

TECHNICAL REPORT

Nuclear medicine instrumentation – Routine tests –
Part 3: Positron emission tomographs

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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

ICS 11.040.50

ISBN 978-2-8322-5230-7

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

**NUCLEAR MEDICINE INSTRUMENTATION –
ROUTINE TESTS –****Part 3: Positron emission tomographs**

FOREWORD

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IEC TR 61948-3, which is a technical report, has been prepared by subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces the first edition published in 2005. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

- a) a clause to check routine performance tests has been added,

- b) a test to check the accuracy of co-registration of PET and CT images has been added,
- c) a test to check image quality has been added,
- d) the test to check pixel size has been removed.

The text of this technical report is based on the following documents:

Enquiry draft	Report on voting
62C/694/DTR	62C/708/RVDTR

Full information on the voting for the approval of this technical report 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.

A list of all parts in the IEC 61948 series, published under the general title *Nuclear medicine Instrumentation – Routine tests*, can be found on the IEC website.

Terms used throughout this document that have been defined in Clause 3 appear in SMALL CAPITALS.

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- withdrawn,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 [IEC TR 61948-3:2018](https://standards.iteh.ai/catalog/standards/sist/dd7f1603-e82a-4465-a05e-970ce40ae1fc/iec-tr-61948-3-2018)
- amended.

A bilingual version of this publication may be issued at a later date.

NUCLEAR MEDICINE INSTRUMENTATION – ROUTINE TESTS –

Part 3: Positron emission tomographs

1 Scope

This part of IEC 61948 describes test methods for POSITRON EMISSION TOMOGRAPHS (PET). As part of QUALITY CONTROL, this document is defining ROUTINE TESTS to be performed by the user of POSITRON EMISSION TOMOGRAPHS to maintain proper operation conditions. The results of these ROUTINE TESTS are compared to the REFERENCE DATA determined during or after ACCEPTANCE TEST. Methods used for ACCEPTANCE TESTS are described in IEC 61675-1:2013.

In addition, today a POSITRON EMISSION TOMOGRAPH often includes X-RAY EQUIPMENT for COMPUTED TOMOGRAPHY (CT). For this document, PET/CT hybrid devices are considered to be state of the art, dedicated POSITRON EMISSION TOMOGRAPHS not including the X-ray component being special cases only.

QUALITY CONTROL tests specific to only the CT component of the PET/CT are described in IEC 61223-2-6. The CT SCANNER also is subject to a TYPE TEST according to IEC 60601-1 and applicable collateral and particular standards.

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 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

IEC 61223-2-6:2006, *Evaluation and routine testing in medical imaging departments – Part 2-6: Constancy tests – Imaging performance of computed tomography X-ray equipment*

IEC 61675-1:2013, *Radionuclide imaging devices – Characteristics and test conditions – Part 1: Positron emission tomographs*

IEC TR 61948-1:2016, *Nuclear medicine instrumentation – Routine tests – Part 1: Gamma radiation counting systems*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 61675-1, IEC TR 61948-1 and the following 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 acceptance test

test carried out after new equipment has been installed, or major modifications have been made to existing equipment, in order to verify compliance with contractual specifications

Note 1 to entry: During or immediately after ACCEPTANCE TEST, REFERENCE DATA are collected to be used as a standard for comparison with future ROUTINE TESTS.

[SOURCE: IEC TR 60788:2004, rm-70-01, modified – Addition of a Note to entry.]

3.2 annihilation radiation

ionizing radiation that is produced when a particle and its antiparticle interact and cease to exist

[SOURCE: IEC 61675-1:2013, 3.1.3.2]

3.3 calibration factor

relation between measured COUNT RATE per reconstructed unit volume and the true ACTIVITY concentration in the object

Note 1 to entry: Although the CALIBRATION FACTOR depends on the acquisition configuration affecting the sensitivity of the system (e.g. 2D, 3D), it is independent of the actual acquisition parameters (e.g. acquisition time, ACTIVITY injected, etc.).

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3.4 count loss

difference between measured COUNT RATE and true COUNT RATE, which is caused by the finite RESOLVING TIME of the instrument

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[SOURCE: IEC 61675-1:2013, 3.8.1]

3.5 count rate

number of counts per unit of time

[SOURCE: IEC 61675-1:2013, 3.8.2]

3.6 line of response LOR

axis of the PROJECTION BEAM

Note 1 to entry: In PET, it is the line connecting the centres of two opposing detector elements operated in coincidence.

[SOURCE: IEC 61675-1:2013, 3.1.3.5]

3.7 line source

straight radioactive source approximating a δ -function in two dimensions and being constant (uniform) in the third dimension

[SOURCE: IEC 61675-1:2013, 3.11]

3.8 normalization

system set-up and corrections to maintain the performance of the system

3.9**positron emission tomograph**

PET

tomographic device which detects the ANNIHILATION RADIATION of positron emitting RADIONUCLIDES by COINCIDENCE DETECTION

[SOURCE: IEC 61675-1:2013, 3.1.3.1]

3.10**projection beam**

beam that determines the smallest possible volume in which the physical property which determines the image is integrated during the measurement process

Note 1 to entry: Its shape is limited by SPATIAL RESOLUTION in all three dimensions

Note 2 to entry: The PROJECTION BEAM mostly has the shape of a long thin cylinder or cone. In positron emission tomography, it is the sensitive volume between two detector elements operated in coincidence.

[SOURCE: IEC 61675-1:2013, 3.1.2.2]

3.11**quality control**

<nuclear medicine> part of the quality assurance including tests of instruments with appropriate test methods

Note 1 to entry: Includes both ACCEPTANCE TEST and ROUTINE TEST.

[SOURCE: IEC TR 61948-1:2016, 3.5]

3.12**random coincidence**

result of a COINCIDENCE DETECTION in which both participating photons emerge from different positron annihilations

[SOURCE: IEC 61675-1:2013, 3.1.3.6.4, modified – Replacement of "do not originate from the same positron annihilation" by "emerge from different positron annihilations".]

3.13**reference data**

set of data measured immediately after ACCEPTANCE TEST, using test methods designed for ROUTINE TEST

[SOURCE: IEC TR 61948-1:2016, 3.7]

3.14**relative sensitivity per line of response**

ratio of the COUNT RATE of TRUE COINCIDENCES, measured for a specific PROJECTION BEAM and assigned to the corresponding LINE OF RESPONSE, to the mean COUNT RATE of TRUE COINCIDENCES of all lines of response

3.15**routine test**

test of a piece of equipment or its components, which is repeated at specified intervals, to establish and document changes from the initial status described by REFERENCE DATA

Note 1 to entry: A ROUTINE TEST could be carried out by the user with simple test methods and equipment.

[SOURCE: IEC TR 61948-1:2016, 3.8]