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INTERNATIONAL STANDARD

NORME INTERNATIONALE

Radionuclide imaging devices – Characteristics and test conditions –
Part 3: Gamma camera based wholebody imaging systems

Dispositifs d'imagerie par radionucléides – Caractéristiques et conditions d'essai –
Partie 3: Systèmes d'imagerie du corps entier à gamma-caméra

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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.
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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.

This bilingual version (2012-11) corresponds to the monolingual English version, published in 1998-02.

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.

The French version of this standard has not been voted upon.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.

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

3 Test methods

All measurements shall be performed with PULSE AMPLITUDE ANALYSER WINDOW as specified in table 1 of IEC 60789. Additional measurements with other settings as specified by the manufacturer can be performed.

Before the measurements are performed, the 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.

Measurements of performance parameters in the planar mode of operation are a prerequisite. A complete set of performance parameters shall be measured as specified in IEC 60789.

Unless otherwise specified, measurements shall be carried out at COUNT RATES not exceeding 20 000 counts per second.

3.1 Scanning constancy

Scanning constancy shall be measured using a POINT SOURCE attached to the DETECTOR HEAD and expressed as COUNT RATE deviation along the full scanning length.

3.1.1 RADIONUCLIDE

The RADIONUCLIDE to be employed for this measurement shall be ^{99m}Tc or ^{57}Co.

3.1.2 Source

The source shall be a POINT SOURCE attached to the COLLIMATOR at the centre of the field of view. The ACTIVITY of the source shall be adjusted to yield a COUNT RATE between 10 000 and 20 000 counts per second, through a 20 % analyzer window, in the DETECTOR FIELD OF VIEW.

3.1.3 Data acquisition and analysis

The scan speed and the acquisition matrix shall be in the range recommended for clinical use. Two scans shall be performed along the full scanning length using different speeds. The image of the POINT SOURCE shall be recorded.

A profile through the image of the POINT SOURCE in the direction of the motion should yield a constant count value. This profile shall have a width between 20 mm and 30 mm in the direction perpendicular to the direction of motion, and shall contain at least 10 000 counts per pixel. The analysis shall exclude the areas at the ends of the profile which are affected by the spatial resolution in the scanning direction.

3.1.4 Report

For the region of analysis, report a graph of the percent deviation from the mean count value. In addition report the value of the maximum percent deviation from the mean. Any deviation greater than expected from Poisson statistics standard deviations is indicative of non-uniform scanning motion and shall be stated. The COLLIMATOR and the scan speeds used in performing the measurements shall be also reported.

3.2 SPATIAL RESOLUTION without scatter

SPATIAL RESOLUTION without scatter shall be measured parallel and perpendicular to the direction of motion, and expressed as FULL WIDTH AT HALF MAXIMUM (FWHM) of the LINE SPREAD FUNCTION.

3.2.1 RADIONUCLIDE

The RADIONUCLIDE to be employed for this measurement shall be ^{99m}Tc or ^{57}Co.

3.2.2 Source

The sources shall consist of two capillary tubes, each having an inside diameter of less than or equal to 1 mm and a length equal to the width of the scanned field of view perpendicular to the direction of motion.

NOTE If a line source of the length specified above is difficult to manufacture or to handle, either a shorter line can be used and scanned in the required number of positions to cover the specified length, or a number of shorter lines spanning the field of view can be scanned simultaneously.

The activity of both sources shall be approximately equal and shall be adjusted to yield a COUNT RATE between 10 000 and 20 000 counts per second, through a 20 % analyzer window, with both capillary tubes in the detector field of view.

3.2.3 Location of sources

The sources shall be placed on the wholebody scanning table. For the measurement of resolution parallel to the direction of motion, one capillary tube shall be placed at the centre of the scanned field of view, perpendicular to the direction of motion to within 1 mm; the second source shall be placed parallel to the first one, at a distance of 100 mm as shown in figure 1.

For the measurement of resolution perpendicular to the direction of motion, one capillary tube shall be placed at the centre of the scanned field of view, parallel to the direction of motion to within 1 mm; the second source shall be placed parallel to the first one, at a distance of 100 mm as shown in figure 2.

3.2.4 Data acquisition

The scan speed shall be in the range recommended for clinical use. Scans shall be performed both above and below the table for the two source positions described in 3.2.3. The camera shall be positioned at a distance of 100 mm from the sources to the face of the COLLIMATOR.

The sampling, perpendicular to the tubes, shall be no coarser than 25 % of the FWHM of the SPATIAL RESOLUTION with the COLLIMATOR being used. The measured quantity, i.e. number of counts, shall be integrated in the direction parallel to the sources within sets of areas with lengths not more than 30 mm. The areas shall abut each other.

3.2.5 Calculation of FWHM

The FWHM shall be calculated in each segment (length of integrated area as specified in 3.2.4) of the central capillary tube, using a gaussian fit method. The values of the FWHM shall be averaged separately for the tubes parallel and perpendicular to the direction of motion, for the measurement above and below the table. The values shall be stated in millimetres.

3.2.6 Report

The FWHM values shall be reported separately for the measurements above and below the table and in the directions parallel and perpendicular to the direction of motion. The COLLIMATOR and scan speed used in performing the measurements shall be reported.

4 ACCOMPANYING DOCUMENTS

A document shall accompany each GAMMA CAMERA BASED WHOLEBODY IMAGING SYSTEM and shall include the following information.

4.1 All items described in clause 4 of IEC 60789.
4.2 Scanning constancy as specified in 3.1 of this standard.
4.3 SPATIAL RESOLUTION as specified in 3.2 of this standard.

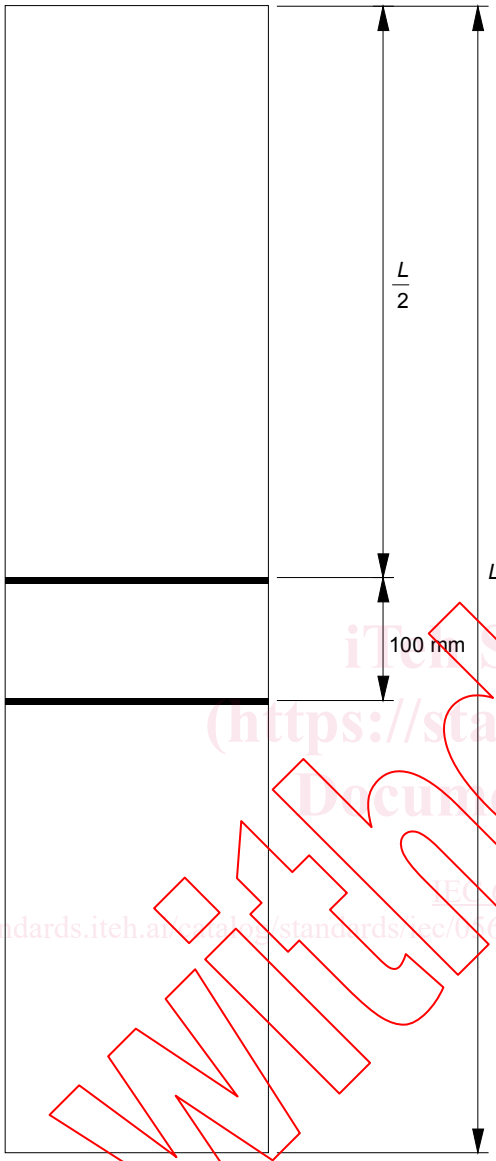

Figure 1 – Source position for resolution measurement parallel to the direction of motion

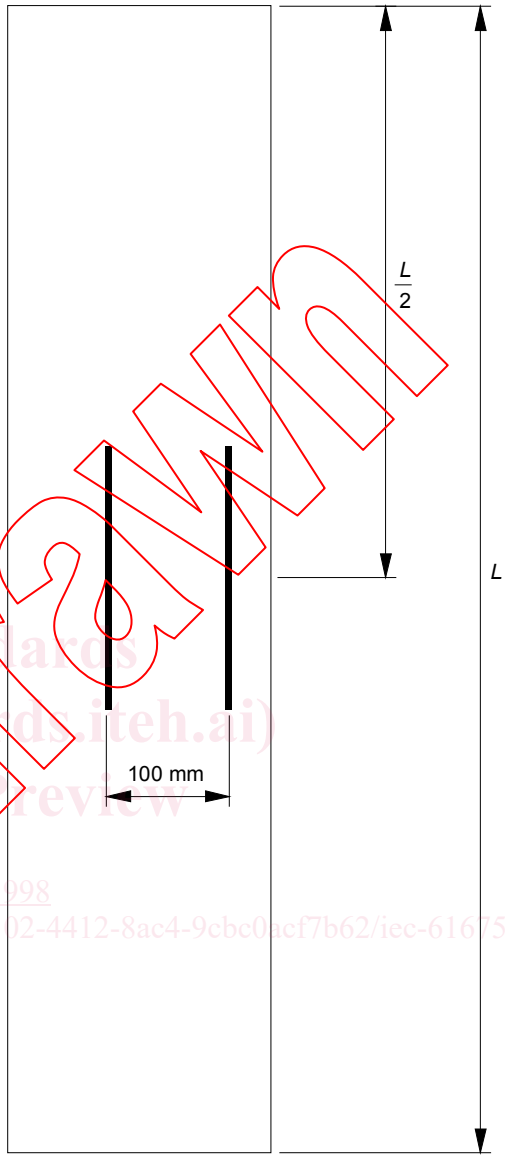

Figure 2 – Source position for resolution measurement perpendicular to the direction of motion