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Project No. 2021/03579

Responsible committee: CH/62/4 Electromedical equipment

Interested committees:

Title: BS EN 60601-2-91 Particular requirement for basic safety and essential performance of non-thermal plasma wound treatment equipment

Please notify the secretary if you are aware of any keywords that might assist in classifying or identifying the standard or if the content of this standard

- i) has any issues related to 3rd party IPR, patent or copyright
- ii) affects other national standard(s)
- iii) requires additional national guidance or information

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Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

UK Vote

Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

Submission of Comments

- **Annotated drafts are not acceptable and will be rejected.**
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Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
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MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/Figure/ Table/Note	Type of comment	Commend (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	

PROJECT NUMBER: IEC 60601-2-91 ED1	
DATE OF CIRCULATION: 2023-01-27	CLOSING DATE FOR COMMENTS: 2023-04-21
SUPERSEDES DOCUMENTS: 62D/1904/NP, 62D/1933A/RVN	

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 CD to the secretary.
FUNCTIONS CONCERNED: ☐ EMC ☐ ENVIRONMENT ☐ QUALITY ASSURANCE ☒ SAFETY	

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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,
- any local regulations or technical reasons that may exist and should be considered should this proposal proceed, recognizing that failure to address such requirements could result in the need for new or existing "in some countries" clauses. See AC/22/2007.

TITLE: Particular requirement for basic safety and essential performance of non-thermal plasma wound treatment equipment
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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

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- amended.