SLOVENSKI STANDARD
oSIST prEN IEC 60601-2-91:2024

01-februar-2024

Posebne zahteve za osnovno varnost in bistveno delovanje opreme za zdravljenje ran z netermično plazmo

Particular requirement for basic safety and essential performance of non-thermal plasma wound treatment equipment

Exigences particulières pour la sécurité de base et les performances essentielles des appareils de traitement des plaies par plasma non thermique

Ta slovenski standard je istoveten z: **prEN IEC 60601-2-91:2023**

ICS:

11.040.99	Druga medicinska oprema	Other medical equipment
11.140	Oprema bolnišnic	Hospital equipment

oSIST prEN IEC 60601-2-91:2024 **en**

62D/2091/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER: **IEC 60601-2-91 ED1**	
DATE OF CIRCULATION: **2023-11-24**	CLOSING DATE FOR VOTING: **2024-02-16**
SUPERSEDES DOCUMENTS: **62D/2020/CD, 62D/2045A/CC**	

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

SECRETARIAT: United States of America	SECRETARY: 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:

Particular requirement for basic safety and essential performance of non-thermal plasma wound treatment equipment

PROPOSED STABILITY DATE: 2029

NOTE FROM TC/SC OFFICERS:

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT

Part 2-91: Particular requirements for the basic safety and essential performance of non-thermal plasma wound treatment equipment

FOREWORD

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

Draft	Report on voting
62D/1904/NP	62D/1933/RVN

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 the editorial rules of 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/standardsdev/publications.

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

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- withdrawn,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

INTRODUCTION

The minimum safety requirements specified in this particular standard are considered to provide for a practical degree of safety in the operation of non-thermal plasma wound treatment equipment.

This particular standard amends and supplements IEC 60601-1: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance, hereinafter referred to as the general standard.

The requirements are followed by specifications for the relevant tests.

A "Particular guidance and rationale" section giving some explanatory notes, where appropriate, about the more important requirements is included in annex AA.

Clauses or subclauses for which there are explanatory notes in annex AA are marked with an asterisk (*).

It is considered that a 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 2-91: Particular requirements for the basic safety and essential performance of non-thermal plasma wound treatment 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 NON-THERMAL PLASMA WOUND TREATMENT EQUIPMENT hereafter referred to as ME EQUIPMENT.

NON-THERMAL PLASMA WOUND TREATMENT EQUIPMENT apples to chronic and acute wounds as well as diverse skin and itching diseases

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 7.2.13 of the general standard.

This document does not apply to:

- ME EQUIPMENT intended for the haemostasis in biological tissue by using ionized gas (see IEC 60601-2-76)

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for NON-THERMAL PLASMA WOUND TREATMENT EQUIPMENT, as defined in 201.3.204.

201.1.3 Collateral standards

Addition:

IEC 60601-1-3, IEC 60601-1-10 and IEC 60601-1-11 do not apply. All other published collateral standards listed in Clause 2 of IEC 60601-1 series and Clause 201.2 of this particular standard apply to this particular standard.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard. Collateral standards are referred to by their document numbers.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix “201” (e.g. 201.1 in this document addresses the content of Clause 1 of the general standard) 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 particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

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.*

"*Replacement*" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

"*Addition*" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

"*Amendment*" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101, however because definitions in the general standard are numbered 3.1 through 3.147 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.

The term "this document" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

NOTE Informative references are listed in the bibliography

Clause 2 of the general standard 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

201.3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

Addition:

201.3.201
ACTIVE TREATED ZONE
area of the treated tissue during INTENDED USE

201.3.202
NON-THERMAL PLASMA
partially ionized gas consisting of reactive species with electrons, ions, ambient molecules, and electromagnetic radiation

201.3.203
NON-THERMAL PLASMA WOUND TREATMENT ACCESSORY
ACCESSORY intended to direct NON-THERMAL PLASMA to the PATIENT

201.3.204
NON-THERMAL PLASMA WOUND TREATMENT EQUIPMENT
ME EQUIPMENT that treat wounds together with related NON-THERMAL PLASMA WOUND TREATMENT ACCESSORY using NON-THERMAL PLASMA for the purpose of promoting wound recovery

201.3.205
REACTIVE SPECIES
excited atoms or molecules consisting of unpaired electrons in their quantum mechanical energy states

201.3.206
WOUND TREATMENT
action of treatment by NON-THERMAL PLASMA to wound tissue

201.4 General requirements

Clause 4 of the general standard applies, except as follows:

201.4.3 ESSENTIAL PERFORMANCE

Addition:

The requirements listed in 201.11.101 shall be considered ESSENTIAL PERFORMANCE requirements.

201.5 General requirements for testing ME EQUIPMENT

Clause 5 of the general standard applies.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies.

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of the general standard applies, except as follows:

201.7.9.2.2 Warnings and safety notices

Addition:

Do not allow NON-THERMAL PLASMA WOUND TREATMENT ACCESSORIES to come in direct contact with the PATIENTS' eyes, unless the RISK MANAGEMENT PROCESS demonstrates that no unacceptable RISK exists from contact with the eye.

Additional subclause:

201.7.9.2.2.101 Additional information in the instructions for use

The instructions for use shall include:

- The recommended usage distance (INTENDED USE distance) between the APPLIED PART and the PATIENT.
- The area of the ACTIVE TREATED ZONE.
- The maximum generated amount of REACTIVE SPECIES (example: ozone, nitrogen monoxide, and nitrogen dioxide [7, 8]) at the INTENDED USE distance, as well as the accumulated amount of each in a closed volume after the recommended treatment time.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT and ME SYSTEMS

201.8.3 Classification of APPLIED PARTS

Addition:

aa) A NON-THERMAL PLASMA WOUND TREATMENT ACCESSORY shall be considered an APPLIED PART.

201.8.7.3 Allowable values