SLOVENSKI STANDARD

oSIST prEN IEC 62220-2:2022

01-november-2022

Medicinska električna oprema - Karakteristike digitalnih naprav za rentgensko slikanje - 2. del: Ugotavljanje učinkovitosti dvoenergijskega odštevanja - Detektorji, ki se uporabljajo pri radiografskem slikanju z dvojno energijo

Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 2: 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: Détermination de l’efficacité de soustraction à double énergie - Détecteurs utilisés en imagerie radiographique

Ta slovenski standard je istoveten z: **prEN IEC 62220-2:2022**

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62B/1288/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER:	
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DATE OF CIRCULATION:	CLOSING DATE FOR VOTING:
2022-08-26	**2022-11-18**
SUPERSEDES DOCUMENTS:	
62B/1260/CD, 62B/1286/CC	

IEC SC 62B : DIAGNOSTIC IMAGING EQUIPMENT	
SECRETARIAT: Germany	SECRETARY: Ms Regina Geierhofer
OF INTEREST TO THE FOLLOWING COMMITTEES:	PROPOSED HORIZONTAL STANDARD: ☐ Other TC/SCs are requested to indicate their interest, if any, in this CDV to the secretary.
FUNCTIONS CONCERNED: ☐ EMC ☐ ENVIRONMENT ☐ QUALITY ASSURANCE ☐ SAFETY	
☒ SUBMITTED FOR CENELEC PARALLEL VOTING **Attention IEC-CENELEC parallel voting** The attention of IEC National Committees, members of CENELEC, is drawn to the fact that this Committee Draft for Vote (CDV) is submitted for parallel voting. The CENELEC members are invited to vote through the CENELEC online voting system.	☐ NOT SUBMITTED FOR CENELEC PARALLEL VOTING

This document is still under study and subject to change. It should not be used for reference purposes.

Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

TITLE:

Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 2: Determination of dual-energy subtraction efficiency - Detectors used for dual-energy radiographic imaging

PROPOSED STABILITY DATE: 2027

NOTE FROM TC/SC OFFICERS:

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT – CHARACTERISTICS OF DIGITAL X-RAY IMAGING DEVICES – Part 2: Determination of dual-energy subtraction efficiency – Detectors used for dual-energy radiographic imaging

FOREWORD

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International Standard IEC 62220-2 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this International Standard is based on the following documents:

FDIS	Report on voting
XX/XX/FDIS	XX/XX/RVD

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

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

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under "http://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.

The National Committees are requested to note that for this document the stability date is 2027.

THIS TEXT IS INCLUDED FOR THE INFORMATION OF THE NATIONAL COMMITTEES AND WILL BE DELETED AT THE PUBLICATION STAGE.

INTRODUCTION

Devices that are capable 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 commercial offerings.

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 commercial offerings.

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 will be beneficial to a number of different parties. It will enable MANUFACTURERS to better optimize and compare systems, expediting internal processes and improving final clinical outcomes. It will support regulatory agencies by providing additional tools to evaluate new DUAL-ENERGY IMAGING devices. Healthcare institutions will 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 will remove 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 must be taken while interpreting results.

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 analyze 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 part of IEC 62220 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 – Characteristics of focal spots*

IEC TR 60788:2004, *Medical electrical equipment – Glossary of defined terms*

IEC 62220-1-1:2015, *Medical electrical equipment – Characteristics of digital X-ray imaging devices – Determination of the detective quantum efficiency – Detectors used in radiographic imaging*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC TR 60788:2004 and the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

3.1
DUAL-ENERGY IMAGING
X-ray imaging technique that includes the acquisition of MULTI-SPECTRAL PRIMARY DATA, and the generation and presentation of one or more corresponding TISSUE-SUBTRACTED IMAGES

3.2
MULTI-SPECTRAL PRIMARY DATA
X-ray data directly derived from RAW DATA of the same object obtained at differing absorbed X-ray spectra

3.3
TISSUE-SUBTRACTED IMAGE
image obtained through TISSUE-SUBTRACTION PROCESSING with the purpose of removing contrast in tissues or structures not relevant to the intended imaging task

3.4
TISSUE-SUBTRACTION PROCESSING
processing of MULTI-SPECTRAL PRIMARY DATA –typically dual-energy logarithmic subtraction– with the goal of removing contrast between structures of similar spectral X-ray ABSORPTION characteristics

3.5
SINGLE-EXPOSURE DEVICE
DIGITAL X-RAY IMAGING DEVICE that achieves the acquisition of MULTI-SPECTRAL PRIMARY DATA with a single IRRADIATION

3.6
MULTI-EXPOSURE DEVICE
DIGITAL X-RAY IMAGING DEVICE that achieves the acquisition of MULTI-SPECTRAL PRIMARY data through multiple IRRADIATIONS obtained at different times and using various X-RAY TUBE VOLTAGE and/or ADDITIONAL FILTRATION

3.7
MULTI-EXPOSURE MOTION ARTIFACTS
image ARTIFACTS present in TISSUE-SUBTRACTED IMAGE that result from object misalignment between the images in the MULTI-SPECTRAL PRIMARY DATA, seen in MULTI-EXPOSURE DEVICES caused by patient motion between IRRADIATIONS

4 Requirements

4.1 Operating conditions

The DIGITAL X-RAY IMAGING DEVICE shall be operated according to MANUFACTURER'S recommendations. The warm-up time shall be chosen according to the recommendations of the MANUFACTURER. The operating conditions shall be the same as those intended for clinical use and shall be maintained during all IRRADIATIONS required for these tests. When multiple clinical use recommendations exist, those that are recommended by the MANUFACTURER for DUAL-ENERGY IMAGING of the chest shall be selected.

4.2 X-RAY EQUIPMENT

For all tests described in the following subclauses, a CONSTANT POTENTIAL HIGH-VOLTAGE GENERATOR is recommended (IEC 60601-2-54). The PERCENTAGE RIPPLE shall be no larger than 4.

The NOMINAL FOCAL SPOT VALUE (IEC 60336) shall be no larger than 1,2.

For the measuring of AIR KERMA, calibrated RADIATION METERS shall be used. The uncertainty (coverage factor 2) of the measurements shall be less than 5 %.