Designation: E 1112 – 00

Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature[1]

This standard is issued under the fixed designation E 1112; 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 monitoring of patient temperatures.

1.2 This specification does not cover infrared thermometers. Specification E 1965 covers specifications for IR thermometers.

1.3 The values stated in SI units are to be regarded as the standard.

1.4 The following precautionary caveat pertains only to the test method portion, Section 5, 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 users of this standard to consult and establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*

E 344 Terminology Relating to Thermometry and Hydrometry[2]

E 1104 Specification for Clinical Thermometer, Probe Covers and Sheaths[2]

E 1965 Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature[2]

2.2 *Underwriters Laboratory Standards:*[3]

UL 544 Standards for safety, medical and dental equipment

UL 913 Standards for safety, intrinsically safe electrical circuits and equipment for use in hazardous location

2.3 *U.S. Pharmacopeia:*[4]

USP Latest Issue Biological Test

2.4 *Federal Regulations:*[5]

CFR Part 87 Establishment Registration and Premarket Notification Procedure

3. Terminology

3.1 *Definitions:*

3.1.1 The definitions given in Terminology E 344 shall apply to this standard.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *battery charger*, *n*—an electrical circuit designed to restore the electrical potential of a battery.

3.2.2 *distributor*, *n*—any person who furthers the marketing of a device from the original manufacturer to the person who makes final delivery or sale to the ultimate consumer or user but who does not repackage or otherwise change the container, wrapper, or labeling of the device or device package.

3.2.3 *electronic thermometer*, *n*—an instrument that provides a display of temperature sensed through the use of a transducer and electronic circuitry.

3.2.4 *manufacturer*, *n*—any person, including any repacker or relabeler, or both, who manufactures, fabricates, assembles, or reprocesses a finished device. (See "Good Manufacturing Practices," Part 807 Code of Federal Regulations 6.)

3.2.5 *measurement time*, *n*—that time required from the time of patient contact to display of temperature to within the stated accuracy.

3.2.6 *predictive thermometer*, *n*—one that provides an indication of the final stabilized temperature of the measurement site in advance of the time necessary for the transducer to reach a stabilized temperature.

3.2.7 *probe*, *n*—an assembly, including the transducer, that is used to position the transducer in the specific location at which the temperature is to be determined.

3.2.8 *probe cover and sheath*, *n*—a device provided for the purpose of preventing biological contact between the patient and probe (see Specification E 1104).

3.2.9 *IR thermometer*, *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).

3.2.10 *transducer*, *n*—a device that provides a measurable output (for example, resistance, emf, etc.) as a function of temperature.

4. Requirements

4.1 *Temperature range*—As a minimum, the instrument shall display temperature over the following range: 35.5 to 41.0 °C (96.0 to 106.0 °F).

[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.

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

[3] Available from Underwriters Laboratories Inc., 1655 Scott Blvd., Santa Clara, CA 92050.

[4] Available from United States Pharmacopeia Convention, Inc.; 12601 Twinbrook Parkway, Rockville MD 20852.

[5] Available from Superintendent of Documents, U. S. Government Printing Office, Washington, DC 20402.

4.2 *Accuracy*—Within the manufacturer's specified temperature range for patient temperature measurement, no individual reading shall be in error by more than the values shown in Table 1.

4.3 *Environment*:

4.3.1 *Operating Environment*—The instrument must meet the accuracy requirements of 4.2 when operated in an environment of 16 to 40 °C (60.8 to 104 °F) and a relative humidity of 15 to 95 % noncondensing.

4.3.2 *Storage Environment*—The instrument shall meet the requirements of 4.2 after having been stored or transported, or both, at any point in an environment of −20 to 50 °C (−4 to 120 °F), and a relative humidity of 15 to 95 %, noncondensing, for a period of one month.

4.3.3 *Labeling*—The instruction manual shall include a statement that informs the user if the performance of the device may be degraded should one or more of the following occur:

4.3.3.1 Operation outside the manufacturer's stated temperature and humidity range.

4.3.3.2 Storage outside the manufacturer's stated temperature and humidity range.

4.3.3.3 Mechanical shock (for example, drop test).

4.3.3.4 Patient temperature is below ambient temperature (operating environment see 4.3.1).

4.4 *Resolution*:

4.4.1 *Analog Display*:

4.4.1.1 *Celsius Graduations*—Celsius display thermometers shall be graduated in intervals of not greater than 0.1 °C. All full-degree graduations shall be long time. Half-degree graduations may be long lines. All other graduations shall be short lines (see 4.4.1.3). As a minimum, appropriate numerals shall be at every full-degree graduation except the numeral 37, which is optional (see 4.4.1.5). Graduation lines shall be spaced at least 0.50 mm (0.02 in.) center to center.

4.4.1.2 *Fahrenheit Graduations*—Fahrenheit display thermometers shall be graduated in intervals of not greater than 0.2 °F. All full-degree graduations shall be long lines (see 4.4.1.3 and 4.4.1.5). Half-degree graduations may be long lines. All other graduations shall be short lines. Appropriate numerals shall be placed as a minimum at every even degree graduation. Graduation lines shall be spaced at least 0.55 mm (0.022 in.) center to center.

4.4.1.3 *Scales Graduation Marks*—All short graduation lines shall not be less than 1.3 mm (0.05 in.) in length. All long graduation lines shall be no less than 25 % longer than the short lines. The lines shall be essentially straight and in line with the pointer. They shall not be wider than the spaces between the graduations, nor wider than 0.45 mm (0.018 in.) and shall not be narrower than 0.10 mm (0.004 in.).

TABLE 1 Maximum Error Temperature Ranges

Temperature	Maximum Error
Celsius Scale:	
Less than 35.8°C	±0.3°C
35.8°C to less than 37°C	±0.2°C
37.0°C to 39.0°C	±0.1°C
Greater than 39.0°C to 41.0°C	±0.2°C
Greater than 41.0°C	±0.3°C
Fahrenheit Scale:	
Less than 96.4°F	±0.5°F
96.4°F to less than 98.0°F	±0.3°F
98.0°F to 102.0°F	±0.2°F
Greater than 102.0°F to 106.0°F	±0.3°F
Greater than 106.0°F	±0.5°F

4.4.1.4 *Pointer Width*—The pointer shall have a maximum width of one-half of the spacing between graduation marks (see 4.4.1.1 or 4.4.1.2).

4.4.1.5 *Reference Marking*—The line at 37 °C (98.6 °F) may be designated by an arrow or other suitable mark. If a reference mark is used, the position shall be within a tolerance of one-half of the minimum graduated interval.

4.4.2 *Digital Display*:

4.4.2.1 *Resolution*—The digital display shall have incremental steps of not more than 0.1 °C or 0.1 °F.

4.4.2.2 *Readability*—At the outside surface of the instrument, the numerals shall appear to be at least 2.5 mm (0.1 in.) high and 1.5 mm (0.059 in.) wide and appear to be separated from one another by a space of at least 0.7 mm (0.027 in.).

4.5 *Battery Condition*—When battery operated, the instrument accuracy and condition shall not be affected by battery condition unless a continuous automatic indication of unreliable condition is provided. The indication of unreliable condition must be presented until the battery condition is corrected. When an instrument uses a rechargeable battery, a position indication shall be provided with the instrument system to indicate that the battery is charging.

4.6 *Construction*:

4.6.1 *Electrical*—The instrument and accessories (such as battery chargers) shall meet the electrical safety requirements of UL 544 (see 5.3).

4.6.2 *Material*:

4.6.2.1 *Case Material*—The case material of the instrument and nondisposable accessories shall withstand biological and physical cleaning without performance degradation (see 5.2). It shall also withstand dropping without presenting an electrical safety hazard.

4.6.2.2 *Patient Contact Materials*—Those parts of the electronic thermometer system intended for contact with anatomical sites for the purpose of temperature measurement as specified by the manufacturer shall be nontoxic (see 5.3).

4.7 *Marking*—All markings for purposes of identification or instruction must be clear and legible. Deterioration shall not occur when subjected to cleaning (see 5.2).

4.7.1 *Instrument Marking*—The instrument shall be marked with the manufacturer's or distributor's name, model designation, serial number or lot number (to indicate the specific period, not to exceed 90 days, in which the thermometer was calibrated) and temperature scale, Celsius or Fahrenheit. Celsius or Fahrenheit may be abbreviated.

4.7.2 *Probe Marking*—Detachable reusable probes shall be marked with at least the manufacturer's or distributor's name or identification and serial or lot number.

4.7.3 *Operating Instructions*—Operating instructions shall be provided on the instrument. When space requirements dictate, the operating instructions on the instrument may be brief if detailed operating instruction are also provided.

4.7.4 *Care and Use Instructions*—Instructions for the care, use, and biological and physical cleaning of the instrument shall be provided. Proper use and application of special

attachments, such as oral or rectal probes and probe covers, shall be indicated. The manufacturer shall provide instructions to decontaminate, following each use, any patient contact component not intended for single use.

4.7.5 *Health and Safety Hazard Marking*— Notices shall be displayed on the instrument if possible.

4.7.5.1 *Hazardous Environmental Safety Warning*—If the instrument or accessories (such as battery charger) do not meet the requirements of UL 913, a warning label, as defined in UL 544, shall be placed on the instrument or accessory.

4.7.6 *Identification*:

4.7.6.1 In order that purchasers may identify products conforming to all requirements of this specification, producers and distributors may include a statement of compliance in conjunction with their name and address on product labels, invoices, sales literature, and the like. The following statement is suggested when sufficient space is available: This thermometer conforms to all of the requirements established in ASTM Standard E 1112. Full responsibility for conformance of this product to the specification is assumed by (name and address of producer or distributor).

4.7.6.2 The following abbreviated statement is suggested when available space on labels is insufficient for the full statement: Conforms to ASTM E 1112 (name and address of producer or distributor).

4.8 *Documentation*:

4.8.1 *Detailed Instructions*—Detailed instructions for use shall be provided. These instructions shall contain sufficient detail to provide a means for training in the operation, application, care, and biological and physical cleaning of the instrument and accessories.

4.8.2 *Service and Repair Manual*—A service manual shall be made available if user repair is permitted by the manufacturer. The service manual shall provide theory of operation, maintenance information, test procedures, test equipment requirements, detailed diagrams, parts list, and specifications.

4.8.3 *Accuracy Determination*—Manufacturer shall make available specific instructions for test to determine the accuracy of the instrument, including the temperature probe. Manufacturers of predictive thermometers must specify corrections to compensate for the difference between in vivo and vitro conditions if required (see 5.4.2).

4.8.4 *Recalibration*—The manufacturer shall recommend a periodic recalibration cycle to ensure continuous performance to the requirements of 4.2. The manufacturer shall provide specific instructions for the adjustment of the instrument if user adjustment is permitted by the manufacturer. Test equipment or fixtures required for adjustment must either be described in sufficient detail to permit fabrication or purchase; or, manufacturer's equipment or fixtures must be made available to users.

4.8.5 *Detailed Specifications*—The manufacturer shall provide specifications of the instrument's temperature range (see 4.1), accuracy (see 4.2), and environment (see 4.3).

5. Performance Tests

5.1 *Significance and Use*—This section describes apparatus and procedures for verifying conformance to certain performance requirements of Section 4. These tests are not required of the manufacturer unless specified by the user. Verification procedures are not included for requirements that can be verified by observation or inspection, or where a standard procedure is not needed (such as the requirements of 4.4.1). The manufacturer shall certify that the product will comply with the requirements if tested in accordance with this section. With the exceptions of the potentially destructive tests, any single electronic thermometer shall be capable of undergoing the following tests in any sequence without impairment of performance.

5.2 *Cleaning Tests*—Perform the manufacturer's recommended biological and physical cleaning procedures a minimum of five times. This shall result in no significant discoloration, detriment to operation, nor degradation of electrical safety.

5.3 *Toxicity Test*—Test materials intended for patient contact in accordance with current issue of USP Biological Test-Plastic Container, Table 1 (Extract of sample in sodium chloride and extract of sample in vegetable oil).

5.4 *Accuracy Test*—Perform the following tests in accordance with manufacturer's user procedures for measuring human temperatures.

5.4.1 *Test Equipment*—The test equipment includes a well stirred constant temperature liquid bath, the temperature of which is accurately calibrated within 0.03 °C on the International Temperature Scale of 1990 as verified by a system whose calibration is traceable to The National Institute of Standards and Technology (NIST) or other appropriate national standards laboratory. The volume of the bath shall be no less than 1 L.

5.4.2 *Test Method*—Insert instrument probe and probe cover (if applicable) into liquid bath in accordance with manufacturer's procedures. Accuracy requirements of 4.2 shall be met. Manufacturers of predictive type thermometers must specify corrections for liquid bath techniques to compensate for the difference between in vivo and vitro conditions if required and must so state in the labeling.

5.5 *Equipment Required for Environmental Test*—A chamber having means for producing ambient temperature and relative humidity conditions described in 4.3 and having means for limiting the rate of change of temperature to a maximum of 10 °C (18 °F) per minute shall be used. The chamber shall be of sufficient size to enclose the instrument under test completely, including charger and probe, if any.

5.5.1 *Operating Environmental Tests*— Expose the instrument, including probe and charger, if any, to the limits of operating environmental conditions described in 4.3.1 allowing a minimum of four hours stabilizing time at each test condition before testing. Test in accordance with 5.5. Test conditions shall include but shall not be limited to the following:

5.5.1.1 *Operating Environmental Test Conditions* (see 4.3.1):

Condition 1	40°C, 15 % RH
Condition 2[A]	40°C, 80 % RH noncondensing
Condition 3	16°C, 40 % RH
Condition 4[A]	16°C, 95 % RH noncondensing

[A] **CAUTION:** To prevent condensation bring device to temperature prior to adding moisture to the chamber.

5.5.1.2 The rate of temperature change between test conditions shall be limited to a maximum of 10 °C (18 °F)/min to avoid thermal shock.

5.5.1.3 Temperatures and relative humidities stated for test conditions in this section have a tolerance of +2 °C and +5 % respectively.

5.5.2 *Storage Environment Test Conditions*—Expose the instrument including probe and charger, if any, to the limits of storage environment described in 4.3.2. Test conditions shall include but shall not be limited to the following:

5.5.2.1 *Storage Environment Test Conditions* (see 4.3.1):

Condition 1	−20°C, RH not applicable
Condition 2[A]	50°C, 15 % RH
Condition 3	35°C, 95 % RH noncondensing

[A] **CAUTION:** To prevent condensation, bring device to temperature prior to adding moisture to the chamber.

5.5.2.2 The rate of change of temperature between test conditions shall be limited to 10 °C (18 °F) per minute to avoid thermal shock. Maintain each test condition for the time duration described in 4.3.2. Remove from test conditions and packaging material and allow 24 h to stabilize to within the limits described in 4.3.1. Test in accordance with 5.5.

5.5.2.3 Temperatures and relative humidities stated for test conditions in this section have a tolerance of ± 2 °C and ± 5 % respectively.

5.6 *Precision and Bias*—All test equipment specified in 5.4.1 shall be sufficiently accurate so that test results produced with the equipment have an expanded uncertainty (k=3) not exceeding 0.045 °C.

6. Keywords

6.1 clinical thermometers; electronic thermometers; intermittent determination of patient temperature