

INTERNATIONAL STANDARD

NORME INTERNATIONALE



**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

<https://standards.iteh.ai/catalog/standards/iec/c1c6f1fd-2bc7-4408-a33e-00c1b3be8aaa/iec-62563-1-2009>



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IEC 62563-1

Edition 1.1 2016-03
CONSOLIDATED VERSION

INTERNATIONAL STANDARD

NORME INTERNATIONALE



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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

ICS 11.040.55

ISBN 978-2-8322-3270-5

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VERSION REDLINE



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INTERNATIONAL ELECTROTECHNICAL COMMISSION

**MEDICAL ELECTRICAL EQUIPMENT –
MEDICAL IMAGE DISPLAY SYSTEMS –****Part 1: Evaluation methods**

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This consolidated version of the official IEC Standard and its amendment has been prepared for user convenience.

IEC 62563-1 edition 1.1 contains the first edition (2009-12) [documents 62B/743/CDV and 62B/768/RVC] and its amendment 1 (2016-03) [documents 62B/983/CDV and 62B/995/RVC].

In this Redline version, a vertical line in the margin shows where the technical content is modified by amendment 1. Additions are in green text, deletions are in strikethrough red text. A separate Final version with all changes accepted is available in this publication.

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

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 the base publication and its amendment will remain unchanged until the stability 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

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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.

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INTRODUCTION to Amendment 1

This amendment is published to introduce colour measurement.

Since publication of IEC 62563-1:2009, IEC 61223-2-5, *Evaluation and routine testing in medical imaging departments Part 2-5: Constancy tests – Image display devices* has been reviewed and withdrawn.

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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 on greyscale and colour~~ 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. **Handheld IMAGE DISPLAY SYSTEMS might require additional or modified versions of the procedures described in this standard.**

It is not in the scope of this standard to define the requirements of acceptance and constancy tests ~~or~~ 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

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

1) Figures in square brackets refer to the Bibliography.