Test protocol for the validation of wearable non-invasive thermometer

Manuscript: Evaluation of wearable non-invasive thermometer for monitoring inner-ear temperature of physically demanding occupations

Test protocol

Part I: **Validation (lab study)**

Part II: In vivo validation and usability in (lab study)

Part III: In vivo validation and usability (field study)

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Table of contents

1 Introduction

1.1 Background

Heat strain among physically demanding occupations is of major concern and needs to be prevented. Heat strain is influenced by four environmental parameters [1]; ambient temperature (T_a) [2-4], air velocity, radiation and (relative) humidity (RH) [5-11]. These parameters can cause heat strain and stress due to a hampered loss of heat by the body which results in increased core temperature (T_c) [12]. Mainly two working conditions play an important role in gaining heat strain [1,5]. Firstly, working in (indoor and outdoor) hot (and humid) environments, as firefighters [3.13-15], underground mineworker [4,7,10] and workers in the steel industry [5], causes a hampered loss of heat by the body during physically active work due to the ambient conditions as T_a and RH and solar radiation [1-12]. Secondly, certain physically demanding occupations require workers to wear personal protective clothing (PPC) and equipment (PPE). This full-body clothing protects workers against chemical or biological substances, thermal exposure and mechanical impacts [16]. However, wearing PPC and PPE during the performance of physically active work, can cause heat strain due to thermal insulation (increase in T_a and RH) and evaporative resistance due to lack of air velocity in the PPC and/or PPE [1-2,5-7,12,17]. These two working conditions can cause heat strain resulting in health problems, such as exhaustion, dehydration, mental confusion and loss of consciousness, affecting productivity and risk perception [7-9,18]. In more extreme cases, heat strain can cause permanent damage and even be life-threatening [5,13,19-20]. Heat strain is influenced by individual factors [3,20-21] such as age, health, fitness and thermal comfort [4,7,10,12,16], resulting in increased metabolic rate, fatigue and health and safety problems [7,11-12,14,17,20,22-23].

1.2 Research motivation

By monitoring the T_c of workers and the ambient working conditions, heat strain could be prevented. T_c can be measured in several invasive and non-invasive ways [24]. Invasive measurements such as esophageal, rectal and gastrointestinal thermometers have high reliability [13,22-23], but are not suitable or inappropriate in a working situation [12,19,23,25-27]. Non-invasive methods, like skin and forehead thermometry, are nowadays wearable [28-29], but often impractical in a working situation because of interference with working conditions [25] or are unreliable [6,13,19,22,30]. Thus, presently, there is a lack of instruments available to continuously and unobtrusively monitor heat strain among physically active workers during the performance of their job [23,26,31-33]. To monitor and prevent heat strain in individual physically active workers, and for the sake of patient health, a reliable, non-invasive and continuous system of measuring in the form of a wearable thermometer is needed [23,31-32,34-37].

A new non-invasive sensor system, the CORTES[2] (Core Temperature and Environmental Sensor System) has been developed. This wearable thermometer measures tympanic temperature using an infrared (IR) sensor [31,38] positioned in the ear canal. Moreover, it also measures ambient conditions (T_a and RH) nearby the participants using a wearable chest box. A new commercially available system, the Cosinussº C-med (Cosinussº GmbH, München, Germany) has also become available. The wearable and non-invasive nature of the CORTES[2] and Cosinussº thermometers, and their ability to measure T_c continuously and on a daily basis, is innovative compared to available products that do not have the combination of these features. They could form the basis of a useful, non-invasive and low-level measuring system, which is easy to use and non-obstructive for the worker and do not hinder the workability. These products could be used in (scientific) research focusing on the development of heat strain, measured in real-life situations during the performance of different types of physically demanding occupations, and to indicate potential ways of preventing heat strain more effectively and to improve the health and safety of physically active workers during the performance of their jobs.

Research into the validity of the Cosinussº One has shown a systematic difference of -1.5ºC compared to infrared tympanic temperature [31]. The validity and usability of the Cosinussº C-med and its interactiveness in working conditions are currently unknown but expected to be higher due to a more accurate sensor. In this study, both systems will be studied in terms of (concurrent) validity and usability in a laboratory and a field study, and compared to tympanic IR thermometer [15,39-40]. The CORTES², Cosinuss C-med and tympanic IR thermometer are all based on tympanic temperature measurement and therefore expected to have comparable outcomes. To compare the outcomes of this study with the validity of the Cosinussº One [31], a tympanic IR thermometer will be selected as reference. In medical settings, tympanic temperature is the clinical standard used to monitor the core temperature of adult patients [14,41-43] due to its fast, non-invasive nature [12] and similarity (±0.2C) to rectal temperature measurements [15,42,44-47]. Besides, multiple studies have stated that tympanic infrared temperature is a reliable method for research purposes [13,44-45,48]. However, the accuracy and validity of tympanic infrared thermometry is questionable when not the real tympanic, but aural temperature is measured [24,49-50]. It is mostly the aural temperature which is measured. While tympanic infrared thermometry is not considered the scientific gold standard, its advantages are that it can be applied easily by the participants and that it is the current clinical gold standard method used when workers are expected to be suffering from excessive heat strain (overheated). So, for this in-vivo study a tympanic IR thermometer will be used as a reference.

1.3 Objective and aims

The objective of this study are to investigate the validity and usability of the CORTES² and Cosinuss C-med thermometers in a controlled lab and real-life working conditions. The aims are (1) to test the validity of the thermometers in controlled conditions; (2) to test validity and (3) explore the usability of the CORTES² and Cosinussº C-med thermometers for monitoring individual tympanic temperatures in a lab study; (4) to test validity and (5) explore the usability of the system to measure tympanic temperatures during the performance of physically demanding occupations, (6) in relation to the micro-climate ambient conditions (T_{cli} and RH) nearby the participant in a field study.

The study design contains three experiments: (I) validation of the thermometer is in a thermostatic water bath, (II) in vivo validation and usability explored in a lab study, (III) in vivo validation and usability explored in a field study. This document contains the test protocol part I Validation (lab study) to answer aim (1) test the validity of the thermometers in controlled condition

2 Materials and methods

2.1 Study design

The validity of the thermometers will be examined in a thermostatic water bath. At a constant temperature, the concurrent validity of the CORTES², Cosinussº and tympanic IR thermometer will be compared to the reference mercury thermometer. The water temperature needs to be increased from 35 to 41ºC in steps of 0.5ºC. Per step 3 measurements will be taken with a frequency of one measurement per minute.

2.2 Participants

For the validation of the thermometer in the lab study, no participants are required.

2.3 Ethical considerations

This study will be carried out in accordance with "The Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans". The Medical Ethics Committee of the University Medical Center Groningen, the Netherlands, issued a waiver for this study, stating that it does not involve medical research under Dutch law (lab study: M16.197311). The participants will to be informed about the study by an information letter (see Appendix I and II) and a verbal explanation before the start of the study. All participants need to sign the informed consent before participating in this study.

2.4 Materials

The following materials are required:

- Cosinussº C-med
- Phone with Cosinussº One app
- CORTES²
- Laptop to readout CORTES²
- Tympanic IR thermometer
- Mercury thermometer
- Thermostatic water bath including heat regulator

2.4.1 Cosinussº

The Cosinussº type C-med (Cosinussº GmbH, München, Germany) is a core thermometer, which can be worn in and around the ear like a hearing aid (dimensions: 45x38x18 mm, 6.5 grams), as shown in Figure 1. Temperature is measured with a contact sensor integrated into a sensor head, which is placed in the ear canal. Data is transported via Bluetooth Smart 4.0 and made visible with the Cosinussº One app. The accuracy of the Cosinussº C-med is ±0.1ºC, with a measurement range of 0 to 50ºC and a working temperature from -15 to 55ºC [51].

Figure 1: The wearable ear thermometer Cosinussº C-med.

2.4.2 CORTES2

The CORTES[2] ear thermometer, with dimensions similar to a hearing aid (dimensions: 65x40x20 mm, 35 grams), contains an infrared (IR) temperature sensor (MLX90641ESF-BAA, Melexis, Ieper, Belgium) in an ear tip, which is placed in the ear canal (see Figure 2). The IR temperature sensor (dimensions: 9x9x17.2 mm) has an accuracy of ±0.2ºC at a range of 0 to 50ºC and a working range of -40 to 125ºC [52]. Data from the ear sensor is sent via Bluetooth Smart 4.0 to a receiver in the chest box.

Figure 2: The wearable ear thermometer CORTES[2] thermometer.

2.4.3 Tympanic infrared thermometer

The Braun (Braun GmbH, Kornberg, Germany) ThermoScan® 7 type IRT 6520 tympanic infrared thermometer will be used as the reference thermometer [23,36]. This thermometer has an accuracy of ±0.2ºC within a body temperature range of 35–42ºC (RH 10–95%) [55]. This thermometer is referred to by validated in research of Purssell et al. (2009) as a reliable reference [31,56] for research about the core temperature of workers in hot environments [14-15,39] with a temperature change up to ±0.6ºC [45-46] in medical settings [42,44,57] and during exercise in heat [23,47,58]. All measurements with this tympanic IR thermometer will be performed in offices with a constant room temperature of 20.0±2.0ºC and 45.0±5.0% humidity.

2.5 Steps

Preparation

1. Prepare the thermostatic water bath and put on the thermoregulator.
2. Warm up the thermostatic water bath to 35.0ºC.
3. Start the CORTES² and connect to laptop.
4. Start the Cosinussº and connect to the Cosinuss One app.
5. Put the mercury thermometer, CORTES², Cosinussº and tympanic IR thermometer with the tip in the water. NOTE: Check if they are fixated well, they are not completely waterproof.
6. Let the thermometers warm up until the measured temperature is not raising and is constant.

Validation

7. Check the temperature of the thermostatic water bath and mercury thermometer. If the T=35.0ºC, measure the temperature with the mercury, CORTES², Cosinuss⁰ and tympanic IR thermometer.
8. Write the output values down.
9. Repeat step 7 and 8 two times with a measurement frequency of once per minute to gain three measurements per device at 35.0ºC.
10. Increase the temperature of the thermostatic water bath to 35.5ºC.
11. When the bath and thermometers are warmed up, measure three times the temperature with the mercury, CORTES², Cosinuss⁰ and tympanic IR thermometer with a measurement frequency of once per minute.
12. Write the output values down.
13. Increase the temperature of the thermostatic water bath to 36.0ºC.
14. When the bath and thermometers are warmed up, measure three times the temperature with the mercury, CORTES², Cosinuss⁰ and tympanic IR thermometer with a measurement frequency of once per minute.
15. Write the output values down.
16. Increase the temperature of the thermostatic water bath to 36.5ºC.
17. When the bath and thermometers are warmed up, measure three times the temperature with the mercury, CORTES², Cosinuss⁰ and tympanic IR thermometer with a measurement frequency of once per minute.
18. Write the output values down.
19. Increase the temperature of the thermostatic water bath to 37.0ºC.
20. When the bath and thermometers are warmed up, measure three times the temperature with the mercury, CORTES², Cosinuss⁰ and tympanic IR thermometer with a measurement frequency of once per minute.
21. Write the output values down.
22. Increase the temperature of the thermostatic water bath to 37.5ºC.
23. When the bath and thermometers are warmed up, measure three times the temperature with the mercury, CORTES², Cosinuss⁰ and tympanic IR thermometer with a measurement frequency of once per minute.
24. Write the output values down.
25. Increase the temperature of the thermostatic water bath to 38.0ºC.
26. When the bath and thermometers are warmed up, measure three times the temperature with the mercury, CORTES², Cosinuss⁰ and tympanic IR thermometer with a measurement frequency of once per minute.

27. Write the output values down.
28. Increase the temperature of the thermostatic water bath to 38.5ºC.
29. When the bath and thermometers are warmed up, measure three times the temperature with the mercury, CORTES^2, Cosinuss^0 and tympanic IR thermometer with a measurement frequency of once per minute.
30. Write the output values down.
31. Increase the temperature of the thermostatic water bath to 39.0ºC.
32. When the bath and thermometers are warmed up, measure three times the temperature with the mercury, CORTES^2, Cosinuss^0 and tympanic IR thermometer with a measurement frequency of once per minute.
33. Write the output values down.
34. Increase the temperature of the thermostatic water bath to 39.5ºC.
35. When the bath and thermometers are warmed up, measure three times the temperature with the mercury, CORTES^2, Cosinuss^0 and tympanic IR thermometer with a measurement frequency of once per minute.
36. Write the output values down.
37. Increase the temperature of the thermostatic water bath to 40.0ºC.
38. When the bath and thermometers are warmed up, measure three times the temperature with the mercury, CORTES^2, Cosinuss^0 and tympanic IR thermometer with a measurement frequency of once per minute.
39. Write the output values down.
40. Increase the temperature of the thermostatic water bath to 40.5ºC.
41. When the bath and thermometers are warmed up, measure three times the temperature with the mercury, CORTES^2, Cosinuss^0 and tympanic IR thermometer with a measurement frequency of once per minute.
42. Write the output values down.
43. Increase the temperature of the thermostatic water bath to 41.0ºC.
44. When the bath and thermometers are warmed up, measure three times the temperature with the mercury, CORTES^2, Cosinuss^0 and tympanic IR thermometer with a measurement frequency of once per minute.

Finishing

45. Store all the data.
46. Remove the mercury, CORTES^2, Cosinuss^0 and tympanic IR thermometer.
47. Turn off the thermostatic water bath.
48. Disconnect and turn off the CORTES^2 and Cosinuss^0.
49. Clean the thermostatic water bath.
50. Clean the mercury thermometer with 70% cleaning alcohol.
51. Clean the CORTES^2 with 70% cleaning alcohol.
52. Clean the Cosinussº with 70% cleaning alcohol.
53. Clean the tympanic IR thermometer with 70% cleaning alcohol.
54. Clean and tidy up the lab.

2.6 Data analysis

For statistical analysis, IBM SPSS Statistics 25 needs to be used. For the validation of the thermometers (aim 1), the mean of the 3 measurements per step will be used in the lab study. Statistically significant differences will be studied with a paired t-test and an intraclass correlation coefficient (ICC, two-way random model, absolute agreement) will be calculated for normally distributed data. The ICC will be considered low when <0.39, moderate when 0.40-0.59, high when 0.60-0.79 and excellent when ≥0.80 [60]. Non-parametric data will also be tested with the Wilcoxon signed rank test. P-values <0.05 are considered statistically significant. The Limits of Agreement (LoA) reflects the average differences between two different measurements and will be calculated as ±1.96*SDdifference [61]. The acceptable level of Limits of Agreement (LoA) will be 0.50. Bland-Altman plots will be made of the individual difference between sessions against the individual mean of the two sessions, to analyze whether the magnitude of the difference will be related to the mean performance. A funnel shape indicates that the magnitude of the difference is related to the mean performance. Parameters will be given for the t-tests together with their standard error of the mean.

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