SLOVENSKI STANDARD
SIST EN 62494-1:2009

01-januar-2009

Medicinska elektriļ na oprema - Indeks izpostavljenosti pri digitalnih sistemih za rentgensko slikanje - 1. del: Definicije in zahteve za sploġno radiografijo (IEC 62494-1:2008)

Medical electrical equipment - Exposure index of digital X-ray imaging systems - Part 1: Definitions and requirements for general radiography (IEC 62494-1:2008)

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

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

Ta slovenski standard je istoveten z: **EN 62494-1:2008**

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EUROPEAN STANDARD

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EN 62494-1

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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	-	-

IEC 62494-1

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

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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;

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– 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.