BS EN IEC 80601-2-71:2018

BSI Standards Publication

Medical electrical equipment

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

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National foreword

This British Standard is the UK implementation of EN IEC 80601-2-71:2018. It is identical to IEC 80601-2-71:2015.

The UK participation in its preparation was entrusted to Technical Committee CH/62/4, Electromedical equipment.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Compliance with a British Standard cannot confer immunity from legal obligations.

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Amendments/corrigenda issued since publication

Date	Text affected

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 80601-2-71

June 2018

ICS 11.040.55

English Version

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)

Appareils électromédicaux - Partie 2-71: Exigences particulières pour la sécurité de base et les performances essentielles des appareils d'imagerie spectroscopique proche infrarouge (NIRS) (IEC 80601-2-71:2015)

Medizinische elektrische Geräte - Teil 2-71: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von funktionalen Oximetriegeräten (IEC 80601-2-71:2015)

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European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

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European foreword

The text of document 62D/1238/FDIS, future edition 1 of IEC 80601-2-71, prepared by SC 62D "Electromedical equipment" of IEC/TC 62 "Electrical equipment in medical practice", and SC 3 “Lung ventilators and related equipment” of ISO/TC 121 “Anaesthetic and respiratory equipment” was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 80601-2-71:2018.

The following dates are fixed:

• latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2018-12-22
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2021-06-22

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC shall not be held responsible for identifying any or all such patent rights.

Endorsement notice

The text of the International Standard IEC 80601-2-71:2015 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 60601-1-10	NOTE	Harmonized as EN 60601-1-10.
IEC 60601-1-11:2010 [1)]	NOTE	Harmonized as EN 60601-1-11:2010 (not modified).

[1)] Superseded by IEC 60601-1-11:2015.

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Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

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

NOTE 1 Where an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

Annex ZA of EN 60601-1:2006 applies except as follows:

Publication	Year	Title	EN/HD	Year
Replacement:				
IEC 60601-1-6	-	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	EN 60601-1-6	-
IEC 60825-1	2014	Safety of laser products - Part 1: Equipment classification and requirements	EN 60825-1	2014
Addition:				
IEC 60601-1	-	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	-
ISO 80601-2-61	-	Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment	EN ISO 80601-2-61	-
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	-	-

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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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.

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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.

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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.

[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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