Appendix I

Evaluation of a wearable non-invasive thermometer for monitoring inner-ear temperature during physically demanding work
Abstract

To protect workers from overheating, body temperature should be measured during work. A wearable inner-ear non-invasive thermometer has been developed (CORTES²) and was compared to a wearable commercial thermometer (Cosinuss° C-med), a mercury thermometer and a tympanic infrared thermometer. The accuracy and usability of the Cosinuss° and tympanic thermometer are described in chapter 6 and 7. This appendix aims to evaluate the accuracy and explore the usability of the CORTES² wearable thermometer in a lab (15 volunteers) monitoring ear canal temperature. The lab study resulted in high correlations between the CORTES² compared to a mercury thermometer (ICC=0.99, p<0.001) and compared to the tympanic thermometer (ICC=0.79, p<0.001). This is comparable to the accuracy of the Cosinuss° (ICC≥0.72, p≤0.001). During physical activity, the CORTES² showed twice abnormal high values exceeding 39.5°C without the subject felt overheated. The usability of the Cosinuss° thermometer was better compared to the CORTES², interfered minimally (or not at all) during physical activity and thus is a better choice to monitor the development of individual ear canal temperature during work. The Cosinuss° and CORTES² both showed a high correlation, but due to the unrealistic high values and the lower usability of the CORTES², this system seems not yet ready to be validated in real-life working condition. Based on these results, only the Cosinuss° was tested in the field study described in chapter 7.
I.1 | Introduction

Body temperature is a good predictor of overheating (Jacklitsch, et al., 2016). Measuring the development of body temperature and giving feedback when overheating is likely to occur will protect workers with a high physical load or when working in a hot and humid environment (Mazgoaker, et al., 2017; Pancardo, et al., 2015; Uth, et al., 2016; Haines, et al., 2017). A new non-invasive sensor system, the CORTES² (Core Temperature and Environmental Sensor System) has been developed. This wearable thermometer measures ear canal temperature ($T_{EC}$) using an infrared (IR) sensor (Chaglla, et al., 2018; Aryal, et al., 2017) positioned in the ear canal. Moreover, it also measures nearby ambient conditions ($T_a$ and RH) using a wearable chest box. At the same time, the Cosinuss° C-med (Cosinuss° GmbH, München, Germany), has become commercially available. The wearable and non-invasive nature of the CORTES² and Cosinuss° thermometer, and their ability to measure body temperature continuously, 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 non-obstructive for the worker and do not hinder the workability.

The objective of this study was to evaluate the accuracy and explore the usability of the CORTES² and Cosinuss C-med thermometers in controlled lab conditions. The aims were (1) to test the accuracy of the CORTES², Cosinuss° and tympanic IR thermometer compared to a mercury thermometer in controlled lab conditions; (2) to test the in-vivo accuracy of ear canal temperature measured with the CORTES² and Cosinuss° compared to tympanic IR thermometer and (3) explore the usability of the CORTES² compared to the Cosinuss° for monitoring individual ear canal temperatures during a variety of physical activities in a lab study.

I.2 | Materials and methods

I.2.1 | Materials

I.2.1.1 | CORTES²

The CORTES² ear thermometer has the dimensions similar to a hearing aid (dimensions: 65x40x20 mm, 35 grams). It contains an infrared (IR) temperature sensor (MLX90641ESF-BAA, Melexis, Ieper, Belgium) in an ear tip, which is placed in the ear canal (see Figure I.1). The IR temperature sensor (dimensions: 9x9x17.2 mm) has an accuracy of ±0.2°C at a range of 0 to 50°C and a working range of -40 to 125°C (Melexis N.V., 2015). Data from the ear
sensor are sent via Bluetooth Smart 4.0 to a receiver in the chest box described in chapter 7.

Figure I.1 | The wearable ear thermometer CORTES2.

I.2.2 | Study design
The same study design, procedures and data analysis as described in the lab study of chapter 7 are used.

I.3 | Results
Subject characteristics and descriptive test results for the Cosinuss° and the tympanic IR thermometer are the same as in chapter X. The results for the CORTES2 are presented in this chapter.

I.3.1 | Accuracy
The mean temperature difference in the thermostatic water bath between the mercury thermometer compared to the CORTES2 was 0.2±0.1°C (p<0.001), compared to the Cosinuss° was -0.44±0.19°C (p<0.001) and compared to tympanic IR was -0.2±0.1°C. The mean differences and the results of the ICC analysis for the CORTES2, Cosinuss° and tympanic IR thermometers are shown in Table I.1.
Table I.1 | CORTES2, Cosinuss\textsuperscript{*} and tympanic IR versus mercury thermometer: The CORTES2, Cosinuss\textsuperscript{*} and tympanic IR were compared with the reference mercury thermometer using the paired t-test and the intraclass correlation coefficient (ICC) with a confidence interval of 95\%, p-value and Limits of Agreement (LoA).

<table>
<thead>
<tr>
<th></th>
<th>MD±SD [95% CI]</th>
<th>P</th>
<th>ICC [95% CI]</th>
<th>p</th>
<th>LoA</th>
</tr>
</thead>
<tbody>
<tr>
<td>CORTES2</td>
<td>0.22±0.11 [0.03;0.15]</td>
<td>&lt;0.001</td>
<td>0.99 [0.57;1.00]</td>
<td>&lt;0.001</td>
<td>±0.22</td>
</tr>
<tr>
<td>Cosinuss\textsuperscript{*}</td>
<td>-0.44±0.19 [-0.56;-0.32]</td>
<td>&lt;0.001</td>
<td>0.97 [0.13;1.00]</td>
<td>&lt;0.001</td>
<td>±0.37</td>
</tr>
<tr>
<td>Tympanic IR</td>
<td>-0.21±0.13 [-0.29;-0.14]</td>
<td>&lt;0.001</td>
<td>0.99 [0.87;1.007]</td>
<td>&lt;0.001</td>
<td>±0.24</td>
</tr>
</tbody>
</table>

Table I.1 shows very high correlations for all three thermometers (ICC≥0.97). The LoA is within the acceptable level of 0.50. In Figure I.2, the Bland-Altman plots of the CORTES\textsuperscript{2}, Cosinuss\textsuperscript{*} and tympanic IR are shown. Sensitivity analysis revealed non-significant differences.

Figure I.2 | Bland-Altman plots of the mean temperature versus the mean temperature difference; CORTES\textsuperscript{2} (left-side), Cosinuss\textsuperscript{*} C-med (middle) and tympanic infra-red (IR) (right-side) thermometer with mean (black), upper and lower Limit of Agreement (LoA) (black dotted line) and zero-line (blue).
I.3.2 | In-vivo validity

The mean of the CORTES² was 36.7±1.2°C (mean±SD) with a within-participants variation of 0.09±0.08°C. The mean calibration factor of the CORTES² was 0.0±1.1°C (min=−1.7°C, max=1.5°C). In Table I.2, the mean differences and the results of the ICC analysis for the non-corrected and corrected CORTES² and Cosinuss* are shown.

The mean differences of the CORTES² are within the acceptable limit (MD=−0.1, p≤0.764). Before calibration, a low correlation (ICC≤0.20) was observed. After calibration, high correlations (ICC≥0.72) were observed with an acceptable LoA (LoA=±0.39) between the CORTES² and tympanic IR. Sensitivity analysis revealed similar ICC and p-values. The Bland-Altman plots are shown in Figure I.3.

Figure I.3 | Bland-Altman plots of the mean ear canal temperature ($T_{EC}$) versus the mean temperature differences; The non-corrected CORTES (top left) and Cosinuss* (top right) and corrected CORTES² (bottom left side) and Cosinuss* (bottom right side) compared to the tympanic IR with mean and upper and lower Limit of Agreement (LoA).
Without calibration, the Bland-Altman plots showed a proportional error between the mean differences. However, the Bland-Altman plots show no funnel shapes. To check for possible systematic errors, the mean difference was analysed with the Pearson test. The non-calibrated Cosinuss° showed a systematic error. In the tympanic IR, calibrated Cosinuss° and CORTES² this error was not detected.

In Table I.3 is shown the mean and maximum $T_{EC}$ measured with the CORTES² and Cosinuss°, during sitting, walking and jumping in personal protective clothing (PPC) (chemical-proof hazmat suit Trellchem®, Super Type T of Ansell Protective Solutions AB, Trelleborg, Sweden, with a separate gas mask). During the activities, the $T_{EC}$ measured with the CORTES² of two participants exceeded 39.5°C, with abnormal values with a max $T_c=40.7±1.5°C$.

### I.3.3 | Usability

The Cosinuss° was more flexible then the CORTES². Resulting in the Cosinuss° being easier to position in and around the ear. Both thermometers were wearable by all participants. Most participants experienced a better fit with the Cosinuss° compared to the CORTES²; the position of Cosinuss° felt stable and well-shaped in and around the ear. Most participants reported the Cosinuss° to be more comfortable and looking more professional. When applying and removing the PPC, in all cases (n=15), the Cosinuss° and CORTES² fell out of the participant’s ear. Positioning the CORTES² whilst putting on the PPC was complicated because the suit is very tight; the CORTES² was larger than the Cosinuss° and attached more problematic around the ear. Overall, both systems stayed in place during sitting, walking and jumping in PPC. There was one instance when the CORTES² felt as if it came out of the participant’s ear during jumping and one time when it became looser in and around the ear. Furthermore, the Cosinuss° adapted more quickly from room temperature to $T_c$ (ranging from 4 to 6 min) than the CORTES² (up to 12 min).

### I.4 | Conclusions

In the lab study, the CORTES² and Cosinuss° both showed high correlations compared to the mercury and tympanic IR thermometer with acceptable differences. During activities, the CORTES² showed twice unrealistic values. Usability of the CORTES² is lower in comparison with the Cosinuss°. The CORTES² seems not yet ready to be validated in real-life working condition, therefor, only the Cosinuss° was tested in the field study.
Acknowledgments

We would like to thank Jan Stegenga for his support and supervision and technical knowledge in this project and the development. And Negotica (Groningen, The Netherlands) and Umaco (Groningen, The Netherlands) for their support during the development of the CORTES$^{2/3}$. 
1.5 | Appendices

**Table I.2** | CORTES² and Cosinuss° versus tympanic IR: The CORTES² and Cosinuss° were compared with the references using the intraclass correlation coefficient (ICC) with a confidence interval of 95%, p-value and Limits of Agreement (LoA).

<table>
<thead>
<tr>
<th></th>
<th>MD±SD [95% CI]</th>
<th>p</th>
<th>ICC [95% CI]</th>
<th>p</th>
<th>LoA</th>
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<tbody>
<tr>
<td>CORTES² (raw)</td>
<td>-0.09±1.10 [ -0.69;0.52]</td>
<td>0.764</td>
<td>0.20 [ -0.37;0.64]</td>
<td>0.243</td>
<td>±2.13</td>
</tr>
<tr>
<td>CORTES² (corrected)</td>
<td>-0.11±0.2 [ -0.22;0.00]</td>
<td>0.042</td>
<td>0.79 [0.44;0.93]</td>
<td>&lt;0.001</td>
<td>±0.38</td>
</tr>
<tr>
<td>Cosinuss° (raw)</td>
<td>1.44±0.54 [1.14;1.74]</td>
<td>&lt;0.001</td>
<td>0.07 [-0.05;0.31]</td>
<td>0.083</td>
<td>±1.05</td>
</tr>
<tr>
<td>Cosinuss° (corrected)</td>
<td>0.03±0.37 [-0.17;0.24]</td>
<td>0.729</td>
<td>0.72 [0.33;0.90]</td>
<td>0.001</td>
<td>±0.72</td>
</tr>
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</table>

**Table I.3** | Ear canal temperature (T_EC), temperature and relative humidity of or nearby the participant: Mean and max ear canal temperature (T_EC) (°C) measured with the CORTES² and corrected Cosinuss° of all participants (n=15) and the mean and max temperature (Tcli) and relative humidity (RH) nearby the skin of the participants.

<table>
<thead>
<tr>
<th></th>
<th>Mean</th>
<th>Max</th>
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<tbody>
<tr>
<td></td>
<td>Sitting</td>
<td>Walking</td>
</tr>
<tr>
<td>T_EC (°C) CORTES²</td>
<td>37.90±1.41</td>
<td>38.24±1.48</td>
</tr>
<tr>
<td>T_EC (°C) Cosinuss°</td>
<td>37.46±0.77</td>
<td>37.53±0.76</td>
</tr>
<tr>
<td>Tcli (°C)</td>
<td>27.43±0.59</td>
<td>27.93±0.51</td>
</tr>
<tr>
<td>RH (%)</td>
<td>42.98±7.42</td>
<td>44.85±7.32</td>
</tr>
</tbody>
</table>
References


Jacklitsch, B. et al., 2016. *NIOSH criteria for a recommended standard: occupational exposure to heat and hot*, Cincinnati, OH, USA: NIOSH.


II.1 | Project description
SPRINT@Work is a project that focused on sustainable employability and specifically on investigating how to keep the aging population healthy and employable until and even beyond their expected retirement. To realize sustainable employability, workers were made aware of their condition by (1) objectively monitoring their cognitive and physical workload and capacity and (2) providing interventions to alter their behaviour to improve their work capacity or lower the workload. Moreover, sensor technologies were developed to enable monitoring, and interventions were created. All of these innovative technologies were validated in controlled laboratory studies, as well as in real-life working situations. Multiple aspects related to workload were investigated, such as cognitive and physical demands, individual responses to these exposures and feedback responses. The project was split into four PhD trajectories:

1. User requirements and needs assessment (Department of Health Sciences, Community and Occupational Medicine, University Medical Center Groningen)
2. Physical workload (Rehabilitation Medicine, University Medical Center Groningen)
3. Cognitive workload (Experimental Psychology, Behavioural and Social Sciences, University of Groningen)
4. Feedback effects and optimization (Operations, Faculty of Economics and Business, University of Groningen)

SPRINT@Work comprised a broad consortium that included five knowledge institutes, 13 companies involved in the development of sensor technologies and seven pilot companies with workers and employers wishing to maintain a healthy working situation and willing to test the developed sensor and intervention technologies.

II.2 | Outcomes
According to the need assessment for workplace health promotion, several workers pointed out that priority should be given to monitoring fatigue, occupational heat stress and exposure to physically demanding jobs using sensor technologies (Spook et al., 2019). Mental fatigue negatively influences productivity during regular working activities. One way to detect productivity deteriorations in the office environment is by monitoring computer usage, for instance, by monitoring typing behaviour. Therefore, a study was performed to investigate whether typing indices can monitor deteriorations in attentional and memory processes by monitoring changes in neural activation (de Jong et al., 2018). This study was performed in a lab setting. The results showed that both younger and older participants
became slower over time, which was reflected in the interkey interval. Moreover, younger adults became less accurate with prolonged task performance. However, they partly corrected for their mistakes using the backspace key. Such changes in the typing indices were correlated with changes in neural activation; that is, those who showed larger deteriorations in attentional and memory processes also showed larger deteriorations in typing performance. The next question was whether the markers that were found to be susceptible to the effects of mental fatigue in a lab setting can also describe the behavioural dynamics in the work environment. To answer this question, typing performance data from a real-life office environment were analysed (de Jong et al., 2020). The results showed that the workers’ typing speed decreased over time, which was reflected in a larger interkey interval. In addition, the workers used the backspace key more often. Interestingly, these effects of prolonged task performance interacted with the effects of time of day. That is, in the morning, workers were able to perform at a constant speed, with an increase in backspace keystrokes, whereas in the afternoon, both the typing speed, measured by the interkey interval, and accuracy, measured by the percentage of backspace keystrokes, decreased. These results suggest that even though these workers take precautions to counteract the effects of mental fatigue during the day (e.g. drinking coffee or taking breaks), the effects of prolonged task performance accumulate over the day. A different study investigated how consuming caffeinated beverages may help counteract the effects of mental fatigue (van den Berg et al., 2020). The results showed that, besides its general arousing effects, caffeine can enhance attention towards relevant information, which is specifically helpful in the work environment, where it is important to pay attention to specific tasks.

To monitor the energetic workload of physically active workers as a parameter of physical fatigue, a portable breathing gas analyser was developed and validated (patent pending; Roossien et al., 2021). The proof of concept of this analyser was found to be more valid than heart rate monitoring and more practical than indirect calorimetry with a mouth mask. Its users reported that the headset is more comfortable and more usable than mouth-mask systems. This proof-of-concept version is not yet as good as mouth masks; however, it has potential and provides opportunities for further professionalization. This headset will be further developed and validated in a follow-up study together with a company specialized in breathing analysis, with the aim of making this system available not only for a large target group of workers, but also for rehabilitation and sports applications. To monitor occupational heat stress, a wearable core thermometer was developed and validated against a commercially available wearable thermometer. Despite the good usability of these thermometers, they are not yet suitable for measuring the core temperature while
performing physically demanding jobs (Roossien et al., 2020). In a follow-up project, a new technology will be developed to fulfil the need for such a device. A suit equipped with sensors was used to investigate the exposure of physically demanding jobs. This suit monitored work postures and related back muscle activity and automatically calculated the net moment of the lower back with a specially developed artificial neural network-based method. This technology was validated on different types of workers, and its function was also demonstrated. However, both the sensor system and software require further development before validating the function of the system in an operational work environment. A smart chair equipped with sensors was used to measure the physical load of office workers. Although the feedback signal did not improve the sedentary behaviour, this smart chair was a useful non-obstructive tool for monitoring the sitting behaviour of office workers (Roossien et al., 2020). Indeed, these systems and technologies will be further developed and validated in follow-up studies and will be made available for workplace health promotion.

To allow workers to benefit from such sensor and intervention technologies in the workplace, the effectiveness, and effects of such technologies on employee autonomy were studied in two experimental field studies. The first study investigated the effects of real-time actionable feedback on workers’ sitting and typing behaviour, in which the typing behaviour is considered a measure of fatigue. If a worker receives feedback messages on fatigue, they alter their typing behaviour almost immediately. However, if they receive feedback on their sitting behaviour, they alter their sitting behaviour only in the long term. This difference is explained by the fact that workers are considerably able to estimate their sitting bouts but hardly able to assess their level of fatigue. These findings show that workers are willing to alter their behaviour if they receive new information, as in the case of the typing behaviour. However, if they can self-monitor their behaviour, as in the case of the sitting behaviour, they show a learning effect over a longer period of time (Bonvanie, 2020).

The second study examined the effects of workers’ use of health self-management applications in the work environment on their perceived autonomy in self-regulating their health-related behaviour. The results showed that workers experience a decline in their perceived autonomy either at home or at work or even both, depending on the type of feedback that they receive, and that this effect is strongest for employees with a high body mass index (BMI). Employees with a high BMI experience more negative emotions when they receive feedback pertaining to not reaching the given norm for physical exercise, and they become more aware of their work environment limitations that prevent them from altering their daily behaviour.
During SPRINT@Work, a context-sensitive perspective was used to contextualize ethical issues in both the development and implementation of sensor and intervention technologies for the work environment. The results of this context-sensitive analysis of ethics showed that the current legal framework for the privacy of workers limits the employers’ opportunities to take full responsibility for the workers’ health. This can, however, be solved using an agency-based approach, in which specific employees with clear roles (agents) have the power to use the personal data of other workers for specific reasons. Additionally, the autonomy of workers using sensor and intervention technologies is affected when the workers are not by default enabled to uphold their own norms and values but rather perceive the norms inherent to the design of these sensor and intervention technologies as pressing. These insights show that applying a context-sensitive approach of ethics may enhance the position of both workers and employers and provide valuable input for future research regarding technologies aimed at health improvement in the workplace.

II.3 | Contribution to journals
The following journal contributions are the current result of SPRINT@Work.


