IEC 80601-2-58

Edition 3.0 2024-03
REDLINE VERSION

INTERNATIONAL STANDARD

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

IEC 80601-2-58:2024-03 RLV(en)

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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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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.~~208~~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 ~~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.~~208~~209 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*

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 41.

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.~~204~~205
HANDPIECE
PROBE
handheld APPLIED PART, an ACCESSORY of LENS REMOVAL DEVICES or VITRECTOMY DEVICES

201.3.~~205~~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.~~206~~207
LASER FRAGMENTATION
method by which the lens is broken into small fragments using LASER energy

201.3.~~207~~208
LENS REMOVAL
removal of unwanted lens tissue

201.3.~~208~~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~~, LIQUEFACTION~~, or LASER FRAGMENTATION

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

~~**201.3.209**~~
~~**LIQUEFACTION FRAGMENTATION**~~
~~**LIQUEFACTION**~~
~~method by which the lens is broken into small fragments by means of pulses of ophthalmic IRRIGATION solution~~

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.~~208~~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 ~~and LIQUEFACTION~~, 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

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 ~~may~~ can also be used for other ocular surgical purposes.

201.4 General requirements

Clause 4 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:

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 ~~the general standard~~ 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 ~~the general standard~~ 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 ~~the general standard~~ 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

~~*Addition:*~~

Symbols for LENS REMOVAL and VITRECTOMY.

If symbols for LENS REMOVAL DEVICES and VITRECTOMY DEVICES that have functions such as DIATHERMY, ~~FRAGMENTATION, LIQUEFACTION FRAGMENTATION~~ 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.

201.7.9.2.2 Warning and safety notices

Addition:

The instructions for use shall additionally include the following warning and safety notices:

a) a warning to use only recommended TUBING SET(s);

b) if an electrically adjustable ophthalmic IRRIGATION solution support pole is used, a warning not to modify pole height or manually force the pole height because this could cause incorrect indication of bottle height and PATIENT injury;

c) a warning never to intentionally modify HANDPIECES or TIPS (e.g. do not bend, cut, or engrave them) as they could break or malfunction;

d) a warning to the OPERATOR not to touch an activated ultrasonic HANDPIECE TIP, as injuries could occur;

e) if applicable, warnings related to lamp replacement (e.g. RISK of injury, ratings of lamp, damage to lamp, damage to machine, etc.);

f) if applicable, a warning to the OPERATOR that care should be taken to avoid concentrating the output of an illumination module on a small area of the retina for unnecessarily prolonged periods of time due to the potential for PHOTORETINITIS and serious permanent PATIENT injury;

g) if applicable, a warning to the OPERATOR that inadvertent activation of functions that are intended for PRIMING or tuning HANDPIECES while the HANDPIECE is in the eye can create a HAZARDOUS SITUATION that could result in PATIENT injury;

h) where gravity is relevant to performance, the ophthalmic IRRIGATION solution source shall be at or above the PATIENT's eye level;

i) a warning to the OPERATOR to ensure sufficient volume of IRRIGATION solution for the PROCEDURE. The level should be monitored during the PROCEDURE;

j) if applicable, a warning to the OPERATOR to ensure that the maximum capacity of the DRAIN CONTAINER is not exceeded as this could cause a HAZARDOUS SITUATION to the PATIENT.

201.7.9.2.8 Start-up PROCEDURE

Addition:

The instructions for use shall include instructions to perform functional checks of the system before the first use of the day.

201.7.9.2.9 Operating instructions

Addition:

The operating instructions shall additionally include:

a) if applicable, instructions regarding loading, PRIMING, changing, and reloading the TUBING SET(s), and the TUBING SET(s) change interval to maintain the specified performance;

b) if applicable, instructions regarding the use of clamps on a TUBING SET, the avoidance of ophthalmic IRRIGATION solution free flow conditions, and the PROCEDURE to be followed when changing the ophthalmic IRRIGATION solution source;

c) instructions regarding securely attaching plugs, HANDPIECE cables and other connectors.

201.7.9.2.12 Cleaning, disinfection and sterilization

Addition:

For parts that are resterilizable, the information for processing shall be in accordance with ISO 17664:~~2004~~2017. This information shall be provided to the RESPONSIBLE ORGANIZATION or the OPERATOR [9].

201.7.9.2.13 Maintenance

Addition:

The instructions for use shall provide the OPERATOR or RESPONSIBLE ORGANIZATION with a recommendation to inspect all HANDPIECE cables and any cords on a regular basis and a recommendation as to the action to take if damage (e.g. exposed wire, nicks in the insulation, deformation, etc.) is observed.

201.7.9.3.1 General

Addition:

For ME EQUIPMENT and ME SYSTEMS that have a DIATHERMY function the technical description shall include reference to group 2 for the device.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 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:

Additional subclause:

201.9.5.101 Particulate matter from APPLIED PARTS

Particulate matter from APPLIED PARTS shall be assessed for acceptable size and quantity through the RISK MANAGEMENT PROCESS. Compliance shall be determined and documented in the RISK MANAGEMENT FILE.

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 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:

201.10.6 Infrared radiation

Refer to clause 201.12.4.101.5, item 2).

201.10.7 Ultraviolet radiation

Refer to clause 201.12.4.101.5, item 1).

201.11 Protection against excessive temperatures and other HAZARDS

Clause 11 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:

201.11.1.2 Temperature of APPLIED PARTS

201.11.1.2.1 APPLIED PARTS intended to supply heat to a PATIENT

Replacement:

HANDPIECES for DIATHERMY, PHACOFRAGMENTATION, LASER ~~and LIQUEFACTION~~, VITRECTOMY are considered to be APPLIED PARTS intended to supply heat to a PATIENT.

The temperature or clinical effects shall be determined and documented in the RISK MANAGEMENT FILE.

201.11.6.7 Sterilization of ME EQUIPMENT and ME SYSTEMS

Addition:

The packaging for terminally sterilized ACCESSORIES for LENS REMOVAL DEVICES and VITRECTOMY DEVICES shall comply with the requirements of ISO 11607-1:~~2006/AMD1:2014.~~2019. Validation requirements for forming, sealing, and assembly processes for this packaging shall be consistent with ISO 11607-2:~~2006/AMD1:2014~~2019.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

Clause 12 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:

201.12.1 Accuracy of controls and instruments

Additional subclauses:

201.12.1.101 Additional accuracy of controls and instruments requirements

NOTE Additional requirements for accuracy of controls and instruments are detailed in 201.12.1.101.1 to 201.12.1.101.5, 201.12.1.101.7 and 201.12.1.101.~~9~~8.

201.12.1.101.1 Accuracy of ~~static~~ IRRIGATION pressure

~~Static~~ IRRIGATION pressure output shall not deviate from the indicated setting on the LENS REMOVAL DEVICES and VITRECTOMY DEVICES by more than ± 20 % or ± 10 mmHg (± 1,3 kPa) whichever is greater for a specific device in a defined configuration (see 201.12.4.101.1 for hazardous output limit).

Compliance is checked by applying the relevant test method(s) 1 and/or 2:

a) Test method 1 (gravity fed IRRIGATION)

1) Set the test environment temperature to 25 °C ± 5 °C.

2) Install the TUBING SET(s) and PRIME the device in accordance with the MANUFACTURER's instructions for use.

3) Zero the pressure meter reading. Connect the pressure meter to the end of the IRRIGATION tubing and position the pressure meter within ± 2,5 cm of the simulated PATIENT eye level, see Figure 201.101.

4) Initiate the flow of fluid in accordance with the MANUFACTURER's instructions for use.

NOTE 1 If the system uses IV pole height without a claim to IRRIGATION pressure (i.e., if there is no defined PATIENT eye level), then zero the pressure sensor reading with the IV pole at zero while the pressure sensor is at a simulated PATIENT eye level. Use the same zero point (simulated PATIENT eye level) for the verification of the hazardous output IRRIGATION pressure in 201.12.4.101.1.

5) Set the gravity feed reservoir height to 0 cm or the lowest setting and record the pressure meter reading after 5 s.

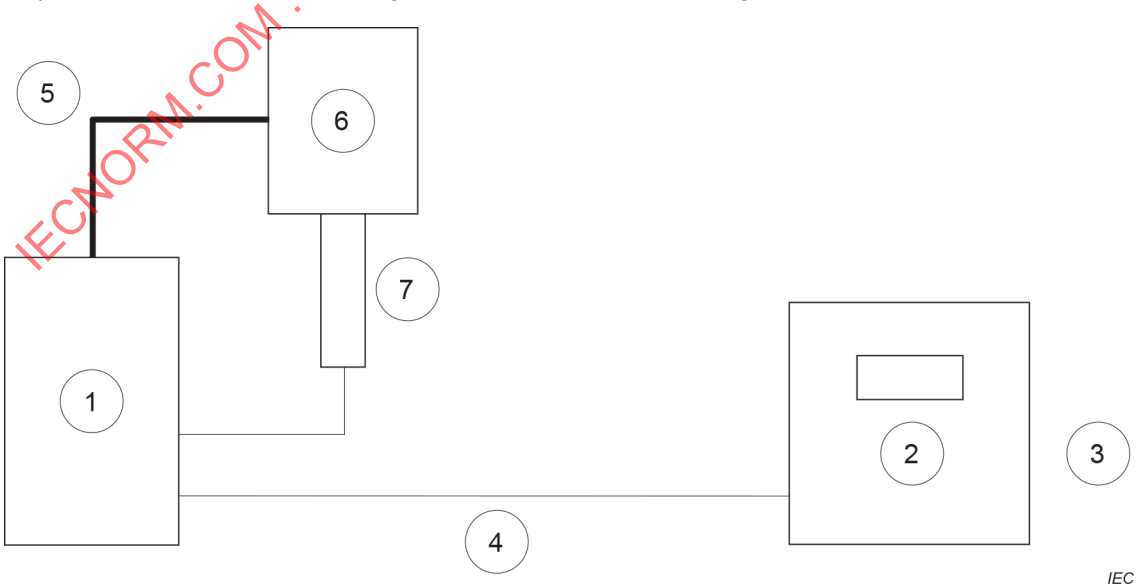
6) Increase the reservoir height by 20 cm and wait for 5 s and record the pressure meter reading.

7) Repeat step 6 until the maximum reservoir height is reached.

8) Record the pressure meter reading at the maximum reservoir height.

9) Repeat the readings at the heights used in steps 5, 6 and 7 as the height is decreased and wait for 5 s and record the pressure meter reading at each point.

10) Confirm that all the readings are within the stated range.



For key, see Table 201.101.

Figure 201.101 – Test method for gravity fed IRRIGATION

b) Test method 2 (pressurized IRRIGATION)

1) Set the test environment temperature to 25 °C ± 5 °C.

2) Install the TUBING SET(S) and PRIME the device in accordance with the MANUFACTURER'S instructions for use.

3) Zero the pressure meter (PM) reading. Connect the pressure meter to the end of the IRRIGATION tubing and position the pressure meter within ± 2,5 cm of the simulated PATIENT eye level, see Figure 201.102.

4) Initiate the flow of fluid in accordance with the MANUFACTURER's instructions for use.

5) Set the test IRRIGATION pressure to 0 mmHg (0 kPa) or lowest setting and record pressure meter reading after 5 s.

6) Increase the test pressure values by 20 mmHg (2,7 kPa).

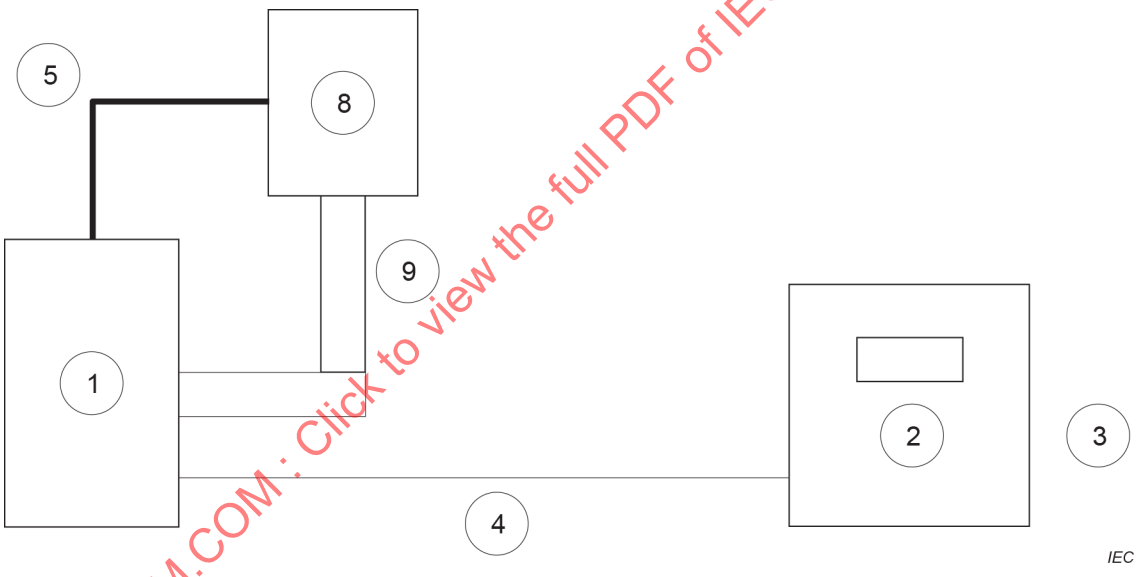
7) Wait for 5 s and record pressure meter reading.

8) Repeat steps 6) and 7) for test pressure setting in 20 mmHg (2,7 kPa) increments until the maximum pressure setting is reached.

9) Repeat the readings used in steps 6), 7) and 8) as the pressure is decreased and wait for 5 s and record the pressure meter reading at each point.

NOTE 2 This ~~may~~ can involve reconnection of the IRRIGATION tubing for the decreasing measurements.

10) Confirm that all the readings are within the stated range.



For key, see Table 201.101.

Figure 201.102 – Test method for pressurized IRRIGATION

201.12.1.101.2 Accuracy of ASPIRATION pressure

ASPIRATION pressure output shall not deviate from the indicated setting on the LENS REMOVAL DEVICES and VITRECTOMY DEVICES by more than ± 20 % or ± 30 mmHg (± 4 kPa) whichever is greater (see 201.12.4.101.2 for hazardous output limit).

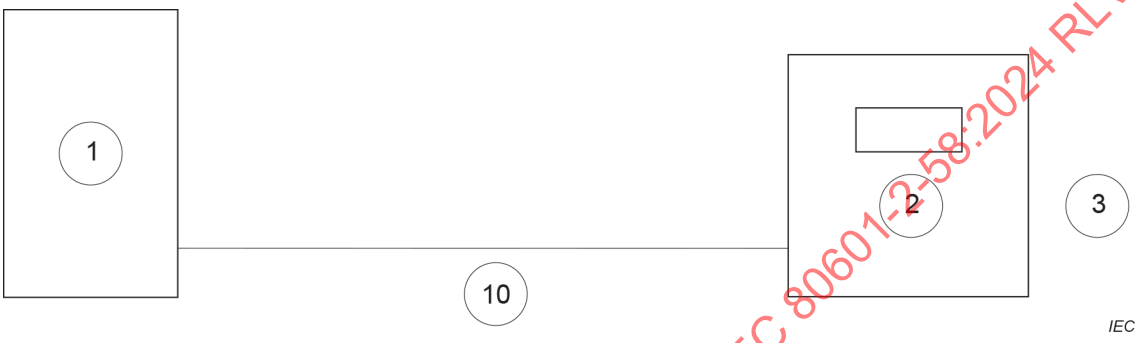
Compliance is checked using the following test method:

Test method: ASPIRATION pressure measurement/display accuracy

1) Install a new TUBING SET to device under test. PRIME the TUBING SET.

2) Zero the pressure meter (PM) reading. Connect the pressure meter to the end of the ASPIRATION tubing and position the pressure meter within ± 2,5 cm of the simulated PATIENT eye level, see Figure 201.103.

3) *In the ASPIRATION mode, adjust the vacuum preset to 50 mmHg (6,7 kPa).*
4) *For flow-based system, set flow rate at least to 10 ml/min.*
5) *Depress (foot) control to activate ASPIRATION vacuum.*
6) *Record the pressure meter reading and the vacuum value displayed on the instrument after 5 s.*
7) *Repeat step 5) and 6) for the test pressure values at 100 mmHg (13,3 kPa) increments steps to the maximum designed vacuum.*
8) *Repeat the tests of step 7) in the reverse order of pressure values.*
9) *Confirm that all the readings are within the stated range.*



For key, see Table 201.101.

Figure 201.103 – Test method for ASPIRATION pressure measurement/display accuracy

Table 201.101 – Key of symbols for Figure 201.101 to Figure 201.103

1	Equipment under test
2	Pressure meter
3	PATIENT eye level
4	IRRIGATION tube
5	Reservoir hanger
6	Gravity feed reservoir
7	Spike
8	Reservoir
9	Pressurized IRRIGATION TUBING SET
10	ASPIRATION tube

201.12.1.101.3 Accuracy of DIATHERMY power

If a DIATHERMY function is provided, the total output power and the actual power as a function of the load resistance shall comply with the requirements of IEC 60601-2-2:2017 and IEC 60601-2-2:2017/AMD1:2023 (see 201.12.4.101.3 for hazardous output limit).

Compliance is checked using the following test method: Test according to the requirements of IEC 60601-2-2:2017 and IEC 60601-2-2:2017/AMD1:2023 and verify the readings are within ranges identified in 201.12.4.101.3 for the DIATHERMY power.

201.12.1.101.4 Accuracy of DIATHERMY frequency

If a DIATHERMY function is provided, the DIATHERMY frequency output shall not deviate by more than ± 20 % from the NOMINAL frequency stated in the instructions for use (see 201.12.4.101.4 for hazardous output limit).

Compliance is checked using the following test method: Connect the DIATHERMY driver signal to an oscilloscope using a high frequency 100X and high impedance 10 MΩ oscilloscope PROBE.

201.12.1.101.5 Accuracy of illumination output

If an illumination function is provided, for settings between 20 % or the lowest setting, whichever is the greater, and maximum output, then the illumination output shall not deviate by more than ± 25 % from the displayed or marked value on the device.

Compliance is checked using the following test method:

1) *Attach illumination HANDPIECE connector to the illumination source.*
2) *Insert distal end of the illumination HANDPIECE into an integrating sphere photometer.*
3) *Turn on illuminator and adjust output to maximum.*
4) *Take the reading after 15 min.*
5) *Repeat the steps above with illuminator output adjusted to 75 %, 50 %, and 25 % of the maximum.*
6) *Confirm that all the readings are within the stated range.*

201.12.1.101.6 * Fragmentation

The LENS REMOVAL DEVICES and VITRECTOMY DEVICES can include one or more fragmentation functions. Apply the relevant requirements and test methods from 201.12.1.101.7 ~~to~~ and 201.12.1.101.~~9~~8.

The MANUFACTURER shall determine through the RISK MANAGEMENT PROCESS if one or more TIP configurations, representing all marketed configurations, are required for testing. Selection of the appropriate TIP configurations for testing shall be confirmed by checking the RISK MANAGEMENT FILE. Any TIP configuration(s) used for testing shall be specified in the instructions for use with the specified performance.

201.12.1.101.7 * Accuracy of ultrasonic velocity of TIP

~~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).~~

If the ultrasonic velocity is not specified in the instruction for use, measurement of the accuracy of the ultrasonic velocity of the TIP is not required. However, measurement of the TIP velocity shall be made to assure the ultrasonic fragmentation function meets the hazardous output limit (see 201.12.4.101.7 for hazardous output limit).

Compliance is checked using the following test methods:

For both methods a camera may be used for visualisation of the image.

1) *Determine stroke using either method: [10]*

a) *Spot method:*

~~a~~*i) Setup the test per Figure 201.104.*

~~b~~*ii) Focus microscope on a point not more than 1,0 mm from the free end of the applicator TIP, which shall be illuminated by a light beam.*

~~c~~*iii) Measure and record its diameter. This will be used for measuring the stroke length.*

~~d~~*iv) When equipment is energized, the point traces a line. The relative orientation of the applicator TIP and the microscope shall be altered until the maximum line length is observed.*

~~e~~*v) The line length (stroke trace), equal to the primary* TIP *vibration excursion ~~to~~ shall be measured to an accuracy of 10 % by means of calibrated eyepiece reticule or micrometer movement.*

~~f~~*vi) Record the stroke length by subtracting the spot diameter from the stroke trace.*

~~g~~*vii) If transverse (torsional) vibrations occur simultaneously, then the point on the applicator describes an elliptical path and length of the major axis of the ellipse shall be measured.*

b) *Shadow light method (longitudinal only):*

i) Setup the test per Figure 201.104.

ii) Suspend needle in water.

iii) Backlight or sidelight applicator TIP (phacoemulsification needle).

iv) Image TIP with a high magnification camera. (Refer to NOTE 1).

v) Turn the TIP so that the point of maximum curvature – the end of the bevel – faces the camera.

vi) Focus to maximize the sharpness of the image of the TIP when it is not moving:

(1) Distance per pixel can be determined by moving the TIP to the top of the screen on a calibrated stage, recording the raster line and displacement of the pixel, then moving it to the bottom of the screen and recording the same two data points. Distance per pixel is the change in displacement, divided by the number of pixels. Record and save this value.

vii) Run the TIP at the target stroke:

(2) The image will be dark at the top of the camera image behind the needle, light at the bottom below the needle, and a partial shadow will be formed in the region where the TIP is moving. There may be a slight curvature to the image, due to the curvature of the end of the needle.

viii) Measure the width of the partial shadow area between the bottom of the dark area and the bottom of the light area, in pixels, and calculate and record the stroke.

NOTE 1 The magnification is high enough if there are enough raster lines across the partial shadow area that the stroke can be estimated when the TIP is running at the minimum desired target stroke. As reflected in Figure 201.105, the full width of the needle will probably not be visible.

NOTE 2 Various image processing software packages are available to assist in this PROCESS.

NOTE 3 A standard optical comparator or projector can be used in place of the microscope with camera in Figure 201.104.

2) *Determine frequency:*

a) *connect the ultrasonic driver signal to an oscilloscope using a high frequency 100X and high impedance 10 MΩ oscilloscope PROBE;*

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

3) *Determine velocity:*

a) *multiply stroke by frequency by π to obtain velocity of device under test.*

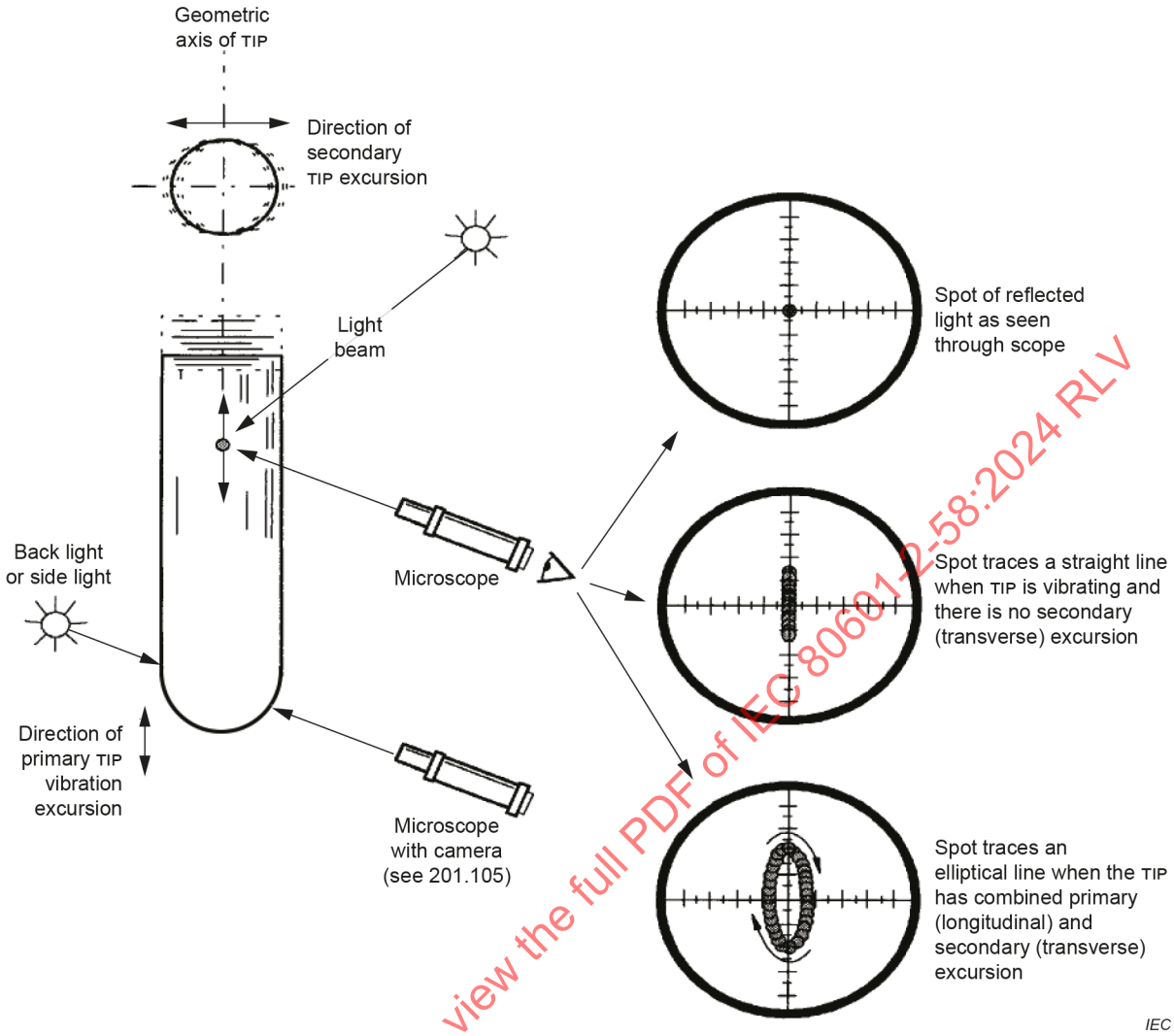


Figure 201.104 – Test method for ultrasonic velocity of TIP accuracy

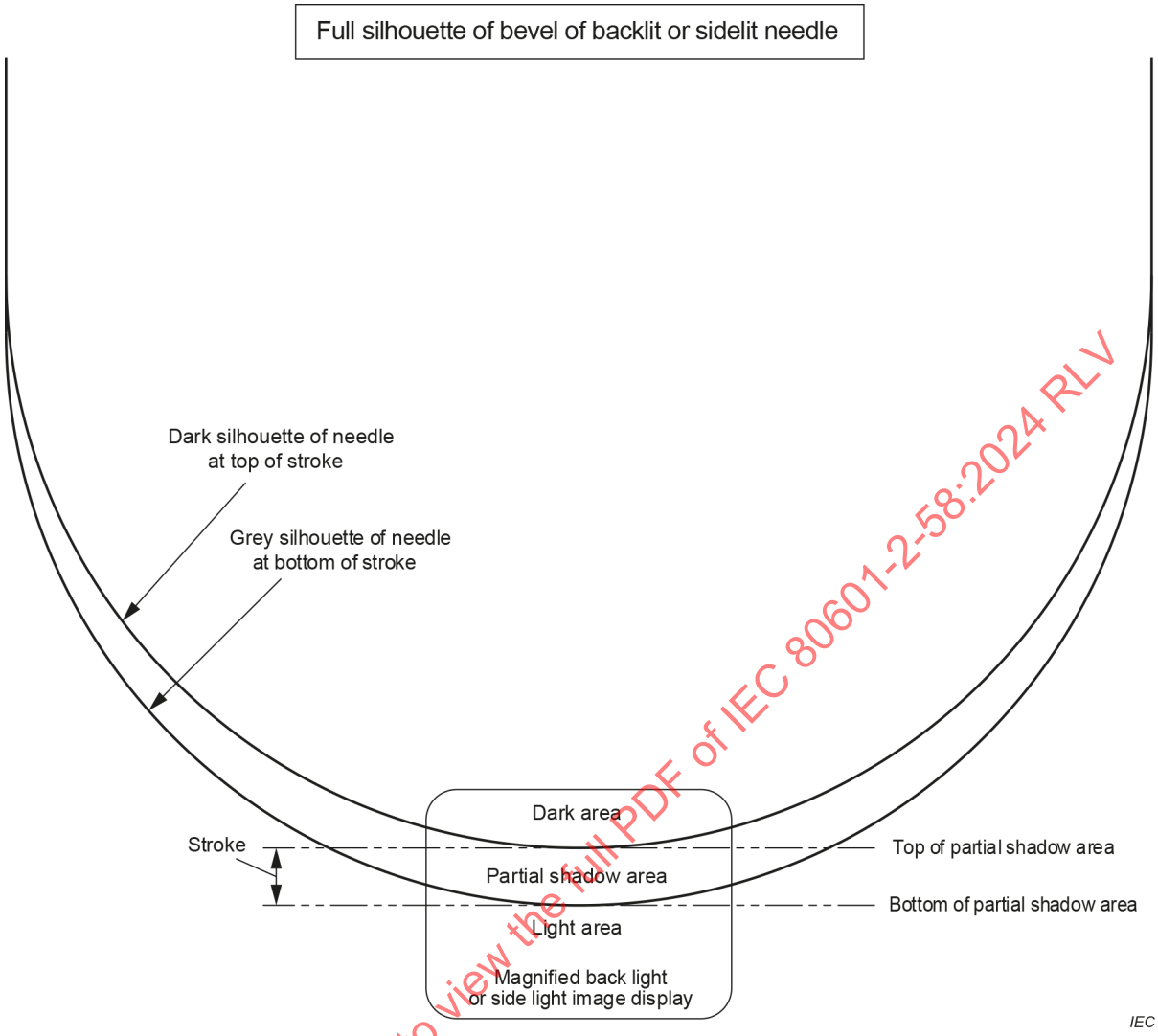


Figure 201.105 – Partial shadow, and camera field of view relative to TIP

~~**201.12.1.101.8 Accuracy of velocity of fluid entering eye for LIQUEFACTION**~~

~~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).~~

~~*Compliance is checked using one of the following test methods:*~~

~~*Method A:*~~

~~*1) Set up the device under test for LIQUEFACTION mode.*~~

~~*2) Position force or pressure transducer distal to the LIQUEFACTION TIP. Place force or pressure transducer perpendicular to the TIP axis at a distance between 0,5 mm and 1,0 mm. (Transducer accuracy shall be within 5 % of the measurement.)*~~

~~*3) Set the device under test into pulsing function.*~~

~~*4) Measure the time past, in µs, from any accessible trigger point to when force or pressure is first indicated on the transducer. A recommended trigger point is the initiation of the electrical power pulse.*~~

~~*5) Stop the pulsing function.*~~

~~*6) Move the transducer a controlled distance between 0,5 mm and 1,0 mm from the LIQUEFACTION TIP on the axis of the TIP.*~~

~~*7) Set the device under test into pulsing function.*~~

~~*8) Measure the time, in microseconds, from the same trigger point to when force or pressure is first indicated on the transducer.*~~

~~*9) Stop the pulsing function.*~~

~~*10) Calculate the fluid velocity by dividing the exact difference in transducer position by the exact difference in time.*~~

~~*Method B:*~~

~~*1) Set up the device under test for LIQUEFACTION mode.*~~

~~*2) Position the tip of liquifaction tip (vertically) into a small beaker on graduation line 200 ml, and adjust to focusing the high speed camera.*~~

~~*3) Set the device under test into pulsing function at 100 %.*~~

~~*4) Record for 30 s to 45 s.*~~

~~*5) Stop the pulsing function.*~~

~~*6) Replay the recorded segment in slow speed (frame by frame) and measure the time in µs at the time liquid exits the tip to the next graduation 175 ml or 150 ml. Distance from 175 ml to 200 ml is approximate 6 mm to 7 mm.*~~

~~*7) Calculate the fluid velocity $Vy = (\Delta y + ½ gt^2)/ t$, where:*~~

~~*g = 9,8 m/s*~~

~~*Δy = travelling distance (m)*~~

~~*t = time from exiting of the tip to the next graduation (s)*~~

201.12.1.101.98 Accuracy of VITRECTOMY PROBE cut rate

If a VITRECTOMY function is provided, the indicated cut rate and actual cut rate shall not deviate by more than ± 20 % from each other or from the limits stated in the instructions for use for each listed configuration (see 201.12.4.101.98 for hazardous output limit).

Compliance is checked using the following test method:

1) Connect VITRECTOMY PROBE to device under test and position under a microscope to observe the port of the VITRECTOMY PROBE.

2) Set a stroboscope flash rate to ± 10 % of the cut rate set on the device under test.

3) Activate the VITRECTOMY PROBE and the stroboscope.

4) Adjust the flash rate of stroboscope to freeze the motion of the cutter in the port.

5) Read the stroboscope frequency to determine the measured cut rate.

6) The difference between the cut rate set on the device under test and the measured cut rate shall not be more than ± 20 %.

201.12.4 Protection against hazardous output

Additional subclauses:

201.12.4.101 Additional requirements for protection against hazardous output

NOTE Additional requirements for protection against hazardous output, in NORMAL CONDITION, are detailed in 201.12.4.101.1 to 201.12.4.101.5, 201.12.4.101.7 and 201.12.4.101.~~9~~8. The ranges stated in these subclauses ~~may be able to~~ can be exceeded based on the MANUFACTURER's RISK MANAGEMENT.

201.12.4.101.1 Hazardous output for ~~static~~ IRRIGATION pressure

The ~~static~~ IRRIGATION pressure output for ME EQUIPMENT shall not exceed 200 mmHg (26,7 kPa).

Compliance is checked using methods 1 and/or 2 in 201.12.1.101.1 as appropriate and verify the reading is within the limit as identified above.

201.12.4.101.2 Hazardous output for ASPIRATION

The relative ASPIRATION vacuum for ME EQUIPMENT shall not exceed 750 mmHg (100 kPa) compared to the ambient atmospheric pressure.

Compliance is checked using the method in 201.12.1.101.2 and verify the reading is within the limit as identified above.

201.12.4.101.3 Hazardous output for DIATHERMY power

If a DIATHERMY function is provided, the DIATHERMY power output for LENS REMOVAL DEVICES and VITRECTOMY DEVICES shall not exceed 40 W.

Compliance is checked according to the relevant method of IEC 60601-2-2:2017 and IEC 60601-2-2:2017/AMD1:2023 and verify the readings are within the 40 W limit as identified above.

201.12.4.101.4 Hazardous output for DIATHERMY frequency

If a DIATHERMY function is provided, the DIATHERMY frequency output for ME EQUIPMENT and ME SYSTEM shall be between 200 kHz and ~~15~~5 MHz.

Compliance is checked using the method in 201.12.1.101.4 and verify the reading is within the range identified above.

201.12.4.101.5 * Hazardous output for Illumination

If an illumination function is provided, the illumination output of the illumination HANDPIECE for ME EQUIPMENT and ME SYSTEM shall comply with the following limit values:

1) Short wavelength limit: the radiant power emitted from the exit aperture of an ~~endo-illuminator~~ ENDOILLUMINATOR in the portion of the spectrum from 305 nm to 400 nm shall have an irradiance no greater than 0,05 mW/cm^2 as measured at a distance of 5 mm in a plane perpendicular to the radiating fibre-optic exiting aperture, when power supply is set to operate at maximum intensity.
2) Long wavelength limit: the radiant power emitted from the exit aperture of an ~~endo-illuminator~~ ENDOILLUMINATOR in the portion of the spectrum from 700 nm to 1 100 nm shall not exceed 100 mW/cm^2, nor shall it exceed irradiance in the range of the spectrum between 380 nm and 700 nm as measured at a distance of the 5 mm in plane perpendicular to the radiating fibre optic exiting aperture when the power supply is set to operate at maximum intensity.

Compliance is checked by verifying the measurement is within the limit identified above, using the following method and Annex AA, 201.12.4.101.5, or by appropriate analysis of filters:

Irradiance shall be determined with the uncertainty less than ±30 %. A spectroradiometer can be used to make these measurements after the light from the ~~endo-illuminator~~ ENDOILLUMINATOR has passed through a 3 mm diameter circular aperture stop positioned 5 mm from the existing aperture of the light guide, or any other 0,26 steradian aperture.

201.12.4.101.6 Fragmentation

The requirements from 201.12.4.101.7 ~~to~~ and 201.12.4.101.~~9~~8 are for methods of performing fragmentation for ophthalmologic surgery. Some of these fragmentation functions may be optional to the ME EQUIPMENT or ME SYSTEM and therefore any functions that are not included with the ME EQUIPMENT or ME SYSTEM shall not be applicable to the appropriate subclauses of 201.12.4.101.7 ~~to~~ and 201.12.4.101.~~9~~8.

201.12.4.101.7 Hazardous output for ultrasonic velocity of TIP

If an ultrasonic fragmentation function is provided, the ultrasonic velocity of TIP OUTPUT for ME EQUIPMENT and ME SYSTEM shall not exceed 20 m/s while operated under full power in water.

Compliance is checked using the method in 201.12.1.101.7 and verify the reading is within the limit identified above.

~~**201.12.4.101.8 Hazardous output for velocity of fluid entering eye for LIQUEFACTION**~~

~~If a LIQUEFACTION function is provided, the VELOCITY OF FLUID ENTERING THE EYE OUTPUT FOR LIQUEFACTION for ME EQUIPMENT and ME SYSTEM shall not exceed 100 m/s while operated under full power.~~

~~*Compliance is checked using the method in subclause 201.12.1.101.8 and verify the reading is within the limit identified above.*~~

201.12.4.101.~~9~~8 Hazardous output for VITRECTOMY PROBE cut rate

If VITRECTOMY PROBE cutting function is provided, the variable output of the VITRECTOMY PROBE cut rate for ME EQUIPMENT and ME SYSTEMS shall have a minimum of 10 cuts/min or greater (except in single cut mode, if available) while operated at minimum setting, in water.

Compliance is checked using the method in 201.12.1.101.~~9~~8 and verify the reading is within the limit identified above.

201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT

Clause 13 of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause 14 of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

201.15 Construction of ME EQUIPMENT

Clause 15 of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

201.16 * ME SYSTEMS

Clause 16 of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

Clause 17 of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

202 Electromagnetic disturbances – Requirements and tests

IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 apply 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 60601-1-2:2014 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~~a) If there is a DIATHERMY function, it shall not be tested for radiated or conducted RF EMISSIONS when the HF output is energized.

~~bb~~b) If there is a DIATHERMY function, it shall comply with the Class A requirements of CISPR 11:2015, CISPR 11:2015/AMD1:2016 and CISPR 11:2015/AMD2:2019 group 1, when it is switched on and in an idle state with the HF output not energized.

~~cc~~c) The ~~FRAGMENTATION function of the LENS REMOVAL devices and~~ VITRECTOMY DEVICES shall comply with the Class A requirements of CISPR 11:2015, CISPR 11:2015/AMD1:2016 and CISPR 11:2015/AMD2:2019 group 1, when it is switched on at its maximum ~~power~~ cut rate. If an illumination function is provided, it shall be turned on ~~at its maximum power~~ while the ~~FRAGMENTATION~~ VITRECTOMY function is tested.

d) For all other functions the settings shall be documented in the test plan of IEC 60601-1-2:2014 and IEC 60601-1-2:2014/A1:2020.

202.8 Electromagnetic IMMUNITY requirements for ME EQUIPMENT and ME SYSTEMS

202.8.1 ~~*~~ General

Addition immediately above Note 5 of 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, if deemed acceptable through the RISK MANAGEMENT PROCESS.

– 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 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 are met with the above changes.

Annexes

The annexes of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 apply, except as follows:

Annex C
(informative)

Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS

Annex C 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.

201.C.5 ACCOMPANYING DOCUMENTS, instructions for use

Addition:

Additional requirements for information to be included in instructions for use of LENS REMOVAL DEVICES and VITRECTOMY DEVICES are found in Table 201.C.101.

Table 201.C.101 – ACCOMPANYING DOCUMENTS, instructions for use of LENS REMOVAL DEVICES and VITRECTOMY DEVICES or their parts

Description of marking	Subclause
TUBING SETS	201.7.9.2.2 a)
Electrically adjustable solution support pole	201.7.9.2.2 b)
Never intentionally modify HANDPIECES or TIPS	201.7.9.2.2 c)
Ultrasonic HANDPIECES	201.7.9.2.2 d)
Lamp replacement	201.7.9.2.2 e)
Concentrated illumination on small area of retina for prolonged periods	201.7.9.2.2 f)
PRIMING or tuning of HANDPIECES while in the eye	201.7.9.2.2 g)
Ophthalmic IRRIGATION solution when gravity is relevant	201.7.9.2.2 h)
Sufficient volume of IRRIGATION solution	201.7.9.2.2 i)
Maximum capacity of DRAIN CONTAINER	201.7.9.2.2 j)
Performance OF ultrasonic velocity of the TIP	201.12.1.101.7
~~Performance of velocity of fluid entering the eye for LIQUEFACTION~~	~~201.12.1.101.8~~
Performance of VITRECTOMY PROBE cut rate	201.12.1.101.~~9~~8
First use of day start-up PROCEDURE	201.7.9.2.8
TUBING SET instructions	201.7.9.2.9 a)
Clamps on a TUBING SET, avoid free flow conditions, and PROCEDURE for changing ophthalmic IRRIGATION solution	201.7.9.2.9 b)
Securely connecting plugs, HANDPIECE cables and other connections	201.7.9.2.9 c)
Processing of resterilizable medical devices	201.7.9.2.12
Maintenance: inspect HANDPIECE cables and cords on a regular basis	201.7.9.2.13
Packaging of terminally sterilized ACCESSORIES	201.11.6.7

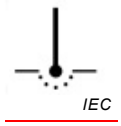
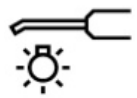
Annex D
(informative)

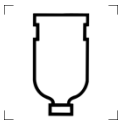
Symbols on marking (See Clause 7)

Annex D 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.

Addition:

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

~~No.~~	~~Symbol~~	~~Reference~~	~~Title~~
~~1~~		~~IEC TR 60878 Error! Reference source not found.~~	~~Electrosurgery, coagulation mode (DIATHERMY)~~
~~2~~		~~See Annex AA, subclause 201.7.6.101~~	~~FRAGMENTATION~~
~~3~~		~~See Annex AA, subclause 201.7.6.101~~	~~LIQUEFACTION FRAGMENTATION~~
~~4~~		~~See Annex AA, subclause 201.7.6.101~~	~~VITRECTOMY~~
~~5~~		~~IEC TR 60878 Error! Reference source not found.~~	~~Illumination~~
~~6~~		~~IEC TR 60878 Error! Reference source not found.~~	~~OCULAR IRRIGATION~~

No.	Symbol	Reference	Title
1		IEC 60417-5782 (2002-10) (IEC TR 60878-5782 [11])	Electrosurgery, coagulation mode (DIATHERMY)
2		IEC 60417-6372 (2017-01) (IEC TR 60878-6372 [11])	Fragmentation (PHACOFRAGMENTATION)
3		IEC 60417-6374 (2016-10) (IEC TR 60878-6374 [11])	VITRECTOMY
4		ISO 7000-1836 (2004-01) (IEC TR 60878-1836 [11])	Fibre-optic HANDPIECE (Illumination)
5		IEC 60417-5747 (2002-10) (IEC TR 60878-5747 [11])	Infusion bottle (OCULAR IRRIGATION)

Annex AA
(informative)

Particular guidance and rationale

~~A.A~~AA.1 General guidance

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, comprised of an equipment console, surgical HANDPIECES, and ACCESSORIES connected to this ME EQUIPMENT.

This particular standard concerns the safety of LENS REMOVAL DEVICES and VITRECTOMY DEVICES for ophthalmic surgery including ESSENTIAL PERFORMANCE. It amends and supplements ~~IEC 60601-1: Medical electrical equipment – Part 1: General requirements for BASIC SAFETY and ESSENTIAL PERFORMANCE~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020. The requirements of this particular standard take priority over those of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and applicable collateral standards.

~~A.A~~AA.2 Rationale for particular clauses and subclauses

The following are rationales for specific clauses and subclauses in this document, with clause and subclause numbers parallel to those in the body of the document.

Subclause 201.1.1 – Scope

The requirements of this document are specified for LENS REMOVAL DEVICES and VITRECTOMY DEVICES, comprised of an equipment console, surgical HANDPIECES, and ACCESSORIES connected to this ME EQUIPMENT.

Subclause 201.1.3 – Collateral standards

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

- IEC 60601-1-3:2008, IEC 60601-1-3:2008/AMD1:2013 and IEC 60601-1-3:2008/AMD2:2021 [2] – LENS REMOVAL DEVICES and VITRECTOMY DEVICES are not Diagnostic X-ray equipment
- IEC 60601-1-9:2007, IEC 60601-1-9:2007/AMD1:2013 and IEC 60601-1-9:2007/AMD2:2020 [3] – LENS REMOVAL DEVICES and VITRECTOMY DEVICES regulatory submissions determine if environmentally conscious design is an acceptable requirement so is not a requirement of the LENS REMOVAL DEVICES and VITRECTOMY DEVICES STANDARD but of the national regulators
- IEC 60601-1-10:2007, IEC 60601-1-10:2007/AMD1:2013 and IEC 60601-1-10:2007/AMD2:2020 [4] – LENS REMOVAL DEVICES and VITRECTOMY DEVICES do not incorporate therapeutic closed-loop controllers
- IEC 60601-1-11:2015 and IEC 60601-1-11:2015/AMD1:2020 [5] – LENS REMOVAL DEVICES and VITRECTOMY DEVICES are not used in the home use environment
- IEC 60601-1-12:2014 and IEC 60601-1-12:2014/AMD1:2020 [6] – LENS REMOVAL DEVICES and VITRECTOMY DEVICES are not used in the emergency medical services environment

Subclause 201.4.3 – ESSENTIAL PERFORMANCE

Per IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 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 document 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 [12].

– ESSENTIAL PERFORMANCE should not be confused with general safety and performance requirements of the European Medical Regulation (EU) 2017/745 [1].

– ESSENTIAL PERFORMANCE should not be confused with the essential principles of safety and performance of medical devices per ~~ISO /TR 16142:2006 [6]~~ ISO 16142-1:2016 [13].

LENS REMOVAL DEVICES and VITRECTOMY DEVICES do not have ESSENTIAL PERFORMANCE within the meaning of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020. 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 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 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 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~~ velocity), 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~~ stresses 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 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 standard or collateral standards requires that ESSENTIAL PERFORMANCE (but not BASIC SAFETY) ~~is to~~ shall 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 document 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 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 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 or degradation of functions or features of the LENS REMOVAL DEVICES and VITRECTOMY DEVICES.

Subclause 201.4.101 – Additional functions

Sections of the more general ISO 15752:2000 [14] standard critical to VITRECTOMY DEVICES originally referenced in the 2008 edition of this particular standard have been incorporated directly into 201.12.4.101.5 to ensure consistency of application in the design of VITRECTOMY DEVICES for ophthalmic surgery. As a result, LENS REMOVAL DEVICES and VITRECTOMY DEVICES should be considered outside the scope of ISO 15752 [14].

~~**Subclause 201.7.6.101 – Additional symbols**~~

~~It is generally recognized by manufacturers of these devices that there is consensus that the symbols number 2, 3 and 4 of Table D.4 represent the surgical functions identified. Symbols number 2, 3, and 4 of Table D.4 are intended as a guideline when designing these symbols. In all cases where standard international symbols exist, they should be used.~~

Subclause 201.12.1.101.6 – Fragmentation

The list of modalities for fragmentation at the time of writing this document encompasses the state of the art for fragmentation.

Subclause 201.12.1.101.7 – Accuracy of ultrasonic velocity of TIP

In the first edition of IEC 80601-2-58:2008 Subclauses 201.12.1.101.7 and 201.12.4.101.1, the first step in the method of checking compliance on the accuracy of the display and limits on output was identified as following one clause and four specific subclauses of IEC 61847:1998 [10].

In the second edition of IEC 80601-2-58:2014, the referenced clauses were removed from IEC 61847:1998 [10] and inserted directly into 201.12.1.101.7. This was done to remove the approach of specifying only part of a standard. The IEC 80601-2-58 committee did not think it was appropriate to apply other parts of IEC 61847:1998 [10], and that it was inappropriate to suggest applying only parts of it. It may be noted that IEC 61847 [10] has not been updated since that time. At that time, Figure 201.104 was added.

Figure 1 of IEC 61847:1998 [10] presents the use of a microscope reticle viewed by a human eye to view the motion of a feature on the TIP as illuminated externally, using either a calibrated reticle or a calibrated micrometer to assess the movement. Nothing in the language either suggests or precludes the use of a camera for viewing the microscopic image, nor does it specify the nature of the point to be observed. Practical experience shows that using a camera will aid in the observation and recording of the result. Furthermore, practical experience shows that nicks on the leading edge of the actuator TIP naturally cause specular reflections that serve as spots, so that tracking the leading edge of the TIP is an effective approach to identifying the spot to be tracked. Finally, practical experience with a variety of illumination types, angles, and camera gains indicate that effective measurements can be made with both side lighting, back lighting, and front lighting.

During the drafting the third edition of the standard, it became clear that some companies would benefit from being made aware of the possibility of using cameras and tracking the edge as a spot to make their measurements. Figure 201.105 has been added to make this possibility more evident.

Subclause 201.12.4.101.5 – Hazardous output for illumination

If a spectroradiometer is used, the intervals should be centered on wavelengths that are a multiple, with a recommended bandwidth of 5 nm or 10 nm as indicated. The recommended measurement units are microwatts per square centimeter per nanometer ($\mu W/cm^2/nm$). This value is recorded and is also multiplied by bandwidth and recorded as microwatts per square centimeter ($\mu W/cm^2$) for that interval. If lamps with narrow spectral lines are used, the bandwidth measurements may need to be less than 5 nm (see ISO 15004-2:2007).

Clause 201.16 – ME SYSTEMS

Non-ME EQUIPMENT that is commonly used with LENS REMOVAL DEVICES and VITRECTOMY DEVICES includes audio/video, information and communication technology equipment in IEC 62368-1:2018 [15], information technology equipment covered in IEC 60950-1:2005, IEC 60950-1:2005/AMD1:2009 and IEC 60950-1:2005/AMD2:2013 [16] and audio and video equipment covered in IEC 60065:2001, IEC 60065:2001/AMD1:2005 and IEC 60065:2001/AMD2:2010 [17] requirements.

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

This particular ME EQUIPMENT or ME SYSTEM is not specified for use only in a shielded location.

~~**Subclause 202.8.1 – General**~~

~~Visual observation of the displayed values of the ME EQUIPMENT or ME SYSTEM is adequate monitoring of the functions.~~

Subclause 202.7.1.2 – Operating modes

Subclause 5.1 of CISPR 11:2015, CISPR 11:2015/AMD1:2016 and CISPR 11:2015/AMD2:2019 (Edition 6.2) provides for the separation of equipment into either group 2 (Equipment that intentionally generates ISM RF frequencies, for, among other purposes, treatment of material), and group 1 (Equipment that is not classified as group 2). DIATHERMY is ISM RF energy for treatment of human tissue. IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 (Edition 4.1) Annex C identifies ME EQUIPMENT and ME SYSTEMS in group 1 (including, for instance, therapeutic ultrasound equipment) and group 2 (including DIATHERMY ME EQUIPMENT). Under all uses without DIATHERMY, LENS REMOVAL / VITRECTOMY equipment would be classified as group 1. The casual observer might conclude that LENS REMOVAL / VITRECTOMY ophthalmic microsystems that include a DIATHERMY function fall within group 2. However, IEC 60601-2-2:2017, subclause 202.7.1.2 a) states that HF equipment shall not be tested for radiated or conducted RF emissions with the HF output energized, and b) states that it shall meet CISPR 11 group 1 limits in these tests. The guidance in IEC 80601-2-58 202.7.1.2 a) and b) restates this so that the user does not have to find this information in IEC 60601-2-2, and is consistent with the guidance in IEC 60601-2-2. 202.7.1.2 c) indicates the operating conditions for the equipment during the test.

Running the ultrasonic lens fragmentation function on the machine during IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 radiated emissions testing is not required, as it has no real impact on the levels measured in the test, and it would require operating the HANDPIECE in a non-typical fashion. Tests can be performed with the HANDPIECE plugged in and the HANDPIECE cable appropriately bundled in a manner consistent with CISPR 11:2015, CISPR 11:2015/AMD1:2016 and CISPR 11:2015/AMD2:2019 Figures 3a and 3b, note B, and Subclause 7.5.2 to include any passive antenna contribution, but with the HANDPIECE in an unpowered, inactive state.

The electrical signal produced to stimulate the ultrasonic HANDPIECE does not significantly contribute to emissions in the 30 MHz to 2,4 GHz range. Failures in the 30 MHz to 2,4 GHz range are largely due to high-frequency narrowband local peaks produced by high-frequency narrowband unmodulated sources, such as clocks and video signals, at their fundamental frequencies as well has the first few harmonics of those frequencies. The HANDPIECE drive signal tends to be in the 25 kHz to 50 kHz range, always below 300 kHz, which is at least two orders of magnitude below the minimum 30 MHz level in the test sweeps. Any harmonic peaks from this contribution have decayed below detectability across this band. Furthermore, any other contribution from the HANDPIECE drive circuit at that level will be significantly suppressed by the large capacitive short created by the crystal capacitance in the HANDPIECE. Informal testing involving observing the noise floor at 30 MHz with the HANDPIECE pulsing on and off at low pulse rates and maximum power does not result in observable shifts in the noise floor.

Where system designs employ high-frequency switch-mode power supplies or amplifier topologies, the potential influence of the high-frequency harmonic content of the supply or amplifier on the radiated disturbance limits of IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 Subclause 7.3 and Table 2 should be considered in the RISK MANAGEMENT FILE and the required test configuration should reflect the results of this consideration, consistent with the requirements of IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020, Subclause 4.3.1.

The typical use time for a HANDPIECE is on the order of a minute or two, much shorter than the time devoted to even one single sweep in the radiated emissions test. The HANDPIECES run at relatively high power levels, and are kept cool by a combination of the fluid flowing through them during surgery and the very low use duty cycle. Failure to keep the HANDPIECES cool during extended continuous stimulation leads to failures of the HANDPIECE, sometimes in the middle of a test. Providing the necessary fluid flow to keep the HANDPIECE cool during the extended testing unnecessarily complicates the test setup, and introduces other elements – such as pump electrical noise and extended partially conductive fluid paths – which could distort the outcome of the radiated emissions test unrealistically.

Because the lens fragmentation HANDPIECE drive is unlikely to contribute to emissions in the band under test, and because the steps necessary to run the circuit for the time periods required for the emissions tests, it is unnecessary to run the lens fragmentation HANDPIECE during the radiated emissions test.

The lens fragmentation function can be conveniently run during the conducted emissions test, which takes much less time and is looking at much lower frequencies in the power supply current waveform.

During immunity testing, the primary RISK is changes at the signal level to the system messages controlling commanded output levels. These changes are as likely to happen on any given function – for instance, ASPIRATION or bipolar – as they are on any other function. Furthermore, in contemporary machines, changes to the drive level will be reflected as changes in the output on the display. Therefore, it is acceptable for the MANUFACTURER to identify any continuous level analog surgical output function they choose to monitor per the MANUFACTURER's test plan.

Annex BB
(informative)

Reference to the general safety and performance requirements

This document has been prepared to support the general safety and performance requirements of regulation (EU) 2017/745 [1].

Conformance with this document provides one means of demonstrating conformance with the specific general safety and performance requirements (GSPRs) of regulation (EU) 2017/745 [1]. Other means are possible. Table BB.1 maps the clauses and subclauses of this document with the general safety and performance requirements of regulation (EU) 2017/745 [1].

NOTE When a general safety and performance requirement does not appear in Table BB.1, it means that it is not addressed by this document.

Table BB.1 – Correspondence between this document and the general safety and performance requirements

General safety and performance requirements of regulation (EU) 2017/745, Annex I [1]	Corresponding clause(s)/sub-clause(s) of this document	Qualifying remarks/Notes
10.6	201.9.5.101	Only the part of GSPR 10.6 relating to design is addressed for the PATIENT.
11.4	201.11.6.7	Only the part of GSPR 11.4 relating to design & packaging are addressed.
14.2 b)	202.5.2.2.2, 202.5.2.2.4, 202.7 (all), 202.8 (all)	Only the part of GSPR 14.2 b) relating to design is addressed.
14.2 f)	202.5.2.2.2, 202.5.2.2.4, 202.7 (all), 202.8 (all)	Only the part of GSPR 14.2 f) relating to design is addressed.
16.3	201.4.101, 201.10 (all)	Only the part of GSPR 16.3 relating to design is addressed. For sub-clause 201.4.101 only IEC 60601-2-22 is relevant.
18.5	202.7 (all), 202.8 (all)	Only the part of GSPR 18.5 relating to design is addressed.
18.6	202.8 (all)	Only the part of GSPR 18.6 relating to design is addressed.
21.1	201.4.101, 201.12.1.101 (all)	Only the protection of the PATIENT is covered. For sub-clause 201.4.101 only IEC 60601-2-22 is relevant.
21.2	201.4.101, 201.12.4.101 (all)	For sub-clause 201.4.101 only IEC 60601-2-22 is relevant.
23.1	201.7.9.2.2, 201.7.9.2.8, 201.7.9.2.9, 201.7.9.2.12, 201.7.9.2.13, 201.7.9.3.1	This is for the first full paragraph of GSPR 23.1.
23.1 g)	201.7.9.2.2	
23.1 h)	201.7.6.101	
23.2 k)	201.11.6.7, 201.7.9.2.12	
23.2 l)	201.11.6.7	
23.2 n)	201.11.6.7	
23.2 o)	201.7.9.2.12	
23.3 a)	201.11.6.7	
23.3 b)	201.11.6.7	

General safety and performance requirements of regulation (EU) 2017/745, Annex I [1]	Corresponding clause(s)/sub-clause(s) of this document	Qualifying remarks/Notes
23.3 c)	201.11.6.7	
23.3 d)	201.11.6.7	
23.3 e)	201.11.6.7	
23.3 i)	201.11.6.7	
23.3 j)	201.11.6.7	
23.4 a)	201.11.6.7, 201.7.9.2.12	
23.4 g)	201.7.9.2.2	
23.4 i)	201.7.9.2.8, 201.7.9.2.9 (a), 201.7.9.2.9 (c), 201.7.9.2.12, 201.7.9.2.13	
23.4 k)	201.7.9.2.2 e), 201.7.9.2.8, 201.7.9.2.12, 201.7.9.2.13	
23.4 m)	201.7.9.2.12, 2017.9.2.13	The preparation of parts for reuse is considered per Subclause 201.7.9.2.13.
23.4 n)	201.7.9.2.12, 201.7.9.2.13	The preparation of parts for reuse is considered per Subclause 201.7.9.2.13.
23.4 p)	201.11.6.7	
23.4 s)	201.7.9.2.2 g)	

Bibliography

[1] (EU) 2017/745, (2017) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices. *OJ L 117, Official Journal of the European Union,* pp. 1-175

[2] IEC 60601-1-3:2008, *Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment*
IEC 60601-1-3:2008/AMD1:2013
IEC 60601-1-3:2008/AMD2:2021

[3] IEC 60601-1-9:2007, *Medical electrical equipment – Part 1-9: General requirements for basic safety and essential performance – Collateral Standard: Requirements for environmentally conscious design*
IEC 60601-1-9:2007/AMD1:2013
IEC 60601-1-9:2007/AMD2:2020

[4] IEC 60601-1-10:2007, *Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers*
IEC 60601-1-10:2007/AMD1:2013
IEC 60601-1-10:2007/AMD2:2020

[5] IEC 60601-1-11:2015, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*
IEC 60601-1-11:2015/AMD1:2020

[6] IEC 60601-1-12:2014, *Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment*
IEC 60601-1-12:2014/AMD1:2020

[7] ISO 15004-2:2007, *Ophthalmic instruments – Fundamental requirements and test methods – Part 2: Light hazard protection*

[8] IEC 60825-1:2014, *Safety of laser products – Part 1: Equipment classification and requirements*

[9] *Recommended Practices for Cleaning and Sterilizing Intraocular Surgical Instruments*, American Society of Cataract and Refractive Surgery Ad Hoc Task Force on Cleaning and Sterilization of Intraocular Surgical Instruments, February 16, 2007

[10] IEC 61847:1998, *Ultrasonics – Surgical systems – Measurement and declaration of the basic output characteristics*

[11] IEC TR 60878, *Graphical symbols for electrical equipment in medical practice*

[12] Council Directive 93/42/EEC of 14 June 1993 *concerning medical devices*, amended by: Directive 98/79/EC (27 October 1998), Directive 2000/70/EC (16 November 2000), Directive 2001/104/EC (7 December 2001), Regulation (EC) No.1882/2003 (29 September 2003), Directive 2007/47/EC (5 September 2007)

[13] ISO 16142-1:2016, *Medical devices – Recognized essential principles of safety and performance of medical devices – Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards*

[14] ISO 15752:2000, *Ophthalmic instruments – Endoilluminators – Fundamental requirements and test methods for optical radiation safety*

[15] IEC 62368-1:2018, *Audio/video, information and communication technology equipment – Part 1: Safety requirements*

[16] IEC 60950-1:2005, *Information technology equipment – Safety – Part 1: General requirements*
IEC 60950-1:2005/AMD1:2009
IEC 60950-1:2005/AMD2:2013

[17] IEC 60065:2001, *Audio, video and similar electronic apparatus – Safety requirements*
IEC 60065:2001/AMD1:2005
IEC 60065:2001/AMD2:2010

Index of defined terms

IEC 80601-2-58

Edition 3.0 2024-03

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

IEC 80601-2-58:2024-03(en-fr)

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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

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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.

– 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*

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

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.

201.7.9.2.2 Warning and safety notices

Addition:

The instructions for use shall additionally include the following warning and safety notices:

a) a warning to use only recommended TUBING SET(s);

b) if an electrically adjustable ophthalmic IRRIGATION solution support pole is used, a warning not to modify pole height or manually force the pole height because this could cause incorrect indication of bottle height and PATIENT injury;

c) a warning never to intentionally modify HANDPIECES or TIPS (e.g. do not bend, cut, or engrave them) as they could break or malfunction;

d) a warning to the OPERATOR not to touch an activated ultrasonic HANDPIECE TIP, as injuries could occur;

e) if applicable, warnings related to lamp replacement (e.g. RISK of injury, ratings of lamp, damage to lamp, damage to machine, etc.);

f) if applicable, a warning to the OPERATOR that care should be taken to avoid concentrating the output of an illumination module on a small area of the retina for unnecessarily prolonged periods of time due to the potential for PHOTORETINITIS and serious permanent PATIENT injury;

g) if applicable, a warning to the OPERATOR that inadvertent activation of functions that are intended for PRIMING or tuning HANDPIECES while the HANDPIECE is in the eye can create a HAZARDOUS SITUATION that could result in PATIENT injury;

h) where gravity is relevant to performance, the ophthalmic IRRIGATION solution source shall be at or above the PATIENT's eye level;

i) a warning to the OPERATOR to ensure sufficient volume of IRRIGATION solution for the PROCEDURE. The level should be monitored during the PROCEDURE;

j) if applicable, a warning to the OPERATOR to ensure that the maximum capacity of the DRAIN CONTAINER is not exceeded as this could cause a HAZARDOUS SITUATION to the PATIENT.

201.7.9.2.8 Start-up PROCEDURE

Addition:

The instructions for use shall include instructions to perform functional checks of the system before the first use of the day.

201.7.9.2.9 Operating instructions

Addition:

The operating instructions shall additionally include:

a) if applicable, instructions regarding loading, PRIMING, changing, and reloading the TUBING SET(s), and the TUBING SET(s) change interval to maintain the specified performance;

b) if applicable, instructions regarding the use of clamps on a TUBING SET, the avoidance of ophthalmic IRRIGATION solution free flow conditions, and the PROCEDURE to be followed when changing the ophthalmic IRRIGATION solution source;

c) instructions regarding securely attaching plugs, HANDPIECE cables and other connectors.

201.7.9.2.12 Cleaning, disinfection and sterilization

Addition:

For parts that are resterilizable, the information for processing shall be in accordance with ISO 17664:2017. This information shall be provided to the RESPONSIBLE ORGANIZATION or the OPERATOR [9].

201.7.9.2.13 Maintenance

Addition:

The instructions for use shall provide the OPERATOR or RESPONSIBLE ORGANIZATION with a recommendation to inspect all HANDPIECE cables and any cords on a regular basis and a recommendation as to the action to take if damage (e.g. exposed wire, nicks in the insulation, deformation, etc.) is observed.

201.7.9.3.1 General

Addition:

For ME EQUIPMENT and ME SYSTEMS that have a DIATHERMY function the technical description shall include reference to group 2 for the device.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

Additional subclause:

201.9.5.101 Particulate matter from APPLIED PARTS

Particulate matter from APPLIED PARTS shall be assessed for acceptable size and quantity through the RISK MANAGEMENT PROCESS. Compliance shall be determined and documented in the RISK MANAGEMENT FILE.

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.10.6 Infrared radiation

Refer to clause 201.12.4.101.5, item 2).

201.10.7 Ultraviolet radiation

Refer to clause 201.12.4.101.5, item 1).

201.11 Protection against excessive temperatures and other HAZARDS

Clause 11 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.11.1.2 Temperature of APPLIED PARTS

201.11.1.2.1 APPLIED PARTS intended to supply heat to a PATIENT

Replacement:

HANDPIECES for DIATHERMY, PHACOFRAGMENTATION, LASER, VITRECTOMY are considered to be APPLIED PARTS intended to supply heat to a PATIENT.

The temperature or clinical effects shall be determined and documented in the RISK MANAGEMENT FILE.

201.11.6.7 Sterilization of ME EQUIPMENT and ME SYSTEMS

Addition:

The packaging for terminally sterilized ACCESSORIES for LENS REMOVAL DEVICES and VITRECTOMY DEVICES shall comply with the requirements of ISO 11607-1:2019. Validation requirements for forming, sealing, and assembly processes for this packaging shall be consistent with ISO 11607-2:2019.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

Clause 12 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.12.1 Accuracy of controls and instruments

Additional subclauses:

201.12.1.101 Additional accuracy of controls and instruments requirements

NOTE Additional requirements for accuracy of controls and instruments are detailed in 201.12.1.101.1 to 201.12.1.101.5, 201.12.1.101.7 and 201.12.1.101.8.

201.12.1.101.1 Accuracy of IRRIGATION pressure

IRRIGATION pressure output shall not deviate from the indicated setting on the LENS REMOVAL DEVICES and VITRECTOMY DEVICES by more than ± 20 % or ± 10 mmHg (± 1,3 kPa) whichever is greater for a specific device in a defined configuration (see 201.12.4.101.1 for hazardous output limit).

Compliance is checked by applying the relevant test method(s) 1 and/or 2:

a) Test method 1 (gravity fed IRRIGATION)

1) Set the test environment temperature to 25 °C ± 5 °C.

2) Install the TUBING SET(s) and PRIME the device in accordance with the MANUFACTURER's instructions for use.

3) Zero the pressure meter reading. Connect the pressure meter to the end of the IRRIGATION tubing and position the pressure meter within ± 2,5 cm of the simulated PATIENT eye level, see Figure 201.101.

4) Initiate the flow of fluid in accordance with the MANUFACTURER's instructions for use.

NOTE 1 If the system uses IV pole height without a claim to IRRIGATION pressure (i.e., if there is no defined PATIENT eye level), then zero the pressure sensor reading with the IV pole at zero while the pressure sensor is at a simulated PATIENT eye level. Use the same zero point (simulated PATIENT eye level) for the verification of the hazardous output IRRIGATION pressure in 201.12.4.101.1.

5) *Set the gravity feed reservoir height to 0 cm or the lowest setting and record the pressure meter reading after 5 s.*

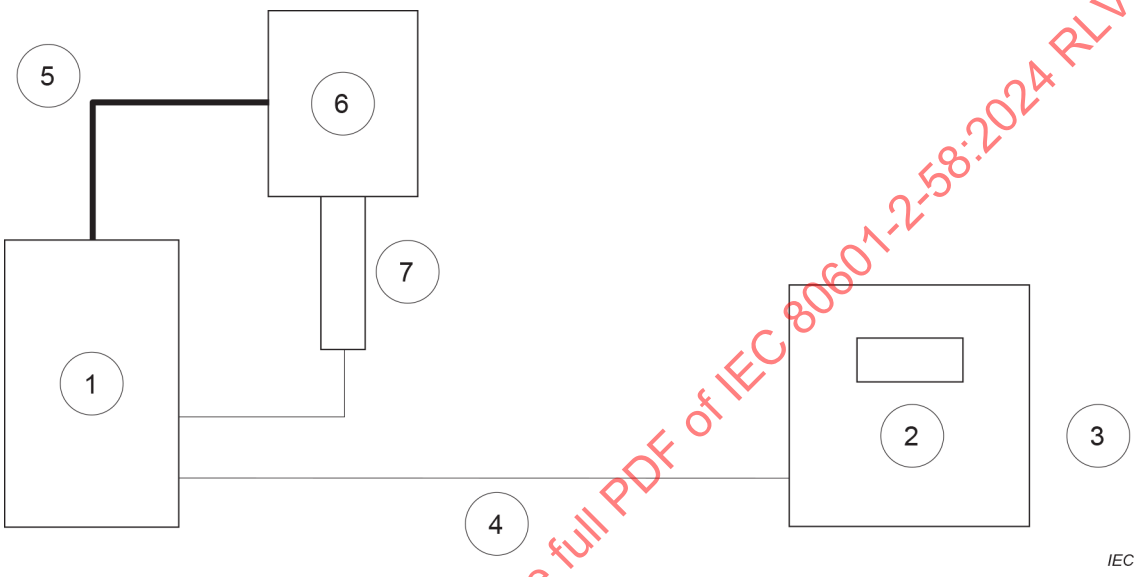
6) *Increase the reservoir height by 20 cm and wait for 5 s and record the pressure meter reading.*

7) *Repeat step 6 until the maximum reservoir height is reached.*

8) *Record the pressure meter reading at the maximum reservoir height.*

9) *Repeat the readings at the heights used in steps 5, 6 and 7 as the height is decreased and wait for 5 s and record the pressure meter reading at each point.*

10) *Confirm that all the readings are within the stated range.*



For key, see Table 201.101.

Figure 201.101 – Test method for gravity fed IRRIGATION

b) *Test method 2 (pressurized IRRIGATION)*

1) *Set the test environment temperature to 25 °C ± 5 °C.*

2) *Install the TUBING SET(S) and PRIME the device in accordance with the MANUFACTURER'S instructions for use.*

3) *Zero the pressure meter (PM) reading. Connect the pressure meter to the end of the IRRIGATION tubing and position the pressure meter within ± 2,5 cm of the simulated PATIENT eye level, see Figure 201.102.*

4) *Initiate the flow of fluid in accordance with the MANUFACTURER's instructions for use.*

5) *Set the test IRRIGATION pressure to 0 mmHg (0 kPa) or lowest setting and record pressure meter reading after 5 s.*

6) *Increase the test pressure values by 20 mmHg (2,7 kPa).*

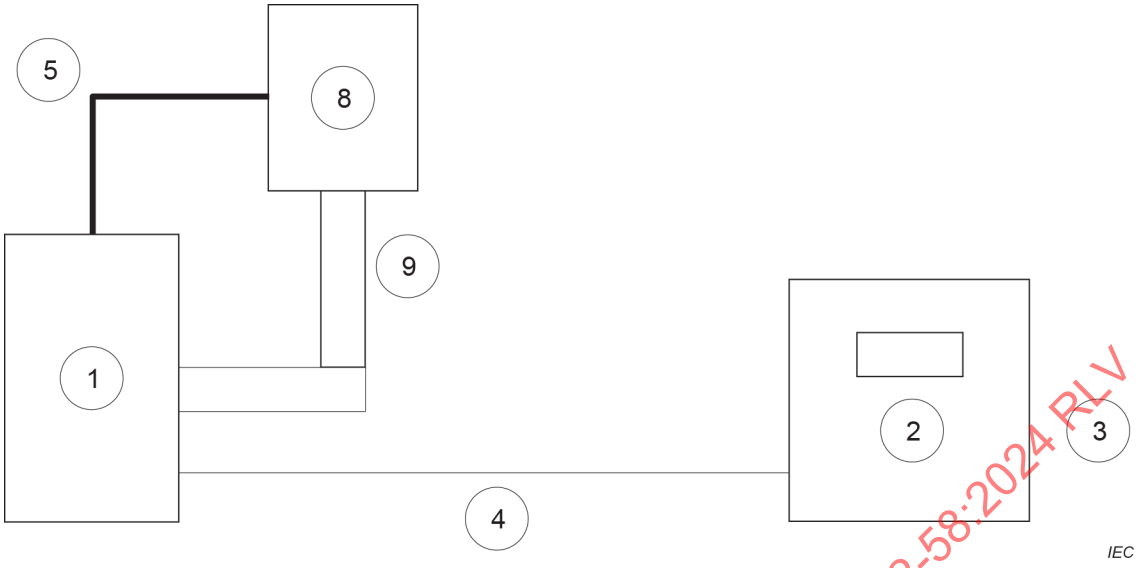
7) *Wait for 5 s and record pressure meter reading.*

8) *Repeat steps 6) and 7) for test pressure setting in 20 mmHg (2,7 kPa) increments until the maximum pressure setting is reached.*

9) *Repeat the readings used in steps 6), 7) and 8) as the pressure is decreased and wait for 5 s and record the pressure meter reading at each point.*

NOTE 2 This can involve reconnection of the IRRIGATION tubing for the decreasing measurements.

10) *Confirm that all the readings are within the stated range.*



For key, see Table 201.101.

Figure 201.102 – Test method for pressurized IRRIGATION

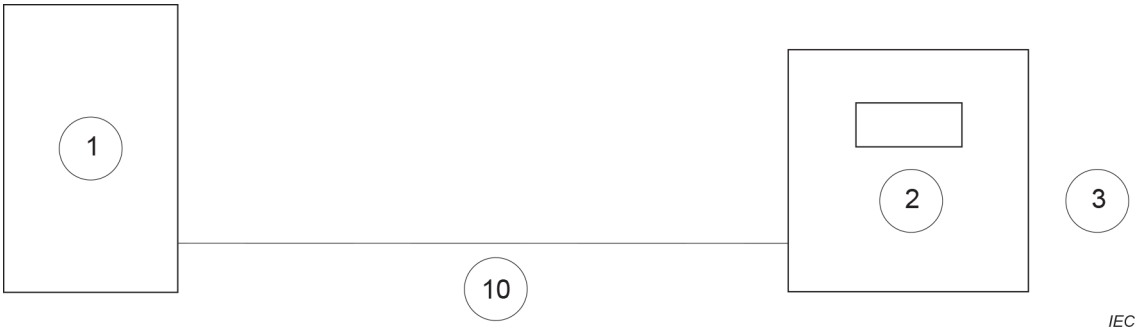
201.12.1.101.2 Accuracy of ASPIRATION pressure

ASPIRATION pressure output shall not deviate from the indicated setting on the LENS REMOVAL DEVICES and VITRECTOMY DEVICES by more than ± 20 % or ± 30 mmHg (± 4 kPa) whichever is greater (see 201.12.4.101.2 for hazardous output limit).

Compliance is checked using the following test method:

Test method: ASPIRATION pressure measurement/display accuracy

1) *Install a new TUBING SET to device under test. PRIME the TUBING SET.*
2) *Zero the pressure meter (PM) reading. Connect the pressure meter to the end of the ASPIRATION tubing and position the pressure meter within ± 2,5 cm of the simulated PATIENT eye level, see Figure 201.103.*
3) *In the ASPIRATION mode, adjust the vacuum preset to 50 mmHg (6,7 kPa).*
4) *For flow-based system, set flow rate at least to 10 ml/min.*
5) *Depress (foot) control to activate ASPIRATION vacuum.*
6) *Record the pressure meter reading and the vacuum value displayed on the instrument after 5 s.*
7) *Repeat step 5) and 6) for the test pressure values at 100 mmHg (13,3 kPa) increments steps to the maximum designed vacuum.*
8) *Repeat the tests of step 7) in the reverse order of pressure values.*
9) *Confirm that all the readings are within the stated range.*



For key, see Table 201.101.

Figure 201.103 – Test method for ASPIRATION pressure measurement/display accuracy

Table 201.101 – Key of symbols for Figure 201.101 to Figure 201.103

1	Equipment under test
2	Pressure meter
3	PATIENT eye level
4	IRRIGATION tube
5	Reservoir hanger
6	Gravity feed reservoir
7	Spike
8	Reservoir
9	Pressurized IRRIGATION TUBING SET
10	ASPIRATION tube

201.12.1.101.3 Accuracy of DIATHERMY power

If a DIATHERMY function is provided, the total output power and the actual power as a function of the load resistance shall comply with the requirements of IEC 60601-2-2:2017 and IEC 60601-2-2:2017/AMD1:2023 (see 201.12.4.101.3 for hazardous output limit).

Compliance is checked using the following test method: Test according to the requirements of IEC 60601-2-2:2017 and IEC 60601-2-2:2017/AMD1:2023 and verify the readings are within ranges identified in 201.12.4.101.3 for the DIATHERMY power.

201.12.1.101.4 Accuracy of DIATHERMY frequency

If a DIATHERMY function is provided, the DIATHERMY frequency output shall not deviate by more than ± 20 % from the NOMINAL frequency stated in the instructions for use (see 201.12.4.101.4 for hazardous output limit).

Compliance is checked using the following test method: Connect the DIATHERMY driver signal to an oscilloscope using a high frequency 100X and high impedance 10 MΩ oscilloscope PROBE.

201.12.1.101.5 Accuracy of illumination output

If an illumination function is provided, for settings between 20 % or the lowest setting, whichever is the greater, and maximum output, then the illumination output shall not deviate by more than ± 25 % from the displayed or marked value on the device.

Compliance is checked using the following test method:

1) *Attach illumination HANDPIECE connector to the illumination source.*
2) *Insert distal end of the illumination HANDPIECE into an integrating sphere photometer.*
3) *Turn on illuminator and adjust output to maximum.*
4) *Take the reading after 15 min.*
5) *Repeat the steps above with illuminator output adjusted to 75 %, 50 %, and 25 % of the maximum.*
6) *Confirm that all the readings are within the stated range.*

201.12.1.101.6 * Fragmentation

The LENS REMOVAL DEVICES and VITRECTOMY DEVICES can include one or more fragmentation functions. Apply the relevant requirements and test methods from 201.12.1.101.7 and 201.12.1.101.8.

The MANUFACTURER shall determine through the RISK MANAGEMENT PROCESS if one or more TIP configurations, representing all marketed configurations, are required for testing. Selection of the appropriate TIP configurations for testing shall be confirmed by checking the RISK MANAGEMENT FILE. Any TIP configuration(s) used for testing shall be specified in the instructions for use with the specified performance.

201.12.1.101.7 * Accuracy of ultrasonic velocity of TIP

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.

If the ultrasonic velocity is not specified in the instruction for use, measurement of the accuracy of the ultrasonic velocity of the TIP is not required. However, measurement of the TIP velocity shall be made to assure the ultrasonic fragmentation function meets the hazardous output limit (see 201.12.4.101.7 for hazardous output limit).

Compliance is checked using the following test methods:

For both methods a camera may be used for visualisation of the image.

1) *Determine stroke using either method: [10]*
   a) *Spot method:*
      i) *Setup the test per Figure 201.104.*
      ii) *Focus microscope on a point not more than 1,0 mm from the free end of the applicator TIP, which shall be illuminated by a light beam.*
      iii) *Measure and record its diameter. This will be used for measuring the stroke length.*
      iv) *When equipment is energized, the point traces a line. The relative orientation of the applicator TIP and the microscope shall be altered until the maximum line length is observed.*
      v) *The line length (stroke trace), equal to the primary TIP vibration excursion shall be measured to an accuracy of 10 % by means of calibrated eyepiece reticule or micrometer movement.*

vi) *Record the stroke length by subtracting the spot diameter from the stroke trace.*

vii) *If transverse (torsional) vibrations occur simultaneously, then the point on the applicator describes an elliptical path and length of the major axis of the ellipse shall be measured.*

b) *Shadow light method (longitudinal only):*

i) *Setup the test per Figure 201.104.*

ii) *Suspend needle in water.*

iii) *Backlight or sidelight applicator TIP (phacoemulsification needle).*

iv) *Image TIP with a high magnification camera. (Refer to NOTE 1).*

v) *Turn the TIP so that the point of maximum curvature – the end of the bevel – faces the camera.*

vi) *Focus to maximize the sharpness of the image of the TIP when it is not moving:*

(1) *Distance per pixel can be determined by moving the TIP to the top of the screen on a calibrated stage, recording the raster line and displacement of the pixel, then moving it to the bottom of the screen and recording the same two data points. Distance per pixel is the change in displacement, divided by the number of pixels. Record and save this value.*

vii) *Run the TIP at the target stroke:*

(2) *The image will be dark at the top of the camera image behind the needle, light at the bottom below the needle, and a partial shadow will be formed in the region where the TIP is moving. There may be a slight curvature to the image, due to the curvature of the end of the needle.*

viii) *Measure the width of the partial shadow area between the bottom of the dark area and the bottom of the light area, in pixels, and calculate and record the stroke.*

NOTE 1 The magnification is high enough if there are enough raster lines across the partial shadow area that the stroke can be estimated when the TIP is running at the minimum desired target stroke. As reflected in Figure 201.105, the full width of the needle will probably not be visible.

NOTE 2 Various image processing software packages are available to assist in this PROCESS.

NOTE 3 A standard optical comparator or projector can be used in place of the microscope with camera in Figure 201.104.

2) *Determine frequency:*

a) *connect the ultrasonic driver signal to an oscilloscope using a high frequency 100X and high impedance 10 MΩ oscilloscope PROBE;*

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

3) *Determine velocity:*

a) *multiply stroke by frequency by π to obtain velocity of device under test.*

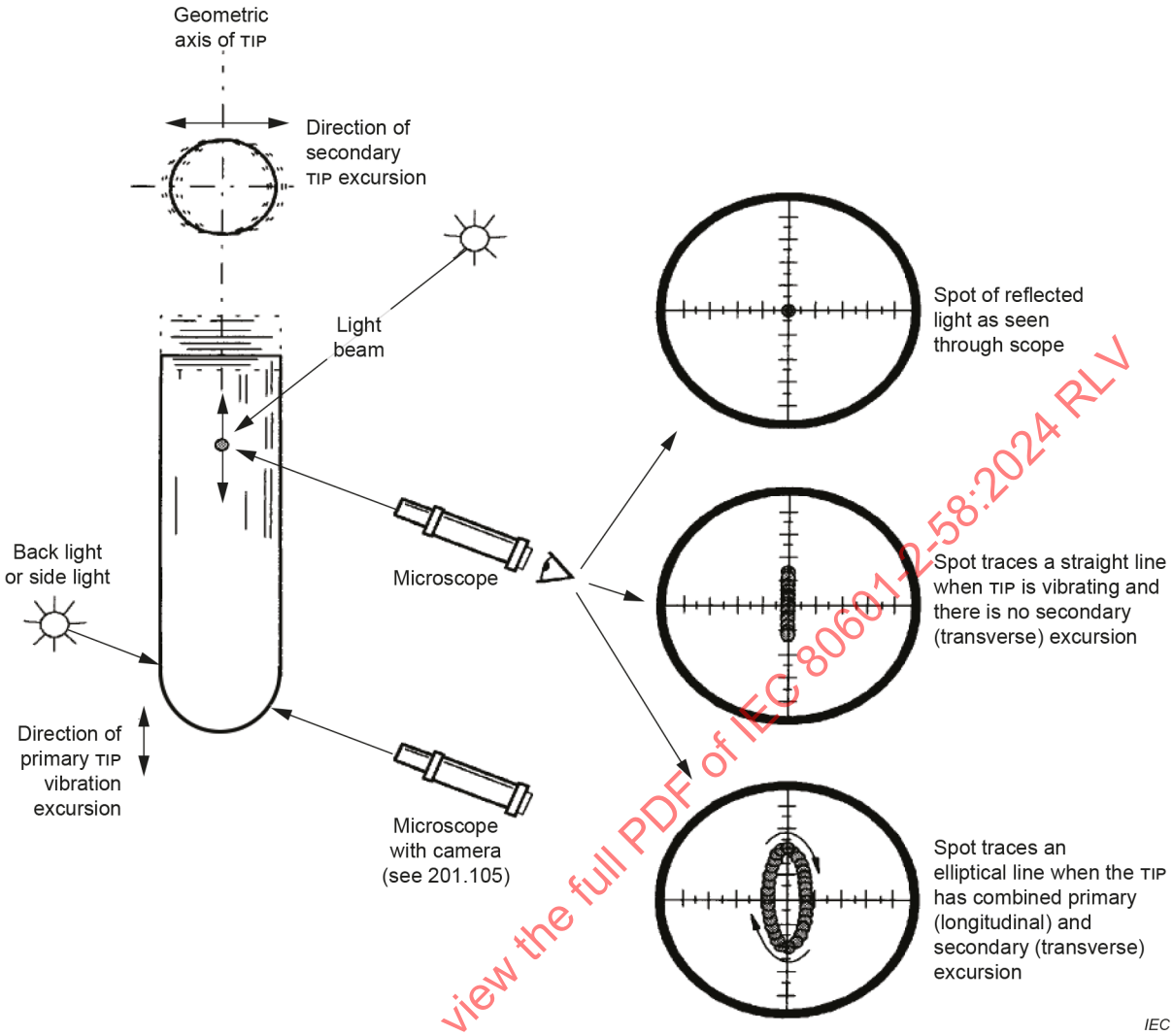


Figure 201.104 – Test method for ultrasonic velocity of TIP accuracy

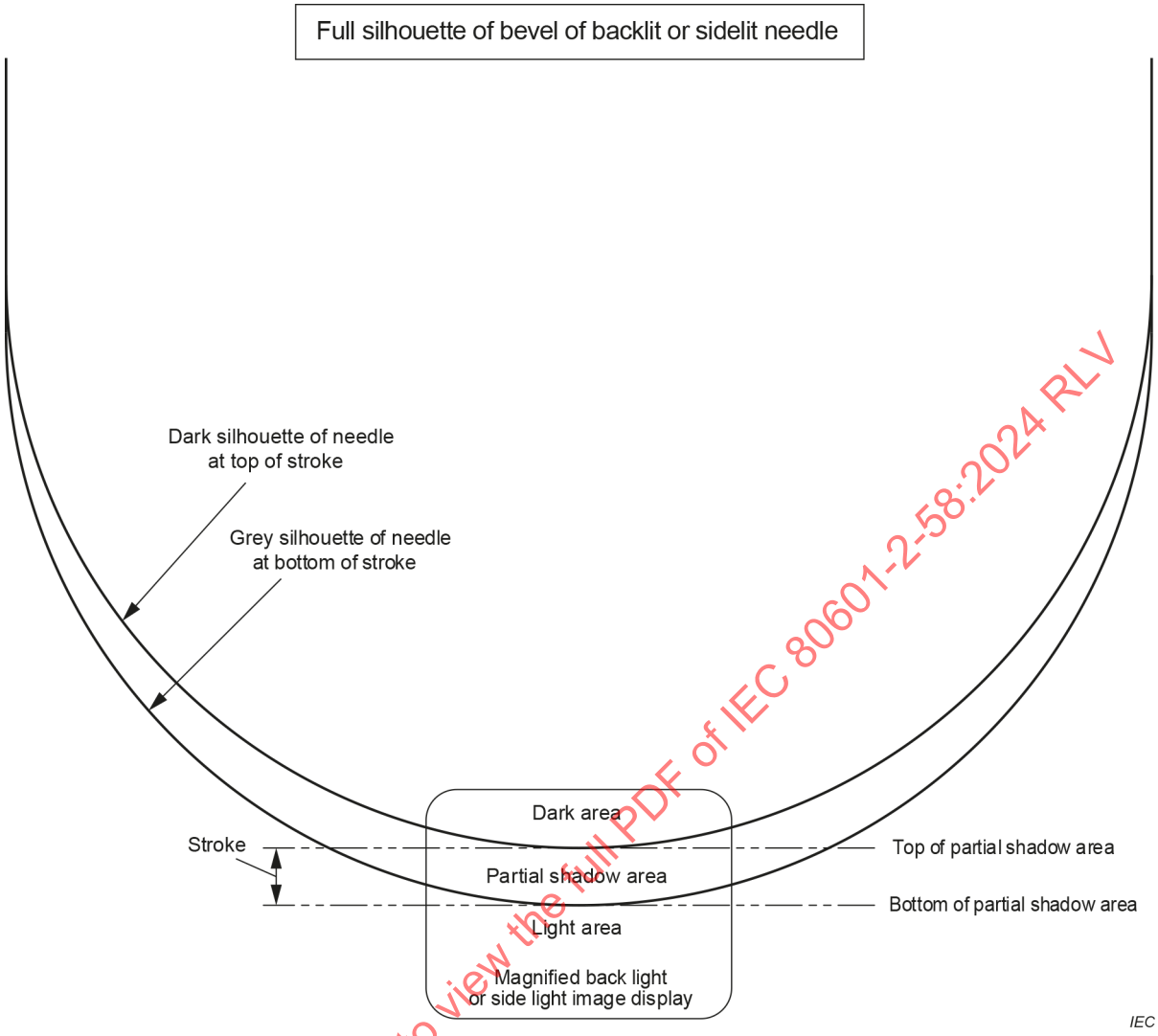


Figure 201.105 – Partial shadow, and camera field of view relative to TIP

201.12.1.101.8 Accuracy of VITRECTOMY PROBE cut rate

If a VITRECTOMY function is provided, the indicated cut rate and actual cut rate shall not deviate by more than ± 20 % from each other or from the limits stated in the instructions for use for each listed configuration (see 201.12.4.101.8 for hazardous output limit).

Compliance is checked using the following test method:

1) *Connect VITRECTOMY PROBE to device under test and position under a microscope to observe the port of the VITRECTOMY PROBE.*
2) *Set a stroboscope flash rate to ± 10 % of the cut rate set on the device under test.*
3) *Activate the VITRECTOMY PROBE and the stroboscope.*
4) *Adjust the flash rate of stroboscope to freeze the motion of the cutter in the port.*
5) *Read the stroboscope frequency to determine the measured cut rate.*
6) *The difference between the cut rate set on the device under test and the measured cut rate shall not be more than ± 20 %.*

201.12.4 Protection against hazardous output

Additional subclauses:

201.12.4.101 Additional requirements for protection against hazardous output

NOTE Additional requirements for protection against hazardous output, in NORMAL CONDITION, are detailed in 201.12.4.101.1 to 201.12.4.101.5, 201.12.4.101.7 and 201.12.4.101.8. The ranges stated in these subclauses can be exceeded based on the MANUFACTURER'S RISK MANAGEMENT.

201.12.4.101.1 Hazardous output for IRRIGATION pressure

The IRRIGATION pressure output for ME EQUIPMENT shall not exceed 200 mmHg (26,7 kPa).

Compliance is checked using methods 1 and/or 2 in 201.12.1.101.1 as appropriate and verify the reading is within the limit as identified above.

201.12.4.101.2 Hazardous output for ASPIRATION

The relative ASPIRATION vacuum for ME EQUIPMENT shall not exceed 750 mmHg (100 kPa) compared to the ambient atmospheric pressure.

Compliance is checked using the method in 201.12.1.101.2 and verify the reading is within the limit as identified above.

201.12.4.101.3 Hazardous output for DIATHERMY power

If a DIATHERMY function is provided, the DIATHERMY power output for LENS REMOVAL DEVICES and VITRECTOMY DEVICES shall not exceed 40 W.

Compliance is checked according to the relevant method of IEC 60601-2-2:2017 and IEC 60601-2-2:2017/AMD1:2023 and verify the readings are within the 40 W limit as identified above.

201.12.4.101.4 Hazardous output for DIATHERMY frequency

If a DIATHERMY function is provided, the DIATHERMY frequency output for ME EQUIPMENT and ME SYSTEM shall be between 200 kHz and 5 MHz.

Compliance is checked using the method in 201.12.1.101.4 and verify the reading is within the range identified above.

201.12.4.101.5 * Hazardous output for Illumination

If an illumination function is provided, the illumination output of the illumination HANDPIECE for ME EQUIPMENT and ME SYSTEM shall comply with the following limit values:

1) Short wavelength limit: the radiant power emitted from the exit aperture of an ENDOILLUMINATOR in the portion of the spectrum from 305 nm to 400 nm shall have an irradiance no greater than 0,05 mW/cm^2 as measured at a distance of 5 mm in a plane perpendicular to the radiating fibre-optic exiting aperture, when power supply is set to operate at maximum intensity.
2) Long wavelength limit: the radiant power emitted from the exit aperture of an ENDOILLUMINATOR in the portion of the spectrum from 700 nm to 1 100 nm shall not exceed 100 mW/cm^2, nor shall it exceed irradiance in the range of the spectrum between 380 nm and 700 nm as measured at a distance of the 5 mm in plane perpendicular to the radiating fibre optic exiting aperture when the power supply is set to operate at maximum intensity.

Compliance is checked by verifying the measurement is within the limit identified above, using the following method and Annex AA, 201.12.4.101.5, or by appropriate analysis of filters:

Irradiance shall be determined with the uncertainty less than ±30 %. A spectroradiometer can be used to make these measurements after the light from the ENDOILLUMINATOR has passed through a 3 mm diameter circular aperture stop positioned 5 mm from the existing aperture of the light guide, or any other 0,26 steradian aperture.

201.12.4.101.6 Fragmentation

The requirements from 201.12.4.101.7 and 201.12.4.101.8 are for methods of performing fragmentation for ophthalmologic surgery. Some of these fragmentation functions may be optional to the ME EQUIPMENT or ME SYSTEM and therefore any functions that are not included with the ME EQUIPMENT or ME SYSTEM shall not be applicable to the appropriate subclauses of 201.12.4.101.7 and 201.12.4.101.8.

201.12.4.101.7 Hazardous output for ultrasonic velocity of TIP

If an ultrasonic fragmentation function is provided, the ultrasonic velocity of TIP OUTPUT for ME EQUIPMENT and ME SYSTEM shall not exceed 20 m/s while operated under full power in water.

Compliance is checked using the method in 201.12.1.101.7 and verify the reading is within the limit identified above.

201.12.4.101.8 Hazardous output for VITRECTOMY PROBE cut rate

If VITRECTOMY PROBE cutting function is provided, the variable output of the VITRECTOMY PROBE cut rate for ME EQUIPMENT and ME SYSTEMS shall have a minimum of 10 cuts/min or greater (except in single cut mode, if available) while operated at minimum setting, in water.

Compliance is checked using the method in 201.12.1.101.8 and verify the reading is within the limit identified above.

201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT

Clause 13 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause 14 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

201.15 Construction of ME EQUIPMENT

Clause 15 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

201.16 * ME SYSTEMS

Clause 16 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

Clause 17 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

202 Electromagnetic disturbances – Requirements and tests

IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 apply 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 60601-1-2:2014 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:

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

b) If there is a DIATHERMY function, it shall comply with the Class A requirements of CISPR 11:2015, CISPR 11:2015/AMD1:2016 and CISPR 11:2015/AMD2:2019 group 1, when it is switched on and in an idle state with the HF output not energized.

c) The VITRECTOMY DEVICES shall comply with the Class A requirements of CISPR 11:2015, CISPR 11:2015/AMD1:2016 and CISPR 11:2015/AMD2:2019 group 1, when it is switched on at its maximum cut rate. If an illumination function is provided, it shall be turned on while the VITRECTOMY function is tested.

d) For all other functions the settings shall be documented in the test plan of IEC 60601-1-2:2014 and IEC 60601-1-2:2014/A1:2020.

202.8 Electromagnetic IMMUNITY requirements for ME EQUIPMENT and ME SYSTEMS

202.8.1 General

Addition immediately above Note 5 of 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, if deemed acceptable through the RISK MANAGEMENT PROCESS.

– 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 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 are met with the above changes.

Annexes

The annexes of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 apply, except as follows:

Annex C
(informative)

Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS

Annex C of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows.

201.C.5 ACCOMPANYING DOCUMENTS, instructions for use

Addition:

Additional requirements for information to be included in instructions for use of LENS REMOVAL DEVICES and VITRECTOMY DEVICES are found in Table 201.C.101.

Table 201.C.101 – ACCOMPANYING DOCUMENTS, instructions for use of LENS REMOVAL DEVICES and VITRECTOMY DEVICES or their parts

Description of marking	Subclause
TUBING SETS	201.7.9.2.2 a)
Electrically adjustable solution support pole	201.7.9.2.2 b)
Never intentionally modify HANDPIECES or TIPS	201.7.9.2.2 c)
Ultrasonic HANDPIECES	201.7.9.2.2 d)
Lamp replacement	201.7.9.2.2 e)
Concentrated illumination on small area of retina for prolonged periods	201.7.9.2.2 f)
PRIMING or tuning of HANDPIECES while in the eye	201.7.9.2.2 g)
Ophthalmic IRRIGATION solution when gravity is relevant	201.7.9.2.2 h)
Sufficient volume of IRRIGATION solution	201.7.9.2.2 i)
Maximum capacity of DRAIN CONTAINER	201.7.9.2.2 j)
Performance OF ultrasonic velocity of the TIP	201.12.1.101.7
Performance of VITRECTOMY PROBE cut rate	201.12.1.101.8
First use of day start-up PROCEDURE	201.7.9.2.8
TUBING SET instructions	201.7.9.2.9 a)
Clamps on a TUBING SET, avoid free flow conditions, and PROCEDURE for changing ophthalmic IRRIGATION solution	201.7.9.2.9 b)
Securely connecting plugs, HANDPIECE cables and other connections	201.7.9.2.9 c)
Processing of resterilizable medical devices	201.7.9.2.12
Maintenance: inspect HANDPIECE cables and cords on a regular basis	201.7.9.2.13
Packaging of terminally sterilized ACCESSORIES	201.11.6.7

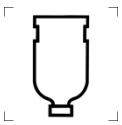
Annex D
(informative)

Symbols on marking (See Clause 7)

Annex D of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows.

Addition:

Table D.4 – LENS REMOVAL and VITRECTOMY symbols

No.	Symbol	Reference	Title
1		IEC 60417-5782 (2002-10) (IEC TR 60878-5782 [11])	Electrosurgery, coagulation mode (DIATHERMY)
2		IEC 60417-6372 (2017-01) (IEC TR 60878-6372 [11])	Fragmentation (PHACOFRAGMENTATION)
3		IEC 60417-6374 (2016-10) (IEC TR 60878-6374 [11])	VITRECTOMY
4		ISO 7000-1836 (2004-01) (IEC TR 60878-1836 [11])	Fibre-optic HANDPIECE (Illumination)
5		IEC 60417-5747 (2002-10) (IEC TR 60878-5747 [11])	Infusion bottle (OCULAR IRRIGATION)

Annex AA
(informative)

Particular guidance and rationale

AA.1 General guidance

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, comprised of an equipment console, surgical HANDPIECES, and ACCESSORIES connected to this ME EQUIPMENT.

This particular standard concerns the safety of LENS REMOVAL DEVICES and VITRECTOMY DEVICES for ophthalmic surgery including ESSENTIAL PERFORMANCE. It amends and supplements IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020. The requirements of this particular standard take priority over those of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and applicable collateral standards.

AA.2 Rationale for particular clauses and subclauses

The following are rationales for specific clauses and subclauses in this document, with clause and subclause numbers parallel to those in the body of the document.

Subclause 201.1.1 – Scope

The requirements of this document are specified for LENS REMOVAL DEVICES and VITRECTOMY DEVICES, comprised of an equipment console, surgical HANDPIECES, and ACCESSORIES connected to this ME EQUIPMENT.

Subclause 201.1.3 – Collateral standards

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

- IEC 60601-1-3:2008, IEC 60601-1-3:2008/AMD1:2013 and IEC 60601-1-3:2008/AMD2:2021 [2] – LENS REMOVAL DEVICES and VITRECTOMY DEVICES are not Diagnostic X-ray equipment
- IEC 60601-1-9:2007, IEC 60601-1-9:2007/AMD1:2013 and IEC 60601-1-9:2007/AMD2:2020 [3] – LENS REMOVAL DEVICES and VITRECTOMY DEVICES regulatory submissions determine if environmentally conscious design is an acceptable requirement so is not a requirement of the LENS REMOVAL DEVICES and VITRECTOMY DEVICES STANDARD but of the national regulators
- IEC 60601-1-10:2007, IEC 60601-1-10:2007/AMD1:2013 and IEC 60601-1-10:2007/AMD2:2020 [4] – LENS REMOVAL DEVICES and VITRECTOMY DEVICES do not incorporate therapeutic closed-loop controllers
- IEC 60601-1-11:2015 and IEC 60601-1-11:2015/AMD1:2020 [5] – LENS REMOVAL DEVICES and VITRECTOMY DEVICES are not used in the home use environment
- IEC 60601-1-12:2014 and IEC 60601-1-12:2014/AMD1:2020 [6] – LENS REMOVAL DEVICES and VITRECTOMY DEVICES are not used in the emergency medical services environment

Subclause 201.4.3 – ESSENTIAL PERFORMANCE

Per IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 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 document 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 [12].
– ESSENTIAL PERFORMANCE should not be confused with general safety and performance requirements of the European Medical Regulation (EU) 2017/745 [1].
– ESSENTIAL PERFORMANCE should not be confused with the essential principles of safety and performance of medical devices per ISO 16142-1:2016 [13].

LENS REMOVAL DEVICES and VITRECTOMY DEVICES do not have ESSENTIAL PERFORMANCE within the meaning of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020. 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 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 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 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 IRRIGATION pressure, ASPIRATION pressure, DIATHERMY (power and frequency), illumination output, lens fragmentation output (ultrasonic velocity), 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 stresses 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 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 standard or collateral standards requires that ESSENTIAL PERFORMANCE (but not BASIC SAFETY) shall 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 document 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 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 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 or degradation of functions or features of the LENS REMOVAL DEVICES and VITRECTOMY DEVICES.

Subclause 201.4.101 – Additional functions

Sections of the more general ISO 15752:2000 [14] standard critical to VITRECTOMY DEVICES originally referenced in the 2008 edition of this particular standard have been incorporated directly into 201.12.4.101.5 to ensure consistency of application in the design of VITRECTOMY DEVICES for ophthalmic surgery. As a result, LENS REMOVAL DEVICES and VITRECTOMY DEVICES should be considered outside the scope of ISO 15752 [14].

Subclause 201.12.1.101.6 – Fragmentation

The list of modalities for fragmentation at the time of writing this document encompasses the state of the art for fragmentation.

Subclause 201.12.1.101.7 – Accuracy of ultrasonic velocity of TIP

In the first edition of IEC 80601-2-58:2008 Subclauses 201.12.1.101.7 and 201.12.4.101.1, the first step in the method of checking compliance on the accuracy of the display and limits on output was identified as following one clause and four specific subclauses of IEC 61847:1998 [10].

In the second edition of IEC 80601-2-58:2014, the referenced clauses were removed from IEC 61847:1998 [10] and inserted directly into 201.12.1.101.7. This was done to remove the approach of specifying only part of a standard. The IEC 80601-2-58 committee did not think it was appropriate to apply other parts of IEC 61847:1998 [10], and that it was inappropriate to suggest applying only parts of it. It may be noted that IEC 61847 [10] has not been updated since that time. At that time, Figure 201.104 was added.

Figure 1 of IEC 61847:1998 [10] presents the use of a microscope reticle viewed by a human eye to view the motion of a feature on the TIP as illuminated externally, using either a calibrated reticle or a calibrated micrometer to assess the movement. Nothing in the language either suggests or precludes the use of a camera for viewing the microscopic image, nor does it specify the nature of the point to be observed. Practical experience shows that using a camera will aid in the observation and recording of the result. Furthermore, practical experience shows that nicks on the leading edge of the actuator TIP naturally cause specular reflections that serve as spots, so that tracking the leading edge of the TIP is an effective approach to identifying the spot to be tracked. Finally, practical experience with a variety of illumination types, angles, and camera gains indicate that effective measurements can be made with both side lighting, back lighting, and front lighting.

During the drafting the third edition of the standard, it became clear that some companies would benefit from being made aware of the possibility of using cameras and tracking the edge as a spot to make their measurements. Figure 201.105 has been added to make this possibility more evident.

Subclause 201.12.4.101.5 – Hazardous output for illumination

If a spectroradiometer is used, the intervals should be centered on wavelengths that are a multiple, with a recommended bandwidth of 5 nm or 10 nm as indicated. The recommended measurement units are microwatts per square centimeter per nanometer ($\mu W/cm^2/nm$). This value is recorded and is also multiplied by bandwidth and recorded as microwatts per square centimeter ($\mu W/cm^2$) for that interval. If lamps with narrow spectral lines are used, the bandwidth measurements may need to be less than 5 nm (see ISO 15004-2:2007).

Clause 201.16 – ME SYSTEMS

Non-ME EQUIPMENT that is commonly used with LENS REMOVAL DEVICES and VITRECTOMY DEVICES includes audio/video, information and communication technology equipment in IEC 62368-1:2018 [15], information technology equipment covered in IEC 60950-1:2005, IEC 60950-1:2005/AMD1:2009 and IEC 60950-1:2005/AMD2:2013 [16] and audio and video equipment covered in IEC 60065:2001, IEC 60065:2001/AMD1:2005 and IEC 60065:2001/AMD2:2010 [17] requirements.

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

This particular ME EQUIPMENT or ME SYSTEM is not specified for use only in a shielded location.

Subclause 202.7.1.2 – Operating modes

Subclause 5.1 of CISPR 11:2015, CISPR 11:2015/AMD1:2016 and CISPR 11:2015/AMD2:2019 (Edition 6.2) provides for the separation of equipment into either group 2 (Equipment that intentionally generates ISM RF frequencies, for, among other purposes, treatment of material), and group 1 (Equipment that is not classified as group 2). DIATHERMY is ISM RF energy for treatment of human tissue. IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 (Edition 4.1) Annex C identifies ME EQUIPMENT and ME SYSTEMS in group 1 (including, for instance, therapeutic ultrasound equipment) and group 2 (including DIATHERMY ME EQUIPMENT). Under all uses without DIATHERMY, LENS REMOVAL / VITRECTOMY equipment would be classified as group 1. The casual observer might conclude that LENS REMOVAL / VITRECTOMY ophthalmic microsystems that include a DIATHERMY function fall within group 2. However, IEC 60601-2-2:2017, subclause 202.7.1.2 a) states that HF equipment shall not be tested for radiated or conducted RF emissions with the HF output energized, and b) states that it shall meet CISPR 11 group 1 limits in these tests. The guidance in IEC 80601-2-58 202.7.1.2 a) and b) restates this so that the user does not have to find this information in IEC 60601-2-2, and is consistent with the guidance in IEC 60601-2-2. 202.7.1.2 c) indicates the operating conditions for the equipment during the test.

Running the ultrasonic lens fragmentation function on the machine during IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 radiated emissions testing is not required, as it has no real impact on the levels measured in the test, and it would require operating the HANDPIECE in a non-typical fashion. Tests can be performed with the HANDPIECE plugged in and the HANDPIECE cable appropriately bundled in a manner consistent with CISPR 11:2015, CISPR 11:2015/AMD1:2016 and CISPR 11:2015/AMD2:2019 Figures 3a and 3b, note B, and Subclause 7.5.2 to include any passive antenna contribution, but with the HANDPIECE in an unpowered, inactive state.

The electrical signal produced to stimulate the ultrasonic HANDPIECE does not significantly contribute to emissions in the 30 MHz to 2,4 GHz range. Failures in the 30 MHz to 2,4 GHz range are largely due to high-frequency narrowband local peaks produced by high-frequency narrowband unmodulated sources, such as clocks and video signals, at their fundamental frequencies as well has the first few harmonics of those frequencies. The HANDPIECE drive signal tends to be in the 25 kHz to 50 kHz range, always below 300 kHz, which is at least two orders of magnitude below the minimum 30 MHz level in the test sweeps. Any harmonic peaks from this contribution have decayed below detectability across this band. Furthermore, any other contribution from the HANDPIECE drive circuit at that level will be significantly suppressed by the large capacitive short created by the crystal capacitance in the HANDPIECE. Informal testing involving observing the noise floor at 30 MHz with the HANDPIECE pulsing on and off at low pulse rates and maximum power does not result in observable shifts in the noise floor.

Where system designs employ high-frequency switch-mode power supplies or amplifier topologies, the potential influence of the high-frequency harmonic content of the supply or amplifier on the radiated disturbance limits of IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 Subclause 7.3 and Table 2 should be considered in the RISK MANAGEMENT FILE and the required test configuration should reflect the results of this consideration, consistent with the requirements of IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020, Subclause 4.3.1.

The typical use time for a HANDPIECE is on the order of a minute or two, much shorter than the time devoted to even one single sweep in the radiated emissions test. The HANDPIECES run at relatively high power levels, and are kept cool by a combination of the fluid flowing through them during surgery and the very low use duty cycle. Failure to keep the HANDPIECES cool during extended continuous stimulation leads to failures of the HANDPIECE, sometimes in the middle of a test. Providing the necessary fluid flow to keep the HANDPIECE cool during the extended testing unnecessarily complicates the test setup, and introduces other elements – such as pump electrical noise and extended partially conductive fluid paths – which could distort the outcome of the radiated emissions test unrealistically.

Because the lens fragmentation HANDPIECE drive is unlikely to contribute to emissions in the band under test, and because the steps necessary to run the circuit for the time periods required for the emissions tests, it is unnecessary to run the lens fragmentation HANDPIECE during the radiated emissions test.

The lens fragmentation function can be conveniently run during the conducted emissions test, which takes much less time and is looking at much lower frequencies in the power supply current waveform.

During immunity testing, the primary RISK is changes at the signal level to the system messages controlling commanded output levels. These changes are as likely to happen on any given function – for instance, ASPIRATION or bipolar – as they are on any other function. Furthermore, in contemporary machines, changes to the drive level will be reflected as changes in the output on the display. Therefore, it is acceptable for the MANUFACTURER to identify any continuous level analog surgical output function they choose to monitor per the MANUFACTURER's test plan.

Annex BB
(informative)

Reference to the general safety and performance requirements

This document has been prepared to support the general safety and performance requirements of regulation (EU) 2017/745 [1].

Conformance with this document provides one means of demonstrating conformance with the specific general safety and performance requirements (GSPRs) of regulation (EU) 2017/745 [1]. Other means are possible. Table BB.1 maps the clauses and subclauses of this document with the general safety and performance requirements of regulation (EU) 2017/745 [1].

NOTE When a general safety and performance requirement does not appear in Table BB.1, it means that it is not addressed by this document.

Table BB.1 – Correspondence between this document and the general safety and performance requirements

General safety and performance requirements of regulation (EU) 2017/745, Annex I [1]	Corresponding clause(s)/sub-clause(s) of this document	Qualifying remarks/Notes
10.6	201.9.5.101	Only the part of GSPR 10.6 relating to design is addressed for the PATIENT.
11.4	201.11.6.7	Only the part of GSPR 11.4 relating to design & packaging are addressed.
14.2 b)	202.5.2.2.2, 202.5.2.2.4, 202.7 (all), 202.8 (all)	Only the part of GSPR 14.2 b) relating to design is addressed.
14.2 f)	202.5.2.2.2, 202.5.2.2.4, 202.7 (all), 202.8 (all)	Only the part of GSPR 14.2 f) relating to design is addressed.
16.3	201.4.101, 201.10 (all)	Only the part of GSPR 16.3 relating to design is addressed. For sub-clause 201.4.101 only IEC 60601-2-22 is relevant.
18.5	202.7 (all), 202.8 (all)	Only the part of GSPR 18.5 relating to design is addressed.
18.6	202.8 (all)	Only the part of GSPR 18.6 relating to design is addressed.
21.1	201.4.101, 201.12.1.101 (all)	Only the protection of the PATIENT is covered. For sub-clause 201.4.101 only IEC 60601-2-22 is relevant.
21.2	201.4.101, 201.12.4.101 (all)	For sub-clause 201.4.101 only IEC 60601-2-22 is relevant.
23.1	201.7.9.2.2, 201.7.9.2.8, 201.7.9.2.9, 201.7.9.2.12, 201.7.9.2.13, 201.7.9.3.1	This is for the first full paragraph of GSPR 23.1.
23.1 g)	201.7.9.2.2	
23.1 h)	201.7.6.101	
23.2 k)	201.11.6.7, 201.7.9.2.12	
23.2 l)	201.11.6.7	
23.2 n)	201.11.6.7	
23.2 o)	201.7.9.2.12	
23.3 a)	201.11.6.7	
23.3 b)	201.11.6.7	

General safety and performance requirements of regulation (EU) 2017/745, Annex I [1]	Corresponding clause(s)/sub-clause(s) of this document	Qualifying remarks/Notes
23.3 c)	201.11.6.7	
23.3 d)	201.11.6.7	
23.3 e)	201.11.6.7	
23.3 i)	201.11.6.7	
23.3 j)	201.11.6.7	
23.4 a)	201.11.6.7, 201.7.9.2.12	
23.4 g)	201.7.9.2.2	
23.4 i)	201.7.9.2.8, 201.7.9.2.9 (a), 201.7.9.2.9 (c), 201.7.9.2.12, 201.7.9.2.13	
23.4 k)	201.7.9.2.2 e), 201.7.9.2.8, 201.7.9.2.12, 201.7.9.2.13	
23.4 m)	201.7.9.2.12, 2017.9.2.13	The preparation of parts for reuse is considered per Subclause 201.7.9.2.13.
23.4 n)	201.7.9.2.12, 201.7.9.2.13	The preparation of parts for reuse is considered per Subclause 201.7.9.2.13.
23.4 p)	201.11.6.7	
23.4 s)	201.7.9.2.2 g)	

Bibliography

[1] (EU) 2017/745, (2017) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices. *OJ L 117, Official Journal of the European Union,* pp. 1-175

[2] IEC 60601-1-3:2008, *Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment*
IEC 60601-1-3:2008/AMD1:2013
IEC 60601-1-3:2008/AMD2:2021

[3] IEC 60601-1-9:2007, *Medical electrical equipment – Part 1-9: General requirements for basic safety and essential performance – Collateral Standard: Requirements for environmentally conscious design*
IEC 60601-1-9:2007/AMD1:2013
IEC 60601-1-9:2007/AMD2:2020

[4] IEC 60601-1-10:2007, *Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers*
IEC 60601-1-10:2007/AMD1:2013
IEC 60601-1-10:2007/AMD2:2020

[5] IEC 60601-1-11:2015, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*
IEC 60601-1-11:2015/AMD1:2020

[6] IEC 60601-1-12:2014, *Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment*
IEC 60601-1-12:2014/AMD1:2020

[7] ISO 15004-2:2007, *Ophthalmic instruments – Fundamental requirements and test methods – Part 2: Light hazard protection*

[8] IEC 60825-1:2014, *Safety of laser products – Part 1: Equipment classification and requirements*

[9] *Recommended Practices for Cleaning and Sterilizing Intraocular Surgical Instruments*, American Society of Cataract and Refractive Surgery Ad Hoc Task Force on Cleaning and Sterilization of Intraocular Surgical Instruments, February 16, 2007

[10] IEC 61847:1998, *Ultrasonics – Surgical systems – Measurement and declaration of the basic output characteristics*

[11] IEC TR 60878, *Graphical symbols for electrical equipment in medical practice*

[12] Council Directive 93/42/EEC of 14 June 1993 *concerning medical devices*, amended by: Directive 98/79/EC (27 October 1998), Directive 2000/70/EC (16 November 2000), Directive 2001/104/EC (7 December 2001), Regulation (EC) No.1882/2003 (29 September 2003), Directive 2007/47/EC (5 September 2007)

[13] ISO 16142-1:2016, *Medical devices – Recognized essential principles of safety and performance of medical devices – Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards*

[14] ISO 15752:2000, *Ophthalmic instruments – Endoilluminators – Fundamental requirements and test methods for optical radiation safety*

[15] IEC 62368-1:2018, *Audio/video, information and communication technology equipment – Part 1: Safety requirements*

[16] IEC 60950-1:2005, *Information technology equipment – Safety – Part 1: General requirements*
IEC 60950-1:2005/AMD1:2009
IEC 60950-1:2005/AMD2:2013

[17] IEC 60065:2001, *Audio, video and similar electronic apparatus – Safety requirements*
IEC 60065:2001/AMD1:2005
IEC 60065:2001/AMD2:2010

Index of defined terms

SOMMAIRE

COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

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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.
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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*

201.3 Termes et définitions

Pour les besoins du présent document, les termes et les définitions de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 ainsi que les suivants s'appliquent.

L'ISO et l'IEC tiennent à jour des bases de données terminologiques destinées à être utilisées en normalisation, consultables aux adresses suivantes:

- IEC Electropedia: disponible à l'adresse https://www.electropedia.org/
- ISO Online browsing platform: disponible à l'adresse https://www.iso.org/obp

NOTE Un index des termes définis est donné à la page 79.

Addition:

201.3.201
ASPIRATION
extraction d'un fluide ou d'un gaz hors de l'œil au moyen d'une succion

201.3.202
DIATHERMIE
technique chirurgicale qui utilise des courants électriques haute fréquence (HF) afin d'arrêter le saignement dans des tissus

Note 1 à l'article: La DIATHERMIE est utilisée, par exemple, pour coaguler le sang ou sceller des tissus.

Note 2 à l'article: Les termes "cautérisation" ou "coagulation" ont également été utilisés dans ce contexte.

201.3.203
RECIPIENT DE DRAINAGE
récipient hermétiquement fermé (ou poche) dans lequel le fluide aspiré est recueilli

201.3.204
ENDOILLUMINATEUR
dispositif constitué d'une source lumineuse et d'un câble de fibre optique lumineux, destiné à être inséré dans l'œil en vue d'éclairer chaque partie de l'intérieur de l'œil

[SOURCE: ISO 15004-2:2007, 3.1.5 [7]]

201.3.205
PIECE A MAIN
SONDE
PARTIE APPLIQUEE tenue à la main, ACCESSOIRE des dispositifs de RETRAIT DU CRISTALLIN ou des DISPOSITIFS DE VITRECTOMIE

201.3.206
LASER
tout dispositif que l'on peut réaliser pour produire ou amplifier un rayonnement électromagnétique compris dans la gamme de longueurs d'ondes de 180 nm à 1 mm, essentiellement par le phénomène d'émission stimulée contrôlée

[SOURCE: IEC 60825-1:2014, 3.44 [8]]

201.3.207
FRAGMENTATION LASER
procédé par lequel le cristallin est brisé en petits fragments au moyen d'une énergie LASER

201.3.208
RETRAIT DU CRISTALLIN
retrait de tissus indésirables du cristallin

201.3.209
DISPOSITIF DE RETRAIT DU CRISTALLIN
APPAREIL EM ou SYSTEME EM conçu pour enlever la matière du cristallin, lequel contient des fonctions d'IRRIGATION et d'ASPIRATION, ainsi qu'un mécanisme de RETRAIT DU CRISTALLIN, comme, par exemple, PHACOFRAGMENTATION ou FRAGMENTATION LASER

Note 1 à l'article: Ces dispositifs peuvent être également utilisés à d'autres fins chirurgicales oculaires.

201.3.210
IRRIGATION OCULAIRE
IRRIGATION
introduction d'un liquide dans l'œil

Note 1 à l'article: Le terme "infusion" a aussi été utilisé dans ce contexte.

201.3.211
PHACOFRAGMENTATION
procédé par lequel le cristallin est brisé en petits fragments en utilisant une énergie comme celle des dispositifs ultrasoniques

Note 1 à l'article: Se reporter à la définition du DISPOSITIF DE RETRAIT DU CRISTALLIN en 201.3.209.

Note 2 à l'article: Historiquement, la PHACOFRAGMENTATION (le terme existe aussi sous la forme phacoémulsification) est une PROCEDURE chirurgicale qui utilise l'énergie ultrasonique pour fragmenter (ou émulsifier) un cristallin atteint de cataracte et enlève la matière du cristallin à travers une petite incision. Depuis peu, d'autres modalités d'énergies émergentes, notamment la FRAGMENTATION LASER, sont également utilisées dans le retrait du cristallin cataracté à travers une petite incision.

201.3.212
PHOTORETINITE
lésion rétinienne provoquée par une exposition rétinienne à un rayonnement très intense

201.3.213
AMORCE
AMORÇAGE
PROCEDURE de mise en condition préopératoire pour remplir les TUBULURES (circuit du liquide) de solution d'IRRIGATION ophtalmique

201.3.214
EMBOUT
garniture creuse de métal semblable à une aiguille raccordée à une PIECE A MAIN

201.3.215
TUBULURES
ensemble des tubes destinés à contenir du fluide, conçus pour assurer une IRRIGATION vers l'œil et une ASPIRATION en provenance de l'œil

201.3.216
VITRECTOMIE
PROCEDURE chirurgicale destinée à enlever de l'humeur vitreuse, des membranes, du sang, des tissus du cristallin et d'autres matières de l'œil, impliquant une IRRIGATION, une ASPIRATION et la coupe du vitreux

Note 1 à l'article: La PROCEDURE peut aussi inclure une illumination, une DIATHERMIE, des échanges liquide/gaz et l'injection de fluides visqueux.

201.3.217
DISPOSITIF DE VITRECTOMIE
APPAREIL EM ou SYSTEME EM utilisé pour réaliser une VITRECTOMIE

Note 1 à l'article: Ces dispositifs peuvent être également utilisés à d'autres fins chirurgicales oculaires.

201.4 Exigences générales

L'Article 4 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:

201.4.2.1 Introduction à la GESTION DES RISQUES

Addition:

L'applicabilité des normes IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013 et IEC 60601-1-6:2010/AMD2:2020 et IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 et IEC 60601-1-8:2006/AMD2:2020 doit être évaluée au moyen du PROCESSUS DE GESTION DES RISQUES. La conformité doit être déterminée et documentée dans le DOSSIER DE GESTION DES RISQUES.

201.4.3 * PERFORMANCE ESSENTIELLE

Paragraphe supplémentaire

201.4.3.101 Généralités

Pour les DISPOSITIFS DE RETRAIT DU CRISTALLIN et les DISPOSITIFS DE VITRECTOMIE, il n'a pas été identifié de PERFORMANCES ESSENTIELLES en général. Lorsque les DISPOSITIFS DE RETRAIT DU CRISTALLIN et les DISPOSITIFS DE VITRECTOMIE ont des fonctions autres que celles spécifiées à l'Article 201.12, le FABRICANT doit identifier lesquelles de ces fonctions de l'APPAREIL EM et des SYSTEMES EM font partie des PERFORMANCES ESSENTIELLES.

La vérification est effectuée par l'examen du DOSSIER DE GESTION DES RISQUES.

Paragraphe supplémentaire:

201.4.101 * Fonctions supplémentaires

Lorsqu'une fonction de DIATHERMIE est assurée sur le DISPOSITIF DE RETRAIT DU CRISTALLIN et le DISPOSITIF DE VITRECTOMIE, cette fonction doit satisfaire aux exigences de l'IEC 60601-2-2:2017 et de l'IEC 60601-2-2:2017/AMD1:2023.

Lorsqu'une fonction LASER est assurée sur l'APPAREIL EM, cette fonction doit satisfaire aux exigences de l'IEC 60601-2-22:2019.

Lorsqu'une fonction d'illumination est assurée sur l'APPAREIL EM ou le SYSTEME EM pour éclairer l'œil pendant l'intervention chirurgicale, cette partie de l'APPAREIL EM ou du SYSTEME EM doit satisfaire aux exigences du 201.12.4.101.5.

201.5 Exigences générales relatives aux essais des APPAREILS EM

L'Article 5 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:

201.6 Classification des APPAREILS EM et des SYSTEMES EM

L'Article 6 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 s'applique.

201.7 Identification, marquage et documentation des APPAREILS EM

L'Article 7 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:

Paragraphe supplémentaire:

201.7.6.101 Symboles supplémentaires

Symboles pour le RETRAIT DU CRISTALLIN et la VITRECTOMIE.

Lorsque des symboles sont utilisés pour les DISPOSITIFS DE RETRAIT DU CRISTALLIN et les DISPOSITIFS DE VITRECTOMIE qui assurent des fonctions telles que la DIATHERMIE, la PHACOFRAGMENTATION, la VITRECTOMIE et l'illumination, ils doivent être fondés sur les symboles recommandés dans le Tableau D.4 et apparaître sur le dispositif ou près du point de connexion de la fonction.

201.7.9.2.2 Avertissement et consignes de sécurité

Addition:

Les instructions d'utilisation doivent inclure en outre les avertissements et les consignes de sécurité suivants:

a) un avertissement qui indique d'utiliser uniquement les TUBULURES recommandées;

b) lorsqu'une tige de maintien à réglage électrique est utilisée pour la solution d'IRRIGATION ophtalmique, un avertissement indiquant de ne pas modifier la hauteur de la tige ou de forcer manuellement la hauteur de la tige, car cela peut provoquer une indication inexacte de la hauteur de la bouteille et des dommages au PATIENT;

c) un avertissement de ne jamais modifier intentionnellement les PIECES A MAIN ou les EMBOUTS (par exemple, ne pas les tordre, les couper ou les graver), car ils peuvent se casser ou tomber en panne;

d) un avertissement à l'OPERATEUR de ne pas toucher un EMBOUT de PIECE A MAIN à ultrasons activé, car cela peut provoquer des lésions;

e) le cas échéant, des avertissements concernant le changement de la lampe (par exemple, les RISQUES de lésions, les caractéristiques assignées de la lampe, les dommages sur la lampe, les dommages sur la machine, etc.);

f) le cas échéant, un avertissement à l'OPERATEUR indiquant qu'il convient de faire attention à éviter de concentrer la sortie d'un module d'illumination sur une petite zone de la rétine pendant une durée inutilement prolongée en raison du potentiel de PHOTORETINITE et de lésions permanentes graves du PATIENT;

g) le cas échéant, un avertissement à l'OPERATEUR indiquant que l'activation par inadvertance de fonctions qui sont destinées à l'AMORÇAGE ou au réglage des PIECES A MAIN pendant que la PIECE A MAIN est dans l'œil peut créer une SITUATION DANGEREUSE susceptible de blesser le PATIENT;

h) lorsque la gravité est à prendre en compte dans la performance, la source de solution d'IRRIGATION ophtalmique doit être au-dessus ou au niveau de l'œil du PATIENT;

i) un avertissement qui indique à l'OPERATEUR de prévoir un volume suffisant de solution d'IRRIGATION pendant la PROCEDURE. Il convient de surveiller le niveau pendant la PROCEDURE;

j) le cas échéant, un avertissement à l'OPERATEUR qui indique d'assurer que la capacité maximale du RECIPIENT DE DRAINAGE n'est pas dépassée, car cela peut entraîner une SITUATION DANGEREUSE pour le PATIENT.

201.7.9.2.8 PROCEDURE de démarrage

Addition:

Les instructions d'utilisation doivent contenir des instructions pour réaliser des essais de fonctionnement du système avant la première utilisation de la journée.

201.7.9.2.9 Instructions de fonctionnement

Addition:

Les instructions de fonctionnement doivent inclure en outre:

a) le cas échéant, des instructions concernant le chargement, l'AMORÇAGE, le changement, et le rechargement des TUBULURES, et l'intervalle de changement des TUBULURES pour maintenir la performance spécifiée;

b) le cas échéant, des instructions concernant l'utilisation de pinces sur des TUBULURES, les précautions pour éviter des conditions d'écoulement libre de la solution d'IRRIGATION ophtalmique, et la PROCEDURE à suivre pour le changement de la source de solution d'IRRIGATION ophtalmique;

c) les instructions concernant le raccordement sécurisé des prises, des câbles des PIECES A MAIN et des autres raccords.

201.7.9.2.12 Nettoyage, désinfection et stérilisation

Addition:

Pour les pièces restérilisables, les informations de traitement doivent être conformes à l'ISO 17664:2017. Ces informations doivent être fournies à l'ORGANISME RESPONSABLE ou à l'OPERATEUR [9].

201.7.9.2.13 Maintenance

Addition:

Les instructions d'utilisation doivent donner à l'OPERATEUR ou à l'ORGANISME RESPONSABLE une recommandation qui indique de vérifier régulièrement tous les câbles des PIECES A MAIN et tous les éventuels fils et une recommandation sur les mesures à prendre lorsque des dommages (par exemple un fil à découvert, des entailles dans l'isolation, une déformation, etc.) sont constatés.

201.7.9.3.1 Généralités

Addition:

Pour les APPAREILS EM et les SYSTEMES EM qui ont une fonction de DIATHERMIE, la description technique doit inclue une référence au groupe 2 pour le dispositif.

201.8 Protection contre les DANGERS d'origine électrique provenant des APPAREILS EM

L'Article 8 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:

201.9 Protection contre les DANGERS MECANIQUES des APPAREILS EM et SYSTEMES EM

L'Article 9 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:

Paragraphe supplémentaire:

201.9.5.101 Corps solides en provenance des PARTIES APPLIQUEES

La taille et la quantité acceptables des corps solides en provenance des PARTIES APPLIQUEES doivent être évaluées au moyen du PROCESSUS de GESTION DES RISQUES. La conformité doit être déterminée et documentée dans le DOSSIER DE GESTION DES RISQUES.

201.10 Protection contre les DANGERS dus aux rayonnements involontaires ou excessifs

L'Article 10 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:

201.10.6 Rayonnements infrarouges

Se reporter au 201.12.4.101.5, point 2).

201.10.7 Rayonnements ultraviolets

Se reporter au 201.12.4.101.5, point 1).

201.11 Protection contre les températures excessives et les autres DANGERS

L'Article 11 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:

201.11.1.2 Température des PARTIES APPLIQUEES

201.11.1.2.1 PARTIES APPLIQUEES destinées à fournir de la chaleur à un PATIENT

Remplacement:

Les PIECES A MAIN pour DIATHERMIE, PHACOFRAGMENTATION, LASER et VITRECTOMIE sont considérées comme des PARTIES APPLIQUEES destinées à fournir de la chaleur à un PATIENT.

La température ou les effets cliniques doivent être déterminés et documentés dans le DOSSIER DE GESTION DES RISQUES.

201.11.6.7 Stérilisation des APPAREILS EM et des SYSTEMES EM

Addition:

L'emballage pour les ACCESSOIRES stérilisés au stade terminal pour les DISPOSITIFS DE RETRAIT DU CRISTALLIN et les DISPOSITIFS DE VITRECTOMIE doit être conforme aux exigences de l'ISO 11607-1:2019. Les exigences de validation pour les procédés de formage, scellage et assemblage pour cet emballage doivent suivre l'ISO 11607-2:2019.

201.12 Précision des commandes, des instruments et protection contre les caractéristiques de sortie présentant des risques

L'Article 12 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:

201.12.1 Précision des commandes et des instruments

Paragraphes supplémentaires:

201.12.1.101 Exigences supplémentaires de précision des commandes et des instruments

NOTE Les exigences supplémentaires relatives à la précision des commandes et instruments sont détaillées de 201.12.1.101.1 à 201.12.1.101.5, au 201.12.1.101.7 et au 201.12.1.101.8.

201.12.1.101.1 Précision de la pression d'IRRIGATION

La sortie de la pression d'IRRIGATION ne doit pas s'écarter du réglage indiqué sur les DISPOSITIFS DE RETRAIT DU CRISTALLIN et les DISPOSITIFS DE VITRECTOMIE de plus de ± 20 % ou ± 10 mmHg (± 1,3 kPa), en retenant la valeur la plus élevée, pour un dispositif donné dans une configuration définie (voir le 201.12.4.101.1 pour la limite des caractéristiques de sortie présentant des risques).

La vérification est effectuée en utilisant la ou les méthodes d'essai appropriées 1 et/ou 2:

a) Méthode d'essai 1 (IRRIGATION en alimentation par gravité)

1) Régler la température d'environnement d'essai à 25 °C ± 5 °C.

2) Installer les TUBULURES et AMORCER le dispositif selon les instructions d'utilisation du FABRICANT.

3) Mettre à zéro le relevé du capteur de pression. Raccorder le capteur de pression à l'extrémité du conduit d'IRRIGATION et placer le capteur de pression à ± 2,5 cm du niveau de l'œil du PATIENT simulé, *voir la Figure 201.101.*

4) Lancer le flux de liquide selon les instructions d'utilisation du FABRICANT.

NOTE 1 Dans le cas où le système utilise la hauteur de la tige IV sans réclamer la pression d'IRRIGATION (c'est-à-dire, lorsqu'aucun niveau de l'œil du PATIENT n'est défini), mettre le relevé du compteur de pression ainsi que la tige IV à zéro pendant que le capteur de pression est à un niveau de l'œil du PATIENT simulé. Utiliser le même point zéro (niveau de l'œil du PATIENT simulé) pour la vérification des caractéristiques de sortie présentant des risques pour la pression d'IRRIGATION spécifiées en 201.12.4.101.1.

5) Régler la hauteur du réservoir d'alimentation par gravité à 0 cm ou au réglage le plus bas et enregistrer le relevé du capteur de pression après 5 s.

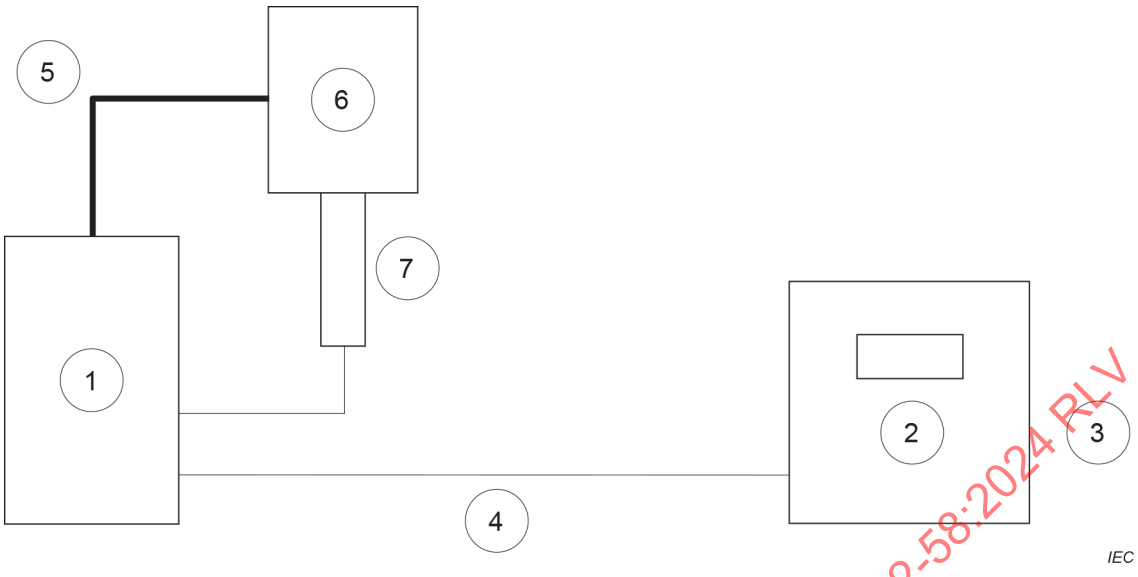
6) Augmenter la hauteur du réservoir de 20 cm et attendre 5 s pour enregistrer le relevé du capteur de pression.

7) Répéter l'étape 6) jusqu'à atteindre la hauteur maximale du réservoir.

8) Enregistrer le relevé du capteur de pression à la hauteur maximale du réservoir.

9) Répéter les relevés aux hauteurs utilisées dans les étapes 5), 6) et 7) à mesure que la hauteur diminue et attendre 5 s pour enregistrer le relevé du capteur de pression à chaque point.

10) Confirmer que tous les relevés sont compris dans la plage indiquée.



Pour les légendes, voir le Tableau 201.101.

Figure 201.101 – Méthode d'essai pour l'IRRIGATION en alimentation par gravité

b) Méthode d'essai 2 (IRRIGATION pressurisée)

1) Régler la température d'environnement d'essai à 25 °C ± 5 °C.

2) Installer les TUBULURES et AMORCER le dispositif selon les instructions d'utilisation du FABRICANT.

3) Mettre à zéro le relevé du capteur de pression (PM - pressure meter). Raccorder le capteur de pression à l'extrémité du conduit d'IRRIGATION et placer le capteur de pression à ± 2,5 cm du niveau de l'œil du PATIENT simulé, voir la Figure 201.102.

4) Lancer le flux de liquide selon les instructions d'utilisation du FABRICANT.

5) Régler la pression d'essai d'IRRIGATION à 0 mmHg (0 kPa) ou au réglage le plus bas et enregistrer le relevé du capteur de pression après 5 s.

6) Augmenter les valeurs de pression d'essai de 20 mmHg (2,7 kPa).

7) Attendre 5 s et enregistrer le relevé du capteur de pression.

8) Répéter les étapes 6) et 7) pour le réglage de la pression d'essai par paliers de 20 mmHg (2,7 kPa) jusqu'à atteindre le réglage de pression maximal.

9) Répéter les relevés utilisés aux étapes 6), 7) et 8) à mesure que la pression diminue et attendre 5 s pour enregistrer le relevé du capteur de pression à chaque point.

NOTE 2 Cela peut impliquer le raccordement à nouveau du conduit d'IRRIGATION pour les mesurages de la diminution.

10) Confirmer que tous les relevés sont compris dans la plage indiquée.