SLOVENSKI STANDARD
SIST EN 60601-2-65:2013/A2:2021

01-september-2021

Medicinska električna oprema - 2-65. del: Posebne zahteve za osnovno varnost in bistvene lastnosti za intraoralni zobni rentgen - Dopolnilo A2 (IEC 60601-2-65:2012/A2:2021)

Medical electrical equipment - Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment (IEC 60601-2-65:2012/A2:2021)

Medizinische elektrische Geräte - Teil 2-65: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von intraoralen zahnärztlichen Röntgeneinrichtungen (IEC 60601-2-65:2012/A2:2021)

Appareils élecromédicaux - Partie 2-65: Exigences particulières pour la sécurité de base et les performances essentielles des appareils à rayonnement X dentaires intra-oraux (IEC 60601-2-65:2012/A2:2021)

Ta slovenski standard je istoveten z: **EN 60601-2-65:2013/A2:2021**

ICS:

11.060.20	Zobotehnična oprema	Dental equipment
13.280	Varstvo pred sevanjem	Radiation protection

SIST EN 60601-2-65:2013/A2:2021 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-65:2013/A2

June 2021

ICS 11.040.50

English Version

Medical electrical equipment - Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment (IEC 60601-2-65:2012/A2:2021)

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Medizinische elektrische Geräte - Teil 2-65: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von intraoralen zahnärztlichen Röntgeneinrichtungen (IEC 60601-2-65:2012/A2:2021)

This amendment A2 modifies the European Standard EN 60601-2-65:2013; it was approved by CENELEC on 2021-06-07. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this amendment 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 amendment 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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, 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: Rue de la Science 23, B-1040 Brussels

Ref. No. EN 60601-2-65:2013/A2:2021 E

European foreword

The text of document 62B/1233/FDIS, future IEC 60601-2-65/A2, prepared by SC 62B "Diagnostic imaging equipment" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-2-65:2013/A2:2021.

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) 2022-03-07
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2024-06-07

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

Endorsement notice

The text of the International Standard IEC 60601-2-65:2012/A2:2021 was approved by CENELEC as a European Standard without any modification.

IEC 60601-2-65

Edition 1.0 2021-05

INTERNATIONAL STANDARD

AMENDMENT 2

Medical electrical equipment –
Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

ICS 11.040.50

ISBN 978-2-8322-9630-1

FOREWORD

This second amendment has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this amendment is based on the following documents:

FDIS	Report on voting
62B/1233/FDIS	62B/1238/RVD

Full information on the voting for the approval of this amendment can be found in the report on voting indicated in the above table.

The committee has decided that the contents of this amendment and the base publication will remain unchanged until the stability date indicated on the IEC website 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.

201.7.9.1 General

Add, under Addition, after the existing second paragraph, the following new text and new note:

If a test or a QUALITY CONTROL PROCEDURE recommended by the MANUFACTURER requires a device-specific arrangement (including a tool, a phantom, a special software or a software setting); that is only available from the MANUFACTURER, the MANUFACTURER shall provide this arrangement for the RESPONSIBLE ORGANIZATION.

NOTE 102 The intention is to perform these QUALITY CONTROL PROCEDURES and tests using only the supplied information.

203.5.2.4.5 Deterministic effects

Add, after the note of this subclause, the following new subclause:

203.5.2.4.6 RISK TO OPERATORS

Addition:

NOTE OPERATORS of HAND-HELD ME EQUIPMENT are assumed to be in the SIGNIFICANT ZONE OF OCCUPANCY when the ME equipment is hand-held during LOADING.

203.6.2.1 Normal initiation and termination of the IRRADIATION

Add, under Addition, after the first paragraph, the following new paragraph and new note:

HAND-HELD ME EQUIPMENT shall have a means to prevent unauthorized initiation of IRRADIATION.

NOTE Example may be a physical key or password.

203.8.5.4 Positioning of the PATIENT and restriction of the irradiated area

Add, under Replacement, after the note, the following new text:

The MANUFACTURER of an INTRA-ORAL image receptor shall make available ACCESSORIES that may be used to hold the INTRA-ORAL X-RAY IMAGE RECEPTOR and align the X-ray beam with the INTRA-ORAL X-RAY IMAGE RECEPTOR during LOADING.

203.12.2 Mounting OF X-RAY SOURCE ASSEMBLIES and X-RAY IMAGING ARRANGEMENTS

Replace, under Replacement, the introductory paragraph of the list with the following:

For DENTAL INTRA-ORAL X-RAY SOURCE ASSEMBLIES intended to be HAND-HELD during LOADING in NORMAL USE, the following information shall be provided with the ACCOMPANYING DOCUMENTS:

203.12.4 LEAKAGE RADIATION in the LOADING STATE

Add, under Replacement, before the first paragraph, the following new text:

1) DENTAL INTRA-ORAL X-RAY SOURCE ASSEMBLIES intended to be HAND-HELD during LOADING in NORMAL USE

In the LOADING STATE, the AIR KERMA due to LEAKAGE RADIATION from X-RAY SOURCE ASSEMBLIES, at any point on the outer surface of the equipment, when operated at the NOMINAL X-RAY TUBE VOLTAGE under conditions of LOADING corresponding to the reference LOADING conditions, shall not exceed 0,05 mGy in one hour.

Compliance is checked by the following test procedure:

a) block the RADIATION APERTURE sufficiently to ensure that measurements of LEAKAGE RADIATION are not affected by RADIATION passing through it. Make and fit any cover used for this purpose to be as close as practicable to the RADIATION APERTURE and not to overlap it to an extent greater than is required for effective blocking;

b) for LOADING during the test

1) use the NOMINAL X-RAY TUBE VOLTAGE for the X-RAY SOURCE ASSEMBLY under test;

2) use a convenient value of CURRENT TIME PRODUCT;

3) do not use LOADINGS so as to cause any specified ratings to be exceeded during the test;

c) determine, if necessary by making measurements, how the determination of LEAKAGE RADIATION will be affected by the settings and configurations specified for the NORMAL USE of the assembly under test. For the test itself, adopt the combination appearing to be the least favourable with regard to compliance;

d) with the appropriate LOADING FACTORS applied, make a sufficient number of measurements to determine the maximum AIR KERMA over the entire surface of the equipment;

e) normalize the MEASURED VALUES at the LOADING FACTORS actually used, to values of AIR KERMA in one hour corresponding to the reference conditions of LOADING stated in the ACCOMPANYING DOCUMENTS, in accordance with 12.3 of the collateral standard;

f) compliance is achieved if no MEASURED VALUE obtained by the test procedure exceeds the required limit.

2) DENTAL INTRA-ORAL X-RAY SOURCE ASSEMBLIES not intended to be HAND-HELD during LOADING in NORMAL USE