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Medical electrical equipment —

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

Appareils électromédicaux —

Partie 2-71: Exigences particulières pour la sécurité de base et les performances essentielles des appareils d'imagerie spectroscopique proche infrarouge (NIRS)

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This draft is submitted to a parallel vote in ISO and in IEC.

Reference number
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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

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IEC 80601-2-71 has been prepared by a Joint Working Group of IEC subcommittee 62D: Particular medical equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems, and ISO subcommittee SC3: Respiratory devices and related equipment used for patient care, of ISO technical committee 121: Anaesthetic and respiratory equipment. It is an International Standard.

This second edition cancels and replaces the first edition published in 2015. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

a) alignment with IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020, IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012, IEC 60601-1-8:2006/AMD2:2020, IEC 60601-1-2:2014, IEC 60601-1-2:2014/AMD1:2020, IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013 and IEC 60601-1-6:2010/AMD2:2020;

b) added requirements for ESSENTIAL PERFORMANCE;

c) added requirements for PRIMARY OPERATING FUNCTIONS;

d) added requirements for protection against excessive temperatures;

e) added requirements for the display legibility for OPERATORS wearing personal protective equipment;

f) harmonization with ISO 20417, where appropriate.

This publication is published as a double logo standard.

The text of this International Standard is based on the following documents of IEC:

Draft	Report on voting
62D/XXX/FDIS	62D/XXX/RVD

Full information on the voting for its approval can be found in the report on voting indicated in the above table. In ISO, the document was approved by XXX P members out of YYY having cast a vote.

The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications.

In this document, 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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 AND IEC 60601-1:2005/AMD2:2020, IN THIS DOCUMENT OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this document, 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 document are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

In this document, 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 document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;

– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;

– "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 and IEC 80601 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 document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn, or
- revised.

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

INTRODUCTION

The minimum safety requirements specified in this document 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 document.

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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.1.1 Scope

Replacement:

This part of IEC 80601 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 document 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 [1][1]; and
– pulse oximeter equipment, which are given in ISO 80601-2-61 [2].

201.1.2 Object

Replacement:

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

NOTE This document has been prepared to address the relevant essential principles [3] and labelling principles [4] of the International Medical Devices Regulators Forum (IMDRF) as indicated in Annex DD.

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1 Numbers in square brackets refer to the Bibliography.

201.1.3 Collateral standards

Addition:

This document refers to those applicable collateral standards that are listed in Clause 2 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and Clause 201.2 of this document.

IEC 60601-1-3 and IEC 60601-1-10 [5] do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Addition:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, including the collateral standards, as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY or ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and applicable collateral standards.

The numbering of clauses and subclauses of this particular standard corresponds to that of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020) 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 document addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.6 in this document addresses the content of Clause 6 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are specified by the use of the following words:

"*Replacement*" means that the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard is replaced completely by the text of this document.

"*Addition*" means that the text of this document additional to the requirements of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard.

"*Amendment*" means that the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard is amended as indicated by the text of this document.

Subclauses, figures or tables which are additional to those of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered starting from 201.101. However due to the fact that definitions in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered 3.1 through 3.154, additional definitions in this document 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.

Where there is no corresponding clause or subclause in this document, the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this document.

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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

Addition:

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

IEC 60825-1:2014, *Safety of laser products – Part 1: Equipment classification and requirements*

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 17664-1:2021, *Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices – Part 1: Critical and semi-critical medical devices*

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*

ISO 20417:2021, *Medical devices – Information to be supplied by the manufacturer*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020, ISO 17664-2:2021, ISO 20417:2021 and the following apply.

ISO and IEC maintain terminology 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

2201.3.203
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 a measure of the width of the spectral power distribution emitted by 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.

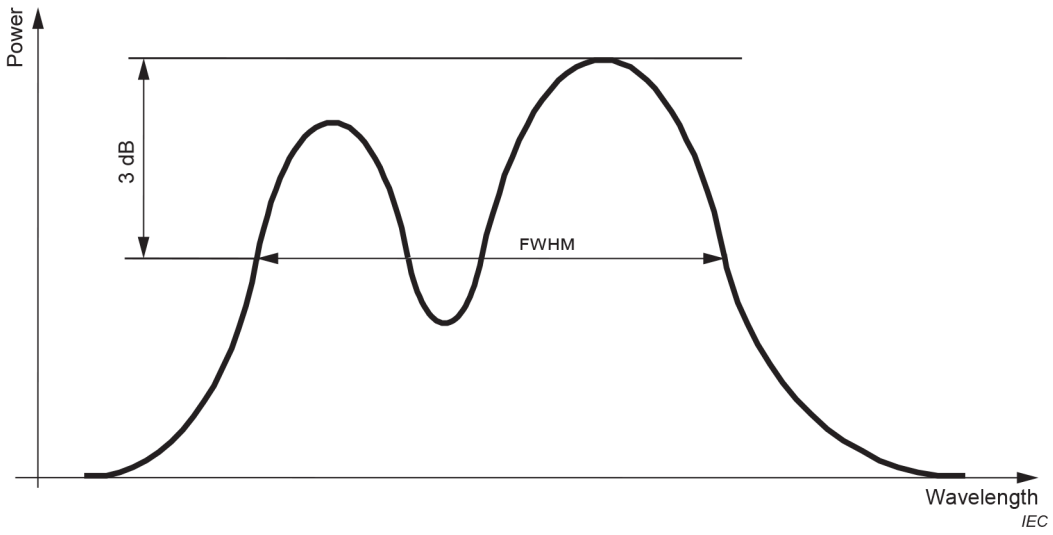


Figure 201.101 – FULL WIDTH AT HALF MAXIMUM OF SPECTRAL POWER DISTRIBUTION

201.3.205
FUNCTIONAL NIRS EQUIPMENT
FUNCTIONAL NEAR-INFRARED SPECTROSCOPY EQUIPMENT
ME EQUIPMENT that estimates PATHLENGTH-DEPENDENT HAEMOGLOBIN CHANGES 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 attenuation 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.

Note 3 to entry: The change in attenuation corresponds to a change in OPTICAL LOSS of the FUNCTIONAL NIRS PHANTOM of the same magnitude.

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 and placed on the entrance side of the FUNCTIONAL NIRS PHANTOM or attenuator

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 BB.3.3.

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
Δc·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 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: The 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
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

201.3.215
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, 3.11]

201.3.216
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: The 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.

201.3.217
SIGNAL CROSS-TALK
signal contamination or interference from other light sources of the same or other EMITTER OPTODES to the relevant CHANNEL