Canadian, US & European Standards on Endoscope Storage

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Overview

Endoscope Storage

- Overview of a number of studies that back up these standards and guidelines.
- Review what healthcare facilities in Canada must follow to meet the CSA standards.
Standards and Studies relating to Endoscopy Storage

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Studies Over the Past 16 Years


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Studies Over the Past 16 Years

- Alfa M., Mock clinical study demonstrates that ATP cleaning monitoring combined with channel purge storage reliably eliminates Escherichia Coli, but not environmental bacteria from duodenoscopes, Sept 2017
- Ofstead CL., Heyman OL, Quick MR., Eiland JE., Wetzler HP. Residual moisture and waterborne pathogens inside flexible endoscopes: Evidence from a multi-site study of endoscope drying effectiveness AJIC , March
Commonalities of Study Findings

In conclusion our mock clinical study demonstrated that, even with repeated soiling of duodenoscopes with high levels of *E.coli*, the use of ATP to monitor MIFU cleaning combined with dry storage in channel-purge storage cabinets eliminated *E.coli* from all 119 duodenoscopes tested. (Alfa)

Inadequate reprocessing and insufficient drying contributed to retained fluid and contamination found during this multisite study. More effective methods of endoscope reprocessing, drying, and maintenance are needed to prevent the retention of fluid, organic material, and bioburden that could cause patient illness or injury. (Olstead)  

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Conclusion: HEPA filtered cabinets with channel purge supplement the drying process and help in the prevention of microorganism growth. This is only after the optimal bedside clean, manual wash, and reprocessing procedure is complete, monitored and documented
CSA Standards: Scope Storage

Z314.8-14: “Decontamination of reusable medical devices”
11.7.12.1 General
Endoscopes shall be stored in a dedicated, closed, ventilated cabinet outside of the decontamination area and procedure room. The cabinet shall be equipped with HEPA filtration. Endoscopes shall not be stored in their transport cases. They

Note: Poorly constructed and poorly maintained storage cabinets have been found to be a source of cross contamination.
11.7.12.4.2
HEPA-filtered channel-purge storage cabinets with non-porous cleanable surfaces should be used.

- **Notes:**
  1. *Auto purge cabinets do not require the use of alcohol (fixative) to expedite drying and ensure that all ports of an endoscope are presented with airflow.*
Storage cabinets should meet the following criteria:

- made of material that can be disinfected weekly with an approved low-level disinfectant,
- ventilated when doors are closed,
- not situated in a procedure room, reprocessing area, or a high traffic area,
- easily accessible to ensure scopes can be placed inside without damage and without putting the HCW at risk (e.g., HCW must reach a high shelf where endoscope is stored),
- should accommodate a sufficient number of endoscope to support the patient volume,
- designed to allow scopes to be stored in the vertical uncoiled position to facilitate drying.
Section 11.8 (page 43)
Flexible endoscopes are stored in a manner that minimizes contamination and damage.

Guidelines
The organization does not store flexible endoscopes coiled or in their cases. Flexible endoscopes with channels or lumens are stored with channel valves stored separately. Flexible
Storage procedures must include the following:

- Remove caps, valves and other detachable components during storage and reassemble just before use; Store close to the endoscope in a manner that minimizes contamination.
- Store endoscopes that have been sterilized in their sterilization containers.
- Do not allow endoscopes to coil, touch the floor or bottom of the cabinet while handling, or be stored in their cases.
- Store semi critical endoscopes by hanging vertically in a dedicated, closed, ventilated cabinet outside of the decontamination area and procedure room.
• HEPA–filtered channel purge drying cabinets should be used for storage.
• Ensure that endoscope storage cabinets are constructed of non-porous material that can be cleaned.
• Clean and disinfect endoscope storage cabinets at least weekly with an approved low-level disinfectant/cleaner.
• Colonoscopes have a maximum shelf life of 7
Recommendation IX

Flexible endoscopes and endoscope accessories should be stored in a manner that minimizes contamination and protects the device or item from damage.

IX.a Cabinets used for storage of flexible endoscopes should be situated in a secure location the clean workroom of the endoscopy processing room in a two-room design, or in a separate clean area close to, but not within, the endoscopy procedure room.

IX.a.1 Storage cabinets should have doors, and be located at least three feet from any sink.
Flexible endoscopes should be stored in a drying cabinet.

The collective evidence shows that optimal storage flexible endoscopes facilitates drying, decreases the potential for contamination, and provides protection from environmental contaminants.

A wide variety of storage cabinets are available. Drying cabinets include a system that circulates HEPA-filtered air through the cabinet while filtered air under pressure is forced through the endoscope channels. The internal and external surfaces of the endoscope are continuously dried, suppressing bacterial growth.
9. STORAGE

Endoscopes must be stored in an area that is clean, well-ventilated and dust-free in order to keep the endoscopes dry and free of microbial contamination. An endoscope that is not dry must be reprocessed before use. Endoscopes should also hang freely so that they are not damaged by physical impact. Endoscopes should be stored in accordance with the endoscope and storage cabinet manufacturers' instructions.
Key considerations in storage include:

a) Use storage cabinets that are made of a material that can be disinfected.

b) In conventional storage, hang endoscopes in a vertical position (with caps, valves, and other detachable components removed) to prevent moisture accumulation and subsequent microbial growth. Make sure that
The endoscope should be hung vertically with the distal tip hanging freely in a well-ventilated, clean area, following the endoscope manufacturer’s written IFU for storage. For example, make sure that the insertion tube hangs vertically and is as straight as possible (no bends). If the scope has an angulation lock, it should be in the open position while in storage. There should be sufficient space between and around scopes to prevent them hitting into one another, which can cause damage to the scopes. All removable parts (e.g., valves and caps) should be detached from the endoscope. To keep the parts together with the scope, a small bag or similar device can be used to attach the parts to the scope.
Rationale: When flexible and semi-rigid endoscopes are hung in the vertical position, coiling or kinking is prevented, allowing any remaining moisture to drain out of the endoscope and decreasing the potential development of an environment conducive to microbial growth in the endoscope. Following recommended storage practices facilitates drying and decreases potential for contamination. All valves and other accessories should be removed in preparation for drying. The scope protector may create an environment favorable for microbial growth if the endoscope is not dry and cannot hang straight (Thomas, 2005; Goldstine, 2005; Bisset et al., 2006). Storing endoscopes with valves or on the scope will trap residual moisture in the internal channels and provide optimal conditions for microbial growth.
a) Cupboards used to store endoscopes must be either designed to hold endoscopes horizontally on a flat surface with continuous air flow through each channel, or be tall enough to allow endoscopes to hang vertically without touching the floor and be well ventilated or have continuous air flow through each channel.

b) Cupboards with continuous air flow should provide filtered air, flow monitoring and audible alarms in the event of failure. If air flow fails, the connections to the cupboard air flow lines will impair fluid drainage and evaporation of residual moisture within endoscope.
d) Provided storage conditions are as recommended above, endoscopes will need to be disinfected prior to use only when the times in the following table have elapsed:

<table>
<thead>
<tr>
<th>Type of endoscope</th>
<th>Storage time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastroscopes, colonoscopes, radial EUS scopes</td>
<td>72 hours</td>
</tr>
<tr>
<td>Duodenoscopes, bronchoscopes and linear EUS scopes</td>
<td>12 hours</td>
</tr>
<tr>
<td>Emergency endoscopes e.g. intubating bronchoscopes</td>
<td>72 hours</td>
</tr>
<tr>
<td>Enteroscopes</td>
<td>72 hours if stored with continuous flow air, 12 hours if hanging storage, as impractical to have hanging vertically without touching the floor</td>
</tr>
</tbody>
</table>

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e) Those endoscopes only used in emergency should be routinely reprocessed every 72 hours to ensure they are ready to be used at any time.

f) Endoscopes must have a full disinfection process performed at the end of the list, using 70% alcohol and forced air drying to enhance the drying process prior to storage. Methylated spirits is NOT suitable for this process.

g) Extended storage is only permitted if recent (within 12 months) routine microbiological surveillance of the endoscope has shown negative culture results.

h) If recent culture results have been positive or if adequate storage facilities are not available, endoscopes should be disinfected prior to use if the storage time has been longer than 12 hours.

i) Endoscopes should not be stored in transport cases as these may have become contaminated and do not allow air to remove residual moisture from the endoscope.
This European Standard specifies storage cabinets which flush the channels and the external surfaces of endoscopes with air.

NOTE 1 The storage cabinet is one of the means that can allow the safe use of the endoscope for an extended period from the time of processing and improve availability for emergency use. CSGNA 2018
Whoa!

· Way too much information!
· Way too many recommendations!
· Way too many risks!

How do we protect our staff and patients from cross contamination while adhering to all these guidelines now and in the future?

Getting rid of those pesky little biofilm bugs is not easy that’s for sure!

But, as we have seen in all the recommendations and studies, HEPA filtered ventilated cabinets with HEPA filtered purging of all endoscope channels certainly helps.
What do we need to know in Canada?

As per CSA Z314.8-14, Canadian Healthcare Facilities shall have cabinets that meet these standards:

- Use an endoscopy storage cabinet that has constant positive pressure HEPA filtered ventilation.
- Be made of a non-porous cleanable surface that is impervious to micro-organism growth, such as stainless steel.
- In non-channel purge cabinets, endoscopes must hang vertically so they do not touch the bottom of the cabinet or each other.
- Scopes can be hung for up to seven days if validated dry prior to storage. If not then they must be reprocessed prior to next procedure.
Again, as per Z314.8-14 Canadian Healthcare Facilities, should have cabinets with the following:

- HEPA Filtered channel purge cabinets with non-porous cleanable surfaces should be used.
- Channel purge storage cabinets use all channel connectors to flush HEPA filtered air through the connected channels during storage.
- Cabinets that store endoscopes horizontally can be used, as long as the channels are connected and purged with HEPA filtered air.
- Alcohol flush is not required if an endoscope is stored in a dedicated channel purge cabinet.
- Endoscopes stored in a dedicated channel purge cabinet for longer than 7 days must be reprocessed.
Best World

While not part of the CSA Standards requirement, the ability to track an endoscope within a channel purge storage cabinet, beginning from when it is stored, to when it is taken out, will help make sure you are using a clean, dry endoscope that is used before 7 days for every procedure. Barcode and RFID scanners are available.
Other HEPA Cabinets

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In Conclusion

• In Canada healthcare facilities, at a minimum, must store their endoscopes in a positive pressure HEPA ventilated cabinet.
• The cabinet must be made of a non-porous cleanable surface.
• Endoscopes can be stored for up to 7 days without reprocessing if verified dry prior to storage in a non-channel purge cabinet.
In Conclusion

- Endoscopes can be stored for 7 days in a HEPA filtered channel purge cabinet, without prior drying.
- All studies point to the importance of drying all channels of endoscopes in a timely manner to eliminate the risk of micro-organism growth and generating bio-film. Most worldwide standards and guidelines are recommending that now as well.
Let’s do what we can to get rid of those pesky bugs.

Questions?