As with all medical storage systems the goal of the endoscope drying, and storage cabinet is to provide the environment in which the processed scope can be safely stored so as to guarantee its suitability for immediate use.

The PQ for each style of cabinet is the same and consists of:

- Testing the drying function
- Testing for contamination of inside surfaces
- Testing for airborne contamination
- Inside the cabinet air quality testing
- Temperature or heating control function testing-if included as a feature of the cabinet
  AND
- The channel aeration tests
- We also like to verify the air exchange rate, temperature, and humidity inside the cabinet. These are not mandatory tests for PQ however I believe they contribute greatly to a better overview of the cabinet's condition and its performance.

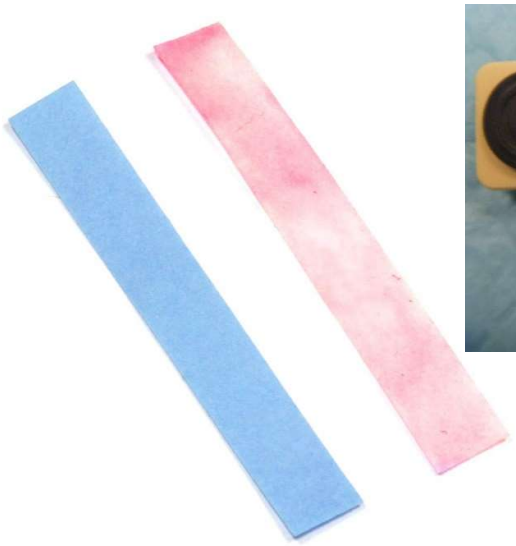
Summary of test programmes

Table A.1 — Summary of tests

Brief description of test	Subclause		Nature of test				
	Requirement subclause	Test subclause	Type test	Works test	Operational qualification	Performance qualification	Routine test
Air changes	5.2.2.3	6.2 D.5	X		X X[a]		
Overpressure	5.2.2.2	6.3	X				
Contamination levels on inside surfaces	5.3.2	6.5				X	O
Maintaining the quality of the endoscopes	4.2.1	E.1 E.2	X			 X[b]	 X[b]
Drying function (if applicable)	4.3	6.4.3 6.4.4 D.9	X X		 X[a]	X X	O O
Air quality-moisture content (if applicable)	5.2.1.1.2	6.6.2			X		X
Air quality-oil content (if applicable)	5.2.1.1.2	6.6.3			X		X
Air quality particulate contamination (if applicable)	5.2.2.4	6.6.1 6.11	 X			X	X
Airborne microbial contamination	5.2.2.1	Annex C	X			X[b]	O

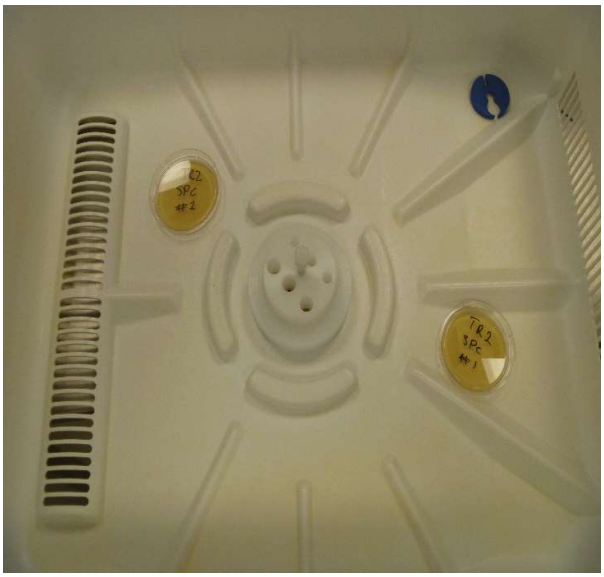
Logic dictates that where possible the endoscope dryness test is undertaken first as there is a mandatory maximum drying test time of 3 hr. It is good to have the representative endoscope reprocessed and stored prior to the PQ beginning to save on wait times.

The dryness as mentioned is checked after a maximum storage of 3 hours with the reference scope connected to the drying cabinet and the storage/drying process instigated as per the manufacturers IFU.



After the mandatory test time the scope is removed and checked visually for any residual water on the exterior of the scope and with a water reactive test paper under the control thumbwheels and in any tight gaps around the connection points. Any residual inside the connected channels is checked by flushing medical grade air down each channel at a pressure of 140Kpa again using a water reactive paper test at the distal end of the scope at a distance of ~100mm. All results obviously must return a negative water residue result for these dryness tests to be successful.

Probably the single most time-consuming test undertaken during PQ on a cabinet is the microbiological surveillance.



All cabinets must offer a dry, clean and organism free environment in which to store the scope post reprocessing. As cabinets now can be validated for storage at 3 or 7 days and maybe beyond it is imperative to confirm that the conditions inside the cabinet are suitable.

So how do we do this?

Prior to PQ being undertaken and dependant on the maximum storage time set for the cabinet the site must undertake a full clean of the cabinet the timing of this is dependent on the maximum storage time set in the cabinet, such as if the maximum storage time is 3 days the cabinet must be cleaned 3 days prior. This will ensure that all usual procedures in relation to the storage parameters and operation of the cabinet are being adhered to and the results gathered during PQ will be reflective of expected results during normal operation.

Once the clean and respective lead time has been undertaken and observed PQ can begin.

Depending on the style of cabinet horizontal tray type or vertically hung single chamber we collect microbiological samples, checking for the presence of bacteria or filamentous fungi as follows:

- In 2 locations where the endoscope will contact the cabinet using contact plates, or swabs
- In 2 locations inside the cabinet (walls/roof/floor)
  AND
- Inside the cabinet with settle plates designed to capture airborne microbiological contamination potentially circulating in the cabinet.

Note: An active air sampler can be employed, this is a piece of equipment the draws air from inside the cabinet over an agar sample plate thus giving a larger volume of air sampled, one problem is with the size of the sample unit required for this makes it difficult to install in cabinets that have separate scope tray storage.

All samples are taken with the machines serial number and their location noted on the plate for identification at the laboratory and on the microbiological report.

As horizontal tray style cabinets employ the use of individual trays these need to be viewed as multiple chamber cabinets, so in a cabinet with 8-10 trays you could imagine the number of micro plates and the subsequent tests needed when compared against its vertical hanging counterparts.

The results from the samples taken are usually available post submission to the lab within 5-7 days and will identify if any Colony Forming Units are present however if a result is positive, subsequent further testing to identify the species found will need to be undertaken, usually at a further cost to the client.

With the testing results we are looking for a maximum of 25 CFU's per 25cm2 however this result is not considered to be acceptable if the microorganism is found to be pathogenic in nature.

If a positive result is detected, you should follow your local infection control guidelines and directions which would include amongst other directions

- Reprocessing of all scopes
- Fully cleaning the cabinet.
- Retesting the equipment

After the micro testing is complete and all samples are on ice, I usually move onto the Air quality tests, these are not the same as the micro samples taken in the previous tests but are designed to identify the size and concentration of any free moving airborne particles.

This sampling is undertaken removing all scopes and installing a particle meter in the geometric centre of the cabinet. This is an instrument that collects and analyses airborne contamination, similar in design to the active air sampler it draws air from inside the cabinet past a sensor that identifies the size and concentration of any airborne matter.

Limits for acceptance are defined by the manufacturer of the cabinet as to permissible maximums of particulate, this is dependant on the class of filtration in use and the frequency at which the cabinets filtration is changed. If a cabinets recommendation for service includes upstream aerosol testing to determine change frequency then this also must be undertaken, this is not common.

Temperature Control

This is an option that is not present on all cabinets but if it is, it must be tested to ensure the operating limits and safe temperature tolerances of the scope and cabinet are not exceeded.

There are two ways to test this option:

The first method is to install up to 12 NATA traceable calibrated temperature probes on and in the reference scope. These are placed at intervals of no more than 750mm on the outside of the umbilical, inside the biopsy channel at a depth of no less than 100mm and on the control head of the endoscope. The temperature is then monitored for the maximum time allowable. This test can be very long and realistically this data can be gathered in a timelier manner during the second style of testing available.

This second test employs the same temperature probes but measures the temperature for the drying phase or for a limited amount of time only. The data gathered is displayed graphically and must not deviate outside of the manufacturers stated temperature band.

Channel Aeration

SLIDE 10 AERATION

Channel aeration is another test that needs to be also undertaken with the use of a surrogate. The surrogate is the same style and dimensions as the surrogate used in cleaning efficacy of the reprocessor however this time we are utilizing the restriction in flow from the surrogate and a test beaker filled with 250ml of water to challenge the drying cabinets ability to air purge connected channels.

The surrogates are connected to all available relevant channel connections in the cabinet and the drying and storage program is instigated. With the distal end of the surrogate under 250ml of water the cabinet must have sufficient air flow and air pressure available to aerate each channel sufficiently. This same test is repeated for each position and channel connection option.

That brings to an end the mandatory tests required for PQ however there are a few tests on the summary of tests that I routinely include.

The air exchange rate if the cabinet and the inside temperature (for non-temperature-controlled cabinets) and relative humidity.

Adding in these two optional tests gives a more complete view in my opinion of the performance f the cabinet and also a strong indication of its ability to dry effectively.

Air flow into the cabinet must be of a volume that sees the air exchange rate be at 10 air exchanges per hour minimum. This is a simple calculation based of ducting size, cabinet volume and flow velocity.

Once you have the three values required the air exchange rate can be calculated and checked. I prefer to not remove any items of mass or volume from the cabinet as this would then give the cabinet an operationally smaller volume thus giving our calculated result an "under challenge" outcome.

The relative humidity and temperature check is also a quick operational test which is undertaken by installing a relative humidity and temperature meter inside a full and running cabinet and allowing the unit to stabilise. RH and temp is then check at 5 minute intervals for a duration of 30 minutes. A cabinet with a warmer than ambient operating temperature and a lower RH should provide a better environment for the scope to be stored.

Routine testing

So, what can you do as a site to ensure that your drying cabinet is still performing where it needs to be?

Well apart from routine servicing and maintenance and of course having your yearly PQ carried out by a reputable company 😊 vigilance of the drying performance is paramount.

Almost everything for a successful storage environment hinges off the question "IS THE SCOPE DRY"

A dry scope is what we need to ensure that the cabinet and its contents are off to the best start that they can possibly have.

Other areas that are no less important are:

- Making sure that all cleaning and reprocessing procedures are strictly followed
- Routinely reprocessing the scope connections
- Routine cleaning of the cabinet's inner surfaces and trays at the specified interval but also directly after servicing or repair.

But apart from these areas which are very straight forward one of the areas you can carry on from where PQ finishes is by routine micro testing of the cabinet yourselves. I would advocate picking a position or tray each month and swabbing the inner surfaces, have the sample cultured and the result documented. By doing this quick test alongside your other routine monitoring in the department you will be adding to the weight of documentation solid evidence of ongoing compliance.