SLOVENSKI STANDARD
SIST EN 60601-1-3:1998

01-september-1998

Medicinska električna oprema - 1. del: Splošne varnostne zahteve - 3. spremljevalni standard: Splošne zahteve za zaščito pred sevanjem pri opremi za rentgensko diagnostiko (IEC 60601-1-3:1994)

Medical electrical equipment - Part 1: General requirements for safety - 3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment (IEC 60601-1-3:1994)

Medizinische elektrische Geräte - Teil 1: Allgemeine Festlegungen für die Sicherheit - 3. Ergänzungs-Norm: Allgemeine Festlegungen für den Strahlenschutz von diagnostischen Röntgengeräten (IEC 60601-1-3:1994)

Appareils électromédicaux - Partie 1: Règles générales de sécurité - 3. Norme collatérale: Règles générales pour la radioprotection dans les équipements à rayonnement X de diagnostic (CEI 60601-1-3:1994)

Ta slovenski standard je istoveten z: **EN 60601-1-3:1994**

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EUROPEAN STANDARD

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EN 60601-1-3

September 1994

ICS 11.040.00

Descriptors: Medical electrical equipment, safety, requirements, X-ray, radiation protection, diagnostic

ENGLISH VERSION

Medical electrical equipment
Part 1: General requirements for safety
3. Collateral Standard: General requirements for radiation protection in diagnostic X-ray equipment
(IEC 601-1-3:1994)

Appareils électromédicaux
Première partie: Règles générales de sécurité
3. Norme Collatérale: Règles générales pour la radioprotection dans les équipements à rayonnement X de diagnostic
(CEI 601-1-3:1994)

Medizinische elektrische Geräte
Teil 1: Allgemeine Anforderungen an die Sicherheit
3. Ergänzungs-Norm: Allgemeine Anforderungen an den Strahlenschutz von diagnostischen Röntgengeräten
(IEC 601-1-3:1994)

This European Standard was approved by CENELEC on 1994-07-05. 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, 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 62B(CO)111, as prepared by Sub-Committee 62B: Diagnostic imaging equipment of IEC Technical Committee 62: Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote in December 1993.

The reference document was approved by CENELEC as EN 60601-1-3 on 5 July 1994.

The following dates were fixed:

- latest date of publication of an identical national standard (dop) 1995-07-01

- latest date of withdrawal of conflicting national standards (dow) 1995-07-01

For products which have complied with the relevant national standard before 1995-07-01, as shown by the manufacturer or by a certification body, this previous standard may continue to apply for production until 2000-07-01.

This European Standard constitutes a Collateral Standard to EN 60601-1: Medical electrical equipment Part 1: General requirements for safety, hereinafter referred to as the General Standard.

In the EN 60601 series Collateral Standards specify general requirements for safety applicable to:

- a group of MEDICAL ELECTRICAL EQUIPMENT (e.g. radiological equipment;

- a specific characteristic of all MEDICAL ELECTRICAL EQUIPMENT, not fully addressed in the General Standard (e.g. electromagnetic compatibility).

The numbering of sections, clauses and subclauses of this Collateral Standard corresponds with that of the General Standard.

Subclauses and figures which are additional to those of the General Standard are numbered starting from 201; additional annexes are lettered AAA, BBB, etc., and additional items aaa), bbb), etc.

Annexes designated "normative" are part of the body of the standard. Annexes designated "informative" are given only for information. In this standard, annexes AAA, BBB, CCC and ZB are informative and annex ZA is normative.

ENDORSEMENT NOTICE

The text of the International Standard IEC 601-1-3:1994 was approved by CENELEC as a European Standard without any modification.

ANNEX ZA (normative)

OTHER INTERNATIONAL PUBLICATIONS QUOTED IN THIS STANDARD WITH THE REFERENCES OF THE RELEVANT 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.

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

IEC Publication	Date	Title	EN/HD	Date
Addition to annex ZA of EN 60601-1:1990/A11:1993:				
406	1975	Radiographic cassettes	HD 356 S1	1977
522	1976	Inherent filtration of an X-ray tube assembly	-	-
627	1978	Characteristics of anti-scatter grids used in X-ray equipment	-	-
658	1979	Radiographic intensifying screens for medical use - Dimensions	-	-
788	1984	Medical radiology - Terminology	HD 501 S1	1988

Other publications:

ICRP Publication 33 - Protection against ionizing radiation from external sources used in medicine (Annals of the ICRP Vol. 9 Nr. 1, 1982) Published by Pergamon Press

ICRP Publication 34 - Protection of the patient in diagnostic radiology (Annals of the ICRP Vol. 9 Nr. 2/3, 1982) Published by Pergamon Press

ICRP Publication 60 - Recommendations of the International Commission on Radiological Protection (Annals of the ICRP Vol. 21 Nr. 1-3, 1990) - Published by Pergamon Press

ANNEX ZB (informative)

OTHER INTERNATIONAL PUBLICATIONS QUOTED IN THIS STANDARD WITH THE REFERENCES OF THE RELEVANT EUROPEAN PUBLICATIONS

IEC Publication	Date	Title	EN/HD	Date
Addition to annex ZB of EN 60601-1:1990/A11:1993:				
601-2-7	1987	Medical electrical equipment - Part 2: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators	HD 395.2.7 S1	1989
601-2-15	1988	Part 2: Particular requirements for the safety of capacitor discharge X-ray generators	HD 395.2.15 S1	1989
601-2-28	1993	Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis	EN 60601-2-28	1993
601-2-29	1993	Part 2: Particular requirements for the safety of radiotherapy simulators	-	-
601-2-32	1994	Part 2: Particular requirements for the safety of associated equipment of X-ray equipment	EN 60601-2-32	1994
637	1979	Marking of and accompanying documents for X-ray tubes and X-ray tube assemblies for medical use NOTE: The requirements of IEC 637 are replaced by corresponding requirements in IEC 601-2-28	-	-
878	1988	Graphical symbols for electrical equipment in medical practice	-	-

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Première édition
First edition
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Première partie:
Règles générales de sécurité

3. Norme collatérale: Règles générales pour la radioprotection dans les équipements à rayonnement X de diagnostic

Medical electrical equipment –

Part 1:
General requirements for safety

3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment

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CONTENTS

Page

FOREWORD 9

INTRODUCTION 13

Clause

SECTION 1: GENERAL

1 Scope, object and relationship to other standards 15
1.201 Scope 15
1.202 Object 15
1.203 Relationship to other standards 15
1.203.1 IEC 601-1 15
1.203.2 Particular Standards 17
1.203.3 Superseded IEC Standards 17
1.203.4 Normative references 17
1.203.5 Other related IEC Standards 17

2 Terminology and definitions 19
2.201 Defined terms 19
2.202 Qualifying conditions for defined terms 19
2.202.1 Boundary and dimensions of the X-RAY FIELD 19
2.202.2 Operating Conditions for NOMINAL X-RAY TUBE VOLTAGE 19
2.202.3 Effective IMAGE RECEPTION AREA 21
2.202.4 The IMAGE RECEPTOR PLANE in X-RAY IMAGE INTENSIFIER TUBES 21
2.202.5 Modes of operation with CONTINUED DISPLAY 23
2.203 Composition of reference materials 23
2.204 Degrees of requirement and miscellaneous terms 23
2.205 RADIATION QUANTITIES and units 23

4 General requirements for tests 23
4.201 Compliance 23
4.201.1 Statement of compliance 23

6 Identification, marking and documents 23
6.1 Marking on the outside of EQUIPMENT or EQUIPMENT parts 23
6.1.201 Marking requirements in subclauses 23
6.1.202 General requirements 23
6.8 ACCOMPANYING DOCUMENTS 25
6.8.201 References in subclauses 25
6.8.202 General requirements 27

SECTION 5: PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

29 X-RADIATION 27
29.201 RADIATION QUALITY 27
29.201.1 Limitation of operating voltage range in dental applications 27
29.201.2 HALF-VALUE LAYERS in X-RAY EQUIPMENT 29
29.201.3 FILTRATION in X-RAY TUBE ASSEMBLIES 33
29.201.4 FILTRATION in X-RAY SOURCE ASSEMBLIES 33
29.201.5 TOTAL FILTRATION in X-RAY EQUIPMENT 35
29.201.6 Indication of FILTER properties 35
29.201.7 Test for FILTRATION by irremovable materials 37
29.201.8 Test for ADDED FILTERS and materials 37
29.201.9 Test for HALF-VALUE LAYER 37
29.202 Limitation and indication of the extent of the X-RAY BEAM 37
29.202.1 Enclosure of X-RAY TUBES 39
29.202.2 Limiting DIAPHRAGM in X-RAY TUBE ASSEMBLIES 39
29.202.3 Confinement of EXTRA-FOCAL RADIATION 39
29.202.4 Methods of beam limitation in X-RAY EQUIPMENT 39
29.202.5 Indication on the EQUIPMENT 41
29.202.6 Indication in the INSTRUCTIONS FOR USE 43
29.202.7 Indication by LIGHT FIELD-INDICATOR 43
29.202.8 Accuracy of marked and written indications 45
29.202.9 Accuracy of indication with a LIGHT FIELD-INDICATOR 45
29.203 Relationship between X-RAY FIELD and IMAGE RECEPTION AREA 47
29.203.1 Positioning of the REFERENCE AXIS 47
29.203.2 FOCAL SPOT TO IMAGE RECEPTOR DISTANCE 47
29.203.3 Interception of the X-RAY BEAM in RADIOSCOPY 49
29.203.4 Correspondence between X-RAY FIELD and IMAGE RECEPTION AREA 49
29.204 LEAKAGE RADIATION 53
29.204.1 Mounting of X-RAY SOURCE ASSEMBLIES 53
29.204.2 Statement of reference LOADING conditions 53
29.204.3 LEAKAGE RADIATION in the LOADING STATE 55
29.204.4 LEAKAGE RADIATION during LOADING for voltage adjustment 57
29.204.5 LEAKAGE RADIATION when not in the LOADING STATE 57
29.205 FOCAL SPOT TO SKIN DISTANCE 59
29.205.1 X-RAY EQUIPMENT for RADIOSCOPY 59
29.205.2 X-RAY EQUIPMENT for RADIOGRAPHY 61
29.205.3 Information in the ACCOMPANYING DOCUMENTS 61
29.206 ATTENUATION of the X-RAY BEAM 61
29.206.1 ATTENUATION by items in the X-RAY BEAM 61
29.206.2 Information in the ACCOMPANYING DOCUMENTS 63
29.206.3 Test for ATTENUATION EQUIVALENT 63
29.207 PRIMARY PROTECTIVE SHIELDING 63
29.207.1 Requirements 63
29.207.2 Test for ATTENUATION of RESIDUAL RADIATION 65
29.207.3 Test for ATTENUATION EQUIVALENT 67

29.208 Protection against STRAY RADIATION 69
29.208.1 Protection by distance 71
29.208.2 Control from a PROTECTED AREA 71
29.208.3 Designated SIGNIFICANT ZONES OF OCCUPANCY 73
29.208.4 SIGNIFICANT ZONES OF OCCUPANCY with limited STRAY RADIATION 73
29.208.5 Handgrips and control devices 75
29.208.6 Test for STRAY RADIATION 77

Annexes

AAA - Recommendations for the provision of information concerning STRAY RADIATION 87
BBB - Index of defined terms 93
CCC - Normative references to ACCOMPANYING DOCUMENTS, INSTRUCTIONS FOR USE and ASSEMBLING INSTRUCTIONS 99

Tables

201 - Subclauses containing requirements for marking 23
202 - Subclauses requiring statements in ACCOMPANYING DOCUMENTS 25
203 - Voltage restrictions in dental X-RAY EQUIPMENT 29
204 - HALF-VALUE LAYERS in X-RAY EQUIPMENT 31
205 - Minimum FOCAL SPOT TO SKIN DISTANCES 59
206 - ATTENUATION EQUIVALENT of items in the X-RAY BEAM 61
207 - Parameters for testing ATTENUATION EQUIVALENT 63
208a - Application categories 67
208b - Requirements for PRIMARY PROTECTIVE SHIELDING 69
209 - STRAY RADIATION in SIGNIFICANT ZONES OF OCCUPANCY 75

Figures

201 - Zone of EXTRA- FOCAL RADIATION 78
202 - Discrepancies in visual indication of the X-RAY FIELD 79
203 - Discrepancies in covering the IMAGE RECEPTION AREA 80
204 - Testing for STRAY RADIATION (undertable tube with X-RAY BEAM horizontal) 81
205 - Testing for STRAY RADIATION (undertable tube with X-RAY BEAM vertical) 82
206 - Testing for STRAY RADIATION (overtable tube with X-RAY BEAM horizontal) 83
207 - Testing for STRAY RADIATION (overtable tube with X-RAY BEAM vertical) 84
208 - Example of presentation of data on STRAY RADIATION 85

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 1: General requirements for safety

3. Collateral standard: General requirements for radiation protection in diagnostic X-ray 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 cooperation 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 liasing with the IEC also participate in this preparation. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determinend by agreement between the two organizations.

2) The formal decisions or agreements of the IEC on technical matters, prepared by technical committees on which all the National Committees having a special interest therein are represented, express, as nearly as possible, an international consensus of opinion on the subjects dealt with.

3) They have the form of recommendations for international use 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.

International Standard IEC 601-1-3 has been prepared by sub-committee 62B: Diagnostic imaging equipment of IEC technical committee 62: Electrical equipment in medical practice. It constitutes a Collateral Standard to IEC 601-1: *Medical electrical equipment - Part 1: General requirements for safety*, hereinafter referred to as the General Standard.

In the 601 series of publications Collateral Standards specify general requirements for safety applicable to:

– a group of MEDICAL ELECTRICAL EQUIPMENT (e.g. radiological equipment);

– a specific characteristic of all MEDICAL ELECTRICAL EQUIPMENT, not fully addressed in the General Standard (e.g. electromagnetic compatibility).

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

DIS	Report on voting
62B(CO)111	62B(CO)123

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table.

The numbering of sections, clauses and subclauses of this Collateral Standard corresponds with that of the General Standard.

Subclauses and figures which are additional to those of the General Standard are numbered starting from 201; additional annexes are lettered AAA, BBB, etc., and additional items aaa), bbb), etc.

Annexes AAA, BBB and CCC are for information only.

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

- requirements, compliance with which can be tested, and definitions: in roman type;
- explanations, advice, general statements, exceptions and references: in smaller type;
- *test specifications and headings of subclauses: in italic type;*
- TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD OR OF THIS COLLATERAL STANDARD OR IN IEC 788: SMALL CAPITALS.

The requirements are followed by specifications for the relevant tests.

INTRODUCTION

The requirements in this Collateral Standard concern protective measures to be taken by the MANUFACTURER in the design and construction of medical diagnostic X-RAY EQUIPMENT and its subassemblies. They relate to the application of the X-RADIATION generated, both deliberately and incidentally, in fulfilling the medical purpose of the EQUIPMENT. Additional measures are necessary to regulate the generation processes themselves. These are described in the general requirements for safety, IEC 601-1, and, where appropriate, in particular requirements for the EQUIPMENT concerned.

The recommended principles governing the use of RADIATION for medical purposes, as stated in Publication 60 of the International Commission on Radiological Protection (ICRP), Chapter 4, have been taken into account. The implementation of these principles is essentially determined in the prevailing circumstances at the point of use. It requires judgements to be made by the USER and the establishment of measures and working practices that are not necessarily connected with the construction of EQUIPMENT. The requirements in this Collateral Standard are intended to be consistent with generally accepted good practice in the administration of X-RADIATION in medicine. In respect of economic factors, it is recognized that certain relatively inexpensive types of EQUIPMENT are sometimes justifiably preferred on grounds of cost. For these, this Collateral Standard avoids imposing requirements that would unduly restrict their medical effectiveness or would add disproportionately to the cost.

In some cases, the formulation of the requirements is deliberately designed to provide scope for accommodating local laws and regulations at the time of installation and commissioning. Several of the requirements include provisions for relevant technical information to be included in ACCOMPANYING DOCUMENTS.

USERS of medical diagnostic X-RAY EQUIPMENT should be aware that effective protection against IONIZING RADIATION requires the consideration of many aspects additional to the construction of the EQUIPMENT. Among these are the following:

- compatibility of components and correct installation of EQUIPMENT;
- the protective properties of rooms where X-RAY EQUIPMENT is installed;
- measures for monitoring and maintaining the safety and effectiveness of EQUIPMENT throughout its life, with particular attention to components that can deteriorate progressively with time and use;
- the need in appropriate circumstances for PROTECTIVE CLOTHING to be worn by staff and for suitable devices to be used to protect PATIENTS;
- the keeping of appropriate records concerning the usage of the EQUIPMENT and the results of tests, with systematic review and the application of corrective action when necessary;
- the training of staff in the principles of radiation protection and in the correct use of EQUIPMENT, including any protective devices provided.

Further advice on these aspects can be found in ICRP Publications 33, 34 and 60.

Readers of this Collateral Standard are reminded that, in accordance with IEC 601-1, clause 4, all the test procedures described are type tests, intended to be carried out in a dedicated testing environment in order to determine compliance. Tests to be carried out by manufacturers to ensure compliance during production or installation and tests for detecting non-compliance subsequently to delivery, are not included.

MEDICAL ELECTRICAL EQUIPMENT -

Part 1: General requirements for safety

3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment

SECTION 1: GENERAL

1 Scope, object and relationship to other standards

1.201 *Scope*

This Collateral Standard applies to medical diagnostic X-RAY EQUIPMENT and to sub-assemblies of such EQUIPMENT.

1.202 *Object*

The object of this Collateral Standard is to establish general requirements for protection against IONIZING RADIATION in medical diagnostic X-RAY EQUIPMENT, in order that the DOSE EQUIVALENT to the PATIENT, the OPERATOR and other staff can be kept as low as reasonably achievable.

Some of the requirements in this Collateral Standard include variations for different types of X-RAY EQUIPMENT. This is intended to widen the scope within which the Collateral Standard can be applied usefully without addition or modification, especially in respect of types of X-RAY EQUIPMENT that are commonly used in MEDICAL DIAGNOSTIC RADIOLOGY.

The requirements in this Collateral Standard apply mainly in respect of X-RADIATION after its generation. Requirements for the control of the electrical energy used to generate X-RADIATION, which is also an important aspect of RADIATION PROTECTION, are included in IEC 601-1 and in Particular Standards for the safety of the EQUIPMENT concerned.

1.203 *Relationship to other standards*

1.203.1 *IEC 601-1*

For diagnostic X-RAY EQUIPMENT, this Collateral Standard complements IEC 601-1: 1988, *Medical electrical equipment - Part 1: General requirements for safety.*

When referring to IEC 601-1 or to this Collateral Standard, either individually or in combination, the following conventions are used:

- "IEC 601-1" designates IEC 601-1 alone;
- "this Collateral Standard" designates this Collateral Standard alone;
- "this Standard" designates the combination of IEC 601-1 together with this Collateral Standard.

1.203.2 *Particular Standards*

A requirement in a Particular Standard takes priority over the corresponding requirement in this Collateral Standard.

1.203.3 *Superseded IEC Standards*

In the following IEC standards, requirements that relate to medical diagnostic X-RAY EQUIPMENT are superseded by the requirements in this Collateral Standard:

IEC 407: 1973, *Radiation protection in medical X-ray equipment 10 kV to 400 kV*

IEC 407A: 1975, *First supplement to IEC 407*

1.203.4 *Normative references*

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All normative documents are subject to revision, and parties to agreements based on this International Standard are encourated to investigate the possibility of applying the most recent editions of the normative documents indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

IEC 406: 1975, *Radiographic cassettes*

IEC 522: 1976, *Inherent filtration of an X-ray tube assembly*

IEC 627: 1978, *Characteristics of anti-scatter grids used in X-ray equipment*

IEC 658: 1979, *Radiographic intensifying screens for medical use - Dimensions*

IEC 788: 1984, *Medical radiology - Terminology*

ICRP Publication 33: *Protection against ionizing radiation from external sources used in medicine (Annals of the ICRP Vol. 9 No. 1, 1982). Published by Pergamon Press*

ICRP Publication 34: *Protection of the patient in diagnostic radiology (Annals of the ICRP Vol. 9 No. 2/3, 1982). Published by Pergamon Press*

ICRP Publication 60: *Recommendations of the International Commission on Radiological Protection (Annals of the ICRP Vol. 21 No. 1-3, 1990). Published by Pergamon Press*

1.203.5 *Other related IEC Standards*

At the time of publication, the following Particular Standards have been identified as containing concurrent requirements for RADIATION PROTECTION in diagnostic X-RAY EQUIPMENT:

IEC 601-2-7: 1987, *Medical electrical equipment - Part 2: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generator*

IEC 601-2-15: 1988, *Medical electrical equipment - Part 2: Particular requirements for the safety of capacitor discharge X-ray generators*