



Ingestible Core Body Temperature Sensor

Item No. HT150002/HT150031

Intended Use/Contraindications

INTENDED USE: CorTemp® is indicated for one time use and for the measurement of core body temperature in patients for whom accurate continuous core body temperatures are clinically necessary for periods exceeding six (6) hours and with whom rectal and tympanic catheters are not appropriate. CorTemp® can only be used on the order of a physician who has clinically evaluated the contraindications and warnings associated with the use of an ingestible thermometer, tympanic probe, or rectal probe.

CONTRAINDICATIONS: The CorTemp® Disposable Temperature Sensor (HT150002) is contraindicated for use under the following conditions:

- In any patient 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 patient exhibiting or having a history of disorders or impairment of the gag reflex.
- In any patient with previous gastrointestinal surgery.
- In any patient having felinization of the esophagus.
- In any patient who might undergo Nuclear Magnetic Resonance (NMR) or MRI scanning during the period that the CorTemp® Disposable Temperature Sensor is within the body.
- In any patient with hypo motility disorders of the gastrointestinal tract including but not limited to Ileus.
- In any patient having a cardiac pacemaker or other implanted electro medical device.

WARNINGS: The following should be carefully considered before determining the CorTemp® Ingestible Temperature Sensor is appropriate for any particular patient:

The CorTemp® Disposable Temperature Sensor may not be appropriate, and should only be used with care, in patients who have experienced swallowing disorders. If a patient experiences difficulty swallowing the CorTemp® Disposable Temperature Sensor, they may not be a candidate for CorTemp® monitoring. Careful consideration should be given before using the CorTemp® Disposable Temperature Sensor for temperature monitoring during abdominal or other surgery that might expose the sensor to ambient air and cause erroneous temperature readings. Careful consideration should be given before using the CorTemp® Disposable Temperature Sensor with obese individuals. The CorTemp® Disposable Temperature Sensor has a radial range of approximately 24 inches from sensor to antenna. In certain obese individuals, sensor transmitting range might be exceeded because of the patient's girth. If it is suspected this range may be exceeded, CorTemp® may not be appropriate for that patient.

Only one CorTemp® Disposable Temperature Sensor should be ingested at a time as the signals transmitted from multiple sensors could cause erroneous temperature readings. If multiple sensors are to be used, be certain each sensor has passed before the patient is administered a new sensor. The CorTemp® Disposable Sensor should be used with caution in any patient exhibiting nausea and/or vomiting.

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