



## **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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#### Summary

1. Decontamination of endoscopes should be undertaken by trained and educated staff in the procedures within dedicated and well designed rooms. There should be one way flow of endoscopes between dirty returns to 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 their own detailed procedures. The wash room [if separated dirty and clean rooms] should be a negative pressure in comparison to the clean side. [see the 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.
2. Staff training should be implemented using a competency framework and 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. As well as any post cleaning processes e.g. drying/storage cabinets or portable storage systems, such as vacuum packing that may be in use. [HTM 01.06 part D]? These systems must be checked on a regular basis and validated by the manufacturer. Added more GS
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 is available, the use of drying/storage cabinets may obviate the need for repeat endoscope reprocessing at the start of each list.
4. Thorough manual cleaning with a CE marked detergent which is compatible with the disinfectant, including the brushing and flushing of all accessible endoscope channels, must be undertaken before automated endoscope disinfection within an endoscope washer disinfectant (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 protein 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 temperature and concentration in accordance with the detergent and disinfectant manufacturers' instructions. Machine testing should include the accuracy 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 detergent and disinfectant as being 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 are omitted. It is also essential that all channels of all endoscopes are reprocessed after every use of the endoscope, even if the channels were not used during the preceding patient procedure.
9. Endoscope washer disinfectors (EWD) should be used to wash and disinfect all endoscopes following manual cleaning. Manual disinfection 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]
10. Filtered air should be used as part of the drying process for each endoscope at the end of each EWD cycle. Endoscope drying/[storage](#) cabinets 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 the fixative properties the use of alcohol to assist in drying endoscopes is no longer recommended.
11. Water used in an EWD should be free of particulate and chemical contamination and of micro-organisms. This can be achieved either by using bacteria-retaining filters or by other methods, for example reverse osmosis. 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 EN ISO 15883 or Health Technical Memorandum (HTM 01-06). 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. 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 that 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.

13. A record should be kept of the serial number of each endoscope used in 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 leak test and manual clean, the EWD and the cycle details, including cycle number, used in decontaminating that endoscope should also be kept. This 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 where a diagnosis of vCJD is being considered or iii) a patient at increased risk (and presumed infected) 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 14 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 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 only be used in situations where no single use equivalent accessory exists, and should be heat tolerant for processing in the SSD. Procedures should be available for tracking each patient use 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 manufacturers' instructions, then decontaminated with their corresponding endoscopes in an EWD, keeping the valves and endoscopes together as a traceable unique set.
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. By contrast the channels of reprocessed endoscopes must be kept dry until the time of next patient use.
20. Health surveillance for staff exposed to disinfectants should be considered, in consultation with occupational health departments. Occupational health records should be retained for 40 years.
21. All staff involved in endoscopy and in endoscope decontamination should wear appropriate personal protective equipment (PPE) in line with local policy.

Out of hours endoscopy should not be done unless there is an individual available who has been assessed as competent in pre 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 procedure

23. Endoscopes used invasively, for example for Natural Orifice Transluminal Endoscopic Surgery (NOTES) and choledochoscopes, should be manually cleaned, processed through a EWD and finally terminally 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)

## 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 sterilization 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/high risk devices” although the procedures for cleaning and disinfection prior to sterilization 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 come into 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 was published in England in 2008 (updated in 2015)(2). This 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 (such as 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 BSG first published guidelines on decontamination in 1998 (3). Over the years many changes have occurred in recommendations for the decontamination of flexible endoscopes. In order to be responsive to these changes this document has been revised as guidance, this allows the flexibility to update this document in line with changes issued by Government agencies and other professional bodies.

## 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 each 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 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 (vCJD, for example).

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 EWD (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 multi drug resistant gram negative bacteria. The BSG issued guidance on reprocessing these endoscopes in 2015 (12). (Table 1)

Four types of micro-organisms have merited particular attention during the last two decades:

- 1 Mycobacteria: the emergence of multi-drug resistant strains of *Mycobacterium tuberculosis* and the high incidence of infections with *M. avium intracellulare* among HIV infected patients has led to a greater awareness of the risk of transmission of Mycobacteria 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 of these infections by endoscopy. Studies have shown that *Clostridium difficile* spores can be completely inactivated by a standard decontamination procedure (13).
- 3 Multi drug resistant gram negative bacilli. These have been linked to transmission during ERCP particularly in the US. There is no evidence to suggest these bacteria are resistant to the commonly used endoscope disinfectants but are more likely to be linked to the design complexity of the duodenoscopes and the quality of reprocessing (8).
- 4 *Pathological Prions including Creutzfeldt Jakob Disease and vCJD*. These infectious particles are extremely resistant to standard decontamination

procedures. Recommendations for minimising the risk of transmission of prion proteins are discussed in Section 3.

Although the greatest potential risk is transmission of infection from one patient to another using the same 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. (See Section 9: *Health, safety and infection control*)

Traditionally patients harbouring potentially infectious micro-organisms are scheduled for the end of endoscopy lists in order to minimise cross-infection. Given the universal endoscope decontamination regime, which presumes that all patients are potentially infectious, there is not normally a need to examine patients with a known infection last on the list. Nonetheless local infection control policies should be adhered to, including cleaning of the procedure room after examining 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:** Creutzfeldt-Jakob disease (CJD) is a rare and ultimately 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 both animals (scrapie in sheep, BSE in cows) and man. The precise nature of the transmissible agent is unknown, but is believed to be an abnormally folded form of a host-encoded prion protein. The normal prion protein (PrP<sup>c</sup>) is expressed in many tissues, but is concentrated within neurones in the central nervous system (CNS). The abnormal form of the protein (PrP<sup>Sc</sup>) accumulates in the CNS in prion diseases and, as the presumed infectious agent, it is remarkably resistant to most forms of degradation.

The sporadic form of CJD affects approximately 1 person per million per annum worldwide. Variant CJD (vCJD) is an acquired form of CJD that was first reported in 1996. It exhibits a unique neuropathological phenotype (15), and affects mainly young adults. The incubation period for vCJD could be as long as 30 years.

Fortunately earlier fears of large numbers of vCJD deaths have not been realised, and the incidence has been in decline for several years. However, there is evidence that many more people might be infected, while 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 smallish number of cases seen so far. In particular, vCJD can be transmitted via blood transfusion (17), and could in theory be passed on by the re-use of surgical instruments. Thus invasive procedures (such as endoscopy with biopsy) have the potential to transmit the disease from affected asymptomatic individuals in the incubation phase.

The differing distribution of the PrP<sup>Sc</sup> in the body in 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<sup>Sc</sup>, and may contain significant levels of infectivity during the incubation period (18). The abnormal form of the prion protein can be 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<sup>Sc</sup>.

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 (See Table 2).

It should be emphasised that aldehyde disinfectants, such as ortho-phthalaldehyde (OPA) and glutaraldehyde, fix protein, a property which may not only anchor prion protein within endoscope channels, but also render it more difficult to remove by other means. Hence the use of 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 for public health purposes.

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 involving use of any accessory passed through the valve. Adequate funding must be available to endoscopy units for the purchase of single-use biopsy forceps, cytology brushes, guidewires and other accessories.

**3.2 Individuals at risk** of vCJD include people (e.g. those with haemophilia) who received plasma based concentrates or antithrombin between 1990 and 2001, 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 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** when mucosa is breached or vaporised and the endoscope accessory and/or tissue vapour make 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 nowadays rarely necessary. It still applies following the performance of an invasive endoscopic procedure in a patient with definite or probable vCJD, or someone regarded as presumed infected having received labile blood products (such as whole blood, red or white cell concentrates) from a donor who subsequently developed vCJD. Temporary 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 still 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 with the same patient in future or, alternatively, for a patient 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 prior to next use.

If invasive endoscopy has been performed in any patient with vCJD or where a diagnosis of vCJD has not yet been ruled out/is still under consideration 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 re-use 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 and, like the remainder of the sheath, is later 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 AER itself, it is recommended that the endoscope washer disinfectant 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 protein. 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 ACDP guidance

<https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group>

#### 4. Decontamination of endoscopes – general principles

**4.1 Definitions:** Sterilization is defined as the complete destruction of all micro-organisms including bacterial spores (1). Sterilization is required for devices that are normally used in sterile areas of the body (e.g. laparoscopes, 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 in order to kill bacteria, viruses, mycobacteria and some spores. Most flexible gastrointestinal endoscopes would not withstand the conditions normally used in a steam sterilization process.

Endoscopes are routinely exposed to mucus and other gastrointestinal secretions, blood, saliva, faeces, bile, and sometimes pus. The process of decontamination comprises two key components with a number of stages:

- 1 manual cleaning, which includes a pre-cleaning routine in the procedure room before the endoscope is disconnected from its stacking system. This is followed by a manual cleaning process in a dedicated decontamination facility, which includes 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 automated disinfection, followed by rinsing of internal and external surfaces and drying of all exposed surfaces of the endoscope.

#### Stages of reprocessing for flexible endoscopes

| Stage                                | Why  |
|--------------------------------------|--|
| <b>Bedside procedure (pre-clean)</b> | 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 |
| <b>Leak test</b>                     | 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                                       |

|                     |  |
|---------------------|--|
| <b>Manual clean</b> | Brushing of accessible channels and flushing of all channels to remove organic matter. This stage will also allow the detection of channel blockages |
| <b>Rinsing</b>      | To remove detergent residues that may affect the performance of the disinfectant   |
| <b>Drying</b>       | To expel excess fluid that may dilute the disinfectant   |
| <b>Disinfection</b> | To eradicate potentially pathogenic microorganisms, i.e. bacteria, including mycobacteria and viruses  |
| <b>Rinsing</b>      | To remove disinfectant residues that could cause a harmful effect to the patient   |
| <b>Drying</b>       | 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, and then packaging and terminal sterilization.

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 infection, 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 in the flowchart (Figure 1) together with the basic anatomy of a flexible endoscope (Figure 2).

Decontamination should begin as soon as the endoscope has been removed from the patient. HTM 01-06 (24) recommends best practice is 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 (Figure 3).

#### **4.2 Pre cleaning**

Before the endoscope is detached from the light source/videoprocessor a *preliminary cleaning* routine should be undertaken. Water and detergent should be sucked through the working channel in order to clear gross debris and ensure that the working channel is not blocked. Similarly the air and water channels (and any auxiliary channel should be irrigated with detergent, not only to check for blockages but also to expel any blood, mucus and other debris. 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 timing, and amounts of air and fluids employed at each step.

#### **4.3 Manual cleaning**

The endoscope is then detached from the light source/videoprocessor securely contained and transported to the decontamination facility. A leak test is then 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 which should also be removed from the insertion tube at this stage. The biopsy port cap should be discarded whenever breached by biopsy forceps or any other accessories passed down the working channel during the endoscopy procedure. 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 appropriate dilution according to 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 from within narrow endoscope channel lumens. In HTM 01-06 guidance for health service units in England no preference for enzymatic detergents is expressed (24). A move away from enzymatic detergents has been prompted by reports of occupational asthma and skin sensitization (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 by the use of an automated flushing device, or manually) Detergent and rinse water must be replaced for each 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.

Recent guidance (HTM 01-06 2016) states that the endoscope must be processed within 3 hours of patient use (see Figure3).

#### **4.4 Automated disinfection**

The fourth stage is *automated cleaning followed by high level disinfection* within an endoscope washer disinfectant (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 their 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 (PCD) (see HTM 01-06) 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 which should be developed with the infection prevention and control team and clinical staff.

#### **4.6 Drying/Storage**

Purpose-built drying/storage chambers deliver high efficiency particulate filtered air (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. 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 72hr to 31 days. (see Section 7 below). Very clear policies and procedures must be in place with a specific storage time set and validated.

#### **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 Table 3, in HTM 03-01 (27) and a publication from the Central Sterilising Club (28). 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 ideally not be poured into the container so as to be lying freely. Prevailing regulations on the transport of contaminated goods must be adhered to; this includes 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 itself need to undergo a decontamination process.

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 that 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.

There are alternative vacuum packing systems 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. An electronic tracking and traceability system is mandatory for units relying on a remote decontamination facility.

**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 for, a transmissible disease such as vCJD. Serial numbers of all endoscopes and accessories must be recorded for each patient examined, and endoscopes must be properly tracked through their decontamination processes. Throughout each stage of the decontamination cycle, tracking of the personnel and patient associated with each endoscope is undertaken using an electronic method. For this to happen each endoscope must have a unique identification code or bar code. Each step of the decontamination cycle should be recorded, including the identity of the person undertaking each step, and this information should be linked to each individual patient examined with that endoscope. It should be possible to demonstrate that an endoscope has been through a full reprocessing cycle prior to each patient use. Documentation should also be able to demonstrate when an endoscope has been kept in a storage cabinet and then been reprocessed on exit.

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 each patient use of any reusable endoscopy accessories. The tracking system operating in each unit should be subject to regular audit.

#### **4.7.3 Accessories**

Water bottles should be changed after each endoscopy session i.e. 3 hours. They should be detached, emptied and cleaned as per manufacturers' instructions, and 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.

#### **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 should be:

- Effective against a wide range of organisms (bactericidal, mycobactericidal, fungicidal, virucidal and sporicidal)
- Active against prion proteins (though no such agent that is suitable for endoscope reprocessing is known to exist)
- Compatible with endoscopes, accessories and endoscope washer disinfectors.
- Type tested in the specific washer disinfectant
- 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) as well as for disposal.
- Low cost

It is essential to use disinfectants in accordance with their manufacturers' instructions. Attention must also be paid to directions from manufacturers of EWD and endoscope manufacturers. Some endoscope manufacturers advise users to undertake specified inspection routines as a precondition of honouring their service contracts and warranties

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). Attention must also be paid to directions from manufacturers of EWD and endoscope manufacturers. Some endoscope manufacturers advise users to undertake specified inspection routines as a precondition of honouring their service contracts and warranties.

The safety data sheet (SDS) must be obtained for all products to ensure appropriate safety precautions, if applicable, are followed.

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 personal protective equipment (PPE) whilst handling these disinfectants. (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 drying/storage cabinets should be employed instead.

## **5. 2 If you intend to change to an alternative disinfectant**

- Consult National guidelines (for example HTM 01-06 in England WHTM 01.06 Wales) (24), local Decontamination Lead personnel, the Authorised Person (Decontamination) (AP(D)) and the Authorising Engineer (Decontamination) (AE(D)) about type testing of disinfectants and detergents.
- Carefully cost the change bearing in mind the 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, personal protective equipment) 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 endoscopes in question

Care should be taken to ensure that all detergents and disinfectants used are approved for use with the EWD, and are employed at the correct temperature and concentration. These chemicals must be type tested to show compatibility with both the EWD and the endoscope. All detergents and disinfectants must be approved for use by the EWD manufacturer.

## **6. Endoscope Washer Disinfectors (EWD)**

These are essential for decontaminating all flexible endoscopes following manual cleaning. They are far more effective than manual cleaning and also protect the user 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 each working day 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 it can run at a time convenient to the Operator. Heat self disinfection is recommended by International Standards Organisation (ISO 15883-4, clause 4.8.1) (30).

The microbiological quality of the rinse water and other fluids must be acceptable (31). The final rinse water must be tested for its microbiological quality on a weekly basis (24, 30) (Figure 4). 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 lime scale on internal pipe work. Advice may need to be taken from a company specialising in water treatment, and from the AE(D). 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 (IPCT) clinicians (31) and the relevant estates staff.

The final rinse water should contain <10 cfu/100ml. This may be achieved either by using bacteria-retaining filters or by other methods purification systems (e.g. reverse osmosis). A water-softening and/or treatment system may be needed to prevent contamination of the EWD with limescale, biofilm and micro-organisms. It is recommended that rinse water is not reused.

Some special features or performance characteristics are optional but all machines 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 washer disinfectant 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 instructions. The machine should be programmable to accommodate the disinfectant contact time recommended by the disinfectant manufacturers and national guidance. Most EWDs have automatic leak-testing facilities incorporated within them, but these devices are varied in operation and design, faults can occur as with all devices, plus they do not angle the endoscope tip during leak testing, and may therefore fail to recognise positional leaks. The 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/models of endoscopes the EWD is intended to reprocess, and should 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 should seek advice from their endoscope and EWD manufacturers where any uncertainty exists. 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.

Following endoscopic examinations in patients with definite or probable vCJD, patients where a diagnosis of vCJD is being considered or those at risk and presumed infected (a very small group at the time of writing) it is recommended that the endoscope 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.

Following an invasive endoscopic examination in patients at risk of vCJD for public health purposes, (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/EN Standards and the testing and validation procedures as specified in the HTM 01.06 and any additional requirements of the relevant UK Devolved Administrations [e.g. WHTM 01.06 Wales]. Newly purchased EWDs must be installed and validated correctly and safely with regard to proper functioning as detailed in the HTM 01.06, safety of personnel and environmental protection. It is important to ensure that the 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, ensure that the system and failure acceptance criteria is known before purchasing

A print-out 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 AP(D) with the AE(D) before purchasing EWDs and associated equipment such as the water purification systems.*

*The same advice applies to the purchase of drying/storage cabinets (see below).*

**An appendix in the HTM 01.06 part D –purchasing specification should be used with direct guidance from the AE(D) and users**

*Local advice and procedures in NHS England and the Devolved Administrations must be undertaken*

## **7. Drying/Active Storage Cabinets**

Drying or active drying/storage cabinets 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 drying/storage cabinets 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 'scope to be connected separately within its own casing following manual cleaning. The scope remains within this casing during disinfection, drying and storage until next patient use. Units considering purchasing these chambers should discuss their 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 AE(MG)
- 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 restricted access levels provided?
- How many endoscopes can be accommodated simultaneously within each cabinet?
- Does the cabinet monitor each endoscope in store, record the data and indicate if the values fall short of specification or the endoscope has been in store too long?
- Does the cabinet allow for continuation of the traceability system?
- Has the cabinet manufacturer produced reliable data to show a stored endoscope may be directly used on a patient without processing?
- 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 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?
- If double ended cabinets are used or installed, check the 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 reprocess it prior to next patient use. It should be clearly labelled.

## **8. Cleaning and Disinfection of Accessories**

Nowadays the vast majority of accessories that are passed via the working channel 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 (such as 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 previous patient uses. Because autoclaving is not reliable in eliminating prion particles, 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) (33) 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 (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 hand-washing 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 (34).

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 40 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 Control of Substances Hazardous to Health Regulations 1994 (COSHH) require employers to assess the risk to the health of staff by exposure to hazardous chemicals to minimise and to avoid such exposure where this is reasonably practicable, and otherwise to ensure adequate control. Engineering methods of control must be used in preference to personal protective equipment. Guidance on ventilation of healthcare premises is discussed in HTM 03-01 (27).

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 to take place. 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 spillage. 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:

- absorbent granules/powder – to absorb liquid spills
- absorbent sock – to contain liquid spills
- chemical inactivator – to neutralise a chemical spill
- plastic apron, gauntlets and respirator/mask – personal protective equipment (PPE)
- orange bag – for containing clinical waste
- dust-pan and brush – to sweep up granules, if used.

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

## **10 Quality assurance of decontamination, drying and storage of endoscopes**

There are a number of audit tools that can be used in the quality assurance of endoscope decontamination practice. One was produced in association with IHEEM (35) and is under the ownership of the Joint Advisory Group on GI Endoscopy. Another has been prepared by the Infection Prevention Society (36). More detailed testing regimens are described in local health and technical memoranda 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 current relevant HTM 01.06. 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 as well as 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).

**CHECK this statement please**

## **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 2008 Health and Social Care Act [NHS England revised 2015) 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 (37) and the British Society of Gastroenterology in conjunction with some of the major endoscope manufacturers have developed a Direct Observation of Practice (DOP) form which can be used to document the training delivered and the competency of the staff member.

<http://www.bsg.org.uk/clinical-guidance/endoscopy/guidelines-for-decontamination-of-equipment-for-gastrointestinal-endoscopy.html>).

The BSG support 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 have an understanding of 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 personal protective equipment and the management of spillage are also essential.

Endoscopy units should consider employing specialist technical staff for the decontamination of flexible endoscopes. These personnel can specialise in decontamination and their presence will free qualified nursing staff for clinical duties.

Standard Operating Procedures (SOPs) 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 (38) (Figure 5). The MHRA has also released guidelines on Managing Medical Devices which sets out some basic principles on decontamination and training (39). Information on relevant standards and guidance relevant to endoscope decontamination are shown in Table 5.

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**Table 1: British Society of Gastroenterology advice on potential transmission of multi resistant bacteria and duodenoscopes.**

The BSG would like to highlight the following points to staff carrying out the decontamination of flexible endoscopes, in particular duodenoscopes.

|   |
|---|
| Adherence to manufacturers' instructions at all times is essential  |
| The pre clean procedure should take place at the patient 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 endoscope washer disinfectant 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 filtered air 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 EN 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.  |
| Staff should receive comprehensive training, and a record retained, on all aspects of the decontamination of endoscopes, in particular, duodenoscopes.  |

**Table 2: Summary of classification of vCJD risk relevant to GI Endoscopic Practice (Section 3):**

| <b>Type and status of vCJD diagnosis</b>   | <b>Management of the endoscope</b>   |
|--|--|
| 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)<br>For details about the different types of at increased risk classification see the ACDP TSE guidance Part 4 (table 4a)<br><a href="https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/427854/Infection_controlv3.0.pdf">https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/427854/Infection_controlv3.0.pdf</a> | Decontaminate and reuse  |

**Table 3 Top ten tips for ventilation in endoscope decontamination facilities**

|  |
|--|
| Ensure that  |
| 1. The ventilation within the decontamination environment complies with all relevant building notes and national standards.  |
| 2. Ventilation requirements include consideration of the thermal load within the decontamination room.   |
| 3. Where there is a single room the flow is from clean to dirty and includes 'bench' level extraction at the dirty end.  |
| 4. The ambient temperature within the decontamination area allows users to work within the environment with all doors and windows closed.  |
| 5. There is a local method of checking both incoming air and extraction (i.e. Magnahelix gauges)   |
| 6. Ventilation requirements are assessed/reassessed when there are any changes in room use including installation of new EWDs.   |
| 7. Staff working within the area are 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. There is a documented process in place for dealing with ventilation problems in a timely manner.  |
| 9. Decontamination audits 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.                    |

**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. |

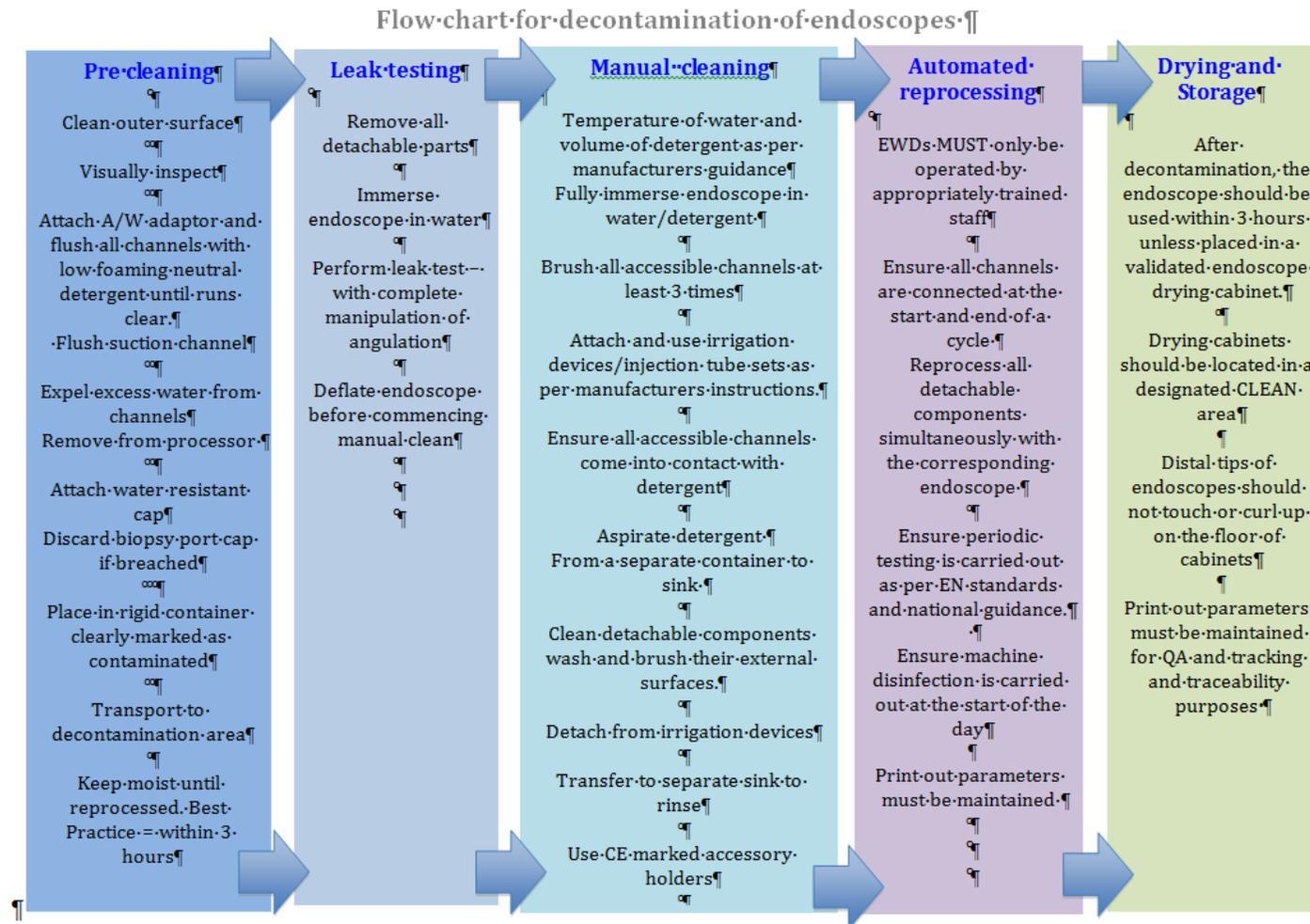
**TABLE 5: Relevant documents on decontamination practice and clinical audit tools**

| 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<br>Part A: Formation of local policy and choices manual<br>Part B: Common elements<br>Part C: Steam sterilisation<br>Part D: Washer disinfectors<br>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                           | Washer disinfectors<br>Part 1 – General requirements<br>Part 4 – Requirements and tests for washer disinfectors employing chemical disinfection for thermo-labile endoscopes<br>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

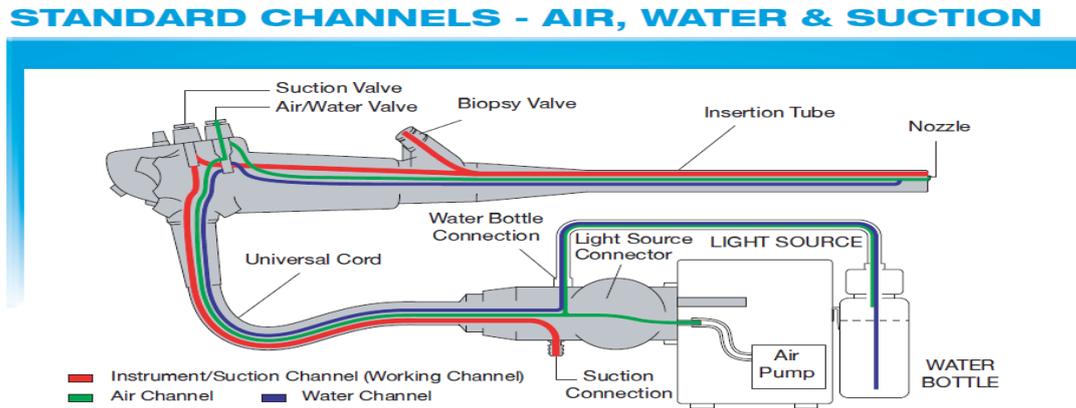
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**Figure 1: Flowchart to summarise the flexible endoscope decontamination process**



It is imperative that manufacturers instructions are followed at ALL times

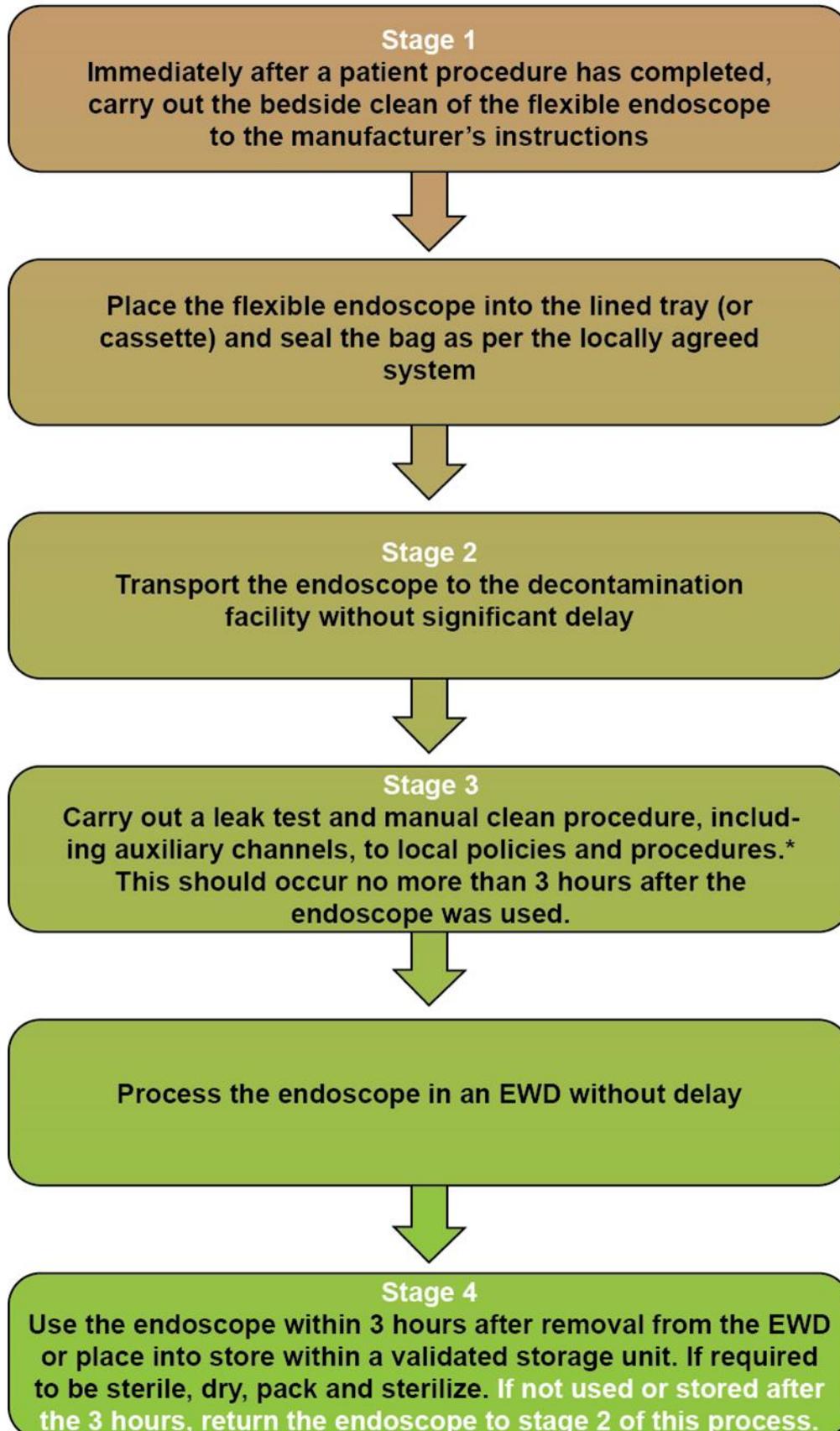
**Figure 2: Basic design of a gastrointestinal endoscope. More complex designs apply for endoscopic ultrasound scopes (balloon channel) and duodenoscopes (elevator wire).**



Courtesy Olympus Keymed UK Ltd

**Figure 3**

**Flexible endoscope decontamination timeline**



## 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 (2016)

[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/553303/HTM01-06\\_PartE.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/553303/HTM01-06_PartE.pdf)

**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-disinfectants'.
- 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.

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

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