NATIONAL STANDARD OF THE

PEOPLE'S REPUBLIC OF CHINA

GB 9706.202-2021

Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

Issued on: December 1, 2021 **Implemented on: May 1, 2023**

Issued by: SAMR; SAC

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Foreword

This document was drafted in accordance with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part 1.Structure and Drafting Rules for Standardization Documents".

This document is Part 2-2 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 2-36.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 9706.4-2009 "Medical electrical equipment - Part 2-2. Particular requirements for the safety of high frequency surgical equipment". Compared with GB 9706.4-2009, except for structural adjustment and editorial changes, the main technical changes are as follows.

- ADD the related content of high current mode (see 3.219, 12.4.101 of this document);

- AMEND the definition of "high frequency" by adding the upper limit of frequency (see 3.220 of this document, see 2.12.108 of the 2009 edition);

- ADD the relevant content of conditions for application and evaluating risk in the

general requirements (see 4 of this document);

- ADD additional information in instructions for use. description of neuromuscular stimulation, non-continuous activation, accessories and the maximum allowable length of accessories and cords (see 7.9.2.2.101);

- AMEND the limit for high frequency leakage current of active accessories (see

8.8.3.102 of this document, see 59.103.5 of the 2009 edition);

- ADD the requirement for high frequency leakage capacitance in active accessories insulation (see 8.8.3.102);

- AMEND the limit for high frequency leakage current of neutral electrode cord insulation (see 15.101.4 of this document, see 59.104.4 of the 2009 edition);

ADD the requirement for high frequency leakage capacitance in neutral electrode cord insulation (see 15.101.4 of this document).

This document uses the redrafting method to amend and adopt IEC 60601-2-2.2017 "Medical electrical equipment - Part 2-2.Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories".

The technical differences between this document and IEC 60601-2-2.2017 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 2 "Normative references", and the specific adjustments are as follows.

* REPLACE CISPR 11.2015 with GB 4824-2019, which is identical to the international standard;

* REPLACE IEC 60601-1-2.2014 with YY 9706.102-2021, which is modified from the international standard;

* REPLACE IEC 60601-1-8.2006 with YY 9706.108-2021, which is modified from the international standard;