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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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 11/23

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EN IEC 62220-2-1

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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)

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

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.

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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

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

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
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**



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IEC 62220-2-1

Edition 1.0 2023-08

INTERNATIONAL STANDARD

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Part 2-1: Determination of dual-energy subtraction efficiency – Detectors used
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DéTECTEURS utilisés en imagerie radiographique à double énergie**

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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

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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.

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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*

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