IEC 80601-2-58

Edition 3.0 2024-03
REDLINE VERSION

INTERNATIONAL STANDARD

colour inside

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 80601-2-58:2024-03 RLV(en)

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INTERNATIONAL
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COMMISSION

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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

FOREWORD

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9) IEC draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). IEC takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, IEC had not received notice of (a) patent(s), which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at https://patents.iec.ch. IEC shall not be held responsible for identifying any or all such patent rights.

This redline version of the official IEC Standard allows the user to identify the changes made to the previous edition IEC 80601-2-58:2014+AMD1:2016 CSV. A vertical bar appears in the margin wherever a change has been made. Additions are in green text, deletions are in strikethrough red text.

IEC 80601-2-58 has been prepared by subcommittee 62D: Particular medical equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems, in co-operation with ISO subcommittee SC 7: Ophthalmic optics and instruments, of ISO technical committee 172: Optics and photonics. It is an International Standard.

It is published as a double logo standard.

This third edition cancels and replaces the second edition published in 2014 and its Amendment 1:2016. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

a) the alignment of this particular standard based on the amendment of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020;
b) the update of collateral, particular and IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 references to align with amendments to IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and other collateral standards;
c) the update of normative references;
d) the addition of a new requirement for particulate matter from APPLIED PARTS in 201.9.5.101;
e) the addition of the shadow light method in 201.12.1.101.7;
f) the clarification of test conditions for EMC requirements in 202.7.1.2;
g) the update of Table D.4 references to include specific IEC references to the symbols and deletion of Annex AA, 201.7.6.101;
h) the addition to Annex AA of 201.12.1.101.7;
i) the inclusion of a new annex to address the relevant general safety and performance requirements of European regulation (EU) 2017/745 [1][1] (Annex BB);
j) the removal of all references of the LIQUEFACTION FRAGMENTATION LENS REMOVAL method.

The text of this International Standard is based on the following documents:

Draft	Report on voting
62D/2096/FDIS	62D/2110/RVD

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications.

In this document, the following print types are used:

– requirements and definitions: roman type.
– *test specifications: italic type.*
– informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

[1] Numbers in square brackets refer to the Bibliography.

– TERMS DEFINED IN CLAUSE 3 OF IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 AND IEC 60601-1:2005/AMD2:2020, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this document, the term

– "clause" means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
– "subclause" means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this document are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

In this document, the conjunctive "or" is used as an "inclusive or", so a statement is true if any combination of the conditions is true.

The verbal forms used in this document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;
– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;
– "may" is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 60601 and IEC 80601 series, published under the general title *Medical electrical equipment,* can be found on the IEC website.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn, or
- revised.

IMPORTANT – The "colour inside" logo on the cover page of this document indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

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 document 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 document.

As all particular standards in the IEC 60601-1 series are based on ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, the user of this document is reminded that RISK MANAGEMENT plays an important role in the use of this particular standard. Compliance with the requirements of this document should be ~~documented~~ recorded in the RISK MANAGEMENT FILE to ensure the HAZARDS associated with the product have been considered fully.

Refer to foreword of this document for list of significant technical changes with respect to the previous edition.

~~INTRODUCTION TO THE AMENDMENT~~

~~This amendment modifies the content of the second edition of IEC 80601-2-58 published in 2014. This Amendment constitutes a technical revision.~~

~~This amendment includes the following significant technical changes with respect to the second edition:~~

~~a) integration of updated definition of ESSENTIAL PERFORMANCE and updating the ESSENTIAL PERFORMANCE analysis;~~

~~b) undating collateral and general standard references to align with amendments to the general standard and other collateral standards;~~

~~c) addition of symbols to standard;~~

~~d) update of EMC requirements.~~

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 standard~~[2] IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.1.1 * Scope

Replacement:

This part of IEC 80601 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of LENS REMOVAL DEVICES and VITRECTOMY DEVICES for ophthalmic surgery (as defined in 201.3.~~208~~209 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 document are not covered by specific requirements in this document except in 7.2.13 of IEC 60601-1:2005 and IEC 60601-1:2005/AMD2:2020 and 8.4.1 of ~~the general standard~~ IEC 60601-1:2005.

NOTE See also 4.2 of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

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~~209 and 201.3.217) and associated ACCESSORIES that can be connected to the ME EQUIPMENT and ~~are to~~ shall be tested together or individually.

NOTE This document has been prepared to address the relevant general safety and performance requirements of European regulation (EU) 2017/745 [1] as indicated in Annex BB.

201.1.3 * Collateral standards

Addition:

This document refers to those applicable collateral standards that are listed in Clause 2 of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, and Clause 201.2.

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

IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 apply as modified in Clause 202. IEC 60601-1-3:2008, IEC 60601-1-3:2008/AMD1:2013 and IEC 60601-1-3:2008/AMD2:2021[2], IEC 60601-1-9:2007, IEC 60601-1-9:2007/AMD1:2013 and IEC 60601-1-9:2007/AMD2:2020[3], IEC 60601-1-10:2007, IEC 60601-1-10:2007/AMD1:2013 and IEC 60601-1-10:2007/AMD2:2020[4], IEC 60601-1-11:2015 and IEC 60601-1-11:2015/AMD1:2020[5], and IEC 60601-1-12:2014 and IEC 60601-1-12:2014/AMD1:2020[6] do not apply.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards specify BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for the particular ME EQUIPMENT and ME SYSTEMS. Particular standards may modify, replace or delete requirements contained in ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and applicable collateral standards as appropriate for the particular ME EQUIPMENT and ME SYSTEMS under consideration~~, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements~~. A requirement of a particular standard takes priority over ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and applicable collateral standards.

~~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 document corresponds to that of the ~~general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020) 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 document addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of the ~~general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are specified by the use of the following words:

"Replacement" means that the clause or subclause of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard is replaced completely by the text of this document.

"Addition" means that the text of this document is additional to the requirements of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard.

"Amendment" means that the clause or subclause of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard is amended as indicated by the text of this document.

Subclauses, figures or tables which are additional to those of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered starting from 201.101. However, due to the fact that definitions in ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered 3.1 through 3.~~139~~154, additional definitions in this document 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 document, the clause or subclause of~~ the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of~~ the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this document.

201.2 Normative references

NOTE Informative references are listed in the bibliography beginning on page 39.

Clause 2 of~~ the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

~~*Replacement:*~~

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

Addition:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012
IEC 60601-1:2005/AMD2:2020

IEC 60601-2-2:2017, *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 60601-2-2:2017/AMD1:2023

IEC 60601-2-22:2019, *Medical electrical equipment – Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment*

CISPR 11:2015, *Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics – Limits and methods of measurement*
CISPR 11:2015/AMD1:2016
CISPR 11:2015/AMD2:2019

ISO 11607-1:~~2006/AMD1:2014~~2019, *Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 11607-2:~~2006/AMD1:2014~~2019, *Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes*

ISO 17664:~~2004~~2017,~~ *Sterilization of medical devices*~~ *Processing of health care products – Information to be provided by the medical device 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 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- IEC Electropedia: available at https://www.electropedia.org/
- ISO Online browsing platform: available at https://www.iso.org/obp

NOTE An index of defined terms is found beginning on page 41.

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
ENDOILLUMINATOR

device consisting of a light source and an associated fibre optic light guide that is intended for insertion into the eye to illuminate any portion of the interior of the eye

[SOURCE: ISO 15004-2:2007, 3.1.5 [7]]

201.3.~~204~~205
HANDPIECE
PROBE
handheld APPLIED PART, an ACCESSORY of LENS REMOVAL DEVICES or VITRECTOMY DEVICES

201.3.~~205~~206
LASER
any device which can be made to produce or amplify electromagnetic radiation in the wavelength range from 180 nm to 1 mm primarily by the PROCESS of controlled stimulated emission

[SOURCE: IEC 60825-1:2014, 3.44 [8]]

201.3.~~206~~207
LASER FRAGMENTATION
method by which the lens is broken into small fragments using LASER energy

201.3.~~207~~208
LENS REMOVAL
removal of unwanted lens tissue

201.3.~~208~~209
LENS REMOVAL DEVICE
ME EQUIPMENT or ME SYSTEM designed to remove lens material which incorporates an IRRIGATION and ASPIRATION function, and a mechanism for LENS REMOVAL such as PHACOFRAGMENTATION~~, LIQUEFACTION~~, or LASER FRAGMENTATION

Note 1 to entry: These devices ~~may~~ can also be used for other ocular surgical purposes.

~~**201.3.209**~~
~~**LIQUEFACTION FRAGMENTATION**~~
~~**LIQUEFACTION**~~
~~method by which the lens is broken into small fragments by means of pulses of ophthalmic IRRIGATION solution~~

201.3.210
OCULAR IRRIGATION
IRRIGATION
introduction of a liquid into the eye

Note 1 to entry: The term "infusion" has also been used in this context

201.3.211
PHACOFRAGMENTATION
method by which the lens is broken into small fragments using energy such as from ultrasonic devices

Note 1 to entry: Refer to the definition of LENS REMOVAL DEVICE in 201.3.~~208~~209.

Note 2 to entry: Historically PHACOFRAGMENTATION (term is also identified as phacoemulsification) has been a surgical PROCEDURE that uses ultrasonic energy to fragment (or emulsify) a cataractous lens and removes the lens material through a small incision. Recently, other emerging energy modalities, including LASER FRAGMENTATION ~~and LIQUEFACTION~~, have also been utilized in the removal of the cataractous lens through a small incision.

201.3.212
PHOTORETINITIS
retinal injury resulting from a very intense retinal radiant exposure

201.3.213
PRIME
PRIMING
pre-operative setup PROCEDURE to fill TUBING SET (fluid path) with ophthalmic IRRIGATION solution

201.3.214
TIP
hollow needle-like device that is attached to a HANDPIECE

201.3.215
TUBING SET
set of tubes to contain fluid, designed to provide IRRIGATION to the eye and ASPIRATION from the eye

201.3.216
VITRECTOMY
surgical PROCEDURE to remove vitreous humour, membranes, blood, lens tissue and other material from the eye, involving IRRIGATION, ASPIRATION and vitreous cutting

Note 1 to entry: The PROCEDURE may also include illumination, DIATHERMY, fluid/gas exchanges, and injection of viscous fluids.

201.3.217
VITRECTOMY DEVICE
ME EQUIPMENT or ME SYSTEM used to perform VITRECTOMY

Note 1 to entry: These devices ~~may~~ can also be used for other ocular surgical purposes.

201.4 General requirements

Clause 4 of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.4.2.1 Introduction to RISK MANAGEMENT

Addition:

IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013 and IEC 60601-1-6:2010/AMD2:2020, and IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020 shall be assessed for applicability through the RISK MANAGEMENT PROCESS. Compliance shall be determined and documented in the RISK MANAGEMENT FILE.

201.4.3 * ESSENTIAL PERFORMANCE

Additional subclause:

201.4.3.101 General

For LENS REMOVAL DEVICES and VITRECTOMY DEVICES, no ESSENTIAL PERFORMANCE has been identified in general. If the LENS REMOVAL DEVICES and VITRECTOMY DEVICES have functions other than those specified in Clause 201.12, the MANUFACTURER shall identify which of these functions of the ME EQUIPMENT and ME SYSTEMS is ESSENTIAL PERFORMANCE.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

Additional subclause:

201.4.101 * Additional functions

If there is a DIATHERMY function used for the LENS REMOVAL DEVICE and VITRECTOMY DEVICE, that function shall meet the requirements of IEC 60601-2-2:2017 and IEC 60601-2-2:2017/AMD1:2023.

If the ME EQUIPMENT includes a LASER function, that function shall meet the requirements of IEC 60601-2-22:2019.

If there is an illumination function used to illuminate the eye during surgery that is part of the ME EQUIPMENT or ME SYSTEM, then that portion of the ME EQUIPMENT or ME SYSTEM shall meet 201.12.4.101.5.

201.5 General requirements for testing of ME EQUIPMENT

Clause 5 of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.