Designation: E 1965 – 98 (Reapproved 2003)

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

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

1. Scope

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

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

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

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

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

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

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

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

2. Referenced Documents

2.1 *ASTM Standards:*

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

E 344 Terminology Relating to Thermometry and Hydrometry[5]

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

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

2.2 *International Electrotechnical Commission Standards:*

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

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

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

2.3 *Other Standards:*

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

3. Terminology

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

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

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

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

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

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

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

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

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

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

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

3.2.4 *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.

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

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

3.2.7 *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.

3.2.8 *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.

3.2.9 *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.

3.2.10 *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.

3.2.11 *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.

3.2.12 *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.

3.2.13 *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.*

3.2.14 *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.).

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

3.2.16 *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).

3.2.17 *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.

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

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

3.2.20 *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.*

3.2.21 *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.

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

3.2.23 *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.

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

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

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

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

3.2.28 *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.*

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

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

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

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

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

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

3.2.35 *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.

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

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

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

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

3.2.40 *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 3.2.8.

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.

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

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 ensurance 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 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 ± 1°C (± 2 °F) from the following temperatures: 23, 30, and 38 °C (73, 86, and 100 °F)

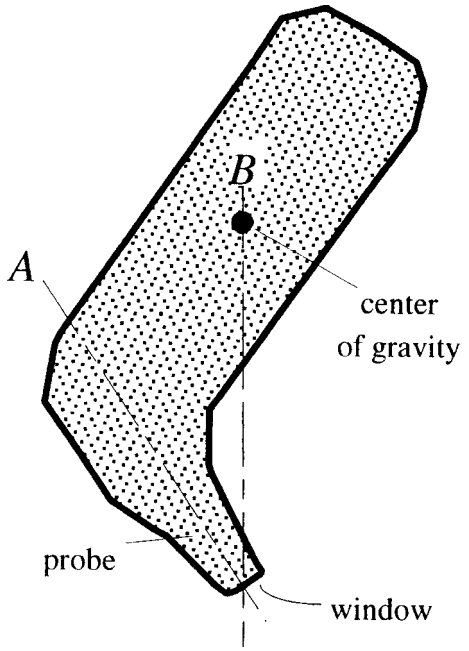
6.1.5.2 The greatest calculated error δ_j from all data sets shall conform with requirements set forth in 5.4.

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 instrumentational 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.



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

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/m^3) 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 ± 0.5 ° C (± 1 °F) from 37 °C (98.6 °F), at ambient temperature in the range from 20 to 26 °C (68 to 79 °F) and relative humidity in the range from 40 to 70 %. A total of at least five 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 (E 1965-98). 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.