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JJF 1778-2019

Program of Pattern Evaluation of Intermittent Measurement Clinical Electronic Thermometers

间歇测量医用电子体温计型式评价大纲

(English Translation)

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12 Type evaluation record format (19)

Appendix A Interval measurement medical electronic thermometer type evaluation record format (20)

Introduction

This outline is based on JJF 1015-2014 "General Specification for Type Evaluation of Measuring Instruments" and JJF 1016-2014 "Measuring "Guidelines for the preparation of appliance type evaluation outlines" are formulated as basic specifications.

The measurement requirements, general technical requirements, test items and test methods in this outline are integrated with GB/T 21416-2008 "Medical Electronic Thermometer" and OIMLR115..1995 (E) "Medical Electronic Body with Maximum Display Device the contents of `` Clinical electrical thermometers with maximum device " include GB/T 21416-in 2008, except "4.9.3 corrosion resistance", "4.11 biological evaluation", "4.12 materials", and "4.14 safety requirements" "Request" and "4.15 environmental test" "low temperature storage test" "high temperature storage test" "damp heat storage test" all items except "Transport Test", and except "5.1 Temperature Probe" in OIMLR115..1995 (E) all items except "5.2 Display Parts" "5.3.4 Temperature Storage" and "5.3.5 Humidity Storage", and adopt Used the mechanical tension in "5.1 Temperature Probe" and the digital height and over-range prompts in "5.2 Display Parts" and other project contents.

The "Maximum Allowable Error of Indication Value" specified in this outline adopts the requirements of GB/T 21416-2008 the test requirements and test methods of the "Environmental Adaptability Test" adopt GB/T 21416-2008 and OIMLR115 Strict regulations in 1995 (E).

This outline is published for the first time.

Outline of Type Evaluation of Medical Electronic Thermometer for Intermittent Measurement

1 Scope

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This outline is applicable to intermittent measurement of human armpits, mouth, rectum, etc. with a classification code of 04060000 Different parts of body temperature, type evaluation of contact medical electronic thermometer with maximum value maintaining function.

2 Reference documents the outline refers to the following documents.

JJG1162-2019 medical electronic thermometer JJF 1001-2011 General Measurement Terms and Definitions JJF 1007-2007 Temperature measurement terms and definitions GB/T 17626.3-2016 Electromagnetic compatibility test and measurement technology RF electromagnetic field radiation immunity test for dated reference documents, only the dated version applies to this outline; for those without date references the latest version (including all amendments) is applicable to this outline.

3 Terminology

The terms and definitions defined in JJF 1001-2011, JJF 1007-2007, JJG1162-2019 and the following apply in this outline.

3.1 Intermittent measurement clinical electronic thermometer After completing a measurement and obtaining and maintaining the maximum body temperature data, the next time can only be performed under a restart Medical electronic thermometer for measurement. Referred to as the electronic thermometer.

3.2 Non-predictiveclinicalelectronicthermometer the medical device with the highest temperature value is displayed and saved only when the temperature probe and the measured part reach thermal equilibrium and stability Digital Thermometer.

3.3 Predictive medical electronic thermometer Before the temperature probe and the measured part reach thermal equilibrium, the equilibrium temperature is predicted by the temperature probe thermal response pre-data Medical electronic thermometer.

4 Overview

Intermittent measurement medical electronic thermometer (hereinafter referred to as electronic thermometer) is mainly composed of temperature sensor, special chip, Digital display, battery and other components are used to measure human body temperature. Its typical structure composition and principle block diagram are shown in Figure 1.

As shown. During measurement, the temperature sensor senses the measured temperature and outputs an electrical signal, and then the electrical signal is input into a dedicated chip After the treatment, the digital display shows the maximum value of the measured temperature during the measurement period, and keeps displaying the maximum value to the electronic thermometer Automatic shut-down. Electronic thermometers can be classified in many ways. according to the structure, they can be divided into integrated electronic thermometers and separate bodies Electronic thermometer; according to the

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measuring principle, it can be divided into actual measuring electronic thermometer and predictive electronic thermometer. Digital Thermometer it has the functions of measurement prompt, over range prompt, low voltage prompt, and memorizing the latest measurement data.

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