Case study: Non-invasive core body temperature measurements during sleep and daily life with greenTEG gSKIN® BodyTemp KIT measured on the wrist

greenTEG AG, 8005 Zürich, Switzerland, Contact: lukas.durrer@greenTEG.com

1. Abstract

In this study, we present the world's first solution to accurately measure core body temperature (CBT) for low activity, e.g. sleep, on the wrist.

The study consists of 20h measurements of 6 healthy candidates between 25 and 70 years old in the sleep-wake laboratory of a university hospital. For the thermal resistance compensating algorithm a PPG signal, two heat flux signals, a skin temperature signal and an accelerometer signal were combined resulting in an **accuracy of <0.15° C** measured on the wrist.

The measurements nicely resolve the temperature cycle between the highest value during daytime of ~37.5 °C and lowest value during nighttime ~36.5 °C that are highly related to the circadian cycle, an important signature for early diagnostics, ovulation tracking, burn-out syndrome, and sleep quality.

"This is the ultimate medical grade solution for any smartwatch or wristband"

2. Introduction – relevance of core body temperature measurements

Early diagnosis of diseases is a powerful tool to increase quality of life and at the same time a promising way to stop or at least slow down the cost explosion of healthcare in developed countries. Wearable devices are recognized as a key technology for early diagnosis because they allow a continuous monitoring of a human's key vital parameters. Combining continuous monitoring of vital signs with state-of-the-art data analysis (big data or machine learning for example), early detection of health issues becomes possible. Besides heart rate, oxygen saturation, blood pressure and respiration rate, core body temperature (CBT) is among the five most important vital parameters of a human being. While heart rate, oxygen saturation and respiration rate are commonly measured in state-of-the-art wearable devices, non-invasive core body temperature and blood pressure sensors are not yet available.
Several scientific studies have concluded that major health disorders such as chronic stress [Oka 2001], insomnia [Lack 2008], Alzheimer's disease [Musiek 2015] and Parkinson's disease [Zhoung 2013] have repercussions on one's core body temperature. CBT is also an important indicator for healthy people when they travel (jet lag [Kojima 2013]), for athletes willing to maximize their performance during competition [Rosa 2016], for detecting ovulation [Baker 2001] or for preventing heat stroke.

According to scientific literature, a key parameter for non-invasive and continuous core body temperature measurement is the heat flux from the human body to the environment [Gunga 2008, Niedermann 2014].

greenTEG produces highly sensitive and robust heat flux sensors that are small enough to be easily integrated into any wearable device and smart textile. For demonstration purposes, greenTEG has developed the gSKIN® BodyTemp KIT for measuring core body temperature at different body parts.

3. Measurement equipment – The gSKIN® BodyTemp KIT

The gSKIN® BodyTemp KIT consists of a standalone three-channel data logger, up to three gSKIN® BodyTemp sensors and a readout software for downloading recorded measurement data via a USB linked to a PC (Figure 1). The BodyTemp sensors are provided with single-use dermal foam patches for a reliable attachment to the skin. This allows integrating the measurements into the daily routine of a person. Compared to greenTEG's previously shown body temperature sensors the newly developed BodyTemp sensor consists of two heat-flux sensors (Figure 2), a skin temperature sensor and an accelerometer.

Figure 1: gSKIN® BodyTemp data logger and sensor

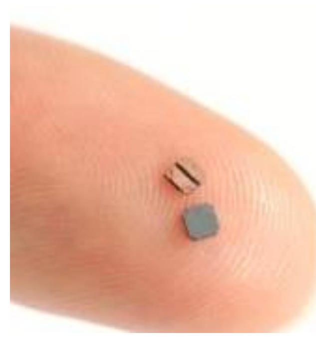


Figure 2: gSKIN® XU heat flux sensor for SMD integration into any wearable; the core element for accurate CBT measurements

4. Experimental set-up

Measurement procedure

The clinical trial of this study is still ongoing and is performed at the sleep-wake laboratory of the university hospital in Bern. So far 6 candidates between the ages of 25 to 70 years participated. All candidates are healthy people. A previously made questionnaire confirmed that no sleep disorder is present.

The candidate swallowed three reference temperature pills 3, 6 and 9 hours prior to the arrival at the hospital. An ingestible radio pill was selected for this purpose (VitalSense Capsule by Respironics Inc., USA, Equivital™ LifeMonitor, Hidalgo Ltd, UK).

Besides the common sensors used for sleep analytics in the hospital, each candidate was equipped with the new BodyTempKIT sensor from greenTEG. The sensor was placed on the upper part of the wrist using the dermal foam patch. PPG was measured directly adjacent to the greenTEG sensor using a common PPG sensor provided by one of greenTEG's customers. Figure 3 shows a fully equipped candidate showing greenTEG's BodyTemp sensor on the wrist.

Each candidate performed two measurement phases. The first phase was a common sleep measurement starting around 9pm to around 6am in the next morning. The second measurement started at 9am in the morning usually to 6pm in the evening. Between the two measurement cycles, some sensors were removed to allow the candidate to have breakfast and also to recharge batteries where needed. During the day measurement, the candidate was either resting in bed (30 min) or trying to stay awake in a dark room (30 min). The room temperature was kept constant by the air-condition system of the hospital.

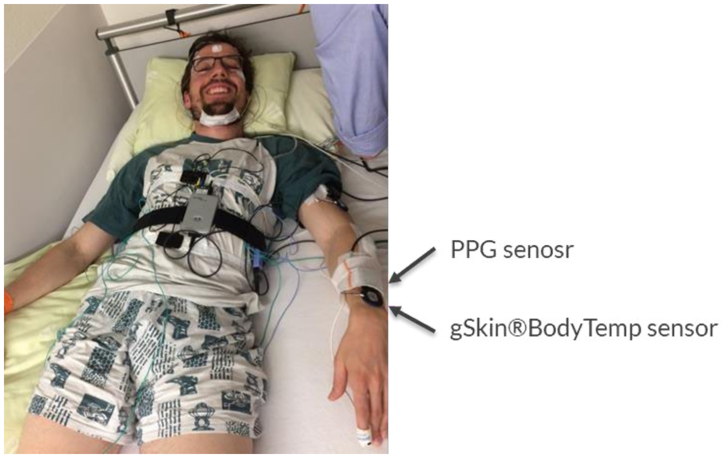


Figure 3: Fully equipped candidate ready for the experiment in the sleep lab. The greenTEG BodyTemp sensor is (for example) placed on the wrist of the left hand.

Data analysis

In the study only raw value were recorded. greenTEG's wrist algorithms were applied to these values and plotted against the core pill reference. Since each person's skin is different due to individual body physiology, a skin factor was introduced in the algorithm. In a future version of the algorithm this skin factor will be determined by a calibration routine. However, to illustrate a worst-case scenario all calculations use the same average skin factor for all patients.
The mean of the difference signal (bias) and the standard deviation of the difference signal (SD) were both calculated. The limit of agreement was defined as ±1 SD.

5. Results and discussion

Figure 4 shows a 20 h core body temperature measurement of a candidate recorded in the controlled hospital environment in the sleep-wake laboratory. The blue dotted lines represent the reading from the reference radio pill, which were swallowed prior to the measurement. The red line shows the (algorithm-driven) core body temperature estimation based on non-invasive measurements on the skin recorded with the greenTEG BodyTemp KIT. These measurements nicely reflect the temperature change based on the circadian cycle over 24h of a healthy person. The temperature drops from approximately 37.4 °C in the evening to approximately 36.5 °C at 6am. During the day, the temperature rises again almost to the original temperature of 37.4 °C.

As mentioned above heat flux and skin temperature were recorded at the wrist. The red line in the graph shows core body temperature estimation based on these recordings using greenTEG's algorithm.

By subtracting each measurement point from the average radio pill value the mean deviation was determined. The mean deviation to the mean core pill signal over 24h is 0.15°C with a standard deviation of 0.1°C. Please note that the radio pills themselves have deviations of 0.1°C.

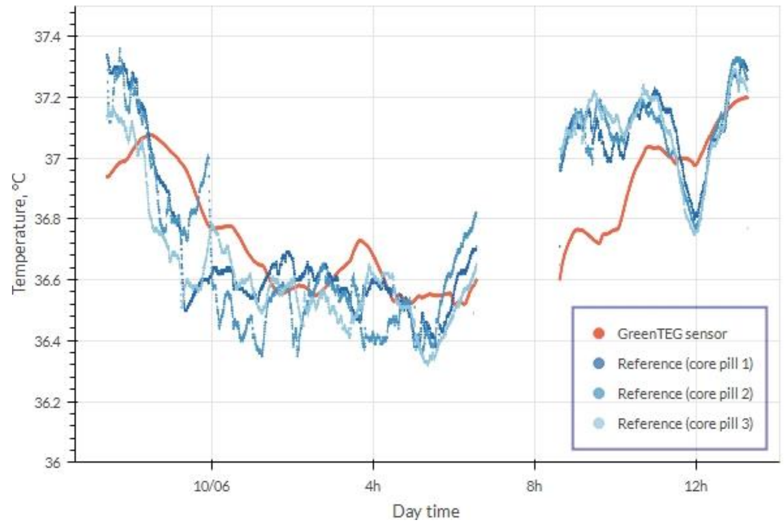


Figure 4: Typical 24h trend of the core body temperature of a healthy candidate with the temperature cycling between 0.5 to 1°C between day and night caused by the circadian cycle. Red line: The core body temperature estimation based on non-invasive skin measurements at the wrist with greenTEG's algorithm solution. Blue lines: The temperature measured in the intestines by reference temperature pills.

As shown in Table 1 the mean deviation (over all candidates) of the core body temperature from the average core pill to the algorithmic one is 0.15 ± 0.1 °C when the skin factor is adapted to each candidate. The personalized skin factor values can be calibrated within the first hour using a reference temperature measured in the ear. In a worst-case scenario an average skin factor can be assumed resulting in a mean deviation of 0.26 ± 0.16 °C.

Table 1: Deviations of the calculated core temperature from the average core pill temperature of all 6 candidates using a personalized and a constant skin factor.

	Mean deviation	Sigma of the mean deviation
Personalized skin factor	0.15 °C	0.1 °C
Constant skin factor	0.26 °C	0.16 °C

6. Conclusions

The gSKIN® BodyTemp sensor solution from greenTEG is able to monitor core body temperature non-invasively and continuously on the wrist during a 24h cycle of sleep and low activity in a controlled environment with an relative accuracy of 0.15 °C. In the authors perspective the achieved accuracy is sufficient to resolve the main features of the circadian cycle, i.e. time of lowest core temperature and amplitude of temperature reduction.

7. Outlook

With the accuracy achieved so far the following use cases can be addressed: Early diagnostics, patient monitoring, ovulation tracking and sleep quality monitoring. Studies investigating free living conditions including higher activity with CBT measurements on the wrist are already planned and interested parties are invited to contact the author for details or participation requests.

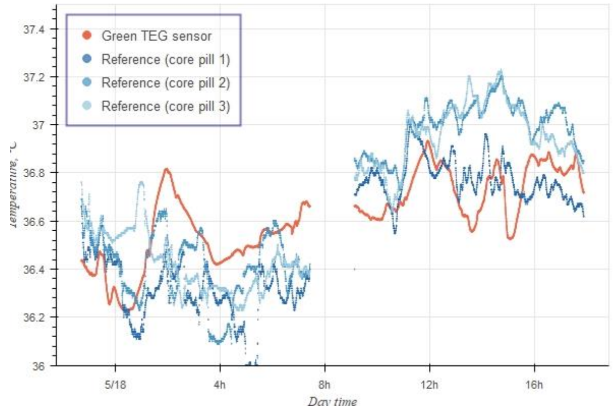
8. Acknowledgement

We would like to thank the Swiss government to the "commission for technology and innovation" for project founding , to the sleep and awake center of the university hospital of Bern and the Zürich University of Applied Science for the support in data analysis.

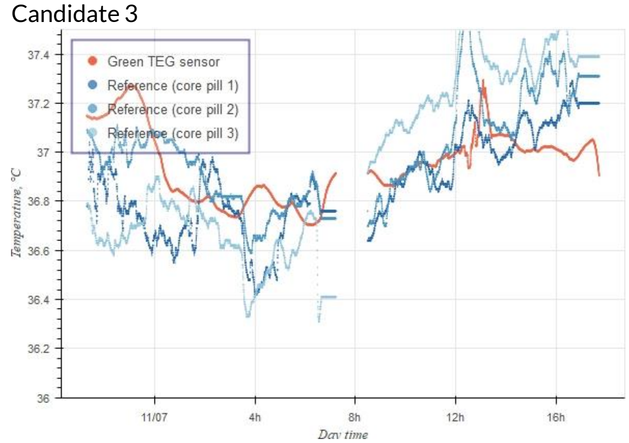
9. Appendix

In the following, all measurements of the 5 additional candidates are shown

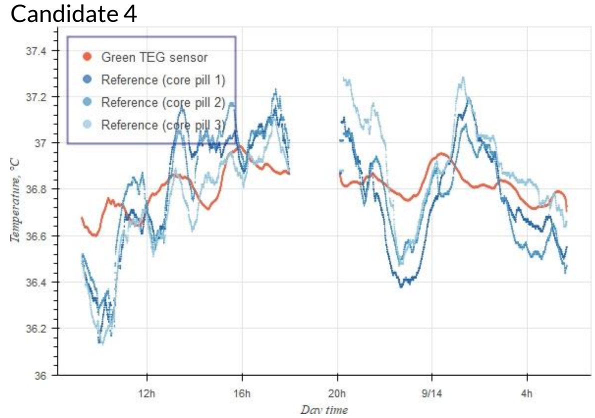
Candidate 2



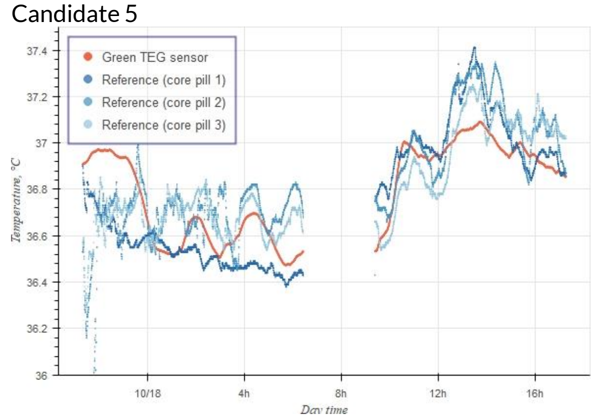
Candidate 3



Candidate 4



Candidate 5



Candidate 6

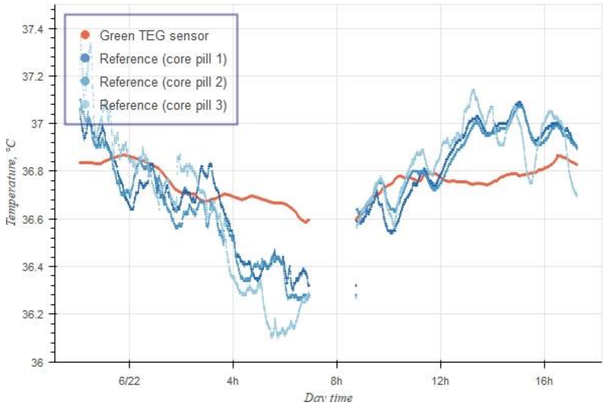


Figure 5: 20h measurements of the core body temperature of 5 additional healthy candidates. Red line: core body temperature estimation based on non-invasive skin measurements at the wrist with greenTEG's algorithm solution. Blue lines: temperature measured in the intestines by reference temperature pills.