IEC 80601-2-58

Edition 2.1 2016-10

CONSOLIDATED VERSION

VERSION CONSOLIDÉE

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

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

IEC 80601-2-58:2014-09+AMD1:2016-10 CSV(en-fr)

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

ICS 11.040.70

ISBN 978-2-8322-3703-8

IEC 80601-2-58

Edition 2.1 2016-10

REDLINE VERSION

VERSION REDLINE

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CONTENTS

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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This Consolidated version of IEC 80601-2-58 bears the edition number 2.1. It consists of the second edition (2014-09) [documents 62D/1151/FDIS and 62D/1161/RVD] and its amendment 1 (2016-10) [documents 62D/1364/FDIS and 62D/1370/RVD]. The technical content is identical to the base edition and its amendment.

In this Redline version, a vertical line in the margin shows where the technical content is modified by amendment 1. Additions are in green text, deletions are in strikethrough red text. A separate Final version with all changes accepted is available in this publication.

International standard IEC 80601-2-58 has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice, and subcommittee SC 7: Ophthalmic optics and instruments of ISO technical committee 172: Optics and photonics.

It is published as a double logo standard.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, 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 THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, 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 standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, 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 standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;

– “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

– “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 series, published under the general title *Medical electrical equipment,* can be found on the IEC website.

The committee has decided that the contents of the base publication and its amendment will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

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INTRODUCTION

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

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

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

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[1] applies, except as follows:

201.1.1 * Scope

Replacement:

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

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

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

NOTE See also 4.2 of the general standard.

201.1.2 Object

Replacement:

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

201.1.3 * Collateral standards

Addition:

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

IEC 60601-1-2~~:2007~~ applies as modified in Clause 202.~~ All other published collateral standards in the IEC 60601-1 series apply as published.~~ IEC 60601-1-3, IEC 60601-1-10, IEC 60601-1-11, and IEC 60601-1-12 do not apply.

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

201.1.4 Particular standards

Replacement:

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

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

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

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

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

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

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

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

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

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

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

201.2 Normative references

NOTE Informative references are listed in the bibliography beginning on page 32.

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

Replacement:

IEC 60601-1-2~~:2007~~[2], *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic ~~compatibility~~ disturbances – Requirements and tests*

Addition:

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

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

CISPR 11, *Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics – Limits and methods of measurement*

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

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

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

201.3 Terms and definitions

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

NOTE An index of defined terms is found beginning on page 33.

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

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