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Standard Specification for Direct-Reading Liquid Crystal Forehead Thermometers[1]

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1. Scope

1.1 This specification covers direct-reading liquid crystal forehead thermometers designed to monitor trends or measure human forehead surface temperatures, or both.

1.2 Thermometers covered by this specification are generally available in continuous or intermittent reading modes. Thermometers meeting the requirements specified herein shall be considered as complying with this specification.

1.3 The following precautionary caveat pertains only to the test method portion, Section 5, of this specification.*This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to consult and establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E344 Terminology Relating to Thermometry and Hydrometry

3. Terminology

3.1 *Definitions*—For definitions of terms used in this specification, refer to Terminology E344.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *center green (CG) or mid green (MG), n*—that temperature which unifies the visual and instrumental evaluation methods and is defined by the equation:

$$CG = MG = \frac{SG + SB}{2} = T°520$$

See 3.2.5.2 for description of T°520.

3.2.2 *color play, n*—the predictable sequence of colors exhibited by a liquid crystal formulation as it passes through its active temperature range. For example, as temperature increases, a formulation exhibits successive tan, red, green, and blue colors.

3.2.3 *manufacturing lot, n*—(*1*) in the case of continuous manufacturing processes, a *lot* is a specifically identified amount produced in a unit of time or quantity in a manner that assumes its having uniform characteristics and quality within specified limits.

(*2*) In the case of batch processes, a *lot* means a batch or specifically identified portion of a batch assumed to have uniform characteristics and quality within specified limits.

3.2.4 *sequencing, n*—a characteristic whereby the thermal profiles of the liquid crystal formulations of a given thermometer follow each other in an orderly predetermined manner.

3.2.5 *specific color phenomena, n* (using instrumental methods of evaluation):

3.2.5.1 *blue*—that temperature at which the intensity of 470 nm light reflected by the liquid crystal is maximum, symbolized as T°470.

3.2.5.2 *green*—that temperature at which the intensity of 520 nm light reflected by the liquid crystal is maximum, symbolized as T°520.

3.2.5.3 *red*—that temperature at which the intensity of 650 nm light reflected by the liquid crystal is maximum, symbolized as T°650.

3.2.6 *start of blue (SB), n*—that temperature at which the liquid crystal first begins to reflect blue light, which is defined as light having a wavelength of 491 nm.

3.2.7 *start of green (SG), n*—that temperature at which the liquid crystal first begins to reflect green light, which is defined as light having a wavelength of 575 nm.

3.2.8 *start of red (SR), n*—that temperature at which the liquid crystal first begins to reflect red light, which is defined as light having a wavelength of 675 nm.

3.2.9 *thermal profile, n*—temperatures at which specific color phenomena occur in a liquid crystal thermometer.

3.2.10 *visible start (VS), n*—that temperature at which the liquid crystal first begins to reflect visible light.

[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.

4. Requirements

4.1 *General*—Thermometers represented as complying with this specification shall meet all of the requirements specified herein.

4.2 *Temperature Range*—The liquid crystal forehead thermometer shall, as a minimum, meet all requirements of this specification over the temperature range of 32.0 to 38.0 °C (90 to 100 °F). Some color must remain visible up to temperatures of 39.5 °C (103 °F).

4.3 *Tolerance*—Whenever a temperature for a specific color phenomenon (3.2.1) is measured, the maximum permissible deviation is ±0.6 °C (±1.0 °F), when tested according to 5.2 of this standard.

4.4 *Sequencing*—Thermal profiles of the liquid crystal formulations must be such that: (*1*) no two readouts are the same color within the temperature range of red start to blue start at the same time; and (*2*) within the temperature range of the device, color must be visible in at least one graphical representation at all times.

4.5 *Environment:*

4.5.1 *Operating Environment*—Liquid crystal forehead thermometers shall meet all requirements of this standard when operated in an environment of 16 to 40 °C (60 to 104 °F) and a relative humidity of 15 to 95 %.

4.5.2 *Storage Environment*—Liquid crystal forehead thermometers shall meet all requirements of this standard after having been stored or transported, or both, in the dark, at any point in an environment of 5 to 65 °C (41 to 149 °F), and at a relative humidity of 15 to 95 %, for a period of 1 month.

4.6 *Labeling:*

4.6.1 The following labeling requirements are the minimum statements that shall appear on every label.

4.6.2 A statement advising the user that the information obtained with a liquid crystal forehead thermometer is different from, and will not necessarily give the same readings as, an oral or rectal thermometer.

4.6.3 A statement giving the accuracy of the thermometer.

4.6.4 A statement explaining any environmental or physical factors which may affect either the readings obtained or the shelf life of the thermometer.

4.6.5 A statement explaining the proper placement and the use of the thermometer, as well as the specific meaning of any numerals, symbols, or colors which may be observed.

4.6.6 A statement advising the user that any unusual liquid crystal forehead thermometer readings should be verified.

4.6.7 Identification—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 and the like. The following statement is suggested when sufficient space is available: "This thermometer conforms to all of the requirements established in this specification. Full responsibility for the conformance of this product to the specification is assumed by (name and address of producer or distributor)." The following abbreviated statement is suggested when available space is insufficient for the full statement: "Conforms to ASTM E1061 (name and address of producer or distributor)."

5. Test Methods

5.1 *General*—The inspections and test procedures contained in this section are to be used to determine the conformance of Liquid Crystal Forehead Thermometers to the requirements of this specification. Each producer or distributor who represents his products as conforming to this specification may use statistically based sampling plans that are appropriate for each particular manufacturing process but shall keep such essential records as are necessary to document his claim that all of the requirements of this specification are met.

5.2 *Test Method for Measuring the Thermal Profile of a Liquid Crystal Forehead Thermometer:*

5.2.1 Place the test sample in a temperature-controlled circulating water bath fitted with a thermometer traceable to NBS reference standards and accurate to ±0.1 °C. Means shall be supplied to heat and cool the circulating water in the bath. The uniformity of temperature of the water within the bath shall be within ±0.2 °C in the test region.

5.2.2 Mount the test sample, if necessary, in a water-proof sample holder.

5.2.3 Immerse the test sample and its holder in the bath and hold the test sample parallel to a flat surface of the bath or the water surface.

5.2.4 Place a white light source, having a flat spectral output, perpendicular to the flat surface of the test sample so that the sample colors may be viewed from a direction perpendicular to the flat surface of the test sample.

5.2.5 The rate of temperature rise of the water in the bath should be less than 0.5 °C/min.

5.2.6 Read for each formulation in the thermometer the temperature of VS, SR, SG, and SB at the defined wavelengths of light (3.2.1) by visual color comparison to reference standard narrow bandpass filters, or the temperature of the photometrically determined maximum reflection (3.2.2) for red - 650 nm, green - 520 nm, or blue - 470 nm light.

5.3 When tested in accordance with these procedures, each liquid crystal forehead thermometer shall meet the requirements of 4.2 – 4.4.

5.4 At the completion of the time period and conditions recommended by the manufacturer, or as specified in 4.5, the liquid crystal forehead thermometer shall meet the requirements of 4.3 and 4.4 when tested according to the procedures of 4.2.