Designation: E 1965 – 98 (Reapproved 2003)

Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature[1]

This standard is issued under the fixed designation E 1965; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ϵ) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This specification covers electronic instruments intended for intermittent measuring and monitoring of patient temperatures by means of detecting the intensity of thermal radiation between the subject of measurement and the sensor.

1.2 The specification addresses assessing subject's body internal temperature through measurement of thermal emission from the ear canal. Performance requirements for noncontact temperature measurement of skin are also provided.

1.3 The specification sets limits for laboratory accuracy and requires determination and disclosure of clinical accuracy of the covered instruments.

1.4 Performance and storage limits under various environmental conditions, requirements for labeling and test procedures are established.

NOTE 1—For electrical safety consult Underwriters Laboratory Standards[2].

NOTE 2—For electromagnetic emission requirements and tests refer to CISPR 11: 1990 Lists of Methods of Measurement of Electromagnetic Disturbance Characteristics of Industrial, Scientific, and Medical (ISM) Radiofrequency Equipment[3].

1.5 The values of quantities stated in SI units are to be regarded as the standard. The values of quantities in parentheses are not in SI and are optional.

1.6 The following precautionary caveat pertains only to the test method portion, Section 6, of this specification: *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*

E 177 Practice for Use of the Terms Precision and Bias in ASTM Test Methods[4]

E 344 Terminology Relating to Thermometry and Hydrometry[5]

E 667 Specification for Mercury-in-Glass Maximum Self-Registering Clinical Thermometers[5]

E 1112 Specification for Electronic Thermometers for Intermittent Determination of Patient Temperature[5]

2.2 *International Electrotechnical Commission Standards:*

IEC 601-1-2: 1993 Medical Electrical Equipment, Part 1; General Requirements for Safety. Collateral Standard: Electromagnetic Compatibility—Requirements and Tests[3]

IEC 1000-4-2: 1995 Electromagnetic Compatibility (EMC)—Part 4: Testing and Measurement Techniques; Section 2: Electrostatic Discharge Immunity Test: Basic EMC Publication (Rev. of IEC 801-2)[3]

IEC 1000-4-3: 1995 Electromagnetic Compatibility[3]

2.3 *Other Standards:*

International Vocabulary of Basic and General Terms in Metrology (VIM)[3]

3. Terminology

3.1 *Definitions*—The definitions given in Terminology E 344 apply.

3.2 *Definitions of Terms Specific to This Standard*—The terms defined below are for the purposes of this specification only. Manufacturers should use this terminology in labeling instruments and in technical and sales literature.

3.2.1 *accuracy, n*—ability of an *infrared thermometer* to give a reading close to the *true temperature.*

3.2.2 *adjusted mode, n*—output of an *IR thermometer* that gives temperature measured and calculated from a subject or object, by correcting such temperature for variations in ambient temperature, *subject's* temperature, emissivity, body site (that is, *oral*, or *rectal*), etc.

[1] This specification is under the jurisdiction of ASTM Committee E20 on Temperature Measurement and is the direct responsibility of Subcommittee E20.08 on Medical Thermometry.

Current edition approved May 10, 2003. Published July 2003. Originally approved in 1998. Last previous edition approved in 1998 as E 1965 – 98.

[2] Available from Underwriters Laboratories Inc., 1655 Scott Blvd., Santa Clara, CA 95050.

[3] Available from Global Engineering Documents, 15 Inverness Way East, Englewood, CO 80112.

[4] *Annual Book of ASTM Standards*, Vol 14.02.

[5] *Annual Book of ASTM Standards*, Vol 14.03.

This document is now PUBLIC

Copyright © ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA 19428-2959, United States.