

INTERNATIONAL STANDARD

IEC 60601-2-11

1997

AMENDMENT 1
2004-07

Amendment 1

Medical electrical equipment –

**Part 2-11:
Particular requirements for the safety
of gamma beam therapy equipment**

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PRICE CODE

K

For price, see current catalogue

FOREWORD

This amendment 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 amendment is based on the following documents:

FDIS	Report on voting
62C/372/FDIS	62C/375/RVD

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

The committee has decided that the contents of this amendment and the base publication will remain unchanged until the maintenance result 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- withdrawn,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.

INTRODUCTION

This amendment is applicable to equipment for multi-source STEREOTACTIC treatment including radiosurgery and RADIOTHERAPY (MSSR). STEREOTAXIS is defined as a method for locating points within the human body using an external three-dimensional frame of reference.

- Though multi-source STEREOTACTIC RADIOTHERAPY equipment is included in the scope of this part of IEC 60601, some requirements and definitions have turned out to be inadequate for current equipment of this very special type. This amendment introduces new terminology in this area.

Modifications to test principles or procedures have not been considered.

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1.1 Scope

bb)

Add, after the existing text , the following new paragraph:

This standard applies also to multi-source STEREOTACTIC RADIOTHERAPY equipment used to IRRADIATE a single ISOCENTRE simultaneously with more than one SEALED RADIOACTIVE SOURCE. The sources may be stationary or moving.

Page 17

2 Terminology and definitions

Replace the existing text of definitions 2.101 and 2.102 by the following:

2.101

BEAM OFF

condition in which the RADIATION SOURCES are fully shielded, and are also in a position in which they can be secured

2.102

BEAM ON

condition in which the RADIATION SOURCES are fully exposed for RADIOTHERAPY

Add, on page 19, the following new definitions:

2.122

HELMET

three-dimensional multi-source ISOCENTRIC BEAM LIMITING SYSTEM (MIBLS) used in MSSR for treatment of a human head

2.123

REPOSITIONING

movement and adjustment of the STEREOTACTIC frame with respect to the MIBLS to alter the intended treatment volume

2.124

REPOSITIONING POINT

retracted position of the MIBLS where REPOSITIONING of the frame is possible

2.125

REPOSITIONING TIME

added time the equipment needs to move from the BEAM ON condition to the REPOSITIONING POINT, to achieve REPOSITIONING and to return from the REPOSITIONING POINT to the BEAM ON condition

2.126

STEREOTAXIS

STEREOTACTIC

method for locating points within the human body using an external, three-dimensional frame of reference

2.127

TRANSITION TIME

time between when the SHUTTER is opened and the MIBLS or SOURCE CARRIER is in the TREATMENT position

2.128

TRANSITION RADIATION

dose received during the TRANSITION TIME

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5 Classification

5.2 According to the degree of protection against electric shock:

Replace the existing text by the following:

EQUIPMENT within the scope of this standard shall be TYPE B EQUIPMENT except for MSSR, which shall be TYPE B EQUIPMENT or TYPE BF EQUIPMENT.

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6.3 Marking of controls and instruments

aa)

1) *Add the following sentence:*

This applies in case of MSSR, with the exception of PATIENT SUPPORT and when needed for patient treatment.

2) *Add the following sentence:*

For MSSR: IEC 61217 shall be used where applicable.

3) *Add the following sentence:*

This requirement is not applicable for MSSR.

4) *Add the following sentence:*

This requirement is not applicable for MSSR.

Page 27

6.8.2 INSTRUCTIONS FOR USE

aa)

10) *Add, on page 29, the following sentence:*

This requirement is not applicable for MSSR;

Page 29

6.8.3 Technical description

a) General

- aa) To assist the USER'S RADIOLOGICAL PROTECTION adviser, the following data shall be provided:

c) *Add the following sentence:*

In case of MSSR the maximum ABSORBED DOSE RATE for the maximum cross-section of the RADIATION BEAM at the ISOCENTRE or at the centre of the common volume defined by all the RADIATION BEAMS for each RADIONUCLIDE for which the requirements of this standard are met.

d) *Add the following sentence:*

This item is not applicable for MSSR.

Add the following new item:

- h) Matrix measurement points for RADIATION levels for BEAM ON and BEAM OFF conditions at the floor level and at 0,5, 1,0, 1,5 and 2,0 m above the floor level in MSSR (see Figure 105).

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22.4 Replacement:

a) *Add the following note after the first paragraph:*

NOTE In case of MSSR, operator action on two switches shall be required to move the PATIENT SUPPORT into the TREATMENT position. However in the case when the TREATMENT is completed or when a single fault condition occurs, no manual activation shall be needed and therefore no switch is used.

Replace the second sentence of the second paragraph by the following new sentence:

At least one set of switches shall be located so as to require the presence of the OPERATOR close to the PATIENT, except for MSSR, to observe the moving parts of the equipment.

Add the following new items:

- f) An interlock or mechanical provision shall be provided to prevent a patient being hit or trapped by the SHUTTERS in MSSR.
- g) Means shall be provided to release a patient mechanically if the PATIENT SUPPORT fails to move from the BEAM ON condition in MSSR.

Page 43

29.1.1.2

Replace the first paragraph by the following:

The duration of the transition from the BEAM OFF condition to the BEAM ON condition together with the return movement shall not exceed 5 s or in the case of MSSR 60 s.

Add the following note after the first paragraph:

NOTE This timing in MSSR is based on the mechanical motion of the PATIENT SUPPORT system from the BEAM OFF to the BEAM ON position when the SHUTTERS are open. This timing also includes the return of the PATIENT from BEAM ON to BEAM OFF position when the sources are in the protected state and the SHUTTERS are closed.

Add after the second paragraph the following new paragraphs:

The following requirements refer to MSSR:

If the duration of the transition from the BEAM OFF condition into the BEAM ON condition exceeds 40 s, the PATIENT shall be moved immediately to the BEAM OFF position.

The ABSORBED DOSE given to a patient during the two TRANSITION TIMES from BEAM OFF to BEAM ON and from BEAM ON to BEAM OFF shall be stated in mGy in the ACCOMPANYING DOCUMENT under condition of maximum rated activity and with the BLD fully open.

29.1.1.3

c) Replace this item by the following:

It shall be possible to operate this manual means in any clinical position of the RADIATION HEAD, or any operational state in case of MSSR.

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29.1.2 BEAM OFF and BEAM ON conditions

Add the following new subclause:

29.1.2.2 DISPLAY of BEAM OFF and BEAM ON conditions for MSSR

Lights shall be provided on the TREATMENT CONTROL PANEL when power is applied to indicate the following four states:

- a) BEAM OFF (green);
- b) BEAM ON (yellow or orange);
- c) TRANSITION and REPOSITIONING states to be indicated by a flashing yellow;
- d) if the TRANSITION TIME or REPOSITIONING TIME exceeds the limits of 29.1.1.2 and 29.1.11j), red shall be indicated.

The status of the equipment shall be indicated also by means other than the colour, e.g. by the shape, location or accompanying text.

The switches used to control the displays shall be operated directly by the SHUTTER and the MIBLS.