

SLOVENSKI STANDARD

SIST EN 60601-2-11:2015

01-september-2015

Nadomešča:

SIST EN 60601-2-11:1998

SIST EN 60601-2-11:1998/A1:2005

Medicinska električna oprema - 2-11. del: Posebne zahteve za osnovno varnost in bistvene lastnosti opreme za gama radioterapijo

Medical electrical equipment - Part 2-11: Particular requirements for basic safety and essential performance of gamma beam therapy equipment

iTeh STANDARD PREVIEW

Medizinische elektrische Geräte - Teil 2-11: Besondere Festlegungen für die Strahlensicherheit von Gamma-Bestrahlungseinrichtungen

[SIST EN 60601-2-11:2015](https://standards.iTeh.com/catalog/standards/sist/b4d136c1-1896-4321-968-ae9e52e42d9d/sist-en-60601-2-11-2015)

Appareils électromédicaux - Part 2-11: Règles particulières de sécurité de base et de performances essentielles pour les appareils de gammathérapie

Ta slovenski standard je istoveten z: EN 60601-2-11:2015

ICS:

11.040.50	Radiografska oprema	Radiographic equipment
11.040.60	Terapevtska oprema	Therapy equipment
13.280	Varstvo pred sevanjem	Radiation protection

SIST EN 60601-2-11:2015 en

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EUROPEAN STANDARD

EN 60601-2-11

NORME EUROPÉENNE

EUROPÄISCHE NORM

May 2015

ICS 11.040.60

Supersedes EN 60601-2-11:1997

English Version

**Medical electrical equipment - Part 2-11: Particular requirements
for the basic safety and essential performance of gamma beam
therapy equipment
(IEC 60601-2-11:2013)**

Appareils électromédicaux - Part 2-11: Exigences
particulières pour la sécurité de base et les performances
essentielles des appareils de gammathérapie
(IEC 60601-2-11:2013)

Medizinische elektrische Geräte - Teil 2-11: Besondere
Festlegungen für die Strahlensicherheit von Gamma-
Bestrahlungseinrichtungen
(IEC 60601-2-11:2013)

This European Standard was approved by CENELEC on 2015-04-14. 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.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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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

EN 60601-2-11:2015**Foreword**

The text of document 62C/552/FDIS, future edition 3 of IEC 60601-2-11, 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 60601-2-11:2015.

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) 2016-01-14
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2018-04-14

This document supersedes EN 60601-2-11:1997.

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.

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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.

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Endorsement notice

The text of the International Standard IEC 60601-2-11:2013 was approved by CENELEC as a European Standard without any modification.

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.

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>
Replacement in Annex ZA of EN 60601-1:2006:				
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 + corrigendum Mar.	2008 2010
-	-			
Addition to Annex ZA of EN 60601-1:2006:				
IEC 61217	-	Radiotherapy equipment - Coordinates, movements and scales	EN 61217	-
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-

EN 60601-2-11:2015

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.

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IEC 60601-2-11

Edition 3.0 2013-01

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment –
Part 2-11: Particular requirements for the basic safety and essential performance
of gamma beam therapy equipment

Appareils électromédicaux –
Partie 2-11: Exigences particulières pour la sécurité de base et les performances
essentielle des appareils de gammathérapie

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

**Part 2-11: Particular requirements for the basic safety
and essential performance of gamma 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 60601-2-11 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 third edition cancels and replaces the second edition of IEC 60601-2-11 published in 1997 and its Amendment 1:2004. This edition constitutes a technical revision which brings this standard in line with the third edition of IEC 60601-1 and its collateral standards.

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

FDIS	Report on voting
62C/552/FDIS	62C/558/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 collateral 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 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

The use of GAMMA BEAM THERAPY EQUIPMENT 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 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 gamma beam therapy equipment. Subclause 201.10.2 states tolerance limits beyond which INTERLOCKS must prevent, INTERRUPT or TERMINATE IRRADIATION in order to avoid an unsafe condition. TYPE TESTS which are performed by the MANUFACTURER, or SITE TESTS, which are not necessarily performed by the MANUFACTURER, are specified for each requirement.

Subclause 201.10.2 does not attempt to define the optimum performance requirements for a GAMMA BEAM THERAPY EQUIPMENT for use in RADIOTHERAPY. Its purpose is to identify those features of design which 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 at which it can be presumed that a fault condition applies, e.g. a component failure, and where an INTERLOCK then operates to prevent continued operation of the ME EQUIPMENT.

It should be understood that, before installation, a MANUFACTURER can provide a compliance certificate relating only to TYPE TESTS. 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 after installation.

The relationship of this particular standard with IEC 60601-1 (including the amendments) and the collateral standards is explained in 201.1.3 and 201.1.4.

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-11: Particular requirements for the basic safety and essential performance of gamma beam therapy equipment

201.1 Scope, object and related standards

Clause 1 of the general standard¹ applies, except as follows:

201.1.1 Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of GAMMA BEAM THERAPY EQUIPMENT, including MULTI-SOURCE STEREOTACTIC RADIOTHERAPY equipment, hereafter referred to as ME EQUIPMENT.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1 of the general standard.

NOTE See also 4.2 of the general standard.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for GAMMA BEAM THERAPY EQUIPMENT.

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 60601-1-3 and IEC 60601-1-10 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

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

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.

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 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 IEC 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the IEC 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:

Replacement:

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*

Addition:

IEC TR 60788:2004, *Medical electrical equipment – Glossary of defined terms*

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

201.3 Terms and definitions

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

NOTE An index of defined terms is found beginning on page 46.

Addition:

201.3.201

BEAM OFF

condition in which the RADIATION SOURCE(S) is(are) fully shielded, and are also in a position in which they can be secured

201.3.202

BEAM ON

condition in which the RADIATION SOURCE(s) is(are) fully exposed for RADIOTHERAPY

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201.3.203

CONTROLLING TIMER

TIMER

device to measure the time during which IRRADIATION occurs and, when a predetermined time is reached, to TERMINATE IRRADIATION

201.3.204

GAMMA BEAM THERAPY EQUIPMENT

RADIONUCLIDE BEAM THERAPY EQUIPMENT, in which the RADIONUCLIDE is a gamma emitter

201.3.205

GANTRY

that part of the ME EQUIPMENT supporting and allowing possible movements of the RADIATION HEAD

Note 1 to entry: MULTI-SOURCE STEREOTACTIC RADIOTHERAPY (MSSR) equipment usually is not equipped with a gantry.

201.3.206

GEOMETRICAL FIELD SIZE

geometrical projection of the distal end of the BEAM LIMITING DEVICE on a plane orthogonal to the RADIATION BEAM AXIS, as seen from the centre of the front surface of the RADIATION SOURCE

Note 1 to entry: The RADIATION FIELD is thus of the same shape as the aperture of the beam limiting device. The geometrical field size may be defined at any distance from the RADIATION SOURCE.

201.3.207

HELMET

three dimensional multi-source ISOCENTRIC BEAM LIMITING SYSTEM used in MSSR for TREATMENT VOLUMES within the head or neck

201.3.208
INTERRUPTION OF IRRADIATION
INTERRUPTION
TO INTERRUPT IRRADIATION
TO INTERRUPT

stopping of/to stop IRRADIATION and movements with the possibility of continuing without reselecting operating conditions

Note 1 to entry: I.e. a return to the READY STATE.

201.3.209
IRRADIATION FIELD SIZE
FIELD SIZE

<radiotherapy> dimensions of an area in a plane perpendicular to the radiation beam axis at a specified distance from the RADIATION SOURCE or at a specified depth in the irradiated object and defined by specified isodose lines

[SOURCE: IEC TR 60788:2004, rm-37-11]

201.3.210
MOVING BEAM RADIO THERAPY

RADIO THERAPY with any planned displacement of the RADIATION FIELD or PATIENT relative to each other or with any planned change of ABSORBED DOSE distribution

[SOURCE: IEC TR 60788:2004, rm-42-41]

201.3.211
MULTI-SOURCE STEREOTACTIC RADIO THERAPY
MSSR

RADIO THERAPY using STEREOTACTIC RADIO THERAPY procedure using more than one RADIATION SOURCE

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201.3.212
NORMAL TREATMENT DISTANCE

SPECIFIED distance measured along the RADIATION BEAM AXIS from the RADIATION SOURCE to the ISOCENTRE or, for ME EQUIPMENT without an ISOCENTRE, to a SPECIFIED plane

201.3.213
PRIMARY/SECONDARY TIMER COMBINATION
PRIMARY/SECONDARY COMBINATION

combination of two TIMERS in which one is arranged to be the PRIMARY TIMER and the other is to be the SECONDARY TIMER

201.3.214
PRIMARY TIMER

controlling timer which is intended to TERMINATE IRRADIATION at the pre-selected time

201.3.215
PROGRAMMABLE ELECTRONIC SUBSYSTEM
PESS

system based on one or more central processing units, including their software and interfaces

Note 1 to entry: These devices may contain one or more central processing units connected to sensors or actuators, for the purpose of control, protection or monitoring.

[SOURCE: IEC 60601-1:2005, 3.91, modified – a note to entry has been added to the definition.]