SLOVENSKI STANDARD
SIST EN 60601-2-11:1998

01-september-1998

Medicinska električna oprema - 2-11. del: Posebne varnostne zahteve za opremo za terapijo z gama žarki (IEC 60601-2-11:1997)

Medical electrical equipment - Part 2-11: Particular requirements for the safety of gamma beam therapy equipment (IEC 60601-2-11:1997)

Medizinische elektrische Geräte - Teil 2-11: Besondere Festlegungen für die Strahlensicherheit von Gamma-Bestrahlungseinrichtungen (IEC 60601-2-11:1997)

Appareils électromédicaux - Partie 2-11: Règles particulières de sécurité pour les appareils de gammathérapie (IEC 60601-2-11:1997)

Ta slovenski standard je istoveten z: **EN 60601-2-11:1997**

ICS:

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

SIST EN 60601-2-11:1998 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-11

September 1997

ICS 11.040.50

Supersedes HD 395.2.11 S2:1990

Descriptors: Medical electrical equipment, gamma radiation equipment, therapy, definitions, safety requirements, protection against electric shock, protection against mechanical hazard, radiation protection, fire protection, environmental conditions

English version

Medical electrical equipment
Part 2: Particular requirements for the safety of gamma beam therapy equipment
(IEC 60601-2-11:1997)

Appareils électromédicaux
Partie 2: Règles particulières
de sécurité pour les appareils de
gammathérapie
(CEI 60601-2-11:1997)

Medizinische elektrische Geräte
Teil 2: Besondere Festlegungen
für die Strahlensicherheit von
Gamma-Bestrahlungseinrichtungen
(IEC 60601-2-11:1997)

This European Standard was approved by CENELEC on 1997-07-01. 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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

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CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

Ref. No. EN 60601-2-11:1997 E

Foreword

The text of document 62C/173/FDIS, future edition 2 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 was approved by CENELEC as EN 60601-2-11 on 1997-07-01.

The following dates were fixed:

- latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 1998-05-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 1998-05-01

Annexes designated "normative" are part of the body of the standard.
Annexes designated "informative" are given for information only.
In this standard, annex ZA is normative and annex AA is informative.
Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-2-11:1997 was approved by CENELEC as a European Standard without any modification.

Annex ZA (normative)

Normative references to international publications with their corresponding European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

NOTE: When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Publication	Year	Title	EN/HD	Year
Addition to annex ZA of EN 60601-1:1990/A2:1995:				
IEC 60788	1984	Medical radiology - Terminology	HD 501 S1	1988
IEC 61217	1996	Radiotherapy equipment - Coordinates, movements and scales	EN 61217	1996

NORME INTERNATIONALE

INTERNATIONAL STANDARD

CEI
IEC
60601-2-11

Deuxième édition
Second edition
1997-08

Appareils électromédicaux –

Partie 2:
Règles particulières de sécurité pour les appareils de gammathérapie

Medical electrical equipment –

Part 2:
Particular requirements for the safety of gamma beam therapy equipment

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Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

CODE PRIX
PRICE CODE X

Pour prix, voir catalogue en vigueur
For price, see current catalogue

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –
Part 2: Particular requirements for the safety of gamma beam therapy equipment

FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the 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, the IEC publishes International Standards. 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. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.

2) The formal decisions or agreements of the IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested National Committees.

3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical reports or guides and they are accepted by the National Committees in that sense.

4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.

5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.

6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 60601-2-11 has been prepared by subcommittee 62C: High energy radiation equipment and equipment for nuclear medicine, of IEC technical committee 62: Electrical equipment in medical practice.

The second edition cancels and replaces the first edition published in 1987, amendment 1 (1988) and amendment 2 (1993).

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

FDIS	Report on voting
62C/173/FDIS	62C/192/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.

Annex AA is for information only.

In this Particular Standard the following print types are used:

– Requirements, compliance with which can be tested, and definitions: in roman type;
– Notes, explanations, advice, introductions, general statements, exceptions and references: in smaller type;
– *Test specifications: in italic type*;
– TERMS USED THROUGHOUT THIS PARTICULAR STANDARD WHICH HAVE BEEN DEFINED IN CLAUSE 2 AND IN IEC 60601-1 OR IEC 60788: SMALL CAPITALS.

INTRODUCTION

The use of GAMMA BEAM THERAPY EQUIPMENT for RADIOTHERAPY purposes may expose PATIENTS to danger if the EQUIPMENT fails to deliver the required dose to the PATIENT, or if the EQUIPMENT design does not satisfy standards of electrical and mechanical safety. The EQUIPMENT may also cause danger to persons in the vicinity if the 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 GAMMA BEAM THERAPY EQUIPMENT. Clause 29 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, and/or SITE TESTS, which are not necessarily performed by the MANUFACTURER, are specified for each requirement.

Clause 29 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 EQUIPMENT. It places limits on the degradation of 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 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 EQUIPMENT after installation.

The relationship of this Particular Standard with IEC 60601-1 (including the amendments) and the Collateral Standards is explained in 1.3.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2: Particular requirements for the safety of gamma beam therapy equipment

SECTION ONE – GENERAL

The clauses and subclauses of this section of the General Standard apply except as follows:

1 Scope and object

This clause of the General Standard applies except as follows:

1.1 *Scope*

Addition:

aa)

This Particular Standard specifies requirements for the safety of GAMMA BEAM THERAPY EQUIPMENT intended for RADIOTHERAPY in human medical practice and includes EQUIPMENT in which the selection and DISPLAY of operating parameters can be controlled by a PROGRAMMABLE ELECTRONIC SYSTEM (PES).

bb)

This Particular Standard applies to EQUIPMENT which is intended to deliver a GAMMA RADIATION BEAM(S) at NORMAL TREATMENT DISTANCES greater than 5 cm using a SEALED RADIOACTIVE SOURCE(S). For EQUIPMENT operating at shorter distances, special precautions may be necessary.

cc)

This Particular Standard applies to EQUIPMENT intended to be:

– used under the authority of appropriately licensed or QUALIFIED PERSONS, by OPERATORS having the skills required for a particular medical application and acting in accordance with the INSTRUCTIONS FOR USE,

– maintained at predetermined intervals,

– subject to regular checks by the USER,

– used for particular specified clinical purposes e.g. STATIONARY RADIOTHERAPY or MOVING BEAM RADIOTHERAPY.

dd)

This Particular Standard is applicable to the manufacture and some installation aspects of GAMMA BEAM THERAPY EQUIPMENT by the inclusion of TYPE TESTS and SITE TESTS respectively.

ee)

This Particular Standard specifies the requirements for EQUIPMENT. It does not specify the requirements for the RADIATION SOURCES.

1.2 *Object*

Addition:

aa)

This Particular Standard establishes requirements to ensure the RADIATION safety and enhance the electrical and mechanical safety of GAMMA BEAM THERAPY EQUIPMENT used in human medical practice and specifies tests for demonstrating compliance with those requirements.

bb)

In EQUIPMENT of the type covered by this Standard, ABSORBED DOSE[1)] is controlled by the time of IRRADIATION. Tolerances for other methods of controlling the ABSORBED DOSE are not included in this Standard.

1.3 *Particular Standards*

Addition:

This Particular Standard amends and supplements IEC 60601-1: 1988, *Medical electrical equipment – Part 1: General requirements for safety* and amendments 1 (1991) and 2 (1995).

IEC 60601-1 is referred to as the General Standard. As in the General Standard, the requirements are followed by compliance tests. The term "this Standard" is used to make reference to the General Standard and this Particular Standard taken together.

The numbering of sections, clauses and subclauses of this Particular Standard corresponds to that of the General Standard. 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 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.

"Amendment" means that the clause or subclause of the General Standard is amended as indicated by the text of this Particular Standard.

Subclauses or figures which are additional to those of the General Standard are numbered starting from 101, additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause of the General Standard applies without modification.

This Standard is to be read in conjunction with the collateral Standard IEC 60601-1-2 (1993): Electromagnetic compatibility. No other collateral Standards apply.

Where it is intended that any part of the General Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this Particular Standard.

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1) In this Particular Standard, all references to ABSORBED DOSE refer to ABSORBED DOSE in water at the depth of maximum BUILD UP.

A requirement of this Particular Standard replacing or modifying requirements of the General Standard takes precedence over these requirements.

2 Terminology and definitions

Addition:

NOTE – Annex AA lists defined terms alphabetically with their source references.

Additional definitions:

2.101 BEAM OFF: The condition in which the RADIATION SOURCE is fully shielded, and is also in a position in which it can be secured.

2.102 BEAM ON: The condition in which the RADIATION SOURCE is fully exposed for RADIOTHERAPY.

2.103 CONTROLLING TIMER (abbreviation: TIMER): Device to measure the time during which IRRADIATION occurs and, when a predetermined time is reached, to TERMINATE IRRADIATION.

2.104 FIELD SIZE: Abbreviation for IRRADIATION FIELD SIZE.

2.105 GANTRY: That part of the EQUIPMENT supporting and allowing possible movements of the RADIATION HEAD.

2.106 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. 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.

2.107 INTERRUPTION (OF IRRADIATION)/TO INTERRUPT (IRRADIATION): Stopping of/to stop IRRADIATION and movements with the possibility of continuing without reselecting operating conditions (i.e. a return to the READY STATE).

2.108 NORMAL TREATMENT DISTANCE: A specified distance measured along the RADIATION BEAM AXIS from the RADIATION SOURCE to the ISOCENTRE or, for EQUIPMENT without an ISOCENTRE, to a specified plane.

2.109 PRIMARY/SECONDARY (TIMER) COMBINATION: Combination of two TIMERS in which one is arranged to be the PRIMARY TIMER and the other is to be the SECONDARY TIMER.

2.110 PRIMARY TIMER: The CONTROLLING TIMER which is intended to TERMINATE IRRADIATION at the preselected time.

2.111 PROGRAMMABLE ELECTRONIC SYSTEM (abbreviation: PES): Term used to cover systems incorporating a wide range of programmable devices including microprocessors, programmable controllers, programmable logic controllers and other computer based devices. These devices may contain one or more central processing units connected to sensors and/or actuators, for the purpose of control, protection or monitoring.

2.112 QUALIFIED PERSON: Person recognised by a competent authority as having the requisite knowledge and training to perform specified duties.

2.113 REDUNDANT (TIMER) COMBINATION: Combination of two CONTROLLING TIMERS in which both are arranged to TERMINATE IRRADIATION at the preselected time.

2.114 RELATIVE SURFACE DOSE: Ratio of the ABSORBED DOSE on the RADIATION BEAM AXIS at the depth of 0,5 mm to the maximum ABSORBED DOSE on the RADIATION BEAM AXIS, both measured in a PHANTOM with its surface at a specified distance.

2.115 SECONDARY TIMER: The CONTROLLING TIMER which is intended to TERMINATE IRRADIATION in the event of failure of the PRIMARY TIMER.

2.116 SITE TEST: After installation, test of the individual device or EQUIPMENT to establish compliance with specified criteria.

2.117 TERMINATION (OF IRRADIATION)/TO TERMINATE (IRRADIATION): Stopping of/to stop IRRADIATION with no possibility of re-starting without the re-selection of all operating conditions, (i.e. returning/to return to the PREPARATORY STATE):

– when the preselected value of elapsed time is reached;

or:

– by deliberate manual act;

– by the operation of an INTERLOCK;

– by preselected value of GANTRY angular position in MOVING BEAM RADIOTHERAPY.

2.118 TREATMENT: The application of a prescribed procedure, or a part thereof, for therapeutic purposes.

2.119 TREATMENT FIELD: In RADIOTHERAPY, area at the PATIENT's surface which is to be IRRADIATED.

2.120 TYPE TEST: For a particular design of device or EQUIPMENT, a test by the MANUFACTURER to establish compliance with specified criteria.

2.121 ZERO APPLICATOR: In a system which includes an INTERLOCK against IRRADIATION without a BEAM APPLICATOR, means to bypass the INTERLOCK.

4 General requirements for tests

This clause of the General Standard applies except as follows:

4.1 *Tests*

Addition:

aa)

Test procedures described in this standard are generally classified into three grades. Their requirements are as follows:

Grade A:

In case of TYPE TEST: analysis of EQUIPMENT design, as related to the specified RADIATION safety provisions, which shall result in a statement included in the ACCOMPANYING DOCUMENTS, regarding the working principles or constructional means by which the requirement is fulfilled.