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**INDUSTRY STANDARD OF THE
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**Program of Pattern Evaluation of Infrared Ear Thermometers
(English Translation)**

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Introduction

The structure and content of this outline is based on JJF 1015-2014 "General Specification for Metrological Appraisal" and JJF 1016-2014 "Measurement instrument type evaluation outline preparation guidelines" related requirements. Test requirements and test methods According to GB/T 21417.1-2008 "Medical Infrared Thermometer Part 1. Ears" and JJF 1107-2003 "Calibration of Infrared Thermometers for Measuring Human Temperature".

The outline of the pilot project contains GB/T 21417.1-2008 in addition to "4.4.4 maximum allowable clinical repeatability" "4.7 Biocompatibility", "4.8 Safety requirements" and "4.15 Environmental test requirements" in the "power supply voltage adaptation Force "other than all the items.

This section of the GB/T 21417.1-2008 in the "5.15 environmental test requirements" in some of the pilot test Method has been adjusted. Added "alarm function - display range" and "alarm function - ambient temperature" test side law. "Vibration test" and "collision test" in the final test link to increase the "specified temperature display range of the most Large permissible error "test." Transport test "in the final test session only" appearance and structure "and" specified Temperature display within the maximum allowable error "test.

The outline for the first release.

Infrared ear thermometer type evaluation outline

1 Scope

This outline applies to the classification of 04061000 infrared ear thermometer (hereinafter referred to as ear thermometer) product type Evaluation.

2 reference file

This outline refers to the following documents.

JJF 1015-2014 General rules for the evaluation of measuring instruments Standard
Practice for Calibration of Infrared Thermometers for Measuring Human Body Temperature
JJF 1107-2003 Environmental requirements and test methods for medical appliances GB/T
14710-2009 Medical infrared thermometers - Part 1. ear - cavity type GB/T 21417.1-2008
for dated references, only the dated edition applies to this syllabus; references that are not
dated , The latest version (including all amendments) applies to this outline.

3 terms and definitions 3.1 calibration mode the ear thermometer shows the pattern of the
temperature measured from the black body of the ear thermometer.

Note:

1. In the calibration mode, the ear thermometer displays the measurement of the blackbody
temperature of the ear thermometer. The calibration mode is that the ear thermometer must
have Working mode for the measurement of laboratory error of ear thermometer.

2. You can set the ear thermometer directly to the calibration mode or by means of
mathematical operations by key operation.

mode.

3.2 laboratory error errorwithinambientoperatingrange Under the specified ambient
temperature and humidity conditions, the ear thermometer is shown in the calibration mode
with the temperature of the ear thermometer difference.

Note:

1. The provisions of the temperature and humidity conditions, including the rated working
conditions and laboratory reference conditions of two environmental conditions.

2. Rated working environment conditions. temperature 16.0 °C ~ 35.0 °C, humidity ≤ 85%
RH.

3. Laboratory reference conditions. temperature of 23 °C ± 2 °C, humidity of 50% RH ± 20%
RH.

4 Overview

Infrared ear thermometer, also known as ear-type infrared thermometer, refers to the use of

ear canal and tympanic membrane and the detector between the infrared radiation Exchange instrument for measuring body temperature. The ear thermometer is usually made up of optical systems, detectors and electrical systems. The thermometer shows the value can be the ear cavity temperature or by the ear cavity temperature projections of other parts of the human body temperature, such as oral temperature, armpit temperature and rectum Temperature and so on.

5 legal management requirements

5.1 Unit of measurement the unit of temperature is in degrees Celsius and the symbol is °C.

5.2 External structure for those who do not allow the user to adjust the ear thermometer, should be closed with the design or leave a sealed seal position.

5.3 logo

Test prototype should identify the factory name or trademark, model specifications, factory number.

The test prototype shall be set aside to mark the marking and number of the manufacturing instrumentation license and the type of measuring instrument Approval mark and number.

6 measurement requirements

6.1 Indicator unit

6.1.1 resolution

The display resolution of the ear thermometer indicating unit should be 0.1 °C or less.

6.1.2 Display

The digit height on the thermometer display is at least 4 mm, or by visual enlargement.

6.2 Temperature display range Temperature display range should cover 35.0 °C ~ 42.0 °C.

6.3 Laboratory errors

6.3.1 Specifies the laboratory error within the display range Rated working environment conditions, 35.0 °C ~ 42.0 °C display range, ear thermometer laboratory error should not exceed ± 0.2 °C.

6.3.2 Specifies the laboratory error outside the range Rated working environment conditions, 35.0 °C ~ 42.0 °C display range, ear thermometer laboratory error should not exceed ± 0.3 °C.

6.3.3 Laboratory errors under changing environmental conditions when the environment is in rated working conditions, but the ambient temperature changes rapidly, the ear thermometer laboratory error should Meet the requirements of 6.3.1, or stop providing