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White Paper: Endoscope Drying and Storage

Safe drying and storage of flexible endoscopes through a new innovative technology

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PURPOSE

Guidelines and standards on reprocessing flexible endoscopes have included statements and recommendations on drying and storage of these devices. However, most of these guidelines and standards do not address the latest technologies available such as horizontal drying and storage.

With this white paper on drying and storage of flexible endoscopes we provided a document that could be useful for those who are involved in adapting new and proven techniques, but also for those who are involved in updating guidelines or other national or local protocols and quality documents.

INTRODUCTION

"Inadequate drying and storage procedures, together with inadequate cleaning and disinfection, are the most important sources of endoscope contamination and post-endoscopic infection"

Flexible endoscopes (FES) are still reusable devices. During their use, they can become heavily contaminated with the patient's microbial flora. Therefore, meticulous cleaning and high-level disinfection is needed to guarantee a clean and safe use on subsequent patients.

This cleaning and disinfection consists of several steps, starting with a bedside cleaning directly after use, followed by a manual pre-cleaning, then a manual cleaning and disinfection, or an automated cleaning and disinfection using a Washer Disinfector (WD). Cleaning and disinfection in Automated Endoscope Reprocessor (AER) or WD is preferred because it is a controlled, validated, and reproducible process. After cleaning, disinfection, and essential final rinsing steps, the FES is still wet.

When FES are not dried appropriately, microorganisms can proliferate due to residual moisture and represent a source of infection for subsequent examined patients. [1, 2] Such a wet condition also promotes biofilm development, which can result in failures in the reprocessing process. [3] Inadequate drying and storage procedures, together with inadequate cleaning and disinfection, are the most important sources of endoscope contamination and post-endoscopic infection. [2] Several outbreaks of Pseudomonas aeruginosa, Klebsiella pneumonia, Acinetobacter spp, and other pathogens have also been caused by insufficient drying. [2, 3, 4, 5] This addresses the sense of urgency for ensuring endoscope dryness and a clean, dry, dust-free storage of these devices. [2, 6, 7]

This document presents a summary of the current recommendations on drying and storage of flexible endoscopes, and highlights a novel technique for drying and storage of flexible endoscopes.

Conventional drying and storage

It is clear that the aim of drying FES is to expel excess fluid or moisture before use on the patient or storage to exclude any risks of the development of biofilm and growth of microorganisms. [1, 2, 3, 4, 5, 6, 7] However, even in guidelines there is a different view on this. While some guidelines state that drying the endoscope after every reprocessing cycle, both between patient procedures and before storage, is crucial, other guidelines state that inadequately or incompletely dried FES can be used for patient procedures if used immediately or within a few hours of reprocessing. [4, 8, 9, 10, 11, 12, 13, 14] It seems that arguments for this are often based on local circumstances, including logistic, organizational, and financial arguments. Table 1 highlights some recommendations on this topic.

In 2019, the ECRI Institute (formerly the Emergency Care Research Institute) recommended purging endoscope channels with clean air at the end of the reprocessing process. [15]

Guideline or guidance	Recommendation
Public Health Canada [2011]	Alcohol rinse and drying is not needed if scope is used immediately on another patient, unless the final rinse was with unfiltered tap water.
Ministère des affaires sociales et de la santé [2016]	If the endoscope is not used immediately, it should be dried with medical air.
SGNA [2016]	An endoscope that is not dry must be reprocessed before use.
GOV UK [2016]	If more than 3 hours elapses between decontamination and use of an endoscope, bacterial growth may occur; therefore, the endoscope should be decontaminated before it is reused.
CDC [2017]	After reprocessing is complete, store endoscopes and accessories in a manner that prevents recontamination, protects the equipment from damage, and promotes drying.
ESGENA [2018]	If the endoscope is to be used for the next patient examination within a short period of time [not specified], removal only of major water residues from the endoscope channels and outer surfaces will be sufficient.
WGO / WEO [2019]	The endoscope may be used on another patient after an initial forced-air drying, but it must be placed in the storage cabinet if not immediately used for another patient procedure.
ECRI [2019]	Purge endoscope channels with clean air at the end of the reprocessing process.
SFERD [2019]	It is preferred to dry the endoscope after disinfection and before use. If the endoscope is intended to be used within 4 hours of disinfection, drying is not necessary.

Table 1

FES drying methods

Drying of FES can be performed in the AER or WD, if the AER or WD has a program for drying. The effectiveness of drying using this method can vary and depends on the time and temperature of the drying cycle. As known from practice, drying cycles in AERs or WDs are often not used because they lengthen the AER or WD reprocessing time, often regarded as less effective and efficient on the total capacity of AER or WDs, volume, and turnover of FES.

The other way of drying, after reprocessing, is drying the exterior surface of the FES with a soft, lint-free cloth, gauze, or sponge, or by using an air gun and drying the endoscope channels and external parts with qualified medical air. To prevent any damage of or in the channels of the FES, it is important that the air used has the correct temperature and pressure. The tip of the air gun should not touch any part of the FES because there could be a risk of contamination. [13] Due to the complexity of the Endoscope channels with different diameters and lengths that lead to different pressure drops, and the fact that some of them are interconnected, drying with an air gun cannot be effective and reproducible.

In some guidelines flushing the endoscope channels with 70–90 % ethyl or isopropyl alcohol is recommended to expel fluid more rapidly and promote drying, whether drying is performed as described or further drying and/or storage is performed in special drying and/or storage cabinets. [16, 17] However, other guidelines do not recommend such alcohol flushes because of the fixative characteristics of alcohol on proteins. [4, 10]

"The use of drying cabinets has increased over the past few years, mainly because the use of these cabinets is recommended in almost all recent guidelines on FES reprocessing"

Vertical drying in drying cabinets

The use of drying cabinets has increased over the past few years, mainly because the use of these cabinets – often combined with a storage function – is recommended in almost all recent guidelines on FES reprocessing, based on many studies and publications. [4] A drying cabinet is a specially designed cabinet that contains a forced air source and circulation and which is also connected directly to the FES channels to inject high-quality air into the channels. Compared to manual drying, drying cabinets are more efficient and effective because of the controlled conditions such as high-grade forced and filtered air, pressure, flow, temperature, and humidity and therefore validated and replicable conditions.

The drying time in a drying cabinet can vary between 30–90 minutes or even longer depending on the manufacturer's instructions for use (MIFU) and the endoscope type. In the most common drying cabinets the FES are placed and dried in a vertical position. Vertical drying is based on the theory that gravity in combination with (or even without if only storage is provided) airflow causes water to expel out of the endoscope channels. Many drying and/or storage cabinets are designed and constructed based on this principle.

That means their height, width, and depth must be sufficient to hang FES vertically in order to avoid the distal tip touching or curling up on the floor of the cabinet. [18] They should also hang freely to prevent damage from physical impact, for example, closing the doors of the cabinet and damaging the tip of the FES. [19] Incorrect handling of FES when placing them in or taking them out of the cabinet could also be a risk for recontamination of the FES or other stored FES. [15] Because water is dripping and blown out of the distal end of the FES, resulting in visible water residues on the bottom inside these cabinets, the bottom of the drying cabinet could also be a source of possible contamination. In some cabinets, pads or towels are placed on the floor to protect the endoscope tip or to collect moisture. These could also be a source of contamination. [18] Clean, disinfected FES should be prevented from contacting such potentially unclean surfaces. [15]

"Drying does not rely on gravity, and FES can also be dried and stored in a horizontal way"

Many guidelines on reprocessing FES still recommend vertical drying and storage of FES in the drying and/or storage cabinet. [1, 4, 7, 14, 18, 20] However, these recommendations are often based on outdated literature on drying related to coiling (1991, 1996, 1997, 2000, and 2008). [7] But as drying cabinets use controlled active drying with high-quality air and with a continuous pressure and flow, drying does not rely on gravity, and FES can also be dried and stored in a horizontal way. [9]

When FES are dried in a drying cabinet, by running the programmed and full drying cycle, they could also remain/be stored here until the next examination. If FES are not used frequently, it is also possible to store them in a storage cabinet. These are often designated, purpose-built cabinets with a door, to prevent recontamination or damage during storage. [1, 4, 7, 14] Most of these storage cabinets are designed to store FES vertically, as recommended by many guidelines, to also prevent coiling or kinking. [1, 4, 7, 14, 18, 20]

Horizontal storage is possible in cabinets that are specially designed and intended for horizontal storage by the manufacturer. [14] When using horizontal storage, directly in a cabinet or in a closed tray, FES are coiled. For this reason, FES should only be stored horizontally if there is a guarantee the FES is completely dry. If not completely dry, stagnation zones with residual moisture might develop in the coiled FES, resulting in biofilm formation and microbial growth. [1, 2, 4] Even when alternative storage systems are used, i.e. vacuum packing systems, it must be ensured that the entire FES is dry before packing and storage. [18]

The recommended storage interval of FES in drying and/or storage cabinets is still undefined/unclear. This storage interval (or shelf life or hang time) after which FES should be reprocessed before use varies mainly from 7 up to 31 days. [7, 8, 9, 17] The length of time may depend on multiple factors like the storage conditions, national guidelines, and the MIFUs for storage cabinets, sometimes combined with an organizational risk assessment that may include endoscope usage and turnover of FES used. [4, 14, 17]

Novel techniques for drying and storage

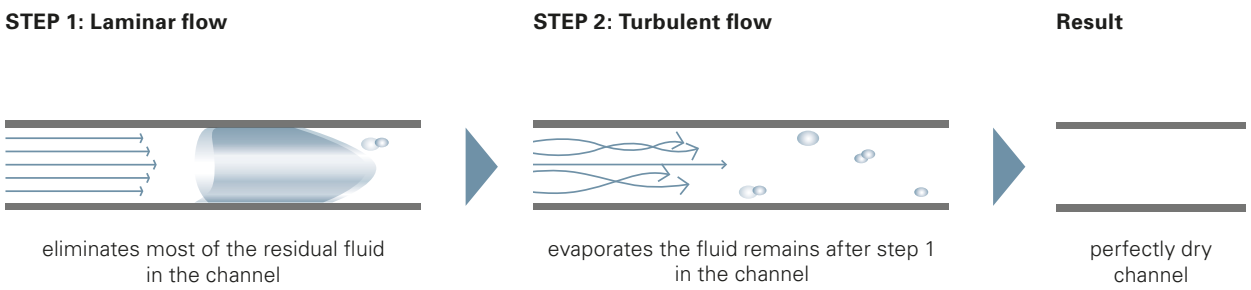
PlasmaTYPHOON and PlasmaBAG
For ultra-fast and complete drying as well as actively storing endoscopes

Even though conventional drying and storage of FES is still predominantly used, a few new initiatives and technologies, like Vac-A-Scope® (2011) or SureStore™ (2015), have been developed, but to date have not been widely accepted/used. Both systems are based on horizontal principles, vacuuming, and storage (Vac-A-Scope®) or hydrogen peroxide injection, vacuuming, and storage (SureStore™). Both systems provide a patient-ready packaged FES with a long shelf life. Depending on the system, shelf life can differ from only 6 hours for an undried but packed FES up to 30–100 days for a dried and packed FES. The SureStore™ system additionally uses a hydrogen peroxide (N-Sure™) to preserve the storage conditions.

Horizontal drying and storage of FES

In 2017, PlasmaBiotics® introduced a newly patented technique for drying and storage of FES, the PlasmaTYPHOON and PlasmaBAG, also based on a horizontal concept. The PlasmaTYPHOON is a small desktop device that creates a special airflow that completely dries even the narrowest channels in the FES in only 1.5 to 5 minutes depending on the endoscope type. The PlasmaTYPHOON device uses a two-step process, where firstly a laminar flow eliminates the water out of the channels without liquid fragmentation, and secondly a turbulent flow with heated medical air completely dries the humidity within the internal channel walls. After drying with the PlasmaTYPHOON, the FES is then disconnected from this device.

The FES is placed aseptic in a specially designed bag (PlasmaBAG) sealed and connected again to the PlasmaTYPHOON. Taking only 6 seconds, the bag is inflated with 4–6 ppm ozone. Ozone is a natural compound that is easily generated from oxygen or air. At this concentration, there are no disadvantages to materials or health hazards to people. Ozone gas is known for its anti-microbial and anti-viral properties and described as an effective means of decontamination for various hard and porous surfaces, in the presence and absence of cell debris and biological fluids. [21] With this unique combination, complete drying and storage of FES in a dry, clean, and dust-free environment provides an ideal solution for both the transport and storage of FES. FES dried, packed, and preserved in this way can be easily and effectively stored horizontally for up to 31 days (product validation reports). The PlasmaBAG also prevents the FES from contamination risks during storage and transport to the next examination.



Special airflow for complete drying

FUTURE OUTLOOK

Drying and storage is an integral part of the reprocessing process for FES. It could be performed in the AER or WD, manually or using drying cabinets by circulating and injecting air over and through the channels of the FES. The importance of drying during storage of FES was already recognized in 1983. [5] More recently published studies and guidelines have highlighted the need to completely dry FES. [2, 4, 6] The importance of drying FES channels is also clearly stated in the MIFUs of endoscope manufacturers.

"A few small drops of fluid were still noted in 42.6% of FES after reprocessing and drying using alcohol flushing followed by forced air drying for 10 minutes"

Risk of infection from incomplete drying

However, in a recent study, a few small drops of fluid were still noted in 42.6 % of FES after reprocessing and drying using alcohol flushing followed by forced air drying for 10 minutes. [22] This then allows the formation of a biofilm and microorganisms to propagate and represent a source of infection to the subsequently examined patient. [1, 2, 3, 4, 5] Of course, it may be clear that the effectiveness of drying depends on the drying cabinet or system used and thus depends on the MIFUs (based on international validation standards). Despite the known importance of drying, some guidelines still recommend skipping drying FES if they are intended to be used for the next patient examination immediately or in a short time period (3–4 hours) after reprocessing. [8, 10] This time interval seems to be based on the growing curve of microorganisms, but no studies are available on the proliferation of microorganisms during this time interval and the risk of introducing these to the next examined patient. This kind of incomplete drying can also increase biofilm formation. [2, 23] If the FES is not used within a short time interval (immediately or within a few hours) after reprocessing, it has to be reprocessed again before an expected use or before drying and storage.

The efficiency of vertical drying systems is questionable

It is assumed that this time interval for using incompletely dried FES (even after reprocessing) is mainly based on multiple organizational factors such as high-volume endoscopy schedules and endoscope usage, turnover of FES used, a limited footprint of the reprocessing department (m^2 floor space), and/or the available number of drying and/or storage cabinets.

Cabinets for vertical drying and storage of FES must have a sufficient height, width, and depth to allow FES to hang freely in a way that they are not damaged by any physical impact. [9] The number of positions for FES in these cabinets is often limited to a maximum of 8–10. Related to the used total area (m^2), volume (m^3), and capacity, and comparing this to systems with horizontal drying and storage, the efficiency of these vertical systems is questionable.

Many guidelines recommend vertical drying and storage of FES in specially designed, automated drying and/or storage cabinets, probably still based on proven theories (including the gravity issue) and technologies. Of course, these cabinets have advantages in drying endoscope surfaces and in reducing the risk of microbial growth post reprocessing. [24]

FES can also be dried and stored in a horizontal way. FES are coiled in a special way (without over coiling and kinking), placed in a special basket, and connected to air connectors in a designated cabinet for this purpose. If FES are only stored in a horizontal way, i.e. in closed storage trays or bags in vacuum systems, it must be guaranteed that the entire FES is completely dry, in order to prevent stagnation zones with possible residual moisture in the coiled FES. [1, 4] Once dried and stored in a controlled environment, the shelf life of the FES can vary from 7 days up to a maximum of 100 days. Of course, this should be in line with the MIFUs and national or even local guidance. [25] When the shelf life has expired, the FES should then be reprocessed.

The dried endoscope is placed in a PlasmaBAG and stored in a horizontal way.

"Compared with vertical storage of FES, horizontal storage is more efficient"

Researchers and manufacturers continuously create, design, and look after technological solutions and engineered safeguards in order to improve patient safety. This also includes improvements to endoscope reprocessing, drying, and storage. Recently some new and proven techniques for endoscope drying and storage have become available, meaning a shift from conventional drying and storage to a more efficient and effective way of drying and storing of FES.

PlasmaTYPHOON in combination with PlasmaBAG is such a recently introduced novel technique, designed and constructed by PlasmaBiotics®.

PlasmaTYPHOON in combination with PlasmaBAG is proven to be more effective and more efficient than conventional drying and storage systems, even when compared with a horizontal vacuum drying and storage system. [26] It is a validated process and meets European standards NF EN 16442 norm. [27, 28, 29]

The technique for PlasmaTYPHOON and PlasmaBAG is compatible with all brands and types of FES and easy to use. It is an ultra-fast drying and storage system, thus saving time. It is also space saving, which is important especially today due to the lack of available space in reprocessing facilities. Only a working space of approximately 1.0 m^2 is needed to place the PlasmaTYPHOON and for the space needed for handling the endoscope and bag. The bags containing the FES can then be stored easily in a horizontal way that does not need any additional equipment.

Compared with vertical storage of FES, horizontal storage is also more efficient. Coiling and kinking of the endoscope is not a problem since the PlasmaBAG was designed taking into account the size of the endoscopes and also the transport suitcase, which comes with the endoscope. Under these circumstances, the minimum diameter of coiling recommended by the endoscope manufacturers is largely respected for all brands and types of FES. To provide a preserved environment, PlasmaTYPHOON and PlasmaBAG use a non-damaging ozone atmosphere, thus no chemicals, such as peroxides, which could possibly have a negative impact on the FES. Inside PlasmaBAG the ozone O_3 create an aseptic atmosphere and recombine within 5 minutes to molecular oxygen O_2.

With PlasmaTYPHOON and PlasmaBAG every FES is individually packed and can be stored for 31 days. Cross contamination and recontamination risks from handling FES (for placement and taking these out of conventional drying or storage cabinets) and transporting them, are eliminated. Even possible risks of physical damage, i.e. tip damage by opening and closing the doors of these cabinets, are eliminated. With the use of PlasmaTYPHOON and PlasmaBAG expensive maintenance of drying/storage cabinets is also not necessary. Periodic technical and microbiological validation can also be skipped. Of course, an initial validation program for PlasmaTYPHOON and PlasmaBAG used test strips to control ozone concentration in the bag. Additional rapid tests for examining the presence of any moisture in the endoscope channels could also be used, i.e. HydroCheck-E®, even on a regular basis, for example once a month.

CONCLUSION

In this time of increasing awareness of patient safety, manufacturers also have a responsibility to develop, design, and create solutions and safeguards in order to guarantee this.

With the novel solution provided by PENTAX Medical, with the proven technique of complete drying using PlasmaTYPHOON and aseptic, clean, dry, and safe storage environment with PlasmaBAG, a safe solution for endoscopy patients can be guaranteed. Compared to other drying and storage solutions, PlasmaTYPHOON combined with PlasmaBAG is proven to be more efficient, effective, easier to use, space saving, and cheaper. [26]

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