EESTI STANDARD EVS-EN 61675-3:2002

Radionuclide imaging devices- characteristics and test conditions - Part 3: Gamma camera based wholebody imaging systems

EESTI STANDARDIKESKUS

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 61675-3:2002 sisaldab Euroopa standardi EN 61675-3:1998 ingliskeelset teksti.	This Estonian standard EVS-EN 61675-3:2002 consists of the English text of the European standard EN 61675-3:1998.
Käesolev dokument on jõustatud 18.12.2002 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.	This document is endorsed on 18.12.2002 with the notification being published in the official publication of the Estonian national standardisation organisation.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

ICS 11.040.50

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 61675-3

April 1998

ICS 11.040.50

English version

Radionuclide imaging devices
Characteristics and test conditions
Part 3: Gamma camera based wholebody imaging systems
(IEC 61675-3:1998)

Dispositifs d'imagerie par radionucléides
Caractéristiques et conditions d'essais
Partie 3: Systèmes d'imagerie du corps entier à gamma-caméra
(CEI 61675-3:1998)

Bildgebende Systeme in der Nuklearmedizin
Merkmale und Prüfbedingungen
Teil 3: Systeme mit Ganzkörperzusatz basierend auf einer Gammakamera
(IEC 61675-3:1998)

This European Standard was approved by CENELEC on 1998-04-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

Ref. No. EN 61675-3:1998 E

Foreword

The text of document 62C/211/FDIS, future edition 1 of IEC 61675-3, 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 was approved by CENELEC as EN 61675-3 on 1998-04-01.

The following dates were fixed:

- latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 1999-01-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2001-01-01

Annexes designated "normative" are part of the body of the standard.
Annexes designated "informative" are given for information only.
In this standard, annex ZA is normative and annex A is informative.
Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 61675-3:1998 was approved by CENELEC as a European Standard without any modification.

Annex ZA (normative)

Normative references to international publications with their corresponding European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

NOTE: When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Publication	Year	Title	EN/HD	Year
IEC 60788	1984	Medical radiology Terminology	HD 501 S1	1988
IEC 60789	1992	Characteristics and test conditions of radionuclide imaging devices Anger type gamma cameras	EN 60789	1993
IEC 61675-2	1998	Radionuclide imaging devices Characteristics and test conditions Part 2: Single photon emission computer tomographs	EN 61675-2	1998

INTERNATIONAL STANDARD

IEC 61675-3

First edition
1998-02

Radionuclide imaging devices – Characteristics and test conditions –

Part 3: Gamma camera based wholebody imaging systems

Dispositifs d'imagerie par radionucléides – Caractéristiques et conditions d'essais –

Partie 3: Systèmes d'imagerie du corps entier à gamma-caméra

Reference number
IEC 61675-3:1998(E)

Numbering

As from 1 January 1997 all IEC publications are issued with a designation in the 60000 series.

Consolidated publications

Consolidated versions of some IEC publications including amendments are available. For example, edition numbers 1.0, 1.1 and 1.2 refer, respectively, to the base publication, the base publication incorporating amendment 1 and the base publication incorporating amendments 1 and 2.

Validity of this publication

The technical content of IEC publications is kept under constant review by the IEC, thus ensuring that the content reflects current technology.

Information relating to the date of the reconfirmation of the publication is available in the IEC catalogue.

Information on the revision work, the issue of revised editions and amendments may be obtained from IEC National Committees and from the following IEC sources:

- **IEC Bulletin**
- **IEC Yearbook**
  On-line access*
- **Catalogue of IEC publications**
  Published yearly with regular updates
  (On-line access)*

Terminology, graphical and letter symbols

For general terminology, readers are referred to IEC 60050: *International Electrotechnical Vocabulary* (IEV).

For graphical symbols, and letter symbols and signs approved by the IEC for general use, readers are referred to publications IEC 60027: *Letter symbols to be used in electrical technology*, IEC 60417: *Graphical symbols for use on equipment. Index, survey and compilation of the single sheets* and IEC 60617: *Graphical symbols for diagrams.*

IEC publications prepared by the same technical committee

The attention of readers is drawn to the end pages of this publication which list the IEC publications issued by the technical committee which has prepared the present publication.

* See web site address on title page.

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Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

PRICE CODE H

For price, see current catalogue

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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RADIONUCLIDE IMAGING DEVICES – CHARACTERISTICS AND TEST CONDITIONS –

Part 3: Gamma camera based wholebody imaging systems

FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the 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, the IEC publishes International Standards. 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. The 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 the 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 National Committees.
3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical reports or guides and they are accepted by the National Committees in that sense.
4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.
5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.
6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 61675-3 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 standard is based on the following documents:

FDIS	Report on voting
62C/211/FDIS	62C/221/RVD

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table.

In this standard the following print types are used:

– requirements, compliance with which can be tested, and definitions: in roman type;
– explanation, advice, introductions, general statements, exceptions and reference: in smaller roman type;
– *test specifications: in italic type;*
– TERMS USED THROUGHOUT THIS STANDARD WHICH HAVE BEEN DEFINED IN CLAUSE 2 OF THIS STANDARD OR LISTED IN ANNEX A; SMALL CAPITALS.

The requirements are followed by specifications for the relevant tests.

Annex A is for information only.

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

RADIONUCLIDE IMAGING DEVICES – CHARACTERISTICS AND TEST CONDITIONS –

Part 3: Gamma camera based wholebody imaging systems

1 General

1.1 Scope and object

The object of this part of IEC 61675 is to specify test methods for describing the characteristics of GAMMA CAMERA BASED WHOLEBODY IMAGING SYSTEMS. As these systems are based on Anger type GAMMA CAMERAS this part of IEC 61675 should be read in conjuction with IEC 60789.

Two additional tests, scanning speed constancy, and system SPATIAL RESOLUTION without scatter, shall be performed. Measurement of system uniformity for wholebody imaging systems is possible but difficult to perform because of the requirement for large and uniform sources. Most of the potential problems that could affect uniformity will also affect the system resolution, and therefore such a uniformity test is not included in this standard.

The test methods specified in this part of IEC 61675 have been selected to reflect as much as possible the clinical use of GAMMA CAMERA BASED WHOLEBODY IMAGING SYSTEMS. It is intended that the test methods be carried out by manufacturers, thereby enabling them to describe the characteristics of GAMMA CAMERA BASED WHOLEBODY IMAGING SYSTEMS.

1.2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of IEC 61675. At the time of publication, the editions indicated were valid. All normative documents are subject to revision, and parties to agreements based on this part of IEC 61675 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

IEC 60788:1984, *Medical radiology – Terminology*

IEC 60789:1992, *Characteristics and test conditions of radionuclide imaging devices – Anger type gamma cameras*

IEC 61675-2: *Radionuclide imaging devices – Characteristics and test conditions – Part 2: Single photon emission computed tomographs*

2 Terminology and definitions

For the purposes of this part of IEC 61675, the definitions given in IEC 60789 and IEC 60788, and IEC 61675-2 (see annex A), and the following definition apply.

2.1
GAMMA CAMERA BASED WHOLEBODY IMAGING SYSTEM
equipment for scintigraphy, employing one or two DETECTOR HEAD(s), in which the image is formed by moving the DETECTOR HEAD(s) and the object relative to each other and relating output information of the RADIOLOGICAL IMAGE