ICS 11.040.50
CCS C39

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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY 1079-2008

Replacing YY 91079-1999

Electrocardiographic monitors

心电监护仪

Issued on: April 25, 2008 **Implemented on: December 1, 2009**

Issued by: National Medical Products Administration

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Foreword

This standard is a reference to the American National Standard ANSI/AAMIEC 13.2002 "heart monitors, heart rate meters and alarms" in the performance section

Points prepared ECG monitor performance standards.

This standard YY 91079-1999 major differences are.

--- Increasing the pacemaker pulse rejection capability requirements;

--- Safety requirements according to GB 9706.25-2005 "Medical electrical equipment Part 2. ECG monitoring equipment safety requirements" and

GB 9706.1-2007 "Medical Electrical Equipment Part 1. General requirements for safety" requirements to perform;

--- Increased by YY 0505-2005 "Medical electrical equipment - Part 1-2. General requirements for safety Collateral standard. Electromagnetic compatibility

Requirements and testing "electromagnetic compatibility requirements;

From the date of implementation of this standard, YY 91079-1999 repealed.

The Standard Appendix A, Appendix B and Appendix C are informative appendices.

This standard was proposed by the National Standardization Technical Committee on Medical Electrical Medical Electronic Instrument Standardization Technical Committee.

This standard by the National Standardization Technical Committee on Medical Electrical Medical Electronic Instrument Standardization Technical Committee.

This standard was drafted. Shanghai Medical Device detection, Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

The main drafters of this standard. and Yu, Guo Hongling.

This standard replaces the standards previously issued as follows.

1 Scope

This standard has been waveform monitor heart rate and expected under this standard specified operating conditions using ECG method, indeed

Established the minimum performance requirements. Such monitors all of the following section shall meet this criteria.

a) obtained from the patient's body through non-invasive detection of ECG heart rate display;

b) amplify and transmit these signals to display the heart rate and/or ECG waveform; and

c) adjustable alarm limits based on the following phenomena associated with heart rate continued to provide an alarm occurs. cardiac arrest, bradycardia, and/or Tachycardia.

Note: The performance requirements specified in this standard mainly to the principles of design specifications for the manufacturer or type of evaluation (assessment type device or a typical

A series of tests must be carried out batch of typical equipment to verify the performance of all design requirements have been met. Manufacturers typically designed for a production

Product models meet all the criteria to obtain a statement of compliance when the formal implementation).

1.1 Standard equipment includes

The following equipment is included in the scope of this standard.

a) is expected in the range of environmental conditions specified in 4.2.1 using a portable ECG monitor and battery-powered ECG monitor;

b) ECG-based operating rooms and intensive care heart rate monitors;

c) the use of telemetry and intensive transfer of ECG;

d) the scope of this standard provides a more complex device basic information described subsystems (such as. Arrhythmia monitor and defibrillator monitor Instrument); and

e) neonatal/pediatric monitors.

1.2 This standard does not include equipment

The following equipment is not included in the scope of this standard.

a) fetal heart rate monitoring equipment;

b) blood pressure monitoring equipment;

c) pulse rate tracings equipment;

d) the use of invasive cardiac catheter or sensor device to obtain electrical activity displayed;

e) telemetry for emergency ambulance or hospital outside the dynamic monitoring equipment or systems;

f) for subsequent analysis of dynamic data stored ECG monitoring equipment, including scanning and reading device;

g) telephone transmission equipment;

h) expected in hospitals and clinics outside extreme or uncontrollable equipment under ambient conditions for use;

i) diagnostic ECG devices (these devices are included in other standards); and

j) which is similar to monitoring functions and the ability to trigger other instruments for collection, these instruments are not expected to be used as the main treatment for patients

Heart monitor equipment (for example. a spherical inner arterial pumps, ventricular assist devices).

NOTE. Provides monitoring and diagnostic features optional equipment, selected functions shall meet the applicable standards. These standards --- heart monitors, heart rate meter, alarm

Standard or diagnostic ECG equipment standards.

1.3 Differences between monitors

Parts of the standard may not apply to all monitors. These monitors is only required to meet the applicable provisions of this standard.

2 Normative references

The following documents contain provisions which, through reference in this standard and become the standard terms. For dated references, subsequent