

### Decontamination of flexible endoscopes

***Part C: Operational management***  
*(Including guidance on non-channelled endoscopes and ultrasound probes)*



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## Overview

### Scope of Welsh Health Technical Memorandum 01-06 Parts A, B, C, D and E

Welsh Health Technical Memorandum (WHTM) 01-06 is part of a suite of evidence-based policy and guidance documents on the management and decontamination of reusable medical devices designed to reflect the need to continuously improve outcomes in terms of:

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

It is also designed to reflect the need to ensure the environment in which decontamination procedures are carried out is fit for purpose.

The WHTM 01-06 suite of documents supersedes the relevant parts of Health Technical Memorandum 2030 dealing with endoscope decontamination.

The documents allow local decisions to be made in the formulation of an appropriately developed, risk controlled, operational environment within the healthcare facilities that decontaminate flexible endoscopes. They also set out how the decontamination of reusable medical devices can be carried out in a cost-effective way using risk assessment controls and procedures whilst placing patient safety as its top priority.

Guidance is also offered on the management and decontamination of flexible endoscopes, principally gastrointestinal scopes and bronchoscopes. They also aim to support healthcare establishments in implementing appropriate and effective decontamination measures to reduce the risks of person-to-person transmission of human prion diseases.

WHTM 01-06 is divided into five parts:

**Part A: Policy and management** sets out the Welsh Government's policy for an endoscope decontamination service. The document covers flexible endoscope management and decontamination only. Clinical issues relating to endoscopy or the manufacture of Automated Endoscope Reprocessors (AERs) are not discussed.

Furthermore, this document does not cover the processing of flexible endoscopes used to examine sterile body sites. These endoscopes should be sterile, possibly using low temperature gas sterilization, and may be the subject of future guidance.

The document discusses transmissible spongiform encephalopathy (TSE) infectious agents and sets out guidance on the management and handling of endoscopes after they have been used on patients at increased risk of vCJD.

**Part B: Design and installation** sets out guidance on the design and installation of endoscope reprocessing units.

**Part C: Operational management** sets out guidance on operational responsibilities together with advice on the procurement and operation of automated endoscope reprocessors (AER). It includes guidance on the decontamination of non-channelled endoscopes and ultrasound probes.

**Part D: Testing methods** discusses the principles and methods that are used in the tests described in this WHTM and detailed in BS EN ISO 15883-4.

**Part E: Validation and verification** highlights the types of tests and maintenance procedure that are needed to provide evidence that decontamination has been achieved.

#### Note

This WHTM 01-06 is based on continued improvement of standards of delivery at the point of use and the continuing aim of reducing the risk element to both users and patients. The technology involved is constantly improving to meet the demands of the service, and evidence-based results and research should always be investigated.

### Who should use WHTM 01-06 Part C

Part C is intended as a guide for management, for technical personnel with appropriate education, training and experience, and also for users responsible for the day-to-day running of decontamination equipment. It is also

intended as a guide on the design of a functional and safe endoscopy decontamination unit and will be of interest to microbiologists, infection prevention control officers, users and endoscopy staff, architects, planners, estates managers, supplies officers, and others in both the public and private sectors.

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# Abbreviations

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

**AP(D):** Authorised Person (Decontamination)

**AER:** Automated endoscope reprocessor

**BS:** British Standard

**CJD:** Creutzfeldt-Jakob disease

**CP(D):** Competent Person (Decontamination)

**DE(W):** Decontamination Engineer (Wales)

**HB:** Health Board

**HIW:** Healthcare Inspectorate Wales

**ISO:** International Standards Organisation

**NWSSP-SES:** NHS Wales Shared Services Partnership  
– Specialist Estates Services

**PPE:** personal protective equipment

**PQ:** performance qualification

**WG:** Welsh Government

**TOC:** total organic carbon

**TOE:** transoesophageal echocardiography

**TRUS:** transrectal ultrasound

**TSE:** transmissible spongiform encephalopathy

**TVC:** total viable count

**TVUS:** transvaginal ultrasound

**vCJD:** variant Creutzfeldt-Jakob disease

**WHBN:** Welsh Health Building Note

**WHTM:** Welsh Health Technical Memorandum

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NHS Supply Chain  
National Institute for Health and Care Excellence (NICE)

# Chapter 1 Personnel

## Summary

Education and training for all staff involved in the decontamination of flexible endoscopes is essential for user and patient safety. 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 automated endoscope reprocessors (AERs). It gives guidance on qualifications, education and training with summaries of responsibilities. This section should be read in conjunction with WHTM 01-01 Part A.

## Education and 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 fulfil their health and safety obligations. They should be educated in decontamination methods recommended for all re-usable flexible endoscopes they are likely to encounter, and should receive specific training on equipment under their responsibilities. They should be trained and have demonstrated competence on those types and models of AER they will use as well as any other techniques required in all the aspects of decontamination. Training should also be given on dealing with COSHH substances and Personal Protective Equipment (PPE) in compliance with the relevant regulations.
- 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 AER 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 and validation of the AER.

## 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 washer-disinfectors (WDs) and AERs may be employed, from a busy sterile services department in a major general hospital to theatre units and a small clinic, it is not possible to prescribe a universally applicable management structure for decontamination, which will be dependent on the size of the organisation.
- 1.6 The approach chosen for this WHTM 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 AER. The philosophy of this WHTM is to invest the User with the responsibility for overseeing that the AER is operated safely and efficiently.

1.8 There are several advantages to the employment of well-educated and 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 AERs 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 The User should ensure compliance with the testing schedules recommended in this document. Routine maintenance of equipment should be carried out in accordance with manufacturers' guidelines and the work should be carried out by competent persons. 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, NWSSP-SES Authorising Engineer (Decontamination) (AE(D)), Decontamination Engineer (Wales) (DE(W)) and personnel from AER manufacturers.

For small installations where the personnel must be identified as qualified to perform all daily and weekly tests and maintenance functions, other key personnel may be necessary to carry out quarterly and annual tests and write the test reports for record and audit.

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 reference should be made to WHTM 01-01 Part A Chapter 5 'Functional

Responsibilities' where they are explained in greater detail.

- Executive Board Lead – Management (e.g. Chief Executive)
- Decontamination Lead
- Designated Person with specific responsibilities in decontamination
- Senior Operational Manager (e.g. estates manager – operational)
- User (e.g. endoscopy manager, sister or SSD manager if decontamination of flexible endoscopes is centralised to the HSDU)
- Authorising Engineer (Decontamination) (AE(D)) at NWSSP-SES
- Decontamination Engineers (Wales) at NWSSP-SES
- Lead for Infection Prevention and Control
- Microbiologist (Decontamination)
- Authorised Person (Decontamination) (AP(D))
- Competent Person (Decontamination) (CP(D))
- AER or specialist equipment manufacturer
- Purchaser (Procurement – NWSSP-PS)
- Management of Surgical Instruments (combined responsibility)
- Operator
- Contractor

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

## Management – definition

1.13 Management of a healthcare organisation or Health Board performing endoscopy procedures 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 educational and 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.

## Management of surgical instruments

1.14 The management of surgical instruments is usually carried out by the endoscope department manager or user. In some cases, depending on location and scale, or policy of the healthcare establishment, the management of or advice on surgical instruments could be provided by a Sterile Services Manager.

1.15 When dealing with flexible endoscopes, the management of their life-cycle requires the input of a number of disciplines at all points in the purchase, use, decontamination, maintenance and decommissioning processes. Specifically, these disciplines will monitor record-keeping on the use of endoscopes and their cleaning, reprocessing, storage and maintenance. Any observed defects in condition or function of an endoscope should be drawn to the attention of the User and Health Board/Trust Management.

1.16 The above duties may be carried out by a named senior User. The role also includes governance provision in support of users across the healthcare establishment. Audit responsibilities are applicable to this role, including review of the local self-audit procedures and any action plans.

1.17 The following checklist applies to the management of surgical instruments associated with flexible endoscopes:

- Keep an inventory of all flexible endoscopes and surgical instruments in use.
- Oversee tracking and traceability systems in the endoscopy unit.
- Liaise with clinical and nursing staff to keep up-to-date with clinical developments and needs.
- Seek advice from outside professional bodies, from procurement to technical organisations.
- Have a plan for the replacement of obsolete scopes.
- Oversee the purchase of new instruments within the healthcare organisation:
  - (i) Are they suitable for purpose?
  - (ii) Do they replicate similar or compatible systems available within the 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?
- (vi) Are they compatible with reprocessing chemicals?
- (vii) Are they suitable and compatible with any IT equipment required and are extra costs involved?
- (viii) Are the endoscopes heat sensitive and/or suitable with the AER process?

- Oversee the loan of instrument policies and contracts and the suitability of chemicals and processes in place with that healthcare organisation.
- Control of instrument repairs: costs, standards, records of the faults and repairs required.
- Oversee local self-audit – advice from Infection Prevention and Control Team or NWSSP-SES.

## User

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

- the Operators;
- the operation of endoscopy decontamination equipment that will be used on the endoscopes under their responsibility. This may include any possible out-stationed drying/storage cabinets;
- reporting issues of concern regarding endoscope instruments or their reprocessing to the Management team of the surgical instruments;
- compliance with the guidance, advice, design and testing contained in the WHTM 01-06 documents.

1.19 In the acute sector, depending on the size of the healthcare organisation, some endoscopy reprocessing can be under the responsibility of a sterile services manager, endoscopy clinical 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; this includes CPD education and training records;

- c. to ensure that decontamination equipment is subject to periodic testing for the AERs and drying cabinets as detailed in Parts D and E of the document;
- d. to ensure that all maintenance is carried out as recommended by the AERs and drying cabinets – all work to be recorded and logged;
- e. to appoint operators where required and ensure that they are adequately trained;
- f. to maintain production records;
- g. to have documented training records demonstrating that they are competent to undertake assigned responsibilities;
- h. to establish procedures for product release in line with the quality management system;
- j. 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;
- k. to develop a plan illustrating development of continuous self-improvement and risk analysis as detailed in WHTM 01-06 Part A.

### Note

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

### The Microbiologist (Decontamination)

- 1.21 Refer to WHTM 01-01 Part A Chapter 5 ‘Functional responsibilities’.
- 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.

# Chapter 2 Choice and procurement of an AER for flexible endoscopes

## Summary

- 2.1 The purchase of an AER 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 AER purchased (for example, separate clean and dirty areas with an AER 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 AERs are selected. Guidance is given on size and number of AERs required to provide an efficient service together with possible delivery issues.
- 2.2 This chapter contains information relevant to the choice of a new AER. It discusses the different types of AER and gives guidance on choosing the size and number of AERs required for a given workload. If older models of AERs are in use, their replacement may form part of risk assessment process and improvement plans for the healthcare establishment.

Refer to WHTM 01-06 Part A 'Policy and management'.

- 2.3 When purchasing an AER, the User should seek advice from the manufacturer of the flexible endoscopes, audit the stock of instruments and review the most suitable method of decontamination. The findings should be reported to the decontamination team.

### Note

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

- 2.4 Dedicated AERs are specifically intended for processing flexible endoscopes. These machines incorporate terminal chemical disinfection using a suitable low temperature liquid process. It is important to understand that the chemicals used for this process will function to their optimum performance within a defined temperature band. The temperature requirements should be clearly stated and services should be designed to deliver the water supply within the defined specification.

### 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 WHTM 01-06 series. A risk assessment of decontamination procedures is advised to determine the best method of processing this equipment.

## Types of AER and cycles

- 2.5 AERs are classified into two groups:
- **Single-door AERs** loaded and unloaded from the same side or top-loading lids.

### Note

If a single door AER is used, Users should ensure there are documented protocols in place to ensure that the decontamination process has been completed prior to release of the product for clinical use.

- **Double-door or pass-through AERs** 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 AER 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 AER are outlined in [paragraph 3.17, '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:

- **bedside flushing immediately after use;**
- concentration of detergent;
- known water supply temperatures and pressures;
- confirmation that process fluid contacts and flows across all surfaces of the endoscope, internal and external;
- compatibility of the AER/chemicals 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 AER 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;
- water supply management.

### 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;
- controlled manual wash procedure prior to the AER use;
- formulation and type of disinfectant 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 important and should be achieved without compromising the cleanliness or safety of the product (see [paragraph 4.53, 'Residual chemicals'](#)). The control of the microbial quality of the rinse-water is critical in this respect (see also [paragraph 4.43, 'Safety of AER chemicals'](#) on the health and safety requirements for chemical additives).

### Choice of an AER

2.10 The choice of an AER will be governed by the nature of the flexible endoscopes to be decontaminated. Quality inspectors/auditors 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 team or lead and responsible management teams, 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) or NWSSP-SES decontamination engineers;
- AER manufacturer/supplier;
- endoscope manufacturer;
- hospital management teams involved in the process or discipline.

2.11 AERs are made with different designs for lumen connectors. It is important that the correct

connectors are available to attach all endoscopes to the chosen AER at the time of first use. Advice on individual cases should be sought, if necessary, from the AE(D) and User 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 AER. The technical specification template (TST) in [Appendix A](#) should be used to ensure the appropriate lumen connectors are available.

- 2.12 All endoscopes will require decontamination using the same AER cycle. It is important that the endoscopes in use are compatible with the AER cycle supplied with the machine. Therefore consultation between the proposed AER 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 The Welsh NHS has an agreement with the NHS Supply Chain, to use a national framework agreement that covers AERs, 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. Advice should be sought from NWSSP – Procurement Services and NWSSP – Specialist Estates Services.

## Information to include when requesting tenders for an AER

- 2.14 Useful insight into operational aspects of AERs can be gained through discussion with existing users. A detailed technical specification template is included in [Appendix A](#).
- 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).
  - Water supply origins and distribution system.
  - Water supply temperatures and pressures.
  - Outline of the unit's available space and room layout (including work space for maintenance).

- The required configuration of equipment: single- or double-door, pass-through, top loader and lid.
- Role of an endoscope dryer, if to be utilised.
- Details of the IQ, OQ and a detailed specification for the performance qualification (PQ) test required.
- 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').
- The needs and connections for tracing and tracking to be compatible with the unit/hospital IT system.
- The type of preferred cleaning and disinfection chemicals as offered by the manufacturer.
- Method of adjudication should problems arise.
- Estimated downtime of the AER for testing and associated work.
- A list which includes endoscope numbers in use, numbers per day that can be processed under the numbers of clinical sessions with the numbers of scopes per session – including cycle times: for example, allow for 60% AER usage time; 40% maintenance and testing.

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

- Floor area required for AER(s) and water management or treatment plant, plus dimensions, weight, clearance and access requirements for routine testing and maintenance.
- If water treatment plant required, who to supply and install: specification of final rinse-water standard to be adopted.
- Details of laboratory to carry out the water analysis and testing to BS EN 15883.
- Chemicals supplied that are fully compatible with the endoscopes in use (if not detailed in the manufacturer's type-test data) including COSHH data.
- Engineering details, flows, pressures and duty requirements for the services for the proposed machines: drainage, water, electricity, sound, ventilation and floor loading (as specified in [Appendix A](#)).
- Pre-tender site inspection by manufacturers:



- site improvement work that may be required;
- access clearance and access for maintenance and repair.
- Site inspection followed by details of delivery and access to the site/unit.
- Type-test list and results in accordance with BS EN 15883 Part 4.
- Price breakdown of AER and associated equipment (for example, connectors, endoscope cradles): running costs including electric power, recommended detergent, disinfectant, water volume and treatment (for example, chemicals, filters, dosing and reverse osmosis as appropriate).
- Validation testing details and contract.
- What arrangements to be made for staff tuition on the new equipment for nurses/ decontamination staff and estates staff/ engineers.
- Supply of endoscope connectors for current stock of endoscopy instruments with the number of lumens detailed following the site audit.
- Service and maintenance contract costs including engineering response time.
- Details of periodic testing contract including details of the test schedules as agreed by the user.
- Cost of a remote diagnostic option, if available.
- Exact details of warranty agreement to include documented commencement and concluding periods.
- Declaration of conformity to relevant BS-EN – ISO standards for all parts of decontamination process.
- Accurate assessment of typical cycle times with the documentation.

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

- Define who is responsible for checking competency of staff working on the new AER and the training manuals.
- Check the availability of AER training and copies of the training manual.

- Check availability and cost of AER 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 It is recommended that a team be set up to investigate the number and type of AERs required ensuring all involved in the facility discipline are consulted. Once the type of AER has been agreed (single scope per chamber, two scopes per chamber, or single-door/lid design, pass-through etc.), preliminary enquiries should be made with a number of manufacturers to obtain basic costing and price for budgetary requirements, including all the consumables and testing. A full detailed specification should be prepared as detailed in the



Endoscopy washroom with top-loading AERs

TST (this specification shall form part of the legal contract between supplier and customer); the data then collated by the user/management team, as supplied by the manufacturer(s), can be very useful for planning purposes. 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 AER 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 WHTM 01-06 Part D Table 1 of ‘Schedule of type tests and works tests’.

## Sizes and numbers of AERs – throughput assessment and workload

2.19 Precise information on the number of AERs required for particular applications is difficult to give, since patterns of use vary. It is very important to review the busiest clinics and sessions of the relevant healthcare facility as this will clearly indicate the heaviest throughput usage of the endoscopes. The number of AERs required will depend on the cycle time and the loading capacity of the machine. Some AER 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 AER 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.

### Note

Throughput can be assisted by the good use and management of drying/storage cabinets as this will mean that endoscopes can be ready for use at the start of a session rather than having to reprocess them first, and the storage can overall assist in the numbers of cycles to be carried out over a day.

### Throughput capacity

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

- The total number of operational hours per week for the department in which AERs are located.

- The numbers, duration and frequency of sessions to be undertaken.
- Design of the AERs (single scope or multiple scope chambers).
- 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 and room designs (clean/dirty, staff movements to and from each process);
  - (iv) start-up and shutdown time each day of the unit;
  - (v) planned audit times and breakdown maintenance shutdowns;
  - (vi) routine, planned periodic and annual testing as specified in WHTM 01-06 Part D;
  - (vii) first morning run to decontaminate endoscopes stored overnight;
  - (viii) planned self-decontamination cycles.

### 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 seven key factors:

- AER cycle time;
- AER capacity and design configuration;
- manual cleaning time;
- machine availability;
- staffing levels for the decontamination process;
- location of decontamination unit from the treatment rooms, transportation time factors;
- competence of staff working in the decontamination area or unit.

### Cycle time

2.22 The operation of a routine cycle should remain very similar after the validation is completed.

- 2.23 The cycle time may be adversely affected by outside changes to the services such as low water pressure and low or high water temperature, set against the operating parameters as set in each AER at validation. The drying time selected will affect the number of cycles possible per day.

### Note

If more than one routine cycle is programmed into each AER (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.) It may be preferable to remove the cycle from the microprocessor controls; advice from the AE(D), AP(D) and manufacturer should be sought.

### AER capacity

- 2.24 AER 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 AER 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 AER 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 AER, they should not lie on top of each other, as decontamination may be compromised due to shadowing (see [paragraph 2.36, 'Load handling equipment'](#)).

### Note

Some manufacturers supply an accessory to allow a number of non-channelled endoscopes to be washed together e.g. nasal endoscopes.

- 2.25 AERs 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. AERs that run cycles in separate chambers can be run independently and may allow a more flexible use of AER time and staff.

### Note

For endoscopes that have been used for invasive procedures in patients at risk of variant Creutzfeldt-Jakob disease (vCJD), see WHTM 01-06 Part A 'Human prion diseases (including CJD and vCJD)'.

### Workload estimate

- 2.26 The workload should be estimated from historical records of operational activity or based on proposed workloads and any expansion of the service. 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 Care 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 as detailed in this series of WHTMs.
- 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 AER's available time will be required for non-patient work, maintenance and testing. AER 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 single-use and disposed of following use regardless of whether they have been breached or not.
- 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.

### Note

Wherever possible, all reusable accessories should be decontaminated in an accredited HSDU facility.

- 2.33 Reusable accessories that should be sterilized in an HSDU – seek advice from the Sterile Services Manager.
- 2.34 For tracking purposes, several items of the same type (for instance, endoscope buttons) may be

needed to allow time for steam sterilization if sent to the HSDU. 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 cleaned and 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.**

#### Note

There should be systems in place to record all consumable items used on patients, whether the consumable items are single-use or reusable devices.

## Load handling equipment

- 2.36 Some endoscopes require protective caps to be fitted to sensitive components before they can be decontaminated in an AER. Advice from the manufacturer should be sought (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. These carriers should be tested with the appropriate load items during the validation tests.
- 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 by shadowing, and so this should be prevented and checked by the operator during the loading and unloading.
- 2.40 The contact points and surfaces between an endoscope and load carrier should be minimal to allow effective fluid contact and cleaning.

## Dosing systems

- 2.41 The AER 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, and should only be adjusted by the nominated competent person.
- 2.43 The stage(s) in the process cycle at which each dosing system admits chemical to the AER should be under the control of the AER microprocessor and documented by the CP(D) at the validation stage, and documented in the issue controlled report.
- 2.44 Working procedures and, where available, mechanical systems need to ensure that the detergent and disinfection supplies are correctly coupled to their respective containers or systems.
- 2.45 Each dosing system should be provided with means to determine the actual volume admitted and the time within the operational cycle. This data should be available to the operator. Failure to admit the specified minimum volume should cause a fault or warning on the panel or printout for the operator.
- 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 AER should be fitted with a system that will indicate when there is insufficient chemical(s) available for the next cycle, therefore not allowing another cycle to be started unless there is sufficient chemical(s) available for completion and safe disinfection of the endoscope(s).
- 2.48 The volume of water used for each stage of the AER process should be monitored. If the water volume for each stage is insufficient, a fault should be indicated. Low or fluctuating water pressures will influence the flow and may cause this problem. Volumes should be known for a correct operating cycle.

## The selection of an AER from tender documents

- 2.49 Reference should also be made to the technical specification template for AERs given in [Appendix A](#). The selection panel should have representation from the interested parties below:
  - (i) a senior endoscopy nurse/manager;
  - (ii) an operational estates representative;

- (iii) the AP(D) for that local unit or department;
- (iv) an infection prevention control/microbiology team member;
- (v) AE(D) or DE(W) from NWSSP-SES;
- (vi) the decontamination lead or member from the directorate management;
- (vii) a risk manager for the Health Board/Trust;
- (viii) a safety officer for the Health Board/Trust;
- (ix) CP(D) responsible for that unit;
- (x) a local procurement officer.

### 2.50 Selection process questions:

- Will the AERs described match the specification and meet the standards?
- Will the engineering requirements match the services and systems available on site?
- Are the AERs described compatible with the existing traceability system?
- Can the AERs be connected to the hospital's or unit's IT system?
- Will the AER work with mains water supply?
- What is the quality of the water input if not supplied direct from mains?
- Is a separate water treatment plant required based on the water supply test results?
- Is the type test data correct to BS EN 15883 Part 4?
- Are reference sites available on the selected AER that show reliability in the field?
- Will the total costs included in the tender cover all the costs involved in the project?
- Will the machines represent value for money in the total installation of supply, installation and operation?
- Has a visit to a reference site been arranged if the equipment is new to the user and team for the AER of the type short-listed?
- Will additional ventilation be required in the wash area due to the chemical being used? (refer to WHTM 03-01)
- Will the AER and the chemicals be compatible with all endoscopes in use?
- Can the manufacturer provide letters or certificates of conformity on the compatibility issues on the equipment supplied?
- What chemicals have been type-tested with this AER?
- Is the AER capable of thermal self-disinfection?
- Is it possible to compare AERs on the data supplied?
  - (i) If not, request additional data and certificates, test reports and conformity statements.
  - (ii) Are type-test results available? See WHTM 01-06 Part D Table 1 in the 'Schedule of type tests and works tests'. Results need to match guidelines or standards.
  - (iii) If insufficient data is available, select another AER design or make.
- Can a supplied AER be guaranteed free of contamination and biofilm on arrival on site?
- Who will carry out IQ, OQ and PQ tests?
- What laboratory will be used for the micro tests, and in compliance with BS EN 15883 Part 4?
- Will they be independent and witnessed by the AP(D) or NWSSP-SES's DE(W) or AE(D)?
- What training is offered for operators?
- What training is offered for the estates staff and CP(D) and how often will the training be provided?
- Will future new users be included in the training?
- Will there be a cost for any ongoing training?
- Is finance available for routine testing and revalidation?
- Who will carry out periodic testing and maintenance?
- Are there any additional costs/revenue implications for ongoing training of staff to meet the requirements, e.g. annual costing?

### Taking delivery of an AER

- 2.51 The delivery of a new AER 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. Although the 28-day micro test will delay operational start dates, if the user is satisfied that the machine is new and has not been previously used, a 7-day period is acceptable from the completion of micro testing, providing that the test results are satisfactory at the end of 7 days. Consultation with the AE(D) and Consultant Microbiologist is required in this case.

- 2.52 It is the manufacturer's responsibility to remove or ensure that any inbuilt bio-film is not present within the AER. The machine cannot be accepted into service until the validation procedure proves there is no internal contamination present.
- 2.53 Storing or delayed delivery of an AER 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 AER should be delivered with replacement pipework, which can be fitted before commissioning and validation.

- 2.54 A works test sheet should accompany an AER when it is delivered to site. The tests detailed on this sheet should be as outlined in the test schedules in WHTM 01-06 Part D, 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.

### Note

The client/purchaser should ask the manufacturer for details of the condition and state of the new AER before delivery. Testing may have been carried out prior to delivery and water may not have been totally drained from the system, and a decontamination certificate may be required to be supplied with the machine before installation. This requirement can be added into the TST on purchasing. This caution would apply to any AER being supplied as an upgraded machine, supplied from another user or being re-located.

# Chapter 3 AER operation and endoscope storage and transport

## Summary

Guidance is given on the operation of an AER, including cleaning, disinfection and rinsing endoscopes. The possible stages of an AER 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 transrectal ultrasound probes.

3.1 AERs vary from manufacturer to manufacturer, but all have a similar operating cycle. The aim of the process is to decontaminate the device in compliance with the latest standards and NHS guidance and render the reprocessed endoscope safe for use:

- free of pathogenic microorganisms;
- clean and free of detectable protein and 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.

## Note

See WHTM 01-06 Part A for guidance on risk management and policy statements.

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 and measure the cycle 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 can be extremely complex in construction and have multiple long narrow lumens that cannot be visually inspected.
- The bedside flush and the manual pre-cleaning is an essential component of the whole decontamination cycle.
- It is essential that all the endoscope lumens are connected to the AER. The AER 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 AERs, flow monitoring takes place in the AER microprocessor control, and will alert the operator if there is a problem, warning or fault condition during a cycle. These cycle parameters and safety systems should be regularly checked via the periodic testing regime to demonstrate correct operation and settings.
- It should be noted that updated models of AER have been designed to work within the tight flow and pressure monitoring tolerances to ensure endoscopes are reprocessed in a safe manner, with balanced irrigation through all lumens and required exposure to process chemicals. This can result in higher instances of possible fault recognition during operational use. To minimise this fact, operators need to be familiar with correct methods of loading/connecting endoscopes to ensure there are minimal unnecessary fault conditions created.

## Operation of an AER

- 3.3 The AER 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 AER 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, i.e. single-shot systems should be used.
- 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) and Infection Prevention and Control Officer/Nurse.
- 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 AER should not be able to be opened or reset without the aid of a special tool, key or code.

### Note

Systems are being developed to reprocess various difficult to clean and disinfect endoscopes or probes with electronic components. A decision can be made to employ such systems to improve patient safety, especially if the disinfection stage is proven. This is of paramount importance. A risk assessment of the system/machine design will need to be investigated and technical advice sought.

## Disinfection requirements

- 3.9 The standard of disinfection required should be defined by the User in consultation with the Infection Prevention and Control Team.
- 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, AER 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 AER equipment supports more than one water inlet, the process water does not need to be of the same quality as the final rinse-water. However, if two separate water supplies are connected, both will have to be managed correctly as discussed in WHTM 01-06 documentation. It is important to clearly label each connected water supply and there should be no chance of misconnection of each service to the incorrect inlet to the AER.

## Self-disinfection requirements

- 3.14 Available operating cycles on the automatic control system should provide for an AER 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 and is a preferred option if available. An AER 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).

(For joint designs and the types of equipment connected in the water supplies to an AER, refer to WHTM 01-06 Part B.)



## Compatibility with items to be processed

- 3.15 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. When replacing or upgrading new equipment such as AERs, or endoscopes, manufacturers' compatibility statements should be sought and investigated. Compatibility statements should be clearly documented and recorded.
- 3.16 If the process conditions recommended by the AER 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

- 3.17 AERs 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.**

### Note

As a general principle and rule, endoscopes should be cleaned and decontaminated in a time period not longer than 3 hours after use. For out-of-hours use, a risk analysis must be completed and rigorous operational procedures employed. Research is currently under way on this topic and the most up-to-date policies, advice and guidance will need to be complied with in all areas of endoscopy.

- 3.18 There are several options available to retain endoscope moisture during return transport to the decontamination unit after use. For example:
- A damp endoscope could be placed in an appropriately designed bag system with a seal. The bag could then be placed onto a tray to support the body of the endoscope to minimise damage 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. Ensure the chemicals used are easily cleaned off the instrument if stored for a prolonged period, and are compatible with the materials of the endoscope.
  - A used endoscope could be put in a tray with a small volume of water and covered. This method carries risk due to the potential for spillages and the need to determine the appropriate volume of water to minimise such spillages.
- 3.19 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 endoscopes to be processed is essential.
- 3.20 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 table or draining board adjacent to the cleaning sinks.
- ### Manual cleaning
- 3.21 The instructions provided by the endoscope manufacturer should be followed, as endoscopes vary in construction and therefore the method of cleaning.
- 3.22 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.
- 3.23 A volume of concentrated detergent is added appropriate to the volume of water already present, as recommended by the detergent manufacturer.

The sinks used for this process should have a measurement system in place, such as permanent markings on the inner surfaces of sink units, or a predetermined volume of water to take detergent(s) for accurate and reproducible detergent dilution. The temperature used in the sink should be within an optimum range recommended by the detergent manufacturer and should be monitored with a basic temperature-measuring device. 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 until clean, with a cleaning brush designed for the instrument in accordance with the endoscope manufacturer's instructions.

- 3.24 Manual cleaning is an essential part of the overall process, and this part is to remove deposits down the lumen(s) and around the controls of an endoscope. An AER is not able to reproduce the brushing action of manual cleaning or brushing between the control wheels. Manual cleaning is particularly important when using simpler-designed AERs, depending on use, as the cleaning action may be limited. After use, the sink is drained, rinsed with tap water, drained, wiped clean and dried.

### Note

Staff undertaking manual washing procedures should ensure the brushes used are complete after use and that no segments remain in the endoscope post manual process.

- 3.25 The second sink is filled with cold water and the washed endoscope is immersed before each lumen is syringed through to remove the detergent.
- 3.26 The endoscope should then be rinsed in clean tap water and carefully examined for damage before connection to an AER. The endoscope is then transferred to the AER, 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 AER process.
- 3.27 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.

### Note

In some circumstances, such as extreme limited space in a wash room, there are automated process sinks and equipment that can be utilised for both the wash and rinse processes via a pumped system. These units could be assessed and used providing that the manufacturer's instructions for use are maintained, and a self-disinfection process is available, including carrying out a regular water test of the appliance.

### Process stages of an AER

### Note

This process should only be carried out by the User after formal education and training by the AER manufacturer.

#### 3.28 1. Connection of endoscope to AER

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 AER to deliver high-pressure fluids to carry out the cycle successfully.

#### 3.29 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 AER 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 AER automatic leak test should not replace a manual leak test. During the manual leak test, it is important to move the endoscope distal end by operating angulation controls that may expose leaks. Modern AERs 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.

#### 3.30 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 AERs 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>.

### 3.31 **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, partial or complete blockage. 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 AERs are designed to carry out the lumen patency test throughout the operating cycle; this is to be preferred if available.

The AER manufacturer should provide clear instructions and information on the ability of the AER to detect partial blockages and channel disconnection within cycle. Individual lumen patency and configured set point capabilities should be identified to the User. The sensitivity to indicate such fault conditions should be documented in line with type test information and should be verified as part of any validation regime. Clear instructions on the methods used to simulate partial blockage/disconnection should be supplied within test reports.

It should be recognised that the ability to detect partial blockages/disconnections may result in increased cycle failures as any debris or damage within the lumen is highlighted as part of the automated process; however, such systems ensure that patient safety is the key consideration in an automated process.

As technology advances, the ability to reliably detect partial blockages should be assessed as part of the specification for new AERs. The AE(D), AP(D) and DE(W) should be consulted for advice interpreting manufacturer's information and the ability of the AER to meet these requirements.

### 3.32 **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 [Chapter 4, 'Process chemicals'](#) for guidance on detergents).

### 3.33 **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. Statements or test certificates must be given by the manufacturer of the AER on compatibility issues.

### 3.34 **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 AER manufacturer should be used (see [Chapter 4, 'Process chemicals'](#)).

### 3.35 **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 AERs that add disinfectants to the final rinse-water that have been validated as compatible with patient safety.

### 3.36 **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 drying cabinet. An alcohol flush at the end of a cycle to aid drying is discouraged, because it is a protein fixative.

### **Choice of drying cabinets**

3.37 Drying cabinets can be used to supplement drying by the AER. If time allows it is best to thoroughly dry endoscopes between patients, but in a busy clinic, time may not be available. The use of drying cabinets or other newly-developed validated technologies for storage of endoscopes is to be

encouraged, as it will provide assurance and will be seen as a further stage in the decontamination process of an endoscope. The choice of drying cabinets is wide depending on local needs, numbers and types of endoscope and space requirements (see WHTM 01-06 Part D, 'Drying cabinets'). The following list may be helpful when comparing cabinets for selection:

- If endoscopes hang in the cabinet, is there a system within the design of the cabinet to prevent the distal end of the endoscope touching the floor?
- Can all lumens in the endoscope be connected to a filtered medical grade air supply and the flow monitored throughout the proscribed storage time?
- What level of filtration is used for the cabinet air supply?
- What is the source of filtered air? Hospital system, bottled supply, self-contained air compressor or remote air compressor?
- If the cabinet requires an external source of filtered medical grade air, the Authorising Engineer (Medical Gas Pipeline Systems) (AE(MG)) should be consulted to determine if this connection is allowed for safety reasons, and the impact this may have on other services supplied from the same source (see WHTM 01-06 Part B, Design and installation, Table 1 in 'Design of an endoscope reprocessing unit').
- Does the cabinet allow that internal air pressure be measured and/or monitored during its operation?
- Can the cabinet be locked, with restricted access levels provided?
- Is there sufficient capacity in the storage cabinet(s) for the unit, with numbers of endoscopes in use?
- Does the cabinet monitor each endoscope in store, record the data and indicate if the values go out of specification or the endoscope has been in store too long?
- Does the cabinet allow for continuation of the traceability system and connection to an IMS log?
- Obtain type test data for the cabinet manufacturer to show a stored endoscope may

be directly used on a patient without reprocessing.

- Which tests have been carried out to show if the cabinet dries endoscopes and keeps them free of contaminating organisms during storage and prevents any residual contamination from growing? From this data, has the manufacturer recommended the maximum safe period of storage? Manufacturer's type test data will assist in this process.
- 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? Wood or fibreboard-type materials are unsuitable materials.
- Are double-ended cabinets required as part of the design? This type could be very useful in limited space areas, and for possible out-of-hours collection if one side is out of the decontamination room(s). See layouts in WHTM 01-06 Part B.

- 3.38 Drying cabinets should not be sited in the endoscope cleaning (wash) area; they may be sited either in the endoscope designated clean area or room, or a clean area near to the point of use.

### Note

Endoscopes with wire lumens should not be stored, as the cabinet is unlikely to dry the lumen.

### Storage cabinets

- 3.39 Storage cabinets are distinct from drying cabinets, as they do not claim to dry endoscopes. Storage cabinets are simply contained areas constructed of non-porous materials where endoscopes may safely be stored to increase security and reduce the likelihood of damage to endoscopes. Endoscopes removed from a storage cabinet will need to be reprocessed before use unless they have been decontaminated within the preceding three hours.
- 3.40 If space allows, drying cabinets should always be used in preference to storage cabinets to provide controlled storage and the possibility of endoscope use directly from storage.
- 3.41 Storing or hanging endoscopes within an open environment in a working area or corridor is not

acceptable as they are liable to damage, theft and contamination.

- 3.42 After decontamination and before release of the product for use, the conditions for storage and handling should not compromise the cleanliness or freedom from microbial contamination of the product.

### Packaging and transport

- 3.43 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.

- 3.44 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. Systems are being developed for this purpose by manufacturers, and careful examination of these systems should be undertaken and risk assessed depending on the needs, location(s), transportation requirements and distance.

- 3.45 Endoscopes should be transported between the AER 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.**

- 3.46 The transport carriers/systems used to carry endoscopes from the AER 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.

- 3.47 Some AERs process the endoscopes in a plastic cassette/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 the drying cabinet for this system is not used, it limits the endoscope storage life to three hours before reprocessing is necessary before reuse. If the drying cabinet is used, and validated, the proscribed time of the validation tests will determine the storage time before reprocessing.

**Consultation with the AE(D) and local decontamination team should take place to determine operational requirements with the user.**

### *Transport of reprocessed flexible endoscopes*

- 3.48 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 AER 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.

- 3.49 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/bags/cassettes to provide support, and prevent damage and contamination during transit. It is important that transit systems/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;
- the tracking and tracing system will support this activity. Care should be taken when transporting the endoscope(s) back to the clinical area not to damage/re-contaminate the reprocessed endoscopes.

## Note

Technological developments are constantly ongoing and alternative methods of providing elongated scope storage are being developed. Where such systems are seen as appropriate for application, they should include a validation process to provide documented evidence of the ability to retain the scope in a safe state for the defined period. Such systems may require scopes to undergo a further drying phase before storage.

## Post-decontamination inspection and release

- 3.50 The User, in consultation with the AE(D) and local decontamination team, should establish documentation procedures to ensure loads are not released for use, or storage, until the User is satisfied:
- that the cleaning stage of the process has been reproduced within the permitted tolerances established;
  - 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;
  - that the disinfection stage of the process has been reproduced within the permitted tolerances established during commissioning, PQ tests and routine validation tests;
  - that, if the endoscope is not used within three hours of reprocessing, the storage facility meets the requirements detailed in 'Drying cabinets' above.
- 3.51 If the endoscope has been sterilized by a validated process, such as gas plasma or EO, 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 intact.
- 3.52 The procedures should ensure that:
- the load has been correctly positioned in the loading basket and/or on the load carrier;
  - the settings for the operating cycle are in accordance with the specification for that load type;

- the instrument/indicator readings and/or chart record for the cycle conforms to the data established during validation within the permitted tolerances;
- the decontaminated endoscope shows no obvious defects – such as damage, residual soiling or staining, which may suggest a faulty operating cycle;
- flow occurred in all lumens of the endoscope;
- no connectors have become dislodged during the cycle.

- 3.53 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.
- 3.54 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 should be investigated.
- 3.55 Documented procedures for reprocessing rejected endoscopes and accessories should be agreed between the User and the AP(D)/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.
- 3.56 When a single-door/lid AER is in use, a system to clearly differentiate between processed and unprocessed endoscopes and accessories will be required.

## Note

Advice should be sought from the HSDU manager, AP(D), NWSSP-SES and AE(D).

## Decontamination of non-channelled endoscopes

### Important Guidance

All non-channelled endoscopes should be reprocessed in accordance with the policy contained within the WHTM 01-06 suite of documents, where applicable.

The safety of the patient is paramount and WHTM 01-06 Part A, as a Code of Practice, gives clear statements and guidance. It sets out the need for improvements in decontamination processes and risk management along with the need for continuous auditing of the processes.

New systems and technologies must always be investigated.

Decontamination of such medical devices should be carried out by the use of a validated process, such as an AER designed for the purpose, or an alternative validated disinfection process specifically designed for electronic devices such as those for transoesophageal echocardiography (TOE), transvaginal and transrectal ultrasound probes.

Consideration should be given to the ‘manufacturer’s instructions for use’ (IFU) prior to instigating decontamination practices.

#### *Non-channelled endoscope procedures*

- Non-channelled endoscopes can be difficult to clean due to their design and the complexity of the electronic sections of the instruments that cannot be immersed in water or solutions.
- Some specialist systems have been developed to clean and disinfect the insertion tube section of the device, with the control head and electronic section protected from the water in a sealed vessel or isolated from the solution via glands or outside the disinfection device. Each system would have to be examined and evaluated for the process required, and the machinery available for use.
- Manufacturers continue to develop and improve AERs, adaptations to AERs and specialist systems for these devices, especially as their use is increasing within the NHS of Wales. Validated systems using chemicals such as hydrogen peroxide are becoming available for the final disinfection of TV and TR probe at point of use. Such systems should only be implemented where the appropriate validation data is available to document the required process effectiveness to ensure devices reprocessed are prepared in a safe manner for re-use on patients.
- Purchasing these endoscopes should always include an assessment of decontamination

equipment designed for purpose that can be validated as required, or equipment available within the organisation that can be utilised.

- IFUs must be available to ensure the best possible method of decontamination is utilised, examined and evaluated with a specified validated process to ensure safety for the patients.

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**Attention is drawn to the MHRA Medical Device Alert [MDA/2012/037](#) dealing with reusable transoesophageal echocardiography, transvaginal and transrectal ultrasound probes (transducers). It is essential that Users read and understand this alert. A summary is provided below:**

The alert refers to an incident where the death of a patient from Hepatitis B infection may have been associated with the failure to appropriately decontaminate a TOE probe between each patient use. The alert sets out the following action:

Review, and if necessary update, local procedures for all ultrasound probes that are used within body cavities to ensure that they are decontaminated appropriately between each patient use, in accordance with the manufacturer’s instructions.

A number of health facilities have adopted a manual decontamination practice using a wipe system in lieu of the optimum decontamination process, i.e. AER or Hydrogen Peroxide Gas Disinfectors. Where a manufacturer describes a wipe system of cleaning as acceptable in their instructions for use, they should be asked to provide evidence that the process has been validated, and to provide the validation report to the facility, and a logbook system to record the processes undertaken.

If a validated wipe system is used as the choice of decontamination, it is important that a full traceability audit of the decontamination process can be achieved. This should include the name of the device, serial number, patient’s name and the person carrying out the decontamination, batch details of the wipe system and the date of cleaning.

TOE endoscopes will still require a validated wipe system as per IFUs for the operating handles, cables and plugs attaching the probes to the hardware equipment.

Similarly, TVUS and TRUS probes will require a validated wipe system for cleaning the equipment, handles, cables, plugs and the trolley handles and supporting cups with the same cleaning procedure.

Advice should be sought from the Infection Prevention and Control Team, AP(D), AE(D) and HSDU managers.

Where the health facility decides to use such a system in contravention of the manufacturer's instructions, to protect the clinical users of the device it is important that the health facility's risk structures have accepted the risk and signed off the risks on behalf of the chief executive and health board.

It should be noted that the MHRA have issued two recent medical device alerts in relation to inadequate decontamination of medical devices and these should therefore be considered when risk-assessing the decontamination method of choice:

- [MDA/2012/037](#) (Decontamination of Transoesophageal Echocardiograph Probes, Transvaginal and Transrectal ultrasound probes).
- [MDA/2013/019](#) (Detergent and disinfectant wipes used on reusable medical devices with plastic surfaces).

## Nasendoscopes

- 3.57 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. In this family of probes and endoscopes, nasendoscopes are usually designed to be fully immersed in water. Therefore the use of a specially-designed AER is the preferred method of decontamination and disinfection. Reference should be made to the manufacturer's decontamination instructions IFUs, compatibility statements for chemicals to be used, and any temperature criteria required for the process.
- 3.58 In some health facilities, distance between the point of use or patient treatment and the decontamination facility has driven the use of manual methods of decontamination. This should be reviewed by the risk structures within a health facility as discussed above. The alternative risk solution is to purchase sufficient endoscopes to allow for properly validated decontamination in accordance with the preferred method as discussed with the local decontamination team, AE(D) and User, and in line with the manufacturer's IFU. Planning should consider the whole-life costs of

a pool of instruments; a larger pool will allow for use over an extended period of time and also ensure that there is sufficient time for validated decontamination procedures. Where manual systems are utilised, organisations must have an agreed action plan documented and in place to progress towards a validated system being used and the installation of the appropriate AER(s) designed for purpose.

1. Any manual methods should include validated and documented procedures that are proven efficient cleaning systems for the used nasendoscope(s) and using a compatible disinfectant for the scopes. The relevant COSHH documents must be provided by the manufacturer.
2. Depending on the complexity of the endoscope, it may be a requirement that selective immersion of parts is undertaken; non-immersible components also need to be disinfected, for example, by wiping as agreed in the risk assessment procedures. Advice should be sought from the Infection Prevention and Control Team and manufacturer to ensure there are no compatibility issues with the materials or electronic parts/components.
3. Cleaning and disinfection procedures as stated are also required even if single-use sheaths are used. Regardless of the operational arrangements and the location in which decontamination is conducted, the requirements of this guidance and the reprocessing instructions of the device manufacturer should be followed.

### Important factors to be considered

It must be noted that in many cases and with most children, a sheath cannot be used because of a restricted pathway in a patient that only allows the narrowest of diameters of the nasendoscope to pass. The use of a sheath can restrict the clarity of the image for the clinician/user. This will emphasise the need to decontaminate any endoscope in the correct manner. Correct manual cleaning methods must be employed, followed by the use of a validated AER or specialist system for these devices.

The use of sheaths should be avoided where possible because of the issues stated above.



- 3.59 Where flexible cannulated nasendoscopes are in use, validated AERs designed for purpose and compliant with BS EN 15883 Parts 1 and 4 should be available in a decontamination reprocessing unit as outlined in WHTM 01-06 Part B. Irrespective of whether an endoscope has lumens, decontamination in an AER will give enhanced risk reduction. The size and location of the decontamination facility will depend on local needs, throughput and clinical needs.
- 3.60 Decontamination staff who work in units where nasendoscopes are reprocessed should receive correct education and training in the guidance and equipment to enable them to decontaminate that type of endoscope correctly. 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, and the correct AER for that purpose.
- 3.61 Nasendoscopes should be stored in a secure, clean, 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, unless that specific unit has a need to have endoscopes ready for use, or out-of-hours accessibility. Then a drying cabinet can be used, validated for the specific time control required for that facility, such as 72 hours to cover periods such as weekends. This is a local decision. For non-lumened nasendoscopes, bacterial contamination on their surface will not replicate in the absence of surface water. Therefore, if stored in a secure manner within a controlled environment, and as long as direct or indirect recontamination with patient body fluids does not occur, no maximum time of storage before reprocessing need be specified.

### Decontamination of transoesophageal echocardiography (TOE), transvaginal and transrectal ultrasound probes

- 3.62 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 or exposed in an AER.
- 3.63 Transrectal 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.

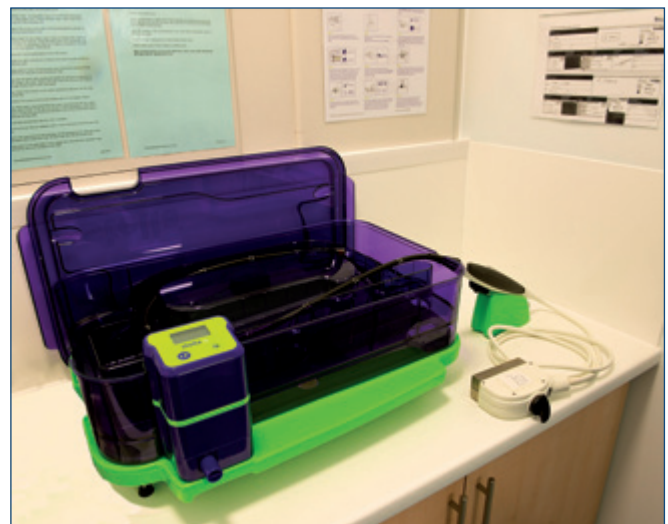
- 3.64 The immersible sections of TOE, TVUS and TRUS probes that do not have internal lumens should be cleaned following an agreed validated process if manual cleaning is carried out directly after they have been used, where this is specified in the manufacturer's IFU.

Health facilities should have fully documented procedures for decontamination. Again as noted in earlier sections, if a health facility decides to allow manual decontamination against the advice of this document and a manufacturer's IFU, it is important that the organisation's risk structures have accepted the risk on behalf of the chief executive and board.

All types and designs of probe without lumens will require the development of a local policy based on evidence and a full understanding of the risks involved.

#### Quality and safety of the procedures for the patient must be paramount.

- 3.65 The use of an AER (or alternative specialist equipment, making use of newly-developed decontamination technologies that are specially designed for the purpose) to decontaminate the immersible parts of these probes is to be preferred and used, as described in the next paragraph (see [Figure 1](#)). Parts of TOE, TVUS and TRUS probes,



An example of appropriate technology designed to decontaminate equipment with non-immersible components

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 as well as the probe shaft because of the operator's handling of this section; 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. The manufacturer's instructions can give specific guidance for these instruments.

**The advice of the Infection Prevention and Control Team, NWSSP-SES or AE(D) should be sought.**

- 3.66 The ultrasound probe decontamination and cleaning can be viewed in two sections: manual decontamination of the non-immersible parts and selective immersion of the insertion tube in an AER or by immersion of the whole device with non-immersible parts sealed in a watertight case.

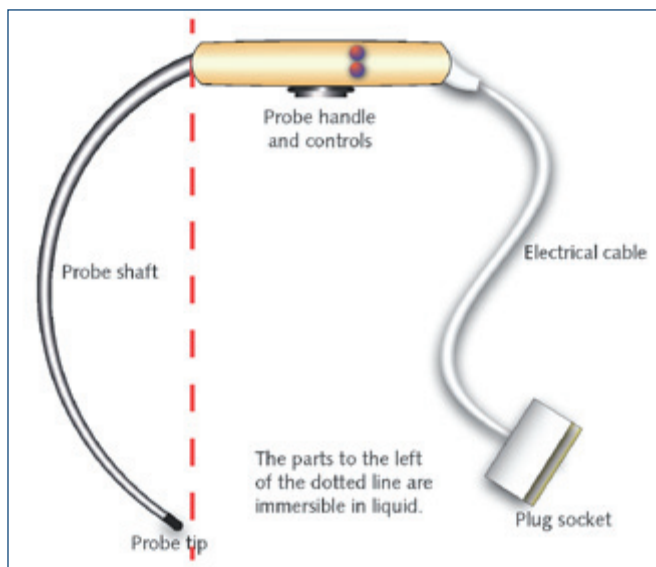


Figure 1 Immersible parts of a probe

- 3.67 The facility for decontamination should include a suitable double sink, one for washing and cleaning, the other for clean rinsing. Both should be of adequate size and depth for cleaning the probe(s) (refer to WHTM 01-06 Part B). In addition, a

clinical wash-hand basin is required. Storage facilities for disinfectants and cleaning materials, including those used in wiping, should be provided.

- 3.68 The design of the decontamination facility should be separate from the clinical procedures room, and should respect the need for a clearly designated flow from used (dirty) through cleaning and disinfection process to clean, storage, then 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.
- 3.69 The process and flow referred to above could be in a designated room. Where the manual decontamination process is combined with the use of an AER adapted for use with these probes, the space afforded should be adequate to continue the principles of a clearly-defined flow of activity and storage.
- 3.70 Quality assurance and validation depend on a reliably applied local policy, procedures, operator training and education, 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;
  - Infection Prevention and Control advice and audits of the procedures.

## TOE probe decontamination equipment design and optional tests

Decontamination systems and automated technologies are improving for all types of probe and non-channelled endoscope. Advice should be sought from NWSSP-SES engineers, the AE(D), the DE(W) and the AP(D) at the time of equipment upgrade or the procurement of new installations.

High-sensitivity post-decontamination protein quantification tests are being piloted. As these are further developed and become available, guidance will be provided by NWSSP-SES which should enhance the validation process and routine monitoring of the process.

As stated in this chapter, health facilities should investigate and work towards the use of automated and validated decontamination systems. However, care should be taken to ensure that any preferred system is manufactured in accordance with relevant latest European standards. In addition, it has to have all the supporting evidence (type test data, conformity statements and performance criteria) to verify effectiveness of process against an identified microbiological challenge to ensure, under defined conditions, high-level disinfection is achieved. Furthermore, the manufacturer should provide documented evidence that the system is compatible with the devices it is intended to reprocess and does not leave process residues after decontamination.

Any installation of a specialist AER, built for purpose, or other developing technologies designed for specific probe decontamination (e.g. ultrasound probes) will need to be carried out with an IQ/OQ/PQ validation schedule as stated in the relevant BS EN standards within the working environment prior to acceptance into service.

Some machines can pass a small electrical current into a probe via the plug socket, making a circuit with a second electrode in the machine/tube. Should there be damage such as a crack or a hole, a small electrical current will be detected and indicate this damage. This type of machine is designed to indicate such a fault and prevent the TOE being put into use.

An appropriate leak test (see [paragraph 3.31](#)), as recommended by a device manufacturer, is also intended to protect the patient, as it should highlight any damage to the insertion tube and reduce any cross-infections in patients.

Advice should be sought from a user team to investigate the electronic side of the instrumentation, such as the stacks, IT and tracking/traceable systems. All these aspects should be reviewed to ensure fitness for purpose in the future use of the instrumentation along with value for money in the long term.

## Transvaginal and Transrectal Ultrasound Probes (TVUS and TRUS probes)

These probes are being used increasingly throughout the NHS, including community clinics, maternity, urology, and radiology, antenatal and outpatients departments. Ultrasound equipment is designed to make it easier for the patient to have safe treatment and a quicker diagnosis.

These new systems bring with them their own challenges in terms of cleaning and disinfection. It is essential that the probes, cables and supporting cups/trolleys are thoroughly cleaned and disinfected between patients (the cleaning methods have been highlighted in the previous sections).

As the trolleys used with these devices are mobile, they can be taken and used in any treatment room, as required. Rigorous procedures are necessary to ensure continued safety for the patient, and this will include all parts of the system as stated.

The plugs for the probes are multi-pin and, if removed too many times, it is possible to damage the pins themselves. Therefore it is recommended that the



*An example of technology designed to provide validated decontamination process of TVUS/TVUR probes*

cleaning and disinfection of this equipment takes place in the location it is being used in, usually in the treatment room.

For traceability and quality assurance purposes, a document system must be in place that ensures that the contamination/decontamination status of each individual probe and trolley is very clear. For example, a system of labelling might be set up that differentiates between equipment that is cleaned and disinfected, ready for use, against a dirty probe/trolley that has just been used. Therefore it is strongly recommended that probes and trolleys be marked up with a system that makes it very clear to untrained staff what the status of these devices is if moved from one clinical area to another, or parked in corridors ready for use, minimising the risk of making inappropriate assumptions.

## Chapter 4 Process chemicals

### Summary for users

Guidance is given on the properties of process chemicals used in an AER cycle in relation to materials, the AER process, load items and water-quality compatibility. Classes of detergent and disinfectant 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 AERs are incompatible with one another. Therefore the chemicals tested by the AER manufacturer and detailed in the type-tests should be used. The AER 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. The chemicals used are such that long-term damage to endoscopes is inevitable and needs to be monitored and managed accordingly.

#### Note

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

- 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 AER and there is a means to verify that the minimum effective concentration is not exceeded.

### Compatibility with the materials of construction of the AER

- 4.5 AER manufacturers may specify some chemicals that over time will lead to accumulated damage to the AER. This statement should be backed up with

documented evidence and test data. The choice of process chemicals should be limited to those tested by the AER 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 AER.

- 4.6 Chemical additives that can be absorbed into, or adsorbed onto, surfaces of the AER (for example, plastic pipework) may be carried over into subsequent stages of the process.
- 4.7 If the chemicals used in the AER 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 AER manufacturers before any changes are introduced. The AER manufacturer should have tested the proposed chemicals to determine their efficacy and the best settings of the AER control system during type-testing.

**Type-test data must be supplied by the manufacturer for compatibility statements and certificates for the chemicals, materials and AERs in use.**

### 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 AER, 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 the 'Water quality and water treatment' section in the 'Design and installation' volume.

## Detergents, enzymatic cleaners and disinfectants

### Note

Research and product developments for the types of detergent, disinfectant and process is continuous, and therefore solutions should be investigated at the time of purchase of AERs and endoscopes for safety, compatibility and efficacy of the cleaning process in line with the latest guidance and BS EN standards.

### 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 contributes to unacceptably high residual levels and possible endoscope damage. The AER manufacturer will have determined the most suitable chemical concentrations, and the AER 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 parts of the endoscope for cleaning and disinfection purposes;
  - the supplied water quality.
- 4.16 The material of construction of the AER (see paragraph 4.5, 'Compatibility with the materials of construction of the AER') 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 AER 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 of the cleaning process and the potential damage to the devices. 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 AER that operates at an elevated temperature during the cleaning stage, otherwise they may have a shortened lifespan.

4.21 When validating and testing a new AER, it is recommended that the detergent as stated in the

type-test data be used. The cleaning results should then be similar to the tests carried out when the AER was developed. It is possible to carry out comparative cleaning tests using different agents, but it is not easy and will take the AER 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. During the factory or works tests, the AER manufacturer will determine the parameters for the AER operation that match the detergent as agreed and selected for use with the AER.
- 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 AERs 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 require at least 10 minutes to clean. Therefore enzymatic cleaners are not suitable for all AER cycles, as some machine designs operate a cold chemical cycle without predetermined heating stages.
- 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 AER 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 AER.
- 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 AERs.
- 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 AER cycle. Technical information from the disinfectant manufacturer should provide information about product activity.
- 4.33 The disinfectant needs to be CE-marked; the AER cycle data (type-test data for the specific disinfectant used) can be obtained from the AER 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.
- 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.
- 4.36 Single disinfectant use (shot) AERs and systems are recommended for use in Wales. This method is recommended as the concentration and antibacterial activity of the disinfectant is known for each cycle. Historically, some AERs reused disinfectant solutions for a number of cycles. When these methods are still in use, safety mechanisms should ensure the automatic cycle will 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 number of uses of the diluted disinfectant has been reached.

## Summary of the main classes of disinfectant used to process flexible endoscopes

### *Peracetic acid*

- 4.37 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 AER rather than manually.

### *Halogen-based disinfectants*

- 4.38 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 AERs.

### *Electrolytically-generated hypochlorous acid*

- 4.39 Electrolytically-generated hypochlorous acid is used in many AER disinfection systems. The disinfectant is produced and supplied on-site via an external generator that directly supplies the AER. 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 AER 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 AER, 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. (Seek technical guidance from the disinfectant manufacturer on these levels.)
  - The recommendations of the manufacturer should be followed to prevent corrosion damage to endoscopes.
- 4.40 Electrolytically-generated hypochlorous acid may be used as the main disinfectant and added to the final rinse-water to kill contaminating organisms.

## Safety of AER chemicals

- 4.41 Safe storage provision is needed for containers of chemicals used in the AER. 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.
- 4.42 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).
- 4.43 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 to 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;
- a hazard notice – to alert other employees/ patients of the spill incident.

### Note

**A spillage policy should be available to all staff and kept near to the spills kit to ensure the spill is cleaned up appropriately.**

- 4.44 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.
- 4.45 Suppliers of both detergents and disinfectants used should provide material safety data sheets for the products supplied. These should include details of biocompatibility studies.
- 4.46 A hazard from AER 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.
- 4.47 In large installations, bulk storage tanks for chemical additives required for the process may be preferred, with a piped distribution system to each AER.
- 4.48 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 section on ‘Drainage’ in WHTM 01-06 Part E ‘Testing methods’).
- 4.49 The AER 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 AER disinfection systems use non-toxic disinfectant, and a rinse stage may not be necessary in the event of cycle failure.
- 4.50 For AERs 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. Advice is available from NWSSP-SES.
- ## Residual chemicals
- 4.51 The chemical additives used during the AER process (detergent, disinfectant, etc.) may not be completely removed by the rinsing stage.
- 4.52 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 where the endoscope is used, patients’ sensitivity to the residual chemical will vary. Therefore, as AERs can process endoscopes to be used in many sites, it is important that the reprocessed endoscope has no detectable chemical carry-over from the process unless the disinfectant is non-toxic.
- 4.53 The supplier of any chemical agent used should provide data on the chemical composition of the chemical agent, method of detection and its compatibility with the AER and endoscopes.
- 4.54 Sampling methods and analytical method should be capable of determining the maximum acceptable level.
- 4.55 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 ‘Chemical additive residual levels’ in WHTM 01-06 Part E ‘Testing methods’).
- 4.56 An exception to the guidance are AERs 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.
- 4.57 Suppliers of wipe systems should provide evidence that any residual chemical is non-toxic to humans.

**Maximum acceptable residual chemical level**

4.58 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.

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

# Chapter 5 Tracking, traceability and audit trail

## Summary

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 recommended that all Health Boards/Trusts 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 and validated 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 AER that has affected endoscopes processed for the last few days.

- 5.5 The recommended objective for any endoscope decontamination facility 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 2007/47/EC** 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. Advice should be sought from the Health Board/Trust Sterile Services Manager on these systems.

## 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, 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 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 Department of Health (England) issued '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.” In Wales, the decision on whether to adopt the GS1 System or an alternative system rests with individual Health Boards/Trusts.

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 that endoscopes are effectively and accurately traced through manual wash, through an AER, through a drying cabinet, dispatched to the user for locating purposes (and finally to use on a patient, followed by the flush through at the bedside after use). 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. The system should NOT allow the endoscope to move on to the next stage of the decontamination process if the previous stage or process was not carried out and recorded with a satisfactory result. **Advice on these systems can be sought from the HB HSDU manager.**

5.13 Traceability records should consist of the following:

- uniquely identified endoscope and accessories (consideration should be given to using the GS1 system);
- manual wash result (pass/fail) including visual inspection, manual leak test and cleaning of valves;
- when required, expiry date, name and batch number of the chemicals used during the manual wash and AER process should be logged;
- the AER used;
- the AER cycle number;
- the AER result (pass/fail);
- if a cassette system is used, the identity of the boxes in use with the specified endoscope;
- where required, record of the drying cabinet (or cassette system) that 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 AER, manual cleaning or drying cabinet.

## Maintenance

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

- AER self-disinfection cycles;
- AER maintenance cycles;
- AER 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 education and training:

- An education and training plan should be agreed between the customer and supplier of the AER, endoscope manufacturer and the tracking and traceability system provider.
- The suppliers should provide a documented training record for the staff who have completed the training.
- System user manuals should be provided, preferably electronically as part of the system, covering every area as required.
- The system should NOT allow staff to carry out parts of the process that they have not been formally trained to do.
- 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 specified AER(s).

## 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 were ever required, unless the sites in question have one shared database on one server. This way they can view both or all sites of endoscope use, enabling them to move the endoscopes from one site to another and carry on with the tracking.

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 provides the most efficient and reliable mechanism to ensure that accurate data is retrievable for each stage of the decontamination cycle. A computerised system should allow the User to generate historical decontamination records in a timely manner. Where appropriate traceability systems are already in place within the healthcare facility, there are many benefits in standardising the decontamination traceability systems.

## 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, AER, storage and finally to use on a patient and the flush through at the bedside. 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 existing users will often determine whether the selected system is suitable for a particular department.

5.29 Barcode technology is used to capture data at each stage of the decontamination process. At every stage the operator and the unique endoscope number are 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;
- barcode 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.

## 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, AER, storage and finally to use on a patient (including the flush through at the bedside) on a single system, backed up on the main hospital server.

### 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;
- 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;
- if the use of the endoscope to the patient has not been recorded, the facility to either do so or record that the endoscope has not been used on a patient should be highlighted to the user/operator.

### The AER process

5.35 Endoscopes should be recorded through the AER 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 AER load key functions could include the following:

- record of the endoscopes into the AER;
- record of AER identification number;
- AER cycle number, time and date;
- endoscope cycle number;
- records of any comments against the cycle;
- load may be left pending for multi-chamber AERs;
- the operator responsible;
- cleaning solution and disinfectant details and batch numbers;
- 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;
- the system should NOT allow the operator to load the endoscope into the AER unless a manual wash activity is recorded.

5.37 The age and design of each AER will dictate the options available for traceable systems and options; an additional traceability system may be required. Advice should be sought and investigated.

5.38 AER unload key functions could include:

- leak-test results;

- record of endoscopes out of the AER;
- AER number;
- AER 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 barcode labels);
- the operator responsible;
- the patient tracer label – if the endoscope is to be placed into a drying cabinet, the label should be able to be produced upon loading the cabinet, or at dispatching to eliminate mixing labels or losing them whilst stored in the specified cabinet. If producing a label on dispatch, the operator should be able to relay to the end-user when the endoscope should be used by (date/time) and print it on the 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;
- if the endoscope has exceeded the AER-to-storage/drying cabinet time, the system should NOT allow the operator to load the endoscope into a cabinet and should warn the operator that the endoscope should be reprocessed.

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;
- if the endoscope has exceeded the prescribed storage time, the drying cabinet should warn the operator that the endoscope should not be used on a patient.

### Dispatching the endoscope to the end-user

5.42 When dispatching endoscopes to end-users, the following procedure should be followed:

- the endoscope should be dispatched to the end-user indicating the department it is being dispatched to by manual input using a computer keyboard and mouse or by scanning a unique number/code for patient identification;
- a patient label should be able to be produced with the 'use-by date' and time on it to be clearly read;
- the operator responsible should be identified;
- all time- and date-stamped entries should be logged and traceable;
- if the endoscope validated storage time or the general 3-hour rule (BSG guidelines) are exceeded, a system should be in place to prevent the endoscope being used on a patient.

### Endoscope to patient

5.43 The use of an endoscope on 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.

5.44 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;

- if the endoscope has exceeded the validated storage time or the general 3-hour rule, the system should not allow the endoscope to be used on a patient and the scope should be reprocessed;
- if in unforeseen circumstances the endoscope has to be used on a patient after it has exceeded the validated storage time or the general 3-hour rule, a responsible person with administration rights should be allowed to record this overruling in the patient's notes;
- single-use items provided by any external suppliers should be able to be recorded in the patient's notes and a full audit report should be available in case of a product recall.

### Operators and engineers

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

5.46 Operator and engineer key functions include:

- the operator responsible;
- details of new cleaning solutions and disinfectants;
- details of cleaning solutions and disinfectants;
- daily operator AER validation cycles;
- non-planned engineer AER tests;
- daily, weekly, monthly and yearly AER validation cycles;
- AER self-disinfection cycles;
- AER load details;
- viewing of AER and cabinet contents at any time;
- all time- and date-stamped entries written to the audit trail;
- when returning an AER from maintenance work or repair, the operator should NOT be allowed to load the AER unless a self-disinfection process or cycle has been carried out, accepted and recorded.

### System administration

5.47 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.

5.48 Key functions of administration could include items from this list:

- supplied with a manual backup system;
- system administration functions to be restricted to authorised personnel;
- comprehensive endoscope inventory should be available and maintained;
- new endoscopes should be added to the inventory by the User before use;
- endoscope details may be edited by the User;
- endoscope inventory detail reports may be produced by the User;
- endoscope inventory barcode (or other method of identification) booklet may be produced by the User;
- operator name badges including barcode identification as produced by the User;
- administrator passwords for use;
- 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 and logged;
- endoscopes may be sent to and returned from repair by the User, with reasons logged and reports filed;
- repair location and company details should be logged;
- new cleaning solution and disinfectant details should be recorded;
- cleaning solution and disinfectant details may be edited, changed, recorded and logged by the User;
- non-conformance barcodes (or other method of identification) may be produced, edited and deleted by the User;
- audit history reports of machines and departments should be produced and recorded as agreed with the Health Board/Trust;
- a comprehensive product to patient report (and vice versa) should be produced by the User;
- AERs and drying cabinets should be named and uniquely identified;
- AER cycles and drying cabinet tests will be validated and only changed with technical advice and agreement with the User, AP(D) and AE(D);
- a system will be set to print a trace for the patient after AER use or after drying cabinet storage;
- the number and type of patient tracer labels required and system will be set by the User;
- any system configuration changes within the system(s) should be logged and recorded and reports 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 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 stored for the correct period of time in a drying cabinet;
  - after reprocessing in the AER, use time and storage time in the drying cabinet may be configured by the User after validation testing and detailed reports have been audited and accepted;
  - maximum drying cabinet time may be configured by the User with validation testing for each type of endoscope;
  - the system may be configured to skip the drying cabinet by the User (depending on times and processing);
  - 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.
- 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.
- 5.53 It is likely that an endoscopy department will be subject to external audit (see [Chapter 6, 'Audit of flexible-endoscope decontamination'](#)).
- 5.54 See also [paragraph 6.9, 'Audit – decontamination'](#).

## Tracking and traceability audit

- 5.49 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.
- 5.50 Attention to detail is important to ensure all data is captured at the correct time. Errors or omissions can be difficult to rectify later.
- 5.51 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.
- 5.52 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.
- 5.55 A backup of the tracking and traceability system should be available and stored off-site in a secure place.
- 5.56 A password system should be used to prevent unauthorised access to the data.
- 5.57 Patient data should be in the form of codes unless the system is protected.
- 5.58 The system database should be well regarded by the trade, reliable, and the appropriate licences should be in place.
- 5.59 The data system should be able to support different identification systems, each to be examined and evaluated, for example:
- bar-code EAN13 and EAN128;
  - two-dimensional data matrix;
  - NHS data interchange (for example, HL7);
  - RFID (radio frequency identification).
- 5.60 Loan equipment should be able to be entered onto the tracking and traceability system using the NHS data interchange, for example HL7.
- 5.61 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 data-handling solution.

- 5.62 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.
- 5.63 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.
- 5.64 It is very important 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. If new machines are being purchased, the IT department must be involved in the process from the beginning and the machines registered on the framework before being put into use.
- 5.65 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 back-up by the hospital will be much easier to arrange.

# Chapter 6 Audit of flexible-endoscope decontamination

## Summary

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, environment, ventilation, tracking and traceability, education and training. 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 of both the decontamination process and the internal structure of the endoscopes in use is required to obtain a satisfactory outcome. The expertise of the AP(D), DE(W) and AE(D) and Infection Prevention and Control teams and sterile service managers 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 the standards and guidance. 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 ongoing quality control survey;
  - b. external audit, when an audit officer from outside the organisation examines the department against the Infection Prevention Society's (IPS), BSW or NWSSP-SES audit tools;
  - 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 have the same layouts or operate in exactly the same manner, and there are several ways of achieving a satisfactory and safe result.
- 6.5 An internal audit tool can be divided into small sections, so that 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/decontamination documents are filed with the unit manager 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 as required by the HB decontamination team or quarterly using the IPS audit tool. For the AER(s) and environment, NWSSP-SES can carry out an audit of the decontamination room(s) and process.
- 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, evidence should be available to demonstrate its effectiveness.

6.11 A full documented history of each AER 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;
- logbooks on the AERs.

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 AER(s);
- operation of the AER(s);
- transfer of the endoscope to either the operating room or into the storage/dryer;
- the endoscope drying/storage system;
- pre-use 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 an 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 it should be 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 5.49, 'Tracking and traceability audit'](#)).

6.15 The maintenance and testing of the AER will form part of the audit as listed above, including the use of a logbook set up for each individual machine, plus evidence of breakdown history.

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

## Audit tool forms (technical)

6.24 The following audit tool forms can be used in Wales:

a. **Infection Prevention Society website**

- Care Setting Process Improvement Tools
- Endoscopy decontamination
- Endoscopy environment

b. **Public Health Wales – Bowel Screening Services website**

- Bowel Screening Services audit tool in conjunction with NWSSP-SES for screening centres.

c. **NHS Wales Shared Services Partnership – Specialist Estates Services website**

- AER(s) and equipment for the users of the Welsh NHS as required.

- All Wales Endoscope Decontamination Audit Tool 2014.

NWSSP-SES carry out an assessment of the decontamination facility, ventilation and the environment.

6.25 Completed audit forms and a non-compliance list should be filed and copies forwarded to the User, Decontamination Team, Infection Prevention and Control team and risk management group. It is important that appropriate action follow an audit, as this is the purpose of the exercise. The Healthcare Inspectorate Wales (HIW) or equivalent regulatory body may regularly request copies of the non-compliance forms, enabling them to check the timescale of highlighted improvements.

6.26 The Joint Advisory Group (JAG) carry out assessments in the service, and these concentrate on the education and training aspects of staff and patient experiences, flows and dignity. The above technical audit tools are involved with decontamination, and support and enhance the process in Wales.

# Appendix A: Technical specification template for the purchase of endoscope washer-disinfectors

This appendix contains a purchasing specification for use when planning to buy automated endoscope reprocessors (AERs).

Advice to be sought from NWSSP-SES DE(W), AE(D) and AP(D) with the User.

# Technical Specification Template for the Purchase of Automated Endoscope Reprocessors (AERs)

## Section 1

Reference document AER TST in support of WHTM 01-06

Name of Health Board	Details
Purchaser	
Hospital site	
Department	
Name of User and contact details	
Name of Estates contact and details	
Technical support	NWSSP – Specialist Estates Services This includes the services of the decontamination engineers DE(W) and the Authorising Engineer (Decontamination)

The machine(s) are to be supplied under the agreement of NHS Wales Shared Services Partnership – Procurement Services and the NHS Supply Chain framework agreement.

Technical support by NHS Wales Shared Services Partnership – Specialist Estates Services.

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

**All equipment suppliers must ensure that all items listed in this template are essential requirements and not optional – the supplier must make very clear to the client any further options available for a final decision and agreed specification before agreements are made on the contract price.**



# 1 AER selection details

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

**Note:** It is recommended that the User complete an internal audit of all Flexible Endoscopes that are intended to be reprocessed through the AER. This ensures correct connections (numbers) and connectors are supplied with the AER.

The audit should highlight the channel configurations and specific reprocessing requirements for each endoscope in alignment with its manufacturer’s instructions.

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 channel configuration.

AER type	AER	Drying cabinet
Numbers of machines		
Chamber capacity – size (nominal)		
Special requirements		

**Requirement:** On submission of the tender to the client, it is a requirement to submit type-test data as part of the documentation for the type and model of AER(s) quoted.

<p><b>Special Reprocessing Requirements:</b></p> <p><b>Details</b></p> <p>Channel patency</p> <p>Details required as per blocked channel/partial blocked channel for the AER(s)</p> <p>AER – will the machine detect full channel blockage? (yes or no)</p> <p>Quote cycle failure pressure set points</p> <p>AER – partial blocked channel operation? (yes or no)</p> <p>Quote cycle failure pressure set points</p>
---

## 2 AER – Washer-disinfector operational cycle requirements

Please discuss options with manufacturer representative.

Type Cycle	Required (yes or no)	Options and comments

## 3 AER – Washer-disinfector process chemical(s) – options

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

**Note:** Type-test data/certificates on compatibility test to be supplied with the tender documents by the manufacturer.

#### 4 AER – Washer-disinfector – self-disinfection options

4.1 Research indicates that thermal disinfection has been shown to be the more efficient method of reducing internal bio-films that 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 any interim storage, installation for 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.

**General comments or details for access, storage, delivery**

#### 6 Delivery details of packing methods

Select:

- Standard packing for basic weather protection – A
- Good weather covering to protect machines under delivery – B
- Dustproof packing and wrapping for further storage needs – C
- Dustproof 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 must be submitted to the client prior to tender to view the details of the installation.
- 8.2 Any drawings such as engineering services supplied or required of the supplier by the client must be clearly agreed and defined during the tender process.
- 8.3 All service(s) and connections must be agreed by the supplier and client (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 must be supplied with the washer-disinfectors on site delivery.

## 10 Air supply (if required)

- 10.1 Compressed air may be required for AER operation.
- 10.2 Details of air standard required by the manufacturer:  
It must be agreed at the tender stage how the air will be supplied to the AERs.  
Select one or more:
  - A Individual machine compressors
  - B Central compressor supply
  - C Other

### Comments and details

## 11 Heating medium (thermal disinfection)

- 11.1 The AERs may be steam- or electrically heated. This will be decided by the purchasing team after consultation with the user and NWSSP-SES engineers. Investigations and information should be sought from all AER suppliers involved in the process. Medium choice will affect the cycle time.
- 11.2 The supplier must discuss the options available and services required with the user.

### Comments and details

## 12 Electrical supply

- 12.1 It must be agreed at the tender stage what the electrical loading/demand is for the installation.
- 12.2 Discussions must be held with the relevant estates department officers and the suppliers to determine the supplies in general, and whether single- or three-phase is available or required.

### Comments and details

## 13 Water supply

- 13.1 An assessment should be carried out on the supply water used in all phases to the AERs prior to the procurement process. It is the policy within NHS Wales that 'potable' supply water is the minimum standard for final rinse applications.
- See Chief Medical Officer professional letter reference CMO (2010)04.
- 13.2 A decision on whether further treatment is required can be assessed in conjunction with NWSSP-SES, the User, the AE(D) and Infection Prevention Control Officers.
- 13.3 The supplier should provide advice on the minimum supply pressure(s) required at each stage of the process(es).

### Comments and details

### Details of water treatment and management (as required)

Water treatment	Required (yes or no)	Comments and details
Filtration requirements		
Softeners		Ability to test for bio-film
Other(s)		

### 14 Endoscope washer-disinfector AER – monitoring

- 14.1 It is a requirement that the AER 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 NWSSP-SES and the client.
- 14.3 It is advisable that the instrumentation be connected to the hospital IT server and system.

<b>Comments and details</b>
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### 15 Consumables

- 15.1 At the time of delivery of the washer-disinfector(s), consumables such as printer rolls and cartridges must be supplied to the unit for a minimum of a three-month operating period of constant use.
- 15.2 Discussions must be held between the supplier and the SSD manager or representative prior to tender to explore the solution options available with machines.
- 15.3 Consumables are required to be supplied with the machines.

<b>Details of general consumables required by the User</b>
--

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

- 16.1 Provide details of equipment needed to load flexible endoscopes into the AER.
- 16.2 If it is a specific 'cassette system' where special brackets are needed, specify special requirements and number of each needed.

<b>Comments and details</b>
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## 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. NWSSP-SES engineers will oversee the work on behalf of the client.**
- 17.3 The AE(D) or DE(W) from NWSSP-SES will be monitoring and auditing all test results.
- 17.4 The supplier will consult with the client and NWSSP-SES engineers for any technical advice required.

<b>Further comments/requirements</b>
<b>Details of any special loads</b>

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

## 18 Service response times and costs

<b>Details and client response time(s) requirements</b>
<b>Breakdown advice time required</b>
<b>Site attendance time required</b>
<b>Spares availability in delivery to site</b>

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

### 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 departmental 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 that downtime is minimised through on-site technical knowledge of the system).
- 20.6 Numbers of staff required for training.

### Comments and details

## 21 Warranties

- 21.1 Details should be quoted and agreed with the client and the date from which they will commence.
- 21.2 Costs in section 2:
  - The agreement must 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 client.

- Quarterly testing contracts – quotation required
- Breakdown callouts – to be defined
- Response times – to be defined
- Maintenance contracts as required – quotation required
- Availability of spares – to be defined

**Details to be given in Section 2 by the supplier.**

## 23 Ventilation requirements of the endoscope washer-disinfectors (AERs)

23.1 Ventilation of the area near AERs may be needed to remove excessive heat and humidity, and also vapours from disinfectants such as peracetic acid. Space requirements may need to be increased for staff safety and increased ventilation to meet the standards.

**Note: Low-level extract will be required where peracetic acid is used by the AER manufacturer.**

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

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

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

23.6 Further guidance can be obtained from WHTM 03-01.

**Basic summary of service requirements (reference template paragraph if necessary):**

To be completed in conjunction with NWSSP-SES, manufacturer, local estates department representative and user.

Services	Requirements	Details
<b>Water supply</b>	Source of the water supply (e.g. mains feed, tank supply, scavenge system, 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 AERs? Can this be achieved by the chosen water supply?	
<b>Compressed air</b>	Determine quality of the compressed air required and required pressure range for reprocessing	
	Method of supplying compressed air (e.g. dedicated compressors, central supply)	
<b>Drainage requirements</b>	Manufacturer's recommendations	

<b>Services</b>	<b>Requirements</b>	<b>Details</b>
<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 client for a good and effective installation.

### INFORMATION TO BE COMPLETED BY SUPPLIER

#### Details of microprocessor control system

The following information shall be provided by the supplier.

Full details and evidence with results of the type-test data conforming to BS EN 15883 Part 4 for the AER considered with this document.

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 preventive maintenance and emergency callout 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 callouts included: \*YES / NO

Price for emergency callout 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 callouts (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**

**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.....

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 WHTM.**

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 an option for consideration.

**Service requirements**

The following information shall 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 washer-disinfector .....  
total sound power all specified washer-disinfector(s) .....  
process chemical cost per cycle .....  
other .....  
cost per cycle .....  
total energy cost per ..... cycle (please specify cycle type) .....

**Overall AER dimensions**

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

m/c no  
internal chamber dimensions [H × W × L] mm .....  
max floor area  
height  
max floor loading force kN/m<sup>2</sup>  
max fascia opening

Total cost of processing 1 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 p/kWh  
Steam £/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 shall be provided by the Supplier.

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

..... W

**Contract Completion**

The following information shall 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 shall be provided by the Supplier.

Item AER Type Model

Name/No

No. off

Agreed NHS Supply Chain contract prices

Discount %

Unit Total Price Chamber Furniture

Cassettes £ Numbers off

Carriages £ Numbers off

Total costs £

AER 1 £..... AER 4 £..... Total costs £.....

AER 2 £..... AER 5 £.....

AER 3 £..... AER 6 £.....

**Summary of Tender**

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

**£**

supply (no. off) ..... Endoscope washer-disinfectors ex works	.....
delivery, offloading and positioning of AER(s)	.....
installation of AER(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 months' service including 4 off quarterly visits	.....
staff training, consisting of ..... days	.....
supply chamber furniture type	.....
costs of consumables	.....
costs of cleaning solutions – detergents/disinfectants etc.	.....
monitoring equipment	.....
supply ..... set(s) of recommended service spares	.....
contingency – to be set by Purchaser	.....
SUB-TOTAL	.....
..... VAT @ ..... % .....	.....

**Hospital:**

**Site:**

**Department:**

**TOTAL £.....**

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



## References

### Acts and Regulations

Control of Substances Hazardous to Health Regulations (COSHH)

[www.hse.gov.uk/coshh](http://www.hse.gov.uk/coshh)

Medical Devices Regulations

Medical Devices Directive 2007/47 EC

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:247:0021:0055:en:PDF>

### British Standards Institution

<http://shop.bsigroup.com/en>

**BS EN ISO 15883-4** Washer-disinfectors. Requirements and tests for washer-disinfectors employing chemical disinfection for thermo-labile endoscopes (Latest version)

**BS EN ISO 13485** Medical devices. Quality management systems – Requirements for regulatory purposes (Latest version)

**BS EN 61010-2-040** Safety requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for sterilizers and washer-disinfectors used to treat medical materials. (Latest version)

**BS EN ISO 13849-2** Safety machinery. Safety-related parts of control systems. Validation. (Latest version)

**BS EN 1041** Information supplied by the manufacturer of medical devices. (Latest version)

**BS EN ISO 17664** Sterilization of medical devices. Information to be provided by the manufacturer for the processing of resterilizable medical devices. (Latest version)

**BS EN ISO 14971** Application of risk management to medical devices. (Latest version)

### Department of Health publications

Coding for success: simple technology for safer patient care

### Infection Prevention Society

[www.ips.uk.net](http://www.ips.uk.net)

### Medicines and Healthcare products Regulatory Agency (MHRA)

[www.mhra.gov.uk](http://www.mhra.gov.uk)

*MHRA provides updated alerts and device bulletins for users of all designs of endoscopes and techniques adopted in the decontamination of such devices. Latest amendments are available from the website.*

DB 2002(05) – Decontamination of Endoscopes

MDA/2012/037 - Reusable Transoesophageal echocardiography, transvaginal and transrectal ultrasound probes (transducers)

MDA/2013/019 - Detergent and disinfectant wipes used on reusable medical devices with plastic surfaces. All manufacturers.

### NHS Wales Shared Services Partnership – Specialist Estates Services

*The publications below are available from the NHS Wales Shared Services Partnership – Specialist Estates Services websites*

*Intranet:* [howis.wales.nhs.uk/whe](http://howis.wales.nhs.uk/whe)

*Internet:* [www.wales.nhs.uk/whe](http://www.wales.nhs.uk/whe)

Welsh Health Technical Memorandum 01-06 – Decontamination of flexible endoscopes Part A Management and environment

Welsh Health Technical Memorandum 01-06 – Decontamination of flexible endoscopes Part B Design and installation

Welsh Health Technical Memorandum 01-06 – Decontamination of flexible endoscopes Part C Operational management

Welsh Health Technical Memorandum 01-06 – Decontamination of flexible endoscopes Part D Validation and verification

Welsh Health Technical Memorandum 01-06 –  
Decontamination of flexible endoscopes  
Part E Testing methods  
Health Building Note 13 – Sterile services department

**NHS Supply Chain**  
[www.supplychain.nhs.uk](http://www.supplychain.nhs.uk)

**National Institute for Health and Care  
Excellence (NICE)**  
[www.nice.org.uk](http://www.nice.org.uk)