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

This standard is issued under the fixed designation E1104; 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~~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 ~~the~~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.

[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.