TRAXIT®

Wearable Thermometer

Technical Safety and Manufacturing Information

The technology embodied in the TraxIt® Wearable Thermometers offers a unique combination of accuracy, speed, safety, convenience and economy in the measurement of temperature. This technology is highly competitive with both electronic and traditional mercury-glass thermometers. Its potential for consumer appeal is especially promising in view of the rapid growth and change in the thermometer market and the prohibition against mercury-glass thermometers in recent years.

Structure and Function

The TraxIt thermometer is a thin, flexible, heart-shaped piece of plastic with HyTape® latex-free adhesive. In the Fahrenheit version, the 55 cavities are arranged in a matrix in the center of the heart-shaped thermometer. The rows of the matrix are numbered in one-degree units. The columns are spaced at 0.2°F intervals covering the range of 94.0°F to 104.8°F. In the case of Celsius version, the 70 cavities are arranged in a double matrix in the center of the heart-shaped thermometer. The rows of the matrix are numbered in half-degree units. The cavities across the rows are spaced at 0.1°C intervals covering the range of 35.0°C to 41.9°C.

Each cavity contains a chemical composition comprised of three cholesteric liquid crystal compounds and a varying concentration of a soluble additive. These chemical compositions have discrete and repeatable change-of-state properties, the temperatures of which are determined by the concentrations of the additive. Additive concentrations are varied in accordance with an empirically established formula to produce a series of change-of-state temperatures consistent with the indicated temperature points on the device. The chemicals are fully encapsulated by a clear polymeric film, which allows observation of the physical change but prevents any user contact with the chemicals.

When the thermometer is placed in an environment within its measuring range, such as 98.6°F (37.0°C), the chemicals in all of the cavities up to and including 98.6°F (37.0°C) change from a liquid crystal to an isotropic clear liquid state. This change of state accompanied by an optical change that is easily viewed by a user. The green component of white light is reflected from the liquid crystal state but is transmitted through the isotropic liquid state and absorbed by the black background. As a result, those cavities containing compositions with transition temperatures up to and including 98.6°F (37.0°C) appear black, whereas those with transition temperatures of 98.8°F (37.1°C) and higher continue to appear green. As the temperature at the site (axilla) changes, either increasing or decreasing, more of the dots turn black or some of the black dots revert to green, thus yielding an updated axial temperature.

Reversibility

The TraxIt® wearable thermometer is designed to continuously monitor skin temperature. This continuous monitoring feature has been established in both *in-vitro* and *in-vivo* studies. The *in-vitro* studies were conducted in 20 water baths, spanning the thermometer's range in increments of 0.4°F (0.2°C). Thermometers placed in these water baths and repetitively immersed after five-minute intervals, gave consistent and accurate readings over both increasing and decreasing temperature sequences.

One important attribute of the automatic and complete reversibility of the TraxIt thermometer is that the product can be shipped and stored under conditions requiring no special precautionary measures. Tests indicate that the product can experience sustained environmental temperatures as high as 140°F (60°C) without compromising its accuracy and readability.

Accuracy and Response Time

The *in-vitro* accuracy of the TraxIt liquid crystal thermometer equals or exceeds that of glass-mercury and electronic thermometers. Millions of production units have shown agreement with calibrated water baths to within 0.2°F in the range of 98.0 – 102.0°F and within 0.4°F elsewhere (0.1°C in the range of 37.0 – 39.0°C and within 0.2°C elsewhere).

In-vivo tests at the University of Arizona resulted in excellent agreement with measurements using specially calibrated glass-mercury thermometers. The mean difference between the TraxIt thermometers and the calibrated glass-mercury equilibrium device was only 0.25°F (0.14°C). The TraxIt thermometer also achieves equilibrium very rapidly, due to its small "drawdown" (the cooling effect on tissue upon introduction of a room-temperature device) and the small amount of energy required to make the physical phase transition.

Safety

The TraxIt thermometer contains only 4 milligrams of liquid crystal chemicals. It is nonetheless desirable to assure the safety of these chemicals; and for this reason, the liquid crystal compounds have been the subjects of detailed toxicity, irritation and sensitization analyses. Parallel tests were applied to control substances formulated for daily oral use, consisting of a popular toothpaste and mouthwash. In all of these tests, the liquid crystal compounds proved non-hazardous, with fewer reactions than either the toothpaste or the mouthwash.

TraxIt® products and packaging are latex-free.

The innocuous nature of these liquid crystal compounds is also an important consideration with regard to the safety of production employees. TraxIt liquid crystal materials exhibit no measurable vapor pressure. There are no adverse effects on contact with the skin and these materials present no discernable risk to the employee.

Stability

The liquid crystal chemistry and encapsulating materials were selected so as to maximize shelf life under both normal and abusive storage and distribution conditions. Thermometers have a shelf life of 5 years from the date of manufacture.

Technical Advantages

Several technical advantages of the TraxIt technology contribute to making temperature taking less costly and burdensome to consumers and professionals than with any existing alternatives:

> ***Cost*** – The TraxIt temperature measurement technology provides lower costs when compared to other temperature devices.
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> ***Safety* –** The safety advantages of TraxIt technology are substantial. There is no danger, as with a conventional thermometer, of glass ingestion or mercury poisoning if a child bites the active part of the unit. TraxIt® and its packaging are latex-free.
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> ***Speed and ease-of-use* –** The TraxIt thermometer is quick, portable, non-breakable and easy to use (e.g. no shakedown or resetting).

Manufacturing Process

The process for manufacturing TraxIt thermometers is essentially a form, fill and seal operation. In the first step, preprinted plastic is embossed with a series of pins to form the cavities. Next, a complex multi-dispensing apparatus fills these cavities with the individually prepared chemistry thermometer points. Finally, a cover film is sealed to the base material, encapsulating the filled cavities. The individual thermometers then have a hypoallergenic latex-free adhesive (HyTape®) applied to their backs, are then die-cut from the web, inspected and suitably packaged. Each lot of the thermometers is sampled using a statistically sound sampling plan and tested for accuracy, appearance tests, etc.

Quality Control Procedures

Chemical Transition Temperatures

Each individual thermometer temperature point is checked for accuracy during chemical production.

In-process Control

Step 1: Each roll of web produced (8,600 units) is tested for accuracy in accordance with the QC specifications. Sequence (firing order) is checked periodically to confirm that the thermometers points fire one point after another in order.

Step 2: Every thermometer in each roll is inspected for fill, appearance issues and print quality. Any thermometer with a cosmetic defect is rejected.

Final Product Accuracy and Appearance Tests

Step 1: After final cutout, TraxIt® thermometers are 100% inspected for visual and cosmetic defects, cleanliness, etc.

Step 2: Samples are randomly taken from each roll of product (8600 units). The samples are tested for accuracy in seven temperature controlled water baths. The accuracy of these samples is determined using water baths that have been calibrated against the NIST reference thermometer.