

ELEKTRILISED MEDITSIINISEADMED. OSA 2-58:
ERINÕUDED SILMAKIRURGIAS LÄÄTSEDE
EEMALDAMISEL JA VITREKTOOMIAS KASUTATAVATE
SEADMETE ESMASELE OHUTUSELE JA OLULISTELE
TOIMIMISNÄITAJATELE

Medical electrical equipment - Part 2-58: Particular requirements for the basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 80601-2-58:2015 sisaldab Euroopa standardi EN 80601-2-58:2015 ingliskeelset teksti.	This Estonian standard EVS-EN 80601-2-58:2015 consists of the English text of the European standard EN 80601-2-58:2015.
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English Version

**Medical electrical equipment - Part 2-58: Particular requirements
for the basic safety and essential performance of lens removal
devices and vitrectomy devices for ophthalmic surgery
(IEC 80601-2-58:2014)**

Appareils électromédicaux - Partie 2-58: Exigences particulières pour la sécurité de base et les performances essentielles des dispositifs de retrait du cristallin et des dispositifs de vitrectomie pour la chirurgie ophtalmique (IEC 80601-2-58:2014)

Medizinische elektrische Geräte - Teil 2-58: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale für Geräte zur Linsenentfernung und Geräte zur Glaskörperentfernung in der Augen Chirurgie (IEC 80601-2-58:2014)

This European Standard was approved by CENELEC on 2014-10-09. CENELEC 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 CENELEC member.

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European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

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

Foreword

The text of document 62D/1151/FDIS, future edition 2 of IEC 80601-2-58 prepared by SC 62D "Electromedical equipment" of IEC/TC 62 "Electrical equipment in medical practice" and SC 7 "Ophthalmic optics and instruments" of ISO/TC 172 "Optics and photonics" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 80601-2-58:2015.

The following dates are fixed:

- latest date by which the document has to be (dop) 2015-11-29
implemented at national level by
publication of an identical national
standard or by endorsement
- latest date by which the national (dow) 2018-05-29
standards conflicting with the
document have to be withdrawn

This document supersedes EN 80601-2-58:2009.

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

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive.

For the relationship with EU Directive 93/42/EEC, see informative Annex ZZ, which is an integral part of this document.

Endorsement notice

The text of the International Standard IEC 80601-2-58:2014 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 60065:2001	NOTE	Harmonized as EN 60065:2002 ¹⁾ (modified).
IEC 60825-1	NOTE	Harmonized as EN 60825-1.
IEC 60950-1	NOTE	Harmonized as EN 60950-1.
IEC 61847	NOTE	Harmonized as EN 61847.
ISO 15004-2:2007	NOTE	Harmonized as EN ISO 15004-2:2007 (not modified).
ISO 15752:2010	NOTE	Harmonized as EN ISO 15752:2010 (not modified).

¹⁾ Superseded by EN 60065:2014 (IEC 60065:2014): DOW = 2017-11-17.

Annex ZA (normative)

Normative references to international publications with their corresponding European publications

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.

NOTE 1 When an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu

Publication	Year	Title	EN/HD	Year
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Annex ZA of EN 60601-1:2006 applies except as follows:

Replacement:

IEC 60601-1-2 (mod)	2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2 + corr. March	2007 ¹⁾ 2010 ¹⁾
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Addition:

IEC 60601-2-2	-	Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories	EN 60601-2-2	-
IEC 60601-2-22	-	Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment	EN 60601-2-22	-
ISO 11607-1	2006	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems	EN ISO 11607-1	2009
ISO 11607-2	2006	Packaging for terminally sterilized medical devices - Part-2: Validation requirements for forming, sealing and assembly processes	EN ISO 11607-2	2006
ISO 17664	2004	Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices	EN ISO 17664	2004

¹⁾ Superseded by EN 60601-1-2:2014 (IEC 60601-1-2:2014): DOW = 2018-12-31.

Annex ZZ
(informative)

Coverage of Essential Requirements of EU Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and within its scope the Standard covers all relevant essential requirements given in Annex I of EU Directive 93/42/EEC of 14 June 1993 concerning medical devices.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

WARNING: Other requirements and other EU Directives can be applied to the products falling within the scope of this standard.

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INTRODUCTION

LENS REMOVAL DEVICES and VITRECTOMY DEVICES are used widely in ophthalmology to perform anterior-segment and posterior-segment surgery on the human eye. Commercial use of these MEDICAL ELECTRICAL EQUIPMENT devices began in the early 1970s. This International Standard defines particular requirements for BASIC SAFETY and ESSENTIAL PERFORMANCE of LENS REMOVAL DEVICES and VITRECTOMY DEVICES, comprising an equipment console, surgical HANDPIECES and ACCESSORIES connected to this ME EQUIPMENT.

In many parts of the world LENS REMOVAL DEVICES and VITRECTOMY DEVICES are used in combination by ophthalmic surgeons to perform combined anterior-segment (lens removal) and posterior-segment (vitreoretinal) surgical PROCEDURES to maximize surgical outcomes. For this reason both LENS REMOVAL DEVICES and VITRECTOMY DEVICES are covered in this International Standard.

As all particular standards in the IEC 60601-1 series are based on the general standard IEC 60601-1, the user of this standard is reminded that RISK MANAGEMENT plays an important role in the use of this particular standard. Compliance with the requirements of this particular standard should be documented in the RISK MANAGEMENT FILE to ensure the HAZARDS associated with the product have been considered fully.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-58: Particular requirements for the basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery

201.1 Scope, object and related standards

Clause 1 of the general standard¹ applies, except as follows:

201.1.1 * Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of LENS REMOVAL DEVICES and VITRECTOMY DEVICES for ophthalmic surgery (as defined in 201.3.208 and 201.3.217) and associated ACCESSORIES that can be connected to this MEDICAL ELECTRICAL EQUIPMENT, hereafter referred to as ME EQUIPMENT.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1 of the general standard.

NOTE See also 4.2 of the general standard.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for LENS REMOVAL DEVICES and VITRECTOMY DEVICES for ophthalmic surgery (as defined in 201.3.208 and 201.3.217) and associated ACCESSORIES that can be connected to the ME EQUIPMENT and are to be tested together or individually.

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

IEC 60601-1-2:2007 applies as modified in Clause 202. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

¹ The general standard is IEC 60601-1, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1 is referred to in this particular standard as the “general standard”. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix “201” (e.g. 201.1 in this standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix “20x” where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

“Replacement” means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

“Addition” means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

“Amendment” means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where “x” is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term “this standard” is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

NOTE Informative references are listed in the bibliography beginning on page 26.

Clause 2 of the general standard applies, except as follows:

Replacement:

IEC 60601-1-2:2007², *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*

Addition:

IEC 60601-2-2, *Medical electrical equipment – Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories*

IEC 60601-2-22, *Medical electrical equipment – Part 2-22: Particular requirements for the basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment*

ISO 11607-1:2006, *Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 11607-2:2006, *Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes*

ISO 17664:2004, *Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1, apply, except as follows:

NOTE An index of defined terms is found beginning on page 27.

Addition:

201.3.201

ASPIRATION

drawing fluid or gas out of the eye by use of suction

201.3.202

DIATHERMY

surgical technique using high frequency (HF) electrical currents to stop bleeding in tissue

Note 1 to entry: Diathermy is used, for example, to coagulate blood or bind tissues together.

Note 2 to entry: The terms “cautery” or “coagulation” have also been used in this context.

201.3.203

DRAIN CONTAINER

sealed container (or bag) in which aspirated fluid is collected

201.3.204

HANDPIECE

PROBE

handheld APPLIED PART, an ACCESSORY of LENS REMOVAL DEVICES or VITRECTOMY DEVICES

² Third edition. Although a new, fourth edition of IEC 60601-1-2 was published in 2014, the normative references to this collateral standard in the present particular standard refer to the third edition, published in 2007.