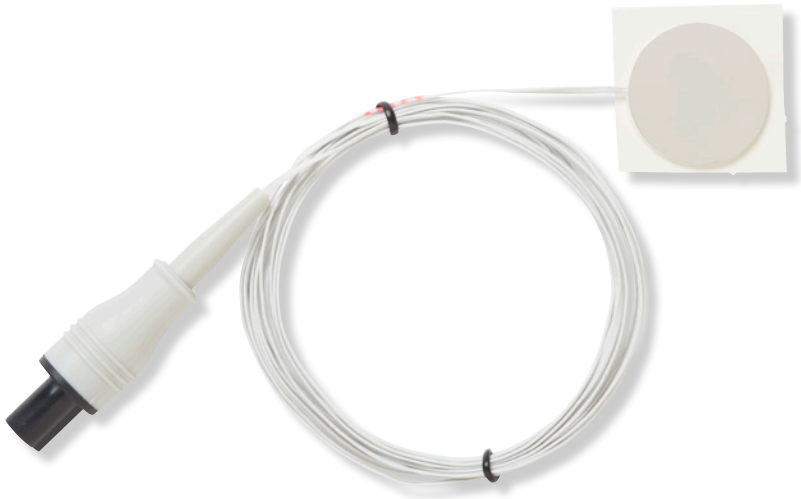
White paper

Skin temperature sensor testing

When newborn patients are placed into a radiant warmer or incubator, they are incredibly fragile—and the first few hours of their life are critical. These delicate patients cannot tell their doctor what is wrong, and they cannot regulate their body temperature. The clinical staff caring for the infant relies on the accuracy and display of body temperature via the skin temperature sensor(s).

Incubators and radiant warmers have at least one skin temperature sensor that is attached to the patient and monitors the baby's temperature. It is this sensor that indicates to the medical staff the temperature of the patient, aids in medical diagnosis, influences the set-point of the incubator/radiant warmer temperature, and alarms staff to potential dangerous environmental situations or a patient's condition.

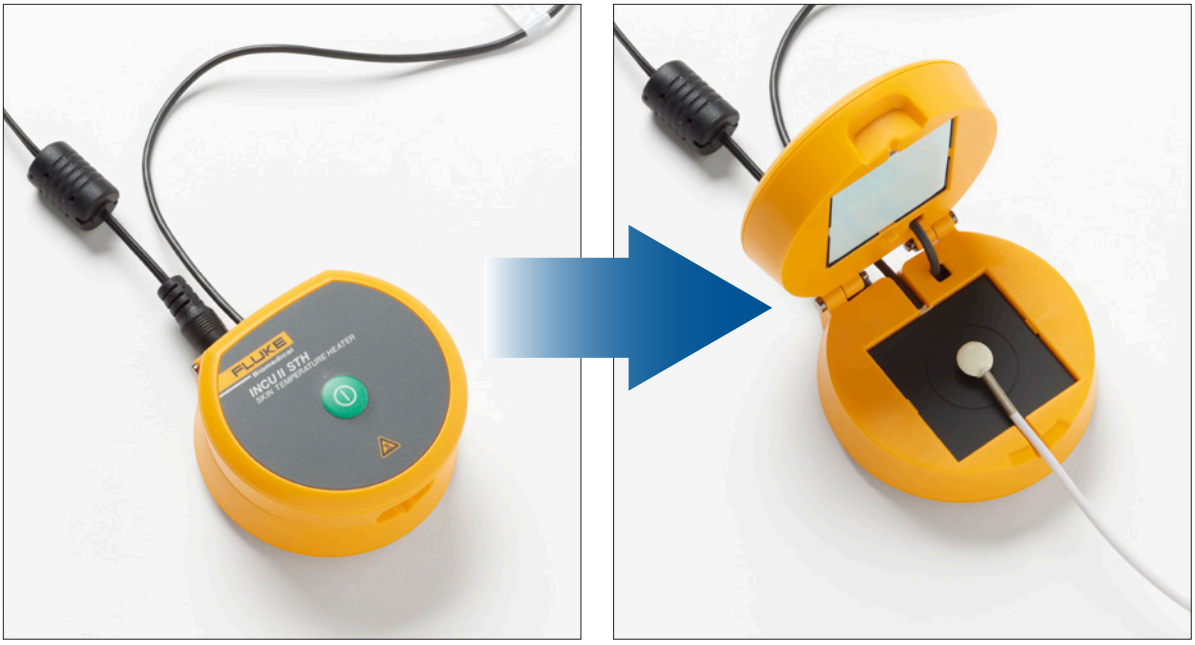
The importance of a skin temperature sensor's reliable and accurate performance is often misunderstood or eluded. Incubators and radiant warmers usually have two modes of operation: 1) manual temperature control, and 2) body temperature control. In manual temperature control, the nurses and clinical staff manually adjust the temperature of the incubator environment or radiant output of the radiant warmer to keep the patient warm. The temperature of the patient is monitored closely and constantly, with the medical staff heavily relying on the measurements and readings of the skin temperature sensor(s). In body temperature control, the medical device is



operating on a servo-control system in which the temperature or radiant output is automatically adjusted based on the temperature of the patient. Again, this temperature measurement is dependent on the skin temperature sensor.

It becomes obvious to see that if these skin temperature sensors are not working properly, it can have dire consequences for the patient. In several incidence reports, the patient harm was attributed to the poor placement and maintenance of the skin temperature sensors[1]. Testing skin temperature sensors is of vast importance and should be considered a mandatory part of performance inspection—but testing them accurately is the key to patient safety.

Traditionally, hot water baths with calibrated reference thermometers have been used to test the accuracy of skin temperature sensors. According to the IEC 60601-2-19 standards[2] for the basic safety and essential performance of infant incubators, the accuracy of the skin temperature sensor must be within ±0.3 °C. In a water bath test, the water must be kept nominally at 36 °C, the skin temperature sensor is immersed in the water, and a thermometer is placed adjacent to the sensor. The measurement taken by the skin temperature sensor, displayed on the DUT, should not vary by more than 0.3 °C, and the uncertainty must be ≤0.05 °C[2]. However, this can take a significant amount of time, is dependent on the degree of accuracy of the reference thermometer, and leaves room for human error.



The most reliable, repeatable, and accurate way to measure the skin temperature is with an external "oven"—a separate heating unit with a carefully controlled environment in which the skin temperature sensor is placed. The skin temperature sensor is simply plugged into the DUT's temperature control module, and the temperature-sensing part of the sensor is placed into the "oven"/heater. The difference between the skin temperature displayed on the DUT and the oven's temperature cannot vary by more than 0.3 °C.

This method reduces human error, is carefully controlled, repeatable, and can also help reduce test time. Furthermore, by using an analyzer specifically for incubator and/or radiant warmer testing, a full picture of device performance can be created. Rather than using individual measurements to manually plot data over time, or separately measuring parameters, an all-in-one analyzer such as the INCU™ II can help build a bigger picture of how each parameter is working in conjunction to create the environment the infant is feeling, and even display automated pass/fail indicators to aid in test analysis.

INCU II Incubator and Radiant Warmer Analyzer, testing an infant incubator.

INCU II with STHA for skin temperature sensor testing.

For complete testing, these analyzers should also include a separate “oven” or heater to test the skin temperature probe. For example, the Skin Temperature Heater Assembly (STHA) is simply plugged into the INCU™ II and the skin temperature sensor is placed inside the STHA box. Within minutes, a reading will be displayed to then compare against the DUT, verifying the accuracy of the skin temperature sensor.

Testing skin temperature sensors is a critical part of incubator and radiant warmer performance inspection and preventive maintenance. Using an external heater or “oven” to test skin temperature sensors helps ensure repeatability, accuracy, and conformance to standards, while saving time and reducing human error.

1. Maramkhah, F., MS. “Don’t let radiant warmers overheat infants.” *Nursing 2017: The Peer-Reviewed Journal of Clinical Excellence*. Nursing: March 2006, Volume 36, Issue 3, p 28. Device Safety. Web. May 2017.

2. IEC 60601-2-19 Standard.

To learn more about the INCU II Skin Temperature Heater Unit and INCU II Incubator/Radiant Warmer Analyzer and other neonatal test equipment from Fluke Biomedical, visit **www.flukebiomedical.com/INCU_II**

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