BS EN 62494-1:2008

BSI British Standards

Medical electrical equipment — Exposure index of digital X-ray imaging systems —

Part 1: Definitions and requirements for general radiography

raising standards worldwide™

BSI British Standards

National foreword

This British Standard is the UK implementation of EN 62494-1:2008. It is identical to IEC 62494-1:2008.

The UK participation in its preparation was entrusted by Technical Committee CH/62, Electromedical equipment in medical practice, to Subcommittee CH/62/2, Diagnostic imaging equipment.

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.

ISBN 978 0 580 57718 5

ICS 11.040.50

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

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 March 2009

Amendments issued since publication

Amd. No.	Date	Text affected

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 62494-1

November 2008

ICS 11.040.50

English version

Medical electrical equipment - Exposure index of digital X-ray imaging systems - Part 1: Definitions and requirements for general radiography

(IEC 62494-1:2008)

Appareils électromédicaux - Indice d'exposition des systèmes d'imagerie numérique à rayonnement X - Partie 1: Définitions et exigences pour la radiographie générale (CEI 62494-1:2008)

Medizinische elektrische Geräte - Dosisindikator digitaler Röntgenbildsysteme - Teil 1: Definitionen und Anforderungen für die allgemeine Radiographie (IEC 62494-1:2008)

This European Standard was approved by CENELEC on 2008-10-01. 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, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the 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 62494-1:2008 E

Foreword

The text of document 62B/680/CDV, future edition 1 of IEC 62494-1, prepared by SC 62B, Diagnostic imaging equipment, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 62494-1 on 2008-10-01.

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) 2009-07-01

– latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2011-10-01

In this standard, the following print types are used:

– requirements, compliance with which can be tested, and definitions: in roman type;

– explanations, advice, notes, general statements, exceptions and references: in smaller type;

– TERMS DEFINED IN CLAUSE 3 OF THIS STANDARD, IN EN 60601-1 OR IN IEC/TR 60788, AS REFERENCED IN THE INDEX OF DEFINED TERMS: SMALL CAPITALS.

Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 62494-1:2008 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 60601-1	NOTE	Harmonized as EN 60601-1:2006 (not modified).
IEC 60601-2-43	NOTE	Harmonized as EN 60601-2-43:2000 (not modified).
IEC 62220-1	NOTE	Harmonized as EN 62220-1:2004 (not modified).
IEC 62220-1-2	NOTE	Harmonized as EN 62220-1-2:2007 (not modified).

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following referenced documents are indispensable for the application 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.

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/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT – EXPOSURE INDEX OF DIGITAL X-RAY IMAGING SYSTEMS –

Part 1: Definitions and requirements for general radiography

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 provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with an IEC Publication.
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) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 62494-1 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

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

Enquiry draft	Report on voting
62B/680/CDV	62B/703/RVC

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

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

– requirements, compliance with which can be tested, and definitions: in roman type;

– explanations, advice, notes, general statements, exceptions and references: in smaller type;

– TERMS DEFINED IN CLAUSE 3 OF THIS STANDARD, IN IEC 60601-1 OR IN IEC 60788, AS REFERENCED IN THE INDEX OF DEFINED TERMS: SMALL CAPITALS.

A list of all parts of the IEC 62494 series, published under the general title *Medical electrical equipment – Exposure index of digital X-ray imaging systems*, can be found on the IEC website.

The committee has decided that the contents of this publication will remain unchanged until the maintenance result date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

INTRODUCTION

The direct connection between the level of detector exposure and optical density is well established in film-screen radiology. This is not the case in digital radiography, where almost always a constant image characteristic is achieved using automatic image processing. Consequently, deviations from the intended exposure, i.e., over- and underexposure, are not noticeable by a corresponding deviation in image brightness. While considerable underexposure results in an increased level of noise, the more alarming aspect (from a radiation protection point of view) is that overexposure cannot be recognized easily in the displayed image.

Therefore, various manufacturers of digital radiography systems have introduced so-called exposure indicators for their equipment. These are numbers, determined from the original image data of each image taken, which allow conclusions about the level of the exposure at the image receptor. However, the exposure indicators are manufacturer or system specific, i.e. they differ for the systems of different manufacturers in their definition and scaling. A unified EXPOSURE INDEX for all digital radiography systems is needed to simplify its usage, e.g. for the establishment of exposure guidelines, particularly when systems of different manufacturers are used within the same department.

This standard defines such a concept of the EXPOSURE INDEX. What is laid down here refers to the definition, the scale and the general requirements for the EXPOSURE INDEX. The process of its calculation in detail (software algorithm) is excluded from this standard as to not obstruct technical progress.

The EXPOSURE INDEX allows the OPERATOR to judge if an image was taken at a detector exposure level suitable for the intended level of image quality. It is important to note that the EXPOSURE INDEX, as defined in this standard, is derived from the image signal, which in turn is usually related to the energy absorbed in the detector, i.e. the detector dose, but not directly to the air kerma at the image receptor. The relation to IMAGE RECEPTOR AIR KERMA (air kerma at the detector surface) is introduced only at one radiation quality through calibration. However, this definition is appropriate as the image quality in digital radiography is determined mainly by the signal-to-noise level, which in turn is determined by the absorbed energy. Annex A provides more details on the rationale, properties and use of the EXPOSURE INDEX.

The level of detector exposure needed to obtain a suitable level of image quality may vary depending on body part, view, or the x-ray imaging system used, as may the appropriate EXPOSURE INDEX. This standard introduces a second parameter, called DEVIATION INDEX, which quantifies the deviation of an actual EXPOSURE INDEX from the appropriate EXPOSURE INDEX (called TARGET EXPOSURE INDEX). While this parameter does not relate to the image receptor dose on an absolute scale, it allows the operator an easy check whether the exposure is considered acceptable for the specific imaging task. Annex B provides more details on the rationale, properties and use of the DEVIATION INDEX.

The storage of the EXPOSURE INDEX (and the DEVIATION INDEX) together with the image data, e.g., in a DICOM tag field, allows the documentation and communication of the image receptor dose level in clinical practice.

The EXPOSURE INDEX does not obviate the use of dose parameters that describe the patient's exposure to radiation, such as, for example, the REFERENCE AIR KERMA or the kerma-area product. Because the relation between patient exposure and detector exposure is influenced by a number of factors that are generally not known under clinical conditions, the EXPOSURE INDEX should not be used to calculate or estimate patient dose.

The EXPOSURE INDEX cannot be used to control the compliance with diagnostic reference levels, which refer to patient dose [1][1)].

1) Figures in square brackets refer to the Bibliography.

MEDICAL ELECTRICAL EQUIPMENT – EXPOSURE INDEX OF DIGITAL X-RAY IMAGING SYSTEMS –

Part 1: Definitions and requirements for general radiography

1 Scope

This part of IEC 62494 specifies definitions and requirements for the EXPOSURE INDEX of images acquired with DIGITAL X-RAY IMAGING SYSTEMS.

This standard is applicable to DIGITAL X-RAY IMAGING SYSTEMS used in general radiography for producing PROJECTION X-ray images for general applications, such as, but not exclusively:

- computed radiography (CR) systems based on stimulable phosphors;
- flat-panel detector based systems;
- charge-coupled device (CCD) based systems.

Image intensifier based systems and systems for mammographic or dental application are not covered in this first edition.

This standard defines the EXPOSURE INDEX only for images generated with a single IRRADIATION event. Images generated from multiple IRRADIATIONS (e.g., tomosynthetic or dual-energy images, multiple views on a single CR plate) are not covered.

2 Normative references

The following referenced documents are indispensable for the application 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/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 and the following apply.

3.1
CALIBRATION CONDITIONS
set of conditions under which EXPOSURE INDEX calibration is done

3.2
CALIBRATION FUNCTION
function expressing the VALUE OF INTEREST as a function of the IMAGE RECEPTOR AIR KERMA that is valid under CALIBRATION CONDITIONS

3.3
DETECTOR SURFACE
accessible area which is closest to the IMAGE RECEPTOR PLANE

NOTE After removal of all parts (including the ANTI-SCATTER GRID and components for AUTOMATIC EXPOSURE CONTROL, if applicable) that can be safely removed from the RADIATION BEAM without damaging the digital X-ray detector.

[IEC 62220-1-2:2007, definition 3.3]

3.4
DEVIATION INDEX
DI
number quantifying the deviation of the actual EXPOSURE INDEX from a TARGET EXPOSURE INDEX

3.5
DIGITAL X-RAY IMAGING DEVICE
device consisting of a digital X-ray detector including the protective layers installed for use in practice, the amplifying and digitizing electronics, and a computer providing the ORIGINAL DATA (DN) of the image

[IEC 62220-1:2003, definition 3.5]

NOTE This may include protecting parts, such as anti-scatter grids or AEC components

3.6
DIGITAL X-RAY IMAGING SYSTEM
X-ray equipment using a DIGITAL X-RAY IMAGING DEVICE, providing PROJECTION images in digital format, comprising subsystems allowing to process, display, print or store the images

3.7
EXPOSURE INDEX
EI
measure of the detector response to radiation in the RELEVANT IMAGE REGION of an image acquired with a DIGITAL X-RAY IMAGING SYSTEM

NOTE For a fixed RADIATION QUALITY, the signal generated in the detector is proportional to the IMAGE RECEPTOR AIR KERMA (or exposure).

3.8
IMAGE RECEPTOR AIR KERMA
K
AIR KERMA at the position of the DETECTOR SURFACE, free-in-air (excluding backscatter)

3.9
INVERSE CALIBRATION FUNCTION
function expressing the IMAGE RECEPTOR AIR KERMA as a function of the VALUE OF INTEREST that is valid under CALIBRATION CONDITIONS

3.10
ORIGINAL DATA
DN
RAW DATA to which the corrections allowed in this standard have been applied

[IEC 62220-1:2003, definition 3.12]

NOTE The relation of the ORIGINAL DATA to the IMAGE RECEPTOR AIR KERMA may include a non-linear, e.g., logarithmic or square-root characteristic.

3.11
RAW DATA
pixel values read directly after the analogue-digital-conversion from the DIGITAL X-RAY IMAGING DEVICE without any software corrections

[IEC 62220-1:2003, definition 3.14]]

3.12
RELEVANT IMAGE REGION
examination-specific sub-area or sub-areas of the image containing the diagnostically relevant information

NOTE This is typically the region for which the exposure parameters should be optimized.

3.13
TARGET EXPOSURE INDEX
EI_T
expected value of the EXPOSURE INDEX when exposing the X-RAY IMAGE RECEPTOR properly

NOTE The TARGET EXPOSURE INDEX may depend on the type of detector, on the type of examination, on the diagnostic question and on other parameters.

3.14
VALUE OF INTEREST
V
central tendency of the original data in the relevant image region

NOTE Central tendency is a statistical term depicting generally the centre of a distribution. It may refer to a variety of measures such as the mean, the median or the mode.

4 Requirements

4.1 Creation of ORIGINAL DATA

The following image-independent corrections of the RAW DATA are allowed for the creation of ORIGINAL DATA in advance of the processing of the data for the determination of the CALIBRATION FUNCTION and the EXPOSURE INDEX.

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

– replacement of the RAW DATA of bad or defective pixels by appropriate data;
– a flat-field correction comprising for example:
  - correction of the non-uniformity of the RADIATION FIELD;
  - correction for the offset of the individual pixels;
  - gain correction for the individual pixels;
  - a correction for velocity variation during a scan;
– a correction for geometrical distortion.

NOTE 1 Some detectors execute linear image processing due to their physical concept. As long as this image processing is linear and image-independent, these operations are allowed as an exception.

NOTE 2 Image correction is considered image-independent if the same correction is applied to all images independent of the image contents.

NOTE 3 Processes that are used to enhance individual images for presentation, such as edge enhancement, noise smoothing, and histogram equalization, are not considered correction even if they are linear and are applied to all images independent of image content.

4.2 Determination of the RELEVANT IMAGE REGION and the VALUE OF INTEREST

The determination of the RELEVANT IMAGE REGION should be done by methods that identify the attenuated regions of the beam that are relevant to the diagnostic purpose of the acquired image.

The selection of the RELEVANT IMAGE REGION can be done by image segmentation, histogram based, or other appropriate methods. The method used shall be documented.

NOTE 1 Several methods to determine the RELEVANT IMAGE REGION exist. These may be based on image histogram evaluation, on image segmentation or a combination of both. The RELEVANT IMAGE REGION need not be a contiguous area of the image

NOTE 2 While it is understood that the selection of the RELEVANT IMAGE REGION is an important step in the generation of the EXPOSURE INDEX and that a single unified method may be desirable, it is not feasible at this time. Future versions of the standard may address this issue.

The VALUE OF INTEREST shall be calculated using the mean, median, mode, trimmed mean, trimean, or other recognized statistical method for the description of central tendency of the ORIGINAL DATA in the RELEVANT IMAGE REGION. The method used shall be documented.

NOTE 3 Care should be taken in the selection of the method used to calculate the central tendency in a manner not influenced by outlying values. Methods such as trimmed mean or trimean reduce the influence of extreme values.

NOTE 4 Background information on the influence of the selection of the RELEVANT IMAGE REGION and the VALUE OF INTEREST is described in Annex A.

4.3 Requirements for the EXPOSURE INDEX

The EXPOSURE INDEX EI shall be related to the VALUE OF INTEREST V according to the formula:

$$EI = c_0 \cdot g(V) \tag{1}$$

where $g(V)$ is an equipment-specific INVERSE CALIBRATION FUNCTION that is defined in subclause 4.6 and c_0 = 100 μGy^{-1} is a constant.

NOTE 1 The INVERSE CALIBRATION FUNCTION accounts for different scalings of the ORIGINAL DATA in different DIGITAL X-RAY IMAGING DEVICES.

The EXPOSURE INDEX shall be calculated directly after image acquisition and after any manual adjustments of the automatic image processing (e.g., when the automatic segmentation or histogram evaluation algorithm failed to correctly identify the RELEVANT IMAGE REGION) so that it is available to the OPERATOR prior to image confirmation.

NOTE 2 Image confirmation is the step concluding the image acquisition process. It may happen either by a user action or automatically. It asserts that the image has been processed properly. This is usually done by examining the image on the display of the acquisition workstation.

If the EXPOSURE INDEX is outside the valid range of the INVERSE CALIBRATION FUNCTION (see subclause 4.6) that effect shall be indicated.

4.4 Calibration of the EXPOSURE INDEX

The EXPOSURE INDEX EI shall be calibrated for the DIGITAL X-RAY IMAGING SYSTEM over the specified operating range of IMAGE RECEPTOR AIR KERMA such that

$$EI = c_0 \cdot K_{CAL} \tag{2}$$

where K_{CAL} is the IMAGE RECEPTOR AIR KERMA in μGy under the CALIBRATION CONDITIONS and c_0 = 100 μGy^{-1} is a constant.

CALIBRATION CONDITIONS shall be:

– homogeneous IRRADIATION of the EFFECTIVE IMAGE RECEPTION AREA;

– IMAGE RECEPTOR AIR KERMA covering the specified operating range of the DIGITAL X-RAY IMAGING DEVICE;

– measurement of the IMAGE RECEPTOR AIR KERMA free-in-air without backscattered radiation as specified in Annex C;

– a single fixed RADIATION QUALITY as specified in Annex C;

– VALUE OF INTEREST computed from a RELEVANT IMAGE REGION that shall be the central 10 % of the area of the homogeneously exposed EFFECTIVE IMAGE RECEPTION AREA.

Conditions needed to verify the CALIBRATION FUNCTION, such as the time interval between exposure and processing in the CR reader, should be supplied by the manufacturer.

NOTE For radiographic techniques other than the one used for calibration, the relation between the EXPOSURE INDEX *EI* and the IMAGE RECEPTOR AIR KERMA *K* will deviate from Eq. (2) because of the energy dependence of x-ray response of the detector, scattered radiation and possibly other effects.

4.5 Determination of the CALIBRATION FUNCTION

The CALIBRATION FUNCTION *f(K)* shall be determined from the relationship between the IMAGE RECEPTOR AIR KERMA K_{CAL} and the VALUE OF INTEREST V_{CAL} for the calibration RADIATION QUALITY from a series of homogenously exposed images. The CALIBRATION FUNCTION *f(K)* is defined by

$$V_{CAL} = f(K_{CAL}) \tag{3}$$

where V_{CAL} is the VALUE OF INTEREST with a RELEVANT IMAGE REGION that is taken to be the central 10 % of the homogeneously exposed EFFECTIVE IMAGE RECEPTION AREA. This relationship shall be measured over the range of IMAGE RECEPTOR AIR KERMA for which the DIGITAL X-RAY IMAGING DEVICE is specified to operate. Intermediate values of *f(K)* are to be interpolated from the measured values.

ADDED FILTER and X-RAY TUBE VOLTAGE used to obtain the RADIATION QUALITY described in Annex C shall be documented.

4.6 Determination of the INVERSE CALIBRATION FUNCTION

The INVERSE CALIBRATION FUNCTION, $g(V_{CAL})$ is defined as

$$K_{CAL} = g(V_{CAL}) = f^{-1}(V_{CAL}) \ . \tag{4}$$

This function expresses the IMAGE RECEPTOR AIR KERMA K as a function of the VALUE OF INTEREST for the CALIBRATION CONDITIONS.

The INVERSE CALIBRATION FUNCTION *g(V)* shall be used for the calculation of the EXPOSURE INDEX according to Eq. (1) for all radiographic techniques

If EXPOSURE INDEX values are provided by a DIGITAL X-RAY IMAGING SYSTEM, the manufacturer or supplier shall specify the INVERSE CALIBRATION FUNCTION and the range of IMAGE RECEPTOR AIR KERMA for which the INVERSE CALIBRATION FUNCTION can be used to calculate the IMAGE RECEPTOR AIR KERMA from the VALUE OF INTEREST under CALIBRATION CONDITIONS. The specified INVERSE CALIBRATION FUNCTION shall have an uncertainty of less than 20 % (coverage factor 2).

NOTE "Uncertainty" and "coverage factor" are terms defined in the Guide to the expression of uncertainty in measurement [2].

4.7 Requirements for the DEVIATION INDEX

The DEVIATION INDEX is a number quantifying the deviation of the actual EXPOSURE INDEX from the TARGET EXPOSURE INDEX that is intended for the type of examination in question on that DIGITAL X-RAY IMAGING SYSTEM.

If TARGET EXPOSURE INDEX values are provided by the DIGITAL X-RAY IMAGING SYSTEM, the DEVIATION INDEX shall be automatically calculated according to:

$$DI = 10 \cdot \log_{10}\left(\frac{EI}{EI_T}\right) \tag{5}$$

where EI is the EXPOSURE INDEX of the actual image and EI_T is the TARGET EXPOSURE INDEX for this examination type on the DIGITAL X-RAY IMAGING SYSTEM.

NOTE 1 For this purpose, the TARGET EXPOSURE INDEX values for different examinations/applications need to be available on the DIGITAL X-RAY IMAGING SYSTEM, e.g., in a data base. Such values may be established by professional societies or by the RESPONSIBLE ORGANIZATION.

NOTE 2 This definition results in a DEVIATION INDEX of 0 when the actual EXPOSURE INDEX equals the TARGET EXPOSURE INDEX; the DEVIATION INDEX changes by ±1 for each +25 %/-20 % change of the EXPOSURE INDEX.

The DEVIATION INDEX shall be calculated directly after image acquisition and after any manual adjustments of the automatic image processing (e.g., when the automatic segmentation or histogram evaluation algorithm failed to correctly identify the RELEVANT IMAGE REGION) so that it is available to the OPERATOR prior to image confirmation.

Annex A
(informative)

Details on the rationale, properties and use of the EXPOSURE INDEX

The EXPOSURE INDEX and the DEVIATION INDEX serve to provide the user with feedback in the form of standardized indices. The EXPOSURE INDEX is a relative measure of the detector dose level for an X-ray image acquired by a particular DIGITAL X-RAY IMAGING SYSTEM. In conjunction with clinical experience, the EXPOSURE INDEX is expected to quantify detector dose, which will facilitate the development of useful EXPOSURE INDEX guidelines.

The EXPOSURE INDEX described in this standard has a number of useful properties. The purpose of this annex is to describe these along with known limitations to facilitate the appropriate use of the EXPOSURE INDEX as well as the DEVIATION INDEX.

With otherwise identical technical factors (kV, filtration, SID, grid) and subject, the EXPOSURE INDEX of a particular DIGITAL X-RAY IMAGING SYSTEM is linearly proportional to the IMAGE RECEPTOR AIR KERMA. For example, doubling the mAs will result in a doubling of the EXPOSURE INDEX.

Under CALIBRATION CONDITIONS (uniform, flat-field exposure of the specified x-ray quality) the IMAGE RECEPTOR AIR KERMA will be directly related to the EXPOSURE INDEX computed from a RELEVANT IMAGE REGION corresponding to the central 10 % of the DIGITAL X-RAY IMAGING DEVICE. This relationship is expected to be useful for many aspects of technical quality control appropriate for DIGITAL X-RAY IMAGING SYSTEMS (for example, medical physicist's acceptance or constancy testing).

The EXPOSURE INDEX also has limitations. It is important to understand these to avoid misinterpretation and misuse of EXPOSURE INDEX values. This is particularly true if EXPOSURE INDEX values from different DIGITAL X-RAY IMAGING SYSTEMS or for images acquired with significantly different technical factors are to be compared.

The EXPOSURE INDEX depends critically on the RELEVANT IMAGE REGION. Therefore, the value of the EXPOSURE INDEX will be directly affected by differences in selection of the RELEVANT IMAGE REGION intrinsic to different DIGITAL X-RAY IMAGING SYSTEMS. Such differences are to be expected because this standard does not specify a method for selecting the RELEVANT IMAGE REGION. To appreciate the potential impact of differences in RELEVANT IMAGE REGION selection, it is only necessary to recall that typical radiographic images span a large range of relative IMAGE RECPTOR AIR KERMA. A representative ORIGINAL DATA radiograph is shown in Figure A.1.

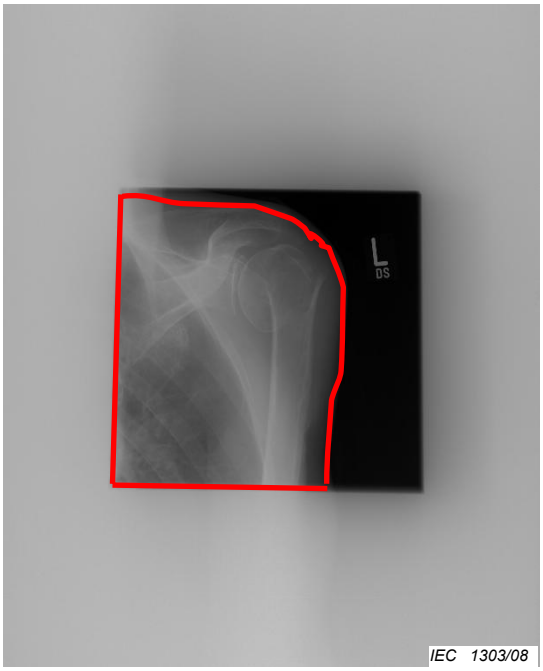
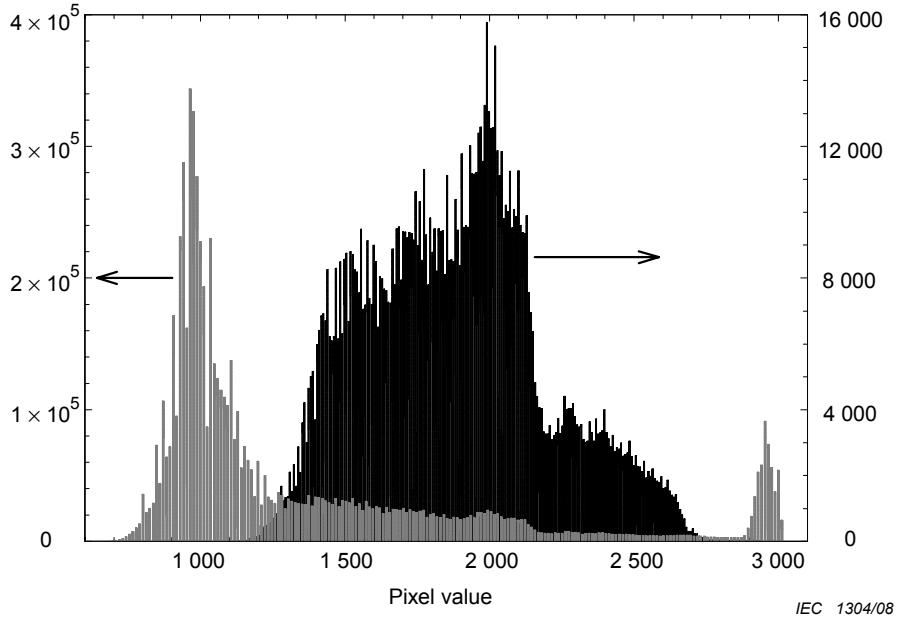


Figure A.1 – Example of an ORIGINAL DATA radiograph with an example of the RELEVANT IMAGE REGION outlined

The histogram for this radiograph is shown in Figure A.2. In this example, pixel values represent 1 000 × log(E), where E is the relative dose incident upon the DIGITAL X-RAY IMAGING DEVICE. The gray histogram in Figure A.2 is computed from pixel values from the entire image. This includes areas containing anatomy, collimated areas and areas receiving direct (unattenuated) x-ray exposure. The range of pixel values is more than 2 000, corresponding to more than a factor of 100 in relative receptor dose. This is typical of many radiographic examinations. The black histogram is computed from pixel values in the anatomical area outlined in red in Figure A.1. This selection is one possible candidate for the RELEVANT IMAGE REGION. The range of pixel values in this histogram is more than 1 000, corresponding to more than a factor of 10 in relative receptor dose [4]. Different plausible selections of the RELEVANT IMAGE REGION can easily lead to EXPOSURE INDEX differences spanning a substantial fraction of that range.

NOTE For testing purposes, a possibility to interactively select the RELEVANT IMAGE REGION may be useful.



Gray histogram is for the entire image and the black histogram is for only the anatomical area (excluding collimated and direct exposure areas).This is one possible candidate for the RELEVANT IMAGE REGION.

Figure A.2 – Histogram of the ORIGINAL DATA for the radiograph shown in Figure A.1

A subtler, but still important factor affecting the EXPOSURE INDEX is the freedom to select any measure of central tendency to compute the VALUE OF INTEREST. The choice of central tendency is not defined or limited by this standard and is therefore open to different interpretation for each DIGITAL X-RAY IMAGING SYSTEM. Depending on the histogram of the image, plausible choices like mean, median or mode may lead to different VALUES OF INTEREST. It is important to recognize that the impact of such differences on the EXPOSURE INDEX is not mitigated by proper calibration. The range of choices will have very little impact on the uniform CALIBRATION CONDITION images because the range of pixel values in the RELEVANT IMAGE REGION is very small, while this is not the case for clinical images.

The result is that even though the same EXPOSURE INDEX may be reported by different systems, the exposure reaching the DIGITAL X-RAY IMAGING DEVICE may be very different. Likewise, significantly different EXPOSURE INDEX values do not necessarily indicate a substantially different dose to the DIGITAL X-RAY IMAGING DEVICES of different DIGITAL X-RAY IMAGING SYSTEMS.

Another important limitation is related to the observation that each DIGITAL X-RAY IMAGING DEVICE responds differently to x-rays of different energies and angles of incidence. However, this standard uses a single x-ray beam quality for calibration. The use of a single calibration condition results in a unique dependence of the EXPOSURE INDEX on technical factors (kV, filtration, SID, grid) for each DIGITAL X-RAY IMAGING DEVICE. Therefore, even though two different DIGITAL X-RAY IMAGING DEVICES may be calibrated to this standard, they may give different EXPOSURE INDEX values for otherwise identical image acquisitions, solely because of differences in x-ray energy response. The energy dependences of detector response have recently been reported for several common detector technologies for four clinically relevant beam conditions (for details see [5]). These data are shown in Figure A.3.

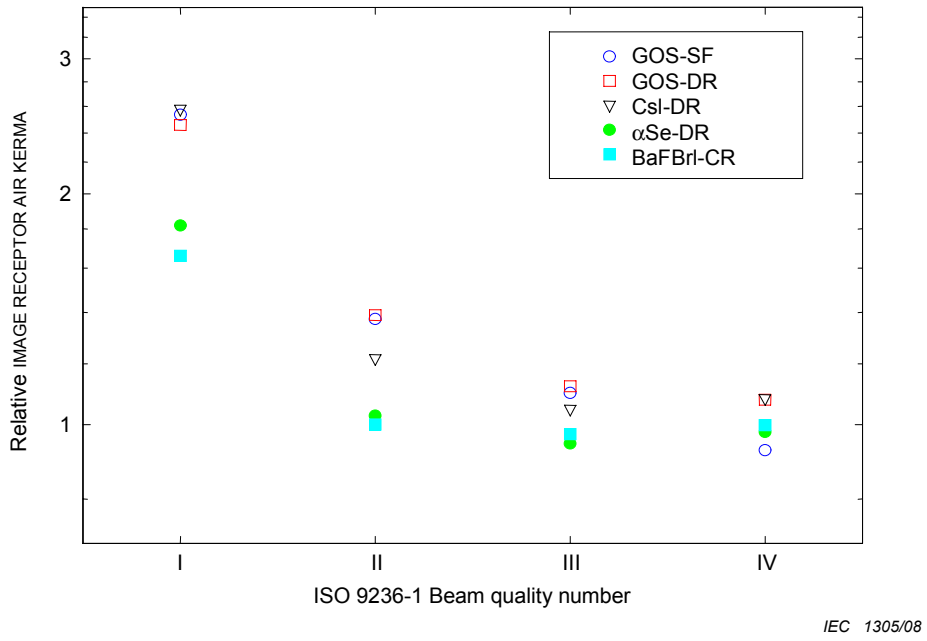


Figure A.3 – Relative IMAGE RECEPTOR AIR KERMA required to produce a fixed detector response for the four x-ray beam qualities defined in ISO 9236-1

ISO Standard 9236-1 specifies four beam conditions that are intended to approximate the X-ray spectrum and scatter conditions commonly used for extremity (I), skull (II), lumbar spine (III), and chest (IV) film/screen imaging. Figure A.3 shows the relative IMAGE RECEPTOR AIR KERMA that is needed for fixed constant response for each of five common imaging detector technologies. For each detector, the IMAGE RECEPTOR AIR KERMA has been normalized by that required for the scatter-free calibration condition (80 kVp with 0,50 mm Cu and 1 mm Al at the tube) [5]. Figure A.3 shows that DIGITAL X-RAY IMAGING DEVICES exhibit a substantial dependence on x-ray beam quality corresponding to widely practiced examinations. The full range of normalized detector responses varies by a factor of 2,78. As a result, the energy dependence of imaging detectors will introduce corresponding detector dependent energy dependences of EXPOSURE INDEX. Therefore, great care must be taken when comparing EXPOSURE INDEX values of images from different DIGITAL X-RAY IMAGING DEVICES or for images acquired with different technical factors (kV, filtration, SID, grid).

This informative annex describing the properties and limitations of the EXPOSURE INDEX is not intended to be exhaustive, but rather to guide the user toward a more complete understanding that will facilitate the correct use and interpretation of the EXPOSURE INDEX.

Annex B
(informative)

Details on the rationale, properties and use of the DEVIATION INDEX

For radiographs of different body parts and views, the EXPOSURE INDEX required to obtain acceptable image quality may vary according to the purpose and clinical diagnostic indications expected for a particular procedure as well as depending on the specific type of detector used. The DEVIATION INDEX is intended to be an indication to the OPERATOR performing or interpreting radiographic examinations whether the signal-to-noise ratio in the RELEVANT IMAGE REGION resulting from the selected radiographic technique is considered acceptable for the specific body part and view imaged.

For that purpose, a database of TARGET EXPOSURE INDEX values needs to be available in the DIGITAL X-RAY IMAGING SYSTEM and the OPERATOR must specify the body part and view to be imaged prior to image acquisition. This allows the DIGITAL X-RAY IMAGING SYSTEM to select the appropriate TARGET EXPOSURE INDEX VALUE from the database to be used in the determination of the DEVIATION INDEX. If no body part and view is selected or if there is no EI_T entry in the table for the selected body part and view, the system reports a value of “N/A” for the DEVIATION INDEX.

For a properly exposed X-ray image the DEVIATION INDEX will be close to zero.

Over- and underexposure compared to the target level of exposure for a specific examination result in positive or negative values of the DEVIATION INDEX, respectively.

Deviations from proper positioning and collimation, which would lead to over- or underexposure in conventional screen-film imaging, lead to positive or negative values of the DEVIATION INDEX.

Annex C
(normative)

Beam conditions to be used for calibration

The RADIATION QUALITY used for the CALIBRATION CONDITIONS shall be characterized by:

– a HALF-VALUE LAYER of (6,8 ± 0,3) mm aluminium,
– an ADDED FILTER of either 21 mm aluminum or 0,5 mm copper and 2 mm aluminum,
– an X-RAY TUBE VOLTAGE in the range of 66 kV – 74 kV.

Adjustment of the X-RAY TUBE VOLTAGE in the range specified above is permitted to achieve the target HALF-VALUE LAYER.

ADDED FILTER and X-RAY TUBE VOLTAGE used for calibration shall be documented.

NOTE 1 This RADIATION QUALITY is close to RQA5 as specified in IEC 61267. For the purpose of this standard, the procedure to realize the RADIATION QUALITY is simplified compared to IEC 61267.

NOTE 2 The use of copper as a component of the ADDED FILTER is allowed in order to reduce the overall thickness of added material. In a prior publication, 0,5 mm of copper was found to minimize the variability in the response of a computed radiography system as the X-RAY TUBE VOLTAGE was varied within 80 kV ± 10% [3]. The additional aluminium material achieves a HALF-VALUE LAYER near the desired nominal value, while keeping the thickness of the copper filter at a value that is readily available. The added aluminium material should be on the beam exit surface of the copper filter so that any characteristic radiation originating from the copper filter is absorbed.

The measurement of the IMAGE RECEPTOR AIR KERMA K_{CAL}, to be used for calibration of the EXPOSURE INDEX (section 4.3) shall be done such that K_{CAL} reflect the primary beam AIR KERMA at the position of the detector, free in air. If the image receptor cannot be removed from the beam, the AIR KERMA should be measured at a position midway between the collimator and the detector and adjusted using multiplication by the square of the distance from the focal spot to the exposure meter divided by the distance from the focal spot to the active layer of the image receptor.

NOTE 3 To account for variability, the AIR KERMA may be monitored at the edge of the beam and a correction made for the AIR KERMA measured in the centre of the field relative to that measured at the edge of the field.

NOTE 4 While additional beam collimation is not required here, the remaining specification corresponds to the geometry described in IEC 62220-1.

Bibliography

[1] Radiological protection and safety in medicine: a report of the International Commission on Radiological Protection. *Ann ICRP* 1996;26(2):p.1–47. [Published correction appears in Ann ICRP 1997;27(2):61.]

[2] ISO/IEC GUIDE 98, *Guide to the expression of uncertainty in measurement (GUM)*

[3] SAMEI, E., SEIBERT, JA., WILLIS, C., FLYNN, M., MAH, E., JUNCK, K. Performance evaluation of computed radiography systems*. Med Phys,* 2001, 24, p. 361-371

[4] VAN METTER, R. and YORKSTON, J. Toward a universal definition of speed for digitally acquired projection images*. Proc SPIE,* 2005, 5745*,* p. 442-457

[5] VAN METTER R. and YORKSTON, J.. Applying a Proposed Definition for Receptor Dose to Digital Projection Images. *Proc SPIE,* 2006, 6142, p. 426-444

[6] IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

[7] IEC 60601-2-43, *Medical electrical equipment – Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures*

[8] IEC 62220-1, *Medical electrical equipment – Characteristics of digital X-ray imaging devices – Part 1: Determination of the detective quantum efficiency*

[9] IEC 62220-1-2, *Medical electrical equipment – Characteristics of digital X-ray imaging devices – Part 1-2: Determination of the detective quantum efficiency – Detectors used in mammography*

[10] ISO 9236-1, *Optics and optical instruments – Optical transfer function – Application – Part 1: Interchangeable lenses for 35 mm still cameras*

Index of defined terms

This page deliberately left blank

British Standards Institution (BSI)

BSI is the independent national body responsible for preparing British Standards. It presents the UK view on standards in Europe and at the international level.

It is incorporated by Royal Charter.

Revisions

British Standards are updated by amendment or revision. Users of British Standards should make sure that they possess the latest amendments or editions.

It is the constant aim of BSI to improve the quality of our products and services. We would be grateful if anyone finding an inaccuracy or ambiguity while using this British Standard would inform the Secretary of the technical committee responsible, the identity of which can be found on the inside front cover.

Tel: +44 (0)20 8996 9000 Fax: +44 (0)20 8996 7400

BSI offers members an individual updating service called PLUS which ensures that subscribers automatically receive the latest editions of standards.

Buying standards

Orders for all BSI, international and foreign standards publications should be addressed to BSI Customer Services.

Tel: +44 (0)20 8996 9001 Fax: +44 (0)20 8996 7001
Email: orders@bsigroup.com

You may also buy directly using a debit/credit card from the BSI Shop on the website **www.bsigroup.com/shop**

In response to orders for international standards, it is BSI policy to supply the BSI implementation of those that have been published as British Standards, unless otherwise requested.

Information on standards

BSI provides a wide range of information on national, European and international standards through its Library.

Various BSI electronic information services are also available which give details on all its products and services. Contact the Information Centre.

Tel: +44 (0)20 8996 7111
Fax: +44 (0)20 8996 7048 Email: info@bsigroup.com

Subscribing members of BSI are kept up to date with standards developments and receive substantial discounts on the purchase price of standards. For details of these and other benefits contact Membership Administration.

Tel: +44 (0)20 8996 7002 Fax: +44 (0)20 8996 7001
Email: membership@bsigroup.com

Information regarding online access to British Standards via British Standards Online can be found at **www.bsigroup.com/BSOL**

Further information about BSI is available on the BSI website at **www.bsigroup.com**

Copyright

BSI Group Headquarters

389 Chiswick High Road London W4 4AL UK

Tel +44 (0)20 8996 9001
Fax +44 (0)20 8996 7001
www.bsigroup.com/standards

raising standards worldwide™

British Standards