SLOVENSKI STANDARD
SIST EN IEC 80601-2-71:2018

01-september-2018

Medicinska električna oprema - 2-71. del: Posebne zahteve za osnovno varnost in bistvene lastnosti funkcionalne opreme spektrometra v bližnjem infrardečem spektru (IEC 80601-2-71:2015)

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)

Ta slovenski standard je istoveten z: **EN IEC 80601-2-71:2018**

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11.040.55	Diagnostična oprema	Diagnostic equipment

SIST EN IEC 80601-2-71:2018 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 80601-2-71

June 2018

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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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN IEC 80601-2-71:2018 E

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• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2021-06-22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.

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	-	-

IEC 80601-2-71

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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
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CONTENTS

FOREWORD....4
INTRODUCTION....6
201.1 Scope, object and related standards....7
201.2 Normative references....9
201.3 Terms and definitions....9
201.4 General requirements....12
201.5 General requirements for testing ME EQUIPMENT....12
201.6 Classification of ME EQUIPMENT and ME SYSTEMS....12
201.7 ME EQUIPMENT identification, marking and documents....12
201.8 Protection against electrical HAZARDS from ME EQUIPMENT....12
201.9 Protection against mechanical HAZARDS of ME EQUIPMENT and ME SYSTEMS....13
201.10 Protection against unwanted and excessive radiation HAZARDS....13
201.11 Protection against excessive temperatures and other hazards....13
201.12 ACCURACY of controls and instruments and protection against hazardous outputs....13
201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT....21
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)....21
201.15 Construction of ME EQUIPMENT....21
201.16 ME SYSTEMS....21
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS....21
Annexes....22
Annex C (informative) Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS....22
Annex AA (informative) Particular guidance and rationale....23
Annex BB (normative) Evaluating ME EQUIPMENT performance using the FUNCTIONAL NIRS PHANTOM....25
Annex CC (informative) Reference to the essential principles....34
Bibliography....36
Index of defined terms....37

Figure 201.101 – FULL WIDTH AT HALF MAXIMUM of spectral power distribution....10
Figure 201.102 – Measurement of AVERAGE OPTICAL POWER....14
Figure 201.103 – Measurement of PEAK WAVELENGTH and FWHM....15
Figure 201.104 – Measurement of signal stability....16
Figure 201.105 – Measurement of RESPONSE TIME....17
Figure 201.106 – Rise time and fall time in RESPONSE TIME....18
Figure 201.107 – Measurement of signal-to-noise ratio....19
Figure 201.108 – Measurement of SIGNAL CROSS-TALK....21
Figure 201.BB.1 – The FUNCTIONAL NIRS PHANTOM in two states with different detected light intensities....28
Figure BB.2 – FUNCTIONAL NIRS PHANTOM measurement using the reference system....29

Figure BB.3 – FUNCTIONAL NIRS PHANTOM measurement using the ME EQUIPMENT to be evaluated 29
Figure BB.4 – Schematic for measurement of OPTICAL LOSS 32

Table 201.101 – Performance tests employing the FUNCTIONAL NIRS PHANTOM or attenuator and the required OPTICAL LOSS 13
Table 201.C.101 – Marking on the outside of FUNCTIONAL NIRS EQUIPMENT or their parts 22
Table 201.C.102 – ACCOMPANYING DOCUMENTS, instructions for use of FUNCTIONAL NIRS EQUIPMENT 22
Table CC.1 – Correspondence between this particular standard and the essential principles 34

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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International standard IEC 80601-2-71 has been prepared by a Joint Working Group of IEC subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice and ISO subcommittee SC3: Lung ventilators and related equipment, of ISO technical committee 121: Anaesthetic and respiratory equipment.

This publication is published as a double logo standard.

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

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

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

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

– Requirements and definitions: roman type.

– *Test specifications: italic type.*

– Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

– "clause" means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);

– "subclause" means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

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

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

– "may" is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in 0.

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

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

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

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

INTRODUCTION

The minimum safety requirements specified in this particular standard are considered to provide for a practical degree of safety in the operation of FUNCTIONAL NIRS EQUIPMENT.

The requirements are followed by specifications for the relevant tests.

A "Particular guidance and rationale" text giving some explanatory notes, where appropriate, about the more important requirements is included in Annex AA. It is considered that knowledge of the reasons for these requirements will not only facilitate the proper application of the standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However, this annex does not form part of the requirements of this standard.

MEDICAL ELECTRICAL EQUIPMENT –

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

201.1 Scope, object and related standards

Clause 1 of the general standard[1] applies, except as follows:

201.1.1 Scope

Replacement:

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

Not included within the scope of this particular standard are:

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

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

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

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

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

201.1.2 OBJECT

Replacement:

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

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

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