
**Medicinska električna oprema - Sistemi za prikazovanje medicinskih slik - 2. del:
Preskusi sprejemljivosti in konstantnosti za prikazovanje medicinskih slik (IEC
62563-2:2021)**

Medical electrical equipment - Medical image display systems - Part 2: Acceptance and
constancy tests for medical image displays (IEC 62563-2:2021)

Medizinische elektrische Geräte - Medizinische Bildschirmsysteme - Akzeptanz- und
Konstanzprüfungen (IEC 62563-2:2021)

Appareils électromédicaux - Systèmes d'imagerie médicale - Partie 2 : Essais
d'acceptation et de constance des systèmes d'imagerie médicale (IEC 62563-2:2021)

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**Medical electrical equipment - Medical image display systems -
Part 2: Acceptance and constancy tests for medical image
displays
(IEC 62563-2:2021)**

Appareils électromédicaux - Systèmes d'imagerie médicale
- Partie 2 : Essais d'acceptation et de constance des
systèmes d'imagerie médicale
(IEC 62563-2:2021)

Medizinische elektrische Geräte - Medizinische
Bildschirmsysteme - Akzeptanz- und Konstanzprüfungen
(IEC 62563-2:2021)

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Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

EN IEC 62563-2:2021 (E)**European foreword**

The text of document 62B/1254/FDIS, future edition 1 of IEC 62563-2, 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 IEC 62563-2:2021.

The following dates are fixed:

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- latest date by which the national standards conflicting with the (dow) 2024-12-15 document have to be withdrawn

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ISO/CIE 11664-1:2019 NOTE Harmonized as EN ISO/CIE 11664-1:2019 (not modified)

IEC 60601-1:2005 NOTE Harmonized as EN 60601-1:2006 (not modified) +A11:2011

Annex ZA (normative)

Normative references to international publications with their corresponding European publications

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.

NOTE 1 Where an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

| <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 | - | - |
| IEC 62563-1 | 2009 | Medical electrical equipment - Medical image display systems - Part 1: Evaluation methods | EN 62563-1 | 2010 |
| /AMD1 | 2016 | | /A1 | 2016 |

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iTeh STANDARD

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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
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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.

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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.

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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