



NSAI
Standards

Irish Standard
I.S. EN 60613:2010

Electrical and loading characteristics of X-ray tube assemblies for medical diagnosis (IEC 60613:2010 (EQV))

I.S. EN 60613:2010

Incorporating amendments/corrigenda issued since publication:

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I.S. xxx: Irish Standard – national specification based on the consensus of an expert panel and subject to public consultation.

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SWiFT xxx: A rapidly developed recommendatory document based on the consensus of the participants of an NSAI workshop.

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 60613

April 2010

ICS 11.040.50

Supersedes EN 60613:1990

English version

**Electrical and loading characteristics of X-ray tube assemblies
for medical diagnosis
(IEC 60613:2010)**

Caractéristiques électriques et de charge
des gaines équipées pour diagnostic
médical
(CEI 60613:2010)

Elektrische und Belastungs-Kennwerte
von Röntgenstrahlern für die medizinische
Diagnostik
(IEC 60613:2010)

This European Standard was approved by CENELEC on 2010-04-01. 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, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

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Foreword

The text of document 62B/774/FDIS, future edition 3 of IEC 60613, 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 60613 on 2010-04-01.

This standard supersedes EN 60613:1990. It constitutes a technical revision. EN 60613:2010 has been adapted to apply to the present technology.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN and CENELEC shall not be held responsible for identifying any or all such patent rights.

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) | 2011-01-01 |
| – latest date by which the national standards conflicting with the EN have to be withdrawn | (dow) | 2013-04-01 |

Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60613:2010 was approved by CENELEC as a European Standard without any modification.

Annex ZA

(normative)

Normative references to international publications with their corresponding European publications

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
IEC 60601-1-3	2008	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment	EN 60601-1-3	2008
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

ELECTRICAL AND LOADING CHARACTERISTICS OF X-RAY TUBE ASSEMBLIES FOR MEDICAL DIAGNOSIS

FOREWORD

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International Standard IEC 60613 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee TC 62: Electrical equipment in medical practice.

This third edition cancels and replaces the second edition of IEC 60613, published in 1989. It constitutes a technical revision. This third edition has been adapted to apply to the present technology.

The text of this standard is based on the following documents:

FDIS	Report on voting
62B/774/FDIS	62B/780/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.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

- requirements and definitions: roman type.
- informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;
- TERMS DEFINED IN CLAUSE 3 OF THIS STANDARD OR AS NOTED: SMALL CAPS.

The committee has decided that the contents of this publication will remain unchanged until the maintenance result date indicated on the IEC web site under "<http://webstore.iec.ch>" in the data related to the specific publication. At this date, the publication will be

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

<p>IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.</p>

ELECTRICAL AND LOADING CHARACTERISTICS OF X-RAY TUBE ASSEMBLIES FOR MEDICAL DIAGNOSIS

1 Scope

This International Standard applies to X-RAY TUBE ASSEMBLIES either with a rotating ANODE X-RAY TUBE or a stationary ANODE X-RAY TUBE, intended for use in medical diagnosis.

For an X-RAY TUBE HEAD, its X-RAY TUBE ASSEMBLY aspects are also within the scope.

This International Standard covers performance-related definitions and conditions of electrical and LOADING characteristics of X-RAY TUBE ASSEMBLIES in relation to their behaviour during and after energization and, where appropriate, methods of presentation and measurement of these characteristics. This International Standard is therefore relevant for the MANUFACTURER and the RESPONSIBLE ORGANIZATION.

NOTE "Measurement" in this standard is always related to practical use. Consequently, "measurement" is meant to consume only a negligible part of the life of the X-RAY TUBE ASSEMBLY.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-3:2008, *Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment*

IEC/TR 60788:2004, *Medical electrical equipment – Glossary of defined terms* (available only in English)

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC/TR 60788:2004, IEC 60601-1:2005 and IEC 60601-1-3:2008 and the following apply.

3.1

X-RAY TUBE VOLTAGE

potential difference applied to an X-RAY TUBE between the ANODE and the CATHODE. Usually X-RAY TUBE VOLTAGE is expressed by its peak value in kilovolts (kV)

[IEC 60601-1-3:2008, 3.88]

3.2

NOMINAL X-RAY TUBE VOLTAGE

highest permitted X-RAY TUBE VOLTAGE for SPECIFIC operating conditions

[IEC 60601-1-3:2008, 3.42]

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