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



## YY 1139-2013

Replacing YY 1139-2000

# Diagnostic electrocardiographic devices

心电诊断设备

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## Foreword

This special standard for medical electrical equipment performance standards.

This dedicated drafting standards in accordance with GB/T 1.1-2009 given rules.

This standard replaces YY 1139-2000 "single-channel and multi-channel ECG machine", and YY 1139-2000 main technical differences are as follows.

--- Remove the sensitivity and output impedance require an external output, replace manual should indicate the correct external device is connected;

--- Remove the sensitivity and input impedance requires an external DC input signal;

--- Remove the print resolution requirements;

--- Adjust the frequency characteristics of the requirements;

--- Adjust the noise level requirements;

--- Increasing the time and amplitude scale requirements;

--- To increase the release of energy loss in patients with the requirements;

--- Increased requirements pacing pulse display capabilities.

Since the implementation of this standard, YY 1139-2000 "single-channel and multi-channel ECG machine" abolished.

The standard reference to American National Standard ANSI/AAMIEC 11.1991/(R) 2001/(R) 2007 "ECG diagnostic equipment."

Please note that some of the content of this document may involve patents. Release mechanism of the present document does not assume responsibility for the identification of these patents.

This standard by the National Standardization Technical Committee on Medical Electrical Medical Electronic Instrument Standardization Technical Committee (TC10/SC5) proposed.

This standard by the National Standardization Technical Committee on Medical Electrical Medical Electronic Instrument Standardization Technical Committee (TC10/SC5) centralized.

This standard was drafted. Shanghai Medical Device detection, Shenzhen City rationale State precision Instruments Incorporated.

The main drafters of this standard. Yu and Tao Kan, Qiu everywhere.



## 1 Scope

This standard ECG diagnostic equipment (hereinafter referred to, or devices) 3.9 definition establishes the minimum performance requirements, the device has credited directly

It means recorded. All parts of ECG diagnostic equipment applicable to this standard, they should include ECG obtained from the body surface, amplifies the signal

And adapted to a diagnosis of cardiac electrical activity displayed the signal. This standard ECG electrodes diagnostic equipment from the input to the output is displayed Regulation Set requirements.

NOTE. In the performance criterion specified in this standard is mainly used to verify the manufacturer's design or evaluation.

Chapter 5 of the ruling purpose test method is to provide some means to explicitly establish compliance with this standard. These test methods are not used

To verify the performance of a single device, whether it is used to check the quality of a manufacturer's warranty or routine inspections within the hospital. In addition, according to the ruling again

Defined test method allows the use of other design verification method, as long as those methods equivalent to those ruled to have test methods comparable test Test results.

### 1.1 For

Apply to this standard includes the following equipment.

a) direct recording ECG;

b) used in other medical devices (eg. patient monitors, defibrillators, stress testing equipment) in the ECG machine, as long as these devices with

ECG diagnostic functions;

c) the patient ECG signal display functions remotely, through their cable, telephone,

telemetry or storage medium, as long as these devices have heart

FIG electrical diagnostic functions. These devices comply with the entire output of the system - the relationship between the input functions of performance requirements.

### 1.2 Not applicable equipment

Within the scope of this standard does not include the equipment.

a) Equipment ECG data collected from the outer surface of the non-human;

b) equipment for the Interpretation and pattern recognition (for example, QRS detection, alarm circuit, heart rate meter, diagnostic algorithms);

c) fetal electrocardiogram monitor;

d) Holter monitoring equipment, including ECG recorders and auxiliary scanning and reading device;

e) diagnostic ECG devices nonpermanent display;

f) vector ECG machine, it is a cycle;

g) ECG device, expected to be used in extreme or uncontrolled environmental conditions of the device in a hospital or clinic outside;

h) with or without a heart rate meter and the alarm of ECG, the monitor is mainly used to detect heart rhythm (ECG monitoring equipment from these

Instrument care covered by the standard).

Note: If the device has both diagnostic functions with monitoring function, the function should be selected must meet the relevant requirements of the standard. meet the diagnostic function ECG diagnostic equipment

The standards, to meet the monitoring function of ECG standards.

## 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. For undated references, the latest edition (including any amendments) applies to this document.