# World Gastroenterology Organisation/ World Endoscopy Organization Global Guidelines



# Endoscope disinfection— a resource-sensitive approach

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### Introduction

Every patient must be considered a potential source of infection, and all endoscopes and accessory devices must be decontaminated with the same degree of rigor following every endoscopic procedure. All health-care personnel in the endoscopy suite should be trained in and adhere to standard infection control procedures for protection of both patients and personnel. For a pathogen to be transmitted, all the links in the so-called "chain of infection" need to be intact. If just one link is interrupted, infection cannot develop.

Although there are few well-designed prospective studies on the incidence of pathogen transmission during gastrointestinal endoscopy, and estimates of pathogen transmission based on case reports may underestimate the true incidence of infection, the available evidence suggests that pathogen transmission is an extremely rare event when infection control procedures are observed. However, there is evidence in the literature that disinfection techniques are less well adhered to in developing countries.

# 1.1 Tropical infections

There is very little evidence available on the risk of transmission of parasitic infections by gastrointestinal endoscopy. To become infective, most parasitic agents require progression in a life cycle that takes time, so that they are not immediately infective. Most potentially infective parasites would not survive endoscope reprocessing with mechanical washing, 2% glutaraldehyde, and alcohol treatment. There is generally considered to be no risk with respect to helminths, nematodes, platyhelminths, Anisakis, or liver flukes such as Fasciola hepatica. However, concerns have been raised with regard to the risk of transmission of Giardia lambliasis, Cryptosporidium species, and amebas.

## 1.2 Endoscope processing sequence

Compliance with guidelines is the chief factor compromising the safety of endoscope reprocessing. The consequences of failure to follow recommendations may be not only transmission of pathogens, but also misdiagnosis (due to pathological material from one patient being introduced into the next patient), instrument malfunction, and a shortened instrument lifespan.

Most guidelines for endoscope reprocessing prescribe the following six steps:

→ Rinsing → Disinfection → Rinsing Cleaning → Drying → Storage Ideally, endoscope reprocessing comprises two basic components, which are expanded on in the following sections:

- Manual cleaning, including brushing and exposure of all external and accessible internal components to a low-foaming, endoscope-compatible detergent (since enzymatic detergents need at least 15 minutes of contact to be effective, nonenzymatic detergents are preferred)
- Automatic disinfection, rinsing, and drying of all exposed surfaces of the endoscope



If there is any doubt about whether an endoscope has undergone complete reprocessing, it should be subjected to a complete cleaning and disinfection cycle. Once properly reprocessed and stored, another reprocessing cycle should not be necessary. There is no agreement on storage at present, and there are requirements for reprocessing after storage for long periods (more than 24-72 hours). Endoscopes should generally be hung in storage, as this saves space and reduces the chance of contamination.

Table 1 Endoscope processing: general principles applying to all levels of resources

Step	General recommendations				
Precleaning	Preclean immediately				
Cleaning	<ul> <li>Always perform leak testing and block testing before immersing the endoscope in a detergent or soap solution, as this may help prevent expensive repairs later</li> </ul>				
Rinsing	Always rinse between cleaning and disinfection				
Disinfection	<ul> <li>Always immerse the endoscope and valves in a disinfectant solution of proven efficacy (see below)</li> </ul>				
	<ul> <li>Always irrigate all channels with a syringe until air is eliminated, to avoid dead spaces</li> </ul>				
	Always observe the manufacturer's recommendations regarding the minimum contact times and correct temperature for the disinfection solution				
	<ul> <li>Always observe the manufacturer's recommendations regarding compressed air values</li> </ul>				
	Always remove the disinfection solution by flushing air before rinsing				
	<ul> <li>Always determine whether the disinfectant solution is still effective by testing it with the test strip provided by the manufacturer</li> </ul>				
Final rinsing	Always discard the rinse water after each use to avoid concentration of the disinfectant and thus damage to mucosa				
	Never use the same container for the first and final rinsing				
Drying	<ul> <li>Always dry the endoscope properly before storage to prevent microorganism growth in the endoscope channels</li> </ul>				
Storage	Never store in a transport container				

## 1.3 WGO cascades—a resource-sensitive approach

A gold standard approach is feasible in regions and countries in which the full range of options is available for endoscope disinfection.

Cascades provide a hierarchical set of endoscope disinfection options, ranked according to the resources available.

#### 2 **Endoscope cleaning**

## **General procedures**

Preliminary cleaning should be started before the endoscope is detached from the light source/video processor. As soon as the endoscope has been removed from the patient, reprocessing can be started, with the following steps being observed:



- 1 Clear gross debris by sucking detergent through the working channel (250 mL/min).
- 2 Ensure the working channel is not blocked.
- 3 Irrigate the air and water channels, with water checking for blockages.
- 4 Expel any blood, mucus, or other debris.
- 5 Wipe down the insertion shaft.
- 6 Check for bite marks or other surface irregularities.
- 7 Detach the endoscope from the light source/video processor.
- 8 Transfer the endoscope to a reprocessing room with atmospheric extraction facilities.
- 9 Conduct a leakage test daily to check the integrity of all channels before reprocessing.

The next stage involves dismantling the detachable parts of the endoscope, with valves and water bottle inlets being removed and detachable tips being taken off the insertion tube. Rubber biopsy valve caps are discarded after any procedure that has involved passage of accessories. Water bottles and suction/air-water valves should be autoclaved.

All exposed internal and external surfaces should then be manually cleaned and rinsed in accordance with the following recommendations:

- Use a low-foaming detergent specifically designated for use in medical instrument cleaning.
- Use the appropriate dilution in accordance with the manufacturer's instructions.
- Flush and brush all accessible channels to remove all organic residues (e.g., blood, tissue) and other residues with a disposable brush-tipped wire designed for this purpose.
- Use brushes of the appropriate size for the endoscope channel, parts, connectors, and openings; bristles should have contact with all surfaces.
- Repeatedly actuate the valves during cleaning to facilitate access to all surfaces.
- Clean the external surfaces and components of the endoscope with a soft cloth, sponge, or brush.
- Subject reusable endoscope accessories and endoscope components to ultrasound cleaning in order to remove material from hard-to-clean areas.
- Dispose of all cleaning items.

If some of the above steps are not feasible due to limited resources, the following alternatives can be considered:

- Cleaning with a nonenzymatic detergent
- Cleaning very carefully with soap and water of acceptable quality, as the minimum standard
- Using sterile, filtered, drinking-quality or boiled water

# 2.2 Ultrasonic cleaning

Ultrasonic cleaning of reusable endoscope accessories and components may be needed in order to remove material from hard-to-clean areas. The same detergent must be used for ultrasound cleaning as for manual cleaning. The recommendations are as follows:



- A nonfoaming detergent should be used that is appropriate for both manual cleaning and ultrasonic cleaning.
- Enzymatic detergent solutions should preferably be used.
- The specific contact time recommended by the manufacturer for enzymatic detergents should be observed.
- Inhalation of enzyme-containing detergent aerosols, with a risk of anaphylactic reactions, should be minimized by covering the detergent container.

## 2.3 Detergents

Detergents with or without enzymes, and detergents containing antimicrobial substances, can be used for endoscope cleaning. Use of nonfoaming detergents is recommended. Foaming can inhibit good fluid contact with device surfaces and prevent a clear field of vision during the cleaning process, with a risk of injury to personnel.

The detergent selected should effectively loosen organic and nonorganic material so that the flushing action of the detergent fluid and subsequent rinsing water removes the unwanted material.

- Detergents containing aldehydes should not be used for cleaning, as they denature and coagulate protein.
- Detergents based on amine compounds or glucoprotamine in combination with glutaraldehyde for disinfection should not be used, as chemical reactions may result in the formation of colored residues.
- Enzymatic detergents should be discarded after each use, as these products are not microbicidal and will not retard microbial growth.
- In Europe, detergents commonly used may contain antimicrobial substances that reduce the risk of infection to reprocessing personnel, but they do not replace disinfection.
- Enzymes generally function more effectively above room temperature (> 20-22 °C) and should be used in accordance with the manufacturer's recommendations.

#### 3 **Endoscope disinfection**

#### 3.1 General procedures

Endoscopes should be disinfected in dedicated rooms by trained staff at the beginning and at the end of each patient list, as well as between patients. The European practice of disinfecting endoscopes just before they are used in patients is not always practiced or recommended in other countries. However, reprocessing the endoscope immediately after use is a commonly accepted standard. An exception can be made when the endoscope is stored in a clean environment.

Recommendations for effective disinfection with a liquid chemical germicide include:

- Using an automatic endoscope reprocessor
- Performing disinfection in a dedicated area with atmospheric extraction facilities



- Flushing high-level disinfectant or chemical sterilant throughout the endoscope at the correct temperature and for the correct duration
- Concluding disinfection by rinsing with sterile or filtered water or alcohol
- Drying each endoscope properly with forced air

To protect staff during the disinfection procedure, the following apparel and equipment are recommended:

- Long-sleeved waterproof gowns, which are changed between patients
- Gloves long enough to cover the forearms
- Goggles to prevent conjunctival irritation and protect from splashes
- Disposable charcoal-impregnated face masks to reduce inhalation of vapor
- An approved vapor respirator available for spillage or other emergencies
- Rooms with appropriate ventilation and air exchange for use with disinfection agents

#### 3.2 Manual disinfection

In manual disinfection, the endoscope and endoscope components should be completely immersed in high-level disinfectant/sterilant, ensuring that all channels are perfused. (Any nonimmersible gastrointestinal endoscopes should already have been removed from circulation.) At least once a day, the water bottle and its connecting tube should be sterilized—these are used for cleaning the lens and irrigation during endoscopy. If possible, the water bottle should be filled with sterile water.

# 3.3 Automatic reprocessing

In automatic endoscope reprocessing (AER), the endoscope and endoscope components are placed in the reprocessor, and all channel connectors are attached in accordance with AER and endoscope instructions. AER ensures exposure of all internal and external surfaces to a disinfectant or chemical sterilant. If an AER cycle is interrupted, disinfection or sterilization cannot be assured and the entire process should be repeated.

Water used for rinsing in automatic endoscope reprocessors should be maintained free of microorganisms and other particles by means of bacterial filters, biocides, or other methods. If the local supply delivers hard water, water softeners should be used. Samples of final rinse water from the automatic reprocessor should be subjected to microbiological testing at least weekly.

## 3.4 Importance of rinsing and drying

Endoscopes are generally not dried between consecutive examinations. The drying process is designed to prevent the growth of microorganisms during storage. The final drying steps greatly reduce the possibility of recontamination of the endoscope with waterborne microorganisms.

The recommended steps are as follows:

- After disinfection, rinse the endoscope and flush the channels with water to remove the disinfectant/sterilant.
- Discard the rinse water after each use/cycle.



- Flush the channels with 70–90% ethyl alcohol or isopropyl alcohol. (An alcohol flush for drying can be skipped if the drying process is carried out properly. Alcohol drying can be hazardous.)
- Dry with compressed air.

The disinfectant or chemical sterilant must be rinsed from the internal and external surfaces of the endoscope. If tap water is used, a flush with 70% alcohol should be performed. Caution is necessary when alcohol is used, due to the risk of explosion.

#### Disinfectants

The ideal disinfectant is effective against a wide range of organisms, including bloodborne viruses and prion proteins; is compatible with endoscopes, accessories, and endoscope reprocessors; nonirritant and safe for users; and it permits environmentally friendly disposal.

Disinfectants must be used at the correct temperature and in accordance with the manufacturer's instructions and current recommendations in the literature. The disinfectants should be tested regularly with test strips and/or kits provided by manufacturers to ensure optimal activity of the products.

Disinfectant spills. Disinfectants such as glutaraldehyde can be toxic and need to be neutralized if accidents occur in the disinfection room. Neutralization of aldehydes can generally be achieved with dilution to less than 5 ppm, with addition of reducing agents (sodium bisulfite) or alkalizing agents (sodium hydroxide). These agents should be kept at hand to render disinfectants harmless to personnel. If staff notice that they are suffering increased secretions from mucosal surfaces, then there is inadequate ventilation in the disinfection room and they should leave the room and obtain adequate respiratory equipment.

Factors influencing the choice of disinfectant include:

- Dilution process
- Stability of the solution
- Number of reuses possible
- Direct cost
- Indirect costs (e.g., appropriate automatic endoscope reprocessor, storage space, conditions for use, staff protection measures)

In many countries, limited budgets do not permit the use of more expensive alternative disinfectants. In some areas, even glutaraldehyde is not affordable and reprocessing is limited to manual washing with a detergent. In such settings, use of automatic endoscope reprocessors or even disinfectant is not possible.

Glutaraldehyde is one of the most commonly used disinfectants in endoscopy units. It is effective and relatively inexpensive, and does not damage endoscopes, accessories, or automated processing equipment. However, health, safety, and environmental issues are of considerable concern. Adverse reactions to glutaraldehyde are common among endoscopy personnel, and substantial reductions in atmospheric levels of glutaraldehyde have been recommended. Glutaraldehyde has been withdrawn from use in some countries. Disposal of glutaraldehyde is a concern and it should not be directly emptied into the sewage system. If diluted to less than 5 ppm, it can undergo natural decomposition.



Orthophthalaldehyde is a more stable alternative disinfectant that has a lower vapor pressure than glutaraldehyde. It is practically odorless, does not emit noxious fumes, and has better mycobactericidal activity than 2% glutaraldehyde. It does not appear to damage the equipment, but like other aldehydes it can stain and cross-link protein material.

Peracetic acid is a highly effective disinfectant which may prove to be a suitable alternative to glutaraldehyde.

Electrolyzed acid water (EAW) has a rapid and pronounced bactericidal action (especially electrolyzed strong acid water). EAW is classified as a nonirritant and has minimal toxicity. It is considered safe for patients, staff, and the environment and does not harm human tissue. A further advantage of EAW is its low production cost, since only salt, tap water, and electricity are required. A disadvantage is that the bactericidal effect is drastically decreased in the presence of organic matter or biofilm, which makes thorough cleaning even more essential. Variations in the free chlorine level of commercial products may result in either damage to the endoscope or inadequate disinfection.

#### 4 **Endoscope sterilization**

Sterilization is used primarily for processing endoscope accessories and is accomplished by either physical or chemical methods. It is important to note that the term "sterilization" should not be equated with "disinfection" and that there is no such state as "partially sterile."

Steam under pressure, dry heat, ethylene oxide gas, hydrogen peroxide, gas plasma, and liquid chemicals are the principal sterilizing methods used in health-care facilities. Flexible endoscopes do not tolerate high processing temperatures (> 60 °C) and cannot be autoclaved or disinfected using hot water or subatmospheric steam. They may be sterilized, however, provided they have been thoroughly cleaned and the manufacturer's processing criteria are met. Although the value of sterilization would seem to be obvious, there is no evidence available indicating that sterilization of flexible endoscopes improves patient safety by reducing the risk of transmission of infection.

#### 5 **Endoscope storage**

Colonized water or residual moisture can be a source of microorganisms, and proper drying will remove any moisture from internal and external surfaces of the endoscope. Drying of endoscopes especially prior to prolonged storage decreases the rate of bacterial colonization. Forced air-drying adds to the effectiveness of the disinfection process.

The following are recommendations for storage:

- Ensure proper drying prior to storage.
- Hang preferably in a vertical position to facilitate drying.
- Remove caps, valves, and other detachable components in accordance with the manufacturer's instructions.
- Uncoil insertion tubes.



- Protect endoscopes from contamination by placing a disposable cover over them.
- Use a well-ventilated room or cabinet for reprocessed endoscopes only.
- Clearly mark which endoscopes have been reprocessed.
- Avoid contamination of disinfected endoscopes by contact with the environment or by prolonged storage in an area that may promote pathogen growth.
- New storage facilities overcome the risk of cross-contamination and allow immediate use of stored endoscopes.

#### 6 **Endoscope accessories**

Disposable accessories should not generally be used more than once. If they are to be used more than once due to limited resources, it is imperative that they should be subjected to a complete cleaning, disinfection, and sterilization cycle between each use.

The steps involved are summarized as follows:

Dismantle → Brush → Flush → Dry

Good-quality water (sterile, filtered, or drinking-quality) and a disinfectant solution, or at least a soap detergent, should be used.

- Accessories that penetrate the mucosal barrier (biopsy forceps, guide wires, cytology brushes, other cutting instruments):
  - Use once only.
  - Or clean ultrasonically/mechanically and then sterilize/autoclave between each patient use.
- Accessories that are not passed through the working channel (water bottles, bougies) should be autoclaved for 20 minutes at 134 °C.
- Rubber valves should be changed after the passage of biopsy forceps, guide wires, and/or other accessories.

# Efficacy of disinfection and quality assurance

The disinfection process eliminates most, if not all, pathogenic microorganisms, with the exception of bacterial spores. Disinfection is usually accomplished by the use of liquid chemicals or wet pasteurization, and its efficacy is affected by the following factors:

- Prior cleaning of the object
- Organic and inorganic load present
- Type and level of microbial contamination
- Concentration of the germicide and time of exposure to it
- Presence of biofilms
- Temperature and pH used for the disinfection process



Table 2 Pathogens that are difficult to eliminate, in decreasing order of resistance to disinfectants/sterilization

- Prions-e.g., Creutzfeldt-Jakob prion
- Bacterial spores—e.g., Bacillus subtilis
- Coccidia-e.g., Cryptosporidium parvum
- Mycobacteria—e.g., Mycobacterium tuberculosis, Mycobacterium terrae
- Nonlipid or small viruses—e.g., poliovirus, coxsackieviruses
- Fungi-e.g., Aspergillus species, Candida species
- Vegetative bacteria—e.g., Staphylococcus aureus, Pseudomonas aeruginosa
- Lipid or medium-sized viruses—e.g., human immunodeficiency virus, herpesviruses, hepatitis B virus

Endoscopic examinations should be avoided in patients with suspected or confirmed variant Creutzfeldt-Jakob disease (vCJD). If endoscopy is considered essential in such patients, either a dedicated endoscope should be used or an endoscope nearing the end of its life that can be reserved for use in similar patients.

The vCJD prion is resistant to all forms of conventional sterilization. The risk of transmission of this agent is probably extremely low, provided that scrupulous attention is paid to detail in the decontamination procedure after each patient. In particular, all accessible endoscope channels should be brushed with a disposable brush-tipped wire assembly designed for the purpose, which has an appropriate length and diameter for each channel.

# 7.1 Quality control

It is important to monitor the efficacy of the disinfection procedure at regular intervals. All endoscope channels should be checked for contamination. The manufacturer's instructions should be followed with regard to the intervals, media, and culture conditions for quality controls.

- Consider whether legal implications allow reuse of endoscope accessories.
- If local regulations allow reuse, arrange for reprocessing with optimal efficacy.
- Consider the implications for manufacturer guarantees.

## 7.2 Personnel training

- Train all health-care personnel in an endoscopy unit in standard infection control measures.
- Provide personnel assigned to reprocess endoscopes with device-specific reprocessing instructions to carry out cleaning and high-level disinfection or sterilization procedures.
- Test the competency of personnel reprocessing endoscopes on a regular basis.
- Provide information to all personnel handling chemicals on the biological and chemical hazards associated with procedures using disinfectants.
- Protective equipment (e.g., gloves, gowns, goggles, face masks, respiratory protection devices) should be readily available to protect staff from exposure to chemicals, blood, or other potentially infectious material.
- Design facilities in which endoscopes are used and disinfected in such a way as to provide a safe environment for health-care workers and patients.



- Use air-exchange equipment (e.g., ventilation system, exhaust hoods) to minimize exposure to potentially toxic vapors from substances such as glutaraldehyde.
- Test the vapor concentration of chemical sterilants used on a regular basis—they should not exceed the permitted limits.

#### 8 Cascade options for endoscope disinfection

By introducing a hierarchy of standard procedures that allow for alternatives in certain resource-sensitive steps in endoscopy reprocessing, these WGO guidelines aim for improved compliance, especially in areas of the world in which external factors limit the available options.

Table 3 Cascade options for endoscope disinfection

Step	Resources	Endoscope processing activity
	Limited	<ul> <li>Clear gross debris by sucking water through the working channel (250 mL minimum)</li> </ul>
	Medium Extensive	<ul> <li>Clear gross debris by sucking detergent through the working channel (250 mL minimum)</li> </ul>
	All levels	Expel any blood, mucus, or other debris
1 Precleaning		Flush the air–water channel and wipe down the insertion shaft
		Check for bite marks or other surface irregularities
		Detach the endoscope from the light source/video processor
		Transport in a closed container to the reprocessing room
	All levels	Conduct leak testing and block testing
	Limited	Immerse the endoscope in detergent or a soap solution
		Clean all surfaces, brush channels, and valves with a clean dedicated brush and a clean swab or tissue
2 Cleaning	Medium Extensive	<ul> <li>Clean all surfaces, brush channels, and valves with a disposable or autoclavable brush and disposable swab or tissue</li> </ul>
		Renew the detergent solution for each new procedure
		Clean and rinse the container before the next procedure
	All levels	<ul> <li>For all accessories, follow the same procedures as for endoscope processing</li> </ul>

Step	Resources	Endoscope processing activity
	Limited Medium	<ul> <li>Rinse the endoscope and valves under running tap water of drinking-water quality</li> <li>Immerse the endoscope and irrigate all channels</li> <li>Discard the rinse water after each use to avoid</li> </ul>
3 Rinsing		concentration of the detergent and the risk of reduced efficacy of the disinfectant solution
	Futonoius	Clean and rinse the container before the next procedure
	Extensive	Forms part of the automatic processing
		Immerse the endoscope and valves in a disinfectant solution of proven efficacy (GA, PAA, OPA, etc.)
	Limited	<ul> <li>Irrigate all channels with a syringe until air is eliminated, to avoid dead spaces</li> </ul>
	Medium	Follow the manufacturer's recommendations for the contact time with the solution
4 Disinfection		Remove the disinfection solution by flushing air before rinsing
		Automatic reprocessing:
		Cleaning with detergent solution of proven efficacy, or as recommended by the manufacturer
	Extensive	Rinsing
		Disinfection
		Final rinsing
	Limited	Rinse the endoscope and valves in drinking-quality or boiled water by immersing the endoscope and irrigating all channels
5 Final rinsing	Medium	<ul> <li>Rinse the endoscope and valves under running filtered water by immersing the endoscope and irrigating all channels</li> </ul>
	Limited Medium	Discard the rinsing water after each use to avoid concentration of the disinfectant and thus damage to the mucosa
	Extensive	Forms part of the automatic processing
6 Drying	Limited Medium	Ensure correct final drying before storage
	Limited	Dry with compressed air, or if not available inject air with a clean syringe
	Medium	Dry with compressed air or a 70% alcohol flush

Step	Resources	Endoscope processing activity
	Extensive	Dry with compressed air of defined quality or a 70% alcohol flush
	All levels	Disassemble the endoscope in a well-ventilated storage cupboard
		Ensure the valves are dry and lubricate if necessary
7 Storage	Limited	Store the endoscope separately or in a clean closed box without the valves
	Medium Extensive	Store the endoscope separately
	All levels	<ul> <li>Alcohol must be properly stored, as evaporation occurs rapidly on exposure to air—if the concentration is &lt; 70%, it cannot be reliably used in the drying process</li> </ul>
Remarks		Brush reprocessing must follow the same procedures as for endoscope reprocessing
		The disinfectant solution should be tested at least every day for efficacy using the manufacturer's test strip
		Drying should be performed after each processing cycle and not just before storage

GA, glutaraldehyde; OPA, orthophthalaldehyde; PAA, peracetic acid.