SLOVENSKI STANDARD
oSIST prEN IEC 80601-2-23:2024

01-julij-2024

Medicinska električna oprema - 2-23. del: Posebne zahteve za osnovno varnost in bistvene lastnosti opreme za skozikožno (transkutano) nadzorovanje delnega (parcialnega) krvnega tlaka

Medical electrical equipment - Part 2-23: Particular requirements for the basic safety and essential performance of transcutaneous partial pressure monitoring equipment

Medizinische elektrische Geräte - Teil 2-23: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Geräten für die transkutane Partialdrucküberwachung

Appareils électromédicaux - Partie 2-23: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de surveillance de la pression partielle transcutanée

Ta slovenski standard je istoveten z: **prEN IEC 80601-2-23:2024**

ICS:

11.040.55	Diagnostična oprema	Diagnostic equipment

oSIST prEN IEC 80601-2-23:2024 **en**

62D/2133/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER:	
IEC 80601-2-23 ED1	
DATE OF CIRCULATION:	CLOSING DATE FOR VOTING:
2024-06-07	**2024-08-30**
SUPERSEDES DOCUMENTS:	
62D/2037A/RR	

IEC SC 62D : PARTICULAR MEDICAL EQUIPMENT, SOFTWARE, AND SYSTEMS

SECRETARIAT:	SECRETARY:
United States of America	Ms Ladan Bulookbashi
OF INTEREST TO THE FOLLOWING COMMITTEES:	PROPOSED HORIZONTAL STANDARD: ☐ Other TC/SCs are requested to indicate their interest, if any, in this CDV to the secretary.

FUNCTIONS CONCERNED:

☐ EMC ☐ ENVIRONMENT ☐ QUALITY ASSURANCE ☒ SAFETY

☒ SUBMITTED FOR CENELEC PARALLEL VOTING	☐ NOT SUBMITTED FOR CENELEC PARALLEL VOTING
Attention IEC-CENELEC parallel voting The attention of IEC National Committees, members of CENELEC, is drawn to the fact that this Committee Draft for Vote (CDV) is submitted for parallel voting. The CENELEC members are invited to vote through the CENELEC online voting system.	

This document is still under study and subject to change. It should not be used for reference purposes.

Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Recipients of this document are invited to submit, with their comments, notification of any relevant “In Some Countries” clauses to be included should this proposal proceed. Recipients are reminded that the CDV stage is the final stage for submitting ISC clauses. (SEE AC/22/2007 OR NEW GUIDANCE DOC).

TITLE:

Medical electrical equipment - Part 2-23: Particular requirements for the basic safety and essential performance of transcutaneous partial pressure monitoring equipment

PROPOSED STABILITY DATE: 2030

NOTE FROM TC/SC OFFICERS:

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-23: Particular requirements for the basic safety and essential performance of transcutaneous partial pressure monitoring 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 60601-2-23 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 fourth edition cancels and replaces the third edition published in 2011. This edition constitutes a technical revision to align with Amendment 1:2012 and Amendment 2:2020 of IEC 60601-1:2005, new versions of collateral standards and amendments thereto.

Further it includes the following technical changes:

– Expansion of the scope to the EMERGENCY MEDICAL SERVICE ENVIRONMENT and HOME HEALTHCARE ENVIRONMENT

– Changed ESSENTIAL PERFORMANCE in Table 201.101

– Changed requirement for ingress protection

159 – Added PRIMARY OPERATING FUNCTIONS
160 – Added requirements for ALARM SYSTEM logging
161

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

FDIS	Report on voting
62DXX/FDIS	62D/XX/RVD

Full information on the voting for the approval of this particular standard can be found in the report on voting indicated in the above table.

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 twenty 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.

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.

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 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.

The National Committees are requested to note that for this document the stability date is 20xx. This text is included for the information of the national committees and will be deleted at the publication stage.

INTRODUCTION

This particular standard concerns the BASIC SAFETY and ESSENTIAL PERFORMANCE of TRANSCUTANEOUS PARTIAL PRESSURE MONITORS. It amends and supplements IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*, hereinafter referred to as the general standard.

The aim of this fourth edition is to bring this particular standard up to date with reference to the edition 3.2 of the general standard and new versions of collateral standards and amendments thereto through technical changes.

The requirements of this particular standard take priority over those of the general standard and collateral standards.

A “General guidance and rationale” for the more important requirements of this particular standard 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, Annex AA does not form part of the requirements of this document.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-23: Particular requirements for the basic safety and essential performance of transcutaneous partial pressure monitoring 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 part of IEC 60601 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of TRANSCUTANEOUS PARTIAL PRESSURE MONITORS as defined in 201.3.203 hereinafter also referred to as ME EQUIPMENT or ME SYSTEM.

This document applies to TRANSCUTANEOUS PARTIAL PRESSURE MONITORS intended for use in professional healthcare facilities in the EMERGENCY MEDICAL SERVICE ENVIRONMENT or the HOME HEALTHCARE ENVIRONMENT.

This standard applies to TRANSCUTANEOUS PARTIAL PRESSURE MONITORS used with adults, children and neonates, and it includes the use of these devices in foetal monitoring during birth.

This standard does not apply to haemoglobin saturation oximeters or to devices applied to surfaces of the body other than the skin (for example conjunctiva, mucosa).

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as follows:

The clause or subclause applies to ME EQUIPMENT, as default. For ME EQUIPMENT with the corresponding safety measure or function not completely integrated into the ME EQUIPMENT but instead implemented in an ME SYSTEM, the ME EQUIPMENT MANUFACTURER shall specify in the ACCOMPANYING DOCUMENTS which functionality and safety requirements shall be provided by the ME SYSTEM to comply with this standard. The ME SYSTEM has to be verified accordingly.

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.

NOTE See also 4.2 of the General Standard.

201.1.2 Object

Replacement:

The object of this particular standard is to establish BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for TRANSCUTANEOUS PARTIAL PRESSURE MONITORS as defined in 201.3.203.

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1 The general standard is IEC 60601-1:2005 , IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*