SLOVENSKI STANDARD
SIST EN 16442:2015

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Shranjevalni prostor z nadzorovanim okoljem za pripravljene termolabilne endoskope

Controlled environment storage cabinet for processed thermolabile endoscopes

Lagerungsschrank mit geregelten Umgebungsbedingungen für aufbereitete, thermolabile Endoskope

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Enceinte de stockage à atmosphère contrôlée pour endoscopes thermosensibles traités

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Ta slovenski standard je istoveten z: EN 16442:2015

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EUROPEAN STANDARD

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Lagerungsschrank mit geregelten Umgebungsbedingungen für aufbereitete, thermolabile Endoskope

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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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of an identical text or by endorsement, at the latest by September 2015 and conflicting national standards shall be withdrawn at the latest by September 2015.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.

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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

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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.

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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

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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

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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

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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.

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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.

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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.

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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.

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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)].

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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.

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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)].

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

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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)].

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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.

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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)].

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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.

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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).

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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.

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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.

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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.

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

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— 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.