SLOVENSKI STANDARD
SIST EN 62563-1:2010

01-maj-2010

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

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

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

Appareils électromédicaux - Systèmes d'imagerie médicale - Partie 1: Méthodes d'évaluation (CEI 62563-1:2009)

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

ICS:

11.040.55	Diagnostična oprema	Diagnostic equipment

SIST EN 62563-1:2010 **en,fr**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 62563-1

March 2010

ICS 11.040.55

English version

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

(IEC 62563-1:2009)

Appareils électromédicaux - Systèmes d'imagerie médicale - Partie 1: Méthodes d'évaluation (CEI 62563-1:2009)

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

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Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

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CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

Central Secretariat: Avenue Marnix 17, B - 1000 Brussels

Ref. No. EN 62563-1:2010 E

Foreword

The text of document 62B/743/CDV, future edition 1 of IEC 62563-1, 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 was approved by CENELEC as EN 62563-1 on 2010-03-01.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN and CENELEC shall not be held responsible for identifying any or all such patent rights.

The following dates were fixed:

– latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2010-12-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2013-03-01

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.

Annex ZA has been added by CENELEC.

Endorsement notice

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

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

[1]	ISO 9241-302	NOTE	Harmonized as EN ISO 9241-302.
[19]	IEC 61223-2-5	NOTE	Harmonized as EN 61223-2-5.
[20]	ISO 9241-303	NOTE	Harmonized as EN ISO 9241-303.
[21]	ISO 9241-305	NOTE	Harmonized as EN ISO 9241-305.
[22]	ISO 9241-307	NOTE	Harmonized as EN ISO 9241-307.

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

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.

NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Publication	Year	Title	EN/HD	Year
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-
ISO 11664-1	2007	Colorimetry - Part 1: CIE standard colorimetric observers	-	-
CIE S010/E	2004	Photometry - The CIE system of physical photometry	-	-

IEC 62563-1

Edition 1.0 2009-12

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

PRICE CODE
CODE PRIX XA

ICS 11.040.55

ISBN 2-8318-1073-5

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.
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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.