

American National Standard



ANSI/AAMI/ IEC 80601- 2-58:2014

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

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

Approved 28 July 2014 by
Association for the Advancement of Medical Instrumentation

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American National Standards Institute, Inc.

Abstract: The purpose of this standard is to set appropriate requirements for the safety and performance of lens removal and vitrectomy devices for ophthalmic surgery to reduce the risk of detrimental impact on the medical treatment to an acceptable level for their intended use. The benefit of this standard is to the medical industry, manufacturers, medical regulators, hospitals, clinics, medical users and finally to the patient.

Keywords: electromedical equipment, safety, ophthalmology

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Contents

Page

Glossary of equivalent standards.....	iv
Committee representation.....	v
Background of ANSI/AAMI adoption of IEC 80601-2-58:2014	vi
Foreword.....	vii
Introduction	ix
201.1 Scope, object and related standards.....	1
201.2 Normative references	2
201.3 Terms and definitions	3
201.4 General requirements	5
201.5 General requirements for testing of ME EQUIPMENT	5
201.6 Classification of ME EQUIPMENT and ME SYSTEMS	5
201.7 ME EQUIPMENT identification, marking and documents	5
201.8 Protection against electrical hazards from me equipment.....	7
201.9 Protection against mechanical hazards of ME EQUIPMENT and ME SYSTEMS.....	7
201.10 Protection against unwanted and excessive radiation hazards	7
201.11 Protection against excessive temperatures and other hazards.....	7
201.12 Accuracy of controls and instruments and protection against hazardous outputs	7
201.13 Hazardous situations and fault conditions for ME EQUIPMENT.....	16
201.14 Programmable electrical medical systems (PEMS)	16
201.15 Construction of ME EQUIPMENT	16
201.16 * ME SYSTEMS	16
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	16
202 Electromagnetic compatibility – Requirements and tests.....	16
Annex C (informative) Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS.....	18
Annex AA (informative) Particular guidance and rationale	19
Bibliography	21
Index of defined terms	22

Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. AAMI maintains a current list of each International Standard that has been adopted by AAMI (and ANSI). Available on the AAMI website at the address below, this list gives the corresponding U.S. designation and level of equivalency to the International Standard.

www.aami.org/standards/glossary.pdf

Committee representation

Association for the Advancement of Medical Instrumentation EV/WG 13 - Lens removal and vitrectomy devices working group

The adoption of IEC 80601-2-58 as a revision of ANSI/AAMI/IEC 80601-2-58:2008 was initiated by the AAMI Lens removal and vitrectomy devices working group, which serves as the U.S. TAG (technical advisory group) for IEC/SC 62D/JWG 13. U.S. representatives played an active role in developing the IEC standard.

Committee approval of the standard does not necessarily imply that all committee members voted for its approval.

At the time this document was published, **the AAMI Lens removal and vitrectomy devices Working Group** had the following members:

Members: *Steven T. Charles, Charles Retina Institute*
 Evelyn De La Vega, Bausch & Lomb Inc
 Leonard Eisner, Eisner Safety Consultants
 Kenneth J. Misajet, Jr., Kaiser Permanente
 Dan Modi, Alcon Laboratories Inc
 Dexiu Shi, FDA/CDRH
 Michele L. Stolberg, Optics and Electro-Optics Standards Council

NOTE—Participation by federal agency representatives in the development of this document does not constitute endorsement by the federal government or any of its agencies.

Background of ANSI/AAMI adoption of IEC 80601-2-58:2014

The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The United States is one of the IEC members that took an active role in the development of this technical report.

International Standard 80601-2-58 was developed by the Joint Working Group (JWG) 9, *Lens removal and vitrectomy devices for ophthalmic surgery*, of Subcommittee (SC) 62D, *Electromedical equipment*.

U.S. participation in IEC/SC 62D- ISO/TC 172/SC 7/JWG 9 is organized through the U.S. Technical Advisory Group for IEC/SC 62D, administered by AAMI on behalf of the United States National Committee, which is a committee of the American National Standards Institute (ANSI). AAMI administers the International Secretariat for IEC/SC 62D on behalf of the United States, and U.S. experts made a considerable contribution to this international standard.

This second edition cancels and replaces ANSI/AAMI/IEC 80601-2-58:2008.

AAMI encourages its committees to harmonize their work with international documents as much as possible. The AAMI EV/WG 13, Lens Removal and Vitrectomy Devices Working Group reviewed IEC 80601-2-58 to formulate the U.S. position while the document was being developed. This close collaboration helped gain widespread U.S. consensus on the document. As the U.S. Technical Advisory Group for IEC/SC 62D on 80601-2-58, the AAMI Lens Removal and Vitrectomy Devices Working Group voted to adopt the IEC Technical Report as written.

The concepts incorporated into this standard should not be considered inflexible or static. This standard, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. To remain relevant, it must be modified as technological advances are made and as new data comes to light.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Technical Programs, AAMI, 4301 N Fairfax Drive, Suite 301, Arlington VA 22203-1633.

NOTE—Beginning with the IEC foreword on page vii, ANSI/AAMI/IEC 80601-2-58:2014, *Medical electrical equipment – Part 2-58: Particular requirements for basic safety and essential performance of lens removal and vitrectomy devices for ophthalmic surgery* is identical to IEC 80601-2-58:2014.

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.
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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.

This second edition cancels and replaces the first edition of IEC 80601-2-58 published in 2008.

It is published as a double logo standard.

The text of this standard is based on the following documents:

FDIS	Report on voting
62D/1151/FDIS	62D/1161/RVD

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by 12 P members out of 12 having cast a vote.

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 this publication 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.

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.