SLOVENSKI STANDARD

SIST EN 60601-2-11:1998/A1:2005

januar 2005

Medicinska električna oprema – 2-11. del: Posebne varnostne zahteve za opremo za terapijo z žarki gama

(istoveten EN 60601-2-11:1997/A1:2004)

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

ICS 11.040.50; 11.040.60; 13.280

Referenčna številka
SIST EN 60601-2-11:1998/A1:2005(en)

EUROPEAN STANDARD **EN 60601-2-11/A1**

NORME EUROPÉENNE

EUROPÄISCHE NORM September 2004

ICS 11.040.60; 13.280

English version

Medical electrical equipment
Part 2-11: Particular requirements for the safety of gamma beam therapy equipment
(IEC 60601-2-11:1997/A1:2004)

Appareils électromédicaux
Partie 2-11: Règles particulières
de sécurité pour les appareils
de gammathérapie
(CEI 60601-2-11:1997/A1:2004)

Medizinische elektrische Geräte
Teil 2-11: Besondere Festlegungen
für die Strahlensicherheit
von Gamma-Bestrahlungseinrichtungen
(IEC 60601-2-11:1997/A1:2004)

This amendment A1 modifies the European Standard EN 60601-2-11:1997; it was approved by CENELEC on 2004-09-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this amendment the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

This amendment exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

CENELEC
European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

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Ref. No. EN 60601-2-11:1997/A1:2004 E

Foreword

The text of document 62C/372/FDIS, future amendment 1 to IEC 60601-2-11:1997, prepared by SC 62C, Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as amendment A1 to EN 60601-2-11:1997 on 2004-09-01.

The following dates were fixed:

- latest date by which the amendment has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2005-06-01
- latest date by which the national standards conflicting with the amendment have to be withdrawn (dow) 2007-09-01

Endorsement notice

The text of amendment 1:2004 to the International Standard IEC 60601-2-11:1997 was approved by CENELEC as an amendment to the European Standard without any modification.

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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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.

Page 13

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

Page 23

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.

Page 25

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).

Page 37

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.