Test protocol for the in vivo validation and usability of wearable non-invasive thermometers

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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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 were 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 CORTES^2, 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 CORTES^2 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 CORTES^2 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 II In-vivo validation and usability (lab study) to answer aims (2) to test validity and (3) explore the usability of the CORTES^2 and Cosinussº C-med thermometers for monitoring individual tympanic temperatures in a lab study.

2 Materials and methods

2.1 Study design

To test the in vivo validity, the T_c of the participants will be measured at rest with the Cosinussº C-med and CORTES[2], and compared to the tympanic IR clinical standard. The T_c will be measured 10 times per participant with a frequency of one measurement per minute, resulting in a 10-minute measurement. All validation measurements will be performed in offices with a constant room temperature of 20.0±2.0ºC and 45.0±5.0% humidity. Participants received time (about 5 minutes, if necessary, the participant received more time with a maximum of 15 minutes) to stabilize to this environment.

Usability will be explored using the user interface design method AEIOU (*Activities Environments Interactions Objectives Users*) through researchers' observations and feedback from the participants. In this descriptive observational study, usability aspects were easy-to-use, positioning and adjustability, wear ability by all kind of users, stability and fixation, and comfort. Participants were asked to wear the Cosinussº C-med and CORTES[2] (with ambient condition box) (*Objects*) whilst putting on and removing personal protective clothing (PPC) (chemical-proof hazmat suit Trellchem®, Super Type T of Ansell Protective Solutions AB, Trelleborg, Sweden, with separated gas mask [59], Figure 1), and in rest (3 minutes), sitting (3 minutes), walking (2 minutes) and jumping (2 minutes) in PPC (*Activities*) for in total 10 minutes. These two tests were performed directly after each other in controlled lab environment under constant ambient conditions (T_a=20.0±2.0ºC and RH=45.0±0.5%) (*Environment*). Each participant (*User*) performed the test twice, once with the Cosinussº and once with the CORTES[2] (*Objects*), alternating between participants. Participants had time to cool down by passive sitting and drinking water for five minutes between the first and second parts of the test. The T_c of the first measurement will be used as an indicator, and, if necessary, the participant received more time to lower the T_c, with a maximum of 10 minutes.

Figure 1: Personal protective clothing used in the lab study. The chemical-proof hazmat suit (Trellchem®, Super Type T of Ansell Protective Solutions AB, Trelleborg, Sweden) with separated gas mask the participant worn in the lab study.

2.2 Participants

The inclusion criterion are that participants were between 18 and 67 years old (representing the European working population). The exclusion criteria included lung, cardio and/or vascular diseases, claustrophobia and problems with losing body heat (as by heat intolerances or difficulties with body thermoregulation due to problems with sweating).

For the in-vivo validation and usability in the lab study, the participants should contain at least 11 volunteers. The minimum sample size will be calculated with a power analysis (non-inferiority trail with a power of 95%, significance level of 0.05, acceptable difference of ±0.2ºC) for the lab study based on the expected outcomes (n≥11 participants).

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 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
- CORTES[2]
- Ambient condition box
- Tympanic IR thermometer
- Personal protective clothing; chemical-proof hazmat suit (Trellchem®, Super Type T of Ansell Protective Solutions AB, Trelleborg, Sweden)
- Personal protective clothing; gas mask
- Laptop for notation of data
- Phone with Cosinuss One app
- Timer
- 70% cleaning alcohol

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 2. 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 2: 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 3). 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.

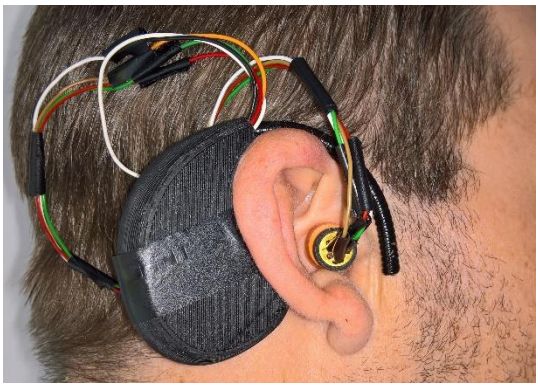

Figure 3: The wearable ear thermometer CORTES[2] thermometer.

2.4.3 Ambient conditions box

The ambient conditions box, worn with elastic chest belts (see Figure 4), contains a temperature and humidity sensor (SHT15 Breakout, Sensirion, Staefa ZH, Switzerland). The box needs to be worn over the first layer of clothing, but under the PPC and PPE to measure the micro-climate nearby the skin of the participant inside the clothing (descripted as temperature inside clothing (T_{cli})) and RH and its effect of working activities on these conditions and its relation to the body thermoregulation. The accuracy of the T_{cli} sensor is ±0.3ºC at 25ºC with a range of -40 to120ºC [53]. The absolute relative humidity accuracy is ±2% at 10 to 90% with a humidity range of 0 to 100% and a response time of 5 to 20 seconds

[53]. The box will be validated in a climatic test cabinet (Clima Temperatur Systeme type C-40/350, Henchingen, Germany, with Pt 100 thermometers with an accuracy of T±0.3ºC and RH±1.5% [54]), resulting in a high to excellent correlation compared to the climatic test cabinet and Pt100 thermometer.

Figure 4: Ambient conditions box with temperature and humidity sensors and data receiver and storage.

2.4.4 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 were performed in offices with a constant room temperature of 20.0±2.0ºC and 45.0±5.0% humidity.

2.5 Steps

Preparation

1. Put all the materials in position.
2. Check if the ambient conditions in lab are meeting the requirements (T_a=20.0±2.0ºC and RH=45.0±0.5%). If not, fix this problem.
3. Start CORTES² and ambient conditions box by putting it on and connect them with each other. CORTES² needs to warm up for about 5 to 15 min.
4. Start Cosinussº by putting it on and connect to the Cosinussº One app on the phone. The Cosinuss needs to warm up for about 5 till 10 min.
5. Put new ear tip on tympanic IR thermometer.
6. Start laptop and open template for participants data.
7. Final check if everything is prepared for participant.

Introduce participant

8. Welcome participant.
9. Check if participant has received and read the information letter.
10. Inform participant about experiment by a verbal explanation.
11. Explain participant rights including its ability to stop at any moment and that the data will be progressed anonymous.
12. Check inclusion and exclusion criteria.
13. Ask if the participant understand everything and if there are any questions.
14. Ask participant to sign the informed consent. If the participant is not willing to sign the informed consent, the experiment will end here.

In-vivo validation

15. Check order of wearable thermometers. NOTE: Each participant will perform this test twice, once with the Cosinussº and once with the CORTES[2] alternating between participant.
16. Put the wearable thermometer in one ear of the participant and let it warm up for about 5 till 10 minutes until the output is constant.
17. Put tympanic IR thermometer in the other ear of the participant.
18. Measure every minute the temperature with the wearable thermometer and tympanic IR thermometer.
19. Write down measurement output of wearable thermometer and tympanic IR thermometer.
20. Repeat the two last steps 10 times in a time span of 10 minutes.
21. Remove wearable thermometer and tympanic IR thermometer.
22. Write down any comments of participant and observations about the CORTES[2].
23. Ask if participants would like to take a break. If so, take a break for 5 up to maximum 15 minutes).
24. Store all the data.

In-vivo validation and usability

25. Ask participant to put on the ambient conditions box and help the participant where needed.
26. Ask participant to put on the PPC (chemical-proof hazmat suit and gas mask) and help the participant where needed.
27. Put the wearable thermometer in the participants ear.
28. Start wearable thermometer measurement.
29. Ask the subject to sit on a chair for 3 minutes.
30. Write down measurement output of the wearable thermometer and ambient condition box every minute.
31. Ask the subjects to walk through the lab for 2 minutes.
32. Write down measurement output of the wearable thermometer and ambient condition box every minute.
33. Ask the subjects to jump (jumping jacks) for 2 minutes.
34. Write down measurement output of the wearable thermometer and ambient condition box every minute.
35. Remove PPC, wearable thermometer and ambient condition box.
36. Provided the participant water and let the participant cool down by passive sitting and drinking water for 5 up to 15 minutes.
37. Write down any comments of participant and observations about the wearable thermometer.
38. Store all the data.

39. Repeat steps 15 up to and including 38 with the other wearable thermometer.

Finishing

40. Ask the participant for any (additional) input about the CORTES[2], Cosinussº and ambient condition box. Be aware of the usability aspects: easy-to-use, positioning and adjustability, wear ability by all kind of users, stability and fixation, and comfort.
41. Write down any comments of participant about the wearable thermometers.
42. Thank the participant for its participation.

Cleaning

43. Store all the data.
44. Cleaning the CORTES[2] with 70% alcohol.
45. Cleaning the Cosinussº with 70% alcohol.
46. Remove ear tip and clean tympanic IR thermometer with 70% alcohol.
47. Cleaning the ambient condition box with 70% alcohol.
48. Cleaning the gas mask with 70% alcohol.
49. Cleaning the chemical-proof hazmat suit with 70% alcohol.
50. Clean and tidy up the rest of the materials and lab.

2.6 Data analysis

Calibration of the Cosinussº and CORTES[2] will be done using the standard clinical tympanic IR thermometer. During the in vivo validation measurements in rest, the T_c will be measured with the tympanic IR thermometer in combination with the Cosinussº or CORTES[2] thermometer in the other ear. The difference between the Cosinussº or CORTES[2] and the tympanic IR temperature will be considered as the calibration factor. In all cases, every second measurement will be selected to calculate the calibration factor (randomly chosen from the first five measurements out of 10 in the lab study).

For statistical analysis, IBM SPSS Statistics 25 needs to be used. For statistical analysis of the in vivo validation of the Cosinussº and CORTES[2] (aim 2), every ninth (out of 10) measurement will be used in the lab study (randomly chosen). 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 were also tested with the Wilcoxon signed rank test. P-values <0.05 were 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 were 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 were given for the t-tests together with their standard error of the mean. Sensitivity analysis will be performed to test differences between the ninth and tenth (lab study). The usability of the lab study will be analyzed using descriptive statistics.

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Appendix I Subject information (lab study)

Information letter

For participation in scientific research:
Validation study about the reliability and wear ability of CORTES² (CORe Temperature and Environment Sensor System) for employees working in air-tight suits

Dear Sir/Madam,

The sustainable employability of employees is important, especially for employees who have to work in air-tight suits. The temperature inside the suit increases due to physical tasks that the employees perform, also resulting in an increasing body temperature. Therefore, employees can only work in these suits for a shorter period. In the UMCG project SPRINT@Work the effect of increasing temperature on the working capacity is studied (http://www.imdi-sprint.nl/current-projects/sprint-work/?lang=en). A new sensor system is developed for the measurement of the core temperature and the environmental conditions. This system, named CORTES² (CORe Temperature and Environment Sensor System), assists in gaining insight in how long an employee can work in the suit without risks and thereby the safety of the employee will be improved. The system CORTES² still has to be validated. For this we need your help. In this information letter you can find more information over the different tests for the validation.

CORTES²

The CORTES² consist of two parts. One part measures the core temperature of employees and the other part measures the environmental conditions, namely the temperature and the humidity in the suit. The core temperature measurer should be worn around the ear and the measurer for the environmental conditions will be attached with an elastic band around the trunk.

Tests

For this experiment you will be asked to wear an air-tight suit, a gas mask, and the CORTES². When you are wearing all the different parts, you will be asked to sit for a number of minutes, to walk and to sit. This will increase the core temperature. With commercial thermometers your core temperature will be measured and compared to the results of the CORTES². The test will take in total between 30 and 45 minutes.

Requirements

For this research we are looking for persons between 20 and 65 years old. You may not participate when you have cardiovascular diseases, having problems with controlling your body temperature or when you are claustrophobic, as wearing an air-tight suit and a gas mask can feel oppressed.

Risks

There is a small risk that you may experience some problems from the high temperatures in the suit due to the different movements.

Participation

When you are willing to participate in this study, then you can contact one of the researchers. At the bottom of the letter you will find the contact details. Prior of the tests you will be asked to sign an informed consent. This form is included with this information letter and will be available in the research room to be signed by you.

During the research you will wear an air-tight suit. Therefore, it is important that you wear comfortable and fitting clothes wherein the suit can easily be worn over it. Besides that, you will be advised to bring some clean clothes and optional a towel for after the tests since it will become sweaty in this air-tight suit.

Of course, we will carefully handle your information and this will be processed anonymous. When the research is finished, you can request for your own data. For further questions you can always contact one of the researchers.

Contact

If you have any question based on this information letter or if you want to know more about the research, please contact one of the researchers, which can be found at the bottom of this letter.

Kind regards,

Jiapeng Hu, Miguel Alejandro Reina Mahecha and Charissa Roossien

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