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REDLINE VERSION

INTERNATIONAL STANDARD



**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**

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

ICS 11.040.70

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CONTENTS

FOREWORD.....	3
INTRODUCTION.....	6
201.1 Scope, object and related standards	7
201.2 Normative references	9
201.3 Terms and definitions.....	10
201.4 General requirements.....	12
201.5 General requirements for testing of ME EQUIPMENT.....	12
201.6 Classification of ME EQUIPMENT and ME SYSTEMS.....	13
201.7 ME EQUIPMENT identification, marking and documents	13
201.8 Protection against electrical HAZARDS from ME EQUIPMENT	14
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS	14
201.10 Protection against unwanted and excessive radiation HAZARDS.....	15
201.11 Protection against excessive temperatures and other HAZARDS.....	15
201.12 Accuracy of controls and instruments and protection against hazardous outputs.....	15
201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT	25
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS).....	25
201.15 Construction of ME EQUIPMENT	25
201.16 * ME SYSTEMS	26
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS.....	26
202 Electromagnetic disturbances – Requirements and tests.....	26
Annexes	28
Annex C (informative) Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS.....	28
Annex D (informative) Symbols on marking (See Clause 7).....	29
Annex AA (informative) Particular guidance and rationale.....	31
Annex BB (informative) Reference to the general safety and performance requirements.....	37
Bibliography.....	39
Index of defined terms	41
Figure 201.101 – Test method for gravity fed IRRIGATION.....	16
Figure 201.102 – Test method for pressurized IRRIGATION.....	17
Figure 201.103 – Test method for ASPIRATION pressure measurement/display accuracy	18
Figure 201.104 – Test method for ultrasonic velocity of TIP accuracy	21
Figure 201.105 – Partial shadow, and camera field of view relative to TIP	22
Table 201.101 – Key of symbols for Figure 201.101 to Figure 201.103	18
Table 201.C.101 – ACCOMPANYING DOCUMENTS, instructions for use of LENS REMOVAL DEVICES and VITRECTOMY DEVICES or their parts	28
Table D.4 – LENS REMOVAL and VITRECTOMY symbols.....	29
Table BB.1 – Correspondence between this document and the general safety and performance requirements	34

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as “IEC Publication(s)”). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
- 2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
- 3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
- 4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
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- 6) All users should ensure that they have the latest edition of this publication.
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- 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 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 201.3.208209 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 201.3.208209 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.

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*

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

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

CONTENTS

FOREWORD.....	3
INTRODUCTION.....	6
201.1 Scope, object and related standards	7
201.2 Normative references	9
201.3 Terms and definitions.....	9
201.4 General requirements.....	11
201.5 General requirements for testing of ME EQUIPMENT.....	12
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Annexes	26
Annex C (informative) Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS.....	26
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Bibliography.....	36
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- 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.
- 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).

¹ Numbers in square brackets refer to the Bibliography.

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.

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 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 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.

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 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 201.3.209 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 IEC 60601-1:2005.

NOTE See also 4.2 of 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 201.3.209 and 201.3.217) and associated ACCESSORIES that can be connected to the ME EQUIPMENT and 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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, and Clause 201.2.

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 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. A requirement of a particular standard takes priority over IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and applicable collateral standards.

The numbering of clauses and subclauses of this document corresponds to that of the 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 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 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 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 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 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 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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered 3.1 through 3.154, 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.

Where there is no corresponding clause or subclause in this document, the clause or subclause of 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 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 36.

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

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 11607-1:2019, *Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems*

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

ISO 17664:2017, *Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices*

SOMMAIRE

AVANT-PROPOS.....	42
INTRODUCTION.....	45
201.1 Domaine d'application, objet et normes connexes	46
201.2 Références normatives	48
201.3 Termes et définitions.....	48
201.4 Exigences générales.....	50
201.5 Exigences générales relatives aux essais des APPAREILS EM	51
201.6 Classification des APPAREILS EM et des SYSTEMES EM.....	51
201.7 Identification, marquage et documentation des APPAREILS EM	51
201.8 Protection contre les DANGERS d'origine électrique provenant des APPAREILS EM.....	53
201.9 Protection contre les DANGERS MECANQUES des APPAREILS EM et SYSTEMES EM.....	53
201.10 Protection contre les DANGERS dus aux rayonnements involontaires ou excessifs.....	54
201.11 Protection contre les températures excessives et les autres DANGERS	54
201.12 Précision des commandes, des instruments et protection contre les caractéristiques de sortie présentant des risques.....	54
201.13 SITUATIONS DANGEREUSES et conditions de défaut pour les APPAREILS EM	64
201.14 SYSTEMES ELECTROMEDICAUX PROGRAMMABLES (SEMP)	64
201.15 Construction de l'APPAREIL EM	65
201.16 * SYSTEMES EM	65
201.17 Compatibilité électromagnétique des APPAREILS EM et des SYSTEMES EM.....	65
202 Perturbations électromagnétiques – Exigences et essais	65
Annexes	67
Annexe C (informative) Guide pour le marquage et exigences d'étiquetage pour les APPAREILS EM et les SYSTEMES EM	67
Annexe D (informative) Symboles des marquages (voir Article 7)	68
Annexe AA (informative) Recommandations particulières et justifications	69
Annexe BB (informative) Référence aux exigences générales en matière de sécurité et de performances	75
Bibliographie.....	77
Index des termes définis	79
Figure 201.101 – Méthode d'essai pour l'IRRIGATION en alimentation par gravité	56
Figure 201.102 – Méthode d'essai pour l'IRRIGATION pressurisée	57
Figure 201.103 – Méthode d'essai pour la précision de l'affichage/du mesurage de la pression d'ASPIRATION	58
Figure 201.104 – Méthode d'essai pour la précision de la vitesse ultrasonique de l'EMBOUT	61
Figure 201.105 – Ombre partielle et champ de vision de la caméra par rapport à l'EMBOUT	62
Tableau 201.101 – Légendes des symboles pour les figures de la Figure 201.101 à la Figure 201.103	58

Tableau 201.C.101 – DOCUMENTS D’ACCOMPAGNEMENT, instructions d’utilisation pour les DISPOSITIFS DE RETRAIT DU CRISTALLIN et les DISPOSITIFS DE VITRECTOMIE ou de leurs pièces	67
Tableau D.4 – Symboles pour le RETRAIT DU CRISTALLIN et la VITRECTOMIE	68
Tableau BB.1 – Correspondance entre le présent document et les exigences générales en matière de sécurité et de performances	75

COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

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

AVANT-PROPOS

- 1) La Commission Électrotechnique Internationale (IEC) est une organisation mondiale de normalisation composée de l'ensemble des comités électrotechniques nationaux (Comités nationaux de l'IEC). L'IEC a pour objet de favoriser la coopération internationale pour toutes les questions de normalisation dans les domaines de l'électricité et de l'électronique. À cet effet, l'IEC – entre autres activités – publie des Normes internationales, des Spécifications techniques, des Rapports techniques, des Spécifications accessibles au public (PAS) et des Guides (ci-après dénommés "Publication(s) de l'IEC"). Leur élaboration est confiée à des comités d'études, aux travaux desquels tout Comité national intéressé par le sujet traité peut participer. Les organisations internationales, gouvernementales et non gouvernementales, en liaison avec l'IEC, participent également aux travaux. L'IEC collabore étroitement avec l'Organisation Internationale de Normalisation (ISO), selon des conditions fixées par accord entre les deux organisations.
- 2) Les décisions ou accords officiels de l'IEC concernant les questions techniques représentent, dans la mesure du possible, un accord international sur les sujets étudiés, étant donné que les Comités nationaux de l'IEC intéressés sont représentés dans chaque comité d'études.
- 3) Les Publications de l'IEC se présentent sous la forme de recommandations internationales et sont agréées comme telles par les Comités nationaux de l'IEC. Tous les efforts raisonnables sont entrepris afin que l'IEC s'assure de l'exactitude du contenu technique de ses publications; l'IEC ne peut pas être tenue responsable de l'éventuelle mauvaise utilisation ou interprétation qui en est faite par un quelconque utilisateur final.
- 4) Dans le but d'encourager l'uniformité internationale, les Comités nationaux de l'IEC s'engagent, dans toute la mesure possible, à appliquer de façon transparente les Publications de l'IEC dans leurs publications nationales et régionales. Toutes divergences entre toutes Publications de l'IEC et toutes publications nationales ou régionales correspondantes doivent être indiquées en termes clairs dans ces dernières.
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- 7) Aucune responsabilité ne doit être imputée à l'IEC, à ses administrateurs, employés, auxiliaires ou mandataires, y compris ses experts particuliers et les membres de ses comités d'études et des Comités nationaux de l'IEC, pour tout préjudice causé en cas de dommages corporels et matériels, ou de tout autre dommage de quelque nature que ce soit, directe ou indirecte, ou pour supporter les coûts (y compris les frais de justice) et les dépenses découlant de la publication ou de l'utilisation de cette Publication de l'IEC ou de toute autre Publication de l'IEC, ou au crédit qui lui est accordé.
- 8) L'attention est attirée sur les références normatives citées dans cette publication. L'utilisation de publications référencées est obligatoire pour une application correcte de la présente publication.
- 9) L'attention est attirée sur le fait que certains des éléments du présent document de l'IEC peuvent faire l'objet de droits de brevets. L'IEC ne prend pas position quant à la preuve, à la validité et à la portée de ces droits de propriété. À la date de publication du présent document, l'IEC n'a reçu aucune déclaration relative à des droits de brevets, qui pourraient être exigés pour la mise en œuvre du présent document. Toutefois, il est rappelé aux responsables de cette mise en œuvre qu'il ne s'agit peut-être pas des informations les plus récentes, qui peuvent être obtenues dans la base de données disponible à l'adresse <https://patents.iec.ch>. L'IEC ne saurait être tenue pour responsable de ne pas avoir identifié de tels droits de brevets.

L'IEC 80601-2-58 a été établie par le sous-comité 62D: Équipements, logiciels et systèmes médicaux particuliers, du comité d'études 62 de l'IEC: Équipement médical, logiciels et systèmes médicaux, en coopération avec le sous-comité 7 de l'ISO: Optique et instruments ophtalmiques, du comité technique 172 de l'ISO: Optique et photonique. Il s'agit d'une Norme internationale.

Elle est publiée comme norme double logo.

Cette troisième édition annule et remplace la deuxième édition parue en 2014 et son Amendement 1:2016. Cette édition constitue une révision technique.

Cette édition inclut les modifications techniques majeures suivantes par rapport à l'édition précédente:

- a) alignement de ce document sur la base des amendements de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et de l'IEC 60601-1:2005/AMD2:2020;
- b) mise à jour des références à l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 et aux normes particulières et collatérales pour les aligner sur les amendements de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 et des autres normes collatérales;
- c) mise à jour des références normatives;
- d) ajout d'une nouvelle exigence relative aux corps solides qui proviennent des PARTIES APPLIQUEES dans le 201.9.5.101;
- e) ajout de la méthode de la lumière rasante dans le 201.12.1.101.7;
- f) clarification des conditions d'essai pour les exigences de CEM dans le 202.7.1.2;
- g) mise à jour des références du Tableau D.4 pour inclure les références IEC spécifiques aux symboles et supprimer le "201.7.6.101" existant de l'"Annexe AA";
- h) addition du 201.12.1.101.7 à l'Annexe AA;
- i) inclusion d'une nouvelle annexe pour couvrir les exigences générales pertinentes en matière de sécurité et de performances du règlement européen (UE) 2017/745 [1]¹ (Annexe BB).
- j) suppression de toutes les références à la méthode de RETRAIT DU CRISTALLIN au moyen de la FRAGMENTATION PAR LIQUEFACTION.

Le texte de cette Norme internationale est issu des documents suivants:

Projet	Rapport de vote
62D/2096/FDIS	62D/2110/RVD

Le rapport de vote indiqué dans le tableau ci-dessus donne toute information sur le vote ayant abouti à son approbation.

La langue employée pour l'élaboration de cette Norme internationale est l'anglais.

Ce document a été rédigé selon les directives ISO/IEC, Partie 2, il a été développé selon les directives ISO/IEC, Partie 1 et les directives ISO/IEC, Supplément IEC, disponibles sous www.iec.ch/members_experts/refdocs. Les principaux types de documents développés par l'IEC sont décrits plus en détail sous www.iec.ch/publications.

Dans le présent document, les caractères d'imprimerie suivants sont utilisés:

- exigences et définitions: caractères romains.
- *modalités d'essai: caractères italiques.*
- indications de nature informative qui apparaissent hors des tableaux, comme les notes, les exemples et les références: petits caractères romains. Le texte normatif à l'intérieur des tableaux est également en petits caractères.
- TERMES DEFINIS A L'ARTICLE 3 DE L'IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 ET L'IEC 60601-1:2005/AMD2:2020, DANS LA PRESENTE NORME PARTICULIERE OU COMME NOTES: PETITES MAJUSCULES.

¹ Les chiffres entre crochets renvoient à la Bibliographie.

Concernant la structure du présent document, le terme:

- “article” désigne l’une des dix-sept sections numérotées dans le sommaire, avec toutes ses subdivisions (par exemple, l’Article 7 inclut les paragraphes 7.1, 7.2, etc.);
- “paragraphe” désigne une subdivision numérotée d’un article (par exemple, le 7.1, le 7.2 et le 7.2.1 sont tous des paragraphes qui appartiennent à l’Article 7).

Dans le présent document, les références à des articles sont précédées du mot “Article” suivi du numéro de l’article concerné. Dans la présente norme particulière, les références aux paragraphes utilisent uniquement le numéro du paragraphe concerné.

Dans le présent document, la conjonction “ou” est utilisée avec la valeur d’un “ou inclusif”, ainsi un énoncé est vrai si une quelconque combinaison des conditions est vraie.

Les formes verbales utilisées dans le présent document sont conformes à l’usage donné à l’Article 7 des Directives ISO/IEC, Partie 2. Pour les besoins du présent document, le modal:

- “devoir” mis au présent de l’indicatif signifie que la satisfaction à une exigence ou à un essai est impérative pour la conformité au présent document;
- “il convient/il est recommandé” signifie que la satisfaction à une exigence ou à un essai est recommandée mais n’est pas obligatoire pour la conformité au présent document;
- “pouvoir” mis au présent de l’indicatif est utilisé pour décrire un moyen admissible pour satisfaire à une exigence ou à un essai.

Lorsqu’un astérisque (*) est utilisé comme premier caractère devant un titre, ou au début d’un titre d’alinéa ou de tableau, il indique l’existence d’une recommandation ou d’une justification à consulter à l’Annexe AA.

Une liste de toutes les parties des séries IEC 60601 et IEC 80601, publiées sous le titre général *Appareils électromédicaux*, se trouve sur le site web de l’IEC.

Le comité a décidé que le contenu de ce document ne sera pas modifié avant la date de stabilité indiquée sur le site web de l’IEC sous webstore.iec.ch dans les données relatives au document recherché. À cette date, le document sera

- reconduit,
- supprimé, ou
- révisé.

INTRODUCTION

Les DISPOSITIFS DE RETRAIT DU CRISTALLIN et les DISPOSITIFS DE VITRECTOMIE sont largement utilisés en ophtalmologie pour opérer le segment antérieur et le segment postérieur de l'œil humain. L'utilisation commerciale de ces APPAREILS ELECTROMEDICAUX a commencé au début des années 1970. Le présent document définit les exigences particulières pour la SECURITE DE BASE et les PERFORMANCES ESSENTIELLES des DISPOSITIFS DE RETRAIT DU CRISTALLIN et des DISPOSITIFS DE VITRECTOMIE, composés de la console d'appareil, des PIECES A MAIN chirurgicales, et des ACCESSOIRES raccordés à ces APPAREILS EM.

Dans beaucoup d'endroits dans le monde, les DISPOSITIFS DE RETRAIT DU CRISTALLIN et les DISPOSITIFS DE VITRECTOMIE sont utilisés en association par les chirurgiens ophtalmiques pour effectuer des PROCEDURES chirurgicales sur le segment antérieur (RETRAIT DU CRISTALLIN) et le segment postérieur (vitréorétinien) pour optimiser les résultats de l'opération. C'est pourquoi le présent document couvre à la fois les DISPOSITIFS DE RETRAIT DU CRISTALLIN et les DISPOSITIFS DE VITRECTOMIE.

Comme toutes les normes particulières de la série IEC 60601-1 sont fondées sur l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020, il est rappelé à l'utilisateur du présent document que la GESTION DES RISQUES joue un rôle important dans l'utilisation de ce document. Il convient d'enregistrer la conformité aux exigences du présent document dans le DOSSIER DE GESTION DES RISQUES afin de garantir que les DANGERS associés au produit ont été pleinement pris en considération.

Consulter l'avant-propos du présent document pour une liste des modifications techniques majeures par rapport à l'édition précédente:

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

201.1 Domaine d'application, objet et normes connexes

L'Article 1 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 s'applique avec les exceptions suivantes:

201.1.1 * Domaine d'application

Remplacement:

La présente partie de l'IEC 80601 s'applique à la SECURITE DE BASE et aux PERFORMANCES ESSENTIELLES des DISPOSITIFS DE RETRAIT DU CRISTALLIN et des DISPOSITIFS DE VITRECTOMIE pour la chirurgie ophtalmique (comme cela est défini en 201.3.209 et 201.3.217) et des ACCESSOIRES liés qui peuvent être raccordés à ces APPAREILS ELECTROMEDICAUX, désignés ci-après comme APPAREILS EM.

Lorsqu'un article ou un paragraphe est spécifiquement destiné à être applicable uniquement aux APPAREILS EM ou uniquement aux SYSTEMES EM, le titre et le contenu de cet article ou de ce paragraphe l'indiquent. Si ce n'est pas le cas, l'article ou le paragraphe s'applique à la fois aux APPAREILS EM et aux SYSTEMES EM, selon le cas.

Les DANGERS inhérents à la fonction physiologique prévue des APPAREILS EM ou des SYSTEMES EM dans le cadre du domaine d'application du présent document ne sont pas couverts par des exigences spécifiques contenues dans le présent document, à l'exception du 7.2.13 de l'IEC 60601-1:2005 et l'IEC 60601-1:2005/AMD2:2020 et du 8.4.1 de l'IEC 60601-1:2005.

NOTE Voir également le 4.2 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020.

201.1.2 Objet

Remplacement:

L'objet de ce document est d'établir les exigences particulières de SECURITE DE BASE et de PERFORMANCES ESSENTIELLES pour les DISPOSITIFS DE RETRAIT DU CRISTALLIN et les DISPOSITIFS DE VITRECTOMIE pour la chirurgie ophtalmique (comme cela est défini en 201.3.209 et 201.3.217) et les ACCESSOIRES associés qui peuvent être raccordés aux APPAREILS EM et doivent être soumis aux essais ensemble ou individuellement.

NOTE Le présent document a été élaboré pour traiter des exigences générales pertinentes en matière de sécurité et de performances du règlement européen (UE) 2017/745 [1] indiquées à l'Annexe BB.

201.1.3 * Normes collatérales

Addition:

Le présent document se rapporte aux normes collatérales applicables énumérées à l'Article 2 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 et l'Article 201.2.

L'IEC 60601-1-2:2014 et l'IEC 60601-1-2:2014/AMD1:2020 s'appliquent comme cela est modifié par l'Article 202. L'IEC 60601-1-3:2008, l'IEC 60601-1-3:2008/AMD1:2013 et l'IEC 60601-1-3:2008/AMD2:2021 [2], l'IEC 60601-1-9:2007, l'IEC 60601-1-9:2007/AMD1:2013 et l'IEC 60601-1-9:2007/AMD2:2020 [3], l'IEC 60601-1-10:2007, l'IEC 60601-1-10:2007/AMD1:2013 et l'IEC 60601-1-10:2007/AMD2:2020 [4], l'IEC 60601-1-11:2015 et l'IEC 60601-1-11:2015/AMD1:2020 [5] et l'IEC 60601-1-12:2014 et l'IEC 60601-1-12:2014/AMD1:2020 [6] ne s'appliquent pas.

201.1.4 Normes particulières

Remplacement:

Dans la série IEC 60601, des normes particulières spécifient des exigences de SECURITE DE BASE et de PERFORMANCES ESSENTIELLES pour les APPAREILS EM et les SYSTEMES EM particuliers. Des normes particulières peuvent modifier, remplacer ou supprimer des exigences contenues dans l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 et dans les normes collatérales applicables en fonction de ce qui est approprié aux APPAREILS EM et aux SYSTEMES EM à l'étude. Une exigence d'une norme particulière prévaut sur une exigence de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 et des normes collatérales applicables.

La numérotation des articles et des paragraphes du présent document correspond à celle de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 avec le préfixe "201" (par exemple, 201.1 du présent document couvre le contenu de l'Article 1 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020) ou à la norme collatérale applicable avec le préfixe "20x", où est (sont) le ou les derniers chiffres du numéro de document de la norme collatérale (par exemple, le 202.4 dans le présent document couvre le contenu de l'Article 4 de la norme collatérale IEC 60601-1-2, le 203.4 concerne le contenu de l'Article 4 de la norme collatérale IEC 60601-1-3, etc.). Les modifications apportées au texte de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 sont précisées en utilisant des termes suivants:

"Remplacement" signifie que l'article ou le paragraphe de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 ou de la norme collatérale applicable est entièrement remplacé par le texte du présent document.

"Addition" signifie que le texte du présent document vient s'ajouter aux exigences de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 ou de la norme collatérale applicable.

"Amendement" signifie que l'article ou le paragraphe de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 ou de la norme collatérale applicable est modifié comme cela est indiqué par le texte du présent document.

Les paragraphes, figures ou tableaux qui s'ajoutent à ceux de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 sont numérotés à partir de 201.101. Toutefois, étant donné que les définitions de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 sont numérotées 3.1 à 3.154, les définitions complémentaires dans le présent document sont numérotées à partir de 201.3.201. Les annexes supplémentaires sont désignées AA, BB, etc., et les éléments supplémentaires aa), bb), etc.

Les paragraphes, figures ou tableaux qui s'ajoutent à ceux d'une norme collatérale sont numérotés à partir de 20x, où "x" est le numéro de la norme collatérale, par exemple 202 pour l'IEC 60601-1-2, 203 pour l'IEC 60601-1-3, etc.

Lorsque le présent document ne comprend pas d'article ou de paragraphe correspondant, l'article ou le paragraphe de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 ou de la norme collatérale applicable, bien qu'il puisse être sans objet, s'applique sans modification. Lorsqu'il est prévu qu'une partie quelconque de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 ou de la norme collatérale applicable, bien que potentiellement pertinente, ne doit pas s'appliquer, cela est expressément mentionné dans le présent document.

201.2 Références normatives

NOTE Une liste des références informatives est donnée dans la bibliographie à la page 77.

L'Article 2 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 s'applique avec l'exception suivante:

Addition:

IEC 60601-1:2005, *Appareils électromédicaux – Partie 1: Exigences générales pour la sécurité de base et les performances essentielles*
IEC 60601-1:2005/AMD1:2012
IEC 60601-1:2005/AMD2:2020

IEC 60601-2-2:2017, *Appareils électromédicaux – Partie 2-2: Exigences particulières pour la sécurité de base et les performances essentielles des appareils d'électrochirurgie à courant haute fréquence et des accessoires d'électrochirurgie à courant haute fréquence*
IEC 60601-2-2:2017/AMD1:2023

IEC 60601-2-22:2019, *Appareils électromédicaux – Partie 2-22: Exigences particulières pour la sécurité de base et les performances essentielles des appareils chirurgicaux, esthétiques, thérapeutiques et de diagnostic à laser*

CISPR 11:2015, *Appareils industriels, scientifiques et médicaux – Caractéristiques de perturbations radioélectriques – Limites et méthodes de mesure*
CISPR 11:2015/AMD1:2016
CISPR 11:2015/AMD2:2019

ISO 11607-1:2019, *Emballages des dispositifs médicaux stérilisés au stade terminal – Partie 1: Exigences relatives aux matériaux, aux systèmes de barrière stérile et aux systèmes d'emballage*

ISO 11607-2:2019, *Emballages des dispositifs médicaux stérilisés au stade terminal – Partie 2: Exigences de validation pour les procédés de formage, scellage et assemblage*

ISO 17664:2017, *Traitement de produits de soins de santé – Informations relatives au traitement des dispositifs médicaux à fournir par le fabricant du dispositif*