SLOVENSKI STANDARD

SIST EN 62274:2006

januar 2006

Medicinska električna oprema – Varnost radioterapevtskih zapisovalno-preverjalnih sistemov (IEC 62274:2005)

(istoveten EN 62274:2005)

Medical electrical equipment - Safety of radiotherapy record and verify systems IEC 62274:2005)

ICS 11.040.50; 11.040.60

Referenčna številka
SIST EN 62274:2006(en)

EUROPEAN STANDARD **EN 62274**

NORME EUROPÉENNE

EUROPÄISCHE NORM June 2005

ICS 11.040.60

English version

Medical electrical equipment – Safety of radiotherapy record and verify systems
(IEC 62274:2005)

Appareils électromédicaux –
Sécurité des systèmes d'enregistrement
et de vérification de radiothérapie
(CEI 62274:2005)

Medizinische elektrische Geräte –
Sicherheit von Aufzeichnungs-
und Verifikationssystemen
für die Strahlentherapie
(IEC 62274:2005)

This European Standard was approved by CENELEC on 2005-06-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard 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 European Standard 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

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

Ref. No. EN 62274:2005 E

Foreword

The text of document 62C/381/FDIS, future edition 1 of IEC 62274, prepared by SC 62C "Equipment for radiotherapy, nuclear medicine and radiation dosimetry" des IEC TC 62 "Electrical equipment in medical practice", was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 62274 on 2005-06-01.

The following dates were fixed:

– latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2006-03-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2008-06-01

In this standard, the following print types are used:

- requirements proper: roman type;
- *test specifications: italic type;*
- notes and explanatory matter: small roman type;
- TERMS USED THROUGHOUT THIS PARTICULAR STANDARD THAT ARE DEFINED IN CLAUSE 3, OR IN OTHER STANDARDS: SMALL CAPITALS.

Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 62274:2005 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 60601-1-6	NOTE	Harmonized as EN 60601-1-6:2004 (not modified).
IEC 60601-2-11	NOTE	Harmonized as EN 60601-2-11:1997 (not modified).
IEC 60601-2-17	NOTE	Harmonized as EN 60601-2-17:2004 (not modified).
IEC 62083	NOTE	Harmonized as EN 62083:2001 (not modified).

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Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following referenced documents are indispensable for the application 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.

NOTE Where an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Publication	Year	Title	EN/HD	Year
IEC 60601-1	1988	Medical electrical equipment Part 1: General requirements for safety	EN 60601-1 + corr. July A1 + corr. July A2 A13	1990 1994 1993 1994 1995 1996
IEC 60601-1-2	2001	Medical electrical equipment Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2	2001
IEC 60601-1-4	1996	Medical electrical equipment Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems	EN 60601-1-4	1996
A1	1999		A1	1999
IEC 60601-2-29	1999	Part 2-29: Particular requirements for the safety of radiotherapy simulators	EN 60601-2-29	1999
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-
IEC 60950-1 (mod)	2001	Information technology equipment - Safety Part 1: General requirements	EN 60950-1 + corr. April + A11	2001 2004 2004
IEC 61000-2-4	2002	Electromagnetic compatibility (EMC) Part 2-4: Environment - Compatibility levels in industrial plants for low-frequency conducted disturbances	EN 61000-2-4	2002
IEC 61217	1996	Radiotherapy equipment - Coordinates, movements and scales	EN 61217	1996

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Medical electrical equipment – Safety of radiotherapy record and verify systems

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT – SAFETY OF RADIOTHERAPY RECORD AND VERIFY SYSTEMS

FOREWORD

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International Standard IEC 62274 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 standard is based on the following documents:

FDIS	Report on voting
62C/381/FDIS	62C/385/RVD

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

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

– requirements proper: roman type;
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– notes and explanatory matter: small roman type;
– TERMS USED THROUGHOUT THIS PARTICULAR STANDARD THAT ARE DEFINED IN CLAUSE 3, OR IN OTHER STANDARDS: SMALL CAPITALS.

The committee has decided that the contents of this 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

A RADIOTHERAPY RECORD AND VERIFY SYSTEM (RVS) is a PEMS (PROGRAMMABLE ELECTRICAL MEDICAL SYSTEM) or a subsystem that is used to help prevent erroneous set-up of a medical ELECTRON ACCELERATOR, GAMMA BEAM THERAPY EQUIPMENT, or other RADIOTHERAPY TREATMENT machine and to record all TREATMENT sessions. This is accomplished through verification of the set-up and preventing machine operation if the set-up does not match predetermined settings. Inaccuracies in the data or errors in the record and verify process may represent SAFETY HAZARDS to PATIENTS. This standard defines requirements to be complied with by MANUFACTURERS in the design and construction of an RVS in order to provide protection against the occurrence of such hazards.