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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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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.

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.

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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;
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- "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;
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- 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*

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 terminology databases for use in standardization at the following addresses:

- IEC Electropedia: available at https://www.electropedia.org/
- ISO Online browsing platform: available at https://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 ARTIFACT
image ARTIFACT present in TISSUE-SUBTRACTED IMAGE that result from object misalignment between the image 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 the 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.