



**NSAI**  
Standards

Irish Standard  
I.S. EN 62563-1:2010&A1:2016

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

**I.S. EN 62563-1:2010&A1:2016**

*Incorporating amendments/corrigenda/National Annexes issued since publication:*

EN 62563-1:2010/A1:2016

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## National Foreword

I.S. EN 62563-1:2010&A1:2016 is the adopted Irish version of the European Document EN 62563-1:2010, Medical electrical equipment - Medical image display systems - Part 1: Evaluation methods

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EUROPEAN STANDARD  
NORME EUROPÉENNE  
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**EN 62563-1:2010/A1**

June 2016

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English Version

**Medical electrical equipment - Medical image display systems -  
Part 1: Evaluation methods  
(IEC 62563-1:2009/A1:2016)**

Appareils électromédicaux - Systèmes d'imagerie médicale -  
Partie 1: Méthodes d'évaluation  
(IEC 62563-1:2009/A1:2016)

Medizinische elektrische Geräte - Medizinische  
Bildwiedergabesysteme - Teil 1: Bewertungsmethoden  
(IEC 62563-1:2009/A1:2016)

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

**CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels**

**EN 62563-1:2010/A1:2016**

**European foreword**

The text of document 62B/983/CDV, future IEC 62563-1:2009/A1, 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 approved by CENELEC as EN 62563-1:2010/A1:2016.

The following dates are fixed:

- latest date by which the document has to be implemented at (dop) 2017-01-28  
national level by publication of an identical national  
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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  
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European Committee for Electrotechnical Standardization  
Comité Européen de Normalisation Electrotechnique  
Europäisches Komitee für Elektrotechnische Normung

**Central Secretariat: Avenue Marnix 17, B - 1000 Brussels**

## 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.

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In this standard, the following print types are used:

- requirements and definitions: roman type;
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- TERMS DEFINED IN CLAUSE 3 OF THIS INTERNATIONAL STANDARD, OR AS NOTED: SMALL CAPITALS.

Annex ZA has been added by CENELEC.

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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.

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

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Edition 1.0 2009-12

# **INTERNATIONAL STANDARD**

# **NORME INTERNATIONALE**



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

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



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# INTERNATIONAL STANDARD

## NORME INTERNATIONALE



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

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

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## CONTENTS

|   |    |
|---|----|
| FOREWORD.....   | 4  |
| INTRODUCTION.....   | 6  |
| 1 Scope.....  | 7  |
| 2 Normative references .....                                | 7  |
| 3 Terms, definitions, symbols and abbreviations.....        | 7  |
| 3.1 Terms and definitions .....                             | 7  |
| 3.2 Symbols .....   | 10 |
| 3.3 Abbreviations .....                                     | 11 |
| 4 General .....   | 11 |
| 5 Prerequisites .....                                       | 11 |
| 6 Equipment and tools.....                                  | 12 |
| 6.1 LUMINANCE meter .....                                   | 12 |
| 6.2 ILLUMINANCE meter.....                                  | 12 |
| 6.3 Colour meter .....                                      | 12 |
| 6.4 TEST PATTERNS .....                                     | 13 |
| 7 Evaluation methods .....                                  | 14 |
| 7.1 General.....  | 14 |
| 7.2 Evaluation method table overview .....                  | 14 |
| 7.3 Visual evaluation methods.....                          | 16 |
| 7.3.1 General .....   | 16 |
| 7.3.2 Overall image quality evaluation .....                | 16 |
| 7.3.3 Greyscale resolution evaluation.....                  | 17 |
| 7.3.4 LUMINANCE response evaluation.....                    | 18 |
| 7.3.5 LUMINANCE uniformity evaluation.....                  | 19 |
| 7.3.6 Chromaticity evaluation .....                         | 19 |
| 7.3.7 Pixel faults evaluation.....                          | 19 |
| 7.3.8 VEILING GLARE evaluation .....                        | 20 |
| 7.3.9 Geometrical image evaluation.....                     | 20 |
| 7.3.10 Angular viewing evaluation .....                     | 21 |
| 7.3.11 Clinical evaluation .....                            | 22 |
| 7.4 Quantitative evaluation methods.....                    | 22 |
| 7.4.1 Basic LUMINANCE evaluation.....                       | 22 |
| 7.4.2 Basic LUMINANCE evaluation without ambient light..... | 23 |
| 7.4.3 LUMINANCE response evaluation.....                    | 23 |
| 7.4.4 LUMINANCE evaluation of multiple displays .....       | 26 |
| 7.4.5 Chromaticity evaluation .....                         | 26 |
| 7.4.6 Chromaticity evaluation of multiple displays.....     | 26 |
| 7.4.7 LUMINANCE uniformity evaluation.....                  | 26 |
| 7.4.8 Viewing angle evaluation .....                        | 26 |
| Annex A (informative) Sample test reports .....             | 28 |
| Annex B (informative) LUMINANCE measurement methods .....   | 43 |
| Annex C (informative) Description of TEST PATTERNS .....    | 46 |
| Bibliography.....   | 55 |
| Index of defined terms .....                                | 57 |

|  |    |
|--|----|
| Figure 1 – Overall image quality evaluation using the TG18-QC TEST PATTERN.....  | 16 |
| Figure 2 – Overall image quality evaluation using the TG18-OIQ TEST PATTERN.....   | 17 |
| Figure 3 – Magnified view of TG18-MP TEST PATTERN showing the 8-bit and 10-bit markers .....   | 18 |
| Figure 4 – A close-up of the TG18-CT TEST PATTERN.....   | 19 |
| Figure 5 – The TG18-GV TEST PATTERN is displayed (left), a close-up of the centre of the TEST PATTERN when covered with a mask (right) .....   | 20 |
| Figure 6 – Geometrical evaluation using the GD pattern .....   | 21 |
| Figure 7 – Visual evaluation of viewing angle response .....   | 22 |
| Figure 8 – Example of the measured LUMINANCE in relation to the standard LUMINANCE response function according to GREYSCALE STANDARD DISPLAY FUNCTION (GSDF) .....   | 25 |
| Figure 9 – An example of the CONTRAST response computed from 18 grey levels as related to the expected CONTRAST response associated with the DICOM 3.14 [2] standard LUMINANCE response with a given tolerance limit (e.g. 15 %) [10]..... | 25 |
| Figure B.1 – Method A, telescopic method .....   | 43 |
| Figure B.2 – Method B, near-range LUMINANCE meter in combination with an ILLUMINANCE meter .....   | 44 |
| Figure B.3 – Method C, frontal integrated LUMINANCE meter in combination with ILLUMINANCE meter .....  | 44 |
| Figure B.4 – Method D, back integrated LUMINANCE meter in combination with ILLUMINANCE meter .....   | 45 |
| Figure C.1 – Example of TG-18 QC pattern for a matrix size of 1536 × 2048.....   | 54 |
| Table 1 – Overview to the definitions of physical parameters .....   | 10 |
| Table 2 – TEST PATTERNS used for display testing .....   | 13 |
| Table 3 – List of the evaluation methods that can be used for testing medical IMAGE DISPLAY SYSTEMS .....  | 15 |
| Table A.1 – Acceptance test sample report of a diagnostic display .....  | 29 |
| Table A.2 – Constancy test sample report of a diagnostic display .....   | 33 |
| Table A.3 – Acceptance test sample report of a monochrome reviewing display .....  | 35 |
| Table A.4 – Constancy test sample report of a monochrome reviewing display .....   | 37 |
| Table A.5 – Acceptance test sample report of a colour reviewing display .....  | 39 |
| Table A.6 – Constancy test sample report of a colour reviewing display.....  | 41 |
| Table C.1 – Description of multi-purpose TEST PATTERNS.....  | 47 |
| Table C.2 – TG18-QC pattern: LUMINANCE levels with 8-bit and [12-bit] pixel values and CX ratings.....   | 50 |
| Table C.3 – The blurring characteristics of the CX reference set utilized in TG18-QC TEST PATTERNS [16] .....  | 51 |
| Table C.4 – Evaluation criteria for the examples of the CLINICAL REFERENCE IMAGES .....  | 52 |
| Table C.5 – Example description of TG-18 QC pattern for a matrix size of 1536 × 2048 .....   | 53 |

## 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.

|   |
|---|
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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.

## **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]

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