

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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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 6 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.

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- 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.

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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 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].

201.2 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.