All staff who may be exposed to contamination by any chemical additive should be trained in the action they should take to minimise harm to themselves and others in the vicinity. This will include: first aid; alerting...
emergency services if necessary; methods for cleaning and decontaminating the affected area; and the correct disposal of the materials used. There should be a written procedure detailing the actions to be taken in the event of spillages and contamination of personnel.

5.17 Any equipment issued to operators should comply with the ‘Provision and Use of Work Equipment Regulations (1992)’.

5.18 Operators and maintenance personnel should be issued with appropriate personal protective equipment (PPE) complying with the ‘Personal Protective Equipment at Work Regulations (1992)’. In providing protection against, or minimising the risks from, hazards to health and safety priority should be given to engineering controls and safe systems of work; PPE should always be regarded as a last resort.

Equipment damage

5.19 The user should ensure that chemical additives used in the decontamination process are compatible with the materials of which the WD is constructed and also with the items to be processed.

5.20 Most WDs are made partly or wholly of stainless steel; the water supplied to the chamber, and the detergent and other chemical additives used, should have a low chloride content to minimise the risk of corrosion.

5.21 Lubricants for squeeze tubes on peristaltic pumps and other dispensing devices should be chosen and used in accordance with the manufacturer’s instructions.

5.22 Care should be taken to ensure that the walls of ultrasonic tanks are not scratched as this can cause serious cavitation erosion.

5.23 Operators should be instructed never to drop or rest load items directly on the bottom of an ultrasonic tank.

Performance qualification

5.24 New load items should not be processed until:

a. performance qualification (PQ) tests as specified in HTM 2030 ‘Validation and verification’ have been conducted by the TP(S) to the satisfaction of the user and the AP(S); or

b. the user is satisfied that the new load item is represented by one of the existing loading conditions/process cycles for which a PQ report exists; or

c. the instructions from the manufacturer of the item are sufficiently detailed and specific that the appropriateness of the proposed treatment is readily apparent.

5.25 The user, in consultation with the manufacturer(s) of the load items, the AP(S) and the control of infection officer as necessary, should ensure that the load is suitable for the process to which it is to be exposed. This should include consideration of the compatibility of all process chemicals used.

In the absence of specific instructions silicone-based lubricants should always be used since petroleum-based lubricants can cause serious damage to many types of plastic tube.
5.26 The process selected will depend on the nature of the load and its ability to withstand the environmental conditions present during the operating cycle. The rates of change of cycle variables, such as temperature and pressure, may also need to be considered.

5.27 Before selecting a process it may be necessary to carry out preliminary tests on the product, or on a surrogate product, to determine both the levels and rates of change of the cycle variables necessary to achieve the required result and to determine which can be tolerated by the product without causing unacceptable changes in its performance.

Loading

5.28 The user should ensure that each load is presented to the process in accordance with documented procedures established and tested during PQ.

5.29 Overloaded baskets or load carriers will result in inefficient cleaning and disinfection.

5.30 Cannulated load items, which are intended to be connected to spigots on the load carrier to ensure flushing of the lumen, will not be adequately cleaned and disinfected if they are not properly connected.

5.31 Small and light items should be secured with a hold-down screen or by other means; if they are free to move around there is a serious risk of damage to the instruments. Small sharp instruments which have moved within the load may also represent a hazard to staff who have to subsequently handle the load.

5.32 Load carriers should only be used with the items for which they were intended.

Documentation

5.33 When the WD is used to process medical devices, other than sanitary appliances, intended for use on a patient without further processing, eg sterilization, each production cycle should be fully documented. The user should ensure that the records are kept securely. Cycles which were aborted, for whatever reason, should also be noted along with the remedial action taken.

5.34 Operators should be encouraged to note and report any indication that the WD may not be working as expected.

5.35 A process log should be kept for those products, other than human-waste containers, which will be used without being subjected to further processing (eg sterilization). This will include items such as anaesthetic accessories and some fibre-optic endoscopes.

5.36 If in doubt as to whether records are required, and if so which records are necessary, the user should consult the AP(S).
Post-decontamination inspection and release for further processing

5.37 The user in consultation with the AP(S) should establish and document procedures to ensure that loads are not released for use or further processing, e.g., sterilization, until the user is satisfied:
   a. that the disinfection stage of the process has been reproduced within the permitted tolerances established during commissioning and PQ; and
   b. that the cleaning stage of the process has been reproduced within the permitted tolerances established; and/or
   c. that visual inspection of the load shows that an acceptable standard of cleanliness has been obtained.

5.38 The procedures should ensure that:
   a. the load has been correctly positioned in the loading basket and/or on the load carrier;
   b. that the settings for the operating cycle are in accordance with the specification for that load type;
   c. that the instrument/indicator readings and/or chart record for the cycle conforms with the data established during validation within the permitted tolerances;
   d. that the decontaminated load shows no obvious defects – such as damage, residual soiling or staining – which may suggest a faulty operating cycle.

5.39 Whenever an operator has cause to suspect that the load may not have been properly disinfected the load must not be released. The user should be informed immediately.

5.40 A small percentage of load items which remain soiled after processing may not be sufficient cause to reject the entire load. The rejected items should be returned for reprocessing. However, the cause of the failure to clean all the items in the load should be investigated.

5.41 Documented procedures for reprocessing rejected loads should be agreed between the user and the AP(S). The method by which rejected loads are returned for reprocessing should be chosen to ensure that product flow in a controlled environment is not compromised.

5.42 For loads which are to be used in connection with the manufacture of medicinal products the quality controller will establish the procedures for product release.

5.43 After decontamination and before release of the product for use or further processing, as appropriate, the conditions for storage and handling should not compromise the cleanliness or freedom from microbial contamination of the product.

5.44 When a single-door WD is in use a system to clearly differentiate between processed and unprocessed loads may be required.
6.0 Maintenance

Introduction

6.1 Disinfection, and to a great extent, cleaning are processes whose efficacy cannot be verified retrospectively by inspection or testing of the product before use. For this reason decontamination processes (cleaning and disinfection and/or sterilization) have to be validated before use, the performance of the process routinely monitored, and the equipment maintained.

6.2 Means of ensuring that a WD is fit for its intended purpose will include the validation and testing programme specified in HTM 2030 ‘Validation and verification’, and also the programme of planned maintenance as described in this chapter.

6.3 The philosophy of maintenance and testing embodies two main principles to ensure that the required standards of performance and safety are met and maintained:

- all WDs are subject to a carefully planned programme of tests to monitor their performance;
- all WDs are subjected to a planned programme of preventive maintenance.

Expertise on the maintenance of WDs is available at two levels, the MP(S) and the AP(S).

Testing of WDs is dealt with in HTM 2030 ‘Validation and verification’.

Planned maintenance (PM) programme

Design of a PM programme

6.4 The PM programme recommended by the manufacturer should be used when it is available. The maintenance programme may be modified subsequently to take account of equipment use, equipment history and local conditions after a suitable period of operational experience.

If no PM programme is available from the manufacturer a maintenance programme should be drawn up in consultation with the AP(S) and MP(S).

6.5 A set of procedures should be developed for each model of WD, each containing full instructions for a particular maintenance task.

6.6 The frequency with which each task will need to be carried out will depend, in part, on the usage level for the WD and also on the quality of the water supplied to the WD. It may be necessary to adjust the programme so that work is carried out more frequently on WDs which are heavily used and/or are supplied with hard water.
6.7 It is important that maintenance is planned so that the WD is out of service as little as possible.

6.8 Systematic records should be kept of all maintenance work undertaken both to demonstrate that the work has been carried out and also to facilitate periodic review of the PM programme.

Maintenance and facilities management software packages (e.g. WIMS) may be used to maintain a full technical and financial history of the equipment.

Warranty period

6.9 After the purchase of a new WD the manufacturer may carry out certain inspection and maintenance procedures under the terms of the warranty. This may not be a full PM programme. The user should ensure that the complete PM programme is carried out by the MP(S) during the warranty period.

6.10 The user should also comply with any reasonable instructions from the manufacturer during the warranty period.

Review of a PM programme

6.11 The PM programme should be reviewed at least annually to ensure that the equipment is being fully maintained but without any unnecessary maintenance activity.

6.12 The review should aim to identify:
   a. the adequacy of maintenance records and compliance with the PM programme;
   b. any emerging defects;
   c. any changes required to the PM programme;
   d. any changes required to any maintenance procedure;
   e. any additional training required by maintenance personnel.

6.13 Proposed changes to the PM programme should be made in consultation with the WD manufacturer whenever possible.

Routine housekeeping

6.14 Certain maintenance tasks may be carried out by the user, or by the operator under the user’s supervision, and should be recorded in the WD log.

6.15 Examples of such tasks include:
   a. checking that the rotating spray arms are free to rotate;
   b. checking that nozzles are not blocked;
   c. removal and cleaning of strainers and filters;
   d. checking that the supply of chemical additives is sufficient for the day’s use and replenishing if necessary;
   e. cleaning the inside of the chamber;
f. cleaning the external surfaces of the WD washing of loading side conveyors and trolleys;

g. for WDs with a built-in water softener, checking the level of salt in the regeneration tank and replenishing if necessary.

Overhauls

6.16 The user should arrange for each WD to receive periodic overhauls. For WDs which incorporate a pressure vessel this should be timed to precede the examination of the pressure vessel by the competent person and the yearly tests.

6.17 Improvements and modifications recommended by the WD manufacturer should be reviewed and considered for implementation before each overhaul.

6.18 The overhauls, and any necessary inspections, should be scheduled so that in any particular installation only one machine needs to be withdrawn from service at a time.

Inspection of pressure vessels

6.19 Under the ‘Pressure Systems and Transportable Gas Containers Regulations 1989’ all WDs which incorporate pressure vessels are subject to a periodic inspection by a competent person (see paragraph 3.13).

6.20 The AP(S) will advise on the application of the Regulations to any particular installation.

6.21 The competent person has five principal duties under the Regulations:

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;

d. assessing the results of the examinations;

e. reviewing the written scheme of examination for its suitability.

6.22 The user should liaise closely with the competent person to ensure that the written scheme of examination is accommodated within the maintenance and testing programmes.

6.23 The competent person may require certain examinations to be carried out more frequently than recommended by the manufacturer.

6.24 Each written scheme of examination should specify detailed procedures for, and the frequency of, examination and be regularly reviewed and updated.
Features requiring special attention

Steam generators

6.25 Steam generators, provided as an integral part of some WDs, are steam boilers and they should be subject to a written scheme of examination for pressure vessels.

6.26 Steam generators constructed from stainless steel will be subject to the risk of stress corrosion cracking. To minimize the risk the manufacturer’s guidance on feedwater quality should be followed.

Stainless steel chambers

6.27 Stainless steel is used in the manufacture of many WD chambers. Over a wide range of specifications, stainless steels are susceptible to cracking from crevice corrosion and from stress corrosion initiated by chemical attack.

Leak tightness of doors

6.28 The door(s) of the WD are intended to prevent the escape of fluids into the surrounding environment, ie to ensure freedom from aerosols which may be potentially infectious in the work place.

6.29 Damaged door seals are the major potential source of leaks and should receive careful attention as advised by the manufacturer.

6.30 The working life of door seals may be prolonged by regular cleaning.

6.31 Door seals should be renewed with spares provided, or approved, by the manufacturer at recommended intervals or when there is any sign of damage/deterioration.

Door interlocks

6.32 The interlocks on door(s) of the WD are intended to
   a. prevent the operator gaining access to the load during processing;
   b. prevent both the loading and unloading doors being open at the same time on “pass-through” WDs;
   c. prevent the operator gaining direct access to a load that has not been satisfactorily processed.

6.33 Maintenance and inspection of door safety devices and door interlocks should be carried out in accordance with the WD manufacturer’s written instructions.

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

Chemical dosing systems

6.35 Admission of the correct amount of chemical additive at the right time in the operating cycle is essential to the correct functioning of a WD. The
6.0 Maintenance

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

a. visual inspection of all piping to ensure freedom from leaks;

b. visual inspection and/or testing that neither the delivery or pick-up piping is blocked by coagulated or hardened chemical additive (many of the chemical additives used are a viscous suspension) – and cleaning or replacing piping as necessary;

c. lubrication of the pinch tubing on peristaltic pumps in accordance with the manufacturer’s instructions;

d. verification that the volume dispensed is within the specified limits.

Water sprays and jets

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

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

• checking that the rotating spray arms, both installed within the chamber and located on load carriers, are free to rotate;

• checking that nozzles are not blocked – clean and/or replace if necessary;

• checking for wear in bearings of rotating parts – replace any worn parts as necessary;

• checking the mating of any necessary connection between the load carrier and the water supply in the chamber.

Ultrasonic transducers

6.37 Many ultrasonic cleaners are not fitted with means to provide continuous monitoring of performance. Transducers can fail or become detached from the ultrasonic tank without being noticed by the operator (other than by the deterioration in the cleaning performance).

6.38 Periodic functional testing of ultrasonic cleaners is described in HTM 2030 ‘Validation and verification’.

6.39 The tank of the ultrasonic cleaner should be cleaned with a suitable neutral detergent and soft brush at least weekly.

Instruments

6.40 Instruments fitted to WDs should be maintained and calibrated in accordance with the manufacturer’s instructions. Any instrument which is reading incorrectly or inconsistently should be repaired by the manufacturer, or scrapped if it is not economical to repair.

6.41 Instruments which are consistent in their readings but are slightly inaccurate compared with a reference instrument should be checked for zero and span and then adjusted to work correctly at the value of interest, eg at the normal working temperature.
6.42 An instrument case should never be left open and any broken glass should be replaced promptly.

6.43 Temperature measuring systems are subject to both inherent errors and to loss of calibration with use. Temperatures read from an indicator or recorder should be treated with caution and interpreted in the light of the established characteristics of the particular measuring system, the load and data from previous cycles.

6.44 Temperature recorders should be used to record the attainment of thermal disinfection conditions for all critical applications.

6.45 The absolute minimum intervention should be made to recording systems which are functioning correctly. Any adjustments should be strictly in accordance with the manufacturer’s instructions.

6.46 Persons who change charts, print rolls and other consumables on recording instruments should be authorised to do so by the user. They should be fully trained and should be aware of the delicate nature of the instruments.

Water treatment plant

6.47 The correct functioning of water treatment plant incorporated in, or otherwise supplying, a WD is essential to maintaining the required cleaning performance.

6.48 The system should be inspected periodically to ensure that it is free from leaks.

6.49 The quality of water supplied should be verified by testing at weekly intervals for a period of three months following commissioning or major repair/overhaul of the water treatment system. At the discretion of the AP(S) and the microbiologist, the frequency of testing may be reduced to monthly intervals after three months of satisfactory weekly test results.

6.50 For water supplied from a de-ioniser or reverse osmosis plant this should include checking the pH and the conductivity to verify that these remain within specified limits.

6.51 When a water softener is used the water supply should be tested for hardness to ensure it remains below the specified maximum concentration of calcium salts.

6.52 Water intended for use as the final rinse water on items to be used invasively on patients or in the production of parenteral medicinal products should be tested for the presence of bacterial endotoxins.

6.53 Water intended for use as the final rinse water after a chemical disinfection process for load items which will not then be sterilized should be tested both for the presence of bacterial endotoxins and for total viable microbial count.

Ventilation plant

6.54 Correct operation of ventilation plant is essential to ensure:

a. the safe operation of WDs which include a chemical disinfection stage;
b. the efficient operation of the drying stage (where this is included);
c. the maintenance of a comfortable working environment.

6.55 All ventilation systems associated with a WD should be inspected, serviced and maintained at least every six months. Guidance on maintenance is given in HTM 2025.

6.56 WDs which include a chemical disinfection stage should have the associated ventilation system examined and tested annually.

6.57 Before undertaking maintenance work on the cabinet, or its associated ventilation system, it may need to be decontaminated and the advice of the designated safety officer should be sought. A permit-to-work system should be in operation.

Returning a washer-disinfector to service

6.58 Whenever any work has been carried out on a WD, whether or not this was part of the PM programme, the user should be satisfied that it is fit for use. Following major repairs, overhauls etc which may affect the performance of the WD the user and AP(S) should draw up a schedule of checks and tests to be carried out before the WD is returned to service. This should include some or all of the recommissioning (yearly) tests specified in HTM 2030 ‘Validation and verification’.

Trouble-shooting

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

Incorrect loading:
   a. items which are not correctly located in an appropriate load carrier will not be subjected to the intended washing process;
   b. overloaded baskets and load carriers will allow some load items to shield others from spray jets etc;
   c. hinged instruments which are not opened prior to washing will not be effectively cleaned.

Blocked spray jets, spray arms that are not free to rotate, or a blocked strainer in the chamber base.

Soiled instruments which have been stored for prolonged periods before decontamination – blood and protein will coagulate if stored for more than eight hours making this hard to remove.

Soiled instruments subjected to heat treatment before decontamination – this will lead to coagulation of blood and protein making this hard to remove.

Incorrect choice or quantity of detergent:
   a. the detergent chosen must be compatible with the loads to be processed, the soil to be removed and the quality of water supplied;
b. malfunction of the dosing system may cause the wrong quantity of chemical additive to be used – too little will not provide the detergency required but too much may also impair cleaning by causing excessive foaming etc.

Inappropriate water quality:

a. initial flush with water which is too hot will lead to coagulation of blood and protein making this hard to remove;

b. the hardness of water used during washing must be compatible with the detergent chosen;

c. hard water used in the final rinse will leave deposits on the surface of instruments.
7.0 Washer-disinfectors for human-waste containers

Introduction

7.1 This type of WD is used to empty, clean and disinfect human-waste containers (eg bedpans, urine bottles, suction jars); both those which are not required to be sterile, eg bedpans (but are required to be disinfected), as well as those which subsequently may be subjected to sterilization, eg suction bottles.

7.2 Disinfection is achieved by direct contact of the load with water, or steam at a pressure near to atmospheric pressure, to raise the temperature of the surface of the load to a specified temperature for not less than a specified time, or a combination of conditions providing equivalent lethality.

7.3 The key requirement for WDs of this type is the safe emptying of the human waste (faeces, urine, blood etc) and the effective cleaning and disinfection of the items for re-use.

7.4 Two distinctly separate types of WD are used for this purpose: a flusher-disinfector in which cleaning is achieved by the physical action of jets of water and no detergent is used (although a de-scaling agent may be used); and a WD which incorporates a detergent washing stage.

Safety precautions

7.5 The area in which the WD is located should be provided with appropriate equipment to deal with spillage from the containers during transfer to the WD (see paragraph 5.13).

7.6 At the end of the operating cycle the washed and disinfected containers may be too hot to handle without protective gloves; containers may also retain significant volumes of hot water with the attendant risks of scalding. Operators should be trained in the use of the WD and provided with appropriate protective clothing.

7.7 Many of the chemical additives used as anti-scaling agents are toxic, irritant and corrosive. They are potentially hazardous and require careful handling and secure storage (see paragraphs 5.15 and 5.16).

Load handling/presentation

7.8 Load carriers are designed for particular types of containers; if it is intended to process a different container the manufacturer’s advice on an appropriate load carrier should be sought.

7.9 The use of an inappropriate load carrier may prevent safe emptying of the container and may not permit effective cleaning and disinfection to take place.
Most WDs for human-waste containers are single-door machines; the area in which they are located should provide facilities for the segregation of containers awaiting processing and those that have been processed. These areas should be maintained in a good state of repair to facilitate the frequent cleaning which is required.

Selection of cycle variables and chemical agents

WDs which are connected to a hard water supply may need to include the use of a de-scaling agent to prevent the build-up of lime-scale on the containers being processed.

WDs for human-waste containers may be provided with a drying stage but this is rarely used for ward installations.

The operating cycle may combine the disinfection stage with the final rinse leaving the containers at high temperature at the end of the cycle. The operator should be provided with insulated gloves to allow safe removal of these hot items; being hot any residual moisture evaporates very quickly.

An option to use a cold final rinse, after disinfection, may be employed to facilitate the safe removal of the containers which will usually then require manual drying before use.

Cycle monitoring

The WD should be provided with either a temperature recorder to monitor and record the temperature attained during the disinfection stage or an indication from the automatic controller that the specified temperature was maintained for the specified time during the disinfection stage.

Product release

Before a product is released for re-use the operator should verify the successful completion of the disinfection stage and visually inspect each load item for cleanliness.

A lime-scale deposit on the containers is not only unsightly but also makes the container more difficult to clean.
8.0 Washer-disinfectors for anaesthetic accessories

Introduction

8.1 This type of WD is used to process anaesthetic and respiratory accessories; both those which are not required to be sterile (but are required to be disinfected) as well as those which will be subject to further processing, eg sterilization.

8.2 Disinfection is achieved by direct contact of the load with water, or steam at a pressure near to atmospheric pressure, to raise the temperature of the surface of the load to a specified temperature for not less than a specified time, or a combination of conditions providing equivalent lethality.

8.3 The key requirement for WDs of this type is the circulation of water (and/or other aqueous solutions), used for washing, and hot air, used for drying, through the lumen of hollow items.

8.4 The facility to process anaesthetic accessories may be provided by a dedicated load carrier using a WD for instruments (see Chapter 9). A separate drying cabinet is often advantageous when a dedicated load carrier is used in a WD for instruments. Drying times for anaesthetic accessories are much greater than for instruments and the use of a separate drying cabinet improves the overall throughput of the WD.

8.5 WDs for anaesthetic accessories may incorporate a drying stage in the automatic process or there may be a separate drying cabinet.

Product compatibility

8.6 The instructions of the manufacturer of the anaesthetic accessories should be followed regarding the suitability of the various items for processing in a WD for anaesthetic accessories.

8.7 A neutral detergent or washing without a detergent may be necessary for some products, eg laryngeal masks made of silicone rubber.

8.8 The maximum temperature attained during disinfection and drying may need to be controlled to minimise the oxidative degradation of rubber materials.

Load handling/presentation

8.9 The use of a load carrier specifically intended for anaesthetic accessories is essential.

8.10 Items with a lumen should be placed over, or connected to, the appropriate nozzle on the load carrier to ensure the free passage of fluids through the lumen during processing.
8.11 Items such as breathing bags and sets and self-inflating resuscitator sets (including valves) may need to be disassembled before being placed in an appropriate load carrier.

8.12 Other items such as Magill forceps and tubing clamps can be decontaminated in a WD for instruments (see Chapter 9).

Selection of cycle variables and chemical agents

8.13 An initial flush (pre-rinse) assists the removal of mucous, blood and other body fluids before washing commences. The water should be at a low temperature to avoid coagulation of proteinaceous material. Organic matter not loosened by the flushing stage may become coagulated during, and not be removed by, the wash cycle.

8.14 Anaesthetic accessories made from plastic may need to be washed, disinfected and dried at temperatures lower than those normally used for instruments and utensils.

8.15 The operating temperature for the drier is a balance between the speed of drying and the longevity of anaesthetic accessories made of rubber.

8.16 The importance of an effective drying stage cannot be over emphasised. Items which are left wet or damp will rapidly become re-colonised with micro-organisms.

8.17 The compatibility of all materials and items to be processed should be established by reference to the manufacturer’s instructions, or when necessary by appropriate performance qualification testing.

Cycle monitoring

8.18 WDs used to disinfect anaesthetic accessories intended for re-use without further processing should be equipped with a temperature recorder, independent of the automatic controller, to monitor and record the temperature attained during the disinfection stage.

8.19 It is desirable that they should be equipped with means of monitoring, directly or indirectly, the flow of water during the flushing and washing stages and the flow of air during the drying stage.

Product release

8.20 Before anaesthetic accessories intended for re-use without further processing are released the recorded cycle variables should be checked to ensure that they are within acceptable limits for the process.

8.21 The load items should be inspected for cleanliness and dryness and to ensure that there are no signs of physical deterioration. For complex items, eg valves, consideration should be given to function testing using a medical grade compressed air supply.

8.22 Items for use without further re-processing should be packaged to protect them from adventitious contamination.
9.0 Washer-disinfectors for instruments and utensils

Introduction

9.1 This type of WD is used to process surgical instruments, instrument trays and re-usable containers and hollowware.

9.2 Disinfection is achieved by direct contact of the load with water, or steam at a pressure near to atmospheric pressure, to raise the temperature of the surface of the load to a specified temperature for not less than a specified time, or a combination of conditions providing equivalent lethality.

Safety precautions

9.3 At the end of the operating cycle the washed and disinfected load may be too hot to handle without using protective gloves; bowls and receivers (particularly those made of polypropylene) may also retain significant volumes of hot water with the attendant risks of scalding. Operators should be trained in the use of the WD and provided with appropriate protective clothing (see paragraph 5.18).

9.4 Many of the chemical additives used are toxic, irritant and corrosive. They may be hazardous and will require careful handling and secure storage (see paragraphs 5.15 and 5.16).

9.5 A written procedure should be available for the filling or connection of all chemical additive containers and staff whose duties include this task should receive formal training.

9.6 Adequate protective clothing, washing and eye washing facilities should be provided. Appropriate hazard labels should be displayed in the vicinity of use.

9.7 When the chemical additive(s) used has a volatile component the measurement of environmental concentrations may be necessary both during commissioning and as periodic routine checks.

9.8 During loading there should be minimal handling of contaminated instruments and equipment. Staff should be trained in the appropriate procedures and provided with suitable protective equipment including gloves and eye protection.

9.9 Before transferring instruments to the WD operators should carefully check the returned instrument trays for hazardous items, eg scalpel handles with the blade left attached. When present, hazardous items should be carefully removed using, if necessary, handling equipment such as forceps or cheatals.

9.10 Operators should dispose of any sharps found into a sharps disposal container complying with BS 7320:1990.
Product compatibility

9.11 The compatibility of all materials and items to be processed should be established by reference to the manufacturer’s instructions, or when necessary by appropriate performance qualification testing.

9.12 Factors to be considered in determining the compatibility of the load to the WD process include, but are not necessarily limited to:
   a. whether or not the load can be immersed in water;
   b. the availability of an appropriate load carrier;
   c. the maximum operating temperature (this will usually occur during the thermal disinfection or drying stages);
   d. the internal pressure to which the lumen of a cannulated instrument may be subjected;
   e. the mechanical damage which may occur from the impact of water jets or other items in the load;
   f. the compatibility of chemical additives used – both with the instrument itself and in combination with other load items (when acidic chemical additives are used metal items of different composition in the same load may be subject to electrolytic corrosion).

Load handling/presentation

9.13 Load carriers specific to the type of load should be used to ensure that all surfaces to be cleaned and disinfected will be exposed to the action of the water jets, will not be dislodged by the water jets and will drain freely.

9.14 For single-door machines facilities to allow segregation of the handling equipment, eg trolleys used for clean and dirty items, is required.

Selection of cycle variables and chemical agents

9.15 A flushing (pre-rinse) stage assists the removal of blood and other body fluids before washing commences. The water used for flushing should be at a low enough temperature to avoid coagulation of proteinaceous material. Organic matter not loosened by the flushing stage may become coagulated during, and not be removed by, the wash cycle.

9.16 The choice of detergent will be based upon a number of factors. These include:
   a. the quality of water available;
   b. the nature of the soiling to be removed;
   c. the nature of the washing process.
Advice should be sought from both the WD and detergent manufacturers.

For most applications mild alkaline detergents, up to pH 10.5, are preferred. The alkalinity contributes to the detergent action by the saponification and emulsification of fats and oils, by the peptidisation of proteins and by softening the water. The presence of alkaline builders also has a synergistic effect with surfactants present in the formulation.
9.17 A low foaming detergent will be required for most WDs since foaming will impair the wash action.

9.18 The use of enzymic detergents may be considered. These are most effective when used for soaking instruments since the contact time is of importance. Many enzymic cleaners are inactivated at the high temperatures used in wash cycles with non-enzymic detergent.

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

9.20 The rinse stage may include a neutralising agent to counteract the detergent and/or minimise the effect of hard water which otherwise would cause "spotting" on the instruments.

9.21 The rinse may include an additive to facilitate free draining of water (rinse aid). Additives intended to lubricate hinged instruments (instrument milk) are also available. The use of these lubricants is generally contra-indicated. Instruments requiring lubrication may be identified on inspection after washing and disinfection and individually lubricated.

9.22 The final hot rinse may be combined with the disinfection stage.

9.23 Water purified by de-ionisation or reverse osmosis is preferred for the final rinse stage since this gives the lowest levels of process residuals and minimises the requirement for rinse additives.

**Cycle monitoring**

9.24 The WD should be equipped with means to provide independent monitoring of all critical cycle variables.

9.25 The following variables may need to be monitored for each of the listed stages – together with the duration of each stage:

**Flushing stage:**
- pump pressure or flow rate for water;
- temperature of water.

**Washing stage:**
- pump pressure or flow rate for water and/or aqueous solutions;
- temperature of water and/or aqueous solutions;
- volume(s) of chemical additives injected.

**Rinsing stage:**
- pump pressure or flow rate for water and/or aqueous solutions;
- temperature of water and/or aqueous solutions;
- volume(s) of any chemical additives injected.
Disinfecting stage (moist heat):

- pump pressure or flow rate for water;
- temperature of water.

9.26 WDs equipped to monitor all these variables have become commercially available only in the past two to three years.

9.27 As a minimum, WDs used to process surgical instruments should monitor the temperature during the disinfection stage and the time during which the temperature met or exceeded the specified minimum. There should also be means of ensuring an adequate flow of water within the chamber and load.

9.28 WDs that do not have independent monitoring of the time for which the specified temperature was maintained do not provide adequate assurance that the load was disinfected; a load that has not been disinfected may not be safe for staff to handle or for re-use.

Product release

9.29 Before a product is released for use or further processing it should be visually inspected for cleanliness and dryness. The attainment of the required temperature for the required time during the disinfection stage should be verified.
10.0 Washer-disinfectors for thermo-labile endoscopes

Introduction

10.1 This type of WD is used to process endoscopes which are thermo-labile and cannot withstand thermal disinfection. They are typically of the flexible fibre-optic or video-endoscope type.

10.2 Disinfection is achieved by direct contact of the load with a chemical disinfectant solution at a specified concentration for a specified time either at a specified temperature or within a previously validated temperature range.

10.3 The disinfection facility may be provided as part of the automatic process or as a separate machine intended to disinfect items which have been cleaned. For this reason equipment for chemical disinfection is considered separately (see Chapter 12).

Product compatibility

10.4 Endoscopes may be harmed by some chemical additives or the use of an inappropriate operating cycle in the WD. The reprocessing instructions supplied by the manufacturer of the endoscope should be followed carefully.

Load handling/presentation

10.5 Few, if any, WDs for thermo-labile endoscopes are capable of cleaning the endoscope without any pre-treatment. As soon as the endoscope is removed from the patient, the channels should be flushed in accordance with the endoscope manufacturer’s instructions. The outside of the instrument should then be wiped with a swab soaked in an aqueous solution of a suitable detergent.

Instrument/biopsy channels should be brushed through several times with a cleaning brush designed for the instrument in accordance with the endoscope manufacturer’s instructions.

10.6 The use of a load carrier specifically intended for the endoscope(s) to be processed is essential.

10.7 The channels of the endoscope should be connected to the appropriate nozzle on the load carrier to ensure the free passage of fluids through the lumens during processing.

Selection of cycle variables

10.8 The cleaning stage should terminate with a rinse stage to remove any chemical agents used in cleaning which may be incompatible with the disinfectant to be subsequently used.
10.9 The automatic process should include means to ensure the removal of residual water which might dilute disinfectants.

Cycle monitoring

10.10 The WD should be equipped with means to provide independent monitoring of all critical cycle variables (see paragraph 9.25).

10.11 This should include means to verify that all channels to be irrigated with cleaning solution are not blocked.

Product release

10.12 Before a product is released for use or further processing it should be visually inspected for cleanliness and dryness. When the process includes a chemical disinfection stage the attainment of the required conditions should be verified (see Chapter 12).
11.0 Manually-loaded ultrasonic washers

Introduction

11.1 This type of washer is used to process metal instruments with complex interstices. It may be used as a pre-cleaning method before processing through a WD for instruments and utensils.

11.2 Ultrasonic cleaners work by subjecting the load to a high intensity of high frequency sound waves which causes cavitation at the surface of the instruments, loosening the soiling.

11.3 Ultrasonic cleaning is not a disinfection process and loads cleaned by ultrasonication must be subjected to a subsequent disinfection or sterilization process as appropriate.

11.4 The guidance offered in this chapter is, when relevant, equally applicable to ultrasonic cleaning processes included in a WD for instruments and utensils.

Safety precautions

11.5 Ultrasonic cleaners should only be operated in accordance with the manufacturer’s instructions. They should only be operated when the lid is in place to avoid the dispersion of aerosols and to protect operators from the noise that may be generated.

11.6 Ear protection may be necessary for operators if the ultrasonic cleaner produces significant audible noise during operation.

11.7 Operators should be instructed not to put their hands, or any other parts of their body, into the ultrasonic tank while it is operating.

11.8 Items washed in an ultrasonic cleaner will only have been cleaned, not disinfected, and should therefore be handled with appropriate precautions.

11.9 Ultrasonic cleaners should never be operated with the tank empty since this can seriously damage the transducers.

Product compatibility

11.10 Ultrasonic cleaners are used to assist in cleaning jointed and serrated stainless steel instruments. Plastics and other similar materials which absorb the ultrasonic energy are not successfully cleaned by this method.

11.11 Cannulated instruments can be cleaned by ultrasonication but this is generally successful only when means are provided to ensure that the cannula is also flushed with cleaning solution during the process.
11.12 Cemented glass syringes and optical systems will be damaged if they are subjected repeatedly to ultrasonication.

11.13 The compatibility of all materials and items to be processed should be established by reference to the manufacturer’s instructions, or by appropriate performance qualification testing when necessary.

**Load handling/presentation**

11.14 Instruments should be placed in the basket provided with the machine.

11.15 The cleaner should be located at a convenient height for loading and unloading. When heavy sets of instruments are to be processed the cleaner should be equipped with a mechanical lifting device.

11.16 Cannulated instruments should be connected to the appropriate nozzle on the load carrier to ensure that the cleaning solution can be pumped through the lumen during processing.

11.17 Hinged instruments should be opened before being placed in the cleaner.

11.18 Gross contamination, such as blood and other visible soil, should be rinsed off instruments before they are immersed in the ultrasonic tank.

**Selection of cycle variables and chemical agents**

11.19 The only variables selectable are the operating temperature (on some machines), the concentration of chemical additives and the exposure time.

11.20 The efficacy of ultrasonic cleaning is improved by the use of a low foaming surfactant or detergent. The choice of detergent and control of the in-use concentration of detergent have a significant effect on cleaning performance. Advice should be sought from both the WD and detergent manufacturers.

**Routine operation**

11.21 The tank should be filled with the volume of clean cold water recommended in the manufacturer’s instructions and the required volume of detergent added. The ultrasonic cleaner should then be brought up to operating temperature (if it is of the thermostatically controlled type) and operated for a period of not less than five minutes to de-gas the solution.

11.22 After de-gassing, the instruments to be cleaned should be loaded into the ultrasonic cleaner using the basket provided and, when the lid is in place, the cleaner operated.

11.23 After the specified time the instrument basket should be removed, the instruments removed and either transferred to a WD for instruments and utensils or thoroughly rinsed in clean hot water (60°C or hotter) before drying prior to sterilization or chemical disinfection.
11.24 The tank should be emptied and refilled with clean solution when the solution has become visibly soiled or every four hours, whichever is the sooner. De-gassing is necessary after each fill, before instruments are processed.

**Cycle monitoring**

11.25 The user should carry out a daily test to verify the activity of the transducers (see HTM 2030 ‘Validation and verification’).

**Product release**

11.26 Before a product is released for use or further processing it should be visually inspected for cleanliness.
12.0 Liquid chemical disinfectors

Introduction

12.1 Machines for the automatic disinfection of items by liquid chemical disinfectants are intended for use only on items previously subjected to a cleaning process.

12.2 The guidance offered in this chapter is equally applicable when the disinfection process is included in a single machine with the cleaning process.

Safety precautions

12.3 Chemical disinfectants are potentially hazardous. Depending on the formulation they may cause irritation to the skin, eyes, respiratory tract and mucous membranes and may be volatile, flammable and corrosive. A risk assessment should be undertaken in accordance with the COSHH Regulations (see paragraph 3.14).

12.4 Staff training should include specific instruction on the procedures to be adopted in the event of equipment malfunction.

Product compatibility

12.5 The compatibility of all materials and items to be processed should be established by reference to the manufacturer’s instructions, or when necessary by appropriate testing.

12.6 Factors to be considered in determining the compatibility of the load to the WD process include, but are not necessarily limited to:

a. whether or not it can be immersed in aqueous solutions;

b. the availability of an appropriate load carrier providing the necessary connection to all channels which require disinfection;

c. the maximum operating temperature;

d. the internal pressure to which the channels may be subjected;

e. the compatibility with the chemical disinfectants used.

Load handling/presentation

12.7 Items to be processed should be:

a. clean, to ensure that all internal channels are clear and that the activity of the disinfectant is not compromised by residual soiling;

b. free from process residues from the cleaning process, e.g., detergent, which may inactivate the disinfectant;
c. dry or free from significant surface moisture which would cause
dilution of the disinfectant solution;
d. verified as undamaged, eg by means of a leak test;
e. disassembled to the extent necessary, eg with valves opened or
demounted as recommended by the manufacturer;
f. protected with any necessary closure to prevent the ingress of aqueous
solutions into the wrong part of the equipment, eg videoscopes which
are only immersible if the protective cap is in place;
g. connected to the disinfector so as to ensure the passage of disinfectant
through all channels.

Selection of cycle variables and chemical agents

12.8 The activity of chemical disinfectants is time and temperature
dependent. The temperature of the disinfectant solution should, therefore, be
either thermostatically controlled or monitored during each cycle to ensure that
it is within the temperature range validated during commissioning.

12.9 The exposure time should be controlled to ensure that the
predetermined minimum exposure time has been attained.

12.10 As the various disinfectant formulations differ considerably in their
properties, the choice of disinfectant should be made in consultation with the
manufacturers of the equipment to be disinfected, the disinfector and the
disinfectant. Guidance on the properties of commonly used disinfectants is
given in ‘Sterilization, disinfection and cleaning of medical equipment,
guidance on decontamination from the Microbiology Advisory Committee to
the Department of Health Medical Devices Agency’.

12.11 The operating cycle must provide adequate rinsing after the chemical
disinfection stage to ensure that residues of the disinfectant have been
reduced to a level at which they do not present a hazard to patients.

12.12 The quality of the final rinse water, especially microbial quality, and the
means of ensuring that quality are important characteristics of the process if
recontamination of disinfected items is to be avoided. The manufacturer’s
instructions should be followed precisely.

Cycle monitoring

12.13 For disinfectant solutions which are formulated for multiple or
prolonged use the date of preparation and/or activation and the number of
operating cycles run should be recorded. Whenever practicable the
concentration of disinfectants intended for re-use should be monitored on a
daily basis.

12.14 The WD should be equipped with means to provide independent
monitoring of all critical cycle variables.

12.15 This should include means to verify that all channels to be irrigated with
disinfectant solution are not blocked.
12.16 The disinfectant temperature and exposure time should be monitored for each cycle.

12.17 The means employed to maintain the quality of the final rinse water should be monitored in accordance with the manufacturer’s instructions.

Product release

12.18 Before a product is released for use or further processing it should be verified that the chemical disinfection stage was within the limits previously determined during commissioning.
13.0 Laboratory washer-disinfectors

Introduction

13.1 This type of WD is used to process laboratory equipment and glassware and may also be used to process containers and equipment for use in the preparation of medicinal products.

13.2 Disinfection is achieved by direct contact of the load with water to raise the temperature of the surface of the load to a specified temperature for not less than a specified time, or a combination of conditions providing equivalent lethality.

Safety precautions

13.3 At the end of the operating cycle the load may be too hot to handle without protective gloves. Operators should be trained in the use of the WD and provided with appropriate protective clothing.

13.4 Many of the chemical agents used are toxic, irritant and corrosive. They are potentially hazardous and require careful handling and secure storage.

13.5 A written procedure should be available for the filling or connection of all chemical additive containers and staff whose duties include this task should receive formal training.

Product compatibility

13.6 The compatibility of all materials and items to be processed should be established by reference to the manufacturer’s instructions, or when necessary by appropriate performance qualification testing.

Load handling/presentation

13.7 Load carriers specific to the type of load should be used to ensure that all surfaces to be cleaned and disinfected will be exposed to the action of the water jets, will not be dislodged by the water jets and will drain freely.

13.8 For single-door machines facilities to allow segregation of the handling equipment, eg trolleys used for clean and dirty items, is required.

Selection of cycle variables and chemical agents

13.9 A flushing (pre-rinse) stage assists the removal of gross soiling and proteinaceous material before washing commences. The water used for flushing should be at a low enough temperature to avoid coagulation of proteinaceous material.
For some applications, particularly where detergent residues would be a significant problem for the intended use of the load, washing without detergent may be used.

13.10 The choice of detergent will be based upon a number of factors. These include:
   a. the quality of water available;
   b. the nature of the load;
   c. the nature of the soiling to be removed;
   d. the nature of the washing process.

Advice should be sought from both the WD and detergent manufacturers.

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

13.12 Water purified by de-ionisation, distillation or reverse osmosis is preferred for the final rinse stage since this gives the lowest levels of process residuals.

13.13 When the WD does not include a separate drying stage the use of a high temperature final rinse will facilitate the rapid natural drying of the load on removal from the WD.

Cycle monitoring

13.14 The WD should be equipped with means to provide independent monitoring of all critical cycle variables.

13.15 The variables which may need to be monitored include those identified for WDs for instruments and utensils (see Chapter 9, paragraph 7.25).

Product release

13.16 Before a product is released for use or further processing it should be visually inspected for cleanliness. When disinfection is required the attainment of the required temperature for the required time during the disinfection stage should be verified.

13.17 For loads which are to be used in connection with the manufacture of medicinal products the quality controller will establish the procedures for product release.
Appendix I: 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.

**Calibration:** The set of operations that establish, under specified conditions, the relationship between values of a quantity indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realised by standards.

**Chamber:** That part of the WD in which the load is processed.

**Chemical disinfection:** Disinfection achieved by the action of one or more chemicals the primary purpose of which is to be microbicidal.

**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.

**Door:** Device provided as a means of closing and sealing the chamber.

**Fail safe:** Attribute of WD design, component or its associated services that minimizes a possible safety hazard.

**Fault:** Recognition by the automatic controller that the pre-set cycle variables for the WD cycle have not been attained.

**Load:** A collective term used to describe all the goods equipment and materials that are put into a WD at any one time for the purpose of processing it by an operating cycle.

**Medical device:** See EN 46001: 1997.

**Monitoring:** The measurement of physical variables, such as the function of the automatic controller to check the attainment, or otherwise, of the pre-set cycle variables essential to the efficacy of the operating cycle.

**Operating cycle:** The complete set of stages of the process that is carried out in the sequence as regulated by the automatic controller.

**Steam generator:** Vessel designed to contain water and a heating system (eg a steam coil or a fully immersed electric element) which is used to heat water to its vapour state.
Sterile: See EN 556.

Sterilization: Process used to render a product sterile.

Tank: A process vessel, integral to the WD, designed to hold solutions during processing.

Thermal disinfection: Disinfection achieved by the action of moist or dry heat.

Viable micro-organism: Micro-organisms, including viruses, which are capable of multiplication under specified culture conditions.

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.

This type of machine does not include those designed specifically to wash linen or clothing.
## Appendix II: Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AP(S)</td>
<td>Authorised Person (Sterilizers)</td>
</tr>
<tr>
<td>BS</td>
<td>British Standard</td>
</tr>
<tr>
<td>°C</td>
<td>degrees Celsius</td>
</tr>
<tr>
<td>COSHH</td>
<td>Control of Substances Hazardous to Health</td>
</tr>
<tr>
<td>EU</td>
<td>European Union</td>
</tr>
<tr>
<td>HBN</td>
<td>Health Building Note</td>
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<tr>
<td>HSE</td>
<td>Health and Safety Executive</td>
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<tr>
<td>HTM</td>
<td>Health Technical Memorandum</td>
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<tr>
<td>ISO</td>
<td>International Standards Organisation</td>
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<tr>
<td>K</td>
<td>Kelvin</td>
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<tr>
<td>MCA</td>
<td>Medicines Control Agency</td>
</tr>
<tr>
<td>MDA</td>
<td>Medical Devices Agency</td>
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<tr>
<td>OEL</td>
<td>Occupational Exposure Limit</td>
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<tr>
<td>PES</td>
<td>Programmable Electronic System</td>
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<tr>
<td>pH</td>
<td>The inverse of the logarithm to base 10 of the hydrogen ion activity of a solution. (Solutions with pH values less than seven are acidic and those with pH values greater than seven are alkaline.)</td>
</tr>
<tr>
<td>TP(S)</td>
<td>Test Person (Sterilizers)</td>
</tr>
<tr>
<td>WD</td>
<td>Washer-disinfector</td>
</tr>
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</table>
Appendix III: Useful addresses

**UK health agencies**

NHS Estates, 1 Trevelyan Square, Boar Lane, Leeds LS1 6AE  
Tel 01132 547000

Medical Devices Agency (MDA)  
Hannibal House, Elephant and Castle, London, SE1 6TQ  
Tel 0171 972 8000

Medicines Control Agency (MCA)  
Market Towers, 1 Nine Elms Lane, London SW8 5NQ  
Tel 0171 273 3000

NHS in Scotland Management Executive, St Andrews House,  
Edinburgh EH1 3DG  
Tel 0131 556 8400

NHS in Scotland  
Healthcare Engineering and Environment Unit,  
University of Strathclyde, Graham Hills Building,  
50 George Street Glasgow G1 1QE  
Tel 0141 548 3446

Scottish Healthcare Supplies, Trinity Park House,  
South Trinity Road,  
Edinburgh, EH4 2RQ  
Tel 0131 552 6255

Welsh Office, Cathays Park, Cardiff CF1 3NQ  
Tel 01222 825111

Estate and Property Division, Estate Services Directorate, HPSS Management  
Executive, Stoney Road, Dundonald, Belfast BT16 0US  
Tel 0232 520025

**Health and safety**

Health and Safety Executive,  
Broad Lane, Sheffield S3 7HQ.  
Tel. 0114-289 2345

Note. Addresses of HSE area offices may be found in the local telephone directory

**Standards organisations**

British Standards Institution  
British Standards House, 389 Chiswick High Road, London W4 4AL  
Tel 0181 996 9000

European Committee for Standardisation  
rue de Stassart 36, B-1050 Brussels
Other organisations

Institute of Healthcare Engineering and Estates Management.
2 Abingdon House, Cumberland Business Centre,
Northumberland Road, Portsmouth PO5 1DS. Tel. 01705 823186
References

Act and Regulations


European Union (EC) Directives


NHS Estates publications


Health Building Notes (HBNs)


Health Technical Memoranda (HTMs)


Firecode


Scottish publications

Scottish Hospital Planning Notes (SHPNs)


Firecode


Department of Health publications

Sterilization, disinfection and cleaning of medical equipment, guidance on decontamination from the Microbiology Advisory Committee to the Department of Health Medical Devices Directorate. Microbiology Advisory Committee, Department of Health, 1993.


Health and Safety Executive publications


Occupational exposure limits (EH40). Health and Safety Executive, HSE Books, issued annually.


British Standards

BS 853 Specification for vessels for use in heating systems.
   Part 1: 1996 Calorifiers and storage vessels for central heating and hot water supply.

BS 1449 Steel plate, sheet and strip.

BS 2745 Washer disinfectors for medical purposes.


BS 5728 Cold potable water in closed conduits.

BS 5726 Microbiological safety cabinets

BS 7320: 1990 Specification for sharp containers.


BS EN 556: 1996 Sterilization of medical devices. Requirements for terminally-sterilized devices to be labelled. ‘Sterile’.

BS EN 724: 1995 Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for non-active medical devices.


References

BS EN ISO 9000 Quality management and quality assurance standards.

BS EN ISO 9001: 1994 Quality systems. Model for quality assurance in design, development, production, installation and servicing.


BS EN 50081 Electromagnetic compatibility. Generic emission standard.

BS EN 50081-1: 1992 Residential, commercial and light industry.


BS EN 50082 Electromagnetic compatibility. Generic immunity standard.

BS EN 50082-1: 1992 Residential, commercial and light industry.

BS EN 50082-2: 1995 Industrial environment.

BS EN 61010 Safety requirements for electrical equipment for measurement, control and laboratory use.

BS EN 61010-1: 1993 General requirements

BS EN 61010-2-045 (Draft) Particular requirements for washer disinfectors and other equipment incorporating washing equipment for the treatment of medical materials and for laboratory processes.

BS EN 61010-1: 1993 General requirements

BS EN 61010-2-045 (Draft) Particular requirements for washer disinfectors and other equipment incorporating washing equipment for the treatment of medical materials and for laboratory processes.

EN (Draft) Washer-disinfectors.

Part 1: 1997 (Draft) General requirements and tests.

Part 2: 1997 (Draft) Requirements and tests before washer-disinfectors for surgical instruments and trays, anaesthetic equipment, hollowware and glassware.


Part 4: 1997 (Provisional) Requirements and tests for washer-disinfectors for thermolabile reusable instruments including endoscopes.

Other publications


Guidance to engineering commissioning. Institute of Hospital Engineering, 1995.
About NHS Estates

NHS Estates is an Executive Agency of the Department of Health and is involved with all aspects of health estate management, development and maintenance. The Agency has a dynamic fund of knowledge which it has acquired during over 30 years of working in the field. Using this knowledge NHS Estates has developed products which are unique in range and depth. These are described below. NHS Estates also makes its experience available to the field through its consultancy services.

Enquiries about NHS Estates should be addressed to:
NHS Estates, Publications Unit, Department of Health, 1 Trevelyan Square, Boar Lane, Leeds LS1 6AE.
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Some NHS Estates products

Activity DataBase – a computerised briefing and design system for use in health buildings, applicable to both new build and refurbishment schemes. NHS Estates

Design Guides – complementary to Health Building Notes, Design Guides provide advice for planners and designers about subjects not appropriate to the Health Building Notes series. SO

Estatecode – user manual for managing a health estate. Includes a recommended methodology for property appraisal and provides a basis for integration of the estate into corporate business planning. SO

Concode – outlines proven methods of selecting contracts and commissioning consultants. Reflects official policy on contract procedures. SO

Works Information Management System – a computerised information system for estate management tasks, enabling tangible assets to be put into the context of servicing requirements. NHS Estates

Health Building Notes – advice for project teams procuring new buildings and adapting or extending existing buildings. SO

Health Guidance Notes – an occasional series of publications which respond to changes in Department of Health policy or reflect changing NHS operational management. Each deals with a specific topic and is complementary to a related HTM. SO

Health Technical Memoranda – guidance on the design, installation and running of specialised building service systems, and on specialised building components. SO

Health Facilities Notes – debate current and topical issues of concern across all areas of healthcare provision. SO

Encode – shows how to plan and implement a policy of energy efficiency in a building. SO

Firecode – for policy, technical guidance and specialist aspects of fire precautions. SO


Model Engineering Specifications – comprehensive advice used in briefing consultants, contractors and suppliers of healthcare engineering services to meet Departmental policy and best practice guidance. NHS Estates

Quarterly Briefing – gives a regular overview on the construction industry and an outlook on how this may affect building projects in the health sector, in particular the impact on business prices. Also provides information on new and revised cost allowances for health buildings. Published four times a year; available on subscription direct from NHS Estates. NHS Estates

Items noted “SO” can be purchased from The Stationery Office Bookshops in London (post orders to PO Box 276, SW8 5DT), Edinburgh, Belfast, Manchester, Birmingham and Bristol or through good booksellers.

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