SLOVENSKI STANDARD
SIST EN 60601-2-1:2002

01-februar-2002

Medicinska električna oprema - 2-1. del: Posebne varnostne zahteve za elektronske pospeševalnike v območju od 1 MeV do 50 MeV (IEC 60601-2-1:1998)

Medical electrical equipment - Part 2-1: Particular requirements for the safety of electron accelerators in the range of 1 MeV to 50 MeV (IEC 60601-2-1:1998)

Medizinische elektrische Geräte - Teil 2-1: Besondere Festlegungen für die Sicherheit von Elektronenbeschleunigern im Bereich von 1 MeV bis 50 MeV (IEC 60601-2-1:1998)

Appareils électromédicaux - Partie 2-1: Règles particulières de sécurité pour les accélérateurs d'électrons dans la gamme de 1 MeV à 50 MeV (CEI 60601-2-1:1998)

Ta slovenski standard je istoveten z: **EN 60601-2-1:1998**

ICS:

11.040.50	Radiografska oprema	Radiographic equipment

SIST EN 60601-2-1:2002 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-1

August 1998

ICS 11.060.40

Descriptors: Medical electrical equipment, electron accelerators, safety requirements, protection against electric shock, protection against mechanical hazard, radiation protection, fire protection, environmental conditions

English version

Medical electrical equipment
Part 2-1: Particular requirements for the safety of electron accelerators in the range of 1 MeV to 50 MeV
(IEC 60601-2-1:1998)

Appareils électromédicaux
Partie 2-1: Règles particulières
de sécurité pour les accélérateurs
d'électrons dans la gamme de
1 MeV à 50 MeV
(CEI 60601-2-1:1998)

Medizinische elektrische Geräte
Teil 2-1: Besondere Festlegungen für die
Sicherheit von Elektronenbeschleuniger
im Bereich von 1 MeV bis 50 MeV
(IEC 60601-2-1:1998)

This European Standard was approved by CENELEC on 1998-08-01. 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.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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

Foreword

The text of document 62C/232/FDIS, future edition 2 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 was approved by CENELEC as EN 60601-2-1 on 1998-08-01.

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) 1999-05-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2001-05-01

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 annexes AA and BB are informative.
Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-2-1:1998 was approved by CENELEC as a European Standard without any modification.

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

IEC 60601-1-1 NOTE: Harmonized as EN 60601-1-1:1993 (not modified).

IEC 60601-1-3 NOTE: Harmonized as EN 60601-1-3:1994 (not modified).

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 (replacement in) annex ZA of EN 60601-1:1990/A2:1995:				
IEC 60601-1	1988	Medical electrical equipment Part 1: General requirements for safety	EN 60601-1 + corr. July	1990 1994
A1	1991		A1 + corr. July	1993 1994
A2	1995		A2[1)] A13	1995 1996
IEC 60601-1-4	1996	Part 1: General requirements for safety 4. Collateral standard: Programmable electrical medical systems	EN 60601-1-4	1996
IEC 60788	1984	Medical radiology - Terminology	HD 501 S1	1988
IEC 61217	1996	Radiotherapy equipment - Coordinates, movements and scales	EN 61217	1996

1) A2 includes corrigendum June 1995 to IEC 60601-1:1988/A2.

NORME INTERNATIONALE
INTERNATIONAL STANDARD

CEI
IEC
60601-2-1

Deuxième édition
Second edition
1998-06

Appareils électromédicaux –

Partie 2-1: Règles particulières de sécurité pour les accélérateurs d'électrons dans la gamme de 1 MeV à 50 MeV

Medical electrical equipment –

Part 2-1: Particular requirements for the safety of electron accelerators in the range 1 MeV to 50 MeV

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Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

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

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SECTION SIX – PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETIC MIXTURES

SECTION NINE – ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-1: Particular requirements for the safety of electron accelerators in the range 1 MeV to 50 MeV

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 60601-2-1 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 second edition cancels and replaces the first edition, published in 1981, and its amendments 1 (1984) and 2 (1990). Substantial revision has been necessary to obtain alignment with IEC 60601-1 (1988), amendment 1 (1991) and amendment 2 (1995). Consideration has been given to developments in technology and clinical usage, and to various hazards encountered and envisaged since the preparation of the first edition.

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

FDIS	Report on voting
62C/232/FDIS	62C/236/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.

Appendix L forms an integral part of this Standard.

Annexes AA and BB are for information only.

In this Particular Standard, the following print types are used:

– requirements, compliance with which can be tested, and definitions: roman type;

– explanations, advice, general statements and exceptions: small roman type;

– *test specifications: italic type;*

– TERMS USED THROUGHOUT THIS PARTICULAR STANDARD WHICH HAVE BEEN LISTED IN ANNEX AA AND DEFINED IN CLAUSE 2, OR IN IEC 60601-1 AND ITS COLLATERAL STANDARDS, OR IN IEC 60788: SMALL CAPITALS.

Certain defined terms have been abbreviated, viz.:

Defined term	Abbreviation
BEAM LIMITING DEVICE	BLD
BEAM LIMITING SYSTEM	BLS
ELECTROMAGNETIC COMPATIBILITY	EMC
INFORMATION TECHNOLOGY EQUIPMENT	ITE
NORMAL CONDITION	NC
NORMAL TREATMENT DISTANCE	NTD
PROGRAMMABLE ELECTRONIC SUBSYSTEM	PESS
SINGLE FAULT CONDITION	SFC
TREATMENT CONTROL PANEL	TCP

Certain other terms have been given their commonly used abbreviations, viz.:

Term	Abbreviation
International Commission on Radiological Protection	ICRP
International Commission on Radiation Units and Measurements	ICRU
Light emitting diode	LED

NOTE 1 – Although the actual titles of the persons fulfilling the following roles may vary from country to country, in this Particular Standard the term "Radiotherapist" is used to denote the person exercising medical supervision and responsibility for determining and prescribing PATIENT treatment. The term "OPERATOR" is used to denote the person responsible for delivering the planned course of prescribed treatment via the ELECTRON ACCELERATOR.

NOTE 2 – Attention is drawn to the existence, in some countries, of legislation containing requirements for:

– IONIZING RADIATION safety, which may not align with the provisions of this Particular Standard, and

– maintenance, quality assurance and other related subjects, which are not covered by this standard.

INTRODUCTION

The use of ELECTRON ACCELERATORS 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 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 EQUIPMENT; it places limits on the degradation of 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 EQUIPMENT.

Clause 29 contains limits beyond which INTERLOCKS prevent, INTERRUPT or TERMINATE IRRADIATION in order 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 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 at installation.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-1: Particular requirements for the safety of electron accelerators in the range 1 MeV to 50 MeV

SECTION ONE – GENERAL

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

1 Scope and object

1.1 Scope

Addition:

This Particular Standard, with the inclusion of TYPE TESTS and SITE TESTS, applies respectively to the manufacture and some installation[1)] aspects of ELECTRON ACCELERATORS[2)]

- 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 (NC) 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[3)] RATES between 0,001 Gy × s^{-1} and 1 Gy × 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,
  - used within the environmental and electrical supply conditions SPECIFIED in the technical description.

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1) In this Particular Standard, all references to installation refer to installation in the USER's premises.

2) See ICRP 33 (128) – (134) and (144) – (156).

3) In this Particular Standard, all references to ABSORBED DOSE refer to ABSORBED DOSE in water.

1.2 Object

Addition:

This Particular Standard establishes requirements to ensure the IONIZING RADIATION safety and enhanced electrical and mechanical safety of ELECTRON ACCELERATORS, and specifies tests to check compliance with those requirements.

NOTE – The adoption of this standard helps to ensure that the EQUIPMENT

- maintains PATIENT safety during 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.

1.3 Particular Standards

Additional subclauses:

1.3.101 Relationship to other standards and documents

NOTE – See Appendix L for normative references.

1.3.102 IEC 60601-1

The requirements of this Particular Standard take priority over those of all other standards; it is to be read in conjunction with IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety* with its amendments 1 (1991) and 2 (1995) – hereinafter referred to as the General Standard – which it amends and supplements. As in the General Standard, the requirements are followed by compliance tests.

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause of the General Standard, although possibly not relevant, applies without modification. 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. Unless otherwise stated, all clauses of the General Standard shall apply. The term "this Standard" is used throughout to refer 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 and Collateral Standards 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, figures or tables that 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.