IEC 60601-2-63

Edition 1.0 2021-05

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 2
AMENDEMENT 2

Medical electrical equipment –
Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment

Appareils électromédicaux –
Partie 2-63: Exigences particulières pour la sécurité de base et les performances essentielles des appareils à rayonnement X dentaires extra-oraux

IEC 60601-2-63:2012-09/AMD2:2021-05(en-fr)

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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/1232/FDIS	62B/1237/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- withdrawn,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.

201.1.1 Scope

Replace Note 1 with the following new note:

NOTE 1 An example of such equipment is an equipment designed to perform PANORAMIC, CEPHALOMETRIC and DENTAL VOLUMETRIC RECONSTRUCTION (hereafter DVR) as defined in 201.3.203.

Add, under Replacement, before Note 5, the following new paragraph:

DENTAL EXTRA-ORAL X-RAY EQUIPMENT are X-RAY EQUIPMENT designed for EXTRA-ORAL RADIOGRAPHY in which the geometrical relations between the X-RAY SOURCE, the anatomical object being imaged in the PATIENT, and the X-RAY IMAGE RECEPTOR, are preset in the design and cannot be arbitrarily altered by the OPERATOR during INTENDED USE. In such equipment, the X-RAY TUBE ASSEMBLY contains the HIGH-VOLTAGE TRANSFORMER ASSEMBLY.

Add, at the end of the existing fifth paragraph, between Note 8 and Note 9, "by entities other than the manufacturer".

201.2 Normative references

Replace, in this clause modified by Amendment 1, under Addition, the reference to IEC/PAS 61910-1:2007 with:

IEC 61910-1:2014, *Medical electrical equipment – Radiation dose documentation – Part 1: Radiation dose structured reports for radiography and radioscopy*

201.3 Terminology and definitions

Add, after definition 201.3.213, the following new terms and definitions:

201.3.214
DENTAL CONE BEAM COMPUTED TOMOGRAPHY
DENTAL CBCT
3-dimensional imaging of DENTAL anatomical structures, performed by reconstruction of a volume from a series of 2-dimensional projections produced by circular or rectangular collimated X-RAY BEAM on an X-RAY IMAGE RECEPTOR rotating around the head of the PATIENT

201.3.215
EXAMINATION PROTOCOL
full set of programmed LOADING FACTORS, control functions and settings, including image processing settings, designed to the image acquisition and DISPLAY

201.4.10.1 Source of power for ME EQUIPMENT

Delete the existing Addition and Subclause 201.4.10.1.101.

201.4.10.2 SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS

Add, under Addition, after the first paragraph, the following new text:

For this purpose, the APPARENT RESISTANCE of SUPPLY MAINS R is determined according to the formula:

$$R = \frac{U_0 - U_1}{I_1}$$

where

U_0 is the no-load MAINS VOLTAGE;

U_1 is the MAINS VOLTAGE under load;

I_1 is the mains current under load.

201.7.9.1 General

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

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 103 The intention is to perform these QUALITY CONTROL PROCEDURES and tests using only the ACCOMPANYING DOCUMENTS.

Add, after Note 102, the following new text and new note:

If the test or PROCEDURE requires a device-specific TOOL that is only available from the MANUFACTURER, the MANUFACTURER shall make this TOOL available to the RESPONSIBLE ORGANIZATION.

NOTE 104 The MANUFACTURER can provide PHANTOM with the equipment, if specified in the local regulations.

203.5.2.4.5 Deterministic effects

Add, under Addition, before the note, the following new subclause:

203.5.2.4.101 EXAMINATION PROTOCOLS

When EXAMINATION PROTOCOLS are proposed by the MANUFACTURER, and preloaded on the EQUIPMENT, the INSTRUCTIONS FOR USE shall state if they constitute recommendations to be applied directly so as to allow optimized operation or if they are only examples/starting points, to be replaced by more specific protocols developed by the user.

Compliance is checked by inspection of the INSTRUCTIONS FOR USE.

203.6 Radiation management

Add, before 203.6.2, the following new instruction and subclause:

Addition:

203.6.1.102 *Management of EXAMINATION PROTOCOLS

If EXAMINATION PROTOCOLS are preloaded and the INTENDED USE of the X-RAY EQUIPMENT covers both adult and paediatric applications, the designation of these protocols shall clearly distinguish between adult and paediatric applications.

For DVR (DENTAL CBCT, DVT) if EXAMINATION PROTOCOLS are preloaded and multiple EXAMINATION PROTOCOLS are intended for both the same clinical task and, if applicable, the same PATIENT size, then those EXAMINATION PROTOCOLS will be differentiated by qualitative indication of their effect on image resolution and dose.

Compliance is checked by inspection or by the appropriate functional tests.

203.6.4.3.102.4 *Accuracy of IRRADIATION TIME

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

For ME EQUIPMENT in which the RADIATION dose is using time-width modulation during the IRRADIATION EVENT, the MANUFACTURER shall provide in the ACCOMPANYING DOCUMENTS a description of the modulation pattern, including the NOMINAL duration(s) of single pulses, which are generated during the IRRADIATION EVENT.

NOTE These pulses are synchronized with the RADIATION cycle used for a single projection image within the DVT or DENTAL CBCT image acquisition sequence and are generated from CONSTANT POTENTIAL HIGH-VOLTAGE GENERATOR.

Replace the compliance statement with the following:

Compliance is checked based on calculation of the IRRADIATION TIME using the examination of typical pulse pattern according to the description provided in the ACCOMPANYING DOCUMENTS on data acquired by the test according to 203.6.4.3.102.2.

203.6.4.3.102.5 Accuracy of CURRENT TIME PRODUCT

Replace the second paragraph with the following note:

NOTE This requirement also applies in cases when the CURRENT TIME PRODUCT is derived by calculation (eg X-RAY TUBE CURRENT and X-RAY TUBE IRRADIATION TIME).

203.6.4.101 READY STATE

Add, after the conformance assessment, the following new subclause:

203.6.4.5.101 RADIATION DOSE STRUCTURED REPORTS

ME EQUIPMENT intended for DENTAL CBCT applications shall be capable of creating RADIATION DOSE STRUCTURED REPORTS (RDSR) and have the ability to perform an RDSR END OF PROCEDURE TRANSMISSION. The relevant elements for the specified type of X-RAY EQUIPMENT and for which data are available shall be populated with relevant data.

Compliance is checked by functional tests.

203.8.5.3 Correspondence between X-RAY FIELD and EFFECTIVE IMAGE RECEPTION AREA

Replace the hyphenated list, including items a) to d), after in DVR, with the following:

The X-RAY FIELD shall not extend beyond the EFFECTIVE IMAGE RECEPTION AREA at the surface of the X-RAY IMAGE RECEPTOR more than 2 % of the FOCAL SPOT TO IMAGE RECEPTOR DISTANCE in one direction or at most 3 % in both directions. In the case of the X-RAY IMAGE RECEPTOR having an active surface side length below 8 cm, the over-RADIATION shall not be larger than 1 % of the FOCAL SPOT TO IMAGE RECEPTOR DISTANCE in one direction or at most 2 % in two directions.

The dimensions of a rectangular X-RAY FIELD are described in terms of the length of its intercepts on each of two orthogonal major axes in the plane of interest.

For circular X-RAY FIELD, the dimensions are described accordingly, replacing the lengths of the intercepts with the diameter.

203.9 FOCAL SPOT TO SKIN DISTANCE

Replace the existing paragraph under Replacement with the following new paragraph:

The FOCAL SPOT TO SKIN DISTANCE shall be nominally 15 cm or greater.

Annex C
(informative)

Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS

Table 201.C.102 – Subclauses requiring statements in ACCOMPANYING DOCUMENTS

Replace the existing table with the following:

Table 201.C.102 – Subclauses requiring statements in ACCOMPANYING DOCUMENTS

Title	Subclause
SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS	201.4.10.2
Electrical input power from the SUPPLY MAINS	201.7.2.7
Cooling conditions	201.7.2.15
ACCOMPANYING DOCUMENTS	201.7.9
LOADING FACTORS	201.7.9.2.1.101
X-RAY SOURCE ASSEMBLY	201.7.9.3.101
Requirements to the SUPPLY MAINS	201.7.9.101
MECHANICAL PROTECTIVE DEVICE	201.9.8.4.101
Management of EXAMINATION PROTOCOLS	203.6.1.102
Connections of external INTERLOCKS	203.6.2.1.101
Accuracy of X-RAY TUBE VOLTAGE	203.6.4.3.102.2
Indication of automatic modes	203.6.4.4
Dosimetric indications	203.6.4.5
AUTOMATIC CONTROL SYSTEM	203.6.5
Correspondence between X-RAY FIELD and EFFECTIVE IMAGE RECEPTION AREA	203.8.5.3
Control of X-RAY EQUIPMENT from a PROTECTED AREA	203.13.2

Annex AA
(informative)

Particular guidance and rationale

Add, after the existing Figure AA.3, the following new rationale:

Subclause 203.6.1.102 – Management of EXAMINATION PROTOCOLS

This subclause defines the PATIENT size to allow the OPERATOR the selection of EXAMINATION PROTOCOLS with low RADIATION DOSES to protect the PATIENT while achieving the clinical image quality needed for the diagnostic task.

This radiation dose selection is a function of size and weight of the PATIENT. Hence, there is a clear overlap between (for example) small female adults and an adolescent patient with obesity. This overlapping between age groups is relevant for the design and designation of EXAMINATION PROTOCOLS.

Likewise, the increased likelihood of image artefacts due to paediatric PATIENT movements during the exposure, as well as the small size and weight of a paediatric PATIENT is relevant for the OPERATOR. Hence the OPERATOR needs access to information allowing to choose an EXAMINATION PROTOCOL for a paediatric patient.

Subclause 203.6.4.3.102.4 – Accuracy of IRRADIATION TIME

Replace the first paragraph with the following:

The IRRADIATION-EVENT may consist of a series of IRRADIATIONS. Typical examples of that are pulsed DENTAL CBCT, where the IRRADIATION is performed with series of several hundred pulses synchronized with the acquisition of the image frames; series of scanning projections for tomosynthesis; and certain special PANORAMIC-like projections consisting of a series of multiple images, such as separate views of both TMJs (temporo-mandibular joints), transversal quasi-tomographic views or sections of the jaw (typically 3 or 4 views); etc.

Index of defined terms used in this particular standard

Replace, in the introductory text, modified by Amendment 1, "IEC/PAS 61910-1:2007" *with* "IEC 61910-1:2014".

Replace the existing term "IRRADIATION-EVENT" *with:*

IRRADIATION-EVENT IEC 61910-1:2014, 3.1

AVANT-PROPOS

Le présent deuxième amendement a été établi par le sous-comité 62B: Appareils d'imagerie de diagnostic, du comité d'études 62 de l'IEC: Equipements électriques dans la pratique médicale.

La présente version bilingue (2021-10) correspond à la version anglaise monolingue publiée en 2021-05.

La version française de cette norme n'a pas été soumise au vote.

Le comité a décidé que le contenu de cet amendement et de la publication de base ne sera pas modifié avant la date de stabilité indiquée sur le site web de l'IEC sous "http://webstore.iec.ch" dans les données relatives à la publication recherchée. A cette date, la publication sera

- reconduite,
- supprimée,
- remplacée par une édition révisée, ou
- amendée.

201.1.1 Domaine d'application

Remplacer la Note 1 par la nouvelle note suivante:

NOTE 1 A titre d'exemple d'un tel appareil, on peut citer celui qui est conçu pour réaliser une RECONSTRUCTION DENTAIRE VOLUMETRIQUE (appelé ci-après DVR – *dental volumetric reconstruction*), comme défini au 201.3.203, y compris PANORAMIQUE et CEPHALOMETRIQUE.

Ajouter, sous Remplacement, avant la Note 5, le nouvel alinéa suivant:

LES APPAREILS À RAYONNEMENT X DENTAIRES EXTRA-ORAUX sont des APPAREILS À RAYONNEMENT X conçus pour la RADIOGRAPHIE DENTAIRE EXTRA-ORALE. Les relations géométriques entre la SOURCE DE RAYONNEMENT X, l'objet anatomique soumis à l'imagerie chez le PATIENT et le RÉCEPTEUR D'IMAGE RADIOLOGIQUE sont préréglées au niveau de la conception et ne peuvent pas être modifiées de façon arbitraire par l'OPÉRATEUR pendant L'UTILISATION PRÉVUE. Dans ce type d'appareil, la GAINE ÉQUIPÉE contient L'ENSEMBLE TRANSFORMATEUR HAUTE TENSION.

Ajouter, à la fin du cinquième alinéa existant entre les Notes 8 et 9, "par des entités autres que le fabricant "*:*

201.2 Références normatives

Remplacer, dans cet article modifié par l'Amendement 1, sous Addition, la référence à l'IEC/PAS 61910-1:2007 par la nouvelle référence suivante:

IEC 61910-1:2014 *Appareils électromédicaux – Documentation sur la dose de rayonnement – Partie 1: Rapports structurés sur la dose de rayonnement pour la radiographie et la radioscopie.*

201.3 Termes et définitions

Ajouter, après la définition 201.3.213, les nouveaux termes et définitions suivants: