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LEARNING OBJECTIVES

1. *List standards for drying and how to meet those standards*
2. *Identify the types of air required to dry medical devices and where they are located in a reprocessing area*
3. *Explain the multiple consequences of inadequate drying*

SELF-STUDY SERIES

Do your medical device drying processes meet the standards?

by Tamara Behm and Pamela Carter

Residual water creates opportunities for the growth of many types of organisms, in many environments. For example, have you ever left wet clothing or towels in the washer until they became smelly from mildew? Did you know that water left in your ear after swimming creates a perfect environment for bacteria to proliferate, which can cause a bacterial infection called swimmer's ear?

In healthcare reprocessing environments, such as gastroenterology (GI) departments and sterile processing departments (SPDs), wet reusable medical devices can be even more dangerous than laundry mildew and swimmer's ear. They can interfere with sterilization and/or disinfection processes. They can also cause device damage and can contribute to the formation of biofilm that contains infectious agents. Biofilm also can prevent effective disinfection or sterilization of the surfaces it adheres to. All these factors can create a serious infection risk for the patients in whom the device is used.

This article will review current recommendations for effective medical device drying, discuss the appropriate types of air to use and explain how to complete drying steps safely in SPD and GI reprocessing areas.

Current standards and rationales

The Association for the Advancement of Medical Instrumentation (AAMI) has numerous standards for decontaminating and sterilizing medical devices. Many of these standards stress the importance of thorough drying and explain the reasons.

For example, ANSI/AAMI ST79 discusses steam sterilization as one of the most commonly used methods in healthcare facilities. Since steam cycles use water to sterilize devices, it may seem counterintuitive that wet reusable devices could hinder the process. However, as ANSI/AAMI ST79 explains, excess moisture can lead to wet packs that supply a pathway for microbial invasion into the pack. It can also lead to device corrosion.

Gas and vapor sterilization processes are even more susceptible to moisture. Ethylene oxide reacts with water, creating a hazardous byproduct called ethylene glycol (ANSI/AAMI ST41). This byproduct can harm patients. In addition, water can prevent vaporized hydrogen peroxide from reaching a device's surface, thereby preventing sterilization (ANSI/AAMI ST58).

Drying is also a critical function when performing high-level disinfection (HLD) or liquid chemical sterilization (LCS) on endoscopes. As ANSI/AAMI ST91 explains, the failure to completely dry endoscopes after processing creates an opportunity for waterborne organisms, like *Pseudomonas aeruginosa,* to colonize in the scopes and potentially form biofilms. This can lead to the transmission of infection to the next patient the endoscope contacts.

Thorough drying is a requirement of all disinfection and sterilization processes. AAMI's standards discuss several methods for drying devices after cleaning and rinsing:

- *Air dry*: placing devices in an area of limited access allowing moisture to evaporate from the device
- *Towel dry*: using a non-linting towel to absorb moisture from the surfaces of devices
- *Mechanical drying*: removing moisture with heat or forced air from device surfaces and lumens

In addition, some standards define an optimal location to perform drying. For example, ANSI/AAMI ST91 states that endoscopes should have a designated area for drying. This standard also stresses the importance of endoscopes being dry before sterilization, storage and patient use. The point in the process at which drying is required depends on the process. Always

refer to the manufacturers' instructions for use (IFU).

Quality of air for medical device drying

Staff in SPD and endoscopy use a combination of tools to dry devices. Non-linting towels quickly absorb surface moisture. Air nozzles supply forced air to hard-to-access areas, lumens and channels. Drying cabinets enhance drying of surfaces and lumens by directing warmed air to and through devices. Independent air pumps flow air through long lumens, such as endoscope channels.

Having good quality air available for medical device drying is vital for safe reprocessing in SPD and GI departments. Healthcare facilities often use *instrument air* and/or *high efficiency particulate air* (HEPA) to assist in the drying process.

Instrument air is sometimes mistaken for medical-grade air. Medical-grade air (respired) is administered to patients and/or used for calibrating powered ventilator equipment, whereas instrument air is a medical gas that falls under the general requirements for medical gases as defined by the National Fire Protection Association, NFPA 99: Health Care Facilities Code. It is compliant with the American National Standards Institute and International Society of Automation ANSI/ISA 7.0.01, which recommends air filtered to 0.01 microns, free of liquids and hydrocarbon vapors, and dry to a dew point of -40°C (-40°F) as the quality standard for instrument air. SPD leadership should work with facilities to ensure that the air supplied meets these requirements. This requires specialized equipment or gas cylinders to deliver the appropriate air.

In addition to its quality, the placement of instrument air tools helps optimize its use by SPD staff during reprocessing. Specifically, instrument air should be available in the decontamination area to help loosen/remove debris from surgical devices, such as lumens and drills, and in the prep and assembly area to remove residual moisture on inner and outer device surfaces when needed.

There are also growing numbers of SPDs and GI departments using HEPA-filtered drying cabinets, with or without automated flushing pumps/channel purge components, on manually cleaned, disinfected or liquid chemical sterilized heat-sensitive devices, such as flexible endoscopes, cystoscopes, bronchoscopes, cameras, light cords and drills. In GI areas, the cabinets are used to enhance drying and protect endoscopes from environmental contamination during storage. In SPDs, the transfer cabinets are used to dry devices before packaging for sterilization. HEPA-filtered enclosed drying cabinets can remove up to 99.97% of particulates from the air. In addition, a recent study conducted by Perumpail et al. (2019) found that using a HEPA-filtered drying cabinet helped to speed up endoscope drying and reduced the risk of microbial growth.

Drying instructions

It's critical to follow each manufacturer's drying instructions to prevent retained moisture and device damage. Manufacturers are required to conduct thorough testing and validation to assure that each device's reprocessing IFU will successfully achieve a safe, reusable device for patient use when all instructions are followed. Instructions may be unique to a particular device, so they may state different drying times, or may specifically require forced, filtered air to remove moisture, for example. Reprocessing staff must know which drying process to use for each device they process.

In addition, a manufacturer's IFU may provide several methods for drying a particular device. Managers can determine which methods are best for their departments. Regardless of the method used, facilities can perform verifications of the drying process. Popular verification methods include:

- Visualization of internal lumens with a borescope (see Figure 1)
- Surface, internal lumen and box lock checks with moisture-sensitive indicator papers (Ofstead et al.)

SPD and endoscopy teams should also review the manufacturer's IFU for all the automated disinfection and sterilization equipment in the department. These systems are also classified as medical devices, so their IFU are thoroughly tested and validated and are, therefore, equally as important to follow in order to assure disinfection or sterilization.

Gas and vapor sterilization methods often include warnings and precautions about wet devices. IFU of some automated endoscope reprocessors (AERs) or liquid chemical sterilant processing systems state to use processed devices immediately after processing or to dry them according to the device manufacturer's IFU. ANSI/AAMI ST58, which provides recommendations for HLD and chemical sterilization, states in Section 6.6.6 that all devices should be dried in accordance with their IFU, to remove residual liquids.

It's also important to follow any IFU specifications for pressure, air type, humidity level and temperature. Ensuring that the pounds per square inch (PSI) is regulated and within a device's safe range will help prevent damage. Also, if a drying cabinet is used, its temperature must be set to a safe level according to the medical device's IFU. Higher temperatures can damage some heat-sensitive components and adhesives.

Where drying takes place

In SPD, drying happens at several points along a surgical device's journey. By understanding the whole process, leadership can better supply the drying resources needed at each point.

Items begin their journey at the decontamination sink. Items are cleaned and rinsed, then they either move on to the washer-disinfector or the pass-through window. At this point, technicians can remove residual moisture before loading them into the automated washer. Residual moisture can be blown from lumens, box locks and other surfaces.

Machine-washed devices must be thoroughly dried before they are assembled into sets for HLD or sterilization. Lint-free towels and instrument air should be used to remove all residual moisture. Some facilities will also use a drying cabinet to enhance the drying process. Pass-through cabinets are often used to allow access to the dried devices on the clean side.

Figure 1: Borescope insertion for visualization of residual moisture within an endoscope channel

Self-Study Test Answers: 1. C, 2. B, 3. A, 4. A, 5. D, 6. C, 7. B, 8. D, 9. D, 10. C

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Devices should be manually dried before placing them into a drying cabinet, following each device's IFU.

Devices enter the prep-and-pack area through the pass-through drying cabinet or the washer-disinfectors. At this point, items should be inspected for residual moisture under magnification. It may also be necessary to use a borescope or moisture-sensitive paper to check lumens. In this area, staff will need access to instrument air and lint-free towels.

In GI departments, scopes should be dried before placing them into an AER or HLD soak because residual water could dilute the AER or HLD chemistries and make them less effective. Even more importantly, the device should be thoroughly dried after AER, HLD or LCS processing is complete and before storage. A recent study by Ofstead et al. (2018) showed that residual fluid remained in nearly 50% of scopes and could be contributing to infections in patients because over 70% of the wet scopes were contaminated with organisms after processing and storage. Therefore, residual water may contribute to cross-contamination of scopes. Kovaleva (2017) wrote that a wet endoscope environment contributed to the replication of gram-negative organisms and that residual moisture created an ideal environment for growth.

Consequences of inadequate drying

In addition to contributing to bacterial proliferation and impeding sterilization and disinfection processes, poor device drying can also be a major contributor to damage and degradation of external and internal device surfaces. Damage can include discoloration, corrosion, rust and pitting. Moisture and debris are notoriously known to hide in tight areas, such as box locks, jaws, lumens and crevices of devices, so thorough drying and magnified inspection needs to be performed to find moisture before it can cause damage or biofilm formation.

Biofilm is a slime-enclosed community of bacterial colonies that can form anywhere on a moist surface. Some examples of surfaces that can form biofilm are water pipes, wet device surfaces and wet internal and concave surfaces of lumened or cannulated devices, such as endoscopes, suction tips, shavers or drill bits. According to Dancer *et al* (2012), coagulase-negative staphylococci (CoNS) and *Bacillus* species found in biofilms on devices were responsible for surgical site infections (SSIs). Also, in a recent review article by Alfa and Singh in *Gastrointestinal Endoscopy*, inadequate manual cleaning and drying storage failures led to biofilm build-up in endoscope channels, causing bacterial replication. The results of several studies show that inadequate cleaning and drying of endoscopes prior to storage are associated with a high risk for contamination, causing healthcare associated infections (HAIs). This risk has led to some healthcare facilities including a borescope in their work instructions to visualize the internal channels of lumened/cannulated devices and check for cleanliness and residual moisture before moving on to the next step of sterilization prep and pack, HLD or placement in a storage cabinet for drying.

Support for an optimal drying program

Medical device drying is an extremely important infection-prevention function in the reprocessing loop. Evidence-based research has reinforced the risks, and standards support its importance. To ensure patient safety, facilities should establish a quality management system (QMS) for monitoring device drying. The QMS needs to identify risks by assessing current practices in order to identify and mitigate potential sources of residual moisture (and therefore potential contamination) that can contribute to SSIs. Documented practices should be based on manufacturers' IFU, hospital standard procedures and industry standards and guidelines, and should be monitored continuously as part of the QMS. In addition, ongoing employee education, training and competency testing need to be provided to help reduce contaminated device events due to ineffective cleaning and drying. Once a drying QMS is in place, consistent, effective drying protocols can be achieved, and patient safety is enhanced. HPN

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CONTINUING EDUCATION TEST • SEPTEMBER 2020

Do your medical device drying processes meet the standards?

Circle the one correct answer:

1. **Which is the quality standard that addresses instrument air?**
   a. ANSI/AAMI ST79
   b. ANSI/AAMI ST 58
   c. ANSI/ISA 7-0-01-1996
   d. SGNA
2. **Instrument air and medical-grade air are the same.**
   a. True
   b. False
3. **To thoroughly dry heat-sensitive devices after manual cleaning, they can be placed in a/an ...**
   a. HEPA-filtered drying cabinet
   b. ETO Sterilizer
   c. Drawer with a towel wrapped around
   d. Steam sterilizer
4. **When would you use a borescope?**
   a. To visualize internal lumens for retained debris or residual water
   b. On a sterile field
   c. To inspect a malleable retractor
   d. On a non-lumened endoscope
5. **Medical device drying is performed _____?**
   a. In GI before storing an endoscope
   b. On the decontamination side in SPD before sending a lumened item through the pass-through window
   c. On the clean side of the SPD before low-temperature or steam sterilization
   d. All of the above
6. **According to ANSI/AAMI and other standards, what guidance should be followed for medical device drying?**
   a. The device manufacturers' IFU
   b. The high-level disinfector/sterilizer manufacturers' IFU
   c. Both a and b
   d. None of the above
7. **Water and moisture create an environment for bacteria to _____.**
   a. Die
   b. Grow or proliferate
   c. Move from one place to another
   d. Easily be removed from a device
8. **Wet instrumentation and endoscopes can be the cause of _____.**
   a. Biofilm formation
   b. Wet packs and corrosion
   c. Failed low-temperature sterilization loads
   d. All of the above
9. **Medical devices that are susceptible to biofilm formation if not cleaned and dried properly include ...**
   a. Endoscopes
   b. Lumened devices such as a Frasier suction
   c. Drill bits
   d. All of the above
10. **Who is responsible for establishing a quality management system for medical device monitoring in the hospital?**
    a. The manufacturers
    b. The sales rep
    c. The healthcare facility
    d. None of the above

CONTINUING EDUCATION TEST SCORING

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