Designation: ~~E825 – 98 (Reapproved 2009)~~ E825 – 98 (Reapproved 2016)

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

This standard is issued under the fixed designation E825; 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 phase change-type clinical thermometers that are designed and intended for ~~one time~~ one-time use.

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E344 Terminology Relating to Thermometry and Hydrometry

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 E344 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~~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.

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[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~~standard's Document Summary page on the ASTM website.

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 43.

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 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.

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.

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 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