SLOVENSKI STANDARD
SIST EN 62563-1:2010/A2:2021

01-november-2021

Medicinska električna oprema - Sistemi za prikazovanje medicinskih slik - 1. del: Metode vrednotenja - Dopolnilo A2 (IEC 62563-1:2009/AMD2:2021)

Medical electrical equipment - Medical image display systems - Part 1: Evaluation methods (IEC 62563-1:2009/AMD2:2021)

Medizinische elektrische Geräte - Medizinische Bildwiedergabesysteme - Teil 1: Bewertungsmethoden (IEC 62563-1:2009/AMD2:2021)

Appareils électromédicaux - Systèmes d'imagerie médicale - Partie 1: Méthodes d'évaluation (IEC 62563-1:2009/AMD2:2021)

Ta slovenski standard je istoveten z: **EN 62563-1:2010/A2:2021**

ICS:

11.040.55	Diagnostična oprema	Diagnostic equipment

SIST EN 62563-1:2010/A2:2021 **en**

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 62563-1:2010/A2

August 2021

ICS 11.040.55

English Version

Medical electrical equipment - Medical image display systems - Part 1: Evaluation methods (IEC 62563-1:2009/AMD2:2021)

Appareils électromédicaux - Systèmes d'imagerie médicale - Partie 1: Méthodes d'évaluation (IEC 62563-1:2009/AMD2:2021)

Medizinische elektrische Geräte - Medizinische Bildwiedergabesysteme - Teil 1: Bewertungsmethoden (IEC 62563-1:2009/AMD2:2021)

This amendment A2 modifies the European Standard EN 62563-1:2010; it was approved by CENELEC on 2021-08-23. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this amendment the status of a national standard without any alteration.

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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 62563-1:2010/A2:2021 E

European foreword

The text of document 62B/1168/CDV, future IEC 62563-1/AMD2, 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 62563-1:2010/A2:2021.

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) 2022–05–23
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2024–08–23

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Endorsement notice

The text of the International Standard IEC 62563-1:2009/AMD2:2021 was approved by CENELEC as a European Standard without any modification.

IEC 62563-1

Edition 1.0 2021-07

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 2
AMENDEMENT 2

Medical electrical equipment – Medical image display systems – Part 1: Evaluation methods

Appareils electromedicaux – Systemes d'imagerie medicale – Partie 1: Méthodes d'évaluation

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT – MEDICAL IMAGE DISPLAY SYSTEMS –

Part 1: Evaluation methods

AMENDMENT 2

FOREWORD

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This amendment has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this amendment is based on the following documents:

Draft	Report on voting
62B/1168/CDV	62B/1203/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 Amendment 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/standardsdev/publications/.

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 to Amendment 2

This amendment is intended to introduce evaluation methods for handheld display devices.

Add, after the existing Annex C, the following new Annex D:

Annex D
(informative)

Evaluation methods for handheld display devices

D.1 General

This annex describes the evaluation methods that apply to handheld display devices. Handheld display devices are defined as portable (carry-along) image display devices that are typically small and lightweight including smartphones and tablet and notebook computers not specifically for medical use. Handheld devices are convenient, easy to access, and can be of use in emergency situations (including for example natural disasters) and for remote consultation. Current handheld viewing technologies with limited workspaces are unlikely to replace dedicated medical IMAGE DISPLAY SYSTEMS in this document better suited for conventional radiology workflow and standard primary reporting. However, mobile devices are enabling timely patient management and collaboration in care. Clear procedures to promote improved practices in the use of handhelds in emergency situations and for remote consultation are required. The major characteristics of typical handheld device and IMAGE DISPLAY SYSTEMS as defined in this document are listed in Table D.1.

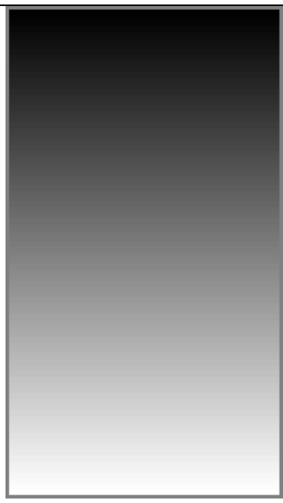
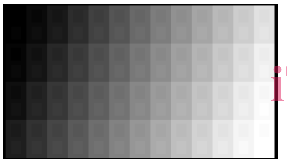
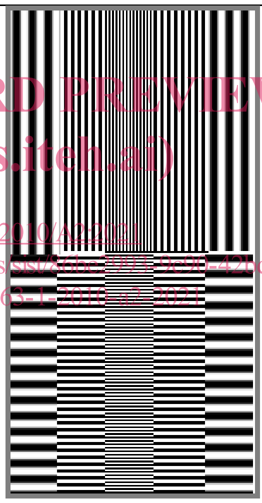
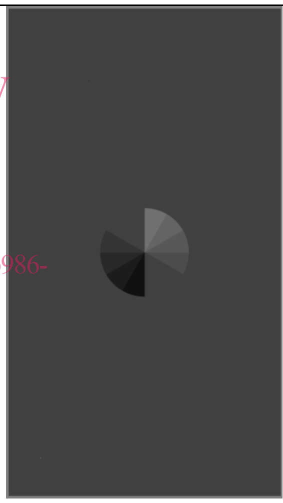
Table D.1 – Major characteristics of typical handheld devices compared to IMAGE DISPLAY SYSTEMS

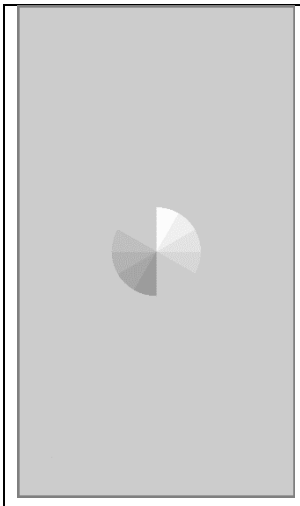
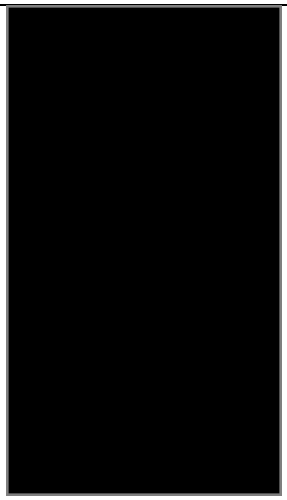
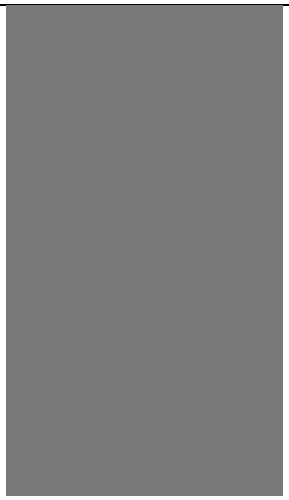
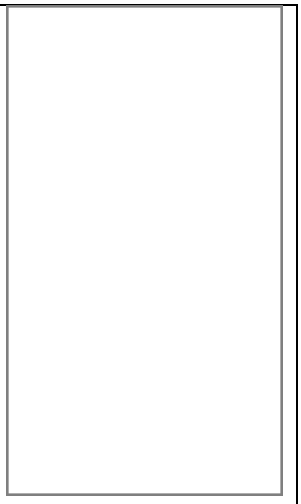
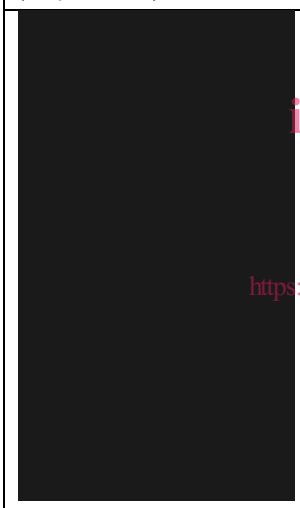
Characteristics	Handheld device	Medical IMAGE DISPLAY SYSTEM (for diagnosis)
Calibration of the LUMINANCE response	Unspecified or not possible	DICOM GSDF
LUMINANCE stability	Uncontrolled	Controlled
Ambient illumination	Variable and uncontrolled	Fixed or controlled
Viewing angle and distance	Variable and uncontrolled	Fixed or limited
QC software	None	Available

D.2 TEST PATTERNS for handheld devices

Table D.2 shows the TEST PATTERNS for handheld devices. Handheld devices can differ from medical IMAGE DISPLAY SYSTEMS in terms of resolution, aspect ratio and screen size. Therefore simple TEST PATTERNS are required. The proposed TEST PATTERNS are described in Table D.4.

Table D.2 – TEST PATTERNS for handheld device

 Hh-Rmp_1H: Ramp delta 1 (horizontal)	 Hh-Rmp_1V: Ramp delta 1 (vertical)	 Hh-Rmp_3H: Ramp delta 3 (horizontal)	 Hh-Rmp_3V: Ramp delta 3 (vertical)
 Hh-Ctr (Landscape): CONTRAST -4/+4	 Hh-Ctr (Portrait): CONTRAST -4/+4	 Hh-SpR: SPATIAL RESOLUTION	 Hh-ANG(64): Angular response (64) (emphasized)

			
Hh-ANG(204): Angular response(204) (emphasized)	Hh-L01(0): LUMINANCE response01(0)	Hh-L09(120): LUMINANCE response09(120)	Hh-L18(255): LUMINANCE response18(255)
			
Hh-UN10(26): Uniformity-10(26)	Hh-UN80(204): Uniformity-80(204)		

D.3 Evaluation methods for handheld devices

D.3.1 General

To perform visual evaluation described in D.3.4 and quantitative evaluation described in D.3.5 by reference to D.3.2, appropriate TEST PATTERNS that have the same display resolutions of handheld device under test shall be used. LUMINANCE response should be evaluated prior to use by performing a visual greyscale test. LUMINANCE uniformity should be evaluated only for handheld devices with 10 inches (25,4 cm) or larger screen size (diagonal). Prior to use, CONTRAST should be evaluated using Hh-Ctr, and pixel resolution should be evaluated using Hh-SpR TEST PATTERN.

D.3.2 Recommended TEST ITEMS

TEST ITEMS recommended are listed in Table D.3.