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**Bogerd, CP, Velt, KB, Annaheim, S, Bongers, CCWG, Eijsvogels, TMH and Daanen, HAM (2018) Comparison of two telemetric intestinal temperature devices with rectal temperature during exercise. Physiological Measurement. ISSN 0967-3334**

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Title: Comparison of two telemetric intestinal temperature devices with rectal temperature during exercise

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## Summary

The experienced discomfort of rectal probes and esophageal probes for the estimation of body core temperatures has triggered the development of GI-capsules that are easy acceptable for athletes and workers due to their non-invasive characteristics.

We compare two new GI-capsule devices with rectal temperature during cycle ergometer exercise and rest. Eight participants followed a protocol of (i) 30 min exercise with a power output of 130 W, (ii) 5 min rest, (iii) 10 min self-paced maximum exercise, and (iv) 15 min rest. Core temperature was measured using two GI-capsule devices (e-Celsius and myTemp) and rectal temperature.

The myTemp system gave temperatures indifferent different from rectal temperature during rest and exercise. However, the factory calibrated e-Celsius system, showed a systematic underestimation of rectal temperature of 0.2 °C that is corrected in the 2018 versions. Finally, both GI-capsules react faster to temperature changes in the body compared to the rectal temperature probe during the rest period following maximum exercise.

Keywords: core temperature, gastrointestinal temperature, comparison, telemetric temperature measurement, myTemp, e-Celsius

# Introduction

It is well established that endurance performance is compromised with uncompensable heat-stress (Cheung *et al.* 2000) where high body core temperatures are attained (Gonzalez-Alonso *et al* 1999). Furthermore, heat tolerance and thus high core temperatures is dependent on training status (Cheung and Mclellan 1998). Therefore, athletes use both internal cooling, e.g., with an ice slurry (Siegel *et al* 2010) or external cooling such as cooling vests or ice pads (Bogerd *et al* 2010, Bongers *et al* 2017a) prior to or during exercise to reduce heat strain, i.e., to keep the core temperature lower compared to the absence of a cooling intervention. The thermal balance during exercise is not easy to maintain since high levels of metabolic heat production, often exceeding 1000 W, have to be exactly matched by heat loss. A discrepancy between metabolic heat production and heat loss will lead to hypothermia or hyperthermia. Severe cases of hyperthermia has been reported at the end of a marathon among finishing athletes (Roberts 2007). Hypothermia leads to suboptimal performance, since muscle contractions are less efficient in cool muscles (De Ruiter and De Haan 2001). For hyperthermia it has been shown that gross efficiency drops by about 1% for every 1 °C core temperature increase for core temperatures up to 38.3 °C (Daanen *et al* 2006). In order to maintain optimal performance it is therefore instrumental to monitor exercise-induced changes in core temperature. A few decades ago, gastro-intestinal (GI)-capsules became available that have been validated to be a good estimator of body core temperature (Byrne and Lim 2007, Teunissen *et al* 2012, Mündel *et al* 2016, Towey *et al* 2017, Travers *et al* 2016).

Although it is well acknowledged that no single core temperature exists and that at each measurement site the local thermal balance defines the temperature (Taylor *et al* 2014), there are some preferred sites for measurement. Rectal temperature is considered to be a good standard for tracking stationary temperatures, but has been shown to have a delayed responsiveness compared to esophageal temperature (Teunissen *et al* 2012). The latter is widely considered as fast and reproducible (Taylor *et al* 2014). The advantage of rectal temperature measurements is that the measurement location is reliable and well defined when the probe is inserted at least 7 cm past the anal sphincter (Buono *et al* 2014). However, the rectal probe insertion may cause discomfort and typically has a wire connection. Therefore, rectal temperature is not suitable in field based conditions (Ducharme *et al* 2001). GI-capsules are comfortable and easily applicable in both lab and field conditions, but the location in the body varies and may lead to variations in recorded temperature. Wilkinson et al. (2008) reported that cold water ingestion has a strong location specific influence on GI-temperature. To avoid interference between fluid ingestion and core body temperature measurements, it is recommended to abstain from drinking during the experiment, to drink water of 37 °C (Ducharme *et al* 2001) or to ingest the capsule several hours prior the start of the experiment to ensure passage through the stomach (Byrne and Lim 2007), up to about 6 hours (Lee *et al* 2000).

This study evaluates two recently developed GI capsule systems (e-Celsius and myTemp) and compares the results with rectal temperature measurements. This is the first in-vivo study evaluating the myTemp GI capsule system with rectal temperature. Previously, we validated the myTemp system ex-vivo (Bongers *et al* 2017b) and compared to e-Celsius and two other systems ex-vivo (Bongers *et al* 2018). Differences were found among the systems. However, the validity, test-retest reliability, and inertia were qualified as very well for all systems. These ex-vivo tests were carried out using a water bath, the question remains how these systems perform in-vivo, while participants ingest the capsule and during exercise. Travers *et al* (2016) recently carried out such in-vivo tests compared the e-Celsius system with rectal temperature and with a GI capsule system available on the market since several years (VitalSense). They find that both GI systems underestimation rectal temperature with 0.2 °C. In this study we include the myTemp system and use a different exercise protocol. Travers *et al* (2016) used two different exercise protocols, one mimicking soccer on a treadmill with over 30 changes in running speed during 15 min and a cycle ergometer test with a constant power output. We used an intermittent cycling exercise with fewer changes in power output compared to Travers *et al* (2016), allowing a better insight into the delay between changes in heat production (related to power output) and core temperature measurement site. We hypothesize that the e-Celsius and myTemp system will give comparable results and show less time lag for temperature changes than rectal temperature.

# Methods

## Participants

Eight male participants voluntarily participated in this study (age: 32 ± 13 yrs, height: 1.88 ± 0.52 m, weight: 80.0 ± 7.6 kg). Participants were included based on a positive evaluation of a health questionnaire by a physician. The experimental protocol was reviewed and approved by the TNO Ethics Committee in accordance with the Helsinki Declaration of 1975, as revised in 2013. All participants gave written consent prior to inclusion.

## Protocol

Participants visited our facilities once. During this visit, participants ingested two GI capsules, one for each GI system, followed by a rest period allowing time for the capsules to pass through the stomach. The time between insertion and onset of measurements was 137 ± 22 minutes. The participants were instructed to wear a T-shirt and shorts. Furthermore, they were not allowed to eat or drink throughout the measurement protocol. Shortly before the start of the measurements the participants inserted a rectal probe (dedicated rectal probe with a DS18B20 temperature sensor, connected with a wire to a logger (MSR, 145WD, Seuzach, Switzerland), additional details are given in Table 2) at least 10 cm beyond the rectal sphincter. The experiment took place in a climatic chamber in order to accurately control the environmental conditions of 29.6 ± 0.1 °C air temperature and 49 ± 1% humidity (3M, QUESTemp° Heat Stress Monitor QT-44, St. Paul, USA). Upon arrival in the climatic chamber, participants rested for 20 minutes in order to familiarize to the circumstances. Thereafter, the participants performed a 30 minute submaximal exercise with a power output of 130 W on a cycle ergometer (Lode, Lode Excalibur, Groningen, The Netherlands). Hereafter, the participants rested for 5 minutes, followed by a maximal exercise phase of 10 minutes on a self-selected pace. All measurements were continued for 15 minutes after exercise cessation. The exercise protocol is summarized in table 1. During the exercise sessions the participants were instructed to keep their cadence constant around a value of their choice, but within 60 – 120 rpm.

**Table 1.** The exercise protocol.

| | Phase | Duration [min] | Power Output [W] |
|---|---|---|---|
| 1 | Exercise | 30 | 130 |
| 2 | Rest | 5 | 0 |
| 3 | Exercise | 10 | Self paced maximum |
| 4 | Rest | 15 | 0 |

## Telemetric intestinal temperature devices

The characteristics of both capsule systems are presented in table 2; the capsules are similar to those used to encapsulate medical agents. The e-Celsius system consisted of a GI capsule and a receiver, referred to as the monitor (BodyCap, Caen, France). Unique to this device is that the capsule is equipped with a memory chip, which allows storage of data in case of loss of connection with the monitor. Data stored in the memory is transferred once the connection with the monitor is restored. The myTemp system (myTemp, Nijmegen, The Netherlands) is a prototype system that is not yet commercially available. This system consists of a GI capsule and a waist belt. The uniqueness of the myTemp system is that the capsule lacks a battery. Its energy supply is created through a magnetic field created by the belt which causes a current in a coil in the capsule. The lifetime of a GI capsule is usually determined by the battery, but the lifetime of the myTemp capsule is infinite (according to the manufacturer) due to external energy supply. Absence of a battery will reduce the environmental pollution. Moreover, the battery is an important cost driver and the MyTemp sensor system will be less expensive than systems with a battery.

The e-Celcius and myTemp systems were factory calibrated. The MSR system for rectal temperature was calibration in our lab, using a thermostat water bath and an externally calibrated PT-100 temperature sensor including logger (P750, Tservice, Gennep, the Netherlands).

**Table 2.** Specifications of devices used to measured core temperature.

| Brand | Type | Sample Time [s] | Accuracy [°C] | Sensor Location | Capsule Size [mm²] | Capsule Mass [g] | Capsule storage Datapoints | Capsule data transmition [MHz] | Equiped With Battery | Software name and version |
|---|---|---|---|---|---|---|---|---|---|---|
| myTemp | * | 10 | 0.01 | Intestines | 20.0 x 8.0 | 8.0 | 0 | 433 | No | e-Performance manager v01.01.00.0C |
| e-Celsius | Performance | 30 | 0.2 | Intestines | 17.7 x 8.9 | 1.7 | 2000 | 433 | Yes | myTemp Manager v01.08 |
| MSR | 145 | 1 | 0.1 | Rectum | - | - | - | - | - | MSR v5.30.18 |

*A type name is not yet defined.

## Data processing and statistics

Rectal temperature was sampled every second, whereas the myTemp and e-Celsius temperature were registered every 10 s and 30 s, respectively. The following parameters were derived for each phase of the experimental protocol (i.e., exercise at 130 W, rest, maximum exercise, and second rest): (i) mean core temperature, ii) Root Mean Square Deviation (RMSD) from the capsule systems with rectal temperature as reference (first difference for every data point for each participant between two parameters, then the root of the squared mean), and (iii) maximum core temperature. In order to investigate the differences in response time among the three different devices, the slope in core temperature was obtained from a linear regression analysis on the last 7.5 min of the final rest period. This is the period after the peak temperature. Finally, Bland-Altman plots were used to visualize the deviation for each system from rectal temperature.

All data is presented as mean ± standard deviation, unless indicated otherwise. Statistical analysis was carried out with Statistica 13.1 and IBM SPSS Statistics 24. A two-way repeated measures ANOVA for within participant effect is applied to these parameters to evaluate differences among the three devices used to measure core temperature. A Bonferroni post-hoc test was employed upon statistical significant effects ($p < .05$).

# Results

Figure 1 shows the average core temperatures measured with the three different devices. Table 3 gives the results per phase for each device separate for mean temperature, RMSD from the capsule systems with rectal temperature, and maximal temperature. The mean absolute temperatures differed between the three investigated systems ($p = .011$). A post-hoc analysis showed that this is due to consistently lower temperatures for e-Celsius compared to myTemp ($p = .015$). The RMSD indicates that the absolute differences between myTemp and rectal are not different from the absolute differences between e-Celsius and rectal ($p = .268$). There are no differences between the investigated systems for maximum temperature ($p = .058$).

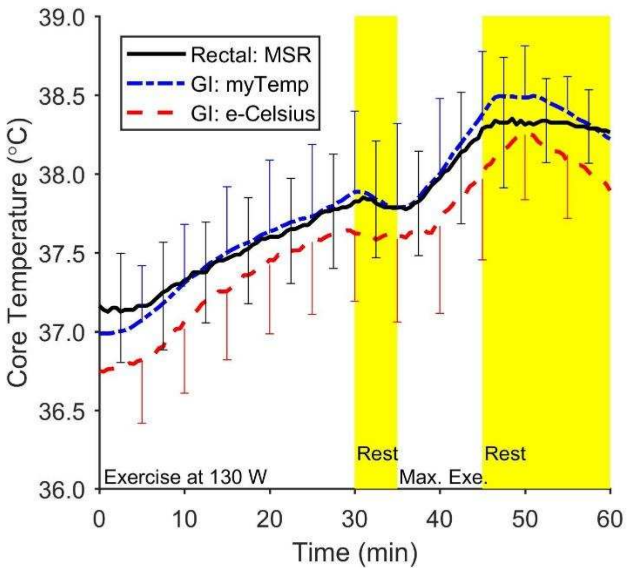


**Figure 1**. Rectal, myTemp, and e-Celsius temperatures during the four phases as indicated (see also table 1) averaged over all participants. The error-bars indicate ± one standard deviation for the capsule systems.

**Table 3.** Mean, root mean square deviation, and maximum temperatures for the different devices and phases.

| Mean Core Temperature per Phase ($^{o}$C) | | | | | |
|---|---|---|---|---|---|
| Device | Submaximal Exercise | Rest | Maximal Exercise | Rest | ANOVA* |
| A: Rectal: MSR | 37.5 ± 0.3 | 37.8 ± 0.4 | 38.0 ± 0.4 | 38.3 ± 0.3 | F = 6.391 |
| B: GI: myTemp | 37.4 ± 0.4 | 37.8 ± 0.5 | 38.0 ± 0.5 | 38.4 ± 0.4 | p = .011 |
| C: GI: e-Celsius | 37.2 ± 0.4 | 37.6 ± 0.5 | 37.7 ± 0.5 | 38.1 ± 0.3 | |

*Results for the within participant effects, post-hoc analysis revealed: p(a vs. b) = 1.000, p(a vs. c) = .640, p(b vs. c) = .015.

| Root Mean Square Deviation of Gastro-Intestinal Core Temperature compared to Rectal Temperature ($^{o}$C) | | | | | |
|---|---|---|---|---|---|
| Device | Submaximal Exercise | Rest | Maximal Exercise | Rest | ANOVA |
| A: GI: MyTemp | 0.19 ± 0.15 | 0.22 ± 0.18 | 0.30 ± 0.20 | 0.24 ± 0.15 | F = 1.451 |
| B: GI: e-Celsius | 0.30 ± 0.13 | 0.25 ± 0.15 | 0.40 ± 0.15 | 0.31 ± 0.15 | P = .268 |

| Maximal Core Temperature per Phase ($^{o}$C) | | | | | |
|---|---|---|---|---|---|
| Device | Submaximal Exercise | Rest | Maximal Exercise | Rest | ANOVA* |
| A: Rectal: MSR | 37.8 ± 0.4 | 37.9 ± 0.4 | 38.3 ± 0.4 | 38.5 ± 0.3 | F = 5.516 |
| B: GI: myTemp | 37.9 ± 0.4 | 37.9 ± 0.5 | 38.4 ± 0.5 | 38.6 ± 0.4 | p = .058 |
| C: GI: e-Celsius | 37.7 ± 0.5 | 37.7 ± 0.5 | 38.0 ± 0.4 | 38.3 ± 0.3 | |

*Results for the within participant effects.

Bland-Atlman plots are given in figure 2, comparing the three devices to each other. The differences among the devices show comparable standard deviations ranging between 0.20 $^{o}$C and 0.27 $^{o}$C. The e-Celsius device shows a mean difference (systemic bias) of -0.22 $^{o}$C and 0.25 $^{o}$C compared to rectal temperature and myTemp, respectively. The systemic bias between myTemp and rectal is the closes to zero with 0.03 $^{o}$C (figure 2).

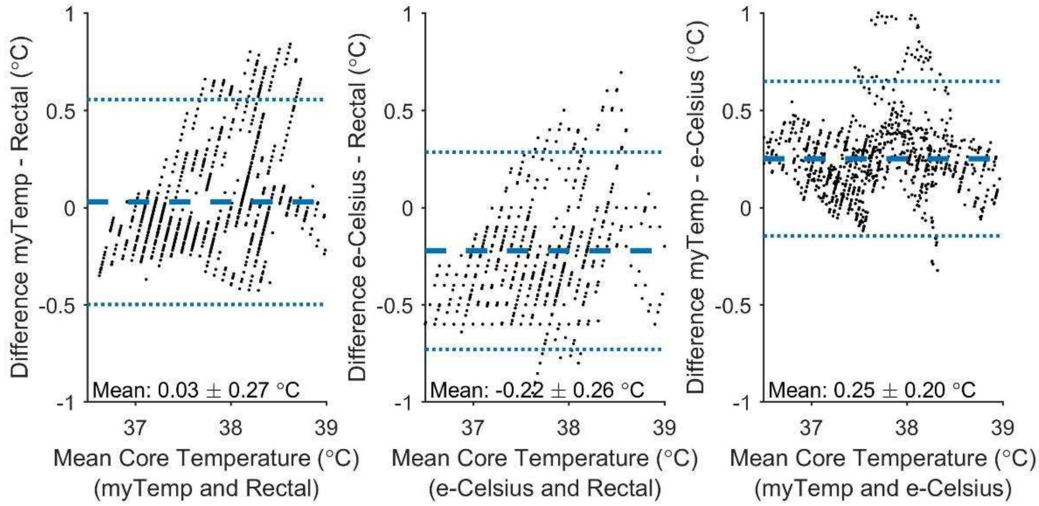


**Figure 2**. Bland-Altman plots comparing the different devices used for measuring core temperature. The middle horizontal line (dark blue) indicates the mean difference between two devices, both outer horizontal lines (light blue) enclose the 95% limits of agreement. The mean difference ± one standard deviation are also given per plot.

The rate of change in core temperature was obtained from the last 7.5 min of the last rest phase (table 4). This slope indicates the responsiveness of the devices. The slope of rectal temperature was significantly different from both GI based devices ($F = 11.520$, $p = .001$). Despite interindividual differences, post-hoc analysis of the one-way ANOVA repeated measures revealed $p = .027$ and $p = .012$ for myTemp and e-Celsius both compared to rectal, respectively. In fact, the rate of core temperature decrease was a factor 3.5 and 3.9 faster for myTemp and e-Celsius compared to rectal, respectively.

**Table 4.** Rate of change in core temperature (°C/h) during the last 7.5 min per participant as well as mean and standard deviation (std).

| Participant | Rectal: MSR | GI: myTemp | GI: e-Celsius |
|---|---|---|---|
| 1 | 0.0 | -3.4 | -2.9 |
| 2 | -0.8 | -2.0 | -3.6 |
| 3 | -0.3 | -2.0 | -2.5 |
| 4 | -1.3 | -1.6 | -2.1 |
| 5 | -1.3 | -1.0 | -1.2 |
| 6 | 1.1 | -0.6 | 0.0 |
| 7 | 0.0 | -1.9 | -0.9 |
| 8 | -1.7 | -3.0 | -4.2 |
| Mean | -0.6 | -1.9 | -2.2 |
| std | 0.9 | 0.9 | 1.4 |

# Discussion

The experienced discomfort of rectal probes and esophageal probes for the estimation of body core temperatures has triggered the development of GI-capsules that are easy acceptable for athletes and workers due to their non-invasive characteristics. A recent ex-vivo investigation showed that the myTemp and e-Celsius systems are able to accurately represent fluid temperatures and fast changes in fluid temperatures (Bongers *et al* 2018). The results of the current in-vivo study focusses on the performance of these GI-capsules during exercise and consecutive rest periods.

The temperatures of the e-Celsius systems were systematically lower than the rectal values by about 0.2 °C averaged over the two exercise and two rest phases. This systematic underestimation of the e-Celsius system was also observed in a recent experiment that compared the e-Celsius system to the Vital Sense system and rectal temperature during running and cycling (Travers *et al* 2016). Both systems showed an underestimation of 0.2 °C compared to the rectal temperature values during cycling and running. This difference was comparable during calibration in water, and led the authors to suggest that calibration of GI-capsules is required prior to their use (Travers *et al* 2016). Our study showed that this does not apply to the myTemp system which can be used without prior calibration. However, the dynamics of the GI system evaluated in this study are very similar as can be observed in figure 2 and table 4.

Rectal temperature showed a slower response compared to both the myTemp and e-Celsius systems. This is particularly visible after the maximum exercise phase; the decrease in core temperature after maximal exercise was more than three times faster for the GI-capsules than for rectal temperature. The slow response of rectal temperature is in line with earlier observations (Byrne and Lim 2007, Lee *et al* 2000). If fast changes in body core temperature have to be determined, esophageal temperature seems most appropriate since it closely resembles the temperature of the blood returning from the peripheral tissues (Teunissen *et al* 2012). For steady-state exercise both rectal probes and GI-capsules may be applied of which the latter provide more comfort to the user. A disadvantage of the GI-capsules is that the location of the capsule in the digestive system varies over time and that the temperature profile in the GI-tract is not constant. Every location in the GI-tract can be considered as a local spot with a specific core temperature (Taylor *et al* 2014). Rectal probes, when appropriately inserted, do not have this disadvantage. During exercise and in the absence of drinking fluids, however, the fluctuations in the GI-tract are considered to be small (Towey *et al* 2017).

In conclusion, the myTemp system yielded temperatures that were not significantly different from rectal temperature values during rest and exercise. The e-Celsius system, however, showed a systematic bias of 0.2 °C that should be corrected for by calibration prior its use. The GI-capsules react faster to temperature changes in the body compared to the rectal temperature probe in particular in the rest period following exercise.

# Acknowledgement

The authors gratefully acknowledge the e-Celsius and myTemp for providing their system for the purpose of this study.

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