IEC 80601-2-58

Edition 2.0 2016-10

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

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(en-fr)

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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

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

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FOREWORD

This amendment 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.

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

FDIS	Report on voting
62D/1364/FDIS	62D/1370/RVD

Full information on the voting for the approval of this particular standard can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by 11 P members out of 11 having cast a vote.

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- withdrawn,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 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.

201.1.3 Collateral standards

Replace the existing title of this subclause by the following new title:

201.1.3 * Collateral standards

Replace the existing text of the second paragraph by the following:

IEC 60601-1-2 applies as modified in Clause 202. IEC 60601-1-3, IEC 60601-1-10, IEC 60601-1-11, and IEC 60601-1-12 do not apply.

201.1.4 Particular standards

Add, in the fourth paragraph of the subclause, "IEC" *before the existing references to "*60601-1-2*" and "*60601-1-3*".*

*Add, in the second sentence of the eight paragraph of the subclause, a comma immediately after "*However*".*

201.2 Normative references

Delete the second footnote of the standard.

Replace the existing reference to IEC 60601-1-2, by the following new reference:

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*

Add, before the existing reference to ISO 11607-1, the following new reference:

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

*Add, in the following references, the reference to Amendment 1 "*AMD1:2014*":*

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*

201.3.205

Replace the existing source by the following new source and add the end of page footnote as follows:

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

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

201.3.208
LENS REMOVAL DEVICE

Replace the existing definition by the following, without modifying the existing Note to entry:

ME EQUIPMENT OR ME SYSTEM designed to remove lens material which incorporates an IRRIGATION and ASPIRATION function, and a mechanism for LENS REMOVAL such as PHACOFRAGMENTATION, LIQUEFACTION, OR LASER FRAGMENTATION

201.7 ME EQUIPMENT identification, marking and documents

Add, after the instruction for subclause 201.7, the following new subcause:

201.7.6.101 * Additional symbols

Addition:

Symbols for LENS REMOVAL and VITRECTOMY.

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

201.7.9.2.12 Cleaning, disinfection, and sterilization

Add, at the end of the last sentence of the subclause, the following reference: [2].

201.11.6.7 Sterilization of ME EQUIPMENT and ME SYSTEMS

*Replace, in the existing text, the references to ISO 11607-1:2006 and ISO 11607-2:2006 by "*ISO 11607-1:2006/AMD1:2014*" and "*ISO 11607-2:2006/AMD1:2014*" respectively.*

201.12.1.101.7 Accuracy of ultrasonic velocity of TIP

Replace the first paragraph by the following:

If the ultrasonic velocity is not specified in the instruction for use, measurement of the ultrasonic velocity of the tip is not required. If an ultrasonic fragmentation function is provided, the ultrasonic velocity of the TIP shall not deviate by more than ± 20 % from the NOMINAL value(s) stated in the instructions for use for each listed configuration. In the case that the ultrasonic velocity is not specified in the instruction for use, measurement of the tip stroke exiting the tip or equivalent shall be made to assure the ultrasonic fragmentation function meets the hazardous output limit (see 201.12.4.101.7 for hazardous output limit).

Add, after the end of item 1) in the list, the following reference to the bibliography "[3]".

Replace the existing text in test method step 2) b) by the following:

b) *verify that the values displayed by the oscilloscope are within ± 20 % of the NOMINAL value(s) for the ultrasonic frequency(ies);*

201.12.1.101.8 Accuracy of velocity of fluid entering eye for LIQUEFACTION

Replace the first paragraph by the following:

If a LIQUEFACTION function is provided, the velocity of fluid entering the eye for LIQUEFACTION shall not deviate by more than ±20 % from the values stated in the instructions for use for each listed configuration. In the case that the velocity of fluid entering the eye for LIQUEFACTION is not specified in the instruction for use, measurement of the fluid velocity or equivalent shall be made to assure the LIQUEFACTION function meets the hazardous output limit (see 201.12.4.101.8 for hazardous output limit).

Replace the formula in Method B, item 7) by the following:

$Vy = (\Delta y + ½\ gt^2)/\ t$

201.13 Hazardous situations and fault conditions for ME EQUIPMENT

Replace the existing title of this subclause by the following new title:

201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT

202 Electromagnetic compatibility – Requirements and tests

Replace the complete text of Clause 202 by the following text:

202 Electromagnetic disturbances – Requirements and tests

IEC 60601-1-2 applies except as follows:

202.5.2.2.2 * Requirements applicable to ME EQUIPMENT and ME SYSTEMS specified for use only in a shielded location SPECIAL ENVIRONMENT

Subclause 5.2.2.2 of IEC 60601-1-2 does not apply.

202.5.2.2.4 Requirements applicable to ME EQUIPMENT that includes RF transmitters

Addition:

If there is a DIATHERMY function, its output shall not be considered an RF transmitter.

202.7 ELECTROMAGNETIC EMISSIONS requirements for ME EQUIPMENT and ME SYSTEMS

202.7.1.2 Operating modes

Insert, after the first paragraph, the following text:

aa) If there is a DIATHERMY function, it shall not be tested for radiated or conducted RF EMISSIONS when the HF output is energized.

bb) If there is a DIATHERMY function, it shall comply with the Class A requirements of CISPR 11 group 1, when it is switched on and in an idle state with the HF output not energized.

cc) The FRAGMENTATION function of the LENS REMOVAL devices and VITRECTOMY devices shall comply with the Class A requirements of CISPR 11 group 1, when it is switched on at its maximum power. If an illumination function is provided, it shall be turned on at its maximum power while the FRAGMENTATION function is tested.

202.8 Electromagnetic IMMUNITY requirements for ME EQUIPMENT and ME SYSTEMS

202.8.1 * General

Insert immediately above Note 5 the following text.

For LENS REMOVAL devices and VITRECTOMY devices, the following degradations shall be considered acceptable because they do not result in unacceptable RISK.

– Intermittent flicker of the display if one is provided with the ME EQUIPMENT or ME SYSTEM.

– Interruption of the output of DIATHERMY, LENS FRAGMENTATION, or ASPIRATION functions or reset into standby mode when clearly indicated on the operation panel of ME EQUIPMENT or ME SYSTEM.

– Change in output power of DIATHERMY, LENS FRAGMENTATION, or ASPIRATION functions as allowed in 201.12.1.101.

Compliance shall be considered to be met if the requirements of IEC 60601-1-2 are met with the above changes.

Annexes

Add, after the existing Annex C, the following new annex:

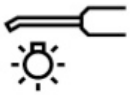
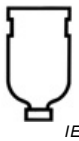
Annex D
(informative)

Symbols on marking (See Clause 7)

Annex D of the general standard applies, except as follows.

Addition:

Table D.4 – LENS REMOVAL and VITRECTOMY symbols

No.	Symbol	Reference	Title
1	 IEC	IEC TR 60878[4]	Electrosurgery, coagulation mode (DIATHERMY)
2	 IEC	See Annex AA, subclause 201.7.6.101	FRAGMENTATION
3	 IEC	See Annex AA, subclause 201.7.6.101	LIQUEFACTION FRAGMENTATION
4	 IEC	See Annex AA, subclause 201.7.6.101	VITRECTOMY
5	 IEC	IEC TR 60878[4]	Illumination
6	 IEC	IEC TR 60878[4]	OCULAR IRRIGATION

Annex AA
(informative)

Particular guidance and rationale

A.A.2 Rationale for particular clauses and subclauses

Add, at the end of the existing 201.1.1, the following new subclause:

Subclause 201.1.3 – Collateral standards

The standards that do not apply to this standard are noted in the below list.

- IEC 60601-1-3 – LENS REMOVAL DEVICES and VITRECTOMY DEVICES are not Diagnostic X-ray equipment
- IEC 60601-1-10 – LENS REMOVAL DEVICES and VITRECTOMY DEVICES do not incorporate therapeutic closed-loop controllers
- IEC 60601-1-11 – LENS REMOVAL DEVICES and VITRECTOMY DEVICES are not used in the home use environment
- IEC 60601-1-12 – LENS REMOVAL DEVICES and VITRECTOMY DEVICES are not used in the emergency medical services environment

Subclause 201.4.3 – ESSENTIAL PERFORMANCE

Replace the complete text of subclause 201.4.3 by the following:

Per IEC 60601-1, definition 3.27, ESSENTIAL PERFORMANCE is performance of a clinical function, other than that related to BASIC SAFETY, where loss or degradation beyond the limits specified by the MANUFACTURER results in an unacceptable RISK. It is noted that it is most easily understood by considering whether its absence or degradation would result in an unacceptable RISK.

In order to achieve its INTENDED USE, LENS REMOVAL DEVICES and VITRECTOMY DEVICES need to perform within certain limits. This particular standard defines those limits on performance of the clinical functions of these systems that are related to BASIC SAFETY, such as limits on hazardous output and accuracy of controls and instruments (201.12). It further provides guidance on ESSENTIAL PERFORMANCE.

– ESSENTIAL PERFORMANCE should not be confused with essential requirements of the European Medical Device Directive 93/42/EEC [5].

– ESSENTIAL PERFORMANCE should not be confused with the essential principles of safety and performance of medical devices per ISO/TR 16142:2006 [6].

LENS REMOVAL DEVICES and VITRECTOMY DEVICES do not have ESSENTIAL PERFORMANCE within the meaning of IEC 60601-1. All of the features and functions of the LENS REMOVAL DEVICES and VITRECTOMY DEVICES were considered, as outlined below, to ensure there were no ESSENTIAL PERFORMANCE for these devices. Assessment of the RISK was made for each of the functions listed in subclause 201.12 with the assumption that the performance would be lost or degraded, and taking into account the severity of the HARM, and probability the HARM would occur. It was found with the application of this RISK MANAGEMENT PROCESS that the RISK is as low as possible – in other words, there is no level of unacceptable RISK to the PATIENTS, OPERATORS, or others.

Following the process outlined in IEC 60601-1, 4.3 for LENS REMOVAL DEVICES and VITRECTOMY DEVICES in general yields the following insight:

– The clinical functions of the devices necessary to achieve their INTENDED USES are those listed in 201.12.1.101 and 201.12.4.101, namely static IRRIGATION pressure, ASPIRATION pressure, DIATHERMY (power and frequency), illumination output, lens fragmentation output (ultrasonic or LIQUEFACTION velocities), and vitreous removal (VITRECTOMY probe cut rate).

– The accuracy of controls specified in 201.12.4.101 constitutes the typical performance limits in both NORMAL CONDITION and SINGLE FAULT CONDITION.

– Typically, the RISK from loss or degradation of the performance beyond these limits is low.

  - Severity of transient or temporary loss or degradation of therapeutic energy output functions – ASPIRATION, DIATHERMY, lens fragmentation and vitreous removal – is very low, as the therapeutic effect is built up over time, and as the OPERATOR (i.e. surgeon) is continually observing and controlling the system outputs for the overall therapeutic effect, not the instantaneous therapeutic rate. The only impact of a transient or temporary degradation of therapeutic energy is a slight increase in treatment time.

  - Severity of permanent loss or degradation of therapeutic energy output functions – ASPIRATION, DIATHERMY, lens fragmentation and vitreous removal – is very low, as the expected impact to the PATIENT is a short delay while an alternative piece of equipment is set up.

  - Severity of transient or temporary loss or degradation of therapeutic supporting output functions – illumination and IRRIGATION – is very low, as the OPERATOR (i.e. surgeon) is continually observing and controlling the system outputs at the surgical site and is in a position to suspend activity briefly in the unlikely event of any observed transient changes.

  - Severity of permanent loss or degradation of therapeutic supporting output functions – illumination and IRRIGATION – is very low, as the expected impact to the PATIENT is a short delay while an alternative piece of equipment is set up.

    Independent degradation of individual functions in response to systemic insults is unlikely, as control of the individual functions is bundled into and shared by common components, such as processors, displays, foot pedals. That is damage to a component that results in degradation of one function would be accompanied by degradation of other elements. Therefore, RISK of degradation of one function, such as IRRIGATION, of two linked functions, such as IRRIGATION and ASPIRATION, in response to systemic stresses, without simultaneous compensating degradation of the other function has an extremely low associated probability and is, therefore, so unlikely as to be unforeseeable.

– Thus, where a clause in the IEC 60601-1 standard or collateral standards requires that ESSENTIAL PERFORMANCE (but not BASIC SAFETY) is to be maintained during a particular test, no additional monitoring is required. Where a clause in a standard requires that both essential performance and basic safety is maintained, only monitoring of BASIC SAFETY elements would be expected, within the appropriate limits as identified in the risk management process.

Where the MANUFACTURER of a LENS REMOVAL DEVICE and VITRECTOMY DEVICE has identified additional unique clinical functionality of their device beyond that identified in this standard as necessary for the device to achieve its intended use, they shall identify that functionality in their risk management system, and proceed to fulfill the process requirements of 4.3 to determine any essential performance associated with that additional clinical functionality.

Some of the elements supporting this evaluation include:

a) The LENS REMOVAL DEVICES and VITRECTOMY DEVICES, are professional use devices, with the operator present / activating the device during use. The device use involves monitoring the patient, and provides feedback to the operator on the device performance. There are no malfunctions of the device that are beyond the response (reaction time) of the operator.

b) Surgery using LENS REMOVAL DEVICES and VITRECTOMY DEVICES can be stopped and restarted at any time during the surgical procedure to mitigate any degradation of performance out of specification. There is no unacceptable risk associated with the failure