

<b>STN</b>	<b>Zdravotnícke elektrické prístroje. Časť 2-1: Osobitné požiadavky na základnú bezpečnosť a nevyhnutné prevádzkové vlastnosti elektrónových urýchľovačov v rozsahu od 1 MeV do 50 MeV.</b>	<b>STN EN 60601-2-1</b>  36 4800
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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

Táto norma obsahuje anglickú verziu európskej normy.  
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 04/16

Obsahuje: EN 60601-2-1:2015, IEC 60601-2-1:2009, IEC 60601-2-1:2009/A1:2014

Oznámením tejto normy sa od 15.09.2018 ruší  
STN EN 60601-2-1 (36 4800) z februára 2002

**122700**

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Úrad pre normalizáciu, metrológiu a skúšobníctvo SR, 2016  
Podľa zákona č. 264/1999 Z. z. v znení neskorších predpisov sa môžu slovenské technické normy  
rozmnžovať a rozširovať iba so súhlasom Úradu pre normalizáciu, metrológiu a skúšobníctvo SR.

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 60601-2-1:2009 + A1:2014)**

Appareils électromédicaux - Partie 2-1: Exigences  
particulières de sécurité de base et de performances  
essentielle pour les accélérateurs d'électrons dans la  
gamme de 1 MeV à 50 MeV  
(IEC 60601-2-1:2009 + A1:2014)

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 60601-2-1:2009 + A1:2014)

This European Standard was approved by CENELEC on 2015-09-15. 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 Committee for Electrotechnical Standardization  
Comité Européen de Normalisation Electrotechnique  
Europäisches Komitee für Elektrotechnische Normung

**CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels**

## European foreword

The text of document 62C/474/FDIS, future edition 3 of IEC 60601-2-1, and the text of document 62C/532/CDV, future IEC 60601-2-1/A1, prepared by SC 62C "Equipment for radiotherapy, nuclear medicine and radiation dosimetry", of IEC/TC 62 "Electrical equipment in medical practice" were submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-2-1:2015.

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) 2016-06-15
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2018-09-15

This document supersedes EN 60601-2-1:1998.

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(s).

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 Standards IEC 60601-2-1:2009 and IEC 60601-2-1:2009/A1:2014 were approved by CENELEC as a European Standard without any modification.

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

IEC 60976:2007	NOTE	Harmonized as EN 60976:2007 (not modified).
IEC 62366	NOTE	Harmonized as EN 62366.

## 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](http://www.cenelec.eu).

***Annex ZA of EN 60601-1:2006 applies, except as follows:***

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
<b><i>Addition to Annex ZA of EN 60601-1:2006:</i></b>				
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-
IEC 61217	1996	Radiotherapy equipment - Coordinates, movements and scales	EN 61217	1996

## **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.



# INTERNATIONAL STANDARD

# NORME INTERNATIONALE

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**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 de sécurité de base et de performances  
essentielles pour les accélérateurs d'électrons dans la gamme de 1 MeV à  
50 MeV**





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# INTERNATIONAL STANDARD

# NORME INTERNATIONALE

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**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 de sécurité de base et de performances essentielles pour les accélérateurs d'électrons dans la gamme de 1 MeV à 50 MeV**

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# INTERNATIONAL ELECTROTECHNICAL COMMISSION

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## 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 IEC subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Electrical equipment in medical practice.

This third edition cancels and replaces the second edition published in 1998 and its Amendment 1 (2002). It constitutes a technical revision.

This third edition addresses the following issues not covered in previous editions:

- alignment with the new relevant collateral standards;
- new technologies in radiotherapy, including:
  - stereotactic radiosurgery (SRS) and stereotactic radiotherapy (SRT);
  - intensity modulated radiotherapy (IMRT);
  - electronic imaging devices (e.g. EPID);
  - moving beam radiotherapy (dynamic therapy).

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

FDIS	Report on voting
62C/474/FDIS	62C/480/RVD

Full information on the voting for the approval of this particular 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.

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 maintenance result 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

The use of ELECTRON ACCELERATORS for RADIOTHERAPY purposes may expose PATIENTS to danger if the ME EQUIPMENT fails to deliver the required dose to the PATIENT, or if the ME EQUIPMENT design does not satisfy standards of electrical and mechanical safety. The ME EQUIPMENT may also cause danger to persons in the vicinity if the ME EQUIPMENT itself fails to contain the RADIATION adequately and/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.

Clause 201.10 contains limits beyond which INTERLOCKS prevent, INTERRUPT or TERMINATE IRRADIATION in order to insure ESSENTIAL PERFORMANCE is maintained to avoid an unsafe condition. TYPE TESTS that are performed by the MANUFACTURER, and/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 end user.

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

This International Standard was first published in 1981. It was amended in 1984 and 1990. A second edition was published in 1998 and amended in 2002. This third edition is prompted by the need to align this particular standard with the third edition of the general standard, IEC 60601-1:2005.

IEC 60976 and IEC/TR 60977 are closely related to this standard. 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 standard per se, but suggests performance values, measured per the methods specified in IEC 60976, that could be achievable with present technology.

## 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 International Standard 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.

This particular standard, with the inclusion of TYPE TESTS and SITE TESTS, applies respectively to the manufacture and some installation aspects of ELECTRON ACCELERATORS

- intended for RADIOTHERAPY in human medical practice, including those in which the selection and DISPLAY of operating 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 and/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 1 m from the RADIATION SOURCE,
  - NORMAL TREATMENT DISTANCES (NTDs) between 0,5 m and 2 m from the RADIATION SOURCE,

and

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

NOTE 2 In this particular standard, all references to ABSORBED DOSE refer to ABSORBED DOSE in water.

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

IEC 61271 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 60676 specifies methods of testing and disclosure of functional performance of medical ELECTRON ACCELERATORS. The standard is intended to facilitate comparisons of accelerator-based ME EQUIPMENTS of different manufacture. IEC 60676 contains no safety requirements, and is therefore not required for compliance with this particular standard. It should also be noted (as stated in the Introduction to IEC 60976:2007) that tests specified in IEC 60976 are not necessarily appropriate for ensuring that any individual medical ELECTRON ACCELERATOR conforms to the declared functional performance during the course of its working lifetime.

NOTE 3 IEC/TR 60977, *Medical electrical equipment – Medical electron accelerators – Guidelines for functional performance characteristics*, is a related technical report that provides performance guidelines. It shall not be construed as a standard.

### 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 standard helps to ensure that the ME EQUIPMENT

- maintains PATIENT safety during ME EQUIPMENT movements and failure of the SUPPLY MAINS,
- delivers the pre-selected RADIATION TYPE, NOMINAL ENERGY, and ABSORBED DOSE,
- delivers the RADIATION in accordance with the pre-selected relationship of the RADIATION BEAM to the PATIENT, by utilizing STATIONARY RADIOTHERAPY, MOVING BEAM RADIOTHERAPY, RADIATION BEAM modifying devices, etc., without causing unnecessary risk to the PATIENT, the OPERATOR, other persons or the environment.

### 201.1.3 Collateral standards

#### *Addition:*

Collateral standards published after the date of publication of this standard shall only apply subject to further amendment to this standard.

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 60601-1-6 apply as modified in Clauses 206. IEC 60601-1-3, IEC 60601-1-8 and 60601-1-10<sup>2</sup> do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

### 201.1.4 Particular standards

#### *Replacement:*

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

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<sup>2</sup> IEC 60601-1-10, Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers



A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of sections, clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix "201" (e.g. 201.1 in this standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix "20x" where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

"Addition" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this standard" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

## 201.2 Normative references

Clause 2 of the general standard applies, except as follows:

NOTE Informative references are listed in the bibliography on page 60.

*Addition:*

IEC/TR 60788:2004, *Medical electrical equipment – Glossary of defined terms* (available in English only)

IEC 61217:1996, *Radiotherapy equipment – Coordinates, movements and scales*

**koniec náhľadu – text ďalej pokračuje v platenej verzii STN**