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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

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EUROPEAN STANDARD

EN 62563-1:2010/A1

NORME EUROPÉENNE

EUROPÄISCHE NORM

June 2016

ICS 11.040.55

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)

This amendment A1 modifies the European Standard EN 62563-1:2010; it was approved by CENELEC on 2016-04-28. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this amendment the status of a national standard without any alteration.

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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.

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 62563-1

March 2010

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**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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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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Annex ZA has been added by CENELEC.

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- [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 - 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	-	-

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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**





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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**

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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:

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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

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- withdrawn,
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- 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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