ELEKTRILISED MEDITSIINISEADMED. OSA 2-1: ERINÕUDED ELEKTRONKIIRENDI ESMASELE OHUTUSELE JA OLULISTELE TOIMIMISNÄITAJATELE VAHEMIKUS 1 MEV KUNI 50 MEV

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

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 60601-2-1:2015 sisaldab Euroopa standardi EN 60601-2-1:2015 ingliskeelset teksti.	This Estonian standard EVS-EN 60601-2-1:2015 consists of the English text of the European standard EN 60601-2-1:2015.
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.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 23.10.2015.	Date of Availability of the European standard is 23.10.2015.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.040.60

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-1

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Supersedes EN 60601-2-1:1998

English Version

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 60601-2-1:2009 + A1:2014)

Appareils électromédicaux - Partie 2-1: Exigences particulières de sécurité de base et de performances essentielles pour les accélérateurs d'électrons dans la gamme de 1 MeV à 50 MeV (IEC 60601-2-1:2009 + A1:2014)

Medizinische elektrische Geräte - Teil 2-1: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Elektronenbeschleunigern im Bereich von 1 MeV bis 50 MeV (IEC 60601-2-1:2009 + A1:2014)

This European Standard was approved by CENELEC on 2015-09-15. 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.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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

European foreword

The text of document 62C/474/FDIS, future edition 3 of IEC 60601-2-1, and the text of document 62C/532/CDV, future IEC 60601-2-1/A1, prepared by SC 62C "Equipment for radiotherapy, nuclear medicine and radiation dosimetry", of IEC/TC 62 "Electrical equipment in medical practice" were submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-2-1:2015.

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) 2016-06-15
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2018-09-15

This document supersedes EN 60601-2-1:1998.

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.

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.

Endorsement notice

The text of the International Standards IEC 60601-2-1:2009 and IEC 60601-2-1:2009/A1:2014 were approved by CENELEC as a European Standard without any modification.

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

IEC 60976:2007	NOTE	Harmonized as EN 60976:2007 (not modified).
IEC 62366	NOTE	Harmonized as EN 62366.

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:

Publication	Year	Title	EN/HD	Year
Addition to Annex ZA of EN 60601-1:2006:				
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-
IEC 61217	1996	Radiotherapy equipment - Coordinates, movements and scales	EN 61217	1996

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.

CONTENTS

INTRODUCTION

The use of ELECTRON ACCELERATORS 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 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 ME EQUIPMENT. It places limits on the degradation of ME 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 ME EQUIPMENT.

Clause 201.10 contains limits beyond which INTERLOCKS prevent, INTERRUPT or TERMINATE IRRADIATION in order to insure ESSENTIAL PERFORMANCE is maintained 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 is understood that SITE TESTS may or may not be required of the MANUFACTURER, per the agreement between the MANUFACTURER and end user.

Given that before installation a MANUFACTURER cannot provide SITE TEST data, 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 at installation.

This International Standard was first published in 1981. It was amended in 1984 and 1990. A second edition was published in 1998 and amended in 2002. This third edition is prompted by the need to align this particular standard with the third edition of the general standard, IEC 60601-1:2005.

IEC 60976 and IEC/TR 60977 are closely related to this standard. The former specifies test methods and reporting formats for performance tests of ELECTRON ACCELERATORS for use in RADIOTHERAPY, with the aim of providing uniform methods for conducting such tests. The latter is not a standard per se, but suggests performance values, measured per the methods specified in IEC 60976, that could be achievable with present technology.

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

201.1 Scope, object and related standards

Clause 1 of the general standard[1)] applies, except as follows:

201.1.1 Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of ELECTRON ACCELERATORS, hereafter referred to as ME EQUIPMENT, in the range 1 MeV to 50 MeV, used for treatment of PATIENTS.

This particular standard, with the inclusion of TYPE TESTS and SITE TESTS, applies respectively to the manufacture and some installation aspects of ELECTRON ACCELERATORS

– 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 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 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.

NOTE 1 In this particular standard, all references to installation refer to installation in the RESPONSIBLE ORGANIZATION'S premises.

NOTE 2 In this particular standard, all references to ABSORBED DOSE refer to ABSORBED DOSE in water.

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