Designation: E 1104 – 98 (Reapproved 2003)

Standard Specification for Clinical Thermometer Probe Covers and Sheaths[1]

This standard is issued under the fixed designation E 1104; 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 all single-use clinical thermometer probe covers and sheaths intended for use with any clinical thermometer. Requirements are given for safety, toxicity, handling, labeling, and physical integrity. Testing procedures for appropriate requirements and a glossary of terms used within the standards are provided.

1.2 The requirements contained herein are intended to ensure adequate isolation of the patient from the temperature-measuring device. In addition, the safety and health of the patient shall not be adversely affected. When used in accordance with the manufacturers instructions, the probe cover, sheath, and temperature measuring device shall remit correct temperature readings as required in Specifications E 667 and E 1112.

2. Referenced Documents

2.1 *ASTM Standards:*

E 344 Terminology Relating to Thermometry and Hydrometry[2]

E 667 Specification for Mercury-in-Glass Maximum Self-Registering Clinical Thermometers [2]

E 1112 Specification for Electronic Thermometers for Intermittent Determination of Patient Temperature[2]

3. Terminology

3.1 *Definitions*—The definitions given in Terminology E 344 shall apply to this Specification with the following additions:

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *measurement time*, *n*—time required from time of patient contact to the time when the clinical thermometer may be removed or read to within the stated accuracy of the clinical thermometer.

3.2.2 *patient*, *n*—any human whose temperature is being taken.

3.2.3 *probe*, *n*—an assembly including the transducer that is used to position the transducer in the specific location from which the temperature is to be determined.

3.2.4 *probe covers and sheaths*, *n*—devices provided for the purpose of preventing biological contact between the patient and the probe or clinical thermometer.

3.2.5 *suitable packaging unit*, *n*—the unit(s) of packaging for 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.

4. Requirements

4.1 *General*—Clinical thermometer probe covers and sheaths represented as complying with this specification shall meet all of the requirements specified herein.

4.2 *Product Safety*—Sheaths and probe covers shall be constructed to preclude sharp points and edges that could cause patient injury. Probe covers and sheaths shall be constructed in such a way that the person using them can install and remove them without touching that portion of the probe cover or sheath that comes in contact with the patient.

4.3 *Physical Integrity*—The clinical thermometer probe covers and sheaths shall be constructed and packaged so that the physical integrity of the probe covers and sheaths will be maintained when applied to, used, and removed from a temperature-taking device as prescribed by the manufacturer (see 5.3).

4.4 *Toxicity*—When the probe covers or sheaths are used as specified by the manufacturers, its parts intended for contact with anatomical sites during patient use shall be nontoxic (see 5.1).

4.5 *Compatibility*—The clinical thermometer probe covers and sheaths shall be compatible with the intended use of the temperature-taking device (see 5.4.1).

4.6 *Labeling*:

4.6.1 Instructions shall be provided for proper usage of clinical thermometer probe covers or sheaths.

4.6.2 Suitable packaging units of the thermometer sheaths or probe covers shall bear in legible characters a designation (either a serial number or a code) to indicate the specific manufacturing lot in addition to all other applicable labeling.

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[1] This specification is under the jurisdiction of ASTM Committee E20 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.

Suitable packaging units and other labeling shall also bear a statement that the thermometer probe covers or sheaths are intended for single use only.

4.6.3 The temperature-taking device for which the clinical thermometer probe cover or sheath is or is not intended shall be specified.

4.6.4 If the temperature-taking device's performance and operating characteristics, such as measurement time or accuracy, are adversely affected by the probe cover or sheath, the consequence to the device's performance characteristics must be specified (see 5.4).

4.6.5 Probe covers and sheaths may fail to isolate the patient from the temperature measuring device shall contain a caution statement. Susceptibility to failure of probe covers or sheaths shall be determined by appropriate testing by each manufacturer or distributor.

4.6.6 *Identification*:

4.6.6.1 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, etc. The following statement is suggested when sufficient space is available: "This thermometer conforms to all of the requirements established in ASTM Standard E 1104. Full responsibility for the conformance of this product to the specification is assumed by (name and address of producer or distributor)."

4.6.6.2 The following abbreviated statement is suggested when available space on labels is insufficient: "Conforms to ASTM Standard E 1104 (name and address of producer or distributor)."

4.7 *Use, Operating, and Storage Environment Conditions*:

4.7.1 *Operating Environment*—16.0 °C (60.8 °F) to 40.0 °C (104.0 °F), 15 % to 95 % RH (non-condensing).

4.7.2 *Storage Environment*— −20.0 °C (−4 °F) to 49.0 °C (120.2 °F) 15 % to 95 % RH for 1 month (non-condensing).

4.7.3 *Use Environment*—Body conditions (oral or rectal).

5. Testing Procedures

5.1 *Significance and Use*—This section describes the procedures necessary to verify conformance to certain requirements of Section 4. Procedures that can be verified by observation are not included. The inspection and test procedures contained in this specification are used to determine the conformance of probe covers or sheaths to the requirements of this specification. Each producer or distributor representing products as conforming to this specification may use statistically based sampling plans that are appropriate for each particular manufacturing process, but shall keep the essential records necessary to document the claim that all of the requirements of this specification are met.

5.2 *Toxicity Test*—Test materials intended for patient contact shall be in accordance with the current issue of USP Biological Test-Plastic Container, Table 1: Extract of sample in sodium chloride and extract of sample in vegetable oil.[3]

5.3 *Leakage Test*—After placement and removal of the clinical thermometer probe cover or sheath onto and from the temperature taking device in accordance with the manufacturers' instructions, apply air at a positive internal gage pressure of 8.4 kPa (1.2 psi) with the probe cover or sheath submerged in water within the operating temperature environment (See 4.7) to the length that is intended for patient contact. There shall be no continuous bubble stream observed within 5 s. Thermometer probe covers and sheaths that are intended to invert when the temperature-taking device is withdrawn may be tested while inverted.

5.4 *Compatibility Test*:

5.4.1 The compatibility of the clinical thermometer probe cover or sheath with any particular temperature-taking device for which it is recommended shall be tested to verify that it meets the device manufacturers' performance characteristics.

5.4.2 A probe cover or sheath shall not degrade the performance (such as measurement time or accuracy) of the temperature-taking device so that it fails to meet the requirements of the applicable ASTM standards for the particular temperature-taking device (for example, Specifications E 667 and E 1112).

5.5 *Storage Environment*—At the completion of the time period and conditions listed in 4.7 (storage environment), the probe covers and sheaths shall pass all the test procedures of Section 5.

6. Keywords

6.1 clinical; probe covers; sheaths; thermometer

[3] Available from United States Pharmacopeial Convention Inc., 12601 Twinbrook Parkway, Rockway, MD 20852.