

INTERNATIONAL STANDARD

NORME INTERNATIONALE

**Medical electrical equipment – Medical image display systems –
Part 2: Acceptance and constancy tests for medical image displays**

**Appareils électromédicaux – Systèmes d'imagerie médicale –
Partie 2: Essais d'acceptation et de constance des systèmes d'imagerie
médicale**



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CONTENTS

FOREWORD.....	4
INTRODUCTION.....	6
1 Scope.....	7
2 Normative references	7
3 Terms, definitions, symbols and abbreviated terms.....	7
3.1 Terms and definitions.....	7
3.2 Symbols.....	8
3.3 Abbreviated terms.....	9
4 General	9
5 Categories.....	10
6 ACCEPTANCE TEST	11
6.1 General.....	11
6.2 When to test	11
6.3 Evaluation items and CRITERIA for ACCEPTANCE TEST.....	11
6.4 ACCEPTANCE TEST result	15
7 CONSTANCY TEST	16
7.1 General.....	16
7.2 Frequency of CONSTANCY TEST	16
7.3 Evaluation items and CRITERIA.....	16
7.4 CONSTANCY TEST result.....	16
Annex A (informative) Sample test reports	17
A.1 General.....	17
A.2 ACCEPTANCE TEST sample report of a category I-A diagnostic display	17
A.2.1 General information	17
A.2.2 Displays	17
A.2.3 Test results.....	17
A.3 CONSTANCY TEST sample report of a category I-A diagnostic display.....	21
A.3.1 General information	21
A.3.2 Displays	21
A.3.3 Test results.....	21
Annex B (informative) Ambient light control.....	24
Annex C (informative) Evaluation CRITERIA examples of clinical images	29
C.1 General.....	29
C.2 Chest image	29
Bibliography.....	34
Index of defined terms	35
Figure B.1 – $L_{\min}$ and E relationship when $r' \geq 250$	24
Figure B.2 – Possible deviation range of E conforming to GSDF ± 10 %	26
Figure B.3 (1 of 2) – Example charts of possible deviation ranges of ILLUMINANCE (E), calibrated at four different ambient LUMINANCE (L_{amb}) levels (shown at right)	27
Figure B.3 (2 of 2) – Example charts of possible deviation ranges of ILLUMINANCE (E), calibrated at four different ambient LUMINANCE (L_{amb}) levels (shown at right)	28
Figure C.1 – Chest clinical image.....	29

Figure C.2 – Visually sharp reproduction of the vessel from hilum to peripheral area	30
Figure C.3 – Visibility of vessels under retro-cardiac area and under diaphragm	30
Figure C.4 – Visually sharp reproduction of trachea and proximal bronchia.....	31
Figure C.5 – Distinct reproduction of frame of spine, lateral protrusion, and spinous process.....	31
Figure C.6 – Distinct reproduction of edge of heart	31
Figure C.7 – Excellent graininess (no artefacts or significant noise) of thorax and underarm soft tissue	32
Figure C.8 – Distinct reproduction of the border of rib and peripheral lung, border of lower edge of lung	33
Table 1 – Overview to the definitions of physical parameters	8
Table 2 – Tests and TEST ITEMS for quantitative evaluation.....	11
Table 3 – Tests and TEST ITEMS for visual evaluation.....	13
Table 4 – Quantitative acceptance and CONSTANCY TESTS	14
Table 5 – Visual acceptance and CONSTANCY TESTS	15

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT – MEDICAL IMAGE DISPLAY SYSTEMS –

Part 2: Acceptance and constancy tests for medical image displays

FOREWORD

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IEC 62563-2 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this International Standard is based on the following documents:

Draft	Report on voting
62B/1254/FDIS	62B/1262/RVD

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 International Standard 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.

In this document, 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 in 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 document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

INTRODUCTION

This document defines ACCEPTANCE and CONSTANCY TESTS for medical image displays. It defines TEST ITEMS for the ACCEPTANCE and CONSTANCY TESTS, as well as the performance CRITERIA and the test frequency for each TEST ITEM, elements of the measurement method related to an image quality parameter in an IMAGE DISPLAY SYSTEM. The evaluation methods of the TEST ITEMS are not described in this document; rather, evaluation methods, along with prerequisites, equipment and tools for the TEST ITEMS, are defined in IEC 62563-1.

ACCEPTANCE and CONSTANCY TESTS are performed on site at the installation facility. 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 can degrade over time, CONSTANCY TESTS are carried out periodically to verify that the performance is maintained.

This document describes appropriate TEST ITEMS and CRITERIA that are considered appropriate as an international standard based on survey of quality control testing standards and guidelines across the world. Although other existing standards and guidelines have been defined by other standard organizations and can be given priority over this document, national authorities are encouraged to adopt or harmonize to this document.

MEDICAL ELECTRICAL EQUIPMENT – MEDICAL IMAGE DISPLAY SYSTEMS –

Part 2: Acceptance and constancy tests for medical image displays

1 Scope

This part of IEC 62563 establishes the performance CRITERIA and test frequencies for the ACCEPTANCE TESTS and CONSTANCY TESTS. The evaluation methods are defined in IEC 62563-1. The scope of this document is directed to practical tests that can be visually evaluated or measured using basic test equipment. This document 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. This document does not apply to information displays and to displays used solely for control of technical settings of all medical information.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 TR 60788:2004, *Medical electrical equipment – Glossary of defined terms*

IEC 62563-1:2009, *Medical electrical equipment – Medical image display systems – Part 1: Evaluation methods*

IEC 62563-1:2009/AMD1:2016

3 Terms, definitions, symbols and abbreviated terms

3.1 Terms and definitions

For the purposes of this document, the terms and definitions in IEC TR 60788:2004, IEC 62563-1:2009/AMD1:2016 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <http://www.iso.org/obp>

3.1.1

ACCEPTANCE TEST

test carried out after equipment has been installed or major modifications have been made to existing equipment to verify compliance with manufacturer's specifications or requirements

3.1.2

CONSTANCY TEST

test carried out to confirm that the functional performance of equipment meets established CRITERIA and to enable the early recognition of changes in the properties of components of the equipment