IEC 80601-2-71

Edition 1.0 2015-06

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

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

IEC 80601-2-71:2015-06(en-fr)

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

ICS 11.040.55

ISBN 978-2-8322-6318-1

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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

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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.

This bilingual version (2018-11) corresponds to the monolingual English version, published in 2015-06.

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.

The French version of this standard has not been voted upon.

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 Annex AA.

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.

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- withdrawn,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

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*.