IEC 63073-1

Edition 1.0 2020-10

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

IEC 63073-1:2020-10(en-fr)

IEC Central Office
3, rue de Varembé
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 It also gives information on projects, replaced and withdrawn publications.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.

IEC 63073-1

Edition 1.0 2020-10

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

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

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 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

3.5
CCFOV
central volume of the field of view of a cardiac camera, located within a radius of 7 cm from the REFERENCE POINT

3.6
CUFOV
field of view of a cardiac camera for which the summed counts for a LINE SOURCE segment are at least 50 % of the summed counts measured with the camera with the LINE SOURCE segment positioned within the CCFOV

3.7
CARDIAC ORIENTATION
image coordinate system specified in reference to the axes of the heart

3.8
SHORT AXIS
SA
in the CARDIAC ORIENTATION, the plane perpendicular to the long-axis of the heart

3.9
LONG AXIS
LA
in the CARDIAC ORIENTATION, a plane parallel to the long-axis of the heart

3.10
HORIZONTAL LONG AXIS
HLA
in the CARDIAC ORIENTATION, the LONG AXIS plane that most closely bisects both the left ventricle and the right ventricle of the heart

3.11
VERTICAL LONG AXIS
VLA
in the CARDIAC ORIENTATION, the LONG AXIS plane, that is perpendicular to the HORIZONTAL LONG AXIS

3.12
LOW-ENERGY-TAIL RATIO
ratio of the counts measured in an ENERGY WINDOW of width $2 \times E_{FWHM}$ centred at energy $E_{peak} - 2 \times E_{FWHM}$ divided by the counts measured in an ENERGY WINDOW of width $2 \times E_{FWHM}$ centred at an energy of E_{peak}, where E_{peak} is the peak energy of the radioisotope being measured and E_{FWHM} is the energy resolution of the detector

4 Test methods

4.1 General

Before the measurements are performed, the tomographic system shall be adjusted by the procedure normally used by the manufacturer for an installed unit and shall not be adjusted specially for the measurement of specific parameters. If any test cannot be carried out exactly as specified in the standard, the reason for the deviation and the exact conditions under which the test was performed shall be stated clearly.

Unless otherwise specified, each CARDIAC DETECTOR HEAD in the system shall be characterized by a full data set.

Unless otherwise specified, SPECT characterization shall be provided for an acquisition covering the minimal rotation required to obtain a complete set of data (e.g. 120° for a three-headed rotating-gantry system). If a rotating-gantry tomograph is specified to operate in a non-circular orbiting mode influencing the performance parameters, test results for the non-circular orbiting mode shall be reported in addition.

Unless otherwise specified, measurements are carried out at COUNT RATES not exceeding 40 000 counts per second on each CARDIAC DETECTOR HEAD and not exceeding 120 000 counts per second for the system.

4.2 Detector characteristics

4.2.1 General

Evaluation of detector characteristics for cardiac systems are performed extrinsically (with COLLIMATORS in place). Additionally, for systems that allow the removal of the COLLIMATOR, intrinsic detector characteristics shall be specified and tested in accordance with IEC 61675-2.

4.2.2 Energy resolution and LOW-ENERGY-TAIL RATIO measurement

4.2.2.1 General

Energy resolution describes the ability of the detector to properly identify the energy of the detected photons. Due to incomplete charge collection, the detector material in some cardiac systems may have an increased fraction of photons detected with reduced energy. The effect is characterized by measuring the LOW-ENERGY-TAIL RATIO.

An energy spectrum is determined for each CARDIAC DETECTOR HEAD.

4.2.2.2 Purpose

The energy resolution is measured to characterize the ability of a GAMMA CAMERA to separate photons with different energies.

4.2.2.3 Method

Measure an energy spectrum in low scatter configuration using an irradiation of the entire CARDIAC DETECTOR HEAD. This measurement is performed separately for each CARDIAC DETECTOR HEAD.

4.2.2.4 RADIONUCLIDE

The sources are ^{99m}Tc and ^{57}Co.

4.2.2.5 RADIOACTIVE SOURCE DISTRIBUTION

A LINE SOURCE with internal diameter of < 1,2 mm is placed so as to illuminate the entire CARDIAC DETECTOR HEAD. The COUNT RATE shall not exceed 40 000 counts per second.

4.2.2.6 Data collection

For each CARDIAC DETECTOR HEAD, the pulse height spectrum is obtained with a channel width less than or equal to 5 % of the expected photopeak FWHM. The number of counts in the peak channel is greater than 10 000. The spectrum is obtained over the entire usable energy range of the detector.

4.2.2.7 Data processing

For the energy spectrum, the channel numbers are expressed in terms of energy by scaling the channel number by the difference in peak energies of the two RADIONUCLIDES divided by the difference in their measured peak channel positions.

4.2.2.8 Data analysis

For each CARDIAC DETECTOR HEAD, the energy resolution, E_{FWHM}, is the FWHM of the full energy absorption peak with a peak energy, E_{peak}, closest to the expected photopeak energy.

For each CARDIAC DETECTOR HEAD, the LOW-ENERGY-TAIL RATIO, Q_{tail}, is defined as:

$$Q_{tail} = Z_{tail} / Z_{peak} \quad (1)$$

where

Z_{peak} is the sum of counts from the averaged energy spectrum in the ENERGY WINDOW centred on the energy peak E_{peak} with the width of $2 \times E_{FWHM}$;

Z_{tail} is the sum of counts from the averaged energy spectrum in the ENERGY WINDOW centred on the energy $E_{peak} - 2 \times E_{FWHM}$ with the width of $2 \times E_{FWHM}$.

4.2.2.9 Report

The energy resolution, expressed as a percentage of the peak energy, and the LOW-ENERGY-TAIL RATIO are reported for each CARDIAC DETECTOR HEAD. The mean and standard deviation of the energy resolution and LOW-ENERGY-TAIL RATIO for the entire system is also reported if the system has more than 5 CARDIAC DETECTOR HEADS.

4.2.3 Shield leakage

4.2.3.1 General

The DETECTOR SHIELD prevents the detection of unwanted photons originated from outside the entrance field of view of the COLLIMATOR.

4.2.3.2 Purpose

The purpose of this test is to identify the locations of the highest leakage and its magnitude.

4.2.3.3 Method

The complete surface of cardiac camera system is swept with a collimated source searching for the maximum leakage COUNT RATES at the rear and the side of the DETECTOR SHIELD and the joints (particularly the joint between the COLLIMATOR and the DETECTOR SHIELD), if it is accessible.

4.2.3.4 RADIONUCLIDE

The source is ^{99m}Tc.

4.2.3.5 RADIOACTIVE SOURCE DISTRIBUTION

A small collimated source, as illustrated in Figure 1, with *d* not larger than 20 mm and *t* not less than 10 mm, totally filled with the RADIONUCLIDE

4.2.3.6 Data collection

The source is placed in contact with the external surface of the DETECTOR SHIELD and the joints if accessible. The entire surface of the DETECTOR SHIELD is swept and the system COUNT RATES measured during a clinical acquisition mode. For systems with a rotating gantry, the data collection is performed at a single gantry angle.

4.2.3.7 Data processing

The maximum leakage COUNT RATES at the rear and the side of the DETECTOR SHIELD, normalized to the source ACTIVITY, are recorded. Also the maximum leakage COUNT RATE at joints in the shield, normalized to the source ACTIVITY, is recorded.

4.2.3.8 Data analysis

The normalized leakage COUNT RATES are divided by the sensitivity of the system as measured in 4.2.5.

4.2.3.9 Report

The three normalized maximum leakage COUNT RATES expressed as a percentage of the sensitivity measured in 4.2.5, and the locations at which they were measured, are reported.

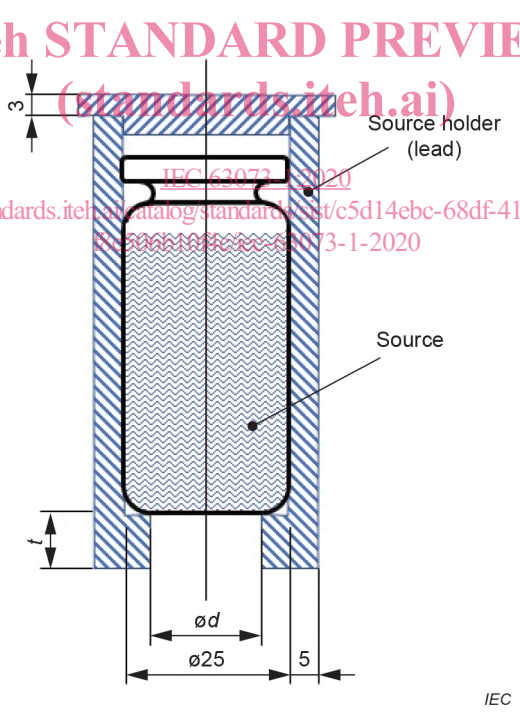

Figure 1 – Small shielded liquid source

NOTE See 4.2.3.5 for recommended values for *d* and *t*.

4.2.4 COUNT RATE performance

4.2.4.1 General

COUNT RATE performance depends in a complex manner on the spatial distribution of ACTIVITY and scattering materials, which therefore should simulate clinical imaging situations. Therefore the tests are conducted with COLLIMATOR and scattering material.

COUNT RATE performance measures the relationship between the registered COUNT RATE and ACTIVITY, i.e. the COUNT RATE CHARACTERISTIC. The COUNT RATE CHARACTERISTIC describes the constancy of the GAMMA CAMERA sensitivity at different ACTIVITY levels and is highly dependent on the set-up of the measurement conditions.

4.2.4.2 Purpose

The procedure described here is designed to evaluate deviations from the linear relationship between COUNT RATE and ACTIVITY, caused by COUNT LOSSES, over a clinically relevant range of COUNT RATES.

4.2.4.3 Method

Measurements of the COUNT RATE are performed at various ACTIVITY levels. The variation of ACTIVITY is normally achieved by RADIOACTIVE decay. No correction is made for COUNT LOSSES and scatter. Each measured count is taken into account only once.

4.2.4.4 RADIONUCLIDE

The RADIONUCLIDE for the measurement is ^{99m}Tc with ENERGY WINDOW of 140 keV ± 10 %.

4.2.4.5 RADIOACTIVE SOURCE distribution

A cylindrical phantom (Figure 2) with a LINE SOURCE insert is used. The phantom is filled with non-radioactive water as a scatter medium. The LINE SOURCE of at least 7 cm in length is inserted and positioned on the central axis of the cylinder. The LINE SOURCE is centred on the REFERENCE POINT of the system and aligned with the patient inferior-superior axis.

Dimensions in millimetres

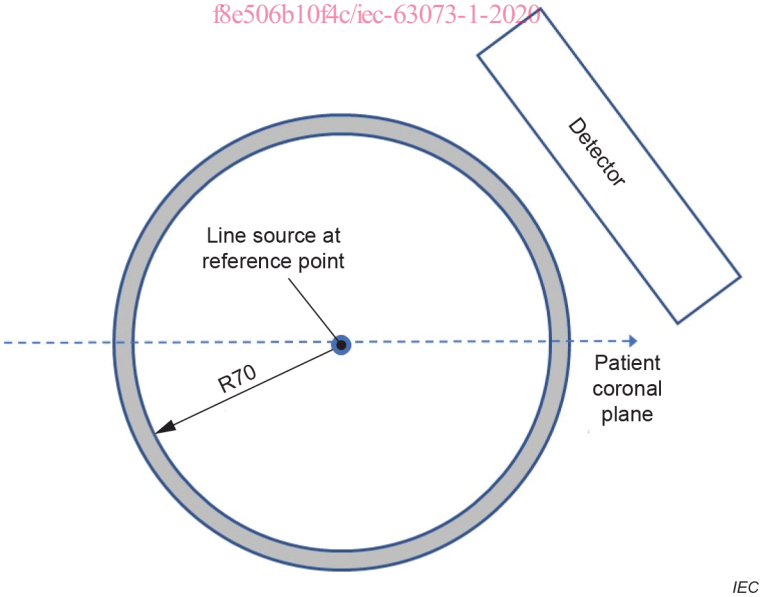

Figure 2 – Transverse slice of phantom used for measuring COUNT RATE performance

4.2.4.6 Data collection

A COUNT RATE CHARACTERISTIC (measured COUNT RATE versus incident COUNT RATE or ACTIVITY) is to be measured by acquiring a series of images over time (e.g. frames). The variation of ACTIVITY is accomplished by RADIOACTIVE decay with measurements continuing over approximately 10 RADIOACTIVE HALF-LIVES. The time per frame is less than one-half of the

RADIOACTIVE HALF-LIFE with the exception of the last three frames, which can be longer. The initial amount of ACTIVITY is chosen to be 2 GBq ± 10 %.

A background acquisition is performed.

4.2.4.7 Data processing

The total counts acquired in each image is processed. Background correction is performed for all frames.

The average of the decaying ACTIVITY, $A_{ave,i}$, during the data acquisition interval for time frame i, $T_{acq,i}$, is determined by the following equation:

$$A_{ave,i} = A_{cal} \frac{1}{\ln 2} \frac{T_{1/2}}{T_{acq,i}} \exp\left[\frac{T_{cal} - T_{0,i}}{T_{1/2}} \ln 2 \right] \left[1 - \exp\left(-\frac{T_{acq,i}}{T_{1/2}} \ln 2 \right) \right] \quad (2)$$

where

A_{cal} is the ACTIVITY Measured at time T_{cal};

$T_{0,i}$ is the acquisition start-time of the time frame i;

$T_{1/2}$ is the RADIOACTIVE HALF-LIFE of the RADIONUCLIDE in use.

From the above measurements, plot the COUNT RATE CHARACTERISTIC (i.e. measured COUNT RATE versus ACTIVITY).

The conversion factor between ACTIVITY and COUNT RATE without COUNT LOSS is determined from each of the three frames with lowest ACTIVITY and averaged. Care is taken to acquire enough counts in these frames to ensure a statistical precision of 1 % or better.

4.2.4.8 Data analysis

The measured COUNT RATE is plotted against the TRUE COUNT RATE.

4.2.4.9 Report

The ACTIVITY is specified as the total amount of ACTIVITY within the phantom.

Report the graph showing the COUNT RATE CHARACTERISTIC. Report the maximum observed COUNT RATE and the ACTIVITY at which it is measured. Report the maximum percent deviation observed from the TRUE COUNT RATE and the ACTIVITY at which it is measured.

4.2.5 System sensitivity

4.2.5.1 General

SYSTEM SENSITIVITY is a parameter that characterizes the effectiveness of a system to identify the radiation emitted from a RADIOACTIVE SOURCE, i.e. the rate at which events are detected in the presence of a RADIOACTIVE SOURCE with low ACTIVITY where COUNT LOSSES are negligible. The measured COUNT RATE for a given ACTIVITY and RADIONUCLIDE depends on many factors, including the detector material, its size and thickness, the size and shape of the RADIOACTIVE SOURCE including its absorption and scatter properties, and instrument's dead time, energy thresholds and COLLIMATOR.

4.2.5.2 Purpose

The purpose of this measurement is to determine the detected rate of events per unit of ACTIVITY for a standard volume source of given dimensions at a specified location and for a specified COLLIMATOR. Variation in sensitivity between detectors in a multi-detector system can introduce artefacts in a reconstructed image and so is also measured.

4.2.5.3 Method

The SYSTEM SENSITIVITY test places a known amount of ACTIVITY of a specified RADIONUCLIDE at a specified REFERENCE POINT for the camera and observes the resulting COUNT RATE. From these values the SYSTEM SENSITIVITY and the sensitivity variation between detectors are calculated. The test is critically dependent upon accurate assays of ACTIVITY as measured in a dose calibrator or well counter as well as the source position.

4.2.5.4 RADIONUCLIDE

The RADIONUCLIDE used for this measurement is ^{99m}Tc and the ENERGY WINDOW is 140 keV ± 10 %.

4.2.5.5 RADIOACTIVE SOURCE distribution

The RADIOACTIVE SOURCE is a 1 ml ± 10 % sphere. The RADIOACTIVE SOURCE is placed at the REFERENCE POINT of the camera.

4.2.5.6 Data collection

Counts are acquired until a minimum of 10 000 counts are recorded in each CARDIAC DETECTOR HEAD. The acquisition duration is recorded. For pixelated detectors, BAD PIXEL corrections are enabled.

4.2.5.7 Data processing

The ACTIVITY in the phantom shall be corrected for decay to determine the average ACTIVITY, A_{ave}, during the data acquisition time interval, T_{acq}, by the following equation

$$A_{ave} = \frac{A_{cal}}{\ln 2}\frac{T_{1/2}}{T_{acq}}\exp\left[\frac{T_{cal}-T_0}{T_{1/2}}\ln 2\right]\left[1-\exp\left(-\frac{T_{acq}}{T_{1/2}}\ln 2\right)\right] \quad (3)$$

where

A_{cal} is the ACTIVITY measured at time T_{cal};

T_0 is the acquisition start time;

$T_{1/2}$ is the RADIOACTIVE HALF-LIFE of the RADIONUCLIDE.

4.2.5.8 Data analysis

The SENSITIVITY S_i for each CARDIAC DETECTOR HEAD i is then found by $S_i = C_i / A_{ave}$, where C_i is the COUNT RATE measured in CARDIAC DETECTOR HEAD i. The SENSITIVITY S_i is expressed in counts · s^{-1}· MBq^{-1}. For each CARDIAC DETECTOR HEAD, the percent deviation from the manufacturer provided expected value, ΔS_i, is calculated. The SYSTEM SENSITIVITY is the sum of S_i over all CARDIAC DETECTOR HEADS.

4.2.5.9 Report

The following values are reported: