SVENSK STANDARD

SS-EN IEC 62220-2-1, utg 1:2024

Fastställd	Sida	Ansvarig kommitté
2024-04-24	1 (24)	SEK TK 62BC

Elektrisk utrustning för medicinskt bruk – Egenskaper hos digitala röntgenbildgivande anordningar – Del 2-1: Bestämning av effektivitet vid dubbelenergisubtraktion – Detektorer för röntgenbildgivning med dubbelenergi

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

Som svensk standard gäller europastandarden EN IEC 62220-2-1:2023. Den svenska standarden innehåller den officiella engelska språkversionen av EN IEC 62220-2-1:2023.

Nationellt förord

Europastandarden EN IEC 62220-2-1:2023

består av:

– **europastandardens ikraftsättningsdokument,** utarbetat inom CENELEC
– **IEC 62220-2-1, First edition, 2023 - 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**

utarbetad inom International Electrotechnical Commission, IEC.

ICS 11.040.50

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 62220-2-1

September 2023

ICS 11.040.50

English Version

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 (IEC 62220-2-1:2023)

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)

Medizinische elektrische Geräte - Merkmale digitaler Röntgenbildgeräte - Teil 2-1: Bestimmung des Wirkungsgrades der Zwei-Energie-Subtraktion - Detektoren für die Zwei-Energie-Röntgenbildgebung (IEC 62220-2-1:2023)

This European Standard was approved by CENELEC on 2023-09-13. 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 CEN-CENELEC Management Centre 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 CEN-CENELEC Management Centre has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN IEC 62220-2-1:2023 E

European foreword

The text of document 62B/1288/CDV, future edition 1 of IEC 62220-2-1, 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 approved by CENELEC as EN IEC 62220-2-1:2023.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2024-06-13
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2026-09-13

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC shall not be held responsible for identifying any or all such patent rights.

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Endorsement notice

The text of the International Standard IEC 62220-2-1:2023 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 standard indicated:

IEC 60601-2-54	NOTE	Approved as EN 60601-2-54
IEC 60601-1-3:2008	NOTE	Approved as EN 60601-1-3:2008 (not modified) + A11:2016
IEC 61674:2012	NOTE	Approved as EN 61674:2013 (not modified)
IEC 62220-1-1:2015	NOTE	Approved as EN 62220-1-1:2015 (not modified)
IEC 60601-2-68:2014	NOTE	Approved as EN 60601-2-68:2015 (not modified)

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

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.

NOTE 1 Where an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cencenelec.eu.

Publication	Year	Title	EN/HD	Year
IEC 60336	-	Medical electrical equipment - X-ray tube assemblies for medical diagnosis - Focal spot dimensions and related characteristics	EN IEC 60336	-
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-

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

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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.
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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*