Advice from IHEEM Decontamination Technical Platform/IHEEM Registered Authorising Engineer (Decontamination) Group.

Controlled Environment Storage Cabinet BS EN 16442, HTM 01-06. Drying function validation

<u>The validation of drying functions and clarification where guidance and standards differ or clarification is required</u>.

Background

This paper is in response to several occurrences where endoscopes have been found to be still wet after more than three hours in a Controlled Environment Storage Cabinet with a drying design and validation documents to suggest compliance. The occurrences have initially become apparent when vacuum bagging endoscopes after more than three hours in a drying cabinet.

This guidance paper is applicable to other systems claiming to dry endoscopes either in existence or developed in the future.

The reprocessing of endoscopes is a difficult challenge which has dramatically improved over recent decades. When an endoscope has been decontaminated through the bedside clean the manual clean and reprocessing through an automated endoscope washer disinfector in most instances the endoscope will be wet with final rinse water which may have some microorganisms. We are permitted to leave the endoscope wet for a period not exceeding three hours and the time limit is to restrict the capacity for multiplication within the wet endoscope. If we are not intending to use the endoscope within this time, we look for other solutions. There are in relation to this several solutions which require the endoscopes to be dried internally and externally again within three hours. The most common way of drying endoscopes is by placing them within a drying cabinet which involves connecting the lumens so that air is forced through each of the lumens also air is passed over the external parts of the device. The controlled environment storage cabinet if drying to BS EN 16442 must dry the endoscope internally and externally from fully waterlogged within three hours unless the instructions for use require a purge before being placed within the cabinet.

Testing and validation documentation

There are both guidance and standards in relation to Controlled Environment Storage Cabinets these being

BS EN 16442: Controlled environment storage cabinet for processed thermolabile endoscopes.

Health Technical Memorandum 01-06: Decontamination of flexible endoscopes

Scottish Health Technical Memorandum 01-06: Decontamination of flexible endoscopes

Welsh Health Technical Memorandum 01-06: Decontamination of flexible endoscopes

The HTM guidance's reference to the standards for the testing of the drying function.

There is one primary difference between the standard and the guidance in relation to the testing of the drying function. The Standard has this as an optional test the guidance lists this as a quarterly required test

Testing the drying function

In terms of how the drying function should be tested we are going to need to follow the standard BS EN 16442:2015 section 6.4 which in summary requires the testing to be carried out with either an appropriate surrogate (see Endoscopy-surrogates-v6.pdf and BS EN 16442 annex F & G) or a live endoscope

This may be carried out using a live endoscope or a surrogate. Aseptic handling techniques should be utilised when handling surrogate devices and/or live endoscopes. Cross contamination with instruments already stored within a shared cabinet should always be considered during periodic validation. If a surrogate device is used a certificate of sterility and packaging or pre-processing in the unit EWD should be supplied/completed to reduce the risk of reuse items cross contaminating the storage cabinet. If the instructions for use for the CESC don't say to purge out the channels before storage, fill all the channels with sterile water. If conducting the test within an in-use CESC purge using a single expel of a 50ml syringe of air before testing to reduce the moisture issues for the other scopes within the CESC. Load the scope or surrogate in the cabinet as the instructions say and run a normal cycle.

After the drying cycle (no more than three hours), use either copper (II) sulphate paper (or crepe paper) to check for moisture on the outside of the endoscopes. When you take the endoscopes out, look for any water coming out and check the paper for a colour change (from white or light blue to deep blue). This shows if there is still water left. Put a piece of the copper (II) sulphate paper in small spaces like between control knobs or in places where water might stay, and check if it gets wet.

For the inside channels, after drying, take the endoscope out and point the tip at a piece of copper sulphate paper (50–100 mm away). Blow suitable compressed air through each channel at up to 120 kPa. Test every channel this way to make sure they are dry.

Compressed air

The compressed air used for the drying CESC needs to meet the requirements of the CESC manufacturer and should be tested routinely for moisture content, oil content and particulate content as applicable (ref BS EN 16442 table A1 summary of tests)

Interim actions to reduce the risk in the event of CESC failure to meet these requirements

There are several actions that can be taken on an interim basis to aid the achievement of drying the endoscope. These include

1) Using the endoscope washer disinfector's purge to remove most water from the lumens. If this reliance is required, then the purge of endoscopes within the washer must be validated on a quarterly basis in relation to time and pressure
2) Relying on and extending the purge time the endoscope washers apply to the endoscope. If this requirement applies, the endoscope purge in the washer should be validated every quarter in relation to time and pressure applied.

3) Manually purging the lumens and externally drying the endoscope using suitable compressed air before placement in the drying CESC

Recommendations

1) The drying function of a drying cabinet should be validated on a quarterly basis as required within Health Technical Memorandum 01-06: Decontamination of flexible endoscopes Part D: section 6 table eight. This being the safer option giving more assurance of this primary function than the standard view of it being an optional test
2) Upon purchase of a Controlled environment storage cabinet with drying function the Type testing report is reviewed by the AE(D) to ensure it sufficiently cover the endoscopes the unit will be used to dry
3) The testing of the drying function of a CESC can be carried out using either a live endoscope or a surrogate but the testing for lumen dryness must be carried by the endoscope or surrogate being removed from the cabinet. Compressed air be used between 80kPA and 120kpa. The 80kPA is a lower figure recommended by the AE(D) technical platform as the absence of a lower figure within the standard allows for no pressure at all which could give a false satisfactory result.
4) Surrogates used for routine validation should reflect the more challenging endoscopes in use that will use the CESC see Endoscopy-surrogates-v6.pdf
5) The recording of a drying function test should record the following details. The type of endoscope, the pressure of compressed air used, the length of time applied to each lumen, where the air was applied see example table below

Type of endoscope			
Drying time			
Lumen tested	Pressure applied	Duration	Pass or fail
Stack suction to distal end button blanked biopsy blanked	100kPA	20seconds	
Air channel from the stack with channel separator in place to the distal end	100kPA	20 seconds	
Water channel from stack end to distal end with channel separator in place	100kPA	20 seconds	
Auxiliary channel from stack end to distal end	100kPA	20 seconds	

6) Any live endoscopes must be reprocessed after being used for drying function testing

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