Designation: E 1299 – 96

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

This standard is issued under the fixed designation E 1299; 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:*

E 344 Terminology Relating to Thermometry and Hydrometry[2]

F 895 Test Method for Agar Diffusion Cell Culture Screening for Cytotoxicity[3]

2.2 *Code of Federal Regulations[4]:*

CFR Title 21, Section 191, II, 1971

3. Terminology

3.1 *Definitions:*

3.1.1 The definitions given in Terminology E 344 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 trademark, or both, of the manufacturer or distributor and a designation (either a serial number or a code) to indicate the specific manufacturing lot.

5.9.2 *Operating Instructions*—Operating instructions shall be provided with the packaging unit.

5.9.3 *Care and Cleaning Instructions*—Instructions for the care and cleaning of the thermometer shall be provided with the packaging unit. A procedure for decontaminating the thermometer following each use shall be included with these instructions.

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[1] This specification is under the jurisdiction of ASTM Committee E-20 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] *Annual Book of ASTM Standards*, Vol 13.01.

[4] Available from the Superintendent of Documents, US Government Printing Office, Washington, DC 20402.

TABLE 1 Maximum Error of Temperature Readings

Celsius Scale	
Temperature Range, °C	Maximum Error, °C
Below 35.8	±0.3
35.8 to 36.9	±0.2
37.0 to 39.0	±0.1
39.1 to 40.4	±0.2

Fahrenheit Scale	
Temperature Range, °F	Maximum Error, °F
Below 98.0	±0.4
98.0 to 102.0	±0.2
Above 102.0	±0.4

5.10 *Toxicity*—When the thermometer is used as specified by the manufacturer, the parts intended for contact with intact natural channels or intact body surfaces during patient use and its phase change chemical compositions shall be nontoxic as determined by 6.5.

6. Test Methods for Performance Verification

6.1 *General*—This section describes the principles, apparatus, and procedures to be used to determine the conformance of phase change reusable thermometers to the requirements of this standard. Each manufacturer or distributor when representing products as conforming to this standard may use statistically based sampling plans that are appropriate. Such essential records as are necessary to document claims that all of the requirements of this specification are met shall be maintained.

6.2 *Accuracy Test*:

6.2.1 *Test Equipment Required*—The test equipment shall include constant-temperature water baths, the temperatures of which are uniform and are known to be within ±0.03°C (±0.05°F), as measured by a thermometer or thermometer system for which the temperature calibration is traceable to the International Temperature Scale of 1990 (ITS-90) as maintained by the National Institute of Standards and Technology (NIST) or another national standards laboratory.[5] The volume of each bath shall be a minimum of 1 L.

6.2.2 *Procedure*—Insert the thermometers in the water bath and test in accordance with the procedures specified by the manufacturer. Use at least 20 temperature points distributed throughout the range on the scale of the thermometer for obtaining data.

6.2.3 *Sampling*—For each manufacturing lot, use a minimum of 200 thermometers in the accuracy determination, making at least five measurements with each thermometer. The criteria for lot acceptance shall be published by the manufacturer.

6.2.4 *Measurement of Retention Time*—After removing thermometers from the water bath, wait 20 s and compare the readings with those obtained immediately upon removing the thermometers from the water bath. These thermometers shall meet the requirements of 5.3 at the temperature extremes of 18 and 33°C (64 and 92°F) and the relative humidity extremes of 15 and 85 %.

6.3 *Operating Environment Test*—This test is used to determine the compliance of the thermometers to the requirement of 5.5.

6.3.1 *Test Equipment*:

6.3.1.1 *Constant-Temperature Water Baths*, (6.2.1),

6.3.1.2 *Forced-Circulation Air Oven*, capable of heating samples to 32 ± 1°C (90 ± 2°F),

6.3.1.3 *Refrigerated Chamber*, capable of cooling samples to 19 ± 1°C (66 ± 2°F).

NOTE 1—The oven and refrigerator must be located in close proximity to the constant temperature water baths.

6.3.2 *Procedure*—Equilibrate samples of thermometers in an immediate ready-to-use status (free of all packaging) at the two temperature extremes, 19 and 32°C (66 and 92°F), for at least 1 h. Remove the thermometers from these operating environments and insert them into the test water bath within 10 s of removal from either the 32°C oven or the 19° chamber and complete the accuracy test in accordance with 6.2.2 and 6.2.4.

6.4 *Storage Environment Test*—This test is used to determine the compliance of the thermometers to the requirements of 5.8.

6.4.1 *Test Equipment*:

6.4.1.1 *Constant-Temperature Water Baths*, (6.2.1).

6.4.1.2 *Environmental Test Chamber*, capable of producing environments of − 20± 2°C (−4 ± 4°F) at 15 and 85 % relative humidities and 50 ± 2°C (120 ± 4°F) at 30 % relative humidity is required. Humidity conditions should be made uniform and reproducible. Relative humidities can be established using saturated solutions of common salts in deionized water.

6.4.2 *Procedure*—Subject unopened storage packages of thermometers to the four extreme combinations of temperature and relative humidity indicated in 5.8. Hold them under these conditions for 30 days. Remove the samples with their packaging unit intact from the test chambers and allow them to remain in an environment within its environmental operating range for 24 h. Then remove the thermometers from their packaging and complete the accuracy test in accordance with 6.2.2 and 6.2.4.

NOTE 2—Toxicity tests: Prior to the animal testing as described in 6.5 and 6.6 it is recommended that the extract and the chemical contents be tested in accordance with Test Method F 895. If the samples pass this test, there is reasonable assurance that the test animals will not suffer. Should the samples fail this test, careful consideration should be made before proceeding to 6.5 and 6.6.

6.5 *Toxicity Test (Extract)*—Place one hundred samples in 100 mL of a 0.85 weight percent NaCl solution and store in an oven at 45°C for a period of time equal to 100 times the maximum patient measurement time recommended by the manufacturer. Use this solution containing any extracts of the thermometers to perform the following tests.

6.5.1 *Acute oral toxicity in rats*, (10 mL of extract/kg of body mass).

6.5.2 *Rabbit eye irritation test*, National Formulary XIII.[6]

6.5.3 *Primary skin irritation test*, CFR, Title 21, Section 191, 11, 1971. The thermometers will be considered nontoxic if the extract produces reactions which are not significantly different from a control (saline) sample.

[5] Available from NIST, Gaithersburg, MD 20899.

[6] Available from United States Pharmacopia Convention, Inc., 12601 Twinbrook Parkway, Rockville, MD 20852.

6.6 *Toxicity Test (Chemical Ingestion)*—Determine the average mass of the chemical contents of one thermometer. Increase this amount 100 fold and administer orally to ten fasting 100-g rats an amount calculated pro rata based on 25 kg (weight of human child). For example, if a thermometer's chemical contents have an average mass of 0.002 g, then the mass administered to a 100-g rat is 0.0008 g ($0.002 \times 100 \times 100/2500 = 0.0008$ g). These rats must be observed for 14 days and their reactions compared with a ten-member control group of rats maintained on a normal diet. If, after 14 days, there is no death or retardation in the dosed animals as compared to the control animals, the phase change chemical compositions are considered nontoxic.

6.7 *Cleaning Tests*—Perform the cleaning procedure as recommended by the manufacturer a minimum of five times. This test shall result in no significant change of the thermometer in meeting the requirements set forth in Section 5.

7. Identification

7.1 In order that purchasers may identify products conforming to all requirements of this specification, distributors and producers 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:

7.1.1 "This thermometer conforms to all the requirements established in ASTM Specification E 1299. Full responsibility for the conformance of this product to the specification is assumed by (name and address of distributor or producer).

7.2 When the available space is insufficient for this full statement, the following abbreviated statement is suggested:

7.2.1 Conforms to ASTM Specification E 1299 (name and address of distributor or producer).