SLOVENSKI STANDARD
SIST EN 60601-2-9:1998

01-september-1998

Medical electrical equipment - Part 2: Particular requirements for the safety of patient contact dosemeters used in radiotherapy with electrically connected radiation detectors (IEC 60601-2-9:1996)

Medical electrical equipment -- Part 2: Particular requirements for the safety of patient contact dosemeters used in radiotherapy with electrically connected radiation detectors

Medizinische elektrische Geräte -- Teil 2: Besondere Festlegungen für die Sicherheit von Dosimetern mit Patientenkontakt, die in der Strahlentherapie mit elektrisch verbundenen Strahlungsdetektoren verwendet werden

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Appareils électromédicaux -- Partie 2: Règles particulières de sécurité des dosimètres au contact du patient utilisés en radiothérapie avec des détecteurs de rayonnement reliés électriquement

Ta slovenski standard je istoveten z: **EN 60601-2-9:1996**

ICS:

11.040.50	Radiografska oprema	Radiographic equipment
17.240	Merjenje sevanja	Radiation measurements

SIST EN 60601-2-9:1998 **en**

2003-01.Slovenski inštitut za standardizacijo. Razmnoževanje celote ali delov tega standarda ni dovoljeno.

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 60601-2-9

December 1996

ICS 11.040.50; 17.240

Supersedes HD 395.2.9 S1:1989

Descriptors: Medical electrical equipment, radiotherapy, dosemeters with electrically connected radiation detectors, safety requirements, protection against electric shock, protection against mechanical hazard, radiation protection, fire protection, environmental conditions

English version

Medical electrical equipment
Part 2: Particular requirements for the safety of patient contact dosemeters used in radiotherapy with electrically connected radiation detectors
(IEC 601-2-9:1996)

Appareils électromédicaux
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Medizinische elektrische Geräte
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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, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, 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

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Foreword

The text of document 62C/158/FDIS, future edition 2 of IEC 601-2-9, 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 EN 60601-2-9 on 1996-10-01.

This European Standard supersedes HD 395.2.9 S1:1989.

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) 1997-07-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 1997-07-01

Annexes designated "normative" are part of the body of the standard.
Annexes designated "informative" are given for information only.
In this standard, annex ZA is normative and annexes AA and ZB are informative.
Annexes ZA and ZB have been added by CENELEC.

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Endorsement notice

The text of the International Standard IEC 601-2-9:1996 was approved by CENELEC as a European Standard without any modification.

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Annex ZA (normative)

Normative references to international publications with their corresponding European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

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

Publication	Year	Title	EN/HD	Year
Addition to (replacement in) annex ZA of EN 60601-1:1990/A2:1995				
IEC 601-1	1988	Medical electrical equipment Part 1: General requirements for safety	EN 60601-1	1990
			+ corr. July	1994
A1	1991		A1	1993
			+ corr. July	1994
A2	1995		A2	1995
			A13	1996
IEC 601-1-1	1992	1. Collateral standard: Safety requirements for medical electrical systems	EN 60601-1-1	1993
A1	1995		A1	1996
IEC 601-1-2	1993	2. Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2	1993
IEC 731	1982	Medical electrical equipment - Dosimeters with ionization chambers as used in radiotherapy		
+ A1	1987		HD 534 S1	1989
IEC 788	1984	Medical radiology - Terminology	HD 501 S1	1988

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Annex ZB (informative)

Normative references to international publications with their corresponding European publications

Publication	Year	Title	EN/HD	Year
Addition to annex ZB of EN 60601-1:1990/A2:1995				
IEC 1010-1 (mod)	1990	Safety requirements for electrical equipment for measurement, control and laboratory use Part 1: General requirements		
+ A1 (mod)	1992		EN 61010-1	1993
A2	1995		A2	1995

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NORME INTERNATIONALE
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CEI
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Deuxième édition
Second edition
1996-10

Appareils électromédicaux –

Partie 2: Règles particulières de sécurité des dosimètres au contact du patient utilisés en radiothérapie avec des détecteurs de rayonnement reliés électriquement

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Medical electrical equipment –

Part 2: Particular requirements for the safety of patient contact dosemeters used in radiotherapy with electrically connected radiation detectors

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IEC

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International Electrotechnical Commission
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SIST EN 60601-2-9:1998

CONTENTS

iTeh STANDARD PREVIEW
(standards.iteh.ai)
SIST EN 60601-2-9:1998

SIST EN 60601-2-9:1998

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2: Particular requirements for the safety of patient contact dosemeters used in radiotherapy with electrically connected radiation detectors

FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, the IEC publishes International Standards. Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.

2) The formal decisions or agreements of the IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested National Committees.

3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical reports or guides and they are accepted by the National Committees in that sense.

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4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.

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5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.

6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 601-2-9 has been prepared by subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of the IEC technical committee 62: Electrical equipment in medical practice.

This second edition of IEC 601-2-9 cancels and replaces the first edition published in 1987. It constitutes a technical revision.

The text of this Particular Standard is based on the following documents:

FDIS	Report on voting
62C/158/FDIS	62C/175/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.

Annex AA is for information only.

SIST EN 60601-2-9:1998

In this Particular Standard, the following print types are used:

– requirements, compliance with which can be tested, and definitions: in roman type;

– explanations, advice, introductions, general statements, exceptions and references: in smaller type;

– *test specifications: in italic type;*

– TERMS USED THROUGHOUT THIS PARTICULAR STANDARD WHICH HAVE BEEN DEFINED IN CLAUSE 2, AND IN IEC 601-1, IEC 601-1-1, IEC 601-1-2, IEC 731 AND IEC 788: SMALL CAPITALS.

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SIST EN 60601-2-9:1998

INTRODUCTION

The use of DOSEMETERS in RADIOTHERAPY with electrically connected RADIATION DETECTORS may expose PATIENTS to danger if the RADIATION DETECTOR is in physical contact with a PATIENT and the DOSEMETER design does not satisfy standards of electrical and mechanical safety.

a) Most DOSEMETERS for RADIOTHERAPY are not intended for use in contact with a PATIENT: these should conform with the normal safety requirements for electronic measuring apparatus in IEC 1010-1.

b) If the DETECTOR ASSEMBLY of a DOSEMETER is intended for use in contact with a PATIENT during RADIOTHERAPY, the more stringent requirements of this Particular Standard as regards electrical safety, robustness and disinfectability will be applied.

c) The MEASURING ASSEMBLY is designed to meet the requirements of IEC 601-1 for allowable PATIENT LEAKAGE CURRENTS because it is electrically connected to the RADIATION DETECTOR.

d) If DETECTOR ASSEMBLIES and MEASURING ASSEMBLIES are sold separately, or can be disconnected from each other, the USER needs to be told which particular DETECTOR ASSEMBLY/MEASURING ASSEMBLY combinations meet the requirements of this Particular Standard for use in contact with a PATIENT.

It is possible, for example, that a DETECTOR ASSEMBLY connected to an unsuitable MEASURING ASSEMBLY (even if they each met all requirements when connected to suitable partners) could unintentionally have its ACCESSIBLE CONDUCTIVE PARTS connected to the polarizing supply; such a combination would be unsafe because of the high probability of grounding of the polarizing supply through the PATIENT and, consequently, incorrect readings.

iTeh STANDARD PREVIEW

This Particular Standard establishes requirements to be complied with by MANUFACTURERS in the design and construction of RADIOTHERAPY DOSEMETERS intended for use in physical contact with a PATIENT.

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