

ICS 11.040.70

CCS C40



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

GB 9706.218-2021

**Medical electrical equipment-Part 2-18:Particular requirements
for the basic safety and essential performance of endoscopic
equipment**

医用电气设备 第2-18部分：内窥镜设备的基本安全和基本性能专用要求
(English Translation)

Issued on: December 1, 2021

Implemented on: May 1, 2023

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

Table of Contents

Foreword...	3
Introduction...	8
201.1 Scope, object and related standards...	10
201.2 Normative references...	12
201.3 Terms and definitions...	12
201.4 General requirements...	16
201.5 General requirements for testing of ME EQUIPMENT...	18
201.6 Classification of ME EQUIPMENT and ME SYSTEMS...	18
201.7 ME EQUIPMENT identification, marking and documents...	19
201.8 Protection against electrical HAZARDS from ME EQUIPMENT...	23

Foreword

This document was drafted in accordance with the provisions of GB/T 1.1-2020

"Directives for standardization - Part 1.Rules for the structure and drafting of standardizing documents".

This document is Part 2-18 of GB 9706 "Medical electrical equipment". GB 9706 has released the following parts.

- Part 1.General requirements for safety;
- Part 1-3.General requirements for basic safety and essential performance - Collateral Standard. Radiation protection in diagnostic X-ray equipment;
- Part 2-1.Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV;
- Part 2-2.Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories;
- Part 2-3.Particular requirements for the basic safety and essential performance of short-wave therapy equipment;
- Part 2-5.Particular requirements for the basic safety and essential performance 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 the 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 the basic safety and essential performance of an anaesthetic workstation;
- Part 2-16.Particular requirements for the basic safety and essential performance 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 2-24.Particular requirements for the basic safety and essential performance 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 electroencephalographs;
- 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 basic safety and essential performance 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 basic safety and essential performance of mammographie X-ray equipment and mammographie 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.

This document replaces GB 9706.19-2000 "Medical electrical equipment - Part 2. Particular requirements for the safety of endoscopic equipment". Compared with GB 9706.19-2000, except for structural adjustment and editorial changes, the main technical changes are as follows.

- In the scope, AMEND "Supplement" to "Replacement"; ADD "essential performance" (see 201.1.1 of this document, 1.1 of the 2000 edition);
- In the object, ADD "essential performance" (see 201.1.2 of this document, 1.2 of

the 2000 edition);

- ADD "Collateral standards" (see 201.1.3 of this document);
- In the particular standards, amend "Supplement" to "Replacement" (see 201.1.4 of this document, 1.3 of the 2000 edition);
- ADD "Normative references" (see 201.2 of this document);
- In the terms and definitions, ADD "CONFIGURATION FOR ENDOSCOPE APPLICATION", "ENERGIZED ENDOSCOPE", "ENERGIZED ENDOTHERAPY DEVICE", "HIGH FREQUENCY", "INTERFACE CONDITION", "NEUTRAL ELECTRODE", "RATED ACCESSORY VOLTAGE"; AMEND "ENDOSCOPE ACCESSORIES" to "ENDOTHERAPY DEVICE" (see 201.3 of this document, Clause 2 of the 2000 edition);
- In the general requirements, AMEND "Energized endotherapy devices", "Ultrasonic diagnostic equipment", "SUPPLY UNITS" and "ADDITIONAL ESSENTIAL PERFORMANCE requirements"; ADD "ESSENTIAL PERFORMANCE", "ME EQUIPMENT or ME SYSTEM PARTS that contact the PATIENT" and "SINGLE FAULT CONDITION for ME EQUIPMENT" (see

201.4 of this document, Clause 3 of the 2000 edition);

- AMEND "General requirements for testing" to "General requirements for testing of ME EQUIPMENT"; ADD "TYPE TESTS" and "Humidity preconditioning treatment" (see 201.5 of this document, Clause 4 of the 2000 edition);
- AMEND "Classification" to "Classification of ME EQUIPMENT and ME SYSTEMS"; ADD "Protection against electric shock" (see 201.6 of this document, Clause 5 of the 2000 edition);
- AMEND "Identification, marking and documents" to "ME EQUIPMENT identification, marking and documents"; AMEND "Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts" and "ACCOMPANYING DOCUMENTS"; ADD "Marking of controls and instruments", "Symbols" (see