

STN	Zdravotnícke elektrické prístroje Časť 2-71: Osobitné požiadavky na základnú bezpečnosť a nevyhnutné prevádzkové vlastnosti prístrojov na funkčnú spektroskopiu v blízkej infračervenej oblasti (NIRS)	STN EN IEC 80601-2-71 36 4800
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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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 04/25

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN IEC 80601-2-71

February 2025

ICS 11.040.55

Supersedes EN IEC 80601-2-71:2018

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 80601-2-71:2025)**

Appareils électromédicaux - Partie 2-71: Exigences
particulières pour la sécurité de base et les performances
essentielles des appareils de spectroscopie dans le proche
infrarouge (NIRS) fonctionnelle
(IEC 80601-2-71:2025)

Medizinische elektrische Geräte - Teil 2-71: Besondere
Festlegungen für die Sicherheit einschließlich der
wesentlichen Leistungsmerkmale von funktionalen
Oximetriegeräten
(IEC 80601-2-71:2025)

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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

EN IEC 80601-2-71:2025 (E)**European foreword**

The text of document 62D/2169/FDIS, future edition 2 of IEC 80601-2-71, prepared by SC 62D "Particular medical equipment, software, and systems" of IEC/TC 62 "Medical equipment, software, and systems" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 80601-2-71:2025.

The following dates are fixed:

- latest date by which the document has to be implemented at national (dop) 2026-02-28 level by publication of an identical national standard or by endorsement
- latest date by which the national standards conflicting with the (dow) 2028-02-29 document have to be withdrawn

This document supersedes EN IEC 80601-2-71:2018 and all of its amendments and corrigenda (if any).

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Endorsement notice

The text of the International Standard IEC 80601-2-71:2025 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 standard indicated:

ISO 80601-2-85:2021	NOTE	Approved as EN ISO 80601-2-85:2021 (not modified)
ISO 80601-2-61:2017	NOTE	Approved as EN ISO 80601-2-61:2019 (not modified)
IEC 60601-1-10	NOTE	Approved as EN 60601-1-10
IEC 60601-2-57:2023	NOTE	Approved as EN IEC 60601-2-57:— ¹ (not modified)
ISO 14159:2002	NOTE	Approved as EN ISO 14159:2008 (not modified)

¹ Under preparation. Stage at the time of publication: FprEN IEC 60601-2-57:2023.

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.cencenelec.eu.

Annex ZA of EN 60601-1:2006², applies, except as follows:

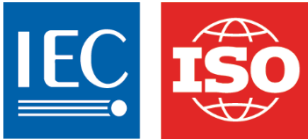
Add:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
-	-		+ AC	2010
+ A1	2012		+ A1	2013
-	-		+ AC	2014
-	-		+ A12	2014
+ A2	2020		+ A2	2021
-	-		+ AC	2022
-	-		+ A13	2024
IEC 60825-1	2014	Safety of laser products - Part 1: Equipment classification and requirements	EN 60825-1	2014
-	-		+ A11	2021
-	-		+ AC	2017-06
IEC 62471 (mod)	2006	Photobiological safety of lamps and lamp systems	EN 62471	2008
IEC 62570	2014	Standard practice for marking medical devices and other items for safety in the magnetic resonance environment	EN 62570	2015

² As impacted by EN 60601-1:2006/AC:2010, EN 60601-1:2006/A1:2013, EN 60601-1:2006/A1:2013/AC:2014, EN 60601-1:2006/A12:2014, EN 60601-1:2006/A2:2021, EN 60601-1:2006/AC:2022-12 and EN 60601-1:2006/A13:2024.

EN IEC 80601-2-71:2025 (E)

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
ISO 17664-1	2021	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices	EN ISO 17664-1	2021
ISO 17664-2	2021	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 2: Non-critical medical devices	EN ISO 17664-2	2023
ISO 20417	2021	Medical devices - Information to be supplied by the manufacturer	EN ISO 20417	2021



IEC 80601-2-71

Edition 2.0 2025-01

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment –

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

Appareils électromédicaux –

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

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Edition 2.0 2025-01

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment –

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

Appareils électromédicaux –

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

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

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INTERNATIONALE

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CONTENTS

FOREWORD.....	4
INTRODUCTION.....	7
201.1 Scope, object and related standards.....	8
201.2 Normative references	10
201.3 Terms and definitions	10
201.4 General requirements.....	14
201.5 General requirements for testing ME EQUIPMENT	14
201.6 Classification of ME EQUIPMENT and ME SYSTEMS.....	14
201.7 ME EQUIPMENT identification, MARKING and documents	14
201.8 Protection against electrical HAZARDS from ME EQUIPMENT	16
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS.....	16
201.10 Protection against unwanted and excessive radiation HAZARDS	16
201.11 Protection against excessive temperatures and other HAZARDS	16
201.12 Accuracy of controls and instruments and protection against hazardous outputs	18
201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT.....	29
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	29
201.15 Construction of ME EQUIPMENT	29
201.16 ME SYSTEMS	30
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	30
201.101 Requirements for the FUNCTIONAL NIRS EQUIPMENT ACCESSORIES	30
202 Electromagnetic disturbances – Requirements and tests.....	30
206 Usability.....	31
Annexes	32
Annex C (informative) Guide to MARKING and labelling requirements for ME EQUIPMENT and ME SYSTEMS	33
Annex AA (informative) Particular guidance and rationale	35
ANNEX BB (normative) Evaluating ME EQUIPMENT performance using the FUNCTIONAL NIRS PHANTOM.....	39
ANNEX CC (informative) Skin temperature at the FUNCTIONAL NIRS PROBE.....	48
Annex DD (informative) Reference to the IMDRF essential principles and labelling guidance	49
Bibliography.....	51
Index of defined terms	55
Figure 201.101 – FULL WIDTH AT HALF MAXIMUM OF SPECTRAL POWER DISTRIBUTION	11
Figure 201.102 – Measurement of the AVERAGE OPTICAL POWER.....	19
Figure 201.103 – Measurement of PEAK WAVELENGTH and FWHM	20
Figure 201.104 – Measurement of the signal stability.....	22
Figure 201.105 – Measurement of the RESPONSE TIME	23
Figure 201.106 – Rise time and fall time in the RESPONSE TIME.....	24
Figure 201.107 – Measurement of the signal-to-noise ratio of the detected light intensity	25

Figure 201.108 – Measurement of signal-to-noise ratio of the PATHLENGTH-DEPENDENT HAEMOGLOBIN CHANGE	27
Figure 201.109 – Measurement of SIGNAL CROSS-TALK.....	28
Figure BB.1 – The FUNCTIONAL NIRS PHANTOM in two states with different detected light intensities	42
Figure BB.2 – FUNCTIONAL NIRS PHANTOM measurement using the reference system.....	43
Figure BB.3 – FUNCTIONAL NIRS PHANTOM measurement using the ME EQUIPMENT to be evaluated	43
Figure BB.4 – Schematic for measurement of OPTICAL LOSS	47
Table 201.101 – Distributed ESSENTIAL PERFORMANCE requirements.....	14
Table 201.102 – Performance tests employing the FUNCTIONAL NIRS EQUIPMENT or attenuator and the required OPTICAL LOSS.....	19
Table 201.C.101 – MARKING on the outside of FUNCTIONAL NIRS EQUIPMENT or their parts.....	33
Table 201.C.102 – ACCOMPANYING DOCUMENTS general	33
Table 201.C.103 – INSTRUCTIONS FOR USE	34
Table 201.C.104 – TECHNICAL DESCRIPTION	34
Table DD.1 – Correspondence between this document and the IMDRF essential principles	49
Table DD.2 – Correspondence between this document and the IMDRF labelling principles	50

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

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IEC 80601-2-71 has been prepared by a Joint Working Group of IEC subcommittee 62D: Particular medical equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems, and ISO subcommittee SC3: Respiratory devices and related equipment used for patient care, of ISO technical committee 121: Anaesthetic and respiratory equipment. It is an International Standard.

This second edition cancels and replaces the first edition published in 2015. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

- a) alignment with IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020, IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012, IEC 60601-1-8:2006/AMD2:2020, IEC 60601-1-2:2014, IEC 60601-1-2:2014/AMD1:2020, IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013 and IEC 60601-1-6:2010/AMD2:2020;
- b) added requirements for ESSENTIAL PERFORMANCE;
- c) added requirements for PRIMARY OPERATING FUNCTIONS;
- d) added requirements for protection against excessive temperatures;
- e) added requirements for the display legibility for OPERATORS wearing personal protective equipment;
- f) harmonization with ISO 20417, where appropriate.

This publication is published as a double logo standard.

The text of this International Standard is based on the following documents of IEC:

Draft	Report on voting
62D/2169/FDIS	62D/2196/RVD

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications.

In this document, 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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 AND IEC 60601-1:2005/AMD2:2020, IN THIS DOCUMENT OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this document, 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 document are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

In this document, 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 document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

- "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;
- "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;
- "may" is used to describe a permissible way to achieve compliance with a requirement or test.

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

A list of all parts of the IEC 80601 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 document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn, or
- revised.

NOTE The attention of the users of this document 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 document 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 document.

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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.1.1 Scope

Replacement:

This part of IEC 80601 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of FUNCTIONAL NIRS EQUIPMENT, as defined in 201.3.205, intended to be used by itself, or as a part of an ME SYSTEM hereinafter referred to as ME EQUIPMENT.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this document are not covered by specific requirements in this document except in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 7.2.13 and 8.4.1.

NOTE Additional information can be found in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 4.2.

This document is not applicable to

- equipment for the measurement of oxygen saturation of the haemoglobin in the micro vessels (capillaries, arterioles and venules), i.e. tissue oximeters;
- frequency-domain and time-domain equipment for functional near-infrared spectroscopy;
- equipment for the measurement of changes in the concentration of chromophores other than oxy- and deoxy-haemoglobin;
- equipment for the measurement of changes in the concentration of oxy- and deoxy-haemoglobin in tissues other than the brain.

This document does not specify the requirements for:

- cerebral tissue oximeter equipment, which are given in ISO 80601-2-85 [1]¹; and
- pulse oximeter equipment, which are given in ISO 80601-2-61 [2].

201.1.2 Object

Replacement:

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

NOTE This document has been prepared to address the relevant essential principles [3] and labelling principles [4] of the International Medical Devices Regulators Forum (IMDRF) as indicated in Annex DD.

¹ Numbers in square brackets refer to the Bibliography.

201.1.3 Collateral standards

Addition:

This document refers to those applicable collateral standards that are listed in Clause 2 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and Clause 201.2 of this document.

IEC 60601-1-3 and IEC 60601-1-10 [5] do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Addition:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, including the collateral standards, as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY or ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and applicable collateral standards.

The numbering of clauses and subclauses of this particular standard corresponds to that of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020) 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 document addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.6 in this document addresses the content of Clause 6 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are specified by the use of the following words:

"Replacement" means that the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard is replaced completely by the text of this document.

"Addition" means that the text of this document additional to the requirements of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard.

"Amendment" means that the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard is amended as indicated by the text of this document.

Subclauses, figures or tables which are additional to those of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered starting from 201.101. However due to the fact that definitions in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered 3.1 through 3.154, additional definitions in this document 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.

Where there is no corresponding clause or subclause in this document, the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this document.

201.2 Normative references

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.

Clause 2 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

Addition:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

IEC 60601-1:2005/AMD1:2012

IEC 60601-1:2005/AMD2:2020

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

IEC 62471:2006, *Photobiological safety of lamps and lamp systems*

IEC 62570:2014, *Standard practice for marking medical devices and other items for safety in the magnetic resonance environment*

ISO 17664-1:2021, *Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices – Part 1: Critical and semi-critical medical devices*

ISO 17664-2:2021, *Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices – Part 2: Non-critical medical devices*

ISO 20417:2021, *Medical devices – Information to be supplied by the manufacturer*

koniec náhľadu – text ďalej pokračuje v platenej verzii STN