IEC 62563-1

Edition 1.1 2016-03
CONSOLIDATED VERSION

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 62563-1:2009-12+AMD1:2016-03 CSV(en-fr)

IEC Central Office
3, rue de Varembé
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
Fax: +41 22 919 03 00
info@iec.ch
www.iec.ch

About the IEC
The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

About IEC publications
The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigenda or an amendment might have been published.

IEC Catalogue - webstore.iec.ch/catalogue
The stand-alone application for consulting the entire bibliographical information on IEC International Standards, Technical Specifications, Technical Reports and other documents. Available for PC, Mac OS, Android Tablets and iPad.

IEC publications search - www.iec.ch/searchpub
The advanced search enables to find IEC publications by a variety of criteria (reference number, text, technical committee,…). It also gives information on projects, replaced and withdrawn publications.

IEC Just Published - webstore.iec.ch/justpublished
Stay up to date on all new IEC publications. Just Published details all new publications released. Available online and also once a month by email.

Electropedia - www.electropedia.org
The world's leading online dictionary of electronic and electrical terms containing 20 000 terms and definitions in English and French, with equivalent terms in 15 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

IEC Glossary - std.iec.ch/glossary
65 000 electrotechnical terminology entries in English and French extracted from the Terms and Definitions clause of IEC publications issued since 2002. Some entries have been collected from earlier publications of IEC TC 37, 77, 86 and CISPR.

IEC Customer Service Centre - webstore.iec.ch/csc
If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: csc@iec.ch.

A propos de l'IEC
La Commission Electrotechnique Internationale (IEC) est la première organisation mondiale qui élabore et publie des Normes internationales pour tout ce qui a trait à l'électricité, à l'électronique et aux technologies apparentées.

A propos des publications IEC
Le contenu technique des publications IEC est constamment revu. Veuillez vous assurer que vous possédez l'édition la plus récente, un corrigendum ou amendement peut avoir été publié.

Catalogue IEC - webstore.iec.ch/catalogue
Application autonome pour consulter tous les renseignements bibliographiques sur les Normes internationales, Spécifications techniques, Rapports techniques et autres documents de l'IEC. Disponible pour PC, Mac OS, tablettes Android et iPad.

Recherche de publications IEC - www.iec.ch/searchpub
La recherche avancée permet de trouver des publications IEC en utilisant différents critères (numéro de référence, texte, comité d'études,…). Elle donne aussi des informations sur les projets et les publications remplacées ou retirées.

IEC Just Published - webstore.iec.ch/justpublished
Restez informé sur les nouvelles publications IEC. Just Published détaille les nouvelles publications parues. Disponible en ligne et aussi une fois par mois par email.

Electropedia - www.electropedia.org
Le premier dictionnaire en ligne de termes électroniques et électriques. Il contient 20 000 termes et définitions en anglais et en français, ainsi que les termes équivalents dans 15 langues additionnelles. Egalement appelé Vocabulaire Electrotechnique International (IEV) en ligne.

Glossaire IEC - std.iec.ch/glossary
65 000 entrées terminologiques électrotechniques, en anglais et en français, extraites des articles Termes et Définitions des publications IEC parues depuis 2002. Plus certaines entrées antérieures extraites des publications des CE 37, 77, 86 et CISPR de l'IEC.

Service Clients - webstore.iec.ch/csc
Si vous désirez nous donner des commentaires sur cette publication ou si vous avez des questions contactez-nous: csc@iec.ch.

IEC 62563-1

Edition 1.1 2016-03
CONSOLIDATED VERSION

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

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

ICS 11.040.55

ISBN 978-2-8322-3270-5

IEC 62563-1

Edition 1.1 2016-03
CONSOLIDATED VERSION

REDLINE VERSION

VERSION REDLINE

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 62563-1:2009-12+AMD1:2016-03 CSV(en-fr)

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –
MEDICAL IMAGE DISPLAY SYSTEMS –

Part 1: Evaluation methods

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.

2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.

3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.

4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.

5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.

6) All users should ensure that they have the latest edition of this publication.

7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.

8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.

9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

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

- 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.

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.

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 ~~n~~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

[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

1) Figures in square brackets refer to the Bibliography.