Designation: E1112 – 00 (Reapproved 2018)

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

This standard is issued under the fixed designation E1112; 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 E1965 covers specifications for IR thermometers.

1.3 The values stated in either SI units or inch-pound units are to be regarded separately as standard. The values stated in each system may not be exact equivalents; therefore, each system shall be used independently of the other. Combining values from the two systems may result in non-conformance with 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 user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

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

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E344 Terminology Relating to Thermometry and Hydrometry

E1104 Specification for Clinical Thermometer Probe Covers and Sheaths

E1965 Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature

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 E344 shall apply to this specification.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *battery charger, n*—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*—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.

[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.

Current edition approved Oct. 1, 2018. Published November 2018. Originally approved in 1986. Last previous edition approved in 2011 as E1112 – 00(2011). DOI: 10.1520/E1112-00R18.

[2] 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] Available from Underwriters Laboratories (UL), 333 Pfingsten Rd., Northbrook, IL 60062-2096, http://www.ul.com.

[4] Available from U.S. Pharmacopeia (USP), 12601 Twinbrook Pkwy., Rockville, MD 20852-1790, http://www.usp.org.

[5] Available from U.S. Government Printing Office Superintendent of Documents, 732 N. Capitol St., NW, Mail Stop: SDE, Washington, DC 20401, http://www.access.gpo.gov.

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*—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*—device provided for the purpose of preventing biological contact between the patient and probe (see Specification E1104).

3.2.9 *IR thermometer, n*—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*—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].

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).

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

4.3.3.4 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.].

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