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An Ergonomic Wearable Core Body Temperature Sensor

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***Abstract*— The observation of core body temperature is important for several hospital and home patients, especially those who have undergone surgical interventions. To provide a continuous estimate of core body temperature, previous approaches have focused on embedding sensors or designing forehead patches that use single or dual heat flows. This work proposes a foam-based Y-shaped sensor with flexible electronics and focuses on the ergonomic aspect. We developed a laboratory setup to derive the heat-flow parameters then tested the sensor on 10 volunteers who wore it on two locations: the forehead and behind their ear (mastoid area). An existing zero-heat-flux sensor (SpotOn by 3M) was used as reference. The sensor had an average heat-up time of 7.7 minutes and a mean error of 0.10 ˚C for the forehead and a heat-up time of 6.9 minutes for the mastoid area with a mean error of 0.03 ˚C. This ergonomic sensor has the potential for continuous core body temperature measurement for mobile patients. The next steps include testing the sensor in a hospital environment and validating it with respect to standard core body temperature sensors, such as esophageal or rectal probes.**

I. Introduction

Core body temperature (CBT) is the operating temperature in deep structures of the body such as the liver, brain and heart. It is normally maintained within a narrow range for healthy subjects (36.5˚C - 37.5˚C) so that the essential homeostasis is not disturbed. However, this is not the case for several groups of patients both in and out of the hospital. A change in CBT can be due to interventions (such as anesthesia during surgery), pathologies, infections and deteriorating conditions. For surgical patients, having intraoperative hypothermia causes serious complications including surgical wound infections and myocardial complications [1]. It also decreases drug metabolism, prolongs recovery, and provokes thermal discomfort. Therefore, clinicians ensure that patients are warmed enough, and their temperature is maintained in a comfortable range throughout the peri-operative journey. Direct measurement of CBT involves using probes (such as esophageal or rectal probes) which are not practical for awake and ambulatory patients. Alternatively, CBT is estimated by using mercury or in-ear thermometers (infrared sensors). These measurements are not continuous and can suffer from inaccuracy [2].

To address these problems, several research groups have focused on the non-invasive measurement of core body temperature that can be done via active or passive sensors. Active sensors involve using a self-heating layer leading to zero heat flux, ensuring that the temperatures measured on the skin surface match CBT. These sensors have shown promising results for non-ambulatory patients [3]–[5]. However, the need for a continuous warming element makes this technology difficult to implement for wearables. Passive sensors on the other hand do not require a heating element and use heat flows through the sensor to estimate CBT. These sensors include single [6] and dual heat flux methods [7], [8]. Single heat flux technologies focus on measuring a single heat flow through a well-insulated sensor, whereas dual heat flux measures two heat flows through materials of different thermal resistance or thickness to derive core body temperature. Although both technologies have shown promising results, ergonomics and underlying skin anatomy leading to uneven thermal distribution still remain an issue, with most of the previous approaches proposing a forehead patch, or even two [8]. This work focuses on developing an ergonomic Y-shaped sensor with passive heat flux technology using several vertical flows, which are outward heat flows from the skin in a perpendicular direction. The sensor was validated versus high accuracy gold-standard thermometers in the laboratory, then tested on healthy subjects in two positions: the forehead and behind the ear.

II. Methods

A. Sensor design, materials and form factor

Sensor design involved the observation of clinical teams and patients throughout the perioperative period as well as intensive care units. We aimed for anatomical locations that are accessible and relatively constant for different patients observed during their peri-operative journey. In particular, we investigated the forehead and the mastoid area, or area behind the ear. Fig 1 shows images from a thermal camera, which was used to observe the overall skin temperature profile for these areas. This was done to determine the influence of the underlying skin anatomy and the effect of vasculature distribution. We found that differences up to 2˚C can be detected between the highest and the lowest temperature points on the skin (even after placing an insulating layer on the skin for several minutes). Thus, instead of relying on one pair of thermistors, we decided to use 3 pairs and select

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maximal values for calculation. The sensor we developed is shown in Fig 2. This sensor can fit on the side of the forehead as well as behind the ear. The sensor prototype consisted of foam body layer, closed cell polyethylene foam thermal isolation layer and thermistors placed in the positions shown. The flexible foil PCB connecting the thermistors was routed in a curly shape to give the sensor improved flexibility and adhesion to the body.

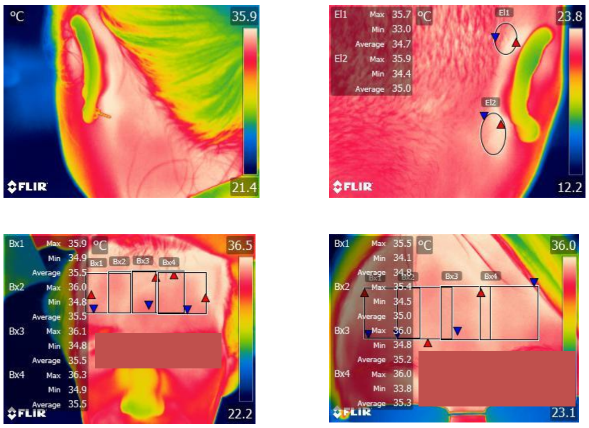


Figure 1. Thermal camera images showing the variability of the temperature profile behind the ear and on the forehead. White areas show higher temperatures.

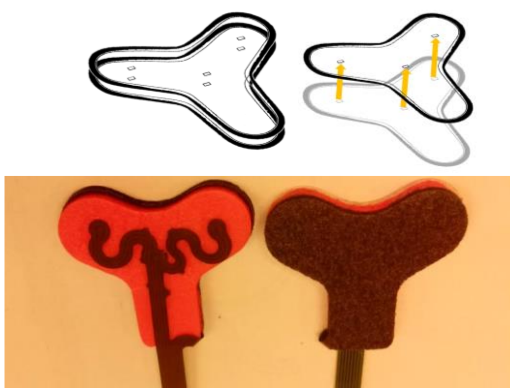


Figure 2. Design of the Y-shaped sensor, showing the position of the three pairs of thermistors and use of 3 heat flows.

The sensor has a width of 44 mm. The thickness of the red foam layer in Fig. 2 was chosen to be 3 mm, to allow a significant heat flow from the body towards the sensor. In addition, a 2 mm thick top layer of foam (darker color in the figure) was used for isolation, ensuring minimal influence from ambient temperature variations to the top layer. A low cost Negative Temperature Coefficient, 18 series thermistor from Murata was chosen to measure temperature. The miniature size (1.6 mm x 0.8 mm) of this thermistor fulfills the compact patch design requirements for a wearable sensor. The foam material used in the sensor is Polyethylene (PE) foam, which is a flexible, lightweight and closed cell foam. With comparatively low thermal conductivity 0.035 W/mK, it can provide good thermal isolation from ambient temperatures. To make sure the sensor has good adhesion to skin, we used a double-coated Polyethylene tape from 3M (with a thickness of 0.16 mm so it does not affect the heat flow through the sensor).

As shown in Fig 2, the sensor has three identical pairs of thermistors, situated at equivalent locations in the sensor plane. This is done to address the unevenness of the skin temperature profile (as shown in Fig 1) and make sure we capture the maximal heat flow.

B. Derivation of core body temperature

Fig 3 shows a simplified heat flow between two layers (among one pair of thermistors). In fact, the thermistors are placed in two locations: on the sensor near the skin measuring T_1 (the bottom or skin temperature) and T_2, the top temperature that is covered with an insulating layer (the darker layer in Fig. 2). Equation (1) models the heat flow starting from the core body temperature T_0 (the temperature to be estimated) outward. We assume a linear flow for a simplified estimation during equilibrium. However, this is not the case for the sensor during heating up and cooling down stages.

$$T_0 = T_1 + \frac{R_0(T_1 - T_2)}{R_1} \quad (1)$$

or, equivalently,

$$T_0 = T_1 + \alpha(T_1 - T_2)$$

Where $\alpha = \frac{R_0}{R_1}$.

R_0 is the thermal resistance of the body (area under the sensor)
R_1 is the thermal resistance of the sensor measured between the bottom layer and the top (insulated) layer.

To apply equation 1 to the sensor in this work, we write the core body temperature as:

$$T_C = T_{bottom} + \alpha \emptyset_{vertical} \quad (2)$$

Where T_C is the estimated core body temperature. T_{bottom} is the maximal temperature among the three thermistors on the bottom layer of the sensor. $\emptyset_{vertical}$ is the corresponding vertical heat flow between the bottom thermistor with the highest temperature and its corresponding top layer thermistor.

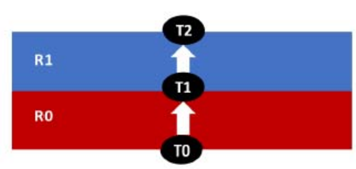


Figure 3. The heat flows across the 2 layers- from the body outwards.

C. Experimental set-up

To test the sensor, a laboratory set up was designed to estimate the parameters for heat flow. This setup consisted of a hot plate (to mimic core body temperature in the human body) covered by a silicone material with a similar thermal resistance to human skin. For reference, a Pt1000 platina temperature sensor was embedded in an aluminum plate of 3 mm thickness and 50x50 mm area, and placed under the silicone layer. The temperature measured by the reference sensor is referred to as T_{ref}. Using the adhesive, the CBT sensor was then attached to the silicone layer. It was connected to a data logger (Grant 2040 series Squirrel Data Logger) via a connecting cable. Temperatures were recorded for each of the 6 thermistors and the reference temperature sensor at a frequency of 1 Hz. The hot plate functioned as a heating source with temperatures ranging from 20 to 40˚C. In reality, the hot plate cannot truly reflect human temperature due to its much faster controlled step response. The change in temperature is slower in humans. Nevertheless, if the sensor were able to track the temperature change of the hot plate, then in principle, it should be able to track much slower human body temperature changes.

A calibration of the thermistors was performed. This included placing the sensors in a water bath and measuring the resistance of thermistors at different temperatures then using the manufacturer's formula to calculate temperatures [9].

III. Results

A. Derivation of sensor parameters

To estimate α, a staircase experiment was conducted using the experimental setup with the sensor placed on the silicone layer over the hot plate. The temperature of the hot plate was increased by 0.5˚C every 30 minutes starting from 37 to 40˚C as shown in Fig 4.

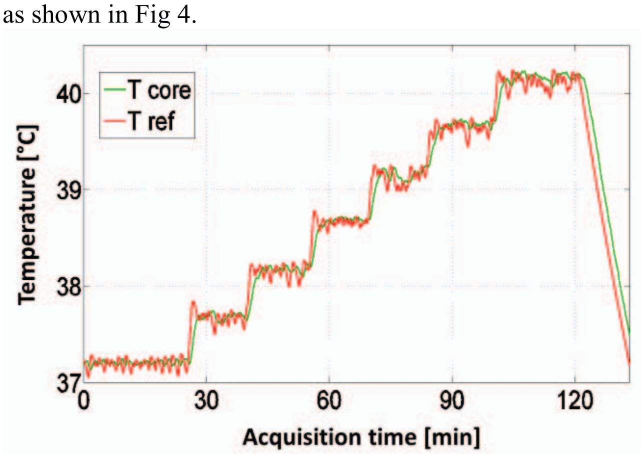


Figure 4. The figure shows the reference temperature T_{ref} in red and the core temperature as estimated using linear least square method.

A linear least square method was utilized to fit a linear model to the data using T_{ref} as an objective function. Thus, the parameter α was estimated to find the minimal values that satisfy the following equation:

$$\min_{\alpha} ||T_{ref} - T_{bottom} - \alpha \emptyset_{vertical}|| \quad (3)$$

Two sets of heat-up experiments were done using two different sensors (Y1 and Y2) placed in close locations on the silicone layer. The parameter α estimated from both experiments is shown in Table I with a mean value of 0.3.

TABLE I
Estimation of the Parameter α

α	Sensor Y1	Sensor Y2
Exp.1	0.2940	0.3107
Exp.2	0.3100	0.2894
Mean α	**0.3010**	

B. Measurement of heat-up time

Using the estimated values of the parameter, we conducted an experiment to measure the heat-up time of the sensor. This is the time needed for the temperature to reach thermal equilibrium. A non-heated sensor was placed on the plate of 37˚C. The sensor heat up time is around 6 minutes in total (reaching thermal equilibrium) - shown in Fig 5.

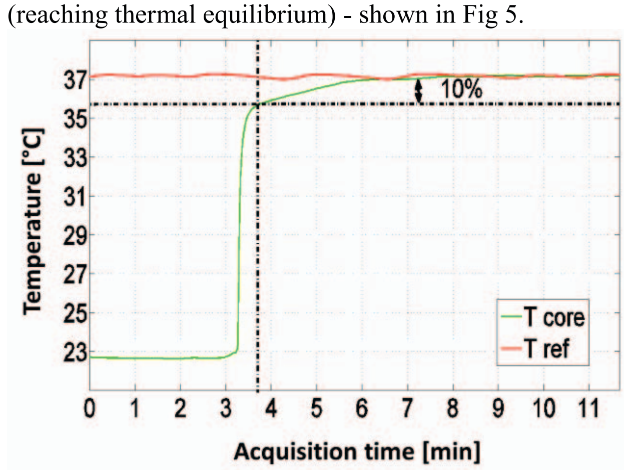


Figure 5. Heat-up experiment showing the time required for thermal equilibrium in a room with ambient temperature of 23˚C.

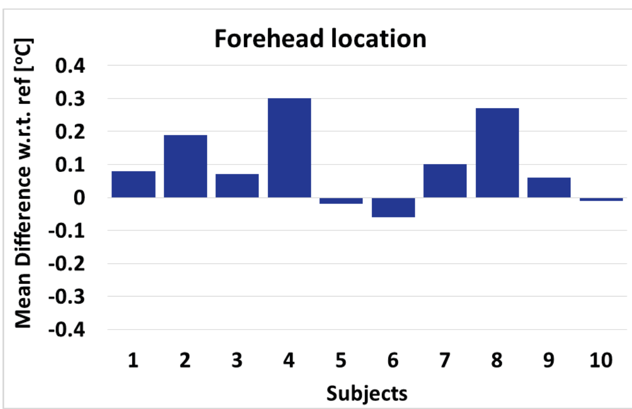
C. Results on volunteers

The sensor was tested on 10 healthy participants using two locations: right forehead and behind the right ear (mastoid area- Fig 6) at room temperature 21(±1)˚C. Results were compared to the 3M SpotOn sensor that uses ZHF (Zero Heat Flux) technology [5]. Participants were aged 27(±4) years - seven males and three females. They wore the sensors for 20 minutes. All volunteers signed a consent form and the study was approved by Philips' Internal Committee for Biomedical Experiments after appropriate safety testing of the setup.

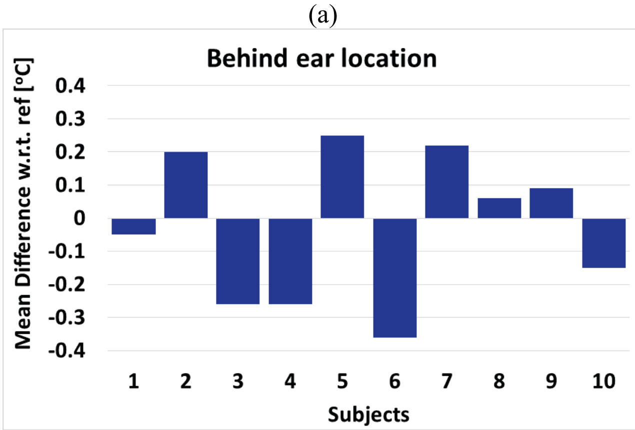
For the calculation of core body temperature, we used the same value of α as above and selected the sensor with the maximal value (on the bottom layer). The mean response time for the sensor to reach equilibrium for the Y sensors was 7.7 minutes for the forehead, and 6.9 minutes for the mastoid area, showing a slightly slower heat-up time than for the lab experiment on the plate.

Fig 7 shows the mean difference between the estimated core body temperature and the 3M SpotOn sensor values when averaged during the stabilization period (after an initial 10 minutes) for the forehead (a) and behind the ear (b). The values show a reasonable mean difference for both scenarios with the forehead sensor over-estimating the temperature compared to the ear. The overall mean difference is 0.10 ˚C (forehead) and 0.03 ˚C (behind the ear).

Figure 6. Showing a volunteer wearing the sensor on the forehead and behind their ear.



(a)



(b)

Figure 7. Results on volunteers: forehead (a) and behind the ear (b).

IV. Conclusions

The Y-shaped sensor showed promising results in estimating core temperature in the lab and on volunteers. The heat-up time (6-7 minutes) is also very reasonable, especially for its use in in-hospital settings. However, these results need to be validated over a larger cohort of subjects with different age groups and physiologies. The 3M SpotOn sensor used in this work was also estimating core temperature rather than measuring it directly. Therefore, the sensor needs to be tested in a hospital environment and compared to standard 'direct' measurements there, such as esophageal and rectal probes. The subjects who participated in this work had stable temperatures. The clinical experiments should validate this sensor on subjects with varying temperatures, due to surgery or fever, for example.

It is worth mentioning that while conducting the lab experiments with volunteers we realized that several factors could affect the accuracy of our results. These include large periods of variations in ambient temperatures, which can affect measurements, as heat flow is not constant during these periods. The sensor needs to reach an equilibrium stage before measurements are used for CBT estimation. This work investigated the CBT module rather than developing a fully wearable solution. To attain a fully wearable solution, the sensor needs to be equipped with a battery and a communicating module. It can then communicate with a smart phone, a patient monitor or other body sensor network modules. Investigating these challenges are some of the next steps for this project.

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