

ICS 11.040.50

CCS C 43



**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB/T 19042.2-2025

Replacing GB/T 19042.2-2005

**Evaluation and routine testing in medical imaging departments
- Part 3-2: Mammographic X-ray equipment imaging
performance acceptance tests**

医用成像部门的评价及例行试验 第3-2部分：乳腺摄影X射线设备成像性能验收试验

(English Translation)

Issued on: August 1, 2025

Implemented on: August 1, 2026

**Issued by: State Administration for Market Regulation, Standardization
Administration of China**

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Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for standardization work Part 1: Structure and drafting rules for standardization documents" Drafting.

This document is part 3-2 of GB/T 19042 Evaluation and routine testing of medical imaging departments. GB/T 19042 has been published.

The following parts.

- Part 3-1. Acceptance tests for imaging performance of X-ray equipment for X-ray radiography and fluoroscopy systems;
- Part 3-2. Acceptance test for imaging performance of mammographic X-ray equipment;
- Part 3-3. Acceptance test for imaging performance of X-ray equipment for digital subtraction angiography (DSA);
- Part 3-4. Acceptance test for imaging performance of dental X-ray equipment;
- Part 3-5. X-ray computed tomography equipment imaging performance acceptance test and stability test;
- Part 3-6. Acceptance and stability testing of imaging performance of mammographic X-ray equipment in breast tomosynthesis imaging mode.

This document replaces GB/T 19042.2-2005 "Evaluation and routine testing of medical imaging departments Part 3-2. Mammography X-ray Compared with GB/T 19042.2-2005, in addition to structural adjustments and editorial changes, the main technical changes are as follows.

- Changed the terms and definitions (see Chapter 3, Chapter 3 of the 2005 edition);
- Added general rules for acceptance tests (see Chapter 4);
- Changed the test methods for mammary X-ray equipment (see 5.1 to 5.11, 5.1 to 5.11 of the 2005 edition);
- Added requirements for digital systems (see 5.12, 5.13.2, 5.14.2, 5.15.2, 5.16);
- Added requirements for screen-film systems (see 5.13.1, 5.14.1, 5.15.1, 5.16);
- Added the requirements for the reference value of the stability test (see Chapter 6);
- Changed the test report and declaration of conformity (see Chapter 7, Chapter 6 of the 2005 edition).

This document modifies the IEC 61223-3-2:2007 "Evaluation and routine testing acceptance tests for medical imaging departments Part 3-2.

Imaging Performance of Mammographic X-ray Equipment.

This document has the following structural adjustments compared to IEC 61223-3-2:2007.

- Adjust Table 1 of IEC 61223-3-2:2007 to 3.2 and add abbreviations (see 3.2);
- Modify Table 2 of IEC 61223-3-2:2007 to Table 1 (see 5.3.2);
- Adjust Appendix A of IEC 61223-3-2:2007 to Appendix C; Adjust Appendix B of IEC 61223-3-2:2007 to Appendix D; Adjust Appendix C of IEC 61223-3-2:2007 to Appendix A; Adjust Appendix D of IEC 61223-3-2:2007 to Appendix B. Adjust Appendix E of IEC 61223-3-2:2007 to Appendix G; Adjust Appendix F of IEC 61223-3-2:2007 to Appendix J; to adjust Appendix G of IEC 61223-3-2:2007 to Appendix K; to adjust Appendix H of IEC 61223-3-2:2007 to Appendix Adjusted to Appendix E; Adjusted Appendix I of IEC 61223-3-2:2007 to Appendix F; Adjusted Appendix J is adjusted to Appendix I; Appendix K of IEC 61223-3-2:2007 is adjusted to Appendix H.

The technical differences between this document and IEC 61223-3-2:2007 and their reasons are as follows.

- The normative reference GB 9706.1 replaces IEC 60601-1 (see 4.3) to adapt to my country's technical conditions and increase operability Sexuality;
- Replaced IEC 60601-2-45 (see 4.6.4, 5.3.1, 5.5.1) with the normative reference GB 9706.245 to adapt to my country's technical standards.

Technical conditions, increase operability;

- Replaced IEC 61674 (see 4.6.5) with the normative reference GB/T 19629 to increase operability;
- Replaced IEC 61223-2-1 (see 4.2) with the normative reference GB/T 17006.2 to increase operability;
- Replaced IEC 60336 (see 5.4.1, 5.4.2) with the normative reference YY/T 0063 to adapt to my country's technical conditions, and added operability;
- Changed the terminology (see 3.1) to coordinate with Chinese standards;
- Adjust the note in 4.1.2 to the main text (see 4.1.2) to adapt to my country's technical conditions.

The following editorial changes have been made to this document.

- To coordinate with the Chinese standard, the name of the standard was changed to "Evaluation and routine testing of medical imaging departments Part 3-2.Mammography "Acceptance test of imaging performance of X-ray equipment";
- Added notes (see Chapter 1, 3.1.1, 5.7.1.2, 5.7.1.3.3, Appendix G);