

Australian/New Zealand Standard™

Medical electrical equipment

**Part 2.18: Particular requirements for
basic safety and essential performance
of endoscopic equipment**



AS/NZS IEC 60601.2.18:2015

This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HE-003, Medical Electrical Equipment. It was approved on behalf of the Council of Standards Australia on 12 October 2015 and on behalf of the Council of Standards New Zealand on 2 October 2015.

This Standard was published on 16 November 2015.

The following are represented on Committee HE-003:

Australian and New Zealand College of Anaesthetists
Australian Dental Association
Australian Society of Anaesthetists
Canterbury District Health Board
College of Biomedical Engineering Engineers Australia
Department of Defence
Engineers Australia
Medical Technology Association of Australia
Ministry of Business, Innovation and Employment, New Zealand
New Zealand Institute of Healthcare Engineering
Testing Interests, Australia
Therapeutic Goods Administration
Wairarapa District Health Board
Waitemata District Health Board

Keeping Standards up-to-date

Standards are living documents which reflect progress in science, technology and systems. To maintain their currency, all Standards are periodically reviewed, and new editions are published. Between editions, amendments may be issued. Standards may also be withdrawn. It is important that readers assure themselves they are using a current Standard, which should include any amendments which may have been published since the Standard was purchased.

Detailed information about joint Australian/New Zealand Standards can be found by visiting the Standards Web Shop at www.saiglobal.com.au or Standards New Zealand web site at www.standards.co.nz and looking up the relevant Standard in the on-line catalogue.

For more frequent listings or notification of revisions, amendments and withdrawals, Standards Australia and Standards New Zealand offer a number of update options. For information about these services, users should contact their respective national Standards organization.

We also welcome suggestions for improvement in our Standards, and especially encourage readers to notify us immediately of any apparent inaccuracies or ambiguities. Please address your comments to the Chief Executive of either Standards Australia or Standards New Zealand at the address shown on the back cover.

This Standard was issued in draft form for comment as DR AS/NZS IEC 60601.2.18:2015.



Documents
Document Sharing Hub

Australian/New Zealand Standard™

Medical electrical equipment

Part 2.18: Particular requirements for basic safety and essential performance of endoscopic equipment

Originated in Australia as AS 3200.2.18—1992.
Previous and first joint edition AS/NZS 3200.2.18:1997.
Jointly revised and redesignated as AS/NZS IEC 60601.2.18:2015.

COPYRIGHT

© Standards Australia Limited/Standards New Zealand

All rights are reserved. No part of this work may be reproduced or copied in any form or by any means, electronic or mechanical, including photocopying, without the written permission of the publisher, unless otherwise permitted under the Copyright Act 1968 (Australia) or the Copyright Act 1994 (New Zealand).

Jointly published by SAI Global Limited under licence from Standards Australia Limited, GPO Box 476, Sydney, NSW 2001 and by Standards New Zealand, Private Bag 2439, Wellington 6140.

ISBN 978 1 76035 302 5

PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HE-003, Medical Electrical Equipment, to supersede AS/NZS 3200.2.18:1997, *Approval and test specification—Medical electrical equipment, Part 2.18: Particular requirements for safety—Endoscopic equipment*.

The objective of this Standard is to establish particular basic safety and essential performance requirements for endoscopic equipment. The requirements of this Standard supplement the general requirements specified in AS/NZS IEC 60601.1.

This Standard is intended to be read in conjunction with AS/NZS IEC 60601.1:2015, which is an identical adoption of IEC 60601-1, Ed.3.1 (2012) and is referred to in the source text as ‘the general standard’.

This Standard is identical with, and has been reproduced from IEC 60601-2-18, Ed.3.0 (2009), *Medical electrical equipment, Part 2-18: Particular requirements for basic safety and essential performance of endoscopic equipment*

As this Standard is reproduced from an International Standard, the following applies:

- (a) In the source text ‘this International Standard’ should read ‘this Australian/New Zealand Standard’.
- (b) A full point substitutes for a comma when referring to a decimal marker.

References to International Standards should be replaced by references to Australian or Australian/New Zealand Standards, as follows:

Reference to International Standard		Australian/New Zealand Standard	
IEC		AS/NZS IEC	
60601	Medical electrical equipment	60601	Medical electrical equipment
60601-2-2	Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories	60601.2.2	Part 2.2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

Only normative references that have been adopted as Australian or Australian/New Zealand Standard have been listed.

The term ‘informative’ has been used in this Standard to define the application of the annex to which it applies. An ‘informative’ annex is only for information and guidance.

CONTENTS

201.1	Scope, object and related standards	8
201.2	Normative references	9
201.3	Terms and definitions	10
201.4	General requirements	12
201.5	General requirements for testing of ME EQUIPMENT	14
201.6	Classification of ME EQUIPMENT and ME SYSTEMS	14
201.7	ME EQUIPMENT identification, marking and documents	14
201.8	Protection against electrical HAZARDS from ME EQUIPMENT	18
201.9	Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS	19
201.10	Protection against unwanted and excessive radiation HAZARDS	20
201.11	Protection against excessive temperatures and other HAZARDS	21
201.12	Accuracy of controls and instruments and protection against hazardous outputs	24
201.13	HAZARDOUS SITUATIONS and fault conditions	25
201.14	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	25
201.15	Construction of ME EQUIPMENT	25
201.16	ME SYSTEMS	26
201.17	Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	26
202	Electromagnetic compatibility – Requirements and tests	26
Annexes		27
Annex C (informative) Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS		27
Annex D (informative) Symbols on marking		29
Annex J (informative) Survey of insulation paths		31
Annex AA (informative) Particular guidance and rationale		33
Annex BB (informative) Clauses of this standard addressing essential principles of safety and performance of medical devices (GHTF/SG1/N41R9:2005)		43
Index of defined terms used in this particular standard		45
Figure 201.101 – Identification of LIGHT EMISSION PART		12
Figure 201.102 – Measurement of CAPACITIVELY-COUPLED HF CURRENT from conductive parts of an ENDOSCOPE		24
Figure 201.J.101 – Insulation example 101		31
Figure 201.J.102 – Insulation example 102		32
Figure 201.J.103 – Insulation example 103		32
Figure AA.101 – Illustration of typical CONFIGURATION FOR ENDOSCOPIC APPLICATION		34
Table 201.101 – List of ESSENTIAL PERFORMANCE requirements		13

	<i>Page</i>
Table 201.C.101 – Marking on the outside of ENDOSCOPIC EQUIPMENT or its parts	27
Table 201.C.102 – Marking on the inside of ENDOSCOPIC EQUIPMENT or its parts	27
Table 201.C.104 – ACCOMPANYING DOCUMENTS, general	28
Table 201.C.105 – ACCOMPANYING DOCUMENTS, instructions for use	28
Table 201.D.101 – Symbols for marking ENDOSCOPIC EQUIPMENT or its parts	29
Table BB.1 – Correspondence between this standard and GHTF/SG1/N41R9:2005	43

IEC FOREWORD

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.

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.

NOTES

AUSTRALIAN/NEW ZEALAND STANDARD

Medical electrical equipment**Part 2.18:****Particular requirements for basic safety and essential performance of endoscopic equipment****201.1 Scope, object and related standards**

Clause 1 of the general standard¹⁾ 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.

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 current, 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.

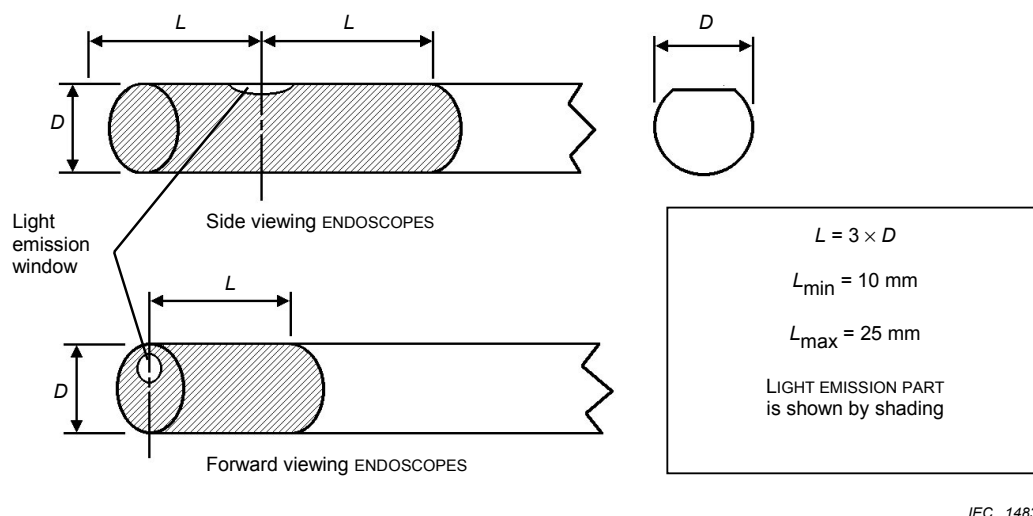


Figure 201.101 – Identification of LIGHT EMISSION PART

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

ULTRASONIC 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: