SLOVENSKI STANDARD
SIST EN 60601-2-68:2015

01-september-2015

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

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Medizinische elektrische Geräte - Teil 2-68: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von röntgenstrahlungsbasierten Geräten für die bildgesteuerte Strahlentherapie zur Verwendung mit Elektronenbeschleunigern, Leichtionen-Strahlentherapiesystemen und Radionuklid-Strahlentherapiesystemen

Appareils électromédicaux - Partie 2-68: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de radiothérapie guidés par image radiologique, destinés à être utilisés avec les accélérateurs d'électrons, les appareils de thérapie par faisceau ionique lumineux et les appareils de thérapie par faisceau provenant de radionucléides

Ta slovenski standard je istoveten z: EN 60601-2-68:2015

ICS:

11.040.50	Radiografska oprema	Radiographic equipment
13.280	Varstvo pred sevanjem	Radiation protection

SIST EN 60601-2-68:2015 en

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-68

May 2015

ICS 11.040.60

English Version

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 (IEC 60601-2-68:2014)

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 (IEC 60601-2-68:2014)

Medizinische elektrische Geräte - Teil 2-68: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von röntgenstrahlungsbasierten Geräten für die bildgesteuerte Strahlentherapie zur Verwendung mit Elektronenbeschleunigern, Leichtionen-Strahlentherapiesystemen und Radionuklid-Strahlentherapiesystemen (IEC 60601-2-68:2014)

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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 62C/595/FDIS, future edition 1 of IEC 60601-2-68 prepared by SC 62C "Equipment for radiotherapy, nuclear medicine and radiation dosimetry" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-2-68:2015.

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)	2015-11-29
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2018-05-29

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.

For the relationship with EU Directive 93/42/EEC, see informative Annex ZZ, which is an integral part of this document.

Endorsement notice

The text of the International Standard IEC 60601-2-68:2014 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following note has to be added for the standard indicated:

IEC 60336:2005	NOTE	Harmonized as EN 60336:2005 (not modified).
IEC 60364-7-710:2002	NOTE	Harmonized as HD 60364-7-710:2012 (modified).
IEC 60522:1999	NOTE	Harmonized as EN 60522:1999 (not modified).
IEC 62220-1:2003	NOTE	Harmonized as EN 62220-1:2004 [1)] (not modified).

[1)] Superseded by EN 62220-1-1:2015 (IEC 62220-1-1:2015): DOW = 2018-04-16.

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 1 When an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu

Publication	Year	Title	EN/HD	Year
Annex ZA of EN 60601-1:2006 applies except as follows:				
Amendment:				
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	EN 60601-1-3 + corr. March	2008 2010
IEC 60601-1-6 +A1	2010 2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	EN 60601-1-6 +A1	2010 2015
Addition:				
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1 + corr. March	2006 2010
+A1	2012		+ A1 + A1/AC +A12	2013 2014 2014
IEC 60601-2-1	2009	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 60601-2-4	2010	Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators	EN 60601-2-4	2011
IEC 60601-2-44 +A1	2009 2012	Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography	EN 60601-2-44 +A11 +A1	2009 2011 2012

Publication	Year	Title	EN/HD	Year
IEC 60731	2011	Medical electrical equipment - Dosimeters with ionization chambers as used in radiotherapy	EN 60731	2012
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-
IEC 60976	2007	Medical electrical equipment - Medical electron accelerators - Functional performance characteristics	EN 60976	2007
IEC 61217	2011	Radiotherapy equipment - Coordinates, movements and scales	EN 61217	2012
IEC 61223-3-5	2004	Evaluation and routine testing in medical imaging departments - Part 3-5: Acceptance tests - Imaging performance of computed tomography X-ray equipment	EN 61223-3-5	2004
IEC 61262-7	1995	Medical electrical equipment - Characteristics of electro-optical X-ray image intensifiers - Part 7: Determination of the modulation transfer function	EN 61262-7	1995
IEC 62083	2009	Medical electrical equipment - Requirements for the safety of radiotherapy treatment planning systems	EN 62083	2009
IEC 62274	2005	Medical electrical equipment - Safety of radiotherapy record and verify systems	EN 62274	2005
IEC 62366	2007	Medical devices - Application of usability engineering to medical devices	-	-
IEC 62396-1	2012	Process management for avionics - Atmospheric radiation effects - Part 1: Accommodation of atmospheric radiation effects via single event effects within avionics electronic equipment	-	-
IEC 62563-1	2009	Medical electrical equipment - Medical image display systems - Part 1: Evaluation methods	EN 62563-1	2010

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 60601-2-68

Edition 1.0 2014-09

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

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

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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

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 60601-2-68 has been prepared by IEC subcommittee 62C Equipment for radiotherapy, nuclear medicine and radiation dosimetry of IEC technical committee 62: Electrical equipment in medical practice.

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

FDIS	Report on voting
62C/595/FDIS	62C/602/RVD

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

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.

INTRODUCTION

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 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.

This particular standard applies to X-ray based IGRT equipment used in-room for IGRT purposes. This particular standard does not apply to standard CT scanners, which are not used for IGRT. However if a CT scanner is used in-room with a linear (electron) accelerator (linac) for IGRT then this particular standard applies.

When performing a HAZARD ANALYSIS, the MANUFACTURER should consider relevant diagnostic standards. For example, IMAGE DISPLAY DEVICE quality is specified in IEC documents in regards 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 standards:

– IEC 62083, *Medical electrical equipment – Requirements for the safety of radiotherapy treatment planning systems*

- IEC 61217, *Radiotherapy equipment – Coordinates, movements and scales*
- IEC 62274, *Medical electrical equipment – Safety of radiotherapy record and verify systems*
- IEC 60976, *Medical electrical equipment – Medical electron accelerators – Functional performance characteristics*
- IEC TR 60977, *Medical electrical equipment – Medical electron accelerators – Guidelines for functional performance characteristics*.

This particular standard may give rise to amendments to some of the above standards.

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

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

201.1 Scope, object and related standards

Clause 1 of the general standard[1] applies, except as follows:

201.1.1 Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of X-ray based IMAGE-GUIDED RADIOTHERAPY equipment for use with EXTERNAL BEAM EQUIPMENT (EBE).

This particular standard covers safety aspects of kilovoltage (kV) and megavoltage (MV) X-ray imaging devices in a known geometrical relationship with EBE 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.

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 EXTERNAL BEAM SYSTEM (X-IGRT EBS). For example the manufacturer will provide an interactive interface for user interaction with the correction suggested by the system.

If a clause or subclause is specifically intended to be applicable to X-IGRT EBE SYSTEMS the content of that clause or subclause will say so. If that is not the case, the clause or subclause applies only to X-IGRT EQUIPMENT.

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 appropriately licensed or QUALIFIED PERSONS by OPERATORS 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

201.1.2 Object

Replacement:

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[1] The general standard is IEC 60601-1:2005 + IEC 60601-1:2005/AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*