

ELEKTRILISED MEDITSIINISEADMED. OSA 2-8:
ERINÕUDED VAHEMIKUS 10 KV KUNI 1 MV TÖÖTAVATE
RÖNTGENRAVISEADMETE ESMASELE OHUTUSELE JA
OLULISTELE TOIMIMISNÄITAJATELE

Medical electrical equipment - Part 2-8: Particular requirements for basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1 MV

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 60601-2-8:2015 sisaldab Euroopa standardi EN 60601-2-8:2015 ingliskeelset teksti.	This Estonian standard EVS-EN 60601-2-8:2015 consists of the English text of the European standard EN 60601-2-8:2015.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
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English Version

Medical electrical equipment - Part 2-8: Particular requirements
for the basic safety and essential performance of therapeutic X-
ray equipment operating in the range 10 kV to 1 MV
(IEC 60601-2-8:2010)

Appareils électromédicaux - Partie 2-8: Exigences
particulières pour la sécurité de base et les performances
essentielles des équipements à rayonnement X de thérapie
fonctionnant dans la gamme de 10 kV à 1 MV
(IEC 60601-2-8:2010)

Medizinische elektrische Geräte - Teil 2-8: Besondere
Festlegungen für die Sicherheit einschließlich der
wesentlichen Leistungsmerkmale von Therapie-
Röntgeneinrichtungen im Bereich von 10 kV bis 1 MV
(IEC 60601-2-8:2010)

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

Foreword

The text of document 62C/499/FDIS, future edition 2 of IEC 60601-2-8, 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 60601-2-8:2015.

The following dates are 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) 2016-01-14
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2018-04-14

This document supersedes EN 60601-2-8:1997.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN and CENELEC 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 see informative Annex ZZ, which is an integral part of this document.

Endorsement notice

The text of the International Standard IEC 60601-2-8:2010 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following note has to be added for the standard indicated:

IEC 60601-2-17 NOTE Harmonized as EN 60601-2-17.

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 with the following exceptions:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
<i>Addition:</i>				
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-
IEC 60601-2-1	2009	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 61217	-	Radiotherapy equipment - Coordinates, movements and scales	EN 61217	-
ISO/IEC Guide 98-3	2008	Uncertainty of measurement - Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)	-	-

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.

NOTE Presumption of conformity with Essential Requirements 13.1 to 13.6 should depend on the manufacturer confirming the accuracy of the accompanying documents in all relevant languages.

WARNING: Other requirements and other EU Directives can be applied to the products falling within the scope of this standard.

CONTENTS

FOREWORD.....	3
INTRODUCTION	5
201.1 Scope, object and related standards.....	6
201.2 Normative references.....	7
201.3 Terms and definitions.....	8
201.4 General requirements.....	8
201.5 General requirements for testing of ME EQUIPMENT.....	9
201.6 Classification of ME EQUIPMENT and ME SYSTEMS.....	11
201.7 ME EQUIPMENT identification, marking and documents.....	11
201.8 Protection against electrical HAZARDS from ME EQUIPMENT.....	14
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS.....	15
201.10 Protection against unwanted and excessive radiation HAZARDS.....	15
201.11 Protection against excessive temperatures and other HAZARDS.....	30
201.12 Accuracy of controls and instruments and protection against hazardous outputs.....	30
201.13 HAZARDOUS SITUATIONS and fault conditions.....	30
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS).....	31
201.15 Construction of ME EQUIPMENT.....	31
201.16 ME SYSTEMS.....	31
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS.....	31
Bibliography.....	32
Index of defined terms used in this particular standard.....	33
Table 201.101 – Data required in the technical description to support Clause 201.10 SITE and TYPE TEST compliance.....	10
Table 201.102 – Permissible LEAKAGE RADIATION.....	16
Table 201.103 – Permissible LEAKAGE RADIATION from X-RAY TUBE ASSEMBLIES with BEAM LIMITING DEVICES.....	18
Table 201.104 – Overview of measurements.....	29

INTRODUCTION

X-RAY EQUIPMENT for RADIOTHERAPY purposes is used for TELETHERAPY, where the RADIATION SOURCE is far from the tissues to be treated (usually more than 50 cm), and also for BRACHYTHERAPY, where the RADIATION SOURCE is positioned within or adjacent to the tissue to be treated. This particular standard covers X-RAY EQUIPMENT for both TELETHERAPY and BRACHYTHERAPY.

The use of X-RAY EQUIPMENT for RADIOTHERAPY purposes may expose the PATIENT 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 the MANUFACTURERS in the design and construction of therapeutic X-RAY EQUIPMENT. Subclause 201.10.1 contains limits beyond which INTERLOCKS prevent, INTERRUPT or TERMINATE IRRADIATION in order to avoid an unsafe condition.

Subclause 201.10.1 does not attempt to define 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, 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 at installation.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-8: Particular requirements for the basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1 MV

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 therapeutic X-RAY EQUIPMENT with NOMINAL X-RAY TUBE VOLTAGES in the range 10 kV to 1 MV when connected to alternating current SUPPLY MAINS, hereafter referred to as ME EQUIPMENT.

NOTE This standard covers TELETHERAPY and BRACHYTHERAPY.

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.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular basic safety and essential performance requirements for therapeutic X-RAY EQUIPMENT. It includes the requirements for accuracy and reproducibility of performance to the extent that these are related to radiation quality and the quantity of ionizing radiation produced and thus must be considered as aspects of safety.

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 60601-1-10²⁾ do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

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

²⁾ 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*

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:

Addition:

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

IEC 60601-2-1:2009, *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 61217, *Radiotherapy equipment – Coordinates, movements and scales*

ISO/IEC Guide 98-3:2008, *Uncertainty of measurement – Part 3: Guide to the expression of uncertainty in measurement* (GUM:1995)

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 33.

Addition:

201.3.201

BRACHYTHERAPY

RADIOTHERAPY using one or more RADIATION SOURCES with the RADIATION SOURCE/sources inside or close to the TARGET VOLUME

NOTE BRACHYTHERAPY techniques include INTERSTITIAL, INTRACAVITARY, SUPERFICIAL or INTRALUMINAL RADIOTHERAPY.

201.3.202

INTERSTITIAL RADIOTHERAPY

RADIOTHERAPY with RADIATION SOURCES inserted within the TARGET VOLUME

201.2.203

INTRACAVITARY RADIOTHERAPY

RADIOTHERAPY in which one or more RADIATION SOURCES, with or without SOURCE APPLICATORS, are introduced into a body cavity through a natural or artificial opening

201.3.204

INTRALUMINAL RADIOTHERAPY

RADIOTHERAPY in which one or more RADIATION SOURCES, with or without SOURCE APPLICATORS, are introduced into a body lumen such as a blood vessel, air way, or the gastrointestinal tract

201.3.205

SOURCE APPLICATOR

<BRACHYTHERAPY> device to bring one or more RADIATION SOURCES into the intended positions

NOTE A SOURCE APPLICATOR may include protective shielding.

201.3.206

TELERADIOTHERAPY

TELEETHERAPY

RADIOTHERAPY with a large RADIATION SOURCE TO SKIN DISTANCE, usually not less than 50 cm

201.4 General requirements

Clause 4 of the general standard applies, except as follows:

Additional subclause: