



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 Inc., 1655 Scott Blvd., Santa Clara, CA 95050.

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 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.

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.

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 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 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 thermom-*

eter 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 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 adjustments 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 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 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 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.

5.6.6 *Electromagnetic Immunity*—An IR thermometer that is intended for professional use shall meet the accuracy requirements of 5.3 or 5.4, or both, for temperature ranges of 6.3.2, during and after exposure to electromagnetic interference.

5.6.7 *Electrostatic Discharge*—An IR thermometer shall meet the accuracy requirements of 5.3 and 5.4, or both, for temperature ranges of 6.3.2, after 5 s from being subjected to electrostatic discharge.

5.7 *Low Power Supply Operation*—The instrument shall operate at power supply voltage lower by no less than 0.1 V

than that required for indication of low power supply sign as specified by 5.8.3. The test of operation is defined in 6.3.2 and 6.3.3.

5.8 Display and Human Interface:

5.8.1 *Resolution*—The resolution of a display shall be 0.1 °C (0.1 °F).

5.8.2 Modes:

5.8.2.1 An IR thermometer shall indicate in what mode the instrument is set.

5.8.2.2 *Unadjusted Mode*—The unadjusted mode shall be accessible by the user either by setting the instrument into that mode directly or by a conversion technique from adjusted mode.

5.8.2.3 Adjusted mode sets an IR thermometer to represent a reference body site, such as core, oral, rectal, etc.

5.8.3 *Warning Signs*—The instrument shall have means to inform the operator when the following are outside the operating ranges specified by the manufacturer: power supply, subject temperature, and ambient temperature.

5.9 Construction:

5.9.1 *Housing Materials*—All materials that may come in contact with the operator or a subject shall be nontoxic.

5.9.2 Probe Covers:

5.9.2.1 To provide a sanitary barrier between a subject and the probe, a probe cover that comes in contact with a subject, if such a probe cover is required by the manufacturer, shall maintain its physical integrity while being placed on the probe and during temperature measurement.

5.9.2.2 A probe and a probe cover of the system shall have shape and dimensions that prevent injury to a subject of any age.

5.9.2.3 A probe cover shall not increase laboratory errors whose limits are set in 5.3.1.

5.10 Labeling and Marking (Instruments and Accessories):

5.10.1 Thermometer and Accessories:

5.10.1.1 A thermometer shall clearly indicate the units of its temperature scale.

5.10.1.2 An IR thermometer housing shall be clearly marked with the trade name or type of the device, or both, model designation, name of the manufacturer or distributor, and lot number or serial number.

5.10.1.3 An IR thermometer intended for professional use shall be conspicuously labeled with indication of the unadjusted or adjusted mode(s), or both, that correspond to the temperature value(s) capable of being displayed by the instrument. Such labeling is optional for IR thermometers that display only one mode and are intended for non-professional use. However, as required in 7.2.1.3, the instruction manual for both professional and non-professional use IR thermometers shall specify the body site(s) (that is, oral, rectal, core) used to reference the adjusted temperature value(s) displayed.

NOTE 3—All markings shall not deteriorate after prolonged use or cleaning.

5.10.2 Probe Covers Package:

5.10.2.1 The package shall state the name and type of the enclosed products, name of the manufacturer or distributor, lot

number or serial number, and expiration date (if the probe covers have limited shelf life).

5.10.2.2 The thermometer model(s) for which the covers are intended for use shall be specified on the probe cover package.

5.10.2.3 The package shall state whether the probe cover is intended for single use or multiple use.

5.10.2.4 Any probe cover handling, application, storage, or cleaning procedures which impact the ability of an IR thermometer to meet the requirements for maximum permissible laboratory error specified in 5.3 shall be stated.

6. Test Methods

6.1 The tests are not required for every produced instrument. However, each producer or distributor who represents its instruments as conforming to this specification shall utilize statistically based sampling plans that are appropriate for each particular manufacturing process, in the design qualification of the device, and shall keep such essential records as are necessary to document with a high degree of assurance its claims that all of the requirements of this specification are met.

6.1.1 The manufacturer shall make the sampling plans available upon request.

6.1.1.1 Laboratory Accuracy Tests:

6.1.1.2 *General*—Laboratory accuracy tests are intended for verifying compliance of the design and construction of a particular type or model of IR thermometer with the error limitations specified in 5.3 or 5.4, or both.

6.1.2 Laboratory accuracy of an IR thermometer shall be tested in all available display modes.

6.1.3 Blackbody:

6.1.3.1 Under laboratory conditions, an IR thermometer shall be tested against a blackbody standard. A recommended blackbody design is provided in Annex A1. The temperature of a blackbody shall be measured by the IR thermometer being tested in accordance with a procedure recommended by the manufacturer for the particular IR thermometer.

6.1.3.2 The true temperature of the blackbody shall be monitored by a contact imbedded or immersed thermometer with uncertainty no greater than ± 0.03 °C (± 0.05 °F).

6.1.3.3 A manufacturer may require that an IR thermometer is tested only with a manufacturer specified blackbody, rather than that described in Annex A1.

6.1.4 Ear Canal Type IR Thermometer:

6.1.4.1 Tests shall be repeated for three blackbody temperatures, t_{BB} set within ± 0.5 °C (± 1 °F) from the following temperatures: 35, 37, and 41 °C, (95, 98.6, and 105.8 °F). At each blackbody temperature, the tests shall be repeated under the ambient conditions stated in Table 1.

NOTE 4—For an IR thermometer that is specified for a different

TABLE 1 Conditions of Ambient Temperature and Humidity for Testing an IR Thermometer with a Blackbody for Each of Three Blackbody Settings

Operating Temperature	Relative Humidity (%)
16 to 18 °C (60 to 65 °F)*	less than 50
16 to 18 °C (60 to 65 °F)*	90 to 95
24 to 26 °C (75 to 80 °F)	40 to 60
38 to 40 °C (100 to 104 °F)*	less than 25
38 to 40 °C (100 to 104 °F)	75 to 85

operating temperature range than that required in 5.6.1.1, temperatures in Table 1 marked with an asterisk shall be changed for the respective limits of such specified operating temperature range.

6.1.4.2 Prior to the measurements, the IR thermometer shall be stabilized at given conditions of ambient temperature and humidity for a minimum of 30 min or longer if so specified by the manufacturer.

6.1.4.3 At each combination of operating temperature and humidity in Table 1, at least six measurements shall be taken for each blackbody temperature, t_{BB} . The number of readings shall be the same for all combinations. A new disposable probe cover (if applicable) must be used for each test reading. The rate and method of temperature taking shall be in compliance with the manufacturer's recommendations.

6.1.4.4 The requirements of 5.3 demand that no individual error δ_j exceeds the specified limits for laboratory error. The individual measurement error is:

$$\delta_j = |t_j - t_{BB}| \quad (1)$$

t_j = displayed or calculated value of unadjusted temperature,
 t_{BB} = true temperature of the blackbody,
 j = sequential number of a reading,
 $||$ = signifies taking an absolute value.

6.1.4.5 In each mode, three data sets shall be formed. Each data set is comprised of values δ_j obtained at the same blackbody temperature setting by pooling together values for all combinations of operating temperature and humidities obtained at that blackbody temperature. The largest δ_j is a measure of the laboratory error of a system.

6.1.4.6 The correction method to arrive at unadjusted temperature t_j from readings in adjusted mode(s) shall be used according to the manufacturer's recommendation. Such recommendations shall be available from the manufacturer on request and provided in the service and repair manual, if any (see 7.3).

6.1.4.7 To comply with this standard, the greatest calculated error δ_j from all data sets measured and calculated for all display modes shall conform with requirements set forth in 5.3.

6.1.5 Skin Type IR Thermometer:

6.1.5.1 Testing is as specified in 6.1.4 except that blackbody temperatures shall be set within $\pm 1^\circ\text{C}$ ($\pm 2^\circ\text{F}$) from the following temperatures: 23, 30, and 38 $^\circ\text{C}$ (73, 86, and 100 $^\circ\text{F}$)

6.1.5.2 The greatest calculated error δ_j from all data sets shall conform with requirements set forth in 5.4.

6.1.6 *Storage Test*—To test compliance with storage conditions, an IR thermometer shall be maintained in an environmental chamber at temperature -20°C (-4°F), relative humidity below 50 %, for a period of 30 days and at 50°C (122°F), relative humidity no less than 75 % noncondensing, for a period of 30 days. After each exposure the IR thermometer shall be tested according to 6.3.2 and 6.3.3.

6.2 *Clinical Accuracy Tests*—This specification does not prescribe an actual method for determining clinical accuracy or establish specifications for values which characterize clinical accuracy. Manufacturers shall perform clinical accuracy testing in accordance with methods acceptable to the U.S. Food and Drug Administration. An example of a method which may be used for this purpose is provided in X2.3.

6.2.1 *Purpose of Tests*—Clinical accuracy tests are intended for evaluation of accuracy of built-in instrumental or combined site offsets, or both, and performance of an IR thermometer in assessing internal body temperatures from actual subjects. While this specification does not set limits for clinical accuracy, it is the responsibility of a manufacturer to determine values characterizing clinical accuracy and disclose them upon request.

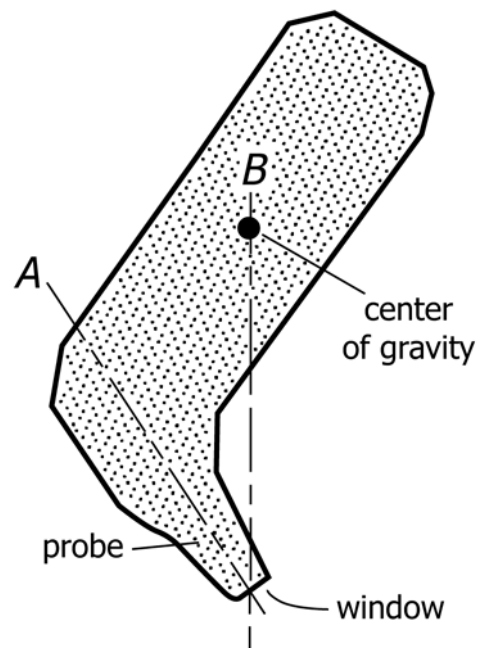
6.2.2 *Reference Sites*—The tests shall be performed on groups of subjects by using an internal body site (for example, pulmonary artery or sublingual cavity) for the reference measurements. During clinical tests, the IR thermometer under test shall be set in the corresponding mode.

6.3 Shock Test:

6.3.1 To test the ability of an IR thermometer to comply with 5.6.3, it shall be subjected to a fall from a height of 1 m (39 in.) onto a 50 mm (2 in.) thick hardwood board (hardwood of density higher than 700 kg/m³) that lies flat on a rigid base (concrete block). The test shall be performed with a controlled orientation of the device once for each of two axes (see Fig. 1) where the IR thermometer probe faces down. Axis A is defined as an optical axis of the probe. Axis B passes through the IR thermometer center of gravity and the point where the window of the probe crosses axis A.

NOTE 5—If axes as in Fig. 1 cannot be identified for a particular thermometer, the drop direction shall be that which may cause the greatest damage.

6.3.2 The IR thermometer's operation shall be tested by measuring the temperature of a blackbody that is set within $\pm 0.5^\circ\text{C}$ ($\pm 1^\circ\text{F}$) from 37°C (98.6°F), at ambient temperature in the range from 20 to 26 $^\circ\text{C}$ (68 to 79 $^\circ\text{F}$) and relative humidity in the range from 40 to 70 %. A total of at least five



NOTE 1—IR thermometer is shown in the fall position along Axis B.
FIG. 1 Axes of IR Thermometer Defined for the Purpose of Shock Test

measurements shall be performed by using a new disposable probe cover (if applicable) for every measurement. The IR thermometer shall be set in an unadjusted mode as specified in 5.8.2.2.

6.3.3 The unadjusted temperature value shall be subtracted from the blackbody setting. The absolute value of the largest error shall be no greater than the error limit set forth in 5.3 (or 5.4, whichever is applicable) for the blackbody temperature range from 36 to 39 °C (96.8 to 102.2 °F).

6.4 *Electromagnetic Susceptibility Test:*

6.4.1 The instrument under test shall be exposed to a modulated electromagnetic radiofrequency field with the following characteristics and in accordance with standards IEC601-1-2 and IEC 1000-4-3.

6.4.1.1 *Field Strength*—3 V/m;

6.4.1.2 *Carrier Frequency Range*—26 MHz to 1 GHz;

6.4.1.3 *Frequency Sweep Interval*: 1 MHz/s, minimum;

6.4.1.4 *Frequency Interval Dwell Time*: The larger of either 1 s. or the measurement response time of the instrument under test;

6.4.1.5 AM modulation, 80 % index with a sine wave or 100 % with a square wave having a 50 % duty cycle. A modulation frequency that is within each significant signal-processing passband of the instrument under test shall be used. For devices not having a defined passband, modulation shall be 1 Hz, 10 Hz, and 1 kHz.

6.4.2 Specific conditions for testing are as follows:

6.4.2.1 No change of the probe covers is required while performing the electromagnetic compatibility test.

6.4.2.2 The IR thermometer probe shall be aimed at a target whose surface temperature is within the display range of the IR thermometer. The target does not have to be a blackbody.

6.4.2.3 IR thermometers capable of producing continuous temperature readings shall have their readings taken successively and compared to one another during the frequency sweep interval.

6.4.2.4 IR thermometers not capable of producing continuous temperature readings shall have their circuitry modified to allow for continuous monitoring of the IR and reference temperature signals. The peak excursions of the monitored IR and reference temperature signals measured during frequency sweep interval shall be recalculated to represent the corresponding temperature excursions. On request, the manufacturer shall make available the method of the circuit modification.

6.4.2.5 IR thermometers having digital output shall have their signal monitored at the output of the analog-to-digital converter.

NOTE 6—Modification of the circuit should not affect dimensions of the circuit board or significantly alter position of components and conductors.

6.4.2.6 Non-conductive and dielectric connections (for example, fiber-optic) shall be used between the IR thermometer and all test equipment so as to minimize perturbations of the electromagnetic field.

6.4.2.7 Calculated temperature excursions shall deviate from one another by value no greater than required by 5.6.6.

6.5 *Electrostatic Discharge Tests:*

6.5.1 The effects of electrostatic discharge on accuracy of an IR thermometer shall be tested in compliance with provisions of standard IEC 1000-4-2: 1995. Specific conditions for testing are as follows:

6.5.1.1 The IR thermometer shall be in a “power on” state when subjected to electrostatic discharge.

6.5.1.2 Ten air and ten contact discharges shall be applied.

6.5.1.3 If IR thermometer under test has no exposed electrically conductive parts, only air discharge shall be applied.

6.5.2 *Air Discharge:*

6.5.2.1 The discharge shall be aimed at an electrically nonconductive part of the IR thermometer probe with no probe cover attached.

6.5.2.2 The level of discharge shall be 2, 4, and 8 kV.

6.5.3 *Contact Discharge:*

6.5.3.1 The probe of the electrostatic discharge device shall touch one of the electrically conductive parts on the outside of the IR thermometer housing.

6.5.3.2 The level of discharge shall be 2, 4, and 6 kV.

6.5.4 After electrostatic discharge, the IR thermometer shall be tested according to the procedures of 6.3.2 and 6.3.3.

7. Documentation

7.1 *Identification:*

7.1.1 In order that purchasers may identify products conforming to requirements of this specification, producers and distributors may include a statement of compliance in conjunction with their name and address on product labels or associated printed materials, or both, such as invoices, sales literature, and the like. The following statement is suggested: “*This infrared thermometer meets requirements established in ASTM Standard (E1965-98). Full responsibility for the conformance of this product to the standard is assumed by (name and address of producer or distributor).*” In the event one or more provisions of this standard are not met, a cautionary statement shall be included.

7.1.2 The IR thermometer shall be identified as intended for professional or consumer use, or both, as applicable.

7.2 *Instruction Manual:*

7.2.1 *Specifications*—An instruction manual shall be provided and contain the system specifications, including but not limited to the following:

7.2.1.1 Displayed temperature range.

7.2.1.2 Maximum laboratory error.

7.2.1.3 Body site(s) used as a reference for adjusting the displayed temperature value.

7.2.1.4 Applicable subject categories for each display mode.

7.2.1.5 Required period of recalibration or reverification, if applicable.

7.2.1.6 Environmental characteristics (operating and storage ranges for temperature and humidity).

7.2.1.7 Statement informing that clinical accuracy characteristics and procedures are available from the manufacturer on request.

7.2.2 *Detailed instructions*—The instruction manual shall contain adequate instructions for use with sufficient detail for training in the operation, application, care, and biological and physical cleaning of the instrument and accessories. The

instruction manual shall include warnings if performance of the instrument may be adversely affected should one or more of the following occur:

7.2.2.1 Operation outside of the manufacturer specified subject temperature range.

7.2.2.2 Operation outside of the manufacturer specified operating temperature and humidity ranges.

7.2.2.3 Storage outside of the manufacturer specified ambient temperature and humidity ranges.

7.2.2.4 Mechanical shock.

7.2.2.5 Manufacturer defined soiled or damaged infrared optical components.

7.2.2.6 Absent, defective, or soiled probe cover (if applicable).

7.2.2.7 Use of unspecified probe covers.

7.2.3 *Blackbody*—The instruction manual shall indicate the type and availability of a blackbody recommended for verifying laboratory or clinical accuracy, or both, if only such type is required by the manufacturer as addressed in 6.1.3.3.

7.2.4 The instruction manual shall specify whether the probe cover is intended for single use or multiple use. If multiple use is allowed, cleaning instructions and criteria for determining when a probe cover should be discarded shall be specified. Cleaning instructions shall be adequate to prevent cross-contamination between patients.

7.2.5 The instruction manual shall inform the user of differences in the accuracy of measurements obtained with IR thermometers versus contact thermometers (that is, mercury-in-glass and electronic thermometers). Such differences shall include, whenever applicable, a description of the anticipated error sources associated with disposable or reusable probe covers and sleeves, operators' technique, anatomical

variations, earwax buildups, subject cooperation, etc. In addition, this section of the instruction manual that explains differences in the accuracy of measurements obtained with IR thermometers versus contact thermometers shall conspicuously include the following statement: “ASTM laboratory accuracy requirements in the display range of 37 to 39 °C (98 to 102 °F) for IR thermometers is ± 0.2 °C (± 0.4 °F), whereas for mercury-in-glass and electronic thermometers, the requirement per ASTM Standards E667-86 and E1112-86 is ± 0.1 °C (± 0.2 °F).”

7.3 Service and Repair Manual:

7.3.1 A detailed service manual shall be made available if user service or repair is permitted by the manufacturer.

7.3.2 A service manual shall disclose values of instrumentation or combined site offsets, or both.

7.3.3 A service manual shall provide a method of arriving to unadjusted readings from temperatures displayed in an adjusted mode.

7.4 *Accuracy Determination*—A manufacturer shall make available upon request specific instructions for tests to determine the laboratory error, clinical bias and clinical repeatability of an IR thermometer. When describing how clinical tests are performed, the manufacturer shall disclose the profile of subject groups tested, including age and febrile status. A detailed procedure for taking reference temperatures also shall be disclosed.

8. Keywords

8.1 auditory canal; body temperature; ear; fever; infrared; medical instrument; temperature; thermometer; tympanic membrane

ANNEX

(Mandatory Information)

A1. STANDARD BLACKBODY DESCRIPTION

A1.1 A blackbody that is intended for use in the laboratory tests shall have effective emissivity approaching unity. The most efficient way of designing a blackbody is to form it in a shape of a cavity whose wall temperature is precisely known and from which infrared radiation is allowed to escape through a small opening (1,2).⁵ A recommended design is based on the blackbody source developed in The National Institute of Standards and Technology (3) and is shown in Fig. A1.1. For the purpose of this specification, emissivity of this blackbody (at the rim X of the opening in the upper portion of the cavity) should be considered equal to unity.

A1.1.1 The blackbody cavity is fabricated of metal having high thermal conductivity, preferably oxygen-free copper. The

outer surface of the cavity may be plated with thin layer of gold over nickel to retard oxidation of the copper surface. The interior surface of the copper cavity is painted with organic enamel paint with thickness after drying of between 20 and 50 μm . Color of paint is not critical. The cavity is immersed into a stirred water bath (liquids other than water may be used). The metal cavity is connected to a surface box fabricated of a material having low thermal conductivity, such as Delrin or ABS plastic. The box shall be reliably secured to the water bath to prevent the blackbody from free floating on the surface of water. Alternatively, the cavity may be secured horizontally with the opening in a water bath wall as in (3).

A1.2 The cavity opening for the insertion of the probe end must have a diameter sufficiently small for the snug fitting of the probe with a probe cover attached (if applicable). The probe end preferably should be aligned with the rim of the opening

⁵ The boldface numbers given in parentheses refer to a list of references at the end of the text.

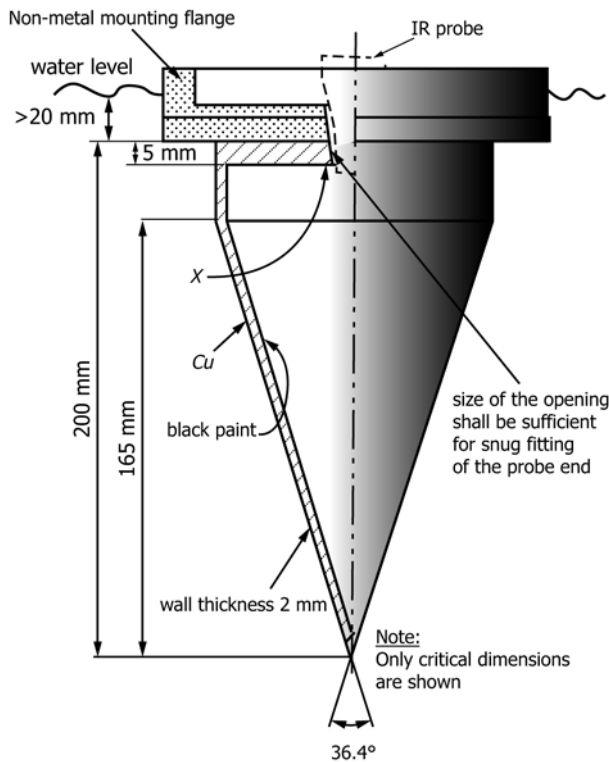


FIG. A1.1 Water-Immersed Blackbody

and should not protrude into the cavity by more than 2 mm (0.08 in.). No metal portion of the cavity should be positioned above the water level. The shape and dimensions of the opening into the blackbody shall correspond to those specified by the manufacturer of the instrument being tested. The opening shall ensure that the probe is properly positioned in the blackbody when manually inserted.

A1.3 The water bath shall have a volume of 2 L (2 qt) or greater and temperature stability within $\pm 0.02^\circ\text{C}$ (0.04°F). True temperature of the water shall be monitored with an uncertainty no greater than $\pm 0.03^\circ\text{C}$ (0.05°F) by an immersed contact thermometer for which the calibration is traceable to a national physical standard of temperature. The contact thermometer should be positioned into the water in close proximity to the blackbody cavity.

A1.4 It is possible for the test purposes to use a blackbody of a different design. However, emissivity of such a blackbody shall be known in comparison to the one described above, and used for correction in measured temperatures.

APPENDIXES

(Nonmandatory Information)

X1. BACKGROUND

X1.1 The materials of this section contain statements which do not represent any standard or requirement and should be used only for reference purposes.

X1.2 The intensity of infrared (IR) radiation represents the temperature of the surface from which it is emitted. A medical IR noncontact thermometer covered by this specification is an electronic device having an optical probe. IR radiation is collected from the field of view of the probe and is converted into an electrical signal for calculation of the surface temperature of the subject. Assessing temperatures measured by IR thermometers has both technical and medical aspects. The former depend on the design of a particular thermometer, while the latter relate to properties of the subject of measurement.

X1.3 Technical Background:

X1.3.1 While contact thermometers, of either equilibrium or predictive type, rely on conductive heat transfer, IR thermometers use naturally emitted electromagnetic radiation. The magnitude and the spectral distribution of the radiation are functions of the subject's and sensor's temperatures and their respective emissivities. The spectral density of the radiation is governed by Planck's law and theoretically occupies an infinitely wide spectrum. However, due to the shape of the density curve and a filtering effect in the optical components, the

bandwidth of a medical IR thermometer is generally limited to the range from 3 to 30 μm , that is well beyond the visible region and is situated in the near and far infrared spectral ranges.

X1.3.2 Wien's displacement law for absolute blackbody radiation of 37°C (98.6°F) gives a peak wavelength at 9.34 μm , while the net IR flux spectral density for blackbody radiation of 37°C and the IR sensor at normal room temperature has a maximum spectral density near 8 μm of wavelength (see Fig. X1.1). The net infrared flux over a broad spectral range may be determined from the Stefan-Boltzmann equation:

$$\Phi_b = A\sigma\epsilon_b\epsilon_s(T_b^4 - T_s^4) \quad (\text{X1.1})$$

where:

- A = the optical coefficient,
- σ = Stefan-Boltzmann constant,
- ϵ_b = emissivity of the subject,
- ϵ_s = emissivity of the sensor,
- T_b = surface temperature (in degrees Kelvin) of the subject, and
- T_s = surface temperature (in degrees Kelvin) of the sensor.

X1.3.3 Eq X1.1 is a fundamental formula for calculating the surface temperature T_b of the subject. For that purpose, the formula is rearranged as:

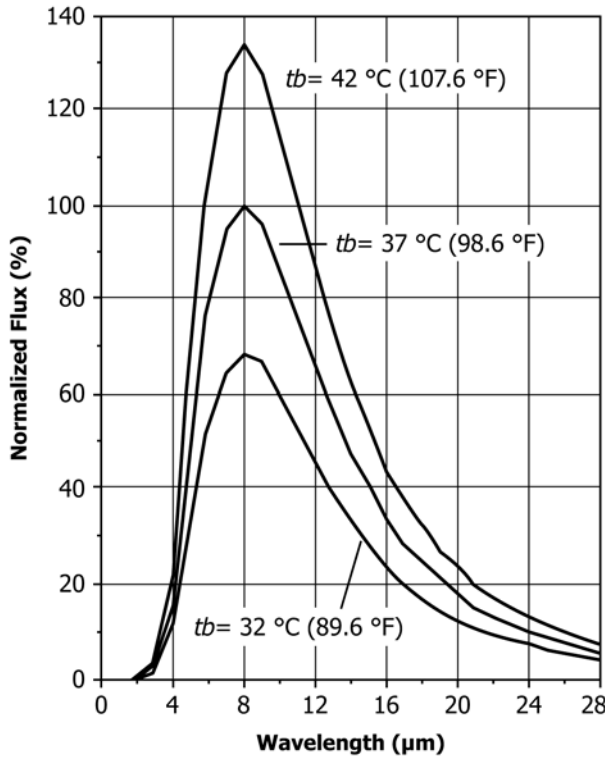


FIG. X1.1 Normalized with Respect to $t_b=37^\circ\text{C}$ Spectral Net Flux Density for Three Blackbody Temperatures and IR Sensor at 20°C (68°F)

$$T_b = \sqrt[4]{T_s^4 + \frac{\Phi_b}{A\sigma\epsilon_b\epsilon_s}} \quad (\text{X1.2})$$

where: T_b represents the calculated temperature.

X1.3.4 The calculation requires an accurate detection of two independent variables, the surface temperature T_s of the sensor (or reference target) and the net infrared flux Φ_b between the sensor and subject.

X1.3.5 It follows from the above that, in general terms, any noncontact IR thermometer must contain at least four essential components: an IR sensor to measure that net thermal radiation flux Φ_b , a reference contact sensor to measure the temperature T_s , an optical component to define the optical coefficient A , and the computational means to calculate the subject's temperature T_b (Fig. X1.2).

X1.3.5.1 In practice, the essential elements of the measurement system may have many configurations and additions to enhance accuracy and add features required for use of the device. These may include the IR flux choppers or shutters, protective probe covers, reference targets, etc. Regardless of any practical implementation, the ultimate technical goal of the instrument is an accurate assessment of the subject's surface temperature T_b .

X1.3.6 Emissivity:

X1.3.6.1 Emissivity is an indicator of how well an object emits electromagnetic radiation from its surface. It is expressed using a dimensionless scale which ranges from 0 to 1.0. An ideal "blackbody" has an emissivity of 1.0 and, by definition, is a perfect emitter. In reality, objects are never this efficient.

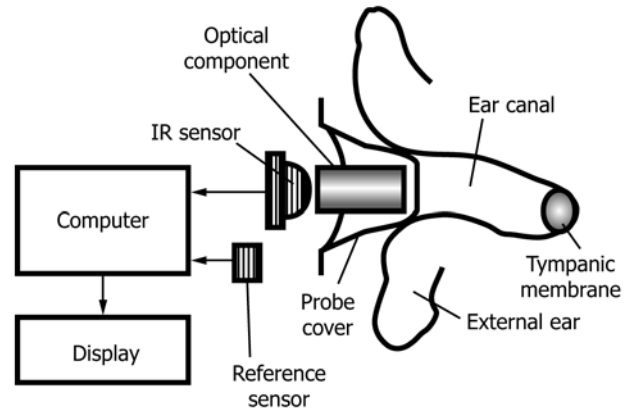


FIG. X1.2 General Structure of a Medical IR Thermometer for Measuring Temperature from an Ear Canal

Therefore, ideal blackbodies are modeled with practical blackbodies which have emissivities approaching unity as closely as possible.

X1.3.6.2 A cavity-type blackbody is commonly used to calibrate and verify the accuracy of IR thermometers. Due to multiple internal reflections of infrared photons inside the cavity, those which emerge through the cavity opening have IR flux characteristics very near that which would emanate from an ideal blackbody surface (1). Thus, the opening in the cavity is considered a blackbody surface, though such a surface does not exist in reality.

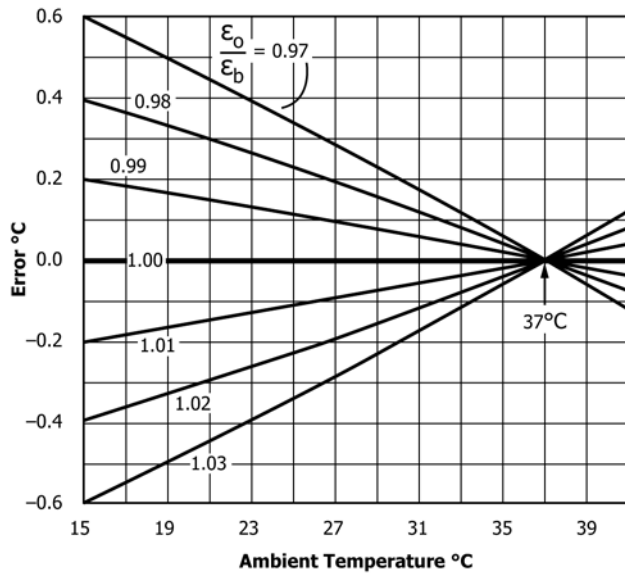
X1.3.6.3 Some practical "blackbodies" may have lower emissivities than that of the recommended blackbody of Annex A1 (often, they are called "graybodies"). In such cases, laboratory error measured according to 6.1 will appear too high.

X1.3.6.4 Therefore, in reality all "blackbodies" do not have the same emissivity. When an IR thermometer's laboratory accuracy is verified according to 6.1 using a blackbody whose emissivity (ϵ_b) is different than that of the blackbody originally used to calibrate the device (ϵ_o), an emissivity error (δ_ϵ) is introduced. The error in temperature measurement by an IR thermometer as function of ambient and subject's temperatures T_a and T_b (in Kelvin) respectively, may be expressed by the following equation:

$$\delta_\epsilon = T_b - \sqrt[4]{\frac{\epsilon_o}{\epsilon_b} (T_b^4 - T_a^4) + T_a^4} \quad (\text{X1.3})$$

X1.3.6.5 The equation suggests that emissivity error grows smaller when ambient temperature approaches that of a subject or when emissivity of a blackbody matches that of the subject. Errors calculated for the object temperature of 37°C are illustrated in Fig. X1.3. When $\epsilon_b < \epsilon_o$, the IR thermometer reading will be too low and will need to be readjusted upward according to Eq X1.3 and Fig. X1.3 before accuracy can be adequately assessed. Conversely, when $\epsilon_b > \epsilon_o$, the IR thermometer readings will be too high and will need to be readjusted downwards.

X1.3.6.6 Example—An IR thermometer previously calibrated with blackbody having emissivity of $\epsilon_o=0.995$ (as measured in comparison with the standard blackbody described in Annex A1) is used at ambient temperature of $t_a=25^\circ\text{C}$ to



NOTE 1—Calculated for object's temperature of 37 °C, for various ratios of ϵ_o/ϵ_b .

FIG. X1.3 Error in Temperature Measurement by an IR Thermometer Calibrated with Blackbody (Emissivity ϵ_o) when Used with an Object Having Emissivity ϵ_b

measure temperature of a blackbody set at $t_{BB}=37\text{ }^{\circ}\text{C}$ and having emissivity of $\epsilon_b=0.985$ (emissivity ratio $\epsilon_o/\epsilon_b=1.01$). The IR thermometer displayed temperature of 36.8 °C. According to Eq X1.3 and Fig. X1.3, the reading shall be corrected for the emissivity error of $-0.11\text{ }^{\circ}\text{C}$ by subtracting that number from the displayed temperature. That is, the corrected reading shall be $36.8 - 0.11 = 36.91\text{ }^{\circ}\text{C}$. After rounding for 0.1° resolution, the corrected value of reading is $36.9\text{ }^{\circ}\text{C}$ which indicates that the IR thermometer under test reads blackbody temperature lower by 0.1° , not by $0.2\text{ }^{\circ}\text{C}$ as it would appear from the uncorrected display.

X1.4 Medical Background—The ultimate medical goal of a body temperature measurement is the accurate determination of core body temperature. This is temperature close to that of the blood in the body's vital organs, such as the brain and heart. As the next best thing to the core temperature measurement, temperatures may be taken from a body interior or body cavity which represents core temperature with acceptable accuracy.

X1.4.1 Measurement Sites:

X1.4.1.1 Medical infrared thermometry has two distinct types of measurements: body temperature measurement and skin surface temperature measurement.

X1.4.1.2 Skin temperature measurements have specific applications in determining surface temperature of a human body. That temperature greatly depends on both the skin blood perfusion and environmental conditions. Therefore, skin temperature can not be independently correlated with the internal body temperature.

X1.4.1.3 Body temperatures traditionally have been measured by contact thermometers in the oral, rectal, or axillary sites. These sites, however, were choices of convenience, rather than of correctness. They often do not represent core body temperature with required fidelity. Thus, during surgical pro-

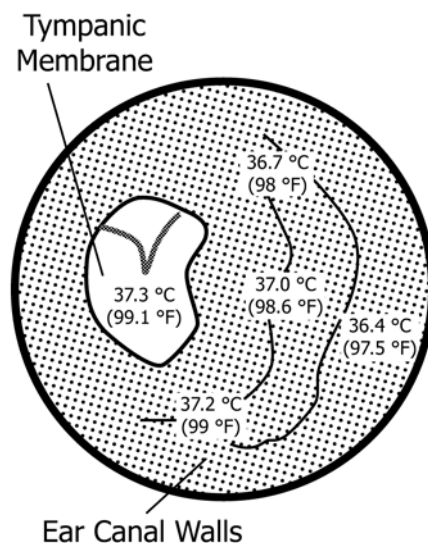
cedures and in intensive care units, temperatures frequently are measured in the pulmonary artery (PA), distal esophagus, urinary bladder, or on the tympanic membrane, that are recognized core temperature sites.

X1.4.1.4 Due to physiological and practical limitations, only the auditory (ear) canal, including the tympanic membrane is suitable for routine noncontact infrared (IR) detection. The auditory canal is a nearly ideal cavity for IR body temperature measurement. It is not affected by respiration, eating, drinking, or smoking. Anatomically, the canal is a slightly curved tube about 3.5 cm (1.4 in.) long in an adult. It is limited inside by the tympanic membrane. The canal is well-insulated from the exterior and is located in close proximity to major brain arteries and veins. It ends only about 3.5 cm (1.4 in.) from the hypothalamus, which is the body thermal regulation center.

X1.4.1.5 Tympanic temperature is a recognized measure of core temperature (4,5,6) and the tympanic membrane is considered a temperature core site. Ear canal temperature as measured by an IR thermometer is relatively close to that of the tympanic membrane and is not significantly influenced by local inflammations (the observed effect of otitis media was an increase of about 0.1° (7) or a moderate amount of ear wax (the observed effect when cerumen occludes the ear canal was between 0.1 and $0.3\text{ }^{\circ}\text{C}$ (8,9). The interior portion of the ear canal quickly reflects dynamic changes in core temperature.

X1.4.1.6 It should be recognized, however, that tympanic temperature (t_{ty}) is somewhat different than average ear canal temperature (t_{ec}). Temperature inside the ear canal generally is not uniform (Fig. X1.4) and may vary substantially from the near ambient on the surface of the auricle to a value approximating the core ($t_{ty} \sim t_c$) on the surface of the tympanic membrane.

X1.4.2 Reference Sites:



NOTE 1—Numbers exemplify temperatures on the surface of the ear canal walls. Tympanic temperature $t_{ty}=37.3\text{ }^{\circ}\text{C}$. The average of all temperatures over the ear canal surface within the field of view represents temperature of the ear canal t_{ec} .

FIG. X1.4 Ear Canal Within a Field View of an Ear Thermometer

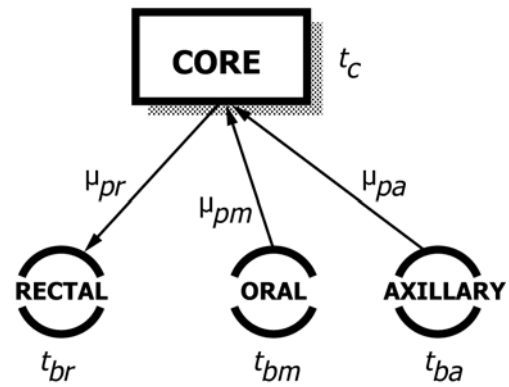
X1.4.2.1 In contrast to industrial types of infrared thermometers whose performance can be fully evaluated with a standardized thermal radiation source (a blackbody), accuracy of a medical infrared noncontact thermometer should, in addition, be assessed under real conditions involving temperature measurements of patients. This demands use of a reference contact temperature probe placed inside the patient's body. Preferably, such a reference probe should be placed into a body site that has a recognized core or near-core body temperature, such as the pulmonary artery, distal esophagus, urinary bladder, or tympanic membrane. Alternatively, reference temperatures may be obtained from such traditional temperature measurement sites as oral cavity or rectum.

X1.4.2.2 Core body temperature is generally considered to be the temperature of the blood in the heart and the brain (10). However, "core" is more a concept than a practical body site. In the same patient, temperatures measured from different "core" areas may vary noticeably. Probably the temperature of the blood perfusing the pre-optic region of the hypothalamus should be considered the body's ultimate core temperature. Unfortunately, the hypothalamus is not easily accessible for temperature measurement. Hence, pulmonary artery, distal esophageal, urinary bladder, tympanic, or even rectal temperatures⁶ are often used for a thermal definition of core, with pulmonary artery temperature considered the "gold standard" (10).

X1.4.2.3 To obtain a core temperature, insertion of an invasive catheter is required. Often, this may not be justified outside of operating rooms or critical care units. Tympanic contact temperature measurements are considered less invasive and whenever possible should be used for the core reference purpose.

X1.4.2.4 An IR thermometer should have at least one adjusted mode in which temperature is displayed by adjusting the direct measurement from the ear canal with respect to a selected reference core or non-core body site. Some IR thermometers may have more than one mode which are adjusted to different body sites. For instance, mode *C* is adjusted to core, mode *O* adjusted to oral, etc., Whenever these display modes are available, the clinical accuracy of the IR thermometer should be also evaluated while using the corresponding body sites for measuring reference temperatures. That is, for the oral adjusted mode, the reference thermometer shall be placed in the either sublingual pocket of the subject, and for the rectal adjusted mode, the reference probe shall be placed in the subject's rectum.

X1.4.2.5 This specification classifies all IR thermometers into two types, depending on the measurements site: ear canal type and skin type. In turn, the ear canal (or ear, for short) IR thermometers may have one or more operating (display) modes. These modes allow to output temperature readings whose numerical values are adjusted to represent specific, for a given mode, body site temperatures. For example, "oral mode" puts on a display not the ear canal temperature, but rather an adjusted temperature which is an estimate of a



NOTE 1—Arrows point toward warmer sites.

FIG. X1.5 Physiological Offsets

subject's sublingual temperature. To arrive to such an estimate, a specific offset (see below) was derived by a manufacturer by comparing the ear canal and a reference body site (in the above example, the oral sublingual) temperatures.

X1.4.3 Offsets:

X1.4.3.1 *Physiological Site Offset*—Traditional body sites that are routinely used by medical professionals and the general public to assess human temperatures provide readings that are different from core temperatures. A body site temperature t_b (for instance, oral or rectal) may be either lower or higher than temperature t_c measured from the core. For example, typical oral temperatures average 0.4 °C and axillary temperatures 0.7° lower than simultaneously measured pulmonary artery temperature (12,13). The temperature difference between the core and another selected body site is called the physiological site offset (14,15) (see Fig. X1.5):

$$\mu_p = t_c - t_b \quad (\text{X1.4})$$

where: t_b represents rectal t_{br} , oral t_{bm} , or axillary t_{ba} temperatures taken by contact equilibrium thermometers⁷ and the respective physiological offsets are μ_{pr} , μ_{pm} , and μ_{pa} .

X1.4.3.2 A physiological site offset is specific for a subject under certain conditions. It may depend on age and size of the subject, ailments, physical activities, and many other factors, but does not depend on the instruments employed for temperature measurements. In spite of its variability, it is possible to define the physiological offset for a limited population of subjects by averaging the individual physiological offsets:

$$\mu_p = \bar{t}_c - \bar{t}_b \quad (\text{X1.5})$$

from a selected group of subjects:

$\bar{t}_c$ = average core temperature
 $\bar{t}_b$ = average body site temperature

X1.4.3.3 When temperatures are measured from the recognized core sites (pulmonary artery, distal esophagus, urinary bladder, or tympanic membrane) the physiological offset is equal to zero by definition (see Eq X1.5), since in this case $\bar{t}_b = \bar{t}_c$.

⁶ At least in adults, rectal temperatures may lag behind the rapid changes in core temperature (11).

⁷ Contact predictive thermometers are not recommended for the purpose of evaluating physiological offsets, as they are generally less accurate.

X1.4.3.4 Instrumentational Offset—A signal detected by an IR sensor depends not only on its own and the subject's true temperatures, but also on size and shape of the probe, its field of view, ambient temperature, and operator technique. As a result, IR thermometers of different types or models may register different temperatures when measuring IR radiation from the same ear.

X1.4.3.5 The difference between core temperature registered by a contact thermometer and temperature registered by an IR ear canal thermometer in an unadjusted mode is called the instrumentational offset (Fig. X1.6). The ear canal temperature is integrated over the field of view of a particular IR thermometer (Fig. X1.4). Contrary to a physiological offset, the value of the instrumentational offset directly relates to the design of the optical probe and shape of the auditory canals of a selected group of patients used to determine the offset. The instrumentational offset is specific for the type or model of an IR thermometer but also may depend on the size of a patient (16,17) and other factors. For this reason, the instrumentational offset should be verified separately for different age groups.

X1.4.3.6 The instrumentational offset is defined as:

$$\mu_d = \bar{t}_c - \bar{t}_{ec} \quad (\text{X1.6})$$

where: $\bar{t}_{ec}$ is the average ear canal temperature of the selected group of subjects.

X1.4.3.7 Because the instrumentational offset depends on IR thermometer design and, therefore, is model-specific, each manufacturer should establish the specific instrumentational offset for its IR thermometer and, if required, make it selectable for different age groups.

X1.4.3.8 The instrumentational offset to some extent may be controlled by a proper design.

X1.4.3.9 Combined Site Offset—When measuring temperature by an IR thermometer one usually deals with two offsets—physiological and instrumentational, where the former relates to the subject of measurement and the latter to the instrument and its interface with the subject.

X1.4.3.10 The combined site offset can be defined as a combination of the instrumentational and physiological offsets, or the difference between the average temperatures of a body site $\bar{t}_b$ and the ear canal $\bar{t}_{ec}$:

$$\mu_s = \mu_d - \mu_p = \bar{t}_b - \bar{t}_{ec} \quad (\text{X1.7})$$

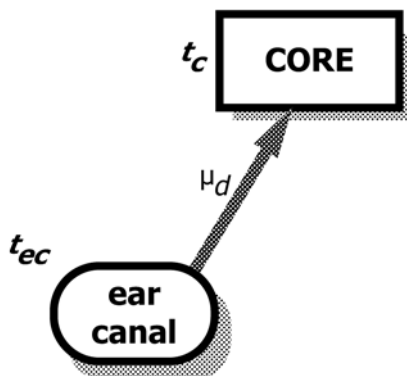


FIG. X1.6 Instrumentational Offset Specific for a Type or Model of an IR Thermometer

X1.4.3.11 It should be clearly recognized that value of $\bar{t}_{ec}$ is a temperature of the ear canal averaged (integrated) over both its surface area within the IR thermometer field of view (Fig. X1.4) and over the selected population of subjects. Unadjusted ear canal temperature $\bar{t}_{ec}$ is measured by a noncontact IR thermometer. Contrary, the value of $\bar{t}_b$ represents the temperature averaged over a group of subjects whose temperatures were measured by contact probes placed into the selected body sites.

X1.4.3.12 The combined site offsets could be added to the unadjusted ear canal temperature t_{ec} of a subject to display, the estimated body site temperatures t_b , such as oral or rectal.

X1.4.3.13 Fig. X1.7 shows the relationship between the physiological, instrumentational, and combined site offsets, where the reference temperature is the core temperature t_c . In most cases, unadjusted temperature t_{ec} of the ear canal, as measured by an IR thermometer, is lower than that of the core t_c . In the diagram, arrows point toward warmer sites.

X1.4.3.14 Core temperature can be estimated and displayed by an IR thermometer by adding the instrumentational offset to the ear canal temperature reading. The noncore body sites, such as oral, rectal, or axillary, would require use of the combined site offsets.

X1.4.3.15 Determination of the internal body temperature is the ultimate goal of medical thermometry, in displaying the temperature. Therefore, the IR thermometer manufacturers should use the appropriate offsets specific for particular IR thermometers and patient age groups, and should refrain from displaying unadjusted ear canal temperature.

X1.4.3.16 For example, under normal conditions, an ear canal type IR thermometer outputs temperature that is adjusted to oral temperature t_{bm} . The displayed temperature t_{bm} can be calculated from Eq X1.7 modified for the individual measurement:

$$t_{bm} = t_{ec} + \mu_{sm} \quad (\text{X1.8})$$

X1.4.3.17 Any ear canal type IR thermometer that is not capable of measuring and displaying true tympanic temperature, t_{ty} , should not be called a “tympanic thermometer.” A more appropriate name is an “infrared ear thermometer.”

X1.4.3.18 Skin Temperature Measurement—Skin temperature measurement technically is similar to that from the ear canal, but with two significant differences. The first is that the skin emissivity may vary from site to site in the range from 0.94 to 0.99 (18), while emissivity of an auditory canal may be considered equal to unity (14). The other difference is the field of view, that in some thermometers may be quite wide. To prevent spurious readings, the instrument design should ensure that infrared radiation is collected from a limited specified area of the skin surface, avoiding any stray thermal radiation from neighboring tissues and objects having different surface temperatures. Thus, contrary to an IR ear thermometer, an IR thermometer for skin measurements should have means to compensate for skin emissivity and for defining the area of measurement.

X1.4.3.19 Probe Covers—Because a medical IR thermometer is used in direct contact with patient tissues, it is imperative to protect the instrument from becoming a carrier of

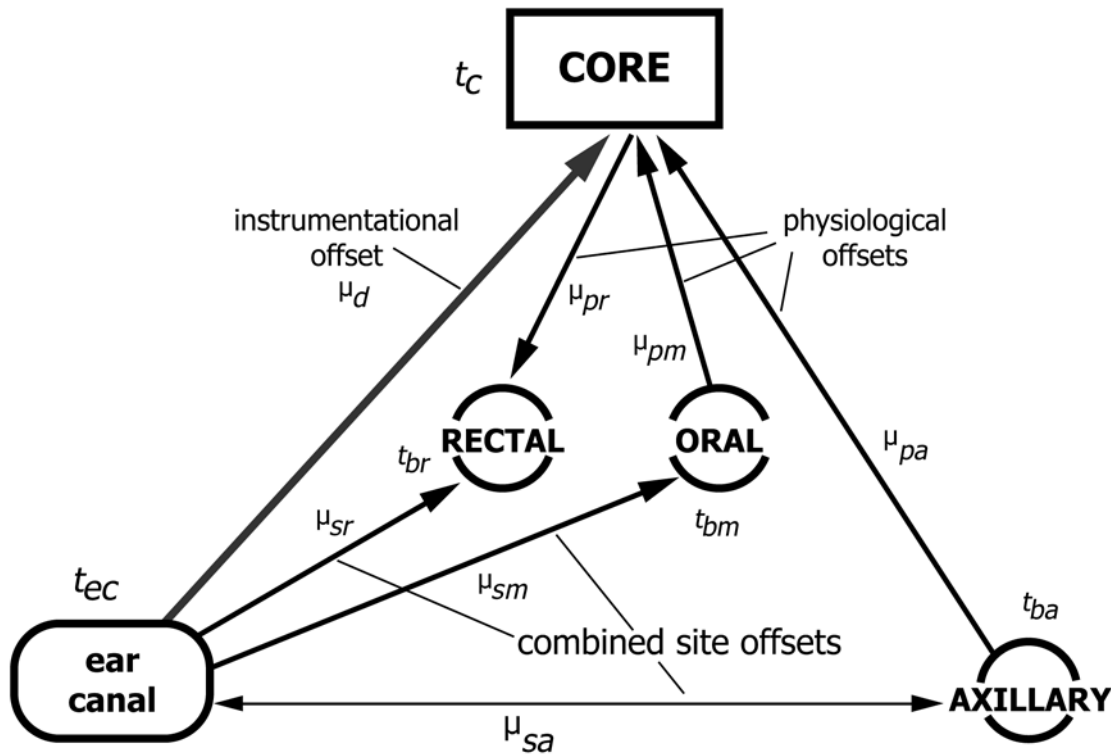


FIG. X1.7 Combined Site Offset is a Scalar Difference Between Instrumentational and Physiological Offsets

soiling compounds and a transmitter of infection from one patient to another (cross-contamination) or even from re-infecting the same patient (recontamination). Thus, any part of a thermometer that may come into contact with patient tissues shall be either protected by a cover or easily cleanable. Any disposable or reusable protective cover placed over the optical probe becomes an attenuator of the net infrared signal and, therefore, may alter the temperature reading. In effect, the probe cover becomes a part of the measurement system (see

Fig. X1.2). This demands that covers be produced with tolerances that allow meeting these specifications by an entire system, which includes both the IR thermometer and the probe cover. Evaluation of an IR thermometer accuracy always shall be made with a probe cover in place (if applicable). A new probe cover shall be used for each temperature measurement with devices whenever such covers are labeled or implied as disposable.

X2. ACCURACY EXPLANATIONS

X2.1 General Notes:

X2.1.1 In general terms, accuracy may be defined as the ability of an IR thermometer to give a response close to the true temperature of the object of measurement. The true temperature shall be measured at a specific location by a reference contact thermometer. Under laboratory conditions, the true temperature is referred to as that of a blackbody. While measuring temperature from a patient, the true temperature is referred to as that of the interior of the human body.

X2.1.2 Performance of an IR thermometer may depend on its coupling with the measured site. Therefore, this specification addresses two types of accuracy, laboratory and clinical. Accuracies are specified in terms of laboratory error and clinical errors for an entire measurement system that generally may include an infrared thermometer and a probe cover. The probe covers may be either reusable or disposable. That is, every time a temperature is measured, the system may include a new probe cover, whose optical and thermal properties

generally differ somewhat from other similar covers used in previous measurements.

X2.1.3 The statistical methodology employed in this specification contends with the fact that the distributions of either laboratory error or clinical bias are generally non-symmetrical. The location of a symmetrical distribution is well defined since the mean value equals the median and equals the center of symmetry. This is not the case for a non-symmetrical distribution—the mean and median are different and there is no center of symmetry. Therefore, the statistical methodology employed by this specification addresses these concerns.

X2.2 Laboratory Error:

X2.2.1 Laboratory error shows how much the system's internal noise, drifts, and manufacturing tolerances, along with other uncertainties in temperature measurement, may affect closeness between the measured temperature and that of a

blackbody when an IR thermometer operates under various conditions of ambient temperature and humidity.

X2.2.2 By taking six measurements, in each of three blackbody settings, at five different ambient temperature and humidity combinations (see 6.1), a total of 90 error measurements are accumulated. From a statistical viewpoint, it is desirable to obtain a level of confidence that future measurements will yield similar results. A one-sided, distribution-free confidence interval is examined during the laboratory testing. A sample-size of 90 measurements, with no single measurement error exceeding the allowable limit, provides a confidence of 99 % that at least 95 % of all measurements will meet the acceptance criteria (Table A.18 in Ref (19)).

X2.2.3 The laboratory tests are performed in all display modes and readings are modified to obtain values of unadjusted temperatures. It is the responsibility of the manufacturer to provide on request the method of such a modification.

X2.2.3.1 *Example*—The ear type IR thermometer under test is evaluated in oral mode. A manufacturer, in the service manual, specifies that for given conditions of ambient temperature and humidity the combined site oral offset $\mu_{sm}=0.55\text{ }^{\circ}\text{C}$. A manufacturer supplied blackbody is used for the evaluation. It is the same type of a blackbody which was used for calibration of the IR thermometer under test. Hence, no correction for the blackbody emissivity is required.

X2.2.3.2 When the temperature of a blackbody having $t_{BB}=37.03\text{ }^{\circ}\text{C}$ is measured, the IR thermometer's display in oral mode with a particular probe cover attached shows $t_{ej}=37.7\text{ }^{\circ}\text{C}$. The unadjusted value of the measured temperature may be calculated as:

$$t_j = t_{ej} - \mu_{sm} = 37.70 - 0.55 = 37.15\text{ }^{\circ}\text{C} \quad (\text{X2.1})$$

Then, according to Eq 1 in 6.1.4.4, that particular measurement was made with an error:

$$\delta_j = |t_j - t_{BB}| = |37.15 - 37.03| = 0.12\text{ }^{\circ}\text{C}$$

X2.2.3.3 To calculate laboratory error, a minimum of six such measurements shall be performed at each of five conditions of ambient temperature and humidity (see Table 1). Thus, at each blackbody temperature setting, at least 30 errors must be obtained for all combinations of operating temperature and humidity.

NOTE X2.1—Each environmental condition may require use of a specific combined site offset μ_{sm} , if so specified by the manufacturer.

X2.2.3.4 The highest value of δ_j from the error set shall be selected and used as a measure of laboratory error at that particular blackbody setting.

X2.2.3.5 In this example, for a blackbody setting near $37\text{ }^{\circ}\text{C}$, a total of 30 measurements have been made at all five required combinations of operating temperatures and humidities and the highest value of an error was found $\delta_{jmax}=|-0.17|\text{ }^{\circ}\text{C}=0.17\text{ }^{\circ}\text{C}$. Therefore, the IR thermometer under test meets part of the requirement of 5.3 since that paragraph specifies that for a blackbody in the range of $37\text{ }^{\circ}\text{C}$, the highest permissible error shall be no more than $0.2\text{ }^{\circ}\text{C}$. The test shall be performed for two other blackbody settings: near $35\text{ }^{\circ}\text{C}$ and near $41\text{ }^{\circ}\text{C}$, at which the highest permissible error is $0.3\text{ }^{\circ}\text{C}$. Therefore, a total of at least 90 measurements with an IR

thermometer shall be performed to evaluate its compliance with the requirements for the laboratory error.

NOTE X2.2—Numbers in the example are provided for the purpose of illustration only and do not represent any particular IR thermometer.

X2.3 Clinical Accuracy:

X2.3.1 Clinical Accuracy Explanations:

X2.3.1.1 This specification recommends that a manufacturer determines two kinds of errors that represent clinical accuracy: clinical bias with stated uncertainty, and clinical repeatability. These characteristics may be evaluated from the same data set: multiple measurements of ear temperatures and actual reference temperature on a selected number of febrile and afebrile subjects in all applicable age groups. Use of power analysis and random sampling are recommended to ensure that the number of subjects in each group is sufficiently large to minimize the effects of random components of the measurement error. For example, paragraph 19.3 on Bias in Practice E177 recommends 30 or more test subjects.

X2.3.1.2 As a guideline, this specification recommends division of all subjects into three age groups, namely: (1) infants—newborn to one year; (2) children—greater than one to five years; and (3) adults—greater than five years old.

X2.3.2 Clinical Bias and its Uncertainty:

X2.3.2.1 Clinical bias ($\bar{x}_d$) specifies an average (mean) difference between temperatures as measured by the ear canal IR thermometer under test operating in all adjusted modes and temperatures of subjects, from a selected group, as measured by contact thermometers positioned in a selected body reference site. Clinical bias is the systematic distortion of a statistical result (20).

X2.3.2.2 It should be clearly understood that clinical bias is a mean value of a set of individual clinical biases obtained from a representative group of patients. As opposed to laboratory error that is a maximum deviation of readings, clinical bias is an average value of individual errors.

X2.3.2.3 The clinical bias for each display mode defines closeness between the measured temperature and that of the reference body site for a specified age group of patients. It is a measure of the validity of the instrumental or combined offsets, or both, built into the IR thermometer. The value of clinical bias should be accompanied by a statement of uncertainty, which has a meaning of one standard deviation and generally is calculated as root-sum-of-squares (RSS) of standard deviation of data and other uncertainty components. Acceptable methods of evaluation of uncertainty are described elsewhere (21,22).

X2.3.2.4 To evaluate clinical bias, at least two measurements should be taken from each subject in a test group. One reading should be taken from an ear canal by an IR ear thermometer under test, and the other should be taken by a reference contact thermometer.

X2.3.2.5 To determine clinical bias ($\bar{x}_d$), a mean value of ear-to-reference differences for all subjects in the test group should be calculated.

X2.3.3 Clinical Repeatability:

X2.3.3.1 Clinical repeatability shows how consistently an ear canal IR thermometer measures temperature from the same

patient when used by the same operator. The repeatability test requires taking several readings from the same patient under the same conditions and comparing these readings with each other. This standard requires that three readings are taken. A reasonable pause between measurements may be required because placement of the IR probe into an ear canal may affect the ear canal surface temperature. A low thermal conductivity of skin prevents a fast surface rewarming. A too short interval between the measurements may compromise the measured value of clinical repeatability. The highest possible rate of taking temperatures from an ear canal should be recommended by the manufacturer.

X2.3.3.2 It is recognized that small variations in ear canal temperature may occur naturally during the time of the test. These variations should be considered as part of clinical repeatability.

X2.3.3.3 For the purpose of determining clinical repeatability, three sequential IR readings should be taken in the same ear of each subject by the same operator. to determine clinical repeatability s_r , three temperature deviations D_{ij} for each subject should be calculated:

$$D_{1j} = t_{e2j} - t_{e1j} \quad (\text{X2.2})$$

$$D_{2j} = t_{e3j} - t_{e2j}$$

$$D_{3j} = t_{e1j} - t_{e3j}$$

where: t_{e1j} , t_{e2j} , and t_{e3j} are the first, second, and third IR temperature readings from the same ear canal of a subject numbered j .

X2.3.3.4 The following formula should be used to calculate the pooled standard deviation s_r of all D_{ij} for all N tested subjects:

$$s_r = \sqrt{\frac{\sum_{i=1}^N (D_{1j}^2 + D_{2j}^2 + D_{3j}^2)}{6N}} \quad (\text{X2.3})$$

where the value of s_r is the measure of clinical repeatability.

X2.3.3.5 Three readings from the same ear are required to calculate three temperature deviations D_{ij} . Since the total number of subjects in a group is N the entire data set includes $n = 3N$ measurements. These numbers represent consistency of multiple readings with respect to one another, regardless of the actual temperatures of subjects or the display mode of the IR thermometer. The measure of the clinical repeatability is the pooled standard deviation of these n numbers.

X2.3.4 Example of Tests for Clinical Accuracy:

X2.3.4.1 Two types of thermometers are used in the tests: an IR thermometer (the device under test) and a contact reference thermometer of electronic type adapted for measuring temperature from a selected reference site—pulmonary artery, distal esophagus, urinary bladder, or tympanic membrane for core, or rectal and oral thermometers for the non-core body sites.

X2.3.4.2 The method of taking temperatures with both IR and reference thermometers shall be in full compliance with the recommendation of their respective manufacturers.

X2.3.4.3 Before or after the tests, laboratory accuracy of the reference thermometer should be verified in a stirred water bath. The water bath should have a volume of 1 L (1 qt) or

greater and temperature stability within $\pm 0.02^\circ\text{C}$ ($\pm 0.04^\circ\text{F}$). True temperature of water should be monitored with an uncertainty no greater than $\pm 0.03^\circ\text{C}$ ($\pm 0.05^\circ\text{F}$) by an immersed contact thermometer with calibration traceable to a national physical standard of temperature. Laboratory accuracy of an IR thermometer under test should be verified in a water-immersed blackbody (see Annex A1) or in the manufacturer recommended blackbody if such a blackbody was used for the device calibration. During data processing, the clinical data should be corrected for calibration inaccuracy, if any, of the IR or reference thermometers, or both.

X2.3.4.4 The tests should be performed separately on the age groups of subjects that are considered as prospective subjects whose temperature would be measured by the IR ear thermometer. Sufficient number of both febrile and afebrile subjects should be tested.

NOTE X2.3.—For the purpose of these tests, fever is defined as core temperature of 38.0°C (100.4°F) or higher.

X2.3.4.5 It should be noted that values characterizing clinical accuracy are functions of both the IR and reference temperatures and may be significantly affected by stability of the reference temperature measurement. Clinical studies have shown that although the mean offset or clinical bias may be correct for a given thermometer, readings which differ from the reference by more than 1°C may exist (23). This may be caused by physiological factors, such as lagging of the rectal reference site (if that site is used as a reference) behind the true core temperature, rather than inaccuracies in the IR thermometer. Other studies also exist that question the accuracy of IR thermometers of various brands (24, 25).

X2.3.4.6 Example for Clinical Bias—An IR thermometer was tested with subjects of various ages. The operating mode was labeled by a manufacturer as adjusted to core temperature. The manufacturer specified in the instruction manual that its IR thermometer can be used on all subjects regardless of age.

X2.3.4.7 For the purpose of evaluation of clinical bias, all subjects were divided into three age groups: from zero to one year of age (infants), older than one to five (children), and older than five (adults).

X2.3.4.8 Subjects with certain characteristics were excluded from the test: external ear inflammation, auditory canal obstruction (anatomic or foreign material), use of medications known to affect body temperature (for example, antipyretics, barbiturates, thyroid preparations, antipsychotics, etc.) within 3 h of the test, or immunization within seven days of the test.

X2.3.4.9 The test was performed at ambient temperatures within the range of 20 to 28°C (68 to 82°F) and the relative humidity from 40 to 70% . Reference temperatures were taken by a contact tympanic probe positioned on the left tympanum of an anesthetized subject. The IR reading were taken of the right ear canal by the IR ear thermometer under test. Within each age group both afebrile and febrile subjects (tympanic temperature of 38°C or higher) were represented by nearly equal numbers (see Table X2.1).

X2.3.4.10 Uncertainty of bias was estimated as RSS of a standard deviation of IR measurements and anticipated uncertainties in calibration of the reference and IR thermometers. Evaluation of $\bar{x}_d$ for Group I indicates that clinical bias is equal

TABLE X2.1 Examples of Comparative Temperature Measurements by IR (t_{e1}) and Reference (t_{c1}) Thermometers of Subjects of Three Age Groups

NOTE 1—The difference between ear and reference readings is Δt_j .

Group I (Infants)				Group II (Children)				Group III (Adults)			
j	t_{e1}	t_{c1}	Δt_j	j	t_{e1}	t_{c1}	Δt_j	j	t_{e1}	t_{c1}	Δt_j
1	37.4	37.65	−0.25	1	36.1	35.90	0.20	1	38.8	38.63	0.17
2	37.4	38.53	−1.13	2	37.3	37.45	−0.15	2	37.3	37.32	−0.02
29	36.8	36.92	−0.12	29	37.1	37.51	−0.41	29	37.1	37.26	−0.16
30	36.9	36.64	0.26	30	38.1	38.04	0.06	...	...	...	...
...	...	...	...	31	37.9	38.05	−0.15	...	...	...	...
$N=30$ $\bar{x}_d$ −0.25				$N=31$ $\bar{x}_d$ −0.16				$N=29$ $\bar{x}_d$ 0.11			
... uncertainty ± 0.35				... uncertainty ± 0.18				... uncertainty ± 0.21			

to -0.25°C with uncertainty of $\pm 0.35^\circ\text{C}$ which is indicative of a wide range for difference between the IR thermometer reading and reference temperature. Although this specification does not set limits for clinical bias, the wide uncertainty range for the bias appears excessively large, indicating that the IR thermometer under test may not be sufficiently accurate for use on infants since errors in temperature measurements may be clinically significant. Therefore, the instrument should be appropriately labeled to restrict its use with such subjects.

X2.3.4.11 Clinical biases and uncertainties for Groups II and III are sufficiently small which is an indication that the IR thermometer under test can be used reliably with these age groups.

NOTE X2.4—Numbers in the example are provided for the purpose of illustration only and do not represent any particular IR thermometer.

X2.3.4.12 *Example for Clinical Repeatability*—In Group II (of example X2.3.4.2), three ear canal temperatures taken from a subject number j by an ear type IR thermometer resulted in the following readings:

$$t_{e1j} = 38.7^\circ\text{C}, t_{e2j} = 38.5^\circ\text{C}, t_{e3j} = 38.6^\circ\text{C}$$

X2.3.4.13 The corresponding temperature deviations are calculated according to Eq X2.3.

$$D_{1j} = 38.5 - 38.7 = -0.2$$

$$D_{2j} = 38.6 - 38.5 = 0.1$$

$$D_{3j} = 38.7 - 38.6 = 0.1$$

Errors from all $N=31$ subjects of the test group were used in the calculation of clinical repeatability according to Eq X2.3 and produced value of $s_r=0.15$, that may be considered reasonably small and not to pose a problem for diagnostic purposes.

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