

ICS 11.040.55

CCS C41



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

GB 9706.237-2020

**Medical electrical equipment-Part 2-37: Particular requirements
for the basic safety and essential performance of ultrasonic
medical diagnostic and monitoring equipment**

医用电气设备 第2-37部分：超声诊断和监护设备的基本安全和基本性能专用要求
(English Translation)

Issued on: April 9, 2020

Implemented on: May 1, 2023

**Issued by: State Administration for Market Regulation;
Standardization Administration of China**

Table of Contents

Foreword...	4
Introduction...	10
201.1 Scope, object and related standards...	11
201.2 Normative references...	13
201.3 Terms and definitions...	13
201.4 General requirements...	22
201.5 General requirements for testing ME EQUIPMENT...	23
201.6 Classification of ME EQUIPMENT and ME SYSTEMS...	23
201.7 ME EQUIPMENT identification, marking and documents...	23
201.8 Protection against electrical HAZARDS from ME EQUIPMENT...	28

Foreword

All technical content of this Part is mandatory.

GB 9706 "Medical electrical equipment" is divided into the following parts.

- Part 1.General requirements for basic safety and essential performance;
- Part 1-3.General requirements for basic safety and essential performance
- Collateral standard. General requirements for radiation protection in diagnostic X-ray equipment;
- Part 2-1.Particular requirements for the safety of electron accelerators in the range 1 MeV to 50 MeV;
- Part 2-2.Particular requirements for the safety of high frequency surgical equipment;
- Part 2-3.Particular requirements for the basic safety and essential performance of short-wave therapy equipment;
- Part 2-4.Particular requirements for the safety of cardiac defibrillators;
- Part 2-5.Particular requirements for the safety of ultrasonic physiotherapy equipment;
- Part 2-6.Particular requirements for the basic safety and essential

performance of microwave therapy equipment;

- Part 2-8.Particular requirements for basic safety and essential performance

of therapeutic X-ray equipment operating in the range 10 kV to 1 MV;

- Part 2-11.Particular requirements for the basic safety and essential performance of gamma beam therapy equipment;

- Part 2-12.Particular requirements for basic safety and essential performance of critical care ventilators;

- Part 2-13.Particular requirements for basic safety and essential performance of an anaesthetic workstation;

- Part 2-16.Particular requirements for the safety of haemodialysis, haemodiafiltration and haemofiltration equipment;

- Part 2-17.Particular requirements for the basic safety and essential performance of automatically-controlled brachytherapy after loading equipment;

- Part 2-18.Particular requirements for the basic safety and essential performance of endoscopic equipment;

- Part 2-19.Particular requirements for the basic safety and essential performance of infant incubators;

- Part 2-22.Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment;

- Part 2-24.Particular requirements for the safety of infusion pumps and controllers;

- Part 2-25.Particular requirements for the basic safety and essential performance of electrocardiographs;

- Part 2-26.Particular requirements for the basic safety and essential performance of electroencephalograph;

- Part 2-27.Particular requirements for the basic safety and essential

performance of electrocardiographic monitoring equipment;

- Part 2-28. Particular requirements for the basic safety and essential

performance of X-ray tube assemblies for medical diagnosis;

- Part 2-29. Particular requirements for the basic safety and essential

performance of radiotherapy simulators;

- Part 2-36. Particular requirements for the basic safety and essential

performance of equipment for extracorporeally induced lithotripsy;

- Part 2-37. Particular requirements for the basic safety and essential

performance of ultrasonic medical diagnostic and monitoring equipment;

- Part 2-39. Particular requirements for the safety of peritoneal dialysis

equipment;

- Part 2-43. Particular requirements for the safety of X-ray equipment for

interventional procedures;

- Part 2-44. Particular requirements for the basic safety and essential

performance of X-ray equipment for computed tomography;

- Part 2-45. Particular requirements for the safety of mammographic X-ray

equipment and mammographic stereotactic devices;

- Part 2-54. Particular requirements for the basic safety and essential

performance of X-ray equipment for radiography and radioscopy;

- Part 2-60. Particular requirements for the basic safety and essential

performance of dental equipment;

- Part 2-63. Particular requirements for the basic safety and essential

performance of dental extra-oral X-ray equipment;

- Part 2-65. Particular requirements for the basic safety and essential

performance of dental intra-oral X-ray equipment;

- Part 2-66. Particular requirements for the basic safety and essential

performance of hearing instruments and hearing instrument systems.

This Part is Part 2-37 of GB 9706.

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

This Part replaces GB 9706.9-2008 "Medical electrical equipment - Part 2-37.

Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment".

Compared with GB 9706.9-2008, the main technical changes in this Part are as follows.

- ADD "Scope" (see 201.1.1);
- ADD "Object" (see 201.1.2);
- ADD "Normative references" (see 201.2);
- Modify "Terms and definitions" (see 201.3; Clause 2 of the 2008 edition);
- ADD content related to ULTRASOUND ENDOSCOPE (see 201.4.1);
- ADD "Additional ESSENTIAL PERFORMANCE requirements" (see 201.4.3.101);
- Modify part of the content of "ME EQUIPMENT identification, marking and documents" (see 201.7; Clause 6 of the 2008 edition);
- ADD "Acoustic output" (see 201.7.2.101);
- ADD "Technical data regarding acoustic output levels" (see 201.7.9.3.101);
- ADD content for TRANSDUCER ASSEMBLIES (see 201.8.7.4.7, 201.8.7.4.8, 201.8.8.3, 201.8.9.3.4 and 201.8.10.4);
- ADD "Ultrasonic energy" (see 201.10.101);
- ADD content for TRANSDUCER ASSEMBLIES (see 201.11.1.3 and 201.11.6.5);
- Modify part of the content of "Accuracy of controls and instruments and protection against hazardous outputs" (see 201.12; 50.2, 51.2 and 51.4 of the 2008 edition);
- ADD "Emissions, deformation of ENCLOSURE or exceeding maximum temperature" (see 201.13.1.2);
- ADD "PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)"