

ICS 11.040.60

CCS C 42



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

GB 9706.206-2020

Replacing GB 9706.6-2007

**Medical electrical equipment - Part 2-6: Particular requirements
for the basic safety and essential performance of microwave
therapy equipment**

医用电气设备 第2-6部分：微波治疗设备的基本安全和基本性能专用要求

(English Translation)

Issued on: July 23, 2020

Implemented on: May 1, 2023

**Issued by: State Administration for Market Regulation, China National
Standardization Administration**

Table of Contents

201.1 Scope, purpose and related standards	1
201.2 Normative references	2
201.3 Terms and Definitions	2
201.4 General requirements	3
201.5 General requirements for ME equipment testing	3
201.6 Classification of ME equipment and ME systems	3
201.7 ME equipment identification, marking and documentation	3
201.8 Protection of ME equipment against electric shock	5
201.9 Protection of ME equipment and ME system against mechanical hazards	5
201.10 Protection against unwanted or excessive radiation risks (sources)	5
201.11 Protection against over-temperature and other hazards (sources)	6
201.12 Accuracy of controllers and instruments and protection of dangerous outputs	6
201.13 Dangerous conditions and fault states of ME equipment	7
201.14 Programmable Medical Electrical System (PEMS)	7
201.15 Structure of ME equipment	7
201.16 ME System	8
201.17 Electromagnetic compatibility of ME equipment and ME systems	8
202 Electromagnetic Disturbance-Requirements and Test	8
Appendix	9
Appendix C (informative appendix) ME equipment and ME system marking and labeling requirements guide	10
Appendix AA (informative appendix) Special guidance and explanation	11
Reference	14

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 an energy of 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 shortwave 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 the 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.Special 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.Special 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.Specifical requirements for the basic safety and basic performance of radiotherapy simulators;

---Part 2-36.Special 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.Special 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.Special 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.Specifical 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 2-6 of GB 9706.

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

This part replaces GB 9706.6-2007 "Medical Electrical Equipment Part 2.Special Requirements for the Safety of Microwave Therapy Equipment", and

Compared with GB 9706.6-2007, the main technical changes are as follows.

--- Deleted the definition of the term "application part" and "radiator" (see 2.1.5, 2.1.102 in the.2007 edition);

--- Added the definition of the terms "contact applicator" and "non-contact applicator" (see.201.3.202,.201.3.205);

---Modified the definitions of some terms (see.201.3.203,.201.3.204,.201.3.206,.201.3.207 and.201.308,.2007 edition

2.12.103, 2.1.101, 2.1.103, 2.12.101, 2.12.102);

---Added basic performance requirements (see.201.4.3.11);

--- Modified the requirements for non-ionizing radiation symbols in external markings (see.201.7.2.101,.2007 edition 6.1);

---Modified the requirements of the non-contact applicator in the specification requirements (see.201.7.9.2.101, 6.8.2 of the.2007 edition);

---Added the requirements of the corresponding diagram of power output and settings in the technical description (see.201.7.9.2.101);

---Modified the test methods of unwanted radiation and microwave leakage, including modifying the microwave power setting value during the test and the requirements of the test applicator,

It is also allowed to use the manufacturer's specified phantom during the test (see.201.10.3, Chapter 31 of the.2007 edition);

---Modified the rated power limit of 250W as a single channel requirement, and increased the power limit requirement for multiple channels (see.201.10.3.103,

31.3 of the.2007 edition);

---Added the temperature requirements of the contact application part (see.201.11.1.2.1);

---Revised the accuracy requirements of microwave power indication, from $\pm 30\%$ to $\pm 20\%$ (see.201.12.1, 50.1 in.2007 edition);

---Added the requirements for the output indicator and the audio signal requirements (see.201.12.4.2.101);

---Clarify that the excitation output requirements are requirements for non-contact applications, and the requirements should also be met after interruption and restoration of the network power supply (see.201.12.4.102,