Designation: E1299 – 96 (Reapproved 2016)

Standard Specification for Reusable Phase-Change-Type Fever Thermometer for Intermittent Determination of Human Temperature[1]

This standard is issued under the fixed designation E1299; 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 reusable phase-change-type clinical thermometers.

1.2 The following safety hazards 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:*[2]

E344 Terminology Relating to Thermometry and Hydrometry

F895 Test Method for Agar Diffusion Cell Culture Screening for Cytotoxicity

2.2 *Code of Federal Regulations*[3]:

CFR, Title 21, Section 191, II, 1971

3. Terminology

3.1 *Definitions:*

3.1.1 The definitions given in Terminology E344 apply to this standard.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *phase-change-type fever thermometer, n*—a reusable instrument utilizing the change of state of chemical compositions to measure and indicate an anatomical site temperature.

3.2.2 *retention time, n*—the duration of time that the optimal signal for reading persists.

4. Classification

4.1 Phase-change-type reusable thermometers for determination of human temperature.

4.2 Scales, Celsius and Fahrenheit.

5. Requirements

5.1 *General*—All thermometers complying with this specification shall meet all the requirements specified herein.

5.2 *Temperature Range*—The instrument shall cover the minimum range from 35.5 to 40.4 °C (96.0 to 104.8 °F).

5.3 *Accuracy*—Within the range specified, no individual reading shall be in error by more than the maximum errors listed in Table 1 when tested in accordance with 6.2 at any point on the temperature scale of the thermometer.

5.4 *Measurement Retention*—A measurement meeting the accuracy requirement of 5.3 will be maintained for a minimum of 20 s when tested in accordance with 6.2.4.

5.5 *Operating Environment*—When used in an environment in which the temperature is in the range of 18 to 33 °C (64 to 92 °F), the thermometers, when tested in accordance with 6.3, shall meet the requirements of 5.3 and 5.4.

5.6 *Graduation*—The thermometer shall be graduated in intervals no greater than 0.1 °C (0.2 °F). As a minimum, appropriate numerals shall be placed at every half degree graduation for Celsius scale thermometers and every degree graduation for Fahrenheit scale thermometers.

5.7 *Stability*—Thermometers shall meet all requirements of this specification over their minimum shelf life of three years.

5.8 *Storage Environment*—When tested in accordance with 6.4, thermometers shall meet the requirements of 5.3 after having been stored in an environment of – 20 to 50 °C (+ 4 °F to 120 °F), and a relative humidity of 15 to 85 % noncondensing, for a period of thirty days, providing that they have been returned to an environment with a temperature of between 18 to 33 °C (64 to 92 °F) and a relative humidity of 30 to 70 % for at least 24 h before testing.

5.9 *Marking and Labeling:*

5.9.1 *Identification*—Suitable packaging units of the thermometer shall bear in legible characters the name or

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