

STN	Zdravotnícke elektrické prístroje. Časť 2-60: Osobitné požiadavky na základnú bezpečnosť a nevyhnutné prevádzkové vlastnosti stomatologických prístrojov.	STN EN 80601-2-60 36 4800
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Medical electrical equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 11/15

Obsahuje: EN 80601-2-60:2015, IEC 80601-2-60:2012

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Úrad pre normalizáciu, metrológiu a skúšobníctvo SR, 2015
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rozmnožovať a rozširovať iba so súhlasom Úradu pre normalizáciu, metrológiu a skúšobníctvo SR.

EUROPEAN STANDARD

EN 80601-2-60

NORME EUROPÉENNE

EUROPÄISCHE NORM

May 2015

ICS 11.040.01

English Version

**Medical electrical equipment - Part 2-60: Particular requirements
for the basic safety and essential performance of dental
equipment
(IEC 80601-2-60:2012)**

Appareils électromédicaux - Partie 2-60: Exigences
particulières pour la sécurité de base et les performances
essentiels des équipements dentaires
(IEC 80601-2-60:2012)

Medizinische elektrische Geräte -- Teil 2-60: Besondere
Festlegungen an die Sicherheit einschließlich der
wesentlichen Leistungsmerkmale von Dental-Geräten
(IEC 80601-2-60:2012)

This European Standard was approved by CENELEC on 2015-04-14. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CENELEC member.

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European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Foreword

The text of document 62D/964/FDIS, future edition 1 of IEC 80601-2-60, prepared by SC 62D, "Electromedical equipment", of IEC/TC 62, "Electrical equipment in medical practice" and SC 6 "Dental equipment" of ISO/TC 106 "Dentistry" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 80601-2-60:2015.

The following dates are fixed:

- latest date by which the document has (dop) 2016-01-14
to be implemented at national level by
publication of an identical national
standard or by endorsement
- latest date by which the national (dow) 2018-04-14
standards conflicting with the
document have to be withdrawn

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive see informative Annex ZZ, which is an integral part of this document.

Endorsement notice

The text of the International Standard IEC 80601-2-60:2012 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 61810-7:2006	NOTE	Harmonized as EN 61810-7:2006 (not modified).
ISO 13732-1:2006	NOTE	Harmonized as EN ISO 13732-1:2008 (not modified).
ISO 17664:2004	NOTE	Harmonized as EN ISO 17664:2004 (not modified).
ISO 7494-2:2003	NOTE	Harmonized as EN ISO 7494-2:2003 (not modified).
ISO 21530:2004	NOTE	Harmonized as EN ISO 21530:2004 (not modified).

Annex ZA (normative)

Normative references to international publications with their corresponding European publications

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Annex ZA of EN 60601-1:2006 applies with the following exceptions:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
<i>Replacement:</i>				
IEC 60664-1	2007	Insulation coordination for equipment within low-voltage systems - Part 1: Principles, requirements and tests	EN 60664-1	2007
IEC 60825-1	-	Safety of laser products - Part 1: Equipment classification and requirements	EN 60825-1	-
<i>Addition:</i>				
IEC 60601-2-2	2009	Medical electrical equipment - Part 2-2: Particular requirements for basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories	EN 60601-2-2 + A11	2009 2011
IEC 60601-2-22	2007	Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, therapeutic and diagnostic laser equipment	-	-
IEC 60601-2-57	2011	Medical electrical equipment - Part 2-57: Particular requirements for basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use	EN 60601-2-57	2011
IEC 60664-4	2005	Insulation coordination for equipment within low-voltage systems - Part 4: Consideration of high-frequency voltage stress	EN 60664-4 + corr. October	2006 2006
IEC 61180-1	-	High-voltage test techniques for low-voltage equipment - Part 1: Definitions, test and procedure requirements	EN 61180-1	-
IEC 61180-2	-	High-voltage test techniques for low-voltage equipment - Part 2: Test equipment	EN 61180-2	-
IEC 61810-1 + corr. February	2008 2010	Electromechanical elementary relays - Part 1: General requirements	EN 61810-1	2008
IEC 62471	-	Photobiological safety of lamps and lamp systems	EN 62471	-
ISO 1942	-	Dentistry - Vocabulary	EN ISO 1942	-

EN 80601-2-60:2015 (E)

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
ISO 7785-2	-	Dental handpieces - Part 2: Straight and geared angle handpieces	EN ISO 7785-2	-

Annex ZZ (informative)

Coverage of Essential Requirements of EU Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and within its scope the Standard covers all relevant essential requirements given in Annex I of EU Directive 93/42/EEC of 14 June 1993 concerning medical devices.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

WARNING: Other requirements and other EU Directives can be applied to the products falling within the scope of this standard.



IEC 80601-2-60

Edition 1.0 2012-02

INTERNATIONAL STANDARD

NORME INTERNATIONALE

**Medical electrical equipment –
Part 2-60: Particular requirements for the basic safety and essential performance
of dental equipment**

**Appareils électromédicaux –
Partie 2-60: Exigences particulières pour la sécurité de base et les performances
essentiels des équipements dentaires**



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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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IEC 80601-2-60

Edition 1.0 2012-02

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment –

**Part 2-60: Particular requirements for the basic safety and essential performance
of dental equipment**

Appareils électromédicaux –

**Partie 2-60: Exigences particulières pour la sécurité de base et les performances
essentiels des équipements dentaires**

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –**Part 2-60: Particular requirements for the basic safety
and essential performance of dental equipment****FOREWORD**

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International standard IEC 80601-2-60 has been prepared by a Joint Working Group of subcommittee 62D: Electrical equipment in medical practice of IEC technical committee 62: Electrical equipment in medical practice and subcommittee 6: Dental equipment of ISO technical committee 106: Dentistry.

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

FDIS	Report on voting
62D/964/FDIS	62D/984/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 16 P-members out of 17 having cast a vote.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

- Requirements and definitions: roman type.
- *Test specifications: italic type.*
- Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

- “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
- “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 60601 series, published under the general title: *Medical electrical equipment*, can be found on the IEC website.

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.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment

201.1 Scope, object and related standards

Clause 1 of the general standard¹⁾ applies, except as follows:

201.1.1 Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of DENTAL UNITS, DENTAL PATIENT CHAIRS, DENTAL HANDPIECES and DENTAL OPERATING LIGHTS, hereafter referred to as DENTAL EQUIPMENT.

Excluded are amalgamators, sterilizers and dental X-ray equipment.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1 of the general standard.

NOTE See also 4.2 of the general standard.

201.1.2 Object

Replacement:

The object of this particular standard is to establish BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for DENTAL EQUIPMENT (as defined in 201.3.202.)

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

IEC 60601-1-3, IEC 60601-1-9²⁾ and IEC 60601-1-10³⁾ do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

¹⁾ The general standard is IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.

²⁾ IEC 60601-1-9:2007, *Medical electrical equipment – Part 1-9: General requirements for basic safety and essential performance – Collateral Standard: Requirements for environmentally conscious design*

³⁾ IEC 60601-1-10:2007, *Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers*

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.

For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

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 standard 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 IEC 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"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, due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard 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 standard" 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 relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

Clause 2 of the general standard applies, except as follows:

Replacement:

IEC 60664-1:2007, *Insulation coordination for equipment within low-voltage systems – Part 1: Principles, requirements and tests*

IEC 60825-1, *Safety of laser products – Part 1: Equipment classification and requirements*

Addition:

IEC 60601-2-2:2009, *Medical electrical equipment – Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories*

IEC 60601-2-22:2007, *Medical electrical equipment – Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment*

IEC 60601-2-57:2011, *Medical electrical equipment – Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use*

IEC 60664-4:2005, *Insulation coordination for equipment within low-voltage systems – Part 4: Consideration of high-frequency voltage stress*

IEC 61180-1, *High-voltage test techniques for low-voltage equipment – Part 1: Definitions, test and procedure requirements*

IEC 61180-2, *High-voltage test techniques for low-voltage equipment – Part 2: Test equipment*

IEC 61810-1:2008, *Electromechanical elementary relays – Part 1: General requirements*

IEC 62471, *Photobiological safety of lamps and lamp systems*

ISO 1942, *Dentistry – Vocabulary*

ISO 7785-2, *Dental handpieces – Part 2: Straight and geared angle handpieces*

koniec náhľadu – text ďalej pokračuje v platenej verzii STN