Ingestible Core Body Temperature Sensor

# ETHICS-CORTEMP-021

# Document Sign-offs

|  | Name/ Title | Date |
| --- | --- | --- |
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| Approved By |  |  |

# Current Status

In Review

# Revision information

Revision No: 1.0

Effective Date:

Next Review Date: (Take date from Revision History below)

# Glossary of Terms

CorTemp: The **Core body temperature monitoring system** wirelessly transmits core body temperature as an orally ingested pill is in the gastrointestinal tract. The sensor’s signal passes harmlessly through the body to the CorTemp™ Data Recorder worn on the outside of the body or in close proximity to the body. This system is designed for human use only and emits a signal at 262 kHz.

# Purpose

To provide guidance on the use of the CorTemp core body temperature monitoring system.

# Scope

REB members

Researchers

# Responsibility

Indicate what specific training the principal investigator will provide any members of the research team using this device or obtaining consent to use this device.

# Distribution of Copies

To be posted on the Research Ethics website. Copies should be distributed to all members of the research team undertaking this type of work.

# Procedure

1. Administer the medical questionnaire. Ensure that you engage one on one with each participant to ensure that accurate responses are being provided.
2. Arrange a time to meet with the participant at least 3-6 hrs prior to the exercise trial. Give the participant the core temperature (Tc) thermistor pill only at the time of the meeting to prevent mishandling and ensure that the thermistor is swallowed at the appropriate time and in the company of the principal investigator.
3. Put on gloves prior to handling the Tc thermistor.
4. Remove the Tc thermistor from the package.
5. Remove the sticker with magnet from the Tc pill. The pill is now activated and is able to sense changes in temperature.
6. Give the Tc pill to the subject with 250 mL of fluid. Instruct the participant to swallow the pill and drink the fluid provided. Make sure you watch the participant to ensure they have no difficulty swallowing the thermistor.
7. Before leaving the participant, input the calibration number found on the package, into the recording device and ensure a signal is being detected and a measurement is being transmitted.
8. Ensure that the participant puts on a wristband indicating the presence of a silveroxide battery and stress that this wristband must be left on until it is confirmed using the recorder that the device is no longer in the participant’s body.

# Wording for Medical Questionnaire

Ensure that the medical questionnaire collects the following information from the participant. Use is contraindicated 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.
* Ask the participant if they have had any previous issues with swallowing food or vitamins etc. and/or have been told by a physician that they have a narrowing of the esophagus. \*\*\*If the participant answers ‘yes’ to the above questions, DO NOT PERMIT the participant to swallow the core temperature (Tc) pill.

# Wording for Consent Forms

You will be asked to swallow a radio pill, about the size of a large vitamin pill, which will monitor your core temperature.

The CorTemp™ sensor is categorized as a disposable, non-invasive medical device commercially developed and distributed by HQ Inc. (Palmetto, FL. It has not been approved for use in Canada by Health Canada.

The sensors (over 30,000) have been previously used in research, military operations, and sports physiology application without any reported negative incident. This core temperature pill will record temperature continually while within range of the handheld monitor.

Specific contraindications for use of the radio pill include,

* individuals weighing less than 36 kg
* obstructive diseases of the gastrointestinal (GI) tract
* inflammatory bowel disease
* history of intra-abdominal surgery
* impaired gag reflex
* esophageal disorders
* hypomotility of the GI tract
* having a cardiac pacemaker or other implanted electro medical device

Until the pill has been excreted, which may vary from 24-72 hours, you should not undergo magnetic resonance imaging (MRI) due to strong radio frequency have the theoretical potential to disrupt the pill’s silveroxide battery which could cause chemical burns or irritation of the intestinal tract if it were to rupture.

Additionally, regulations related to commercial air travel restrict the use

of devices that emit radio frequencies and therefore, participants should not fly

prior to passing the ingestible core pill.

You will be given the opportunity to return to the lab following the experimental trial to ensure that the telemetric pill has passed through the gastrointestinal tract. If the handheld monitor cannot connect to the telemetric pill, it can be assured that the core temperature has been excreted. Until you are certain that the telemetric pill has been passed, you will be required to wear an orange wristband indicating the presence of a silveroxide battery within your body. This wristband will be given to you prior to the ingestion of the core temperature pill.

If you experience any constipation following the ingestion of the telemetric pill, an over the counter laxative could be used to aid in the passing of the pill.

# Wording for Website

SOP will be posted on the website.

# Documentation/Record Keeping

Researchers must keep a record of who receives CorTemp sensor, when it was ingested, and when confirmation is obtained that it is no longer in the body.

# External Regulatory Requirements

n/a

# Internal Related, or Referenced Policies, Procedures

n/a

# References

n/a

# Revision History

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| 1.0 |  |  |  |  |

# Review Cycle

Click on here to enter sources of documents used to write the procedure

# Appendix

Appendix 1: Intended Use/Contraindications provided by CorTemp.

Appendix 2: Letter (supplied by CorTemp) from Department of Health and Human Services indicating that the CorTemp can be marketed in the US. Note that this letter indicates that it is not FDA approval.

Appendix 3: Letter from Dr. S. Collins attesting to safety of this product.