ICS 11.040.60
CCS C39

YY



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

# YY 0782-2010

## Medical electrical equipment - Part 2-51: Particular requirements for the safety and essential performance of recording and analysing single channel and multichannel electrocardiographs

医用电气设备 第2-51部分：记录和分析型单道和多道心电图机安全和基本性能专用要求

**Issued on: December 27, 2010** **Implemented on: June 1, 2012**

**Issued by: National Medical Products Administration**

# Table of Contents





## Foreword

This document was issued on 27 December 2010 by the National Medical Products Administration and takes effect on 1 June 2012.

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

It is classified under ICS 11.040.60, Chinese classification C39.

Medical electrical equipment standard series of standards, the series standard consists of two parts.

--- Part 1. General requirements for safety of medical electrical equipment;

--- Part 2. Medical electrical equipment requirements for the safety. This special standard - Part 2-51 Medical electrical equipment. The specific standard is based on GB 9706.1-2007 "Medical Electrical Equipment Part 1. General Requirements for Safety "(hereinafter. General Standard) of the specific standards, it is GB 9706.1 of changes and additions, And supporting the use of GB 9706.1. The use of specific standard translation method identical with IEC 60601-2-51.2003 "Medical electrical equipment - Part 2-51. recording and analysis Single and multi-channel ECG machine safety and essential performance. " The specific standard IEC 60601-2-51.2003 made the following editorial changes.

--- Other international standards quoted in the standard, if it has the appropriate standards into our country, places of reference standards prevail;

--- Remove IEC 60601-2-51.2003 cover and foreword, according to GB/T 1.1 standards

require rewriting; The specific standard of medical equipment by the National Standardization Technical Committee of Standardization Technical Committee of Medical Appliances (SAC/TC10 / SC5) centralized. The specific standard drafting unit. Shenzhen Mindray Bio-Medical Electronics Co., Ltd., Shenzhen Edan Precision Instrument Co., Ltd., Shanghai Medical Spa instrument detection. The main drafters of this specific standard. Ye Wenyu Xie Xicheng, Shiwen Li, Ye Jilun. YY 0782-2010/IEC 60601-2-51.2003

## Introduction

This standard relates to special additional safety records and analysis of single and multi-channel ECG device. It changes and additions The GB 9706.1-2007, hereinafter referred to as the universal standard version. The specific requirements of the standard in preference to "Medical Electrical Equipment Part

1 Score. General Requirements for Safety "common standards. For the "general guidelines and basic principles," the special requirements of this standard in Annex AA. Standard text in front of the reg number raises a "*" indicates that provision in Annex AA further explanation and clarification. We believe that these requirements will not only help to understand the proper use of this standard, and in time to accelerate due to changes in clinical practice or Technological development and to accelerate the standard revision process. However, this is not a standard part of the Appendix of this requirement. YY 0782-2010/IEC 60601-2-51.2003 Medical electrical equipment - Part 2-51. Recording and analysis of single and multi-channel ECG machine safety And essential performance The first chapter outlines In addition to the following, the common standards Benpian apply.

## 1 Scope

YY 0782 is the mandatory Chinese standard for recording and analysing electrocardiographs, the single and multichannel machines that produce a printed or stored ECG and, in most cases, an automated interpretation. It sets the particular safety and essential performance requirements for such equipment, covering the fidelity of the recorded waveform, the frequency response and gain accuracy that make small ST deviations measurable, the noise and common mode rejection, the recording medium and the automated measurement and interpretation where provided. The automated reading is what a non-specialist often acts on, which is why its performance is treated as essential rather than incidental. Being a YY standard without the /T suffix, compliance is compulsory in China.

In addition to the following, the common standards in this chapter apply. 1.1 * Range Addition. This standard specifies the special safety requirements for recording and analyzing single channel and multi-channel ECG machine and the basic performance requirements. Single-channel and multi-channel heart FIG electric machine has been defined in the 2.101,2.111,2.117,2.123,2.126, hereinafter referred to as devices. Such

equipment may have been Custody or unattended. This special supplement standard GB 10793-2000.

1.2 Purpose Alternative. In addition to GB 10793-2000 in terms of security made some additional requirements beyond the specific purpose of the standard is to establish a close For recording and analyzing single channel and multi-channel ECG machine safety and essential performance of special requirements. The only requirements for particular application.

--- Type recording ECG;

--- ECG machine, ECG machine that is part of one of the other medical electrical equipment, such as exercise test system, if the ECG FIG machine is used to record the ECG and for diagnostic purposes;

--- ECG is used as the database management system of the output unit of the ECG machine, or place in the absence of a recording device as an output ECG unit;

--- Analytical ECG machines, systems and computing equipment, which by electrocardiogram electronic data processing and pattern recognition approach Measurement (such as intervals and amplitudes) and diagnostic instructions;

--- Having realized analytical analysis of patient ECG monitor ECG or other special part of ECG machine. This standard does not apply to Holter ECG, invasive ECG, patient monitoring systems, and other high-resolution other than the above ECG (electrocardiogram machine such as HIS bundle with late potential detection of ECG).

1.3 Specific Standard Addition. The specific reference standard GB 9706.1-2007 "Medical Electrical Equipment Part 1. General requirements for safety" and GB 10793-2000 "Medical electrical equipment - Part 2-25. ECG requirements for the safety." YY 0782-2010/IEC 60601-2-51.2003