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Review Article

Recommendations and guidelines for endoscope reprocessing: Current position statement of digestive endoscopic society of Taiwan

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Abstract Reprocessing of gastrointestinal (GI) endoscopes and accessories is an essential part of patient safety and quality control in GI endoscopy centers. However, current endoscopic reprocessing guidelines or procedures are not adequate to ensure patient-safe endoscopy. Approximately 5.4 % of the clinically used duodenoscopes remain contaminated with high-concern microorganisms. Thus, the *Digestive Endoscopy Society of Taiwan (DEST)* sets standards for the reprocessing of GI endoscopes and accessories in endoscopy centers. DEST organized a task force working group using the guideline-revision process. These guidelines contain principles and instructions of step-by-step for endoscope reprocessing. The updated guidelines were established after a thorough review of the existing global and local guidelines, systematic reviews, and health technology assessments of clinical effectiveness. This guideline aims to provide detailed recommendations for endoscope reprocessing to ensure adequate quality control in endoscopy centers.

Introduction

Gastrointestinal (GI) endoscopy plays an important part in the prevention, diagnosis, and treatment of many digestive diseases.[1,2] However, despite the standard recommended procedures for endoscope reprocessing, studies have revealed that between 42 and 95 % of working channels still contain residual fluid even 24 h after undergoing HLD and being placed in storage cabinets.[3–6] It carries the potential for the transmission of pathogenic microorganisms, raising significant concern for patients, clinicians, and health care facilities.[7]

Duodenoscopes intended for patient use were initially designed with an anticipated contamination rate of under 0.4 %.[8] However, the 2019 United States Food and Drug Administration (FDA) issued a warning indicating that 5.4 % of duodenoscopes used in clinical settings still tested positive in cultures for high-concern microorganisms, even after following the recommended reprocessing instructions.[8] Endoscope reprocessing failures have been reported by the Emergency Care Research Institute as one of the top 10 most significant threats to patient health.[9] Moreover, several concerning endoscope reprocessing issues remain unresolved based on the currently available guidelines.[7,10,11]

Endoscopes used in endoscopy units are complex and essential medical devices require meticulous cleaning and reprocessing. Strict compliance with following established reprocessing guidelines can significantly reduce or eliminate pathogen transmission in patients undergoing endoscopy.[7] However, the current endoscopy reprocessing guidelines or procedures are not adequate to ensure patient-safe endoscopy across the United States,[10,12,13] Taiwan,[14,15] and Asian countries.[11,16,17] Several reports of those endoscopic-associated outbreaks have led to a revived focus on optimizing endoscope reprocessing.[1,7,8,18]

The revised guideline were prompted by new evidence in relation to the aim of ensuring that endoscopes are free of residual contamination and viable microbes before being used on a patient.[1,7,18] The implementation of the updated endoscope reprocessing guidelines should be based on existing global and local guidelines, burden on patients, local medical resources, and novel reprocessing technologies.[1,10,11,14,18–20]

The Digestive Endoscopy Society of Taiwan (DEST) has issued the first version of the endoscope reprocessing *guideline* on December 2018.[21] DEST organized a task force working group using the guideline revision process. The updated 2023 guidelines were established after a thorough review of existing guidelines, systematic reviews, and novel reprocessing technology assessments, and reaching a consensus between task force members. However, there is no English version of the guideline available, which presents a challenge in sharing information and providing details on endoscope reprocessing practices from Taiwan and referencing global guidelines. The first English version of these guidelines is a good example to consider in the context of Taiwan's clinical situations and local resource availability. The updated guideline aims to provide detailed recommendations for endoscope reprocessing to ensure adequate quality control in endoscopy units.

Guidelines for endoscope reprocessing

Patient-used endoscope reprocessing involves four main steps: (1) The point of use treatment, (2) manual cleaning, (3) high-level disinfection (HLD), and (4) storage (Fig. 1).

Point of use treatment

The point of use treatment, must be performed at the bedside immediately following the completion of the endoscopic procedure, to prevent the drying of soil and secretions, and biofilm formation. Following the guidelines from the AAMI (Association for the Advancement of Medical Instrumentation) and ASGE (American Society for Gastrointestinal Endoscopy), the terminology of "precleaning" has been changed to "point of use treatment", which covers precleaning the scope, disposal of all single-use items, and documenting handoff information.[7,10] This assists the scope-cleaning personnel in identifying not only where, when, and on which patient the flexible scope was used but also when the pretreatment occurred. In case of a delay or failure in point of use treatment, the endoscope should be processed using delayed-processing protocols in accordance with the device manufacturer's IFU.

The Taiwan Food and Drug Administration (TFDA) has established regulations for medical devices involved in endoscope reprocessing. According to these regulations, all detergent solution products used in various stages, including point of use treatment, manual cleaning, and HLD, must receive approval from the TFDA.[20] The point of use treatment must be performed at the bedside immediately following the completion of the endoscopic procedure.[1,7] The point of use treatment involves five procedures: (1) wiping, (2) suction, (3) function control, (4) visual inspection, and (5) transportation.

(1) **Wiping**: After the completion of the endoscopic procedure, the exterior of the endoscope should be cleaned with a clean, single-use gauze soaked in detergent. The entire insertion section should be wiped down from the boot of the control section to the distal end (Fig. 2A).[18,22]

(2) **Suction**: The detergent solution aspirated through the working channel until no visible debris is observed. The distal end of the endoscope must be placed into a detergent solution and aspirated to remove any residual contaminants remaining inside the working channel. The distal end must be removed from the detergent solution, and air aspirated through the working channel by pressing the suction valve (Fig. 2B). Finally, air aspirated through the working channel until no more fluid is present.

Immediately aspirate the detergent solution and flush the working channel after the completion of endoscopy. This can prevent body tissue or non-tissue residue from attaching to the channel, and effectively clean the endoscope from blood, polysaccharides, lipids, and biofilm during endoscopy. The detergent must be suctioned through the endoscope channels, alternating with air until the solution appeared clean. Removing contaminants from the channel by alternately suctioning detergent and air is more effective than simply aspirating the detergent solution.[1,10,11]

(3) **Function control**: The distal end of the endoscope must be immersed into clean water, the suction valve depressed to alternatively blow air and water for approximately 15 s (Fig. 2B). The air/water channel cleaning adapter could be used to confirm that the channel is unobstructed (Fig. 2C). The control section

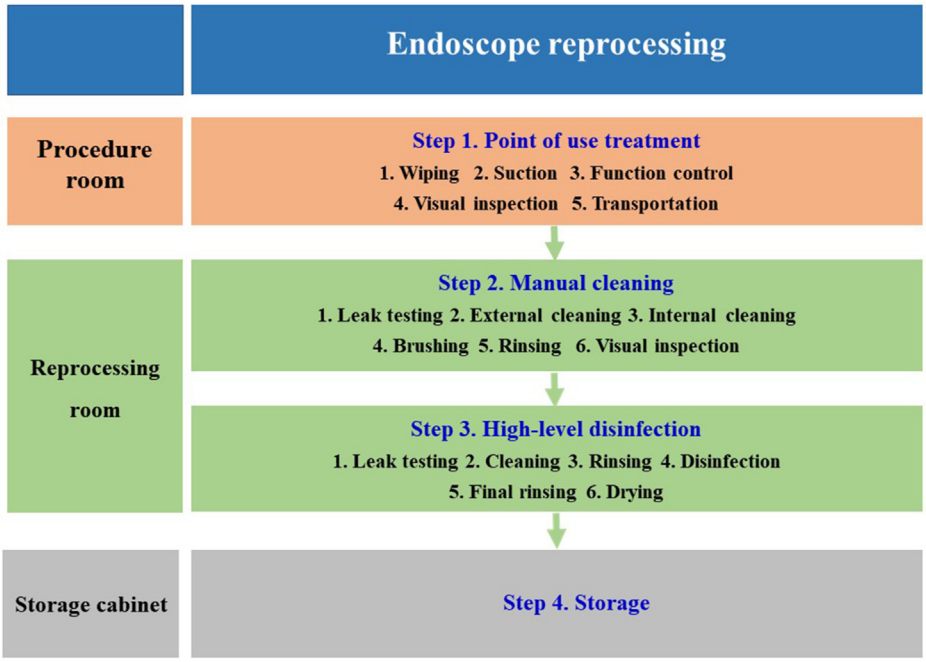

Figure 1. Main steps of endoscope reprocessing.

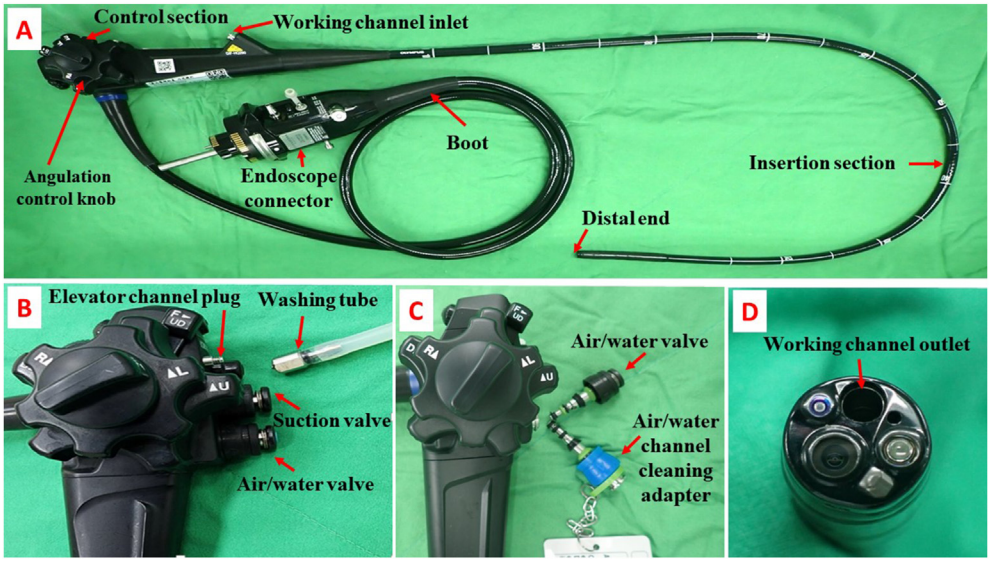

Figure 2. Typical endoscope structure (Olympus GIF-HQ290) (A), control section side view (Olympus TJF-260V) (B), air/water valve and cleaning adaptor structure (Olympus GIF-HQ290) (C), and distal end view (Olympus GIF-HQ290) (D).

should be loosened. The angulation control locks should be in a free position (Fig. 2A). The tip of the endoscope shall be straightened to a neutral position. Reprocessing a new variable-stiffness colonoscope differs from the standard adult colonoscope. The variable-stiffness colonoscope should be adjusted for relative flexibility by turning the dedicated wheel on colonoscope's shaft.[10]

(4) **Visual inspection**: Visual inspection must be performed to check for any damage, including surface irregularities and bite marks, on the endoscope.[7]

(5) **Transportation**: The power of video processor and light source must be turned off. The endoscope must be detached from the light source. A water-resistant cap could be attached over any electrical components, if applicable.[7]

After the point of use treatment, the contaminated endoscopes and accessories must be transported to the reprocessing room for further processing. Endoscopes and those hard and sharp accessories, such as biopsy forceps and alligator jaw grasping forceps, should be contained separately but transported them together.[1,7,10] Endoscopes and accessories should be transported in the puncture-resistant, leak-proof, clearly labeled, adequately sized and covered or closed containers such as carts, boxes, or bags.[1,7,10] Tight looping should be avoided to prevent puncture or penetration damage to the endoscope. Reusable containers should be regularly cleaned and disinfected. When containers become worn or compromised, they should be replaced with new ones.

When immediate point of use treatment is not feasible or when manual cleaning is delayed for more than 1 h after the point of use treatment, please follow the details described in the section of 5.2, Delayed reprocessing. Transportation of the contaminated instruments to the reprocessing room should be performed as quickly as possible. Hand-off communication, from the transporter to reprocessing room personnel, should include the point of use treatment completion time.

Manual cleaning

Manual cleaning must be performed following the step of point of use treatment. Manual cleaning involves 6 procedures: (1) leak testing, (2) external cleaning, (3) internal cleaning, (4) brushing, (5) rinsing, and (6) visual inspection.

(1) **Leak testing:** Fresh enzymatic detergent is prepared in a clean sink or basin for each endoscope to avoid cross contamination.[1,7,18] The endoscope components must be disconnected and disassembled before manual cleaning. Leak testing must be performed before immersing the endoscope in a detergent.

(2) **External cleaning:** The endoscope of the exterior is cleaned with a fresh, soft, lint-free sponge saturated with an enzymatic detergent as per the manufacturer's instructions for use (IFU).[7,18]

(3) **Internal cleaning:** All channels must be flushed with a detergent solution to remove debris. If an automatic flushing system is used, the connection tubing and equipment should be cleaned and disinfected daily.[7]

(4) **Brushing:** Brushes appropriately for the sized for the endoscope channels should be used to clean all internal channels until all residual debris is removed.[1,7,18] A brush should be used to clean all removable parts, including the suction valve, air/water valve, and working channel inlet and outlet (Fig. 2A and D).[1,7,18]

(5) **Rinsing:** After each passage, the brush should be rinsed in the detergent solution, and any visible debris should be removed before retraction and reinsertion. Reusable brushes should be inspected between uses and replaced if they are worn, bent, or

damaged. Worn bristles are ineffective for cleaning, and damaged brushes may damage the endoscope channels. The reusable brushes should undergo cleaning and disinfection with HLD between cases. The endoscope and all removable parts should be thoroughly rinsed with clean water to remove residual debris and detergent.[1,7,18]

(6) **Visual inspection:** The exterior of the endoscope and associated accessories should be visually inspected after manual cleaning for cleanliness and damage.[1,7,10]

High-level disinfection

High-level disinfection (HLD)

HLD of medical devices results in the reduction or destruction of all vegetative microorganisms, mycobacteria, small or virus without lipid envelop, medium or lipid-enveloped virus, and fungal spores, except for a small numbers of bacterial spores.[23]

High-level disinfectants and liquid chemical sterilant

(1) **Glutaraldehyde (GA):** GA is considered a high-level disinfectant used in the endoscopy units. GA may be irritating to the skin, eyes, nose, and lungs without proper ventilation. Endoscopy reprocessing rooms require proper ventilation when GA vapors are used. Vapor concentration is the unit of measurement for the environmental presence of GA.[24]

(2) **Orthophthalaldehyde (OPA):** OPA is a widely used disinfectant that has demonstrated better microbiological efficacy compared to that of GA. OPA could cause irritation to the respiratory tract and eyes and may also lead to anaphylactic reaction. OPA has lower vaporization activity and is less toxic. Compared to the GA toxicity, OPA serves as a safer alternative disinfectant for reprocessing personnel.[25] The reprocessing room must have appropriate ventilation, with an air exchange rate at least 10 times per hour when using GA and OPA for HLD.[20]

(3) **Liquid chemical sterilant:** PAA has demonstrated more rapid bactericidal effects than OPA or GA against *S. aureus* and *P. aeruginosa* biofilms, which are associated with endoscopy-related infections.[26] PAA is a more potent and faster-acting disinfecting compared to GA and OPA. Please follow the details described in the section of 2.2.5, Peracetic acid (PAA). The Food and Drug Administration has approved PAA products as high-level disinfectants or liquid chemical sterilants according to the manufacturer's IFU.[7, 20]

Automated endoscope reprocessor (AER)

AERs are designed to eliminate microorganisms on or within reusable endoscopes by exposing their exterior surfaces and interior channels to high-level disinfectant or liquid chemical sterilant solutions. AERs offer several advantages over manual reprocessing: they automate and standardize several crucial reprocessing steps, decrease the likelihood of missing an essential reprocessing step, and lower personnel exposure to high-level disinfectants or chemical sterilants.[7] Manual processing with HLD is no longer recommended due to the variability and inconsistency in personnel responsible for the reprocessing.[7]

An AER can perform standardized disinfection processes and reduce personnel exposure to disinfectants. The use of AER for the HLD involves six procedures: (1) leak testing, (2) cleaning, (3) rinsing, (4) disinfection, (5) final rinsing, and (6) drying.

(1) **Leak testing:** Any damage to the interior or exterior of the endoscope must be detect before cleaning. Leak testing can be performed manually or with a leak tester that immerses and soaks the endoscope in water for at least 60 s. Whether there is a stream of air bubbles coming out of the interior of the endoscope must be carefully observed.[7] If air bubbles continue to exit the endoscope, it is a possible that the scope has a hole in the channel. The endoscopic reprocessing process should be stopped immediately, and the potentially damage endoscope must be returned back to the manufacturer for further examination and/or repair.

(2) **Cleaning:** All detachable parts must be removed from the endoscope, and all channel connectors must be attached according to the corresponding manufacturer's IFU. They were then immersed in a detergent solution using an ultrasonic cleaner for leaning.

(3) **Rinsing:** All channels of the endoscope should be flushed with filtered or sterile water, to remove residual detergent. Air purges all the channels.

(4) **Disinfection:** The endoscope and detachable part must be completely immersed in undiluted high-level disinfectants (GA, OPA, or PAA). Every minimum effective concentration (MEC) of the disinfectants must be checked following the manufacturer's IFU.

(5) **Final rinsing:** All channels of the endoscope must be flushed with filtered or sterile water to remove residual disinfectants. Air purges all the channels.[2,27]

(6) **Drying:** Channels must be flushed with 75 % alcohol. Air purge using compressed air was employed to facilitate the drying of the channels.[3,27]

Storage

After HLD, the reprocessed endoscopes should be stored in a designated, well-ventilated, temperature- and humidity-measurable storage cabinet with sufficient height and width.[7]

Reprocessed endoscopes should be stored according to corresponding the manufacturer's IFU. The endoscopes should be placed horizontally or vertically, according to the corresponding manufacturer's IFU. The endoscopes should not contact to each other in a storage cabinet. The distal end of the endoscopes should not touch the floor of the storage cabinet when hanging in a vertical position.[1, 7 23]

All detachable parts and accessories must be removed from the reprocessed endoscopes and stored separately. The inner parts of storage cabinets should be cleaned with 75 % alcohol daily. The storage time is recommended to be

less than seven days for regular endoscopes and three days for high-risk endoscopes, including duodenoscopes and linear ultrasound endoscopes. Endoscopes that were stored longer than the recommended storage time, the second cycle of HLD should be performed at morning before using on the next patient.[1,7,10,28,29] The endoscopes should be stored and maintained according to the corresponding manufacturer's IFU. After repair or maintenance, endoscopes should be reprocessed by standard endoscope reprocessing before storage.[1,7]

Medical devices and spaulding classification system

The Spaulding classification system allows for the categorization of medical devices based on their risk of infection (Table 1).[20] High-risk endoscopes, such as duodenoscopes and linear ultrasound endoscopes, feature complex elevator designs. Transitioning from high-level disinfection to sterilization may help reduce the risk of transmission of infections related to high-risk endoscopes. AAMI and ASGE recommend that high-risk endoscopes should be reclassified from semi-critical items to critical items in the Spaulding classification system.[7,8,10]

(1) **Critical use items:** Medical devices enter sterile tissues or vascular spaces and hence carry a significant risk of infection if contaminated. Processing for reusing of these items requires sterilization.
(2) **Semi-critical use items:** Medical devices come into contact with mucous membranes and do not ordinarily penetrate sterile tissue. Processing for reusing these items requires at least HLD.
(3) **Non-critical items:** Medical devices that do not ordinarily touch the patient or touch only intact skin. These items can be cleaned using low-level disinfection.

When sterilization is required, in addition to the standard endoscope reprocessing, five additional procedures are required to process high-risk endoscopes to minimize the risk of infection in patients.

(1) Detachable distal endcaps may reduce bacterial contamination by allowing better access to the elevator for cleaning and reprocessing (Fig. 3B).[30,31] The forceps elevator must be raised and lowered at least three times at the point of use treatment while continuing the immersion and the aspiration (Fig. 3).[7,30]
(2) To ensure that elevator wire channel is thoroughly cleaned, the washing tube must be connected to the elevator channel plug following the manufacturer's IFU during function control at the point of use treatment (Fig. 2B).[32]
(3) For those complex components with an elevator and recess groove, visual inspection under lighted magnification has been suggested[1,7,18]
(4) Traditional endoscope reprocessing methods using HLD may not effectively disinfect duodenoscopes with complex elevator designs. AORN, ASGE, and the FDA recommended that endoscopy units could use at least one supplemental measure to HLD in the reprocessing of duodenoscopes, such as liquid chemical sterilization, ethylene oxide sterilization, or double HLD.[7,10,33]

However, studies of double HLD have demonstrated no reduction of the contamination rate of duodenoscopes.[34–36] This issue remains challenging and requires further investigation. With the infection risk that endoscopes present to the patient, sterilization is the preferred method of microbial inactivation and the only option for instruments to be used in "critical" uses entering sterile body cavities, tissues, or vascular spaces. Please follow the details described in the section of 2.1, High-risk endoscopes and section of 2.2, Potential advanced reprocessing measures GI endoscopes.

Table 1 Spaulding classification system for GI endoscopes and accessories.

	Type of medical devices	Infection risk classification
(1)	Critical items	1. Endoscopic accessories that enter the blood vessels or tissues and penetrate mucosal barriers when used. 2. These items need to be sterilized and cannot be reused after single used, such as injection needles and others. 3. Reusable endoscopic accessories (according to the manufacturer's instructions for use), need to be sterilized, such as biopsy forceps and others. 4. High-risk endoscopes could be reprocessed using ethylene oxide sterilization or liquid chemical sterilization.
(2)	Semi-critical items	1. Endoscopic accessories that contact damaged skin or mucosa during use, but do not enter the blood vessels or tissues. 2. High-level disinfection is required after use. 3. Reusable endoscopic accessories (according to the manufacturer's instructions for use), such as endoscope, mouthpiece, and others.
(3)	Non-critical items	1. Medical items that contact intact skin during use, but do not contact damaged skin or mucosa. 2. Low-level disinfection or cleaning is required after use. 3. Reusable medical items (according to the manufacturer's instructions for use), such as blood pressure cuff and others.

Abbreviations: Gastrointestinal, GI.

Table 2 Potential advanced reprocessing measures for GI endoscopes.

Potential advanced measures	Rational approach for disinfection or sterilization
Steam sterilization	1. GI flexible endoscopes are heat-labile instruments and cannot be autoclaved with high temperatures. 2. GI flexible endoscopes cannot underwent high temperature steam sterilization
Hydrogen peroxide sterilization	1. Hydrogen peroxide sterilization requires vapor filling the channel, contacting, and sterilizing exposed device surfaces. 2. Hydrogen peroxide vapor cannot effectively fill the long, narrow internal channels with bends of GI endoscope. 3. Hydrogen peroxide sterilization systems did not approved by GI endoscope manufacturer's IFU.
Ethylene oxide sterilization	1. Ethylene oxide sterilization is efficacious and compatible with GI flexible endoscopes. 2. Major drawbacks include long turnaround times, flammability, high toxicity, and carcinogenicity.
Liquid chemical sterilization	1. FDA has approved PAA as a liquid chemical sterilant. 2. PAA is the most practical solution for GI endoscopes sterilization. 3. PAA is a more powerful and more rapidly disinfecting agent compared to GA and OPA.
Double high-level disinfection	1. Double HLD consists of either a second cycle of HLD or repetition of the entire reprocessing procedure. 2. Extended reprocessing step for endoscopes stored longer than the recommended storage time.

Abbreviations: Gastrointestinal, GI; Food and Drug Administration, FDA; instructions for use, IFU; peracetic acid, PAA; glutaraldehyde, GA; orthophthalaldehydem, and OPA; high-level disinfection, HLD.

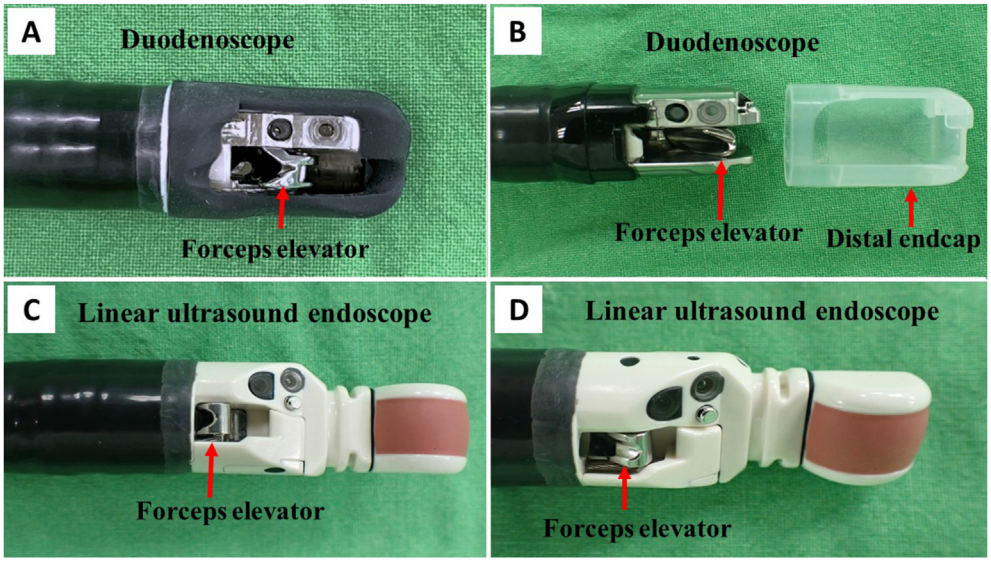

Figure 3. High-risk endoscopes with forceps elevator. (A) duodenoscope (Olympus TJF-260V); (B) duodenoscope (Olympus TJF-Q290V) with detachable distal endcap; (C) linear ultrasound endoscope (Olympus GF-UCT260) with raised and (D) lowered the forceps elevator.

(5) For high-risk endoscopes, storage time is recommended to be less than three days.

High-risk endoscopes

High-risk endoscopes, including duodenoscopes and linear ultrasound endoscopes, have a complex elevator designs (Fig. 3). According to AAMI (Association for the Advancement of Medical Instrumentation) guidelines updated in 2021,[7] considering the infection risk that endoscopes pose to the patient, sterilization is the preferred method for microbial inactivation and the only option for instruments to be used in "critical" uses entering sterile body cavities, tissues, or vascular spaces. Please follow the details described in the section of 2, Medical Devices and Spaulding classification system.[7]

Potential advanced reprocessing measures for GI endoscopes (Table 2)

Steam sterilization

GI flexible endoscopes are heat-labile instruments and cannot be autoclaved at high temperatures. GI flexible endoscopes cannot undergo high-temperature steam sterilization.

Hydrogen peroxide sterilization systems

The hydrogen peroxide sterilization process involves filling the sterilizer chamber with hydrogen peroxide vapor, which comes into contact with and sterilizes the exposed surfaces of the device. Hydrogen peroxide vapor cannot effectively reach the long, narrow internal channels with bends of GI endoscope. Therefore, GI flexible endoscopes are not compatible with hydrogen peroxide sterilization.[36,37] Hydrogen peroxide and hydrogen peroxide-ozone sterilization systems, are not approved by the current GI endoscope manufacturer's IFU.

Double high-level disinfection

Double HLD consists of either a second cycle of HLD or a repetition of the entire reprocessing procedure.[34—36] AAMI and ASGE did not provide clear definition of double HLD.[7,10] What kind of disinfection agents should be used during double DLD? When is the optimal time to perform the second cycle of HLD? Should the second cycle of HLD be conducted immediate after the first cycle of HLD or in the morning before use on the next patient? The varying concepts of definition makes it difficult to compare between these studies.

For contaminated endoscopes that have undergone point of use treatment, manual cleaning, followed by HLD reprocessing, and were stored in the storage cabinet. If they have been stored longer than the recommended storage time, the second cycle of HLD should be performed in the morning before use on the next patient. Please follow the details described in the section of 1.4, Storage.[1,7,10,28,29]

Ethylene oxide sterilization

Ethylene oxide sterilization is recommended to eliminate microorganisms and spores.[34,35] Global guidelines have recommended the use of ethylene oxide sterilization for endoscopes.[7,23] Among the currently available sterilization methods, only ethylene oxide sterilization is both effective and compatible with GI flexible endoscopes.[10] However, contact with ethylene oxide in liquid or gas form is toxic and can lead to serious eye irritation, a sore throat, difficulty breathing, blurred vision, and an increased risk of cancer.[7,10,33] Ethylene oxide sterilization requires a lengthy aeration period of 8—12 h. Additionally, ethylene oxide can trigger an explosive chain reaction with potentially severe risks. Major drawbacks of ethylene oxide sterilization includes high toxicity, long turnaround times, and flammability.[10]

Contaminated endoscopes should undergo point of use treatment, manual cleaning, and followed by HLD. Ethylene oxide sterilization must be performed after HLD. Endoscopes must be placed in disinfection bags or containers with internal indicators inside. Temperature and time of sterilization should be documented and adherent to the manufacturer's IFU.

Peracetic acid (PAA)

PAA is a colorless liquid with a strong, pungent acrid odor.[38] It is a mixture of acetic acid and hydrogen peroxide. PAA has a wide antimicrobial spectrum against bacteria, bacterial spores, fungi, and viruses and effectively at removes contaminants from GI endoscopes. The antimicrobial activity of PAA during endoscope reprocessing varies depending on its concentration, temperature, and exposure time.[7] PAA has demonstrated more rapid bactericidal effects than OPA or GA against *S. aureus* and *Pseudomonas aeruginosa* biofilms, which are associated with endoscopy-related infections.[26] PAA is a more potent and faster-acting disinfecting compared to GA and OPA (Table 2). The Food and Drug Administration has approved PAA products as high-level disinfectants or liquid chemical sterilants according to the manufacturer's IFU.*7, 20* Minimum effective concentration (MEC), temperature, and exposure time of PAA should be adherent to the manufacturer's IFU.

PAA degrades into acetic acid and readily biodegradable in water, making it environmentally friendly and providing a safer alternative to GA or OPA for endoscopy staff.[26] PAA products are aqueous solutions containing stabilizers and various ingredients. Commercial PAA are presented as single-use or reusable products, aqueous solutions, or packages in the AER. PAA is a highly corrosive. Long term PAA exposure may corrode the metallic components of endoscopes. PAA contact can irritate and burn the *skin* and *eyes*. Thus, products safety warnings and instructions must be adhered to the manufacturer's IFU.[39,40]

Reprocessing of endoscope accessories

Single-use accessories cannot to be reused. Reusable accessories must be disinfected or sterilized according to the manufacturer's IFU.[20]

Water bottle and water bottle accessories

Water bottles should be filled before use with sterile or distilled water to the specified water level marks (Fig. 4). Water bottles and water bottle accessories should be regularly subjected to HLD or steam sterilization[7,41—43] They are reprocessed in 2 steps: (1) manual cleaning and (2) HLD or steam sterilization.

(1) Manual cleaning

The water bottle (lid, water tube, O-ring, container, and container protector) and water bottle tubes (cleaning cap and metal tip) should be placed under running water. A cleaning cap must be attached to the metal tip, the syringe must be filled with tap water, and water bottle tube should be rinsed. A syringe was used to inject a large amount of air to dry the interior of the water bottle tube. A clean treatment towel or gauze was used to dry the water bottle and water bottle accessories.

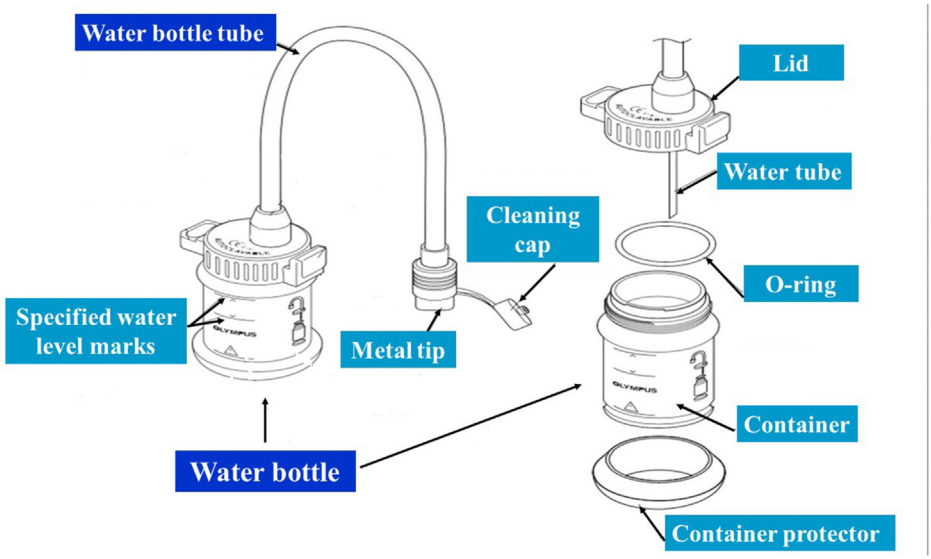

Figure 4. Water bottle and water bottle accessories. This picture is used with courtesy of Olympus.

(2) High-level disinfection or steam sterilization

After manual cleaning, water bottle and water bottle accessories were soaked in a high-level disinfectant. The metal tip must be attached the cleaning cap, and a high-level disinfectant must be injected into the water bottle tube. After removing all the air, cleaning cap opened. After soaking the water bottle in a high-level disinfecting solution, it must be thoroughly rinsed. Finally, a syringe was used to inject a large amount of air to dry the interior of the water bottle tube. Sterile towel or gauze was used to dry the water bottle and water bottle accessories. The steam sterilization step must be performed according to the manufacturer's IFU.

Auxiliary water channel and related accessories

The reprocessing of auxiliary water channels and related accessories (Fig. 5) should follow the manufacturer's IFU. After the endoscopic procedure, auxiliary water channel was flushed with clean water.[32] A syringe or automatic flushing system was used to flush the auxiliary water channel with detergent and water, followed by air in the reprocessing room.[32] The automatic reprocessing must follow the manufacturer's IFU. During storage, the auxiliary water inlet cap must not be in place, and the auxiliary water channel must be kept unlocked.[32]

Quality control and documentation

For all endoscopic reprocessing procedures, reprocessing methods, reprocessing equipment, and patient identifiers should be documented and maintained. Tracking is essential in the event of a disinfection failure and for responding to patient, endoscope, accessory, or product recalls.

Visual inspection, cleaning verification, and microbial culture

Visual inspection must be performed at the point of use treatment, and immediately after manual cleaning. Lighted magnification is suggested for the visual inspection of the complex endoscope components with an elevator and surrounding recess.[1,7,18] To ensure the effectiveness of the manual cleaning, the cleanliness of the endoscope should be regular verified using tests for adenosine triphosphate (ATP), residual protein, hemoglobin, or carbohydrates.[7,18,20] After reprocessing the endoscope, a borescope can be used to check for any remaining contaminants or damage to the channel.[7,15] Regularly performing microbial culture surveillance can help to monitor the quality of endoscope reprocessing.[2,7,20] Surveillance cultures can be considered as the affirmation of the overall endoscope reprocessing. The culturing of endoscopes every month is recommended by the Taiwan reprocessing guidelines.[14,20]

Documentation

(1) High-level disinfectants: Each MEC of disinfectant should be recorded before the disinfection process.[1]
(2) Endoscope and reprocessing equipment: Preventive maintenance and repair of the endoscope and reprocessing equipment should followed the manufacturer's IFU.[7]
(3) Endoscopy procedure: A record for each endoscopy procedure, including the time of endoscopy procedure, the point of use treatment completion time, storage time, patient's name, and medical record number.[1,7]
(4) Quality control: Keeping all the documentation is essential for both tracking and assessing of the

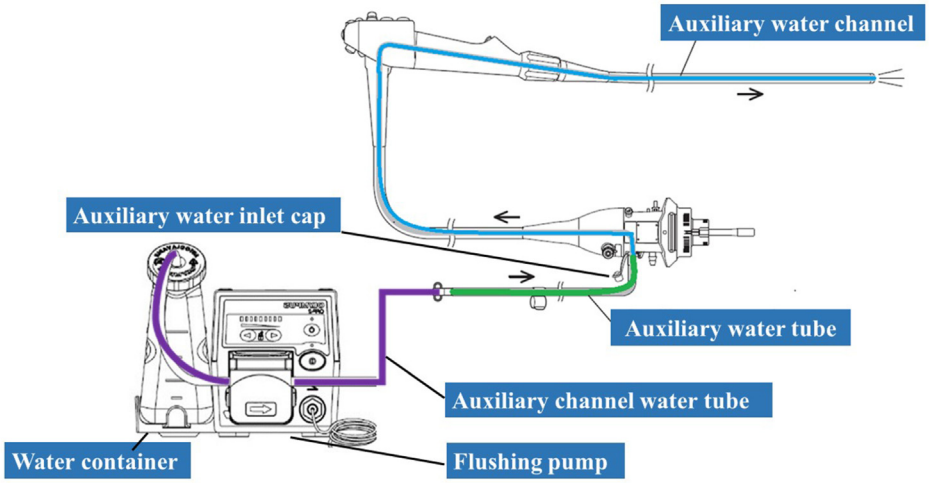

Figure 5. Auxiliary water channel and accessories. This picture is used with courtesy of Olympus.

reliability and safety of endoscope reprocessing. The documentation should be reviewed regularly to *improve the performance of the* endoscopy staff.[1,7]

Special endoscope reprocessing

Simethicone

Simethicone is commonly administrated to reduce the gas bubbles during endoscopy. Standard reprocessing protocols may not effectively remove simethicone from the working channels,[6,44,45] which can lead to increased bioburden and biofilm formation, as well as crystal deposits that may occlude the endoscopic lumens.[6,44] Endoscopy manufacturers, such as Olympus, Fujifilm and Pentax, discourage the use of simethicone.[46–48]

The American Society for Gastrointestinal Endoscopy guidelines suggests the use of the lowest concentration (0.5 mL simethicone in 99.5 mL water; 0.5 % v/v; 10 mg/100 mL) and the smallest volume of simethicone if required to be administered through the endoscope working channel, rather than a water bottle/irrigation jet channel.[1,6,45,49]

Figurer 6. Delayed reprocessing.

Delayed reprocessing

When manual cleaning of an endoscope is delayed for ≥1 h after the point of use treatment a delayed reprocessing protocol should be performed (Fig. 6). The protocol for delayed endoscopic reprocessing includes leak testing and presoaking the endoscope in an enzymatic detergent, flushing all channels with detergent, and manually cleaning the endoscope before HLD.[1,7,18]

Workflow of the endoscopy unit

The design workflow of the endoscopy unit should consider infection control, patient privacy, and employee safety (Fig. 7). The endoscopy unit must be divided into clean zones and contaminated zones. The clean zones include the patient reception, preparation, recovery room, and storage rooms. The contaminated zones include the endoscopy procedure room and reprocessing rooms.

The design workflow of the endoscopy unit must follow the following principles: (1) Three independent circulation routes for endoscopes, inpatients, and outpatients should be designed. Patient paths should be arranged in a way that avoids overlap or result in conflicts with the movement pattern of the staff.[50,51] To control of infections, reduce stress, and enhance patient privacy and dignity, outpatients and inpatients should follow separate paths into the procedure room; (2) Reprocessing rooms should be designed to facilitate a "one-way" flow pattern from the contaminated area of the room toward the clean area to prevent potential cross-contamination. The entire endoscope reprocessing should take place in a designated cleaning room physically separated from the procedure room and storage room[7,10]; (3) The three circulation routes should progress in one direction; and (4) Three circulation routes should not exhibit crossover or overlapping points.[20,52]

Personal protective equipment (PPE)

PPE is intended for healthcare personnel performing reprocessing or physicians who are performing endoscopy. PPE is crucial as it is the ultimate line of defense against infections. The person in charge of the endoscopy unit

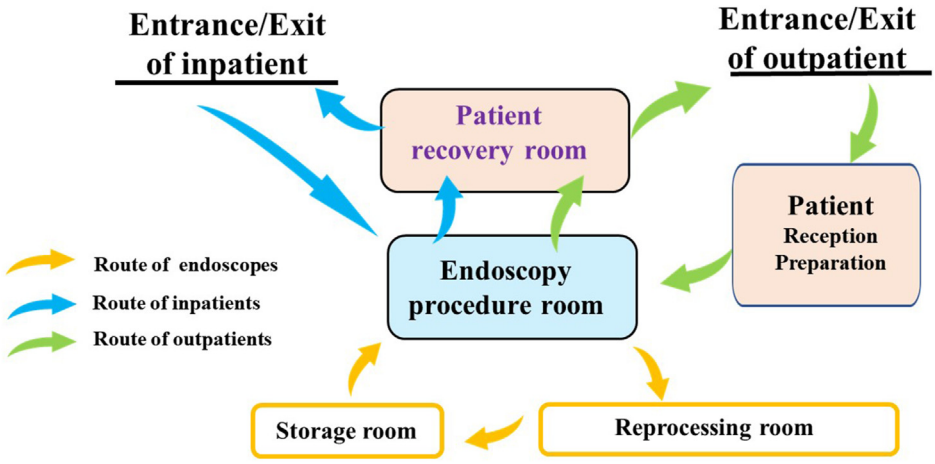

Figure 7. Workflow of the endoscopy unit.

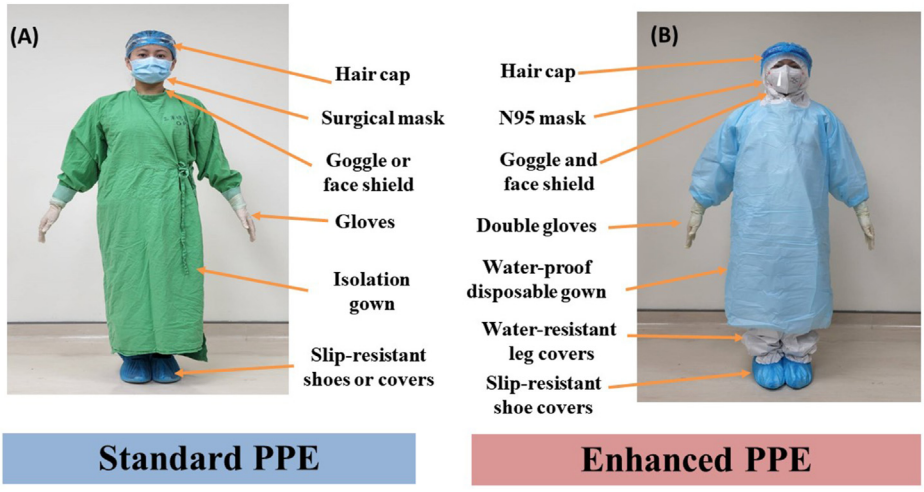

Figure 8. Personal protective equipment (PPE).

should provide a sufficient supply and reserve of PPE. Health care providers in endoscopy units should understand the appropriate methods for donning and doffing PPE (Fig. 8).

(1) Standard personal protective equipment

Endoscope reprocessing need to be performed by staff wearing appropriate standard PPE, including a hair cap, surgical mask, goggles or a face shield, gloves, and an isolation gown with fully covered arms that is long enough and of sufficient thickness and durability (Fig. 8A).[20] To prevent slips and falls, slip-resistant work shoes or slip-resistant disposable shoe covers are recommended.

(2) Enhanced personal protective equipment

When performing endoscopy procedures on patients at high-risk of infection transmission, especially through spreading via an airborne route, enhanced PPE must include hair cap, goggle and face shield, N95 mask, double gloves, water-proof disposable isolation gown, water-resistant leg covers, and slip-resistant disposable shoe covers (Fig. 8B).[20,53–55]

Conclusions

Endoscope reprocessing guidelines were compiled based on existing global and local guidelines to provide standards for endoscope reprocessing. The updated guidelines were established after a thorough review of existing guidelines, systematic reviews, and novel reprocessing technology assessments, and reaching a consensus between DEST task force members. Compliance with these guideline will minimize the risk of transmission of endoscopy-related infection and ensure adequate quality control in endoscopy units.

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Conflicts of interest

All authors declare that they have no relevant conflicts of interest related to this article.

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