IRISH DECONTAMINATION INSTITUTE

IDI Conference
Kilkenny Hotel

PuriCore
Pure Science. Pure Life.

Gary Walters

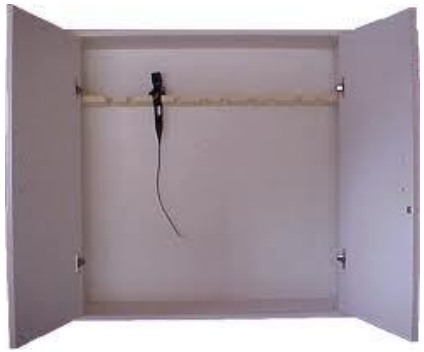
Finally, a standard for Flexible Endoscope Storage?

Contents

- Background Drivers
- Many guidelines but no standards
- Storage Cabinet Specifications
- Extending the storage time
- New standards
- New developments
- What's next

It can be a minefield!

PuriCore
Pure Science. Pure Life.



With no clear standards for Endoscope Storage Cabinets, the cleanliness of your scopes can be compromised

Background Drivers

PuriCore
Pure Science. Pure Life.

2003
BSG Guidelines – All endoscopes must have been exposed to a full decontamination cycle not more than 3 hours prior to use

2006
Labcaire (now PuriCore) introduces its range of 72 hour Endoscope Storage Cabinets fully compliant to BSG and HTM20-30 Guidelines

2008
Introduction of French Standard for Storage of Heat Sensitive Endoscopes – AFNOR NF S98 – 030
BSG update their guidelines

2011
Draft Document from European Committee for Standardisation – CEN/TC 102/WG 8 N
CFPP 01-06 Final Draft Document circulated
PuriCore extend validated storage time to 31 days

2012
CfPP 01-06 Released
Draft BS EN 16442 Controlled environment storage cabinet for disinfected thermolabile endoscopes released for comment .
PuriCore launches fully compliant Endoscopy Drying Cabinet range

British Society of Gastroenterology Guidelines

PuriCore
Pure Science. Pure Life.

BRITISH SOCIETY OF GASTROENTEROLOGY

In 2008 BSG updated their Guidelines to include for Storage Cabinets saying…

“Traditionally it has been recommended that, before the start of each list, each endoscope to be used should undergo a full reprocessing cycle unless last used and decontaminated within the preceding 3 hours. Many units are now using purpose built drying and storage chambers, some of which have been shown to prevent colonisation of endoscope channels for up to 72hr (some manufacturers claim 7days). Where appropriate quality assurance data is available, the use of such chambers may obviate the need for repeat endoscope reprocessing at the start of each list.”

They also added …

“Filtered air should be used as part of the drying process at the end of the working day prior to endoscope storage. An alternative is to dry and store endoscopes in cabinets that are designed to deliver high efficiency particulate filtered air to the internal channels at the appropriate temperature and flow rate.”

Endoscope Storage Cabinet Specification

PuriCore
Pure Science. Pure Life.

Key Design Requirements

- Provide a clean, lockable environment
- Flow filtered air down each endoscope lumen
- HEPA filtered air should be flowed within the cabinet
- The inside of the cabinet should be able to hold a higher pressure than the outside, typically >10 Pascals
- Ensure that any endoscope is not stressed during storage
- The storage time is clearly stated by the manufacturer and supported by validation data
- The storage time of each scope should be recorded for traceability purposes

Typical Test Requirements - HTM Guidelines

PuriCore
Pure Science. Pure Life.

HTM recognised tests should be carried out by suitably qualified personnel to determine a Storage Cabinet's

- Effectiveness of load drying capability following reprocessing
- Ability to remove possible residual microbiological contamination on all external surfaces of an endoscope including the control wheels
- Ability to remove possible residual microbiological contamination on all internal endoscope surfaces i.e. lumens
- All internal surfaces, connections and loading trays should be tested for possible microbiological contamination
- Temperature, flow and pressure of the exhaust air to be monitored

Evidence of an effective Storage Cabinet

PuriCore
Pure Science. Pure Life.

Storage Time (Hours)	Endoscope Type and Serial Number	Number of Viable Bacteria per Swab	Pro-tect® M Protein Tests (Colour Levels 1-4)	Lightning MVP™ ATP Detection (565 nm)	Air Measurements (100mm below the filter face of the HEPA filter)	
					Airflow (m/s)	Temp (°C)
0 (Control)	Colonoscope, CF-20HL, S/N 2911005	0	1/2 (Greenish Grey)	6096 (Zone 2.8)	0.6	27.5
	Gastroscope, GIF-2T200, S/N 2500778	36	1/2 (Greenish Grey)	6172 (Zone 2.8)		
	Colonoscope, CF-200S 1, S/N 2610459	0	1/2 (Greenish Grey)	6264 (Zone 2.8)		
0.5 (30 min)	Colonoscope, CF-20HL, S/N 2911005	0	1 (Green)	1174 (Zone 2.1)	0.6	27.5
	Gastroscope, GIF-2T200, S/N 2500778	0	1 (Green)	1168 (Zone 2.1)		
	Colonoscope, CF-200S 1, S/N 2610459	0	1 (Green)	1169 (Zone 2.1)		
1	Colonoscope, CF-20HL, S/N 2911005	0	1 (Green)	1064 (Zone 2.1)	0.6	27.5
	Gastroscope, GIF-2T200, S/N 2500778	0	1 (Green)	1065 (Zone 2.1)		
	Colonoscope, CF-200S 1, S/N 2610459	0	1 (Green)	1063 (Zone 2.1)		
2	Colonoscope, CF-20HL, S/N 2911005	0	1 (Green)	1047 (Zone 2.1)	0.6	27.5
	Gastroscope, GIF-2T200, S/N 2500778	0	1 (Green)	1043 (Zone 2.1)		
	Colonoscope, CF-200S 1, S/N 2610459	0	1 (Green)	1048 (Zone 2.1)		
24	Colonoscope, CF-20HL, S/N 2911005	0	1 (Green)	1016 (Zone 2.0)	0.6	27.5
	Gastroscope, GIF-2T200, S/N 2500778	0	1 (Green)	1018 (Zone 2.0)		
	Colonoscope, CF-200S 1, S/N 2610459	0	1 (Green)	1012 (Zone 2.0)		
72	Colonoscope, CF-20HL, S/N 2911005	0	1 (Green)	1009 (Zone 2.0)	0.6	27.5
	Gastroscope, GIF-2T200, S/N 2500778	0	1 (Green)	1006 (Zone 2.0)		
	Colonoscope, CF-200S 1, S/N 2610459	0	1 (Green)	973 (Zone 2.0)		

Extending the Effective Storage Time

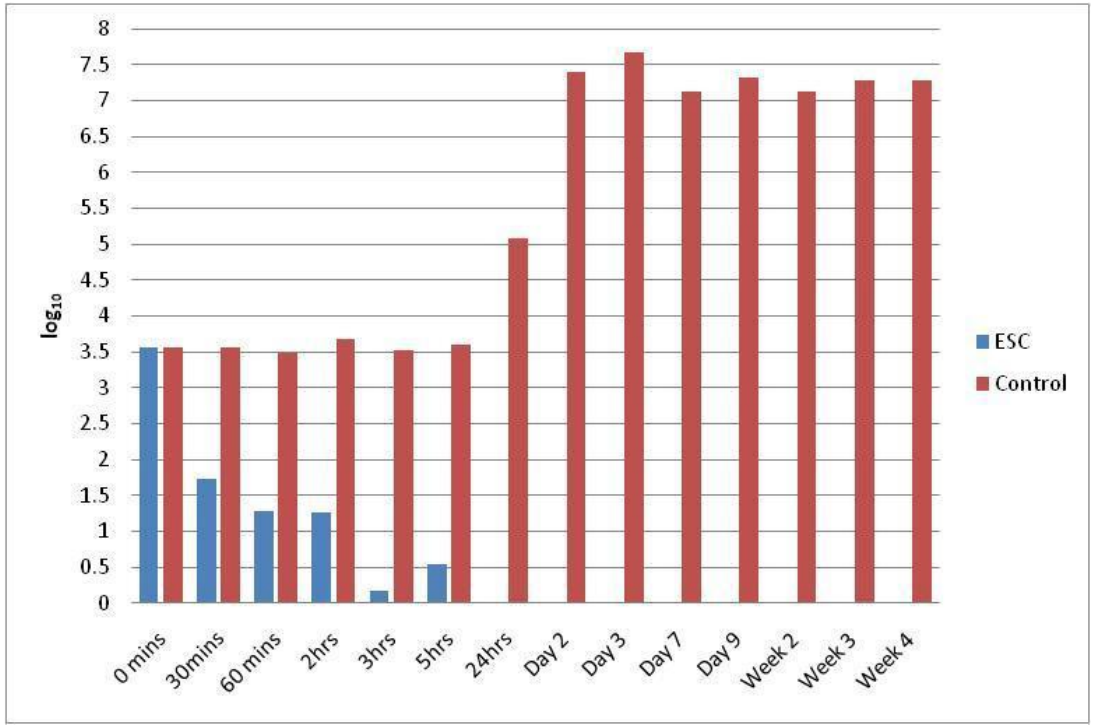
PuriCore
Pure Science. Pure Life.

- Market needs required endoscopes to be stored for longer than 3 days
- In 2011 PuriCore launched their 31 day Endoscope Storage Cabinet providing effective storage for up to 10 Flexible Endoscopes for up to 31 days
- The original ESC type test was repeated with all microbiological testing extended to in excess of 31 days
- The extended storage time is fully supported by 3rd party reviewed validation documentation

31 days Microbiological Results

PuriCore
Pure Science. Pure Life.

This interim data set is part of a greater study into extended storage efficacy



The study methodology is based on the French standard and surrogates were used to provide the necessary number of replicates and time points. The data shows the mean population of *Ps.aeruginosa* recovered from 1.5m long (2mm ID) surrogate tubes throughout the storage period. The blue columns show data from surrogates stored in the ESC and the red columns show data from surrogates stored in a cupboard without environmental control.

AFNOR NF S98 – 030 Standard

In January 2008 the Association Francaise de Normalisation (AFNOR) produced a specification for the effective storage of Flexible Endoscopes which differentiated between Storage and Drying Cabinets and included standards for:

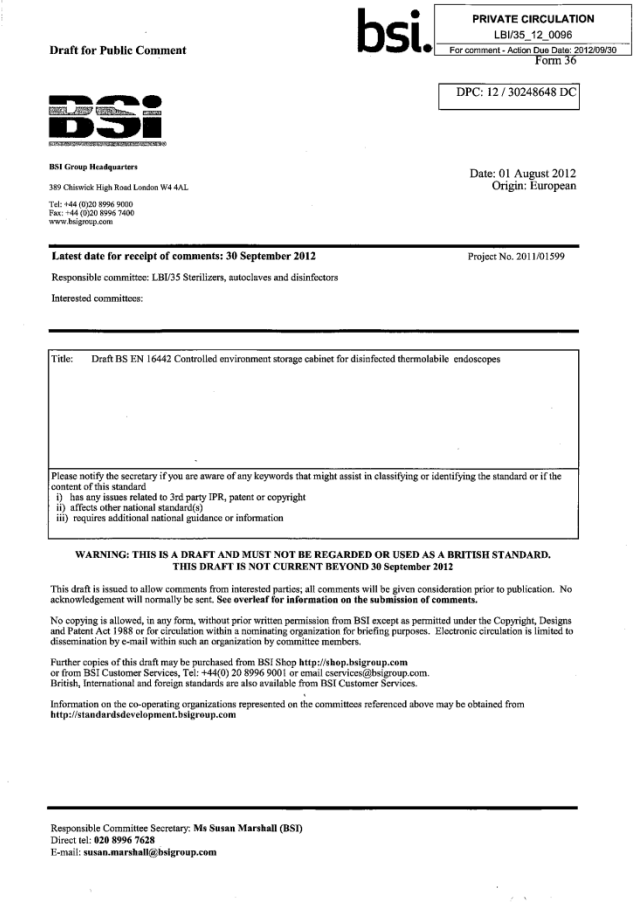
- The methods to be used for reference tests designed to verify that Storage Cabinets meet the specified requirements
- The methods to be used for any tests that can be carried out to check that the installed Storage Cabinet continues to comply with the validated operating conditions
- A drying function is optional but if a cabinet does not comply with the specification of a Drying Cabinet then clear instruction are to be given on how to dry a scope prior to storage.

Finally a specification for the storage of Flexible Endoscopes!

European Committee for Standardisation

PuriCore
Pure Science. Pure Life.

- In May 2011 the European Committee for Standardisation circulated its draft specification document CEN/TC 102/WG 8 N for Controlled Environment Storage Cabinet for Disinfected Thermolabile Endoscopes
- It took much of its guidance from the French AFNOR Standard (AFNOR NF S98 – 030)
- Now determined BS EN16442, the document has been released for review with a probable publication date early 2013. It will set the standard for all Endoscope Storage and Drying Cabinets
- The standard clearly recognises the need for physical removal of liquid and evaporation as the means to produce a ‘dry’ endoscope



Draft for Public Comment

bsi. **PRIVATE CIRCULATION**
LBI/35_12_0096
For comment - Action Due Date: 2012/09/30
Form 36

DPC: 12 / 30248648 DC

BSI

BSI Group Headquarters

389 Chiswick High Road London W4 4AL

Tel: +44 (0)20 8996 9000
Fax: +44 (0)20 8996 7400
www.bsigroup.com

Date: 01 August 2012
Origin: European

Latest date for receipt of comments: 30 September 2012 Project No. 2011/01599

Responsible committee: LBI/35 Sterilizers, autoclaves and disinfectors

Interested committees:

Title: Draft BS EN 16442 Controlled environment storage cabinet for disinfected thermolabile endoscopes

Please notify the secretary if you are aware of any keywords that might assist in classifying or identifying the standard or if the content of this standard
i) has any issues related to 3rd party IPR, patent or copyright
ii) affects other national standard(s)
iii) requires additional national guidance or information

WARNING: THIS IS A DRAFT AND MUST NOT BE REGARDED OR USED AS A BRITISH STANDARD. THIS DRAFT IS NOT CURRENT BEYOND 30 September 2012

This draft is issued to allow comments from interested parties; all comments will be given consideration prior to publication. No acknowledgement will normally be sent. **See overleaf for information on the submission of comments.**

No copying is allowed, in any form, without prior written permission from BSI except as permitted under the Copyright, Designs and Patent Act 1988 or for circulation within a nominating organization for briefing purposes. Electronic circulation is limited to dissemination by e-mail within such an organization by committee members.

Further copies of this draft may be purchased from BSI Shop **http://shop.bsigroup.com** or from BSI Customer Services, Tel: +44(0) 20 8996 9001 or email cservices@bsigroup.com. British, International and foreign standards are also available from BSI Customer Services.

Information on the co-operating organizations represented on the committees referenced above may be obtained from **http://standardsdevelopment.bsigroup.com**

Responsible Committee Secretary: **Ms Susan Marshall (BSI)**
Direct tel: **020 8996 7628**
E-mail: **susan.marshall@bsigroup.com**

Summary of Standard

Storage:

- User instructions for cabinets that do not have a drying function shall state that the device (outside surfaces and internal channels) should be dried before storage
- If the cabinet has been designed to store several endoscopes at the same time, means shall be provided to avoid any cross- contamination between the different articles in the load
- There shall be no increase or adverse change in microbial contamination .

Drying:

- The manufacturer shall state the procedures required to minimize microbial contamination on the internal surfaces of the cabinet. These procedures shall not adversely affect the quality of the load under normal conditions of use.
  - Filtration of the air using filters having not less than 99.997% removal of particles of 0.5µm (EN 1822-1 class H12 or H13)
  - Moisture < 0.05 mg/l
  - Oil < 0.10 mg/l
  - Air pressure : equal to or at least >10 Pa higher than the ambient pressure
  - Cabinet RH expected to be equal to or less than 30% at ambient temperature after drying
-

Summary of Standard

Verified channel air irrigation system:

- Series of checks to make sure that during storage, process air flows through each of the internal channels and/or cavities of the device.
- Connectors qualification
- Temperature control
- Fault indicator system
- Instruments and control devices
- Temperature indicators
- Pressure indicators
- Traceability
  - **This shall include but shall not be limited to:**
  - identification of the endoscopes
  - Storage time for each endoscope,
  - conformity of all manufacturer-defined critical parameters
  - identification of the operator loading and unloading the endoscope from the cabinet

Load Dryness Evaluation

PuriCore
Pure Science. Pure Life.

Method 1

- To evaluate the ability of the storage/drying cabinet to dry the endoscope internal channels after XX minutes of storage as claimed by the manufacturer
- At the end of the drying time specified by the manufacturer (60 minutes), the endoscope is removed from the storage/drying cabinet and is held vertically.
- Compressed medical grade air at a pressure of 105 to 120 kPa is blown into each channel of the endoscope in turn, with the distal end of the endoscope positioned between 50 mm and 100 mm above and perpendicular to the crepe paper.
- The crepe paper is examined to check if it contains traces of moisture indicated by dark spots.

Load Dryness Evaluation

PuriCore
Pure Science. Pure Life.

Method 2 Alternative Test

The current test method described in EN ISO 15883-4 (load dryness) can be used to prove the air purge capabilities of the endoscope channel drying system but not be an appropriate method to prove the overall drying capabilities of a drying system.

The following method is recommended as an alternative drying test.The method is based on the “wet bulb temperature measurement principle” (Figure D.1).

The measurement takes place in a cylinder partially filled with water. One temperature sensor is placed in the water and the other sensor above the water.

Connected to the cylinder is a Teflon tube (3 mm ID) representing an endoscope channel on the other side of the cylinder is the outgoing channel connected, Teflon tube (3 mm ID). The test set up is shown in Figure D.2.(next slide)

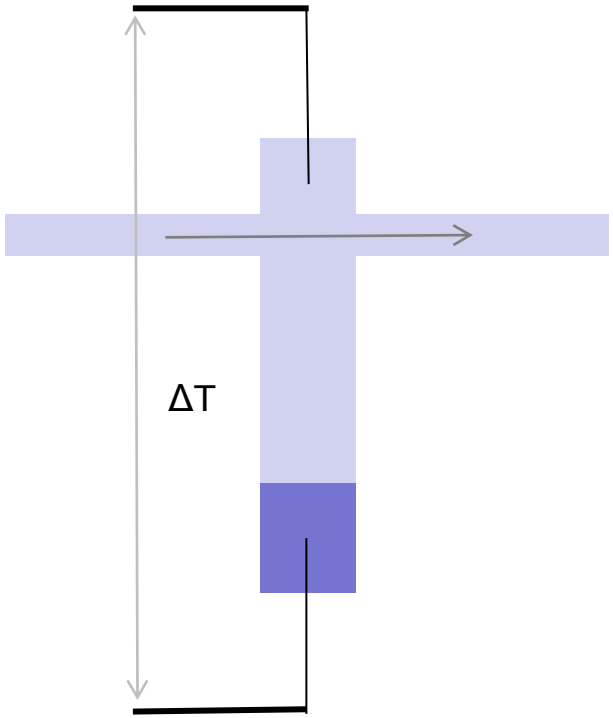
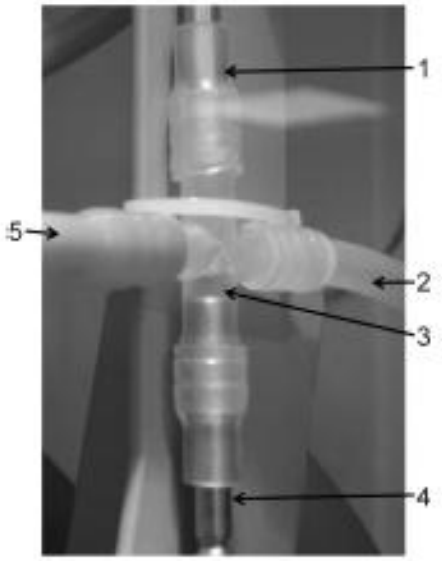


Figure D.1 — Alternative drying test method

Load Dryness Evaluation

- Method 2 continued
- Connect the inlet tube (air in, Figure D.2) to the endoscope channel drying system
- Start the endoscope drying process
- During the drying stage the temperature will fluctuate between the sensors (ΔT, Figure D.1), the sensor in the water will show a lower temperature than the sensor above the water
- At the end of the drying stage if the liquid is dried the temperature is stable and there is no difference between the sensors.



Key
1 dry temperature probe
2 air out
3 water
4 wet temperature probe
5 air in

Figure D.2 — Test apparatus

The Standard's Principle and Benefits

The use of Endoscope Storage/ Drying Cabinets consistent with the essential requirements of the draft BS EN 16442 combined with a routine sampling program to monitor the microbiological quality of the endoscopes and the cabinet should:

- Permit to increase the maximum storage time allowed before reprocessing endoscopes partially or completely prior to use.
- Increase the microbiological quality of an endoscope
- Reduce the staff time per procedure
- Decrease endoscope reprocessing cost per procedure

Critical Parameters

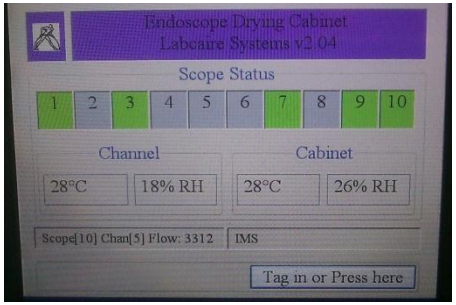
The draft BS EN 16442 Standard determines the critical parameters for the effective storage of flexible endoscopes are:

- Cabinet RH after drying <30%
- If heat is used to dry the scope the maximum acceptable temperature for endoscopes is 60˚C
- Continual conditioning with HEPA filtered air
- Minimum air flow through channels *not specified*
- Pressure differential >10 Pascals between inside and outside of cabinet
- Maximum scope drying time 3 hours

PuriCore Endoscope Drying Cabinet Range

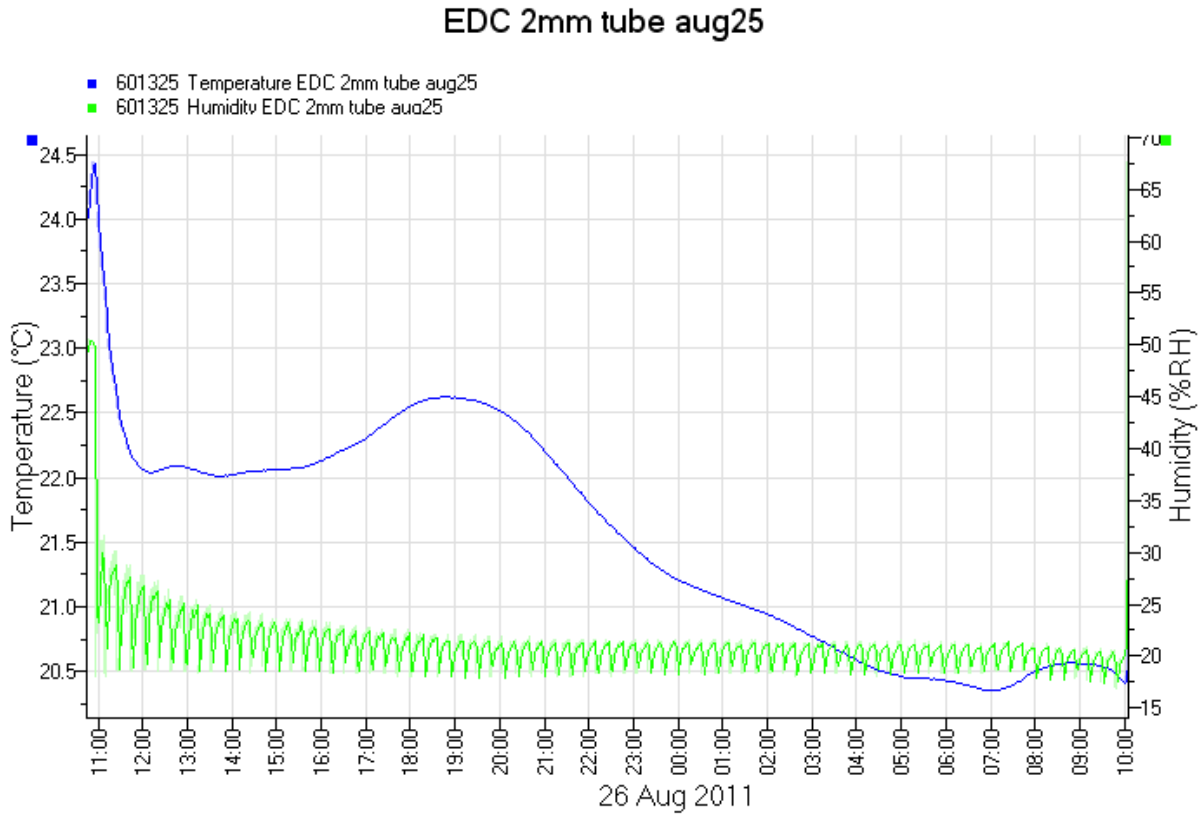
PuriCore
Pure Science. Pure Life.

- Cabinet relative humidity <30%
- Air Pressure Diff – 10 Pascals
- Air Pressure in lumens - < 2barg
- Air Flow per channel – 4 l/m
- Scope Drying Time – <60 minutes
- Channel Patency monitoring
- Track and Traceability capability
- Up to 31 Days Storage
- Vertical or load carrier storage option



Improved Drying Performance

PuriCore
Pure Science. Pure Life.

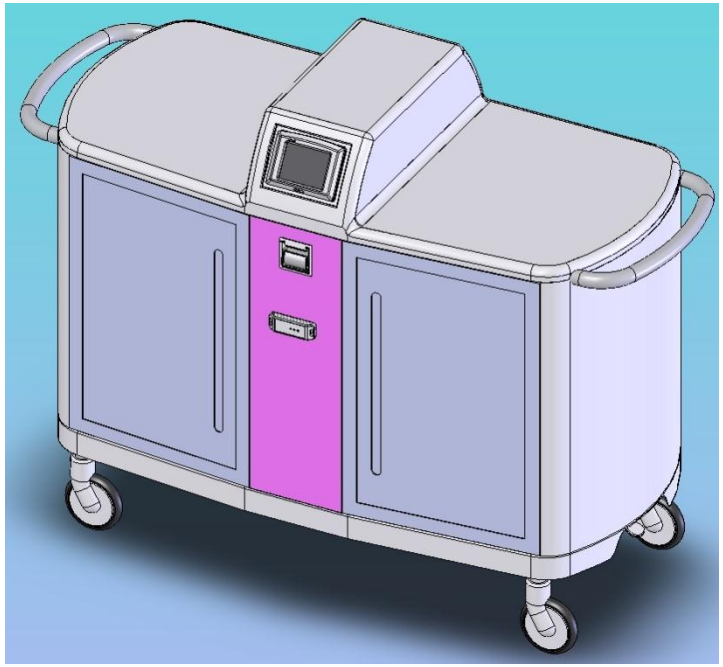


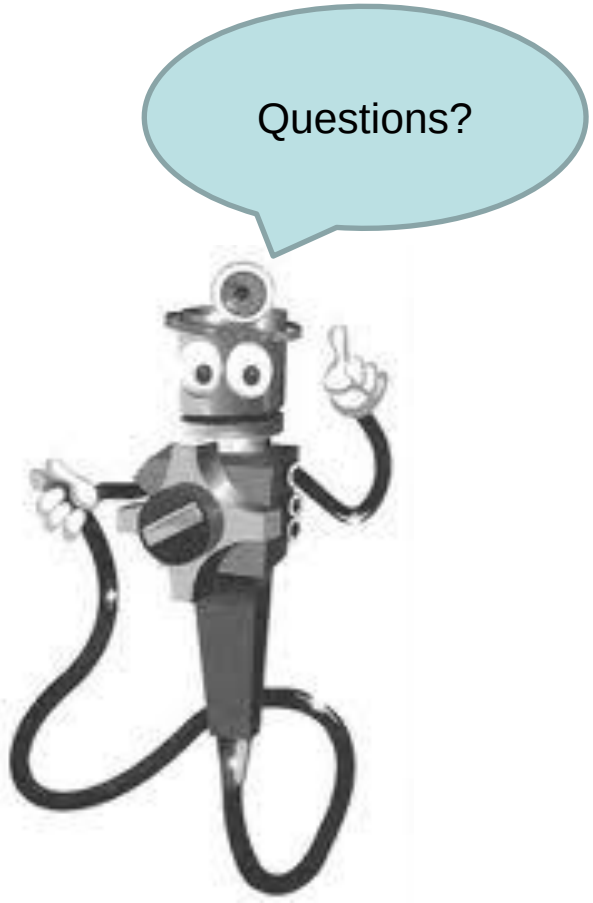
Temperature <25˚C and RH <30% decreasing to <20% produces a dry scope within 60 minutes

From Storage To Transportation of Scopes

PuriCore
Pure Science. Pure Life.

- Draft BS EN 16442 establishes that continual conditioning a scope with clean, dry air is the most ideal environment to store them.
- Therefore, the increasing requirement to transport scopes should follow the same rules
- PuriCore will unveil a new concept for the safe transportation of endoscopes, providing
  - The same continual conditioning using clean, dry air as our storage cabinets
  - Safe, traceable transportation and storage of both clean and dirty scopes
  - Minimal scope handling
  - Extended range battery pack for transportation between hospitals
  - Optional powered wheel drive




Questions?