Art. "3205324n", 17.11.03, seitenweise

ESGE Guidelines Commitee
Co-Chairman:
J.-F. Rey[1]
ESGE Guidelines Commitee
Co-Chairman:
A. Kruse[2]
President of ESGENA:
C. Neumann[3]

ESGE (European Society of Gastrointestinal Endoscopy)

European Society of Gastrointestinal Endoscopy Nurses and Associates

ESGE/ESGENA Technical Note on Cleaning and Disinfection

Foreword

The ESGE together with ESGENA and the biomedical industry met under the auspices of the ESGE Guidelines Committee to discuss and propose this technical note on cleaning and disinfection in order to clarify this technically difficult topic for the daily user.

I. Introduction

It is all important to emphasize that the most critical step in cleaning/disinfection is cleaning. It is impossible to disinfect or even terminally sterilize an inadequately cleaned instrument. Protein debris can become fixed and induce biofilm on the biopsy channel of the scope, if the manual cleaning, brushing, and rinsing step are not properly carried out. In short, all disinfection processes, whether done manually or by washer-disinfector, should be performed only after proper cleaning.

Furthermore, due to the fear of prion particle contamination, some guidelines recommend a double brushing procedure in order to remove all protein particles more efficiently. We should underline that our society has published numerous guidelines during the past ten years and that, as a result, the safety of digestive endoscopy has never before been at such a high level. The importance of endoscopy, as a diagnostic and therapeutic tool, is far behind the isolated report of nosocomial risk linked to the endoscopic procedure, as most of the cases can be considered malpractice. The onset of variant Creutzfeldt Jakob Disease (vCJD) has raised some concern about the safety of digestive endoscopy. However, now that we understand that the number of cases in France and the United Kingdom are limited (most of the potential patients are probably already infected), we should come back to our usual concerns: viruses and, more often, bacteria such as pseudomonas.

It is also necessary to note that important technical progress in scope and accessory design has led to improved cleanability.

II. Available Products

A) Glutaraldehyde (GA)

2% glutaraldehyde (e.g., Cidex, Asep, Totacide 28, Steranios)

Characteristics

GA is currently the most widely used chemical germicide in endoscopic reprocessing. The standard method of disinfection is a 20 min soak in GA. Two percent glutaraldehyde solutions range in concentration from 2.4% to 2.6% and have variable maximum use lives. For example, the maximum use life of an alkaline (activated) 2% glutaraldehyde without surfactants is 14 days. Olympus, Pentax, and Fujinon list glutaraldehyde as compatible with their endoscopes. Glutaraldehyde is compatible with automated reprocessors except for Steris System 1.

Disadvantages

1. Adverse effects for medical staff and the environment. GA has irritant and sensitizing properties. GA can lead to allergic problems (skin, eyes, ENT). It can cause dermatitis, conjunctivities, nasal irritation, asthma. GA was also found to exhibit cytotoxic and genotoxic potential in cultured human cells. The potential hazards for staff are considerable and toxicity has been suspected in 35% of endoscopic units and harmful or potentially harmful problems in 63%.

Institution
[1] Department of Hepatology and Gastroenterology, Institute Arnault Tzanck, St. Laurent du Var, France
[2] Department of Surgical Gastroenterology, Aarhus University Hospital, Aarhus, Denmark
[3] c/o Clinical Investigation Unit, City Hospital NHS Trust, Birmingham, United Kingdom

Corresponding Author
J.-F. Rey, MD · Department of Hepatology and Gastroenterology · Institute Arnault Tzanck · Avenue du Dr. Maurice Donat · 06700 St. Laurent du Var · France · Fax: +33-4-93075158 · E-mail: jean-francois.rey@wandoo.fr

Bibliography
Endoscopy 2003; 35 (10): 869–877 © Georg Thieme Verlag Stuttgart · New York · ISSN 0013-726X

2. Adverse effects on patients. Residues of GA after insufficient rinsing can cause colitis, abdominal cramps, bloody diarrhea.
3. GA can fix proteins and allows for biofilm creation.
4. Glutaraldehyde's failure to eliminate all atypical *mycobacteria* using standard contact times creates diagnostic problems in bronchoscopy and specific cross-infection risks in immunocompromised patients, e.g. with *Mycobacterium avium* complex (MAC). This is further complicated by the emergence of glutaraldehyde-resistant mycobacteria.

According to the guidelines of the British Society of Gastroenterology (BSG), alternatives to GA have to be at least as microbicidal as GA, non-irritant and compatible with both endoscope components and decontamination equipment.

B) Orthophthalaldehyde (OPA)
(e.g. 0.55% – Cidex OPA, Johnson & Johnson's Advanced Sterilization Products)

Characteristics

A high level disinfectant, contains 0.55% 1,2-benzenedicarboxaldehyde. Studies have shown superior mycobactericidal activity compared to glutaraldehyde (5-log reduction of mycobacteria in 5 minutes). OPA completely destroys all viable common bacteria in 5 minutes of exposure and provides partial elimination of organisms of the *Bacillus* even under the organic material. OPA requires longer exposure times to be effective against glutaraldehyde-resistant mycobacteria. It does not produce noxious fumes, it requires no activation, and is stable at a wider pH range of 3 to 9. Exposure to OPA vapours may be irritating to the respiratory tract and eyes. Use in a well-ventilated area and in closed containers with tight-fitting lids is recommended.

Advantages

1. High level disinfection in 12 min, APIC and FDA approved, long lifespan (2 weeks), non-irritant.

Disadvantages

1. Little data available on hazards of long-term exposure and safe exposure levels.
2. OPA fixes proteins and allows for biofilm creation.
3. The efficacy and the properties of these new disinfectants needs to be evaluated further.
4. Exposure to the agent develops staining to linens, clothing, skin, instrument, automatic cleaning devices, etc. by reaction with amino radicals and thiol radicals.
5. Specific and detailed instruction required for adequate rinsing of the instrumentation.

C) Peracetic Acid (PAA)
(e.g., Nu Cidex 0.35%, Steris 0.20%, Anioxyde 1000, Sekusept Aktiv)

Characteristics

When talking of peracetic acid it is important to understand that instead of one product we are dealing with numerous brands with very different chemical formula. It would be more precise to refer to peracetic acids as being a group of products. A study carried out on one brand cannot be extrapolated to all the brands in the peracetic group.

Advantages

1. Compared to GA, PAA has similar or even better biocidal efficacy. A contact time of 5 min is recommended for the destruction of vegetative bacteria and viruses (HBV, HIV); the sporicidal activity requires 10 min immersion (for 0.35 PAA). A contact time of 10 min or 15 min and concentration > 0.09% PAA are recommended for destruction of bacteria, fungi and viruses by French and German test guidelines (Anioxyde1000, Sekusept aktiv). Sporicidal efficacy according to the French test guidelines and NHS tests requires a 30-min contact time and a concentration > 0.09% PAA. PAA has a significantly greater efficacy at higher temperatures, e.g. a 6 log reduction of spores at 50 °C in less than 2 minutes.
2. Compared to GA, PAA is claimed to be less irritating for staff and safer for the environment. Potential adverse effects are strongly linked to the pH value of the application solution – minimal effects are observed in a pH range between 7.5 to 10.0. It would therefore, however, seem unwise to recommend that PAA can be used safely without adequate ventilation and personal protective measures, especially for manual immersion methods.
3. PAA does not fix proteins and does not allow for biofilm creation. Whereas GA preserves the organic material if used without or with inadequate manual cleaning, PAA dissolves it. PAA has the ability to remove GA-hardened patient material from biopsy channels, this has been demonstrated using surface spectroscopy.
4. PAA has not been reported to cause the development of resistance in microorganisms in its long history of application to the food and medical system; its broad chemical reactivity suggests that microorganisms are unlikely to develop resistance to it.

Disadvantages

1. PAA is less stable than GA. Shelf life of PAA containing products is between 12 and 18 months depending on storage conditions. Products with a longer shelf life can be prepared for generate PAA at customer site by chemical reaction directly before first application (Anioxyde 1000, Sekusept aktiv). Once prepared it requires replacement every 24 hours (Nu Cidex 0.35%). Used solution requires replacement between 24 hours (Nu Cidex 0.35%) to one week. PAA concentration has to be checked by proper test kits that detect the minimal effective concentration against the complete range of claimed germs.
2. If diluted solutions or RTU products are used, large volumes have to be stored. The use of concentrated products like Sekusept aktiv avoid this disadvantage.
3. PAA has corrosive abilities and has a vinegar-like odour. PAA can be corrosive depending on its formulation. Both properties are strongly linked to the pH value, temperature, PAA concentration, and the composition of the disinfectant (i.e. anticorrosive agent, etc.). Damage of flexible scopes has been reported after disinfection with some brands of PAA. The oxidizing ability of PAA may expose the leaks in internal channels of the scope, especially if the scope was previously disinfected with GA. PAA also causes cosmetic discoloration of endoscopes, but without any functional damage. There is concern about the effect of Nu Cidex on some disinfection machines that contain polymer based seals and brass components

within the hydraulic circuit. Scope damage due to the use of PAA in the US market has also been reported by the Californian Company Metrex.
4. High cost. The cost effects of other supplied PAA based products still has to be evaluated.

In a recent survey conducted by the Associates Group of the BSG (as yet unpublished), 15 of 106 respondents reported they had tried or were using **Nu Cidex** as an alternative to glutaraldehyde. Six of these reported irritancy problems, eight stated that in their opinion, ventilation was required, six were concerned with processor compatibility, and five with endoscope compatibility. Two of the 15 users reported no problems.

The Steris Corporation has marketed **Steris 20 Sterilant Concentrate**, a 35% peroxyacetic acid concentrate, for use in the Steris System 1. The processor dilutes and mixes this concentrate to its final concentration of 0.2% peracetic acid with a neutral pH, which is sporicidal at 50 °C. The processing cycle is approximately 30 minutes including multiple rinsing and reaches temperatures of 50 – 55.5 °C.

Efficacy: the Steris System 1 has validated efficacy against multiple spores, cysts, mycobacteria, fungi and viruses including Clostridium difficile, Cryptosporidium parvum, Candida albicans, Vancomycin-resistant Enterococcus (VRE), Staphilococcus aureus, Methicillin-resistant Staphylococcus aureua (MRSA), and Retroviridae (HIV). Steris System 1 is validated to work as a process using only the Steris 20 PAA formulation and controlling all the cycle parameters. The process can be validated in the field to EN/ISO 14937. Care should be taken not to damage the Steris 20 Concentrate sealed container. The concentrate may cause irritation of the nose, throat, and lungs and is corrosive to the eye and skin, potentially causing irreversible eye damage or severe burns.

D) Peroxygen Compounds
(e.g. Virkon)

Virkon is a stable peroxygen disinfectant that is effective against most vegetative bacteria and viruses, but has proven to be less effective than glutaraldehyde against mycobacteria and enteroviruses such as poliovirus. Furthermore, some peroxygen compounds affect the components of endoscopes and automated processing equipment. The Working Party of the BSG does not recommend peroxygen disinfectants for gastrointestinal endoscopy.

E) Electrolyzed Acid Water (EAW)

EAW is produced by using water and salt under electrolysis with membrane separation. It contains HCLO, generating hydroxy radicals that have a rapid and potent bactericidal effect. Additionally, the low pH (pH 2.7) and high oxidation-reduction potential (1100 mV) are toxic to microorganisms. Bacteria do not survive in an environment with redox potential greater than 900 mV and pH lower than 3. EAW breaks the bacterial cell wall and degenerates various inner components of the bacterium (including chromosomal DNA). At present, two types of EAW are available, namely electrolyzed strong acid water (pH < 3, e.g. **Cleantop WM-S**) and electrolyzed weak acid water (pH 6 – 7, e.g. **Sterilox**).

Advantages

1. Rapid and strong bactericidal effect (especially for electrolyzed strong acid water). After manual cleaning, freshly generated EAW was found to be higly effective against M. tuberculosis; M. avium-intracellulare; Mycobacterium chelonae; E. coli; Enterococcus faecalis; P. Aeruginosa; Bacillus subtilis var. niger spores; methicillin-resistant St. aureus; Candida albicans, poliovirus type 2, HIV1, giving a 5 $\log_{10}$ (99.999%) or greater reduction in 2 minutes or less. The chlorine content is 10 ppm ± 2 ppm, to be controlled via test paper.
2. Non-irritating, has minimal toxicity. EAW was classified as non-irritant. No sensitisation to EAW has been reported during 2.5 years of clinical use in endoscopic units in Japan.
3. Safe for patient, staff, and environment. If EAW is not continuously supplied with H^+, HCLO, Cl_2 by electrolysis, the solutions rapidly loses its oxidative and acidic properties therefore safe in the environment and does not harm human tissue.
4. Low cost. Operating costs are minimal, requiring only salt, tap water and electricity.

Disadvantages

1. The bacterial effect of EAW is drastically decreased in the presence of organic matter or biofilm. To ensure a full microbicidal effect, it is essential that items be cleaned thoroughly.
2. Non-stable. To ensure a full microbicidal effect, it is essential that all the manufacturer's production criteria are met – for example, generating current, redox potential and pH. If EAW is not continuously supplied with H^+, HCLO, Cl_2 by electrolysis, the solutions rapidly loses its oxidative and acidic properties. At present, it is possible to provide freshly generated EAW to an endoscope.
3. There is not much experience with EAW in Europe. High oxidation-reduction potential, high concentration of sodium chloride and low pH could damage the components of the scope after long-term exposure. Recently, to minimize the corrosive effect, EAW was prepared by electrolysis of solutions containing a low concentration of sodium chloride.
4. An adequate ventilation is required to reduce the toxicity of chlorine gas. If pH becomes 2.5 or less, the larger amount of chlorine emits and the disinfection effect loses certainty.

EAW provided by the **Cleantop WM-S** operates with the following parameters: pH < 2.7; ORP > 1000 mV; FRCL 10 ppm (± 2 ppm) by using a low sodium chloride concentration (0,1%), to reduce possible endoscope damage-risk. To work with the mentioned parameters is only possible when the "production" of the disinfectant and the disinfectant itself are operated at the same time in the same device. This differentiates this method from other methods using super oxidized water and minimizes the major disadvantage of EAW, its instability, since the actual parameters of the disinfectant are monitored and can be (until a certain extent) corrected during the actual disinfection process. The full disinfecting potential of EAW and its long term compatibility for endoscopes remain to be examined.

Sterilox, often referred to as super oxidised water, is a mixture of active species derived from salt by electrolysis in a proprietary electrochemical cell. Sterilox is a dilute mixture of mild oxidants at neutral pH with the single largest component species being common salt. The primary active species is hypochlorous acid

that is an extremely powerful disinfectant completely non-toxic in the low, clinically effective small concentrations necessary in Sterilox. The active agents in Sterilox decompose slowly to harmless species. For this reason Sterilox is generated on site, on demand, and stored no longer than 24 hours.

F) Chlorine Dioxide
(e.g. Tristel 700 – 1000 ppm av Cl, Dexit, Medicide)
Chlorine dioxide is a powerful oxidizing agent and is active against non-sporing bacteria, including mycobacteria and viruses, in less than 5 min. It is also rapidly sporicidal (e.g., 10 min). It can damage the metallic and polymer components of the endoscope, but commercial preparations contain an inhibitor. Instrument disinfectants, such as **Tristel**, **Dexit**, and **Medicide**, are available commercially. These products are comprised of two components, a base and an activator, requiring addition and dilution in accordance with the manufacturer's instructions. Errors in the preparation are possible although this does not apply to Tristel and Medicide, as these are supplied at their use concentration.

Sporicidal activity is maintained for 7–14 days provided that the disinfectant is stored in sealed containers with minimal head space above the solution. This requirement is difficult to attain in many automated washer-disinfectors and after a 14 day period further tests are necessary to assess the stability of the concentration. Listed as a respiratory irritant, the fumes of the chlorine dioxide cause irritation and should be stored in sealed containers. As with other respiratory irritants, irritation can be substantially reduced if enclosed and/or exhaust ventilated facilities are used. Lower less problematic concentrations have now been introduced.

Chlorine dioxide is more damaging to the instrument and processor components than glutaraldehyde. Experience with chlorine dioxide has demonstrated discoloration of the black plastic casing of flexible endoscopes, but this change may be only cosmetic. If chlorine dioxide is used in automated washer disinfectors, component contact times are likely to be much longer and, therefore, damage is even more likely. It is another possible alternative to glutaraldehyde, if approved by the instrument and processor manufacturers.

G) Quaternary Ammonium Compounds
(e.g. Sactimed Sinald, Dettol ED, Thermoton Endo)
These are relatively non-toxic and non-damaging, but usually have deficiencies in their antimicrobial spectrum. The Working Party of the BSG stated that **Dettox** (now **Dettol ED**), based on a combination of quaternary ammonium compounds, EDTA and surfactants, cannot be recommended for routine use due to its poor virucidal activity. An improved product, **Sactimed** (Sinald), shows a moderate mycobactericidal effect, but evidence of effectiveness against enteroviruses is lacking. It is right to state that quaternaries have deficiencies in their antimicrobial spectrum but these deficiencies (e.g. mycobacterial efficacy) can be solved by a) combining them with amines and biguanides (manual disinfection), and b) by combining them with temperature (in washing machine). Quaternary ammonium compounds have a high affinity to hard surfaces based on synthetic material. Residue layers can be created. As a result of this sticky effects are observed.

Recently, a new disinfectant based on quaternary ammonium compounds only was introduced by the Dr Schumacher GmbH under the brand name **Thermoton Endo**. Thermoton Endo is based on low-foaming quaternary ammonium compounds, defoamed by a special system that has no influence on the microbicidal effectiveness. The required exposure time in washer-disinfectors is 5 min at 55 °C – 60 °C. The manufacturer claims that – at this temperature – Thermoton Endo is effective within 3 to 5 minutes against a wide spectrum of bacteria and viruses. At present, there is not much experience with Thermoton Endo. The properties of this new disinfectant remain to be examined.

H) Amine Compounds/Glucoprotamin
(e.g. Sekusept PLUS, Korsolex AF)
Concentrated alkylamine/glucoprotamin based products are widely used chemical disinfectants for manual reprocessing of endoscopes in Central Europe. Products containing these active substances are highly effective against Mycobacteria including GA-resistant atypical species (**Sekusept PLUS**), other vegetative bacteria, fungi, and a wide range of viruses including Papillomavirus. Using a contact time of 15 min they are effective in dilution rates between 1 : 25 to 1 : 33. For some applications lack of efficacy against some eneteroviruses and spores can be a disadvantage.

Alkylamine/glucoprotamin does not fix proteins and does not support biofilm creation. Available products based on these active substances are offered in combination with surfactants. They have an excellent cleaning performance and give the opportunity of removing small amounts of residue during the HLD in case of a prior non-proper cleaning procedure. Differences between glucoprotamin and alkylamine based products have been observed in terms of material compatibility and safety handling. In some cases skin irritation and an unpleasant smell are reported about alkylamine based products.

III. Cleansing Products – Detergents

The proper cleansing of endoscopes is key to obtaining a good performance in the complete reprocessing process. Commonly used product types for this purpose are:
1. Detergents with or without enzymes.
2. Detergents containing antimicrobial substances.

Non-foaming detergents are recommended so that the device can be clearly visualized during the cleaning process to preclude personnel injury and to allow for complete cleaning of lumen surfaces. Excessive foaming can inhibit good fluid contact with the device surfaces. The objective is to choose a detergent that is most effective at lifting off the soil (including particulate soil) and microorganisms so these can be washed off by the flushing action of the detergent fluid and by subsequent water rinses.

For ultrasonic cleaning it is necessary to use the same detergent as used for the manual cleaning step. The detergent should be a non-foaming solution, compatible for manual cleaning and ul-

trasonic cleaning. Enzymatic type detergent solutions are recommended. These types of detergents require a specific contact time as instructed by the manufacturer. When using enzymatic detergents for ultrasonic cleaning on endoscopic accessories the container has to be covered properly avoiding anaphylactic shock reaction caused by inhaled enzyme containing aerosols.

Combinations with quaternary ammonium compounds, biguanidine, alcohols and aldehydes are available. Detergents containing aldehydes must not be used for the cleaning step, because they denature and coagulate protein, fixing it. Products based on amine compounds or glucoprotamin should not be used in combination with GA for disinfection. In some cases, coloured residues have been observed as a result of a suspected chemical reactions. In some European countries detergents containing antimicrobial substances are commonly used. The application of this product type reduces the infection risk to reprocessing personnel. This type of detergent formulation does not replace the HLD. Proteinases break protein debris into smaller subunits that are more soluble. Amylase catalyses the breakdown of starch and lipase breaks up fat-containing debris. Enzymes (proteins with biological activity) can function at room temperature (20 °C to 22 °C), but they generally function more effectively at elevated temperatures in accordance with the manufacturer's recommendations.

Detergents contain:
1. Surfactants (Surfactants reduce surface tension, thereby facilitating soil removing)
2. Activated H_2O_2 (Activated H_2O_2 is effectively able to lift soil at room temperature)
3. Enzymes

Recommended active substances with supporting properties for cleansing performance are:
1. Amin compounds/glucoprotamin (see paragraph HLD)
2. Peracetic acid
3. Hydrogen peroxide

IV. Automated Endoscope Reprocessors

According to the definition contained in the international guideline prEN ISO 15883-1, washer-disinfectors are intended to clean and disinfect loads containing flexible endoscopes. Cleaning is an essential part of the reprocessing cycle. Therefore only washer-disinfectors that offer relevant cycle steps (cleaning + disinfection + rinse) should be recommended for use.

Washer-disinfectors have become an essential part of most endoscopy units, as they increase instrument through-put and reduce staff's contact with disinfectants. The machine must be effective, safe, reliable, and able to cope with endoscope design and through-put. Several endoscope washer-disinfectors of different design are available. They do not negate the need for manual pre-cleaning of the insertion tube, suction/biopsy channel, instrument tip, and valve recesses, but do offer several advantages:

1. They ensure complete irrigation of all channels – that is: biopsy, suction, air, water, auxiliary water, CO_2. However, the elevator channel on duodenoscopes cannot be irrigated by most currently marketed machines. Consideration should be given to machines that can flush the duodenoscope elevator channel due to the increased risk to patients during ERCP.
2. They avoid cross-contamination for example of prions (vCJK) to other reprocessing batches by single use of all solutions used (for cleansing, disinfection, rinse).
3. They offer a more reliable and reproducible decontamination procedure than manual processing and are more convenient for endoscopy staff.
4. They reduce the likelihood of eye, skin, and often respiratory exposure to the disinfectant.

It is important to note the following about endoscope washer-disinfectors though:
1. Regular maintenance is required to ensure tanks, pipework, strainers, filters, and other machine components are free from deposits, biofilm, and limescale. (Water softeners, membrane cartridge filtration down to 0.2 µm, ultraviolet light, and heat treatment have all been used to prevent contamination with limescale, biofilm, and microorganisms.)
2. Processed endoscopes may become recontaminated during the rinsing stage of the cycle either from the machine or the water supply.
3. Manual cleaning of the endoscope remains an essential prerequisite to automated cleaning and disinfection.
4. If no provision is made to contain or extract irritating vapour, atmospheric levels may be increased due to displacement of disinfectant laden air when fluids are pumped or drained from compartments of the machine.
5. The machines, exhaust ventilation (if additionally needed), and water treatment systems (if additionally needed) are expensive to purchase, install, and maintain.
6. Excessive dilution of the disinfectant with a subsequent reduction in potency, may occur as a result of the carry over of cleansing solution or rinse waste (this will not happen with fully proven/validated systems; machine + scopes + chemicals).
7. A build-up of disinfectant will occur if the rinse water is reused. This may transfer toxic residues to the endoscope and cause irritation of the patient's mucosa or the endoscopist's eyes. The rinse water should not be reused.
8. Some special features or performance characteristics are optional, but all machines should clean, disinfect, and rinse all internal channels and external surfaces of the range of endoscopes.
9. Machines offering disinfectant exposure cannot correctly be described as reprocessing machines.
10. Instructions and training should be given by the machine manufacturers on how to connect the endoscope to the washer-disinfector to ensure all channel irrigation. The machine should be programmable to accommodate disinfectant contact times.

Other features to consider when purchasing a machine:

1. The number of endoscopes that can be processed simultaneously.
2. A cycle counter and fault indicator.
3. A control system for use when the disinfectant produces an irritating or sensitising vapour. Machines are available that are able to contain and/or condense irritating vapours or expel them either directly outside or absorb them into a carbon filter.
4. A water treatment system that prevents recontamination of processed instruments during rinsing.
5. A reliable, effective and simple machine disinfection cycle and self-disinfection cycle.
6. An air drying facility to expel fluids and dry the channels of the endoscope at the end of a cycle.
7. An automatic leak test facility.
8. A printout of cycle and disinfection/disinfectant parameters that can be retained for quality assurance records.
9. A channel (irrigation) control system block.

V. Sterilisation Options

Unfortunately flexible endoscopes will not tolerate high processing temperatures (in excess of 60 °C) and cannot therefore be autoclaved or disinfected using hot water or subatmospheric steam. They may be sterilised, however, by other means provided they are thoroughly clean and the manufacturer's processing criteria are met. Sterilisation options include ethylene oxide and gas plasma. An alternative is the Steris System 1, however, this is a "Just in Time Process" and does not allow packaging or sterile storage.

A) Ethylene Oxide

Low pressure or subatmospheric ethylene oxide sterilisers operating at temperatures below 60 °C are suitable for sterilising most flexible endoscopes provided an EO venting cap is fitted in accordance with the manufacturer's instructions and the instrument is suitably packaged or contained. However, very few hospitals have an ethylene oxide steriliser.

The gas is dangerous and should only be used where suitable equipment, strict environmental controls, and specially trained staff are available. Biological indicators are required for routine monitoring. This process is unlikely to be suitable if a quick turn around of instruments is required, because of the lengthy periods required for processing, the incubation period for indicators, and aeration to remove residual gas.

B) Hydrogene Peroxide Gas Plasma

This is a highly excited body of gas produced by the application of energy to a gas under vacuum, making ions and molecules within the plasma collide to produce free radicals. These interact with microorganisms to disrupt their function.

The best known system is **Sterrad™** which utilises a low temperature (< 50 °C) hydrogen peroxide gas plasma. The manufacturer (Advanced Sterilisation Products) claims that flexible endoscopes may be processed using this particular system, but special adapters (H_2O_2 boosters) are required for use with devices with lumens to ensure the disinfectant or sterilant gains access to these areas. Very long narrow lumens, and those closed at one end, are unsuitable for sterilisation using gas plasma. The endoscope must be thoroughly clean and dry before sterilisation and process compatible packaging materials must be used. The entire cycle takes only 75 minutes but, as with ethylene oxide, biological indicators are required for routine monitoring and these require lengthy incubation periods.

Although no toxic emissions result from the process, these technical problems, especially the long cycle time, make gas plasma impractical for routine processing of most gastrointestinal instruments.

VII. Tables

The tables on the following pages express:

1. The various disinfection options for endoscopes (Table **1**)
2. Selected washer-disinfectors (Table **2**)
3. Microbiological efficacy of the detergents (Table **3**)
4. A comparison of selected guidelines (Table **4**)
5. The members of the ESGE Guidelines Committee (Table **5**)

Table **1** Disinfectant Options for Endoscopes

	Properties/Advantages	*Disadvantages*
2% Activated Alkaline Glutaraldehyde (e.g. Cidex, Asep, Totacide 28)	– Non damaging, excellent materials compatibility – Numerous use studies published – Sporicidal in > 3 h – Mycobactericidal in 20 – 60 min – Virucidal, bactericidal in < 5 min – Relatively inexpensive – Stable for 14 – 28 days after activation	– Sensitising, irritant to skin eyes and respiratory tract – Adverse effects for patients after insufficient rinsing – Environmental controls expensive – Slow in action against bacterial spores and mycobacteria – A fixative, support biofilm creation, thorough cleaning is essential
0.35% Peracetic Acid (e.g. Nu-Cidex)	– Sporicidal in 10 min – Mycobactericidal, virucidal, bactericidal in < 5 min – Activity not adversely affected by organic material – Environmently friendly – Does not coagulate or fix tissues to surfaces	– Potential material incompatibility – Expensive – Irritant to skin, eyes, and respiratory tract (especially concentrated solution) – Unstable, once prepared it requires replacement every 24 hours – Strong odour of acetic acid – ventilation may be required – Large volumes to be stored
0.2% Peracetic Acid (only Steris System)	– Low-temperature (50 °C – 55 °C) liquid immersion sterilization, rapid sterilization cycle time (30 – 45 min). Process can be validated to ISO/EN 14937 – Single use dose of disinfectant so no dilution within the machine – Environmentally friendly – Does not coagulate or fix tissues to surfaces, activity not adversely affected by organic material – Dedicated enclosed processing facility, fully automated – Provides procedure standardization (constant dilution, temperature, exposure). Chemical and biological indicator available for process standardization	– Expensive, one endoscope reprocessing – Potential material incompatibility with cosmetic effects on anodysed aluminium only – Irritant to skin, eyes and respiratory tract (especially concentrated solution) – Single use only, large volumes to be stored – Has to be used within a dedicated machine which does not include cleaning as part of cycle – Biological indicator may not be suitable for routine monitoring
Chlorine Dioxide 700 – 1100 ppm av Cl (e.g.Tristel)	– Sporicidal in 10 min – Mycobactericidal, virucidal, bactericidal in < 5 min – Reusable, sporicidal activity is maintained for 7 – 14 days	– Irritant to skin, eyes, and respiratory tract, should be stored in sealed containers – Strong odour of chlorine – ventilation is required – Damaging, endorsement of compatibility with instruments and processors is required – Sporicidal activity is maintained for 7 – 14 days if the disinfectant is stored in sealed containers with minimal head space above the solution
Peracetic Acid/Hydrogen Peroxide (e.g. Cidex PA)	– High level disinfectant claim 25 min at 20 °C – Sterilization claim 8 h at 20 °C – No activation required, reusable (reuse life 14 days) – No known respiratory toxicity	– Damaging, material compatibility concerns (lead, brass, copper, zinc), both cosmetic and functional – It may cause skin irritation and eye damage – Limited clinical use
> 0.1% Peracetic Acid, pH 7 – 8.5 (e.g. Sekusept Aktiv)	– Mycobactericidal, virucidal (incl. Polio virus) bactericidal in 15 min at 20 °C – Sporicidal in 30 min – Does not coagulate or fix tissues to surfaces – High cleansing performance – High material compatibility with endoscopes – Concentrated product – low volume to be stored – Safe handling – Environmentally friendly	– Unstable, once prepared it requires replacement every 24 hours – Powder product, it has to be dissolved in water at right concentration – Preparation time of 15 min
> 0.1% Peracetic Acid, pH 5 – 7 (e.g. Anioxyde 1000)	– Mycobactericidal, virucidal, bactericidal in 10 min – Sporicidal in 30min – Does not coagulate or fix tissues to surfaces – Environmentally friendly	– Preparation time of 15 min – Material compatibility has to be evaluated – Large volumes to be stored
Ortho-phthalaldehyde (e.g. Cidex OPA)	– High level disinfectant claim 10 min at 20 °C – Sterilization claim 10 h at 25 °C – No noxious fumes, requires no activation, and is stable at a wider pH range of 3 to 9	– Eye irritant, stains skin, and environmental surfaces – Few data on hazards of long-term exposure and safe exposure levels
Superoxidized Water (e.g. Sterilox)	– Sporicidal in 5 min – Non-irritating, has minimal toxicity – Low cost (requires only salt, tap water, electricity) – Single use product – No COSHH or H&S implications – Does not coagulate or fix tissues to surfaces	– Unstable, it is necessary to provide freshly generated solution to the endoscope – Affected by organic matter – Little experience outside United Kingdom – The full disinfecting potential of the EAW and its long compatibility for endoscopes remain to be examined – Apparatus for generating Sterilox available to lease
Glucoprotamin (e.g. Sekusept PLUS)	– High level disinfectant claim 15 min at 20 °C – Material compatibility approved by Olympus – Does not coagulate or fix tissues to surfaces – High cleansing performance – Concentrated – low volume to be stored	– Mixing with water at right ratio (dosing device is recommended) – Lack of efficacy against some enteroviruses and spores

Table **2** Selected Washer-Disinfectors

Manufacturer	*Detergent Solution*	*Disinfectant Solution*	*Temperature*	*Number of Scopes*	*Cycle time*	*Self-Disinfection Cycle*	*Leakage Test*	*Traceability*	*Alarm for Channel Blocking*	*Commercially Available*
Cleantop CBC-Kaigen	NO	EAW (electrolyzed acid water)	Cold	1	7 min	YES	YES	YES	YES	YES
Genesis Bioquell	Any	Any	Cold	1 or 2	18 min	YES	YES	YES	YES	YES
Olympus ETD2	Provided by Olympus	GA	55 – 60 °C	2	35 – 39 min	YES	YES	YES		YES
Olympus ETD2 Plus	Provided by Olympus	PAA	35 °C	2	35 – 39 min	YES	YES	YES		On trial
Sreris System 1	NO	PAA	50 – 55 °C	1	30 min	YES	NO	YES	NO	YES
ASP 5000 Johnson & Johnson	Neutral enzymatic	PAA	36 °C	2	19 min	YES	YES	YES	YES	YES
Soluscope 3	Enzymatic	GA	40 °C or 45 °C	1	20 min	YES	YES	YES	YES	YES
System 83 plus Sterilox	Ultrasonic energy pump	GA, oxidizing liquid, Sterilox	Depends on disinfectant	1 to 4	14 min + contact time	YES	NO	YES	YES	YES
WD 420 (ILS)	Enzymatic	PAA	programmable	2		YES	YES	YES		YES
BHT E3 (ILS)		PAA	programmable	2		YES	YES	YES		YES
Fibro Cleaner ASR	Aperlan	PAA	Cold	2		YES	YES	YES		YES
Sterilox Technologies International QED	Neutral	Most commercially available disinfectants and Sterilox Models	Room < 30	2 – 3	Appr. 18 min	YES	NO	YES print out and hard drive	YES	YES
Sterilox Technologies International SAFER	Triple 'S'	EAW (Sterilox)	Room < 30	1 or 2 versions	Appr. 18 min	YES	YES	YES print out a nd hard drive	YES	YES

Table **3** Microbiological Efficacy of Detergents

PRODUCT BASE	*European Norm*	*FONGICIDY*	*SPORICIDY*	*HBV*	*BK*	*HIV*	*ALDEHYDE*
Amonium Proprionates Quartenary Guanidium Acetate	EN1040 NFT72-170 NFT72-300	NFT72-201	NO	YES	YES	YES	FREE
Quaternary Amonium + Polyhexanide	EN1040 NFT72-171 NFT72-190 NFT72-300	NFT72-200	NO	YES	YES	YES	FREE
Quaternary Amonium + Biguanide	NFT72-190 NFT72-171 NFT72-150	NFT72-202	NO	YES	YES	YES	FREE
Quaternary Amonium + Biguanide	NFT72-150 NFT72-170 EN 1040 EN 1276	NFT72-200 EN 1275	NO	YES	YES	YES	FREE
Quaternary Amonium +Proteolitique Enzyme	NFT72-301 NFT72-151 NFT72-171	NFT72-201 EN 1275	NO	YES	YES	YES	FREE
Quaternary Amonium + Glucoprotamin	EN 1040 NFT 72-171 NFT 72-180 Pr EN 13727	NFT 72-202 EN 1275	NO	YES	YES	YES	FREE
Quaternary Amonium + Alkylamine	DGHM	DGHM	NO	YES	YES	YES	FREE
Quaternary Amonium + Amphoteric Surfactant	DGHM	DGHM	NO	YES	YES	YES	FREE
Glucoprotamin	DGHM	DGHM	NO	YES	YES	YES	FREE
Alkylamine	DGHM	DGHM	NO	YES	YES	YES	FREE
Peracetic Acid pH 7 – 8.5	DGHM EN 1040 Pr EN 13727 NFT 72-170 NFT 72-230 NFT 72-301	DGHM EN 1275	YES	YES	YES	YES	FREE

Table **4** Comparison of Selected Guidelines

Guideline	*Precleaning*	*Disinfecting Agent Recommended*	*Disinfectant Contact Time*	*Antibiotic Prophylaxis*	*Personnel Health Recommendations*	*Outbreak Investigation Recommendations*
APIC Endoscopy Guideline	*Immediately* after use with enzymatic detergent	2 % Glutaraldehyde, hydrogen peroxide, peracetic acid; preparations of glutaraldehyde with phenol derivatives and quaternary ammonium compounds are not recommended	≥ 20 min at 20 °C	None given	Glutaraldehyde use and sensitivities; hepatitis B virus; mantoux skin testing with purified protein derivative	Perform standard methods of outbreak investigation; related infections or pseudo infections should be reported to institution's infection control, FDA, state health officials, CDC, manufacturers
Working Party – British Society of Gasteroenterology	*Immediately* after use with neutral detergent; enzyme may be useful	2 % Glutaraldehyde; peracetic acid; chlorine dioxide; does not recommend glutaraldehyde phenol derivatives	2 % Glutaraldehyde 20 min, 60 – 120 min after patient with *M. aviium intracellulare* or other highly resistant mycobacteria; peracetic acid and chlorine dioxide 5 min	None given	Glutaraldehyde use and sensitivities including a health screening program; hepatitis B virus	None given
ASGE/SGNA Position Paper	Does not give agent but stresses importance of cleaning	High level disinfectants; glutaraldehyde and hydrogen peroxide as examples	≥ 20 min at 20 °C	None given	Adhere to Occupational Safety and Health Administration rules; no other recommendations given	None given
Working Party – World Congress	*Immediately* after use with detergent	2 % Glutaraldehyde or similar agent	10 min	None given	Glutaraldehyde use; hepatitis B virus	None given
ASGE Infection Control during Gastrointestinal Endoscopy	Does not give agent but stresses importance of cleaning	High level disinfectants; glutaraldehyde	≥ 20 min at 20 °C	Practice standards for patient condition; procedure contemplated; antibiotic prophylaxis recommended	Adhere to Occupational Safety and Health Administration rules; ASGE Position Paper on Personal Protective equipment	None given
SGNA Standards for Infection Control and Reprocessing of Flexible Gastrointestinal Endoscopes SGNA Guideline for the Use of High-level Disinfectants and Sterilants for Reprocessing of Flexible Gastrointestinal Endoscopes	*Immediately* after use with enzymatic detergent	High level disinfectants; glutaraldehyde; peracetic acid; hydrogen peroxide	≥ 20 min at 20 °C (*)	None given	Liquid-chemical germicide spill containment plan; PPE	None given
RKI (German Health Authority) Endoscopy recommendation	Immediately after use with detergent reducing surface tension or cleaner with antimicrobial claim or alkaline cleaner	At 20 °C; disinfectant approved by DGHM or RKI; at elevated temperature: disinfectant effective against bacteria, fungi and viruses approved by supplier	15 min at 20 °C None given at elevated temperature	None given	Personnel health recommendation are given regarding: – protection against contamination; – protection against injuring; – vaccination; – risk reduction in case of aldehyde use.	

(*)The "20 minutes at 20 °C" needs a note: this is for glutaraldehyde only and is an off label claim. The label claims 45 minutes for high level disinfection; this is currently under review by the FDA and CDC in the USA where these guidelines have been developed.

Table **5** Members ESGE Guidelines Committee

ESGE: Dr Jean-François REY (Committee co-chairman, ESGE President Elect), Dr Aksel KRUSE (Committee co-chairman), Prof. Anthony AXON (ESGE Past President), Prof. Michael JUNG, Dr Konstantin KUZNETSOV
ESGENA: Mrs Ulrike BEILENHOFF, Mrs Dianelle DUFOREST-REY, Mrs Christiane NEUMANN, Mrs Stanca POPOVIC
BIOMEDICAL INDUSTRY: Dr Holger BIERING (ECOLAB EUROPE), Mr Edmund BRENNAN (COOK IRELAND), Mrs Joan GRAY (STERILOX TECHNOLOGIES), Mr Dieter HOFMANN (CBC-KAIGEN), Mr John MILLS (STERIS), Mr Stephan NEUMAIER (FUJINON), Dr Henning SCHUMACHER (DR SCHUMACHER), Mr Keith B. SPENCER (OLYMPUS EUROPE), Mr Matthias STIEF (PENTAX), Mr Katsuyuki SUZUKI (CBC-KAIGEN), Mr Alex WAGTEVELD (COOK IRELAND), Mr Darin WILSON (BOSTON SCIENTIFIC)