

ICS 11.040.50

CCS C 43



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

GB 9706.244-2020

Replacing GB 9706.18-2006

**Medical electrical equipment - Part 2-44: Particular
requirements for the basic safety and essential performance of
X-ray equipment for computed tomography**

医用电气设备 第2-44部分：X射线计算机体层摄影设备的基本安全和基本性能专用要求

(English Translation)

Issued on: December 24, 2020

Implemented on: May 1, 2023

Issued by: State Administration for Market Regulation

Table of Contents

Preface

201.1 Scope, purpose and related standards

201.2 Normative references

201.3 Terms and Definitions

201.4 General requirements

201.5 General requirements for testing of ME equipment

201.6 Classification of ME equipment and ME systems

201.7 ME equipment identification, marking and documentation

201.8 Protection of ME equipment against electric shock risk

201.9 Protection of ME equipment and ME system against mechanical hazards

201.10 Protection against unwanted or excessive radiation hazards (sources)

201.11 Protection against over-temperature and other hazards (sources)

201.12 Accuracy of controllers and instruments and protection of dangerous outputs

201.13 Dangerous conditions and fault states of ME equipment

201.14 Programmable Medical Electrical System (PEMS)

201.15 Structure of ME equipment

201.16 ME System

201.17 Electromagnetic compatibility of ME equipment and ME systems

201.101 Requirements for CT scanning devices to provide images for radiotherapy planning (RTP)

202 Electromagnetic compatibility---requirements and tests

203 Radiation protection of diagnostic X-ray equipment

Appendix

Appendix AA (informative appendix) Selection of loading factors in the test

Appendix BB (informative appendix) Estimation of CTDI_{vol} value of plain scan

Appendix CC (informative appendix) The concept of CTDI₁₀₀ in this proprietary standard: the relationship between CTDI₁₀₀ and CTDI_{infinity}

Appendix DD (informative appendix) Measurement by CTDI_{freeair}

References

Foreword

GB 9706 "Medical Electrical Equipment" is divided into the following parts:

- Part 1: General requirements for basic safety and basic performance;
- Part 1-3: General requirements for basic safety and basic performance Parallel standard: Radiation protection of diagnostic X-ray equipment;
- Part 2-1: Specific requirements for the basic safety and basic performance of electron accelerators with energy from 1MeV to 50MeV;
- Part 2-2: Special requirements for the basic safety and basic performance of high-frequency surgical equipment and high-frequency accessories;
- Part 2-3: Special requirements for basic safety and basic performance of short-wave treatment equipment;
- Part 2-4: Special requirements for the basic safety and basic performance of cardiac defibrillators;
- Part 2-5: Special requirements for the basic safety and basic performance of ultrasonic physical therapy equipment;
- Part 2-6: Special requirements for the basic safety and basic performance of microwave therapy equipment;
- Part 2-8: Special requirements for the basic safety and basic performance of therapeutic X-ray equipment with an energy of 10kV to 1MV;
- Part 2-11: Special requirements for basic safety and basic performance of gamma beam therapy equipment;
- Part 2-12: Special requirements for the basic safety and basic performance of intensive care ventilators;
- Part 2-13: Special requirements for basic safety and basic performance of anesthesia workstations;
- Part 2-16: Specific requirements for basic safety and basic performance of hemodialysis, hemodiafiltration and hemofiltration equipment;
- Part 2-17: Special requirements for basic safety and basic performance of automatic control brachytherapy after-installation equipment;
- Part 2-18: Specific requirements for basic safety and basic performance of endoscopic equipment;
- Part 2-19: Special requirements for basic safety and basic performance of infant incubators;

- Part 2-22: Special requirements for basic safety and basic performance of laser equipment for surgery, plastic surgery, treatment and diagnosis;
- Part 2-24: Specific requirements for basic safety and basic performance of infusion pumps and infusion controllers;
- Part 2-25: Special requirements for basic safety and basic performance of electrocardiograph;
- Part 2-26: Specific requirements for the basic safety and basic performance of EEG machines;
- Part 2-27: Special requirements for basic safety and basic performance of ECG monitoring equipment;
- Part 2-28: Special requirements for the basic safety and basic performance of medical diagnostic X-ray tube components;
- Part 2-29: Specific requirements for the basic safety and basic performance of radiotherapy simulators;
- Part 2-36: Specific requirements for the basic safety and basic performance of in vitro lithotripsy equipment;
- Part 2-37: Special requirements for the basic safety and basic performance of ultrasonic diagnostic and monitoring equipment;
- Part 2-39: Specific requirements for the basic safety and basic performance of peritoneal dialysis equipment;
- Part 2-43: Special requirements for the basic safety and basic performance of interventional X-ray equipment;
- Part 2-44: Special requirements for the basic safety and basic performance of X-ray computed tomography equipment;
- Part 2-45: The basic safety and basic performance of mammography equipment and mammography stereotaxic devices Claim;
- Part 2-54: Specific requirements for the basic safety and basic performance of X-ray photography and fluoroscopy equipment;
- Part 2-60: Special requirements for basic safety and basic performance of dental equipment;
- Part 2-63: Special requirements for the basic safety and basic performance of extraoral imaging dental X-ray machines;
- Part 2-65: Specific requirements for the basic safety and basic performance of intraoral imaging dental X-ray machines;

---Part 2-66: Special requirements for basic safety and basic performance of hearing equipment and hearing equipment system:

This part is part 2-44 of GB 9706:

This section was drafted in accordance with the rules given in GB/T 1.1-2009:

This part replaces GB 9706.18-2006 "Medical electrical equipment Part 2: X-ray computer tomography equipment safety special Claim":

Compared with GB 9706.18-2006, the main technical changes in this part are as follows:
increased:

---Basic performance requirements (see:201:4:3);

--- The scope of application clarifies that only CT scanning devices intended for the head and body (see:201:1:1);

---Some terms have been modified and some terms have been added (see:201:3);

---Patient's release (see:201:9:2:5), tensile safety factor (see:201:9:8:2), dynamic load from human weight (see 201:9:8:3:3), the requirement for CT scanning device to provide images for radiotherapy planning (RTP) (see:201:101), out of focus Radiation limit (see 203.8: 4) and other related requirements:

edited:

---Weighted CTDI100 and other terms (see:201:3, 29:103 in GB 9706.18-2006);

--- Emergency stop of motor-driven movement (see:201:9:2:4:101:1, 22:7:101 of GB 9706.18-2006), patient support and scan the linear movement of the tracing frame (see:201:9:2:4:101:3, 22:4:101 of GB 9706.18-2006) and other relevant requirements:

This part uses the redrafting method to amend and adopt IEC 60601-2-44:2016 "Medical Electrical Equipment Part 2-44: X-ray calculation Specific requirements for basic safety and basic performance of body layer photography equipment:

The technical differences between this part and IEC 60601-2-44:2016 and the reasons are as follows:

---Regarding normative reference documents, this section has made adjustments with technical differences to adapt to my country's technical conditions and adjustments:

The situation is collectively reflected in:201:2 "Normative Reference Documents", and the specific adjustments are as follows:

- Replace IEC 60601-1-2:2014 (see:201:1:3 and related provisions) with YY0505 which is equivalent to adopting international standards;
- Replace IEC 60601-1-3:2013 with GB 9706.103-2020 which is modified to adopt