© Copyright AAMI 2020. Single user license only. Copying, networking, and distribution prohibited.

Drying and Storage of Flexible Endoscopes: An Area of Growing Concern

The drying and storage of flexible endoscopes after liquid chemical disinfection currently is a hot topic of debate and research.¹ However, the importance of endoscope drying prior to storage is not new. In 1982, Gerding et al.² showed that 31% of stored endoscopes were contaminated with bacteria. Introducing forced-air drying prior to storage reduced the contamination rate to 5%. That and many other studies that followed have shown the importance of drying to control microorganism proliferation during storage (see Kovaleva³ and Alfa and Singh⁴ for comprehensive reviews).

Although the importance of drying flexible endoscopes postprocessing is well recognized, recent articles have shown that:

- 95% of stored, patient-ready scopes (19 of 20 evaluated) retained residual liquid after automated endoscope processing, which included a programmed alcohol flush and air purge.⁵
- The percentage of stored, patient-ready scopes with residual liquid was 83% (10 of 12) and 85% (11 of 13) at two clinical sites.⁶ At a third site, endoscopes were consistently dry when a 10-minute forced-air drying procedure was used.
- Of 249 U.S. institutions surveyed concerning duodenoscope processing practices, 52.2% did not use forced-air drying after processing.⁷

Clearly, effective drying and storage of endoscopes is a challenging process.

Why Is Drying so Difficult?

A review of recent flexible endoscope processing manuals by the authors illustrated why drying is so difficult. Explicit channel-drying instruction is lacking. Typically, users are simply told to "dry the channels." Reference to local standards may be provided, and the manuals may mention that alcohol can be used. However, details about the type of air to use, how to apply the air, and the time required to dry are missing.

ANSI/AAMI ST91:20158 offers guidance for drying of flexible endoscopes. Specifically, the standard states: "Drying can be achieved by flowing air through all endoscope channels for a specified period of time. Drying should be facilitated by using 70-80% ethyl or isopropyl alcohol. When using alcohol, personnel should follow manufacturer's written IFU (instructions for use) on the volume of alcohol and method used for each endoscope lumen and ensure remaining alcohol is removed with medical-grade forced air until no visual signs of moisture remain (or as otherwise recommended by the endoscope manufacturer)." (Note: At the time this article was being written, ST91 was being updated. Once released, readers are encouraged to review the new version of the standard for the most current recommendations for drying and storing flexible endoscopes.)

The standard further instructs to avoid using syringes for channel drying; rather, compressed air at the "force of air pressure to channel size" provided by the manufacturer's IFU should be used. ST91 guides users to the manufacturer's IFU, and as already mentioned, detailed drying instructions are lacking. Therefore, users must determine how to dry on their own.

A lack of simple, sensitive methods for verifying channel dryness further complicates the issue. The instrument channel can be visualized using a borescope. However, most other channels cannot be directly visualized due to their small size (e.g., 1-1.4 mm internal diameter for portions of the air/water channel) and sharp bends that do not allow passage of most borescopes.9 For channels that cannot be directly visualized, the only options are water detection papers^{6,10–13} or humidity sensors.¹³ However, these methods are not as sensitive or simple to use compared with visual borescope evaluation performed by trained personnel.

Perumpail et al.¹⁰ reported that the detection limit of cobalt (II) chloride paper

Tamara Behm, MSN, RN, CIC, is aclinical education specialist in theInfection Prevention TechnologiesDivision of STERIS Corporation inMentor, OH. Email: tamara_behm@steris.com

Nancy Robinson, PhD, is a distinguished scientist in the Infection Prevention Technologies Division of STERIS Corporation in Mentor, OH. Email: nancy_ robinson@steris.com STERILIZATION CENTRAL © Copyright AAMI 2020. Single user license only. Copying, networking, and distribution prohibited.

> was greater than 250 µL water for a duodenoscope air/water system, demonstrating that this method is not sensitive enough to confirm all channels in a flexible endoscope are dry. Ofstead et al.,⁶ using a cobalt chloride-based paper, found that 10 µL water could be detected when using cotton swabs to sample endoscope channel openings. Michels13 showed that both isopropanol wetted copper (II) sulfate paper and a humidity probe were able to detect 5 µL residual water in a simple, simulated endoscope channel. However, the alcohol-wetted paper changed color after five minutes due to the ambient air humidity, potentially making this method difficult to interpret.

> Two international standards, DS/EN 16442:201511 and EN ISO 15883-4:2018,12 describe methods for assessing channel and external surface drying efficacy for development of flexible endoscope storage cabinets and washer disinfectors, respectively. Both use copper (II) sulfate paper as the detection method. For internal channels, the distal end of the endoscope is pointed at the paper, which is held 5 to 10 cm away. Next, the channels are flushed with 17.4 psi or greater medical grade air. However, the air flush duration and method used to direct air into the channels are not provided. For external drying verification, the paper is inserted into crevices (e.g., between the control knobs). Of note, drying the control knob crevices is difficult; therefore, verifying dryness of this area using a water-sensitive paper may be beneficial.

Should Alcohol Be Used for Drying Flexible Endoscope Channels?

Some professional organizations recommend using alcohol to enhance drying flexible endoscope channels.^{8,14} However, use of alcohol is controversial due to its reported fixative properties^{15,16} and the potential danger and health risks¹⁷ associated with its use. Further, Alfa and Sitter¹⁸ demonstrated that, with a 10-minute dry time of duodenoscope channels, an alcohol rinse was not required to prevent proliferation of bacteria during storage. The Association of periOperative Registered Nurses (AORN) recommends that a multidisciplinary team conduct a risk assessment to determine whether the channels should be flushed with 70% to 90% alcohol after disinfection.¹⁹

These results and directions call into question the necessity of flushing flexible endoscope channels with alcohol to promote drying. Therefore, the decision of whether to use alcohol is another example of facilities not having access to clear guidance.

How Do We Store Flexible Endoscopes?

In the past, many facilities stored patientready endoscopes in transport bins, in original endoscope boxes with foam inserts, and upright in cabinets with and without air flow. At that time, storage was viewed as a means to keep the scope out of the patient's reach and to prevent accidental damage. Today's expanded view includes prevention of recontamination of the endoscope prior to patient use, even when stored for days. Users must always follow storage instructions provided by the original equipment manufacturer for each endoscope model. If explicit instructions are not provided, professional societies offer storage recommendations (summarized in Table 1).

The importance of proper storage is highlighted in the recent study by Ofstead et al.,6 which showed microbial growth in 71% (32 of 45) of sampled stored endoscopes. In an Australian study, a contamination rate of 15.5% (of which 0.5% were pathogens) was reported after an average storage period of 37.6 hours (range 5.3–165.3 hours).²¹ Of important note, having a single organism survive the disinfection process can lead to organism proliferation if that endoscope is not dried and stored properly. According to Thacker and Muthusamy,22 facilities should "consider automated drying steps." They give examples of cabinets for scope storage with active air circulation, forced-air designs, or both; one used high-efficiency particulate filtered air.

Using automated drying steps is an adjunct for drying of flexible endoscopes. In addition, evidence indicates that drying cabinets with static air do not effectively dry compared with cabinets that circulate filtered air through the endoscope channels for at

STERILIZATION CENTRAL

© Copyright AAMI 2020. Single user license only. Copying, networking, and distribution prohibited.

Source	Recommendation
Healthcare Infection Control Practices Advisory Committee (2017) ²⁰	A risk assessment should be performed for storage of endoscopes, as appropriate. Store endoscopes and accessories in a manner that prevents recontamination, protects equipment from damage, and promotes drying. Store processed flexible endoscopes in a cabinet of sufficient height, width, and depth to allow flexible endoscopes to hang vertically without coiling or touching the bottom of the cabinet or in one designed and intended for horizontal storage. Storage cabinet features that are optimal for preventing contamination have not been determined.
ANSI/AAMI ST91:2015 ⁸	The workflow should be unidirectional to the storage area. Liquid chemically disinfected endoscopes should be hung vertically with angulation lock open (if so equipped), all removable parts detached, and the endoscope tagged or labeled with the date of processing and individuals who performed the processing. Sterilized endoscopes should be stored in the container or packaging in which they were sterilized.
Society of Gastroenterology Nurses and Associates Inc. (2018) ¹⁴	Storage areas should be suitable for clean endoscopes (clean, well ventilated, and dust free) and allow endoscopes to hang freely and vertically. Do not attach removable parts during storage.
Guidelines for Perioperative Practice (2020) ¹⁹	Storage is recommended in a drying cabinet, a closed cabinet with HEPA filtered air, or a cabinet that is designed for horizontal storage or of sufficient size for hanging vertically.

Table 1. Recommendations for proper storage of flexible endoscopes. Abbreviation used: HEPA, high-efficiency particulate air.

least an hour.²³ For this reason, storage cabinets without filtered circulating air are falling out of favor.

How Long Is Too long for 'Hang Time'?

How long can an endoscope be stored before it must be processed? Often called "hang time," the shelf life of a high-level– disinfected or liquid chemically sterilized endoscope depends on the microbiocidal process used, the results of an internal risk assessment, and professional society guideline followed. Table 2 lists professional society recommendations and study results identifying maximum hang times before the endoscope must be processed.

It is interesting to note that published studies give widely varying results for safe storage times. For example, Schmelzer et al.²⁶ concluded that endoscopes can be stored for seven days (based on their analysis of published studies), but Lacy et al.²⁷ showed that a 12-week hang time is

Source	Recommendation
ANSI/AAMI ST91:2015 ⁸	"Due to the lack of consensus and evidence on the storage time, it is recommended that the health care facility conduct a risk assessment to determine the maximum storage time for an endoscope before it needs to be processed to use on the next patient."
Society of Gastroenterology Nurses and Associates Inc. (2018) ¹⁴	Seven-day storage if scopes were processed and stored according to professional guidelines and manufacturer instructions.
Guidelines for Perioperative Practice (2020) ¹⁹	There is limited evidence for establishing storage times. No consensus exists regarding maximum storage time. A multidisciplinary team should establish a policy to determine maximum storage time.
Healthcare Infection Control Practices Advisory Committee (2017) ²⁰	"The available data on the maximum interval of endoscope storage before reprocessing is required prior to use is inconclusive. The length of time may depend on multiple factors as identified on organizational risk assessment that may include endoscope usage/turnover of endoscopes used and manufacturer's instructions-for-use."
VHA Directive (2016) ²⁴	If the scope is processed, dried, and hung properly, it may hang for 12 days before it must be processed.
Ingram et al. (2013) ²⁵	Sufficient prevention of bacterial growth was proven for 8 weeks.
Schmelzer et al. (2015) ²⁶	"Endoscopes can be stored for 7 days if they have been effectively reprocessed and appropriately stored. Ongoing surveillance cultures are necessary to verify reprocessing effectiveness."
Lacy et al. (2019) ²⁷	During a 12-week shelf life study, it was concluded that proper aseptic storage practice and effective decontamination, not the duration of storage, are the keys to protecting endoscopes from contamination.

Table 2. Current state of flexible endoscope hang time. Abbreviations used: ANSI, American National Standards Institute; VHA, Veterans Health Administration.

STERILIZATION CENTRAL © Copyright AAMI 2020. Single user license only. Copying, networking, and distribution prohibited.

> possible. The latter researchers proposed that the key drivers of endoscope contamination are inadequate disinfection and/or poor storage practices.

Considering the current state of understanding, AAMI,⁸ AORN,¹⁹ and the Healthcare Infection Control Practices Advisory Committee²⁰ make it clear that the maximum hang time remains an unresolved issue. Facilities must conduct a risk assessment to determine their own policy, procedures, and practices. Because each facility has a unique inventory of flexible endoscope and storage procedures, as additional evidence-based guidance for endoscope storage is developed, facilities will need to incorporate the new information into their facility-specific risk analysis.

Where Do We Go from Here?

Endoscope manufacturers and researchers must take the lead to provide complete drying and storage instructions so that potentially harmful organisms do not proliferate during storage postprocessing. However, the scientific understanding of "how dry is dry?" is missing. More research is needed to:

- 1. Define the benchmark for "dry."
- 2. Develop and validate moisture detection methods that are able to reliably verify whether surfaces and internal channels are "dry."
- 3. Provide practical drying verification tests for use at clinical sites.

If the current situation for drying endoscopes sounds familiar, that is because it echoes medical device cleaning concerns. The question "how clean is clean?" has been debated for two decades, and significant progress has been made. We are just beginning the journey to understanding endoscope drying and storage. For example, the lack of specific drying instructions is in stark contrast to the detailed instructions given for cleaning. Device-specific cleaning adapters direct cleaning fluids and rinse water into the channels, resulting in a consistent and reproducible process. The same diligence used for developing cleaning instructions²⁸ must be applied to drying and storage of flexible endoscopes. Minimally, instructions for manual or automated (e.g., drying

cabinet or endoscope processor) processes should include:

- 1. Where and how to apply filtered, compressed air, including identifying if adapters are attached to the endoscope and/or the specific type of air nozzle used.
- 2. The pressure, quality, and duration of applied filtered compressed air.
- 3. The type of cloth used to dry the exterior and, if reusable, the duration of use and how to process.

These drying instructions must be verified to be effective and then validated through human factors testing.²⁸

It is time for action. Manufacturers of flexible endoscopes, endoscope processors, and storage cabinets need to work with each other, as well as with professional societies, regulatory bodies, researchers, processing staff, infection preventionists, and endoscopists, to provide answers to the knowledge gaps highlighted above. The only way to ensure the development of optimal drying—and therefore ensure flexible endoscope safety poststorage—is through a multifunctional team approach.

References

- Cohen J, Desilets DJ, Hwang JH, et al. Gastrointestinal Endoscopy Editorial Board Top 10 Topics: Advances in GI Endoscopy in 2018. *Gastrointest Endosc.* 2019;90(1): 35–43.
- Gerding DN, Peterson LR, Vennes JA. Cleaning and Disinfection of Fiberoptic Endoscopes: Evaluation of Glutaraldehyde Exposure Time and Forced-Air Drying. *Gastroenterology*. 1982;83(3):613–8.
- Kovaleva J. Endoscope Drying and its Pitfalls. J Hosp Infect. 2017;97(4):319–28.
- Alfa MJ, Singh H. Impact of Wet Storage and other Factors on Biofilm Formation and Contamination of Patient-ready Endoscopes: a Narrative Review. *Gastrointest Endosc.* 2020;91(2):236–47.
- Ofstead CL, Wetzler HP, Johnson EA, et al. Simethicone Residue Remains Inside Gastrointestinal Endoscopes Despite Reprocessing. *Am J Inject Control.* 2016;44(11):1237–40.
- Ofstead CL, Heymann OL, Quick MR, et al. Residual Moisture and Waterborne Pathogens Inside Flexible Endoscopes: Evidence from a

STERILIZATION CENTRAL © Copyright AAMI 2020. Single user license only. Copying, networking, and distribution prohibited.

Multisite Study of Endoscope Drying Effectiveness. *Am J Inject Control.* 2018;46(6):689–96.

- Thacker AM, Muthusamy VR, Sedarat A, et al. Duodenoscope Reprocessing Practice Patterns in U.S. Endoscopy Centers: A Survey Study. *Gastrointest Endosc.* 2018;88(2):316–22.
- 8. ANSI/AAMI ST91:2015. Flexible and semi-rigid endoscope processing in health care facilities. Arlington, VA: Association for the Advancement of Medical Instrumentation.
- Visrodia K, Peterson, BT. Borescope Examination: Is There Value in Visual Assessment of Endoscope Channels? *Gastrointest Endosc*. 2018;88(4):620–3.
- Perumpail RB, Marya NB, McGinty BL, Muthusamy VR. Endoscope Reprocessing: Comparison of Drying Effectiveness and Microbial Levels with an Automated Drying and Storage Cabinet with Forces Filtered Air and a Standard Storage Cabinet. *Am J Inject Control.* 2019;47(9):1083–9.
- 11. DS/EN 16442:2015. Controlled environmental storage cabinet for processed thermolabile endoscopes. Nordhavn, Denmark: Danish Standards Foundation.
- EN ISO 15883-4:2018. Washer-disinfectors—Part
 Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes. Geneva, Switzerland: International Organization for Standardization.
- **13.** Michels W. Proof of drying within the channels of flexible endoscopes. *Zentralsterilisation-Central Service.* 2015; 23(2):94–7.
- 14. Society of Gastroenterology Nurses and Associates Inc. Standards of Infection Prevention in Reprocessing Flexible Gastrointestinal Endoscopes. www.sgna. org/Portals/0/SGNA%20Standards%20of%20 infection%20prevention%20in%20reprocessing_ FINAL.pdf?ver=2018-11-16-084835-387. Accessed Feb. 21, 2020.
- Costa DM, Lopes LKO, Hu H, et al. Alcohol fixation of bacteria to surgical instruments increases cleaning difficulty and may contribute to sterilization inefficacy. *Am J Infect Control.* 2017;45(8):e81–6.
- 16. British Society of Gastroenterology. BSG Guidance for Decontamination of Equipment for Gastrointestinal Endoscopy. www.bsg.org. uk/wp-content/uploads/2019/12/Guidancefor-Decontamination-of-Equipment-for-Gastrointestinal-Endoscopy_-2017-Edition-3.pdf. Accessed Feb. 21, 2020.

- 17. Thermo Fisher Scientific. Safety Data Sheet for Isopropyl alcohol, 70% in water. www.fishersci. com/store/msds?partNumber=A4591&productDes cription=ipa-isopropyl-alcohol--vv-fisherchemical& vendorId=VN00033897&keyword=true&countryCo de=US&language=en. Accessed March 16, 2020.
- Alfa MJ, Sitter DL. In-hospital Evaluation of Contamination of Duodenoscopes: a Quantitative Assessment of the Effect of Drying. *J Hosp Infect.* 1991;19(2):89–98.
- 19. Van Wicklin SA, Conner R, Spry C. Guideline for processing flexible endoscopes. In: Guidelines for Perioperative Practice. Denver, CO: Association of periOperative Registered Nurses; 2020.
- 20. Centers for Disease Control and Prevention. Essential Elements of a Reprocessing Program for Flexible Endoscopes: Recommendations of the HICPAC. www.cdc.gov/hicpac/ recommendations/flexible-endoscopereprocessing.html. Accessed Feb. 21, 2020.
- 21. Osborne S, Reynolds S, George N, et al. Challenging endoscopy reprocessing guidelines: a prospective study investigating the safe shelf life of flexible endoscopes in a tertiary gastroenterology unit. *Endoscopy*. 2007;39(9):825–30.
- 22. Thaker A, Muthusamy R. Innocent bystanders or legitimate culprits? The role of moisture and simethicone in endoscopically transmitted infections. *Gastrointest Endosc.* 2019;89(1):133–6.
- **23.** Saliou P, Cholet F, Jezequel J, et al. The Use of Channel-Purge Storage for Gastrointestinal Endoscopes Reduces Microbial Contamination. *Infect Control Hosp Epidemiol.* 2015;36(9):1100–2.
- 24. Department of Veteran Affairs. Sterile Processing Services: 2016. VHA Directive 1116(2). Washington, DC: Department of Veteran Affairs.
- 25. Ingram J, Gaines P, Kite R, et al. Evaluation of Medically Significant Bacteria in Colonoscopes after 8 Weeks of Shelf Life in Open Air Storage. *Gastroenterol Nurs*. 2013;36(2):106–11.
- 26. Schmelzer M, Daniels G, Hough H. Safe Storage Time for Reprocessed Flexible Endoscopes: A Systematic Review. JBI Database System Rev Implement Rep. 2015;13(9):187–243.
- Lacy V, Good K, Toliver C, et al. Evaluation of 12-Week Shelf Life of Patient-Ready Endoscopes. Gastroenterol Nurs. 2019;42(2):159–64.
- 28. Food and Drug Administration. Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff. www.fda.gov/ media/80265/download. Accessed March 16, 2020.