



Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature¹

This standard is issued under the fixed designation E1965; 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.*

¹ This specification is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.33 on Medical/Surgical Instruments.

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² Available from Underwriters Laboratories (UL), 2600 N.W. Lake Rd., Camas, WA 98607-8542, <http://www.ul.com>.

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

2. Referenced Documents

2.1 ASTM Standards:⁴

E177 Practice for Use of the Terms Precision and Bias in ASTM Test Methods

E344 Terminology Relating to Thermometry and Hydrometry

E667 Specification for Mercury-in-Glass, Maximum Self-Registering Clinical Thermometers

E1112 Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature

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 Tests³

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 Compatibility³

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 E344 apply.

3.2 Definitions of Terms Specific to This Standard:

3.2.1 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.

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

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

⁴ For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For Annual Book of ASTM Standards volume information, refer to the standard's Document Summary page on the ASTM website.

*A Summary of Changes section appears at the end of this standard