GB

NATIONAL STANDARD OF THE

PEOPLE'S REPUBLIC OF CHINA

ICS 11.040.70

CCS C 40

GB 9706.218-2021

Replacing GB 9706.19-2000

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

(IEC 60601-2-18:2009, MOD)

Issued on: December 01, 2021 **Implemented on: May 01, 2023**

Issued by: State Administration for Market Regulation;
Standardization Administration of the People's Republic of China.

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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 201.7 of this document, Clause 6 of the 2000 edition);

- ADD "Classification of APPLIED PARTS", "Separation of parts"; AMEND "Insulation", "CREEPAGE DISTANCES and AIR CLEARANCES" (see 201.8 of this document);

- AMEND "HAZARDS associated with moving parts", "Expelled parts HAZARD"; ADD "HAZARDS associated with surfaces, corners and edges", "Instability HAZARDS", "Pressure vessels and parts subject to pneumatic and hydraulic pressure", "HAZARDS associated with support systems" (see 201.9 of this document, Section IV of the 2000 edition);

- ADD "Lasers and light emitting diodes (LEDs)", "Other visible electromagnetic radiation", "Infrared radiation", "Ultraviolet radiation" (see 201.10 of this document);

- ADD "Thermal and other HAZARDS from INTERCONNECTION CONDITIONS with LASERS"; AMEND "APPLIED PARTS not intended to supply heat to a PATIENT", "GUARDS", "Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS", "Thermal and other HAZARDS from INTERCONNECTION CONDITIONS with HF SURGICAL EQUIPMENT" (see 201.11 of this document);

- ADD "USABILITY", "Alarm systems", "Protection against hazardous output" (see 201.12 of this document);

- ADD "Image observation" (see 201.13 of this document);

- ADD "PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)" (see 201.14 of this document);

- ADD "Construction of connectors"; AMEND "General", "Rough handling test" (see 201.15 of this document);

- ADD "ME SYSTEMS" (see 201.16 of this document);

- AMEND "Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS", "Electromagnetic compatibility - Requirements and tests" (see 201.17 and Clause 202 of this document, Clause 36 of the 2000 edition).

This document uses the redrafting method to amend and adopt IEC 60601-2-18:2009 "Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment".

The technical differences between this document and IEC 60601-2-18:2009 and their reasons are as follows:

- Regarding normative references, this document has made adjustments with technical differences to adapt to the technical conditions of China. The adjustments are concentrated in 201.2 “Normative references”, and the specific adjustments are as follows:

  ● REPLACE IEC 60601-1-2:2007 with YY 9706.102, which is modified from the international standard (see Clause 202);

  ● REPLACE IEC 60601-2-2:2017 with GB 9706.202, which is modified from the international standard (see 201.7.9.2.14, 201.11.101.2);

  ● REPLACE IEC 60601-2-37 with GB 9706.237, which is modified from the international standard (see 201.4.1.102).

- DELETE 201.7.9.2.12 Cleaning, disinfection and sterilization, to adapt to the technical conditions of China.

The following editorial changes have been made to this document:

- AMEND the informative Annex BB;

- Replace the international documents in the bibliography with the corresponding Chinese documents, as follows:

  ● REPLACE ISO 594 with GB/T 1962 (all parts), which is identical to the international standard;

  ● REPLACE ISO 14971 with YY/T 0316, which is identical to the international standard;

  ● REPLACE IEC 60601-1-8 with YY 9706.108, which is modified from the international standard.

- DELETE the index of defined terms of the international standard.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. The issuing authority shall not be held responsible for identifying any or all such patent rights.

This document was proposed and shall be under the jurisdiction of the National Medical Products Administration.

The previous released versions replaced by this document are as follows:

- It is first published in 2000 as GB 9706.19-2000;

- This is the first revision.

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

201.1 Scope, object and related standards

Clause 1 of the general standard applies, except as follows:

201.1.1 * Scope

Replacement:

This document applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of ENDOSCOPIC EQUIPMENT together with its INTERCONNECTION CONDITIONS and INTERFACE CONDITIONS.

201.1.2 Object

Replacement:

The object of this document is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for ENDOSCOPIC EQUIPMENT (as defined in 201.3.204).

NOTE: This object includes endoscopic intense light source equipment which is part of the ENDOSCOPIC EQUIPMENT including its supply unit, therefore IEC 60601-2-57 does not apply.

201.1.3 Collateral standards

Addition:

This document refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this document.

YY 9706.102 applies as modified in Clause 202. GB 9706.103 does not apply. All other published collateral standards in the GB 9706 series apply as published.

201.1.4 Particular standards

Replacement:

In the GB 9706 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the

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