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)

IEC Central Office
3, rue de Varembé
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
Fax: +41 22 919 03 00
info@iec.ch
www.iec.ch

About the IEC
The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

About IEC publications
The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigenda or an amendment might have been published.

IEC Catalogue - webstore.iec.ch/catalogue
The stand-alone application for consulting the entire bibliographical information on IEC International Standards, Technical Specifications, Technical Reports and other documents. Available for PC, Mac OS, Android Tablets and iPad.

IEC publications search - www.iec.ch/searchpub
The advanced search enables to find IEC publications by a variety of criteria (reference number, text, technical committee,…). It also gives information on projects, replaced and withdrawn publications.

IEC Just Published - webstore.iec.ch/justpublished
Stay up to date on all new IEC publications. Just Published details all new publications released. Available online and also once a month by email.

Electropedia - www.electropedia.org
The world's leading online dictionary of electronic and electrical terms containing more than 30 000 terms and definitions in English and French, with equivalent terms in 15 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

IEC Glossary - std.iec.ch/glossary
More than 60 000 electrotechnical terminology entries in English and French extracted from the Terms and Definitions clause of IEC publications issued since 2002. Some entries have been collected from earlier publications of IEC TC 37, 77, 86 and CISPR.

IEC Customer Service Centre - webstore.iec.ch/csc
If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: csc@iec.ch.

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

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

ICS 11.040.55

ISBN 978-2-8322-2717-6

CONTENTS

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.
2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
6) All users should ensure that they have the latest edition of this publication.
7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
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 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.

[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.

---

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.

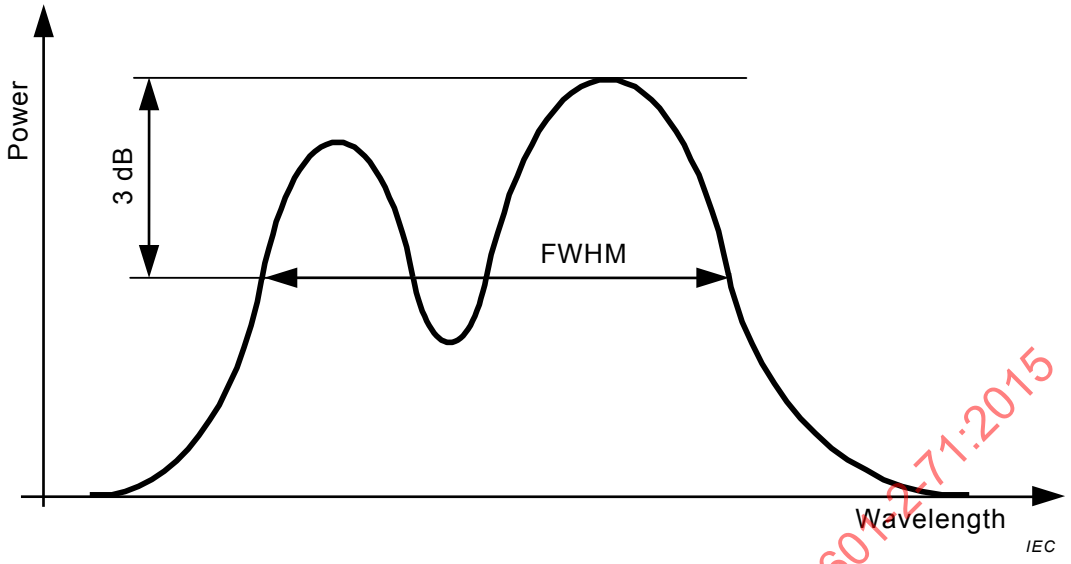


Figure 201.101 – FULL WIDTH AT HALF MAXIMUM of spectral power distribution

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

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:

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

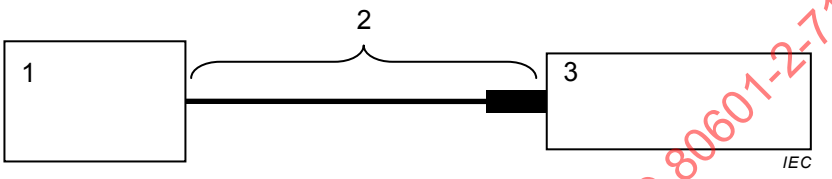
Performance	FUNCTIONAL NIRS PHANTOM	Attenuator	OPTICAL LOSS
SIGNAL CROSS-TALK		✔	> 40 dB

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.

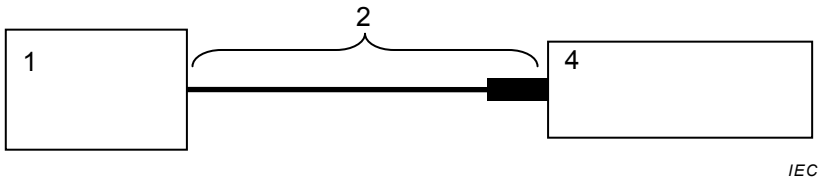
a) *Set up the ME EQUIPMENT and power meter and indicators shown in Figure 201.102.*

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.



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.

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*

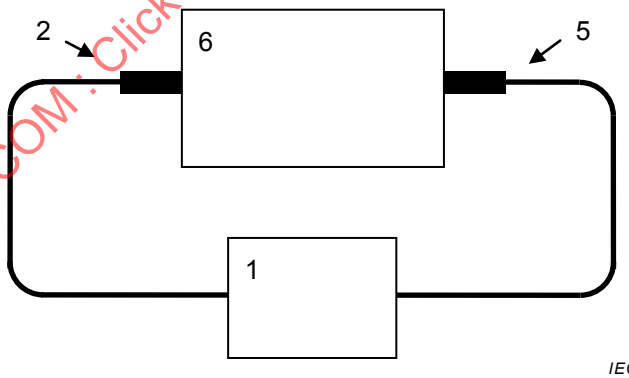
g) *The signal stability, S_{stab}, is given by the following formula.*

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

where $\overline{\Delta c \cdot L} = \dfrac{\sum_{j=1}^{k}\left(\Delta c \cdot L\right)_j}{k}$ *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

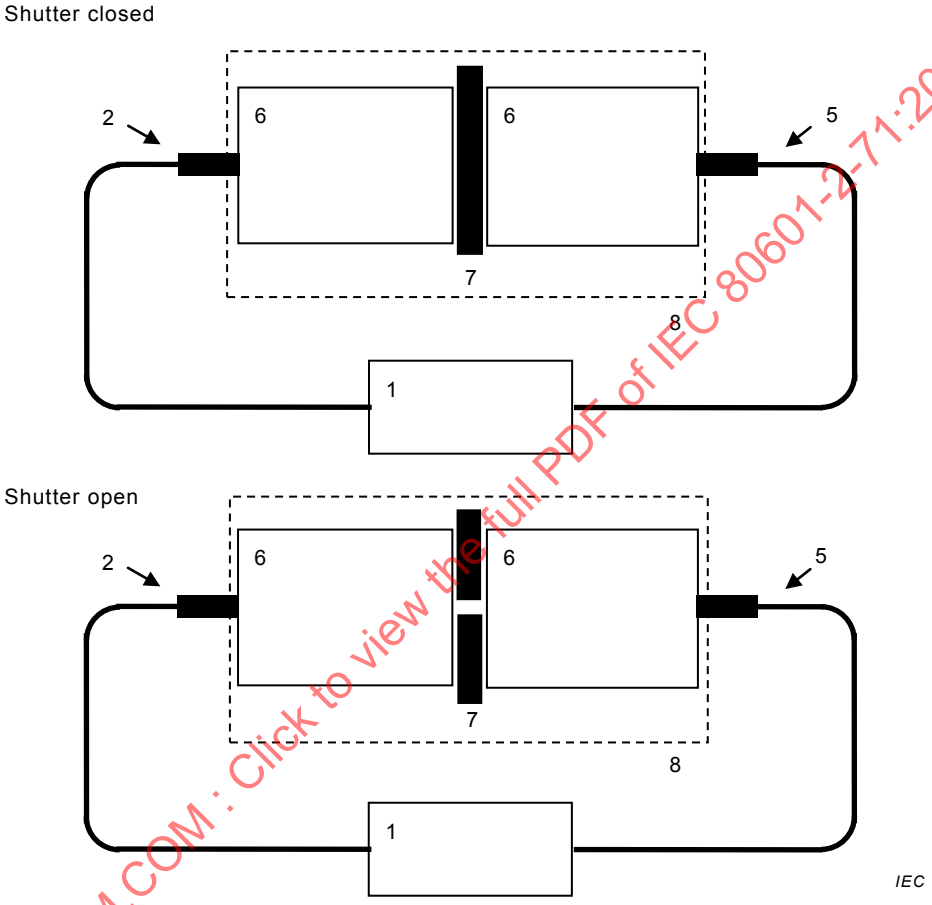
Figure 201.104 – Measurement of signal stability

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.*

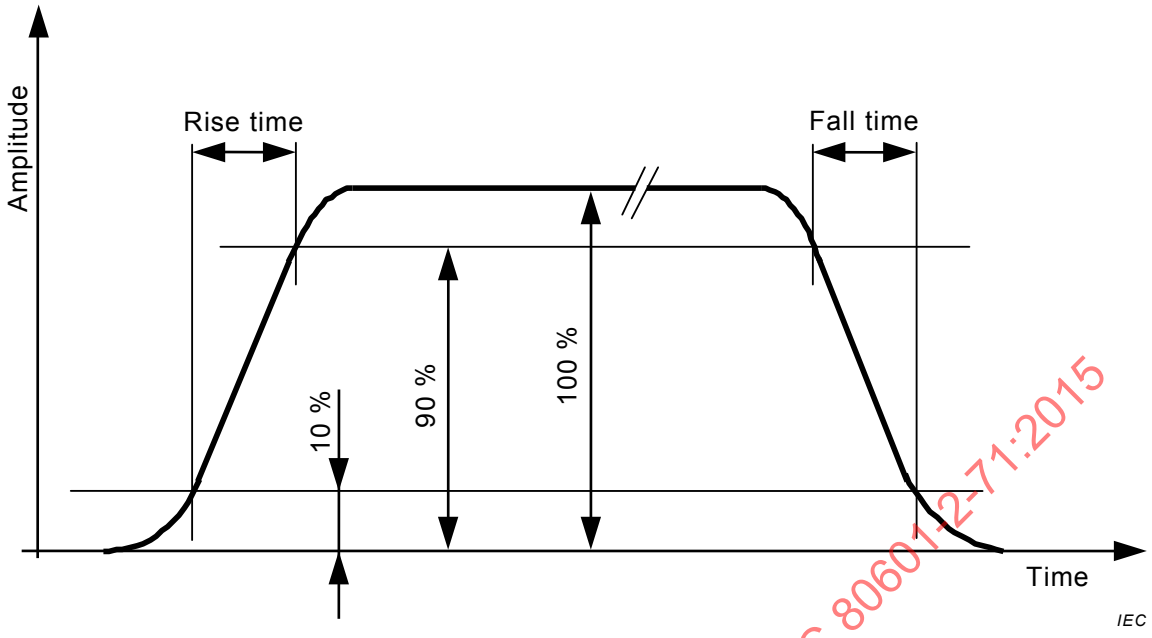
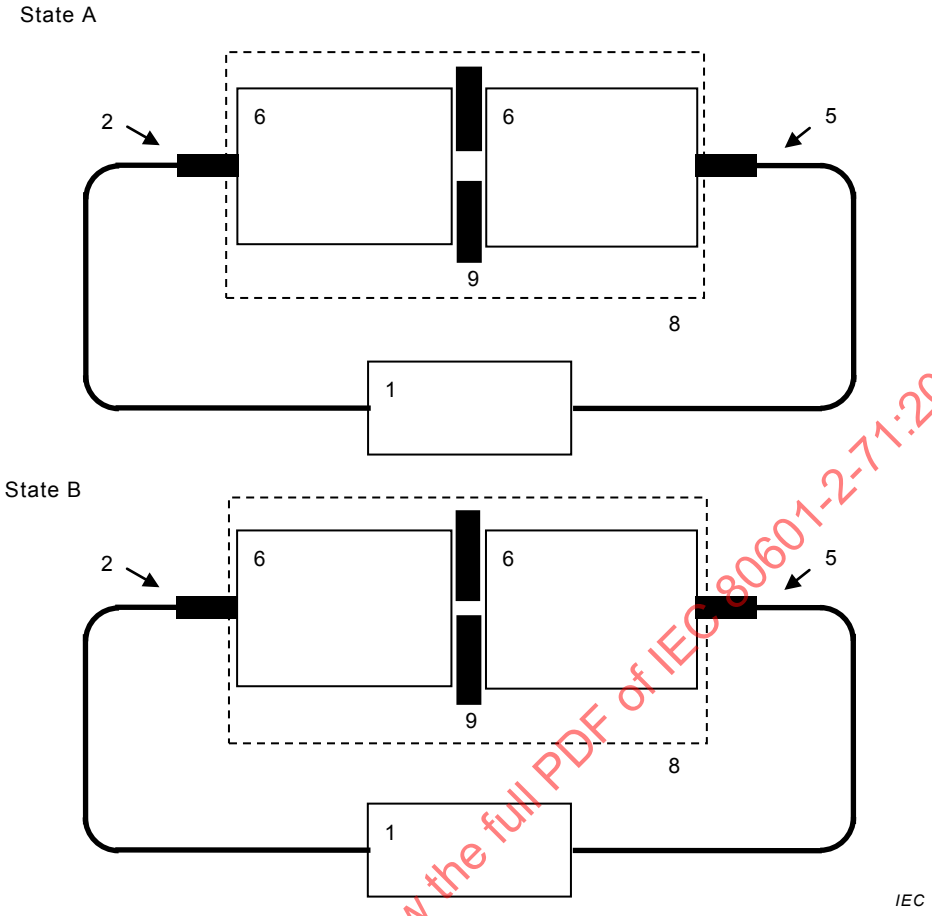


Figure 201.106 – Rise time and fall time in RESPONSE TIME

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.



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.*

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

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

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.

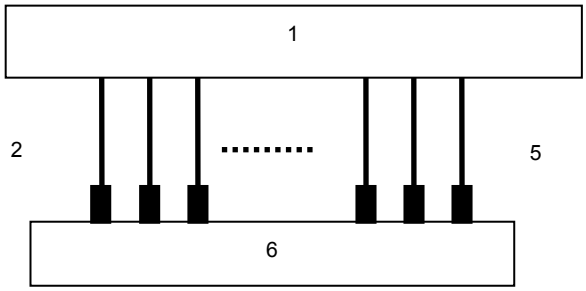
b) The attenuator shall be made of scattering and absorbing materials which have OPTICAL LOSS of more than 40 dB.

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

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

$$XT = 20 \log_{10} \left| V_0/V \right|$$

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.*



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.

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

Annex AA
(informative)

Particular guidance and rationale

AA.1 General guidance

This annex provides a rationale for the important requirements of this particular standard. Its purpose is to promote effective application of the standard by explaining the reasons for the requirements and the tests to check the performances.

FUNCTIONAL NIRS EQUIPMENT has become commercially available and widely used in clinical practice such as diagnosis in psychiatry, neurosurgery or pediatrics. The continuous-wave near-infrared spectroscopy made it possible to measure haemodynamic change in the living tissue, or more precisely the product of the change in haemoglobin concentration in the living tissue and the mean optical pathlength, as described in definition 201.3.211. The equipment helps physicians to obtain physiologically useful information in the human body with non-invasive, i.e. safe and relatively low-cost method and has been applied to other medical uses, e.g. monitoring oxygen metabolism in the muscles, or real-time measurement of brain activity.

The FUNCTIONAL NIRS EQUIPMENT usually incorporates lasers or light-emitting diodes as a light source. The light source and the probe as the APPLIED PART should be properly specified to ensure the safety of the equipment. Moreover, as a physiological parameter-measuring device, particular requirements for the equipment should include the following:

– defining the terms used for haemodynamic measurement with near-infrared spectroscopy,
– standardization of the test PROCEDURES to measure performances of the FUNCTIONAL NIRS EQUIPMENT, and
– how to build the FUNCTIONAL NIRS PHANTOM that is essential to evaluate the PATHLENGTH-DEPENDENT HAEMOGLOBIN CHANGE measurement.

AA.2 Rationale for particular clauses and subclauses

The numbering of the following rationale corresponds to the numbering of the clauses and subclauses in this document. The numbering therefore is not consecutive.

Subclause 201.12.1.101.8 – Signal-to-noise ratio

The signal-to-noise ratio of FUNCTIONAL NIRS EQUIPMENT depends on the wavelength of the ME EQUIPMENT and the attenuation in the living tissue. This standard specifies the FUNCTIONAL NIRS PHANTOM of which OPTICAL LOSS is more than 60 dB to evaluate the signal-to-noise ratio of the ME EQUIPMENT. However, the signal-to-noise ratio in clinical use can be significantly influenced by attenuation in the living tissue.

Subclause BB.3.3 – Specification of the FUNCTIONAL NIRS PHANTOM for evaluating the performance of the ME EQUIPMENT measuring PATHLENGTH-DEPENDENT HAEMOGLOBIN CHANGE

The material should be:

– similar to the living tissue in optical characteristics;
– conventionally obtainable; and
– easily moulded.

Epoxy, silicon, polyoxymethylene (POM), etc. have been used for FUNCTIONAL NIRS PHANTOM material. Polymerized and cured epoxy or silicon can be used by mixing appropriate amounts of light scattering and absorbing materials in both base resin and hardener before

PROCESSING. However, the high viscosity of base resin and hardener before polymerization makes it difficult to uniformly mix scattering and absorption materials with them. In addition, this high viscosity of base resin and hardener also makes it difficult to mix the two agents uniformly in polymerization reaction. In contrast, POM has good mechanical and moulding properties, so it is widely used for structural materials and mechanism elements in electrical devices, automobile components or precision machinery components. In particular, white POM is recommended as the FUNCTIONAL NIRS PHANTOM material because of:

– having approximately the same reduced scattering coefficient as the human tissues;
– being so low-cost and easily obtainable that it is widely used as a typical engineering plastic in various industries; and
– being so easily moulded and fabricated that it can be manufactured into arbitrary shapes.

Some of the ME EQUIPMENT has an all-in-one probe, where EMITTER PROBES and DETECTOR PROBES are built in together. The transmissive FUNCTIONAL NIRS PHANTOM specified in Annex BB cannot be applied to the all-in-one probes. Moreover, some of these kinds of all-in-one probes have more than one detector or the distance between radiation and detection varies depending on the ME EQUIPMENT. Reflective FUNCTIONAL NIRS PHANTOMS made of a homogeneous material having optical properties similar to those of human tissues are needed to measure performances of this kind of ME EQUIPMENT. The reflective FUNCTIONAL NIRS PHANTOM shall have the same performance related to OPTICAL LOSS as the transmissive FUNCTIONAL NIRS PHANTOM described in Clause BB.3

It is necessary to make materials for the reflective FUNCTIONAL NIRS PHANTOM with suitable repeatability and invent a mechanism that causes a change in OPTICAL LOSS between 3 dB and 4 dB. This standard specifies the reflective FUNCTIONAL NIRS PHANTOM conforming to the requirements for the transmissive FUNCTIONAL NIRS PHANTOM; however at the time of this writing a solution has not been identified.

Annex BB
(normative)

Evaluating ME EQUIPMENT performance using the FUNCTIONAL NIRS PHANTOM

BB.1 General

This annex discusses the method to evaluate the performance of the ME EQUIPMENT that measures PATHLENGTH-DEPENDENT HAEMOGLOBIN CHANGE using the FUNCTIONAL NIRS PHANTOM.

The FUNCTIONAL NIRS PHANTOM is a measuring object which has a mechanism that can change the light intensity detected by the ME EQUIPMENT. Precisely speaking, the inside mechanism of the FUNCTIONAL NIRS PHANTOM is changed to create two specific states, A and B. Different light intensity is given to the ME EQUIPMENT corresponding to each state. The measurement is conducted in these two different conditions and the ME EQUIPMENT receives two light intensities, the ratio of which is known. Therefore PATHLENGTH-DEPENDENT HAEMOGLOBIN CHANGE can be simulated. If the reference value of the PATHLENGTH-DEPENDENT HAEMOGLOBIN CHANGE to be measured using the FUNCTIONAL NIRS PHANTOM is determined in advance with a reference system, the relative difference between the reference value and the value measured with the ME EQUIPMENT represents the performance evaluation.

It is noted that MANUFACTURERS of FUNCTIONAL NIRS EQUIPMENT do not use the same wavelengths, and the light intensity change caused by the FUNCTIONAL NIRS PHANTOM varies depending on the MANUFACTURER. Therefore, the reference values of the PATHLENGTH-DEPENDENT HAEMOGLOBIN CHANGE are likely to differ for different MANUFACTURERS.

BB.2 Principle of the measurement of PATHLENGTH-DEPENDENT HAEMOGLOBIN CHANGE using NEAR-INFRARED SPECTROSCOPY

Red and near-infrared light in the wavelength range from 650 nm to 900 nm propagates more deeply into living tissue than visible light of wavelengths shorter than 650 nm, which is strongly absorbed by pigments such as haemoglobin and myoglobin, or light of wavelengths longer than 1 000 nm, which is also strongly absorbed by water. Thus haemodynamics in the living body can be non-invasively monitored by using the light in this wavelength range where the absorption characteristics of oxyhaemoglobin and deoxyhaemoglobin in the blood are different.

Pulse oximeters, whose measuring objects are typically thin living tissues such as fingers, employ the transmission method where a measuring object is placed between the light source and the opposing detector. However, when trying to measure the absorption in thick living tissues like human heads, the long optical path causes detection of very weak light due to strong light scattering and makes the measurement very difficult. In practice, the reflection method is employed to measure the absorption by human heads using multiple light sources and detectors which are separately placed at regular intervals on the surface of the living body such as the scalp.

Generally, the attenuation of the light intensity by a non-scattering homogeneous medium is given by the Beer-Lambert law. However, living tissue such as the human head, for example, is highly scattering. Moreover, it has an inhomogeneous structure consisting of the scalp, the skull, the cortex, etc. and the blood is also inhomogeneously distributed. The modified Beer-Lambert law can be approximately applied in this kind of scattering media as shown below.

According to the modified Beer-Lambert law, if the haemoglobin concentrations change from state A to state B, and $I_A(\lambda_i)$ and $I_B(\lambda_i)$ represent the detected light intensities corresponding to each state at wavelength λ_i, the ratio of $I_B(\lambda_i)$ to $I_A(\lambda_i)$ is related to the change in the absorption coefficient $\Delta\mu_a$ by:

$$\frac{I_B(\lambda_i)}{I_A(\lambda_i)} = \exp\left[-\Delta\mu_a(\lambda_i)\cdot L(\lambda_i)\right] \quad \text{(B.1)}$$

where Δ represents the difference between states A and B, and the mean optical pathlength in the tissue $L(\lambda_i) = L$ is assumed to be independent of wavelength and time during the measurement. Equation (B.1) is valid if scattering does not change between states A and B and if the absorption change $\Delta\mu_a$ is small and spatially uniform. The values of $\Delta\mu_a$ and L cannot be separately obtained from the measurement with continuous light, but rather their product $\mu_a(\lambda_i)L$.

Oxyhaemoglobin and deoxyhaemoglobin play a major role in absorption of near-infrared light in the human tissue, and it is assumed here that they are the only chromophores which contribute to the functional absorption change. Hence, the change in the absorption coefficient at wavelength λ_i, is considered to be due to the changes in these haemoglobin concentrations.

The attenuation change which is defined as

$$\Delta A(\lambda_i) = \log_{10}\left[I_A(\lambda_i)/I_B(\lambda_i)\right] \quad \text{(B.2)}$$

can then be written as

$$\Delta A(\lambda_i) = \varepsilon_{O_2Hb}(\lambda_i)\Delta c_{O_2Hb}\cdot L + \varepsilon_{HHb}(\lambda_i)\Delta c_{HHb}\cdot L \quad \text{(B.3)}$$

where Δc_{O2Hb} and Δc_{HHb} are the changes in the oxyhaemoglobin and deoxyhaemoglobin concentrations, respectively, and $\varepsilon_{O2Hb}(\lambda_i)$ and $\varepsilon_{HHb}(\lambda_i)$ are the corresponding (decadic) molar absorption coefficients.

By measuring $\Delta A(\lambda_i)$ at two or more wavelengths and solving Equation (B.3), the PATHLENGTH-DEPENDENT HAEMOGLOBIN CHANGES, $\Delta c_{O2Hb}\cdot L$ and $\Delta c_{HHb}\cdot L$, can be obtained. For example, by using two wavelengths, λ_1 and λ_2, $\Delta c_{O2Hb}\cdot L$ and $\Delta c_{HHb}\cdot L$ are given by Equations (B.4) and (B.5), respectively:

$$\Delta c_{O_2Hb}\cdot L = \frac{\varepsilon_{HHb}(\lambda_2)\Delta A(\lambda_1) - \varepsilon_{HHb}(\lambda_1)\Delta A(\lambda_2)}{\varepsilon_{O_2Hb}(\lambda_1)\varepsilon_{HHb}(\lambda_2) - \varepsilon_{O_2Hb}(\lambda_2)\varepsilon_{HHb}(\lambda_1)} \quad \text{(B.4)}$$

$$\Delta c_{HHb}\cdot L = \frac{\varepsilon_{O_2Hb}(\lambda_1)\Delta A(\lambda_2) - \varepsilon_{O_2Hb}(\lambda_2)\Delta A(\lambda_1)}{\varepsilon_{O_2Hb}(\lambda_1)\varepsilon_{HHb}(\lambda_2) - \varepsilon_{O_2Hb}(\lambda_2)\varepsilon_{HHb}(\lambda_1)} \quad \text{(B.5)}$$

Due to multiple scattering, the mean optical pathlength, L, is longer than the geometrical distance between the light source and the detector, and varies depending on this distance as well as measured sites or individuals. The mean optical pathlength L is currently difficult to measure. Therefore, measured physical quantities $\Delta c_{O2Hb}\cdot L$ and $\Delta c_{HHb}\cdot L$ are the product of the change in the haemoglobin concentrations and the mean optical pathlength, and their unit is denoted by the product of the concentration and the distance, e.g., mM·mm. Thus, care should be taken that the values of $\Delta c_{O2Hb}\cdot L$ and $\Delta c_{HHb}\cdot L$ vary with L which depends on the distance between the light source and the detector.

In this standard, $\Delta c_{O2Hb}\cdot L$ and $\Delta c_{HHb}\cdot L$ are called PATHLENGTH-DEPENDENT OXYHAEMOGLOBIN CHANGE and PATHLENGTH-DEPENDENT DEOXYHAEMOGLOBIN CHANGE, respectively, and, when

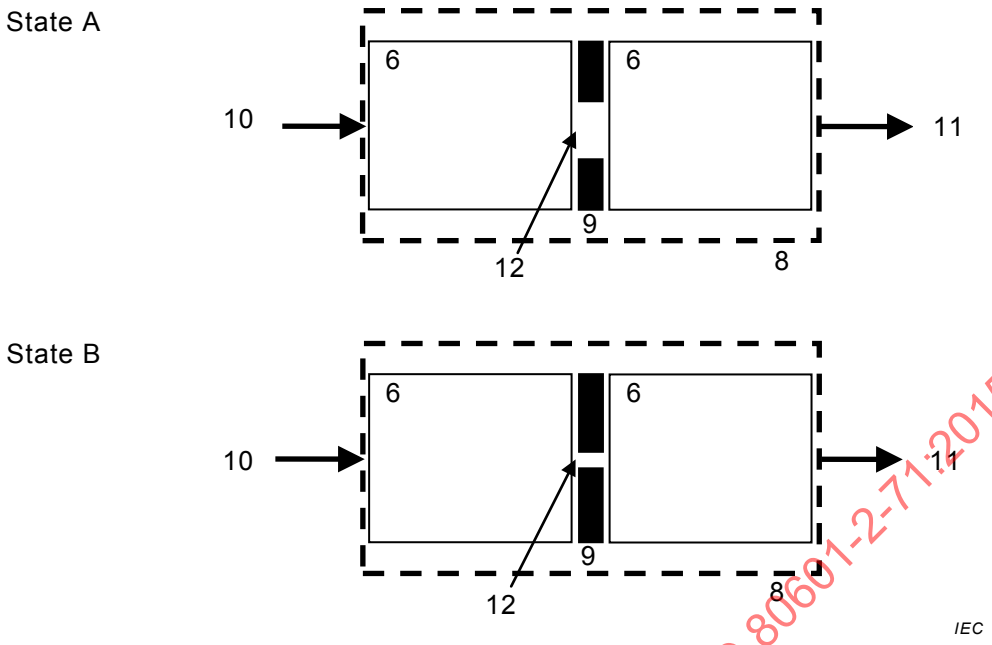
unnecessary to distinguish the oxygenation states, simply called PATHLENGTH-DEPENDENT HAEMOGLOBIN CHANGE.

BB.3 FUNCTIONAL NIRS PHANTOM to evaluate the ME EQUIPMENT measuring PATHLENGTH-DEPENDENT HAEMOGLOBIN CHANGE

BB.3.1 Principle of evaluating the ME EQUIPMENT using the FUNCTIONAL NIRS PHANTOM

Without using living tissues the PATHLENGTH-DEPENDENT HAEMOGLOBIN CHANGE determined by Equations (B.1)-(B.5) is measured by using the FUNCTIONAL NIRS PHANTOM that artificially creates light intensity change. The mechanism of the FUNCTIONAL NIRS PHANTOM is manipulated to create two states in which two light intensities, I_A and I_B, are measured by the ME EQUIPMENT. The light intensity changes detected at the various wavelengths are considered to be caused by changes in the oxyhaemoglobin and deoxyhaemoglobin concentrations. The calculated value of the PATHLENGTH-DEPENDENT HAEMOGLOBIN CHANGE is compared with the reference value which is obtained in advance with a reference system. Then the performance of the ME EQUIPMENT can be evaluated. The evaluating FUNCTIONAL NIRS PHANTOM that creates states A and B and a reference system which is capable of measuring the reference light intensity changes are needed to conduct these PROCEDURES. The reference system consists of a stabilized light source and a calibrated power meter.

The evaluating FUNCTIONAL NIRS PHANTOM is composed of a material which has scattering characteristics similar to human tissues. Light intensity is mainly attenuated by scattering in the FUNCTIONAL NIRS PHANTOM. The FUNCTIONAL NIRS PHANTOM has a means to change the light attenuation in order to vary the detected light intensity. The transmission method is employed because it is easy to change the light attenuation and to perform the measurement with a good accuracy; whereas the reflection method is usually employed for thick human tissues. The amount of light transmission is varied with the (variable) optical aperture inside the FUNCTIONAL NIRS PHANTOM as shown in Figure 201.BB.1. For example, state A and state B correspond with the cases of the aperture area S_{apA} and S_{apB}, respectively. Changing the transmitted light intensity by changing the aperture area is considered to be equivalent to changing the absorption coefficient of the entire FUNCTIONAL NIRS PHANTOM, μ_a. The ratio of the areas of the aperture, S_{apB}/S_{apA}, represents the ratio of transmitted light intensity, I_B/I_A. The directionality of light is lost because sufficiently thick scattering and absorbing materials are placed in front of and at the rear of the optical aperture, resulting in S_{apB}/S_{apA} being equal to I_B/I_A. When measuring at wavelengths λ_1 and λ_2, the ratios of measured transmitted light intensity, $I_B(\lambda_1)/I_A(\lambda_1)$ and $I_B(\lambda_2)/I_A(\lambda_2)$, are substituted in equation (B.1) and $\Delta A(\lambda_1)$ and $\Delta A(\lambda_2)$ are obtained. Then the value of the PATHLENGTH-DEPENDENT HAEMOGLOBIN CHANGE can be obtained from equations (B.4) and (B.5).



Key

6 Attenuator

8 FUNCTIONAL NIRS PHANTOM

9 Changeable aperture

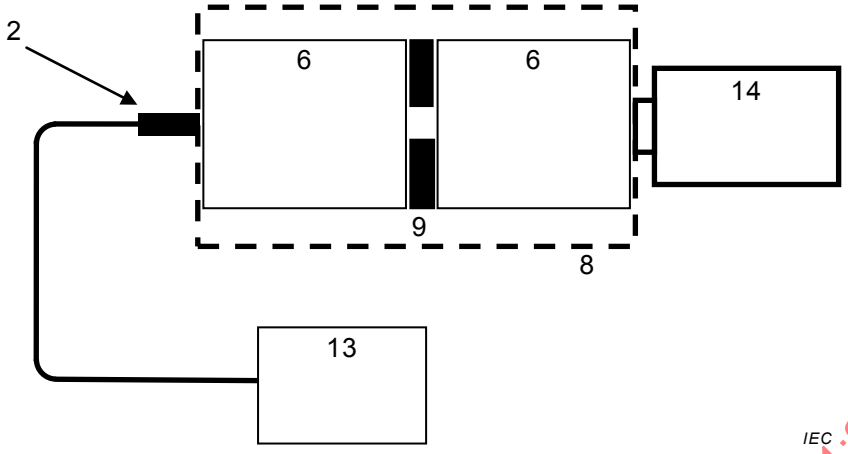
10 Incident light intensity I_0

11 Detected light intensity: I_A and I_B, respectively

12 Area of aperture

Figure 201.BB.1 – The FUNCTIONAL NIRS PHANTOM in two states with different detected light intensities

The reference PATHLENGTH-DEPENDENT HAEMOGLOBIN CHANGE is measured in advance with a reference system using this FUNCTIONAL NIRS PHANTOM as shown in Figure BB.2. Then the value is measured using the FUNCTIONAL NIRS PHANTOM with the ME EQUIPMENT being tested as shown in Figure BB.3. The value is compared with the reference value measured with the reference system. The difference between the two values shall be within 5 %.



Key

2 EMITTER PROBE

6 Attenuator

8 FUNCTIONAL NIRS PHANTOM

9 Changeable aperture

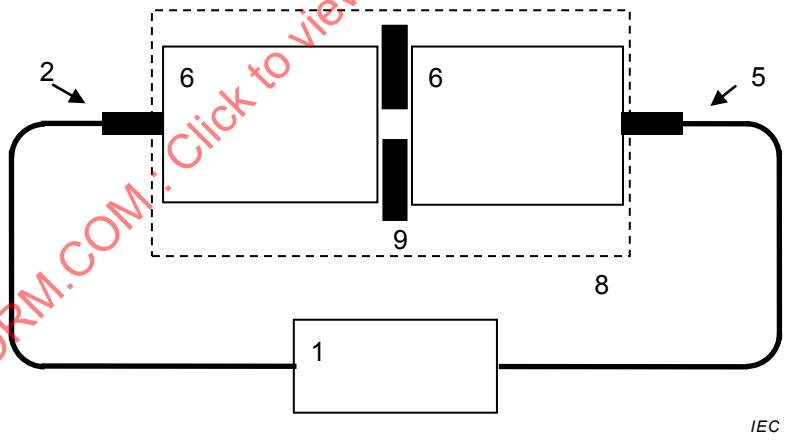
13 Stabilized light source

14 Calibrated power meter

NOTE State A OPTICAL LOSS: > 40 dB;

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

Figure BB.2 – FUNCTIONAL NIRS PHANTOM measurement using the reference system



Key

1 FUNCTIONAL NIRS MONITOR

2 EMITTER PROBE

5 DETECTOR PROBE

6 Attenuator

8 FUNCTIONAL NIRS PHANTOM

9 Changeable aperture

Figure BB.3 – FUNCTIONAL NIRS PHANTOM measurement using the ME EQUIPMENT to be evaluated

Example for the calculation of the reference values of the simulated PATHLENGTH-DEPENDENT HAEMOGLOBIN CHANGES:

An increase in attenuation of 3 dB from state A to state B, i.e. $I_B = I_A / 2$ corresponds to a change $\Delta A = \log_{10}(2) = 0{,}301$. It is assumed that this change is independent of wavelength, $\Delta A(\lambda) = \Delta A$. For two typical wavelengths, λ_1 = 690 nm and λ_2 = 830 nm, and absorption spectra taken from Matcher et al., the following values of the molar decadic absorption coefficient are relevant.

ε_{O2Hb}(690 nm) = 0,3123 l/mmol/cm, ε_{HHb}(690 nm) = 2,1382 l/mmol/cm

ε_{O2Hb}(830 nm) = 1,0507 l/mmol/cm, ε_{HHb}(830 nm) = 0,7804 l/mmol/cm.

Insertion into Eqs. (B.4) and (B.5) yields

$\Delta c_{O2Hb} \cdot L$ = 204 (µmol/l)·cm = 2,04 mM·mm and $\Delta c_{HHb} \cdot L$ = 111 (µmol/l) cm = 1,11 mM·mm.

NOTE 1 The simulated PATHLENGTH-DEPENDENT HAEMOGLOBIN CHANGES derived from a 3 dB increase in attenuation at 690 nm and 830 nm are both positive.

NOTE 2 The results will be different if the attenuation change deviates from 3 dB or if it is not independent of wavelength, and also if the wavelengths differ from the values assumed. Moreover, the use of spectra from different literature sources may lead to slight deviations.

NOTE 3 Typical attenuation changes and related PATHLENGTH-DEPENDENT HAEMOGLOBIN CHANGES found for brain activation in humans are considerably smaller in magnitude and differ in direction.

BB.3.2 Additional description of measurement of OPTICAL LOSS

In the optical systems in Figures BB.2 and BB.3, in state A the FUNCTIONAL NIRS PHANTOM shall have an OPTICAL LOSS of greater than 40 dB. A changeable optical aperture sandwiched between two attenuating parts allows for the attenuation change between states A and B. The light attenuation change between states A and B is to be 3 dB to 4 dB at each wavelength of the ME EQUIPMENT. In practice, a calibrated power meter is used as the detector of the reference system.

The OPTICAL LOSS of a FUNCTIONAL NIRS PHANTOM or attenuator based on diffusely scattering and absorbing material is defined in this standard as the ratio of the total power exiting a circular aperture on the exit side of specified diameter ($2\,r_{ex}$ = 8 mm) and the power injected on the entrance side:

$$OL = P_{ex,total}/P_{in} \tag{B.6}$$

or, when expressed in dB, $OL_{dB} = 10 \log_{10}(OL)$. OL denotes the OPTICAL LOSS. $P_{ex,total}$ is the total power emitted from the entire exit aperture area into the full half space. The power meter used to record the exiting power may not collect the total power due to its limited sensor area and a finite distance from the surface, leading to an overestimation of the OPTICAL LOSS. A related correction factor can be determined based on the following considerations:

The aperture has a diameter $2\,r_{ex}$ (= 8 mm) and is centred on the axis of the cylindrical material. The illuminated area is small compared to the diameter of the diffusely scattering and absorbing material and centred on its entrance face. The geometrical dimensions and optical properties of the material are as specified in BB.3.3. Under these conditions it can be assumed that the light emerging from the exit face has a Lambertian angular characteristic and a uniform distribution across the aperture. Then the total power exiting the medium through the aperture is

$$P_{ex,total} = \pi L_{rad}\left(\pi r_{ex}^2\right). \tag{B.7}$$

where L_{rad} is the radiance. The photosensitive area of the power meter is assumed to have a spatially uniform sensitivity. It is separated from the surface of the FUNCTIONAL NIRS PHANTOM or attenuator by the distance d_r (see Figure BB.4). If the exit face of the material and the photosensitive area of the power meter are both perpendicular to the optic axis connecting

their centres, the radiant power transferred from the exit aperture to the photosensitive area of the power meter with the diameter 2 r_{pow} is given by

$$P_{pow} = \frac{2L_{rad}\left(\pi r_{ex}^2\right)\left(\pi r_{pow}^2\right)}{r_{ex}^2 + r_{pow}^2 + d_r^2 + \sqrt{\left(r_{ex}^2 + r_{pow}^2 + d_r^2\right)^2 - 4 r_{ex}^2 r_{pow}^2}}. \quad \text{(B.8)}$$

NOTE See Handbook of Optics, Chapter 34.4 Radiant Transfer Equations.

A correction factor k_{pow} (>1) can be inferred that relates $P_{ex,total}$ to the power P_{pow} measured by the power meter:

$$k_{pow} = P_{ex,total}/P_{pow} = \frac{r_{ex}^2 + r_{pow}^2 + d_r^2 + \sqrt{\left(r_{ex}^2 + r_{pow}^2 + d_r^2\right)^2 - 4 r_{ex}^2 r_{pow}^2}}{2 r_{pow}^2} \quad \text{(B.9)}$$

The OPTICAL LOSS is then obtained as

$$OL = k_{pow} P_{pow}/P_{in} \quad \text{(B.10)}$$

In the ideal case that the photosensitive element of the power meter could be directly attached to the medium (d_r = 0), the correction factor simplifies to k_{pow} = 1 for $r_{pow} \geq r_{ex}$ and k_{pow} = r_{ex}^2 / r_{pow}^2 for $r_{pow} < r_{ex}$. As an example for a finite distance, with d_r = 2 r_{pow} = 2 r_{ex} the correction factor is k_{pow} = 5,8 corresponding to 7,7 dB. Without applying the correction, the OPTICAL LOSS would be overestimated by this amount.

Since the optical properties of the FUNCTIONAL NIRS PHANTOM or attenuator, in particular the scattering, are in general wavelength-dependent, the OPTICAL LOSS shall be evaluated for all wavelengths of the ME EQUIPMENT separately. The required minimal OPTICAL LOSS (see Table 201.101) shall be achieved for all of these wavelengths.

The diameter of the DETECTOR PROBE varies depending on the MANUFACTURER or the type of ME EQUIPMENT, but it is usually smaller than 8 mm – the detection-side window diameter of the FUNCTIONAL NIRS PHANTOM. Therefore, the light attenuation that is effective in the performance test measurement by the ME EQUIPMENT, i.e. with the DETECTOR PROBE attached to the FUNCTIONAL NIRS PHANTOM, is larger than the OPTICAL LOSS determined by means of the power meter. For the attenuation change (3 dB to 4 dB) the correction described for the estimation of the total OPTICAL LOSS is irrelevant. Thus the determination of the attenuation change in the reference measurement is valid, irrespective of the diameter of the power meter and the detector PROBE.