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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB/T 21417.1-2008

**Clinical infrared thermometers -- Part 1: Ear [including
MODIFICATION 1]**

医用红外体温计 第1部分：耳腔式

(English Translation)

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Appendix A (informative) To determine the accuracy of clinical trials

Foreword

GB/T 21417 "medical infrared thermometer" is divided into two parts.

--- Part 1. ear cavity;

--- Part 2. skin type.

This section GB/T Part of 121,417.

Chapter 6 of this section are recommended, the rest are all mandatory technical content. And it shall GB 9706.1 "Medical electrical equipment - Part 1 Part I. General Requirements for Safety "supporting the use of.

Medical infrared thermometer is an infrared radiation through the exchange and the appropriate correction value with the measured object detector measures the ear cavity between the input Display certain parts of the body temperature of a medical optical instruments. The thermometer ear cavity by measuring the thermal radiation to show the object to be measured body temperature.

This section is not equivalent to the technical requirements BSEN12470-5:2003 "Medical thermometers - Part 5. infrared ear thermometer chamber Performance (with a maximum limit of the device). " Appendix A of this section is an informative annex.

This part is proposed by the State Food and Drug Administration.

This part of the National Technical Committee of Standardization for medical appliances (SAC/TC10) centralized.

This section drafted by. State Food and Drug Administration Guangzhou Medical Device

Quality Supervision and Inspection Center, in Guangdong Province Drug Administration Bureau of Medical Devices Department.

1 Scope

GB/T 21417 in the provisions of this part of the terms and definitions ear cavity medical infrared thermometer, requirements, test methods, inspection rules and Signs, instructions, packaging, transportation and storage.

This section applies to the infrared radiation through the exchange and the appropriate correction value with the measured object detector measures the ear cavity between the output display body Certain parts of the body temperature of the ear cavity medical infrared thermometer (hereinafter referred to as the thermometer). The thermometer ear cavity by measuring the thermal radiation to be displayed Measured temperature of the object.

2 Normative references

The following documents contain provisions which, through reference GB/T 21417 in this section constitute provisions of this section. For dated reference documents Member, all subsequent amendments (not including errata content) or revisions do not apply to this section, however, encouraged to reach under this section Parties to research agreement to use the latest versions of these documents. For undated reference documents, the latest versions apply to this section.

GB/T 191-2000 Packaging - Pictorial signs (eqv ISO 780:1997) GB/T 2829-2002 periodic inspection Sampling procedures and tables (suitable for process stability test) GB 9706.1 Medical Electrical Equipment Part 1. General requirements for safety (GB 9706.1-2007, IEC 60601-1. 1988, IDT) GB 9969.1 Instructions General Industrial Products GB/T 14710-1993 Medical electrical equipment environmental requirements and test methods GB/T 16886.1-2001 Biological evaluation of medical devices - Part 1. Evaluation and testing (idt ISO 10993-1:1997)

3 Terms and Definitions

The following terms and definitions apply to this part of the GB/T 21417 of.

Ear cavity for the measured object in a non-contact infrared temperature measurement mode optical instruments.

Precisely know any opening hole wall temperature and emissivity of the hole is approximately porous reference infrared radiation source 1.0.

Measured temperature. (pulmonary artery, bladder, ear cavity, oral, rectal or axillary example) in a particular part of the body.

Thermometer reading their body parts to represent the indicated temperature (measured by

a standard thermometer) proximity.

Clinical deviation and its standard deviation represents the estimate obtained by testing with a standard thermometer temperature measurement test the average difference between the temperature of the object.