VALIDITY OF CORE SENSOR IN HEAT TRAINING FOR FEMALE AND MALE ENDURANCE ATHLETES

by

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A THESIS

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Heat acclimation and performance is of huge importance in summer endurance sports such as cycling, distance running, and triathlon. Continuously monitoring the internal temperature of athletes during training and events is crucial in preventing heat illness and optimizing performance, but traditional means of measuring body core temperature are not feasible for everyday use due to cost, comfort, and invasiveness. An alternative to rectal and intestinal temperature has been produced by Calera®/ GreenTEG and functions to estimate body core temperature based upon skin temperature, heart rate, and inputted athlete metrics in real time. The validity of this device has not been adequately studied in women or in extreme environmental conditions that could greatly affect skin temperature, a crucial measurement used in the device's calculation of body temperature.

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Introduction

Outdoor endurance sports that take place in the summer months are characterized by an extended exercise sometimes exceeding six hours in duration, during which athletes are exposed to increasingly significant heat stress as the climate crisis progresses. Among others, such events include road cycling, track running, and the marathon. The risk of heat illness in these conditions has increased drastically since the late 20th century [5], and even when no heat illness occurs heat is a significant performance limiting factor. When athletes train or compete in a hot environment, substantial volumes of blood must be diverted to the skin to facilitate cooling, which compromises the delivery of oxygenated blood to the working muscles. Cutaneous blood vessels are compliant, which means that the blood is not returned to the heart quickly. This effect results in cardiac drift, or a perpetually increasing heart rate throughout exercise, which occurs in part as a result of the reduced venous return from compliant vascular beds in the skin. Increased heart rate for the same amount of work over time coupled with dehydration (which given time can reduce blood plasma volume) can result in a reduction in performance that athletes strive to avoid. Heat training provides benefits that reduce these negative effects [18] and is an increasingly popular practice among athletes and their coaches. In fact, some athletes may choose to undergo some of their training in hot conditions regardless of the season, because it has been shown that the performance benefits carry over into cool conditions [12]. Lorenzo et al.'s 2010 study on heat acclimation showed improvements in the functioning of the heart as a result of heat acclimation. The training led to increased cardiac output (as a result of greater stroke volume), increased plasma volume, better clearance of lactate

and reduced usage of glycogen (glycogen sparing) and oxygen at a given intensity [12]. In other words, the athletes became more efficient. Heat acclimatization is often accomplished through repeated bouts of exercise in temperatures approaching 40 °C at submaximal intensities, with durations between 45 minutes [12] and 90 minutes [10]. In some cases, the exercise intensity is modulated to maintain an internal body temperature, and in the case of Kirby et al. a rectal temperature of ~38.5 °C was maintained for the duration [10]. There are also optimal temperatures for safety, as internal temperatures exceeding 40 °C are associated with an increased risk of heat stroke, which is the third most common cause of death among athletes [8]. In order to maintain a body temperature suitable for training while also avoiding unsafe temperatures, athletes require a device that can accurately track their body temperature during training and competition.

Several methods are commonly employed to assess internal body temperature, or body core temperature (Tc) during exercise. These methods include esophageal temperature, intestinal temperature (via an ingestible pill temperature sensor), and rectal temperature. Though effective in a laboratory setting, these methods of monitoring Tc are invasive or simply too expensive to be used on a daily basis even by elite athletes [3]. The CORE sensor created by greenTEG is intended to fill this gap by providing an estimate of internal body temperature based on variables that are collectable by a wearable sensor (skin temperature, heart rate) as well as those inputted into the smartphone application (body mass, height, and age). Because the device requires minimal training to operate and is accessible to most athletes, it could be a boon for training and competition in the heat. However, because the Tc data collected by the

CORE is an estimate, it is necessary to validate the device against one of the aforementioned methods of collecting Tc. This is critically important because decisions made by athletes based on inaccurate data could be at best harmful to their training and at worst damaging to their health. The primary concern is that the CORE aims to estimate Tc while using two variables that change much more quickly than Tc: heart rate and skin temperature are both highly variable in comparison. It is conceivable that rapid changes in heart rate and skin temperature could lead the device to over or under-estimate core temperature.

Verdel et al. [19] completed a study of the device, but notably did not include female subjects or environmental conditions that would likely be selected by athletes looking to conduct heat training. Specifically, the conditions were 30.7°C ± 0.7°C and 39.0% ± 6.0% relative humidity. Athletes using this product are very likely to compete in conditions that are higher in both temperature and humidity, and it is in these more difficult conditions that the CORE device must work. Additionally, there is limited research on female athletes and heat acclimation, but differences have been found in optimal heat training for women [10] and so it is both prudent and critical that devices intended for use as a safety precautionary measure are validated with the inclusion of female subjects. Another study conducted by Goods et al. did include female athletes but lacked both steady state exercise because the athletes were involved in team sports, and also only included warm/humid conditions [7]. The purpose of this investigation was to determine whether the CORE and Calera Research devices devised by greenTEG are accurate and reliable in female and male runners and cyclists, and in conditions that were hot, dry, and humid when compared to an HQ Inc. Cortemp® Pill.

It was hypothesized that an over-reliance on skin temperature could result in comparatively low readings in dry conditions and high readings in humid exercise conditions due to well-known relationships between relative humidity and exercise skin temperature.

Literature Review

During exercise, athlete body temperature can be assessed using a variety of devices and strategies. However, as discussed previously, despite being the most informative, body core temperature (Tc) collected via ingestible pill or rectal probe is not convenient for most athletes in training or in competition. It is for this reason that many non-invasive methods of body temperature measurement have been devised. For our purposes, a non-invasive technique does not cause significant discomfort to the athlete, is simple to operate, and can be set up minutes before exercise rather than hours.

Some of the most straightforward methods of non-invasively evaluating temperature during exercise include tympanic, temporal, and oral temperatures. These were evaluated in a hot and humid environment, and it was found that tympanic and temporal temperatures were passable substitutes for rectal and esophageal Tc when those methods are not available [3]. The limitations of these two methods are that they are difficult to continuously monitor and record and that they have not been validated in a dry heat setting.

While Tsk is generally lower and can fluctuate more rapidly than Tc, it is easier to measure and so numerous attempts have been made to estimate core temperature based on skin temperature. Niedermann et al. were able to create a model that was predictive of core temperature using skin temperature at multiple body sites as well as heat flux and heart rate [14]. Other variables besides Tsk were necessary because skin temperature alone does not indicate the rate at which heat is being generated nor does it indicate how quickly heat is being lost, which is the function served by calculating heat flux. The researchers recommended that even more sites across the body should be used

to measure Tsk in future studies for increased accuracy [14]. Measuring temperature at numerous sites across the body makes preparation more difficult and may be prohibitive for many athletes during heat training. It is important to note that in contrast the CORE device measures skin temperature at a single site on the lower chest and only estimates heat flux.

Ultimately, most methods of estimating Tc non-invasively will incorporate skin temperature, heart rate, and heat flux in some fashion. While the latter may be categorized as difficult to collect outside of a lab setting, the other two are very simply measured. Heart rate indicates effort level to a certain extent but can remain elevated for long periods of time even after an individual reduces exercise intensity and is subject to cardiovascular drift. Cardiovascular drift is especially relevant here because it causes heart rate to increase drastically over prolonged exercise (even at a constant intensity) and is worsened as Tc increases. Cardiovascular drift occurs as a result of reduced stroke volume in the heart caused by the distribution of blood to the skin for cooling [15]. Athletes exercising or competing in the heat will have higher heart rates than in cool conditions for a given pace or power output, which is part of the reason that heart rate is a valuable indicator of heat stress when compared between environmental conditions.

Heat flux in this context is the loss of energy from the exercising body through the skin per unit surface area. Heat energy can be lost via the evaporation of sweat, conduction, convection, and radiation, and can be gained through metabolic processes (both resting and during exercise) as well as through solar radiation. Surface area is tremendously important for the loss of heat during exercise and having a higher surface

area to mass ratio is beneficial to performance in the heat [15]. Differences between individual athletes in terms of body morphology is a large barrier to perfectly estimating heat loss, and simple metrics such as BMI do not account for limb-to-torso ratios which alter surface area greatly.

Tsk is highly variable depending on both the energy production of the athlete and the conditions that they are exercising in, which impact how well the skin can cool. Evaporation is an extremely important thermoregulatory tool used by athletes during exercise, and the extent to which sweat can evaporate plays a substantial role in Tsk. While athletes are constantly sweating, water is also commonly poured on runners, cyclists, and triathletes to cool them down, functioning simultaneously to cool the skin via conduction and evaporation. However, it is well understood that relative humidity (RH) can have an impact on the efficacy of evaporation [15]. A high humidity in the environment reduces the rate of evaporation and increases skin temperature due to an impaired concentration gradient, which further complicates the usage of Tsk in evaluating an athlete's temperature situation. The CORE device currently has no way of collecting data on the RH the athlete is exercising in.

The CORE sensor uses a proprietary algorithm to estimate Tc based upon heart rate, skin temperature, and estimated heat flux in real time. Heat Flux is likely estimated using the athlete data that can be entered into the CORE mobile application prior to exercise. Along with metrics such as height and weight, the CORE device collects age which could potentially aid with interpreting heart rate data. CORE is in use among numerous professional athletes, largely within the spheres of cycling, running, and triathlon. As referenced previously, a recent study tested the CORE device in 13 male

subjects cycling in a warm environment (30.7°C ± 0.7°C and 39.0% ± 6.0% relative humidity) [19]. The cyclists exercised for 80 minutes, including 5 minutes of warmup and 15 minutes of cooldown. The 60 minutes of steady state exercise were completed at an intensity of 90% of their VT1 (first ventilatory threshold). The CORE device was compared against a rectal probe for reference. Female athletes were not included in the study and the researchers cited potential temperature fluctuations associated with the menstrual cycle as their reasoning despite each subject serving as their own control. The Slovenian researchers detected inaccuracies at the beginning of exercise but noted that these early minutes of exercise were less important to measure accurately because Tc was low enough to be insignificant in terms of training or safety. They also entertained the possibility that these inaccuracies were a result of the CORE device being connected to the heart rate monitor when the subject is at rest, because heart rate connection is recommended by the manufacturer only during exercise. However, there is not much choice in the matter as heart rate cannot easily be connected and disconnected. They also found that the CORE device underestimated Tc at core temperatures exceeding 39.5 °C, which could pose a serious risk to safety [19].

Goods et al. conducted a study of the CORE device with women's field hockey players training in the heat. The researchers used the BodyCap temperature pill as the reference, which is similar in function to the HQ Cortemp® pill. Their findings were similar to those of the previous study; over four sessions they observed a negative bias on the CORE device, and the underestimation worsened with higher core temperatures [7]. Their conditions were warm and high humidity; sessions 3 and 4 (the more extreme) were 27.6 °C, 80% RH and 27.4 °C, 74% RH (similar to the humid condition

in the present study). Interestingly, the device performed in a manner consistent with the Slovenian study despite the lack of steady state exercise. Ultimately, they found that the CORE device was not a valid replacement for a temperature pill in heat training female team sports athletes [7].

When selecting a reference device, both rectal probes and ingestible pills are acceptable options for measuring Tc [3]. Both have significant limitations. In the case of the rectal thermistor, subject discomfort and mobility restrictions make it unusable in many situations [14]. Ingestible pills on the other hand can produce inaccurate data if they are not ingested at the proper time or if cold fluids are ingested [14].

Both athlete studies of the CORE device thus far were ultimately conservative in terms of temperature conditions. Although their conditions were by no means cool, the temperatures reached in summer events such as the Tour de France far surpass 30 °C, and it is in these potentially hazardous conditions that the CORE device would prove most useful for training and safety.

Methods

Subjects. Prior to participating, all subjects provided written informed consent as outlined in the Declaration of Helsinki, and all protocols were approved by the Institutional Review Board of the University of Oregon. Subjects were required to be trained (tier 2) or highly trained (tier 3) runners, cyclists, and triathletes aged between 18 and 59 years. Tiers were defined using the Participant Classification Framework from McKay et al. [13] and were self-identified by subjects. Triathletes selected their preferred exercise modality between running and cycling which was held consistent between all three lab visits. Subjects were capable and willing to take the HQ Inc. Cortemp pill [see Appendix E.].

Overall Study Design. Subjects completed 3 visits to the lab during which they exercised. The first visit consisted of a VO_2peak test followed by a super max test to validate VO_2max was reached on either a cycle ergometer or a treadmill. During the two subsequent visits athletes exercised in the environmental chamber for 45 minutes in two environmental conditions, the order of which was randomly determined.

First Visit – VO_2 Peak Test. Runners completed a test in which the treadmill gradient was increased by 1% at the beginning of each 1-minute stage, and in this case the gradient of the Supermax was 10% steeper than the final completed stage while the speed remained the same. Cyclists completed a cycling stepwise test that involved an increase in wattage at the beginning of each 1-minute stage, and they were stopped either when cadence dropped below 60 rotations per minute or when they no longer wished to continue. For female cyclists, the first stage was set at 75 Watts (W) with an increase of 25 W each stage while for male cyclists the test began at 90 W followed by

increases of 30 W each stage. There was a 10-minute rest period between the two tests, during which subjects could drink water as needed. Supramaximal testing was implemented according to Poole & Jones [13] with the reasoning that a true VO_2 plateau is not always reached during the conventional staged test. The Supramaximal workload was set 10% higher than the final completed stage during the conventional test, and subjects exercised as long as possible at this constant workload. A difference of 5% or greater between the peak VO_2 measured during the two portions of the test was considered grounds for re-testing, while anything within that range was considered a verification of the first test.

Second and Third Visits: Environmental Chamber. Subjects exercised in the same modality as their VO_2max test in a controlled environmental chamber which was set to either 38 °C & 20% RH or 28 °C & 80% RH. Exercise was 45 minutes at 60% of VO_2 Peak workload, which for cyclists was 60% of the power in watts of the final stage completed. For runners, the workload was calculated using 60% of the METS from their last completed stage. METS were calculated using table IV from Jetté et al. [9]. The order of these two visits was randomized. Subjects wore CORE devices for at least 25 minutes before beginning exercise to ensure thermal equilibrium between the device and the skin.

Environmental Chamber Measurements. Temperature measurements were taken during the second and third visits using one greenTEG device on the chest adjacent to each armpit. One of these was the CORE sensor® (consumer version/ "ConCORE") and the other was the Calera Research variant ("RCORE"). Also used were an ingestible HQ inc. Cortemp® pill, and 8 iButtons® placed on the forehead, right chest, right upper

arm, right forearm, right upper back, right abdomen, right thigh, and right calf. HQ Cortemp® temperature was assessed each minute, and subjects who reached 39.5 degrees Celsius were stopped and escorted from the chamber, where they could rehydrate and cool down. CORE devices automatically record data every minute, but their readings were also recorded by a hand every 5 minutes in the case of problems uploading to the cloud. Subject Rating of Perceived Exertion (RPE) was assessed and recorded using the Borg Scale (see Appendix A) and Thermal Comfort via the Minson scale (see Appendix B) every 5 minutes of exercise. Heart rate was collected by a Garmin HRM1G monitor and strap, which was paired with both CORE devices. Urine specific gravity (USG) was assessed prior to exercise to evaluate hydration status and subjects above 1.020 were asked to drink 500 mL of water prior to entering the chamber. Nude body mass was assessed before and after exercise and pregnancy status was assessed for subjects capable of pregnancy prior to entering the chamber.

Statistical Methods. CORE device data were saved to the cloud and downloaded in a minute-by-minute format. Similarly, iButton data were downloaded immediately following exercise in one-minute resolution. HQ inc. Cortemp® pill data were recorded by hand every minute. There were several cases where missing data occurred either due to problems for the CORE device in uploading to the Cloud, in which case five minute hand-recorded data were used for analysis. There were also cases when subjects ended exercise early due to discomfort or as a result of reaching the Tc safety threshold of 39.5 °C as measured by the Cortemp® pill. At each of three timepoints covered in the Results below, Tc from both CORE devices and the Cortemp® pill were compared using a two-way ANOVA with repeated measures. Tests reporting significance (significance

threshold of $p < 0.05$) were examined with multiple comparisons. All statistical analyses were completed using GraphPad Prism 10. Sample means were reported with SD and mean differences were reported with SE.

Results

Subjects. Participants were 17 trained (tier 2) and 7 highly trained (tier 3) runners, cyclists, and triathletes aged 27 ± 11 years. Tiers were defined using the Participant Classification Framework from McKay et al. [13] and were self-identified. Subjects included 11 females (2 cyclists and 9 runners) as well as 13 males (6 runners and 7 cyclists). Subject VO_2peaks were 57.6 ± 5.8 ml/kg/min (59.5 ± 6.0 for male subjects and 55.3 ± 4.6 for female subjects.)

Representative Tracings. Most CORE device data were characterized by a drop in the beginning of exercise, followed by a rapid increase in Tc (see Figure 1 below).

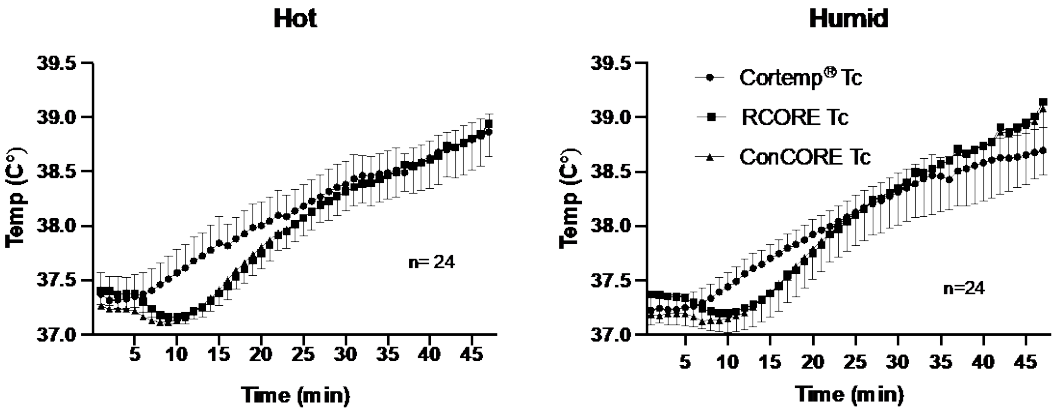


Figure 1. Tc Representative Tracings

Cortemp® Pill Tc displayed with Tc calculated by the two CORE devices. There is a drop in Tc calculated by CORE devices early during exercise before a rise that visually matches Cortemp® Pill Tc in the Hot condition and visually surpasses it in the Humid condition.

Ramanathan Tsk was intended to represent whole body mean Tsk and was calculated using the following formula: $0.3(Tsk_{Chest}) + 0.3(Tsk_{arm}) + 0.2(Tsk_{thigh}) + 0.2(Tsk_{leg})$, from Ramanathan [17]. See Figure 2 below for representative tracings of

heart rate and skin temperature. Ramanathan Tsk was higher in the Hot condition than in the Humid ($p = 0.0009$, n=24), with a mean difference of 1.83 ± 0.48°C.

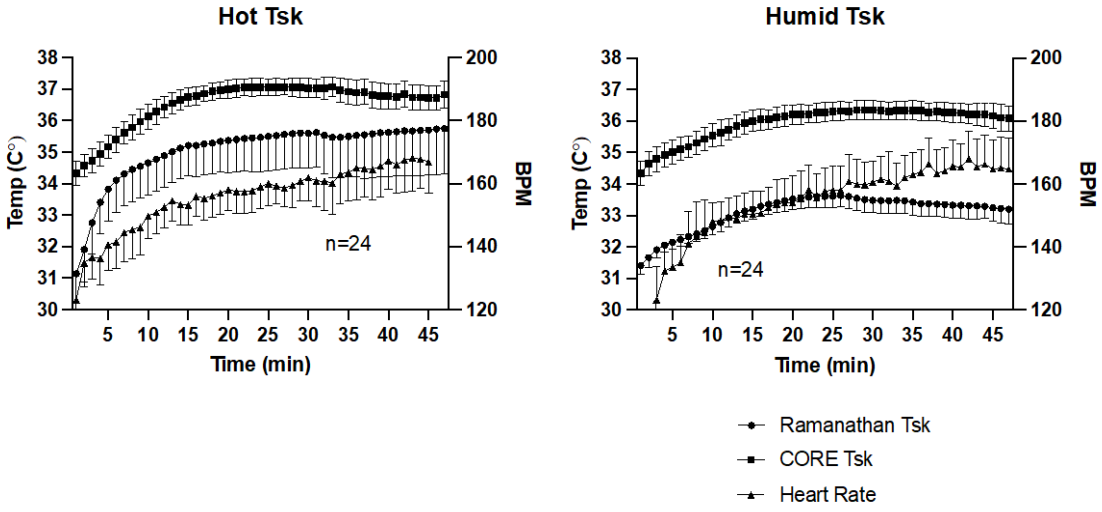


Figure 2. Skin Temperature and Heart Rate Rep. Tracings

Skin Temperature and Heart Rate over time in both environmental conditions. CORE Tsk is higher because the CORE devices measure temperature near the armpit, usually below clothing.

Device Agreement at Baseline. Baseline refers to measurements taken 5 minutes prior to the beginning of exercise in the environmental chamber. Because subjects were in ambient lab conditions and had not yet entered the chamber, data from the "Hot" and "Humid" conditions was combined, with each of 24 subjects contributing two data points. Cortemp® Pill Tc mean was 37.26 ± 0.33 °C, Research CORE Tc (RCORE) mean was 37.31 ± 0.32 °C, and Consumer CORE Tc (ConCORE) mean was 37.22 ± 0.20 °C. The latter two were significantly different ($p < 0.01$), but neither was significantly different than gold-standard Tc (Cortemp® Pill).

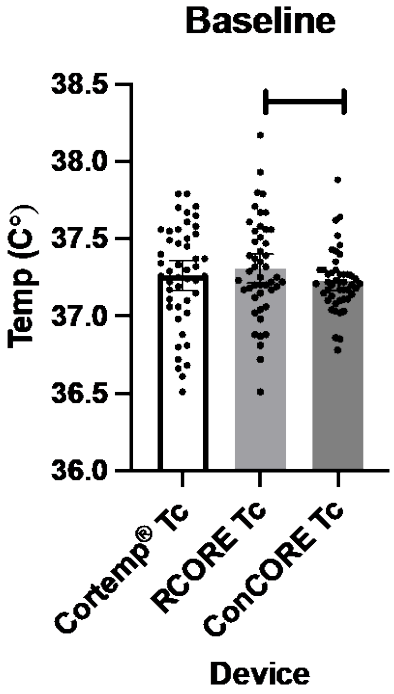


Figure 3. Baseline Measurements.

Mean reading for each device at baseline is displayed along with a scatterplot displaying each individual subject at the same time point. Error bars display 95% Confidence Interval. ** denotes significant difference between Research CORE Tc and Consumer CORE Tc ($p<0.01$).

Device Agreement at 10 Minutes. Early in exercise there was an easily observable drop in the Tc calculated by the CORE devices. This Nadir is near the 10-minute mark, which was used for analysis given that data were available for all subjects at this time point (whereas in other cases a device did not upload to the cloud properly and the researchers took data by hand only in five-minute intervals). Cortemp® Pill Tc mean was 37.68 ± 0.53 °C in the Hot condition and 37.56 ± 0.30 °C in the humid condition. Research CORE Tc mean was 37.22 ± 0.18 °C in the Hot condition and 37.25 ± 0.20 °C in the Humid condition. Consumer CORE mean was 37.21 ± 0.17 °C in the Hot condition and 37.21 ± 0.21 °C in the Humid condition. The Cortemp® Pill reported Tc values significantly higher than both CORE devices in both Hot ($p< 0.001$, $n=24$) and Humid ($p < 0.0001$, $n=24$) conditions. Cortemp® Pill Tc was higher than the

Research CORE device by a mean of 0.46 ± 0.11 °C in the Hot condition and 0.31 ± 0.06 °C in the Humid Condition. Cortemp® Pill Tc was higher than the Consumer CORE device by a mean of 0.47 ± 0.12 °C in the Hot condition and 0.36 ± 0.07 °C in the Humid Condition.

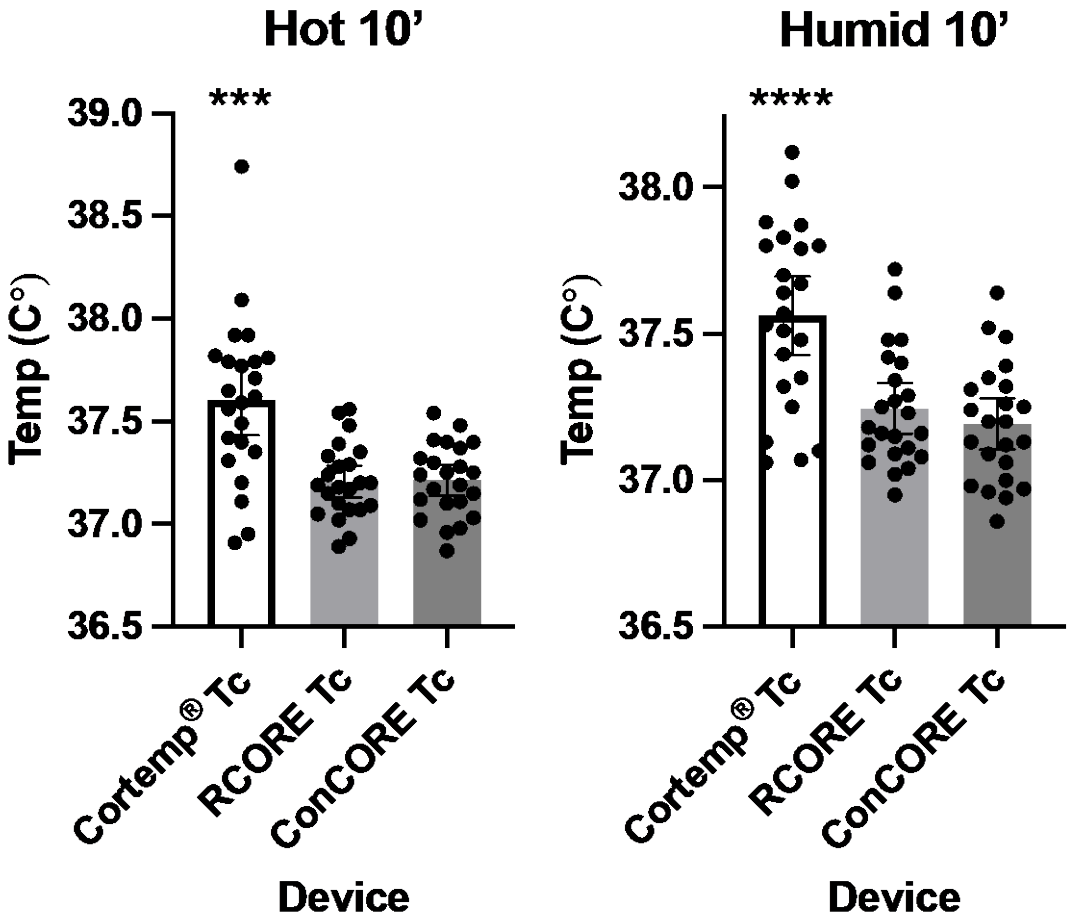


Figure 4. Ten Minute Time Point

Mean temperature of each device at ten minutes is displayed along with scatterplot including each subject at the same time point for each device. Error bars are 95% Confidence Interval. *** denotes significant difference between Cortemp® Pill Tc and the two CORE devices ($p < 0.001$). **** denotes significant difference between Cortemp® Pill Tc and the two CORE devices ($p < 0.0001$).

Device Agreement at Peak Tc. Device agreement was analyzed at peak temperature, which in most cases was the final reading recorded before exercise stopped. Peak temperature was higher in the Hot condition (though not significantly, p=0.063), and 7 subjects did not exercise the full 45 minutes due to either reaching the safety threshold of 39.5 °C or because they wished to stop, compared with 2 in the Humid condition. Cortemp® Pill Tc mean was 38.94 ± 0.47 °C in the Hot condition and 38.74 ± 0.50 °C in the humid condition. Research CORE Tc mean was 38.75 ± 0.63 °C in the Hot condition and 39.06 ± 0.67 °C in the Humid condition. Consumer CORE Tc was 38.74 ± 0.62 °C in the Hot condition and 39.01 ± 0.66 °C in the Humid condition. Unlike Cortemp® Pill Tc, both CORE devices reported significantly higher peak temperatures in the Humid condition than in the Hot condition ($p = 0.004$ & 0.01, n=24). In the Humid condition, Cortemp® Pill Tc was significantly lower than both Research CORE ($p = 0.003$, n=24) and Consumer CORE ($p = 0.01$, n=24). There was no significant difference between devices in the Hot condition ($p>0.05$, n=24). In the Humid Condition, the Research CORE was higher than Pill Tc by a mean of 0.31 ± 0.10 °C and Consumer CORE read higher by a mean of 0.27 ± 0.10 °C.

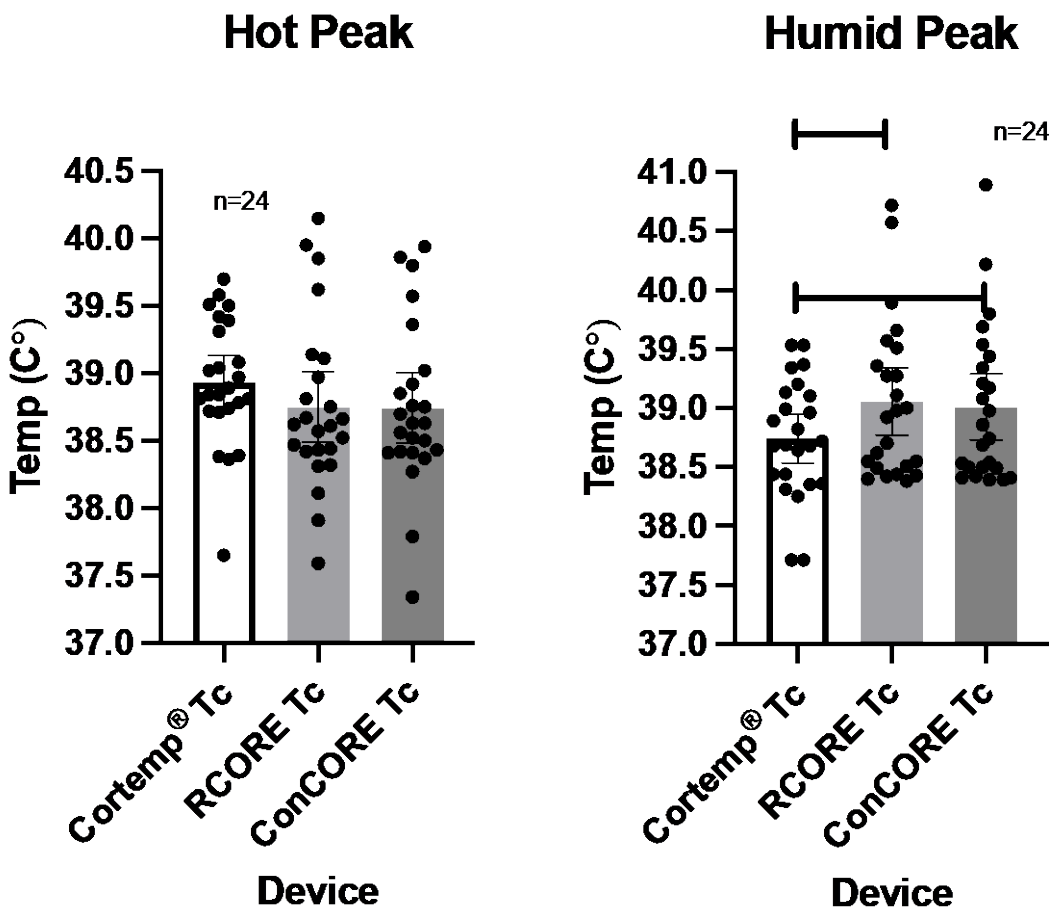


Figure 5. Peak Tc

Bars represent mean temperature at peak for each device, and scatterplot represents individual subject peak Tc. Error bars are 95% Confidence Interval. ** denotes significant difference between Cortemp® Pill Tc and Research CORE Tc ($p < 0.01$). * denotes significant difference between Cortemp® Pill Tc and Consumer CORE Tc ($p < 0.05$).

CORE Data Representative Tracings. The CORE devices use heart rate and skin temperature to calculate Tc, but the formula used is unknown. Heart rate and Tsk can be plotted along with the Tc calculated by the CORE devices to visually inspect how the

formula might work, though no mathematical attempt to replicate the CORE formula was made in the present study.

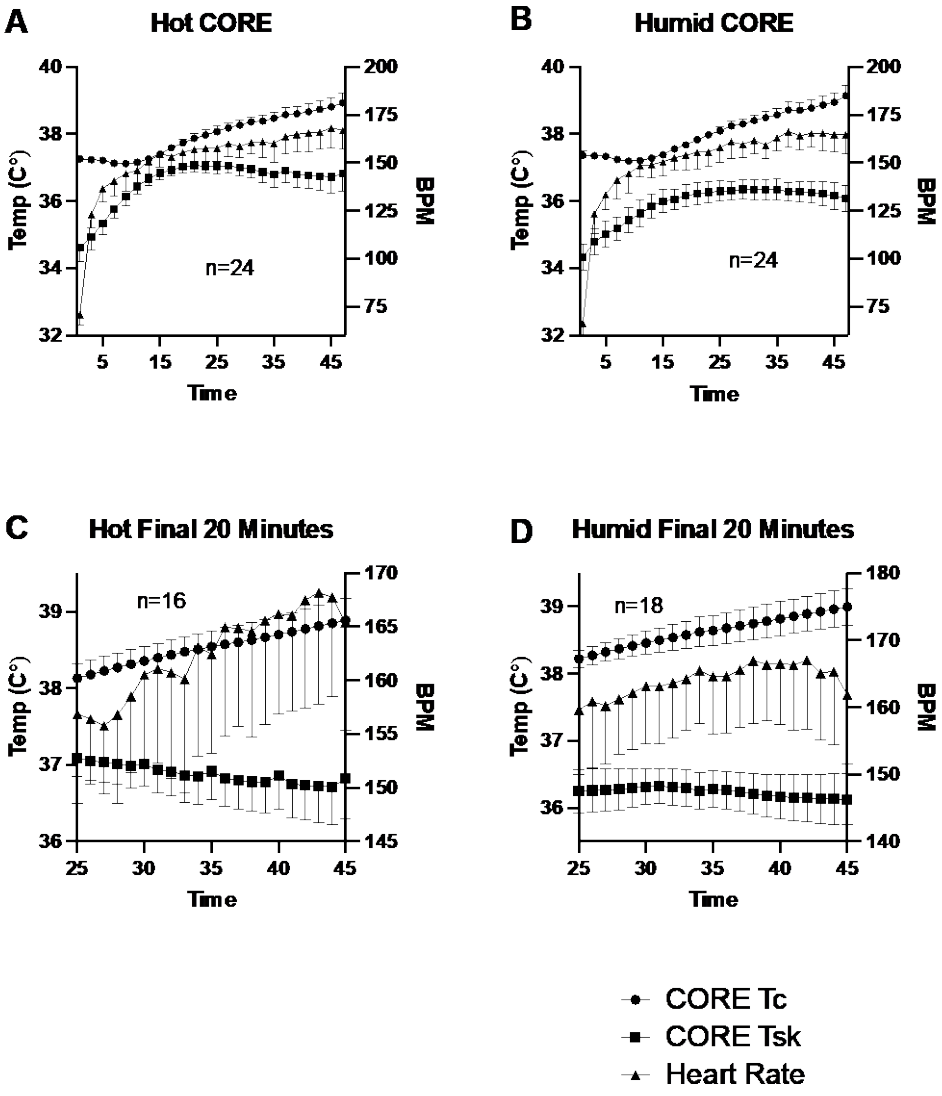


Figure 6. CORE device data including estimated Tc, measured skin temperature, and measured heart rate.

A and B display the entire duration of exercise, while C and D display only the final 20 minutes (including only subjects who completed all 45 minutes of exercise). A and B demonstrate a decrease in Tc despite rapid increase in Tsk and HR at the outset of exercise. C demonstrates a steady linear increase of Tc as heart rate increases and Tsk decreases. D demonstrates a steady linear increase of Tc as heart rate and Tsk remain relatively stable.

Discussion

Baseline Device Performance. It is very likely a safe assumption that few CORE device users are paying careful attention to their temperature at rest. The device is after all designed to clip on to the strap of a heart rate monitor, and these are seldom worn on the couch. That aside, the CORE device does appear to function adequately when the wearer is at rest. It is odd that the two iterations of the CORE differed by 0.08 ± 0.05 °C ($p = 0.023$), but both devices were statistically and practically close to the Tc measured by the pill [see Figure 3 and corresponding description]. Verdel et al. noted the difficulty in following the CORE device manual in this case; the heart rate monitor is not intended to be connected to the device for measurement during rest, but in order to use the device for exercise measurements it must be connected (and cannot easily be connected or disconnected) [18]. While having one CORE device connected to heart rate and the other disconnected might have had a sizable effect on data, this did not occur in the present study, as both CORE devices were connected to HR at all times in which data was recorded.

Early Exercise Device Performance. At the beginning of exercise, CORE device Tc readings are characterized by a sharp drop in temperature [see Fig. 1]. If not for the diligent record of skin temperature, this could have been explained by a decrease in Tsk which in turn would have affected the CORE device's estimation. At the beginning of exercise, vasoconstriction in the skin causes reduced blood flow which can briefly reduce skin temperature before it begins to rise. This drop in Tsk could have explained the incongruous drop in Tc calculated by the CORE device's algorithm, but does not appear to have been the case in the present study, as no drop in skin temperature is

apparent in either the Ramanathan skin temperature or the CORE device's own measurement of Tsk [see figure 2]. In fact, as the CORE Tc is decreasing, both variables that are used to calculate it are rising rapidly. This is most evident in Figure 6A (Hot CORE), where heart rate and skin temperature are both rising rapidly, but Tc is declining. It is very nearly impossible to explain why the CORE device's Tc measurement would be dropping when both known factors that contribute to it are rising rapidly. And yet at the 10' mark, there was a significant ($p<0.01$) difference of ~0.46 °C between Intestinal Tc and the CORE device in the Hot condition and a significant ($p<0.0001$) difference of ~0.33 °C in the Humid condition [see results for exact means]. This performance is as poor as it is unexplainable given the mysterious downward trend of CORE device Tc at the outset of exercise. Verdel et al. encountered a similar effect and noted that most athletes are not overly concerned about body core temperature in the first fifteen minutes of exercise, and so this effect is unlikely to be an insurmountable problem [19]. The body size and age statistics that users input into the CORE app may have an effect on the functioning of the algorithm, but these remain static and so it is difficult to imagine them playing any role here. Another possibility is that the CORE devices were intended to mimic the very slight drop that is sometimes observed in intestinal or rectal temperature at the outset of exercise, and that the adjustment was over-exaggerated, but there is no way to speak to this with the data available.

One might try and describe this early exercise discrepancy as the time required for the surface of the device to come up to body temperature, but in accordance with our protocol and the CORE manual, subjects wore the CORE device for a minimum of 25

minutes prior to entering the environmental chamber and beginning exercise. Because the device performs well at resting, it is clear that the transition between rest and hard exercise is not optimally modeled by the CORE device's algorithm.

Peak Temperature Device Performance. The most critical period to measure core temperature (Tc) comes when athletes are reaching their peak temperature. Monitoring Tc in these cases allows athletes to maintain a temperature zone that is effective for training, and to avoid becoming so warm that it poses a risk to their health. By comparing the data provided by the Cortemp® Pill to the CORE devices at Peak Temperature during exercise, the validity of the latter for training in high heat and for safety was examined. The primary hypothesis of the present study was that during exercise in a humid environment, the inability of the skin to cool by evaporation would lead to high skin temperature relative to Tc, which result in overestimation of Tc by the CORE device. This is precisely what was observed at Peak Temperatures, or after 40 minutes of exercise. In the Hot condition, differences between devices were insignificant, but in the Humid condition both CORE devices were higher than Cortemp® Pill Tc at peak temperature [see Figure 5]. This difference of 0.31 ± 0.10 °C to the Research CORE and of 0.27 ± 0.10 °C to the Consumer CORE is sufficient that athletes might be stopped for safety reasons prior to it being strictly necessary if a CORE device was the only device being used to measure Tc in an event or in training. It must be noted that this is vastly preferable to the inverse situation, where a device reads low and an athlete is exposed to potentially hazardous internal temperatures while they or their training staff believe them to be within a healthy range.

The cause of this discrepancy may be visually apparent in Figure 6. In C (Hot Final 20 Minutes) skin temperature is decreasing, likely because the athlete's skin is covered in sweat which can evaporate nicely in 20% RH. However, in D (Humid Final 20 Minutes) the skin temperature is clearly still rising which might be the cause of the CORE device outpacing Pill Tc (which can be clearly seen in Figure 1 (Humid)).

Interestingly, Verdel et al. and Goods et al. both found that the CORE device underestimated Tc, something only observed at the outset of exercise in the present investigation. This difference in findings could be attributed to intensity and mode of exercise or to environmental conditions. Goods et al. was conducted on female field hockey players participating in intermittent exercise rather than steady state, while Verdel et al. conducted exercise in much less extreme conditions (30.7 ± 0.7 °C, and 39.0 ± 6.0% RH) [18]. If overestimation occurred as a result of high Tsk, it follows that it did not occur in conditions with lower activity level or lower humidity.

CORE devices in the Field. Though it was not evaluated in this indoor and stationary study, it is possible that the device reliance on skin temperature would result in an inaccurate depiction of cooling compared to 'real' internal body temperature during outdoor activities where the athlete is moving quickly and changing their velocity. When a cyclist is climbing a steep climb for a prolonged period, their skin temperature might behave in similar fashion to the present study, and Tsk might be further elevated by Solar Radiation. This could result in a skin surface that is saturated in sweat, and when the cyclist descends the other side of the mountain at speeds exceeding 40 miles per hour (64 km/h) this could result in very rapid convective cooling

of the skin. As the CORE device detects a rapid decrease in Tsk, it may calculate Tc to be decreasing at a larger rate than it is in reality.

Another question that has largely been unanswered by the present study and any other is the effect of interval training on the CORE device. High intensity intervals manipulate skin temperature and (most especially) heart rate in a very different fashion when compared to steady state exercise. At present, the most relevant data in this discussion comes from Goods et al., which was conducted on elite female field hockey players training in the heat [7]. Given that they were largely playing scrimmages, they were not running continuously, but rather stopping and starting constantly. The researchers found that the CORE device was underestimating Tc gathered by a temperature pill at high Tc. It is possible that in this situation the CORE device was unable to account for the effect that many bursts of sprinting would have on Tc. Given that the conditions these athletes exercised in were remarkably similar to the humid condition of the present study (27.6 °C & 80% RH) and the CORE device in fact *over*estimated Tc when athletes were exercising as steady state, it seems very likely that the changing intensity had something to do with this difference in device performance. Unfortunately, most events outside the sphere of running, triathlon, and a handful of cycling events do not require athletes to simply exercise at steady state. Of course, these endurance sports are arguably the events where heat training would grant the largest performance advantage and thus the events where this device is most likely to be put to use.

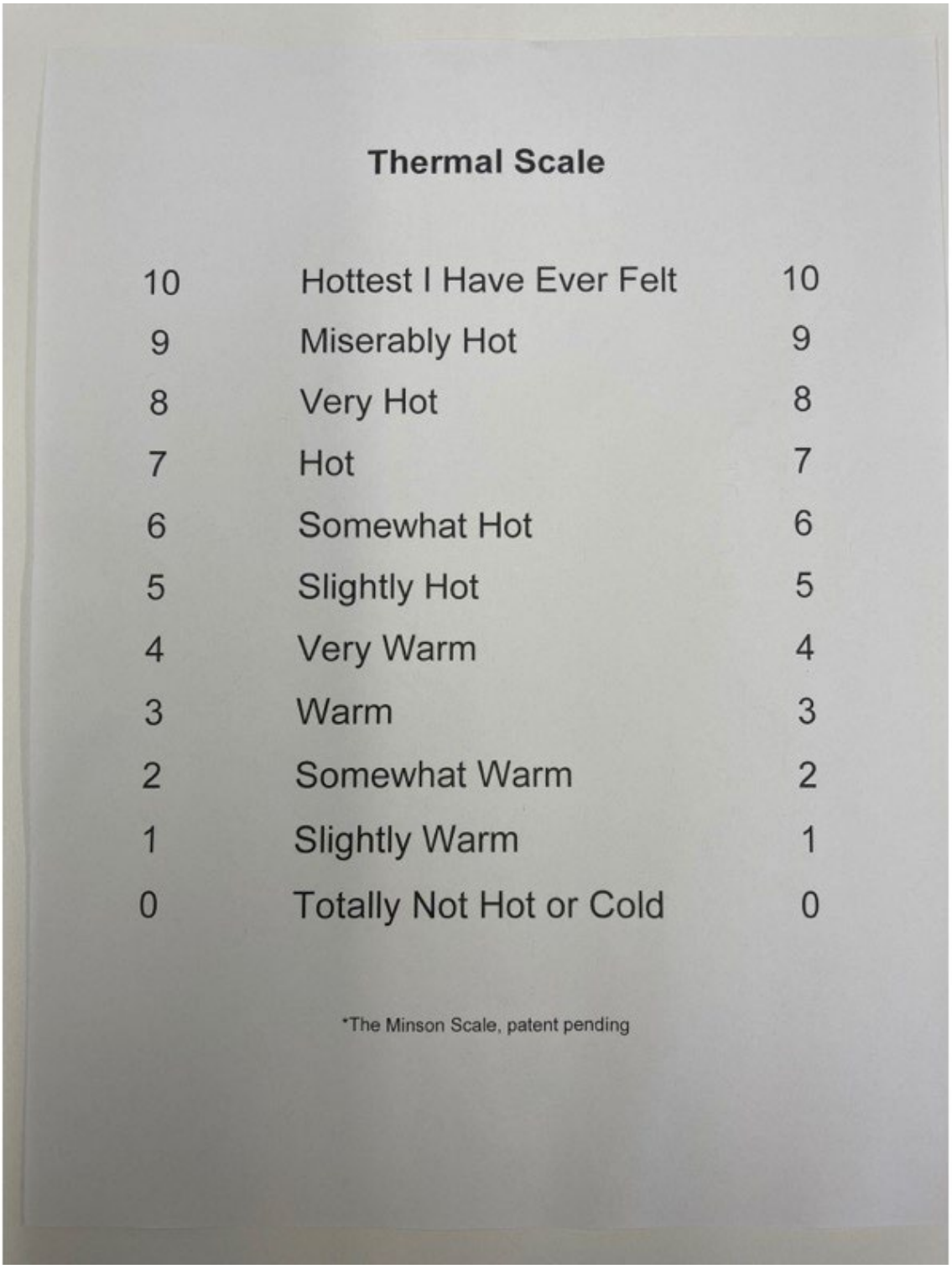
Conclusion

The findings of the present study do not support the use of the CORE device in steady state aerobic exercise in a warm and humid environment (28 °C & 80% RH) or early in exercise, either for safety or training purposes. While inaccuracies early in exercise will likely not be an issue for most athletes, high humidity exercise is not uncommon in training or competition. Ironically, the CORE suit sold from corebodytemp.com would result in an extremely humid microclimate that would very likely exceed the 80% RH of the present study and lead to further inaccuracies in the CORE device. This suit and others like it do not allow sweat to evaporate and create an extremely wet skin surface in which the CORE device has not been tested to my knowledge. Over dressing during training is also a common practice that athletes use to facilitate heat acclimation, and could potentially lead to a similar problem.

While the CORE device may still be a useful tool for many athletes, it is important to note that it does not perform consistently across various environmental conditions, and therefore a given Tc produced by the device will not mean the same thing in different environmental conditions.

Appendix A: Borg Scale (RPE)

Appendix B: Minson Scale (Perceived Thermal Comfort)



Thermal Scale

10	Hottest I Have Ever Felt	10
9	Miserably Hot	9
8	Very Hot	8
7	Hot	7
6	Somewhat Hot	6
5	Slightly Hot	5
4	Very Warm	4
3	Warm	3
2	Somewhat Warm	2
1	Slightly Warm	1
0	Totally Not Hot or Cold	0

*The Minson Scale, patent pending

Appendix C: Consent Document

Consent for Research Participation

Title: "The Validity of CORE Sensor in Heat Training for Male and Female Endurance Athletes"

Sponsor: Wu Tsai Human Performance Alliance

Researcher(s): Samantha Chacon, Christopher Minson, PhD, and colleagues, University of Oregon

Researcher Contact Info: 541-357-9782
mritzow@uoregon.edu

You are being asked to participate in a research study. The box below highlights key information about this research for you to consider when making a decision whether or not to participate. Carefully consider this information and the more detailed information provided below the box. Please ask questions about any of the information you do not understand before you decide whether to participate.

Key Information for You to Consider

- **Voluntary Consent**. You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate or discontinue participation.
- **Purpose**. The purpose of this research is to test the accuracy of the CORE body temperature monitoring devices on athletes exercising in a variety of environments.
- **Duration.** It is expected that your participation will last four to six hours spread across three visits.
- **Procedures and Activities.** You will be asked to undergo a test to measure your aerobic fitness and to exercise on a treadmill or cycle ergometer in a heated chamber while wearing a body temperature measurement device. You will be asked to swallow a small temperature sensing device the size of a pill. You will participate in a high-intensity exercise test and exercise in the heat.
- **Risks.** Some of the foreseeable risks or discomforts of your participation include headache, fatigue, shortness of breath, nausea, and dizziness from exercising in the heat.
- **Benefits**. You will not receive any direct benefit from participating in this study. However, the researchers hope to learn whether the CORE monitor is a reliable system for athletes to track their core body temperature rise during exercise. You will be financially compensated for your time and effort.
- **Alternatives.** Participation is voluntary and the only alternative is to not participate.

Why is this research being done?

The purpose of the research is to verify the claims of CORE™ body temperature monitors to accurately calculate core body temperature from skin temperature and heart rate during exercise under varying environmental conditions. This device, and its algorithm for calculating core body temperature are experimental. The devices are not FDA approved or cleared for the intended uses of this study. You are being asked to participate because you are a highly trained athlete between the ages of 18 and 59. About 40 people (20 females and 20 males) will take part in this research.

How long will I be in this research?

We expect that your participation will last the duration of this screening visit (1-2 hours) and 1.5 – 2 hours on two experimental visit days (separated by at least one week), for a total of four to six hours over a seven-to-ten-day period.

What happens if I agree to participate in this research?

If you agree to be in this research, your participation will include a VO_2 Peak test to measure your aerobic fitness level and two exercise sessions in a heated chamber with varying levels of humidity, detailed below.

Screening session (0.5 - 1 hour). During this visit we will ask you some questions about your health history to see if you qualify for this study. You will meet with one of the investigators of the study to discuss the project, read this form, view the laboratory, go over any questions you might have, and sign this form if you want to participate. You can choose to take this form home with you if you want more time to decide whether to participate. If you are a person who can become pregnant, you will be asked to undergo a pregnancy test. The pregnancy test we use is commonly used in medical settings such as hospitals and doctor's offices. Tests have shown this method has a 1.6% false negative rate. This means there is a chance (about 1 in 62) our test will give the result, "not pregnant" even though a pregnancy exists. For the pregnancy test, you will be asked to collect a sample of urine in a private restroom in the lab. If the test is positive, indicating that you are pregnant, you will not be allowed to participate and will be advised to see your physician or the University of Oregon Health Center. After having reviewed all the information about this study, if you choose to participate, we will give you an exercise test (VO_2 Peak) during the same visit, as described below.

VO_2 Peak/Max Test (0.5 - 1 hour). After your screening session, you will have your peak aerobic power and maximal heart rate determined with a graded maximal cycle ergometer or treadmill running test. This means, you will either run on a treadmill or ride on a stationary bicycle while we increase the exercise intensity in a stepwise manner. This test will be used to assess your levels of aerobic fitness and monitor heat related changes to your performance. We will monitor your heart rate with a strap that you will place around your chest. You will cycle on a stationary cycle ergometer (a stationary bicycle with adjustable resistance settings) or run on a treadmill while wearing a mouthpiece and nose clip. After 4 minutes of spinning/running at a comfortable speed, the resistance of the ergometer or the speed and incline of the treadmill will increase each minute until you reach exhaustion. This is to measure your

overall aerobic fitness level. It normally takes 8 to 12 minutes for people to reach their maximal effort. This test will measure your maximal oxygen uptake and will be used to select an appropriate workload for the heated exercise sessions. Upon completion of the exercise test, you will be offered a snack (granola bar) and fluids (12 oz Gatorade) to eat and drink. You should notify the investigator immediately if you feel any significant discomfort or concern about your well-being at any time during the exercise test. Some examples of discomfort include fatigue and muscle soreness.

At the end of this visit, we will give you an ingestible core temperature pill and show you how to use it. You will swallow this pill the night before (or 5-10 hours before) you come for the experimental visit.

Experimental Visit (1.5-2 hours). The exercise sessions in a heated environment will take place in an environmental chamber in the Bowerman Sports Science Center in Hayward Stadium at the University of Oregon. The chamber is a 12 ft x 12 ft x 12 ft room where we can control temperature, humidity, and wind speed. We will ask you to arrive hydrated (drink water before arriving), having abstained from intense exercise for 24 hours, and wearing or bringing clothes appropriate for exercise training in the heat. We will ask you to wear the same clothing for your second session (at least seven days later). We will ask you to record what you ate that day and to consume a similar meal prior to your second experimental visit.

Your core temperature will be measured with an ingestible temperature pill, manufactured by HQ Inc or BodyCap, that you will swallow the night before. These temperature pills have been tested for safety and accuracy and given approval by the U.S. Food and Drug Administration (HQ Inc) or the European Medicines Agency which regulates drugs and devices in the European Union (BodyCap). Both models have been validated by various research studies. Although BodyCap has not been approved by the FDA [Pending approval], it has passed safety and compatibility testing in the European Union. The single-use core temp pill is the size of a multivitamin and will harmlessly pass through your system within 2 days. When you arrive, we will check that the pill is properly communicating with the sensor. In the unlikely event that we are unable to detect the temperature pill with the sensor, we may ask you to use a temperature sensing probe that you will insert into your rectum or to come back on a different day after swallowing another temperature pill. If you opt to use the rectal thermistor (temperature-measuring flexible probe), you will be given instructions on how to self-insert, as well as how to remove and clean it. It is made of a thin flexible rubber material that is inserted 10 cm (approximately 4 inches) past the anal sphincter. The thermistor will remain in place throughout the entire exercise session. The thermistor has a “tail” that will be connected to an external apparatus. The procedure may be a little uncomfortable at first (during insertion), but it should not be painful at any time. Once in place, you may not feel the thermistor at all. This technique is widely used, and it’s considered the gold standard procedure for measuring body (core) temperature.

Before each session, you will be asked to collect a small urine sample in a private restroom in the lab to ensure you are sufficiently hydrated and to test for pregnancy. If the test is positive for pregnancy, you will not be able to participate. We may ask you to drink some water before starting exercise in the heat. You will also be provided with

water during the heat exercise session. While in the restroom, we will ask you to remove your clothing and step on a scale so we can record your nude body weight. The readout for the scale is outside the bathroom and will be recorded by a researcher who is the same sex as you. Nude body weight will be measured at the beginning and end of the experimental sessions in order to calculate fluid losses due to sweat. This allows us to ensure you drink enough water during the heat stress conditions to prevent dehydration. You will change into your exercise attire after your nude body weight has been recorded.

You will be instrumented with a Garmin® heart rate chest strap in order for the CORE devices to work appropriately and not safety purposes regarding your heart rate. Research personnel will attach from 4 - 8 skin temperature sensors at various locations on your body. Additionally, a CORE™ Body Temperature Sensor and a *Calera Research* monitor by CORE™ will both be attached to the heart rate strap about 20 cm (~8 in) below each arm pit. You will rest at room temperature while the temperature sensors adjust to your body temperature. Then, we will collect thirty minutes of temperature and heart rate baseline readings. At the end of the baseline measurements, you will enter the chamber which has been set to one of the following conditions, randomly assigned for each visit:

1. Hot/dry (38°C/100.4°F with 10-20% relative humidity)
2. Hot/humid (28°C/83°F with 80-100% relative humidity)

We have included a range for the relative humidity (RH) setting, because the climate camber may not have the capacity to hold a steady RH at extreme levels and while participants are exercising and sweating.
Once you start to feel hot, we will use box fans to make you more comfortable. We will continuously check in with you to ask if you feel dizzy, nauseous, or uncomfortably warm. Following our standard lab practices, we will remove you from the heated chamber if your core temperature exceeds 39.5°C (103.1°F), even if you feel fine, or if you report any of the previously mentioned symptoms.
You will mount the cycle ergometer or treadmill in the chamber and will be permitted to do warm-up exercises for five minutes. When you are ready to begin, you will cycle or run in these conditions for 45 minutes at an absolute workload of 60% VO_2 Max/Peak. While in the chamber, you will be allowed to drink as much room temperature water as you like but ask you not to pour any water over your body. Your temperature and heart rate will be monitored in real time for the duration of the exercise session. We will ask you if you are feeling any adverse effects or unpleasant symptoms from exercising in the heat. We will stop you from exercising if any of the following experimental end points occur:

- Subject voluntarily stops exercising or is not able to maintain the pace at 60% VO_2 Max.
- Internal core temperature reaches 39.5°C (core pill)

- Subject completes 45 minutes of exercise
- Subject experiences light-headedness, confusion, nausea, or any symptoms of heat illness.

If any of these situations occur, you will be removed from the chamber to rest and cool off. Symptoms of heat exhaustion do not typically occur until core temperature rises above 40°C/104°F. All symptoms subside upon lowering core temperature. Ice packs will be on hand if rapid cooling is necessary. We will continue to monitor your temperature and heart rate until you have fully recovered.

At the end of the heated exercise period (45 minutes), you will be transferred out of the chamber and to a recovery chair. We will continue to monitor your core temperature until it has fallen below 38.5°C (101.3°F). If your core temperature remains high or if you report feeling too hot, dizzy, or nauseous, you will be cooled down more quickly with cold packs. Once your core temperature is below 38.5°C and you feel fine, we will remove any sensors from your body. Then, you will enter the private bathroom to provide your nude body weight and have the opportunity to change your clothes. We will offer you a snack (e.g., granola bar) and fluids (e.g., 12 oz Gatorade) to eat and drink. You will be asked to return in about one week to repeat the procedure under the other heat and humidity conditions listed above.

We will tell you about any new information that may affect your willingness to continue participation in this research.

Possible reasons for withdrawal. The investigators may stop you from participating in this study. The reasons for withdrawal might include:

- It is in your best interest
- You have a symptom that requires stopping the research
- You need a treatment not allowed in this research
- You become pregnant
- The research is cancelled by the FDA, the sponsor, or the IRB
- You are unable to keep your scheduled appointments

What happens to the information collected for this research?

Information collected for this research will be used to determine whether CORE™ is accurate at calculating the core body temperature of athletes exercising in a variety of hot environments. It may be used in published reports and conference presentations. Your name will not be used in any published reports or conference presentations about this study. Identifiers might be removed from identifiable private information collected in this research. After removal of identifiers, the information may be used for future research or distributed to another investigator for future research without obtaining additional consent.

How will my privacy and data confidentiality be protected?

We will take measures to protect your privacy including conducting research in a private setting and using secure data collection platforms. Despite taking steps to protect your privacy, we can never fully guarantee your privacy will be protected.

It is possible that some of the sessions may involve more than one subject participating at the same time, so subjects may learn each other's identities. However, optional privacy measures are available upon request including:

- Scheduling your sessions when no other subjects are present
- "Do not disturb" door sign
- Privacy screens to partially or completely block the view of other subjects and non-essential research staff

We will take measures to protect the security of all your personal information including coding all data collected in connection with this study by assigning a subject identification number. The document that links your identity with your subject number will be kept in a password protected file on a password protected computer in the lab, separated from all data. The coded list of names will be destroyed when study results are published or 24 months after completion of the study, whichever comes first. Any information that can be identified with you will remain confidential and will be disclosed only with your permission. Other information (de-identified) may be stored by the researchers indefinitely. Despite these precautions to protect the confidentiality of your information, we can never fully guarantee confidentiality of all study information. Heart rate data will be collected in conjunction with the CORE. All heart rate data is coded such that no identifiable information will be accessible.
Biospecimens (urine) collected as part of this research will not be used or distributed for future research studies. The urine samples will be immediately disposed of after testing for hydration levels and pregnancy (if applicable). There is absolutely no chance that your specimens could ever be used for commercial profit.
You will be asked to complete a medical history form for screening purposes. This form will list personal identifying information (name, address, phone, emergency contact info) so that in the unlikely event of a medical emergency in which we would activate the emergency medical system, we would be able to provide this information to emergency healthcare providers. This document will be retained in a locked file cabinet in the lab. When your involvement in the study ends, identifiable information will be redacted from this document. Deidentified data may be kept on file indefinitely.
Individuals and organizations that conduct or monitor this research may be permitted access to and inspect the research records. This may include access to your private information and medical results. These individuals and organizations include:

- The Institutional Review Board (IRB) that reviewed this research
- Government regulatory agencies
- The Food and Drug Administration

If data is shared with researchers outside of the University of Oregon physiology lab for the purpose of statistical analysis, all personally identifiable information will be removed.
A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you.

At most, the Web site will include a summary of the results. You can search this Web site at any time.

What are the risks if I participate in this research?

Exercise testing: There is some minor discomfort associated with exercise testing, including temporary fatigue, shortness of breath, and muscle soreness. These sensations resolve within minutes after the test is completed. There is the possibility of some residual muscle soreness in the few days following the exercise test. There is also the risk of a heart attack or death during an exercise test. The risk of a complication requiring hospitalization is about 1 incident in 1000. The risk of a heart attack during or immediately after an exercise test is less than 1 incident in 2500. The risk of death during or immediately after an exercise test is less than 1 incident in 10,000.

Core temperature pill: Your core temperature will be measured with a core temperature pill that is the size of a multivitamin and is designed and approved for human use. The risks of using the temperature pills include discomfort during swallowing and irritation (pain, swelling) of the lining of the digestive tract, which can be avoided by drinking enough water with the pill. It will harmlessly pass through your system within about 2 days. The pill is disposable and is not recovered. Other risks may include discomfort with swallowing. Hundreds of thousands of core temperature pills have been distributed since the 1960's with only one known case of an adverse event. In this case, the pill became lodged in an individual's digestive tract, which required surgical removal. No other risks have been identified. Volunteers with a history of obstructive diseases of the gastrointestinal tract (blockages in your digestive system) including diverticulosis (bulging pouches in the colon wall), diverticulitis (inflamed pouches in the colon wall), inflammatory bowel disease (chronic inflammation of the digestive tract), peptic ulcer disease (sores in the lining of the stomach, Crohn's disease (chronic inflammation of the digestive tract, ulcerative colitis (inflammation and sores in the colon), or previous GI surgery should not use a core temperature pill. Before swallowing the pill, please inspect the pill for cracks or any other damage before ingesting. If you notice a crack or any other damage, do not take the pill and contact the researchers. The BodyCap core temperature pill we are using to monitor your temperature is not yet cleared or approved by the Food and Drug Administration (FDA) so we don't know how safe or effective it will be at measuring your core temperature and there may be unknown risks from using this pill.

Rectal thermistor *(optional)***:** The use of rectal thermistors to measure core temperature carries minimal risk. The primary risk is damage to the lining of the rectum; however, this risk is very slight as we use a flexible thermistor that is designed for this purpose. You will be asked to self-insert the rectal temperature probe. If someone is not available to assist you, there may be a slight increased risk of discomfort. Individuals with recent rectal, anal, vaginal, or prostate surgery should not use a rectal thermistor. In addition, those who have a personal history of heart disease should not use a rectal thermistor, as the use of a rectal thermometer can cause a vagal reaction (sudden drop in heart rate and blood pressure in reaction to a stressor), increasing the potential for arrhythmias (irregular heartbeat) and fainting. There is also the risk of infection. The risk of infection is similar to that of having a bowel movement and is considered minimal.

Heat exposure: There are some risks associated with heat exposure, including: fatigue, light-headedness, muscle cramps, dehydration, and neurological detriments (i.e. heat stroke). However, these symptoms do not typically occur until core temperature rises above 40°C (104° F). Your core temperature will be constantly monitored (by ingestible pill or rectal probe), and you will be removed from the heat immediately if either core temperature reaches 39.5°C or you experience any symptoms of heat-related illness. You will be instructed to notify the investigators immediately if you experience any of these symptoms. All symptoms subside upon lowering core temperature. Ice packs will be on hand for rapid cooling if necessary.

Risks for subjects who are pregnant: Potential risks to subjects who are pregnant, in addition to the other risks already mentioned, include exercising beyond what is recommended by your doctor (see 'exercise testing' above) and potential harm to the fetus from heat exposure. There is not enough research on the effects of heat on a developing fetus. Overheating during the first trimester may result in neural tube (brain and spine) defects or miscarriage. Overheating later in pregnancy may result in dehydration of the pregnant person. Therefore, the American College of Obstetricians and Gynecologists suggests that pregnant people should avoid elevations in core body temperature. Therefore, subjects who are pregnant or trying to conceive may not participate in this study. Due to the increased risk of exercise testing and heat exposure, any subject with childbearing potential will be required to take a pregnancy test when they arrive to the lab for their informed consent and on the experimental visit days. Thus, subjects who are pregnant or trying to conceive will be excluded from the study. The risk associated with taking a pregnancy test is finding out that you are pregnant.

Emergencies: In the event of a non-life-threatening emergency, investigators will follow the established Human Physiology Emergency procedures. In the event of a life-threatening emergency, investigators will follow the established Human Physiology Emergency procedures which include an investigator providing basic first aid as appropriate (including high quality CPR and use of an Automated External Defibrillator (AED) if needed) and calling 911 to activate an emergency response. After the activation of an emergency response, the emergency personnel will determine if transport is necessary. If transport is needed, the subject will be transported by ambulance to a local emergency facility.

Tracking of taxable income: Please note, compensation from participation in Human Subjects Research studies is taxable income. If your compensation totals $600 or more in a calendar year, the University is required to report the income to the IRS. The University requires its departments to track participant compensation and may contact you to complete a Form W-9 for tax reporting purposes. Because of the federal and University tracking requirements, your name will be associated with participation in research. Department and University administrators will have access to this information but will not have access to research data.

What are my responsibilities if I choose to participate in this research?
If you take part in this research, you will be responsible for:

- Adhering to scheduled sessions and communicating with the researchers in the event that you need to reschedule any sessions.
- Adhering to instructions from the researchers regarding when you need to fast, refrain from consuming caffeine or medications, abstain from alcohol, exercise, or heat therapy for specific testing days.

What if I want to stop participating in this research?
Taking part in this research study is your decision. Your participation in this study is voluntary. You do not have to take part in this study, but if you do, you can stop at any time. You have the right to choose not to participate in any study activity or completely withdraw from continued participation at any point in this study without penalty or loss of benefits to which you are otherwise entitled. Your decision whether or not to participate will not affect your relationship with the researchers or the University of Oregon.
If you choose to stop participating in this research, the data collected on you as a subject to the point of withdrawal remains part of the study database and may not be removed.

Will it cost me money to take part in this research?
There are no costs associated with participation in this research study.

What if I am injured because of participating in this research?
If you are injured or get sick because of being in this research, call the researchers immediately.

In the event you suffer a research-related injury, your medical expenses will be your responsibility or that of your insurance company (or other third-party payer), although you are not precluded from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research. If you are a UO student or employee and are covered by a UO medical plan, that plan might have terms that apply to your injury.

If you experience harm because of the project, you can ask the State of Oregon to pay you. If you have been harmed, there are two University representatives you need to contact. Here are their addresses and phone numbers:

General Counsel/ Office of the President 1226 University of Oregon Eugene, OR 97403-1226 (541) 346-3082	**Research Compliance Services** 5237 University of Oregon Eugene, OR 97403-5237 (541) 346-2510 ResearchCompliance@uoregon.edu

A law called the Oregon Tort Claims Act may limit the amount of money you can receive from the State of Oregon if you are harmed.

Will I be paid for participating in this research?
With full participation, we anticipate you will receive $40 - $60 total ($10/hour of time in the lab) in the form of a check or deposit into your ClinCard account after completion

of the study. If you decide to stop participating part way through the study, or if you are excluded for failure to comply with protocols or for another unforeseen reason, your payment will be prorated based on your time in the study.
Please be aware, compensation for participation in research may be considered taxable income. The University requires tracking for compensation that is paid to you; this may include your name and contact information. This information is stored confidentially and separate from research data. If you receive $600 or more in a calendar year, you may be contacted to provide additional information (e.g. Social Security Number) for tax reporting purposes.

Who can answer my questions about this research?
If you have questions, concerns, or have experienced a research related injury, contact the research team at:

Dr. Minson
(541) 346-4105
minson@uoregon.edu

An Institutional Review Board ("IRB") is overseeing this research. An IRB is a group of people who perform independent review of research studies to ensure the rights and welfare of participants are protected. UO Research Compliance Services is the office that supports the IRB. If you have questions about your rights or wish to speak with someone other than the research team, you may contact:

Research Compliance Services
5237 University of Oregon
Eugene, OR 97403-5237
(541) 346-2510
ResearchCompliance@uoregon.edu

STATEMENT OF CONSENT
I have had the opportunity to read and consider the information in this form. I have asked any questions necessary to make a decision about my participation. I understand that I can ask additional questions throughout my participation.
I understand that by signing below, I volunteer to participate in this research. I understand that I am not waiving any legal rights. I have been provided with a copy of this consent form. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.
I consent to participate in this study.

Name of Adult Participant	Signature of Adult Participant	Date

Researcher Signature (to be completed at time of informed consent)
I have explained the research to the participant and answered all of his/her questions. I believe that he/she understands the information described in this consent form and freely consents to participate.

Name of Research Team Member	Signature of Research Team Member	Date

Appendix D: Phone Questionnaire

Telephone/In-Person Screening Script: CORE Study

Study Team: Hello, my name is [*name*] from the department of Human Physiology at the University of Oregon. May I please speak to [*name*]?

If the Person is not available: Thank the person who answered and say goodbye.

If the Person is available: Confirm that you are speaking to the correct person.

I am contacting you because you expressed interest in the CORE research study.

Study Team: Is this an appropriate time to talk?

If the person says "No" or "I'm not sure".

Study Team: Okay. [*Ask if you can schedule another time to talk. If the person is not sure or seems hesitant, thank him/her, and say goodbye.*]

If the Person says "Yes". [Proceed with giving them information about the study].

Study Team: Great, let's start by giving you some information about the study. The pre-screening will take approximately 30 minutes to complete, and you will not receive compensation for participating in the pre-screening. Additionally, there are no benefits to participating in the pre-screening. [Provide a brief description about the study and include the following].

- The CORE devices are marketed to athletes and the general population as a tool to monitor core body temperature during exercise. Since prolonged exercising in a hot environment runs the risk of heat illness, our study investigates whether the device can accurately, and reliability detect core temperature when compared to an ingestible core temperature pill.
- The purpose of this study is to assess the reliability of external core temperature sensing devices compared to an ingestible temperature pill while exercising during two different environmental conditions.
- The study involves 3 visits to the lab. Day 1 consists of screening and pre-testing. The pre-test includes either a treadmill VO2 max test or cycle ergometer VO2 peak test. Day 2 and 3 will consist of experimental visits.
- The experimental days will be randomized and involve you exercising for 45 minutes in an environmental chamber in either a hot/dry climate (38°C/100.4°F and 10-20% relative humidity) or hot/humid climate (28°C/82.4°F and 80-100% relative humidity).
- Prior to arriving to the lab, you will receive an ingestible core temperature

pill that you will take the night before exercising.
- Upon arrival to the lab, you will be weighed and provide a small sample of urine for assessment of hydration status and pregnancy status if applicable. You will then place a heart rate monitor and two external CORE sensors on your chest.
- You will rest in a thermoneutral room for 20-30 minutes and then exercise for 45 minutes in an environmental simulation chamber set to the randomized condition.
- After exercising, you will be escorted out of the environmental chamber, take your post exercise weight, and allowed to recover in a thermoneutral room. You will be offered a cold beverage at this time and a light snack too.
- Each visit will take approximately 1.5 hours and the total estimated time in the lab will be 4-6 hours.

Study Team: Do you have any questions? *[Answer any questions, then proceed.]*

Study Team: May I ask a few questions to help determine if you may qualify for the study?

If the person says, "No", thank the person for his/her time and politely end the call.

If the person says, "Yes", [Proceed].

Study Team: I will be collecting your answers to these questions for screening purposes. The information obtained during this pre-screening will not be used or distributed for future research studies, even if identifiers are removed. The information we collect from you is kept private and used only for the research study we are discussing. There is minimal risk associated with a breach of confidentialty and protected health information you provide to us. If at any time in the screening process you do not wish to continue on, please let me know and we will stop imediately. Participating in the screening process is completely voluntery.

The information you provide will not be kept if you choose not to enroll in the study or if you do not qualify to be in the study.

Do I have your permission to proceed with the screening process?

If the person says, "No, I do not wish to continue any further", thank the person for his/her time and politely end the call.

If the person says, "Yes", [Proceed with screening process].

Study Team: Great, now I am going to ask you a series of questions to see if you qualify for the study.

- Are you 18-59 years old? [Yes]
- Do you currently smoke nicotine or cannabis? [No]
- Do you have any heart or vascular conditions? [No]
- Are you taking any medication that affects heart or vascular function? [No]
- Are you pregnant, breast feeding, trying to concieve, or undergoing treatment to increase sperm count? [No]
- Do you have a history of: [No]
    - Stroke, cloting disorders, or venous thrombosis?
    - Heat illness or heat injury?
    - Obstructive diseases of the gastrointestinal tract including diverticulosis, diverticulitis, inflammatory bowel disease, peptic ulcer disease, Chron's disease, ulcerative colitis, or GI surgery?
- Are you considered a highly trained or an elite cyclist, runner, or triathlete under one of these two categories? [Yes]
    - **Tier 3:** Highly Trained/National Level (Provincial/State or Academy Programs)
        - Competing at the national level.
        - Team-sport athletes competing in national and/or state leagues/tournaments.
        - Achievement of within ~20% of world-record performance and/or world-leading performance.
        - NCAA Division II and III athletes.
        - Completing structured and periodized training and developing towards (within 20%) of maximal or nearly maximal norms within the given sport.
        - Developing proficiency in skills required to perform sport (ie, biomechanics, ball skills, acquired decision-making components).
    - **Tier 2:** Trained/Developmental
        - Local-level representation.
        - Regularly training ~3 times per week.
        - Identify with a specific sport.
        - Training with a purpose to compete.
        - Limited skill development.

If the person did not meet the inclusion criterion, please inform them they do not quality to participate in the study.

If the person answers the following questions with the bracketed [ ] response, proceed with scheduling a time to come into the lab to complete the screening and perform a graded exercise test.

Study Team: Great, it appears you are qualified for this study; we need to get you scheduled to complete the screening in-person and perform a graded exercise test. What day works best for you? Do you have any questions? [Schedule first day in the lab, address any questions, and provide them with the primary contact email: sjchacon@uoregon.edu and phone number (541) 357 – 9782 to contact if they have any further questions about the study].

Appendix E: Pill Contraindications

Subject #:_____
Date:_____

Core Temperature Pill Contraindications Questionnaire

Do any of the following apply to you?

	Circle one
Contraindications:	
1. Body weight less than 80 pounds?	Yes No
2. Known or suspected obstructive disease of the gastrointestinal tract, including but not limited to Crohn's disease, diverticulitis, and inflammatory bowel disease?	Yes No
3. Exhibiting or having a history of disorders or impairments of the gag reflex?	Yes No
4. Previous gastrointestinal surgery?	Yes No
5. Felinization of the esophagus?	Yes No
6. Undergoing and Nuclear Magnetic Resonance (NMR) / Magnetic Resonance Imaging (MRI) scanning during the period that the CorTemp Temperature Sensor is within the body?	Yes No
7. Hypomotility disorders of the gastrointestinal tract, including but not limited to ileus?	Yes No
8. Cardiac pacemaker or other implanted electromedical device?	Yes No
Warnings:	
1. Have you experienced swallowing disorders and/or experienced difficulty swallowing the sensor before?	Yes No
2. Exhibiting nausea and/or vomiting?	Yes No

Investigator Signature: _____
Date: _____

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