Health Protection Scotland

NHS National Services Scotland

Endoscope Reprocessing: Guidance on the Requirements for Decontamination Equipment, Facilities and Management.

Note: This document provides interim guidance pending publication of the final version.

Version 1.1

December 2004 (Amended September 2007)
(See version control for changes)

Version Control

Version 1.0 Issued December 2004

Version 1.1 Issued September 2007

Amendments

The Idealised Schematics which were in Section 2.18 have been removed as these are under review. Exemplar layouts will be included in the web-based working draft of SHPN 13 Part 3, which will be available soon. If you require urgent advice on layouts please contact the Decontamination Team at decon_team@hps.scot.nhs.uk

Reference to Neighbourhood Decontamination Units has been removed as this concept is not being taken forward and will not be included in the revision of SHPN 13.

Contents

Foreword

This document has been prepared to provide guidance on the technical requirements for the decontamination of flexible endoscopes and the options available.
The document is intended to summarise key information on best practice in a manner which is readily accessible to the user/manager.

This guidance has been prepared by utilising published guidance from expert bodies, existing best practice guidance and standards, both published and in draft form. Many of the referenced standards are harmonised standards in respect of the Medical Device Directive.

Information has been drawn from various expert groups and reference sources. These are referenced throughout the document. The principle sources are described below:

- The Medical Devices Agency (MDA) (which has now been incorporated in the Medicines and Healthcare products Regulatory Agency) has published guidance on the Decontamination of Endoscopes (including MDA DB2002(05)) .

- The Joint Transmissible Spongiform Encephalopathy (TSE) Working Group of the Advisory Committee on Dangerous Pathogens and the Spongiform Encephalopathy Advisory Committee Joint Working Group (ACDP/SEAC JWG) has published guidance on safe working and prevention of infection relating to CJD and related diseases (see http://www.advisorybodies.doh.gov.uk/acdp/tseguidance/Index.htm)

- Working Group (WG) 8 of CEN/TC102 and WG13 of ISO/TC198 is responsible for the preparation of a European /International standard on the requirements and tests for endoscope washer disinfectors, as the fourth part of the 15883 series of standards. The working draft has been circulated for public comment, a second public comment stage is anticipated later this year, with publication as a harmonised BS EN ISO standard under the Medical Devices Directive in 2005.

- The Scottish Health Technical Memorandum 2030 'Washer-disinfectors' (2001) includes guidance on the choice, specification, purchase, installation, validation, periodic testing, operation and maintenance of endoscope WDs; published by the Property and Environment Forum Executive.

- The Health Technical Memorandum 2030 'Washer-Disinfectors' (1997) is published by NHS Estates. This document is substantially similar to SHTM 2030 but includes details of the microbiological testing required.

- NHS Estates published a NHS Model Engineering Specification C32 'Automated Endoscope Reprocessors for Flexible Endoscopes' in 2003.

- The guidance of the Microbiology Advisory Committee to the Department of Health Medical Devices Agency (MAC Manual) Part 3, Section 2 offers guidance on sterilization and disinfection of endoscopes.

- Guidance is also available from specialist professional bodies e.g. European Society for Gastroenterology **(**www.esge.com), British Society for Gastroenterology (www.bsg.org.uk) , British Thoracic Society(www.thoraxjnl.com).

See also Reference section.

Decontamination practice in endoscopy, particularly given the thermolabile and complex nature of the target device, presents many challenges for cleaning and chemical disinfection. Those with responsibility for decontamination need to ensure that they are kept aware of current developments in a rapidly developing/evolving field. These include not only changes in the nature of decontamination equipment that may be available, the design and function of endoscopes etc but also includes changes in requirements in the light of new information about transmissible diseases. Within NHS Board Divisions in Scotland, overall responsibility for risk assessment and

management processes relating to decontamination, infection control, medical devices management and cleaning services is held by a senior manager designated by the Chief Executive, in line with HDL(2001)10. The Authorised Persons (Sterilizers) should be consulted for further detailed guidance and, in particular, guidance on the choice, validation, maintenance, testing and operation of decontamination equipment.

This document has been drafted by staff at Health Protection Scotland (HPS, formerly SCIEH) and is currently subjected to review by relevant professionals in NHSScotland and the independent sector.

1. Introduction

In 2003, the Sterile Services Provision Review Group (Glennie Group) recognised that there was a lack of guidance on the provision of decontamination facilities specifically for endoscopy. The Glennie technical requirements do not cover the decontamination of thermolabile endoscopes but are limited to those instruments where decontamination involves the application of heat disinfection and/or sterilization processes. It was recognised that, when designing endoscopy facilities and choosing equipment, it is important to be fully aware of the appropriate options. To assist in this, the *Decontamination team of HPS /* Decontamination Technical Advisory Panel (DTAP) has been commissioned to prepare guidance on behalf of the Glennie Group.

Endoscopes and their accessories are classified as medical devices under the Medical Devices Directive (MDD). The essential requirements of this directive include:

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

Failure to adequately decontaminate flexible and rigid endoscopes between use may increase the risk of transmission of infection between patients and/or compromise the quality of clinical samples eg biopsy samples (ref HAZ(SC)04/05). The choice of appropriate decontamination process for devices used in a range of clinical procedures is typically based on the classification system first proposed by Dr E H Spaulding. The appropriate level of decontamination will depend on the procedure for which the endoscope is used (see Table 1) – for example sterilization is the appropriate choice for arthroscopes used in critical procedures.

Table 1 Spaulding Classification applied to Endoscopy

Classification	Type of Procedure	Appropriate Level of Decontamination
Critical	Invasive device enters tissue that is usually sterile or enters the vascular system. This includes contact with breaches in the skin and/or mucous membrane e.g. arthroscopes, biopsy forceps, papillotomes etc.	Sterilization
Semi-critical	Device contacts intact mucous membrane but does not penetrate sterile tissue; e.g. gastroscopes, colonoscopies.	High level disinfection Sterilization preferred where practicable.
Non-critical	Device only contacts intact skin e.g., stethoscope, sphygmomanometer cuff.	Cleaning (and low level disinfection where necessary).

A further limitation on the choice of decontamination process is the materials used for the construction of the flexible endoscope which are thermolabile (heat sensitive) or may be incompatible with specific process chemicals including the detergent for cleaning or the liquid chemical disinfectant.

Concern about the risk of transmission of TSEs has led to specific recommendations for the decontamination of endoscopes used on symptomatic patients or on patients considered at risk of developing CJD. Attention is drawn to the current UK guidance from the ACDP-SEAC published on http://www.advisorybodies.doh.gov.uk/acdp/tseguidance/Index.htm
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Process Efficacy and Validation

Endoscope decontamination involves a series of processes whereby the used device is cleaned, disinfected, rinsed and dried prior to its return 'fit for purpose' to the clinical unit. Each process is subject to a number of variables, for example the nature and concentration of detergent, the volume, quality and temperature of the water and the physical energy applied in the cleaning process for each type of endoscope. Assurance of process efficacy cannot be given by simple visual inspection of the device before use – it requires an understanding and control of these critical process variables.

Manual processes have limited control and rely on operator training and careful adherence to agreed procedures to give any degree of consistency. In contrast, automated processing in an endoscope washer-disinfector (EWD) is capable of automatic control to pre-set specifications and of verification that the required standard is consistently met. This is the basis of the term 'validation' – 'a documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications'.

Validation principles apply throughout the total decontamination process, beginning with the review of the specification against which the equipment is purchased. Evidence that the EWD has been designed and manufactured to the agreed specification should be provided as 'type test' and 'works test' data from the EWD manufacturer to the purchaser. Tests and checks are required on delivery ('installation qualification (IQ)' and 'operational qualification (OQ)') before beginning the detailed process of obtaining and documenting evidence that the EWD 'as installed and operated in accordance with operational procedures, consistently performs in accordance with predetermined criteria and thereby yields product meeting its specification'. In effect, this means evidence that the EWD produces endoscopes that are cleaned and disinfected to the required standard – a process described as 'performance qualification' (PQ). Only after satisfactory completion of the stages up to performance qualification (also described as 'commissioning') should the EWD be regarded as validated and acceptable for the decontamination of endoscopes in clinical practice.
Performance is then monitored during routine use and by periodic tests, to ensure that the critical process control variables determined during performance qualification are still met. Tests are also required before an EWD is returned to service after repairs or modification that may have affected the process control.

Four key aspects, embodied in the control protocols of SHTM 2030, ensure that the required standards of performance and safety are met:

a) all EWDs are subjected to a planned programme of tests to validate their performance, that is to provide experimental evidence that, when operated under specified conditions, the WD will reliably produce cleaned and disinfected items to the standard required;
b) all EWDs are subjected to a planned programme of tests to monitor their performance;
c) all EWDs are operated in accordance with an agreed procedure by staff trained in the use of the WD;
d) all EWDs are subjected to a planned programme of preventative maintenance irrespective of whether a preventative maintenance scheme is operated on the premises.

Expertise in obtaining and recording the results of the planned programme of tests is provided by the qualified Test Person (TP(S)) and Maintenance Person (MP(S)).
The test procedures and reports should be audited by the AP(S) who will provide interpretation of the test results for the User. The scheduled test programme includes simple routine tests to be undertaken by the operator as well as more complex validation and periodic tests to be undertaken by the TP(S) and MP(S).

Schedules for type tests, pre-delivery works tests (when necessary), installation tests and checks, operational qualification, performance qualification and periodic tests are presented in Annex 1. The tests procedures, incorporating the tests proposed for the harmonised European standard for endoscope washer disinfectors (BS EN ISO 15883-1,4) are described in Annex 2.

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Facilities for decontamination

The document 'Local Decontamination Units: Provisional Guidance on the requirements for Equipment, Facilities and Management:' recognizes three classes of decontamination unit:

- CDU - a central decontamination unit (sterile service department/unit)
- LDU - a local decontamination unit
- ERU - an endoscope re-processing unit

Endoscopy re-processing unit (ERU)

This is a unit set up to re-process only flexible, thermo-labile, usually fibre-optic, endoscopes and their accessories. The terminal decontamination process stage is high level disinfection using a liquid chemical disinfectant. Specialist endoscope washer-disinfectors (also described as automatic endoscope reprocessors) are used.

An endoscopy reprocessing unit may be set up as an LDU, supplying only adjacent endoscopy clinics in the same building, or as a CDU.

In addition it should be noted that, generally:

- the management and staff responsible for decontamination may have other eg clinical duties.
- an ERU may serve a single clinical speciality or several (eg linked to an operating theatre suite)in the same building.

The nature of the terminal disinfection process means that the disinfected device is not packaged and protected against recontamination. The endoscope washer-disinfector should therefore be close to the point of use of the endoscope or careful measures should be taken to transport the decontaminated endoscope in a manner that does not compromise its status.

Decontamination in practice

The following table summarises the essential requirements for endoscope decontamination.

Function	Requirements
Equipment	• Compliance with this document for manual cleaning. • Compliance with SHTM 2030 and, when published, BS EN ISO 15883-1,4 for all endoscope washer-disinfectors in use.
Facilities	• Effective separation of clean and dirty processes in accordance with the 'Local Decontamination Units: Guidance on the Requirements for Equipment, Facilities and Management'
Staff	• All personnel carrying out decontamination processes have documented training needs assessment and record of training received, as part of a formal quality assurance system.
Management	• Senior member of staff with documented responsibility for decontamination processes and capable of assessing and treating risks associated with ineffective decontamination processes. • Senior Manager with overview in accord with HDL 2001(10) • Compliance with the MDA Device Bulletin DB9801 Medical Devices and Equipment Management for Hospital and Community based Organisation

The guidance that follows identifies and expands on the principles of decontamination that have been embodied in previous decontamination initiatives. Suggested methods by which these principles can be upheld and compliance achieved are provided. In providing guidance it is recognised that there is a need to provide:

- optimal methods applicable to new units;
- methods that can be applied to existing units that recognise the diversity of:
  - management arrangements;
  - location of decontamination activities;
  - clinical activity;
  - facilities and equipment;
  - policies, procedures and records;
  - staff training / competencies;
  - quality assurance;
  - resources.

It is recognised also that different solutions may be required for different types of endoscopy practice and for different endoscopes.

Figure 1: PROCESS CHOICES TO ACHIEVE REQUIRED LEVEL OF DECONTAMINATION

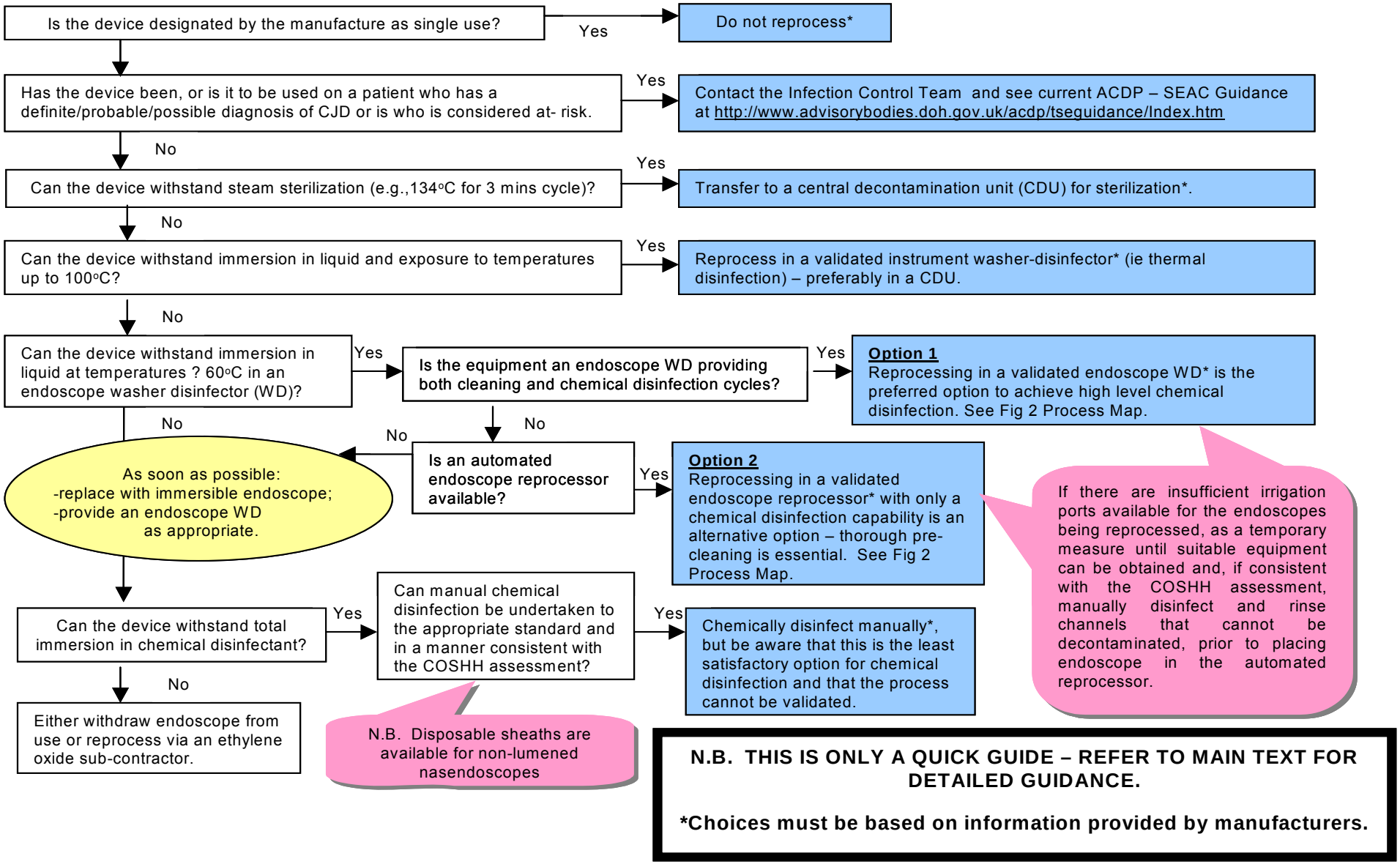
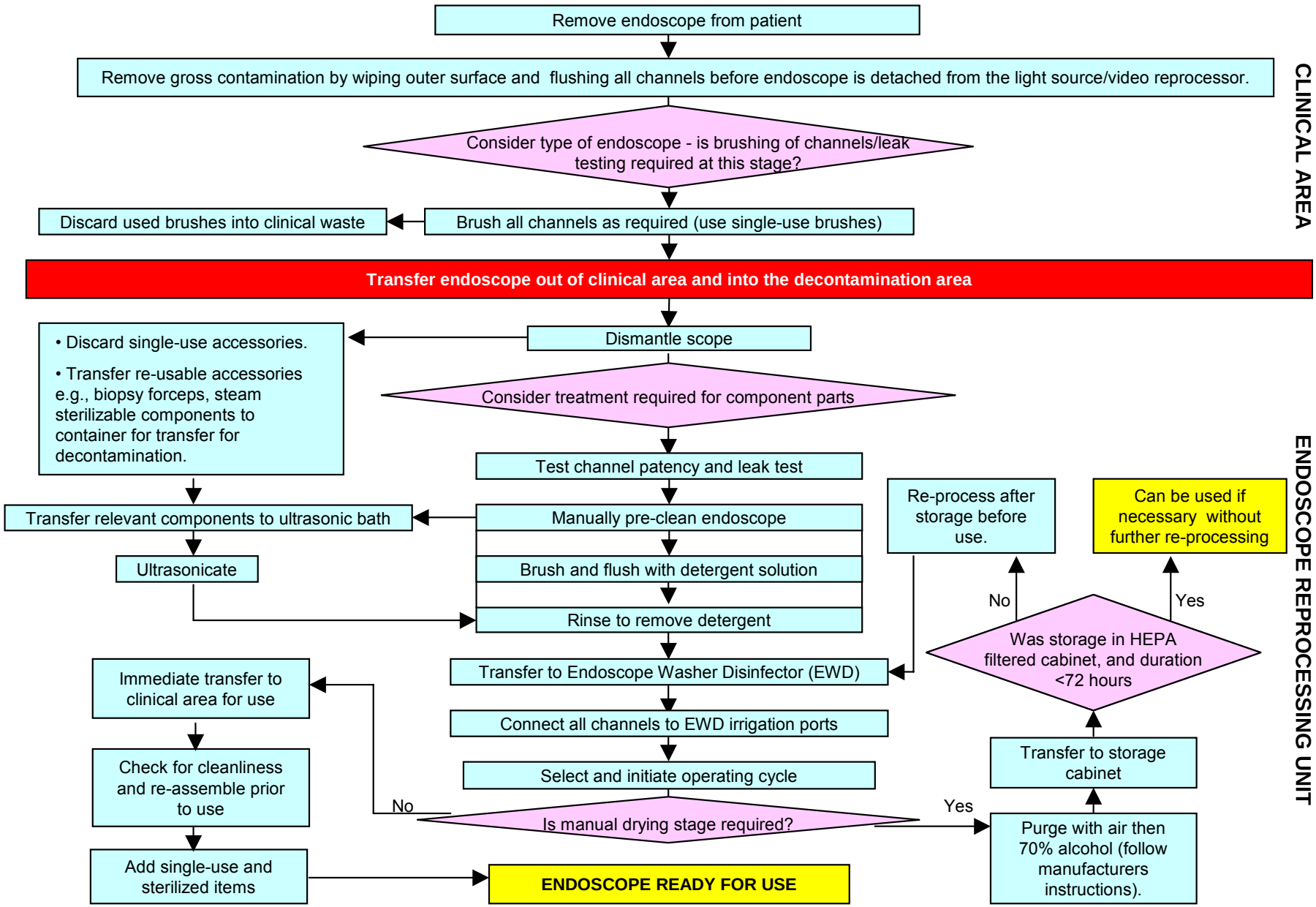


Figure 2: ENDOSCOPE DECONTAMINATION PROCESS MAP (Elements of the decontamination process will vary dependent on the type of endoscope)



2. Summary of requirements and methods of attainment

Note: In the tables below where various options are given for methods by which the requirements may be met the options are numbered in order of preference. Where the options are un-numbered there is no preference for which method should be adopted.

2.1 Records of endoscopes/ EWDs/accessories

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.1.1	An inventory should be maintained of all the endoscopes available for use, their location/s for use and the location/s for reprocessing.	List to include: Manufacturer Supplier Model Number Serial number Type of endoscope Date of purchase Asset Number Location List the ownership status of the endoscope (eg owned by Health Board or equivalent, on loan or borrowed from another site).	Maintaining detailed records should ensure that the actions required in respect of hazard notices (eg the recent Medical Device Alert – MDA 2004/028 – Hazard Notice HAZ(SC)04/05) and similar information / updates from manufacturers can be addressed for specified models in a timely manner. Maintaining local detailed records, for example serial numbers for traceability and asset register records for maintenance/procurement should ensure effective endoscope management.
2.1.2	All endoscopes and endoscope WDs should meet the essential requirements of the Medical Device Directive.	Endoscopes and endoscope WDs purchased after 13/06/98 should bear the CE mark and should be manufactured to meet the requirements of the appropriate harmonised European standards under the Medical Device Directive. Devices including endoscopes purchased prior to that date, without a CE mark, should be phased out of use.	Endoscopes are classified as medical devices under the Medical Device Directive. Endoscope WDs are also classified as medical devices under the MDD, given their specific purpose for the disinfection of medical devices. The Official Journal of the European Community (OJEC) gives the formal reference for harmonised standards under the Medical Device Directive.

2.1 Records of endoscopes/ EWDs/accessories (continued)

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.1.3	All re-usable endoscopic devices including accessories that are currently in stock should be capable of being decontaminated by an available and agreed decontamination processes.	Review the endoscope manufacturer's instructions for all reusable endoscopes and accessories currently in stock. Review the endoscope decontamination policy established for the site, to determine how the manufacturer's instructions will be implemented. Review the available decontamination capability and plan the necessary resource.	Instructions for the reprocessing of a device are required from the device manufacturer under the Medical Device Directive. Copies of these instructions should be available in the endoscope reprocessing unit (ERU). A site-specific, local policy for endoscope decontamination (including choice of process chemical, reprocessing facilities and equipment) should be established.

2.2. Acquisition of endoscopes, endoscope WDs and ancillary materials

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.2.1	**General**		
	The procurement of endoscopes, accessories and endoscope reprocessing equipment should be to agreed specifications, with prior consideration of decontamination issues and that should comply with the documented purchasing policy.	Agree a documented purchasing policy. Record the consultation process involving appropriate specialists, to include: - endoscopy staff; - procurement / purchasing; - infection control team - Medical and Nursing Directors, - estates / engineering; - sterile services department; - medical physics; - risk management, - Authorized Person (Sterilizers); - Microbiologist (Sterilizers). Consult the AP(S) for guidance on the specification of the equipment used for the decontamination of endoscopes and their accessories.	General advice on purchasing equipment within the NHS is given in MDA DB 9801 February 1999 'Medical Device and Equipment Management for Hospital and Community-based Organisations'. SHTM 2030 'Design Considerations' gives an overview of procurement of a WD, specification and contract (sections 2.0, 3.0 and 4.0) and more detailed guidance on the specification for endoscope WDs in section 12.0. The draft BS EN ISO 15883-1 and 15883-4 gives specific guidance on the specification of endoscope WDs. See also Annex 4 in this document.
2.2.2	Prior to purchase, it should be established that all reusable endoscopes are capable of being decontaminated by an available decontamination process.	The documented policy for purchasing re-usable devices should include a review of the endoscope manufacturer's instructions in conjunction with the local endoscope decontamination policy.	For devices not previously purchased a full specification may be required. Replacement of previously purchased devices may only require an unambiguous reference for the supplier.
2.2.3	Sufficient endoscopes should be available to allow the necessary time for re-processing without adversely affecting throughput.	Review clinical demand *versus* device stock and the time required for reprocessing; allowing time for necessary maintenance and repair. Establish and maintain stocks to the required level.	

2.2. Acquisition of endoscopes, endoscope WDs and ancillary materials (continued)

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.2.4	Single-use components and accessories should be used.	Review the endoscope manufacturer's information on the accessories and components available for the specific endoscope. (1) Use single-use components and accessories. (2) Use re-usable accessories that are capable of being sterilised by steam.	MDA DB2002(05) states that 'where practicable, single-use devices should be used'. NHS MEL (1999) 65, advising on minimising the risk of transmission of vCJD, states that 'where there are practical options for using single-use instruments, which do not compromise clinical outcome, consideration should be given to using these for surgical procedures'. The BSG Working Party (2003) specifies particular components and accessories that should be considered as single use only. These include endoscopic biopsy forceps and brush-tipped wires used for manual cleaning. Rubber biopsy valve channel caps should be discarded after any endoscopic procedures that involve passage of biopsy forceps or other accessories through the valves (Recommendation 9, BSG 2003). The ACPD/SEAC in their TSE guidance, Annex F, on decontamination of endoscopes (Sept 2004) state the channel cleaning brushes and the valve on the biopsy/instrument channel port used with flexible endoscopes should be disposed of as clinical waste after each use.

2.2. Acquisition of endoscopes, endoscope WDs and ancillary materials (continued)

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.2.5	There should be sufficient EWDs to meet the needs of the respective endoscopy department.	Calculate the requirement for EWDs in a particular unit based on current and planned clinical need, the number of endoscopes and the minimum time required for the endoscope decontamination process.	Detailed guidance on how to determine the required EWD capacity is given in SHTM 2030-1. A check list is also provided in the ESGE/ESGENA Guidelines 2000 for this purpose, requiring data on: - how many endoscopic interventions are performed in the endoscopy department per year; - how many endoscopic procedures are on each list per day (average); - what type of procedures are offered in the department and with which frequency; - how many procedure rooms the endoscopy unit has, if simultaneous working in different endoscopy suites is possible and in how many rooms; - how many endoscopy reprocessing rooms/ ERUs the unit has; - how many staff are available for reprocessing endoscopes and equipment; - how much time is scheduled for reprocessing a flexible endoscope.

2.2. Acquisition of endoscopes, endoscope WDs and ancillary materials (continued)

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.2.6	Means should be provided to ensure that the EWD, as **designed and manufactured**, is fit for its intended purpose	Prepare a detailed specification, based on the reprocessing needs of endoscopy and including the type, model number and any design features relevant for decontamination for each endoscope that the EWD is intended to process. Specify a requirement for compliance with BS EN ISO 15883-1,4 (when published) and BS EN ISO 61010-2-045. Prior to publication of BS EN ISO 15883, compliance with the design specification in SHTM 2030-1 should be stated.	The specification should be prepared by the User with input from other key personnel including the AP(S). General guidance on drawing up the specification and contract is given in SHTM 2030-1, section 4. See also the NHS Estates publication 'Model Engineering Specification C32 'Automated Endoscope Reprocessors for Flexible Endoscopes' (2003).
2.2.7	The EWD should be manufactured in a manner that will ensure its quality and conformance to specification.	The EWD manufacturer should ensure that the EWD is designed, manufactured and tested within a quality system complying with the requirements of BS EN ISO 13485.	BS EN ISO 13485 describes a quality management system applicable to medical device decontamination. See 3.5.1.
2.2.8	Means should be provided to ensure that the particular EWD **as delivered and installed on site** is fit for purpose.	Subject the EWD to a planned programme of testing both before delivery and on-site, using the procedures described in Annex 1 and 2. These should include installation qualification, operational qualification and process qualification (see below) and should include also tests and checks carried out during manufacture.	See Annex 1 and 2.

2.2. Acquisition of endoscopes, endoscope WDs and ancillary materials (continued)

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.2.9	Works tests should be undertaken to establish that the EWD meets the performance standards established during type testing.	Before delivery of the EWD, the manufacturer should subject the machine to a programme of factory tests. It is rarely necessary to attend the factory to witness works tests but the manufacturer should make the results of these tests available on or before delivery of the WD. The EWD Manufacturer should carry out pre-delivery works testing. The extent of testing will depend on whether the product is in serial production or a 'one-off' and, for machines in serial production, whether the manufacturer has obtained a certificate of compliance to a relevant British or European Standard by means of a type test for the particular type and size of EWD.	See schedule for type tests and works tests in Annex 1 and 2.
2.2.10	Pre-installation checks should be undertaken to establish that the area in which the EWD is installed and the quality / quantity of all services are to the required standard.	The contractor should verify that the site services are adequate for the operation and performance of the WD before it is delivered. The contractor should verify the condition of the water supply and set chemical dosing levels as appropriate.	Guidance is given in SHTM 2030-1, Section 2. For example, the EWD may require ancillary equipment such as water softeners, deionization or reverse osmosis (RO) water treatment plant, extract ventilation (with or without condensers), bulk storage and dispensing facilities for process chemicals including chemical disinfectants. Such requirements have implications for the space and services required and the overall design of the ERU.

2.2. Acquisition of endoscopes, endoscope WDs and ancillary materials (continued)

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.2.11	Installation tests should ensure that the equipment is properly connected to all services and is safe to operate.	The contractor, who may also be the manufacturer, should complete the installation checks and tests specified in SHTM 2030-3 to the satisfaction of the MP/TP before the WD can be accepted for use in accordance with the contract. The contractor should provide the test instruments and equipment (but unless otherwise specified in the contract, should not be expected to provide the test loads). The test instruments provided should meet the standards for test instruments described in SHTM 2030-3-8. The contractor should carry out the required installation checks on delivery of the WD to ensure the WD has been supplied and installed correctly and is safe to operate. Ventilation systems should be checked by the contractor responsible for their installation. When the checks have been completed and found satisfactory the contractor should carry out the installation tests necessary to demonstrate that the WD is working satisfactorily. Any assistance required from the purchaser should be agreed as part of the purchase contract.	See Annex 1 and 2.
2.2.12	Acceptance of the installation should be based on the test data generated after any required changes have been made at the installation site.	If any modification, maintenance or repair work is carried out for example on the water, compressed air ventilation or drainage systems after the installation tests have been completed, the relevant installation tests should be repeated before the operational tests are undertaken.	

2.2. Acquisition of endoscopes, endoscope WDs and ancillary materials (continued)

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.2.13	Operational qualification tests should ensure that the EWD functions correctly.	When the EWD has been installed and accepted, the MP/TP should carry out a sequence of operational qualification tests to evaluate the basic performance and safety of the EWD. Some of these tests are identical to those specified as installation tests and need not be repeated if operational testing follows within ten working days of the completion of the installation tests.	See Annex 1 and 2.
2.2.14	Performance qualification tests should ensure that the EWD produces endoscopes that are cleaned and disinfected to the required standard.	When the operational qualification tests have been completed and accepted, the MP/TP should undertake a sequence of performance qualification tests to show that: - soil removal and cleaning have been effective throughout the load and the WD chamber and that the product is of the required standard of cleanliness, free from process residues (where applicable); - disinfection conditions have been attained throughout the load and the WD chamber and to the required standard for the type of load being processed.	See Annex 1 and 2.
2.2.15	**Ancillary materials** (Process chemicals, process indicators etc) All ancillary materials should be appropriate for their intended use.	Purchase from reputable/ approved suppliers. Purchase to relevant BS EN specifications. Review the device manufacturer's instructions for compatibility. Review of decontamination equipment manufacturer's instructions for compatibility.	Process chemicals should be chosen to ensure that they are compatible with the medical devices to be processed, the decontamination equipment to be used and the process in which they will be employed. Care should be taken to ensure that the facilities available are appropriate for storage, use and disposal of the process chemicals, particularly when toxic or noxious chemicals are involved.

2.2 Acquisition of endoscopes, endoscope WDs and ancillary materials (continued)

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.2.16	Process chemicals Means should be provided to ensure that the process chemicals are fit for their intended use.	Obtain information for each specific process chemical to be used, concerning: • Compatibility - with other process chemicals - with the endoscope - with the EWD • Toxicity profile for - staff - the environment - patients • Packaging - presentation - labelling • Storage • Shelf-life • Antimicrobial efficacy - range of microorganisms - lethal rate • Conditions of use (concentration / temperature / time) • Evidence that the process chemical has been validated • for use in the specific EWD.	This information may be obtained from various reference sources including the Material Safety Data Sheet provided by the process chemical manufacturer. Evidence that the process chemical has been validate for use in the specific EWD should be provided by the EWD manufacturer. Further guidance should be sought from the: • manufacturer of the device to be decontaminated; • Microbiologist (Sterilizers); • Safety Officer; • AP (S).
2.2.17	The use of process chemicals should not be extended beyond the active life stated by the manufacturer.	Ensure that all process chemicals, in manual and automated processes, are prepared, used and discarded according to the manufacturer's instructions. Use single-shot disinfectants in preference to multi-dose formulations.	Indicators are available to monitor the process eg cleaning efficacy or to monitor the concentration of an 'active' chemical such as the concentration of disinfectant. The latter option is not available for all disinfectants. The disinfectant manufacturer may give an indication of the period of time during which a chemical solution may be reused. Such information will be modified by many local factors, such as the individual practice, inactivation by soiling on the device, dilution in the EWD etc. Re-use of disinfectant solutions gives a variable, non-quantifiable product (ie a non-validated process) and may compromise the efficacy of the disinfection process.

2.3 Processing environment

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.3.1	The decontamination process should have no adverse effect on the clinical environment.	(1) Physically segregate the decontamination processes that have the potential to contaminate the clinical environment eg a designated decontamination area / ERU separated from the patient treatment area by means of a wall.	Physical segregation would require those decontamination processes that may contribute to contamination of the environment (eg dis-assembly and cleaning of used devices) to be carried out in a separate room.
2.3.2		(2) Provide mechanical ventilation and designated work stations to ensure that the flow of any contamination arising from the decontamination process will be away from the patient area.	See Annex on Ventilation in Local Decontamination Units: Guidance on the Requirements for Equipment, Facilities and Management.
2.3.3	The decontamination process should have no adverse effect on staff or third parties.	Physically segregate decontamination processes that have the potential to contaminate the external environment. Restrict access to the decontamination area /ERU where these activities are carried out Provide appropriate PPE to staff within the decontamination area.	Decontamination should not be carried out in public access areas, corridors etc. Access to the decontamination area /ERU should be restricted to staff who have received appropriate training.
2.3.4	Elements of the decontamination process for one device should have no adverse effect on other medical devices.	(i) Physically segregate dirty decontamination processes (such as manual pre-cleaning) from the inspection/storage of the reprocessed device.	
		(ii) Provide mechanical ventilation and designated work stations to ensure that the flow of any contamination arising from the decontamination process will be away from disinfected/ reprocessed device.	

2.4 Decontamination processes

Para	Principle	Methods to Achieve	Explanatory Notes/ Reference
2.4.1	Decontamination processes should ensure that: • at the point of use, reprocessed devices are free from: - residues of previous procedures; - residues from the decontamination process; - adventitious contamination eg particulates and other environmental contaminants; - microbial contamination. .	Ensure that all aspects of the decontamination process are controlled, to include: - design of decontamination equipment and processes; - choice of process chemicals; - quality of water used in decontamination process; - environmental control; - use of appropriate cleaning and disinfection methods; - appropriate transport systems; - validation, testing and record keeping.	Removal of contamination present from previous use of the device is best assured by the use of effective, validated, cleaning processes in an automated EWD. Manual pre-cleaning will also be required. The choice of process chemicals will affect both the cleaning efficacy and the ease with which process residues may be removed. Only free rinsing detergents should be used; surgical hand scrubs are not a suitable substitute. The quality of water used for the final rinse will also affect the extent of process residues; hard water will leave lime-scale deposits. Control of adventitious contamination from the environment may be achieved by physical segregation from sources of contamination, ventilation to move airborne contaminants away from the device and appropriate environmental cleaning. Evidence of the required standards of decontamination can only be achieved through keeping records of appropriate testing, monitoring, maintenance and operation of the decontamination equipment.
2.4.2	• there is evidence of attainment of the required standards of decontamination.	Keep all records of the testing, monitoring, maintenance and operation of the decontamination equipment available in the ERU.	Other departments such as Estates, Medical Physics or sub-contractors eg EWD manufacturer test persons may also hold test records. These records/reports should be available to the User. They provide an essential history of the equipment's performance and reliability. All such records should be available for internal and external audit as required.

2.4 Decontamination processes (continued)

Para	Principle	Methods to Achieve	Explanatory Notes/ Reference
2.4.3	Decontamination processes should ensure that • the decontamination process is designed and carried out in a manner that minimises the risk of recontamination of clean devices.	Use decontamination equipment that is designed and constructed to prevent environmental dispersal of contamination from devices being reprocessed.	The design and construction requirements for EWDs to ensure that the door does not leak or generate aerosol contamination are given in BS EN 61010-2-05 Ultrasonic cleaners should only be operated with the lid in place.
2.4.3		Use techniques that minimise the generation and dispersal of environmental contamination eg aerosols.	Manual pre-cleaning procedures should be carried out with the device immersed.
2.4.4		Physically segregate those elements of the decontamination process dealing with contaminated devices and those dealing with cleaned/disinfected devices.	Inspection, drying and storage of reprocessed endoscopes are clean procedures. The arrangements for decontamination in the ERU should ensure that they cannot become contaminated by used devices or the pre-cleaning process.
2.4.5		Provide a linear work flow and extract ventilation to ensure that the flow of any contamination arising from the decontamination process dealing with contaminated devices will be away from cleaned/disinfected devices.	A work flow plan should be established showing a logical progression from dirty to clean without the possibility of cross contamination. The plan should clearly identify the pathway to introduce clean decontaminated supplies and the pathway to remove contaminated waste for safe disposal. Further guidance on ventilation is given in the LDU guidance document.

2.5 Choice of decontamination processes

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.5.1	Decontamination processes should be chosen to be: • effective for the device to be processed.	Refer to the endoscope manufacturer's instructions for reprocessing. Refer to the EWD manufacturer's type test data or information supplied to confirm that the requirements for reprocessing (channel irrigation, temperature control etc) are met for the specific device. If the available information is inadequate and cannot be remedied by recourse to other reference sources or requires a process or a level of complexity of equipment which is not available on the site, then the preferred option is to withdraw the device from use until such time that any omissions can be remedied. Substitution of an alternative decontamination method from that given by the endoscope manufacturer and without appropriate validation should only be made on the understanding that the User/Management now assumes liability for the microbial quality and function of the reprocessed device.	Manufacturers of reusable medical devices are required to give instructions for reprocessing, under the MDD. See also BS EN ISO 17664. Manufacturers of EWDs are required to provide evidence of the validation of their process for specific (named) types or families of endoscope. Users may also seek advice from the manufacturers of the chemical disinfectant, the AP(S), the Infection Control team and from national reference centres such as HPS.
2.5.2	• Compatible with the devices to be processed.	Refer to information provided by the endoscope manufacturer. Refer to information provided by the process chemical (detergent and disinfectant) manufacturers' instructions.	Evidence of the compatibility/incompatibility of a particular manufacturer's device and the process chemical requires precise investigation, typically by the endoscope manufacturer. Prior to the release of such evidence, an assumption may be made by the User from observations in practice. Caution should be applied to such interpretations and emphasis should be placed on thorough rinsing of all process chemicals from the surfaces of the device.

2.5 Choice of decontamination processes (continued)

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
	Decontamination processes should be chosen to be:		
2.5.3	• Capable of providing the level of decontamination required for the clinical procedures to be undertaken.	Refer to device manufacturers' instructions. Refer to the local decontamination policy. Practice example: A compromise two tier system for non-lumened endoscopes where there are time constraints and difficulty with immediate access to a endoscope WD is: • At the beginning and end of each day reprocess the scope in an endoscope washer disinfector. • Between patients: - use a disposable sheath over scope for each patient; - wipe over scope with a detergent and water solution, - rinse to remove detergent residue; - wipe over with alcohol. The undernoted provisos apply: • The integrity of the disposable sheath should be checked at the end of the procedure (fill with water and check for leaks). If the sheath is not intact the scope should be reprocessed through a washer disinfector. • If the procedure becomes inadvertently invasive, the scope should be reprocessed through a washer disinfector.	See Spaulding classification (Introduction, Table 1). This classification should be used to inform the choice of process appropriate for the level of risk and the tolerance of the equipment. This should be documented and available to staff within the ERU.

2.5 Choice of decontamination processes (continued)

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.5.4	• Capable of ensuring freedom from contamination that could lead to an erroneous diagnosis.	Ensure that the EWD is subject to a self-disinfection process, in line with the EWD manufacturer's instructions.	Contamination of endoscopes, particularly bronchoscopes, with environmental mycobacteria have led to the misdiagnosis of mycobacterial infection. The contamination has arisen from a variety of sources including mains water used for the final rinse and from contaminated foci within the endoscope and the EWD.
2.5.5	• Appropriate for the environment available for decontamination processing.	Design and operate the ERU to ensure a safe working environment, compatible with the chosen method of segregating dirty and clean devices.	
2.5.6	• Capable of providing the throughput required to maintain the desired level of clinical service.	Refer to the planning calculations made in determining the EWD requirements for a particular ERU and revise in response to any changes, for example increased clinical need.	See 2 2.6

2.5 Choice of decontamination processes (continued)

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.5.7	• Amenable to independent verification of the decontamination standards achieved.	Ensure that the EWD is capable of verifying by process record the attainment of the specified process variables determined at validation to be critical to the satisfactory outcome of the cleaning and disinfection process. Ensure that the verification is independent of the automatic controller.	The EWD is equipped with a multi-channel recorder, with sensors and signal processing independent from the controller, to record the process variables which were determined during validation studies to be critical to the satisfactory outcome of the cleaning and disinfection processes. (see SHTM 2030) This level of process control applies to EWDs as an example of washer-disinfectors for products which will be used without further processing and where the risks arising from an unsatisfactory cleaning and/or disinfection process are unacceptable. A similar requirement for independent process verification is given in prEN 15883-1,4.
2.5.8	▪ Value for money.	Determine the cost of providing and running a compliant ERU. Determine the number of sites in which endoscope reprocessing is undertaken and the associated costs. Consider the cost of providing and running compliant ERUs in multiple locations *versus* the cost of necessary instrumentation, transport and service to be provided from a centralised, compliant ERU or CDU.	The perpetuation of non-compliant decontamination facilities and equipment is not an acceptable option. This document summarises the requirements for achieving compliance with current standards.

2.6 Cleaning (including pre-cleaning)

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.6.1	Decontamination should begin as soon as the endoscope has been removed from the patient.	A preliminary removal of gross contamination by flushing should be undertaken before the endoscope is detached from the light source/video processor and taken to the decontamination room / ERU. Follow the instructions provided by the endoscope manufacturer, which would typically include the following stages: - suck water and detergent through the working channel in order to clear gross debris and ensure that the working channel is not blocked; - irrigate the air and water channels with freshly drawn water of at least potable quality water, not only to check for blockages but also to expel any blood, mucus and other debris; - wipe down the insertion shaft externally and check for any bite marks or other surface irregularities; - detach the endoscope from the light source / video processor and transfer to the decontamination room / ERU.	In addition to the specific instructions provided by endoscope manufacturer, guidance is given in BSG 2003. Bottled sterile water for irrigation may be used as a more convenient option for irrigation. This stage should not be excluded even when devices are being transferred for processing in a centralised decontamination unit (CDU).
2.6.2	On receipt in the ERU the endoscope should be disassembled, to remove items requiring separate processing.	Dismantle the detachable parts of the endoscope, including valves and water bottle inlets. Discard single-use accessories. Prepare any re-usable accessories for reprocessing and send to CDU or, if this facility is not available, to an LDU in accordance with the LDU guidance.	Some endoscopes have detachable tips which should also be disengaged from the insertion tube at this stage, Rubber biopsy valves should be discarded whenever breached by biopsy forceps or any other accessory during the last endoscopy procedure. (BSG 2003) Safe transfer of the contaminated endoscope from the site of clinical use to the ERU may require particular containment to avoid the transfer of contamination or damage to the endoscope. See 2.13

2.6 Cleaning (including pre-cleaning) - continued

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.6.3	The integrity of all channels should be checked before and after subsequent processing, by means of a leak test.	Attach the endoscope to the leak/leakage test device to check the integrity of all channels before and after manual reprocessing. Repeat the leak test before and after automated reprocessing in an EWD. Ensure that the instructions provided by the endoscope manufacturer and the EWD manufacturer are followed.	A manual leak test may be carried out at the flushing stage, before the endoscope is received in the ERU. Some EWDs include an integral leak test which is performed automatically before and after the reprocessing cycle.
2.6.4	Component parts of endoscopes which cannot withstand immersion in water or aqueous solutions should be protected from immersion.	Process such components in accordance with the manufacturer's instructions and provide protection from immersion during the automated cycle in the EWD.	Examples of such component parts include electronic connectors.

2.6 Cleaning (including pre-cleaning) - continued

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.6.5	Cleaning should be carried out using a validated cleaning process.	This is currently a two stage process, requiring the endoscope manufacturer's instructions for a manual (and therefore non-validated) pre-clean to be undertaken on the endoscope prior to automated processing in a validated EWD. <u>Stage 1</u> Thorough manual pre-cleaning of all surfaces (internal and external) according to the documented procedure, using an appropriate detergent (eg low-foaming enzymatic) and including the brushing of all accessible channels <u>Stage 2</u> Transfer the endoscope to the EWD for automated reprocessing (which includes a validated cleaning stage). Priority must be given to confirming the cleaning performance of each EWD currently in use, by validation of the cleaning stage and periodic monitoring for protein residues.	Guidance on cleaning processes and their validation is given in SHTM2030, particularly in respect of the automated cleaning process in the EWD. Guidance on manual cleaning is given in the 'Protocol for Local Decontamination of Surgical Instruments' and in MDA DB2002(05) The use of an EWD with a validated cleaning stage does not remove the requirement for the manual pre-cleaning as recommended by the endoscope manufacturer. The EWD cleaning stage is validated according to a 'worst-case' scenario, for example inadequate pre-cleaning or lack of awareness of a channel which is missed and remains heavily contaminated when connected to the EWD The draft European standard (EN ISO 15883-1,4) requires the that the EWD manufacturer's instructions *'shall recommend that any requirements for manual cleaning and or disassembly of the endoscope, prior to processing in the WD, provided by the device manufacturer should be followed'.* The test methods required for the validation of cleaning are described in Annex 2

2.6 Cleaning (including pre-cleaning) - continued

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.6.6	Cleaning should be carried out in all channels of the endoscope and should include all surfaces (internal and external) of the endoscope which are required to be disinfected by the WD.	Determine the exact number of channels present on the endoscope to be cleaned. Determine any constraints on accessibility for manually cleaning for any channel, by reference to the endoscope manufacturer's instructions. Ensure that only endoscopes for which all channels are capable of being manually pre-cleaned are retained in clinical use. Ensure that the pre-cleaning procedure is carried out in all channels, irrespective of whether or not the channel was in use during the endoscopy procedure. Determine the number of irrigation ports available for use in the EWD. Ensure that the automated cleaning process on the EWD will irrigate and clean all channels on the endoscope. If this cannot be achieved with a model of EWD in current use, an interim policy should be established on the basis of a risk assessment, prior to purchasing a compatible EWD. Options to be considered include: - transfer the endoscope to another ERU on the site which has a compatible EWD; - transfer the endoscope to an external site that has a compatible EWD. - apply a specific manual cleaning (and disinfection) procedure to the channels which cannot otherwise be irrigated in the EWD process.	The documented record of the number of channels present for each type of endoscope should be updated for each new model of endoscope processed in the ERU (see 2.1.1). Narrow lumened channels, for example the elevator channel/bridge) may need to have the pre-cleaning and rinsing fluids applied using a syringe. Follow the endoscope manufacturer's instructions and/or seek further advice. Some models of EWD may have insufficient irrigation ports to provide cleaning within all the endoscope channels. Connectors may be provided to facilitate the irrigation of more than one endoscope channel from a single EWD port. The efficacy of using particular connectors for this purpose on the EWD should be demonstrated as a performance validation test and subsequent periodic test.. In the draft BS EN ISO 15883-1,4, the EWD manufacturer is required to state the devices and/or device families for which the WD manufacturer has evidence that they can be processed satisfactorily and any precautions necessary for particular devices or operational conditions. The EWD manufacturer is also required to provide a diagram of the circulation pathway of the fluids for all channels of each medical device that the WD is intended to process, based on information from the manufacturer of each device.

2.6 Cleaning (including pre-cleaning) - continued

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.6.7	Cleaning should be carried out only by trained staff.	Establish a formal training programme. Maintain process records verifiable against skills register.	Process records should be kept indicating who was responsible for cleaning the devices (pre-cleaning and operating the EWD). Evidence that the person carrying out the work is trained and capable to do so should be verifiable from the skills register. (see 2.21)
2.6.8	Manual pre-cleaning should follow an agreed documented procedure in line with the endoscope manufacturer's instructions.	Manually wash endoscope channels and outer envelope, taking account of the manufacturer's instructions for each type of endoscope and giving careful consideration to: - local water quality; - water temperature; - detergent type/detergent concentration; - brushing and flushing of channels.	
2.6.9	Cleaning of re-usable accessories in the ERU, if required in the local decontamination policy, should follow an agreed documented procedure including the use of ultrasonics, in line with the endoscope manufacturer's instructions.	Follow the manufacturer's instructions for the cleaning of re-usable accessories prior to sterilization, using an ultrasonic cleaning bath as appropriate. In the ultrasonic cleaning procedure, give careful consideration to: - water quality/temperature; - detergent type/concentration; - process time.	Further guidance on ultrasonic cleaning is given in the LDU guidance Refer to SAN(SC)03/11 for guidance on the changing of aqueous solutions, rinsing and the necessary characteristics of detergents used in ultrasonic cleaners
2.6.10	After washing, the devices should be rinsed with water of appropriate quality.	Ensure that the rinsing process irrigates all channels of the endoscope in addition to the outer envelope. Drain the endoscope prior to transfer to the EWD	It is necessary to rinse to remove soils and avoid any interaction between the process chemicals used in pre-cleaning and those of the EWD processing cycle. The EWD may also include a flushing stage prior to the washing stage for additional safety.

2.6 Cleaning (including pre-cleaning) - continued

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.6.11	After manual pre-cleaning and rinsing, the endoscope, including all device channels and/or cavities, should be subjected to a validated cleaning process as part of the operating cycle in the EWD.	Ensure that the detergent used in the EWD is in accordance with a product specified by the EWD manufacturer. Place the endoscope in the EWD, ensuring that any protective caps are fitted to protect non-immersible parts as specified by the endoscope manufacturer. Run the operating cycle.	The automatic processing in an EWD is recommended because the process reliably exposes external and internal components of the endoscope to thorough cleaning, disinfection and rinsing. It does not obviate the need for manual pre-cleaning as given in the endoscope manufacturer's instructions. The EWDs specified in draft BS EN ISO-15883-1-4 are intended to process devices that can be immersed in water or aqueous solutions. For some devices, for example videoscopes, this will require that, prior to processing, relevant parts of the device are protected from immersion in accordance with the device manufacturer's operating instructions. Older, non-immersible endoscopes should be phased out of use.
2.6.12	All solutions used in the cleaning stage should be used once only.	Ensure that all solutions used in the cleaning stage (including flushing, washing and post-washing rinsing) are discharged to drain during or after each process cycle.	

2.7 Disinfection

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.7.1	The disinfection process should provide the highest possible assurance of freedom from microbial contamination.	Ensure that, prior to disinfection, the device has been cleaned using a validated process.	The efficacy of chemical disinfectants may be seriously impaired by residual soiling including inorganic salts remaining on the device prior to disinfection
2.7.2		Ensure that disinfection of the thermolabile endoscope is undertaken using a validated, automated process in an EWD.	EWDs that are manufactured to meet the design and performance requirements of SHTM2030 incorporate those features which facilitate process validation for all stages, including disinfection. The BSG(2003) guidance states 'the use of automated endoscope reprocessors is mandatory; manual disinfection is no longer acceptable' (Recommendation 3).
2.7.3	Disinfection efficacy should be specified across the spectrum of activity appropriate for the intended use.	Ensure that the required spectrum of activity and the extent of microbial lethality has been specified for each use application. Evaluate the test data provided by the manufacturer (or supplier) of the chemical disinfectant, in support the efficacy claims.	*In vitr*o tests of microbial activity should consider the conditions of use-in the EWD, for example, if there is no rinsing after the cleaning stage, the disinfectant should be tested in the presence of interfering substances, ie 'dirty conditions'. Test data should be assessed by the microbiologist, infection control team and user. Further advice can be obtained from reference centres such as HPS. The microbiological rationale for the choice of disinfectant should be placed on record, for example in the local decontamination policy.

2.7 Disinfection (continued)

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.7.4	The chemical disinfectant used in the disinfection stage should be compatible with the endoscope and the EWD.	Ensure that the choice of chemical disinfectant is: 1) As recommended by the EWD manufacturer, with input from the endoscope manufacturer and the disinfectant manufacturer. 2) An alternative product/formulation that is demonstrated from information supplied by the manufacturer and by performance testing to be equivalent to the product used by the EWD manufacturer in type testing.	It is important to seek information from the endoscope manufacturer concerning compatibility with the device. For new disinfectants, this data will not be available before a period of extensive testing. The EWD manufacturer should provide information on the disinfectant (and detergent) to be used, as established during type testing. Different formulations / types of disinfectant that have not been type tested by the EWD manufacturer may require changes to the set control values for the disinfection stage and may have a deleterious effect on the materials used in the endoscope and the EWD.
2.7.5	The disinfection process should be carried out in an EWD and will consistently meet the specified performance requirements for disinfection.	Ensure that type test data is available from the EWD manufacturer confirming attainment of the required disinfection conditions for the chemical disinfectant specified for the EWD, to include: - concentration - volume - temperature range - contact time	The conditions of time, temperature and chemical disinfectant concentration should be those specified, under the conditions of use, by the disinfectant manufacturer, or by an independent test laboratory. Appropriate additional testing (eg compatibility with the endoscope, environmental safety, disinfectant stability) should have been performed also.
2.7.6		Ensure that on installation, tests are undertaken to confirm that the process variables for disinfection are controlled within the limits established during type testing. Ensure that a microbiological validation of disinfection efficacy is undertaken to demonstrate the required microbial reduction factor.	The monitoring of process conditions should be under the control of the automatic controller on the EWD. A surrogate device is used in performance qualification to simulate the endoscope load. Inoculated carriers are placed in the surrogate device to monitor disinfection efficacy. In addition for performance qualification and routine tests the disinfection process may be verified by sampling endoscopes after clinical use, before and after processing. See test methods described in Annex 2.

2.7 Disinfection (continued)

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.7.7	The disinfectant should be in contact with all surfaces requiring disinfection at the required concentration and for the required time.	Ensure that the chemical disinfectant solution flows through all channels in the endoscope. Ensure that appropriate connectors are fitted to facilitate channel irrigation. Ensure that it is not possible for the operator to interrupt a cycle before completion.	The EWD manufacturer should state the number and type of connections required for channel irrigation for each device/device family that can be processed on the EWD. Different channels in different endoscopes may require different flow rates. The control system should permit regulation of pump pressure and inlet pressure to the various connections to allow the WD to be adjusted for particular types of endoscope. It is desirable that this should be a programmable option on the automatic controller. The locked and enclosed system in the appropriately specified EWD prevents the inadvertent removal of the cleaned endoscope before completion of the disinfection stage.
2.7.8	The temperature throughout the disinfection stage should be monitored to ensure that it remains within the specified limits.	Ensure that this is achieved, by either: - controlling the temperature of the disinfectant solution; - operating the WD at ambient temperature with means to prevent operation of the EWD when the disinfectant temperature is outside the specified range.	This should be under the control of the automatic controller. The temperature limits (range) are set by the disinfectant manufacturer in collaboration with the endoscope manufacturer to ensure optimal efficacy for the chemical disinfectant (dependent on the Q_{10} value) and compatibility with the temperature limits for the device to be processed. At cooler temperatures, the action of the chemical disinfectant will be slower and may compromise disinfection efficacy in the time set for the disinfection stage.

2.7 Disinfection (continued)

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.7.9	The chemical disinfectant solution should be used once and discarded.	(1) Use single-use containers of chemical disinfectant. (2) For EWDs that re-use disinfectant solutions for a number of cycles, ensure that the cycle will not start when the disinfectant concentration has fallen to, or below, the minimum recommended by the manufacturer or established by independent testing. Ensure that the EWD manufacturer's instructions concerning re-use of disinfectant solutions are followed.	Re-use of the same disinfectant solutions for several operating cycles is often justified on grounds of economy. This may be a false economy if second and subsequent processes with the same batch of disinfectant solution are not subject to the same control as the initial use. Some disinfectant manufacturers provide test strips and/or kits, the use of which they recommend in ensuring optimal activity of their product.
2.7.10	Disinfection should be carried out only by trained staff.	Establish a formal training programme. Maintain process records verifiable against skills register.	Process records should be kept indicating who was responsible for disinfecting the device (ie operating the EWD). Evidence that the person carrying out the work is trained and capable to do so should be verifiable from the skills register. For further information on staff training see 2.21.

2.8 Rinsing

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.8.1	Rinsing should be undertaken to reduce the concentration of process chemicals and other residual contamination on the endoscope.	Manually rinse the endoscope at the end of the manual pre-cleaning stage with freshly drawn water of at least potable quality, prior to transfer to the EWD. Run the operating cycle in the EWD as set, to include: - if necessary, a flushing stage before washing - if necessary, a post-washing rinsing stage - the final (post-disinfection) rinsing stage (see 2.8.2) Ensure that water used in the flushing stage is discharged during or after each process cycle and not re-used. Ensure that the rinsewater quality for the post-washing rinsing stage is as specified by the EWD manufacturer (this should be of at least potable potable quality). .	Flushing the internal and external surfaces of the endoscope as the first stage in the EWD may be necessary to eliminate residual soils and to avoid any interaction between the chemicals used during the manual pre-cleaning stage and those of the WD operating cycle. Rinsing between the washing stage and disinfection may be necessary to reduce the concentration of residues (process chemicals and soiling including microbial contamination) to a level that would not impair the efficacy of the chemical disinfection process. Some high level disinfectants are readily inactivated by protein and other organic soil. The EWD manufacturer may not include a post-washing rinsing stage if it has been established that there is no reaction between incompatible process chemicals being used in the cleaning and disinfection stages and that there is no adverse reaction between suspended or residual soiling and the disinfectant. The regulations that govern the quality of drinking water supplies in Scotland are the " Water Supply (Water Quality) (Scotland) Regulations 2001" and the "Water Supply, Scotland: The Private Water Supplies (Scotland) Regulations 1992".

2.8 Rinsing (continued)

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.8.2	The chemical and microbial quality of the final rinse water should not impair the standard of cleanliness and disinfection of the processed endoscope.	Ensure that the rinsing stage is carried out with water of a quality that does not lead to recontamination of the endoscope with micro-organisms coming from the incoming water supply reservoirs, including pipework within the machine. Ensure that for invasive endoscopes ('critical' and requiring sterilization in Spaulding's classification), the final rinsewater is sterile and contains no more than 0.25 endotoxin units/ml Ensure that for non-invasive endoscopes ('semi-critical' and requiring high level disinfection or sterilization in Spaulding's classification) the final rinsewater by preference is sterile.	After an effective cleaning and disinfection process the microbial quality of the final rinsewater will determine the microbial contamination which may be present on the endoscope on re-use. The chemical purity of the rinse water used after the disinfection stage shall be of, at least, that specified for potable water in the European Directive. For endoscopes intended to be used invasively, the rinsewater specification is equivalent to that of sterile water for irrigation. The most reliable method of providing water of the quality required for the final rinse is to use sterile 'bottled' water.
2.8.2	On completion of the final rinse stage, the water should not be stored for subsequent re-use in the rinsing stage of subsequent cycles.	Ensure that EWD is designed to prevent storage of the final rinsewater for use in subsequent rinsing stages.	

2.9 Drying

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.9.1	The endoscope should be dry before storage, to avoid contamination with and growth of microorganisms.	Ensure that means are provided at the end of the final rinse stage in the EWD to purge rinse water from the channels of the endoscope. If an automatic drying stage is not included in the EWD, ensure that the endoscope is manually dried prior to storage by purging the decontaminated device with 70% alcohol and allow this to evaporate. Follow the instructions provided by the endoscope manufacturer and the EWD manufacturer.	An additional drying stage may be included as a user selectable option on the EWD. Automatic EWD cycles in which the device is not completely dried are intended for use with devices which will be used without storage, ie returned to clinical use immediately after decontamination. Storage of incompletely dried devices may lead to contamination with, and growth of microorganisms. The use of isopropyl alcohol for flushing endoscope channels is recommended as part of the drying process at the end of the working day prior to storage. (BSG 2003) If an automatic drying stage is not included in the EWD, the manufacturer's instruction for use should indicate that the device and the channels of the device shall be manually dried prior to storage, in accordance with the device manufacturer's instructions. The test method and requirement for the drying stage in a validated EWD is given in Annex 2.
2.9.2	The quality of air used to purge the channels of any remaining rinsewater should not contribute to physical, chemical or microbial recontamination of the decontaminated endoscope.	Ensure that the air used for purging is oil-free and is filtered through a filter providing not less than 99.9% arrestance to particles of 0.2µm and larger.	
2.9.3	The quality of alcohol used to purge the channels of residual moisture should not contribute to physical, chemical or microbial recontamination of the decontaminated endoscope.	(1) Purchase the alcohol solution to specification 'sterile' or 'spore-free'. (2) Filter the alcohol solution (eg 70% iso-propanol) through a 0.2µm filter before use .	Bulk containers of 70% alcohol are frequently contaminated with bacterial spores and other environmental contaminants.
2.9.4	Manual drying should be carried out only by trained staff.	Maintain process records verifiable against skills register	Process records should be kept indicating who was responsible for drying the devices. Evidence that the person carrying out the work is trained and capable to do so should be verifiable from the skills register. For further information on staff training see 2.21

2.10 Storage

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.10.1	Decontaminated endoscopes should be stored in a manner that will not compromise their status.	Store endoscopes hanging vertically in a designated dry and well-ventilated storage cupboard. Ensure that all detachable components remain detached during storage and are not replaced until the endoscope is next used. Storage facilities for decontaminated endoscopes should be secure and only accessible to personnel who have a legitimate need.	Storage of the endoscope as a coiled device (for example in the lidded case) will not facilitate the drainage of any residual moisture and may introduce re-contamination / encourage proliferation of contamination. Secure storage should minimise the risk of placing an uncontaminated endoscope in storage intended for decontaminated devices.
2.10.2	Storage of endoscopes should be for a defined period after which reprocessing is undertaken prior to use.	Following storage, reprocess endoscopes (disinfection stage), prior to use. Only use endoscopes directly from storage if stored for less than 72 hours in a purpose built cabinet providing HEPA filtered air drying.	Use of a purpose-built storage cabinet providing a HEPA filtered air drying system keeps dry endoscopes free from adventitious microbial contamination. The risk of contamination increases with storage time and 72 hours is the maximum period validated by the manufacturers.
2.10.3	Sterile devices such as single use accessories and sterilized re-usable accessories should be stored in a manner that will not compromise their status.	Only devices that were sterilized as wrapped items may be stored and used as sterile devices. Sterile single-use accessories and sterilized re-usable accessories must be stored in clean dry conditions away from sources of water and contamination. Stored devices should be used in strict date order ie 'first in, first out' (FIFO) to ensure that storage is not prolonged unnecessarily. Storage facilities for sterile and sterilized products should be secure and only accessible to personnel that have a legitimate need	Secure storage should ensure that the devices are only accessible to personnel who have a legitimate need.
2.10.4	Clinical waste for disposal, including used accessories for disposal, must be stored safely.	Clinical waste for disposal should be stored in appropriate containers.	Guidance on storage of waste is given in SHTN No 3 Management and Disposal of Clinical Waste (2002).

2.11 Inspection and reassembly prior to use

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.11.1	All cleaned and disinfected endoscopes should be inspected for cleanliness.	Prior to reuse or storage, all endoscopes should be carefully examined for organic material (on the external surfaces and by purging channels where appropriate). Where practicable inspection should be carried out by a person not responsible for cleaning the item. Records should be kept.	Detailed inspection may require the use of a magnifier and task lighting to provide a higher level of illumination than is available for general room lighting.
2.11.2	All cleaned and disinfected endoscopes should be tested and or inspected for functionality.	Prior to use, all decontaminated endoscopes should be carefully examined for damage (using task lighting and magnification where appropriate). Inspection, maintenance and testing of items should be carried out by trained persons in accordance with the manufacturers instructions. Where practicable inspection and testing should be carried out by a person not responsible for reprocessing the item. Records should be kept.	Extent to which this is necessary depends on the nature of the device, the nature of the procedure for which it is being used and the ease with which the clinician can determine from its in-use performance that the device should be replaced / repaired before the defect becomes critical.
2.11.3	Devices that fail inspection for cleanliness or functionality should be segregated.	Redirect soiled items for further cleaning. Quarantine worn or damaged instruments pending repair or replacement.	Quarantine in locked storage would prevent unauthorised access.

2.12 Other processes - Sterilization

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.12.1	All endoscopes intended for use in invasive procedures (eg arthroscopes, some choledochoscopes) should be sterilized using a validated sterilization process.	For flexible endoscopes, their thermolabile nature limits the choice of validated sterilization process to: - ethylene oxide (EO) – a specialist process to be carried out by an accredited EO sub-contractor. - hydrogen peroxide plasma – this process may be appropriate for devices with very short lumens (less than 600mm) or non-lumened devices. The process should be undertaken using a validated sterilizer in an accredited sterilization facility eg a CDU. The endoscope manufacturer, the sterilizer manufacturer and the AP(S) should be consulted to ensure that the device is compatible with the intended process.	Because it is not practicable to test units of product (endoscopes) for sterility prior to release for use it is necessary to establish that the process when correctly operated will consistently and reliably produce the required outcome – this is demonstrated during the validation process. A generic standard on the validation of all sterilization processes (particularly relevant for the more recent 'novel' sterilization processes such as hydrogen peroxide plasma which were otherwise unregulated) has been published - BS EN ISO 14937 (2001) – 'Sterilization of healthcare products – General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices'. Standards on the validation of ethylene oxide and the specification of the ethylene oxide sterilizer are published. Guidance on ethylene oxide sterilization is given in SHTM 2010 parts 3 and 5. Information should be obtained from the sterilizer manufacturer to confirm compliance with BS EN ISO 14937 or specific process standards for the particular device/s to be processed. Advice on sterilization processes should be sought from the AP(S).
2.12.2	The endoscope should be subjected to a validated cleaning process prior to sterilization.	Process the endoscope by manual pre-clean and automated process in a validated EWD before despatch for sterilization.	Cleaning before sterilization is required to remove interfering contamination and reduce the microbial bioburden to a minimum level. Both options given above for sterilization lack cleaning and disinfection stages,

2.12 Other processes – Sterilization (continued)

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.12.3	All re-usable accessories and components should be sterilized by steam using a validated process.	(1) Transport to a centralised decontamination unit (CDU) for reprocessing. (2) Process locally, following the guidance for steam sterilization given in 'Local Decontamination Units: Provisional Guidance on the Requirements for Equipment, Facilities and Management'.	Steam sterilization of re-usable accessories in a porous load sterilizer to BS EN 285 in a CDU has many advantages, not least that the product is released dry and contained in suitable wrapping for storage. Local reprocessing of unwrapped re-usable devices or wrapped goods in sterilizers which do not meet BS EN 285 should only be undertaken after careful consideration of the LDU guidance.
2.12.4	The re-usable accessories and components should be subjected to a validated cleaning process prior to sterilization.	(1) Responsibility given to the CDU for processing the re-usable accessories and components by thermal disinfection in a validated surgical instrument WD. (2) Follow the guidance for cleaning and disinfection prior to steam sterilization given in 'Local Decontamination Units: Provisional Guidance on the Requirements for Equipment, Facilities and Management'.	
2.12.5	Sterilization should be carried out only by trained staff.	Maintain process records verifiable against skills register.	Process records should be kept indicating who was responsible for sterilizing the devices. Evidence that the person carrying out the work is trained and capable to do so should be verifiable from the skills register. For further information on staff training see 2.17 below.

2.12 Other processes – Sterilization (continued)

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.12.6	Each sterilization cycle should be reviewed and formally accepted as satisfactory before devices from that cycle are released as sterile and ready for use.	Ensure that 'sterile product release' documentation and procedures are used The operator should ensure that: - all maintenance and test records are up to date and satisfactory - the sterilizer's automatic controller indicates a satisfactory cycle - the requirements for thermometric release for steam sterilization are met - the load type and configuration was correct for the type of sterilizer - for goods wrapped throughout the sterilization process, that the packaging is intact and not wet. In addition, for low temperature sterilization processes, verify that the results of biological incubation meet the requirement for sterilization prior to sterile product release.	Advice should be sought from the AP(S). Advice concerning the arrangements for the culture of biological indicators and interpretation of the results should be sought from the Microbiologist (Sterilizers). Sterile product release documentation from sub-contractors or other units should be supplied to the User as confirmation of the formal sterile product release.
2.12.7	Sterile devices should be labelled as 'STERILE'.	Ensure that the label on wrapped sterile goods bears the legend 'STERILE' and is clearly distinguishable from similar items that are 'non-sterile'.	As well as information on the contents of the pack, the label should bear also a reference from which the processing history can be traced (see 2.14) and which will facilitate control of stock rotation. Where sterilized devices may be stored for some time the process date should also be included to facilitate stock rotation.
2.12.8	If the ERU includes a steam sterilization facility, eg for re-usable accessories, means should be provided to separate items that have been sterilized from those that have not.	Ensure clear physical separation of sterile and non-sterile (awaiting processing) items Use a process indicator to BS EN 867.	Process indicators may be provided by the use of packaging printed with a process indicator, or for steam sterilization, by the use of autoclave indicator tape. A changed indicator only demonstrates that the item has been in the sterilizer, NOT that sterilizing conditions have been attained.

2.13 Transport of endoscopes before and after reprocessing

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.13.1	Used endoscopes, including reusable accessories, should be decontaminated as soon as practicable after use.	Transfer all devices to the ERU as soon as they have been used.	
2.13.2	Used endoscopes should be transported in a manner that provides safe containment of contamination (microbial, body fluids and tissues etc)	Transport used endoscopes in re-usable solid walled leak proof containers/trolleys which are also designed to prevent damage to the endoscope Label all containers that are to be transported through public access areas with an appropriate label.	
2.13.3	Reprocessed endoscopes should be transported in a manner that will not compromise their status	Ensure that the re-usable transport container/trolley is clean and disinfected in addition to the requirements given in 2.13.2 above.	Where possible, use transport containers which can be re-processed by thermal disinfection in a surgical instrument WD. For trolleys, provision should be made for a trolley wash area, preferably an automated process or manual.
2.13.4	Sterilized endoscopes, re-usable accessories and single-use accessories should be transported in a manner that will not compromise their status.	Ensure that the re-usable transport container is clean and disinfected, dry, solid walled and leak-proof. Ensure that the re-usable transport container provides mechanical protection to prevent damage to endoscopes and to flexible packaging.	
2.13.5	Transport of endoscopes from the area of clinical use to the storage facility prior to reuse should be undertaken in a timely manner.	Ensure that there are an adequate number of transport containers and/or trolleys at the appropriate collection/transit sites. Ensure that the transport provision to off-site decontamination facilities is planned to meet clinical need.	

2.14 Traceability

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.14.1	Systems should be in place to track all endoscopes and re-usable endoscopic equipment through the decontamination process and to the patient on whom devices have been used.	Ensure that all endoscopes, including any loan endoscopes, have a unique identifier / serial number before use. Keep accessories other than single-use items together with a single endoscope, forming a unique set. Keep a log/ record of the serial number / unique set number of devices through processing and to patients.	NHS MEL (1999) 65 required immediate action to be taken to enable rapid tracing of endoscope, to avoid the risk of all endoscopes of a similar type being quarantined and possibly destroyed in the event of a vCJD related incident.
2.14.2	**Through processing:** The methods, operational cycles and personnel involved in processing a particular device, or set of devices should be traceable.	Record each process event carried out on the endoscope, including the manual pre-cleaning stage, the EWD used, the cycle number and the personnel involved. Make the record using: (1) IT based system (2) Manual (paper based systems)	An appropriately specified EWD has the facility to enter the endoscope serial number before the appropriate operating cycle starts. The process record generated by the EWD would therefore link directly to the specific endoscope processed in that cycle.
2.14.3	**To patients:** For all endoscopic procedures, the device or set of devices, used in a particular treatment episode should be traceable.	Record the details of the endoscope used as part of the patient record for the endoscopic procedure. (1) IT based systems may be used. (2) Manual (paper based) recording systems. Patient records may be annotated manually, using 'peel-off' labels or as part of an IT based system.	The log record is important for contact tracing when possible endoscopic transmission of disease is being investigated (BSG 2003 Recommendation 5). This information is also needed to exclude the endoscope/ potentially inadequate decontamination process as the source of cross-infection in an investigation of HAI. It is regarded as essential where there is a recognised risk of transmission of CJD.

2.15 Decontamination equipment

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.15.1	**Manual pre-cleaning**		
2.15.1.1	The specified equipment should be provided.	Ensure that there is a separate sink(s) for decontamination (ie one that is not also used as wash hand basins, filling kettles etc). Ensure that there are separate sinks for washing and rinsing if possible. Provide means to fill the decontamination sink to a known volume. Provide means to dispense detergent in known volumes. Ensure that there are adequate cleaning materials and cleaning implements, as specified by the endoscope manufacturer. Provide PPE for staff, to include gloves, face masks, waterproof apron, and goggles or visor. Ensure that a separate handwash basin is provided in the immediate vicinity.	The facility should be equipped in accordance with the guidance on manual washing in the Glennie Report 'Protocol for Local Decontamination of Surgical Instruments'. The known fill volume may be determined by simple measurement and marking the required fill level on the sink. Unless the volume of water and the volume of detergent are known it is not possible to prepare the cleaning solution at the specified concentration of detergent.
2.15.1.2	The specified services should be provided	Ensure that there is provision of: - hot water (domestic hot water), mixed to a temperature which provides optimal cleaning efficacy for the detergent without causing damage to the thermolabile endoscope; - water for rinsing; - manual washing detergents (neutral or enzymatic) as specified in the endoscope manufacturer's instructions	The detergent should be specified as suitable for purpose by the endoscope manufacturer and/or detergent manufacturer. Dishwashing detergents, surgical hand scrubs etc should not be used. Where the mains water supply is soft water of good quality (eg free from numic and fulvic acids) freshly drawn potable water may be used for rinsing. In hard water area, or where the water is discoloured, the water should be purified (ie by de-ionisation or reverse osmosis). Softening alone is insufficient since this does not reduce the level of total dissolved solids, which can be left on the instruments as a residue.

2.15 Decontamination equipment : Manual pre-cleaning (continued)

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.15.1.3	Routine testing of process variables should be undertaken.	Ensure that the periodic testing is undertaken, to include:- - accuracy of water temperature measurement; - accuracy of dispensed volume of detergent; - quality of rinse water.	See LDU guidance.
2.15.1.4	Routine maintenance of the facility should be undertaken.	Normal housekeeping to maintain cleanliness.	See also 2,23 Environmental cleaning.
2.15.1.5	Operational procedures should be followed as specified and in accordance with endoscope manufacturer's instructions.	Follow a documented procedure, in compliance with the endoscope manufacturer's instructions. Ensure all staff undertaking the manual pre-clean are trained in the procedure. Ensure a controlled and monitored wash temperature. Ensure a controlled detergent concentration. Ensure a controlled soak time (where applicable). Ensure that the cleaning brushes and other cleaning aids are in accordance with the endoscope manufacturer's instructions and are single-use wherever possible. Carry out the washing stage with the device immersed wherever possible. Protect non-immersible elements of the endoscope from immersion during the washing stage. Drain off excess detergent solution before transferring to rinse. Record details of items processed.	The cleaning aids should be made of materials which do not damage the endoscope – wherever possible use the cleaning aids supplied by the endoscope manufacturer. If the cleaning aids are not single-use, they will need to be thoroughly cleaned after use, preferably using a thermal process in an instrument WD. Immersion of the endoscope during manual pre-cleaning reduces the risk of aerosol dissemination of contamination. Endoscopes that are not designed to be completely immersed in liquid should be phased out of service. Some endoscope require protective caps to be fitted to sensitive components before they can be decontaminated in an EWD eg videoscopes need a cap on the video plug.

2.15 Decontamination equipment (continued)

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.15.2	**Endoscope WD**		
2.15.2.1	The EWD intended for the cleaning and disinfection of endoscopes is classified as a medical device and should meet the essential requirements of the Medical Device Directive.	Use an EWD that complies with the requirements of the harmonised standard 15883 Parts 1 and 4. In the interim period before the publication of BS EN ISO 15883, use an EWD that complies with the specification given in SHTM 2030-1.	The general requirements for all WDs including EWDs are in Part 1 of BS EN 15883 which is to be published in 2005. The additional requirements specific for EWDs are drafted in the revised prEN 15883 Part 4 which will be issued for national comment in 2005. EWDs that are manufactured to meet the design and performance requirements of SHTM 2030 incorporate those features which facilitate process validation for all stages, including disinfection. On publication, the harmonised standard BS EN 15883-1,4 will set the design and performance requirements and state the means of compliance with the MDD.
2.15.2.2	The EWD should be designed and constructed to meet the specified safety requirements to protect the operator and surroundings for the operator.	Ensure that the design and methods of construction used give adequate protection for the operator and the surrounding area against: - electric shock or burn; - mechanical hazards; - spread of fire from the equipment; - effects of fluids and fluid pressure; - liberated gases and pathogenic substances, explosion and implosion.	These requirements are specified in BS EN 61010-2-045.

2.15 Decontamination equipment - EWD (continued)

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.15.2.3	The specified requirements for construction should be met.	Ensure that the materials used are:- - capable of tolerating chemical, mechanical and thermal strains encountered during normal use - resistant to reaction with process chemicals (acid, alkaline, oxidising etc) Ensure that the EWD is designed to withstand not less than 10,000 operational cycles without suffering failure when operated according to the EWD manufacturer's instructions. Ensure that the EWD is constructed to enable access without the use of tools for routine tasks which are intended to be carried out by the operator. The method of construction of the chamber should ensure that it is self-draining and free from sharp internal corners which cannot be cleaned during the normal cleaning cycle. The load carrier intended to accommodate the endoscope should be designed and constructed to minimize the possibility of damage to the endoscope at the time of loading, during processing and during the course of unloading. Ensure that floor mounted EWDs are fitted with adjustable feet to compensate for irregular surfaces.	Those parts of the WD which come into contact with the load should be manufactured from materials which have corrosion and abrasion resistant properties equal to or better than stainless steel. Detailed mechanical and process requirements for materials, design and manufacture/construction are given in draft BS EN ISO 15883-1 and –4 and in SHTM2030-1.

2.15 Decontamination equipment - EWD (continued)

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.15.2.4	The specified performance requirements for the process should be met.	The specified performance should be achieved by an operating cycle under the control of the automatic controller, to include - leak testing (where appropriate) - cleaning (which may include several stages) - disinfecting - final rinsing - drying (when appropriate Ensure that type test data is available from the EWD manufacturer to demonstrate the specified performance capability for all types / families of endoscope that the EWD is designed to process Ensure that means are provided to deliver the set volume of process chemicals to an accuracy of ± 5% or better. Ensure that when the EWD uses two or more different process chemicals, means are provided to always make the connection to the correct container. Ensure that the dosing system for each process chemical is provided with means to determine that the volume admitted and the time within the operational cycle when the admission occurred were as programmed in the automatic controller. Ensure that a fault is indicated if the minimum volume is not admitted.	The efficacy of the process (including cleaning and disinfection) depends on a number of factors which include: - the characteristics of the endoscope; - the extent and nature of the soiling; - the temperature; - the mechanical energy (type, output); - the detergent system; - the nature, volume and temperature of the cleaning and disinfectant solutions and their ability to wet the surfaces to be cleaned and disinfected; - the duration of the various process stages; - the removal of suspended soiling. Other important factors include the design of connectors and the accessibility of the channels, valve housing etc. After the complete process in the EWD, the endoscope should be free from vegetative bacteria (but not necessarily spores) and other contamination. Detailed performance requirement specifications are given in draft BS EN ISO 15883-1 and –4 and in SHTM2030-1.

2.15 Decontamination equipment - EWD (continued)

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.15.2.5	The specified mechanical and process requirements should be met.	Ensure that compliance with all the specified requirements is met. Key requirements are listed as follows:-	Full details of the requirements should be noted from the specification standards (BS EN ISO 15883-1,4 (awaiting publication); SHTM2030).
2.15.2.6		<u>Automatic controller</u> Ensure that the automatic control system :- - is capable of being programmed with the pre-set cycle variables essential for each stage of the operating cycle; - gives a visual indication (and audible, if required) that a fault has occurred if any values of the cycle variables are outside the limits set by the EWD manufacturer.	The automatic controller checks the attainment of the pre-set variables and ensures reproducibility during each subsequent cycle. If a fault is indicated, it should be assumed that the EWD load has not been subjected to the decontamination process and the endoscope should be reprocessed.
2.15.2.7		<u>Doors and their controls</u> Ensure that it is not possible for the operator to start the process if the lid / door is not locked. Ensure that after initiation of the operating cycle, the door for loading/unloading is capable of being unlocked and opened only after completion of the operating cycle. Ensure that there is no leak from the door-seal during the operating cycle. Ensure that if a fault occurs during the operating cycle it is displayed and access to the load restricted to use of a special key, code or tool.	The EWD may be fitted with one door, which serves for both loading and unloading, or two doors of the 'pass-though' type. Wherever practicable double door (pass through) machines should be chosen to provide the best possible segregation of clean and dirty. The inability to interrupt the cycle and remove an endoscope is both a safety and performance requirement. Adverse outcomes include the failure to disinfect because of inadequate contact time with the chemical disinfectant.

2.15 Decontamination equipment - EWD (continued)

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.15.2.8	The specified mechanical and process requirements should be met.	Pipework and fittings Ensure that the pipework, pumps, valves and fittings are installed and operated so that any residual fluid flows towards a drain discharge point.	Residual water that does not drain from the internal pipework of the EWD can provide an environment for microbial growth and re-contamination of the load. Residual fluids may also lead to corrosion.
2.15.2.9		Tanks Ensure that tanks for storing water in the EWD are: - free-draining; - located for cleaning without dismantling other parts of the EWD (other than panels); - drained down automatically or manually when the machine is switched off; - fitted with a warning to indicate overfilling.	There should be no static water stored within the WD at a temperature above 10°C or below 55°C for more than four hours if it is intended to come into contact with the load. This should be controlled and monitored by the automatic controller.
2.15.2.10		Switches and indicating devices Ensure that the operating cycle is started by means of a single switch. Ensure that each switch, gauge or indicating device intended to be used by the operator is marked with an appropriate symbol and/or labelled with a description of the function. The following indicators shall be located at the loading end of the WD: - 'in-process'; - 'fault'; - hours run meter or cycle counter that cannot be re-set by the user; - 'cycle complete'; - 'insufficient process chemicals to complete cycle'; - temperature.	The instrument reading and legend shall be legible at a distance of 1 m from the machine when tested in accordance with 6.6.2.

2.15 Decontamination equipment - EWD (continued)

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.15.2.11	The specified mechanical and process requirements should be met. (continued)	<u>Endoscope channel irrigation</u> Ensure that the various process fluids (cleaning solutions, disinfectant, rinsewater) are able to flow through each of the internal channels and/or cavities of the endoscope. Assurance that this has taken place shall be provided: (1) by the automatic controller providing means to verify the flow of process fluids through each channel during at least part of the cleaning, disinfecting and rinsing stages. (2) by requiring in the instructions for use that the user: - verifies that all channels allow the flow of water before the device is loaded into the EWD; - confirms that all necessary connections were made before, and were still in place at the end of, the cycle; - confirms by reference to the EWD process record that the supply of process fluids was maintained during each stage of the process; - verifies flow through each endoscope channel at the end of each operational cycle or immediately before use. Ensure that the EWD manufacturer provides a diagram of the circulation pathway of the fluids for all channels of the endoscope, based on information from the endoscope manufacturer.	Even though the flow of fluid though channels may have been verified before the instrument was place in the EWD, blockage can occur during processing when soiling dislodged from one place becomes trapped in a more restricted part of the instrument. Option (1) allows for repeated automatic confirmation of flow and the abortion of the cycle if a channel is blocked or has no means of flow in place. Before choosing equipment conforming with option 2) users should consider the increased requirement for staff training, staff time during reprocessing and the lack of an independent record that the process was carried out in a satisfactory manner. The flow diagram should be provided for each type or family of endoscope that the EWD is intended to process The flow diagram and/or instructions should show any limitations on how, or to which port on the WD, the endoscope channels can be connected.

2.15 Decontamination equipment - EWD (continued)

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.15.2.12	The specified mechanical and process requirements should be met. (continued)	Endoscope channel irrigation (continued) The minimum and maximum flow and maximum pressure that the EWD is designed to deliver to each channel or channel system should be specified. In the case where different channels are irrigated at different pressures, the connection systems shall be designed to prevent incorrect connection. Ensure that when one or more channels of the device is obstructed, to an extent that would impair the efficacy of the process, the automatic controller shall cause a fault to be indicated. Ensure that when one or more channels of the device is not connected to the WD the automatic controller shall cause a fault to be indicated. Ensure that the automatic controller verifies that the duration of flow of the relevant process fluids met or exceeded the minimum exposure times established, during validation studies, as necessary for each process stage. Failure to achieve the required flow shall cause a fault to be indicated. Ensure that when there is a common connection for fluid at the same supply pressure to more than one channel, the WD manufacturer shall provide evidence that the flow through each of the channels meets, or exceeds, the minimum required for effective cleaning, disinfection and rinsing of each device to be processed.	In EWDs meeting the appropriate specification, the entry of the endoscope code at the start of the cycle should automatically prompt the controller to confirm that the appropriate number of channels for that endoscope are attached and being irrigated. With some designs of endoscope a blockage in one channel may cause the flow in the EWD to be diverted to another channel or port. Under these circumstances detection of an obstruction by the automatic controller may not be reliable. The user should refer to the device manufacturer's instructions for the method to be used to verify that all channels are free from obstructions.

2.15 Decontamination equipment - EWD (continued)

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.15.2.13	The EWD should be fitted with means to verify and record the attainment of the specified process conditions.	Verify by process record, independent from the automatic controller. The EWD should be equipped with a multi-channel recorder, with sensors and signal processing independent of the automatic controller, to record the process variables determined during validation studies to be critical to the satisfactory outcome of the cleaning and disinfection processes. Ensure that the recorder produces a permanent record that should remain legible for the duration of record storage required by national regulations.	This level of process verification gives confirmatory evidence that both the cleaning and disinfection processes have taken place within the limits established during validation. It is required because the endoscope will typically be used without further processing and the risks of unsatisfactory cleaning and/or disinfection are unacceptable. The verification also gives assurance of cleaning in lumens/ channels which cannot be visually inspected. Thermal record papers are unlikely to meet the requirement for a permanent record.
2.15.2.14	The specified requirements for self-disinfection of the EWD should be met.	Ensure that the self-disinfection cycle: - is operated under the control of the automatic controller; - is a user-selectable cycle; - provides for disinfection of the chamber and all liquid transport systems (excluding single-use containers for process chemicals); - includes means to warn the user that the WD must be operated without any load in the chamber and, so far as may be practicable, includes means to verify that no device is present before the cycle will operate; - in the case of a thermal self-disinfection of the WD, ensure that all the parts of the heating system and the associated pipework, via which the water or the steam reach the WD tank, attain an A_o value of at least 600.	The self-disinfection process is designed to: - ensure that the EWD does not become a focus for contamination of the load; - provide a means of disinfecting the EWD after interventions for maintenance, repairs or testing - deal with a situation where the EWD has become contaminated eg through failure of the water treatment system. The EWD manufacturer should provide details of the EWD parts subjected to the self-disinfection cycle and whether this includes the water treatment equipment. Fluid paths including the piping for rinse water may develop a layer of biofilm containing micro-organisms in a state in which they are highly resistant to chemical disinfection. Thermal disinfection using moist heat is therefore the preferred method of self-disinfection. Because the endoscope is not in place during this cycle, the temperature can be higher than the normal operating cycle. The methods for testing compliance (thermometric or microbiological as appropriate) are given in Annex 2.

2.15 Decontamination equipment - EWD (continued)

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.15.2.16	The specified engineering services should be provided.	The EWD will require external service connection. These may include:- - water (of various qualities) - electrical connection - compressed air - drainage - ventilation The EWD manufacturer must make clear at an early stage which services will be needed and give detailed requirements for each service.	Failure to take note of the installation requirements specified by the EWD manufacturer can lead to unnecessary delays in installation and performance qualification. These requirements may also have implications for the choice of location and the space required, for example for any water treatment plant.
2.15.2.17	The validated EWD should remain in compliance with the agreed specification.	Subject each EWD to validation tests (installation and performance qualification on first installation). Undertake a programme of routine tests. Demonstrate continued compliance by periodic testing. Establish a programme of documented planned preventive maintenance, in line with the manufacturer's instructions. Repeat the validation tests after any major break-down or design modification of the installed machine.	See Annex 1 and 2.
2.15.2.18	The EWD should be operated in accordance with the manufacturer's instructions.	Prepare and implement a documented procedure for each EWD, in line with the EWD manufacturer's instructions. Ensure that the EWD is operated by staff who have been trained and are assessed against a skills register. Record details of the endoscopes processed, cycle and operator details. Undertake periodic audits of equipment, staff and facility.	

2.15 Decontamination equipment (continued)

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.15.3	**Drying / storage cabinet**		
2.15.3.1	Endoscopes should be stored hanging vertically in a designated dry and well ventilated cupboard.	1) Use a purpose-built storage cabinet, providing a HEPA filtered air drying system. 2) Use a designated cupboard which is ventilated and dry. Ensure that the endoscopes have sufficient space to hang vertically.	Use of a purpose-built storage cabinet providing a HEPA filtered air drying system keeps dry endoscopes free from adventitious microbial contamination. The risk of contamination increases with storage time and 72 hours is the maximum period validated by the manufacturers.
2.15.3.2	The drying / storage cabinet should meet the specified requirements.	Key requirements include: - forced air circulation; - temperature controlled; - temperature indicator; - lockable door.	Endoscope drying cabinets are available that incorporate u/v light as a means of prohibiting re-contamination during storage.
2.15.3.3	The appropriate services should be provided	Ensure an electrical connection is available.	
2.15.3.4	Validation procedures should be undertaken	Measure the temperature profile throughout chamber. Establish the minimum time/temperature required for drying	
2.15.3.5	Routine testing	Portable Appliance Testing (PAT).	
2.15.3.6	Maintenance procedures should be undertaken.	For maintenance and repair of the purpose-built drying/storage cabinet, follow the manufacturers instructions.	
2.15.3.7	The drying cabinet should be operated in accordance with agreed procedures.	Prepare and implement a documented procedure. Ensure that staff are trained and assessed against a skills register. Record details of items stored by the operator.	

2.15 Decontamination equipment (continued)

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.15.4	**Ultrasonic cleaner – for reusable accessories**		
2.15.4.1	The ultrasonic cleaner should be designed and manufactured to meet the required cleaning performance.	Ensure that, if specified in the endoscope manufacturer's instructions, an ultrasonic cleaner to an appropriate specification is used for cleaning re-usable accessories. Key features of the specification include the following:- - a securely fitting lid to prevent the emission of aerosols; - a timer to control exposure time; - heater to control temperature of the tank; - a drainage tap at the base of the free draining tank, to ensure the detergent solution can changed regularly *in situ;* - a dispenser for known volumes of detergent.	Ultrasonic cleaners are used to dislodge soiling from intricate, difficult to clean items such as reusable accessories. They are not generally suitable for endoscopes. Ultrasonic cleaners are less effective on plastic which absorbs much of the ultrasonic energy. Larger ultrasonic baths have a lid interlock to ensure that the operator's hand cannot be immersed in the ultrasonic cleaner during an operating cycle. The process is controlled by time and temperature. Ultrasonic cleaners in medical device applications are typically operated at temperatures between ambient and 40ºC to minimise the rate of coagulation of proteinaceous material in soiling and be compatible with enzymatic detergents. Validation using test soils is recommended. For more detailed guidance on design specification and testing, see SHTM 2030-1, SHTM 2030-3 and the LDU guidance.
2.15.4.3	The ultrasonic tank should be filled with an aqueous solution of detergent meeting the appropriate specification.	Follow the ultrasonic bath manufacturer's instructions and specification of detergent. Use a low foaming detergent with good surfactant and soil dispersion properties. Use softened or purified water Ensure the detergent solution is changed frequently	See SAN (SC) 03/11 Decontamination of re-usable medical devices: Control of aqueous solutions in ultrasonic cleaners The solution in the tank should always be drained and refilled if visibly coloured or cloudy. It should not be left unchanged during use for intervals exceeding 4 hrs. After use, the tank should be drained dry.

2.15 Decontamination equipment – (continued)

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.15.4.4	The ultrasonic cleaner should be operated in accordance with agreed procedures.	Prepare and implement a documented procedure, including cycle time, temperature, choice of detergent. Ensure that staff are trained and assessed against a skills register. Record details of items processed by the operator.	If the ultrasonic cleaner does not have a lid interlock the procedure should specify that: - the cleaner should not be operated unlidded; - that operators should not put their hands in the water while the ultrasonics are active.
2.15.4.5	Routine testing and maintenance should be carried out.	Test the ultrasonic activity by observing the erosion pattern on aluminium foil strips. Undertake PAT testing. Follow the manufacturer's instructions on maintenance.	Details of the foil ablation test are given in SHTM 2030-3.

2.15 Decontamination equipment (continued)

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.15.5	**Small steam sterilizer – for reusable accessories**		
2.15.5.1	Steam sterilization of re-usable accessories should be undertaken in a validated sterilizer designed to meet the specified performance.	Ensure that the endoscope manufacturer's instructions are followed, including any limitations on the sterilization temperature. Ensure that the sterilizer is used for the type of product for which it is designed. Ensure that the suitability of a particular steam sterilization procedure for a particular re-usable accessory is verified by validation.	The need to keep re-usable accessories in a controlled set with the endoscope may necessitate the use of a small steam sterilizer to SHTM 2010 or the recent standard BS EN 13060 which would be located in the ERU. Guidance on the validation, maintenance and testing of small steam sterilizers is given in the LDU guidance and MDA DB 2002(6).
2.15.5.2	The re-usable accessories should be thoroughly clean before sterilization.	Ensure that the endoscope manufacturer's instructions for manual and/or ultrasonic cleaning are followed.	Guidance on the use of ultrasonic cleaners is given in 2.15.4 and in the LDU guidance.
2.15.5.3	The option of using a steam sterilization process should be compared with using single-use accessories.	Considerations in using a small steam sterilizer in the ERU include:- - the time required for daily testing; - installation and commissioning tests; - maintenance and periodic testing; - operational costs (electricity, sterile water, insurance etc); - cost of training operators; - reliability factor (where assessable); - cost of meeting legal requirements.	Aim to use single-use accessories wherever possible.

2.16 Water supply

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.16.1	The quality of water used at all stages in the decontamination process is critical to the successful outcome of the process. Water of optimum quality for each stage of the decontamination process should be provided.	Manual pre-cleaning – the water quality should be compatible with the detergent used and the materials of construction of the endoscope. Seek advice from the manufacturer of the endoscope and the manufacturer of the process chemical(s). Automated processing in the EWD At each stage in the process the water quality should be compatible with: - the materials of construction of the WD; - the load items to be processed; - the process chemical (additive) used; - the process requirements of that particular stage. The EWD manufacturer should specify the quality of water required for each process stage. The quality of the final rinsewater is critical. Seek advice also from the manufacturer of the endoscope, the manufacturer of the process chemical, water treatment plant manufacturer and the AP(S).	The key factors, listed in SHTM 2030-1, are: - hardness - temperature - ionic contaminants - microbial population - bacterial endotoxins
2.16.2	Water from the mains should be subjected to an appropriate treatment to provide the optimum quality for each stage in the decontamination process.	The available methods of water treatment appropriate for endoscope decontamination are: - water softeners - water deionisers - reverse osmosis	

2.16 Water supply (continued)

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.16.3	The quality of the water supplied to the EWD should be monitored.	Ensure that the attainment of the required water quality supplied to the EWD is:- - monitored continuously; or - monitored periodically.	The monitoring function can be provided by equipment external to the EWD, installed on the water supply system.
2.16.4	When water treatment equipment is part of the EWD, the former shall be designed and constructed so that it can be submitted to a disinfection procedure periodically.	Carry out the disinfection of the water treatment equipment in the EWD during the self-disinfection cycle	The frequency of disinfection shall be decided by the user, based upon known ie seasonal variation sin the quality of water supplied to the EWD and the operational history of the water treatment equipment.
2.16.4	EWDs must be designed, constructed, installed, operated and maintained in accordance with the requirements of the relevant Model Water Byelaws, whose scope includes the prevention of waste, undue consumption, misuse or contamination of the water supply.	Care must be taken in respect of the mains water supply and return to waste throughout the decontamination process. Seek advice from the AP(S) and the EWD manufacturer to ensure local compliance.	All the organisations responsible for water supply have the statutory power to make and enforce byelaws to prevent waste, excessive consumption, misuse or contamination of the water supply. The Model Water Byelaws form the basis of such byelaws. Attention is drawn in SHTM 2030-1 to: Bye-law 38-41 concerning storage cisterns. Bye-law 25 Schedule A concerning the possibility of backflow being harmful to health due to a substance being continuously or frequently present (for example a disinfectant) .The required protection is a Type A air gap at the point of use. Detailed guidance on the Water Supply Bye-laws is provided by the Water Research Council.

2.17 Repair, loan and disposal of endoscopes

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.17.1	Before despatch from the ERU for repair, refurbishment or disposal the endoscope should be rendered safe to handle,	Ensure that the endoscope is decontaminated to an appropriate level before despatch, packed securely and accompanied by a certificate stating the method by which it has been decontaminated. Operate a 'Permit to work' system.	The decontamination process should not cause further damage, for example by immersing an endoscope that has failed a leak test and permitting further ingress into the sheath prior to its repair. However, the emphasis should always be on presenting a device which is as safe as possible to handle on receipt.. As a minimum, the external surfaces should be wiped clean, the device packaged securely and a full explanation given on the accompanying certificate. A leaflet giving guidance on 'Permit to Work Systems', is published by the Health & Safety Executive (1997).
2.17.2	Before despatch from the clinical unit or ERU for loan to another clinical unit, the endoscope should be decontaminated,	Ensure that the endoscope is clean, disinfected and dry before transfer.	
2.17.3	Scrapped devices must not fall into the hands of those who may misuse them,	Endoscopes that are being scrapped should be transported and destroyed by known, reliable contractors who will certify their destruction.	

2.18 Design of decontamination facilities

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
	Decontamination Area – Endoscope Reprocessing Unit (ERU)		
2.18.1	Decontamination should be undertaken in a designated endoscope reprocessing unit (ERU).	Ensure that the ERU is in a planned location: - adjacent to the clinical endoscopy areas; - centralised and providing a planned service to a number of different user sites in the hospital; - incorporated as part of an existing LDU or CDU, as appropriate. Factors to be considered in selecting a location include: - availability of appropriately sized unit; - access routes between users and reprocessing facility; - transport requirements; - revenue and capital costs; - turnaround times (taking into account the process time, number of patients per session *versus* number of endoscopes); - instrument inventory; - IT systems; - engineering services and service utilities required e.g., water, electricity, drainage, ventilation; - personnel required; - security issues; - statutory consent e.g., planning permission, building warrant; - customer base; - access to / communication with clinical unit; - transfer and storage facilities at clinical unit.	Typically, this facility would be provided adjacent to the clinical endoscopy areas in the endoscopy unit or operating theatre. The decontamination facilities provided in a central decontamination unit eg sterile service unit are particularly appropriate for the reprocessing of rigid endoscopes and for sterilization of reusable accessories. In some instances, the SSD may also provide decontamination facilities for the off-site reprocessing of flexible endoscopes. Ad hoc arrangements for the local decontamination of endoscopes in clinics and wards should be discouraged unless these facilities are fully compliant with the specified requirements for endoscope decontamination facilities. Guidance on the design and planning of decontamination facilities is given in SHPN 26 Operating Department, SHPN 13 Sterile Service Departments and NHSScotland Sterile Services Provision Review Group 1st Report (The Glennie Framework) including Technical Requirements and Protocol for Local Decontamination of Surgical Instruments. See idealised schematics in Figures 3, 4 & 5.

2.18 Design of decontamination facilities (continued)

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.18.2	The ERU should be designed and equipped to facilitate effective decontamination.	Design the unit so that it is physically separated from all other work areas. Ensure that there is a planned work flow from the 'dirty' (receipt of contaminated endoscopes to transfer into the EWD) to 'clean' (inspection, drying and storage of the decontaminated endoscope). Segregate the 'dirty' and 'clean' activities wherever possible. Provide ventilation to ensure a pressure differential between the dirty reprocessing area and linked areas (clean reprocessing, patient treatment, hospital corridor). Ensure that the decontamination room in the unit is equipped with:- - dedicated sink/s for pre-cleaning; - compressed airline; - work surfaces; - EWD/s and associated services; - extract ventilation linked to the EWD (if required); - task lighting; - hand wash sink; - storage facilities. Ensure that finishes on walls and other surfaces are smooth, water resistant and able to withstand frequent cleaning. Ensure that the junctions between walls, floors and ceilings are coved and flush. Ensure that floors are covered in a washable non-slip sheet material which is adequately sealed. Ensure that there is adequate lighting to permit good working practice eg visual inspection of devices and the results of process residue tests.	The room in which a EWD is installed and operated should meet the requirements of the Workplace (Health, Safety and Welfare) Regulations 1992. These Regulations have considerable implications for the design of accommodation for EWDs. Fire safety precautions should comply with NHSScotland Firecode. The workload demand of the facility will depend on the number of clinical units served and the activity (patient throughput) of each of these units e.g., number of sessions per week to be supported and the number of patients per session. The facility should be sized taking into account foreseeable future requirement e.g., space for additional EWDs if required.

2.18 Design of decontamination facilities (continued)

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.18.3	The decontamination room should be designed to protect personnel from exposure to infectious agents, toxic and/or hazardous substances.	Ensure personnel working in decontamination have: - appropriate clothing and footwear; - personal protective equipment; - hand washing facilities. Ensure the following facilities are provided in proximity to the decontamination room- - male and female changing facilities; - shower and toilet facilities; - secure lockers for storage of outside clothing and valuables.	
2.18.4	Entry into the decontamination room should be restricted to authorised personnel only.	Ensure that appropriate training on the entry procedure is given to all staff. Maintain a means of communication eg telecom between staff in the different areas.	
2.18.5	There should be sufficient trained staff to undertake the required decontamination activities.	Undertake a staffing review when designing a new ERU.	Consideration should be given to: - the number of clinical sessions supported; - the number of patients/endoscopes per session; - the cycle time for decontamination; - the hours that the ERU will operate.
2.18.5	All staff should be trained in risks associated with activities carried out in this area.	Implement a staff training programme.	See 2.21.
2.18.6	Access should be provided to computer facilties.	Ensure sufficient electricity supply, computer terminal points and work stations in the ERU and associated clinical areas to make appropriate use of IT, Management Information Systems (MIS), audit tools, on-line training etc.	The use of computers and IT is a rapidly developing facility within decontamination. MIS is used to track and trace medical devices through the decontamination system and to the patients on whom they are used. A computer-based audit tool for Endoscope Decontamination (EDAT) has been developed.

2.18 Design of decontamination facilities (continued)

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.18.7	**Storage facilities**		
2.18.8	Storage facilities should be provided for bulk items, external to the decontamination room.	Ensure that the facility(ies) are designed to meet the different storage requirements for specific items eg process chemicals, sterile packs of single-use accessories, PPE stock, In general the storage facilities should be: - secure with access restricted to authorised personnel only; - mechanically ventilated, free from opening windows; - dry; - hygienically fitted, free from pendant light fittings; - maintained in good condition; - appropriate for process consumables to be held in accordance with the COSHH Regulations.	
2.18.9	Decontaminated endoscopes should be stored hanging vertically in a designated dry and well ventilated cupboard.	Use a purpose-built storage cabinet, providing a HEPA filtered air drying system; Use a designated cupboard which is ventilated and dry.	See 2.15.3.
2.18.10	Process chemicals should be stored in a safe manner.	Undertake a COSHH assessment. Store hazardous chemicals in a locked, flameproof cupboard.	

Figures 3 - 5

[Note: The Schematics have been removed as they are under review. If you require urgent advice on this then please contact the Decontamination team at decon_team@hps.scot.nhs.uk]

2.19 Management of decontamination

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.19.1	Chief Executives of NHS Trusts are required to ensure that a senior manager (ie a member of the Trust Board or directly accountable a member of the Trust Board) is designated as having overall responsibility for risk assessment and management processes relating to decontamination, infection control, medical device management and cleaning services.	Ensure that the senior manager HDL(2001)10 has been appointed. Ensure that relevant advice on decontamination received by the senior manager HDL(2001)10 from SEHD and other agencies is circulated to relevant staff including the decontamination manager of the ERU.	This senior management post is a requirement in HDL(2001)10 'Decontamination of Medical Devices' published in 2001. The background and experience of the senior manager HDL (2001)10 is not specified.
2.19.2	A manager with responsibility for decontamination should be appointed to the ERU.	Ensure that an Endoscopy Decontamination Manager is appointed with defined responsibility for the control of the decontamination of endoscopes and re-usable accessories. Ensure that the decontamination manager's job description sets out their responsibilities to run the decontamination service in accordance with legal requirements and national standards (including best practice guidance published by SEHD). Ensure that the decontamination manager undertakes periodic training to update their knowledge, skills and competence to manage the decontamination service.	The Endoscopy Decontamination Manager of an ERU would fulfil the role of "user" as specified in SHTM2030

Management of decontamination (continued)

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.19.3	The decontamination manager should ensure compliance with guidance in MDA Device Bulletin DB9801 (Medical Devices and Equipment Management for Hospital and Community based Organisation).	Documented and defined accountability for: - all parts of the decontamination cycle including acquisition and disposal of devices; - contractors where the ERU buys in services; - professional liability where the ERU sells decontamination services to other organisations. Produce written policies and procedures which: - define, document, and control all stages of the decontamination process; - are available to all personnel involved in any aspect of decontamination. Access to up to date legislation and guidance	
2.19.4	Staff should be aware of the legislation and guidance related to their work activity.	Have arrangements in place to deal with Health Department Letters (HDLs) and Safety Action Notices. Maintain a secure readily available filing system for information on medical devices, including, acquisition, use, decontamination and eventual disposal that is accessible to all staff who may need the information.	
2.19.5	An Authorised Person (Sterilizers) should be appointed by management to each decontamination facility.	Ensure that the particular activities to be undertaken by the AP(S) in respect of each ERU are specified, for example, in the AP(S) contract with the organisation. .	The principal responsibilities of the AP(S) are described in SHTM2030 Part 1. The AP(S) is qualified to provide independent auditing and advice in decontamination, including guidance on the choice, validation, maintenance, testing and operation of decontamination equipment including EWDs and to review and witness validation. A register of suitably qualified AP(S) is maintained by the Institute of Healthcare Engineering and Estates Management.

2.19 Management of decontamination (continued)

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.19.6	A number of key personnel to be designated by management with principal responsibilities pertinent to EWDs are defined below –		See following details in SHTM 2030
2.19.7	The User	defined as the person designated by management to be responsible for the management of the EWD.	The principal responsibilities of the user are as follows: - to certify that the EWD is fit for use; - to hold all documentation related to the EWD; - to ensure that the EWD is subject to periodic testing and maintenance; - to appoint operators where required and ensure that they are adequately trained; - to maintain process records. This could be the decontamination manager in the ERU. Alternative management arrangements may apply if the sterile service department employs and trains operators to work in the ERU.
2.19.8	Test Person (Washer-disinfectors)	defined as a person designated by management to carry out the validation of WDs and to provide advice on testing, maintenance and procedures. The test person should either: - be a test person (Sterilizers) as defined in SHTM 2010; - be qualified to at least HNC level in engineering or relevant sciences and have at least two years experience in the validation; - have at least 5 years experience in the testing of WD processes (preferably EWDs).	The principal responsibilities of the TP are:- - to advise on programmes of periodic testing and periodic maintenance of EWDs; - to advise on routine operational procedures; - to conduct the validation test specified in SHTM 2030-3 and to prepare the validation report; - to conduct the periodic tests specified in SHTM 2030-3 and to prepare reports as required by the user; - to conduct additional tests requested by the user.

2.19 Management of decontamination (continued)

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.19.9	Maintenance Person (Washer-disinfectors).	defined as a person designated by management to carry out maintenance duties on WDs. The Maintenance Person should be a fitter or electrician with documentary evidence to demonstrate competence in the maintenance of one or more types of WD (preferably EWDs). He or she should be in a position to deal with any breakdown in an emergency and have the ability to diagnose faults and carry out repairs or to arrange for repairs to be carried out by others.	The principle responsibilities of the Maintenance Person are: - to carry out the maintenance tasks as outlined in SHTM 2030 Part 2 operational management; - to carry out additional maintenance and repair work at the request of the user. A Maintenance Person who has a minimum of 5 years experience in the maintenance of EWDs may by agreement perform the duties of the Test Person for the daily, weekly, quarterly and yearly test as described in SHTM 2030 Part 3.
2.19.10	Microbiologist (Sterilizers)	defined as a person designated by management to be responsible for advising the user on microbiological aspects of disinfection. The microbiologist (sterilizers) should have a degree or equivalent training in microbiology and would normally be a member of the hospital staff.	The principle responsibilities of the M(S) are:- - to provide general and impartial advice on all matters concerned with washing and disinfection; - to advise the user on the microbiological aspects of all disinfection procedures; - to arrange for the culturing of biological indicators used in microbiological testing; - to audit the documentation from the EWD which has been tested by microbiological methods
2.19.11	Control of Infection Officer	defined as the person designated by management to be responsible for advising the user on all infection control aspects.	
2.19.12	Quality Manager	defined as a person designated by management to be responsible for the quality management system operated within the endoscopy reprocessing unit, irrespective of their other quality management duties within decontamination and/or the healthcare facility.	

2.19 Management of decontamination (continued)

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.19.13	Contractor	defined as a person or organisation designated by management to be responsible for the supply and installation of the EWD and for carrying out the installation checks and tests. The contractor is usually the manufacturer of the EWD.	
2.19.14	There are defined management responsibilities on procurement and validation of an EWD.	Management should nominate, when necessary, an AP(S) to provide advice on validation and an MP/TP to carry out the checks and test required. The AP(S) should review the results of pre-delivery works test carried out by the manufacturer and review the test instruments provided by either or both the contractor and the MP/TP to ensure that their accuracy, calibration and condition meet the standards for test instruments described in SHTM 2030-3. The MP/TP should witness the installation checks and test carried out by the contractor, including ensuring that the calibration of each test instrument provided by the contractor has been checked on site and is satisfactory and arrange for test loads to be supplied as required. The TP should carry out the initial operational qualification and performance qualification tests.	

2.19 Management of decontamination (continued)

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.19.15	Accurate and efficient record keeping is an essential part of the management of an EWD.	Summary Sheets On completion of the validation process the MP/TP should immediately prepare a summary report containing the results of commissioning and performance qualification tests and essential working data. The summary report should be signed off by the MP/TP and countersigned by the user to certify that the EWD is fit for use. Summary reports should be securely retained by the user and be available for ready reference. Validation Report Within one month of the completion of the validation process the MP/TP should prepare a full validation report which should include: - all the data supplied by the contractor, collected during installation checks and tests, with written confirmation that they meet the manufacturer's specification; - written confirmation that the calibration of all measuring instruments fitted to the WD have been verified; - all the data collected during the commissioning test / performance qualification with written confirmation that the data meet the specified requirements; - data showing the correlation between the performance of the measuring instruments fitted to the WD and the test instruments used; - reports containing all the data collected during the performance qualification tests with written confirmation from the MP/TP and the user for the loading condition and types of endoscope which may be satisfactorily processed in the WD.	Guidance is given in SHTM 2030-2

2.19 Management of decontamination (continued)

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.19.15 continued	Accurate and efficient record keeping is an essential part of the management of an EWD. (continued).	Validation report (continued) When data is in the form of electronic data files, the report should include copies of disks or tapes containing the data in a format agreed with the user and a printout of the directory of each, annotated to show where the data from each test is to be found. The MP/TP should certify that all necessary tests have been carried out and that the results are satisfactory. The records of any microbiological tests should be signed by the Microbiologist (Sterilizer). The AP(S) should review and countersign the completed validation report. The validation report should be retained by the user. Copies may be retained as necessary by the MP/TP, the AP(S), the M(S), Estates Dept and where applicable, the Quality Controller.	
2.19.16	Periodic tests are the responsibility of the user, Microbiologist (Sterilizers) and the MP/TP.	The daily, weekly and quarterly test schedules provide evidence that the EWD continues to operate within the limits established during commissioning. The yearly test schedule is a revalidation procedure and provides a more comprehensive test programme than other periodic tests; its serves to demonstrate that data collected during commissioning and the performance qualification remains valid.	

2.19 Management of decontamination (continued)

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.19.17	There should be access to infection control and specialist support.	Establish of links and liaison with other specialists including:- - Infection Control team; - Consultant in Public Health Medicine for Communicable Diseases/Environmental Health; - Sterile Services Department / CDU; - Occupational Health Services; - Estates Department particularly in relation to: - planning new facilities for clinical procedures and/or decontamination; - development of engineering and building services; - purchase of decontamination equipment (EWDs, ultrasonic cleaners, sterilizers); - choice of process chemicals; - contracting out services with infection control implications (e.g. cleaning / housekeeping, clinical waste, decontamination).	

2.20 Health and Safety

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.20.1	The endoscopy decontamination manager should be aware of the current health and safety regulations and guidelines which require implementation to meet the health and safety needs of the EDU staff and endoscopy patients.	Have arrangements in place to obtain competent health and safety advice. Ensure decontamination facilities and activities comply with relevant legislation, which includes: - Health and Safety at Work etc Act 1974 - The Management of Health and Safety at Work Regulations 1992 - The Workplace (Health, Safety and Welfare) Regulations 1992 - The Provision and Use of Work Equipment Regulations 1992 - Electricity at Work Regulations 1989 - The Health and Safety (First Aid) Regulations 1981 - The Control of Substances Hazardous to Health Regulations (COSHH) 1998 - The Manual Handling Operation Regulations 1992 - Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) 1985 - Pressure Systems Safety Regulations 2002 - Personal Protective Equipment at Work (PPE) Regulations (1992) Prepare a local health a safety policy which is known to staff, up to date and regularly reviewed.	

2.20 Health and Safety (continued)

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.20.2	**H&SAW etc - COSHH**		
2.20.3	Decontamination should be carried out in a manner that minimises the risk to staff from: - contamination on used devices; - process chemicals.	Identify the decontamination processes that may produce, or involve the use of, substances hazardous to health. Assess the risk that may arise from exposure. Keep a detailed record of the assessment Decide what precautions are needed for prevention or adequate control of exposure, to include; - environmental controls to prevent dispersal; - work practices.(eg automated disinfection rather than manual); - enclosed equipment and engineering controls eg EWD; - control exposure at source eg single-dose containers; - standard infection control precautions; - safe containment and storage of chemicals (see 2.20.11); - personal protective equipment; - staff training; - emergency facilities available (spillage kits, eye wash bottles, first aid kit). Take the appropriate actions to implement the necessary precautions / control measures. Review the assessment periodically and in response to changes such as a redesign of the decontamination facilities or use of a new chemical disinfectant.	Substances hazardous to health, covered by the COSHH regulations, include: - chemicals classified under CHIP (labelled as hazardous and provided with a safety data sheet). - micro-organisms in healthcare. - substances with occupational exposure limits (listed in the HSE publication 'Occupational Exposure limits. The COSHH risk assessment therefore includes the contaminated endoscope, EWD and various process chemicals including detergents and chemical disinfectants.

2.20 Health and Safety (continued)

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.20.4	Decontamination should be carried out in a manner that minimises the risk to 3rd parties (eg patients) from contamination on used devices	Identify the decontamination processes that may generate substances hazardous to health. Segregate these processes, wherever possible, from patient areas. Contain these processes by appropriate precautions.	See examples of precautions given in 2.20.3.
2.20.5	Control measures should be used and maintained properly.	Provide staff with training, information, written procedures and appropriate supervision. Ensure that the EWD and other decontamination equipment are maintained in efficient working order and good repair. Ensure local exhaust ventilation is regularly tested. Undertake periodic internal audits of compliance with the control measures. Record and review accidents, incidents and near misses e.g. disinfectant spillage).	The ERU should have a procedure for dealing with disinfectant spillage, agreed with local health and safety advisors / disinfectant manufacturers and prominently displayed within the unit. All staff must be trained in its implementation. The ERU should have a procedure for dealing with body fluid spillage, agreed with the infection control team.
2.20.6	The exposure to hazardous substances should be monitored, if necessary.	Measure the concentration of hazardous substances in the air breathed by staff if the COSHH assessment concludes that: - there would be serious risks to health if control measures failed; - exposure limits might be exceeded; - control measure might not be working properly.	
2.20.7	Appropriate health surveillance should be carried out.	Provide access to occupational health services for all staff, to include as appropriate:- - pre-employments health checks and screening; - immunisation of staff; - on-going health advice and information.	The BSG Guidelines (2003) recommend pre-employment health checks regarding asthma, skin and mucosal sensitivities and lung function by spirometry. Records should be kept for 40 years. Occupational Health should have local staff surveillance policies which may include annual health questionnaires and spirometry.

2.20 Health and Safety (continued)

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.20.8	Plans and procedures to deal with accidents, incidents and emergencies should be adhered to.	Prepare procedures and set up warning and communication systems to enable an appropriate response if an incident occurs.	This requirement applies particularly to microbial contamination.
2.20.9	ERU staff should be properly informed, trained and supervised	Provide training to include:- - the risk presented by substances they work with; - the main findings of the COSHH risk assessment; - the precautions they should use to protect themselves and other; - how to use PPE; - emergency procedures that need to be followed.	Staff should be made fully aware of their responsibility for the health and safety of themselves and others. Control measures will not be fully effective if staff do not know their purpose, how to use them properly or the importance of reporting faults. A named individual should be given responsibility to ensure that information on hazards and other safety matters is distributed and acted upon.
2.20.10	Hazardous substances should be stored in appropriate containers and areas.	Check the hazard status / labelling for all chemicals, seeking advice from the manufacturer as appropriate. Store flammable liquids and chemicals that have a risk of explosion in flame-proof cupboards which should be kept locked and closed. Care should be taken to avoid the storage of incompatible substances in close proximity to each other.	Flammable liquids include alcohol solutions. Solutions with a risk of explosion include concentrated chlorine dioxide. Incompatible chemicals include acids and oxidising agents. Many of the chemical additives used in EWDs and their associated ancillary equipment, for example water treatment plant, are corrosive, toxic or otherwise hazardous and require special provision for their storage and use.

2.20 Health and Safety (continued)

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.20.11	Process chemicals should be stored, handled and used safely and in accordance with the requirements of the Control of Substances Hazardous to Health (COSHH) Regulations).	Produce written policy and procedures, accessible to staff, covering all aspects of process chemicals, to include:- - procurement, receipt, storage, use and disposal; - the action to be taken in case of inhalation, ingestion, skin contact or environmental spillage; - error reporting (to encourage open reporting in a non-blame culture); Provide emergency treatment kits for contact with personnel (neutralisation) and for dealing with spillages; Ensure that for all process chemicals there is: - formal process qualification (validation) and re-validation of the EWD for each change in the process chemical(s); - instructions for use in accordance with the instructions provided by the manufacturers (chemical, endoscope and automated equipment eg EWD or ultrasonic cleaner). Ensure that the storage is: - lockable; - enables storage below head height; - organised with due regard for chemical properties eg strong oxidising agents should not be stored with flammable materials, high and low pH materials should not be stored together. Keep keys of all storage cupboards securely. Use single-use containers of diluted chemicals or prepare dilutions immediately prior to their use. Maintain up to date reference sources, accessible to staff, for every product used, e.g., the Material Safety Data sheet. Record ordering, receipt, supply, use and disposal of all process chemicals to maintain an audit trail.	

2.20 Health and Safety (continued)

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.20.12	The risk of transmission of healthcare associated infections to staff handling a contaminated endoscope should be minimised.	Provide personal protective equipment/clothing as indicated by the COSHH assessment. Apply procedures and equipment to minimise the risks associated in particular with the flushing of bulk contamination in the patient treatment room and the manual pre-cleaning in the ERU.	
2.20.13	The risk of transmission of healthcare associated infections between patients undergoing endoscopy should be minimised.	Ensure that an endoscope is not returned for use on a patient unless it has been subject to formal/documented release after decontamination using validated reprocessing equipment and in line with the manufacturer's instructions.. Ensure that current copies of approved infection control policies /procedures/guidance pertinent to decontamination activities are readily accessible to staff in each area.	.

2.20 Health and Safety (continued)

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.20.14	**Safety standards for equipment**		
2.20.15	The decontamination equipment should be designed to provide safe operation.	Ensure that safety requirements are included in the specification. BS EN 61010-2-04 specifies the requirements to ensure that the design and methods of construction used for EWDs provide adequate protection for the operator and the surrounding area against: - electric shock or burn; - mechanical hazards; - spread of fire from the equipment; - effects of fluids and fluid pressure; - liberated gases, pathogenic substances, explosion and implosion.	BS EN 61010-2-04 is currently under revision. Guidance on the safe operation of EWDs is also given in SHTM 2030-2.
2.20.16	The repair of equipment should be undertaken in a safe manner.	Operate a 'permit-to-work' system to ensure that equipment such as the EWD is declared safe to work on for repair and maintenance, and that personnel working on them have documented authority to do so. Ensure that, after repair, the equipment is formally released as safe to use for the operator, ie a 'permit to operate' system.	A leaflet giving guidance on 'Permit to Work Systems', is published by the Health & Safety Executive (1997).

2.21 Training

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.21.1	There should be a fully implemented and documented training programme for all staff in the ERU.	Implement a training programme which ensures that all staff have a sound general knowledge of the principles and practice of decontamination. Ensure that all staff are appropriately trained and skilled in the tasks they are expected to carry out. Ensure that information is provided about the up-date of policies, feedback of audit results and actions needed to correct deficiencies. Documented records of all training. Maintain training records for all staff.	All grades of staff, administrative and technical, working within the facility need regular training. Consideration should be given to providing a practical training area within the unit adjacent to but separate from the main work areas. The area should have access to teaching materials, including computer facilities.
2.21.2	There should be a skills register for all staff.	Construct and maintain a skills training matrix which relates staff to competencies, indicating the date trained and the date training needs to be reviewed.	
2.21.3	Decontamination processes in the ERU should be carried out by appropriately trained and qualified staff.	Provide documented training procedures for all staff who will carry out decontamination. Ensure that decontamination staff are: - trained in the techniques and skills relevant to decontamination and the procedures they will be undertaking. - trained on the endoscopes and EWD/s that they will be using. - trained in the safe use of equipment. - Training should include competency assessment. Keep training records. Undertake periodic review and reinforcement training.	

2.21 Training (continued)

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.21.4	There should be documented records of training and the acquisition of required skills in decontamination for key personnel.	Document the records of training and acquisition of the required skills in decontamination for key staff, to include: - Test Person (WD) carrying out annual tests; - Maintenance Person (WD) or TP carrying out quarterly and weekly tests and maintenance; - Microbiologist (Sterilizers) with responsibility for overseeing the process; - Operator carrying out daily tests and housekeeping; - Operator/supervisor releasing re-processed devices. Ensure that the infection control staff and other staff with decontamination management responsibilities (including the senior manager HDL(2001)10)) have received specific training in decontamination. Ensure that all clinical staff are aware of the implications of decontamination on clinical practice, on the selection of reusable devices, scheduling of procedures *versus* available instrumentation.	See 'Decontamination – Cleaning, Disinfection and Sterilization' guidance leaflet published by NHSScotland and PEFE. External training courses are available for the qualification of MP(S), TP(S) and AP(S). A national training programme for M(S) is currently under consideration. On-site and external training is available from private training establishments and from manufacturers of endoscopes and EWDs.
2.21.5	If an emergency endoscopic procedure is performed out of normal working hours, arrangements should be made for the endoscope to be decontaminated by trained staff.	Ensure that the ERU has sufficient trained staff to cover the needs of emergency endoscopy procedures.	

2.22 Quality Management and Risk Management Systems

Para	Principle	Methods to Achieve	Explanatory Notes/ Reference
2.22.1	**Quality Management**		
2.22.2	A quality management system should be developed to ensure that the customer (patient) requirements for endoscope decontamination are determined and met.	Ensure that Top / Senior Management are committed to and involved in the design, implementation and monitoring of a documented quality management system (QMS) for endoscope decontamination. Involve key staff to ensure a co-ordinated multidisciplinary approach, including: - HDL(2001)10 Senior Manager - Clinical staff - ERU staff - Microbiologist (Sterilizers) - Infection Control staff - Authorized Person (Sterilizers) [AP(S) - Estates/Maintenance personnel	The International Standards ISO 13485: 2003 'Medical devices – Quality Management systems – Requirements for regulatory purposes' specifies requirements for a quality management system that can be applied to endoscope decontamination. The aim is to undertake the decontamination process to the best possible standard and provide the highest quality of care for the patient receiving the reprocessed device.
2.22.3	The QMS should include as key elements: - resource management; - product realization (where the product is a decontaminated endoscope); - measurement, analysis and improvement.	Incorporate into the QMS:- **Resource management** - determination and provision of the necessary resources including adequately trained and competent personnel, infrastructure and work environment. **Product realization -** risk analysis, design and development of the decontamination facilities, equipment and processes, procurement of raw materials including process chemicals, the decontamination process to produce an endoscope 'fit for purpose' for re-use on the patient, process control, process validation, records and traceability. **Measurement, analysis and improvement -** the results of internal audit, measures on meeting Customer requirements (feedback from the clinical unit), external independent audit, operational tests and inspection, periodic tests on the EWD and planned preventative maintenance, including corrective and preventive action.	

2.22 Quality Management and Risk Management Systems (continued)

Para	Principle	Methods to Achieve	Explanatory Notes/ Reference
2.22.4	The 8 principles of quality management to be applied are: ■ Customer focus .Within the context of healthcare practice the 'customer' is the patient. It is necessary to understand their current and future needs, to meet their requirements and to strive to exceed their expectations.	Ensure that, by achievement of cleanliness and freedom from microbial contamination in the decontaminated endoscope, there is no adverse / harmful outcome for re-use of the endoscope on the next patient. Ensure that the reprocessing is organised to produce all the devices necessary for a procedure in a timely manner.	
2.22.5	■ Leadership Leadership is necessary to establish unity of purpose, direction and an appropriate work environment in which personnel can be fully involved in achieving the unit's objectives.	Ensure that there is a defined manager and management structure for the ERU.	
2.22.6	■ Involvement of people People are the essence of an organisation. The full involvement of personnel at all levels enables their abilities to be used for the benefit of the practice.	Ensure that all personnel are fully involved by: - providing a clear definition of responsibilities; - identifying training needs; - provision of staff training.	
2.22.7	■ Process approach The desired result may be obtained more efficiently and reliably when the necessary resources and activities, and their inter-relationships, are fully identified, provided and managed as a complete package.	Construct a simple flow diagram identifying each of the steps in the re-usable device 'life cycle diagram', where each step is undertaken, the equipment to be used, the staffing required etc. Use this diagram to identify areas that need attention, to facilitate the production of relevant, concise written work instructions will materially assist in identifying areas that need attention. This should also facilitate the production of relevant concise written work instructions and recording systems.	

2.22 Quality Management and Risk Management Systems (continued)

Para	Principle	Methods to Achieve	Explanatory Notes/ Reference
2.22.8	■ System approach to management Identifying, understanding and managing interrelated processes that contribute to the specified objective(s) in a systematic manner makes a major contribution to the effectiveness and efficiency of the practice.	Provide the basis of systematic management by producing documented policies and procedures for decontamination activities, to include clearly defined responsibilities and accountabilities.	
2.22.9	■ Continual improvement This should be a permanent objective of the unit. Maintaining the effectiveness of the system is the minimum requirement.	Aim to implement continual improvements, to include: - economic improvements by making processes more efficient; - minimising environmental impact. There should be no scope for improvement in the decontamination standard since this should be at the required level; however, it is essential that the effectiveness of the reprocessing system is maintained through constant attention to maintenance, testing, staff training etc.	
2.22.10	■ Factual approach to decision making Effective decisions are based on the logical and appropriate analysis of relevant data and information.	Clearly define the operational requirements for decontamination (eg number and type of procedures) to provide a realistic determination of resource requirements. For example, the number of re-usable medical devices needed, decontamination equipment capacity and number of machines to the required specification, seeking expert advice as necessary.	
2.22.11	■ Mutually beneficial supplier relationships Dealings with suppliers should be conducted in an open manner that engenders trust and cooperation on both sides to the mutual benefit of both parties.	Define the products / services required, by clear expression and using detailed contractual terms, in writing. Seek expert advice for specialist equipment and services eg EWD manufacturer, AP(S), Document all purchase orders.	

2.22 Quality Management and Risk Management Systems (continued)

Para	Principle	Methods to Achieve	Explanatory Notes/ Reference
2.22.12	Documented policies, procedures and records for all the key elements of the decontamination process are required.	Implement policies and procedures to control the decontamination process, where the absence of such procedures may adversely affect the quality of the decontamination service. Non-process related records including, but not limited to: - EWD purchase specification; - EWD validation; - EWD maintenance; - EWD periodic tests; - EWD water treatment; - Ultrasonic cleaner purchase specification; - Ultrasonic cleaner validation; - Ultrasonic cleaner maintenance; - Ultrasonic cleaner periodic test; - Ultrasonic cleaner water treatment; - Environmental cleaning; - Staff training; - Device purchase specifications; - Facilities maintenance; - Audit. Process related records including, but not limited to: - Manual washing records; - Washer disinfector records; - Inspection records.	Step-wise procedures should be written for each stage of the process; these procedures may then be used also as in-house training documents. Quality records for endoscopy decontamination are in two categories; process related and non-process related.

2.22 Quality Management and Risk Management Systems (continued)

Para	Principle	Methods to Achieve	Explanatory Notes/ Reference
2.22.13	Policies and procedures should be audited periodically to ensure: - Staff compliance; - Relevance to activities; - Compliance with regulatory requirements and guidance.	Undertake a documented review of policies and procedures, not less than annually.	
2.22.14.	Records should be maintained, securely stored and readily accessible to permit traceability to the extent required (see 2.14).	Maintain traceability records: - covering all items cleaned and sterilized within the unit; - that provide evidence (an audit trail) that all re-usable endoscopes used on patients have been subjected to a satisfactory decontamination process since their use on a previous patient.	The effectiveness of the traceability system should be demonstrated periodically by a practical trial of the ability of the system to permit retrieval of the appropriate process records.

2.22 Quality Management and Risk Management Systems (continued)

Para	Principle	Methods to Achieve	Explanatory Notes/ Reference
2.22.15	**Risk Management Systems**		
2.22.16	Effective risk management allows managers to be aware of potential risks and offers the opportunity to deal with them before any loss, particularly a financial loss, occurs. It is regarded an integral part of quality management.		
2.22.17	Procedures should be in place to identify the hazards associated with the decontamination process, to estimate and evaluate the risks, control these risks and monitor the effectiveness of the control	Apply risk management systems to the entire process of endoscope decontamination. Consider all the stages in the decontamination activity: - the design and manufacture of a specific medical device or accessory; - its presentation as a contaminated device; - the design, manufacture and performance of decontamination equipment such as the EWD; - use of process chemicals (detergent, chemical disinfectant); - quality of water used in the process; - the procedures used in reprocessing; - the inspection and storage prior to reuse. The term 'manufacturer', as applied under the MDD, is used to describe the individual with responsibilities in all these areas.	The decontamination of medical devices such as endoscopes entails a significant degree of risk, not least because of the complexity and thermolabile nature of the endoscope, the limitations of the liquid chemical disinfection process and the capability of the endoscope to transfer contamination from various sources to the next patient. Accurately estimating the risk to the patient of an inadequately decontaminated endoscope is difficult because: - it is not possible to be certain that a given infection results from a contaminated endoscope; - infection may not become apparent until after the patient has been discharged from hospital; - the contaminated endoscope may not be recognised as the source of infection. There are many aspects of the decontamination activity that may give rise to risk – the equipment, process chemicals or other hazardous substances, the activity of staff and the systems in place. A risk management system provides a framework within which experience, insight and judgement are applied systematically to manage risks (BS EN ISO 14971 2000 'Medical devices – Application of risk management to medical devices').

2.22 Quality Management and Risk Management Systems (continued)

Para	Principle	Methods to Achieve	Explanatory Notes/ Reference
2.22.18	Procedures should be in place to identify the hazards associated with the decontamination process.	Compile a list of foreseeable hazards associated with each stage in the decontamination process. Maintain the list of hazards in a risk management file	
2.22.19	All premises, equipment and processes used to decontaminate re-usable medical devices contain elements of risk and hazards which need to be identified, monitored, controlled and managed.	Produce a comprehensive, written, decontamination policy with clear reference to risk management to cover services, equipment, processes and premises involved in decontamination that includes: - Health and Safety; - Management arrangements for emergencies and untoward incidents; - Provision to learn from incidents; - Formal arrangements for making and recording contracts; - Compliance with all relevant legislation including the Health and Safety at Work etc Act and Medical Devices Regulations.	
3.22.20	There should be appropriate assurance that all risks associated with decontamination premises, equipment and services are identified, assessed and managed.	Identify and assess all risks associated with all stages of the decontamination process. Institute control measures for identified risks. Undertake monitoring to verify compliance with policies and procedures. Document arrangements for responding to emergencies. Have arrangements for access to technical advice beyond the knowledge and competence of staff. Provide a staff training programme. Identify, record, analyse and learn from adverse events and 'near misses'. Have a reporting procedure for reporting accidents and incidents to the relevant authorities.	

2.22 Quality Management and Risk Management Systems (continued)

Para	Principle	Methods to Achieve	Explanatory Notes/ Reference
2.22.21	Procedures should be in place to control the risks and monitor the effectiveness of the control.	Controls include: - training to ensure that no staff undertake procedures beyond their competence. - use of automated decontamination equipment incorporating independent process monitoring and control (EWD meeting specified requirements) Actively involve all staff involved in decontamination. A co-ordinated multidisciplinary approach should be taken involving for example: - HDL(2001)10 Senior Manager - Clinical staff - Reprocessing personnel - Microbiologist (Sterilizers) - Infection Control Nurse - Authorized Person (Sterilizers) [AP(S)]. - Estates/Maintenance personnel Monitor effectiveness by internal and external audit.	
2.22.22	Any risk should be reduced to the lowest level practicable, bearing in mind the benefits of accepting the risk and the practicability of further reduction	Be aware that in the absence of successful risk management, the impression that 'nothing has gone wrong from using a defective process' may not apply in the future. Incidents of bad decontamination practice must not be disregarded. Compliance with legislation such as the Health and Safety at Work etc Act is mandatory. Requlatory bodies require compliance with the Medical Device Regulations and the national standards in decontamination,. The emphasis should be on objectively assessing the risks, spending money on eliminating the risks and improving safety and maintenance levels.	Practicability refers to the ability of the 'manufacturer' to reduce the risk. Practicability has two components - technical practicability - the ability to reduce the risk by technical innovation, regardless of cost; - economic practicability – the ability to reduce to reduce the risk without making the provision of the decontaminated endoscope an unsound economic proposition. An example would be where disposable sheaths have been developed to protect non-lumened endoscopes eg nasendoscopes and minimize contamination (see 2.5.3)..

2.23 Environmental cleaning

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.23.1	The environmental cleaning procedures and schedules adopted must ensure that contamination from handling used devices, clinical waste and process chemicals is removed from the environment and not dispersed to clean areas.	Segregate cleaning equipment: 1) have separate cleaning equipment for clean and dirty areas stored in the same DSR; 2) use the same equipment for both clean and dirty areas; with the cleaning equipment thoroughly cleaned after use; clean areas cleaned first followed by dirty areas.	Control of environmental cleaning is a key aspect of the day to day operation of an ERU. Dispersal of contamination to clean areas may occur through the use of inappropriate cleaning equipment and/or techniques or through the use of contaminated cleaning equipment.
2.23.1	The equipment and methods used should minimise the dispersal of contamination.	Use appropriate floor cleaning equipment and method: - mop and bucket using 'two bucket' system and a free rinsing detergent; - vacuum cleaner fitted with HEPA filtered exhaust	Do not use rotary scrubbers and polishers in the decontamination room (unless all devices are first removed from the area and all horizontal work surfaces are cleaned after the floors).
2.23.2	The cleaning agents should be appropriate.	For floor cleaning, use a free-rinsing detergent in warm water. Disinfectants are <u>not</u> required. If disinfectants are used they should be: - only used following thorough cleaning; - fresh diluted from concentrate immediately before use - rotated quarterly to prevent build up of resistant organisms	

2.23 Environmental cleaning

Para	Principle	Methods to Achieve	Explanatory Notes / Reference
2.23.3	Cleaning should be at a frequency that will maintain the required standard of cleanliness.	Schedule for floor cleaning - Floors should be cleaned daily - Floors should be cleaned also when visibly soiled	
2.23.4	Work surfaces should be clean and free from contamination.	Clean work surfaces at least daily with a hot aqueous solution of a free rinsing detergent and dried after cleaning using a single-use cloth. Work surfaces should be wiped down periodically during the working day using spore free 70% iso-propanol (this provides both a disinfection and drying effect).	
2.23.5	Provision should be made to deal with spillages	Provide spillage kits to contain and remove spillages of body fluids. Provide spillage kits to contain, neutralise if necessary and remove spillages of process chemicals.	Guidance on the specific requirements should be found in the Material Safety Data Sheet supplied by the process chemical manufacturer.
2.23.6	The adequacy of cleaning should be verified.	The cleaning should be monitored by regular documented inspection of the cleanliness of the environment and the cleaning equipment.	

3. References

- Advisory Committee on Dangerous Pathogens and the Spongiform Encephalopathy Advisory Committee, "Transmissible spongiform encephalopathy agents: safe working and the prevention of infection" (see http://www.advisorybodies.doh.gov.uk/acdp/tseguidance/Index.htm)
- British Society of Gastroenterology Working Group Report (2003) BSG Guidelines for Decontamination of Equipment for Gastrointestinal Endoscopy (See http://www.bsg.org.uk/clinical_prac/guidelines/disinfection.htm)
- BS EN 285 (1997) Sterilization – Steam sterilizers – Large sterilizers, BSI.
- BS EN 61010-2-045 (2001) Safety requirements for electrical equipment for measurement, control, and laboratory use: Particular requirements for washer disinfectors used in medical pharmaceutical, veterinary and laboratory fields.
- BS EN ISO 13485 (2003) Medical devices – Quality management systems – Requirements for regulatory purposes, BSI
- BS EN ISO 14971 (2001) Medical devices – Application of risk management to medical devices
- **BS EN ISO 15883 Washer-Disinfectors – Part 1: General Requirements, definitions and tests (Draft 2004) Clause 8. Information to be supplied by the manufacturer**
- BS EN ISO 17664 (2004) Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices, BSI.
- BS EN ISO 14937 (2001) Strerilization of health care products – General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices, BSI.
- Glennie Group (NHSScotland Sterile Services Provision Review Group) Report [HDL(2001)66] (See http://www.show.scot.nhs.uk/publicationsindex.htm)
- HDL(2001)10 Decontamination of Medical Devices (See http://www.show.scot.nhs.uk/sehd/mels/HDL2001_10.htm).
- HDL(2003)42 Decontamination. – NHSScotland Sterile Services Provision Review Group (Glennie Group) (See http://www.show.scot.nhs.uk/publicationsindex.htm)
- Health & Safety Executive (1997) Permit to Work Systems (See http://www.hse.gov.uk/pubns/indg98.pdf)
- Medical Devices Agency, Sterilization, disinfection and cleaning of medical equipment: Guidance on decontamination from Microbiology Advisory Committee to the Department of Health Medical Devices Agency (The MAC Manual) Part 1 Principles (1993 updated 2002) Part 2 Protocols (1996), Part 3 Procedures (199, updated 2000 and 2002). (http://www.medical-devices.gov.uk/mda/mdawebsitev2.nsf/webvwSearchResults/AAAADF24915B412280256C8B003EE71F?OPEN)
- MDA DB 9801 (1999) Medical Device and Equipment Management for Hospital and Community-based Organisations. (See http://www.medical-devices.gov.uk/mda/mdawebsitev2.nsf/webvwMDASafetyWarnings/91BB7CD751A08AB580256C8B0052570F?OPEN)
- MDA DB 2000(04) Single-use Medical Devices: Implications and Consequences of Reuse (See http://www.medical-devices.gov.uk/mda/mdawebsitev2.nsf/webvwMDASafetyWarnings/B7D0158A173D0C5A80256C8B004DE2B7?OPEN)
- MDA DB 2002(05)) Decontamination of endoscopes (See http://www.medical-devices.gov.uk/mda/mdawebsitev2.nsf/webvwMDASafetyWarnings/C2377C4B2E2BA7D680256C8B004F1A41?OPEN)
- MHRA DB 2003(05) Management of Medical Devices Prior to Repair Service or Investigation (See http://www.medical-devices.gov.uk/mda/mdawebsitev2.nsf/webvwMDASafetyWarnings/5EC97FD1EF5E62E180256D4E00542622?OPEN)
- NHS Estates (1997) HTM 2030 Washer Disinfectors, HMSO

- NHS Estates (2003) NHS Model Engineering Specification C32 Automated Endoscope Reprocessors for Flexible Endoscopes
- NHS MEL (1999) 65 Variant Creutzfelt-jacob disease (vCJD): Minimising the risk of transmission
- prEN ISO 15883-4 Washer-Disinfectors Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermo-labile endoscopes (second prEN 2004)
- SAN(SC)03/11 NHSScotland Safety Action Notice: Decontamination of Re-usable Medical Devices: Control of Aqueous Solutions in Ultrasonic Cleaners (See http://www.show.scot.nhs.uk/shs/hazards_safety/SANPDF/SAN0311.pdf)
- SAN(SC)04/31 NHSScotland Safety Action Notice: Advanced Sterilization Products CIDEX® OPA: Risk of Adverse Reaction (See http://www.show.scot.nhs.uk/shs/hazards_safety/SANPDF/SAN0431.pdf.
- SHTM 2030 (2001) Washer Disinfectors Part 1 Design Considerations, Part 2 Operational Management and Part 3 Validation and verification (See http://www.show.scot.nhs.uk/pef/guest/)
- SHTN 3 Management and disposal of clinical waste
- Spaulding E H, Chemical Disinfection of Medical and Surgical Materials in Lawrence CH, Black SS, Disinfection, Sterilization and Preservation, (1968) **32**: 517-531, Henry Kimpton, London.
- Water Supply (Water Quality) (Scotland) Regulations 2001
- Water Supply, Scotland: The Private Water Supplies (Scotland) Regulations 1992

4. Contact Details

Service	Organisation	Address	Contact Number
For procurement	Scottish Healthcare Supplies	Gyle Square 1 South Gyle Crescent Edinburgh EH2 9EB	0131 275 6778
For installation, validation, maintenance and testing	Scottish Healthcare Supplies	Gyle Square 1 South Gyle Crescent Edinburgh EH2 9EB	0131 275 6390
For general guidance and enquiries	Health Protection Scotland	Clifton House Clifton Place Glasgow G3 7LN	0141 300 1153

5. Glossary

AP(S)	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. AP(S) are also able to provide independent auditing and advice on washing/disinfection and WDs and to review and witness validation of these processes and machines. (See SHTM 2010 Part 1 for a full definition of the responsibilities with respect to sterilizers and the qualifications and experience required).
Automatic endoscope reprocessor	An AER is a machine intended for the automated decontamination of endoscopes. Note: This generic term can be applied to any automated machine designed for endoscope reprocessing and has been applied inconsistently throughout published guidance. Automated machines that enable endoscopes to be immersed in a high level disinfectant/sterilant but lack a cleaning stage (eg the Steris reprocessor) may be described usefully as an AER. This provides a distinction from automated machines that clean and disinfect which are defined as endoscope washer-disinfectors (EWDs) within the scope of BS EN ISO 15883.
Batch	Items processed at the same time under the same process conditions.
CE mark	The CE mark means that a manufacturer is satisfied that his product conforms with the relevant Essential Requirements in the relevant European Directive and that it is fit for its intended purpose.
Contractor	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. (SHTM 2030-3).
Control of Infection Officer	The person designated by management to be responsible for advising the user on all infection control aspects (SHTM2030-3).
Decontamination	Totality of the processes required to render a used re-usable medical device fit for use on a subsequent patient. (This will normally include at least cleaning, inspection for cleanliness and functionality and disinfection and/or sterilization).
Decontamination manager	Person with designated, written, responsibility and authority to manage all operational aspects of the decontamination units.
Decontamination room	Designated room in which decontamination equipment is located in the Endoscopy Reprocessing Unit.
Disinfection - High level disinfection	Capable of killing all micro-organisms with the exception of high numbers of bacterial spores [Summarised from - Rutala W A APIC (Association of Professionals In Infection Control and Epidemiology) Guidelines for selection and use of disinfectants. Am J Infect Control 1996, 24, 313-342.]
Disinfection - Low level disinfection	Capable of killing most bacteria, some viruses and some fungi but cannot be relied upon to kill resistant bacteria [Summarised from - Rutala W A APIC (Association of Professionals In Infection Control and Epidemiology) Guidelines for selection and use of disinfectants. Am J Infect Control 1996, 24, 313-342.]
Disinfection Medium level disinfection	Capable of killing mycobacteria, vegetative bacteria, most viruses and most fungi but not necessarily bacterial spores [Summarised from - Rutala W A APIC (Association of Professionals In Infection Control and Epidemiology) Guidelines for selection and use of disinfectants. Am J Infect Control 1996, 24, 313-342.]

5. Glossary (continued)

Endoscope washer-disinfector	washer-disinfector intended to clean and disinfect loads containing flexible endoscopes to the required standard (prEN ISO 15883-1).
Hazard	The potential to cause harm including ill health and injury, damage to property, plant, products or the environment, production losses or increased liabilities
Invasive procedure	A medical or surgical procedure which penetrates intact skin or mucous membrane or penetrates a sterile body cavity.
Management	The owner, occupier, employer, general manager, chief executive or other person who is ultimately responsible for the premises (SHTM 2030-3)
Manufacturer	A person or organisation responsible for the manufacture of a WD
Medical Device	As defined in the Medical Device Directive (42/93/EEC); includes surgical instruments
Microbiologist (Sterilizers)	A person designated by management to be responsible for advising the user on microbiological aspects of washing and disinfecting non-medicinal products (SHTM 2010)
Operator	A 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 (SHTM2030-3)
Performance Qualification	The process of obtaining documented evidence that equipment, as commissioned, will produce an acceptable product when operated in accordance with the specification
Policy	A statement of intent; in particular with reference to an operational matter.
Procedure	A statement of steps required to fulfil a policy
Purchaser	The person or organisation who orders the WD and is responsible for paying for it (SHTM 2030-3)
Q_{10}	The change in reaction rate for a 10^{o}C change in temperature. (For many chemical reactions the Q_{10} value lies between 2 and 3).
Quality Manager	A person designated by management to be responsible for the quality management system operated within the endoscopy re-processing unit irrespective of their other quality management duties within decontamination and/or the healthcare facility.
Re-usable medical device	A medical device designated by its manufacturer as suitable for multiple episodes of use; either for a defined maximum number of use cycles or until inspection reveals wear or damage to the extent that the device must be repaired or replaced.
Risk	Combination of the probability of the occurrence of harm and the severity of that harm (BS EN ISO 14971).

5. Glossary (continued)

Risk analysis	Systematic use of available information to identify hazards and estimate the risk (BS EN ISO 14971).
Risk assessment	Overall process comprising a risk analysis and a risk evaluation (BS EN ISO 14971).
Risk evaluation	Judgement, on the basis of risk analysis, of whether a risk which is acceptable has been achieved in a given context based on the current values of society (BS EN ISO 1497).
Test Person (Washer-Disinfectors)	A person designated by management to carry out validation of WDs and to provide advice on testing, maintenance and procedures shorter term 'Test Person' or TP.
User	the person designated by management to be responsible for the management of a WD (SHTM2030-3).

6. Abbreviations and symbols used

ACDP	Advisory Committee on Dangerous Pathogens	LDU	Local Decontamination Unit
AP(S)	Authorised Person (Sterilizers)	MDA	Medical Devices Agency
BS	British Standard	MDD	Medical Devices Directive
BSG	British Society of Gastroenterology	MHRA	Medicines and Healthcare Products Regulatory Agency
CDU	Central Decontamination Unit	MP(S)	Maintenance Person (Sterilizers)
CHIP	Chemicals (Hazard Information and Packaging for Supply) Regulations 2002	OEL	Occupational exposure Limit
CJD	Creutzfeld Jacob Disease	OJEC	Official Journal of the European Community
COSHH	Control of Substances Hazardous to Health	OP	Operational Qualification
DSR	Domestic Services Room	PAT	Portable Appliance Testing
DTAP	Decontamination Technical Advisory Panel	PQ	Performance Qualification
EN	European Standard	PPE	Personal protective equipment
ERU	Endoscope Reprocessing Unit	prEN	Draft European Standard
ESGE	European Society of Gastrointestinal Endoscopy	RIDDOR	Reporting of Injuries, Diseases and Dangerous Occurrences Regulations
ESGENA	European Society of Gastroenterology and Endoscopy Nurses and Associates	SAN(SC)	Safety Action Notice (Scotland)
EWD	Endoscope Washer-disinfector	SCIEH	Scottish Centre for Infection and Environmental Health
FIFO	First in first out	SEAC	Spongiform Encephalopathy Advisory Committee
HAI	Healthcare Associated Infection	SHTM	Scottish Health Technical Memorandum
HEPA	High Efficiency Particulate Arrestance	SHTN	Scottish Health Technical Note
HSE	Health & Safety Executive	SHPN	Scottish Health Planning Note
HDL	Health Department Letter	TP(S)	Test Person (Sterilizers)
HPS	Health Protection Scotland	TR	Technical Requirement
H&SAW	Health and Safety At Work etc Act	TSE	Transmissible Spongiform Encephalopathy
IQ	Installation Qualification	WFI	Water for irrigation BP
ISO	International Standards Organisation	WHB	Wash hand basin

Annex 1 – Test programme for Endoscope Washer-disinfectors (EWDs)

Brief description of test	Annex 2 Clause	Reference Documents	Factory site tests		User site tests		
			Type test	Works test	Operational qualification	Performance qualification	Routine test
Leak test	1	A*, B*, D	Y	Y	Y	N	Y (Q)
Leak test failure alarm	2	D	Y	Y	Y	N	Y (Q)
Cleaning efficacy							
Type test / OQ	3.2.1	A, B, C, D	Y	N	Y	N	N
Performance qualification	3.2.2	A, B, C, D	N	N	N	Y	Y
Ninhydrin test	4	A, B, C, D	Y	N	Y	Y	Y
Disinfection efficacy							
- In vitro activity	5	A*, B,C, D	Y	N	N	O	N
- Self-disinfection	6	A*, B, D	Y	N	N	Y	Y (A)
- Disinfection of load							
- type test	7.2.1	A*, B, C, D	Y	N	N	O	N
- PQ / routine	7.2.2	B, C, D	N	N	N	Y	Y (A)
Water quality							
- Final rinse water	8	~~A~~*, B, C, D	Y	Y	Y	Y	Y (W)
- All process stages prior to OQ/ PQ	8	B	Y	Y	Y[a]	Y	-
- Periodic check of all process stages	8	B	-	-	-	-	Y (A)
Water supply temperature	9	A, B	Y	Y	Y	N	O
Water supply pressure	10	A, B	Y	Y	Y	N	O
Overflow test	11	A, B,	Y	Y	Y	N	Y (A)
Volume of water per stage	12	A, B, C	Y	Y	Y	N	Y (A)
Treatment of water supply: for final rinse water quality	13	C	Y	N	Y	Y	Y

Annex 1 – Test programme for Endoscope Washer-disinfectors (EWDs) - continued

Brief description of test	Annex 2 Clause	Reference Documents	Factory site tests		User site tests		
			Type test	Works test	Operational qualification	Performance qualification	Routine test
Disinfection of liquid transport systems	14						
- type test	14.3.1	C	Y	N	-	-	-
- operational / routine test	14.3.2	C	-	-	Y	N	Y
-							
Thermometric tests							
- chamber and load	15	A, B, C	Y	Y	Y	Y	Y
- over-temperature protection	15	A, B, C	Y	Y	Y	Y	Y
- self-disinfection	16	A, B,C	Y	Y	Y	y	Y
Channels non-obstructed	17	A, B, D	Y	Y	Y	N	Y (Q)
Channels not connected	18	D	Y	Y	Y	N	Y (Q)
Load dryness	19	A, B, C	Y	O	Y	N	N
Fluid emission							
- Fluids and vapour	20.1, 20.2	B, C	Y	Y	Y	N	N
- Chamber leak proof	20.3	B, C	Y	Y	Y		
Protection against hazards from fluids	21	E	Y	Y	N	N	N
Doors and interlocks							
Cycle start interlock	22	A, B, C	Y	Y	Y	N	Y (Q)
In-cycle interlock		A, B, C	Y	Y	Y	N	Y (Q)
On sensor failure		B, C	Y	Y	Y	N	Y (Q)
Process residues	23	C	Y	N	N	Y	N
Chemical dosing							
Accuracy and repeatability	24.1	A, B, C	Y	Y	Y	N	Y (Q)
Low level indicator	24.2	A, B, C	Y	Y	Y	N	Y (Q)
Single dose container	24.3	D	Y	Y	Y	N	0

Annex 1 – Test programme for Endoscope Washer-disinfectors (EWDs) - continued

Brief description of test	Annex 2 Clause	Reference Documents	Factory site tests		User site tests		
			Type test	Works test	Operational qualification	Performance qualification	Routine test
Automatic control test	25	A, B, C	Y	Y	Y	Y	Y
Free draining (tanks, chamber, load carriers, pipework)	26	A ,B, C	Y	N	Y	N	Y
Estimation of the dead volume of pipework	27	A, B, C	Y	N	Y	N	Y
Operating cycle							
- Spray system	28.1	A, B, C	Y	Y	Y	Y	Y
- Reproducibity	28.2	A, B, C	Y	Y	Y	Y	O
- Fault indication	28.3	A, B, C	Y		Y	N	O
Instrumentation							
Legibility	29.1	C	Y	N	N	N	
Calibration	29.2	C	Y	Y	Y	N	Y (A)
Load carriers – stability, alignment and fitting	30	C	Y	N	Y	Y	O
Disinfection of water treatment equipment	31	C	Y	O	Y	N	Y
Sound pressure	32	A* B* C* E	Y	O	N	N	N
Air quality	33	C	Y	N	Y	N	Y (A)
Routine safety checks	34	A, B	Y	Y	Y	N	Y (W)

Codes used in Annex 1

Reference Documents
A. SHTM 2030
B. HTM 2030
C. draft BS EN ISO 15883-1
D. draft BS EN ISON 5883.4
E. IEC 61010-2-045

An asterisk* against the reference code signifies that there is a requirement but no method given.

Y - recommended **N** - not recommended **O** - optional test which can be requested by the purchaser or user

Routine test frequency
A annual test interval
Q quarterly test interval
M monthly test interval
W weekly test interval
D daily test interval

[a] not needed to be repeated when reliable data are already available, the data may be provided by the user.
[b] applies to an EWD employing a thermal self disinfection cycle.
[c] applies to EWDs employing chemical disinfection with controlled temperature.

NOTE 1 The tests included in this table assume that all necessary installation qualification checks and tests have been completed satisfactorily.

NOTE 2 Optional tests may be carried out at discretion / by agreed with the user, AP(S), M(S).

NOTE 3 Test intervals are for guidance only. Individual programmes of routine tests should be defined on the basis of risk analysis, taking into account the conditions and reliability of the EWD, the extent and nature of the data and the use to which the EWD is put. For example, a routine test frequency may start as 'weekly' to determine the consistency and range before moving to monthly or quarterly for as long as a satisfactory performance is maintained.

Annex 2 Test methods and requirements for EWD

Contents

1. Leak test

1.1 Purpose / Objective - to demonstrate that the endoscope will not be damaged during the EWD operating cycle by liquid ingress into the sheath etc.
This test should only be regarded as a test of the integrity of the endoscope when all parameters of the EWD leak tests (eg pressure, duration, maximum leak accepted) are consistent with those specified by the endoscope manufacturer.

The test may be carried out as an automatic leak test on the EWD (prior to any contact with process fluids, and optionally at the end of the process) or the EWD manufacturer may instruct the User to carry out the test manually.

1.2 Test method and performance requirement

Test equipment
(i) Test piece consisting of a length of tubing terminated at one end with a connector suitable for connection to the WD and at the other end with a flow control valve; the internal volume of the tube should be within ± 10 % of the internal volume of the largest endoscope which the WD is intended to process.
(ii) Pressure transducer capable of reading to ± 1 mbar (± 0·1 kPa) over the range of the system's operating pressure.

Procedure
1. Calibration
Verify the calibration of the pressure sensor by comparison with a test instrument in a known state of calibration in accordance with ISO 10012-1, traceable to the national standard.

2. Testing the pressure relief device
Connect the test piece to the WD with the flow control valve fully closed. The pressure regulation system shall be disabled. Initiate the leak test. Record the pressure at which the pressure relief system operates (P_a). Continue operating until the pressure reading from the transducer is steady and record the pressure (P_b).
Performance Requirement
Verify that P_a and P_b do not exceed the maximum pressure specified by the WD manufacturer.

3. Testing the leak rate test - indication of a leak
3.1 Fault condition
Adjust the flow control valve on the test piece to give a leak rate, at the leak test pressure (P_i), greater than that specified by the WD manufacturer. Connect the test piece to the WD and operate the leak test. Verify from readings taken from the pressure transducer that a fail condition has been produced.
Performance Requirement
Verify that the EWD indicates a fault.

3.2 Pass condition
Adjust the flow control valve on the test piece to give a leak, at the leak test pressure (P_i), at 80 % of the fail value specified by the WD manufacturer. Connect the test piece to the WD and operate the leak test. Verify from readings taken from the pressure transducer that a pass condition has been produced.
Requirement
Verify that the EWD indicates a pass.

2. Leak test failure alarm

2.1 Purpose / objective - in the event of a leak in an endoscope detected during an automatic leak test, to ensure that the automatic controller on the EWD prevents progression to the operating cycle and that an audible and visible alarm is given.

2.2 Test method and performance requirement
For EWDs with an automatic controller, undertake the leak rate test under tests as described in 1.2 above.

Requirement
Verify that the EWD indicates a pass, with an audible and visible alarm and that the cycle is halted.

3. Cleaning Efficacy Tests

3.1 Purpose / objective - to demonstrate the ability of the EWD to remove soiling and contamination from all required surfaces.
Since verification of cleaning efficacy by visual inspection throughout the lumened device is not possible, a series of test systems are applied. These include the use of natural contamination and the use of standardised test soils to overcome some of the variability (amount, nature etc) of natural contamination. Cleaning efficacy tests include type tests undertaken by the EWD manufacturer; the validation of cleaning efficacy at installation by performance monitoring tests using soiled surrogate devices (3.2.1) prior to testing the EWD on naturally contaminated endoscopes (3.2.2), with periodic tests thereafter.

3.2 Test method and performance requirement

3.2.1 Type test and operational qualification test
The measurement of cleaning efficacy is made on the cleaning stage alone, but includes any processes that take place in the EWD prior to the admission of disinfectant.
To minimise the possibility of damaging an endoscope it is prudent to establish the efficacy of the process by using a surrogate device before using an endoscope. Cleaning efficacy tests are carried out first on the surrogate device and subsequently on sufficient (but at least two) different devices to be representative of the devices that the WD is intended to process.

For the WD manufacturer to claim that particular device(s) can be processed in the WD, data will be required to establish that the particular device(s) can be effectively cleaned in the WD. Where an endoscope is one of a 'family' of essentially similar devices it shall be sufficient to test a representative sample for the 'family' of endoscopes. Where the WD manufacturer's instructions for use with a particular endoscope requires a pre-treatment eg manual cleaning of a particular component or channel, that pre-treatment may be included as part of the test procedure.

Load carrier
The load carrier chosen for the test load shall be of the type recommended by the WD manufacturer for the device to be processed.

Test soil and loads
Materials
- water 50 ml;
- glycerol 30 ml;
- horse serum 30 ml;
- dehydrated hog mucin 5 g;
- unbleached plain flour 2 g;
- 2 % m/m aq safranine solution 1 ml.

Apparatus
- laboratory measuring equipment;
- mechanical mixing device;
- disposable gloves;
- drainage tray;
- syringe or similar inoculating device;
- stopwatch.

Preparation of test soil

Mix all the constituents together to give a liquid of uniform consistency.
Use immediately or store in an air-tight container at 2 °C to 5 °C for not more than one month.

Test pieces

A general surrogate device is constructed from a minimum of one 2.0 m length of 1 mm internal diameter and two 2.0 m lengths of 4 mm internal diameter (ID) PTFE tube with a wall thickness between 0.5 mm and 1.0 mm. These are bound together with adhesive tape at intervals of approximately 150 mm and terminated with a device allowing connection to the channel irrigation system of the WD. The surrogate device shall be designed to determine the cleaning efficacy in all channels for which the EWD provides a cleaning function.
For type testing, a device that is representative of the specific endoscope that is intended to be processed eg a stripped lumen version of the endoscope may be used.

Inoculation of test pieces

If the soil has been stored allow it to equilibrate to room temperature before use.
Don the protective gloves. Apply the soil to the inner surface of the test pieces by injecting the soil into the tubes of the surrogate device. Lay the tubes on a horizontal surface and roll them to distribute the soil over the inner surface. Then apply an even coat of soil to the outer surface using the paintbrush. Allow excess soil to drain from the items and allow them to dry at room temperature (15 °C to 25 °C) for not less than 30 min and not more than 2 h.

Test procedure

Prepare the test load (using soiled surrogate device/s as described above) and also contaminate the EWD chamber walls and load carrier by application of the test soil using the paintbrush. Allow to dry at room temperature (15 °C to 25 °C) for not less than 30 min and not more than 2 h.
Place the test load, contaminated with the test soil, in the chamber and connect it to the channel irrigation devices in accordance with the EWD manufacturer's instructions. Start a normal operating cycle for the load type under test. Interrupt the cycle just prior to the start of the disinfection stage. Visually examine the test load, chamber walls and load carrier for the presence of residual soil.

Requirement

For the cleaning process to be regarded as satisfactory there shall be no visible residual soil present.

For type testing, the manufacturer should establish 'worst case' conditions of temperature, detergent concentration and water pressure/flow rate for use during testing. By analysing the fraction of soil removed during the cleaning process when operated for various time periods shorter than those that will normally be used a quantitative comparison of cleaning efficacy can be made. The recommended minimum operating conditions given by the manufacturer should be based on these data which should be made available to the user.

NOTE When necessary the adequacy of the cleaning process on the device may be verified by using a method for the detection of residual proteinaceous soiling - see Annex 2 § 4.0

3.2.2 Cleaning efficacy – performance qualification test

This test is undertaken following satisfactory completion of the installation qualification test (3.2.1). The EWD is tested using endoscopes contaminated by normal use, specified by the user as being representative of loads that it is intended to process.

Test method and performance requirement
Operate not less than 3 cycles using actual loads contaminated by normal use of the type that it is intended to process.
Interrupt the cycle just prior to the start of the disinfection stage. Visually examine the test load, chamber walls and load carrier for the presence of residual contamination.
Requirement
The test load should be free from visual contamination and no contamination should have been transferred to the chamber walls or load carrier.

When the load is visually clean, the endoscope should be further tested to detect the presence of residual proteinaceous contamination. The cleaned endoscope should be brushed through with a disposable cleaning brush which is then tested for traces of residual protein using the ninhydrin method (see Annex 2, § 4.0)

4. Ninhydrin method for the detection and assessment of residual proteinaceous contamination

4.1 Purpose / objective - to provide a pass/fail test for residual protein on an endoscope.

Note; much of the contamination that occurs on reusable medical devices is, in whole or part, proteinaceous in nature. This method has a high level of sensitivity for proteins and amino acids (detection limit equivalent to 2 mg/m^2 glycine).

4.2 Test method and performance requirement

Equipment and materials

- disposable cleaning brush
- 2% ninhydrin in 70 % isopropanol;
- sterile distilled water;
- oven (110 °C).

Test Procedure

Moisten the endoscope cleaning brush with sterile distilled water and brush through the channel. Visually inspect the brush – any discolouration indicates that the instrument was not clean and there is no need to proceed further.

Place a drop (approximately 0.05 ml) of the ninhydrin reagent on the brush tip and allow to air dry for approximately 5 min. If a purple coloration develops, residual protein/amino acids have been detected and no further action is needed.

If no colour has developed, transfer the swab to the oven and heat at 100 °C to 110 °C for 30 min and re-examine the swab for purple colouration.

Run a positive control (eg 25 µl drop of 0.5 g/l arginine solution dried onto a cleaning brush) and negative control (a cleaning brush moistened with sterile water) for each series of tests carried out. It is particularly important to establish that the materials of the cleaning brush do not interfere with the reaction and/or give a false positive result.

Performance requirement

(i) there shall be no discoloration of the brush tip prior to the application of the ninhydrin reagent;
(ii) there shall be no visible purple discoloration of the brush tip after application of the ninhydrin reagent.

5. Disinfection efficacy – *in vitro* chemical disinfectant efficacy

5.1 Purpose / Objective - an initial set of tests intended to verify, *in vitro*, the microbicidal (bactericidal, fungicidal, mycobactericidal, virucidal, and sporicidal) activity of the disinfectant solution under conditions representative of those which will be applied at the time of the EWD cycle's disinfection stage.

These data should be obtained from the disinfectant manufacturer, by testing carried out by or on behalf of the EWD manufacturer or from a third party.

Draft standard 'in vitro' tests of the bactericidal, fungicidal, mycobactericidal and virucidal activity of liquid chemical disinfectants intended for use on medical devices such as endoscopes are in preparation within the CEN committee, CEN/TC216 and will be harmonised standards under the Medical Device Directive.

5.2 Test methods and performance requirements
Each product in the list of useable disinfectants provided by the EWD manufacturer shall be tested. The data provided to demonstrate 'in vitro' disinfectant efficacy prior to direct testing within the EWD should include the following:

Concentration
The product should be tested at the minimum concentration recommended by the WD manufacturer for the disinfection phase.
In the case where it is intended that a disinfectant solution be reused, the efficacy of the solution shall be determined as a function of its minimum concentration.

Temperature
Two cases should be considered:
- if the disinfection temperature phase is carried out under ambient conditions, the test temperature should be the minimum temperature permitted during the cycle's disinfection phase;
- if the disinfection phase is carried out under temperature controlled conditions, the test temperature should correspond to the disinfection temperature specified by the EWD manufacturer.

Contact time
Two cases should be considered:
- if the disinfection phase is carried out under ambient conditions, the contact time observed during the tests should be equal to the minimum duration of the disinfection phase;
- if the disinfection phase is carried out under temperature controlled conditions, the contact time observed during the tests should be equal to the minimum duration of the disinfection phase during which the temperature of the disinfectant solution is constantly at, or above, the minimum specified temperature.

Soiling
The performance of the disinfectant under a range of soiling conditions (low level and high level) should be evaluated.

Water quality
If the efficacy of the disinfectant is liable to be impaired by dilution with hard water then testing should be carried out with a disinfectant solution prepared by dilution with water of standard hardness.

Neutralisation

Before commencing an investigation of the efficacy of the disinfectant a method of neutralising the disinfectant at the end of the exposure period must be demonstrated and documented. This should include demonstration that, for any neutralising agent used, neither the neutralising agent nor its reaction product with the disinfectant are microbicidal. When a secondary host such as a cell culture is used as the detection system for the survival of test organisms the absence of carry over effects on the cell culture system and detection of low numbers of test organisms added as a challenge to the test system should be demonstrated.

Test organisms

Test organisms should be selected on the basis of the following criteria:

- documented high resistance to the disinfectant under investigation;
- species typically found on product to be processed;
- species of clinical significance that may be found on product to be processed;
- representative species of a major group of organisms e.g. Gram positive bacteria.

As a minimum the test organisms should include Gram positive and Gram negative vegetative bacteria, bacterial spores, mycobacteria, non-lipid viruses, lipid viruses and fungi (including spore forms and yeasts).

Presentation of test organisms

While initial potency tests may be carried out using a suspension of test organisms the demonstration of activity on contaminated surfaces is required. The surfaces of the test pieces to be inoculated with test organisms should be representative of those found in the EWD chamber and the devices to be processed. Experimental controls should be used to establish the viable population on the surface immediately prior to exposure to the disinfectant solution.

Detection of test organisms

The culture method used to enumerate the number of surviving microorganisms after exposure to the disinfectant must be validated. The culture method should be capable of recovering a low number (approximately 10) of the chosen test organisms.

Performance Requirement

The test report of microbiocidal efficacy tests should clearly state the test conditions, the required quantified reduction factor and the conditions under which the chemical disinfectant met or failed the defined requirements. The data provided should be assessed in respect of the conditions prevailing during the disinfection stage in the EWD, prior to the evaluation of type tests and operational qualification of the chemical disinfection performance in the operating cycle.

6. Disinfection efficacy – Self-disinfection test

6.1 Purpose / objective

The self-disinfection cycle (whether auto or manually selected) should ensure that the EWD does not become a focus for contamination of the load. The disinfection of those parts of the EWD that come into contact with fluids which contact the load must be verified.

The test is designed to ensure that the self disinfection cycle will disinfect contaminated tubing by evaluating the effect of the cycle against a biofilm containing *Pseudomonas aeruginosa*.

The self-disinfection cycle may be achieved by thermal disinfection (preferred) or by chemical disinfection (using a different active from that used for the routine disinfection cycle). This test should be undertaken on any EWD that lacks a thermal self-disinfection stage; as a type test and before any operational tests of the microbiocidal efficacy of the disinfection stage are performed on such an EWD.

Note: Thermal self-disinfection systems should be evaluated by thermometric tests.

6.2 Test method and performance requirement

6.2.1.Type Test and Installation test

Production of biofilm test pieces

The following equipment and materials are necessary:

a. peristaltic pump;
b. incubator at 30ºC ± 2ºC;
c. 1 litre conical flask fitted with rubber bung, air vent and two glass tubes;
d. connecting tubing;
e. 1.5 metre length of 6 mm ID Teflon tubing;
f. nutrient agar supplemented with 1 g/*l* sodium desoxycholate and 0.025 g/*l* 2.4.4'-trichlor-2'-hydroxydiphenylether;
g. *Pseudomonas aeruginosa* ATCC 25619;
h. liquid growth medium: phosphate buffer (containing 1.2 g/*l* sodium phosphate, dibasic and 0.5 g/*l* potassium phosphate, monobasic) containing 0.25 g/*l* sodium glutamate and 0.1 g/*l* citric acid.

Method of preparation for the biofilm

Inoculate a petri dish containing supplemented nutrient agar with *Pseudomonas aeruginosa* ATCC 25619 and incubate at 30°C ± 2°C for 36 to 48 hours.

Inoculate a 1 litre conical flask containing 500 ml of the sterile liquid growth medium with mucoid colonies of *Pseudomonas aeruginosa* from the agar plate and incubated at 30°C ± 2°C for 18 to 24 hours.

Fit the flask with a bung through which passes an air vent, filtered to 0.22 µm, and two glass tubes one of which reaches to the bottom of the flask and one of which terminates above the level of liquid in the flask.

Connect the glass tubes, via a peristaltic pump and short lengths of flexible tubing, to a 1.5 to 2.0 metre length of 6 mm ID PTFE tubing. Pump the culture around the tubing system at 50–75 ml/min throughout the incubation period. Maintain the system in an incubator at 30°C ± 2°C for 72 to 96 hours.

Evaluation of the self-disinfection cycle

Identify a suitable section of tubing, 30 cm length (T1) prepared with biofilm to be subjected to the recovery procedure described below.

a. Remove a section of the piping in the endoscope channel irrigation system of the EWD and replace with the test system. The test system consists of two 30 cm lengths of the biofilm test piece tubing connected via isolating valves and 'Y' piece connectors in place of the removed section of pipework.
b. With the valves open, set the EWD to operate a 'self-disinfect' cycle.
c. At the end of any wash stage, and immediately before the start of the chemical disinfection stage, close the valves isolating one of the test pieces (T2). On completion of the disinfection stage and any subsequent rinse stage remove both test pieces (T2 and T3) and carry out the recovery procedure described below.
d. Replace the test pieces with two more sections of the tubing with biofilm and carry out a further self-disinfect cycle. Isolate one of the test pieces (T4) at the end of the disinfection stage and before any rinsing process. On completion of the cycle remove both test pieces (T4 and T5) and carry out the recovery procedure described below.

Cut the 30 cm length of tube into 6 portions each of approximately 5 cm length. Transfer three of these into individual universal containers containing nutrient broth and incubate at 30ºC ± 2ºC.

Cut the remaining 3 sections in half longitudinally and transfer each pair to 10 ml of ¼ strength ringers solution containing 0.05% Polysorbate 80 in a thin walled universal container. Treat the container with ultrasonics for 10 minutes at 45 MHz. Prepare tenfold serial dilutions of the eluate obtained and use these for enumeration of the surviving organisms by the spread plate technique. Carry out all determinations in duplicate.

Results

The data obtained gives the following information:

- T1 – recoverable population on the original test piece;
- T2 – recoverable population after the washing stage;
- T3 – recoverable population after wash, disinfect and rinse stages;
- T4 – recoverable population after wash and disinfect stage;
- T5 – recoverable population after wash, disinfect and rinse stages
- T3 and T5 should have the same population within the limits of experimental error; the difference between them is a measure of the reproducibility of the system;
- T1 – T2 is the loss during the washing stage;
- T3 – T4 and T5 – T4 are the loss during the post-disinfection rinse;
- T2 – T4 is the loss due to the disinfection process.

Performance requirement

On testing the full self-disinfect cycle there should be no recovery of organisms from T3, T4 and T5. When this is the case the test should be repeated with the exposure time reduced to half the normal value. The reduced exposure time should give a reduction of at least 10^3 in the number of recoverable micro-organisms (T2 – T4 $\geq 10^3$).

6.2.2 Operational and routine test and requirement

The test on the final rinse water is sufficient to verify the self-disinfection cycle during operational and routine testing. (see 7). The sample should be taken from any suitable point that ensures that the collected water has circulated through the components that were to be disinfected.

7. Disinfection efficacy – chemical disinfection of the load

7.1 Purpose/Objective - to establish the capability of the EWD to disinfect the device.

The method uses a surrogate device to simulate the load items. Inoculated carriers are incorporated as part of the surrogate device to monitor the efficacy of the disinfection stage. The test determines the microbial inactivation factor for the chemical disinfection stage in the EWD under the specified conditions of disinfectant concentration, volume, temperature and contact time.

7.2 Test method and performance requirement

7.2.1 Microbiological type test method of performance

Test organisms

A range of organisms representing the major groups and showing high resistance to the disinfectant should be used.

NOTE The organisms listed below are suggested as suitable. Additional organisms, or alternate organisms, that demonstrate high resistance to the disinfectant under the intended conditions of use (temperature, concentration etc), or that are relevant for a particular application, may be used at the discretion of the microbiologist, or at the request of the user.

Preferred species, as defined strains from a type culture collection, from which to make an informed choice are:

Pseudomonas aeruginosa (e.g. ATCC 15442)
Staphylococcus aureus (e.g. ATCC 6538)
Serratia marcescens
Enterococcus faecium
Enterococcus hirae (e.g. ATCC 10541)
Mycobacterium terrae (e.g. ATCC 15755)
Mycobacterium avium (e.g. ATCC 15769)
Candida albicans (e.g. ATCC 10231)
Aspergillus (spores) fumigatus or niger
Adenovirus type 5 Adenoid 75 (e.g. ATCC VR-5)
Poliovirus Type 1 LCs-2ab a
Bovine parvovirus strain Haden (e.g. ATCC VR-767),
Bacteriophage (eg Swedish coliphage - Felix01 with Salmonella typhimurium 395 M RO as host bacterial strain)
Hepatitis A virus (vaccine strain)
Geobacillus stearothermophilus (eg ATCC 7953)
Bacillus subtilis (eg ATCC 6633)

The test shall be carried out either with a range of the above organisms, identified as most resistant to the particular disinfectant in preliminary tests (see § 5 Disinfection efficacy – *in vitro* chemical disinfectant efficacy), or such other organisms as have been determined to have particular resistance to the disinfection process or to be particularly relevant to the intended application.

NOTE 1 Tests should include challenges with one or more virus strains

NOTE 2 Elimination of bacterial spores is not expected from a disinfection process. The low level of activity against spores compared with vegetative cells makes the spores a useful indicator of the extent of removal compared with kill. The use of a thermophilic spore facilitates recovery without interference from mesophyllic micro-organisms which are also present.

Preparation of inoculum

Culture conditions

Details of the culture conditions for the specific microbe should be reported with the results. Wherever possible standard published methods shall be used.

Suspending menstruum

Suspend bacterial spores in sterile distilled water.

Suspend the other test organisms in a suitable sterile isotonic solution eg for bacteria, peptone water with 10 % w/v sodium glutamate.

Inoculum

The inoculum shall contain known high numbers of the test organism eg for bacteria the inoculum shall contain not less than 10^8 cfu per ml. Count the population in the original inoculum and deposit on the test piece for exposure to the disinfection process using a validated method.

Test pieces

Construct a surrogate device for investigation of disinfection from a minimum of one 2.0 m length of 1 mm internal diameter and two 2.0 m lengths of 4 mm internal diameter (ID) PTFE tube with a wall thickness between 0.5 mm and 1.0 mm. Bind these together with adhesive tape at intervals of approximately 150 mm and terminated with a device allowing connection to the channel irrigation system of the EWD. The surrogate device shall be designed to determine the disinfection efficacy in all channels for which the EWD provides a disinfection function.

Form test pieces for inoculation from 150 mm lengths of the same diameters of tubing. Position these at each end and in the middle of the long lengths of tubing. They should be held in position with a sleeve made from a short length of silicone rubber tube of greater diameter. The overall length of each tube, including the three test pieces, should be not less than 1·5 m.

Inoculation method

Use a microsyringe or similar pipettor device to dispense 25 µl aliquots into each of the 150 mm length test pieces. Rotate these until visibly dry. Repeat the procedure three more times.

Recovery method

Transfer the inoculated test piece to a sterile isotonic solution containing a suitable neutraliser for the disinfectant. Remove the inoculated test piece after the validated exposure time to the neutraliser. Cut the 150 mm length of inoculated test piece in half and then cut one of the halves in half again and then slit lengthwise with a sterile scalpel. Transfer the split halves to 20 ml of sterile ¼ strength Ringers solution containing 0·05% Polysorbate 80 in a thin walled glass screw capped container (eg 25 ml universal bottle). Transfer the container to an ultrasonic bath and ultrasonicate for 10 min at 45 KHz.

Use the eluate to prepare a dilution series from which a viable count shall be determined.

Transfer the other half of the test piece to recovery medium (growth/no growth test).

Test Procedure

Evaluation of initial inoculum
Test the test pieces prepared as described by the recovery method to establish the population of each test organism which can be recovered from the inoculum.

Evaluation of physical removal using spores as an indicator organism
Expose surrogate devices incorporating test pieces inoculated with *Geobacillus stearothermophilus* spores to the disinfection stage and recover by the method described. The difference in population between the two test pieces and the original inoculum is a measure of the extent to which test organisms are physically removed by the EWD disinfection stage.

Requirement
There shall be not less than 10^5 spores remaining on each of the test pieces exposed to the EWD disinfection process.

If there is significant sporicidal activity from the disinfectant it will be necessary to evaluate the physical removal of test organisms by repeating the study with *Geobacillus stearothermophilus* spores with the disinfectant solution replaced by water.

When it can be established that the disinfectant formulation does not include surfactant and/or detergent activity the test may be carried out using vegetative organisms eg *Enterococcus faecium* and replacing the disinfectant solution with water.

Evaluation of disinfection efficacy
The surrogate devices incorporating test pieces inoculated with test organism shall be exposed to the EWD disinfection stage and recovered by the method described. All tests shall be carried out in duplicate.
The $\log_{10}$ reduction obtained for each test organism used shall be reported.

Requirement
There shall be not less than 10^5 spores remaining on each of the test pieces exposed to the EWD disinfection process.

7.2.2 Performance qualification and routine tests

Verify the process by sampling endoscopes after clinical use, before and after processing. Estimate the initial microbial contamination on the endoscopes by analysis of samples taken immediately prior to the commencement of the disinfection stage. Estimate the post-disinfection microbial contamination by analysis of samples taken immediately after the post-disinfection rinsing stage. Use sufficient samples for each test to provide a statistically valid estimate of the reduction in microbial contamination.

Requirement
There should be a reduction of microbial contamination to the level reported at type testing

8. Water quality

8.1 Purpose / objective: to demonstrate that the specified chemical, microbial and physical quality of water is met.

A continuous supply of water of the specified chemical, microbial and physical quality is essential for the correct functioning of all WDs. Water that is too hard or has too high a concentration of dissolved solids may impair the activity of detergents and disinfectants and cause deposits, scaling or corrosion of items being processed. Water containing high numbers of microorganisms and/or endotoxins may re-contaminate disinfected endoscopes. Means should be provided in the EWD to ensure that the chemical and microbial quality of the final rinse water will not impair the standard of cleanliness and disinfection of the processed endoscope.

The following section describes analytical methods which may be used to determine the various biological, physical and chemical properties of water samples for the various qualities of water used in the various stages of the EWD process. Particular emphasis is placed on the quality of the final rinse water, which is required to be purified to a high chemical and microbial quality. The quality of the supply water needs to be established prior to installation of the EWD, to determine any treatment that may be required to optimize the detergent and disinfectant activity. It should be re-tested periodically, at a frequency determined by local circumstances affecting the quality and consistency of the source.

The methods of analysis required to detect chemical contaminants at low concentrations with a high level of accuracy require the use of a laboratory with appropriate expertise, facilities and experience. Some tests that can be carried out on-site or with very simple laboratory equipment at, or shortly after, the time of sampling are sufficient for most purposes and options for such 'field-testing' are included wherever possible. The precision, accuracy, sensitivity and limits of detection of these 'field test' options are usually inferior to those of laboratory methods. They are useful, however, in that they provide evidence of any gross failure and the results are available straightaway making them of diagnostic value during a fault finding exercise. They are generally economical compared with more sophisticated laboratory analysis and can be carried out by non-specialist personnel after appropriate training. It is not necessary to use experienced chemical analysts to undertake the on-site analysis of water samples described. It is, however, essential that personnel receive appropriate training before attempting to carry out this work. Recourse to more precise laboratory analysis may be needed in the event of a dispute between two parties.

For any given determinand, there may be several suitable methods that cover the range of concentrations of interest. The methods described are intended to be representative of suitable methods, including options for on-site testing. A number of test kits / systems are available commercially. Before adopting one of these methods care should be taken to ensure that the test(s) provides results of sufficient accuracy and sensitivity. The chosen determinands are known to influence the efficacy of the process. Further guidance on appropriate test methods may be obtained from BS 1427: 1993.

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

a. **instrumental tests** using portable instruments designed for on-site use for example portable pH meters, ion selective electrodes etc;
b. **spectrophotometric tests** based on measurement of the absorbance of a coloured reaction product; measurement may be visual or photometric and may be against a precalibrated coloured disc or against standard reference solutions;
c. **titrimetric tests** these may be carried out using standard laboratory equipment or with commercially available apparatus designed for field use; the latter is usually much simpler to use.

For all the instrumental methods described there is commercially available equipment specifically intended for field use. All the variables for which instrumental methods are described are temperature dependent. The equipment used should be temperature compensated. Also the equipment should be allowed sufficient time on site, before it is put into use, to equilibrate to the local ambient temperature.

Commercially available test kits based on visual or photometric comparison with coloured discs have become an accepted standard for on site analysis. Manufacturers usually supply a complete test system, including kits of reagents. To ensure compatibility, and maintenance of the manufacturers claimed sensitivity and accuracy for the method, the kit specified by the manufacturer should not be substituted.

8.2 Sample collection

Sample the water from the water supply pipe, at draw-off points as close as practicable to the EWD. When the rinse water is stored in a tank within the WD, heated in a calorifier in the WD or otherwise treated within the WD, samples shall also be taken from the discharge point into the chamber. Additional samples may need to be taken from any water treatment plant when trying to identify the cause of a non-conformity.

Choose a sampling procedure that is suitable for all the physical, chemical, and biological determinands of interest. It may be used for water samples throughout the water distribution system. The sampling containers used should be specific for the determinands of interest. This may include, as appropriate:

a. 250 ml sterile, pyrogen free, single use containers (for determination of bacterial endotoxin levels and/or total viable count);
b. 1 litre acid washed, borosilicate bottles, (for determination of cations);
c. 1 litre polypropylene bottles, (for determination of anions, total dissolved solids);
d. 100 ml high density polyethylene bottles (for determination of pH, conductivity).

Note: care should be taken to ensure that the containers are free from interfering residues such as detergents.

Run the first 50 ml of sample taken at each sampling point to waste. Take duplicate samples. Test samples within four hours of collection or store at 2ºC to 5ºC and test within 48 hours of collection. Label the container with details of the sampling point and the time and date the sample was collected.

8.3 Tests of chemical quality

8.3.1 Electrical conductivity

Equipment and materials

A variety of portable conductivity meters are available. The unit chosen should meet the performance criteria given below across the required range. For measurement of pure quality rinse water, the conductivity meter should include the range 0.0 to 199 µS.cm $^{-1}$, resolution 0.1 µS.cm $^{-1}$, accuracy ± 1 % full scale). Higher ranges may also be required for the assessment of mains water on site prior to installation of the EWD. The conductivity meter should be temperature compensated over the range 0ºC to 40ºC. A separate test vessel such as a beaker will be required for conductivity meters with an immersion probe.

Test method and performance requirement

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

> Note : The working standards are stable for up to 1 week when stored well sealed, in cool conditions. A comprehensive range of standard conductivity reference solutions, including pure or 'absolute' water reference standard are available commercially, standardised at 25ºC and traceable to national standards.

After calibration, thoroughly rinse the sample cup, or immersion probe, with pure water. Collect the sample (for on-site tests, this may be collected in a high density polyethylene bottle) and test as soon as practicable. Pour an aliquot of the sample into the sample cup of the conductivity meter or, for meters with an immersion probe, into the clean beaker. The meter manufacturers instructions for making the measurement should be followed; this will usually require a short stabilisation period before noting the reading.

Requirement

The conductivity at 25ºC should not exceed:	*10 µS.cm $^{-1}$*	*for De-ionised water*
	30 µS.cm $^{-1}$	*for Reverse osmosis water*
	300 µS.cm $^{-1}$	*for softened or mains water*
		(Conductivity levels in excess of this value are indicative of a high concentration of dissolved solids).

8.3.2 pH

Equipment

Two suitable methods for on-site measurement of pH are available:

(a) small portable, calibrated pH meter, with built in temperature compensation.

Although many portable pH meters provide suitable accuracy for general applications, their use in the determination of the pH in water of high purity may give unstable or unreliable readings. Use pH meters specifically designed for the measurement of low ionic strength solutions for determining the pH of DI or RO water.

(b) Colour disc comparator

Colorimetric tests for pH are suitable for high purity, low conductivity, water samples of the type that are required to be tested. If colorimeter methods are being used for other field tests, this may be the more appropriate method. The accuracy is limited and discrimination may not be better then 0.2 pH units. This is, however, quite suitable for field tests. Colour, turbidity or strong oxidants in the sample all interfere with the test. A narrow range indicator (or two for use on successive samples) should be chosen to cover the required range of pH 4 to pH 8. Manufacturers of colorimeters usually provide indicators to cover a range of 2 or 3 pH units. Wide range indicators should not be used because of their poor discrimination.

Test method and performance requirement

Operate the pH meter or colour disc comparator in accordance with the manufacturer's instructions.

For the colorimetric method, pay particular attention to the accuracy of volumes of both sample and reagent, and monitor both temperature and reaction time. Match the colour of the reacted sample against the calibrated colour disc viewed through a blank sample. Read the value in pH units directly from the disc.

For either method, the calibration should be verified using standard buffer solutions made up in advance and kept in capped bottles until required. The buffer solutions should be chosen to have a pH in the midpoint of the range used in the determination.

Requirement for final rinse water

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

8.3.3 Hardness (as $CaCO_3$)

Hardness of water is due to the presence of dissolved salts of the alkaline earth metals (Calcium, Magnesium and Strontium). Their presence causes limescale formation from heated water, may inactivate detergents and disinfectants and causes scaling on load items. Two methods suitable for field testing are described.

8.3.3.1 ISE method

Use ion selective electrodes for calcium and also for divalent cations (total hardness). Ion selective electrodes are not **specific** for a particular ion but have a relative selectivity for a particular ion or group of ions. They are sensors which provide a potentiometric response to the activity of the ions in solution. The activity is proportional to the concentration for determinations carried out in solutions of the same ionic strength. A high impedance millivoltmeter is used to measure the potential between the ion selective electrode and a suitable reference electrode. The measured potential is proportional to the logarithm of the concentration of the ion(s) in solution.

Adjust the analyte and calibration standard solutions to the same ionic strength, within the optimum working pH range 4 to 9. An adjustment buffer consisting of 4M KCl solution is often used. Phosphate buffers must not be used since the calcium activity will be lowered by complexation or precipitation. The electrodes are free from any major interference except Zinc ions. They are however poisoned by a number of biological fluids. The calcium electrode requires a single junction reference electrode. Calibration is made against two or more standard solutions. These are commercially available.

Range

The calcium selective electrodes which are available have a Nernstian response for concentrations from 1 M down to about 5 x 10 -6 M and a selectivity ratio of better than 2000 against Magnesium. This range is suitable for analysis of softened water and purified water (RO or DI).

8.3.3.2 Titrimetric method

Commercially available kits for the titrimetric determination of both total hardness and calcium hardness are available. They are based on the same reaction in which divalent cations are complexed with the disodium salt of ethylenediaminetetra-acetic acid (EDTA). When the reaction is carried out, at pH 10 to 11, with Eriochrome Black as the complexiometric indicator, all the calcium and magnesium ions are chelated by the EDTA and the absence of free calcium and magnesium ions causes a colour change in the indicator.

At pH values above 12 magnesium ions are precipitated as the hydroxide and do not react with the EDTA. Calcium hardness can be determined using Patton and Reeders indicator powder as a complexiometric indicator. The commercially available kits often use novel titration devices instead of burettes. The test reagents and range are specific to each kit. The manufacturers instructions should be followed.

Requirement

The hardness expressed as mg/l $CaCO_3$ should not exceed: 50 mg/l for softened / purified water
200 mg/l for water used in the flushing stage

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

8.3.4 Total dissolved solids

8.3.4.1 Evaporative residue method:
The method of choice is the determination of the weight of dissolved solids by evaporating a known sample volume to dryness.

Materials and equipment.

a. silica or borosilicate evaporating dish or beaker of > 150 ml capacity;
b. oven set to 110ºC ± 2ºC;
c. boiling water bath or heating mantle set to 100ºC ± 2ºC;
d. balance weighing to 0.1 mg;
e. 100 ml pipette or measuring cylinder.

Test method and performance requirement
Collect a 500ml sample. Take the silica dish (or equivalent), dried for 2 hours in the oven set to 100ºC ± 2ºC and then cooled to ambient temperature and weigh it to the nearest 0.1 mg. Dispense 100 ml of the sample into the weighed dish and evaporate it over the boiling water bath until visibly dry. Evaporate two further 100 ml aliquots of the sample in the same dish in the same manner. Dry the dish in the oven to constant weight to an accuracy of 0.1 mg.
Calculate the mass of residue in the dish and hence calculate the mass of residue per 100 ml of water.

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

8.3.4.2 Estimation by conductivity method
For field testing, when a water sample contains predominantly ionizable solids of relatively constant composition in solution, an approximation of the total dissolved solids may be obtained from the electrical conductivity of the sample. This method is not valid in the presence of nonionic dissolved material such as organic contamination which does not contribute to the conductivity reading but would be detected in the evaporative residue.

Equipment and materials

a. conductivity meter
b. phenolphthalein indicator;
c. 5% w/w acetic acid solution;
d. 5% w/w sodium hydroxide solution.

Neutralise the sample, using phenolphthalein as the indicator, by dropwise addition of 5% w/w sodium hydroxide solution or 5% w/w acetic acid solution. Measure the conductivity of the sample (see 8.3.1) and multiply by the conversion factor to give an estimate of the TDS in mg/l.
Use a conversion factor derived experimentally for waters of consistent ionic composition by making direct comparison of the measured mass of total dissolved solids and the electrical conductivity. Alternatively, a common arbitrary factor of 6.7 is used, based on sodium sulphate as the ionic species.
For conductivity at 25ºC measured in $\mu S.m^{-1}$ then, TDS mg/l = electrical conductivity $\mu S.m^{-1}$ x 6.7.

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

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

8.3.5 Chloride

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

8.3.5.1: Ion selective electrode method

The commercially available chloride selective electrodes have a working range from 1M to 10^{-5} M. They work over the pH range 3–10 and the sample should be adjusted for ionic strength using an adjustment buffer consisting of 5M $NaNO_3$ solution. The electrodes show poor selectivity against other halides and cyanide ions. Sulphide ions should be absent.

The chloride electrode requires a double junction 0.1M $NaNO_3$ reference electrode. Calibration is made against two or more standard solutions, available commercially.

8.3.5.2: Silver nitrate titration

Commercial titrimetric kits based on the method described in BS 6068 Section 2.37 are available.
The method employs the titration of the sample at pH 5 to pH 9 with silver nitrate using a potassium chromate indicator solution. The analytical range extends from 5 mg/l to 150 mg/l.

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

8.3.5.3 : The British Pharmacopoeia (BP) limit test, based on comparison of the turbidity obtained from a known chloride concentration, may also be used.

Requirement
The chloride concentration in final rinse water for EWDs processing metal items should not exceed 10 mg/l.
The chloride concentration in other water supplies for WDs processing metal items should not exceed 120 mg/l.

8.3.6 Heavy metals

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

Test method and performance requirement

This may be determined using the limit test described in the British Pharmacopoeia, which compares the colour density of the sample reacted with thioacetamide reagent in acetate buffer at pH 3.5 with standard lead solution containing 1 ppm lead chloride.

Requirement
The total concentration of heavy metals should not exceed 10 mg/l determined as lead in untreated water.
There should be no detectable heavy metals determined as lead in purified / final rinse water.

8.3.7 Iron

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

Test method and performance requirement

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

Equipment

a. colour disc comparator kit;
b. reagents; (The prepackaged reagents available from the manufacturer of the comparator should be used.)
c. a standard 0.702 g/l iron (II) ammonium sulphate solution $(NH_4)_2 Fe(SO_4)_2$;
d. a mercury in glass thermometer graduated in 0.5ºC steps conforming to BS 1704: 1985.

The commercially available colour disc comparator kits are typically based on the reference method described in BS 6068 Section 2.2. The reaction of iron (II) with 1,10 phenanthroline in solution yields a red complex with peak absorption at around 510 nm. Most kits include methods and reagents for pretreatment to reduce any iron (III) compounds to the iron (II) form in which they can be analysed. The kit manufacturer's instructions should be followed.

The method is generally suitable for determination of the concentration of iron in untreated water. A standard 0.702 g/l iron (II) ammonium sulphate solution provides a standard solution of 100 mg/l iron. The solution should be prepared as required and not stored. Working standards spanning the usable range of the colour disc comparator can be prepared by appropriate dilution. It is important to measure the sample temperature before commencing the analysis. After the kit manufacturer's specified reaction time has elapsed the colour intensity of the sample is used to estimate the concentration of iron in the sample.

The spectrophotometric determination of the red colouration produced by reaction of iron (II) with 1,10 phenanthroline in solution may also be used to detect iron across the required range,

Requirement

Untreated and softened water should have less than 2 mg/l iron present.
There should be no detectable iron in purified / final rinse water.

8.3.8 Phosphate

Phosphate is readily absorbed on to many plastic surfaces. If polypropylene bottles are used as sample containers, the sample for phosphate analysis should be transferred immediately to an acid washed glass container and assayed as soon as possible.

Test method and performance requirement

For field testing, a colour disc comparator kit may be used. The calibrated phosphate colour disc should be calibrated in $P_2 O_5$ mg/l. A sensitivity range of 0 to 5 mg/l is commercially available and provides adequate precision. Discs offering extended ranges are also available but the discrimination of intermediate concentrations becomes unacceptably poor). The prepackaged reagents available from the manufacturer of the comparator should be used.

Spectrophotometric method

Commercially available kits are generally based on the reference method described in BS 6068: Section 2.28. The sample is reacted in acidic solution with antimony and molybdate ions to form an antimony phosphomolybdate complex. This is reduced with ascorbic acid to form a molybdenum blue complex. A more sensitive assay uses a similar molybdate reaction with stannous chloride.

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

The test methods measure ortho-phosphate. Pre-treatment would be necessary to convert other forms of phosphate to ortho-phosphate, if required. Some phosphates such as condensed phosphates and labile organic phosphates are slowly hydrolysed under the acidic conditions of the test. Undue delay in reading the reaction may result in a gradual increase in phosphate concentration as hydrolysis proceeds. The presence of oxidising agents and sulphides will interfere with the reaction.
Temperature has a significant effect on reaction time, at 20ºC the reaction is typically completed within 3–4 minutes. Before making the measurement it is necessary to ensure that the reaction is complete, but to avoid excessive delays which can cause errors from hydrolysis of otherphosphates. Reading the measurement at 10–15 minutes after the start of the reaction is generally suitable.

Requirement

The phosphate concentration of the final rinse water should not exceed 0.2 mg/l expressed as P_2O_5.

8.3.9 Silicate

Silicate will react with metal items, including stainless steel, causing corrosion and discolouration.

Test method and performance requirement

For field testing, a colour disc comparator kit may be used. Typically the kits are based on the analytical method described in BS 2690 part 104, which is a recognised reference method. Reactive silica is reacted with ammonium molybdate under acidic conditions to form molybdosilicic acid which is then reduced to molybdenum blue. The colour disc comparator method is generally suitable for determination of SiO 2 level in softened and untreated water but is only sufficiently sensitive to act as a limit test for purified (RO or DI) water.

A standard 3.132 g/l disodium hexafluorosilicate solution (Na_2SiF_6) provides a stock standard solution of 1000 mg/*l* as SiO_2 . The solution is stable for several months after preparation stored in a sealed polyethylene bottle. Working standards spanning the usable range of the colour disc comparator can be prepared by appropriate dilution.

It is important to measure the sample temperature before commencing the analysis. For most kits the temperature must be 15ºC to ensure that the reaction will go to completion. If the sample temperature is below this, or below the minimum temperature specified by the kit manufacturer, the sample should be warmed.

Requirement

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

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

8.4 Tests of microbial quality

8.4.1 Sample collection

Take samples from draw-off points adjacent to the EWD ('supply sample') and from the point of discharge into the EWD chamber or load ('EWD sample').
Ensure that the samples are taken downstream of any filter or other device or equipment intended to remove or control microbial contamination in the water supply.
Swab the discharge surfaces of the sampling points thoroughly with 0.2 µm filtered 70 % iso-propanol and allow to dry by evaporation immediately before taking the sample. Using sterile, endotoxin-free containers of 250ml or larger, collect a sample of not less than 200 ml, or as specified, from each sampling point for each test to be carried out. Label the sample containers with details of the sampling point, the time and date the sample was taken.
Ensure that the samples are tested in the laboratory within 4 h of collection or store at 2 °C to 5 °C and test within 48 h of collection.

The following tests should be carried out as operational / performance qualification tests and as periodic tests. For EWDs that are intened to process endoscopes that may be used invasively, it is recommended that the frequency of periodic tests for the final rinse water should be set at weekly intervals initially and then reviewed by the microbiologist and AP(S).

8.4.2 Total viable count

Purpose / objective: to ensure that the microbial quality of the final rinse water meets the specification.

This test will detect the presence of mesophilic aerobic bacteria that do not have specialised nutritional requirements. It should be demonstrated to recover small numbers of *Pseudomonas aeruginosa*. If specific micro-organisms with defined requirements are of concern then other recovery conditions (growth medium, incubation temperature etc) may used as appropriate, for example the presence of legionellae may be detected using the method described in ISO 11731:1998.
A specific test for environmental mycobacteria is described in 8.3.3. The advice of the microbiologist concerning additional testing should be sought.

Test method and performance requirement

Equipment and materials
a. sterile filter membranes (0.45 µm pore size and of appropriate diameter for the filtration apparatus eg 47 mm diameter);
b. suction filtration apparatus;
c. incubator set at 35ºC ± 2ºC;
d. tryptone soya agar plates (The medium should have been demonstrated as capable of recovering an inoculum of 10–100 cells of *Pseudomonas aeruginosa*)
Note: an alternative medium for the recovery of bacterial contamination in water is R_2A medium described in draft BS EN ISO 15883-1.
e. 70% isopropanol and non-woven wipes.

Take water samples as described in 8.4.1.
In the laboratory, filter a 100 ml aliquot of the sample through a 0.45 µm filter. Aseptically transfer the filter to the surface of a TSA plate and incubate at 35ºC ± 2ºC for 48 to 72 hours. Carry out the test in duplicate. Examine the filters daily and record the number of colony forming units.
Requirement
The total viable count in the final rinse water should be less than 10 cfu in each of two 100 ml samples.
The final rinse water samples should be free of Pseudomonas aeruginosa.
The total viable count in all other water supplied to the EWD (excluding the final rinse water) should have less than 100 cfu in each of two 100 ml samples.

8.4.3 Environmental mycobacteria

Purpose / objective - to ensure that the mycobacterial quality of the final rinse water meets the specification.

Environmental, non-pathogenic mycobacteria present a particular problem when they contaminate the final rinse water in the EWD. Cells of the environmental mycobacteria are easily confused, on initial detection, with pathogenic mycobacteria and may lead to mis-diagnosis. Other mycobacteria which occur in water, for example *M. kansasii* and *M. chelone*i, are opportunistic pathogens.

Test method and performance requirements

Equipment and materials
a. sterile filter membranes (0.45 µm pore size and of appropriate diameter for the filtration apparatus eg 47 mm diameter);
b. suction filtration apparatus;
c. incubator set at 30ºC ± 2ºC;
d. Middlebrook 7H10 plates; (The medium should have been demonstrated as capable of recovering an inoculum of 10–100 cells of M gordonae.)
e. 70% isopropanol and non-woven wipes.

Take water samples as described in 8.4.1.
In the laboratory, filter a 100 ml aliquot of the sample through a 0.45 µm filter.
Aseptically transfer the filter to the surface of a Middlebrook 7H10 plate and incubate at 30ºC ± 2ºC for 28 days. Carry out the test in duplicate.
Examine the cultures weekly and record the number of colony forming units per sample.

NOTE 1 The petri dish should be sealed to prevent dehydration of the growth medium.

NOTE 2 If plates are overgrown by relatively faster growing contaminants within 48-72 hours, it may be necessary to resample and perform a preliminary partial decontamination of the sample with one or more chemicals to which mycobacteria are more resistant than the other organisms.

NOTE 3 If growth is observed the cultures should be transferred to a laboratory with established expertise in mycobacterial identification for further identification.

Requirement
The final rinse water should be free of mycobacteria in both 100ml samples.

8.4.4 Bacterial endotoxins

Purpose / objective - to determine that the endotoxin level of the final rinsewater is within the specified limit.

A limit for endotoxin in the final rinse water has been set for EWDs whose intended use includes endoscopes that will be used invasively. Bacterial endotoxins are detected by the Limulus Amoebocyte Lysate (LAL) gel formation method, as specified in the European Pharmacopoeia (EP) and US Pharmacopoeia. Other LAL methods (Chromogenic,Turbidimetric or Kinetic Turbidimetric)are equally suitable. The test is not applicable as a field test - it requires controlled laboratory facilities and meticuluous attention to detail by experienced, trained staff.

Test method and performance requirement

Equipment

The equipment required will be dependant on the method chosen, but the following common elements will apply:

a. endotoxin-free pipettes / pipettors
b. endotoxin free water, for dilutions
c. LAL reagent (reconstituted Limulus amoebocyte lysate).
d. standard endotoxin;
e. endotoxin-free reaction tubes;
f. non-circulating water bath or dry block incubator capable of maintaining 37 ± 1ºC;
g. test tube racks for reaction tubes;
h. vortex mixer, to mix the reconstituted lysate.
i. paraffin wax sealing film;

Ensure that all apparatus used for collecting samples is endotoxin-free. Use single-use sterile, apyrogenic polystyrene containers. Alternatively, borosilicate glass collection bottles may be depyrogenated by dry heat. Take the water samples as described in 8.4.1.

In the laboratory, undertake the endotoxin assay as soon as practicable. Store the water sample frozen at -20°C prior to testing.

Strict adherence to the assay instructions provided by the manufacturer is essential. The presence of substances that denature protein, chelate cations, adsorb, absorb or bind endotoxin or alter the hydrophobic nature of the endotoxin may interfere. Interference may be detected by the indication of significantly more or less endotoxin than that expected when the sample is tested after the addition of a known amount of standard endotoxin. It is necessary to verify each batch of sample containers as non-pyrogenic and free from interfering substances. This may be done by taking representative random samples, rinsing the containers with endotoxin- free water and testing the rinse water.

Procedural details will vary according to the method chosen (single-test vial, quantitative, LAL gel formation, chromogenic, turbidometric etc). In the LAL gel formation test, an aliquot of the test water sample is incubated with LAL lysate for 1 hour at 37ºC and examined for the formation of a solid clot which holds upon inversion of the test tube. Select the lysate, reconstituted from lyophilised Limulus amoebocyte lysate, to give the required level of sensitivity. Semi-quantitative results may be obtained by testing dilutions of the sample to be tested and by the use of lysates with different levels of sensitivity.

Requirement

The endotoxin concentration in final rinse water for endoscopes intended for invasive use should not exceed 0.25 EU/ml.

8.5 Physical quality

Appearance

Purpose / objective - to confirm that the water supplied to the EWD is clean, colourless and free from visible particulate matter.

Test method and performance requirement

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

Method
Mix the test sample by shaking and transfer an aliquot to a clear colourless glass bottle which is then tightly stoppered. Shake the sample well and examine visually against a white background, preferably in a north light. If the sample is turbid, filter it through qualitative grade filter paper. Examine the filter paper and report the description of the retained material. Examine the filtrate vusually, as previously described. The appearance should be reported in terms of both colour and the intensity of any colour. If the sample is coloured it should be examined carefully to see if there is visible evidence of colloidal material present.

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

9.0 Water supply temperature

Purpose / objective - to demonstrate the attainment of the specified water supply temperature.

A minimum supply temperature may be specified by the EWD manufacturer, to facilitate attainment of the optimium temperature for the process stages and minimise the operating cycle time. A maximum temperature is required to prevent damage to the endoscope, in line with the endoscope manufacturer's specfication.

> Note : Water stored and supplied in the temperature range 25ºC to 40ºC presents a serious risk of microbial contamination of the system. Further treatment would be necessary to achieve water of the microbial quality required for the final rinse water.

Test method and performance requirement

Equipment
An indicating or recording thermometer.

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

When it is not convenient, or practicable, to run the water to waste from a sampling point close to the WD, an alternative method may be used. The water temperature may be estimated by measurement of the temperature of the outer surface of the supply pipe. When it is intended to use this method the correlation between the temperature of the water flowing out of the pipe and the surface temperature of the pipe at a particular point should be established during installation testing. The surface temperature should be measured using a sensor designed for the purpose and the manufacturer's instructions for ensuring good thermal contact with the surface should be followed. The temperature should be noted or recorded during a normal operating cycle not less than 30 seconds after the start of water flow through the pipe to the EWD.

Requirement
The noted value for water supply temperature should be within the temperature range specified for the installation.

10.0 Water supply pressure

Purpose / objective – to ensure the attainment of the specified water supply pressure.

If the pressure of the water supply to the WD is below the minimum pressure specified by the EWD manufacturer the performance and productivity of the WD will be affected adversely. If the pressure of the water supply to the WD is above the maximum pressure specified by the manufacturer the capacity of overflow devices may be inadequate, the designed performance characteristics of valves etc may be exceeded and in extreme cases there may be the risk of damage to components of the WD or to products being processed. Many flexible endoscopes are likely to be damaged if subjected to internal pressures greater than 35 kPa.

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

Test method and performance requirement

Equipment
Pressure indicator or recorder for 0–10 bar.

Connect the pressure sensor to each of the water supply pipes to the EWD, as close to the EWD as may be practicable, on the supply side of the EWD isolating valve for that supply. Observe and record the static pressure when the valve is closed and the pressure indicated throughout a normal operating cycle.

When the water service also supplies other equipment on the same supply line, the test should be run both with the other equipment operating throughout the test (or their operation simulated by an appropriate discharge to waste) and with no other equipment operating.

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

11.0 Overflow test

Purpose / objective - to verify, for EWDs which incorporate one or more water storage tanks, the capacity of the overflow(s) to discharge all excess water, as intended, without spillage into the EWD or working area.

Test method and performance requirement

Method a: Type test or Works test
Connect the EWD to all necessary services and the water supply pressure adjusted to not less than 6 bar under the conditions of flow which prevail with the supply valve(s) fully open. Fully open the supply valve(s). Observe the level of water in each tank or cistern until this has been unchanged for not less than 2 minutes.

Method b. Installation test
Connect the EWD to all necessary services. Fully open the supply valve(s). Observe the level of water in each tank or cistern until this has been unchanged for not less than 2 minutes.

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

12.0 Volume of water used per stage

12.1 Purpose / objective - to determine and verify the volume of water used at each stage.

During type testing the manufacture should be required to determine the volume of water used during each stage of the cycle. These data are used in calculations of the service requirement.

In addition, during installation or operational testing, the volume of water used for each stage should be verified. If the volume of water used is insufficient the efficacy of the cleaning and disinfection processes may be adversely affected. If the volume is greater than that specified an unexpected heavy demand may be placed upon the water supply.

12.2 Test method and performance requirement

Equipment
A water flow meter or volumetric measuring equipment.

Different methods are available for determining the volume of water used, as appropriate for the particular installation.

Method a
Measure the volume of water used at each stage of the operating cycle using suitable volumetric measuring vessels. The accuracy of the vessels shall be equal to, or better than 1 % of the volume to be measured, as specified by the manufacturer.
Method b
When the EWD is supplied from a readily accessible tanked supply the make-up to the tank may be interrupted and the water level marked. Determine the volume of water required to restore the level after an operating cycle stage, by the addition of a measured volume of water.
Method c
For those EWDs which discharge all the water from each stage at the end of each stage a suitable estimate of the volume used may be obtained by volumetric measurement of the discharge from the drain.
Method d
Measure the volume by interposing a total volume flow meter(s) in the pipe(s) supplying the WD and determining the volume used from readings taken immediately before and after each stage of the operating cycle. Ensure that the meter is in a known state of calibration, suitable for the operating pressure range of the WD and designed for connection within a supply pipe of the diameter used on the WD. Locate the meter on a straight section of pipe with not less than 20 pipe internal diameters from the nearest bend or obstruction on either side of the meter.

NOTE Volume / time flow meters should not be used since the calculation of the total volume from measurements of time and varying flow are unlikely to be sufficiently accurate.

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

13. Treatment of water supply: for final rinse water quality.

13.1 Purpose / objective - to establish the capability of the water treatment method to provide final rinse water of a microbial quality that will not impair the standard of cleanliness and disinfection.

The EWD manufacturer should specify a particular water treatment method, having established its efficacy using the microbiological type test described below.

13.2 Test method and performance requirement

13.2.1 Microbiological type test

Challenge the efficacy of the treatment system by inoculation with a test organism (E coli K12) upstream of the treatment system. The inoculum should be sufficient to produce a population of 10^6 organisms per millilitre in the final rinse water if there was no effect from the treatment system.
Collect a sample of the final rinse water (not less than 200 ml) during an operating cycle. Analyse two 100 ml aliquots for the number of remaining organisms by the filtration method. Report the number of colony forming units recovered from each of the two tests.

Requirement
There shall be less than 10 cfu recovered from each of two 100 ml aliquots tested.

13.2 Operational test

Various treatment methods are used to ensure that the final rinse water is of appropriate microbial quality before use. The test shall verify the performance of the particular system by the method specified by the manufacturer.
This shall include, as necessary:

- verification of filter performance by an integrity test (e.g. bubble point test);
- verification of thermal disinfection by thermometric testing.

Tests for microbial quality

Make a total viable count by membrane filtration of not less than 100 ml final rinse water sample. Place the filter on R_2A-medium[1] or other suitable low nutrient medium and incubate at 28 °C to 32 °C for a minimum of 5 days to determine the aerobic mesophillic viable count.

Requirement
There shall be less than 10 cfu recovered from each of two 100 ml aliquots tested.

NOTE Other methods, including rapid methods such as ATP bioluminescence, that have been validated to be at least equivalent to the above method in terms of both specificity and sensitivity may also be used.

[1]The microbiological recovery medium for the estimation of bacterial contamination of water (R_2A medium) consists of: Yeast extract (0.5g), Proteose Peptone (0.50g), Casein Hydrolysate (0,50g), Glucose (0.5g), Starch (0.5g), Sodium Pyruvate (0.30 g), K_2HPO_4 (0.30g), $MgSO_4$ (0.024g) , Agar (15.00 g) Purified water (1000.00 ml) .Adjust the pH to 7.2 with crystalline K_2HPO_4 or KH_2PO_4 before adding agar. Heat to boiling to dissolve agar, and autoclave for 15 min at 121 °C.

14. Disinfection of liquid transport systems following failure of water treatment equipment

14.1 Purpose / objective - to evaluate the disinfection of the water treatment plant, by simulating various incidents that might arise during normal use of the EWD.

The methods are intended to simulate various incidents that might arise during normal use of the EWD, and that could give rise to contamination of the EWD.
The test requires deliberate contamination of the EWD and is designed primarily as a type test.

14.2 Preparation of contaminated EWD

14.2.1 Materials and equipment

a) Contamination suspension of *Pseudomonas aeruginosa* CIP A22 (or equivalent), 1×10^9 cfu.ml $^{-1}$ to 1×10^{10} cfu ml $^{-1}$ in sterile distilled water.
b) Maintenance and counting medium; Soybean Casein Digest (SCD) agar (see EN 12353).
c) EWD with the following cycles – operating cycle;
self disinfection cycle
sampling cycle
contamination cycle
d) External tank containing the contamination suspension

14.2.2 Sampling cycle

The sampling cycle corresponds to a standard endoscope cleaning and disinfection cycle interrupted during the stage before disinfection, and for which the detergent shall be replaced by sterile distilled water. Once the cycle has been interrupted, take a sample from the bottom of the tank containing water having circulated in the machine's pipe work..

Note. This cycle only includes the cleaning and rinsing phase and circulates water throughout the machine's pipe work, without there being any addition of disinfectant or detergent product. If the cycle cannot be interrupted immediately prior to the disinfection stage then a complete cycle substituting water for all process chemical solutions shall be used.

14.2.3 Contamination cycle

This special program corresponds to a standard cleaning and disinfection cycle for which the disinfectant solution heating system (if fitted) is deactivated, and the detergent and disinfectant are replaced by sterile distilled water. During this contamination cycle, the machine is connected to the external tank containing the contamination solution so that during each phase of the contamination cycle, the machine is only fed with the contamination solution contained in the external tank.

14.2.4 Procedure

External tank disinfection

Before each test, subject the external tank in which the contamination solution is prepared to a thermal disinfection cycle with an Ao of not less than 600.

14.2.5 Verification of absence of microbiocidal residue in the external tank after disinfection

During the last rinsing stage of the external tank, collect 9 ml of the water circulating in the external tank and associated pipework.
Incorporate 1 ml of a bacterial suspension of *Pseudomonas aeruginosa* at 10^3 bacteria/ml in the previously-sampled 9 ml of water.
After mixing thoroughly and 10 min of contact time, establish the number of viable bacteria present in the reaction mixture (T_N) by serial dilution and counting on a SCD agar plate
The rinsing is only considered to be valid if $10 \times T_N / T_t \geq 0{,}8$

where

T_N is the number of viable bacteria present in the reaction mixture;

T_t is the exact concentration of bacteria in the bacterial suspension (control).

14.2.6 Preparation of the contamination solution

Fill the external tank with 30 l of tap water and 30 ml of a *Pseudomonas aeruginosa* suspension containing 10^9 cfu/ml. After thorough mixing, take a sample in order to establish, by serial dilution and counting on a SCD agar plate the exact concentration of micro-organisms in the contamination solution (T_c).

14.2.7 Contamination of the machine via the water supply network

After having prepared the contamination solution and deactivated EWD water treatment unit, connect the machine subjected to the tests to the external tank. Then start the machine contamination cycle in order to ensure circulation of the contamination solution in all the internal piping of the machine.

14.2.8 Determination of the WD contamination level

During the different tests, determine the contamination level of the EWD by running a sampling cycle and then establishing the concentration of micro-organisms in the water having circulated in all the piping of the machine during this cycle. For this, during the sampling cycle collect 2 l of water in the tank of the machine. Filter 10 ml, 100 ml and 1000 ml of the 2 l of water through 0.2 µm membranes. Then rinse the membranes with 3 x 50 ml of sterile distilled water, placed on counting medium and incubate at 37°C for 24 h.

After incubation, count and identify the number of colony forming units (cfu), and express the results as a number of cfu/l.

14.3 Test method and performance requirement for establishing the efficacy of the disinfection of the contaminated liquid transport system

14.3. 1 Type test

The EWD manufacturer should provide test data using one of two methods:-

a) Method 1 (see 14.3.1.1) tests the self-disinfection cycle after a simulated water treatment equipment malfunction that, although repaired quickly (24 h later), has caused a contamination of the EWD by the micro-organisms present in the supply water.

b)

c) Method 2 (see 14.3.1.2) also simulates the case of EWD contamination by micro-organisms present in the supply water following a malfunction of the internal water treatment equipment. However, in this case, the self-disinfection cycle is only applied one week after a water equipment malfunction, and that during this week the machine has continued to be used (one endoscope washing/disinfection cycle per day). This allows evaluation of the efficiency of the self-disinfection cycle of a potentially contaminated machine, after one week of use. Moreover, monitoring the internal level of contamination of the machine during the interval of time between the water treatment equipment failure and the execution of the self-disinfection cycle will allow evaluation of whether the machine's design limits the development of micro-organisms in the pipes of the machine.

d)

14.3.1.1 Method 1

Proceed as follows:

1) 1) install the machine;
2) 2) run a self-disinfection cycle;
3) 3) run a sampling cycle;
4) 4) determine the EWD contamination level;
5) 5) deactivate the water treatment system (i.e. remove filter, deactivate heating system);
6) 6) disinfect the external tank;
7) 7) prepare the contamination solution;
8) 8) contaminate the machine via the water supply network;
9) 9) leave the EWD at room temperature (not less than 20 °C) to incubate for 24 h;
10) 10) connect the machine normally;
11) 11) re-activate the water treatment system;
12) 12) run a self-disinfection cycle;
13) 13) run a sampling cycle;
14) 14) determine the contamination level of the machine (see 14.2.8);
15) 15) If the analysis of the results shows more than 10 cfu per 100 ml in the sample taken during step 14), repeat steps 12), 13) and 14) until reduction of the
16) contamination to not more than 10 cfu per 100 ml.;
17) 16) Report the number of self disinfection cycles needed to reduce the contamination to not more than 10 cfu per 100 ml.
18)
19) Note. It is not necessary to determine the contamination level before the disinfection cycle (step 12 above) since the extent of contamination that will occur is specific to the design of the EWD liquid transport system. Carrying out such sampling may also remove significant microbial contamination from the system.
20)
21) *Requirement*
22) *It shall be possible to reduce the contamination to not more than 10 cfu per 100 ml in a single self-disinfection cycle.*
23)

14.2.1.2 Method 2

Proceed as follows:-

1) install the machine;
2) run a self-disinfection cycle;
3) run a sampling cycle;
4) determine the contamination level of the EWD;
5) deactivate the water treatment system;
6) disinfect the external tank;
7) prepare the contamination solution;
8) contaminate the machine via the water supply network;
9) leave the EWD at room temperature (not less than 20 C) to incubate for 48 h;
10)
11)
12) connect the machine normally;

13) re-activate the water treatment system;
14) run a standard endoscope cleaning and disinfection cycle;
15) run a sampling cycle;
16) determine the contamination level of the EWD (see 14.2.8);
17) leave the EWD at room temperature (not less than 20°C) to incubate for 24 h;
18) run a standard endoscope washing-disinfection cycle;
19) run a sampling cycle;
20) determine the contamination level of the EWD (see 14.2.8);
21) leave the EWD at room temperature (not less than 20°C) to incubate for 24 h;
22) run a standard endoscope washing-disinfection cycle;
23) run a sampling cycle;
24) determine the contamination level of the EWD (see 14.2.8);
25) leave the EWD at room temperature (not less than 20ºC) to incubate for 24 h;
26) run a standard endoscope washing-disinfection cycle;
27) run a sampling cycle;
28) determine the contamination level of the EWD (see 14.2.8);
29) leave the EWD at room temperature (not less than 20ºC) to incubate for 24 h;
30) run a standard endoscope washing-disinfection cycle;
31) run a sampling cycle;
32) determine the contamination level of EWD (see 14.2.8);
33) leave the EWD at room temperature (not less than 20º C) to incubate for 48 h;
34) run a self-disinfection cycle;
35) run a sampling cycle;
36) determine the contamination level of the EWD (see 14.2.8);
37) if the analysis of the results shows the presence of more than 10 cfu per 100 ml in the sample taken during step 33), repeat steps 32), 33) and 34) until reduction
38) of the contamination to not more than 10 cfu per ml
39) 36) report the number of self disinfection cycles needed to reduce the contamination to not more than 10 cfu/100 ml.

e)

1) *Requirement*

2) *It shall be possible to reduce the contamination to not more than 10 cfu per 100 ml in a single self-disinfection cycle.*

f)

14.3.2 Operational and routine test

The test on the final rinse water shall be sufficient to verify the self-disinfection cycle. (see 8.4.2). The sample shall be taken from any suitable point that ensures that water is collected that has circulated through the components that were to be disinfected.

15. Thermometric tests: chamber and load temperature

15.1 Chamber and load temperature during process cycle

Purpose / objective - to establish that temperature during the process cycle is within the set limits.

Test method and performance requirement

15.1.1 Test of chamber and load temperature during process, for thermostatically regulated EWD.

Test equipment
Thermometric recording instrument(s) which record the temperature from a minimum of twelve temperature sensors. The channels may be multiplexed or independent of one another. The data recording interval for each channel shall not exceed 2.5 s. All data sampled shall be used for the interpretation of results.
The scale range shall include 0 °C to 100 °C. The limit of error for the recording instrument, excluding temperature sensors, between 0 °C and 100 °C shall not exceed ± 0.25. K when tested in an ambient temperature of (20 ± 3) °C.

The additional error due to changes in environmental temperature shall not exceed 0.04 K/K.

For analogue instruments the minor mark interval shall not exceed 1 K and the chart speed shall be not less than 15 mm/min. The resolution shall be not less than 0.5 K.

Digital instruments shall register and record in increments of not more than 0.1 K.

The overall diameter of the temperature sensor(s) within the channels of the endoscope(s) should not block the channel(s).

Calibration of test equipment
Calibration shall be carried out in accordance with the instrument manufacturer's instructions by a validated method using a working or reference standard that is traceable to a national standard.

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

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

One or more thermometric recording instrument(s) shall be used in conjunction with the temperature sensors to record the temperatures measured in the locations specified in the tests described. They may also be used to verify the readings obtained from instruments fitted to the EWD.

Test load : a reference load or a performance qualification load of an endoscope representative of the types which the EWD is intended to process.

Procedure for Chamber and load temperature throughout process

Locate the temperature sensors as follows:

- at two diagonally opposite positions in the chamber;
- one in the approximate geometric centre of the surface of the door or lid;
- one adjacent to each automatic control temperature sensor;
- one adjacent to each process recorder temperature sensor;
- one on the control head of the endoscope in contact with a metal component;
- one in at least one channel of the endoscope at the distal end to a depth of not less than 10 cm;
- the remaining sensors on the outer surface of the insertion tube and umbilical cord of the endoscope at intervals not exceeding 75 cm.

The sensors shall be in direct physical contact with the item or installed sensor in each position being monitored and shall be placed, as far as possible, in or on the part which will be slowest to achieve the specified temperature.

Record the temperatures obtained throughout a process cycle. Perform the test in triplicate.

Results

The maximum deviation for each sensor from the specified temperature for each stage of the process shall be reported and checked for compliance with the following requirements.

Requirement

General

Throughout the operating cycle, the temperature recorded on the surface of the chamber and on all surfaces of the device being processed shall be within the operating temperature range specified by the WD manufacturer for each stage of the operating cycle.

Temperature control of the washing stage

Throughout the washing stage, the temperature recorded on the surface of the chamber and on all surfaces of the device being processed shall be within 0 C to +5 C of the washing temperature specified by the WD manufacturer.

For EWDs with thermostatic control of the disinfection stage

Throughout the disinfection stage, the temperature recorded on the surface of the chamber and on all surfaces of the device being processed shall be within 0 C to +5 C of the disinfection temperature specified by the WD manufacturer.

For EWDs with a minimum operating temperature for the washing and / or disinfection stage

Throughout the washing and /or disinfection stage, when the temperature on the surface of the chamber and of the liquid process medium are below the minimum temperature specified by the device manufacturer a fault shall be indicated.

15.1.2 Test for operating cycle temperature limits on washing and chemical disinfection stages on an EWD that is not thermostatically regulated

Test method and requirement
Test equipment

Use test equipment as described in 15.1.1.
Locate the temperature sensors as described in 15.1.1. Run a cycle, supplying the detergent and/or disinfectant solution at a temperature 2 °C to 4° C below the minimum temperature specified for the washing / disinfectant stage respectively. Run a second cycle. Supply the detergent and/or disinfectant solution at a temperature 2°C to 4° C above the minimum temperature specified for the washing/disinfection stage respectively.

Report the minimum temperature attained by the load and chamber surface during the washing and/or disinfection stage and whether or not a fault was indicated by the automatic controller.

Requirement
Throughout the washing and /or disinfection stage, when the temperature on the surface of the chamber and of the liquid process medium are below the minimum temperature specified by the device manufacturer a fault shall be indicated.

15.2 Over temperature protection

Purpose / objective – to verify that the load will be protected from exposure to excessive temperature.

EWDs are intended to process items which may be damaged at high temperatures. The EWD is fitted with one or more temperature cut-outs to ensure that, in the event of the automatic control failing to control the temperature in the EWD, the temperature will not rise to a level which would damage the load.

Test method and performance requirement

Equipment
Temperature recorder complying with the requirements specified in 15.1.1.
NOTE Three independent data loggers and a temperature recorder having at least one sensor can be used as an alternative.

Locate the temperature sensors at two diagonally opposite corners of the load carrier, in the approximate geometric centre of the load carrier and adjacent to the temperature sensor used as the reference sensor for chamber temperature. Operate the WD empty, except for the load carrier, on a normal operating cycle. For multi-cycle machines, test the two cycles having the highest and lowest operating temperatures. During the stage of the cycle when the maximum temperature is attained, disable the temperature control system in the manner specified by the manufacturer e.g. by removing the temperature sensor connected to the automatic controller.

Requirement
The test shall be considered satisfactory if the temperature cut-outs are demonstrated to operate at a temperature not more than 5 °C higher than the highest temperature provided by any temperature control or temperature-limiting device.

16. Thermometric tests : self disinfection cycle

16.1 Purpose / objective - to evaluate the temperature during 'self-disinfection' mode.
This test applies only to those EWDs that have a thermal self-disinfection cycle

16.2 Test method and performance requirement

Use the test equipment described in 15.1.1, but without a load.
Place sensors in those parts of the system specified by the EWD manufacturer as representative of the lowest temperatures in the system.
Run the self-disinfection cycle

Requirement
The entire system subjected to thermal disinfection shall attain the required disinfection temperature.

17. Channels non-obstruction test

17.1 Purpose / objective – to ensure that a fault is indicated when one or more channels of the device are obstructed to an extent that would impair the efficacy of the process.
EWDs should be fitted with means to ensure that each of the channels is patent so that process fluids and rinse solutions will flow through each channel. The test demonstrates first that the flow of liquid in each channel is detected by the automatic controller. It then demonstrates that obstruction in any channel is detected.

> NOTE With some designs of endoscope a blockage in one channel may cause the flow to be diverted to another channel or port. Under these circumstances detection of an obstruction by the automatic controller may not be reliable. The user should refer to the device manufacturer's instructions for the method to be used to verify that all channels are free from obstructions.

17.2 Test method and performance requirement

Test equipment
Use a surrogate device to simulate the medical device. The surrogate device shall be constructed of lengths of polytetrafluoroethylene (PTFE) tubing,

For each channel present in the device(s) the corresponding tube shall be within ± 10 % of the internal diameter of the corresponding channel of the device(s) to be processed. The length of the tubes shall be 600 mm to 650 mm, 1300 mm to 1500 mm, and 2000 mm to 2250 mm for EWDs intended to process devices with channels of length up to 650 mm, 650 mm to 1500 mm and 1500 mm to 2250 mm, respectively.
When the EWD is intended to process a range of devices, it shall be sufficient to ensure that the channels with the smallest and largest diameter are represented within the surrogate device.

A surrogate device shall be constructed in which each tube can be obstructed, at the distal end, to limit the flow of liquid to an extent equal to the maximum specified by the EWD manufacturer.

In some circumstances, eg where one connector is used to irrigate two or more channels, the test shall be repeated with a surrogate device modified to provide the corresponding number of tubes with a common connector. The distal end of one of the tubes shall be obstructed to limit the flow of liquid.

Procedure
For EWDs on which the automatic controller includes provision to detect obstructed channels, run the operating cycle with the surrogate device in place. Repeat the operating cycle with the surrogate device with one channel obstructed. Repeat this test so that each available channel in turn has been obstructed.
Report whether or not a fault was indicated when each channel was obstructed.

Requirement
The automatic controller shall verify that the duration of flow of the relevant process fluids met or exceeded the minimum exposure times established as necessary for each process stage. Failure to achieve the required flow in each obstructed channel shall cause a fault to be indicated.

18 Channels not connected test

18.1 Purpose – to ensure that a fault is indicated when one or more channels of the device are not connected to the EWD.

18.2 Test method and performance requirement

Test equipment
Use a surrogate device as described in 12.2 to simulate the medical device. Ensure that all channels are unobstructed at the distal end.

Procedure
For WDs on which the automatic controller includes provision to detect failure to connect channels, run the operating cycle with the non-obstructed surrogate device and repeat the cycle with the non-obstructed surrogate device with one channel not connected. Repeat this test so that each available channel has not been connected.

Requirement
A fault should be indicated when each channel in turn is not connected.

19 Load dryness

19.1 Purpose / objective - to evaluate the ability of the drying stage, if present on the EWD, to remove residual water which may otherwise promote re-contamination and microbial growth.

19.2 Test method and performance requirement

Fully load the EWD (endoscope or surrogate device) and carry out a normal operating cycle. On completion, remove the load (an endoscope or surrogate device) and position the endoscope so that there is a continuous fall to the lumen orifice being tested. Discharge medical grade compressed air at a pressure of 105 kPa to 120 kPa through each channel in turn with the distal end 50 mm to 100 mm above, and normal to a sheet of coloured (e.g. blue or green) crepe paper.

Tests on endoscopes shall be made on all channels with the air flow from both the umbilical side and the control valve.
Examine the paper for dampness shown by dark spots on the paper.

Requirement
There should be no droplets of moisture discharged from the distal end of the endoscope/surrogate device.

20 Fluid emission

Purpose / objective – to ensure that there is no vapour or liquid emitted from door during the operating cycle.

Faulty or damaged lid / door seals can give rise to fluid emission into the working area and the leakage of potentially infectious material from the EWD.

Excessive and persistent leakage may cause deterioration of walls and their surface finishes. When a EWD employs chemical additives for which there are specified exposure limits (usually disinfectants) under the COSHH Regulations it is necessary to determine that the emissions from the EWD do not cause personal exposure to exceed the legal limit.

20.1 Test method and performance requirement for fluids and vapour

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

Test method and performance requirement.
Load the EWD, close the door and wipe the joints between the door and the door surround to remove any moisture.
Carry out an operating cycle.
Throughout the operating cycle use the mirror(s) to check if water vapour escapes from the door seal or from the condenser (if fitted).
At the end of the operating cycle, with the door still closed, use the absorbent wipes to wipe the joints between the door and the door surround as close as possible to the door seal. Examine the wipes for dampness.
A further four operating cycles should be run with the checks described above being carried out on the final cycle.

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

20.2 Test method and performance requirement for chemical vapour emission

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

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

20.3 **20.3 Chamber leak tightness**

Purpose / objective – to verify that during normal operation of the EWD the chamber, pipework and associated components are free from leaks apparent to visual inspection.

Test method and performance requirement

Fill the chamber containing a load carrier (if appropriate) and a test load equal to the maximum volume that could be accommodated with a volume of water equivalent to the maximum volume of water used for any stage of the cycle. Inspect the WD for leakage.

Requirement

There should be no visible leak from the chamber.

21. Protection against hazards from fluids

21.1 Hazards from cleaning fluids during the EWD cleaning process

Purpose / objective - to check that the during external cleaning of the EWD, as specified by the EWD manufacturer, the process does not cause a direct hazard, nor an electrical hazard nor a hazard resulting from the corrosion or other weakening of electrical parts relied upon for safety.

Test method and performance requirements for protection during EWD cleaning
Clean the equipment three times, if a cleaning process is specified, in accordance with the manufacturer's instructions. Immediately after this treatment, look for any signs of wetting of parts likely to cause a hazard.

Requirement
If there are any signs of wetting of parts likely to cause a hazard, the equipment shall pass the voltage test described in § 6.8 of BS EN 61010-1 (without humidity pre-conditioning) and accessible parts shall not be below or exceed the limits of § 6.3.1.

21.2 Hazards in the event of spillage

Purpose / objective - to check that the EWD has been designed so that no hazard would result from a spillage, for example as a result of wetting of insulation or of internal insulated parts that are hazardous live.

Test method and performance requirements for protection in the event of spillage
Check by inspection. In case of doubt, pour 0.2 l water steadily from a height of 0.1 m over a period of 15 s into each point in turn where liquid might gain access to electrical parts. Immediately after this treatment, undertake the following voltage test.

Requirement
The equipment shall pass the voltage test described in § 6.8 of BS EN 61010-1 (without humidity pre-conditioning) and accessible parts shall not below exceed the limits of § 6.3.1.

21.3 Hazards from overfilling a process chemical container

Purpose / objective – to check that liquid overflowing from any container in the EWD which can be overfilled shall not cause a hazard during normal use, for example as a result of wetting of insulation or of internal uninsulated parts that are hazardous live.

Test method and performance requirement
Fill the liquid container completely. Pour in a further quantity of liquid equal to 15% of the capacity of the container or 0.25 l, whichever is the greater, steadily over a period of 60s. Immediately after this treatment, undertake the following voltage test.

Requirement
The equipment shall pass the voltage test described in § 6.8 of BS EN 61010-1 (without humidity pre-conditioning) and accessible parts shall not be below or exceed the limits of § 6.3.1.

22 Doors and door interlocks

22.1 Cycle start interlock

Purpose / objective - to ensure that the interlock will prevent a cycle being started with the door open.

Test method and performance requirement
Leave the door / lid open and unlocked. Ensure that all services are connected. Make an attempt to initiate an operating cycle. Close and lock the door.
Make a further attempt to initiate an operating cycle.
For machines with double doors, make the attempt to initiate a cycle with each door left unlocked in turn and with both doors unlocked.
Requirement
It should not be possible to initiate an operating cycle with the door left open, or with either door open in a double-ended EWD.
It should be possible to initiate an operating cycle with the door closed, or with both doors closed in a double-ended EWD.

22.2 In-cycle interlock

Purpose / objective – to ensure that the interlock will prevent the door being deliberately or inadvertently opened while the EWD is in operation.
Test method and performance requirement for single door
Close and lock the door. Start the operating cycle. While the operating cycle is in progress, make an attempt to unlock the door and report whether it is possible.
Requirement
In these circumstances it should not be possible to unlock the door.

Test method and performance requirement for double-ended EWDs
Make attempts both during and between cycles to open either or both the loading door and unloading door of the double ended EWD. Report whether it is possible to open either door.
Requirement
It should not be possible to open the unloading door after initiation of a cycle until a cycle has been completed satisfactorily.
It should not be possible for both doors to be opened at the same time.
It should not be possible to open the loading door until a cycle has been satisfactorily completed and the unloading door has been opened and closed.

22.3 Cycle complete door interlock

Purpose / objective
Test method and performance requirement
During an operating cycle, make an attempt to open the door. Report whether it was possible to open the door(s) before the operating cycle was completed. Report whether the 'cycle complete' indication was cancelled when the unloading door was opened.
Requirement
It should not be possible to open the door before the cycle is complete.
The 'cycle complete' indication should be cancelled when the unloading door is opened.

22.4 Failed cycle interlock

Purpose / objective - to ensure that the interlock will prevent an operator from removing a load in the normal manner at the end of a cycle which has failed.

Test method and performance requirement
Interrupt one or more of the services to the EWD during an operating cycle, sufficient to cause a cycle failure. Attempt to open the door.

Requirement
A 'fault' should be indicated. It should not be possible to open the door manually. It should only be possible to open the door by means of a special key, code or tool.

23 Process residues

Purpose / objective - to demonstrate that the rinsing stage has reduced the concentration of process chemicals on the load to a level not exceeding that specified by the manufacturer, or supplier, of the process chemical(s) as safe in the context of the intended use of the load.

The nature and amount of residues which can be of concern depend on the process chemicals used and the intended use of the washed and disinfected endoscope. The process chemicals used during the process (detergents, disinfectants etc.) may not be completely removed by the rinsing process. The sampling method and analytical method should be capable of determining the presence of the process chemical at concentrations below that specified as potentially harmful i.e. as the maximum acceptable level.

Tests method and performance requirement
Use the upper limit of the normal dose of the process chemical (detergent or disinfectant). Run the operating cycle using a test load of simulated product. Carry out an analysis, by the method recommended by the manufacturer on the final rinse water and on the simulated product. When the cycle includes a neutraliser for the process chemical under study, use the neutraliser at the lower limit of the normal dose.

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

NOTE Where residual limits are not specified and/or no analytical method is available biocompatibility testing to ISO 10993 may be used to meet the requirements of this clause.

24 Chemical dosing

The EWD should be fitted with dosing systems for controlling the admission of all necessary process chemicals. Each dosing system should be provided with means to determine, directly or indirectly, that the volume admitted and the time within the operational cycle when the admission occurred were as programmed in the automatic controller.

24.1 Test for accuracy and repeatability

Purpose / Objective – to verify the settings for the dispensed volume of chemical additive for each of the dosing systems provided and to ensure that it is reproducible within defined limits.

Test method and performance requirement
Use the test method specified by the manufacturer or, if no method is specified, use the appropriate method given below.

24.1.1 Volumetric method

g) Fill a measuring cylinder of appropriate volume approximately two thirds full with the chemical to be dispensed. Place the suction tube in the measuring cylinder and carry out a normal operating cycle. At the end of the cycle fill the measuring cylinder accurately to the maximum marked level. Carry out a further operating cycle.
Fill a second measuring cylinder accurately to the maximum marking with the same chemical. At the end of the cycle use the contents of the second measuring cylinder to replenish the first cylinder to the maximum marked level. Note the volume of chemical dispensed from the second measuring cylinder and thus the volume of chemical used for the second operating cycle. Compare this with the nominal volume dispensed.
Run a further operating cycle and repeat the measurements as above.

24.1.2 Concentration method

For EWDs designed to dispense the chemical to produce a measured concentration in the solution within the WD chamber, independently determine the nominal volume to be dispensed. Take a sample of the water to be used for that stage of the operating cycle and determine the volume of chemical required per litre of water in the chamber by direct measurement (e.g. with an Ion Selective Electrode, spectrophotometrically). The nominal volume can then be calculated by multiplying the value obtained by either the volume determined in accordance with 6.4.4 or by separate measurement of the volume retained within the holding tank in the WD.

Requirement
Each dosing system shall be deliver the specified volume and the time within the operational cycle when the admission occurred were as programmed in the automatic controller. The volume admitted for each of the dosing systems should be within 10% of the nominal dispensed volume, as specified by the EWD manufacturer.

24.2 Indication of insufficient process chemical for a cycle

Purpose / objective – to demonstrate that an operating cycle is not initiated when there is insufficient process chemical remaining to complete a cycle.

Test method and performance requirement
Fill an otherwise empty container with sufficient chemical for more than 3 but less than 5 operational cycles. Run the WD on 5 consecutive cycles. Estimate the volume remaining at the end of each cycle (pre-marked container, dipstick, or weight).

Requirement
The EWD should indicate that there is insufficient chemical remaining to complete a cycle.

24.3 Chemical dosing test for single-dose container

Purpose / objective – for those EWDs in which the required dose of process chemical is contained in a single-dose container which is replaced before each cycle, to demonstrate that the intended volume of process chemical has been dispensed.

Test method and performance requirement
Run cycles using containers which contain 90 % to 79 % of the intended volume.

Requirement
The automatic controller should indicate a fault.

25 Automatic control test

Principle / objective - to demonstrate that the operating cycle functions correctly as shown by the values of the cycle variables indicated and recorded by the instruments fitted to the EWD.

With the increasing use of EWDs meeting the required standard for independent monitoring and recording, this test is required less frequently.
Temperature sensors for thermometric testing shall be connected to the chamber during this test. If a sensor is placed adjacent to each of the sensors connected to the installed temperature measuring instruments the calibration of these instruments may be checked during periods of stable temperature in the automatic control test.

Test method and performance requirement
Load the EWD with endoscope(s) appropriate for the type of EWD. For EWDs equipped with multiple cycle capability, select the operating cycle to be tested.
Start the cycle. Ensure that a process record is made by the recording instrument fitted to the EWD. If the EWD does not have a recorder observe and note the elapsed time, indicated chamber temperatures and times at all significant points of the operating cycle, for example the beginning and ending of each stage or sub-stage, and the maximum values during the holding time.
At the approximate mid-point of the disinfection hold time, note the elapsed time and the indicated chamber temperature.
Repeat the test three times to ensure that the automatic controller consistently produces operating cycles controlled within the limits specified by the manufacturer.

Requirements
The test shall be considered satisfactory if the following characteristics are observed:

a) *a visual display indicating 'cycle complete' occurs.*
b) *During the whole of the operational cycle the values of the cycle variables as indicated by the instruments on the EWD or shown on the batch record are within the limits specified;*
c) *during the disinfection stage:*
    1. *the indicated and recorded chamber temperatures are within the range specified;*
    2. *the time for which the disinfection stage was maintained was not less than that specified*
d) *the door(s) cannot be opened until the cycle is complete;*
e) *the person conducting the test does not observe any mechanical or other anomaly.*

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

Purpose / objective – to verify that, as designed, built and installed, the EWD will effectively discharge all the water from the system.

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

26.1 Free draining of chamber and load carriers

Test method and performance requirement
At the end of an operating cycle, aborted before the commencement of any drying stage, visually inspect the chamber and load carriers for pools of retained water. Droplets on vertical and sloping surfaces that slowly coalesce and drain away are not considered to be retained water.

Requirement
There should be no pools of retained water in the chamber and load carrier

26.2 Free draining of tanks

Test method and performance requirement
Fill all tanks and reservoirs for water and aqueous solutions with water to the maximum level required for normal operation and then allow them to drain. Inspect the tanks for evidence of pools of retained water.

Requirement
There should be no pools of retained water in the drained tank

26.3 Pipework flow to discharge point

Test method and performance requirement
Visually inspect all pipework to determine whether the slope (i.e. the angle made with the horizontal) is such that any contained liquid will tend to drain towards the discharge point. When necessary, use a spirit level to determine whether the slope is in the required direction.

Requirement
Any contained fluid in pipework should drain to the discharge point

27. Estimation of the dead volume of pipework

Purpose / objective - to determine and verify the volume of pipework which is not purged by the usual flow of liquids during the operating cycle.

This test should be carried out after the satisfactory completion of the checks for free drainage (see 26). It is intended to verify the volume stated by the manufacturer. The test is also of value when investigating problems such as carry over of detergents or microbial contamination occurring in a EWD.

Test method and performance requirement

Equipment
Volumetric measuring vessels of appropriate size.

Flush the pipework of the EWD which is known to be dry (either following disassembly and re-assembly or purging with compressed air for not less than 30 min) with a known volume of water (simulating the flow that would occur in normal use). The volume of water flushed through the system should be twice that determined as the volume used per operating cycle (see 12). Measure the volume of water discharged and the dead volume, estimated as the volume retained, calculated from the difference between the two values.

When the WD has two or more pipework systems which are entirely separate e.g. for flushing water, wash water, rinse water, chemical disinfectant solution each system may be tested separately. Report whether the volume of retained water was equal to or less than the maximum retained volume stated by the manufacturer

Requirement
The volume of retained water should be equal to or less than the maximum retained volume stated by the manufacturer.

28 Operating cycle

28.1 Spray systems

Purpose / objective - to verify that the spray nozzles are not blocked and that they provide the specified flow.

Test methods and performance requirement
Use the method provided by the EWD manufacturer, in the instructions for use, to check that the spray nozzles are not blocked and that the spray arms are free to move to the extent specified by the EWD manufacturer.
Use the method provided by the EWD manufacturer, in the instructions for use, to check that the fixed nozzles intended to provide fluids for the irrigation of the internal channels of hollow instruments provide the specified flow of water and/or aqueous solutions.

Requirement
The spray nozzle function should be demonstrated and the flow of irrigation fluids confirmed, as specified in the EWD manufacturer's method.

28.2 Reproducibility

Purpose / objective – to demonstrate the continued reproducibility of the validated process cycle.

Test methods and performance requirements
WDs shall be tested periodically in accordance with a documented schedule to demonstrate the continued reproducibility of the validated process cycle.
Guidance on those tests which should be included are given in Annex 1 under 'Routine test'.

28.3 Fault indication on sensor failure

Purpose / objective - to demonstrate that a failure of any sensor used as part of the control system of the EWD will cause a fault to be indicated by the automatic controller.

Test method and performance requirement
Start an operating cycle. During, or before, the stage of the cycle at which the sensor is intended to provide data used to determine the control of the cycle, disable the sensor. Each sensor should be tested in turn, in both 'open circuit' and 'short circuit' failure modes. Report whether a fault was indicated. Report whether it was possible to open the door on a single-ended WD or the unloading door of a double-ended WD.

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

Note : If a fault develops in a double-ended EWD, it shall only be possible to open the loading door

28.4 Fault indication on service failure

Purpose / objective - to demonstrate that a failure of any service required by the EWD will cause a fault to be indicated by the automatic controller.

Test method and performance requirement
Start an operating cycle. During, or before, the stage of the cycle at which the service is required, interrupt the service supply. Carry out the test for each service required by the EWD. Report whether a fault was indicated. Report whether it was possible to open the door on a single-ended WD or the unloading door of a double-ended WD.

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

Note : If a fault develops in a double-ended EWD, it shall only be possible to open the loading door

28.5 Blocked drain protection

Purpose / objective - to verify that the interlock provided to prevent the door being opened if, on completion of an operating cycle, the water level within the chamber remains above the lowest point of the chamber door seal is functioning.

Test method and performance requirement
Block the drain to prevent discharge of water from the chamber of the EWD. Close the door and start the operating cycle. On completion of the operating cycle attempt to open the door using the normal door release procedure. If the door opens and the level of the retained water is below the door seal close the door and start another operating cycle. Repeat the operating cycle as many times as necessary for either the water level at the end of the cycle to be above the level of the door seal or for a fault to be indicated. Report whether a fault was indicated before the water level reached the level of the door seal and whether the door could be opened using the normal release procedure.

Requirement
A fault should be indicated before the water level reaches the level of the door seal and it should not be possible to open the door using the normal release procedure.

29 Instrumentation

29.1 Legibility

Purpose / objective – to verify that all indicators and gauges fitted to the EWD are legible by visual observation.

Test method and requirement
The test should be undertaken by an observer with normal vision, corrected if necessary. View each indicator or gauge under diffuse illumination of (300 ± 100) lx at a near point distance of 25 - 30 cms and at a far point distance of 95 – 100 cms. Determine whether the reading is legible.
Requirement
The indicators and gauges should be legible under the test conditions

29.2 Calibration

Purpose / objective - to ensure that the relationship between values of a quantity indicated by a measuring instrument or measuring system, and values represented by a material measure or a reference material is within specification.

Instruments should be subjected to a planned maintenance and calibration programme in accordance with the instrument manufacturer's recommendations.

Test method and performance requirement

Carry out calibration of the test instrument in accordance with the instrument manufacturer's instructions, using a validated method applying a working or reference standard that is traceable to a national standard. Monitor the drift status of instruments to ensure that they remain within their intrinsic specification. Label each instrument with a unique reference number, a calibration date, date due and a reference to a UKAS/NAMAS laboratory reference from which its current calibration status may be traced,

Verify the calibration of all test instruments at a frequency defined by the stability of the equipment. In the first instance the period should be at least yearly. Calibration should be carried out against reference instruments with a valid certificate of calibration provided within a NAMAS or ISO/EN17025 scheme of accreditation. A written procedure that describes the calibration method should be prepared and made available for the AP(S) to review.

Verify the calibration of all measuring equipment fitted to the automatic controller or process verification system by comparison with a test instrument. The test instrument shall be in a known state of calibration in accordance with ISO 10012-1, traceable to a relevant national standard for the level of accuracy specified in this standard.

Carry out the verification of calibration with the sensor of both the EWD system and the test instrument maintained under steady state conditions. The steady state condition shall be at the value at which readings will be made during an operational cycle, or at two or more values in the range of values over which readings will be made during an operational cycle, as specified by the manufacturer. Compare the readings obtained from the test instrument and the WD system.

Requirement
The calibration requirements for Instrumentation on the EWD should be met.

30 Load carriers – stability, alignment and fitting

Purpose / objective – to verify that the load carrier for the EWD is stable and does not impede the any process stages.

Test method and performance requirement

h) Fully load the system for supporting the load within the chamber (if fitted) and operate it in the manner specified by the manufacturer. During loading and after cycle completion carry out an inspection to see if the requirements given below are met.

i) Requirements

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

It should not be possible to mis-position the load carrier in a manner which would prevent the free drainage of water and the penetration of water into the load by connection to service supplies within the chamber in the manner intended by the manufacturer;

31 Disinfection of water treatment equipment used to ensure the quality of the final rinse water

Principle / objective – to demonstrate that the water treatment equipment used to ensure the quality of the final rinse water is disinfected periodically.

The EWD manufacturer should specify the minimum frequency of disinfection of the water treatment system. The actual frequency should be decided by the user based upon known e.g. seasonal variations in the quality of water supplied to the WD and the operational history of the water treatment equipment.

The disinfection method shall not cause any damage to, nor impair the efficacy of, the treatment equipment.

Means shall be provided to disinfect incoming water used for the final rinse. The disinfection process shall ensure that there are fewer than 10 cfu per 100 ml sample of final rinse water and shall be free from *legionella, pseudomonas aeruginosa and mycobacteria* when tested by the method given in Annex A.

Test method and performance requirement

a) if the water treatment equipment is part of the EWD, its disinfection may be carried out during the self-disinfection process (see 6 and 16).

b) If the water treatment equipment is not part of the EWD, the EWD manufacturer should specify the requirements for water supplied to the EWD. This shall include the requirement to control the microbial contamination of the water supply.

Note: This may require the user to make provision for disinfection of the external water treatment equipment.

Requirement

The efficacy of the water equipment disinfection procedure to provide self-disinfection shall be deemed to have been established if there are less than 10 cfu recovered from each of two 100 ml samples of rinse water and other controlling parameters have been achieved.

32 Sound pressure

Purpose / objective – the EWD should be designed to provide protection against the effects of internally generated noise (the sound from alarms are excluded).

Installation instructions should specify mean and peak sound power levels generated by the WD, expressed as an A-weighted sound power level.

Test method and performance requirement

Type testing

Equipment
Sound level meter conforming to either type 1 of IEC 60651 or, if an integrated sound meter, to Type 1 of IEC 60804.
A semi-reverberant test room, with a hard reflecting floor

Measure the maximum A-weighted sound pressure at the operator's position and at bystanders' positions. The distance between any wall or other object and the surface of the equipment is not less than 3 m.
Ensure that during measurement, any part necessary for the correct operation of the equipment and supplied by the manufacturer as an integral part of the equipment for example a pump is fitted and operated as in normal use.
Ensure that the equipment is tested with the combination of load and other operating conditions (for example pressure, flow, temperature) which creates the maximum sound pressure level.

Requirement
The EWD should nor produce noise at a level which may cause a hazard (> 85 dBA above a reference sound pressure of 20μPA)
The A-weighted sound power level should be stated by the manufacturer in the installation instructions.

33 Air quality

Purpose / objective - to verify the performance of the air filter installation.

Air filters installed within the WD
The EWD may be fitted with air filters intended to ensure that air free from microbial contamination is used for drying the load.

Test method and performance requirement

Test the complete installation using the method described in ISO/DIS 14644-3. Introduce a challenge aerosol of inert particles of the type produced by a dispersed oil particle generator into the air upstream of the filter. Scan the downstream face of the filter and its housing for leakage using a photometer.

Requirement
The test shall be considered satisfactory if the reading on the photometer is steady and repeatable and does not exceed 0,01 % of the upstream reading.

34 Periodic safety checks

Before starting the weekly tests, the TP(S) should undertake the following safety checks:

a. examine the door seal (s);
b. check the security and performance of the door safety device

A programme of annual safety checks should be established, as necessary for the particular installation. The original installation tests and checks may be used as the basis for the yearly safety checks, paying particular attention to those factors which affect safety and especially to those that have changed since the previous annual safety check (or installation test). The adequacy and safety of all engineering services should be verified.

ANNEX 3 Information to be supplied by the endoscope manufacturer

User information (as given in MDA DB2002(05)

a. Instructions on how to clean and, where necessary, dismantle the device**.**

Comment: The level of detail required will depend on the complexity of the endoscope/accessory.

b. The types of agents that may be used to clean, disinfect or sterilize the device.

Comment: This may not necessarily be branded named agents but an indication of the generic agents demonstrated to be compatible with the endoscope / accessory.

c. A warning of any compounds or processes which may be detrimental to the device, or any special precautions and any other contraindications eg the maximum temperature used.

d. The compatibility of the device with the conditions within any sterilization or automated disinfection system such as an AER.

Comment: This should include pressure and vacuum, as may be experienced during the decontamination process.

e. Any ancillary equipment required to be able to process the endoscope.

Comment: This may include adapters/connectors for use with AERs or for sterilization.

f. . If the device can be sterilized by a physical method eg using steam under pressure (autoclaving), the method of sterilization should be indicated.

Comment: This should include all process variables such as temperature and time of exposure, taking into account the availability of the recommended process to the user.

ANNEX 4 Information to be supplied prior to purchasing an EWD

A4.1 Information to be supplied by the Manufacturer of the EWD

abstracted from:-

EN ISO 15883 Washer-Disinfectors – Part 1: General Requirements, definitions and tests (Draft 2004) Clause 8. Information to be supplied by the manufacturer

and

prEN ISO 15883-4 Washer-Disinfectors Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermo-labile endoscopes (second prEN 2004)

A.4.1.1. General

The manufacturer of the WD shall provide the following information:

j) Any pre-treatment of the item to be processed in the WD which may be necessary to achieve the required performance standard shall be stated by the manufacturer.

k)

Note: The nature of the item to be processed can require additional actions such as dismantling for separate processing, the pre-cleaning of difficult surfaces (inaccessible sites) by a manual process etc. prior to the item being processed by the EWD. Such pre-cleaning can be necessary to reduce the initial bioburden and/or contamination.

l)

m) For each operating cycle that can be used the following parameters shall be described by the manufacturer:

n)

- the specific purpose for which the WD is intended, including any restrictions;
- the type of products which the process is designed to clean/disinfect, this information shall be based on validation studies on specific products and/or product families;
- the process chemicals;
- the values of the cycle variables of the processes e.g. time, temperature, amount of water, amount of process chemicals, disinfecting time/temperature;
- the maximum rate of change of process variables e.g. pressure, temperature (see 4.1.4).

1)

o) The conditions necessary to meet the performance requirements for each stage of the process and for each operating cycle shall be stated by the manufacturer.

p)

q) For WDs in serial production the manufacturer shall state the standard service time required to carry out all routine maintenance tasks and the intervals at which these shall be carried out.

A.4.1.2 Before delivery of the WD and for installation

In order to enable the purchaser to prepare for installation, and then correctly to install and operate the WD and to perform routine maintenance and testing (see also 15883-1 clause 10), before delivery of the WD and for installation, the WD manufacturer shall provide the purchaser with the following information:

a) installation instructions, including the overall dimensions and overall mass of the EWD,

b) the floor loading at each support when the WD is filled with water,

c) the clearance required for access and the masses of the principal heavy components;

d) details of the services required (i.e. steam, water, gases, electricity, compressed air, drainage and ventilation), including the maximum demand and the minimum and maximum values for the correct functioning of the EWD.

This shall include for each validated process, for each water connection:

- the volume of water used per cycle and for each process stage, with tolerances;
- the maximum flow of water and condensed steam to the drain;
- and the maximum temperature of effluent that may be discharged from the machine during normal operation and in a single fault condition;
- the maximum hardness value, the range of pH and the conductivity of the water.

r) e) the maximum total heat in watts transmitted to the surrounding air when the WD is operated in an ambient temperature of (23 ± 2) °C in still air;
s)
t) f) the maximum heat in watts transmitted from the fascia when the WD is operated in an ambient temperature of (23 ± 2) °C in the working area;
u)
v) g) the mean and peak sound power levels generated by the WD, expressed as an A-weighted sound power level (see IEC 61010-2-45);
w)
x) h) the type of doors and information on the necessary space required for the movement of the door(s);
y)
z) i) suitable process chemicals for each stage of the process where these are required;
aa)
bb) j) details of any supplied materials or necessary materials (detergents, chemical disinfectants etc.) which are to be used for the correct functioning of the WD and which are subject to control under national guidelines for the safe handling of chemicals or have environmental limits set. The chemical constituents (active ingredients) shall be listed and any national guidance on exposure limits [e.g. the Time Weighted Average (TWA) and 10 min Short-Term Exposure Levels (STEL)] shall be provided;
cc)
dd) k) details of the independent body where complete programme and 'software' are lodged, when this is required by the purchaser (see 15883-1, 5.21);
ee)
ff) l) the maximum deviation from a plane horizontal surface that can be accommodated (see 5.1.4);

A.4.1.3 Delivery of the WD

At delivery of the WD, the manufacturer shall provide the purchaser with at least the following information:

a) operating instructions, short form of manual;

NOTE 1 An abridged version of the manual should be available in waterproof material

b) user instructions with at least:

- range of application;
- type of load;
- load configuration;
- correct loading procedure;
- total chamber volume;
- design pressure, allowable working pressure and allowable temperature;
- description of the available operating (cleaning and disinfection) cycles;
- description of controls and indicating devices;
- description and setting of safety devices;
- instructions for malfunctions;
- instructions for purging and disinfecting the WD;
- instructions for cleaning the panelling;
- instructions for checking that spray nozzles are not blocked;
- instructions for checking that spray arms are free to move;
- instructions for checking the flow through nozzles for irrigation of hollow instruments;

c) dimensions of the usable space of the chamber;

gg) d). loading capacity;

hh)

e) a description of the WD operating cycle or cycles;

Note: This should include a diagram showing the sequence of operation of all components and the process variable used to control each stage e.g. time, attainment of temperature, together with details of the maximum operating temperature and time for each stage.

a) information on process security details (e.g. door interlocking mechanism);

ii)

b) maintenance manual:

Note: This should include:

- maintenance tests and the frequency they should be carried out;
- electrical diagrams and circuits;
- hydraulic plans and circuits;
- the dead volume of pipework;
- the recommended method of cleaning all injection lines and valves;
- actions required to produce test conditions specified in clause 6

- a complete spare parts list;
- a list of the special tools necessary for maintaining and testing;
- type of guarantee offered;
- list of service stations;

h) guidance on tracing and rectifying causes of malfunction.

i) documented evidence of compliance with this standard;
jj)
kk) j) the facsimile of the marking on the vessel (see Clause 9).
ll)
mm)

Part 4: Clause 8. Information to be supplied by the manufacturer

In addition to the information specified in prEN ISO 15883-1:2004, clause 8 the WD manufacturer shall provide the following information:

a) the devices and/or device families for which the WD manufacturer has evidence that they can be processed satisfactorily and any precautions necessary for particular devices or operational conditions;

b) the maximum flow and pressure of fluids which may be delivered to each channel during processing in the WD;

c) the maximum permissible restriction of flow through each channel before the automatic controller will indicate a fault;

nn) d) the maximum temperature of any process fluid which may be in contact with the device during processing in the WD and which may cause degradation of the device;
oo)
pp) e) the maximum temperature variation permissible during the automatic leak test (if fitted);
qq)
rr) f) details of which parts of the WD are subjected to disinfection during the self-disinfection cycle;
ss)
tt) g) guidance on the frequency at which any water treatment equipment that is part of the WD should be disinfected;
uu)
vv) h) diagram of the circulation of fluids in the WD used to irrigate channels in the device;
ww)
xx) i) instructions for use including:
- yy) - the recommendation to use thermal disinfection for heat stable devices and accessories;
- zz) - guidance on the need for drying devices which are to be stored before use;
- aaa) - means to verify the flow of process fluids through each channel (see 5.2.1.1)
- bbb) - the method and frequency for disinfection of the connection between the WD and the water;
- ccc) - supply for post-disinfection rinse water;
- ddd) - the method to be used for collecting samples of final rinse water from the chamber;

eee)

fff) j) maintenance instructions, including the planned preventive maintenance required on the piping used to convey post-disinfection rinse water to the endoscope and the frequency at which such tubing should be replaced;

ggg)

k) the detergent(s) and disinfectant(s) to be used with the WD (as established during type testing).

hhh)

iii) l) If the water treatment equipment is not part of the WD, the requirements for water supplied to the WD including the requirement to control the microbial contamination of the water supply.

jjj)

A4.2 Information to be requested from the purchaser by the supplier of the WD

abstracted from:-

EN ISO 15883 Washer-Disinfectors – Part 1: General Requirements, definitions and tests
(draft 2004) Part 1 Clause 8. Information to be supplied by the manufacturer
and
prEN ISO 15883-4 Washer-Disinfectors Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermo-labile endoscopes (2nd prEN 2004)

In order to ensure that equipment supplied will meet the purchasers requirements it is recommended that the following information should be requested from the purchaser:

NOTE Regional or national regulations may address these requirements also.

kkk) a) any statutory or other regulations, in particular, local water regulations, to which the WD is required to conform, other than those stated in the foreword to this standard;

lll) b) the name of each regulatory Authority responsible for formulating the regulations referred to in item a);
mmm)

nnn) c) the type of goods to be disinfected, the maximum acceptable processing temperature for thermolabile products, any particular requirements for water quality (e.g. freedom from bacterial endotoxins) and the class(es) of chemicals which can be used with the devices;
ooo)

d) the maximum capacity per operating cycle for each load type that can be processed
ppp)

qqq) e) the required type and size (internal dimensions) of WD;
rrr)

sss) f) whether inspection of pressure vessels is to be carried out by the manufacturer only and not by the Inspecting Authority;
ttt)

g) the required location of any emergency stop buttons or switches;

h) the type of recorder(s) to be fitted, if any;

i) the environmental temperatures to be expected for the working area and for the maintenance area;

j) the load supporting and handling equipment required;

uuu) k) details of the operating cycle(s) required that do not correspond to any of the operating cycles specified in subsequent parts of this standard, as relevant;
vvv)

www) l) the language for documentation;
xxx)

yyy) m) location, including any restriction in the overall size of the machine that can be installed or any
zzz) restriction on access for maintenance;
aaaa)

bbbb) n). electrical terminals required for dosing systems;

o). location of loading and unloading doors;

p). ductwork to be supplied;

cccc) q). services available;
dddd)

eeee) r). the number of dosing systems required and the number of additional dosing systems for which provision should be made to allow for their later addition;
ffff)

gggg) s). the quality of the water supplied;
hhhh)

t). the test method(s) and soil(s) to be used for operational qualification of cleaning efficacy;

u). whether software security provision is required.

Part 4 Clause 10. Information to be requested from the purchaser by the manufacturer

The requirements of prEN ISO 15883-1:2004, clause 10 apply.
In addition, the following information shall be requested from the user:

a) the means that shall be provided to ensure that connection is made to the correct container of process chemical see

b) list of all types of endoscopes and devices that the user intends to process in the WD

Annex 5 Process Chemicals

The efficacy of process chemicals used in endoscope decontamination is determined by various attributes that form a dynamic interaction with the microbe, the endoscope, the water and the reprocessing equipment. This Annex summarises the properties of cleaning agents and chemical disinfectants, including their limitations and the rationale for selection.

Properties of cleaning agents

Detergents are formulations containing surfactants and subsidiary constituents (builders, sequestering agents, fillers etc). Surfactants act by reducing the surface tension of water and are classified as anionic, cationic or non-ionic in nature. Anionic surfactants include soaps (carboxylates) which are traditionally made from fats and oils combined with a mineral alkali - such as sodium or potassium hydroxide. The cleaning efficacy of soaps compares less favourably with more modern synthetic detergents and is reduced in the presence of hard water, the soap reacting with mineral salts to form an insoluble precipitate (film or scum) that does not rinse away easily. Soap solutions should not be used for cleaning endoscopes or other medical devices.

Cleaning using detergents is a complex interaction of a number of functions. The surface to be cleaned and the soil to be removed must initially be wetted and the soils solubilised, resuspended or dispersed such that it will not re-deposit on the surface but is rinsed away. Alkalinity improves the efficacy of detergents both by enhancing their inherent cleaning capabilities – neutralising and helping to remove acid soils, emulsifying oils and fats and peptidising proteins – and by synergistic action with other detergent compounds. Mildly alkaline or neutral detergents provide a reasonable balance between cleaning efficacy and compatibility with the materials used in the endoscope and reprocessing equipment.

The soiling on medical devices is mainly, but not exclusively, proteinaceous. The development of enzymatic cleaners / detergents with specific action against protein (proteases) in particular, but also lipids (lipases) and carbohydrates (amylases) has provided a range of products of particular application for manual and automated cleaning of endoscopes. Coagulation of proteins traps particulate material on surfaces. The enzymatic action of proteases breaks down the binder protein, enabling the soil to be dispersed with the action of the associated detergent. Enzymatic detergents are active over a limited range of pH and temperature, depending on the nature of the particular enzyme.

Cleaning agents for use in EWDs should be:

- liquid – to facilitate accurate dispensing;
- non-abrasive;
- low foaming;
- free rinsing;
- biodegradable.

Cleaning agents should not contain:

- artificial colouring agents;
- optical brighteners;
- perfumes;
- halides at an in-use concentration greater than 120mg/l;
- fatty soaps, glycerine or lanolin.

Properties of chemical disinfectants

Disinfectants are characterised by the specific 'active' chemical in the formulation that is responsible for the lethal effect on the microorganism. The objective of their use is to ensure that the number and range of contaminating microbes are reduced to a level which presents no harm to the patient on whom the reprocessed endoscope and accessories are to be used. A limited number of disinfectants possess the required level of lethality across the antimicrobial spectrum, under the conditions required for endoscope disinfection. In addition to their antimicrobial properties, disinfectants exhibit a range of other important properties, which are summarised as examples for some formulations in current use (Tables A1 - A5).

Manual disinfection of endoscopes is no longer recommended, with the development of automated, validated processes. Responsibility lies with the EWD manufacturer to design and manufacture the machine to meet the optimum performance requirements for the chosen disinfectant/s, in collaboration with the disinfectant and endoscope manufacturers. The user needs to be provided with detailed type test data for at least two disinfectant formulations (and a third option with a different 'active' if a chemical self-disinfection cycle is required) for a range of microbes to demonstrate the basis for the critical disinfection cycle parameters of time, concentration, volume, temperature etc.

Instructions for use supplied with the disinfectant should include:

- the quality of water with which the product should be diluted (whether manually or by an automated process);
- the storage life – the life before dilution or activation (or before use if supplied at the required concentration for use);
- the use-life – the storage life after dilution and storage under stated conditions within which the unused disinfectant will retain activity at, or above, the minimum specified by the manufacturer;
- the use concentration and information about how the 'active' may be measured (directly or indirectly) or monitored in use;
- the required volume and temperature of the disinfectant solution (including tolerances);
- conditions of storage of bulk chemical prior to use
- the re-use life – the extent to which the disinfectant may be re-used, specified as time, the number of load items processed or the number of disinfection cycles.

Note: it is recommended that the disinfectant is used once and discarded.

Factors affecting the choice of Process Chemical

The choice of specific chemicals for manual pre-cleaning, automated cleaning and disinfection is based on many factors:

1. EFFICACY

- compatibility with – medical device;
- compatibility with – reprocessing equipment;
- compatibility with – water quality;
- compatibility with - further processing (eg sterilization, if required);
- the nature of the 'active'
- spectrum of microbicidal activity;
- interaction with soiling
- interaction with residual detergent;
- process control
  - stability;
  - spectrum of activity;
  - monitoring of concentration of active;
  - temperature dependence;
  - contact time;
- biocompatibility of residues

2. PERSONNEL

- known toxicity
- known sensitisation / Occupational exposure limits (OEL)
- volatile nature
- indication of known hazards (toxic, harmful by inhalation, ingestion or skin absorption, irritant, dangerous to the environment, corrosive, explosive, flammable).

3. ENVIRONMENT

- biodegradable / persistence
- discharge to sewer

4. ECONOMICS

- single / multi-use
- life/stability/monitoring
- unit cost
- facilitating costs eg machine modifications required

Compatibility

Compatibility with the endoscope

The chemical additives used must be compatible with the materials of which the endoscopes are constructed and should not cause chemical or physical damage – eg phenolic compounds used in some detergents and disinfectants may cause material changes in rubber and plastics, while prolonged contact with alcohol may weaken the cement around lenses. Some oxidising disinfectants are incompatible with the polymer coatings of some models of endoscopes, for example earlier formulations of Sterilox denatured the outer coating of the endoscope which left a sticky surface and adversely affected the functional use of the endoscope. The manufacturers of Sterilox now supply the Scope Protection System, which the user applies periodically to the insertion and light guide tubes of certain endoscopes to minimise potential damage. For Olympus endoscopes, there is evidence that even when employing this system, the life of the insertion tube is reduced. Changes of a more cosmetic nature are found with some peracetic acid and chlorine dioxide formulations. Users are asked to regularly inspect the reprocessed endoscope and record any deterioration which may be attributed to the incompatible agent and would otherwise affect the endoscope manufacturer's warranty. Information about compatibility is available from endoscope manufacturers, for example both Pentax and Olympus list a number of aldehyde-based products including *ortho*-phthalaldehyde (Cidex-OPA) and glutaraledhyde formulations as compatible with their products. Further collaboration between disinfectant manufacturers and endoscope manifacturers may lead to the development of more resistant coatings compatible with the more aggressive / corrosive chemicals.

Compatibility with the materials of construction of the washer-disinfector

The pH, redox potential and ionic nature of the chemical additive is important in determining whether it will cause corrosion or electrolytic attack (either between different materials in the WD or between the WD and items in the load). Chemical additives which can be absorbed into, or adsorbed onto, surfaces of the EWD, such as plastic pipework, may be carried over into subsequent stages of the process. The materials used in EWDs intended to use oxidising disinfectants will require careful choice to avoid problems with corrosion, affecting not only the EWD chambers but also the materials of construction for the disinfectant reservoir and pipework.

Compatibility with the process

The performance of the additive must be matched to the physical characteristics of the operating cycle, eg jet washing action systems require low foam detergents, if the washing action is not to be impaired. The chemical additives used must be readily removed from the load items by rinsing with water and should be biologically compatible with the intended use of the load items.

Compatibility with the quality of water

Many detergents and disinfectants are seriously impaired in their activity by hard water. If the mains water supply provided locally is of hard water quality, then consideration should be given to water treatment for both the process and, essentially, for the final rinse water.

Compatibility with other chemical additives

Many of the chemical additives which might be used are incompatible with one another – eg quaternary ammonium compounds which are often used as surfactants will rapidly destroy the activity of enzymatic cleaners, while many detergents will inactivate chemical disinfectants. The additives used should be both compatible with other chemicals used in the same process stage and, as far as may be practicable, with those used in preceding and subsequent stages to minimise the adverse effect of any carryover.

Microbial activity

Quantitative test data on the antimicrobial activity of chemical disinfectants, including combined detergent/disinfectant formulations is needed in making an informed choice of product. The spectrum required may be broad (bactericidal, virucidal, fungicidal, some sporicidal) but is likely also to focus on particular target organisms for which their survival presents higher risks in different clinical specialities and for different patient groups. In the first instance, screening of a large number of microbes can be undertaken by simple quantitative suspension or surface tests. The development of harmonised standardised tests within CEN to meet the essential requirement for liquid chemical disinfectants intended to process medical device, under the MDD, is likely to provide useful comparative data. The choice of test organisms, the extent of the challenge and the nature of the soiling need to be specific for the medical field and it would be useful to see data generated from the more recent methods designed for endoscope disinfectants. Prior to this, some disinfectant manufacturers have made use of methods such as BS EN 1276 (1997) 'Chemical disinfectants and antiseptics. Quantitative suspension tests for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas. Test method and requirement'. Data on the effect of particular test soils simulating both clean and dirty conditions gives useful indication of the degree of inactivation under 'worst case' cleaning conditions.

Some microbes will be intrinsically more resistant to certain disinfectants, and a judgement needs to be made as to the implications of this in practice. There have also been isolated reports of the emergence of glutaraldehyde and peracetic acid resistant *Mycobacterium chelonae.*

Evidence of the efficacy of the disinfectant's performance is required by direct testing in the EWD, prior to routine clinical use. A range of organisms should have been tested under defined conditions (concentration, water quality, temperature, volume etc) by the EWD manufacturer and reported prior to installation. The user may choose to repeat some of these challenges during performance qualification on the users' site and also include other microbes that are pertinent to meet local circumstances. It is important that data on the precise formulation to be used is available - the 'active' may be affected by different adjuvants in different formulations.

Formal approval schemes for disinfectants used in EWDs do not exist in the UK, but are available in a number of other countries. One of the most developed schemes is the FDA's 510K approval scheme in the USA. Data published on their website (www.fda.gov/cdrh/ode/germlab.html) has been included in Tables A1-A5.

Process controls

In almost all cases, attainment of the specified concentration of chemical additives is essential to provide effective processing. The addition of too little will impair the process while too much is wasteful, may also impair the process and may contribute to unacceptably high residual levels. It is also important that the required concentration can be accurately and reproducibly delivered, by manual dosing or automatically generated by the dosing system(s) on the EWD. Suppliers of process chemicals should provide product data sheets and material safety data sheets for the products supplied. These should include details of biocompatibility studies.

Biocompatibility of process chemicals

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

Safety considerations

The mechanism of action of a chemical disinfectant is rarely, if ever, specific to a target found only in microbial cells. It is not therefore surprising that chemical disinfectants have a range of effects on human tissue. The use of all disinfectants should be subject to COSHH assessment and procedures established to include the precautions necessary to prevent or minimise exposure.

Major concerns about the problems associated with the use of glutaraldehyde in endoscope disinfection has had a significant impact. Release of the vapour from unsealed automated disinfectors of very simple design compared to their continental counterparts, during use of open troughs or at the time of mixing/activating the chemicals for use may have contributed to health problems such as occupational asthma, rhinitis and conjunctivitis. Improvements in practices, including the banning of open containers of glutaraldehyde (DB 2002 (05)) and the design of EWDs to meet the safety standards of BS EN 61010-2-045, may have led to improvements. Prior to the withdrawal of glutaraldehyde from supply in the UK, the HSE had set a Maximum Exposure Limit (MEL) of 0.05 ppm over an 8-hour Time Weighted Average (TWA). It should be noted, however, that other disinfectant formulations are also subject to occupational exposure limits, for example chlorine dioxide has a short term exposure limit of 0.03 ppm and an 8 hr TWA of 0.01 ppm.

The need to manually dispense and mix chemical disinfectants should continue to diminish with the development of single-shot or automatically activated and dispensed systems. Much can also be achieved for health and safety at work by appropriate training and design of facilities. Other process chemicals may also have significant occupational safety implications, for example the use of enzymatic cleaners containing proteins (often derived from the bacteria *Bacillus subtilis* and *Geobacillus stearothermophilus*) and may be sensitising or allergenic agents, eliciting a similar adverse reaction experienced by some users of domestic biological washing powders.

Employers are required by law to do everything that is reasonably practicable to protect the health of their workers. In seeking alternatives to glutaraldehyde that exhibit fewer problems for occupational health, there should also be an awareness of the essential requirement for disinfectant efficacy of a quality that protects the health of the patient. The search for an 'ideal effective, safe and compatible' alternative continues.

Table A5.1

Chlorine Dioxide	eg *Tristel One-shot* (other formulations include *Medicide*)
Active ingredient in formulation	Chlorine dioxide as a 0.0225% (w/v) aqueous solution, generated as single-use solution on-site from activator (3.7% sodium chlorite solution in de-mineralised water), base (4.0% solution of citric acid with preservatives and corrosion inhibitors in de-mineralised water) and water.
Mode of action	Oxidizing agent, acting on proteins, lipoproteins and nucleic acids. Inhibits enzymes, blocks the metabolism of glutamic acid.
Microbiological efficacy	Bactericidal, virucidal, sporicidal. More active than chlorine-releasing agents against *Giardia* cysts and *Cryptosporidium* oocysts. No activity against prions.
Inactivation	Less inactivated by organic load than are other chlorine releasing agents such as super-oxidised water (eg *Sterilox).*
Stability	Solutions are highly unstable and the concentration of chlorine dioxide rapidly diminishes during the disinfection process.
Safety considerations	Some problems as a respiratory irritant. The use of on-site generation systems for single-shot use at the EWD have aleviated some of the problems of storage for chlorine dioxide since the compressed gas is explosive.
Materials compatibility	Chlorine dioxide is highly corrosive for metals.
Practical limitations	Instability and corrosion. Space required for generation on site, using equipment external to the EWD.
Rationale for choice	Broad spectrum action, non-fixative, relatively active in the presence of residual soil, compatible with validated EWDs eg Wassenburg
FDA- 510K Cleared Sterilant (Nov 2003)	Not listed as approved
FDA- 510K Cleared High level disinfectant (Nov 2003)	Not listed as approved

Table A5.2

Glutaraldehyde	eg *Cidex* (now withdrawn from UK market). A range of glutaraldehyde based products are in current use elsewhere in Europe and the USA eg *Rapicide*
Active ingredient in formulation	glutaraldehyde, at a range of concentrations. Activity enhanced at raised temperature eg 35ºC
Mode of action	Alkylating agent, highly chemically reactive, combining with –NH2, -COOH and –SH groups (proteins, nucleic acids, lipids, cell wall polysaccharides etc).
Microbiological efficacy	Broad-spectrum microbicidal activity, highly active against bacteria, viruses, fungi and their spores. Mycobacteria and bacterial spores are more resistant and require extended contact time (several hours for sporicidal activity). No activity against prions. Some reports of acquired resistance (*Mycobacterium chelonae).*
Inactivation	Limited inactivation by organic soil including proteins, in practice.
Stability	Remains stable over extended periods (14 - 28 days after activation), depending on formulation.
Safety considerations	Sensitising, irritant to eyes, skin and respiratory mucosa.
Materials compatibility	Good compatibility with metals, rubber and lenses.
Practical limitations	Protein fixative, requiring thorough pre-cleaning, relatively slow-acting, not readily available in UK market, strongly linked by HSE to occupational asthma problems in workplace.
Rationale for choice	Non-corrosive, compatible with endoscopes and EWDs, broad spectrum activity, extensive experience of use in endoscopy.
FDA- 510K Cleared Sterilant (Nov 2003)	*Rapicide*™ (2.5% glutaraldehyde) - indication for device sterilant. Contact conditions establised by simulated use testing with endoscopes and additional information.
FDA- 510K Cleared High level disinfectant (Nov 2003)	*Rapicide*™ (2.5% glutaraldehyde) - high level disinfectant contact conditions in Automated Endoscoep Reprocessor 5.0 min at 35C. (for processing in an AER only with FDA-cleared capability to maintain solution at 35ºC).

Table A5.3

***Ortho*-phthalaldehyde**	eg CIDEX ® OPA (J&J)
Active ingredient in formulation	0.55 % ortho-phthalaldehyde
Mode of action	Alkylating agent, highly chemically reactive, combining with –NH2, -COOH and –SH groups (proteins, nucleic acids, lipids, cell wall polysaccharides etc).
Microbiological efficacy	Broad-spectrum microbicidal activity, highly active against bacteria, viruses, fungi and their spores. Has good mycobactericidal activity but less active against bacterial spores. No activity against prions.
Inactivation	Binds readily to protein – the active is the same chemical used in the detection of protein contamination by the OPA method.
Stability	Use directly from bottle – no activator required
Safety considerations	Ortho-phthalaldehyde has a lower vapour pressure than other aldehydes such as glutaraldehyde, and does not require the same control of ventilation and monitoring of vapour levels. Skin and gastro-intestinal tract irritation. HSE's Working Group for the assessment of toxic chemicals (WATCH) concluded that OPA may have the potential to cause occupational asthma, based on knowledge of asthmagenic properties of other dialdehyde molecules and its high protein reactivity. ASP Cidex® OPA has been linked to anaphylactic reactions in some patients with a history of bladder cancer undergoing repeated cystoscopy procedures. Precautions and advice are outlined in SAN(SC)04/31.
Materials compatibility	Compatible with metals, plastics, elastomers, adhesives, dental materials. However, the product stains proteins on surfaces to grey-black.
Practical limitations	Protein fixative. If the product to be disinfected is not scrupulously clean, residual proteins will be stained grey-black.
Rationale for choice	As a rapid and safer alternative to glutaraldehyde.
FDA- 510K Cleared Sterilant (Nov 2003)	No indication for device sterilization Passes the AOAC Sporicidal Activity test in 32 hrs at 20ºC and 25ºC
FDA- 510K Cleared High level disinfectant (Nov 2003)	Automated Endoscope Reprocessors - 5 min at 25ºC (for processing in an AER with FDA-cleared capability to maintain solution temperature at 25ºC). Contact conditions established by simulated use testing with endoscopes.

Table A5.4

Peracetic acid	eg *Aperlan* (Lancer) (other formulations include Steris 20™sterilant containing 0.2% peracetic acid, used in the Steris System 1™)
Active ingredient in formulation	mixture of peracetic acid (PAA), hydrogen peroxide in chemical equilibrium with acetic acid.
Mode of action	rapid oxidising agent acting on both the cell wall and cytoplasmic contents, disrupting enzyme systems leading to microbial death.
Microbiological efficacy	Rapidly cidal against bacteria including mycobacteria, fungi and bacterial spores. Not active against prions**.** **Peracetic acid (and glutaraldehyde) resistant Mycobacterim chelonae have been reported.**
Inactivation	remains active in the presence of organic matter including protein, although its microbial efficacy and use life diminishes.
Stability	highly unstable, decomposing to acetic acid (producing a smell of vinegar in some formulations), oxygen and other degradation produces including hydrogen peroxide. If diluted to use concentration, activity is rapidly lost and the solution should be discarded on a single-use basis. It also loses activity rapidly on heating above 30°C. Difficult to measure airborne concentrations of PAA and set threshold limits for occupational exposure (HSE) because always exists in equilibrium with hydrogen peroxide and acetic acid.
Safety considerations	lachrymatory, an irritant and a vesicant (causing blistering) on prolonged contact. Care needs to be taken to avoid exposure to concentrated solutions (5% and greater) – also storage conditions must be controlled as the containers may leak or explode due to the evolution of gaseous decomposition products.
Materials compatibility	highly corrosive and incompatible with brass, copper, plain steel and galvanized iron. The inclusion of effective anti-corrosion inhibitors is necessary for any formulation that is intended to be used on medical devices including endoscopes.
Practical limitations	Unstable - PAA concentrations should be checked using test kits designed to detect minimal effective concentration. Requires careful formulation to minimise corrosive effects
Rationale for choice	Non-fixative, non-aldehyde with no evidence of any link to asthma in occupational use, broad-spectrum, rapid acting.
FDA- 510K Cleared Sterilant (Nov 2003)	*Steris* 20™ cleared for use with the *Steris System* 1 reprocessor only for device sterilization in 12 min at 50 - 60C.
FDA- 510K Cleared High level disinfectant (Nov 2003)	*Peract*™ 20 (1.0% hydrogen peroxide and 0.08% peracetic acid) cleared for high level disinfectant contact conditions in 25 min at 20ºC.

Table A5.5

Super-oxidised water	eg Sterilox (other formulations include Suprox from Medipure)
Active ingredient in formulation	Hypochlorite at 180 - 220 ppm available free chlorine, pH 5.75 to 6.75
Mode of action	Highly reactive oxidising agent acting on enzyme proteins (particularly thiol groups) and cell envelope proteins.
Microbiological efficacy	Broad spectrum activity in clean conditions. No evidence of activity against prions.
Inactivation	Readily inactivated by contamination such as protein. Minimised by meticulous pre-cleaning and automated cleaning in the EWD.
Stability	Highly unstable. Required to be generated on a daily basis.
Safety considerations	Generally regarded as having minimal safety implications, other than those related to the release of chlorine.
Materials compatibility	Incompatible with some endoscopes, shortens useful life. A periodic treatment system (the Scope Protection System), applied by the user, is recommended to minimise adverse effects.
Practical limitations	Poor compatibility with endoscopes and EWDs, readily inactivated by organic soil, requires scrupulous attention to cleaning, limited choice of compatible EWDs meeting the required validated standard, unstable. Requires space for generation of disinfectant external to EWD on site, some limitations of microbial efficacy at a concentration chosen to reduce damage to endoscopes, requires use of the Scope Protection System.
Rationale for choice	Non- fixative, non-sensitising, broad spectrum
FDA- 510K Cleared Sterilant (Nov 2003)	No indication for device sterilization. A more concentrated formulation (650 - 675 ppm available Cl_2) passed the modified AOAC sporicidal activity test in 24 hrs at 25C.
FDA- 510K Cleared High level disinfectant (Nov 2003)	The more concentrated formulation (not available in the UK) passed the high level disinfectant contact conditions at 10 min at 25ºC. (Note: Sterilox at the lower concentration available in the UK is not approved as a high level disinfectant in the USA. While use of the higher concentration may enhance antimicrobial efficacy, it would be likely to have more adverse effects on the endoscope and some EWDs).