SLOVENSKI STANDARD

SIST EN 60601-2-1:2002/A1:2003

marec 2003

Medicinska električna oprema - 2. del: Posebne varnostne zahteve za elektronske pospeševalnike v območju od 1 MeV do 50 MeV - Dopolnilo A1 (IEC 60601-2-1:1998/A1:2002)

Medical electrical equipment - Part 2-1: Particular requirements for the safety of electron accelerators in the range of 1 MeV to 50 MeV; Amendment A1 (IEC 60601-2-1:1998/A1:2002)

ICS 11.040.60

Referenčna številka
SIST EN 60601-2-1:2002/A1:2003(en)

EUROPEAN STANDARD **EN 60601-2-1/A1**

NORME EUROPÉENNE

EUROPÄISCHE NORM June 2002

ICS 11.040.60

English version

Medical electrical equipment
Part 2-1: Particular requirements for the safety of electron accelerators in the range of 1 MeV to 50 MeV
(IEC 60601-2-1:1998/A1:2002)

Appareils électromédicaux
Partie 2-1: Règles particulières
de sécurité pour les accélérateurs
d'électrons dans la gamme
de 1 MeV à 50 MeV
(CEI 60601-2-1:1998/A1:2002)

Medizinische elektrische Geräte
Teil 2-1: Besondere Festlegungen für die
Sicherheit von Elektronenbeschleunigern
im Bereich von 1 MeV bis 50 MeV
(IEC 60601-2-1:1998/A1:2002)

This amendment A1 modifies the European Standard EN 60601-2-1:1998; it was approved by CENELEC on 2002-06-01. 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, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

Ref. No. EN 60601-2-1:1998/A1:2002 E

Foreword

The text of document 62C/329/FDIS, future amendment 1 to IEC 60601-2-1:1998, 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 60601-2-1:1998 on 2002-06-01.

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) 2003-03-01

– latest date by which the national standards conflicting with the amendment have to be withdrawn (dow) 2005-06-01

Endorsement notice

The text of amendment 1:2002 to the International Standard IEC 60601-2-1:1998 was approved by CENELEC as an amendment to the European Standard without any modification.

INTERNATIONAL STANDARD

IEC 60601-2-1

1998

AMENDMENT 1
2002-05

Amendment 1

Medical electrical equipment –

Part 2-1:
Particular requirements for the safety of electron accelerators in the range 1 MeV to 50 MeV

Amendement 1

Appareils électromédicaux –

Partie 2-1:
Règles particulières de sécurité pour les accélérateurs d'électrons dans la gamme de 1 MeV à 50 MeV

International Electrotechnical Commission, 3, rue de Varembé, PO Box 131, CH-1211 Geneva 20, Switzerland
Telephone: +41 22 919 02 11 Telefax: +41 22 919 03 00 E-mail: inmail@iec.ch Web: www.iec.ch

Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

PRICE CODE D

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/329/FDIS	62C/334/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 the base publication and its amendment will remain unchanged until 2005. At this date, the publication will be

- reconfirmed;
- withdrawn;
- replaced by a revised edition, or
- amended.

INTRODUCTION

Subclause 29.3.1.1 of IEC 60601-2-1:1998 sets limits to X-ray leakage radiation through beam limiting devices (BLDs) in the patient plane in order to reduce the detrimental effects on the patient due to leakage radiation. This clause restricts leakage through the main X and Y BLDs to a maximum of 2 % and an average of 0,5 %. Multi-element BLDs were assumed to replace a beam shielding block which attenuated the beam to about 5 %, and this was the upper limit applied to multi-element BLDs.

With the growth of techniques such as conformal therapy and IMRT, multi-element BLDs (which allow higher leakage levels) are being used to shield more of the radiation field area than was the case with conventional techniques using beam blocks. It is now proposed in the replacement subclause 29.3.1.1 to set a leakage tolerance on the total beam limiting system (the X and Y BLDs themselves may be single element, multi-element, or a combination of both) and to limit the leakage to an average of 0,75 %.

Page 87

29.3.1.1 X-radiation

Replace the existing text of this subclause by the following:

Measurements of LEAKAGE RADIATION through all combinations of BLDs shall be made with any residual aperture shielded by at least two TENTH-VALUE LAYERS OF X-RADIATION absorbing material[7]. For non-overlapping BLDs, measurements shall be made at minimum RADIATION FIELD size.

Adjustable or interchangeable BLDs shall be provided. Where any set or combinations of BLDs (including any multi-element BLDs) can overlap, these requirements shall apply to each independent set or combination measured together at the same time:

a) each BLD (excluding those multi-element BLDs for which c) applies) shall attenuate X-RADIATION such that anywhere in the area *M*, excepting the residual rectangular RADIATION FIELD, the ABSORBED DOSE due to leakage RADIATION does not exceed 2 % of the maximum ABSORBED DOSE measured on the REFERENCE AXIS at NTD in a 10 cm × 10 cm RADIATION FIELD;

b) for RADIATION FIELDS of any size, the average ABSORBED DOSE D_{LX}, due to LEAKAGE RADIATION through the BLDs, including multi-element BLDs, in the area *M*, shall not exceed 0,75 % of the maximum ABSORBED DOSE on the REFERENCE AXIS at NTD in a 10 cm × 10 cm RADIATION FIELD. If this limit is exceeded when areas of greater than 300 cm^2 at NTD are protected by multi-element BLDs, the conditions under which the limit is exceeded and the extent to which the limit is exceeded shall be stated in the ACCOMPANYING DOCUMENTS;

c) when a multi-element BLD is provided that by itself does not comply with the requirements of a) and b) above, and consequently requires adjustable or interchangeable BLDs in order to comply, these shall be adjusted automatically to provide the minimum size rectangular RADIATION FIELD surrounding the RADIATION FIELD defined by the multi-element BLD;

d) the ABSORBED DOSE due to LEAKAGE RADIATION through the parts of a multi-element BLD that project into the rectangular RADIATION FIELD formed by the automatically adjustable BLDs referred to in c) above shall not exceed 5 % of the maximum ABSORBED DOSE measured on the REFERENCE AXIS at NTD in a 10 cm × 10 cm RADIATION FIELD.

Compliance is checked as follows:

a) TYPE TEST grade B – Procedure:

1) locate the area of maximum LEAKAGE RADIATION from the evaluation of DIRECT or INDIRECT RADIOGRAMS produced at maximum X-RADIATION ENERGY and at NTD, for BLD settings of maximum RADIATION FIELD size FX_{max} by minimum RADIATION FIELD size FY_{min}. Repeat for settings of FX_{min} by FY_{max};

2) perform a RADIATION DETECTOR measurement at the point of maximum LEAKAGE RADIATION. The cross-sectional area of the RADIATION DETECTOR shall not exceed 1 cm^2; the measurement shall be made in a PHANTOM at the depth of the ABSORBED DOSE maximum. Repeat for all X-RADIATION ENERGIES.

a) SITE TEST grade B – Procedure: perform a RADIATION DETECTOR measurement as described in the TYPE TEST data for a) 2) above, at the X-RADIATION ENERGY corresponding to the maximum LEAKAGE RADIATION.

---

7) See ICRP 33 (234 et seq.).

b) TYPE TEST grade B – Procedure: perform RADIATION DETECTOR measurements as in a) 2) above, at each of the 24 points shown in figure 104, for symmetrical settings of those BLDs provided to produce rectangular RADIATION FIELDS at maximum field size FX_{max} by minimum field size FY_{min}. Determine D_{LX}, the average of all these measurements, as a percentage of the maximum ABSORBED DOSE measured on the REFERENCE AXIS at NTD in a 10 cm × 10 cm RADIATION FIELD. Repeat for symmetrical settings of FX_{min} by FY_{max}. Repeat for all X-RADIATION ENERGIES. If a multi-element BLD exists, then open adjustable or interchangeable BLDs to a square RADIATION FIELD of area 300 cm^2 and close the multi-element BLDs to the smallest opening consistent with this area (e.g. using a thin T or + shaped field). Perform RADIATION DETECTOR measurements in the area protected by the multi-element BLDs. From these measurements calculate the average ABSORBED DOSE D_{LX} due to LEAKAGE RADIATION through the BLDs, including multi-element BLDs, in the area M.

NOTE The use of two-dimensional arrays of RADIATION DETECTORS may shorten the time required for this test.

b) SITE TEST grade B – Procedure: as TYPE TEST.

c) TYPE TEST grade B – Procedure: use DIRECT or INDIRECT RADIOGRAMS to demonstrate the capability of automatic adjustment of the adjustable or interchangeable BLDs.

c) SITE TEST grade B – Procedure: use DIRECT or INDIRECT RADIOGRAMS to confirm the automatic adjustment capability.

d) TYPE TEST grade B – Procedure:

1) close up all the elements of an opposed pair of multi-element assemblies symmetrically to give the minimum aperture. Open two pairs of elements, one fully and the other partially, furthest away from the REFERENCE AXIS. From the evaluation of DIRECT or INDIRECT RADIOGRAMS, locate the point of maximum LEAKAGE RADIATION outside the now T-shaped residual minimum aperture. Repeat for all X-RADIATION ENERGIES;

2) perform RADIATION DETECTOR measurements under the conditions given in the TYPE TEST data for a) 2) above.

d) SITE TEST grade B – Procedure: perform a RADIATION DETECTOR measurement at the position of, and under the same conditions as, the highest value of LEAKAGE RADIATION given in the TYPE TEST a) 2) above.