



Designation: E667 – 98 (Reapproved 2017)

Standard Specification for Mercury-in-Glass, Maximum Self-Registering Clinical Thermometers¹

This standard is issued under the fixed designation E667; 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 mercury-in-glass, reusable maximum self-registering clinical thermometers of the types commonly used for measuring body temperatures of humans and of animals. Requirements are given for bulb and stem glasses, mercury, legibility and permanency of markings, dimensions, temperature scale ranges, and graduations, as well as for thermometer stability, ease of resetting, retention of temperature indication, and for accuracy of scale reading. Appropriate methods of testing to determine compliance are provided. Also included is a glossary of terms used in the standard and an appendix with additional information on thermometer glasses and stability.

1.2 All values of temperature in this standard are with reference to the International Temperature Scale of 1990.

1.3 This specification was developed to provide nationally recognized marketing classifications and quality requirements for mercury-in-glass, maximum self-registering clinical thermometers. It is also intended to provide producers, distributors, and users with a common understanding of the characteristics of this product.

1.4 The following precautionary statement pertains only to the test method portion, Section 6 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 establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.5 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

¹ This specification is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of F04.33 on Medical/Surgical Instruments.

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2. Referenced Documents

2.1 ASTM Standards:²

E29 Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications

E344 Terminology Relating to Thermometry and Hydrometry

3. Terminology

3.1 *Definitions*—The definitions given in Terminology E344 apply to this specification.

3.2 Definitions of Terms Specific to This Standard:

3.2.1 *bore, n*—hole or lumen in the stem.

3.2.2 *calibration date, n*—date on which the scale is affixed to a thermometer.

3.2.3 *ceramic marking, n*—marking produced by fusing a ceramic colorant onto the glass surface.

3.2.4 *constriction, n*—obstruction in the bore of a clinical thermometer which permits the passage of mercury from the bulb when the bulb is heated, but which restricts its passage back to the bulb when heat is removed.

3.2.5 *fire cracks, n*—cracks in glass caused by local temperature shock.

3.2.6 *flat magnifying lens, n*—thermometer stem glass in which the numerals, graduations, and lens lie on the same relative surface.

3.2.6.1 *Discussion*—It is so named for its approximately flat cross section (See Fig. 1.)

3.2.7 *fractures, n*—internal or external breaks or cracks in the glass.

3.2.7.1 *Discussion*—Internal fractures usually occur in the area between the bulb and the constriction.

3.2.8 *graduations, n*—series of lines on the stem of the thermometer that designate the temperature scale intervals.

3.2.9 *hard shaker thermometer, n*—thermometer in which the constriction is overly severe thereby restricting the passage

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.

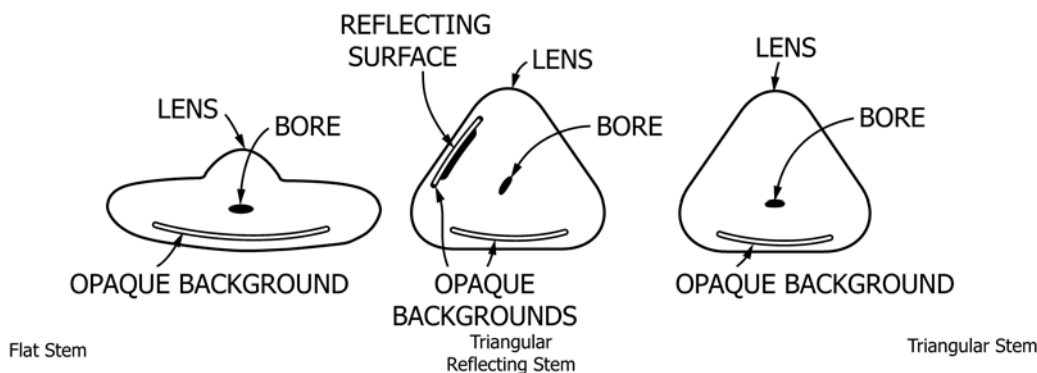


FIG. 1 Composite and Sectional Views of Clinical Thermometers (These sketches are for illustration only.)

of mercury back to the bulb causing the thermometer to fail the ease-of-resetting requirements.

3.2.10 *index, n*—upper point of the mercury column whose position, when noted with respect to the corresponding numerals and graduations, indicates the temperature of the mercury within the bulb.

3.2.11 *magnifying lens, n*—stem glass that, due to its configuration, results in a magnification of the mercury column.

3.2.12 *normal human temperature, n*—conventionally accepted average body temperature in healthy human beings (37 °C or 98.6 °F).

3.2.13 *ovulation thermometer, n*—thermometer specifically designed for obtaining body temperature for the purpose of determining the date of ovulation or the basal body temperature.

3.2.14 *reflecting stem, n*—stem glass containing a colored stripe along its length in a location that, when reflected on the mercury column, allows greater contrast and enables the column to appear tinted.

3.2.15 *residual mercury column, n*—mercury that lies in the bore of the stem above the constriction.

3.2.16 *retreating index thermometer, n*—thermometer in which the constriction is not sufficiently small to prevent the passage of mercury back to the bulb (or the mercury index from falling) without shaking when heat is removed from the bulb.

3.2.17 *scale range, n*—range of temperature through which a thermometer is usable.

3.2.18 *stained marking, n*—marking produced by diffusing colorant into the glass surface.

3.2.19 *subnormal thermometer, n*—clinical thermometer specifically designed for obtaining lower than normal body temperatures.

3.2.19.1 *Discussion*—A subnormal thermometer is marked with a subnormal scale range. See 4.4.

3.2.20 *triangular magnifying lens, n*—thermometer stem glass in which the numerals and graduations lie on surfaces that smoothly merge to form a lens.

3.2.20.1 *Discussion*—It is so named for its approximately triangular cross section. (See Fig. 1.)

4. Classification

4.1 Clinical thermometers covered by these specifications are generally available in the following classifications. Other designs and configurations of thermometers meeting the requirements specified herein shall also be considered as complying with this specification.

NOTE 1—The requirements of this specification shall not preclude the manufacture and sale of special thermometers having different temperature ranges and degrees of subdivision designed for specific medical uses. Packaging on any “special” thermometers shall state that the thermometer is a special one intended for a specific use and, therefore, is not necessarily in compliance with this specification. In addition, the special thermometer must be marked in such a way so as to identify it as a special thermometer.

4.2 *Types*—Thermometers are classified by types as follows (see Fig. 2):

4.2.1 *Human:*

4.2.1.1 *Basal or Ovulation*, with large cylindrical bulb (ovulation scale).

4.2.1.2 *Multiuse (Oral or Rectal)*, with stubby bulb (regular scale).

4.2.1.3 *Oral*, with cylindrical bulb (regular scale).

4.2.1.4 *Rectal*, with pear shaped bulb (regular scale).

4.2.1.5 *Subnormal*.

4.2.2 *Veterinary:*

4.2.2.1 *Ring Top*, 100-mm (4 in.), with stubby bulb (regular scale).

4.2.2.2 *Heavy Duty Ring Top*, 125-mm (5 in.) with stubby bulb (extended scale).

4.3 *Stems*—Thermometer stems are classified as follows (see Fig. 2):

4.3.1 Flat magnifying lens.

4.3.2 Triangular reflecting magnifying lens.

4.3.3 Triangular magnifying lens.

4.4 *Scales*—Thermometer temperature scales and ranges are classified as follows:

4.4.1 Celsius (formerly known as Centigrade):

4.4.1.1 *Regular Scale*, at least 35.5 to 41 °C,

4.4.1.2 *Ovulation Scale*, at least 35.5 to 38 °C,

4.4.1.3 *Extended Scale*, at least 35.5 to 44 °C, and

4.4.1.4 *Subnormal Scale*, at least 21 to 38 °C.

4.4.2 Fahrenheit (Note 2):

4.4.2.1 *Regular Scale*, at least 96 to 106 °F,

4.4.2.2 *Ovulation Scale*, at least 96 to 100 °F,

4.4.2.3 *Extended Scale*, at least 96 to 110 °F,

4.4.2.4 *Subnormal Scale*, at least 70 to 100 °F.

NOTE 2—The Fahrenheit temperatures given in parentheses throughout this specification are not necessarily exact Celsius conversions but are the values to be used when testing thermometers with Fahrenheit scales for conformance with this specification.

4.5 *Marking*—Thermometer markings are classified as follows:

4.5.1 Etched and filled.

4.5.2 Stained.

4.5.3 Ceramic marked.

4.5.4 Marked in other ways that meet all of the requirements of this specification.

5. Requirements

5.1 *General*—All thermometers represented as complying with this specification shall meet all of the requirements specified herein. Terms shall be as defined in Section 4.

5.2 *Glass*—Thermometers shall be made from bulb glass and magnifying lens stem glass (glasses) having properties and characteristics that ensure stability, accuracy, and reliability in accordance with the requirements of this specification. (See Appendix X1.)

5.3 *Mercury*—Mercury used in the thermometers shall have the purity, properties, and characteristics that will enable the finished thermometers to comply with all the performance requirements of this specification. In addition, when finished thermometers are visually examined, the bulb and the mercury column shall be free of gas or other foreign material.

5.4 *Fabrication of Regular-Scale Thermometer for Human Use:*

5.4.1 *Length*—The overall length of the thermometers shall not be less than 98 mm (3⅞ in.).

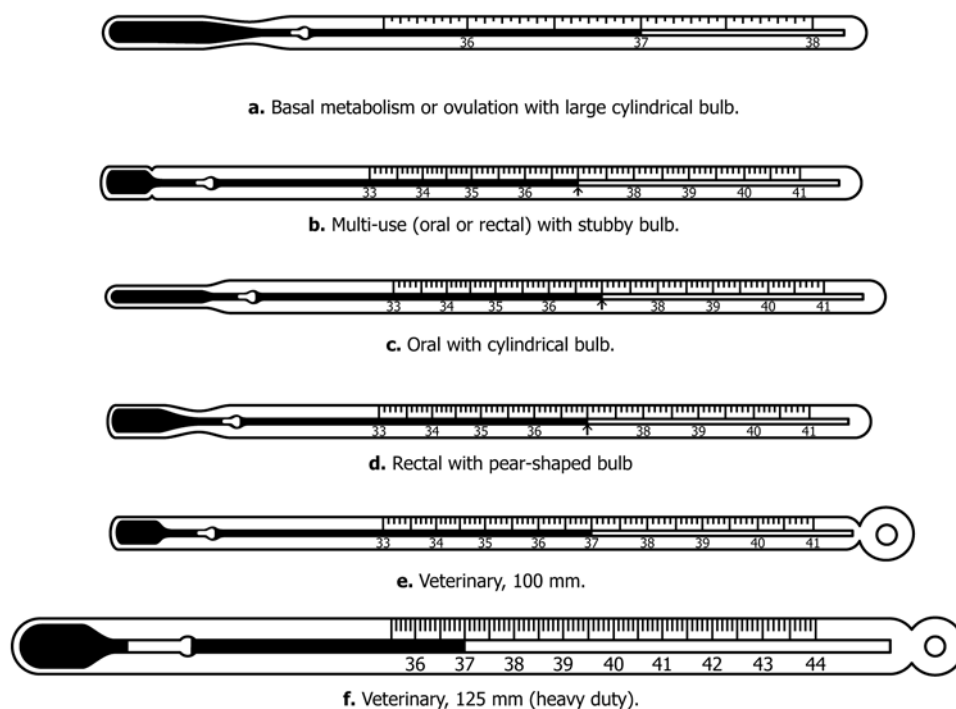


FIG. 2 Types of Clinical Thermometers (These sketches are for illustration only.)