SVENSK STANDARD SS-EN 60601-2-45

Fastställd	Utgåva	Sida	Ingår i
2001-10-26	2	1 (1+41)	SEK Område 62

Svenska Elektriska Kommissionen, SEK

Elektrisk utrustning för medicinskt bruk – Säkerhet – Del 2-45: Särskilda fordringar för mammografiutrustning och utrustning för stereotaktisk mammografi

Medical electrical equipment – Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices

Som svensk standard gäller europastandarden EN 60601-2-45:2001. Den svenska standarden innehåller den officiella engelska språkversionen av EN 60601-2-45:2001.

Nationellt förord

Europastandarden EN 60601-2-45:2001

består av:

- **europastandardens ikraftsättningsdokument,** utarbetat inom CENELEC
- **IEC 60601-2-45, Second edition, 2001 - Medical electrical equipment - Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices**

  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.

Tidigare utgiven svensk standard SS-EN 60601-2-45, utgåva 1, 1999, gäller ej fr o m 2004-07-01.

ICS 11.040.50

Denna standard är fastställd av Svenska Elektriska Kommissionen, SEK, som också kan lämna upplysningar om **sakinnehållet** i standarden.
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EUROPEAN STANDARD **EN 60601-2-45**

NORME EUROPÉENNE

EUROPÄISCHE NORM July 2001

ICS 11.040.50 Supersedes EN 60601-2-45:1998

English version

Medical electrical equipment
Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices
(IEC 60601-2-45:2001)

Appareils électromédicaux
Partie 2-45: Règles particulières de sécurité pour les appareils de radiographie mammaire et les appareils mammographiques stéréotaxiques
(CEI 60601-2-45:2001)

Medizinische elektrische Geräte
Teil 2-45: Besondere Festlegungen für die Sicherheit von Röntgen-Mammographiegeräten und mammographischen Stereotaxie-Einrichtungen
(IEC 60601-2-45:2001)

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 60601-2-45:2001 E

Foreword

The text of document 62B/427/FDIS, future edition 2 of IEC 60601-2-45, 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 60601-2-45 on 2001-07-01.

This European Standard supersedes EN 60601-2-45:1998.

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) 2002-04-01

– latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2004-07-01

Annexes designated "normative" are part of the body of the standard.
Annexes designated "informative" are given for information only.
In this standard, annexes AA and CC are normative and annex BB is informative.

In this standard, the following print types are used:

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

– explanations, advice, notes, general statements and exceptions: smaller roman type;

– *test specifications and headings of subclauses: italic type;*

– TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD, IN THIS STANDARD, IN IEC 60788 OR IN OTHER IEC STANDARDS REFERENCED IN ANNEX AA: SMALL CAPITALS.

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

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Endorsement notice

The text of the International Standard IEC 60601-2-45:2001 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 60417-2	NOTE Harmonized as EN 60417-2:1998 (not modified).
IEC 60601-2-32	NOTE Harmonized as EN 60601-2-32:1994(not modified).
IEC 60613	NOTE Harmonized as EN 60613:1990 (not modified).

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CONTENTS

SECTION 6: PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETIC MIXTURES

SECTION 7: PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS

SECTION 8: ACCURACY OF OPERATING DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT

SECTION 9: ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS

SECTION 10: CONSTRUCTIONAL REQUIREMENTS

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices

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 contains requirements for the safety of X-RAY EQUIPMENT designed for mammography and MAMMOGRAPHIC STEREOTACTIC DEVICES. The safety requirements for the X-RAY GENERATOR and its sub-assemblies form an integral part of this standard.

1.2 Object

Replacement:

The object of this standard is

1 to formulate appropriate design and manufacturing requirements for the safety of mammographic X-RAY EQUIPMENT and MAMMOGRAPHIC STEREOTACTIC DEVICES, reflecting the particular characteristics and circumstances of use of such equipment;

2 to establish particular requirements to ensure safety and to specify methods for demonstrating compliance with those requirements.

NOTE 1 Requirements for reproducibility, linearity, constancy and accuracy are given because of their relationship to the quality and quantity of the IONIZING RADIATION produced and are confined to those considered necessary for safety.

NOTE 2 Both the levels for compliance and the tests prescribed to determine compliance reflect the fact that the safety of HIGH-VOLTAGE GENERATORS is not sensitive to small differences in levels of performance. The combinations of LOADING FACTORS specified for the tests are therefore limited in number but chosen from experience as being appropriate in most cases. It is considered important to standardize the choice of combinations of LOADING FACTORS so that comparison can be made between tests performed in different places on different occasions. However, combinations other than those specified could be of equal technical validity.

NOTE 3 The safety philosophy on which this standard is based is described in the introduction to the General Standard and in IEC 60513.

NOTE 4 Concerning RADIOLOGICAL PROTECTION it has been assumed in the preparation of this standard that MANUFACTURERS and USERS do accept the general principles of the International Commission on Radiological Protection (ICRP) as stated in ICRP 60, 1990, paragraph 112,[1)] namely:

"(a) No practice involving exposures to radiation should be adopted unless it produces sufficient benefit to the exposed individuals or to society to offset the radiation detriment it causes. (The justification of a practice.)

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1) ICRP Publication 60: *Recommendations of the International Commission on Radiological Protection (Annals of the ICRP Vol. 21 No 1-3, 1990)*. Published by Pergamon Press.

(b) In relation to any particular source within a practice, the magnitude of individual doses, the number of people exposed and the likelihood of incurring exposures where these are not certain to be received should all be kept as low as reasonably achievable, economic and social factors being taken into account. This procedure should be constrained by restrictions on the doses to individuals (dose constraints), or the risks to individuals in the case of potential exposures (risk constraints), so as to limit the inequity likely to result from the inherent economic and social judgements. (The optimisation of protection.)

(c) The exposure of individuals resulting from the combination of all the relevant practices should be subject to dose limits, or to some control of risk in the case of potential exposures. These are aimed at ensuring that no individual is exposed to radiation risks that are judged to be unacceptable from these practices in any normal circumstances. Not all sources are susceptible of control by action at the source and it is necessary to specify the sources to be included as relevant before selecting a dose limit. (Individual dose and risk limits.)"

NOTE 5 Most of the requirements on X-RAY EQUIPMENT and its sub-assemblies for protection against IONIZING RADIATION are given in the Collateral Standard IEC 60601-1-3.

This standard does, however, deal with some aspects of RADIOLOGICAL PROTECTION, mainly those that depend upon the supply, control and indication of electrical energy from the HIGH-VOLTAGE GENERATOR.

NOTE 6 It is recognized that many of the judgements necessary to follow the ICRP general principles have to be made by the USER and not by the MANUFACTURER of the EQUIPMENT.

1.3 Particular Standards

Addition:

This Particular Standard, hereinafter referred to as "this standard", amends and supplements a set of IEC publications, hereinafter referred to as "General Standard", consisting of IEC 60601-1: 1988, *Medical electrical equipment – Part 1: General requirements for safety*, its amendments 1 (1991) and 2 (1995) and all Collateral Standards.

The numbering of sections, clauses and subclauses of this standard corresponds to that of the General Standard. The changes to the text of the General Standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the General Standard is replaced completely by the text of this standard.

"Addition" means that the text of this standard is additional to the requirements of the General Standard.

"Amendment" means that the clause or subclause of the General Standard is amended as indicated by the text of this standard.

Subclauses or figures which are additional to those of the General Standard are numbered starting from 101, additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Where there is no corresponding section, clause or subclause in this standard, the section, clause or subclause of the General Standard applies without modification.

Where it is intended that any part of the General Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this standard.

A requirement of this standard replacing or modifying requirements of the General Standard takes precedence over the original requirements concerned.