IEC 60601-2-18

Edition 3.0 2009-08

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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Medical electrical equipment –
Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment

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Appareils électromédicaux –
Partie 2-18: Exigences particulières pour la sécurité de base et les performances essentielles des appareils d'endoscopie

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IEC 60601-2-18:2009

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment

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International standard IEC 60601-2-18 has been prepared by IEC subcommittee 62D: Electromedical equipment, of IEC technical committee 62, Electrical equipment in medical practice.

This third edition cancels and replaces the second edition, published in 1996, and its Amendment 1 (2000). This edition constitutes a technical revision and has been aligned or harmonized with IEC 60601-1:2005.

The main changes with respect to the previous edition include:

a) alignment of requirements with IEC 60601-1:2005;
b) inclusion of essential performance requirements;
c) the inclusion of energized endoscopes and energized endotherapy devices used through second and subsequent punctures within the scope of the standard;
d) reference to IEC 60601-2-2 for the dielectric strength testing of HF energized endotherapy devices, rather than defining different tests.

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

Enquiry draft	Report on voting
62D/682/CDV	62D/743/RVC

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

This publication 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).

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References to clauses within this standard are preceded by the term "Clause" followed by the clause number. References to subclauses within this collateral standard are by number only.

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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 Annex H 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 publication will remain unchanged until the maintenance result date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
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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 endoscopic equipment.

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

The requirements are followed by specifications for the relevant tests.

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic 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 International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of ENDOSCOPIC EQUIPMENT together with its INTERCONNECTION CONDITIONS and INTERFACE CONDITIONS.

201.1.2 Object

Replacement:

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The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for ENDOSCOPIC EQUIPMENT [as defined in 201.3.204].

NOTE This object includes endoscopic intense light source equipment which is part of the ENDOSCOPIC EQUIPMENT including its supply unit, therefore IEC 60601-2-57 does not apply.

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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.

IEC 60601-1-2 applies as modified in Clause 202. IEC 60601-1-3 does not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

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.

For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

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

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 standard 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 IEC 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 due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard 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.

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The term "this standard" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

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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

Clause 2 of the general standard applies, except as follows:

Amendment:

IEC 60601-1-2:2007, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*

Addition:

IEC 60601-2-2:2009, *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 60601-2-37, *Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment*

ISO 8600-1, *Optics and photonics – Medical endoscopes and endotherapy devices – Part 1: General requirements*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 apply, except as follows:

NOTE An index of defined terms is found beginning on page 45.

Addition:

201.3.201
*** CAPACITIVELY COUPLED HF CURRENT**
unavoidable HIGH FREQUENCY current flowing due to capacitive coupling from an ENERGIZED ENDOTHERAPY DEVICE that is the APPLIED PART of HF SURGICAL EQUIPMENT to the ENDOSCOPE

201.3.202
*** CONFIGURATION FOR ENDOSCOPIC APPLICATION**
combination of ENDOSCOPIC EQUIPMENT by means of INTERFACE CONDITIONS and/or INTERCONNECTION CONDITIONS with one or more of the following:

– ENERGIZED ENDOTHERAPY DEVICE(S)
– MEDICAL ELECTRICAL EQUIPMENT
– non-MEDICAL ELECTRICAL EQUIPMENT
– MEDICAL ELECTRICAL SYSTEM

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NOTE Not all of the items in the CONFIGURATION FOR ENDOSCOPIC APPLICATION are included in the scope of this particular standard. See Figure AA.101 in Annex AA for a diagrammatic explanation.

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201.3.203
ENDOSCOPE
medical instrument having viewing means, with or without optics, introduced into a body cavity through a natural or surgically created body opening for examination, diagnosis or therapy

[ISO 8600-1, definition 3.1]

NOTE 1 ENDOSCOPES may be of rigid, flexible or capsule type, each of which may have different image pick-up systems (e.g. via lenses or electronic/ultrasonic sensors) and different image transmission systems (e.g. optical (via lenses or fiber bundles), or electrical/electronic).

NOTE 2 NOTE 1 differs from NOTE 1 of definition 3.1 in ISO 8600-1 in order to include 'capsule' endoscopes.

201.3.204
ENDOSCOPIC EQUIPMENT
an ENERGIZED ENDOSCOPE together with its SUPPLY UNIT(s), as required for its INTENDED USE

201.3.205
ENDOTHERAPY DEVICE
medical device intended to be inserted into a natural or surgically created body opening during endoscopic procedures, whether through the same or a different orifice from the ENDOSCOPE, for examination, diagnosis or therapy

NOTE ENDOTHERAPY DEVICES include the instrument through which an ENDOSCOPE or ENDOTHERAPY DEVICE is inserted, such as a guide tube, trocar tube or sliding tube, etc. ENDOTHERAPY DEVICES include the devices to be inserted through openings other than the opening for an ENDOSCOPE, to ensure the safety of the devices for the intended use under the endoscopic view.

[ISO 8600-1, definition 3.2]

201.3.206
*** ENERGIZED ENDOSCOPE**
an ENDOSCOPE that is an APPLIED PART of ME EQUIPMENT using energy for producing the internal view or image, for example illumination and signal processing

201.3.207
*** ENERGIZED ENDOTHERAPY DEVICE**
an ENDOTHERAPY DEVICE that is an APPLIED PART of ME EQUIPMENT, which may or may not be ENDOSCOPIC EQUIPMENT, introduced into a PATIENT through the same orifice as the ENDOSCOPE, or through a second or subsequent orifice, using energy for providing its INTENDED USE, for example HF currency, ultrasound and laser

201.3.208
HIGH FREQUENCY
HF
frequencies generally greater than 200 kHz

[IEC 60601-2-2:2009, definition 201.3.218]

201.3.209
HF SURGICAL EQUIPMENT
MEDICAL ELECTRICAL EQUIPMENT, including associated ACCESSORIES, intended for the performance of surgical operations, such as the CUTTING or COAGULATION of biological tissue by means of HIGH FREQUENCY currents

[IEC 60601-2-2:2009, definition 201.3.222]

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201.3.210
INTERCONNECTION CONDITIONS
conditions that shall be fulfilled to achieve BASIC SAFETY when one or more ENERGIZED ENDOSCOPES are used simultaneously with one or more ENERGIZED ENDOTHERAPY DEVICES

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201.3.211
INTERFACE CONDITIONS
conditions that shall be fulfilled to achieve BASIC SAFETY for any FUNCTIONAL CONNECTION between ENDOSCOPIC EQUIPMENT and other ME EQUIPMENT or non-ME EQUIPMENT in the CONFIGURATION FOR ENDOSCOPIC EQUIPMENT

201.3.212
LIGHT EMISSION PART
that part of the insertion portion of an ENERGIZED ENDOSCOPE surrounding the light emission window, delineated as follows:

the area of the surface of the insertion portion within three times the maximum diameter of the insertion portion, measured at the tip (distal cover removed) for forward viewing ENERGIZED ENDOSCOPES or the centre of the light emission window for side viewing ENERGIZED ENDOSCOPES, measured in both longitudinal directions from the centre of the light emission window, but with a minimum of 10 mm and a maximum of 25 mm. See also Figure 201.101.

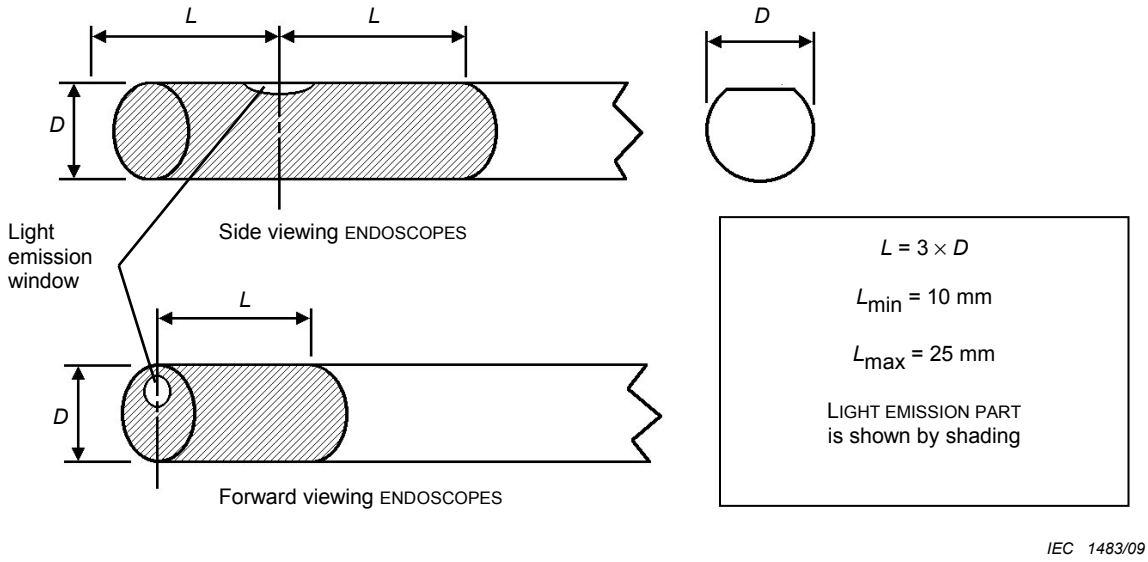

Figure 201.101 – Identification of LIGHT EMISSION PART

201.3.213
NEUTRAL ELECTRODE
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electrode of a relatively large area for connection to the body of the PATIENT, intended to provide a return path for the HIGH FREQUENCY current with such a low current density in the body tissue that physical effects such as unwanted burns are avoided

NOTE The NEUTRAL ELECTRODE is also known as plate, plate electrode, passive, return or dispersive electrode.

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[IEC 60601-2-2:2009, definition 201.3.227]

201.3.214
RATED ACCESSORY VOLTAGE

maximum peak HF output voltage which may be applied to a MONOPOLAR HF SURGICAL ACCESSORY with respect to an NE connected to the PATIENT. For a BIPOLAR HF SURGICAL ACCESSORY, the maximum peak HF output voltage which may be applied to pairs of opposite polarity.

[IEC 60601-2-2:2009, definition 201.3.228]

201.3.215
*** SUPPLY UNIT**

that part of ME EQUIPMENT, directly connected to an ENDOSCOPE, supplying necessary functions forming the ENERGIZED ENDOSCOPE

201.3.216
ULTRSONIC DIAGNOSTIC EQUIPMENT

MEDICAL ELECTRICAL EQUIPMENT that is intended for ultrasonic medical examination

[IEC 60601-2-37, definition 201.3.217]

201.4 General requirements

Clause 4 of the general standard applies, except as follows:

201.4.1 Conditions for application to ME EQUIPMENT or ME SYSTEMS

Addition:

201.4.1.101 * Energized endotherapy devices

Where requirements for ENDOTHERAPY DEVICES given in other applicable particular standards conflict with the requirements for INTERCONNECTION CONDITIONS of this particular standard, the requirements of this particular standard shall take precedence.

201.4.1.102 Ultrasonic diagnostic equipment

For the ultrasonic safety aspects of ENDOSCOPIC EQUIPMENT which is also ULTRASONIC DIAGNOSTIC EQUIPMENT, that part which is intended for ultrasonic diagnosis shall comply with the requirements of IEC 60601-2-37 and the other parts shall comply with the requirements of this particular standard.

201.4.1.103 * SUPPLY UNITS

For SUPPLY UNITS providing a plurality of functions where different particular standards apply, the appropriate parts of these shall comply with the requirements of the relevant particular standards.

201.4.3 ESSENTIAL PERFORMANCE

Addition:

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201.4.3.101 * Additional ESSENTIAL PERFORMANCE requirements

Additional ESSENTIAL PERFORMANCE requirements are found in the subclauses listed in Table 201.101.

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Table 201.101 – List of ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
To that there is no unacceptable RISK if the view observed by the OPERATOR has an unexpected image orientation.	Applicability and condition as defined by manufacturer
To ensure that there is no unacceptable RISK, if there is a lack of, or significant error in, provision of a particular spectral output or frequency necessary to provide accurate diagnosis or therapy, which is not identifiable by a trained OPERATOR.	201.12.4.4
To ensure that there is no unacceptable RISK that the OPERATOR is viewing the live image during an endoscopic procedure, rather than a recorded image.	201.13.1.101

NOTE See 201.7.9.2.2 g) for warning and safety notices related to the ESSENTIAL PERFORMANCE requirements.

201.4.6 * ME EQUIPMENT or ME SYSTEM PARTS that contact the PATIENT

Addition:

Light guide cables are treated as ME SYSTEM parts that CONTACT the PATIENT for the purposes of this particular standard, unless the RISK MANAGEMENT FILE indicates otherwise for specific configurations.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.