SLOVENSKI STANDARD
SIST EN IEC 63073-1:2021

01-februar-2021

Namenske naprave za slikanje z radionuklidi - Karakteristike in preskusni pogoji - 1. del: Preiskava srca SPECT (IEC 63073-1:2020)

Dedicated Radionuclide Imaging Devices - Characteristics and Test Conditions - Part 1: Cardiac SPECT (IEC 63073-1:2020)

Spezielle Radionuklid-Bildgebungsgeräte - Merkmale und Prüfbedingungen - Teil 1: Kardiale 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)

Ta slovenski standard je istoveten z: **EN IEC 63073-1:2020**

ICS:

11.040.50	Radiografska oprema	Radiographic equipment

SIST EN IEC 63073-1:2021 **en**

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN IEC 63073-1

December 2020

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English Version

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

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CENELEC

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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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• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2023-11-30

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Endorsement notice

The text of the International Standard IEC 63073-1:2020 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 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 STANDARD

NORME INTERNATIONALE

colour inside

Dedicated radionuclide imaging devices – Characteristics and test conditions – Part 1: Cardiac SPECT

Dispositifs d'imagerie par radionucléides dédiés – Caractéristiques et conditions d'essai – Partie 1: SPECT pour scintigraphie cardiaque

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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CONTENTS

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DEDICATED RADIONUCLIDE IMAGING DEVICES – CHARACTERISTICS AND TEST CONDITIONS –

Part 1: Cardiac SPECT

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 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.

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
- 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.

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.

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