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Medical electrical equipment - Medical image display systems - Part 1: Evaluation methods (IEC 62563-1:2009 + IEC 62563-1:2009/A1:2016 + IEC 62563-1:2009/AMD2:2021)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 62563-1:2010+A1 +A2:2021 sisaldab Euroopa standardi EN 62563-1:2010 ja selle muudatuste A1:2016 ja A2:2021 ingliskeelset teksti.	This Estonian standard EVS-EN 62563-1:2010+A1 +A2:2021 consists of the English text of the European standard EN 62563-1:2010 and its amendments A1:2016 and A2:2021.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas. Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 05.03.2010, muudatused A1 03.06.2016 ja A2 27.08.2021.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation. Date of Availability of the European standard is 05.03.2010, for A1 03.06.2016 and A2 27.08.2021.
Muudatusega A1 lisatud või muudetud teksti algus ja lõpp on tekstis tähistatud sümbolitega [A1] ⟨A1⟩. Muudatusega A2 lisatud või muudetud teksti algus ja lõpp on tekstis tähistatud sümbolitega [A2] ⟨A2⟩. Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.	The start and finish of text introduced or altered by amendment A1 is indicated in the text by tags [A1] ⟨A1⟩. The start and finish of text introduced or altered by amendment A2 is indicated in the text by tags [A2] ⟨A2⟩. The standard is available from the Estonian Centre for Standardisation and Accreditation.

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ICS 11.040.55

EUROPEAN STANDARD

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EUROPÄISCHE NORM

EN 62563-1 + A1 + A2

March 2010, June 2016, August 2021

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English Version

Medical electrical equipment - Medical image display systems - Part 1: Evaluation methods (IEC 62563-1:2009 + IEC 62563-1:2009/A1:2016 + IEC 62563-1:2009/AMD2:2021)

Appareils électromédicaux - Systèmes d'imagerie médicale - Partie 1: Méthodes d'évaluation (CEI 62563-1:2009 + IEC 62563-1:2009/A1:2016 + IEC 62563-1:2009/AMD2:2021)

Medizinische elektrische Geräte - Medizinische Bildwiedergabesysteme - Teil 1: Bewertungsmethoden (IEC 62563-1:2009 + IEC 62563-1:2009/A1:2016 + IEC 62563-1:2009/AMD2:2021)

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European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
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Ref. No. EN 62563-1:2010 E + EN 62563-1:2010/A1:2016 E + EN 62563-1:2010/A2:2021 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.

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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.

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A1 Amendment A1 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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A2 Amendment A2 European foreword

The text of document 62B/1168/CDV, future IEC 62563-1/AMD2, 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/A2:2021.

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IEC 62563-1

Edition 1.2 2021-07
CONSOLIDATED VERSION

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

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

Appareils electromedicaux – Systemes d'imagerie medicale – Partie 1: Méthodes d'évaluation

IEC 62563-1:2009-12+AMD1:2016-03+AMD2:2021-07 CSV(en-fr)

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

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

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IEC 62563-1

Edition 1.2 2021-07
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INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

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

Appareils electromedicaux – Systemes d'imagerie medicale – Partie 1: Méthodes d'évaluation

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CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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.

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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.

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〈A1〉 AMENDMENT A1 FOREWORD

This amendment has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this amendment is based on the following documents:

CDV	Report on voting
62B/983/CDV	62B/995/RVC

Full information on the voting for the approval of this amendment can be found in the report on voting indicated in the above table.

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- amended. 〈A1〉

AMENDMENT A2 FOREWORD

This amendment has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this amendment is based on the following documents:

Draft	Report on voting
62B/1168/CDV	62B/1203/RVC

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this Amendment is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/standardsdev/publications/.

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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.

A1 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. A1

INTRODUCTION to Amendment 2

This amendment is intended to introduce evaluation methods for handheld display devices.

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.

〚A1〛This standard applies to medical IMAGE DISPLAY SYSTEMS, which can display image information on greyscale and colour IMAGE DISPLAY SYSTEMS 〚A1〛. 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. 〚A1〛 Handheld IMAGE DISPLAY SYSTEMS might require additional or modified versions of the procedures described in this standard. 〚A1〛

It is not in the scope of this standard to define the requirements of acceptance and constancy tests 〚A1〛 or 〚A1〛 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]