

INTERNATIONAL STANDARD

NORME INTERNATIONALE



**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**



THIS PUBLICATION IS COPYRIGHT PROTECTED

Copyright © 2020 IEC, Geneva, Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either IEC or IEC's member National Committee in the country of the requester. If you have any questions about IEC copyright or have an enquiry about obtaining additional rights to this publication, please contact the address below or your local IEC member National Committee for further information.

Droits de reproduction réservés. Sauf indication contraire, aucune partie de cette publication ne peut être reproduite ni utilisée sous quelque forme que ce soit et par aucun procédé, électronique ou mécanique, y compris la photocopie et les microfilms, sans l'accord écrit de l'IEC ou du Comité national de l'IEC du pays du demandeur. Si vous avez des questions sur le copyright de l'IEC ou si vous désirez obtenir des droits supplémentaires sur cette publication, utilisez les coordonnées ci-après ou contactez le Comité national de l'IEC de votre pays de résidence.

IEC Central Office
3, rue de Varembe
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
info@iec.ch
www.iec.ch

About the IEC

The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

About IEC publications

The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigendum or an amendment might have been published.

IEC publications search - webstore.iec.ch/advsearchform

The advanced search enables to find IEC publications by a variety of criteria (reference number, text, technical committee,...). It also gives information on projects, replaced and withdrawn publications.

IEC Just Published - webstore.iec.ch/justpublished

Stay up to date on all new IEC publications. Just Published details all new publications released. Available online and once a month by email.

IEC Customer Service Centre - webstore.iec.ch/csc

If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: sales@iec.ch.

Electropedia - www.electropedia.org

The world's leading online dictionary on electrotechnology, containing more than 22 000 terminological entries in English and French, with equivalent terms in 16 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

IEC Glossary - std.iec.ch/glossary

67 000 electrotechnical terminology entries in English and French extracted from the Terms and Definitions clause of IEC publications issued since 2002. Some entries have been collected from earlier publications of IEC TC 37, 77, 86 and CISPR.

A propos de l'IEC

La Commission Electrotechnique Internationale (IEC) est la première organisation mondiale qui élabore et publie des Normes internationales pour tout ce qui a trait à l'électricité, à l'électronique et aux technologies apparentées.

A propos des publications IEC

Le contenu technique des publications IEC est constamment revu. Veuillez vous assurer que vous possédez l'édition la plus récente, un corrigendum ou amendement peut avoir été publié.

Recherche de publications IEC -

webstore.iec.ch/advsearchform

La recherche avancée permet de trouver des publications IEC en utilisant différents critères (numéro de référence, texte, comité d'études,...). Elle donne aussi des informations sur les projets et les publications remplacées ou retirées.

IEC Just Published - webstore.iec.ch/justpublished

Restez informé sur les nouvelles publications IEC. Just Published détaille les nouvelles publications parues. Disponible en ligne et une fois par mois par email.

Service Clients - webstore.iec.ch/csc

Si vous désirez nous donner des commentaires sur cette publication ou si vous avez des questions contactez-nous: sales@iec.ch.

Electropedia - www.electropedia.org

Le premier dictionnaire d'électrotechnologie en ligne au monde, avec plus de 22 000 articles terminologiques en anglais et en français, ainsi que les termes équivalents dans 16 langues additionnelles. Egalement appelé Vocabulaire Electrotechnique International (IEV) en ligne.

Glossaire IEC - std.iec.ch/glossary

67 000 entrées terminologiques électrotechniques, en anglais et en français, extraites des articles Termes et Définitions des publications IEC parues depuis 2002. Plus certaines entrées antérieures extraites des publications des CE 37, 77, 86 et CISPR de l'IEC.

INTERNATIONAL STANDARD

NORME INTERNATIONALE



**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

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

ICS 11.040.50

ISBN 978-2-8322-8967-9

**Warning! Make sure that you obtained this publication from an authorized distributor.
Attention! Veuillez vous assurer que vous avez obtenu cette publication via un distributeur agréé.**

CONTENTS

CONTENTS	2
FOREWORD	3
INTRODUCTION	5
1 Scope	6
2 Normative references	6
3 Terms and definitions	6
4 Test methods	7
4.1 General	7
4.2 Detector characteristics	8
4.2.1 General	8
4.2.2 Energy resolution and LOW-ENERGY-TAIL RATIO measurement	8
4.2.3 Shield leakage	9
4.2.4 COUNT RATE performance	10
4.2.5 System sensitivity	12
4.2.6 Non-uniformity for each CARDIAC DETECTOR HEAD	14
4.2.7 SCATTER FRACTION	14
4.3 Characteristics of tomographic images	16
4.3.1 CENTRE OF ROTATION (COR)	16
4.3.2 REFERENCE POINT localization in the reconstructed FOV	16
4.3.3 Accuracy of tomographic system sensitivity modelling	17
4.3.4 Tomographic SPATIAL NON-LINEARITY	19
4.3.5 Tomographic SPATIAL RESOLUTION	21
4.3.6 Image quality assessment using a heart phantom	23
5 Additional testing	26
6 ACCOMPANYING DOCUMENTS	27
Bibliography	28
Index of defined terms	29
Figure 1 – Small shielded liquid source	10
Figure 2 – Transverse slice of phantom used for measuring COUNT RATE performance	11
Figure 3 – Evaluation of SCATTER FRACTION	15
Figure 4 – Calculation of FWHM and measurement of the location of the maximum value	17
Figure 5 – Transaxial view of the 7 LINE SOURCE Phantom	18
Figure 6 – Transaxial view of the 7 LINE SOURCE phantom centred within a 140 mm diameter water-filled cylinder	22
Figure 7 – Placement of ROIs in SHORT AXIS view of myocardium	25
Figure 8 – Placement of ROIs in LONG AXIS view of myocardium	26
Table 1 – Relative ACTIVITY concentration of compartments of the anthropomorphic phantom	24

INTERNATIONAL ELECTROTECHNICAL COMMISSION

**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.
- 2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
- 3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
- 4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
- 5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
- 6) All users should ensure that they have the latest edition of this publication.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
- 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

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 conditions*, 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