

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

**Medical electrical equipment –
Part 2-58: Particular requirements for the basic safety and essential performance
of lens removal devices and vitrectomy devices for ophthalmic surgery**

**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**



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IEC Central Office
3, rue de Varembe
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
Fax: +41 22 919 03 00
info@iec.ch
www.iec.ch

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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.

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

FDIS	Report on voting
62D/1364/FDIS	62D/1370/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. In ISO, the standard has been approved by 11 P members out of 11 having cast a vote.

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- withdrawn,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.

INTRODUCTION TO THE AMENDMENT

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) undating 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.

201.1.3 Collateral standards

Replace the existing title of this subclause by the following new title:

201.1.3 * Collateral standards

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

IEC 60601-1-2 applies as modified in Clause 202. IEC 60601-1-3, IEC 60601-1-10, IEC 60601-1-11, and IEC 60601-1-12 do not apply.