SLOVENSKI STANDARD
SIST EN 60601-2-64:2015/oprA1:2024

01-april-2024

Medicinska električna oprema - 2-64. del: Posebne zahteve za osnovno varnost in bistvene lastnosti medicinske opreme za lahkoionsko terapijo - Dopolnilo A1

Amendment 1 - Medical electrical equipment - Part 2-64: Particular requirements for the basic safety and essential performance of light ion beam medical electrical equipment

Medizinische elektrische Geräte - Teil 2-64: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Leichtionen-Bestrahlungseinrichtungen

Appareils électromédicaux - Partie 2-64: Exigences particulières pour la sécurité de base et les performances essentielles des appareils électromédicaux par faisceau d'ions légers

Ta slovenski standard je istoveten z: **EN 60601-2-64:2015/prA1:2024**

ICS:

11.040.60	Terapevtska oprema	Therapy equipment

SIST EN 60601-2-64:2015/oprA1:2024 **en**

62C/905/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER: **IEC 60601-2-64/AMD1 ED1**	
DATE OF CIRCULATION: **2024-02-09**	CLOSING DATE FOR VOTING: **2024-05-03**
SUPERSEDES DOCUMENTS: **62C/878/CD, 62C/890A/CC**	

IEC SC 62C : EQUIPMENT FOR RADIOTHERAPY, NUCLEAR MEDICINE AND RADIATION DOSIMETRY

SECRETARIAT: Germany	SECRETARY: Ms Regina Geierhofer
OF INTEREST TO THE FOLLOWING COMMITTEES:	PROPOSED HORIZONTAL STANDARD: ☐ Other TC/SCs are requested to indicate their interest, if any, in this CDV to the secretary.

FUNCTIONS CONCERNED:

☐ EMC ☐ ENVIRONMENT ☐ QUALITY ASSURANCE ☒ SAFETY

☒ SUBMITTED FOR CENELEC PARALLEL VOTING	☐ NOT SUBMITTED FOR CENELEC PARALLEL VOTING

Attention IEC-CENELEC parallel voting

The attention of IEC National Committees, members of CENELEC, is drawn to the fact that this Committee Draft for Vote (CDV) is submitted for parallel voting.

The CENELEC members are invited to vote through the CENELEC online voting system.

This document is still under study and subject to change. It should not be used for reference purposes.

Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Recipients of this document are invited to submit, with their comments, notification of any relevant “In Some Countries” clauses to be included should this proposal proceed. Recipients are reminded that the CDV stage is the final stage for submitting ISC clauses. (SEE AC/22/2007 OR NEW GUIDANCE DOC).

TITLE:

Amendment 1 - Medical electrical equipment - Part 2-64: Particular requirements for the basic safety and essential performance of light ion beam medical electrical equipment

PROPOSED STABILITY DATE: 2024

NOTE FROM TC/SC OFFICERS:

In the attached CDV, red characters represent changes from Ed1 to AMD1/CD1, blue characters represent changes from AMD1/CD1 to AMD1/CD2, purple characters represent changes from AMD1/CD2 to AMD1/CDV, respectively, based on the NCs' comments and discussion in WG 1.

As indicated in 62C/766/Q, the scope of AMD1 is as follows:

1) Harmonization with IEC 60601-1 Ed1/AMD2

2) Harmonization with IEC 62667 (light ion performance) for defined terms

3) Neutrons outside the field of irradiation.

In addition, a correction to the current edition has been prepared for CDV, while any other comments, such as the introduction of a new concept, are excluded and are expected to be discussed in a future amendment or edition.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Particular requirements for the basic safety and essential performance of LIGHT ION BEAM ME EQUIPMENT

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of 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, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). 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. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.

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

International Standard IEC 60601-2-64 has been prepared by subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Medical equipment, software, and systems.

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

FDIS	Report on voting

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

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

- Requirements and definitions: roman type.
- *Test specifications: italic type.*
- Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

- “clause” means one of the numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
- “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment,* can be found on the IEC website.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

INTRODUCTION

The use of LIGHT ION BEAM ME EQUIPMENT 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 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 LIGHT ION BEAM ME EQUIPMENT 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 that ESSENTIAL PERFORMANCE is maintained and to avoid an unsafe condition. TYPE TESTS that are performed by the MANUFACTURER, 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 ME EQUIPMENT at installation.

Closely related to this standard is IEC 62667~~ which is currently being developed~~. It specifies test methods and reporting formats for performance tests of LIGHT ION BEAM ME EQUIPMENT for use in RADIOTHERAPY, with the aim of providing uniform methods of doing so. The annex of IEC 62667 provides forms for presenting performance values, measured per the methods SPECIFIED.

MEDICAL ELECTRICAL EQUIPMENT –

Particular requirements for the basic safety and essential performance of LIGHT ION BEAM ME EQUIPMENT

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 LIGHT ION BEAM ME EQUIPMENT, hereafter referred to as ME EQUIPMENT, used for treatment of PATIENTS.

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.

This particular standard, with the inclusion of TYPE TESTS and SITE TESTS, applies respectively to the manufacture and some installation aspects of LIGHT ION BEAM ME EQUIPMENT

– 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, in NORMAL USE, deliver a RADIATION BEAM of LIGHT IONS having ENERGY PER NUCLEON in the range 10 MeV/n to 500 MeV/n,

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 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.

NOTE 3 Information regarding x-ray image guidance can be found in IEC 60601-2-68 ~~(under development)~~.

NOTE 4 IEC 61217 gives guidance on the designation of ME EQUIPMENT movements, the marking of scales, their zero positions and the direction of movement with increasing value (see 201.7.4.101).

201.1.2 Object

Replacement:

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1 The general standard is IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012/AMD2:2020, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for LIGHT ION BEAM ME EQUIPMENT in the range 10 MeV/n to 500 MeV/n and to SPECIFY tests to check compliance to those requirements.

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

– maintains PATIENT safety during ME EQUIPMENT movements and failure of the SUPPLY MAINS;

– delivers the pre-selected RADIATION TYPE, ENERGY PER NUCLEON, LIGHT ION species, and ABSORBED DOSE;

– delivers pre-selected LIGHT ION BEAMS to the PATIENT, by utilizing LIGHT ION BEAM modifying devices, etc., without causing unnecessary risk to the PATIENT, the OPERATOR, other persons or the environment.

201.1.3 Collateral standards

Addition:

Collateral standards published after the date of publication of this standard shall only apply subject to further amendment to this standard.

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 60601-1-6 applies as modified in Clause 206. IEC 60601-1-3, IEC 60601-1-8, IEC 60601-1-9[2] and IEC 60601-1-10[3] do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

NOTE Collateral standards published after the date of publication of this standard will only apply subject to further amendment to this standard.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard or 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.

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2 IEC 60601-1-9, *Medical electrical equipment – Part 1-9: General requirements for basic safety and essential performance – Collateral Standard: Requirements for environmentally conscious design*

3 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*

"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:

Replacement:

IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests*
IEC 60601-1-2:2014/AMD1:2020

Addition:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012
IEC 60601-1:2005/AMD2:2020

~~IEC 60601-2-1:2009~~2020, ~~*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 60601-2-11:2013, *Medical electrical equipment – Part 2-11: Particular requirements for the basic safety and essential performance of gamma beam therapy equipment*~~

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

IEC 61217:2011, *Radiotherapy equipment – Coordinates, movements and scales*

ISO/IEC 14165-321:2009, *Information technology – Fibre channel – Part 321: Audio video (FC-AV)*

NOTE Informative references are listed in the bibliography.

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005/AMD1:2012/AMD2:2020~~+A1:2012~~, IEC 60601-2-1:~~2009~~2020, and IEC TR 60788:2004 apply, except as follows:

Additional definitions:

201.3.201
APPLICATOR CARRIAGE
the most distal part of the RADIATION HEAD that can not be removed without using tools to which interchangeable LIGHT ION BEAM APPLICATORS are attached and which may extend toward and retract away from the ISOCENTRE or ERP.

Note 1 to entry: Colloquially the APPLICATOR CARRIAGE has sometimes been called a snout.

201.3.202
BEAM FLUENCE DISTRIBUTION MONITOR
system to monitor directly or indirectly the FLUENCE distribution of the beam to provide beam steering or lateral spreading information

Note 1 to entry: This monitor may be used as a surrogate monitor for the DOSE distribution delivered to the patient.

Note 2 to entry: Examples of BEAM FLUENCE DISTRIBUTION MONITORS include quadrant foil ionization chambers, concentric ring ionization chambers, multi-strip ionization chambers, scintillator plates, and scanning magnet field probes.

201.3.203
BEAM FLUX MONITOR
system to monitor the FLUX of the beam

Note 1 to entry: This monitor may be used as a surrogate monitor for the DOSE rate delivered to the patient.

201.3.204
BEAM GATING
allowance or inhibition of IRRADIATION and related equipment movements according to the status provided by a BEAM GATING SIGNAL

201.3.205
BEAM GATING SIGNAL
signal generated for the purpose of BEAM GATING

EXAMPLE Examples include a respiratory spirometer, electrocardiogram, optical sensor, etc.

201.3.206
CONTROLLING TIMER
device to measure the time during which IRRADIATION occurs and, if a predetermined time is reached, to TERMINATE IRRADIATION

[SOURCE: IEC 60601-2-1:~~2009~~2020, 201.3.~~202~~210]

201.3.207
DOSE MONITOR UNIT
a parameter, reported by the DOSE MONITORING SYSTEM, from which, through a calibration procedure and with additional information, the ABSORBED DOSE delivered can be calculated

201.3.208
DOSE MONITOR UNIT RATE
DOSE MONITOR UNIT per unit time

201.3.209
DOSE MONITOR UNIT RATE MONITORING SYSTEM
system of devices for the measurement and DISPLAY of a radiation quantity related to DOSE MONITOR UNIT RATE

201.3.210
DOSE MONITORING SYSTEM
system of devices for the measurement and DISPLAY of a radiation quantity related to the ABSORBED DOSE

201.3.211
ENERGY PER NUCLEON
~~the~~ total kinetic energy of the ion divided by the number of nucleons in the nucleus at the point where the ion enters the RADIATION HEAD before passing through any beam modifiers

201.3.212
EQUIPMENT REFERENCE POINT
ERP
point in space used for referencing dimensions of equipment and performing dosimetry measurements

Note 1 to entry: Typically the reference point is coincident with the ISOCENTRE. If the beam delivery equipment is not ISOCENTRIC, then the centre of the PATIENT alignment systems may be used.

Note 2 to entry: The corresponding note to entry in the French text indicates that the abbreviation "ERP" stands for "EQUIPMENT REFERENCE POINT" in English.

201.3.213
FLUENCE
~~particles per unit area~~the quotient of dN by dA~~a~~, where dN is the number of particles incident on a sphere of cross-sectional area dA~~a~~, thus

$\Phi = dN/dA$

Note 1 to entry: Definition from ~~See ICRU 33~~ICRU 85a.

201.3.214
FLUX
~~particles per unit time~~

~~Note 1 to entry: See ICRU 33, ICRU 85a.~~

the quotient of dN by dt, where dN is the increment of the particle number in the time interval dt, thus

$\dot{N} = dN/dt$

Note 1 to entry: Definition from ICRU 85a.

201.3.215
HARD-WIRED
term used where the features of a system can be modified only by physically removing and re-routing wires

[SOURCE: IEC 60601-2-1: ~~2009~~2020, 201.3.~~208~~224]

201.3.216
INTERRUPTION OF IRRADIATION
TO INTERRUPT IRRADIATION
stopping of/to stop IRRADIATION and movements with the possibility of continuing without reselecting operating conditions

[SOURCE: IEC 60601-2-1: ~~2009~~2020, 201.3.~~210~~227]

201.3.217
LATERAL SPREADING DEVICE
LSD
device used to increase the lateral (X~~x~~g, Y~~y~~g) ~~(x_b, y_b)~~ dimensions of a small diameter LIGHT ION BEAM produced by an accelerator

EXAMPLE Examples of spreading devices include a thin metal foil for scattering the ions or a magnet to defocus the beam or to scan the beam laterally across the intended ~~target volume~~TARGET VOLUME.

Note 1 to entry: Xg and Yg are defined in IEC 61217:2011.~~The definition was taken from IEC 60601-2-64:2014 but further review after publication of the standard showed that the GANTRY frame of reference would be more appropriate.~~

201.3.218
LIGHT ION
species of ion with an atomic number less than or equal to that of neon ($Z \leq 10$) and SPECIFIED by its number of protons, number of nucleons and ionization state

201.3.219
LIGHT ION BEAM
collection of LIGHT IONS travelling in the same general direction

201.3.220
LIGHT ION BEAM APPLICATOR
device for holding a BEAM LIMITING DEVICE or ACCESSORY close to the PATIENT's skin during delivery of LIGHT ION BEAM

Note 1 to entry: Several LIGHT ION BEAM APPLICATORS may be available to reduce the weight of APERTURES lifted by the OPERATOR~~therapists~~, decrease the ACCESSORY~~bolus~~ to skin distance and reduce leakage radiation.

~~Note 2 to entry: ACCESSORIES that may be held by the LIGHT ION BEAM APPLICATOR include but are not limited to range shiftersRANGE SHIFTERs, alignment cross-wires, ridge filters, mirror or camera for viewing the PATIENT, beam monitor.~~

201.3.221
LIGHT ION BEAM DISTRIBUTION SYSTEM
system of components and a control system used to transport the RADIATION from a RADIATION SOURCE to several TREATMENT stations, experimental stations or beam dumps

EXAMPLE Examples of components include vacuum pipes, magnets, and steering coils.

201.3.222
LIGHT ION RANGE
the depth in a PHANTOM most distant from its surface at which the ABSORBED DOSE is a SPECIFIED value, given in the ACCOMPANYING DOCUMENTS, of the dose at the nominal centre-of-modulation depth or of the dose maximum for a non-range-modulated beam, which is measured on the RADIATION BEAM AXIS in a SPECIFIED RADIATION FIELD and with the surface of the PHANTOM at a SPECIFIED distance from the ERP without RANGE SHIFTERS or ACCESSORIES installed in the RADIATION HEAD downstream of the ENERGY PER NUCLEON or range monitoring system