PD IEC/TR 61948-3:2018

BSI Standards Publication

Nuclear medicine instrumentation - Routine tests

Part 3: Positron emission tomographs

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National foreword

This Published Document is the UK implementation of IEC TR 61948-3:2018. It supersedes PD IEC/TR 61948-3:2005, which is withdrawn.

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 secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Published by BSI Standards Limited 2018

ISBN 978 0 580 99184 4

ICS 11.040.50

Compliance with a British Standard cannot confer immunity from legal obligations.

This Published Document was published under the authority of the Standards Policy and Strategy Committee on 28 February 2018.

Amendments/corrigenda issued since publication

Date	Text affected

IEC TR 61948-3

Edition 2.0 2018-01

TECHNICAL REPORT

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

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

ICS 11.040.50

ISBN 978-2-8322-5230-7

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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
- 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 61948-3:2016, *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