

# 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**



**THIS PUBLICATION IS COPYRIGHT PROTECTED**  
**Copyright © 2024 IEC, Geneva, Switzerland**

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either IEC or IEC's member National Committee in the country of the requester. If you have any questions about IEC copyright or have an enquiry about obtaining additional rights to this publication, please contact the address below or your local IEC member National Committee for further information.

Droits de reproduction réservés. Sauf indication contraire, aucune partie de cette publication ne peut être reproduite ni utilisée sous quelque forme que ce soit et par aucun procédé, électronique ou mécanique, y compris la photocopie et les microfilms, sans l'accord écrit de l'IEC ou du Comité national de l'IEC du pays du demandeur. Si vous avez des questions sur le copyright de l'IEC ou si vous désirez obtenir des droits supplémentaires sur cette publication, utilisez les coordonnées ci-après ou contactez le Comité national de l'IEC de votre pays de résidence.

IEC Secretariat  
3, rue de Varembe  
CH-1211 Geneva 20  
Switzerland

Tel.: +41 22 919 02 11  
[info@iec.ch](mailto:info@iec.ch)  
[www.iec.ch](http://www.iec.ch)

#### About the IEC

The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

#### About IEC publications

The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigendum or an amendment might have been published.

#### IEC publications search - [webstore.iec.ch/advsearchform](http://webstore.iec.ch/advsearchform)

The advanced search enables to find IEC publications by a variety of criteria (reference number, text, technical committee, ...). It also gives information on projects, replaced and withdrawn publications.

#### IEC Products & Services Portal - [products.iec.ch](http://products.iec.ch)

Discover our powerful search engine and read freely all the publications previews, graphical symbols and the glossary. With a subscription you will always have access to up to date content tailored to your needs.

#### IEC Just Published - [webstore.iec.ch/justpublished](http://webstore.iec.ch/justpublished)

Stay up to date on all new IEC publications. Just Published details all new publications released. Available online and once a month by email.

#### Electropedia - [www.electropedia.org](http://www.electropedia.org)

The world's leading online dictionary on electrotechnology, containing more than 22 500 terminological entries in English and French, with equivalent terms in 25 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

#### IEC Customer Service Centre - [webstore.iec.ch/csc](http://webstore.iec.ch/csc)

If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: [sales@iec.ch](mailto:sales@iec.ch).

IEC 80601-2-58:2024

<https://standards.iteh.ai/catalog/standards/iso/85c96919-3909-44f1-8c58-9c64d25ecd23/iec-80601-2-58-2024>

#### A propos de l'IEC

La Commission Electrotechnique Internationale (IEC) est la première organisation mondiale qui élabore et publie des Normes internationales pour tout ce qui a trait à l'électricité, à l'électronique et aux technologies apparentées.

#### A propos des publications IEC

Le contenu technique des publications IEC est constamment revu. Veuillez vous assurer que vous possédez l'édition la plus récente, un corrigendum ou amendement peut avoir été publié.

#### Recherche de publications IEC -

[webstore.iec.ch/advsearchform](http://webstore.iec.ch/advsearchform)

La recherche avancée permet de trouver des publications IEC en utilisant différents critères (numéro de référence, texte, comité d'études, ...). Elle donne aussi des informations sur les projets et les publications remplacées ou retirées.

Découvrez notre puissant moteur de recherche et consultez gratuitement tous les aperçus des publications, symboles graphiques et le glossaire. Avec un abonnement, vous aurez toujours accès à un contenu à jour adapté à vos besoins.

#### IEC Just Published - [webstore.iec.ch/justpublished](http://webstore.iec.ch/justpublished)

Restez informé sur les nouvelles publications IEC. Just Published détaille les nouvelles publications parues. Disponible en ligne et une fois par mois par email.

#### Electropedia - [www.electropedia.org](http://www.electropedia.org)

Le premier dictionnaire d'électrotechnologie en ligne au monde, avec plus de 22 500 articles terminologiques en anglais et en français, ainsi que les termes équivalents dans 25 langues additionnelles. Egalement appelé Vocabulaire Electrotechnique International (IEV) en ligne.

#### Service Clients - [webstore.iec.ch/csc](http://webstore.iec.ch/csc)

Si vous désirez nous donner des commentaires sur cette publication ou si vous avez des questions contactez-nous: [sales@iec.ch](mailto:sales@iec.ch).

IEC Products & Services Portal - [products.iec.ch](http://products.iec.ch)



# 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**

INTERNATIONAL  
ELECTROTECHNICAL  
COMMISSION

COMMISSION  
ELECTROTECHNIQUE  
INTERNATIONALE

**Warning! Make sure that you obtained this publication from an authorized distributor.  
Attention! Veuillez vous assurer que vous avez obtenu cette publication via un distributeur agréé.**

# 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

201.6 Classification of ME EQUIPMENT and ME SYSTEMS ..... 12

201.7 ME EQUIPMENT identification, marking and documents ..... 12

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..... 14

201.11 Protection against excessive temperatures and other HAZARDS..... 14

201.12 Accuracy of controls and instruments and protection against hazardous outputs..... 15

201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT ..... 24

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) ..... 24

201.15 Construction of ME EQUIPMENT ..... 24

201.16 \* ME SYSTEMS ..... 24

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS..... 25

202 Electromagnetic disturbances – Requirements and tests ..... 25

Annexes ..... 26

Annex C (informative) Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS..... 26

Annex D (informative) Symbols on marking (See Clause 7)..... 27

Annex AA (informative) Particular guidance and rationale ..... 28

Annex BB (informative) Reference to the general safety and performance requirements..... 34

Bibliography..... 36

Index of defined terms ..... 38

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 ..... 26

Table D.4 – LENS REMOVAL and VITRECTOMY symbols..... 27

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.
- 5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
- 6) All users should ensure that they have the latest edition of this publication.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
- 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.

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]<sup>1</sup> (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](http://www.iec.ch/members_experts/refdocs). The main document types developed by IEC are described in greater detail at [www.iec.ch/publications](http://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.
- 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).

<sup>1</sup> 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](https://webstore.iec.ch) in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn, or
- revised.

<https://standards.iteh.ai/>

<https://standards.iteh.ai/catalog/standards/iso/85c96919-3909-44f1-8c58-9c64d25ecd23/iec-80601-2-58-2024>



## 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.

**iTeh Standards**  
**(<https://standards.iteh.ai>)**  
**Document Preview**

[IEC 80601-2-58:2024](https://standards.iteh.ai/catalog/standards/iec/80601-2-58:2024)

<https://standards.iteh.ai/catalog/standards/iso/85c96919-3909-44f1-8c58-9c64d25ecd23/iec-80601-2-58-2024>



## 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.

[IEC 80601-2-58:2024](https://standards.iteh.ai/catalog/standards/iso/85c96919-3909-44f1-8c58-9c64d25ecd23/iec-80601-2-58-2024)

<https://standards.iteh.ai/catalog/standards/iso/85c96919-3909-44f1-8c58-9c64d25ecd23/iec-80601-2-58-2024>

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.

<https://standards.iteh.ai/catalog/standards/iso/85c96919-3909-44f1-8c58-9c64d25ecd23/iec-80601-2-58-2024>

*"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*

## 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 38.

*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]]

**201.3.205**

**HANDPIECE**

**PROBE**

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

**201.3.206**

**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]]

**201.3.207**

**LASER FRAGMENTATION**

method by which the lens is broken into small fragments using LASER energy

**201.3.208**

**LENS REMOVAL**

removal of unwanted lens tissue

**201.3.209**

**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, or LASER FRAGMENTATION

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

**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 201.3.209.

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, 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

<https://standards.iteh.ai/catalog/standards/iso/85c96919-3909-44f1-8c58-9c64d25ecd23/iec-80601-2-58-2024>

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 can also be used for other ocular surgical purposes.

**201.4 General requirements**

Clause 4 of 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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

### **201.6 Classification of ME EQUIPMENT and ME SYSTEMS**

Clause 6 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

### **201.7 ME EQUIPMENT identification, marking and documents**

Clause 7 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

*Additional subclause:*

#### **201.7.6.101 Additional symbols**

Symbols for LENS REMOVAL and VITRECTOMY.

If symbols for LENS REMOVAL DEVICES and VITRECTOMY DEVICES that have functions such as DIATHERMY, PHACOFRAGMENTATION, VITRECTOMY, and illumination are used, they shall be based on the recommended symbols of Table D.4 and be on the device or near the connection point of the function.