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JJG

NATIONAL METROLOGY VERIFICATION REGULATION OF THE PEOPLE'S REPUBLIC OF CHINA

JJG 1164-2019

Infrared Ear Thermometers

红外耳温计检定规程

(English Translation)

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Introduction

JJF1002 "Rules for the preparation of national metrological verification regulations", JJF1001 "General metrological terms and definitions", JJF1059.1 "Measurement Uncertainty Evaluation and Expression" together constitute the basic series that supports the formulation of this regulation specification.

This regulation refers to GB/T 21417.1-2008 "Medical infrared thermometer Part 1: Ear cavity type", ISO 80601-2-56.:2017 (E) "Medical Electrical Equipment Part 2-56.Medical Thermometers for Human Body Temperature Measurement Basic Safety and Main Performance Requirements (Medicalelectricalequipment-Part 2-56.Particularre-quirementsforbasicsafetyandessentialperformanceofclinicalthermometersforbody temperaturemeasurement), ASTME1965-98 (2016) "Infrared temperature for intermittent measurement of patient body temperature Standard Specification for Infrared Thermometers for Intermittent Deter-minationofPatientTemperature) and JJF1107-2003 "Infrared Thermometer Calibration for Measuring Human Body Temperature specification".

Terminology refers to ISO 80601-2-56.:2017 (E). "Laboratory error" requirements refer to GB/T 21417.1-2008.The conformity determination method refers to GB/T 21417.1-2008, ISO 80601-2-56.:2017 (E) and ASTME1965-98 (2016).

This regulation is issued for the first time.

Verification Regulations of Infrared Ear Thermometer

1 Scope

This regulation is applicable to the first inspection of infrared ear thermometers measuring human body temperature in the measuring range of 35.0 °C ~ 42.0 °C Inspection, follow-up inspection and inspection in use.

2 Reference documents this regulation refers to the following documents.

JJF1007-2007 Temperature measurement terms and definitions JJF1107-2003 Calibration Specification of Infrared Thermometer for Measuring Human Body Temperature GB/T 21417.1-2008 Medical infrared thermometer Part 1: Ear cavity type ISO 80601-2-56.:2017 (E) Medical Electrical Equipment Part 2-56.Medical for Human Body Temperature Measurement Thermometer basic safety and main performance requirements (Medicalelectricalequipment-Part 2-56.Particular requirementsforbasicsafetyandessentialperformanceofclinicalthermometersforbody temperaturemeasurement) ASTME1965-98 (2016) Standard Specification for Infrared Thermometers for Intermittent Measurement of Patient's Body Temperature (Standard SpecificationforInfraredThermometersforIntermittentDeterminationofPatientTem-perature) for dated reference documents, only the dated version applies to this regulation; for undated

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references the latest version (including all amendments) is applicable to this regulation.

3 Terminology

3.1 Infrared earthermometer A temperature measuring instrument that measures the temperature of the human body using the heat radiation exchange between the ear canal and the eardrum and the detector.

3.2 Test mode

A specific working state or method of the infrared ear thermometer; in this mode, the output of the ear thermometer does not include the human body Part temperature correction.

Note: Also known as calibration mode, it is the mode used during verification.

3.3 Laboratory error in the test mode, the difference between the infrared ear thermometer and the black body temperature.

4 Overview

Infrared ear thermometer (hereinafter referred to as ear thermometer) uses the approximate black body cavity formed by the ear canal and the eardrum to measure the human body temperature. The measurement principle can be described by formula (1).

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