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Controlled environment storage cabinet for processed thermolabile endoscopes

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National foreword

This British Standard is the UK implementation of EN 16442:2015.

The UK participation in its preparation was entrusted to Technical Committee CH/198, Sterilization and Associated Equipment and Processes.

A list of organizations represented on this committee can be obtained on request to its secretary.

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Controlled environment storage cabinet for processed thermolabile endoscopes

Enceinte de stockage à atmosphère contrôlée pour endoscopes thermosensibles traités

Lagerungsschrank mit geregelten Umgebungsbedingungen für aufbereitete, thermolabile Endoskope

This European Standard was approved by CEN on 19 December 2014.

EUROPEAN COMMITTEE FOR STANDARDIZATION
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Foreword

This document (EN 16442:2015) has been prepared by Technical Committee CEN/TC 102 “Sterilizers for medical purposes”, the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by September 2015 and conflicting national standards shall be withdrawn at the latest by September 2015.

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Introduction

Endoscope storage cabinets are designed to provide a controlled environment for the storage of endoscope(s) (with or without channels) and, if necessary, drying of the endoscope(s) including the endoscope(s) channels.

The controlled environment provided by the storage cabinet ensures that during storage there is no deterioration of the microbiological quality of the endoscope. The drying function is intended to supplement, if necessary, any drying conducted during automated or manual processing of the endoscope.

The storage cabinet is designed to allow for the safe use of endoscopes at an extended period from the time of processing improving availability for use.

NOTE 1 Drying of an endoscope in a washer-disinfector can require a prolonged cycle time. The use of a storage cabinet including a drying function can increase the number of endoscopes that can be processed in the washer-disinfector for a defined time period.

NOTE 2 It is strongly recommended to verify the microbiological quality of the endoscopes intended to be stored in the cabinet before installation of the storage cabinet.

NOTE 3 The storage cabinet is not designed to clean and/or disinfect endoscopes and any contaminated endoscope stored in the cabinet can still be contaminated after the storage period.

NOTE 4 Storage cabinets for processed thermolabile endoscopes are not considered as medical devices.

1 Scope

This European Standard specifies the performance requirements applying to cabinets designed to store, or store and dry, thermolabile endoscopes following automated or manual processing.

The storage cabinets are designed to provide a controlled environment for storage of endoscope(s), with or without channels, and when necessary drying of the endoscope(s), including the endoscope(s) channels.

The controlled environment provided by the storage cabinet ensures that during storage there is no deterioration of the microbiological quality of the endoscope. The drying function is intended to supplement, if necessary, any drying provided as part of the automated or manual processing cycle.

This European Standard specifies storage cabinets which flush the channels and the external surfaces of endoscopes with air.

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

NOTE 2 Thorough drying of an endoscope in a washer-disinfector can require a prolonged cycle time; the use of a storage cabinet including a drying function can enhance throughput of the endoscopes.

The cabinet is not intended to provide any cleaning or disinfection function.

This European Standard does not include the use of other chemicals for drying and maintaining the quality of endoscopes during storage

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 60584-1:2013, *Thermocouples — Part 1: EMF specifications and tolerances (IEC 60584-1:2013)*

EN 60751:2008, *Industrial platinum resistance thermometers and platinum temperature sensors (IEC 60751:2008)*

EN ISO 14644-3:2005, *Cleanrooms and associated controlled environments — Part 3: Test methods (ISO 14644-3:2005)*

3 Terms and definitions

For the purposes of this document the following terms and definitions apply.

3.1
drying function
additional feature of a storage cabinet carried out in the sequence as regulated by the automatic controller to remove moisture

3.2
drying phase
part of the storage cycle that is dedicated to the drying of the endoscope

3.3
drying temperature band
range of temperatures expressed as the minimum and the maximum controlled temperatures, which may prevail throughout the load during drying

3.4
endoscope storage cabinet connector
ESC connector
device used to connect endoscope channels inside the cabinet to the flushing system

3.5
endoscope surrogate device
item designed to represent construction elements of endoscope specific characteristics affecting the flow conditions in an endoscope

Note 1 to entry: Construction elements can include channel length and diameter, connectors, channel separators, port closures, return valves, etc.

3.6
processing
activity including cleaning, disinfection and sterilization (if necessary and applicable), to prepare a new or used medical device for its intended use

3.7
storage cabinet
equipment controlled by an automatic control system that maintains the microbiological quality of processed thermolabile endoscope

3.8
storage cycle
time between connecting and disconnecting the endoscope(s) inside the storage cabinet

Note 1 to entry: A storage cycle can include a drying phase.

3.9
storage temperature band
range of temperatures expressed as the minimum and the maximum controlled temperatures, which may prevail throughout the load during storage

3.10
thermolabile
damaged by exposure to temperatures within the range used for thermal disinfection

Note 1 to entry: The minimum temperature for thermal disinfection specified in ISO 15883-1 is 65°C.

4 Performance requirements

4.1 General

4.1.1 Storage cabinets are designed to provide a controlled environment for storage of endoscopes (with or without channels). The controlled environment provided by the cabinet shall ensure that during storage there is no deterioration of the microbiological quality of the endoscope. An optional drying function is intended to supplement, if necessary, any drying provided as part of the automated or manual processing cycle

The cabinet is not intended to provide any cleaning or disinfection function.

NOTE 1 Thorough drying of an endoscope in a washer-disinfector can require a prolonged cycle time; the use of a storage cabinet including a drying function can enhance throughput of the endoscopes.

NOTE 2 Table A.1 gives a summary of the tests and Clause 6 on the test methods that can be used to check that the storage cabinets meet the specified requirements.

4.1.2 Detailed requirements for information to be provided by the manufacturer are specified in Clause 8.

4.1.3 The value of any process variable shall be pre-set and adjustment shall require the use of a key, code or tool.

4.1.4 Throughout the drying phase and/or storage the values and rate of change in temperature, pressure or any other process variable shall be within limits which will not cause damage to the device(s) stored in the storage cabinet.

4.2 Storage

4.2.1 The storage cabinet shall maintain the microbiological quality of the endoscopes during storage. Tests shall be performed according to Annex E.

4.2.2 A risk analysis with consideration of the different parameters on the storage cabinet performance shall be performed and the means used to minimize the identified risks shall be verified (see 6.1).

NOTE 1 According to the design of the storage cabinet those parameters can include:

- potential for contamination between different endoscopes stored simultaneously (see Annex B);
- ingress of contamination during loading and/or unloading;
- potential for contamination caused by accessories and connectors/connections (see Annex B);
- potential for contamination caused by endoscopes accessories;
- environmental conditions (e.g. temperature, humidity, etc.) where the storage cabinet is installed;
- potential for contamination caused by improper air quality in the storage compartment;
- potential for contamination caused by inefficient drying procedure prior to storage;
- potential for growth of the initial contamination of a contaminated endoscope accidentally introduced in the storage cabinet.

NOTE 2 EN ISO 14971 establishes the requirements for risk management to determine the safety of a medical device by the manufacturer during the product life cycle and may be used.

4.2.3 If the storage cabinet does not have a drying phase, it has to be specified that the endoscope (outside surfaces and internal channels) has to be dried before storage [see 8.2 j)].

4.2.4 Any instructions given by the manufacturer for drying the inside and outside of the endoscope shall conform to the endoscope manufacturer's instructions (on pressure issues, temperature issues, etc.).

4.2.5 Any requirements regarding the quality of the air supplied to the storage cabinet (see 5.2) shall be specified [see 8.2 f) 1)].

4.2.6 The maximum storage time in the storage cabinet shall be determined [see 8.2 c)]

NOTE The maximum storage time can be limited by national or regional recommendations or regulations.

4.3 Drying

For storage cabinets that provide a drying function [see 8.2 d) 1)] the following requirements apply:

a) The time required to dry the endoscopes [see 8.2 d) 4)] shall be specified when tested according to 6.4 and shall not exceed 3 hours.

NOTE 1 Drying times can be different according to the type of endoscope involved.

NOTE 2 3 hours is an acceptable drying time to reduce the potential risk of growth of microorganisms present in endoscope channels.

b) The efficacy of the drying function shall be deemed to be satisfactory if, when tested according to 6.4, there are no visible moisture droplets on the test paper.

4.4 Endoscope storage cabinet connectors (ESC connectors)

4.4.1 General

Two types of ESC connectors exist:

a) ESC connectors providing independent air flow to each endoscope channel; and

b) ESC connectors providing air flow to a group of endoscope channels via a manifold (between the storage cabinet and the endoscope).

NOTE In the absence of a system that allows control of air flow in each tube of the ESC connector, flow of air in endoscope channels depends on:

— air connection tubing to the storage cabinet,

— the design of the manifold that insures air separation to supply each channels of the endoscope, and

— the internal design of the endoscope.

4.4.2 ESC connector qualification

Each ESC connector type shall be qualified during type testing.

A test protocol shall be provided to enable the user to verify the compliance of the ESC connectors with the specifications during routine testing [see 8.2 i)].

5 Mechanical and procedure requirements

5.1 Materials – design, manufacture and assembly

5.1.1 Load carriers, trays or holding systems intended to accommodate the device(s) to be stored shall be designed and constructed to avoid the possibility of damage to the device(s) at the time of loading, during storage and during the course of unloading.

5.1.2 The procedures required to minimize microbial contamination on the internal surfaces of the storage cabinet shall be described. These procedures shall not adversely affect the quality of the load under normal conditions of use [see 8.2 r)].

5.1.3 For storage cabinets in which the endoscopes are stored in a vertical hanging position:

a) the endoscope hanger shall be designed to ensure that all endoscopes specified for storage and/or drying in the storage cabinet [see 8.2 a) and d) 2)] will not touch the bottom of the storage cabinet, or

b) a means shall be provided to position the distal end of the endoscope to prevent contact with the bottom of the storage cabinet.

5.2 Air quality

5.2.1 Air supplied to the storage cabinet

5.2.1.1 General

5.2.1.1.1 Air supplied to the storage cabinet shall be of a quality which shall not impair the cleanliness of, nor introduce microbial contamination to, the load.

5.2.1.1.2 The quality of the air supplying the storage cabinet shall be specified [see 8.2 f)] and may include specifications for maximum relative humidity, pressure, oil content, particulate count and flow rate.

5.2.1.1.3 The material used in the pipework of the air distribution system shall be compatible with the intended use of the storage cabinet.

5.2.1.1.4 The specifications of the air quality shall be measured on installation and at specified intervals [see 8.2 f) 3)].

5.2.1.2 Compressed air

5.2.1.2.1 Where the storage cabinet is supplied with compressed air, the compressor shall be fitted with a filter and dryer system to meet the required specifications (see 5.2.1.1.2) and minimise the risk of contamination of the storage cabinet and stored endoscopes by microorganisms.

5.2.1.2.2 Where the storage cabinet is provided with a compressor, the frequency for changing pre- and post-compression filters on the air compressor shall be specified [see 8.2 h) 2)].

5.2.1.2.3 When compressed air is used the oil content shall not exceed 0,1 mg/ m^3.

NOTE 1 This quality is equivalent to Class 2 as defined in ISO 8573-1.

NOTE 2 Compressed air coming from an oil free compressor is deemed to meet this requirement.

5.2.2 Environmental conditions inside the storage cabinet

5.2.2.1 General

Air inside the storage cabinet and flowing through the channels of the endoscope shall be of a microbiological quality which will not impair the quality of the load. Tests shall 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 EN 1822-1:2009 can be regarded as suitable.

Recommendations on the relevant alert and action limits to be set for the results of particulate (if claimed) and microbiological monitoring [see 8.2 g) 3)] shall be specified, including the action to be taken when specified limits are exceeded [see 8.2 g) 5)].

5.2.2.2 Overpressure

When tested according to 6.3, 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 [see 8.2 v)].

5.2.2.3 Air changes

The number of air changes per hour inside the storage cabinet chamber using the method described in 6.2 shall be specified [see 8.2 w)].

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.

5.2.2.4 Particulate contamination

5.2.2.4.1 If a specific cleanliness level is claimed and when tested according to 6.6.1 the particulate contamination within the storage cabinet shall be consistent with the claims [see 8.2 g) 1) and 2)].

NOTE Classifications of air cleanliness are defined in EN ISO 14644-1.

5.2.2.4.2 Where the air in the storage cabinet is filtered, means shall be provided to enable the filtration system to be tested (see 6.11). This shall 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.

5.2.2.5 Temperature control

5.2.2.5.1 If the storage cabinet operates at temperatures different from ambient, the temperature inside the storage cabinet shall be specified and controlled within the temperature limits [see 8.2 b) and 8.2 d) 3)]. The temperature limits of the endoscopes have to be considered.

5.2.2.5.2 When tested according to 6.8 and 6.9 the rate and extent of any change in temperature throughout the operating cycle shall be within specified limits, and will not cause damage to the endoscope(s) stored in the storage cabinet [see 8.2 b) and 8.2 d) 3)].

5.2.2.6 Pressure

Throughout the operating cycle the rate and extent of any change in pressure in endoscope channels shall be within specified limits, which will not cause damage to the endoscope(s) stored in the storage cabinet [see 8.2 e) 4)].

5.3 Contamination of the storage cabinet chamber surfaces

5.3.1 The internal surfaces of the storage cabinet chamber shall be capable of withstanding routine cleaning and disinfection [see 8.2 r)], without deterioration.

NOTE Removable trays of a cabinet, designed to store endoscopes, are considered as chambers.

5.3.2 A cleaning-disinfection procedure shall 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 when tested as described in 6.5 [see 8.2 r)].

NOTE This can include the use of liquid/gas, cleaning-disinfection procedures or any other validated methods giving the same result.

5.4 Drying process control

Drying shall be achieved by evaporation of residual moisture from the endoscope. The rate of drying shall be enhanced by air flow.

NOTE The air can be heated and/or dry.

5.5 Endoscope channel aeration system

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 shall 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 [see 8.2 j)];

NOTE 1 If the endoscope is cleaned and disinfected using a validated processing procedure this verification is included (e.g. EN ISO 15883-4:2009, 5.2.2).

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 [see 8.2 i)];

c) verifying the air circulation in each tubing of the ESC connector using specified means [see 8.2 e) 1)];

For single channel ESC 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, and in compliance with 6.7.

5.5.2 It shall be specified whether the automated channel flushing control system used is able to run controls on each channel independently or on a set of channels [see 8.2 e) 2)].

5.5.3 Where there is a system for monitoring the free passage of air through the endoscope channels, the detection limit beyond which the system can no longer reliably check that air is properly circulating through the channels [see 8.2 e) 5)] shall be specified.

5.5.4 The endoscopes from the list of endoscopes that can be stored/dried in the storage cabinet and for which the airflow through one or more channels is below the detection limit of the monitoring system (if there is one), together with details of any recommended practices and/or specific limitations applying to the use of these endoscopes shall be provided [see 8.2 e) 6)].

NOTE Any instances where air is unable to pass through one or more channels can lead to lack of drying and potential growth of microorganisms.

5.5.5 A diagram of the circulation pathway of the air for all channels of each endoscope that the storage cabinet is intended to store [see 8.2 e) 3)] shall be provided.

5.5.6 The minimum and maximum pressure that the storage cabinet is designed to deliver to each channel or channel system of the endoscope that are connected to the storage cabinet shall be specified. The pressure limits of the endoscopes have to be considered [see 8.2 e) 4)].

5.5.7 In the case where different channels are flushed at different pressures (e.g. an elevator channel or a channel fitted with a backflow check valve), means shall be provided to prevent incorrect connection.

NOTE Different pressures can be required to ensure air flow throughout endoscope channels with different diameters.

5.6 Automatic temperature control

5.6.1 Any heating system shall 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.

5.6.2 When doors of the storage cabinet are closed, a fault shall be indicated if the temperature during the storage and/or drying function is outside the specified storage and/or drying temperature band [see 8.2 b) and d) 3)].

5.7 Fault indication/monitoring

5.7.1 If the doors are opened for more than the defined maximum time an alarm shall be indicated or sounded [see 8.2 x)].

The time required to load and connect, or disconnect and unload, an endoscope should be considered.

5.7.2 If the cycle parameters are outside the specified tolerances or in the event of a failure of a service supply (e.g. air, electricity) that prevents the attainment of these parameters, the automatic controller shall cause a visual indication that a fault has occurred.

5.7.3 When an audible signal is installed, this signal shall be temporarily mutable.

5.7.4 If the storage cabinet is connected to a printer, the message indicating the fault shall also be printed out and be immediately identifiable.

5.7.5 Fault-triggering events shall include, when applicable, the following:

— the temperature during the process (storage or drying) is outside the temperature band [see 8.2 b) and d) 3)].;

— the pressure during the process (storage or drying) is outside the limits specified [see 8.2 e) 4)].;

— the air flow through the tube connected to the storage cabinet [see 5.5.1 c)] is below the minimum limit specified [see 8.2 b) and d) 3)] when fitted with an automatic channel air flow control system (see 5.5.1);

— for storage cabinet fitted with an automatic channel flushing control system (see 5.5.1), the air flow to the device used to connect the endoscope is below the minimum limit or above the maximum limit specified [see 8.2 e) 4) and 5.5.6];

— any changes in storage conditions (such as the door being left open, etc.) that may have an impact on the microbiological quality of the endoscope;

— any failure to keep within the limit in any other parameters that has been specified as critical.

5.7.6 When a fault has been indicated, the instructions for use shall described how:

— the fault can be corrected [see 8.2 s)],

— the indication of the fault can be reset [see 8.2 t)], and

— the endoscopes stored in the storage cabinet shall be treated (e.g., repeated processing) [see 8.2 u)].

5.7.7 The storage cabinet shall be fitted with a system indicating the interruption of any external services such as electrical power or compressed air that might have an adverse effect on storage and/or drying.

5.7.8 The operations that need to be carried out in the event of a break in electrical power [see 8.2 n)] shall be specified.

NOTE For storage cabinet fitted with a system able to record the length of any electrical power cut, the operations to be carried out can be different according to the length of the power cut.

5.8 Cycle indicators

The storage cabinet shall be equipped with a system displaying the period of storage of each endoscope in the storage cabinet.

The following cycle indicators shall be located in such a way that they are clearly visible by the user:

a) "status" indicator;

b) "fault" indicator;

c) ”storage time” indicator for each endoscope;

d) hours run meter or cycle counter that cannot be re-set by the user.

NOTE Visualisation of the hours run meter or cycle counter can require interrogation of the process controller.

5.9 Instruments and control devices

5.9.1 Instruments and controls shall be designed, positioned and protected so that their performance as specified in this European Standard is maintained when operating in an ambient temperature range of 5 °C to 40 °C and with a relative humidity not exceeding 80 % for temperatures up to 31 °C decreasing linearly to 50 % relative humidity at 40 °C.

5.9.2 Each gauge and indicating device shall be marked or labelled with a description of its function and, if used for temperatures, shall identify the location of its sensor. If an instrument is connected, in turn, to more than one sensing point, these points shall continuously indicate the active sensor that is being monitored.

NOTE The identification of sensor location can be sufficient to allow the operator to understand the significance of the instrument reading e. g., 'storage cabinet temperature'.

5.9.3 The characters on each indicating instrument or display shall be clearly visible at viewing distances of 0,25 m and 1,0 m when tested in accordance with 6.10.

5.9.4 For calibration purposes, each measurement system shall be provided with means of adjustment without dismantling it or removing it from its position. The system of adjustment shall be protected, e. g. by means of a cover or a locking screw, against inadvertent readjustment. A key, a code or a special tool shall be required in order to gain access to the settings adjustment system employed.

NOTE 1 Removal of the connected sensor can be necessary.

NOTE 2 Calibration, adjustment and verification of calibration can be carried out only by trained and authorised personnel.

5.9.5 Means shall be provided to enable the calibrated instruments and process controls to be independently verified during an operating cycle.

5.9.6 At least one temperature sensor shall be located in a position that has previously been determined as being representative of the lowest temperature achieved within the load.

NOTE This temperature can be defined as the temperature in the endoscope storage chamber.

5.10 Temperature indicators

5.10.1 Temperature sensors shall be either platinum resistance types complying with Class B of EN 60751:2008 or thermocouples complying with Tolerance Class 2 of EN 60584-1:2013 or other systems of demonstrated equivalence.

5.10.2 The storage cabinet's chamber temperature indicating system shall:

a) be either digital or analogue;

b) be graduated in degrees Celsius;

c) have a scale which includes the range 5 °C to 70 °C;

d) have an accuracy of at least 1 °C over the scale range 10 °C to 70 °C;

e) for analogue instruments be graduated in divisions not greater than 1 °C;

f) for digital instruments have a resolution of at least 1 °C;

g) when used for a control function, have broken sensor protection which will fail up-scale;

h) have an ambient temperature error compensation not exceeding 0,08 K/K;

i) have the means to be adjusted in situ by the use of a special key, code or tool without dismantling the instrument.

5.11 Relative humidity indicator

The storage cabinet's relative humidity indicator (indicating system) shall:

a) be digital;

b) be graduated in percentage relative humidity;

c) have a scale that includes the range from 30%RH to 80%RH;

d) have a resolution of at least 1%RH;

e) have an accuracy of 5% RH;

f) when used for a control function, have broken sensor protection which will fail up-scale.

5.12 Pressure indicators

The storage cabinet's air pressure indicating system shall:

a) be either digital or analogue;

b) indicate overpressure, relative to ambient pressure;

c) be graduated in kPa or equivalent;

d) have a scale which includes the range 0 kPa to 120% of the upper level of the pressure range specified for air delivered to the endoscope [see 8.2 f) 2)];

e) have an accuracy of at least 5% over the pressure range specified [see 8.2 f) 2)];

f) for analogue instruments be graduated in divisions not greater than 10 kPa;

g) for digital instruments have a resolution of at least 10 kPa;

h) for digital instruments have the sampling rate of at least every 5 s;

i) when used for a control function, have broken sensor protection which will fail up-scale;

j) have an ambient temperature error compensation not exceeding 0,08 K/K;

k) have the means to be adjusted *in situ* by the use of a special key, code or tool without dismantling the instrument.

The scale of the pressure indicator shall range from 0 % to 120 % of the upper level of the specified pressure range [see 8.2 e) 4)].

The pressure indicator shall have an accuracy of 5 % over the specified pressure range for air delivered to the endoscope [see 8.2 e) 4)].

5.13 Traceability

The storage cabinet shall be designed to allow the recording of all critical cycle parameters and faults.

NOTE This can be record by a controller, printer or connection to a computer system.

This shall include but is not limited to:

a) any fault indicated during storage and/or drying;

b) the time for which each endoscope is stored;

c) conformity of all defined critical parameters;

d) recording of the identity of each endoscope;

e) recording time and date when each endoscope was placed, dried (when applicable)and when it was removed from storage ;

f) recording the identity of the operator(s) loading and unloading the endoscope.

5.14 Double-ended storage cabinets

Double-ended storage cabinets shall have:

— the control initiating the storage and/or drying cycle at the loading side of the storage cabinet only;

— the visual indication of a fault given at both the loading and unloading side of the storage cabinet;

— means that prevent the operator to open or close an opposite door while standing at one end of the storage cabinet;

— means that avoid under normal operation simultaneously opening of both doors to permit free passage of air through the storage cabinet;

— a visual display provided at each end of the storage cabinet to indicate when a storage cycle is in progress;

— the printed record (if installed) produced on the unloading side of the storage cabinet, unless otherwise specified.

6 Testing for conformity

6.1 General

6.1.1 Tests conditions shall take into account:

— environmental conditions where the storage cabinet will be installed (e.g. temperature, humidity) and

— the state of the endoscope (e.g. volume of water in endoscope channels prior storage).

6.1.2 Endoscope surrogate devices and/or endoscopes from each relevant endoscope type test group (see F.3) shall be included in type testing.

These test devices shall be selected using the method described in Annex F, considering the specific characteristics and limitations of the storage cabinet.

Performance qualification tests shall be performed on at least one model of each relevant endoscope type tests group as defined in Annex F and 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 (see Annex G) for which the same ESC connector set is used, if it is demonstrated that the endoscopes selected are the most challenging.

6.2 Air changes

The measurement of ‘air flow’ inside the cabinet to ensure the specified number of air changes per hours is performed according to the method given in D.5 or EN ISO 14644-3:2005, B.4.

6.3 Overpressure

6.3.1 Reagents and/or materials

The pressure indicator used for measuring the pressure in the storage cabinet shall:

a) be either digital or analogue;

b) indicate overpressure, relative to ambient pressure

c) be graduated in Pa;

d) 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 (see 5.2.2.2);

e) have an accuracy of at least 10% over the specified pressure range;

f) for analogue instruments be graduated in divisions not greater than 1 Pa;

g) for digital instruments have a resolution of at least 1 Pa;

h) for digital instruments have the sampling rate of at least every 5 s;

i) have an ambient temperature error compensation not exceeding 0,08 K/K;

j) have the means to be adjusted *in situ* by the use of a special key, code or tool without dismantling the instrument.

6.3.2 Procedure

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 [see 5.2.2.2 and 8.2 v)]. Record the pressure.

6.3.3 Acceptance criteria

The result is acceptable when the pressure in the usable space of the storage cabinet is within the specified ranges (see 5.2.2.2).

6.4 Drying

6.4.1 Principle

Storage cabinets designed to dry the entire load (interior and exterior surfaces) shall be tested using the test methods specified in 6.4.3 and 6.4.4.

If the purge of the channels of the endoscope is not required in the instructions for use prior storage inside the storage cabinet [see 8.2 j)], tests conditions shall be modified such that all endoscope channels are completely filled with water.

6.4.2 Reagents and/or materials

6.4.2.1 Copper (II) sulphate paper (or an alternative such as crepe paper).

6.4.2.2 Compressed air.

6.4.3 Exterior surface drying

6.4.3.1 Procedure

Load the storage cabinet, following the instructions for use. Carry out a normal operating cycle. Immediately following the recommended drying period (see 4.3), use a piece of anhydrous copper (II) sulphate paper (or crepe paper) to test the presence of moisture on the load exterior surfaces. When removing the load from the storage cabinet, and as the individual load items are being inspected, observe and record any water being discharged. Examine the paper for colour change (i.e. anhydrous copper (II) sulphate paper from white or light blue to deep blue) as evidence of residual water.

Place a piece of copper (II) sulphate paper in any crevice between the control knobs on the endoscope housing or any crevices where water may linger (e.g. valve housing) and subsequently check the paper for moisture.

NOTE 1 This test can be used for routine testing but in this case the endoscope used are required to be processed before patient use.

NOTE 2 The test is intended to be performed in the worst case scenario and depending on the design of the storage cabinet the most challenging load can range from one endoscope to a full load.

6.4.3.2 Expression of results

Record if residual water was observed or not.

6.4.4 Channel drying

6.4.4.1 Procedure

At the end of the drying phase, the endoscope shall be removed from the cabinet. Direct the distal end of the endoscope towards a horizontal piece of anhydrous copper (II) sulphate paper at a distance of 50 mm to 100 mm and flush medical grade air at a positive pressure up to 120 kPA through each channel system. The full length of each channel in each endoscope shall be tested.

NOTE For type testing compressed air is sufficient.

6.4.4.2 Expression of results

Record if residual water was observed or not.

6.5 Contamination of the inside surfaces of the storage cabinet

6.5.1 Procedure

6.5.1.1 The efficacy of the recommended cleaning/disinfection procedure (see 5.3.2) shall be verified by determining the contamination level with contact agar from 4 zones in the chamber located as follows:

— 2 zones that could be physically in contact with the endoscope during storage,

— 1 zone at other location in the chamber of the storage cabinet, and

— 1 zone at the bottom.

The zones tested shall 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.

6.5.1.2 Testing shall be performed at the end of the recommended time before application of the recommended cleaning/disinfection procedure (see 5.3.2).

6.5.2 Acceptance criteria

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

NOTE 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 device. This situation can require further investigation to identify the type and source of contamination.

6.6 Air quality

6.6.1 Air cleanliness

6.6.1.1 Principle

If a specific level of particulate cleanliness for the air used in the storage cabinet is claimed/required, then measurements of the specific level of particle cleanliness shall be carried out to check whether the particulate cleanliness class achieved matches the manufacturer's claims (see EN ISO 14644-3).

NOTE When dealing with multi-compartment storage cabinets with the same source of air delivery, tests can be run on one of the compartments.

6.6.1.2 Reagents and/or materials

Particle counter capable of sampling air and able to count particles in the sampled air that are 0,5 µm and larger and 5 µm and larger. The particle counter shall be able to measure both particle sizes in one measurement. The counter shall be able to count up to 4×10^6 particles/m^3 of 0,5 µm and larger and up to $3,5 \times 10^4$ particles/m^3 of 5 µm and larger.

6.6.1.3 Procedure

6.6.1.3.1 Position the particle counter probe in at least one location in the storage cabinet considering the instruction for use of the particle counter.

6.6.1.3.2 The test shall be performed with the storage cabinet chamber containing no endoscopes, with the air supply fully operational and the doors closed. The measurement shall be carried out in air taken from the geometric centre of the storage cabinet chamber after a stabilization period of not less than 15 min and not more than 20 min. Three successive samples of 0,1 m^3 shall be performed.

6.6.1.3.3 Record the reading after 15 min to 20 min.

6.6.1.4 Acceptance criteria

The result is acceptable when the calculated number of particles of both size ranges is below the specified values [see 8.2 g) 2)].

6.6.2 Moisture content

6.6.2.1 Reagents and/or materials

6.6.2.1.1 Relative humidity (RH) detector to include an RH sensor and any readout equipment.

6.6.2.1.2 Dew point meter or detector tube, suitable for the specified humidity range.

6.6.2.2 Procedure

6.6.2.2.1 Position the RH detector in the storage compartment.

6.6.2.2.2 Wait for the RH value to stabilize.

6.6.2.2.3 Read the RH value or calculate from the measured dew point.

6.6.2.2.4 For measuring the RH in the air that is provided to the endoscope channels, connect the RH sensor or detector tube to the ESC connector in the storage cabinet.

6.6.2.2.5 When a dew point meter is used, it may be necessary to position the measuring device in a suitable container that has a connection for a tube and an outlet at the opposite side. The container is connected to the ESC connector in the storage cabinet, enabling the air from the ESC connector to replace the air in the container.

6.6.2.2.6 Wait for the RH value to stabilize.

6.6.2.2.7 Read the RH value or calculate from the measured dew point.

6.6.2.3 Acceptance criteria

The result is acceptable when the measured %RH is within the specifications [see 5.2.1.1.2 and 8.2 f) 2)].

6.6.3 Oil content

6.6.3.1 Reagents and/or materials

6.6.3.1.1 Detector tube or oil impactor, suitable to determine that the oil content is below 0,1 mg/m^3.

6.6.3.1.2 Tube to connect the detector tube or oil impactor to the ESC connector in the storage cabinet.

6.6.3.2 Procedure

Follow the instructions of the supplier of the detector tube or oil impactor.

6.6.3.3 Acceptance criteria

The result is acceptable when the measured concentration of oil is below 0,1 mg/m^3.

6.7 Channel aeration test

6.7.1 Principle

Bubble testing shall be carried out by placing the end of each channel of each endoscope surrogate device (see 6.1.2) under water to verify that air is passing through the channels.

NOTE Immersing the channels too deep in the water can cause a backpressure and prevent the flow of air.

6.7.2 Procedure

Connect the endoscope surrogate device to the storage cabinet's air circulation system, following the 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 check for air bubbles at the distal end of the surrogate device. Record the indication given by the system to show air circulation.

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 [see 5.5.1 c)] and confirm that the system is able to detect when air is not flowing.

6.7.3 Acceptance criteria

The results are deemed satisfactory if, for each channel:

a) air bubbles appear when the channel is not blocked;

b) the system is able to detect when air is not flowing.

6.7.4 Endoscope channels blockage test

If the storage cabinet is claimed to detect blockage in individual channels repeat the test as described in 6.7.1 to 6.7.3 while blocking each channel of the endoscope surrogate device one by one and checking that the system is able to detect that air is not circulating.

6.8 Thermometric testing 1 – chamber and load temperature testing

6.8.1 Reagent and/or materials

Temperature sensors shall be platinum temperature sensors that are Class A-compliant with EN 60751:2008 or thermocouples that are compliant with Class 1 of EN 60584-1:2013, or any sensor that has been proven equivalent (see EN ISO 15883-1:2009, 6.2.1), but having an overall diameter such that the temperature sensor(s) inside the endoscope channels will not block the channel(s).

6.8.2 Procedure

Fit the temperature sensors as follows:

— one sensor on the control head of the endoscope;

— one sensor in at least one endoscope channel at the distal end, placed at a depth of at least 10 cm;

— other sensors placed on the outer surface of the insertion tube and on the endoscope's umbilical cord at intervals of no greater than 75 cm.

The sensors shall be in direct physical contact with each position being monitored.

Record the temperature readings obtained during the specified maximum endoscope storage time.

6.8.3 Acceptance criteria

The results are deemed to be satisfactory when the temperatures recorded are within the specified temperature band [see 8.2 b) and 8.2 d) 3)].

6.9 Thermometric test 2- chamber and load temperature testing

6.9.1 Procedure

Repeat the tests specified in 6.8 during a drying phase or a limited time frame during the storage cycle with at least one sensor specified in 6.8.

6.9.2 Acceptance criteria

The results are considered to be satisfactory when the temperatures recorded are within the specified temperature band for the corresponding stage [see 8.2 b) and d) 3)].

6.10 Readability

Use visual observation to determine the degree of readability of the indicators and gauges with which the storage cabinet is equipped. An observer with normal vision, wearing glasses if necessary, shall be able to see the gauge or indicator under (300 ± 100) lux lighting at a distance of $0{,}25^{+0{,}05}_{0}$ m and at a distance of $1{,}0^{0}_{-0{,}05}$ m to determine whether the indications given are readable.

6.11 Tests for air filtration

6.11.1 Procedure

Test the air filtration system using the method described in ISO 14644-3. Introduce a challenge aerosol into the air upstream of the filter. Scan the downstream face of the filter and its housing for leakage using a particle counter.

6.11.2 Acceptance criteria

The results are considered satisfactory if the reading on the photometer is steady and repeatable and does not exceed 0,01 % of the upstream reading (see 5.2.2.4.2).

7 Documentation

All documentation necessary for safe and efficient installation, operating and maintenance of the storage cabinet shall be compliant with regional and national regulations for language.

8 Information to be supplied with the storage cabinet

8.1 General

The information specified in 8.2 shall accompany the storage cabinet delivery.

NOTE National regulations for installation and operation of the equipment can apply in the country of use.

8.2 Information to be supplied before delivery

Before delivery of the storage cabinet and for installation qualification, the following information shall be provided to the purchaser:

a) list of endoscopes that can be stored in the storage cabinet;

NOTE 1 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.

b) storage temperature band (see 5.2.2.5, 5.6.2 and 6.8.3);

c) maximum storage time (see 4.2.6);

d) information regarding the drying function:

   1) whether the storage cabinet is equipped with a drying function or not (see 4.3);

   2) list of endoscopes that can be dried in the storage cabinet (if applicable);

   3) drying temperature band (if applicable) (see 5.2.2.5, 5.6.2 and 6.8.3);

   4) time required to dry the endoscopes (if applicable);

e) information regarding channel aeration system:

   1) means for checking air circulation in each channel at the endoscope connection ports (see 5.5.1);

   2) whether the automated channel flushing control system used is able to run independent controls on each channel or on a set of channels (see 5.5.2);

   3) circulation diagram illustrating air flows in the system used to irrigate the endoscope channel(s) (see 5.5.5);

   4) minimum flow rate and/or pressure and the maximum pressure that the storage cabinet is designed to deliver into each channel or channel system (see 5.5.6);

   5) 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 (see 5.5.3);

   6) list of endoscopes belonging to the list of endoscopes that can be stored/dried in the storage cabinet and for which the airflow through one or more channels is below the detection limit of the control system (see 5.5.4);

f) information regarding the quality of the air supplied to the storage cabinet:

   1) any requirements regarding the quality of the air supplied to the storage cabinet (see 4.2.5);

   2) the maximum humidity, pressure, oil content, particulate count and flow rate of the air supplying the storage cabinet (see 5.2.1.1.2);

   3) the frequency at which the specifications for the air supplied to the storage cabinet shall be tested (see 5.2.1.1.4);

g) information regarding particulate contamination:

   1) whether a specific cleanliness level is claimed;

   2) the claimed values for particle sizes of 0,5 µm and larger and 5 µm and larger (see 5.2.2.4);

3) the relevant alert and action limits to be set for the results of particulate (if claimed) and microbiological monitoring (see 5.2.2.1);

4) the frequency at which the particulate contamination test shall be performed (if claimed) (see 5.2.2.4);

5) instruction for use in the event of particulate (if claimed) and microbiological monitoring are outside specifications (see 5.2.2);

h) information regarding maintenance:

1) maintenance instructions, including the required scheduled preventive maintenance on the ESC connectors and how often they shall be changed;

2) maintenance instructions, including the required scheduled preventive maintenance on the accessories used in the storage cabinet and how often they shall be changed (see 5.2.1.2.2);

i) test instructions for the ESC connectors (see 4.4.2);

j) the operations to be carried out on the processed endoscope before it can be stored in the storage cabinet, during storage and before the endoscope can be reused once it has been removed from the storage cabinet (e.g. extensively air-flushing of channels, etc.) (see 4.2.3 and 5.5.1)

NOTE 2 The absence of purge of internal channels of endoscopes at the end of a washing/disinfection procedure could impact the storage cabinet efficiency. It is reminded to users that it is important to conform to manufacturer's recommendations and instructions.

k) characteristics and usage limitations of the various user-selectable storage cabinet cycles;

l) storage cabinet servicing instructions;

m) any guidance for transferring endoscopes into the storage cabinet after processing;

n) instructions for use in the event of an electrical power cut (see 5.7.8);

o) name and address of the manufacturer or their authorized representative;

p) issue number, revision number and date of instructions for use and maintenance;

q) any restriction regarding the quality of the environmental conditions where the storage cabinet is to be installed;

r) cleaning and/or disinfection procedure to be applied to limit the contamination of surfaces that may contact the endoscope (see 5.1.2, 5.3.1 and 5.3.2);

s) how a fault can be corrected (see 5.7.6);

t) how the indication of a fault can be reset (see 5.7.6);

u) how the devices stored in the storage cabinet shall be treated if a fault occurred (see 5.7.6);

v) the stabilization time for the overpressure inside the storage cabinet (see 5.2.2.2);

w) the air change per hour inside the storage cabinet (see 5.2.2.3);

x) the maximum time during which the doors may remain open without an alarm is indicated or sounded (see 5.7.1).

8.3 Marking and labelling

The storage cabinet shall be marked with at least the following:

— name/company and address of the manufacturer; address shall include: street/road, number/house/floor, postal code, city, state/region and country;

— name and address of authorized representative within the European Community in the case where the manufacturer does not have a registered place of business in the community;

— unique identification number;

— model identification;

— year and place of manufacture (not required if this is included in the identification markings).

8.4 Packaging

The storage cabinet package shall be designed to protect the cabinet and preserve its characteristics during intended transport, storage and installation.

NOTE Storage cabinets and packaging design are elements that either individually or collectively provide protection against transport challenges.

9 Information to be requested from the purchaser by the manufacturer

9.1 Storage cabinets shall meet the requirements of this European Standard when installed with the following requirements:

a) expected room temperatures for both the workspace and the maintenance area;

b) energy services available;

c) quality of the air supply;

d) any other specified services required.

NOTE The performance of a storage cabinet is dependent upon its design and construction together with the quality of services provided. When services do not meet the specified requirements the performance of the storage cabinet can be affected adversely.

9.2 To ensure that the equipment supplied meets the needs of the users, the following information shall be obtained from the user:

a) maximum capacity per cycle for each type of load the storage cabinet can process;

b) housings required for any buttons or emergency stops;

c) type of logger(s) to be built in, where appropriate;

d) language in which documentation shall be drafted (see clause 7);

e) placement of the storage cabinet, including any constraints related to the overall machine size or any constraints on access for servicing;

f) placement of load-in and load-out doors;

g) pipes and fittings to be provided.

NOTE These requirements can also be stipulated by regional and national regulations.

Annex A
(informative)
Summary of test programmes

Table A.1 — Summary of tests

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

Brief description of test	Subclause		Nature of test				
	Requirement subclause	Test subclause	Type test	Works test	Operational qualification	Performance qualification	Routine test
Temperature control (if fitted)	5.2.2.5 5.6	6.8 6.9	X			 X	
Channel aeration test	5.5.1	6.7 D.10	X		X[b] X[a]	 X[a]	
Readability	5.9.3	6.10	X				
Cross contamination	4.2.2	Annex B	O				

X – Recommended, B – Not recommended, O – Optional

[a] Alternative test procedure for the parametric operational and/of performance qualification of storage cabinet is given in Annex D of this standard

[b] These tests are optional if the parametric operational and performance qualification procedures are followed (see Annex D)

Annex B
(informative)
Cross-contamination between endoscopes

B.1 Type-testing 1

B.1.1 Objective

The objective of this test is to determine whether storing a contaminated endoscope in a storage cabinet can cause contamination of another endoscope being stored at the same time.

B.1.2 Principle

Three endoscopes (A, B and C) are subjected to a cleaning-disinfection procedure. Two of them (A and B) are contaminated with water containing $1{,}5 \times 10^4$ to 5×10^4 *Pseudomonas aeruginosa* per ml in order to reproduce the scenario whereby an endoscope would be contaminated by microorganisms present in the water used in the final rinsing stage. The two contaminated endoscopes (A and B) and the third, non-contaminated endoscope (C) are placed into the storage cabinet for the time necessary to have at least 5 air changes. The initially non-contaminated endoscope is then removed for analysis according to a validated method specific to each endoscope.

The efficiency of the storage cabinet is evaluated by determining the level of contamination of the initially non-contaminated endoscope at the end of the maximum recommended time-in-storage.

B.1.3 Reagent and/or materials

See E.1.3.

B.1.4 Procedure

B.1.4.1 Endoscope sampling procedure

See E.1.4.1.

B.1.4.2 Sample analysis

See E.1.4.2.

B.1.4.3 Endoscope cleaning-disinfection procedure

See E.1.4.3.

B.1.4.4 Test bacterial suspension

See E.1.4.4.

B.1.4.5 Endoscope contamination

Two of the three endoscopes are contaminated by injecting 15 ml of the test bacterial suspension into the endoscope channels.

This 15 ml of bacterial suspension test is distributed through the different endoscope channels in such a way that an equal volume of bacterial suspension is injected into each channel.

After a 30 minute incubation at room temperature, endoscope channels are purged with 50 ml of air in order to remove any surplus contamination solution and then maintained for one hour or according to the manufacturer's instructions [8.2 j)].

B.1.4.6 Test

The two contaminated endoscopes and the non-contaminated endoscope are placed in the storage cabinet and connected to the air circulation system, according to the storage cabinet instructions for use, via the adaptors specific to each endoscope.

After 5 air renewals:

— the contamination level of the last ten centimetres of the distal end of endoscope C (expressed in cfu/distal end) is determined by swabbing;

— the number of viable microorganisms remaining in endoscope channels C (expressed in cfu/endoscope) is determined following the method specified in E.1.4.

Tests are repeated so that each of the three selected endoscopes can be tested in the presence of two other contaminated endoscopes, running the tests in duplicate each time (i.e. a total of 2 × 3 series of tests).

B.1.4.7 Acceptance criteria

The results are deemed to be satisfactory if, no detectable test microorganism is found at the level of the distal end of the endoscope or in the endoscope channels.

B.2 Type-testing 2

B.2.1 Objective

The objective of this test is to determine whether storing a contaminated endoscope in a storage cabinet is liable to cause the later contamination of another endoscope stored in the same place as the first.

B.2.2 Principle

Two endoscopes (A and B) of the same type are subjected to a cleaning-disinfection procedure. The first one (endoscope A) is contaminated with a suspension containing $1{,}5 \times 10^4$ to 5×10^4 *Pseudomonas aeruginosa* per ml in order to reproduce the scenario whereby an endoscope would be contaminated by microorganisms present in the water used in the final rinsing stage. Endoscope A is then placed in the storage cabinet. After 5 air renewals, the contaminated endoscope (A) is removed and replaced with (non-contaminated) endoscope B. This second endoscope is stored in the storage cabinet for 5 air renewals, and then removed for analysis according to a validated method specific to each endoscope.

B.2.3 Reagents and/or materials

See E.1.3.

B.2.4 Procedure

B.2.4.1 Endoscope sampling procedure

See E.1.4.1.

B.2.4.2 Sample analyses

See E.1.4.2.

B.2.4.3 Endoscope cleaning-disinfection procedure

See E.1.4.3.

B.2.4.4 Test bacterial suspension

See E.1.4.4.

B.2.4.5 Endoscope contamination

See E.1.4.5.

B.2.4.6 Test

The contaminated endoscope (A) is placed in the storage cabinet and connected to the air circulation system via the adaptors specific to each endoscope, then left in the storage cabinet for 5 air renewals before being disconnected and removed from the chamber as specified in the storage cabinet instructions for use. Then, within the following 5 air renewals, the second endoscope (B) of the same type but non-contaminated is connected to the air circulation system at the same place than the one previously occupied by the contaminated endoscope, again following the storage cabinet manufacturer's instructions for use.

After 5 air renewals:

— the contamination level of the last ten centimetres of the distal end of endoscope B (expressed in cfu/distal end) is determined by swabbing;

— the number of viable microorganisms (X) remaining in the endoscope channels C (expressed in cfu/endoscope) is determined following the method set out in E.1.4.

NOTE It is crucial to follow the manufacturer's instructions for connecting the endoscopes to the storage cabinet's air circulation system. Tests are repeated using three endoscopes that are typical of the endoscopes intended to be stored in the storage cabinet.

B.2.4.7 Acceptance criteria

The results are deemed to be satisfactory if, for all tested endoscopes, X and contamination level of distal end of endoscope B are respectively less than 10 cfu/endoscope and 10 cfu /distal end, and with no detectable test microorganism.

Annex C
(normative)
Methods for evaluation of airborne microbial contamination in the storage cabinet

C.1 General

For the evaluation of the airborne microbial contamination in the storage cabinet (see 5.2.2.1) one of the test given in C.2 and C.3 shall be selected.

C.2 Active sampling

The airborne aerobic mesophilic microbial contamination in the storage cabinet can be determined by using an active air sampling method.

For the purpose of this test 1 m^3 of air is sampled on Trypticase soya agar. The agar 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.

The results are deemed to be satisfactory if the airborne aerobic mesophilic microbial contamination in the storage cabinet, determined by active air sampling, does not exceed 100 cfu/m^3 corresponding to Class 8 of ISO 14644-1.

NOTE A contamination level lower than 100 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.

C.3 Sedimentation

The sampling for the microbial cleanliness of the air circulating in the storage cabinet can be checked via sedimentation onto a solid culture medium.

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 cultures 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.

The tests are deemed satisfactory if the total number of colonies on the four plates is less than 50 cfu corresponding to Class 8 of ISO 14644-1.

NOTE 1 The exposure time cannot exceed 1 h as drying of the surface of the growth medium can impair recovery of microorganisms.

NOTE 2 A contamination level lower than 50 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.

Annex D
(informative)
Procedure for parametric performance qualification

D.1 Principle

Endoscopes that can be stored in the cabinet should be specified [see 8.2 a) and d) 2)]. It is recommended to verify which endoscope models can be stored in the storage cabinet used before purchase. New or loaned endoscopes should be verified as compatible prior to use. This can require the use of specific ESC connectors for connection to the storage cabinet. By including an endoscope on a compatibility list, the storage cabinet manufacturer specified that the endoscope will be properly dried and stored, provided that the proper ESC connectors are used in the storage cabinet, and that the correct pre-treatment of the endoscope is performed. This also means that the user does not have to test that endoscopes can be dried and stored in the storage cabinet. When a new endoscope is not listed in the compatibility list, the endoscope manufacturer can declare that the endoscope can be effectively dried and stored in the corresponding storage cabinet. If not, the user should not use the storage cabinet for storage of that particular endoscope.

Storage cabinet process parameters should be specified for the storage cabinet, so that physical measurements can confirm the storage cabinet still functions within specifications. Process parameters may 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, so that it can be verified by measurement.

D.2 General

Storage cabinets compliant with this standard can be parametrically tested for performance qualification to the following requirements (see Annex E for microbiological performance qualification):

a) the endoscope that is dried and stored in the storage cabinet is on the list of specified compatible endoscopes [see 8.2 a) and d) 2)];

b) for every endoscope the ESC connectors used are those specified for that endoscope;

c) the ESC connectors are maintained as specified [see 8.2 h 1), h) 2) and i)];

d) the air that is provided to the channels is HEPA filtered and that it is confirmed that the HEPA filter is exchanged at the specified intervals;

e) the air that is provided to the storage compartment of the storage cabinet is HEPA filtered and that it is confirmed that the HEPA filter is exchanged at the specified intervals;

f) where the temperature of the air provided to the channels and in the storage compartment is a controlled or limited variable, the temperature is within the specifications, when tested as described in 6.9;

g) where the humidity of the air provided to the channels and the storage compartment is a controlled or limited variable, the humidity is within the specifications [see 8.2 f) 2)], when tested as described in D.3;

h) where the air provided to the channels or the storage compartment is from a source that can add oil to the air, the oil content is below the value given in 5.2.1.2.3, when tested as described in D.4;

i) the air pressure in the storage compartment is maintained at the specified over-pressure [see 8.2 v)], when tested as described in 6.1;

j) the air in the storage compartment is refreshed at the specified rate [see 8.2 w)] as when tested as described in D.5;

k) the particulate contamination of the air in the storage compartment is below the specified maximum values [see 8.2 g) 2)], when tested as described in D.6;

l) the pressure at each ESC connector in the storage cabinet is maintained within the specified limits [see 8.2 e) 4)], when the endoscope with the identified highest air demand and the endoscope with the lowest air demand are connected to the storage cabinet, using the prescribed ESC connectors, when tested as described in D.7;

m) the flow of air from each ESC connector to the endoscope is maintained within the specified limits [see 8.2 e) 4)], when the endoscope with the highest air demand and the endoscope with the lowest air demand are connected to the storage cabinet, using the prescribed ESC connectors, when tested as described in D.8;

n) where the drying cycle is different from the storage cycle, the duration of the drying cycle is as specified [see 8.2 d) 4)], when tested as described in D.9;

o) it is verified that the system for monitoring the free passage of air through the endoscope channels (when fitted), functions within its specifications [see 8.2 e) 5)], using the method in D.10;

p) it is verified that the internal surfaces of the storage compartment and the ESC connectors are cleaned and disinfected at the prescribed intervals [see 8.2 r)], using the prescribed chemistry.

D.3 Relative humidity

D.3.1 Materials

Relative humidity (RH) detector, such as a RH sensor and readout equipment or, dew point meter or, detector tube, suitable for the specified humidity range.

D.3.2 Procedure

D.3.2.1 Position the RH detector in the storage compartment.

D.3.2.2 Wait for the RH to stabilize.

D.3.2.3 Read the RH value or calculate from the measured dew point.

D.3.2.4 For measuring the RH in the air that is provided to the endoscope channels connect the RH sensor or detector tube to the ESC connector in the storage cabinet.

D.3.2.5 When a dew point meter is used it can be necessary to position the measuring device in a suitable container that has a connection for a tube and an outlet at the opposite side. The container is connected to the ESC connector in the storage cabinet, enabling the air from the ESC connector to replace the air in the container.

D.3.2.6 Wait for the RH to stabilize.

D.3.2.7 Read the RH value or calculate from the measured dew point.

D.3.3 Acceptance

The result is acceptable when the measured %RH is within the specifications.

D.4 Oil content

D.4.1 Materials

D.4.1.1 Detector tube or oil impactor, suitable to determine that the oil content is below 0,1 mg/m^3.

D.4.1.2 A tube to connect the detector tube or oil impactor to the ESC connector in the storage cabinet.

D.4.2 Procedure

Follow the instructions of the supplier of the detector tube or oil impactor.

D.4.3 Acceptance

The result is acceptable when the measured concentration of oil is below 0,1 mg/m^3.

D.5 Air volume

D.5.1 Materials

D.5.1.1 In-line velocity meter or volume displacement meter suitable to measure ten times the volume of the storage compartment in one hour, with an accuracy of at least 10 %.

D.5.1.2 A suitable accessory to position the meter in front of the air inlet to the fan that supplies the air to the storage compartment.

D.5.2 Procedure

Follow the instructions of the manufacturer of the meter to determine the velocity of the in-flowing air or the volume per time interval.

From this measurement, calculate the volume of air flowing into the storage compartment per hour.

NOTE If the air outlet is well defined this measurement can be done determining the volume of the out-flowing air.

D.5.3 Acceptance

The result is acceptable when the calculated volume per hour is at least ten times the volume of the storage compartment.

D.6 Particulate contamination

D.6.1 Materials

D.6.1.1 Particle counter capable of sampling air and able to count particles in the sampled air that are ≥ 0,5 µm and that are ≥ 5 µm, simultaneously. The counter is required to count up to 4×10^6 particles/m^3 of 0,5 µm and larger and up to $3,5 \times 10^4$ particles/m^3 of 5 µm and larger.

D.6.1.2 The isokinetic sampling pipe that is intended to be used with the particle counter.

D.6.2 Procedure

D.6.2.1 Follow the instructions of the manufacturer of the particle counter.

D.6.2.2 Position the isokinetic sampling pipe in the storage compartment to sample air at the geometric centre of the storage compartment.

D.6.2.3 Record the reading after 15 min to 20 min.

D.6.3 Acceptance

The result is acceptable when the calculated number of particles of both size ranges is below the specified value.

D.7 Pressure

D.7.1 Materials

D.7.1.1 Pressure indicator suitable for the specified range, with an accuracy of at least 5 %.

D.7.1.2 Tubing to connect the pressure indicator between the ESC connector and the endoscope.

NOTE This tubing is required to be able to connect with the ESC connector at one end and the connector to the endoscope at the other end (T-connector).

D.7.1.3 Endoscope, from the list of compatible endoscopes and that is used by the user, that has the highest air demand (least resistance to air flow) including the connectors and tubing that are to be used to connect this endoscope to the storage cabinet.

D.7.1.4 Endoscope, from the list of compatible endoscopes and that is used by the user, that has the lowest air demand (highest resistance to air flow) including the connectors and tubing that are to be used to connect this endoscope to the storage cabinet.

D.7.2 Procedure

D.7.2.1 Connect the pressure indicator tubing to the storage cabinet.

D.7.2.2 Connect the endoscope channel or group of channels to the pressure indicator tubing.

D.7.2.3 Wait for steady reading on the pressure indicator.

D.7.2.4 Record the indicated pressure.

D.7.2.5 Repeat this procedure for every connection from the storage cabinet to this endoscope (when more than one connection point is offered).

D.7.2.6 Repeat both procedures with the other endoscope.

D.7.3 Acceptance

The results are acceptable when the recorded pressures are within the specified limits [see 8.2 e) 4)] for the particular endoscopes.

D.8 Air flow rates

D.8.1 Materials

D.8.1.1 Flow meter suitable for the specified range with an accuracy of at least 5 %.

D.8.1.2 Tubing to connect the flow meter between the ESC connector and the endoscope.

NOTE This tubing is required to be able to connect with the ESC connector at one end and the connector to the endoscope at the other end.

D.8.1.3 The endoscopes identified in D.7.1.3 and D.7.1.4, including the connectors and tubing that are to be used to connect these endoscopes to the storage cabinet.

D.8.2 Procedure

D.8.2.1 Connect the flow meter to the storage cabinet.

D.8.2.2 Connect the endoscope channel or group of channels to the flow meter.

D.8.2.3 Wait for steady reading on the flow meter.

D.8.2.4 Record the indicated flow rate.

D.8.2.5 Repeat this procedure for every connection from the storage cabinet to this endoscope (when more than one connection point is offered).

D.8.2.6 Repeat both procedures with the other endoscope.

D.8.3 Acceptance

The results are acceptable when the recorded flow rates are within the specified limits [see 8.2 e) 4)] for the particular endoscopes.

D.9 Drying time

D.9.1 Materials

Chronometer.

D.9.2 Procedure

D.9.2.1 Position an endoscope in the storage cabinet.

D.9.2.2 Record the identification of the endoscope.

D.9.2.3 Start the drying cycle and record the time.

D.9.2.4 Observe when the storage cabinet indicates that the drying cycle ends.

D.9.2.5 Record the time.

D.9.2.6 Calculate the length of the drying cycle.

D.9.3 Acceptance

The result is acceptable when the calculated length of the drying time is within the specified limits for the particular endoscope.

D.10 Automatic control of channel aeration (if fitted)

D.10.1 Materials

D.10.1.1 The two endoscopes identified in D.7.1.3 and D.7.1.4 and the connectors and tubing that are to be used to connect these endoscopes to the storage cabinet.

D.10.1.2 Means to block the flow of air from the storage cabinet to the channels of the endoscope, e.g. artery clamp.

D.10.2 Procedure

D.10.2.1 Block the flow of air in each tubing of the ESC connector one by one.

D.10.2.2 Record the moment the storage cabinet indicates a fault.

D.10.3 Acceptance

Verify that the moment the fault is indicated corresponds to the setting of the channel aeration control.

Annex E
(normative)
Internal residual contamination of endoscopes after storage

E.1 Type testing

E.1.1 Objective of the test

To verify that during storage in the storage cabinet there is no increase or adverse change in microbial contamination (see 4.2) compared to an endoscope stored outside the storage cabinet (without circulation of air through endoscope channels and on the external surfaces).

NOTE Comparison with an endoscope stored outside the cabinet provides a comparison with the naturally occurring reduction in microbial population that can occur.

E.1.2 Principle

The tests devices are defined in E.1.3.1 are subjected to a cleaning-disinfection procedure and then contaminated with a suspension containing $1{,}5 \times 10^3$ to 5×10^3 *Pseudomonas aeruginosa* per ml. After contamination and any pre-storage procedure (according to storage cabinet instructions for use), the test devices are placed in the storage cabinet for 0 h; 12 h; 24 h, 48 hours, the maximum storage time and for a storage time 24 h shorter than the maximum storage time. The test devices are then removed for analysis according to a validated method specific to each endoscope.

The performance of the storage cabinet is assessed by determination of the endoscope contamination levels for each storage period and condition (inside and outside the storage cabinet) compared to a positive control and comparison of these data with the contamination level before storage.

If the purging of the channels of the endoscope is not necessary prior to storage inside the storage cabinet [see 8.2.j)] it is recommended that test conditions are modified with endoscope channels completely filled with water.

E.1.3 Reagents and/or materials

E.1.3.1 Test devices

Based on a risk assessment the most relevant endoscopes or endoscope surrogate devices to be included in type testing considering the specific characteristics and limitations of the storage cabinet shall be selected (see 6.1.2).

NOTE Annex F can be used to select the most relevant test devices.

Before each test series, the test devices are sampled for analysis according to the experimental protocol described in E.1.4.1 in order to verify that there is no contamination liable to invalidate the test results.

E.1.3.2 Bacterial strain

The tests shall be carried out using the following test strain of *Pseudomonas aeruginosa* (such as ATCC 15442[1]).

NOTE National regulation can suggest additional strains.

E.1.3.3 Sampling solution

Polysorbate 80	3 ml
Lecithin	0,3 g
L-Histidin	0,1 g
Sodium thiosulphate	0,5 g
Demineralised water	up to 100 ml

E.1.3.4 Diluent

Tryptone	26,22 g/l
Sodium chloride	7,78 g/l

E.1.3.5 Maintenance and counting medium

Trypticase soya agar.

E.1.4 Procedure

E.1.4.1 Test device sampling procedure

During the sampling phase, the recovery solution is injected into all the channels of the test device through specific adaptors that have been cleaned and disinfected beforehand.

NOTE For the surrogate device, an alternative sampling method can be used.

The sampling procedure used for each test device shall be described.

E.1.4.2 Sample analysis

The samples collected from the test devices are analysed by pour plate and membrane filtration through 0,45 µm pore-size filters. The filtration membranes are placed on counting agar and incubated for 48 hours at (37 ± 1) °C, like agars used for enumeration.

Following incubation, colonies formed are counted and the results are expressed in number of viable microorganisms per endoscope (X) taking into account the recovery ratio of the sampling method (see E.1.4.6.2).

[1)] ATTC American Type Culture Collection, 10801 University Boulevard, Manassas, VA 20110-2209, USA, www.attc.org

The ATCC number is the collection numbers of strains supplied by these culture collections. This information is given for the convenience of users of this European Standard and does not constitute an endorsement by CEN of the product named.

E.1.4.3 Test devices cleaning-disinfection procedure

Immediately before contamination and after each test, test devices and their adaptors used to connect to the storage cabinet shall be subjected to a validated cleaning-disinfection procedure.

E.1.4.4 Test bacterial suspension

A bacterial suspension of *Pseudomonas aeruginosa* (such as ATCC 15442) containing between $1{,}5 \times 10^8$ cfu/ml and 5×10^8 cfu/ml is prepared in the diluent (see E.1.3.4) from a second subculture of the microorganism stock culture. Use the test suspension within 2 hours.

The suspension obtained is then diluted to obtain 15 ml of a suspension containing between $1{,}5 \times 10^3$ cfu/ml and 5×10^3 cfu/ml (test suspension).

The titer of the test suspension is verified by successive tenfold dilutions and inclusion of 2 × 1 ml of each dilution into the counting agar. After inoculation, plates are incubated for 48 hours at (37 ± 1) °C.

The number of colonies obtained on each agar plate is determined and the number of viable cells in the bacterial suspension test (N cfu/ml) is calculated using equitation (E.1):

$$N = \frac{c}{n_1 + 0{,}1 n_2 \cdot d} \qquad \text{(E.1)}$$

where:

N concentration of bacteria in the bacterial suspension test;

c sum of the colonies counted on all plates taken into account (only dishes giving 15 cfu/dish to 300 cfu/dish are used for the calculation);

n_1 number of plates taken into account at the first dilution;

n_2 number of plates taken into account at the second dilution;

d dilution factor for the first dilution taken into account.

E.1.4.5 Test device contamination

The test devices are contaminated by injecting 15 ml of the test bacterial suspension into the test device channels.

This 15 ml of test bacterial suspension is distributed through the different test device channels. After a 30-minute incubation at room temperature, the test device channels are purged with 50 ml of air in order to remove any surplus contamination solution and then maintained for one hour or according to the manufacturer's instructions [8.2 j)].

After the incubation period the pre-storage procedure (according to instructions for use), shall be performed.

E.1.4.6 Preliminary testing

E.1.4.6.1 Determination of the efficiency of the test device contamination method

Each test device is subjected to a cleaning-disinfection procedure (see E.1.4.3), contaminated (see E.1.4.5), submitted to the pre-storage procedure (according to storage cabinet instructions for use) and then sampled to determine the average contamination level of each test device post-contamination (3 tests are conducted for each test device).

The efficiency of contamination method (R) is then calculated using equation (E.2):

$$R = \frac{A}{N \cdot V} \quad \text{(E.2)}$$

where

R the efficiency of the contamination method;

A is the initial test device contamination level after contamination and before storage (number of cfu/endoscope) determined by sampling as described in E.1.4.1 and E.1.4.2;

N is the concentration of microorganisms in the test bacterial suspension used to contaminate the endoscope (number of cfu/ml);

V the volume of test bacterial suspension injected.

During the actual testing phase, the R value can be used to calculate the theoretical level of pre-storage test device contamination based on the concentration of microorganisms in the bacterial suspension test and the volume of contamination solution injected.

E.1.4.6.2 Determination of the recovery rate of the sampling method

Each test device is cleaned and disinfected, contaminated (see E.1.4.5), and submitted immediately after contamination to a repeated round of sample collection (as defined in E.1.4.1) to define the recovery rate of the sampling method (see EN ISO 11737-1:2006, C.1).

E.1.4.7 Procedure

E.1.4.7.1 Main test

After being cleaned and disinfected, (E.1.4.3), the test devices are contaminated, (E.1.4.5), placed in the storage cabinet following the storage cabinet manufacturer instructions (e.g. air purge of some channels, endoscope drying etc.), and connected to the air circulation system via the adaptors specific to each test device.

NOTE In most cases, after processing in a WD, endoscopes are not dry and any drying applies to the endoscope before testing cannot represent the worst case scenario.

After the storage time, the test devices are sampled for analysis, and the number (X) of viable microorganisms remaining in the endoscope channels is determined by employing the method described in E.1.4.1 and E.1.4.2 The tests are performed in duplicate for each test device and repeated for storage times for 0; 12; 24 and 48 hours, at the end of the storage time and 24 hours before the end of the maximum storage time.

For each test device and storage time, the evolution of the residual test device contamination (E_{int}) is determined by calculating the difference between the log value of the number of viable microorganisms identified in the test device's internal channels after storage (X_{n}) and the log value of the theoretical number of microorganisms in the test device before storage (B) [see equation (E.3)].

$$E_{\text{int}} = \log_{10}(X_n) - \log_{10}(B) \quad \text{(E.3)}$$

where

E_{int} is the evolution of the residual test device contamination;

X_{n} is the number of viable microorganisms identified in the test device's internal channels after storage;

B is the theoretical number of microorganisms in the test device before storage.

B is calculated based on the concentration of microorganisms in the test bacterial suspension used to contaminate the endoscope (N), the volume of test bacterial suspension injected (V) and the efficiency of the contamination method (R) [see equation (E.4)].

$$B = N \cdot V \cdot R \quad \text{(E.4)}$$

where

B is the theoretical number of microorganisms in the test device before storage;

R is the efficiency of the contamination method as defined in E.1.4.6.1;

N is the concentration of microorganisms in the test bacterial suspension used to contaminate the endoscope (number of cfu/ml);

V the volume of test bacterial suspension injected.

E.1.4.7.2 Validation of the sampling method

Considering that for storage time longer than 12 hours:

— There is a risk that the bacteria remaining in endoscope channels cannot be flushed out by the sampling method (fixation of the bacteria to the channel surface, biofilm formation).

— The recovery ratio of the sampling method for endoscopes stored more than 12 hours may be different than the one defined in E.1.4.6.2.

Additional tests might need to be performed to demonstrate that for endoscopes stored more than 12 hours, that the contamination level defined by the method given in E.1.4.1 and E.1.4.2 is representative of the real contamination level of the endoscope.

After being cleaned and disinfected, each test device is contaminated, placed in the storage cabinet following the storage cabinet manufacturer instructions (e.g. air purge of some channels, endoscope drying etc.), and connected to the air circulation system via the adaptors specific to each test device.

NOTE In most cases, after processing in a washer-disinfector (WD), endoscopes are not dry and any drying apply to the endoscope before testing cannot represent the worst case scenario.

After the storage time, the biopsy/suction channel of each test device is sampled for analysis, and the number (X) of viable microorganisms remaining in the endoscope biopsy/suction channel is determined by employing the method described in E.1.4.1 and E.1.4.2. Immediately after this first sample a second sampling procedure, including a brushing of the biopsy channel with a sterile brush is performed, and the number (X_b') of viable microorganisms remaining in the endoscope biopsy/suction channel is determined by employing the method described in E.1.4.2.

To validate the sampling method, X_b shall remain less than X.

The tests are performed in duplicate for each test device and repeated for storage times of 0; 12; 24 and 48 hours, at the end of the storage time and 24 hours before the end of the maximum storage time.

E.1.4.7.3 Positive control (if applicable)

In order to evaluate the effect of any pre-storage procedure recommended by the storage cabinet manufacturer (see E.1.4.7) on the efficacy of the storage cabinet, a series of tests identical to those described in E.1.4.7.2 is then conducted with the test devices sampled just after application of the pre-storage procedure recommended [see 8.2 j)].

The test device contamination after application of the pre-storage procedure (E_{psp}) is determined by calculating the difference between the log value of the number of viable microorganisms identified in the test device's internal channels after the pre-storage procedure (X_n') and the log value of the theoretical number of microorganisms in the device before the pre-storage procedure (B) [see equation (E.5)].

$$E_{psp} = \log_{10}\left(X_n'\right) - \log_{10}\left(B\right) \quad \text{(E.5)}$$

where

E_{psp} is the test device contamination after application of the pre-storage procedure;

X_n' is the number of viable microorganisms identified in the test device's internal channels after the pre-storage procedure;

B is the theoretical number of microorganisms in the device before the pre-storage procedure.

B is calculated based on the concentration of microorganisms in the contamination solution (N), the volume of test bacterial suspension injected (V) and the efficiency of the contamination method (R) [see equation (E.6).

$$B = N \cdot V \cdot R \quad \text{(E.6)}$$

where

B is the theoretical number of microorganisms in the device before the pre-storage procedure;

N is the concentration of microorganisms in the test bacterial suspension used to contaminate the endoscope (number of cfu/ml);

V the volume of test bacterial suspension injected.

R The efficiency of the contamination method

E.1.4.7.4 Change in the internal residual contamination of the test device after storage outside of the storage cabinet

A series of tests identical to those described above are then conducted with the test devices stored outside of the storage cabinet. For each test device and storage time, the evolution of the residual contamination of the test device stored outside of the storage cabinet, (E_{ext}), is determined by calculating the difference between the log value of the number of viable microorganisms identified in the test device after storage (X_t) and the log value of the number of microorganisms in the test device before storage (B) [see equation (E.7).

$$E_{ext} = \log_{10}\left(X_t\right) - \log_{10}\left(B\right) \quad \text{(E.7)}$$

where

E_{ext} is the residual contamination of the test device stored outside of the storage cabinet;

X_t is of the number of viable microorganisms identified in the test device after storage;

B is the theoretical number of microorganisms in the test device before storage.

The efficiency of the storage cabinet is then evaluated by comparing the evolution of the residual contamination inside the test device under both storage approaches (E_{int} and E_{ext}).

Temperature and humidity during testing shall be recorded and shall be within the specified limits for normal use condition.

E.1.4.8 Acceptance criteria

The results are considered to be satisfactory if $E_{int} \leq 0$ and $E_{int} < E_{ext}$ for all test device tested.

NOTE $E_{int} \leq 0$ makes it possible to check that there is no increase in test device contamination levels. $E_{int} < E_{ext}$ makes it possible to double-check that there is a positive change in contamination levels when the test device is stored inside the storage cabinet.

For each test device, the effect of the pre-storage procedure (if applicable) shall be determined. The effect of the pre-storage procedure on the initial contamination level of the test device shall not exceed 1 log reduction ($E_{int} - E_{psp} < 1$).

The theoretical number of microorganisms in the device before the pre-storage procedure (B) shall be at least 10^3 cfu/test device after any pre-storage procedure. If the pre-storage procedure induces a greater reduction, the test shall be repeated with a reduced pre-storage procedure or with a higher level of contamination of the device.

E.2 Performance qualification and routine testing

E.2.1 General

The tests described below are designed to check that the storage cabinet once installed (performance qualification) or tested at regular intervals (routine testing), is capable of maintaining the microbiological quality of the endoscopes intended to be stored inside.

Performance qualification tests shall be performed on at least one model of each endoscope type tests group as defined in Annex F. 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 (see Annex G) for which the same ESC connector set is used, if it is demonstrated that the endoscopes selected are the most challenging.

E.2.2 Procedure

E.2.2.1 The endoscopes intended to be stored in the storage cabinet are cleaned and disinfected (following the procedure in force in the unit where the storage cabinet is installed) and then stored in the storage cabinet according to the instructions for use for the maximum storage time specified for the type of endoscope being tested [see 8.2 c)].

NOTE 1 Performance qualification testing can be carried out by taking samples from all endoscopes available in the unit where the storage cabinet is installed and that are intended to be stored in the storage cabinet (initial assessment). If there is no detailed data available on the microbiological quality of all endoscopes intended to be stored in the storage cabinet at the time the storage cabinet is put into service or just before, then in the event that a routine test is positive, there would be no way of determining the source of the contamination (poor initial microbiological quality of the endoscope or a functional problem with the storage cabinet).

NOTE 2 The interval schedule for routine testing can be specified in national guidelines.

NOTE 3 Any alternative test based on parametric verification and for which a demonstration of the efficacy has been done can be used (see Annex D).

E.2.2.2 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 [n] days at (30 ± 1) °C.

E.2.2.3 Following incubation, the colonies formed are counted and the results are expressed in number of viable microorganisms per endoscope (X) taking into account the recovery ratio of the sampling method (see E.1.4.6.2).

E.2.2.4 After testing, each endoscope should be processed using a validated cleaning-disinfection procedure (e.g. automated processing in an endoscope washer disinfector in compliance with EN ISO 15883-4) before storage in the storage cabinet.

E.2.3 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 1 A result indicating a contamination level higher than 25 cfu/endoscope can require further tests to identify the cause(s) of this contamination which can be caused by factors not related to the storage cabinet.

NOTE 2 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 device. This situation can require further investigation to identify the type and source of contamination.

Annex F
(normative)
Establishing endoscope type test groups

F.1 Introduction

This Annex is intended to be used by the storage cabinet manufacturers to provide a rationale for their choice of endoscope type test groups.

The endoscopes for which evidence exists that they can be processed satisfactorily [see 8.2 a)] shall be listed. This implies that a number of the type tests shall be repeated for every flexible endoscope on the list.

Considering the vast number of flexible endoscopes that are in use in the healthcare settings at any given moment (different brands, types, generations), this is impossible to do. The work load can be reduced by grouping the devices based on the similarities of design. The type tests can then be performed on a representative sample of each of these endoscope type test groups.

F.2Establishing endoscope type test groups

General as well as specific features of flexible endoscopes shall be considered when clustering endoscopes in endoscope type test groups. This consists of consideration of:

— the same general channel design as specified in Table F.2, and

— similarity of specific characteristics affecting the flow conditions in the endoscope, including:

  — ports;

  — connectors;

  — channel separators;

  — port closures;

  — internal non-return valves;

  — restrictions in channels;

  — internal connection between channels.

The following procedure shall be followed:

1) Establish the specifications for the channels in the endoscope. This shall include the length and diameter of each channel. If this information is not available, the endoscope shall be excluded from the list of compatible devices.

2) All claimed compatible endoscopes will be identified into a block or combination of blocks according to Table F.2.

NOTE 1 The blocks under Table F.2 were established based upon the majority of currently marketed endoscopes.

3) Special attention shall be paid to constructions such as endoscopes containing balloon channels.

4) Each block combination may need to be further reviewed to ensure that specific endoscope design characteristics, e.g. any non-return valves and/or restrictions in the channels, any interconnections between channels and any other design characteristic affecting the flow conditions in the endoscope, are represented by the block combination.

5) Where one or more channels of the endoscope are not represented by any of the blocks in Table F.2, establish the specifications for designing a new block or modifying an existing block.

6) An endoscope type test group shall consist of the same general block combination and be similar in its specific characteristics affecting the flow conditions in the endoscope.

NOTE 2 Refer to Table F.1 for examples of establishing endoscope type test groups for storage cabinet type testing.

F.3 Choosing relevant type test groups for type testing

The procedure according to F.2 can result in a large variety of endoscope type test groups.

Based on a risk assessment, the storage cabinet manufacturer is responsible for selecting the most relevant endoscope type test groups (see Table F.1) to be included in type testing, taking into consideration the specific characteristics and limitations of the storage cabinet.

The risk assessment should consider, and where necessary, include the measurement of parameters that can influence the efficacy of the process (such as pressure, flow, etc.) in combination with the storage cabinet.

Table F.1 — Example for establishing relevant endoscope type test groups for storage cabinet type testing

<table>
<tr><th>Endoscope</th><th>Endoscope Block</th><th>ESC connector</th><th>Separator/ Closure</th><th>Type Test Group (TTG)</th><th>Relevant for Type Test</th></tr>
<tr><td rowspan="4">Endoscope 1</td><td rowspan="2">A1</td><td>1</td><td rowspan="2">X1</td><td rowspan="4">TTG1</td><td rowspan="4">–</td></tr>
<tr><td>2</td></tr>
<tr><td rowspan="2">B1</td><td>1</td><td rowspan="2">Y1</td></tr>
<tr><td>3</td></tr>
<tr><td rowspan="4">Endoscope 2</td><td rowspan="2">A1</td><td>1</td><td rowspan="2">X2</td><td rowspan="4">TTG2</td><td rowspan="4">Yes</td></tr>
<tr><td>2</td></tr>
<tr><td rowspan="2">B1</td><td>1</td><td rowspan="2">Y1</td></tr>
<tr><td>3</td></tr>
<tr><td>Endoscope 3</td><td>A2</td><td>1</td><td>X1</td><td>TTG3</td><td>–</td></tr>
</table>

F.4 Definition of relevant surrogate devices and endoscopes for type testing

Type testing shall be performed with the help of surrogate devices and/or representative endoscopes from every relevant type test group as specified in the test procedures described in this standard. When a surrogate device is used it shall be verified to ensure that it has similar flow characteristics as the original endoscope(s), using the following procedure:

1) Establish the specifications for the channels and the ports in the endoscope as in F.2,1).

2) From these specifications [see F.4, 1)], develop a channel irrigation plan. This plan shall ensure that all channels and all parts of the channels are effectively irrigated during the process.

3) Specify the necessary ESC connectors to connect the endoscope channels to the storage cabinet. Where applicable, specify any channel separators and/or port closures. The ESC connectors shall ensure that the channels will be irrigated according to the irrigation plan.

4) During an operating cycle, measure and record the flow and pressure at each connection to the endoscope.

5) From the blocks identified in F.2,1), build a surrogate device that represents the complete set of channels of the endoscope and its ports and define the necessary ESC connectors.

6) During an operating cycle, with all connectors to the surrogate device in place, measure and record the flow and pressure at each connection to each channel of the surrogate device.

NOTE All channels can be connected to ensure that the flow through any channel is realistically influenced by the other connected channels. The extent of the inter-channel influence can depend on the type of air flowing system of the particular storage cabinet.

7) Establish whether the flow and pressure values at each connection to the surrogate device is equal to the flow and pressure values at each connection to the original endoscope(s). This is necessary in order to verify that the surrogate device correctly represents the original endoscope(s).

If it cannot be established that the surrogate device is a valid model for the endoscope(s), then restart at 1) or abandon the procedure as the endoscope was not qualified for storing in the storage cabinet.

After successful completion of storage cabinet type testing, the storage cabinet manufacturer may declare compatibility with all endoscopes that are included in the establishment of the endoscope type test groups according to F.2.

F.5Verification procedure for new endoscopes

The following procedure shall be followed:

1) Investigate the new endoscope for compatibility into a block or combination of blocks according to Table F.2 and its specific characteristics.

2) Check whether the new endoscope consists of the same general block combination and is similar with regard to specific characteristics affecting the flow conditions in the endoscope, e.g. ESC connectors, channel separators, port closures, return valves, etc. with one of the previously established endoscope type test groups.

3) In case of doubt, verify that the flow through the channels of the new endoscope is similar, when measured as described in F.4, 4).

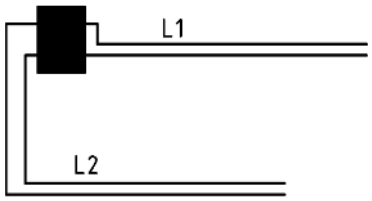
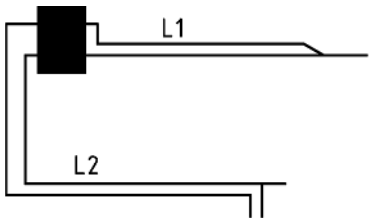
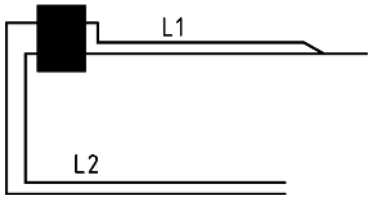
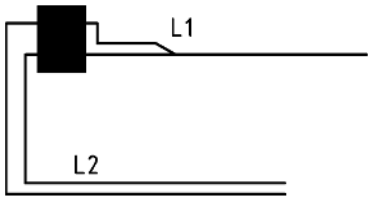
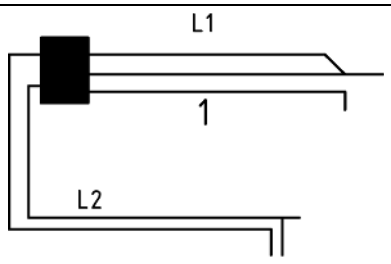
4) If all of these conditions are satisfied, then the endoscope is a member of the type test group and can be added to the list of compatible endoscopes without the necessity of further testing. The results of this assessment shall be documented.

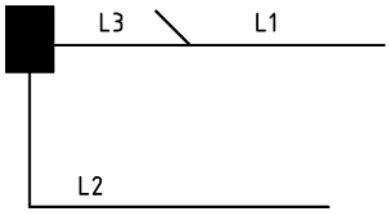
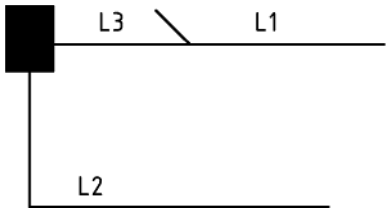
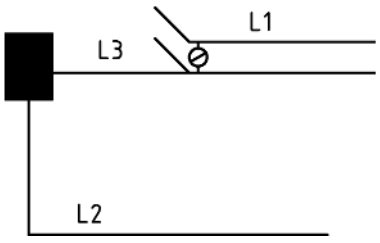
5) If the new endoscope does not belong to any previously established endoscope type test group, then it becomes the first member of a new endoscope type test group. Based on an additional risk assessment for this new type test group, it shall be stated whether the type testing already covers the new type test group or if further type testing is required.

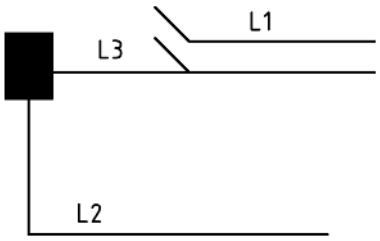
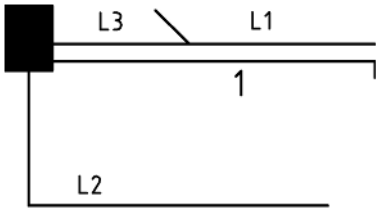
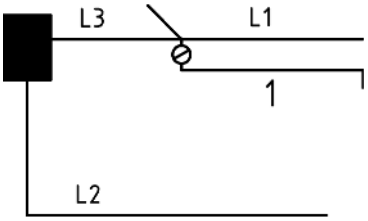
F.6 List of Endoscope blocks

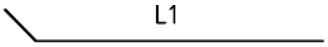
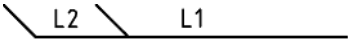
Examples of specified endoscope blocks are provided in Table F.2.

Table F.2 — Examples of specified endoscope blocks

Endoscope Block A, air water channels		Specification
A1	 **Key** L1 = Valve – Distal end L2 = Valve - Connector	Single air channel and water channel: • not combined • Ø 0,7 mm < d < Ø 1,7 mm Channel lengths: • 600 mm < L1 < 2 600 mm • 800 mm < L2 < 2 000 mm
A2	 **Key** L1 = Valve – Distal end L2 = Valve – Connector	Single air channel and water channel: • combined • Ø 0,8 mm ≤ d ≤ Ø 2,4 mm Channel lengths: • 900 mm < L1 < 2 900 mm • 1 400 mm < L2 < 2 000 mm
A3	 **Key** L1 = Valve – Distal end L2 = Valve – Connector	Single air channel and water channel: • combined • Ø 0,7 mm < d < Ø 1,7 mm Channel lengths: • 600 mm < L1 < 2 600 mm • 800 mm < L2 < 2 000 mm
A4	 **Key** L1 = Valve – Distal end L2 = Valve – Connector	Single air channel and water channel: • combined • Ø 0,7 mm < d < Ø 1,7 mm Channel lengths: • 600 mm < L1 < 2 600 mm • 800 mm < L2 < 2 000 mm
A5		Single air channel and water channel: • Combined with balloon fill channel Air channel and water channel: • Ø 0,8 mm < d < Ø 1,2 mm Balloon channel: • Ø 0,8 mm < d < Ø 1,2 mm Channel lengths:

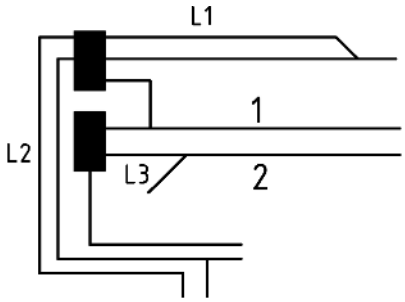
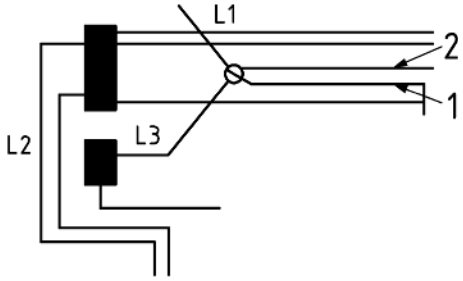
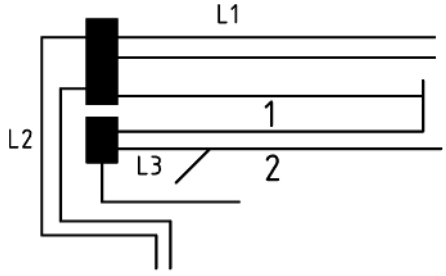
	Key 1 Balloon fill channel L1 Valve – Distal end L2 Valve – Connector	• 1 200 mm < L1 < 2 200 mm • 1 600 mm < L2 < 2 000 mm L1 = Valve – Distal end L2 = Valve – Connector
Endoscope Block B, Biopsy suction channels		**Specification**
B1	 **Key** L1 Biopsy channel – Distal end L2 Valve - Connector L3 Biopsy channel – Valve	Biopsy / suction channel: • Ø 1,2 mm ≤ d < Ø 2,5 mm Channel lengths: • 600 mm < L1 < 2 800 mm • 1 400 mm < L2 < 2 000 mm • L3 < 300 mm
B2	 **Key** L1 Biopsy channel – Distal end L2 Valve - Connector L3 Biopsy channel – Valve	Biopsy / suction channel: • Ø 2,5 mm ≤ d < Ø 4,5 mm Channel lengths: • 1 200 mm < L1 < 2 200 mm • 1 400 mm < L2 < 2 000 mm • L3 < 200 mm
B3	 **Key** L1 Biopsy channel – Distal end L2 Valve - Connector L3 Biopsy channel – Valve	Biopsy / suction channel: • Ø 4,5 mm ≤ d < Ø 6,5 mm Channel lengths: • 600 mm < L1 < 1 200 mm • 1 400 mm < L2 < 2 000 mm • L3 < 200 mm
B4	 **Key** L1 Biopsy channel – Distal end L2 Valve - Connector L3 Biopsy channel – Valve	Double biopsy / suction channel: • Valve • Ø 2,5 mm < d < Ø 4,5 mm Channel lengths: • 1 100 mm < L1 < 2 200 mm • 1 400 mm < L2 < 2 000 mm • L3 < 200 mm

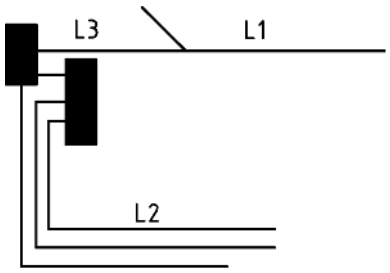
B5	 **Key** L1 Biopsy channel – Distal end L2 Valve - Connector L3 Biopsy channel – Valve	Double biopsy / suction channel: • Ø 2,5 mm ≤ d ≤ Ø 4,5 mm Channel lengths: • 1 100 mm < L1 < 2 200 mm • 1 400 mm < L2 < 2 000 mm • L3 < 300 mm
B6	 **Key** 1 Balloon drain channel L1 Biopsy channel – Distal end L2 Valve - Connector L3 Biopsy channel – Valve	Biopsy / suction channel: • Ø 1,2 mm < d < Ø 2,5 mm Balloon drain channel: • Ø 0,8 mm < d < Ø 1,2 mm Channel lengths: • 1 200 mm < L1 < 2 200 mm • 1 400 mm < L2 < 2 000 mm • L3 < 200 mm
B7	 **Key** 1 Balloon drain channel L1 Biopsy channel – Distal end L2 Valve - Connector L3 Biopsy channel – Valve	Biopsy / suction channel: • Ø 1,2 mm < d < Ø 2,5 mm Balloon drain channel with valve: • Ø 0,8 mm < d < Ø 1,2 mm Channel lengths: • 1 200 mm < L1 < 2 200 mm • 1 400 mm < L2 < 2 000 mm • L3 < 200 mm
Endoscope Block C, water jet channel / air balloon channel double balloon system		**Specification**
C1	 **Key** L1 Valve – Distal end L2 Valve – Connector	Water jet channel: • Ø 0,7 mm ≤ d ≤ Ø 1,6 mm Channel lengths: • L1 (Block A) • L1+L2 (Block A)

C2	 **Key** L1 Valve – Distal end L2 Valve – Connector	Balloon channel: • Ø 0,6 mm ≤ d ≤ Ø 1,5 mm Channel lengths: • L1 (Block A) • L1+L2 (Block A)
Endoscope Block D, Elevator channel		**Specification**
D	 **Key** L1 Valve – Distal end	Elevator channel: • Wire: Ø 0,3 mm ≤ d ≤ Ø 0,8 mm • Channel: Ø 0,8 mm ≤ d ≤ Ø 1,2 mm • Delta 0,1 mm ≤ d ≤ 0,4 mm Channel lengths: • 1 000 mm < L1 <1 700 mm
Endoscope Block E, small calibre endoscopes (e.g. cystoscopes, bronchoscopes)		**Specification**
E1	 **Key** L1 Biopsy channel – Distal end	Biopsy / suction channel: • Ø 0,5 mm ≤ d ≤ Ø 3,4 mm Channel lengths: • 300 mm < L1 <1 000 mm
E2	 **Key** L1 Biopsy channel – Distal end L2 Biopsy channel – Valve	Biopsy / suction channel: • Ø 0,5 mm ≤ d ≤ Ø 3,4 mm Channel lengths: • 300 mm < L1 <1 000 mm • L2 < 300 mm

Examples of endoscopes that cannot be divided into blocks due to interconnections between water/air and biopsy/suction channels or combinations with balloon channels are described in Table F.3.

Table F.3 — Examples of endoscopes that cannot be divided into blocks due to interconnections

Diagrams of endoscopes not possible to divide into blocks due to interconnections between water/air and biopsy/suction channels or combinations with balloon channels.	Specification
 **Key** 1 Balloon channel 2 Biopsy / suction channel L1 Biopsy channel – Distal end L2 Valve - Connector L3 Biopsy channel – Valve	***Ultrasound endoscope*** Air channel and water channel: • Ø 0,8 mm ≤ d ≤ Ø 2,4 mm Biopsy / suction channel: • Ø 1,2 mm ≤ d ≤ Ø 3,7 mm Balloon channel: • Ø 0,8 mm ≤ d ≤ Ø 1,4 mm Channel lengths: • 1 200 mm < L1 < 2 200 mm • 1 400 mm < L2 < 2 000 mm • L3 < 300 mm
 **Key** 1 Balloon channel 2 Biopsy / suction channel L1 Biopsy channel – Distal end L2 Valve - Connector L3 Biopsy channel – Valve	***Ultrasound endoscope*** Air channel and water channel: • Ø 0,8 mm < d < Ø 1,2 mm Biopsy / suction channel: • Ø 1,2 mm < d < Ø 2,5 mm Balloon channel: • Ø 0,8 mm < d < Ø 1,2 mm Channel lengths: • 1 200 mm < L1 < 2 200 mm • 1 400 mm < L2 < 2 000 mm • L3 < 200 mm
 **Key** 1 Balloon channel 2 Biopsy / suction channel L1 Biopsy channel – Distal end L2 Valve - Connector L3 Biopsy channel – Valve	***Ultrasound endoscope*** Air channel and water channel: • Ø 0,8 mm < d < Ø 1,2 mm Biopsy / suction channel: • Ø 1,2 mm < d < Ø 2,5 mm Balloon channel: • Ø 0,8 mm < d < Ø 1,2 mm Channel lengths: • 1 200 mm < L1 < 2 200 mm • 1 400 mm < L2 < 2 000 mm • L3 < 200 mm

 **Key** L1 Valve – Distal end L2 Valve – Connector L3 Biopsy channel – Valve	***Paediatric GI endoscope*** Air channel, water channel, biopsy, suction: • Ø 1,2 mm < d < Ø 2,5 mm Channel lengths: • 1 200 mm < L1 < 2 200 mm • 1 400 mm < L2 < 2 000 mm • L3 < 200 mm

Annex G
(normative)
Establishing endoscope product families

G.1 General

This Annex provides guidance for performance qualification at the user's facility (see 6.1.2).

The choice of the storage cabinet shall be appropriate for the particular load used in the respective endoscopy unit.

For performance qualification the process is verified by sampling endoscopes and determining their hygienic status (see E.2). Clustering endoscopes into endoscope product families can reduce the number of endoscopes required to be sampled for performance qualification, but still allow for coverage of the range of endoscopes used in the respective healthcare facility.

Three endoscope product families have been identified and defined based on the relevant characteristics of endoscopes (see G.2). For endoscopes that do not belong to one of these three endoscope product families, or for a different brand endoscope, or for endoscopes that have a different ESC connector set, further tests need to be performed.

G.2 Classification of endoscope product families

G.2.1 Endoscope product family 1

Endoscope product family 1 includes Endoscopes:

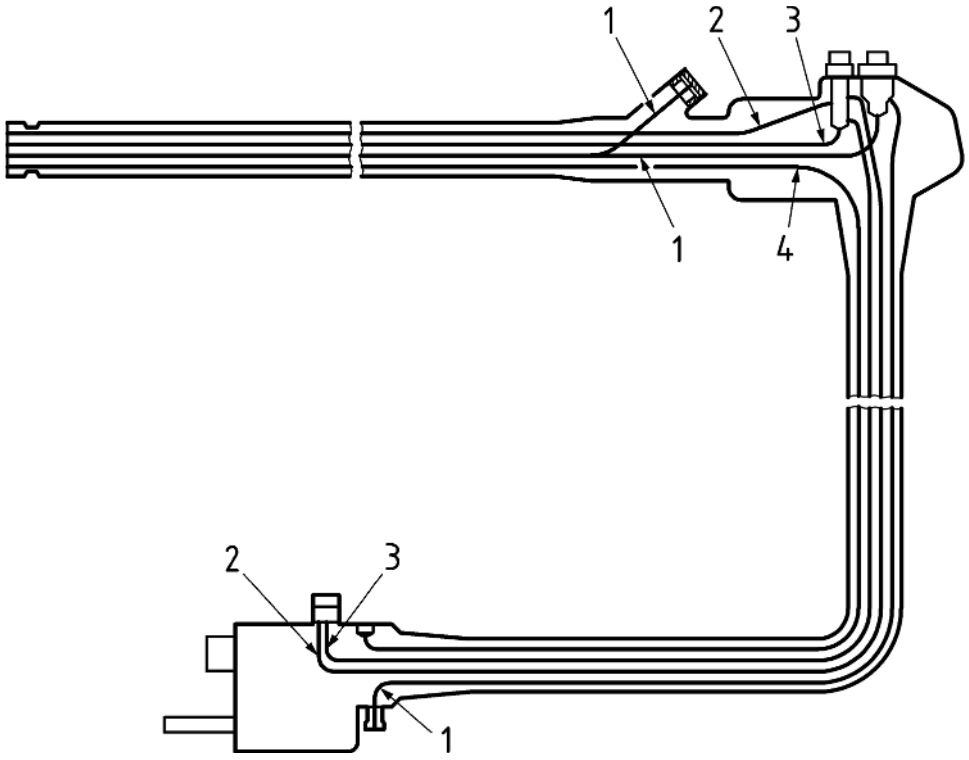
— with air/water channels;

— with biopsy/suction channel;

— with/without additional instrument channel;

— with/without water jet channel.

Endoscopes belonging to this family are typically intended for use in the gastrointestinal (GI) tract. Gastroscopes and colonoscopies are the main representatives of this endoscope product family, and duodenoscopes with an encapsulated elevator wire, also belong to this group (see Figure G.1).



Key

1 Biopsy/suction channel
2 Air channel
3 Water channel
4 Water jet channel

Figure G.1 — Example of an endoscope product family 1

G.2.2 Endoscope product family 2

Endoscope product family 2 includes Endoscopes:

— with air/water channels;

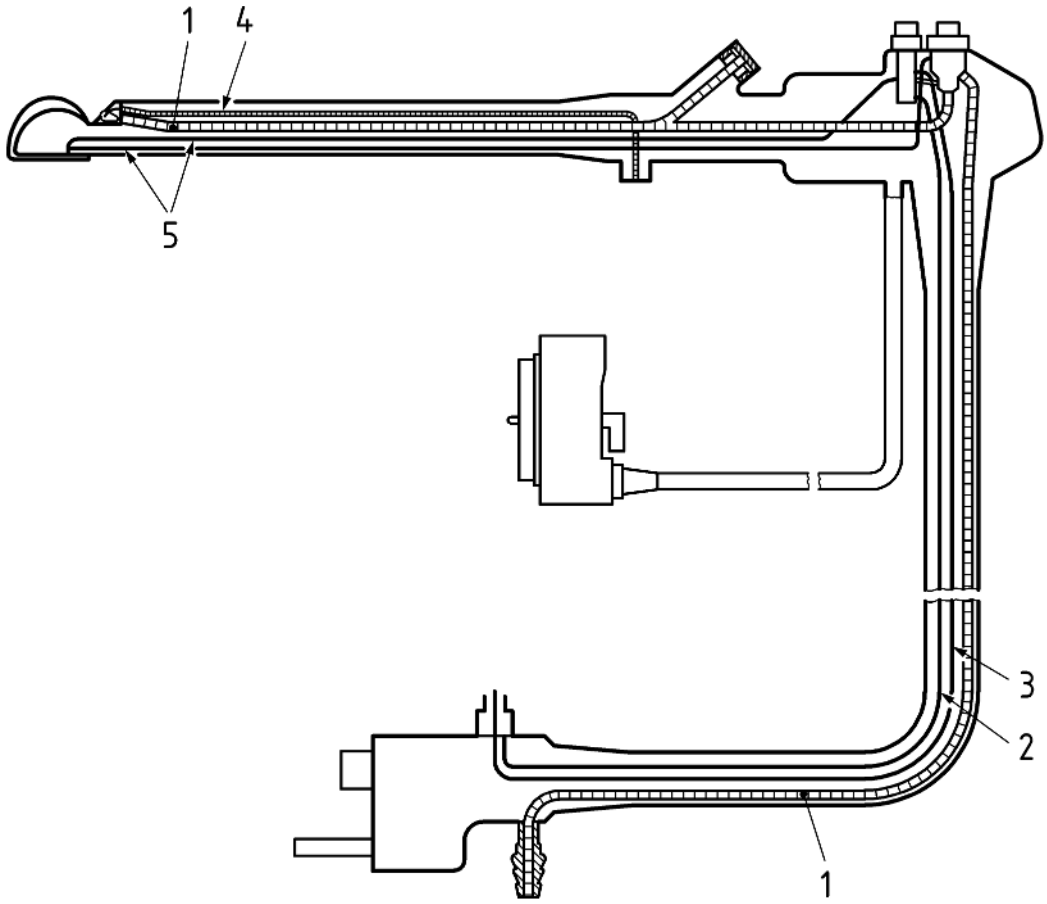
— with biopsy/suction channel;

— with/without additional instrument channel;

— with/without elevator wire channel;

— with up to two control channels for balloon functions.

Endoscopes belonging to this family include models which can be used in the gastrointestinal tract. They are equipped with a so-called elevator wire channel and/or control channels, the latter designed to fill and deflate balloons as components of the endoscope. Examples for this product family are duodenoscopes with open elevator channel, endoscopes for endoscopic ultrasound, and enteroscopes (see Figure G.2).



Key

1 Instrument /suction channel
2 Air channel
3 Water channel
4 Elevator channel
5 Balloon channel

Figure G.2 — Example of an endoscope product family 2

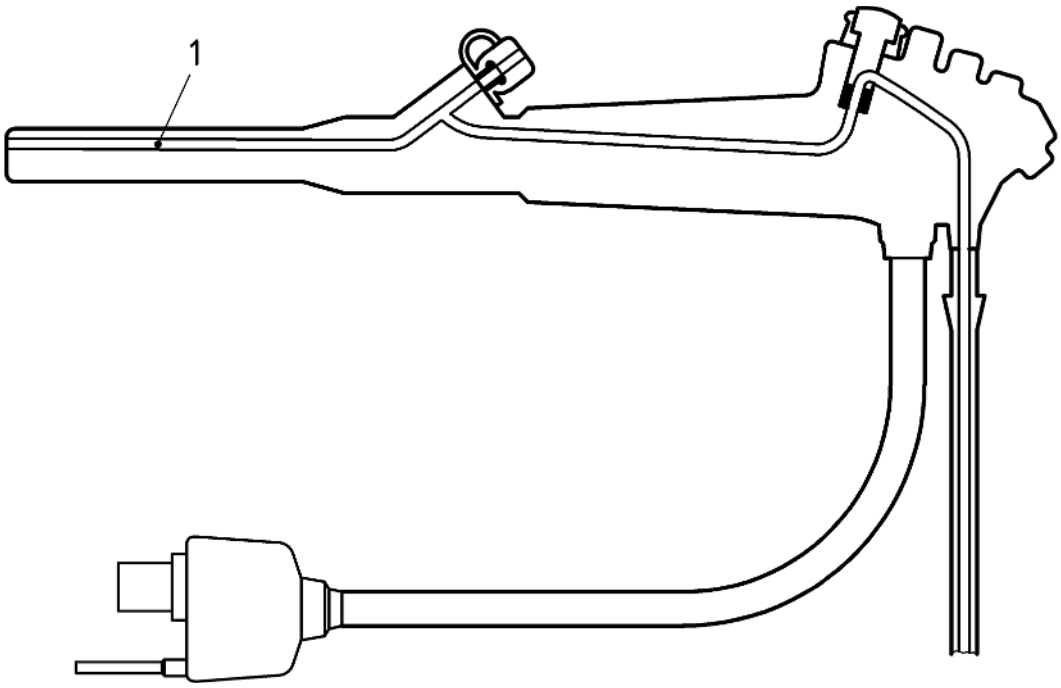
G.2.3 Endoscope product family 3

Endoscope product family 3 includes Endoscopes:

— with up to two instrument channels, but without channel system in the umbilical cord; or

— without any channels within the entire endoscope.

Endoscopes belonging to this family comprise models with only one channel system for biopsy, irrigation and suction, or models without any channel. They are used in bronchoscopy, ear-nose-throat applications, gynaecology and urology (see Figure G.3).



Key

1 Biopsy /suction channel

Figure G.3 — Example of an endoscope product family 3

Bibliography

EN 1822-1:2009, *High efficiency air filters (EPA, HEPA and ULPA) — Part 1: Classification, performance testing, marking*

EN ISO 11737-1:2006, *Sterilization of medical devices — Microbiological methods — Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2006)*

EN ISO 14644-1, *Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness (ISO 14644-1)*

EN ISO 14971, *Medical devices — Application of risk management to medical devices*

EN ISO 15883-1:2009, *Washer-disinfectors — Part 1: General requirements, terms and definitions and tests (ISO 15883-1:2006)*

EN ISO 15883-4:2009, *Washer-disinfectors — Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes (ISO 15883-4:2008)*

ISO 8573-1, *Compressed air — Part 1: Contaminants and purity classes*

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