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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY 9706.247-2021

Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems

医用电气设备 第2-47部分：动态心电图系统的基本安全和基本性能专用要求

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Foreword

This document was issued on 6 September 2021 by the National Medical Products Administration and takes effect on 1 May 2024.

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

It is classified under Chinese classification C39.

All technical content of this part is mandatory. "Medical Electrical Equipment" is divided into two parts.

--- Part 1: General and side-by-side requirements;

--- Part 2: Specific requirements. This part is part 2-47. This section is drafted in accordance with the rules given in GB/T 1.1-2009. This part replaces YY 0885-2013 "Medical Electrical Equipment Part 2: Special Requirements for Safety and Basic Performance of Holter Monitoring Systems" Compared with YY 0885-2013, the main technical changes other than editorial changes are as follows.

--- Added normative references (see.201.2);

--- Added some terms and definitions (see.201.3.201,.201.3.205,.201.3.207~209,.201.3.214,.201.3.216~ 224);

--- Modified the terms and definitions of "continuous recorder" and "playback device" (see.201.3.204,.201.3.215, 2.110 of the 2013 edition, 2.103);

--- Deleted the term and definition of "patient electrode" (see 2.106 of the 2013 edition);

--- Added general requirements (see.201.4);

--- Introduce the concept and requirements of basic performance (see.201.4.101);

--- Supplemented the classification of ME EQUIPMENT and ME SYSTEMS (see.201.6);

--- Supplemented ME EQUIPMENT identification, marking and documentation (see.201.7);

--- Added requirements for arrhythmia algorithm (see.201.12.1.101.1.5.2);

--- Supplement the requirements for algorithms with optional functions (see.201.12.1.101.1.5.3);

--- Added requirements for heart rate, heart rate variability or RR interval variability (see.201.12.1.101.2.3.3);

--- Added the requirement for segment-segment comparison (see.201.12.1.101.2.4);

--- Removed the requirement for the minimum detection signal (see 51.5.10 of the 2013 edition);

--- Added requirements for Programmable Medical Electrical Systems (PEMS) (see.201.14);

--- Revised the drop height requirement for drop test under working condition, from 75mm to 5cm (see.201.15.3.4.2,.2013 edition 21.5);

--- Increased the requirements for the ME system (see.201.16);

--- Deleted the requirements for dielectric strength (see 20 of the 2013 edition);

--- Increased electromagnetic compatibility requirements and tests for ME EQUIPMENT and ME SYSTEMS (see 202);

--- Added index of references and terms. This section uses the redrafted method to modify and adopt IEC 60601-2-47.2012 "Medical Electrical Equipment Part 2-47: Holter Particular requirements for basic safety and basic performance of systems. The technical differences between this part and IEC 60601-2-47.2012 and their reasons are as follows.

--- Regarding normative reference documents, this part has made adjustments with technical differences to adapt to the technical conditions of our country and the circumstances of the adjustment. The situation is reflected in the chapter "Normative References", and the specific adjustments are as follows. * Added reference to GB 4824; * Replacing IEC 60601-1-2.2007 with YY 9706.102 which has been modified to adopt the international standard. Please note that some content of this document may be patented. The issuing authority of this document assumes no responsibility for identifying these patents. This part is proposed by the State Drug Administration. This part is approved by the National Medical Electrical Equipment Standardization Technical Committee Medical Electronic Instrument Standardization Sub-Technical Committee (SAC/TC10/SC5) focal point. This section is drafted by: Shanghai Optoelectronics Medical Electronic Instrument Co., Ltd., Shanghai Medical Device Testing Institute. The main drafters of this section. Zhou Yuanyi, Yang Yongbin, Zhao Yang. The previous versions of the standards replaced by this part are as follows.

---YY 0885-2013.

Introduction

This section deals with the basic safety and essential performance of the Holter monitor system. This part modifies and supplements GB 9706.1-2020 "Medical Electrical equipment - Part 1: General requirements for basic safety and basic performance", hereinafter referred to as the general standard. The requirements of this section take precedence over the general standard. A "General Guidance and Rationale" for the more important requirements of this part is contained in Appendix AA. In this section, the terms marked with an asterisk (*) are explained in Appendix AA. We believe that understanding these requirements not only facilitates the correct application of this part, but also expedites timely due to changes in clinical practice or The process of revising standards as technology evolves. However, Appendix AA is not part of the requirements of this section. Medical Electrical Equipment Part 2-47. Basic Safety and Essential Performance of Holter Systems Dedicated requirements 201.1 Scope, Purpose and Related Standards Clause 1 1) of the General Standard applies, except for the following. 1) The general standard refers to 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 specific requirements for the basic safety and basic performance of Holter monitoring systems. This section applies to the basic safety and basic performance of the Holter electrocardiogram system (hereinafter referred to as the ME system). If a chapter or an article applies only to ME EQUIPMENT or ME SYSTEM, the title and content of these chapters or articles will give a clear statement. Such as If not stated, this clause or clause applies to both ME EQUIPMENT and ME SYSTEMS. In addition to 7.2.13 and 8.4.1 of the general standard, inherent hazards to the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this part harm is not covered by the specific requirements of this section. NOTE. See General Criteria 4.2. The following types of systems are within the scope of this section.

a) A system that continuously records and analyzes the electrocardiogram, and which gives the basic Same result. The system can record and store ECGs for analysis in a separate unit, or record concurrently with the analysis. This standard does not address the type of storage medium used.

b) Systems capable of providing continuous analysis and only partial or limited recording. The system cannot perform a complete reanalysis of the ECG. Systems that meet any of the above types are applicable to the safety requirements of this section. If the Holter monitoring system provides automatic ECG analysis, the minimum performance requirements for the measurement and analysis functions specified in this section apply. By GB 9706.225 "Medical Electrical Equipment Part 2-25: Special Requirements for Basic Safety and Basic Performance of ECG Machines" and Covered by GB 9706.227 "Medical Electrical Equipment Part 2-27: Special Requirements for Basic Safety and Basic Performance of ECG Monitoring Equipment" Medical electrical equipment is not within the

scope of this section. This section does not apply to systems that cannot continuously record and analyze the ECG (eg, "intermittent event recorder"). 201.1.2 Purpose replace. The purpose of this section is to specify specific requirements for the basic safety and essential performance of Holter monitoring systems. 201.1.3 Tied standards Replenish. This section refers to Chapter 2 of the General Standard and the applicable collateral standards listed in.201.2 of this section. YY 9706.102 Section 202 as amended applies. GB 9706.103-2020, YY 9706.108-2021 and IEC 60601-1-10 does not apply.

1 Scope

YY 9706.247 is the mandatory Chinese standard for ambulatory ECG systems, the Holter recorders and their analysis software that capture a patient's rhythm over a day or longer during normal activity. It sets the particular requirements for basic safety and essential performance on top of the general medical electrical safety standard, covering the fidelity of the recorded signal, the handling of artefact from movement and poor electrode contact, the accuracy of the automated arrhythmia detection, and the battery and storage that have to last the whole recording. The point of the test is to catch events that a resting ECG misses, so a system that drops or misclassifies them fails at its only job. Being a YY standard without the /T suffix, compliance is compulsory. It takes effect in May 2024.