SLOVENSKI STANDARD
SIST EN 60601-2-68:2015/oprA1:2023

01-oktober-2023

Medicinska električna oprema - 2-68. del: Posebne zahteve za osnovno varnost in bistvene lastnosti rentgenskih naprav pri slikovno vodeni radioterapiji z elektronskimi pospeševalniki, napravami za lahkoionsko radioterapijo in napravami za radionuklidno radioterapijo - Dopolnilo A1

Amendment 1 - Medical electrical equipment - Part 2-68: Particular requirements for the basic safety and essential performance of X-ray-based image-guided radiotherapy equipment for use with electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment

Amendement 1 - Appareils électromédicaux - Partie 2-68: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de radiothérapie à rayonnement X assistée par imagerie médicale, destinés à être utilisés avec les accélérateurs d'électrons, les appareils de thérapie par faisceau d'ions légers et les appareils de thérapie par faisceau de radionucléides

Ta slovenski standard je istoveten z: **EN 60601-2-68:2015/prA1:2023**

ICS:

11.040.50	Radiografska oprema	Radiographic equipment
13.280	Varstvo pred sevanjem	Radiation protection

SIST EN 60601-2-68:2015/oprA1:2023 **en**

62C/876/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER: **IEC 60601-2-68/AMD1 ED1**	
DATE OF CIRCULATION: **2023-08-04**	CLOSING DATE FOR VOTING: **2023-10-27**
SUPERSEDES DOCUMENTS: **62C/774/CD, 62C/834A/CC**	

IEC SC 62C : EQUIPMENT FOR RADIOTHERAPY, NUCLEAR MEDICINE AND RADIATION DOSIMETRY

SECRETARIAT: Germany	SECRETARY: Ms Regina Geierhofer
OF INTEREST TO THE FOLLOWING COMMITTEES: SC 62B	PROPOSED HORIZONTAL STANDARD: ☐ Other TC/SCs are requested to indicate their interest, if any, in this CDV to the secretary.

FUNCTIONS CONCERNED:

☐ EMC ☐ ENVIRONMENT ☐ QUALITY ASSURANCE ☒ SAFETY

☒ SUBMITTED FOR CENELEC PARALLEL VOTING	☐ NOT SUBMITTED FOR CENELEC PARALLEL VOTING
Attention IEC-CENELEC parallel voting The attention of IEC National Committees, members of CENELEC, is drawn to the fact that this Committee Draft for Vote (CDV) is submitted for parallel voting. The CENELEC members are invited to vote through the CENELEC online voting system.	

This document is still under study and subject to change. It should not be used for reference purposes.

Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Recipients of this document are invited to submit, with their comments, notification of any relevant “In Some Countries” clauses to be included should this proposal proceed. Recipients are reminded that the CDV stage is the final stage for submitting ISC clauses. (SEE AC/22/2007 OR NEW GUIDANCE DOC).

TITLE:

Amendment 1 - Medical electrical equipment - Part 2-68: Particular requirements for the basic safety and essential performance of X-ray-based image-guided radiotherapy equipment for use with electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment

PROPOSED STABILITY DATE: 2029

NOTE FROM TC/SC OFFICERS:

For supporting information please see 62C/877/INF, which contains IEC 60601-2-68:2014 with the changes proposed by this CDV, visibly incorporated.

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-68: Particular requirements for the basic safety and essential performance of X-ray-based image-guided radiotherapy equipment for use with electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment

AMENDMENT 1

FOREWORD

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Amendment 1 to IEC 60601-2-68:2014 has been prepared by subcommittee SC 62: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee TC 62: Medical equipment, software, and systems.

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

Draft	Report on voting
XX/XX/XXXX	XX/XX/XXX

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

The language used for the development of this Amendment is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications/.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

INTRODUCTION to Amendment 1

Since the publication of IEC 60601-2-68:2014, changes have taken place in the standards environment.

The following standards relevant to X-IGRT EQUIPMENT were updated or newly published:

– IEC 60601-2-1:2020, *Medical electrical equipment – Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV*

– IEC 60601-2-44:2009+A1:2012+A2:2016, *Medical electrical equipment – Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography*

– IEC 60601-2-64:2014, *Medical electrical equipment – Part 2-64: Particular requirements for the basic safety and essential performance of light ion beam medical electrical equipment*

– IEC TR 62926:2019, *Medical electrical system – Guidelines for safe integration and operation of adaptive external-beam radiotherapy systems for real-time adaptive radiotherapy*

– IEC TR 63183:2019, *Guidance on error and warning messages for software used in radiotherapy*

This amendment clarifies the scope of IEC 60601-2-68 to CT SCANNERS, intended to be used in the same room with an EXTERNAL BEAM EQUIPMENT (EBE).

This amendment introduces updated requirements related to MECHANICAL HAZARDS, RADIATION HAZARDS, PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS), ACCOMPANYING DOCUMENTATION of an ME SYSTEM, and REMOTE OPERATION.

Another purpose of this amendment is to reference IEC 60601-1:2005/A2:2020 and to make some minor technical clarifications.

INTRODUCTION

Replace the introduction with the following:

Modern RADIOTHERAPY practices utilize information from various imaging modalities, acquired prior to initiating administration of the therapy, to plan the TREATMENT. The imaging provides information about the location of the TARGET VOLUME and other anatomical features so that a TREATMENT PLAN can be developed that provides an optimal dose distribution to have the best chance of achieving the intended effect of TREATMENT while minimizing side effects.

However, difficulties arise when trying to administer the RADIATION, since TARGET VOLUMES/critical structures are constantly moving within the body. For example, in parts of the body moving with respiration, the TARGET VOLUMES/critical structures may change position or shape during the RADIATION BEAM delivery throughout any given fraction. Furthermore, a course of therapy may extend over many days, during which the TARGET VOLUME/PATIENT may shrink or grow and/or move. Hence, the exact location of the TARGET VOLUME/critical structures may change between the time of TREATMENT planning imaging and the actual administration of a TREATMENT.

IMAGE-GUIDED RADIOTHERAPY (IGRT) combines planar or volumetric imaging during the course of RADIOTHERAPY in order to adjust the TREATMENT delivery based on the PATIENT anatomy and PATIENT position. This enables the OPERATOR AND/OR EXTERNAL BEAM EQUIPMENT (EBE) to adjust the RADIATION BEAM delivery based on the imaging information, such as the position of the TARGET VOLUME, critical organs and/or other reference features, to compensate for anatomical changes including internal organ motions and/or TREATMENT setup uncertainties. The increased accuracy and precision achieved allows higher doses of RADIATION to be delivered to the TARGET VOLUME and a reduction in the margin of healthy cells affected by the RADIATION. This is often used in conjunction with other monitoring equipment.

This particular standard establishes requirements to be complied with by MANUFACTURERS in the design and construction of X-RAY IGRT EQUIPMENT (X-IGRT).

This particular standard covers safety aspects of kilovoltage (kV) and megavoltage (MV) X-ray imaging devices in a known geometrical relationship with an EXTERNAL BEAM EQUIPMENT such as an ELECTRON ACCELERATOR, medical LIGHT ION BEAM MEDICAL ELECTRICAL EQUIPMENT or RADIONUCLIDE BEAM THERAPY EQUIPMENT, for the purpose of IGRT. It covers aspects of communication and relationships between the EXTERNAL BEAM EQUIPMENT and X-ray imaging devices, attached or not directly attached to but in the same RADIATION shielded area as, and dedicated for use only with, the EXTERNAL BEAM EQUIPMENT.

When performing a HAZARD ANALYSIS, the MANUFACTURER should consider relevant diagnostic standards. For example, IMAGE DISPLAY DEVICE quality is specified in IEC documents in regard to diagnostic use (e.g., IEC 62563-1:2009, Ed. 1.0). However, since IGRT usage may or may not require such high requirements, it is left to the MANUFACTURER to specify what is required for use with their X-IGRT EQUIPMENT.

This particular standard deals with the safety aspect of image acquisitions, image analysis, data transfer and TREATMENT replanning or EBE/PATIENT repositioning.

This particular standard deals with equipment for REAL-TIME X-IGRT, ONLINE X-IGRT and OFFLINE X-IGRT.

X-IGRT EQUIPMENT is also related to the following current publications:

– IEC 60601-2-1, *Medical electrical equipment – Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV*
– IEC 60601-2-44, *Medical electrical equipment – Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography*
– IEC 60601-2-64, *Medical electrical equipment – Part 2-64: Particular requirements for the basic safety and essential performance of light ion beam medical electrical equipment*
– IEC 62083, *Medical electrical equipment – Requirements for the safety of radiotherapy treatment planning systems*

180 – IEC 61217, *Radiotherapy equipment – Coordinates, movements, and scales*
181 – IEC 62274, *Medical electrical equipment – Safety of radiotherapy record and verify systems*
182 – IEC TR 62926, *Medical electrical system – Guidelines for safe integration and operation of adaptive*
183 *external-beam radiotherapy systems for real-time adaptive radiotherapy*
184 – IEC TR 63183, *Guidance on error and warning messages for software used in radiotherapy*
185 This particular standard may give rise to amendments to some of the above standards.

186 This particular standard will focus on the safety aspects of the primary function of X-IGRT. It will not
187 focus on emerging technologies within the field so as to not hinder progress, yet it will define a safe way
188 of achieving X-IGRT.

201.1 Scope, object and related standards

201.1.1 Scope

Replace the existing third paragraph with:

This particular standard deals with equipment for REAL-TIME X-IGRT, ONLINE X-IGRT and OFFLINE X-IGRT. It covers procedures to reduce the risk of over-reliance on the X-IGRT EBE SYSTEM. For example, the MANUFACTURER will provide an interactive interface for user interaction with the correction suggested by the system.

Add after third paragraph:

This particular standard does not apply to standard CT SCANNERS, which are not used for IGRT. However, if a CT SCANNER is used in the same room and is electrically, mechanically, or functionally, including the PATIENT SUPPORT, connected to with an EBE for IGRT then this particular standard applies.

If the X-IGRT EQUIPMENT is combined with an MEE, any requirement that is the same for the X-IGRT EQUIPMENT and the MEE, such as a PATIENT POSITIONER, does not to be tested twice, but can be accepted as tested by the MEE.

Requirements that are being tested according to another standard can be identified by the manufacturer and if identical do not require retesting, instead evidence can refer to corresponding test report.

This particular standard applies for X-RAY EQUIPMENT for RADIOGRAPHY, RADIOSCOPY, and COMPUTED TOMOGRAPHY used for IGRT.

Replace the existing fifth paragraph with:

This particular standard, with the inclusion of TYPE TESTS and SITE TESTS, applies respectively to the MANUFACTURER and some installation aspects of X-IGRT EBE SYSTEMS intended to be

- for NORMAL USE, operated under the authority of the RESPONSIBLE ORGANIZATION by QUALIFIED PERSONS having the required skills for a particular medical application, for particular specified clinical purposes, e.g., STATIONARY RADIOTHERAPY or MOVING BEAM RADIOTHERAPY,
- maintained in accordance with the recommendations given in the INSTRUCTIONS FOR USE,
- subject to regular quality assurance performance and calibration checks by a QUALIFIED PERSON.

NOTE In this particular standard, all references to installation refer to installation in the RESPONSIBLE ORGANIZATION'S premises

201.1.4 Particular standards

Replace the existing first paragraph with:

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 MEE under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

201.2 Normative references

Update the following normative references:

Replacement:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012
IEC 60601-1:2005/AMD2:2020

IEC 60601-1-3:2008, *Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment*

IEC 60601-1-3:2008/AMD1:2013
IEC 60601-1-3:2008/AMD2:2021

IEC 60601-1-6:2010, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*
IEC 60601-1-6:2008/AMD1:2013
IEC 60601-1-6:2008/AMD2:2020

Addition:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012
IEC 60601-1:2005/AMD2:2020

IEC 60601-2-1:2020, *Medical electrical equipment – Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV*

IEC 60601-2-44:2009, *Medical electrical equipment – Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography*
IEC 60601-2-44:2009/AMD1:2012
IEC 60601-2-44:2009/AMD2:2016

IEC 60601-2-64:2014, *Medical electrical equipment – Part 2-44: Particular requirements for the basic safety and essential performance of light ion beam medical electrical equipment*

Delete the following normative references:

IEC 60976:2007, *Medical electrical equipment – Medical electron accelerators – Functional performance characteristics*

IEC 62366:2007, *Medical devices – Application of usability engineering to medical devices*

201.3 Terms and definitions

Replace first paragraph with the following:

For the purposes of this document, the terms and definitions given in IEC 60601-2-1:2020, IEC 60601-1:2005, IEC 60601-1:2005 /AMD1:2012, and IEC 60601-1:2005/AMD2:2020, and IEC/TR 60788:2004 apply, except as follows:

After the existing first paragraph add:

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

Replace the existing term and definition 201.3.201 with:

201.3.201
COMPUTED TOMOGRAPHY DOSE INDEX 100
***CTDI*$_{100}$**

integral of the DOSE PROFILE representative of a single axial scan along a line perpendicular to the TOMOGRAPHIC PLANE divided by $N \times T$ according to the following:

for $N \times T$ less than or equal to 40 mm

$$CTDI_{100} = \int_{-50\,mm}^{+50\,mm} \frac{D(y)}{N \times T} dy$$

for $N \times T$ greater than 40 mm (all IGRT IMAGING PROTOCOL except collimation are kept the same for these measurements)

$$\frac{D_{Ref}(y)}{(N \times T)_{Ref}} dy \times \frac{CTDI_{free\ \ air,N \times T}}{CTDI_{free\ \ air,Ref}}$$

where:

D(y) is the DOSE PROFILE representative of a single axial scan along a line perpendicular to the TOMOGRAPHIC PLANE, where dose is reported as ABSORBED DOSE in air and is evaluated within a polymethylmethacrylate (PMMA) dosimetry PHANTOM (see 201.102.6.2);

$(N \times T)_{Ref}$ is a specific $N \times T$ of 20 mm or the largest $N \times T$ available not greater than 20 mm;

$D_{Ref}(y)$ is the DOSE PROFILE representative of a single axial scan along a line perpendicular to the TOMOGRAPHIC PLANE, where dose is reported as ABSORBED DOSE in air and is evaluated within a polymethylmethacrylate (PMMA) dosimetry PHANTOM (see 201.102.6.2) for $(N \times T)_{Ref}$;

$CTDI_{free\ air,\ N \times T}$ is the $CTDI_{free\ air}$ (201.3.202) for a specific value of $N \times T$;

$CTDI_{free\ air,\ Ref}$ is the $CTDI_{free\ air}$ (201.3.202) for $(N \times T)_{Ref}$;

N is the number of TOMOGRAPHIC SECTIONS produced in a single axial scan of the X-ray source;

T is the NOMINAL TOMOGRAPHIC SECTION THICKNESS.

Note 1 to entry: The dose is reported as ABSORBED DOSE to air, but for practical purposes the evaluation of ABSORBED DOSE to air within a PMMA dosimetry PHANTOM is well approximated by measurement of the AIR KERMA.

Note 2 to entry: This definition assumes that the DOSE PROFILE is centred on y = 0.

Note 3 to entry: A single axial scan is typically a 360° rotation of the X-ray source. For CBCT partial rotations are still considered as a single axial scan.

Note 4 to entry: When the TOMOGRAPHIC SECTIONS overlap, e.g., in CT SCANNERS with a "y-flying FOCAL SPOT" or with CBCT modes that merge multiple scans, the denominator of the integral needs to be replaced by the total nominal width along y of overlapping tomographic sections. For example, if the percentage of overlap is 50%, then the denominator would be replaced by 0,5 x *N* x *T*.

Note 5 to entry: Typically, the *y*-axis is the axis of rotation (the *y*-axis corresponds to the z-axis in the DICOM coordinate system.)

Note 6 to entry: The $CTDI_{100}$ is designed to include most of the scattered RADIATION.

Note 7 to entry: See IEC 60601-2-44:2009/AMD1:2012, Annex CC for more explanation.

Note 8 to entry: It is assumed for MV CBCT that an appropriate calibrated pencil chamber is used.

Note 9 to entry: The note to entry concerning the origin of the abbreviation *CTDI* APPLIES TO THE FRENCH TEXT ONLY.

[SOURCE: IEC 60601-2-44:2009/AMD1:2012, 201.3.203, modified – Notes 3, 4 and 5 to entry have been extended, and Note 8 to entry added.]

Replace the existing term and definition 201.3.202 with:

201.3.202
COMPUTED TOMOGRAPHY DOSE INDEX FREE-IN-AIR
***CTDI*$_{free\ air}$**

integral of the DOSE PROFILE representative of a single axial scan along a line through ISOCENTRE and perpendicular to the TOMOGRAPHIC PLANE divided by $N \times T$ according to the following

$$CTDI_{freeair} = \int_{-L/2}^{+L/2} \frac{D(y)}{N \times T} dy$$

where

D(y) is the DOSE PROFILE representative of a single axial scan along a line through ISOCENTRE and perpendicular to the TOMOGRAPHIC PLANE, where dose is reported as ABSORBED DOSE in air and is evaluated free-in-air in the absence of a PHANTOM and the PATIENT SUPPORT;

N is the number of TOMOGRAPHIC SECTIONS produced in a single axial scan of the X-ray source;

T is the NOMINAL TOMOGRAPHIC SECTION THICKNESS;

L is at least $(N \times T)$ +40 mm.

Note 1 to entry: This definition assumes that the DOSE PROFILE is centred on $y = 0$. The y axis corresponds to the z axis in the DICOM coordinate system

Note 2 to entry: When the TOMOGRAPHIC SECTIONS overlap, e.g., in CT SCANNERS with a "y-flying FOCAL SPOT" or with CBCT modes that merges multiple scans, the denominator of the integral needs to be replaced by the total nominal width along *y* of overlapping tomographic sections. For example, if the percentage of overlap is 50 %, then the denominator would be replaced by $0{,}5 \times N \times T$.

Note 3 to entry: Typically, a RADIATION DETECTOR of length *L* or longer is used. Annex DD provides an example for alternate measurements.

Note 4 to entry: For CBCT the imaging is not slice based and $N \times T$ is the scan length along a line perpendicular to the TOMOGRAPHIC PLANE with the NOMINAL collimation.

Note 5 to entry: It is assumed for MV CBCT that an appropriate calibrated pencil chamber or ion chamber, and a build-up cap is used.

[SOURCE: IEC 60601-2-44:2009/AMD1:2012, 201.3.215, modified – Note 1 and 2 to entry have been extended and Notes 4 and 5 to entry added.]

Replace the existing term and definition 201.3.205 with:

201.3.205
DOSE-LENGTH PRODUCT
DLP

index characterizing the product of the $CTDI_{vol}$ and the total length scanned

Note 1 to entry: For axial, helical scanning, and scanning involving back-and-forth patient support movement between two positions (shuttle mode) use the definition provided in IEC 60601-2-44.

a) For axial scanning

$$DLP = CTDI_{vol} \times \Delta d \times n$$

where

Δd is the PATIENT SUPPORT travel in y-direction between consecutive scans;

n is the number of scans in the series.

b) For helical scanning

$$DLP = CTDI_{vol} \times L$$

where

L is the table travel during the entire LOADING, adjusted for dynamic collimation modes if applicable.

Note 1 to entry: *L* might be longer than the programmed scan length.

Note 2 to entry: The time weighted average of $CTDI_{vol}$ is to be used if $CTDI_{vol}$ is variable.

Note 3 to entry: A way for obtaining *L* could be to use the FWHM along a line perpendicular to the TOMOGRAPHIC PLANE at isocentre of the free-in-air DOSE PROFILE for the entire scan. In the absence of dynamic collimation this is approximately equivalent to table travel during the entire LOADING.