

BSG GUIDANCE FOR DECONTAMINATION OF EQUIPMENT FOR GASTROINTESTINAL ENDOSCOPY

The Report of a Working Party of the British Society of Gastroenterology Endoscopy Committee

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Members of the British Society of Gastroenterology Endoscopy Section Committee Working Party on Decontamination of Equipment for Gastrointestinal Endoscopy 2014:

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Summary

- 1) Decontamination of endoscopes should be undertaken by staff trained and educated in the procedures within dedicated and well-designed rooms. There should be one-way flow of endoscopes between dirty returns and clean dispatch areas to prevent cross contamination. Best practice is that there should be physical separation of dirty and clean procedures and areas, each with its own detailed procedures. The washroom area, if separated dirty and clean rooms are used, should have a negative pressure in comparison to the clean side. See Health Technical Memorandum (HTM) 01-06 part B. If a single room procedure is used, the room must be well designed to ensure a good and safe flow is well managed. Units should be moving away from single-room facilities and all new designs should have split rooms with clearly segregated clean and dirty areas.
- 2) Staff training should be implemented using a competency framework and should be documented and revalidated annually. Training should include an awareness of the channel configuration of all endoscopes, manual cleaning procedures and of the endoscope washer disinfectors (EWD) and available irrigation adaptors, and any post cleaning processes (e.g. controlled environment storage cabinets [CESCs]) or portable storage systems, such as vacuum packing, that may be in use. See HTM 01-06 part D. These systems must be checked on a regular basis and validated by the manufacturer.
- 3) Traditionally, it has been recommended that before the start of each list, each endoscope to be used should undergo a full reprocessing cycle unless last used and decontaminated within the preceding 3 hours. Where appropriate quality assurance data are available, the use of CESCs or portable storage systems may obviate the need for repeat endoscope reprocessing at the start of each list.
- 4) Thorough manual cleaning with a CE marked detergent that is compatible with the disinfectant, including the brushing and flushing of all accessible endoscope channels, must be undertaken before automated endoscope disinfection within an EWD. This routine must be undertaken during lists, between patients and after each patient examination.
- 5) Units should no longer be using aldehyde- and alcohol-based disinfectants because of their fixative properties, which in theory could anchor prion and other proteins within endoscope channels. Units should employ single-use disinfectants within purpose-designed washer disinfectors.
- 6) All detergents and disinfectants must be compatible with the EWD and endoscope and used at the correct temperatures and concentrations in accordance with the detergent and disinfectant manufacturers' instructions. Machine testing should include the efficacy and reproducibility of the detergent and disinfectant dosing system, in accordance with the EWD manufacturer's instructions.

- 7) It is important to ensure that both the endoscope and EWD manufacturers have type-tested the chosen detergents and disinfectants that are compatible for use with their products.
- 8) It is essential that all reprocessing stages are included and documented after every use of the endoscope, and that none is omitted. It is also essential that all channels of all endoscopes are reprocessed after every use of the endoscope, even those that were not used during the preceding patient procedure.
- 9) EWDs should be used to wash and disinfect all endoscopes following manual cleaning. Manual disinfection alone is unacceptable. Some endoscopes may need to be sterilised depending upon their intended use, with a sterilisation process that is compatible with the endoscope. Users must ensure that the correct adaptors are available for all endoscopes to ensure irrigation of all channels. See HTM 01-06 part E.
- 10) Filtered air should be used as part of the drying process for each endoscope at the end of each EWD cycle. CESC's are recommended to store cleaned endoscopes. These are designed to deliver high-efficiency particulate filtered air (HEPA) to the internal channels at the appropriate temperature and flow rate. Due to its fixative properties, the use of alcohol to assist in drying endoscopes is no longer recommended.
- 11) Water used in an EWD should be free from particulate and chemical contamination and micro-organisms. This can be achieved either by using water purification systems, which can be a combination of high-level filtration and additional disinfection methods (e.g. ultraviolet light), or by using a reverse osmosis plant. In-line water softeners may be needed if the local supply delivers hard water. The final rinse water should be sampled from the EWD and tested weekly for its microbiological quality in accordance with International Organization for Standardization ISO 15883-4:2018 or HTM 01-06 part E. Trending of results is advised to identify any potential problems.
- 12) Hospitals undertaking endoscopy outside normal working hours will need to ensure that any remote facility is able to accept endoscopes for reprocessing on weekend days and public holidays. All endoscopes should be reprocessed as soon as possible following use, but routinely within 3 hours. Endoscope drying and storage facilities need to be present both in the endoscopy unit and in the remote facility. Any processed endoscope that remains outside such storage facilities or are unwrapped will need to be used within three hours of reprocessing, which must include (i) the transportation time between reprocessing or leaving storage at the remote site and the return to storage at the endoscopy unit PLUS (ii) the time between storage and use in the next patient in the unit itself. An electronic tracking and traceability system is mandatory for units relying on a remote decontamination facility.
- 13) A record should be kept of the serial number of each endoscope used on each patient. This log should include any loan endoscopes. This is important for any future contact tracing when possible endoscopic transmission of disease is being

investigated. Details of each decontamination step, including the operator performing the bedside clean, leak test and manual clean, the EWD and the cycle details, including cycle number, used in decontaminating that endoscope should also be kept. This log should also include loan endoscopes.

- 14) The agent of variant Creutzfeldt-Jakob disease (vCJD) is believed to be resistant to all forms of conventional sterilisation. The risk of transmission of this agent is extremely low provided that scrupulous attention to detail is routinely employed in the decontamination process after every patient. In particular, all accessible endoscope channels should be brushed through with a single use purpose-made device or brush tipped wire assembly that has an appropriate length and diameter for each channel.
- 15) Any endoscopic procedure that breaches gut mucosa and is followed by the withdrawal of an unsheathed accessory through the working channel of an endoscope is deemed “invasive”. Procedures that cause tissue vaporisation (e.g. diathermy) are also deemed “invasive”. If an invasive procedure is undertaken in i) a patient with definite or probable vCJD, ii) a patient in whom a diagnosis of vCJD is being considered or iii) a patient at increased risk of vCJD (in whom infection should be presumed) through receipt of labile blood products, such as red cells from a donor who later developed vCJD, it will necessitate the subsequent quarantining of the endoscope used.
- 16) The performance of an “invasive” procedure (defined in it15 above) in a patient at risk of vCJD due to receipt of pooled plasma concentrates is no longer deemed to confer a high risk of endoscope contamination. A single quality assured decontamination cycle according to these guidelines is considered sufficient, but the endoscope should be decontaminated separately from other equipment within an EWD and with a single-use disinfectant. There is no longer a requirement to quarantine the endoscope provided that routine traceability data can demonstrate thorough reprocessing.
- 17) Single-use accessories should always be used. The choice of single-use biopsy forceps, guidewires and cytology brushes helps to minimise any possible risk of transmitting prion disease. Reusable accessories should be used only in situations where no single-use equivalent accessory exists, and they should be heat tolerant for sterilisation in the Sterile Services Department. Procedures should include a system for tracking use in each patient in these circumstances.
- 18) Rubber biopsy port caps must be discarded after all procedures involving the passage of biopsy forceps, guidewires and/or other accessories through the endoscope. Other detachable valves (primarily air/water and suction valves/pistons) should be manually cleaned according to the manufacturers’ instructions, then decontaminated with their corresponding endoscopes in an EWD, keeping the valves and endoscopes together as a traceable unique set. There is an increasing move towards using single-use endoscope valves to enable full traceability and to prevent cross infection caused by inadequate processing.

- 19) Due to the increase in demand for endoscopy, many units have had to expand in limited space, with the result that decontamination facilities have been moved to a location away from the endoscopy unit. Used endoscopes and their internal channels must be kept moist during transfer to decontamination facilities, and it is best practice that endoscopes are placed in an EWD within 3 hours of patient use. In addition, there must be electronic tracking of endoscopes between units and remote facilities.
- 20) By contrast, the channels of reprocessed endoscopes should ideally be dried prior to use in the next patient.
- 21) Control systems, like appropriate monitors, environmental testing, low level extraction and routine health screening, should be undertaken to minimise risks to staff. Occupational health records should be retained for 30 years.
- 22) All staff involved in endoscopy and in endoscope decontamination should wear appropriate personal protective equipment (PPE) in line with local policy.
- 23) Out-of-hours endoscopy should not be performed unless there is an individual available who has been assessed as competent in pre-cleaning and manual cleaning processes. If the decontamination facility is remote from the endoscopy unit, it is best practice to be able to accept endoscopes for reprocessing every day of the week. A detailed risk procedure must be in place for this process.
- 24) Endoscopes used invasively, for example for Natural Orifice Transluminal Endoscopic Surgery (NOTES), and choledochoscopes should be manually cleaned, processed through an EWD and finally sterilised using a validated, compatible sterilisation process. High-level disinfection is not sufficient. Reusable sheathed accessories passed up the bile duct may also require sterilisation (see section 8 below).

Exclusions

Flexible endoscopes that enter normally sterile body cavities are regarded as “critical devices” and these flexible endoscopes must be decontaminated by manual cleaning, automated washing, and disinfection, followed by sterilisation using a process that is compatible with the endoscope. Examples of such endoscopes that may require sterilisation include choledochoscopes, those used for NOTES (natural orifice transluminal endoscopic surgery), cystoscopes, utereteroscopes and nephroscopes. **This guidance is not intended for critical or high-risk devices, although the procedures for cleaning and disinfection prior to sterilisation do apply.**

1. Introduction and Historical Perspective

Flexible endoscopes are complex reusable instruments that require unique consideration with respect to decontamination. Their external surfaces and internal channels for air, water, aspiration and accessories are all potentially exposed to body fluids and other contaminants.

In contrast to rigid endoscopes, flexible endoscopes are heat labile and cannot be autoclaved. Most flexible endoscopes are classed as “semi-critical devices” as they are in contact with mucous membranes during use and present a moderate degree of infection risk if contaminated at the time of use (1). The process of flexible endoscope decontamination is referred to as “high-level disinfection”. This is the term given to a process that eliminates or kills all vegetative bacteria, mycobacteria, fungi and viruses except for small numbers of bacterial spores.

The *Health and Social Care Act: Code of Practice on the prevention and control of infections* and related guidance were published in England in 2008 and updated in 2015 (2). The Act stipulates the roles of decontamination leads and decontamination programmes. It emphasises the need for staff to be trained in decontamination processes and to hold appropriate competencies for their role. It decrees the need for monitoring systems to ensure that decontamination processes are fit for purpose and meet required standards. Finally, it requires that there are systems in place for tracking reusable medical devices, (e.g. endoscopes and reusable accessories) through decontamination processes, not only to assist with assuring their quality, but also to enable the identification of patients on whom the medical devices have been used. Similar guidance is employed in the other UK devolved nations.

The British Society of Gastroenterology (BSG) first published guidelines on decontamination in 1998 (3). Over the years many changes have been made to recommendations for the decontamination of flexible endoscopes. In order to be responsive to changes issued by Government agencies and other professional bodies, this guidance document has been revised twice.

2. Transmission of Infection at Endoscopy

A guiding principle for decontamination is that of standard precautions: any patient must be considered a potential infection risk, and every endoscope and device must be reprocessed with the same rigour following every endoscopic procedure. Few data exist as to the absolute risk of transmission of infection from patient to patient at endoscopy. In 1993 one report suggested that the reported frequency was 1 in 1.8 million procedures (4). Estimating the infection risk is difficult for several reasons: complications such as septicaemia following endoscopic retrograde cholangiopancreatography (ERCP) may be due to the induction of endogenous infection as opposed to the endoscope being a vehicle of infection. Additionally, the onset of infections complicating endoscopy may be delayed until after the patient has been discharged home following their procedure. There is also the potential for transmission of infective particles with very long incubation periods, such as vCJD.

Endoscopy-induced infection is usually due to procedural errors in decontamination (5–11). These include failure to decontaminate all channels, including auxiliary and duodenoscope elevator wire channels, and the use of incompatible connectors between endoscopes and EWDs (5).

A published review of endoscopy-associated infection identified that inadequate decontamination procedures and equipment malfunction were two leading causes of post-endoscopic infection and contamination. It was suggested that improved quality control systems could prevent over 90% of such infections (6). More recently, duodenoscopes have been implicated in numerous outbreaks with multidrug-resistant Gram-negative bacteria. The BSG issued guidance to staff carrying out the decontamination of flexible endoscopes, in particular duodenoscopes in 2015 (Table 1) (12).

Table 1: BSG Advice on Potential Transmission of Multidrug-Resistant Bacteria and Duodenoscopes

Adherence to manufacturers' instructions at all times is essential
The pre-clean procedure should take place at the patient's bedside, as described in the instructions from the UK suppliers and BSG guidance.
The cover on the raiser bridge mechanism at the distal tip should be removed prior to brushing all areas of the distal tip and cleaning with detergent and replaced on completion of the decontamination process. The brush must be used on all surface areas of the distal tip ensure that all debris is removed.
The elevator wire channel should be flushed with detergent during the manual cleaning ensuring the correct size syringe is used. If automated flushing systems are used for this stage of the process, staff should ensure that this channel is included.
Staff should ensure that the EWD has the capability of flushing the elevator wire channel with detergent, disinfectant and rinse water.
If stored in a drying cabinet, the elevator wire channel should be flushed with HEPA along with all the other channels. If this channel is not flushed with air, the endoscope should be used within 3 hours or the endoscope reprocessed before patient use. Not all cabinets have this facility. An international standard, EN 16442, has now been published for endoscope storage drying cabinets.

Routine microbiological surveillance of processed endoscopes is not recommended. However, this may be carried out on advice from the infection prevention and control team if an outbreak is known or suspected.
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Staff should receive comprehensive training, and a record retained, on all aspects of the decontamination of endoscopes, in particular, duodenoscopes.
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Four types of micro-organisms have merited particular attention during the past two decades:

- 1) **Mycobacteria:** the emergence of multidrug-resistant strains of *Mycobacterium tuberculosis* and the high incidence of infections with *M. avium intracellulare* among HIV-infected patients have led to greater awareness of the risk of transmission of *Mycobacteria* spp during bronchoscopy. Mycobacteria in general, and especially waterborne mycobacteria (such as *M. chelonae*), are extremely resistant to glutaraldehyde.
- 2) **Bacterial spores (*Bacillus* and *Clostridium*):** spores from these organisms can be isolated from endoscopes but there are no reported cases of transmission by endoscopy. Studies have shown that *Clostridium difficile* spores can be completely inactivated by standard decontamination procedures (13).
- 3) **Multidrug-resistant Gram-negative bacilli:** these have been linked to transmission during ERCP, particularly in the USA. There is no evidence to suggest these bacteria are resistant to the commonly used endoscope disinfectants. More likely is that risk of transmission is linked to the design complexity of the duodenoscopes and the quality of reprocessing (8).
- 4) **Pathological prions:** these infectious particles, including those associated with Creutzfeldt Jakob disease (CJD) and vCJD, are extremely resistant to standard decontamination procedures. Recommendations for minimising the risk of transmission of prion proteins are discussed later in section 3.

Although the greatest potential risk is transmission of infection from one patient to another through use of the a contaminated endoscope, there is also the potential for transmission of infection to healthcare workers. Studies have suggested that endoscopes are potential vectors for the transmission of *Helicobacter pylori* (14). Healthcare workers are also at potential risk of infection with blood-borne viruses. This is discussed further in section 9.

Traditionally, patients harbouring potentially infectious micro-organisms are scheduled for the end of endoscopy lists in order to minimise cross-infection. However, given the universal endoscope decontamination regime, which presumes that all patients are potentially infectious, there is not normally a need to examine patients with known infections last on the list. Nonetheless local infection control policies should be adhered to, including cleaning of the procedure room after examination of certain at-risk patients. Infection prevention and control managers often mandate the scheduling of patients with, for example, meticillin-resistant *Staphylococcus aureus* (MRSA) or *Clostridium difficile* at the end of lists.

3. Relevance of Transmissible Spongiform Encephalopathies (CJD) to Endoscopic Practice

3.1. Background

CJD is a rare fatal degenerative brain disease that falls within a group of neurological disorders known as the transmissible spongiform encephalopathies (TSEs). Otherwise known as prion diseases, they can affect animals (e.g. scrapie in sheep and bovine spongiform encephalitis in cows) and humans. The precise nature of the transmissible agents is unknown but is believed to be an abnormally folded forms of host-encoded prion proteins. Normal cellular prion protein (PrP^c) is expressed in many tissues but is concentrated within neurons in the central nervous system (CNS). The assumed infective form of the protein (PrP^{Sc}) accumulates in the CNS in prion diseases and is remarkably resistant to most forms of degradation.

The sporadic form of CJD affects approximately one person per million per annum worldwide. vCJD is an acquired form that was first reported in 1996 (15). It exhibits a unique neuropathological phenotype and affects mainly young adults. The incubation period for vCJD could be as long as 30 years.

Fortunately, early fears of large numbers of vCJD deaths have not been realised, and the incidence has been in decline for several years. However, evidence suggests that many more people are infected but not showing any symptoms (16). If these people are infective, the risk of secondary (person-to-person) transmission could be greater than implied by the small number of cases seen so far. In particular, vCJD can be transmitted via blood transfusion (17) and, in theory, could be passed on by the re-use of surgical instruments. Thus, invasive procedures (e.g. endoscopy with biopsy) have the potential to transmit the disease from affected asymptomatic individuals in the incubation phase.

The differing distributions of PrP^{Sc} in the body for sporadic and vCJD reflects their different pathogenesis. In sporadic CJD, prion infectivity is largely limited to the CNS and retina. Gastrointestinal endoscopy is not considered to be a potential vector for the transmission of sporadic CJD because infected tissue is not breached during the procedure. No special precautions are necessary during or after the procedure and the endoscope should be cleaned and disinfected in the normal thorough way. By contrast, in vCJD the lymphoreticular system throughout the body contains PrP^{Sc} and may confer significant infectivity during the incubation period (18). PrP^{Sc} has been detected in rectal tissue and Peyer's patches (19, 20). Since lymphoid follicles and germinal centres are widely distributed in the gastrointestinal tract (and are often biopsied), endoscopic interventions in patients who are incubating vCJD could expose the instrument (and particularly the biopsy forceps) to PrP^{Sc}.

Risks of transmitting vCJD from one person to another depend on the infectivity of tissues involved, the amount of tissue contaminating the instrument, the effectiveness of decontamination processes and the susceptibility of subsequently exposed patients (Table 2).

Table 2: Summary of classification of vCJD risk relevant to GI Endoscopic Practice

Type and status of vCJD diagnosis	Management of the endoscope
1. vCJD diagnosis confirmed	Destroy or decontaminate and store in quarantine for use on the same patient
2. Symptoms of CJD but awaiting diagnosis	Decontaminate and store in quarantine. If vCJD confirmed manage as 1. above
3. Asymptomatic patients at increased risk through receipt of labile blood components (whole blood, red cells, white cells or platelets) from a donor who later developed vCJD. Presumed infected	Destroy or decontaminate and store in quarantine for use on the same patient
4. Asymptomatic patients at increased risk for public health purposes (e.g. plasma product recipients). For details about the different types of at-risk classifications, see the ACDP guidance Part 4	Decontaminate and reuse

It should be emphasised that aldehyde disinfectants, such as orthophthalaldehyde and glutaraldehyde, fix protein. This property may not only anchor prion protein within endoscope channels but also render it more difficult to remove by other means. Hence, for public health purposes these agents must not be used when decontaminating endoscopes that have been used in patients with definite or suspected vCJD or in patients considered to be at risk of vCJD.

At present, conventional sterilisation methods cannot reliably destroy the infecting agent in vCJD. All those involved in endoscopy must recognise the potential for transmission through poor decontamination practice and ensure that procedures are in place to minimise contamination and maximise cleaning (21, 22).

Biopsy port caps must be discarded after any endoscopic procedure. Adequate funding must be available to endoscopy units for the purchase of single-use biopsy forceps, cytology brushes, guidewires and other accessories.

3.2. vCJD Risk Groups

Individuals at risk of vCJD include people who received plasma-based concentrates or antithrombin between 1990 and 2001 (e.g. those with haemophilia), and also a small group who received labile blood or blood products derived from donors who subsequently developed vCJD. The at-risk group also includes patients who have donated blood to someone who went on to develop vCJD, other people who have received blood from such a

donor and patients who have received blood from 300 or more donors since 1990. This cohort of individuals will have been informed by Public Health England that they are at risk.

Endoscopic procedures with the potential to introduce vCJD-contaminated tissue particles into the working channels of endoscopes are deemed potentially invasive procedures (i.e. when mucosa is breached or vaporised and the endoscope accessory and/or tissue vapour makes contact with the working channel of the endoscope). Invasive procedures include mucosal biopsy, sphincterotomy and any procedure employing diathermy or other forms of tissue vaporisation.

3.3. Practical Guidance

Until recently it was advised that any invasive procedure in any at-risk patient necessitates the quarantining the endoscope. Given the absence of any known transmission of vCJD by means of endoscopy or surgery, and the dramatic fall in the incidence of vCJD, the UK Advisory Committee for Dangerous Pathogens revised its risk assumptions in 2015 (23). The updated guidance means that quarantining of the endoscope is rarely necessary. It still applies following the performance of an invasive endoscopic procedure in a patient with definite or probable vCJD or someone who is presumed to be infected after having received labile blood products (e.g. whole blood or red or white cell concentrates) from a donor who subsequently developed vCJD. Quarantining is also indicated following invasive endoscopy in a patient with undiagnosed neurological illness when vCJD cannot be excluded or where subclassification of CJD infection is pending (Table 2). Unless the potential vCJD infection risk to that endoscope can later be rescinded, the quarantined endoscope cannot return to normal use and will only be available for use in the same patient or other patients with established vCJD.

If it becomes necessary to quarantine an endoscope, it should be stored in a drying cabinet, but it must be clearly marked or secured as not being in use, so as to avoid it becoming mixed up with endoscopes in storage for normal use.

If invasive endoscopy has been performed in any patient with vCJD or where a diagnosis of vCJD has not yet been ruled out or classified, the endoscope used should be reprocessed before being quarantined. If a contamination risk is confirmed, the endoscope should be either destroyed or retained for dedicated reuse for the same patient. For some procedures, it may be possible to shield the working channel of the endoscope from contamination by means of a disposable sheath. Once the procedure is completed, the tip of the accessory (e.g. biopsy forceps) is withdrawn into the sheath, before the tip of the sheath is cut off. After the procedure all parts of the sheath should be destroyed by incineration.

It is recommended that single-use disinfectants should be used for endoscopes that have been used in any at-risk individual, and that such endoscopes should be decontaminated separately from any other endoscope (23). Whilst the dilutions and flows of fluids preclude any significant risk of contaminating the EWD itself, it is recommended that the EWD should be put through an empty self-disinfection cycle after it has been used to decontaminate an endoscope that has been used for the performance of an invasive procedure in an at-risk patient.

Rigid metal sigmoidoscopes and proctoscopes should be thoroughly cleaned and then autoclaved. The same recommendations apply for all other surgical instruments with the capacity to withstand this method. This should not be interpreted as being a procedure that eliminates risk altogether given the resistant nature of prion proteins. There is no substitute for thorough manual cleaning.

As research progresses, it is likely that other procedures will be developed to inactivate prion infectivity and to remove proteins from instrument surfaces. The development of such techniques (along with more sensitive tests for prion detection) may well have an impact on future advice concerning endoscopy and transmissible spongiform encephalopathies.

Regularly updated healthcare guidelines appear in the transmissible spongiform encephalopathy section of the [Advisory Committee on Dangerous Pathogens guidance](#).

4. Decontamination of Endoscopes – General Principles

4.1. Definitions

Sterilisation is defined as the complete destruction of all micro-organisms, including bacterial spores (1). Sterilisation is required for devices that are normally used in sterile areas of the body (e.g. laparoscopes and microsurgical instruments). Flexible endoscopes (which make contact with mucous membranes but do not ordinarily penetrate normally sterile areas of the body) are generally reprocessed by high-level disinfection rather than sterilisation, which kills bacteria, viruses, mycobacteria, and some spores. Most flexible gastrointestinal endoscopes would not withstand the conditions used in steam sterilisation processes.

Endoscopes are routinely exposed to mucus and other gastrointestinal secretions, blood, saliva, faeces and bile, and sometimes to pus. After bedside cleaning and leak testing, the process of decontamination comprises two key components:

- 1) manual cleaning, which includes a pre-cleaning routine in the procedure room before the endoscope is disconnected from its stacking system followed by a manual cleaning process in a dedicated decontamination facility by brushing of all accessible channels with a purpose-built single-use cleaning device and exposure of all external and accessible internal components to a low-foaming medical-grade detergent known to be compatible with the endoscope;
- 2) and automated disinfection, followed by rinsing of internal and external surfaces and drying of all exposed surfaces of the endoscope.

The reasons for each reprocessing procedure are described in Table 3.

Table 3: Stages of reprocessing for flexible endoscopes

Stage	Why
Stage 1	
Bedside procedure (pre-clean)	To remove readily detachable organic matter. This will help to reduce the possibility of drying and causing channel blockages, especially if there is a delay before manual cleaning takes place
Leak test	To ensure the integrity of the endoscope. Any damage to the outer surface could allow body fluids or chemicals into the internal workings of the endoscope
Manual clean	Brushing of accessible channels and flushing of all channels to remove organic matter with specifically designed single-use tools. This stage will also allow the detection of channel blockages
Rinsing	To remove detergent residues that may affect the performance of the disinfectant
Drying	To expel excess fluid that may dilute the disinfectant
Stage 2	
Disinfection	To eradicate potentially pathogenic micro-organisms, (i.e. bacteria, including mycobacteria, viruses, and some bacterial spores)
Rinsing	To remove disinfectant residues that could cause a harmful effect to the patient
Drying	To expel excess fluid before use on the patient or storage

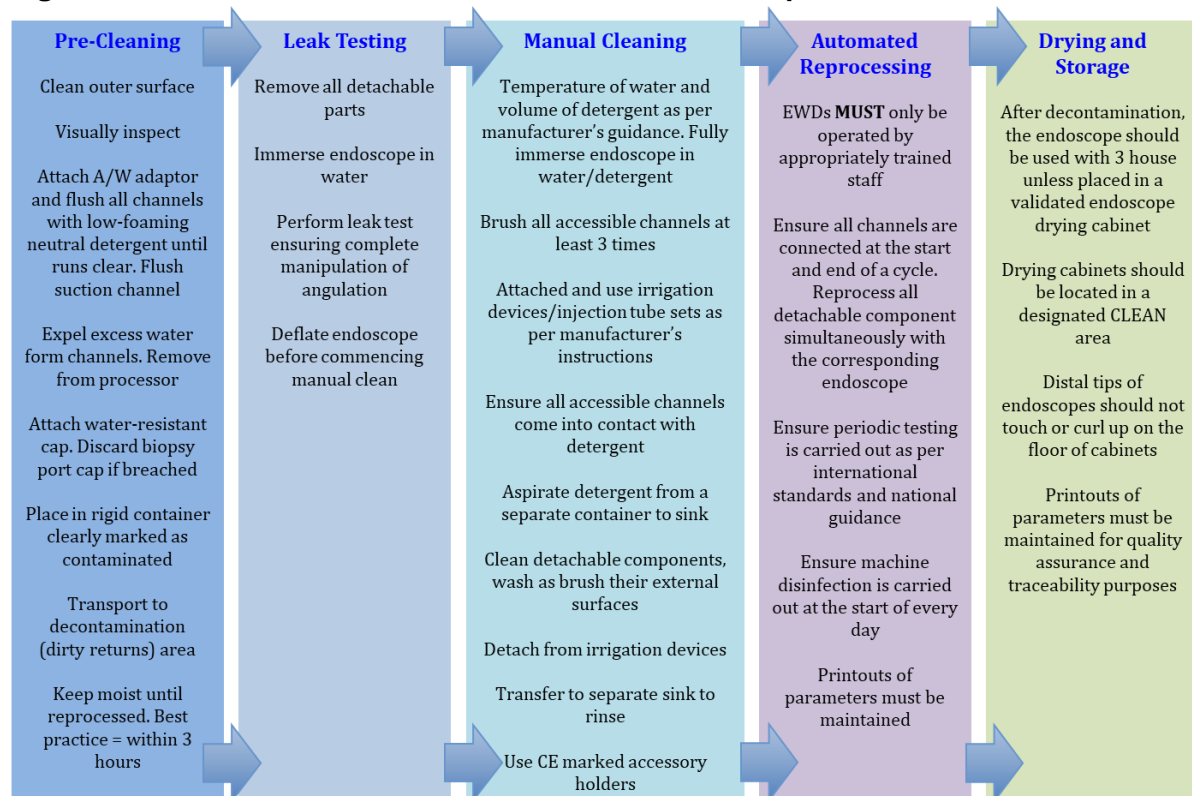
When dealing with invasive endoscopes (e.g choledochoscopes), automated disinfection is required, followed by rinsing and drying of all exposed surfaces of the endoscope. The dried endoscope is packaged with systems complying to relevant standards that are suitable for the terminal sterilisation used.

It is essential that all reprocessing stages, including leak testing, are undertaken after every use of the endoscope, and that none are omitted. Failure to follow these recommendations

may not only lead to transmission of infective organisms but also to misdiagnosis (e.g. if pathological material from one patient is included in specimens from the next patient) and to instrument malfunction and shortened lifespan.

The process is summarised Figure 1 and together the basic anatomy of a flexible endoscope is portrayed in Figure 2.

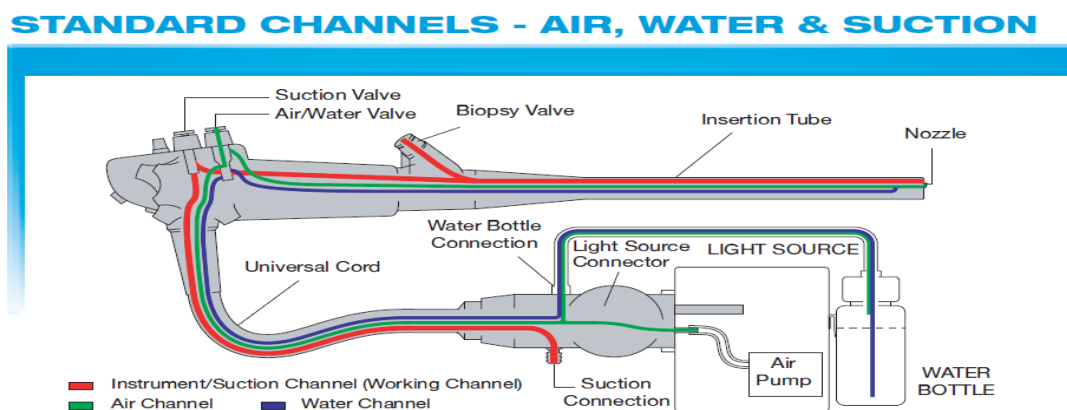
Figure 1: Flowchart to Summarise the Flexible Endoscope Decontamination Process



It is imperative that manufacturers' instructions are followed at all times

Figure 2: Basic Design of a Gastrointestinal Endoscope.

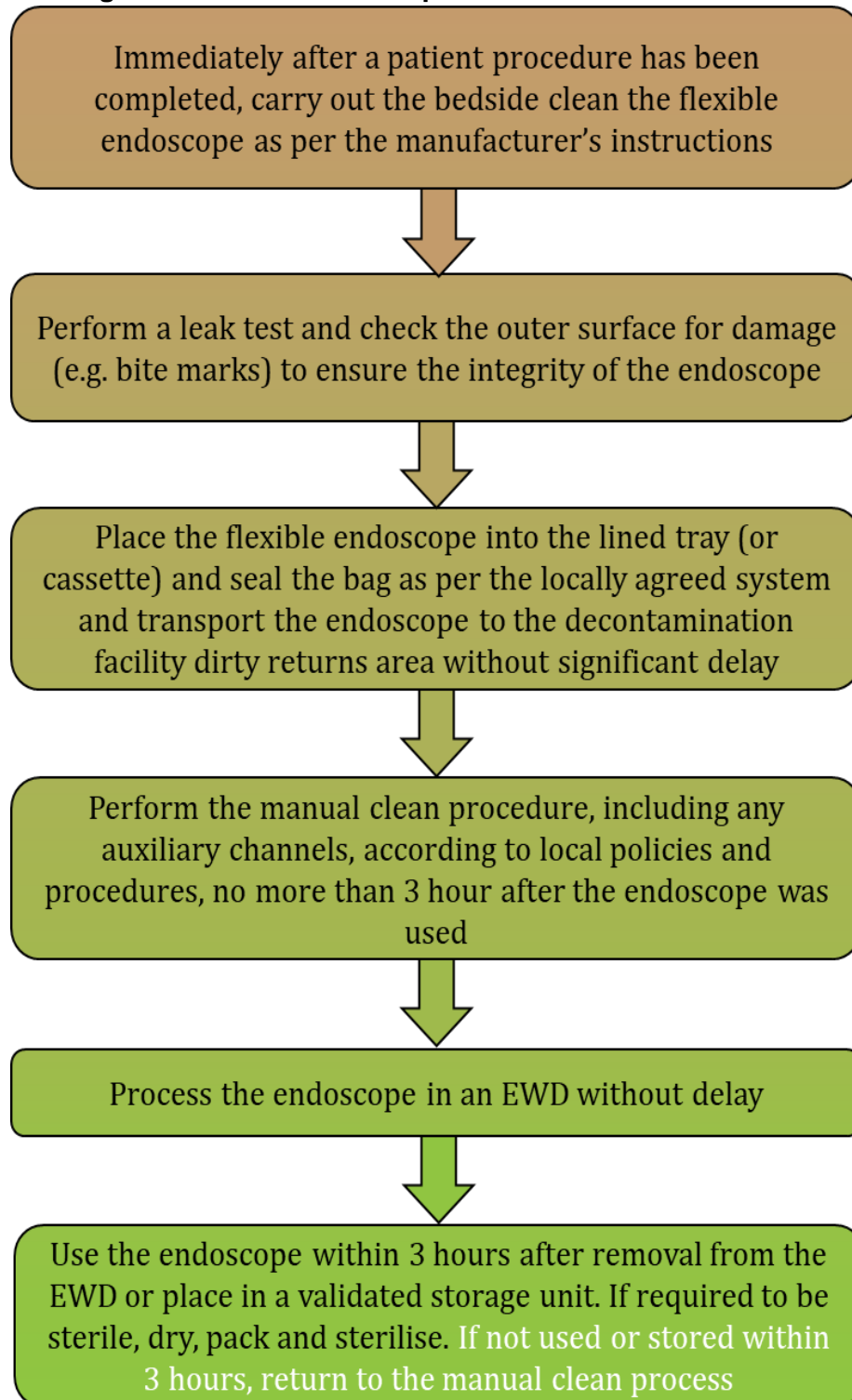
More complex designs apply for endoscopic ultrasound scopes (balloon channel) and duodenoscopes (elevators wire).



Courtesy Olympus Keymed UK Ltd.

Decontamination should begin as soon as the endoscope has been removed from the patient. HTM 01-06 (24) recommends that the cleaning stage of the decontamination process should be completed and the EWD cycle commenced within 3 hours of completion of the endoscopic procedure as best practice (Figure 3).

Figure 3: Flexible Endoscope Decontamination Timeline



4.2. Pre-Cleaning

Before the endoscope is detached from the light source or videoprocessor, a *preliminary cleaning* routine should be undertaken. Water and detergent should be sucked through the working channel, the air and water channels and any auxiliary channels in order to clear gross debris and ensure that they are not blocked. The insertion shaft is wiped down externally and checked for any bite marks or other surface irregularities. Excess fluid should then be expelled from all channels by flushing with air. It is essential to follow the endoscope manufacturer's recommendations with regard to the timing and amounts of air and fluids that should be employed at each step.

It is recommended that endoscopists with appropriate training carry out the bedside pre-clean to minimise the occupational transfer of infection between personnel (2).

4.3. Manual Cleaning

Once detached from the light source/videoprocessor, the endoscope should be securely contained and transported to the decontamination facility. Another *leak test* should then be carried out to check the integrity of all channels before reprocessing. If a leak is detected, the decontamination process should not be carried out as further damage to the endoscope may occur.

The second stage is the *dismantling* of detachable parts of the endoscope, which includes the removal of valves. Some endoscopes (e.g. duodenoscopes) have detachable tips that should also be removed from the insertion tube at this stage. The biopsy port cap should be discarded. Detachable parts that are to be re-used (e.g. air/water and suction valves/pistons) should be reprocessed together with the corresponding endoscope as a unique set in order to allow traceability.

The third stage is *manual cleaning* and rinsing of all exposed internal and external surfaces. This should be undertaken within a sink in the dirty section of the decontamination area. An endoscope-compatible detergent that has been specifically designated for medical instrument cleaning should be used at the dilution given in the manufacturer's instructions. The detergent should be aspirated from a clean bowl, separate from the contents of the sink used for manual cleaning. This is to avoid the possibility of recirculation of tissue/protein removed from the channels. Automated devices that pump detergent through endoscope channels are also available.

Previous editions of this guidance have recommended the use of enzymatic detergents based on their theoretical ability to digest mucus and other biological material within narrow endoscope channel lumens, but in HTM 01-06, no preference for enzymatic detergents is expressed (24). A move away from enzymatic detergents has been prompted by reports of occupational asthma and skin sensitisation (25, 26).

Endoscope manufacturers provide purpose-designed irrigation tube sets that connect with each channel to facilitate cleaning. All accessible channels should be exposed to detergent by means of brushing with a purpose-built single-use cleaning device. This is followed by flushing with detergent and rinsing of all external surfaces and channels (either with an automated flushing device or manually). Detergent and rinse water must be replaced for

each endoscope for the manual process. Two separate sinks (one for clean, one for rinse) are required and should not be used for any other purpose.

Detachable components (e.g. air/water and suction valves/pistons), once removed from the endoscope, should be manually cleaned by washing and brushing their external and internal surfaces in detergent then rinsing them in water prior to exposure to disinfectant.

Some endoscopes (particularly older models) have channels that are not accessible to automated decontamination procedures. Special consideration must be given to the cleaning of auxiliary water channels, exposed elevator wire channels and balloon inflation channels in endoscopic ultrasound probes. The channels of these models must be manually cleaned and disinfected according to manufacturers' instructions.

HTM 01-06 states that the endoscope must be processed within 3 hours of patient use (Figure 3) (24).

4.4. Automated disinfection

The fourth stage is ***automated** cleaning followed by high-level disinfection* within an EWD. **Manual disinfection is NOT acceptable.** The endoscope is reprocessed along with its detachable components (e.g. air/water and suction valves/pistons). All connectors should be specifically designed for their intended purpose. It is important to note that even the use of the most modern and sophisticated EWD does not replace the need for prior thorough manual cleaning, including brushing of all working channels. The EWD must be used in accordance with the manufacturer's instructions for use and must be capable of irrigating all the channels of the endoscopes, including auxiliary channels. It must also be subjected to weekly cleaning verification tests using a validated process challenge device (24) and weekly testing for the total viable count of the final rinse water. Disinfectants and EWDs used in endoscope reprocessing are discussed in more detail in sections 5 and 6.

4.5. Rinsing

The process of decontamination should be concluded with *further rinsing* with water of a defined microbiological quality. This is part of an EWD cycle, and the quality of the final rinse water should be tested weekly for the total viable count. An action plan should be in place in the event of bacterial contamination being detected and should be developed with the infection prevention and control team and clinical staff.

4.6 Drying/Storage

Purpose-built Controlled Environment Storage cabinets (CESCs) deliver HEPA to the internal channels of the endoscope at the appropriate temperature and flow rate. Their use may avoid the need for endoscopes to undergo early morning repeat decontamination cycles, but cabinets vary in their quality assurance concerning maximum duration of storage before a repeat reprocessing cycle becomes necessary. The manufacturer of the cabinet will have validated the maximum storage time, which can vary from 72 hours to 31 days. Further details are provided in section 7 below. Very clear policies and procedures must be in place and include a set and validated specific storage time. Time frames longer than 7 days must be risk assessed based upon use and number of times scopes are placed within/or removed from the cabinet; the greater activity, the more chance there is of contaminating the scope as a result of environment and/or poor aseptic handling.

4.7. Other Considerations

4.7.1. Decontamination Facilities

Decontamination should be done in a dedicated area with atmospheric extraction facilities that have been properly maintained. Guidance on ventilation in healthcare premises is given in HTM 03-01 (27) and a publication from the Central Sterilising Club (28). Ventilation regimes should present an air-change rate in line with the EWD manufacturer's specification, a pressure in the washroom negative to that in the surrounding environment and a pressure in the clean room positive to that in the surrounding environment. Low-level extraction should ensure chemical odours are evacuated for routine operation, with provision of high-speed extraction in the event of a spillage.

Some helpful tips are as follows:

- 1) The ventilation within the decontamination environment should comply with all relevant building notes and national standards.
- 2) Ventilation requirements include consideration of the thermal load within the decontamination room.
- 3) Where the dirty and clean areas are in a single room, the flow should be one way, from clean to dirty, and include 'bench' level extraction at the dirty end.
- 4) The ambient temperature within the decontamination area should allow users to work within the environment with all doors and windows closed.
- 5) There should be a local method of checking both incoming air and extraction (i.e. Magnehelic gauges)
- 6) Ventilation requirements should be assessed/reassessed when there are any changes in room use, including installation of new EWDs.
- 7) Staff working within the area should be aware of and adhere to all relevant health and safety policies regarding safe working practices, including number of personnel working in the area and wearing of PPE.
- 8) A documented process should be in place for dealing with ventilation problems in a timely manner.
- 9) Decontamination audits must include the function and efficiency and effectiveness of the room ventilation.
- 10) Ventilation installation and maintenance is only carried out by competent persons with a working and up-to-date knowledge of the requirements within a decontamination environment.

There must be separate areas for the receipt of endoscopes following patient use (dirty area) and for the storage and drying of endoscopes following automated reprocessing (clean area). It is recommended that separate teams of staff work in these areas and not cross between them to avoid the risk of cross contamination. One-way flow of endoscopes from dirty to clean areas should be assured. To this end, many units employ “pass-through” EWDs. Examples of the layout for endoscope decontamination facilities are given in HTM 01-06 (24).

There is a growing trend for locating decontamination facilities away from endoscopy units. The preliminary cleaning routine should take place immediately after the endoscope is removed from the patient and used endoscopes must have their channels kept moist during transfer to the reprocessing facility by maintaining a humid environment around the endoscope. In practice, this means they should be placed in a plastic lined tray as soon as possible after the pre-clean procedure, but water should not be poured into the container so as to be lying freely. Prevailing regulations on the transport of contaminated goods must be adhered to, including the clear labelling of packaging as “used medical device/equipment” (29).

When transporting endoscopes to and from areas outside the endoscopy unit, they must be transferred in a rigid container with a solid lid. A lockable mobile trolley is advisable for the transportation of multiple endoscopes from a unit to a centralised decontamination facility, especially if the trolley is to be left unattended in a publicly accessible area. The endoscope tray and the mobile trolley will also need to undergo decontamination.

Hospitals undertaking endoscopy outside normal working hours will need to ensure that any remote facility is able to accept endoscopes for reprocessing on weekend days and public holidays. Endoscope drying and storage facilities need to be present both in the endoscopy unit and in the remote facility. Any processed endoscope that remains outside such storage facilities will need to be used within three hours, which includes (i) the transportation time between reprocessing or leaving storage at the remote site and the return to storage at the endoscopy unit PLUS (ii) the time between storage and next patient use in the unit itself. An electronic tracking and traceability system is mandatory for units relying on a remote decontamination facility.

Vacuum packing systems are available for transportation, but if this method is employed to return a processed endoscope to an endoscopy unit, it must be ensured that the manufacturers’ instructions for use are followed (e.g. drying of all channels before packing).

4.7.2. Tracking and Traceability

Even though the risk of transmitting infection by endoscopy is very small, all units should have a process for tracking equipment used during each procedure in the event that a patient is subsequently suspected of having or being at high risk of a transmissible disease, such as vCJD. Serial numbers of all endoscopes and accessories must be recorded for each patient examined and tracked throughout the decontamination processes. At each stage of the decontamination cycle, tracking of the personnel undertaking each step of the decontamination process and the patient associated with each endoscope and all its accessories should be undertaken using an electronic method. For this to happen, each endoscope must have a unique identification code or bar code. It should be possible to

demonstrate that an endoscope has been through a full reprocessing cycle prior to use in any new patient.

The detachable components should be kept with their corresponding endoscope, forming a unique set. A record of the decontamination process should be retained. There must also be a means of tracking for each patient use of any reusable endoscopy accessories. The tracking system operating in each unit should be subject to regular audit. There is a move towards using single-use endoscope valves to enable full traceability and prevent cross infection caused by inadequate reprocessing (30).

4.7.3. Accessories

Water bottles should be changed after every endoscopy session (i.e. 3 hours). They should be detached, emptied and cleaned as per manufacturers' instructions, then sent for steam sterilisation (refer to manufacturer's instructions for use). They should be filled with fresh sterile water immediately prior to use. The sterilisation of the water bottles and the sterile water used should be tracked for purposes of traceability. Single-use water bottles and connectors are available but there is no strong evidence to support their use over a reusable system, and cost and environmental issues regarding use of plastics should be considered.

4.7.4. Loan Endoscopes

The handling of loan endoscopes requires special consideration. They will arrive without detachable components (valves), and units will be expected to provide these. Loan scopes need to be reprocessed prior to first patient use and incorporated within the tracking and traceability process. It is essential that valves are removed and discarded before the endoscope is returned to the manufacturer. Units may consider the use of single-use valves for this purpose.

5. Disinfectants

The ideal disinfectant would be:

- Effective against a wide range of organisms (bactericidal, mycobactericidal, fungicidal, virucidal and sporicidal)
- Active against prion proteins (although no such agent that is suitable for endoscope reprocessing is known to exist)
- Compatible with endoscopes, accessories and EWDs
- Type tested in the specific EWD
- Non-irritant and safe for users
- Stable during storage and use
- Environmentally friendly in terms of packaging size (concentrated for ease of storage and shipment) and disposal
- Low cost

Other factors that influence the choice of disinfectant include the process of dilution, stability of the solution and the cost of using the particular disinfectant (e.g. costs of the appropriate EWD, storage space, and conditions required for use, including staff protection measures). It is essential to use disinfectants in accordance with their manufacturers' instructions. Some endoscope manufacturers advise users to undertake specified inspection routines as a precondition of honouring their service contracts and warranties.

The safety data sheet must be obtained for all products to ensure that appropriate safety precautions, if applicable, are followed. A Control of Substances Hazardous to Health (COSHH) risk assessment must be undertaken for the use of disinfectants that are designated hazardous chemicals. This should consider use within the machine, including changing the chemical, storage and risk in the event of spillages.

All endoscope disinfectants may under certain conditions become potential skin and respiratory irritants in some users. This risk can be reduced if the agents are used within the confines of an EWD in a well-ventilated room. Healthcare workers should use appropriate PPE whilst handling these disinfectants, as discussed in section 9. A spillage procedure and kit must be available within the department.

5.1. Use of Alcohol

Previous guidelines have recommended the use of alcohol for flushing channels after rinsing to encourage the drying of channels. Due to its fixative properties, the use of alcohol is no longer recommended. Commercially available CESC's should be employed instead.

5.2. If you Intend to Change to an Alternative Disinfectant

- Consult National guidelines (e.g. HTM 01-06 in England and WHTM 01-06 in Wales) (24) and local decontamination lead personnel are (the Authorised Person [Decontamination] and the Authorising Engineer [Decontamination]) about type testing of disinfectants and detergents.
- Carefully cost the change, including use, concentration, stability, storage life and additional equipment required for processing.

- Remember that a single-use disinfectant preparation is strongly recommended in the UK.
- Ensure the processed items are thoroughly cleaned and that the disinfectant manufacturers' recommended contact times are achieved, unless alternative advice from professional organisations is available.
- Ensure compatibility between endoscope, EWD and the chosen disinfectant to avoid invalidating service contracts.
- Establish what is required in terms of COSHH regulations (e.g. ventilation, PPE) and ensure that these are included in the costing.
- Liaise with the disinfectant manufacturer about the quality of diluent water required.
- Ensure that the manufacturer agrees with the proposed policy and gives written compatibility statements for both the EWD and the endoscopes in question.

Alternative chemistries can be considered if appropriate testing has been carried out to ensure the efficacy and compatibility of the proposed alternative with both the EWD and the endoscope (31).

6. Endoscope Washer Disinfectors (EWDs)





EWDs are essential for decontaminating all flexible endoscopes following manual cleaning. They are far more effective than manual cleaning and protect users from hazardous reprocessing chemicals, such as disinfectants. All EWDs should have been validated and tested in accordance with prevailing national guidance, manufacturer's instructions and relevant standards, where available. The EWD should have flow monitoring for each individual channel to detect blockages.

It is essential that these machines are properly maintained and should be disinfected at the start of every working day by employing the EWD's self-disinfection cycle. Available operating cycles on the automatic control system should provide for an EWD self-disinfection cycle to ensure that all pipework, tanks, pumps, water treatment 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-disinfection cycle should be user-selectable and programmable so that it can run at a time convenient to the operator. Heat self-disinfection is recommended by the International Organization for Standardization in ISO:15883-4:2018 (32).

The microbiological quality of the rinse water and other fluids must be acceptable (32). The final rinse water must be tested for its microbiological quality on a weekly basis (Figure 4) (24, 32). Water filters should be checked and changed in accordance with the manufacturers' instructions or more often if the water quality is poor (as suggested by frequent clogging of filters). Hard water can cause a deposit of limescale on internal pipe work. Advice may need to be taken from a company specialising in water treatment, and from the local Authorising Engineer (Decontamination). An action plan in response to the detection of contaminated final rinse water should be prepared in conjunction with the Infection Prevention and Control Team clinicians (33) and the relevant estates staff.

Figure 4: Total Viable Count Results Guide

Table 2 Total viable count results guide

Aerobic colony count in 100 mL	Interpretation/action	Colour grade
Less than 1	Satisfactory	 Green
1–9 on a regular basis	Acceptable – indicates that bacterial numbers are under a reasonable level of control	 Yellow
10–100	Risk assessment required to investigate potential problems and super-chlorinate or repeat EWD self-disinfect	 Orange
Over 100	Risk assessment required to consider taking EWD out of service until water quality improved	 Red

Notes:

Microbiological results from weekly tests should be plotted on a graph to give a trend. This will allow the "normal" and "unusual" results to be distinguished for a particular situation. Investigation of unusual or unsatisfactory results can then be undertaken if results demand (for example, if routine results are below 10 cfu/100 mL, occasionally some of the results may be above 10 cfu/100 mL).

If a bacterial count above 10 cfu/100 mL is obtained from test water, identification of the species is advised. If a significant proportion of the microbes appear the same species from their colonial morphology, carry out an oxidase test to presumptively identify *Pseudomonas* spp. Then if the test is positive, further investigations are required to determine whether *Pseudomonas aeruginosa* is present.

Adapted from: Willis, C. (2006). "Bacteria-free endoscopy rinse water – a realistic aim?" *Epidemiology and Infection*. Vol. 134 No. 2, pp. 279–284.

From HTM 01 06 Part E (24)

The final rinse water should contain <10 cfu/100 mL (34). This may be achieved either by using bacteria-retaining filters or by other purification systems (e.g. reverse osmosis). A water-softening and/or treatment system may be needed to prevent contamination of the

EWD with limescale, biofilms and micro-organisms. It is recommended that rinse water is not reused.

Some special features or performance characteristics are optional, but all EWDs should expose all internal and external endoscope surfaces to disinfectant and rinse water in accordance with the local hospital infection control committee protocols and national guidelines. Ideally, each channel irrigated should be verified during all cycles. Instructions and training should be given by the machine manufacturers on how to connect the instrument to the EWD to ensure all channels are irrigated.

It should be ensured that the connectors between endoscopes and EWDs are designed to irrigate all endoscope channels and that all channels are disinfected in accordance with endoscope manufacturer's instructions. The machine should be programmable to accommodate the disinfectant contact times recommended by the disinfectant manufacturers and national guidance. Most EWDs have incorporated automatic leak-testing facilities, but these devices vary in operation and design. Faults can occur as with all devices or, if they do not angle the endoscope tip during leak testing, the system may fail to recognise positional leaks. Therefore, presence of an automated leak tester on the EWD does not negate the need for a manual leak test, it enhances the process.

EWD manufacturers should specify in their 'intended use' statements the makes and models of endoscopes the EWD is intended to reprocess. They should also supply the necessary channel connection systems to allow effective reprocessing of the identified endoscopes. Some EWDs have the capacity to irrigate/flush auxiliary and/or duodenoscope wire elevator channels. Users of duodenoscopes or balloon channelled endoscopes should ensure that their EWDs can decontaminate all internal channels, and, if any uncertainty exists, should seek advice from their endoscope and EWD manufacturers. It should be noted that some echo endoscopes (used for endoscopic ultrasound) are not compatible with the chambers of all EWDs. Additional manual cleaning and disinfection of the elevator wire channel may be necessary.

For endoscopes used to examine patients with definite or probable vCJD and patients in whom a diagnosis of vCJD is being considered or those at risk and presumed to be infected, it is recommended that each is decontaminated separately from other endoscopes within the EWD. This should be undertaken with a single-use disinfectant, and the EWD should be subjected to an extra rinsing cycle before the next endoscope is reprocessed. The endoscope will need to be quarantined if an invasive procedure has been undertaken (see section 3). Any solid waste and/or tissue remaining within the EWD should be disposed of by incineration. The outlet filter (or strainer) should also be discarded, incinerated and replaced with a new filter. Liquid waste should be discarded by normal direct discharge from the EWD.

For public health purposes, following an invasive endoscopic examination in a patient at risk of vCJD (as distinct from those presumed infected), it is recommended that the endoscope is decontaminated separately from other endoscopes within the EWD with a single-use disinfectant. Provided that a rigorous tracked standard decontamination cycle has been carried out, no further precautions are necessary.

When purchasing an EWD it should be ensured that it conforms to the minimum specifications set out in the ISO standards (32, 33) and the testing and validation procedures as specified in the HTM 01-06 (24) and any additional requirements of the relevant UK Devolved Administrations (e.g. the WHTM 01-06 in Wales). Newly purchased EWDs must be installed and validated correctly and safely to ensure correct functioning, safety of personnel and environmental protection. It is important to ensure that the new EWD will irrigate all channels of each endoscope being processed and verify that irrigation has taken place. This facility should include alerting the user to endoscope blockages (partial or full) and disconnections within the EWD. These systems differ in design and operation, so make sure that the system and failure acceptance criteria are known before purchasing.

A printout of cycle parameters which can be retained for quality assurance records, whether electronic or paper, must be included.

NOTE

*Users are advised to review independent test reports and consult their local decontamination lead or teams and the Authorised Person (Decontamination) and the Authorising Engineer (Decontamination) before purchasing EWDs and associated equipment, such as the water purification systems. The same advice applies to the purchase of CESC. Guidance from the Authorising Engineer (Decontamination) should be coupled with the **purchasing specification suggested in HTM 01-06 part D**. Local advice and procedures in NHS England and the devolved administrations must be included in decisions.*

7. Controlled Environment Storage cabinets (CESCs)

Drying or active Controlled Environment Storage cabinets (CESCs) are recommended to supplement drying by the EWD and to store endoscopes until next patient use. They should be located either in the clean zone of the endoscope reprocessing area or in a separate clean area close to the endoscopy procedure room (but not in the procedure room itself). A wide choice of CESCs is available. If endoscopes are hung vertically, care should be taken to ensure that the height of the cabinet is sufficient to avoid the distal tip touching or curling up on the floor of the cabinet. The use of pads on the base of the cabinet to protect the tip and collect moisture **must NOT be used**. There are other systems of endoscope reprocessing that allow each endoscope to be connected separately within its own casing following manual cleaning. The endoscope remains within this casing during disinfection, drying and storage until next use. Units considering purchasing these chambers should discuss compatibility with their endoscope manufacturer, as well as involving their infection control and decontamination officers in scrutinising the microbiological and safety data supplied by the manufacturers.

The following list may be helpful when comparing cabinets.

- Can all lumens in the endoscope be connected to a filtered air supply and the flow monitored throughout the storage time?
- What level of filtration is used for the cabinet air supply?
- What is the source of filtered air? Does the cabinet require an external source of filtered air? If medical air is to be used, the Authorising Engineer (Medical Gases) should be consulted to determine the impact this may have on other services supplied from the same source. It is not acceptable in many locations to connect directly to the existing system. This can cause balance problems in gas flows depending on the location and scale of the installation, and back flow of the gases is not accepted by the Authorising Engineer (Medical Gases).
- Independent or integral gas compressors are the preferred solution.
- Does the cabinet allow internal air pressure to be monitored during its operation?
- Can the cabinet be locked, and access levels restricted?
- How many endoscopes can be accommodated simultaneously within each cabinet?
- Does the cabinet monitor each endoscope during storage, record the data and indicate values that fall short of specification or whether the endoscope has been in storage too long since reprocessing?
- Does the cabinet allow for continuation of the traceability system?
- Has the cabinet manufacturer produced reliable data to show that a stored endoscope may be directly used on a patient without reprocessing?
- Which tests have been carried out to show whether the cabinet dries endoscopes and keeps them free from contaminating organisms during storage and prevents any residual contamination from growing?
- From these data, has the manufacturer set alarms or indicators for the validated maximum safe period of storage?
- Can endoscopes be added or removed from the cabinet without contaminating other endoscopes in the cabinet?
- Is the cabinet easy to clean and constructed of non-porous material with sealed joints?

- Manufacturers recommendations on the cleaning procedures should be undertaken along with the local policies.
- Are double-ended pass-through cabinets required as part of the design (e.g. to allow one-way flow from a dirty to clean area)?
- If double ended cabinets are used or installed, check that door interlocks are functioning correctly.

If an endoscope is used infrequently, it is reasonable to store it separately hanging vertically in a purpose-built cabinet (as opposed to a drying cabinet) and to reprocess it prior to next patient use. It should be clearly labelled.

8. Cleaning and Disinfection of Accessories

Most accessories that are passed via the working channels of endoscopes are single use. These include cytology brushes, polypectomy snares, injection needles and most ERCP accessories. Single-use balloons are widely used as an alternative to bougies for dilatation and are also available for forced pneumatic balloon dilatation in patients with achalasia.

Accessories that are not passed through the working channel of endoscopes, such as water bottles and bougies, are often marketed as reusable. Autoclavable accessories should be chosen whenever possible. Argon plasma coagulation catheters are marketed as single use, but other therapeutic devices passed via the endoscope working channel (e.g. heater probes) are reusable and can be autoclaved. All reusable accessories that are passed into the gastrointestinal tract (e.g. bougies) need to be tracked and a register kept of every use. Because autoclaving is not reliable in eliminating prion material, heater probes and other reusable accessories must be discarded after any invasive therapeutic procedures in patients with confirmed or probable vCJD or patients at increased risk of vCJD (23). Any flushing devices that accompany an endoscope can be flushed with detergent, rinsed with clean water and dried with forced air (if applicable) at the end of each working day.

The Medical Devices Agency Bulletin DB 2006(04) (35) advises on potential hazards, clinical and legal, associated with reprocessing and reusing medical devices intended for single use. Users who disregard this information and prepare single use items for reuse without due precautions may be transferring legal liability for the safe performance of the product from the manufacturer to themselves or their employers.

9. Health, Safety and Infection Control

All staff involved in decontamination should wear appropriate personal protective equipment (PPE) (Table 4) including long sleeved gowns/aprons, full face visors, masks (where appropriate) and single-use (preferably nitrile) gloves. Forearms must be protected during the endoscope dismantling and manual cleaning stages and whilst handling detergent and disinfectant solutions. Staff should be trained in effective handwashing in a separate sink from that used for endoscope decontamination. All work surfaces must be of a medical grade and wipeable, and care should be taken to clean and disinfect them at the beginning and end of each working day (36).

Table 4: Personal Protection during Endoscope Decontamination

1.	Wear long-sleeved waterproof gowns. These should be changed between sessions within the decontamination area or on transfer between the dirty and clean area
2.	Use nitrile gloves which are long enough to cover the sleeves, so as to protect the forearms from splashes. Hands should be washed or disinfected after removing protective clothing.
3.	Full face visors protect the wearer from splashes to the conjunctiva.
4.	Face masks may reduce inhalation of vapour from disinfectants, but should be used and disposed of according to manufacturers' instructions
5.	An HSE-approved vapour respirator should be available in case of spillage or other emergencies. It should be stored with the spillage kit away from disinfectants as the charcoal adsorbs fumes. Respirators should be regularly replaced as per the manufacturers' recommendations.

Health surveillance for staff exposed to disinfectants should be considered, in consultation with occupational health departments. Departments should conduct a risk assessment of substances used in their hospitals' endoscopy units and, when regular staff health surveillance monitoring is indicated, lung function testing by spirometry should be carried out at the pre-employment medical visit and annually thereafter. Occupational health records should be retained for 30 years. Staff should be encouraged to report any health problems to their line management and occupational health department.

All staff working with endoscopes should be immunised in accordance with local policy.

The Health and Safety at Work Act 1974 requires employers to ensure, as far as is reasonably practicable, the health, safety and welfare of all employees. The Act also requires employees to comply with the precautions established to ensure safe working. The COSHH Regulations 1994 require employers to assess the risk to the health of staff by exposure to hazardous chemicals, and to minimise and to avoid such exposure where this is

reasonably practicable or otherwise ensure adequate control. To improve safety, hazardous chemicals should be stored in purposely designed ventilated cabinets.

Engineering methods of control must be used in preference to PPE. Guidance on ventilation of healthcare premises is discussed in HTM 03-01 (27). Facilities should consider monitoring chemicals (e.g. peracetic acid levels) within the environment to establish that control measures such as ventilation are appropriate and effective.

Some units employ electronic devices for flushing endoscope channels during manual cleaning. Care must be taken to avoid any contact between cables and sinks.

There should always be sufficient numbers of trained staff and items of equipment to allow enough time for thorough cleaning and disinfection. Procedures for dealing with EWD malfunctions and adverse incidents should be adhered to. Each endoscopy unit must have a local policy for dealing with disinfectant or body-fluid spillages. This policy should be prominently displayed within the unit and all staff must be trained in its implementation. Training of staff should be documented and reviewed annually.

A spillage kit suitable for endoscopy units should contain as a minimum the following components:

- 1) **Absorbent materials:** including absorbent socks, absorbent pads or granules/powder, should be chemically inert, meaning they should not react with the spill, particularly if a chemical spill has occurred. Some absorbent materials used for bodily fluids may not be compatible with certain chemicals. Ensure enough absorbent materials are available so that the volume they can absorb is appropriate for the spill.
- 2) **PPE:** such as respirators/masks, gauntlets, overalls, goggles. In the case of chemical spills, PPE should be resistant to the chemical. Ensure respirators are appropriate for the chemical – often these will need to be more than particulate filters. Refer to site COSHH/risk assessment information.
- 3) **Waste bags:** waste from clearing bodily fluids may be disposed of as clinical waste. Waste from clearing a spill should not be disposed of as normal or clinical waste, but rather following site policy for hazardous waste. Clearly mark on the bags what the chemical hazard is to ensure proper handling of waste.
- 4) **Optional:** barrier tape and keep out signs to help ensure that access to the area of a spillage is restricted.

Periodic checks are required to ensure that all the items in the above kit have not exceeded their expiry date.

All chemical residues must be disposed of in an appropriate manner to include use of nominated contractors licensed for purpose.

10 Quality Assurance of Decontamination, Drying and Storage of Endoscopes

Various audit tools can be used to assess quality assurance of endoscope decontamination practice. One was produced in association with the Institute of Healthcare Engineering and Estate Management (37) and is under the ownership of the Joint Advisory Group on GI Endoscopy. Another has been prepared by the Infection Prevention Society (38). More-detailed testing regimens are described in local HTMs and in HTM 01-06 (24).

Local audit tools can be specified by the Devolved administrations or screening services.

Quality assurance of an EWD requires regular testing in accordance with the HTM 01-06 (24). Weekly total viable counts of bacteria in end rinse water from EWDs is required in all audits. There should also be quarterly testing for atypical mycobacteria and *Pseudomonas aeruginosa*, with culture plates incubated at 30°C and 37°C for atypical mycobacteria. More frequent testing for atypical mycobacteria and *Ps. aeruginosa* may be prudent in centres carrying out procedures in augmented care. Annual testing for endotoxin has been suggested, but there is no real evidence to support this additional step in non-sterile endoscopy practice and it is no longer included in HTM 01-06.

11. Roles and Responsibilities of Staff Working within Endoscope Decontamination

HTM 01-06, part C (24) describes the roles and responsibilities of all staff involved in the decontamination of medical devices.

The 2015 update of the 2008 Health and Social Care Act emphasises the need for staff to be trained in decontamination processes and to hold appropriate competencies for their role. It describes the need for monitoring systems to ensure that decontamination processes are fit for purpose and meet required standards. Competencies have been set out in the Institute of Decontamination Science's educational framework (39) and the BSG, in conjunction with some of the major endoscope manufacturers, has developed a [direct observation of practice form](#) that can be used to document the training delivered and the competency of the staff member.

The BSG supports annual updates of staff to ensure that competency is maintained. Therefore, comprehensive records of all decontamination processes and all staff training must be maintained and revalidated annually.

The decontamination of endoscopy equipment is a specialised procedure and should only be carried out by personnel who have been trained for the purpose and who understand the principles involved. It is essential that personnel at all levels should have a sound general knowledge of the anatomy of flexible endoscopes the principles of decontamination, the basic elements of infection prevention and control, microbiology and process chemicals and the potential hazards posed by these. Training in the use of PPE and the management of spillages is also essential.

Endoscopy units should consider employing specialist technical staff for the decontamination of flexible endoscopes. Their presence will free qualified nursing staff for clinical duties.

Standard operating procedures that cover working practices in the decontamination area of each unit should be clearly documented and understood by all staff.

It is recommended that the Medicines and Healthcare Products Regulatory Agency (MHRA) table entitled "Top Ten Tips" is prominently displayed in all endoscopy units (Figure 5) (40).

Figure 5: MHRA Top Ten Tips Endoscope Decontamination

Top Ten Tips Endoscope Decontamination



- 1 Quality** – Ensure that all processes are controlled using an appropriate quality system eg BS EN ISO 13485:2012 'Medical devices. Quality management systems. Requirements for regulatory purposes' and that all equipment is operated and controlled in accordance with the manufacturer's instructions.
- 2 Staff training** – Ensure all staff, including new staff, involved in the decontamination process are fully trained* and that this training is regularly updated as appropriate (see Department of Health publication '[Choice Framework for local Policy and Procedures 01-06](#) – Decontamination of flexible endoscopes: Policy and management'). Staff working within devolved administrations should consider the relevant documentation for their country.
- 3 Compatibility** – Ensure compatibility with the existing hospital decontamination processes, including compatibility with the decontamination equipment. Do not reprocess single-use devices. Use pre-purchase questionnaires that require input and acceptance from decontamination and/or infection control teams prior to purchase.
- 4 Identification** – Identify all endoscopes and decontamination equipment used in the hospital to ensure they are being maintained and that the correct decontamination process is being used. Ensure endoscopes can be tracked throughout the decontamination process and traced to the patients on which they were used.
- 5 Channel connection** – Check the number of channels in each endoscope and ensure that they can all be connected to the automated endoscope reprocessor using the correct connectors/ connection sets provided by the manufacturer.
- 6 Manual cleaning** – Ensure endoscopes and accessories are manually cleaned prior to processing in an automated endoscope reprocessor or washer disinfectant, including the flushing of all channels even if they have not been used during the procedure.
- 7 Chemical compatibility** – Use only chemicals compatible with the endoscope, its accessories and the automated endoscope reprocessor. Chemicals must be used at the correct concentration, temperature and contact times as recommended by the manufacturer throughout the decontamination process. See '[Choice Framework for local Policy and Procedures 01-06](#)'.
- 8 Process validation** – Use only validated processes following the manufacturer's instructions and the appropriate standards e.g. the BS EN ISO 15883 series 'Washer-disinfectors'.
- 9 Preventative maintenance** – Have regular, planned preventative maintenance in place with records kept for all endoscopes and decontamination equipment.
- 10 Incident reporting** – Report any problems relating to endoscope decontamination equipment or associated chemicals to the MHRA via our [website](#). Report identified problems with any decontamination process to the local consultant in communicable disease control (CCDC) at your local health protection unit.

Products claiming to remove/inactivate prion protein from contaminated medical devices: It is important that, until the efficacy of these products and technologies is established fully against human prions, clinicians ensure they follow the [current Department of Health guidelines](#).

*Manufacturers of endoscopes and decontamination equipment and other external organisations provide courses in endoscope decontamination.

Note: The importance of decontamination needs to be clearly understood at all levels throughout the organisation. There could be legal implications if failures in this process are identified.

The MHRA has also released guidelines on managing medical devices which set out some basic principles on decontamination and training (41). Information on relevant standards and guidance relevant to endoscope decontamination are shown in Table 5.

Table 5: Relevant documents on decontamination practice and clinical audit tools

Document	Remit	Countries in which applicable	Linked audit tool
Health and Social Care Act (2015)	Code of practice on prevention and control of infections and related guidance	England	
HTM 01-01 (2016)	Surgical instruments Part A: Formation of local policy and choices manual Part B: Common elements Part C: Steam sterilisation Part D: Washer disinfectors Part E: Alternatives to steam for sterilising reusable devices	England	
HTM 01-06 (2016)	Flexible endoscopes: all aspects decontamination, infrastructure and QA	England	IPS (see link in references)
WHTM 01-06 [2014 and 2017]	As above	Wales	
Health Protection Scotland guidance	Flexible endoscopes: all aspects on decontamination, infrastructure and QA	Scotland	
Joint Advisory Group (The JAG)	Standards	UK (not mandated, but forms part of JAG accreditation visits)	Integral
ISO 15883 (32, 42, 43)	Washer disinfectors Part 1 – General requirements Part 4 – Requirements and tests for washer disinfectors employing chemical disinfection for thermo-labile endoscopes Part 5 - Test soils and methods for demonstrating cleaning efficacy	International*	
ISO 13485	Medical device quality system requirements	International*	

ISO 14971	Application of risk management to medical devices	International*	
MHRA DB (2015)#	Managing medical devices	UK	
MHRA Top Ten Tips	Summary document for end users	UK	
UNECE	Transport of dangerous goods	International	

*Adopted by European Union products Regulatory Agency. # Medicines and Healthcare.

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