



**SLOVENSKI STANDARD**  
**oSIST prEN IEC 61223-3-8:2022**

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**Vrednotenje in rutinsko preskušanje v medicinskih oddelkih za slikanje - 3-8. del:  
Preskusi sprejemljivosti in konstantnosti - Slikovni učinek rentgenske opreme za  
radiografijo in radioskopijo**

Evaluation and routine testing in medical imaging departments - Part 3-8: Acceptance  
and constancy tests - Imaging performance of X-ray equipment for radiography and  
radioscopy

*iTeh STANDARD PREVIEW  
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Essais d'évaluation et de routine dans les services d'imagerie médicale - Partie 3-8:  
Essais d'acceptation et de constance - Performance d'imagerie des appareils à  
rayonnement X pour la radiographie et la radioscopie

**Ta slovenski standard je istoveten z: prEN IEC 61223-3-8:2022**

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TITLE:

**Evaluation and routine testing in medical imaging departments - Part 3-8: Acceptance and constancy tests - Imaging performance of X-ray equipment for radiography and radioscopy**

PROPOSED STABILITY DATE: 2026

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## INTERNATIONAL ELECTROTECHNICAL COMMISSION

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**EVALUATION AND ROUTINE TESTING  
IN MEDICAL IMAGING DEPARTMENTS –**
**Part 3-8: Acceptance and constancy tests–  
Imaging performance of X-ray equipment for radiography and radioscopy**
**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.
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The text of this International Standard is based on the following documents:

FDIS	Report on voting
62B/XX/FDIS	62B/XX/RVD

Full information on the voting for the approval of this International Standard can be found in the report on voting indicated in the above table.

This document has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this document, the following print types are used:

- 313 – requirements, compliance with which can be tested, and definitions: in roman type.  
314 – explanations, advice, notes, general statements, exceptions and references: in smaller type.  
315 – *test specifications: in italic type.*  
316 – TERMS USED THROUGHOUT THIS DOCUMENT THAT HAVE BEEN LISTED IN THE INDEX OF DEFINED  
317 TERMS AND DEFINED IN CLAUSE 3, OR IN OTHER STANDARDS: IN SMALL CAPITALS.

318 The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC  
319 Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- 320 – “shall” means that compliance with a requirement or a test is mandatory for compliance with  
321 this standard;  
322 – “should” means that compliance with a requirement or a test is recommended but is not  
323 mandatory for compliance with this standard;  
324 – “may” is used to describe a permissible way to achieve compliance with a requirement or  
325 test.

326 An asterisk (\*) as the first character of a title or at the beginning of a paragraph or table title  
327 indicates that there is guidance or rationale related to that item in Annex A.

328 A list of all parts of the IEC 61223 series, published under the general title *Evaluation and*  
329 *routine testing in medical imaging departments*, can be found on the IEC website.

330 The committee has decided that the contents of this document will remain unchanged until the  
331 stability date indicated on the IEC website under "<http://webstore.iec.ch>" in the data related to  
332 the specific document. At this date, the document will be

- 333 • reconfirmed,
- 334 • withdrawn,
- 335 • replaced by a revised edition, or
- 336 • amended.

337 NOTE The attention of the users of this document is drawn to the fact that equipment MANUFACTURERS and testing  
338 organizations might need a transitional period following publication of a new, amended or revised IEC publication in  
339 order to develop contractual specifications in accordance with the new test procedures and to equip themselves for  
340 conducting new or revised tests. It is the recommendation of the committee that the content of this publication be  
341 adopted for implementation nationally not earlier than 3 years from the date of publication.

342

343

## INTRODUCTION

344 IEC 61223 (all parts) gives methods for ACCEPTANCE TESTS and CONSTANCY TESTS for diagnostic  
345 X-RAY EQUIPMENT.

346 IEC 60601-2-54 and IEC 60601-2-43 require that the MANUFACTURER provides ACCOMPANYING  
347 DOCUMENTS with instructions for MANUFACTURER-recommended QUALITY CONTROL PROCEDURES  
348 and tests to be performed on the X-RAY EQUIPMENT by the RESPONSIBLE ORGANIZATION. In this  
349 document these instructions are referred to as a QUALITY CONTROL manual.

350 This part of IEC 61223 provides guidance on the content to be considered for inclusion in the  
351 QUALITY CONTROL manual for X-RAY EQUIPMENT for RADIOGRAPHY and RADIOSCOPY, including  
352 INTERVENTIONAL X-RAY EQUIPMENT. The QUALITY CONTROL manual is intended to be used  
353 independently by the RESPONSIBLE ORGANIZATION to ensure safe and effective equipment  
354 performance during its EXPECTED SERVICE LIFE, without the need to consult IEC standards.

355 This part of IEC 61223 provides parameters to be evaluated, examples of test methods,  
356 recommended minimum frequencies of evaluation and tools intended to be used by the  
357 RESPONSIBLE ORGANIZATION on installed X-RAY EQUIPMENT within the scope of this standard.  
358 Acceptance criteria are supplied by MANUFACTURERS and (local) compliance criteria are given  
359 by the regulatory authorities.

360 A major purpose of this standard is that of facilitating technical communication between  
361 stakeholders in the areas of ACCEPTANCE and CONSTANCY TESTING. The three major stakeholders  
362 responsible for assuring the safety and efficacy of X-RAY EQUIPMENT are the MANUFACTURER, the  
363 RESPONSIBLE ORGANIZATION and the regulatory authorities.

364 Generally, equipment installed in accordance with the MANUFACTURER'S QUALITY CONTROL  
365 PROCESS will comply with applicable IEC standards as well as meeting both local regulatory  
366 requirements and the MANUFACTURER'S general specifications and contractual specifications by  
367 the RESPONSIBLE ORGANIZATION.

368 The performance of installed equipment that need to be tested are assessed by the RESPONSIBLE  
369 ORGANIZATION and regulators using a wide variety of PROCESSES and tools. Similarly,  
370 acceptability criteria and PROCESSES often differ from those of equipment MANUFACTURERS.

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## EVALUATION AND ROUTINE TESTING IN MEDICAL IMAGING DEPARTMENTS –

### Part 3-8: Acceptance and constancy tests – Imaging performance of X-ray equipment for radiography and radioscopy

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#### 380 **1 Scope and object**

381 This part of IEC 61223 applies to evaluation of the performance of X-RAY EQUIPMENT for  
382 RADIOGRAPHY and RADIOSCOPY that conform to IEC 60601-2-54 or IEC 60601-2-43.

383 NOTE Cone-beam CT is a MODE OF OPERATION in INTERVENTIONAL X-RAY EQUIPMENT. This standard discusses such  
384 MODE OF OPERATION in the informative Annex F.

385 This standard applies to the evaluation of the performance of the entire imaging chain from  
386 image acquisition, image processing and image display.

387 This standard applies to ACCEPTANCE TESTS and CONSTANCY TESTS, which are part of the QUALITY  
388 ASSURANCE PROGRAM in medical imaging departments and is intended to be performed by or  
389 under the responsibility of the RESPONSIBLE ORGANIZATION. A detailed discussion of the position  
390 of these tests within the medical radiological equipment lifecycle is provided in A.2 of Annex A.  
391 The methods included rely mainly on non-invasive measurements that use appropriate test  
392 equipment and are performed after the installation is completed in accordance with the  
393 MANUFACTURER'S installation instructions.

394 IEC 60601-2-54 and IEC 60601-2-43 require information to be provided to the RESPONSIBLE  
395 ORGANIZATION with respect to QUALITY CONTROL. This standard provides guidance to  
396 MANUFACTURERS regarding the ACCEPTANCE and CONSTANCY TESTS for the X-RAY EQUIPMENT in a  
397 MANUFACTURER supplied QUALITY CONTROL manual. Annex G provides detailed guidance for such  
398 a manual.

#### 399 **2 Normative references**

400 The following documents are referred to in the text in such a way that some or all of their content  
401 constitutes requirements of this document. For dated references, only the edition cited applies.  
402 For undated references, the latest edition of the referenced document (including any  
403 amendments) applies.

404 IEC 60336:2020, *Medical electrical equipment – X-ray tube assemblies for medical diagnosis –*  
405 *Focal spot dimensions and related characteristics*

406 IEC 60522-1:2020, *Medical electrical equipment – Diagnostic X-rays – Part 1: Determination of*  
407 *quality equivalent filtration and permanent filtration*

408 IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety*  
409 *and essential performance*

410 IEC 60601-1:2005/AMD1:2012

411 IEC 60601-1:2005/AMD2:2020

412 IEC 60601-1-3:2008 *Medical electrical equipment – Part 1-3: General requirements for basic*  
413 *safety and essential performance – Collateral standard: Radiation protection in diagnostic X-*  
414 *ray equipment*

415 IEC 60601-1-3:2008/AMD1:2013

416 IEC 60601-1-3:2008/AMD2:2021

417 IEC 60601-2-43:2010, *Medical electrical equipment – Part 2-43: Particular requirements for the*  
 418 *basic safety and essential performance of X-ray equipment for interventional procedures*  
 419 IEC 60601-2-43:2010/AMD1:2017  
 420 IEC 60601-2-43:2010/AMD2:2019

421 IEC 60601-2-54:2009, *Medical electrical equipment – Part 2-54: Particular requirements for the*  
 422 *basic safety and essential performance of X-ray equipment for radiography and radioscopy*  
 423 IEC 60601-2-54:2010/AMD1:2015  
 424 IEC 60601-2-54:2010/AMD2:2018

425 IEC 61267:2005, *Medical diagnostic X-ray equipment – Radiation conditions for use in the*  
 426 *determination of characteristics*

427 IEC 61674:2012, *Medical electrical equipment – Dosimeters with ionization chambers and/or*  
 428 *semi-conductor detectors as used in X-ray diagnostic imaging*

429 IEC 61676:2002, *Medical electrical equipment – Dosimetric instruments used for non-invasive*  
 430 *measurement of X-ray tube voltage in diagnostic radiology*  
 431 IEC 61676:2002/AMD1:2009

432 IEC 62220-1-1:2015, *Medical electrical equipment – Characteristics of digital X-ray imaging*  
 433 *devices – Part 1-1: Determination of the detective quantum efficiency – Detectors used in*  
 434 *radiographic imaging*

435 IEC 62494-1:2008, *Medical electrical equipment – Exposure index of digital X-ray imaging systems*  
 436 *– Part 1: Definitions and requirements for general radiography*

437 IEC 62563-1:2009, *Medical electrical equipment – Medical image display systems – Part 1:*  
 438 *Evaluation methods*

439 IEC 62563-1:2009/AMD1:2016

440 IEC 62563-1:2009/AMD2:2021

441 IEC 62563-2:2021, *Medical electrical equipment – Medical image display systems – Part 2:*  
 442 *Acceptance and constancy tests*

### 443 **3 Terms, definitions, symbols and abbreviated terms**

#### 444 **3.1 Terms and definitions**

445 For the purposes of this document, the terms and definitions in IEC 60601-1, IEC 60601-1-3,  
 446 IEC 60601-2-54, IEC 60601-2-43 and the following apply.

447 ISO and IEC maintain terminological databases for use in standardization at the following  
 448 addresses:

- 449 • IEC Electropedia: available at <http://www.electropedia.org/>
- 450 • IEC Glossary; available at <http://std.iec.ch/glossary>
- 451 • ISO Online browsing platform: available at <http://www.iso.org/obp>

##### 452 **3.1.1**

##### 453 **ACCEPTANCE TEST**

##### 454 **ACCEPTANCE TESTING**

455 test carried out after new equipment has been installed, or major modifications have been made  
 456 to existing equipment, in order to verify compliance with specifications

457 Note 1 to entry: The specifications could include contractual specifications, requirements enforced by legislation, the  
 458 MANUFACTURER'S specifications or requirements from standards, for example in the IEC 60601 series.

459 [SOURCE: IEC TS 61223-1:1993, 3.2.4, modified – contractual specifications replaced by  
460 specifications and note 1 to entry added]

### 461 3.1.2

#### 462 ACTUAL FOCAL SPOT

463 area on the surface of the anode that intercepts the beam of accelerated particles

464 [SOURCE: IEC 60336:2020, 3.1 modified – target has been replaced by anode, note 1 to entry  
465 has been removed]

### 466 3.1.3

#### 467 ANTI-SCATTER GRID

468 device to be placed before the IMAGE RECEPTION AREA in order to reduce the incidence of  
469 SCATTERED RADIATION upon that area and thus increase the contrast in the X-RAY PATTERN

470 [SOURCE: IEC 60627:2013, 3.1.1]

### 471 3.1.4

#### 472 ARTEFACT(S)

473 apparent structure(s) visible in the image, which does not represent a structure within the object  
474 and which cannot be explained by noise or the MODULATION TRANSFER FUNCTION of the system

475 [SOURCE: IEC 61223-3-3:1996, 3.3.1, modified – artifact changed to ARTEFACT]

### 476 3.1.5

#### 477 ASSOCIATED EQUIPMENT

478 in a RADIOLOGICAL INSTALLATION, ME EQUIPMENT other than those for the production and control  
479 of IONIZING RADIATION, but essential for its application

480 [SOURCE: IEC TR 60788:2004, rm-30-01, modified – equipment has been replaced by ME  
481 EQUIPMENT]

### 482 3.1.6

#### 483 BASELINE VALUES

484 reference value of functional parameter, which is either:

- 485 – the value obtained for this parameter in the initial CONSTANCY TEST immediately following an  
486 ACCEPTANCE TEST, or
- 487 – where described in a corresponding particular standard, the mean value of values obtained  
488 in a series of initial CONSTANCY TESTS, immediately following an ACCEPTANCE TEST

489 Note 1 to entry: The CONSTANCY TEST method can be different from the ACCEPTANCE TEST method. In case the methods  
490 are the same, the value obtained in the ACCEPTANCE TEST can be used.

491 [SOURCE: IEC 61223-3-6:2020, 3.1.5, modified – term status test replaced by ACCEPTANCE  
492 TEST and note 1 to entry added]

### 493 3.1.7

#### 494 BASIC CHECK

495 a test that can be performed routinely and uses simple means and methods to enable the early  
496 detection of changes in the functional performance of equipment

497 Note 1 to entry: BASIC CHECKS are intended to be performed by the RESPONSIBLE ORGANIZATION frequently and without  
498 any measurement instruments (e.g., DOSIMETER, LUMINANCE meter).