SLOVENSKI STANDARD
SIST EN 60601-2-43:2002

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Medicinska električna oprema - 2-43. del: Posebne varnostne zahteve za rentgensko opremo za intervencijske postopke (IEC 60601-2-43:2000)

Medical electrical equipment - Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures (IEC 60601-2-43:2000)

Medizinische elektrische Geräte - Teil 2-43: Besondere Festlegungen für die Sicherheit von Röntgeneinrichtungen für interventionelle Verfahren (IEC 60601-2-43:2000)

Appareils électromédicaux - Partie 2-43: Règles particulières de sécurité pour les appareils radiologiques lors d'interventions (CEI 60601-2-43:2000)

Ta slovenski standard je istoveten z: **EN 60601-2-43:2000**

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EUROPEAN STANDARD

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English version

Medical electrical equipment
Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures
(IEC 60601-2-43:2000)

Appareils électromédicaux
Partie 2-43: Règles particulières de sécurité pour les appareils radiologiques lors d'interventions
(CEI 60601-2-43:2000)

Medizinische elektrische Geräte
Teil 2-43: Besondere Festlegungen für die Sicherheit von Röntgeneinrichtungen für interventionelle Verfahren
(IEC 60601-2-43:2000)

This European Standard was approved by CENELEC on 2000-08-01. 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, Czech Republic, 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 62B/401/FDIS, future edition 1 of IEC 60601-2-43, prepared by SC 62B, Diagnostic imaging equipment, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-2-43 on 2000-08-01.

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) 2001-06-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2003-08-01

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

Endorsement notice

The text of the International Standard IEC 60601-2-43:2000 was approved by CENELEC as a European Standard without any modification.

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 annex ZA of EN 60601-1:1990/A2:1995:				
IEC 60601-2-32	1994	Medical electrical equipment Part 2: Particular requirements for the safety of associated equipment of X-ray equipment	EN 60601-2-32	1994
IEC 60788	1984	Medical radiology - Terminology	HD 501 S1	1988

Annex ZB
(informative)

Other international publications mentioned in this standard with the references of the relevant European publications

Publication	Year	Title	EN/HD	Year
Addition to annex ZB of EN 60601-1:1990/A2:1995:				
IEC 60601-2-7	1998	Medical electrical equipment Part 2-7: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators	EN 60601-2-7	1998
IEC 60601-2-28	1993	Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis	EN 60601-2-28	1993

INTERNATIONAL STANDARD

IEC 60601-2-43

First edition
2000-06

Medical electrical equipment –

Part 2-43:
Particular requirements for the safety of X-ray equipment for interventional procedures

Appareils électromédicaux –

Partie 2-43:
Règles particulières de sécurité pour les appareils radiologiques lors d'interventions

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Commission Electrotechnique Internationale
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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures

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 specifications, technical reports or guides and they are accepted by the National Committees in that sense.
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.
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 60601-2-43 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

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

FDIS	Report of voting
62B/401/FDIS	62B/408/RVD

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

Annexes AA, EE and FF form an integral part of this standard.

Annexes BB, CC and DD are for information only.

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

– requirements, compliance with which can be tested and definitions: roman type;
– notes, explanations, advice, introductions, general statements, exceptions and references: smaller type;
– *test specifications: italic type;*
– TERMS USED THROUGHOUT THIS PARTICULAR STANDARD WHICH HAVE BEEN DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD, IN IEC 60788 OR IN THIS STANDARD: SMALL CAPITALS.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 3.

The committee has decided that the contents of this publication will remain unchanged until 2005. At this date, the publication will be

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

A bilingual version of this standard may be issued at a later date.

INTRODUCTION

In recent years, there have been major developments in the use of X-RAY EQUIPMENT for RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES. These procedures may involve prolonged IRRADIATIONS and may subject PATIENTS and OPERATORS to higher levels of risk than those which normally prevail.

A consequence is the occurrence of deterministic injury when procedures involve the delivery of substantial amounts of RADIATION to localized areas on the PATIENT. Another consequence is the large contribution to the stochastic risk for the RADIATION induced cancers etc. collectively to the PATIENT.

This Particular Standard deals with these additional risks and thereby complements the General Standard with special provisions for this particular domain. Interventional procedures of the type envisaged are well established in clinical fields such as:

– invasive cardiology;
– interventional RADIOLOGY;
– interventional neuroradiology.

These procedures also include many newly developing and emerging applications in a wide range of medical and surgical specialities.

NOTE Attention is drawn to the existence of legislation in some countries concerning RADIOLOGICAL PROTECTION, which may not align with the provisions of this standard.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures

SECTION 1: GENERAL

The clauses and subclauses of this section of the General Standard apply, except as follows:

1 Scope and object

This clause of the General Standard applies, except as follows:

1.1 Scope

Addition:

This Particular Standard applies to X-RAY EQUIPMENT declared by the MANUFACTURER to be suitable for prolonged RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES. Its scope excludes, in particular:

- equipment for RADIOTHERAPY;
- equipment for COMPUTED TOMOGRAPHY;
- ACCESSORIES intended to be introduced into the PATIENT;
- mammographic X-RAY EQUIPMENT.

NOTE 1 Examples of prolonged RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES, for which the use of EQUIPMENT complying with this standard is recommended, are given in annex BB.

NOTE 2 The particular requirements of this standard are not essential for EQUIPMENT used in all RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES. Examples of procedures, for which the use of EQUIPMENT complying with this standard is considered not to be essential, are given in annex BB.

EQUIPMENT declared by the MANUFACTURER to be suitable for RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES, which does not include a PATIENT SUPPORT as part of the system, is exempt from the PATIENT SUPPORT provisions of this standard.

1.2 Object

Replacement:

The object of this standard is:

- to establish safety requirements for the design and manufacture of X-RAY EQUIPMENT for prolonged RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES;
- to specify information which is to be provided with such EQUIPMENT for the assistance of the USER and OPERATOR in managing the RADIATION risk arising from these procedures which could affect PATIENTS and staff.