IEC TR 62926

Edition 1.0 2019-05

TECHNICAL REPORT

colour inside

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

IEC TR 62926:2019-05(en)

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

ICS 11.040.50

ISBN 978-2-8322-6911-4

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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- withdrawn,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.

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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.

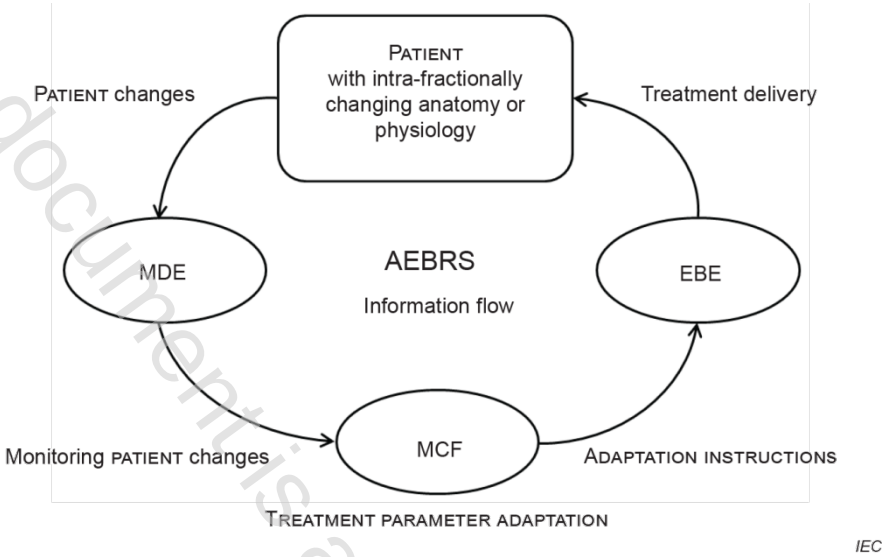

Figure 1 – Concept of AEBRS with information flow

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.

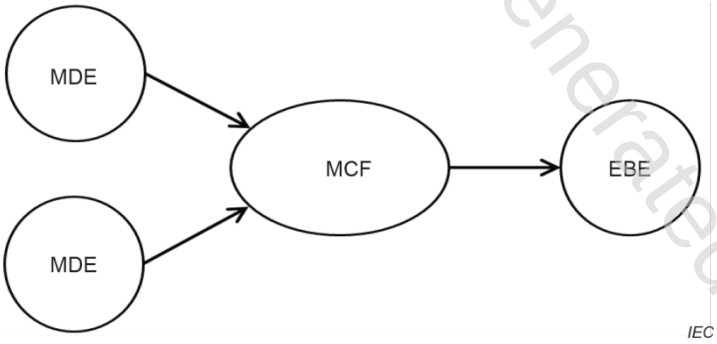

Figure 2 – Example of system configuration

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.