

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

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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.
-

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

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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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CONTENTS

FOREWORD.....	5
■ _{A1} AMENDMENT A1 FOREWORD ■ _{A1}	7
■ _{A2} AMENDMENT A2 FOREWORD ■ _{A2}	8
INTRODUCTION.....	9
■ _{A1} INTRODUCTION to Amendment 1 ■ _{A1}	10
■ _{A2} INTRODUCTION to Amendment 2 ■ _{A2}	11
1 Scope.....	12
2 Normative references	12
3 Terms, definitions, symbols and abbreviations.....	12
3.1 Terms and definitions	12
3.2 Symbols	15
3.3 Abbreviations	16
4 General	16
5 Prerequisites	16
6 Equipment and tools.....	17
6.1 LUMINANCE meter	17
6.2 ILLUMINANCE meter.....	17
6.3 Colour meter	17
6.4 TEST PATTERNS	18
7 Evaluation methods	19
7.1 General.....	19
7.2 Evaluation method table overview	19
7.3 Visual evaluation methods.....	21
7.3.1 General	21
7.3.2 Overall image quality evaluation	21
7.3.3 Greyscale resolution evaluation	22
7.3.4 LUMINANCE response evaluation.....	23
7.3.5 LUMINANCE uniformity evaluation.....	24
7.3.6 Chromaticity evaluation	24
7.3.7 Pixel faults evaluation.....	24
7.3.8 VEILING GLARE evaluation.....	25
7.3.9 Geometrical image evaluation.....	25
7.3.10 Angular viewing evaluation	26
7.3.11 Clinical evaluation	27
7.4 Quantitative evaluation methods.....	27
7.4.1 Basic LUMINANCE evaluation.....	27
7.4.2 Basic LUMINANCE evaluation without ambient light	28
7.4.3 LUMINANCE response evaluation.....	29
7.4.4 LUMINANCE evaluation of multiple displays	31
7.4.5 ■ _{A1} Chromaticity uniformity evaluation ■ _{A1}	31
7.4.6 ■ _{A1} Chromaticity evaluation across multiple displays ■ _{A1}	31
7.4.7 LUMINANCE uniformity evaluation.....	31
7.4.8 Viewing angle evaluation	32
■ _{A1} 7.4.9 Greyscale chromaticity evaluation ■ _{A1}	32
Annex A (informative) Sample test reports	33

Annex B (informative) LUMINANCE measurement methods	51
Annex C (informative) Description of TEST PATTERNS	54
A2 Annex D (informative) Evaluation methods for handheld display devices A2	63
Annex ZA (normative) Normative references to international publications with their corresponding European publications	73
Bibliography	74
Index of defined terms	76
 Figure 1 – Overall image quality evaluation using the TG18-QC TEST PATTERN	21
Figure 2 – Overall image quality evaluation using the TG18-OIQ TEST PATTERN	22
Figure 3 – Magnified view of TG18-MP TEST PATTERN showing the 8-bit and 10-bit markers	23
Figure 4 – A close-up of the TG18-CT TEST PATTERN	24
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)	25
Figure 6 – Geometrical evaluation using the GD pattern	26
Figure 7 – Visual evaluation of viewing angle response	27
Figure 8 – Example of the measured LUMINANCE in relation to the standard LUMINANCE response function according to GREYSCALE STANDARD DISPLAY FUNCTION (GSDF)	30
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]	30
Figure B.1 – Method A, telescopic method	51
Figure B.2 – Method B, near-range LUMINANCE meter in combination with an ILLUMINANCE meter	52
Figure B.3 – Method C, frontal integrated LUMINANCE meter in combination with ILLUMINANCE meter	52
Figure B.4 – Method D, back integrated LUMINANCE meter in combination with ILLUMINANCE meter	53
Figure C.1 – Example of TG-18 QC pattern for a matrix size of 1536 × 2048	62
Figure D.1 – Hh-Ctr TEST PATTERN	67
Figure D.2 – Grey level emphasized angular target	67
 Table 1 – Overview to the definitions of physical parameters	15
Table 2 – TEST PATTERNS used for display testing	18
Table 3 – List of the evaluation methods that can be used for testing medical IMAGE DISPLAY SYSTEMS	20
Table A.1 – Acceptance test sample report of a diagnostic display	34
Table A.2 – Constancy test sample report of a diagnostic display	38
Table A.3 – Acceptance test sample report of a monochrome reviewing display	41
Table A.4 – Constancy test sample report of a monochrome reviewing display	43
Table A.5 – Acceptance test sample report of a colour reviewing display	45
Table A.6 – Constancy test sample report of a colour reviewing display	48
Table C.1 – Description of multi-purpose TEST PATTERNS	55
Table C.2 – TG18-QC pattern: LUMINANCE levels with 8-bit and [12-bit] pixel values and CX ratings	58

Table C.3 – The blurring characteristics of the CX reference set utilized in TG18-QC TEST PATTERNS [16]	59
Table C.4 – Evaluation criteria for the examples of the CLINICAL REFERENCE IMAGES	60
Table C.5 – Example description of TG-18 QC pattern for a matrix size of 1536×2048	61
Table D.1 – Major characteristics of typical handheld devices compared to IMAGE DISPLAY SYSTEMS	63
Table D.2 – TEST PATTERNS for handheld device	64
Table D.3 – Recommended TEST ITEMS for handheld devices	66
Table D.4 – Description of TEST PATTERNS for handheld devices	68

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.

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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**

A2 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**

A2 INTRODUCTION to Amendment 2

This amendment is intended to introduce evaluation methods for handheld display devices. **A2**

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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]