CorTemp® Core Body Temperature Sensor - Intended Use and Contraindications

INTENDED USE: The CorTemp® Core Body Temperature Sensor is designed for the measurement of core body temperature in individuals for whom accurate, continuous core body temperatures are required and may be used only on the order of a physician who has clinically evaluated the contraindications and warnings associated with the use of an ingestible thermometer sensor.

CONTRAINDICATIONS: The CorTemp® Core Body Temperature Sensor (HT150002) is contraindicated for HQI under the following conditions:

- In any subject whose body weight is less than eighty (80) pounds.
- In the presence of any known or suspected obstructive disease of the gastrointestinal tract, including but not limited to diverticulitis and inflammatory bowel disease.
- In any subject exhibiting or having a history of disorders or impairment of the gag reflex.
- In any subject with previous gastrointestinal surgery.
- In any subject having felinization of the esophagus.
- In any subject who might undergo Nuclear Magnetic Resonance (NMR) / Magnetic Resonance Imaging (MRI) scanning during the period that the CorTemp® Core Body Temperature Sensor is within the body.
- In any subject with hypomotility disorders of the gastrointestinal tract, including but not limited to Ileus.
- In any subject having a cardiac pacemaker or other implanted electromedical device.

WARNING: The following should be carefully considered before determining if the CorTemp® Core Body Temperature Sensor is appropriate for an individual:

The CorTemp® Core Body Temperature Sensor may not be appropriate in individuals who have experienced swallowing disorders. If an individual experiences difficulty swallowing the sensor, they may not be a candidate for CorTemp® Core Body Temperature monitoring. Careful consideration should be given before using the CorTemp® Core Body Temperature Sensor for temperature monitoring during abdominal or other surgery that might expose the sensor to ambient air and cause inaccurate temperature readings. Special consideration should be given to the placement of the CorTemp® Data Recorder when monitoring obese individuals. The CorTemp® Data Recorder may have to be repositioned as the sensor travels through the digestive tract. Also, the CorTemp® Core Body Temperature Sensor should be used with caution in any individual exhibiting nausea and / or vomiting.

Only one CorTemp® Core Body Temperature Sensor should be ingested at a time. The signals transmitted from multiple sensors could cause inaccurate temperature readings. If multiple sensors are to be used, be certain each previously administered sensor has passed before the individual is administered a new sensor.

HQInc. Wireless Sensing Systems & Design
www.hqinc.net

CorTemp®
Core Body Temperature Sensor
User Manual

HT150002

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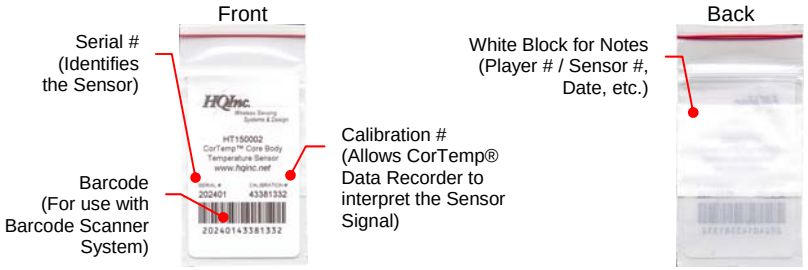
CorTemp® Core Body Temperature Sensor (HT150002)

The CorTemp® Core Body Temperature Sensor, or "Pill", is a one time use, small electronic device (0.88" Length x 0.42" Diameter) which senses core body temperature and transmits that temperature to a receiver positioned within a radial proximity (approximately 40cm) to the sensor. The sensor is intended to be swallowed and passes harmlessly through the gastrointestinal tract at the normal rate of motility which varies by individual. The CorTemp® Core Body Temperature Sensor is powered by a silver-oxide battery that will last for several days. The sensor components are encapsulated in an epoxy resin then coated in silicone. Each sensor has a unique calibration and serial number. These numbers MUST be entered into the CorTemp® data recorder to ensure accurate interpretation of each sensor's signal. Prior to ingestion, the sensor is activated by removing the small magnet attached to the orange Warranty Seal.

A. Sensor Storage

The CorTemp® Core Body Temperature Sensors are shipped with magnets attached. These magnets keep the sensors turned off. If the sensors are stored too closely together, in close proximity to metal objects such as metal drawers / shelving, or within electromagnetic fields generated by large equipment such as MRI, the sensors may turn on and drain the batteries. It is extremely important that individual sensors are stored with at least one inch separating each sensor. **NEVER** store the sensors in or near metal objects. The sensors are shipped within custom-made foam inserts to maintain constant separation between sensors. The sensors should be stowed in these foam inserts during storage. Use the *SENSOR TEST* feature of your CorTemp® Data Recorder to verify if stored sensors are turned off.

B. Sensor Packaging



The CorTemp® Core Body Temperature Sensor is intended for one-time use only. The sensor is factory calibrated and packaged in a sealed plastic bag. This bag should not be opened until the sensor is ready for use. A small magnet is attached to the sensor, which keeps the sensor turned off during storage. To activate the sensor, simply remove the magnet. Once the bag is opened, the sensor should be used immediately.
To turn the sensor off once the magnet has been removed, using *SENSOR TEST*, hold the sensor near the CorTemp® Data Recorder, making sure that you see *SENSOR ON* displayed on the CorTemp® Data Recorder screen. Move the magnet on the sensor until SENSOR OFF is displayed on the CorTemp® Data Recorder screen.

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C. Warranty Seal

Each CorTemp® Core Body Temperature Sensor is covered by a limited warranty. This warranty is evidenced by the bright ORANGE Warranty Seal placed around each sensor. HQI tests each sensor for accurate calibration and operation. If, for any reason, the CorTemp® Core Body Temperature Sensor fails to operate, it may be returned to HQI for replacement at no cost to the user, as long as the Warranty Seal is unbroken.

D. Administering the Sensor and Checking the Signal

Before administering the sensor, be sure to review the *Intended Use / Contraindications* for the CorTemp® Core Body Temperature Sensor on the back cover of this manual. ***NOTE: The sensor should be administered at least 3-4 hours before monitoring begins, preferably before a meal, to ensure the sensor has transitioned from the stomach to the intestinal area.***

To administer the CorTemp® Core Body Temperature Sensor, do the following:
(Refer to *CorTemp® Core Body Temperature Monitoring System* manual for Data Recorder operation)

1. Enter the pill's unique calibration number into the sensor schedule in the recorder.
2. Remove the magnet from the CorTemp® Core Body Temperature Sensor.
3. Verify the sensor signal using the *SENSOR TEST* function.
4. From *EXIT / STBY* mode, press *READ* to take a manual temperature reading. A temperature reading will verify communication between the sensor and the CorTemp® Data Recorder.
5. Hold the sensor in the palm of the hand, allowing the sensor to warm. Take another manual temperature reading to verify a change in temperature.
6. Remove the sensor Warranty Seal.
7. Give the sensor to the subject to swallow with a glass of tepid water.

E. Limited Warranty

HQ, Inc. warrants for a single use and to the original purchaser that the CorTemp® Core Body Temperature Sensor and the component parts thereof, will be free from defects in workmanship and material and may be stored for a period of three (3) months from the date of purchase. This assumes that all storage instructions described in Section A of this manual have been observed. All functional testing may be accomplished with the Warranty Seal in place and it should not be removed until the user has determined that the sensor is functioning properly. Once this seal has been removed, the sensor will be deemed to have been used and all warranties are void.

HQ, Inc. will, without charge, replace the defective CorTemp® Core Body Temperature Sensor within 90 days of receipt of product. An RMA number must be obtained prior to return of the equipment. Contact Customer Service at (941) 721–7588 for an RMA.

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