IEC 62220-2-1

Edition 1.0 2023-08

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment – Characteristics of digital X-ray imaging devices – Part 2-1: Determination of dual-energy subtraction efficiency – Detectors used for dual-energy radiographic imaging

Appareils électromédicaux – Caractéristiques des dispositifs d'imagerie à rayonnement X – Partie 2-1: Détermination de l'efficacité de soustraction à double énergie – Détecteurs utilisés en imagerie radiographique à double énergie

IEC 62220-2-1:2023-08(en-fr)

IEC Secretariat
3, rue de Varembé
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
info@iec.ch
www.iec.ch

About the IEC
The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

About IEC publications
The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigendum or an amendment might have been published.

IEC publications search - webstore.iec.ch/advsearchform
The advanced search enables to find IEC publications by a variety of criteria (reference number, text, technical committee, …). It also gives information on projects, replaced and withdrawn publications.

IEC Just Published - webstore.iec.ch/justpublished
Stay up to date on all new IEC publications. Just Published details all new publications released. Available online and once a month by email.

IEC Customer Service Centre - webstore.iec.ch/csc
If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: sales@iec.ch.

IEC Products & Services Portal - products.iec.ch
Discover our powerful search engine and read freely all the publications previews. With a subscription you will always have access to up to date content tailored to your needs.

Electropedia - www.electropedia.org
The world's leading online dictionary on electrotechnology, containing more than 22 300 terminological entries in English and French, with equivalent terms in 19 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

A propos de l'IEC
La Commission Electrotechnique Internationale (IEC) est la première organisation mondiale qui élabore et publie des Normes internationales pour tout ce qui a trait à l'électricité, à l'électronique et aux technologies apparentées.

A propos des publications IEC
Le contenu technique des publications IEC est constamment revu. Veuillez vous assurer que vous possédez l'édition la plus récente, un corrigendum ou amendement peut avoir été publié.

Recherche de publications IEC - webstore.iec.ch/advsearchform
La recherche avancée permet de trouver des publications IEC en utilisant différents critères (numéro de référence, texte, comité d'études, …). Elle donne aussi des informations sur les projets et les publications remplacées ou retirées.

IEC Just Published - webstore.iec.ch/justpublished
Restez informé sur les nouvelles publications IEC. Just Published détaille les nouvelles publications parues. Disponible en ligne et une fois par mois par email.

Service Clients - webstore.iec.ch/csc
Si vous désirez nous donner des commentaires sur cette publication ou si vous avez des questions contactez-nous: sales@iec.ch.

IEC Products & Services Portal - products.iec.ch
Découvrez notre puissant moteur de recherche et consultez gratuitement tous les aperçus des publications. Avec un abonnement, vous aurez toujours accès à un contenu à jour adapté à vos besoins.

Electropedia - www.electropedia.org
Le premier dictionnaire d'électrotechnologie en ligne au monde, avec plus de 22 300 articles terminologiques en anglais et en français, ainsi que les termes équivalents dans 19 langues additionnelles. Egalement appelé Vocabulaire Electrotechnique International (IEV) en ligne.

IEC 62220-2-1

Edition 1.0 2023-08

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment – Characteristics of digital X-ray imaging devices – Part 2-1: Determination of dual-energy subtraction efficiency – Detectors used for dual-energy radiographic imaging

Appareils électromédicaux – Caractéristiques des dispositifs d'imagerie à rayonnement X – Partie 2-1: Détermination de l'efficacité de soustraction à double énergie – Détecteurs utilisés en imagerie radiographique à double énergie

INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

ICS 11.040.50

ISBN 978-2-8322-7305-0

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

_____

MEDICAL ELECTRICAL EQUIPMENT – CHARACTERISTICS OF DIGITAL X-RAY IMAGING DEVICES –

Part 2-1: Determination of dual-energy subtraction efficiency – Detectors used for dual-energy radiographic imaging

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of 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, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). 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. 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 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 IEC National Committees.
3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
6) All users should ensure that they have the latest edition of this publication.
7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) IEC draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). IEC takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, IEC had not received notice of (a) patent(s), which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at https://patents.iec.ch. IEC shall not be held responsible for identifying any or all such patent rights.

IEC 62220-2-1 has been prepared by subcommittee 62B: Medical imaging equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems. It is an International Standard.

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

Draft	Report on voting
62B/1288/CDV	62B/1316/RVC

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

The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications.

A list of all parts in the IEC 62220 series, published under the general title *Medical electrical equipment – Characteristics of digital X-ray imaging devices*, can be found on the IEC website.

In this document, terms printed in SMALL CAPITALS are used as defined in IEC 60788, in Clause 3 of this document or in other IEC publications referenced in the Index of defined terms. Where a defined term is used as a qualifier in another defined or undefined term, it is not printed in SMALL CAPITALS, unless the concept thus qualified is defined or recognized as a “derived term without definition”.

NOTE Attention is drawn to the fact that, in cases where the concept addressed is not strongly confined to the definition given in one of the publications listed above, a corresponding term is printed in lower-case letters.

In this document, certain terms that are not printed in SMALL CAPITALS have particular meanings, as follows:

- "shall" indicates a requirement that is mandatory for compliance;
- "should" indicates a strong recommendation that is not mandatory for compliance;
- "may" indicates a permitted manner of complying with a requirement or of avoiding the need to comply;
- "specific" is used to indicate definitive information stated in this document or referenced in other standards, usually concerning particular operating conditions, test arrangements or values connected with compliance;
- "specified" is used to indicate definitive information stated by the manufacturer in accompanying documents or in other documentation relating to the equipment under consideration, usually concerning its intended purposes, or the parameters or conditions associated with its use or with testing to determine compliance.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under 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.

INTRODUCTION

Devices that are capable of DUAL-ENERGY IMAGING have been commercially available for over four decades and are well-known to provide clinical benefits. SINGLE-EXPOSURE DEVICES were the first to be successfully commercialized in a clinical environment, followed at the beginning of the century by MULTI-EXPOSURE DEVICES, enabled by the digitalization of X-RAY IMAGE RECEPTORS. More recently, advances in the field of DUAL-ENERGY IMAGING and a reduction in component costs have allowed more equipment MANUFACTURERS to enter this market, supporting a wider clinical adoption and more diverse technological approaches.

Despite this, there is presently no standard metric or associated measurement method to evaluate the quality of the TISSUE-SUBTRACTED IMAGES – therefore their physical imaging performance – that different DUAL-ENERGY IMAGING devices produce. This has resulted in a number of recent challenges for all stakeholders involved, exacerbated by the increasing diversity in technological approaches.

This document has therefore been developed in order to establish a common, fair, objective, and reproducible metric and measurement procedures for the evaluation of performance characteristics of DUAL-ENERGY IMAGING devices.

This document is beneficial to a number of different parties. It enables MANUFACTURERS to better optimize and compare systems, expediting internal processes and improving final clinical outcomes. It supports regulatory agencies by providing additional tools to evaluate new DUAL-ENERGY IMAGING devices. Healthcare institutions gain the ability to interpret results of external clinical studies and receive a new tool to aid in the development of their own internal protocols. Lastly, by replacing the current lengthy and costly qualitative nature of TISSUE-SUBTRACTED IMAGE assessment, it removes a barrier of entry for new companies, thereby increasing market diversity.

The metrics and methods described in this document evaluate a DUAL-ENERGY IMAGING device independent of its MANUFACTURER'S TISSUE-SUBTRACTION PROCESSING. This enables a true analysis of the device's physical imaging characteristics, without the effects of proprietary processing algorithms.

Note that, while this document presents metrics that describe the physical imaging performance of DIGITAL X-RAY IMAGE DEVICES, the connection between these parameters and the decision performance of a human observer of the TISSUE-SUBTRACTED IMAGES is not yet completely understood. Furthermore, exhaustive experimental confirmation of the presented metrics has not yet been carried out, and thus care is taken while interpreting results.

MEDICAL ELECTRICAL EQUIPMENT – CHARACTERISTICS OF DIGITAL X-RAY IMAGING DEVICES –

Part 2-1: Determination of dual-energy subtraction efficiency – Detectors used for dual-energy radiographic imaging

1 Scope

This document describes the performance metrics associated with DUAL-ENERGY IMAGING capable DIGITAL X-RAY IMAGING DEVICES meant for medical applications and specifies the methods for their determination. These metrics can be used to analyse TISSUE-SUBTRACTED IMAGES and to evaluate dose performance, noise characteristics, and tissue-subtraction efficacy of DIGITAL X-RAY IMAGING DEVICES. The described methods indicate the procedures to obtain MULTI-SPECTRAL PRIMARY DATA and to compute their derived TISSUE-SUBTRACTED IMAGES.

The intended users of this document are MANUFACTURERS and well-equipped test laboratories. This document is restricted to DIGITAL X-RAY IMAGING DEVICES that are used for single or multiple exposure dual-energy radiographic imaging based on, for example, CR systems, direct and indirect flat panel-detector based systems.

This document excludes and is not applicable to:

– DIGITAL X-RAY IMAGING DEVICES intended to be used in mammography or in dental RADIOGRAPHY;
– slot scanning DIGITAL X-RAY IMAGING DEVICES;
– COMPUTED TOMOGRAPHY or CONE-BEAM COMPUTED TOMOGRAPHY;
– photon-energy discriminating devices such as photon counting X-RAY IMAGING DEVICES;
– devices for dynamic imaging (where series of images are acquired, as in fluoroscopy or cardiac imaging).
– DIGITAL X-RAY IMAGING DEVICES intended to be used with RADIOTHERAPY beams.

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 60336, *Medical electrical equipment – X-ray tube assemblies for medical diagnosis – Focal spot dimensions and related characteristics*

IEC TR 60788:2004, *Medical electrical equipment – Glossary of defined terms*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC TR 60788:2004 and the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- IEC Electropedia: available at https://www.electropedia.org/
- ISO Online browsing platform: available at https://www.iso.org/obp

3.1
DUAL-ENERGY IMAGING
X-ray imaging technique that includes the acquisition of MULTI-SPECTRAL PRIMARY DATA, and the generation and presentation of one or more corresponding TISSUE-SUBTRACTED IMAGES

3.2
MULTI-SPECTRAL PRIMARY DATA
X-ray data directly derived from RAW DATA of the same object obtained at differing absorbed X-ray spectra

3.3
TISSUE-SUBTRACTED IMAGE
image obtained through TISSUE-SUBTRACTION PROCESSING with the purpose of removing contrast in tissues or structures not relevant to the intended imaging task

3.4
TISSUE-SUBTRACTION PROCESSING
processing of MULTI-SPECTRAL PRIMARY DATA – typically dual-energy logarithmic subtraction – with the goal of removing contrast between structures of similar spectral X-ray ABSORPTION characteristics

3.5
SINGLE-EXPOSURE DEVICE
DIGITAL X-RAY IMAGING DEVICE that achieves the acquisition of MULTI-SPECTRAL PRIMARY DATA with a single IRRADIATION

3.6
MULTI-EXPOSURE DEVICE
DIGITAL X-RAY IMAGING DEVICE that achieves the acquisition of MULTI-SPECTRAL PRIMARY data through multiple IRRADIATIONS obtained at different times and using various X-RAY TUBE VOLTAGE and/or ADDITIONAL FILTRATION

3.7
MULTI-EXPOSURE MOTION ARTIFACT
image ARTIFACT present in TISSUE-SUBTRACTED IMAGE that result from object misalignment between the image in the MULTI-SPECTRAL PRIMARY DATA, seen in MULTI-EXPOSURE DEVICES caused by patient motion between IRRADIATIONS

4 Requirements

4.1 Operating conditions

The DIGITAL X-RAY IMAGING DEVICE shall be operated according to the MANUFACTURER'S recommendations. The warm-up time shall be chosen according to the recommendations of the MANUFACTURER. The operating conditions shall be the same as those intended for clinical use and shall be maintained during all IRRADIATIONS required for these tests. When multiple clinical use recommendations exist, those that are recommended by the MANUFACTURER for DUAL-ENERGY IMAGING of the chest shall be selected.

4.2 X-RAY EQUIPMENT

For all tests described in the following subclauses, a CONSTANT POTENTIAL HIGH-VOLTAGE GENERATOR is recommended (IEC 60601-2-54). The PERCENTAGE RIPPLE shall be no larger than 4.

The NOMINAL FOCAL SPOT VALUE (IEC 60336) shall be no larger than 1,2.

For the measuring of AIR KERMA, calibrated RADIATION METERS shall be used. The uncertainty (coverage factor 2) of the measurements shall be less than 5 %.

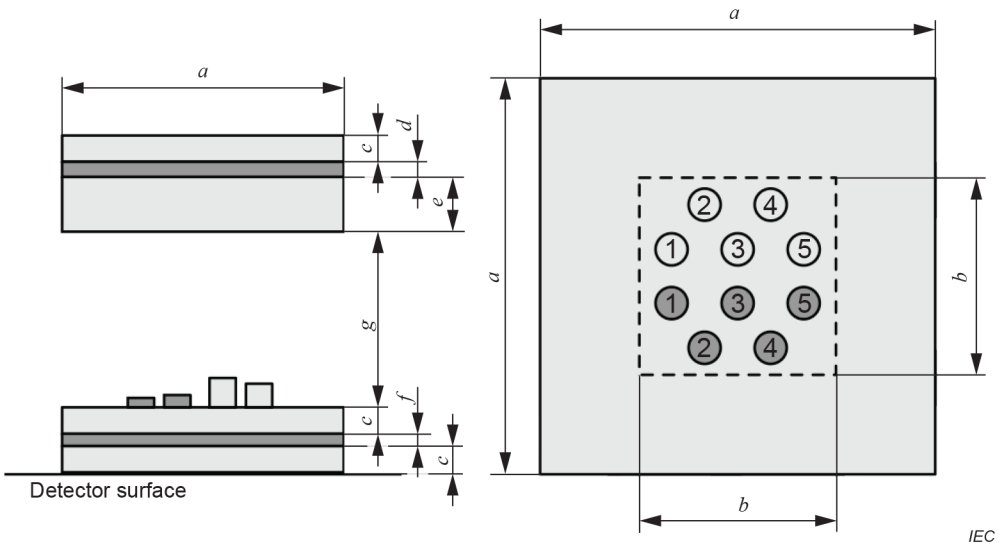
4.3 RADIATION QUALITY

The RADIATION QUALITIES selected for each IRRADIATION shall use a fixed X-RAY TUBE VOLTAGE, an ADDITIONAL FILTRATION material and an ADDITIONAL FILTRATION material thickness that match those recommended by the MANUFACTURER for clinical applications of DUAL-ENERGY IMAGING of the chest. If a MULTI-EXPOSURE DEVICE is being used, a different value of each of these parameters can be selected for each IRRADIATION.

4.4 TEST DEVICE

The TEST DEVICE for the determination of the dual-energy contrast shall consist of alternating layers of acrylic (polymethyl methacrylate) and aluminum plates. Each layer shall be a solid square cuboid slab of material, arranged in the configuration described in Figure 1. The dimensions of each of these slabs, as labelled in Figure 1, shall be $a = 300\ \text{mm}$, $b \leq 150\ \text{mm}$, $c = 9{,}5\ \text{mm}$, $d = 2{,}5\ \text{mm}$, $e = 54\ \text{mm}$, $f = 1{,}6\ \text{mm}$, $g = 190\ \text{mm}$. The purity of the constituent aluminum shall be at least 98 % and the density of the acrylic used shall be $1{,}19 \pm 0{,}02\ \text{g/cm}^3$.

A feature insert shall be placed on top of the second aluminum layer and provides the necessary material contrast for the calculation of the metric. This insert shall contain ten cylindrical protrusions of either acrylic or aluminum. Each material feature shall be numbered 1 through 5 and be of uniformly increasing thickness. Their relative arrangement in the insert shall follow that shown in Figure 1. Each cylinder shall be 25 mm in diameter and be separated from all other features by at least 11 mm from any point in either feature's perimeter. The thicknesses of aluminum features shall be, in increasing label order, 0,5 mm, 1,0 mm, 1,5 mm, 2,0 mm, and 2,5 mm. The thickness of the acrylic features shall be, in increasing label order, 2 mm, 4 mm, 6 mm, 8 mm, and 10 mm.



A side view of the TEST DEVICE (left) and a top view of the feature insert (right) are shown. The TEST DEVICE shall consist of alternating square cuboid layer of acrylic (light grey) and aluminum (dark grey). Note the air gap between some central layers of the device. The feature insert shall contain cylindrical features of either material, labelled 1 through 5 for each material.

Figure 1 – TEST DEVICE for the determination of the dual-energy contrast

4.5 Geometry

The geometrical set-up of all X-RAY EQUIPMENT and of the TEST DEVICE shall comply with Figure 2 for all IRRADIATIONS. The TEST DEVICE shall be placed as close as possible and parallel to the DETECTOR SURFACE. Other X-RAY EQUIPMENT can be present between the TEST DEVICE and the DETECTOR SURFACE, such as ANTI-SCATTER GRIDS or AUTOMATIC EXPOSURE CONTROL sensors. Any X-RAY EQUIPMENT present during IRRADIATIONS (such as a VERTICAL EXAMINATION STAND, ANTI-SCATTER GRID, or AUTOMATIC EXPOSURE CONTROL sensor) that does not comply with or is not included in Figure 2 can be used only if it is recommended by the MANUFACTURER for clinical use.

The distance between the FOCAL SPOT of the X-RAY TUBE and the DETECTOR SURFACE, h, shall be no less than 150 cm. If, for technical reasons, this distance requirement cannot be met, a smaller distance can be chosen and shall be explicitly declared when reporting results. The REFERENCE AXIS shall be aligned with the CENTRAL AXIS.

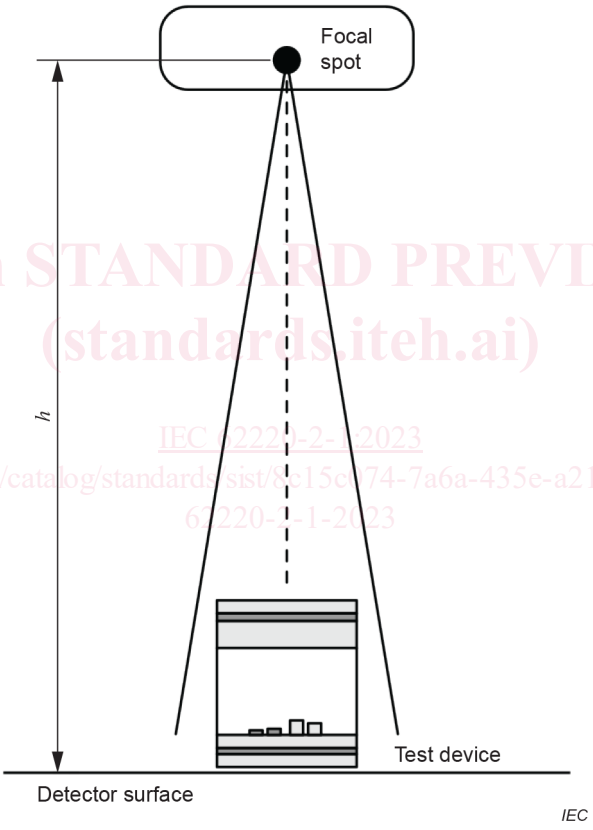


Figure 2 – Geometry for all IRRADIATIONS of the TEST DEVICE

4.6 IRRADIATION conditions

4.6.1 General conditions

Calibration of the DIGITAL X-RAY IMAGING DEVICE shall be carried out prior to any testing as specified by the MANUFACTURER. The measurements specified in this document shall be executed in their entirety without a recalibration of the DIGITAL X-RAY IMAGING DEVICE. Offset calibrations are excluded from this requirement.

The AIR KERMA level shall be chosen as that used when the DIGITAL X-RAY IMAGING DEVICE is operated for the intended use in clinical practice. If a MULTI-EXPOSURE DEVICE is being evaluated, the AIR KERMA level of each IRRADIATION shall be denoted $K_{a1}, K_{a2}, \ldots, K_{an}$. The total AIR KERMA level shall be denoted as K_a, and calculated using $K_a = \sum_{i=1}^{n} K_{ai}$. The ratio between the AIR

KERMA levels of each IRRADIATION shall follow MANUFACTURER recommendations for clinical use. If a SINGLE-EXPOSURE DEVICE is being evaluated, the AIR KERMA level is denoted K_a and is considered equivalent to the total AIR KERMA for a MULTI-EXPOSURE DEVICE. All AIR KERMA values shall be expressed in units of MILLIGRAY (mGy).

4.6.2 IRRADIATION for the determination of the dual-energy contrast

The IRRADIATIONS shall be carried out using the geometry described in 4.5. The IRRADIATION field area used shall be as close as possible to square and the RADIATION BEAM sized such that the entirety of the TEST DEVICE is irradiated.

The TEST DEVICE shall be placed as close as possible to the DETECTOR SURFACE, and adjusted in such a way that it is perpendicular to the REFERENCE AXIS of the RADIATION BEAM. The feature insert shall be included as part of the TEST DEVICE in the location indicated in Figure 1. The TEST DEVICE shall be angled such that its square sides are parallel to the axes of the PIXEL rows and PIXEL columns of the DIGITAL X-RAY IMAGING DEVICE.

The TEST DEVICE shall be imaged using the DIGITAL X-RAY IMAGING DEVICE and the RADIATION QUALITIES recommended by the MANUFACTURER for DUAL-ENERGY IMAGING of the chest. Gain settings of the DIGITAL X-RAY IMAGING DEVICE can be modified between IRRADIATIONS for a MULTI-EXPOSURE DEVICE.

Two independent sets of such IRRADIATIONS shall be carried out. Care shall be taken to ensure all X-RAY EQUIPMENT settings and geometries are the same between these two IRRADIATION sets. Each set will independently be used in the generation of TISSUE-SUBTRACTED IMAGES, both sets of which are later used in the determination of dual-energy contrast.

4.6.3 AIR KERMA measurement

The AIR KERMA level for IRRADIATIONS described in 4.6.2 shall be calculated. An appropriate RADIATION DETECTOR shall be placed at 100 cm from the FOCAL SPOT of the X-RAY TUBE and at least 25 cm from the TEST DEVICE. All other IRRADIATION conditions shall match those used during the dual-energy contrast IRRADIATIONS. If not possible to place the RADIATION DETECTOR at 100 cm from the FOCAL SPOT, the minimum 25 cm distance to the TEST DEVICE shall still be respected and the AIR KERMA level at 100 cm calculated via the inverse square distance law.

From AIR KERMA level at 100 cm, the AIR KERMA level at the DETECTOR SURFACE as defined in 4.6.1, K_a shall be calculated using the inverse square distance law and the distance between the FOCAL SPOT of the X-RAY TUBE and the DETECTOR SURFACE.

5 Corrections of RAW DATA

The following corrections of the RAW DATA are allowed for the creation of MULTI-SPECTRAL PRIMARY DATA. Other corrections can be performed as long as they only involve linear and image-independent image processing.

All the following corrections, if used, shall be made as in normal clinical use:

– replacement of bad or defective PIXELS in the RAW DATA by appropriate data;
– a flat-field correction comprising some or all of:
  - correction of non-uniformities of the RADIATION FIELD of the UNATTENUATED BEAM;
  - correction for the offset of individual PIXELS;
  - gain correction for the individual PIXELS;
– a correction for geometrical distortion and tiling.

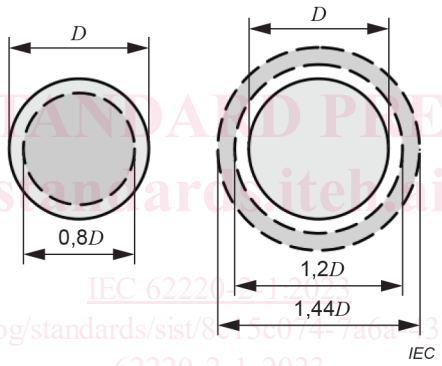
6 Definitions of the REGIONS OF INTEREST

All images of the TEST DEVICE will display contrast generated by the ten features in the feature insert. For each of these features as shown in Figure 3, two REGIONS OF INTEREST are defined: the feature region and the background region.

The feature REGION OF INTEREST is a circular region centred on the circular image generated by the feature and of a diameter of 80 % of the number of PIXELS of the apparent diameter of said feature in the image, rounded to the nearest PIXEL.

The background REGION OF INTEREST is an annular region centred on the circular image generated by the feature with an inner diameter of 120 % of the number of PIXELS of the apparent diameter of said feature in the image, rounded to the nearest PIXEL, and an outer diameter of 144 % of the number of PIXELS of the apparent diameter of said feature in the image, rounded to the nearest PIXEL.

Each REGION OF INTEREST shall be binary (that is, an image PIXEL can only be considered to be inside or outside of it, but not partially in it) and be as close as possible to its respective shape given the necessary rasterization to the DIGITAL X-RAY IMAGING DEVICE PIXEL grid.



REGIONS OF INTEREST are shown (dashed line, dark grey) with respect to the circular image generated by their respective feature (solid line, light grey). Feature REGION OF INTEREST (left) is defined as a circle of 80 % of apparent feature radius. Background REGION OF INTEREST (right) is defined as an annular region with inner and outer radii of 120 % and 144 % of apparent feature radius, respectively.

Figure 3 – Feature and background REGIONS OF INTEREST defined about circular image of features

Each REGION OF INTEREST is denoted based on the region type – F for feature regions, B for background regions –, with a superscript indicating the material type – Ac for acrylic, Al for aluminum –, and with a subscript indicating the feature number label as described in 4.4. For example, F_3^{Ac} corresponds to the feature REGION OF INTEREST for the third acrylic cylindrical protrusion of the feature insert.

7 Calculation of derived images

7.1 Calculation of high-energy and low-energy images

After the creation of MULTI-SPECTRAL PRIMARY DATA for each IRRADIATION described in 4.6.2, this data shall be used to compute two images, one that represent higher average absorbed X-ray spectrum, called the high-energy image, and one representing a lower average absorbed X-ray spectrum, called the low-energy image.