



NEXTEMP®

Disposable & Reusable Thermometer

Technical Safety and Manufacturing Information

The technology embodied in the NexTemp® Disposable and Reusable 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 NexTemp thermometer is a thin, flexible, paddle-shaped plastic strip containing multiple cavities. In the Fahrenheit version, the 45 cavities are arranged in a double matrix at the functioning end of the unit. The rows of the matrix are numbered in one-degree units. The columns are spaced at 0.2°F intervals covering the range of 96.0°F to 104.8°F. In the case of Celsius version, the 50 cavities are arranged in a double matrix at the functioning end of the unit. 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 35.5°C to 40.4°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 is 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. After the thermometer is removed from the 98.6°F (37.0°C) environment and returned to room temperature, the black dots begin to return to their original green state after about 30 seconds, thereby providing the user with more than ample time to make a reading. NexTemp thermometers and their packaging are latex-free.

Reversibility

The NexTemp® thermometer is designed to return automatically to a reusable state (original green color) after a few minutes. Complete reversibility 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). NexTemp 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 NexTemp 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 NexTemp liquid crystal thermometer equals or exceeds that of glass-mercury and electronic thermometers. More than one hundred million 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 in the U.S., Japan and Italy resulted in excellent agreement with measurements using specially calibrated glass-mercury thermometers. The mean difference between the NexTemp thermometers

and the calibrated glass-mercury equilibrium device was only 0.12°F (0.07°C). The NexTemp 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 NexTemp thermometer contains only 2 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.

NexTemp® 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. NexTemp 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.

Insofar as it is desirable to clean and disinfect thermometers after each use, such sanitizing measures can be applied more efficaciously to the NexTemp device than to glass-mercury or electronic devices. Unlike these latter types, the NexTemp thermometer can be washed in warm soapy water or with an alcohol swab.

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 NexTemp technology contribute to making temperature taking less costly and burdensome to consumers and professionals than with any existing alternatives:

Cost – The NexTemp temperature measurement technology provides lower costs when compared to other temperature devices.

Safety – The safety advantages of NexTemp 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. NexTemp® and its packaging are latex-free.

Speed and ease-of-use – The NexTemp thermometer is quick, portable, non-breakable and easy to use (e.g. no shakedown or resetting).

Reduced chance of cross-contamination of patients – The NexTemp disposable product comes individually wrapped and is intended to be used and then discarded. The reusable version of the product is for single patient use over time with cleaning between uses.

Manufacturing Process

The process for manufacturing NexTemp ® 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 are inspected then die-cut from the web, ready for suitable packaging. 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 (29,000 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 marked by the inspector and is automatically rejected in the final cutout process.

Step 3: During final cutout, thermometers are continuously sampled and visually checked for cleanliness (free of adhesive and foreign matter), placement of the dots, miscuts, absence of filaments and other cosmetic defects.

Final Product Accuracy and Appearance Tests

Step 1: 500 samples are randomly selected from each roll of 29,000 units. 120 of these are tested for accuracy in the six temperature controlled water baths (20 units per bath). The accuracy of these samples is determined using water baths that have been calibrated against the NIST reference thermometer, which is certified by an independent laboratory annually.

Step 2: The 500 samples in step 1 are first examined from each roll are visually examined for major and minor defects. Defects exceeding thresholds established by a statistically sound sampling plan are cause for the roll to be rejected or undergo 100% inspection.

Calibration

The individual high-resolution mercury-in-glass thermometers used to measure the temperatures in each of the six temperature controlled water baths are calibrated against a National Institute of Standard Testing (NIST) thermometer every three months. The NIST thermometer is sent out annually to a certified independent laboratory for recertification. All water bath temperatures are set and maintained to within 0.02°F (0.01°C).

Administrative Control

An investigator from the United States FDA periodically inspects the company. This inspection measures the company's manufacturing and quality assurance practices against the FDA's published GMP standards and cites all adverse findings. A written response to such findings is required in which the company must present its plan for correcting any deficiencies. This plan must be implemented within the period allowed. In its last inspection of the manufacturing facility, the FDA reported no adverse findings.

The company is also audited annually by an investigator from the British Standards Institute (BSI). The company must take all corrective actions to deficiencies cited by the investigator on a timely basis in order to retain its European Certification (CE mark).

Quality control reports for each lot are retained in a permanent file. When requested, a Certificate of Conformance, signed by the regulatory manager, will be issued at the time of shipment.

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