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TECHNICAL REPORT

colour inside

Medical electrical system – Guidelines for safe integration and operation of adaptive external-beam radiotherapy systems for real-time adaptive radiotherapy

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL SYSTEM –

GUIDELINES FOR SAFE INTEGRATION AND OPERATION OF ADAPTIVE EXTERNAL-BEAM RADIOTHERAPY SYSTEMS FOR REAL-TIME ADAPTIVE RADIOTHERAPY

FOREWORD

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IEC TR 62926, which is a technical report, has been prepared by subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this technical report is based on the following documents:

Enquiry draft	Report on voting
62C/729/DTR	62C/737/RVDTR

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

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

In this document, the following print types are used:

- requirements and definitions: roman type;
- TERMS DEFINED IN CLAUSE 3 OR AS NOTED: SMALL CAPITALS.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under "http://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- withdrawn,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.

A bilingual version of this publication may be issued at a later date.

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INTRODUCTION

Recent developments in RADIOTHERAPY using EXTERNAL BEAM EQUIPMENT (EBE) allow the delivery of doses to TARGET VOLUMEs with greater precision and accuracy than before, while also sparing surrounding critical structures to a higher degree. Three-dimensional or four-dimensional volumetric images are increasingly being used as PATIENT ANATOMY MODELs in RADIOTHERAPY TREATMENT PLANNING SYSTEMs (RTPSs) when simulating a dose distribution. The intended dose distribution is achievable when the four-dimensional location and shape of the TARGET VOLUME and organs at RISK (OARs) during TREATMENT match those of the TARGET VOLUME and OARs at the time of TREATMENT PLANNING. PATIENT anatomy and related physiology are subject to continuous changes as may result from respiration, cardiac motion, and digestive motion, both in the short and long term perspective during RADIOTHERAPY. These include changes in position, orientation, and deformation of the TARGET VOLUME.

Consideration for changes in anatomy or physiology during the course of RADIOTHERAPY, as well as during each fraction, is an important issue in modern RADIOTHERAPY. For example, lung tumours can exhibit translational and rotational changes which may result in underdosage of the TARGET VOLUME and overdosage of OARs. Techniques have been developed to reduce these RISKS by adapting the TREATMENT to the tumour as it moves in real-time. This can be achieved by instructing the EBE to perform a BEAM HOLD during translational motion of the TARGET VOLUME, by repositioning the PATIENT using a robotic PATIENT POSITIONER, by tilting or moving the RADIATION HEAD, by dynamically adapting the MULTILEAF COLLIMATORs (MLCs) of the EBE, or by changing the scanning field of LIGHT ION BEAM equipment operating in scanning mode.

During delivery of ADAPTIVE RADIOTHERAPY, the PATIENT anatomy or physiology is monitored and changes to TREATMENT PARAMETERS are allowed throughout the course of TREATMENT based upon the monitored information (see definition of ADAPTIVE RADIOTHERAPY). ADAPTIVE RADIOTHERAPY is increasingly being used to assure delivery of the prescribed ABSORBED DOSE distribution during intra-fractional changes of TARGET VOLUMEs. There are many different types of MOTION DETECTION EQUIPMENT (MDE) used to monitor intra-fractional organ changes. Some of these use imaging techniques, e.g. X-RAY BASED IMAGE-GUIDED RADIOTHERAPY, ULTRASOUND EQUIPMENT, and MAGNETIC RESONANCE EQUIPMENT, while others use surrogate parameters. Examples of equipment that use surrogate parameters include air flow meters, STRAIN GAUGEs, infrared sensors, optical surface mapping devices, and magnetic field sensors. In some cases, multiple MDEs are combined with a single EBE to monitor intra-fraction motion of multiple organs.

When ADAPTIVE RADIOTHERAPY includes intra-fraction monitoring of the TARGET VOLUME position and shape using an MDE, coordination between the MDE and the EBE is crucial to apply TREATMENT PARAMETER changes at the correct time. A MOTION COORDINATION FUNCTION (MCF) ensures that information about position and shape is appropriately linked to the TREATMENT PLAN, selects TREATMENT PARAMETERS, and sends ADAPTATION INSTRUCTIONs to the EBE. Integration and operation of the MDE, EBE, and MCF is essential to perform ADAPTIVE RADIOTHERAPY safely for a PATIENT with an intra-fractionally changing TARGET VOLUME. There are many possible combinations of EBEs, MDEs and MCFs. Each one can function independently or be integrated as a part of another. Because each function could be an independent piece of MEDICAL ELECTRICAL EQUIPMENT (MEE) and since the safety discussed in this document depends upon the safe integration and operation of the EBEs, MDEs, and MCFs, this combination will be dealt with as a MEDICAL ELECTRICAL SYSTEM. An adaptive external-beam RADIOTHERAPY system (AEBRS) consists of these three main pieces of equipment and respective functions.

The MCF part of an AEBRS can be software or a PROGRAMMABLE ELECTRICAL MEDICAL SYSTEM, and should be subject to the requirements of IEC 62304 or IEC 60601-1. The MDE can be components or systems which are not necessarily compliant with IEC 60601-1.

The reader's attention is drawn to ASTM F-2761 (a publication of the American Society for Testing and Materials) which describes an integrated clinical environment (ICE). The general requirements and the conceptual model of an ICE are described in F-2761. This document uses similar concepts and presents guidance for AEBRS RISK MANAGEMENT.

The reader's attention is also drawn to RADIATION PROTECTION N° 181 which contains general guidelines on RISK MANAGEMENT in external beam radiotherapy.

The concept of an AEBRS with representative information flow is shown in Figure 1.

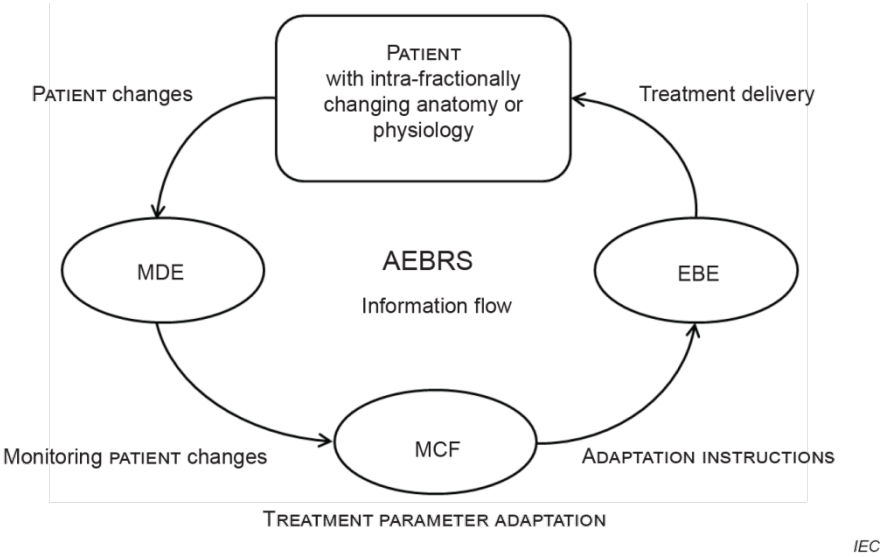

Figure 1 – Concept of AEBRS with information flow

This document provides guidelines for the safe integration and operation of an AEBRS for REAL-TIME ADAPTIVE RADIOTHERAPY. Since real-time monitoring of deformations of TARGET VOLUMEs is still a work-in-progress at this moment, this document addresses rigid TARGET VOLUMEs exhibiting intra-fractional translations and rotations. Deformations of TARGET VOLUMEs are not considered.

This document covers systems, whose configuration may be represented by Figure 2, where potential use of multiple MDEs in one AEBRS is reflected.

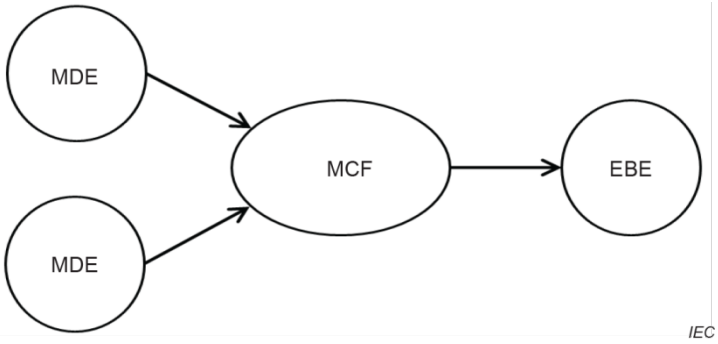

Figure 2 – Example of system configuration

Some EQUIPMENT for image or data acquisition and motion coordination is not covered by existing standards. Therefore, there are safety aspects that arise from the integration of various EQUIPMENT into an AEBRS that should be considered and that are not addressed by existing standards. Based on the considerations discussed above, guidelines should be developed to mitigate the RISKs arising from the integration and operation of ME EQUIPMENT and other various equipment (including non-ME EQUIPMENT) into an AEBRS, as shown in Figures 1 and 2.

This document discusses potential RISKs to be considered during the RISK ANALYSIS and provides recommendations for the safe integration and operation of an AEBRS. Since not all equipment may have an IEC/ISO standard, or an existing standard may not cover the use of the equipment as part of an AEBRS, this document also provides guidelines for individual pieces of EQUIPMENT that are part of the AEBRS. These guidelines are meant to enhance and not supersede requirements that may already exist.

Regarding existing standards, IEC 60601-2-68 includes requirements for X-ray-based MDE in an AEBRS. Requirements and recommendations in IEC 60601-2-68 are often applicable to an AEBRS where the MDE is other than an X-ray-based imaging device, such as optical, ULTRASOUND, or MAGNETIC RESONANCE IMAGING devices. For example, requirements addressing protection against electrical, mechanical, and RADIATION HAZARDs, or requirements addressing X-IGRT LATENCY, which is the time between initiation of image acquisition to delivery of the output signal by an MDE, are also applicable to non X-ray-based imaging devices. MANUFACTURERS or RESPONSIBLE ORGANIZATIONs who integrate an AEBRS for intra-fractionally moving rigid TARGET VOLUMEs should use IEC 60601-2-68 as guidance even when they utilize non X-ray-based imaging devices as MDE in the AEBRS.

Finally, this document addresses safety issues of the AEBRS without assuming specific clinical procedures. As with any testing within a clinical environment, the RESPONSIBLE ORGANIZATION should consider its clinical workflows and practices when devising tests for its facility.

MEDICAL ELECTRICAL SYSTEM –

GUIDELINES FOR SAFE INTEGRATION AND OPERATION OF ADAPTIVE EXTERNAL-BEAM RADIOTHERAPY SYSTEMS FOR REAL-TIME ADAPTIVE RADIOTHERAPY

1 Scope

This document provides guidelines for safe integration and operation of an adaptive external-beam RADIOTHERAPY system (AEBRS) for intra-fractionally moving rigid TARGET VOLUMEs, where required equipment can be sourced from one or several MANUFACTURERs. In particular it addresses guidelines to help ensure safe integration and operation for the PATIENT, OPERATOR, other persons and sensitive devices in the vicinity. In this document, the word “system” is hereafter used to refer to an AEBRS.

This document specifies the safety guidelines for a MANUFACTURER or RESPONSIBLE ORGANIZATION who integrates the AEBRS for intra-fractionally moving rigid TARGET VOLUMEs. If a RESPONSIBLE ORGANIZATION integrates an AEBRS, then it takes the role of MANUFACTURER and will be referred to as a MANUFACTURER throughout this document.

This document includes reference models of the AEBRS for intra-fractionally moving rigid TARGET VOLUMEs and HAZARDs which, at a minimum, are considered during the RISK ANALYSIS.

Although TARGET VOLUMES and OARs can deform during motion, adaptations in response to deformations of the TARGET VOLUME are out of the scope of this document. The scope is limited to rigid TARGET VOLUMEs exhibiting intra-fractional movements, both translational and rotational. While technical HAZARDs are discussed in this document, the RESPONSIBLE ORGANIZATION is reminded that clinical judgement is always employed when determining clinical usability and reviewing TREATMENT PARAMETER changes.

This document does not specifically address HAZARD mitigations for each of the HAZARDs mentioned in the document; however, some mitigations are given as examples in Clauses 4 and 5. All guidelines in this document are intended to be implemented in accordance with the general standard IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, with special attention to 4.2 of IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

ISO 14971:2007, *Medical devices – Application of risk management to medical devices*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

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

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

3.1
ADAPTATION INSTRUCTION
instruction generated for TREATMENT PARAMETER ADAPTATION

3.2
ADAPTIVE RADIOTHERAPY
radiotherapy that monitors PATIENT anatomy or physiology and, based upon the monitored information, allows changes to TREATMENT PARAMETERs throughout the course of treatment

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

3.3
BEAM GATING
allowance or inhibition of IRRADIATION and related equipment movements according to the status provided by a BEAM GATING SIGNAL

[SOURCE: IEC 60601-2-64:2014, 201.3.204]

3.4
BEAM GATING SIGNAL
signal generated for the purpose of BEAM GATING

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

[SOURCE: IEC 60601-2-64:2014, 201.3.205]

3.5
BEAM HOLD
condition during IRRADIATION in which the MEE has minimized the TREATMENT IRRADIATION output (approximating the IRRADIATION off condition)

NOTE 1 TO ENTRY: BEAM HOLD is not the same as INTERRUPTION OF IRRADIATION where the MEE is changed to the beam off state

NOTE 2 TO ENTRY: BEAM HOLD is a subcondition of IRRADIATION for the purpose of rapid transition to intended TREATMENT IRRADIATION output

Note 3 to entry: This is commonly used during gating, IMRT, etc.

[SOURCE: IEC 60601-2-1:20–, 201.3.208]

3.6
EXTERNAL BEAM EQUIPMENT
EBE
external RADIATION EQUIPMENT utilizing ELECTRON ACCELERATORS, LIGHT ION BEAM EQUIPMENT or RADIONUCLIDE BEAM THERAPY EQUIPMENT

Note 1 to entry: The note to entry concerning the origin of the abbreviation EBE applies to the French text only

[SOURCE: IEC 60601-2-68:2014, 201.3.207]

3.7
IRRADIATION
exposing of a living being or matter to RADIATION

Note 1 to entry: In RADIOLOGY, exposing of a living being or matter to IONIZING RADIATION.

Note 2 to entry: Examples of ionizing radiation include: x-rays, gamma-rays, electrons, neutrons, and light ions.

[SOURCE: IEC TR 60788:2004, rm-12-09, modified – moved examples of IONIZING RADIATION to a note.]

3.8
LATENCY
time interval between initiation of an event and its effect

[SOURCE: IEC 60601-2-1:20—, 201.3.232]

3.9
MANUFACTURER
natural or legal person with responsibility for the design, manufacture, packaging, or labelling of ME EQUIPMENT, assembling an ME SYSTEM, or adapting ME EQUIPMENT or an ME SYSTEM, regardless of whether these operations are performed by that person or on that person's behalf by a third party

Note 1 to entry: ISO 13485 defines "labelling" as written, printed or graphic matter

– affixed to a medical device or any of its containers or wrappers, or
– accompanying a medical device,
related to identification, technical description, and use of the medical device, but excluding shipping documents. In this standard, that material is described as markings and ACCOMPANYING DOCUMENTS.

Note 2 to entry: "Adapting" includes making substantial modifications to ME EQUIPMENT or an ME SYSTEM already in use.

Note 3 to entry: In some jurisdictions, the RESPONSIBLE ORGANIZATION can be considered a MANUFACTURER when involved in the activities described.

Note 4 to entry: Adapted from ISO 14971:2007, definition 2.8.

[SOURCE: IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.55]

3.10
MOTION COORDINATION FUNCTION
MCF
function that evaluates and combines information provided by one or more MDEs to derive and adapt TREATMENT PARAMETERS

Note 1 to entry: The MCF can include a PREDICTION MODEL, a function generating ADAPTATION INSTRUCTIONS and a function for evaluating validity and deliverability of the ADAPTATION INSTRUCTIONS.

3.11
MOTION DETECTION EQUIPMENT
MDE
equipment that acquires data for monitoring changes in PATIENT anatomy or physiology

Note 1 to entry: This includes changes in position, orientation and deformation of the TARGET VOLUME, and changes in PATIENT setup or surface positioning.

3.12
MULTILEAF COLLIMATOR
MLC
a multi-element BLD capable of defining RADIATION FIELDS of irregular shapes

Note 1 to entry: The positions of the individual elements can either be static or can be changed dynamically during IRRADIATION.

[SOURCE: IEC 60601-2-1:20—, 201.3.233]

3.13
PREDICTION MODEL
algorithm that predicts changes, such as changes in PATIENT anatomy or physiology, based on information from one or more MDEs

Note 1 to entry: This includes predicting changes in position, orientation and deformation of the TARGET VOLUME.

3.14
RADIATION HEAD
structure from which the RADIATION BEAM emerges

[SOURCE: IEC TR 60788:2004, rm-20-06]

3.15
REAL-TIME ADAPTIVE RADIOTHERAPY
radiotherapy that, throughout therapeutic IRRADIATION, monitors PATIENT anatomy or physiology and based upon that information, allows autonomous adjustments of TREATMENT PARAMETERs throughout the therapeutic IRRADIATION without OPERATOR intervention

3.16
TREATMENT PARAMETER ADAPTATION
change of TREATMENT PARAMETERS based on monitored changes, such as changes in PATIENT anatomy or physiology

Note 1 to entry: BEAM GATING and tracking are examples of TREATMENT PARAMETER ADAPTATION.

3.17
X-IGRT LATENCY
time from initiation of image acquisition to delivery of output signal by X-IGRT EQUIPMENT to the EBE

Note 1 to entry: It is expected that the EBE should also state its LATENCY time from receiving a signal to providing the requested action.

Note 2 to entry: The X-IGRT LATENCY includes the hardware and software LATENCIES.

Note 3 to entry: Network transfer times vary from one installation to another as there are too many factors involved that are supplied by the user. Network transfer LATENCY therefore is not considered as part of the X-IGRT LATENCY time.

[SOURCE: IEC 60601-2-68:2014, 201.3.234, modified – In Note 1 to entry, "correction" was replaced by "requested action".]

4 General safety guidelines for an AEBRS for intra-fractionally moving rigid TARGET VOLUMES

4.1 TARGET VOLUMEs addressed in this document

The effects of intra-fraction TARGET VOLUME translations, rotations and deformations on delivered dose distributions depend not only on the extent of these changes but also on the size and shape of the TARGET VOLUME and on changes in the surrounding tissues. For example, the dose distribution for a rotated small spheroid shaped target (e.g. a baseball shape) will not change much as the rotation angle increases, while the dose distribution can change significantly for a rotated long narrow cylinder target (e.g. a cigar shape) if rotated perpendicularly to its long axis.

The detection of TARGET VOLUME translations, rotations and deformations during the delivery of a single fraction is difficult without real-time volumetric imaging techniques. However, TARGET VOLUME changes can be predicted by combining 4D volumetric planning images with information from associated surrogate detectors such as orthogonal 2D imaging with implanted fiducial markers, spirometers, expansion belts, or PATIENT surface scanning

EQUIPMENT. Monitoring of deformations by volumetric imaging in real-time is still considered a work-in-progress at this moment. Therefore, it will not be addressed in this document.

The RESPONSIBLE ORGANIZATION should investigate the effects of translations, rotations and deformations and the clinical tolerances allowed for their PATIENT population and select the appropriate combination of sensors, software and other MEES. This document addresses safety issues associated with integrating these combinations but does not address the clinical applications.

4.2 Relationship between system configuration of an AEBRS, existing standards, and this document

4.2.1 General

The RISK arising from the integration of equipment in an AEBRS should be addressed by the MANUFACTURER and this should be done according to existing STANDARDS, where available.

Irrespective of the system configuration of an AEBRS, IEC 60601-1 and its collaterals always apply. Particular standards may exist to cover equipment integrated in an AEBRS. Examples of such particular standards are IEC 60601-2-1 and IEC 60601-2-64 for EBE, IEC 60601-2-68 for MCF or a combination of MCF and MDE, and IEC 60601-2-33 and IEC 60601-2-44 for MDE.

This document provides further guidance in implementing 4.2 and Clause 14 from IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012.

The MANUFACTURER of an AEBRS should ask the MANUFACTURER of any MEE to be integrated to provide applicable conditions of interoperability and requirements for acceptability.

Mitigation of AEBRS RISKS is the responsibility of the integrating party, and the mitigation should be demonstrated by a completed Test Report Form for the IEC 60601-1 series of standards.

Compliance of the AEBRS can be documented by referencing the corresponding clauses or subclauses of existing standard(s) for the integrated devices.

NOTE 1 An example of MEEs covered by particular standards in the IEC 60601 series is illustrated when assessing the RISK associated with an AEBRS using LIGHT ION BEAM equipment as an EBE and utilizing X-ray RADIOSCOPY as an MDE. IEC 60601-2-64:2014 applies to the EBE and IEC 60601-2-68:2014 applies to the MDE and MCF.

NOTE 2 An example of an MEE not covered by IEC 60601 particular standards is illustrated when assessing the RISK associated with an AEBRS utilizing a 3D camera as MDE. The latter is not addressed by any of the standards in the IEC 60601-1 series.

Annexes A to C show examples of RISK MANAGEMENT of an AEBRSs as explained in 4.3.2.

4.2.2 Representative configurations of AEBRSs, their relationships to existing standards, and this document

4.2.2.1 General

Representative configurations of AEBRSs, their relationships to existing standards and this document are described in the following subclauses. The dotted line in each figure indicates the function or EQUIPMENT covered by the standard cited in each of the following paragraphs and figures. This document covers the entire system as described by the series of examples.

4.2.2.2 Relationship with standards for MOTION DETECTION EQUIPMENT (MDE)

Figure 3 shows an example of an AEBRS incorporating MDE that are addressed by particular standards (e.g. IEC 60601-2-33 for MRI, IEC 60601-2-68 for X-IGRT).