Designation: E 825 – 98 (Reapproved 2003)

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

This standard is issued under the fixed designation E 825; 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.

This standard has been approved for use by agencies of the Department of Defense.

1. Scope

1.1 This specification covers phase change-type clinical thermometers that are designed and intended for one time use.

2. Referenced Documents

2.1 *ASTM Standards:*

E 344 Terminology Relating to Thermometry and Hydrometry[2]

2.2 *Other Standards:*

National Formulary, Volume XIII Code of Federal Regulations, Title 21, Section 191, II 1971.

3. Terminology

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

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *intermittent determination of human temperature*, *n*—determination of human body temperature that is made periodically by a series of entirely separate measurements.

3.2.2 *manufacturing lot*, *n*—in the case of a continuous manufacturing process, a lot is a specific identified quantity or amount produced in a unit of time made in a manner that assures its having uniform character and quality within specified limits. In the case of a batch process, a lot means a batch or specific identified portion of a batch having uniform character and quality within specified limits.

3.2.3 *measurement time*, *n*—length of time required from the time of patient contact to the time when the thermometer may be removed to read within its stated accuracy.

3.2.4 *predictive thermometer*, *n*—any thermometer that provides an indication of the final stabilized temperature of the measurement site in advance of the time for the sensing part of the thermometer to reach the equilibrium temperature of that site.

3.2.5 *storage package*, *n*—smallest package intended by the manufacturer for long-term storage at the user's facility.

3.2.6 *suitable packaging unit*, *n*—unit(s) of packaging to which a specific requirement of marking and labeling is logically applicable. It shall not be less than the smallest unit intended for sale by the manufacturer or distributor to the final user.

3.2.7 *temperature offset*, *n*—designed difference in predictive thermometer readings and water bath test temperatures.

4. Classification

4.1 Phase change disposable thermometers for the intermittent determination of human temperature.

NOTE 1—The requirements of this specification shall not preclude the manufacture and sale of special thermometers having different temperature ranges and degrees of subdivision designed for specific medical uses. Packaging on any "special" thermometers shall state that the thermometer is a special one intended for a specific use and, therefore, is not necessarily in compliance with this specification. In addition, the special thermometer must be marked in such a way as to identify it as "special."

4.2 *Scales*, Celsius and Fahrenheit.

NOTE 2—The Fahrenheit temperatures given in parentheses throughout this specification are not necessarily exact Celsius conversions but are the values to be used when testing thermometers with Fahrenheit scales for conformance with this specification.

5. Requirements

5.1 *General*—All thermometers represented as complying with this specification shall meet all of the requirements specified herein. Terms are defined in Section 4.

5.2 *Temperature Range*—The instrument shall cover the minimum range from 35 to 40.4 °C (96 to 104.8 °F) unless otherwise obviously labeled. If any thermometer does not meet

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

the range 35 to 40.4 °C (96 to 104.8 °F), it shall additionally be obviously marked as "Limited Range" on suitable packaging units.

5.3 *Accuracy*—The accuracy of the thermometer shall be in conformance with Table 1 and Table 2 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 requirements of 5.3 will be maintained for a minimum of 1 min 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 from 18 to 33 °C (64 to 92 °F), the thermometers, when tested in accordance with 6.3, shall meet the requirements of 5.3. Any thermometer product not meeting this requirement shall be marked on a suitable packaging unit or other labeling of the thermometers with a cautioning statement indicating the ambient temperature range in which it can be used with specified accuracy.

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 degree graduation for Celsius scale thermometers and at every even degree graduation for Fahrenheit scale thermometers.

5.7 *Workmanship*—There shall be no constructional defects that would prevent the measurement of temperature within the accuracy requirements of 5.3.

5.8 *Stability*—Thermometers shall meet all requirements of this specification over their shelf life. If the shelf life of the product is less than 5 years when stored in compliance with the manufacturer's instructions, an uncoded expiration date shall be displayed on the labeling of the product.

5.9 *Storage Environment*—When tested in accordance with 6.4, thermometers shall meet the requirements of 5.3 after they have been stored for 1 day at any point in an environment of −18 to 38 °C (0 to 100 °F) and at relative humidities from 15 to 90 %. When tested in accordance with 6.4, thermometers shall also meet the requirements of 5.3 after they have been stored for 1 month at any point in an environment of 15.5 to 32 °C (60 to 90 °F) and 30 to 75 % relative humidity. Any thermometer product not meeting this requirement shall be marked on a suitable packaging unit or other labeling of the thermometers with a cautioning statement indicating the storage temperature range that is applicable.

5.10 *Marking and Labeling*:

5.10.1 *Identification*—Suitable packaging units of the thermometers 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. Suitable packaging units and other labeling shall also bear a statement that the thermometers are intended for single use only.

TABLE 1 Accuracy of Thermometers With a 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 41.0	±0.2
Above 41.0	±0.3

TABLE 2 Accuracy of Thermometers With a Fahrenheit Scale

Temperature Range, °F	Maximum Error, °F
Below 98	±0.4
98 to 102	±0.2
Above 102	±0.4

5.10.2 *Operating Instructions*—Operating instructions must be provided. When space limitations dictate, the operating instructions on an individual thermometer may be omitted if detailed instructions are provided on or with a suitable packaging unit.

5.10.3 *Additional Marking and Labeling*— Additional marking and labeling that may be required by 5.2, 5.5, 5.8, 5.9, and 6.2.3 shall be clear, concise, and adequate for the intended purpose. The temperature measurement offset shall be included in the labeling of the thermometers.

5.11 *Toxicity*—When the thermometer is used as specified by the manufacturer, its parts intended for contact with anatomical sites during patient use and its melting point chemicals shall be nontoxic as determined by 6.5.

6. Test Methods for Performance Verification

6.1 *Significance and Use*—This section describes the principles, apparatus, and procedures to be used to determine the conformance of disposable thermometers to the requirements of this specification. Each manufacturer or distributor who represents his products as conforming to this specification may use statistically based sampling plans that are appropriate. He shall keep such essential records as are necessary to document his claim that all the requirements of this specification are met. This section does not include any procedure for requirements that can be verified by visual inspection (such as 5.2).

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 thermometry 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 other appropriate National Standards Laboratory. The volume of each bath shall be a minimum of 1 L.

6.2.2 *Procedure*—Insert the thermometers into the water bath and test in accordance with the manufacturer's specified procedures. Use at least 20 points distributed throughout the temperature range on the scale of the thermometer for obtaining data. Do not use a given thermometer for obtaining more than one datum point.

6.2.3 *Sampling*—Statistically based sampling of manufacturing lots is required for the determination of accuracy because of the destructive nature of the test as applied to a disposable thermometer. Use a minimum of 200 measurements in the accuracy determination for a manufacturing lot with not fewer than 10 measurements at a specified temperature. The criteria for lot acceptance shall be stated by the manufacturer in his literature (labeling).

6.2.4 *Measurement Retention Test*—Test the thermometers in accordance with 6.2.2 and read. One minute later, read the thermometers again. They shall meet the requirements of 5.3.

6.3 *Operating Environment Test*—Use this test to determine the compliance of thermometers to the requirement of 5.5.

6.3.1 *Test Equipment Required*—Constant-temperature water baths (6.2.1); a forced-circulation air oven capable of heating thermometer samples to 32 ± 1 °C (90 ± 2 °F); a refrigerated chamber capable of cooling thermometer samplings to 19.0 ± 1 °C (66 ± 2 °F). The oven and refrigerated chamber 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 90 °F), for at least 1 h. Transfer thermometers for testing at any specific bath temperature, handling as in normal use, and insert into the test water bath within 10 s of removal from either the 32 °C oven or the 19 °C chamber and complete the accuracy test in accordance with 6.2.2.

NOTE 3—If an environmental test chamber of sufficient size is available in which the test water baths can be set up without loss of bath temperature control, it may be used in place of the oven and refrigerated chamber.

6.4 *Storage Environment Test*—Use this test to determine the compliance of thermometers to the requirements of 5.9.

6.4.1 *Test Equipment Required*—The constant-temperature water baths from 6.2.1 and an environmental test chamber capable of producing environments of −20 ± 2 °C (−4 ± 4 °F) at 15 to 90 % relative humidities and 38 ± 3 °C (100 ± 5 °F) at 30 to 75 % relative humidities are required. Humidity conditions should be made uniform and reproducible. An alternative procedure, requiring less sophisticated facilities, is to store disposable thermometers for the times and temperatures required in 5.9 in closed chambers with humidities therein obtained through the use of saturated solutions of common salts or deionized water as indicated in Table 3.

6.4.2 *Procedure*—Subject unopened storage packages to the four extreme combinations of temperature and relative humidity indicated in 5.9. Hold them at these conditions for the time periods indicated (1 day and 1 month). Remove the samples with their packaging unit intact from the test chambers and allow 24 h for the product to return to its operating environment (5.5). Then remove the thermometers from their packaging and complete the accuracy test in accordance with 6.2.2.

TABLE 3 Relative Humidities Produced by Some Solutions in a Closed Chamber at Various Temperatures

Temperature, °C (°F)	Nominal RH, %	Saturated Solutions
−17.7 (0)	90	H_2O
−17.7 (0)	15	LiCl
37.7 (100)	15	LiI
37.7 (100)	90	KNO_3
15.5 (60)	33	$MgCl_2$
15.5 (60)	76	NaCl
32.2 (90)	32	$MgCl_2$
32.2 (90)	75	NaCl
18.3 (65)	33	$MgCl_2$
18.3 (65)	76	NaCl
34.4 (94)	32	$MgCl_2$
34.4 (94)	75	NaCl

6.5 *Toxicity Tests*:

6.5.1 *Toxicity Test (Extract)*—Place 100 samples in 100 mL of a 0.85 g % NaCl solution in an oven at 45 °C for a period of time equal to 100 times the manufacturer's recommended patient measurement time (3.2.3). After the thermometers have been in the solution for the proper length of time at 45 °C, perform the following tests on the resulting solution (containing any extracts from the thermometers).

6.5.1.1 Acute oral toxicity in rats (10 mL/kg of body weight).

6.5.1.2 Rabbit eye irritation test, National Formulary XIII.

6.5.1.3 Primary skin irritation, Code of Federal Regulations, Title 21, Section 191, II, 1971. The thermometers will be considered nontoxic if the extract produces reactions not significantly different from a blank (saline) sample.

6.5.2 *Toxicity Test (Chemical Ingestion)*— Remove the entire melting point chemical contents of one thermometer from a thermometer. Divide the weight of these chemicals by 25 kg (weight of a human child) to calculate the dosage per kilogram of body weight. Increase this dosage level 100 times and orally feed in proportion to their body weight to 10 fasting 100-g rats. Observe the rats for 14 days and compare their reactions to 10 control group rats (not fed the chemicals). If, after 14 days, there is no death or retardation in the dosed rats as compared to control animals, the melting point chemicals are considered nontoxic.

6.6 *Precision and Bias*—All test equipment specified in 6.2.1 shall be sufficiently accurate so that test results produced with the equipment have an expanded uncertainty (k=3) not exceeding 0.045 °C.

7. Identification

7.1 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:

7.1.1 "This thermometer conforms to all of the requirements established in ASTM Standard E 825. Full responsibility for the conformance of this product to the specification is assumed by (name and address of producer or distributor)."

7.2 The following abbreviated statement is suggested when available space on labels is insufficient for the full statement:

7.2.1 "Conforms to ASTM E 825 (name and address of producer or distributor."

8. Keywords

8.1 clinical thermometer; disposable; phase-change