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INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

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

Appareils électromédicaux – Systèmes d'imagerie médicale – Partie 1: Méthodes d'évaluation

IEC 62563-1:2009

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT – MEDICAL IMAGE DISPLAY SYSTEMS –

Part 1: Evaluation methods

FOREWORD

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International Standard IEC 62563-1 has been prepared by subcommittee 62B: Diagnostic imaging equipment of technical committee 62: Electrical equipment in medical practice.

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

Enquiry draft	Report on voting
62B/743/CDV	62B/768/RVC

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

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

In this standard, the following print types are used:

– requirements and definitions: roman type;

– informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;

– TERMS DEFINED IN CLAUSE 3 OF THIS INTERNATIONAL STANDARD, OR AS NOTED: SMALL CAPITALS.

A list of all parts of the IEC 62563 series, published under the general title *Medical electrical equipment – Medical image display systems,* can be found on the IEC website.

The committee has decided that the contents of this publication will remain unchanged until the maintenance result date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

INTRODUCTION

This International Standard provides evaluation methods for testing IMAGE DISPLAY SYSTEMS used in MEDICAL ELECTRICAL EQUIPMENT and medical electrical systems for diagnostic imaging.

On site or after installation, two types of testing can be carried out. An acceptance test is carried out after a new IMAGE DISPLAY SYSTEM has been installed, or major modifications have been made to the existing IMAGE DISPLAY SYSTEM. Since an IMAGE DISPLAY SYSTEM may degrade over time, the constancy test is carried out by the user in a periodic cycle to verify that the performance is maintained for the intended use.

The standard describes various evaluation methods without dictating what particular tests shall be used for acceptance and/or constancy tests.

Rather, it is the intention of this standard to be a reference for other standards and guidelines specific to each modality or to be defined by national authorities who will refer to the evaluation methods of this standard and mention limiting values and frequencies for acceptance and constancy tests. Annex A shows sample reports of such a reference.

To maintain the homogeneity in the IEC standards for MEDICAL ELECTRICAL EQUIPMENT, IEC 61223-2-5, *Evaluation and routine testing in medical imaging departments – Part 2-5: Constancy tests – Image display devices* should be reviewed.

MEDICAL ELECTRICAL EQUIPMENT – MEDICAL IMAGE DISPLAY SYSTEMS –

Part 1: Evaluation methods

1 Scope

This part of IEC 62563 describes the evaluation methods for testing medical IMAGE DISPLAY SYSTEMS.

The scope of this International Standard is directed to practical tests that can be visually evaluated or measured using basic test equipment. More advanced or more quantitative measurements can be performed on these devices, but these are beyond the scope of this document.

This standard applies to medical IMAGE DISPLAY SYSTEMS, which can display monochrome image information in the form of greyscale values on colour and greyscale IMAGE DISPLAY SYSTEMS (e.g. CATHODE RAY TUBE (CRT) monitors, FLAT PANEL DISPLAYS, PROJECTION SYSTEM). This standard applies to medical IMAGE DISPLAY SYSTEMS used for diagnostic (interpretation of medical images toward rendering clinical diagnosis) or viewing (viewing medical images for medical purposes other than for providing a medical interpretation) purposes and therefore having specific requirements in terms of image quality. Head mounted IMAGE DISPLAY SYSTEMS and IMAGE DISPLAY SYSTEMS used for confirming positioning and for operation of the system are not covered by this standard.

It is not in the scope of this standard to define the requirements of acceptance and constancy tests nor the frequencies of constancy tests.

2 Normative references

The following referenced documents are indispensable for the application 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 60788:2004, *Medical electrical equipment – Glossary of defined terms*

ISO 11664-1:2007, *Colorimetry – Part 1: CIE standard colorimetric observers*

CIE S 010/E:2004 *Photometry – The CIE system of physical photometry*

3 Terms, definitions, symbols and abbreviations

3.1 Terms and definitions

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

3.1.1
accuracy
closeness of agreement between a test result and the accepted reference value

[ISO 5725-1:1994, definition 3.6]

3.1.2
brightness
LUMINANCE as perceived by the human visual system

3.1.3
cathode ray tube
CRT
picture tube
component of an IMAGE DISPLAY SYSTEM in which images defined via electrical signals are visualized by means of an electron beam striking a phosphor

3.1.4
clinical reference image
specific medical image typical for the intended use of the IMAGE DISPLAY SYSTEM

NOTE The anatomical patterns reported in Annex C are examples of CLINICAL REFERENCE IMAGE.

3.1.5
clock artefact
artefact in form of distorted vertical bars or stripes, visible on the screens of fixed-pixel type IMAGE DISPLAY DEVICES (e.g. LCD), when the frequency of the internal dot clock is different from that of the incoming analogue signal

3.1.6
contrast

<IMAGE DISPLAY DEVICES> ratio of the difference of the LUMINANCE of two image areas, L_1 - L_2, divided by the average of the two LUMINANCE values:

$$\text{CONTRAST} = 2 \cdot (L_1 - L_2)/(L_1 + L_2)$$

3.1.7
digital driving level
DDL
digital value given as input to an IMAGE DISPLAY SYSTEM producing a LUMINANCE

3.1.8
display controller
electronic component of an IMAGE DISPLAY SYSTEM that provides the analogue or digital interface between the computer hardware and the IMAGE DISPLAY DEVICE

3.1.9
flat panel display
IMAGE DISPLAY DEVICE that is flat and thin

NOTE E.g. liquid crystal display (LCD), plasma display (PDP), field emission display (FED), surface-conduction electron-emitter display (SED), carbon-nano-tube display (CNT), organic light-emitting display (OLED).

3.1.10
flicker
perception of unintentional fluctuations of the LUMINANCE over time

3.1.11
greyscale standard display function
GSDF
mathematically defined mapping of input, DIGITAL DRIVING LEVEL (DDL) to LUMINANCE values based on the Barten model

[Source: DICOM PS 3.14:2007, see [2][1)]]

3.1.12
illuminance
measurement of the luminous flux incident on a surface per unit area (unit: Lux (lx), lx = lm/m^2)

3.1.13
image display device
monitor
specific hardware/medium used to display images presented through an analogue or digital interface

3.1.14
image display system
workstation consisting of an IMAGE DISPLAY DEVICE, DISPLAY CONTROLLER and computer hardware and software, capable of displaying images

3.1.15
luminance
ratio of luminous flux penetrating (impinging on) a surface area in a specified direction to the product of the irradiated solid angle and the projection of the surface area onto a plane perpendicular to the viewing direction (unit: candela per square meter (cd/m^2))

NOTE This definition has been derived from the term in DIN 5031-3:1982-03 [18] and is equivalent to the definition in the International Electrotechnical Vocabulary (IEV).

3.1.16
phase artefact
artefact in form of blurred edges of displayed objects (letters, lines, etc.), visible on the screens of fixed-pixel type IMAGE DISPLAY DEVICES (e.g. LCD), when the phase setting of the internal dot clock is different from that of the incoming analogue signal

3.1.17
precision
closeness of agreement between independent test results obtained under stipulated conditions

[ISO 5725-1:1994, definition 3.12]

3.1.18
projection system
large-screen IMAGE DISPLAY DEVICE which enlarges the small image generated on a plane by central projection to a second plane

3.1.19
resolution addressability ratio
RAR
measured pixel at 50 % point of LUMINANCE at peak or nominal rating expressed as a percentage of addressable space available

3.1.20
spatial resolution
measure of the ability of an IMAGE DISPLAY SYSTEM to distinguish spatial features of interest within an image

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1) Figures in square brackets refer to the Bibliography.

NOTE Systems designed with adequate SPATIAL RESOLUTION characteristics are necessary to assure that spatial details of interest are preserved when a medical image is displayed. Portraying image data on a IMAGE DISPLAY DEVICE with insufficient resolution will compromise the ACCURACY of the radiological interpretation.

3.1.21
test image
test pattern
image for testing or verifying the IMAGE DISPLAY SYSTEMS

3.1.22
veiling glare
enhancement of the LUMINANCE measurable on the IMAGE DISPLAY DEVICE caused by internal scatter processes

NOTE The value of the LUMINANCE enhancement is dependent on the illuminated portion of the image displayed.

3.1.23
window setting
display of a subset of the pixel values existing in the digital image

NOTE The WINDOW SETTING is determined by the window width and level (centre) and serves for CONTRAST enhancement.

3.2 Symbols

The symbols of physical parameters used in this standard are listed in Table 1. All measurements referred to in Table 1 are in the centre of the IMAGE DISPLAY DEVICE. Note that LUMINANCE may also be measured at other locations according to the methodologies described in this document.

Table 1 – Overview to the definitions of physical parameters

Abbreviation	Mathematically derived	Definition and explanation
L_{amb}		LUMINANCE generated by the ambient light on the surface of an IMAGE DISPLAY DEVICE when the IMAGE DISPLAY DEVICE is off.
L_{min}		Minimum LUMINANCE generated by a IMAGE DISPLAY DEVICE at DIGITAL DRIVING LEVEL (DDL) = 0 measured at the centre of the screen. It includes VEILING GLARE specific to TEST PATTERN used for measurement. It is measured with ambient light totally switched off (in the dark).
L_{max}		Maximum LUMINANCE generated by a IMAGE DISPLAY DEVICE at DIGITAL DRIVING LEVEL (DDL) = max measured at the centre of the screen. It includes VEILING GLARE specific to TEST PATTERN used for measurement. It is measured with ambient light totally switched off (in the dark).
L'_{min}	$L_{min} + L_{amb}$	LUMINANCE that will be perceived by the human eye at the centre of the screen at DIGITAL DRIVING LEVEL (DDL) = 0. It contains VEILING GLARE and L_{amb}
L'_{max}	$L_{max} + L_{amb}$	LUMINANCE produced by the IMAGE DISPLAY DEVICE at the maximum DIGITAL DRIVING LEVEL (DDL) measured at the centre of the screen. It contains VEILING GLARE and L_{amb}.
R_d		Diffuse reflection coefficient (provided by manufacturer with a specific measurement method, ideally following the methods described in Reference [10] using a CIE standard illuminant A and an aperture size 20 to 30 % larger than the diameter of the LUMINANCE meter).
r'	L'_{max}/L'_{min}	LUMINANCE ratio of an IMAGE DISPLAY DEVICE containing VEILING GLARE and ambient LUMINANCE.
E		ILLUMINANCE.
a	L_{amb}/L'_{min}	Safety factor.
$\Delta u'v'$	$((u_1'-u_2')^2 + (v_1'-v_2')^2)^{1/2}$	Maximum distance in u'-v' space.

3.3 Abbreviations

The following abbreviations are used in this standard.

CRT cathode ray tube
CT computed tomography
DDL digital driving level
DICOM digital imaging and communication in medicine
LCD liquid crystal display
MR magnetic resonance

4 General

In IMAGE DISPLAY SYSTEMS, every individual component can limit or reduce the image quality of the system. Therefore it is necessary to adopt suitable measures for quality monitoring. If IMAGE DISPLAY SYSTEMS are correctly adjusted and maintained, these devices can consistently generate similar images.

Simple test equipment is used (LUMINANCE meter, TEST IMAGES) with PRECISION appropriate for the purpose of a test. Before a test, all test equipment shall be checked for its functioning according to the manufacturer's specifications.

The manufacturer's data (e.g. requirements on operating voltage, humidity etc.) are required for the correct setting of the IMAGE DISPLAY SYSTEM and for correct installation. The manufacturer's data shall be enclosed with the technical documentation of the IMAGE DISPLAY SYSTEM.

The tests listed in this International Standard are a compilation of all the evaluation methods that may be used for testing an IMAGE DISPLAY SYSTEM. A subset of these test items or test methods may be selected and applied in any order depending on the intended purpose of the IMAGE DISPLAY SYSTEM.

For mobile systems, a fixed location for these tests shall be determined and used so that it is representative for the locations where such mobile systems may be used. Care should be taken to ensure that the ambient lighting in these areas can be adequately controlled.

5 Prerequisites

Prior to testing an IMAGE DISPLAY SYSTEM, the following shall be considered:

a) The testing of an IMAGE DISPLAY SYSTEM shall include the complete system including software, hardware and settings involved in image handling.
b) For all IMAGE DISPLAY SYSTEMS to be tested, all components including computer, IMAGE DISPLAY DEVICE, display card, display software, and software version shall be traceable.
c) The TEST IMAGES and the clinical images shall be presented in the same way on the IMAGE DISPLAY SYSTEM.
d) Before starting the tests, the front surface of the IMAGE DISPLAY DEVICE shall be cleaned according to the instructions for use.
e) It shall be ensured that no prior nominal settings have been changed.
f) Room lights, windows, viewing devices etc. shall not cause any disturbing reflections on the IMAGE DISPLAY DEVICE. Methods to prevent reflections are described in the standards ISO 9241-302, ISO 9241-303, ISO 9241-305 and ISO 9241-307.
g) The ambient lighting in the room shall be maintained at normally used conditions.

h) Before initiating a test, the IMAGE DISPLAY SYSTEM shall be installed and started up according to the manufacturer's recommendations; to ensure stable performance, the IMAGE DISPLAY DEVICE shall be switched on before the test for a period as specified by the manufacturer (e.g. 30 min). The IMAGE DISPLAY SYSTEM should be set to the desired display function. The GREYSCALE STANDARD DISPLAY FUNCTION (GSDF) is recommended and is a necessary prerequisite for some tests.

6 Equipment and tools

6.1 LUMINANCE meter

A LUMINANCE meter shall have the following specifications. The range of the LUMINANCE meter shall cover at least the range of LUMINANCE of the IMAGE DISPLAY SYSTEM with a PRECISION of at most 5 % (repeatability), and an ACCURACY of at most 10 %, with a calibration traceable to a primary standards laboratory. The manufacturer of the meter shall provide a clear calibration program. The aperture angle shall not exceed 5°. The relative spectral sensitivity shall correspond to the BRIGHTNESS CIE standard photopic spectral response (CIE S 010/E:2004). The influence of the photopic response shall be within the overall ±10 % ACCURACY described in this paragraph.

For near range LUMINANCE meters, a predefined angle and distance of measurement result in a defined measurement field size. During a measurement, the area to be measured shall be displayed by a field (or patch) that is significantly bigger than the defined measurement field size.

A LUMINANCE meter can be integrated into the IMAGE DISPLAY SYSTEM or be a stand-alone device.

6.2 ILLUMINANCE meter

An ILLUMINANCE meter may be required for testing IMAGE DISPLAY SYSTEMS with a range of 1 to 1 000 lux with an ACCURACY of at most 10 % and a PRECISION of at most 5 % (repeatability). The device calibration shall be traceable to a primary standards laboratory and shall have a clear calibration program. It shall have a uniform response to a Lambertian light source.

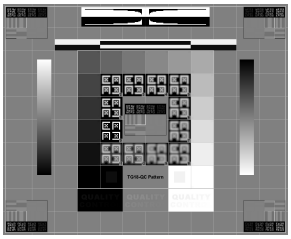
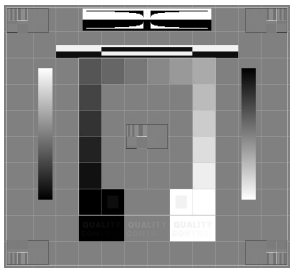
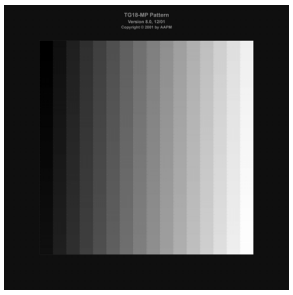
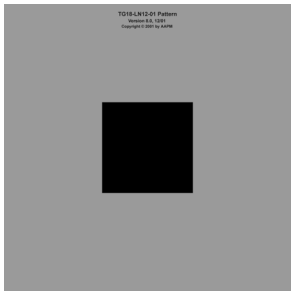
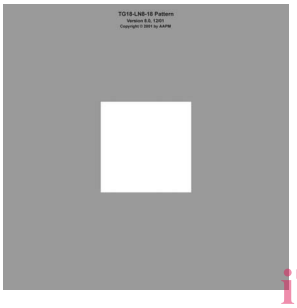
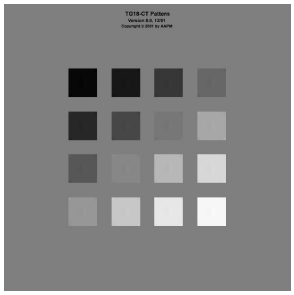
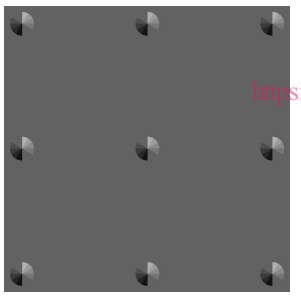
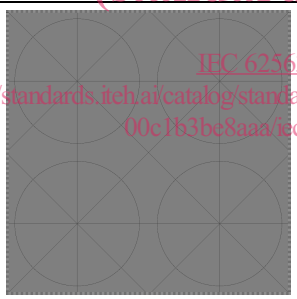
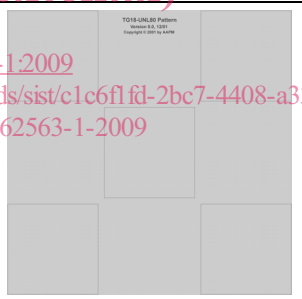
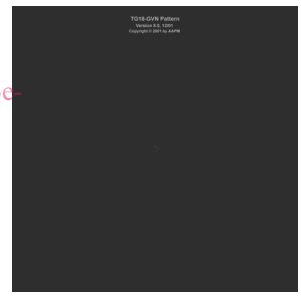
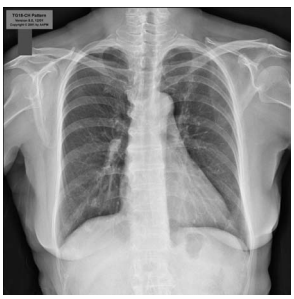
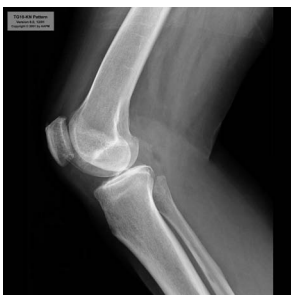
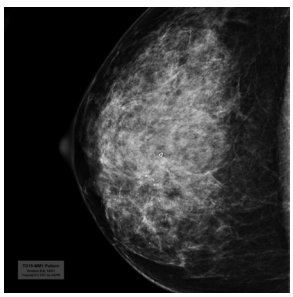
In measurement method B, C and D (described in Annex B), the ILLUMINANCE meter is ideally located at the centre of the screen facing outward. Side locations will also be acceptable as long as they provide similar measured values.

6.3 Colour meter

A colour meter may be required for testing IMAGE DISPLAY SYSTEMS. The meter shall be able to evaluate the CIE-specified (ISO11664-1:2007) colour coordinate with better than ±0,004 ACCURACY in the u',v' space (0,007 in the x,y space) for a standard illuminant, within the LUMINANCE range of the IMAGE DISPLAY SYSTEM. The device calibration shall be traceable to a primary measurement standard and shall have a clear calibration program.

6.4 TEST PATTERNS

Table 2 – TEST PATTERNS used for display testing

 TG18-QC for overall testing CATHODE RAY TUBE (CRT and LCD)	 OIQ for overall testing (LCD)	 TG18-MP for LUMINANCE resolution	 TG18-LN8-01 for LUMINANCE
 TG18-LN8-18 for LUMINANCE	 TG18-UN10 for LUMINANCE uniformity	 TG18-UN80 for LUMINANCE uniformity	 TG18-CT for LUMINANCE response
 ANG for angular response	 GD for geometrical properties	 TG18-UNL80 for LUMINANCE uniformity	 TG18-GVN for VEILING GLARE
 TG18-GV for VEILING GLARE	 TG18-CH as example chest radiograph	 TG18-KN as example extremity radiograph	 TG18-MM1 as example mammogram