WILLIAM MARTINS JANUÁRIO

VALIDITY AND RELIABILITY OF TWO CORE TEMPERATURE MEASUREMENT TECHNIQUES DURING PHYSICAL EXERCISE IN THE HEAT: CORE SENSOR AND EXERGEN TAT-5000

Dissertation submitted to the Postgraduate Program in Physical Education of the Universidade Federal de Viçosa in partial fulfillment of the requirements for the degree of Magister Scientiae.

Adviser: Thales Nicolau Prímola Gomes

Co-adviser: Emille Rocha Bernardino de Almeida Prata

VIÇOSA - MINAS GERAIS

2023

Ficha catalográfica elaborada pela Biblioteca Central da Universidade Federal de Viçosa - Campus Viçosa

T
J35v
2023

Januário, William Martins, 1991-
Validity and reliability of two core temperature measurement techniques during physical exercise in the heat: CORE SENSOR and EXERGEN TAT-5000 / William Martins Januário. – Viçosa, MG, 2023.
1 dissertação eletrônica (107 f.): il.

Inclui anexos.
Inclui apêndices.
Orientador: Thales Nicolau Prímola Gomes.
Dissertação (mestrado) - Universidade Federal de Viçosa, Departamento de educação física, 2023.
Inclui bibliografia.
DOI: https://doi.org/10.47328/ufvbbt.2024.015
Modo de acesso: World Wide Web.

1. Alterações na temperatura corporal. 2. Ciclismo. 3. Termômetros e termometria. 4. Transtornos de estresse por calor. 5. Onda de calor. I. Gomes, Thales Nicolau Prímola, 1978-. II. Universidade Federal de Viçosa. Departamento de educação física. Programa de Pós-Graduação em Educação Física. III. Título.

CDD 22. ed. 612.01426

Bibliotecário(a) responsável: Bruna Silva CRB-6/2552

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APPROVED: December 20, 2023.

Assent:

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Verifique em https://validar.iti.gov.br

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THALES NICOLAU PRIMOLA GOMES
Data: 18/01/2024 18:07:28-0300
Verifique em https://validar.iti.gov.br

Thales Nicolau Prímola Gomes
Adviser

ACKNOWLEDGMENTS

I would like to express my gratitude to God for allowing me to complete this cycle. It's difficult to put into words how blessed and thankful I feel at this moment. I know that this victory would not have been possible without his guidance, grace, and infinite love. The Lord has been my refuge in times of doubt, my strength in moments of weakness, and my light in the darkest hours.

To my family, who has been with me in every step of the trajectory, my wife Juliana, my daughters Lívia and Flávia, I thank you from the bottom of my heart for the unwavering support and unconditional love. Without you none of this would have been possible.

To my parents, José Flavio and Iraci Fernandes, I offer my deep gratitude for being the pillars of my life, and for their words of encouragement, love and constant support that have guided me throughout my life.

To my dear Camila Martins, Willian Freitas, and Gabriela Martins, I want to express my deep appreciation for all the support, understanding, and joy you have brought into my life, as well as the happy moments we have shared.

To my dear father-in-law and mother-in-law, Carlos Helvécio and Maria das Graças for always trusting me, and being there as constant support in moments of uncertainty and constant encouragement.

To my friends from the GETEF study group - Ana Júlia, Carlos, Cristovão, Natália, and Leonardo - I am grateful for their unwavering support during the experiments and for our study companionship.

To all 16 volunteers who were willing to participate in my research.

To my friend Luciano, for his fundamental support throughout my master's degree.

To all my teachers and staff at the Physical Education Department, who were fundamental throughout the process, especially Geysa and Meilene for their technical support.

To professors, Antonio Natali, Christiano Machado, Emille Rocha, Samuel Wanner and Fernanda Suarez for their exceptional contribution throughout the production of this work.

To the Universidade Federal de Viçosa for the opportunity and for giving me all the necessary structure to complete a quality master's degree.

To my teacher Thales Nicolau Prímola Gomes, for his guidance that extended beyond the academic realm, and for his genuine care for my personal and professional growth, I am deeply grateful. Your words of encouragement, patience, and knowledge were instrumental. I am profoundly thankful for the privilege of having you as my mentor and for all that I have learned under your guidance.

To CNPq and FAPEMIG for financial support.

This study was financed in part by the Coordenação de Aperfeiçoamento de Pessoal de Nível Superior – Brasil (CAPES) – Finance Code 001

To the Coordenação de Aperfeiçoamento de Pessoal de Nível Superior (CAPES), to granting the scholarship.

"The more I learn, the more I realize how much I don't know."

(Albert Einstein)

ABSTRACT

JANUÁRIO, William Martins, M.Sc., Universidade Federal de Viçosa., December, 2023.**Validity and reliability of two core temperature measurement techniques during physical exercise in the heat: CORE SENSOR and EXERGEN TAT-5000**. Adviser: Thales Nicolau Prímola Gomes

Objective: The aim of this study was to assess the validity and reliability of the CORE Sensor and Exergen TAT-5000 in estimating core temperature during cycling exercise in a hot environment. **Methods:** Eight men and eight women, regular cyclists (Age: 33.9±8 years; VO_{2max}: 53.6±7.0 $mL.kg^{-1}.min^{-1}$) underwent two similar cycling trials in a controlled environment at 32°C, relative humidity 60%. The protocol consisted of an initial 10-minute rest, followed by an exercise protocol (60 minutes) in a hot environment, comprising 10 minutes at 20% of maximal aerobic power, 25 minutes at 55%, and 25 minutes at 75%, with an additional 25 minutes of post-exercise recovery. Core temperature was recorded simultaneously every minute using a gastrointestinal capsule ($T_{CAPSULE}$) and the CORE Sensor (T_{CORE}). Bland–Altman analysis was performed to calculate bias, upper (LCS) and lower (LCI) concordance limits, and the 95% confidence interval (CI95%). The maximum acceptable difference between the two devices was ±0.4°C. A mixed linear model was used to model the paired differences between the two measurement systems, considering the subjects, reliability and environmental conditions as random effects and the activities as a fixed effect. **Results:** The CORE Sensor recorded an ICC value of 0.98. A non-significant bias value of 0.01, LCS of 0.38°C, LCI of -0.35°C and 95% CI of ±0.36°C were found. The Exergen TAT-5000 recorded an ICC value of 0.90. A significant bias value of -0.59, LCS of 0.82°C, LCI of -2.05°C and 95% CI of ±1.44°C were found. **Conclusion:** Compared to $T_{CAPSULE}$, the CORE Sensor was considered valid and reliable in estimating core temperature during cycling exercise in a hot environment. Compared to $T_{CAPSULE}$, the Exergen TAT-5000 was considered reliable but invalid in estimating core temperature during cycling exercise in a hot environment.

KEYWORDS

Body Temperature; Cycling Exercise; Heat Wave; Thermometers; Heat Illnesses.

RESUMO

JANUÁRIO, William Martins, M.Sc., Universidade Federal de Viçosa., dezembro de 2023. **Validade e confiabilidade de duas técnicas de medição da temperatura central durante o exercício físico no calor: CORE SENSOR e EXERGEN TAT-5000**. Orientador: Thales Nicolau Prímola Gomes

Objetivo: O objetivo deste estudo foi avaliar a validade e confiabilidade do CORE Sensor e do Exergen TAT-5000 na estimativa da temperatura central durante exercício de ciclismo em ambiente quente. **Métodos:** Oito homens e oito mulheres, ciclistas regulares (Idade: 33,9±8 anos; VO_{2max}: 53,6±7,0 $mL.kg^{-1}.min^{-1}$) foram submetidos a dois ensaios de ciclismo semelhantes em ambiente controlado a 32°C, umidade relativa 60%. O protocolo consistiu de um descanso inicial de 10 minutos, seguido de um protocolo de exercício (60 minutos) em ambiente quente, compreendendo 10 minutos a 20% da potência aeróbica máxima, 25 minutos a 55% e 25 minutos a 75%, com mais 25 minutos de recuperação pós-exercício. A temperatura central foi registrada simultaneamente a cada minuto usando uma cápsula gastrointestinal ($T_{CAPSULE}$) e pelo sensor CORE (T_{CORE}). A análise de Bland-Altman foi realizada para calcular o viés, os limites de concordância superior (LCS) e inferior (LCI) e o intervalo de confiança de 95% (IC95%). A diferença máxima aceitável entre os dois dispositivos foi de ±0,4°C. Um modelo linear misto foi utilizado para modelar as diferenças pareadas entre os dois sistemas de medição, considerando a individualidade dos sujeitos, a confiabilidade e as condições ambientais como efeitos aleatórios e a atividade física como efeito fixo. **Resultados:** O Sensor CORE registrou um valor ICC de 0,98. Foi encontrado um valor de viés não significativo de 0,01, LCS de 0,38°C, LCI de -0,35°C e IC 95% de ±0,36°C. O Exergen TAT-5000 registrou um valor de ICC de 0,90. Foi encontrado um valor de viés significativo de -0,59, LCS de 0,82°C, LCI de -2,05°C e IC 95% de ±1,44°C. **Conclusão:** Comparado ao $T_{CAPSULE}$, o Sensor CORE foi considerado válido e confiável na estimativa da temperatura central durante exercício de ciclismo em ambiente quente. Comparado ao $T_{CAPSULE}$, o Exergen TAT-5000 foi considerado confiável, mas inválido na estimativa da temperatura central durante exercício de ciclismo em um ambiente quente.

Palavras-chave: Alterações na Temperatura Corporal; Ciclismo; Onda de Calor; Termômetros; Transtornos de Estresse por Calor.

LIST OF ACRONYMS AND ABBREVIATIONS

%BF: Percentage of Body Fat

±: Plus-Minus

°C: Degree Celsius

APP: Application

BSA: Body Surface Area

CAAE: Ethics Committee on Human Research

CAPES: Coordenação de Aperfeiçoamento de Pessoal de Nível Superior

CL95%: Confidence Interval 95%

CM: Centimeter

CNPq: Conselho Nacional de Desenvolvimento Científico e Tecnológico

DOI: Digital Object Identifier

EHI: Exertional Heat Illness

FAPEMIG: Fundação de Amparo à Pesquisa do Estado de Minas Gerais

Fig: Figure

HR: Heart Rate

ICC: Intra-Class Correlation Coefficient

Kg: Kilograms

LOA: Limits Of Agreement

M/s: Meters Per Second

mL: Millimeter

P_{max}: Maximum Aerobic Power

Post-Ex: Post-Exercise

Pre-EX: Pre-Exercise

PROSPERO: International Prospective Register of Systematic Reviews

PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-analysis

RPE: Rate Of Perceived Exertion

SD: Standard Deviation

$T_{ambient}$: Ambient Temperature

T_{blood}: Aortic blood temperature

T_{body}: Body Temperature

$T_{CAPSULE}$: Gastrointestinal Temperature Per Capsule

T_{CORE}: Core Sensor Temperature

TC: Thermal Comfort

TS: Thermal Sensation

$T_{esophageal}$: Esophageal Temperature

$T_{EXERGEN}$: Exergen temporal Temperature

$T_{gastrointestinal}$: Gastrointestinal Temperature

$T_{internal}$: Core Temperature

T_{PA}: Pulmonary Artery Temperature

T_{rectal}: Rectal Temperature

T_{skin}: Skin Temperature

$T_{temporal}$: Temporal Temperature

UFV: Universidade Federal de Viçosa

USG: Urine Specific Gravity

Vo_{2Max}: Maximal Oxygen Consumption

W: Watts

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1.INTRODUCTION

1.1. Climate changes

Climate change has been a concerning issue in the current global scenario. (Ripple *et al*., 2023). The implications of climate change have a direct impact on various aspects of people's daily lives and have been demanding coordinated efforts from nations in the pursuit of public policies aimed at mitigating the damages (Aylett, 2015). Potential health impacts and increased mortality are just a few of the consequences of this phenomenon (Hatuka *et al*., 2018). Climate changes can affect a wide range of sectors, from agriculture and food production to the increase in the number of forest fires, the proliferation of disease-carrying insects, urban infrastructure, and the scarcity of water and other natural resource (Watts *et al*., 2018; Westerling, 2018).

An important effect of climate change has been a significant increase in heatwaves. Although there is no consensus on the best definition of what constitutes a heatwave, this phenomenon is generally defined as extended periods of extreme heat (Hajat *et al*., 2006). The heatwaves that struck Europe in 2003, Russia in 2010, and India in 2015 resulted in thousands of deaths (Fouillet *et al*., 2006; Sarath chandran *et al*., 2017; Shaposhnikov *et al*., 2014). Current data is alarming, with recent studies suggesting that in the coming years, heatwaves will be even more numerous, intense, and prolonged (Amengual *et al*., 2014).

1.2. Exertional Heat Illness (EHI)

The increasing incidence of heatwaves has led scientists around the world to increasingly analyze their impacts on human health (Jay *et al*., 2021). It is known that exposure to environmental heat stress, caused by a hot environment, combined with the stress of physical exertion, which does not necessarily need to be related to formal physical exercise, can result in a range of harmful health conditions, commonly referred to as "Exertional Heat Illness (EHI) (Stacey *et al*., 2015).

EHI are subdivided into:

i) Cramps - They can manifest as tingling sensations or muscle spasms and typically occur during or after excessive heat exposure. It is believed that the loss of sodium due to intense and/or prolonged sweating, dehydration, and/or neuromuscular fatigue play a significant role in the etiology of muscle cramps, leading to a contraction of the interstitial fluid compartment and hyperexcitability of the neuromuscular junction (Bergeron, 2003).

ii) Heat syncope - It is the sudden loss of consciousness and that often occurs after an individual has been standing for extended periods or rapidly assumes an upright posture after being at rest or seated. Exposure to high ambient temperatures leads to peripheral vasodilation and postural blood pooling, reducing venous return and decreasing cardiac output, resulting in temporary loss of consciousness (Casa *et al*., 2015)

iii) Exhaustion - Heat exhaustion refers to the inability to continue physical exercise and typically occurs when the core temperature is between 38.5°C and 40°C. During heat exhaustion, cardiac output is attenuated due to concurrent demands for blood flow to skeletal muscles, perfusion of vital organs, and heat dissipation through the skin. It is believed that generalized peripheral vasodilation and associated central fatigue are responsible for heat exhaustion (Mehta; Dubrey, 2009).

iv) Heat injury - Heat injury is a condition typically resulting from strenuous physical activity and prolonged exposure to high ambient temperatures. It is characterized by organ damage, such as the liver and kidneys, and tissue damage, including the intestines and muscles. The core temperature can often, (though not always, exceed 40.5°C (Casa *et al*., 2015).

v) Heat Stroke – Heat stroke is the most severe condition and the leading cause of death in heat-related illnesses. It is characterized by a core temperature >40°C, the absence of sweating due to advanced dehydration, reduced blood pressure, and cardiac output, which can lead to multiple organ failure, unconsciousness, and coma (Bouchama; Knochel, 2002).

EHI can range from milder conditions such as cramps, dizziness, and minor skin burns to more severe issues like fainting, exhaustion, and heat stroke (Sorensen; Hess, 2022). Such problems can lead to fatalities if necessary medical care is not provided promptly (Carter *et al*., 2005). The onset of symptoms is a result of the excessive increase in core temperature ($T_{internal}$). In milder cases, it can be below 38.5°C, while in more severe cases, it can exceed 40°C (Planinc; Knafelj; Zupet, 2016).

The magnitude of EHI effects can vary depending on the presence of one or more risk factors, namely (Périard; Eijsvogels; Daanen, 2021):

i) Individual factors - age, gender, body mass, pre-existing conditions (e.g., diabetes, obesity, cardiovascular diseases);
ii) Environmental factors - ambient temperature, relative humidity, wind speed, solar radiation level;
iii) Task-related factors - duration of sun exposure, type of activity performed, and clothing worn.

In the field of sports and physical activity in general, the study of EHI is crucial because during physical exercise, the generation of endogenous heat can increase significantly, potentially reaching up to 25 times higher than resting levels. This increase is directly related to the intensity and type of activity being performed (Cramer; Jay, 2016). The transient or persistent imbalance between heat gained and heat lost to the environment may lead to an increased rate of body heat storage and, consequently, hyperthermia (Tikuisis; Meunier; Jubenville, 2001)

1.3 Monitoring Methods

The development of rapid and effective interventions, as well as ways to acclimatize individuals to hot environments, has been the subject of studies in recent years (White-Newsome *et al*., 2014). The purpose of preventing hyperthermia involves the need for continuous and accurate monitoring of core temperature ($T_{internal}$). There are different methods and sites for monitoring core temperature. The validity of these methods varies depending on the objectives, so it is necessary to assess the strengths and limitations of each measurement in relation to the purpose (Taylor; Tipton; Kenny, 2014).

Blood temperature in the pulmonary artery (T_{PA}) - In humans, T_{PA} is considered the "true" core temperature and it is considered the most accurate, as the artery brings blood directly from the core of the body and its surroundings (Giuliano *et al*., 1999). To perform such a measurement, it is necessary to insert a catheter directly into the pulmonary artery through a surgical procedure (Fulbrook, 1997). Although it provides the best performance in measuring core temperature, due to patient safety risks, the use of this method is not recommended for all populations and it is restricted to surgical and critically ill patients.

Rectal temperature (T_{rectal}) - The rectum is the most commonly used and recommended site for measuring core temperature in pediatric care, scientific research, and clinical procedure monitoring (Lyon, 2008). Rectal temperature (T_{rectal}) is considered the "gold standard" for assessing core temperature in healthcare systems and it is recommended by the National Athletic Trainers Association as the standard criterion for measuring core temperature under conditions of rest, during, and after physical exercise (Casa *et al*., 2015). The measurement of this technique can be performed by inserting a thermistor probe between 10 and 15cm or by using a suppository-type capsule inserted 8 to 10cm into the rectal cavity. In clinical practice, a thermometer is inserted to a depth of 3 to 6cm (Wakamura; Tokura, 2002). Despite its good accuracy, this method has a longer response time compared to other techniques due to the thermal inertia characteristic of this body segment. This time lag in response can range from 6 to 60 minutes and may compromise responses of <0.5°C to >1.0°C during extreme conditions (Gollan, 1959).

Gastrointestinal temperature ($T_{gastrointestinal}$) – $T_{gastrointestinal}$ is measured by ingesting a telemetric capsule coated with silicone, measuring 20mm in length and

10mm in diameter. The capsule contains a telemetric temperature sensor system that transmits gastrointestinal temperature to an external device using low-frequency radio waves (Hunt; Stewart, 2008). The gastrointestinal telemetric capsule is a reliable and valid method for measuring core temperature in both laboratory and field settings. This is due to its good precision (±0.01°C), measurement frequency, the ability to measure in motion, and its non-invasive nature, making it suitable for using in sports and daily activities (Gant; Atkinson; Williams, 2006). However, there are limiting factors associated with capsules, such as the potential for contamination from food ingestion, their disposable and costly nature, and the fact that values may differ throughout the entire intestinal tract, making monitoring more challenging (Taylor; Tipton; Kenny, 2014).

Esophageal temperature ($T_{esophageal}$) - $T_{esophageal}$ is measured by inserting a probe directly into the patient's esophagus, typically through the nose or mouth, and positioned to be close to the heart and the core of the body. The probe is equipped with sensitive sensors that capture the internal temperature of the esophagus, providing an accurate reading of core temperature independent of inspired air temperature (Jaeger1 *et al*., 1980). However, recorded values can be altered due to swallowing of saliva and the ingestion of liquids (Taylor; Tipton; Kenny, 2014).

Less invasive and portable methods can estimate core temperature through measurements at other parts of the body, such as the armpit, temporal area, mouth, wrist, forehead, and ear. However, studies have reported that these devices are not valid as the measurements have poor agreement with gold standard thermometers (Casa *et al*., 2007; Mazerolle *et al*., 2011). Other devices use the interaction of physiological parameters such as heart rate (HR) and skin temperature (T_{skin}) to estimate core temperature through the use of mathematical algorithms (Daanen; Kohlen; Teunissen, 2023).

CORE Sensor (T_{CORE}) – The T_{CORE} is a wearable device that contains an internal temperature estimation sensor through the measurement of skin temperature and heart rate (HR), followed by calculation through algorithms. Then, the data is sent to a mobile app or heart rate monitor watch via the ANT+ protocol for core temperature recording. According to the manufacturer's instructions, this sensor should be positioned on the torso approximately 20 cm below the armpit and attached to a body

strap (Verdel *et al*., 2021). The manufacturer offers two different versions of this sensor: CORE and COREresearch, with the latter transmitting data every second and capable of storing records for 3.5 days. While the Core Sensor is already commercially available and used by many athletes, to the best of our knowledge, its validity has not been confirmed yet. Some studies have examined the device in exercise and resting conditions, comparing it to rectal temperature (T_{rectal}). On those occasions, the average differences found exceeded the maximum acceptable limit of ±0.3°C (Daanen; Kohlen; Teunissen, 2023; Verdel *et al*., 2021). In another study, the CORE Sensor was compared to an ingestible telemetric capsule during training sessions of a women's field hockey team. The results showed that the devices disagreed by ±0.3°C in 41-60% of the measurements (Goods *et al*., 2023). The ability to measure a decrease in core temperature due to the ingestion of cold water was also analyzed during a 5 km time trial running protocol in the heat. On that occasion, the results indicated that the CORE provides a clinically relevant underestimation of 0.5°C (Jolicoeur Desroches *et al*., 2023).

Temporal temperature ($T_{temporal}$) involves the use of an infrared scanner that detects skin temperature in the temporal region, presumably from the temporal artery. From this value, the device estimates core temperature using an algorithm that takes into account ambient temperature and skin-to-core temperature gradients (Harioka *et al*., 2000). Temporal thermometers are used by professionals in clinical settings, especially in pediatrics, due to their portability and high response speed, allowing for non-invasive and easily accessible measurements. However, some studies have shown that the device may not be very accurate for measuring core temperature in infants (Greenes; Fleisher, 2001). A study conducted in 2006 tested the temporal device under various conditions, and at that time, the measurements showed inconsistent results. During rest, the device underestimated $T_{internal}$, and during physical exercise, the values were overestimated (Kistemaker; Den hartog; Daanen, 2006).

The validation of a device designed to measure body temperature is conducted by comparing its measurement with that of another previously validated and well-accepted device. The level of precision is represented through values expressed in confidence intervals (IC95%), and average bias, plotted using the Bland-Altman proposal (Martin bland; Altman, 1986). The assessment of reliability pertains to the degree of consistency in measurements, conducted through test and retest, where

conditions are replicated similarly on two separate days, ensuring the evaluation of the device under comparable circumstances. In the context of temperature sensor evaluation, reliability assessment is conducted through tests that examine the correlation between two-day protocols. A widely utilized metric for this purpose is the intraclass correlation coefficient (ICC). This indicator quantifies the consistency and agreement of measurements over time, providing a robust approach to assess the stability and reliability of the sensor under varying conditions. The utilization of ICC as an evaluation metric contributes to a more precise understanding of the sensor's ability to deliver consistent and replicable results, making it a valuable tool in the validation of temperature measurement devices (Shrout; Fleiss, 1979).

2. OBJECTIVE

2.1. General

To investigate different methods of measuring core temperature during cycling exercise in the heat.

2.2. SPECIFICS

a) Systematically review the literature in search of the normal $T_{CAPSULE}$ value measured in healthy adult humans.

b) Evaluate whether the CORE Sensor device is valid and reliable for estimating core temperature during cycling exercise in the heat.

c) Evaluate whether the Exergen TAT5000 Temporal Scanner device is valid and reliable for estimating core temperature during cycling exercise in the heat.

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CHAPTER 1

ARTICLE

NORMAL GASTROINTESTINAL TEMPERATURE VALUES MEASURED THROUGH INGESTIBLE CAPSULES TECHNOLOGY: A SYSTEMATIC REVIEW.

Normal gastrointestinal temperature values measured through ingestible capsules technology: A systematic review.

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ABSTRACT

Climate change has amplified the importance of continuous and precise body core temperature ($T_{internal}$) monitoring in the everyday life. In this context, assessing $T_{internal}$ through ingestible capsules technology, i.e., gastrointestinal temperature ($T_{gastrointestinal}$), emerges as a good alternative to prevent related illness. Therefore, we conducted a systematic review to point out values of normal $T_{gastrointestinal}$ measured through ingestible capsules in healthy humans. The study followed PRISMA guidelines and searched the PubMed and Scielo databases from 1971 to 2023. Our search strategy included the descriptors ("gastrointestinal temperature") AND ("measurement"), and eligible studies had to be written in English and measured $T_{gastrointestinal}$ using ingestible capsules or sensors in healthy adults aged 18-59 at rest. Two pairs of researchers independently reviewed titles and abstracts and identified 35 relevant articles out of 1,088 in the initial search. An average value of 37.13°C with a standard deviation of 0.24°C was observed, independently of the gender. The values measured ranged from 36.70°C to 37.69°C. In conclusion, this systematic review pointed out the mean value of 37.13±0.24°C measured by ingestible capsules as reference for resting $T_{gastrointestinal}$ in healthy adult individuals.

KEYWORDS: Body Temperature; Climate change; Heat Illness; Sensors.

INTRODUCTION

In recent years, the Earth is facing climate change, which contributes to global warming and leads to more frequent and intense heatwaves (Breshears et al., 2021). Such phenomenon raises concerns, as the resulting thermal stress poses a risk to the public health (Ward et al., 2016).

In medical physiology, body temperature (T_{body}) is typically divided into two distinct compartments: the core and the shell ("Glossary of Terms for Thermal Physiology," 2003). $T_{internal}$ represents the temperature of internal organs and deep tissues, which is strictly regulated to around 37°C. Shell temperatures are usually represented by measurements taken at various points on the skin (T_{skin}), which are more variable and susceptible to changes in the room/environmental temperature (Lim et al., 2008). In the current scenario of global warming, the development of medical technologies for measuring human $T_{internal}$ during daily activities, in a non-invasive manner and across different environments, becomes crucial to face heat-related illnesses (Ou et al., 2023). Among the medical technologies for measuring $T_{internal}$, the ingestion of telemetric capsules to measure $T_{gastrointestinal}$ have gained popularity (Taylor et al., 2014). Both in clinical and sports settings, its use has become frequent due to its ease of use, be a wireless measurement technology, and its high accuracy when compared to other thermometers considered 'gold standards,' with a reported accuracy of ± 0.1°C (Casa et al., 2005; Lee et al., 2000; O'Brien et al., 1998).

However, to the best of our knowledge, there is still no consensus on the normal $T_{internal}$ of humans and the upper normal limit beyond which the actual $T_{internal}$ could indicate either fever or heat-related illnesses (Mackowiak et al., 2021). To illustrate, a recent systematic review, encompassing 7,636 healthy adult individuals and 9,227 measurements, reported resting $T_{internal}$ values of 36.59±0.43°C (Geneva et al., 2019).

Nevertheless, their study assessed $T_{internal}$ at rectal, tympanic, urine, oral, and axillary sites, excluding then $T_{gastrointestinal}$. Gathering data from studies on this issue is important to clarify the expected $T_{gastrointestinal}$ range measured through ingestible capsules technology in healthy individuals. Therefore, the aim of this study was to systematically review the literature to point out values of normal $T_{gastrointestinal}$ measured through ingestible capsule technologies in healthy humans.

METHODS

This review followed the "Preferred Reporting Items for Systematic Reviews" (PRISMA) guidelines (Page et al., 2021) and was registered in the International Prospective Register of Systematic Reviews - PROSPERO database (number CRD42023466557). A peer-reviewed search was conducted to identify relevant studies in the "PubMed" and "Scielo" databases from 1971 to 2023.

The search strategy employed had as descriptors ("gastrointestinal temperature") AND ("measurement"). The eligible studies had to be written in English, and measured $T_{internal}$ through either ingestible gastrointestinal capsules or sensors in healthy adult individuals aged 18-59 years, either at rest or at the basal point of a physical exercise session/performance. The following brands of ingestible capsules or sensors were considered: *"CorTemp HQ," "e-Celsius®," "JonahTM," "Vitalsense," and "Equivital Inc."*

The screening of titles and abstracts were independently carried out by two pairs of authors who used the eligibility criteria to include the article in the review. Likewise, the pairs of authors performed the full-text screenings and under consensus included those studies that met the eligibility criteria. The discrepancies were resolved by the authors after discussion.

We recorded from the selected studies authorship, year of publication, the sample gender, and the recorded temperature of interest. To compare the temperature values obtained from the selected studies, both between the measurement sites and between genders, we used the unpaired Student's t test. The significance level adopted was 5%.

RESULTS

The search identified 1,088 articles, and the screening of their primary titles and abstracts generated 1,034 articles. Then these 54 articles were reviewed in full, and 35 articles met the inclusion and exclusion criteria. Figure 1 shows the flow diagram and the reasons for exclusion.

Figure 1 - Flowchart of the study selection process for the systematic literature review.

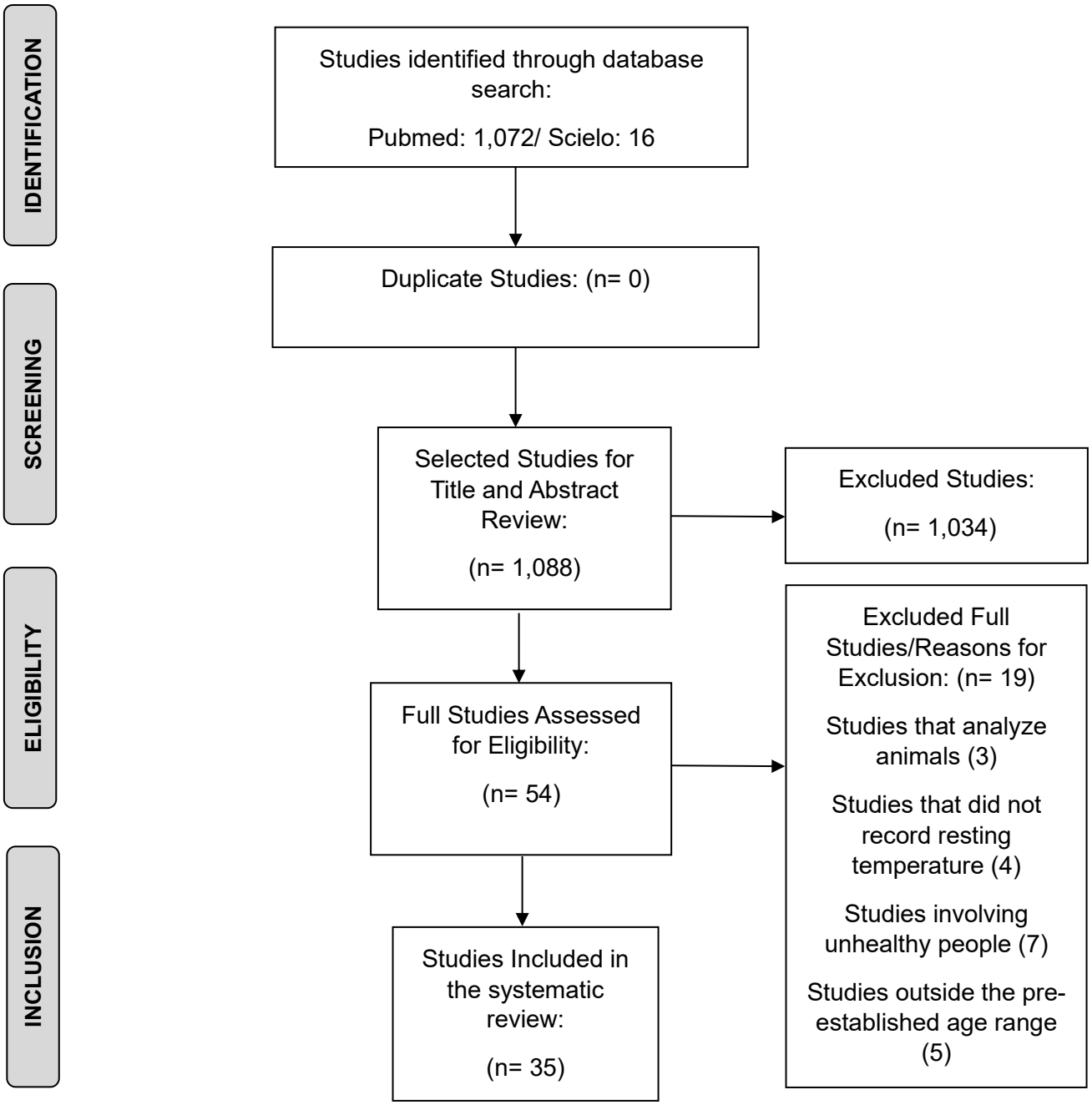

Figure 1. Flowchart detailing the search and selection process for systematic review studies.

Figure 2 shows the distribution of the studies over the years. The year of 2018 exhibited the highest number of published studies.

Figure 2. Distribution of studies analyzed over the years.

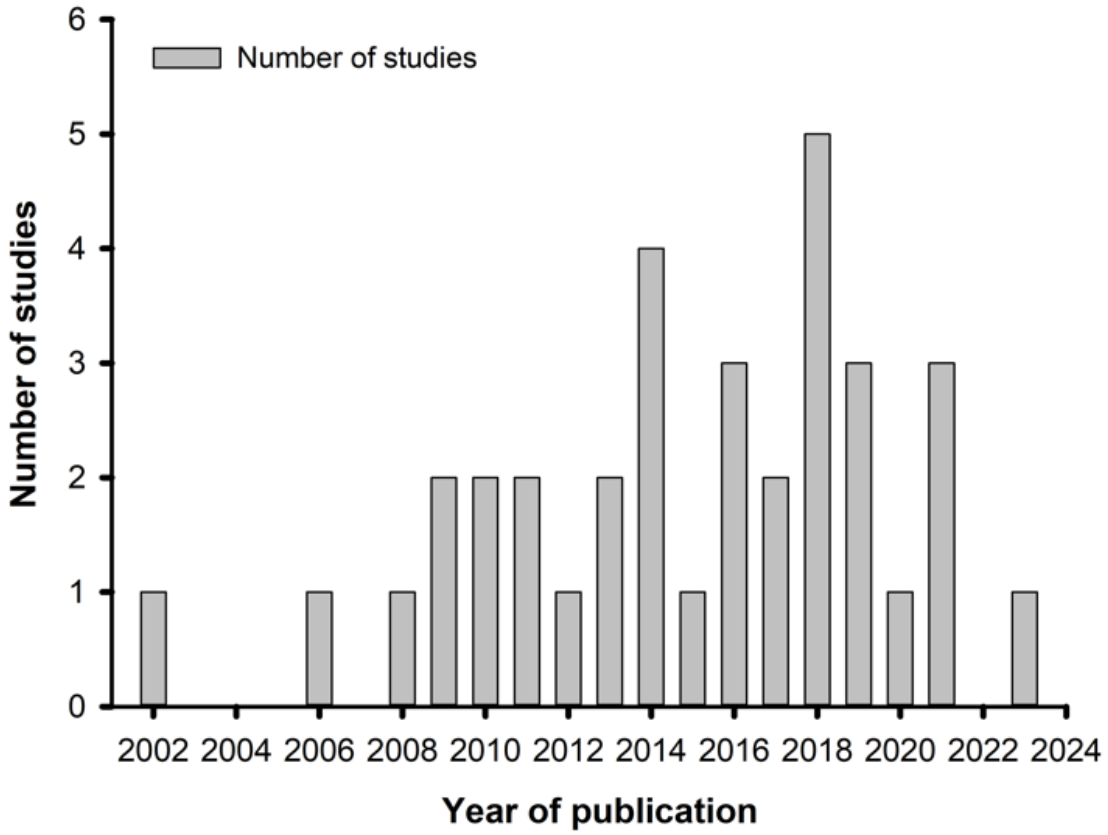

Figure 2. The bar chart represents the number of studies according to the year. Each gray bar represents a year, and the height of the bar corresponds to the number of studies conducted in that year.

The data recorded from the selected articles are showed in table 1. Most studies (i.e., 25) were carried out on men while 10 studies used samples comprised of men and women. The 513 studied individuals presented $T_{gastrointestinal}$ of 37.13 °C on average, and standard deviation of 0.24°C. After stratification by gender, the mean $T_{gastrointestinal}$ was 37.09±0,21°C in men and 37.17±0.28°C in women.

Table 1. Summary of normal $T_{gastrointestinal}$ ranges stratified by sample size and gender.

Author	Year	Gender	n	$T_{gastrointestinal}$
Koumar et al.	2023	F-M	23	36.70°C
Mundel et al.	2016	M	08	36.70°C
Roxane et al.	2018	F-M	23	36.80°C
Kellawan et al.	2009	M	10	36.81°C
Lee et al.	2013	M	10	36.85°C
Burdon et al.	2013	M	10	36.90°C
Hue et al.	2014	F-M	09	36.90°C
Pearson et al.	2012	M	08	36.96°C
Bogerd et al.	2018	M	08	37.00°C
Coris et al.	2009	M	11	37.00°C
Lindsay et al.	2017	M	15	37.00°C
Ross et al.	2014	M	10	37.00°C
Riera et al.	2016	M	09	37.00°C
Klous et al.	2020	M	09	37.00°C
Funnell et al.	2019	M	14	37.01°C
Maroni et al.	2018	M	12	37.06°C
Brake et al.	2002	M	36	37.10°C
Kingma et al.	2021	M	23	37.10°C
Ihsan et al.	2010	M	07	37.10°C
Levels et al.	2014	M	12	37.10°C
Alhadad et al.	2021	M	10	37.10°C
Lopez et al.	2011	F-M	14	37.20°C
Yeargin et al.	2006	M	11	37.20°C
Wilson et al.	2018	F-M	28	37.20°C
Hosokawa et al.	2016	F-M	30	37.20°C
Wilkinson et al.	2008	F-M	10	37.23°C
Brearley et al.	2014	M	04	37.30°C
Bardis et al.	2017	M	10	37.30°C
Batchelder et al.	2010	M	17	37.35°C
Bagley et al.	2011	F-M	25	37.40°C
Hunt et al.	2019	M	09	37.40°C
Hedge et al.	2021	F-M	11	37.40°C
Bongers et al.	2019	M	01	37.60°C
Veltmeijer et al.	2015	M	58	37.60°C
Smith et al.	2018	F-M	26	37.69°C
N: 513	**mean:**37.13°C	**SD:**0.24°C	**SE:**0.43°C	

F: female; M: male; n: number of participants; SD: standard-deviation, SE: standard-error. Temperature is shown in increasing order.

Figure 3 displays the boxplot analysis of the statistical distribution of $T_{gastrointestinal}$. The data analyses revealed that the first quartile was 37.00°C, the median was 37.10°C, the mean was 37.13°C, and the third quartile was 37.26°C.

Figure 3. Boxplot Graph representing the distribution of normal $T_{gastrointestinal}$.

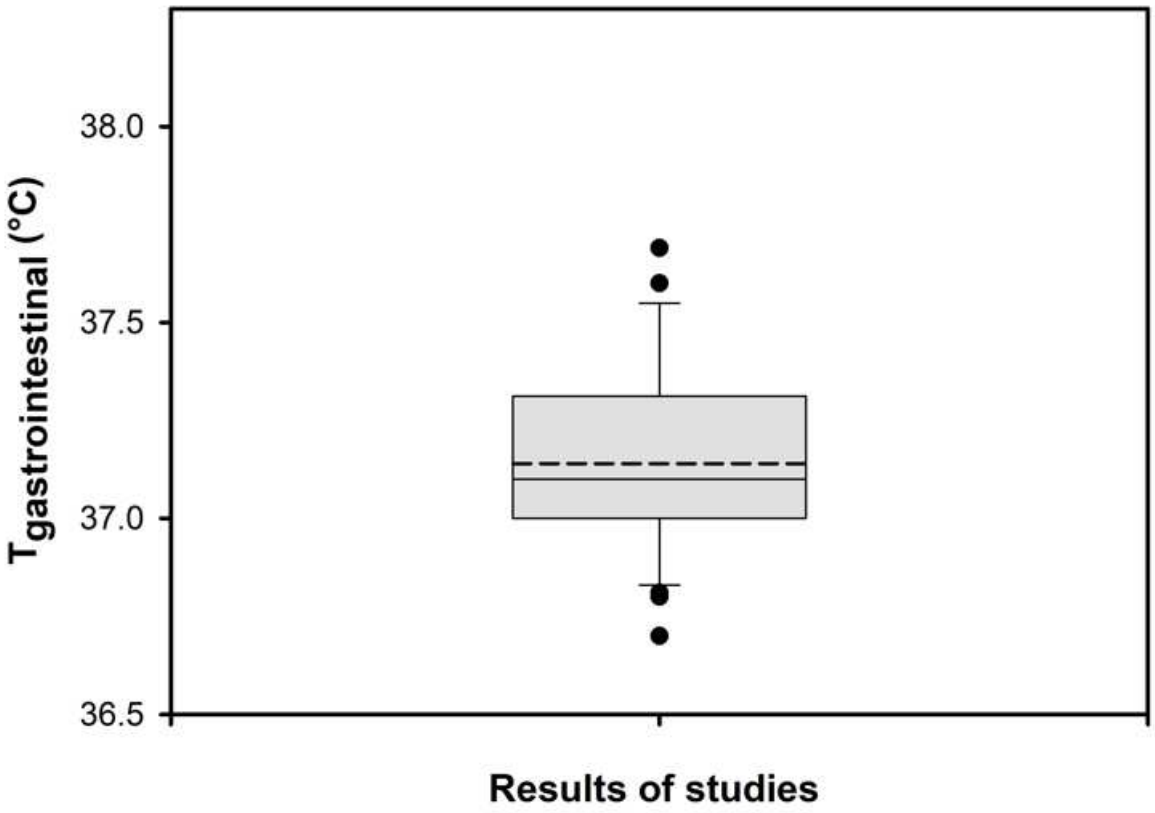

Figure 3. The boxplot graph displays the statistical distribution of gastrointestinal temperature, with the median (solid line within the box), quartiles (edges of the box), outliers (points outside the "whiskers"), and the mean (dotted line in the box). Number of individuals (513).

DISCUSSION

In present study we systematically reviewed the literature to gather information around the expected $T_{gastrointestinal}$ range measured through ingestible capsules technologies in healthy humans. Our results showed an average temperature of 37.13±0.24°C obtained from 513 men and women in the 35 selected articles; and that $T_{gastrointestinal}$ ranged from 36.70 to 37.69°C.

A previous review found a resting $T_{internal}$ mean value of 36.59±0.43°C after 9,227 measurements in 7,636 healthy adult individuals (Geneva et al., 2019). They also reported the following $T_{internal}$ values for each site of measurement: i) rectal = 37.04±0.36°C; ii) tympanic = 36.64±0.44°C; iii) urine = 36.61±0.50°C; iv) oral = 36.57±0.42°C; and v) axillary = 35.97±0.48°C. It is observed that the $T_{gastrointestinal}$ found in the present study is closer and similar (p=0.4226) to that of the rectal site reported previously, even when stratifying younger adults by the rectal site measurements (37.10±0.26°C) or when considering the average of all sites' measurements (36.69±0.34°C).

The variations that we observed in the values for $T_{gastrointestinal}$ in the present study may be attributed to factors such as the time of day when the capsule was ingested, since the circadian rhythm directly influences $T_{gastrointestinal}$ (Weinert & Waterhouse, 2007). Moreover, variations between individuals exist, because food intake, and the capsule´s position in the gastrointestinal tract may influence temperature data recordings (Casa et al., 2007).

While we conducted a review of 35 studies, only 10 of them assessed $T_{internal}$ in women, when stratification was applied, we found similar results for men and women, respectively (37.09±0.21°C vs. 37.17±0.28°C; p=0.5137). Despite that, it is noteworthy that some aspects such as menstrual cycle, hormones, contraceptive use, pregnancy, and menopause may alter $T_{internal}$ in women (Baker et al., 2020; Dervis et al., 2021; Kattapong et al., 1995; Freedman & Wooodward, 1996).

Despite the lack of consensus on the distinction between normal temperature and febrile conditions in clinical environments (Mackowiak et al., 2021), our results clarify the resting or basal value for $T_{gastrointestinal}$ measured by telemetry ingestible

capsules in healthy adult individuals. Under a crescent use of such technology, our finding is of clinical relevance since it may contribute to the development of early treatments and the prevention of more serious conditions concerning heat-related illnesses (Dolson et al., 2022).

Under the constant surveillance awakened by the Covid-19 pandemic, the use of thermometers that allow continuous monitoring without direct contact between individuals has turned ingestible capsules into a crucial tool in clinical hospital settings (Mukherjee et al., 2022). Such technology plays a fundamental role in ensuring the safety of patients and healthcare professionals by enabling constant T_{body} evaluation without exposing individuals to additional contamination risks. Furthermore, it contributes not only to the control of hospital-acquired infections but also to the early detection of fever, a key symptom in various clinical conditions, including infectious diseases (Huang et al., 2020).

Another important applicability for these sensor technologies concerns the environment of physical activity and competitions in general (Yang & Hsu, 2010). Different sport competitions will be held under extreme challenging thermal conditions in the coming years (e.g., 2026 FIFA World Cup, hosted across the United States, Canada, and Mexico). Certainly, athletes will face on with a variety of weather stressing situations during that global event. In addition to environmental thermal stress, athletes experience increased metabolic heat production resulting from muscular contractions, being the magnitude of increase proportional to the work performed (Saltin et al., 1968). Thus, the use of ingestible capsules emerges as an excellent option for T_{core} monitoring during these competitions due to its portability, safety, and possibility of accurate real-time recording data.

In conclusion, this systematic review pointed out the mean value of 37.13±0.24°C measured by ingestible capsules as reference for resting $T_{gastrointestinal}$ in healthy adult individuals. Such finding is relevant as it may support clinicians, coaches, athletes, and governmental agencies to coup with the ongoing scenario of global warming.

ACKNOWLEDGMENTS

This study was supported by grants from CNPq (Conselho Nacional de Desenvolvimento Científico e Tecnológico), CAPES (Coordenação de Aperfeiçoamento de Pessoal de Nível Superior) and FAPEMIG (Fundação de Amparo à Pesquisa do Estado de Minas Gerais). A. J. Natali is a CNPq fellow.

DISCLOSURE OF INTEREST

The authors report there are no competing interests to declare.

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CHAPTER 2

ARTICLE

VALIDITY AND RELIABILITY OF THE CORE SENSOR TO ESTIMATE CORE TEMPERATURE DURING PHYSICAL EXERCISE IN THE HEAT.

Validity and reliability of the CORE Sensor to estimate core temperature during physical exercise in the heat.

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HIGHLIGHTS

- Evaluating the accuracy and consistency of temperature sensors is necessary in the current context of heat waves.
- The CORE Sensor was found to be a reliable method of estimating core temperature during cycling exercise in the heat.
- 97% of measurements recorded through the CORE Sensor were below the pre-established limit of ±0.4°C.
- The CORE Sensor was considered a valid method and an alternative to invasive sensors for estimating core temperature during cycling exercise in the heat.

ABSTRACT

Recent heatwaves have increased the importance of accurate and continuous monitoring of body temperature. The rise in body temperature, characteristic of physical activity combined with thermal stress, increases the risk of heat-related illnesses. The use of valid and reliable devices acts as an essential tool to ensure safe sports practice and enhance performance. Thus, the aim of this study was to assess the validity and reliability of the CORE Sensor in estimating core temperature during cycling exercise in a hot environment. Methods: Seven men and eight women, regular cyclists (Age:33.4±8 years; VO_{2max}:53.8±7.7 $mL.kg^{-1}.min^{-1}$), underwent two similar cycling trials in a controlled environment at 32°C, RH 60%. The protocol consisted of an initial 10-minute rest, followed by an exercise protocol (60 minutes) in a hot environment, comprising 10 minutes at 20% of maximal aerobic power, 25 minutes at 55%, and 25 minutes at 75%, with an additional 25 minutes of post-exercise recovery. Core temperature was recorded simultaneously every minute using a gastrointestinal capsule ($T_{CAPSULE}$) and the CORE Sensor (T_{CORE}). Bland–Altman analysis was performed to calculate bias, upper (LCS) and lower (LCI) concordance limits, and the 95% confidence interval (CI95%). The maximum acceptable difference between the two devices was ±0.4°C. A mixed linear model was used to model the paired differences between the two measurement systems, considering the subjects, reliability and environmental conditions as random effects and the activities as a fixed effect. An ICC value of 0.98 was recorded. A non-significant bias value of 0.01, LCS of 0.38°C, LCI of -0.35°C, and CI95% of ±0.36°C were found. Compared to $T_{CAPSULE}$, the CORE Sensor was considered valid and reliable in estimating core temperature during cycling exercise in a hot environment.

KEYWORDS

Cycling Exercise; Body Temperature; Heat Wave; Thermometers; Heat Illnesses

1. INTRODUCTION

The recent heatwaves, a consequence of global warming, have raised significant concern and alarm within the scientific community worldwide (Ripple et al., 2023). For instance, the heatwaves that struck France and Italy in 2003 and Russia in 2010 resulted in the deaths of thousands of people (Fouillet et al., 2006; Shaposhnikov et al., 2014). Some studies report that in the coming years, heatwaves are expected to become increasingly frequent, prolonged, and intense (Amengual et al., 2014; Meehl and Tebaldi, 2004). Thus, the development of effective and prompt interventions, as well as strategies to adapt the body to thermal stress, is crucial in addressing heat-related illnesses (Jay et al., 2021).

In the field of sports sciences and physical activity in general, the study of human body exposure and acclimatization to exercise in the heat is also important. Often, athletes need to train, adapt, and compete under thermally stressful conditions, making them susceptible to heat-related illnesses (Wallace et al., 2005). A central aspect in this context concerns the continuous and accurate monitoring of deep body temperature (Taylor et al., 2014).

Although it is accepted that the measurement of this temperature is the same as that of aortic blood, including branches in the carotid arteries, the impracticality and limited applicability of these measures are recognized (Bligh, 1973). Thus, other indices have been proposed as indicators of deep body temperature, i.e., rectal temperature - T_{rectal}. (Jensen et al., 2000), esophageal temperature -$T_{esophageal}$ (Gibson et al., 1981) and gastrointestinal temperature - $T_{gastrointestinal}$ (Beaumont, 1977). Despite being valid and reliable methods, some characteristics make its use impractical during physical exercise, such as being invasive, uncomfortable, limiting freedom of movement, the financial cost, and the need for proximity to a data center (Taylor et al.,

2014). There are also less invasive and more practical methods, such as measuring in other parts of the body, like the axilla, temporal area, mouth, pulse, forehead, and ear. However, previous studies have reported that these techniques are not valid, as the measurements showed poor agreement with the considered gold standard thermometers (Casa et al., 2007; Mazerolle et al., 2011). Thus, there is still a need for the development of practical and reliable tools to measure deep body temperature during physical exercise, assisting both in exercise prescription and in combating heat-related illnesses. With this goal in mind, some companies have developed wearable, portable devices that promise to estimate real-time temperature values through the interaction of certain physiological parameters (Daanen et al., 2023; Dolson et al., 2022; Welles et al., 2018). Recently, the company Greenteg AG presented the CORE Sensor to the market, a wearable device that utilizes machine learning algorithms to estimate $T_{internal}$ from heat flux values and skin temperature. The CORE Sensor can also be used during physical exercise, and in this case, it is recommended to be used in conjunction with a compatible heart rate monitor connected to the CORE via ANT+ protocol.

Although the Core Sensor is already commercially available and used by many athletes, to the extent of our knowledge, its validity and reliable still lack evaluation under different conditions of physical exercise and thermal environments. Up to the present, four studies have assessed the CORE Sensor. Two studies analyzed the temperature measured by the CORE (T_{CORE}), comparing it with T_{rectal}. In Daanen's study, a cycling test was conducted until exhaustion at 18ºC with 50% RH, with incremental increases of 14W implemented at each 3min interval (Daanen et al., 2023). In Verdel's study, the CORE Sensor was assessed under two identical 60min sessions of steady-state cycling in an environment at 19°C and 30% RH (Verdel et al., 2021). It

was observed that the average differences exceeded the adopted maximum difference limit of 0.3°C (Daanen et al., 2023; Verdel et al., 2021). In another study, T_{CORE} was compared to $T_{gastrointestinal}$ (measured through an ingestible telemetric capsule) during training sessions of a female field hockey team. The results indicated that the devices disagreed by ±0.3°C in 41-60% of the measurements (Goods et al., 2023). A recent study assessed the ability of the CORE Sensor to measure the decline in deep body temperature induced by the ingestion of cold water during a 5 km time-trial running protocol in the heat. The results showed that the CORE Sensor clinically underestimated deep body temperature by 0.5°C (Jolicoeur Desroches et al., 2023). Collectively, under the adopted experimental conditions, these previous studies found that, in terms of validity, the CORE was not accurate in measuring core temperature. Regarding reliability, the only study that assessed the CORE Sensor in two similar environmental conditions showed that the device was reliable (Verdel et al., 2021).

An important and unclear issue in the literature is that studies evaluating the CORE Sensor assumed a maximum acceptable difference limit between devices of 0.3°C (95% CI) (Daanen et al., 2023; Goods et al., 2023; Jolicoeur Desroches et al., 2023; Verdel et al., 2021). Together, these studies justified the choice of this limit based primarily on two previous studies that compared $T_{gastrointestinal}$ with T_{rectal} (Gant, 2006; Casa 2007). The first mentioned study assessed the validity and reliability of measuring $T_{gastrointestinal}$ during an intermittent running protocol, i.e., LIST protocol, showing that it can be used under these conditions when compared to T_{rectal} (Gant et al., 2006). The second study evaluated the validity of various instruments, including ingestible pills for measuring $T_{gastrointestinal}$, to assess body temperature during outdoor physical exercise in the heat. The issue is that in both reference studies used, the statistical or even physiological rationale for the choice of the 0.3°C limit is not clear, and this value was

also assumed. On the other hand, a previous study calculated the agreement between $T_{gastrointestinal}$ and T_{rectal} using the Bland and Altman method, based on data from validation studies of the gastrointestinal capsule during exercise (Byrne et al., 2006). It has been suggested that there is substantial evidence for a 95% CI value of <0.4°C as acceptable between the two measures, as several factors can affect the agreement between them, such as calibration, gastrointestinal motility, gastrointestinal temperature gradients, interference of fluid and food intake, time elapsed since the ingestion of the gastrointestinal capsule, and electromagnetic interference.

Thus, the present study was developed to assess the validity and reliability of the CORE Sensor in estimating $T_{internal}$ during cycling exercise in the heat. For this purpose, an experimental protocol was designed in which T_{CORE} could be evaluated during rest, during a long-duration incremental cycling exercise, as well as during post-exercise recovery.

2. MATERIAL AND METHODS

2.1. Participants

In the present study, 15 adults were selected (33.4 ± 8.2 years), comprising 7 men and 8 women. All selected volunteers were healthy individuals and regular practitioners of physical activity, i.e., either engaging in 30-60 minutes of moderate-intensity cycling 5 days/week or 30-60 minutes of vigorous-intensity cycling 3 days/week. The following exclusion criteria were used for sample selection: i) individuals with any form of disability; ii) smokers; iii) individuals with diagnosed cardiovascular or pulmonary complications; iv) diabetics (fasting blood glucose above 126 mg/dL); v) individuals with a history of thermal injuries; vi) pregnant women or

those using contraceptives. The volunteers signed an informed consent form, and the experiment was previously approved by the Ethics Committee on Human Research of the Federal University of Viçosa (CAAE: 63310522.6.0000.5153) and followed the ethical standards established in the Helsinki Declaration.

2.2. Experimental Procedures

The participants attended 3 laboratory visits with a 48-hour interval between visits, always arriving at 7:00 am. Common procedures were adopted for all visits: i) Volunteers were instructed to arrive at the laboratory well-fed and rested. ii) Upon arrival, the volunteers had their hydration status assessed using urine specific gravity (USG) with a portable refractometer (Instrutherm - RTP-20ATC), with a cutoff value of 1.020 (Nakamae et al., 1980), and ingested 500 mL of water. iii) All experimental sessions were conducted in a climate-controlled room, with ambient temperature ($T_{ambient}$) and relative humidity (RH) maintained at 32ºC and 60%, respectively. iv) All exercise bouts were performed on a bicycle mounted on an electrically braked cycle ergometer (Tacx Flow Smart T2240). v) Heart rate was measured at the wrist, minute by minute, using a heart rate monitor (Garmin Forerunner 745). vi) The rate of perceived exertion (RPE) was assessed appropriately using the Borg Scale, ranging from 6 (no exertion) to 20 (maximum exertion) (Borg, 1982).

2.2.1. Preliminary Day

The first laboratory visit was used for baseline parameter collection and familiarization with the research procedures and instruments. Measurements included height using a stadiometer (Sanny ES2020), body mass using a scale (Filizola-ex),

and skinfold thickness (triceps, subscapular, chest, subaxillary, suprailiac, abdominal, and thigh) using a caliper (Cescorf®). Body fat percentage (%BF) was calculated using the DC formula (g/cm³) = 1.112 - 0.00043499 × (sum of 7 skinfolds) + 0.00000055 × (sum of 7 skinfolds) × 2 – 0.00028826 × (Age), and subsequently G% = [(4.95 / DC) – 4.50] × 100 (Jackson and Pollock, 1978). The body surface area (BSA in m²) was calculated according to the following equation: BSA = (0.007184) × ($X^{0.425}$) × ($Y^{0.725}$), where X is body mass (kg), and Y is height (cm) (Du Bois and Du Bois, 1916).

Finally, aerobic capacity was assessed by measuring P_{max} (W) in an incremental protocol on the cycle ergometer, with the following configuration: 2 minutes at 50 rpm and 50 W, followed by progressive increases of 25 W every 2 minutes until voluntary fatigue. The test was stopped when participants: i) reported an RPE of 20; ii) could not maintain the predetermined cadence of 50 rpm; or iii) voluntarily requested to stop the exercise. P_{max} was calculated as the power of the last completed stage in W + [(time spent in the incomplete stage in seconds / 120 s) × 25 W] (Kuipers et al., 1985). From P_{max}, VO_{2max} (mL.kg^{-1}.min^{-1}) was calculated as = (12 × maximum aerobic power + 300) / body mass in kg (ACSM, 2000).

2.2.3. Trials 1 and 2

Two trials were conducted with similar procedures and data collection. The purpose of conducting Trial 2 was to assess the reliability of the CORE. On the night before each experimental session, volunteers ingested telemetric capsules for measuring $T_{gastrointestinal}$, always 10 hours before the start of data collection. After checking USG and hydration status, volunteers were weighed, equipped with the CORE Sensor Research (greenTEG AG, Rümlang, Switzerland), and a heart rate

monitor (Garmin Forerunner 745). At this point, the functionality of the gastrointestinal capsules was also verified.

After these procedures, volunteers underwent the following sequence on the cycle ergometer: i) Pre-Ex. Moment – 10 minutes seated at rest for pre-exercise data collection; ii) 20% P_{max} Moment – 10 minutes of exercise at 20% of P_{max}; iii) 55% P_{max} Moment – 25 minutes of exercise at 55% of P_{max}; iv) 75% P_{max} Moment – 25 minutes of exercise at 75% of P_{max}; v) Post-Ex. Moment – 25 minutes of post-exercise recovery seated on the bicycle. In total, the experimental session lasted 96 minutes.

$T_{gastrointestinal}$ was measured through the ingestion of a telemetric capsule model (CorTemp® Pill) 10 hours before the start of data collection, following the recommended minimum period to avoid contamination from food or liquid intake (Wilkinson et al., 2008). Each capsule was paired with a data logger (Data Recorder 262k w/HR HT 130042), and the data were recorded every minute. The gastrointestinal temperature recorded by the capsules ($T_{CAPSULE}$) was chosen as a comparison parameter due to its consideration as a valid and reliable method for measuring $T_{internal}$ under both resting and physical activity conditions, with a reported accuracy of ±0.01°C (Gant et al., 2006).

The temperature recorded by the CORE Sensor (T_{CORE}) was obtained by attaching the sensor to a strap provided by the manufacturer, positioned on the torso approximately 20 cm below the armpit, following the manufacturer's manual guidelines. The device was then paired with the heart rate monitor watch. During the experimental procedures, firmware version 0.8.2 was used for all processes. Before each measurement, the sensor was charged, calibrated, and settings were changed to the 'Sport' mode. For different subjects in the sample, weight, age, and height data were

entered into the application as per the manufacturer's guidance. Finally, the data shared with the Core App were recorded minute by minute

2.4 Data processing and statistics

A mixed linear model was employed, incorporating both fixed and random effects. The factor proposed as a fixed effect was physical exercise, and concerning random effects, the individuality of subjects, reliability, and environmental conditions were assumed as random effects (Parker et al., 2020).

The normality of the data was tested using the Shapiro-Wilk test for $T_{ambient}$ and RH, and the Kolmogorov-Smirnov test for $T_{CAPSULE}$ and T_{CORE}. The variance over time for T_{CORE} and $T_{CAPSULE}$ was analyzed using the Friedman Test with the Student-Newman-Keuls post-hoc test. $T_{ambient}$ and RH were evaluated using the Mann-Whitney Rank Sum Test. The Mann-Whitney Rank Sum test was used to analyze the means between the two devices in trials 1 and 2. All analyses are presented for the total time as well as for each experimental moment. Data are shown as mean ± SD in which the level of significance was set at $P < 0.05$.

The intra-class correlation coefficient model (ICC) was used to assess reliability. The following criteria were established for ICC values: Poor: $ICC < 0.40$; Fair: $0.40 \leq ICC < 0.70$; Good: $0.70 \leq ICC < 0.90$; Excellent: $ICC \geq 0.90$ (Shrout and Fleiss, 1979)

The validity of T_{CORE} was tested using the Bland-Altman method to assess agreement between the two measurement devices, T_{CORE} and $T_{CAPSULE}$ (a method that has already been validated and previously accepted). The systematic bias and 95% limits of agreement (LOA) were derived from the Bland-Altman plot (Martin Bland and Altman, 1986).

All statistical analyses were conducted using the RStudio software version 2023.09.1 Build 494© 2009-2023 Posit Software, PBC (R Core Team, 2017).

3. RESULTS

3.1. Sample Characteristics

Table 1 presents the general characteristics of the sample measured in the preliminary trial.

3.2. Reliability

During the experimental tests, environmental conditions were maintained at 32.37±0.05°C, 60.3±0.8%, 0m/s (Trial 1) and 32.36±0.04°C, 59.5±0.4%, 0m/s (Trial 2) for $T_{ambient}$ (p =0,308), RH (p =0.009) and wind speed (p = 1.000), respectively.

The Figure 1 depicts the adjustments of $T_{internal}$ over the protocol time for $T_{CAPSULE}$ (circle) and T_{CORE} (triangle). When analyzed together, a time effect was observed (p = 0.041); $T_{internal}$ increased from 20 minutes for all measurements, not returning to baseline values after 25 minutes of post-exercise recovery.

Table 2 presents the results of the reliability of T_{CORE} compared between Trials 1 and 2 at the Pre-Ex. (10min), 20% P_{max} (10min), 55% P_{max} (25min), 75% P_{max} (25min), and Post-Ex. (25min) moments. As observed, no differences in T_{CORE} were found between Trials 1 and 2 (p=0.129). The ICC obtained at all evaluated moments showed an excellent correlation. The overall ICC recorded showed a value of 0.98.

3.3. Validity

Table 3 presents the validity results at the Pre-Ex. (10min), 20% P_{max} (10min), 55% P_{max} (25min), 75% P_{max} (25min), and Post-Ex. (25min) moments. As observed, no differences were found between the mean temperatures of T_{CORE} and $T_{CAPSULE}$ ($p = 0.838$). Additionally, the bias was not significant (Full time: 0.01ºC), and the 95% CI value was ±0.36ºC. Finally, for the criterion of the adopted borderline difference of ±0.4ºC in the present study, it was observed that only 3% of the values recorded for T_{CORE} exceeded the accepted variation. These results can be seen in Figure 3, with each of the 15 individuals in the sample represented by distinct symbols.

4. DISCUSSION

The present study assessed the validity and reliability of the CORE Sensor (T_{CORE}) in estimating central temperature during cycling exercise in the heat, compared to the measurement of $T_{gastrointestinal}$ using a telemetric capsule ($T_{CAPSULE}$). To achieve this, an experimental protocol was designed to evaluate T_{CORE} at different time points, i.e., Pre-Ex. (10min), 20% P_{max} (10min), 55% P_{max} (25min), 75% P_{max} (25min), and Post-Ex. (25min). Our main findings were that for the utilized protocol: i) Reliability – the CORE Sensor was reliable with a high correlation (ICC = 0.98), regardless of the protocol moment; ii) Validity – the CORE Sensor was deemed valid (95% CI = ±0.36 ºC) according to the proposed ≤0.04ºC limit.

4.1. Reliability

Regarding reliability, our data showed that for all evaluated moments, from Pre-Ex. to Post-Ex., high ICC values were recorded. In total, an ICC value of 0.98 was found.

As observed in Fig. 1, the temperature curves were similar between Trials 1 and 2. Our experimental protocol was designed to assess the adjustments of T_{CORE} under resting conditions Pre-Ex., progressing through moments of light, moderate, and high intensities, until Post-Ex. recovery. The variance over time detected in both instruments from minute 20 can be explained by the end of the 20% P_{max} warm-up period and the beginning of the moderate 55% P_{max} phase, where the generation of work (W) is considerably higher.

This is only the second study that has looked at the reliability of the CORE Sensor. Our findings showed similarity with another study by Verdel et al., which also analyzed the reliability of the CORE Sensor in two similar days. However, it is worth noting that in our present study, the environmental conditions were slightly different, with a +1.37°C higher ambient temperature and +21% higher relative humidity. In a warmer and more humid environment, the physiological effort to control body temperature is greater, and consequently, the rate of body heat generation. Nevertheless, the CORE Sensor proved consistent in both instances.

Throughout the entire protocol, the ICC was considered excellent, leading us to consider the T_{CORE} reliable under different exercise conditions, from pre-exercise to higher intensities, as well as during the recovery period. A device that reliably estimates central body temperature in various conditions and intensities is essential. Sports inherently involve different levels of intensity, and engaging in sports in extreme environments and conditions is becoming increasingly common. The use of the CORE Sensor device has proven to be a reliable alternative in such circumstances.

4.2. Validity

Regarding validity, our findings demonstrated that T_{CORE} showed good agreement with $T_{CAPSULE}$. The mean bias of -0.01 demonstrated that the sensor does not exhibit a systematic error trend throughout the measurement protocol, ranging from -0.09 to 0.09. The absence of trend in the differences is visible throughout the study, being slightly lower at Pre-Ex, 20% P_{max}, and 55% P_{max} (-0.11, -0.13, and -0.1, respectively) and higher at 75% P_{max} and Post-Ex moments (0.06 and 0.08).

The main way to evaluate the accuracy of a device is by analyzing the 95% limits of agreement (LOA) proposed by Bland-Altman. Through this value, it is possible to observe that 95% of all measurements are within a specific value range (Martin Bland and Altman, 1986). In the present study, the upper and lower limits of agreement ranged from -0.35 to 0.38, and the overall 95% confidence interval (CI95%) was (±0.36) the limits of agreement were within the proposed maximum acceptable of ±0.4.

Our findings differ from other studies that assessed the validity of the CORE Sensor under both resting and exercise conditions (Daanen et al., 2023; Goods et al., 2023; Jolicoeur Desroches et al., 2023; Verdel et al., 2021). Up to the date of completion of this study, no other trial had identified a CI 95% as low as ±0.36. Several factors may explain these differences, among which we can highlight the different firmware used between the studies. The version 0.8.2 (used in this study) is the latest version and, according to the manufacturer, comes with improvements regarding the device's accuracy. The use of a compatible heart rate monitor watch is another aspect that differs from other studies, along with factors such as the individuality of the studied sample, average measurement time, acclimatization status, gender present in the sample and comparison parameter.

When compared to the threshold proposed by other authors of ±0.3°C, T_{CORE} remains below in 85% of the recorded measurements. However, following the 95% CI, the value exceeds by 0.6°C (±0.36°C). The interpretation of such a value is necessary due to the fact that the use of this equipment in extreme conditions may not be recommended, as small increases in temperature could be sufficient to exacerbate hyperthermia or lead to more serious complications (Armstrong et al., 2007).

The differences recorded throughout the measurement protocol indicated that the CORE Sensor remained below the pre-established limit of ±0.4°C in 97% of the measurements conducted. The CORE Sensor device was able to monitor the increase in temperature induced by physical exercise in a hot environment that ranged from ±37.04 to 38.56 °C, throughout the procedure. During physical exercise in the heat, changes in body temperature can occur very rapidly. It is of utmost importance that a device designed to measure such a variable be able to accurately and effectively track this change.

The high agreement during most part of the test makes us consider the device valid for estimating core temperature during cycling exercise in a hot environment.

4.3. Limitations

Although $T_{CAPSULE}$ is considered a valid method for measuring central body temperature, some characteristics may limit the results. Despite all individuals in the sample ingesting the capsule at the same time, the intestinal transit time varies among individuals, which may cause the capsule to change position for each individual, thus altering the results (Taylor et al., 2014).

The procedures were conducted in an artificially climate-controlled room, which means that factors such as solar radiation and convective effects of heat and wind

were not detected. Studies on the validity of the CORE Sensor in men and women during outdoor physical exercise are necessary.

5. CONCLUSION

The aim of our study was to analyze the validity and reliability of T_{CORE} in estimating $T_{internal}$ during stationary cycling exercise in heat conditions, compared to $T_{CAPSULE}$. Our findings consider the CORE Sensor device valid and reliable for central temperature estimation during cycling exercise in the heat and support the use of the device as a valid portable alternative to other invasive methods. It is important to emphasize that, as mentioned earlier, the validity of each device may vary according to its specific use and the target population.

6. ACKNOWLEDGMENTS

This study was supported by grants from CNPq (Conselho Nacional de Desenvolvimento Científico e Tecnológico) with the grant numbers 403824/2021-4 and 407925/2023-6, CAPES (Coordenação de Aperfeiçoamento de Pessoal de Nível Superior) and FAPEMIG (Fundação de Amparo à Pesquisa do Estado de Minas Gerais) with the grant number APQ-01828-23. A.J. Natali and S.P. Wanner are CNPq fellows. W.M. Januário W.M. and N.F. Lessa were CAPES fellows. A.J.O. Schittine was CNPq fellow and is currently FAPEMIG fellow.

7. DISCLOSURE OF INTEREST

The authors report there are no competing interests to declare.

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TABLES AND FIGURES LEGENDS

Table 1 – Sample characteristics.

Table 2 - Reliability results of T_{CORE} compared between Trials 1 and 2.

Table 3 - Validity results between $T_{CAPSULE}$ and T_{CORE}.

Figure 1 - Adjustments of T_{CORE} and $T_{CAPSULE}$ over the protocol time in Trials 1 and 2. * = indicates time-dependent differences ($p<0.05$). Data are presented as mean ± SD.

Figure 2 – Bland-Altman plots of the data for the moments Pre-Ex. (10min), 20% P_{max} (10min), 55% P_{max} (25min), 75% P_{max} (25min) and Post-Ex.(25min). The dashed lines represent the limits of agreement (LoA) and the solid lines the bias.

TABLE 1.

Sample	Mean	±	SD
Age (years)	33.4	±	8.2
Body mass (Kg)	67.1	±	9.2
Stature (cm)	171	±	6.8
%BF	20.4	±	5.3
BSA (m^2)	1.78	±	0.1
VO_{2max} ($mL.kg^{-1}.min^{-1}$)	53.8	±	7.7
P_{max} (W)	290	±	43

%BF: Percentage of Body Fat; BSA: Body Surface Area; Vo_{2Max}: Maximal Oxygen Uptake; P_{max}: Maximal aerobic power.

TABLE 2.

Moments	T_{CORE} (°C) Trial 1	T_{CORE} (°C) Trial 2	Bias (°C)	ICC
Pre-Ex.	36.90 ± 0.24	36.96 ± 0.16	0.06	0.98
20% P_{max}	37.04 ± 0.23	37.08 ± 0.25	0.04	0.96
55% P_{max}	37.67 ± 0.26	37.60 ± 0.26	-0.07	0.99
75% P_{max}	38.56 ± 0.41	38.37 ± 0.29	-0.18	0.95
Post-Ex.	38.75 ± 0.35	38.54 ± 0.29	-0.20	0.98
Full-Time	38.05 ± 0.76	37.94 ± 0.69	-0.10	0.98

The results are shown for the moments Pre-Ex. (10min), 20% P_{max} (10min), 55% P_{max} (25min), 75% P_{max} (25min) e Post-Ex. (25min). * = indicates difference of T_{CORE} between Trials 1 and 2. Data are shown as mean ± SD.

TABLE 3.

Moments	T_{CORE} (°C)	$T_{CAPSULE}$ (°C)	Bias (°C)	LoA	IC95%	% > 0.3°C	% > 0.4°C
Pre-Ex.	36.92 ± 0.20	37.04 ± 0.21	-0.12	-0.40 to +0.24	±0.32	7%	5%
20% P_{max}	37.06 ± 0.24	37.19 ± 0.22	-0.13	-0.41 to +0.23	±0.32	10%	0%
55% P_{max}	37.63 ± 0.26	37.65 ± 0.26	-0.02	-0.41 to +0.36	±0.39	14%	4%
75% P_{max}	38.46 ± 0.35	38.40 ± 0.31	0.05	-0.25 to +0.36	±0.30	9%	2%
Post- Ex.	38.64 ± 0.32	38.56 ± 0.36	0.08	-0.25 to +0.44	±0.34	15%	6%
Full-Time	37.99 ± 0.73	37.97 ± 0.67	0.01	-0.35 to +0.38	±0.36	15%	3%

The results are shown for the moments Pre-Ex. (10min), 20% P_{max} (10min), 55% P_{max} (25min), 75% P_{max} (25min) e Post-Ex. (25min). % > = indicates the percentage of measurements that were above the respective validity limit. The data is presented as mean ± SD.

FIGURE 1.

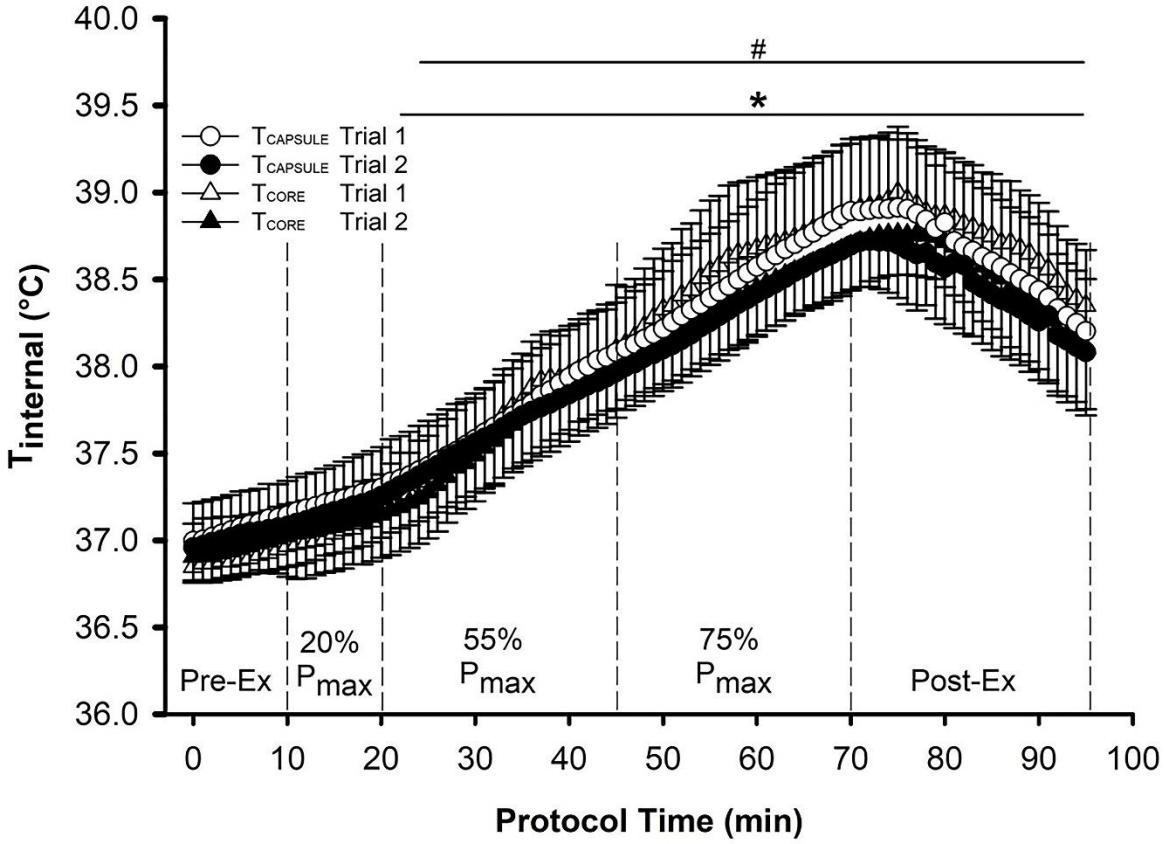
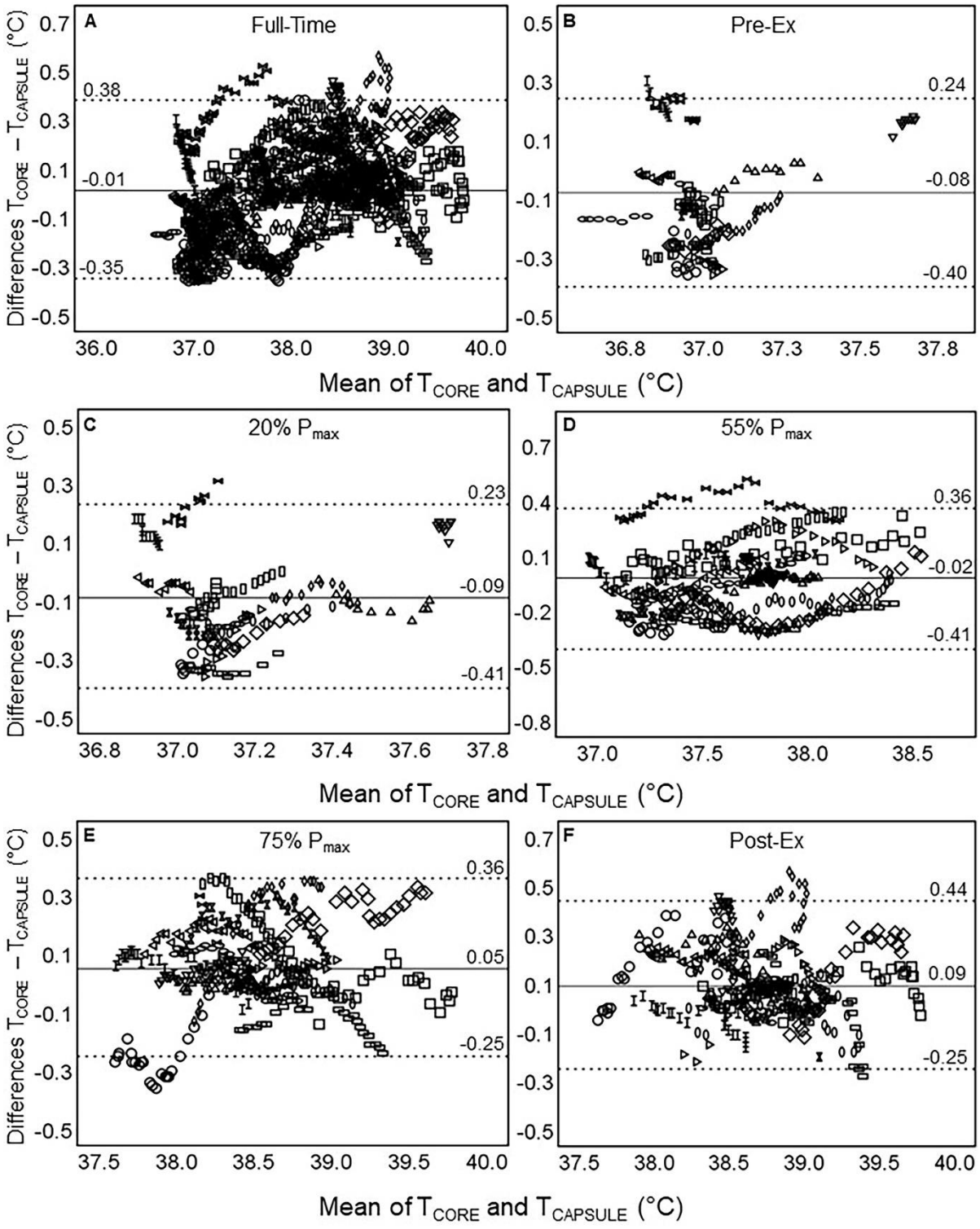

40.0
39.5
39.0
38.5
38.0
37.5
37.0
36.5
36.0
$T_{internal}$ (°C)
#
*
$T_{CAPSULE}$ Trial 1
$T_{CAPSULE}$ Trial 2
T_{CORE} Trial 1
T_{CORE} Trial 2
Pre-Ex
20% P_{max}
55% P_{max}
75% P_{max}
Post-Ex
0
10
20
30
40
50
60
70
80
90
100
Protocol Time (min)

FIGURE 2


A
Full-Time
0.38
-0.01
-0.35
B
Pre-Ex
0.24
-0.08
-0.40
C
20% Pmax
0.23
-0.09
-0.41
D
55% Pmax
0.36
-0.02
-0.41
E
75% Pmax
0.36
0.05
-0.25
F
Post-Ex
0.44
0.09
-0.25
Differences TCORE – TCAPSULE (°C)
Mean of TCORE and TCAPSULE (°C)

CHAPTER 3

ARTICLE

VALIDITY AND RELIABILITY OF THE EXERGEN TAT5000 TEMPORAL SCANNER TO ESTIMATE CORE TEMPERATURE DURING PHYSICAL EXERCISE IN THE HEAT.

VALIDITY AND RELIABILITY OF THE EXERGEN TAT5000 TEMPORAL SCANNER TO ESTIMATE CORE TEMPERATURE DURING PHYSICAL EXERCISE IN THE HEAT.

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ABSTRACT

OBJECTIVE: The aim of this study was to assess the validity and reliability of the Exergen TAT-5000 Temporal Scanner in estimating internal temperature during cycling exercise in a hot environment. **METHODS**: Eight men and eight women, regular cyclists (Age:33.9±8 years; VO_{2max}:53.6±7.0 $mL.kg^{-1}.min^{-1}$), underwent two similar cycling trials in a controlled environment at 32°C, RH 60%. The protocol consisted of an initial 10-minute rest, followed by an exercise protocol (60 minutes) in a hot environment, comprising 10 minutes at 20% of maximal aerobic power, 25 minutes at 55%, and 25 minutes at 75%, with an additional 25 minutes of post-exercise recovery. Core temperature was recorded simultaneously every minute using a gastrointestinal capsule ($T_{CAPSULE}$) and by Exergen TAT-5000 Temporal Scanner ($T_{EXERGEN}$). Bland–Altman analysis was performed to calculate bias, upper (LCS) and lower (LCI) concordance limits, and the 95% confidence interval (CI95%). The maximum acceptable difference between the two devices was ±0.4°C. A mixed linear model was used to model the paired differences between the two measurement systems, considering the subjects, reproducibility and environmental conditions as random effects and the activities as a fixed effect. The intra-class correlation coefficient model (ICC) was used to assess reliability. **RESULTS**: An ICC value of 0.90 was recorded. A significant bias value of -0.59, LCS of 0.82°C, LCI of -2.05°C, and CI95% of ±1.44°C were found. **CONCUSION:** Compared to $T_{CAPSULE}$, the Exergen TAT-5000 was considered reliable but invalid in estimating core temperature during cycling exercise in a hot environment.

KEYWORDS

Bicycling; Body Temperature; Climate Change; Thermometers

INTRODUCTION

Climate change has contributed to a significant increase in the number and intensity of heat waves. It is estimated that the heat wave that hit Europe in 2003 caused the deaths of more than 15,000 people [1]. The year 2022 recorded the most intense heatwave in a month of July in the United Kingdom, reaching a maximum temperature of 37.3°C during the days of July 17th to 19th [2]. Expectations are that in the coming years, heatwaves will continue to increase, even if global warming is stabilized at 1.5°C [3].

The increase in mortality rates and hospitalizations is associated with cases of Exertional Heat Illness (EHI) [4]. The cumulative stress from physical exertion (which does not necessarily need to be related to formal physical exercise) and thermal stress caused by a hot environment can result in a series of conditions that are harmful to health [5]. The effects of EHI can range from milder conditions such as cramps and light dizziness to more severe situations like exhaustion, syncope, and heat stroke. In the latter case, if necessary medical care is not provided, the situation can worsen, leading to a fatal outcome [6].

The magnitude of the effects of EHI is related, among other factors, to high internal body temperature ($T_{internal}$). In humans, $T_{internal}$ is regulated at around 37°C. This value is considered optimal for the main chemical processes in the body [7]. Small deviations from this thermal pattern will activate autonomic or behavioral thermoregulatory responses with the aim of maintaining thermal homeostasis [8]. During exercise, the increase in oxygen consumption (VO_2) necessary to meet the energetic demands of active muscles results in greater production of body heat [9]. When exercise intensity is high and performed in a stressing environment (high temperature and relative humidity), heat dissipation is impaired and the risk of heat

storage increases [9]. During the 2016 Union Cycliste Internationale Road World Championships, some cyclists reached 41.5°C of internal body temperature ($T_{internal}$) [10].

In the coming years, the occurrence of major sporting events in intense heat conditions will be increasingly common, e.g., Olympics Games 2024 Paris and FIFA World Cup 2026™ (Canada, Mexico and the United States). For safe sports practice without a minimum decrease in performance, continuous and accurate monitoring of $T_{internal}$ is essential [11]. There are different ways and locations to assess $T_{internal}$, and accuracy varies depending on these locations and methods [11]. The methods considered most valid are also the most invasive, e.g., rectal temperature (T_{rectal}), aortic blood temperature (T_{blood}) and esophageal temperature ($T_{esophageal}$) [12–14]. Other locations such as the mouth, forehead, ear, armpit and wrist are more portable, but their accuracy has already been reported by some authors as low [15–17].

A commonly used method to estimate $T_{internal}$ in humans is temporal temperature ($T_{temporal}$). The measurement is carried out using an infrared scanner that detects the skin temperature in the temporal region, presumably of the temporal artery, based on this value, the device estimates central body temperature using an algorithm that considers ambient temperature and skin temperature gradients toward the center of the body [18]. During the COVID-19 pandemic, this method was widely used by healthcare professionals, as its application was easily accessible and did not require direct contact between the healthcare professional and the assessed individual [19].

Despite being considered a relatively cheap and easy-to-use method, the validity of this device remains uncertain. Some authors have assessed the validity and reliability of $T_{temporal}$ under various conditions, and the results were not deemed

satisfactory. A study conducted in 2006 tested the temporal thermometer in various conditions and found inconsistent results, during rest, the device underestimated internal body temperature, and during moderate cycling exercise in a hot environment, the values were overestimated [20]. Another study conducted in 2007 assessed $T_{temporal}$ under passive heating in 16 healthy adults, comparing temporal thermometry with gastrointestinal temperature. The authors concluded that, while both methods provide similar values under thermoneutral conditions, temporal thermometry does not estimate adequately internal temperature during induced passive heating [21].

With technological progress, certain companies have refined temporal temperature sensors through the implementation of algorithms designed to estimate internal temperature more precisely and expeditiously. The TAT-5000 model, developed by Exergen Corporation, calculates the $T_{internal}$ by interpreting both ambient temperature and by detecting skin surface temperature, as outlined in the manufacturer guide. To the extent of our knowledge, no study has evaluated the validity and reliability of the Exergen TAT-5000 in estimating the $T_{internal}$ in both men and women during rest and physical exercise in hot conditions. This characterization outlines the objective of the present study.

METHODS

Study design and participants

The sample was composed of 16 adults (33.9 ± 8.1 years), comprising 8 men and 8 women. All selected volunteers were healthy individuals and regular practitioners of physical activity, i.e., either engaging in 30-60 minutes of moderate-intensity cycling 5 days/week or 30-60 minutes of vigorous-intensity cycling 3 days/week. The following

exclusion criteria were used for sample selection: 1) individuals with any form of disability; 2) smokers; 3) individuals with diagnosed cardiovascular or pulmonary complications; 4) diabetics (fasting blood glucose above 126 mg/dL); 5) individuals with a history of thermal injuries; 6) pregnant women or those using contraceptives. The volunteers signed an informed consent form, and the experiment was previously approved by the Ethics Committee on Human Research of the Federal University of Viçosa (CAAE: 63310522.6.0000.5153) and followed the ethical standards established in the Helsinki Declaration.

Experimental Procedures

The participants attended 3 laboratory visits with a 48-hour interval between visits, always arriving at 7:00 am. Common procedures were adopted for all visits: 1) Volunteers were instructed to arrive at the laboratory well-fed and rested; 2) Upon arrival, the volunteers had their hydration status assessed using urine specific gravity (USG) with a portable refractometer (Instrutherm - RTP-20ATC), with a cutoff value of 1.020 [22]. After the mentioned assessment, the volunteers ingesting 500 mL of water. 3) All experimental sessions were conducted in a climate-controlled room, with ambient temperature ($T_{ambient}$) and relative humidity (RH) maintained at 32ºC and 60%, respectively; 4) All exercise bouts were performed on a bicycle mounted on an electrically braked cycle ergometer (Tacx Flow Smart T2240); 5) Heart rate was measured at the wrist, minute by minute, using a heart rate monitor (Garmin Forerunner 745); 6) The rate of perceived exertion (RPE) was assessed appropriately using the Borg Scale, ranging from 6 (no exertion) to 20 (maximum exertion) [23].

Preliminary Day

The preliminary protocol was used to collect baseline parameters and familiarize with research procedures and instruments. Measurements included height using a stadiometer (Sanny ES2020), body mass using a scale (Filizola-ex), and skinfold thickness (triceps, subscapular, chest, subaxillary, suprailiac, abdominal, and thigh) using a caliper (Cescorf®). Body fat percentage (%BF) was calculated using the DC formula (g/cm^3) = 1.112 - 0.00043499 × (sum of 7 skinfolds) + 0.00000055 × (sum of 7 skinfolds) × 2 – 0.00028826 × (Age), and subsequently G% = [(4.95 / DC) – 4.50] × 100 [24]. The body surface area (BSA in m^2) was calculated according to the following equation: $BSA = (0.007184) \times (X^{0.425}) \times (Y^{0.725})$, where X is body mass (kg), and Y is height (cm) [25].

Finally, aerobic capacity was assessed by measuring P_{max} (W) in an incremental protocol on the cycle ergometer, with the following configuration: 2 minutes at 50 rpm and 50 W, followed by progressive increases of 25 W every 2 minutes until voluntary fatigue. The test was stopped when participants: 1) reported an RPE of 20; 2) could not maintain the predetermined cadence of 50 rpm; or 3) voluntarily requested to stop the exercise. P_{max} was calculated as the power of the last completed stage in W + [(time spent in the incomplete stage in seconds / 120 s) × 25 W] [26]. From P_{max}, VO_{2max} ($mL.kg^{-1}.min^{-1}$) was calculated as = (12 × maximum aerobic power + 300) / body mass in kg [27].

Two trials were carried out with similar procedures and data collection. The objective of carrying out Test 2 was to evaluate the reliability of the Exergen TAT 5000 thermometer ($T_{EXERGEN}$). The night before each experimental session, volunteers ingested telemetric capsules to measure the gastrointestinal tract, always 10 hours before the start of data collection. After checking the USG and hydration status, the volunteers were weighed, equipped with an Exergen TAT 5000 thermometer and a

heart rate monitor (Garmin Forerunner 745). At this point, the functionality of the gastrointestinal capsules was also checked.

After these procedures, volunteers underwent the following sequence on the cycle ergometer: 1) Pre-Ex. Moment – 10 minutes seated at rest for pre-exercise data collection; 2) 20% P_{max} Moment – 10 minutes of exercise at 20% of P_{max}; 3) 55% P_{max} Moment – 25 minutes of exercise at 55% of P_{max}; 4) 75% P_{max} Moment – 25 minutes of exercise at 75% of P_{max}; 5) Post-Ex. Moment – 25 minutes of post-exercise recovery seated on the bicycle. In total, the experimental session lasted 96 minutes.

$T_{gastrointestinal}$ was measured through the ingestion of a telemetric capsule model (CorTemp® Pill) 10 hours before the start of data collection, following the recommended minimum period to avoid contamination from food or liquid intake [28]. Each capsule was paired with a data logger (Data Recorder 262k w/HR HT 130042), and the data were recorded every minute. The gastrointestinal temperature recorded by the capsules ($T_{CAPSULE}$) was chosen as a comparison parameter due to its consideration as a valid and reliable method for measuring $T_{internal}$ under both resting and physical activity conditions, with a reported accuracy of ±0.01°C [29].

The $T_{EXERGEN}$ was measured using a modified procedure recommended by the manufacturer during heat conditions involving the presence of sweat. The measurement was conducted behind the right ear up to the midpoint of the mastoid process [30]. Measurements were taken every minute and recorded by the evaluator.

Statistical analyses

A mixed linear model was employed, incorporating both fixed and random effects. The factor proposed as a fixed effect was physical exercise; on the other hand,

the individuality of subjects, reliability, and environmental conditions were assumed as random effects [31].

The normality of the data was tested using the Shapiro-Wilk test for $T_{ambient}$ and RH, and the Kolmogorov-Smirnov test for $T_{CAPSULE}$ and $T_{EXERGEN}$. The variance over time for $T_{EXERGEN}$ and $T_{CAPSULE}$ was analyzed using the Friedman Test with the Student-Newman-Keuls post-hoc test. $T_{ambient}$ and RH were evaluated using the Mann-Whitney Rank Sum Test. The Mann-Whitney Rank Sum test was used to analyze the means between the two devices in trials 1 and 2.

For the present study, a 95% CI value of <0.4°C was proposed as acceptable between the two measurements, due to several factors that may affect the agreement between them, e.g., calibration, gastrointestinal motility, gastrointestinal temperature gradients, interference from liquid and food intake, time elapsed since ingestion of the gastrointestinal capsule and electromagnetic interference.

All analyses are presented for the total time as well as for each experimental moment. Data are shown as mean ± SD in which the level of significance was set at $P < 0.05$. The intra-class correlation coefficient model (ICC) was used to assess reliability. The following criteria were established for ICC values: Poor: ICC < 0.40; Fair: 0.40 ≤ ICC < 0.70; Good: 0.70 ≤ ICC < 0.90; Excellent: ICC ≥ 0.90 [32]. The validity of $T_{EXERGEN}$ was tested using the Bland-Altman method to assess agreement between the two measurement devices, $T_{EXERGEN}$ and $T_{CAPSULE}$ (a method that has already been validated and previously accepted). The systematic bias and 95% limits of agreement (LOA) were derived from the Bland-Altman plot [33]. All statistical analyses were conducted using the RStudio software version 2023.09.1 Build 494© 2009-2023 Posit Software, PBC [34]

RESULTS

Sample Characteristics

Table 1 presents the general characteristics of the sample measured in the preliminary trial.

Reliability

During the experimental tests, environmental conditions were maintained at 32.37±0.05°C, 60.3±0.8%, 0m/s (Trial 1) and 32.36±0.04°C, 59.5±0.4%, 0m/s (Trial 2) for $T_{ambient}$ (p =0,308), RH (p =0.009) and wind speed (p = 1.000), respectively.

The Figure 1 depicts the adjustments of $T_{internal}$ over the protocol time for $T_{CAPSULE}$ (circle) and $T_{EXERGEN}$ (triangle). When analyzed together, a time effect was observed (p = 0.039); $T_{internal}$ increased from 20 minutes for all measurements, not returning to baseline values after 25 minutes of post-exercise recovery.

Table 2 presents the results of the reliability of $T_{EXERGEN}$ compared between Trials 1 and 2 at the Pre-Ex. (10min), 20% P_{max} (10min), 55% P_{max} (25min), 75% P_{max} (25min), and Post-Ex. (25min) moments. As observed, no differences in $T_{EXERGEN}$ were found between Trials 1 and 2 (p=0.175). The overall ICC recorded showed a value of 0.90.

Validity

Table 3 presents the validity results at the Pre-Ex. (10min), 20% P_{max} (10min), 55% P_{max} (25min), 75% P_{max} (25min), and Post-Ex. (25min) moments. As observed, differences were found between mean temperatures of $T_{EXERGEN}$ and $T_{CAPSULE}$

(p=0.0002). Additionally, the bias was significant (Full time: -0.59ºC), and the 95% CI value was -±1.44ºC. Finally, for the criterion of the adopted borderline difference of ±0.04ºC in the present study, it was observed that 76% of the values recorded for $T_{EXERGEN}$ exceeded the accepted variation. These results can be seen in Figure 3, with each of the 16 individuals in the sample represented by distinct symbols.

DISCUSSION

The present study assessed the validity and reliability of the Exergen TAT 5000 ($T_{EXERGEN}$) in estimating the $T_{internal}$ during cycling exercise in the heat, compared to the measurement of gastrointestinal temperature using a telemetric capsule ($T_{CAPSULE}$).

To evaluate the reliability and validity of the Exergen TAT-5000 Temporal Scanner, a stationary cycling protocol on a cycle ergometer was developed at different intensity levels in a hot environment (32°C), held on two similar days, with the aim of imposing thermal stress on participants. During this protocol, Pre-EX and Post-Ex measurements were also analyzed in order to attest to the device capacity to monitor the different conditions imposed by the rest and recovery phases.

Regarding reliability, our main findings demonstrate that the Exergen TAT 5000 was reliable with an excellent degree of correlation (ICC = 0.90), when analyzed throughout the protocol period. At one of the moments, 75% P_{max}, the ICC was considered fair (0.57), demonstrating that the reliability of the device can be reduced in conditions where the exercise intensity is very high.

The reliability of a device is determined by the consistency of the measurements that are performed; a measurement that produces highly inconsistent results over time cannot be considered an alternative tool for use. However, the use of analysis methods

that are based on correlation coefficients and regression only provide an indication of “relative reliability” and further comparisons are necessary in order to fully assess the effectiveness of a device [35].

Regarding validity, the Exergen TAT-5000 Temporal Scanner recorded a 95% CI of ±1.44°C, exceeding the pre-established limit of ≤0.4°C by more than 1°C. The findings of the present study make us consider $T_{EXERGEN}$ as invalid for using during rest, physical exercise and recovery conditions. The analysis carried out at different moments of the protocol identified a significant bias value at all moments of the study, with a variation from -0.31 to -1.02 as seen in table 3. The low agreement among measurements is evident throughout the entire protocol. The analysis conducted revealed that 76% of the measurements exceeded the threshold of ±0.4°C, while 84% surpassed the limit of ±0.3°C.

An analysis derived from the Bland-Altman proposal illustrates the dispersion of differences throughout the different moments of the study. The limits of agreement varied from -2.05 to 0.82 throughout the protocol, as seen in figure 2. To analyze the validity of a device, it is expected that the confidence interval is reduced and as close to zero as possible. The high limit observed together with 95% CI value illustrates the low agreement between the measurement methods.

The low agreement between the measurement methods recorded in the present study is aligned with the results reported by others who also evaluated the temporal scanner technology to estimate $T_{internal}$ [20,21].

Some factors can impact temporal readings, and one of them is the presence of sweat in the region where the readings were taken. During the exercise protocol in this study, participants experienced evaporation caused by the intensity of the exercise,

combined with stress induced by the hot and humid environment. The recommendation of the manufacturer of relocating the measurement site to behind the ear, close to the mastoid process, in the presence of sweat does not appear to be sufficient in preventing measurement contamination. The proposal to use a value that is supposed to be measuring the temperature of the temporal artery seems to be uncertain since the device cannot accurately identify the true location of the artery. This is evident from the proposed method of changing the measurement location for cases where sweat is present.

Despite being widely used in clinical settings, to the best of our knowledge, no study has conclusively validated the effectiveness of temporal scanner technology in estimating internal temperature. While the device is not explicitly recommended for use in sports contexts by the manufacturer, it does not explicitly discourage such application. During sports practice, the use of non-invasive devices that can accurately measure internal temperature would allow users to practice safer practice in addition to allowing adaptation procedures to thermal stress, e.g., acclimatization. The findings of the present study demonstrate that the Exergen TAT-5000 does not accurately estimate the $T_{internal}$ during rest, cycling exercise, and recovery. Therefore, despite being considered a reliable measure, its use in the sporting context is not recommended.

CONCLUSION

It is concluded that $T_{EXERGEN}$ is reliable but invalid in estimating of $T_{internal}$, and is therefore not recommended for use in the sports context under the conditions of assessment.

ACKNOWLEDGMENTS

This study was supported by grants from CNPq (Conselho Nacional de Desenvolvimento Científico e Tecnológico) with the grant numbers 403824/2021-4 and 407925/2023-6, CAPES (Coordenação de Aperfeiçoamento de Pessoal de Nível Superior) and FAPEMIG (Fundação de Amparo à Pesquisa do Estado de Minas Gerais) with the grant number APQ-01828-23. A.J. Natali and S.P. Wanner are CNPq fellows. W.M. Januário W.M. and N.F. Lessa were CAPES fellows. A.J.O. Schittine was CNPq fellow and is currently FAPEMIG fellow.

DISCLOSURE OF INTEREST

The authors report there are no competing interests to declare.

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TABLES AND FIGURES LEGENDS

Table 1 – Sample characteristics.

Table 2 - Reliability results of $T_{EXERGEN}$ compared between Trials 1 and 2.

Table 3 - Validity results between $T_{CAPSULE}$ and $T_{EXERGEN}$.

Figure 1 - Adjustments of $T_{EXERGEN}$ and $T_{CAPSULE}$ over the protocol time in Trials 1 and 2. * = indicates time-dependent differences ($p<0.05$). Data are presented as mean ± SD.

Figure 2 – Bland-Altman plots of the data for the moments Pre-Ex. (10min), 20% P_{max} (10min), 55% P_{max} (25min), 75% P_{max} (25min) and Post-Ex.(25min). The dashed lines represent the limits of agreement (LoA) and the solid lines the bias.

TABLE 1.

Sample	Mean	±	SD
Age (years)	33.9	±	8.1
Body mass (Kg)	66.6	±	9.0
Stature (cm)	171	±	6.2
%BF	20.7	±	5.3
BSA (m^2)	1.79	±	0.3
VO_{2max} ($mL.kg^{-1}.min^{-1}$)	53.6	±	7.0
P_{max} (W)	292	±	45

%BF: Percentage of Body Fat; BSA: Body Surface Area; Vo_{2Max}: Maximal Oxygen Uptake; P_{max}: Maximal aerobic power.

TABLE 2.

Moments	$T_{EXERGEN}$ (°C) Trial 1	$T_{EXERGEN}$ (°C) Trial 2	Bias (°C)	ICC
Pre-Ex.	36.67 ± 0.40	36.57 ± 0.43	0.09	0.99
20% P_{max}	36.94 ± 0.23	36.82 ± 0.46	0.12	0.98
55% P_{max}	37.32 ± 0.55	37.35 ± 0.54	-0.03	0.97
75% P_{max}	37.74 ± 0.72	38.01 ± 0.73*	-0.26	0.57
Post-Ex.	37.26 ± 0.57	37.44 ± 0.81	-0.18	0.95
Full-Time	37.30 ± 0.67	37.40 ± 0.80	-0.10	0.90

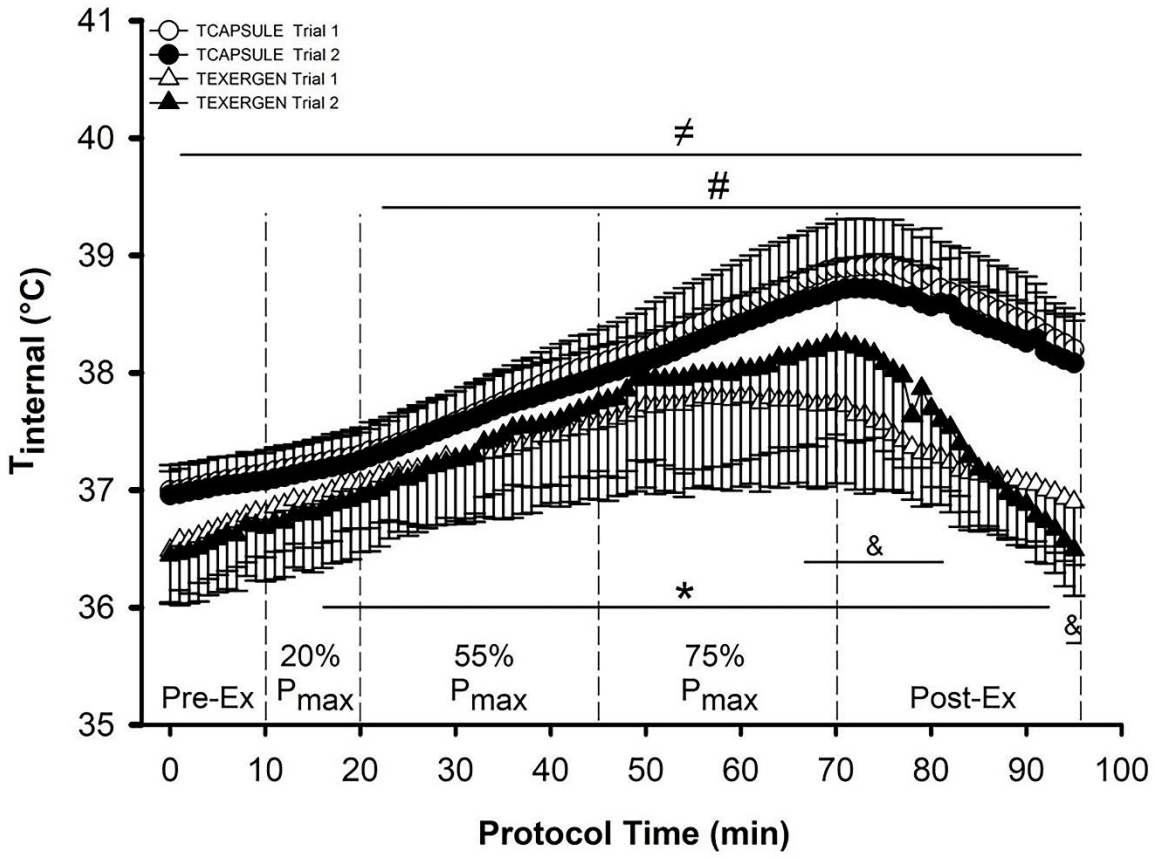
The results are shown for the moments Pre-Ex. (10min), 20% P_{max} (10min), 55% P_{max} (25min), 75% P_{max} (25min) e Post-Ex. (25min). * = indicates difference of $T_{EXERGEN}$ between Trials 1 and 2. Data are shown as mean ± SD.

TABLE 3.

Moments	$T_{EXERGEN}$ (°C)	$T_{CAPSULE}$ (°C)	Bias (°C)	LoA	IC95%	% > 0.3°C	% > 0.4°C
Pre-Ex.	36.62 ± 0.42	37.05 ± 0.21*	-0.43	-1.35 to +0.50	±0.92	75%	63%
20% P_{max}	36.88 ± 0.43	37.19 ± 0.21*	-0.31	-1.18 to +0.56	±0.87	69%	52%
55% P_{max}	37.33 ± 0.54	37.64 ± 0.34*	-0.31	-1.38 to +0.75	±1.06	75%	65%
75% P_{max}	37.86 ± 0.73	38.39 ± 0.31*	-0.53	-2.15 to +1.09	±1.62	93%	88%
Post- Ex.	37.35 ± 0.70	38.55 ± 0.42*	-1.02	-2.48 to +0.09	±1.28	93%	90%
Full-Time	37.37 ± 0.73	37.96 ± 0.66*	-0.59	-2.05 to +0.82	±1.44	84%	76%

The results are shown for the moments Pre-Ex. (10min), 20% P_{max} (10min), 55% P_{max} (25min), 75% P_{max} (25min) e Post-Ex. (25min). % > = indicates the percentage of measurements that were above the respective validity limit. * = indicates difference between $T_{EXERGEN}$ and $T_{CAPSULE}$.The data is presented as mean ± SD.

FIGURE 1


TCAPSULE Trial 1
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Pre-Ex
20% Pmax
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41
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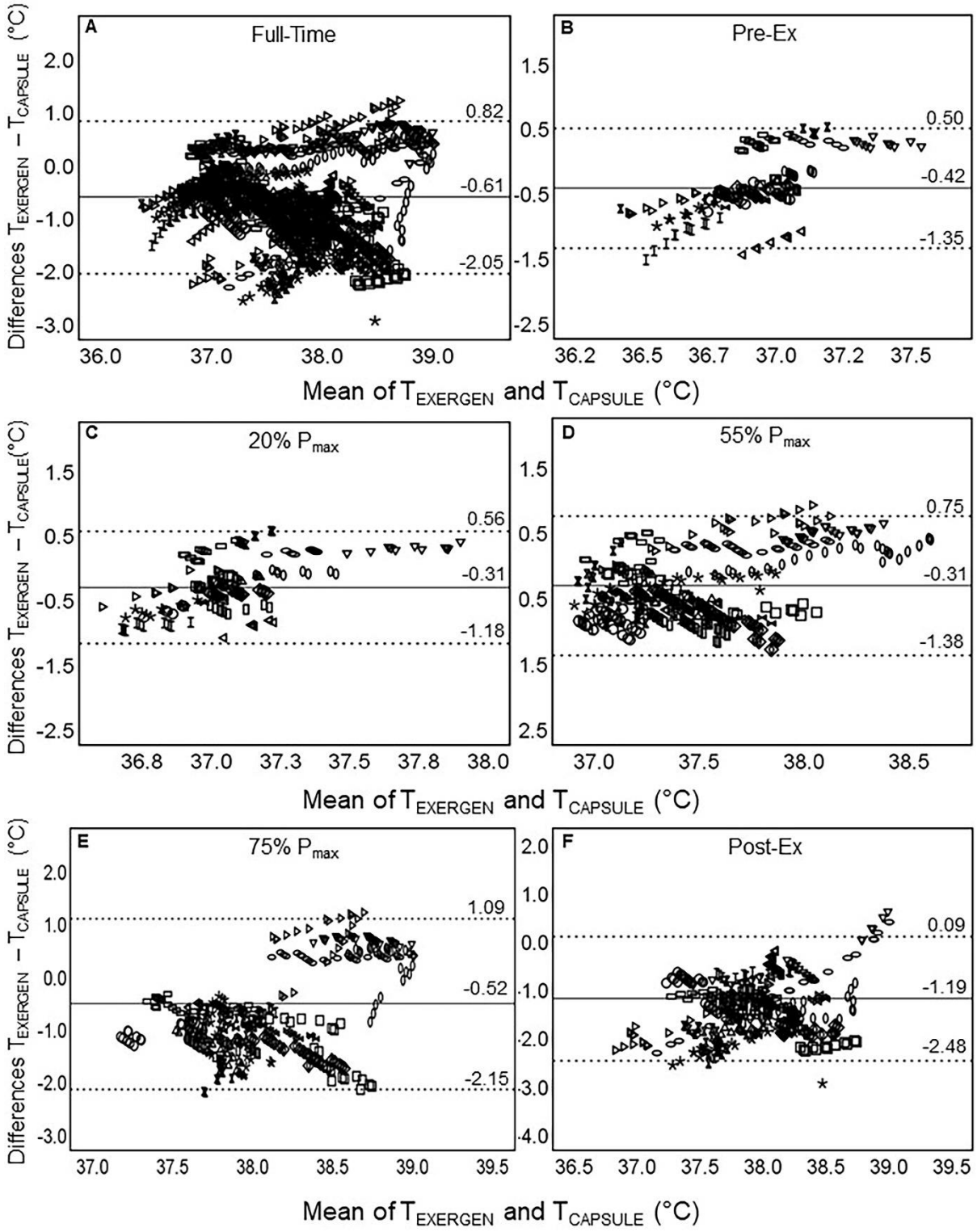
FIGURE 2


A
Full-Time
0.82
-0.61
-2.05
B
Pre-Ex
0.50
-0.42
-1.35
C
20% Pmax
0.56
-0.31
-1.18
D
55% Pmax
0.75
-0.31
-1.38
E
75% Pmax
1.09
-0.52
-2.15
F
Post-Ex
0.09
-1.19
-2.48
Differences TEXERGEN − TCAPSULE (°C)
Mean of TEXERGEN and TCAPSULE (°C)

General Conclusion

The systematic review completed in the present work indicated the average value of 37.13±0.24°C measured by ingestible capsules as reference for resting $T_{gastrointestinal}$ in healthy adult individuals.

Our findings consider the CORE Sensor device valid and reliable for central temperature estimation during cycling exercise in the heat and support the use of the device as a valid portable alternative to other invasive methods. Regarding the Exergen TAT-5000, according to the results, it is concluded that $T_{EXERGEN}$ is reliable, but invalid in the $T_{internal}$ estimate, and is therefore not recommended for use in the sports context.

APPENDIX:

FIGURE 1

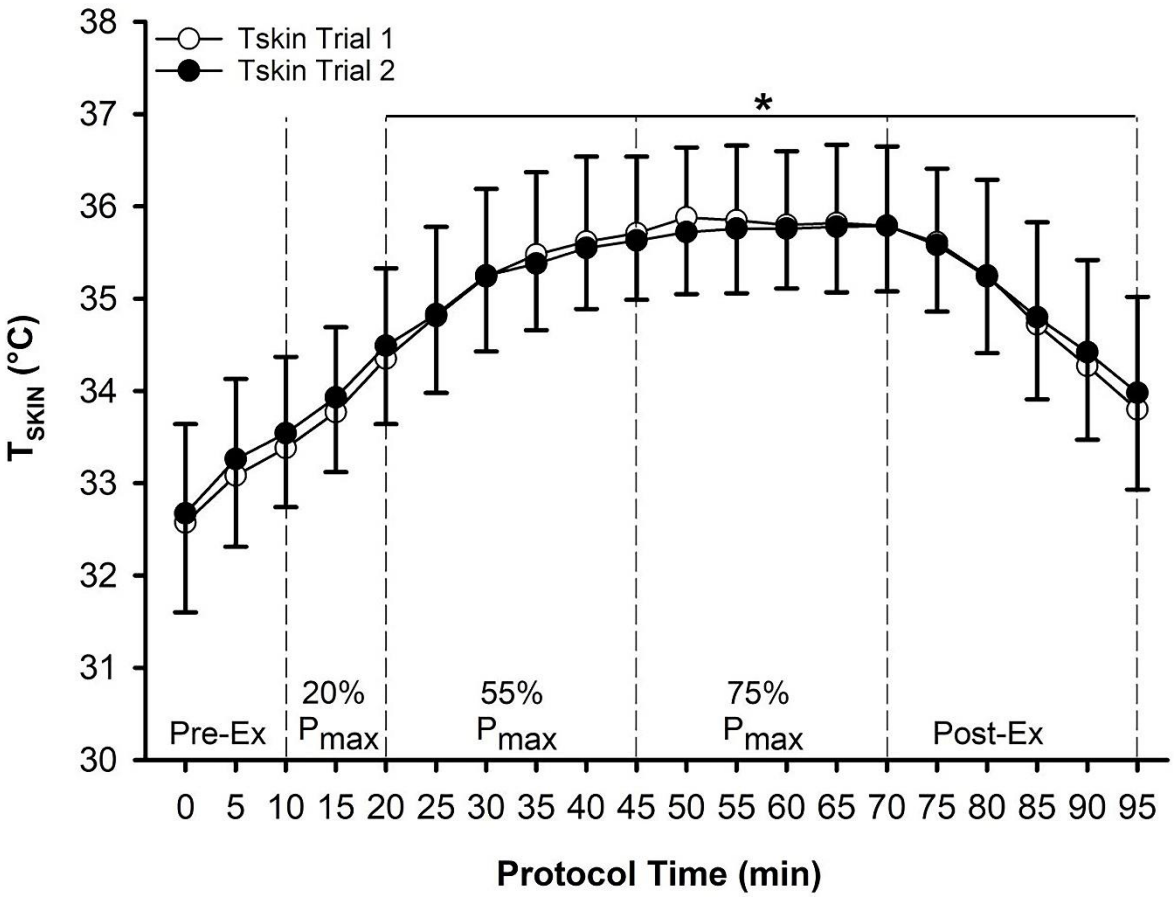


FIGURE 2

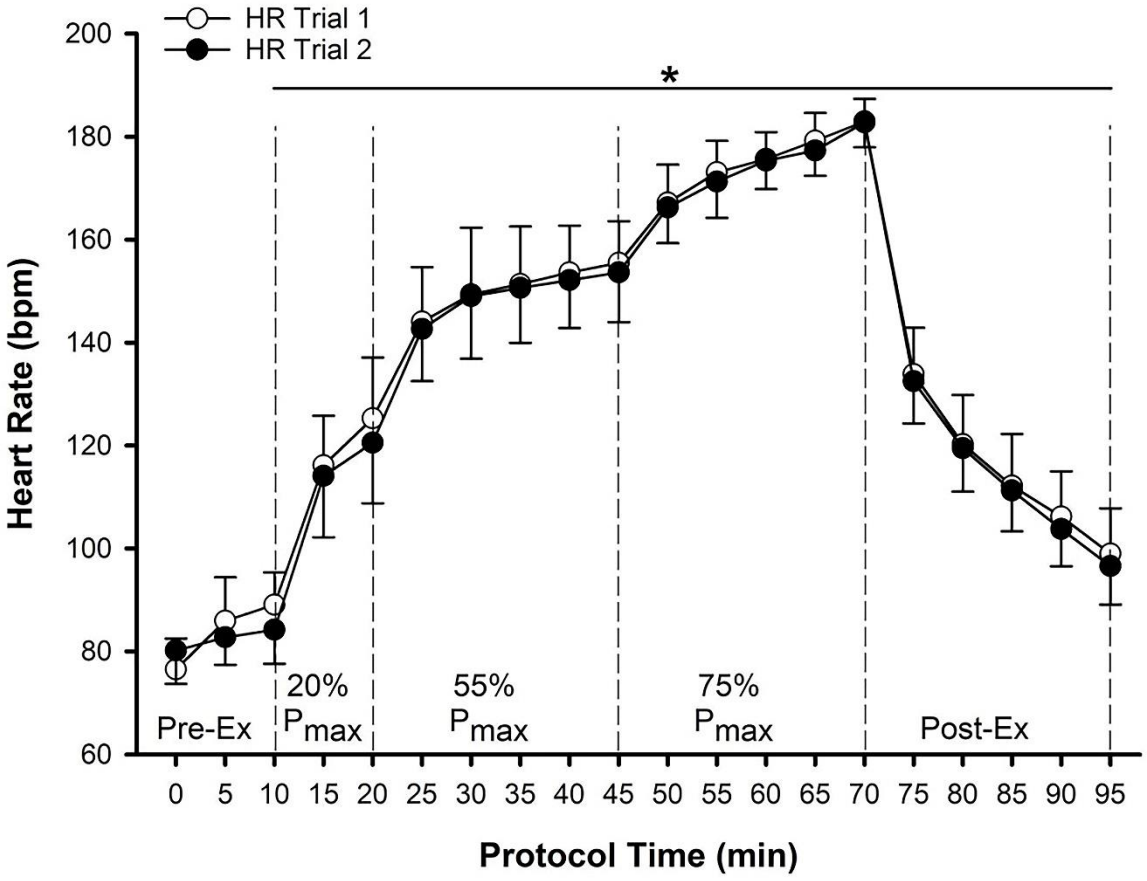

HR Trial 1
HR Trial 2
*
Heart Rate (bpm)
200
180
160
140
120
100
80
60
Pre-Ex
20% Pmax
55% Pmax
75% Pmax
Post-Ex
0 5 10 15 20 25 30 35 40 45 50 55 60 65 70 75 80 85 90 95
Protocol Time (min)

FIGURE 3

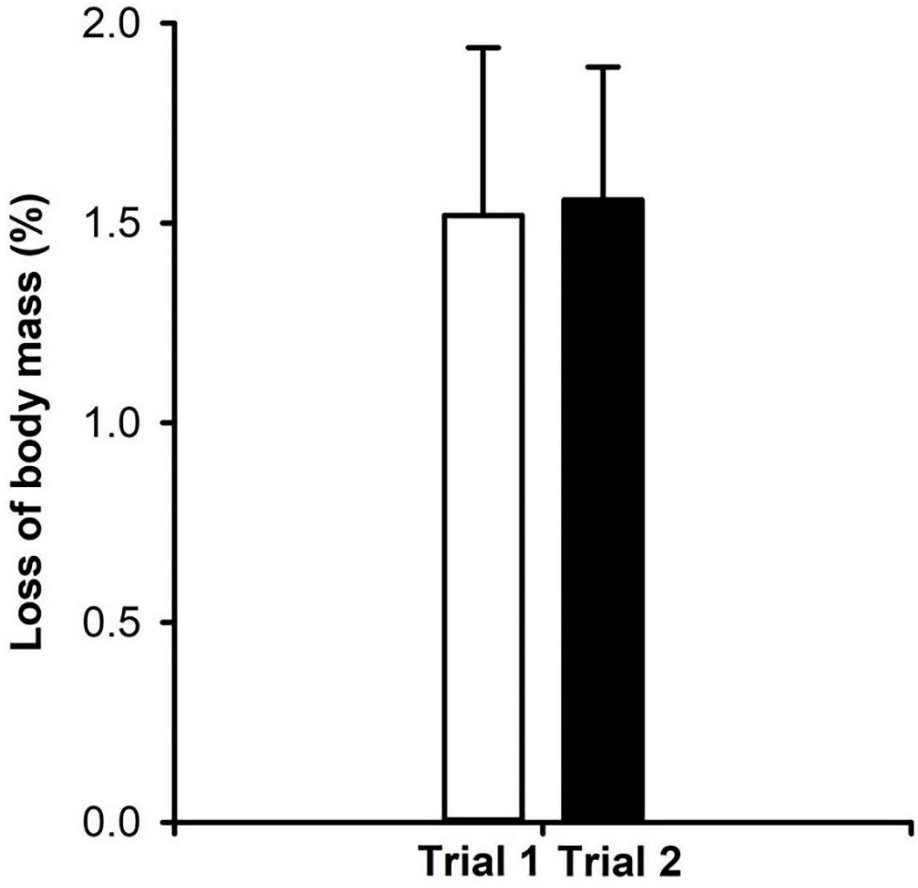


FIGURE 4

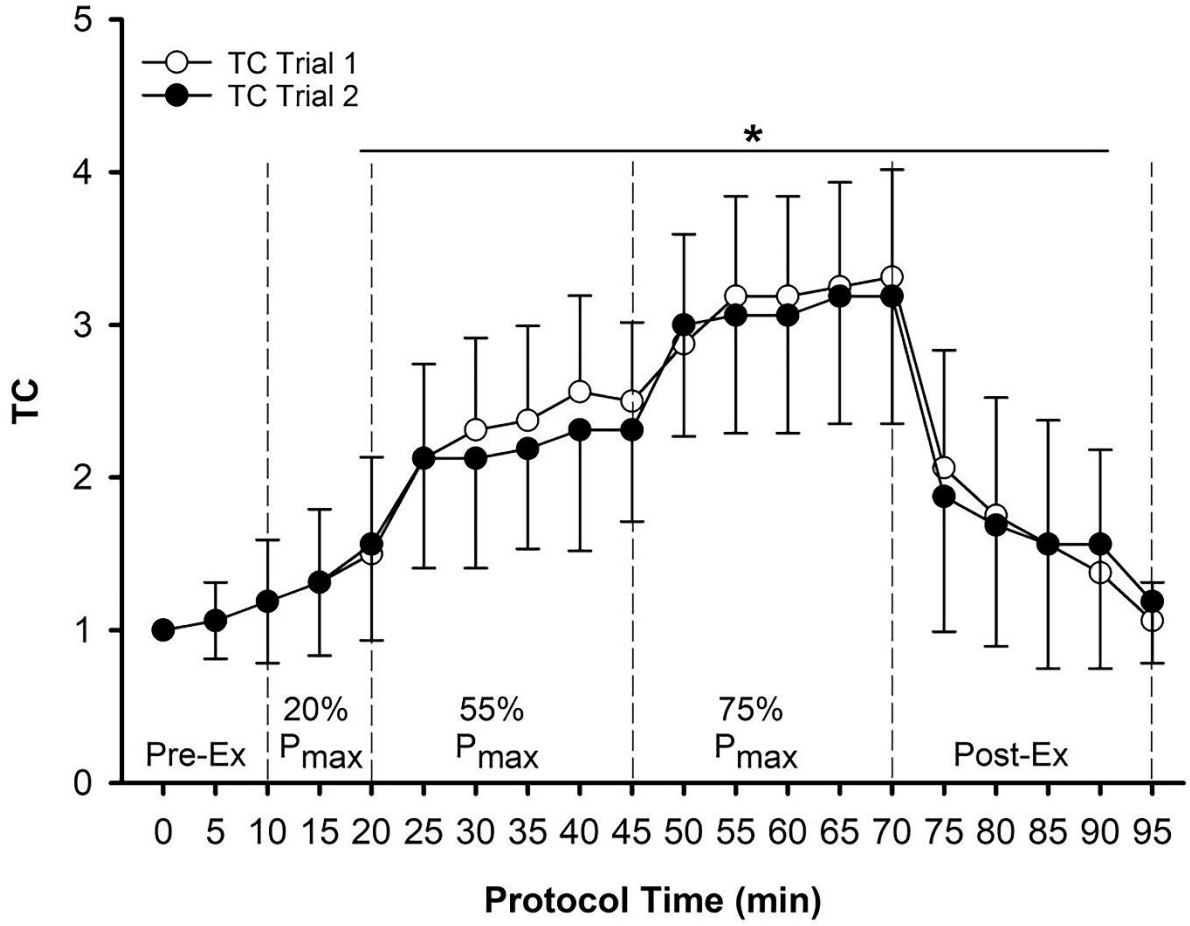

TC Trial 1
TC Trial 2
*
TC
Pre-Ex
20% Pmax
55% Pmax
75% Pmax
Post-Ex
Protocol Time (min)
0
1
2
3
4
5
0 5 10 15 20 25 30 35 40 45 50 55 60 65 70 75 80 85 90 95

FIGURE 5

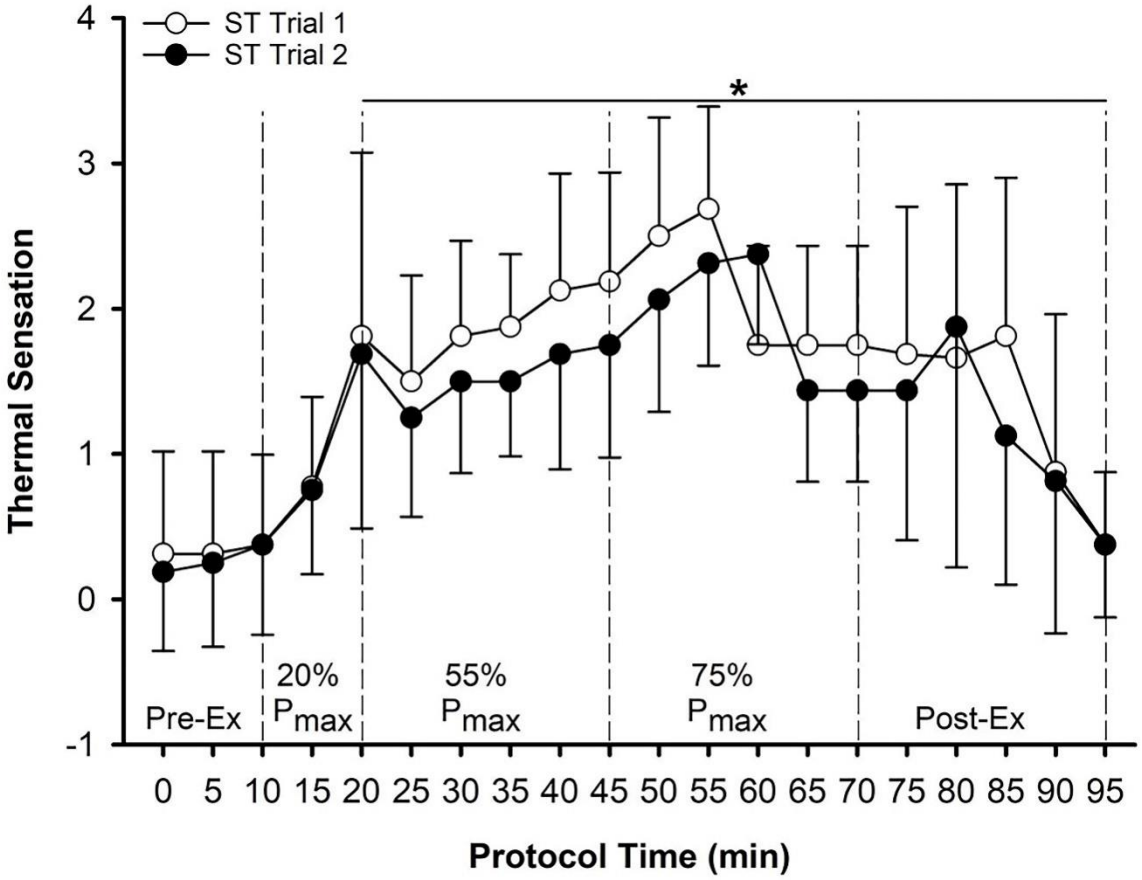
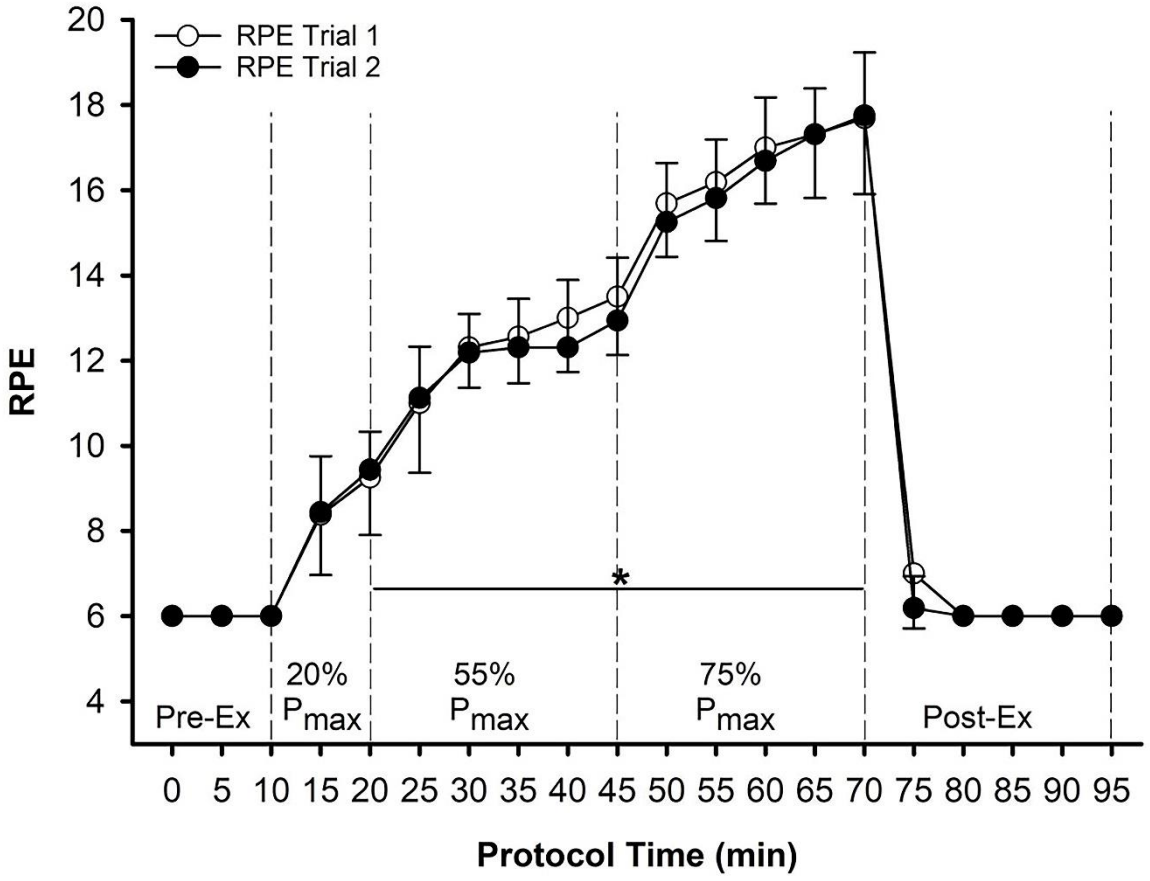

ST Trial 1
ST Trial 2
*
Thermal Sensation
4
3
2
1
0
-1
Pre-Ex
20% Pmax
55% Pmax
75% Pmax
Post-Ex
0 5 10 15 20 25 30 35 40 45 50 55 60 65 70 75 80 85 90 95
Protocol Time (min)

FIGURE 6


RPE Trial 1
RPE Trial 2
RPE
20
18
16
14
12
10
8
6
4
*
Pre-Ex
20% Pmax
55% Pmax
75% Pmax
Post-Ex
0 5 10 15 20 25 30 35 40 45 50 55 60 65 70 75 80 85 90 95
Protocol Time (min)

UNIVERSIDADE FEDERAL DE VIÇOSA - UFV

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Validade e confiabilidade de duas técnicas de medida da temperatura central durante o exercício físico no calor: CALERA® Sensor e Exergen TAT5000 Temporal Scanner

Pesquisador: Thales Nicolau Prímola Gomes
Área Temática:
Versão: 2
CAAE: 63310522.6.0000.5153
Instituição Proponente: Departamento de Educação Física
Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 5.751.716

Apresentação do Projeto:
O projeto "Validade e confiabilidade de duas técnicas de medida da temperatura central durante o exercício físico no calor: CALERA® Sensor e Exergen TAT5000 Temporal Scanner" será realizado sob responsabilidade do Prof. Thales Nicolau Prímola Gomes do Departamento de Educação Física. Os sujeitos de pesquisa serão 20 adultos de idade 18-59 anos, sendo 10 homens e 10 mulheres praticantes de ciclismo regular.
Serão utilizadas questões problematizadoras para promover debate e o mesmo será gravado e para os egressos será enviado questionário on-line.

Participarão do estudo: pessoas saudáveis, considerando o PAR-Q e o IPAQ, praticantes de atividade física regular, de acordo com as recomendações do Colégio Americano de Medicina Esportiva (ACSM), que pratiquem de 30-60min de ciclismo com intensidade moderada, 5 dias/sem ou de 30-60min de ciclismo com intensidade vigorosa, 3 dias/sem.

Serão excluídas do estudo pessoas com deficiência de qualquer natureza, fumantes, pessoas com complicações cardiovasculares ou pulmonares diagnosticadas, diabéticos (glicemia em jejum acima

de 126 mg/dl, segundo as diretrizes da Sociedade Brasileira de Diabéticos), e indivíduos com histórico de injúrias térmicas.

Coleta de dados:

- Temperatura da pele será medida utilizando termopares (tipo K, S-09K INSTRUTHERM) fixados com fita adesiva em diferentes regiões do corpo (peito, escápula, tríceps, ombro, quadríceps e panturrilha). Os valores serão medidos continuamente, em repouso, durante e após a sessão de exercício.

- Temperatura central: a temperatura gastrointestinal será mensurada por meio de uma cápsula ingerível (HT150002CorTemp® Pill) e um aparelho de telemetria (HT130042 CorTemp® DATA Recorder262K wiHR). As temperaturas serão medidas a cada 5 minutos, no repouso, exercício e pós exercício; Temperatura retal será mensurada através de sondas retais descartáveis modelo MSH (padrão ouro); O dispositivo Core Green tech será afixado em uma fita estilo Polar e pareado no frequencímetro assim como descrito na embalagem do fabricante, os valores serão coletados a cada 5 minutos no repouso, exercício e pós exercício; Também será utilizado o escâner temporal (Exergen TAT5000 Temporal Scanner) as temperaturas serão medidas a cada 5 minutos, no repouso, exercício e pós exercício.

- Ao término do exercício o participante será "secado e retirado o excesso de suor do corpo com uma toalha, os equipamentos serão retirados e o voluntário realizará uma nova pesagem, (vestindo somente a sunga,)"

- Os participantes comparecerão quatro vezes ao laboratório.

Objetivo da Pesquisa:

avaliar se os dispositivos CALERA® Sensor e Exergen TAT5000 Temporal Scanner são válidos e confiáveis para mensurar a temperatura central durante exercício de ciclismo no calor.

Avaliação dos Riscos e Benefícios:

RISCOS: no TCLE foram informados os riscos adequadamente e as medidas que a equipe de pesquisadores adotará para minimizá-los.

BENEFÍCIOS: foram apresentados benefícios diretos e indiretos.

Comentários e Considerações sobre a Pesquisa:

Projeto muito bem escrito.

Considerações sobre os Termos de apresentação obrigatória:

1. Informações Básicas do Projeto: em conformidade
2. TCLE: em conformidade
3. Projeto Detalhado: em conformidade
4. Folha de Rosto: em conformidade
5. Orçamento: em conformidade (financiamento próprio).
6. Cronograma: em conformidade
7. Autorização da instituição: em conformidade.

Conclusões ou Pendências e Lista de Inadequações:

Aprovado.

Considerações Finais a critério do CEP:

Ao término da pesquisa é necessário apresentar, via notificação, o Relatório Final (modelo disponível no site www.cep.ufv.br). Após ser emitido o Parecer Consubstanciado de aprovação do Relatório Final, deve ser encaminhado, via notificação, o Comunicado de Término dos Estudos para encerramento de todo o protocolo na Plataforma Brasil.

Projeto aprovado autorizando o início da coleta de dados com os seres humanos a partir da data de emissão deste parecer.

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_1994279.pdf	25/10/2022 15:19:28		Aceito
Outros	CartaResposta1.pdf	25/10/2022 15:17:35	WILLIAM MARTINS JANUARIO	Aceito
Outros	TCLE_modificado.pdf	25/10/2022 15:15:09	WILLIAM MARTINS JANUARIO	Aceito
Declaração de Instituição e Infraestrutura	Autorizacaodainstituicao.pdf	25/10/2022 15:14:05	WILLIAM MARTINS JANUARIO	Aceito
TCLE / Termos de	termo.pdf	06/09/2022	WILLIAM MARTINS	Aceito

Assentimento / Justificativa de Ausência	termo.pdf	09:58:05	JANUARIO	Aceito
Projeto Detalhado / Brochura Investigador	projetofinalpronto.pdf	06/09/2022 09:55:46	WILLIAM MARTINS JANUARIO	Aceito
Cronograma	CRONOGRAMA.pdf	06/09/2022 09:55:14	WILLIAM MARTINS JANUARIO	Aceito
Folha de Rosto	folhaderosto.pdf	06/09/2022 09:23:34	WILLIAM MARTINS JANUARIO	Aceito

Situação do Parecer:
Aprovado

Necessita Apreciação da CONEP:
Não

VICOSA, 10 de Novembro de 2022

Assinado por:
Guilherme de Azambuja Pussieldi
(Coordenador(a))