

MDA Guidelines

Sterilisation of Endoscopes

EXECUTIVE SUMMARY

This revised and updated Device Bulletin replaces the Medical Devices Agency's earlier Bulletin MDA DB9607 'Decontamination of Endoscopes' (published in November 1996) and was produced following consultation with a wide range of organisations including:

- MDA's Microbiology Advisory Committee
- Medical & nursing professional bodies
- Endoscope manufacturers
- Automated endoscope reprocessor manufacturers
- Disinfectant manufacturers
- Department of Health

The areas of particular concern addressed in this Bulletin include:

- Types of agent that present an infection risk.
- Guidance on reprocessing various types of endoscope.
- Guidance on the use of disinfectants.

This Bulletin is intended to offer advice and guidance to both users and manufacturers of devices and reprocessing equipment. It draws together existing advice, with particular reference to disinfectant contact times. Personnel with responsibility for decontamination and infection control may base their processing procedures on this information. The Bulletin reviews the use of established disinfectants and processing equipment and provides information on some of the new or emerging technologies available for the decontamination of endoscopes. It provides information on all stages of the reprocessing of endoscopes – from the initial cleaning to storage following reprocessing. The Bulletin also looks at the health and safety aspects of reprocessing endoscopes and highlights some of the problems that may occur.

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1. INTRODUCTION

Endoscopic procedures carry a risk of causing infection. Estimating this risk accurately is difficult because:

- it is not possible to be certain that a given infection results from a contaminated endoscope;
- infection may not become apparent until after the patient has been discharged from hospital; and
- the contaminated endoscope may not be recognised as the source of infection.

Infectious agents contaminating an endoscope can originate from failures in the decontamination process, from contamination during storage, or from previous patients.

Decontamination should begin as soon as possible after endoscopes and their accessories have been used. Thorough manual cleaning with a suitable detergent and in accordance with the endoscope manufacturer's instructions is an essential first stage. This will involve dismantling the endoscope and cleaning it carefully with brushes, paying particular attention to long narrow lumens and occluded surfaces. Thorough rinsing completes the manual cleaning. The use of ultrasonic baths and enzyme detergent solutions for cleaning endoscope accessories is also recommended where the process is compatible with the device.

After manual cleaning the instrument must be either disinfected or sterilized. This may be performed manually or by using an automated endoscope reprocessor (AER). The final stage of the process is drying and ensuring safe storage.

All processes should be validated and the manufacturer's instructions should be referred to.

Where practicable single-use devices should be used.

If unavailable, reusable accessories should be autoclavable. It is recommended that all reprocessing of rigid endoscopes and reusable accessories should be carried out by a Sterile Services Department (SSD). Reusable accessories should be traceable in accordance with the Department of Health's publication, Health Service Circular HSC2000/032 (see Section 2.4).

Failure to remove deposits of blood, faeces, tissue, mucus, infectious agents or biofilm may result in infection, misdiagnosis or instrument malfunction. Thorough cleaning, though often difficult to achieve, is therefore an essential component of the decontamination process.

The major problems leading to inadequate decontamination are:

- inadequate cleaning;
 - hard deposits of organic material on endoscope surfaces, caused by:
 - damaged and deformed surfaces
 - perforated instrument channels
 - parts of the instrument not being exposed to the cleaning process because they are closed off by valves or seals (occluded surfaces)
 - failure to clean intricate areas such as hinge joints, recessed surfaces and long narrow apertures (lumens)
 - ineffective final rinsing and drying;
- contamination of wash-bottles and tubes connected to the endoscope;

- inappropriate or incomplete decontamination methods e.g. choice of disinfectant and contact time, both of which are critical;
- continued use of disinfectant diluted below its effective concentration or used beyond its recommended shelf-life;
- design faults in automatic endoscope processor systems, allowing the growth or persistence of infectious agents on some parts of the endoscope and/or AER;
- use of water or other fluids of poor microbiological quality for decontamination (see Section 5).

If an automated endoscope reprocessor (AER) is used, it should have been validated and tested in accordance with the guidance provided in the NHS Estates publication HTM 2030 and relevant standards where available. It is essential that the machine has itself been properly cleaned and disinfected before use, employing, where possible, the AER's self-disinfection cycle. The cleaning and disinfection of the AER should be carried out in accordance with the manufacturer's instructions. The microbiological quality of the rinse water and other fluids must be acceptable.

The health and safety aspects of the use of disinfectants e.g. the maximum exposure limit (MEL) for glutaraldehyde, must be considered when assessing reprocessing arrangements.

The uncertainties associated with variant Creutzfeldt-Jakob Disease (vCJD) have a particular impact on the management of expensive invasive devices such as endoscopes and accessories.

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2. ASSESSMENT OF INFECTION RISK

Although the overall incidence of infection following endoscopy is very low, there is a significant risk for transmission of infectious agents to an individual patient which is dependent on a number of factors:

- the type of endoscopic procedure undertaken;
- the infectious agents present in any previous patient's secretions;
- the effectiveness of the method used to reprocess the endoscope;
- environmental re-contamination of the endoscope during or after processing and storage;
- the susceptibility of the patient to infection. The sensitivity of surveillance methods in this area often suffers because of inadequate patient follow-up and laboratory investigation.

2.1 Surveillance of infection following endoscopy

In 2001, it was estimated that more than 10 million gastrointestinal endoscopic procedures were performed in the United States alone and the risk of infection was reported to be 'extraordinarily low' (Weber and Rutala 2001). This is supported by a retrospective analysis of 265 articles published between 1966 and 1992 (Spach et al 1993) which revealed a remarkably small number of reported infections (281 following gastrointestinal endoscopy and 96 following bronchoscopy).

2.2 The endoscopic procedure

The infection risk is directly related to the clinical condition of the patient, nature of the procedure and the type and contamination status of the endoscope used, i.e. rigid or flexible. The recommended level of decontamination will depend upon the procedure for which the endoscope has been used. In addition the decontamination process is limited by the materials used in the construction of the endoscope which may be thermolabile (heat sensitive) or incompatible with a specific chemical decontamination agent.

2.2.1 Invasive or non-invasive procedures

The risk of infection can be classified according to the degree of invasiveness of the procedure. Transient bacteraemia occurs with a variety of procedures which produce mucosal trauma and has been associated with all endoscopic procedures (Cowen 1991).

Endoscopes that are passed into normally sterile body cavities are deemed invasive and should be sterilized prior to use since the risk of infection following the use of a contaminated endoscope is high. Endoscopes used for invasive procedures e.g. arthroscopes, laparoscopes and cystoscopes should ideally be sterilized by either steam or gas plasma. If this is not possible e.g. non-autoclavable rigid endoscopes or flexible endoscopes, then the use of high-level chemical disinfectants should be considered.

Endoscopes that come into contact with intact mucous membranes but do not invade sterile cavities are deemed non-invasive and can be decontaminated by high-level disinfection using liquid chemical disinfectants.

2.2.2 Endoscopic retrograde cholangiopancreatography

Endoscopic retrograde cholangiopancreatography (ERCP) is associated with the 'highest risk' of serious clinical infection. Septic complications occur in 0.8-3.4% of cases (Cowen 1991) and there are numerous case reports of fatalities.

The risk factors associated with ERCP include duct obstruction, endoscope and accessory contamination, and tissue injury. The risks may be increased if the patient is immunocompromised. Bile proximal to an obstructing lesion represents an ideal medium for multiplication of bacteria

introduced by ERCP. *Pseudomonas aeruginosa* and other Gram-negative bacilli are the major culprits (Bilbao et al 1976).

2.3 Patient-to patient transmission

Over the past 30 years reports have highlighted the ready transmission of pathogenic and commensal infectious agents by contaminated medical devices including endoscopes. These endoscope-transmitted infections may be caused by infectious agents transferred from patient to patient or from the environment to the patient. During a procedure, an endoscope can become contaminated with any organism contained in patient secretions that subsequently can be transmitted between patients if the instrument is not properly decontaminated. Whilst satisfactory decontamination procedures do exist, a lack of training, time pressures or insufficient resources may lead to process failure.

Transmission between patients may not be limited to microbiological infection. There may be the additional risk of 'seeding' of malignant cells in the absence of complete cleaning and decontamination, particularly when endoscopic or laparoscopic forceps have been used to remove tissue either during biopsy or definitive treatment. There may be design features, particularly of fine forceps, that lead to particular difficulties in ensuring proper decontamination of these instruments. However, the MDA has not received any reports implicating this mode of patient-to-patient transmission.

Reported transmission of exogenous infectious agents from contaminated endoscopes include:

i) Gram-negative bacteria

The commonest organisms associated with infection following endoscopy are the aerobic Gram-negative bacilli, e.g. *Pseudomonas aeruginosa*, *Klebsiella* spp, *Enterobacter* spp and *Serratia marcescens*. The transfer of *Salmonella* spp, including *Salmonella typhi* has occurred, usually in association with oesophagogastroduodenoscopy but less often with colonoscopy. In the paper by Spach et al, out of 84 patients reported to have developed salmonella infection, six patients suffered bacteraemia and one died. More recently, contamination of endoscopic accessories and patient-to-patient transmission of *Helicobacter pylori* has been reported. It is likely that clearly defined Gram-negative bacilli, e.g. *Pseudomonas aeruginosa* serotype 10 phage type 1214 associated with ERCP will alert any surveillance system but a patient with an *Escherichia coli* or Gram-positive *Streptococcus bovis* bacteraemia may not be recognised as an adverse event following endoscopy.

ii) Mycobacteria

Mycobacterium tuberculosis has been transmitted by fibre-optic bronchoscopy (Ayliffe 2000) but the lack of reports associated with gastrointestinal (GI) endoscopy may be due to the low incidence of gut tuberculosis in patients in the UK, the long incubation period and a low level of awareness. Whilst well-documented individual cases of procedure-acquired infection via endoscopy have taken place, evidence of wide scale mycobacterial contamination is not available. In a retrospective analysis of 8,750 bronchoscopies, there was evidence of cross-contamination on eight occasions but no evidence of transmission of infection (Leclerc et al 1985).

Several reports identify cross-contamination with environmental mycobacteria via AER. In a large outbreak, *Mycobacterium chelonae* was isolated from bronchial washings, brushings or sputum in 72 patients (Pappas et al 1982). Two developed clinical disease and one patient died. Misdiagnosis of tuberculosis has been reported due to contamination of the instruments with environmental mycobacteria from the rinse water which subsequently contaminated bronchial washings sent for culture (Nye et al 1990).

iii) Viruses

Blood-borne viruses, especially hepatitis B and C and human immunodeficiency virus (HIV) are present in most body fluids of infected individuals. In spite of the high degree of infectivity of hepatitis B surface antigen (HBsAg) positive patients, documented transmission of hepatitis B virus by endoscopy is uncommon; only one convincing case has been reported. A number of clinical studies have followed up patients with endoscopic exposure to HBsAg with essentially negative results; these 12 reports included 394 exposed patients (McClelland et al 1978).

Thorough cleaning with detergent of endoscopes contaminated with HIV has been shown to decontaminate them effectively (Hanson et al 1991). To date, the endoscopic transmission of HIV has not been reported.

iv) Other infectious agents

Other organisms transmitted by endoscopic procedures include *Burkholderia pseudomallei*, *Strongyloides stercoralis*, *Trichosporon beigelli*, *Giardia*, *Cryptosporidium* and pseudoepidemics of *Rhodotorula rubra*. Whilst cleaning removes the majority of organisms, isolated cases of rare infectious agents being transmitted via endoscopes continue to be reported. Furthermore, some parasites are resistant to many of the usual disinfectants used.

2.4 Variant Creutzfeld-Jakob Disease (vCJD)

Whilst there is still much that is not understood about the infectivity and transmission of the abnormal prion protein thought to be responsible for vCJD, it is clear that special attention needs to be paid to minimising the risks associated with this agent (Axon et al 2001). Endoscopes, and especially flexible endoscopes, present a particular challenge to those carrying out the decontamination process (Rutala and Weber 2001a). Dedicated endoscopes are available from specialist units for use on known vCJD patients. Further details are available from the National CJD Surveillance Unit, Western General Hospital, Crewe Road, Edinburgh EH4 2XH (0131 537 2128).

The Department of Health has advised that cleaning is of the utmost importance in minimising the risk of transmission of vCJD via medical devices. Further details are available in HSC 1999/178 'vCJD – Minimising the risk of transmission'. With regard to flexible endoscopes, the HSC advises of the need to implement traceability of these devices. The issues relating to the management of endoscopes with relation to CJD and related diseases is under review by the Department of Health.

Whilst tracking systems for surgical instruments are still being developed (HSC 2000/032), flexible endoscopes are already generally supplied with a unique serial number which can be used to facilitate traceability of the device to individual patients upon which it has been used. Any accessories used with or associated with a particular endoscope must be kept together with that endoscope, forming a unique set. The whole set then benefits from the unique serial number and can be traced.

Wherever possible single-use devices should be used provided they do not compromise the clinical outcome.

2.5 Environmental contamination

Many of the agents used for the decontamination of endoscopes and accessories deposit toxic residues that must be adequately rinsed off before the endoscope can be used. Tap water may contain microbes including *Pseudomonas* spp and *Mycobacterium* spp and there are many reports of procedure-acquired infection and pseudo-infection with these organisms via contaminated rinse water.

The effectiveness of AERs depends on a number of factors, including their design, regular cleaning and disinfection of the AER and the quality of the water used for rinsing. These factors have played an important role in outbreaks of infections (or pseudo-infections) associated with the use of these machines (see Section 5). In addition to these documented problems there is evidence to suggest that environmental mycobacteria are becoming resistant to glutaraldehyde resulting in persistent contamination of AERs (Griffiths et al 1997 and Manzoor et al 1999). Some strains of *Mycobacterium chelonae* have been shown to develop resistance to glutaraldehyde.

2.6 Patient susceptibility

A variety of clinical circumstances may increase the danger of infection associated with endoscopy, particularly the immune status of the individual. Increasing numbers of immunocompromised patients are undergoing endoscopy either for diagnostic or therapeutic reasons. Such patients are at a greater risk of contracting infection than the rest of the population and are liable to become infected not only with pathogenic organisms but also with opportunists such as environmental mycobacteria, fungi and *Pseudomonas* spp.

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3. Types of Endoscopes and Compatibility with Decontamination Procedures

3.1 Types of Endoscope

Endoscopes can be categorised by their design as being flexible or rigid. Whilst rigid endoscopes are primarily used for invasive procedures and flexible endoscopes for non-invasive procedures, flexible versions of invasive instruments are available.

All flexible and most rigid endoscopes are designed to be reused. When purchasing endoscopes and accessories, consideration should always be given to the ease with which they may be thoroughly decontaminated. Single-use and reusable accessories are available.

3.1.1 Flexible endoscopes

Flexible bronchoscopes, gastrointestinal endoscopes and other flexible endoscopes are more complex than rigid endoscopes thus creating more problems with cleaning, disinfection and sterilization

Flexible endoscopes contain a wide range of materials including alloys, plastics, rubber, optical glass, stainless steel, and epoxy resin. Following the introduction of fully immersible instruments in 1983, internal channel configurations have been simplified to ease decontamination (Dietze et al 2001). Sophisticated sealing mechanisms incorporated into the control body design ensure a watertight construction. The provision of a leakage test facility allows their integrity to be checked.

Flexible endoscopes are heat sensitive and therefore chemical disinfection or sterilization must be performed at temperatures in accordance with the manufacturers' instructions. Most flexible endoscopes are compatible with ethylene oxide and certain liquid chemical disinfectants.

The problems associated with the use of the most commonly used disinfectant, glutaraldehyde (see Section 7) have prompted the development of non-aldehyde alternatives. Examples of such are those based on peracetic acid and chlorine, although unfortunately, these may be more damaging to some instrument components than glutaraldehyde. The diverse range of materials (all with varying degrees of resistance to corrosion and different coefficients of expansion) now incorporated into endoscopes, their accessories and AERs, make it essential that advice is sought from the endoscope manufacturer on compatibility with any new disinfectant or decontamination process.

Ethylene oxide and low temperature steam and formaldehyde may be used for the sterilization of flexible endoscopes. However, there are very few, if any, of these systems currently in use in the UK health service and are therefore not seen as a viable option.

Since the mid-1980s a transition from fibre-optic to video endoscopes has occurred, but is limited to large diameter devices and smaller diameter instruments such as 'ureteroendoscopes' will remain fibre-optic for the foreseeable future.

3.1.2 Rigid endoscopes

Rigid bronchoscopes, arthroscopes and other rigid endoscopes are relatively easy to clean, disinfect and sterilize.

Whilst rigid endoscopes are functionally less sophisticated than flexible instruments, considerable development has occurred to produce autoclavable endoscopes, with high reliability and durability to facilitate improved decontamination. Most rigid endoscopes are now used in conjunction with CCTV systems and most suppliers of rigid endoscopes have introduced autoclavable telescopes eliminating the need for the use of liquid chemical disinfectants.

Most rigid endoscopes are compatible with steam, formaldehyde, ethylene oxide and certain liquid chemical disinfectants. As with flexible endoscopes, it is essential to check with the device manufacturer to establish the compatibility of the device with the process.

3.1.3 Accessories

A range of long, flexible, small diameter devices, each designed for a specific purpose, are used

as accessories in flexible endoscopy procedures. These may be 2 metres or more in length, with diameters from 1.2mm. The devices are precision engineered, usually made from stainless steel and some may be coated in insulating plastic. The different types can be grouped according to their use e.g. biopsy forceps, grasping forceps, diathermy snares and knives, wire baskets, cannulae, balloon catheters and drainage tubes or stents.

Accessories used during rigid endoscopic procedures are diverse in nature.

Wherever possible single-use accessories should be used (Haber 2000). However, many of the accessories now available for use with flexible endoscopes can be reprocessed. If these are used they should be reprocessed in accordance with the manufacturer's instructions.

Conventionally, initial decontamination of endoscope accessories has been achieved by manual and/or ultrasonic cleaning followed by autoclaving or immersion in cold liquid chemical disinfectants. Later designs include flushing ports which facilitate decontamination of the internal operating mechanism and, more recently, modular hand instruments have been introduced which can be fully disassembled for cleaning and sterilization.

Where possible all reprocessing of autoclavable endoscopes and their reusable accessories should be carried out by a SSD.

3.2 Implications of the Medical Devices Regulations

Manufacturers of CE marked reusable medical devices are required, under the Medical Devices Regulations 2002, to provide information on the appropriate methods of cleaning, disinfecting, packaging and, where appropriate, sterilization to allow reuse of the device. Manufacturers must also supply similar information if the devices are supplied non-sterile and are required to be sterilized prior to use.

AERs should also be CE marked and be provided with instructions for use which include information on the decontamination of the machine itself.

Whilst the level of detail provided will vary depending on the complexity of the device and the level of reprocessing required, the type of information that should be available to the user is provided in Table 1. A draft standard (prEN 17664 'Sterilization of medical devices. Information to be provided

by the manufacturer for the reprocessing of resterilizable devices') outlining the information to be provided is currently being prepared.

Table 1: Information to be supplied by the manufacturer of the endoscope or accessory

User information	Comments
Instructions on how to clean and, where necessary, dismantle the device. Instructions on how to maintain the device.	The level of detail required will depend on the complexity of the endoscope/accessory.
<p>The types of agents that may be used to clean, disinfect or sterilize the device.</p> <p>A warning of any compounds or processes which may be detrimental to the device, any special precautions and any other contraindications e.g. the maximum temperature that can be used.</p>	<p>This may not necessarily be brand named agents but an indication of generic agents demonstrated to be compatible with the endoscope/accessory.</p> <p>Note: The manufacturer is only able to provide advice on which agents are compatible with the endoscope or accessory and not the disinfectant contact time which is discussed in Section 6. Contact times will, however, be indicated by the manufacturer of the disinfectant and/or AER and these should be borne in mind when formulating policy.</p>
The compatibility of the device with the conditions within any sterilization or automated disinfection system such as an AER.	This should include pressure and vacuum, as may be experienced during the decontamination process.
Any ancillary equipment required to be able to process the endoscope.	This may include adapters for use with AERs or for sterilization.
If the device can be sterilized by a physical method e.g. using steam under pressure (autoclaving), the method of sterilization should be indicated.	This should include all process variables such as temperature and time of exposure, taking into account the availability of the recommended process to the user.

Any ancillary equipment, such as adapters or special connectors needed for the reprocessing of endoscopes in an automated endoscope reprocessor, should also be listed and, where necessary, advice on their use sought from the AER manufacturer.

Liquid chemical disinfectants intended specifically for the decontamination of medical devices are subject to the Medical Devices Regulations 2002 and shall bear a CE marking. The type of information that should be supplied by the manufacturer of liquid chemical disinfectants is provided in Table 2.

Table 2: Information to be supplied by the manufacturer of the disinfectant

User information	Comments
A statement of the intended use of the disinfectant.	e.g. for decontamination of medical devices.
The microbicidal activity of the disinfectant including:	
<ul style="list-style-type: none"> specified contact/immersion times; lowest effective concentration; stability; instructions on the necessity for pre-cleaning the item prior to the disinfection process. 	Experimental studies should demonstrate proven efficacy against infectious agents of significance in terms of their resistance and their association with particular endoscopic procedures.
Instructions on the preparation of the disinfectant prior to use.	This should include where appropriate, details of activation, dilution or in-use concentration.
Details of the compatibilities/incompatibilities under its intended use.	This should comprise: <ul style="list-style-type: none"> compatibility with materials of construction of a device or processing equipment; other processing agents with which it may adversely react; other conditions which may affect the antimicrobial efficiency of the disinfectant
Safety data, to include details of toxicity, flammability and corrosive properties. Handling precautions, including recommended protective clothing, and the action to be taken in the event of a spillage.	Users of hazardous chemicals, e.g. glutaraldehyde, should ensure that their practices are in accordance with COSHH (see Section 6).

3.3 Future developments and singleuse items

With the continuing evolution of techniques and technology, changes in endoscope design may substantially affect the reprocessing options available to the user. Careful consideration should therefore be given to decontamination during the development stage.

Some suppliers are now providing single-use surgical telescopes that can be supplied sterile ready for immediate use. As yet they do not have the optical characteristics of the reusable telescope and image quality may therefore be compromised. These instruments may not be accepted in the market because rigid endoscopes are relatively simple to clean and disinfect, or sterilize.

Most healthcare establishments now use a combination of both single-use and reusable devices, each being selected to ensure optimum operating performance. The perceived limitations of the single-use product are cost and the environmental problems associated with their disposal.

A recent innovation in the USA is that of a reusable fibre-optic endoscope that is used in association with a single-use sheath. It is thus designed to reduce the level of decontamination required. Although available commercially, the choice of such endoscopes is limited and potential users appear to be evaluating them on a cost basis only. In addition, sterile, single-use sheaths are also being provided for use with external video cameras and the laparoscope itself. While the former have become increasingly popular, little experience of the telescope sheath is yet available. Sheaths intended for use with flexible laryngoscopes are available in the UK. However concerns remain over the ability to detect damage to the integrity of the sheath.

Guidance on the implications and consequences of the reuse of single-use medical devices is available in the Medical Devices Agency Device Bulletin DB2000(04).

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4. Decontamination of Rigid and Flexible Endoscopes

The effective decontamination of endoscopes requires input from at least the following areas of expertise:

- the instrument manufacturer or supplier who is familiar with the design and function of the item and its compatibility with heat and chemicals;
- the infection control personnel who are responsible for advising on the selection and use of a suitable decontamination process;
- the endoscopy nurse, sterile services personnel, Authorised Person (Sterilizers) or other person responsible for reprocessing;
- the clinician or the user of the instrument who is familiar with the risks associated with the procedure and the financial and other constraints imposed upon the service;
- the manufacturer or supplier of the automated endoscope reprocessor (AER);
- the manufacturer of the chemical disinfectant or decontamination process.

All procedures for the cleaning, disinfection and/or sterilization of the endoscopes should be carried out in accordance with the manufacturer's instructions. Appropriate personal protective equipment (PPE) should be worn (see Section 8.5).

The traceability of devices during their life cycle is important in identifying which endoscope has been used on which patient. Systems should be put in place in accordance with current Department of Health guidance (see Section 2.4).

Further advice is provided in MDA's publication 'Sterilization, Disinfection, and Cleaning of Medical Equipment: Guidance on Decontamination from the Microbiology Advisory Committee'.

4.1 Cleaning

Effective cleaning is an essential pre-requisite to disinfection and sterilization and is vital to ensure removal of debris. In most cases a manual clean is necessary and should include brushing each channel at least three times prior to further processing in an AER.

Thorough cleaning will ensure that adherent infectious agents are largely removed together with the organic matter that protects them. It also ensures better contact between the disinfectant and any remaining infectious agents in subsequent stages of decontamination. Heat and some disinfectants, e.g. alcohol and aldehydes, are tissue fixatives and may cause lumens to block or the taps and moving parts of the endoscope to stiffen if the surfaces and channels are not thoroughly cleaned before sterilization/disinfection.

Cleaning with warm water and a neutral or enzymatic detergent is recommended, though advice on suitable cleaning agents should be sought from the endoscope manufacturer and the AER manufacturer (see Section 3). The detergent should be changed at a frequency recommended by the manufacturer to prevent its contamination with organic matter. However, where possible single-use detergents should be used.

There are very few machines available that are capable of cleaning as well as disinfecting endoscopes. It is essential that initial manual cleaning of the insertion tube and air/water channel, at the point of use, is performed before either a) placing in a fully automated washer-disinfector or b) as noted above, further manual cleaning and brushing in an open sink before placing in an AER. For this to be done effectively, staff should be appropriately trained and possess knowledge of the devices being reprocessed.

Appropriate cleaning brushes i.e. clean and dedicated for the purpose, should be used for all accessible channels and ports. These brushes should, if not supplied for single-use, be reprocessed in accordance with the manufacturer's instructions. The use of one brush or set of brushes for each endoscope is recommended to help with the traceability of the endoscope during the life cycle of use of the device.

Ultrasonic washers may be used for most rigid endoscope components and accessories with the exception of the telescope. It should be noted that flexible endoscopes may be damaged if processed in ultrasonic washers. All lumens should be irrigated during ultrasonic cleaning, to remove dislodged organic matter. Irrigation pumps are available for flushing instrument lumens and components.

Either cleaning and disinfection or sterilization of the devices, whichever is appropriate, should be undertaken before the endoscopy list, between each procedure, at the end of the list and prior to inspection, service or repair (Department of Health's Health Service Guidance HSG(93)26). A record should be maintained of the cleaning, disinfection and sterilization process for each endoscope.

4.2 Disinfection

Immersion in a suitable liquid chemical disinfectant is the most widely used procedure for the decontamination of flexible and heat sensitive rigid endoscopes. However, immersion in static disinfectant has been demonstrated to have limitations, compared to non-static systems where fresh disinfectant is being continually presented to the surface of the device. The most widely used agents (at present) are aldehydes, notably 2% activated glutaraldehyde, although other disinfectants are increasingly being used (see Section 6). An AER used for decontamination of endoscopes should be designed and validated in accordance with NHS Estates' Health Technical Memorandum HTM2030 and/or other relevant British and European Standards where possible.

NHS Estates' Health Technical Memorandum HTM2030 provides guidance on appropriate AERs for rigid and flexible endoscopes. The guidance covers safety features such as toxic vapour extraction systems as well as quality of water supply (including rinse water). It also describes detailed and stringent commissioning and performance tests including cleaning and disinfection efficacy.

Serial processing of endoscopes in automated systems may reduce disinfectant potency through contamination with the detergent and water that are used for cleaning. The disinfectant should therefore be changed at a frequency to prevent such contamination. Advice on the minimum effective concentration and dilution rate of the disinfectant should be sought from the disinfectant manufacturer and the AER manufacturer respectively. The use of disinfectants for the decontamination of rigid endoscopes should be discouraged in favour of heat processes that can be more tightly controlled. As an alternative to the use of liquid chemicals, rigid endoscopes may be high-level disinfected using various other methods (see box).

Alternative methods for disinfecting rigid endoscopes (moist heat)

- low temperature steam (LTS) held at 73°C-80°C for a minimum of 10 minutes;
- by processing in a thermal washer-disinfector meeting the time/temperature relationships with holding temperatures of :
 - 73°C for 3 minutes,
 - 80°C for 1 minute, or
 - 90°C for 12 seconds

4.3 Sterilization

Steam under pressure is preferred to the use of liquid chemical disinfectants for the disinfection of all invasive or surgical endoscopes. It is unsuitable for heat sensitive instruments.

Sterilization is the preferred process for rigid endoscopes. Many are now heat tolerant (see Section 3 for further details) and all components, including the telescope, are autoclavable. It is usual for manufacturers to mark instruments as autoclavable.

Unfortunately heat sterilization processes are impractical for heat sensitive flexible instruments. It is therefore essential that the heat, chemical, pressure and moisture tolerance of the instrument be established from the manufacturer before selecting the method of decontamination, to ensure that the process will not damage the endoscope.

Sterilization processes require routine monitoring, regular and preventative maintenance and periodic testing of the sterilizer (NHS Estates Health Technical Memorandum HTM 2010).

A summary of some of the process options for the decontamination of all endoscopes are described below.

4.4 Endoscope decontamination process options

Examples of process options for both rigid and flexible endoscopes are given in the box.

	Rigid endoscopes	Flexible endoscopes
Sterilization	Steam Gas plasma	Gas plasma
Disinfection	Thermal washer-disinfector Low temperature steam	AER

Liquid chemical disinfectants can be used to achieve a high level of disinfection which is determined by various factors including the contact time and temperature. Liquid chemical disinfectants should always be used in accordance with the manufacturer's instructions, and their compatibility with the materials of the endoscopes being reprocessed should be established.

Boiling water is not recommended, as there are difficulties in ensuring that the required temperature is maintained. Moreover it does not kill spores. The advice of both the supplier of the endoscope and the supplier of the AER should always be sought before the decontamination of any instrument is undertaken.

Procedures for the automated disinfection and sterilization of rigid endoscopes are not included in this document.

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5. Use Of Automated Endoscope Reprocessors (Aers)

Automated machines used for cleaning and disinfecting endoscopes, can themselves be a potential source of infectious agents, leading to endoscope contamination and subsequent patient infection and/or misdiagnosis. Advice on the validation, maintenance and periodic testing of AERs is provided in NHS Estates Health Technical Memorandum HTM2030 and may also be available from the local Authorised Person (Sterilizers) (AP(S)).

Suitable adapters should be supplied by the manufacturers of the AER to enable connection of different endoscopes to the machine during processing.

The Medical Devices Agency has received reports indicating that recontamination of endoscopes has occurred as a result of inadequate cleaning and disinfection of reservoir tanks and fluid pathways in the machines (see box below)

Problems involving AERs reported to the MDA

- Incorrect and 'home-made' connections.
- Spillages due to incorrect placing of the endoscope in the AER.
- Insufficient disinfectant in system.
- No water filters used.
- Blocked channels resulting in low or no flow of the disinfectant.
- Recontamination of devices from the AER.

5.1 Contamination of AERs

The use of mains water of inappropriate quality can also be a contributory factor to the contamination of both the machine and the endoscope. A number of factors have been associated with contamination of machines. These factors include:

- inadequate cleaning, disinfection and maintenance of the machine;

- the use of static water remaining within pipework or tanks;
- the use of a water supply of poor microbiological quality;
- the use of hard water;
- inadequate pre-cleaning of the endoscope;
- contamination by disinfectant-resistant mycobacteria; and
- the formation of biofilm within the machine.

Colonisation of the fluid pathway of an AER will occur more rapidly if it is not disinfected at an appropriate frequency. The manufacturer of the AER should provide advice on compatible cleaning agents and disinfectants and the appropriate methodology to ensure no damage to the machine.

Flushing of the fluid pathways of the AER after such cleaning should be performed to ensure that any dislodged biofilm is removed (Kressel and Kidd 2001).

Some machines have a dedicated pre-programmed self-disinfection cycle, whilst others are able to carry out self-disinfection using the normal operating cycle in the absence of an endoscope. Those

machines that are not fully automated, and do not have this facility, will require manual disinfection of the fluid pathways. Whichever disinfection regimen is adopted, it is essential that all parts of the machine that come into contact with fluids are accessed. This includes disinfection of the water delivery system and, where appropriate, water filters. It is recommended that an agent other than that used for the endoscope is used to disinfect the machine.

Additional operational procedures that need to be addressed include:

- using water of suitable microbiological quality and hardness (see Section 5.2 below) for:
 - the dilution of cleaning agents and disinfectants;
 - the rinsing of endoscopes following manual cleaning and prior to introduction into the automated machine; and
 - the final rinsing of endoscopes following disinfection (which is necessary to remove irritant and toxic disinfectant residues);
- ensuring that tanks and fluid pathways of the machine are drained and left dry when not in use or leaving the fluid pathway in contact with fresh disinfectant solution;
- regularly cleaning and disinfecting the machine, i.e. at the beginning of each session and preferably during each cycle or as otherwise instructed by the manufacturer (see MDA Safety Action Bulletin SAB(93)32).

The involvement of infection control and estates personnel is advised in addressing all of the above points.

5.2 Water quality

A number of the preceding points relate to the quality of water used for the decontamination of endoscopes.

The hardness of the water may lead to the build up of lime scale on the internal pipework of the AER. This build up may be reduced by using softened water, although, in-line water softeners should only be used if a hard water problem is known to exist.

The water supply may be of poor microbiological quality and may contain environmental mycobacteria, e.g. *Mycobacterium chelonae*, *Pseudomonas* spp and other Gram-negative bacilli, which may contaminate the instrument. Sterile water is recommended for the final rinsing of all types of endoscope to be used for invasive procedures and, wherever possible, endoscopes used for non-invasive procedures.

There are essentially two options to obtain a supply of water of suitable microbiological quality:

- the use of pre-sterilized bottled water, for stand alone machines;
- the use of pre-treated water, for mains connected machines.

The type of pre-treatment e.g. heat, filtration, ultraviolet, reverse osmosis and chlorination cannot be specified in a publication such as this as it is very much dependent on the quality of the source water.

We recommend that a company specialising in water treatment be contacted to determine individual needs as there are many factors that need to be considered in providing water of a suitable quality (see box). The local consultant microbiologist should also be contacted for advice.

Factors to be considered regarding the main water supply include:

- mineral content (e.g. hard or soft);
- particulate contamination;
- microbiological quality;
- volume and flow rate of water required to supply the AER;
- effect of the installation of any water treatment device on these parameters;
- location of the water treatment device
- maintenance of the water treatment device.

Any water treatment system should be installed between the water softener system, if required, and the AER. The failure to maintain water treatment systems can also present a source of contamination of the machine and in conjunction with the machine these systems should undergo routine maintenance and decontamination if required, to ensure their continued effectiveness. Advice should be obtained from the manufacturer of the water treatment system. Further guidance is available from the Hospital Infection Society and Public Health Laboratory Service (Joint Working Group Report 2001).

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6. Disinfectants

Whilst steam under pressure is the preferred method of sterilization, liquid chemical disinfectants can be used in the decontamination of instruments which cannot withstand sterilization or disinfection by heat. However, chemical disinfection is a difficult process to control (see box).

Potential disadvantages of using chemical disinfectants

- risk of re-contamination of the endoscope and the transfer of infection with reusable disinfectants;
- the need to determine the concentration of the active components of reused disinfectants;
- risk of exposing both users and patients to chemical substances potentially harmful to their health;
- rapid inactivation of many disinfectants by the presence of organic matter (remaining after cleaning), detergent and rinse water;
- difficulty in ensuring that all parts of the item are in contact with the disinfectant;
- development of organisms resistant to a disinfectant or its components; and
- incompatibility of certain disinfectants with some instrument materials.

The decision as to which disinfectant to use for a particular situation is ultimately made at a local level. The establishment of a decontamination policy must involve infection control personnel, as such a decision is based on a number of different factors, including the information supplied by the manufacturer of the endoscope or accessory (see Section 3), the disinfectant supplier and the AER manufacturer. Once a policy has been agreed and implemented, deviations should not be permitted unless there has been prior consultation with local infection control personnel.

Local policies should include a risk assessment, taking into account advice from professional bodies, manufacturers, current guidance and published scientific literature.

6.1 Information on the disinfectant

Disinfectants intended for use with medical devices must be CE marked under the Medical Devices Directive (93/42/EEC).

The supplier of the disinfectant must provide the information relevant to its intended use as detailed in Table 2, Section 3.2. This information should be provided on the container label or on a separate information sheet supplied with the disinfectant.

Sources of experimental data, other than those provided by the manufacturer, should be sought. Articles from peer reviewed journals may provide a source of independent assessment of the microbicidal activity of a particular disinfectant product. The methodology used for any studies should be carefully scrutinised.

6.2 Advice from professional bodies

Various professional bodies have provided a number of recommendations for the decontamination of particular types of endoscopes and their accessories. This information is summarised in Appendix 2. However it should be noted that all procedures must be carried out in accordance with the endoscope, AER and disinfectant manufacturers' instructions or the user/hospital may become liable if anything goes wrong.

Professional bodies and endoscope manufacturers have for many years recommended the use of 2% glutaraldehyde for the disinfection of these devices. However, due to increasingly stringent controls on the use of glutaraldehyde, both users and manufacturers are turning to other disinfectants. Moreover the availability of glutaraldehyde may be reduced. The more commonly used alternatives include disinfectants based on peracetic acid, chlorine dioxide and hypochlorous acid (also referred to as superoxidized saline). Other, more traditional compounds such as alcohols, other aldehydes e.g. succindialdehyde and ortho-phthalaldehyde, and quaternary ammonium compounds (QACs) are used less frequently.

There is, however, some discrepancy between the various professional recommendations with respect to the disinfectant contact time. Furthermore these contact times may be at variance with the recommendations of the manufacturer of the chosen disinfectant. It should be borne in mind that the particular guidance relates to a specified type of endoscope and/or procedure and the level of disinfection recommended may therefore vary (see Section 2).

6.3 Types of disinfectant

The disinfectants discussed briefly below are listed alphabetically and not in order of preference. Before choosing a specific disinfectant the compatibility of the endoscope with the disinfectant should be checked to reduce the likelihood of causing damage to the endoscope during processing (MDA Safety Notice SN2001(28)).

6.3.1 Alcohols

Ethanol or isopropanol at an appropriate concentration (typically 70% v/v), are the alcohols most commonly used for disinfection. Alcohol has good bactericidal, fungicidal properties, is active against most types of virus and has been shown to be tuberculocidal (Griffiths et al 1999). Alcohol is fast acting but does not penetrate well into organic matter. It is therefore most effective when used on clean surfaces and is often used as a base for other bactericides.

6.3.2 Aldehydes

Glutaraldehyde has bactericidal, fungicidal and virucidal activity. It is sporicidal but acts slowly. It is generally non-corrosive to most materials, although this is dependent upon the formulation of the disinfectant. Alkaline solutions require activation and have a limited life while acidic solutions are more stable and do not require activation but act slowly on spores at ambient temperatures. Glutaraldehyde penetrates organic matter slowly and is not greatly inactivated by its presence but it is a strong fixative hardening protein deposits.

Many glutaraldehyde-based products are designed to be used at room temperature. Formulations that can be used at elevated temperatures may have higher activity at lower concentrations and shorter contact times. However, elevated temperatures may be incompatible with flexible endoscopes, will shorten the use-life of the disinfectant and increase production of vapour which must be contained or removed during the disinfection procedure (see Section 8).

Ortho-phthalaldehyde (OPA), a member of the aldehyde family, has recently been introduced as a liquid chemical disinfectant for medical devices. OPA is a fast acting, high-level disinfectant with tuberculocidal activity although it has only limited activity against bacterial spores. Whilst being a member of the aldehyde group of chemicals, it is more stable and has a lower vapour pressure than glutaraldehyde making it less hazardous to use. A commercial formulation of 0.55% OPA solution, which requires no activation, is now available. The solution is compatible with a wide range of endoscopes, other medical devices and AERs and is easy to dispose of by discarding down hospital drains in accordance with local water regulations.

Formaldehyde is mainly used as a gaseous fumigant. When used as such it requires carefully controlled temperature and humidity to be effective. Other aldehydes e.g. succindialdehyde, or mixtures of aldehydes have similar properties to glutaraldehyde (Fraud et al 2001) but may not require a buffer. Their activity depends on aldehyde concentration.

6.3.3 Chlorine dioxide

Chlorine dioxide has been used extensively for the purification of water and as a disinfectant in the food industry. It is also used as an aqueous solution in the healthcare sector as a high-level disinfectant. Chlorine dioxide is a powerful but selective oxidising agent and therefore material compatibility needs to be considered carefully; titanium, stainless steel, silicone rubber, ceramics, PVC and polyethylene are generally considered to be compatible with chlorine dioxide.

The antimicrobial activity of chlorine dioxide is similar to that of chlorine, although it has greater sporicidal activity and can be used at room temperature (Coates 2001).

6.3.4 Peroxygen compounds

Peracetic acid is a peroxygen compound. Its antimicrobial activity has been reported in the literature as bactericidal, tuberculocidal, fungicidal, virucidal and sporicidal. Peracetic acid is more effective than glutaraldehyde at penetrating and removing organic matter e.g. biofilms. It is known to be highly corrosive and its use as a disinfectant in its natural state is therefore limited unless a corrosion inhibitor is included in the formulation.

Several systems based on peracetic acid are currently available in the UK. Peracetic acid can be used either at an elevated temperature in a dedicated system or as a cold disinfectant solution, depending on the chosen system (Izatt 2001). The peracetic acid is provided either as a concentrated, buffered solution that contains corrosion inhibitors or as a powder. The solution is diluted to the recommended concentration.

6.3.5 Quaternary ammonium compounds

Quaternary ammonium compounds (QACs) are not suitable for endoscope disinfection.

QACs tend to be less active against Gram-negative bacteria than against Gram-positive bacteria. In low concentration they tend to be bacteriostatic rather than bactericidal. Although QACs are fungicidal, they are not sporicidal, not generally mycobactericidal and have variable activity against viruses. QACs are easily inactivated by soaps, detergents and organic matter.

6.3.6 Superoxidized saline

Superoxidized saline is a mixture of active species, primarily hypochlorous acid, derived from salt by electrolysis through a proprietary electrochemical cell. It is sporicidal and mycobactericidal, as long as there is minimal or no soiling. It should not be stored for more than 24 hours prior to use. 6.3.7 Vapour phase hydrogen peroxide (VHP)

This is an emerging technique that is not currently widely available. VHP has been offered as a method for the decontamination of rooms, sterilizing of dental instruments and is an emerging technology for the sterilization of endoscopes. Generally VHP is delivered via a vacuum or using air as a carrier gas to items requiring sterilization. Cycle times can vary depending on the load size, hydrogen peroxide concentration and temperature.

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7. STERILIZATION PROCESSES

The sterilization processes discussed briefly below are listed alphabetically and not in order of preference.

Ethylene oxide (EtO) and low temperature steam and formaldehyde (LTSF) may be used for the sterilization of flexible endoscopes. However, there are very few, if any, of these systems currently in use in the UK health service and are therefore not seen as a viable option.

This is an emerging technique (Rutala and Weber 2001b) that is not currently widely available.

Gas plasma is a highly active gas containing ions and molecules and free radicals that are capable of inactivating micro-organisms. It is a complicated process that has been developed and adapted for the sterilization of medical devices.

Instruments such as flexible and rigid endoscopes may be processed using this method but it is important to use special adapters with long or narrow lumen devices due to the inability of the agent to readily access these areas. In addition, instruments need to be dry and can only be packaged in specially designed packaging. No toxic emissions or residues are said to result from the process. Compatibility with specific instruments should be checked with the manufacturer of the endoscope.

Porous load autoclaves that sterilize at 121-124°C for a minimum of 15 minutes or 134-137°C for a minimum of 3 minutes are suitable for processing autoclavable rigid endoscopes and accessories. The endoscopes should be processed in accordance with the manufacturer's instructions using, where possible, the higher temperature.

It is important to note that instruments with narrow lumens, such as endoscopes, from which air can not be readily displaced or instruments contained within packaging must be sterilized in a porous load sterilizer that has been validated for the load. Others should be processed in a basket or tray and covered on removal from the sterilizer. Steam sterilized endoscopes should not be rapidly cooled as this may stress components and shorten the life of the instrument.

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8. Safe Use of Disinfectants

This section deals mainly with health and safety matters related to the use of glutaraldehyde although other chemical disinfectants are discussed briefly.

8.1 Health problems

Glutaraldehyde poses problems with regard to its safe use. The major health problem is that it is an irritant and sensitiser. The vapour can cause rhinitis, conjunctivitis and asthma while the liquid can cause dermatitis. Individuals sensitised to glutaraldehyde can experience reactions when exposed to smaller amounts than those that would ordinarily induce sensitisation. Other non-specific symptoms of exposure to glutaraldehyde include headache, nausea and vomiting.

It is very important that the use of glutaraldehyde is strictly controlled and Occupational Health Departments (OHDs) should be consulted for advice and guidance. The Health and Safety Executive (HSE) have set a Maximum Exposure Limit (MEL) of 0.05 ppm over an 8-hour Time Weighted Average (TWA) reference period for glutaraldehyde (Health and Safety Executive EH40(2001)). The odour threshold is 0.04ppm and therefore, if the smell of glutaraldehyde is detectable, it is possible that the limits are being exceeded and that further action needs to be taken.

Users should give serious consideration to the use of alternative disinfectants to glutaraldehyde due to the health and safety aspects and the difficulty in complying with the requirements for its continued safe use.

The following guidance on the use of glutaraldehyde is available:

- 'Glutaraldehyde and you' (IAC64), HSC 2001
- 'Glutaraldehyde' (HSC 1998/208), Department of Health 1998
- 'Is there an alternative to glutaraldehyde? A review of agents used in cold sterilization' Royal College of Nursing 2000

8.2 Legal requirements

Employers are required by health and safety law to carry out a risk assessment to ensure that all reasonable steps have been taken to ensure the health of their employees. The use of glutaraldehyde is covered by the Control of Substances Hazardous to Health Regulations (COSHH, Health and Safety Executive 1999 – see box). Although details given below relate to glutaraldehyde, the principles should be followed for the use of any chemical disinfectant.

Failure to comply with COSHH constitutes an offence and renders the employer liable under the Health and Safety at Work etc Act 1974.

The COSHH Regulations require that a risk assessment be carried out to determine the following:

- can its use be avoided?
- the way in which glutaraldehyde is used;
- the precautions necessary to prevent exposure of employees and others to glutaraldehyde;
- the monitoring and/or health surveillance required;
- the amount of information, instruction and training that will need to be provided.

8.3 Department of Health guidelines on use of glutaraldehyde

The current Department of Health guidelines are described in Health Circular HC(91)33 (see box). This recommendation was based on the contact times stated by the manufacturers of glutaraldehyde solutions, with the provision of an additional margin of safety. Although the immersion times may appear prolonged, they are recommended to ensure adequate penetration. This recommendation is also re-iterated in the 'Guidance for Clinical Health Care Workers: Protection against infection with HIV and hepatitis viruses' produced by the Expert Advisory Group on AIDS, with the additional recommendation that '**endoscopes which enter sterile body cavities must be immersed for a minimum of 3 hours**'.

HC(91)33 recommendation

- 'A freshly activated solution containing 2% glutaraldehyde at room temperature for 30 minutes is recommended for contamination with HIV or HBV, if contamination with mycobacteria is suspected a 2% solution of glutaraldehyde should be used for 60 minutes'.

If a local policy decision is made to reduce the contact time from that in the conservative guidelines from the Department of Health, it is advised that an automated cleaning process be used in a machine commissioned and operated strictly in accordance with documented procedures. These should include routine monitoring and effective decontamination of the machine.

The Department does not recommend that the disinfectant contact time be reduced to less than the minimum specified by the manufacturer of the disinfectant.

8.4 Control measures

Use of glutaraldehyde can be reduced if alternative processes such as heat sterilization or single-use accessories are used. Wherever possible the disinfection of endoscopes should be carried out using AERs with adequate fume extraction. All activities (decanting, use, rinsing and discarding of glutaraldehyde) should be encapsulated by fume extraction.

The use of open containers of glutaraldehyde should be forbidden.

The advantage of automated machines is that they reduce the possibility of splashing and skin contact with the disinfectant. However, they may increase the vapour levels of glutaraldehyde if the machine is not properly sealed. The exposure to glutaraldehyde can also be reduced by use of local exhaust ventilation (LEV). This can be achieved by housing the machines in extraction cabinets or by using automated machines with integral extraction. The exhaust ventilation system of most disinfecting machines is only effective when the machine is used correctly and most older machines do not have alarms to indicate inadequate performance.

The vapour must discharge safely outside the building, preferably at least one metre above the height of the building. LEV systems must be checked at least once every 14 months (Regulation 9, COSHH, HSE 1999) to ensure that they are working efficiently. An assessment of airflow is desirable together with an indication of filter saturation, if a filter is fitted. If an integral fume extraction facility is not available, machines should be operated in a fume cupboard (preferably meeting the British Standard 7258 (1994)) or under an extraction hood.

Safe working practices should be adopted. Disinfection should be carried out in a dedicated room away from other staff and members of the public. Rooms where glutaraldehyde is used should have vapour extraction equipment and be provided with a sink with running water so that staff and patients are protected from exposure to glutaraldehyde during the activation, preparation, use and discharge of the disinfectant.

Care should be taken when disposing of glutaraldehyde. Discharge into the sewer with copious amounts of water is usually acceptable due to the dilution effect. However it is suggested that advice be sought from the appropriate water authority prior to the commencement of routine disposal in this

way.

8.5 Use of personal protective equipment

Personal protective equipment (PPE) should always be used when handling glutaraldehyde.

Nitrile gloves, impermeable plastic aprons, eye protection and respiratory protective equipment (RPE) should be used when mixing glutaraldehyde or dealing with spillages (see Appendix 4). For further advice on RPE and atmospheric monitoring, contact your local Health & Safety Executive office

8.6 Atmospheric monitoring.

The levels of atmospheric glutaraldehyde should be monitored, at a frequency determined by local policy, to indicate the effectiveness of control measures. The frequency of monitoring may need to be adjusted if working practices are changed, if there is evidence of health problems or indications that the LEV is showing a deterioration in performance. These situations should be included in the agreed protocol for testing and maintenance. Atmospheric monitoring should only be carried out by a competent person designated by management. There are devices commercially available for measuring atmospheric levels of glutaraldehyde or alternatively a company specialising in atmospheric monitoring may be used. It is suggested that both personal exposure and static location sampling be carried out in accordance with documented procedures. Personal exposure can be determined by staff wearing samplers with the sampling head located in the breathing zone. Static location samples can be taken by placing the samplers at head height positions over containers and automated cleaning units.

8.7 Health surveillance

Staff who may be exposed to glutaraldehyde should receive regular health surveillance. Pre-employment medical checks of such staff carried out by OHDs should include lung function testing and enquiry regarding asthma, rhinitis, conjunctivitis and dermatoses. Assessment of employees for the appearance of symptoms can then be conducted annually by questionnaire. If surveillance demonstrates the occurrence of occupational dermatitis or asthma, further exposure must be avoided. Staff should be encouraged to report any health problems to their line management and OHDs.

8.8 Training and instruction

All staff who may be exposed to glutaraldehyde must be informed of the risks involved and trained in the correct use of the control measures. Employees are required by law to take part in the training programmes and to use glutaraldehyde in a safe manner. Safe working procedures should be available in written form and distributed to all staff involved. The procedures should include instructions for the use of control measures and spillage procedures. Staff should not be authorised to use glutaraldehyde until they have completed the training programme satisfactorily.

8.9 Other disinfectants

Although glutaraldehyde has traditionally been the disinfectant most widely used for the disinfection of endoscopes, other chemicals are now increasingly being used. The same general principles described for use with glutaraldehyde should be applied to all other chemical agents. Suitable protective equipment, i.e. eye protection, gloves and waterproof garments should be used when working with large volumes and/or concentrated solutions of chemical disinfectants. All operations should be carried out in adequately ventilated areas.

The health and safety aspects of some alternative disinfectants are outlined in the box below.

Succindialdehyde and formaldehyde pose similar problems to glutaraldehyde. They are potential eye and nasal irritants which can also cause respiratory distress and allergic dermatitis.

Ortho-phthalaldehyde (OPA) is a clear, light blue liquid at room temperature. It is practically odourless and is non-flammable. It is non-sensitising but may aggravate pre-existing asthma, bronchitis or dermatitis.

Peracetic acid is a colourless liquid with a strong odour. It is a highly irritant chemical when used at high concentration. It may also be corrosive to some metals, notably brass and copper.

Ethylene oxide is toxic and flammable. At low concentrations it is odourless and colourless. It is classified as a human carcinogen and therefore staff and the workplace must be monitored when ethylene oxide is used.

Isopropanol/isopropyl alcohol/2-propanol (IPA) is flammable and a possible skin irritant on prolonged contact.

Chlorine dioxide must be stored under refrigeration to prevent decomposition and may become explosive under certain conditions. The use of chlorine dioxide at temperatures above ambient may result in the production of toxic fumes.

Peroxygen compounds in powder form should be handled using PPE and inhalation avoided. Peroxygen compounds are non-irritant to the skin and eyes at in-use concentrations although they are corrosive to some metals.

Superoxidized saline is a dilute mixture of mild oxidants at neutral pH. The associated health risks are low if used as indicated.

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9. STORAGE AND PREPARATION OF ENDOSCOPES

At the completion of an endoscopy session, the endoscope should be visually inspected, dismantled as necessary, leak tested, cleaned, and disinfected or sterilized as appropriate in accordance with the endoscope and AER manufacturers' instructions.

A local policy should be developed for the storage of endoscopes in conjunction with the device manufacturer's instructions.

9.1.1 Sterilized endoscopes

Sterilized endoscopes (i.e. rigid endoscopes that have been autoclaved) must be stored sealed in the container or packaging in which they were sterilized. Agreement should be sought between the user and the Sterile Service Department or other decontamination facility on a maximum shelflife for the packaged endoscope. Steps should be taken to ensure that stock rotation occurs.

9.1.2 Disinfected endoscopes

On completion of disinfection, the endoscope should be purged with compressed air to facilitate thorough drying. Alternatively, 70% alcohol may be used to dry internal surfaces and channels. The alcohol will evaporate and therefore the endoscope does not require subsequent rinsing. Lensed instruments should not be immersed in alcohol for periods in excess of 5 minutes as this causes damage to lens cements. Consideration needs to be given to the quality of compressed air (microbial and particulate) to prevent recontamination of the endoscope. Other fixed and detachable nonautoclavable components should also be dried.

Flexible endoscopes should be stored suspended vertically in ventilated storage cabinets, to allow circulation of air. They should not be in contact with other endoscopes or flat surfaces. Ideally, control valves, distal hoods, caps and other detachable components should be stored separately. However, it may be necessary to store a gastrointestinal endoscope and a bronchoscope fully assembled and available for out of hours emergency use.

Before storage, the rubber seals of the suction and air/water valves should be lubricated sparingly with silicone oil or in accordance with the manufacturer's instructions.

Note: If the endoscope has been subjected to a physical disinfection process such as low temperature steam (LTS), then the procedure for packaging and handling described above would apply.

Prior to the next use of an endoscope or accessory which has been sterilized by autoclaving, the user must check that the seals are intact, the packaging is undamaged and dry and that any chemical indicators are showing the correct colour change consistent with exposure to a sterilizing agent.

Chemical indicators should not be relied upon to demonstrate sterility of the package contents.

Endoscopes which have been subjected to high-level disinfection should be reprocessed again in accordance with the manufacturer's instructions, depending on the time elapsed since the previous disinfection procedure e.g. greater than 3 hours.

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10 GLOSSARY OF TERMS

Abnormal prion protein

A form of protein thought to be the causative agent of transmissible spongiform encephalopathies (TSEs) e.g. Creutzfeldt-Jakob Disease (CJD). They are remarkably resistant to conventional methods of disinfection and sterilization.

Accessory

An article which whilst not a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device. (Definition taken from Medical Devices Directive 93/42/EEC)

Automated endoscope reprocessor (AER)

An AER is a machine intended for the decontamination of endoscopes. The AER will have a disinfection phase and may also include a washing phase prior to the disinfection cycle. Many AERs have integrated fume extraction systems.

Bioburden

The population of viable infectious agents contaminating a medical device.

Cleaning

A process that physically removes infectious agents and the organic matter on which they thrive but does not necessarily destroy infectious agents. The reduction of microbial contamination depends upon many factors, including the effectiveness of the cleaning process and the initial bioburden. Cleaning is an essential pre-requisite to ensure effective disinfection or sterilization.

Contamination

The soiling or pollution of inanimate objects or living material with harmful, potentially infectious or other unwanted material. In the clinical situation, this is most likely to be organic matter and infectious agents but may also include other undesirable inorganic substances e.g. chemical residues, radioactive material, degradation products, packaging materials etc. Such contamination may have an adverse effect on the function of a medical device and may be transferred to a person during use or subsequent processing and storage. The nature and extent of microbial contamination is referred to as the bioburden.

Decontamination

A process which removes or destroys contamination and thereby prevents infectious agents or other contaminants reaching a susceptible site in sufficient quantities to initiate infection or any other harmful response. Within endoscopy differing levels of decontamination are used. They are: cleaning followed by high-level disinfection or cleaning followed by sterilization, depending on the device, the clinical procedure and chemicals used.

Disinfectant

A chemical agent which, under defined conditions, is capable of disinfection.

Disinfection

A process used to reduce the number of viable infectious agents but which may not necessarily inactivate some microbial agents, such as certain viruses and bacterial spores. Disinfection may not achieve the same reduction in microbial contamination levels as sterilization.

High-level disinfectant

A liquid chemical agent which can kill bacteria, viruses and spores. It is only sporicidal under certain conditions.

Infectious agents

The term includes micro-organisms, viruses and other transmissible agents e.g. prions.

Reprocess

To make good the device for reuse by cleaning and either disinfection or sterilization (or both). The Medical Devices Regulations 2002 require the manufacturer of reusable devices to provide validated reprocessing instructions.

Sterilant

A chemical agent which can kill bacteria, viruses and spores. However this term is not precise and is not used in this Device Bulletin as the term highlevel disinfectant is preferred.

Sterilization

A process used to render an object free from viable infectious agents including viruses and bacterial spores.

Superoxidized saline

A mixture of active species, primarily hypochlorous acid, derived from salt by electrolysis through a proprietary electrochemical cell. It is sporicidal and mycobactericidal.

Washer-disinfector

An automated machine intended to clean and disinfect medical devices, also known as an automated endoscope reprocessor when dedicated to endoscope decontamination.

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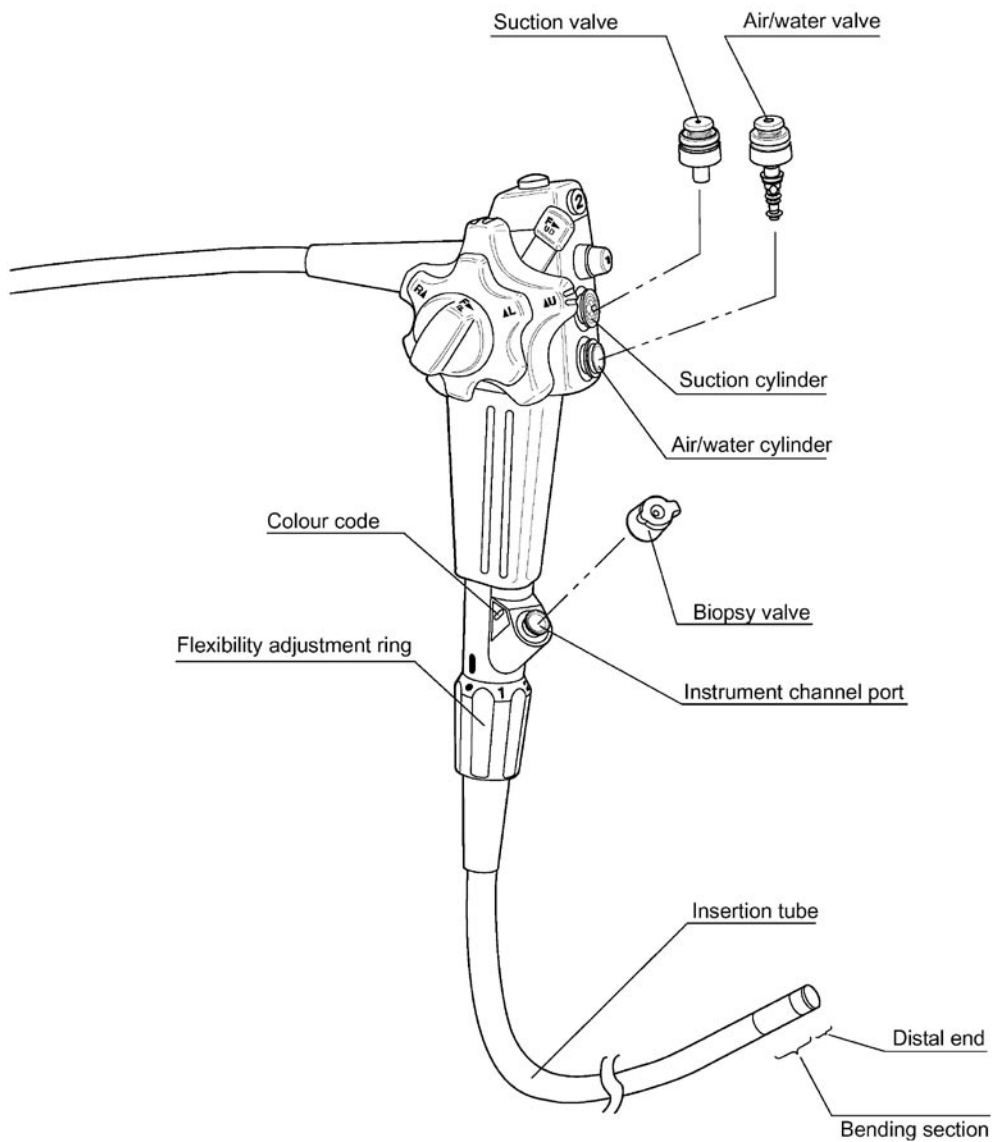
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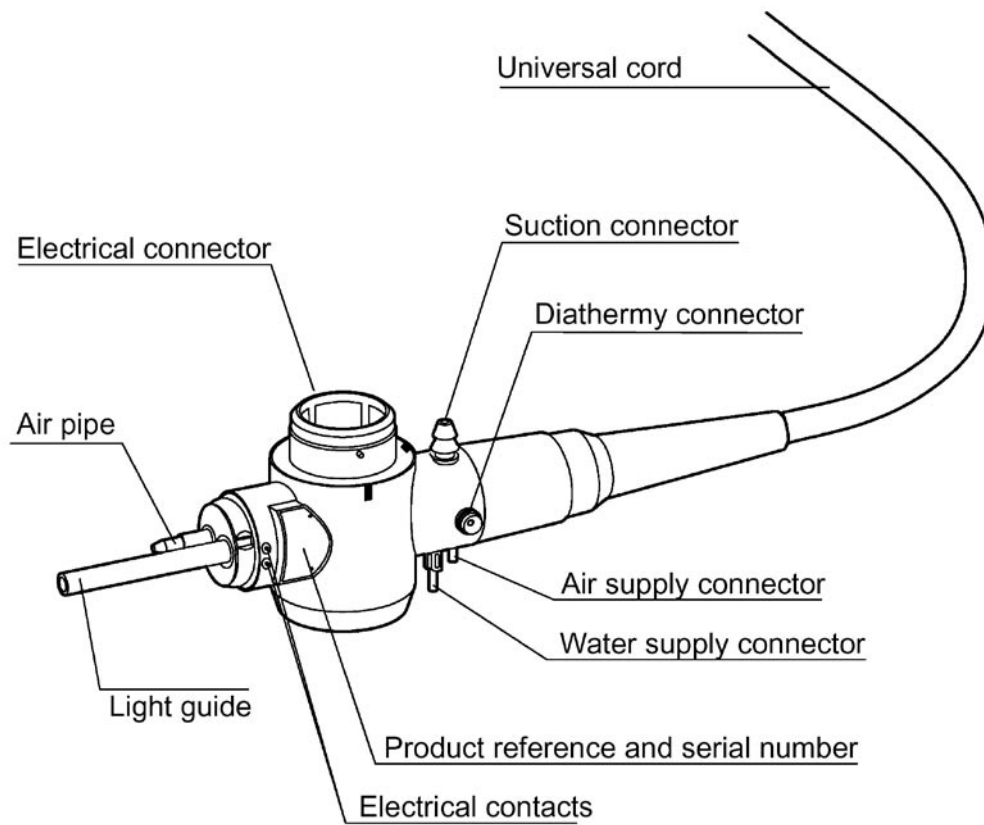
Sterilisation of Endoscopes

APPENDIX 1

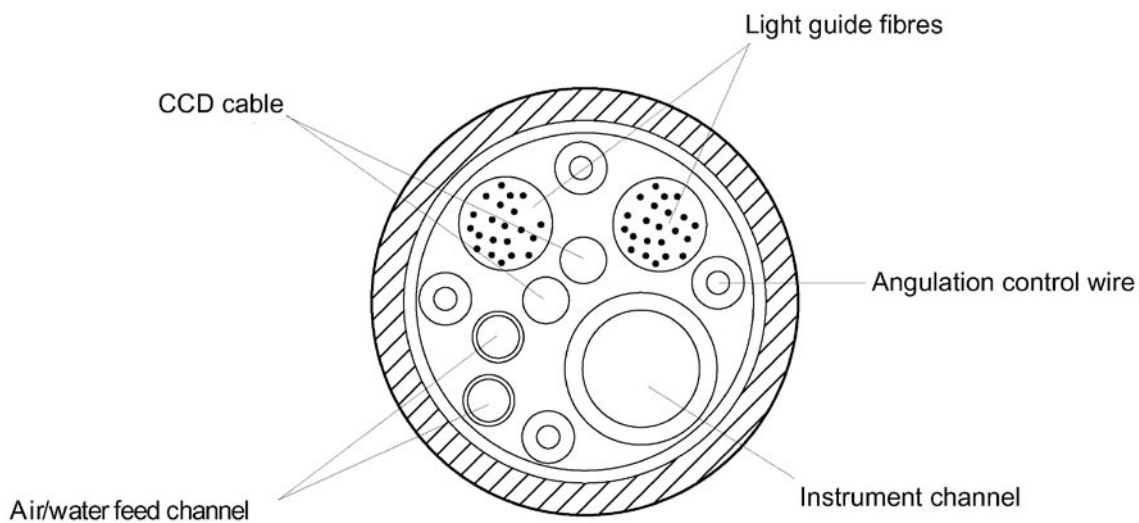
Diagrammatic representation of a typical flexible endoscope



Flexible endoscope universal cord



Cross-section of flexible endoscope insertion tube



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Sterilisation of Endoscopes

APPENDIX 2

Summary of the current recommendations provided by professional bodies for the decontamination of endoscopes using liquid chemical disinfectants.

Organisation	Method	Contact Time	Endoscope
British Society of Gastroenterology(1)	Mechanical cleaning with detergent followed by: 2% activated alkaline glutaraldehyde	10 minutes - before each session and after each patient 20 minutes - after each session, before and after use in immunocompromised patients 60-120 minutes - after a patient with Mycobacterium avium intracellulare	Flexible GI endoscopes
	0.35% Peracetic acid	5 minutes - before each session and after each patient 5 minutes - after each session, before and after use in immunocompromised patients 5 minutes - after a patient with Mycobacterium avium intracellulare Sporicidal activity is achieved after 10 minutes	
	Chlorine dioxide	5 minutes - before each session and after each patient 5 minutes - after each session, before and after use in immunocompromised patients 5 minutes - after a patient with Mycobacterium avium intracellulare Sporicidal activity is achieved after 10 minutes	
British Association of Urological Surgeons (2)	Pre-cleaning with detergent followed by: 2% activated alkaline glutaraldehyde	10 minutes 1 hour - for known or suspected mycobacterial infections	Cystoscopes
British Thoracic Society (3)	Wash and brush in neutral detergent followed by: 2% activated glutaraldehyde	20 minutes - at the start and end of a session and between cases 1 hour - before use in immunocompromised patients	Bronchoscopes

Organisation	Method	Contact Time	Endoscope
Association for Practitioners in Infection Control (4)	Pre-cleaning with nonabrasive, enzymatic detergent followed by: Environmental Protection Agency (EPA) registered disinfectant e.g. glutaraldehyde, hydrogen-peroxide, peracetic acid	At least 20 minutes	Flexible endoscope
World Congress of Gastroenterology(5)	Thorough manual cleaning followed by: 2% activated glutaraldehyde or disinfectant of similar potency	5 to 10 minutes	Endoscopes – types not specified

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APPENDIX 3

Summary of glutaraldehyde exposure times known to be effective against main pathogens

Pathogen	Exposure time	Reference
Vegetative organisms including Pseudomonas	1 minute	1
Bacterial spores	3 hours	2
Mycobacterium tuberculosis	20 minutes	3
Mycobacterium avium intracellulare	1 hour	
HIV	2 minutes	4
HBV	5 minutes	5

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APPENDIX 4

Procedures for dealing with spillages of glutaraldehyde and other aldehydes.

This procedure is based on information provided in Croner's Substances Hazardous to Health - Emergency Spillage Guide (1995) for dealing with aldehyde spillages.

In the event of a spillage the following actions should be taken immediately:

- Eliminate all possible sources of ignition (aldehydes may produce flammable vapours).
- Instruct others to keep at a safe distance well away from the spillage.
- Where possible open windows and close doors on way out.

Decide whether to control the spillage on site or evacuate the building by sounding the fire-alarm and calling in the local fire brigade.

Local spillage control

Suitable personal protective equipment e.g. nitrile gloves, a plastic apron, eye protection, suitable boots and a full face respirator with filter should be worn when dealing with spillages.

All spillages should be dealt with by nominated, trained personnel.

For small spills (up to 0.5 litre)

Absorb the aldehyde on paper towelling, seal in an appropriately labelled disposal bag and incinerate.

For larger spills (up to 25 litres)

Absorb the aldehyde on dry sand. Add excess sodium bisulphite solution to ensure complete reduction of any peracid (a possible breakdown product of glutaraldehyde). Add a small amount of water, mix well and scoop into large receptacles (5 litre plastic buckets). Stir the mixture well, allow to stand for 2-3 hours and finally wash down the drain with x1000 volume of cold tap water.

Before disposal

The discharge of effluent down the drain requires prior consent from the appropriate authority e.g. the National Rivers Authority or Environmental Agency. Check where the drain chosen for disposal leads and if it goes to a sewer check that consent has been obtained from the sewerage authority.

If washing a spillage to drain causes a breach of consent it should be discharged of in another way e.g. incineration. Ensure that the disposal site is licensed to accept this type of waste.

DISTRIBUTION

This Device Bulletin should be brought to the attention of all hospital and community healthcare staff who are involved in the decontamination of endoscopes. It should be of particular interest to staff in operating theatres, endoscopy units and sterile services departments (SSDs); and infection control doctors, infection control nurses, consultant microbiologists, MDA liaison officers (for onward distribution) and directors of public health.

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