

ICS 11.040.50

CCS F 91



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

GB/T 19046-2013

Replacing GB/T 19046-2003

Medical Electron Accelerators - Acceptance and Periodic Tests

医用电子加速器 验收试验和周期检验规程

(English Translation)

Issued on: December 17, 2013

Implemented on: August 1, 2014

**Issued by: General Administration of Quality Supervision, Inspection and
Quarantine of the People's Republic of China**

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Foreword

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

This standard replaces GB/T 19046-2003 "Medical Electron Accelerator Acceptance Test and Periodic Inspection Procedure".

This standard compared with GB/T 19046-2003, the main technical changes are as follows.

a) Added chapter 3 terms and definitions.

b) Chapters 4 and 5 increase the performance and test methods of the following new technologies.

Intensive radiation therapy (IMRT);

Stereotactic Radiotherapy (SRT)/Stereotactic Surgery (SRS);

- electronic imaging device;

--- multi-limiting device.

c) Chapter 7 adds the "Recommended frequency of periodic inspection of the electronic accelerator working life".

Refer to IEC/T R60977..2008 "Guidelines for the Performance of Medical Electron Accelerators for Medical Electrical Equipment" System, and IEC/T R60977..2008 consistency degree is not equivalent.

IEC/T R60977..2008 The recommended performance indicators in Chapter 3 have been national standards GB 15213-2016 "Medical Electron Accelerator Performance and test methods "and incorporated into Chapter 5 of the standard. Taking into account the corresponding relationship with the national standard GB 15213-2016, this standard compared with IEC/T R60977..2008, made the following editorial changes.

a) modify the name of the standard to show the difference between GB 15213-2016;

b) The chapters and choreography of chapters 1 to 5 are basically in accordance with GB

15213-2016;

c) Removed some of the contents of IEC/T R60977..2008, Chapter 3, and Chapters 4 and 5.

For ease of comparison, the information on this standard is listed in the Appendix C and IEC/T R60977..2008 and GB 15213-

2016 Chapter of the control list.

Taking into account the feasibility of the standard, this standard compared with IEC/T R60977..2008, made the following technical changes.

a) make appropriate modifications and additions to the technical specifications in Chapter 4 Performance Requirements;

b) Removed the "maximum absorbed dose ratio of electron radiation", "Optical field indication of electron radiation field" "Parallelism of the rotation axis of the treatment bed";

c) Added normative Appendix A "Acceptance test project selection reference" and normative Appendix B "Periodical inspection project selection reference";

d) Increased safety requirements for radiation protection. "Spurious X-Radiation in Electron Irradiation" and "Relative Surface Dose in X Irradiation" (see 4.2);

e) an illustration of the contents of GB 15213-2016 relating to the contents of this standard.

These technical differences are described separately in the Data Appendix D.

1 Scope

This standard specifies the performance requirements, test methods, test conditions and inspection cycles for medical electronic accelerator acceptance tests and cycle tests.

This standard applies to the medical electronic accelerator after the initial installation, the manufacturer, the user and a third party jointly conducted acceptance test, and set in the normal work, the user carries out the periodic inspection.

This standard applies to medical care for the purpose of radiation therapy, can produce X-radiation and electron radiation, the nominal energy of 1MeV ~ 50MeV medical electronic accelerator.

This standard is applicable to medical electronic accelerators equipped with an isocenter rack, and the performance and test methods of non-center equipment carried out.

2 Normative reference documents

The following documents are indispensable for the application of this document. For dated references, only the dated edition applies to this article Pieces. For undated references, the

latest edition (including all modifications) applies to this document.

GB 9706.5-2008 Medical electrical equipment - Part 2. Energy for the 1MeV to 50 MeV electronic accelerator Claim Performance and test methods for medical electronic accelerators GB 15213-2016 Medical Radiology Terminology GB/T 17857

3 Terms and definitions

GB 9706.5-2008, GB 15213-2016, GB/T 17857 The terms and definitions defined apply to this document.

4.1.1 Repeatability

Reproducibility S is characterized by a coefficient of variation, and for X-radiation and electron radiation, under the same irradiation condition, the dose monitoring count and the absorbed dose the coefficient of variation for the ratio of measured values should not be greater than 0.5%.

Repeatability S is determined by the coefficient of variation given by equation (1).

$$R = \frac{\sum (R - R_i)^2}{n}$$

$$100\% \quad (1)$$

Where.

R - the average of the ratio R_i determined by Eq. (2) R_i - the ratio of the dose monitoring count to the absorbed dose measured at the i-th measurement;

n - number of measurements.