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Please notify the secretary if you are aware of any keywords that might assist in classifying or identifying the standard or if the content of this standard

- i) has any issues related to 3rd party IPR, patent or copyright
- ii) affects other national standard(s)
- iii) requires additional national guidance or information

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This draft is issued to allow comments from interested parties; all comments will be given consideration prior to publication. No acknowledgement will normally be sent. **See overleaf for information on the submission of comments.**

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Full document details: 21/30433033 DC

Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

UK Vote

Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

Submission of Comments

- **Annotated drafts are not acceptable and will be rejected.**
- All comments should be submitted online at <https://standardsdevelopment.bsigroup.com/>. You will need to register in order to comment.

Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/Figure/ Table/Note	Type of comment	Commend (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	



62D/1924/CD

COMMITTEE DRAFT (CD)

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2021-11-26

CLOSING DATE FOR COMMENTS:

2022-02-18

SUPERSEDES DOCUMENTS:

62D/1809/RR

IEC SC 62D : ELECTROMEDICAL EQUIPMENT	
SECRETARIAT: United States of America	SECRETARY: Ms Ladan Bulookbashi
OF INTEREST TO THE FOLLOWING COMMITTEES:	PROPOSED HORIZONTAL STANDARD: ☐ Other TC/SCs are requested to indicate their interest, if any, in this CD to the secretary.
FUNCTIONS CONCERNED: ☐ EMC ☐ ENVIRONMENT ☐ QUALITY ASSURANCE ☒ SAFETY	

This document is still under study and subject to change. It should not be used for reference purposes.

Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

TITLE:

Medical electrical equipment - Part 2-71: Particular requirements for the basic safety and essential performance of functional near-infrared spectroscopy (NIRS) equipment

NOTE FROM TC/SC OFFICERS:

IEC 80601-2-71 is revised to align to the Amendment projects of the IEC 60601-1 series. Other updates to the standard are proposed at this time. Please see IEC 62D/1808/INF and 62D/1828/AC for more information. National Committees are invited to submit comments at this stage.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-71: Particular requirements for the basic safety and essential performance of functional near-infrared spectroscopy (NIRS) 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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- 9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

International standard IEC 80601-2-71 has been prepared by a Joint Working Group of IEC subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice and ISO subcommittee SC3: Lung ventilators and related equipment, of ISO technical committee 121: Anaesthetic and respiratory equipment.

This second edition cancels and replaces the first edition (IEC 80601-2-71:2015), which has been technically revised. The main changes compared to the previous edition are as follows:

- alignment with IEC 60601-1:2005+AMD1:2012+AMD2:2020, IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, IEC 60601-1-2:2014+AMD1:2020 and IEC 60601-1-6:2010+AMD1:2013+AMD2:2020.
- added requirements for ESSENTIAL PERFORMANCE;
- added requirements for PRIMARY OPERATING FUNCTIONS;
- added requirements for protection against excessive temperatures;
- added requirements for the display legibility for OPERATORS wearing personal protective equipment;
- harmonization with ISO 20417, where appropriate.

128 This publication is published as a double logo standard.

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

FDIS	Report on voting
62D/1238/FDIS	62D/1261/RVD

130 Full information on the voting for the approval of this standard can be found in the report on
131 voting indicated in the above table. In ISO, the standard has been approved by 14 P-members
132 out of 14 having cast a vote.

133 This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

134 A list of all parts of the IEC 60601 series, published under the general title *Medical electrical*
135 *equipment*, can be found on the IEC website.

136 The committee has decided that the contents of this publication will remain unchanged until the
137 stability date indicated on the IEC web site under "<http://webstore.iec.ch>" in the data related to
138 the specific publication. At this date, the publication will be

- 139 • reconfirmed,
- 140 • withdrawn,
- 141 • replaced by a revised edition, or
- 142 • amended.

143 NOTE The attention of National Committees and Member Bodies is drawn to the fact that equipment manufacturers
144 and testing organizations may need a transitional period following publication of a new, amended or revised IEC or
145 ISO publication in which to make products in accordance with the new requirements and to equip themselves for
146 conducting new or revised tests. It is the recommendation of the committees that the content of this publication be
147 adopted for implementation nationally not earlier than 3 years from the date of publication.

148

INTRODUCTION

The minimum safety requirements specified in this particular standard are considered to provide for a practical degree of safety in the operation of FUNCTIONAL NIRS EQUIPMENT.

The requirements are followed by specifications for the relevant tests.

A "Particular guidance and rationale" text giving some explanatory notes, where appropriate, about the more important requirements is included in Annex AA. It is considered that knowledge of the reasons for these requirements will not only facilitate the proper application of the standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However, this annex does not form part of the requirements of this standard.

In this standard, the following print types are used:

- Requirements and definitions: roman type.
- *Test specifications: italic type.*
- Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

- "clause" means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
- "subclause" means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

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

In this standard, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- "shall" indicates a requirement;
- "should" indicates a recommendation;
- "may" indicates a permission;
- "can" is used to describe a possibility or capability; and
- "must" indicates an external constraint.

Requirements in this document have been decomposed so that each requirement is uniquely delineated. This is done to support automated requirements tracking.

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.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-71: Particular requirements for the basic safety and essential performance of functional near-infrared spectroscopy (NIRS) 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 FUNCTIONAL NIRS EQUIPMENT, as defined in 201.3.205, intended to be used by itself, or as a part of an ME SYSTEM hereinafter referred to as ME EQUIPMENT.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this document are not covered by specific requirements in this standard except in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 7.2.13 and 8.4.1.

NOTE Additional information can be found in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 4.2.

This document is not applicable to

- equipment for the measurement of oxygen saturation of the haemoglobin in the micro vessels (capillaries, arterioles and venules), i.e. tissue oximeters.
- frequency-domain and time-domain equipment for functional near-infrared spectroscopy.
- equipment for the measurement of changes in the concentration of chromophores other than oxy- and deoxy-haemoglobin.
- equipment for the measurement of changes in the concentration of oxy- and deoxy-haemoglobin in tissues other than the brain.

This document does not specify the requirements for:

- cerebral tissue oximeter equipment, which are given in ISO 80601-2-85; and
- pulse oximeter equipment, which are given in ISO 80601-2-61.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for FUNCTIONAL NIRS EQUIPMENT as defined in 201.3.205.

NOTE 1 This document has been prepared to address the relevant ESSENTIAL PRINCIPLES and labelling^[6] guidances of the International Medical Devices Regulators Forum (IMDRF) as indicated in Annex DD.

NOTE 2 This document has been prepared to address the relevant ESSENTIAL PRINCIPLES OF SAFETY AND PERFORMANCE of ISO 16142-1:2016 as indicated in Annex EE.

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

227 NOTE 3 This document has been prepared to address the relevant general safety and performance requirements of
228 European regulation (EU) 2017/745 as indicated in Annex FF.

229 **201.1.3 Collateral standards**

230 *Addition:*

231 This particular standard refers to those applicable collateral standards that are listed in Clause
232 2 of the general standard and Clause 201.2 of this particular standard.

233 IEC 60601-1-3 and IEC 60601-1-10^[1] do not apply. All other published collateral standards in
234 the IEC 60601-1 series apply as published.

235 **201.1.4 Particular standards**

236 *Replacement:*

237 In the IEC 60601 series, particular standards may modify, replace or delete requirements
238 contained in the general standard, including the collateral standards, as appropriate for the
239 particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY OR ESSENTIAL
240 PERFORMANCE requirements.

241 A requirement of a particular standard takes priority over the general standard and applicable
242 collateral standards.

243 For brevity, IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and
244 IEC 60601-1:2005/AMD2:2020 is referred to in this particular standard as the general standard.
245 Collateral standards are referred to by their document number.

246 The numbering of clauses and subclauses of this particular standard corresponds to that of the
247 general standard with the prefix "201" (e.g. 201.1 in this standard addresses the content of
248 Clause 1 of the general standard) or applicable collateral standard with the prefix "20x"
249 where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this
250 particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard,
251 203.4 in this particular standard addresses the content of Clause 6 of the IEC 60601-1-3
252 collateral standard, etc.). The changes to the text of the general standard are specified by the
253 use of the following words:

254 "Replacement" means that the clause or subclause of the general standard or applicable
255 collateral standard is replaced completely by the text of this particular standard.

256 "Addition" means that the text of this particular standard is additional to the requirements of the
257 general standard or applicable collateral standard.

258 "Amendment" means that the clause or subclause of the general standard or applicable
259 collateral standard is amended as indicated by the text of this particular standard.

260 Subclauses, figures or tables which are additional to those of the general standard are
261 numbered starting from 201.101. However due to the fact that definitions in the general standard
262 are numbered 3.1 through 3.154, additional definitions in this standard are numbered beginning
263 from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

264 Subclauses, figures or tables which are additional to those of a collateral standard are
265 numbered starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for
266 IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

267 The term "this standard" is used to make reference to the general standard, any applicable
268 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

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

Addition:

IEC 60601-1, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*
Amendment 1:2012
Amendment 2:2020

IEC 60825-2:2021, *Safety of laser products - Part 2: Safety of optical fibre communication systems (OFCSS)*

IEC 62471:2006, *Photobiological safety of lamps and lamp systems*

IEC 62570:2014, *Standard practice for marking medical devices and other items for safety in the magnetic resonance environment*

ISO 16142-1:2016, *Medical devices — Recognized essential principles of safety and performance of medical devices — Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards*

ISO 17664-2:2021, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in the general standard, ISO 16142-1:2016, ISO 17664-2:2021, ISO 20417:2021 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at <https://www.electropedia.org/>
- ISO Online browsing platform: available at <https://www.iso.org/obp>

201.3.201

AVERAGE OPTICAL POWER

temporal average power of continuous light or repeated light pulses from each discrete wavelength, from the EMITTER OPTODE connected to the FUNCTIONAL NIRS MONITOR

201.3.202**DETECTOR OPTODE**

part of the FUNCTIONAL NIRS PROBE which detects light from the living tissue that forms part of the APPLIED PART

201.3.203**EMITTER OPTODE**

part of the FUNCTIONAL NIRS PROBE which emits light to the living tissue that forms part of the APPLIED PART

Note 1 to entry: An EMITTER OPTODE can contain two or more light sources (e.g. laser diodes or light-emitting diodes) operating at different NOMINAL wavelengths.

201.3.204**FWHM****FULL WIDTH AT HALF MAXIMUM OF SPECTRAL POWER DISTRIBUTION**

difference of the wavelength between the two points whose corresponding power values are equal and 3 dB lower than the values at each PEAK WAVELENGTH

Note 1 to entry: FWHM is the measurement of spectral power distribution illuminated from the EMITTER OPTODE connected to the FUNCTIONAL NIRS MONITOR. Figure 201.101 provides a visual representation. If there are more than two wavelengths where power value is 3 dB lower than the values at each PEAK WAVELENGTH, FWHM shall be calculated from the difference between minimum and maximum wavelengths.

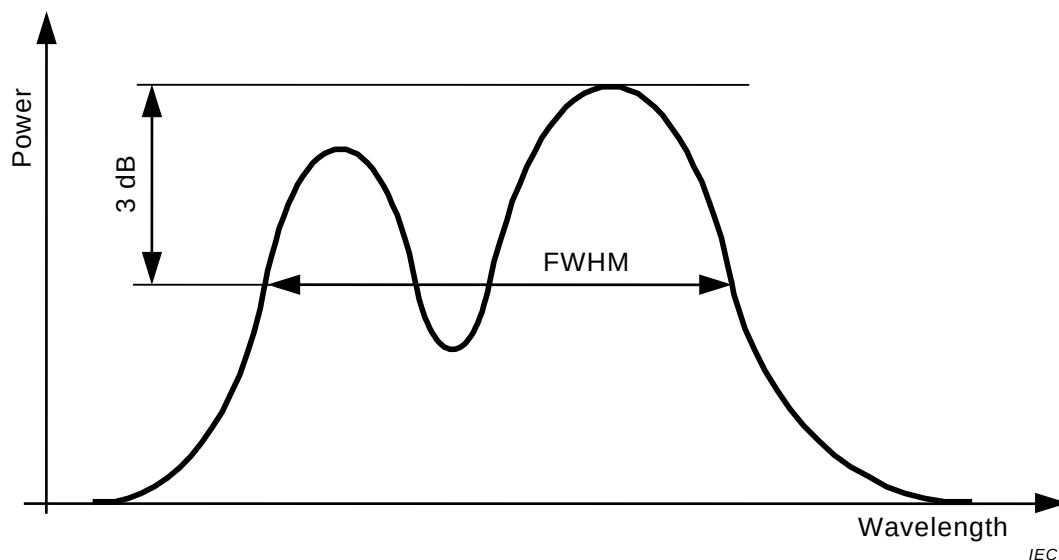


Figure 201.101 – FULL WIDTH AT HALF MAXIMUM of spectral power distribution

201.3.205**FUNCTIONAL NIRS EQUIPMENT****FUNCTIONAL NEAR-INFRARED SPECTROSCOPY EQUIPMENT**

ME EQUIPMENT that measures PATHLENGTH-DEPENDENT HAEMOGLOBIN CHANGE in living tissue by illuminating tissue with continuous light and detecting changes in the infrared and visible light intensity diffusively reflected from the tissue

201.3.206**FUNCTIONAL NIRS MONITOR****FUNCTIONAL NEAR-INFRARED SPECTROSCOPY MONITOR MONITOR**

part of the FUNCTIONAL NIRS EQUIPMENT that encompasses the electronics, display and operator-equipment interface excluding the EMITTER OPTODES and DETECTOR OPTODES

Note 1 to entry: The FUNCTIONAL NIRS MONITOR typically encompasses the electronics, display and OPERATOR-EQUIPMENT INTERFACE. It can consist of a separate control unit, a computer and a display. Electronics or a control unit integrated in the APPLIED PART are not part of the FUNCTIONAL NIRS MONITOR.

201.3.207**FUNCTIONAL NIRS PROBE****FUNCTIONAL NEAR-INFRARED SPECTROSCOPY PROBE PROBE**

part of the FUNCTIONAL NIRS EQUIPMENT that includes the APPLIED PART

Note 1 to entry: This definition of PROBE is consistent with the definition of PROBE for cerebral tissue oximeters as given in ISO 80601-2-85.

Note 2 to entry: The PROBE contains single or multiple EMITTER OPTODES and DETECTOR OPTODES. A reflectance PROBE design is the typical configuration.

201.3.208**FUNCTIONAL NIRS PHANTOM**

apparatus that simulates a PATHLENGTH-DEPENDENT HAEMOGLOBIN CHANGE by giving the ME EQUIPMENT a specified known change in OPTICAL LOSS to evaluate the difference between the measured value of the pseudo PATHLENGTH-DEPENDENT HAEMOGLOBIN CHANGE obtained from the measurement on the phantom and the reference value calculated from the attenuation change

Note 1 to entry: The FUNCTIONAL NIRS PHANTOM plays a role in determining the performance of FUNCTIONAL NIRS EQUIPMENT, especially PATHLENGTH-DEPENDENT HAEMOGLOBIN CHANGE measurement. A description of the function and specifications regarding the manufacturing of the FUNCTIONAL NIRS PHANTOM is found in Annex BB.

Note 2 to entry: A FUNCTIONAL NIRS PHANTOM is developed during design and is used at the time of inspection in manufacturing or after being placed into service.

201.3.209**MEASUREMENT CHANNEL****CHANNEL**

combination of an EMITTER OPTODE and a DETECTOR OPTODE that provide an output

201.3.210**OPTICAL LOSS**

ratio of the total optical power exiting the FUNCTIONAL NIRS PHANTOM or attenuator through a specified aperture, to the optical power emitted by the EMITTER OPTODE connected to the FUNCTIONAL NIRS MONITOR

Note 1 to entry: The OPTICAL LOSS is denoted in dB. X dB OPTICAL LOSS is equivalent to $10^{-X/10}$.

Note 2 to entry: The optical power exiting the EMITTER OPTODE and the FUNCTIONAL NIRS PHANTOM can be measured with an optical power meter.

Note 3 to entry: For details of the measurement of the OPTICAL LOSS refer to Annex BB.3.2

201.3.211**PATHLENGTH-DEPENDENT DEOXYHAEMOGLOBIN CHANGE**

value calculated from the changes in detected light intensities, equal to the product of the apparent change in the concentration of deoxyhaemoglobin and the mean optical pathlength

201.3.212**PATHLENGTH-DEPENDENT HAEMOGLOBIN CHANGE** **$\Delta c \cdot L$**

collective term which signifies the product of apparent haemoglobin concentration change and the mean optical pathlength inclusive of two chromophores (oxyhaemoglobin and deoxyhaemoglobin), as well as total haemoglobin

Note 1 to entry: The calculation of the PATHLENGTH-DEPENDENT HAEMOGLOBIN CHANGE from measured changes in attenuation based on the multivariate modified Beer-Lambert law is described in Annex BB.2.

Note 2 to entry: The concentration changes are termed “apparent” values since they are obtained from a homogeneous model while the structure of the human head as well as the spatial distribution of haemoglobin concentration changes are substantially heterogeneous.

Note 3 to entry: Total haemoglobin concentration is the sum of oxy- and deoxyhaemoglobin concentrations.

201.3.213**PATHLENGTH-DEPENDENT OXYHAEMOGLOBIN CHANGE**

value calculated from the changes in detected light intensities, equal to the product of the apparent change in the concentration of oxyhaemoglobin and the mean optical pathlength

Note 1 to entry: Oxyhaemoglobin is the haemoglobin bonded with oxygen molecules.

201.3.214**PATHLENGTH-DEPENDENT TOTAL HAEMOGLOBIN CHANGE**

value calculated as a sum of PATHLENGTH-DEPENDENT OXYHAEMOGLOBIN CHANGE and PATHLENGTH-DEPENDENT DEOXYHAEMOGLOBIN CHANGE

201.3.215**PEAK WAVELENGTH**

wavelength where the power is the largest in the spectral power distribution for each of the distinct NOMINAL wavelengths in the light radiated from the EMITTER OPTODE

201.3.216**PRIMARY OPERATING FUNCTION**

function that involves user interaction that is related to the safety of the medical device

Note 1 to entry: Often a PRIMARY OPERATING FUNCTION is interacted with by a series of tasks that can be broken down into a series of user interactions.

Note 2 to entry: The concept of safety includes loss or degradation of performance resulting in an unacceptable RISK to the PATIENT, including use error that prevents the user from effectively using the medical device to achieve its intended medical purpose. In IEC 60601-1, this is referred to as ESSENTIAL PERFORMANCE.

[SOURCE: IEC 62366-1:2015+AMD1:2020, 3.11]

201.3.217**RESPONSE TIME**

time required for the step response of the ME EQUIPMENT to move from its specified percentage of the final steady-state value to the other specified percentage

Note 1 to entry: RESPONSE TIME is conventionally denoted by the rise time or fall time that represents the interval between the times corresponding to 10 % and 90 % of the step response amplitude during the transition. See also 201.12.1.101.7 and Figure 201.106.

201.3.218**SIGNAL CROSS-TALK**

signal contamination or interference from other light sources of the same or other EMITTER OPTODES to the relevant CHANNEL in multiple CHANNEL equipment

201.4 General requirements

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

Addition:

201.4.3.101 * Additional requirements for ESSENTIAL PERFORMANCE

Table 201.101 indicates the ESSENTIAL PERFORMANCE of FUNCTIONAL NIRS EQUIPMENT, unless the MANUFACTURER identifies through their RISK MANAGEMENT PROCESS that the FUNCTIONAL NIRS EQUIPMENT has no ESSENTIAL PERFORMANCE.

Table 201.101 — Distributed ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
Adequate reproduction of the temporal profiles of the PATHLENGTH-DEPENDENT HAEMOGLOBIN CHANGES	^a
or generation of an ALARM CONDITION	
- low signal of detected light intensity	201.12.1.101.11
- high signal of detected light intensity	201.12.1.101.12
^a Subclause 202.8.1.101 indicates methods of evaluating the adequate reproduction of the temporal profiles of the PATHLENGTH-DEPENDENT HAEMOGLOBIN CHANGES as acceptance criteria following specific tests required by this document.	

Box Note 1

Attention of National Committees and Member Bodies is drawn to the following:

While the first edition of this standard claimed that FUNCTIONAL NIRS EQUIPMENT was considered not to have ESSENTIAL PERFORMANCE, the committees are here proposing the case of FUNCTIONAL NIRS EQUIPMENT that has ESSENTIAL PERFORMANCE to be included as in the new subclause 201.4.3.101. At the same time, the committees recognized that there may be clinical applications where FUNCTIONAL NIRS EQUIPMENT does not have ESSENTIAL PERFORMANCE where loss or degradation can cause unacceptable RISK to the PATIENT. Therefore, the proposed text distinguishes between FUNCTIONAL NIRS EQUIPMENT with and without ESSENTIAL PERFORMANCE.

During the further work on this document, the committees are interested in achieving broader consensus, notably including input from a wider range of MANUFACTURERS of FUNCTIONAL NIRS EQUIPMENT.

The proposed ESSENTIAL PERFORMANCE requirement (together with the new subclauses 201.12.1.101.11 and 201.12.1.101.12) is based on the consideration of the clinical functions of FUNCTIONAL NIRS EQUIPMENT that depend on its INTENDED USE, in particular on the medical purpose. The committees believe that the temporal profiles (temporal evolution on a time scale of seconds) of the PATHLENGTH-DEPENDENT HAEMOGLOBIN CHANGES represent a clinical function that is relevant in various clinical application scenarios. Diagnostic information can be derived from changes in the shape of the temporal profile and/or a relative change in the magnitude of the PATHLENGTH-DEPENDENT HAEMOGLOBIN CHANGES (oxyhaemoglobin, deoxyhaemoglobin) when comparing the recorded temporal profiles at different probe positions on the human head.

Appropriate levels of the detected light intensities are considered major technical prerequisites to achieve this clinical function. They must exceed a certain limit in order to reliably record the amplitude and the time course of the (usually small) PATHLENGTH-DEPENDENT HAEMOGLOBIN CHANGES. In addition, detector saturation that causes nonlinearity of the signals needs to be avoided. Indications of these two conditions are commonly used during the setup PROCEDURE, i.e. the assessment of signal quality during application of the probe to the PATIENT'S head, before starting a measurement, and are often also used by the MANUFACTURERS for an indication

of CHANNELS with inadequate signals during the course of the measurement. Too low or too high signal of detected light intensity were identified as criteria for signal inadequacy.

Note: Safety aspects related to optical power of the light sources that were mentioned in 201.4.3 in the first edition of this document are now covered in the new subclause 201.10.4, consistent with ISO 80601-2-85 for cerebral tissue oximeter equipment which is technically similar to FUNCTIONAL NIRS EQUIPMENT.

Please answer each of the following questions in your comments to this CD:

Q1: Is the proposed declaration for ESSENTIAL PERFORMANCE appropriate or are there proposals for different or additional requirements?

Q2: Are the conditions for low signal and high signal (as indicated in the new subclauses 201.12.1.101.11 and 201.12.1.101.12) appropriate?

Q3: Is the signal-to-noise ratio of the detected light intensity (as indicated in the new subclause 201.12.1.101.8) an appropriate method of evaluating the adequate reproduction of the temporal profiles of the PATHLENGTH-DEPENDENT HAEMOGLOBIN CHANGES as acceptance criteria following specific tests?

201.5 General requirements for testing ME EQUIPMENT

Clause 5 of the general standard applies.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies.

201.7 ME EQUIPMENT identification, MARKING and documents

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

Additional subclauses:

201.7.1.101 INFORMATION TO BE SUPPLIED BY THE MANUFACTURER

a) The information supplied by the manufacturer of FUNCTIONAL NIRS EQUIPMENT and its accessories shall conform with ISO 20417:2021.

b) In applying ISO 20417:2021, the terms in this document and those in IEC 60601-1:2005 + IEC 60601-1:2005/AMD1:2012 + IEC 60601-1:2005/AMD2:2020 shall be used as follows.

1) The term "ACCOMPANYING INFORMATION" shall assume the same meaning as ACCOMPANYING DOCUMENTS.

2) The term "MEDICAL DEVICE" shall assume the same meaning as ME EQUIPMENT.

3) The term "USER" shall assume the same meaning as OPERATOR.

4) The term "PATIENT" shall include animals.

Check conformance by application of ISO 20417:2021.

201.7.2.4.101 Additional requirements for ACCESSORIES

a) ACCESSORIES supplied separately shall:

1) fulfil the requirements of 201.101.1; and

2) be MARKED with an indication of any limitations or adverse effects of the ACCESSORY on the BASIC SAFETY or ESSENTIAL PERFORMANCE of the FUNCTIONAL NIRS EQUIPMENT, if applicable. See also 201.7.2.101.

b) If MARKING the ACCESSORY is not practicable, this information may be placed in the INSTRUCTIONS FOR USE.

Check conformity by inspection, inspection of the RISK MANAGEMENT FILE for any limitations or adverse effects of the ACCESSORY, and where necessary, inspection of the INSTRUCTIONS FOR USE.

201.7.2.101 Additional requirements for MARKING on the outside of ME EQUIPMENT or ME EQUIPMENT parts

a) The MARKING on the ME EQUIPMENT shall be CLEARLY LEGIBLE and shall include its classification as specified in Clause 7 of IEC 60825-1:2014.

b) For FUNCTIONAL NIRS EQUIPMENT intended to be used in the magnetic resonance (MR) environment, OPERATOR-accessible FUNCTIONAL NIRS EQUIPMENT, parts or ACCESSORIES shall have CLEARLY LEGIBLE MARKINGS in accordance with IEC 62570:2014 of the following:

1) SYMBOL 7.3.1-1 (Table 201.D.2.101, SYMBOL 14) or SYMBOL 7.3.1-2 (Table 201.D.2.101, SYMBOL 15) of IEC 62570:2014 for an 'MR Safe' FUNCTIONAL NIRS EQUIPMENT, or

2) SYMBOL 7.3.2 of IEC 62570:2014 (Table 201.D.2.101, SYMBOL 16) for an 'MR Conditional' FUNCTIONAL NIRS EQUIPMENT.

Check conformity by inspection.

201.7.9.2.1 General

Amendment (add as fifth bullet following the first paragraph):

— the intended position of the OPERATOR;

Additional subclause:

201.7.9.2.14.101 Additional requirements for ACCESSORIES, supplementary equipment, used material

The INSTRUCTIONS FOR USE of the FUNCTIONAL NIRS EQUIPMENT shall identify at least one set of ACCESSORIES necessary for the FUNCTIONAL NIRS EQUIPMENT'S INTENDED USE.

Check conformity by inspection.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of the general standard applies, except as follows:

Additional subclause:

201.8.3.101 Additional requirements for classification of APPLIED PARTS

APPLIED PARTS of FUNCTIONAL NIRS EQUIPMENT shall be TYPE BF or TYPE CF APPLIED PARTS.

Check conformance by inspection.

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 of the general standard applies.

201.10 Protection against unwanted and excessive radiation HAZARDS

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

201.10.4 Lasers

Replacement:

aa) Depending on the light sources used in the EMITTER OPTODE, the FUNCTIONAL NIRS EQUIPMENT shall comply with the relevant requirements of:

- 1) IEC 60825-1:2014; or
- 2) IEC 62471:2006.

NOTE IEC 60601-2-57^[2] does not apply because there are no intended photobiological effects.

Check conformance by application of the requirements of IEC 60825-1:2014 or IEC 62471:2006, as applicable.

201.11 Protection against excessive temperatures and other HAZARDS

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

201.11.1.2.2 APPLIED PARTS not intended to supply heat to a PATIENT

Amendment (add at the end of 11.1.2.2):

aa) The FUNCTIONAL NIRS EQUIPMENT PROBE-tissue interface shall be evaluated for each FUNCTIONAL NIRS EQUIPMENT MONITOR and FUNCTIONAL NIRS EQUIPMENT PROBE indicated in the INSTRUCTIONS FOR USE.

- 1) The evaluation of worst case temperature rise shall take into consideration the potential for tissue injury due to the combined effect of conduction from the probe and photothermally induced temperature rise

NOTE Additional information is found in Annex CC.

bb) If the surface temperature of the FUNCTIONAL NIRS EQUIPMENT PROBE at the tissue interface can exceed 41 °C, then:

- 1) the FUNCTIONAL NIRS EQUIPMENT PROBE shall have an OPERATOR-adjustable control for activating any elevated temperature mode that exceeds 41 °C;
 - i) A deliberate sequence of OPERATOR actions shall be required to activate this mode.
 - ii) The INSTRUCTIONS FOR USE shall describe this sequence of OPERATOR actions.
- 2) the FUNCTIONAL NIRS EQUIPMENT shall provide a means to limit the duration of an elevated temperature mode in excess of 41 °C;
 - i) The duration of the elevated temperature mode shall not exceed 4 h at 43 °C or 8 h at 42 °C.
- 3) the INSTRUCTIONS FOR USE shall include a statement to the effect that the use of temperature settings greater than 41 °C requires special attention in PATIENTS with susceptible skin, such as neonates, geriatric PATIENTS or burn victims;
- 4) the FUNCTIONAL NIRS EQUIPMENT shall indicate when it is in the elevated temperature mode; and