

Evaluation and routine testing in medical imaging departments - Part 2-4: Constancy tests - Hard copy cameras

This document is a preview generated by EVS

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 61223-2-4:2016 sisaldab Euroopa standardi EN 61223-2-4:1994 ingliskeelset teksti.	This Estonian standard EVS-EN 61223-2-4:2016 consists of the English text of the European standard EN 61223-2-4:1994.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 09.06.1994.	Date of Availability of the European standard is 09.06.1994.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.040.50

Standardite reprodutseerimise ja levitamise õigus kuulub Eesti Standardikeskusele

Andmete paljundamine, taastekitamine, kopeerimine, salvestamine elektroonsesse süsteemi või edastamine ükskõik millises vormis või millisel teel ilma Eesti Standardikeskuse kirjaliku loata on keelatud.

Kui Teil on küsimusi standardite autorikaitse kohta, võtke palun ühendust Eesti Standardikeskusega:

Aru 10, 10317 Tallinn, Eesti; koduleht www.evs.ee; telefon 605 5050; e-post info@evs.ee

The right to reproduce and distribute standards belongs to the Estonian Centre for Standardisation

No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying, without a written permission from the Estonian Centre for Standardisation.

If you have any questions about copyright, please contact Estonian Centre for Standardisation:

Aru 10, 10317 Tallinn, Estonia; homepage www.evs.ee; phone +372 605 5050; e-mail info@evs.ee

UDC 615.84:771.31:620.1

Descriptors: Electromedical equipment, hard copy camera, medical imaging, constancy test, evaluation testing, routine testing

ENGLISH VERSION

Evaluation and routine testing in medical imaging departments

Part 2-4: Constancy tests - Hard copy cameras
(IEC 1223-2-4:1994)

Essais d'évaluation et de routine dans les services d'imagerie médicale
Partie 2-4: Essais de constance
Reprographes

(CEI 1223-2-4:1994)

Bewertung und routinemäßige Prüfung in Abteilungen für medizinische Bildgebung
Teil 2-4: Konstanzprüfungen
Bildokumentationssysteme
(IEC 1223-2-4:1994)

This European Standard was approved by CENELEC on 1994-03-08. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

Central Secretariat: rue de Stassart 35, B-1050 Brussels

FOREWORD

The text of document 62B(CO)105, as prepared by Sub-Committee 62B: Diagnostic imaging equipment, of IEC Technical Committee 62: Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote in May 1993.

The reference document was approved by CENELEC as EN 61223-2-4 on 8 March 1994.

The following dates were fixed:

- latest date of publication of an identical national standard (dop) 1995-03-01
- latest date of withdrawal of conflicting national standards (dow) 2000-03-01

Annexes designated "normative" are part of the body of the standard. Annexes designated "informative" are given only for information. In this standard, annexes A and ZA are normative and annexes B, C, D and E are informative.

ENDORSEMENT NOTICE

The text of the International Standard IEC 61223-2-4:1994 was approved by CENELEC as a European Standard without any modification.

generated by EVS

CONTENTS

	Page
FOREWORD	7
INTRODUCTION	11
Clause	
1 Scope and object	13
1.1 Scope	13
1.2 Object	13
2 Normative references	15
3 Terminology	15
3.1 Degree of requirements	15
3.2 Use of terms	17
3.3 Definitions	17
4 General aspects of CONSTANCY TESTS	17
4.1 General conditions affecting test procedures	19
4.2 Establishment of BASELINE VALUES	19
4.3 Frequency of CONSTANCY TESTS	19
4.4 Identification of equipment, instrumentation and test conditions	19
4.5 Measured functional parameters	19
5 Test methods	21
5.1 Summary	21
5.2 Test equipment	21
5.3 Test procedure	25
5.4 Data evaluation	29
5.5 Criteria to be applied	31
5.6 Test report	31
5.7 Action to be taken	31
5.8 Frequency of testing	33
6 Statement of compliance	33
Figures	
1 Schematic representation of a test pattern used to check the constancy with respect to grey-scale reproduction	35

Figures	Page
2 Schematic representation of a test pattern used to check the constancy with respect to geometry and line structure	37
3 Schematic representation of a crosshatched pattern used to carry out measurements with respect to geometry	39
4 Schematic representation of a test pattern used to check the constancy with respect to resolution	41
Annexes	
A Terminology – Index of terms	43
B Example of a form for the standardized test report	45
C Guidance on action to be taken	49
D Rationale	51
E Bibliography – Reference test pattern	55

INTRODUCTION

Some provisions or statements in the body of this part of IEC 1223 require additional information. Such information is presented in annex D, Rationale. An asterisk in the left margin of a clause or subclause indicates the presence of such additional information.

This document is a preview generated by EVS

EVALUATION AND ROUTINE TESTING IN MEDICAL IMAGING DEPARTMENTS -

Part 2-4: Constancy tests - Hard copy cameras

1 Scope and object

1.1 Scope

This part of IEC 1223 applies to HARD COPY CAMERAS producing images on monochrome continuous tone material (such as photographic films and materials sensitive to infrared radiation), and comprising types of cameras using a cathode ray tube, laser beam, or a thermoprinting system, as used in diagnostic imaging systems such as:

- digital radiography;
- digital subtraction angiography;
- imaging in COMPUTED TOMOGRAPHY;
- magnetic resonance imaging;
- ultrasound imaging;
- imaging in NUCLEAR MEDICINE.

* The test methods are based on the use of test patterns.

This standard does not apply to x-y (analogue) recording systems used in NUCLEAR MEDICINE.

This standard is a part of a series of Particular Publications (standards and technical reports) which give methods of tests for the constancy of properties of diagnostic imaging systems as described in IEC 1223-1 (see clause 2).

*1.2 Object

This part of IEC 1223 describes a method to check, in terms of functional parameters, the constancy of the quality of images produced by HARD COPY CAMERAS in order to ensure that the required conditions for producing consistent hard copies are maintained after the calibration and adjustment have been carried out.

The aims of the method are:

- to establish a reference level of performance for the HARD COPY CAMERA when such equipment has been accepted;
- to detect and verify any significant variation in functional parameters which may then require corrective actions.

With regard to the measurements, reference is made to methods described in related publications, which for practical reasons should be carried out prior to the application of the method described in this standard (see clause 2).

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of IEC 1223. At the time of publication, the editions indicated were valid. All normative documents are subject to revision, and parties to agreements based on this part of IEC 1223 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

IEC 788: 1984, *Medical radiology – Terminology*

IEC 1223-1: 1993, *Evaluation and routine testing in medical imaging departments – Part 1: General aspects*

IEC 1223-2-1: 1993, *Evaluation and routine testing in medical imaging departments – Part 2-1: Constancy tests – Film processors*

IEC 1223-2-2: 1993, *Evaluation and routine testing in medical imaging departments – Part 2-2: Constancy tests – Radiographic cassettes and film changers – Film-screen contact and relative sensitivity of the screen-cassette assembly*

IEC 1223-2-3: 1993, *Evaluation and routine testing in medical imaging departments – Part 2-3: Constancy tests – Darkroom safelight conditions*

IEC 1223-2-5: 1994, *Evaluation and routine testing in medical imaging departments – Part 2-5: Constancy tests – Image display devices*

IEC 1223-2-12: 19XX, *Evaluation and routine testing in medical imaging departments – Part 2-12: Constancy tests - Film illuminators (under consideration)*

3 Terminology

3.1 Degree of requirements

In this part of IEC 1223 the verbal form:

"shall"	implies that compliance with a requirement is mandatory for compliance with the standard;
"should"	implies that compliance with a requirement is strongly recommended but is not mandatory for compliance with the standard;
"may"	implies that compliance with a requirement is permitted to be accomplished in a particular manner, for compliance with the standard.

The term:

"specific"	when used with parameters or conditions: refers to a particular value or standardized arrangement, usually to those required in an IEC publication or a legal requirement;
"specified"	when used with parameters or conditions: refers to a value or arrangement to be chosen for the purpose under consideration and indicated usually in ACCOMPANYING DOCUMENTS.