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Standard Specification for Clinical Thermometer Probe Covers and Sheaths¹

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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 manufacturer's instructions, the probe cover, sheath, and temperature measuring device shall remit correct temperature readings as required in Specifications E667 and E1112.

2. Referenced Documents

2.1 *ASTM Standards*:²

E344 Terminology Relating to Thermometry and Hydrometry

E667 Specification for Mercury-in-Glass, Maximum Self-Registering Clinical Thermometers

E1112 Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature

3. Terminology

3.1 *Definitions*—The definitions given in Terminology E344 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 its 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.

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 Document Summary page on the ASTM website.