IEC 60601-2-76

Edition 1.0 2018-04

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

IEC 60601-2-76:2018-04(en-fr)

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MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

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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.

The text of this International Standard is based on the following documents:

FDIS	Report on voting
62D/1554/FDIS	62D/1573/RVD

Full information on the voting for the approval of this International Standard can be found in the report on voting indicated in the above table.

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 will remain unchanged until the stability date indicated on the IEC website under "http://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.

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.

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 standard[1] 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.

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

For brevity, IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 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

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1 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 an alternating, direct or composite voltage or current averaged over 1 s unless stated otherwise.

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:

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

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

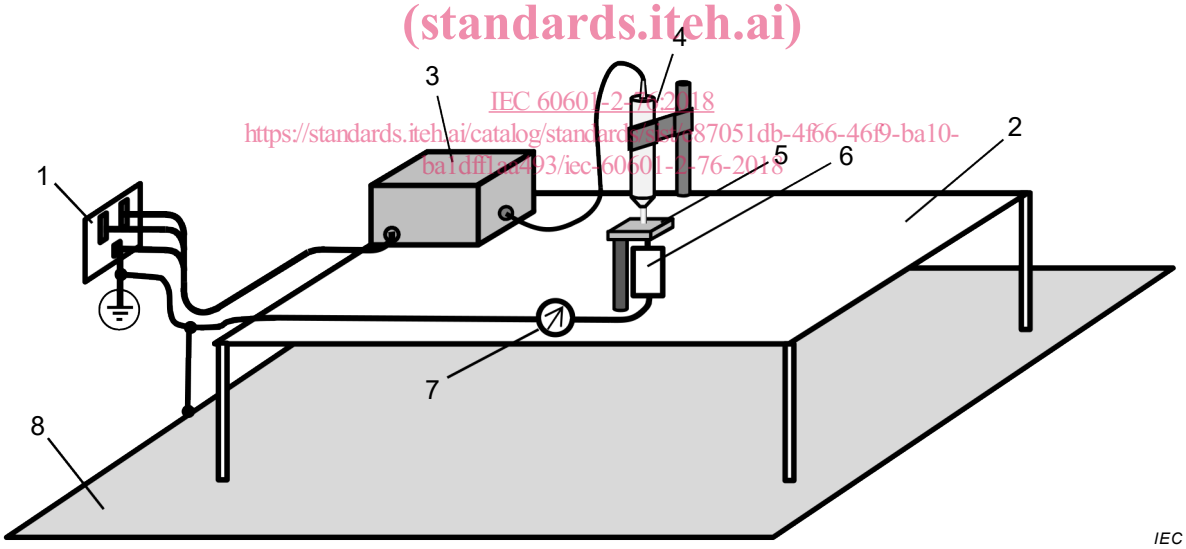
Additional subclause:

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 ± 2 % at 20 mA and a measurement range of at least 30 kHz through 20 MHz.



Key

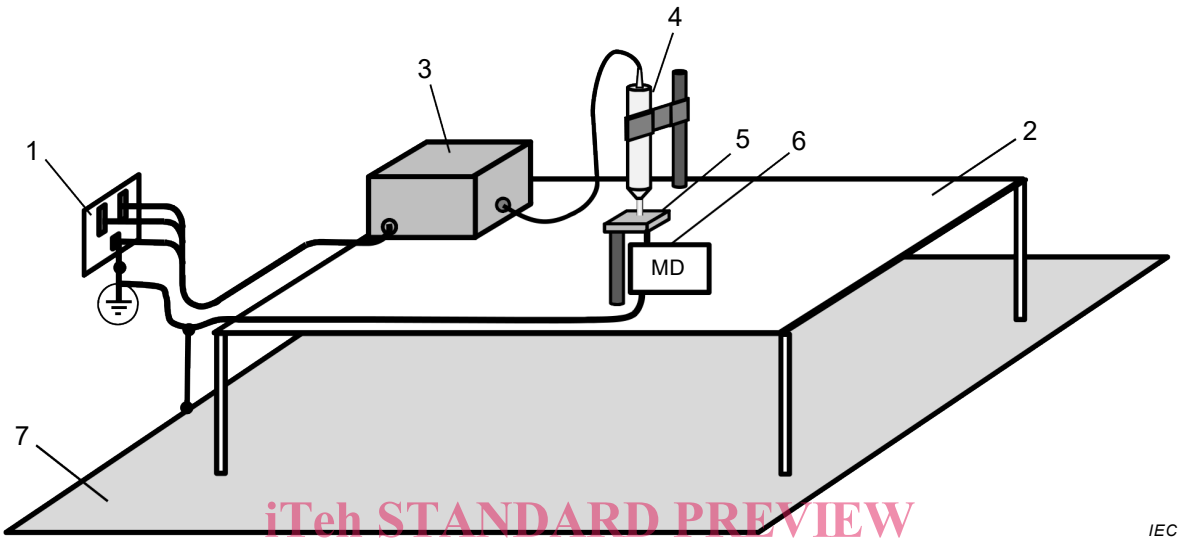
1 supply mains
2 table, made of insulating material
3 Equipment Under Test (EUT)
4 handpiece
5 flat copper plate (100 mm × 100 mm × 1 mm)
6 200 Ω non-inductive resistor
7 RF current meter
8 earthed conductive plane

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.



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:

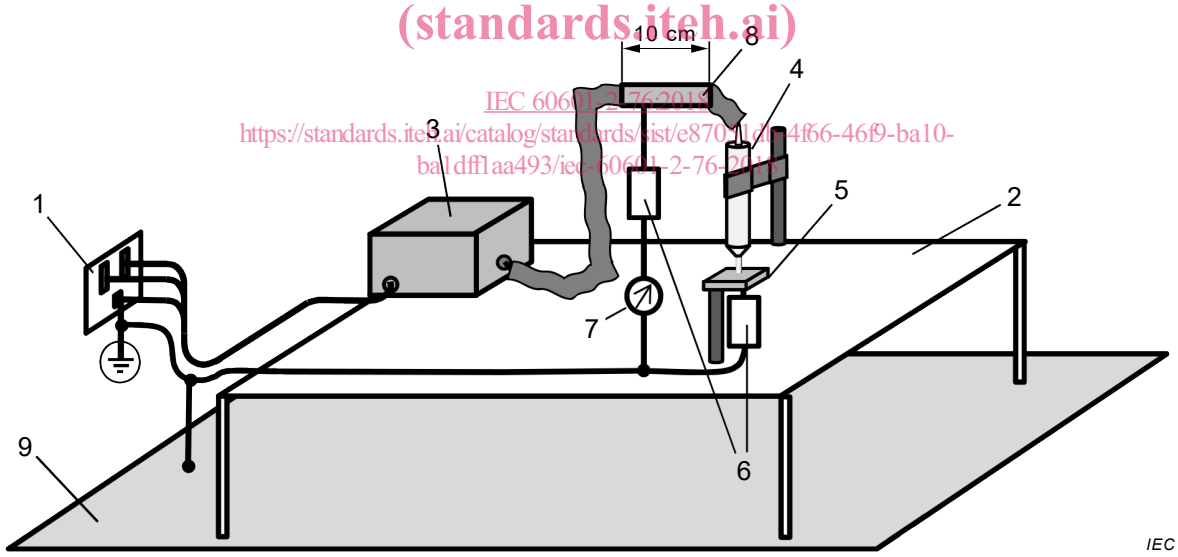
$$I_{\text{leakage}}\ (\text{mA}) = 4{,}0 \times 10^{-5} \times d \times L \times f_{\text{test}} \times U_{\text{peak}}$$

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 ± 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