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

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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 Clinical Thermometers (Maximum Self-Registering, Mercury-in-Glass)[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 *probe covers and sheaths, n*—devices provided for the purpose of preventing biological contact between the patient and the probe or clinical thermometer.

3.2.2 *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.

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

3.2.4 *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.

3.2.5 *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. 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.

[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.