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Title: BS EN IEC 60601-2-92 Medical electrical equipment

Part 2-92: Particular requirements for the basic safety and essential performance of MRI based image guided radiotherapy equipment for use with electron accelerators

Please notify the secretary if you are aware of any keywords that might assist in classifying or identifying the standard or if the content of this standard

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- ii) affects other national standard(s)
- iii) requires additional national guidance or information

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Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

UK Vote

Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

Submission of Comments

- **Annotated drafts are not acceptable and will be rejected.**
- All comments should be submitted online at <https://standardsdevelopment.bsigroup.com/>. You will need to register in order to comment.

Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/Figure/ Table/Note	Type of comment	Commend (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	



62C/918/CD

COMMITTEE DRAFT (CD)

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DATE OF CIRCULATION:
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SUPERSEDES DOCUMENTS:
62C/849/NP, 62C/860A/RVN

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		

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 local regulations or technical reasons that may exist and should be considered should this proposal proceed, recognizing that failure to address such requirements could result in the need for new or existing "In Some Countries" 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 MRI based image guided radiotherapy equipment for use with electron accelerators

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-92: Particular requirements for the basic safety and essential performance of MR guided radiotherapy equipment for use with EBE

FOREWORD

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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.

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

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

98 In this document, the following print types are used:

- 99 – requirements and definitions: roman type;
- 100 – *test specifications: italic type*;
- 101 – informative material appearing outside of tables, such as notes, examples and references: in smaller type.
102 Normative text of tables is also in a smaller type;
- 103 – TERMS DEFINED in Clause 3 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 AND
104 IEC 60601-1:2005/AMD2:2020, in this document or as noted: SMALL CAPITALS.

105 In referring to the structure of this document, the term

- 106 – "clause" means one of the seventeen numbered divisions within the table of contents,
107 inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
- 108 – "subclause" means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all
109 subclauses of Clause 7).

110 References to clauses within this document are preceded by the term "Clause" followed by the
111 clause number. References to subclauses within this document are by number only.

112 In this document, the conjunctive "or" is used as an "inclusive or" so a statement is true if any
113 combination of the conditions is true.

114 The verbal forms used in this document conform to usage described in Clause 7 of the ISO/IEC
115 Directives, Part 2. For the purposes of this document, the auxiliary verb:

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

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

124 A list of all parts of the IEC 60601 and IEC 80601 series, published under the general title
125 *Medical electrical equipment*, can be found on the IEC website.

126 The committee has decided that the contents of this document will remain unchanged until the
127 stability date indicated on the IEC website under webstore.iec.ch in the data related to the
128 specific document. At this date, the document will be

- 129 • reconfirmed,
- 130 • withdrawn,
- 131 • replaced by a revised edition, or
- 132 • amended.

133

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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 may change position or shape during the RADIATION BEAM delivery throughout any given fraction. Furthermore, a course of therapy may extend over many days, during which the TARGET VOLUME/PATIENT may shrink or grow and/or move. Hence, the exact location of the TARGET VOLUME/critical structures may 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 in order to adjust the TREATMENT delivery based on the PATIENT anatomy and PATIENT position. This enables the OPERATOR and/or EXTERNAL BEAM EQUIPMENT (EBE) to adjust the RADIATION BEAM delivery based on the imaging information, such as the position of the TARGET VOLUME, critical organs and/or other reference features, to compensate for anatomical changes including internal organ motions and/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.

This particular standard establishes requirements to be complied with by MANUFACTURERS in the design and construction of MAGNETIC RESONANCE Guided Radiotherapy (MRGRT) EQUIPMENT.

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 IGRT usage may or may not require such high 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 aspect 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 MRI image quality for IGRT.

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*

- 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

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-92: Particular requirements for basic safety and essential performance of MR guided radiotherapy equipment for use with EBE

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 MRI based IMAGE 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 EBE for the purpose of IGRT. 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, which are not used for IGRT. However, if an MR EQUIPMENT is used in the same room with an EBE for IGRT then this particular standard applies.

If the MRGRT EQUIPMENT is combined with an EBE or includes another MEE, any requirement that is the same for the MRGRT EQUIPMENT and the EBE or the MEE, such as a PATIENT POSITIONER, does not to be tested twice, but can be accepted as tested by the EBE or the MEE.

Requirements that are being tested according to another standard can be identified by the manufacturer and if identical do not require retesting, instead evidence can refer to corresponding test report.

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 EBE 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 and MRGRT EBE SYSTEMS

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 apply as modified in Clause 206.

IEC 60601-2-33:2022 Applies with modification in Clause 233

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.

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.

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 3.154, additional definitions 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.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 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 and IEC 60601-1:2005/AMD2:2020

IEC 60601-2-1:2020, 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 60601-2-33:2022, Medical electrical equipment – Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis

IEC 60601-2-4:2010, Medical electrical equipment – Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators

IEC 60731:2011, Medical electrical equipment - Dosimeters with ionization chambers as used in radiotherapy

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

IEC 60976:2007, Medical electrical equipment – Medical electron accelerators – Functional performance characteristics

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

312 IEC 62083:2009, *Medical electrical equipment – Requirements for the safety of radiotherapy*
313 *treatment planning systems*

314 IEC 62366-1:2015/AMD1:2020, *Medical devices – Application of usability engineering to*
315 *medical devices*

316 **201.3 Terms and definitions**

317 For the purposes of this document, the terms and definitions given in IEC 60601-1:2005,
318 IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, IEC 60601-1-3:2008,
319 IEC 60601-1-3:2008/AMD1:2013 and IEC 60601-1-3:2008/AMD2:2021, IEC 60601-2-54:2022,
320 IEC TR 60788:2004, IEC 61910-1:2014, IEC 62220-1-1:2015 and the following apply.

321 NOTE The location of defined terms is listed in the Index of defined terms.

322 ISO and IEC maintain terminological databases for use in standardization at the following
323 addresses:

- 324 • IEC Electropedia: available at <http://www.electropedia.org/>
- 325 • ISO Online browsing platform: available at <http://www.iso.org/obp>

326 *Addition:*

327 **201.3.201**

328 **ADAPTIVE RADIOTHERAPY**

329 RADIOTHERAPY that monitors PATIENT anatomy or physiology and, based upon the monitored
330 information, allows changes to TREATMENT PARAMETERS throughout the course of TREATMENT

331 Note 1 to entry: IMAGE GUIDED RADIATION THERAPY (IGRT) is one form of ADAPTIVE RADIOTHERAPY

332 [SOURCE: IEC 60601-2-1:2020]

333 **201.3.202**

334 **EQUIPMENT REFERENCE POINT**

335 **ERP**

336 point in space used for referencing dimensions and positions of equipment and performing dosimetry
337 measurements

338 Note 1 to entry: Typically the EQUIPMENT REFERENCE POINT is coincident with the ISOCENTRE. If the beam delivery equipment is
339 not ISOCENTRIC, then the centre of the PATIENT alignment system may be used.

340 [SOURCE: IEC 60601-2-64, ed. 1.0 (2014-09)]

341 **201.3.203**

342 **EXTERNAL BEAM EQUIPMENT**

343 **EBE**

344 external RADIATION EQUIPMENT utilizing ELECTRON ACCELERATORS, LIGHT ION BEAM MEDICAL
345 ELECTRICAL EQUIPMENT OR RADIONUCLIDE BEAM THERAPY EQUIPMENT

346 [SOURCE: IEC 60601-2-68:]

347 **201.3.204**

348 **IMAGE GUIDED RADIOTHERAPY**

349 **IGRT**

350 radiotherapy process by which the location of a radiotherapy beam relative to the intended
351 TARGET VOLUME within a patient's anatomy is determined by imaging of the TARGET VOLUME and

surrounding anatomical structures at the time of treatment, so as to enable any necessary positional corrections to the intended relative location of beam to TARGET VOLUME

Note 1 to entry: The time period of "at the time of TREATMENT" is specified in the definitions of REAL-TIME IGRT, ONLINE IGRT and OFFLINE IGRT.

[SOURCE: IEC 60601-2-1:2020]

201.3.205

IMAGE RECONSTRUCTION

a method to process acquired data into an image data set that can be used for analysis

Note 1 to entry: The analysis of the reconstructed image data set can be for the purpose of IMAGE REGISTRATION against reference data.

[SOURCE: IEC 60601-2-1:2020]

201.3.206

IMAGE REGISTRATION

a method for mapping or registering corresponding points from one image data set to another

Note 1 to entry: IMAGE REGISTRATION can be rigid or deformable.

[SOURCE: IEC 60601-68]

201.3.207

IMAGING SESSION

the length of continuous time that images are taken of the PATIENT while the PATIENT remains on the PATIENT positioning device

Note 1 to entry: If the PATIENT is removed from the PATIENT positioning device, the imaging session is ended.

201.3.208

LATENCY

time interval between occurrence or initiation of an event and its detection or effect

[SOURCE: IEC 60601-2-1:2020]

201.3.209

MAGNETIC RESONANCE ISOCENTRE

MR ISOCENTRE

null point of the spatially encoding gradients

NOTE 1 Typically this also corresponds to the region of highest magnet homogeneity

NOTE 2 Typically this corresponds with the position in the system targeted for imaging.

[SOURCE: IEC 60601-2-33:2022]

201.3.210

MRGRT EBE SYSTEM

a system comprising of MRGRT EQUIPMENT and EXTERNAL BEAM EQUIPMENT

201.3.211

MRGRT EQUIPMENT

ME EQUIPMENT that provides IGRT functionality when MR is used

390 NOTE: Guidance may be non-image based.

391 **201.3.212**

392 **NORMAL USE**

393 operation, including routine inspection and adjustments by any OPERATOR, and STAND-BY,
394 according to the INSTRUCTIONS FOR USE

395 Note 1 to entry: NORMAL USE should not be confused with INTENDED USE. While both include the concept of use
396 as intended by the MANUFACTURER, INTENDED USE focuses on the medical purpose while NORMAL USE incorporates
397 not only the medical purpose, but maintenance, service, transport, etc. as well.

398 Note 2 to entry: NORMAL USE is all functions performed by the OPERATOR. This includes warmup, calibration and
399 other testing “physics” modes.

400 [SOURCE: IEC 60601-1:2012, definition 3.71, modified – note 2 has been added.]

401 **201.3.213**

402 **OFFLINE IGRT**

403 IGRT for the purpose of PATIENT setup and/or treatment plan adjustment to be applied in
404 subsequent treatment delivery

405 [SOURCE: IEC 60601-2-1:2020]

406 **201.3.214**

407 **ONLINE IGRT**

408 IGRT for the purpose of PATIENT setup or treatment plan adjustment immediately prior to or
409 during the therapeutic IRRADIATION session requiring operator initiated adjustments.

410 Note 1 to entry: The PATIENT stays on the PATIENT positioning device and is immobile during and in-between imaging
411 and treatment.

412 [SOURCE: IEC 60601-2-1:2020]

413 **201.3.215**

414 **OFFLINE ADAPTIVE RADIOTHERAPY**

415 process wherein the PATIENT setup or TREATMENT PLAN is adjusted for application in subsequent
416 TREATMENT delivery sessions

417 [SOURCE: IEC 60601-2-1:2020]

418 **201.3.216**

419 **ONLINE ADAPTIVE RADIOTHERAPY**

420 process wherein the PATIENT setup or TREATMENT PLAN is adjusted immediately prior to or during the
421 therapeutic IRRADIATION session requiring OPERATOR initiated adjustments.

422 Note 1 to entry: The PATIENT stays on the PATIENT POSITIONER and is immobile during and in-between adaptive calculations and
423 TREATMENT.

424 [SOURCE: IEC 60601-2-1:2020]

425 **201.3.217**

426 **REAL TIME IGRT**

427 IGRT that images throughout therapeutic IRRADIATION and based upon that information, allows
428 automatic adjustments of treatment parameters throughout the therapeutic IRRADIATION without
429 OPERATOR intervention

430 [SOURCE: IEC 60601-68]