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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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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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- withdrawn,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

3.1.3
LUMINANCE STABILIZER
embedded functionality of IMAGE DISPLAY SYSTEM which detects LUMINANCE deviation of light source by sensor (e.g. at bootup, degradation over time, or temperature change) caused by the IMAGE DISPLAY SYSTEM characteristics itself or its environments and adjusts light source automatically to stabilize display LUMINANCE

3.1.4
CRITERIA
acceptable deviation or limit defined for each test described in this document for the results of an ACCEPTANCE or a CONSTANCY TEST which signal a conforming performance of the equipment tested

3.1.5
TEST ITEM
element of the measurement method related to an image quality parameter in an IMAGE DISPLAY SYSTEM

3.1.6
RESPONSIBLE ORGANIZATION
entity accountable for the use and maintenance of a medical electrical (ME) equipment or a medical electrical (ME) system

[SOURCE: IEC 60601-1:2005, 3.101]

3.2 Symbols

The symbols of physical parameters described in IEC 62563-1 are listed in Table 1. All measurements referred to in Table 1 are in the centre of the IMAGE DISPLAY DEVICE; LUMINANCE can also be measured at other locations according to the methodologies described in this document.

Table 1 – Overview to the definitions of physical parameters

Symbol	Mathematically derived	Definition and explanation
L_{amb}		LUMINANCE generated by the ambient light on the surface of an IMAGE DISPLAY DEVICE when the IMAGE DISPLAY DEVICE is off.
L_{min}		Minimum LUMINANCE generated by an IMAGE DISPLAY DEVICE at DIGITAL DRIVING LEVEL (DDL) = 0 measured at the centre of the screen. It includes VEILING GLARE specific to TEST PATTERN used for measurement. It is measured with ambient light totally switched off (ambient ILLUMINANCE lower than 5 lux at the face of the IMAGE DISPLAY).
L_{max}		Maximum LUMINANCE generated by an IMAGE DISPLAY DEVICE at DIGITAL DRIVING LEVEL (DDL) = max. measured at the centre of the screen. It includes VEILING GLARE specific to TEST PATTERN used for measurement. It is measured with ambient light totally switched off (ambient ILLUMINANCE lower than 5 lux at the face of the IMAGE DISPLAY).
L'_{min}	$L_{min} + L_{amb}$	LUMINANCE that shall be perceived by the human eye at the centre of the screen at DIGITAL DRIVING LEVEL (DDL) = 0. It contains VEILING GLARE and L_{amb}.
L'_{max}	$L_{max} + L_{amb}$	LUMINANCE produced by the IMAGE DISPLAY DEVICE that shall be perceived by the human eye at the maximum DIGITAL DRIVING LEVEL (DDL) measured at the centre of the screen. It contains VEILING GLARE and L_{amb}.
L'_{target}		Target LUMINANCE at maximum DIGITAL DRIVING LEVEL (DDL) being the IMAGE DISPLAY DEVICE vendor recommended value or the value used during calibration (including the ambient light contribution).

Symbol	Mathematically derived	Definition and explanation
$\Delta L'_{max}$	$(L'_{max} - L'_{target})/L'_{target}$ [%]	Percentage of difference from L'_{target} and measured actual L'_{max} at maximum DDL.
a	L_{amb}/L'_{min}	Safety factor
R_d		Diffuse reflection coefficient (provided by manufacturer with a specific measurement method, ideally following the methods described in [1][1] using a CIE standard illuminant A and an aperture size 20 % to 30 % larger than the diameter of the LUMINANCE meter).
r'	L'_{max}/L'_{min}	LUMINANCE ratio of an IMAGE DISPLAY DEVICE containing VEILING GLARE and ambient LUMINANCE.
E		ILLUMINANCE
$\Delta u'v'$	$((u_1'-u_2')^2 + (v_1'-v_2')^2)^{1/2}$	Distance between two points (u_1,v_1) and (u_2,v_2) in u'-v' space.

3.3 Abbreviated terms

CT computed tomography
DDL digital driving level
DICOM digital imaging and communication in medicine
GSDF greyscale standard display function
LCD liquid crystal display
MR magnetic resonance
QC quality control

4 General

In IMAGE DISPLAY SYSTEMS, every individual component can limit or reduce the image quality of the system. Therefore, it is necessary to adopt suitable measures for quality monitoring. If IMAGE DISPLAY SYSTEMS are correctly adjusted and maintained, these devices can consistently generate similar images.

Simple test equipment is used (LUMINANCE meter, TEST IMAGES) with PRECISION appropriate for a test. Before a test, all test equipment shall be checked for its functioning according to the manufacturer's specifications. IMAGE DISPLAY DEVICE should be placed in a likely clinical position while performing the measurements.

According to Clause 5, IMAGE DISPLAY DEVICES shall be categorized, and ACCEPTANCE TEST and CONSTANCY TEST shall be performed respectively. ACCEPTANCE TEST shall be performed after a new IMAGE DISPLAY SYSTEMS installation or major modification of an existing IMAGE DISPLAY SYSTEM. The CONSTANCY TEST shall be performed periodically to confirm that the performance is maintained.

The results of ACCEPTANCE and CONSTANCY TESTING shall be recorded. If the test did not meet the CRITERIA, immediate response (e.g., as recommended by the IMAGE DISPLAY DEVICE manufacturer) such as repair service, re-calibration, or replace of IMAGE DISPLAY DEVICE (s) shall be performed. It is optimal to manage systems properly and not fail the tests. If tests fail, analysis of results or more frequent testing is advisable. Testing conditions, test instruments, TEST PATTERNS and evaluation methods are defined in IEC 62563-1. Annex A shows a sample ACCEPTANCE and CONSTANCY TEST report.

[1] Numbers in square brackets refer to the Bibliography.

5 Categories

IMAGE DISPLAY DEVICES shall be categorized in three categories: I, II and III. Category I is further categorized in 2 subcategories: I-A and I-B.

The following application categories and subcategories are defined.

Category I-A: IMAGE DISPLAY DEVICE which has at least a 2 048 × 2 048 pixel array size and a GSDF LUMINANCE response. This category is recommended if consistent visibility of subtle contrast and finest detail is required for accurate diagnosis. Application examples include mammography and digital breast tomosynthesis.

Category I-B: IMAGE DISPLAY DEVICE which has at least a 1 024 × 1 024 pixel array size and a GSDF LUMINANCE response. This category is recommended if consistent visibility of low contrast and fine detail is required for the clinical application. Application examples include images such as chest X-ray, CT and MR, and breast biopsy.

Category II: IMAGE DISPLAY DEVICE which has a GSDF LUMINANCE response. This category is recommended if consistent visibility of contrast is required for the clinical image viewing application. Application examples include acquisition and viewing workstations, ultrasound, angiography and fluoroscopy.

Category III: IMAGE DISPLAY DEVICE which has a defined LUMINANCE response function other than GSDF. This category is recommended if quality assured visibility of contrast is required for the clinical image viewing application. Application examples include acquisition and viewing workstations, ultrasound, angiography and fluoroscopy.

The application examples given for each of these categories and subcategories are not normative. Before performing an ACCEPTANCE TEST, clinical institutions or physicians shall decide in which category and subcategory a specific IMAGE DISPLAY DEVICE is categorized taking possible regionally applicable regulations into account and the IMAGE DISPLAY DEVICE manufacturer's information.

If an IMAGE DISPLAY DEVICE is used for multiple applications, its application category shall be determined on its most stringent application.

The above application categories and subcategories are defined based on the IMAGE DISPLAY DEVICE technologies currently used in medical IMAGE DISPLAY SYSTEMS. It is possible that newer technology IMAGE DISPLAY DEVICES do not fit into one of the above application categories; in this case, the clinical institution or physician shall define an appropriate application categorization system and QC program.

These categories and subcategories are based on IMAGE DISPLAY DEVICE performance only; however, the entire IMAGE DISPLAY SYSTEM shall be considered. Clinical institutions or physicians shall ascertain if all other IMAGE DISPLAY SYSTEM components besides the IMAGE DISPLAY DEVICES are suitable for the application.

In some cases, in addition to the examples given in the category descriptions, category II and category III IMAGE DISPLAY DEVICES can be part of systems that include diagnostic procedures. For category III IMAGE DISPLAY DEVICES, various types of LUMINANCE responses are currently used depending on the application, and it is difficult to define a set of QC tests applicable for all possible LUMINANCE responses. In this case, the IMAGE DISPLAY SYSTEM shall conform with the QC test(s) defined by the manufacturer or RESPONSIBLE ORGANIZATION.

6 ACCEPTANCE TEST

6.1 General

Based on the category decided by physicians or medical institution, an ACCEPTANCE TEST shall be performed after a new IMAGE DISPLAY SYSTEM or a new IMAGE DISPLAY DEVICE is installed, or after major modifications to the existing IMAGE DISPLAY SYSTEM or IMAGE DISPLAY DEVICE. The test shall be performed in the actually-used environment, including placement and ambient lighting, after calibration if needed. Follow instructions on test preparations according to Clause 4, Clause 5 and Clause 6 of IEC 62563-1:2009.

6.2 When to test

When an IMAGE DISPLAY SYSTEM or an IMAGE DISPLAY DEVICE is installed or following any major modification, testing shall be performed before using them. Major modifications include:

– change on category for IMAGE DISPLAY DEVICE;
– major component replacement which affects the quality of IMAGE DISPLAY DEVICE (e.g. LCD panel) due to repair; contact the manufacturer for the impact;
– major modification of the IMAGE DISPLAY DEVICE (e.g. maximum LUMINANCE, minimum LUMINANCE, or LUMINANCE response);
– change of the installed location (e.g. installed room) or ambient light setting; See Annex B for more details how to control ambient light;
– change to IMAGE DISPLAY SYSTEM which affects the image quality (e.g. change of the display controller or driver software); contact the manufacturer for the impact.

The RESPONSIBLE ORGANIZATION shall check the test result and shall take appropriate actions if needed.

6.3 Evaluation items and CRITERIA for ACCEPTANCE TEST

Table 2 and Table 3 show quantitative and visual test and its TEST ITEMS for ACCEPTANCE TEST. Table 4 and Table 5 show CRITERIA by categories. Evaluation methods are based on IEC 62563-1.

Table 2 – Tests and TEST ITEMS for quantitative evaluation

IEC 62563-1:2009 and IEC 62563-1:2009/ AMD1:2016	TEST ITEM	TEST PATTERN	Description
7.4.1 Basic LUMINANCE evaluation	Minimum r'	TG18-LN-01,-18, BN-01,-18	Confirm the LUMINANCE ratio r' (= L'_{max}/L'_{min}) is equal or more than specified CRITERIA.
	L_{amb}/L'_{min} relationship	TG18-LN-01, BN-01	Confirm that the minimum value of L'_{min} or the maximum value of L_{amb} satisfies the requirement on the safety factor "a", which defines the relationship L_{amb} and L'_{min}.
	Tolerance of $\Delta L'_{max}$	TG18-LN-18, BN-18	Confirm a deviation from L'_{target} to L'_{max} is equal or less than CRITERIA.
	Minimum of L'_{max}	TG18-LN-18, BN-18	Confirm L'_{max} is equal or more than CRITERIA.
7.4.3 LUMINANCE response evaluation	GSDF tolerance limit	TG18-LN-01 to 18, BN-01 to 18	Confirm GSDF tolerance evaluated by contrast response is equal or less than the CRITERIA. Compute contrast response from measured 18 grey levels and obtain deviation from expected value. See 7.4.3 in IEC 62563-1:2009 for calculation.

IEC 62563-1:2009 and IEC 62563-1:2009/ AMD1:2016	TEST ITEM	TEST PATTERN	Description
7.4.4 LUMINANCE evaluation of multiple displays	Tolerance of multiple displays (LUMINANCE)	TG18-LN-18, BN-18	The maximum LUMINANCE deviation is calculated as a percent difference between the highest and lowest LUMINANCE values relative to their lowest value, $100 \times (L_{highest} - L_{lowest})/L_{lowest}$ [%] Confirm this value is equal to or less than CRITERIA.
7.4.5 Chromaticity uniformity evaluation	Tolerance of chromaticity uniformity	TG18-UNL80	Using a colour meter, measure the (u',v') colour coordinates at the centre and at the four corners of the screen and compute the distance $\Delta u'v'$, as the maximum distance in u'-v' space between any possible pairs of (u', v') points. Confirm this value is equal to or less than CRITERIA.
7.4.6 Chromaticity evaluation across multiple displays	Tolerance of multiple displays (chromaticity)	TG18-UNL80	If multiple IMAGE DISPLAY DEVICES are associated with the same IMAGE DISPLAY SYSTEM the (u', v') chromaticity in the centre of every IMAGE DISPLAY DEVICE shall be compared. Compute the distance $\Delta u'v'$, as the maximum distance in u'-v' space between any possible pair of central measurements as $\Delta u'v' = ((u_1'-u_2')^2 + (v_1'-v_2')^2)^{1/2}$. If this distance $\Delta u'v'$ is calculated to more than two IMAGE DISPLAY DEVICES, the two with the biggest (u',v') distance shall be used in line with IEC 62563-1. Confirm this value is equal to or less than the CRITERIA.
7.4.7 LUMINANCE uniformity evaluation	Tolerance of LUMINANCE uniformity	TG18-UNL80	LUMINANCE uniformity within the IMAGE DISPLAY DEVICE. The deviation amongst measured LUMINANCE at centre and four corners as $200 \times (L_{highest} - L_{lowest})/(L_{highest} + L_{lowest})$ [%] Confirm this value is equal to or less than the CRITERIA.
7.4.9 Greyscale chromaticity evaluation	Tolerance of greyscale chromaticity	TG18-LN-01 to 18, BN-01 to 18	Chromaticity amongst greyscales. With only the measurements corresponding to recorded LUMINANCE values higher than or equal to 5 cd/m^2, the distances in the u'-v' space with respect to the measurement at full white are computed as: $\Delta u_i' v_i' = ((u_i'-u_{18}')^2 + (v_i'-v_{18}')^2)^{1/2}$ Confirm this value is equal to or less than the CRITERIA.

Table 3 – Tests and TEST ITEMs for visual evaluation

IEC 62563-1 and IEC 62563-1:2009/ AMD1:2016	TEST ITEM	TEST PATTERN	Description
7.3.2 Overall image quality evaluation	Visual check of line-pair (high)	TG18-QC or OIQ	Make sure that the high contrast line-pair patterns at the centre and four corners are all detectable.
	Visual check of line-pair (low/2pixel)		Make sure that the 2-pixel width low-contrast line-pair patterns at the centre and four corners are all detectable.
	Visual check of 5 % and 95 % patches		Make sure that that 5 % and 95 % patches are clearly detectable.
	Visual check of characters		Detect all designated characters in the designated areas.
	Visual check of white-black		Borders are clearly visible (and no trailing observed) both white-to-black and black-to-white transitions.
	Visual check of 16 LUMINANCE patches		All 16 LUMINANCE patches are clearly distinguishable.
	Visual check of greyscale		Make sure that the ramp bars are continuous and monotonic.
	Visual check of borders/straight		Make sure that all borders are visible and lines are straight in the ACTIVE AREA OF IMAGE DISPLAY DEVICE.
	Visual check of centring		Make sure that the pattern is centred in the ACTIVE AREA OF IMAGE DISPLAY DEVICE.
	Visual check of FLICKER		Evaluate the overall appearance of the TEST PATTERN, and confirm no FLICKER affecting diagnosis or referencing observed.
	Visual check of noise		Evaluate the overall appearance of the TEST PATTERN, and confirm no noise affecting diagnosis or referencing observed.
	Visual check of video artefacts		Evaluate the overall appearance of the TEST PATTERN and confirm no video artefacts affecting diagnosis or referencing observed.
7.3.3 Greyscale resolution evaluation	Visual check of greyscale resolution	TG18-MP	Confirm sufficient grayscale resolution based on 8- and 10-bit markers.
7.3.5 LUMINANCE uniformity evaluation	Visual check of LUMINANCE uniformity	TG18-UN80	Confirm the display does not have LUMINANCE non-uniformities that affects diagnosis or referencing.
7.3.6 Chromaticity evaluation	Visual check of colour uniformity	TG18-UN80	Confirm there are no significant colour differences within an IMAGE DISPLAY DEVICE that affects diagnosis or referencing.
	Visual check of colour uniformity amongst multiple displays	TG18-UN80	Confirm there are no significant colour differences that affects diagnosis or referencing, amongst multiple IMAGE DISPLAY DEVICES of the same type associated with a particular IMAGE DISPLAY SYSTEM.
7.3.7 Pixel faults evaluation	Counting pixel faults (type A)	TG18-UN10	Confirm the number of type A pixel faults are equal or less than CRITERIA. The CRITERIA are described as a number per 1 M pixels (per 1 024 × 1 024 rounded to an integer).
7.3.11 Clinical evaluation	Clinical image efficacy	CLINICAL REFERENCE IMAGES	Show specified CLINICAL REFERENCE IMAGE(S) and confirm there are no problems for diagnosis. This CLINICAL REFERENCE IMAGE can be specified in a facility or can be used ones specified by authorities. Examples of evaluation CRITERIA of CLINICAL REFERENCE IMAGES are provided in Annex C.