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Program of Pattern Evaluation of Electrocardiographic Monitors

心电监护仪型式评价大纲

(English Translation)

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Introduction

This outline is intended to provide the technical basis for a complete ECG pattern evaluation. This outline is based JJF 1015-2002 "Measuring Instruments type evaluation and type approval of universal norms" and JJF 1016-2009 "Measuring Instruments type

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evaluation Outline guidelines for the preparation, "written and major references, and reference the following documents.

JJG760-2003 ECG

GB/T 14710-2009 medical electrical environmental requirements and test methods GB/T 17626.2-2006 Electromagnetic compatibility - Testing and measurement techniques - Electrostatic discharge immunity test GB/T 17626.4-2008 Electromagnetic compatibility - Testing and measurement techniques - Electrical fast transient burst immunity test GB/T 17626.5-2008 Electromagnetic compatibility - Testing and measurement techniques - Surge (impact) immunity test GB/T 17626.11-2008 Electromagnetic compatibility Testing and measurement techniques - Voltage dips, short interruptions and voltage Variations immunity tests this outline is the first release.

ECG pattern evaluation outline

1 Scope

This type of evaluation framework applicable to ECG (including multi-parameter monitor ECG monitoring section and cardiac defibrillators Care instrument ECG monitoring section) of the type evaluation.

2. References

This outline references the following documents.

JJG760-2003 ECG

GB/T 14710-2009 medical electrical environmental requirements and test methods GB/T 17626.2-2006 Electromagnetic compatibility - Testing and measurement techniques - Electrostatic discharge immunity test GB/T 17626.4-2008 Electromagnetic compatibility - Testing and measurement techniques - Electrical fast transient burst immunity test GB/T 17626.5-2008 Electromagnetic compatibility - Testing and measurement techniques - Surge (impact) immunity test GB/T 17626.11-2008 Electromagnetic compatibility Testing and measurement techniques - Voltage dips, short interruptions and voltage Variations immunity tests these documents contain provisions which through reference in this syllabus constitute provisions of this outline. For dated reference documents Members, release date only applies to this outline. For undated references, the latest edition (including all Amendments) apply to this outline.

3 Overview

ECG (hereinafter referred to as the monitor) is a human ECG, heart rate monitoring and dynamic measuring instrumentation.

According to the structure and function can be divided into the following four types. ECG display type, display type ECG heart rate, electrocardiogram Type display records, display ECG heart rate and ECG recording type.

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4 legal management requirements 4.1 units of measurement requirements Measuring instruments shall be the legal units of measurement.

4.2 With regard to legal metrology marking and identification requirements for measuring instruments Measuring instruments must nameplate or panel, table top clear part of legal metrology marking and labeling standard measuring instruments Knowledge, its marks, logos and instructions must be clear, solid and reliable.

4.2.1 legal metrology signs generally include the following

--- Measurement equipment manufacturing license logo and number (test prototype should stay out of the corresponding position);

--- Measurement equipment type approval mark and number (test prototype may be left out of the corresponding position; this item is not mandatory Provisions);

--- Product quality stamps certificate (this can be provided separately from the body and measuring instruments).

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