

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**



THIS PUBLICATION IS COPYRIGHT PROTECTED
Copyright © 2021 IEC, Geneva, Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either IEC or IEC's member National Committee in the country of the requester. If you have any questions about IEC copyright or have an enquiry about obtaining additional rights to this publication, please contact the address below or your local IEC member National Committee for further information.

Droits de reproduction réservés. Sauf indication contraire, aucune partie de cette publication ne peut être reproduite ni utilisée sous quelque forme que ce soit et par aucun procédé, électronique ou mécanique, y compris la photocopie et les microfilms, sans l'accord écrit de l'IEC ou du Comité national de l'IEC du pays du demandeur. Si vous avez des questions sur le copyright de l'IEC ou si vous désirez obtenir des droits supplémentaires sur cette publication, utilisez les coordonnées ci-après ou contactez le Comité national de l'IEC de votre pays de résidence.

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

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

About the IEC

The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

About IEC publications

The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigendum or an amendment might have been published.

IEC publications search - webstore.iec.ch/advsearchform

The advanced search enables to find IEC publications by a variety of criteria (reference number, text, technical committee, ...). It also gives information on projects, replaced and withdrawn publications.

IEC Just Published - webstore.iec.ch/justpublished

Stay up to date on all new IEC publications. Just Published details all new publications released. Available online and once a month by email.

IEC Customer Service Centre - webstore.iec.ch/csc

If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: sales@iec.ch.

IEC online collection - oc.iec.ch

Discover our powerful search engine and read freely all the publications previews. With a subscription you will always have access to up to date content tailored to your needs.

Electropedia - www.electropedia.org

The world's leading online dictionary on electrotechnology, containing more than 22 000 terminological entries in English and French, with equivalent terms in 18 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

A propos de l'IEC

La Commission Electrotechnique Internationale (IEC) est la première organisation mondiale qui élabore et publie des Normes internationales pour tout ce qui a trait à l'électricité, à l'électronique et aux technologies apparentées.

A propos des publications IEC

Le contenu technique des publications IEC est constamment revu. Veuillez vous assurer que vous possédez l'édition la plus récente, un corrigendum ou amendement peut avoir été publié.

Recherche de publications IEC -

webstore.iec.ch/advsearchform

La recherche avancée permet de trouver des publications IEC en utilisant différents critères (numéro de référence, texte, comité d'études, ...). Elle donne aussi des informations sur les projets et les publications remplacées ou retirées.

IEC Just Published - webstore.iec.ch/justpublished

Restez informé sur les nouvelles publications IEC. Just Published détaille les nouvelles publications parues. Disponible en ligne et une fois par mois par email.

Service Clients - webstore.iec.ch/csc

Si vous désirez nous donner des commentaires sur cette publication ou si vous avez des questions contactez-nous: sales@iec.ch.

IEC online collection - oc.iec.ch

Découvrez notre puissant moteur de recherche et consultez gratuitement tous les aperçus des publications. Avec un abonnement, vous aurez toujours accès à un contenu à jour adapté à vos besoins.

Electropedia - www.electropedia.org

Le premier dictionnaire d'électrotechnologie en ligne au monde, avec plus de 22 000 articles terminologiques en anglais et en français, ainsi que les termes équivalents dans 16 langues additionnelles. Egalement appelé Vocabulaire Electrotechnique International (IEV) en ligne.

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**

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

ICS 11.040.55; 31.120

ISBN 978-2-8322-1039-8

**Warning! Make sure that you obtained this publication from an authorized distributor.
Attention! Veuillez vous assurer que vous avez obtenu cette publication via un distributeur agréé.**

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 $\pm 10\%$	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

INTERNATIONAL ELECTROTECHNICAL COMMISSION

**MEDICAL ELECTRICAL EQUIPMENT –
MEDICAL IMAGE DISPLAY SYSTEMS –****Part 2: Acceptance and constancy tests
for medical image displays**

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.
- 2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
- 3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
- 4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
- 5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
- 6) All users should ensure that they have the latest edition of this publication.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
- 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

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