Designation: E1965 – 98 (Reapproved 2023)

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

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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.7 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

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 (Withdrawn 2022)[5]

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 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 E344 apply.

3.2 *Definitions of Terms Specific to This Standard:*

[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.

[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.

[5] The last approved version of this historical standard is referenced on www.astm.org.

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.

3.2.4 *axillary temperature [t_{ba}], n*—temperature at the apex of either axilla (armpit) as measured by a *contact thermometer*.

3.2.5 *blackbody, n*—a reference source of infrared radiation made in the shape of a cavity and characterized by precisely known temperature of the cavity walls and having effective emissivity at the cavity opening arbitrarily considered equal to unity.

3.2.6 *blackbody temperature [t_{BB}], n*—temperature of blackbody cavity walls as measured by an imbedded or immersed *contact thermometer*.

3.2.7 *bladder temperature, n*—temperature of the interior of the urinary bladder as measured by a *contact thermometer*.

3.2.8 *body temperature, n*—temperature measured from the interior of a human body cavity, such as pulmonary artery, distal esophagus, urinary bladder, ear canal, oral, or rectal.

3.2.9 *clinical accuracy, n*—ability of an infrared ear canal thermometer to give a reading close to *true temperature* of the site that it purports to represent.

3.2.10 *clinical bias [$\bar{x}_d$], n*—mean difference between IR thermometer output and an internal body site temperature from *subjects* at specified conditions of ambient temperature and humidity and averaged over a selected group of subjects.

3.2.11 *clinical repeatability [s_r], n*—pooled standard deviation of changes in multiple *ear canal temperature* readings as taken from the same subject from the same ear with the same *infrared thermometer* by the same operator within a relatively short time.

3.2.12 *combined site offset [μ_s], n*—calculated difference in degrees of measured temperature between a selected reference body site and *ear canal temperature* and averaged over the population of representative study samples.

3.2.13 *contact thermometer, n*—an instrument that is adapted for measuring temperature by means of thermal conductivity by determining temperature at the moment when negligible thermal energy flows between the thermometer and the object of measurement.

3.2.14 *core temperature [t_c], n*—temperature at a *subject's* body site, such as the pulmonary artery, distal esophagus, urinary bladder, or tympanic membrane, recognized as indicative of internal body temperature and obtained with a *contact thermometer*.

3.2.15 *mode, n*—an output of an *IR thermometer* that gives a representation of a temperature using a disclosed calculation technique with respect to selected reference (for example, *blackbody, oral, rectal*, etc.).

3.2.16 *displayed temperature range, n*—temperature range in degrees Celsius or Fahrenheit that can be shown by an *IR thermometer*.

3.2.17 *IR thermometer type, n*—an optoelectronic instrument that is capable of noncontact *infrared* temperature measurement when placed into the auditory canal of a *subject* (ear canal type) or from the *subject's* body surface (skin type).

3.2.18 *ear canal temperature [t_{ec}], n*—displayed unadjusted temperature measured from the *field of view* of an *IR thermometer* whose *probe* is placed into the auditory canal of a *subject* according to the manufacturer's recommendations.

3.2.19 *field of view, n*—area of a subject's surface that exchanges thermal radiation with the sensor.

3.2.20 *infrared (IR), adj*—of the electromagnetic radiation within the mid- and far infrared spectral ranges (approximately from 3 to 30 μm wavelength).

3.2.21 *infrared (IR) thermometer, n*—optoelectronic instrument adapted for noncontact measurement of the temperature of a subject by utilizing *infrared* radiation exchange between the *subject* and the *sensor*.

3.2.22 *instrumentational offset [μ_d], n*—calculated difference in degrees of measured temperature between *core temperature* and *ear canal temperature*, derived from the population of representative study samples.

3.2.23 *internal, adj*—of the interior of *subject's* body or body cavity, such as pulmonary artery, urinary bladder, oral, rectal, etc.

3.2.24 *laboratory error [δ], n*—difference between *unadjusted temperature* as measured by an *IR thermometer* and temperature of a blackbody, over specified operating conditions of ambient temperature and humidity and *blackbody* temperature ranges.

3.2.25 *operating temperature, n*—ambient temperature that allows operation of an *IR thermometer* within specified *laboratory error* range.

3.2.26 *operating humidity, n*—relative humidity of ambient air which allows operation of an *IR thermometer* within a specified *laboratory error* range.

3.2.27 *oral temperature [t_{bm}], n*—posterior sublingual temperature as measured by a *contact thermometer*.

3.2.28 *physiological site offset, [μ_p], n*—difference in degrees of measured temperature between two body sites derived from the representative study samples.

3.2.29 *probe, n*—part of an *IR thermometer* that channels net *infrared* radiation between the *subject* and the *sensor* and is intended to be positioned near or inside the *subject*.

3.2.30 *probe cover, n*—disposable or reusable sanitary barrier enveloping that part of the *probe* which otherwise would come in contact with a *subject*.

3.2.31 *professional use, n*—intended or implied use of an instrument by individuals that are licensed or certified for collecting information for medical diagnosing purposes.

3.2.32 *rectal temperature [t_{br}], n*—temperature in the anal canal as measured by a *contact thermometer.*

3.2.33 *resolution, n*—minimum temperature increment displayed by an *IR thermometer* in degrees Celsius or Fahrenheit.

3.2.34 *scale, n*—graduation of temperature display in degrees Celsius or Fahrenheit.

3.2.35 *sensor, n*—device designed to respond to net *IR* radiation and convert that response into electrical signals.

3.2.36 *skin temperature, n*—average temperature of a flat skin surface as measured from the *field of view* of an IR skin type thermometer, with an appropriate adjustment for skin emissivity.

3.2.37 *system, n*—combination of an *IR thermometer* and an installed *probe cover*.

3.2.38 *subject, n*—a human whose temperature is measured.

3.2.39 *true temperature, n*—temperature attributed to a particular site of a *subject* or object of measurement and accepted as having a specified uncertainty.

3.2.40 *tympanic temperature [t_{ty}], n*—temperature of either tympanic membrane as measured by a *contact thermometer*.

3.2.41 *unadjusted mode, n*—an output of *IR thermometer* that displays temperature measured and calculated from a *subject* or object, without any corrections for variations in *operating temperature*, subject temperature, emissivity, etc.

4. Classification

4.1 IR thermometers may be classified into two types: "ear canal IR thermometers" and "skin IR thermometers."

4.1.1 The ear canal IR thermometer is intended for assessing the internal temperature of a subject.

4.1.2 The skin IR thermometer is intended for assessing the outer surface temperature of a subject.

5. Requirements

5.1 The following requirements shall apply to any IR thermometer that is labeled to meet these specifications.

5.2 *Displayed Temperature Range:*

5.2.1 In any display mode, an ear canal IR thermometer shall display a subject's temperature over a minimum range of 34.4 to 42.2 °C (94.0 to 108.0 °F).

5.2.2 A skin IR thermometer shall display a subject's temperature over a minimum range of 22 to 40.0 °C (71.6 to 104.0 °F).

5.3 *Maximum Permissible Laboratory Error (for an Ear Canal IR Thermometer):*

5.3.1 Within the manufacturer's specified operating ambient conditions (see 5.6), laboratory error δ as measured according to 6.1.4 shall be no greater than values specified below:

5.3.1.1 For blackbody temperature range from 36 to 39 °C (96.8 to 102.2 °F):

0.2 °C (0.4 °F).

5.3.1.2 For blackbody temperatures less than 36 °C (96.8 °F) or greater than 39 °C (102.2 °F):

0.3 °C (0.5 ° F).

5.4 *Maximum Permissible Laboratory Error (for a Skin IR Thermometer):*

5.4.1 Within the manufacturer's specified operating ambient conditions (see 5.6) over the display temperature range as specified in 5.2.2, laboratory error δ as measured according to 6.1.5 shall be no greater than 0.3 °C (0.5 °F).

5.5 *Special Requirements:*

5.5.1 *Clinical Accuracy:*

5.5.1.1 The clinical accuracy requirement is applicable only to an ear canal IR thermometer system and the corresponding age groups of subjects for which such a thermometer is labeled or implied to be used.

5.5.1.2 Clinical accuracy shall be determined separately for each of the following conditions: for each device model, for each adjusted display mode, and for every age group of febrile and afebrile subjects on which the IR thermometer is intended to be used.

5.5.1.3 Any disclosure of clinical accuracy claims shall be accompanied by disclosure of methodology and procedures. Such information shall be made available on request.

5.5.1.4 Clinical accuracy should be determined in the form of two characteristics—clinical bias with stated uncertainty and clinical repeatability, as defined in 3.2.9.

5.6 *Ambient Conditions:*

5.6.1 *Operating Temperature Range:*

5.6.1.1 The system shall meet laboratory error requirements as specified in 5.3 or 5.4, or both, when operating in an environment from 16 to 40 °C (60.8 to 104.0 °F).

5.6.1.2 If the operating temperature range is narrower than specified in 5.6.1.1, the device shall be clearly labeled with a cautionary statement of the maximum or minimum operating temperatures, or both.

5.6.1.3 Under no circumstances may the upper limit of operating temperature range be less than 35 °C (95 °F).

5.6.2 *Operating Humidity Range*—The relative humidity range for the operating temperature range as specified in 5.6.1 is up to 95 %, noncondensing.

5.6.3 *Shock:*

5.6.3.1 The instrument with batteries installed (if applicable) without a carrying (storage) casing shall withstand drops with controlled orientation of the device without degradation of accuracy as specified in 5.3 or 5.4, or both, for a blackbody temperature of or near 37 °C (98.6 °F), when tested according to 6.3.

5.6.3.2 If an IR thermometer does not meet the requirement of 5.6.3.1, a means of detecting and informing the user of its inoperable state, after being subjected to shock, shall be provided.

5.6.4 *Storage Conditions*—The instrument shall meet the accuracy requirements of 5.3 or 5.4, or both, after having been stored or transported, or both, at any point in an environment of –20 to +50 °C (–4 to +122 °F) and relative humidity up to 95 %, noncondensing, for a period of one month. The test procedure is specified in 6.1.6.

5.6.5 *Cleaning and Disinfection*—Instrument performance shall not be degraded by using the manufacturer's recommended procedures for cleaning and disinfection provided in the instruction manual. Such procedures are part of the required documentation in 7.2.2.