PENTAX® MEDICAL

WHITE PAPER: AUTOMATED PRE-CLEANING OF ENDOSCOPES

Optimized pre-cleaning of flexible endoscopes through a new innovative technology

Paul J Caesar, Mihaela Cirisan

Optimized pre-cleaning of flexible endoscopes through a new innovative technology

Paul J Caesar, Mihaela Cirisan

Guidelines and standards on reprocessing reusable flexible endoscopes (RFES) have included statements and recommendations on cleaning of these devices after examination and before high-level disinfection. However, most of these guidelines and recommendations do not address new innovative technologies and improvements related to the cleaning of reusable flexible endoscopes.

PURPOSE

This white paper on optimized pre-cleaning of reusable flexible endoscopes provides in the first part an overview of the currently used methods and processes for endoscope pre-cleaning, including the outcomes of recent studies. Then, in the second part, it gives a comprehensive description of the innovative technology employed in this new automated process, pointing-out the benefits of this process compared to the currently used manual method, in terms of risk reduction, workflow and productivity improvement, as well as in terms of contribution to sustainability. This overview is intended to healthcare facilities and entities who are involved in updating guidelines, national or local protocols and quality documents related to endoscope reprocessing.

INTRODUCTION

Most of reusable flexible endoscopes, have delicate designs with long and/or narrow channels, inlets and valves which can become heavily contaminated with the patient's microbial flora during the procedure. Endoscope reprocessing is needed to decontaminate flexible endoscopes for subsequent reuse, starting with a meticulous pre-cleaning, followed by high-level disinfection and ending with drying and storage. Endoscope reprocessing is often known as a complex process and deviations to the process may result in transmissions of exogenous bacteria and possibly lead to infections. These so-called **endoscopy associated infections** have become issues of high attention since first outbreaks of multi-drug resistant bacteria occurred some years ago.

To prevent transmission of exogenous bacteria, single-use duodenoscopes, cystoscopes and bronchoscopes were introduced. Semi-reusable duodenoscopes with a disposable end cap, were also introduced, like PENTAX Medical's ED34-i10T2 DEC™ duodenoscope and the Slim DEC™ duodenoscope. The design of the distal end and use of the disposable elevator cap improves the ability to clean the distal end.

Despite the introduction of these innovations on the market, fully reusable flexible endoscopes are still most commonly used in daily endoscopy practice, and related reprocessing is needed.

The distal end of the ED34-i10T2 with the single-use distal end cap (PENTAX Medical)

ENDOSCOPE REPROCESSING

During an endoscopy procedure, the outer surface and inner channels of the endoscope may be contaminated with patient's microbial flora and soil, composed of proteins, fats, carbohydrates, and various chemical salts from blood and other body fluids. The endoscope reprocessing procedure is intended to ensure that reusable flexible endoscopes are thoroughly cleaned from the mentioned contaminations, disinfected and dried before being used on the subsequent patient. Thus, endoscope reprocessing is meant to reduce the risk of infection to ensure patient safety.

All well-known guidelines, like CDC, BSG, WGO and GESA, recommend endoscope reprocessing to consist of a bedside cleaning in the procedure room, manual pre-cleaning (preceded by a leak test) in the reprocessing area, followed by automated cleaning and high-level disinfection in an automated endoscope reprocessor (AER), and finally drying.[1),2),3),4)] This means even when an AER is used, manual pre-cleaning is still necessary.[5)]

After this process and after storage in a clean, dry and dust-free environment, the endoscope can be used for the next procedure.

Once the endoscopy procedure is completed, it is important to prevent the soil, being retained on and in the endoscope, from drying and hardening, as this will hinder next steps in reprocessing. As it is impossible to high-level disinfect endoscopes which are not thoroughly cleaned, cleaning is still regarded as the most important step of the reprocessing cycle.[6)]

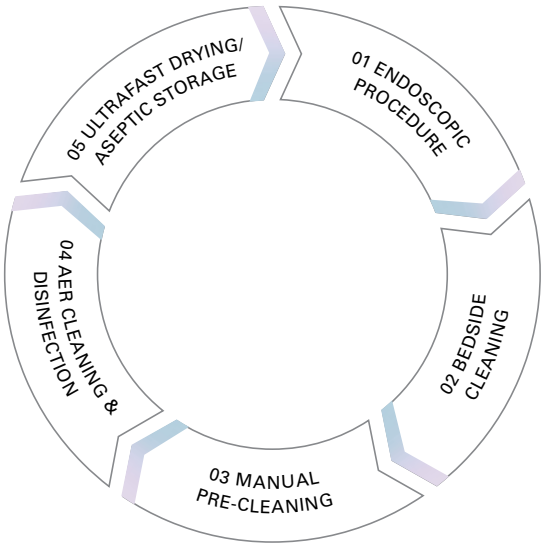
Two steps can be pointed out:

1. **Bedside cleaning** (or point of use cleaning or pre-cleaning) in the procedure room:

   Bedside cleaning refers to the removal of organic residues and gross contamination from the endoscope immediately after ending the endoscopy procedure.

2. **Manual pre-cleaning** in the reprocessing area:

   Manual pre-cleaning refers to all cleaning actions on the endoscope in the reprocessing unit before automated cleaning and high-level disinfection in an AER or before manual cleaning and high-level disinfection.



Endoscope reprocessing cycle

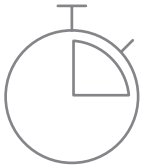
Bedside cleaning

As there may be discussions on when the reprocessing of flexible endoscopes begins, reprocessing starts already at the point of use, the examination room, with the bedside cleaning. This step should start immediately after finishing the endoscopic procedure. The purpose of bedside cleaning is to remove blood, body fluids and other organic soil, as well as gross contamination, from the endoscope before it dries, by wiping the external surface of the insertion tube and flushing the internal channels.[7)]

Many microorganisms can adhere to the surfaces of the endoscope and grow to produce a robust biofilm.[8)] A thoroughly bedside cleaning not only removes soil, but also reduces any build-up of microorganisms or growth of biofilms.[6)] Biofilm removal is essential as biofilm microorganisms are also more resistant to disinfectants.[8)] Allowing bioburden to dry on surfaces makes cleaning very difficult. It is recommended that microorganisms, protein or other materials not to be allowed to dry on flexible endoscopes before cleaning.[9)]

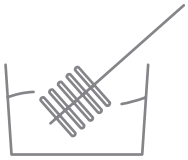
From these reasons, endoscopy nurses and other assisting staff should have knowledge and competency in reprocessing flexible endoscopes, and they should strictly comply with the cleaning steps written in the endoscope reprocessing instructions for use (rIFU).

Timely Transport



Timely and safely transport of the endoscope and its accessories from the procedure room to the reprocessing unit is important to prevent drying of remaining residues, prevent further biofilm formation and bioburden build up, and to minimize the risk of contamination for the staff.[6)] As centralization of the reprocessing is more commonly used practice, distance between the point of use and reprocessing area is increasing. This may have a negative impact on a timely transport and increased delay for starting the manual pre-cleaning.

Manual pre-cleaning



In order to prevent further drying and hardening of the soil, as well as prevent biofilm formation and bioburden build-up, manual pre-cleaning should start as soon as possible after the bedside cleaning. Therefore, it is important to follow the rIFU of the endoscope manufacturer and the national guidelines.[6)]

Manual pre-cleaning should be started within 30 minutes after finishing the bedside cleaning.[6)] Before starting the manual pre-cleaning, a leak test shall be performed to check the integrity of the endoscope. Only endoscopes that passed the leak test should be cleaned and reprocessed.

During manual pre-cleaning, the RFES is soaked in a detergent solution (prepared following manufacturer's instructions) and remaining residuals and gross contamination are removed by thoroughly manually brushing, flushing, wiping and rinsing the entire external surface and all inlets and internal channels of the endoscope. This means all outer surfaces of the endoscope are wiped with a clean, soft, lint-free disposable cloth, sponge or gauze. Difficult to reach areas, like in between the steering wheels, inlets and distal end are cleaned using a suitable brush.

Not all endoscope channels can be brushed. Brushable channels must be brushed using a suitable brush, inserted into and pulled through the channel as recommended in the rIFU of the endoscope. After each brush pull-through step, the brush should be inspected for visible debris. If debris is noticed, inlets or channels should be brushed again until no debris is visible anymore.

European guidelines recommend only the use of single-use brushes for each endoscope. This is intended to improve and standardize the cleaning quality, as frequently used reusable brushes may be damaged and cause damages to the endoscope.[6)] Even the reuse of single-use brushes may lead to improper cleaning of endoscope channels and inlets. On the other side, the use of single-use consumables for each reprocessed endoscope generates large amount of waste every day.[10)]

After brushing, all channels are filled with a detergent solution, mostly using syringes. Sometimes automatic flush pumps are used to pump the detergent solution through the endoscope channels. Nevertheless, submerging the entire endoscope in the detergent solution, and the process time as recommended per IFU of the detergent manufacturer must always be respected. Finally, the entire endoscope – including all channels – should be thoroughly flushed with a drinking quality water to remove all possible residual debris and detergent residuals. This is intended to improve the efficacy and quality of the next step in the reprocessing cycle.

Inexistent or unreliable traceability of the manual pre-cleaning is another issue characterizing this reprocessing step. In some cases, when for example automatic flush pumps are used, automatic traceability for the flushing step is provided. Nevertheless, due to the predominant manual aspect of the pre-cleaning process, one shall be aware of the human risk factor it carries.

Human factor impact

Depending on the brand and type of the endoscope, the above steps may vary significantly. Furthermore, although not addressed in the steps above, endoscopes come equipped with reusable and disposable accessories. Reprocessing staff must always identify the brand and type of the endoscope, in order to identify the specific steps and needed equipment to reprocess the endoscope, as well as reusable and disposable accessories to be used at the appropriate stages of the reprocessing procedure. While the importance of manual pre-cleaning has to be emphasized, one needs to be aware that it is also prone to human errors.

Despite endoscope design improvements and more detailed rIFUs, the human factor still has an impact on the quality of manual pre-cleaning. Therefore, only well educated, trained and competent staff should be in charge to clean and reprocess flexible endoscopes. Staff education shows to decrease the rate of endoscope contamination after high-level disinfection.[11)]

Healthcare facilities are responsible of ensuring that their staff is trained to perform reprocessing as intended by the manufacturer instructions.[7)] Finally, one shall not neglect the impact of the human variability factor on the quality of manual pre-cleaning, due to the fact that it is performed by different operators, having different experience, working habits, as well as work conditions in the reprocessing unit.

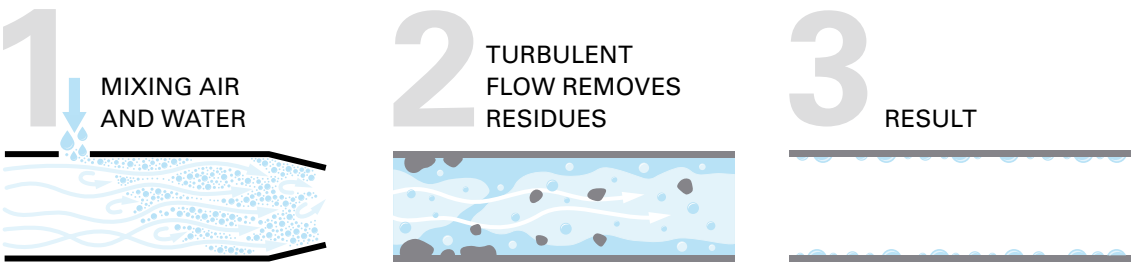
In addition, some other factors may have impact on reprocessing, especially the manual pre-cleaning step. One of the main issues may be the tension and expectations between the endoscopy ward management and the reprocessing or decontamination unit, leading to high turnover volumes of endoscopes. Time pressure and noncompliance with guidelines and occupational health problems related to reprocessing were reported by reprocessing staff.[6)] Speeding up the process due to these high volume loads may lead to increased errors.[11)] This may lead to shortening or skipping steps in the manual reprocessing procedure, and finally lead to a less effective reprocessing result. Recently, **Chen et al** also found the human error was the most common cause of endoscope contamination. Identified insufficient scope brushing time, forgetting to brush one of the endoscope channels, and the use of inappropriate sized brushes, as well as other human errors are risk factors for endoscope contamination.[11)] **Hildebrand et al** even concluded that if errors are made during reprocessing, endoscopes may do more harm than good.[7)]

From this point of view, automation of manual pre-cleaning could reduce the human error factor and result in a more effective endoscope reprocessing process, thus reducing the risk of infection and enhancing patient safety.

NOVEL TECHNIQUES FOR PRE-CLEANING OF FLEXIBLE ENDOSCOPES

Being aware of the above mentioned drawbacks of the manual methods currently used for flexible endoscopes pre-cleaning, manufacturers of medical devices are working on the development of new solutions based on innovative technologies to fulfill this market need.

For example, recently a novel technique was introduced as an alternative solution to the manual pre-cleaning of flexible endoscopes: the AquaTYPHOON™ system. Developed and manufactured by PlasmaBiotics and placed on the market by PENTAX Medical, this innovative solution offers fully automated brushless pre-cleaning of all endoscope channels, including the non-brushable ones, in just 2 to 7 minutes depending on the endoscope type. This process is based on a pending patent brushless technology using only air and water to effectively remove the residues from endoscope channels.[12)] Water is introduced in a pulsed manner into the turbulent flow of the medical air, which then disperses the water into millions of tiny droplets and accelerates them to up to 200 km/h. This highly turbulent two-phase fluid flow creates a strong shear stress that enables elimination of residuals from the endoscope channels walls.



In the AquaTYPHOON, water is introduced in a pulsed manner into the turbulent flow of medical air.

In the endoscope, highly turbulent two-phase fluid flow creates a strong shear stress that eliminates residues from the channel walls.

Afterwards, the endoscope channel is free of residues.

AquaTYPHOON system

AquaTYPHOON system in operation in the reprocessing unit

This small desktop system is intended to be placed next to a sink in the reprocessing unit, where the pre-cleaning of the endoscope can be performed, before placing the endoscope in the AER for further cleaning and disinfection.

In addition, AquaTYPHOON™ offers an integrated leak-test, as well as AquaJET™ – water pistol intended for external cleaning of the endoscope, including the distal end.

Finally, in order to protect the operator and surrounding environment from splashing with contaminated water, the AquaBOX™ can be used. Placed in the sink, AquaBOX™ enables for the entire process to be performed in the confined environment, thus contributing to the comfort and safety of the reprocessing staff.

AquaTYPHOON system with AquaBOX and peripheral devices

Automation as key in pre-cleaning

Due to the fact that the AquaTYPHOON™ system is an automated device, the pre-cleaning process is fully standardized, reproducible and controlled, via integrated build-in validation and security systems, thus preventing human errors. Leak-test and cleaning of endoscope channels are fully automated. The only remaining manual aspect refers to external cleaning of the endoscope and connection of the endoscope to the AquaTYPHOON™ device. In addition, full traceability of the process is ensured thanks to the provided peripheral devices (barcode or RFID scanner, printer).

The AquaTYPHOON™ process is designed in an intuitive way, to guide the user though the entire pre-cleaning procedure. Clear step-by-step instructions displayed on the screen eliminate the need for users to remember every detail of each step, requiring knowledge to be maintained in their memory, thus strongly minimizing risks based on individual cognitive properties. Finally, automation of the pre-cleaning process also enables to reduce the labour time necessary for the staff to complete this step of the reprocessing cycle.[12)]

Automation of the pre-cleaning process ensures standardized, controlled and effective pre-cleaning of flexible endoscopes, preventing human errors, thus reducing the risk of infection and enhancing patient safety.

Contribution to sustainability

Sustainability is a significant topic worldwide nowadays. As stated by L. Donnelly[10)] in his article: "In healthcare, endoscopy is a major contributor to the environmental footprint - generating around 3.09 kg of waste per bed day." Due to this, "There is a necessity for endoscopy services as a specialty to lead the way in creating more sustainable departments. It is important we seek to explore and implement practical measures to ensure endoscopy services are working to meet our sustainability goals."[10)]

Compared to manual pre-cleaning, AquaTYPHOON™ provides significant contribution to sustainability by eliminating the use of single-use consumables, like brushes, syringes, sponges or wipes, as well as by eliminating the use of detergent. In this manner, the quantity of waste generated during the pre-cleaning process is largely reduced (more than 99%, not taking into account the personal protective equipment).[12)] In addition, AquaTYPHOON™ enables to reduce water consumption by 70% to 90% compared to the manual pre-cleaning.[12)] All this may lead to reduction of the environmental footprint of the endoscopy reprocessing department, as well as to reduction of the costs of a reprocessing cycle.

70-90%
LESS WATER

compared to manual pre-cleaning

CONCLUSION

In this time of increasing awareness of patient safety, but also of the need to preserve our planet, manufacturers also have the responsibility to develop, design, and create solutions in order to ensure and achieve these goals.

With the AquaTYPHOON™ system, the innovative solution provided by PENTAX Medical, for fast and effective brushless pre-cleaning of endoscope channels as alternative to manual pre-cleaning, enhanced safety for endoscopy patients can be guaranteed.

At the same time, the AquaTYPHOON™ system is a fully sustainable and economical solution, enabling for significant reduction of the waste generation, as well as water consumption, compared to the traditional manual pre-cleaning method.

REFERENCES

1) CDC Essential Elements of a Reprocessing Program for Flexible Endoscopes – Recommendations of the Healthcare Infection Control Practices Advisory Committee. June 28, 2017.
2) British Society of Gastroenterology Endoscopy Section Committee Working Party on Decontamination of Equipment for Gastrointestinal Endoscopy. BSG Guidance on Decontamination of Equipment for Gastrointestinal Endoscopy. June 2020
3) World Gastroenterology Organisation. Endoscope disinfection update: a guide to resource-sensitive reprocessing. April 2019.
4) Devereaux BM, Jones D, Wardle E, on behalf of the Infection Control in Endoscopy Committee. Infection Prevention and Control in Endoscopy 2021. Melbourne: Gastroenterological Society of Australia, 2021.
5) FDA Executive Summary. Reducing the Risk of Infection from Reprocessed Duodenoscopes. November 2019. P27.
6) Beilenhoff Ulrike et al. Reprocessing in GI endoscopy: ESGE–ESGENA Position Statement – Update 2018 … Endoscopy 2018; 50
7) Hildebrand et al. The Human Factors of Reprocessing Reusable Medical Equipment
8) Mariscal A, Carnero-Varo M, Gutierrez-Bedmar M et al. A fluorescent method for assessing the antimicrobial efficacy of disinfectant against Escherichia coli ATCC 35218 biofilm. Appl Microbiol Biotechnol (2007) 77:233–240
9) Merritt K, Hitchins VM, Brown SA. Safety and cleaning of medical materials and devices. J Biomed Mater Res. 2000;53(2):131-136
10) Donnelly L., Green endoscopy: practical implementation, Frontline Gastroenterology 2022; 13: e7-e12
11) Chen SH, Liu T, Lai HW et al. Monthly endoscopy surveillance culture facilitates detection of breaches in the scope reprocessing procedure: 5-year experience in an endoscopy center Adv Dig Med. 2020;1–9)
12) AquaTYPHOON Verification and Validation Overview, PlasmaBiotics, 2023.

Distributor
PENTAX Europe GmbH
Julius-Vosseler-Straße 104, 22527 Hamburg, Germany
T +49 (0)40 561 92-0 • F +49 (0)40 561 92-247
info.emea@pentaxmedical.com • www.pentaxmedical.com

Manufacturer
PlasmaBiotics SAS
116 Quai de Bezons, 95100 Argenteuil, France
T +33 (0)1 30 25 96 76
support@plasmabiotics.com • plasmabiotics.com

PENTAX® MEDICAL

MKHYG-4049EN-G Rev 2 (v2.0)