SLOVENSKI STANDARD
oSIST prEN IEC 60601-2-18:2026

01-julij-2026

Medicinska električna oprema - 2-18. del: Posebne zahteve za osnovno varnost in bistvene lastnosti endoskopske opreme

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

Medizinische elektrische Geräte - Teil 2-18: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von endoskopischen Geräten

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

Ta slovenski standard je istoveten z: **prEN IEC 60601-2-18:2026**

ICS:

11.040.50	Radiografska oprema	Radiographic equipment

oSIST prEN IEC 60601-2-18:2026 **en**

62D/2302/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER: **IEC 60601-2-18 ED4**	
DATE OF CIRCULATION: **2026-06-05**	CLOSING DATE FOR VOTING: **2026-08-28**
SUPERSEDES DOCUMENTS: **62D/2193/RR**	

IEC SC 62D : PARTICULAR MEDICAL EQUIPMENT, SOFTWARE, AND SYSTEMS	
SECRETARIAT: United States of America	SECRETARY: Ms Ladan Bulookbashi
OF INTEREST TO THE FOLLOWING COMMITTEES:	HORIZONTAL FUNCTION(S):
ASPECTS CONCERNED: Safety	
☒ SUBMITTED FOR CENELEC PARALLEL VOTING	☐ NOT SUBMITTED FOR CENELEC PARALLEL VOTING

Attention IEC-CENELEC parallel voting

The attention of IEC National Committees, members of CENELEC, is drawn to the fact that this Committee Draft for Vote (CDV) is submitted for parallel voting.

The CENELEC members are invited to vote through the CENELEC online voting system.

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TITLE:

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

PROPOSED STABILITY DATE: 2030

NOTE FROM TC/SC OFFICERS:

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.

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International standard IEC 60601-2-18 has been prepared by IEC subcommittee 62D: Particular medical equipment, software, and systems, of IEC technical committee 62, Medical equipment, software, and systems.

This Amendment to the third edition cancels and replaces the third edition, published in 2009. This edition constitutes a technical revision and has been aligned or harmonized with IEC 60601-1:2020.

The main changes with respect to the previous edition include:

a) alignment of requirements with IEC 60601-1:2020;

b) New addition of essential performance definition;

c) New definition of the term: LIGHT EMISSION PART

d) Reference to ISO 80369-7, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors with 6% (Luer) taper for intravascular or hypodermic applications*

e) 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/XX/XX	62D/XX/XX

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 60601-1:2005 and Amendment 1:2012 and Amendment 2:2020: *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, the reference [1] in the bibliography, 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 60601-1-2:2017 and its Amendment 1:2023, IEC 60601-1-6:2010 and its Amendment 1:2013 and Amendment 2:2020, and IEC 60601-1-12:2014 and its Amendment 1:2020 apply as modified in Clause 202, 206, 212. IEC 60601-1-3 and IEC 60601-1-11 do not apply.

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.

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

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

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:

Replacement:

IEC 60601-1-6:2010, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*
Amendment 1:2013
Amendment 2:2020

Addition:

IEC 60601-1-12:2014, *Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment*
Amendment 1:2020

IEC 60601-2-2:2017, *Medical electrical equipment – Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories*
Amendment 1:2023

IEC 60601-2-37:2024, *Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment*

ISO 8600-1:2015, *Endoscopes – Medical endoscopes and endotherapy devices – Part 1: General requirements*

201.3 Terminology and definitions

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

NOTE An index of defined terms is found beginning on page 47.

Addition:

201.3.201
*** CAPACITIVELY COUPLED HF LEAKAGE CURRENT**
unavoidable HF LEAKAGE 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 to entry: 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

[SOURCE: ISO 8600-1:2015, definition 3.1]

Note 1 to entry: 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 to entry: Note 1 to entry of definition 3.1 in ISO 8600-1 extended by 'or capsule type'.

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 to entry: 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.

[SOURCE: ISO 8600-1:2015, 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.

EXAMPLE energy for illumination and/or 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 using energy for providing its INTENDED USE

EXAMPLE energy in form of HF current, ultrasound and/or laser

201.3.208
HIGH FREQUENCY
HF
frequencies less than 5 MHz and frequencies generally greater than 200 kHz

[SOURCE: IEC 60601-2-2:2017, definition 201.3.220]

201.3.209
HF SURGICAL EQUIPMENT
MEDICAL ELECTRICAL EQUIPMENT, which generates HIGH FREQUENCY currents intended for the performance of surgical tasks, such as the CUTTING or COAGULATION of biological tissue by means of these HIGH FREQUENCY currents

[SOURCE: IEC 60601-2-2:2017, definition 201.3.224]

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

Note 1 to entry: For forward viewing ENERGIZED ENDOSCOPES, the LIGHT EMISSION PART is the area within three times the maximum diameter of the insertion portion, measured at the tip, but with a minimum of 10 mm and a maximum of 25 mm, with no removable attachment such as a distal cover. See also Figure 201.101.

Note 2 to entry: For side viewing ENERGIZED ENDOSCOPES, the LIGHT EMISSION PART is the area within three times the maximum diameter of the insertion portion, measured from the centre of the light emission window in both longitudinal directions, but with a minimum of 10 mm and a maximum of 25 mm for each direction. See also Figure 201.101.

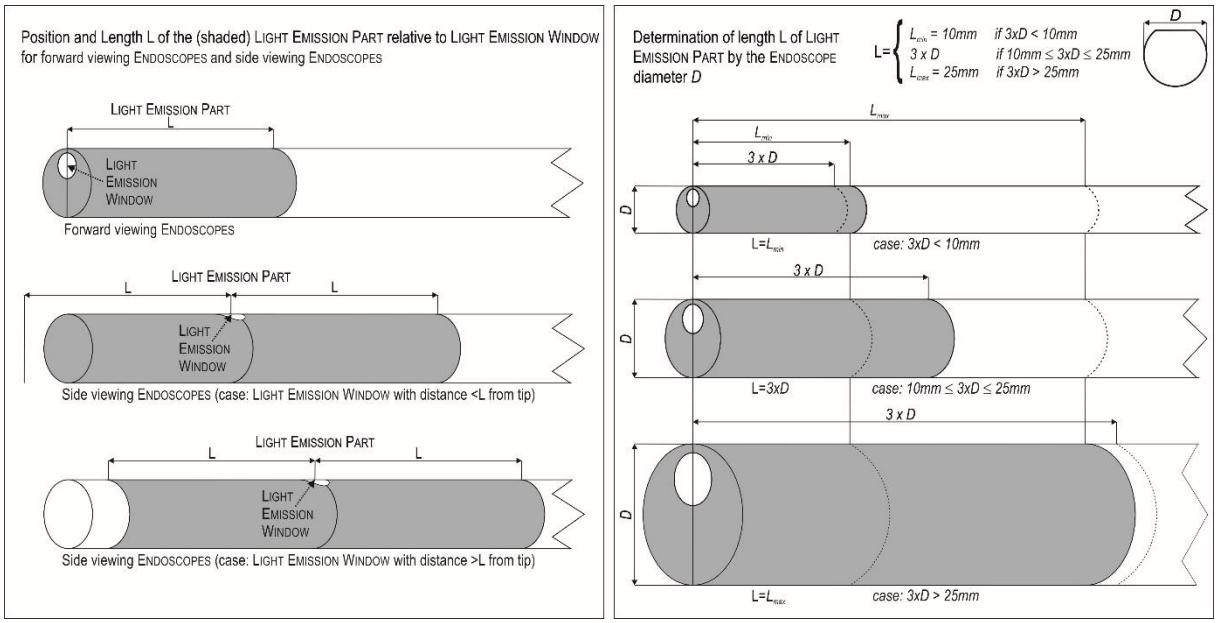

Figure 201.101 – Identification of LIGHT EMISSION PART

201.3.213
NEUTRAL ELECTRODE
NE
electrode intended to provide an electrical return path for the MONOPOLAR application of HIGH FREQUENCY current with such a low current density in the PATIENT'S tissue that effects such as excessive rise in temperature or unwanted burns are avoided

Note to entry: The NEUTRAL ELECTRODE is also known as plate, plate electrode, passive, return or dispersive electrode.

[SOURCE: IEC 60601-2-2:2017, definition 201.3.230]

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

[SOURCE: IEC 60601-2-2:2017, definition 201.3.231

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
ULTRASONIC DIAGNOSTIC EQUIPMENT
MEDICAL ELECTRICAL EQUIPMENT that is intended for ultrasonic medical examination

[SOURCE: IEC 60601-2-37:2024, 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:

Subclause 201.13.1.101 and 201.12.4.4 of this particular standard requires to ensure that there is no unacceptable RISK in the specific conditions listed in Table 201.101. The MANUFACTURER shall take into account these conditions during the identification PROCESS of ESSENTIAL PERFORMANCE in subclause 4.3 of the general standard.

NOTE Other ESSENTIAL PERFORMANCE requirements can be added by application of RISK MANAGEMENT.

Table 201.101 – List of requirements for ESSENTIAL PERFORMANCE assessment

Requirement	Subclause
To ensure that there is no unacceptable RISK, if the view observed by the OPERATOR has an unexpected image orientation.	201.13.1.101
To ensure that there is no unacceptable RISK, if there is a lack of, or significant error in, provision of a particular color spectral output 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

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

Addition:

Light guide cables shall be treated as parts that can come in contact with the PATIENT for the purposes of this particular standard unless the RISK MANAGEMENT FILE indicates otherwise for specific configurations.

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:

NOTE 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 or the light guide cable. See subclause 201.5.1 in Annex AA.

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: