

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

**Appareils électromédicaux – Indice d'exposition des systèmes d'imagerie
numérique à rayonnement X –
Partie 1: Définitions et exigences pour la radiographie générale**



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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

Part 1: Definitions and requirements for general radiography

FOREWORD

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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

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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.

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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⁾.

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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 stimuable 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

IEC 62494-1:2008

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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).

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3.8

IMAGE RECEPTOR AIR KERMA

[IEC 62494-1:2008](#)

K

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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:

$$EI = c_0 \cdot g(V) \quad (1)$$

where $g(V)$ is an equipment-specific INVERSE CALIBRATION FUNCTION that is defined in subclause 4.6 and $c_0 = 100 \mu\text{Gy}^{-1}$ 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

$$EI = c_0 \cdot K_{CAL} \quad (2)$$

where K_{CAL} is the IMAGE RECEPTOR AIR KERMA in μGy under the CALIBRATION CONDITIONS and $c_0 = 100 \mu\text{Gy}^{-1}$ 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 homogeneously exposed images. The CALIBRATION FUNCTION $f(K)$ is defined by

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

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, $g(K_{CAL})$ is defined as

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

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:

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