SLOVENSKI STANDARD
oSIST prEN IEC 60601-2-92:2026

01-april-2026

Medicinska električna oprema - 2-92. del: Posebne zahteve za osnovno varnost in bistvene lastnosti opreme za radioterapijo z magnetno resonanco, ki se uporablja z opremo za zunanje obsevanje

Medical electrical equipment - Part 2-92: Particular requirements for the basic safety and essential performance of magnetic resonance guided radiotherapy equipment for use with external beam equipment

Sample Document

get full document from standards.iteh.ai

Ta slovenski standard je istoveten z: **prEN IEC 60601-2-92:2026**

ICS:

11.040.50	Radiografska oprema	Radiographic equipment

oSIST prEN IEC 60601-2-92:2026 **en**

2003-01.Slovenski inštitut za standardizacijo. Razmnoževanje celote ali delov tega standarda ni dovoljeno.

Sample Document

get full document from standards.iteh.ai

62C/972/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER: **IEC 60601-2-92 ED1**	
DATE OF CIRCULATION: **2026-02-13**	CLOSING DATE FOR VOTING: **2026-05-08**
SUPERSEDES DOCUMENTS: **62C/918/CD, 62C/933A/CC**	

IEC SC 62C : EQUIPMENT FOR RADIOTHERAPY, NUCLEAR MEDICINE AND RADIATION DOSIMETRY	
SECRETARIAT: Germany	SECRETARY: Ms Regina Geierhofer
OF INTEREST TO THE FOLLOWING COMMITTEES: SC 62B	HORIZONTAL FUNCTION(S):
ASPECTS CONCERNED: 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.	

Sample Document
get full document from standards.iteh.ai

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:

Medical electrical equipment - Part 2-92: Particular requirements for the basic safety and essential performance of magnetic resonance guided radiotherapy equipment for use with external beam equipment

PROPOSED STABILITY DATE: 2030

Copyright © 2025 International Electrotechnical Commission, IEC. All rights reserved. It is permitted to download this electronic file, to make a copy and to print out the content for the sole purpose of preparing National Committee positions. You may not copy or "mirror" the file or printed version of the document, or any part of it, for any other purpose without permission in writing from IEC.

NOTE FROM TC/SC OFFICERS:

Sample Document

get full document from standards.iteh.ai

oSIST prEN IEC 60601-2-92:2026

CONTENTS

CONTENTS 2
FOREWORD 2
INTRODUCTION 5
201.1 Scope, object and related standards 7
201.2 Normative references 9
201.3 Terms and definitions 10
201.4 General requirements 13
201.5 General requirements for testing ME EQUIPMENT 13
201.6 Classification of ME EQUIPMENT and ME SYSTEMS 14
201.7 ME EQUIPMENT identification, marking and documents 14
202 Protection against electrical HAZARDS from ME EQUIPMENT 20
203 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS 21
204 Protection against unwanted and excessive radiation HAZARDS 23
205 Protection against excessive temperatures and other HAZARDS 23
206 Accuracy of controls and instruments and protection against hazardous outputs 23
207 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT 24
208 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) 24
209 Construction of ME EQUIPMENT 24
210 ME SYSTEMS 24
211 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS 24
201.101 Reference data for GUIDED RADIOTHERAPY 25
201.102 GUIDED RADIOTHERAPY acquisition 28
201.103 GUIDED RADIOTHERAPY Analysis and correction 30
202 Electromagnetic compatibility – Requirements and tests 34
206 Usability 34
Annexes 35
Annex B (informative) Sequence of testing 35
Annex I (informative) ME SYSTEMS aspects 35
Annex AA (informative) Particular guidance and rationale 36
Annex BB (normative) 38
Bibliography 38
Index of defined terms 39

Figure A. 1 Signals related to GRT LATENCY 38

Table 201.101 – Data required in the technical description 17
Table 201.102 – Clauses and subclauses in this particular standard that require the provision of information in the ACCOMPANYING INFORMATION, INSTRUCTIONS FOR USE and the technical description 18

Sample Document
get full document from standards.iteh.ai

oSIST prEN IEC 60601-2-92:2026 • https://standards.iteh.ai/catalog/standards/sist/0074276c-ed27-43d6-b54f-db2d35b03022/osist-pren-iec-60601-2-92-2026

oSIST prEN IEC 60601-2-92:2026

INTERNATIONAL ELECTROTECHNICAL COMMISSION

_____

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-92: Particular requirements for the basic safety and essential performance of magnetic resonance guided radiotherapy equipment for use with external beam 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.
2) The formal decisions or agreements of 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 IEC National Committees.
3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
6) All users should ensure that they have the latest edition of this publication.
7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
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 60601-2-92 has been prepared by IEC subcommittee 62C Equipment for radiotherapy, nuclear medicine and radiation dosimetry of IEC technical committee 62: Medical equipment, software, and systems.

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

Draft	Report on voting

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

Sample Document

oSIST prEN IEC 60601-2-92:2026 • https://standards.iteh.ai/catalog/standards/sist/0074276c-ed27-43d6-b54f-db2d35b03022/osist-pren-iec-60601-2-92-2026

oSIST prEN IEC 60601-2-92:2026

The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/standardsdev/publications.

In this document, 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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 AND IEC 60601-1:2005/AMD2:2020, in this document or as noted: SMALL CAPITALS.

In referring to the structure of this document, the term

– "clause" means one of the seventeen 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 document are preceded by the term "Clause" followed by the clause number. References to subclauses within this document are by number only.

Sample Document

In this document, 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 document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;
– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;
– "may" is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 60601 and IEC 80601 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 document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

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

oSIST prEN IEC 60601-2-92:2026 • https://standards.iteh.ai/catalog/standards/sist/0074276c-ed27-43d6-b54f-db2d35b03022/osist-pren-iec-60601-2-92-2026

oSIST prEN IEC 60601-2-92:2026

IMPORTANT – The "colour inside" logo on the cover page of this document 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.

133

Sample Document

get full document from standards.iteh.ai

oSIST prEN IEC 60601-2-92:2026 • https://standards.iteh.ai/catalog/standards/sist/0074276c-ed27-43d6-b54f-db2d35b03022/osist-pren-iec-60601-2-92-2026

oSIST prEN IEC 60601-2-92:2026

INTRODUCTION

Modern RADIOTHERAPY practices utilize information from various imaging modalities, acquired prior to initiating administration of the therapy, to plan the TREATMENT. The imaging provides information about the location of the TARGET VOLUME and other anatomical features so that a TREATMENT PLAN can be developed that provides an optimal dose distribution to have the best chance of achieving the intended effect of TREATMENT while minimizing side effects.

However, difficulties arise when trying to administer the RADIATION, since TARGET VOLUMES/critical structures are constantly moving within the body. For example, in parts of the body moving with respiration, the TARGET VOLUMEs/critical structures can change position or shape during the RADIATION BEAM delivery throughout any given fraction. Furthermore, a course of therapy can extend over many days, during which the TARGET VOLUME/PATIENT can shrink, grow or move. Hence, the exact location of the TARGET VOLUME/critical structures can change between the time of TREATMENT planning imaging and the actual administration of a TREATMENT.

IMAGE GUIDED RADIOTHERAPY (IGRT) combines imaging during the course of RADIOTHERAPY to adjust the TREATMENT delivery based on the PATIENT anatomy and PATIENT position. Guided Radiotherapy (GRT) encompasses IGRT and includes other non-imaging technologies for precise position of TREATMENT. When magnetic resonance is used for guidance, this is known as MR GUIDED RADIOTHERAPY (MRGRT). This process enables the OPERATOR or EXTERNAL BEAM EQUIPMENT (EBE) to adjust the RADIATION BEAM delivery based on the information from the MRGRT EQUIPMENT, such as the position of the TARGET VOLUME, critical organs or other reference features, to compensate for anatomical changes including internal organ motions or TREATMENT setup uncertainties. The increased accuracy and precision achieved allows higher doses of RADIATION to be delivered to the TARGET VOLUME and a reduction in the margin of healthy cells affected by the RADIATION. This is often used in conjunction with other monitoring equipment.

Sample Document

This particular standard establishes requirements to be complied with by MANUFACTURERS in the design and construction of MRGRT EQUIPMENT.

get full document from standards.iteh.ai

When performing a HAZARD ANALYSIS, the MANUFACTURER should consider relevant diagnostic standards. For example, IMAGE DISPLAY DEVICE quality is specified in IEC documents in regard to diagnostic use (e.g., IEC 62563-1, ed. 1.0 (2009-12)). However, since GRT usage does not necessarily have image display requirements, it is left to the MANUFACTURER to specify what is required for use with their MRGRT EQUIPMENT.

This particular standard deals with the safety aspects of MRGRT EQUIPMENT relating to alignment of reference frames between EBE and MR, geometric integrity of MR imaging, adapt to position, real time tracking / motion monitoring, and MR image quality for GRT.

MRGRT EQUIPMENT is also related to the following current standards:

– IEC 60601-2-1, *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 60601-2-68. *Medical Electrical equipment - Part 2-68: Particular requirements for the basic safety and essential performance of X-ray-based image-guided radiotherapy equipment for use with electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment*

– IEC 62083, *Medical electrical equipment – Requirements for the safety of radiotherapy treatment planning system*

– IEC 61217, *Radiotherapy equipment – Coordinate movements and scales*

– IEC 62274, *Medical electrical equipment – Safety of radiotherapy record and verify systems*

– IEC 60601-2-33:2022 *Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis*

oSIST prEN IEC 60601-2-92:2026 • https://standards.iteh.ai/catalog/standards/sist/0074276c-ed27-43d6-b54f-db2d35b03022/osist-pren-iec-60601-2-92-2026

oSIST prEN IEC 60601-2-92:2026

182 – ISO/TS 10974:2018 *Assessment of the safety of magnetic resonance imaging for patients*
183 *with an active implantable medical device*

184 – IEC TR 62926, *Medical electrical system – Guidelines for safe integration and operation of*
185 *adaptive external-beam radiotherapy systems for real-time adaptive radiotherapy*

186

Sample Document

get full document from standards.iteh.ai

oSIST prEN IEC 60601-2-92:2026 • https://standards.iteh.ai/catalog/standards/sist/0074276c-ed27-43d6-b54f-db2d35b03022/osist-pren-iec-60601-2-92-2026

oSIST prEN IEC 60601-2-92:2026

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-92: Particular requirements for basic safety and essential performance of magnetic resonance guided radiotherapy equipment for use with external beam equipment

201.1 Scope, object and related standards

Clause 1 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.1.1 Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MAGNETIC RESONANCE GUIDED RADIOTHERAPY EQUIPMENT used in radiation therapy for use with EXTERNAL BEAM EQUIPMENT (EBE).

This particular standard covers safety aspects of MR EQUIPMENT in a known geometrical relationship with EXTERNAL BEAM EQUIPMENT for the purpose of GUIDED RADIOTHERAPY, which is defined as MRGRT EQUIPMENT It covers aspects of communication and relationships between the EXTERNAL BEAM EQUIPMENT and MR EQUIPMENT, attached or not directly attached to but in the same RADIATION shielded area as, and dedicated for use only with, the EXTERNAL BEAM EQUIPMENT.

This particular standard does not apply to stand alone MR EQUIPMENT, that are not used for MRGRT. However, if an MR EQUIPMENT is used in the same room with an EBE for GRT then this particular standard applies.

If a clause or subclause is specifically intended to be applicable to EBE SYSTEMS, the content of that clause or subclause will say so. If that is not the case, the clause or subclause applies only to MRGRT EQUIPMENT.

This particular standard, with the inclusion of TYPE TESTS and SITE TESTS, applies respectively to the MANUFACTURER and some installation aspects of MRGRT SYSTEMS intended to be

- for NORMAL USE, operated under the authority of the RESPONSIBLE ORGANIZATION by QUALIFIED PERSONS 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 In this particular standard, all references to installation refer to installation in the RESPONSIBLE ORGANIZATION'S premises

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for MRGRT EQUIPMENT

oSIST prEN IEC 60601-2-92:2026 • https://standards.iteh.ai/catalog/standards/sist/0074276c-ed27-43d6-b54f-db2d35b03022/osist-pren-iec-60601-2-92-2026

oSIST prEN IEC 60601-2-92:2026

201.1.3 Collateral standards

Addition:

This document refers to those applicable collateral standards that are listed in Clause 2 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and Clause 201.2 of this document.

IEC 60601-1-6 applies as modified in Clause 206.

IEC 60601-2-33:2022 Applies with modifications

IEC 60601-1-8, IEC 60601-1-9, IEC 60601-1-10 and IEC 60601-1-11 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

Collateral standards published after the date of publication of this standard shall 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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

Sample Document

A requirement of a particular standard takes priority over IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

get full document from standards.iteh.ai

The numbering of clauses and subclauses of this particular standard corresponds to that of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 with the prefix "201" (e.g. 201.1 addresses the content of Clause 1 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020) or applicable collateral standard with the prefix "20x.101" where x is the final digit(s) of the collateral standard document number (e.g. 202.4 addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of the IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard are specified by the use of the following words:

"*Replacement*" means that the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or the 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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or the applicable collateral standard.

"*Amendment*" means that the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or the applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered starting from 201.101. However, due to the fact that definitions in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered 3.1 through

oSIST prEN IEC 60601-2-92:2026 • https://standards.iteh.ai/catalog/standards/sist/0074276c-ed27-43d6-b54f-db2d35b03022/osist-pren-iec-60601-2-92-2026