BS EN IEC 63073-1:2020

BSI Standards Publication

Dedicated radionuclide imaging devices — Characteristics and test conditions

Part 1: Cardiac SPECT

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This British Standard is the UK implementation of EN IEC 63073-1:2020. It is identical to IEC 63073-1:2020.

The UK participation in its preparation was entrusted to Technical Committee CH/62/3, Equipment for radiotherapy, nuclear medicine and radiation dosimetry.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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Published by BSI Standards Limited 2020

ISBN 978 0 580 95575 4

ICS 11.040.50

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This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 December 2020.

Amendments/corrigenda issued since publication

Date	Text affected

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 63073-1

December 2020

ICS 11.040.50

English Version

Dedicated radionuclide imaging devices - Characteristics and test conditions - Part 1: Cardiac SPECT (IEC 63073-1:2020)

Dispositifs d'imagerie par radionucléides dédiés - Caractéristiques et conditions d'essai - Partie 1: SPECT pour scintigraphie cardiaque (IEC 63073-1:2020)

Spezielle Radionuklid-Bildgebungsgeräte - Merkmale und Prüfbedingungen - Teil 1: Kardiale SPECT (IEC 63073-1:2020)

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European Committee for Electrotechnical Standardization
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Europäisches Komitee für Elektrotechnische Normung

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European foreword

The text of document 62C/740/CDV, future edition 1 of IEC 63073-1, prepared by SC 62C "Equipment for radiotherapy, nuclear medicine and radiation dosimetry" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 63073-1:2020.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2021-08-30
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2023-11-30

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Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 1 Where an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

Publication	Year	Title	EN/HD	Year
IEC 61675-2	2015	Radionuclide imaging devices - Characteristics and test conditions - Part 2: Gamma cameras for planar, wholebody, and SPECT imaging	EN 61675-2	2015

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

DEDICATED RADIONUCLIDE IMAGING DEVICES – CHARACTERISTICS AND TEST CONDITIONS –

Part 1: Cardiac SPECT

FOREWORD

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International Standard IEC 63073-1 has been prepared by subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Electrical equipment in medical practice.

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

CDV	Report on voting
62C/740/CDV	62C/765/RVC

Full information on the voting for the approval of this document can be found in the report on voting indicated in the above table.

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

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In this document, the following print types are used:

– terms defined in Clause 3 of this document or listed in the index of defined terms: SMALL CAPITALS.

The requirements are followed by specifications for the relevant tests.

A list of all parts in the IEC 63073 series, published under the general title *Dedicated radionuclide imaging devices – Characteristics and test condtions*, can be found on the IEC website.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
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INTRODUCTION

The test methods specified in this part of IEC 63073 have been selected to reflect as much as possible the clinical use of GAMMA CAMERAS that are dedicated to cardiac SINGLE PHOTON EMISSION COMPUTED TOMOGRAPHY (SPECT). It is intended that the test methods are carried out by manufacturers thereby enabling them to describe the characteristics of the systems on a common basis.

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DEDICATED RADIONUCLIDE IMAGING DEVICES – CHARACTERISTICS AND TEST CONDITIONS –

Part 1: Cardiac SPECT

1 Scope

This document specifies terminology and test methods for describing the characteristics of SINGLE PHOTON EMISSION COMPUTED TOMOGRAPHY (SPECT) systems designed specifically for tomographic cardiac imaging. This includes dedicated systems or general purpose systems with dedicated sub-systems which are not included in the scope of IEC 61675-2.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 61675-2:2015, *Radionuclide imaging devices – Characteristics and test conditions – Part 2: Gamma cameras for planar, wholebody, and SPECT imaging*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

3.1
REFERENCE POINT
defined 3D position in the FOV of the camera, specified by the manufacturer, or, if not specified by the manufacturer, assumed to be the centre of the FOV of the camera

3.2
BAD PIXEL
detector pixel that has been physically or electronically turned off such that gamma rays which interact in that BAD PIXEL are not recorded by the camera

3.3
CARDIAC DETECTOR HEAD
assembly of detector components associated with a single COLLIMATOR

3.4
CARDIAC DETECTOR HEAD ELEMENT
smallest discrete unit of the CARDIAC DETECTOR HEAD that is able to provide distinct energy, spatial, and timing information about detected photons

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