Health Facilities Scotland

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Scottish Health Technical Memorandum 01-06

Decontamination of thermolabile flexible endoscopes and Transoesophageal Echocardiograph (TOE) ultrasound probes in Endoscope Decontamination Units Part E: Storage cabinets and packing systems for containment of disinfected endoscopes

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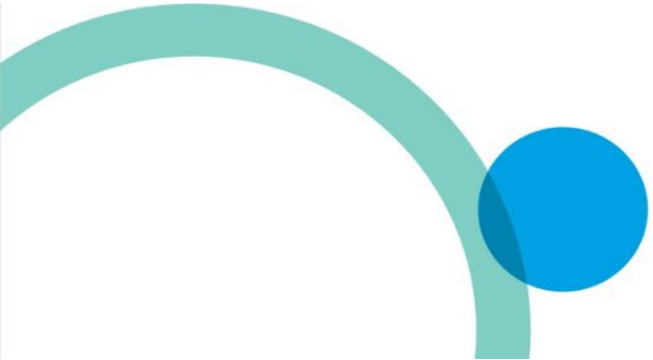

Contents

1. Introduction

General

1.1 After completion of an operating cycle in an Endoscope Washer Disinfector, the endoscope or Transoesophageal Echocardiograph (TOE) ultrasound probe may be used immediately or be contained (stored) for future use. It is essential that whichever containment method is employed the endoscope is maintained in its clean disinfected state prior to use.

Scope

1.2 This guidance covers design considerations, pre-purchase specification, operation, maintenance requirements and validation requirements for equipment used to contain flexible thermolabile endoscopes that have previously been subjected to a high level chemical disinfection process. This containment equipment includes:

- storage cabinets (compliant with standard BS EN 16442: 2015);
- vacuum pack systems (not covered by published standards as at 2022);
- pressure pack systems (not covered by published standards as at 2022).

This guidance (SHTM 01-06 Part E) establishes best practice performance requirements for these containment systems.

Out of scope

1.3 This guidance is not applicable to rigid endoscopes or ultrasound probes (excepting TOE ultrasound probes subject to both the TOE manufacturer and the storage cabinet or pack system manufacturer approval).

Flexible endoscopes required to be sterile or kept in uncontrolled environments e.g. transport trays with tray liners or sterile paper bags.

Note 1.1: The packing systems and resultant packed product described in this guidance relates to clean, disinfected endoscopes only. This should not be confused with a packaging system used for sterile product as described in the SHTM 01-01:2018 series.

1.4 Further guidance for the management of medical devices and equipment including general equipment specifications, health and safety requirements and procurement can be found in SHTM 01-06 parts A and B and SHTN 00-04: 2021.

Manufacturers of endoscope storage and packaging systems should demonstrate compliance with relevant parts of Standards:

- BS EN 837-1: 1998 (Pressure gauges);
- BS EN ISO 3746: 2010. (Acoustics);
- BS EN 61010-1: 2010+A1:2019 (electrical safety);

- BS EN IEC 61010-2-040: 2021;
- BS EN 61000-series for Electromagnetic compatibility (EMC).

Note 1.2: Explanation of differing containment - a storage cabinet and a pack provide different environments and level of protection to the endoscope contained within. For example, a decontaminated endoscope located within a storage cabinet is exposed to moving filtered air and is physically protected by the secure fixed structure of the cabinet. Whereas a decontaminated endoscope sealed within a pack is exposed to stationary air (under vacuum or pressure) and may have a conditioning chemical added (e.g. hydrogen peroxide or ozone). In this case the endoscope is protected by the packaging format while the pack is handled, moved onto/off a shelf/trolley and transported.

Factors to consider prior to purchase

1.5 The manufacturer of the containment system should verify which endoscope makes and models are compatible with the endoscope storage cabinet or packing system being considered for purchase. New makes and models or on-loan endoscopes should also be verified as being compatible with the containment system prior to receipt.

Note 1.3: Where the use of a storage cabinet or packing system is being considered for the storage of cleaned, disinfected TOE ultrasound probes the suitability of the storage system should be verified by the TOE ultrasound probe manufacturer prior to use.

1.6 Several factors require consideration prior to purchase or use of containment systems, including:

- the size of the EDU;
- The engineering service provision e.g. room ventilation requirements and space available in the proposed location (see sections1.11 and 2.17);
- the containment system manufacturer’s instruction for use including maintenance and cleaning requirements;
- the number of endoscopes to be stored/packed;
- type and location of clinical service supplied;
- maintenance of segregation of decontamination activities within the EDU as shown in SHPN 13 part 3: 2010;
- the maximum required storage time/shelf life;
- any requirement to store TOE ultrasound probes;
- storage cabinet loading patterns;
- channel flow as specified by the endoscope manufacturer;
- air flow volume rate and pressure (to cabinet interior);
- air quality (particulate and microbial for cabinet interior);

- air temperature;
- maximum and minimum operational temperatures;
- maximum pump pressure;
- display type;
- tracking and traceability capable of recording the identity of staff loading and unloading the endoscopes and a record of the identity of the endoscope e.g. serial number or Unique Device Identification number (UDI);
- compatibility of existing endoscopes with the proposed equipment;
- If a chemical is used in the system and if so evidence of its biocompatibility;
- the financial and environmental costs of any procurement exercise.

Note 1.4: Prior to purchase, the capacity of a storage cabinet should be assessed on the number of endoscopes of each type that can be stored, for the maximum validated storage time. Ensure the capacity requirements make allowance for downtime, including testing, maintenance and servicing.

Note 1.5: The use of a storage cabinet with a drying function (as defined in BS EN 16442:2015) can mean shorter EWD cycles and an increased throughput of endoscopes within a defined time period.

Risk assessment

1.7 Manufacturers should group endoscopes of similar design and complexity (e.g., endoscopes with the same type and number of channels into endoscope Type test groups and 'Product Families' (as defined in BS EN 16442: 2015 Annex F and G). An independent risk assessment in line with standard BS EN ISO 14971: 2019 should be carried out prior to purchase of any endoscope containment (storage) system to assess the endoscope Product Families (PF) that can be used with each system. The AP(D), AE(D) and Infection Prevention and Control (IPC) team and the clinical services supplied should be consulted.

1.8 The risk analysis should include consideration of all essential parameters of the equipment performance and should have mitigating measures applied to minimise identified risks. The effectiveness of all mitigating measures should be monitored and verified.

1.9 Depending on the design of the containment system the risks can include:

- environmental contamination during loading/unloading of an endoscope storage cabinet including during cleaning, maintenance, and testing;
- the integrity of the packed endoscope is compromised prior to use;
- the packed endoscope is damaged due to mishandling during placing onto/off a shelf or during transport;
- the potential for contamination caused by system accessories and connectors/connections);
- the potential for contamination caused by endoscope accessories;

- the environmental conditions (e.g. temperature, humidity, etc.) in the room where the storage cabinet/vacuum pack or pressure pack will be installed;
- the potential for contamination caused by improper air quality in the storage compartment/package;
- the potential for contamination caused by an inefficient drying procedure prior to storage;
- the potential for growth of micro-organisms within a contaminated endoscope inadvertently introduced into a containment system;
- the potential for contamination between different endoscopes stored simultaneously in an endoscope storage cabinet (as Annex B of BS EN ISO 16442: 2015).

Note 1.6: Advice should also be sought where additional measures may be required to maintain the status of the stored endoscopes e.g. where the use of double - ended storage cabinets is considered. All staff involved in loading and unloading should also be consulted e.g. where EDU staff load the cabinet and clinical staff unload (in a clinical area).

Note 1.7: Storage cabinets and packing systems are not designed to clean and/or disinfect endoscopes. A contaminated endoscope placed in a storage cabinet or packing system may still be contaminated at the time of use. Therefore, it is recommended that the microbiological quality of endoscopes processed in an EWD is determined prior to the introduction of any new storage cabinet or packing system.

1.10 Packing systems (vacuum packs/pressure packs) may be considered for use where:

- endoscope use is difficult to plan in advance e.g. emergency situations;
- endoscopes are required out with normal Endoscope Decontamination Units (EDU) hours e.g. in operating theatres;
- endoscopy units are in remote locations;
- the provision of an on-site EDU is not cost effective or practical for example a small rural clinic runs one session per week and a centralised EDU can supply the required number of decontaminated endoscopes in a packing system.

1.11 Where packed endoscopes or endoscope storage cabinets are located out with the EDU e.g. in clinical areas, an Authorising Engineer (Decontamination) and the Infection Prevention and Control Team should be consulted on operational aspects.

Any assessment should verify that:

- the room size, workflow and environmental conditions including airflow, and air pressure differentials are maintained and appropriate e.g. storage cabinet doors can blow open if the room environment has a lower pressure than the storage cabinet interior;
- consideration of the services such as electrical supply etc. in the room and the size of doors and access points are adequate to enable instillation, validation and testing;

- access to the storage cabinets is controlled i.e. only authorised personnel can access the stored endoscopes;
- the worst-case scenario of time between removing from EWD to its final storage system has been considered. Endoscopes should be placed in their final storage location as soon as possible after processing in the EWD and their time out of storage for transport and packing should be under 3 hours;
- tracking and traceability of endoscopes and staff is maintained to the patient;
- the required shelving for storage of packed endoscopes is available and suitable for use.

Note 1.8: To ensure the integrity of any packaging system used, guidance on the planning and selection of suitable storage equipment can be found in HFS document GUID 5010 - 'Theatres and CDU Guidance Management of reusable surgical instruments during transportation, storage and after clinical use Part A – design advice note for planning:2014.

Further guidance on the planning and selection of equipment and facilities can be found in Scottish Health Planning Note (SHPN) 13 part 3: 2010 – 'Decontamination Facilities: Endoscope Decontamination Units and part A of the SHTM 01-06 series.

2. Design and specification of storage cabinets

General

2.1 HFS guidance ‘GUID 5013 Requirements for Compliant Endoscope Decontamination Units’ published in 2014 requires that decontamination equipment is installed, validated and periodically tested.

Note 2.1: The maximum storage period of stored endoscopes varies depending on the storage system used. It is essential that the end users are consulted prior to introducing any new storage system to ensure availability of processed endoscopes as and when they are required.

Storage cabinets configurations

2.2 Storage cabinets, including those with a drying function, are available in various sizes and configurations (horizontal or vertical storage) of the endoscopes as examples shown in image 2.1 and 2.2. One or two doors or double ended (pass through) storage cabinets are also available.

The type of storage cabinet purchased will be dependent on local requirements based on:

- the numbers of endoscopes to be stored;
- frequency of use;
- the space available for storage cabinets;
- the need for storage in the clinical area.

Image 2.1: Example of a single door storage cabinet storing disinfected endoscopes in horizontal trays.

Image 2.2: Example of two door storage cabinets in which disinfected endoscopes are stored vertically.

Information to be supplied before delivery of the equipment

2.3 Prior to the selection of an endoscope storage cabinet the User should establish a list of potential 'Product Families' (PF) from the endoscope master list. The User should then confirm with the endoscope manufacturer that the type test groups used during testing are representative of the endoscopes to be stored.

2.4 As part of this process ensure the endoscope manufacturer receives a detailed specification for the equipment being considered for purchase, including the on-site service requirements. The equipment manufacturer should also provide confirmation that the User's pre-defined requirements can be met. Further guidance on preparation of a specification can be found in Parts A and B of this SHTM 01-06 series.

Information to be supplied by the purchaser

2.5 To ensure that the equipment supplied meets the operational needs of the EDU, the following information should be agreed with service users and made available to the manufacturer:

- required storage period;
- make model and product families of endoscopes in use;
- proposed location of the storage cabinet, including any constraints related to the equipment size and design (e.g. double ended cabinets which have load/unload door(s) connecting to different areas);
- access requirements for servicing;
- fittings to be provided e.g. endoscope supports and storage for endoscope accessories;
- available services (electrical, air compressors where required);

- IT connections required;
- quality of the room air supply and positioning of air vents and balance flaps.

Note 2.2: The User should provide a site location architectural drawing indicating where the equipment will be located.

2.6 Where multiple units are required, consideration should also be given to their usability (i.e. there is adequate room to load and unload them without contaminating processed endoscopes).

Note 2.3: In the event of a breakdown, periodic testing or other issue that may halt normal production, the loss of a storage cabinet could have an impact on endoscope availability. Therefore, for service continuity purposes consideration should be given to the number of storage cabinets put into service. Consideration of future clinical service developments should also be factored in.

Information to be provided by the manufacturer

2.7 Prior to purchase the following information should be provided to allow the suitability of each available storage system to be assessed:

- housings required for any storage cabinet buttons or emergency stops;
- any limitations to the type of device that can be stored (e.g. challenge presented by duodenoscopes);
- the maximum storage capacity and maximum storage period for each endoscope test type group;
- evidence that type test groups are representative of the product families in use;
- evidence (where applicable) that any drying/storage time claimed by the manufacturer;
- any limitations or exceptions to use should be clearly stated by the manufacturers in the instructions for use;
- a description of the recording and control system including the independent monitoring system fitted to the storage cabinet;
- engineering specifications (including where available drawings showing dimensions of the equipment and those of the packaged equipment);
- an audit of the access route from delivery point to point of installation should be carried out to ensure access is possible;
- installation requirements to include service requirements to operate the equipment, any special measures needed for access for installation;
- operational specifications including routine testing and maintenance requirements, and schedules (to assess ease and cost of maintenance), operator manuals (to assess ease of use) and spare parts lists.

2.8 These factors may vary depending on the make model and design of the storage cabinet being considered. The User, Authorised Person (Decontamination), AP(D)

and the Authorising Engineer (Decontamination) (AE(D)) should be consulted to ensure all essential factors are identified.

Note 2.4: The User and technical advisors should consider a site visit to a facility where the equipment is currently installed.

2.9 The manufacturer's instructions for use should be reviewed and seen to comply with BS EN ISO 17664 -1:2021 and include the action(s) required on the activation of alarms, or where a break in electrical power or other service occurs.

Note 2.5: Where double ended storage cabinets are being considered to assist with access by clinical staff, they should not open into public access areas. Processed endoscopes should only be accessed by staff trained and authorised to handle them.

2.10 A test protocol should be provided by the manufacturer to enable the AP(D) and User to verify the compliance of the system with BS EN 16442: 2015 and the original design specification. Refer to SHTM 01-06 Part E Appendix 2 for information on type testing of storage cabinets.

Compliance with standard for storage cabinets

2.11 Endoscope storage cabinets including those with a drying function should be compliant with the requirements of standard BS EN 16442: 2015 titled Controlled environment storage cabinet for processed thermolabile endoscopes.

2.12 The standard indicates that storage cabinets are designed to provide a controlled environment for the storage of endoscope(s) (with or without channels). The controlled environment provided by the storage cabinet should ensure that there is no deterioration of the microbiological quality of stored endoscopes.

2.13 Some cabinets also provide a drying function that will dry internal channels of an endoscope(s). The drying function is intended to supplement purging in the endoscope washer disinfector or manual drying during the subsequent endoscope inspection stage. Where the manufacturer claims a drying function they must be able to demonstrate with type test data that the requirements of the standard are achieved.

2.14 The manufacturer/supplier should provide data for type testing of all essential parameters including:

- establishment of worst-case conditions of temperature, airflow, air pressure and simulation of blockages and disconnected channels to demonstrate the safe storage of endoscopes when a failure of the services occurs;
- establishment of a quantitative comparison of efficacy for the operation of the storage cabinet, for a range of specified time periods (including those shorter than the recommended storage period);
- throughout the drying phase and/or storage, the values and rate of change in temperature, pressure or any other process variable should be within the limits shown not to cause damage to stored endoscopes (as recommended by the endoscope manufacturer);

- the value of any process variable should be pre-set and adjustment only possible via the use of a key, code or tool.

2.15 The recommended minimum operating conditions given by the manufacturer should be based on this data. Information on the requirements for type testing are included in Appendix 2 of SHTM 01-06 Part E.

2.16 Test conditions should also allow for the environmental conditions of the room in which the storage cabinet is planned to be installed.

Room ventilation

2.17 To ensure the room ventilation is not adversely affected by the positioning of the storage cabinets any air supply and extract grills and any pressure relief dampers should be kept free of obstructions. Storage cabinets should not be installed directly under or in front of the room air supply/extract grills. Consult the planning note SHPN 13 part 3: 2010 for the room ventilation requirements when locating storage cabinets within the Endoscope Decontamination Unit.

Note 2.6: Manufacturers of storage cabinets with a drying function may specify a room air supply of a specified number of air changes per hour.

Air supply to the storage cabinet

2.18 The quality of air supplied to endoscope storage cabinets can be critical in maintaining the disinfected state of the endoscope. Therefore, the material used in the pipework of the air distribution system should be compatible with the intended use of the storage system. The manufacturer of the endoscope storage cabinet should demonstrate (via type test data) that the air supply does not increase the particulate or microbial contamination of any endoscope stored in the cabinet.

2.19 High-efficiency particulate air (HEPA) filters (Class H 13) as specified in BS EN 1822-1:2019 should be used for air supplied to the interior of the storage cabinet and endoscope internal lumens.

Endoscope connection points

2.20 The layout of air outlet connection points to the stored endoscopes should be consistent for all storage cabinets of the same make and model, including identification within the automatic control system.

2.21 Storage cabinet ports for connection to the endoscope should allow the dedicated connection of biopsy, air, water and auxiliary channels as specified during the pre-purchase consultation.

2.22 All endoscope channel connection points should have a distinctive design that is not interchangeable, to prevent incorrect connection to other endoscope ports.

2.23 Where each endoscope channel is connected directly to the storage cabinet air supply, a method of assuring enough air is delivered to each endoscope channel should be provided. Air can be delivered continuously or intermittently.

2.24 When a manifold is used to supply several channels from one storage cabinet connection point the manufacturer should provide a way of verifying the specified airflow is achieved to all endoscope channels.

2.25 Where individual channels require air to be delivered at different pressures (e.g. an elevator channel or a channel fitted with a backflow check valve), a method should be provided to prevent incorrect connection of this endoscope channel to any other connector.

2.26 When the airflow level required for a specific endoscope is below the detection limit of any available monitoring system, the Infection Prevention and Control Team should be consulted regarding any limitations to the use and storage of these endoscopes.

Note 2.7: Colour coding alone is not an adequate means of channel identification.

2.27 Where the storage cabinet manufacturer claims a drying function as defined in BS EN 16442: 2015 They should demonstrate during type testing and Performance Qualification testing that the cabinet can dry the type of endoscopes planned to be stored in the cabinet within 3 hours. Endoscopes such as colonoscopes provide a significant challenge to the drying process.

Endoscope support systems

2.28 When a storage cabinet is supplied with a system for supporting endoscopes during storage and/or transferring endoscopes into and out of the cabinet (e.g. trays or baskets) these should:

- be constructed from durable, corrosion-resistant materials able to withstand the environment within the cabinet;
- have a means to prevent damage, wear and tear or excessive stress on the load carrier (e.g. point loadings) or the cabinet;
- ensure adequate spacing between endoscopes to prevent accidental contamination when loading/unloading the storage cabinet;
- prevent incorrect positioning that could restrict the penetration of air, into lumens, or the free evaporation of water from the endoscope surface;
- support endoscopes to prevent contact between stored endoscopes and internal surfaces of the storage cabinet such as the storage cabinet floor;
- the load configuration will prevent re-contamination by the interior environment of the storage cabinet or other endoscopes stored within the storage cabinet during operational use;
- be operated in accordance with the manufacturer's instructions.

Storage cabinet automatic controller

2.29 The automatic controller should include verification that the process conditions for temperature, relative humidity, pressure and air flow specified by the manufacturer were attained. Standard BS EN 16442: 2015 'Controlled environment storage cabinet

for processed thermolabile endoscopes sets the requirements for any automatic control system and states that the automatic control system should permit regulation of the pump and inlet pressure.

2.30 The automatic controller should also be equipped with a system to display essential operational parameters including:

- a status indicator;
- a fault indicator;
- storage air flow/air pressure;
- temperature and humidity;
- the storage time as a run meter or counter that cannot be re-set by the user (this can display time remaining or time stored).

2.31 Each gauge or display should be clearly labelled with a description of its function and if connected to more than one sensing point, should continuously indicate the sensor being monitored e.g. 'storage cabinet temperature', as this can assist the operator in understanding if the reading is significant and requires action.

2.32 It is also desirable that the automatic control system allows the storage cabinet to be adjusted for a range of endoscope types and any such adjustment should be a programmable option. Changes to the operational program should only be possible using a key, code or tool.

Calibration of measurement systems

2.33 A method of adjusting each measurement system without the need to dismantle or remove it should be provided. To allow independent confirmation of cycle parameters and calibration a key, code or a special tool should be provided to the User for use during periodic testing.

Note 2.8: Calibration adjustment or verification of calibration, should only be carried out by trained and authorised personnel, as removal of the connected sensor can be necessary during maintenance and testing. Therefore, to prevent accidental readjustment the use of any key, code or a special tool should be the responsibility of the User/AP(D).

Control of airflow

2.34 A method to verify the airflow control system, including assurance that the airflow through each endoscope channel meets the original type test data should be provided. This can be achieved by a visual inspection of the air circulation system display, or by confirmation of the storage cabinet process record. This information should be accessible by the User or Operator to allow confirmation that the storage cabinet is functioning as specified.

2.35 The air supply should be filtered to ensure that 99.95% retention of particles 0.25 µm or greater is achieved.

Note 2.9: Filters conforming to Class H 13 as specified in BS EN 1822-1:2019 should be used for all air sources entering the storage cabinet to prevent particulates, oil droplets and microbial contamination from air.

2.36 A method of removing excess moisture from the interior environment of the storage cabinet should be included to ensure the relative humidity is within the limits specified (see BS EN 16442: 2015). This can be achieved by active heating of the air to achieve the required dryness level or, passing through a desiccator or condenser followed by re-filtration.

2.37 The number of air changes inside the cabinet should be at least ten times the volume of the storage compartment per hour.

2.38 The air pressure within the storage cabinet should be specified and a reducing valve, or other automatic device, should be fitted to ensure the pressure of air does not exceed the maximum supply pressure specified by the endoscope manufacturer. A pressure relief valve may also be required to ensure safe venting of excess pressure.

Airflow for Endoscope channels

2.39 Many endoscopes have multiple narrow working channels/lumens and all working channels in use must be identified and specific dedicated connectors provided by the storage cabinet manufacturer.

2.40 Any flow of air into the endoscope lumens should be controlled, and the pressure and flow rate regulated.

2.41 The endoscope manufacturer as well as the storage cabinet manufacturer should confirm the dedicated channel connectors are fit for purpose.

2.42 A diagram for the circulation pathway of air for each endoscope type test group the storage cabinet is intended to store should be provided. The manufacturer should also specify the minimum and maximum pressure that the storage cabinet is designed to deliver to each channel, or channel system.

2.43 Any detection limit of the cabinet for monitoring the free passage of air delivered to the endoscope channels should be specified by the storage cabinet manufacturer.

2.44 For storage cabinets claiming a drying function it should be specified whether the automated channel flushing control system operates controls on each channel independently or, on a set of channels via a manifold.

2.45 The storage cabinet manufacturer should also provide a method of verifying that the supply of air to the manifold and each endoscope connector was maintained during the storage period.

2.46 The temperature of air in contact with the load during storage should be controlled within the limits stated by the endoscope manufacturer.

2.47 Endoscope storage cabinet connection points should also have:

- filtration of air passed through narrow bore channels of endoscopes to avoid endoscope blockages;
- been designed with fittings, that can withstand a minimum of 250 repeat connections;
- a means of identifying that they have been installed in their correct position;
- been designed to prevent connection to the endoscope leak test connection port;
- The following points should also be considered.

Internal cleaning and disinfection

2.48 Storage cabinets (including removable supports and trays) should be capable of withstanding routine cleaning and disinfection. The storage cabinet manufacturer should specify how their storage cabinet is cleaned and disinfected at the specified intervals, and after maintenance, repairs or testing. Compatible cleaning and disinfection solutions should be stipulated by the manufacturer.

2.49 The manufacturer should demonstrate during type testing that any cleaning and disinfection schedule prevents the build-up of microorganisms within the storage cabinet. Surface contamination levels inside the storage cabinet should remain below 25 colony forming units (cfu)/25cm^2 when tested in accordance with BS EN 16442:2015, clause 6.5. The standard also states in clause 6.5.2 that a contamination level lower than 25 cfu/endoscope is not considered to be satisfactory if the microorganisms recovered are pathogenic for the intended use of the device. This situation can require further investigation to identify the type and source of contamination. During such investigations the storage cabinet should be taken out of use.

2.50 The responsibility for ensuring microbiological tests are completed as per the schedule rests with the User. The scope and contents of any tests should be incorporated into local polices and have established action and alert levels. Any actions required should be agreed with the User, AE(D), microbiologist and IPC team.

Alarm capability

2.51 Where the storage cabinet becomes isolated from any of the essential services e.g. electricity or compressed air supply, a visual and audible alarm should alert the operator. The action required should be specified by the manufacturer and the IPC team should be consulted.

2.52 To prevent contamination of the stored endoscopes it should also be a requirement for visual and audible alarms to activate when:

- the doors are open for more than the validated period shown by the manufacturer;
- if the pre-set value for the internal pressure of the cabinet falls to or below the ambient pressure of the room in which it is located;

- where the air flow rate through connected endoscope channels is interrupted or below the validated flow rate, due to a blockage or if a disconnection occurs.

Note 2.10: Some storage cabinets may need a target endoscope channel flow rate for the type of endoscope being stored to be set within the automatic controller to enable the detection of a blocked channel or disconnection of an endoscope.

2.53 It should not be possible to override any visual alarm without a code, tool or key and any audible alarm should only be mutable for a short period.

2.54 The storage cabinet should have a display that alerts the operators to the storage time remaining or expired, for each endoscope stored.

Note 2.11: Where there is an interruption to any service endoscopes may be fit for use for a limited time. A risk assessment should be carried out in consultation with the IPC team to determine the time that endoscopes are still fit for use.

Any endoscopes removed to allow routine maintenance and not protected from environmental contamination or used within 3 hours must be reprocessed.

3. Design and specification of packing systems

General

3.1 There are a range of packing systems with different specifications and methods of maintaining the microbial quality of the disinfected endoscope over the pack shelf life.

These packing systems may:

- produce a vacuum packed product (vacuum pack);
- produce a pressurized/inflated pack (pressure pack);
- have a drying function;
- employ dedicated heat sealers while others make use of self-seal pouches;
- have variation in the depth of vacuum employed or pressure applied;
- inject a chemical conditioner such as ozone, or 1.5% aqueous hydrogen peroxide;
- have chemical conditioners of variable concentrations e.g. the chemical employed in vacuum pack chemicals (VPc) may differ from pressure pack chemicals (PPc) as detailed in table 3.1.

3.2 At the time of publication of this SHTM 01-06 guidance there was no published standard that specified the performance requirements for packing systems designed to pack, or dry and pack, flexible thermolabile endoscopes following automated processing. Table 3.1 establishes a packing system classification system with the associated quality attributes of the packed endoscope product.

Table 3.1: Packing system classification

	Quality attributes of the packed endoscope product	
	Functional endoscope	**Endoscope is safe for use**
Packing system classification	***Verification required***	***Verification required***
VPc - Vacuum Pack with chemical dosing	No adverse impact of vacuum and chemical used	Maintenance of microbial quality No adverse impact of chemical – e.g. irritant for patient
VP - Vacuum Pack with no chemical employed	No adverse impact of vacuum	Maintenance of microbial quality
PPc - Pressure Pack with chemical dosing	No adverse impact of pressure and chemical used	Maintenance of microbial quality No adverse impact of chemical – e.g. irritant to patient

3.3 Vacuum pack and Pressure pack systems can have a range of properties that vary dependent on the system manufacturer. These include:

- a variable shelf life dependent on the dryness level of the endoscope prior to packing;
- the addition of process chemicals to influence shelf life or in other cases no chemicals are added to the packed product;
- variable depth of vacuum;
- variable rate of draw of vacuum;
- variable positive pressure delivered within packs;
- vacuum packs with/without an inside former to protect the endoscope;
- a bench top system or a floor standing system.

3.4 The total processing time may vary based on the type of endoscopes being processed and the post decontamination state of the endoscope i.e. whether the endoscope is wet or dry. For example, cycle times may be longer for endoscopes with channels than those without channels.

3.5 A range of components can form the vacuum pack/pressure pack system; examples include:

- supportive trays;
- a solution for chemical dosing;
- pouches;
- sterile collection pads;
- liners;
- labels;
- transit cases;
- a lockable cart.

3.6 Though not a standard on pressure pack systems, Annex F of EN 16442: 2015 provides information on ‘Product Families’. The User should confirm with the pressure pack system manufacturer that the type test groups used during testing are representative of the endoscopes to be packed.

Risk Assessment

3.7 A risk analysis should have been undertaken prior to purchase including consideration of the different parameters on endoscope vacuum pack/pressure systems performance given. BS EN ISO 14971: 2019 establishes the requirements for risk management to determine the safety of a medical device by the manufacturer during the product life cycle and this may be used. Mitigating measures should be applied to minimise identified risks. The effectiveness of all mitigating measures should be verified.

3.8 Depending on the design of the vacuum pack/pressure pack system the risks can include:

- contamination between different endoscopes processed in sequence;
- where pressure or vacuum is applied a loss of seal integrity resulting in a loss of the microbial quality of the pack and or contamination from the environment in which it is stored;
- damage to packed endoscopes due to inaccurate and inconsistent pressure or vacuum being applied;
- packing of endoscopes that have not been validated by the pack system manufacturer;
- a pressure or vacuum that exceeds the limits stated by the endoscope manufacturer or they have not approved such packing methods;
- contamination caused by accessories and connection points including endoscope channel connectors for air purging and dosing of chemicals;
- residual chemicals on the packed endoscope at the time of use;
- unsuitable environmental conditions (e.g. temperature, humidity, etc.) in the room where the packed endoscope is stored;
- contamination caused by inadequate air quality;
- contamination caused by an inefficient drying procedure;
- growth of micro-organisms within a contaminated endoscope inadvertently introduced into the pressure pack system.

3.9 Type test data should be provided on request from the packaging system manufacturer for review by the AP(D) and User prior to purchase. A cost benefit analysis should also be carried out to ensure a safe, best value solution is purchased.

Configuration and load handling

3.10 The pressure pack or vacuum pack systems should have a track and trace system capable of allowing tracking of the device to the patient. Consideration should be given to integration of equipment specific track and trace systems to one which may be used in a decontamination department linked to the EDU.

3.11 Printed labels compliant with BS EN ISO 15223-1:2021 ‘Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied Part 1: General requirements’ are also required. Packaging labels should provide the following as a minimum:

- the date and time of production and a batch number;
- use by date and time;
- a means of verification of the packaging integrity and where applicable that the vacuum/pressure has been maintained;
- include any specific limitations on conditions of storage of the packed product.

3.12 The stated product shelf life should be verified by the manufacturer with type test data. In addition, endoscope connection points should be:

- protected from the passage of particles, that may block connectors or endoscope lumens by a filter that retains 99.95% of particles and microbes of 0.25µm or less. Filters conforming to Class H 13 as specified in BS EN 1822-1:2009 are suitable to prevent particulates, oil droplets and microbial contamination;
- designed with fittings, that can withstand a minimum of 250 repeat connections;
- have a means of identifying that they have been installed in their correct position;
- designed to prevent connection to the endoscope leak test connection port;
- accessible for cleaning without dismantling any part of the machine other than normally removable connectors or support systems is required.

3.13 Where the vacuum pack or pressure pack system flushes the endoscope channels with a process chemical that can change the microbial state of the packed endoscope this should be validated at type testing.

3.14 During manufacturers type testing of the packing system the biocompatibility of any process residue should be verified as described in the standard BS EN ISO 10993 series.

Pressure pack systems

3.15 Pressure pack systems have a range of properties that vary dependent on the system manufacturer. These include:

- a variable product shelf life - dependent on the pressure pack system's ability to process wet endoscopes or the requirement to dry the endoscope prior to packing;
- the possible addition of a process chemical to influence shelf life;
- variable pressure in the pack;
- variable rate of pressure increase;
- pressure packs with/without an inside former to protect the endoscope;
- a bench top system or a floor standing system;
- the system can comprise of multiple components e.g. separate dedicated equipment for drying of the endoscope and, injecting the chemical and packing of the endoscope.

3.16 Validation data should be provided on request from the pressure pack system manufacturer for review by the AP(D) and User prior to purchase.

3.17 A range of configurations of pressure pack solutions are available (an example is shown in image 3.1). The choice of system purchased will be dependent on local requirements based on numbers of endoscopes to be packed, the shelf space available for storage and to allow safe handling of processed endoscopes.

Image 3.1: An example of a pressure pack system with chemical injected

3.18 All support systems should:

- be operated in accordance with the manufacturers' instructions;
- prevent incorrect positioning that could restrict the penetration of air or process chemicals, into channels, or the free evaporation of water from the endoscope surface;
- be constructed from durable, corrosion-resistant materials.

3.19 All working channels for endoscopes in use must be identified and specific dedicated connectors provided by the pressure pack system manufacturer.

3.20 The automatic controller should include verification that the process conditions specified by the manufacturer were attained.

3.21 Any system for monitoring the free passage of air delivered to the endoscope channels and any detection limit of the pressure pack system should be specified.

3.22 Components of the compressed air system that require servicing and maintenance, such as filters, should be accessible for service or exchange.

3.23 For pressure pack systems claiming a drying function the manufacturer should demonstrate that the endoscopes can be dried to the required level or specify that the endoscope should be pre-dried and specify whether the automated channel flushing control system can run controls on each channel independently or on a set of channels via a manifold.

3.24 In addition pressure pack system endoscope connection points should be:

- protected from the passage of particles, that may block connectors or endoscope lumens by a filter that retains 99.95% of particles and microbes of 0.25µm or less. Filters conforming to Class H 13 as specified in EN 1822-1:2019 are suitable to prevent particulates, oil droplets and microbial contamination;
- designed with fittings, that can withstand a minimum of 250 repeat connections;
- have a means of identifying that they have been installed in their correct position;
- be removable for cleaning and disinfection both inside and outside;

- designed to prevent connection to the endoscope leak test connection port;
- access for cleaning without dismantling any part of the machine other than normally removable connectors or support systems is required.

3.25 The automatic controller should permit regulation of the pump and inlet pressure and be equipped with a system to display essential operational parameters including:

- a status indicator;
- a fault indicator or alarms to prompt the user or operator to a failure in any external services such as; electrical power, compressed air;
- storage air flow/air pressure;
- temperature and humidity.

3.26 Each gauge or display should be clearly labelled with a description of its function and if connected to more than one sensing point, should continuously indicate the sensor being monitored.

3.27 It should be possible to independently verify instrument and process controls during an operating cycle.

3.28 Where applicable a method should be provided to verify that any airflow or chemical control system is controlled, and the pressure and flow rate is regulated:

- the flow through each endoscope channel meets the manufacturers' original 'type test' data;
- alerts or alarms should be activated when the flow is interrupted or below the validated flow rate, that is a blockage or disconnection occurs.

3.29 To prevent contamination of the packed endoscopes it should also be a requirement for visual and audible alarms to activate when:

- the pre-set value for the internal pressure of the packaging does not meet the recommended limits during inflation;
- the air flow rate through connected endoscope channels is interrupted or below the validated flow rate, that is a blockage or disconnection occurs.

3.30 An access key, code or a special tool should be required to gain access to the settings adjustment system and it should not be possible to override any visual alarm without a code or tool. Audible alarms should only be mutable for short periods.

3.31 Where the pressure pack system claims a validated storage period this should be verified by the manufacturer with type test data.

3.32 Where the pressure pack system flushes the endoscope channels with a process chemical that can change the microbial state of the stored endoscope, the packing system chemical dosing system should be type tested, refer to Appendix 4, Table A4.1.

3.33 During type testing of the packing system the biocompatibility of any process residue should be verified as described in the standard BS EN ISO 10993 series.

Vacuum pack systems

3.34 On completion of a satisfactory decontamination cycle, the endoscope is placed inside the vacuum bag. The bag is sealed and a vacuum is drawn. On confirmation of a satisfactory vacuum process, the vacuum packed endoscope is then ready for transportation and use. See examples in image 3.2 and 3.3.

Image 3.2: An example of a floor standing vacuum pack system showing the endoscope positioned within a former and connected to an endoscope's channels

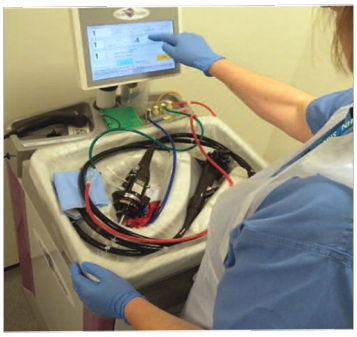

Image 3.3: An example of benchtop vacuum pack system in which no chemicals are injected

3.35 A range of configurations of vacuum pack systems are available (see image 3.2 and 3.3). The choice of system purchased will be dependent on local requirements based on the numbers of endoscopes to be stored, the space available for packed product and to allow safe handling of processed endoscopes.

3.36 Some vacuum pack systems can be positioned against a wall or between other equipment. While other free standing vacuum pack systems have four independently lockable castors.

3.37 All support systems should:

- be operated in accordance with the manufacturers' instructions;
- prevent incorrect positioning that could restrict the penetration of air or process chemicals, into channels or the free evaporation of water from the endoscope surface;
- be constructed from durable corrosion-resistant materials.

3.38 All working channels for endoscopes in use must be identified and specific dedicated connectors provided by the vacuum pack system manufacturer.

3.39 Automatic controllers should include verification that the process conditions specified by the manufacturer were attained.

3.40 Any system for monitoring the free passage of air delivered to or from the endoscope channels and any detection limit of the vacuum pack system should be specified by the cabinet manufacturer.

3.41 Components of the compressed air system that require servicing and maintenance, such as filters (HEPA H13 grade as BS EN 1822-1: 2019), should be accessible for service or exchange.

3.42 For vacuum pack systems claiming a drying function it should be specified whether the automated channel flushing control system can run controls on each channel independently or on a set of channels via a manifold.

3.43 The automatic controller should permit regulation of the pump and inlet pressure and be equipped with a system to display essential operational parameters including:

- a status indicator;
- a fault indicator.

3.44 Each gauge or display should be clearly labelled with a description of its function and if connected to more than one sensing point, should continuously indicate the sensor being monitored.

3.45 It should be possible to independently verify instrument and process controls during an operating cycle.

3.46 An access key, code or a special tool should be required to gain access to the settings adjustment system to prevent accidental readjustment.

3.47 Where applicable a method should be provided for the verification of any airflow or chemical control system during periodic testing and maintenance. Confirmation that the flow through each endoscope channel meets the manufacturers' original type test data during operation by the User or Operator should also be available.

3.48 For vacuum pack systems claiming a drying function the manufacturer should demonstrate that the endoscopes can be dried to the required level or specify that the endoscope should be pre-dried.

3.49 The vacuum pack system should be fitted with alerts or alarms to prompt the user or operator to a failure in any external services.

3.50 An alert or alarm should be activated when the air or process chemicals flow through the connected endoscope channels is out with the validated flow rate, as may arise due to a blockage or a channel connector becoming disconnected.

3.51 To prevent contamination of the packed endoscopes it should also be a requirement for visual and audible alarms to activate when:

- the pre-set value for the internal vacuum is not achieved in the specified time during the evacuation process;

- a blockage occurs.

3.52 It should not be possible to override any visual alarm without a code or tool and any audible alarm should only be mutable for a short period.

3.53 Any flow of air or process chemicals into the endoscope channels should be controlled, and the pressure and flow rate regulated. The values should be recorded by the automatic control system.

4. Validation and verification of storage cabinets

General

4.1 A test programme for storage cabinets is outlined in Annex A of BS EN 16442: 2015.

Prior to the installation of storage cabinets the guidance in sections 1 and 2 of this SHTM (01-06 Part E) should be considered. This includes planning, a review of manufacturers information against the agreed specification. It is advisable to conduct a site audit of the intended point of installation including an assessment of access routes from delivery point to point of installation. An assessment should also be made of the suitability of the engineering services prior to installation of the storage cabinet. Further guidance and requirements for equipment installation within an EDU is included in SHPN 13 Part 3: 2010.

Type testing

4.2 Type tests should be carried out by the manufacturer at their premises prior to release onto the market. The manufacturer should carry out type tests on representative samples of storage cabinets in serial production to demonstrate compliance with the requirements stated in EN 16442: 2015. Tests should also be performed on each serially produced unit as part of the manufacturers quality management system. The summary of test programmes in Annex A of BS EN 16442: 2015 includes tests on:

- the number of air changes/hour;
- overpressure;
- maintaining the quality of the endoscopes;
- drying function (if applicable);
- air quality particulate contamination (if applicable);
- airborne microbial contamination;
- temperature control (if fitted);
- channel aeration test;
- readability;
- cross contamination (optional).

4.3 The type tests should be carried out using, endoscope surrogate devices and/or endoscopes from each relevant endoscope ‘type test group’ selected using the method described in BS EN 16442:2015, Annex F, 6.3.

4.4 Refer to Appendix 2 Table A2 (of this SHTM 01-06 Part E) for more detailed information on type testing of storage cabinets carried out by the manufacturer.

Surrogate devices and product families

4.5 A range of test pieces (surrogate devices) should be developed by the endoscope or EWD manufacturer to represent each product family or type test group to be stored as advised in BS EN 16442: 2015 Annex F. Endoscopes in use should also be grouped into Product Families (PF) based on their complexity as described in BS EN 16442: 2015, Annex G.

4.6 Allowance has been made for limited use of surrogates for some type tests where the tests require the destruction of a device to enable sampling or where a device is unavailable due to its scarcity or cost. Surrogate device design should be based on the range of endoscopes in use.

When required surrogate devices should have similar;

- geometry;
- thermal mass;
- surface finishes;
- number of channels/lumens;
- lumen diameters;
- joints made with trumpet valves and ports as BS EN 16442:2015.

4.7 The surrogate device should also be constructed to incorporate the appropriate temperature sensors (where applicable).

4.8 This will ensure the storage cabinet is able to maintain the microbiological quality of the stored endoscopes and as applicable provide a drying time of less than three hours (clause 4.3 of BS EN 16442:2015) for any endoscope placed within it.

Testing ancillary equipment and engineering services

4.9 Testing ancillary equipment and engineering services (installation qualification) should be carried out before testing of the storage cabinet begins.

4.10 The cabinet and ancillary equipment manufacturer or installation contractor(s) are not responsible for the correct functioning of services and ancillary equipment unless this was agreed in the purchase contract.

Information to be provided by the manufacturer

4.11 All documentation necessary for safe and efficient operation should be supplied by the manufacturer to the User including:

- the list of endoscopes that can be stored in the storage cabinet;
- storage temperature band;
- maximum storage time;
- information regarding the drying function;
- whether the storage cabinet is equipped with a drying function or not;

- the list of endoscopes that can be dried in the storage cabinet (if applicable);
- drying temperature band (if applicable);
- time(s) required to dry the range of endoscopes to be used (if applicable);
- information regarding the channel aeration system;
- the means for checking air circulation in each channel at the endoscope connection ports;
- whether the automated channel flushing control system used is able to run independent controls on each channel or on a set of channels;
- a circulation diagram illustrating air flows in the system used to irrigate the endoscope channel(s);
- the minimum flow rate and/or pressure and the maximum pressure that the storage cabinet is designed to deliver into each channel or channel system;
- the minimum flow rate that the storage cabinet's visual or automatic monitoring system is capable of detecting and designed to check air circulation in the endoscope channels;
- any requirements regarding the quality of the air supplied to the storage cabinet;
- the maximum humidity, pressure, oil content, particulate count and flow rate of the air supplying the storage cabinet;
- the frequency at which the air supplied to the storage cabinet shall be tested;
- whether a specific cleanliness level is claimed;
- the claimed values for particle sizes of 0.5 µm and larger and 5 µm and larger in the filtered air stream.

Note 4.1: A roles and responsibilities matrix should be established during the planning process.

Installation qualification

4.12 Inspection of the engineering services should be made to ensure they have been installed correctly, are adequate to meet the demands of the equipment, there are no leaks and all necessary isolating valves/switches and test points are installed.

4.13 Ensure all equipment has been supplied in accordance with the specification agreed in the contract and that the manufacturer has supplied all required documentation (e.g. prints, drawings, operating and maintenance manuals and spare parts list as clause 8.2 of BS EN 16442: 2015).

Note 4.2: Endoscope accessories (e.g. valves) can be stored inside the storage cabinet but it is not the intention of the storage cabinet to maintain the microbiological quality of these accessories.

4.14 Ensure verification certificates for calibration of measuring instruments and controller(s) on the storage cabinet have been supplied and that no defects are apparent from a visual inspection of the equipment.

4.15 Check all electrical equipment is correctly connected to the electrical service and carry out the following electrical tests:

- insulation resistance;
- phase sequence (for three-phase installations);
- polarity;
- bonding and earth continuity;
- the maximum current ratings are met and supply voltage falls within the required range.

4.16 The calibration of controls and instrumentation should be verified and a suitable maintenance programme in place. Reference should be made to the storage cabinet manufacturer's maintenance schedules. Identify the periodic testing requirements, including their frequency, specified in the manufacturer's manuals. If the storage cabinet is a double-ended storage cabinet checks will be required on the loading side and the unloading side.

Operational qualification

4.17 The Operational Qualification (OQ) should be carried out after installation with an empty storage cabinet. The summary of test programmes in Annex A (informative) of BS EN 16442: 2015 outlines the following tests for the OQ of the storage cabinet:

- air changes;
- drying function (if applicable);
- air quality – moisture (if applicable);
- air quality – oil content (if applicable);
- channel aeration test.

A detailed overview is given in table 4.1.

Table 4.1: Outline of OQ requirements in BS EN 16442:2015

OQ tests [and BS EN 16442: 2015 Requirement clause]	Requirement [and test clause from BS EN 16442: 2015]
Air changes [5.2.2.3] See paragraph 4.50	The number of air changes per hour inside the storage cabinet chamber should be specified. An air change of at least ten times the volume of the storage compartment per hour is an acceptable value to reduce the risk of contamination from the environment following, for example, a door opening and to reduce the moisture content during drying. [6.2 & D.5]
Drying function (if applicable) [4.3] See paragraph 4.56	Use of a chronometer to measure the drying time. [D.9]
Air quality-moisture content (if applicable) [5.2.1.1.2] See paragraph 4.51	The quality of the air supplying the storage cabinet should be specified and include specifications for maximum relative humidity, pressure, oil content, particulate count and flow rate. [6.6.2]

OQ tests [and BS EN 16442: 2015 Requirement clause]	Requirement [and test clause from BS EN 16442: 2015]
Air quality-oil content (if applicable) [5.2.1.1.2] See paragraph 4.54	The quality of the air supplying the storage cabinet should be specified and include specifications for maximum relative humidity, pressure, oil content, particulate count and flow rate. [6.6.3]
Channel aeration test [5.5.1] See paragraph 4.63	Throughout the storage, air has to flow through each of the internal channels and/or cavities of the device. The air circulation may be either continuous or intermittent. Instructions should be provided on the verification of air circulation and include: a) verifying that all channels allow the passage of air before the endoscope is loaded into the storage cabinet]; If the endoscope is cleaned and disinfected using a validated processing procedure this verification is included. Some washer-disinfectors and manual processing procedures do not monitor flow through the endoscope channels. b) confirming that all necessary connections were made before, and were still in place at the end of, the storage cycle; c) verifying the air circulation in each tubing of the storage cabinet connector using specified means]; For single channel storage cabinet connectors, means should be provided to allow the verification of air flow in each tubing. When a manifold is used means provided should allow the verification at least in the tube connected to the storage cabinet. The attention of the user is drawn on the fact that means provided to verify the free passage of air can be either continuous or intermittent, automatic and under the control of the automatic controller of the storage cabinet (i.e. control of the air flow through each endoscope channel) or require a verification by the user (e.g. visual indication of the air circulation). d) Confirming by reference to the storage cabinet process record that the supply of air to the device used to connect the endoscope was maintained during each stage of the process; Conformity should be demonstrated by cross-checking with the storage cabinet instructions for use.. [6.7 optional & D.10]

4.18 The following information should also be verified:

- the selection of automatic or manual control is by key, code or tool;
- throughout the operating period the indicated and recorded values of critical variables are within the limits specified by the storage cabinet manufacturer and within the limits required by BS EN 16442: 2015;
- there is no evidence of interference to or from other equipment connected to the same services or electromagnetic interference to or from other equipment;
- all instruments operate correctly, and readings are accurate within specified tolerances;
- the automatic controller has operated in accordance with the parameter values determined at validation;
- all data from all sensors is present and correlated and that all data from the Independent Monitoring System and storage cabinet are downloaded correctly;
- for double-ended storage cabinet models, the door interlock system operates satisfactorily.

Note 4.3: The manufacturer should be consulted for a description of methods which may be used to simulate faults. Some of the methods may be an inbuilt selectable maintenance function within the automatic controller activated by a key, code or tool.

4.19 During a defined test period, the following faults (as appropriate to the type of cabinet) should be simulated:

- door open alert;
- power failure;
- air changes;
- air pressure low;
- air pressure high;
- air temperature high;
- air temperature low;
- air relative humidity (RH) high;
- air RH low;
- failure of air circulation system;
- channel obstruction test for each available channel on the storage cabinet (using surrogate devices for each defined ‘product families’ conforming to Annex H of BS EN 16442: 2015);
- drying function (if applicable);
- channel aeration test;
- communication systems failure.

Performance qualification

4.20 Performance Qualification (PQ) testing is the process of obtaining and documenting evidence that the storage cabinet operates consistently and gives reproducible results when installed and operated within the pre-defined acceptance criteria, agreed in the process specification. PQ confirms the ability of the cabinet to maintain the condition of the types of endoscope encountered in the location in which it is installed. The summary of test programmes in Annex A (informative) of BS EN 16442: 2015 outlines the following tests for the PQ of the storage cabinet:

- contamination levels on inside surfaces;
- *maintaining the microbiological quality of the endoscopes;
- drying function (if applicable);
- air quality particulate contamination (if applicable);
- airborne microbial contamination;
- temperature control (if fitted);
- channel aeration test.

An outline overview is given in table 4.2.

Table 4.2 – Outline of PQ requirements in BS EN 16442:2015

PQ [and BS EN 16442: 2015 Requirement clause]	Requirement [and BS EN 16442: 2015 Test clause]
Contamination levels on inside surfaces (of the storage cabinet) [5.3.2] See paragraph 4.58	A cleaning-disinfection procedure should be provided, including any requirements regarding the frequency of the use, to ensure that surface contamination levels inside the storage cabinet that might contact endoscopes remain below 25 Colony Forming Units (CFU)/25 cm^2 [6.5].
*Maintaining the microbiological quality of the endoscopes [4.2.1] See paragraph 4.67	The storage cabinet should maintain the microbiological quality of the endoscopes during storage. Tests should be performed according to Annex E. [E.2]
Drying function (if applicable) [4.3] See paragraph 4.56	For storage cabinets that provide a drying function the following requirements apply: a) The time required to dry the endoscopes should be specified and should not exceed 3 hours. b) The efficacy of the drying function should be deemed to be satisfactory if there are no visible moisture droplets on the test paper. [6.4.3 & 6.4.4]
Air quality particulate contamination (if applicable) [5.2.2.4] See paragraph 4.52	If a specific cleanliness level is claimed and when tested the particulate contamination within the storage cabinet should be consistent with the claims. Where the air in the storage cabinet is filtered, means should be provided to enable the filtration system to be tested. This should include means of access upstream of the filter where a controlled particulate aerosol can be injected and means of access downstream of the filter where an iso-kinetic sampling probe can be placed. [6.6.1]
Airborne microbial contamination [5.2.2.1] See paragraph 4.59/4.60	Air inside the storage cabinet and flowing through the channels of the endoscope should be of a microbiological quality which will not impair the quality of the load. This can be achieved by filtration of the air using filters having not less than 99,95 % retention to particles of 0,3 µm. Filters conforming to Class H 13 as specified in BS EN 1822-1:2019 can be regarded as suitable. Active air sampling or passive air sampling may be carried out. The limit of active air sampling being 100cfu/m^3 and for passive air sampling 50 cfu in total from four plates. Recommendations on the relevant alert and action limits to be set for the results of particulate (if claimed) and microbiological monitoring should be specified, including the action to be taken when specified limits are exceeded. [Annex C]
(Automatic) temperature control (if fitted) [5.6] See paragraph 4.61	Any heating system should be inherently safe so that in the event of impairment or failure of the air flow the maximum temperature will not exceed the maximum temperature tolerated by the endoscopes intended to be dried and/or stored in the storage cabinet. When doors of the storage cabinet are closed, a fault should be indicated if the temperature during the storage and/or drying function is outside the specified storage and/or drying temperature band. [6.9]
Channel aeration test [5.5.1] See paragraph 4.63	Throughout the storage, air has to flow through each of the internal channels and/or cavities of the device. The air circulation may be either continuous or intermittent. Instructions should be provided on the verification of air circulation and can include: a) verifying that all channels allow the passage of air before the endoscope is loaded into the storage cabinet; If the endoscope is cleaned and disinfected using a validated processing procedure this verification is included.

PQ [and BS EN 16442: 2015 Requirement clause]	Requirement [and BS EN 16442: 2015 Test clause]
	Some washer-disinfectors and manual processing procedures do not monitor flow through the endoscope channels. b) confirming that all necessary connections were made before, and were still in place at the end of, the storage cycle; c) verifying the air circulation in each tubing of the storage cabinet connector using specified means]; For single channel storage cabinet connectors, means should be provided to allow the verification of air flow in each tubing. When a manifold is used means provided should allow the verification at least in the tube connected to the storage cabinet. The attention of the user is drawn on the fact that means provided to verify the free passage of air can be either continuous or intermittent, automatic and under the control of the automatic controller of the storage cabinet (i.e. control of the air flow through each endoscope channel) or require a verification by the user (e.g. visual indication of the air circulation). d) confirming by reference to the storage cabinet process record that the supply of air to the device used to connect the endoscope was maintained during each stage of the process; Conformity should be demonstrated by cross-checking with the storage cabinet instructions for use. [D.10]

4.21 PQ tests are performed after the storage cabinet has been satisfactorily installed on site and the operational qualification completed satisfactorily. The storage cabinet should then be tested for each loading condition that the storage cabinet is expected to encounter. For example, a load comprising of four non-lumen endoscopes constitutes a different loading pattern and challenge to the cabinet's air handling system compared to that provided by a single endoscope comprising of multiple channels.

4.22 Users should adopt the following procedure for every storage cabinet:

- confirm the list of potential 'Product Families' (PF) as defined in BS EN 16442:2015 and their corresponding 'type test group';
- establish a list of the different loading conditions type of connectors etc. required for each product family stored in the storage cabinet;
- agree a range of surrogate devices representing each PF, for use in the air flow and cross-contamination microbiological tests.

Microbial quality of endoscopes

4.23 Where the microbiological quality of the endoscopes intended to be stored is unknown prior to the storage cabinet being put into service, and a later routine microbiological test of an endoscope stored in the storage cabinet is positive, there would be no way of determining the source of the contamination. That is, was the endoscope contaminated prior to storage, or, was it a result of a functional problem with the storage cabinet.

4.24 Annex E of BS EN 16442: 2015 a normative (mandatory) annex on internal residual contamination of endoscopes after storage. Note 1 of E.2.2.1 of BS EN 16442: 2015 states that prior to performance qualification testing and as part of an initial

assessment, microbiological testing can be carried out by taking samples from all endoscopes available in the unit representative of the range of endoscopes to be stored in the storage cabinet, using a validated sampling method. Procedure E.2.2.1 also states that the endoscopes should then be reprocessed in the EWD and stored in the storage cabinet according to the instructions for use, for the maximum storage time specified for the type of endoscope selected before being tested.

4.25 Performance qualification tests are then performed on at least one model of each endoscope type tests group (as defined in Annex F of BS EN 16442: 2015) available on site. Alternatively, performance tests may be performed with one model of each endoscope product family (as described in Annex G of the standard) for which the same storage cabinet connector set is used, if the endoscopes selected have been shown to be the most challenging.

4.26 Note 3 of E.2.2.1 of BS EN 16442: 2015 states any alternative test based on parametric verification and for which a demonstration of the efficacy has been done can be used.

Parametric testing

4.27 Annex D of BS EN 16442: 2015 (an informative annex) on the procedure for parametric performance qualification indicates storage cabinet process parameters should be specified.

4.28 Process parameters should include the quality, temperature and pressure of the air flowing through the endoscope's channels and the air in the storage compartment. All specifications are required to be stated in measurable quantities, to allow subsequent physical measurements to be taken during PQ testing to verify the storage cabinet still functions within the stated specifications.

4.29 British standard BS EN 16442:2015 also states storage cabinets compliant with the standard can be parametrically tested for performance qualification using Endoscope surrogate devices and/or endoscopes from each relevant endoscope type test group. These test devices should be selected using the method described in Annex F, while considering the specific characteristics and limitations of the storage cabinet. When tested by the CP(D) using test methods in line with section 6 of the standard and as described in section 4.37 to 4.67 of this guidance document.

4.30 Additional PQ tests will be required when:

- a new endoscope that presents a greater challenge than previous validation loads is to be stored;
- extensive maintenance of critical storage cabinet components or a major repair has been undertaken.

4.31 Test data obtained from the PQ tests should be recorded in a written report which clearly identifies the storage cabinet parameters. The User, the AP(D) and AE(D) should confirm the suitability of the report.

4.32 The AE(D) should be satisfied that the range of installation, operational and performance qualification tests undertaken is representative of the product families to be stored in a particular storage cabinet. This should be documented.

4.33 The results should be used as the base values for comparison with future performance requalification tests, to confirm that the storage cabinet continues to meet the performance standards established during PQ testing and that the data established during the initial PQ tests remain valid.

Periodic testing

4.34 Requirements for periodic tests are defined in BS EN 16442: 2015. The summary of test programmes in informative Annex A of BS EN 16442: 2015 outlines the following tests for the periodic testing of the storage cabinet:

- contamination levels on inside surfaces (optional);
- maintaining the microbiological quality of the endoscopes - the test is optional if the parametric operational and performance qualification procedures are followed as per Annex D of BS EN 16442:2015;
- drying function (if applicable) (optional);
- air quality – moisture (if applicable);
- air quality – oil content (if applicable);
- air quality particulate contamination (if applicable);
- airborne microbial contamination (optional).

Table 4.3 – Outline of periodic testing in BS EN 16442:2015

Routine (Periodic) test	Requirement [and BS EN 16442: 2015 Test clause]
Contamination levels on inside surfaces (of the storage cabinet) See paragraph 4.58	A cleaning-disinfection procedure should be provided, including any requirements regarding the frequency of the use, to ensure that surface contamination levels inside the storage cabinet that might contact endoscopes remain below 25 Colony Forming Units (CFU)/25 cm^2 [6.5].
Maintaining the microbiological quality of the endoscopes See paragraph 4.67	The storage cabinet should maintain the microbiological quality of the endoscopes during storage. Contamination of the internal channels of the endoscope should be less than 25 cfu/endoscope [E.2]
Drying function (if applicable) See paragraph 4.56	For storage cabinets that provide a drying function the following requirements apply: a) The time required to dry the endoscopes should be specified when tested and should not exceed 3 hours. b) The efficacy of the drying function should be deemed to be satisfactory if, there are no visible moisture droplets on the test paper. [6.4.3 & 6.4.4]
Air quality-moisture content (if applicable) See paragraph 4.51	The quality of the air supplying the storage cabinet should be specified and may include specifications for maximum relative humidity, pressure, oil content, particulate count and flow rate. The RH level should be within the storage cabinet manufacturer's specification [6.6.2]
Air quality-oil content (if applicable) See paragraph 4.54	The quality of the air supplying the storage cabinet should be specified and may include specifications for maximum relative humidity, pressure, oil content, particulate count and flow rate. The measured concentration of oil should be below 0.1mg/m^3. [6.6.3]

Routine (Periodic) test	Requirement [and BS EN 16442: 2015 Test clause]
Air quality particulate contamination (if applicable) See paragraph 4.52	If a specific cleanliness level is claimed and when tested the particulate contamination within the storage cabinet should be consistent with the claims. Where the air in the storage cabinet is filtered, means should be provided to enable the filtration system to be tested. This should include means of access upstream of the filter where a controlled particulate aerosol can be injected and means of access downstream of the filter where an iso-kinetic sampling probe can be placed. [6.6.1]
Airborne microbial contamination See paragraph 4.59/4.60	Air inside the storage cabinet and flowing through the channels of the endoscope should be of a microbiological quality which will not impair the quality of the load. This can be achieved by filtration of the air using filters having not less than 99,95 % retention to particles of 0,3 µm. Filters conforming to Class H 13 as specified in BS EN 1822-1:2019 can be regarded as suitable. Active air sampling or passive air sampling may be carried out. The limit of active air sampling being 100cfu/m^3 and for passive air sampling 50 cfu in total from four plates. Recommendations on the relevant alert and action limits to be set for the results of particulate (if claimed) and microbiological monitoring should be specified, including the action to be taken when specified limits are exceeded. [Annex C]

Note 4.4: The standard BS EN 16442: 2015 does not define the frequency of periodic (routine) testing. This guidance (SHTM 01-06 Part E) requires the seven periodic tests outlined in table 4.3 to be carried out annually. The storage cabinet manufacturer may set a higher testing frequency and where this is the case their testing schedule should be followed.

4.35 Tests should only be undertaken after completion of the planned maintenance tasks described in 'Planned preventative maintenance programme 'SHTM 01-06 Part B. The results of periodic tests should be recorded, documented and filed securely, in electronic or paper format.

Note 4.5: All process records for decontamination equipment should be kept in line with the Scottish Governments Records Management Code of Practice, for health and social Care organisations processing NHS information: 2020, to allow tracking and tracing of thermolabile flexible endoscopes back to patient episodes, in the event of an adverse event A local policy should be in place and maintained including a retention schedule detailing the retention periods by default for the information we process and have procedures for mandatory archival of records (when these apply)

4.36 Other annual tests to consider include:

- Alarms and alerts for;
  - disconnection of essential services;
  - doors open;
  - temperature, RH or pressure out of recommended range;
  - channel blockage test.
- Doors and door interlocks;

  - door open alarm check;
  - fault indication on sensor failure;
  - double ended cabinets door lock checks;
- Calibration, limits and function, including any independent monitoring system;
- Number of air changes per/hr;
- Annual safety checks and verify the adequacy/safe connection of all engineering services;
- Automatic control test for each period;
- Verification of calibration of storage cabinet instruments;
- Load carriers-wear and alignment (as required);
- Channel aeration test;
- Over temperature cut-out test (if fitted).

Test methods

Introduction

4.37 This section gives detailed methods for carrying out tests required during the Installation Qualification (IQ), Operational Qualification (OQ), Performance Qualification (PQ) and periodic testing of storage cabinets used in an Endoscope Decontamination Unit. Test equipment calibration methods are detailed in SHTM 01-06 Part B.

Calibration verification of storage cabinet instrumentation

4.38 The calibration of instrumentation and any independent monitoring system fitted to the storage cabinet should be verified by comparison with calibrated test instruments during steady-state conditions. The manufacturer should provide a method for adjustment of cabinet measuring chains and information on measurement chain stability over time. SHTM 01-06 Part B should be consulted for calibration requirements for test equipment. Values should be recorded before and after any adjustment. Where adjustments of calibration are required and carried out on the storage cabinet, the measured results and corrections should be clearly identified in the validation or service report. Instruments should be adjusted to an accuracy of:

- 1°C for temperature measurements;
- 5kPa for pressure measurements within the range from atmospheric pressure to the maximum operating pressure plus 20% to allow for pressure failure.

Note 4.6: The cabinet will be calibrated prior to shipping as part of works testing in accordance with the manufacturers quality management system. If adjustment is required during installation qualification an investigation into why such adjustment is necessary including the possibility of sensor damage during transportation should be carried out. Modern measurement chains are generally reliable and stable. If adjustment is required during periodic testing, investigations should be made to ensure a fault has not developed rather than calibration drift.

Instrument display clarity

4.39 The instrument display should be checked to ensure the characters are visible at viewing distances of 0.25 metre and 1.0 metre for individuals with normal vision or wearing corrective glasses/lenses. During installation all displays should be checked for visibility and damage and the displayed values confirmed as within the recommended values established during type testing.

Note 4.7: Ideally this should be confirmed during factory acceptance tests and inspection or certified by the manufacturer during type testing. However, unless backlit displays are implemented the ability to read unlit displays will depend on ambient light conditions. Correcting a failure to meet the acceptance criteria specified above on site would require further infrastructure changes.

Instrument display storage period accuracy verification

4.40 The display should start counting from the point the endoscope has been entered into the storage cabinet tracking system or when all channels are connected and stop when endoscopes are disconnected from the system and scanned out of the storage tracking system.

Method:

- ensure that all services are connected;
- check the storage time display is at zero if no endoscope connected;
- scan or log an endoscope into storage;
- check the display records the storage time (this can be the time remaining or time stored).

Acceptance criteria:

- the storage time display indicates correctly as specified in 4.40.

Door (s) security

4.41 The security and settings of door safety switches and any interlocks should be checked. Maintenance and inspection of door safety devices and door cabinet sealing systems should be carried out in accordance with the manufacturer's instructions for use.

Door (s) security In-period check

4.42 A secure door lock is required to ensure the door(s) cannot be deliberately or inadvertently opened by unauthorised staff.

Method:

- close the door(s) and start the operating cycle;
- attempt to unlock and open the door(s) without the use of a valid operator ID or valid keycode.

Acceptance criteria:

- it should not be possible to open the doors.

Doors security - interlock for double-ended storage cabinets

4.43 For storage cabinets with a loading and unloading side it should not be possible to open both the loading and unloading doors at the same time. It should not be possible for unauthorised staff to open the door.

Method:

- with the use of a valid keycode/operator IDs attempt to open both the loading and unloading doors at the same time.

Acceptance criteria:

- it should not be possible to open the loading or unloading doors at the same time i.e. the interlock is operating satisfactorily.

Door on sensor failure

4.44 This test should be carried out during PQ and yearly.

Method:

- disable each door sensor in turn and attempt to open each corresponding door. Where practicable, avoid undertaking this check during an operating period.

Note 4.8: The manufacturers method should be used to disable the sensor otherwise sensor damage may occur.

Acceptance criteria:

- in each case it should not be possible to open the door(s);
- a visual indication of a fault is given at both the loading and unloading side of the storage cabinet when doors remain open beyond the recommended loading/unloading time;
- both the loading and unloading doors cannot be opened at the same time on ‘double ended storage cabinets.

Doors seals

4.45 The door(s) of the storage cabinet are intended to maintain the air at higher than the room ambient pressure and prevent the room air entering the storage cabinet environment. Excessive and persistent leakage also carries the risk of causing deterioration in the microbial state of stored endoscopes. Damaged door seals should be replaced in accordance with the storage cabinet manufacturer’s instructions. The integrity of the door seal should be tested as part of the OQ and PQ tests.

Method:

- door seals should be regularly inspected for damage and cleaned and maintained in accordance with manufacturers recommendations.

Acceptance criteria:

- the door(s) seals should appear in good condition and be undamaged.

Automatic controller testing when a sensor fails

4.46 This test should be carried out during PQ and yearly.

Method:

- a fault should be indicated during or at the end of the operating period.

Acceptance criteria:

- it should not be possible to open the unloading door of the storage cabinet without a key, code, or tool.

Thermometric tests wall temperature and load testing

4.47 Thermometric tests should be used for all stages where the temperature is a critical parameter. Thermometric tests are carried out to verify that the manufacturers specified operational temperatures are achieved throughout the cabinet during the operating period.

Equipment:

- the equipment specifications for temperature measurement systems (thermocouples and data loggers) are given in SHTM 01-06 Part B section 2 ‘Decontamination test equipment’. The use of recorders with fixed sensors may be impractical due to the configuration of the storage cabinet. In these instances, self contained data loggers that can be placed in the storage cabinet should be used;
- storage cabinets may be tested consecutively or concurrently. In the latter case seven sensors should be used for each cabinet. The storage cabinet should be operated empty except for, load carriers.

Method:

- locate thermocouples as follows;
  - two diagonally opposite in the cabinet (one near the top and one near the bottom);
  - one in the centre of the two side walls;
  - one adjacent to the temperature control sensor;
  - one adjacent to the process recorder temperature sensor;
  - one in the centre of the door;
- the sensors should be in direct contact with the items or sensor and placed as far as possible on or in the part of the storage cabinet that is slowest to heat up;

Note 4.9: Sensor location in order to establish thermal homogeneity within the cabinet space should be considered.

- measure the temperature attained throughout the storage cabinet during three operating periods. The first of these tests should be carried out from a cold start (at least 60 minutes since the machine was last used). The remaining three tests should be carried out with no more than a fifteen-minute interval between storage periods (a hot start).

Acceptance criteria:

- the temperatures should be as follows;
  - the temperatures recorded on the surface of the cabinet should be within the range 10 to 40ºC or where heated, within the manufacturers recommended temperature band throughout the storage period;
  - the temperatures recorded on the surface of the cabinet should be within ±1ºC of the set temperature for the relevant stage and throughout the storage period;
  - the temperature indicated/recorded by the storage cabinet instruments should be within ±1ºC of that recorded by the test instrument from the sensor adjacent to the reference sensor, throughout the storage period;
  - the temperature profile obtained for the operating period should be consistent within ±2ºC for the last three test periods;
  - the temperature within the cabinet (top to bottom) should be within ±2ºC of that indicated at the reference sensor position. All measured temperatures should be below that maximum temperature specified for the storage period.

Note 4.10: Exceeding the maximum temperature allowed for an endoscope may cause damage.

Over-temperature cut-out

4.48 The storage cabinet should be fitted with an over temperature cut-out to control the operational temperature in the storage cabinet. This prevents the temperature from rising to a level that would damage the endoscopes in the event of the automatic control failing. The manufacturer's procedure for testing the over-temperature cut-out should be followed to avoid potential damage to the storage cabinet.

Equipment:

- temperature measuring equipment, according to the 'Decontamination test equipment' section of SHTM 01-06 Part B section 2 should be used. No less than four sensors should be used or three independent self-contained data loggers and a temperature recorder having at least one sensor may be used as an alternative.

Method:

- locate temperature sensors at two diagonally opposite corners of the drying cabinet, in the centre of the load carrier and adjacent to the temperature sensor used as the reference sensor for cabinet temperature;
- operate an empty storage cabinet for the normal operating period. For storage cabinets with different storage periods test the storage cabinet with the highest and lowest operating temperatures;
- during the stage of the period when the maximum temperature is attained, disable the temperature control system using the manufacturers recommended method.

Acceptance criteria:

- the over-temperature cut-out should operate at a temperature not more than 5ºC higher than that provided by any temperature control or temperature limiting device.

Air pressure test (cabinet interior)

4.49 As part of the PQ and periodic tests, comparison of internal storage cabinet and external room air pressure should be made. The air pressure within the cabinet should be greater than that of the room environment.

Equipment:

- pressure monitor with a scale from zero to storage cabinet manufacturers maximum recommended pressure plus 20%.

Method:

- place the air pressure monitor in the cabinet;
- allow reading to stabilize;
- record the reading;
- record the air pressure within the room.

Acceptance criteria:

- the storage cabinet internal pressure value should be within the pressure range advised by the manufacturer and greater than the room ambient pressure.

Air flow rate (cabinet interior)

4.50 For airflow within the storage cabinet space should prevent contamination from the room environment.

Equipment:

- in line velocity meter or volume displacement meter suitable for measuring 10x the cabinet volume per hour, with an accuracy of 10%.

Method:

- position in front of the fan supplying air to the cabinet;
- close doors and leave for 1 hour or until the airflow reading stabilises.

Acceptance criteria:

- air flow should be a minimum of 10 x the volume of the cabinet per hour +/- 10 %.

Air quality moisture - Relative humidity

4.51 The Relative Humidity (RH) of the storage cabinet air is a critical parameter and should be controlled by the automatic control system. Where the RH is higher or lower than the specified limits an alarm should be activated. The storage cabinet should be tested for failure under both conditions.

Equipment:

- RH detector.

Method:

- place the detector in the storage cabinet;
- allow to stabilise;
- read the RH value;
- to measure the RH of air delivered to endoscope channels connect the meter to the air inlet connector.

Acceptance criteria:

- the RH level should be within the storage cabinet manufacturer's specification;
- the cabinet should alarm when out with specification.

Airflow particulate contamination

4.52 The particle levels in the airflow in the storage cabinet should be within the level specified by the storage cabinet manufacturer.

Equipment:

- particle counters capable of measuring 5μm particles up to 3.5 x 10^4 per m^3 and 0.5μm particles up to 4x10^6 per m^3.

Method:

- carefully follow the instructions from the sampler manufacturer when taking measurements;
  - place the particle counter sampling system in the cabinet;
  - close the cabinet door(s);
  - leave for 15 to 20 mins;
  - begin to record the reading;

- take readings over a 30 minute period to establish the peak and trough values.

Acceptance criteria:

- as specified by the manufacturer.

HEPA air filters (for drying) testing

4.53 Many storage cabinets are fitted with High-Efficiency Particulate Air (HEPA) filters (for example, 99.95 % retention of particles of 0.25 µm or greater. Filters conforming to Class H 13 as specified in BS EN 1822-1:2019 can be regarded as suitable. The full requirements of the method are specified in BS EN 16442:2015. The complete installation should be tested, and the method specified in BS EN ISO 14644-3: 2019 followed.

Method:

- a challenge aerosol of inert particles of the type produced by a dispersed oil particle generator should be introduced into the air upstream of the filter;
- the downstream face of the filter and its housing should then be scanned for leakage using a photometer.

Acceptance criteria:

- the reading on the photometer should be steady and repeatable and should not exceed 0.01% of the upstream reading.

Compressed air - air quality – oil content

4.54 The oil content level in the airflow into the storage cabinet should be specified by the storage cabinet manufacturer.

Equipment:

- detector tube or oil impactor, suitable to determine that the oil content is below 0.1 mg/m^3;
- tube to connect the detector tube or oil impactor to the storage cabinet connector in the storage cabinet.

Method:

- follow the instructions of the supplier of the detector tube or oil impactor.

Acceptance criteria:

- the measured concentration of oil should be below 0.1mg/m^3.

Endoscope connectors airflow tests

4.55 The volume/rate of flow of air or air pressure delivered to endoscope connectors for each test type group should be provided by the storage cabinet manufacturer. This will affect the type and length of time endoscopes can be stored before requiring

reprocessing. This data should be used to allow verification during PQ and periodic testing.

Equipment:

- in line velocity or displacement meter.

Method:

- connect the displacement meter to each endoscope channel connection point in the storage cabinet;
- close doors leave for 1 hour;
- check each connection point in sequence and in parallel (this will simulate the airflow when the cabinet is in full use;
- read the value flow rate from the device;
- visual inspection of connectors-replacement as required or, as per the storage cabinet manufacturers' maintenance schedule.

Acceptance criteria:

- the air flow to each endoscope channel should be as specified by the storage cabinet manufacturer;
- air pressure delivered to endoscope lumens should not exceed the endoscope manufacturers recommended pressure.

Load dryness

4.56 Where the manufacturer claims that the storage cabinet has a drying function, the drying cabinet should comply with the requirement in BS EN 16442: 2015 and dry the endoscope within 3 hours. The following drying efficacy test should be carried out.

Equipment:

- processed endoscope/surrogate device;
- crepe paper and/or a mirror;
- medical grade compressed air.

Method:

- after processing in an EWD;
  - place a processed endoscope (or surrogate device) that represents the type test groups identified by the storage cabinet manufacturer in the drying cabinet;
  - connect the surrogate device to the air channels of the storage cabinet. Hang in the storage cabinet for 3 hours;
  - remove the endoscope or surrogate device from storage and place a sheet of coloured crepe paper;

  - place a small section of coloured crepe paper and place between the control mechanism of the endoscope handle;
  - examine the crepe paper for any staining or residual water;
- for endoscopes with channels;
  - flush medical grade dry compressed air through the lumen onto a mirror surface or coloured crepe paper;
  - observe for water droplets or a change in the colour of the crepe paper to a darker shade.

Acceptance criteria:

- no residual water from the load should be observed on the crepe paper or, where relevant, on the mirror surface.

Load carriers

4.57 Load carriers come in a variety of forms including, hubs, carriages and baskets. Their correct functioning is essential to the successful outcome of a storage cabinet operating period. It is important that they cannot easily be misaligned, that they function correctly and when applicable, they fully connect with service supply points in the cabinet and with load items. This should be carried out during PQ and periodic testing including weekly checks for wear and tear and misalignment.

Method/Acceptance criteria:

- verify the alignment of load carriers, by observing their connection to, air and any connection to all working channels of the endoscopes and that the endoscopes do not come in contact with the floor or sides of the storage cabinet.

Contamination levels on inside surfaces (of the storage cabinet)

4.58 The efficacy of the recommended cleaning/disinfection procedure of the cabinet should be verified by determining the contamination level with contact agar.

Method:

- Testing should be performed at the end of the recommended time before application of the recommended cleaning/disinfection procedure;
- Four zones inside the chamber are located as follows;
  - two zones that could be physically in contact with the endoscope during storage;
  - one zone at other location in the chamber of the storage cabinet, and;
  - one zone at the bottom;
  - The zones tested should have a surface area of around 25 cm^2, with Trypticase soya agar to determine the presence of bacteria and filamentous fungi by incubation at (30±1)°C for at least five days.

Acceptance criteria

- The contamination levels identified should be less than 25 cfu/25 cm^2.

Microbiological methods - Active air sampling of interior of storage cabinet

4.59 Following the instructions of the air sampling equipment, 1 m^3 of air is sampled (impinged) onto Trypticase soya agar plates. The agar plate is then incubated at 30 ± 1 °C for 5 days. Following incubation, the colonies formed are counted and the results are expressed in number of cfu/m^3 of air.

Acceptance criteria:

- the airborne aerobic mesophilic microbial contamination in the storage cabinet should not exceed 100 cfu/m3.

Note 4.11: BS EN 16442: 2015 indicates a contamination level lower than 100 is not considered to be satisfactory if the microorganisms recovered are considered to be pathogenic for the intended use of the endoscope. This situation can require further investigation to identify the type and source of contamination.

Sedimentation – passive air sampling of interior of storage cabinet

4.60 Microbiological sampling of the storage cabinet air is carried out by passive air sampling to determine the level is satisfactory.

Method:

- four open Trypticase Soya agar plates are placed on the floor of each chamber of the storage cabinet and left for 1 hour, making sure that the doors of the storage cabinet remain closed during the test period;
- the agar plates are then incubated at 30 ± 1 °C for 5 days;
- following incubation, the colonies formed are counted and the results are expressed in number of cfu per plate.

Acceptance criteria:

- the total number of colonies on the four plates should be less than 50 cfu.

Note 4.12: BS EN 16442: 2015 indicates a contamination level lower than 50 is not considered to be satisfactory if the microorganisms recovered are considered to be pathogenic for the intended use of the endoscope. This situation can require further investigation to identify the type and source of contamination.

Temperature control

4.61 The automatic controller should control the air temperature within the cabinet within the range of 5 °C to 40°C. The temperature recorded within the storage cabinet and on the load during ‘type testing’, should be within +/-2 °C of the recommended temperature. Test sensors should be of the platinum resistance types complying with Class B of BS EN 60751: 2008 or thermocouples with Tolerance Class 2 of BS EN 60584-1: 2013 or other equivalent systems. The storage cabinet's cabinet temperature indicating system can be digital or analogue and should be:

- graduated in degrees Celsius;

- have a scale with the range 5°C to 70°C;
- be accurate to within 1°C over the entire scale range;
- have a resolution of at least 1°C for both analogue and digital instruments.

When gauges or displays are used for a control function, they should have broken sensor protection which will fail ‘up-scale’ and ambient temperature error compensation, not exceeding 0.08 K/K. At least one temperature sensor should be located in a position that has been identified as representing the area that achieves lowest temperature during type testing. The temperature for any drying function should not exceed 60°C (the temperature shown to damage thermolabile endoscopes); the endoscope manufacturer should be consulted.

Note 4.13: Temperature instrumentation should only be adjusted by the use of a special key, code or tool and without moving or dismantling the instrument.

Overpressure test

4.62 A pressure indicator used for measuring the pressure in the storage cabinet should be compliant with SHTM 01-06-part B and be:

- either digital or analogue;
- indicate overpressure, relative to ambient pressure;
- be graduated in Pa;
- have a scale which includes the range 0 Pa to 120% of the upper level of the specified pressure range for the usable space of the storage cabinet;
- have an accuracy of at least 10% over the specified pressure range;
- for analogue instruments be graduated in divisions not greater than 1 Pa;
- for digital instruments have a resolution of at least 1 Pa;
- for digital instruments have the sampling rate of at least every 5 s;
- have an ambient temperature error compensation not exceeding 0.08 K/K;
- have the means to be adjusted in situ by the use of a special key, code or tool without dismantling the instrument.

Method:

- connect the pressure indicator to the storage cabinet so that it will indicate the pressure inside the usable space, relative to ambient pressure;
- close the doors and allow the pressure to stabilize for the specified period;
- record the pressure.

Acceptance criteria:

- the pressure in the usable space of the storage cabinet should be within the ranges specified by the manufacturer;
- air flow provides a minimum of 10 air changes per hour and the cabinet pressure is maintained at greater than the pressure of the room in which it is tested.

Channel aeration test

4.63 This test is carried out using the bubble test method and should only be carried out using surrogate devices.

Method:

- connect the endoscope surrogate device to the storage cabinet's air circulation system, following the instructions below;
  - immerse the distal end of one of the channels into a beaker containing about 250 ml of water;
  - start the storage cycle;
  - check for air bubbles from the distal end of the surrogate device;
  - record the indicated air flow rate given by the storage cabinet control system;
- repeat the operating cycle, immersing each channel of the endoscope surrogate device one by one into the beaker;
- repeat the test by blocking the tube connected to the storage cabinet and confirm that the system is able to detect when air is not flowing.

Acceptance criteria:

- the results are deemed satisfactory when;
  - for each channel: air bubbles appear when the channel is submerged;
  - the tube connected to the storage cabinet is blocked, a failure indication is observed.

Endoscope channel blockage test

4.64 The following test is applicable where the storage cabinet manufacturer claims the storage cabinet can detect a blockage in an individual channel.

Method:

- connect the endoscope surrogate device to the storage cabinet's air circulation system, following the storage cabinet manufacturers' instructions for use;
  - immerse the distal end of one of the channels into a beaker containing about 250 ml of water;
  - start the storage cycle and wait for bubbles to appear;
  - induce a blockage at surrogate device connection point to the storage cabinet;
- block each surrogate channel in turn;
- repeat for a selection of hanging positions in the storage cabinet.

Acceptance criteria:

- the automatic control system should initiate an alert or alarm indicating that air is not flowing.

Note 4.14: Both the bubble test and the blockage detection can be carried out at the same time using surrogate devices representing the PF in use.

Thermometric tests of the endoscope

4.65 The temperature of the endoscopes in the cabinet should be within the temperature band set for the cabinet.

Method:

- using platinum temperature sensors compliant class A of BS EN 60751:2008 Class 1 of BS EN 60584-1:2013 or equivalent but which will not block the endoscope channel. Place thermocouples at the following positions;
  - one on the control head of the endoscope;
  - one sensor within one endoscope channel to a depth of at least 10 cm. Ensure the sensor does not block the flow of air from the endoscope channel. This may warrant the use of fine thermocouple leads which will be fragile and require careful handling;
- additional sensors should be placed on the outer surface of the endoscope insertion tube at intervals of no less than 75cm;
- ensure the sensors are in contact with the endoscope surface;
- start a storage cycle;
- allow the temperature to equalize and record the temperature displayed and recorded.

Acceptance criteria:

- all temperatures recorded are within the specified temperature band and do not vary by more than 2°C between sensor readings.

Thermometric test of the cabinet

4.66 Repeat the tests during a drying phase or for a specified time during the storage cycle with at least one sensor specified. The quality, temperature and pressure of the air flowing through the endoscope's channels and the storage compartment are measured.

Acceptance criteria:

- the results are considered to be satisfactory when the temperatures recorded are within the specified temperature band for the corresponding stage.

Note 4.15: Where a drying function is claimed then the manufacturer should also demonstrate that the storage cabinet can dry a colonoscope within 3 hours using the tests described in the standard. Using endoscopes from the identified type test groups and representative of the product families in use. Where the storage cabinet does not include a drying function, the manufacturer must specify that the endoscope should be dry before placing in the storage cabinet.

Note 4.16: All specifications are required to be stated in measurable quantities, so that it can be verified by measurement.

Testing the microbiological quality of the endoscope

4.67 The endoscopes are processed in an Endoscope Washer Disinfector (EWD) and then placed in the storage cabinet and held for the specified storage time prior to testing.

Note 4.17: Where required performance qualification testing at installation can be carried out by taking microbiological samples from all endoscopes available in the Endoscope Decontamination Unit as an initial assessment. Detailed data on the microbiological quality of all endoscopes intended to be stored is required such that in the event that a routine test is positive, the source of the contamination may be determined.

Method:

- samples taken from the distal ends of the endoscopes are split into two equal volumes. Each volume is analysed by membrane filtration through 0.45 µm pore-size filter;
- the filtration membranes are placed on Tryptone soya agar and Sabouraud dextrose agar with chloramphenicol and incubated for 5 days at (30 ± 1) °C;
- record the number of viable microorganisms per endoscope taking into account the recovery ratio of the sampling method;
- after testing, each endoscope should be processed through an EWD.

Acceptance criteria:

- the results are deemed to be acceptable if contamination of the internal channels of the endoscope is less than 25 cfu/endoscope.

Note 4.18: A result indicating a contamination level higher than 25 cfu/endoscope can require further tests to identify the cause(s) of this contamination which may be caused by factors not related to the storage cabinet. A contamination level lower than 25 cfu/endoscope is not considered to be satisfactory if the microorganisms recovered are considered to be pathogenic for the intended use of the endoscope. This situation can require further investigation to identify the type and source of contamination.

5. Validation and verification of vacuum pack systems

5.1 At the time of publication of guidance series SHTM 01-06 there was no published standard that specified the performance requirements for vacuum pack systems i.e. no type tests, validation or periodic tests specified. Manufacturers of vacuum pack systems should have available type test data to support any claims on the operational effectiveness of their system.

5.2 It is noted a vacuum pack system may comprise of multiple components either combined or standalone. Each item of equipment should be validated i.e. subjected to Installation Qualification and Operational Qualification in the first instance.

5.3 Each stage of the process using the vacuum pack system should be considered during type testing and validation. This may include as relevant:

- conditioning of the endoscope prior to packing by drying and/or dosing with a chemical;
- sealing the pack with a heat sealer or closure of a self-seal pouch.

Type testing

5.4 The vacuum pack system manufacturer should demonstrate that the maintenance of the disinfected state of the endoscope is achieved over the claimed shelf life and that the endoscope is functional and safe for use. Type testing requirements (Refer to Appendix 3 Table A3) are established in this guidance and should be considered until a published standard defining performance requirements is released. Surrogate device/endoscopes from range of type test groups that could be vacuum packed should be used for type testing.

Installation qualification

5.5 The Installation Qualification (IQ) should consider the following. Ensure all equipment has been supplied in accordance with the purchasing specification and that the manufacturer has supplied to the User all required documentation for the safe and efficient operation. This may include:

- the list of endoscopes that can be processed in the vacuum pack system;
- shelf life of the vacuum packed product;
- information regarding the drying function if included;
- the drying temperature band (if applicable);
- the time required to dry each type of endoscope to be packed;
- whether the automated channel flushing control system used is able to run independent controls on each channel or on a set of channels;
- the maximum vacuum that the vacuum pack system is designed to deliver;

- details of installation requirements, safety features, operational instructions for use, testing methods, maintenance requirements, troubleshooting and a spare parts list.

5.6 Verify all manual(s) have been supplied and are applicable to the equipment received and ensure verification certificates for calibration of measuring instruments and controller(s) have been supplied. Perform visual checks of the equipment as instructed and ensure no defects are apparent. Follow the manufacturer's installation instructions and perform any power up and electrical safety tests specified. Only when these test results are verified as satisfactory should the next qualification stage Operational Qualification, be performed on the vacuum pack system.

5.7 Documented evidence that the system will not cause damage to the endoscope should be obtained from the endoscope manufacturer. The number of process cycles the endoscope can be subjected to should be stated by the system manufacturer. The lifetime of all accessories including connectors should be stated.

Operational qualification

5.8 The Operational Qualification (OQ) should be carried out after installation and with no endoscope loaded in the vacuum pack system. Requirements are detailed as table 5.1.

Table 5.1: OQ requirements for vacuum pack systems

OQ test/check	Requirement	Method
Chemical dosing/ concentration See paragraph 5.17	If chemical dosing is employed – verify the dose is delivered as specified to each channel (surrogate). Note: Consult with the manufacturer to verify this check is possible when there is no endoscope placed in the vacuum pack system.	Dose the chemical into a beaker and use weight difference to confirm the required minimum and maximum volume is dosed. Perform for each channel. Verify the dose is within specified limits.
Vacuum See paragraph 5.16	The vacuum level is achieved as specified by the manufacturer.	Place an empty former in a vacuum pouch and seal. Operate the vacuum and visually confirm that the pouch has compressed (around any former if applicable) and holds this shape.
Channel blockage test See paragraph 5.15	Using a surrogate device confirm each channel ,when blocked, produces a failed cycle.	Manual block of the tubing.
Seal system and Seal test See paragraph 5.18	Confirmation of the satisfactory operation of the seal system and satisfactory seal.	Visual
Automatic control (if fitted)	ACT -. The control of the packaging process should take place automatically	Note the process stages and confirm these are as per the manufacturer's specification and take place fully automatically. Verify calibration of any measuring chains using the method provided by the manufacturer

5.9 Also confirm that:

- the automatic controller can monitor all critical cycle parameters and in the case of a system failure, a failed cycle should be indicated;
- any chemical delivery dose that is below specification is detected by the machine and that a failed cycle is indicated;
- manual blocking of channels produces a failed cycle;
- leaving the pouch disconnected when activating the vacuum pump produces a failed cycle;
- tracking and traceability is provided, and the system should be capable of printing labels for attachment to the exterior of the packed endoscope;
- the label information includes the batch number, production date, expiry date, endoscope type and serial number or UDI number and that the product is vacuum packed. An instruction should be included which informs the User not to use the product if the pack integrity is compromised;
- a record of the monitored data is available for review and be able to be downloaded by the User;
- operator training is given and a record of training maintained.

Performance qualification

5.10 Performance Qualification (PQ) checks should consist of on-site tests/checks performed by an AP(D) or the vacuum pack system manufacturer's service engineer as instructed by the User. Laboratory testing of microbiological samples taken during the qualification exercise may be required.

5.11 All specifications should be stated in measurable quantities, that can be verified by measurement. For systems employing chemical dosing, a means of measuring the quantity of chemicals delivered would be required during performance qualification testing. Requirements for PQ are detailed in table 5.2.

Table 5.2: PQ requirements for vacuum pack systems

PQ	Requirement
Chemical dosing/ concentration See paragraph 5.17	If chemical dosing is employed - Verify the chemical dose/concentration is achieved as per the manufacturer's specification for each channel of the endoscope model(s) under test. Confirm whether a volume measurement and or weight measurement is employed (or other means).
Channel blockage test See paragraph 5.15	Confirm blocked channels result in a failed cycle.
Vacuum See paragraph 5.16	The vacuum level is achieved as per the manufacturer's specification. Confirm a vacuum failure will result in a failed cycle.
Maintaining the microbiological quality of the endoscopes	The vacuum pack should maintain the microbiological quality of the endoscopes during storage. Verify that at the end of the claimed shelf life there is no increase or adverse change in microbial contamination of the endoscope. BS EN 16442 :2015 Annex E.2. and acceptance criteria E.2.3

PQ	Requirement
See paragraph 5.14	states acceptable if contamination of the internal channels of the endoscopes is less than 25 cfu/endoscope.
Drying function (if applicable)	For vacuum pack systems that provide a drying function the following requirements apply: a) The time required to dry the endoscopes should be specified; b) The efficacy of the drying function should be tested and no visible moisture droplets detected on the test paper. Note –some vacuum pack systems do not require drying of the endoscope prior to processing.
Shelf life testing	Confirmation that the vacuum pack remains sealed over the stated shelf life
Seal system and seal test See paragraph 5.18	Confirmation of the satisfactory operation of the seal system and confirmation of the method stated to verify the seal is satisfactory and the pack integrity after the sealing process.
Labelling	The label content should be visibly clear, correctly aligned and contain the agreed information. – Board/site, Scope model/serial no or UDI, date processed, expiry date, cycle ref no, stated satisfactorily processed and alert information – do not use is seal or the pack is damaged.
(Automatic) control (if fitted)	ACT – each stage of the process should meet the manufacturer's specification. A batch record is produced by the equipment (either paper or electronic).

5.12 Also confirm the following:

- door/lids cannot be opened during a cycle. Confirm there are no mechanical defects in line with manufacturer's instructions;
- the tests described designed to check that the packed item once prepared (performance qualification), is capable of maintaining the microbiological quality of the endoscopes in the pack;
- the PQ report should make a clear declaration (that when all the requirements have been met) the vacuum pack system is deemed fit for use. The PQ report should be signed off by the User and an AP(D);
- performance qualification tests shall be performed on at least one model of each endoscope type tests group. The choice shall be made according to the endoscopes available on site. Alternatively, performance tests may be performed with one model of each endoscope product family if it is demonstrated that the endoscopes selected are the most challenging.

Periodic testing

5.13 Periodic testing should be carried out in line with the manufacturer's instructions. The requirements in table 5.3 should be met annually.

Table 5.3: Periodic testing requirements for vacuum pack systems

Periodic test	Requirement
Chemical dosing/ concentration See paragraph 5.17	If chemical dosing is employed - Verify the chemical dose/concentration is achieved as per the manufacturer's specification for each channel of the endoscope model(s) under test. Confirm whether a volume measurement and or weight measurement is employed (or other means).
Channel blockage test See paragraph 5.15	Confirm blocked channels result in a failed cycle.

Periodic test	Requirement
Vacuum See paragraph 5.16	The vacuum level is achieved as per the manufacturer's specification. Confirm a vacuum failure will result in a failed cycle.
Maintaining the microbiological quality of the endoscopes See paragraph 5.14	The vacuum pack should maintain the microbiological quality of the endoscopes during the pack shelf life. To verify that at the end of the claimed shelf life there is no increase or adverse change in microbial contamination of the endoscope in the vacuum pack. BS EN 16442 :2015 Annex E.2. and acceptance criteria E.2.3 state acceptable if contamination of the internal channels of the endoscopes is less than 25 cfu/endoscope.
Drying function (if applicable)	For vacuum pack systems that provide a drying function the following requirements apply: a) the time required to dry the endoscopes should be specified b) the efficacy of the drying function should be deemed to be satisfactory. when tested there are no visible moisture droplets on the test paper.
Shelf life testing	Confirmation that the vacuum pack remains integral over the stated shelf life.
Seal system and Seal test See paragraph 5.18	Confirmation of the satisfactory operation of the seal system and confirmation of the method stated to verify the seal is satisfactory and the pack integrity after the sealing process.
Labelling	The label content should be visibly clear, correctly aligned and contain the agreed information. – Board/site, Scope model/serial no or UDI, date processed, expiry date, cycle ref no, stated satisfactorily processed and alert information – do not use if the pack integrity is damaged.
Automatic control (if fitted)	ACT – each stage of the process should meet the manufacturer's specification. A batch record is produced by the equipment (either paper or electronic).

Test methods

Maintaining the microbiological quality of the endoscope

5.14 The endoscopes intended to be packed are processed in an Endoscope Washer Disinfector (EWD) and then packed according to the instructions for use and held for the specified shelf life prior to testing.

Note 5.1: Where microbiological sampling of packed endoscopes is required as part of performance qualification testing refer to section 4.67 of this guidance document which details points to consider prior to testing.

Method:

- samples taken from the distal ends of the endoscopes are split into two equal volumes;
- each volume is analysed by membrane filtration through 0.45 µm pore-size filter. The filtration membranes are placed on Tryptone soya agar and Sabouraud dextrose agar with chloramphenicol and incubated for 5 days at (30 ± 1) °C;
- record the number of viable microorganisms per endoscope taking into account the recovery ratio of the sampling method. After testing, each endoscope should be processed through an EWD.

Acceptance criteria:

- the results are deemed to be acceptable if contamination of the internal channels of the endoscopes is less than 25 cfu/endoscope.

Note 5.2: A result indicating a contamination level higher than 25 cfu/endoscope can require further tests to identify the cause(s) of this contamination which may be caused by factors not related to the packing system. A contamination level lower than 25 cfu/endoscope is not considered to be satisfactory if the microorganisms recovered are considered to be pathogenic for the intended use of the endoscope. This situation can require further investigation to identify the type and source of contamination.

Channel blockage test

5.15 If applicable and as directed by the manufacturer carry out a manual test – manually block each channel in turn and run a cycle to confirm a failed cycle is produced (and printed on the label for the cycle).

Acceptance criteria:

- blocking each channel results in a failed cycle on each occasion.

Vacuum

5.16 This may be a visual test.

Method:

- place an empty former in a vacuum pack and seal;
- operate the vacuum as directed and complete the cycle.

Acceptance criteria:

- the pack should be seen to compress around the former and hold this shape.

Chemical dosing

5.17 To demonstrate that the chemicals are delivered to the processed endoscope as specification using a weighing method.

Equipment:

- scales laboratory quality;
- volumetric flasks

Method:

- weigh or measure a known volume of the chemical. There should be at least enough fluid for more than 4 cycles;
- place the connector into the container;
- initiate a cycle. (Disregard result from the first run);

- repeat the test 3 times;
- measure the remaining quantity of fluid in the container after each test run.

Acceptance criteria:

- the measured quantity is above the minimum quantity specified by the manufacturer for each cycle tested;
- the reproducibility should be within that specified by the manufacturer.

Pack seal

5.18 Self seal pouch or seal produced by heat sealer.

Method:

- follow the manufacturer's instructions to seal the pack;
- carry out a visual inspection of the seal(s);
- operate the vacuum cycle.

Acceptance criteria:

- the seal should be seen to be consistent and intact over its length. Once the vacuum is applied the pack should be seen to hold the vacuum.

6. Validation and verification of pressure pack systems

6.1 At the time of publication of guidance series SHTM 01-06 there was no published standard that specified the performance requirements for pressure pack systems i.e. no type tests, validation or periodic tests were specified. Manufacturers of such systems should provide all relevant type test data to verify and validate process effectiveness and to identify key variables that need maintaining to ensure continued operation in line with type testing. It is noted a pressure pack system may comprise of multiple components either combined or standalone. Each item of equipment should be validated i.e. subjected to an IQ/OQ in the first instance. Drying of the endoscope if required/applicable, dosing with chemical if applicable, pressurising/inflating, sealing the pack (pouch) with a heat sealer if applicable (or use of a self-seal pouch) should be considered.

Type testing

6.2 The manufacturer of the pressure pack system should demonstrate that the maintenance of the disinfected state of the endoscope is achieved over the claimed shelf life and that the endoscope is functional and safe for use. Type testing requirements (Refer to Appendix 4 Table A4) are established in this guidance and should be considered until a published standard defining performance requirements is released.

Installation qualification

6.3 The Installation Qualification (IQ) should consider the following. Ensure all equipment has been supplied in accordance with the contract and that the manufacturer has supplied all required documentation. All documentation necessary for safe and efficient operating should be supplied by the manufacturer to the User including:

- the list of endoscopes and or TOE ultrasound probes that can be processed in the pressure pack system;
- the shelf life of the pressure packed product;
- information regarding the drying function;
- the drying temperature band (if applicable);
- the time required to dry the endoscopes (if applicable);
- whether the automated channel flushing control system used is able to run independent controls on each channel or on a set of channels;
- the maximum pressure that the pressure pack system is designed to deliver;
- details of installation, safety features, operational use, testing, maintenance, troubleshooting and a spare parts list.

6.4 Inspection of the engineering services should be made to ensure they have been installed correctly and are adequate to meet the demands of the equipment.

6.5 Verify the manual(s) supplied are applicable to the equipment received. Ensure verification certificates for calibration of measuring instruments and controller(s) have been supplied and that no defects are apparent from a visual inspection of the equipment. Follow the manufacturer's installation instructions. Perform visual checks as instructed and perform any power up and electrical safety tests specified. Only when these test results are verified as satisfactory should the next qualification stage, Operational Qualification, be performed.

6.6 Documented evidence that the system will not cause damage to the endoscope (or TOE ultrasound probe if applicable) should be obtained from the relevant manufacturer. The number of process cycles the endoscope can be subjected to should be stated by the system manufacturer. The lifetime of all accessories including connectors should be stated.

Operational qualification

6.7 The Operational Qualification (OQ) should be carried out after installation with no endoscope loaded in the pressure pack system. Requirements are detailed in table 6.1 below.

Table 6.1: Pressure pack system OQ requirements

OQ test/check	Requirement	Method
Drying	For pressure pack systems that provide a drying function the following requirements apply: a) the drying temperature and period is as specified by the manufacturer. b) the efficacy of the drying function should be deemed to be satisfactory. when tested there are no visible moisture droplets on the test paper.	When tested there are no visible moisture droplets on the test paper.
Chemical dosing/ concentration See paragraph 6.17	If chemical dosing is employed – verify the dose is delivered as specification to each channel (surrogate). Note Consult with the manufacturer to verify this check is possible when there is no endoscope placed in the pressure pack system.	Dose the chemical into a beaker and use weight difference to confirm the required minimum is dosed. Perform for each channel. Verify the dose is acceptable. If below specification a failed cycle should be indicated.
Pressure	The pressure level is achieved as specified by the manufacturer.	Where the pump is activated to inflate the pouch but no pouch is connected the equipment should indicate a failed cycle.
Channel blockage test See paragraph 6.15	Using a surrogate confirm each channel when blocked produces a failed cycle.	Manual block of the tubing.
Seal system and Seal test See paragraph 6.18	Confirmation of the satisfactory operation of the seal system and satisfactory seal.	Visual
Automatic control (if fitted)	ACT - The automatic controller should monitor all critical cycle parameters and in the case of a system failure, a failed cycle should be indicated.	Note the process stages and confirm these are as per the manufacturer's specification and verify calibration.

6.8 Tracking and traceability should be provided, and the pressure pack system should be capable of printing labels for attachment to the exterior of the packed endoscope. The label information should include the batch number, production date, expiry date, endoscope type and serial number or UDI and that the product is pressure packed. An instruction should be included informing the User not to use the product if the seal(s) or any part of the pack is found to be damaged compromising its integrity. A record of the monitored data should be available for review and be able to be downloaded by the User. Verify operator training is given.

Performance qualification

6.9 Performance Qualification (PQ) tests are intended to demonstrate that the packed item once prepared is capable of maintaining the microbiological quality of the endoscopes in the pack. A mix of on-site tests/checks performed by an AP(D) or a manufacturer's service engineer, laboratory testing of samples taken during the qualification exercise can be used to demonstrate this has been achieved. Requirements are stated in table 6.2.

Table 6.2: Pressure pack system PQ requirements

PQ	Requirement
Chemical dosing/ concentration See paragraph 6.17	If chemical dosing is employed - Verify the chemical dose/concentration is achieved as per the manufacturer's specification for each channel of the endoscope model(s) under test. Confirm whether a volume measurement and or weight measurement is employed (or other means).
Channel blockage test See paragraph 6.15	Confirm blocked channels will result in a failed cycle.
Pressure See paragraph 6.16	The inflated level is achieved as per the manufacturer's specification. Confirm a pressure failure will result in a failed cycle.
*Maintaining the microbiological quality of the endoscopes See paragraph 6.14	The pressure pack should maintain the microbiological quality of the endoscopes during storage. To verify that at the end of the claimed shelf life there is no increase or adverse change in microbial contamination of the endoscope in the pressure pack. BS EN 16442 :2015 Annex E.2. and acceptance criteria E.2.3 states acceptable if contamination of the internal channels of the endoscope is less than 25 cfu/endoscope
Drying function (if applicable)	For pressure pack systems that provide a drying function the following requirements apply: a) the time required to dry the endoscopes shall be specified b) the efficacy of the drying function shall be deemed to be satisfactory. when tested there are no visible moisture droplets on the test paper.
Shelf life testing	Confirmation that the pressure pack remains sealed over the stated shelf life.
Seal system and seal test See paragraph 6.18	Confirmation of the satisfactory operation of the seal system. Confirmation that the method used to verify the seal is satisfactory. Check the pack integrity after the sealing process.
Labelling	The label content should be visibly clear, correctly aligned and contain the agreed information. – Board/site, Scope model/serial no or UDI, date processed, expiry date, cycle ref no, stated satisfactorily processed and alert information – do not use if the pack integrity is damaged.

PQ	Requirement
(Automatic) control (if fitted)	ACT – each stage of the process should meet the manufacturer's specification. A batch record is produced by the equipment (either paper or electronic).

6.10 Pressure pack system process parameters should be provided in measurable quantities, that can be verified by physical measurement. This will allow confirmation that the pressure pack system still functions within the original specifications. Process parameters measured may include the pressure applied on inflating. For those systems that employ chemical dosing, a means of measuring the chemical dose would be required for parametric qualification. Risk analysis standard BS EN 14971:2019 should be used in considering the potential for compromising the integrity of the pack from transport, handling and storing on a shelf.

Other items:

6.11 Confirm there are no mechanical defects in line with manufacturer's instructions. The PQ report should make a clear declaration (that where all the requirements have been met) the equipment is deemed fit for use.

6.12 The PQ report should be signed off by the User, an AP(D) and PQ tests should be performed on at least one model of each endoscope type tests group. The choice should be made according to the endoscopes available on site. Alternatively, performance tests may be performed with one model of each endoscope product family if it is demonstrated that the endoscopes selected are the most challenging.

Periodic testing

6.13 Periodic testing should be carried out in line with the manufacturer's instructions. The requirements in table 6.3 should be met annually.

Table 6.3: Pressure pack system - Periodic test requirements

Periodic	Requirement
Chemical dosing/ concentration See paragraph 6.17	If chemical dosing is employed - Verify the chemical dose/concentration is achieved as per the manufacturer's specification for each channel of the endoscope model(s) under test. Confirm whether a volume measurement and or weight measurement is employed (or other means).
Channel blockage test See paragraph 6.15	Confirm blocked channels result in a failed cycle.
Pressure See paragraph 6.16	The inflated level is achieved as per the manufacturer's specification. Confirm a pressure failure will result in a failed cycle.
*Maintaining the microbiological quality of the endoscopes See paragraph 6.14	The vacuum pack should maintain the microbiological quality of the endoscopes during storage. To verify that at the end of the claimed shelf life there is no increase or adverse change in microbial contamination of the endoscope in the pressure pack. BS EN 16442 :2015 Annex E.2. and acceptance criteria E.2.3 states acceptable if contamination of the internal channels of the endoscopes is less than 25 cfu/endoscope.
Drying function (if applicable)	For pressure pack systems that provide a drying function the following requirements apply: a) the time required to dry the endoscopes shall be specified

Periodic	Requirement
	b) the efficacy of the drying function shall be deemed to be satisfactory. when tested there are no visible moisture droplets on the test paper.
Shelf life testing	Confirmation that the pressure pack remains integral over the stated shelf life.
Seal system and seal test See paragraph 6.18	Confirmation of the satisfactory operation of the seal system and confirmation of the method stated to verify the seal is satisfactory and the pack integrity after the sealing process.
Labelling	The label content should be visibly clear, correctly aligned and contain the agreed information. – Board/site, Scope model/serial no or UDI, date processed, expiry date, cycle ref no, stated satisfactorily processed and alert information – do not use if the pack integrity is damaged.
Automatic control (if fitted)	ACT – each stage of the process should meet the manufacturer's specification. A batch record is produced by the equipment (either paper or electronic).

Test methods

Maintaining the microbiological quality of the endoscope

6.14 The endoscopes intended to be pressure packed are processed in an Endoscope Washer Disinfector (EWD) and then packed according to the instructions for use and held for the specified shelf life prior to testing.

Note 6.1: Where microbiological sampling of packed endoscopes is required as part

Method:

- samples taken from the distal ends of the endoscopes are split into two equal volumes;
- each volume is analysed by membrane filtration through 0,45 µm pore-size filters. The filtration membranes are placed on Tryptone soya agar and Sabouraud dextrose agar with chloramphenicol and incubated for 5 days at 30 ± 1 °C;
- record the number of viable microorganisms per endoscope taking into account the recovery ratio of the sampling method. After testing, each endoscope should be processed through an EWD.

Acceptance criteria:

- the results are deemed to be acceptable if contamination of the internal channels of the endoscopes is less than 25 cfu/endoscope.

Note 6.2: A result indicating a contamination level higher than 25 cfu/endoscope can

Channel blockage test

6.15 If applicable and as directed by the manufacturer carry out a manual test.

Method:

- manually block each channel in turn and run a cycle to confirm a failed cycle is produced (and printed on the label for the cycle).

Acceptance criteria:

- blocking each channel results in a failed cycle on each occasion.

Inflating the pack

6.16 This may be a visual test.

Method:

- seal the pressure pack and inflate/pressurize the pack.

Acceptance criteria:

- the pack should be seen to hold the pressurised/inflated state over a defined period of greater than 24 hours.

Chemical dosing

6.17 To demonstrate that the chemicals are delivered to the processed endoscope as specified using a weighing method.

Equipment:

- weighing scales and volumetric flasks.

Method:

- weigh or measure a known volume of the chemical. There should be at least enough fluid for more than 4 cycles;
- place the connector into the container;
- initiate a cycle. (Disregard result from the first run);
- repeat the test 3 times;
- measure the remaining quantity of fluid in the container after each test run.

Acceptance criteria:

- The measured quantity is above the minimum and below the maximum quantity specified by the manufacturer for each cycle tested. The reproducibility should be within that specified by the manufacturer.

Pack seal

6.18 Follow the manufacturer’s instructions to seal the pack using the Self seal pouch and manufacturers heat sealer.

Method:

- after sealing;
  - carry out a visual inspection of the seal(s);
  - operate the pressure cycle.

Acceptance criteria:

- the seal should be seen to be consistent and intact over its length. Once the pack is inflated it should be seen to hold the pressure over the period shown in 6.16.

7. Operation and maintenance

Operation - general

7.1 All documentation necessary for safe and efficient operating should be supplied by the manufacturer to the User. This information should be verified at the Installation Qualification (IQ). Ensure a list of endoscopes that can be stored in the storage cabinet or packed in a packing system is available. Follow the manufacturer's instructions for operation of the storage cabinet or packing system.

Operation of storage cabinet

Loading

7.2 Prior to loading the Storage Cabinet:

- ensure the external surface of the endoscope is dried;
- place the endoscope in the storage cabinet as soon as possible after drying/inspection;
- use your personal identification number/tag to unlock the drying cabinet;
- enter/ scan the unique endoscope code;
- connect all working channels of the endoscope to the connectors and check all caps are in place;
- place the endoscope accessories in the dedicated holder (keep tracking record/tickets and accessories with the endoscope);
- check air is flowing from the distal end of the endoscope (as applicable);
- do not coil the endoscope tightly;
- avoid contact of the endoscope with the internal cabinet surface or other endoscopes already stored in the cabinet;
- record the time in the endoscope tracking record/system (this may be an automatic function linked to the in-built track and trace system).

Unloading prior to use

7.3 Before removing endoscopes:

- confirm that the endoscope is stored in the cabinet for no longer than the validated time stated by the storage cabinet;
- where practicable, ensure that the required type of endoscope closest to expiry time is used first;
- ensure the storage cabinet door is open for the minimum time required to unload the endoscope;
- use the personal identification number/tag to unlock the storage cabinet;
- enter/ scan the unique code for the endoscope to record its removal from the cabinet;

- confirm all connectors have not become disconnected during storage;
- remove the endoscope and its associated accessories and place into a clean endoscope tray, prepared with a single use tray liner;
- cover tray and clearly mark as ‘processed’ and with the expiry time of the endoscope;
- follow the relevant part of the endoscope product release and update the tracking system as applicable;
- log any non-conformances found;
- transfer the endoscope adhering to transportation procedure.

Storage cabinets daily operational checks

7.4 At the start of the day check all indicators of the storage cabinet status (e.g. air flow, temperature, pressure and power source) are operational and confirm the pressure and temperature of the storage cabinet are within the set limits.

7.5 Check the storage time indicators for each endoscope to identify any endoscopes that are past their validated storage period.

7.6 Check door seals and locks for wear / tear.

7.7 Check endoscope connectors for blockages, wear and tear.

Operation of packing systems

7.8 Operational practice applicable to both use of vacuum packing systems and pressure pack systems includes:

- confirm the requirement for dryness of the endoscope prior to packing the endoscope;
- use the packing system that has been validated by the manufacturer for the endoscopes to be packed;
- check there a valid calibration label on the packing system prior to its use;
- follow the packing system manufacturer’s instructions in packing the endoscope;
- on completion of the packing process confirm the details of the equipment printout are satisfactory as applicable;
- verify by visual examination that the pack integrity including seal(s) is satisfactory;
- confirm the pack product label details are correct.

7.9 Once confirmed the product can be released for use. A production record should be retained detailing the cycle and the operator.

Product release

7.10 This procedure verifies that an endoscope has been satisfactorily processed prior to release for use. General criteria for product release include:

- verify that all stages of the decontamination process were completed satisfactorily;
- confirm that there is no visible sign of damage or contamination to the endoscope;
- update the electronic tracking system to indicate product release.

7.11 Specific additional criteria for storage cabinets includes:

- confirm there has been no cabinet alarms during the period of storage that may have impacted on the endoscope quality status;
- verify that the endoscope is still within its validated storage period on removal from the cabinet;
- If an endoscope is found to be beyond its maximum storage period in the cabinet, return the endoscope for processing.

7.12 Specific additional criteria for packing systems includes:

- in line with the manufacturer's instructions verify that the packing system has delivered a satisfactory cycle in producing the vacuum pack or pressure pack;
- verify the pack integrity is satisfactory;
- confirm product details on the pack label are legible and correct.

7.13 In 2017 HFS published the NHS Scotland Endoscope Decontamination Documentation System (EDDS): Decontamination Policy for flexible thermolabile endoscopes PRO 179-1. This included reference to standard operating procedures which include inspection of endoscopes, product release, use of storage cabinets and vacuum packing.

Maintenance

7.14 A maintenance schedule should be in place and specified by the storage cabinet or packing system manufacturer. The AE(D) and AP(D) should be consulted. Maintenance should include any associated services and infrastructure. Maintenance should be carried out as specified in the Endoscope Decontamination Unit (EDU)'s quality management system and any spares fitted to equipment should be sourced from approved suppliers.

7.15 Following any modification to the equipment including software upgrades, operating period parameters or process chemicals in use (where applicable), the AE(D) should be consulted to advise on any re-validation tests necessary.

7.16 Maintenance should be planned so that the equipment is out of service for the minimum time possible. Maintenance should, where practicable, be scheduled to precede periodic tests. In line with the EDU's quality management system a set of

procedures should be in place for each model of equipment containing full instructions for the required maintenance tasks. Tests are also recommended before equipment is returned to service, after repairs of one or more critical components that could affect critical process control parameters, or where a change to a parameter is made. On completion of maintenance a report should be completed by the CP(D) Indicating if the unit passed or failed. A service label with date, time and CP(D) signature and indicating a pass or fail should be attached to the unit. Records should be kept of all maintenance work undertaken. This should demonstrate that the work has been carried out and facilitate periodic review of the maintenance programme. These records can be stored as electronic or paper records.

7.17 The Planed Preventative Maintenance (PPM) programme should be reviewed annually. The review should aim to identify:

- the adequacy of maintenance records and compliance with the PPM programme;
- any emerging defects;
- any persistent and regular occurrence of alarms;
- any recommended upgrades or changes suggested by the manufacturer;
- any changes required to the PPM programme;
- any changes required to any maintenance procedure;
- any additional training required by maintenance personnel.

Proposed changes to the PPM programme should be made in consultation with the AE(D) and manufacturer whenever possible.

Returning equipment to service

7.18 Whenever any work has been carried out on equipment e.g. major repairs, overhauls, etc. which may affect the performance, the User and AP(D) with assistance from the AE(D), should draw up a schedule of checks and tests. These should be carried out before the equipment is returned to service. See guidance on the permit to work system given in SHTM 01-06 Part B.

Warranty period

7.19 After purchase of new equipment the manufacturer may carry out inspection and maintenance procedures under the terms of the warranty. The User should comply with any reasonable instructions from the manufacturer during the warranty period. Failure to do so could allow the manufacturer or supplier to pass some, if not all of its liability on to the Health Board.

7.20 Where maintenance is carried out under a lump sum term contract, such failure may be a breach of contract and could give the manufacturer or supplier cause to terminate the contract.

Note 7.1: Manufacturers attending site under the terms of clause 7.19 shall comply with the departmental operating procedures (e.g. hygiene measures and gowning policies, health and safety practices). Consideration should be given to health board policies with regard vaccination requirements when working on health board premises.

Investigating a failure

7.21 Manufacturer's instructions should be consulted in the first instance when investigating a failure in the use of endoscope storage cabinet or packing system. Where a remedial action is not provided, or the fault is not covered by the manufacturers' instructions a number of additional points should be considered:

- has the endoscope product family or type test group been validated for use?;
- was there a failure to follow standard operating procedures during operation?;
- has the drying challenge presented to the storage cabinet by a given endoscope design been underestimated?

7.22 A failure of the storage system/ cabinet may be caused by:

- incorrect loading; flexible endoscopes that are not correctly installed will not be subjected to the intended storage process;
- poorly loaded storage systems can cause some parts of endoscopes to be contaminated or damaged;
- the manufacturer's Instructions for Use (IFU) have not been followed. For example, the thermolabile flexible endoscopes may not have been correctly connected to an irrigation system as required by the manufacturer IFU;
- special attention should be paid to the requirements for more complex endoscopes such as duodenoscopes, which require disassembly and connection to ancillary ports on the endoscope during processing;
- issues with the storage systems such as blocked channels;
- the introduction of additional models of thermolabile flexible endoscopes that have not been through performance qualification tests at validation of the storage system;
- inadequate parameters such as the storage times and or air flow are insufficient or the temperature is not suitable;
- errors in calibration of built in measuring devices;
- worn or damaged accessories e.g., equipment connectors or defective packing materials
- damage to packing systems during storage and handling.

Note 7.2: New models should be assessed for inclusion in an existing product family preferably before purchase and introduction into clinical use. A new PQ exercise will be needed if the new scope has characteristics which do not fit into an existing PF for which the storage system has been validated.

Any decontamination incident or failure should be reported to the Infection, Prevention and Control Team. Refer to SHTM 01-06 Part A for further details.

Appendix 1: References

These references were current at the time this document was produced. Anyone who uses this document should ensure that they refer to the current versions of any references.

Standards

BS EN 837-1: 1998 Pressure gauges. Bourdon tube pressure gauges. Dimensions, metrology, requirements and testing. BSI.

BS EN ISO/IEC 17025: 2017 General requirements for the competence of testing and calibration laboratories. BSI.

BS EN 61000-4-3: 2006+A2: 2010. Electromagnetic compatibility (EMC). Testing and measurement techniques. Radiated, radio-frequency, electromagnetic field immunity test. BSI.

BS EN 61000-6-1: 2019 Electromagnetic compatibility (EMC). Generic standards. Immunity for residential, commercial and light-industrial environments. BSI.

BS EN 61000-6-3: 2007+A1: 2011.Electromagnetic compatibility (EMC). Generic standards. Emission standard for residential, commercial and light-industrial environments. BSI.

BS EN 61010-1: 2010+A1:2019. Safety requirements for electrical equipment for measurement, control, and laboratory use. General requirements. BSI.

BS EN ISO 3746: 2010. Acoustics. Determination of sound power levels and sound energy levels of noise sources using sound pressure. Survey method using an enveloping measurement surface over a reflecting plane. BSI.

BS EN ISO 14971: 2019, Medical devices — Application of risk management to medical devices. BSI.

BS EN ISO 17664: 2021 – Part 1 Processing of health care products. Information to be provided by the medical device manufacturer for the processing of medical devices - Critical and semi-critical medical devices. BSI.

BS IEC 61010-2-120: 2018. Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-120: Particular safety requirements for machinery aspects of equipment. BSI.

BS EN 16442: 2015 titled Controlled environment storage cabinet for processed thermolabile endoscopes

BS EN 60751:2008 Industrial platinum resistance thermometers and platinum temperature sensors

BS EN 60584-1:2013: Thermocouples - EMF specifications and tolerances

BS EN 1822-1:2019: High efficiency air filters (EPA, HEPA and ULPA) - Classification, performance testing, marking

BS EN ISO 15223-1:2021 ‘Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied Part 1: General requirements.

BS EN ISO 10993 series for the Biological evaluation of medical devices. BSI.

Healthcare Facilities Scotland publications

Scottish Health Planning Note 13 Part 3: 2010. Decontamination Facilities - Endoscope Decontamination Unit.

Requirements for compliant Endoscope Decontamination Units, GUID 5013; 2014 v2

Scottish Health Technical Memorandum (SHTM) 01-06 series 2022.

Endoscope Decontamination Documentation system’ (EDDS) 2017.

Regulations

UK Medicines and Medical devices Act 2021

UK Medical Device Regulations: 2002, MHRA

Regulation (EU) 2017/745 on medical devices: 2017.

Control of substances hazardous to health (COSHH) Regulations: 2002.

Electromagnetic Compatibility Regulations: 1992.

Provision and Use of Work Equipment Regulations 1998 (amended by the Health and Safety (Miscellaneous Amendments) Regulations 2002 and the Health and Safety (Miscellaneous Repeals, Revocations and Amendments) Regulations 2013).

Workplace (Health, Safety and Welfare) Regulations: 1992.

Appendix 2: Type testing storage cabinets

Carried out by the equipment manufacturer.

Table A2.1: Type testing of storage cabinets as BS EN 16442:2015

Type testing [and BS EN 16442: 2015 Requirement clause]	Requirement [and BS EN 16442: 2015 Test clause]
Air changes [5.2.2.3]	The number of air changes per hour inside the storage cabinet chamber should be specified. NOTE An air change of at least ten times the volume of the storage compartment per hour is an acceptable value to reduce the risk of contamination from the environment following, for example, a door opening and to reduce the moisture content during drying. [6.2]
Overpressure [5.2.2.2]	When tested, the air pressure in the storage cabinet chamber shall be higher than the ambient pressure where the storage cabinet is located. Measurements shall be made when the doors of the storage cabinet are closed and after the defined stabilization time. [6.3]
*Maintaining the quality of the endoscopes [4.2.1]	The storage cabinet shall maintain the microbiological quality of the endoscopes during storage. Tests shall be performed according to Annex E. [E.1]
Drying function (if applicable) [4.3]	For storage cabinets that provide a drying function the following requirements apply: a) The time required to dry the endoscopes should be specified and should not exceed 3 hours. b) The efficacy of the drying function should be deemed to be satisfactory if, when tested, there are no visible moisture droplets on the test paper. [6.4.3 & 6.4.4]
Air quality particulate contamination (if applicable) [5.2.2.4]	If a specific cleanliness level is claimed and when tested the particulate contamination within the storage cabinet should be consistent with the claims. Where the air in the storage cabinet is filtered, means shall be provided to enable the filtration system to be tested. This should include means of access upstream of the filter where a controlled particulate aerosol can be injected and means of access downstream of the filter where an iso-kinetic sampling probe can be placed. [6..11]
Airborne microbial contamination [5.2.2.1]	Air inside the storage cabinet and flowing through the channels of the endoscope should be of a microbiological quality which will not impair the quality of the load. Tests should be done according to Annex C. NOTE 1 This can be achieved by filtration of the air using filters having not less than 99,95 % retention to particles of 0,3 µm. NOTE 2 Filters conforming to Class H 13 as specified in BS EN 1822-1:2009 can be regarded as suitable. (Now 2019 version). Recommendations on the relevant alert and action limits to be set for the results of particulate (if claimed) and microbiological monitoring shall be specified, including the action to be taken when specified limits are exceeded. [Annex C]
Automatic temperature control (if fitted) [5.2.2.5]	If the storage cabinet operates at temperatures different from ambient, the temperature inside the storage cabinet should be specified and controlled within the temperature limits. The temperature limits of the endoscopes have to be considered. When tested the rate and extent of any change in temperature throughout the operating cycle should be within specified limits, and will not cause damage to the endoscope(s) stored in the storage cabinet. [6.8]

Type testing [and BS EN 16442: 2015 Requirement clause]	Requirement [and BS EN 16442: 2015 Test clause]
*Channel aeration test [5.5.1]	Throughout the storage, air has to flow through each of the internal channels and/or cavities of the device. The air circulation may be either continuous or intermittent. Instructions should be provided on the verification of air circulation and can include: a) verifying that all channels allow the passage of air before the endoscope is loaded into the storage cabinet; NOTE 1 If the endoscope is cleaned and disinfected using a validated processing procedure this verification is included. NOTE 2 Some washer-disinfectors and manual processing procedures do not monitor flow through the endoscope channels. b) confirming that all necessary connections were made before, and were still in place at the end of, the storage cycle; c) verifying the air circulation in each tubing of the storage cabinet connector using specified means]; For single channel storage cabinet connectors, means shall be provided to allow the verification of air flow in each tubing. When a manifold is used means provided shall allow the verification at least in the tube connected to the storage cabinet. NOTE 3 The attention of the user is drawn on the fact that means provided to verify the free passage of air can be either continuous or intermittent, automatic and under the control of the automatic controller of the storage cabinet (i.e. control of the air flow through each endoscope channel) or require a verification by the user (e.g. visual indication of the air circulation). d) Confirming by reference to the storage cabinet process record that the supply of air to the device used to connect the endoscope was maintained during each stage of the process; Conformity shall be demonstrated by cross-checking with the storage cabinet instructions for use. [6.7]
Readability [5.9.3]	The characters on each indicating instrument or display should be clearly visible at viewing distances of 0.25 m and 1.0 m. [6.10].
Cross contamination [4.2.2]	A risk analysis with consideration of the different parameters on the storage cabinet performance should be performed and the means used to minimize the identified risks shall be verified. [Annex B –optional]

Appendix 3: Type testing vacuum pack systems

Carried out by the equipment manufacturer. All equipment (and any associated consumables) characteristics that impact on the product quality shall be verified.

Note A3.1: The characteristics shown in table A3.1 for which type testing should be

Table A3.1: Type testing vacuum pack system requirements established by SHTM 01-06

Type testing	Requirement
Chemical dosing/ concentration	If chemical dosing is employed a means of determining the dose (and concentration) is required and the results of testing provided. If a range of dose is employed, a specification for the minimum and maximum dose. A specification for the time that the endoscope (channels) are exposed to the chemical and whether flushing of the channels is performed post use of the chemical. Evidence that the specification was met. Record the method of flushing e.g. HEPA filter air/water/other. If flushing is used, evidence that the dosing chemical concentration is reduced to a specified (safe) level. Confirmation from the endoscope manufacturer that the chemical used in dosing (and at the specified concentration) over the vacuum pack shelf life will not adversely affect the endoscope quality or functionality. Confirmation that the chemical and concentration employed (i.e. maximum dose) is not toxic and will not be an irritant* to the patient when the endoscope is used i.e. at the point of use any residuals present are at a level which present a minimal risk to the health of the user or the patient.
Channel blockage test	Each channel of the endoscope should be checked for blockages and the system which indicates channel blockages performs satisfactorily.
Vacuum	The vacuum level shall be specified by the manufacturer. The manufacturer shall verify that the vacuum applied will not have an adverse effect on the endoscope functionality (for each type of endoscope for which the storage system is specified).
*Maintaining the quality of the endoscopes	The vacuum pack should maintain the microbiological quality of the endoscopes during storage. The manufacturer shall verify that at the end of the claimed shelf life of the pack there is no increase or adverse change in microbial contamination.
Drying function (if applicable)	For vacuum pack systems that provide a drying function the following requirements apply: a) the time required to dry the endoscopes shall be specified and verified; b) the efficacy of the drying function shall be deemed to be satisfactory when there are no visible moisture droplets on the test paper.
Shelf life testing	Confirmation that the vacuum pack remains integral over the stated shelf life. The manufacturer shall specify the method employed and the acceptance criteria indicating satisfactory performance
Seal system and seal test	Confirmation of the satisfactory operation of the seal system and confirmation of the method stated to verify the seal is satisfactory after the sealing process. Note whether a self-seal pouch is employed or a heat sealer as part of the system. Note if the heat sealer is a separate dedicated component.

Type testing	Requirement
Automatic control (if fitted)	Verify that each stage of the process is within specification. Where chemicals are in use verify the flushing stages are satisfactory as specification.
*It has been identified that a number of patients undergoing an endoscopy procedure exhibited signs of mucosal blanching when the water channel was activated. The root cause of this effect was believed to be retention of some hydrogen peroxide solution in the endoscope. - FSCA Identifier: Ref. 18-01-053 (July 2018)	

Appendix 4: Type testing pressure pack systems

Carried out by the equipment manufacturer. All equipment (and any associated consumables) characteristics that impact on the product quality should be verified.

Table A4.1: Type testing pressure pack system requirements established by SHTM 01-06

Type testing	Requirement
Chemical dosing/ concentration	If chemical dosing is employed a means of determining the dose (and concentration) is required. If a range of dose is employed, specify the minimum and maximum dose. Specify the time that the endoscope (channels) are exposed to the chemical and whether flushing of the channels is performed post use of the chemical. Record the method of flushing e.g. HEPA filter air/water/other. Confirmation from the endoscope manufacturer that the chemical using in dosing (and at the specified concentration) over the pressure pack shelf life will not adversely affect the endoscope functionality. Confirmation that the chemical concentration employed (i.e. maximum dose) will not be an irritant* to the patient when the endoscope is used.
Channel blockage test	Each channel of the endoscope should be checked for blockages.
Pressure	The pressure level shall be specified by the manufacturer. The manufacturer shall verify that the pressure applied will not have an adverse effect on the endoscope functionality (for each type of endoscope for which the storage system is specified).
*Maintaining the quality of the endoscopes	The pressure pack should maintain the microbiological quality of the endoscopes during storage. To verify that at the end of the claimed shelf life there is no increase or adverse change in microbial contamination.
Drying function (if applicable)	For pressure pack systems that provide a drying function the following requirements apply: a) the time required to dry the endoscopes shall be specified. If heated air is employed the temperature range shall be specified and demonstrated. If air is used to flush the channels the quality of air employed shall be specified and verified. b) the efficacy of the drying function shall be deemed to be satisfactory when tested there are no visible moisture droplets on the test paper.
Shelf life testing	Confirmation that the pressure pack remains integral over the stated shelf life. The method by which this is established shall be specified by the manufacturer.
Seal system and seal test	Confirmation of the satisfactory operation of the seal system(s). Note if more than one seal type is employed in sealing the pack. Confirm the method stated to verify the seal is satisfactory after the sealing process. Note whether a self-seal pouch is employed or a heat sealer as part of the system. Note if the heat sealer is a separate dedicated item of equipment.
Automatic control (if fitted)	Verify that each stage of the process is within specification. Where chemicals are in use verify the pressure (inflating) stages are satisfactory as specification.