Draft for Public Comment

Form 36

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Project No. 2021/00216

Responsible committee: CH/62/4 Electromedical equipment

Interested committees:

Title: Draft BS EN IEC 60601-2-83 Amendment 1 - Medical electrical equipment. Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy 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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This draft is issued to allow comments from interested parties; all comments will be given consideration prior to publication. No acknowledgement will normally be sent. **See overleaf for information on the submission of comments.**

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Information on the co-operating organizations represented on the committees referenced above may be obtained from https://standardsdevelopment.bsigroup.com/.

Responsible Committee Secretary: Miss Jacinta Hampton (BSI)
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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 Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.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.**
- All comments should be submitted online at **https://standardsdevelopment.bsigroup.com/**. You will need to register in order to comment.

Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx

1	2	(3)	4	5	(6)	7
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.	

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62D/1857/CD

COMMITTEE DRAFT (CD)

PROJECT NUMBER: **IEC 60601-2-83/AMD1 ED1**	
DATE OF CIRCULATION: **2021-04-30**	CLOSING DATE FOR COMMENTS: **2021-06-25**
SUPERSEDES DOCUMENTS: **62D/1810/RR**	

IEC SC 62D : ELECTROMEDICAL EQUIPMENT	
SECRETARIAT: United States of America	SECRETARY: Ms Hae Choe
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	

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.

TITLE:

Amendment 1 - Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment

NOTE FROM TC/SC OFFICERS:

The first edition of IEC 60601-2-83 was published in May 2019. This standard is amended to align with the 2020 amendments of IEC 60601-1 and its collateral standards. Initial experiences with this new standard might reveal a need for adaptation of its requirements. Therefore, National Committees are invited to submit comments in case they identified any such need. No comments were received in the previous consultation; see 62D/1792/DC, 62D/1808/INF and 62D/1810/RR.

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