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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1307-2024

Replacing YY/T 1307-2016

Medical digital X-ray image detector used in mammography

医用乳腺数字化X射线摄影用探测器

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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 replaces YY/T 1307-2016 "Detectors for Medical Digital Mammography" and is consistent with YY/T 1307-2016. In addition to structural adjustments and editorial changes, the main technical changes are as follows:

a) Added "Calibration", "Center Axis", "Original Bright Field Image", "Original Dark Field Image", "Noise Equivalent Dose", "Frame Rate", "Exposure Window" 9 terms and definitions (see 3.1, 3.2, 3.3, 3.4, 3.5, 3.10, 3.11, 3.12) and 3.13);

b) Changed the definition of "linear dynamic range" (see 3.6,

3.2 of the.2016 edition);

c) The definition of "blind zone" has been changed (see 3.7,

3.3 of the.2016 edition);

d) Added "Classification" (see 4.1);

e) Added "noise equivalent dose" (see 5.4) and "noise equivalent dose" test method (see 6.4);

f) Deleted the "dose linear range" (see

5.4 of the.2016 edition) and the "dose linear range" test method (see 6.4);

g) Changed the "Linear Dynamic Range" (see 5.6,

5.5 of the.2016 version) and the "Linear Dynamic Range" test method (see 6.6, Version 6.5);

h) Changed the expression of "spatial resolution" (see 5.7,

1 Scope

YY/T 1307 is the product standard for the digital detector used in mammography. Mammography asks more of a detector than any other radiographic application: it has to resolve microcalcifications a few tenths of a millimetre across while distinguishing soft tissue densities that differ barely at all, and it has to do so at a dose low enough to screen healthy women repeatedly. Spatial resolution, detective quantum efficiency, contrast response and defective pixel behaviour are therefore not general characteristics but the properties on which a cancer is seen or missed. The 2024 edition takes effect on 20 July 2025. For a manufacturer or an importer of mammography detectors, or a system integrator specifying one for the Chinese market, this is the standard the type testing follows.

This document specifies the classification, composition and requirements of detectors for medical mammography (hereinafter referred to as detectors), and describes the corresponding test method. This document applies to detectors used in mammography equipment with single or multiple exposure imaging capabilities, including but not limited to amorphous Silicon detector, amorphous selenium detector, CCD (charge coupled device) detector, CMOS (complementary metal oxide semiconductor) detector, IGZO (Indium Gallium Zinc Oxide) detectors, photon counting detectors, etc. This document does not apply to.

--- Detectors for general photography and detectors for dental photography;

--- Detectors for computed tomography;

---Detector for dynamic imaging.

2 Normative references

The contents of the following documents constitute essential clauses of this document through normative references in this document. For referenced documents without a date, only the version corresponding to that date applies to this document; for referenced documents without a date, the latest version (including all amendments) applies to This document.

GB 9706.1 Medical electrical equipment Part

3 Terms and definitions

The terms and definitions defined in YY/T 0590.2-2010, GB/T 10149-1988, YY/T 0481-2016 and the following apply in this document.

3.1 Calibration The detector performs necessary operations to make the image meet the evaluation requirements. These processes should be linear and independent of the image.

Examples. background correction, gain correction, and bad pixel correction, etc.

3.2 Central axis A straight line perpendicular to the incident plane and passing through the center of the incident field.