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**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY 0828-2011

ECG cables and lead wires

心电监护仪电缆和导联线

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Foreword

This standard is not equivalent to the American National Standard ANSI/AAMIEC 53.1995 A1.1998 "ECG cables and lead wires." This standard was proposed by the State Food and Drug Administration. This standard by the National Standardization Medical Electrical Medical Electronic Instrument Standardization Technical Committee Technical Committee (SAC/TC10/SC5) Centralized. This standard was drafted. Shenzhen Mindray Bio-Medical Electronics Co., Ltd., Shanghai Medical Device detection. The main drafters of this specific standard. Caojian Fang, Zhang Yi Dong, Shi Wenli, Zhang Xu.

ECG monitoring equipment is widely used in clinical practice, design and patient safety and clinical effect of interest income and lead cable lines with its use Off, and the country is not yet relevant standards. In order to ensure safe and effective products, while facilitating and international standards, this standard is not equivalent ANSI/AAMIEC 53.1995 A1.1998, according to the mandatory implementation of industry standards. The standard American Standard ANSI/AAMIEC 53.1995 A1.1998 the following changes were made.

--- To clarify the scope of the standard, the standard Chinese name changed to "ECG cables and lead wires";

--- Because of the actual situation, necessary and reasonable ECG cables and lead wires live longer than the original estimate AAMI standards, using Frequency significantly higher than the estimate AAMI standard benchmarks. Determined according to the actual situation, a corresponding increase in ECG cables and leads Line and the number of plug test durability and cleaning, sterilization cycles;

--- ANSI/AAMIEC 53.1995 A1. The 1998 Construction Requirements section is not conducive to innovation and product miniaturization trend, and Currently interchangeability of different manufacturers ECG cable between whether the United States, other countries in the international arena, China has failed to achieve, The section as a recommendation into Annex B;

--- Given standard recommended cables and lead wires durability test swing frequency; Cables tensile strength of the force standard duration

--- Remove ANSI/AAMIEC 53.1995 A1.1998 cover, foreword and introduction. ECG cables and lead wires

1 Scope

YY 0828 is the mandatory Chinese standard for ECG cables and lead wires. These look like the most trivial part of a monitoring system and have caused deaths: lead wires with exposed pin connectors have been plugged directly into mains sockets by patients and relatives, electrocuting them, which is why protected connectors became a requirement worldwide. The standard sets the requirements such cables have to meet and the test methods that verify them, covering the connector design and its protection against contact with a live conductor, the electrical performance and defibrillation protection, the mechanical durability through repeated flexing, and the labelling. Being a YY standard without the /T suffix, compliance is compulsory in China.

Body surface ECG This standard applies to YY 1079-2008 "ECG" defined by the standard ECG used (ECG) monitoring of patients with cables and lead wires.

1.1 Standard equipment includes This standard includes a guide-line of disposable and reusable lead wires, some of the sections of this standard applies to two types of lead wires, which Certain sections apply to only one type of lead wire (in the following manner in the corresponding chapter after chapter titles marked Scope. "Applies Leads to two types of line "," suitable for disposable lead wires "or" suitable for reusable lead line "). The standard test is for manufacturers to verify whether their products comply with the following safety and performance specifications and design. Above tests Should not be performed by the end user device. The standard cable in Appendix B to the junction box and the lead wire connector recommended a safe (no exposed metal pins), common interface.

1.2 This standard does not include equipment ECG cables and lead wires may be used in applications that require special performance, such as ambulance ECG equipment, telemetry equipment, operating room And cardiac catheterization lab etc is not the scope of this standard. In addition to ECG monitoring function, this standard includes cables and lead wires patient It can also support other functions such as impedance respiration monitoring. Unless otherwise specified, the patient cable and lead wires must comply with all of the standard Claim.

2 Normative references

The following documents for the application of this document is essential. For dated references, only the dated version suitable for use herein Member, undated references, the latest edition (including any amendments) applies to this document.

YY 1079-2008 ECG ANSI/AAMIES1.1993 Medical Device Safety current limit
(Safecurrentlimitsforelectromedicalapparatus)

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 Cable Assemblies cableassembly For patient connected to ECG by a plurality of individual wires and/or beam components into the wiring harness inside a jacket. through Typically, the cable assembly consists of a main cable and a set of patient leads lines. Lead wire may be separated from the main cable or main cable together constitute A cable assembly (integrated cable and lead wire assembly).

3.2 Cable distributor cableyoke Located at one end of the main cable, lead wires for patient access.