

GB

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

GB 9706.1-2020

Replacing GB 9706.1-2007, GB 9706.15-2008

**Medical electrical equipment - Part 1: General
requirements for basic safety and essential
performance**

医用电气设备

第 1 部分：基本安全和基本性能的通用要求
(IEC 60601-1:2012, MOD)

Issued on: April 09, 2020

Implemented on: May 01, 2023

**Issued by: State Administration for Market Regulation;
Standardization Administration of the PRC.**

Table of Contents

Foreword.....	4
1 Scope, object and related standards.....	11
2 Normative references	12
3 * Terminology and definitions.....	17
4 General requirements	51
5 * General requirements for testing ME EQUIPMENT.....	62
6 * Classification of ME EQUIPMENT and ME SYSTEMS	69
7 ME EQUIPMENT identification, marking and documents.....	70
8 * Protection against electrical HAZARDS from ME EQUIPMENT	96
9 * Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS.....	174
10 * Protection against unwanted and excessive radiation HAZARDS.....	204
11 Protection against excessive temperatures and other HAZARDS	207
12 * Accuracy of controls and instruments and protection against hazardous outputs.....	226
13 * HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT.....	229
14 * PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS).....	238
15 Construction of ME EQUIPMENT.....	246
16 * ME SYSTEMS	265
17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS...	274
Annex A (Informative) General guidance and rationale.....	275
Annex B (Informative) Sequence of testing	435
Annex C (Informative) Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS	439
Annex D (Informative) Symbols on marking	443
Annex E (Informative) Examples of the connection of the measuring device (MD) for measurement of the PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT (see 8.7)	452

Annex F (Informative) Suitable measuring supply circuits	454
Annex G (Normative) Protection against HAZARDS of ignition of flammable anaesthetic mixtures	457
Annex H (Informative) PEMS structure, PEMS DEVELOPMENT LIFE-CYCLE and documentation	476
Annex I (Informative) ME SYSTEMS aspects	487
Annex J (Informative) Survey of insulation paths (see 8.5.1)	493
Annex K (Informative) Simplified PATIENT LEAKAGE CURRENT diagrams	496
Annex L (Normative) Insulated winding wires for use without interleaved insulation (8.8.2)	499
Annex M (Normative) Reduction of pollution degrees (see 8.9.1.8)	503
Bibliography	504

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 safety - 3. 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;