IEC 80601-2-71

Edition 1.0 2015-06

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

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

Appareils électromédicaux –
Partie 2-71: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de spectroscopie dans le proche infrarouge (NIRS) fonctionnelle

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Appareils électromédicaux – Partie 2-71: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de spectroscopie dans le proche infrarouge (NIRS) fonctionnelle

INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

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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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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.

This bilingual version (2018-11) corresponds to the monolingual English version, published in 2015-06.

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

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

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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.

The French version of this standard has not been voted upon.

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 Annex AA.

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

The committee has decided that the contents of this publication will remain unchanged until the 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.

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.

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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.

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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

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*.

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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.*

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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.

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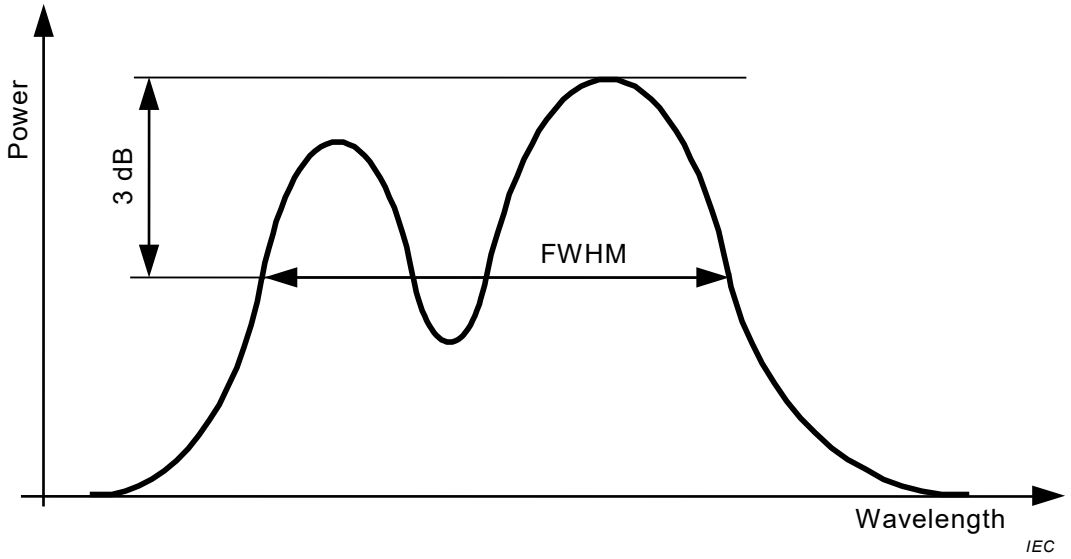


Figure 201.101 – FULL WIDTH AT HALF MAXIMUM of spectral power distribution

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

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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

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201.4 General requirements

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

201.4.3 ESSENTIAL PERFORMANCE

Addition:

For the purposes of this standard, FUNCTIONAL NIRS EQUIPMENT is considered not to have ESSENTIAL PERFORMANCE. Notwithstanding this fact, when this standard refers to ESSENTIAL PERFORMANCE as an acceptance criterion, the AVERAGE OPTICAL POWER shall be evaluated. Subclause 201.12.1.101.2 indicates a method of evaluating AVERAGE OPTICAL POWER as acceptance criterion following specific tests required by this standard.

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:

201.7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts

Additional subclause:

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

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.

201.7.9 ACCOMPANYING DOCUMENTS

Additional subclause:

201.7.9.2.101 Additional requirements for instructions for use

The performances specified in 201.12.1.101 shall be disclosed in the instructions for use.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

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

201.8.3 Classification of APPLIED PARTS

Additional subclause:

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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.

Compliance is checked 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.

201.11 Protection against excessive temperatures and other hazards

Clause 11 of the general standard applies.

201.12 ACCURACY of controls and instruments and protection against hazardous outputs

Clause 12 of the general standard applies, except as follows:

201.12.1 Accuracy of controls and instruments

Additional subclauses:

201.12.1.101 Performance of FUNCTIONAL NIRS EQUIPMENT

201.12.1.101.1 General

In the following performance test items, if there are multiple EMITTER PROBES and DETECTOR PROBES, combinations of EMITTER PROBES and DETECTOR PROBES should be selected according to RISK MANAGEMENT defined by each MANUFACTURER. The selected combinations shall be recorded.

The FUNCTIONAL NIRS PHANTOM and the attenuator consisting of scattering and absorbing materials with the required OPTICAL LOSS shall be used for testing the performance of FUNCTIONAL NIRS EQUIPMENT as shown in Table 201.101.

Table 201.101 – Performance tests employing the FUNCTIONAL NIRS PHANTOM or attenuator and the required OPTICAL LOSS

Performance	FUNCTIONAL NIRS PHANTOM	Attenuator	OPTICAL LOSS
PATHLENGTH-DEPENDENT HAEMOGLOBIN CHANGE	✔		State A: > 40 dB, state B: 3 dB to 4 dB larger than in state A
Signal stability		✔	> 40 dB
RESPONSE TIME	✔		State A: > 40 dB, state B: 3 dB to 4 dB larger than in state A
Signal-to-noise ratio	✔		State A: > 60 dB, state B: 3 dB to 4 dB larger than in state A

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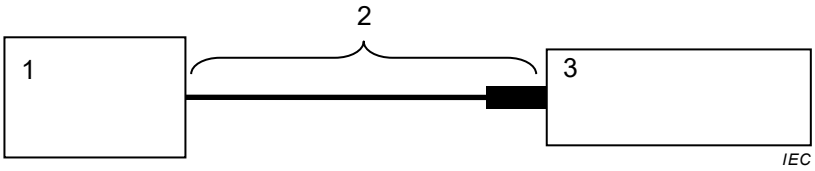
Performance	FUNCTIONAL NIRS PHANTOM	Attenuator	OPTICAL LOSS
SIGNAL CROSS-TALK		✔	> 40 dB

NOTE 1 The FUNCTIONAL NIRS PHANTOM can also be used as an attenuator with the same OPTICAL LOSS.

NOTE 2 For the measurement of signal-to-noise ratio, the FUNCTIONAL NIRS PHANTOM with > 40 dB can be used, with an appropriate neutral density filter added.

201.12.1.101.2 AVERAGE OPTICAL POWER

The AVERAGE OPTICAL POWER of the ME EQUIPMENT shall be measured for each EMITTER PROBE and for each light source and disclosed in the instructions for use.



Key

1 FUNCTIONAL NIRS MONITOR

2 EMITTER PROBE

3 Power Meter

Figure 201.102 – Measurement of AVERAGE OPTICAL POWER

Compliance is checked by inspection of the instructions for use and the following test.

a) Set up the ME EQUIPMENT and power meter and indicators shown in Figure 201.102.

b) Confirm that the size of effective light-receiving area is sufficiently larger than the beam size on the area. If not, the beam should be made convergent using a suitable adjunct optical element. A suitable adapter should be used to appropriately fix the EMITTER PROBE.

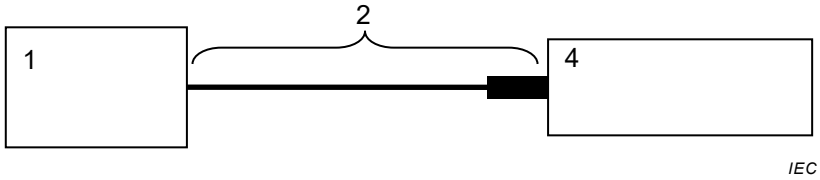
c) Measure the AVERAGE OPTICAL POWER with the detector of the power meter and verify that the value is within the limit specified by the maximum permissible exposure (MPE) of skin (IEC 60825-1:2014).

201.12.1.101.3 PEAK WAVELENGTH

The PEAK WAVELENGTHS of the ME EQUIPMENT shall be measured and disclosed in the instructions for use.

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Key

1 FUNCTIONAL NIRS MONITOR

2 EMITTER PROBE

4 Spectrophotometer or optical spectrum analyzer

Figure 201.103 – Measurement of PEAK WAVELENGTH and FWHM

Compliance is checked by inspection of the instructions for use and the following test.

a) Set up the ME EQUIPMENT, a spectrophotometer or an optical spectrum analyzer and an indicator as shown in Figure 201.103.

b) Measure the wavelength with the spectrophotometer or an optical spectrum analyzer and verify that the value is within the specified limit.

c) If the channel of the ME EQUIPMENT has more than one light source, the measurement shall be performed for each light source.

201.12.1.101.4 FULL WIDTH AT HALF MAXIMUM OF SPECTRAL DISTRIBUTION

The FWHM of the spectral distribution shall be measured and disclosed in the instructions for use for each light source.

Compliance is checked by inspection of the instructions for use and the following test.

a) Set up the ME EQUIPMENT, a spectrophotometer or an optical spectrum analyzer and an indicator as shown in Figure 201.103.

b) Measure the spectral distribution of the output of the ME EQUIPMENT with the spectrophotometer or optical spectrum analyzer.

c) The FWHM is obtained from the spectral distribution according to the definition in 201.3.204.

d) If the channel of the ME EQUIPMENT has more than one light source, the measurement shall be performed for each light source.

NOTE The spectral power distribution related to each NOMINAL wavelength of the ME EQUIPMENT is considered separately.

201.12.1.101.5 PATHLENGTH-DEPENDENT HAEMOGLOBIN CHANGE

The PATHLENGTH-DEPENDENT HAEMOGLOBIN CHANGE shall be measured and disclosed in the instructions for use.

Compliance is checked by inspection of the instructions for use and the test described in Annex BB.

201.12.1.101.6 Signal stability

The signal stability of the ME EQUIPMENT shall be measured and disclosed in the instructions for use.

Compliance is checked by inspection of the instructions for use and the following test.

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a) Set up the ME EQUIPMENT by selecting an EMITTER PROBE, a DETECTOR PROBE, and an attenuator as shown in Figure 201.104

b) The attenuator is made of optical filter or scattering attenuating material that has more than 40 dB OPTICAL LOSS for each applicable wavelength. The OPTICAL LOSS is measured in advance with an optical power meter or, in case of an optical filter, with a spectrophotometer.

c) Turn on the mains power switches of all the instruments and wait until the instruments warm up sufficiently if necessary.

d) Set the power of ME EQUIPMENT to the maximum level.

e) Obtain data samples of the PATHLENGTH-DEPENDENT HAEMOGLOBIN CHANGE as a time series for more than 15 min and PROCESS with a filter which has a time constant of less than 5 s.

f) Calculate signal stability, S_{stab}, for oxyhaemoglobin and deoxyhaemoglobin

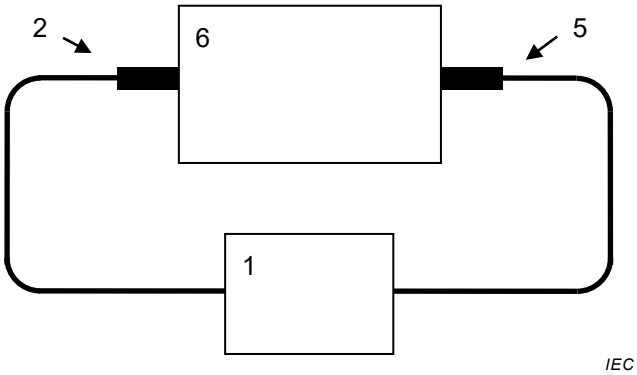
g) The signal stability, S_{stab}, is given by the following formula.

$$S_{\text{stab}} = \sqrt{\frac{\sum_{j=1}^{k}\left\{\left(\Delta c \cdot L\right)_j - \overline{\Delta c \cdot L}\right\}^2}{k-1}}$$

where $\overline{\Delta c \cdot L} = \frac{\sum_{j=1}^{k}\left(\Delta c \cdot L\right)_j}{k}$ *and k denotes the number of samples in a time series.*

NOTE $\Delta c \cdot L$ is related to the change from the baseline sample, not a change in the attenuation.

The larger value of the S_{stab} for oxyhaemoglobin and deoxyhaemoglobin is taken as the signal stability.



Key

1 FUNCTIONAL NIRS MONITOR

2 EMITTER PROBE

5 DETECTOR PROBE

6 Attenuator

NOTE Attenuator OPTICAL LOSS for this test: > 40 dB

Figure 201.104 – Measurement of signal stability

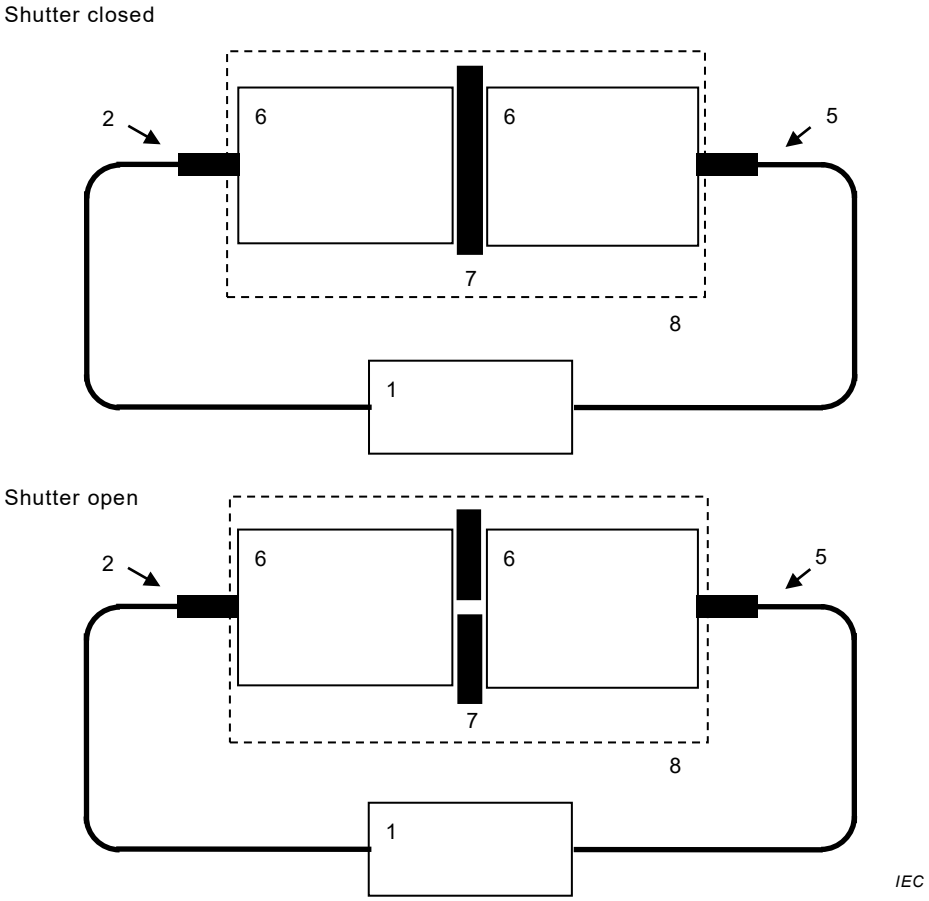
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201.12.1.101.7 RESPONSE TIME

The RESPONSE TIME of the ME EQUIPMENT shall be given as the rise time or fall time for the step response, which is given as the interval between the times corresponding to 10 % and 90 % of the step response amplitude during the transition (see Figure 201.106).

The RESPONSE TIME shall be measured and disclosed in the instructions for use.

Compliance is checked by inspection of the instructions for use and the following test.



Key

1 FUNCTIONAL NIRS MONITOR

2 EMITTER PROBE

5 DETECTOR PROBE

6 Attenuator

7 Shutter

8 FUNCTIONAL NIRS PHANTOM

NOTE Shutter closed: OPTICAL LOSS: ∞ , shutter open: OPTICAL LOSS: > 40 dB

Figure 201.105 – Measurement of RESPONSE TIME

a) Set up the ME EQUIPMENT, an optical shutter and two attenuators as shown in Figure 201.105 and described in Annex BB.3.3.

b) Measure the rise time or fall time of the step response of the PATHLENGTH-DEPENDENT HAEMOGLOBIN CHANGE signal caused by the shutter movement as shown in Figure 201.106.

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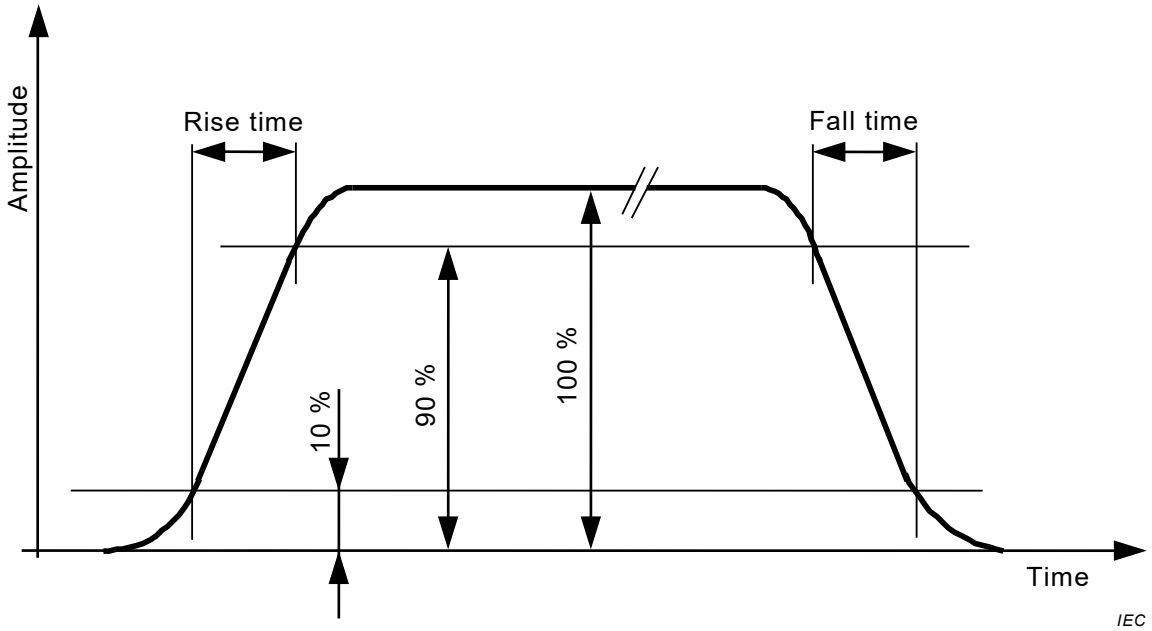


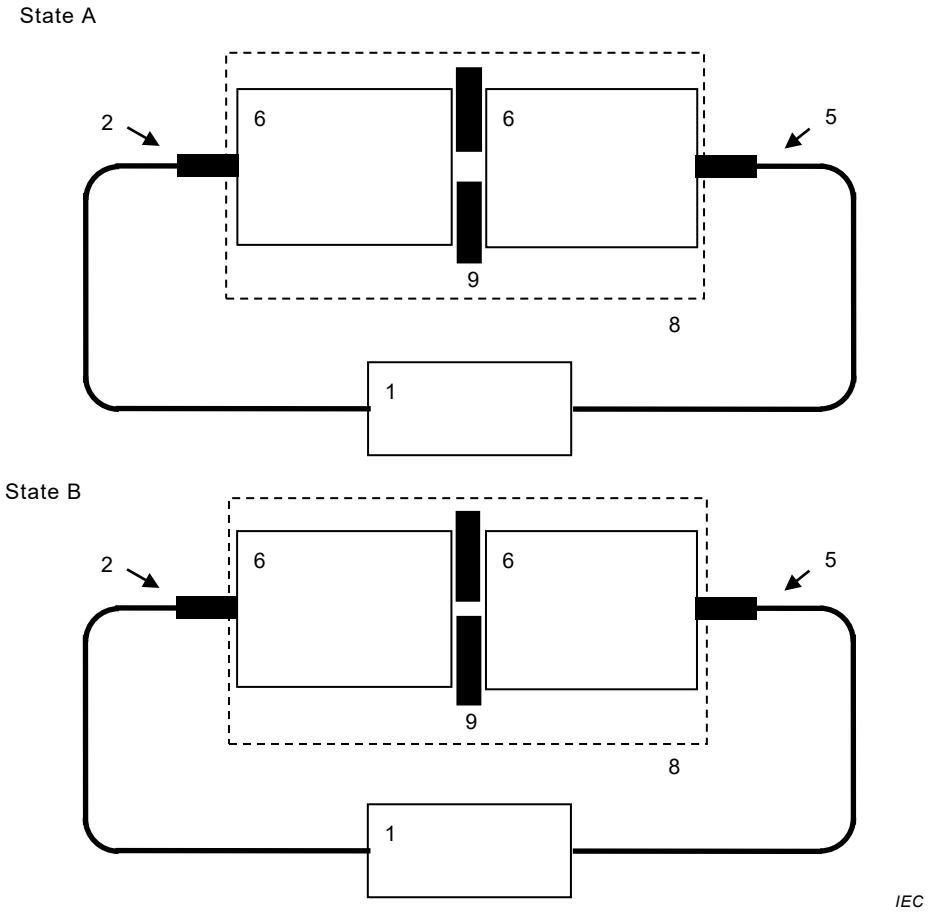
Figure 201.106 – Rise time and fall time in RESPONSE TIME

201.12.1.101.8 *Signal-to-noise ratio

The signal-to-noise ratio and the maximum sampling rate of the ME EQUIPMENT shall be measured and disclosed in the instructions for use.

Compliance is checked by inspection of the instructions for use and the following test.

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Key

1 FUNCTIONAL NIRS MONITOR

2 EMITTER PROBE

5 DETECTOR PROBE

6 Attenuator

8 FUNCTIONAL NIRS PHANTOM

9 Changeable aperture

NOTE State A OPTICAL LOSS: > 60 dB;

NOTE State B OPTICAL LOSS: 3 dB to 4 dB larger than OPTICAL LOSS at state A

Figure 201.107 – Measurement of signal-to-noise ratio

a) Set up the optical system that consists of the ME EQUIPMENT, an optical aperture and two attenuators as shown in Figure 201.107 and described in BB.3.3.

b) The attenuator OPTICAL LOSS, including the loss by the optical aperture and an additional optical neutral density filter, shall be more than 60 dB (state A). The change in the diameter of the optical aperture shall increase the loss by 3 dB to 4 dB (state B), which induces signal change in the ME EQUIPMENT. The OPTICAL LOSS is measured and adjusted as described in Annex BB.3.2.

c) The signal change of the ME EQUIPMENT shall be measured at 10 or more sampling events by 4 or more repetitions with the highest sampling rate of the ME EQUIPMENT.

d) The signal-to-noise ratio of the ME EQUIPMENT that is denoted as S/δS, is the ratio of the signal change S produced by changing the optical aperture in the optical system to the standard deviation of the signal variation δS. The signal values S_A and S_B, which denote the signal at state A and at state B respectively, are measured and calculated from the following.

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$$\delta S = \sqrt{\frac{\sum_{i=1}^{n}\left(\sum_{j=1}^{m}\left\{\left(\Delta c \cdot L\right)_{j,\mathrm{A}} - \overline{\Delta c \cdot L}_{\mathrm{B}}\right\}^2\right)}{m \cdot n - 1}}$$

$$S = S_{\mathrm{A}} - S_{\mathrm{B}}$$

where $S_{\mathrm{A}} = \overline{\Delta c \cdot L}_{\mathrm{A}} = \dfrac{\sum_{j=1}^{m}\left(\Delta c \cdot L\right)_{j,\mathrm{A}}}{m}$,

$S_{\mathrm{B}} = \overline{\Delta c \cdot L}_{\mathrm{B}} = \dfrac{\sum_{j=1}^{m}\left(\Delta c \cdot L\right)_{j,\mathrm{B}}}{m}$,

where m is the number of sampling events and n is the number of repetitions.

e) *The PATHLENGTH-DEPENDENT HAEMOGLOBIN CHANGES, PATHLENGTH-DEPENDENT OXYHAEMOGLOBIN CHANGE and PATHLENGTH-DEPENDENT DEOXYHAEMOGLOBIN CHANGE shall be obtained from the measurement.*

201.12.1.101.9 SIGNAL CROSS-TALK

If the ME EQUIPMENT has more than one MEASUREMENT CHANNEL, the SIGNAL CROSS-TALK of the ME EQUIPMENT shall be measured and disclosed in the instructions for use. The SIGNAL CROSS-TALK is affected by the spatial arrangement of the EMITTER PROBES and DETECTOR PROBES as well as the time-varying emissions by individual light sources. These combinations of each light source and spatial arrangements shall be included in this disclosure of SIGNAL CROSS-TALK.

NOTE There may be sources of SIGNAL CROSS-TALK internal to the ME EQUIPMENT which can affect these systematic measures of SIGNAL CROSS-TALK described in the testing below. The device may need shielding and filtering of channels to prevent these sources from impacting the output.

Compliance is checked by inspection of the instructions for use and the following test.

a) Set up the ME EQUIPMENT and an attenuator as shown in Figure 201.108. Arrangement and separations between EMITTER PROBES and DETECTOR PROBES are set for NORMAL USE and shall be disclosed.

b) The attenuator shall be made of scattering and absorbing materials which have OPTICAL LOSS of more than 40 dB.

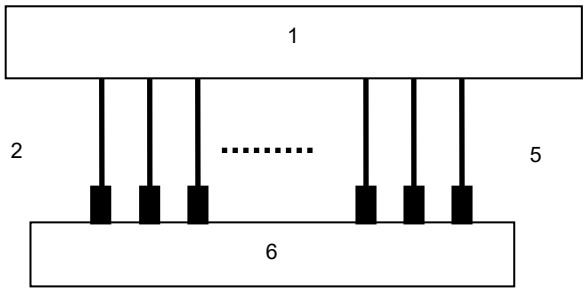
c) Operate the ME EQUIPMENT in accordance with its instructions for use.

d) The SIGNAL CROSS-TALK XT is represented as follows:

$$XT = 20 \log_{10} \mid V_0/V \mid$$

where V is the voltage of the detector of the relevant channel as measured for each wavelength from the relevant EMITTER PROBE, proportional to the optical intensity detected with regard to operation according to the instructions for use and V_0 is the one received in the condition of no optical emission from the EMITTER PROBE of the relevant channel.

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Key

1 FUNCTIONAL NIRS MONITOR

2 EMITTER PROBE

5 DETECTOR PROBE

6 Attenuator

NOTE Attenuator OPTICAL LOSS for this test: > 40 dB

Figure 201.108 – Measurement of SIGNAL CROSS-TALK

201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT

Clause 13 of the general standard applies.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause 14 of the general standard applies.

201.15 Construction of ME EQUIPMENT

Clause 15 of the general standard applies.

201.16 ME SYSTEMS

Clause 16 of the general standard applies.

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

Clause 17 of the general standard applies.

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Annexes

The annexes of the general standard apply, except as follows:

Annex C
(informative)

Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS

Annex C of the general standard applies, except as follows:

201.C.1 Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts

Addition:

Additional requirements for marking on the outside of the FUNCTIONAL NIRS EQUIPMENT or its parts are found in Table 201.C.101.

Table 201.C.101 – Marking on the outside of FUNCTIONAL NIRS EQUIPMENT or their parts

Description of marking	Subclause
Classification specified in Clause 7 of IEC 60825-1:2014	201.7.2.101

201.C.5 ACCOMPANYING DOCUMENTS, instructions for use

Addition:

Additional requirements for ACCOMPANYING DOCUMENTS, instructions for use of FUNCTIONAL NIRS EQUIPMENT are found in Table 201.C.102.

Table 201.C.102 – ACCOMPANYING DOCUMENTS, instructions for use of FUNCTIONAL NIRS EQUIPMENT

Description of disclosure	Subclause
Performances specified in subclause 201.12.1.101	201.7.9.2.101
AVERAGE OPTICAL POWER	201.12.1.101.2
PEAK WAVELENGTHS of the ME EQUIPMENT	201.12.1.101.3
FWHM of the spectral distribution	201.12.1.101.4
PATHLENGTH-DEPENDENT HAEMOGLOBIN CHANGE	201.12.1.101.5
Signal stability of the ME EQUIPMENT	201.12.1.101.6
RESPONSE TIME	201.12.1.101.7
Signal-to-noise ratio and the maximum sampling rate of the ME EQUIPMENT	201.12.1.101.8
SIGNAL CROSS-TALK of the ME EQUIPMENT	201.12.1.101.9

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