IEC 60601-2-18

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INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

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

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

INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

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

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.

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,
- withdrawn,
- replaced by a revised edition, or
- amended.

IMPORTANT – The "colour inside" logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this publication using a colour printer.

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.

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:

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.

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.

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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.

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

Where there is no corresponding clause or subclause in this 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

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.

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]

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

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.

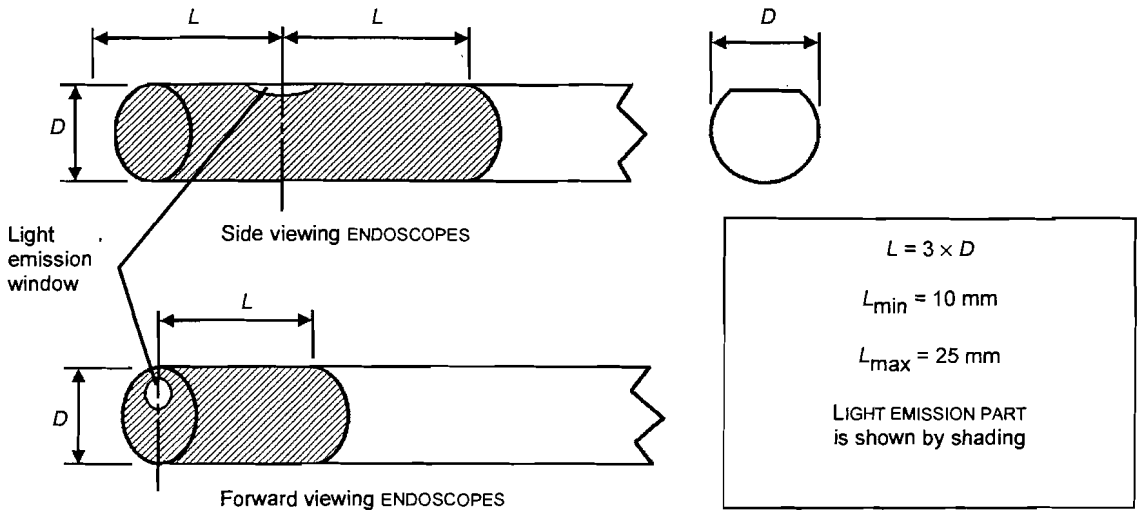


Figure 201.101 – Identification of LIGHT EMISSION PART

201.3.213
NEUTRAL ELECTRODE
NE
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.

[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:

201.4.3.101 * Additional ESSENTIAL PERFORMANCE requirements

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

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.

201.4.7 SINGLE FAULT CONDITION for ME EQUIPMENT

Addition:

To be SINGLE FAULT SAFE, the INTERCONNECTION CONDITIONS and INTERFACE CONDITIONS as defined by the MANUFACTURER shall be taken into account as part of the RISK MANAGEMENT process.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

201.5 General requirements for testing of ME EQUIPMENT

Clause 5 of the general standard applies, except as follows:

201.5.1 TYPE TESTS

Addition:

The definition of ENERGIZED ENDOSCOPE necessarily includes ENDOSCOPES that are energized only by light energy and for which the required F-TYPE APPLIED part isolation is provided in the SUPPLY UNIT. Under these conditions, there is no unacceptable electrical RISK for the PATIENT or OPERATOR. Therefore there is no need to conduct electrical safety TYPE TESTS, such as those detailed in Clause 8.

201.5.7 * Humidity preconditioning treatment

Addition:

ACCESS COVERS of ENDOSCOPIC EQUIPMENT which can be opened without the use of a TOOL, but which inactivate the EQUIPMENT (e.g. by an interlock) once opened, may remain closed and/or attached during humidity preconditioning unless the RISK MANAGEMENT process suggests that the ENDOSCOPIC EQUIPMENT can be exposed to high humidity during the periods when ACCESS COVERS are opened.

ENERGIZED ENDOSCOPES and ENERGIZED ENDOTHERAPY DEVICES which according to their intended use or instructions for use are subject to disinfection and/or sterilization processes prior to use are excluded from humidity preconditioning treatment according to this subclause, but shall instead be subjected to subclauses 11.6.6 and/or 11.6.7 of the general standard, as appropriate, prior to any relevant tests.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies, except as follows:

201.6.2 Protection against electric shock

Replacement of final paragraph:

APPLIED PARTS of ENDOSCOPIC EQUIPMENT shall be classified as TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS (see 8.3). These APPLIED PARTS may be classified as DEFIBRILLATION-PROOF APPLIED PARTS.

201.7 ME EQUIPMENT identification, marking and documents

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

201.7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts

201.7.2.1 Minimum requirements for marking on ME EQUIPMENT and on interchangeable parts

Replacement:

If the size of the ME EQUIPMENT, an ME EQUIPMENT part or an ACCESSORY, or the nature of its ENCLOSURE, does not allow affixation of all markings specified in 7.2.2 to 7.2.20 (inclusive) of the general standard, then at least the markings as indicated in 7.2.2, 7.2.5, 7.2.6 (not for PERMANENTLY INSTALLED ME EQUIPMENT), 7.2.10 and 7.2.13 (if applicable) of the general standard shall be affixed and the remaining markings shall be recorded in full in the ACCOMPANYING DOCUMENTS. Where no marking of the ME EQUIPMENT or ACCESSORY is practicable, these markings may be affixed to the individual packaging.

Any material, component, ACCESSORY or ME EQUIPMENT that is intended for a single use or its packaging shall be marked "Do Not Reuse" or with symbol ISO 7000-1051 (2004-01) (see Table D.1, symbol 28 of the general standard).

201.7.2.9 * IP classification

Addition:

ENERGIZED ENDOSCOPES and ENERGIZED ENDOTHERAPY DEVICES supplied with specific instructions detailing allowable reprocessing methods and parameters are excluded from this requirement. No symbol is required to identify the reprocessing procedure by this particular standard. See also subclause 7.9.2.12 of the general standard.

201.7.2.10 APPLIED PARTS

Addition:

Where no marking of an APPLIED PART is practicable, the required marking may be affixed to the individual packaging.

Compliance is checked by inspection.

Additional subclauses:

201.7.2.101 Alternative marking

Information, which is accessible by the user on an output device (e.g. display) of ENDOSCOPIC EQUIPMENT is considered equivalent to marking on the EQUIPMENT for requirements 7.2.3, 7.2.5, 7.2.11 and 7.2.13 of the general standard, as long as the marking is visible at the time the information is required.

Compliance is checked by inspection of the results of the USABILITY ENGINEERING process and / or by inspection of the ACCOMPANYING DOCUMENTS.

201.7.2.102 * Illumination lamps

SUPPLY UNITS having replaceable illumination lamps accessible without the use of a TOOL shall be provided with permanently affixed and clearly legible markings near the lamps, either inside or outside the SUPPLY UNIT, giving the MODEL OR TYPE REFERENCE (preferably by use of the symbol 111 of Table 201.D.101).

For replaceable illumination lamps built into the distal end of ENDOSCOPES, the MODEL OR TYPE REFERENCE shall be stated in the ACCOMPANYING DOCUMENTS as a minimum.

For replaceable illumination lamps accessible only by SERVICE PERSONNEL with the use of a TOOL, the MODEL OR TYPE REFERENCE shall be stated in the ACCOMPANYING DOCUMENTS as a minimum.

201.7.4 Marking of controls and instruments

201.7.4.3 Units of measure

Addition:

For ENDOSCOPES and ENDOTHERAPY DEVICES, the measure 'French' or 'Charrière', symbol F_r, may be used to indicate the size of certain circular or non-circular cross-sections, defined as:

$$F_r = 3u/\pi$$

where u is the perimeter of the cross-section, expressed in mm.

NOTE Taken from ISO 8600-1.

201.7.6 Symbols

201.7.6.2 Symbols from Annex D

Addition:

At the option of the MANUFACTURER, symbols to denote certain functions of ENDOSCOPIC EQUIPMENT may be used, but if used shall be explained in the instructions for use. If symbols are used, Appendix D lists those preferred symbols, which may be used to denote the functions described.

201.7.9 ACCOMPANYING DOCUMENTS

201.7.9.2 Instructions for use

201.7.9.2.2 * Warning and safety notices

Addition:

The instructions for use of ENDOSCOPIC EQUIPMENT shall include the following warning and safety notices where appropriate:

Warning and safety notices regarding ENDOSCOPIC EQUIPMENT:

a) Warnings if surface temperatures on an APPLIED PART are likely to exceed 41 °C (see also 201.11.1.2.2).

b) Warnings that high energy radiated light may be transmitted from the light emission window of the ENDOSCOPE, giving rise to high temperatures in front of the light emission window, and advice on how to minimize associated RISKS.

c) Prevention of unacceptable RISKS if ENDOSCOPIC EQUIPMENT loses functions.

d) Prevention of HAZARDOUS SITUATIONS, WHICH MAY CAUSE HARM, SUCH AS, burns and eye damage, by the replacement of the illumination lamp.

e) Warning that the TYPE F APPLIED PART status of ENERGIZED ENDOSCOPES intended for use with a multiplicity of SUPPLY UNITS and/or light guide cables is ensured by, for instance, using only SUPPLY UNITS having isolated light guide output sockets.

f) That before each use, the outer surface of the portions of ENERGIZED ENDOSCOPES which are intended to be inserted into a PATIENT should be checked to ensure there are no unintended rough surfaces, sharp edges or protrusions which may cause HARM.

g) That before each use or after a change of viewing modes / settings, the OPERATOR should check to ensure the view observed through the ENDOSCOPE provides a live image (rather than a stored one) and has the correct image orientation.

Warning and safety notices regarding INTERCONNECTIONS CONDITIONS:

h) Warning that INTERCONNECTIONS CONDITIONS require the APPLIED PARTS of other ME EQUIPMENT used within the CONFIGURATION FOR ENDOSCOPIC APPLICATION to be TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS.

i) Warnings regarding RISKS resulting from gas embolism caused by, for example, over-insufflation of air, inert gas prior to HIGH FREQUENCY surgery, or laser assist gas.

j) Warnings that when ENERGIZED ENDOSCOPES are used with ENERGIZED ENDOTHERAPY DEVICES, PATIENT LEAKAGE CURRENTS may be additive. It should be noted that this is particularly important if a TYPE CF APPLIED PART ENDOSCOPE is used, in which case a TYPE CF APPLIED PART ENERGIZED ENDOTHERAPY DEVICE should be used in order to minimize total PATIENT LEAKAGE CURRENT.

k) Avoidance of risks in the event of explosive gas concentrations being present in the area of use of HF ENERGIZED ENDOTHERAPY DEVICES.

l) When ENERGIZED ENDOSCOPES and/or ENERGIZED ENDOTHERAPY DEVICES is/are used with laser equipment, advice concerning their safe use shall be given, including avoidance of potential eye damage to the OPERATOR by, for example, wearing suitable protective filtering spectacles, or by inserting a suitable filter in the eyepiece of the ENERGIZED ENDOSCOPE.

m) That before each use, the compatibility of the ENDOSCOPIC EQUIPMENT with any ACCESSORIES and/or ENERGIZED ENDOTHERAPY DEVICES should be checked according to any criteria for safe use defined in the instructions for use.

n) That before each use, the outer surface of the portions of any ENERGIZED ENDOTHERAPY DEVICES which are intended to be inserted into a PATIENT should be checked to ensure there are no unintended rough surfaces, sharp edges or protrusions which may cause HARM.

Warning and safety notices regarding INTERFACE CONDITIONS:

o) Advice when ENDOSCOPIC EQUIPMENT is used with ACCESSORIES, other ME EQUIPMENT and/or non-ME EQUIPMENT within a CONFIGURATION FOR ENDOSCOPIC APPLICATION, on the avoidance of RISKS caused by their use together (see also 16.2 of the general standard and 201.15.4.1 of this particular standard).

Compliance is checked by inspection of the instructions for use.

201.7.9.2.12 Cleaning, disinfection and sterilization

Addition:

If the ACCOMPANYING DOCUMENTS provide instructions for visual and/or other inspection by the OPERATOR or the RESPONSIBLE ORGANIZATION to enable checking the suitability for reuse prior to each use, then the number of cycles the ENDOSCOPIC EQUIPMENT parts or ACCESSORIES can tolerate need not be given.

201.7.9.2.14 ACCESSORIES, supplementary equipment, used material

Addition:

When ENERGIZED ENDOTHERAPY DEVICES are used with HF SURGICAL EQUIPMENT, advice concerning their safe use shall be given in the instructions for use in accordance with the relevant requirements of IEC 60601-2-2.

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

Replacement of requirement c):

c) An APPLIED PART of ENDOSCOPIC EQUIPMENT shall be a TYPE BF APPLIED PART or TYPE CF APPLIED PART. INTERCONNECTION CONDITIONS require the APPLIED PARTS of other ME EQUIPMENT used within the CONFIGURATION FOR ENDOSCOPIC APPLICATION also to be TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS.

Replacement of requirement d):

d) For a part of ENDOSCOPIC EQUIPMENT or an ENERGIZED ENDOTHERAPY DEVICE that is identified according to 4.6 of the general standard as needing to be subject to the requirements for an APPLIED PART (except for marking), requirement c) above shall apply.

201.8.5 Separation of parts

201.8.5.2 Separation of PATIENT CONNECTIONS

201.8.5.2.2 TYPE B APPLIED PARTS

Replacement:

This subclause does not apply to ENERGIZED ENDOSCOPES and ENERGIZED ENDOTHERAPY DEVICES.

201.8.5.2.3 * PATIENT LEADS

Addition:

The above requirements do not apply to ENERGIZED ENDOSCOPES and ENERGIZED ENDOTHERAPY DEVICES if the RISK MANAGEMENT process demonstrates that there is no unacceptable RISK.

NOTE For requirements for PATIENT LEADS associated with HF SURGICAL EQUIPMENT, see IEC 60601-2-2.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

201.8.8 Insulation

201.8.8.3 * Dielectric strength

Addition:

This subclause shall not apply to HF ENERGIZED ENDOTHERAPY DEVICES, requirements for which are given in subclause 201.11.101.2 of this particular standard.

201.8.9 CREEPAGE DISTANCES and AIR CLEARANCES

201.8.9.1 Values

201.8.9.1.1 * General

Addition:

CREEPAGE DISTANCES and AIR CLEARANCES may be reduced in the APPLIED PART to allow the construction of small dimension parts if adequate safety is demonstrated by the RISK MANAGEMENT process, in which case the requirements of subclause 8.5.1.3 of the general

standard for two MEANS OF OPERATOR PROTECTION, pollution degree 1, shall be met. See also Annex J.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 of the general standard applies, except as follows:

201.9.2 HAZARDS associated with moving parts

Addition:

This subclause does not apply to ENERGIZED ENDOSCOPES and ENERGIZED ENDOTHERAPY DEVICES.

201.9.3 HAZARDS associated with surfaces, corners and edges

Addition:

For ENERGIZED ENDOSCOPES the applicability of the requirements of the ISO 8600-1 regarding surfaces, corners and edges shall be reviewed and evaluated as part of the RISK MANAGEMENT process.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

201.9.4 Instability HAZARDS

Addition:

Subclause 9.4 of the general standard does not apply to ENERGIZED ENDOSCOPES and ENERGIZED ENDOTHERAPY DEVICES.

201.9.4.2 Instability – overbalance

201.9.4.2.4 Castors and wheels

201.9.4.2.4.3 * Movement over a threshold

Addition:

MOBILE ME SYSTEMS for use within the CONFIGURATION FOR ENDOSCOPIC APPLICATION mounted on a workstation ('stack') with a total mass exceeding 45 kg shall be able to pass over a 15 mm threshold without resulting in an unacceptable RISK.

Compliance is checked by the following test:

The MOBILE ME SYSTEM is configured in its transport position with any SAFE WORKING LOAD in place as indicated in the ACCOMPANYING DOCUMENTS. The MOBILE ME SYSTEM is moved in accordance with instructions or recommendations in the ACCOMPANYING DOCUMENTS or, if no such instructions are given, as in NORMAL USE 10 times in forward direction over (up and down) a solid vertical plane obstruction with a rectangular cross-section, 15 mm high and at least 20 mm wide that is affixed flat on the floor. The upper corners of the obstruction may have radiuses of up to 2 mm applied. All wheels and castors are to impact the obstruction at a speed of 0,3 m/s ± 0,1 m/s for manual MOBILE ME SYSTEMS, or, for motor driven MOBILE ME SYSTEMS, the maximum speed capable of being maintained.

It is unacceptable for MOBILE ME SYSTEMS to be unable to go over (up) the obstruction (due to small wheel diameter, for example). Overbalancing or any unacceptable RISK constitutes a failure.

Unacceptable RISK is determined by inspection of the MOBILE ME SYSTEM, its parts, and the RISK MANAGEMENT FILE.

201.9.5 Expelled parts HAZARD

Addition:

This subclause does not apply to ENERGIZED ENDOSCOPES and ENERGIZED ENDOTHERAPY DEVICES.

201.9.7 Pressure vessels and parts subject to pneumatic and hydraulic pressure

201.9.7.5 Pressure vessels

Addition:

This subclause does not apply to ENERGIZED ENDOSCOPES and ENERGIZED ENDOTHERAPY DEVICES.

201.9.7.6 Pressure-control device

Replacement:

In ENDOSCOPIC EQUIPMENT for which subclause 9.7.7 of the general standard requires a pressure relief device, any pressure control device responsible for regulating the pressure shall be capable of performing under RATED load for an appropriate number of cycles of operation determined by the MANUFACTURER and shall prevent the pressure from exceeding 90 % of the setting of the pressure relief device under any condition of NORMAL USE.

Compliance is checked by inspection of the MANUFACTURER'S data for the component, inspection of the ME EQUIPMENT, inspection of the RISK MANAGEMENT FILE, and where necessary, by functional test.

201.9.7.7 Pressure-relief device

Replacement of requirement h):

h) The minimum number of cycles of operation shall be RATED in accordance with the EXPECTED SERVICE LIFE of the pressure-relief device, taking into account the environmental conditions and resultant RISKS should the pressure-relief valve not operate as expected. For one-time use devices, such as bursting disks, the environmental conditions and resultant RISKS should the pressure-relief valve not operate as expected shall be taken into account.

201.9.8 HAZARDS associated with support systems

Addition:

This subclause does not apply to ENERGIZED ENDOSCOPES and ENERGIZED ENDOTHERAPY DEVICES.

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of the general standard applies, except as follows:

201.10.4 * Lasers and light emitting diodes (LEDs)

Addition:

This subclause does not apply to light emitting diodes (LEDs) which are intended to provide illumination for an internal view or image generated by ENDOSCOPIC EQUIPMENT, requirements for which are included in clauses 201.10.5, 201.10.6 and 201.10.7 of this particular standard.

201.10.5 Other visible electromagnetic radiation

Replacement:

When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT process the RISKS associated with visible electromagnetic radiation, including LEDs intended to provide illumination for an internal view or image generated by ENDOSCOPIC EQUIPMENT.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

201.10.6 Infrared radiation

Replacement:

When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT process the RISKS associated with infrared radiation, including LEDs intended to provide illumination for an internal view or image generated by ENDOSCOPIC EQUIPMENT.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

201.10.7 Ultraviolet radiation

Replacement:

When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT process the RISKS associated with ultraviolet radiation, including LEDs intended to provide illumination for an internal view or image generated by ENDOSCOPIC EQUIPMENT.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

201.11 Protection against excessive temperatures and other HAZARDS

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

201.11.1 Excessive temperatures in ME EQUIPMENT

201.11.1.2 Temperature of APPLIED PARTS

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

Addition:

The maximum temperature need not be disclosed in the instructions for use when:

- the surface temperature of the insertion portion of an ENDOSCOPE exceeds 41 °C as a result of its use with an ENERGIZED ENDOTHERAPY DEVICE;
- the LIGHT EMMISSION PART of an ENDOSCOPE exceeds 41 °C;
- light guide connectors connecting to either a SUPPLY UNIT or an ENDOSCOPE exceed 41 °C.

Under the above circumstances, the instructions for use shall give appropriate warnings and advice on measures that should be taken to avoid unacceptable RISK to the PATIENT. These warnings shall include a description of the potential clinical consequences of high surface temperatures, for instance permanent tissue damage or coagulation (see also subclause 201.7.9.2.2 of this particular standard).

Compliance is checked by inspection of the RISK MANAGEMENT FILE and instructions for use.

201.11.1.4 GUARDS

Addition:

Illumination lamps of SUPPLY UNITS may be accessible without the aid of a TOOL, but there shall be marking on or near the ACCESS COVER provided for lamp replacement (preferably by use of symbol of IEC 60417-5041 (2002-10)) and a caution shall be included in the instructions for use (see also 201.7.9.2.2).

201.11.6 Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT

201.11.6.5 * Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS

Addition:

ENERGIZED ENDOSCOPES and ENERGIZED ENDOTHERAPY DEVICES intended to be cleaned, disinfected and/or sterilized are excluded from this requirement but shall meet the requirements of 11.6.6 and/or 11.6.7 of the general standard, as appropriate.

Additional subclauses:

201.11.101 INTERCONNECTION CONDITIONS

201.11.101.1 Thermal and other HAZARDS from INTERCONNECTION CONDITIONS with LASERS

The MANUFACTURER'S RISK MANAGEMENT process shall address the possibility of thermal and other RISKS to the PATIENT or OPERATOR from the use of laser equipment with ENERGIZED ENDOSCOPES and/or ENERGIZED ENDOTHERAPY DEVICES, including, under NORMAL USE and SINGLE FAULT conditions:

- thermal damage (including ignition) to the ENDOSCOPE from reflected laser energy;
- potential eye damage from reflected laser energy.

Compliance is determined by inspection of the RISK MANAGEMENT FILE.

201.11.101.2 * Thermal and other HAZARDS from INTERCONNECTION CONDITIONS with HF SURGICAL EQUIPMENT

a) The MANUFACTURER'S RISK MANAGEMENT process shall address the possibility of thermal and other RISKS to the PATIENT or OPERATOR from the use of HF SURGICAL EQUIPMENT with ENERGIZED ENDOSCOPES and/or ENERGIZED ENDOTHERAPY DEVICES, including, under NORMAL USE and SINGLE FAULT CONDITION:

   1) thermal damage to the ENDOSCOPE caused by electrical discharge or CAPACITIVELY COUPLED HF CURRENT;

   2) image interference on video screens from HF electromagnetic energy.

Compliance is determined by inspection of the RISK MANAGEMENT FILE.

b) Sufficient dielectric strength shall be provided on ENERGIZED ENDOTHERAPY DEVICES which are APPLIED PARTS of HF SURGICAL EQUIPMENT to protect the PATIENT and/or OPERATOR from unacceptable RISK.

Compliance of ENERGIZED ENDOTHERAPY DEVICES is checked by following the test methods in subclauses 201.8.8.3.103 and 201.8.8.3.104 of IEC 60601-2-2:2008.

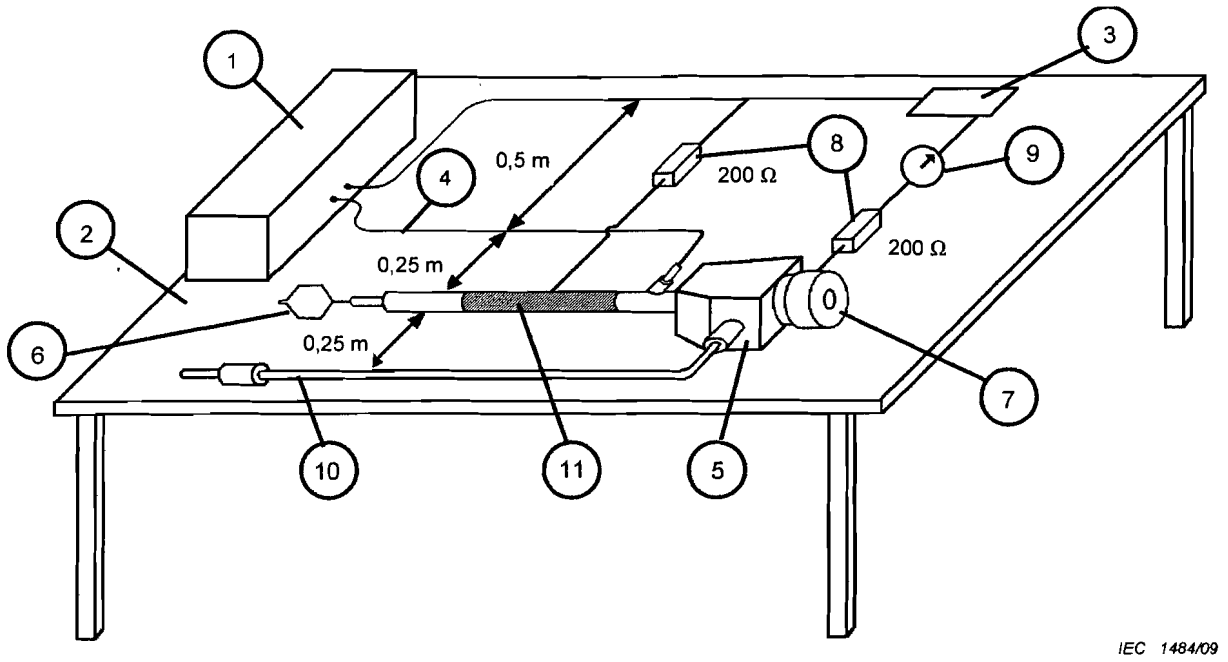
c) Conductive parts of an ENERGIZED ENDOSCOPE accessible to touch in NORMAL USE intended for use with ENERGIZED ENDOTHERAPY DEVICES, which are the APPLIED PARTS of HF SURGICAL EQUIPMENT, shall be isolated in order to protect the OPERATOR from the thermal effects of CAPACITIVELY COUPLED HF CURRENT. Non-conducting coatings, such as lacquer and the like, which cannot provide durable isolation, shall not be used.

Compliance is determined:

1) *By inspection of the RISK MANAGEMENT FILE if under NORMAL USE and SINGLE FAULT CONDITION it is determined that it is not possible to conduct a CAPACITIVELY COUPLED HF CURRENT from the ENERGIZED ENDOTHERAPY DEVICE to the exposed conductive part.*

2) *By the following test if condition 1) above is not satisfied:*

Measure the CAPACITIVELY COUPLED HF CURRENT from each exposed conductive part using the circuit and layout shown in Figure 201.102. The CAPACITIVELY COUPLED HF CURRENT shall not exceed 50 mA.



1	HF SURGICAL EQUIPMENT operated in accordance with IEC 60601-2-2, i.e. 400 kHz ± 100 kHz, and with the RATED ACCESSORY VOLTAGE in cut mode specified in the instructions for use of the ENDOSCOPE	7	Exposed conductive part
2	Table made of insulating material	8	200 Ω non-inductive resistor
3	NEUTRAL ELECTRODE	9	HF current meter
4	Active cable	10	Light guide cable (only if permanently attached)
5	ENDOSCOPE	11	Metal foil wrapped around 50 % of the insertion portion of the ENDOSCOPE with a pressure of 0,5 N/cm^2
6	ENERGIZED ENDOTHERAPY DEVICE		

Figure 201.102 – Measurement of CAPACITIVELY-COUPLED HF CURRENT from conductive parts of an ENDOSCOPE

201.12 Accuracy of controls and instruments and protection against hazardous outputs

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

201.12.2 USABILITY

Addition:

If the RISK MANAGEMENT process concludes there is no unacceptable RISK in relation to USABILITY, this subclause does not apply.

NOTE The USABILITY ENGINEERING process and USABILITY validation may be based on an evaluation of historical data if the intended use and handling of ENDOSCOPIC EQUIPMENT, ACCESSORIES and ENERGIZED ENDOTHERAPY DEVICES are identical or substantially similar.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

201.12.3 Alarm systems

Addition:

NOTE 1 This particular standard does not specify an ALARM CONDITION priority.

NOTE 2 An INFORMATION SIGNAL is any signal that is not an ALARM SIGNAL or a REMINDER SIGNAL (as defined in IEC 60601-1-8).

201.12.4 Protection against hazardous output

201.12.4.4 Incorrect output

Addition:

A significant error in or the lack of the provision of a particular spectral output or frequency necessary to provide accurate diagnosis or therapy which is not identifiable by a trained OPERATOR shall be addressed in the RISK MANAGEMENT process.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

201.13 HAZARDOUS SITUATIONS and fault conditions

Clause 13 of the general standard applies, except as follows:

201.13.1 Specific HAZARDOUS SITUATIONS

Additional subclause:

201.13.1.101 Image observation

The possibility of an OPERATOR (intentionally or unintentionally) viewing a recorded image rather than the live image during an endoscopic procedure shall be addressed in the RISK MANAGEMENT process.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

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:

201.15.3 Mechanical strength

201.15.3.1 General

Addition:

Subclauses 15.3.1 to 15.3.7 of the general standard do not apply to ENERGIZED ENDOSCOPES and ENERGIZED ENDOTHERAPY DEVICES.

201.15.3.5 * Rough handling test

Addition:

Subclause 15.3.5 of the general standard does not apply to MOBILE ME SYSTEMS installed on a workstation ('stack') intended for use within the CONFIGURATION FOR ENDOSCOPIC APPLICATION.

201.15.4 ME EQUIPMENT components and general assembly

201.15.4.1 * Construction of connectors

Addition to requirement b):

The MANUFACTURER of ENDOSCOPIC EQUIPMENT and ENDOTHERAPY DEVICES shall carry out a RISK MANAGEMENT process to consider the probability of misconnection of medical devices intended for connection to ENDOSCOPES or ENDOTHERAPY DEVICES to non-endoscopic PATIENT CONNECTIONS (e.g. intravenous applications).

For applications where the INTENDED USE of connectors includes more than one application, the design used shall be that most unlikely to be misconnected according to its specific intended use, as identified by the RISK MANAGEMENT process.

NOTE Where relevant standards exist for connectors that match the intended use of the equipment, these should be used unless contraindicated by the RISK MANAGEMENT process.

Compliance is determined by inspection of the RISK MANAGEMENT FILE.

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.

202 Electromagnetic compatibility – Requirements and tests

IEC 60601-1-2:2007 applies except as follows:

202.6.2 IMMUNITY

202.6.2.1 General

202.6.2.1.10 Compliance criteria

Addition:

The following shall not be considered unacceptable DEGRADATIONS for ENDOSCOPIC EQUIPMENT:

– the short interruption of illumination or image display, or resetting to 'standby' or 'safe' mode, when clearly indicated on the operation panel of the SUPPLY UNIT;
– if the RISK MANAGEMENT process shows that the DEGRADATION does not lead to an unacceptable RISK.

Compliance is determined by inspection of the equipment and/or the RISK MANAGEMENT FILE.

Annexes

The annexes of the general standard apply, except as follows:

Annex C
(informative)

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

Annex C of the general standard applies except as follows:

201.C.1 Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts

Addition:

201.C.1.101 Marking on the outside of ENDOSCOPIC EQUIPMENT or its parts

The requirements for marking on the outside of ENDOSCOPIC EQUIPMENT and its parts are found in 201.7.2. Additional requirements for marking on the outside of ENDOSCOPIC EQUIPMENT and its parts are found in the subclauses listed in Table 201.C.101. Symbols and safety signs used in marking on the outside of ENDOSCOPIC EQUIPMENT are found in Annex D.

Table 201.C.101 – Marking on the outside of ENDOSCOPIC EQUIPMENT or its parts

Description of marking	Subclause
Illumination lamp, MODEL OR TYPE REFERENCE: marking of	201.7.2.101
Illumination lamp, ACCESS COVER: marking of	201.11.1.4

201.C.2 Marking on the inside of ME EQUIPMENT, ME SYSTEMS or their parts

Addition:

201.C.2.101 Marking on the inside of ENDOSCOPIC EQUIPMENT or its parts

The requirements for marking on the inside of ENDOSCOPIC EQUIPMENT and its parts are found in 201.7.3. Additional requirements for marking on the inside of ENDOSCOPIC EQUIPMENT and its parts are found in the subclauses listed in Table 201.C.102. Symbols and safety signs used in marking on the inside of ENDOSCOPIC EQUIPMENT are found in Annex D.

Table 201.C.102 – Marking on the inside of ENDOSCOPIC EQUIPMENT or its parts

Description of marking	Subclause
Illumination lamp, MODEL OR TYPE REFERENCE: marking of	201.7.2.101

201.C.4 ACCOMPANYING DOCUMENTS, general

Addition:

The requirements for general information to be included in the ACCOMPANYING DOCUMENTS are found in 201.7.9. Additional requirements for general information to be included in the ACCOMPANYING DOCUMENTS are found in the subclauses listed in Table 201.C.104.

Table 201.C.104 – ACCOMPANYING DOCUMENTS, general

Description of marking	Subclause
Alternative to marking on the outside of ENDOSCOPIC EQUIPMENT	201.7.2.1
MODEL OR TYPE REFERENCE of illumination lamps accessible only by SERVICE PERSONNEL	201.7.2.102
MODEL OR TYPE REFERENCE of illumination lamps built into the distal end of an ENDOSCOPE	201.7.2.102
Configuration of SAFE WORKING LOAD on a MOBILE ME SYSTEM	201.9.4.2.4.3
Instructions or recommendations for moving a MOBILE ME SYSTEM	201.9.4.2.4.3

201.C.5 ACCOMPANYING DOCUMENTS, instructions for use

Addition:

The requirements for information to be included in the instructions for use are found in 201.7.9.2. Additional requirements for information to be included in the instructions for use are found in the subclauses listed in Table 201.C.105.

Table 201.C.105 – ACCOMPANYING DOCUMENTS, instructions for use

Description of marking	Subclause
Explanation of symbols used on ENDOSCOPIC EQUIPMENT	201.7.6.2
Warnings and advice on the avoidance of RISK from parts of ENDOSCOPIC EQUIPMENT that exceed 41 °C	201.11.1.2.2
Caution note regarding the possibility of high temperatures near access covers for illumination lamps	201.11.1.4

Annex D
(informative)

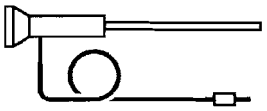
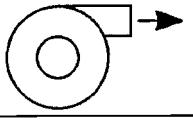
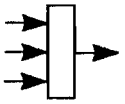
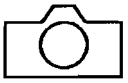
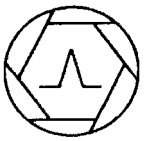
Symbols on marking

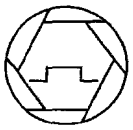
Annex D of the general standard applies except as follows:

Addition:

Additional symbols that may be used for marking ENDOSCOPIC EQUIPMENT are found in Table 201.D.101.

Table 201.D.101 – Symbols for marking ENDOSCOPIC EQUIPMENT or its parts

No.	Symbol	Reference	Title
101		N/A	Endoscope
102		N/A	Air feeding
103		N/A	Suction
104		N/A	Water bottle
105		N/A	Suction bottle
106		N/A	Optical filter
107		N/A	Still photography
108		N/A	Spot light measuring
109		N/A	Center-weighted light measuring

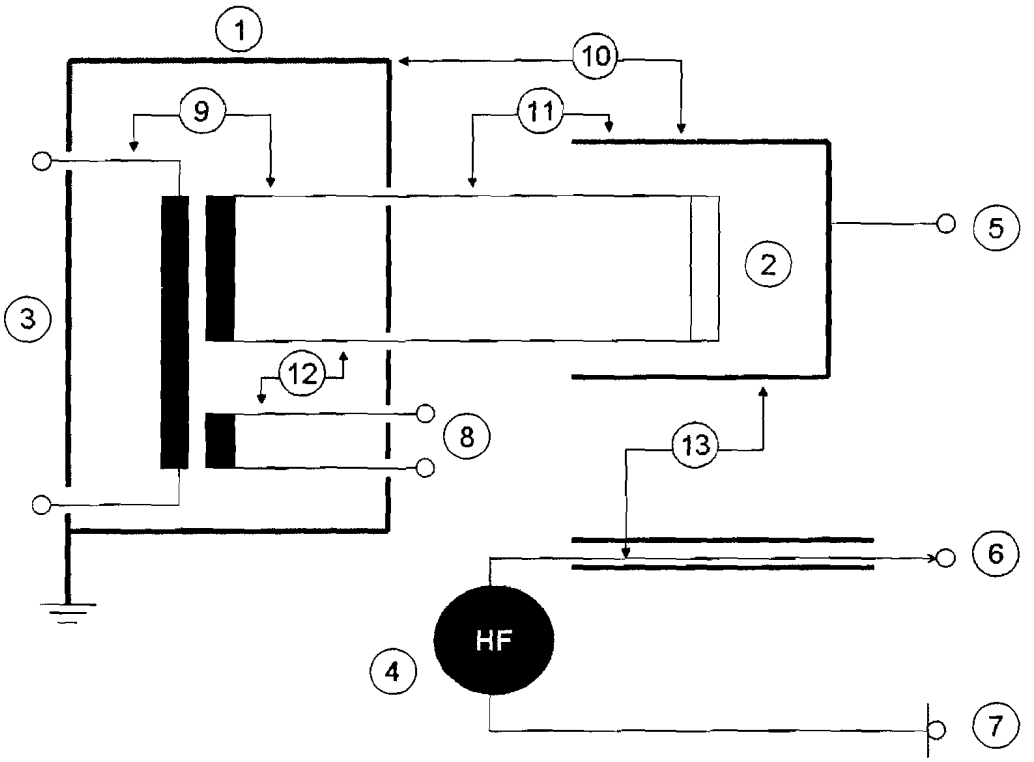
No.	Symbol	Reference	Title
110		N/A	Average light measuring
111		N/A	Illumination lamp MODEL OR TYPE REFERENCE

Annex J
(informative)

Survey of insulation paths

Annex J of the general standard applies except as follows:

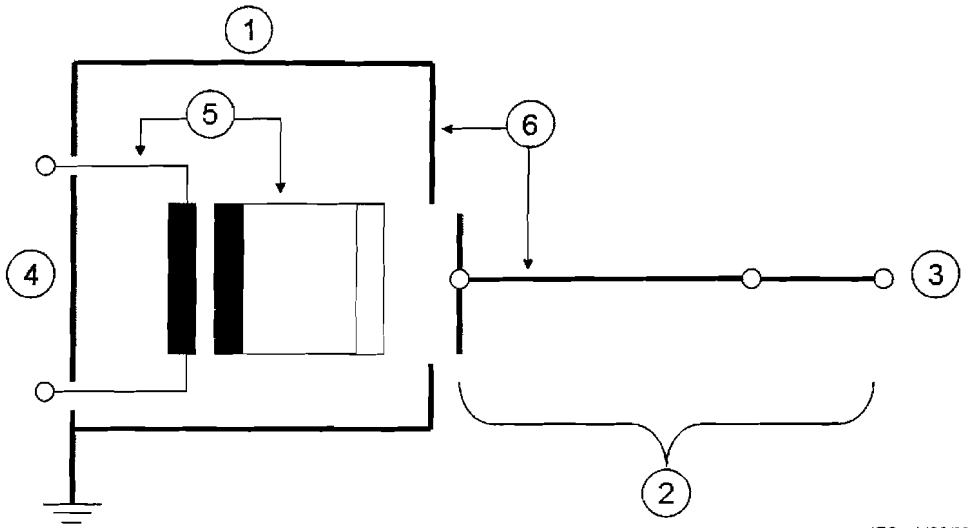
Addition:



1	SUPPLY UNIT		
2	ENERGIZED ENDOSCOPE		
3	MAINS PART		
4	HF SURGICAL EQUIPMENT		
5	PATIENT CONNECTION with ENERGIZED ENDOSCOPE		
6	PATIENT CONNECTION of HF ENERGIZED ENDOTHERAPY DEVICE		
7	PATIENT CONNECTION of HF NEUTRAL ELECTRODE		
8	SIGNAL INPUT/OUTPUT PART (may include INTERFACE CONDITION)		
	Combinations of INSULATION CO-ORDINATION:		
	Example 1	**or**	**Example 2**
9	2 × MOPP (MAINS VOLTAGE)	9	2 × MOOP (MAINS VOLTAGE)
10	2 × MOPP (WORKING VOLTAGE) and 1 × MOPP (MAINS VOLTAGE) [a]	10	2 × MOPP (WORKING VOLTAGE) and 1 × MOPP (MAINS VOLTAGE) [a]
		11	2 × MOPP (WORKING VOLTAGE) and 1 × MOPP (MAINS VOLTAGE) [a]
12	2 × MOPP (WORKING VOLTAGE) and 1 × MOPP (MAINS VOLTAGE) [a]	12	2 × MOOP (MAINS VOLTAGE)
13	INTERFACE CONDITION (compliance of the ENERGIZED ENDOTHERAPY DEVICE – see subclause 201.11.101.2)		

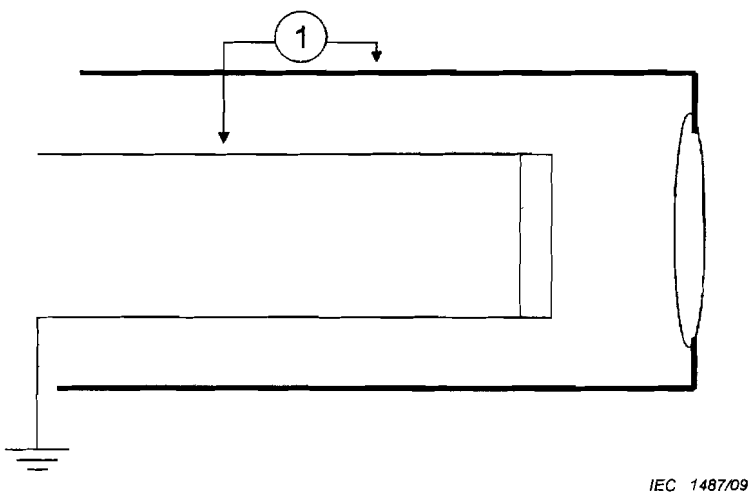
[a] See subclause 8.5.2.1 of the general standard for the separation of F-TYPE APPLIED PARTS.

Figure 201.J.101 – Insulation example 101



1 SUPPLY UNIT
2 APPLIED PART(S) (e.g. light connector, light cable, ENDOSCOPE)
3 PATIENT CONNECTION with ENERGIZED ENDOSCOPE
4 MAINS PART
5 2 × MOOP (MAINS VOLTAGE)
6 2 × MOPP (WORKING VOLTAGE) and 1 × MOPP (MAINS VOLTAGE)

Figure 201.J.102 – Insulation example 102



1 2 × MOOP (MAINS VOLTAGE) (refer to subclause 201.8.9.1.1: example for reduced CREEPAGE DISTANCES and AIR CLEARANCES)

Figure 201.J.103 – Insulation example 103

Annex AA
(informative)

Particular guidance and rationale

AA.1 General guidance

This annex provides a concise rationale for the important requirements of the standard and is intended for those who are familiar with products covered by this standard but who have not participated in its development. An understanding of the reasons for the main requirements is considered to be essential for the proper application of the standard. Furthermore, as clinical practice and technology change, it is believed that a rationale for the present requirements will facilitate any revision of the standard necessitated by these developments.

AA.2 Rationale for particular clauses and subclauses

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.

Subclause 201.1.1 – Scope

The use of ENERGIZED ENDOTHERAPY DEVICES for an increasing number of endoscopic applications may give rise to other particular standards being applied inappropriately for INTERCONNECTION CONDITIONS with ENDOSCOPES and INTERFACE CONDITIONS within the CONFIGURATION FOR ENDOSCOPIC APPLICATION. This subclause establishes priority of application of this particular standard in the event of conflicting requirements or tests.

The reason for this is that endoscopic use of MEDICAL ELECTRICAL EQUIPMENT and/or its APPLIED PARTS should be considered independently from non-endoscopic use, due to the structure and physical requirements of ENDOSCOPES and ENDOTHERAPY DEVICES.

The scope of this third edition of the standard differs from the previous edition through the inclusion of ACCESSORIES that pass into the PATIENT through second or subsequent punctures, whereas the previous edition covered only ACCESSORIES that passed into the PATIENT through the same orifice as the ENDOSCOPE. This extension of scope has necessarily led to the definition of the CONFIGURATION FOR ENDOSCOPIC APPLICATION to fully embrace all relevant INTERFACE CONDITIONS.

Definition 201.3.201 – CAPACITIVELY COUPLED HF CURRENT

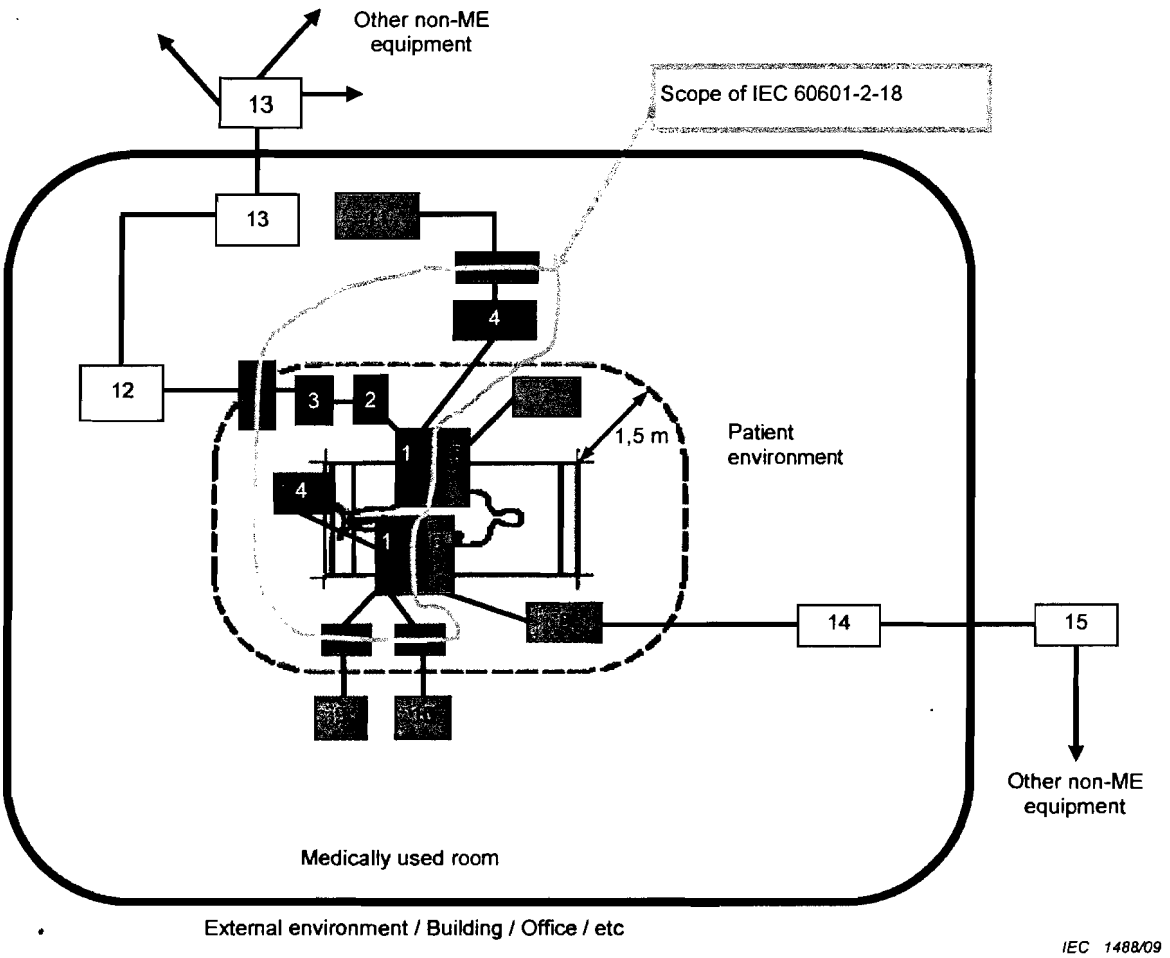
The design and narrow dimensions of ENDOSCOPES result in them being electrically capacitively coupled to any ENERGIZED ENDOTHERAPY DEVICES with which they are used. If the ENERGIZED ENDOTHERAPY DEVICE is powered by HIGH FREQUENCY SURGICAL EQUIPMENT, some of this HIGH FREQUENCY current will be coupled from the ENERGIZED ENDOTHERAPY DEVICE to the ENDOSCOPE and may flow from the ENDOSCOPE via the PATIENT and/or OPERATOR back to the HIGH FREQUENCY SURGICAL EQUIPMENT.

Definition 201.3.202 – CONFIGURATION FOR ENDOSCOPIC APPLICATION

Endoscopic procedures are often carried out with a multiplicity of equipment and instrumentation embracing, in addition to the ENDOSCOPIC EQUIPMENT, ENDOTHERAPY DEVICES, some of which may be energized, other ME EQUIPMENT or ME SYSTEMS, and non-MEDICAL EQUIPMENT, each of which has to interact or interface with the ENDOSCOPIC EQUIPMENT. The definition of a CONFIGURATION FOR ENDOSCOPIC APPLICATION is intended to delineate the scope

of this particular standard and allow the definition of requirements for these INTERCONNECTION CONDITIONS and INTERFACE CONDITIONS.

The CONFIGURATION FOR ENDOSCOPIC APPLICATION is best explained by reference to Figure AA.101, which illustrates the equipment used in a typical endoscopic procedure. Non-exhaustive examples of the type of equipment in each category are provided for clarification purposes.



ENDOSCOPIC EQUIPMENT

INTERFACE CONDITION

MEDICAL ELECTRICAL EQUIPMENT

INTERCONNECTION CONDITION

ENERGIZED ENDOTHERAPY DEVICE

NON-MEDICAL ELECTRICAL EQUIPEMENT

Typical examples of each type of instrumentation in above CONFIGURATION FOR ENDOSCOPIC EQUIPMENT:

1	ENERGIZED ENDOSCOPE	6	Laser fibre	11	Irrigation pump
2	Camera head	7	HF SURGICAL EQUIPMENT	12	VCR/DVD recorder
3	Video processor	8	Laser	13	TV monitor
4	Light source (SUPPLY UNIT)	9	Suction pump	14	PC/laptop
5	HF forceps	10	Insufflator	15	Computer network

Figure AA.101 – Illustration of typical CONFIGURATION FOR ENDOSCOPIC APPLICATION

Definition 201.3.206 – ENERGIZED ENDOSCOPE

Only ENDOSCOPES connected to some form of SUPPLY UNIT are ENERGIZED ENDOSCOPES and therefore included within the definition of MEDICAL ELECTRICAL EQUIPMENT. ENDOSCOPES without a SUPPLY UNIT are therefore outside the scope of this particular standard.

ENERGIZED ENDOSCOPES are sometimes used through other ENERGIZED ENDOSCOPES, in which case the requirements of this particular standard, including relevant INTERCONNECTION CONDITIONS, will need to be met by both ENERGIZED ENDOSCOPES.

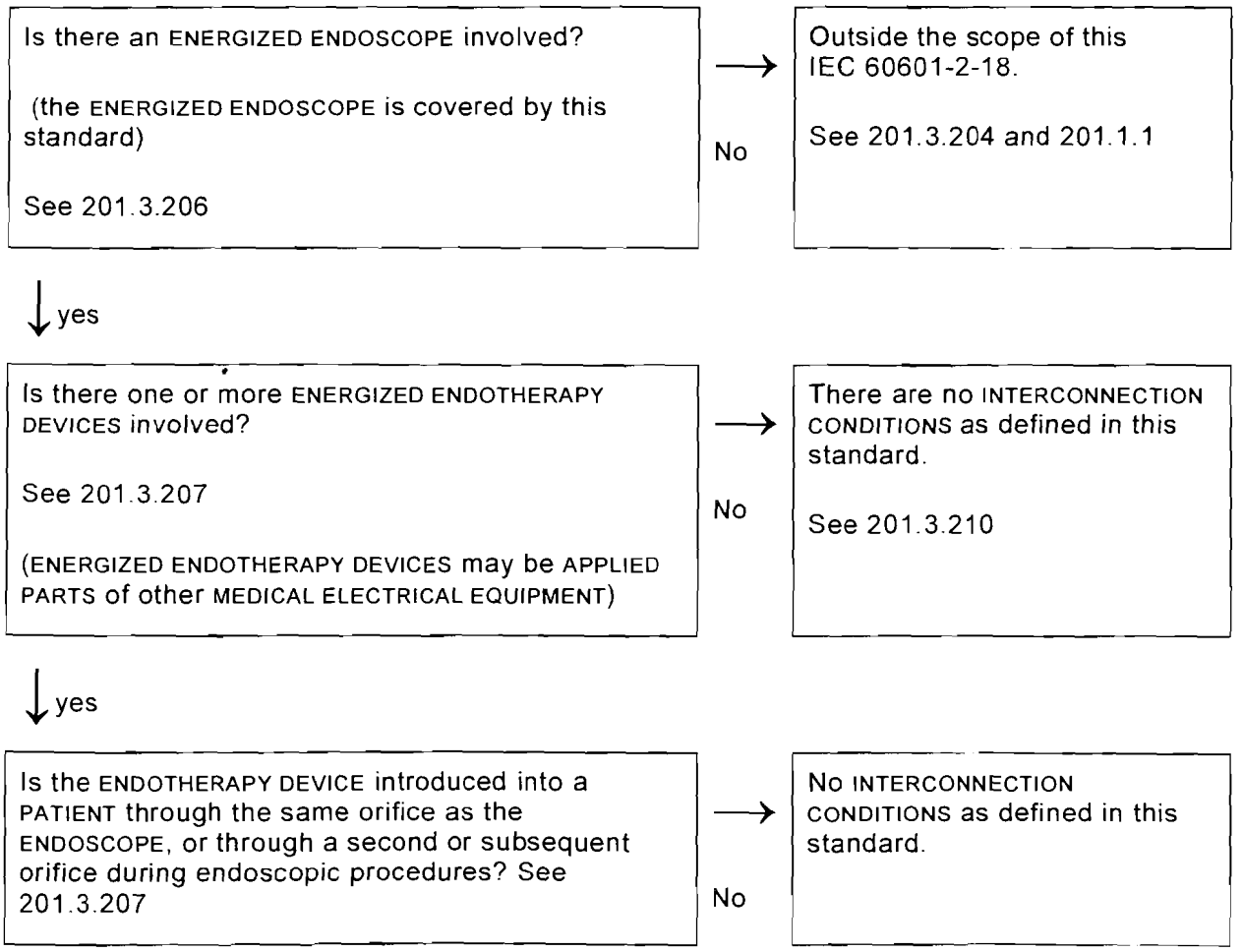
This definition includes ULTRASONIC DIAGNOSTIC EQUIPMENT when used with invasive probes (with or without optical viewing means), but the requirements for these are cross-referenced to IEC 60601-2-37 (see 201.3.216).

Definition 201.3.207 – ENERGIZED ENDOTHERAPY DEVICE

ENERGIZED ENDOTHERAPY DEVICES may be APPLIED PARTS of other MEDICAL ELECTRICAL EQUIPMENT. If so, they are covered by the standards pertaining to that type of MEDICAL ELECTRICAL EQUIPMENT, but requirements for their INTERCONNECTION CONDITIONS with ENDOSCOPIC EQUIPMENT are given in this particular standard.

Definition 201.3.210 – INTERCONNECTION CONDITIONS

Relationship between definitions:



↓ yes

This particular standard defines requirements for the INTERCONNECTION CONDITIONS. See 201.3.210 e.g.: 201.4.7 SINGLE FAULT CONDITION for ME EQUIPMENT 201.7.9.2.2 Warning and safety notices Warning and safety notices regarding INTERCONNECTIONS CONDITIONS 201.11.101 **INTERCONNECTION CONDITIONS**

Definition 201.3.215 – SUPPLY UNIT

SUPPLY UNITS will include: light sources, video processors, ultrasonic processors and the like, that is MEDICAL ELECTRICAL EQUIPMENT required to enable the ENERGIZED ENDOSCOPE to function as intended. TV cameras and their processors, which can be electrically and/or mechanically connected to an ENDOSCOPE, are included in the definition of SUPPLY UNIT (although the cameras may also be APPLIED PARTS).

Subclause 201.4.1.101 – ENERGIZED ENDOTHERAPY DEVICES

The use of ENERGIZED ENDOTHERAPY DEVICES for an increasing number of endoscopic applications may give rise to other particular standards being applied inappropriately for INTERCONNECTION CONDITIONS. This subclause establishes priority of application of this particular standard in the event of conflicting requirements or tests. The reason for this is that endoscopic use of MEDICAL ELECTRICAL EQUIPMENT and/or its APPLIED PARTS should be considered independently from non-endoscopic use, because of the structure and physical requirements of ENDOSCOPES.

Subclause 201.4.1.103 – SUPPLY UNITS

The definition of ENDOSCOPIC EQUIPMENT includes invasive ultrasonic probes and their SUPPLY UNITS, used either with or without integral or separate viewing means. Whilst the electrical safety aspects of this type of MEDICAL ELECTRICAL EQUIPMENT are covered by this particular standard, the ultrasonic functional safety aspects are covered by IEC 60601-2-37.

In order to enhance the functionality of certain MEDICAL ELECTRICAL EQUIPMENT used during endoscopic procedures, it is common for additional functions to be integrated into SUPPLY UNITS provided with only one connection to a SUPPLY MAINS which are not necessary for the ENDOSCOPE to produce the intended view or image. In such cases, it is reasonable to expect the parts which produce a particular function to meet the requirements of its appropriate particular standard. This may, by necessity, also include the entire unit complying with requirements specified in other particular standards, for example for spillage, ingress of liquids, separation, etc., as it may be impossible to apply these specific requirements to individual parts of a unit.

Subclause 201.4.3.101 – Additional ESSENTIAL PERFORMANCE requirements

Endoscopic equipment often is controlled by software algorithms. A correct presentation of image information is likely to be relied upon (is essential) for diagnosis, treatment or image documentation. Under some circumstances this information may be influenced by other factors (e.g. electromagnetic interference) which can cause hazardous loss of performance.

As these essential performance requirements are determined by the unique design of the specific device or procedure, the manufacturer of the device has to assess the applicable factors within the risk management file.

In addition the warning and safety notices in 201.7.9.2.2 g) reflect some usability aspects which can be handled within the instructions for use to bring the users attention to this issue.

Subclause 201.4.6 – ME EQUIPMENT or ME SYSTEM PARTS that contact the PATIENT

Light guide cables are not included in the definition of APPLIED PART because in NORMAL USE they do not necessarily come into physical contact with the PATIENT for ME EQUIPMENT or an ME SYSTEM to perform its function. However, they can make physical contact with the PATIENT during normal use, so it is recommended they be treated as APPLIED PARTS for the purposes of this particular standard, unless the RISK MANAGEMENT FILE shows there is no unacceptable RISK for specific configurations of light source, light guide cable and ENERGIZED ENDOSCOPE.

For example, if the required F-TYPE APPLIED PART isolation is provided within the light source, and there is no risk of accidental connection of exposed conductive parts of the light guide cable contacting grounded casework or similar parts, then RISK MANAGEMENT would probably conclude that it would be unnecessary to consider the light guide cable as an APPLIED PART.

However, if the required F-TYPE APPLIED PART isolation is integral to the light guide cable, or provided as part of the ENERGIZED ENDOSCOPE, then RISK MANAGEMENT would probably conclude that potential HAZARDS exist in NORMAL and/or SINGLE FAULT CONDITION, in which case the light guide cable should be considered as an APPLIED PART and therefore subject to the requirements of this particular standard.

Subclause 201.5.7 – Humidity preconditioning treatment

It is considered inappropriate for ACCESS COVERS, such as for access to illumination lamps of SUPPLY UNITS, which, upon opening, inactivate the equipment, to be open during preconditioning, especially as ENDOSCOPIC EQUIPMENT is virtually always used in a controlled environment. The RISK MANAGEMENT process should therefore be used to identify if specific parts of ENDOSCOPIC EQUIPMENT may be exposed to high humidity during any periods when ACCESS COVERS are likely to be open.

ENERGIZED ENDOSCOPES and ENERGIZED ENDOTHERAPY DEVICES which according to their intended use or instructions for use are subject to disinfection and/or sterilization processes prior to use will not need to be subjected to humidity preconditioning treatment, as fulfilling the requirements of subclauses 11.6.6 and/or 11.6.7 of the general standard will provide the necessary pre-treatment.

Subclause 201.7.2.9 – IP classification

ENERGIZED ENDOSCOPES and ENERGIZED ENDOTHERAPY DEVICES supplied with specific instructions detailing allowable reprocessing methods and parameters are excluded from the requirement to be marked with an IP classification because this additional information is likely to confuse OPERATORS, and the IP marking will not inform the OPERATOR of the necessary details to allow safe and effective reprocessing. An alternative marking (e.g. by a symbol), replacing the IP symbol could not be standardized by this particular standard because of the different reprocessing procedures. See also 7.9.2.12 of the general standard.

Subclause 201.7.2.102 – Illumination lamps

In order to avoid HAZARDS posed by the connection of lamps of an incorrect type, marking of the MODEL OR TYPE REFERENCE is required, as marking only the voltage and/or wattage may lead to lamps of the wrong type being fitted.

Subclause 201.7.9.2.2 – Warning and safety notices

The warnings and safety notices required by this subclause of this particular standard are not exhaustive and the MANUFACTURER'S RISK MANAGEMENT process should identify other specific relevant risks and HAZARDOUS SITUATIONS that cannot be eliminated by design, and therefore need to be mitigated by the use of warning and safety notices either on the item or in the instructions for use.

For example, when HIGH FREQUENCY SURGICAL EQUIPMENT is used with ENDOSCOPIC EQUIPMENT and/or ENERGIZED ENDOTHERAPY DEVICES, there are many potential HAZARDS to the PATIENT and/or OPERATOR that should be considered in addition to those listed in this subclause of the particular standard, including:

a) keeping the working part of the active electrode in the view field of the OPERATOR to avoid accidental HIGH FREQUENCY burns;

b) avoiding contact with metal parts of the ENDOSCOPE and other conductive ACCESSORIES, including the aspiration of fluids (which may be conductive) before activation of the HIGH FREQUENCY output, by ensuring that the active electrode is in the correct position for the procedure, at a sufficient distance from the tip of the ENDOSCOPE;

c) the use of insulated non-HIGH FREQUENCY secondary ACCESSORIES or ENDOTHERAPY DEVICES where there is a possibility that they might be contacted by the active electrode during the procedure;

d) avoidance of contra-lateral HF burns, by ensuring that any lesion being subjected to HIGH FREQUENCY current is not allowed to touch normal mucosa during activation of the active electrode;

e) the use of a non-conductive eyepiece on the ENDOSCOPE to reduce the risk of HIGH FREQUENCY burns to the OPERATOR'S face around the eye;

f) the selection of an initial HIGH FREQUENCY output power setting suitable for the particular intended procedure in order to avoid thermal invasion of the tissue, which can be caused by too low a setting, or insufficient coagulation, resulting in excessive bleeding, which can be caused by too high a setting.

   IEC 60601-2-2 requires inclusion in the instructions for use of HIGH FREQUENCY SURGICAL EQUIPMENT that: "The output power selected should be as low as possible for the intended purpose. Certain devices or ACCESSORIES may present a HAZARD at low power settings." For endoscopic HIGH FREQUENCY surgery such a HAZARD to the PATIENT may exist if too low a power output is used, as it will take longer for the cutting or coagulation effect to be realized that with conventional HIGH FREQUENCY surgical active electrodes. This, in turn, may cause excessive thermal invasion of the surrounding tissue.

   For ENERGIZED ENDOTHERAPY DEVICES, therefore, MANUFACTURERS should consider explaining in the instructions for use that the initial output setting should be set in accordance with the clinician's experience, by reference to appropriate clinical references, or as a result of appropriate training.

g) Gas, which may support combustion, is sometimes present in the gastrointestinal tract of an unprepared PATIENT and certain patient-preparation substances used prior to lower GI endoscopy can enhance methane production. This is particularly relevant to colonoscopy, but has also been recorded in the upper GI tract. In addition, during transurethral resection of the prostate, it has been recorded that hydrogen can accumulate in the bladder above the irrigant solution. The MANUFACTURER may therefore need to consider providing advice on how to avoid HAZARDS associated with these gases.

h) MANUFACTURERS should also refer to subclause 201.7.9.2.2.101 of IEC 60601-2-2 and the relevant rationale in Annex AA of that particular standard for further requirements and guidance.

Additionally, there are other potential hazards when lasers are used with ENDOSCOPES and/or ENDOTHERAPY DEVICES. In addition to those listed in this subclause of this particular standard, advice concerning avoidance of the following potential HAZARDS should be considered by the MANUFACTURER and included where appropriate:

1) HAZARDS associated with failure of the laser delivery fibre being used via an ENDOSCOPE, including the need to de-energize the laser output should the fibre fail;

2) laser damage to the distal tip of the ENDOSCOPE, which can be avoided by ensuring that the tip of the laser delivery fibre can be seen through the ENDOSCOPE before energization.

Subclause 201.8.5.2.3 – PATIENT leads

Endoscopic procedures require constant supervision by suitably trained medical personnel. PATIENTS are not left unattended with ENDOSCOPIC EQUIPMENT attached to them, nor are they moved from one location to another with ENDOSCOPIC EQUIPMENT attached. As a result, the misconnection of APPLIED PART connectors to other than compatible EQUIPMENT is considered to be very unlikely. It is therefore considered appropriate for any relevant HAZARDS and subsequent RISKS to be addressed via the MANUFACTURER'S RISK MANAGEMENT process.

Subclause 201.8.8.3 – Dielectric strength

For HIGH FREQUENCY ENERGIZED ENDOTHERAPY DEVICES, thermal HAZARDS present a greater RISK to the PATIENT and OPERATOR than RISKS associated with electric shock. Tests for dielectric strength of materials at high frequencies have therefore been included in subclause 201.11.101.2 of this particular standard.

Subclause 201.8.9.1.1 – General

Because of the constructional requirements of ENDOSCOPES necessary to meet the appropriate clinical requirements, it may not be possible for the APPLIED PARTS of ENDOSCOPIC EQUIPMENT to meet the requirements of subclause 8.9 of the general standard. Because ENDOSCOPES are sealed units and any LIVE circuits within the ENDOSCOPE are always on the secondary side, it is considered that an adequate level of safety for these parts will be provided by two MEANS OF OPERATOR PROTECTION, pollution degree 1.

Subclause 201.9.4.2.4.3 – Movement over a threshold

It is considered inappropriate for endoscopic ME SYSTEMS mounted on workstations (often referred to as 'stacks') to be able to pass the same test for movement over a threshold as for individual ME EQUIPMENT. This is because endoscopic stacks will have several pieces of equipment mounted on a number of shelves or platforms, perhaps with total mass of 200 kg or more, and in the majority of cases, these individual items will not be secured to the shelves. OPERATORS will therefore be very aware that movement of such combinations of equipment requires extra care, and that stability is likely to be limited. The test parameters have therefore been amended from those for ME EQUIPMENT to better suit the likely conditions of NORMAL USE for endoscopic systems, including reference to the instructions for use where these contain specific recommendations for movement.

Subclause 201.10.4 – Lasers and light emitting diodes (LEDs)

It is considered that light emitting diodes (LEDs) used for illumination in endoscopic applications should, for the purposes of PATIENT and OPERATOR safety, be considered the same as other endoscopic illumination means.

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

The surface temperature of the LIGHT EMISSION PART may exceed 41 °C because the clinical requirements of ENDOSCOPES demand high intensity light transmission within narrow dimensions, resulting in light energy of high density and thus relatively high local surface temperatures through absorption of energy by the material immediately surrounding the light emission window. In performing endoscopic procedures however, the LIGHT EMISSION PART does not usually contact the tissue and, because of the low thermal mass of this part, occasional contact will not create a HAZARD to the PATIENT.

Of greater potential consequence to the PATIENT is the absorption of radiant energy emanating from the light emission window, which may fall directly on the tissue. Requiring particular maximum surface temperatures will not, therefore, address the potentially most hazardous parameter. The temperatures associated with this radiated light will depend on a number of factors outside the ENDOSCOPE MANUFACTURER'S control, including the type and power of the lamp in the SUPPLY UNIT and the condition of the light emission window.

For these reasons, and because laboratory tests are unlikely to be wholly representative of actual use, it is not considered appropriate to specify a maximum allowable temperature of the LIGHT EMISSION PART. However, warnings and advice on measures the OPERATOR can take to minimize HAZARDS for the PATIENT are required in the instructions for use.

There may also be thermal effects resulting from the combined use of ENDOSCOPES and ENERGIZED ENDOTHERAPY DEVICES which may be the APPLIED PARTS of other MEDICAL ELECTRICAL EQUIPMENT used during endoscopic procedures, for instance the current density of CAPACITIVELY COUPLED HF CURRENT, not the absolute value of the current, is more relevant to thermal RISKS. This is also dependent on factors outside of the control of the MANUFACTURER, and thus it is impossible for MANUFACTURERS to quote maximum temperatures. See the rationale for 201.11.101.2 for further information.

Light guide cables may be APPLIED PARTS, but the connectors will generally become hotter than 41 °C in NORMAL USE. As these parts are not intended to come into contact with the PATIENT, it is considered unnecessary to quote a maximum temperature. A warning should be included in the instructions for use, however, to advise OPERATORS of potential HAZARDS associated with handling these parts after use. See also 201.7.9.2.2 of this particular standard.

Subclause 201.11.6.5 – Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS

ENERGIZED ENDOSCOPES and ENERGIZED ENDOTHERAPY DEVICES intended to be cleaned, disinfected and/or sterilized are excluded from this requirement of the general standard because they have to meet their own specifications and design criteria for cleaning, disinfection and/or sterilization, thus the requirement to meet subclauses 11.6.6 and/or 11.6.7 of the general standard, as appropriate. See also 201.7.2.9 of this particular standard and its associated rationale.

Subclause 201.11.101.2 – Thermal and other HAZARDS from INTERCONNECTION CONDITIONS with HF SURGICAL EQUIPMENT

Thermal effects may result from the combined use of ENDOSCOPES and ENERGIZED ENDOTHERAPY DEVICES, WHICH are the APPLIED PARTS of HF SURGICAL EQUIPMENT, by virtue of

the current density of CAPACITIVELY COUPLED HF CURRENT. The MANUFACTURER'S RISK MANAGEMENT process should be used to identify such RISKS under both NORMAL and SINGLE FAULT CONDITIONS, so that appropriate RISK reduction measures can be taken during the design process, and/or relevant safety warnings can be provided in the instructions for use.

Such CAPACITIVELY COUPLED HF CURRENT may also be responsible for thermal damage to the ENDOSCOPE, and therefore sufficient dielectric strength must be provided on HF ENERGIZED ENDOTHERAPY DEVICES to protect the PATIENT, OPERATOR and the ENDOSCOPE itself. The tests required by 201.8.8.3.103 and 201.8.8.3.104 of IEC 60601-2-2:2009 are considered appropriate to confirm the suitability of the dielectric strength of ENERGIZED ENDOTHERAPY DEVICES.

Exposed conductive parts of ENDOSCOPES that may be used with ENERGIZED ENDOTHERAPY DEVICES must also be isolated to protect the OPERATOR from the thermal effects of CAPACITIVELY COUPLED HF CURRENT. The isolation can be achieved by different measures, e.g. by separation of components or by an insulation. A maximum HF current of 50 mA flowing from such exposed conductive parts is considered to provide sufficient protection.

During insertion of the ENERGIZED ENDOTHERAPY DEVICE through the channel of an ENDOSCOPE, parts of it that are intended to contact the PATIENT will also contact the ENDOSCOPE. This is acceptable, as HIGH FREQUENCY current should not be activated until the working part of the ENERGIZED ENDOTHERAPY DEVICE can be seen through the ENDOSCOPE by the OPERATOR.

It should also be considered that an INTERCONNECTION CONDITION exists during use between the handle of an ENERGIZED ENDOTHERAPY DEVICE and the OPERATOR.

Subclause 201.15.3.5 – Rough handling test

It is not considered appropriate to apply the requirements for rough handling contained in subclause 15.3.5 of the general standard to 'stacks' of ENDOSCOPIC EQUIPMENT, as these are intended to be used within or close to the PATIENT ENVIRONMENT, and will not generally be subjected to the type of rough handling detailed in this subclause. It is considered sufficient for such 'stacks' to meet the requirements of 201.9.4 of this particular standard.

Subclause 201.15.4.1 – Construction of connectors

The MANUFACTURER of ENDOSCOPES and ENDOTHERAPY DEVICES should use ISO 14971 to consider the probability of misconnection of medical devices intended for connection to ENDOSCOPES or ENDOTHERAPY DEVICES to non-endoscopic PATIENT CONNECTIONS (e.g. intravenous applications).

The purpose of the RISK MANAGEMENT process is to assess both the physical possibility of a misconnection of such medical devices to non-endoscopic PATIENT CONNECTIONS, particularly to Luer connectors in accordance with ISO 594, and the probability of occurrence of such a misconnection, together with the potential severity of harm for the PATIENT. Where relevant standards exist for connectors that match the INTENDED USE of the ENDOSCOPE, ENDOTHERAPY DEVICE or medical device intended for connection to ENDOSCOPES or ENDOTHERAPY DEVICES, these should be used unless contraindicated by the RISK MANAGEMENT process.

This rationale provides guidance for MANUFACTURERS of ENDOSCOPES, ENDOTHERAPY DEVICES and medical devices intended for connection to ENDOSCOPES and ENDOTHERAPY DEVICES in assessing the level of RISK associated with connectors in endoscopy systems related to their INTENDED USE, where specific connectors in accordance with relevant standards do not exist.

As outlined in ISO 14971, RISK estimation for medical devices should be accomplished by combining two components:

– the probability of occurrence of HARM, that is how often the HARM may occur;

– the consequences of that HARM, that is how severe it might be.

Where possible, the estimation of probability of occurrence should be based on quantitative data, but if there is no such data, then a qualitative approach should be taken, commonly involving the prediction of probability using analytical or simulation techniques, and/or the use of expert judgment.

The severity of HARM will generally be easier to quantify, perhaps distinguishing between only three or four levels.

The acceptability of RISK is generally recognized to fall into three regions – broadly acceptable; as low as reasonably possible (ALARP); and intolerable.

When considering endoscopy system connectors, the MANUFACTURER'S RISK ANALYSIS should include consideration of 'probability' and 'severity' of at least the following factors:

– cross-connection within the endoscopy system;
– misconnection to unrelated PATIENT CONNECTIONS;
– misconnection to unrelated medical devices;
– security of connection under normal and SINGLE-FAULT CONDITIONS;
– intended use of connector (e.g. dedicated or multi-use);
– reprocessing of reusable connectors.

In making an assessment of the probability of such possible events, consideration should also be given to other factors of use, including:

– intended or anticipated location of use (e.g. use in an intensive care facility, where a number of PATIENT CONNECTIONS are probable, may present higher RISKS of misconnection than use in an endoscopy suite);
– whether it is normal for PATIENT CONNECTIONS to be covered/hidden from immediate view for the intended procedure;
– the proximity of the endoscopy system connections to other probable PATIENT CONNECTIONS;
– whether use of the connector is intended to take place inside or outside the PATIENT ENVIRONMENT;
– whether PATIENT CONNECTIONS made during the endoscopy procedure remain in place after the procedure;
– whether it is possible/impossible for the connector to reach the PATIENT in NORMAL USE/SINGLE FAULT CONDITION;
– the normal level of supervision/staffing associated with the procedure.

For reusable devices, the RISKS of changing from the status quo should also be assessed, including any transitional provisions that may be necessary should devices with 'new' connectors be expected to be used safely in combination with devices having 'old' connectors.

Where, following application of risk management in accordance with ISO 14971, a manufacturer decides to use a Luer connector in accordance with ISO 594, then it is advisable to record a full justification for this decision in the risk management file, as misconnection of endoscope supply lines (e.g. insufflating gas, suction, irrigation fluid) and substances delivered via syringes (e.g. air, water, contrast media, topical anesthetic, sclerosant, mucosa staining fluid, etc.) may prove fatal if misconnected to particular non-endoscopic patient ports (such as high pressure gas insufflation to the vascular system).

Annex BB
(informative)

Clauses of this standard addressing essential principles of safety and performance of medical devices (GHTF/SG1/N41R9:2005)

The following clauses of this standard, as detailed in Table BB.1, are likely to support Essential Principles of Safety and Performance of Medical Devices[2] complementary to the clauses of the general standard IEC 60601-1. The clauses of the general standard and of the collateral standards are not covered by this annex.

WARNING: Other requirements and legal documents may be applicable to the product(s) falling within the scope of this standard.

Table BB.1 – Correspondence between this standard and GHTF/SG1/N41R9:2005

Clauses/sub-clauses of this standard	Corresponding annexes / paragraphs of Essential Principles of Safety and Performance of Medical Devices	Comments
All clauses	5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.9.2	
201.4.1	5.9.1,	
201.4.3	5.2, 5.6	
201.4.6	5.13.4,	
201.4.7	5.7.1, 5.12.1	
201.5.1	5.5,	
201.5.7	5.5, 5.7.2	
201.6.2	5.12.7	
201.7.2.1	5.5, 5.16	
201.7.2.9	5.16	
201.7.2.10	5.16	
201.7.2.101	5.16	
201.7.2.102	5.16	
201.7.4	5.16	
201.7.6	5.16	
201.7.9.2.2	5.9.2, 5.16	
201.7.9.2.12	5.7.2, 5.7.3, 5.8.1, 5.8.2, 5.8.5, 5.8.7, 5.16	
201.7.9.2.14	5.7.2, 5.7.3, 5.7.4, 5.8.1, 5.8.2, 5.8.5, 5.8.7, 5.9.1, 5.16	
201.8.3	5.12.7	
201.8.5	5.12.7, 5.13.4	
201.8.8	5.12.7	
201.8.9	5.12.7	
201.9.2	5.9.1, 5.13	
201.9.3	5.13	
201.9.4	5.5, 5.9.1, 5.13	

2) GHTF/SG1/N41R9:2005, *Essential Principles of Safety and Performance of Medical Devices*, The Global Harmonization Task Force, Study Group 1.

Clauses/sub-clauses of this standard	Corresponding annexes / paragraphs of Essential Principles of Safety and Performance of Medical Devices	Comments
201.9.5	5.7.5, 5.7.6, 5.13	
201.9.7	5.7.5, 5.7.6, 5.13	
201.9.8	5.7.5, 5.7.6, 5.13	
201.10.4	5.11.1, 5.11.2, 5.11.3	
201.10.5	5.11.1, 5.11.2, 5.11.3	
201.10.6	5.11.1, 5.11.2, 5.11.3	
201.10.7	5.11.1, 5.11.2, 5.11.3	
201.11.1	5.5, 5.7.1, 5.7.6, 5.9.3, 5.11.2, 5.11.3, 5.11.4.1, 5.13.5	
201.11.6	5.5, 5.7.5, 5.7.6	
201.11.101.1	5.9.1, 5.14.1, 5.14.2	
201.11.101.2	5.9.1, 5.14.1, 5.14.2	
201.12.2	5.10, 5.14.1, 5.14.2, 5.14.3	
201.12.4	5.10, 5.7.5, 5.7.6, 5.14.1, 5.14.2, 5.14.3	
201.13	5.5, 5.14.1, 5.14.2, 5.14.3	
201.15.3	5.13	
201.15.4	5.7.1, 5.9.1, 5.13.4	
201.16	5.9.1	
201.17	5.12.5, 5.12.6	

Bibliography

IEC 60601-2-57, *Medical electrical equipment – Part 2-57: Particular requirements for the safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use*[3)]

GHTF/SG1/N41R9:2005, *Essential Principles of Safety and Performance of Medical Devices*, The Global Harmonization Task Force, Study Group 1

3) To be published.

Index of defined terms used in this particular standard