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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

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

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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

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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/.

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- withdrawn,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.

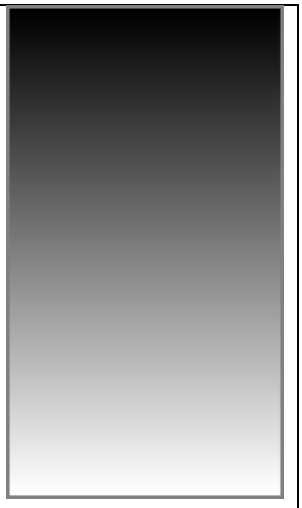
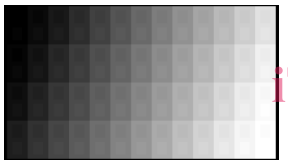
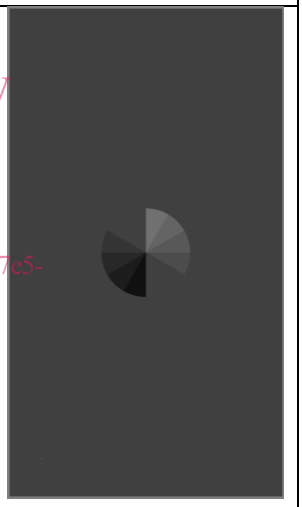
Table D.1 – Major characteristics of typical handheld devices compared to IMAGE DISPLAY SYSTEMS

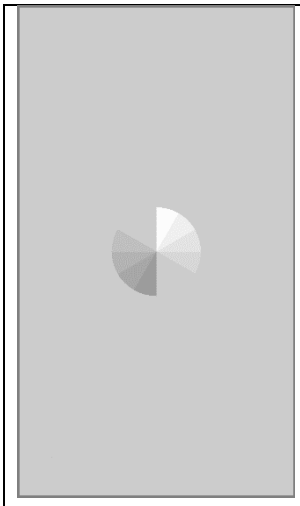
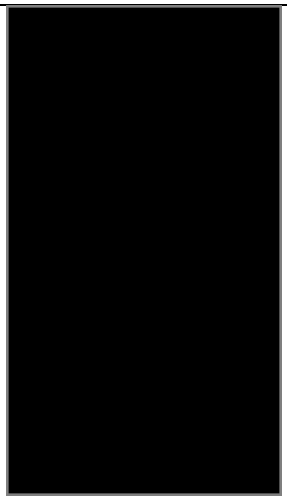
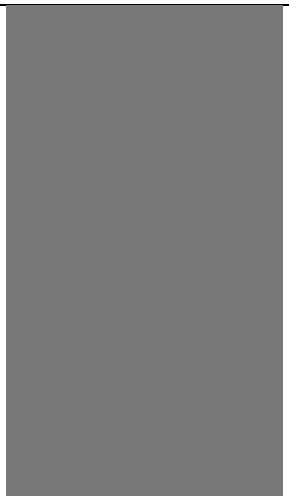
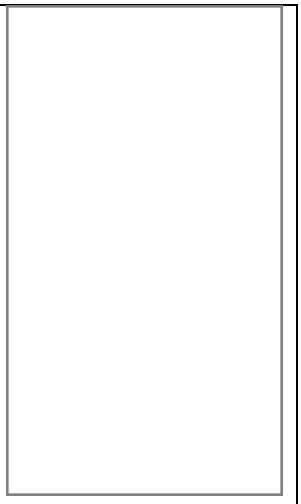
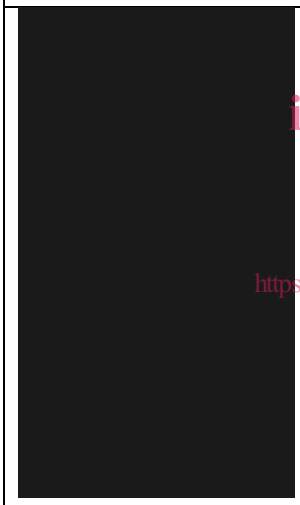
Characteristics	Handheld device	Medical IMAGE DISPLAY SYSTEM (for diagnosis)
Calibration of the LUMINANCE response	Unspecified or not possible	DICOM GSDF
LUMINANCE stability	Uncontrolled	Controlled
Ambient illumination	Variable and uncontrolled	Fixed or controlled
Viewing angle and distance	Variable 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.

Table D.3 – Recommended TEST ITEMS for handheld devices

	TEST ITEM	Prior to use	Acceptance and constancy testing	TEST PATTERN
Visual	Greyscale evaluation	R	HR	Hh-Rmp_1H, 1V
	Greyscale (CONTRAST) resolution evaluation	R	HR	Hh-Rmp_3H, 3V
	CONTRAST evaluation	HR	HR	Hh-Ctr
	Pixel resolution evaluation	HR	HR	Hh-SpR
	Angular viewing evaluation	R	R	Hh-ANG(64), (204)
Measurement	LUMINANCE response test	-	HR	Hh-L01(0)-L18(255)
	LUMINANCE uniformity test	-	HR (for devices larger than 10 inches (25,4 cm) diagonal)	Hh-UN10(26), UN80(204)
Key				
HR	Highly recommended			
R	Recommended			

D.3.3 Conditions of viewing test

Evaluation should be conducted using actual use conditions either in portrait or landscape mode. Scaling shall not be performed in TEST PATTERNS Hh-SpR, Hh-ANG(64), (204). If such TEST PATTERNS are scaled up or down, it should be recognized due to the lack of one or more borders, location of border, or unevenness of line spacing of Hh-SpR.

D.3.4 Visual evaluation method

D.3.4.1 Greyscale evaluation

Evaluate Hh-Rmp_1H, 1V TEST PATTERNS for continuous appearance of greyscale.

D.3.4.2 Greyscale (CONTRAST) resolution evaluation

Evaluate Hh-Rmp_3H, 3V TEST PATTERNS for appearance of greyscale steps of staircase.

D.3.4.3 CONTRAST evaluation

Evaluate Hh-Ctr TEST PATTERN for visibility of two rectangles inside each of the 52 rectangles.

The following diagram (Figure D.1) schematically shows the arrangement of the patches in the Hh-Ctr TEST PATTERN. A full textual description of Hh-Ctr TEST PATTERNS is provided in Table D.4.

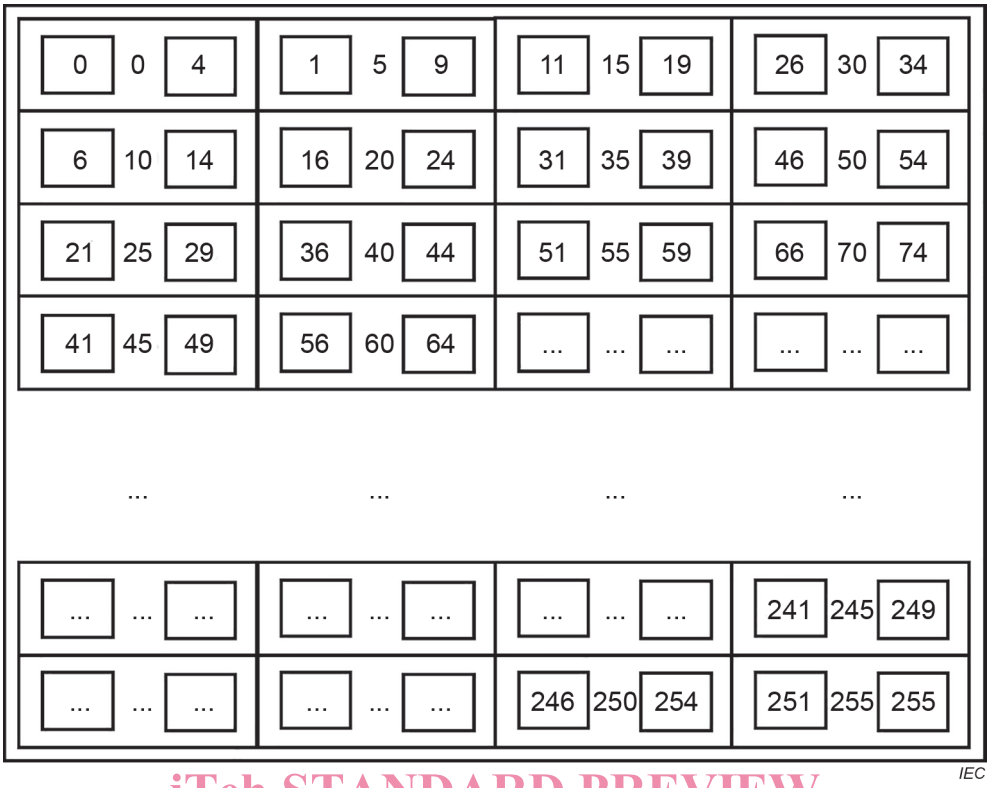


Figure D.1 – Hh-Ctr TEST PATTERN

D.3.4.4 Pixel resolution evaluation

Evaluate the equal interval appearance of Hh-SpR TEST PATTERNS at 3on/3off, 2on/2off and 1on/1off each for horizontal and vertical respectively.

D.3.4.5 Angular viewing evaluation

Read the target in the centre of Hh-ANG(64), (204) TEST PATTERNS (Figure D.2) at perpendicular viewing, and then determine the maximum angle in off-normal directions (for example, in the horizontal and vertical directions) where the number of visible lines is not fewer compared to the perpendicular viewing direction. Both numbers of lines are always between 0 and 10 as shown in Figure D.2.

Figure D.2 – Grey level emphasized angular target

D.3.5 Quantitative evaluation methods

D.3.5.1 LUMINANCE response test

Using a calibrated LUMINANCE meter and the Hh-L01(0)-L18(255) TEST PATTERNS, the LUMINANCE L in the test region shall be measured for all 18 DIGITAL DRIVING LEVEL (DDL) P-values, L(P), by the measurement methods in Annex B. Evaluate the plot appearance (by comparison with ideal curve) and variation from last test.

D.3.5.2 LUMINANCE uniformity test

Measure the LUMINANCE at five locations on the faceplate of the handheld device (centre and four corners) using the Hh-UN10(26), UN80(204) TEST PATTERNS and method A or B in Annex B. The maximum LUMINANCE deviation is calculated as a percent difference between the highest and lowest LUMINANCE values relative to their average value, 200 × ($L_{highest}$ - L_{lowest}) / ($L_{highest}$ + L_{lowest}).

D.4 Description of TEST PATTERNS for handheld devices

The TEST PATTERN's matrix size shall fit into the screen matrix size of the handheld device and it is essential to make a one-on-one relationship between the image pixels and the display pixels. Pixel dimensions, locations and pixel values of each feature are described in Table D.4. The width of borders within patterns except for Hh-Ctr and Hh-UN10(26), UN80(204) are set to 0,5 % of the long side of the handheld device. The border is used to see if borders are on the edges of the screen correctly or not, to make sure TEST PATTERNS are not scaled. The parameters indicated in the Table D.4 show the number of pixels. For example the value of Hh-Rmp_1H with a matrix size of 1 080 × 1 920 for handheld device. Short side: S = 1 080, Long side: L = 1 920, Border: B = 10, Width of a ramp: N_H=1 060, Width of a patch: P_H=4 or 5.

Table D.4 – Description of TEST PATTERNS for handheld devices

TEST PATTERN/features	Pixel dimensions and location	Pixel values 8-bit
Hh-Rmp_1H		
Border	The width of the border (equal for both the long and the short side of the display) is 0,5 % of the number of pixels in the long direction – rounded up to the nearest integer value. B = ROUNDUP (L × 0,5 %)	128
LUMINANCE ramp	A LUMINANCE ramp is arranged to the right side from the left side in the area except for border from background of a display. Ramp width $N_H = S - B \times 2$.	0, 1, …, 255 n=256
Width of a patch	Width of a patch $P_H = N_H / 256$ Adjust the width as appropriate.	
Hh-Rmp_1V		
Border	The width of the border (equal for both the long and the short side of the display) is 0,5 % of the number of pixels in the long direction – rounded up to the nearest integer value. B = ROUNDUP (L × 0,5 %)	128
LUMINANCE ramp	A LUMINANCE ramp is arranged to the lower side from the upper side in the area except for border from background of a display. Ramp width $N_V = L - B \times 2$	0, 1, …, 255 n=256

TEST PATTERN/features	Pixel dimensions and location	Pixel values 8-bit
Width of a patch	Width of a patch $P_V = N_V / 256$ Adjust the width as appropriate	
Hh-Rmp_3H		
Border	The width of the border (equal for both the long and the short side of the display) is 0,5 % of the number of pixels in the long direction – rounded up to the nearest integer value. B = ROUNDUP(L × 0,5 %)	128
CONTRAST resolution pattern	A CONTRAST resolution pattern is arranged at equal intervals to the right side from the left side except for border from background of a display. Pattern width $N_H = S – B × 2$	0, 3, …, 255
Width of a patch	Width of a patch $P_H = N_H / 86$ Adjust the width as appropriate.	
Hh-Rmp_3V		
Border	The width of the border (equal for both the long and the short side of the display) is 0,5 % of the number of pixels in the long direction – rounded up to the nearest integer value. B = ROUNDUP(L × 0,5 %)	128
CONTRAST resolution pattern	A CONTRAST resolution pattern is arranged at equal intervals to the lower side from the upper side except for border from background of a display. Pattern width $N_V = L – B × 2$	0, 3, …, 255
Width of a patch	Width of a patch $P_V = N_V / 86$ Adjust the width as appropriate.	
Hh-Ctr (Portrait)		
Border	Border thickness is at least 0,5 % of the long size of the pattern. If needed, the thickness of the vertical borders shall be increased until the width of the central area is a multiple of 4 pixels. If needed, the thickness of the horizontal borders shall be increased until the height of the central area is a multiple of 13 pixels.	0
Background rectangles	52 background rectangles are arranged in a grid of 4 columns and 13 rows. The first rectangle with pixel value 0 is located at the top left position (0, 0) in the grid. The following rectangles are following diagonal lines with the following positions (horizontal, vertical) in the grid: (1,0), (0,1), (2,0), (1,1), (0,2), (3,0), (2,1), (1,2), (0,3), (3,1), (2,2), (1,3), (0,4), (3, 2), …	0, 5, …, 255
Foreground rectangles	Inside each background rectangle, two smaller foreground rectangles are present: one foreground rectangle (left) with pixel value (background rectangle pixel value - 4) and one foreground rectangle (right) with pixel value (background rectangle pixel value + 4). Inside the first background rectangle, where the background pixel value is 0, the left foreground rectangle has pixel value 0. Inside the last background rectangle, where the background pixel value is 255, the right foreground rectangle has pixel value 255. The two foreground rectangles inside each background rectangle should be separated vertically and horizontally from the border of the background rectangle, and horizontally from each other, with a distance which is approximately 25 % of the height of the background rectangle.	-4/+4