CCS C43

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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY 9706.233-2021

Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis

医用电气设备 第2-33部分：医疗诊断用磁共振设备的基本安全和基本性能专用要求

Issued on: March 9, 2021 **Implemented on: May 1, 2023**

Issued by: National Medical Products Administration

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Foreword

This document was issued on 9 March 2021 by the National Medical Products Administration and takes effect on 1 May 2023.

It is a YY standard without the /T suffix: compliance is mandatory in China.

It is classified under Chinese classification C43.

All technical content in this section is mandatory. The "Medical Electrical Equipment" series of standards is divided into two parts.

---Part 1: General and parallel requirements;

---Part 2: Special requirements. This part is part 2-33. This section was drafted in accordance with the rules given in GB/T 1.1-2009. This part replaces YY 0319-2008 "Medical Electrical Equipment Part 2-33: Special Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis Compared with YY 0319-2008, the main technical changes in this part are as follows.

---Added the requirements of the compatibility technical specification sheet

[see.201.7.9.3.101b)];

---Added functional requirements in the user interface [see.201.7.9.2.101w)];

---Modified the SAR limit (mainly for temperature and local SAR, see.201.12.4.103, 51.103 of YY 0319-2008);

---Modified the static magnetic field protection limit (see.201.12.4.104, 51.104 of YY 0319-2008);

--- Increased the maximum radio frequency absorbed energy dose limit (see.201.12.4.103.2 for details);

---Added the options of "Fixed Parameter Options" (see.201.12.4.106 for details);

---Modified the noise measurement method (see Appendix BB, 26 of YY 0319-2008). This part uses the redrafting law to amend and adopt IEC 60601-2-33.2015 "Medical Electrical Equipment Part 2-33: For Medical Diagnosis Special Requirements for the Safety of Magnetic Resonance Equipment. The technical differences between this part and IEC 60601-2-33.2015 and the reasons are as follows.

---Regarding normative reference documents, this section has made adjustments with technical differences to adapt to my country's technical conditions and adjustments. The situation is collectively reflected in Chapter.201.2 "Normative Reference Documents", and the specific adjustments are as follows. * Replace IEC 60601-1-2.2014 with YY 9706.102 which is modified to adopt international standards; * Replace IEC 60601-1.2012 with GB 9706.1 which is modified to adopt international standards; * Due to non-standard quotation of IEC 60601-1-6.2013, IEC 60601-1-6.2013 was deleted; * Due to non-standard quotation of IEC 60601-1-8.2012, IEC 60601-1-8.2012 is deleted; * Deleted NEMAMS4.2010; * Deleted NEMAMS8.2008.

---In order to match GB 9706.1-2020, the content of the electromagnetic compatibility part of the standard, IEC 60601-1-2 quoted by the original text. 2014 was revised to quote the content of IEC 60601-1-2.2007. This section also made the following editorial changes.

---Informative appendix BB is added, and the content refers to NEMAMS4.2010;

---Informative appendix CC is added, and the content refers to NEMAMS8.2008. Please note that some of the contents of this document may involve patents. The issuing agency of this document is not responsible for identifying these patents. This part was proposed by the State Drug Administration. This part is under the jurisdiction of the National Medical Electrical Apparatus Standardization Technical Committee Medical Electronic Instrument Subcommittee (SAC/TC10/SC5). Drafting organizations of this section. Siemens (Shenzhen) Magnetic Resonance Co., Ltd., Shanghai Medical Device Testing Institute, Shanghai United Imaging Medical Technology Co., Ltd. the company. The main drafters of this section. Wang Jun, Hu Sheng, He Qiang, Weng Dehe, Yang Yu, Xing Xiaocong. The

previous releases of the standards replaced by this part are as follows.

---YY 0319-2002, YY 0319-2008. Medical Electrical Equipment Part 2-33: Medical Basic safety and safety of diagnostic magnetic resonance equipment Special requirements for basic performance 201.1 Scope, purpose and related standards In addition to the following, Chapter 1 of the general standard 1) applies. 1) The general standard is GB 9706.1-2020 "Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Basic Performance". 201.1.1 Scope replace. This part specifies the special requirements for the basic safety and basic performance of magnetic resonance equipment for medical diagnostics. This part is applicable to medical diagnostics. Magnetic resonance equipment (hereinafter referred to as ME equipment). This section does not cover applications other than the intended use of magnetic resonance equipment. If a clause or sub-clause is specifically expected to apply only to ME equipment, or only to ME systems, the subject of the clause or sub-clause The questions and content will be explained. Otherwise, this clause or sub-clause applies to both ME equipment and ME system. This section does not cover special requirements for the use of magnetic resonance equipment or magnetic resonance systems in interventional procedures. 201.1.2 Purpose replace. The purpose of this part is to put forward special requirements for basic performance and basic safety of magnetic resonance equipment (defined in.201.218 and.201.320). Designed to provide protection for patients and MRI staff. 201.1.3 Parallel standards supplement. This section refers to the applicable parallel standards listed in Chapter 2 of the General Standard and Chapter.201.2 of this Part. The application modification of YY 9706.102 is in Chapter 202: GB 9706.103, YY/T 9706.110, YY/T 9706.111 and YY/T 9706.112 is not applicable. All other published parallel standards in the series of general requirements for medical electrical safety are in accordance with the published standards. Implement. 201.1.4 Specific standards replace. In the series of medical electrical safety standards, considering the application of special ME equipment, special standards can be modified, replaced or deleted. The requirements contained in the standard and parallel standards, and other basic safety and basic performance requirements can be added. The requirements of specific standards take precedence over the requirements of general standards. For brevity, GB 9706.1 is referred to as the general standard in this section. The parallel standard quotes its document number. The numbering of the chapters and articles in this part corresponds to the general standard number plus the prefix "201" (for example,.201.1 in this part corresponds to the general standard number). Corresponding to the content in Chapter 1 of the Standard), or the applicable parallel standard number plus the prefix "20x", where x is the end of the parallel standard document number One digit (for example, 202.4 in this part corresponds to the content of Chapter 4 in the collateral standard YY 9706.102, 203.4 in this part

1 Scope

YY 9706.233 is the mandatory Chinese standard for diagnostic MRI equipment. MRI

presents hazards no other imaging modality does: a static field strong enough to turn a steel object into a projectile, gradient switching that stimulates peripheral nerves and produces damaging acoustic noise, and radiofrequency energy that heats tissue and implanted metal. This standard sets the particular requirements for basic safety and essential performance on top of the general medical electrical safety standard, covering the limits on each of those exposures, the controlled access to the magnet room, the emergency provisions including quench, and the information given to operators and patients. At more than fifty thousand words it is one of the longest in the series. Being a YY standard without the /T suffix, compliance is compulsory. It took effect in May 2023.