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

GB/T 17006.11-2015

Replacing GB/T 17006-1997

**Evaluation and routine testing in medical imaging departments
-- Part 2-6: Constancy tests -- Imaging performance of
computed tomography X-ray equipment
(English Translation)**

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Foreword

This standard was drafted in accordance with GB/T 1.1-2009 given rules.

This standard replaces GB/T 17006-1997 "evaluation in medical imaging departments and routine testing - Part 2-6. X-ray computed Tomography equipment Stability Test. " the standards are compared with the GB/T 17006-1997 main changes as follows.

- The number of chapters has been adjusted;
- On the "program" has been modified and added a few details of the note;
- On the part of the definition has been modified;
- Increases the volume of CT concepts and requirements;
- On the part of the standardization of terminology translation made;
- The term "CT operating state" to "CT operating conditions." this standard is equivalent to using the International Electrotechnical Commission IEC 61223-2-6:2006 "evaluation of medical imaging departments and routine testing 2-6 Section. X-ray computed tomography imaging equipment performance stability test. " Correspondence between the consistency of the standards of international documents and normative references of the following documents.
- GB 9706.18-2006 Medical electrical equipment - Part 2. X-ray computer tomography equipment requirements for the safety (IEC 60601-2-44:2002, IDT);
- GB/T 19042.5-2006 medical imaging departments - Evaluation and routine testing - Part 3-5. X-ray computed tomography camera Movies imaging equipment performance acceptance test (IEC 61223-3-5:2004, IDT).

Please note that some of the content of this document may involve patents. Release mechanism of the present document does not assume responsibility for the identification of these patents.

This standard was proposed by the State Food and Drug Administration.

This standard by the National Technical Committee of Standardization for medical electrical equipment and medical X-ray appliances Technical Committee (SAC/TC10/SC1) Centralized.

This standard was drafted. Liaoning Provincial Medical Device Testing, China Quality Certification Center sub-centers in Shenyang, Shanghai Siemens medical instruments have Limited.

1 Scope

This standard is in the X-ray computed tomography apparatus (hereinafter referred to as CT scanning device) provide guidance on stability testing.

This standard applies to components that affect image quality, patient dose and positioning of the CT scanning device.

This standard.

- Define the basic parameters of the CT scanner statements regarding image quality,

patient dose and positioning performance; see these parameters to be measured 4.5;

--- Detailed description of these measurements basic parameters;

--- Providing the evaluation of measurement data parameters for random document regulatory compliance used by the standard deviation of the reference value and.

These methods rely on non-invasive measurements, using appropriate test equipment, by testing to ensure that the functional performance of equipment in line with the establishment of a quasi Then, or be able to change the early identification of equipment components characteristics.

Purpose is to test about image quality, patient dose and patient positioning specification compliance.

This standard does not relate to.

--- Mechanical and electrical safety;

--- Mechanical, electrical and software performance, unless they are elements of the implementation of the stability tests, and directly affect image quality, patient Dose and positioning.

2 Normative references

The following documents for the application of this document is essential. For dated references, only the dated version suitable for use herein Member. For undated references, the latest edition (including any amendments) applies to this document.

IEC 60788:2004 Medical electrical equipment defined in the glossary
(Medicalelectricalequipment-Glossaryof definedterms) IEC 61223-3-5:2004 Evaluation and routine medical imaging departments - Part 3-5 test. X-ray computed tomography apparatus Imaging performance acceptance test
(Evaluationandroutinetestinginmedicalimagingdepartments-Part 3-5.
Accept-ancetests-ImagingperformancesofcomputedtomographyX-rayequipment) IEC 60601-2-44:2002 Medical electrical equipment - Part 2-44. X-ray computer tomography equipment requirements for the safety (Medicalelectricalequipment-Part 2-44.
ParticularrequirementsforthesafetyofX-rayequipment forcomputedtomography)

3 Terms and Definitions

IEC 60788:2004 and the following definition of terms and definitions apply to this document.

Note 1: The standard term used in the index definition is given in this standard.

Note 2: In this standard, the small print of the 5th term blackbody expressed in GB/T 17006.1 or IEC 60788 has been defined it.