IEC 80601-2-71

Edition 1.0 2015-06

INTERNATIONAL STANDARD

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

IEC 80601-2-71:2015-06(en)

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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

ICS 11.040.55

ISBN 978-2-8322-2717-6

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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

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 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 publication is published as a double logo standard.

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

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

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

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 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" 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 0.

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 stability 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.

A bilingual version of this publication may be issued at a later date.

NOTE The attention of National Committees and Member Bodies 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 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.

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 standard[1] applies, except as follows:

201.1.1 Scope

Replacement:

This International standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of FUNCTIONAL NIRS EQUIPMENT intended to be used by themselves, or as a part of an ME SYSTEM, for the production of FUNCTIONAL NIRS EQUIPMENT output for adjunctive diagnostic purposes, hereinafter referred to as ME EQUIPMENT.

Not included within the scope of this particular standard are:

a) the part of ME EQUIPMENT, if provided, that measures oxygen saturation of the haemoglobin in the micro vessels (capillaries, arterioles and venules);

b) near-infrared spectroscopy (NIRS) tissue oximeter equipment, which is not intended for obtaining FUNCTIONAL NIRS EQUIPMENT output;

c) pulse oximeter equipment, which is not intended for obtaining FUNCTIONAL NIRS EQUIPMENT output. The requirements for pulse oximeter equipment are found in ISO 80601-2-61.

d) frequency-domain and time-domain equipment for functional near-infrared spectroscopy, which may require different test procedures than defined herein.

e) FUNCTIONAL NEAR-INFRARED SPECTROSCOPY EQUIPMENT which measure changes in the concentration of chromophores other than oxy- and deoxy-haemoglobin, which may require different test procedures than defined herein.

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.

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.

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

IEC 60601-1-3 and IEC 60601-1-10[2] do 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 or 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 60601-1:2005 + IEC 60601-1:2005/AMD1:2012 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 6 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.

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2 IEC 60601-1-10, *Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers.*

201.2 Normative references

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

Replacement:

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

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

Addition:

IEC 60601-1, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

ISO 80601-2-61, *Medical electrical equipment – Part 2-61: Particular requirements for the basic safety and essential performance of pulse oximeter equipment*

ISO/TR 16142:2006, *Medical devices – Guidance on the selection of standards in support of recognized essential principles of safety and performance of medical devices*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1, IEC 60601-1-6, ISO/TR 16142:2006 and IEC 60825-1:2014 and the following apply.

Addition:

201.3.201
AVERAGE OPTICAL POWER
temporal average power of continuous light or repeated light pulses from each discrete wavelength, from the EMITTER PROBE connected to the FUNCTIONAL NIRS MONITOR

201.3.202
DETECTOR PROBE
part of the FUNCTIONAL NIRS EQUIPMENT which detects light from the living tissue that forms part of the APPLIED PART

201.3.203
EMITTER PROBE
part of the FUNCTIONAL NIRS EQUIPMENT which emits light to the living tissue that forms part of the APPLIED PART

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 PROBE 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.

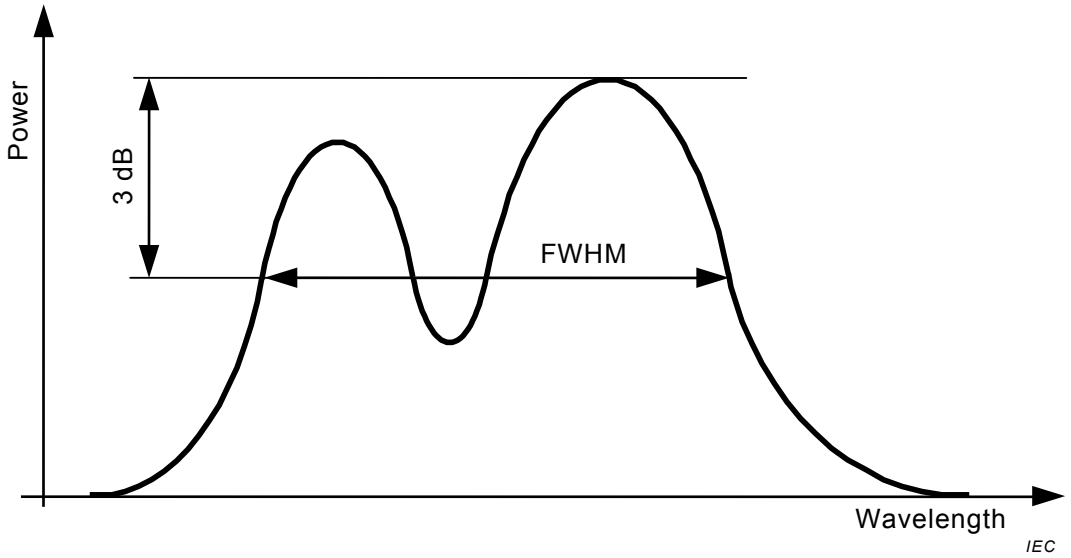

Figure 201.101 – FULL WIDTH AT HALF MAXIMUM of spectral power distribution

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

201.3.207
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 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.

201.3.208
MEASUREMENT CHANNEL
combination of an EMITTER PROBE and a DETECTOR PROBE that provide an output

201.3.209
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 PROBE 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 PROBE 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

201.3.210
PATHLENGTH-DEPENDENT DEOXYHAEMOGLOBIN CHANGE
value calculated from the received signals of the ME EQUIPMENT given by the multivariate modified Beer-Lambert law whose equation is shown in Annex BB.2 and which is equal to the product of the change in the concentration of deoxyhaemoglobin and the mean optical pathlength

201.3.211
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 change

Note 1 to entry: The calculation of the PATHLENGTH-DEPENDENT HAEMOGLOBIN CHANGE from measured changes in attenuation is described in Annex BB.2.

201.3.212
PATHLENGTH-DEPENDENT OXYHAEMOGLOBIN CHANGE

value calculated from the received signal of the ME EQUIPMENT given by the multivariate modified Beer-Lambert law, equal to the apparent value of the product of the change in concentration of oxyhaemoglobin and the mean optical pathlength

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

201.3.213
PATHLENGTH-DEPENDENT TOTAL HAEMOGLOBIN CHANGE
value calculated as a sum of PATHLENGTH-DEPENDENT OXYHAEMOGLOBIN CHANGE and PATHLENGTH-DEPENDENT DEOXYHAEMOGLOBIN CHANGE

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 PROBE

201.3.215
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.

201.3.216
SIGNAL CROSS-TALK
signal contamination or interference from the other MEASUREMENT CHANNEL(s) to the relevant channel in multiple channel equipment