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

GB/T 19042.6-2023

**Evaluation and routine testing in medical imaging departments - Part 3-6:
mammographic X-ray equipment used in a mammographic tomosynthesis mode
of operation imaging performance acceptance and constancy tests**

医用成像部门的评价及例行试验 第3-6部分:乳腺断层合成成像模式下乳腺摄影X
射线设备成像性能验收与稳定性试验

(English Translation)

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Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part 1: Structure and Drafting Rules of Standardization Documents" Drafting:

This document is Part 3-6 of GB/T 19042 "Evaluation and Routine Testing of Medical Imaging Departments": GB/T 19042 has been released the following sections are included:

---Part 3-1: Imaging performance acceptance test of X-ray equipment for X-ray photography and fluoroscopy systems;

---Part 3-2: Mammography X-ray equipment imaging performance acceptance test;

---Part 3-3: Digital subtraction angiography (DSA) X-ray equipment imaging performance acceptance test;

---Part 3-4: Dental X-ray equipment imaging performance acceptance test;

---Part 3-5: X-ray computed tomography equipment imaging performance acceptance test and stability test;

---Part 3-6: Imaging performance acceptance and stability test of mammography X-ray equipment in breast tomosynthesis imaging mode:

This document is modified to adopt IEC 61223-3-6:2020 "Evaluation and routine testing of medical imaging departments Part 3-6: Acceptance and stabilization Experimental study on the imaging performance of mammography X-ray equipment in breast tomosynthesis imaging mode:

The technical differences between this document and IEC 61223-3-6:2020 and their reasons are as follows:

---Replaced IEC 60601-2-45 with GB 9706.245-2020 (see Chapter 3 and related provisions);

---Replaced IEC 61223-3-2:2007 with GB/T 19042.2 (see Chapter 3 and related provisions);

---Replaced IEC 61674:2012 with GB/T 19629 (see Chapter 3 and related provisions);

---Change "anode/filtration" to "target/filtration" (see 4.6:3, 10:1:3);

---Modify "When the results of the acceptance test meet the expected value, this value will be used as the benchmark value for subsequent stability tests:" in the Scope chapter to No: 5 Chapter, and add the voluntary verb "can" to express the degree of requirement (see 5.1):

The following editorial changes have been made to this document:

---In order to coordinate with the existing standards, the name of the standard is changed to "Evaluation and Routine Testing of Medical Imaging Departments Part 3-6: Breast Gland

Transsection" Imaging performance acceptance and stability test of mammography X-ray equipment in layer synthesis imaging mode";

---Deleted the note on English language;

---Adjusted references;

--- Removed terminology index:

Please note that some content in this document may be subject to patents: The publisher of this document assumes no responsibility for identifying patents:

Introduction

GB/T 19042 "Evaluation and Routine Testing of Medical Imaging Departments" establishes a system of diagnostic X-ray equipment acceptance and stability test methods the system is divided into the following 6 parts:

---Part 3-1: Acceptance test of imaging performance of X-ray equipment for X-ray photography and fluoroscopy systems: The purpose is to give X-rays Test methods and requirements related to X-ray equipment for photography and fluoroscopy systems:

---Part 3-2: Mammography X-ray equipment imaging performance acceptance test: The purpose is to provide the cost of mammography X-ray equipment Like relevant test methods and requirements:

---Part 3-3: Digital subtraction angiography (DSA) X-ray equipment imaging performance acceptance test: The purpose is to give the number minus Test methods and requirements related to angiography X-ray equipment:

---Part 3-4: Dental X-ray equipment imaging performance acceptance test: The purpose is to give tests related to dental X-ray equipment methods and requirements:

---Part 3-5: X-ray computed tomography equipment imaging performance acceptance test and stability test: The purpose is to give X Test methods and requirements related to radiographic computed tomography equipment:

---Part 3-6: Imaging performance acceptance and stability test of mammography X-ray equipment in breast tomosynthesis imaging mode: Head the aim is to provide the test methods and requirements related to mammography X-ray equipment imaging in breast tomosynthesis imaging mode:

This document establishes the imaging performance acceptance and stability testing of mammography X-ray equipment in breast tomosynthesis imaging mode method:

Evaluation and routine testing of medical imaging departments Part 3-6: Breast tomosynthesis imaging mode Mammography X-ray equipment imaging performance acceptance and Stability test