

INTERNATIONAL STANDARD

NORME INTERNATIONALE



Medical electrical equipment –

Part 2-76: Particular requirements for the basic safety and essential performance of low energy ionized gas haemostasis equipment

Appareils électromédicaux –

Partie 2-76: Exigences particulières pour la sécurité de base et les performances essentielles des appareils d'hémostase à gaz ionisé à faible pouvoir calorifique



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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-76: Particular requirements for the basic safety and essential performance of low energy ionized gas haemostasis equipment

FOREWORD

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as “IEC Publication(s)”). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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This consolidated version of the official IEC Standard and its amendment has been prepared for user convenience.

IEC 60601-2-76 edition 1.1 contains the first edition (2018-04) [documents 62D/1554/FDIS and 62D/1573/RVD] and its amendment 1 (2023-08) [documents 62D/2047/FDIS and 62D/2076/RVD].

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

International standard IEC 60601-2-76 has been prepared by IEC subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

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

In this standard, the following print types are used:

- requirements and definitions: roman type;
- *test specifications: italic type*;
- informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;
- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

- “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
- “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment*, can be found on the IEC website.

The committee has decided that the contents of this document and its amendment 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,
- replaced by a revised edition, or
- amended.

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INTRODUCTION

The minimum safety requirements specified in this particular standard are considered to provide for a practical degree of safety in the operation of LOW ENERGY IONIZED GAS HAEMOSTASIS EQUIPMENT.

This particular standard amends and supplements IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*, hereinafter referred to as the general standard (see 201.1.4).

The requirements are followed by specifications for the relevant tests.

A "Particular guidance and rationale" section giving some explanatory notes, where appropriate, about the more important requirements is included in Annex AA.

Clauses or subclauses for which there are explanatory notes in Annex AA are marked with an asterisk (*).

It is considered that knowledge of the reasons for these requirements will not only facilitate the proper application of the standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However, this annex does not form part of the requirements of this document.

INTRODUCTION to Amendment 1

At the October 2019 meeting of IEC SC 62D in Shanghai, China, the subcommittee discussed the need for administrative/technical changes to most 62D standards after completion of the 29 amendment projects within the IEC 60601-1 series. Those projects were all completed and the amendments published in 2020.

The full list of IEC SC 62D documents that will be amended or revised can be found within the IEC document 62D/1792/DC. The results and comments on the DC can be found within 62D/1808/INF. The review report for this amendment is 62D/1811A/RR.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-76: Particular requirements for the basic safety and essential performance of low energy ionized gas haemostasis equipment

201.1 Scope, object and related standards

Clause 1 of the general standard¹ applies, except as follows:

201.1.1 Scope

Replacement:

This part of IEC 60601 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of LOW ENERGY IONIZED GAS HAEMOSTASIS EQUIPMENT hereafter referred to as ME EQUIPMENT.

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 and 8.4.1 of the general standard.

NOTE See also 4.2 of the general standard.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular requirements for BASIC SAFETY and ESSENTIAL PERFORMANCE of LOW ENERGY IONIZED GAS HAEMOSTASIS EQUIPMENT as defined in 201.3.207.

201.1.3 Collateral standards

Addition:

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

201.1.4 Particular standards

Replacement:

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

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

¹ The general standard is IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.

For brevity, IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are referred to in this particular standard as the general standard. Collateral standards are referred to by their document numbers.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix “201” (e.g. 201.1 in this document addresses the content of Clause 1 of the general standard) 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 particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

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

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

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

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101, however because definitions in the general standard are numbered 3.1 through 3.147 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 document” is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

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

201.2 Normative references

NOTE Informative references are listed in the bibliography.

Clause 2 of the general standard 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

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, IEC 60601-1:2005/AMD2:2020 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <http://www.iso.org/obp>

Replacement of NOTE 1 by the following:

NOTE 1 Where the terms "voltage" and "current" are used in this document, they mean the RMS values of a voltage or current unless stated otherwise. When a direct voltage and current is measured, the voltage or current is averaged over 1 s with a sampling rate of at least 10^4 sample/s. When an alternating, ~~direct~~ or composite voltage or current ~~averaged over 1 s unless stated otherwise~~ is measured, a minimum of one second is measured.

Addition:

201.3.201

FINGERSWITCH

device generally included with an IONIZED GAS ACCESSORY which, when activated by the OPERATOR, enables IONIZED GAS output to be produced and, when released, disables the IONIZED GAS output

201.3.202

* HAEMOSTASIS

control or prevention of bleeding from capillaries and similar small blood vessels in biological tissues using IONIZED GAS

201.3.203

IONIZED GAS

gas composed in part of charged particles and excited atoms or molecules

Note 1 to entry: The frequency used to create the IONIZED GAS is called the ionization frequency.

201.3.204

IONIZED GAS ACCESSORY

ACCESSORY intended to direct IONIZED GAS to the PATIENT

201.3.205

IONIZED GAS ACCESSORY CABLE

portion of the IONIZED GAS ACCESSORY between the IONIZED GAS CONNECTOR and the part held by the OPERATOR

201.3.206

IONIZED GAS CONNECTOR

part of a IONIZED GAS ACCESSORY intended for connection to the output TERMINAL DEVICE of LOW ENERGY IONIZED GAS HAEMOSTASIS EQUIPMENT

201.3.207

* LOW ENERGY IONIZED GAS HAEMOSTASIS EQUIPMENT

ME EQUIPMENT including an IONIZED GAS ACCESSORY and any other associated ACCESSORIES which uses IONIZED GAS for the purpose of HAEMOSTASIS in biological tissue and limits the ionization frequency LEAKAGE CURRENT to 20 mA or less

201.3.208

MAXIMUM IONIZATION VOLTAGE

maximum peak voltage used to create the IONIZED GAS under NORMAL CONDITION

201.3.209

PLASMA FLARE

visible IONIZED GAS emitted from the IONIZED GAS ACCESSORY

201.4 * General requirements

Clause 4 of the general standard applies.

NOTE See Annex AA for additional information.

201.5 General requirements for testing ME EQUIPMENT

Clause 5 of the general standard applies.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies.

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of the general standard applies, except as follows:

201.7.9.2.1 * General

Replace the third dashed item by the following dashed items:

- advice for the OPERATOR to avoid LOW ENERGY IONIZED GAS HAEMOSTASIS EQUIPMENT output settings that may exceed the rating(s) of the IONIZED GAS ACCESSORY;
- any known contraindication(s) to the use of the ME EQUIPMENT. For LOW ENERGY IONIZED GAS HAEMOSTASIS EQUIPMENT this shall include, at minimum, a statement that the equipment is not intended for use where blood flow is at arterial pressure; and

Additional subclause:

201.7.9.2.2.101 Additional warnings

The instructions for use shall include the following warnings:

- 1) the IONIZED GAS ACCESSORY CABLE should be positioned in such a way that contact with the PATIENT or other leads is avoided;
- 2) for PATIENTS with cardiac pacemakers or other active implants, a possible HAZARD exists because interference with the action of the pacemaker may occur, or the pacemaker may be damaged. In case of doubt, approved qualified advice should be obtained.

201.7.9.2.14 ACCESSORIES, supplementary equipment, used material

Addition:

The instructions for use shall include:

Advice for the OPERATOR to avoid using the IONIZED GAS ACCESSORY with LOW ENERGY IONIZED GAS HAEMOSTASIS EQUIPMENT output settings that may exceed the rating(s) of the ACCESSORY.

201.7.9.3 Technical description

201.7.9.3.1 General

Addition:

- Voltage output data. The MAXIMUM IONIZATION VOLTAGE.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of the general standard applies, except as follows:

201.8.3 * Classification of APPLIED PARTS

Addition:

- aa) IONIZED GAS ACCESSORIES shall be considered APPLIED PARTS, and shall be TYPE BF or TYPE CF because the PLASMA FLARE provides a conductive path between the IONIZED GAS ACCESSORY and the PATIENT.

Additional subclause:

201.8.4.101 Excitation current monitoring circuits

Circuits monitoring the flow of current used to generate the IONIZED GAS shall be isolated from earth by at least two MEANS OF PATIENT PROTECTION.

201.8.5.1.2 * MEANS OF PATIENT PROTECTION (MOPP)

Amendment:

For IONIZED GAS ACCESSORIES including IONIZED GAS ACCESSORY CABLES and IONIZED GAS CONNECTORS, separation between the circuits used to generate the IONIZED GAS and the ENCLOSURE including SIGNAL INPUT PARTS and SIGNAL OUTPUT PARTS need not be subjected to the dielectric strength test of 201.8.8.3.

The CREEPAGE DISTANCES and AIR CLEARANCES of the equipment other than IONIZED GAS ACCESSORIES tested according to 201.8.8.3.101 and that are intended to prevent contact with circuits used to generate the IONIZED GAS shall be as follows:

- a) For an ionization frequency less than 1 kHz, the general standard applies.
b) For an ionization frequency between 1 kHz and 200 kHz, the greater value of the following calculation is chosen:

$$\text{CREEPAGE DISTANCE: } 16 - \frac{13f}{200} \text{ mm/kV, or } 21 - \frac{17,3f}{200} \text{ mm}$$

$$\text{AIR CLEARANCE: } 9,14 - \frac{6,14f}{200} \text{ mm/kV, or } 12,2 - \frac{8,2f}{200} \text{ mm}$$

where

f is the frequency in kHz.

- c) For an ionization frequency higher than 200 kHz, the CREEPAGE DISTANCE and AIR CLEARANCE is at least 3 mm/kV or 4 mm, whichever is the greater.

The reference voltage shall be the maximum peak voltage.

This requirement does not apply for components when the adequacy of ratings can be demonstrated, for example by component manufacturers' ratings or by the dielectric strength test of 201.8.8.3.

This requirement described in 201.8.5.1.2 does not apply to IONIZED GAS ACCESSORIES. On the other hand, the requirements and tests for IONIZED GAS ACCESSORIES are found in 201.8.8.3.

201.8.7.3 Allowable values

Amendment:

Item e) does not apply

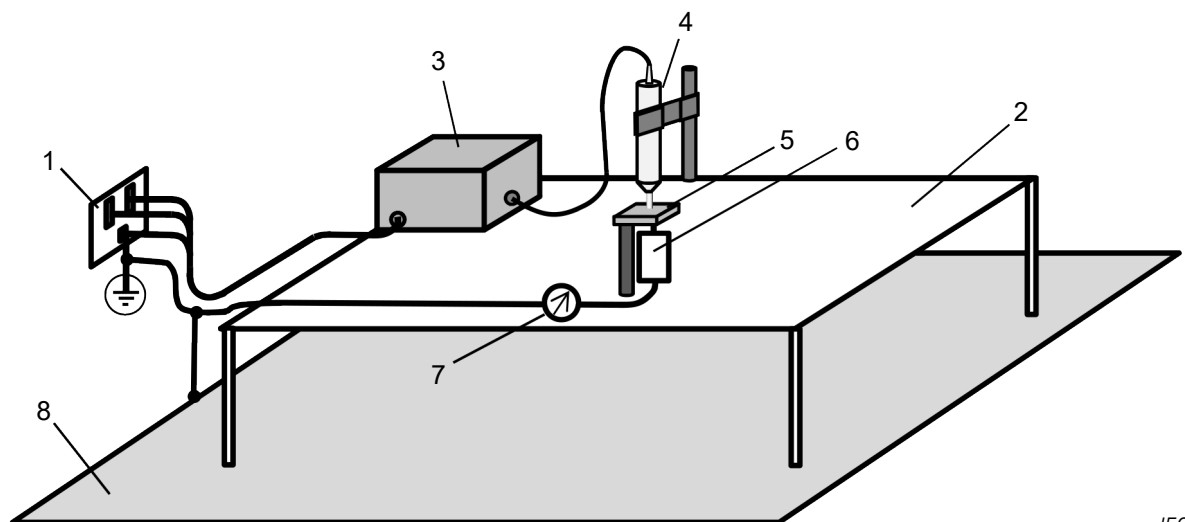
Additional subclause:

201.8.7.3.101 * LEAKAGE CURRENTS

- a) In order to prevent burning or neural stimulation, the LEAKAGE CURRENT from the PLASMA FLARE shall not exceed 20 mA.

Compliance is checked as follows:

The LEAKAGE CURRENT produced by the PLASMA FLARE is measured according to Figure 201.101. The handpiece shall be positioned to ensure the PLASMA FLARE strikes the centre surface of the copper plate but does not close off the gas flow. The LEAKAGE CURRENT shall be measured using an RF current meter with an accuracy of at least $\pm 2\%$ at 20 mA and a measurement range of at least 30 kHz through 20 MHz.



IEC

Key

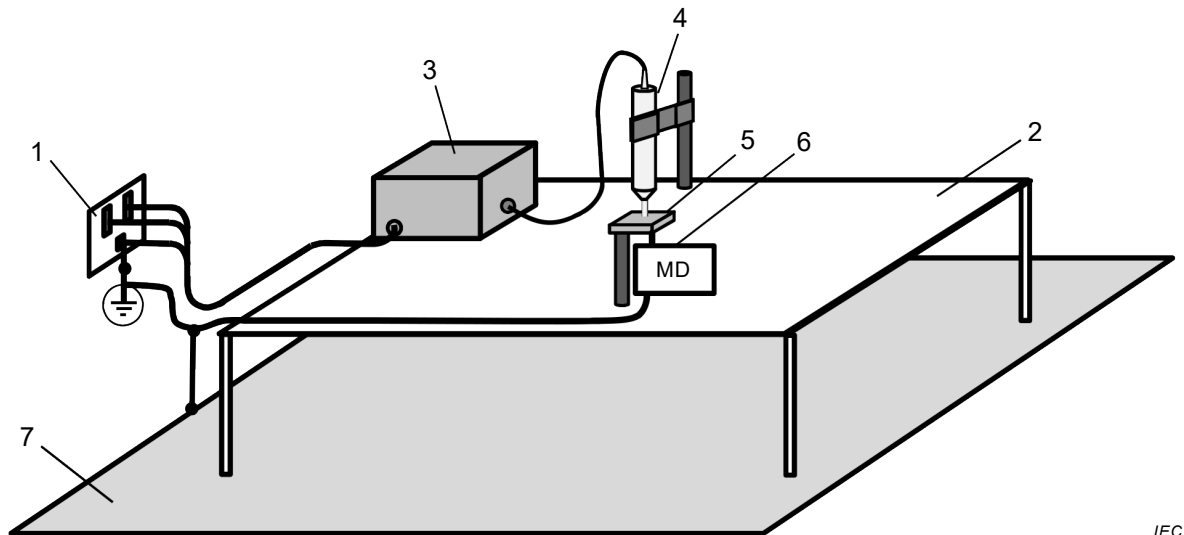
- 1 supply mains
- 2 table, made of insulating material
- 3 Equipment Under Test (EUT)
- 4 handpiece
- 5 flat copper plate (100 mm × 100 mm × 1 mm)
- 6 200 Ω non-inductive resistor
- 7 RF current meter
- 8 earthed conductive plane

Figure 201.101 – Measurement of LEAKAGE CURRENT from the PLASMA FLARE

- b) In order to prevent electric shock, PATIENT LEAKAGE CURRENT from the PLASMA FLARE shall not exceed the limits from Table 3 of the general standard for the declared APPLIED PART type.

Compliance is checked as follows:

The PATIENT LEAKAGE CURRENT produced by the PLASMA FLARE is measured according to Figure 201.102 using the MD (measuring device) as defined in Figure 12 of the general standard.



IEC

Key

- 1 supply mains
- 2 table, made of insulating material
- 3 Equipment Under Test (EUT)
- 4 handpiece
- 5 flat copper plate (100 mm × 100 mm × 1 mm)
- 6 Measuring Device (MD) from the general standard
- 7 earthed conductive plane

Figure 201.102 – Measurement of low frequency PATIENT LEAKAGE CURRENT

- c) LEAKAGE CURRENT limits for IONIZED GAS ACCESSORY CABLES shall be determined as follows:
Where the MAXIMUM IONIZATION VOLTAGE is conducted by two physically separated cables, the LEAKAGE CURRENT limit for each cable shall be:

$$I_{\text{leakage}}(\text{mA}) = 2,0 \times 10^{-5} \times d \times L \times f_{\text{test}} \times U_{\text{peak}}$$

where

d is the smallest outer dimension of the insulation in mm,

f_{test} is the test voltage frequency in kHz,

L is the length of sample insulation through which LEAKAGE CURRENT passes, in cm, and

U_{peak} is the lesser of the MAXIMUM IONIZATION VOLTAGE or 400 V_{peak} .

The corresponding limit for cables where the gas ionization voltage is conducted inside a single cable (such as a coaxial cable) or within a single handpiece, the LEAKAGE CURRENT limit shall be:

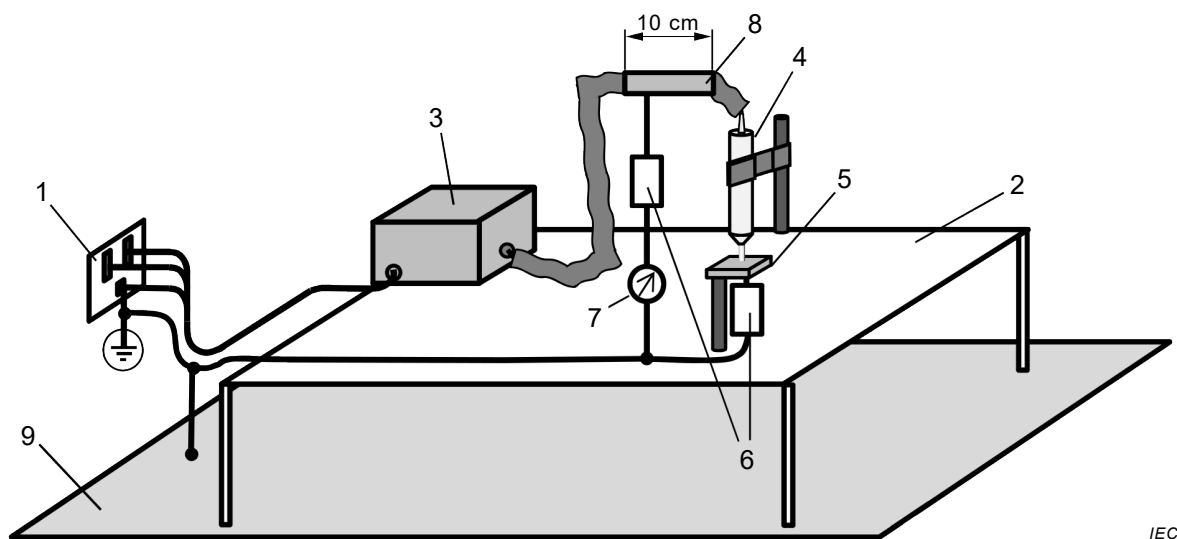
$$I_{\text{leakage}} \text{ (mA)} = 4,0 \times 10^{-5} \times d \times L \times f_{\text{test}} \times U_{\text{peak}}$$

Compliance is checked as follows:

LEAKAGE CURRENTS from the IONIZED GAS ACCESSORY CABLE shall be measured utilizing a RF current meter with an accuracy of at least $\pm 2\%$ at 20 mA and a measurement range of at least 30 kHz through 20 MHz.

The following test is performed on each single output of the equipment in turn:

- 1) IONIZED GAS ACCESSORY CABLES, including those that are not being tested but that are connected in NORMAL USE, are arranged as shown in Figure 201.103.
- 2) Wrap the entire length of the cable being tested (excluding IONIZED GAS CONNECTORS and the handpiece) with a porous cloth soaked in 0,9 % saline solution.
- 3) Wrap the mid-section of the saline-soaked cloth with metal foil covering a 10 cm length connected to earth through a 200 Ω (non-inductive) resistor.
- 4) The LEAKAGE CURRENT is then measured through the 200 Ω resistor while the equipment is operated to generate a test voltage of the lesser of the MAXIMUM IONIZATION VOLTAGE or 400 V_{peak} .



Key

- 1 supply mains
- 2 table, made of insulating material
- 3 Equipment Under Test (EUT)
- 4 handpiece
- 5 flat copper plate (100 mm × 100 mm × 1 mm)
- 6 200 Ω non-inductive resistors (2x)
- 7 RF current meter
- 8 saline-soaked wrap covered by 10 cm metal foil
- 9 earthed conductive plane

Figure 201.103 – Measurement of IONIZED GAS ACCESSORY CABLE LEAKAGE CURRENT

201.8.8.3 Dielectric strength

Addition:

The requirements and tests for IONIZED GAS ACCESSORIES including IONIZED GAS ACCESSORY CABLES and IONIZED GAS CONNECTORS are given in 201.8.8.3.101.

Additional test conditions:

- aa) If, during dielectric strength testing of solid insulation forming MEANS OF PATIENT PROTECTION, a breakdown or flashover occurs through the atmosphere at the AIR CLEARANCE specified in 8.9 of the general standard and 201.8.5.1.2 of this document, an insulating barrier may be placed to prevent this breakdown so that the protective insulation can be tested.
- bb) If, during dielectric strength testing of solid insulation forming MEANS OF PATIENT PROTECTION, a breakdown or flashover occurs at the CREEPAGE DISTANCE specified in 8.9 of the general standard and 201.8.5.1.2 of this document, then the test shall be carried out on the components which provide MEANS OF PATIENT PROTECTION, such as transformers, relays, optocouplers or CREEPAGE DISTANCES on printed circuit boards.

Additional subclauses:

201.8.8.3.101 * IONIZED GAS ACCESSORY insulation

IONIZED GAS ACCESSORIES including IONIZED GAS ACCESSORY CABLES and IONIZED GAS CONNECTORS shall be sufficiently insulated to mitigate unintended thermal burn risk to the PATIENT and OPERATOR under conditions of NORMAL USE.

Compliance is checked as follows:

Test samples, other than those marked for single use, shall have undergone the sterilization methods and number of cycles as outlined in the instructions for use. See 7.9.2.12 in the general standard.

The insulated parts of IONIZED GAS ACCESSORY CABLES excluding IONIZED GAS CONNECTORS shall be preconditioned by immersion in 0,9 % saline for 12 h. Operative conductors which may have been exposed in preparation for testing, as well as the insulation of the cords of IONIZED GAS ACCESSORIES within 100 mm of the ends, shall be protected from contact with saline. Upon completion of this preconditioning, excess saline shall be removed from surfaces and cavities by shaking and/or wiping with a dry cloth.

Immediately following saline preconditioning, applicable electrical testing shall be conducted in the following order:

- IONIZED GAS ACCESSORY ionization frequency dielectric strength (201.8.8.3.102);
- IONIZED GAS ACCESSORY mains frequency dielectric strength (201.8.8.3.103).

201.8.8.3.102 IONIZED GAS ACCESSORY ionization frequency dielectric strength

The insulation applied to an IONIZED GAS ACCESSORY shall be capable of withstanding a voltage of 120 % of the MAXIMUM IONIZATION VOLTAGE without breakdown when tested at the nominal ionization frequency.

Compliance is checked as follows:

The insulation of the IONIZED GAS ACCESSORY, including the handpiece, shall be wrapped in a porous cloth soaked in 0,9 % saline. This cloth shall cover the entire exterior surface of the insulation. One output pole of the test voltage source shall be connected to the porous cloth

and the other pole of the test voltage source shall be connected to all of the conductor(s) of the IONIZED GAS ACCESSORY.

The peak test voltage is monitored between the test voltage source output poles. The output of the test voltage source is then increased until the peak voltage equals 120 % of the MAXIMUM IONIZATION VOLTAGE and maintained for 30 s in such a manner that it stresses the insulation of the test sample. The frequency of the test voltage shall be the nominal frequency used to create the ionized gas. No breakdown of the insulation material shall occur and the same insulation shall subsequently be tested at mains frequency according to 201.8.8.3.103.

201.8.8.3.103 IONIZED GAS ACCESSORY mains frequency dielectric strength

The insulation applied to a IONIZED GAS ACCESSORY, including those portions of insulation having been tested at the ionization frequency according to 201.8.8.3.102, shall withstand a direct current (DC) or mains frequency peak voltage of 1 000 V greater than the MAXIMUM IONIZATION VOLTAGE specified by the MANUFACTURER of the IONIZED GAS ACCESSORY.

Compliance is tested as follows:

The test voltage source shall produce a direct current (DC) or mains frequency signal. The test duration shall be 30 s for IONIZED GAS ACCESSORY handpieces and IONIZED GAS CONNECTORS. The test duration for IONIZED GAS ACCESSORY CABLES shall be 5 min. Although corona discharge may occur, no breakdown of the insulation or flashover shall occur. Immediately after this dielectric strength test, any incorporated FINGERSWITCH shall be operated 10 times. An ohmmeter shall be used to test whether the switching mechanism operates as intended to ensure that, when connected to LOW ENERGY IONIZED GAS HAEMOSTASIS EQUIPMENT, the IONIZED GAS output will be disabled when the FINGERSWITCH is released.

The insulated parts of IONIZED GAS CONNECTORS more than 10 mm CREEPAGE DISTANCE from exposed operative conductors shall be wrapped with a porous cloth soaked in 0,9 % saline. The midsection of the cloth is then wrapped with metal foil. The test voltage is applied between the foil and all of the operative IONIZED GAS CONNECTOR contacts.

The entire length of the insulation IONIZED GAS ACCESSORY CABLES, including that portion previously tested according to this subclause, but exclusive of the sections within 100 mm of the ends, shall be immersed in a bath of 0,9 % saline. The test voltage is simultaneously applied between a conductive electrode immersed in the saline bath and all of the conductors in the IONIZED GAS CONNECTOR.

IONIZED GAS ACCESSORY handpieces complete with any detachable electrodes are prepared for testing and connected to the test voltage source using the same techniques as described above. The saline-soaked cloth and foil applied for that test may be left in place for this test provided care is taken to ensure that the cloth remains thoroughly wetted.

201.8.9.1.1 General

Addition:

- for CREEPAGE DISTANCES and AIR CLEARANCE intended to provide separation from MAXIMUM IONIZATION GAS ACCESSORY VOLTAGE circuits in parts of the ME EQUIPMENT other than the IONIZATION GAS ACCESSORY, only the separation defined in 201.8.5.1.2 shall apply.

201.8.9.1.5 ME EQUIPMENT rated for high altitude

Addition:

This requirement does not apply to separation distances between MAXIMUM IONIZATION VOLTAGE circuits and the ENCLOSURE including SIGNAL INPUT/OUTPUT PARTS and between different MAXIMUM IONIZATION VOLTAGE circuits.

201.8.10.4.1 Limitation of operating voltages

Subclause 8.10.4.1 of the general standard does not apply. See 201.8.10.4.101.

Additional subclauses:

201.8.10.4.101 Switch sensors

201.8.10.4.101.1 General requirements for IONIZED GAS activation switches

LOW ENERGY IONIZED GAS HAEMOSTASIS EQUIPMENT shall be provided with a switch requiring continuous activation in order to energize and enable flow of the IONIZED GAS.

The switch shall be supplied from a power source isolated from the MAINS PART and from earth. The power source shall have a voltage not exceeding 12 V, if a conductive connection to the APPLIED PART exists, and not exceeding 24 V AC or 34 V DC in other cases.

NOTE This requirement applies to voltages appearing within the switch. Common-mode ionization excitation voltages should be disregarded.

Under SINGLE FAULT CONDITION the switch shall not cause low-frequency PATIENT LEAKAGE CURRENT(S) exceeding the allowable limits (see 201.8.7.3).

Compliance is checked by inspection, functional testing, and by measurement of voltage and LEAKAGE CURRENT(S).

Where the switch is provided with input terminals intended for connection to external electrical switch contacts, it shall not be possible to activate any IONIZED GAS OUTPUT of the LOW ENERGY IONIZED GAS HAEMOSTASIS EQUIPMENT when the input terminals are bridged by a non-inductive resistance equal to or greater than 1 000 Ω .

Compliance is checked by a functional test.

201.8.10.4.101.2 Footswitches

Footswitches shall comply with the following requirement.

The force required to actuate the switch shall be not less than 10 N, applied over an area of 625 mm² anywhere on the operating surface of the footswitch.

Compliance is checked by measurement of the actuating force.

201.8.10.4.2 * Connection cords

Replacement:

Anchorage of IONIZED GAS ACCESSORY CABLES and gas tubing shall be designed to minimize the RISK to PATIENTS and OPERATORS arising from damage to conductors, insulation or tubing caused by flexure or excessive tension.

Compliance shall be checked by inspection and by the following test:

The anchorages on IONIZED GAS ACCESSORY CABLES and tubing are tested one at a time.

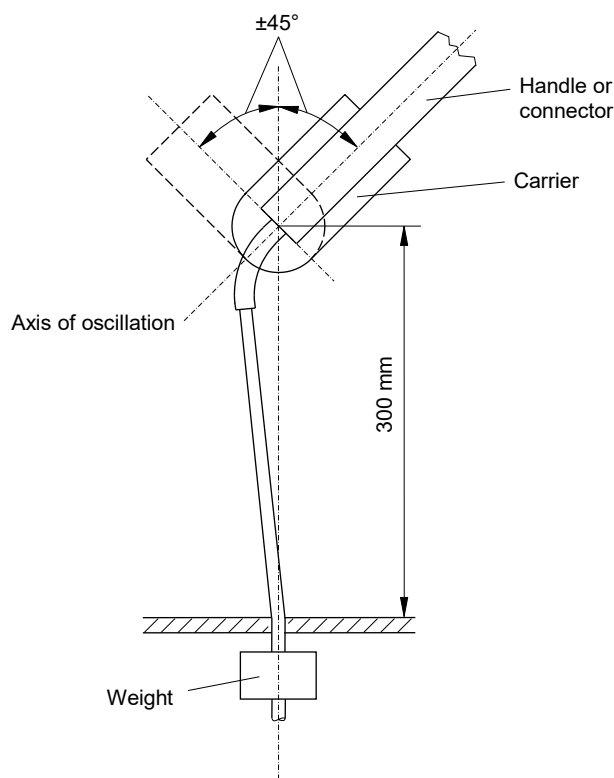
The IONIZED GAS ACCESSORY CABLES or tubing under test is fixed in an apparatus similar to that shown in Figure 201.104 so that when the oscillating member of the apparatus is at the middle of its travel, the axis of the cord or tube, where it leaves the part under test is vertical and passes through the axis of oscillation. The cord is passed through an aperture 300 mm from the axis of oscillation and a weight equal to the cord or tube and connector of the IONIZED GAS ACCESSORY is affixed to the cable below this aperture for the purpose of applying tension. The maximum diameter of the hole should not be more than 2 times the diameter of the cord or tube.

Where an anchorage of the IONIZED GAS ACCESSORY CABLES under test is fitted with two or more cords or tubes, these shall be tested together, with the total weight affixed to the anchorage being the sum of the weights required to be applied to each cord individually.

The oscillating member is rotated through an angle of 90° (45 ° on each side of the vertical).

The number of cycles applied to handpiece cable anchorages of cords or tubes shall be 10 000 (200 for IONIZED GAS ACCESSORIES marked for single use only) at the rate of approximately 30 cycles per minute. The number of cycles applied to anchorages of cables and tubes of IONIZED GAS CONNECTORS shall be 5 000 (100 for IONIZED GAS ACCESSORIES marked for single use only) at the rate of approximately 30 cycles per minute.

After the test, the cord or tube shall not have worked loose nor shall it show any damage. For multi-conductor cables there shall be no short circuits between individual conductors. The tensioning weight shall be increased to 1 kg and individual conductors checked for continuity using DC current not in excess of 1 A.



IEC

Figure 201.104 – Test apparatus for anchorages of IONIZED GAS ACCESSORY CABLES

201.9 Protection against mechanical HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 of the general standard applies.

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of the general standard applies.

201.11 Protection against excessive temperatures and other HAZARDS

Clause 11 of the general standard applies, except as follows:

201.11.1.2.2 * APPLIED PARTS not intended to supply heat to a PATIENT

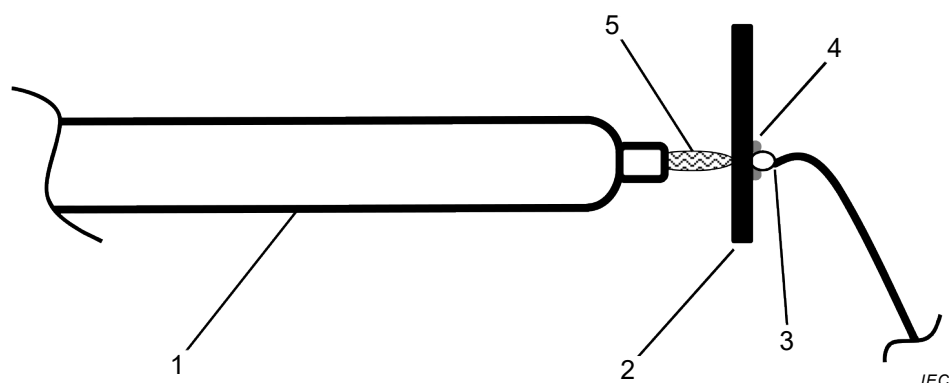
Addition:

The maximum temperature generated by the PLASMA FLARE shall not exceed 48 °C.

Compliance is tested as follows:

A k-type thermocouple with a diameter of 0,32 mm covered by a 1,7 mm long by 0,4 mm thick fluoride polymer cover is attached to the bottom of a 100 mm x 100 mm x 1 mm thick flat copper plate using thermal grease having a thermal conductivity of $\geq 4,5$ W/mK.

The nozzle of the IONIZED GAS ACCESSORY is positioned as shown in Figure 201.105. The distance from nozzle to the surface of the copper plate and the output controls of the LOW ENERGY IONIZED GAS HAEMOSTASIS EQUIPMENT are set to the values that produces the maximum temperature and do not close off the gas flow. The PLASMA FLARE is ignited and the temperature of the copper plate is monitored for 10 min using the thermocouple. The highest temperature measured is recorded.



Key

- 1 ionized gas accessory
- 2 flat copper plate (100 mm × 100 mm × 1 mm)
- 3 thermocouple
- 4 thermal grease
- 5 plasma flare

Figure 201.105 – Measurement of temperature from the PLASMA FLARE

201.11.6.3 Spillage on ME EQUIPMENT and ME SYSTEMS

Replacement:

The ENCLOSURE of the LOW ENERGY IONIZED GAS HAEMOSTASIS EQUIPMENT in NORMAL USE shall be constructed so that liquid spillage in NORMAL USE does not wet electrical insulation or other components which, when wetted, are likely to affect adversely the safety of the LOW ENERGY IONIZED GAS HAEMOSTASIS EQUIPMENT.

Compliance is checked by the following test:

A quantity of one litre of water is poured steadily onto the middle of the top surface of the LOW ENERGY IONIZED GAS HAEMOSTASIS EQUIPMENT over a period of 15 s. Parts of the LOW ENERGY IONIZED GAS HAEMOSTASIS EQUIPMENT intended to be built into a wall or mounted in a cabinet are not subjected to this test. After this treatment, the LOW ENERGY IONIZED GAS HAEMOSTASIS EQUIPMENT shall withstand the applicable dielectric strength tests specified in 201.8.8.3, and inspection shall show that water which may have entered the ENCLOSURE cannot adversely affect the safety of the LOW ENERGY IONIZED GAS HAEMOSTASIS EQUIPMENT. In particular, there shall be no trace of water on the insulation for which CREEPAGE DISTANCES are specified in 8.9.1 of the general standard.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

Clause 12 of the general standard applies, except as follows:

Additional subclauses:

201.12.2.101 Usability HAZARDS

Where a FINGERSWITCH is provided to enable the IONIZED GAS output of the LOW ENERGY IONIZED GAS HAEMOSTASIS EQUIPMENT, it shall be designed such that the RISK of unintended activation is minimized.

201.12.4.101 Output indicator

The LOW ENERGY IONIZED GAS HAEMOSTASIS EQUIPMENT shall provide an audible and visual indication when the PLASMA FLARE is active.

201.12.4.4.101 Maximum allowed output in SINGLE FAULT CONDITIONS

LOW ENERGY IONIZED GAS HAEMOSTASIS EQUIPMENT shall be provided with a system to alarm and disable the output of IONIZED GAS when, in SINGLE FAULT CONDITION, the PLASMA FLARE output increases to a point where there may be HARM to the PATIENT as determined via the RISK MANAGEMENT FILE.

NOTE The PLASMA FLARE output has both an electrical component and a gas flow component.

Compliance is checked by examination of the RISK MANAGEMENT FILE and testing by simulation of appropriate SINGLE FAULT CONDITIONS.

201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT

Clause 13 of the general standard applies.

201.14 Programmable electrical medical systems (PEMS)

Clause 14 of the general standard applies.

201.15 Construction of ME EQUIPMENT

Clause 15 of the general standard applies, except as follows:

201.15.4.7.3 Entry of liquids

Addition:

- aa) FINGERSWITCHES used to activate the output of LOW ENERGY IONIZED GAS HAEMOSTASIS EQUIPMENT shall be resistant to the effects of saline spills.

The electrical parts of FINGERSWITCHES shall be protected against the effects of ingress of liquids that might cause inadvertent energizing of the output or failure to comply with the dielectric strength tests of 201.8.8.3.102 or 201.8.8.3.103.

Compliance is checked by the following test.

The alternating current (AC) impedance of each of the switching terminals of the IONIZED GAS ACCESSORY CONNECTOR shall be measured using a frequency of at least 1 kHz and a voltage of less than 12 V. The handpiece is supported horizontally at least 50 mm above any surface with the switch activating parts uppermost. One litre of 0,9 % saline solution is poured steadily from above over the handpiece over a period of 15 s so as to wet its entire length. The liquid is allowed to drain away freely. The alternating current (AC) impedance of the switching terminals shall remain greater than 2 000 Ω .

Immediately after, each FINGERSWITCH is operated and released 10 times. The alternating current (AC) impedance of the switching terminals shall exceed 2 000 Ω within 0,5 s after each release.

Where there is doubt whether the saline has penetrated, the dielectric strength tests of 201.8.8.3.102 and 201.8.8.3.103 are performed.

201.16 ME SYSTEMS

Clause 16 of the general standard applies.

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

Clause 17 of the general standard applies.

Annex AA (informative)

Particular guidance and rationale

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

Definition 201.3.202 – HAEMOSTASIS

In the context of this document, HAEMOSTASIS of blood is intended to specifically refer to the interaction of plasma (IONIZED GAS) with blood cells causing haemostasis of the blood which then occupies breaches in the vessel walls, stopping blood flow. Because flow is blocked by the HAEMOSTASIS of blood, LOW ENERGY IONIZED GAS HAEMOSTASIS EQUIPMENT is only able to stop the flow of blood from capillaries and similar blood vessels where the blood does not flow under pressure (also referred to as “oozing”).

The term was defined in this document to distinguish the action of LOW ENERGY IONIZED GAS HAEMOSTASIS EQUIPMENT from **HIGH FREQUENCY SURGICAL EQUIPMENT** which is also used to stop blood flow.

Definition 201.3.207 – LOW ENERGY IONIZED GAS HAEMOSTASIS EQUIPMENT

The term “low energy” is used because in this type of ME EQUIPMENT, the temperature of the neutral gas and ions in the IONIZED GAS is low, resulting in a PLASMA FLARE temperature that is unlikely to damage tissue. In addition, ohmic heating caused by the PLASMA FLARE current that could cause damage to PATIENT tissue is low.

Subclause 201.4 – General requirements

After a careful consideration of the clauses within this document, it was decided that they all deal with BASIC SAFETY as defined in the general standard. MANUFACTURERS have the ability to identify functions of LOW ENERGY IONIZED GAS HAEMOSTASIS EQUIPMENT which are considered ESSENTIAL PERFORMANCE in accordance with their RISK management process.

Subclause 201.7.9.2.1 – General

One of the primary characteristics that differentiates LOW ENERGY IONIZED GAS HAEMOSTASIS EQUIPMENT from higher energy devices that stop blood flow by cauterization is the significantly lower energy levels transferred to the PATIENT. However, these same lower energy levels prevent the ME EQUIPMENT from being used to coagulate blood flowing at elevated pressures (e.g. from arteries). Therefore it was felt that a specific contraindication should be provided to remind clinicians of this restricted intended use. See also the rationale for 201.3.202 – HAEMOSTASIS.

Subclause 201.8.5.1.2 – MEANS OF PATIENT PROTECTION (MOPP)

For an ionization frequency less than 1 kHz, the general standard applies as these currents carry a nominal RISK of neuromuscular stimulation. The 1 kHz is selected as it is the cutoff frequency of the low pass filter in the measuring device of Figure 12 of the general standard.

For an ionization frequency higher than 200 kHz, the CREEPAGE DISTANCE and AIR CLEARANCE is 3 mm/kV or 4 mm, whichever is greater. These reduced requirements are considered to be adequate because the voltages stressing the insulation are of high frequency and therefore, if insulation fails between the circuit used to generate IONIZED GAS and the ENCLOSURE, the RISK is much lower than at lower frequencies.

For an ionization frequency between 1 kHz and 200 kHz: a linear reduction is applied between the 1 kHz cutoff frequency and 200 kHz. For both, a greater value is chosen:

$$\text{CREEPAGE DISTANCE: } 16 - \frac{13f}{200} \text{ mm/kV, or } 21,3 - \frac{17,3f}{200} \text{ mm}$$

$$\text{AIR CLEARANCE: } 9,14 - \frac{6,14f}{200} \text{ mm/kV, or } 12,2 - \frac{8,2f}{200} \text{ mm}$$

where

f is the frequency in kHz.

The intermediate circuit used to generate IONIZED GAS are parts that have to be treated as APPLIED PARTS in the context of this subclause. In this case the term intermediate circuit would be the secondary circuit as defined in 3.110 and shown in Figure J.5 of the general standard.

Subclause 201.8.7.3.101 – LEAKAGE CURRENTS

- a) The 20 mA maximum value for LEAKAGE CURRENT flowing from the PLASMA FLARE to the PATIENT was chosen to ensure that energy transferred to the PATIENT was sufficiently low to prevent tissue damage.

The test method was developed by measuring the leakage current produced by LOW ENERGY IONIZED GAS HAEMOSTASIS EQUIPMENT.

The PLASMA FLARE leakage current was then measured using two geometries of copper “target”. One target had a hemispherical shape (based on the shape and size of the nozzle). The second was a flat plate. In both cases, the “targets” were connected to earth ground through a 200 Ω non-inductive resistor.

The measured current using the hemispherical “target” was approximately 10 % higher and showed lower experimental fluctuation using the flat plate for the sample device. However, the plasma discharge location was not stable (moving on the surface of the hemispherical shape). In addition, use of the hemispheric target would require that different size “targets” be fabricated for each device/nozzle based on size and geometry.

Therefore, it was determined that for the measurement of PLASMA FLARE leakage current from nozzles of various sizes and geometries (larger nozzles and/or a non-round shaped nozzles such as rectangular), a flat plate is preferable. The dimension of the copper plate is 100 mm x 100 mm x 1 mm to accept likely nozzle shapes and sizes.

In order to assure that oxidation does not affect the measurement, the surface of the copper plate contacted by the PLASMA FLARE should be cleaned before each measurement.

- b) The PATIENT LEAKAGE CURRENT is given by the general standard and the allowable is 100 μA for TYPE BF APPLIED PARTS and 10 μA for TYPE CF APPLIED PARTS using the frequency compensated MD circuit as shown in Figure 12 of general standard. The frequency response of the MD is flat up to 1 kHz. Above 1 kHz, the measurement is frequency compensated by 20 dB per decade. For this reason, the RISK of ventricular fibrillation is mitigated at any frequency.

Subclause 201.8.8.3.101 – IONIZED GAS ACCESSORY insulation

LOW ENERGY IONIZED GAS HAEMOSTASIS EQUIPMENT is capable of producing high voltages which will appear on the insulated conductive parts of IONIZED GAS ACCESSORIES. The insulation of these ACCESSORIES shall withstand this voltage stress and limit the LEAKAGE CURRENT density appearing on exposed surfaces in order to reduce the RISK of unintended burns to the PATIENT and the OPERATOR. This insulation is subjected to considerable stress in practical use, and therefore the requirements contain a safety margin. The insulation applied to any part of an IONIZED GAS ACCESSORY shall maintain adequate dielectric strength after extended exposure to conductive fluids and, except for accessories intended for single use, repeated sterilization.

Subclause 201.8.10.4.2 – Connection cords

The IONIZED GAS ACCESSORY CABLE could be subject to considerable stress in use and typical failure modes can present a HAZARD to staff and/or PATIENTS. It is known that once a cable is used, fatigue begins. These requirements will establish a reference level for durability of such cables.

Subclause 201.11.1.2.2 – APPLIED PARTS not intended to supply heat to a PATIENT

The temperature limit was selected based on metals and liquids because the PLASMA FLARE has high thermal conductivity. The 10 min contact time was chosen based on the conclusion that 10 min will far exceed the longest period of time the PLASMA FLARE will be in contact with a single area of tissue.

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COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

APPAREILS ÉLECTROMÉDICAUX –

Partie 2-76: Exigences particulières pour la sécurité de base et les performances essentielles des appareils d'hémostase à gaz ionisé à faible pouvoir calorifique

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L'IEC 60601-2-76 édition 1.1 contient la première édition (2018-04) [documents 62D/1554/FDIS et 62D/1573/RVD] et son amendement 1 (2023-08) [documents 62D/2047/FDIS et 62D/2076/RVD].

Dans cette version Redline, une ligne verticale dans la marge indique où le contenu technique est modifié par l'amendement 1. Les ajouts sont en vert, les suppressions sont en rouge, barrées. Une version Finale avec toutes les modifications acceptées est disponible dans cette publication.

La Norme internationale IEC 60601-2-76 a été établie par le sous-comité 62D de l'IEC: Appareils électromédicaux, du comité d'études 62 de l'IEC: Équipements électriques dans la pratique médicale.

Ce document a été rédigé selon les Directives ISO/IEC, Partie 2.

Dans la présente norme, les caractères d'imprimerie suivants sont utilisés:

- exigences et définitions: caractères romains;
- *modalités d'essais: caractères italiques;*
- les indications de nature informative apparaissant hors des tableaux, comme les notes, les exemples et les références: petits caractères. Le texte normatif à l'intérieur des tableaux est également en petits caractères;
- TERMES DEFINIS A L'ARTICLE 3 DE LA NORME GENERALE, DANS LA PRESENTE NORME PARTICULIERE OU COMME NOTES: PETITES MAJUSCULES.

Concernant la structure de la présente norme, le terme

- «article» désigne l'une des dix-sept sections numérotées dans la table des matières, 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, 7.1, 7.2 et 7.2.1 sont tous des paragraphes appartenant à l'Article 7).

Dans la présente norme, les références à des articles sont précédées du terme «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 la présente norme, la conjonction «ou» est utilisée avec la valeur d'un «ou inclusif». Ainsi, un énoncé est vrai si une combinaison des conditions, quelle qu'elle soit, est vraie.

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- «devoir» mis au présent de l'indicatif signifie que la satisfaction à une exigence ou à un essai est obligatoire pour la conformité à la présente norme;
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Lorsqu'un astérisque (*) est utilisé comme premier caractère devant un titre ou au début d'un alinéa ou d'un titre de tableau, il indique l'existence d'une recommandation ou d'une justification à consulter dans l'Annexe AA.

Une liste de toutes les parties de la série IEC 60601, publiées sous le titre général *Appareils électromédicaux*, peut être consultée sur le site web de l'IEC.

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