

ICS 11.040.20

CCS C 45



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

GB 9706.216-2021

**Medical electrical equipment - Part 2-16: Particular requirements for the
basic safety and essential performance of haemodialysis,
haemodiafiltration and haemofiltration equipment**

医用电气设备 第2-16部分：血液透析、血液透析滤过和血液滤过设备的基本安全
和基本性能专用要求

(English Translation)

Issued on: August 10, 2021

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	3
201.4 General requirements	5
201.5 General requirements for testing of ME equipment	8
201.6 Classification of ME equipment and ME systems	8
201.7 ME equipment identification, marking and documentation	8
201.8 Protection of ME equipment against electric shock hazard (source)	11
201.9 Protection of ME equipment and ME systems against mechanical hazards	12
201.10 Protection against unwanted or excessive radiation hazards (sources)	12
201.11 Protection against over-temperature and other hazards (sources)	12
201.12 *The accuracy of controllers and instruments and the protection of dangerous outputs	13
201.13 Dangerous conditions and fault states of ME equipment	21
201.14 Programmable Medical Electrical System (PEMS)	21
201.15 Structure of ME equipment	21
201.16 *ME system	22
201.17 Electromagnetic compatibility of ME equipment and ME systems	23
202 Electromagnetic compatibility---requirements and tests	23
208 General requirements, testing and guidance for alarm systems in medical electrical equipment and medical electrical systems	23
209 Environmental Awareness Design Requirements	24
210 Physiological closed-loop controller development requirements	24
211 *Requirements for medical electrical equipment and medical electrical systems used in home care environments	25
Appendix	26
Appendix G (Normative Appendix) Protection against the danger (source) of igniting flammable anesthetic mixtures	27
Appendix AA (informative appendix) special guide and principle description	28
Appendix BB (informative appendix) Examples of hazards (sources), foreseeable sequence of events and dangerous situations of hemodialysis equipment	41
References	50

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 the basic safety and basic performance of the anesthesia workstation;
- Part 2-16.Specific requirements for the basic safety and basic performance of hemodialysis, hemodiafiltration and hemofiltration equipment;
- Part 2-17.Special requirements for the basic safety and basic performance of automatic control brachytherapy after-installation equipment;
- Part 2-18.Specific requirements for the 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 the 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.Specific 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
- Require;
- 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.Special 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 2-16 of GB 9706.

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

This part replaces GB 9706.2-2003 "Medical Electrical Equipment Part 2-16.Hemodialysis, Hemodiafiltration and Hemofiltration

Compared with GB 9706.2-2003, the main technical changes are as follows.

- Increased the scope of application (see.201.1.1);
- Added the requirements of basic performance (see.201.4.
- Added anticoagulation requirements (see.201.12.4.4.112);
- Added the requirements of the programmable medical electrical system (PEMS) (see.201.14);
- Added the requirements of the ME system (see.201.16);
- Added requirements for testing and guidelines for medical electrical equipment and alarm systems in medical electrical systems (see Chapter 208);
- Added environmental awareness design requirements (see Chapter 209);
- Added the development requirements of the physiological closed-loop controller (see Chapter 210);
- Added requirements for medical electrical equipment and medical electrical systems used in home care environments (see Chapter 211);
- The requirement for arterial pressure has been deleted (see 51.105, 51.108 in the.2003 edition);
- Deleted the requirement for hemodiafiltration without buffer (see 51.108, 51.111 in the.2003 edition);
- Deleted the requirements for temperature and overload control devices (see 56.6 in the.2003 edition);
- Modified the test method of air injection (see.201.12.4.4105, 51.106 in the.2003 edition).

This part uses the redrafting law to amend and adopt IEC 60601-2-16.2018 ``Medical Electrical Equipment Part 2-16.Hemodialysis,

Special requirements for the basic safety and basic performance of hemodiafiltration and