STANDARDISERINGEN I SVERIGE
SWEDISH STANDARDS INSTITUTION

SVENSK STANDARD SS-EN 60601-2-7

Handläggande organ	Fastställd	Utgåva	Sida	Ingår i
Svenska Elektriska Kommissionen, SEK	1998-08-28	1	1(1+42)	SEK Översikt 62
				Reg 486 03 27

Elektrisk utrustning för medicinskt bruk – Säkerhet – Del 2-7: Särskilda fordringar på högspänningsgeneratorer för diagnostisk röntgenutrustning

Medical electrical equipment – Part 2-7: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators

Som svensk standard gäller europastandarden EN 60601-2-7:1998. Den svenska standarden innehåller den officiella engelska språkversionen av EN 60601-2-7:1998.

Nationellt förord

Europastandarden EN 60601-2-7:1998

består av:

– **europastandardens ikraftsättningsdokument,** utarbetat inom CENELEC
– **IEC 60601-2-7, Second edition, 1998 - Medical electrical equipment - Part 2-7: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators**

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-IEC 601-2-7, utgåva 1, 1988, gäller ej fr o m 2001-01-01.

ICS 11.040.50

Standarder kan beställas hos SIS som även lämnar allmänna upplysningar om svensk och utländsk standard.
Postadress: SIS, Box 6455, 113 82 STOCKHOLM
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Upplysningar om **sakinnehållet** i standarden lämnas av SEK.
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Prisgrupp R

Tryckt i oktober 1998

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-7

April 1998

ICS 11.040.50

Supersedes HD 395.2.7 S1:1989

Descriptors: Medical electrical equipment, X-ray equipment, radiodiagnostic X-ray generator, high-voltage generators, safety requirements, protection against electric shock, protection against mechanical hazard, radiation protection, fire protection, environmental conditions

English version

Medical electrical equipment
Part 2-7: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators
(IEC 60601-2-7:1998)

Appareils électromédicaux
Partie 2-7: Règles particulières de sécurité pour générateurs radiographiques de groupes radiogènes de diagnostic
(CEI 60601-2-7:1998)

Medizinische elektrische Geräte
Teil 2-7: Besondere Festlegungen für die Sicherheit von Röntgengeneratoren von diagnostischen Röntgenstrahlenerzeugern
(IEC 60601-2-7:1998)

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 60601-2-7:1998 E

Foreword

The text of document 62B/329/FDIS, future edition 2 of IEC 60601-2-7, 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 60601-2-7 on 1998-04-01.

This European Standard supersedes HD 395.2.7 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) 1999-01-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2001-01-01

Endorsement notice

The text of the International Standard IEC 60601-2-7:1998 was approved by CENELEC as a European Standard without any modification.

CONTENTS

Page

SECTION 1: GENERAL

Clause

SECTION 2: ENVIRONMENTAL CONDITIONS

SECTION 3: PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

SECTION 4: PROTECTION AGAINST MECHANICAL HAZARDS

SECTION 5: PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

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

Tables

Figures

Annexes

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-7: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators

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

Replacement:

This Particular Standard applies to HIGH-VOLTAGE GENERATORS of medical diagnostic X-RAY GENERATORS and to their subassemblies including the following:

– HIGH-VOLTAGE GENERATORS that are integrated with an X-RAY TUBE ASSEMBLY;

– HIGH-VOLTAGE GENERATORS of radiotherapy treatment simulators.

Where appropriate, requirements for X-RAY GENERATORS are given but only where these concern the functioning of the associated HIGH-VOLTAGE GENERATOR.

This standard excludes

– CAPACITOR DISCHARGE HIGH-VOLTAGE GENERATORS (these are covered by IEC 60601-2-15),

– HIGH-VOLTAGE GENERATORS for mammography,

– HIGH-VOLTAGE GENERATORS for RECONSTRUCTIVE TOMOGRAPHY.

1.2 Object

Replacement:

The object of this standard is 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 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.)

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 subassemblies 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.

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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.