

Controlled environment storage cabinet for processed
thermolabile endoscopes

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 16442:2015 sisaldab Euroopa standardi EN 16442:2015 ingliskeelset teksti.	This Estonian standard EVS-EN 16442:2015 consists of the English text of the European standard EN 16442:2015.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 18.03.2015.	Date of Availability of the European standard is 18.03.2015.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.140

Standardite reprodutseerimise ja levitamise õigus kuulub Eesti Standardikeskusele

Andmete paljundamine, taastekitamine, kopeerimine, salvestamine elektroonsesse süsteemi või edastamine ükskõik millises vormis või millisel teel ilma Eesti Standardikeskuse kirjaliku loata on keelatud.

Kui Teil on küsimusi standardite autorikaitse kohta, võtke palun ühendust Eesti Standardikeskusega:

Aru 10, 10317 Tallinn, Eesti; koduleht www.evs.ee; telefon 605 5050; e-post info@evs.ee

The right to reproduce and distribute standards belongs to the Estonian Centre for Standardisation

No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying, without a written permission from the Estonian Centre for Standardisation.

If you have any questions about copyright, please contact Estonian Centre for Standardisation:

Aru 10, 10317 Tallinn, Estonia; homepage www.evs.ee; phone +372 605 5050; e-mail info@evs.ee

ICS 11.140

English Version

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.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.



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

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

Contents

Page

Foreword	4
Introduction	5
1 Scope	6
2 Normative references	6
3 Terms and definitions	6
4 Performance requirements	7
4.1 General	7
4.2 Storage	8
4.3 Drying	8
4.4 Endoscope storage cabinet connectors (ESC connectors)	9
5 Mechanical and procedure requirements	9
5.1 Materials – design, manufacture and assembly	9
5.2 Air quality	10
5.3 Contamination of the storage cabinet chamber surfaces	11
5.4 Drying process control	11
5.5 Endoscope channel aeration system	12
5.6 Automatic temperature control	13
5.7 Fault indication/monitoring	13
5.8 Cycle indicators	14
5.9 Instruments and control devices	14
5.10 Temperature indicators	15
5.11 Relative humidity indicator	15
5.12 Pressure indicators	15
5.13 Traceability	16
5.14 Double-ended storage cabinets	16
6 Testing for conformity	17
6.1 General	17
6.2 Air changes	17
6.3 Overpressure	17
6.4 Drying	18
6.5 Contamination of the inside surfaces of the storage cabinet	19
6.6 Air quality	19
6.7 Channel aeration test	21
6.8 Thermometric testing 1 – chamber and load temperature testing	21
6.9 Thermometric test 2- chamber and load temperature testing	22
6.10 Readability	22
6.11 Tests for air filtration	22
7 Documentation	22
8 Information to be supplied with the storage cabinet	22
8.1 General	22
8.2 Information to be supplied before delivery	23
8.3 Marking and labelling	25
8.4 Packaging	25
9 Information to be requested from the purchaser by the manufacturer	25
Annex A (informative) Summary of test programmes	26
Annex B (informative) Cross-contamination between endoscopes	28

Annex C (normative) Methods for evaluation of airborne microbial contamination in the storage cabinet	31
Annex D (informative) Procedure for parametric performance qualification	32
Annex E (normative) Internal residual contamination of endoscopes after storage	38
Annex F (normative) Establishing endoscope type test groups	46
Annex G (normative) Establishing endoscope product families	55
Bibliography	59

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.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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