Nederlandse

Wijzigingsblad

norm

NEN-EN-IEC 60601-2-1/A1 (en; fr)

Medische elektrische toestellen - Deel 2-1: Bijzondere eisen voor de veiligheid van medische elektronenversnellers in het gebied van 1 MeV tot 50 MeV (IEC 60601-2-1:1998/A1:2002,IDT)

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

augustus 2002
ICS 11.040.60

Als Nederlands wijzigingsblad is aanvaard:
- EN 60601-2-1:1998/A1:2002,IDT
- IEC 60601-2-1:1998/A1:2002,IDT

Normcommissie 301 062 "Medische elektrische toestellen"

NEN

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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

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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 %.

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