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

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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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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.*

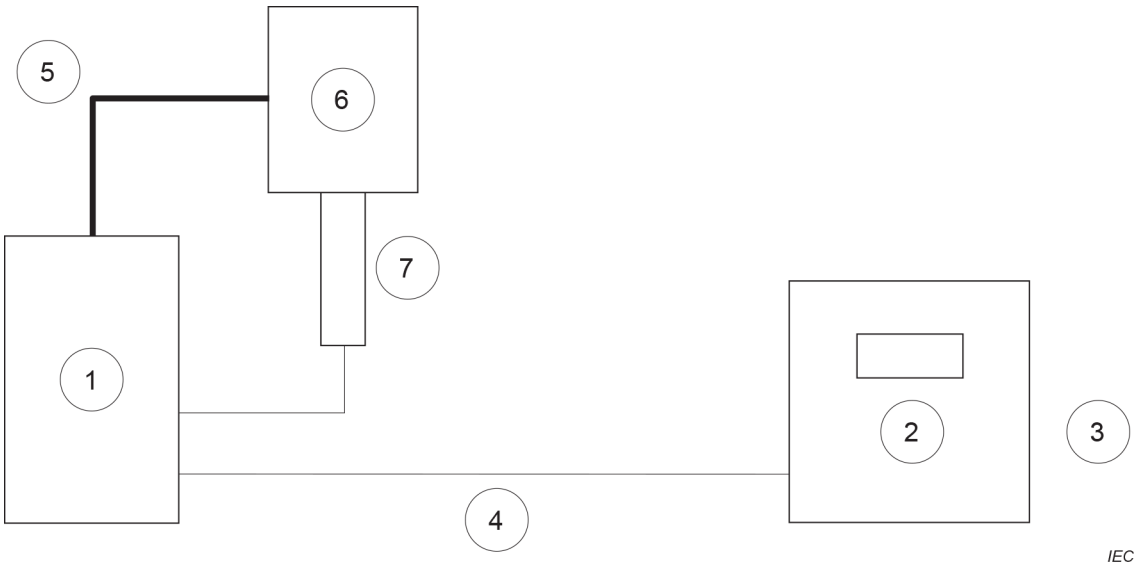
6) *Increase the reservoir height by 20 cm and wait for 5 s and record the pressure meter reading.*

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).*

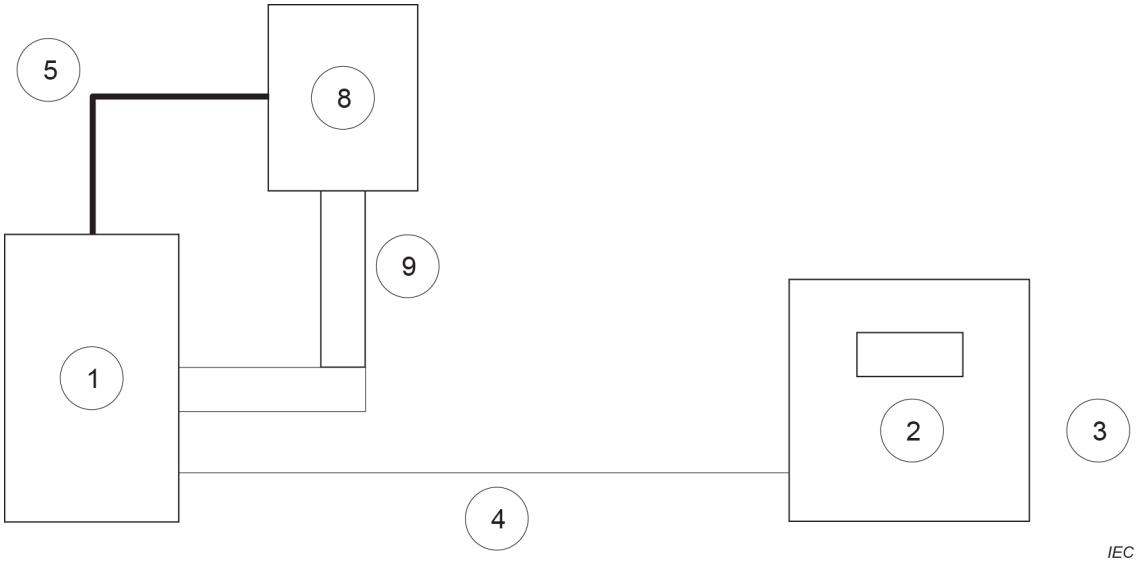
7) *Wait for 5 s and record pressure meter reading.*

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

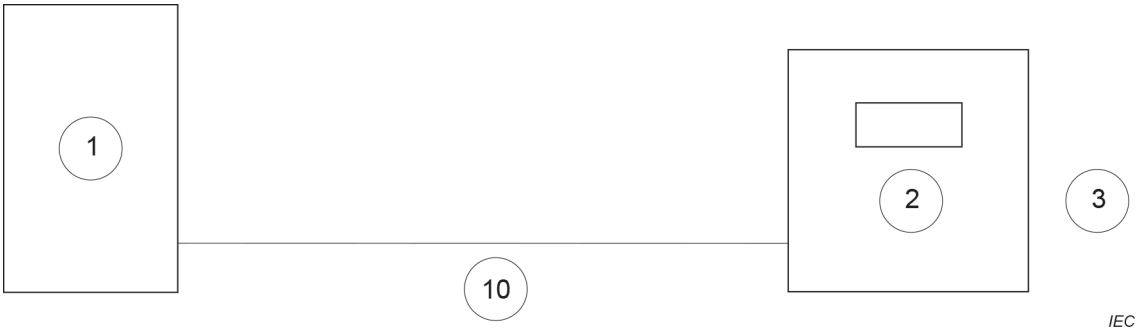
201.12.1.101.2 Accuracy of ASPIRATION pressure

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.*

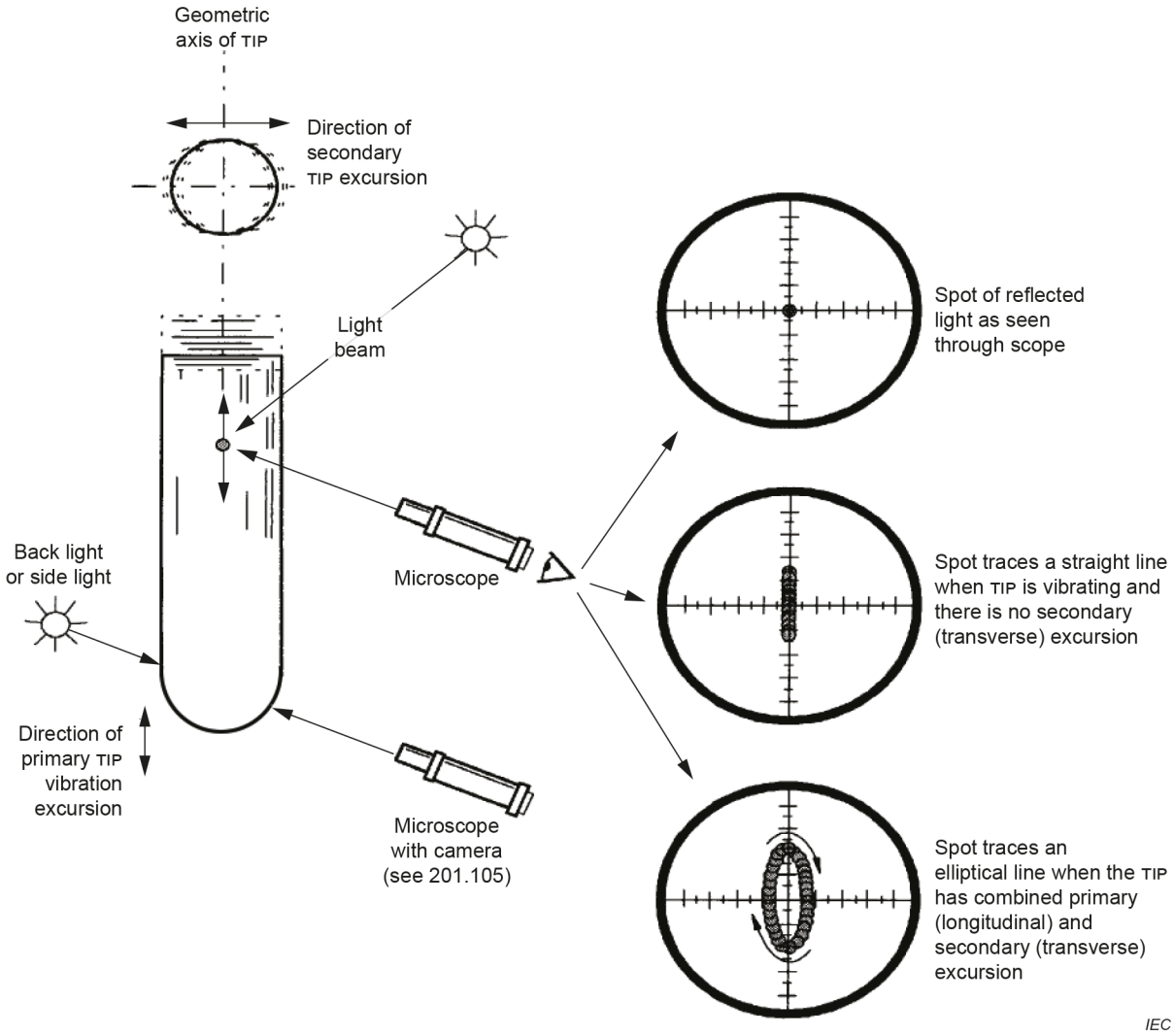


Figure 201.104 – Test method for ultrasonic velocity of TIP accuracy

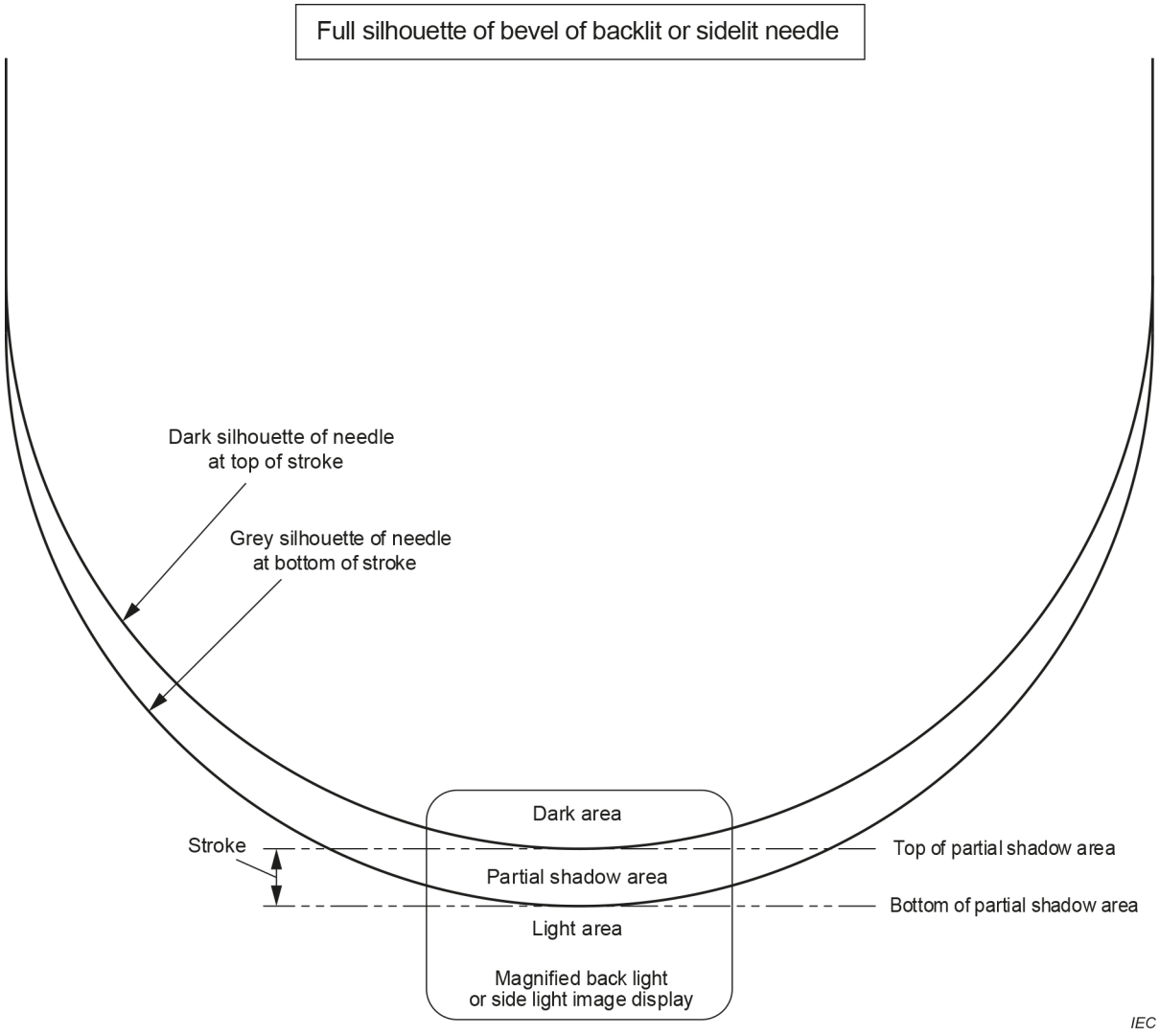


Figure 201.105 – Partial shadow, and camera field of view relative to TIP

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.