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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This document replaces:	*This document is based on:*	*Published:*
EN 60613:1990	EN 60613:2010 EN 60613:1990	16 April, 2010 11 September, 1990

This document was published under the authority of the NSAI and comes into effect on:
4 May, 2010

ICS number:
11.040.50

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I.S. EN 60613:2010

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)

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CENELEC

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

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Ref. No. EN 60613:2010 E

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– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2013-04-01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

Publication	Year	Title	EN/HD	Year
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

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of 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, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). 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. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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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.

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.

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]