



# SLOVENSKI STANDARD

## SIST EN 80601-2-60:2015

01-september-2015

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### Medicinska električna oprema - 2-60. del: Posebne zahteve za osnovno varnost in bistvene lastnosti zobozdravstvene opreme

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

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

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

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Ta slovenski standard je istoveten z: **EN 80601-2-60:2015**

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#### **ICS:**

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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  
essentielles 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.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.



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**

EN 80601-2-60:2015 (E)

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- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2018-04-14

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	-

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## **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.

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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

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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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 standard<sup>1)</sup> 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 60601-1-9<sup>2)</sup> and IEC 60601-1-10<sup>3)</sup> 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*