



Department  
of Health

# Health Technical Memorandum 01-06: Decontamination of flexible endoscopes

Part C: Operational management

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# Preface

## Introduction

This HTM supersedes the Choice Framework for local Policy and Procedures (CFPP) series, which was a pilot initiative by the Department of Health.

The CFPP series of documents are reverting to the Health Technical Memorandum title format. This will realign them with HTM 00 – ‘Policies and principles of healthcare engineering’ and ‘HTM 01-05: Decontamination in primary care dental practices’ and the naming convention used for other healthcare estates and facilities related technical guidance documents within England. It will also help to address the recommendation to align decontamination guidance across the four nations.

In 01-01 and 01-06 DH will be retaining the Essential Quality Requirements and Best Practice format, this maintains their alignment with HTM 01-05 and the requirement of ‘The Health and Social Care Act 2008: Code of Practice on the prevention and control of infections and related guidance’ which requires that “decontamination policy should demonstrate that it complies with guidance establishing essential quality requirements and a plan is in place for progression to best practice”. We are aware that policy within the devolved nations differs on this particular issue but the aim is that the technical content should be consistent and able to be adopted by the devolved nations so that the requirements of the ACDP-TSE Subgroup’s amended guidance can be met.

The purpose of HTM is to help health organisations to develop policies regarding the management, use and decontamination of reusable medical devices at controlled costs using risk control.

This HTM is designed to reflect the need to continuously improve outcomes in terms of:

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

## Essential Quality Requirements and Best Practice

The Health Act Code of Practice recommends that healthcare organisations comply with guidance establishing Essential Quality Requirements and demonstrate that a plan is in place for progression to Best Practice.

Essential Quality Requirements (EQR), for the purposes of this best practice guidance, is a term that encompasses all existing statutory and regulatory requirements. EQRs incorporate requirements of the current Medical Devices Directive and Approved Codes of Practice as well as relevant applicable Standards. They will help to demonstrate that an acute provider operates safely with respect to its decontamination services.

Local policy should define how a provider achieves risk control and what plan is in place to work towards Best Practice.

Best Practice is additional to EQR. Best Practice as defined in this guidance covers non-mandatory policies and procedures that aim to further minimise risks to patients; deliver better patient outcomes; promote and encourage innovation and choice; and achieve cost efficiencies.

Best Practice should be considered when developing local policies and procedures based on the risk of surgical procedures and available evidence. Best Practice encompasses guidance on the whole of the decontamination cycle, including, for example, improved instrument management, where there is evidence that these procedures will contribute to improved clinical outcomes.

The HTM 01 suite is listed below.

- HTM 01-01: Management and decontamination of surgical instruments (medical devices) used in acute care
- HTM 01-04: Decontamination of linen for health and social care
- HTM 01-05: Decontamination in primary care dental practices [check title]
- HTM 01-06: Decontamination of flexible endoscopes.

### **Note**

This guidance remains a work in progress which will be updated as additional evidence becomes available; each iteration of the guidance is designed to help to incrementally reduce the risk of cross-infection.

# Abbreviations

**ACDP:** Advisory Committee on Dangerous Pathogens

**ACDP-TSE [Subgroup]:** Advisory Committee on Dangerous Pathogens – Transmissible Spongiform Encephalopathies [Subgroup]

**AE(D):** Authorising Engineer (Decontamination)

**BS:** British Standard

**CJD:** Creutzfeldt-Jakob disease

**CQC:** Care Quality Commission

**DH:** Department of Health

**DIPC:** Director of Infection Prevention and Control

**EN:** European norm

**EWD:** endoscope washer-disinfector

**HCAI:** healthcare-associated infections

**HCAI Code of Practice:** DH's 'Health and Social Care Act 2008: Code of Practice for the NHS on the prevention and control of healthcare associated infections and related guidance'

**ISO:** International Standards Organisation

**MHRA:** Medicines and Healthcare products Regulatory Agency

**sCJD:** sporadic Creutzfeldt-Jakob disease

**TSEs:** transmissible spongiform encephalopathies

**vCJD:** variant Creutzfeldt-Jakob disease

# Executive summary

Health Technical Memorandum (HTM) 01-06 provides best practice guidance on the management and decontamination of flexible endoscopes (principally gastrointestinal scopes and bronchoscopes). In addition, this guidance also provides advice on the management and handling of an endoscope following use on a patient at increased risk of vCJD.

This document covers flexible endoscope management and decontamination only. Clinical issues relating to endoscopy or the manufacture of EWDs are not discussed. In addition this document does not cover the processing of flexible endoscopes used to examine sterile body tissues. These endoscopes should be sterile, possibly using low temperature gas sterilization (for compatible processes, see HTM 01-01 Part E).

HTM 01-06 is divided into five parts:

- Part A 'Policy and management' sets the Department of Health's (DH) policy context and discusses the Essential Quality Requirements and Best Practice recommendations for an endoscope decontamination service. Transmissible spongiform encephalopathy (TSE) infectious agents are discussed and guidance is given on the management and handling of an endoscope after it has been used on a patient at increased risk of vCJD.
- Part B 'Design and installation' gives guidance on the design and fitting of endoscope reprocessing units.

- Part C 'Operational management' gives guidance on operational responsibility together with advice on the procurement and operation of an endoscope washer-disinfector (EWD).
- Part D 'Validation and verification' highlights the types of tests and maintenance procedures that are needed to ensure that decontamination has been achieved.
- Part E 'Testing methods' discusses the principles and methods that are used in the tests described in this HTM and the tests detailed in BS EN ISO 15883-4.

## Why has the guidance been updated?

HTM 01-06 has been updated to take account of changes to the ACDP-TSE Subgroup's general principles of decontamination ([Annex C](#)). In relation to the decontamination of flexible endoscopes, paragraphs C5 and C20 from the Annex state:

### Paragraph C5:

For endoscopes, the bedside clean should take place immediately after the procedure has been carried out, and it is recommended that the endoscopes should be manually cleaned according to the manufacturer's recommendations and passed through an Endoscope Washer Disinfector as soon as possible after use.

### Paragraph C20:

A routine test for washer disinfectors could be developed to measure the cleaning efficacy at validation and routine testing, such as daily or weekly tests. This method could be based on a process challenge device system that will monitor the optimised wash cycles; the results must be quantifiable and objective.

Essentially, therefore, this update focuses on improving the washing and cleaning process, reducing the time from patient use to the decontamination process, and monitoring the cleaning efficacy of endoscope washer-disinfectors.

It is also important to point out that the ACDP-TSE Subgroup's Annex C deprecates the use of ninhydrin in the detection of protein levels because of its insensitivity. Alternative available technologies should be considered for the detection of residual proteins on the internal surfaces of flexible endoscopes following reprocessing. Therefore reprocessing units should:

- a. consider the available technologies and make a risk-based decision on the methodology to be adopted (for example BS EN ISO 14971);
- b. use technologies with the best available sensitivity, consistent measurement standards and quantifiable results to measure effective control of residual protein levels;
- c. use trend analysis as a tool for self-improvement to demonstrate decreasing protein levels over time both on the outside of the endoscope and the

lumens using available testing technologies.

### Note

This remains a work in progress which will be updated as additional evidence becomes available.

## List of major changes to Part C since the 2013 edition

- CFPP 01-06 has reverted to the Health Technical Memorandum title format and now becomes Health Technical Memorandum 01-06.
- New section on storage of flexible endoscopes in Chapter 3 which replaces “Choice of drying cabinets” and “Storage cabinets” sections. This aligns the guidance with the new British Standard (BS EN 16442) and with the new chapter on “controlled environment storage cabinets” in HTM 01-06 Part D – ‘Validation and verification’.
- All references updated.



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# 1 Personnel

## Summary for commissioners and quality inspectors

Training for all staff involved in the decontamination of flexible endoscopes is essential. Guidance is given on appropriate staff training and the need to keep up to date with new developments with accompanying records.

Also covered is the need for all staff involved to have clearly defined roles and responsibilities that are documented.

**1.1** This chapter introduces the personnel who share responsibility for the safe and efficient operation of endoscope washer-disinfectors (EWDs). It gives guidance on qualifications and training and summarises areas of responsibility. This section should be read in conjunction with HTM 01-01 Part A.

### Training

**1.2** It is essential that personnel at all levels should have a sound general knowledge of decontamination, including some knowledge of the basic elements of infection control, microbiology and process chemicals in order to ensure their health and safety obligations. They should be trained in the decontamination of all endoscopes they will encounter. They should be trained and have demonstrated competence on those types and models of EWD they will use as well as any other techniques required in decontamination.

**1.3** Training and competence assessment given to individuals should be recorded and reviewed at least annually as part of an annual personal development planning (PDP) review.

**1.4** Detailed training on a particular model of EWD is essential and requires that adequate and separate training should be provided by the manufacturer, either on site or by courses at their premises. The training should be undertaken without delay during and following the successful commissioning of the EWD(s).

### Operational responsibility

**1.5** There have been profound changes in the management philosophy of healthcare over recent years. With the wide range of circumstances in which an EWD may be employed, from a busy sterile services department in a major general hospital to a small clinic, it is not possible to prescribe a universally applicable management structure for decontamination.

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

individual may take on more than one role. Whatever model of operational management is chosen, it is essential that the roles and responsibilities of the individuals involved are clearly defined and documented.

**1.7** In every case, however, it should be possible to identify a User who is responsible for the day-to-day management of the EWD. The philosophy of this HTM is to invest the User with the responsibility for seeing that the EWD is operated safely and efficiently.

**1.8** There are several advantages to the employment of trained specialist staff for the decontamination of flexible endoscopes:

- their specialist skills reduce the risk of errors and cross-contamination;
- they have a specialist knowledge of health and safety issues relating to reprocessing flexible endoscopes;
- they have a specialist knowledge of the structure and operation of the endoscopes under their care;
- they have a specialist knowledge of the operation and care of the EWDs in their unit;
- they can receive training in decontamination, auditing and quality assurance, improving the standard of the endoscopy department;
- qualified nursing staff can attend to clinical duties.

**1.9** For small installations where the User is qualified to perform all daily and weekly tests and maintenance functions, other personnel may be necessary to carry out quarterly and annual tests. Alternatively, the User may oversee testing and maintenance carried out by competent third parties. However, it is strongly recommended that in all cases the User has access to professional advice from a suitably qualified Microbiologist (Decontamination), Infection Control Doctor, an Authorising Engineer (Decontamination) (AE(D)) and EWD manufacturer. Success should be achieved by

adopting a good strong team approach involving all relevant professions or disciplines, including clinical staff.

## Key personnel

**1.10** This section gives information on the key personnel who have specific responsibilities within decontamination.

**1.11** For the following roles, see 'Staffing roles and responsibilities' in HTM 01-01 Part A:

- Executive Manager;
- Decontamination Lead;
- Designated Person;
- Senior Operational Manager;
- Authorising Engineer (Decontamination) (AE(D));
- Director of Infection Prevention and Control (DIPC);
- Infection Control Doctor;
- Operator.

**1.12** For the following, see 'Responsibilities' in HTM 01-01 Part B:

- Authorised Person (Decontamination) (AP(D));
- Competent Person (Decontamination) (CP(D));
- Manufacturer;
- Contractor;
- Purchaser.

**1.13** Other key roles in endoscope decontamination are discussed in more detail below.

## Management – definition

**1.14** Management of a healthcare organisation performing endoscopy is defined as the owner, chief executive or other person of similar authority who is ultimately accountable for the

safe operation of the premises, including decontamination. Endoscopy managers should have documented training records to demonstrate that they are competent at assessing the risks involved in inadequate decontamination of medical devices. Endoscopy managers training should also include an awareness of the roles and responsibilities of key personnel in the operation and testing of decontamination equipment.

### Surgical Instrument Manager/coordinator

**1.15** The Surgical Instrument Manager has responsibility for the endoscopes at all points in the purchase, use, decontamination and decommissioning processes. Specifically, the manager will monitor record-keeping on the use of endoscopes and their decontamination. Any observed defects in condition or function of an endoscope should be drawn to the attention of the Surgical Instruments Manager.

**1.16** The above duties may be carried out by a named senior user(s). The role also includes governance provision in support of users across the institution. Audit responsibilities are applicable to this role including review of the local self-audit.

**1.17** Role of Surgical Instrument Manager:

- Keep an inventory of all surgical instruments including endoscopes.
- Oversee tracking and traceability systems in the SSD and endoscopy unit.
- Liaise with clinical and nursing staff to keep up-to-date with clinical developments.
- Oversee the purchase of new instruments within the healthcare organisation:
  - (i) Are they suitable for purpose?
  - (ii) Do they replicate similar items available within the healthcare organisation?

- (iii) Can the instruments be decontaminated within the healthcare organisation?
- (iv) Can the instruments be purchased on a contract basis?
- (v) Are the instruments competitively priced and value for money?

- Oversee the loan of instruments.
- Control local and distant instrument repairs.
- Oversee local self-audit (or carry it out)

### User

**1.18** The User is defined as the person designated by Management to have operational responsibility of the process. The User is also responsible for:

- the Operators;
- the operation of endoscopy decontamination equipment that may be used on the endoscopes under their responsibility, but not on site (for example, out-stationed drying cabinets).
- reporting issues of concern regarding endoscope instruments or their reprocessing to the Surgical Instrument Manager.
- compliance with the guidance contained in this document.

**1.19** In the acute sector, the User could be a sterile services manager, endoscopy clinic manager or theatre manager.

**1.20** The principal responsibilities of the User that should be included in their job descriptions are:

- a. to certify that the decontamination equipment is fit for use;
- b. to hold all documentation relating to the decontamination equipment, including the names of other key personnel;

- c. to ensure that decontamination equipment is subject to periodic testing and maintenance;
- d. to appoint operators where required and ensure that they are adequately trained;
- e. to maintain production records;
- f. to have documented training records demonstrating that they are competent to undertake assigned responsibilities;
- g. to establish procedures for product release in line with the quality management system;
- h. to ensure that procedures for production, quality control and safe working are documented and adhered to in the light of statutory requirements and accepted best practice.
- j. To develop a plan illustrating development from Essential Quality Requirements to

Best Practice for the decontamination unit (see HTM 01-06 Part A – ‘Policy and management’ for further guidance).

### Note

The User should seek the advice of the infection prevention and control team, which may include a DIPC, Control of Infection Doctor or Nurse, and Microbiologist (Decontamination).

### The Microbiologist (Decontamination)

**1.21** See ‘Staffing roles and responsibilities’ in HTM 01-01 Part A.

**1.22** The Microbiologist (Decontamination) should also interpret records from endoscope decontamination equipment that have relevance to microbiological methods, infection prevention and related risk management.

## 2 Choice and procurement of an EWD for flexible endoscopes

### Summary for commissioners and quality inspectors

**2.1** The purchase of an EWD suitable for reprocessing flexible endoscopes is discussed together with cycle stages necessary to produce clean, safe and disinfected instruments. The design of the decontamination area will influence the type of EWD purchased (for example, separate clean and dirty areas with an EWD between). As cleaning forms an essential part of the decontamination process, its importance is discussed. The need for staff training is highlighted together with suggestions on gathering relevant data and forming a core group of interested parties before EWDs are selected. Guidance is given on size and number of EWDs required to provide an efficient service together with possible delivery issues.

**2.2** This chapter contains information relevant to the choice of a new EWD. It discusses the different types of EWD and gives guidance on choosing the size and number of EWDs required for a given workload. If older models of EWDs are in use, their replacement may form part of the move from Essential Quality Requirements to Best Practice.

See HTM 01-06 Part A – ‘Policy and management’ for further details of Essential Quality Requirements and Best Practice.

**2.3** When purchasing an EWD, the User should seek advice from the manufacturer of

the endoscope on the most suitable method of decontamination.

#### Note

All lumens of the endoscope to be processed should be connected to an EWD outlet, as each lumen should be flushed by the process fluids.

**2.4** Dedicated EWDs are specifically intended for processing flexible endoscopes. These machines incorporate terminal chemical disinfection using a suitable low temperature liquid process.

#### Note

Any flexible endoscopes used for critical procedures requiring a sterile instrument should be sterilized separately prior to use. The use of a low temperature sterilization process is normally confined to flexible endoscopes used to examine the brain or other sterile tissue and is not covered in this HTM. A risk assessment of decontamination procedures is advised to determine the best method of processing this equipment.

### Types of EWD and cycles

**2.5** EWDs are classified into two groups:

- Single-door EWDs that are loaded and unloaded from the same side.



- Double-door (or pass-through) EWDs allow dirty flexible endoscopes to load on one side and be processed. The clean, disinfected instruments are unloaded on the other side of the unit. This type of EWD allows endoscopy decontamination to pass through a dividing wall and provide clean and dirty areas with separate entrances and air supplies.

**2.6** The cycles of an EWD are outlined in [paragraph 3.19, 'Cycle of use and decontamination of endoscopes'](#).

### Key factors in determining cleaning efficacy

**2.7** Key factors in determining the cleaning efficacy of the process include:

- concentration of detergent;
- confirmation that process fluids contacts and flows across all surfaces of the endoscope, internal and external;
- compatibility of the EWD to the endoscope;
- temperature of the cleaning process;
- type of wash process (for example, soak or spray);
- pressure of water jets, if used;
- orientation of endoscope in an EWD to give good chemical access to all external surfaces;
- pressure and/or flow of detergent down all lumens to be cleaned;
- contact time;
- water quality.

### Key factors in determining microbial efficacy

**2.8** Key factors in determining the microbial efficacy of the process include:

- assurance that the load is clean;

- formulation and type of disinfectant(s) used;
- concentration of the disinfectant;
- microbial quality of the final rinse-water;
- temperature at which the cleaning agent and disinfectant are used;
- contact time with the endoscope;
- quality and temperature of water used to dilute (if applicable) disinfectant;
- confirmation of disinfectant flow across all surfaces, internal and external, of the endoscope;
- absence of inhibitory materials, such as residual soiling and residual chemicals from the cleaning stage;
- pressure and flow down lumens;
- scope orientation;
- absence of fissures and holes in the endoscope and its lumens.

**2.9** The removal of the chemical disinfectant after the disinfection stage is of importance and should be achieved without compromising the cleanliness or safety of the product (see [paragraph 4.54, 'Residual chemicals'](#)). The control of the microbial quality of the rinse-water is critical in this respect (see also [paragraph 4.44, 'Safety of EWD chemicals'](#) on the health and safety requirements for chemical additives).

### Choice of an EWD

**2.10** The choice of an EWD will be governed by the nature of the endoscopes to be decontaminated. Quality inspectors should be aware of the important nature of this compatibility, which can be checked through specifications and records. All relevant personnel within the healthcare organisation, under the guidance of the Decontamination Lead and Surgical Instrument Manager, should be consulted at appropriate points during this



process to ensure that all operational and user aspects are taken into account, including:

- User and endoscopy clinicians;
- the estates and facilities department;
- purchasing department or organisation;
- infection prevention and control;
- Microbiologist (Decontamination);
- AE(D);
- EWD manufacturer/supplier;
- endoscope manufacturer.

**2.11** EWDs are made with different designs for lumen connectors. It is important that the correct connectors are available to attach all endoscopes to the chosen EWD at the time of first use. Advice on individual cases should be sought, if necessary, from the AE(D) before any decision is made.

### Note

When preparing a tender document, it is important to specify the manufacturer and model of all endoscopes that will be processed in the EWD. The particular specification on page 43 should be used to ensure the appropriate lumen connectors are available.

**2.12** All endoscopes will require decontamination using the same EWD cycle. It is important that the endoscopes in use are compatible with the EWD cycle supplied with the machine. Therefore consultation between the proposed EWD manufacturer/supplier and the endoscope unit should take place to confirm that the cycle parameters and chemicals to be used are suitable for the endoscopes in use.

**2.13** NHS Supply Chain has in place a national framework agreement that covers EWDs, drying cabinets, water treatment systems, training, maintenance and validation. The framework enables procurement of these

products and services tailored to specific reprocessing needs without the need to instigate an OJEU tender.

## Information to include when requesting tenders for an EWD

**2.14** Useful insight into operational aspects of EWDs can be gained through discussion with existing users.

### 2.15 Data to be supplied by the purchaser:

- Water-supply test results prior to any tender actions (these tests may include hardness, total organic carbon (TOC), total viable count (TVC), conductivity).
- Outline of the unit's layout: configuration – single- or double-door/lid.
- Role of an endoscope dryer, if required.
- Specification for the performance qualification (PQ) test.
- The tracking and traceability system to be used including print-out of cycle data to be attached to the patient's notes (see [Chapter 5, 'Tracking, traceability and audit trail'](#)).
- Cleaning and disinfection chemicals, if possible (if not detailed in the manufacturer's type-test data).
- Method of adjudication should problems arise.
- Breakdown of endoscope numbers per day that can be processed including cycle times: for example, allow for 60% EWD usage time; 40% maintenance and testing.

### 2.16 Data to be supplied by the manufacturer/agent:

- Floor area required for EWD(s) and water treatment plant, plus dimensions, weight, clearance and access requirements.

- If water treatment plant required, who to supply and install: specification of final rinse-water standard to be adopted.
- Engineering details for the proposed machines: drainage, water, electricity, sound, ventilation and floor loading.
- Pre-tender site inspection by manufacturers: -site improvement work that may be required; -access clearance and access for maintenance and repair.
- Type-test list and results (see Table 1 in HTM 01-06 Part D – ‘Validation and verification’).
- Price breakdown of EWD and associated equipment (for example, connectors, endoscope cradles): running costs including electric power, recommended detergent, disinfectant, water volume and treatment (for example, filters, reverse osmosis).
- Commissioning contract.
- What arrangements to be made for staff tuition on new equipment for nurses/ decontamination staff and engineers.
- Supply of endoscope connectors for current stock of endoscopy instruments with the number of lumens detailed.
- Service and maintenance contract costs including engineering response time.
- Cost of a remote diagnostic option, if available.

**2.17** It is important that staff training is undertaken when purchasing a new EWD and when new endoscopes are purchased (see [Chapter 1, ‘Personnel’](#)):

- Define who is responsible for checking competency of staff working on the new EWD and the training manuals.
- Check the availability of EWD training and copies of the training manual.
- Check availability and cost of EWD training after one year’s use and

thereafter for new staff or staff who had not previously attended.

- Check availability of endoscope connections training (likely to be unit-specific).
- Check availability of training on in-use flexible endoscopes together with lumen diagrams.
- Write, or obtain, staff training manuals and the means of recording staff training episodes.

**2.18** Once the type of EWD has been decided (for example, single-door/lid or double-door/lid), preliminary enquiries should be made with a number of manufacturers to obtain specifications and price lists. The ‘Data to be supplied by the manufacturer/agent’ section above lists some of the information that will be useful for planning purposes and which should be obtained at this stage. In addition, a copy of the type tests carried out on the prospective purchase together with the results should be obtained. This will allow a direct comparison between machines of similar function, but different build types and operation. The EWD must be CE-marked in compliance with the essential requirements of the Medical Devices Directive and certified by a notified body (examples of type tests that may be carried out as part of the CE application are detailed in Table 1 of ‘Schedule of type tests and works tests’ (in HTM 01-06 Part D – ‘Validation and verification’)).

## Sizes and numbers of EWDs

**2.19** Precise information on the numbers of EWDs required for particular applications is difficult to give, since patterns of use vary. The number of EWDs required will depend on the cycle time and the loading capacity of the machine. Some EWD models are constructed to process one endoscope at a time; others can process two endoscopes independently. This flexibility is limiting when the design of the EWD requires that endoscopes to be processed should wait until there is a full load,

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

Commissioners and quality inspectorates should ensure that the decontamination capacity available is a good reflection of the demands imposed by the care frameworks in place.

## Assessment of throughput and workload

### Throughput capacity

**2.20** Throughput capacity is affected by a number of variables. These include:

- The number of operational hours per week for the department in which EWDs are located.
- The machine utilisation factor expressed as a percentage of the number of operational hours. This will be influenced by several factors including:
  - (i) delivery schedules from clinical areas, if separate from the decontamination area;
  - (ii) peak throughput dependent on list scheduling;
  - (iii) staff availability for loading and unloading;
  - (iv) start-up and shutdown time each day;
  - (v) planned and breakdown maintenance time;
  - (vi) routine, periodic and annual testing;
  - (vii) first morning run to decontaminate endoscopes stored overnight;
  - (viii) self-decontamination run.

### Throughput time

**2.21** Throughput time for endoscopes is the shortest practicable turnaround time required in order to maintain an effective clinical service; this time is affected by four key factors:

- EWD cycle time;
- EWD capacity and design configuration;
- manual cleaning time;
- machine availability.

#### *Cycle time*

**2.22** The operation of a routine cycle should remain the same whatever the drying time selected.

**2.23** The cycle time may be adversely affected by inadequate services such as low water pressure and low or high water temperature. The drying time selected will affect the number of cycles possible per day.

### Note

If more than one routine cycle is programmed into each EWD (excluding the drying time), the testing time will be longer, as each routine cycle should be tested separately for quarterly and annual tests. Cycles not used should be disabled and an entry made into the logbook. (Disabled cycles need not be tested, as they are not used.)

#### *EWD capacity*

**2.24** EWD capacity, specified by the manufacturer, is normally stated in terms of the number of compatible endoscopes that can be accommodated in one basin or chamber. Subject to both the endoscope and EWD manufacturer's advice for small endoscopes that have few lumens, one set of lumen connectors may be used to process two endoscopes, so long as only one lumen is connected to one EWD outlet and the lumen flow is not compromised. Endoscope traceability should not be compromised by this

action. If more than one endoscope is processed in the chamber of an EWD, they should not lie on top of each other, as decontamination may be compromised due to shadowing (see paragraph 2.36, 'Load handling equipment').

**2.25** EWDs that process two endoscopes, or more, at a time may be of little benefit in reducing throughput time unless the endoscopes are ready for processing at the same time. EWDs that run cycles in separate chambers can be run independently and may allow a more flexible use of EWD time.

### Note

For endoscopes that have been used for invasive procedures in patients at risk of variant Creutzfeldt-Jakob disease (vCJD), see Chapter 5 in HTM 01-06 Part A – 'Policy and management'.

### Workload estimate

**2.26** The workload should be estimated from historical records of operational activity or based on proposed workloads. An approximate assessment of the workload can be determined from the actual, or expected, weekly caseload.

**2.27** Account should be taken of the care pathways serviced by the provider organisation and the NICE (National Institute for Health and Clinical Excellence) quality standards that apply.

### Downtime

**2.28** Downtime is the total time that machines are unavailable for routine use. This needs to be calculated as time is required for carrying out the machine disinfection procedure, routine servicing and maintenance and for compliance with the recommended testing regime.

**2.29** Guidance on estimating this time can be found in Health Building Note 13 – 'Sterile services department'. As a guide, approximately 30–40% of an EWDs available time will be required for non-patient work,

maintenance and testing. EWD downtime should be checked with a current user of the same equipment to verify the data.

### Reprocessing accessories

**2.30** The reprocessing of patient-invasive accessories should be avoided wherever possible and single-use instruments substituted.

**2.31** Biopsy valves should be disposed of if breached during a patient procedure.

**2.32** When reprocessing reusable accessories (for example, endoscope valves, water bottles and cleaning tools), additional cleaning may be required, such as brushing and flushing. It is important to note that valves need to be actuated to ensure adequate cleaning is achieved.

**2.33** Reusable accessories should be in an open position to allow steam to access all surfaces.

**2.34** For tracking purposes, several items of the same type (for instance, endoscope buttons) may be needed to allow time for steam sterilization. When an endoscope is purchased, several spare buttons can be ordered at the same time and identified. This will allow one set of buttons to be sterilized while another set is in use and recorded.

**2.35** Single-use brushes, biopsy forceps or other single-use instruments should not be reused.

### Load handling equipment

**2.36** Some endoscopes require protective caps to be fitted to sensitive components before they can be decontaminated in an EWD (for example, videoscopes need a protective cap on the video plug).

**2.37** The load carrier (and connectors) should be appropriate for the range of endoscopes that it is intended to process.

**2.38** The load carrier may need to provide connection to the various lumens within the endoscope to allow the cleaning/disinfection solutions and rinse-water to flow through the lumens. Holders may need to be provided for disassembled components, valves etc.

**2.39** If more than one endoscope is processed together, the load carrier should be designed to prevent the devices touching each other. If endoscopes touch, their surfaces may be inadequately washed, disinfected and rinsed and so this should be prevented.

**2.40** The contact between an endoscope and load carrier should be minimal to allow effective fluid contact and cleaning.

## Dosing systems

**2.41** The EWD should be fitted with a system for controlling the admission of chemicals (detergent, disinfectant etc), and a system to act as a watchdog to monitor correct function.

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

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

**2.44** Working procedures and, where available, mechanical systems need to ensure that the detergent and disinfection supplies are correctly coupled to their respective inputs.

**2.45** Each dosing system should be provided with means to determine the volume admitted and the time within the operational cycle when the admission occurred. This data should be available to the operator. Failure to admit the specified minimum volume should cause a fault to be indicated.

**2.46** The manufacturer should specify the accuracy and reproducibility of the control of

volume admitted for each of the dosing systems used (detergent and disinfectant) per cycle.

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

**2.48** The volume of water used for each stage of the EWD process should be monitored. If the water volume for each stage is insufficient, a fault should be indicated. Water pressure may influence flow and may also be measured.

## The selection of an EWD from tender documents

**2.49** Reference should also be made to the particular specification for EWDs on page 43.

- Does the selection panel represent all interested parties?
  - (i) senior endoscopy nurse/manager;
  - (ii) estates representative;
  - (iii) Surgical Instrument Manager;
  - (iv) infection control/microbiology;
  - (v) AP(D) and/or AE(D);
  - (vi) Decontamination Lead;
  - (vii) risk manager;
  - (viii) safety officer;
  - (ix) CP(D);
  - (x) supplies officer.
- Do the EWDs described match the specification?
- Do the engineering requirements match those available on site?
- Are the EWDs described compatible with the existing traceability system?
- Will the EWD work with mains water supply?



- Is a separate water treatment plant required based on the water supply test results?
- Is data available on the selected EWD that shows reliability in the field?
- Do the costs included in the tender cover all the costs involved in the project?
- Do the machines represent value for money?
- Arrange a site visit to an EWD of the type short-listed.
- Will additional ventilation be required?
- Will the EWD be compatible with all endoscopes in use?
- What chemicals have been type-tested? Are the chosen chemicals compatible with the EWDs and endoscopes?
- Is it possible to compare EWDs on the data supplied?
  - (i) If not, request additional data.
  - (ii) Are type-test results available? See Table 1 in HTM 01-06 Part D – ‘Validation and verification’. Results need to match guidelines or standards.
  - (iii) If insufficient data is available, select another EWD make.
- Can a supplied EWD be guaranteed free of contamination and biofilm?
- Who will carry out commissioning tests? Will they be independent and witnessed by an AE(D)?
- What training for operators and engineers is offered?

- Is finance available for routine testing and revalidation?
- Who will carry out periodic testing and maintenance?

## Taking delivery of an EWD

**2.50** The delivery of an EWD needs special attention. Not only should the delivery path of the machine through the building to where it is to be installed be worked out in detail, also the services need to be in place so that the machine can be operated without delay.

**2.51** The manufacturer should take steps to dry the internal surfaces of an EWD before leaving the factory after final tests to limit the growth of biofilm during delivery/ storage.

**2.52** Storing or delayed delivery of an EWD may be unavoidable. Water remaining in the machine after its factory testing will allow biofilm to develop within pipework (which will be very difficult to remove). If delays have occurred since the date of manufacture, and it was not dried before delivery, arrangements should be made to have a replacement pipe set fitted to the machine and a self-disinfection cycle run before it is tested and used. A new EWD should be delivered with replacement pipework, which can be fitted before commissioning.

**2.53** A works test sheet should accompany an EWD when it is delivered to site. The tests detailed on this sheet should be similar to those listed in Table 1 in HTM 01-06 Part D – ‘Validation and verification’, together with the results. It is important that test results are compared with European Standards and national guidelines and found acceptable, as otherwise it will be more difficult to resolve problems if the machine is allowed to be installed and connected.

# 3 EWD operation, and endoscope storage and transport

## Summary for commissioners and quality inspectors

Guidance is given on the operation of an EWD, including cleaning, disinfection and rinsing endoscopes. The possible stages of an EWD are discussed together with the inspection, release and handling of flexible endoscopes after processing. Also included are issues when processing nasendoscopes and transoesophageal echocardiography, transvaginal and trans-rectal ultrasound probes.

**3.1** EWDs vary from manufacturer to manufacturer, but all have a similar operating cycle. The aim of the process is to meet Essential Quality Requirements and render the reprocessed endoscope:

- free of pathogenic microorganisms;
- clean and free of detectable protein free of any chemical residue from the decontamination process other than the disinfectant added to the final rinse-water as part of a controlled process.

See Chapter 3 in HTM 01-06 Part A – ‘Policy and management’ for further details of Essential Quality Requirements.

**3.2** The performance of adequate flexible endoscope decontamination poses special challenges for the following reasons:

- Flexible endoscopes are usually thermolabile and often too expensive for single use.
- Flexible endoscopes usually need to be chemically disinfected, which has its own challenges:
  - (i) difficult to control critical parameters;
  - (ii) chemicals are subject to inactivation by residual detergent, poor water quality and residual protein;
  - (iii) lower quality assurance of disinfection compared to thermal processes.
- Flexible endoscopes have multiple long narrow lumens that cannot be visually inspected.
- Manual pre-cleaning is an essential component of the decontamination cycle.
- It is essential that all the endoscope lumens are connected to the EWD. The EWD should monitor the flow of cleaning and disinfectant fluids through all lumens (including the raiser bridge – if present) and this should be compared to the validation parameters. In modern EWDs, flow monitoring takes place in the internal computer and will alert the Operator if there is a problem. These internal systems should be regularly checked to demonstrate correct operation.

- It does not allow for preprocess wrapping, leading to the possibility of post-process recontamination.

## Operation of an EWD

**3.3** The EWD should be an enclosed system. It should be a requirement for the chamber access to be locked before it is possible to start a cycle.

**3.4** The control system should permit regulation of pump and inlet pressure to the various connections to allow the EWD to be adjusted for particular types of instrument. This should be a programmable option on the automatic controller.

**3.5** The disinfectant solution should be used once and discarded. A less satisfactory system is to reuse disinfectant solutions for a number of cycles; If this system is used, means should be incorporated to ensure that the automatic cycle will not start when the disinfectant concentration has fallen to, or below, the minimum recommended by the manufacturer or established by independent testing.

**3.6** Reuse of a reusable disinfectant solution for several operating cycles is subject to risk as it may be difficult to reliably predict or control dilution and contamination giving reduced activity. Consult the suppliers or an AE(D).

**3.7** For single-use chemicals, there needs to be a method of detecting when the stock-concentrated chemical is at a low level. In addition the reproducibility of chemical volumes used during the process should not be in excess of  $\pm 5\%$  nominal volume.

**3.8** It should not be possible for the operator to interrupt a cycle before completion without alarm activation and a cycle interruption message. The EWD should not be able to be opened or reset without the aid of a special tool, key or code.

## Disinfection requirements

**3.9** The standard of disinfection required should be defined by the User, in consultation with the Infection Control Doctor.

**3.10** In general:

- endoscopes that, in use, are passed into sterile body cavities are considered to be invasive and should be free of viable microorganisms and endotoxins;
- endoscopes that, in use, come into contact with mucous membranes but do not invade sterile body cavities can be decontaminated using high-level disinfection, that is, free of pathogenic microorganisms with a low bioburden.

**3.11** The choice of disinfectant should be based on the level of decontamination required and on the compatibility with the endoscope, EWD and the constructional materials of both. It is recommended to use a disinfectant that was included in the type-test data so the machine operating system can be set up to suit the chemical that has been shown to be effective (see [Chapter 4, 'Process chemicals'](#)).

## Process water (except for final rinse-water)

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

**3.13** Where EWD equipment supports more than one water inlet, the process water does not need be of the same quality as the final rinse-water, which will be delivered separately.

## Final rinse-water

**3.14** For guidance on the microbial quality of final rinse-water, see Table 2 in HTM 01-06 Part E – 'Testing methods'.

**3.15** On completion of an EWD cycle, the EWD should drain to leave the minimum residual water in the tubes and fittings that come into



contact with the final rinse-water. EWDs should be designed and constructed so they can be drained and dried when not in use. Data on EWD residual water volume should be available in the type-test data.

## Self-disinfection requirements

**3.16** Available operating cycles on the automatic control system should provide for an EWD self-decontamination cycle to ensure that all pipework, tanks, pumps, water filtration systems and other fittings that are used to carry aqueous solutions intended to come into direct contact with the endoscope are cleaned and disinfected. The self-decontamination cycle should be user-selectable and programmable, so it can run at a time convenient to the Operator. Heat self-disinfection is recommended in BS EN ISO 15883-4, clause 4.8.1. An EWD in which the endoscope process cycle provides for disinfection of the chamber – and all piping and tanks that come into contact with the water or solutions used for cleaning, disinfecting and rinsing the load – will meet this requirement without provision of an additional self-disinfection cycle (see BS EN ISO 15883-4, clause 4.8.2).

## Compatibility with items to be processed

**3.17** For any particular load item, it should be ensured that all cleaning and decontamination processes are carried out in strict accordance with the manufacturer's instructions. All endoscopes, but particularly those incorporating flexible systems, are easily damaged.

**3.18** If the process conditions recommended by the manufacturer (including maximum temperatures, internal pressures, nature of any physical treatment (such as a spray system) and limitations on the chemicals that can be used) are ignored, serious damage can be caused to these expensive instruments (see [Chapter 4, 'Process chemicals'](#)).

## Cycle of use and decontamination of endoscopes

### Handling of endoscopes after use and before decontamination

**3.19** EWDs are incapable of cleaning the endoscope without any pre-treatment. As soon as the endoscope is removed from the patient, the lumens should be flushed in accordance with the endoscope manufacturer's instructions. The outside of the instrument should then be wiped with a swab soaked in an aqueous solution of a suitable detergent (for instance, an enzymatic solution). Flexible endoscopes should be kept moist after use and before manual cleaning. If endoscopes are allowed to dry during this period, soil will be difficult to remove. Therefore endoscopes should be transferred from the point of use to the decontamination area as soon as possible.

**3.20** There are several options available to retain endoscope moisture during return transport to decontamination unit after use. For example:

- A damp endoscope could be placed in a plastic bag and the bag sealed. The bag could then be placed onto a tray to support the body of the endoscope and transported on a purpose-built trolley.
- A used endoscope could be sprayed and injected with a non-drying fluid and then transported in a plastic lined tray designed for the purpose.
- A used endoscope could be put in a tray with a small volume of water and covered.

**3.21** Endoscopes should not be transported with the lumen full of fluid. This will pose a spill hazard of potentially infective fluids. The use of a load carrier specifically intended for the endoscope(s) to be processed is essential.

**3.22** The control valves should be removed during pre-cleaning at the point of use; they will then accompany the endoscope to the

decontamination room for special attention. The dirty endoscope enters the decontamination room and is laid onto a cleanable surface, such as a stainless steel draining board.

### Manual cleaning

**3.23** The instructions provided by the endoscope manufacturer should be followed, as endoscopes vary in construction and therefore the method of cleaning.

**3.24** Before cleaning, all endoscopes should be tested to determine whether there is a fracture or leak. A leak test should be performed and shown to be satisfactory before cleaning is undertaken. The endoscope manufacturer's instructions should be followed for this task.

**3.25** A volume of concentrated detergent is added appropriate to the volume of water already present, as recommended by the detergent manufacturer. The use of engraved or other permanent markings on the inner surfaces of sink units may be helpful as may the use of pre-drilled holes to take detergent transfer pipework, supporting accurate and reproducible detergent dilution. The endoscope and accessories should be soaked in the detergent solution recommended by the detergent manufacturer. Under detergent fluid, the instrument/biopsy lumens should be brushed through several times with a cleaning brush designed for the instrument in accordance with the endoscope manufacturer's instructions.

**3.26** Manual cleaning is essential to remove deposits down the lumen and around the controls of an endoscope. An EWD is not able to reproduce the brushing action of manual cleaning or brushing between the control wheels. Manual cleaning is particularly important when using older EWDs, as the cleaning action may be limited. After use, the sink is drained, rinsed with tap water, drained, wiped clean and left dry.

**3.27** The second sink is filled with cold water and the washed endoscope is immersed before each lumen is syringed through to remove the detergent.

**3.28** The endoscope should then be rinsed in clean tap water and carefully examined for damage before connection to an EWD. The endoscope is then transferred to the EWD, taking care water does not drip onto surfaces and the floor. Hands should be washed and clean gloves used before removing the cleaned endoscope after the EWD process.

**3.29** The reprocessed endoscope should be stored in a clean area or drying cabinet. If the endoscope is to be used directly, it may be laid onto a lined transport tray and covered ready for reuse.

### Process stages of an EWD

#### **3.30 (1) Connection of endoscope to EWD.**

The lumens of the endoscope should be connected to the appropriate nozzle on the load carrier to ensure the free passage of fluids through the lumens during processing. If the endoscope to be processed has a open raiser bridge lumen, this should be connected to a specific connector on the EWD to deliver high pressure fluids to carry out the cycle successfully.

**3.31 (2) Leak test.** An automatic leak test can be used to supplement the manual leak test carried out during manual cleaning. Approximately 200 mbar of air is pumped into the body of the endoscope. The air pressure is measured over time, approximately 45 seconds. If the EWD system does not detect a significant drop in pressure, the cycle should be allowed to continue. An automatic test may not pick up minor leaks. An EWD automatic leak test should not replace a manual leak test. During the manual leak test, moving the endoscope distal end and operating angulation controls may expose leaks. Modern EWDs may conduct a continuous leak test throughout the process cycle. The cycle may fail if the internal pressure of the endoscope falls below a predetermined level. In addition a final leak test may be performed at the end of the cycle to check no leaks have been induced during the process.

**3.32 (3) Initial flush (optional).** Cool water at a temperature below 45°C is flushed through all the endoscope lumens and over the endoscope body to remove major debris. During this stage some EWDs carry out the lumen patency test for blocked lumens. The water quality used for the initial flush is not critical, but should be below 200 mg/L CaCO<sub>3</sub>.

**3.33 (4) Lumen patency.** This stage detects lumen blockages, partial blockages and disconnected lumen connectors. Each manufacturer uses a different system to detect blocked or disconnected lumens, but they all should fail the cycle if there is a disconnection, or partial or complete block. Lumen patency checks specified by the manufacturer should be capable of detecting a partial blockage as well as full occlusion. In addition information should be available at the end of the cycle indicating which lumen failed, whether it was blocked or whether a connector tube became detached. Modern EWDs are designed to carry out the lumen patency test throughout the operating cycle; this is to be preferred if available. The EWD manufacturer should state the lumen patency tests specific to their machine with clear instructions.

**3.34 (5) Cleaning.** Water and detergent are used to clean the endoscope. Detergents act both as wetting agents – in which the reduction of surface tension allows contact with all surfaces – and also as a solvent and/or dispersant of soil. They also can degrade soil components, making them more soluble and easier to remove (see ‘Process chemicals’ for guidance on detergents).

**3.35 (6) Rinsing (optional).** Rinsing of the load may be required to remove the cleaning agent before use of a chemical disinfectant, as they may not be compatible.

**3.36 (7) Chemical disinfection.** Disinfection is achieved by the action of a microbicidal chemical solution maintained on the surface (internal and external) to be disinfected at a particular concentration for a set time at a specified temperature. It is important that the

disinfectant solution reaches all parts of the endoscope for the correct time to achieve the correct level of disinfection. Therefore all lumens should be flushed with the solution, whether they were used in the clinical procedure or not. A disinfectant from the selection type-tested by the EWD manufacturer should be used (see Chapter 4, ‘Process chemicals’).

**3.37 (8) Final rinse.** The removal of chemical disinfectant after the disinfection stage is important and should be achieved without compromising the microbial quality of the product. The final rinse should remove any traces of process chemicals to prevent them coming into contact with patient tissue except EWDs that add disinfectants to the final rinse-water that have been validated as compatible with patient safety.

**3.38 (9) Drying.** Drying or blowing is an integral part of the cycle, usually by the circulation of air over and through the lumens of the endoscope and may be supplemented by a separate storage/drying cabinet. An alcohol flush at the end of a cycle to aid drying is discouraged, because it is a protein fixative.

### Storage of flexible endoscopes

**3.39** While much of the water will be removed from endoscopes following the final rinse, there is a possibility that the droplets of any remaining water will allow bacterial growth and biofilm to develop when in storage.

**3.40** There are two options for post-decontamination storage of flexible endoscopes:

- a. The endoscopes are stored in a cabinet which keeps them secure and away from unintentional contact with contaminated surfaces, but which does not dry them. These cabinets are referred to as “storage cabinets”. If more than three hours elapses between decontamination and use of an endoscope, bacterial growth may occur; therefore the endoscope should be decontaminated before it is reused.

- b. The endoscopes are stored in a cabinet that passes clean air around the endoscopes and through all of their lumens. This dries them so that bacteria will not replicate and preserves their decontaminated status. These are referred to as “controlled environment storage cabinets” with specifications detailed in BS EN 16442. If such a cabinet is being considered, Users should require verification from manufacturers of the time that endoscopes can be stored as well as assurance that all their endoscopes – particularly those with wire-carrying channels (as in some duodenoscopes) or narrow balloon-inflating channels (such as in some ultrasound endoscopes) – can be successfully dried and stored.

**3.41** Users may choose to have a combination of both cabinet types, for example:

- controlled environment storage cabinets for those endoscopes likely to be in daily use; and
- storage cabinets for those endoscopes only in occasional use where reprocessing before use is feasible and cost-effective.

**3.42** See also Chapter 6 ‘Controlled environment storage cabinets’ in HTM 01-06 Part D.

**3.43** The following list may be helpful when considering cabinets for endoscope storage:

- Does the storage cabinet have a drying function as defined by BS EN 16442?
- Can all endoscopes be hung in the cabinet without the distal end touching the bottom of the cabinet?
- Does the cabinet allow the differential pressure between the inside and the outside of the cabinet to be taken during its operation?
- Can the cabinet be locked and is restricted access allowed?

- Does the cabinet monitor each endoscope in storage, record the data and indicate whether the values are out of specification or the endoscope has been in storage beyond the validated retention time?
- Does the cabinet allow for continuation of the traceability system?
- Has the cabinet manufacturer produced reliable data to show a stored endoscope may be directly used on a patient without reprocessing for a validated time?
- Which tests have been carried out to show if the cabinet dries endoscopes, keeps them free of contaminating organisms during storage and prevents any residual contamination from growing? From these data, has the manufacturer recommended a maximum safe period of storage?
- Can endoscopes be added or removed from the cabinet without contaminating other endoscopes in the cabinet?
- Is the cabinet easy to clean and constructed of non-porous material with sealed joints?
- Are double-ended cabinets required as part of the departmental design?

**3.44** Cabinets for endoscope storage should not be sited in the endoscope cleaning area; they may be sited either in the endoscope clean area or in a clean area near to the point of use.

**3.45** Hanging endoscopes up in a working area or corridor is not acceptable as they are liable to contamination as well as damage and theft.

### Packaging and transport

**3.46** Transport of reprocessed endoscopes should not compromise the cleanliness or bioburden of the device. If the endoscope is to be used in an adjacent room to the decontamination area, careful handling and, if necessary, protection will be required to prevent contamination. The transport of soiled



endoscopes needs equal care to prevent contamination of staff and the environment.

**3.47** If the endoscope has to be transported to another part of the hospital for use, the endoscope needs protection from contamination and also from potential damage during transportation. Systems are available to transport reprocessed endoscopes on a plastic liner in a suitable tray covered with a plastic sheet and solid cover/lid. On completion of the endoscope procedure, the top sheet is turned inside out and the used endoscope placed inside to be transported back to the reprocessing unit.

**3.48** Endoscopes should be transported between the EWD and drying cabinets (if used) in as short a time as possible. If endoscopes are not dried soon after processing, a biofilm will be produced from the residual water remaining in the endoscope lumen. Once dry, this growth stops and the endoscope does not become increasingly contaminated.

**3.49** The transport carriers used to carry endoscopes from the EWD to the drying cabinets should be decontaminated if required to transport endoscopes to the procedure room. The carriers may be used to carry used endoscopes back to the reprocessing unit.

**3.50** Some EWDs process the endoscopes in a plastic container, which serves both as process chamber and carrier. The endoscope remains in the container for most of its life, only being removed during patient examinations, manual cleaning and inspection. If this precludes the application of a drying cabinet, it limits the endoscope storage life to three hours before reprocessing is necessary before reuse. At present there are no specific tests for these systems to confirm satisfactory operation without causing long-term mechanical damage to endoscopes. Consultation with the AE(D) should take place to determine essential operational requirements,

#### *Transport of reprocessed flexible endoscopes*

**3.51** Decontaminated endoscopes are not usually packaged for transport and may not have been thoroughly dried. Under these circumstances the product is only suitable for immediate use and the EWD should be installed within easy reach of the point of use. Prolonged storage (for example, for more than two or three hours) could cause contamination to occur followed by the growth of a large microbial population.

**3.52** Owing to the design of some hospitals, endoscope reprocessing units may not be adjacent to the point of use. If this is the case, special arrangements will be required to prevent endoscopes becoming externally contaminated during transportation within the same hospital. These may include:

- use of drying cabinets to thoroughly dry the devices before issue (see 'Drying cabinets' section above);
- use of special carriage systems to provide support, and prevent damage and contamination during transit. It is important that transit trays are fitted with a hard lid to protect the endoscope during transit;
- rapid delivery of endoscopes to the point of use so they are not stored for longer than three hours, as the storage conditions are important determinants of contamination. The time of processing should be recorded on any endoscope package to allow the transit time to be checked before use.

#### **Post-decontamination inspection and release**

**3.53** The User, in consultation with the AE(D), should establish documentation procedures to ensure loads are not released for use, or storage, until the User is satisfied:

- a. that the cleaning stage of the process has been reproduced within the permitted tolerances established;

- b. that visual inspection of the endoscope, particularly the valve ports and surfaces between the angulation controls, shows that an acceptable standard of cleanliness has been obtained;
- c. that the disinfection stage of the process has been reproduced within the permitted tolerances established during commissioning and PQ;
- d. that, if the endoscope is not used within three hours of reprocessing, the storage facility meets the requirements detailed in 'Drying cabinets' above.

**3.54** If the endoscope has been sterilized by a validated process before which it was wrapped in such a way as to prevent post-sterilization contamination, it may be stored before use for a time determined by the local risk assessment and can be used as sterile as long as the wrapping remains in tact.

**3.55** The procedures should ensure that:

- a. the load has been correctly positioned in the loading basket and/or on the load carrier;
- b. the settings for the operating cycle is in accordance with the specification for that load type;
- c. the instrument/indicator readings and/or chart record for the cycle conforms to the data established during validation within the permitted tolerances;
- d. the decontaminated endoscope shows no obvious defects – such as damage, residual soiling or staining, which may suggest a faulty operating cycle;
- e. flow occurred in all lumens of the endoscope;
- f. no connectors have become dislodged during the cycle.

**3.56** Whenever an operator has cause to suspect that the endoscope may not have been properly decontaminated, the endoscope

should not be released for patient use. The User should be informed immediately.

**3.57** If a small area on an endoscope or accessory remains soiled after processing, this will be sufficient to reject the endoscope and accessories. The rejected load should be returned for reprocessing and the cause of failure be investigated.

**3.58** Documented procedures for reprocessing rejected endoscopes and accessories should be agreed between the User and the AE(D). The method by which rejected loads are returned for reprocessing should be chosen to ensure that product flow in a controlled environment is not compromised.

**3.59** When a single-door/lid EWD is in use, a system to clearly differentiate between processed and unprocessed endoscopes and accessories will be required.

## Decontamination of nasendoscopes

**3.60** Nasendoscopes are used for the examination of nasopharynx, larynx and hypopharynx. They are short flexible endoscopes, usually without lumens. The decontamination of these endoscopes requires the same standards of cleanliness and disinfection as other flexible endoscopes. All Essential Quality Requirements outlined in HTM 01-06 Part A – 'Policy and management' apply, except that nasendoscopes without lumens can be manually decontaminated using wipes and procedures validated for that purpose.

**3.61** Owing to the distance involved in many hospitals between where nasendoscopes are used and a suitable decontamination facility, manual methods of decontamination are often used. All manual methods should include efficient cleaning of the used nasendoscope followed by controlled wiping with, or immersion in, an effective, compatible disinfectant. If selective immersion is used, non-immersible components also need to be disinfected, for example by wiping. Cleaning and disinfection are

required even if single use sheaths are used. Regardless of the operational arrangements and the location in which decontamination is conducted, the Essential Quality Requirements of this guidance and the reprocessing instructions of the device manufacturer should be followed.

**3.62** Ideally, where flexible cannulated nasendoscopes are in use, purpose-designed EWDs should be available in a central reprocessing unit. If this is not possible, endoscopes may be processed in a smaller reprocessing unit operating to the same standards as a central unit. Irrespective of whether an endoscope has lumens, decontamination in an EWD is likely to give enhanced risk reduction.

**3.63** Decontamination staff who work in units where nasendoscopes are reprocessed should receive training to enable them to decontaminate that type of endoscope. Where more complex endoscopes are decontaminated, such as those with wire-carrying channels, staff doing this will require additional training to deal with them. Staff should be trained to decontaminate the most complex endoscope that they will have to reprocess.

**3.64** Nasendoscopes should be stored in a secure clean area, for example, a purpose-built cupboard or cabinet made of non-porous material that is easy to clean. Where nasendoscopes do not contain lumens, they do not need to be stored in a drying cabinet. For non-lumened nasendoscopes, bacterial contamination on their surface will not replicate in the absence of liquid water. Therefore, as long as direct or indirect recontamination with patient body fluids does not occur, no maximum time of storage before reprocessing can be specified.

## Decontamination of transoesophageal echocardiography, transvaginal and trans-rectal ultrasound probes

**3.65** Transoesophageal echocardiography (TOE) allows real-time visualisation of the heart via the

stomach and oesophagus using ultrasonic emission from the distal end of a flexible probe. These probes do not have lumens. Only the patient insertion tube can be immersed in liquid.

**3.66** Trans-rectal ultrasound (TRUS) probes and transvaginal ultrasound (TVUS) probes are used to examine the prostate gland and female reproductive organs, respectively. These do not generally have lumens but some TRUS probes have an internal lumen that allows passage of a biopsy needle through the probe and then into the prostate gland via the rectal wall.

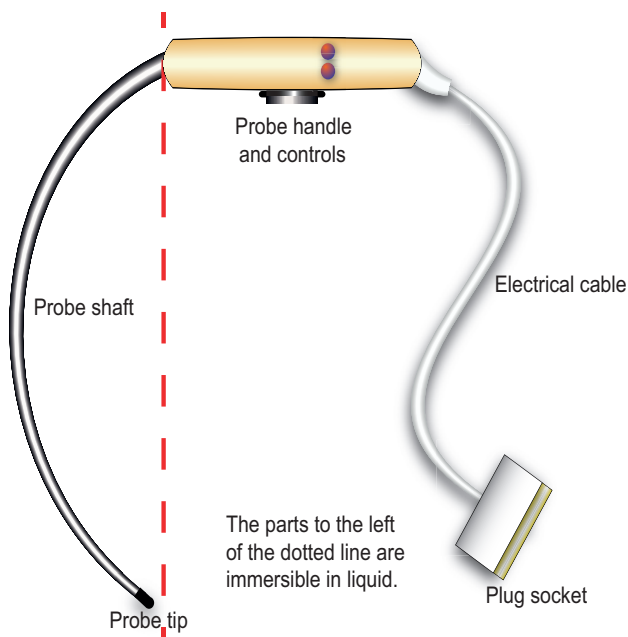
**3.67** The cleaning and decontamination of TOE, TVUS and TRUS probes that do not have internal lumens is normally carried out manually directly after they have been used. This includes wiping until clean with detergent-soaked cloths or sponges, followed by wiping with a disinfectant-soaked cloth or sponge several times. The probe is then rinsed with water and dried. The manufacturer's instructions should be followed carefully. A local policy should be drawn up to describe the decontamination procedure.

**3.68** The use of an EWD to decontaminate the immersible parts of these probes is to be preferred, as described in the next paragraph (see Figure 1). Parts of TOE, TVUS and TRUS probes, including the transducer head and probe handle with tip angulation controls, are not immersible. The control section with tip angulation wheels is likely to have become contaminated because of the operator's handling of this section as well as the probe shaft; the electrical cable and plug socket can similarly become contaminated. Therefore the whole of the probe – not just the insertion tube – should be carefully cleaned followed by wiping with disinfectant, taking care not to excessively wet parts other than the insertion tube. Careful inspection of all parts/components should be conducted after cleaning to ensure no visible residue remains.

**3.69** There are two approaches to ultrasound probe decontamination:

- a. decontamination can be fully manual (cleaning and disinfectant wiping); or

Figure 1 Immersible parts of a probe



b. it can be approached by manual decontamination of the non-immersible parts and selective immersion of the insertion tube in an EWD or by immersion of the whole device with non-immersible parts sealed in a watertight case.

**3.70** A controlled gross clean followed by both detergent clean and disinfectant wipe is an Essential Quality Requirement. A local risk assessment could indicate that manual cleaning immersion of the insertion tube in an EWD whilst manually cleaning and disinfecting the non-immersible parts would represent progress towards Best Practice.

**3.71** The facility for decontamination should include a suitable sink of adequate size for cleaning the probe. In addition, a clinical wash-hand basin is required. Storage facilities for disinfectants and cleaning materials including those used in wiping should be provided. The design of the facility used, be it in a separate room or incorporated in a clinical procedures room, should respect the need for a clearly designated flow from used (dirty) through cleaning and disinfection process to clean and available for storage and use. Separating dirty and clean areas is a major step in eliminating probe recontamination or mistakenly using a probe that has not been fully decontaminated

(see also Chapter 3 in HTM 01-06 Part A – ‘Policy and management’ and Chapter 1 in HTM 01-06 Part B – ‘Design and installation’).

**3.72** The process and flow referred to above could be in a separate designated room. Where the manual decontamination process is combined with the use of an EWD adapted for use with these probes, the space afforded should be adequate to continue the principles of a clearly defined flow of activity.

**3.73** Quality assurance and validation depend on a reliably applied local policy, procedures, operator training, supervision and record-keeping. Record-keeping should include:

- operator identity;
- the probe’s unique identifier (GS1 where available);
- a record such that the patient identity retrospectively be clearly established against the equipment used and the validated decontamination procedure applied;
- date and time;
- visual inspection (separate operator preferred);
- batch number or code such as to permit the materials or chemistry used in decontamination to be identified;
- evidence that the probe is operating satisfactorily (there is a duty of care on the clinical user to ensure this is the case);
- confirmation from the User that the probe has been satisfactorily decontaminated.

### Note

High-sensitivity post-decontamination protein quantification tests are being piloted. As these become validated and available, this guidance will be amended to incorporate their use.



## 4 Process chemicals

### Summary for commissioners and quality inspectors

Guidance is given on the properties of process chemicals used in an EWD cycle in relation to materials, the EWD process, load items and water-quality compatibility. Classes of detergents and disinfectants are discussed and the possible presence of residual chemicals retained on reprocessed endoscopes.

**4.1** Harm to endoscopes may result from some process chemicals. The reprocessing instructions supplied by the endoscope manufacturer should be followed carefully.

**4.2** A few process chemicals used in EWDs are incompatible with one another. Therefore the chemicals tested by the EWD manufacturer and detailed in the type-tests should be used. The EWD control settings need to match the chemicals used.

**4.3** Chemicals used in the reprocessing of endoscopes and their accessories should be compatible with the range of endoscopes in use. This implies that the chemicals employed are such that long-term damage to the endoscopes is acceptable.

All chemicals used in the EWD process should be CE-marked or generated from a CE-marked EWD.

**4.4** It is important to ensure that the formulation of each chemical is compatible with

the quality of water available. It is also important that the required concentration can be accurately and reproducibly generated by the dosing system(s) on the EWD and if reused there is a means to verify that the minimum effective concentration is not exceeded.

### Compatibility with the materials of construction of the EWD

**4.5** EWD manufacturers may specify some chemicals that over time will lead to accumulated damage to the EWD. The choice of process chemicals should be limited to those tested by the EWD manufacturer at the type-test stage, with supporting evidence of efficacy. Users should enquire about the erosive or damaging characteristics of the chemical agents recommended. The manufacturer should offer at least three different disinfectants and detergents suitable for their EWD.

**4.6** Chemical additives that can be absorbed into, or adsorbed onto, surfaces of the EWD (for example, plastic pipework) may be carried over into subsequent stages of the process.

**4.7** If the chemicals used in the EWD are changed, care should be taken that the new chemicals do not react with traces or deposits of the previous detergent or disinfectant. Advice should be obtained from both chemical and EWD manufacturers before any changes are introduced. The EWD manufacturer should have tested the proposed chemicals to determine their efficacy and the best settings of the EWD control system during type-testing.

## Compatibility with the flexible endoscopes being processed

**4.8** Flexible-endoscope manufacturers will advise on chemicals that may cause damage to their equipment. Use of such chemicals may invalidate any guarantee and cause irreparable, or very expensive damage, to the endoscope or accessories. Chemical damage to an endoscope also poses a risk to patients. Therefore, endoscopes should be fully inspected before patient use, and assurances should be obtained from the device manufacturers that warranties and guarantees will be upheld.

**4.9** As part of setting up an endoscope reprocessing unit or changing the EWD, information should be obtained from the endoscope manufacturer with regard to chemicals and maximum lumen pressures that are known to be compatible with their range of equipment.

## Compatibility with the quality of water used during the process

**4.10** See Chapter 2 in HTM 01-06 Part B – ‘Design and installation’.

## Detergents, enzymatic cleaners and disinfectants

### General

**4.11** Attainment of the specified concentration of detergent and disinfectant is essential to effective processing. The addition of too little will impair the process while too much is wasteful and contribute to unacceptably high residual levels and possible endoscope damage. The EWD manufacturer will have determined the most suitable chemical concentrations, and the EWD control system should be set to these values.

**4.12** Suppliers of detergents and disinfectants should provide details of the analytical methods that may be used to detect residual

concentrations of the products. 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.

**4.13** The automatic process should include means to ensure the removal of residual water, which might dilute disinfectants.

**4.14** Means should include verifying that all lumens to be irrigated with cleaning solution are not blocked, partially blocked or disconnected.

**4.15** Key factors in determining the efficacy of the process include:

- the concentration of the chemical disinfectant and detergent;
- the temperature of use;
- the contact time with the chemicals;
- the absence of inhibitory materials, such as residual soiling;
- confirmation that the process chemicals reach all part of the endoscope for cleaning and disinfection purposes;
- water quality.

**4.16** The material of construction of the EWD (see [paragraph 4.5, ‘Compatibility with the materials of construction of the EWD’](#)) and of the items in the load (see [paragraph 4.8, ‘Compatibility with the flexible endoscopes being processed’](#)) should not inhibit the disinfectant or detergent.

### Detergents

**4.17** Detergents can be divided into:

- acid detergents;
- alkaline detergents;
- anionic detergents;
- cationic detergents;
- non-ionic detergents;

- pH neutral detergents;
- enzymatic detergents.

**4.18** For use with flexible endoscopes, neutral or neutral enzymatic detergents are normally recommended as they have the least damaging effect on endoscopes (not all enzymatic detergents are neutral).

**4.19** Some EWD manufacturers recommend alkaline detergents, but they should be used with caution and under the manufacturer's stated conditions.

**4.20** The choice of detergent is a balance between efficacy and corrosion. Alkaline detergents are known for their good cleaning effect, but corrosion increases with temperature and their compatibility with materials can vary considerably depending on their formulation. Therefore it is important not to use alkaline detergents in an EWD that operates at an elevated temperature during the cleaning stage, otherwise endoscopes may suffer damage.

**4.21** When setting up a new EWD, it is recommended that the detergent detailed in the type-test document is used. The cleaning results should then be similar to the tests carried out when the EWD was developed. It is possible to carry out comparative cleaning tests using different agents, but it is not easy and will take the EWD out of service, as the dilution of the test detergent and stage time will need to be changed to suit recommendations.

### Enzymatic cleaners

**4.22** Enzymes used in enzymatic detergents can include either a mixture designed to digest protein, fat and carbohydrates or those in combination with other chemicals to assist cleaning. Enzymatic formulations always include buffering agents to maintain the pH within the preferred range, detergents and other components.

**4.23** Enzyme-based detergents will only be fully effective if both the time of contact with the detergent and the temperature at which this

occurs are controlled to meet the detergent manufacturer's recommendations. This may not always be feasible and therefore non-enzymatic detergents may be more suitable. During works tests, the EWD manufacturer will determine the parameters for the EWD operation that match the detergent selected for use with the EWD.

**4.24** Enzymatic formulations for cleaning solid surfaces are available in two forms:

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

**4.25** EWDs normally operate with a water pre-soak followed by a cleaning stage. Enzymatic agents can be used in the cleaning stage, but they operate best at elevated temperatures above 30°C and required at least 10 minutes to clean. Therefore enzymatic cleaners are not suitable for all EWD cycles.

**4.26** The inclusion of enzymes in the cleaning stage may give rise to allergic reactions. Care should be taken when choosing enzymatic-cleaning agents for manual cleaning; tests should be carried out to detect allergic reactions and sensitivity in humans.

### Disinfectants

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

**4.28** While these times may be reduced if the items are processed in a validated EWD with appropriate routine monitoring, the exposure time should in all cases be at least that specified by the disinfectant manufacturer. Elevated cleaning temperatures may allow the stage to be shortened.

**4.29** Instructions for use supplied with the disinfectant should include:

- the **quality of water** with which the product should be diluted;
- 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 **reuse life** – the extent to which the disinfectant may be reused. This may be specified as time, the number of load items processed or the number of disinfection cycles specific to a particular EWD.

**4.30** Diluted disinfectant should not be reused once it has been used as part of an endoscope process cycle: there is a danger of protein from one endoscope being deposited onto the next endoscope to be processed and over-dilution of the disinfectant.

*Criteria for selecting a chemical disinfectant*

**4.31** Chemical disinfectants differ in their ability to kill microorganisms. Although there are numerous disinfectant formulations available on the market, there are relatively few generic types of disinfectant suitable for chemical disinfection in EWDs.

**4.32** In order to choose a disinfectant for a particular application, it is necessary to know the microbicidal activity required – both the number and types of organisms that may be encountered and the assurance that they will be inactivated during the EWD cycle. Technical information from the disinfectant manufacturer should provide information about product activity.

**4.33** The disinfectant needs to be CE-marked (the EWD cycle data (type-test data) using selected disinfectants will be available from the EWD manufacturer).

**4.34** Glutaraldehyde is now no longer recommended for use when disinfecting flexible endoscopes due to its toxicity and fixative properties. Many alternative disinfectants are now available to process flexible endoscopes.

**Note**

The use of an aldehyde (including orthophthalaldehyde (OPA)) as the disinfectant is not recommended. This group of chemicals fix protein making its removal very difficult and has implications for the removal of prions associated with transmissible spongiform encephalopathies (see Chapter 5 in HTM 01-06 Part A – ‘Policy and management’) from an endoscope and EWD.

**4.35** The guidelines from various professional bodies are not in agreement on the use of disinfectants as the situation is complex. Furthermore, these guidelines may not be in accord with the recommendations from the manufacturer of the endoscope to be disinfected or from the manufacturer of the disinfectant. It is essential to comply with the disinfectant manufacturer’s recommendations as detailed in the type-test data. See also the Medicines and Healthcare products Regulatory Agency’s (MHRA) DB2002 (05) ‘Decontamination of endoscopes’ and ‘Sterilization, disinfection and cleaning of medical equipment: guidance on decontamination from the Microbiology Advisory Committee [MAC] to the Department of Health’ (also known as the ‘MAC manual’).

**4.36** The disinfectant solution should be used once and discarded. This system is recommended as the concentration and antibacterial activity of the disinfectant is known for each cycle. Older EWDs that reuse disinfectant solutions for a number of cycles should ensure that the automatic cycle should not start when the disinfectant concentration has fallen to, or below, the minimum recommended by the manufacturer or that established by independent testing. If this

system is not available, a cycle counter should be set to alarm when the maximum of uses have been made of the diluted disinfectant.

**4.37** The control system should permit regulation of pump pressure and inlet pressure to the various connections to suit the endoscope being routinely processed.

**4.38** The following is a summary of the main classes of disinfectants used to process flexible endoscopes:

#### *Aldehyde-based disinfectants*

**4.39** This group of chemicals is widely used in EWDs and provides a reliable disinfection service. However, with the requirement to protect patients from Creutzfeldt-Jakob disease (CJD) carryover, these chemicals are now not recommended. Aldehydes fix protein onto surfaces and make subsequent removal a greater challenge than normal.

#### *Peracetic acid*

**4.40** Disinfectants based on peracetic acid have some, mostly minor, corrosion capacity and the manufacturer's assurance of compatibility should be obtained and instructions followed. Peracetic acid disinfectants are supplied as components that need to be mixed in specific ratios to attain an active solution. It is an advantage if this is done by the EWD rather than manually.

#### *Halogen-based disinfectants*

**4.41** Halogen-based disinfectants (chlorine being the most popular) have the potential to corrode metal and some plastics. Precautions may be necessary to prevent this action. The recommendations of the chemical manufacturer should be followed to prevent damage to both endoscopes and EWDs.

#### *Electrolytically generated hypochlorous acid*

**4.42** Electrolytically generated hypochlorous acid is used in many EWD disinfection systems. The disinfectant is produced and supplied on-

site via an external generator that directly supplies the EWD. The generator is required to be CE-marked. The disinfectant has a limited life: therefore, it is recommended that the following precautions be taken:

- Before starting an EWD cycle, if there has been a delay since last use, the liquid in the supply tube should be dumped to drain. This should be done automatically at the start of each day's work.
- If the hypochlorous acid generator is not installed in the same room as the EWD, there should be a visual indication that the generator is operating correctly. This would allow the User to confirm disinfectant activity.
- The water supply used for the final rinse should have a TOC below 1 mg/L as an additional criterion.
- The recommendations of the manufacturer should be followed to prevent corrosion damage to endoscopes.

**4.43** Electrolytically generated hypochlorous acid may be used as the main disinfectant and added to the final rinse-water to kill contaminating organisms.

## Safety of EWD chemicals

**4.44** Safe storage provision is needed for containers of chemicals used in the EWD. These chemicals are irritants, toxic and frequently corrosive. Provision should be made in, or adjacent to, the storage area for an emergency eye-wash station, a source of running water to dilute any spillage and a spills kit.

**4.45** Employers are required by law to do everything that is reasonably practical to protect the health of their workers. The safe use of these compounds is covered by the Control of Substances Hazardous to Health Regulations (COSHH).



**4.46** A spills kit suitable for endoscopy units should contain at least:

- absorbent granules/powder – to absorb liquid spills;
- absorbent sock – to contain liquid spills;
- chemical inactivator – to neutralise a chemical spill;
- Fuller’s earth – to inactivate a spill if the neutraliser is not available and soak up liquid;
- plastic apron, gauntlets and respirator/mask – personal protective equipment (PPE);
- orange bag – for containing clinical waste;
- dust-pan and brush – to sweep up granules and Fuller’s earth, if used.

**4.47** The spills kit should be kept outside the decontamination room, but be easy to access in the event of a spill. This allows the operator to leave the area of immediate danger and don appropriate PPE prior to returning to address the spill.

**4.48** Suppliers of both detergents and disinfectants used should provide material safety data sheets for the products supplied. These should include details of biocompatibility studies.

**4.49** A hazard from EWD chemicals is when stock containers of concentrate are changed. Strict precautions and PPE in line with local risk assessments are required: chemical resistant gloves/ gauntlets, respirator/mask (grade to suit chemical being handled), apron and good ventilation.

**4.50** In large installations, bulk storage tanks for chemical additives required for the process may be preferred with a piped distribution system to each EWD.

**4.51** When the disinfectant solution is to be discharged to drain, the drainage system

should be trapped, sealed and vented to a safe position. The drainage system should be checked to ensure that it is not possible for chemical vapours to be vented into any other part of the building (see tChapter 4 in HTM 01-06 Part E – ‘Testing methods’)

**4.52** The EWD should be an enclosed system. It is a requirement for the lid to be locked before it is possible to start a cycle. If a cycle aborts during the disinfection stage, there should be an automatic rinse before the operator can access the load with the use of a key or code. Some EWD disinfection systems use non-toxic disinfectant, and a rinse stage may not be necessary in the even of cycle failure.

**4.53** For EWDs employing volatile chemicals, the exhaust ventilation must maintain the environmental concentration below any limit specified for occupational exposure and the discharge must be to a safe place.

## Residual chemicals

**4.54** The chemical additives used during the EWD process (detergent, disinfectant etc) may not be completely removed by the rinsing stage.

**4.55** The residual level that may be tolerated will depend upon the nature of the chemical and the intended use of the flexible endoscope. Depending on the site the endoscope is used, patients’ sensitivity to the residual chemical will vary. Therefore as EWDs can process endoscopes to be used in many sites, it is important that the reprocessed endoscope has no detectable chemical carryover from the process unless the disinfectant is non-toxic.

**4.56** The supplier of any chemical agent used should provide data on the chemical composition of the chemical agent, method of detection and its compatability with the EWD and endoscopes.

**4.57** Sampling methods and analytical method should be capable of determining the maximum acceptable level.



**4.58** The rinse process efficacy to remove residual chemical should be tested using twice the normal concentration of the chemical in a routine operating cycle. The test load should be a surrogate endoscope. Analysis of the final rinse-water residual chemical should form part of the type tests carried out by the manufacturer unless the disinfectant is non-toxic (see Chapter 13 in HTM 01-06 Part E – ‘Testing methods’).

**4.59** An exception to the guidance are EWDs where diluted disinfectant is added to the final rinse-water. The rinse-water will then not support bacterial growth. The concentration of

the chemical in the final rinse should be non-toxic to humans.

#### Maximum acceptable residual chemical level

**4.60** The concentration of chemical on the surrogate device or simulated endoscope (see BS EN ISO 15883-4) should be lower than the specified maximum acceptable level. If this test fails, additional final rinses may be required to validate removal of the residual chemical to an acceptable level.

**4.61** If disinfectant is added to the final rinse-water, the EWD manufacturer will provide information on the chemical levels expected.

## 5 Tracking, traceability and audit trail

### Summary for commissioners and quality inspectors

With the emergence of transmissible spongiform encephalopathies (TSEs), the importance of tracking and tracing the journey of flexible endoscopes through decontamination and clinical use is underlined. The need to identify endoscopes with patient episodes and the ability to record these events is discussed. Outlined is the information required for successful traceability together with audit trail requirements and testing systems. Information is provided on the requirements of a tracking system, either manual or computerised, with an example of operation. Audit security of tracking and traceability systems are covered with reference to relevant guidelines.

**5.1** It is essential for healthcare organisations to operate a tracking and traceability system to allow endoscopes to be tracked through each stage of the decontamination process to ensure the processes have been carried out effectively.

**5.2** An effective tracking and traceability audit trail should ensure it is possible to identify the complete life cycle of a unique endoscope. To ensure patient safety, it should be possible to identify that an endoscope has been through a compliant decontamination cycle prior to being used on a patient.

**5.3** In addition to tracking progress of an endoscope and its attachments through decontamination, it is also necessary to identify

the patients who come in contact with each endoscope and any reusable tools and equipment used during the procedure.

**5.4** Any tracking and traceability system, once in use, should be tested to determine whether the system can handle likely events such as:

- an endoscopy patient subsequently found to suffer from vCJD;
- an endoscope placed in quarantine, pending its future;
- an endoscope sent off for refurbishment;
- an endoscope found to have a blockage that has been present for some time;
- a fault found with the EWD that has affected endoscopes processed for the last few days.

**5.5** The Best Practice objective for endoscope decontamination facilities should be to operate management and quality systems in compliance with BS EN ISO 13485 and operate in a manner consistent with Annex V of the Medical Devices Directive with regard to quality systems and surveillance. Computerised tracking, traceability and quality audit are key components of such a quality system and should cover all endoscopes processed, including those placed in quarantine and sent off for refurbishment.

### Tracking

**5.6** Flexible endoscopes are expensive pieces of equipment and if they have to be quarantined as a result of exposure to vCJD and then

subsequently destroyed or relined, there is a large cost attached. Therefore tracking of individual instruments and accessories, which includes identification of the endoscope's location, is essential, otherwise clean endoscopes may be quarantined due to a lack of information.

**5.7** It is vital that all endoscopes in the department have a unique identifier so that they can be recorded through each stage of the decontamination process and to the patient. If they cannot be distinguished from identical endoscopes in the department, then all endoscopes in that department should be destroyed or relined because of the possibility of their having been exposed to vCJD; this is in accordance with guidance from the CJD Incidents Panel.

**5.8** It can be a challenge to attach a permanent unique identifier to a flexible scope, especially one that is both machine- and human-readable. There are several systems now available including bar-coding on a chemical-resistant label and etching the instrument with a unique mark that can be machine-read. All endoscopes are uniquely identifiable by their serial number.

**5.9** Buttons and other permanent accessories to a particular endoscope need to be marked as they have the potential to carry and transfer organisms and protein from patient to patient.

**5.10** In 2007, the DH issued of 'Coding for success: simple technology for safer patient care'. This states:

"The Department of Health is recommending that the GS1 System should be adopted throughout the healthcare system in England, both for manufactured products and for coding systems used within healthcare settings. Where possible, the GS1 coding standard should be adopted, and endoscopes marked with a GS1 code, not a proprietary code."

**5.11** A tracking, traceability and audit trail system should enable the User to generate and maintain an inventory of uniquely identified endoscopes.

### Important note

Traceability cannot be achieved if the endoscope and its accessories are not uniquely identified.

### Traceability

**5.12** A traceability system should record each process of the decontamination cycle to ensure that only endoscopes that have been reprocessed correctly and within the documented timescales can be safely used on a patient. The system should ensure endoscopes are effectively and accurately traced through manual wash, through an EWD, through a drying cabinet (and finally to use on a patient). If an endoscope is kept in a storage cabinet and reprocessed on exit, this also should be recorded. The traceability system should also include information on loan endoscopes.

**5.13** Traceability records should consist of the following:

- uniquely identified endoscope and accessories (preferably GS1 system);
- manual wash result (pass/fail) including visual inspection, manual leak test and cleaning of valves;
- when required, chemicals used during the manual wash and EWD process;
- EWD used;
- EWD cycle number;
- EWD result (pass/fail);
- where required, record of the drying cabinet an endoscope has been stored in;
- data to show correct operation of the drying cabinet;

- evidence that the endoscope is fit for use on a patient, for example checks to see whether all components are present;
- compliance to shelf-life requirements;
- patient identification;
- the responsible operator at each operational stage;
- all data entries dated and time-stamped.

## Audit trail

**5.14** The system should have the capability to produce “product to patient” and “patient to product” reports in a timely manner. The reports should allow the User to determine that the uniquely identified endoscope has been through a compliant decontamination cycle prior to being used on a patient.

**5.15** The data system should be able to highlight any non-compliant processes within the EWD, manual cleaning or drying cabinet.

## Maintenance

**5.16** The system should enable the User to record the following:

- EWD self-disinfection cycles;
- EWD maintenance cycles;
- EWD validation cycles;
- storage cabinet maintenance;
- storage cabinet validation;
- list of accessories;
- unique endoscope repairs;
- unique endoscope status (quarantine);
- use of loan equipment (preferably marked using the GS1 system).

**5.17** System training:

- A training plan should be agreed between the customer and supplier of the EWD, endoscope manufacturer and the tracking and traceability system provider.
- The suppliers should provide a documented training record for the staff that has completed the training.
- System user manuals should be provided.
- A lumen diagram should be provided by the endoscope supplier for each type of endoscope used in the department together with the connection system to the EWD.

## Testing tracking, traceability and quality systems after installation

**5.18** The supplier should provide the customer with evidence to indicate that the system has been installed in accordance with their specification. An audit history report containing the information listed in ‘Traceability’ should be provided.

**5.19** Maintaining the traceability of endoscopes and accessories that are transferred between organisations has always been difficult, and the trend for cross-site lending is increasing. Therefore, if possible, arrangements should be made with the source of the loan endoscopes in advance of any loan, to determine how traceability records are to be kept.

**5.20** The primary reason for the traceability problem is that once an endoscope has been moved, it is no longer under the single control of the owner, but split between the various organisations. Although it would be possible that the receiving and lending organisations have processes and controls in place to handle the receipt and return of endoscopes, it is unlikely that the owner could produce an uninterrupted audit record if it was ever required.

**5.21** In order to provide the best possible patient care and to minimise the risk of cross-infection from the use of loan endoscopes, it is strongly recommended that a full decontamination and usage history be maintained at all times.

**5.22** There should be an electronic method to capture the movement of an endoscope and accessories between sites, or a facility to centrally record a full decontamination cycle and usage history.

**5.23** It should be possible to trace the full decontamination cycle, including use on a patient of the loan endoscope within the tracking and traceability system.

**5.24** If there is no other system available, a print-out of all the available data on endoscope decontamination and use should be produced to send out with the used decontaminated endoscope to provide information for the next User. This data should not contain a patient's details, just a code that can be traced back to a patient if required.

## Tracking, traceability and quality system options

### A fully computerised floor management system

**5.25** This option is the most effective and provides a mechanism to ensure accurate data is recorded at each stage of the decontamination cycle. A computerised system should allow the User to generate historical decontamination and usage reports in a timely manner.

### Manual system

**5.26** This system will not be as effective, but will still provide the User with a mechanism to record accurate information at each stage of the decontamination cycle. Considerable storage space will be required for data archive purposes. Obtaining historical decontamination and usage reports will be very labour-intensive.

Reports for audit purposes will also be time-consuming and may not meet the standards of the inspection authority.

### Example specification for a computerised tracking system

**5.27** This is an example of a single-module computerised tracking and traceability software solution for use in endoscope reprocessing units. It allows the User to track and trace the endoscope decontamination process through manual wash, EWD, storage and finally to use on a patient. The use of the GS1 HL7 standard is included.

**5.28** The use of a pre-existing program makes the system easier to use and ideal for endoscope reprocessing units. When choosing an endoscope tracking system, it is wise to choose one that has been used in similar circumstances. There are several software systems on the market; contact with an existing User will often determine whether the selected system is suitable for a particular department.

**5.29** Bar-code technology is used to capture data at each stage of the decontamination process. At every stage the operator and the unique endoscope number is captured. There are several methods of marking equipment; the choice is dependent on reliability, ease of reading and cost of marking new equipment, including buttons and accessories.

**5.30** The example is password-controlled for management administration purposes. The reporting package allows the User to produce meaningful detailed endoscope reprocessing and endoscope usage reports. The system database records every event and builds a valuable history, which can be used as an effective management-reporting tool. The software can be located on a stand-alone computer workstation or can be networked.

**5.31** Example of computer tracking requirements:

- tracker software;



- client server licence;
  - computer workstation;
  - label printer;
  - laser printer;
  - bar-code or other reader system;
  - uninterruptible power supply (UPS) (recommended for protection against mains failure of workstations and server);
  - specialist consumables (tracer labels, ribbons, endoscope labels etc);
  - installation and commissioning;
  - training;
  - ongoing support for both hardware and software.
- details of the cleaning solution together with the dilution used;
  - details of the cleaning solution batch;
  - details of the cleaning solution use-by date (expiry);
  - cleaning solution details;
  - time-and-date recorded entries written to the audit trail;
  - confirmation that the scope has been leak-tested and manually cleaned in accordance with internal procedures.

## An example of the journey of an endoscope through the system

### Endoscopy suite

**5.32** The tracker system should allow the User to track and trace the endoscope decontamination process through manual wash, EWD, storage and finally to use on a patient on a single computer system.

### Manual wash

**5.33** Endoscopes should be recorded through the initial rinse in the operating/clinical room and the manual wash process. This activity may be achieved by manual input using a computer keyboard and mouse, or by scanning the unique endoscope identification tag, together with the identification of the operator who carried out the work.

**5.34** Manual wash key functions may include:

- record of the manual leak test plus inspection;
- record of the endoscopes through the manual wash process;
- record of the operator responsible;

### EWD process

**5.35** Endoscopes should be recorded through the EWD process. This activity may be achieved by manual input using a computer keyboard and mouse or by scanning the unique endoscope identification tag.

**5.36** EWD load key functions could include the following:

- record of the endoscopes into the EWD;
- record of EWD number;
- EWD cycle number;
- endoscope cycle number;
- records of any comments against the cycle;
- load may be left pending for multi-chamber EWDs;
- the operator responsible;
- cleaning solution and disinfectant details;
- cleaning solution and disinfectant batch details;
- cleaning solution and disinfectant use-by date (expiry) details;
- cleaning solution and disinfectant details;
- all time- and date-stamped entries written to the audit trail.



**5.37** Not all EWDs will have all the listed options; an additional traceability system may be required.

**5.38** EWD unload key functions could include:

- leak-test results;
- record of endoscopes out of the EWD;
- EWD number;
- EWD cycle number;
- endoscope cycle number;
- cleaning solution and disinfectant details;
- load may non-conform;
- individual items may non-conform;
- reasons for non-conformance (manual entry);
- reasons for non-conformance (using bar-code labels);
- the operator responsible;
- patient tracer label;
- all time- and date-stamped entries written to the audit trail.

### Drying cabinet

**5.39** Endoscopes should be recorded into and out of a drying cabinet. This activity may be achieved by manual input using a computer keyboard and mouse or by scanning the unique endoscope identification tag.

**5.40** Cabinet load key functions include:

- record of endoscopes into the cabinet;
- endoscope cycle number;
- records of any comments against the cabinet;
- the operator responsible;
- all time- and date-stamped entries written to the audit trail.

**5.41** Cabinet unload key functions include:

- record of endoscopes out of the cabinet;
- endoscope cycle number;
- the operator responsible;
- patient tracer label;
- all time- and date-stamped entries written to the audit trail.

### Endoscope to patient

**5.42** The use of an endoscope to a patient should be recorded. This activity may be achieved by manual input using a computer keyboard and mouse or by scanning a unique patient identification tag.

**5.43** Endoscope to patient key functions include:

- record of unique endoscope to a unique patient;
- endoscope cycle number written to the audit trail;
- the operator responsible;
- procedure date;
- procedure time;
- all time- and date-stamped entries written to the audit trail.

### Operators and engineers

**5.44** Operators and engineers should perform daily maintenance and routine testing activities, and these should be recorded onto the system.

**5.45** Operator and engineer key functions include:

- the operator responsible;
- details of new cleaning solutions and disinfectants;
- details of cleaning solutions and disinfectants;

- daily operator EWD validation cycles;
- non-planned engineer EWD tests;
- daily, weekly, monthly and yearly EWD validation cycles;
- EWD self-disinfection cycles;
- EWD load details;
- viewing of EWD and cabinet contents at any time;
- all time- and date-stamped entries written to the audit trail.

### System administration

**5.46** Day-to-day administration of the tracker system may be conducted in the administration section of the module. The administration module section should form the backbone of the tracker system. Depending on the manufacturer, the system may have the following characteristics:

- clear and simple methodology requiring minimal keyboard input to operate its functions;
- all records held in the system should be simple to locate and report on, and adding new records should be simple;
- most housekeeping tasks should be accomplished with User instruction input, for example self-disinfection programmed at a convenient time for the endoscope reprocessing unit;
- the system should monitor all endoscopes processed through the endoscopy suite whilst providing an audit trail that documents manual wash, automated reprocessing, cabinet storage and finally use on a patient;
- the software system should be designed so it cannot be altered once written, otherwise it will be of little value as evidence if required at a later date;
- the audit trail should also identify those responsible and highlight conformance

and non-conformance with the procedure.

**5.47** Key functions of administration could include:

- supplied with a manual backup system;
- system administration functions to be restricted to authorised personnel;
- comprehensive endoscope inventory should be available;
- endoscope inventory details should be maintained;
- new endoscopes should be added to the inventory by the User;
- endoscope details may be edited by the User;
- endoscope inventory detail reports may be produced by the User;
- endoscope inventory bar-code (or other method of identification) booklet may be produced by the User;
- process bar-code (or other method of identification) booklets may be produced;
- operator name badges may be produced by the User;
- administrator passwords should be granted;
- extra processes may be recorded against an endoscope by the User;
- protein-monitoring system for cleanliness check should be recorded against an endoscope;
- endoscopes may be removed from and returned to use following a period of quarantine by the User;
- the reason the endoscope has been removed from use should be recorded by the User;
- endoscopes may be sent to and returned from repair by the User;

- the reason the endoscope has been sent for repair should be recorded by the User;
- repair location details should be entered;
- new cleaning solution and disinfectant details should be added;
- cleaning solution and disinfectant details may be edited by the User;
- cleaning solution and disinfectant details may be deleted by the User;
- non-conformance bar-codes (or other method of identification) may be produced by the User;
- non-conformance bar-code (or other method of identification) details may be edited by the User;
- non-conformance bar-code (or other method of identification) details may be deleted by the User;
- audit history reports should be produced;
- production charts may be produced;
- repair reports should be produced;
- EWD history reports should be produced;
- comprehensive product to patient reports should be produced by the User;
- comprehensive patient to product reports should be produced by the User;
- EWDs should be named and identified;
- EWD cycles may be set and amended;
- appropriate EWD data may be set;
- drying cabinets should be named and identified;
- appropriate cabinet data may be set;
- system may be set to print patient tracer after EWD use or after drying cabinet storage by the User;
- number of patient tracer labels required may be set by the User;
- type of patient tracer label may be selected by the User;
- system configuration changes should be recorded;
- system configuration change reports may be produced by the User;
- the system may be configured to enable or disable manual wash process by the User;
- the system may be configured to enable or disable endoscope use to patient by the User;
- the system may be configured to enable and disable the solution screen on reprocessing by the User;
- the system may be linked to the Unisoft G1 or other clinical reporting system;
- the system may be configured to display a message if the endoscope has not been in a cabinet;
- EWD to use shelf-life may be configured by the User;
- EWD to cabinet shelf-life may be configured by the User;
- drying cabinet to use shelf-life may be configured by the User;
- EWD self-disinfection shelf-life may be configured by the User;
- maximum drying cabinet time may be configured by the User;
- the system may be configured to skip self-disinfection by the User;
- the system may be configured to skip enforced manual wash by the User;
- the system may be configured to skip the drying cabinet by the User;
- the system may be configured to disable the drying cabinets by the User;

- the system may be configured to enable or disable the requirement to record the operator's name by the User;
- the system may be configured to request patient confirmation by the User;
- endoscope unique identification tags may be produced by the User;
- printer settings may be configured;
- additional patient labels from the last cycle may be produced by the User;
- inventory display details may be configured by the User.

## Tracking and traceability audit

**5.48** The tracking and traceability system described is similar to a chain. Each link should be in place and shown to work, otherwise the chain will fall apart.

**5.49** Attention to detail is important to ensure all data is captured at the correct time. Errors or omissions can be difficult to rectify later.

**5.50** Computer-based tracking and traceability systems should have checks and balances built into the software so Users are made aware of any errors or omissions.

**5.51** Internal or external audit of a tracking and traceability system can be undertaken at different levels:

- a. The highest level of audit should take place during installation and commissioning to prove each element of the system works.
- b. A six-monthly audit should be carried out and may take the form of a system overview by the computer. All records should be scanned to determine whether there are any errors or omissions.
- c. A limited audit should take place if:
  - (i) any software systems have been changed;

- (ii) any endoscopes or accessories have been added to the inventory;
- (iii) any endoscopes or accessories have been taken out of service;
- (iv) any operators or Users change;
- (v) the endoscope equipment labelling system is changed.

**5.52** It is likely that an endoscopy department will be subject to external audit (see [Chapter 6, 'Audit of flexible-endoscope decontamination'](#)).

**5.53** See also [paragraph 6.9, 'Audit – decontamination'](#).

## Tracking and traceability security

**5.54** A backup of the tracking and traceability system should be available and stored off-site in a secure place.

**5.55** A password system should be used to prevent unauthorised access to the data.

**5.56** Patient data should be in the form of codes unless the system is protected.

**5.57** The system database should be well regarded by the trade, reliable and the appropriate licences should be in place.

**5.58** The data system should be able to support different identification systems, for example:

- Bar-code EAN13 and EAN128;
- two-dimensional data matrix;
- NHS data interchange (for example, HL7);
- RFID (radio frequency identification).

**5.59** Loan equipment should be able to be entered onto the tracking and traceability system using the NHS data interchange, for example HL7.

**5.60** Printed labels should have a life of at least 10 years, and the data should be capable of extraction and deposition in a variety of formats

to allow long-term retention of the information, often in excess of any one data-handling solution.

**5.61** To aid security, the tracking and traceability system supplier or agent should be able to support the system in case of maintenance, breakdown or reconfiguration.

**5.62** Data from the tracking and traceability system should be backed-up. Users should be satisfied that system back-up is available to ensure rapid data recovery in the event of a component failure in the data management system.

**5.63** It is essential to involve the hospital IT department, both with communication between the tracking and traceability system and the hospital network, and for advice on system back-up and operation.

**5.64** If the tracking and traceability system chosen for endoscopy is based on an existing tracking and traceability system used within the hospital sterile services department arrangements for the installation of the new system, communication and backup by the hospital will be much easier to arrange.

## 6 Audit of flexible-endoscope decontamination

### Summary for commissioners and quality inspectors

The purpose of audit is discussed and the guides that can be used to carry out the exercise. Audits may be internal or external to the decontamination department, but they may include the same material to be examined. Guidance is given to the areas covered by audit, including equipment history, testing of systems, tracking and traceability. Internal audit information is provided with actions required if non-compliances are found.

**6.1** The audit of flexible-endoscope decontamination requires knowledge of how the department works and access to suitable audit tools. Expertise in decontamination is essential to set up and operate flexible-endoscope decontamination, as flexible endoscopes are a challenge to clean and disinfect. A full understanding both of the decontamination process and the internal structure of the endoscopes in use is required to obtain a satisfactory outcome. The expertise of an AE(D) should be utilised in any audit of endoscope decontamination facilities and processes.

**6.2** The purpose of audit is to determine if endoscope reprocessing is suitable for purpose and if it meets Essential Quality Requirements. Audit is limited to the information at its disposal, but the aim is to confirm systems are in place to provide endoscopes safe for next patient use, being clean and free of biological contamination.

**6.3** Audit can take four forms, for example:

- a. internal audit as an on-going quality control survey;
- b. external audit, when an audit officer from outside the organisation examines the department against the Infection Prevention Society's (IPS) audit tool;
- c. audit against quality standards such as BS EN ISO 13485;
- d. audit to address specific issues/ compliance with guidance and standards.

### Internal audit – decontamination

**6.4** Internal audit can be adapted to suit a particular endoscopy department. No two endoscopy departments operate in exactly the same manner, and there are several ways of achieving a satisfactory result.

**6.5** An internal audit tool can be divided into small sections, so not all the department is audited at the same time. It will flag up problems early so they can be resolved before becoming a major issue.

**6.6** If audit documents are filed close to the decontamination area, this can simplify the task for an external auditor seeking clear evidence of compliance. Conversely, deficiencies or risks can be more readily spotted. In addition, evidence may be provided to show that problem areas are in the process of being addressed.

**6.7** The key to effective internal audit is to give the process the time it deserves. As a result,



changes should occur with actions addressing any identified shortfalls. Audit should be carried out regularly.

**6.8** Staff may require tuition and training on how to carry out an internal audit of their endoscopy unit.

## Audit – decontamination

**6.9** It is strongly recommended that endoscopy units should audit their reprocessing units quarterly using the IPS audit tool (forthcoming).

**6.10** Not all facets of the IPS audit tool apply to endoscopy departments in all areas, as there will be operational variations. If the unit can show that the practice in use is at least as good as that of national guidance, this will normally be satisfactory. If a novel procedure is in use, then evidence should be available to demonstrate its effectiveness.

**6.11** A full documented history of each EWD will be required including:

- initial commissioning report;
- annual validation reports;
- quarterly reports;
- weekly test results;
- data on the disinfectant in use;
- evidence of routine maintenance;
- data on the final rinse-water quality.

**6.12** An audit of endoscope decontamination will include a review of the following processes:

- removal of the endoscope from the patient and its preparation for decontamination;
- handling of the endoscope in transit from operating area to the decontamination area;
- manual leak test;
- manual wash;

- transfer and connection to the EWD;
- operation of the EWD;
- transfer of the endoscope to either the operating room or into the storage/dryer;
- the endoscope drying/storage system;
- preuse checks of the endoscope and the quality of water used.

**6.13** In addition to checking the above processes, audit will also involve a review of health and safety including infrastructure, ventilation, spillage policies, protective clothing and handling of chemicals.

**6.14** Tracking and traceability will also be covered during and audit. There should be a clear understanding by all endoscopy staff of how the local system works. The audit tool should identify the critical points in the tracking and traceability system and check they are satisfactory. The tracking and traceability should be tested by taking a current patient identification number and checking that the endoscopes and reusable accessories used on this patient can be tracked against patients who have been in contact with these devices over the preceding three months, or longer. In addition, an endoscope should be identified and checked that the patients on whom it has been used can be identified over the preceding three months. Checks will also be required to identify how loan endoscopes and reusable accessories are tracked and traced during their use in the department. In addition a check could be made of the history of loan equipment and how much information the loan company provide and require on the return of the endoscope (see also [paragraph 5.48, 'Tracking and traceability audit'](#)).

**6.15** The maintenance and testing of the EWD will form part of the audit as listed above.

**6.16** The method of checking the cleaning stage of the EWD will be included in the audit, as this is a critical part of the EWD cycle.

**6.17** It is difficult to test the quality of decontamination of an individual endoscope, and therefore data on the dilution of the disinfectant together with proof that the chemical is CE-marked will be required. If the disinfectant is produced locally from a CE-marked generator, a copy of the CE certificate should be available.

**6.18** A record of the disinfectant activity at the dilution in use from an independent laboratory or the EWD type-test data from the manufacturer should form part of the background information.

### Internal audit organisation

**6.19** The following is a suggested method of setting up an internal audit based on the IPS audit tool.

**6.20** The short form audit should take place on a regular basis to keep a check on standards and non-compliances noted for action with date lines.

**6.21** A list of non-compliances should be kept available for inspection by any visiting inspector. Regular checks on areas of non-compliance

should take place to ensure the required actions listed are moving forward.

**6.22** The completed audit form should be dated, the unit identified and the name of the person carrying out the audit included.

**6.23** On completion of the internal audit, the User should review the list of non-compliances. This list can form the basis for action, with date lines, to correct the problems or highlight them to other authorities.

### Examples of audit tool forms

**6.24** An example section of an audit listing specific questions requiring “Yes/No” is given below.

**6.25** Completed audit forms and a non-compliance list should be filed and copies forwarded to the User, Decontamination Lead, infection prevention and control team and risk management group. It is important that appropriate action follows an audit, as this is the purpose of the exercise. The Care Quality Commission (CQC) or equivalent regulatory body may regularly request copies of the non-compliance forms enabling them to check the timescale of highlighted improvements.

Audit area	Yes/No	Comment/action
EWD operation: does the EWD have a maintenance contract?		
Was an initial commissioning carried out?		
Was the initial commissioning satisfactory?		
Are weekly TVC checks carried out?		
Are the TVC results below 10 cfu/100 mL?		
Are quarterly tests carried out?		
Are the quarterly tests satisfactory?		
Are annual tests carried out?		
Are the annual test results satisfactory?		
Is there an EWD logbook available in the unit?		
Are the EWD connectors available for all the endoscopes to be processed?		

# Particular specification for endoscope washer-disinfectors (EWDs)

## Section 1

Refer to Health Technical Memorandum (HTM) 01-06

<b>Name of Trust</b>	<b>Details</b>
<b>Purchaser</b>	
<b>Hospital site</b>	
<b>Department</b>	
<b>Name of User and contact details</b>	
<b>Name of estates contact and details</b>	
<b>Authorising Engineer (Decontamination)</b>	

The machine(s) are to be supplied under the Trust Contract Conditions or the NHS Supply Chain framework agreement.

**Note:** Site visit(s) are required by the supplier to ensure that the machine(s) will fit correctly and that no problems will be encountered during the delivery process. All engineering systems and services should be surveyed during the visit(s).

Standards relevant to this equipment:

BS EN ISO 15883-4:2009. Washer-disinfectors. Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes.

**Standards relevant to decontamination management**

BS EN ISO 13485:2003. Medical devices. Quality managements systems. Requirements for regulatory purposes.

**Standards relevant to safety requirements for decontamination equipment**

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

BS EN ISO 13849-2:2008. Safety machinery. Safety-related parts of control systems. Validation.

**Standards relevant to medical devices**

BS EN 1041:2008. Information supplied by the manufacturer of medical devices.

BS EN ISO 17664:2004. Sterilization of medical devices. Information to be provided by the manufacturer for the processing of resterilizable medical devices.

BS EN ISO 14971:2009. Application of risk management to medical devices.

**1 EWD selection details**

**Total number of machines required .....as below**

The audit should highlight all lumen configurations and specific reprocessing requirements for each endoscope in alignment with its manufacturer’s instructions (endoscope).

Scope connectors and accessories: these can incur additional costs and should be considered thoroughly during the procurement process.

Consideration should be given to the reprocessing of endoscopes that may have a typical lumen configuration.

<b>EWD type</b>	<b>Standard cabinet EWD</b>	<b>Drying cabinet</b>
<b>Numbers of machines</b>		
<b>Chamber capacity (nominal)</b>		
<b>Special requirements</b>		

**Special processing requirements**

## 2 EWD cycles requirements

Cycle	Required (yes or no)	Options and comments

## 3 EWD process chemicals – options

Chemistry used within operating cycles	Required (yes or no)	Options and preferred choice
<b>Wash detergent</b>		
<b>Chemical disinfection</b>		
<b>Self-disinfection (if required)</b>		
<b>Other(s)</b>		

#### 4 EWD self disinfection – options

4.1 Research indicates that thermal disinfection is a more efficient method of reducing internal biofilms, which may form within the internal supply pipework of the integral water systems.

Self-disinfection method	Required (yes or no)	Options and preferred choice
Chemical		
Thermal		

#### 5 Details of delivery/installation requirements

5.1 Any comments on interim storage requirements or installation of the delivered equipment prior to final installation.

5.2 It is the responsibility of the supplier to establish the site access, route and requirements of delivery of the equipment to the final installation site.

**Comments**

#### 6 Delivery details of packing methods

**Select:**

**Standard packing for basic weather protection - A**

Good weather covering to protect machines under delivery - B

Dust-proof packing and wrapping for further storage needs - C

Dust-proof packing and timber casing - D



## 7 Removal and disposal of existing plant, equipment and services

### Details:

Washer-disinfectors

Plant

Services

## 8 Drawings

8.1 Layout drawings should be submitted to the User prior to tender to view the details of the installation.

8.2 Any drawings such as engineering services supplied by the supplier or required by the User should be clearly agreed and defined during the tender process.

8.3 All service(s) and connections should be agreed by the supplier and User (or representative) during the tender process. These connections will then be clearly illustrated on the drawings as submitted with the tender.

## 9 Documentation

9.1 Machine manuals should be supplied with the EWDs on site delivery.

## 10 Air supply (if required)

10.1 Compressed air may be required for EWD operation.

10.2 It should be agreed at the tender how the air will be supplied to the EWD(s).

Select one or more:

A Individual machine compressors

B Central compressor supply

C Other

### Comments

## 11 Heating medium (thermal disinfection)

11.1 EWDs may be steam- or electrically heated in the various stages. Medium choice will affect the cycle time. The supplier should discuss the options available and services required with the User.

### Comments and details

## 12 Electrical supply

12.1 It should be agreed at the tender stage what the electrical loading/demand is for the installation.

12.2 Discussions should be held with the relevant estates department officers and the suppliers to determine the supplies in general, and if single- or three-phase is available or required.

### Further details

## 13 Water supply

13.1 An assessment should be carried out on the supply water used in all phases to the EWDs prior to the procurement process.

13.2 A decision on what further treatment is required can be assessed in conjunction with the User and AE(D).

13.3 The supplier should provide advice on the minimum supply pressure(s) required at each stage of the process(s).

### Further details

**Details of water treatment (if required)**

Water treatment	Required (yes or no)	Comments and details
<b>Filtration requirements</b>		
<b>Softeners</b>		
<b>Other(s)</b>		

**14 EWD monitoring**

14.1 EWDs should be fitted with means to verify and record the attainment of the specified process conditions.

14.2 Monitoring could be a built-in supervisor system, electronic independent system or data recorder as agreed with the AE(D)/User.

14.3 Instrumentation should be connected to the hospital IT server and system.

**Details****15 Consumables**

15.1 At the time of delivery of the EWD(s), consumables such as printer roles and cartridges SHOULD be supplied to the unit for a minimum of a three-month operating period of constant use.

15.2 Discussions should be made by the supplier with the User or representative prior to tender to discuss the solution options available with machines.

15.3 Consumables are required to be supplied with the machines.

**Details of general consumables required by the User**

## 16 Internal equipment required to reprocess flexible endoscopes (e.g. cassettes, loading carriages etc)

16.1 Provide details of equipment needed to load flexible endoscopes into the EWD.

16.2 If it is a specific cassette system where special brackets are needed, specify special requirements and number of each needed.

### Comments and details

## 17 Testing and validation

17.1 Factory testing is not normally carried out, but if there is a requirement to carry out this function, the costs will have to be built into the tender.

17.2 Validation testing will be carried out by the manufacturer.

17.3 The AE(D) will be monitoring and auditing all test results.

17.4 The supplier will consult with the User and AE(D) for any technical advice required.

### Further comments/requirements

### Details of any special loads

**Testing and maintenance contracts are to be quoted by the manufacturer during the tender for the costs to be analysed by the User for machine care after the warranty period.**

## 18 Service response times and costs

Details and User response time(s) requirements

Breakdown advice time required

Site attendance time required

Spares availability in delivery to site

## 19 Fascia and panelling (if required) (only for pass-through EWDs)

Details of panelling required

## 20 Training requirements

20.1 Staff training is required before the machine(s) can be put into service.

20.2 The training will include the monitoring system and logging requirements.

20.3 Factory testing can be arranged by prior agreement with the manufacturer.

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

20.5 Estates staff training will be provided if required (this is highly beneficial to ensure downtime is minimised through on-site technical knowledge of system):

20.6 Numbers of staff required for training:

### Comments and details

## 21 Warranty

21.1 Warranty details should be quoted and agreed with the client and the date from which it will commence.

21.2 Costs in section 2

- The agreement should be clear before the purchase is made
- Extended warranty options can be quoted and discussed with the client to cover both maintenance and testing as required. Quote for all available variations of extended warranty
- Number of visits per year
- Cost of each visit

## 22 Contract testing/maintenance

22.1 Contracts can be built into the tender with full consultation with the User.

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

**Details to be given in section 2 by the supplier**



## **23 Ventilation requirements of EWDs**

23.1 Ventilation of the area near EWDs may be needed to remove excessive heat and humidity, and also vapours from disinfectants such as peracetic acid.

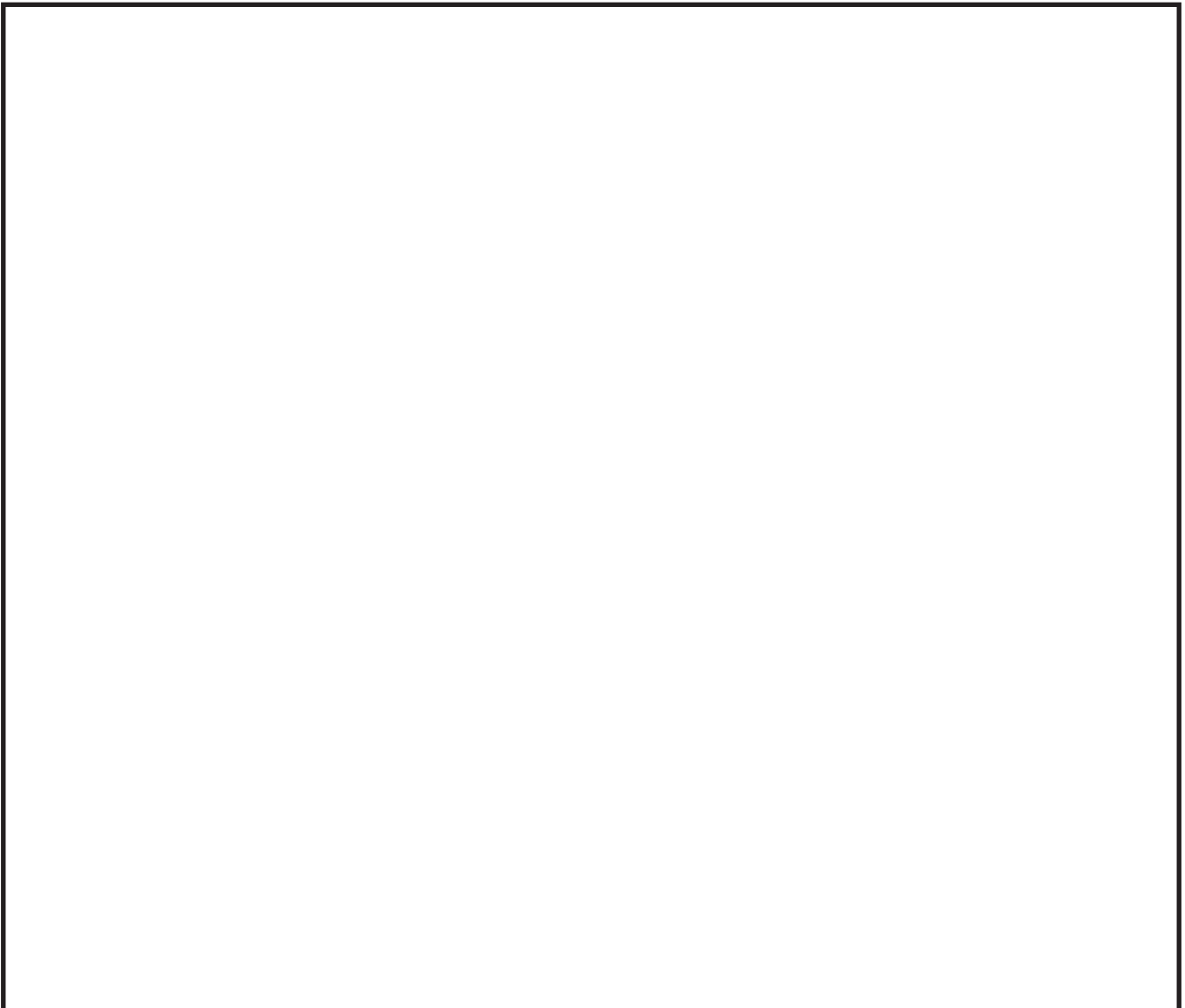
23.2 Drawings and air duties should be supplied with the tender documents.

23.3 The supplier should inform the purchaser if fan(s) are required as part of the machine as supplied.

23.4 The supplier should inform the purchaser if a complete system is required and where it will be terminated under the supply contract, i.e. for others to design and extend the system to a safe extract position outside the building.

23.5 The supplier should ensure that the estates department is fully consulted in the early stages of procurement so that appropriate designs can be drawn up with the User. This will include drawings for consultation.

Further guidance can be obtained from Health Technical Memorandum 03-01.



<b>Services</b>	<b>Requirements</b>	
<b>Water supply</b>	Source of the water supply (e.g. mains feed, tank supply, reverse osmosis plant etc)	
	Tests to be carried out to determine microbial quality of supply water prior to installation (e.g. TVC, conductivity, hardness etc)	
	Are there any specific installation problems complying with local water acts or regulations?	
	What is the supply pressure range required for the EWDs? Can this be achieved by the chosen water supply?	
<b>Compressed air</b>	Determine quality of the compressed air required and required pressure range needed for reprocessing.	
	Method of supplying compressed air (e.g. dedicated compressors, central supply)	
<b>Drainage requirements</b>	Manufacturer's recommendations	
<b>Electrical services</b>	Manufacturer's recommendations	
<b>Process chemicals</b>	Detergent Disinfection Self-disinfection (if applicable)	
	Specify the temperature range required for the water supply to ensure the efficacy of the process chemicals is maintained.	
<b>Ventilation (machine and environment)</b>	Manufacturer's recommendations	

## Section 2

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

### INFORMATION TO BE COMPLETED BY SUPPLIER

#### Details of microprocessor control system

##### The following information should be provided by the supplier:

Details of independent body where complete program and software are lodged.

Details of interface and file protocol requirements for transfer of data in the storage device to an external computer.

Details of diagnostic checks incorporated in the system.

Details (including cost) of the data storage device.

Maximum ambient temperature within the protective case .....°C

with an ambient temperature of .....°C

#### Interim storage requirements

Suppliers are required to advise of the storage conditions required if different from final installed location.

If interim storage is needed – state storage conditions required

Details:

#### Warranty details

Length of standard/free warranty period offered:

Number of included service visits during warranty period:

#### Conditions of warranty

Projected mean time between failures:

Guaranteed up-time:

**Please state definition of up-time:**

.....  
.....  
.....

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

.....  
.....  
.....

### **Extended warranty options for service and maintenance**

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

Number of service visits ..... per annum

Duration of service visits.....hours per machine

Normal working hours are 0800–1800 unless otherwise stated:

All emergency call-outs included: \*YES / NO

Price for emergency call-out during normal working hours, if not included: £..... per hour

All out of hours working included: \*YES / NO

\*DELETE AS NECESSARY

### **Details continued**

Price for Saturday working £.....per hour

Price for Sunday working £.....per hour

Price for evening working £.....per hour

Price for bank holiday working £.....per hour

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

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

Base of engineer to service this site .....

How many other sites does he/she service .....

Number of engineers available to service this site .....

### **All spare parts included \*YES / NO**

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

#### **Ten most used commodities by volume**

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

- 1.....
- 2.....
- 3.....

**Most used commodities by value:**

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

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

Location of spare parts .....

Delivery lead time for spare parts .....

**Is remote maintenance and diagnosis via modem available: \*YES / NO**

Price for supply and installation: £.....

**Software upgrades (during warranty or maintenance contract period):**

**Safety/defect upgrades \*Free of charge / At cost**

New Applications \*Free of charge / At cost

\*DELETE AS NECESSARY

**Annual maintenance contract costs including validation to the latest HTM**

Contract price for one year £..... exc. VAT

Five-year maintenance contract £..... exc. VAT

**Annual maintenance contract costs excluding validation:**

Contract price for one year £..... exc. VAT

Five-year maintenance contract £..... exc. VAT

Contract price for five years paid annually (including warranty).

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

## Service requirements

**The following information should be provided by the supplier for each type of machine supplied (based on a standard cycle being processed).**

### SERVICE REQUIREMENTS

- machine number. ....
- water flow rate. ....
- water supply pressure.....
- water consumption per cycle.....
- drain flow rate. ....
- drain size. ....
- drain type.....
- drain vent size and type. ....
- compressed air flow rate. ....
- compressed air supply pressure. ....
- compressed air consumption per cycle. ....
- electricity voltage. ....
- electricity current. ....
- electricity maximum power kW.....
- air filter (air removal) expected life.....
- test procedure(s) for filter integrity .....
- If steam heating is used:
  - steam flow rate – average .....
  - steam flow rate – maximum .....
  - steam consumption per cycle .....
  - steam supply pressure .....
  - safety valve outlet size .....
  - condensate flow rate .....



sound power per EWD .....  
total sound power all specified EWD(s) .....  
process chemical cost per cycle: .....  
other.....  
cost per cycle .....  
total energy cost per ..... cycle (please specify cycle type)  
.....

**Overall EWD dimensions**

**The following information should be provided by the Supplier.**

m/c no  
internal chamber dimensions (H x W x L) mm.....  
max floor area  
height  
max floor  
loading  
force kN/m<sup>2</sup>  
max fascia opening  
Total cost of processing one flexible endoscope (including energy and process chemical costs):  
.....  
Energy cost basis:  
Mains cold water £ /m<sup>3</sup>  
Hot water £ /m<sup>3</sup>  
Chemicals used £ /L  
Electricity per kWh  
Steam £ per 1000 kg  
Other.....

**Overall cycle(s) time(s)**

The average cycle time for each cycle configuration shall be provided by the Supplier.

Details (including weight and dimensions):

.....  
.....  
.....

## Heat emission

### The following information should be provided by the Supplier.

Heat emission during normal operation at ambient temperature of 25°C:  
..... W

## Contract completion

### The following information should be provided by the Supplier:

time required from receipt of order in works ..... weeks  
time required for installation and pre-commissioning on site..... weeks  
time required for commissioning on site ..... weeks

## Detailed cost breakdown

### The following information should be provided by the Supplier:

Item EWD Type Model  
Name/No  
No. of  
Agreed NHS Supply Chain contract prices  
Discount %  
Unit Total Price      Chamber furniture  
Cassettes      £      Numbers off  
Carriages      £      Numbers off  
Total costs      £  
EWD 1      £.....      EWD 4 £.....      Total costs £.....  
EWD 2      £.....      EWD 5 £.....  
EWD 3      £.....      EWD 6 £.....

**Summary of tender**

**The following information should be provided by the Supplier: £**

supply [nos of]..... EWD(s) ex works	.....
delivery, offloading & positioning of EWD(s)	.....
installation of EWD(s)	.....
supply and installation of services	.....
supply and installation of fascia panelling	.....
site commissioning, i.e. installation checks and tests	.....
test equipment, test loads and materials (if required)	.....
12-month service including 4 off quarterly visits	.....
staff training, consisting of ..... days	.....
supply chamber furniture /racks/loading trollies/ etc. type	.....
costs of consumables	.....
costs of cleaning solutions – detergents/disinfectants etc	.....
independent monitoring equipment	.....
supply ..... set(s) of recommended service spares	.....
contingency – to be set by Purchaser	.....
SUB-TOTAL	.....
..... VAT @ ..... % .....	.....
Hospital:	
Site:	
Department:	
TOTAL £.....	

**Comments**

**Date of tender .....**

## References

NHS Supply Chain.

NICE quality standards.

Health Building Note 13 – ‘Sterile services department’.

BS EN ISO 15883-4.

DB 2002(05).

Sterilization, Disinfection and Cleaning of Medical Equipment, the ‘MAC Manual’ (WITHDRAWN).

COSHH Regulations.

HSE guidance on the COSHH Regulations.

BS EN ISO 13485.

Medical Devices Directive.

CJD Incidents Panel.

‘Coding for success: simple technology for safer patient care’.

Infection Prevention Society.

IPS audit tool.