SVENSK STANDARD SS-EN 60601-2-43

Fastställd	Utgåva	Sida	Ingår i
2001-05-29	1	1 (1+37)	SEK Översikt 62

Svenska Elektriska Kommissionen, SEK

Elektrisk utrustning för medicinskt bruk – Säkerhet – Del 2-43: Särskilda fordringar på röntgenutrustning för interventionella procedurer

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

Som svensk standard gäller europastandarden EN 60601-2-43:2000. Den svenska standarden innehåller den officiella engelska språkversionen av EN 60601-2-43:2000.

Nationellt förord

Europastandarden EN 60601-2-43:2000

består av:

– **europastandardens ikraftsättningsdokument**, utarbetat inom CENELEC
– **IEC 60601-2-43, First edition, 2000 - Medical electrical equipment - Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures**

utarbetad inom International Electrotechnical Commission, IEC.

Standarden skall användas tillsammans med SS-EN 60601-1, Elektromedicinsk utrustning - Säkerhet - Del 1: Allmänna fordringar, och dess separat utgivna ändringar och tillägg.

Till SS-EN 60601-1 utges en serie tilläggsstandarder som anger allmänna fordringar på säkerhet som är tillämpliga på

– en grupp av elektrisk utrustning för medicinskt bruk, t ex radiologisk utrustning
– särskilda egenskaper hos all elektrisk utrustning för medicinskt bruk, ej särskilt behandlade i SS-EN 60601-1, t ex elektromagnetisk kompatibilitet.

ICS 11.040.50

Denna standard är fastställd av Svenska Elektriska Kommissionen, SEK,
som också kan lämna upplysningar om **sakinnehållet** i standarden.
Postadress: SEK, Box 1284, 164 29 KISTA
Telefon: 08 - 444 14 00. *Telefax*: 08 - 444 14 30
E-post: sek@sekom.se. *Internet*: www.sekom.se

EUROPEAN STANDARD **EN 60601-2-43**

NORME EUROPÉENNE

EUROPÄISCHE NORM December 2000

ICS 11.040.50

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)

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 60601-2-43:2000 E

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.

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Endorsement notice

The text of the International Standard IEC 60601-2-43:2000 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 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

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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.