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(पहला पुनरीक्षण)

Draft Indian Standard

Medical Electrical Equipment — Medical Image Display Systems

Part 1 Evaluation methods

(First Revision)

[ICS 11.040.55]

Electromedical, Diagnostic Imaging and Radiotherapy
Equipment Sectional Committee, MHD 15

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NATIONAL FOREWORD

(Adoption clause will be added later)

This standard was originally published as IS/IEC 62563-1: 2016 which was an identical adoption of IEC 62563-1: 2016 Medical electrical equipment — Medical image display system — Part 1 Evaluation method. The first revision has been brought out to align the Indian Standard with the consolidated version of IEC 62563-1:2009+AMD1:2016+AMD2:2021.

The text of IEC standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are however not identical to those used in Indian Standards. Attention is particularly drawn to the following:

- Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'; and
- Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standard also exists. The corresponding Indian Standards, which are to be substituted in their respective places, are listed below along with their degree of equivalence for the editions indicated:

<i>International Standard</i>	<i>Corresponding Indian Standard</i>	<i>Degree of Equivalence</i>
IEC 60788: 2004, Medical electrical equipment – Glossary of defined terms	IS/IEC/TR 60788: 2004 Medical electrical equipment - Glossary of defined terms	Identical

The technical committee has reviewed the provisions of the following International Standards referred in this adopted standard and has decided that these are acceptable for use in conjunction with this standard:

<i>International Standard</i>	<i>Title</i>
ISO 11664-1:2007	Colorimetry – Part 1: CIE standard colorimetric observers
CIE S 010/E:2004	Photometry – The CIE system of physical photometry

In reporting the result of a test or analysis made in accordance with this standard, if the final value, observed or calculated, is to be rounded off, it shall be done in accordance with IS 2: 2022 ‘Rules for rounding off numerical values (*second revision*)’. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

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.

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.

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

It is not in the scope of this standard to define the requirements of acceptance and constancy tests or the frequencies of constancy tests.

The technical content of the document has not been enclosed as it is identical with the corresponding ISO standard. For details, please refer to IEC 62563-1: 2009+AMD1: 2016 +AMD2: 2021 or kindly contact:

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