

ELEKTRILISED MEDITSIINISEADMED. OSA 2-1:  
ERINÕUDED ELEKTRONKIIRENDI ESMASELE  
OHUTUSELE JA OLULISTELE TOIMIMISNÄITAJATELE  
VAHEMIKUS 1 MEV KUNI 50 MEV

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

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

See Eesti standard EVS-EN IEC 60601-2-1:2021 sisaldab Euroopa standardi EN IEC 60601-2-1:2021 ingliskeelset teksti.	This Estonian standard EVS-EN IEC 60601-2-1:2021 consists of the English text of the European standard EN IEC 60601-2-1:2021.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 16.07.2021.	Date of Availability of the European standard is 16.07.2021.
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ICS 11.040.60

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English Version

**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 60601-2-1:2020)**

Appareils électromédicaux - Partie 2-1: Exigences  
particulières pour la sécurité de base et les performances  
essentielle des accélérateurs d'électrons dans la gamme  
de 1 MeV à 50 MeV  
(IEC 60601-2-1:2020)

Medizinische elektrische Geräte - Teil 2-1: Besondere  
Festlegungen für die Sicherheit einschließlich der  
wesentlichen Leistungsmerkmale von  
Elektronenbeschleunigern im Bereich von 1 MeV bis 50  
MeV  
(IEC 60601-2-1:2020)

This European Standard was approved by CENELEC on 2020-12-02. 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.

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## European foreword

The text of document 62C/770/FDIS, future edition 4 of IEC 60601-2-1, 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 IEC 60601-2-1:2021.

The following dates are fixed:

- latest date by which the document has to be implemented at national (dop) 2022-01-16 level by publication of an identical national standard or by endorsement
- latest date by which the national standards conflicting with the (dow) 2024-07-16 document have to be withdrawn

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In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 60601-1-3:2008	NOTE	Harmonized as EN 60601-1-3:2008 (not modified)
IEC 60601-1-3:2008/A1:2013	NOTE	Harmonized as EN 60601-1-3:2008/A1:2013 (not modified)
IEC 60601-1-9:2007	NOTE	Harmonized as EN 60601-1-9:2008 (not modified)
IEC 60601-1-9:2007/A1:2013	NOTE	Harmonized as EN 60601-1-9:2008/A1:2013 (not modified)
IEC 60601-1-10:2007	NOTE	Harmonized as EN 60601-1-10:2008 (not modified)
IEC 60601-1-10:2007/A1:2013	NOTE	Harmonized as EN 60601-1-10:2008/A1:2015 (not modified)
IEC 60601-2-11:2013	NOTE	Harmonized as EN 60601-2-11:2015 (not modified)
IEC 60601-2-17:2013	NOTE	Harmonized as EN 60601-2-17:2015 (not modified)
IEC 60601-2-64:2014	NOTE	Harmonized as EN 60601-2-64:2015 (not modified)
IEC 60976:2007	NOTE	Harmonized as EN 60976:2007 (not modified)
IEC 62083:2009	NOTE	Harmonized as EN 62083:2009 (not modified)
IEC 62366-1:2015	NOTE	Harmonized as EN 62366-1:2015 (not modified)
IEC 62680-2-1:2015	NOTE	Harmonized as EN 62680-2-1:2015 (not modified)

## Annex ZA (normative)

### Normative references to international publications with their corresponding European publications

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 Where 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](http://www.cenelec.eu).

*The Annex ZA of EN 60601-1:2006/A1:2013 applies with the following replacements:*

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 60601-1-2	2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	EN 60601-1-2	2015
IEC 60601-1-6	2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	EN 60601-1-6	2010
+ A1	2013		+ A1	2015

*The Annex ZA of EN 60601-1:2006/A1:2013 applies with the following additions:*

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
-	-		+ corrigendum Mar.	2010
+ A1	2012		+ A1	2013
-	-		+ A12	2014
IEC 60601-2-68	2014	Electrical medical 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	EN 60601-2-68	2015
IEC 61000-4-3	-	Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test	EN IEC 61000-4-3	-

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 61217	2011	Radiotherapy equipment - Coordinates, EN 61217 movements and scales		2012
IEC/TR 60788	2004	Medical electrical equipment - Glossary of - defined terms		-
CISPR 11	-	Industrial, scientific and medical equipment - EN 55011 Radio-frequency disturbance characteristics - Limits and methods of measurement		-

# INTERNATIONAL STANDARD

## NORME INTERNATIONALE

**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**

**Appareils électromédicaux –  
Partie 2-1: Exigences particulières pour la sécurité de base et les performances  
essentiels des accélérateurs d'électrons dans la gamme de 1 MeV à 50 MeV**



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# INTERNATIONAL STANDARD

## NORME INTERNATIONALE

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essentielles des accélérateurs d'électrons dans la gamme de 1 MeV à 50 MeV**

INTERNATIONAL  
ELECTROTECHNICAL  
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INTERNATIONALE

ICS 11.040.60

ISBN 978-2-8322-8942-6

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## INTERNATIONAL ELECTROTECHNICAL COMMISSION

**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**

## FOREWORD

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International Standard IEC 60601-2-1 has been prepared by subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Electrical equipment in medical practice.

This fourth edition cancels and replaces the third edition published in 2009 and Amendment 1:2014. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

- a) alignment with the new relevant collateral standards;
- b) addition of computer interface and control;
- c) addition of new technologies in RADIOTHERAPY, including
  - BEAM GATING, and
  - ADAPTIVE RADIOTHERAPY.

The text of this International Standard is based on the following documents:

FDIS	Report on voting
62C/770/FDIS	62C/785/RVD

Full information on the voting for the approval of this document 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 document, the following print types are used:

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In referring to the structure of this document, the term

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- "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;
- "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 document will remain unchanged until the stability date indicated on the IEC website under "<http://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.

NOTE The attention of users of this document is drawn to the fact that equipment MANUFACTURERS and testing organizations may need a transitional period following publication of a new, amended or revised IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication.

## INTRODUCTION

The use of ELECTRON ACCELERATORS for RADIOTHERAPY purposes may expose PATIENTS to danger if the ME EQUIPMENT fails to deliver the required dose distribution to the PATIENT, or if the ME EQUIPMENT design fails to meet the requirements of BASIC SAFETY and ESSENTIAL PERFORMANCE. The ME EQUIPMENT may also cause danger to persons in the vicinity if the ME EQUIPMENT itself fails to contain the RADIATION adequately or if there are inadequacies in the design of the TREATMENT ROOM.

This particular standard establishes requirements to be complied with by MANUFACTURERS in the design and construction of ELECTRON ACCELERATORS for use in RADIOTHERAPY; it does not attempt to define their optimum performance requirements. Its purpose is to identify those features of design that are regarded, at the present time, as essential for the safe operation of such ME EQUIPMENT. It places limits on the degradation of ME EQUIPMENT performance beyond which it can be presumed that a fault condition exists and where an INTERLOCK then operates to prevent continued operation of the ME EQUIPMENT.

Clauses 201.10, 201.103, 201.104, 201.105 and 201.108 contain limits beyond which INTERLOCKS prevent, INTERRUPT or TERMINATE IRRADIATION in order to insure ESSENTIAL PERFORMANCE is maintained to avoid an unsafe condition. In this document, the information in Clause 201.10 has either been reorganized or moved to other clauses in order to better reflect current usage and broaden the applicability of certain clauses to always apply to the ME EQUIPMENT when IRRADIATION is being produced and not just when a PATIENT is being treated. Annex AA provides a table showing the relationship between the clauses in IEC 60601-2-1:2009 and IEC 60601-2-1:2009/AMD1:2014 and the clauses in this document.

TYPE TESTS that are performed by the MANUFACTURER, or SITE TESTS, which are not necessarily performed by the MANUFACTURER, are SPECIFIED for each requirement. It is understood that SITE TESTS may or may not be required of the MANUFACTURER, per the agreement between the MANUFACTURER and RESPONSIBLE ORGANIZATION.

Given that before installation a MANUFACTURER cannot provide SITE TEST data, data obtained from SITE TESTS should be incorporated in the ACCOMPANYING DOCUMENTATION, in the form of a SITE TEST report, by those who test the ME EQUIPMENT at installation.

IEC 60601-2-1 was first published in 1981. It was amended in 1984 and 1990. A second edition was published in 1998 and amended in 2002. The third edition was prompted by the need to align IEC 60601-2-1 with the third edition of the general standard, IEC 60601-1:2005, and was amended in 2014. This fourth edition is prompted by the need to update IEC 60601-2-1 for the technology that is in current use as well as to bring it into alignment with IEC 60601-1:2005 and IEC 60601-2-1/AMD1:2012. This prompted the relabelling and organization of Clause 201.10 as well as the addition of Clauses 201.102 through 201.109.

IEC 60976:2007 and IEC TR 60977:2008 are closely related to the third edition of this document. The former specifies test methods and reporting formats for performance tests of ELECTRON ACCELERATORS for use in RADIOTHERAPY with the aim of providing uniform methods for conducting such tests. The latter is not a performance standard but suggests performance values, measured per the methods specified in IEC 60976, that could be achievable with technology available at the time of publication. Until IEC 60976:2007 and IEC TR 60977:2008 are updated to match this document, it is suggested that MANUFACTURERS replace the word "ISOCENTRE" with "EQUIPMENT REFERENCE POINT" when reading the test methods.

When a stated requirement does not apply to a given piece of equipment because the function involved does not exist on that equipment, compliance with that requirement is not necessary. However, when that stated requirement addresses a RISK that could be caused by a substantially similar function of the equipment, the MANUFACTURER needs to address the RISK caused by that similar function in the RISK MANAGEMENT FILE.



## 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

#### 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 part of IEC 60601 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of ELECTRON ACCELERATORS, hereafter referred to as ME EQUIPMENT, in the range 1 MeV to 50 MeV, used for TREATMENT of PATIENTS.

NOTE 1 While ELECTRON ACCELERATORS used for TREATMENT of PATIENTS are always ME EQUIPMENT, there are times in this document where they are referred to as EXTERNAL BEAM EQUIPMENT (EBE). Usage of EBE does not remove the requirements placed on the ME EQUIPMENT but is meant to clarify that the ME EQUIPMENT being discussed is the EBE and not some other ME EQUIPMENT that may be part of the system configuration.

This particular standard, with the inclusion of TYPE TESTS and SITE TESTS, applies to the manufacture and some installation aspects of ELECTRON ACCELERATORS and their included equipment used to increase the precision, accuracy and volumetric targeting of the TREATMENT delivery

- intended for RADIOTHERAPY in medical practice, including those in which the selection and DISPLAY of TREATMENT PARAMETERS can be controlled automatically by PROGRAMMABLE ELECTRONIC SUBSYSTEMS (PESS),
- that, under NORMAL CONDITIONS and in NORMAL USE, deliver a RADIATION BEAM of X-RADIATION or ELECTRON RADIATION having
  - NOMINAL ENERGY in the range 1 MeV to 50 MeV,
  - maximum ABSORBED DOSE RATES between  $0,001 \text{ Gy} \times \text{s}^{-1}$  and  $1 \text{ Gy} \times \text{s}^{-1}$  at the ERP from the RADIATION SOURCE, and
  - REFERENCE TREATMENT DISTANCES (RTDs) between 0,5 m and 2 m from the RADIATION SOURCE;

and

- intended to be
  - for NORMAL USE, operated under the authority of the RESPONSIBLE ORGANIZATION by QUALIFIED PERSONS appropriately licensed or having the required skills for a particular medical application, for particular SPECIFIED clinical purposes,
  - maintained in accordance with the recommendations given in the INSTRUCTIONS FOR USE, and
  - subject to regular QUALITY ASSURANCE performance and calibration checks by a QUALIFIED PERSON.

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

NOTE 2 In this particular standard, all references to installation refer to installation in the RESPONSIBLE ORGANIZATION's premises.

NOTE 3 In this particular standard, all references to ABSORBED DOSE refer to ABSORBED DOSE in water.

NOTE 4 The limits on maximum ABSORBED DOSE RATES are included for two reasons. The first is due to requirements related to time in this document. This restriction limits the total dose that could be delivered during a SPECIFIED time (examples: timer, TIME TO INTERRUPT or TERMINATE, LATENCY). The second is to limit the amount of RADIATION damage that can occur during the time required to take action (often as a follow up to an INTERRUPTION or TERMINATION OF IRRADIATION). Wherever requirements were made to limit the amount of dose delivered before action is taken, the RADIATION damage was considered to be independent of the dose rate and only dependent on the dose. This would largely hold true if the dose rate stayed within the range stated above.

IEC 61217 gives guidance on the designation of ME EQUIPMENT movements, the marking of scales, their zero positions and the direction of movement with increasing value (see 201.7.4.101).

IEC 60976:2007 specifies methods of testing and disclosure of functional performance of medical ELECTRON ACCELERATORS and is intended to facilitate comparisons of accelerator-based ME EQUIPMENTS of different manufacture. IEC 60976:2007 contains no safety requirements, and is not required to show compliance with this document. Until IEC 60976:2007 and IEC TR 60977:2008 are updated to match this document, it is suggested that MANUFACTURERS replace the word "ISOCENTRE" with "EQUIPMENT REFERENCE POINT" when reading the test methods.

IEC TR 62926 provides guidance for integration of ELECTRON ACCELERATORS with other equipment.

IEC TR 63183 provides guidance on the construction of error and warning messages.

### 201.1.2 Object

#### *Replacement:*

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for ELECTRON ACCELERATORS in the range 1 MeV to 50 MeV and to specify tests to check compliance to those requirements.

NOTE The adoption of this document helps to ensure that the ME EQUIPMENT

- maintains PATIENT safety during ME EQUIPMENT movements and failure of the SUPPLY MAINS,
- maintains OPERATOR and general public safety during ME EQUIPMENT NORMAL USE and failure of the SUPPLY MAINS,
- delivers the pre-selected RADIATION TYPE, NOMINAL ENERGY, and ABSORBED DOSE, and
- delivers the RADIATION in accordance with the pre-selected relationship of the RADIATION BEAM to the PATIENT, without causing unnecessary RISK to the PATIENT, the OPERATOR, other persons or the environment.

### 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 60601-1-2:2014 applies. IEC 60601-1-6:2010 and IEC 60601-1-6:2010/AMD1:2013 apply as modified in Clause 206. IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013, IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012, IEC 60601-1-9:2007 and IEC 60601-1-9:2007/AMD1:2013, IEC 60601-1-10:2007 and IEC 60601-1-10:2007/AMD1:2013, IEC 60601-1-11 and IEC 60601-1-12 do not apply, and all other collateral standards in the IEC 60601-1 series do not apply.