CCS C39

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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY 9706.240-2021

Medical electrical equipment - Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment

医用电气设备 第2-40部分：肌电及诱发反应设备的基本安全和基本性能专用要求

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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 C39.

All technical content in this section is mandatory. YY 9706 "Medical Electrical Equipment" is divided into two parts.

---Part 1: General and parallel requirements;

---Part 2: Special requirements. This part is part 2-40 of YY 9706. This section was drafted in accordance with the rules given in GB/T 1.1-2009. This part replaces YY 0896-2013 "Medical Electrical Equipment Part 2: Special Requirements for Safety of Electromyography and Induced Response Equipment". this Compared with YY 0896-2013, the main technical changes except for editorial changes are as follows.

--- Deleted the requirements for EMC test phantom (see 36.201 in the 2013 edition);

---Modified the working system (see.201.6, 5.6 of the 2013 edition);

---The test method of continuous masking sound pressure level has been added (see.201.12.4.6);

---The test method of visual stimulator has been added (see.201.12.4.104);

--- Added the description of "Audible and visible indications that do not meet the requirements of YY 0709 are allowed" (see.201.12.3);

---Modified the EMC test requirements (see 202, 36 in the 2013 edition). This part is revised and adopted the International Electrotechnical Commission standard IEC 60601-2-40.2016 "Medical Electrical Equipment Part 2-40: Electromyography and Special Requirements for Basic Safety and Basic Performance of Induced Response Equipment (English version). Compared with IEC 60601-2-40.2016, this part has mainly made the following technical modifications.

---Refer to YY 9706.102 for technical provisions related to electromagnetic compatibility. Compared with IEC 60601-2-40.2016, this part has mainly made the following editorial changes.

---Some layout formats have been modified in accordance with GB/T 1.1;

---The informational note in.201.2 and.201.3 has been deleted. The Chinese documents that have a consistent correspondence with the international documents cited in this section are as follows.

---GB/T 25498.1-2010 Electroacoustic head simulator and ear simulator Part 1: Ear simulation for calibrating earphones (IEC 60318-1.1998, IDT);

---GB/T 25498.3-2010 Electroacoustics Human head simulator and ear simulator Part 3: Calibration of sound for indentation earphones Coupler (IEC 60318-3.1998, IDT);

---GB/T 25498.5-2017 Electroacoustic head simulator and ear simulator Part 5: Measuring hearing aids and inserting methods A 2cm3 acoustic coupler (IEC 60318-5.2006, IDT) is used for earphones that are coupled to the human ear. 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 organized by the National Medical Electrical Appliance Standardization Technical Committee Medical Electronic Instrument Standardization Subcommittee (SAC/TC10/SC5) Focus. Drafting organizations of this section. Medtronic (Shanghai) Management Co., Ltd., Shanghai Medical Device Testing Institute, General Electric Medical Systems (China) Limited company. The main drafters of this section. Shi Daifeng, Zhang Jun, Bao Xiaojiang, Zhao Yang. The previous releases of the standards replaced by this part are as follows.

---YY 0896-2013. Medical electrical equipment-Part 2-40: Electromyography and induction Specific requirements for basic safety and basic performance of reaction equipment 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 section specifies the special requirements for basic safety and basic performance of electromyography and induced response equipment (hereinafter referred to as ME equipment). this Part of the special requirements for basic safety and basic performance applicable to ME equipment. Note. EMG feedback device, the capture of muscle contraction is based on EMG, which belongs to the scope of this standard. 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. If this is not the case, this clause or sub-clause applies to both ME equipment and ME systems. The following ME equipment is excluded. ME equipment intended for transcutaneous electrical nerve stimulation and muscle electrical stimulation (see YY 9706.210). 201.1.2 Purpose replace. The purpose of this section is to propose the basic performance and basic performance of electromyography equipment and evoked response equipment [defined in.201.3.201 and.201.32] Security specific requirements. 201.1.3 Parallel standards Supplement. This section refers to Chapter 2 of the general standard and

applicable collateral standards listed in.201.2 of this section. The application modification of YY 9706.102 is in Chapter 202: GB 9706.103, YY 9706.108 and YY 9706.110 are not applicable. Medical All other issued parallel standards in the series of general requirements for electrical safety shall be implemented as issued. 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 document 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 Corresponding to the content of Chapter 4 in the parallel standard GB 9706.103, etc.). Changes to the text of the general standard require the use of the following words.

1 Scope

YY 9706.240 is the mandatory Chinese standard for electromyography and evoked response equipment, the systems that record electrical activity from muscle and nerve and the responses evoked by stimulation. It sets the particular requirements for basic safety and essential performance on top of the general medical electrical safety standard, covering the amplification of signals measured in microvolts, the noise floor that determines whether a small response is visible at all, the stimulator output and the limits on current delivered to a patient, and the isolation that matters especially when needle electrodes are inserted. These systems are used to diagnose neuropathy and motor neurone disease and to monitor nerves during surgery. Being a YY standard without the /T suffix, compliance is compulsory. It took effect in May 2023.