IEC 61675-2

Edition 1.0 1998-01

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

Dispositifs d'imagerie par radionucléides – Caractéristiques et conditions d'essai –
Partie 2: Systèmes de tomographie d'émission à photon unique

IEC 61675-2:1998-01(en-fr)

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INTERNATIONAL
ELECTROTECHNICAL
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COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

PRICE CODE
CODE PRIX
T

ICS 11.040.50

ISBN 978-2-8322-1974-4

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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.
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.
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International Standard IEC 61675-2 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 (2014-12) corresponds to the English version, published in 1998-01.

The text of this standard is based on the following documents:

FDIS	Report on voting
62C/206/FDIS	62C/215/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:

– TERMS 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 2: Single photon emission computed tomographs

1 General

1.1 Scope and object

This part of IEC 61675 specifies terminology and test methods for describing the characteristics of Anger type rotational GAMMA CAMERA SINGLE PHOTON EMISSION COMPUTED TOMOGRAPHS (SPECT), equipped with parallel hole collimators. As these systems are based on Anger type GAMMA CAMERAS this part of IEC 61675 shall be used in conjunction with IEC 60789. These systems consist of a gantry system, single or multiple DETECTOR HEADS and a computer system together with acquisition, recording, and display devices.

The test methods specified in this part of IEC 61675 have been selected to reflect as much as possible the clinical use of Anger type rotational GAMMA CAMERA SINGLE PHOTON EMISSION COMPUTED TOMOGRAPHS (SPECT). It is intended that the test methods be carried out by manufacturers thereby enabling them to describe the characteristics of SPECT systems on a common basis.

No test has been specified to characterize the uniformity of reconstructed images because all methods known so far will mostly reflect the noise of the image.

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

2 Terminology and definitions

For the purpose of this part of IEC 61675 the definitions given in IEC 60788, IEC 60789 and IEC 61675-1 (see annex A), and the following definitions apply.

Defined terms are printed in small capital letters.

2.1
SYSTEM AXIS

Axis of symmetry characterized by geometrical and physical properties of the arrangement of the system

NOTE – The SYSTEM AXIS of a GAMMA CAMERA with rotating detectors is the axis of rotation.

2.1.1
COORDINATE SYSTEMS

2.1.2
FIXED COORDINATE SYSTEM

Cartesian system with axes X, Y, and Z, Z being the SYSTEM AXIS. The origin of the FIXED COORDINATE SYSTEM is defined by the centre of the TOMOGRAPHIC VOLUME (see figure 1). The SYSTEM AXIS is orthogonal to all TRANSVERSE SLICES.

2.1.3
COORDINATE SYSTEM OF PROJECTION

Cartesian system of the IMAGE MATRIX of each two-dimensional projection with axes X_p and Y_p (defined by the axes of the IMAGE MATRIX). The Y_p axis and the projection of the system axis onto the detector front face have to be in parallel. The origin of the COORDINATE SYSTEM OF PROJECTION is the centre of the IMAGE MATRIX (see figure 1).

2.1.4
CENTRE OF ROTATION (COR)

Origin of that COORDINATE SYSTEM, which describes the PROJECTIONS of a TRANSVERSE SLICE with respect to their orientation in space

NOTE – The CENTRE OF ROTATION of a TRANSVERSE SLICE is given by the intersection of the SYSTEM AXIS with the mid-plane of the corresponding OBJECT SLICE.

2.1.5
OFFSET

Deviation of the position of the PROJECTION of the COR (X'_p) from $X_p = 0$. (See figure 1)

2.2
TOMOGRAPHY (see annex A)

2.2.1
TRANSVERSE TOMOGRAPHY

In TRANSVERSE TOMOGRAPHY the three-dimensional object is sliced by physical methods, e.g. collimation, into a stack of OBJECT SLICES, which are considered as being two-dimensional and independent from each other. The transverse image planes are perpendicular to the SYSTEM AXIS.

2.2.2
EMISSION COMPUTED TOMOGRAPHY (ECT)

Imaging method for the representation of the spatial distribution of incorporated RADIONUCLIDES in selected two-dimensional SLICES through the object

2.2.2.1
PROJECTION

Transformation of a three-dimensional object into its two-dimensional image or of a two-dimensional object into its one-dimensional image, by integrating the physical property which determines the image along the direction of the PROJECTION BEAM

NOTE – This process is mathematically described by line integrals in the direction of projection and called the Radon-transform.

2.2.2.2

PROJECTION BEAM

Determines the smallest possible volume in which the physical property which determines the image is integrated during the measurement process. Its shape is limited by the SPATIAL RESOLUTION in all three dimensions.

NOTE – In SPECT the PROJECTION BEAM usually has the shape of a long thin diverging cone.

2.2.2.3

PROJECTION ANGLE

Angle at which the PROJECTION is measured or acquired

NOTE – For illustration see figure 1.

2.2.2.4

SINOGRAM

Two-dimensional display of all one-dimensional PROJECTIONS of an object slice, as a function of the PROJECTION ANGLE

The PROJECTION ANGLE is displayed on the ordinate. The linear PROJECTION coordinate is displayed on the abscissa.

2.2.2.5

OBJECT SLICE

A slice in the object. The physical property of this slice that determines the measured information is displayed in the tomographic image.

2.2.2.6

IMAGE PLANE

A plane assigned to a plane in the OBJECT SLICE

NOTE – Usually the IMAGE PLANE is the mid-plane of the corresponding OBJECT SLICE.

2.2.2.7

TOMOGRAPHIC VOLUME

Ensemble of all volume elements which contribute to the measured PROJECTIONS for all PROJECTION ANGLES

NOTE – For a rotating GAMMA CAMERA with a circular field of view the TOMOGRAPHIC VOLUME is a sphere provided that the radius of rotation is larger than the radius of the field of view. For a rectangular field of view, the TOMOGRAPHIC VOLUME is a cylinder.

2.2.2.7.1

TRANSVERSE FIELD OF VIEW

Dimensions of a slice through the TOMOGRAPHIC VOLUME, perpendicular to the SYSTEM AXIS. For a circular TRANSVERSE FIELD OF VIEW it is described by its diameter.

NOTE – For non-cylindrical TOMOGRAPHIC VOLUMES the TRANSVERSE FIELD OF VIEW may depend on the axial position of the slice.

2.2.2.7.2

AXIAL FIELD OF VIEW

Dimensions of a slice through the TOMOGRAPHIC VOLUME parallel to and including the SYSTEM AXIS. In practice it is specified only by its axial dimension given by the distance between the centres of the outermost defined IMAGE PLANES plus the average of the measured AXIAL SLICE WIDTH measured as EQUIVALENT WIDTH (EW).

2.2.2.7.3

TOTAL FIELD OF VIEW

Dimensions (three-dimensional) of the TOMOGRAPHIC VOLUME

2.3
IMAGE MATRIX

Arrangement of MATRIX ELEMENTS in a preferentially cartesian coordinate system

2.3.1
MATRIX ELEMENT

Smallest unit of an IMAGE MATRIX, which is assigned in location and size to a certain volume element of the object (VOXEL)

2.3.1.1
PIXEL

MATRIX ELEMENT in a two-dimensional IMAGE MATRIX

2.3.1.2
TRIXEL

MATRIX ELEMENT in a three-dimensional IMAGE MATRIX

2.3.2
VOXEL

Volume element in the object which is assigned to a MATRIX ELEMENT in the IMAGE MATRIX (two-dimensional or three-dimensional). The dimensions of the VOXEL are determined by the dimensions of the corresponding MATRIX ELEMENT via the appropriate scale factors and by the system's SPATIAL RESOLUTION in all three dimensions.

2.4
POINT SPREAD FUNCTION (PSF)

Scintigraphic image of a POINT SOURCE

2.4.1
PHYSICAL POINT SPREAD FUNCTION

For tomographs, a two-dimensional POINT SPREAD FUNCTION in planes perpendicular to the PROJECTION BEAM at specified distances from the detector

NOTE – The PHYSICAL POINT SPREAD FUNCTION characterizes the purely physical imaging performance of the tomographic device independent from, e.g. sampling, image reconstruction and image processing, but dependent on the COLLIMATOR. A PROJECTION BEAM is characterized by the entirety of all PHYSICAL POINT SPREAD FUNCTIONS as a function of distance along its axis.

2.4.2
AXIAL POINT SPREAD FUNCTION

Profile passing through the peak of the PHYSICAL POINT SPREAD FUNCTION in a plane parallel to the SYSTEM AXIS

2.4.3
TRANSVERSE POINT SPREAD FUNCTION

Reconstructed two-dimensional POINT SPREAD FUNCTION in a tomographic IMAGE PLANE

NOTE – In TOMOGRAPHY, the TRANSVERSE POINT SPREAD FUNCTION can also be obtained from a line source located parallel to the SYSTEM AXIS.

2.5
SPATIAL RESOLUTION

Ability to concentrate the count density distribution in the image of a POINT SOURCE to a point

2.5.1
TRANSVERSE RESOLUTION

SPATIAL RESOLUTION in a reconstructed plane perpendicular to the SYSTEM AXIS

2.5.1.1
RADIAL RESOLUTION

TRANSVERSE RESOLUTION along a line passing through the position of the source and the SYSTEM AXIS

2.5.1.2
TANGENTIAL RESOLUTION

TRANSVERSE RESOLUTION in the direction orthogonal to the direction of RADIAL RESOLUTION

2.5.2
AXIAL RESOLUTION

For tomographs with sufficiently fine axial sampling fulfilling the sampling theorem, SPATIAL RESOLUTION along a line parallel to the SYSTEM AXIS

2.5.3
EQUIVALENT WIDTH (EW)

Width of that rectangle having the same area and the same height as the response function, e.g. the POINT SPREAD FUNCTION

2.6 Tomographic sensitivity

2.6.1
SLICE SENSITIVITY

Ratio of COUNT RATE as measured on the SINOGRAM to the ACTIVITY concentration in the phantom

NOTE – In SPECT the measured counts are not numerically corrected for scatter by subtracting the SCATTER FRACTION.

2.6.2
VOLUME SENSITIVITY

Sum of the individual SLICE SENSITIVITIES

2.6.3
NORMALIZED VOLUME SENSITIVITY

VOLUME SENSITIVITY divided by the AXIAL FIELD OF VIEW of the tomograph or the phantom length, whichever is the smaller

2.7
SCATTER FRACTION (SF)

Ratio between the number of scattered photons and the sum of scattered plus unscattered photons for a given experimental set-up

2.8
SINGLE PHOTON EMISSION COMPUTED TOMOGRAPHY (SPECT)

EMISSION COMPUTED TOMOGRAPHY utilizing single photon detection of gamma-ray emitting RADIONUCLIDES

2.8.1
DETECTOR POSITIONING TIME

Fraction of the total time spent on an acquisition which is not used in collecting data

2.8.2
DETECTOR HEAD TILT

Deviation of the COLLIMATOR axis from orthogonality with the SYSTEM AXIS

2.8.3
RADIUS OF ROTATION

Distance between the SYSTEM AXIS and the COLLIMATOR front face

2.9
RADIOACTIVE SOURCE

See rm-20-02 of IEC 60788

2.9.1
POINT SOURCE

RADIOACTIVE SOURCE approximating a δ-function in all three dimensions

2.9.2
LINE SOURCE

Straight RADIOACTIVE SOURCE approximating a δ-function in two dimensions and being constant (uniform) in the third dimension

3 Test methods

All measurements shall be performed with the PULSE AMPLITUDE ANALYZER 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 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 DETECTOR HEAD in the system shall be characterized by a full data set covering an angular range of 360°. For multiheaded systems, characterization shall also be provided for an acquisition covering the minimal rotation required to obtain a complete set of data (e.g. 120° for a three-headed system). If the tomograph is specified to operate in a non-circular orbiting mode influencing the performance parameters, test results shall be reported in addition.

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

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.

3.1 Calibration measurements

3.1.1 Measurement of the CENTRE OF ROTATION (COR)

An error-free reconstruction requires the knowledge of the position of the PROJECTION of the COR into the coordinate system X_p, Y_p for each PROJECTION (i.e. for each PROJECTION angle) of that slice. For a circular rotation of the DETECTOR and for an ideal system, the PROJECTION of a POINT SOURCE at the COR will be at the same position X'_p in the projection matrix for all angles of PROJECTION (see figure 1).

To determine the CENTRE OF ROTATION, the OFFSET X'_p has to be measured. POINT SOURCE(S) are used. A minimum of 32 projections equally spaced over 360° are acquired and displayed as a SINOGRAM. The RADIUS OF ROTATION shall be set to 20 cm. The source(s) shall be positioned radially at least 5 cm from the system axis to get SINOGRAMS with a discernible shape of a sine function. The OFFSET shall be determined for a minimum of three slices with axial positions, (Z direction), one at the centre of the FIELD OF VIEW and the other two, ±1/3 of the AXIAL FIELD OF VIEW from the centre.

At least 10 000 counts per view shall be acquired. The length of PIXEL side shall be less than 4 mm. For the calculation of the centroid (centre of gravity) $X_p(\theta)$ of the source in the X_p direction, 50 mm wide strips in the Y direction centred around the Y_p position of each source shall be used. This shall be done for each projection angle θ. Then the OFFSET is determined by fitting a sine function to the $X_p(\theta)$ values of each source, where

$$X_p(\theta) = A \sin(\theta + \varphi) + X'$$

where

θ is the angle of projection;

A is the amplitude;

φ is the phase shift of the sine function;

X' is the average OFFSET to be reported for the three different axial positions.

NOTE – If there is a DETECTOR HEAD TILT the position of the image of the POINT SOURCE will move not only in the x_p direction, but also in the Y_p direction. To determine the X_p movement not influenced by the Y_p movement (for a reasonable amount of head tilt), the centroid is calculated using the 50 mm wide strip. The subscript p refers to the projection space (see figure 1).

NOTE – If a system uses an automatic OFFSET correction which cannot be switched off, then X' shall be zero.

In addition, the difference between fit and data shall be plotted (showing the error) as a function of θ. The maximum difference for each axial position shall be reported. The values are valid only for the COLLIMATOR used and shall be stated in millimetres.

NOTE – Systematic deviations (trends) are indicative of varying OFFSET during rotation of the detector.

3.1.2 DETECTOR HEAD TILT

An error-free reconstruction requires that the direction of the COLLIMATOR holes is orthogonal to the SYSTEM AXIS for each angle of projection. Deviations from this requirement are called DETECTOR HEAD TILT.

Using the measurements according to 3.1.1 the DETECTOR HEAD TILT can be determined by calculating the centroid $Y_p(\theta)$ of the image of the POINT SOURCE in the Y_p direction, using strips over the full field-of-view in the X_p direction. This calculation shall be done for each angle of projection. A sine function is fitted to all those values,

$$Y_p(\theta)= B \sin(\theta + \varphi) + D$$

where

θ is the angle of projection;

B is the amplitude;

φ is the phase shift of the sine function.

Report the head tilt angle value a = arcsin B/A, where A is the amplitude resulting from the COR measurement (3.1.1).

NOTE – If there is no DETECTOR HEAD TILT, B must be zero and D must be the Y_p position of the source.

In addition the difference between fit and data shall be plotted (showing the error) as a function of θ.

3.2 Measurement of COLLIMATOR hole misalignment

If all holes of a parallel hole COLLIMATOR are parallel, the OFFSET is constant for all source positions within the measuring volume, assuming linearity of the positioning electronics. To detect possible misalignments of the collimator holes, the OFFSET shall be determined using a point source placed at all intersections of an orthogonal positioning grid, lying in the *X*, *Z* plane, covering the field of view. The grid lines shall be 10 cm apart. The radius of rotation shall be at least 20 cm. The mean value of all measured OFFSETS shall be calculated and the maximum deviation from that value stated.

3.3 Measurement of SPECT system SENSITIVITY

3.3.1 DETECTOR POSITIONING TIME

In combination with the acquisition time chosen, the DETECTOR POSITIONING TIME determines that fraction of the total time spent on an acquisition which is not useful in collecting data. Therefore it will influence the sensitivity of a tomographic device. This is especially true for a rotating detector working in "step and shoot" mode.

A POINT SOURCE of ^{99m}Tc shall be placed at the CENTRE OF ROTATION in air. The COUNT RATE shall be greater than 1 000 cps. Two 360° tomographic acquisitions of a stated number, P_j, PROJECTIONS (one with at least 60, the other with at least 120 PROJECTIONS) shall be performed using an acquisition time ΔT_{acq} per PROJECTION of 10 s. The subscript *j* is either "low" or "high" corresponding to the range of approximately 60 or 120 projections. The time T_j from the start of acquisition of the first projection to the end of the acquisition of the last projection shall be measured. A corresponding static acquisition of duration T_j shall also be performed directly after the tomographic acquisition. The data shall be decay corrected for the different starting times.

The total DETECTOR POSITIONING TIME T_{pos} shall be calculated according to:

$$T_{\text{pos},j} = \frac{\left(N_{\text{static},j} - N_{\text{total},j}\right)T_j}{N_{\text{static},j}}$$

where

N_{total} is the sum of the counts in all PROJECTIONS;

N_{static} is the number of counts in the static acquisition.

The mean positioning time per PROJECTION ΔT_{pos} is then calculated by dividing T_{pos} by the number of transitions between PROJECTION steps actually used.

$$\Delta T_{\text{pos},j} = \frac{T_{\text{pos},j}}{\left(P_j - 1\right)}$$

The correction factor c_j for the calculation of the VOLUME SENSITIVITY is then given by

$$c_j = \frac{\Delta T_{\text{acq},j}}{\Delta T_{\text{acq},j} + \Delta T_{\text{pos},j}}$$

The correction factor c_j shall be calculated and reported for the subscript *j* with corresponding acquisition times per PROJECTION $\Delta T_{\text{acq},j}$ of 30 s (low) and 15 s (high), respectively. This corresponds to a typical clinical situation of total acquisition time of 30 min.

3.3.2 NORMALIZED VOLUME SENSITIVITY

The measurement shall be carried out using a cylindrical phantom of 200 mm ± 3 mm outside diameter, of wall thickness 3 mm ± 1 mm, and 190 mm ±3 mm inside length (see figure 2), filled homogeneously with a water solution of ^{99m}Tc.

The ACTIVITY concentration a_{ave} (kBq/cm^3) shall be accurately determined by counting at least two samples from that solution in a calibrated well counter and correcting the result for radioactive decay to the time of measurement (midpoint of acquisition interval).

NOTE – The test is critically dependent upon accurate assays of radioactivity as measured in a dose calibrator or well counter. It is difficult to maintain an absolute calibration with such devices to accuracies better than 10 %. Absolute reference standards using appropriate (γ-emitters should be considered if higher degrees of accuracy are required.

The phantom shall be positioned so that its long axis coincides with the SYSTEM AXIS (parallel to and as close as possible to the SYSTEM AXIS). The radius of rotation R shall be 20 cm. For each COLLIMATOR used routinely for SPECT imaging at least one million counts shall be acquired in static imaging mode and the acquisition time T_a [sec] recorded. For a rectangular region of interest (ROI) centred on the image of the phantom the number of counts N_{ROI} shall be determined. The width of the ROI shall be at most 240 mm to cover the cylinder diameter, and the length l shall be at least 150 mm in the axial direction and centred to the phantom. The NORMALIZED VOLUME SENSITIVITY S_{norm} is then calculated by dividing the number of counts N_{ROI} registered from the ROI by the activity concentration a_{ave}, the acquisition time T_a, the axial length l of the ROI, and by multiplying by the correction factor c_j (see 3.3.1) according to the following equation:

$$S_{\text{norm}} = \frac{N_{\text{ROI}}}{a_{\text{ave}} T_a l}\, c_j \qquad \left[\text{cps}/\left(\text{kBq}/\text{cm}^2\right)\right]$$

The values shall be specified and stated for the subscript j of low and high respectively.

NOTE – For a given phantom set-up and parallel hole COLLIMATOR, the NORMALIZED VOLUME SENSITIVITY and the SYSTEM SENSITIVITY measured according to 3.1 of IEC 60789 are related by a fixed ratio and the correction factor c_j.

3.4 Scatter

The scattering of primary gamma rays results in events with false information for radiation source localization. Variations in design and implementation cause emission tomographs to have different sensitivities to scattered radiation. The purpose of this procedure is to measure the relative system sensitivity to scattered radiation, expressed by the SCATTER FRACTION (SF), as well as the values of the SCATTER FRACTION in each slice(SFI).

3.4.1 Scatter measurement

The measurements shall be performed by imaging a single line source at three different radial positions within a water-filled test phantom, using the COLLIMATOR used for SPECT imaging, a circular orbit and a 20 cm radius of rotation.

Unscattered events are assumed to lie within a 2 × FWHM wide strip centred on the image of the line source in each SINOGRAM. This width region is chosen because the scatter value is insensitive to the exact width of the region, and a negligible number of unscattered events lie more than one FWHM from the line image.

The width of the scatter response function allows a simplified analysis method. A linear interpolation across the strip from the points of intersection of the scatter tails and the edges of the 2 × FWHM wide strip is used to estimate the amount of scatter present in the strip. The area under the line of interpolation plus the contributions outside the strip constitute the estimated scatter.

Estimates of the SCATTER FRACTION for uniform source distributions are made under the assumption of slow radial dependence. In this assumption, the measure of SCATTER FRACTION for a line source on-axis is applied to a cross-sectional area out to a radius of 22,5 mm. The SCATTER FRACTION for a line source of 45 mm off-axis is applied to an annulus between 22,5 mm and 67,5 mm. Likewise, the SCATTER FRACTION for a line source 90 mm off-axis is