

BUREAU OF INDIAN STANDARDS

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भारतीय मानक मसौदा

चिकित्सा विद्युत उपकरण – चिकित्सा निदान के लिए एक्स-रे ट्यूब असेंबली - फोकल स्पॉट आयाम और संबंधित विशेषताएं

(संशोधित, IEC 60336:2020)

Draft Indian Standard

**Medical electrical equipment – X-ray tube assemblies for medical diagnosis –
Focal spot dimensions and related characteristics**

(MOD, IEC 60336:2020)

[ICS 11.040.50]

Electromedical, Diagnostic Imaging and Radiotherapy
Equipment Sectional Committee, MHD 15

Last Date for Comments: 17 July 2023

NATIONAL FOREWORD

(Adoption clause will be added later)

This standard was first published in 1986 as IS 12024 which was based on IEC Pub 336 (1982) 'Characteristics of focal spots in diagnostic X-ray tube assemblies for medical use'. It was superseded by IS/IEC 60336:2005 which was an identical adoption of IEC 60336:2005 'Medical electrical equipment — X-ray tube assemblies for medical diagnosis — Characteristics of focal spots'. This publication supersedes IS/IEC 60336:2005.

Corrigendum 1 issued in 2022 to IEC 60336:2020 has been incorporated at the end of this publication.

The text of IEC Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are however not identical to those used in Indian Standards. Attention is particularly drawn to the following:

- Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.

- b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standard for which Indian Standard also exists. The corresponding Indian Standard, which is to be substituted in its respective place, is listed below along with its degree of equivalence for the edition indicated:

<i>International Standard</i>	<i>Corresponding Standard</i>	<i>Degree of Equivalence</i>
IEC 60601-1:2005, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance IEC 60601-1:2005/AMD1:2012	Doc No. MHD 15(22648) Medical electrical equipment : Part 1 General requirements for basic safety and essential performance (Third Revision) (<i>under preparation</i>)	Modified
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 60601-1-3:2008/AMD1:2013	Doc No. MHD 15(22652) Medical electrical equipment – Part 1 General requirements for basic safety and essential performance, Section 3 Radiation protection in diagnostic X-ray equipment (First Revision) (<i>under preparation</i>)	Not equivalent
IEC TR 60788:2004, Medical electrical equipment – Glossary of defined terms	IS/IEC/TR 60788:2004 Medical electrical equipment – Glossary of defined terms	Identical

The technical committee has reviewed the provisions of the following International Standards referred in this adopted standard and has decided that these are acceptable for use in conjunction with this standard:

<i>International Standard</i>	<i>Title</i>
IEC 60417	Graphical symbols for use on equipment
IEC 60613:2010	Electrical and loading characteristics of X-ray tube assemblies for medical diagnosis

This standard is a modified adoption as some of the Indian standards cross-referred (Column 2) in the first table above are not identical to the referred (Column 1) International standards.

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated, expressing the result of a test or analysis shall be rounded off in accordance with IS 2 : 2022 ‘Rules for rounding off numerical values (*Second Revision*)’. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Note: The technical content of the document has not been included as it is identical with the corresponding IEC standard. For details, please refer to IEC 60336:2020 or kindly contact:

Head (MHD)
Bureau of Indian Standards
Manak Bhawan
9, Bahadur Shah Zafar Marg
New Delhi-110002
Email: hmhd@bis.gov.in; mhd@bis.gov.in

Scope

This document applies to FOCAL SPOTS in medical diagnostic X-RAY TUBE ASSEMBLIES for medical use, operating at X-RAY TUBE VOLTAGES up to and including 150 kV.

This document describes the test methods employing digital detectors for determining:

- a) FOCAL SPOT dimensions in terms of NOMINAL FOCAL SPOT VALUES, ranging from 0,1 to 3,0;
- b) LINE SPREAD FUNCTIONS;
- c) one-dimensional MODULATION TRANSFER FUNCTIONS;
- d) FOCAL SPOT PINHOLE RADIOGRAMS,

and the means for indicating compliance.