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Date: 24 July 2015
Origin: International

Latest date for receipt of comments: 30 September 2015

Project No. 2015/01310

Responsible committee: CH/62/4 Electromedical equipment

Interested committees:

Title: Draft BS EN 80601-2-58:2015/A1 Medical electrical equipment

Part 2-58: Particular requirements for basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery Amendment 1 Proposed horizontal standard

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

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Introduction

This draft standard is based on international discussions in which the UK has taken an active part. Your comments on this draft are welcome and will assist in the preparation of the consequent standard. There is a high probability that this text could be adopted by CENELEC as a reference document for harmonization or as a European Standard. Recipients of this draft are requested to comment on the text bearing in mind this possibility.

UK Vote

Please indicate whether you consider the UK should submit a negative (with reasons) or positive vote on this draft.

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Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	(7)
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/ Figure/ Table/Note	Type of comment	Comment (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.	



DRAFT AMENDMENT IEC/DIS 80601-2-58:2014/DAM 1

ISO/TC 172/SC 7

Secretariat: **DIN**

Voting begins on
2015-07-24

Voting terminates on
2015-10-24

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Medical electrical equipment —

Part 2-58:

Particular requirements for basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery

AMENDMENT 1: Proposed Horizontal Standard

Appareils électromédicaux —

Partie 2-58: Exigences particulières pour la sécurité de base et les performances essentielles des dispositifs de retrait du cristallin et des dispositifs de vitrectomie pour la chirurgie ophtalmique

AMENDEMENT 1: Proposition de Norme Horizontale

ICS 11.040.70

This draft is submitted to a parallel enquiry in ISO and a CDV vote in the IEC.

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FOREWORD

This amendment has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice, and subcommittee SC 7: Ophthalmic optics and instruments of ISO technical committee 172: Optics and photonics.

This Amendment modifies the content of the second edition of IEC 80601-2-58 published in 2014. This Amendment constitutes a technical revision.

This Amendment includes the following significant technical changes with respect to the second edition:

- a) Integration of updated definition of ESSENTIAL PERFORMANCE and updating the ESSENTIAL PERFORMANCE analysis;
- b) Updating collateral and general standard references to align with amendments to the general standard and other collateral standards;
- c) Addition of symbols to standard;
- d) Update of EMC requirements

It is published as a double logo standard.

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

FDIS	Report on voting
62D/XXXX/FDIS	62D/XXXX/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.

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.

The National Committees are requested to note that for this publication the stability date is 2020.

THIS TEXT IS INCLUDED FOR THE INFORMATION OF THE NATIONAL COMMITTEES AND WILL BE DELETED AT THE PUBLICATION STAGE.

201.1.3 Collateral standards

Replace the existing text of the second paragraph with the following: