

Sensors@Work

Towards monitoring of physical workload
for sustainable employability



Charissa Roossien

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Sensors@Work

Towards monitoring of physical workload for sustainable
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PhD thesis

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Chapter 1

General introduction



1.1 | Sustainable workforce

Worldwide, life-expectancy is rapidly increasing and the population is aging (Gotmark, et al., 2018; Rechel, et al., 2013; Huang, 2018; Ota, et al., 2018; Lyons, et al., 2018). By 2025, it is predicted that more than 20% of European society will be older than 65 years and this figure will double by 2060 (Gotmark, et al., 2018; Koolhaas, et al., 2009; Stoeldraijer, et al., 2017). An effect of an aging population is a lower number of younger citizens and workers (between 18 and 45 years) and an increase in older citizens and workers (≥ 45 years (Koolhaas, et al., 2009; Hupkens, 2006; Kenny, et al., 2008)) resulting in an aging workforce (Rechel, et al., 2013; Huang, 2018; Lyons, et al., 2018; Koolhaas, et al., 2009). Biological aging comes with physical changes (Adams & White, 2004) associated with a decrease of muscle mass and lower energy levels (Koolhaas, et al., 2009; Brouwer, et al., 2013; Shephard, 1997; Ilmarinen, 2001). Next to biological aging, the presence of chronic diseases plays an important role (Koolhaas, et al., 2009; Weerding, et al., 2005). In the Netherlands, 40% of older workers have one or multiple chronic diseases, which cause 54% of them to have problems performing their daily job (Koolhaas, et al., 2009; Weerding, et al., 2005; Jorgensen, et al., 2013). This number will increase rapidly with the increase of the average age of workers. This will affect well-being as well as workability, work performance, quality, and safety (Koolhaas, et al., 2009; Brouwer, et al., 2013; Varianou-Mikellidou, et al., 2019; Arts & Otten, 2013; Kirkland & Dobbin, 2009). Additionally, it will lead to an increase in absenteeism costs for companies, the government and the (working) population, not only in the Netherlands but across Europe and the Western world (Koolhaas, et al., 2009; Kenny, et al., 2008; Brouwer, et al., 2013; Ilmarinen, 2001; Kirkland & Dobbin, 2009). To redeem the costs of aging and to maintain a stable workforce and economy, multiple countries have increased the retirement age (Rechel, et al., 2013; Brouwer, et al., 2013; Arts & Otten, 2013). This alone, however, will not be enough to maintain a sustainable health care system nor a sustainable and healthy workforce.

To create a sustainable workforce, the balance between work capacity and workload plays an important role (Wu & Wang, 2002). The workability of workers is influenced by multiple factors as shown in Figure 1.1, the expanded model of the World Health Organization (WHO) International Classification of Functioning (ICF). These aspects can be roughly divided into external (physical and mental) factors, personal factors, and health (Heerkens, et al., 2004). The external factors of work determine the workload, whereas personal factors and health determine work capacity.

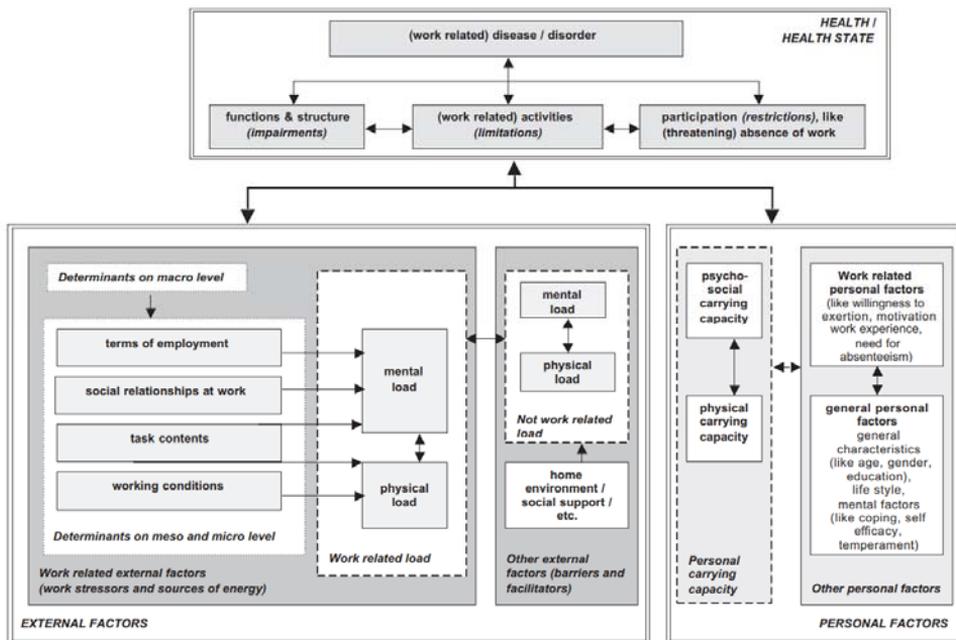


Figure 1.1 | The expanded model of the World Health Organization (WHO) International Classification of Functioning (ICF) by Heerkens (2004); the ICF scheme including mental and physical external factors and personal factors influencing the workability (Heerkens, et al., 2004).

Every worker has an individual workload which depends on the type of work he/she does, the work activity and its intensity (Heerkens, et al., 2004; Karasek & Theorell, 1990; Bakker, 2002; Ng & Feldman, 2013; Costa-Black, et al., 2013). The workload and demand influence the external load, such as work posture, the weight of objects, the duration of the task and the actual working method (Westgaard & Winkel, 1996) (Hoozemans, et al., 1998). These external workloads create an internal load on the body of the worker (Costa-Black, et al., 2013; Hoozemans, et al., 1998; Schultz, et al., 2007). This internal workload causes an acute response within the body with a short and long-term effect on the body, health and work capacity (Schultz, et al., 2007; Westgaard & Winkel, 1996; Hoozemans, et al., 1998; van Dijk, et al., 1990). The individual (work) capacity depends on the health (presence of diseases), age, lifestyle, and physical and cognitive fitness of the worker (Heerkens, et al., 2004; Costa-Black, et al., 2013; Schultz, et al., 2007). In balance, the work capacity exceeds or is the same as the workload. When the work capacity is lower than the workload, there is an imbalance and overload will occur (Kenny, et al., 2008). Due to biological aging and the presence of chronic diseases, work capacity lowers. With an unchanged workload, this can result in an imbalance causing structural overload. Structural overload will result in fatigue, lowered



well-being, health problems and finally absenteeism (Kenny, et al., 2008; Ilmarinen, 2001; Weerding, et al., 2005; Costa-Black, et al., 2013). To gain a healthy aging working population, structural overload needs to be prevented (Korshoy, et al., 2013; Wu & Wang, 2002; Karasek & Theorell, 1990; Bakker, 2002).

1.2 | Physical workload

Mainly physically active workers, such as construction workers and firefighters, experience work-related health problems caused by a lower capacity due to aging or presence of chronic diseases (Koolhaas, et al., 2009; Brouwer, et al., 2013; Shephard, 1997; Ilmarinen, 2001) and a high physical workload for the body (Spook, et al., 2019; Andersen, et al., 2016). Physically underloaded workers, such as office workers, also experience discomfort, however, this is caused by high local physical loads on the body caused by inactivity (Netten, et al., 2011; Thorp, et al., 2012; Healy, et al., 2013). Despite the different characters, both forms of physical workload can cause health problems and require attention (Andersen, et al., 2016; Hallman, et al., 2016; Mathiassen, 2006).

This physical workload can be divided into mechanical and energetic loads (Jorgensen, et al., 2013; Kuijter, et al., 1999; van der Molen, et al., 2008). The mechanical workload is the load on the musculoskeletal system (internal load) caused by working posture, load on the muscles, and repetition (external load). This could be a static load, such as working for a prolonged period of time in the same position which is typical for office and assembly line workers, or a dynamic load where the working posture frequently varies as typical for workers in physically demanding occupations (SBCM, 2013). The energetic workload is the amount of energy that the body must expend (internal load) to be able to perform work-related activities (external load) (Bernmark, et al., 2012; Seeherman, et al., 1981; Deerenberg, et al., 1998; Bruce, et al., 1973; Taylor, et al., 1955). It depends on the duration and intensity of these activities and will be affected by influences such as heat exposure and temperature change (external loads) (Bernmark, et al., 2012; Wingo, et al., 2005; Seeherman, et al., 1981; Deerenberg, et al., 1998; Bruce, et al., 1973). As illustrated in the conceptual model of Panel on Musculoskeletal Disorders and the Workplace (2001) (see Figure 1.2) (Schultz, et al., 2007; Panel on Musculoskeletal Disorders et al., 2001), which zooms in on the external and personal factors presented in the expanded model of WHO-ICF (2004) (Figure 1.1), the external workloads of the workplace, as task contents and working conditions, create an internal load on the worker on which the body reacts with a physiological response (Schultz, et al., 2007; Panel on Musculoskeletal Disorders et al., 2001). This can cause a mechanical strain and (physical) fatigue. With an imbalance between

workload and capacity, it can cause long-term pain, discomfort, impairment, and disabilities. This misbalance could be prevented by (1) monitoring the individual balance between workload and capacity, and (2) interventions to lower the workload and/or increase work capacity and support to the worker during work.

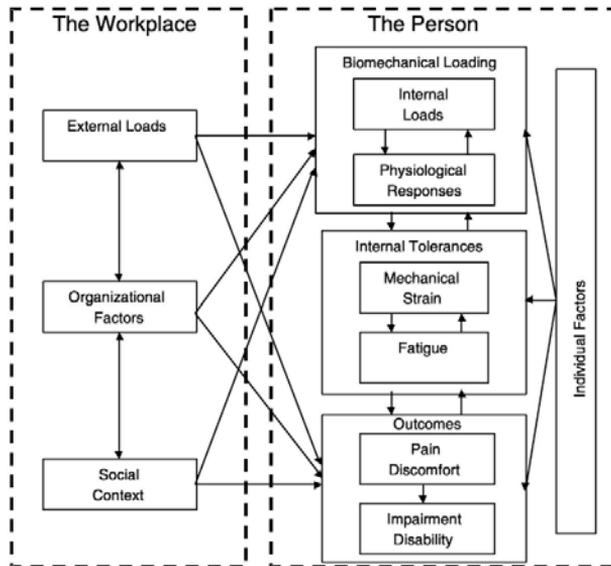


Figure 1.2 | Conceptual model of the roles and influences individual, external and internal factors on (musculoskeletal) workload and health from Panel on Musculoskeletal Disorders and the Workplace, Commission on Behavioural and Social Sciences and Education, National Research Council (NRC) and Institute of Medicine (IOM) (Panel on Musculoskeletal Disorders et al., 2001).

1.3 | Sensor technologies

The main challenge is monitoring the workload and specifically the individual balance between this and work capacity whilst performing the job. Nowadays, the workload is monitored by questionnaires, observations, or in controlled lab situations (Radwin & Lavander, 1999). Self-reporting questionnaires are based on an individual’s perception and provide limited information about the actual workload (Cleland, et al., 2014; Harvey, et al., 2013; Clark, et al., 2011). Visual observations by trained specialist are time-consuming, come with high labour costs, are often snapshots of the overall daily working conditions and do not take into account individual aspects such as the presence of diseases or being overweight which affects the internal reaction on external load (Ng & Feldman, 2013; Cavuoto & Nussbaum, 2014; Maman, et al., 2017; Michalos, et al., 2018; Gallagher & Heberger, 2013; Garg & Kappellusch, 2009). The available objective monitoring systems



need to be used in controlled lab situations (Maman, et al., 2017; Vandermissen, et al., 2014; Perronia, et al., 2014), interfere with workability or are not validated or reliable (Wu & Wang, 2002; Vandermissen, et al., 2014; Takala, et al., 2010; Kuijper & Frings-Dresen, 2004; Verschoof, et al., 2005; Boa, et al., 2004). There is a lack of objective monitoring instruments and a need for wearable sensor technologies to monitor individual workload during work time (Wu & Wang, 2002; Maman, et al., 2017; Verschoof, et al., 2005; Aryal, et al., 2017; Netten, et al., 2011; Pancardo, et al., 2015; Mazgoaker, et al., 2017; Patel, et al., 2012). Sensor technologies may be useful for objectively monitoring workers' workloads (Zhang, et al., 2017). However, there is a lack of sensor technologies that reliably and validly measure aspects of the workload during work without limiting workability (Maman, et al., 2017; Vandermissen, et al., 2014; Takala, et al., 2010; Kuijper & Frings-Dresen, 2004; Verschoof, et al., 2005; Boa, et al., 2004; Aryal, et al., 2017; Netten, et al., 2011; Wu & Wang, 2002; Pancardo, et al., 2015; Mazgoaker, et al., 2017; Patel, et al., 2012).

In the project SPRINT@Work it has been investigated how sustainable employability can be created and how an aging population can be kept healthy and employable in the long-term. One of the challenges was to avoid a structural overload concerning the physical workload. The aim was to make workers aware of their behaviour by (1) monitoring workload and capacity objectively by developing and testing sensor technologies and telemonitoring, and (2) providing interventions to increase their work capacity or lower the workload.



Figure 1.3 | SPRINT@Work is facing the challenge to make the aging population healthy and deployable.

1.4 | Needs and relevance

For workers and companies, as well as the European population, it is very important to realise a sustainable workforce, and sensor and intervention technologies may contribute to this. Although this will not solve all the problems surrounding realising a sustainable workforce, such as working conditions and safety hazards, it will increase insight regarding internal workload as well as contributing to the workers' awareness about their own working behaviour (Spook, et al., 2019). This should ultimately have a positive effect on the workability, health, well-being, quality, and safety of workers and contribute to the existence of a sustainable workforce. For workers and employers, sensor and intervention technologies are of interest to monitor the workload during work with a wearable and easy-to-use system. By using these, workers can be made aware of their working behaviour and provided with personalized, real-time feedback (Spook, et al., 2019; Zhang, et al., 2017). These technologies must not interfere with workability and must be robust whilst complying with company and workplace regulations (Spook, et al., 2019). Moreover, the system must be safe to use (Santos, et al., 2020), data ownership must be clear, and privacy protected (Spook, et al., 2019). And workers should be able to use outcomes to later open a dialogue about workplace improvements (Spook, et al., 2019).

According to literature research and a needs assessment among companies (employees and employers) in Northern-Netherlands (Spook, et al., 2019), there is a need for sensor technologies to monitor the workload and three physical aspects emerge (Radwin & Lavander, 1999). Firstly, the mechanical load of workers. Musculoskeletal disorders and low back pain (Jorgensen, et al., 2013; Holterman, et al., 2013; Andersen, et al., 2007; Bakker, et al., 2009; Andersson, 1999) are common health problems and a major cause of work absence among office and physically active workers (Coenen, et al., 2016; Jezukaitis & Kapur, 2011; Palmer & Goodson, 2015). This is mainly caused by a prolonged working in same the working posture (static load) or (high external loads while) working in unfavourable postures (Schultz, et al., 2007; Panel on Musculoskeletal Disorders et al., 2001). There is a need, but lack on methods or instruments to monitor the working posture (and related load on the back (internal load)) during the performance of the job (Jorgensen, et al., 2013; Netten, et al., 2011; Takala, et al., 2010; Xu, et al., 2012; Juul-Kristensen, et al., 2001) of individuals (Hansson, et al., 2006). Secondly, the energetic workload and its health consequence fatigue (internal load) (Spook, et al., 2019; Radwin & Lavander, 1999). Due to aging, the energetic capacity declines starting at an age of 30 years (Kenny, et al., 2008; Ilmarinen, 2001; Chan, et al., 2000; Bellew, et al., 2005) and significantly influences the workability of physically active workers. When the workload exceeds the work capacity, overload will occur resulting in fatigue (Kenny, et al., 2008; Ilmarinen, 2001; Weerding, et





al., 2005; Costa-Black, et al., 2013; Bos, et al., 2004). To prevent chronic fatigue and maintain the individual balance between workload and capacity, there is a need for objective, valid and reliable measurement tool to monitor energetic workload during work (Faria, et al., 2018; Alberto, et al., 2017) on a non-obstructive manner which does not influence the workability (Catal & Akbulut, 2018; Hoehn, et al., 2018). Thirdly, the energetic workload related aspect heat exposure (internal reaction on external load) (Spook, et al., 2019; Radwin & Lavander, 1999). Heat exposure during physically demanding work, as working in (indoor and outdoor) hot (and humid) environments and the wear of personal protective clothing (PPC) and equipment (PPE), can result in heat strain (internal reaction on heat production and regulation) and heat stress (internal and external load) (McQuerry, et al., 2018; Costello, et al., 2015; Yazdi & Sheikhzadeh, 2014; Nunneley, 1989; Levels, et al., 2014). This heat strain and stress can result in short and long-term health problems as heat exhaustion, dehydration, physical fatigue and loss of consciousness (Chang, et al., 2017; Cvirn, et al., 2019; Epstein & Moran, 2006; McInnes, et al., 2017; Barr, et al., 2010). Heat strain and stress among physically demanding occupations is of major concern and needs to be prevented. However, there is an urge for a continuous, accurate, instrument to monitor core temperature and heat stress development during the performance of the job on a non-invasive and easy-to-use manner (Mazgoaker, et al., 2017; Moran & Mendal, 2002; Chaglla, et al., 2018; McKenzie & Osgood, 2004; Uth, et al., 2016; Steck, et al., 2011).

1.5 | Outline and aims of dissertation

The overarching aim of this dissertation is to contribute to a sustainable workforce by making the (mis)balance between workload and work capacity measurable with sensor technologies. When the workload and work capacity can be monitored, misbalance could be prevented. The focus is on prevention of misbalance by making workers aware of their behaviour by firstly developing and testing sensor technologies to measure workload and capacity objectively, secondly by measuring the workload, and thirdly by providing interventions to increase their work capacity or lower the workload. The objective of the studies in this dissertation is to develop and test sensor technologies that are usable in the workplace and able to monitor (1) working postures and movements and related internal mechanical workload, (2) the internal energetic workload, and (3) internal reaction on external heat exposure. The focus will be on user-centred design, the physical workload of individuals, developments that are personalized, smart, and user-driven and make workers aware of their working behaviour.

In *Chapters 2 and 3*, the focus is on working postures and mechanical workload. *Chapter 2 'Can a smart chair improve the sitting behaviour of office workers?'* is a study of the mechanical workload of office workers. With a smart sensor chair the sedentary behaviour, sitting postures, and duration of sitting of office workers are monitored. Additionally is investigated if a tactical feedback signal could improve this behaviour. This study aimed to (1) investigate the effect of the feedback signal on the sitting behaviour; (2) investigate the effect of the feedback signal on the perceived local musculoskeletal discomfort related to working while seated for a prolonged time; (3) investigate the difference between the measured sitting duration with the smart chair and behaviour measured both in and out of the chair with an activity tracker (sitting duration and amount of steps).

In *Chapter 3 'Automatically determining the moment of the lumbar load during physically demanding work'*, the mechanical workload of physically active workers is investigated. With a "sensor suit" and with a specially developed artificial neural network-based method, the backload related to the working postures can be estimated. The aim of this study was to test if this sensor system can distinguish the estimated lumbar load of different intensity and variability levels relative to the perceived task loads using discriminant validity.

To be able to monitor the energetic workload, a mouth mask-less breathing gas analyser has been developed and presented in *Chapter 4 'Patent application of an instrument, system and method for use in respiratory exchange ratio measurement'*. In *Chapter 5 'Can breathing gases be analysed without a mouth mask? Proof-of-concept and concurrent validity of a newly developed breathing-gases analysing headset'*, this monitoring system is validated. This proof-of-concept study aimed to investigate (1) the validity of $\dot{V}O_2$, carbon dioxide production ($\dot{V}CO_2$) and respiratory exchange ratio (RER) measurements produced by the developed breathing-gas analysing headset compared to a mouth mask (reference system), (2) the validity of $\dot{V}O_2$ measurements produced by the developed breathing-gas analysing headset compared to estimated $\dot{V}O_2$ based on HR, (3) the influence of wind on the validity of the system, and (4) the user experience of the developed headset system.

To monitor the heat exposure of physically active workers, in *Chapter 6 'Monitoring core temperature of firefighters to validate a wearable non-invasive core thermometer in different types of protective clothing: concurrent in-vivo validation'*, the accuracy of a wearable thermometer is investigated and the development of the core temperature of firefighters in two types of personal protective clothing is monitored during a simulation exercise. The aims of this study were (1) to test the validity and reliability of a wearable non-invasive core temperature sensor in rest in comparison to an invasive temperature sensor pill and standard inner-ear IR thermometer and (2) during realistic firefighting simulation



tasks in comparison to an invasive temperature sensor pill, and (3) to compare the change in core temperature recorded with the wearable non-invasive core thermometer and an invasive temperature sensor pill of firefighters during realistic firefighting simulation tasks in two types (traditional turnout gear versus a new concept) of protective clothing. In chapter 7, '*Evaluation of a wearable non-invasive thermometer for monitoring ear canal temperature during physically demanding work*', the wearable thermometer for monitoring heat stress is investigated and validated in a lab (controlled conditions) and a field (real-life working conditions) study among different types of physically active workers. The aims were to (1) test the in-vitro accuracy of the non-invasive thermometer in controlled lab conditions; (2) test the in-vivo accuracy as an inner-ear thermometer in controlled lab conditions; (3) test the in-vivo accuracy of the thermometer during the performance of physically demanding occupations; (4) investigating the influence of the environmental conditions wind, temperature changes and lack of ventilation due to PPC and PPE on the accuracy of the Cosinuss[®]; and (5) explore the usability to measure inner-ear temperatures during the performance of physically demanding occupations. In Appendix I the results of the in-vitro and in-vivo validity of another newly developed non-invasive thermometer CORTES can be found.

Implementation of personalized monitoring technologies in workplaces comes with privacy and responsibility concerns for both workers and employers. In Chapter 8 '*Ethics in design and implementation of technologies for workplace health promoting technologies*', the ethical considerations behind monitoring workload are evaluated. Despite a comprehensive ethics framework, there is still a lack of knowledge on (1) how to overcome the divide in ethical approaches to designing and implementing innovative technologies, (2) how context can play a role when addressing critical ethical issues such as privacy and autonomy, and (3) how ethical responsibilities of the different stakeholders can be made manifest and used. The aim of this paper is to address these challenges by analysing two ethical issues, privacy, and autonomy of workers, in a real-life research setting.

In *Chapter 9*, sensor technologies and their implementation in the workplace are discussed, considering an evaluation of the results, the relevance of these developments, future research, and perspectives.

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Chapter 2

Can a smart chair improve the sitting behaviour of office workers?

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Abstract



Prolonged sitting can cause health problems and musculoskeletal discomfort. There is a need for objective and non-obstructive means of measuring sitting behaviour. A 'smart' office chair can monitor sitting behaviour and provide tactile feedback, aiming to improve sitting behaviour. This study aimed to investigate the effect of the feedback signal on sitting behaviour and musculoskeletal discomfort. In a 12-week prospective cohort study (ABCB design) among office workers (n=45) was measured sitting duration and posture, feedback signals and musculoskeletal discomfort. Between the study phases, small changes were observed in mean sitting duration, posture and discomfort. After turning off the feedback signal, a slight increase in sitting duration was observed (10 minutes, $p=0.04$), a slight decrease in optimally supported posture (2.8%, $p<0.01$), and musculoskeletal discomfort (0.8, $p<0.01$) was observed. We conclude that the 'smart' chair is able to monitor the sitting behaviour, the feedback signal, however, led to small or insignificant changes.

Keywords: sedentary behaviour, smart sensor chair, tactile feedback

2.1 | Introduction

Office workers sit for long periods during their working hours (Thorp et al., 2012). Workers usually exceed recommendations regarding maximum time working in a sitting position (Netten et al., 2011; Goossens et al., 2012; Ryan et al., 2011). Prolonged sitting results in an increased risk of developing health problems (Healy et al., 2013; Chau et al., 2010) and musculoskeletal discomfort (Mathiassen, 2016; Hallman et al., 2016; Zemp et al., 2017). Due to the static character of sitting, the level of muscular tension may cause fatigue and, with insufficient recovery, can result in long-term health problems (Hamburg-van Reenen, 2008). To prevent these health problems, the sitting behaviour of office workers must be improved (Thorp et al., 2012; Robertson et al., 2009; Straker et al., 2013).

To gain a more comprehensive insight into the sitting behaviour of office workers, there is a need for objective and non-obstructive means of measuring sitting behaviour (Thorp et al., 2012; van Uffelen et al., 2010; Netten et al., 2011; Wells et al., 2007). Sitting behaviour can be measured with questionnaires and activity trackers (Robertson et al., 2008 and 2009; Amick et al., 2012; Straker et al., 2013). Multiple studies have investigated the reliability of questionnaires for measuring sedentary behaviour and have shown that self-reported measures are a valid way of assessing sedentary behaviour (Clemens et al., 2012; Craig et al., 2003; Healy et al., 2011). However, questionnaires are based on self-reporting and therefore reflect the individual's own perceptions (Harvey et al., 2013; Clark et al., 2011), and do not provide detailed information about the actual sitting behaviour (Cleland et al., 2014; Healy et al., 2011; Clemes et al., 2011). Activity trackers can be used to objectively measure sitting and standing duration (Robertson et al., 2009; Straker et al., 2013), but they cannot measure sitting postures (Netten et al., 2011; Healy et al., 2011). A measuring tool to provide more detailed patterns of sitting throughout the day is needed. (Zemp et al., 2016).

With a 'smart' office chair (*Axia Smart Chair*, BMA Ergonomics, Zwolle, the Netherlands) equipped with sensors located in the seat surface (4 sensors) and backrest (2 sensors), see Figure 2.1, sitting behaviour can be objectively monitored. Additionally, a tactile feedback signal (vibration) can be provided to the user if a set duration limit is reached. Application of this intervention in an eight-week pilot study appeared to shorten sitting duration and improve posture (van der Doelen et al., 2011; Netten et al., 2011), but the initial effects decreased over time (Goossens et al., 2012). None of these studies, however, tested for longer durations or controlled for the sitting duration, amount of activity away from the smart chair during working hours, or the effects of tactile feedback. Additionally, it is unknown if improved sitting behaviour reduces health problems and musculoskeletal



discomfort (Cascioli et al., 2016; Netten et al., 2011). These shortcomings were addressed in the present study.



Figure 2.1 | BMA Axia Smart Chair with label with sensor location. (BMA Ergonomics, 2017)

In this study the smart chair and its feedback signal were further investigated and its effect on sitting behaviour and musculoskeletal discomfort was explored. The aims of this study were to: (1) investigate the effect of the feedback signal on the sitting behaviour, defined as sitting duration (30 and 60 minutes), posture and the dynamic (alternation between sitting and non-sitting and postures) and static components (sitting blocks and blocks of sitting in one posture) of sitting; (2) investigate the effect of the feedback signal on the perceived local musculoskeletal discomfort related to working while seated for a prolonged time; (3) investigate the difference between the measured sitting duration with the smart chair and behaviour measured both in and out of the chair with an activity tracker (sitting duration and amount of steps).

2.2 | Methods

2.2.1 | Design

In this 20-week prospective cohort study, sitting behaviour was monitored among the office workers of five companies. Based on the availability of materials, this study was performed in two cohorts of 24 and 25 subjects, respectively, between 2015 and 2016. For this study, the first 12 weeks were divided into four phases (ABCB design). Phase 1 (week 1; acclimatization): the Axia Smart Chair and the subject's workplace were adjusted according to ergonomic guidelines in dynamic interrelation, followed by one week of acclimatization (Goossens et al., 2012). Phase 2 (weeks 2-3; monitoring I): the subject's sitting behaviour was monitored while the feedback signal was deactivated. Phase 3 (weeks 4-9; intervention): the feedback signal was activated and the subject's sitting behaviour was monitored. Phase 4 (weeks 10-12; monitoring II): the feedback signal was deactivated and

the subject’s sitting behaviour was monitored. In weeks 2 (begin monitoring phase I), 4 (begin intervention phase), 9 (end intervention phase) and 12 (end monitoring phase II), the subjects wore an activity tracker (Actigraph GT3X+, ActiGraph LLC, Fort Walton Beach, FL, United States) throughout the whole working week. On one specific day in weeks 2, 3, 9 and 12, the subjects received questionnaires by mail (at the beginning and end of their working day) about their experienced local musculoskeletal discomfort (LMD questionnaire of van der Grinten and Smitt, 1992), and the second cohort received two additional questionnaires in weeks 5 and 7 to gain further insight into the discomfort experienced during the intervention phase. The measurement scheme is presented in Table 2.1. Except for the additional questionnaire, all subjects followed the same protocol and received the same intervention.

Table 2.1 | Experimental planning: Materials used during this study per phase and week, x means used in this week.

	Phase 1: Acclimatization	Phase 2: Monitor I		Phase 3: Intervention				Phase 4: Monitor II				
Week number	1	2	3	4	5	6	7	8	9	10	11	12
Sitting behaviour	X	X	X	X	X	X	X	X	X	X	X	X
Activity trackers		X		X					X			X
Physical discomfort questionnaire (group 1)		X	X						X			X
Physical discomfort questionnaire (group 2)		X	X		X		X		X			X

2.2.2 | Subjects

The subjects were office workers recruited by distributing flyers within the selected companies, followed by an oral presentation to inform participants about the contents of the study. The companies were active in medical care, technical services, civil engineering, industrial cleaning and the petro chemistry industry. Inclusion criteria: the subjects worked at least three days a week, five hours a day (37.5% of a working week) and had a personal workplace. Pregnant women were excluded due to the shift of their center of gravity (Casagrande et al., 2015). 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 (M15.175675).

2.2.3 | Material

2.2.3.1 | Office Chair



This study used the Axia Smart Chair developed by BMA Ergonomics (Zwolle, the Netherlands). This chair is a 'regular' office chair equipped with pressure sensors located in the seat surface (4 sensors) and backrest (2 sensors). The measuring interval was 1 second and the data, logged once per minute, included the most dominant posture and the related score for this time span. The data were collected using Axia Insight software (BMA Ergonomics, Zwolle, the Netherlands). In the output, eight postures were defined as follows: (1) optimal support (van der Doelen et al., 2011), (2) poor upper back contact, (3) poor lower back contact, (4) too much to the left, (5) too much to the right, (6) slouching, (7) edge of the chair and (8) not sitting. Feedback was provided based on an algorithm (BMA Ergonomics, Zwolle, the Netherlands) that accounted for sitting posture, duration and alternation between postures. Based on this score, a feedback signal was provided to the subject; a (vibration) feedback signal was given when the user demonstrated prolonged periods (30 or 60 minutes, standard 60 min) in unfavourable sitting postures and a low number of alternations (≤ 3 alternations in posture per 60 min) (Goossens, 2009) for more than a present amount of time during the preceding hour (van der Doelen et al., 2011; Netten et al., 2011). The tactile feedback signal was located in the seat surface and consisted of four short pulses over four seconds. The subjects received the feedback signal and information about their sitting behaviour was also available from a fixed tab attached to the seat of the chair. The user could activate this fixed tab themselves whenever they wanted. This fixed tab on the chair showed the current sitting posture, the most dominant sitting posture over the preceding half hour and the average score (between 1 and 5, with higher scores indicating more optimal sitting behaviours).

2.3.3.2 | Questionnaire

Musculoskeletal discomfort was measured with the Localized Musculoskeletal Discomfort (LMD) questionnaire (van der Grinten and Smitt, 1992). The LMD is a reasonably reliable and sensitive method by which to measure localized musculoskeletal discomfort of low static musculoskeletal loads caused by static postures within subjects and groups (van der Grinten and Smitt, 1992; Hamburg-van Reenen, 2008). Subjects rated the following five body areas on perceived LMD at the beginning (9:00) and end (15:00) of the working day on specific days (see Table 2.1): (1) forearms and hands, (2) neck, shoulders and upper arms, (3) upper back, (4) lower back, (5) buttocks and legs. The first cohort (companies 1, 2 and 3) received this questionnaire at the beginning of the monitoring phase and at the end of the monitoring, intervention and monitoring II phases (week numbers 2, 3, 9 and 12). The second cohort (companies 4 and 5) received an additional LMD questionnaire in weeks 5

and 7 in the intervention phase to gain more insight regarding that phase. Ratings could vary from 0 to 10 (Borg scale, in increments of 0.5), with 0 indicating no discomfort, 0.5 indicating extremely little discomfort and 10 indicating extreme discomfort (almost maximum). An invitation to the questionnaires were send 15 minutes before 9 or 15 hours to the subjects by mail. If the questionnaire was not completed within about 1 hours after receiving the invitation, a reminder was send. Each questionnaire was available for 2.5 hours.

2.3.3.3 | *Activity tracker*

The activity tracker Actigraph GT3X+ (ActiGraph LLC, Fort Walton Beach, FL, United States) was used to measure when the participant was not sitting on the smart chair (sitting, standing and walking). This activity tracker has been proven capable of reliably detecting sitting, standing and walking in daily life (Kooiman et al., 2015; Aguilar-Farías et al., 2014). In total, 38 subjects received an activity tracker due to limited availability. These subjects were selected based on gender, age and the company they were working to create a representative group of the subjects.

2.2.4 | *Data analysis*

From the 'smart' chair the sitting duration and sitting postures were obtained per working day and phase. Sitting duration and posture were split up into 6 parameters containing a static and dynamic component. The sitting duration was expressed in (1) sitting duration; (2) static sitting blocks (of >30 min and >60 min); (3) dynamic alternation between sitting and non-sitting. Sitting postures was expressed in (4) sitting in an optimal supported posture; (5) static sitting blocks in one posture (>15 min); (6) dynamic alternation between sitting postures. Non-sitting was defined as not sitting in the 'smart' chair and could be standing (sit/stand desk) or walking or sitting on another chair. From the activity trackers was calculated; (1) amount of steps; (2) sitting duration. The data of the activity tracker was linked to the sitting duration of the 'smart' chair. From the LMD questionnaire was calculated: (1) the overall discomfort score; (2) discomfort score per body part.

For statistical analysis, only workdays with more than 60 minutes of sitting were included. The same holds for wearing the activity tracker more than 60 minutes. Since the duration of the working days differed across subjects and days, all data were equalized by converting the data to an eight-hour working day for statistical analysis. This was done by converting the percentage of work time into an eight-hour working day. For example a working day of 7 hours with a sitting duration of 60.0% was converted to a working day of 8 hours with a sitting duration of 68.6% ($= (60.0\% / 7 \text{ hours}) \times 8 \text{ hours}$).



To test the research questions, a paired t-test was used for normally distributed data. For non-normally distributed data, the non-parametric Friedman test was used. For all parameters, difference between the phases were tested; phase 1 versus 2, phase 2 versus 3, phase 3 versus 4 and phase 2 versus 4. Differences with p-values <0.05 were considered statistically significant. Parameters were given for the t-tests together with their standard error of mean, and for the Friedman test with chi-square (χ^2) (degrees of freedom). The tests were performed using SPSS (IBM SPSS Statistics 24, New York, United States). Missing data from the LMD questionnaire and activity trackers were not imputed and analysed with listwise deletion. Sensitivity analyses were performed to test differences between participants with complete and incomplete data sets.

2.3 | Results

2.3.1 | Sitting behaviour in chair

Forty-nine office workers participated in this study (20-65 years of age). Three subjects prematurely ended their participation during or at the end of the intervention phase due to reorganization, absence due to (long-term) illness and a new job at another company. One subject had technical issues with the sensor chair. These four subjects did not provide complete data sets and therefore were not included, resulting in a study group of 45 subjects (19 males, 26 females) with a mean age of 43.1±11.0 years (mean±SD).

Over the 12-week study period, the subjects were present at their own workplace about 3.6 days per week, resulting in 1948 days of data gathered with the smart chair. In Table 2.2, we present these subjects' sitting behaviour per phase (duration of working day in hours), expressed in (1) sitting duration, (2) sitting blocks of more than 30 and 60 minutes, (3) alternation between sitting and not sitting, (4) sitting in an optimally supported posture, (5) sitting blocks of more than 15 minutes in one posture, and (6) alternation between sitting postures. Changes in mean sitting duration between all phases were small and insignificant ($p>0.228$) except between the intervention and monitoring phase II of sitting blocks of more than 60 minutes ($p=0.007$, $t(44)=2.804$). During monitoring phase II, a decrease in sitting in an optimally supported posture was observed ($p=0.001$, $\chi^2(3)=16.684$), as compared to the intervention phase ($p=0.000$, $\chi^2(1)=22.348$) and monitoring phase I ($p=0.011$, $\chi^2(1)=6.422$). The other parameters did not change significantly over the phases ($p>0.16$). All working days longer than 60 minutes were included in the analyses.

With sensitivity analyses, the results of working days longer than 20 minutes of sitting instead of 60 minutes were investigated. The same or similar ($\leq 0.3\%$ change) results were also found for changes within phases.

During the intervention phase, 796 feedback signals were provided to the subjects. The subjects received, on average, 0.8 ± 0.8 feedback signals per working day. In the last week of the intervention phase, a significantly greater number of feedback signals were provided ($p=0.037$, $\chi^2(1)=4.333$). When comparing those subjects who received very low numbers of feedback signals (on average less than one signal a day) ($n=26$) to the subjects who received more than one feedback signal a day ($n=19$), it was found that these subjects were significantly more regularly sitting in an optimally supported position ($20.2\% \pm 17.3$ compared to $5.5\% \pm 6.5$ (mean \pm SD).) ($p=0.000$, $\chi^2(1)=16.173$). The other parameters presented in Table 2.2 did not change or differ significantly.





Table 2.2 | Sitting behaviour per phase: The mean sitting behaviour (n=45) measured with the 'smart' chair and activity tracker. All data is the mean with standard deviation (mean±SD) per working day per phase.

	Parameters	Acclimatization	Monitoring I	Intervention phase	Monitoring II	Average
Sedentary behaviour (activity tracker)	Duration of working day (h)	7.5 ± 1.5	7.9 ± 0.8	7.7 ± 1.0	7.6 ± 1.0	7.7 ± 1.1
	Steps (counts)	-	3226 ± 1092	3061 ± 1331	2899 ± 1357	3033 ± 1333
Sitting duration (smart chair)	Sitting duration (%)	85.9 ± 8.7 (6.9 hours)	89.1 ± 4.4 (7.1 hours)	89.6 ± 4.9 (7.2 hours)	90.4 ± 4.2 (7.2 hours)	88.8 ± 6.0 (7.1 hours)
	Sitting duration (%)	66.3 ± 14.5 (5.3 hours)	67.0 ± 10.1 (5.4 hours)	67.9 ± 10.8 (5.3 hours)	65.8 ± 10.8 (5.2 hours)	66.7 ± 11.1 (5.3 hours)
Sitting posture (smart chair)	Sitting blocks of >30 min (counts)	3.6 ± 1.3	3.8 ± 1.0	3.8 ± 0.9	3.7 ± 1.2	3.7 ± 1.1
	Sitting blocks of >60 min (counts)	1.5 ± 1.0	1.5 ± 0.7	1.5 ± 0.7	1.3 ± 0.6	1.4 ± 0.8
	Alternation between sitting vs non sitting (counts)	13.7 ± 6.3	13.8 ± 6.7	13.9 ± 6.3	13.8 ± 6.8	13.8 ± 6.5
Sitting posture (smart chair)	Sitting in optimal supported posture (%)	12.4 ± 13.6	14.1 ± 14.6	14.0 ± 15.6	11.2 ± 13.7	12.9 ± 14.3
	Sitting blocks of >15 min in one posture (counts)	3.5 ± 3.6	3.4 ± 3.3	3.3 ± 3.0	3.2 ± 2.9	3.3 ± 3.2
	Alternation between sitting postures (counts)	95.4 ± 33.3	95.3 ± 33.2	97.5 ± 28.9	94.7 ± 31.4	95.7 ± 31.5

2.3.2 | LMD

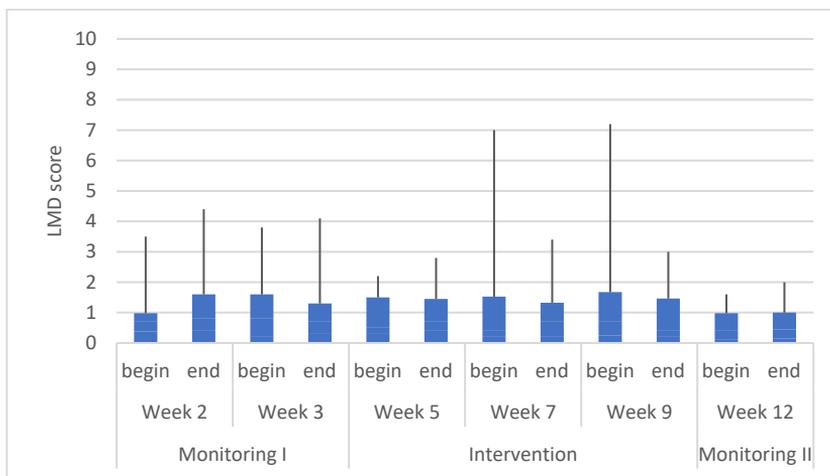


Figure 2.2 | Local Musculoskeletal Discomfort (LMD): Mean overall LMD score with standard deviation per week at the begin and end of measuring day (n=22).

The average LMD score was 1.0 ± 1.2 during this study. Figure 2.2 shows a significant decrease ($p=0.008$, $\chi^2(3)=11.943$) in experienced discomfort during monitoring phase II ($p=0.001$, $\chi^2(1)=11.645$). Sitting in an optimally supported posture significantly decreased during monitoring phase II ($p=0.001$, $\chi^2(2)=14.247$), as compared to monitoring phase I ($p=0.019$, $\chi^2(1)=5.538$) and the intervention phase ($p=0.000$, $\chi^2(1)=12.462$).

Figure 2.3 shows the LMD score per region. All group level changes are small, and most are insignificant. However, lower back discomfort decreases significantly during monitoring phase I ($p=0.050$, $\chi^2(1)=3.846$) and increases during the intervention phase ($p=0.041$, $\chi^2(1)=4.172$). Discomfort in the buttocks and legs decreases significantly in monitoring phase I ($p=0.046$, $\chi^2(1)=4.000$). Discomfort in all regions decreases significantly ($p=0.000$, $\chi^2(29)=65.822$) during monitoring phase II, except for the upper back: lower arms and hands ($p=0.008$, $\chi^2(1)=7.143$); neck, shoulders and upper arms ($p=0.001$, $\chi^2(1)=11.842$); lower back ($p=0.001$, $\chi^2(1)=11.560$); buttocks and legs ($p=0.005$, $\chi^2(1)=8.067$).



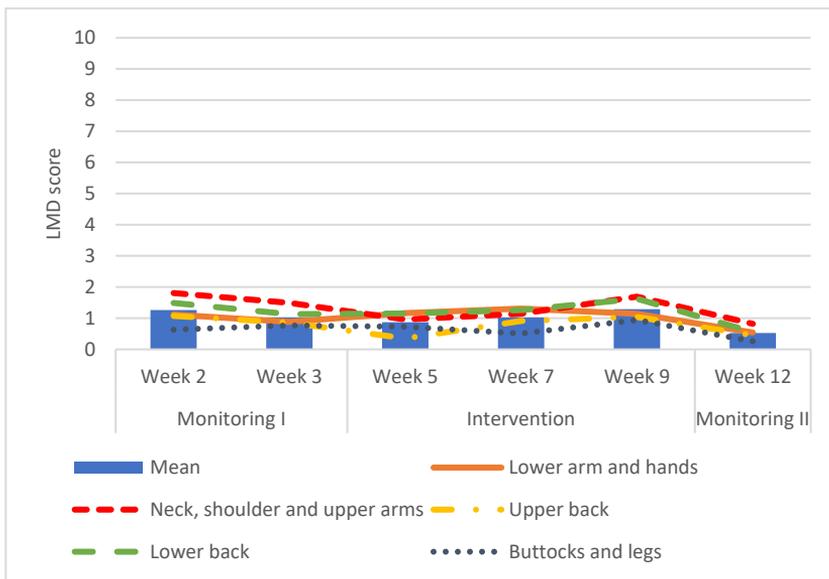


Figure 2.3 | Local Musculoskeletal Discomfort (LMD) per body region: Mean LMD score per body region per phase (n=22).

Overall, 21 subjects did not complete one or more questionnaires. In total, 37.4% of the LMD questionnaires were completed. For sensitivity analyses, the sitting behaviour of the respondents who completed the LMD questionnaires was compared to the sitting behaviour of all subjects. The results were the same or somewhat improved: sitting duration, 1.2 to 2.0%; sitting in optimally supported posture, 1.1 to 2.3%; sitting block during monitoring phase II, 0.5; alternation between sitting postures, 1.1 to 5.1. These changes were not significant as compared to all subjects, and the same significant changes in sitting behaviour between the phases were found. The subjects who did not fill in the questionnaire were 43.6 ± 10.7 years (mean \pm SD) of age and 57.1% female.

2.3.3 | Sitting behaviour in- and outside chair

38 subjects received an activity tracker (18 males, 20 females) with a mean age of 43.9 ± 10.8 years (mean \pm SD). The activity trackers were worn 70.1% of the total time during this study. According to the chair data, the subjects spent, on average, 67.0% of their time in a sitting position. Adding sitting duration away from the smart chair showed that the subjects were sitting 88.8% of the working day. The sitting duration increased slightly and insignificantly ($p \geq 0.07$) between the acclimatization phase, monitoring phase I and intervention phase, and decreased during monitoring phase II. The activity tracker showed an increase in sitting duration during monitoring phase II ($p=0.007$, $\chi^2(3)=12.231$), as compared to the baseline ($p=0.011$, $\chi^2(1)=6.533$) and the intervention phase ($p=0.040$, $\chi^2(1)=4.235$). In line with this

finding, an insignificantly decreasing trend in the number of steps taken is shown between monitoring phase I and monitoring phase II ($p=0.054$, -293.7 ± 801.3 , $[-592.9;5.5]$). For sensitivity analyses, the sitting behaviour of the subjects who wore the activity tracker was compared to the sitting behaviour of all subjects. The same or comparable results (changes $\leq 1.6\%$) were found with no significant changes.

2.4 | Discussion

In this study it is shown that it is possible to monitor the sitting behaviour of office workers for long durations using a smart chair. During the intervention phase, sitting behaviour did not change significantly. After turning off the feedback signal, the subjects sat for longer periods of time and less often in an optimally supported posture. The experienced discomfort did not decrease during the intervention phase. After turning off the feedback signal, the amount of experienced discomfort decreased. A temporal effect of sitting behaviour on musculoskeletal discomfort could not be proven. The subjects were sitting for about 89% of the whole day and at the workplace in the smart chair for approximately 67% of the working day. We had expected a decrease in sitting duration, sitting blocks and LMD score, an increase in amount of alternations of sitting postures, and alternation between sitting vs non sitting, amount of steps in the intervention phase compared to monitoring phase I and II. This was, however, not observed. Thus, an effect of feedback signal on sitting behaviour was not observed, which led to the conclusion that the feedback signal improved neither sitting behaviour nor discomfort. The feedback aimed to increase the duration sitting in an optimal supported posture with the common belief to lower the musculoskeletal discomfort, however no research to support this in a clinical setting. Some observed changes achieved statistical significance, yet these changes were small and their relevance is unclear. The results show large SD indicating large difference between subjects and a non-homogenous sample. The inter-individual differences are probably responsible for the small, but significant changes. Given these minimal changes, a temporal effect of sitting behaviour on musculoskeletal discomfort is unlikely, as is an effect of the feedback signal on experienced local musculoskeletal discomfort related to prolonged sitting work. A slight improvement in sitting behaviour and LMD at the beginning of the intervention phase was observed, but this change was not a significant or retentive effect, and the response rate for the questionnaire was very low.

Our findings may be indicative of no effect. There are, however, alternative explanations for our observations in this study. Differences in study design compared to others (Netten et al., 2011; Goossens et al., 2012) were that the workplaces of the subjects were adjusted





according to ergonomic guidelines where necessary, and at least one week was set aside for subjects' acclimatization to their adjusted workplace to eliminate the effect of this factor. This may explain a smaller effect of the present study. One other explanation for our findings could be the low feedback frequency, which resulted in a low number of feedback signals provided to the subjects. Half of the subjects received a very low number of feedback signals (less than one feedback signal a day), indicating a naturally good sitting posture with a small improvement range (floor effect). This is also the case for perceived local musculoskeletal discomfort. The average and starting LMD score was low, resulting in a minimal improvement range. Moreover, the response rate for the LMD questionnaires was low, with a random rather than systematic bias. Besides, a few subjects mentioned that they had performed an activity that was not chair- or work-related, like sport, which could have caused an increase in the LMD results during the intervention phase. The LMD questionnaire was taken once per phase (twice a day) for the first group. The remarkable results were the increase in sitting duration and decrease in optimally supported posture sitting during monitoring phase II versus the decrease in experienced musculoskeletal discomfort. The difference between the sitting duration in the chair (5.4 hours) and out of the chair (7.1 hours) is consistent with existing literature (Netten, 2011), demonstrating the need for an additional measure to capture all sitting (in multiple chairs) during a full day.

The strengths of this study are that this research was performed for the same or a longer period than other research regarding the smart chair, and experienced musculoskeletal discomfort was taken into account and related to the feedback signal. In addition, this study was performed in a real-life working environment of five different companies with office workers with diverse jobs. Moreover, an activity tracker was used to provide insight into sitting behaviour away from the smart chair (e.g., during meetings or appointments outside the office) to get more detailed information about the subject's sitting behaviour over the working day. In addition, in this research, multiple parameters of sitting behaviour were used. Usually, research is performed regarding one parameter of sitting behaviour, such as sitting duration (Clark et al., 2011; Clemes et al., 2012; Dunstan et al., 2012; Hallman et al., 2016; Healy et al., 2011 and 2013) or (alternation of) sitting postures (Amick et al., 2012; Grooten et al., 2017; Mathiassen, 2006). Only a few studies have included multiple parameters of sitting behaviour (Netten et al., 2011; Mathiassen, 2006; Goossens et al., 2012). A limitation of this study is that, although the subjects received instruction not to adjust the chair, at least six subjects did adjust the chair during the 12-week study. Depending on the type of adjustment, this could have influenced the outcomes. Based on a small lab study and instructions of the manufacture, in line with research of Netten (2011), van der Doelen (2011) and Goossens (2012), the working of the chair is most optimal when

it was installed according to ergonomic guidelines. Adjustments can cause no or less contact with the sensors resulting in incorrect detection of the sitting posture. Besides, not allowing making adjustment to the chair is creating an unnatural situation which was necessary to ensure that potential effects were due to the intervention and not caused by adjustment of the chair. Furthermore, the data were converted into an eight-hour working day, and this extrapolation could have influenced the results. In addition, there could be a difference between the two cohorts due the period of measurement; the first cohort was measured from September 2015 to January 2016 while the second cohort was measured from February 2016 to June 2016. The influence of this difference on the outcome is unknown. Moreover, while this study explored differences between subgroups (amount of alternation in sitting posture) and task-related trends, it was underpowered for these sub analyses.

Insight regarding the parameters of the sitting behaviour of office workers is gained in this study. There is a knowledge gap with regard to, in particular, the alternation between sitting and standing, different sitting postures and movements on the chair (Lin et al., 2017; Claus, et al., 2016; Cascioli et al., 2016; Mathiassen, 2006). A smart chair could be a useful non-obstructive tool by which to gain greater insight into the sitting behaviour of office workers, its patterns, and its parameters. This information is necessary to make office workers aware of their own sitting behaviours and to develop a comprehensive definition of healthy sitting behaviour. While health risks related to sitting are well studied (Dunstan et al., 2012; Thorp et al., 2012; van Uffelen et al., 2010), there is no agreed definition of healthy sitting behaviour. Since clear guidelines are unavailable (Dunstan et al., 2012; Healy et al., 2013), healthy sitting guidelines should probably contain a combination of duration and posture, indicating that duration should not exceed 20 or 30 minutes, and posture should include 'dynamic sitting', referring to alternation of sitting postures (Mathiassen, 2016; Thorp et al., 2012; Hallman et al., 2016). With this definition, sitting behaviour could be more efficiently improved and sitting-related health problems could be prevented.

In future research, the moments of feedback signal provision to the user must be further investigated. The parameters behind the feedback signal are probably a good reflection of the sitting behaviour but increasing the feedback frequency and adding another kind of feedback, such as visual or combination feedback, could be more effective. Furthermore, subjects with health complaints and musculoskeletal discomfort must be included. Future studies might use the results of this study to answer targeted study questions. In addition, coupling an activity tracker and the chair to a single platform would create a more complete representation of the subject's sitting behaviour over the whole day, including the amount of activity away from the chair. Moreover, with data per second it is possible to measure

movements on the chair alongside shifts in posture, which could provide more detail regarding sitting patterns.



2.5 | Conclusion

The results of this study show that tactile feedback did not cause significant changes in the sitting behaviour and musculoskeletal discomfort of office workers.

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Disclosures

Any findings, and conclusions or recommendations presented in this article are those of the author(s) and do not necessarily reflect the views of BMA Ergonomics. There is no conflict of interest.

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Chapter 3

Automatically determining lumbar load during physically demanding work: an in-vivo validation study

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Abstract



Several studies have proposed that a sensor-based system using inertial magnetic measurement units and surface electromyography is suitable for objectively and automatically monitoring the lumbar load during physically demanding work. However, the validity and usability of this system in the uncontrolled real-life working environment of physically active workers are still unknown. The objective of this study was to test the discriminant validity of an artificial neural network-based method for load assessment during actual work. Nine physically active workers performed work-related tasks while wearing the sensor system. The main measure representing lumbar load was the net moment around the L5/S1 intervertebral body, estimated using a method that is based on artificial neural network and perceived workload (measured with CR-10 rating scale). The hypotheses were (1) the lumbar load and perceived workload are higher during heavy tasks than during light tasks, and (2) the variation in moments during dynamic tasks is higher than during static tasks. The mean differences (MD) were tested using a paired t-test. During heavy tasks, the net moment ($MD=64.3\pm 13.5\%$, $p=0.028$) and the perceived workload ($MD=5.1\pm 2.1$, $p<0.001$) observed was significantly higher than during light tasks. The lumbar load had significantly higher variations during dynamic tasks ($MD=33.5\pm 36.8\%$, $p=0.026$) and the perceived workload was significantly higher ($MD=2.2\pm 1.5$, $p=0.002$) than during static tasks. It was concluded that the validity of this sensor-based system was supported, because the differences in the lumbar load were consistent with the perceived intensity levels and character of the work tasks.

Keywords: Physically active workers, low back pain, EMG, inertial motion units

3.1 | Introduction

Physically active workers sometimes can experience muscle and spinal overload while performing their physically demanding jobs (Ilmarinen, 2001). Such an overload is hypothesized to be due to a misbalance between the physical workload and the individual capacity of each worker (Wu & Wang, 2002). This misbalance may cause health problems among these workers, such as musculoskeletal disorders, like lower back pain (Coenen, et al., 2016; Jorgensen, et al., 2013; Holterman, et al., 2013; Andersen, et al., 2007; Bakker, et al., 2009). These problems usually result in the loss of productivity (Weerding, et al., 2005; Pransky, et al., 2005; Karpansalo, et al., 2002), loss of quality and safety (Ilmarinen, 2001; Varianou-Mikellidou, et al., 2019; Brouwer, et al., 2013), and absenteeism (Ilmarinen, 2001; Kenny, et al., 2008). Hence, to help prevent these health problems and promote sustainable employability, it is important to investigate and optimize the musculoskeletal load while performing physically demanding jobs (Nath, et al., 2017; Heerkens, et al., 2004; Costa-Black, et al., 2013).

There is a need for a device that can measure the individual working posture and related lumbar load objectively while performing a physically demanding job (Coenen, et al., 2014). Typically, this lumbar load is represented by the net moment around the center of the intervertebral body at spinal level L5/S1. Inertial motion capture systems are useful for monitoring the lumbar load of individuals in terms of 3D net moments and forces in the lower spine and for investigating the kinematics while working in industrial environments (Baten, et al., 1995, 2015, 2018; Kingma, et al., 2001; Dolan, et al., 1998; Valevicus, et al., 2018; Faber, et al., 2015; Xu, et al., 2012; Coenen, et al., 2014). Various methods have been developed to estimate the net moment in the lower back under known load-handling conditions (de Looze, et al., 1992; Baten, et al., 1995, 1996, 2000, 2015; Faber, et al., 2015). All of these methods use 3D body segment kinematics data acquired using marker-based motion analysis systems. By using e.g., the reaction forces exerted on the hands or from detailed information on the load and measured or known external forces exerted on the human body. Using inertial magnetic measurement units (IMMUs) allows for more freedom in 3D kinematics assessments in comparison to marker-based motion analysis systems (Baten, et al., 2007). However, the need to measure all the forces exerted on the human's lower body e.g., by force plates embedded in the lab floor severely limits their practical applications. A more mobile alternative is to use instrumented shoes that measure ground reaction forces while walking around (Schepers, et al., 2007, 2010; Baten, et al., 2015; Faber, et al., 2015). This system provides more freedom of movement but requires that no other external forces be exerted on the lower body (e.g., by leaning against a table or supporting the load being handled). Additionally, the relatively large weight of these shoes and their





current design make them less usable in practice. Therefore, several alternative methods for estimating lumbar load assessment were that do not require force assessment were developed. In this study, an artificial neural network (ANN) based method was developed to estimate 3D net moments (L5/S1) from electromyography (EMG) and trunk kinematics. It is trained in the initial part of each session from a limited set of calibration trials (Baten, et al., 1995, 1996, 2000, 2007, 2015). Generally, ANNs are supervised mode target net moments for the calibration trials become available by direct estimation using a linked segment model (LSM-based method; Kingma, et al., 2001; Baten, et al., 1996) scaled by the length and weight of the subject. Methods based on the LSM are driven by kinematic data from IMMUs on the trunk and arms. Details on the known loads handled during the calibration trials are required. Therefore, in the actual trials, a trained ANN-based method was used to estimate the net moments from the IMMU kinematics data and EMG data of a subject during actual work.

ANN-based methods have been evaluated in lab studies for ambulatory movement analysis, and the results were found to be promising (Baten, et al., submitted; Kingma, et al., 2001). This system is considered potentially useful for monitoring human postures and movement of workers while they are performing their jobs. As well as for estimating the mechanical workload and individual muscle response to this load while performing physically demanding jobs (Baten, et al., 1996, 2000, 2015; Valevicus, et al., 2018). Ultimately, this may represent a tool that provides workers and ergonomists with instant feedback, which may contribute to preventing overload. However, the validity and usability of this system in the uncontrolled real-life working environment of physically active workers are still unknown.

The objective of this study was to test the discriminant validity of an ANN-based method for load assessment during actual work. The research questions were: (1) what is the correlation between the ANN-based method and the LSM-based method to estimate lumbar load? (2) Can this ANN-based method detect differences in load intensity and perceived workload during light and heavy tasks? (3) Can the system detect differences in load-variability during static and dynamics tasks? And (4) can the system detect (a)symmetrical lumbar load difference around the anterior-posterior, mediolateral and longitudinal axes?

3.2 | Methods

3.2.1 | Subjects

A total of 23 subjects participated in this study, all of whom were physically active workers recruited through flyers distributed within selected companies. These selected companies were active in medical disinfection care, industrial chemical cleaning, and technical services. All subjects were informed about the study through an information letter and received a verbal explanation before the start of the study. The inclusion criterion was being a physically active worker aged between 18 and 67. The exclusion criteria were having any cardiovascular diseases; using pacemakers or other vital electronic devices; having high levels of pain or injuries in the back, shoulders, or upper extremities; or being at an advanced stage (around 20 weeks) of pregnancy. 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 according to the Dutch law (M17.208063), and all subjects signed an informed consent form.

3.2.2 | Study design and procedures

Each session with every subject comprised three phases: (1) trials for upper body segment calibration, (2) trials with known loads for supervised training and training quality validation, and (3) trials illustrating performance during a set of work-related tasks.

In phase 1 the subjects were asked to perform a set of movements while wearing IMMUs surface electromyography (sEMG) to calibrate the IMMUs to the orientation of the IMMUs relative to the body segments. The set contained 90° trunk bending, 45° trunk lateroflexion, 45° trunk rotation, 45° shoulder flexion, and 90° shoulder abduction. This was repeated five times and followed by three seconds of standing in a neutral anatomic position with the arms hanging next to the body with thumbs pointing forward. The resulting segment calibration parameters were used to translate all sensor casing kinematics within a session to body segment and joint kinematics.

To test correlation between the ANN-based method and the LSM-based method (question 1), in phase 2 trunk bending, flexion, and rotation movements were performed without (0 kg) and with holding a load of 6 and 10 kg in the hands. For all trials, 'target' net lumbar moments (spinal level L5/S1) were calculated from only the upper body kinematics applying a LSM-based method (Baten, et al 1996; Kingma, et al. 2001). Subsequently, the ANN-based estimator was trained to estimate the target moment data driven by EMG plus the kinematics data for the trials with 0 and 10 kg. Then the trained ANNs were applied to estimate the net moment for the trial of 6 kg driven by EMG and kinematics data of this





trial. The resulting net moment data estimates were validated against the target net moment data for the corresponding 6 kg trial. This direct comparison provided a quantitative assessment of the estimation accuracy. Finally, the ANN-based estimator was trained for all the bending, flexion and rotation movements and for all three weights (0, 6 and 10 kg) to be used for application in phase 3. For all training, optimal settings for ANN-based method have been used. Those settings were determined beforehand in a sensitivity study by Baten, et al. (submitted) for many combinations of the ANN settings, input data selection and preparation method parameters. This resulted in a standard feed-forward neural network with one hidden layer with 31 nodes in the hidden layer as well as sigmoid input transfer functions.

Questions 2, 3 and 4 about the discriminant validity of the ANN-based method were explored in phase 3. The subjects performed job-specific work-related tasks for 5–10 min of different intensity and dynamically were performed. For all these tasks net moment curves were estimated using the ANN-based network trained at the end of phase 2. Additionally, these tasks were ranked according to the checklist of physical workload (Peereboom & de Langen, 2012). Before the start of the measurements, the subjects received a questionnaire to identify the daily tasks and the frequency, duration, and perceived workload per task. All subjects ranked tasks according to the load, starting with the heaviest task (Peereboom & de Langen, 2012). From the list of work-related tasks, four tasks were defined, which may vary from one individual to another: (1) a light task with a low workload on the lumbar muscles, (2) a heavy task with a high workload on the lumbar muscles, (3) a static task (working with the lumbar region in the same posture), and (4) a dynamic (lifting) task in different (spinal) working postures (Arbo, 2013; Dutch Ministry of Social Affairs and Employment, 2017). To explore question 2 and 4, the task with the highest workload was selected as a heavy task, and the task with the lowest workload was selected as a light task. Net moment data curve appearances were discussed with respect to the trial perceived workload. To explore question 3 and 4, the criterion for the static task was that the lumbar region is held in the same posture or joint position for at least 4 s throughout the task with low variations in the lumbar posture when changing the posture (ISO standard 11226:2000; Arbo, 2013). The criteria for the dynamic task were as follows: the task must be a lifting one and the lumbar spine should vary in posture. After every task, the subjects were asked to rate the perceived workload of the three tasks using Borg CR-10 rating scale, ranging from 0 to 10 (0=*not burdensome*, 10=*extremely heavy* (Borg, 1998).

3.2.3 | Materials

3.2.3.1 | *Surface electromyography acquisition*

All sEMG recordings were performed using a wearable sEMG instrument (Polybench Dipha; Inbiolab, Roden, the Netherlands). Bipolar electrodes (Covidien Kendall™ H124SG Ag/AgCl electrodes; Medtronic, Minneapolis, MN, USA) with an interelectrode distance of 2 cm (heart to heart) were placed on the longissimus thoracis muscle at L1 (± 3 cm horizontal from L1) and the iliocostalis lumborum muscle at L2-L3 (± 6.5 cm horizontal from L2-L3), along with a reference electrode placed at the processus spinosus of C7 (Roy, et al., 1995) (see Figure 3.1).

3.2.3.2 | *Kinematics acquisition and net moment estimation*

Six wired IMMUs (MVN Awinda; Xsens, Enschede, the Netherlands) were used to record 3D body segment kinematics. The IMMUs were placed on the sternum, upper and lower arms, and pelvis (sacrum; Baten, et al., 2000, 2015; Koopman, et al., 2018), as shown in Figure 3.1. The sample rate was 50 Hz. All IMMU data-acquisition procedures, as well as the translation of IMMU casing kinematics data to body segment and joint kinematics data, were performed with the FusionTools/XCM software suite (Roessingh Research and Development, Enschede, the Netherlands; Baten, 2015, 2018) using the Xsens application programming interface. Using the same software suite, EMG data preparation (amplitude estimation by smoothed rectification, intrapolated resampling to 50 Hz) and synchronization with IMMU data were performed. All load exposure estimations were also performed using this software suite, with both LSM-based and ANN-based method. As well the calculation of all the descriptive statistics of the net moment curves and root-mean-square error (RMSE) values and correlation coefficients, comparing the target and estimated net moments.



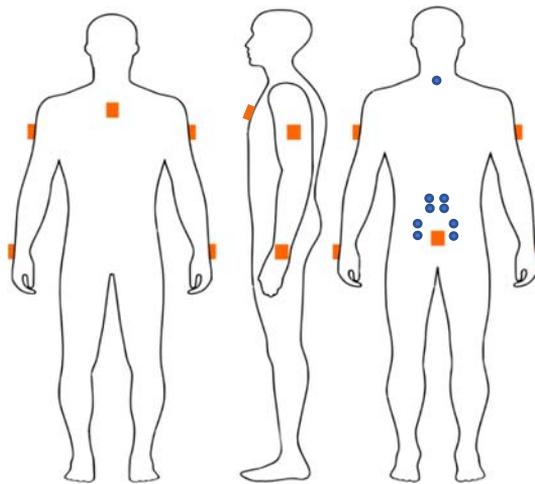


Figure 3.1 | The positioning of the sEMG electrodes and IMMUs on the body. The surface electromyography (sEMG electrodes, blue rounds) positioned on the longissimus thoracis muscle at L1 and the iliocostalis lumborum muscle at L2-L3 with a reference electrode placed at the processus spinosus of C7. The Inertial Magnetic Measuring Units (IMMUs, orange blocks) positioned on the sternum, upper and lower (left and right) arms, and pelvis (sacrum) with front (left), side (middle), and back view (right).

3.2.4 | Data analysis

To test the correlation between the ANN-based method and the LSM-based method (question 1), in phase 2 the main evaluation comprised a comparison of ANN-based estimated and target net moment trajectories in 3D. The primary outcome was the moment and RMSE at the moment magnitude ($||M||$, calculated through the net moment vector norm). Evaluation was performed for every rotation axis and net moment magnitude by means of visual inspection of data plots. And by evaluating RMSE values between the estimated and target moments and Pearson's correlation coefficient (r with $0.1 < r < 0.3$ indicating a small correlation, $0.3 < r < 0.5$ indicating a medium correlation, and $0.5 < r < 1.0$ indicating a strong correlation (Kristiansen, et al., 2019) and its squared value (r^2). Trunk bending is a movement in the mediolateral transverse (Y) axis, trunk lateroflexion is a movement in the anterior-posterior (X) axis and trunk rotation is a combined movement mainly in the longitudinal (Z) axis. If a strong correlation was found for these movements in these axes between the ANN-based method and the LSM-based method, the ANN-based method was of acceptable level.

In phase 3, the results of the questionnaire were categorized on the basis of the perceived workload, with 1 meaning a light task and 5 meaning a very heavy task (Peereboom & de

Langen, 2012). According to these scores, the tasks to test questions 2, 3 and 4 were selected. To test whether this sensor system can distinguish differences between intensity and variability of the estimated lumbar load, a discriminant validity analysis was performed. Primary parameters were mean, peak (max) and variation (deviation within a subject) of the net moment in the lumbar region and perceived workload (Borg CR-10) (Borg, 1998).

To explore if this ANN-based method can distinguish estimated lumbar load differences in intensity levels (question 3) differences between light and heavy tasks were analysed. The hypothesis was that during heavy tasks the mean net moments in the lumbar region were significantly higher. Additionally, the hypothesis that the perceived workload (Borg CR-10 score) of the heavy tasks were significantly higher than the light tasks was tested. The hypothesis of question 3 (variability level) was that the variability in net moments in the lumbar region were higher during dynamics tasks than during the static tasks.

To explore the (a)symmetrical character of working posturers, the movement direction of the moment around the anterior-posterior, mediolateral and longitudinal axes (question 4) was assessed. The direction of the net moment was divided in a positive and a negative movement direction; anterior-posterior with lateroflexion to the left (positive) and right (negative), mediolateral with flexion (positive) and extension (negative), longitudinal with rotation to the left (positive) and right (negative) axes. The hypothesis was that the tasks had asymmetrical character. These separated moment directions were tested with the same hypothesis described for question 2 and 3.

Questions 2, 3 and 4 were tested by firstly explore the distribution of the data using a Shapiro–Wilk test of normality and was considered to be normally distributed if $p \leq 0.05$. Normally distributed data between the tasks were assessed using a paired t-test and non-normally distributed data were also tested using the Wilcoxon signed-rank test. A difference of the net moment was significant when $p \leq 0.05$. The results are presented as the absolute and relative mean or mean difference (MD) \pm the standard deviation (SD). All statistical analyses were performed using IBM SPSS Statistics (version 25; IBM Corp., Armonk, NY, USA).

3.3 | Results

Out of the 23 workers who participated in this study, the data of 12 subjects were not useable because of a data-acquisition error in either the IMMUs or sEMG during essential trials. Moreover, the data of another two subjects performing dynamic and/or heavy tasks contained data-acquisition errors. Therefore, these 14 subjects were excluded from the



analysis, leaving a set of data of nine subjects (eight males, one female): four medical cleaners, three maintenance engineers, and two chemical cleaners. Their mean age was 33.7 ± 10.3 years, length 185 ± 9 cm, and weight 93 ± 12 kg. Eight subjects were right-handed, and one subject was left-handed.

3.3.1 | Question 1: Correlation ANN-based and LSM-based method

Table 3.1 shows the correlation between the ANN-based method and the LSM-based method. For one subject (subject 6), the data of the calibration movement with 6 kg were not usable and, hence, were not included in the mean results. These results differ per subject due to the individual character of the results. Calibration differs from one subject to another, which can be due to differences between the three calibration sets with three different weights or due to an unidentified event. This resulted in nonperfect calibration for subject 8, with overall medium to small correlations.

Strong correlations were observed in trunk bending (mean $r^2=0.84\pm 0.29$) and lateroflexion (mean $r^2=0.76\pm 0.27$). For both movements, one subject (subject 8) showed a small correlation ($r^2 \leq 0.12$), whereas the other subjects showed strong correlations ($r^2 \geq 0.72$). Strong correlations were also observed during trunk rotation in the longitudinal axis ($r^2=0.51\pm 0.28$), although a medium correlation was observed in the anterior-posterior axis ($r^2=0.47\pm 0.28$). Overall, the results were within the acceptable range ($r > 0.5$).

Table 3.2 compares the RMSE values between the ANN-based method and the LSM-based method. These results indicate a mean estimation errors of 9.25 ± 6.01 Nm, relative to the typical net moment ranges from 150 to 220 Nm (see Table 3.4).



Table 3.1 | ANN-based method performance in handling known loads.

Movement	Axis	Subject												
		1	2	3	4	5	6	7	8	9	Mean	SD		
Bending	Y	r	0.97	0.98	0.96	0.97	0.98	-	0.96	0.98	0.35	0.98	0.89	0.22
		r ²	0.94	0.95	0.93	0.93	0.96	-	0.92	0.96	0.12	0.96	0.84	0.29
Lateroflexion	X	r	0.94	0.93	0.95	0.95	0.94	-	0.85	0.92	0.32	0.92	0.85	0.22
		r ²	0.89	0.87	0.91	0.90	0.88	-	0.72	0.84	0.10	0.84	0.76	0.27
Rotation	Z	r	0.63	0.23	0.84	0.84	0.81	-	0.76	0.92	0.38	0.92	0.68	0.24
		r ²	0.40	0.06	0.70	0.70	0.65	-	0.58	0.84	0.15	0.84	0.51	0.28

Shown are the correlation between the net moment at L5/S1 estimated with the ANN-based method and with the LSM-based method. Correlation is represented by the Pearson correlation coefficient (r) and determination coefficient (r^2) and are shown only for the axis of movement in each task (i.e. in the mediolateral axis (y) for the trunk bending tasks, in the anterior-posterior axis (x) for the lateroflexion tasks (y) and the longitudinal axis (z) for the rotation tasks respectively). Shown are individual values for each subject plus the mean and standard deviation (SD) over all subjects. No valid data were obtained for subject number 6 for reasons of partially missing data in the 6 kg trial.

3.3.2 | Question 2: Intensity

Table 3.3 shows the tasks per job according to the results of the questionnaire. All the subjects, except for one industrial cleaner, perceived the dynamic task as the heaviest task of their job. Small differences in the checklist for physical workload scores were observed, which were related to the diversity in the individual job description.

Table 3.3 | Tasks per job type, based on the results of the checklist for the physical workload.

Task perception	Medical disinfect care	Technical services	Industrial chemical cleaning
Light	Changing working clothing	Administration	Disassemble gas mask
Static	Assembly or lamination of surgical instruments	Tinkering under a machine	Cleaning chemical hazard suit
Heavy and dynamic	Carrying bins of 3 up to 10 kg	Moving (pushing and/or pulling) bin with wastewater of 1000 kg or carrying toolbox of 35 kg	Carrying bins of 5 up to 10 kg

In Table 3.4 presents the net moment per task together with the experienced workload of the tasks according to the subjects. During all the tasks, the mean net lumbar moment was 25.2 ± 16.8 Nm, the mean peak moment was 179.5 ± 152.9 Nm, and the mean variation was 15.5 ± 11.5 Nm.

Table 3.4 | Net moments, load ranking, and perceived workload for each task.

Task perception	Net moment (Nm)			Questionnaire load factor (1-5)	Perceived workload (Borg 0-10)
	Mean	Peak	Variation		
Light task	18.7 ± 8.1	166.4 ± 195.5	13.0 ± 10.6	1.0 ± 0.0	0.9 ± 0.8
Static task	26.3 ± 19.2	153.5 ± 106.1	13.7 ± 9.9	3.6 ± 1.3	3.8 ± 1.6
Heavy and dynamic task	30.7 ± 20.0	218.5 ± 154.4	19.8 ± 13.8	4.8 ± 0.4	6.0 ± 2.0

The questionnaire workload factor with 1=light work and 5=very heavy task. The experienced workload (Borg CR-10) according to the subjects with 0=not burdensome and 10=extremely heavy.

Table 3.5 summarizes the differences between light and heavy tasks presented for all subjects, with a typical example in Figure 3.2. It can be seen that the net moments estimated using the ANN-based method exhibit overall higher moments during heavy tasks with more variations than during light tasks. The differences in the mean net moment between light and heavy tasks were significant ($MD=64.3 \pm 72.1\%$, $p=0.028$), whereas the other differences

were not. The perceived workload was significantly higher during the heavy tasks than during light tasks (MD=5.1±2.1, p<0.001).

Table 3.5 | Light vs heavy tasks.

Parameter	Absolute [Nm]		Relative (%)		p
	MD±SD	[95% CI]	MD±SD	[95% CI]	
Mean	12.0±13.5	[1.7;22.4]	64.3±13.5	[8.9;119.8]	0.028
Peak	52.1±256.9	[-145.4;249.6]	23.9±117.6	[-66.5;114.2]	0.560
Variation	6.8±9.4	[-0.4;14.0]	52.1±71.8	[-3.1;107.3]	0.061

Shown are the absolute [Nm] and relative [%] differences between the light tasks and the heavy tasks through mean (MD), standard deviation (SD), and 95% confidence interval (CI) of these differences for the moment magnitude ($||M||$).

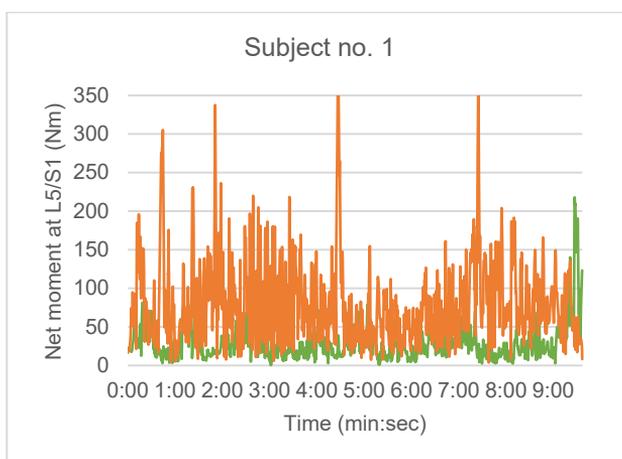


Figure 3.2 | Typical example of net moment curves during light (green) and heavy (orange) tasks (Subject 1).

3.3.3 | Question 3: Variation

Table 3.6 summarizes the differences between static and dynamic tasks presented for all subjects, with a typical example in Figure 3.3. It can be seen that the mean net moments of the magnitude estimated using the ANN-based method exhibit overall higher values during dynamic tasks with more variations than during static tasks. The difference in the variation between static and dynamic tasks was significant (MD=44.8±48.9%, p=0.025). The perceived workload was significantly higher during the dynamic tasks than during static tasks (MD=2.2±1.5, p=0.002).

Table 3.6 | Static vs dynamic tasks.

Parameter	Absolute [Nm]		Relative (%)		p
	MD±SD	[95% CI]	MD±SD	[95% CI]	
Mean	4.42±8.03	[-1.8;10.6]	16.8±30.6	[-6.7;40.4]	0.137
Peak	65.0±138.6	[-41.5;171.5]	42.3±90.3	[-27.0;111.7]	0.197
Variation	6.13±6.69	[1.0;11.3]	44.8±48.9	[7.2;82.4]	0.025

Shown are the absolute [Nm] and relative [%] differences between the static tasks and the dynamic tasks through mean (MD), standard deviation (SD), and 95% confidence interval (CI) of these differences for the moment magnitude ($|M|$).

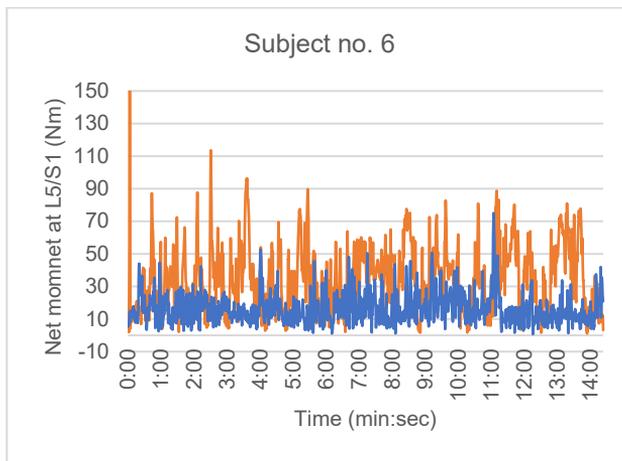


Figure 3.3 | Typical example of net moment curves during static (blue) and heavy (orange) tasks (Subject 6).

3.3.4 | Question 4: (a) Symmetrical lumbar load

Table 3.7 summarizes the differences between light and heavy tasks presented while taking into account the direction of the movement around the axis (e.g., flexion versus extension). Similar results of the intensity levels were observed as in Table 3.5. It was observed that the mean net moment is significantly higher during heavy tasks than during light tasks ($MD \geq 92.3 \pm 105.4\%$, $p \leq 0.030$) as well as in the singular anterior-posterior axis ($MD \geq 56.8 \pm 44.9\%$, $p \leq 0.016$). All the other differences were not significant.

Table 3.7 | Direction of the net moment around the axis of the light vs heavy tasks.

Parameter	Direction	Axis	Absolute [Nm]		Relative (%)		p	
			MD±SD	[95% CI]	MD±SD	[95% CI]		
Mean	Positive	M	152.0±92.8	[80.6;223.4]	1324.0±808.6	[702.4;1945.5]	0.001	
		Mx	5.6±4.4	[2.2;8.9]	56.8±44.9	[22.3;91.3]	0.005	
		My	-0.6±8.6	[-7.2;6.0]	-2.5±33.6	[-28.4;23.3]	0.828	
	Negative	Mz	1.3±3.6	[-1.5;4.1]	15.6±43.7	[-18.0;49.1]	0.317	
		M	9.5±10.9	[1.8;17.9]	92.3±105.4	[11.3;173.3]	0.030	
		Mx	8.4±8.3	[2.1;14.8]	95.0±93.6	[23.1;166.91]	0.016	
	Variation	Positive	My	3.4±13.5	[-5.7;12.5]	24.4±97.2	[-41.0;90.4]	0.424
			Mz	4.8±7.2	[-0.7;10.3]	53.5±79.7	[-7.8;114.8]	0.079
			M	6.6±13.5	[-2.5;15.7]	37.3±76.8	[-14.2;88.9]	0.138
Negative		Mx	1.3±7.5	[-3.8;6.4]	11.9±68.0	[-33.8;57.5]	0.575	
		My	1.1±11.2	[-6.5;8.6]	6.8±72.4	[-41.8;55.5]	0.762	
		Mz	-1.1±6.7	[-5.6;3.5]	-12.2±76.7	[-63.7;39.3]	0.610	
Negative		M	2.2±9.5	[-4.2;8.6]	17.3±73.7	[-32.2;66.8]	0.453	
		Mx	5.3±9.6	[-1.2;11.8]	38.1±69.4	[-8.6;84.7]	0.099	
		My	1.1±8.6	[-4.7;6.8]	9.9±79.0	[-43.1;63.0]	0.686	
Mz	2.3±8.4	[-3.3;8.0]	24.3±88.4	[-35.0;83.7]	0.382			

Shown are the absolute [Nm] and relative [%] differences between the static tasks and the dynamic tasks through mean (MD), standard deviation (SD), and 95% confidence interval (CI) of these differences for the anterior-posterior (Mx) with lateroflexion to the left (positive) and right (negative), mediolateral (My) with flexion (positive) and extension (negative), longitudinal (Mz) with rotation to the left (positive) and right (negative) axes separately and for the moment magnitude (||M||). Statistically significant differences are marked green.

Table 3.8 | Direction of the net moment around the axis of the static vs dynamic tasks.

Parameter	Direction	Axis	Absolute [Nm]		Relative (%)		p
			MD±SD	[95% CI]	MD±SD	[95% CI]	
Mean	Positive	M	100.5±132.8	[11.3;189.7]	302.7±399.7	[34.1;571.2]	0.031
		Mx	-6.6±14.8	[-16.6;3.3]	-34.5±76.9	[-86.1;17.1]	0.168
		My	-18.1±25.7	[-35.4;-0.8]	-47.1±66.9	[-92.0;-2.1]	0.042
	Negative	Mz	-6.5±8.6	[-12.3;-0.7]	-45.2±60.2	[-85.7;-4.8]	0.032
		M	-44.9±156.2	[-149.9;60.0]	-276.5±960.7	[-921.9;368.9]	0.362
		Mx	-7.7±38.6	[-33.6;18.3]	-54.0±272.6	[-237.1;129.1]	0.526
Variation	Positive	My	-22.4±78.0	[-74.8;30.0]	-161.7±561.8	[-539.1;215.7]	0.362
		Mz	-6.7±21.4	[-21.0;7.7]	-59.0±189.5	[-186.3;68.3]	0.326
		M	-6.9±44.9	[-37.1;23.2]	-39.4±254.7	[-210.5;131.7]	0.619
	Negative	Mx	-5.1±12.5	[-13.6;3.3]	-46.2±112.8	[-122.0;29.6]	0.204
		My	-4.8±13.1	[-13.6;3.9]	-31.2±84.3	[-87.8;25.4]	0.248
		Mz	-8.0±10.5	[12.1;0.9]	-90.8±10.5	[-171.2;10.4]	0.031
Negative	M	-27.2±97.5	[-92.7;38.3]	-210.5±755.0	[-717.7;296.8]	0.377	
	Mx	-1.5±25.3	[-18.5;15.5]	-10.7±182.2	[-133.1;111.7]	0.849	
	My	-6.4±26.1	[-23.9;11.1]	-59.0±240.5	[-220.6;102.5]	0.434	
Mz	-3.3±17.6	[-15.1;8.5]	-34.4±183.7	[-157.8;89.1]	0.549		

Shown are the absolute [Nm] and relative [%] differences between the static tasks and the dynamic tasks through mean (MD), standard deviation (SD), and 95% confidence interval (CI) of these differences for the anterior-posterior (Mx) with lateroflexion to the left (positive) and right (negative), mediolateral (My) with flexion (positive) and extension (negative), longitudinal (Mz) with rotation to the left (positive) and right (negative) axes separately and for the moment magnitude (||M||).

Table 3.8 summarizes the differences between static and dynamic tasks while taking into account the direction of the movement around the axis. When the direction of the moment around the separated axis was considered, significantly less variation was observed during rotation to the left around the longitudinal axis during dynamic tasks ($MD = -90.8 \pm 10.5\%$, $p = 0.031$). In addition, significant differences in the mean moment ($\|M\|$, M_y , and M_z) were observed in the positive direction ($MD \leq 302.7 \pm 399.7\%$, $p \leq 0.042$).

3.4 | Discussion

The results of the analysed data showed that the ANN-based method can estimate the net moments of the 6 kg test trials with an accuracy of about 9 Nm in comparison with a LSM-based method after being trained with 0 and 10 kg test trials. These results are in line with the research of Baten, et al. (submitted) and support the notion that the ANN-based method can be used for evaluating lumbar load exposure patterns and exposure levels in real-life work settings. This ANN-based method seemed to be capable of distinguishing differences in the intensity level between light and heavy tasks which are in line with the perceived workload. Also, it can distinguish differences in variation level between static and dynamic tasks. When the direction of the moment around the (anterior-posterior, lateroflexion or longitudinal) axis was considered, similar results were observed between light and heavy tasks. However, between static and dynamics tasks, the variation differences of the net moment were not observed. This is because of the differences due to the direction of the moment around the axis. This indicates that it is important to include the direction of the movement and, thereby, the moment around the axis and (a)symmetrical character of the movement when analysing the lumbar load. It is also important to know in which direction the user is moving, instead of focusing only on the size this moment. This study showed that this system can measure the lumbar load and the direction of this load around the different axes in uncontrolled real-life working conditions.

Like in state-of-the-art research, this study provides insights as provided insight into the usability and validity of this ANN-based method. This method requires only EMG and IMMU data without does require any a priori knowledge on the regarding load for monitoring the lumbar load of physically active workers. Tasks were selected on the basis of actual working activities performed in the natural environments of physically demanding jobs. This study also explored the effect of the direction of the moment around the axis with which asymmetrical working routines can be investigated. For example, in case of a paver who uses only one hand to lift tiles or fabric workers who mainly rotate in one direction or axis. Insight in these movements and moments can provide useful information that can help



prevent musculoskeletal complaints might effectively. It should also be mentioned that the diversity in the jobs, related workloads, and selected tasks was a challenging aspect. For example, it was challenging to select uniform tasks for the workers because of the differences in their working activities. Real-life tasks are not merely light, heavy, static, or dynamic; rather, a static or dynamic task may also be light or heavy, which results in an overlap between tasks.



The main weakness of this study is the lack of a reference method during actual work. Currently, the mechanical workload of physically active workers is assessed by observations (video), questionnaires, performance tests, or combinations of motion trackers and force sensors (Jorgensen, et al., 2013; Vieira & Kumar, 2004; Faber, et al., 2015). Both observations and questionnaires are indirect methods and do not provide information about the working posture or related lumbar load. Reference systems, such as Vicon motion-capture cameras, are not practical or allowed in the real-life working environment (Koopman, et al., 2018; Jorgensen, et al., 2013; Xu, et al., 2012; Juul-Kristensen, et al., 2001). The closest option for a reference method is the method that uses IMMUs and ground reaction forces assessed using an instrumented shoe (Scheepers, et al., 2007; Faber, et al., 2018; Koopman, et al., 2018). This method, however, has two major drawbacks. The first drawback is that it yields erroneous results every time an external force other than the ground reaction force is exerted on the lower body (e.g., external forces resulting from supporting loads handled with any part of the lower body or from leaning against a table or workbench). The second drawback is that it requires wearing heavy and somewhat bulky instrumented shoes, which constitutes potential noncompliance with shoe safety functionality and regulations.

The current setup is not usable in real-life physically demanding jobs. Gathering data during actual work seemed to be technically challenging and resulted in the data of 14 out of the 23 subjects not being used in the study analysis. To improve the usability, means an improved data-acquisition setup is required for future studies and applications. This method needs to be validated in follow-up research further with more subjects and in more real-life working situations. Preferably this should be done in work situations in which the instrumented shoes method can serve as a reference and/or situations in which all external forces are known in a way. The environment's influence on the system (e.g., disturbance in the observability of the earth's magnetic field) also needs to be further explored (de Vries, et al., 2008) and dealt with. Moreover, the design (mechanical) of the system needs to be improved (e.g., by integrating the sensors in the clothes). In addition, the monitored working posture and lumbar load exposure should be linked to ergonomic guidelines to obtain feedback regarding exceeding acceptable loading levels or loading patterns. This

information can be provided to the user (e.g., using a traffic light model) to indicate areas of overload risk. Preferably fully automated with instant feedback to the user. Such a system would provide workers with feedback regarding their working behaviours, which can help them improve their behaviour and decrease their complaints. Both work postures and their net moments as well as the link to ergonomic guidelines need to be further explored in follow-up research. Estimated net moment data seem to be very suitable for exposure variation analysis. Adding load exposure pattern analysis to the current analysis of only the amount of load exposure (Mathiassen and Winkel, 1991), by means of generating a 2D graph of the joint distribution of intensity and of the net moment data dynamically.

The results of this study show that not only can the ANN-based method be used in monitoring lumbar back load exposure in physically demanding jobs, but also it has the potential to be used with office workers (lumbar load during sedentary behaviour) and in the fields of rehabilitation medicine and sports applications.

3.5 | Conclusion

In an in-vivo setup, lumbar loads could be distinguished with the ANN-based method in terms of intensity and variation levels. The moments in the lumbar region are significantly higher during heavy tasks than during light tasks and the amount of variation is significantly higher during dynamic tasks than during static tasks. The estimated net moments were consistent with perceived intensity levels and character of the work task in physically demanding occupations. It was concluded that the results of this study support the validity of this sensor-based system.

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Disclosures

There is no conflict of interest.

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Chapter 4

Patent application of an instrument, system and method for use in respiratory exchange ratio

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Pending

Abstract

The instrument has sensors for sensing oxygen and/or carbon dioxide content in exhaled air received in a receiving area in front of a mouth, an air flow rate sensor for sensing exhaled air flow rates in a flow rate sensing location and an air shield for shielding the receiving area and the flow rate sensing location from air flows from the environment. The air shield leaves a space between the air shield and the mouth of the person in open communication with the environment. The air flow rate sensor senses air flow speed in a location spaced from the exhaled air receiving area, rearward of a front end of the exhaled air receiving area and above a lower end of the exhaled air receiving area. In another embodiment a sensor for sensing ambient wind is provided.



4.1 | Field and background of the invention

The invention relates to an instrument according to the introductory portion of claim 1 and to a system according to the introductory portion of claim 10. The invention also relates to methods according to the introductory portions of each of claims 14 and 15. Such an instrument, such a system and such methods are known from European patent application 2 913 003.

Monitoring the energetic workload of physically active workers, such as fire fighters, chemical cleaners and construction workers allows to identify types of tasks of which the workload is too high to allow the task to be performed over longer periods of time without entailing an increase of the risk of health complaints and/or to allow the task to be performed without a decrease of body control that entails a safety hazard and/or a reduced quality of the result of the performed task. Other applications for which such instruments, systems methods can be used include monitoring patients during revalidation exercises, athletes during training and measuring performance capacity indicators of athletes, such as maximum oxygen intake.

A reliable method of measuring energetic workload over longer periods of time is measuring the respiratory exchange ratio (RER). The RER is the ratio of the produced volume of carbon dioxide (CO₂) to the consumed volume of oxygen (O₂) (i.e.: $\dot{V}CO_2/\dot{V}O_2$). During steady state low-intensity activity, the RER is generally between 0.7 to 0.8 and up to about 0.88. During such activity, fatty acids constitute the primary fuel. During steady state higher intensity activity, the RER is between 0.85 and 1.0 indicating that a mix of fat and carbohydrates is being burned, the proportion of carbohydrates increasing with effort. During steady state very high intensity activity, the RER can exceed 1.0 as a result of hyperventilation and increased buffering of blood lactic acid from muscles, carbohydrate being the predominant fuel source. Thus the RER is a parameter indicating steady state effort in relation to maximum effort for a subject even though a range of values has been found as indicative of maximum effort.

The RER is measured by determining oxygen consumption and carbon dioxide production from oxygen and carbon dioxide contents in inhaled and exhaled air and volumes of breathed air. In some applications, measuring only (maximum) oxygen consumption or (maximum) carbon dioxide production is desired or sufficient.

Measurement of maximum oxygen consumption and carbon dioxide production conventionally requires a time-consuming and expensive laboratory test. It cannot be used to measure in a working situation. For measurement of the RER in working situations,





wearable breathing gas analyzers are commercially available such as the 'Oxycon Mobile' available from Vyair Medical, U.S., the 'K5' available from Cosmed, Italy and the VmaxST available from SensorMedics, U.S.. A disadvantage of such systems is that its use involves wearing a facemask or a mouthpiece, which increases breathing resistance, is experienced as claustrophobic and oppressive, increases the breathing resistance and makes communication by speech practically impossible. Especially in a working situation of physically active workers communication is in most cases very important, also for safety. Additionally, it is uncomfortable, which makes it less suitable for measuring during a full working day. A presently used alternative is the use of a widely commercially available heart rate monitor. While inexpensive, unobtrusive and practical in use, the measurement properties for individual determination of energetic workload are unacceptable, unless the heart rate is individually calibrated with a previously mentioned laboratory test and other conditions apply (e.g. no heart rate medication).

From European patent application 2 913 003 an instrument for collecting a sample of humanly breathed air is known which includes a funnel or tube shaped housing element arranged for guiding inhaled and/or exhaled air along, around or through a sensor unit. The funnel or tube shaped housing element is provided with an opening so that the inhaled and/or exhaled air is at least partially guided through the opening. The funnel or tube shaped housing element may be held at a distance from the mouth, nose and/or other portions of the face, so that the funnel or tube shaped housing element provides a partially open volume of space of the inhaled and/or exhaled air. This allows avoiding heat accumulation, pressure area and/or a sense of constriction and allows comfort of wear and use to be improved.

4.2 | Summary of the invention

It is an object of the present invention to provide an instrument, a system and a method that allows accurate measurement of volumes of inhaled and exhaled air and of concentrations of oxygen and/or carbon dioxide in at least the exhaled air while leaving an at least partially open volume of space directly in front of the nose and mouth of the person.

According to the invention, this object is achieved by providing an instrument according to claim 1 and a method according to claim 15. Because the air flow rate sensor is an air flow speed sensor for sensing air speed in an area spaced from the exhaled air receiving area or areas rearward of a front end of the exhaled air receiving area or areas and above a lower end of the exhaled air receiving area or areas, the velocity of exhaled air over a period of

time can be used as an accurate measure of the volume of exhaled air over that period of time. In particular, in this air flow rate sensing location, exhaled air from the mouth as well as exhaled air from the nose is still sufficiently far upstream of the exhaled air receiving area so as to be undisturbed by elements receiving the exhaled air for sensing the oxygen and/or carbon dioxide contents in the received air. This allows the air speed to be measured accurately without significant disturbance by the oxygen and/or carbon dioxide sensing surfaces.

The invention can also be embodied in a system according to claim 11 and in a method according to claim 16.

Flows of air other than flows of air inhaled and exhaled by the person can disturb the measurement of the flow rate of air inhaled and/or exhaled by the person. By providing a wind speed sensor for sensing wind speed in a wind speed sensing location outside of an area rearward of the shield, flows of air other than flows of air inhaled and exhaled by the person, in particular ambient air, which influence the measurement of the flow rate of air inhaled and/or exhaled by the person, can be measured as well. The system according to this embodiment further comprises a signal processor connected to the oxygen and/or carbon dioxide sensors for receiving signals representing measured oxygen and/or carbon dioxide contents, connected to the air flow rate sensor for receiving signals representing measured air flow rates and connected to the wind sensor for receiving signals representing measured wind speed. The signal processor is arranged for calculating oxygen consumption from the signals representing oxygen contents and for calculating carbon dioxide production from the signals representing carbon dioxide contents and from air flow rates while applying a correction or suppression in accordance with a value of the wind speed signal. A suppression of measured oxygen consumption signals causes signals obtained during time intervals in a given period of time in which a strong wind has been measured to be given less than full weight or no weight in the calculation of the oxygen consumption over the given period of time. If too much wind has been sensed during the entire period of time or during a too large portion of the period of time, the signal processing device may output a signal indicating that no sufficiently reliable measurement over the given period of time was possible.

Thus, the calculated oxygen consumption can be corrected and/or suppressed in accordance with sensed wind speeds. The calculated oxygen consumption can for instance be corrected in accordance with sensed wind speeds within a first range and additionally be suppressed in response to sensed wind speeds in a range that significantly affects the



accuracy of even the corrected measurement of flow rates and/or oxygen contents and/or carbon dioxide contents.

Particular elaborations and embodiments of the invention are set forth in the dependent claims.

Further optional features, effects and details of the invention appear from the detailed description and the drawings.

4.3 | Brief description of the drawings

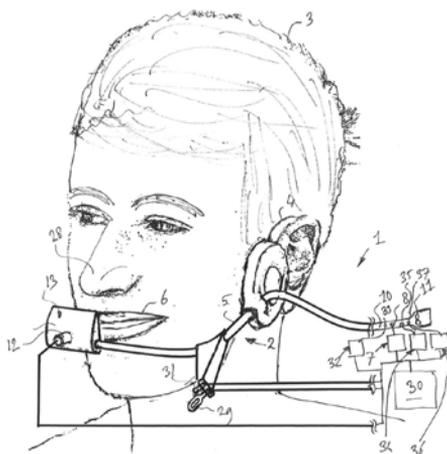


Figure 4.1 | The energetic headset: a perspective view of a head of a person wearing an example of an instrument according to the invention.

Figure 4.1 is a perspective view of a head of a person wearing an example of an instrument according to the invention;

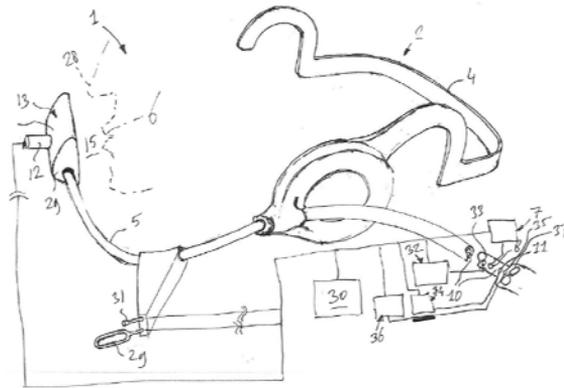


Figure 4.2 | The energetic headset: a perspective view of a head of the instrument.

Figure 4.2 is a perspective view of a head of the instrument shown in Figure 4.1;

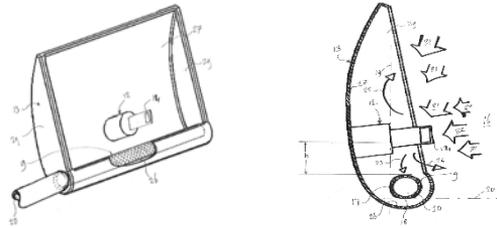


Figure 4.3 (left) | Air shield of the energetic headset; a perspective partially cut-away view with the air flow speed sensor. Figure 4.4 (right): Air shield of the energetic headset; a cross-sectional side view with air flow speed sensor and flow directions illustrated.

Figure 4.3 is a perspective partially cut-away view of an air shield, an air flow speed sensor and a portion of an air guiding conduit and sensor carrier bracket adjacent to the air shield, all of the instrument shown in Figures 4.1 and 4.2;

Figure 4.4 is a cross-sectional side view of the air shield and air flow speed sensor shown in Figure 4.3; and

Figure 4.5 is a flow chart of an example of a method according to the invention of calculating a RER from signals representative of air flow speed, wind speed and oxygen contents and carbon dioxide contents of at least exhaled air.



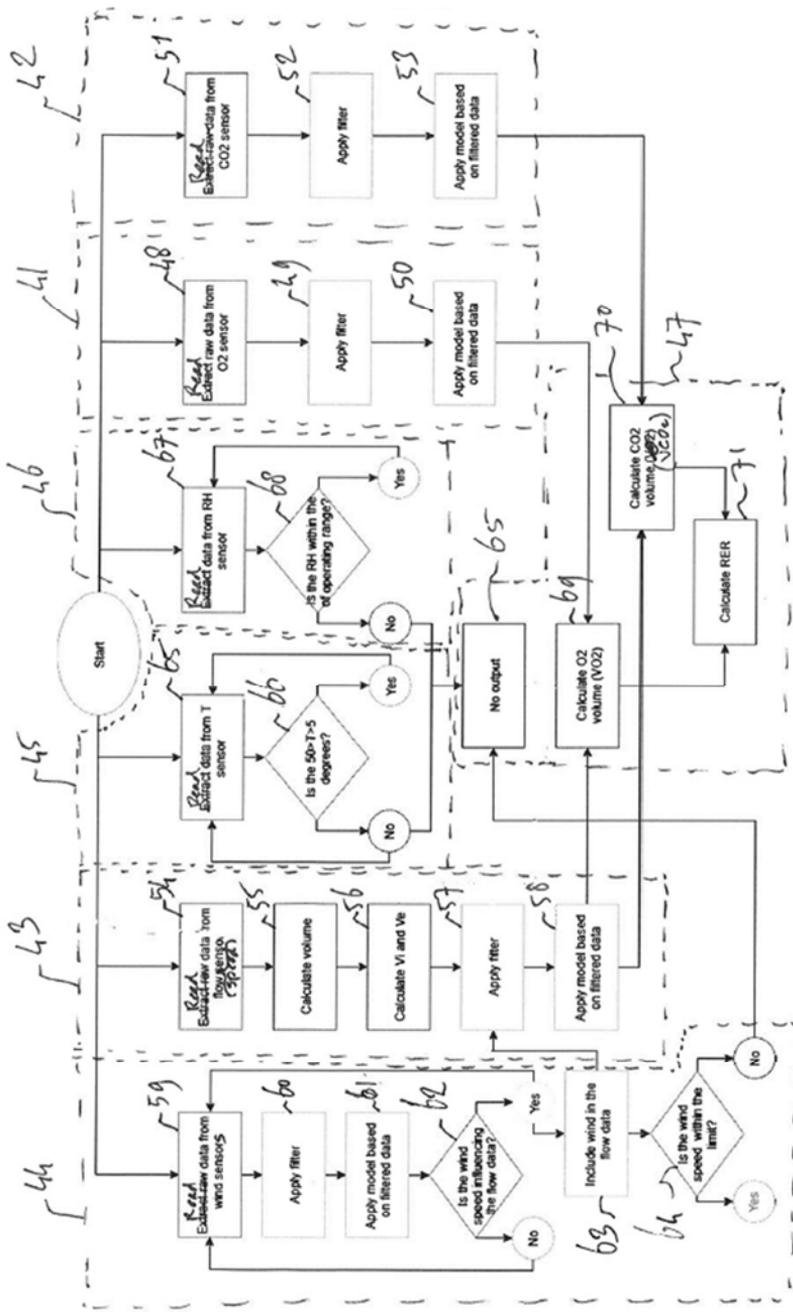


Figure 4.5 | Flow chart of a method to calculate the Respiratory Exchange Ratio (RER) from the oxygen (O₂), carbon dioxide (CO₂), air flow speed and wind speed sensors.

4.4 | Detailed description

In Figures 1-4 an example of an instrument 1 according to the invention is shown. The instrument 1 has a bracket 2 for mounting the instrument to a head 3 of a person, of whom the RER is to be measured or monitored, in an operating position as shown in Figure 4.1.

The bracket 2 is composed of a head engagement portion 4 and a sensor carrier portion 5 projecting forwardly and downwardly from the head engagement portion 4 when the instrument 1 is in the operating position. The bracket 2 is arranged such that the sensor carrier portion 5 can extend to an area closely in front of a mouth 6 of the person when the head engagement portion 4 is in engagement with the head 3 holding the instrument 1 in the operating position.

The instrument 1 further includes an oxygen content sensor 7 for sensing oxygen content in air received in exhaled air receiving areas 9 (see Figures 2-4) in front of the mouth 6. In this example, the oxygen sensor 7 has a sensing interface 8 in a conduit 10 from the exhaled air receiving areas 9 to a suction generator in the form of a ventilator 11. In this example, the suction generator is located downstream of the oxygen sensing interface 8, but the ventilator or other air displacement member may also be located upstream of the oxygen sensing interface. The air receiving areas 9 are formed by openings in a tube forming an upstream end of the conduit 10. A carbon dioxide sensor 36 with a carbon dioxide sensor sensing interface 37 in the conduit 10 is provided for sensing carbon dioxide contents in the air received in the exhaled air receiving area 9.

An air flow rate sensor 12 (see Figures. 3 and 4) is arranged for sensing exhaled air flow rates in an exhaled air flow rate sensing location. In this example, the air flow rate sensor has a sensor interface 14 located in the air flow rate sensing location. However, the air flow rate sensor may also have a sensing interface located outside the air flow rate sensing location, for instance in the form of a pressure sensing interface located in a pitot tube having an open end in the air flow rate sensing location or located in a conduit communicating with a venturi in the air flow rate sensing location.

In front of the air receiving areas 9 and the air flow rate sensing location, an air shield 13 is provided for shielding the exhaled air receiving areas 9 and the air flow rate sensing location from air flows from an environment forwardly of the shield 13. The air shield 13 is shaped and positioned for leaving a space 15 (see Figure 4.2) between the air shield 13 and the mouth 6 of the person, which space 15 is in open communication with the environment.

The air flow rate sensor is an air flow speed sensor 12 having a hot air surface sensing interface 14. The air flow rate sensing location is located spaced from the exhaled air



receiving areas 9 in an area 16 (see Figure 4.4) rearward of a front end 17 of the exhaled air receiving areas 9 and above a lower end 18 of the exhaled air receiving areas 9. In the example shown in Figure 4.4, this air flow rate sensing location 16 is located to the right of vertical dash-and-dot line 19 and above horizontal dash-and-dot line 20.

The instrument 1 is wearable and can be used for sensing at least oxygen or carbon dioxide contents and flow rates of air exhaled by a human person when attached in an operating position to the head 3 of the person, as is shown in Figure 4.1.

The air flow rate sensor is an air flow speed sensor 12 for sensing air speed in an area 16 spaced from the exhaled air receiving areas 9, rearward of a front end 17 of the exhaled air receiving areas 9 and above a lower end 18 of the exhaled air receiving areas 9. In this air flow rate sensing location 16, exhaled air from the mouth 6, as indicated by arrows 21, or from the nose 28, as indicated by arrows 22, is still sufficiently far upstream of the exhaled air receiving areas 9 so as to be undisturbed by the tube in which the openings form the exhaled air receiving areas 9 for receiving the exhaled air are provided. This allows the air speed to be measured accurately, so that the velocity of exhaled air over a period of time can be used as an accurate measure of the volume of exhaled air over that period of time.

In this example, the sensing interface 8 for sensing oxygen contents in the air received via the openings forming the exhaled air receiving areas 9 is located downstream of the exhaled air receiving areas 9. It is, however, also conceivable to arrange the sensing interface or interfaces directly in the exhaled air receiving areas. In such an embodiment, the sensing interface or interfaces form the exhaled air receiving area or areas. Also in such an embodiment, the location of the air flow rate sensing location spaced from the exhaled air receiving area or areas, rearward of a front end of the exhaled air receiving area or areas and above a lower end of the exhaled air receiving area or areas ensures that exhaled air from the mouth and/or from the nose, is still sufficiently far upstream from structures in the exhaled air receiving area or areas so as to be undisturbed, which allows the air speed to be measured accurately.

For reliably ensuring that the speed of the exhaled air flow is undisturbed where the air speed is measured, the air flow speed sensing area 16 is preferably located at a distance h of at least 5 mm and more preferably at least 10 mm above the exhaled air receiving area or areas 9.

For reliably receiving both exhaled air from the nose 28 (arrows 21) and exhaled air from the mouth 6 (arrows 22) free from ambient air, the exhaled air receiving areas 9 are located behind a lower quarter portion of the air shield 13. Thus, air from the nose can flow along



the shield 13 towards the exhaled air receiving areas 9 (arrow 23 in Figure 4.4) and partially past the exhaled air receiving areas 9 (arrow 24 in Figure 4.4) while being shielded from mixing with ambient air (both upstream and downstream of the air flow speed sensing interface 14), while air from the mouth flows directly against the air shield 13 and drives any ambient air away from the exhaled air receiving areas 9. After having passed the air flow speed sensing interface 14 air exhaled from the mouth can flow partially to the exhaled air receiving areas 9 (arrow 23), partially past the exhaled air receiving areas 9 (arrow 24) and partially away from the exhaled air receiving areas 9 (arrow 25). Thus, a particularly small air shield 13 is sufficient for keeping ambient air away when receiving exhaled air from the nose 28 and when receiving exhaled air from the mouth 6 for measuring the contents of oxygen and/or carbon dioxide in the exhaled air.

For guiding exhaled air from the nose 28 and the mouth 6 towards the exhaled air receiving areas 9 and effectively keeping ambient air away from the exhaled air receiving areas 9, the air shield 13 has an upwardly facing wall surface 26 extending from underneath the exhaled air receiving areas 9 until rearward of the exhaled air receiving area.

The air shield 13 has a rearward facing wall surface 27 extending from forwardly of the exhaled air receiving areas 9 until upwardly of the air flow rate sensing location formed by the air flow speed sensing interface 14. This rearward facing wall surface 27 is particularly effective for, on the one hand, deflecting exhaled air 21 from the nose 28 downward along the air flow rate sensing location and deflecting exhaled air 22 from the mouth 6 upward after at least a portion of that exhaled air has passed the air flow rate sensing location, so that a particularly representative flow of air along the exhaled air receiving areas 9 is obtained, regardless whether the air is exhaled via the nose 28 or via the mouth 6.

For effectively deflecting the exhaled air while causing little flow resistance, the rearward facing wall surface 27 of the air shield 13 is curved with a hollow curvature. The curvature preferably has a radius or radii of curvature between 5 and 15 cm. The curvature preferably extends over an angle of deflection of 5 to 15°.

If, as in the present example, the upwardly facing wall surface 26 is contiguous with the rearward facing wall surface 27, exhaled air is lead to the exhaled air receiving areas 9 particularly effectively and inflow of ambient air between the upwardly facing wall surface 26 and the rearward facing wall surface 27, which could mix with the exhaled air is avoided.

For driving an air stream through the entry passages 9 into and through the air duct 10, the air displacement device 11 is provided. The oxygen content sensor 7 includes an oxygen sensing surface 8 downstream of the entry passage 9. Thus, in use at least a portion of the



exhaled air that reaches the exhaled air receiving areas 9 is drawn away through the opening 9 and towards the oxygen sensing surface 8 and the carbon dioxide sensing interface 37. This allows exhaled air to be sampled in a representative manner throughout each cycle of exhaling air, because air is continuously drawn in from a flow of air along the exhaled air receiving areas 9.

While air is inhaled, ambient air will flow to the air receiving areas 9 and is drawn away through the opening 9 and towards the oxygen sensing surface 8 and the carbon dioxide sensor sensing interface 37. This allows to intermittently measure the oxygen and carbon dioxide contents of inhaled air using the same sensing interfaces 8, 37. It is also possible to measure the concentrations of oxygen and carbon dioxide of inhaled (usually ambient) air outside the air conduit 10, for instance using separate sensors exposed to ambient air or using a separate apparatus measuring concentrations of oxygen and carbon dioxide in ambient air. Since concentrations of oxygen and carbon dioxide in ambient air tend to vary quite slowly, these concentrations can be measured at a much lower frequency than the concentrations of oxygen and carbon dioxide in exhaled air.

The entry openings 9 are distributed over a major portion of a width of the air shield 13, so that exhaled air is sampled over the major portion of the width of the air shield 13, which is also advantageous for representative sampling from the flow of exhaled air. The major portion is preferably at least half of the width of the air shield, more preferably at least 75% of the width of the air shield and yet more preferably essentially the full width of the air shield 13 minus portions of the air shield occupied by end walls 29. The exhaled air receiving areas 9 are, on average, located centrally in lateral directions relative to the air shield 13, so that, on average, exhaled air is sampled from a laterally central portion of the air shield 13.

Instead of a plurality of air receiving areas 9, a single air receiving area can be provided, for instance in the form of a single, for instance elongate, opening. Instead of by an opening, the air receiving area or areas may also be formed by the sensing surface or, respectively, the sensing surfaces for sensing the contents of carbon dioxide and oxygen in the air received at this surface or at these surfaces.

The instrument 1 is further equipped with a wind speed sensor 29 for sensing wind speed in a wind speed sensing location outside of the area 15 rearward of the shield 13. The instrument 1 is part of a system for measuring oxygen consumption, which further includes a signal processor 30 connected to the oxygen sensor 7 for receiving signals representing measured oxygen contents, to the carbon dioxide sensor 36 for receiving signals representing measured carbon dioxide contents, to the air flow rate sensor 12 for receiving

signals representing measured air flow rates and to the wind sensor 29 for receiving signals representing measured wind speed. The signal processor 30 is arranged for calculating oxygen consumption from the signals representing the oxygen contents and the air flow rates while applying a correction or suppression in accordance with a value of the wind speed signal. The signal processor 30 is also arranged for calculating carbon dioxide production from the signals representing the carbon dioxide contents and the air flow rates while applying the correction or suppression in accordance with the value of the wind speed signal.

Flows of air other than the flows of air inhaled and exhaled by the person can disturb the measurement of the flow rate of air inhaled and/or exhaled by the person. Such flows of for instance ambient air may in particular be caused by wind, which may for instance be weather related wind or draft and/or wind caused by movement of the person who may for instance be walking, running, riding or be located on a moving vessel. By providing a wind speed sensor 29 for sensing wind speed in a wind speed sensing location outside of the area 15 rearward of the shield 13, flows of air other than flows of air inhaled and exhaled by the person, which influence the measurement of the flow rate of air inhaled and/or exhaled by the person, can be measured as well. The correction or suppression of the measured contents signals allows correcting or suppressing of the measured oxygen consumption and carbon dioxide production in accordance with sensed wind speeds. The calculated oxygen consumption and carbon dioxide production can for instance be corrected in accordance with sensed wind speeds within a first range, for instance to compensate for admixing of ambient air into the exhaled air, and be suppressed in response to sensed wind speeds in a range that does not allow sufficiently accurate measurement of flow rates and/or oxygen and carbon dioxide contents.

The instrument 1 is further provided with a wind direction sensor 31 for sensing a direction of the wind. The wind direction sensor 31 also communicates with the signal processor 30. The signal processor 30 may for instance be arranged for responding differently to wind from ahead than to side wind or wind from above. In response to wind from ahead of a given wind speed, a correction or suppression is preferably less than in response to wind of the same speed from a side or from above, which tends to cause more admixing of ambient air in to the exhaled air than wind from ahead.

For reliable sensing of wind from any direction (e.g. head wind, side wind, rear wind or wind from above or below), the wind speed sensor 29 is located laterally spaced from the air shield 13. The distance from the wind speed sensor 29 to the air shield 13 is preferably at least 5 cm and more preferably at least 7 cm.



For allowing a further increase in the reliability of measuring oxygen consumption, the instrument 1 is further equipped with a temperature sensor 32 with a temperature sensing interface 33 in the conduit 10 and a relative humidity sensor 34 with a humidity sensing interface 35 in the conduit 10.

Correction or suppression of the measured oxygen consumption and carbon dioxide production in accordance with air flow speeds in a location outside of the area 15 between the shield 13 and the mouth and nose of the person wearing the instrument can also be advantageously applied if the flow rate of exhaled air is measured in a different manner than using an air speed sensor for measuring air speed in areas spaced from the exhaled air receiving area and above the lower end of the exhaled air receiving area and to the rear of the front end of the exhaled air receiving area, for example by measuring the pressure of exhaled air in the exhaled air receiving area.

Operation of the system according to the described example is further described with reference to the flow chart shown in Figure 4.5. The computer program for determining the RER from output signals of the sensors 7, 12, 32, 34 and 36 is composed of six modules. Three main modules are an oxygen contents determination module 41, a carbon dioxide contents determination module 42 and a flow rate determination module 43. Other modules are a wind condition correction module 44, temperature and relative humidity checking modules 45 and, respectively, 46, and a measurement output determination module 47.

In step 48 of oxygen contents determination module 41, raw oxygen concentration data obtained over a given period of time are read from a memory containing captured oxygen contents signals received from the oxygen contents sensor 7. Preferably, the concentration data are directly indicative of oxygen concentrations, by converting and calibrating direct sensor output signals. In step 49 a filter is applied to the read data. The filter may for instance be a Kalman filter, a low pass filter or a recursive least square (RLS) filter. In step 50 a model is applied to the filtered data to obtain to further reduce noise from the filtered data, for instance by fitting the filtered concentration data obtained over the given period of time to characteristics of variation of oxygen concentration over time during a breathing cycle.

In step 51 of carbon dioxide determination module 42, raw carbon dioxide concentration data obtained over the same period of time are read from a memory containing captured carbon dioxide contents signals received from the carbon dioxide contents sensor 36. Preferably, the concentration data are directly indicative of carbon dioxide concentrations, by converting and calibrating direct sensor output signals. In step 52 a filter is applied to the



read data. The filter may for instance be a Kalman filter, a low pass filter or an RLS filter and is preferably the same filter as the filter applied to the oxygen concentration data. In step 53 a model is applied to the filtered data to obtain to further reduce noise from the filtered data, for instance by fitting the filtered concentration data obtained over the given period of time to characteristics of variation of carbon dioxide concentration over time during a breathing cycle. This model may differ from the model applied to the filtered oxygen concentration data.

In step 54 of flow rate determination module 43, raw flow speed data over the given period of time are read from a memory containing captured flow speed signals received from the flow speed sensor 12. The flow speed data preferably represent flow speed directly, so that for instance a resistance signal from a hot wire flow speed sensor has already been converted into a calibrated flow speed signal. In step 55 flow rates, i.e. volumes per unit of time, are calculated from the read flow speed data. These calculations include determining a breathing frequency from the number of peaks and/or valleys in the flow speed signal per unit of time or from the time between peaks and/or valleys and determining the volumes from the measured flow speeds and the breathing frequency.

Since the relationship between air flow speed and air flow rate tends to be different for air exhaled through the nose from air exhaled through the mouth, preferably the conversion from air flow speed to air flow rate is made in accordance with mutually different relationships for breathing out through the nose and breathing out through the mouth. Whether breathing out is carried out through the nose or through the mouth can be taken into account by including a breathing frequency from cyclic variations of the air flow speed over a period of time and air flow speeds in the determination of the volumetric breathing air flow rate. This can for instance be accomplished using the following formula:

$$\text{Air flow rate (L/s)} = \text{Air Flow (m/s)} * (\text{Breathes per minute} * b) - c$$

in which b is a factor determining the extent to which the breathing frequency affects the flow rate and c is a constant. The values of b and c depend on the actual design of the device. b may for instance be between 0.03 and 0.12 and c may for instance be between 0.3 and 1.2. In step 56 inhaled volumes V_i and exhaled volumes V_e are calculated by integration of the calculated flow rate over several breathing cycles from the flow rates calculated in step 55. In step 57 a filter is applied to the inhaled volumes V_i and exhaled volumes V_e . The filter may for instance be a Kalman filter, a low pass filter or an RLS filter. In step 58 a model is applied to the filtered volume data, for instance by fitting the filtered volumetric data obtained over the given period of time to a model of characteristics of the typical variation of the flow rate over time during a breathing cycle.



In step 59 of wind condition correction module 44, wind speed data are read from captured wind speed signals received from the wind speed sensor 29. The wind speed data are preferably directly indicative of wind speed, so that for instance a resistance signal from a hot wire wind speed sensor has already been converted into a calibrated wind speed signal. Wind direction data are also read from captured wind direction signals received from the wind direction sensor 31. In step 60 a filter is applied to the read data. The filter may for instance be a Kalman filter, a low pass filter or an RLS filter. In step 61, a model is applied to the filtered data to obtain a normalized value for the influence of the wind on the measured flow rate of exhaled air. In step 62, it is determined whether the wind speed at the determined wind direction is above a first critical level at which the relationship between, on the one hand, measured flow speeds of inhaled and exhaled air and, on the other hand, inhaled volumes V_i and exhaled volumes V_e is influenced by the wind. If it is not, the wind condition correction module 44 returns to step 59 to continue monitoring wind conditions. If the wind speed at the determined wind direction is determined to be above the first critical level, the wind condition correction module 44 also returns to step 59 to continue monitoring wind conditions, but additionally continues to step 63 in which the influence of wind speed and wind direction is stored for inclusion in the air flow rate data to which filter 57 is applied. The result of step 63 is filtered in the filtering step 57 of the flow rate determination module 43 and entered into processing step 58 to correct the inhaled volumes V_i and exhaled volumes V_e for the influence of ambient wind. For instance, up to wind speeds of about 10 ± 2 m/s depending on wind direction, the influence may be determined in step 61 on the basis of wind speed, wind direction, while extent to which the filtered influence value is used for correcting the measured flow rate of exhaled air in processing step 58 depends on the value of the measured exhaled air flow rate (the higher the measured flow rate, the higher the wind speed must be for generating a given disturbance).

After step 63, the wind condition correction module 44 further continues to step 64 in which it is determined whether the wind speed at the determined wind direction is above a second critical level for that wind direction, e.g. above about 10 ± 2 m/s depending on wind direction, higher than the first critical level for that wind direction, at which the relationship between, on the one hand, measured flow speeds of inhaled and exhaled air and, on the other hand, inhaled volumes V_i and exhaled volumes V_e is disturbed by the wind to such an extent that no sufficiently reliable result can be obtained. If it is not (i.e. the wind speed at the determined direction is below the second critical limit for that direction), the wind condition correction module 44 is not further affected. If the wind speed at the determined wind direction is determined to be above the second critical level for that wind direction,

the wind condition correction module 44 triggers a no output step 65 of the measurement output determination module 47. The no output step 65 signals that no reliable measurement could be made to an output and registration interface.

In step 65 of temperature checking module 45, temperature data indicating ambient temperature are read from a memory containing temperature signals received from the temperature sensor 32. In step 66, it is determined whether the temperature is within an allowed range. The end points of this range depend on the types of oxygen and carbon dioxide concentration sensors and may for instance be 5 °C and 50 °C. If the temperature is within the allowable range, the temperature checking module 45 returns to step 65 to continue monitoring temperature conditions. If the temperature is determined to be outside the allowable range, the temperature checking module 45 also returns to step 65 to continue monitoring temperature conditions, but additionally causes trigger data to be outputted to the no output step 65 of the measurement output determination module 47. The trigger data trigger the no output step 65 to signal that no reliable measurement could be made to an output and registration interface.

In step 67 of relative humidity checking module 46, relative humidity data indicating ambient relative humidity are read from a memory containing relative humidity signals received from the relative humidity sensor 34. In step 68, it is determined whether the relative humidity is within an allowed range in which the oxygen and carbon dioxide concentration sensors operate reliably and accurately, for example 30 – 85 %. If the relative humidity is within the allowable range, the relative humidity checking module 46 returns to step 67 to continue monitoring relative humidity conditions. If the relative humidity is determined to be outside the allowable range, the relative humidity checking module 46 also returns to step 67 to continue monitoring relative humidity conditions, but additionally causes trigger data to be outputted to the no output step 65 of the measurement output determination module 47. The trigger data cause the no output step 65 to output data signalling that no reliable measurement could be made to an output and registration interface.

In step 69 of the measurement output determination module 47 the volume of consumed oxygen $\dot{V}O_2$ is determined from oxygen contents data determined in step 50 and the volume data determined in step 58. This involves integrating oxygen concentrations over inhaled and exhaled flow rates in a window of time and calculating the difference between inhaled and exhaled oxygen volumes. Unless overruled by a no output command from step 65, the determined volume of consumed oxygen $\dot{V}O_2$ is outputted to the output and registration interface.



In step 69 of the measurement output determination module 47 the volume of produced carbon dioxide $\dot{V}CO_2$ is determined from carbon dioxide contents data determined in step 53 and the volume data determined in step 58. This involves integrating carbon dioxide concentrations over inhaled and exhaled flow rates in a window of time and calculating the difference between inhaled and exhaled carbon dioxide volumes. Unless overruled by a no output command from step 65, the determined volume of produced carbon dioxide $\dot{V}CO_2$ is outputted to the output and registration interface.

In step 70 of the measurement output determination module 47 the respiratory exchange ratio RER over the given window of time is determined from the volume of consumed oxygen $\dot{V}O_2$ determined in step 69 and the volume of produced carbon dioxide $\dot{V}CO_2$ determined in step 70 ($RER = \dot{V}CO_2 / \dot{V}O_2$). Unless overruled by a no output command from step 65, the determined respiratory exchange ratio RER is outputted to the output and registration interface.

In the example, the exhaled air of which the contents of oxygen and/or carbon dioxide is to be measured is received in a plurality of air receiving areas. Essentially the same effects are also achieved when the exhaled air of which the contents of oxygen and/or carbon dioxide is to be measured is received in a single air receiving area. Furthermore, instead of or in addition to the oxygen sensor 7, a carbon dioxide sensor can be provided.

Several features have been described as part of the same or separate embodiments. However, it will be appreciated that the scope of the invention also includes embodiments having combinations of all or some of these features other than the specific combinations of features embodied in the examples.

4.5 | Claims

1. A wearable instrument for sensing oxygen and/or carbon dioxide contents in and flow rates of air exhaled by a human person when attached in an operating position to a head of the person, the instrument comprising:

- a bracket arranged for mounting the instrument to the head in the operating position, the bracket comprising a head engagement portion and a sensor carrier portion projecting forwardly and downwardly from the head engagement portion when the instrument is in the operating position, the bracket being arranged such that the sensor carrier portion can extend to an area closely in front of a mouth of

the person when the head engagement portion is in engagement with the head holding the instrument in the operating position;

- an oxygen content sensor for sensing oxygen content in air received in at least one exhaled air receiving area in front of the mouth;
- a carbon dioxide content sensor for sensing carbon dioxide content in the air received in the at least one exhaled air receiving area; and
- an air flow rate sensor for sensing exhaled air flow rates in an air flow rate sensing location;
- an air shield in front of the air receiving area and the air flow rate sensing location for shielding the exhaled air receiving area and the air flow rate sensing location from air flows from an environment forwardly of the shield, the air shield being shaped and positioned for leaving a space between the air shield and the mouth of the person in open communication with the environment;
- characterized in that the air flow rate sensor is an air flow speed sensor and the air flow rate sensing location is located spaced from the exhaled air receiving area, rearward of a front end of the exhaled air receiving area and above a lower end of the exhaled air receiving area.

2. An instrument according to claim 1, wherein the air flow rate sensing location is located at least 5 mm above the exhaled air receiving area.

3. An instrument according to claim 1 or 2, wherein the exhaled air receiving area is located behind a lower quarter portion of the air shield.

4. An instrument according to claim 3, wherein the air shield has an upwardly facing wall surface extending from underneath the exhaled air receiving area until rearward of the exhaled air receiving area.

5. An instrument according to claim 3 or 4, wherein the air shield has a rearward facing wall surface extending from forwardly of the exhaled air receiving area until upwardly of the air flow rate sensing location.

6. An instrument according to claim 5, wherein, seen in cross-sectional side view, the rearward facing wall surface of the air shield is curved with a hollow curvature.

7. An instrument according to claims 4 and 5, wherein the upwardly facing wall surface is contiguous with the rearward facing wall surface.

8. An instrument according to any of the preceding claims, wherein the exhaled air receiving area is formed by at least one opening forming an entry passage into an air duct, wherein



an air displacement device is provided for driving an air stream through said entry passage into and through said air duct, and wherein the oxygen and/or carbon dioxide content sensors include sensing surfaces downstream of said entry passage.

9. An instrument according to claim 8, wherein a plurality of said entry openings is distributed over at least half of a width of said air shield or wherein said entry opening extends over at least half of the width of said air shield.

10. A system comprising an instrument according to any of the preceding claims and a signal processor connected to the air flow speed sensor for receiving signals representing measured air flow speeds, wherein the signal processor is arranged for registering air flow speeds measured over a period of time, determining breathing frequencies from cyclic variations of the air flow speed over said period of time, and determining an air flow rate over said period of time from the breathing frequencies and the air flow speeds of exhaled over said period of time.

11. A system for measuring oxygen consumption and/or carbon dioxide production comprising a wearable instrument for sensing oxygen and/or carbon dioxide contents in and flow rates of air exhaled by a human person when attached in an operating position to a head of the person, the instrument comprising:

- a bracket arranged for mounting the instrument to the head in the operating position, the bracket comprising a head engagement portion and a sensor carrier portion projecting forwardly and downwardly from the head engagement portion when the instrument is in the operating position, the bracket being arranged such that the sensor carrier portion can extend to an area closely in front of a mouth of the person when the head engagement portion is in engagement with the head holding the instrument in the operating position;
- an oxygen content sensor for sensing oxygen content in air received in at least one exhaled air receiving area in front of the mouth;
- a carbon dioxide content sensor for sensing carbon dioxide content in the air received in the at least one exhaled air receiving area; and
- an air flow rate sensor for sensing exhaled air flow rates in an air flow rate sensing location;
- an air shield in front of the air receiving area and the air flow rate sensing location for shielding the exhaled air receiving area and the air flow rate sensing location from air flows from an environment forwardly of the shield, the air shield being



shaped and positioned for leaving a space between the air shield and the mouth of the person in open communication with the environment;

- characterized in that the instrument further comprises a wind speed sensor for sensing wind speed in a wind speed sensing location outside of an area rearward of the shield; and
- the system further comprises a signal processor connected to the oxygen sensor and the carbon dioxide sensor for receiving signals representing measured oxygen and/or carbon dioxide contents, to the air flow rate sensor for receiving signals representing measured air flow rates and to the wind sensor for receiving signals representing measured wind speed, the signal processor being arranged for calculating oxygen consumption from the signals representing the oxygen contents, carbon dioxide production from the signals representing the carbon dioxide contents and air flow rates while applying a correction or suppression in accordance with a value of the wind speed signal.

12. A system according to claim 11, further comprising a wind direction sensor for sensing a direction of said wind.

13. A system according to claim 11 or 12, wherein said wind speed sensor is located laterally spaced from said air shield.

14. A system according to any of the claims 11-13, wherein said wind speed sensor is located at least 5 cm away from said air shield.

15. A method for sensing oxygen and/or carbon dioxide contents in and flow rates of air exhaled by a human person using an instrument attached in an operating position to a head of the person, the instrument comprising:

- an oxygen content sensor sensing oxygen content in air received in at least one exhaled air receiving area in front of a mouth of the person;
- a carbon dioxide content sensor sensing carbon dioxide content in the air received in the at least one exhaled air receiving area; and
- an air flow rate sensor sensing exhaled air flow rates in an air flow rate sensing location;
- an air shield in front of the air receiving area and the air flow rate sensing location shielding the exhaled air receiving area and the air flow rate sensing location from air flows from an environment forwardly of the shield, the air shield leaving a space between the air shield and the mouth of the person in open communication with the environment;



- characterized in that the air flow rate sensor senses air flow speed sensor and the air flow rate sensing location is located spaced from the exhaled air receiving area in an area rearward of a front end of the exhaled air receiving area and above a lower end of the exhaled air receiving area.

16. A method for measuring oxygen consumption and/or carbon dioxide production using a system comprising a wearable instrument sensing oxygen and/or carbon dioxide contents in and flow rates of air exhaled by a human person, the instrument being attached in an operating position to a head of the person, the instrument comprising:

- an oxygen content sensor sensing oxygen content in air received in at least one exhaled air receiving area in front of the mouth;
- a carbon dioxide content sensor sensing carbon dioxide content in the air received in the at least one exhaled air receiving area; and
- an air flow rate sensor sensing exhaled air flow rates in an air flow rate sensing location;
- an air shield in front of the air receiving area and the air flow rate sensing location shielding the exhaled air receiving area and the air flow rate sensing location from air flows from an environment forwardly of the shield, the air shield leaving a space between the air shield and the mouth of the person in open communication with the environment;
- characterized in that the instrument further comprises a wind speed sensor sensing wind speed in a wind speed sensing location outside of an area rearward of the shield; and
- the system further comprises a signal processor receiving signals representing measured contents of oxygen and/or carbon dioxide, signals representing measured air flow rates and signals representing measured wind speed, the signal processor calculating oxygen consumption from the signals representing the contents of oxygen, carbon dioxide production from the signals representing the contents of carbon dioxide and air flow rates while applying a correction or suppression in accordance with a value of the wind speed signal.





Chapter 5

Can breathing gases be analysed without a mouth mask? Proof-of-concept and concurrent validity of a newly developed design with a mask-less headset

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Abstract

A portable headset has been developed to analyse breathing gases and establish the energetic workload of physically active workers. This proof-of-concept study aimed to investigate the following: (1) the validity of the headset compared to indirect calorimetry using a mouth mask; (2) the validity of the headset compared to the validity of oxygen consumption ($\dot{V}O_2$) estimated on the basis of heart rate; (3) the influence of wind on validity; and (4) user experiences of the headset. Fifteen subjects performed a submaximal cycling test twice, once with the headset, and once with a mouth mask and heartrate monitor. Concurrent validity of the headset was analysed using an intraclass correlation coefficient (ICC). Across all phases, a good correlation between the headset and mouth mask was observed for $\dot{V}O_2$, carbon dioxide production ($\dot{V}CO_2$) and exhaled volume ($\dot{V}E$) ($ICC \geq 0.72$). The headset tended to underestimate $\dot{V}O_2$, $\dot{V}CO_2$ and $\dot{V}E$ at low intensities and to overestimate it at higher intensities. The headset was more valid for estimating $\dot{V}O_2$ ($ICC=0.39$) than estimates based on heart rate ($ICC=0.11$) ($n=7$). Wind flow caused an overestimation ($md \geq 18.4 \pm 16.9\%$) and lowered the correlation of $\dot{V}O_2$ between the headset and the mouth mask to a moderate level ($ICC=0.48$). The subjects preferred the headset over the mouth mask because it was more comfortable, did not hinder communication and had lower breathing resistance. The headset appears to be usable for monitoring development of the energetic workloads of physically active workers, being more valid than heart rate monitoring and more practical than indirect calorimetry with a mouth mask. Proof-of-concept was confirmed. Another design step and further validation studies are needed before implementation in the workplace.

Keywords: Energy expenditure, energetic workload, physically demanding jobs, blue-collar worker, indirect calorimetry, cardiopulmonary exercise testing



5.1 | Introduction

Workers' work capacity is dependent upon factors such as health, age, lifestyle and physical fitness (Heerkens et al., 2004; Costa-Black et al., 2013; Schultz et al., 2007). Energetic capacity (one of the aspects of physical fitness) depends on the condition of the respiratory system. The functioning of the human respiratory system declines with age, starting at about the age of 30 (Ilmarinen 2001; Chan et al., 2000; Bellew et al., 2005) and resulting in a declining energetic (work) capacity among older, physically active workers (Kenny et al., 2008). When the workload exceeds the energetic (work) capacity, overload occurs (Kenny et al., 2008) resulting in concentration problems, lowered well-being, fatigue, health problems and absenteeism (Costa-Black et al., 2013; Ilmarinen, 2001; Kenny et al., 2008; Weerding et al., 2005; Bos et al., 2004). For a sustainable workforce, it is important to maintain the balance between workload and individuals' work capacity (Soer et al., 2014; Catal & Akbulut, 2018).

To determine this balance, there is a need for objective measurement tools that monitor the energetic workload and capacity of individuals at work in their natural working environment (Catal & Akbulut, 2018; Faria et al., 2018; Alberto et al., 2017). The energetic workload and -capacity of physically active workers can be measured in various ways. Direct calorimetry and doubly labelled water techniques are the most accurate methods, followed by indirect calorimetry using a mouth mask (Catal & Akbulut, 2018; Kenny et al., 2017; Borges et al., 2019; Hoehn et al., 2018; Rexhepi & Brestovci, 2011; Bini et al., 2019). These methods need to be performed in controlled laboratory conditions (Kenny et al., 2017). Moreover, they are expensive, interfere with workability, have high breathing resistance and are uncomfortable (Hoehn et al., 2018). Indirect calorimetry is not feasible in the workplace because the mouth mask is impractical and hinders communication, which is often crucial for safety during work (Catal & Akbulut, 2018; Hoehn et al., 2018; Borges et al., 2019; Rexhepi & Brestovci, 2011). Alternatively, heart rate (HR) measurements can be taken to estimate oxygen consumption ($\dot{V}O_2$) (Astrand & Ryhming, 1954). HR measurement is more feasible in the workplace and is generally accepted (Hiiloskorpi et al., 2003; Keytel et al., 2005). However, prediction of energy expenditure from HR is far less valid than direct and indirect calorimetry (Bos et al., 2004; Catal & Akbulut, 2018; Bernmark et al., 2012; Butte et al., 2012; Livingstone et al., 1992; Rennie et al., 2005; Ceesay et al., 1989; Leonard et al., 2003) and can only be applied if the HR is between 125 and 170 beats/min (Astrand & Ryhming, 1954). A wearable breathing-gas analyser without a mouth mask would fill the validity and feasibility gaps between these measurement strategies. With this headset, we aim to introduce a system whose measurement validity and usability are positioned between indirect calorimetry and HR monitoring.



A new wearable breathing-gas measurement and analysing system has been developed (Figure 5.1). This newly developed system collects breathing gases via a headset close to the mouth and nose, where a sample of breathing gases is taken and transported to the rear part of the headset for analysis. Because work activities can change during a working day and over several days, it is necessary to measure energy consumption over prolonged periods of time (Bos et al., 2004). With this wearable system, it may be possible to gain a complete overview of the energetic workload and capacity of workers during performance of different types of work. Moreover, the system is developed to monitor individual physiologic responses to these work activities. It can be used in various conditions, and the headset enables communication during work.

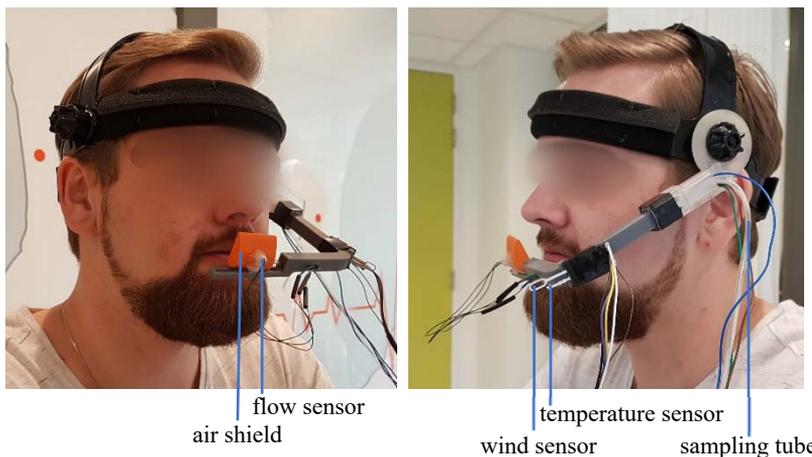


Figure 5.1 | The head part of the breathing gas analysing headset. The head part with the air shield with flow sensor, temperature and wind sensor and a sampling tube to transport the breathing gases to the back part.

The validity of this breathing-gas analysing headset and the influence of wind when applied in outdoor workplaces have not yet been evaluated. This proof-of-concept study aimed to investigate the following:

1. the validity of $\dot{V}O_2$, carbon dioxide production ($\dot{V}CO_2$) and respiratory exchange ratio (RER) measurements produced by the developed breathing-gas analysing headset compared to a mouth mask (reference system);
2. the validity of $\dot{V}O_2$ measurements produced by the developed breathing-gas analysing headset compared to estimated $\dot{V}O_2$ based on HR;
3. the influence of wind on the validity of the system;
4. the user experience of the developed headset system.

5.2 | Materials and methods

5.2.1 | Subjects

The 15 subjects in this study were healthy volunteers, recruited by distributing flyers at a university and hospital. Inclusion criteria were people aged between 18 and 67 who were experienced daily cyclers (at least 30 min at 15 km/h). Exclusion criteria were use of pacemakers or other vital electronic devices, lung-, heart- and/or vessel diseases, and injuries to or dysfunction of the lower extremities.

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), and the study was approved (M16.190947).

5.2.2 | Study design and procedures

In this concurrent validity study, the validity of the breathing-gas analysing headset was investigated and compared to the reference system, an indirect calorimetry breathing-gas system using a mouth mask, and heart rate monitoring. Healthy subjects performed a submaximal cycling test on an ergometer (Ergoline GmbH, Bitz, Germany; Hoehn et al., 2018; Rexhepi & Brestovci, 2011) twice in the same setup: once with the headset and once with the mouth mask and HR measurement. The submaximal cycling test contained four phases: (I) resting, (II) cycling without resistance, (III) cycling with a 75 W load and (IV) cycling with a 125 W load (Table 5.1). Cycling loads were selected based on the workload of different types of workers. Phases I (resting) and II (0 W) represented the workload of office workers, and phases III (75 W) and IV (125 W) represented the workload of physically active workers. To examine the influence of wind on the validity of the headset, each phase was structured as follows: (a) a steady state period of 2 min; (b) a 45-second measurement period; (c) simulated wind flow (using a fan at a distance of 1 meter from the subject, with a wind speed of 10 ± 1 m/second) from the side for 45 seconds; (d) simulated wind flow from the front for 45 seconds; and (e) fluctuating wind flow in front for 45 seconds (Table 5.1). The total duration of the cycling test was 20 min (5 min resting and 15 min cycling) with a constant cycling speed of 65–70 rpm. To eliminate the effects of fatigue, the order of cycling with the headset or with the mouth mask and HR was alternated between subjects. The two cycling tests were performed on the same day with a break of at least 15 min in between to allow for recovery.



Table 5.1 | Study design containing four phases with 5 conditions per phase.

Phase			Duration	
I	Rest	a	Steady state	2 min
		b	Measurement	45 sec
		c	Wind (side)	45 sec
		d	Wind (front)	45 sec
		e	Wind (front fluctuating)	45 sec
II	0W	a	Steady state	2 min
		b	Measurement	45 sec
		c	Wind (side)	45 sec
		d	Wind (front)	45 sec
		e	Wind (front fluctuating)	45 sec
III	75W	a	Steady state	2 min
		b	Measurement	45 sec
		c	Wind (side)	45 sec
		d	Wind (front)	45 sec
		e	Wind (front fluctuating)	45 sec
IV	125W	a	Steady state	2 min
		b	Measurement	45 sec
		c	Wind (side)	45 sec
		d	Wind (front)	45 sec
		e	Wind (front fluctuating)	45 sec

To position the headset, the subjects were asked to breath in rest for about 20 s and blow shortly (about 3 s) harder via the nose and mouth. The headset was positioned correctly when the subject felt a light bounce off of the air flows by the part in front of the mouth and when in the recording of the air flow was clearly visible. The mean distance between the mouth and the sensor in the headset was 4 cm (range 3-5 cm) and between the nose and headset was 5 cm (range 3- 6 cm).

Subjects' experiences with the headset were explored using the user interface design method AEIOU (activities, environments, interactions, objectives and users). In this descriptive observational study, the subjects (*users*) provided feedback (*interactions*) by thinking aloud. The user interface was explored through researcher (AEIOU) observations. Subjects were asked to think aloud as they were putting on and taking off the headset and mouth mask (*objects*), and during and after the cycling test (*activities*). At the end of the study, the subjects were asked questions about their experiences in terms of comfort, functionality, adjustability and positioning, and usability (Likert, 1932; Finstad, 2010). They were also given the opportunity to provide additional feedback or comments. The study was performed in an exercise laboratory at a medical rehabilitation center under constant ambient conditions (an ambient temperature of $21.0 \pm 2.0^\circ\text{C}$) (*environment*).



5.2.3 | Materials

5.2.3.1 | *Breathing gas analysing headset*

The indirect calorimetry breathing-gas analyser without a mouth mask is a wearable headset. It contains an oxygen (O₂), carbon dioxide (CO₂), flow, wind, temperature and humidity sensor. Flow was measured in front of the mouth, and wind speed and temperature were measured at the side of the headset. Breathing gases (from the nose and mouth) were collected by an air shield on the headset in front of the mouth. This air shield (height 35 mm, width 45 mm and depth 12 mm) is designed to collect breathing gases from the nose and mouth as illustrated in Figure 5.2. In this air shield the flow sensor and sampling tube, which transports the breathing gases to the rear box (located at the back of the worker) for analysis. This box contained the O₂, CO₂, temperature and humidity sensor, two pumps with an extraction speed of 3.2 L/min and a battery pack (see Figure 5.3). The O₂ sensor (Oxygen Sensor OOM109-LF2; EnviteC-Wismar GmbH, Wismar, Germany) has a measurement range of 0–100% with an accuracy of <1%, an operating temperature range of 0–50°C and a response time of <300 ms (T90) (Envitec by Honeywell, 2008). The Treymet Comet II CO₂ sensor (TreyMed, Inc., Pewaukee, Wisconsin, USA) has a measurement range of 0–13% with an accuracy of ±0.2 mmHg or 5% of the actual concentration, an operating temperature range of 5 to 55°C and a response time of <28 ms (TreyMed, 2007). The thermal mass-flow sensor FS5 has a measurement range of 0–100 m/second with an accuracy of <3%, an operating temperature range of -20 to +150°C and a response time of 160 ms (Innovative Sensor Technology, Unknown). To measure and correct for environmental wind, the Rev. P hot-wire anemometer (Modern Device, Providence, Rhode Island, USA) was used, which has a measurement range of 0–67 m/second and an accuracy of 1% (Modern Device, 2019) (Prohasky & Watkins, 2014). The head part weighted 190 gram and the back part 1255 gram resulting in a total weight of the breathing gas analysing headset of 1445 gram.



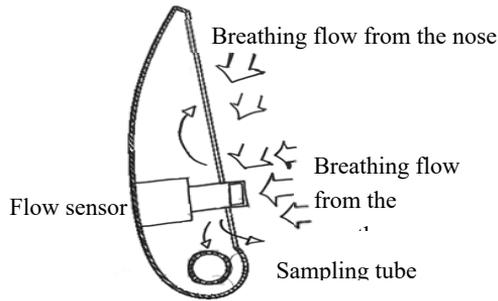


Figure 5.2 | Air shield. The air shield in front of the mouth with flow sensor and hole of the sampling tube. The wide arrows indicate how the breathing flow from the nose and mouth is catches up by the air shield and measured by the flow sensor, and the narrow single arrows indicate the discharge of exhaled breathing flow and the transport to the back part of the system by a sampling tube.

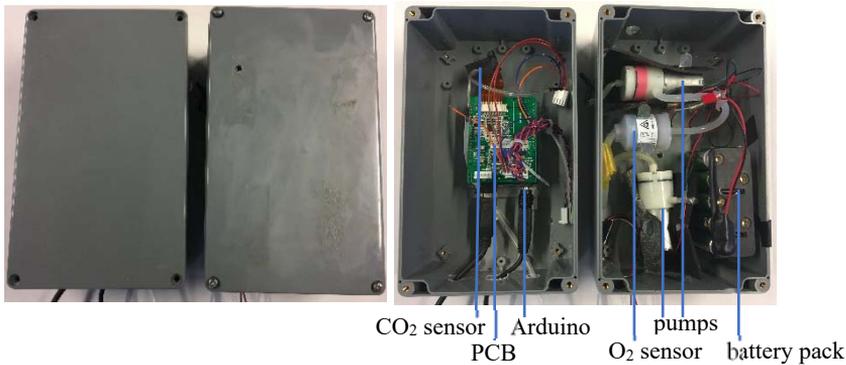


Figure 5.3 | The back part of the breathing gas analysing headset. The back part with oxygen (O₂) and carbon dioxide (CO₂) sensor, two pumps, a printed circuit board (PCB), Arduino Uno, and a 12V battery pack.

The headset had a sample frequency of <1 second. $\dot{V}O_2$, $\dot{V}CO_2$ and respiratory exchange ratio ($RER = \text{ratio of } \dot{V}CO_2 \text{ over } \dot{V}O_2$) were calculated per 5 seconds (in line with the reference system). The sensors were calibrated according to the instructions in their manuals using a standard certified commercial gas preparation (range O₂ from 16 to 21%, CO₂ from 0.05 to 5%, breathing frequency from 5 to 45 breaths per minute, $\dot{V}E$ from 10 to 60 L/min). In-vitro and in-vivo studies explored the sensitivity of the O₂, CO₂ and flow sensor to capture nose and mouth breathing. To standardize for metabolic calibration, the headset data were trained with machine learning (computational learning theory) on learning data in a two-step approach. These learning data were gathered in two pilot studies including, in total, 26 subjects. During these pilot studies, the subjects were measured in rest and when cycling with up to 125W resistance, according to the protocol described in the study design. This

data contained an O₂ range of 13 to 21%, CO₂ from 0.05 up to 6% and a flow range of 5 to 45 breaths per minute. Additionally, the sensitivity of the flow sensor to capture nose and mouth was explored with a breathing frequency ranging from 5 to 20 breaths per minute (by mouth breathing and by nose breathing). An algorithm was developed based on the best fitting model (Pearson correlation coefficient), resulting in a linear regression model using the gradient descent methodology per parameter, i.e., $\dot{V}O_2$, $\dot{V}CO_2$, RER and its parameters fraction inhaled (FiO₂) and exhaled O₂ (FeO₂), fraction inhaled (FiCO₂) and exhaled CO₂ (FeCO₂) and exhaled volume ($\dot{V}E$). Different (adaptive) filtering techniques (including (extended) Kalman and (normalized and recursive) least mean squares) were examined. Based on the outcomes of the learning data, no filter was applied during this study.

5.2.3.2 Indirect calorimetry with mouth mask

As a reference, respiratory breath-by-breath gas analysis was measured with CareFusion's JAEGER™ Vyntus™ CPX (CareFusion Germany 234 GmbH, Hoechberg, Germany). This indirect calorimetry breathing-gas analysing system is an accurate and reliable method (Perez-Suarez et al., 2018; Carlomagno et al., 2015) that is used for (medical) diagnostics (Skrгат et al., 2018; Rokkedal-Lausch et al., 2019). The mouth-mask system has a ventilation measurement range of 0–300 L with an accuracy of 2% or 0.5 L/min, a volume range of 0–10 L with an accuracy of 2% or 50 mL, and a $\dot{V}O_2$ and $\dot{V}CO_2$ measurement range of 0–7 L/min with an accuracy of 3% or 0.05 L/min (CareFusion, 2016). The resolution is 0.01Vol% with a response time of (T10–90)=75 ms (CareFusion, 2016). The flow range is 0–15 L/second with an accuracy of 3% or 70 mL/second, and the calculated RER has a measurement range of 0.6–2.0 with an accuracy of 4% or 0.04 (CareFusion, 2016).

5.2.3.3 Heart rate monitor

HR was measured using the Cardiac Acquisition Module (CAM-14) of the CardioSoft™ Diagnostic System Exercise Stress Testing ECG application (GE Healthcare, Wauwatosa, US). This 15-leads ECG has a sampling rate of 16.000 samples/second per lead with an analysing frequency of 500 samples/second. The dynamic range is 320±10 mV with a resolution of 4.88 µV/LSB at 500 Hz and <15 µV noise (GE Healthcare, 2017). HR was registered using automatic arrhythmia detection (GE Healthcare, 2017).

5.2.4 | Data analysis

The main measurement parameter for studying the headset's validity (aims 1–3) was $\dot{V}O_2$, and the secondary parameters were $\dot{V}CO_2$ and RER. The mean value of the last 30 seconds of every measurement was used for data analysis. Validity (aims 1–3) was tested using paired t-tests (normally distributed data) or the Wilcoxon signed-rank test (non-normally distributed data) and by the intraclass correlation coefficient (ICC, two-way mixed model,



absolute agreement) per parameter. The mean difference (MD) was shown per result with the standard deviation (SD). The ICC was considered as excellent when $ICC \geq 0.80$; good when $0.60 \leq ICC < 0.79$; moderate when $0.40 \leq ICC < 0.59$; and low when $ICC < 0.40$ (Cicchetti, 1994), and was presented with limits of agreement (LoA) ($\pm 1.96 * SD$ difference (Bland & Altman, 1999)). Bland-Altman plots were used to analyse individual differences between two measurement methods (headset, mouth mask and/or HR) against the individual mean of the headset (Bland & Altman, 1999). Level of significance was set at $p \leq 0.05$. The following outcomes were interpreted as acceptable for proof-of-concept: accuracy of $\pm 5\%$; moderate, good or excellent ICC compared to the mouth mask; and an ICC for the headset higher than the ICC for HR compared to the mouth mask. The scores for user experiences (aim 4) were presented as median and interquartile range. A good or excellent user rating (Likert score ≥ 4) was defined as acceptable for this proof-of-concept.

5.3 | Results

The 15 subjects (eight male and seven female) had an age (mean \pm SD) of 31.0 ± 14.4 years, a height of 180.9 ± 9.1 cm and a weight of 79.6 ± 11.2 kg. Of these 15 subjects, eight started with the headset, followed by the mouth mask, and seven started with the mouth mask, followed by a measurement with the headset.

5.3.1 | Validity of the headset compared to the mouth mask

Table 5.2 shows the MD and ICC of $\dot{V}O_2$, $\dot{V}CO_2$, $\dot{V}E$ and RER between the measurements with the headset compared with the mouth mask. For $\dot{V}O_2$ across all phases, the difference between the headset and mouth mask was acceptable (MD=1.93%), and an excellent ICC was observed (ICC=0.86). For $\dot{V}CO_2$ and $\dot{V}E$ over all phases and while cycling at 75 W, differences between the headset and mouth mask were acceptable (MD \leq 3.96%) with a moderate to good ICC (ICC \geq 0.48). In other phases, the differences between the headset and mouth mask exceeded the acceptable level of 10% (MD \geq 9.96%), and a low ICC with the mouth mask was observed (ICC \leq 0.40). The Bland-Altman plot (Figure 5.4) shows a proportional error for $\dot{V}O_2$ and $\dot{V}CO_2$ at 125 W. However, this error was not present across all phases. The headset tended to overestimate $\dot{V}O_2$, $\dot{V}CO_2$ and $\dot{V}E$ at low intensities (resting and 0 W) and underestimate it at higher intensities (75 W and 125 W).

Table 5.2 | Validity of the headset compared to the mouth mask for measuring $\dot{V}O_2$, $\dot{V}CO_2$, $\dot{V}E$ and RER.

Parameter	Phase	MD \pm SD		p ^a	ICC [95% CI]	p ^b	LoA
		Absolute	Relative (%)				
$\dot{V}O_2$ (L/min)	Mean	-0.02 \pm 0.29	-1.93 \pm 25.40	0.543	0.86 [0.78;0.92]	<0.001	\pm 0.57
	Rest	0.22 \pm 0.15	52.99 \pm 36.13	<0.001	0.27 [-0.11;-0.66]	0.017	\pm 0.29
	OW	0.11 \pm 0.19	14.44 \pm 34.95	0.045	0.26 [-0.17;0.65]	0.122	\pm 0.37
	75W	-0.14 \pm 0.16	-9.96 \pm 11.38	0.005	0.40 [-0.07;0.74]	0.018	\pm 0.31
	125W	-0.28 \pm 0.31	-14.20 \pm 15.73	0.003	0.30 [-0.11;-0.67]	0.046	\pm 0.61
$\dot{V}CO_2$ (L/min)	Mean	-0.01 \pm 0.30	-0.79 \pm 30.81	0.844	0.83 [0.73;0.90]	<0.001	\pm 0.59
	Rest	0.18 \pm 0.13	50.40 \pm 36.40	<0.001	0.35 [-0.12;0.72]	0.008	\pm 0.26
	OW	0.15 \pm 0.20	24.99 \pm 14.13	0.011	0.18 [-0.18;0.57]	0.172	\pm 0.39
	75W	0.00 \pm 0.16	0.00 \pm 14.13	0.536	0.48 [-0.02;0.79]	0.032	\pm 0.32
	125W	-0.33 \pm 0.35	-18.02 \pm 19.11	0.003	0.10 [-0.17;-0.47]	0.262	\pm 0.69
$\dot{V}E$ (L/min)	Mean	0.00 \pm 3.09	0.00 \pm 10.90	0.999	0.72 [0.33;0.90]	0.001	\pm 6.06
	Rest	5.84 \pm 5.20	43.22 \pm 38.48	0.001	0.27 [-0.12;0.65]	0.041	\pm 10.18
	OW	4.88 \pm 7.84	24.27 \pm 38.99	0.030	0.05 [-0.30;0.48]	0.401	\pm 15.37
	75W	-1.25 \pm 5.26	-3.96 \pm 16.67	0.374	0.52 [0.04;0.81]	0.020	\pm 10.31
	125W	-9.48 \pm 10.01	-19.64 \pm 20.74	0.003	0.06 [-0.19;0.42]	0.344	\pm 19.63
RER	Mean	0.01 \pm 0.09	1.74 \pm 11.13	0.231	0.50 [0.05;0.79]	0.015	\pm 0.18
	Rest	-0.02 \pm 0.09	-2.34 \pm 10.51	0.324	0.33 [-0.19;0.71]	0.109	\pm 0.17
	OW	0.06 \pm 0.11	7.62 \pm 13.97	0.053	-0.17 [-0.51;0.30]	0.789	\pm 0.23
	75W	0.06 \pm 0.04	7.45 \pm 4.97	<0.001	0.09 [-0.10;0.40]	0.207	\pm 0.09
	125W	-0.05 \pm 0.06	-5.37 \pm 6.44	0.018	-0.09 [-0.38;0.33]	0.681	\pm 0.13

Mean differences (MD: headset – mouth mask) and p-value and the intraclass correlations (ICC) with a confidence interval (CI) of 95%, p-value and Limits of Agreement (LoA) of oxygen consumption ($\dot{V}O_2$), carbon dioxide production ($\dot{V}CO_2$) and Respiratory Exchange Ratio (RER) measured with the reference system indirect calorimetry with mouth mask against the headset. ^a p-value of paired t-test. ^b p-value of ICC.

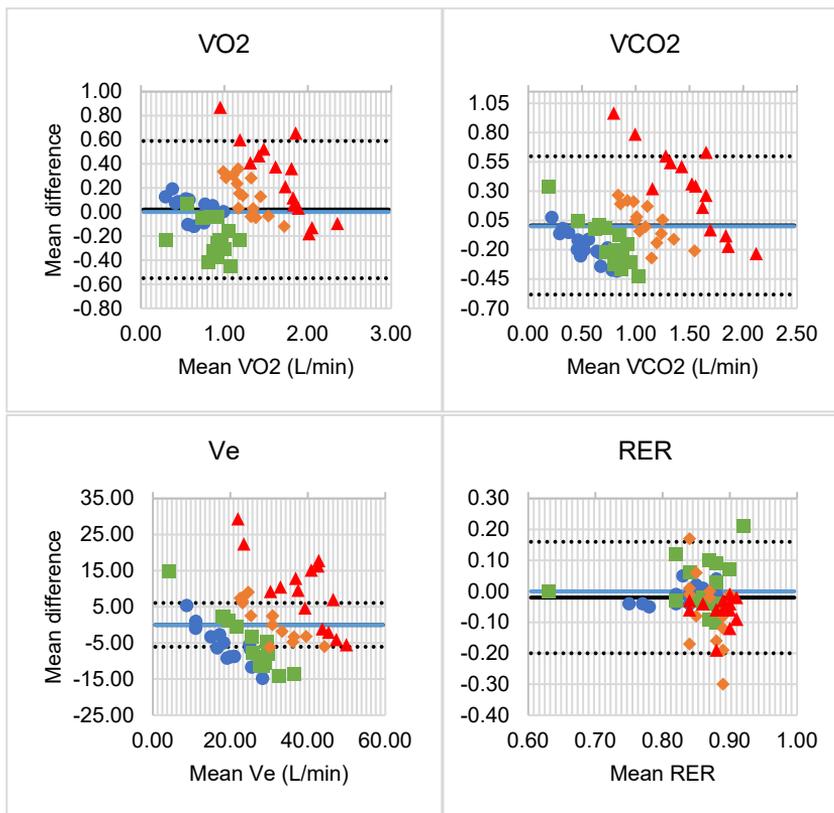


Figure 5.4 | Bland-Altman plot of $\dot{V}O_2$, $\dot{V}CO_2$, $\dot{V}E$ and RER. Bland-Altman plots of the mean oxygen consumption ($\dot{V}O_2$) (upper-left), carbon dioxide production (upper-right), and exhalation volume (lower-left) in L/min and respiratory exchange ratio (RER) (lower-right) measured with the headset versus the mean difference between the mouth mask minus the headset with mean (black line) and upper and lower Limit of Agreement (LoA) (black dotted line), mean $\dot{V}O_2$ in rest (blue dot), 0W (green square), 75W (orange diamond) and 125W phase (red triangle) and zero-line (blue line).

For RER, across all phases and in rest differences between the headset and mouth mask were acceptable ($MD \leq 2.34\%$) and a moderate ICC was observed across all phases ($ICC = 0.50$). When cycling the acceptable levels were exceeded ($MD \geq 5.37\%$) and within the different phases, low correlations were observed ($ICC \leq 0.33$). Appendix A presents the validity of the parameters behind calculation of $\dot{V}O_2$ and $\dot{V}CO_2$.

5.3.2 | Validity of the headset compared to validity of $\dot{V}O_2$ estimated according to heart rate

Since $\dot{V}O_2$ based on HR can be calculated only if HR is between 125 and 170 beats/min (Astrand & Ryhming, 1954), the validity of $\dot{V}O_2$ estimated according to HR could only be determined during cycling at 125 W; seven subjects had an HR between 125 and 170

beats/min (149.14 ± 17.18 beats/min); seven subjects had an HR exceeding the lower level (103.7 ± 30.1 beats per minute); and one subject had an HR exceeding the upper level (180.1 beats/min). Table 5.3 shows the validity of $\dot{V}O_2$ measured with the headset compared to the mouth mask, and the validity of estimations based on HR compared to the mouth mask for these seven subjects.

Table 5.3 | Validity of $\dot{V}O_2$ at 125 W, measured with the headset compared to $\dot{V}O_2$ based on heart rate and to $\dot{V}O_2$ measured by mouth mask.

Methods		MD \pm SD		p ^a	ICC [95% CI]	p ^b	LoA
		Absolute	Relative (%)				
Headset	Mouth mask	-0.26 \pm 0.33	-13.05 \pm 16.56	0.084	0.39 [-0.20;0.84]	0.112	\pm 0.65
HR	Mouth mask	-0.19 \pm 0.26	-9.54 \pm 13.05	0.095	0.11 [-0.35;0.70]	0.366	\pm 0.50

Mean differences (MD: headset – mouth mask) and p-value and the intraclass correlations (ICC) with a confidence interval (CI) of 95%, p-value and Limits of Agreement (LoA) of oxygen consumption ($\dot{V}O_2$) measured with the reference system indirect calorimetry with mouth mask against the headset and heart rate (HR) using Åstrand-Ryhming nomogram. ^a p-value of paired t-test. ^b p-value of ICC.

$\dot{V}O_2$ estimated with HR compared to $\dot{V}O_2$ measured with the mouth mask was within the acceptable level (MD=9.54%). $\dot{V}O_2$ measured with the headset exceeded the acceptable level (MD=13.05%). The correlations fulfilled the proof-of-concept criteria; the headset had a higher ICC (ICC=0.39) than $\dot{V}O_2$ calculated with HR (ICC=0.11). The Bland-Altman plots are shown in Figure 5.5.

5.3.3 | Validity of results under the influence of wind

Table 5.4 presents the influence of wind for both the mouth mask and the headset in terms of $\dot{V}O_2$, $\dot{V}CO_2$, $\dot{V}E$ and RER. Appendix C presents the comparison between the headset with and without wind, and between the mouth mask with and without wind. Also the effects of wind per phase are presented in appendix C.



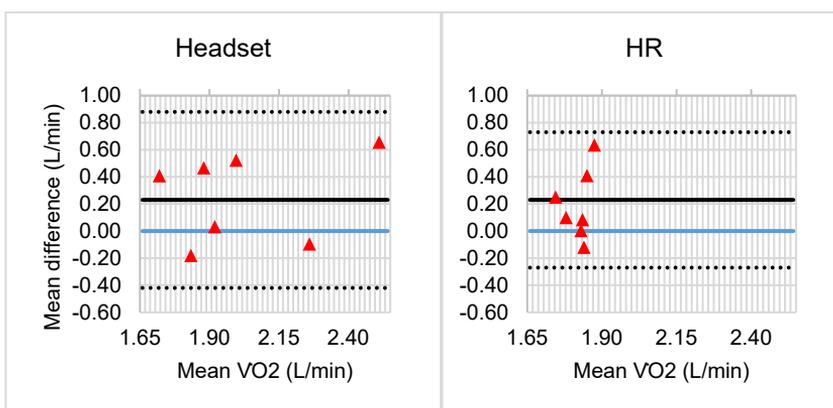


Figure 5.5 | Bland-Altman plot of $\dot{V}O_2$ measured with (left) the headset and (right) estimated based on HR. Bland-Altman plot of the mean oxygen consumption ($\dot{V}O_2$) measured with the headset versus the mean difference between the mouth mask minus the headset (left) and $\dot{V}O_2$ measured with the mouth mask minus $\dot{V}O_2$ estimated based on the heart rate (HR) (right) with mean (black line) and upper and lower Limit of Agreement (LoA) (black dotted line), mean difference $\dot{V}O_2$ (red triangle) and headset and HR (orange diamond), and zero-line (blue line).

Table 5.4 | The influences of wind on the validity of the headset compared to the mouth mask for measuring $\dot{V}O_2$, $\dot{V}CO_2$, $\dot{V}E$ and RER influence by wind.

System	Wind	MD \pm SD		p ^a	ICC [95% CI]	p ^b	LoA
		Absolute	Relative (%)				
Headset with wind versus mouth mask with wind							
$\dot{V}O_2$ (L/min)	Side	-0.03 \pm 0.15	-2.57 \pm 13.48	0.473	0.42 [-0.10;0.76]	0.056	\pm 0.30
	Front	-0.05 \pm 0.14	-4.75 \pm 13.07	0.181	0.51 [0.05;0.80]	0.018	\pm 0.27
	Fluctuating	-0.06 \pm 0.38	-5.55 \pm 33.21	0.528	-0.05 [-0.57;0.47]	0.574	\pm 0.74
$\dot{V}CO_2$ (L/min)	Side	0.04 \pm 0.18	4.21 \pm 18.30	0.388	0.17 [-0.36;0.62]	0.266	\pm 0.35
	Front	0.04 \pm 0.13	4.15 \pm 13.43	0.251	0.50 [0.03;0.80]	0.022	\pm 0.26
	Fluctuating	0.04 \pm 0.18	3.72 \pm 17.76	0.505	0.39 [-0.17;0.75]	0.081	\pm 0.35
$\dot{V}E$ (L/min)	Side	1.27 \pm 4.13	4.47 \pm 14.57	0.255	0.20 [-0.30;0.63]	0.220	\pm 8.10
	Front	4.58 \pm 3.28	16.14 \pm 11.57	<0.001	0.22 [-0.12;0.60]	0.039	\pm 6.43
	Fluctuating	0.90 \pm 7.53	3.19 \pm 26.53	0.649	-0.26 [-0.72;0.31]	0.815	\pm 14.75
RER	Side	0.01 \pm 0.04	0.75 \pm 4.54	0.532	0.03 [-0.50;0.53]	0.456	\pm 0.08
	Front	0.01 \pm 0.04	0.79 \pm 4.80	0.535	-0.01 [-0.60;0.43]	0.634	\pm 0.08
	Fluctuating	-0.01 \pm 0.05	-0.95 \pm 6.23	0.564	-0.50 [-0.86;0.05]	0.967	\pm 0.11

Mean differences (MD; headset – mouth mask) and p-value and the intraclass correlations (ICC) with a confidence interval (CI) of 95%, p-value and Limits of Agreement (LoA) of oxygen consumption ($\dot{V}O_2$), carbon dioxide production ($\dot{V}CO_2$), exhaled volume ($\dot{V}E$) and Respiratory Exchange Ratio (RER) measured with the reference system indirect calorimetry with mouth mask (mouth mask) against the headset. The mouth mask and headset are compared with each other while a wind flow (10m/second) was blowing at the systems from the side, front and fluctuating in front. ^a p-value of paired t-test. ^b p-value of ICC.

The mean difference between the headset with wind and the mouth mask without wind across all phases was increased due to the wind. Despite for $\dot{V}O_2$ with fluctuating wind (MD=5.55%) and V_e with wind from the front (MD=16.14%), the differences were still acceptable (MD \leq 4.75%). All ICC's between the headset and the mouth mask lowered from good to moderate and low (ICC \leq 0.51). At low intensities, the headset tended to overestimate $\dot{V}O_2$, $\dot{V}CO_2$ and $\dot{V}E$, indicating a major influence of wind on the validity of the headset and resulting in ICCs varying from good to low. This proportional error was also visible in the Bland-Altman plot of $\dot{V}O_2$, $\dot{V}CO_2$ and $\dot{V}E$ (Figure 5.6) in all three wind directions.

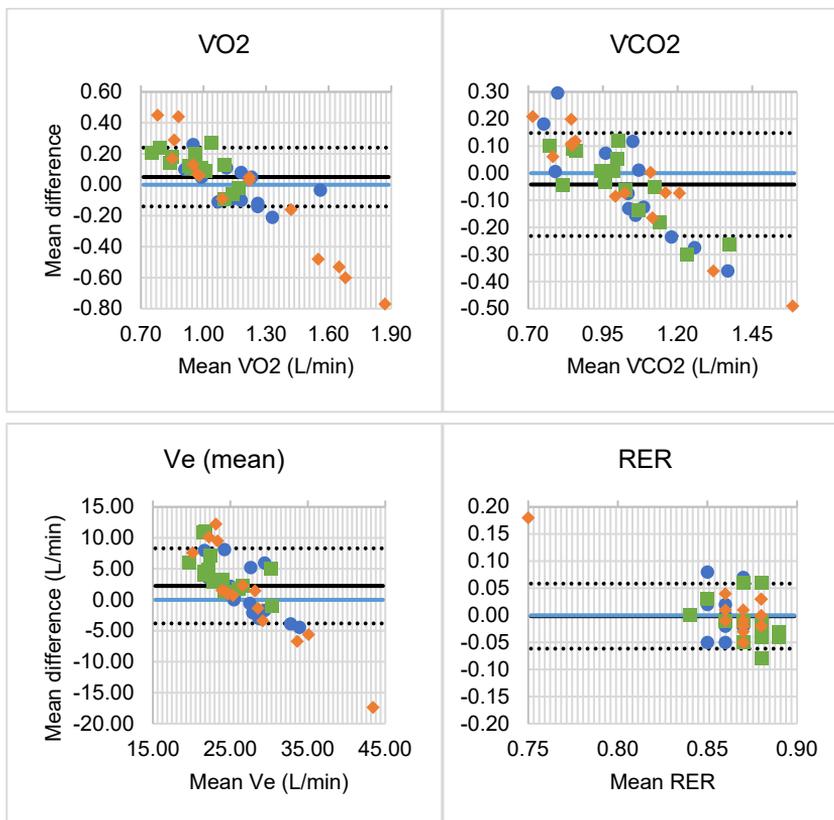


Figure 5.6 | Bland-Altman plot of $\dot{V}O_2$, $\dot{V}CO_2$, $\dot{V}E$ and RER. Bland-Altman plot of oxygen consumption ($\dot{V}O_2$) (upper-left) carbon dioxide production ($\dot{V}CO_2$) (upper-right), exhaled volume ($\dot{V}E$) (lower-left) and respiratory exchange ratio (RER) (lower-right) measured with the headset versus the mean difference between the mouth mask minus the headset, with mean (black line) and upper and lower Limit of Agreement (LoA) (black dotted line), mean difference between reference system and headset with a wind flow from the side (blue dot), wind flow from the front (green square) and fluctuating from the front (orange diamond), and zero-line (blue line).



5.3.4 | User experience

All subjects preferred the headset to the mouth-mask system. One subject stated: “After the test with the system with mouth mask, I understand why the headset is being designed. The mouth-mask system is not comfortable, causes irritation and impedes communication.” The results of the questionnaire are presented in Figure 5.7. All medians were 4.

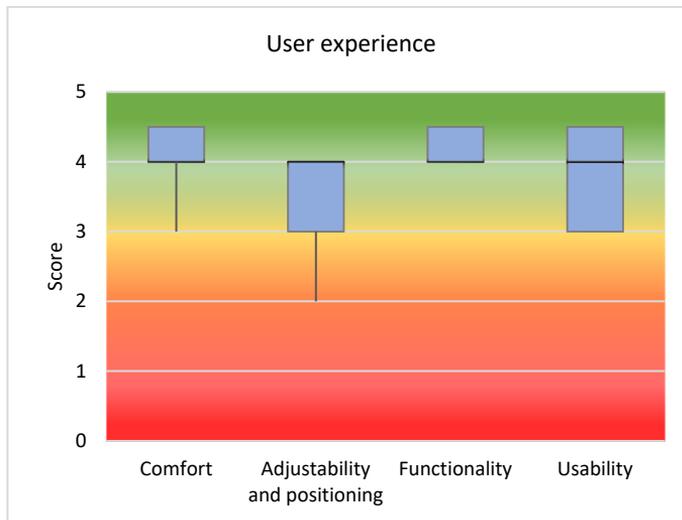


Figure 5.7 | User experience. Boxplot presenting median (black line), interquartile range of the questionnaire about user experience with aspects comfort, functionality, adjustability and positioning, and usability with a score of 1 indicating a very poor and 5 indicating an excellent score.

The headset was considered to be more practical due to the fact that it does not hinder communication and does not cause breathing resistance or the “trapped feeling” that the mouth mask does. Subjects felt that absence of the mouth mask made it more comfortable, less obtrusive and therefore preferable to the system with a mouth mask, for use during the working day. Two subjects mentioned that they experienced much greater breathing resistance with the mouth mask, which influenced their breathing pattern. Four subjects were not able to comment on the potential usability of this version in the workplace. One subject mentioned that for long-term wear (throughout the day), the headset could be heavy, and a lighter model would be preferable. Moreover, two subjects (and the researchers themselves) felt that hygiene of the headset needed to be improved. The fabric layer on the forehead could be cleaned, but it absorbed sweat which would be undesirable if the headset was shared by different users. Furthermore, the flow sensor in the air shield catching gases inhaled through the nose and mouth was complex and time-consuming to clean, also requiring optimization before implementation in the workplace. All but one subject felt that the headset was stable once in position during cycling and head

movements. One subject mentioned that the arm of the headset was constantly visible at the corners of the visual field, which was disturbing. According to all subjects, the headset did not interfere during the cycling test and seemed to be feasible during performance of physically active jobs. A final comment made by one of the subjects was that the design of the headset and back part is unattractive and too big and heavy. Subjects indicated the need for a professionalized prototype.

5.4 | Discussion

The aim of this study was to evaluate the validity and usability of a newly developed headset to measure energetic workload. The headset showed moderate to good validity when compared to the mouth mask for $\dot{V}O_2$, $\dot{V}CO_2$ and RER. The headset had better concurrent validity with the mouth mask (gold standard) than $\dot{V}O_2$ estimated on the basis of HR. Users considered the headset to be more practical than the mouth mask. However, at low air flows (e.g., when the user was resting), lower values for $\dot{V}O_2$ and $\dot{V}CO_2$ were measured, and magnifying algorithms were required. This led to a tendency to overestimate gas concentrations at high air flows (as when cycling at 125 W). The disturbing wind flow caused overestimation of the volume (mainly when the user was resting) and decreased the validity from good without wind to moderate or low with wind flow. However, the mean difference for $\dot{V}O_2$ across all phases was still acceptable. More extensive training and machine learning are required to optimize the algorithm of the headset, especially at high and low breathing volumes. Moreover, large intra-individual differences of $\dot{V}O_2$, $\dot{V}CO_2$ and RER were observed. In line with the comments of two subjects, the researchers noticed that the breathing pattern differed between cycling with the headset versus the mouth mask, which could have affected the outcomes. Before the headset can be implemented in the workplace, its design needs to be professionalized. Overall, the usability of the headset is promising. Because most of the quality criteria were fulfilled, proof-of-concept of the present version of the headset was supported.

A key strength of this study is the use of this completely new and innovative breathing-gas analysing system and comparison with current (medical and practical) standards in order to explore its concurrent validity and usability. This is the first study in which such a device has been presented and validated. The strength of the system is the lack of mouth mask, making it a more wearable design (headset), which provides the opportunity for users to communicate while wearing it. The system is comfortable and non-obtrusive and can potentially be used for prolonged periods of time. Individual physiological responses during activities can be investigated with this system. Our study included a broad range of subjects



varying widely in age, physical fitness and smoking habits. While all subjects passed the minimum cycling requirement of 30 min a day at 15 km/h, some far exceeded this lower limit. Some did smoke, others not. The variation in $\dot{V}O_2$ and $\dot{V}CO_2$ between subjects suggests that physical fitness varied, however, measurement of the subjects' maximum physical capacity was not needed for the objective of this study. Another strength of this study is the simulation of environmental conditions during outdoor work by correcting the system for wind.

A limitation of this study is the method used to calibrate the sensors on the headset. An optimal calibration procedure and suitable equipment are not yet available for this device. This could have caused deviations in the measurements within and between subjects. It is expected that these deviations were small and irrelevant due to the constant ambient laboratory conditions. However, the development of a calibration procedure requires further attention. In future studies, it would be preferable to validate the system against direct calorimetry methods. Moreover, the sample size in this study was limited for comparison with the validity of the $\dot{V}O_2$ estimated on the basis of heart rate ($n=7$), so the results only provide first indications. The limited amount of data that could be used for this comparison was caused by the limiting heart rate range (125 to 170 beats/min) of the Astrand-Ryhming nomogram. However, this also indicates that the headset would be applicable in a much wider activity range compared to the estimation based on heart rate. The reliability and accuracy of the headset will always be lower than with systems using a mouth mask. A mouth mask creates a closed environment in which all breathing gases pass one opening, which makes it easier to precisely measure all concentrations. The headset creates more open conditions in which breathing gases are directly mixed with environmental gases, resulting in lower measured O_2 and CO_2 concentrations. Magnifying algorithms and prediction models can in part compensate for this limitation.

Now that proof-of-concept has been established, further development and research need to be undertaken to increase the system's accuracy, validity and reliability. A professional prototype needs to be developed (TRL 5) based on this proof-of-concept, and the filtering methods, algorithms and models need to be optimized using more learning datasets. The design and mechanical features of the proof-of-concept version could be improved by designing a smaller headset with fewer fixation points around the head; a wind shield around the flow sensor; and a more professionalized and attractive design. Additionally, individual fitting, the most optimal distance in front of the nose and mouth and sustaining that position needs to be further ensured. With this improved prototype, more (validation) research, and research on test-retest reliability should be performed with a larger sample, including the target group of physically active workers. Moreover, the influence of working



activities (e.g. noise, vibration and body movements) on the validity of the system should be studied. In addition, the validation and usability of this headset need to be investigated in real-life working conditions (Havenith & Heus, 2004) associated with different kinds of physically demanding occupations. Furthermore, the future system should provide the user with personalized real-time feedback.

There is increasing interest in the potential of this breathing-gas analysing headset to monitor physiological responses of individuals during different kinds of activities (Tamura, 2019; Liu et al., 2019). The headset can be used to monitor individual responses to activity over full working days. Aside from the importance of such a system for monitoring the $\dot{V}O_2$ of physically active workers, there is also the potential for this system to be used in (occupational) healthcare and sports settings. The headset system could be an objective measurement tool for monitoring the energetic workload and capacity of individuals during various activities (working, rehabilitation and sports) carried out in users' actual environment over longer periods of time. This system is likely to be of interest as a low-level, comfortable and easy-to-use device for monitoring the physical fitness of subjects during their training in multiple settings. As the system can be used over longer periods of time in a comfortable manner, more complete information about the subject can be gathered rather than snapshots. This headset could fill a gap in the existing range of instruments for measuring energy consumption by being more valid than heart rate measurements and more usable than indirect calorimetry measurements with a mouth mask.

5.5 | Conclusion

The gas-exchange measuring headset has shown moderate to good validity compared to indirect calorimetry using a mouth mask for measuring $\dot{V}O_2$, $\dot{V}CO_2$, $\dot{V}E$ and RER. The headset is more valid compared to $\dot{V}O_2$ estimated on the basis of HR. Wind disturbances hampered the validity of the headset, but even with wind, the validity of the system remained acceptable. Users experienced the headset as more comfortable and usable compared to the mouth-mask system. The present version is not yet completely valid, but its potential is supported and indicates opportunities for further professionalization.



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Disclosures

C.C. Roossien, G.J. Verkerke and M.F. Reneman declare the following interests which may be considered as potential competing interests: pending patent application of University of Groningen and University Medical Center Groningen about the development breathing gases analysing headset [application number EP19189792.5]. All authors declare that they have no known financial interests related to this patent application or personal relationships that could have appeared to influence the work reported in this paper.



5.6 | Appendices

5.6.1 | Appendix A Validity compared to indirect calorimetry

Table 5.A.1 | Mean $\dot{V}O_2$, $\dot{V}CO_2$, V_e and RER per phase.

Phase	$\dot{V}O_2$ (L/min)	$\dot{V}CO_2$ (L/min)	$\dot{V}E$ (L/min)	RER
Mouth mask				
Rest	0.42±0.08	0.36±0.09	13.51±3.04	0.86±0.10
0W	0.76±0.09	0.60±0.10	20.11±2.27	0.79±0.08
75W	1.41±0.12	1.13±0.13	31.55±3.44	0.81±0.05
125W	1.97±0.20	1.83±0.18	48.26±6.47	0.93±0.06
Headset				
Rest	0.63±0.20	0.53±0.18	23.05±3.59	0.83±0.04
0W	0.87±0.22	0.75±0.21	25.20±4.90	0.85±0.07
75W	1.27±0.19	1.11±0.19	27.43±6.21	0.87±0.02
125W	1.69±0.37	1.50±0.35	31.46±6.41	0.89±0.02

Mean with standard deviation (SD) (mean±SD) for oxygen consumption ($\dot{V}O_2$), carbon dioxide production ($\dot{V}CO_2$) in L/min and respiratory exchange ratio (RER) measured with the mouth mask and headset.



Table 5.A.2 | Validity of the headset compared to the mouth mask for measuring O₂ and CO₂.

Parameter	Phase	MD±SD		p ^a	ICC [95% CI]	p ^b	LoA
		Absolute	Relative (%)				
FiO ₂ (%)	Mean	Z=1.996 *	-0.14±0.29	0.046	0.30 [-0.15;0.68]	0.130	±0.12
	Rest	-0.01±0.08	-0.05±0.39	0.568	0.20 [-0.35;0.64]	0.236	±0.16
	0W	-0.03±0.06	-0.14±0.29	0.067	0.50 [0.04;0.79]	0.015	±0.11
	75W	-0.04±0.07	-0.19±0.34	0.063	0.13 [-0.28;0.56]	0.285	±0.14
	125W	-0.04±0.08	-0.19±0.38	0.065	0.14 [-0.28;0.56]	0.276	±0.15
FeO ₂ (%)	Mean	0.00±0.43	0.00±10.63	0.996	0.80 [0.68;0.87]	<0.001	±0.84
	Rest	-0.97±0.69	-5.65±4.02	<0.001	0.16 [-0.11;0.53]	0.083	±1.35
	0W	-0.16±0.46	-0.97±2.80	0.198	0.60 [0.18;0.84]	0.006	±0.90
	75W	0.47±0.72	3.02±4.62	0.024	0.26 [-0.15;0.64]	0.109	±1.40
	125W	0.25±0.68	-1.58±4.29	0.172	0.45 [-0.02;0.77]	0.033	±1.33
FiCO ₂ (%)	Mean	0.02±0.02	18.25±18.25	0.019	0.20 [-0.18;0.59]	0.162	±0.04
	Rest	-0.04±0.05	-27.94±34.93	0.013	0.06 [-0.25;0.46]	0.377	±0.09
	0W	-0.02±0.03	-18.49±27.74	0.024	0.21 [-0.18;0.61]	0.157	±0.05
	75W	0.04±0.02	42.63±21.31	<0.001	0.05 [-0.08;0.30]	0.263	±0.04
	125W	0.04±0.02	42.94±21.47	<0.001	0.04 [-0.06;0.24]	0.272	±0.04
FeCO ₂ (%)	Mean	0.00±0.18	0.00±4.45	0.984	0.93 [0.81;0.98]	<0.001	±0.52
	Rest	0.39±0.17	11.54±4.20	<0.001	0.75 [-0.06;0.94]	<0.001	±0.33
	0W	0.20±0.33	5.42±8.95	0.030	0.73 [0.31;0.90]	<0.001	±0.64
	75W	-0.21±0.19	-4.72±4.27	0.001	0.83 [0.15;0.96]	<0.001	±0.36
	125W	-0.38±0.45	-8.00±9.48	0.005	0.54 [0.01;0.83]	0.002	±0.88
Ve/VCO ₂	Mean	0.94±5.48	3.24±18.85	0.516	0.39 [-0.15;0.74]	0.075	±10.74
	Rest	-10.52±18.27	-27.26±47.32	0.043	0.28 [-0.15;0.66]	0.106	±35.80
	0W	-3.83±17.28	-11.30±51.02	0.406	0.16 [-0.37;0.61]	0.282	±33.87
	75W	3.05±3.81	10.90±13.62	0.008	0.29 [-0.12;0.66]	0.068	±7.47
	125W	4.51±5.22	17.09±19.77	0.005	0.30 [-0.11;0.67]	0.053	±10.23

Mean differences (MD: headset – mouth mask) and p-value and the intraclass correlations (ICC) with a confidence interval (CI) of 95%, p-value and Limits of Agreement (LoA) of inhaled (FiO₂) and exhaled (FeO₂) concentration oxygen and inhaled (FiCO₂) exhaled (FeCO₂) concentration carbon dioxide and ventilatory efficiency (V_e/VCO₂) measured with the reference system indirect calorimetry with mouth mask against the headset. * Non-parametric data. ^a p-value of paired t-test. ^b p-value of ICC.



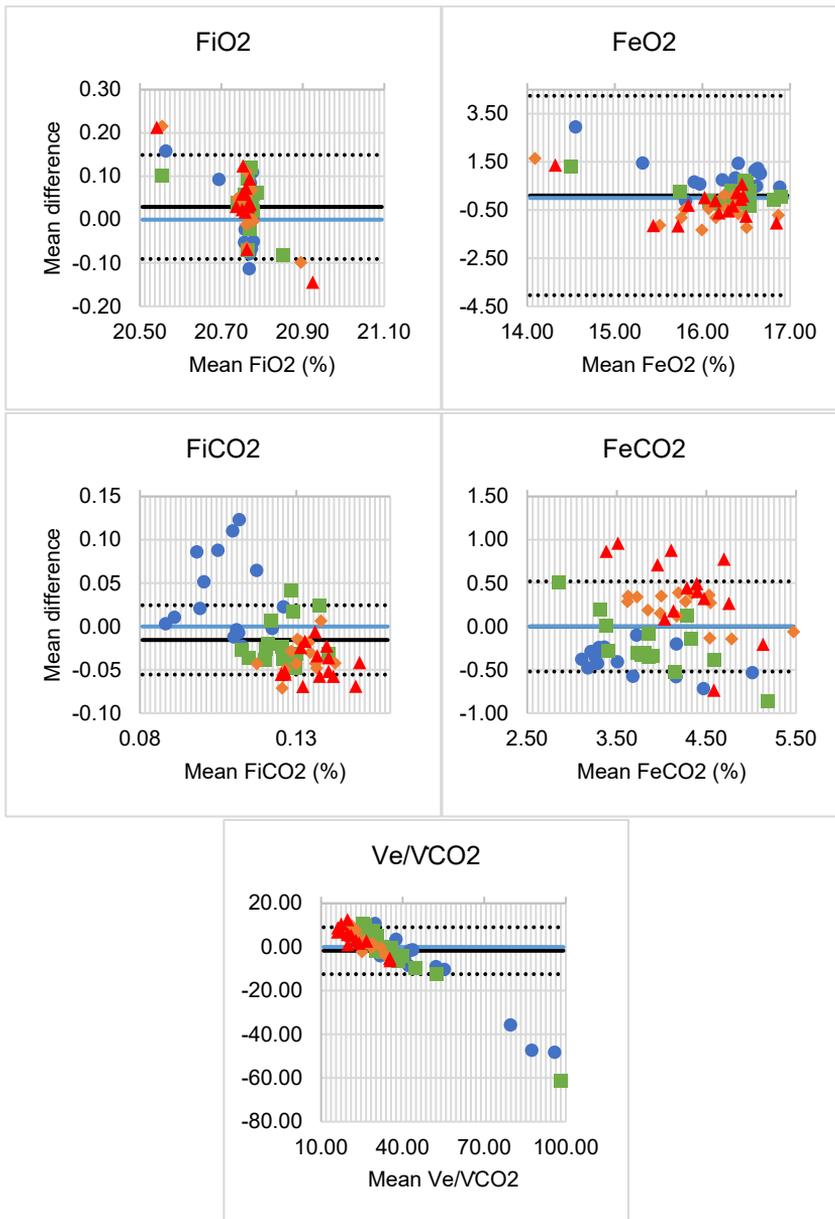


Figure 5.A.1 | Bland-Altman plot of FiO_2 , FeO_2 , $FiCO_2$, $FeCO_2$ and $Ve/\dot{V}CO_2$. Bland-Altman plots of the mean difference oxygen inhaled (FiO_2) (upper-left), oxygen exhaled (FeO_2) (upper-middle), carbon dioxide inhaled ($FiCO_2$) (lower-left) and carbon dioxide exhaled ($FeCO_2$) (lower-middle) in percentages and ventilatory efficiency ($Ve/\dot{V}CO_2$) (lower-right) versus the mean difference between indirect calorimetry with mouth mask and the headset with mean (black line) and upper and lower Limit of Agreement (LoA) (black dotted line), mean $\dot{V}O_2$ in rest (blue dot), 0W (green square), 75W (orange diamond) and 125W phase (red triangle) and zero-line (blue line).

5.6.2 | Appendix B Validity compared to $\dot{V}O_2$ estimated according to heart rate

Table 5.B.1 | Mean $\dot{V}O_2$ and HR per phase.

Phase	$\dot{V}O_2$ mouth mask (L/min)	$\dot{V}O_2$ headset (L/min)	HR (beats/min)
Rest	0.42±0.08	0.63±0.20	75.82±16.50
0W	0.76±0.09	0.87±0.22	80.05±15.92
75W	1.41±0.12	1.27±0.19	104.23±23.99
125W	1.97±0.20	1.69±0.37	126.58±27.54

Mean with standard deviation (SD) (mean±SD) for oxygen consumption ($\dot{V}O_2$) measured with the mouth mask and headset and heart rate (HR) in beats/min per phase.



5.6.3 | Appendix C Validity with influence of wind

Table 5.C.1 | Mean $\dot{V}O_2$, $\dot{V}CO_2$, $\dot{V}E$ and RER with influence of wind per phase.

Load	$\dot{V}O_2$ (L/min)	$\dot{V}CO_2$ (L/min)	$\dot{V}E$ (L/min)	RER
Rest	0.38±0.08	0.35±0.09	75.81±15.61	0.88±0.10
0W	0.73±0.08	0.59±0.07	78.91±15.63	0.81±0.06
75W	1.42±0.13	1.23±0.13	104.81±23.36	0.85±0.05
125W	1.95±0.16	1.81±0.14	128.10±28.06	0.92±0.06

Mean with standard deviation (SD) (mean±SD) for oxygen consumption ($\dot{V}O_2$), carbon dioxide production ($\dot{V}CO_2$) in L/min and respiratory exchange ratio (RER) measured with the mouth mask per phase with influence of the wind flow from the side, front and fluctuating in the front.



Table 5.C.2 | The influences of wind on the validity of the headset and the mouth mask for measuring $\dot{V}O_2$, $\dot{V}CO_2$, $\dot{V}E$ and RER influence by wind.

System	Wind	MD±SD		p ^a	ICC [95% CI]	p ^b	LoA
		Absolute	Relative (%)				
Mouth mask with wind vs mouth mask without wind							
$\dot{V}O_2$	Side	0.02±0.07	1.36±5.73	0.373	0.81 [0.52;0.93]	<0.001	±0.13
	Front	0.04±0.07	3.26±6.40	0.069	0.72 [0.35;0.90]	<0.001	±0.14
	Fluctuating	0.00±0.08	0.35±7.09	0.853	0.73 [0.37;0.90]	0.001	±0.16
$\dot{V}CO_2$	Side	0.00±0.06	-0.47±5.78	0.757	0.85 [0.60;0.95]	<0.001	±0.11
	Front	-0.01±0.07	-1.09±6.95	0.554	0.77 [0.45;0.92]	<0.001	±0.13
$\dot{V}e$	Fluctuating	0.02±0.08	2.11±8.25	0.340	0.67 [0.27;0.88]	0.002	±0.16
	Side	0.00±1.85	0.07±6.48	0.975	0.84 [0.58;0.94]	<0.001	±3.63
	Front	0.21±1.79	0.74±6.27	0.655	0.83 [0.57;0.94]	<0.001	±3.51
RER	Fluctuating	-0.66±2.33	-2.31±8.16	0.296	0.69 [0.31;0.88]	0.001	±4.57
	Side	0.01±0.02	1.38±2.78	0.075	0.79 [0.48;0.93]	<0.001	±0.05
	Front	0.02±0.02	2.43±2.54	0.002	0.75 [0.14;0.92]	<0.001	±0.04
	Fluctuating	0.03±0.02	3.06±2.44	<0.001	0.66 [-0.06;0.90]	<0.001	±0.04

Table 5.C.2 | (continued)

System	Wind	MD±SD		p ^a	ICC [95% CI]	p ^b	LoA
		Absolute	Relative (%)				
Headset with wind vs headset without wind							
VO ₂	Side	-0.18±0.16	-18.43±16.91	0.001	0.32 [-0.11;0.69]	0.025	±0.32
	Front	-0.01±0.14	-1.32±14.19	0.724	0.61 [0.15;0.85]	0.007	±0.27
	Fluctuating	-0.22±0.37	-23.13±38.21	0.034	0.06 [-0.30;0.48]	0.399	±0.73
VCO ₂	Side	0.04±0.17	4.55±17.73	0.337	0.45 [-0.05;0.77]	0.039	±0.34
	Front	0.04±0.16	3.84±16.30	0.377	0.51 [0.02;0.80]	0.024	±0.31
	Fluctuating	0.05±0.20	5.57±20.31	0.323	0.53 [0.04;0.82]	0.020	±0.39
V _e	Side	1.27±4.54	4.47±16.03	0.298	0.10 [-0.41;0.56]	0.358	±8.91
	Front	4.58±4.15	16.14±14.65	0.001	0.09 [-0.14;0.44]	0.251	±8.14
	Fluctuating	0.90±7.09	3.19±25.00	0.629	-0.07 [-0.59;0.46]	0.599	±13.89
RER	Side	0.00±0.02	0.52±2.72	0.473	0.21 [-0.33;0.64]	0.222	±0.05
	Front	0.01±0.02	1.16±2.71	0.063	0.26 [-0.18;0.65]	0.130	±0.05
	Fluctuating	0.00±0.05	0.28±5.58	0.850	-0.40 [-0.82;0.17]	0.918	±0.09

Mean differences (MD) and p-value and the intraclass correlations (ICC) with a confidence interval (CI) of 95%, p-value and Limits of Agreement (LoA) of oxygen consumption (VO₂), carbon dioxide production (VCO₂), exhaled volume (V_e) and Respiratory Exchange Ratio (RER) measured with the reference system indirect calorimetry with mouth mask (mouth mask) and the headset. The mouth mask and headset are compared with themselves while a wind flow (10m/second) was blowing at the systems from the side, front and fluctuating in front. ^a p-value of paired t-test. ^b p-value of ICC.

Table 5.C.3 | Validity of the headset compared to the mouth mask for measuring VO2 with wind.

Wind	Phase	MD±SD		p ^a	ICC [95% CI]	p ^b	LoA
		Absolute	Relative (%)				
Mouth mask without wind vs mouth mask with wind							
Side	Mean	-0.02±0.07	-1.36±5.73	0.373	0.81 [0.52;0.93]	<0.001	±0.13
	Rest	-0.04±0.08	-9.54±18.42	0.065	0.46 [0.00;0.77]	0.024	±0.15
	0W	-0.02±0.04	-2.80±5.83	0.084	0.85 [0.60;0.95]	<0.001	±0.09
	75W	0.02±0.09	1.21±6.73	0.496	0.71 [0.32;0.89]	0.001	±0.19
Front	125W	-0.02±0.13	-0.92±6.41	0.587	0.78 [0.45;0.92]	<0.001	±0.25
	Mean	-0.04±0.07	-3.26±6.40	0.069	0.72 [0.35;0.90]	<0.001	±0.14
	Rest	-0.05±0.06	-12.30±13.27	0.003	0.58 [0.01;0.85]	0.001	±0.11
	0W	-0.05±0.04	-6.41±5.88	0.001	0.76 [0.10;0.93]	<0.001	±0.09
Fluctuating	75W	-0.01±0.12	-0.85±8.54	0.705	0.58 [0.11;0.84]	0.011	±0.24
	125W	-0.04±0.17	-2.00±8.53	0.378	0.60 [0.16;0.85]	0.007	±0.33
	Mean	0.00±0.08	-0.35±7.09	0.853	0.73 [0.37;0.90]	0.001	±0.16
	Rest	-0.01±0.10	-2.91±23.72	0.642	0.45 [-0.08;0.78]	0.045	±0.19
0W	Mean	-0.04±0.05	-4.79±6.55	0.013	0.75 [0.29;0.92]	<0.001	±0.10
	75W	0.04±0.14	2.67±9.69	0.305	0.50 [0.02;0.80]	0.024	±0.27
	125W	0.00±0.14	-0.24±6.88	0.896	0.71 [0.32;0.89]	0.001	±0.27

Table 5.C.3 | (continued)

Wind	Phase	MD±SD		p ^a	ICC [95% CI]	p ^b	LoA
		Absolute	Relative (%)				
Mouth mask without wind vs headset with wind							
Side	Mean	-0.03±0.15	-2.57±13.48	0.473	0.42 [-0.10;0.76]	0.056	±0.30
	Rest	0.53±0.17	140.80±46.13	<0.001	0.03 [-0.03;0.18]	0.188	±0.34
	0W	0.20±0.18	27.38±24.17	0.001	0.16 [-0.13;0.53]	0.131	±0.35
	75W	-0.21±0.29	-14.57±20.74	0.017	0.20 [-0.18;0.59]	0.163	±0.58
	125W	-0.41±0.34	-20.93±17.45	<0.001	0.10 [-0.13;0.44]	0.216	±0.67
Front	Mean	-0.05±0.14	-4.75±13.07	0.181	0.51 [0.05;0.80]	0.018	±0.27
	Rest	-0.30±0.24	-82.88±65.34	<0.001	0.02 [-0.14;0.30]	0.446	±0.47
	0W	-0.30±0.23	-42.31±31.68	<0.001	0.08 [-0.11;0.40]	0.234	±0.45
	75W	0.13±0.28	9.66±20.35	0.087	0.42 [-0.05;0.75]	0.039	±0.55
	125W	0.26±0.28	13.50±14.39	0.003	0.27 [-0.12;0.64]	0.065	±0.55
Fluctuating	Mean	-0.06±0.38	-5.55±33.21	0.528	-0.05 [-0.57;0.47]	0.574	±0.74
	Rest	-0.47±0.27	-115.86±68.08	<0.001	0.06 [-0.08;0.32]	0.240	±0.54
	0W	-0.31±0.35	-42.12±48.47	0.005	-0.07 [-0.30;0.31]	0.667	±0.69
	75W	0.15±0.45	10.55±31.24	0.212	0.04 [-0.43;0.52]	0.440	±0.88
	125W	0.37±0.69	18.73±34.85	0.056	-0.07 [-0.43;0.39]	0.619	±1.34

Table 5.C.3 | (continued)

Wind	Phase	MD±SD		p ^a	ICC [95% CI]	p ^b	LoA
		Absolute	Relative (%)				
Headset without wind vs headset with wind							
Side	Mean	-0.18±0.16	-18.43±16.91	0.001	0.32 [-0.11;0.69]	0.025	±0.32
	Rest	-0.37±0.16	-69.26±30.42	<0.001	0.21 [-0.07;0.60]	0.005	±0.32
	OW	-0.19±0.17	-25.56±22.52	0.001	0.46 [-0.10;0.79]	0.003	±0.33
	75W	-0.11±0.33	-9.99±30.07	0.219	0.21 [-0.29;0.63]	0.215	±0.65
	125W	-0.04±0.38	-2.97±25.39	0.657	0.41 [-0.13;0.76]	0.064	±0.75
Front	Mean	-0.01±0.14	-1.32±14.19	0.724	0.61 [0.15;0.85]	0.007	±0.27
	Rest	-0.07±0.24	-13.54±44.48	0.258	0.10 [-0.39;0.57]	0.348	±0.47
	OW	-0.13±0.18	-17.71±24.15	0.013	0.48 [0.00;0.79]	0.009	±0.36
	75W	0.04±0.26	4.05±23.30	0.512	0.44 [-0.08;0.77]	0.047	±0.50
	125W	0.11±0.33	7.29±22.32	0.226	0.37 [-0.13;0.73]	0.077	±0.66
Fluctuating	Mean	-0.22±0.37	-23.13±38.21	0.034	0.06 [-0.30;0.48]	0.399	±0.73
	Rest	-0.34±0.38	-62.85±70.59	0.004	-0.11 [-0.34;0.27]	0.788	±0.74
	OW	-0.28±0.39	-37.21±51.78	0.015	-0.01 [-0.31;0.39]	0.531	±0.76
	75W	-0.19±0.51	-16.81±45.86	0.178	-0.12 [-0.55;0.38]	0.689	±0.99
	125W	-0.10±0.62	-6.58±41.65	0.551	0.28 [-0.27;0.69]	0.154	±1.22

Mean differences (MD: headset – mouth mask) and p-value and the intraclass correlations (ICC) with a confidence interval (CI) of 95%, p-value and Limits of Agreement (LoA) of oxygen consumption (VO2) measured with the reference system indirect calorimetry with mouth mask against the headset. The mouth mask and headset are compared with each other and with themselves while a wind flow (10m/second) was blowing at the systems from the side, front and fluctuating in front per phase. ^a p-value of paired t-test. ^b p-value of ICC.

Table 5.C.4 | Validity of the headset compared to the mouth mask for measuring $\dot{V}CO_2$ with wind.

Wind	Phase	MD±SD		p ^a	ICC [95% CI]	p ^b	LoA
		Absolute	Relative (%)				
Mouth mask without wind vs mouth mask with wind							
Side	Mean	0.00±0.06	-0.47±5.78	0.757	0.85 [0.60;0.95]	<0.001	±0.11
	Rest	-0.03±0.07	-7.93±20.19	0.151	0.64 [0.23;0.86]	0.003	±0.14
	0W	-0.01±0.04	-1.74±7.31	0.372	0.87 [0.67;0.96]	<0.001	±0.09
	75W	0.05±0.09	4.75±8.17	0.041	0.63 [0.19;0.86]	0.002	±0.18
Front	125W	-0.03±0.09	-1.83±4.81	0.163	0.86 [0.65;0.95]	<0.001	±0.17
	Mean	-0.01±0.07	-1.09±6.95	0.554	0.77 [0.45;0.92]	<0.001	±0.13
	Rest	-0.03±0.04	-9.65±12.58	0.010	0.80 [0.34;0.93]	<0.001	±0.09
	0W	-0.02±0.04	-3.54±6.30	0.047	0.89 [0.67;0.96]	<0.001	±0.07
Fluctuating	75W	0.05±0.10	4.04±8.45	0.085	0.62 [0.20;0.85]	0.003	±0.19
	125W	-0.03±0.17	-1.79±9.16	0.463	0.58 [0.12;0.84]	0.010	±0.33
	Mean	0.02±0.08	2.11±8.25	0.340	0.67 [0.27;0.88]	0.002	±0.16
	Rest	0.00±0.08	-0.79±23.20	0.897	0.61 [0.14;0.85]	0.008	±0.16
	0W	-0.01±0.04	-1.24±6.66	0.483	0.90 [0.73;0.97]	<0.001	±0.08
	75W	0.11±0.14	10.14±12.10	0.006	0.37 [-0.09;0.72]	0.027	±0.27
	125W	-0.02±0.14	-1.20±7.83	0.561	0.59 [0.12;0.94]	0.010	±0.28

Table 5.C.4 | (continued)

Wind	Phase	MD±SD		p ^a	ICC [95% CI]	p ^b	LoA
		Absolute	Relative (%)				
Mouth mask without wind vs headset with wind							
Side	Mean	0.04±0.18	4.21±18.30	0.388	0.17 [-0.36;0.62]	0.266	±0.35
	Rest	0.43±0.16	132.01±49.68	<0.001	0.08 [-0.05;0.36]	0.051	±0.32
	0W	0.19±0.21	32.96±35.61	0.003	0.07 [-0.19;0.44]	0.323	±0.41
	75W	-0.09±0.34	-7.86±28.58	0.305	0.08 [-0.43;0.55]	0.385	±0.66
Front	125W	-0.37±0.43	-20.62±23.77	0.005	-0.02 [-0.26;0.35]	0.544	±0.84
	Mean	0.04±0.13	4.15±13.43	0.251	0.50 [0.03;0.80]	0.022	±0.26
	Rest	0.26±0.22	79.59±69.21	0.001	0.00 [-0.17;0.31]	0.498	±0.44
	0W	0.31±0.20	53.89±69.21	<0.001	0.07 [-0.10;0.35]	0.245	±0.40
Fluctuating	75W	-0.07±0.26	-6.35±22.54	0.287	0.37 [-0.14;0.73]	0.078	±0.51
	125W	-0.33±0.30	-18.48±16.77	0.001	0.09 [-0.14;0.43]	0.259	±0.59
	Mean	0.04±0.18	3.72±17.76	0.505	0.39 [-0.17;0.75]	0.081	±0.35
	Rest	0.46±0.17	132.55±49.42	<0.001	0.07 [-0.08;0.35]	0.190	±0.33
75W	0W	0.40±0.26	67.19±44.03	<0.001	0.12 [-0.09;0.46]	0.096	±0.51
	125W	-0.13±0.22	-10.28±18.16	0.124	0.25 [-0.23;0.66]	0.165	±0.44
	Mean	-0.48±0.36	-26.80±20.01	<0.001	0.13 [-0.10;0.48]	0.119	±0.70

Table 5.C.4 | (continued)

Wind	Phase		MD±SD		p ^a	ICC [95% CI]	p ^b	LoA
	Absolute	Relative (%)	Absolute	Relative (%)				
Headset without wind vs headset with wind Side	Mean	0.04±0.17	4.55±17.73	0.337	0.45 [-0.05;0.77]	0.039	±0.34	
	Rest	0.23±0.19	42.79±35.25	<0.001	0.31 [-0.12;0.69]	0.020	±0.37	
	OW	0.03±0.19	4.39±25.84	0.505	0.62 [0.17;0.85]	0.006	±0.37	
	125W	-0.01±0.34	-1.11±31.11	0.892	0.22 [-0.35;0.66]	0.215	±0.67	
Front	Mean	-0.07±0.41	-4.83±27.36	0.505	0.38 [-0.15;0.74]	0.078	±0.80	
	Rest	0.04±0.16	3.84±16.30	0.377	0.51 [0.02;0.80]	0.024	±0.31	
	OW	0.05±0.29	8.46±54.28	0.556	-0.07 [-0.59;0.46]	0.599	±0.57	
	125W	0.14±0.20	18.56±27.10	0.019	0.48 [-0.02;0.77]	0.017	±0.40	
Fluctuating	Mean	0.00±0.27	-0.17±24.88	0.979	0.46 [-0.08;0.78]	0.045	±0.54	
	Rest	-0.03±0.36	-2.22±24.01	0.726	0.35 [-0.21;0.73]	0.101	±0.71	
	OW	0.05±0.20	5.57±20.31	0.323	0.53 [0.04;0.82]	0.020	±0.39	
	125W	0.26±0.25	48.11±47.36	0.002	0.25 [-0.13;0.64]	0.070	±0.50	
	Mean	0.13±0.24	17.36±32.24	0.065	0.27 [-0.18;0.67]	0.130	±0.47	
	Rest	0.02±0.25	1.83±22.39	0.764	0.54 [0.02;0.83]	0.023	±0.48	
	125W	-0.19±0.46	-12.73±30.35	0.141	0.19 [-0.29;0.63]	0.226	±0.89	

Mean differences (MD: headset – mouth mask) and p-value and the intraclass correlations (ICC) with a confidence interval (CI) of 95%, p-value and Limits of Agreement (LoA) of carbon dioxide production (VCO₂) measured with the reference system indirect calorimetry with mouth mask against the headset. The mouth mask and headset are compared with each other and with themselves while a wind flow (10m/second) was blowing at the systems from the side, front and fluctuating in front per phase. ^a p-value of paired t-test. ^b p-value of ICC.

Table 5.C.5 | Validity of the headset compared to the mouth mask for measuring VE with wind.

Wind	Phase	MD±SD		p ^a	ICC [95% CI]	p ^b	LoA
		Absolute	Relative (%)				
Mouth mask without wind vs mouth mask with wind							
Side	Mean	0.00±1.85	0.07±6.48	0.975	0.84 [0.58;0.94]	<0.001	±3.63
	Rest	0.47±2.63	3.48±19.46	0.486	0.63 [0.20;0.86]	0.005	±5.15
	OW	0.28±1.71	1.39±8.50	0.540	0.65 [0.22;0.87]	0.004	±3.35
	75W	-0.84±2.99	-2.66±9.48	0.295	0.64 [0.23;0.86]	0.004	±5.86
	125W	0.65±2.67	1.35±5.53	0.360	0.93 [0.80;0.98]	<0.001	±5.23
Front	Mean	0.21±1.79	0.74±6.27	0.655	0.83 [0.57;0.94]	<0.001	±3.51
	Rest	0.78±1.51	5.77±11.17	0.066	0.83 [0.55;0.94]	<0.001	±2.96
	OW	0.50±1.32	2.49±6.56	0.165	0.78 [0.47;0.92]	<0.001	±2.59
	75W	-0.47±2.76	-1.49±8.75	0.519	0.68 [0.27;0.88]	0.002	±5.41
	125W	0.04±4.39	0.08±9.10	0.975	0.82 [0.54;0.94]	<0.001	±8.61
Fluctuating	Mean	-0.66±2.33	-2.31±8.16	0.296	0.69 [0.31;0.88]	0.001	±4.57
	Rest	-0.08±2.51	-0.59±18.58	0.907	0.66 [0.23;0.87]	0.003	±4.92
	OW	0.13±1.24	0.65±6.17	0.680	0.84 [0.59;0.94]	<0.001	±2.43
	75W	-2.47±3.88	-7.83±12.30	0.027	0.47 [0.0;0.78]	0.015	±7.60
	125W	-0.21±4.11	-0.44±8.52	0.845	0.80 [0.51;0.93]	<0.001	±8.06

Table 5.C.5 | (continued)

Wind	Phase	MD±SD		p ^a	ICC [95% CI]	p ^b	LoA
		Absolute	Relative (%)				
Mouth mask without wind vs headset with wind							
Side	Mean	1.27±4.13	4.47±14.57	0.255	0.20 [-0.30;0.63]	0.220	±8.10
	Rest	-12.26±5.75	-90.75±42.53	<0.001	0.07 [-0.06;0.33]	0.137	±11.26
	OW	-2.27±4.61	-11.29±22.93	0.077	0.16 [-0.27;0.58]	0.245	±9.04
Front	75W	3.25±6.19	10.30±19.62	0.061	0.01 [-0.37;0.46]	0.475	±12.13
	125W	16.35±9.50	33.88±19.68	<0.001	0.00 [-0.10;0.20]	0.515	±18.61
	Mean	4.58±3.28	16.14±11.57	<0.001	0.22 [-0.12;0.60]	0.039	±6.43
Fluctuating	Rest	-5.52±3.65	-40.86±27.02	<0.001	0.08 [-0.10;0.37]	0.221	±7.15
	OW	-1.16±4.78	-5.76±23.77	0.364	-0.03 [-0.52;0.48]	0.539	±9.37
	75W	6.46±5.35	20.47±16.96	<0.001	0.09 [-0.13;0.43]	0.235	±10.49
Fluctuating	125W	18.51±6.39	38.35±13.23	<0.001	0.06 [-0.04;0.30]	0.068	±12.52
	Mean	0.90±7.53	3.19±26.53	0.649	-0.26 [-0.72;0.31]	0.815	±14.75
	Rest	-9.36±5.07	-69.25±37.53	<0.001	0.16 [-0.08;0.22]	0.404	±9.94
Fluctuating	OW	-3.59±6.27	-17.85±31.18	0.044	-0.14 [-0.47;0.32]	0.754	±12.29
	75W	1.76±9.92	5.58±31.44	0.503	-0.14 [-0.63;0.40]	0.695	±19.4
	125W	14.79±13.31	30.65±27.64	0.001	-0.07 [-0.25;0.26]	0.772	±26.15

Table 5.C.5 | (continued)

Wind	Phase	MD±SD		p ^a	ICC [95% CI]	p ^b	LoA
		Absolute	Relative (%)				
Headset without wind vs headset with wind							
Side	Mean	1.27±4.54	4.47±16.03	0.298	0.10 [-0.41;0.56]	0.358	±8.91
	Rest	-11.42±6.93	-79.60±48.28	<0.001	0.00 [-0.10;0.22]	0.483	±13.58
	OW	-2.56±5.72	12.92±28.88	0.105	0.07 [-0.36;0.52]	0.384	±11.22
	75W	3.35±6.78	10.57±21.43	0.077	-0.11 [-0.48;0.37]	0.679	±13.29
	125W	15.71±9.87	32.98±20.72	<0.001	0.00 [-0.11;0.22]	0.520	±19.34
Front	Mean	4.58±4.15	16.14±14.65	0.001	0.09 [-0.14;0.44]	0.251	±8.14
	Rest	-4.86±4.12	-33.87±28.73	0.001	0.05 [-0.15;0.37]	0.363	±8.08
	OW	-1.45±6.42	-7.29±32.39	0.398	-0.31 [-0.73;0.24]	0.870	±12.58
	75W	6.56±6.54	20.73±20.67	0.002	-0.07 [-0.27;0.28]	0.705	±12.82
	125W	17.87±7.02	37.51±14.74	<0.001	0.06 [-0.05;0.30]	0.105	±13.76
Fluctuating	Mean	0.90±7.09	3.19±25.00	0.629	-0.07 [-0.59;0.46]	0.599	±13.89
	Rest	-8.52±5.12	-59.34±35.65	<0.001	0.03 [-0.09;0.27]	0.338	±10.03
	OW	-3.88±6.42	19.57±32.38	0.035	0.03 [-0.32;0.46]	0.448	±12.58
	75W	1.85±9.52	5.86±30.09	0.463	-0.03 [-0.54;0.49]	0.538	±18.66
	125W	14.15±13.10	29.71±29.71	0.001	-0.03 [-0.22;0.29]	0.603	±27.74

Mean differences (MD: headset – mouth mask) and p-value and the intraclass correlations (ICC) with a confidence interval (CI) of 95%, p-value and Limits of Agreement (LoA) of exhale volume (V_e) measured with the reference system indirect calorimetry with mouth mask against the headset. The mouth mask and headset are compared with each other and with themselves while a wind flow (10m/second) was blowing at the systems from the side, front and fluctuating in front per phase. ^a p-value of paired t-test. ^b p-value of ICC.

Table 5.C.6 | Validity of the headset compared to the mouth mask for measuring RER with wind.

Wind	Phase	MD±SD		p	ICC [95% CI]	p	LoA
		Absolute	Relative				
Mouth mask without wind vs mouth mask with wind							
Side	Mean	0.01±0.02	1.38±2.78	0.075	0.79 [0.48;0.93]	<0.001	±0.05
	Rest	0.15±0.05	17.93±6.25	0.285	0.85 [0.61;0.95]	<0.001	±0.10
	0W	0.01±0.03	1.39±3.53	0.150	0.92 [0.78;0.97]	<0.001	±0.05
	75W	0.03±0.04	3.69±4.56	0.007	0.60 [0.06;0.85]	0.001	±0.07
	125W	-0.01±0.04	-1.01±3.93	0.335	0.83 [0.57;0.94]	<0.001	±0.07
Front	Mean	0.02±0.02	2.43±2.54	0.002	0.75 [0.14;0.92]	<0.001	±0.04
	Rest	0.02±0.63	2.74±73.87	0.173	0.78 [0.47;0.92]	<0.001	±1.24
	0W	0.02±0.35	2.31±44.99	0.067	0.86 [0.61;0.95]	<0.001	±0.69
	75W	0.04±0.03	5.05±4.02	<0.001	0.54 [-0.09;0.84]	<0.001	±0.06
	125W	0.00±0.03	-0.04±3.69	0.970	0.84 [0.59;0.94]	<0.001	±0.07
Fluctuating	Mean	0.03±0.02	3.06±2.44	<0.001	0.66 [-0.06;0.90]	<0.001	±0.04
	Rest	0.02±0.05	2.85±5.86	0.081	0.85 [0.59;0.95]	<0.001	±0.10
	0W	0.03±0.05	3.78±6.52	0.041	0.67 [0.25;0.88]	0.001	±0.10
	75W	0.06±0.03	7.30±4.20	<0.001	0.42 [-0.10;0.79]	0.001	±0.07
	125W	-0.01±0.04	-1.02±4.00	0.339	0.77 [0.45;0.92]	<0.001	±0.07

Table 5. C.6 | (continued)

Wind	Phase	MD±SD		p	ICC [95% CI]	p	LoA
		Absolute	Relative				
Mouth mask without wind vs headset with wind							
Side	Mean	0.01±0.04	0.75±4.54	0.532	0.03 [-0.50;0.53]	0.456	±0.08
	Rest	-0.01±0.09	-0.78±10.52	0.777	0.22 [-0.35;0.66]	0.217	±0.18
	OW	0.06±0.07	6.89±8.63	0.008	-0.01 [-0.28;0.38]	0.522	±0.14
	75W	0.03±0.06	4.06±6.88	0.038	-0.13 [-0.45;0.33]	0.735	±0.11
Front	125W	-0.05±0.07	-5.47±7.68	0.015	-0.03 [-0.32;0.38]	0.567	±0.14
	Mean	0.01±0.04	0.79±4.80	0.535	-0.01 [-0.60;0.43]	0.634	±0.08
	Rest	-0.02±0.10	-2.22±11.53	0.469	0.01 [-0.52;0.51]	0.490	±0.20
	OW	0.06±0.07	7.29±8.84	0.006	-0.11 [-0.35;0.29]	0.750	±0.14
Fluctuating	75W	0.03±0.05	3.84±6.16	0.030	-0.07 [-0.39;0.37]	0.637	±0.10
	125W	-0.04±0.07	-4.56±7.29	0.030	-0.07 [-0.39;0.37]	0.629	±0.13
	Mean	-0.01±0.05	-0.95±6.23	0.564	-0.50 [-0.86;0.05]	0.967	±0.11
	Rest	-0.02±0.10	-2.33±11.08	0.429	0.05 [-0.48;0.54]	0.434	±0.19
75W	OW	0.05±0.06	6.04±7.63	0.008	-0.11 [-0.37;0.30]	0.745	±0.12
	125W	0.01±0.05	1.11±6.14	0.494	0.08 [-0.46;0.56]	0.390	±0.10
	Mean	-0.07±0.15	-7.63±16.40	0.093	-0.21 [-0.57;0.28]	0.825	±0.30

Table 5.C.6 | (continued)

Wind	Phase	MD±SD		p	ICC [95% CI]	p	LoA
		Absolute	Relative				
Headset without wind vs headset with wind							
Side	Mean	0.00±0.02	0.52±2.72	0.473	0.21 [-0.33;0.64]	0.222	±0.05
	Rest	0.03±0.04	3.74±4.86	0.010	0.20 [-0.16;0.59]	0.150	±0.08
	OW	0.00±0.07	0.52±7.73	0.798	0.17 [-0.40;0.62]	0.277	±0.13
	75W	0.00±0.03	-0.01±3.66	0.992	-0.13 [-0.65;0.41]	0.676	±0.06
	125W	-0.02±0.03	-1.69±3.23	0.061	0.21 [-0.22;0.62]	0.182	±0.06
Front	Mean	0.01±0.02	1.16±2.71	0.063	0.26 [-0.18;0.65]	0.130	±0.05
	Rest	0.03±0.05	3.09±5.82	0.059	-0.13 [-0.48;0.34]	0.728	±0.10
	OW	0.13±0.06	15.74±6.48	0.363	0.78 [-0.14;0.74]	0.077	±0.11
	75W	0.01±0.03	1.13±2.93	0.158	0.30 [-0.18;0.68]	0.116	±0.05
	125W	0.00±0.03	0.25±3.03	0.750	0.20 [-0.37;0.64]	0.237	±0.05
Fluctuating	Mean	0.00±0.05	0.28±5.58	0.850	-0.40 [-0.82;0.17]	0.918	±0.09
	Rest	0.03±0.04	3.06±4.81	0.027	0.15 [-0.23;0.55]	0.245	±0.08
	OW	0.02±0.07	1.89±8.58	0.404	-0.13 [-0.61;0.40]	0.681	±0.14
	75W	0.01±0.03	0.65±3.61	0.499	0.15 [-0.39;0.61]	0.290	±0.06
	125W	-0.04±0.13	-3.95±14.66	0.314	-0.04 [-0.53;0.46]	0.563	±0.25

Mean differences (MD: headset – mouth mask) and the intraclass correlations (ICC) with a confidence interval (CI) of 95%, p-value and Limits of Agreement (LoA) of respiratory exchange ratio (RER) measured with the reference system indirect calorimetry with mouth mask against the headset. The mouth mask and headset are compared with each other and with themselves while a wind flow (10m/second) was blowing at the systems from the side, front and fluctuating in front per phase.

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Chapter 6

Monitoring core temperature of firefighters to validate a wearable non-invasive core thermometer in different types of protective clothing: concurrent in-vivo validation

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Abstract

This study aims (1) to test the validity of a new non-invasive core thermometer, Cosinuss°, in rest and (2) during firefighting simulation tasks, against invasive temperature pill and inner-ear temperature and (3) to compare the change in core temperature of firefighters when working in two types of protective clothing (traditional turnout gear versus new concept). 11 active firefighters performed twice a selection of tasks during their periodic preventive medical examination and a fire-extinguishing task. Without correction no correlation between the Cosinuss° and thermometer pill ($ICC \leq 0.09$, $p \geq 0.154$, $LoA \geq 1.37$) and a moderate correlation between Cosinuss° and inner-ear infrared ($ICC = 0.40$, $p = 0.044$, $LoA \pm 1.20$) was observed. With individual correction both correlations were excellent ($ICC \geq 0.84$, $p = 0.000$, $LoA \leq 0.30$). However, during and after working all correlations were poor and non-significant ($ICC \leq 0.38$, $p \geq 0.091$, $LoA \geq 1.71$). During firefighting tasks, the Cosinuss° is invalid for measuring the core temperature. No differences in heat development in the two types of protective clothing was proven.

Keywords: ambient conditions, core temperature, heat stress, physical activity



6.1 | Introduction

During their job firefighters are exposed to a high thermal load due to heavy physical activity, external heat exposure from fires and the wear of highly insulated protective clothing. High thermal load can cause heat stress (McQuerry, et al., 2018;Costello, et al., 2015; Yazdi & Sheikzadeh, 2014; Nunneley, 1989; Levels, et al., 2014), resulting in heat exhaustion, dehydration, mental confusion, physical fatigue and loss of consciousness which affects productivity and risk perception (Chang, et al., 2017; Cvirn, et al., 2019; Epstein & Moran, 2006; McInnes, et al., 2017; Barr, et al., 2010). To monitor and prevent heat stress among firefighters, a reliable and continuous thermometer which is able to measure the real-time core temperature of firefighters is desirable (Mazgoaker, et al., 2017; Savage, et al., 2014; Steck, et al., 2011; Uth, et al., 2016).

Invasive core temperature (T_c) measurements may not be practical in a working situation (Levander & Grodzinsky, 2017; Lim, et al., 2008; Saurabh, et al., 2014; Taylor, et al., 2014). The invasive temperature sensor pill is minimally invasive, but at the moment it is only available for remote T_c monitoring for a specific period of time and it is difficult to standardize the location of the sensor in the gastrointestinal tract (Mazgoaker, et al., 2017). Additionally, the pill must be swallowed at least 4 to 6 hours prior to the measurement (HQInc., 2018) which is difficult in occupations such as firefighting because it is unknown when duty will call. Moreover, temperature sensor pills are impractical due to the high cost and inability for them to be reused (Mazgoaker, et al., 2017). In addition, food and liquid intake can influence the accuracy of the temperature sensor pill and higher body weights and/or abdominal proportions obstruct reading of the sensor. Other methods and research concerning non-obstructive measurement or prediction of T_c , e.g., via skin temperature or multiple parameters are not yet reliable or available for workers (Langridge, et al., 2012; Gonzalez-Alonso, et al., 1999; Lim, et al., 2008; Richmond, et al., 2015; Yang, et al., 2017).

The Cosinuss° C-med (Cosinuss° GmbH, München, Germany) is a new wearable, non-obstructive and commercially available inner-ear thermometer that could be useful to monitor T_c continuously and in a non-invasive manner. This sensor system could provide more detailed and long-term insight in the change in T_c during firefighting activities, as well as the role of different types of protective clothing (Barr, et al., 2010), either as an individual measuring system or in combination with multiple variables (Richmond, et al., 2015). In research of Chaglla et al. (2018) the Cosinuss° One demonstrated a deviation of -1.5°C in comparison to inner-ear infrared (IR) thermometry. The correlation of the Cosinuss° C-med and compared to the research standard of gastrointestinal temperature is unknown (Towey, et al., 2017; Langridge, et al., 2012; Gonzalez-Alonso, et al., 1999).



The objective of this study is to investigate the validity of the Cosinuss° to monitor changes in core temperature during realistic physical active firefighting simulation tasks instead of standard lab controlled treadmill protocols to mimic the real-life situation as well as possible (Havenith & Heus, 2004). The aim of this study was (1) to test the validity and reliability of a wearable non-invasive T_c sensor, Cosinuss°, in rest in comparison to an invasive temperature sensor pill and standard inner-ear IR thermometer and (2) during realistic firefighting simulation tasks in comparison to an invasive temperature sensor pill, and (3) to compare the change in T_c recorded with the Cosinuss° and an invasive temperature sensor pill of firefighters during realistic firefighting simulation tasks in two types (traditional turnout gear versus a new concept) of protective clothing.

6.2 | Materials and methods

6.2.1 | Subjects

The subjects participated voluntarily and were recruited by distributing flyers and during an information meeting organized by the fire department via the local safety region. Inclusion criteria were firefighters with an age between 18 and 67 years who passed the Periodic Preventive Medical Examination (PPMO). Exclusion criteria were body weights lower than 40 kg, problems or complaints with the gastrointestinal tract and/or infestation of propreflex, and needing to undergo Nuclear Magnetic Resonance Imaging or Magnetic Resonance Imaging in the next 24 hours after swallowing the thermometer pill (HQInc., 2018). Subject information was protected by double-blinding the data; the fire department gave every subject a letter and the researchers coupled a number to this letter using a random number generator.

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 and approved the study (M17.209969).

6.2.2 | Materials

6.2.2.1 | *Cosinuss°*

The Cosinuss° type C-med (Cosinuss° GmbH, München, Germany) is a wearable core thermometer which measures the temperature in the inner-ear. This hearing-aid shaped thermometer can be used in working conditions of -15 to 55°C. According to Cosinuss° (Cosinuss°, 2016) the sample frequency is 100 Hz and the accuracy is $\pm 0.1^\circ\text{C}$.



6.2.2.2 | CorTemp®

The CorTemp® HT150002 is an ingestible core body temperature sensor (dimensions: 2.4x10.7 mm) that has been approved by the US Food and Drug Administration (no. K880639) (HQ Inc., 2018). This thermometer sensor pill has a temperature range 30 to 40°C and an accuracy of $\pm 0.1^\circ\text{C}$ (HQ Inc., 2018). The pill data was continuously collected using the CorTemp® Data Recorder (dimensions 120x60x25mm, 193 grams) with a sampling rate of 10 seconds (HQ Inc., 2018). The data recorder used CorTrack™ II Software version 2.7 (HQ Inc., 2006) and needed to be worn around the hips.

6.2.2.3 | Inner-ear infrared thermometer

The Braun ThermoScan® 7 type IRT 6520 (Braun GmbH, Kornberg, Germany) is an inner-ear IR thermometer. Due to its fast, easy to use and non-invasive nature, inner-ear IR thermometry is being used as a clinical standard (Garcia-Souto & Dabnichki, 2016; Nederlands Huisartsen Genootschap, 2016; Kocoglu, et al., 2002). The Braun ThermoScan® has a measurement range temperature of 35 to 42°C with an accuracy of $\pm 0.2^\circ\text{C}$ compared to rectal temperature measurements in an operating T_a of 10 to 40°C (Braun GmbH, sd; Moran-Nabarro, et al., 2018).

6.2.2.4 | Ambient conditions box

To measure the ambient temperature (T_a) and relative humidity (RH) (SHT15 Breakout, Sensirion, Staefa ZH, Switzerland) inside the protective clothing, an ambient conditions box was worn. The box was positioned on the chest using elastic belts and was worn over the first layer of clothing (a cotton t-shirt) and below the fire suit measuring the micro-climate inside the personal protective clothing. The temperature inside the clothing was described as T_{cli} (Lotens, 1993). The T_{cli} sensor has an accuracy of $\pm 0.3^\circ\text{C}$ and the RH sensor has an accuracy of $\pm 2.0\%$ at a range of 10 to 90% RH (Sensirion, 2010). The response time was 5 to 20 seconds and the operating temperature was -40 to 120°C (Sensirion, 2010).

6.2.2.5 | Personal protective clothing

Two types of personal protective clothing were used; suit A and B. Suit A is traditional turnout gear composed of a trouser with jacket. Both trouser and jacket contained three layers; (1) outer fabric made of XT5 Nomex® Delta T; (2) moisture barrier made of MO3 Gore-tex® fireblocker; and (3) thermal barrier and inner layer made of Q01 thermal felt quilted to Nomex® viscose (standard EN469:2005) (Bristol Uniforms, 2007). This suit has a water vapor resistance of 28m2Pa/W, a thermal heat insulation (HTI) resistance HTI 24 of 21.3s and HTI 24-12 of 6.3s, and a radiation thermal heat insulation (RHTI) RHTI 24 of 26.2s and RHTI 24-12 of 7.1s. Suit B is a new protective clothing concept composed of a coverall with jacket. The jacket contained two layers; (1) an outer fabric made of TenCate Millenia™



Mi 9200 and (2) an inner layer made of TenCate Defender™ CZ 760. The coverall contains three layers; (1) an outer fabric made of TenCate Mllenia™ MI 9200 and Tecasafe® Plus XL 9700; (2) an inner layer of TenCate Defender™ CZ760 (upper part) and DM9180 (lower part); and (3) a thermal barrier of TenCate thermal membrane CX 140 (Safety Masters, 2017). This suit has a water vapor resistance of 12.6m²Pa/W, a thermal heat insulation (HTI) resistance HTI 24 of 17.4s and HTI 24-12 of 5.3s, and a radiation thermal heat insulation (RHTI) RHTI 24 of 21.0s and RHTI 24-12 of 7.4s.

The main difference between suit A and B was the clothing ensembles and its protection level. Suit A (traditional turnout gear) contains a trouser and jacket which both need to be worn during firefighting work with protection level 2 according to the standard EN469 (EN 469:2005/A1:2006 Protective clothing for firefighters – Performance requirements for protective clothing for firefighting). Suit B (new protective clothing concept) contains a coverall with jacket of which the jacket only is mandatory during indoor fire-extinguishing work to provide protection level 2 of the standard EN469. The coverall without the jacket provided only protection level 1. The difference in design of the clothing ensemble (amount of layers) was expected to influence the ventilation and release of heat and so the rise in T_c during the performance of the work.



Figure 6.1 | Left: Suit A, traditional turnout gear of Bristol Uniforms containing a trouser with jacket; Right: Suit B, a new protective clothing concept of Safety Masters containing a coverall combined with a separate outer jacket.

6.2.3 | Study design

The protocol contained the following three stages: (1) concurrent validation measurement; (2) performance of realistic firefighting simulation tasks; (3) concurrent validation measurement. In the concurrent validation measurements in stage 1 and 3, the T_c of the

subjects was measured five times at rest with a frequency of one measurement per minute. The T_c was recorded using the Cosinuss^o (in one ear) and using the CorTemp[®] and an inner-ear IR thermometer (in other ear) as references. These concurrent validation measurements were performed in a room with a constant T_a of $20.0 \pm 2.0^\circ\text{C}$ and RH of $45.0 \pm 5.0\%$. Stage 2 contained a simulation of two realistic firefighting simulations tasks of approximately 15 minutes per task. First, a selection of standardized tasks were performed selected from the Periodic Preventive Medical Examination (PPMO) protocol namely:

- track including rolling out and up a fire hose of 15 m;
- climbing and descending a ladder (96 steps) with a fire hose of 20 kg over the shoulder;
- crawling through two tunnels (tunnel of 3 m long and 1.2 m height with 3 m between the two tunnels) with a fire hose;
- a demolition operation where a ball of 5 kg needs to be hit the upper side of a basket ten times with a stick of 6 kg on a height of 2.5 m;
- and punching a door with a forcible entry tool of 16 kg.
- The PPMO was performed in a room with a constant T_a of $20.0 \pm 2.0^\circ\text{C}$ and RH of $45.0 \pm 5.0\%$. Secondly, a hot fire-extinguishing task while wearing self-contained breathing apparatus (SCBA) including:
 - extinguishing a fire,
 - searching for victim,
 - and kneeling in front of a fire of 220 a 225°C .

The T_c of the subjects was recorded continuously using the Cosinuss^o (one measurement per second) and using the CorTemp[®] (one measurement per 10 seconds) as reference. Due to the non-wearable character of the inner-ear thermometer this thermometer could not be included in stage 2. The hot fire-extinguishing task was performed in a practice building with a fireplace of 220 a 225°C . The task started outdoor with a T_a of $13.0 \pm 2.0^\circ\text{C}$, RH of $72.0 \pm 5.0\%$ and mean wind speed of 3.2m/s. The estimated heat radiations was about $4\text{kW}/\text{m}^2$.

In all three stages the subjects wore suit A (trouser and jacket) or suit B (coverall with jacket). After the first round of stage 2 the subject changed suit and performed this stage again in the second suit. To avoid order effects, the order in which the suits were worn alternated per subject. Both measurements in the different suits were performed on the same day in the same order: a concurrent validation measurement, the PPMO, the hot fire-extinguishing task and a concurrent validation measurement. The PPMO test was done before the hot fire-extinguishing task, because according to regulations after the hot fire-



extinguishing task the subjects needed to clean their clothing. Between the three stages, the two tasks and between the measurements in suit A and B, the subjects had time to acclimatize or cool down by passive sitting and drinking water for a period of 10 minutes. In Table 6.1, this study design is presented.

To test the in-vivo validity and reliability of the Cosinuss° in rest (aim 1), in the concurrent validity study of stage 1 and 3 the Cosinuss° was compared to the references CorTemp® and an inner-ear IR thermometer. To test the in-vivo validity and reliability of the Cosinuss° during work (aim 2), in stage 2 the Cosinuss° was compared to the reference CorTemp®. To explore the change in individual T_c , T_{cli} and RH of the subjects (aim 3), during stage 2 the T_c was continuously recorded with the Cosinuss° and CorTemp® and T_{cli} and RH were continuously recorded using the ambient conditions box (measurement frequency of one measurement per second). To compare the change in T_c , T_{cli} and RH in the two types of protective clothing, the two tasks in stage 2 were performed twice; once in suit A and once in suit B.



Table 6.1 | Study design; study design including stages 1 to 3. NB. Stage 2 was performed twice (once wearing suit A, once wearing suit B) with the order counterbalanced between subjects.

Stage	Activity	Measurement	Task	Thermometers	Measurement frequency	Duration
0	Dress up	-	Put on suit A	CorTemp®	-	-
1	Acclimatization	-	Passive sitting and drinking water	Cosinuss® CorTemp®	-	10 min
	Measurement	Concurrent validity	Rest (passive sitting)	Cosinuss® CorTemp® Inner-ear	Once per minute	5 min
	Measurement	Performance of job simulation	Periodic Preventive Medical Examination	Cosinuss® CorTemp®	Continuously during task	15 min
2	Cool down	-	Passive sitting and drinking water	Cosinuss® CorTemp®	-	10 min
	Measurement	Performance of job simulation	Fire-extinguishing task	Cosinuss® CorTemp®	Continuously during task	15 min
	Cool down	-	Passive sitting and drinking water	Cosinuss® CorTemp®	-	10 min
2	Dress up	-	Put off suit A, put on suit B	CorTemp®	-	10 min
	Acclimatization	-	Passive sitting and drinking water	Cosinuss® CorTemp®	-	10 min
	Measurement	Performance of job simulation	Periodic Preventive Medical Examination	Cosinuss® CorTemp®	Continuously during task	15 min
3	Cool down	-	Passive sitting and drinking water	Cosinuss® CorTemp®	-	10 min
	Measurement	Performance of job simulation	Fire-extinguishing task	Cosinuss® CorTemp®	Continuously during task	15 min
	Cool down	-	Passive sitting and drinking water	Cosinuss® CorTemp®	-	10 min
3	Measurement	Concurrent validity	Rest (passive sitting)	Cosinuss® CorTemp® Inner-ear	Once per minute	5 min

6.2.4 | Data analysis

Field calibration to correct the Cosinuss° was explored and conducted based on both the CorTemp® and the inner-ear IR thermometer during stage 1. To correct the Cosinuss° the second measurement of stage 1 was used; per subject in one ear the T_c was recorded with the Cosinuss° and compared to the T_c recorded with the CorTemp® and the inner-ear IR thermometer in the other ear. The difference between the measured T_c of the Cosinuss° and CorTemp® or inner-ear thermometer was considered as the individual correction factor of the Cosinuss°. The CorTemp® sensors were factory calibrated and the HQ Inc data loggers were calibrated according to the user instructions.

To test the aims, statistical analysis was performed using IBM SPSS Statistic 25. To test the validity and reliability of the Cosinuss° in rest (aim 1), of stage 1 and 3 the fourth concurrent validation measurement was used, including the T_c recorded with the Cosinuss°, CorTemp® and inner-ear thermometer. To test the validity and reliability of the Cosinuss° during work (aim 2), of stage 2 the mean T_c per task and of both tasks recorded with the Cosinuss and CorTemp® was used. To compare the development of T_c while working in two types of protective clothing (aim 3), per subject two datasets were generated, one in suit A and one in suit B. Of stage 2 the mean T_c , T_{cli} and RH per task and of both tasks per suit was used. Sensitivity analysis was performed to test differences between the fourth and fifth measurement (stage 1 and 3) and the mean of all measurements (all stages), in addition to being performed on only complete datasets (all stages). These sensitivity analyses were performed to verify if the fourth measurement and incomplete datasets are representative.

Parametric data were analysed using the paired t-test and by calculating the intraclass correlation coefficient (ICC, two-way random model). Non-parametric data were analysed with the Wilcoxon signed rank test. The results are shown with mean or the mean difference (MD) and standard deviation (SD) (mean \pm SD). P-values ≤ 0.05 were considered statistically significant. The interpretation of the ICC: ICC < 0.39 is poor, $0.40 > \text{ICC} > 0.59$ is moderate, $0.60 > \text{ICC} > 0.79$ is good and ICC ≥ 0.80 is excellent (Cicchetti, 1994). The Limits of Agreement (LoA), calculated as $\pm 1.96 * \text{SD}_{\text{difference}}$, has an acceptable level of LoA ≤ 0.50 (Bland & Altman, 1999). To illustrate if the magnitude of the difference was related to the mean performance, Bland-Altman plots were made (Bland & Altman, 1999). The individual difference were plotted against the individual mean of the stages (Bland & Altman, 1999).



6.3 | Results

Eleven firefighters (10 male and one female) with a mean age of 40.1 ± 8.0 years participated in this study. One subject was not able to perform the study in the suit A and due to an error not all data of the Cosinuss° and ambient condition box datasets were stored. The usability and sample size of the incomplete datasets varies per aim. Per aim, table and figure the sample size is mentioned. Statistical analysis was performed on as well all available data and only complete datasets.

6.3.1 | In-vivo validity and reliability in rest

During the concurrent validation measurements (stage 1 and 3) ($n=11$), the mean T_c recorded with Cosinuss° was $36.0 \pm 0.8^\circ\text{C}$ with a mean SD within subjects of $0.1 \pm 0.1^\circ\text{C}$. The mean T_c recorded with CorTemp® was $37.5 \pm 0.4^\circ\text{C}$ with a mean SD within subjects of $0.1 \pm 0.2^\circ\text{C}$. The mean of T_c recorded with the inner-ear IR was $36.6 \pm 0.4^\circ\text{C}$ with a mean SD within subjects of $0.1 \pm 0.1^\circ\text{C}$. Individual correction (in stage 1) based on the CorTemp® resulted in an average correction factor of $1.5 \pm 0.7^\circ\text{C}$ and based on the inner-ear IR of $0.6 \pm 0.6^\circ\text{C}$. In Table 6.2 the MD of the T_c recorded with the Cosinuss° and compared to CorTemp® and inner-ear IR are shown.

Table 6.2 | Mean difference (MD) in core temperature (T_c) ($^\circ\text{C}$) measurements in both suits ($n=11$) of Cosinuss° C-med versus reference thermometers; CorTemp® and inner-ear infrared (IR).

	Thermo-meter	Stage 1 (before working)			Stage 3 (after working)		
		MD \pm SD	[CI]	p	MD \pm SD	[CI]	p
Non-corrected	Cosinuss° vs CorTemp®	-0.4 \pm 0.7	[-1.84;-0.90]	0.000	-1.5 \pm 1.2	[-2.28;-0.70]	0.002
	Cosinuss° vs IR	-0.5 \pm 0.6	[-0.89;-0.07]	0.026	-0.3 \pm 1.0	[-0.97;0.30]	0.265
Corrected with CorTemp®	Cosinuss° vs CorTemp®	0.1 \pm 0.1	[0.04;0.18]	0.006	0.0 \pm 1.0	[-0.67;0.65]	0.976
	Cosinuss° vs IR	1.0 \pm 0.4	[-0.88;0.46]	0.000	1.2 \pm 1.0	[0.42;1.87]	0.006
Corrected with IR	Cosinuss° vs CorTemp®	-0.7 \pm 0.3	[-0.88;-0.46]	0.000	-0.8 \pm 0.9	[-1.38;-0.20]	0.013
	Cosinuss° vs IR	0.2 \pm 0.2	[0.11;0.32]	0.001	-0.4 \pm 1.0	[-0.28;1.00]	0.233
Non-corrected	CorTemp® vs IR	0.9 \pm 0.3	[0.67;1.12]	0.000	1.2 \pm 0.9	[0.53;1.78]	0.002



In stage 1, significant acceptable differences were found between the Cosinuss° corrected and compared to CorTemp® (MD=0.1±0.1, CI [0.04;0.18], p=0.006) and the Cosinuss° corrected and compared to inner-ear IR (MD=0.2±0.2, CI [0.11;0.32], p=0.001). The other combinations showed significantly high differences between the Cosinuss° and CorTemp®. In stage 3, significantly high differences were found in T_c recorded with the Cosinuss° and CorTemp® (MD≥-0.8, p≤0.013). The Cosinuss° corrected and compared to CorTemp® showed an acceptable, but non-significant mean difference with a high SD (MD=0.0±1.0, CI [-0.67;0.65], p=0.976). In Table 6.3 is shown the ICC for Cosinuss°, CorTemp® and inner-ear IR.

Table 6.3 | Intraclass correlations (ICC) and Limits of Agreement (LoA) of T_c measurements in both suits (n=11) of Cosinuss° C-med versus reference thermometers; CorTemp® and inner-ear infrared (IR).

	Thermometer	ICC [95% CI]	p	LoA
Stage 1 (before working)				
Non-corrected	Cosinuss° vs CorTemp®	0.09 [-0.08;0.43]	0.154	±1.37
	Cosinuss° vs IR	0.40 [-0.10;0.78]	0.044	±1.20
Corrected with CorTemp®	Cosinuss° vs CorTemp®	0.94 [0.45;0.99]	0.000	±0.20
	Cosinuss° vs IR	0.19 [-0.05;0.61]	0.007	±0.68
Corrected with IR	Cosinuss° vs CorTemp®	0.30 [-0.08;0.73]	0.005	±0.61
	Cosinuss° vs IR	0.84 [0.00;0.70]	0.000	±0.30
Non-corrected	CorTemp® vs IR	0.24 [-0.06;0.68]	0.004	±0.66
Stage 3 (after working)				
Non-corrected	Cosinuss° vs CorTemp®	0.01 [-0.16;0.37]	0.464	±3.29
	Cosinuss° vs IR	0.27 [-0.32;0.73]	0.193	±1.85
Corrected with CorTemp®	Cosinuss° vs CorTemp®	0.38 [-0.32;0.79]	0.130	±1.93
	Cosinuss° vs IR	0.05 [-0.19;0.46]	0.374	±2.12
Corrected with IR	Cosinuss° vs CorTemp®	0.29 [-0.15;0.71]	0.091	±1.71
	Cosinuss° vs IR	0.18 [-0.39;0.68]	0.280	±1.86
Non-corrected	CorTemp® vs IR	0.01 [-0.17;0.37]	0.474	±1.82

In stage 1 and 3, without individual correction of the Cosinuss° no correlation between the Cosinuss° and CorTemp® was observed and a moderate correlation was observed between Cosinuss° and inner-ear with an unacceptably high LoA (ICC=0.40, p=0.044, LoA=±1.20). The Cosinuss° corrected with the CorTemp® (stage 1) resulted in an excellent correlation with an acceptable LoA compared to the CorTemp® (ICC=0.94, p=0.000, LoA=±0.20) and a poor correlation compared to the inner-ear IR (ICC=0.19, p=0.007, LoA=±0.68). The Cosinuss° corrected with the inner-ear IR resulted in a poor correlation compared to the CorTemp® (ICC=0.30, p=0.005, LoA=±0.61) and an excellent correlation with an acceptable LoA compared to the inner-ear IR (ICC=0.84, p=0.000, LoA=±0.30). No correlation or a poor



correlation was found between the CorTemp® and inner-ear IR thermometer ($ICC \leq 0.24$). In Figure 6.2, the Bland-Altman plots before working (stage 1) are shown.

After working (stage 3), all correlations between the Cosinuss°, CorTemp® and inner-ear IR were lowered to non-significant and poor with unacceptable LoA ($ICC \leq 0.38$, $p \geq 0.091$, $LoA \geq 1.71$). In Figure 6.3, the Bland-Altman plots after working (stage 3) are shown. Sensitivity analysis revealed similar results.



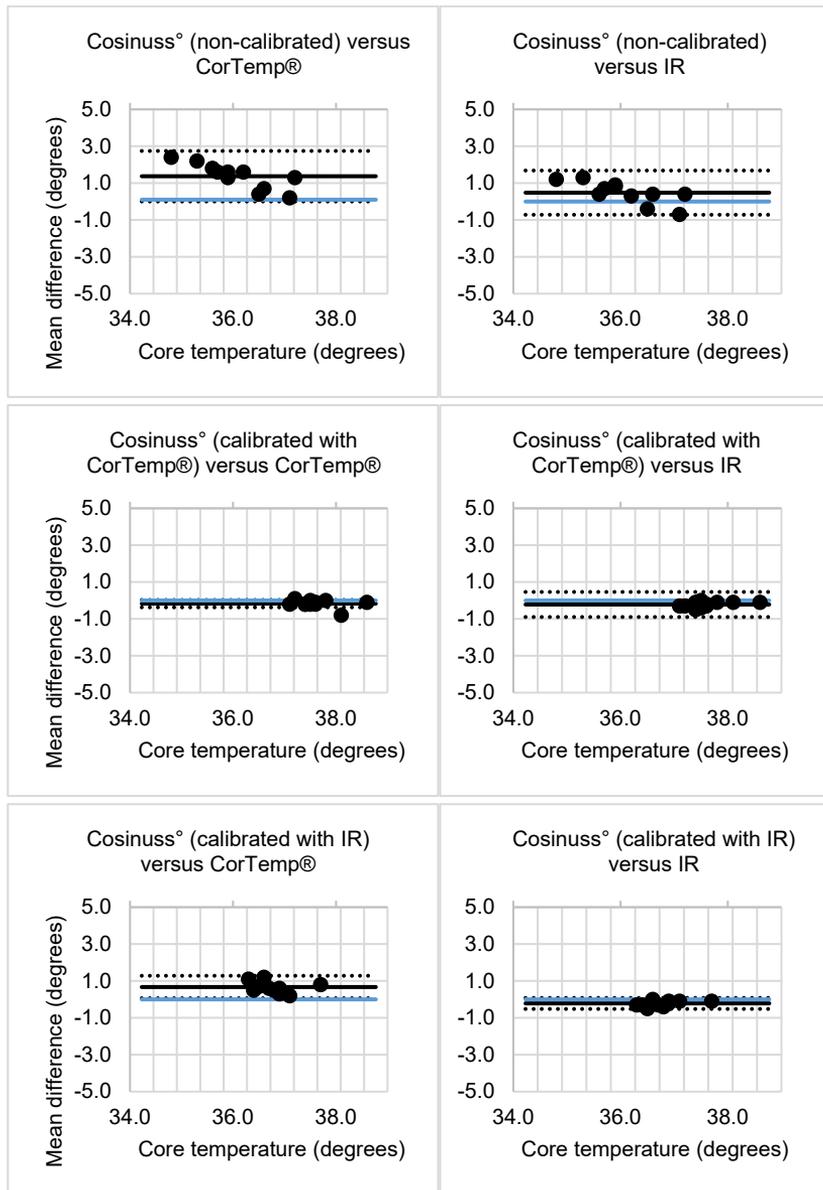


Figure 6.2 | Bland-Altman plots of the mean core temperature versus the mean temperature difference before working (stage 1) in both suits between the non-corrected and corrected Cosinuss° compared to the CorTemp® and inner-ear IR with mean (black line) and upper and lower Limit of Agreement (LoA) (black dotted line) and zero-line (blue line), n=11.

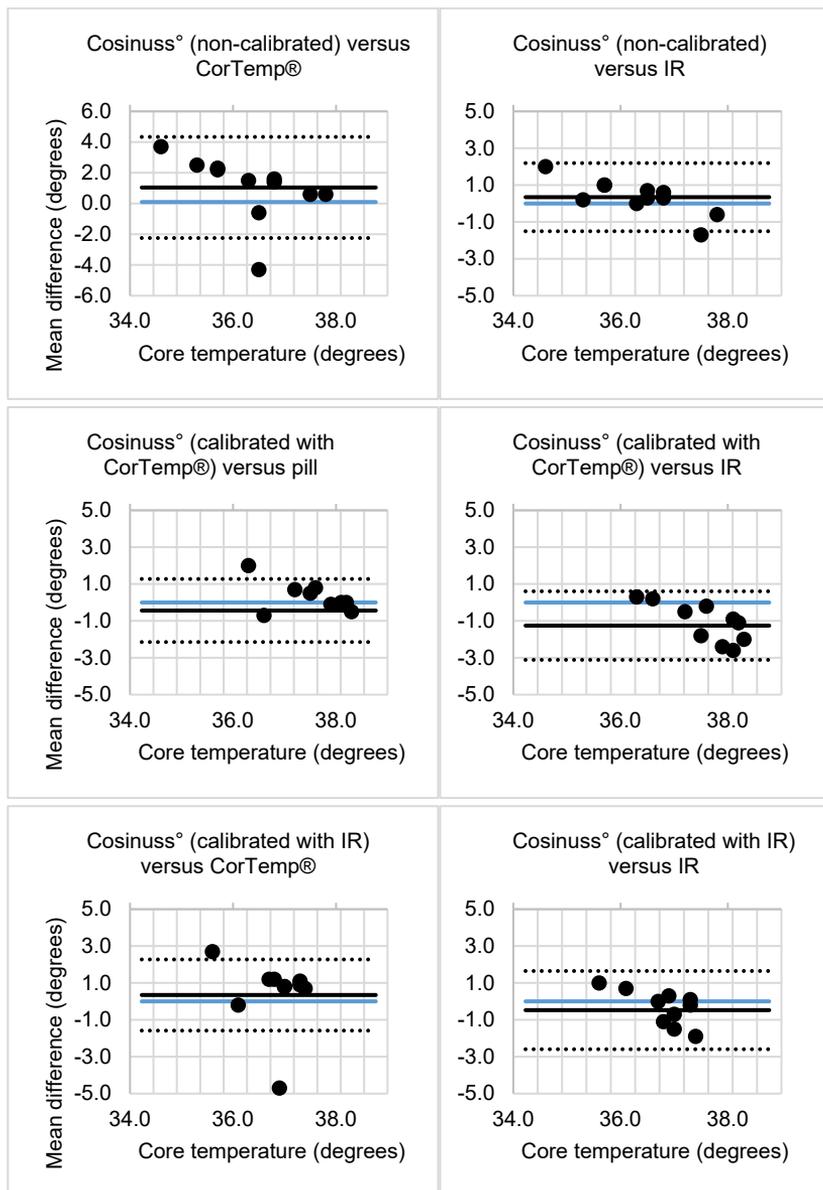


Figure 6.3 | Bland-Altman plots of the mean core temperature versus the mean temperature difference after working (stage 3) in both suits between the non-corrected and corrected Cosinuss° compared to the CorTemp® and inner-ear IR with mean (black line) and upper and lower Limit of Agreement (LoA) (black dotted line) and zero-line (blue line), n=11.



6.3.2 | In-vivo validity and reliability during realistic firefighting simulation tasks

During the two realistic firefighting simulation tasks (stage 2) in both suits, the mean T_c recorded with Cosinuss° was $36.1 \pm 1.1^\circ\text{C}$ ($n=17$). The mean T_c recorded with CorTemp® was $37.6 \pm 0.5^\circ\text{C}$. In Table 6.4 the MD of the T_c recorded with the Cosinuss° and compared to CorTemp® are shown.

Table 6.4 | Mean difference (MD) in core temperature (T_c) ($^\circ\text{C}$) measurements in both suits ($n=17$) of Cosinuss° C-med versus reference thermometers; CorTemp® and inner-ear infrared (IR).

	Thermometer	Task	Stage 2 (during working)		
			MD \pm SD	[CI]	p
Non-corrected	Cosinuss° vs CorTemp®	Both	-1.4 \pm 1.5	[-2.09;-0.60]	0.002
		PPMO	-1.4 \pm 1.3	[-2.07;-0.64]	0.001
		Fire-extinguishing	-1.5 \pm 1.2	[-2.20;-0.90]	0.000
Corrected with CorTemp®	Cosinuss° vs CorTemp®	Both	0.2 \pm 1.5	[-0.55;1.02]	0.534
		PPMO	0.2 \pm 1.3	[-0.51;0.91]	0.559
		Fire-extinguishing	0.0 \pm 1.2	[-0.62;0.67]	0.931
Corrected with IR	Cosinuss° vs CorTemp®	Both	-0.5 \pm 1.4	[-1.26;0.18]	0.129
		PPMO	-0.5 \pm 1.3	[-1.22;0.13]	0.108
		Fire-extinguishing	-0.7 \pm 1.2	[-1.36;-0.02]	0.045

In stage 2, the T_c recorded with the non-corrected Cosinuss° differs significantly compared to the CorTemp® ($\text{MD} \geq -0.7$, $p \leq 0.002$). The Cosinuss° corrected and compared to the CorTemp® showed an acceptable, but non-significant difference ($\text{MD} \leq 0.2$, $p \geq 0.534$). In Table 6.5 is shown the ICC for Cosinuss° and CorTemp®.

Table 6.5 | Intraclass correlations (ICC) and Limits of Agreement (LoA) of T_c measurements of Cosinuss° C-med versus reference thermometer; CorTemp®, in both suits.

	n	Task	Stage 2 (firefighting simulation tasks)		
			ICC [95% CI]	p	LoA
Non-corrected	17	Both	0.08 [-0.30;0.49]	0.362	± 2.22
	16	PPMO	0.06 [-0.44;0.53]	0.409	± 2.63
	15	Fire-extinguishing	0.00 [-0.32;0.41]	0.512	± 2.21
Corrected with CorTemp®	17	Both	0.24 [-1.34;0.74]	0.310	± 2.24
	16	PPMO	0.18 [-1.51;0.72]	0.361	± 2.62
	15	Fire-extinguishing	0.09 [-2.10;0.71]	0.434	± 2.29
Corrected with IR	17	Both	0.26 [-0.67;0.71]	0.253	± 2.20
	16	PPMO	0.22 [-0.90;0.71]	0.302	± 2.49
	15	Fire-extinguishing	0.05 [-1.02;0.63]	0.451	± 2.37

During the realistic firefighting simulation tasks in stage 2, no correlations between the Cosinuss° and the CorTemp® were proven ($ICC \leq 0.26$, $p \geq 0.253$) with unacceptable high LoA's ($LoA \geq 2.20$). Sensitivity analysis revealed similar results. In Figure 6.4, the Bland-Altman plots during the both realistic firefighting simulation tasks are shown.

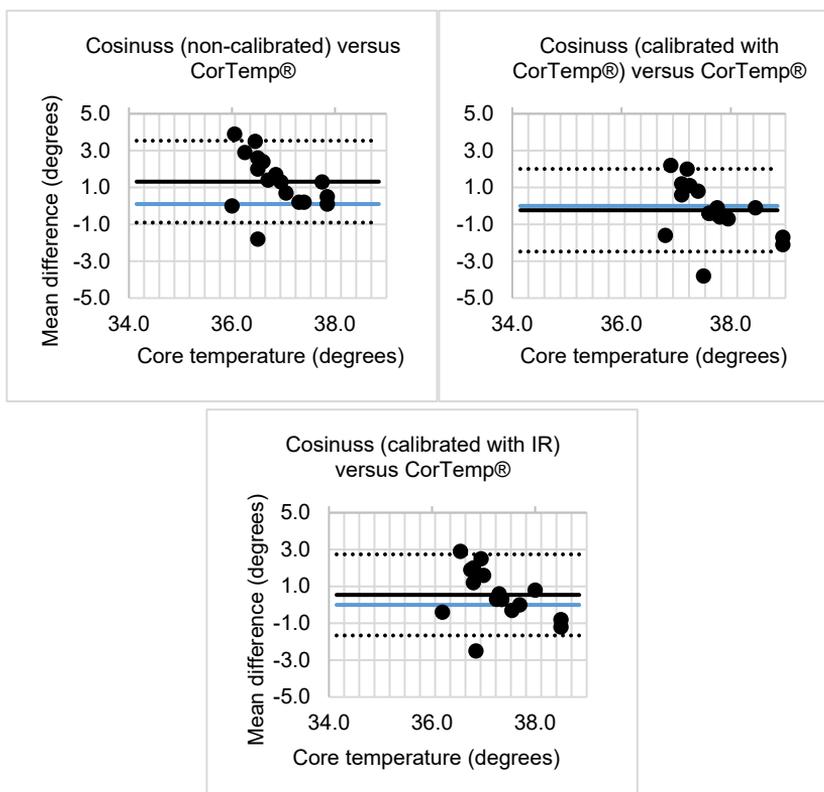


Figure 6.4 | Bland-Altman plots of the mean core temperature versus the mean temperature difference during both firefighting simulation tasks (stage 2) in both suits between the non-corrected and corrected Cosinuss° compared to the CorTemp® with mean (black line) and upper and lower Limit of Agreement (LoA) (black dotted line) and zero-line (blue line), $n=17$.

6.3.3 | Comparison of the change in core temperature

During the two during realistic firefighting simulation tasks, every subject showed a different pattern in the change in T_c , T_{cli} and RH. The mean change in T_c in both suits recorded with the Cosinuss° was $0.06 \pm 0.14^\circ\text{C}/\text{minute}$ and the mean change in T_c recorded the CorTemp® was $0.02 \pm 0.10^\circ\text{C}/\text{minutes}$. The mean T_{cli} in both suits increased with $0.4 \pm 0.4^\circ\text{C}/\text{minute}$ with a mean T_{cli} of $29.7 \pm 2.1^\circ\text{C}$ and the RH increased with



1.6±3.2%/minute with a mean RH of 68.4±10.8%. In Table 6.6 the mean T_c recorded with the Cosinuss° and CorTemp® and T_{cli} and RH per task per suit are shown.

Table 6.6 | Mean and maximum core temperature (T_c) (°C) recorded with the CorTemp® and (non-corrected) Cosinuss°, temperature inside de clothing (T_{cli}) (°C) and humidity (RH) (%) per (Periodic Preventive Medical Examination (PPMO) and hot fire-extinguishing) task per suit A and B.

	PPMO			Fire-extinguishing task		
	n	Suit A	Suit B	n	Suit A	Suit B
Mean T_c CorTemp® (°C)	10	37.4±0.4	37.3±0.7	10	37.8±0.3	37.7±0.5
Mean T_c Cosinuss° (°C)	7	36.4±1.6	37.0±0.9	6	37.7±1.4	37.9±1.0
Mean T_{cli} (°C)	8	26.4±1.9	29.0±2.2	7	29.1±3.3	32.5±2.3
Mean RH (%)	8	59.9±14.6	68.7±12.1	7	72.1±17.3	80.2±11.9
Max T_c CorTemp® (°C)	10	38.1±0.5	38.4±0.6	10	38.3±0.4	38.4±0.4
Max T_c Cosinuss° (°C)	7	38.8±1.5	38.9±1.0	6	40.1±1.2	39.8±1.0
Max T_{cli} (°C)	8	39.3±4.3	32.1±2.9	7	33.0±4.3	35.5±3.2
Max RH (%)	8	84.9±20.2	82.3±15.6	7	92.9±15.7	91.4±15.3

The maximum T_c recorded with the Cosinuss° was 40.1°C and with the CorTemp® 38.4°C (both during the fire-extinguishing task). However, on average the maximum T_c recorded with the Cosinuss° is significant lower compared to the CorTemp® during both tasks (during PPMO MD=1.1±1.2, CI [0.45;1.68], p=0.002, during the fire-extinguishing task MD=1.1±1.1, CI [0.51;1.73], p=0.001). In Table 6.7 the MD and ICC of the T_c recorded with the Cosinuss° CorTemp®, T_{cli} and RH in both suits between the Periodic Preventive Medical Examination (PPMO) and hot fire-extinguishing task are shown.



Table 6.7 | Mean difference in core temperature (T_c) ($^{\circ}\text{C}$) recorded with the (non-corrected) Cosinuss $^{\circ}$ and the CorTemp $^{\circ}$, temperature inside the clothing (T_{cli}) ($^{\circ}\text{C}$), humidity (RH) and their change (Δ) between the Periodic Preventive Medical Examination (PPMO) and hot fire-extinguishing task in both suits.

	n	MD \pm SD	CI	p
Mean T_c CorTemp $^{\circ}$ ($^{\circ}\text{C}$)	21	0.4 \pm 0.4	[0.19;0.56]	0.000
Mean T_c Cosinuss $^{\circ}$ ($^{\circ}\text{C}$)	16	0.2 \pm 0.8	[-0.21;0.67]	0.285
Mean T_{cli} ($^{\circ}\text{C}$)	16	3.3 \pm 1.2	[2.66;3.94]	0.000
Mean RH (%)	16	12.0 \pm 13.7	[4.39;19.59]	0.004
ΔT_c CorTemp $^{\circ}$ ($^{\circ}\text{C}/\text{minute}$)	21	0.00 \pm 0.12	[-0.52;0.06]	0.900
ΔT_c Cosinuss $^{\circ}$ ($^{\circ}\text{C}/\text{minute}$)	16	0.11 \pm 0.18	[0.01;0.21]	0.033
ΔT_{cli} ($^{\circ}\text{C}/\text{minute}$)	16	0.27 \pm 0.54	[-0.03;0.57]	0.349
ΔRH ($\%/ \text{minute}$)	16	1.22 \pm 4.89	[-1.49;3.93]	0.077

During the fire-extinguishing task (stage 2), T_c recorded with the CorTemp $^{\circ}$ was significantly higher compared to the PPMO (MD=0.4 \pm 0.4 $^{\circ}\text{C}$, CI [0.19;0.56], p=0.000), as well as T_{cli} (MD=3.3 \pm 1.2 $^{\circ}\text{C}$, CI [2.66;3.94], p=0.000) and RH (MD=12.0 \pm 13.7%, CI [4,39;19.59], p=0.004). T_c recorded with the Cosinuss $^{\circ}$ did not differ significantly (p=0.285) and an excellent correlation between the PPMO and fire-extinguishing tasks was found (ICC=0.88, CI [0.66;0.96], p=0.000). However, it increased significantly faster during the hot task compared to the PPMO (MD=0.11 \pm 0.18 $^{\circ}\text{C}/\text{minute}$, CI [0.01;0.21], p=0.033). The T_{cli} also increased more rapidly during the hot task, but this was non-significant (MD=0.27 \pm 0.54 $^{\circ}\text{C}/\text{min}$, CI [-0.03;0.57], p=0.077). In Table 6.8 the MD of the T_c recorded with the Cosinuss $^{\circ}$ or CorTemp $^{\circ}$, T_{cli} and RH per task of suit A compared to suit B are shown.



Table 6.8 | Mean difference in core temperature (T_c) ($^{\circ}\text{C}$) recorded with the (non-corrected) Cosinuss $^{\circ}$ and the CorTemp $^{\circ}$, temperature inside the clothing (T_{cli}) ($^{\circ}\text{C}$), humidity (RH) and their change (Δ) per (Periodic Preventive Medical Examination (PPMO) and hot fire-extinguishing) task between suit A and B.

Task		n	MD \pm SD	CI
PPMO	T_c CorTemp $^{\circ}$ ($^{\circ}\text{C}$)	10	-0.3 \pm 0.8	[-0.87;0.33]
	T_c Cosinuss $^{\circ}$ ($^{\circ}\text{C}$)	7	0.6 \pm 0.9	[-0.28;1.55]
	T_{cli} ($^{\circ}\text{C}$)	8	1.9 \pm 1.5	[0.47;3.27]
	RH (%)	8	4.1 \pm 15.8	[-10.6;18.69]
	ΔT_c CorTemp $^{\circ}$ ($^{\circ}\text{C}/\text{minute}$)	10	0.01 \pm 0.17	[-0.11;0.05]
	ΔT_c Cosinuss $^{\circ}$ ($^{\circ}\text{C}/\text{minute}$)	7	-0.04 \pm 0.09	[-0.14;0.05]
	ΔT_{cli} ($^{\circ}\text{C}/\text{minute}$)	8	0.63 \pm 4.51	[-4.11;5.37]
	ΔRH ($\%/ \text{minute}$)	8	-0.02 \pm 0.48	[-0.52;0.48]
Fire-extinguishing	T_c CorTemp $^{\circ}$ ($^{\circ}\text{C}$)	10	-0.1 \pm 0.5	[-0.53;0.31]
	T_c Cosinuss $^{\circ}$ ($^{\circ}\text{C}$)	6	0.1 \pm 0.4	[-0.43;0.63]
	T_{cli} ($^{\circ}\text{C}$)	7	2.6 \pm 2.5	[0.00;5.16]
	RH (%)	7	6.5 \pm 18.6	[-13.06;26.06]
	ΔT_c CorTemp $^{\circ}$ ($^{\circ}\text{C}/\text{minute}$)	10	0.00 \pm 0.04	[-0.03;0.03]
	ΔT_c Cosinuss $^{\circ}$ ($^{\circ}\text{C}/\text{minute}$)	6	0.02 \pm 0.06	[-0.06;0.09]
	ΔT_{cli} ($^{\circ}\text{C}/\text{minute}$)	7	0.20 \pm 4.04	[-4.81;5.21]
	ΔRH ($\%/ \text{minute}$)	7	-0.13 \pm 0.44	[-0.68;0.41]



The T_{cli} in suit B was significant higher compared to suit A (during PPMO MD=1.9 \pm 1.5 $^{\circ}\text{C}$, CI [0.47;3.27], $p=0.017$, during the hot task MD=2.6 \pm 2.5 $^{\circ}\text{C}$, CI [0.00;5.16], $p=0.050$) and during the PPMO no correlation was found between the T_{cli} of suit A and B (ICC=0.74, CI [0.06;0.96], $p=0.017$, $n=8$). No other significant differences were found between suit A and B with a good to excellent correlation between the T_c recorded with Cosinuss $^{\circ}$ (ICC \geq 0.74, $p\leq 0.017$, $n=7$). Additionally, no significant difference in the T_c , T_{cli} and RH change between the suits during the tasks was found ($p\geq 0.308$). Sensitivity analysis revealed similar results.

6.4 | Discussion

The T_c of the non-corrected Cosinuss $^{\circ}$ showed no correlations with the CorTemp $^{\circ}$ and a poor to moderate correlation with inner-ear IR thermometry, indicating the impact of individual correction. Individual correction resulted in excellent correlations. However, it should be noted that this depends on the calibration method and it is unknown if individual calibration using the CorTemp $^{\circ}$ performed once is valid over longer periods of time. Moreover, no correlation was found between the CorTemp $^{\circ}$ and inner-ear IR and no correlation or a poor correlation was found between the CorTemp $^{\circ}$ and Cosinuss $^{\circ}$ during

the two tasks, indicating a difference due to the measurement method and location (Towey, et al., 2017; Taylor, et al., 2014). The measured change in T_c by the Cosinuss°, as well as by inner-ear IR, is expected to be the local temperature and/or caused by a preliminary or side effect (Levander & Grodzinsky, 2017; Kuht & Farmery, 2014). Therefore calibration should be done using at least an invasive reference, such as CorTemp®, however calibration with a controlled thermostat bath at different temperatures is preferred. The correlations were poor after performance of the tasks. This is probably caused by a secondary human-device interaction factor, e.g., a shift of the sensor in the ear caused by movement. Overall, the Cosinuss° is an invalid method for measuring core temperature of firefighters during the performance of their job. The influence of the consumption of hot and cold food and drinks was noted by the research and clearly visible in the results of the CorTemp® (Collin, et al., 2015).

The strength of this study is that validation of the T_c measurements was performed using the invasive (Mazgoaker, et al., 2017; Langridge, et al., 2012; Gonzalez-Alonso, et al., 1999) as well as the inner-ear clinical standard (Moran-Nabarro, et al., 2018; Nederlands Huisartsen Genootschap, 2016; Itani, et al., 2018; Ouahrani, et al., 2017; Nadipi Reddy, et al., 2017). Furthermore this applied research was performed in a field situation with realistic firefighting tasks which are used to train and test firefighters (Havenith & Heus, 2004). Also, in addition to insight in the validity of the wearable thermometer, research was performed on two different types of protective suits and the difference in the development of heat stress between tasks was assessed. The main limitation was the duration of the tasks. The schedule was planned 30 minutes per task, but participants only took approximately 10 up to 15 minutes per task. This time span will result in only limited heating up of the body and less useful results. Especially in the case of exploring differences in heat development in the two types of protective clothing 10 minutes was not long enough to gain realistic insights and draw conclusions which are representing real-life firefighting tasks in protective clothing. Besides, it would have been interested to also include suit B without the jacket (only coverall with protection level 1) to explore the change in T_c , T_{cli} and RH during the PPMO task and to falsify if this new protective clothing concept is lowering the heat stress development during no firefighting activities. In addition, some datasets were incomplete. This resulted in a lower amount of data which could result in the risk over overestimating the results. In this case it was not a selective drop-out which significantly could have influenced the data. Moreover, according to a power analysis and the two measurements (suits A and B) per subject, enough data was gathered for analysis resulting in no need to replace these missing data. Besides, the failures of the systems provided useful input about the usability and weaknesses of the systems. Another limitation could be the difference in



measurement frequency between the thermometers, although not much influence is expected since the temperature rise is only gradually.

To be able to apply the Cosinuss°, the system should be valid and reliable. The urge for individual calibration should be investigated, as well as using the Cosinuss° in a multivariable system to increase the accuracy of the T_c prediction. In addition, to improve the low correlation during and after performance of the tasks (stage 2 and 3), movements of the Cosinuss° should be limited. Further research should study the change in T_c over longer periods of time and with more participants. Furthermore, improvements are necessary to fix the device more stable in the ear. Without movement of the sensor relative to the ear its performance might be much improved. And the integration of the ear part with the ambient condition box would possibly improve the usability of this system. By eliminating the chest box, which was not experienced as very comfortable, a multivariable single-instrument system could be created. Above all, to make this system useable and safe in use for firefighters during their work, the system needs to be made heat- and fire-resistant. Currently the Cosinuss° is made of a thermoplastic with silicone developed to be used in ambient temperatures of -15 to 55°C (Cosinuss°, 2016), which can cause burns during long-term use in heat exposure nor is fulfilling the safety standards.



If the reliability of the Cosinuss° can be improved, as part of a multivariable system (Richmond, et al., 2015) the Cosinuss° could play a role in predicting T_c and heat storage. However, a reliable single-instrument system is preferred. A wearable thermometer could overcome the disadvantages of the temperature pill if it is an accurate, valid and reliable measurement system that does not underestimate the T_c . A wearable thermometer is non-invasive, usable for all body proportions, reusable with low costs and not influenced by food and liquid intake (Mazgoaker, et al., 2017; Saurabh, et al., 2014; Taylor, et al., 2014; Lim, et al., 2008). In addition, it is immediately usable without a waiting time (Collin, et al., 2015). Wearable non-invasive thermometers are of interest in multiple fields for (health) monitoring purposes (Chaglla, et al., 2018; Mazgoaker, et al., 2017; Li, et al., 2019; Diaz-Piedra, et al., 2019; Steck, et al., 2011). Next to firefighters, other physical active workers are at risk of work-related overheating and are interested in such a device (Pancardo, et al., 2015), including astronauts who want to launch wearables into space to monitor their health during their stay (Jones, 2006). However, the Cosinuss° in its present form is not suitable for this.

6.5 | Conclusion

The validity of the Cosinuss° C-med was not confirmed in this study. Without individual correction, the Cosinuss° showed poor to moderate correlations resulting in an invalid, but reliable system. With individual correction, depending on the instruments used for field calibration in resting conditions an excellent correlation for measuring core temperature was found, resulting in a valid and reliable system. During and after subject performance of the tasks, non-significant poor correlations were found. This is most likely caused by firstly the measurement location and secondly non-adequate fixation of the Cosinuss° causing a movement of the sensor relative to the ear. This indicates that Cosinuss° is an invalid method for measuring core temperature of firefighters during the performance of their job. The temperature inside the suit was significantly higher in the new protective clothing concept compared to the traditional turnout gear. No significant differences were found in the change in core temperature, temperature, and humidity inside the suit.

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Declaration of interest

The Cosinuss° C-med used in this study were borrowed from Cosinuss° during execution of this study. Any findings, and conclusions or recommendations presented in this article are those of the author(s) and do not necessarily reflect the views of Cosinuss° GmbH. There is no conflict of interest.



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Chapter 7

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

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Abstract

Aimed at preventing heat strain, health problems, and absenteeism among workers with physically demanding occupations, a continuous, accurate, non-invasive measuring system may help such workers monitor their body (core) temperature. The aim of this study is to evaluate the accuracy and explore the usability of the wearable non-invasive Cosinuss° °Temp thermometer. Ear canal temperature was monitored in 15 volunteers in a laboratory setting and 49 workers in real-life working conditions. After individual correction, the results of the laboratory and field study revealed high correlations compared to ear canal infrared thermometry for hospital use. Under real-life working conditions after work, this correlation was found to be moderate. It was also observed that the ambient environmental conditions and personal protective clothing influenced the accuracy and resulted in unrealistic ear canal temperature outliers. It was found that the Cosinuss° °Temp thermometer did not result in significant interference during work. Therefore, it was concluded that, without a correction factor, the Cosinuss° °Temp thermometer is inaccurate. Nevertheless, with a correction factor, the accuracy of this wearable ear canal thermometer was confirmed at rest, but not in outdoor working conditions or while wearing a helmet or hearing protection equipment.

Keywords: Thermal physiology; heat strain; heat stress; overheating; personal protective clothing.



7.1 | Introduction

Heat stress is an important factor that should be considered in physically demanding occupations. Heat stress is generally influenced by many factors, such as heavy workload, use of personal protective equipment (PPE), and environmental factors (e.g., heat, humidity), and is of major concern among workers with physically demanding occupations (Gao, et al., 2018; Udayraj, et al., 2019; Song & Wang, 2016; Chan, et al., 2016). The two main factors influencing heat stress are the environmental conditions and use of personal protective clothing (PPC) and PPE (Gao, et al., 2018; Krishnamurthy, et al., 2017). Working in hot (and humid) environments causes the body temperature to increase as a result of the inhibition of body heat loss (Gao, et al., 2018; Song & Wang, 2016; Chan, et al., 2016; Fernandes, et al., 2016; Larsen, et al., 2015). Wearing full-body PPC and PPE also stimulates and increases heat stress as a result of thermal insulation and evaporative resistance (Gao, et al., 2018; Udayraj, et al., 2019; Jacklitsch, et al., 2016; Roghanchi & Kocsis, 2018). Both heat stress and the strain resulting from it are influenced by individual factors (Larsen, et al., 2015; Morgado, et al., 2017; Broday, et al., 2017), such as age, health, and fitness level (Jacklitsch, et al., 2016; Sunkpal, et al., 2018), and may lead to subsequent health problems, such as exhaustion, dehydration, mental confusion, and loss of consciousness (Roghanchi & Kocsis, 2018; Piil, et al., 2018). In extreme cases, heat strain may cause permanent damage and may even be life-threatening (Krishnamurthy, et al., 2017; Morgado, et al., 2017), may affect productivity and risk perception, and may cause safety problems (Roghanchi & Kocsis, 2018; Quinn, et al., 2018; Costello, et al., 2015; Dube, et al., 2019). Repeated or prolonged heat stress may even lead to cardiovascular disease (Smith & Petruzzello, 1998).

Monitoring the workers' body (core) temperature and the ambient working conditions may potentially help prevent heat strain (Horn, et al., 2018). Body (core) temperature can be measured using several invasive and non-invasive methods (Taylor, et al., 2014). Although invasive measurements, such as esophageal, rectal, and gastrointestinal thermometers, are highly reliable (Langridge, et al., 2012; Gonzalez-Alonso, et al., 1999; Moran & Mendal, 2002), their application is not suitable in daily work situations (Jacklitsch, et al., 2016; Buller, et al., 2015; Lim, et al., 2008; Holland, et al., 2002). Moreover, although non-invasive methods, such as ear, skin, and forehead thermometry, have become wearable, they are often impractical in work situations because they either interfere with the working conditions (Saurabh, et al., 2014) or are unreliable at the individual level (Yang, et al., 2017; Lim, et al., 2008; Dube, et al., 2019; Gonzalez-Alonso, et al., 1999; Ng, et al., 2009). Therefore, up till now, no accurate instruments are available for continuously and non-obtrusively monitoring heat strain while performing physically demanding work (Quinn, et al., 2018; Chaglla, et al., 2018; Mazgoaker, et al., 2017; Pancardo, et al., 2015). Therefore,



there is a need for a reliable, non-invasive, continuous temperature measuring system in the form of a wearable thermometer to be able to perform real-time monitoring and prevent heat strain in physically active individuals (Quinn, et al., 2018; Buller, et al., 2015; Horn, et al., 2018).

Cosinuss° °Temp (Cosinuss° GmbH, Munich, Germany) is a new, non-invasive, wearable thermometer that can continuously measure ear canal temperature in real time. Research on the accuracy of this thermometer has shown a systematic difference of -1.5°C compared to infrared (IR) tympanic temperature (Chaglla, et al., 2018; Roossien, et al., 2020). Such a systematic difference can be compensated by software adjustments to the measuring device. Although this thermometer appeared to accurately measure the core temperature at rest, its accuracy appeared to be low during firefighting tasks (Roossien, et al., 2020), which may be due to some factors as follows. First, the ear canal temperature may not be representative of the deep body temperature while performing physically demanding activities (Muir, et al., 2001; Taylor, et al., 2014; Towey, et al., 2017). Second, imprecise alignment in the ear may result in measuring the aural temperature instead of the ear canal temperature (Muir, et al., 2001; Roossien, et al., 2020; Ganio, et al., 2009; Casa, et al., 2007). Third, if the insulation of the thermometer is insufficient in the ear (Gao, et al., 2018; Krishnamurthy, et al., 2017; Fernandes, et al., 2016), it is possible for the environmental or local temperature to influence the measurements (Muir, et al., 2001; Moran & Mendal, 2002). To summarize, the Cosinuss° °Temp thermometer may form the basis for a non-invasive, non-obstructive monitoring system for workers with physically demanding occupations. Therefore, it is necessary to investigate its accuracy in more detail to explore the factors influencing it, to assess whether its accuracy can be improved or whether it is possible to prevent its accuracy from decreasing, and to determine the type of work or application in which this system may potentially be used.

In this study was investigated the *in vitro* and *in vivo* accuracy of the Cosinuss° °Temp thermometer as a wearable thermometer used for monitoring heat stress among workers with physically demanding occupations. The aims were to (1) test the *in vitro* accuracy of the Cosinuss° °Temp thermometer under controlled laboratory conditions; (2) test the *in vivo* accuracy of the Cosinuss° °Temp thermometer as an ear canal thermometer under controlled laboratory conditions; (3) test the *in vivo* accuracy of the Cosinuss° °Temp thermometer while performing physically demanding work; (4) investigate the influence of environmental conditions (e.g., wind, temperature changes, and lack of ventilation resulting from wearing PPC or PPE) on the accuracy of the Cosinuss° °Temp thermometer; and (5) explore the usability of the Cosinuss° °Temp thermometer for measuring the ear canal temperature while performing physically demanding work.



7.2 | Materials and methods

7.2.1 | Subjects

The inclusion criterion was that the subjects should be physically active workers between 18 and 67 years of age (representing the European working population). The exclusion criteria included lung diseases, cardiovascular disease, claustrophobia, and problems associated with body heat loss (e.g., heat intolerance or difficulties with body thermoregulation resulting from sweating problems). The minimum sample size was calculated using a power analysis (non-inferiority trial with a power of 95%, significance level of 0.05, and acceptable difference of $\pm 0.2^{\circ}\text{C}$) for the laboratory study on the basis of the expected outcomes ($n \geq 11$ subjects) and for the field study on the basis of the results of the laboratory study ($n \geq 26$ subjects, with $n \geq 7$ per job category).

The subjects of the laboratory study were 15 volunteers (mean age: 25.1 ± 4.2 years, nine males, six females) with no experience of wearing PPC or PPE, whereas the subjects of the field study were 49 physically active workers (mean age: 40.4 ± 10.2 years, 47 males, two females). All subjects were recruited by distributing flyers in selected companies with different working situations: (1) chemical cleaners working with chemical-proof PPC combined with other PPE, (2) mechanics working in a warm, humid factory, (3) firefighters working with PPC and PPE, and (4) neighbourhood maintenance workers working outdoors in different weather conditions. The diversity in work-related tasks and working conditions between the subject groups, as specified, provided a broad picture of their influence on the accuracy and usability of the wearable thermometer discussed.

This study was performed in accordance with the Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans. This study was approved by the Medical Ethics Committee of University Medical Center Groningen, the Netherlands, stating that it does not involve medical research under the Dutch law (laboratory study: M16.197311, field study: M17.209969). All subjects were informed of the study via an information letter and a verbal explanation before the start of the study, and all of them signed an informed consent form before participating in the study.

7.2.2 | Materials

7.2.2.1 | *Cosinuss° Temp*

Cosinuss° Temp (*Cosinuss° GmbH*) is an ear canal thermometer that can be worn in and around the ear like a hearing aid (dimensions: $45 \times 38 \times 18$ mm, weight: 6.5 g), as shown in Figure 7.1. Temperature is measured using a thermistor contact sensor integrated into a



sensor head, which is placed in the ear canal. Then, data are sent via Bluetooth Smart 4.0 and viewed on the Cosinuss° One smartphone application. According to the specifications, the accuracy of the Cosinuss° °Temp thermometer is $\pm 0.1^{\circ}\text{C}$, with a measurement range of 0°C to 50°C and a working temperature range of -15°C to 55°C (Cosinuss°, 2016).



Figure 7.1 | The wearable ear thermometer Cosinuss° °Temp. Left: Cosinuss° position in the ear. Right: Cosinuss° with IR sensor in the white ear tip.

7.2.2.2 | Ambient conditions box

The ambient conditions box, worn with elastic chest belts (see Figure 7.2), contains a temperature and humidity sensor (SHT15 Breakout; Sensirion, Stäfa, Switzerland) mounted on the outside of the box. This box is worn under PPC and PPE to measure the micro-climate around the skin of the subject under their clothes (described as the temperature inside clothing, T_{cli}) as well as the relative humidity (RH). This T_{cli} sensor has a measurement range of -40°C to 120°C and an accuracy of $\pm 0.3^{\circ}\text{C}$ at 25°C (Sensirion, 2010). It can also measure the RH with an accuracy of $\pm 2\%$ at 10% to 90% with a humidity range of 0% to 100% and a response time of 5–20 s (Sensirion, 2010). This box was validated in a climatic test cabinet (type C-40/350; CTS Clima Temperatur Systeme GmbH, Hechingen, Germany) with Pt100 thermometers with an accuracy of $T \pm 0.3^{\circ}\text{C}$ and $\text{RH} \pm 1.5\%$ (CTS Clima Temperatur Systeme GmbH, sd.), resulting in a high to very high correlation compared to the climatic test cabinet and Pt100 thermometers.





Figure 7.2 | Ambient conditions box with temperature and humidity sensors and data receiver and storage.

7.2.2.3 | Reference ear canal infrared thermometer

The Braun ThermoScan® 7 IRT6520 ear canal IR thermometer (Braun GmbH, Kronberg, Germany) has an accuracy of $\pm 0.2^{\circ}\text{C}$ and can perform measurements within the temperature range of 35°C – 42°C (RH 10%–95%; Braun GmbH, 2017). This thermometer is a commercially available ear canal measurement device for hospital use that was calibrated according to the national standard for medical devices (EN ISO 14971:2012 and EN ISO 10993-1:2009), electrical equipment (EN 60601-1:2006 and 2007, EN 60601-1-11:2010 14971), and clinical thermometers (EN 12470-5:2203; Braun GmbH, 2017) by an authorized service center. All measurements with this thermometer are performed in offices with a constant room temperature of $20.0 \pm 2.0^{\circ}\text{C}$ and $45.0\% \pm 5.0\%$ humidity.

7.3.2.4 | Mercury thermometer

As a reference, a mercury thermometer was used (ET 31; Lauda Dr. R. Wobser GmbH & Co., Lauda-Königshofen, Germany). This mercury-in-glass thermometer has a measurement range of 0°C to 100°C , an immersion depth of 90 mm, and a median thread temperature of 30°C (Lauda Dr. R. Wobser GmbH & Co., 1998). The accuracy of this thermometer was calibrated in ice and boiling water with an accuracy of $\pm 0.1^{\circ}\text{C}$ according to the national standard for thermometers (EN ISO 14971:2012, EN ISO 10993-1:2009, and EN 12470-5:2203).

7.2.3 | Study design

The *in vitro* accuracy of the Cosinuss° °Temp thermometer (aim 1) was examined in a thermostatic water bath. At a constant temperature, the temperature of the water bath was first measured with the Cosinuss° °Temp thermometer and a reference ear canal IR thermometer and compared to the results of the reference mercury thermometer. Then, the water temperature was increased from 35°C to 41°C in increments of 0.5°C , and the



temperature measured was checked against that of the mercury thermometer. Three measurements were performed at every step, with a frequency of one measurement per minute. The sensors were pointed downward in the water, with an angle of 90° between the sensor's tip and the water surface. Before starting this laboratory study, the ear canal IR and mercury thermometers were (re)calibrated according to the national standard for medical thermometers (EN ISO 14971:2012, EN ISO 10993-1:2009, and EN 12470-5:2203).

To test the *in vivo* accuracy of the thermometer under controlled laboratory conditions (aim 2), the ear canal temperature (T_{EC}) of the subjects was measured at rest using the Cosinuss° °Temp thermometer and compared to the results obtained from the tympanic IR thermometer. The T_{EC} value was measured 10 times per subject with a frequency of one measurement per minute, yielding a 10 min measurement. All measurements were performed in offices with a constant room temperature of $20.0^{\circ}\text{C}\pm 2.0^{\circ}\text{C}$ and $45.0\%\pm 5.0\%$ humidity, and all subjects were allowed to acclimatize to this environment (for about 10 min; if necessary, every subject was allowed to have more time with a maximum of 15 min depending on their personal preference or if the T_{EC} value was not stable).

The field study comprised three stages: (1) accuracy measurements, (2) performance of daily jobs, and (3) accuracy measurements. To test the *in vivo* accuracy of the thermometer (aim 3), at stages one and three, the T_{EC} value of the subjects was measured at rest using the Cosinuss° °Temp thermometer and a tympanic IR thermometer. In total, five measurements of T_{EC} were performed, with a frequency of one measurement per minute, yielding a 5 min measurement. In both the laboratory and field studies, ear canal thermometer positioning was monitored continuously and adjusted if needed.

To investigate the influence of real-life working conditions on the accuracy of the Cosinuss° °Temp thermometer (aim 4), during stage two, the T_{EC} values and environmental conditions of the subjects were monitored while they were performing physically demanding work. All subjects performed their daily jobs while wearing the Cosinuss° °Temp thermometer, and the T_{EC} , T_{cli} , and RH values were continuously monitored using a wearable ambient conditions box. The duration of stage two depended on the duration of the subject's task, lasting between 30 min and 3 h. When unrealistically high or low T_{EC} values were observed, the subjects were asked how they feel and whether they have any thermoregulation-related issues or health complaints.

The usability of the Cosinuss° °Temp thermometer was explored (aim 5) using the AEIOU (*Activities, Environments, Interactions, Objects, and Users*) user interface design method via researchers' observations and feedback from the subjects. In this descriptive observational study, the usability aspects were ease of use, positioning, wearability by all types of users,



fixation, and comfort. In the laboratory study, subjects (*Users*) were asked to wear the Cosinuss° °Temp thermometer (*Objects*) while putting on and removing PPC (TRELLECHEM® chemical-proof hazmat suit, Super type T; Ansell Protective Solutions AB, Trelleborg, Sweden) with a separate gas mask (Ansell Protective Solutions AB, 2017; see Figure 7.3) during rest (3 min), while sitting (3 min), while walking (2 min), and while jumping (2 min) in PPC (*Activities*) for a total of 10 min. These two tests were performed directly after each other under constant ambient conditions ($T_a=20.0^{\circ}\text{C}\pm 2.0^{\circ}\text{C}$, $\text{RH}=45.0\%\pm 0.5\%$) (*Environments*). Under real-life working conditions (*Environments*), this was equivalent to the performance of daily jobs (*Activities*) in physically demanding occupations (*Users*).



Figure 7.3 | The chemical-proof hazmat personal protective suit (Trellchem®, Super Type T of Ansell Protective Solutions AB, Trelleborg, Sweden) with a separated gas mask the subject worn in the lab study.

7.2.4 | Data analysis

To check whether the *in vivo* difference in the accuracy of the Cosinuss° °Temp thermometer compared to the IR thermometer was due to a misalignment in the ear canal caused by the thermometer's positioning in the ear and/or individual differences (inner-ear dimensions), a correction factor was introduced. This individual correction factor was calculated using the second accuracy measurement (randomly chosen from the first five measurements out of 10 in the laboratory study and from the first three measurements out of five in the field study) during the *in vivo* measurements at rest. The T_{EC} value was



measured using an IR thermometer in combination with a Cosinuss° °Temp thermometer in the other ear, and the difference between their measurements was used as the correction factor.

All statistical analyses were performed using IBM SPSS Statistics (version 25; IBM Corp., Armonk, NY, USA). To test the *in vitro* accuracy of the thermometer (aim 1), the mean of three measurements per step was used in the laboratory study. To statistically analyze the *in vivo* accuracy of the Cosinuss° °Temp thermometer (aim 2), every ninth measurement (out of 10) was used in the laboratory study and every fourth measurement (out of five) was used in the field study (aim 3). Differences were assessed using a paired *t*-test, and an intraclass correlation coefficient (ICC, two-way mixed model, absolute agreement) was calculated for normally distributed data. The ICC was considered low at <0.39, moderate at 0.40–0.59, high at 0.60–0.79, and very high at ≥0.80 (Cicchetti, 1994). Non-parametric data were also tested using Wilcoxon's signed rank test. All *p*-values less than 0.05 were considered statistically significant. The limit of agreement (LoA) reflects the average difference between two different measurements and is calculated as $\pm 1.96 * SD_{\text{difference}}$ (Bland & Altman, 1999). For this study, the acceptable level for accuracy was set at mean difference (MD) $\pm 0.2^{\circ}\text{C}$, with a moderate or (very) high ICC (≥ 0.40) and an LoA value of ≤ 0.50 . Bland–Altman plots were created to analyse the individual differences between measurements against the individual mean of the two measurements. Generally, a funnel shape indicates that the magnitude of the difference is related to the mean performance. Sensitivity analyses were also performed to test the differences between the ninth and tenth measurements (laboratory study) and between the fourth and fifth measurements (field study), as well as for all the measurements. Descriptive statistics were used to analyse the usability in the laboratory and field studies (aims 3 and 5).

7.3 | Results

7.3.1 | In-vitro accuracy

It was observed that the mean temperature difference in the thermostatic water bath between the mercury thermometer and the Cosinuss° °Temp thermometer was $-0.4 \pm 0.2^{\circ}\text{C}$ (mean \pm SD; $p < 0.001$), whereas that between the mercury thermometer and IR thermometer was $-0.2^{\circ}\text{C} \pm 0.1^{\circ}\text{C}$ ($p < 0.001$). Table 7.1 shows the results of the ICC analysis for the three thermometers.

Table 7.1 | Cosinuss° and IR thermometer versus mercury thermometer using the paired t-test with mean difference (MD) with standard deviation (SD) and the intraclass correlation coefficient (ICC) with a confidence interval of 95%, p-value and Limits of Agreement (LoA).

	MD±SD [95% CI]	p	ICC [95% CI]	p	LoA
Cosinuss°	-0.44±0.19 [-0.56;-0.32]	<0.001	0.97 [0.13;1.00]	<0.001	±0.37
Ear canal IR	-0.21±0.13 [-0.29;-0.14]	<0.001	0.99 [0.87;1.007]	<0.001	±0.24

Table 7.1 shows a very high correlation between the Cosinuss° °Temp and IR thermometers compared to the mercury thermometer (ICC ≥ 0.97), with an LoA value of ≤0.37 (within the acceptable level of 0.50). Figure 7.4 shows Bland–Altman plots. Sensitivity analysis revealed non-significant differences.

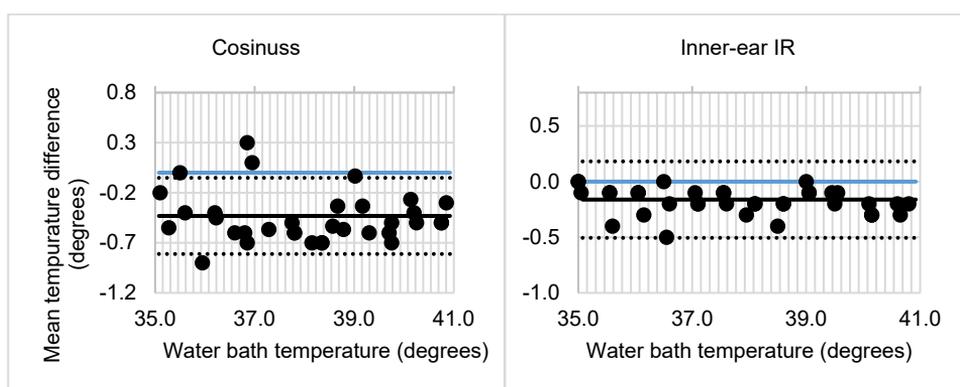


Figure 7.4 | Bland-Altman plots of the mean temperature versus the mean temperature difference. The (A) Cosinuss° °Temp, and (B) IR thermometer compared to mercury thermometer with mean (black), upper and lower Limit of Agreement (LoA) (black dotted line) and zero-line (blue).

7.3.2 | In-vivo accuracy under controlled conditions

It was observed that the mean T_{EC} value measured using the Cosinuss° °Temp thermometer was $35.2^{\circ}\text{C} \pm 0.6^{\circ}\text{C}$ with a within-subject difference of $0.1^{\circ}\text{C} \pm 0.1^{\circ}\text{C}$. Table 7.2 shows the mean differences and results of the ICC analysis.

Table 7.2 | Cosinuss° versus ear canal IR thermometer.

	MD±SD [95% CI]	p	ICC [95% CI]	p	LoA
Raw	1.44±0.54 [1.14;1.74]	<0.001	0.07 [-0.05;0.31]	0.083	±1.05
With correction factor	0.03±0.37 [-0.17;0.24]	0.729	0.72 [0.33;0.90]	0.001	±0.72

Cosinuss° versus ear canal IR thermometer. The Cosinuss° was compared with the references using the intraclass correlation coefficient (ICC) with a confidence interval of 95%, p-value and Limits of Agreement (LoA) (n=15).

It was observed that the mean T_{EC} difference between the Cosinuss° °Temp thermometer and the IR thermometer exceeded the acceptable level ($MD=-1.4^{\circ}C$, $p<0.001$) and exhibited a low correlation ($ICC=0.07$, $p=0.083$). However, after an individual correction factor (mean: $1.4^{\circ}C\pm 0.6^{\circ}C$, min: $0.7^{\circ}C$, max: $-2.5^{\circ}C$) was applied, this mean difference decreased to an acceptable level ($0.0^{\circ}C$, $p=0.729$) and a high correlation ($ICC \geq 0.72$) was found. Figure 7.5 shows a Bland–Altman plot. Without correction, the Bland–Altman plot showed bias between the mean differences; however, no funnel shape was visible. Sensitivity analysis revealed similar ICC and p -values.

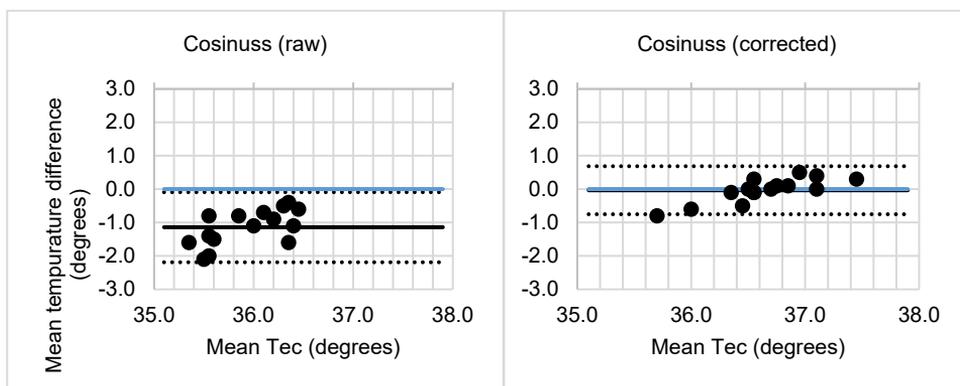


Figure 7.5 | Bland–Altman plots of the mean ear canal temperature versus the mean temperature difference. The ear canal temperature (T_{EC}) measured with non-corrected (A) Cosinuss° and corrected (B) Cosinuss° compared to the IR thermometer with mean and upper and lower Limit of Agreement (LoA).



7.3.3 | In vivo accuracy under real-life conditions

In five subjects of the field study, the Cosinuss° °Temp thermometer stopped working because of the sweat that they produced while performing their jobs; the system was not fully waterproof, resulting in sweat on the electrical components (circuit board), corroding them over the course of the study. This resulted in loss of data and fewer results after work. Despite the incomplete datasets, all subjects were included in the accuracy study.

It was found that the mean T_{EC} of the Cosinuss° °Temp thermometer during the accuracy measurements was $35.0\pm 1.4^{\circ}C$ (mean \pm SD) without correction. The mean correction factor was $-1.7\pm 1.1^{\circ}C$ (min= $0.1^{\circ}C$, max= $-6.0^{\circ}C$, outlier). Table 7.3 shows the mean differences and results of the ICC analysis for raw and corrected systems before and after work.

Table 7.3 | Cosinuss° non-corrected and corrected per subject.

Working	MD±SD [95% CI]	p	ICC [95% CI]	p	LoA
Raw					
Before (n=49)	1.45±1.18 [1.08;1.81]	<0.001	0.13 [-0.08;0.37]	0.021	±2.23
After (n=43)	1.45±1.24 [1.068;1.82]	<0.001	0.25 [-0.09;0.54]	0.002	±2.44
Corrected per subject					
Before (n=49)	-0.24±0.21 [-0.30;-0.17]	<0.001	0.77 [0.19;0.91]	<0.001	±0.43
After (n=43)	-0.24±0.97 [-0.53;0.06]	0.110	0.55 [0.32;0.73]	<0.001	±1.90

The Cosinuss° was compared with the IR thermometer per company using the intraclass correlation coefficient (ICC) with a confidence interval of 95% and p-value.

Before correction, an unacceptable high difference (MD=1.5°C, p<0.001) and a low correlation (ICC≤0.25, p≤0.021) were observed, consistent with the laboratory study. However, after correction, the mean difference decreased to an acceptable level (MD=-0.2°C, p≤0.110) and the correlation between the Cosinuss° °Temp thermometer and IR thermometer became high, with an acceptable LoA value (ICC=0.77, p<0.001, LoA=±0.43). After the subjects performed their jobs, it was observed that the correlation between the Cosinuss° °Temp thermometer and IR thermometer decreased to a moderate level, exceeding the acceptable level of the LoA (ICC=0.55, p<0.001, LoA=±2.44). Figure 7.6 shows Bland–Altman plots. Sensitivity analysis revealed similar results, with the sensitivity analysis of complete datasets only revealing non-significant differences.



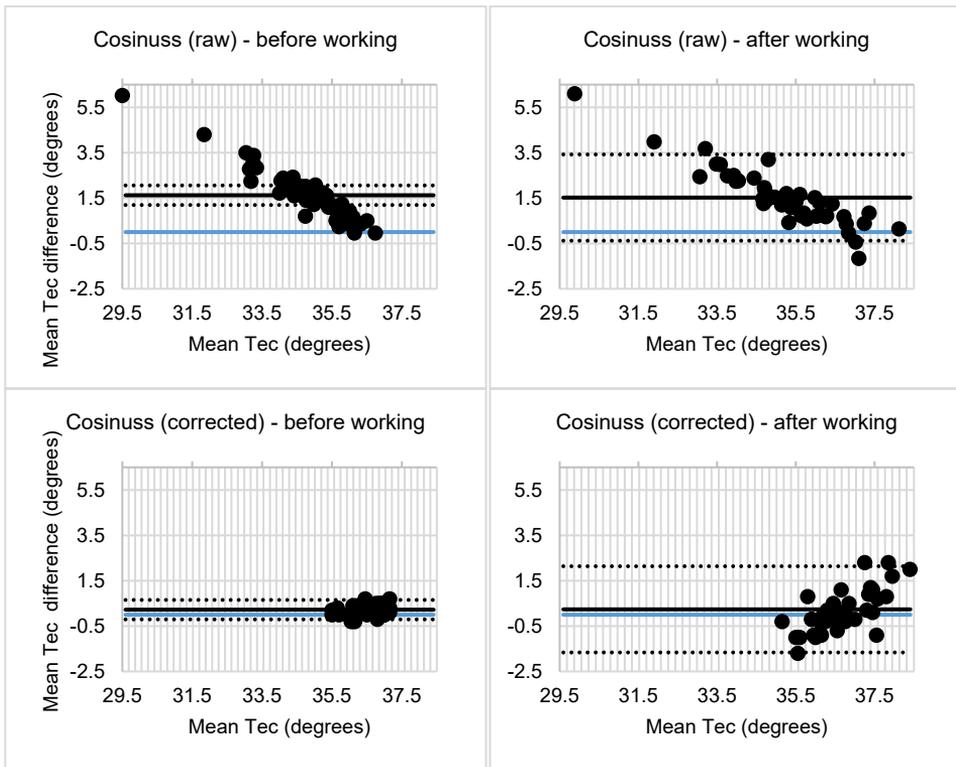


Figure 7.6 | Bland-Altman plots of the mean ear canal temperature versus the mean temperature difference. The ear canal temperature (T_{EC}) raw and corrected Cosinuss^o (A) before and (B) after working compared to the IR thermometer with mean and upper and lower Limit of Agreement (LoA).



7.3.4 | Influences of real-life working conditions on accuracy

While the workers were performing their jobs, it was observed that the mean T_{EC} was $36.8^{\circ}\text{C} \pm 1.6^{\circ}\text{C}$, with a mean T_{cli} value of $26.9^{\circ}\text{C} \pm 4.9^{\circ}\text{C}$ and mean RH of $62.6\% \pm 12.7\%$. Table 7.4 shows the mean T_{EC} , T_{cli} , and RH measured using the Cosinuss^o °Temp thermometer while the workers were performing their jobs. Each subject exhibited individual patterns of development of T_{EC} , with the micro-climate (T_{cli}) and RH differing from one job to another. Figure 7.7 shows the values of T_{EC} , T_{cli} , and RH over time while four representative individuals were performing their jobs. Tables 7.4 and 7.5 outline the mean differences and results of the ICC analysis for the four different jobs mentioned earlier (with corrected Cosinuss^o °Temp thermometer data; the raw Cosinuss^o °Temp thermometer data are shown in the Appendix).

Table 7.4 | Ear canal temperature, micro-climate temperature and relative humidity of all subjects and per job measured.

Job type	n	Mean T _{EC} (°C) (corrected)	Mean T _{cli} (°C)	Mean RH (%)	Max T _{EC} (°C)	Max T _{cli} (°C)	Max RH (%)
All subjects	49	36.83±1.55	26.90±4.86	62.55±12.70	46.41±1.99	39.54±6.07	92.56±13.56
Chemical cleaners	9	37.61±1.51	26.93±1.86	78.76±5.70	46.41±2.78	32.96±1.79	91.86±2.10
Mechanics	13	36.09±0.80	27.96±2.20	49.67±8.98	38.32±0.58	36.46±2.67	75.88±10.91
Firefighters	14	37.87±0.72	31.15±2.22	67.60±7.69	41.64±1.15	39.54±2.98	92.53±3.39
Neighbourhood maintainers	13	35.99±1.96	21.24±4.82	60.13±8.72	42.68±1.98	28.90±4.76	88.40±8.24

Mean and max ear canal temperature (T_{EC}) (°C), nearby micro-climate temperature (T_{cli}) (°C) and relative humidity (RH) (%) of all subjects and per job measured with Cosinuss° and ambient conditions chest box.

Table 7.5 | Cosinuss° corrected per subject.

Job type	n	MD±SD [95% CI]	p	ICC [95% CI]	p
Before performance of the job					
Chemical cleaners	9	-0.21±0.18 [-0.35;-0.08]	0.007	0.88 [0.16;0.98]	<0.001
Mechanics	13	-0.11±0.22 [-0.25;0.02]	0.087	0.81 [0.47;0.94]	<0.001
Firefighters	14	-0.34±0.16 [-0.43;-0.25]	<0.001	0.51 [-0.08;0.85]	<0.001
Neighbourhood maintainers	13	-0.22±0.26 [-0.37;-0.06]	0.012	0.67 [0.11;0.90]	0.001
After performance of the job					
Chemical cleaners	7	-0.43±0.55 [-0.93;0.08]	0.083	0.60 [-0.06;0.91]	0.029
Mechanics	13	0.22±0.47 [-0.07;0.50]	0.121	0.63 [0.18;0.87]	0.005
Firefighters	13	-0.72±1.04 [0.57;1.85]	0.029	0.28 [-0.16;0.68]	0.110
Neighbourhood maintainers	10	0.10±1.19 [-0.75;0.95]	0.796	-0.09 [-0.77;0.57]	0.594

The Cosinuss° was compared with the ear canal IR thermometer per company using the intraclass correlation coefficient (ICC) with a confidence interval of 95% and p-value.

In the case of mechanics and neighbourhood maintenance workers, it was observed that the working environment (i.e., temperature, RH) played a major role and influenced the development of T_{EC}, T_{cli}, and RH while they were performing their jobs. For mechanics, the values of T_{cli} and RH in the indoor working environment were constant within the subjects (see Figure 7.7, mechanics), resulting in a relatively constant T_{EC}. Before and after work, the mean difference was within the acceptable level (MD ≤ ±0.2, p ≥ 0.087) with a (very) high correlation (ICC ≥ 0.63, p ≤ 0.005). For neighbourhood maintenance workers, it was observed that the outdoor working environment fluctuated, resulting in small fluctuations in T_{EC} (see Figure 7.7, neighbourhood maintenance worker). Although the mean difference was within the acceptable level (MD ≤ ±0.2, p ≤ 0.796), the ICC value decreased from high (ICC=0.67, p=0.001) to negative, indicating a non-random effect influenced by a third variable (Shrout & Fleiss, 1979). For two mechanics and four neighbourhood maintenance



workers, the value of T_{EC} was lower than 35.0°C . Given these results, the six subjects were asked how they felt, and all of them mentioned that they did not have any thermoregulation-related or health complaints. All six of them worked in cold, rainy/foggy, and/or windy environments, which implies that these measurement errors may have been due to the environmental conditions (e.g., wind or temperature of the working environment; Taylor, et al., 2014).

In the case of chemical cleaners and firefighters, both the PPE (breathing apparatus) and chemical-proof PPC as well as the fire-proof PPC and helmet caused an increase in T_{cli} , RH, and T_{EC} as a result of transpiration and lack of ventilation. It was observed that when the PPC was removed after finishing the task, the values of T_{cli} and RH dropped rapidly, followed by the T_{EC} value (see Figure 7.7, firefighters). Before work, the firefighters showed a moderate correlation ($\text{ICC}=0.51$, $p<0.001$), which decreased to a low correlation after work ($\text{ICC}=0.28$, $p=0.110$). For chemical cleaners, this correlation remained high ($\text{ICC} \geq 0.60$, $p \leq 0.029$). While working, the T_{EC} value of nine subjects exceeded 40.0°C , with abnormal values reaching a maximum T_{EC} of $46.4^{\circ}\text{C} \pm 2.0^{\circ}\text{C}$. These nine subjects comprised three chemical cleaners wearing PPC and PPE, four firefighters wearing PPC and PPE, and two neighbourhood maintenance workers wearing temporary PPE (hearing protection). None of these subjects had any thermoregulation-related or health complaints, which implies that such an abnormal increase was due to them wearing PPC and PPE or due to environmental conditions. Sensitivity analysis (of complete datasets) revealed similar results or non-significant differences, and similar patterns were observed in all job types.



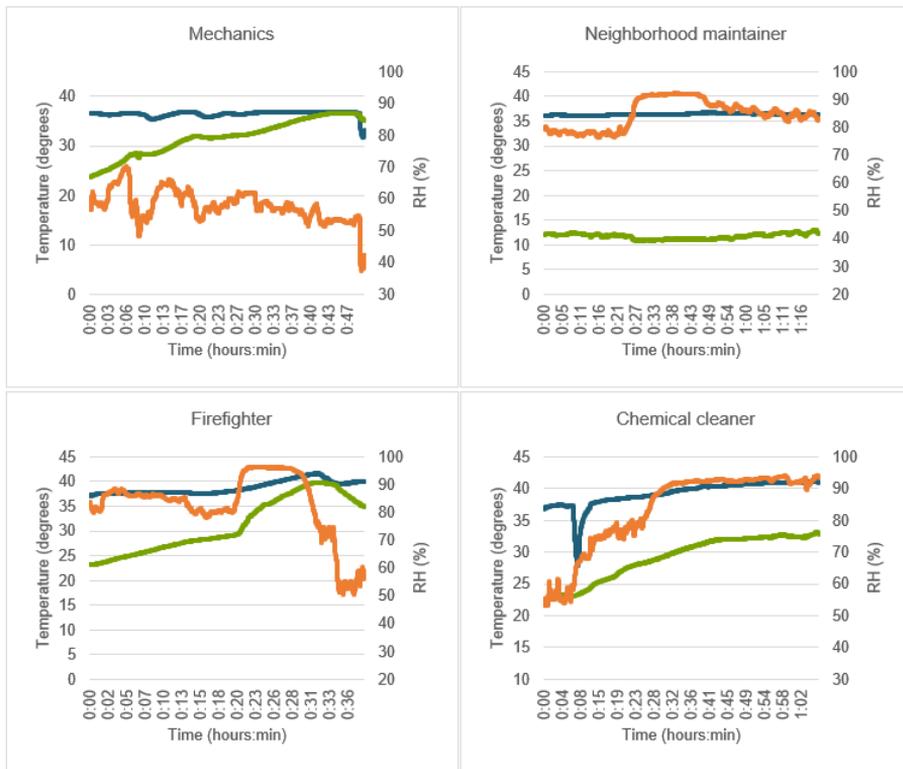


Figure 7.7 | Individual graph during the performance of the job. (A) Mechanics; (B) Neighbourhood maintainer; (C) Firefighters; (D) Chemical cleaner. Ear canal temperature (°C) (dark blue), nearby micro-climate temperature (°C) (green) and relative humidity (RH) (%) (orange) of 4 subjects with different jobs.

7.3.5 | Usability

Generally, the Cosinuss° °Temp thermometer is easy to position in and around the ear. All subjects experienced a good fit with the Cosinuss° °Temp thermometer, and most of them reported it to be comfortable and to look professional. In the laboratory study, at rest, two subjects reported that the Cosinuss° °Temp thermometer felt loose and that they needed to reposition it by pushing it a little into their ears. It was reported that the thermometer remained in place during sitting, walking, and jumping in PPC. However, in all cases ($n=15$), while the subjects were either wearing or taking off their chemical-proof suits, the thermometer fell out of their ears.

In real-life working conditions, all subjects reported that the Cosinuss° °Temp thermometer was non-obstructive and in general remained well fixated within their ears while they were performing their jobs. In two subjects, the thermometer fell out of the subjects' ears while



they were performing their jobs. In three subjects, the Cosinuss° °Temp thermometer felt loosely fixated within the ear and was repositioned by the subject. In eight subjects (seven chemical cleaners, one firefighter), the thermometer fell out of their ears while they were taking off their PPC, helmets, or head-related parts of their chemical-proof suits. Figure 7.7 shows how the falling of the thermometer out of the ear reflects in a drop of T_{EC} (see Figure 7.7, chemical cleaners). Importantly, the Cosinuss° °Temp thermometer did not interfere with task performance. Although the firefighters mentioned that there may be some complications for workers who need to wear in-ear hearing protection equipment or an in-ear communication device.

7.4 | Discussion

The aim of this study is to explore and evaluate the accuracy of the Cosinuss° °Temp thermometer as a wearable thermometer used in monitoring the ear canal temperature while performing physically demanding work. For hospital use, both the Cosinuss° °Temp thermometer and IR thermometers showed very high correlations compared to mercury thermometers in an *in vitro* study. However, a laboratory and field study indicated the need for a correction factor and calibration before use, because the Cosinuss° °Temp thermometer showed a continuously lower ear canal temperature of -1.4°C , which is in line with previous research (Roossien, et al., 2020) as well as research on Cosinuss° One (Chaglla, et al., 2018). Monitoring the in-ear placement of the thermometer and applying an individual correction factor caused the accuracy of the Cosinuss° °Temp thermometer to increase, indicating the influence of individual ear/in-ear dimensions and lack of fit in the ear. After correction, the results obtained in the *in vivo* studies supported the accuracy of this system. It should be noted that, on the one hand, obtaining unrealistically low temperatures indicates the influence of weather conditions (e.g., wind) on the accuracy of the Cosinuss° °Temp thermometer and the need for insulation. On the other hand, obtaining unrealistically high temperatures indicates the influence of PPC and PPE on the accuracy of the Cosinuss° °Temp thermometer. In general, lack of ventilation and/or air circulation while wearing PPC and PPE around the ear results in local warming of the environment near the ear. Both of these findings indicate that the Cosinuss° °Temp thermometer is sensitive for measuring environmental conditions instead of ear canal temperature. To check for possible systematic errors, Pearson's test was used to analyse the mean differences between the Cosinuss° °Temp thermometer and the reference thermometer. A systematic error was detected in the raw results of the Cosinuss° °Temp thermometer, while no error was detected with the ear canal IR thermometer or corrected Cosinuss° °Temp thermometer. Moreover, under some working conditions, the Cosinuss°



°Temp thermometer was found to be less accurate than without wearing PPC, PPE or working indoor, likely because of the lack of insulation in the ear while performing physically demanding work or lack of close fit. Therefore, it is important to improve the fit of the Cosinuss° °Temp device.

Compared to currently available research, one of the strengths of this study is that we explored the interaction among the user (human), device, and different working environments. This study was performed both in a laboratory and in real-life working environments. The accuracy of the Cosinuss° °Temp thermometer was assessed in multiple work situations to gain an insight into the influence of PPC and PPE as well as the environmental conditions on the thermometer. In the field study, the subjects were workers who experienced temperature-related challenges while performing their jobs. Because they work under similar conditions on a daily basis, that is, under different (outdoor) environmental conditions from those of neighbourhood maintenance workers, they were able to provide adequate feedback. Hence, we were able to gain insights into the development of body temperature among different types of workers, which is relevant for an objective and more accurate prediction of heat strain. This represents a first step in improving the health and safety of workers with physically demanding occupations.

A limitation of this study was the ear canal infrared reference thermometer. Although this non-invasive and fast reference (Jacklitsch, et al., 2016) is currently the measurement standard for hospital use (Calusic, et al., 2012; Itani, et al., 2018), it can probably not be considered as the gold standard for lab-based studies (Moran & Mendal, 2002; Coso, et al., 2008; Casa, et al., 2007; Ganio, et al., 2009). Measuring the inner-ear temperature is a reliable method (Coso, et al., 2008; van Staaïj, et al., 2003; Gasim, et al., 2013) for monitoring body temperature in scientific research (Shelton-Rayner, et al., 2012; Chaglla, et al., 2018; Kocoglu, et al., 2002; Ammann, et al., 2015), although some studies have shown that this method is less accurate than other methods. This method usually results in less accurate ($\pm 1.0^{\circ}\text{C}$) measurements (Moran & Mendal, 2002; Coso, et al., 2008; Casa, et al., 2007; Ganio, et al., 2009), given that the local temperature could be measured instead of the ear canal temperature (Towey, et al., 2017; Levander & Grodzinsky, 2017; Kuht & Farmery, 2014). This method can, however, be applied in working conditions (Mogensen, et al., 2018) in which workers are expected to be subjected to excessive heat strain (Holland, et al., 2002). Although concurrent validity measurements using rectal thermometers, invasive “temperature pills” (mini thermometers that can be swallowed), or zero-heat-flux thermometers are preferable (Moran & Mendal, 2002; Teunissen, et al., 2012), they are impossible to apply in real-life working conditions because they do not work continuously and are either impractical (e.g., rectal thermometer) or are influenced by hot/cold food and



liquid intake (temperature pill), which is crucial in physically demanding occupations (Mazgoaker, et al., 2017; Saurabh, et al., 2014; Taylor, et al., 2014; Lim, et al., 2008). One of the limitations in this study was that the Cosinuss° °Temp thermometer could not be validated in the presence of PPC and/or PPE. Although we could not prove that the Cosinuss° °Temp thermometer shifted as a result of movement, this is the most likely reason. Moreover, because the Cosinuss° °Temp thermometer is not explosion-proof, it was not allowed in all working locations, resulting in a limited representation of the working population.

It should be noted that the Cosinuss° °Temp thermometer is sensitive to misalignment in the ear canal, which may lead to the measurement of the aural temperature instead of the tympanic membrane temperature (Gao, et al., 2018; Taylor, et al., 2014; Towey, et al., 2017). This may result in the over- or underestimation of the actual heat strain (Moran & Mendal, 2002; Coso, et al., 2008; Casa, et al., 2007; Ganio, et al., 2009). Perhaps this can be prevented using individually tailored components; hence, more research in this direction is recommended. Suggestions for further research include studying the properties of the Cosinuss° °Temp thermometer in the laboratory using an invasive scientific standard to investigate its accuracy compared to deep body temperature measurements. Moreover, it is important to investigate the correction factor (before each use of the sensor) and calibration method in more depth in a repeatability study. It is also crucial to further validate this system over a full day and on different working days, as well as in other types of work and environments. Furthermore, researchers should also investigate the development and relationship between ear canal temperature, environmental temperature, and humidity, as well as other physiological parameters, such as the heart rate (Dube, et al., 2019; Buller, et al., 2015), to make full use of this thermometer to prevent overheating on an individual level. Developing a mathematical algorithm may help combine the output of the parameters and increase the accuracy of heat strain prediction. The system also needs to be optimized in terms of accuracy and stability, including its fixation and isolation in the ear, taking into account different ear shapes (Ban & Jung, 2020). In addition, the system needs to be resistant to explosions and to be equipped with more sensors to measure more parameters, such as heat radiation and air velocity. Although none of the subjects reported that the Cosinuss° °Temp thermometer interfered with their workability, the thermometer slightly reduced their hearing capability. For workers who need to wear in-ear hearing protection equipment, further research should be performed to make the ear attachment soundproof to protect the workers against noise or to integrate the device in hearing protection equipment. For workers who use in-ear communication, it is important to make the



Cosinuss° °Temp thermometer compatible with or integrated within communication systems. This would be a great advantage for workers such as firefighters.

In general, it is important to develop a continuous, non-invasive instrument that can prevent heat strain among workers and improve their health and safety while working (Chaglla, et al., 2018; Mazgoaker, et al., 2017; Pancardo, et al., 2015; Uth, et al., 2016). In general, wearable thermometers should be suitable for all body proportions, reusable with low costs, and resistant to the effects caused by food and liquid intake (Mazgoaker, et al., 2017; Saurabh, et al., 2014; Taylor, et al., 2014). The results obtained in this study show that the Cosinuss° °Temp thermometer can be used to monitor the ear canal temperature over time during work. It can also be used for screening purposes (Mogensen, et al., 2018), by providing an insight into the risks that may lead to excessive heat strain, and may potentially help prevent work-related overheating and dehydration (Pancardo, et al., 2015; Coso, et al., 2008) for workers. On the one hand, on the group level, it can be used to gain an insight into the risks that may lead to excessive heat strain. On the other hand, on the individual level, it needs to be more accurate at rest and requires individual calibration. It should be noted that this device can be used in other fields as well, such as health care (Dias & Cunha, 2018; Sun & Zhang, 2014), remote health monitoring (Uth, et al., 2016; Mansor, et al., 2013; Al Rasyid, et al., 2015), sports applications, and even space (Jones, 2006).

7.5 | Conclusions

From the results of the laboratory study, high correlations were observed between the Cosinuss° °Temp thermometer and tympanic IR thermometers. Furthermore, an *in vivo* accuracy study showed the need for individual correction factors for the Cosinuss° °Temp thermometer. Without these corrections, this thermometer lacks accuracy. When a correction factor was applied to correct individual differences, moderate to high correlations were found with an acceptable accuracy. At the beginning of physically demanding work, the Cosinuss° °Temp thermometer showed a very high correlation for measuring the ear canal temperature. However, after a certain amount of time, this correlation decreased and became moderate, with some unrealistic ear canal temperature results obtained while the workers were performing their jobs. This was probably due to environmental factors (e.g., wind), wearing helmets and hearing protection equipment, and lack of insulation of the area around the ear. When an individual correction factor was used, it was confirmed that the thermometer is accurate at rest, but not during outdoor work or while wearing helmets and/or hearing protection equipment. Hence, it can be concluded that the Cosinuss° °Temp thermometer is comfortable, causes minimal interference (or not



at all) during work, and can be used to monitor the development of the individual ear canal temperature of workers with physically demanding occupations.

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Disclosure statement

Authors declare no conflicts of interest. Any findings, and conclusions or recommendations presented in this article are those of the author(s) and do not necessarily reflect the views of Cosinuss^o GmbH.



7.6 | Appendices

Table 7.A.1 | Ear canal temperature, micro-climate temperature and relative humidity of all subjects and per job measured.

Job type	n	Mean T_{EC} (°C) (raw)	Max T_{EC} (°C) (raw)
All subjects	49	34.88±1.93	44.71±2.32
Chemical cleaners	9	34.70±2.87	38.77±3.32
Mechanics	13	34.62±1.51	37.25±0.82
Firefighters	14	35.97±1.18	44.71±2.15
Neighbourhood maintainers	13	34.13±1.90	42.58±2.18

Mean and max ear canal temperature (T_{EC}) (°C), nearby micro-climate temperature (T_{cli}) (°C) and relative humidity (RH) (%) of all subjects and per job measured with Cosinuss° (raw) and ambient conditions chest box.

Table 7.A.2 | Cosinuss° raw per subject.

Job type	n	MD±SD [95% CI]	p	ICC [95% CI]	p
Before performance of the job					
Chemical cleaners	9	-1.67±0.36 [-1.94;-1.39]	0.000	0.19 [-0.02;0.64]	0.001
Mechanics	13	-1.04±0.73 [-1.48;-0.60]	0.000	0.17 [-0.11;0.55]	0.092
Firefighters	14	-1.64±0.87 [-2.13;-1.13]	0.000	0.08 [-0.08;0.36]	0.167
Neighborhood maintainers	13	-1.65±1.86 [-2.77;-0.52]	0.008	0.09 [-0.21;0.50]	0.309
After performance of the job					
Chemical cleaners	7	-1.46±0.59 [-2.00;-0.92]	0.001	0.21 [-0.07;0.71]	0.039
Mechanics	13	-1.37±0.94 [-1.94;-0.80]	0.000	0.18 [-0.11;0.57]	0.077
Firefighters	13	-1.21±1.05 [-1.85;-0.57]	0.001	0.25 [-0.13;0.64]	0.066
Neighbourhood maintainers	10	-1.92±2.02 [-3.37;-0.47]	0.015	0.01 [-0.26;0.46]	0.487

The (raw) Cosinuss° was compared with the ear canal IR thermometer per company using the intraclass correlation coefficient (ICC) with a confidence interval of 95% and p-value.



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Chapter 8

Ethics in Design and Implementation of Technologies for Workplace Health Promotion

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Abstract

Introduction: Responsible research- and innovation studies have established a firm framework for addressing ethical issues in designing and using new digital health technologies. However, despite this comprehensive ethics framework, there is still a lack of knowledge on (1) how to overcome the divide in ethical approaches to designing and implementing innovative technologies, (2) how context can play a role when addressing critical ethical issues such as privacy and autonomy, and (3) how ethical responsibilities of the different stakeholders can be made manifest and used. These three problems are a major challenge for the development and implementation of new digital health technologies. The aim of the present study is to address this challenge by analysing two ethical issues, privacy and autonomy of workers, in a real-life research setting.

Procedure: This study is an instrumental case study of a multidisciplinary research project, which aimed to develop sensor and intervention technologies for a sustainable workforce while considering both implementation and design. The analyses focus on two cases and reflect a real-life research setting of doing ethics. Design-use dynamics are identified and a context-specific approach of ethics is applied in a reiterating process of development and small-scale implementation of health-related technologies in the workplace.

Case studies: The results show how protecting the privacy and autonomy of workers cannot be seen as stand-alone issues, but rather, there is an interplay between these values, the work context, and the responsibilities of workers and their employer. Consequently, digital health technologies in this multidisciplinary research project are designed to improve worker conscientious autonomy, while concurrently creating balance between privacy and health, and assigning responsibilities to the appropriate stakeholders. At the same time, a close watch is kept on other critical values, such as privacy and autonomy.



Conclusions: Focusing on a contextual conceptualization of core ethical principles identified during the project helps to avoid compartmentalization, generalization, and neglect of responsibility. Developing context-specific ethics makes it possible to examine the particular implications of a certain value for a specific situation. There is a need for a practical, adaptive tool or guideline that helps engineers, researchers and other stakeholders in this process. This adaptive tool can only be developed if more researchers document and publish their ethics practices.

Keywords: Privacy, autonomy, generalization, responsibility, ethics, responsible research and innovation



8.1 | Introduction

A major challenge caused by the aging workforce is to keep workers fit for work (Kenny, Yardley, Martineau, & Jay, 2008) to achieve a sustainable workforce. Technological interventions can assist to maintain individual workability, for instance by addressing the needs of aging workers in an objective manner (Truxillo, Cadiz, & Hammer, 2015) and creating balance between individual capacity and workload through well-designed workplace health interventions (Kenny et al., 2008). Examples of digital health technologies that are applied in the workplace are accelerometers, measuring bending, standing and walking activity (Villumsen, Madeleine, Jørgensen, Holtermann, & Samani, 2017) and wearable sensors for measuring fatigue (Aryal, Ghahramani, & Becerik-Gerber, 2017). Technologies such as these are aimed at automatically measuring and intervening worker behaviour, by giving (automated) feedback through digital means such as smart phones or stand-alone digital applications. These digital health technologies are used in addition to existing workplace health practices.

Research into the design and implementation of digital health technologies is surrounded by ethical issues that require responsible research. It is important to think about what impact this technology might have on individuals who are targeted as potential users or even on society as a whole. Responsible research and innovation (RRI) is a field of science that aims to highlight these socio-ethical issues in research and innovation practices (Grunwald, 2014; Owen, Macnaghten, & Stilgoe, 2012). In the past decade, new knowledge and guidelines have been developed that empower researchers to incorporate the researcher's responsibility throughout the innovation process (Stahl, 2013; Stilgoe, Owen, & Macnaghten, 2013), focusing on anticipation of (un)foreseen ethical qualms, reflexivity on one's own role, inclusion of a diversity of perspectives, and responsiveness to societal needs. Studies that describe the employed techniques to overcome the socio-ethical issues in development are lacking (Fisher et al., 2015), and publications in the field of responsible research and innovation still struggle with three critical problems: compartmentalization, generalization, and vagueness about responsible use (Efstratiou et al., 2007; Kortuem et al., 2007; Leclercq-Vandelannoitte, 2017; Palm, 2009).

Compartmentalization of focus in the current setting refers to the focus on one part of the development or implementation phase, while not including the tension between the intended and actual use of a technology. That is, until now, studies have mostly focused on ethical issues in either the design of new sensor technologies (Aryal et al., 2017; Efstratiou et al., 2007; Motti & Caine, 2014; Saurabh, Rao, Amrutur, & Sundarajan, 2014) or ethical issues in the implementation of existing technologies (Kortuem et al., 2007; Leclercq-



Vandelannoitte, 2017; Sole, Musu, Boi, Giusto, & Popescu, 2013). The issues surrounding implementation takes technologies as a given and does not question their inherent values in the design. This situation does not do justice to reality: if design and implementation do not acknowledge each other's ethical concerns and intended values, the final use of the technology will not reflect the intentions of both sides. A broader view on the transition between design and implementation is called for (Jakobsen, Fløysand, & Overton, 2019) to facilitate responsiveness between these phases of RRI.

In case of the second problem, generalization, a single issue is identified as a core problem and addressed in a general way without attention to the specific context. For example, privacy is one of the significant issues in the development and application of new technologies that collect large amounts of data of individuals (Al Ameen, Liu, & Kwak, 2012; Conger, Pratt, & Loch, 2013; Nissenbaum, 2010; Zhu, Gao, & Li, 2016). However, most analyses of privacy issues focus on technologies that are used in the public space. These analyses do not necessarily fit other important contexts, such as use of sensor technologies in the work environment designed for health promotion. With regard to new technologies designed for the working environment, specific issues that concern privacy in the worker-employer relationship remain unaddressed. Additionally, discussion lacks about how privacy is embedded in the broader context of the effect of for example digital health technologies on the autonomy of people, specifically workers. That is, research suggests that workers both experience (Leclercq-Vandelannoitte, 2017) and fear (Damman, van der Beek, & Timmermans, 2015) a loss of privacy and autonomy due to the use of (preventive) technology in the workplace. This lack of context-specific knowledge on both privacy and autonomy results in ethical issues that are not appropriately addressed in the development of new technologies. More research is necessary to address and contextualize these issues in the design and implementation of new digital health technologies.

Finally, the topic of responsible use of digital health technologies remains vague and unaddressed. Providing transparency about responsible use as well as identifying who is responsible are lacking. For example, Leclercq-Vandelannoitte (2017, p. 151) observed that in the use of ubiquitous technologies in the workplace, neither workers nor employers recognize who is responsible for technology, nor do they understand the importance of responsible use of these technologies. Furthermore, designers do not provide insight into the responsible use of their designs. Thus, identifying responsible use is notoriously difficult due to interdependent design-use dynamics (Kiran, 2012). These dynamics entail that design and use continuously impact one another because a particular function is often the reason for the design of a technology application. However, the adoption of the design can substantially change the function. An example is the innovation of the Short Message



Service (SMS), which was designed to enable mobile owners to receive messages about incoming voicemails as well as bills from the mobile company (Taylor & Vincent, 2006). However, SMS developed into a primary function for communication between individuals, thereby posing additional design demands as well as responsibilities that were not relevant to the original function. These interdependent design-use dynamics make it difficult to predict how a technology will be used, and whether it will be used as intended. However, this difficulty should not hinder designers from at least outlining the responsibilities inherent in their designs.

This study aims to overcome these issues of generalization and compartmentalization and additionally identify relevant responsibilities in the design and implementation of digital health technologies in the workplace. First, the present study outlines current knowledge on ethical (and legal) issues on the implementation of technologies in the workplace, specifically focusing on the two ethical issues that play an important role in the worker-employer relation: privacy (Spook, Koolhaas, Bültmann, & Brouwer, 2019) and autonomy (Damman et al., 2015; Leclercq-Vandelannoitte, 2017). Secondly, two cases were explored using a context-sensitive approach of ethics to investigate these ethical issues during the development and implementation of sensor and intervention technologies for health purposes in the workplace.

8.1.1 | Privacy of workers

Employers are obligated to guarantee a safe working environment for their workers and should be reluctant when it comes to meddling with the workers' private lives and personal data. Interfering with workers' health behaviour, especially as connected to lifestyle, is dubious at best. It targets individuals (at work and in private) instead of organizational and collective problems, even if the goal is sustainable employability (van Berkel et al., 2014). Therefore, sensor and intervention technologies should comply with several criteria to ensure worker privacy.

Firstly, according to the EU General Data Protection Regulation, article 15, section 1 (GDPR, 2016), the worker should be able to access all personal data and outcomes of sensor and intervention technologies, without the interference of others. Secondly, the employer should not have access to data and outcomes of individual workers or be able to derive these outcomes from group data (GDPR, 2016, sec. 6). Current regulations on data collection and individual privacy limit the possibilities of data sharing (GDPR, 2016). As stated in article 6, section 1, subsection d of the GDPR, data processing is only valid if it is necessary to protect the vital interests of the subject, hence, a life-or-death situation.



Legally, data sharing at a group level is only allowed if the data does not contain identifiable information, such as personal data traceable to individuals (GDPR, 2016, sec. 4). Specifically when it comes to sensor data that cross the border between work and private life, serious legal concerns arise regarding data and health privacy (Brassart Olsen, 2020). It could be argued, however, that sharing digital health data with relevant actors, such as health and safety workers, is beneficial for workers in specific contexts. In case of workplace improvements, the use of personal data could help improve working conditions. The GDPR, however, does not provide a legal basis for the exchange of personal data in these specific relationships (Arora, 2019), making it difficult to use digital health data in the working environment, even if it can improve a worker's health.

A needs assessment among workers with physically demanding work identified a demand for sensor and intervention technologies (Spook et al., 2019). However, respondents expressed concerns about what would happen with the personal data retrieved by the sensors, fearing their privacy would be violated, especially if employers had access to the data. These apprehensions confirm the findings of other studies (Choi, Hwang, & Lee, 2017; Jacobs et al., 2019). The GDPR, as described above, offers an extensive legal framework protecting the rights and freedoms of data subjects, ensuring data minimization, informed consent, good practice via the Data Protection Impact Assessment (DPIA), and privacy by design (GDPR, 2016; Lodge & Crabtree, 2019; Mulligan, Koopman, & Doty, 2016). Although this legal framework is intended to protect workers, in some cases workers are not necessarily protected by it, or do they want to be protected in this manner. That is, workers also declared that they would share their data with their employer to explore possibilities to improve working conditions if they could retain full ownership of the data (Spook et al., 2019).

Absolutizing a legal framework endangers narrowing the fundamental questions of why privacy is an essential moral value. Data protection is significant to ensure privacy, but it does not embrace a comprehensive understanding of the concept. Numerous scholars have warned against a reductionist conceptualization of privacy as merely about the protection of the personal sphere, raising questions about possible conditions under which this protection can be overruled (Barocas et al., 2013; DeCew, 2015; Dwork, 2006; Mulligan et al., 2016; Nissenbaum, 2010; Solove, 2008). They have argued for a broader understanding of privacy based on a reflection of practice and context. A legal framework for privacy by nature is fixed; however, privacy as a value should be shaped by each situation. Nissenbaum (2010, p. 2) succinctly summarized this concept: *'What people care about is not simply restricting the flow of information, but ensuring it flows appropriately'*.



Privacy as an essentially contested and malleable concept is dependent upon, amongst other things, the context in which it is examined, and the social and technological circumstances that apply to its context. As the theoretical debate about privacy continues, there is a need for a context-sensitive approach. Mulligan et al. (2016, p. 15) have suggested an approach based on four questions: *'While dilemmas between privacy and publicity, or privacy and surveillance, or privacy and security persist, the question we more often face today concerns the plurality available to us amidst contests over privacy: Which privacy? For what purpose? With what reason? As exemplified by what?'* These questions enable researchers and practitioners to pragmatically define the relevant characteristics of the applicable notion of privacy.

8.1.2 | Worker autonomy

A significant challenge for a workforce that will continue working into older age is to keep workers fit for work (Kenny et al., 2008). van der Klink et al. (2016, p. 74) suggest to focus on sustainable employability based on a capabilities approach. Maintaining and supporting the ability of workers to continue working depends on the adaptation of work behaviour to changing circumstances. Worker autonomy in the self-regulation of work behaviour is crucial in this process (Ryan & Deci, 2006). Hence, organizations are introducing an increasing number of digital health devices on the work floor with which workers can regulate their tasks and work behaviour to ensure the autonomy needed for self-regulation.

Technological interventions can assist in maintaining workers' ability to work, for instance by developing technology that addresses the needs of ageing workers objectively, such as interventions that increase physical activity and ergonomically flexible workplaces (Truxillo et al., 2015). Thus, digital workplace health interventions can create a balance between workers' capacity and workload (Kenny et al., 2008), and sensor technologies, such as activity monitors and heart rate monitors, can accurately monitor workload. Additional intervention technologies, such as smart chairs (Goossens, Netten, & Van der Doelen, 2012; Roossien et al., 2017) can support workers in altering behaviour to prevent and solve health problems effectively.

Workers are willing to adopt sensor technologies that are perceived as useful (Choi et al., 2017; Jacobs et al., 2019), but workers' willingness to use these technologies depends on the addressing of concerns about data security and technology misuse (Jacobs et al., 2019). Philosophically, autonomy is complex, and caution is necessary to narrow the notion of autonomy to an idea of self-determination. Autonomy is a normative idea that directs actions governed by a responsible commitment to the norms with which one binds oneself. It can be about one's willed ideals as well as a commitment to the norms and standards



people encounter and adopt because of the setting, such as the workplace (Kukla, 2005). Thus, autonomy, also referred to as ‘conscientious autonomy’ (Kukla, 2005), covers the high moral values that direct peoples’ lives as well as small practical commitments that shape ordinary happenings. For instance, if someone values being healthy, practical commitments could include walking to work instead of driving and taking the stairs instead of riding in an elevator.

8.1.3 | Responsibility in the work environment

The ultimate responsibility for safeguarding the working environment lies with employers. Employers are responsible for the capabilities of their workers, actively preventing harm and accidents (Arbeidsomstandighedenwet, 1999; Palm, 2009). For workers who labour physically, employers must protect workers’ safety via periodic occupational health examinations and safety monitoring (Arbeidsomstandighedenwet, 1999). Despite employers’ limited access to the outcomes of regular health checks, this examination protects workers because occupational physicians can access health data and warn workers of potential issues while bound to professional confidentiality.

To protect workers while using sensor and intervention technology, all stakeholders must be responsible for the proper use of these technologies (Johnson & Powers, 2005), although employers may have different views on this responsibility than workers (van Berkel et al., 2014). Both workers and employers acknowledge the responsibility to prevent harm in the workplace. However, many employers consider the responsibility to stay healthy and fit for the job to be the worker's responsibility, while workers embrace autonomy in their lifestyle choices (van Berkel et al., 2014). These contrary views see health as either a safety discourse or a lifestyle discourse (Allender, Colquhoun, & Kelly, 2006). Nevertheless, the responsibilities of workers and employers in both discourses must be examined through context-specific ethics to prevent ambivalence in the worker-employer relationship (van Berkel et al., 2014).

8.2 | Practical examples

8.2.1 | Project description

The project SPRINT@Work is an EU-funded interdisciplinary project aimed at developing and evaluating sensor and intervention technologies that contribute to keeping ageing workers healthy and effectively employable (Bonvanie, Broekhuis, Janssen, Maeckelberghe, & Wortmann, 2020; de Jong, Bonvanie, Jolij, & Lorst, 2020; de Jong, Jolij, Pimenta, & Lorst, 2018; Roossien, Heus, Reneman, & Verkerke, 2020; Roossien, Krops, Wempe, Verkerke, &



Reneman, 2021; Roossien et al., 2017). These health-related technologies were developed and implemented by researchers and engineers from a variety of disciplines (cognitive neuroscience, information management, biomedical engineering and rehabilitation medicine, community and occupational medicine), in collaboration with companies. The developed sensor and intervention technologies lead toward an automated, digital process of behavioural assessment of employees for health self-management purposes. Cognitive neuroscience and information management were represented by one professor and one PhD candidate, biomedical engineering and rehabilitation medicine were represented by two professors and one PhD candidate, and community and occupational medicine were represented by two professors, one post-doctoral researcher, and one PhD candidate. The four PhD candidates acted as executing researchers.

8.2.2 | Procedure: context-specific approach of ethics

In several intervision sessions between the executing researchers, and later, the entire project team, the following issues were addressed: (a) whether the legal framework of privacy identifies sufficiently what is at stake in the context of the development and implementation of sensor technologies for sustainable employability, and (b) whether self-management devices aimed to promote self-regulation can assist in enabling the autonomy of workers. The team developed a conceptual framework that contextualizes data protection and privacy issues. As well as the notion of worker autonomy into a framework of context-sensitive ethics that is helpful for both designing and implementing sensor technologies. This framework functioned as a benchmark for the researchers, so they could continuously check whether their proposed design was in line with context-specific ethics. During the project, this normative framework was continuously adapted using insights from the executed studies.

8.2.3 | Case studies

The present study highlights two case studies that were performed by the researchers of SPRINT@Work. The first case study was about monitoring the core temperature as a parameter of heat stress of firefighters. The objective of this study was to validate a wearable non-invasive core thermometer to monitor the core temperature of firefighters during firefighting simulation tasks (Roossien et al., 2020). The second case study was about a research on health self-management applications in the workplace of health care workers. This study aimed at investigating whether use of sensor and intervention technology enhances the autonomy of workers in self-regulating their health-related behaviour (Bonvanie et al., 2020).



8.2.4 | Participants

In both studies, the employer decided whether the study could be executed within the company. Thereafter, workers could voluntarily participate in the field studies. Employers were not allowed to oblige workers to use the sensor technology, nor can they ask for data if the worker voluntarily uses a sensor technology (Dutch Data Protection Agency, 2016). The intentions were articulated according to the declaration of Helsinki on research involving human subjects (World Medical Association, 2013), stating that participants should voluntarily give informed consent.

8.3 | Case study 1

8.3.1 | Privacy in the working environment: a case of firefighters

Firefighters would strongly benefit from sharing personal data about health measures such as bodily temperature acquired from wearable sensor and intervention technologies when entering a fire. During their job firefighters are exposed to a high thermal load due to heavy physical activity, external heat exposure from fires and the wear of highly insulated protective clothing (Roossien et al., 2020). This can lead to heat stress and subsequent related health problems, such as exhaustion, dehydration, mental confusion, and loss of consciousness (Roghanchi & Kocsis, 2018). In more extreme cases, heat strain can cause permanent damage and even be life-threatening (Krishnamurthy et al., 2017; Morgado, Talaia, & Teixeira, 2017), affect productivity and risk perception, and cause safety problems (Roghanchi & Kocsis, 2018). To monitor and prevent heat stress among firefighters, a wearable thermometer to measure the real-time body temperature is desirable. The firefighters themselves are not allowed to be distracted by immediate feedback about the obtained data, because they need to focus on the situation at hand. They neither have time nor opportunity to monitor the feedback and data from their own sensors. However, if the captains could monitor the current body temperature of their workers on-site using the real-time information from wearable sensor and intervention technologies, decline of the health and safety of the workers could be prevented.

Legally, an employer cannot ask permission to access the personal data of workers (GDPR, 2016, sec. 4), even if it is to the workers' advantage and safety. This issue points to ambiguity in the data protection law regarding the protection of workers' privacy opposed to the responsibility of the employer to safeguard workers' health and safety. Employers cannot, under any circumstance, use personal sensor data for the protection of health and safety of their workers. Although employers have the responsibility to protect workers from harm in



the work environment. An ensuing focus for the research team was to explore how privacy could be conceptualized in the specific context of sensor technologies at the workplace, despite such ambiguity.

8.3.2 | Context-specific approach to privacy

Following the pragmatic approach of Mulligan, the data sharing of these firefighters to determine what privacy might provide the protected firefighters in this case was analysed. Control over personal information, such as the core temperature and heart rate of the firefighter, is a critical target for protection. As previously stated, from the perspective of the GDPR, this type of data can only be accessed under stringent circumstances and must be handled by a health professional who is bound by professional confidentiality. Nevertheless, in the case of a fire, no such health professional is available. Thus, the harm that supposedly would be prevented by enforcing data protection might be superseded by the prevention of more prominent harm. This example illustrates how information becomes ethically and normatively significant. Not because it is about specific values such as privacy but because the context allows its use for action. In this case, the possible prevention of overheating. Hence, it is not about what information one has but about what one can do with that information.

Manson and O’Neill (2007) called the above explanation an agency-based model of informing and communicating, where it is necessary to analyse what the agent, in this case, the firefighter captain, can do with the private information obtained. If overheating can be prevented, firefighters might want the option to share sensor information with their captain, although the captain is not bound by confidentiality as a health professional. Hence, the firefighters’ permission for the captain to access this information is based on the specific agency of the captain to protect the firefighters from overheating. A different way to protect the privacy of firefighters is making sure firefighter captains are bound by the confidentiality of their own profession.

The answers to Mulligan et al. (2016) questions—‘Which privacy? For what purpose? With what reason? As exemplified by what?’—is that in the case of the firefighters, the privacy at stake is the ownership of personal data obtained by sensor technologies. The purpose of privacy is to give the firefighters control over their data, not only to prevent the employer’s use of this personal information but also to allow the firefighters to share the data as they deem acceptable. The agency-based model exemplifies this purpose: in an ideal situation, the firefighter can opt to share data for protection from health hazards with the captain, who can act to prevent health hazards but cannot use the data for any other purposes. This example shows that a narrow interpretation of privacy might result in diminishing safety: if



privacy is unidimensional, and the only choice would be to decide to share the data with the employer, either the firefighter would accept more significant risks during the execution of the job because the data would be hidden (as in the GDPR), or the employer would have full access to all data, which could lead to misuse for other purposes.

8.3.3 | Responsibilities of stakeholders

In the case of the firefighters, the employer is serious about the responsibility for the health of the workers. The GDPR, however, prevents the employer from using personal data to protect firefighters from overheating in an emergency. In this case, the workers are at an impasse. Distraction from the task could cause immediate risks to themselves and colleagues; thus, it is impossible to self-monitor their current health parameters. This gap between the desired situation and current regulations is frustrating for the fire department because the captains wish to protect their firefighters, but the law prevents it.

8.4 | Case study 2

8.4.1 | Autonomy in the working environment: a case of health care workers

Healthcare workers are often subject to irregular working hours, performing shifts and night work, thereby impacting lifestyle choices such as their daily exercise and diet (De Jongh & Mcdougal, 2014). An unhealthy lifestyle for a healthcare worker not only impacts their employability in the long term (Hendriksen, Snoijer, de Kok, van Vilsteren, & Hofstetter, 2016), but also impacts the public's view on the healthcare institution, because the healthcare workers are assumed to 'know best' about the impact of lifestyle choices on long-term health. Both the issues of long-term health and the exemplary function of their work are well-known to healthcare workers, which is why many of them actively try to keep up good behaviour. An activity tracker is relevant for these workers, because it allows them to monitor their behaviour despite the changing hours and workload, and thereby supports these workers in becoming and staying healthy (Kalantari, 2017).

The use of sensor technologies to assist in sustainable employability hinges on offering workers objective feedback and interventions that allow them to self-regulate behaviour. Illustrative for the ideal of autonomy was a participant, self-identified as overweight and unfit, who was eager to experiment with an activity tracker. This activity tracker enabled her to receive automated digital feedback on her daily exercise behaviour. This worker was committed to improving her condition:



“I value a healthy lifestyle. I have difficulties keeping up with that for all sorts of reasons, and this is an opportunity for me to get some non-intrusive and time-saving support. I also would like to be an example for the patients who visit here. They need people like me as role models, people who struggle but make an effort to improve their health.”

She referred to her value of personal health. Receiving an activity tracker did not provide autonomy. However, due to the activity tracker, she could autonomously commit to her value of becoming healthy. This value had a different application in her work context, a healthcare organization, where she wanted to set an example for others. She wanted to show that increasing daily exercise by walking more and taking the stairs is an essential commitment to improving health. Thus, in the work context, the worker wanted to achieve a healthy lifestyle as well as provide the moral value of being an example. She translated the value of her health and her position at work into a daily practical commitment of taking more steps. Thus, the use of this sensor technology helped her to achieve her ideal.

Nevertheless, the commitment of the worker was not only shaped by a momentous decision to accept the activity tracker. Her commitment was confirmed by making some progress in walking more steps. However, it was disaffirmed when a colleague from higher management rebuked her for taking the elevator, saying that was not why she was given the activity tracker. This encounter made her question whether the entire experiment was about her improvement in health and realizing her values, or whether it was ultimately about organizational control and cost reduction.

8.4.2 | Context-specific approach to autonomy

This example, although an individual experience, illustrates how personal autonomy can easily be threatened in a work environment if personal values are not acknowledged. Giving workers a health device does not merely provide a means for self-regulation. Because the technology is embedded in a context that can promote or disavow the responsible commitment to the norms to which one is bound. This realization calls for reflection on how the introduction of technology can affect workers' autonomy, and how the context of the implemented technology influences the perceptions regarding workers' autonomy.

Worker autonomy as a prerequisite for health self-regulation was empirically investigated in the study of Bonvanie et al. (2020). It examined activity trackers that give feedback information on health-related behaviour to workers. The example of activity trackers is of interest because it is used as a technology that enables workers to self-regulate a healthy lifestyle (Bravata et al., 2007; Mattila et al., 2013). The underlying assumption was that the



use of digital health technologies provides workers with autonomy via feedback and the freedom to respond to self-regulate health-related behaviour. The findings revealed that the use of a sensor technology did not significantly increase perceived autonomy and may have even reduced autonomy under certain conditions, especially for less healthy workers (Bonvanie et al., 2020). Moreover, workers who had used an activity tracker to monitor their behaviour before they received an employer-provided device experienced the same decrease in autonomy as workers who used the activity tracker for the first time. This finding suggests that the activity tracker does not limit the autonomy of workers; instead, perceived autonomy may decrease due to the hierarchical relationship between workers and employers.

Kukla (2005) identified the idea of conscientious autonomy: autonomy that is committed to one's willed ideals as well as the norms and standards encountered in a particular setting that are adapted as normative (Kukla, 2005). Hence, one can determine why the autonomy of certain workers declines when using a sensor technology. The normative standards of the activity tracker that were applied were externally imposed. The goal was to walk 10 000 steps per day and take ten flights of stairs. Some participants agreed with this goal and internalized the normative standard. Others, however, did not and perceived the feedback as pressure to aim for 10 000 steps.

Moreover, the employer demonstrated a value for healthy workers. Before the experiment, several activities, such as a week of taking the stairs and a healthy cafeteria project, showed the values and norms of the employer. Participants who shared the same value of healthy living but had other ideas to implement it, felt as if the activity tracker forced them to commit to someone else's normative standards. Therefore, employers must be cautious when implementing sensor technologies in the workplace.

8.4.3 | Responsibilities of stakeholders

Similar to the case of the firefighters, the employer was responsible for the health of the health-care workers. In order to improve healthy behaviour, the employer initiated the workplace health promotion program. This blended program of physical and digital support focused on improving physical health of the workers by giving workers an activity tracker, offering a smoke-free property, promoting a week of taking the stairs, and providing a healthy cafeteria. Although the employer implemented methods to improve the workers' health, the study of Bonvanie and colleagues (2020) showed that this approach might have actually been counterproductive for workers of lesser health. Participation in the study and being able to discuss the impact of technologies with different stakeholders within the development process, thereby caused the employer to reconsider these workplace health



promotion policies. That is, the employer altered the strategy to include a more diverse group of workers in the decision-making process regarding new technologies, thereby aiming to facilitate a healthy workplace and lifestyle for all workers.

8.5 | Discussion

Previous literature on responsible research and innovation struggled with three major problems: (1) compartmentalization, (2) generalization, and (3) vagueness about responsibilities. Rather than developing a theoretical approach to these problems, we highlighted two cases in SPRINT@Work. We aimed at describing how we explored two critical ethical issues in the development and implementation of digital health technologies, privacy and autonomy in the setting of doing research and developing the technologies. A context-specific analysis of both values was employed, keeping in mind previous research and the legal context. For the firefighters case study, this analysis resulted in the description of an agency-based concept of privacy, where it is necessary to analyse and regulate what the agent can do with the private information obtained (Manson & O'Neill, 2007). For the case study of the health-care professionals, this resulted in a conscientious autonomy enhancing approach for the design and implementation of digital health technologies in the workplace. When this approach is employed, all stakeholders (with a specific emphasis on the user(s)) have to be actively involved in the design and implementation phase in order to achieve the intended goal of the technology, which is to enhance health-related behaviour (Kukla, 2005).

8.5.1 | Decompartmentalization of focus

These case studies show the necessity of including the tension between the intended and actual use in the development and implementation of a new technology. However, in the present, responsibilities regarding the assessment of risks of the new technology get indistinguishable when a transition between phases occurs (Jakobsen et al., 2019). More specifically, although the researchers might have reflected on the impact of the technology, after the development phase responsibilities shift towards the user or organizations that implement the technology. They do not necessarily reflect on possible ethical and societal risk, and primarily focus on productivity or increasing product acceptance (Chatfield, Borsella, Mantovani, Porcari, & Stahl, 2017; Leclercq-Vandelannoitte, 2017). In this study, the reflection on both design and field experiments involving health-related technologies in the workplace, caused the researchers to reflect on the interpretation and implications of the concepts of privacy and autonomy. This approach of integrating development and use was necessary to successfully implement techniques from the field of RRI, such as reflexivity



and responsiveness. The project allowed for a cyclic approach, using outcomes from early implementations of technologies as input for further development. As a result, we were able to take unforeseen ethical issues into consideration, because they appeared during use by end-users. This then allowed us to alter the technology or the choices that were made during development and implementation. In the case study of the firefighters, the balance between privacy and health was only reached because the researchers were able to use input from actual use, thereby improving the application of the core thermometer in the workplace, which consequently benefits the firefighters' health.

8.5.2 | Prevention of out-of-context generalization

A responsible decision to provide workers with sensor technologies to sustain their employability requires careful analysis of the values at stake (ten Have, van der Heide, Mackenbach, & de Beaufort, 2013) in the context of the specific workplace and the individual worker. The case studies showed that generalized ideas of privacy and autonomy were insufficient because these generalized ideas did not answer contextualized questions specific to the work environment. In contrast, concepts that guide reflection towards identifying what is at stake in a specific context are more helpful. Both the agency-based model of privacy (Manson & O'Neill, 2007) and the notion of conscientious autonomy (Kukla, 2005) provide a framework of what is at stake in a specific context. The cases of the firefighters and the healthcare professionals are illustrations of how these concepts help to identify bottlenecks, implicit norms, and courses of action. These examples are a source of moral knowledge, given that the experiences in the field informed the researchers about what users' value and the dynamics between the engineer, employer, and user were explored by testing the conceptualization of ethical principles in the work environment and further adjusted as deemed necessary.

In case of privacy, the GDPR offers a basic framework for the implementation of protection measures, while it also leaves room for interpretation and discussion. The GDPR (2016) obligates and ensures that the decisions regarding data protection taken by the controller, for instance an engineer or a researcher, are taken with great care, especially when *"processing of the data could result in high risk to the rights and freedoms of natural persons"* (GDPR, 2016, sec. 35 (3)). In order to help the controller, make responsible decisions regarding privacy of individuals, the data protection impact assessment (DPIA) (Bieker, Friedewald, Hansen, Obersteller, & Rost, 2016) is developed as a risk assessment method. This includes a multiple stakeholder approach during which privacy risks are identified. During meetings with stakeholders, a context-specific method of privacy by design is applied to design protection measures that are appropriate for a specific context.



Similar to the DPIA, the current study used a context-specific approach of ethics to assess privacy and autonomy concerns in the workplace. Both approaches are reiterative and need to be performed again when the context or risks change. Even though the DPIA builds upon the same principles as the context-specific approach of doing ethics, the DPIA's (and the GDPR's) main focus is to protect the privacy of the user without including other ethical issues in its analysis. Although it is a step in the right direction, in the development of new digital health technologies other values, such as health, autonomy and responsibility, and the interplay between these values need to be reflected upon as well.

8.5.3 | Making implied responsibilities explicit

The two core ethical concepts of privacy and autonomy contribute to identifying responsibilities. Both cases demonstrated that engineers and researchers of digital health technologies for the workplace must reflect explicitly on the critical ethical principles of what they design as well as the implications of these principles in implementation and use of the design. A commitment to ensuring privacy as described in the context of this multidisciplinary project gave the team the responsibility to design an agency-based handling of data.

Acting responsibly regarding health in the workplace is considered important (van Berkel et al., 2014) but employers experience difficulties taking their responsibility, and in the case of health promoting technologies in the workplace, other stakeholders find it difficult to share this responsibility. Leclercq-Vandelannoitte (2017), in a study about the use of ubiquitous technologies in the workplace, observed that *"despite their prevalence and the importance of their consequences for workers, neither salespeople nor managers seem to be aware of them, feel responsible for them, or appear able or willing to identify the responsibilities involved in this process"*. In the case of workplace health promoting technologies, responsibility involves multiple stakeholders with a prominent role for the employers (Palm, 2009), engineers (Doorn, 2012) and researchers (Doorn & van de Poel, 2012; La Fors, Custers, & Keymolen, 2019). To protect the privacy of workers while gathering personal data, all stakeholders need to take their responsibility for the use of the involved technology (Johnson & Powers, 2005).

The engineers have the responsibility to design the technology in such a way that it guarantees the privacy of the user and supports the user in his/her ability to react autonomously (Robaey, Spruit, & van de Poel, 2018; van de Poel & Verbeek, 2006; Verbeek, 2011). However, engineers often do not offer sufficient insight into what constitutes a responsible use of their designs (Leclercq-Vandelannoitte, 2017). Technologies are never value neutral (Martin & Freeman, 2004), and it is important that researchers and engineers



explore how the development and implementation of their technologies influence and mould the ethical values such as privacy, but also the autonomy of employers and workers and help them reflect on this explorative process (Robaey et al., 2018; van de Poel & Verbeek, 2006; Verbeek, 2011). The responsibility of engineers and/or researchers should focus on perspectives such as value-sensitive design, critical technical practice, reflective design, and values in design (Cummings, 2006; Shilton, 2013).

The ethical responsibilities inherent to the designs should be identified and based on value-sensitive design, critical technical practice, reflective design, and values in design, and should always be included in designing and implementing technologies (Jing & Doorn, 2019). However, ethical concerns arise as soon as technological innovations are introduced into the workplace (Martin & Freeman, 2004), and although an ethical script of an innovation shows what the default choices regarding privacy, responsibility and autonomy are. At the same time, the reaction of the environment on this built-in ethical script plays a significant role. The ethical script is mainly developed by the engineers and researchers who develop the technological intervention, but the response of the employer on this ethical script largely determines the privacy of workers and their possibility to exercise autonomy in the workplace. The case studies thereby add an interesting view on the responsible research and innovation of health-related technologies to be used in the workplace and gives employers more hands-on advice on how to responsibly implement these technologies.

The reflection on the responsibility of workers and employers is not a one-time action. As stated before, differences in interpretations of responsibilities can cause significant problems between workers and employers (van Berkel et al., 2014), and the use of technology often alters the original function (Kiran, 2012). When using new technologies, workers and employers should discuss the responsibilities and intended actions of these technologies with the designers. This discussion should also entail the continuous reflection of the employer, to determine whether the conscientious autonomy of the worker has improved: In the case of the healthcare professionals, sensor technologies enabled workers to take responsibility to target work-related health parameters within the workplace. In general, however, these technologies are most effective when workers feel autonomous to self-regulate health-relevant actions (Bonvanie et al., 2020). Thus, employers should be alert for non-intended effects of sensor technologies and ensure an environment that facilitates workers to take their responsibility. When workers and employers share values, such as health, technologies that support the workers' personal goals could increase a sense of conscientious autonomy, thereby improving the self-regulation of healthy behaviour.



8.5.4 | Call for an adaptive tool

Laws and regulations aim to offer protection to users of new technologies, but tend to focus on data access and privacy, thereby leaving out other values, such as responsibility and autonomy, that are in close interplay with privacy (GDPR, 2016). It is therefore important that engineers and researchers themselves consider how the design and implementation of their technologies influence and mould the values of the users and adapt their technologies, to protect the user from harm, but also to increase the acceptance. Multiple tools are available, but there is a need for a practical tool that is formed by looking at the various practices in which one can involve all those stakeholders and learn from those lessons instead of having to keep reinventing the wheel. An adaptive tool which helps guide them in the assessment of the interplay between values inherent in the design and implementation of new technologies are lacking. This tool must automatically lead to the information you need in your own deliberation process. In order to be able to develop this adaptive tool or guideline, more multidisciplinary teams involved in innovation practices should publish their way of doing ethics (Fisher et al., 2015).

8.6 | Conclusions

This study aimed to create more awareness of the importance of context-specific ethics in design and implementation of digital health technologies. Focusing on a contextual conceptualization of the core ethical principles in the design and implementation of digital health technologies helps to avoid compartmentalization, out-of-context generalization, and neglect of identifying responsibilities. Although it is a long reiterative process in which all stakeholders need to be included in order to assess all critical ethical issues sufficiently, this process is crucial for achieving the intended goal of a technology. There is a need for a practical and adaptive tool or guideline that helps engineers, researchers and other stakeholders to address these ethical issues. This study contributes to the development of such a tool by giving an elaborate description of our approach and techniques, but is not directly applicable to similar projects. Such an adaptive tool, however, can only be developed if multiple research teams describe and publish their approaches and techniques used to solve their ethical issues.



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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.



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Chapter 9

General discussion

9.1 | Aim and evaluation of main findings

The overarching aim of this dissertation was to contribute to a sustainable workforce by making the (mis)balance between workload and work capacity measurable with sensor technologies. To realize this, the first step was designing and testing sensor technologies to make workload and capacity measurable and secondly to measure the balance between workload and capacity. Then, by utilizing data gained from sensor technologies, appropriate interventions can be made to align physical workload and individual work capacity more closely for each worker. This strategy was applicable to all kinds of workers. Throughout this dissertation, the focus was on monitoring (1) the mechanical workload, (2) the energetic workload, and (3) the reaction to heat exposure of physically active and/or office workers.

9.1.1 | Physically active workers

For physically active workers, the main problems include an unfavourable working posture, heat exposure, and physical fatigue due to a high physical workload (Spook, et al., 2019; Andersen, et al., 2016). The following monitoring technologies were designed and/or studied:

- a sensor suit to monitor working postures and movements, muscle activity and automatically estimating the internal mechanical workload (Chapter 3);
- a headset which analyses breathing gas to monitor internal energetic workload (Chapters 4 and 5);
- a wearable body thermometer to monitor the internal reaction to external heat exposure (Chapter 6 and 7).

With a sensor suit of inertial magnetic measurement units and an artificial neural network (ANN), the working posture and movements and muscle activity was measured, and the related low back load was estimated. Different intensity and variation levels of the moment in lumbar load exposure could be distinguished with this method between light and heavy tasks as well as between static and dynamic tasks. It was concluded that the sensor system and ANN indeed showed differences in the physical load exposure in the lumbar region consistent with the perceived intensity levels and character of the work task. This study showed the validity of this monitoring system for physically demanding occupations.

A portable headset has been developed to analyse breathing gases and determine the energetic workload of physically active workers. A proof-of-concept experiment confirmed the headset's results and showed that it was more valid compared to oxygen consumption estimated on the basis of heart rate. The headset was found to be comfortable, presented a low breathing resistance, and did not hinder communication. The headset provides a



compromise between the cumbersome mouth mask and the relatively inaccurate heartrate monitoring. The present version is not yet completely validated, but its potential is supported and indicates opportunities for further professionalization.

A wearable thermometer was studied to monitor body temperature and heat strain of physically active workers. First, the thermometer was validated against the medical standard, an ear canal temperature reading. Without correction, the wearable was not accurate. With a correction factor applied, however, the accuracy of the thermometers was confirmed at rest, but not during working conditions. The Cosinuss° thermometer was comfortable and interfered minimally (or not at all) during work. Second, the thermometer was validated against the scientific standard, an invasive temperature pill. The validity of the thermometer was not confirmed in this scenario, and thus this wearable thermometer is an invalid method for measuring the core temperature of firefighters when in working conditions. However, if the reliability of the thermometer can be improved, it could play a role in predicting core temperature and heat storage as part of a multivariable system.

9.1.2 | Office workers

For office workers, the main problem is an unfavourable working posture causing too high or too low local physical loads on the body due to inactivity. The working posture and duration, and perceived musculoskeletal discomfort were monitored with a 'smart' sensor chair (Chapter 2). The intervention of the sensor chair was a tactile feedback signal given to the worker whenever prolonged working in an unfavourable posture was detected. Although this feedback signal led to small or insignificant changes, insight into individual reactions to workplace health promoting feedback was provided. And this chair proved to be a useful tool to monitor sitting behaviour in the workplace in a non-obstructive manner.

9.2 | Relevance

The potential value of this dissertation is that the summarization of data surrounding sensor technologies in the workplace will help to realise a sustainable workforce in the future (Kadir, et al., 2019; Warmelink, et al., 2020; Waschull, et al., 2020; Papagiannidis & Arikyan, 2020; Edirisinghe, 2019; Kuruganti, 2019; Ullrich, et al., 2019). The useful results of this research were achieved by (1) the collaboration with specialists of different fields of expertise and (2) an in-depth needs assessment as a basis for the personalized and user-driven designs. Additional strengths of this dissertation are (3) a diversity of focus areas within aspects of physical workload, (4) the focus on individual responses instead of a group



focus, and (5) the discovery of the ethical agenda related to the design and implementation of sensor technologies.

This dissertation offers a broad analysis of the needs and applications of sensor technologies in the workplace. These newly designed technologies range from scratch up to the application of commercially available technologies. A strength is their validation in a variety of workplaces (Havenith & Heus, 2004) or, if not yet suitable, under lab conditions. The studies discussed herein helped to gain useful insight into the usability and implementation of the systems and provided user-centred input to optimize the technologies.

These health-promoting technologies in the workplace will help to lower the workload if needed and may improve the workability and safety of workers (Lee, et al., 2020; Yang & Ahn, 2019; Bowen, et al., 2019). Several of the presented technologies can already contribute to monitor the workload and work capacity and assess the individual physiological response to the workload.

All four technologies show potential to objectively monitor individual response to the workload. By combining these technologies, individual internal load, physiological responses to heat exposure, energetic strain, and mechanical strain can be investigated per individual. Based on the output of these technologies, the tasks or working conditions can be adjusted, or interventions can be designed to align the mechanical and energetic load to prevent structural overload, discomfort or disability, and other health problems (Panel on Musculoskeletal Disorders and the Workplace, et al. 2001). They can vary from simple feedback (Punt, et al., 2019) provided via a smartphone or smartwatch to exoskeletons that take over a part of the workload.

The acceptance of the sensor and intervention technologies into the workplace is a very important criterion for success. These are discussed as follows. First, evidence about the technologies to objectively measure has been proven. Second, the technologies could contribute positively to the safety of the workplace and workers. Third, it has been explored if the workplace offers workers a positive and safe climate to act autonomously (Jacobs, et al., 2019; Palm, 2009; Johnson & Powers, 2005). In addition, the first steps for ethical implementation were provided.

The presented sensor and intervention technologies are widely applicable. Aside from monitoring work-related factors, they could be utilized in health care for prevention of illness or a fallback after rehabilitation therapy and could also be used in sports training. These wearable and non-invasive technologies could contribute to diagnostics and



treatment that ultimately improve the quality of health care through (remote) monitoring (Patel, et al., 2012).

9.3 | Evidence of devices

The different kinds of technologies that have been designed fulfil the goals set at the start of this study.

- They monitor individual physiological responses to the workload in an objective manner according to the models in Figures 1.1 and 1.2 (Chapter 1) (Panel on Musculoskeletal Disorders and the Workplace, et al., 2001; Heerkens, et al., 2004).
- Physically demanding occupations can be monitored as well as office workers.
- Workers can be monitored over long periods of time instead of only in snapshots.

The sensor technologies investigated in this dissertation fulfil the requirements of workers and employers.

- The devices provide information about the individual physiological response to the workload.
- The devices do not interfere with workability and are safe in use.
- The devices are non-obstructive and easy-to-use.
- Except for the sensor chair, the devices are wearable.
- The devices can monitor a broad range of workers.

In terms of Technology Readiness Level (TRL) (Straub, 2015; Altunok & Cakmak, 2010) the following levels have been realized.

- The breathing gas-analysing headset started with a concept (proof-of-principle; TRL 2). After analytical and experimental examination of the critical function and the development of a proof-of-concept (TRL 3), the technology was validated in a lab study (TRL 4).
- The studies about the wearable thermometer started with the development of proof-of-principle (TRL 2) and proof-of-concept (TRL 3). The technologies were validated in lab studies (TRL 4) and in real-life working conditions (TRL 5 and 6).
- The sensor suit and ANN-based method started with a basic validation was performed in lab environment (TRL 4). Then, the technology was validated in the real-life working environment (TRL 5) and the function of the technology was demonstrated (TRL 6).



- The office chair was validated in an operational environment demonstrating its functioning (TRL 7). For monitoring sitting behaviour, its function was demonstrated (TRL 8) and its technological development is currently complete (TRL 9).

9.4 | Further testing

It is uncertain if all requirements will be met by all technologies that are designed. Thus, further testing is required. Future research needs to focus on the validity, reliability, and usability of these technologies for their purpose as objective monitoring tools.

9.4.1 | Breathing-gases analysis

The proof-of-concept experiment of the breathing gas-analysing headset showed that the usability of the headset is promising (Chapter 5). To further study the validity and usability, the professionalized prototype should be studied in real-life working conditions (Havenith & Heus, 2004) among different types of physically active (and office) workers. To go from the lab studies (TRL 4) to validation in real-life working conditions (TRL 5), the proof-of-concept needs to be optimized into a prototype for validation in the field.

9.4.2 | Heat stress

After validation in lab studies (TRL 4) and real-life working conditions (TRL 5 and 6), the thermometer did not work properly and the technology concept need to be reformulated (TRL 2). The wearable thermometer needs to be optimized to increase the accuracy of the predicted heat stress in an objective manner. A reliable instrument capable of predicting core temperature instead of measuring tympanic or aural temperature is preferred. An alternative is the extension of the non-invasive thermometer to a multiparameter system. This would increase the validity and reliability to objectively predict core temperature and heat stress during physically active work. New research and developments (Kim, 2018; Apykhtin, et al., 2018; Diaz-Piedra, et al., 2019; Chaglla, et al., 2018) should investigate the potential of such a multiparameter system. Also, individual differences in the development of heat stress should be taken into account. For workers using communicating systems, the wearable thermometer needs to be integrated with hearing protection and/or communication systems.

9.4.3 | Working posture and lumbar load exposure

The sensor suit and ANN-based method started with a basic validation was performed in lab environment (TRL 4) (Baten et al., 2008-2018) and validation among the real-life working environments of the users (TRL 5). Thus, the function of the technology was demonstrated



(TRL 6). However, the current system is not yet usable in the uncontrolled real-life working conditions. Large amount of data could not be analysed due to data-acquisition error during essential trials (Chapter 3). And the mechanical design of the system needs to be improved by integrating the sensors in the work clothes. So, the sensor system and software require further development into a prototype. This prototype must be usable in working conditions to allow validating the system in an operational working environment (TRL 7).

9.4.4 | Sitting behaviour

The function of monitoring sitting behaviour with the sensor chair has been demonstrated (TRL 9). The intervening feedback signal requires additional investigation and development to move from the theoretical basis (TRL 4) to a demonstrated working feedback signal (TRL 9).

9.5 | Further developments

Some requirements are not met yet. More research and design are required to fulfil the following open standing requirements and needs of the workers and employers.

9.5.1 | Feedback and behavioural awareness

Workers want to become aware about their own working behaviour (Patel, et al., 2012) and would like to receive personalized real-time feedback (Spook, et al., 2019). Like the smart chair, all monitoring technologies should be equipped with a feedback system. More research is needed to optimize and develop new feedback systems regarding how they can be linked to ergonomic guidelines and signalled to the worker in an easy-to-use yet meaningful manner (Spook, et al., 2019). This should make the workers aware of their working behaviour and offer them an opportunity to improve their behaviour if needed. This can only be achieved by interdisciplinary collaborations with behaviour-change specialists, among others.

9.5.2 | Interventions

The design and investigation of interventions are underexposed in the dissertation. To realise a sustainable workforce, interventions need to be designed, tested, and their results should be studied. Intervention technologies could play an interesting role in supporting the worker and lowering the relative workload. Currently, an exoskeleton for surgeons, or for physically active workers, is being designed. This exoskeleton is intended to lower the back and neck load of workers. For physically underexposed workers, interventions that increase the amount of physical activity need to be explored. The focus should mainly be on how a



long-lasting effect can be created. In addition, it would be interesting to investigate how this can be achieved without interfering with the private life (e.g. offering time to exercise during working hours) (Dutta, et al., 2019; Sui, et al., 2019; Bergman, et al., 2018). This could potentially improve the capacity and the workability of workers in physically demanding occupations, as well as office workers. These interventions need to be explored and the effects investigated.

9.5.3 | Data sharing

One of the requirements was that these technologies should help the workers to open a dialogue about workplace improvements (Spook, et al., 2019). The realization of a toolbox and the role of an occupational physician (Chapter 8) are important to fulfil this requirement. The future perspective is the realization of a toolbox that combines multiple sensor and intervention technologies and provides a low-level overarching feedback to the worker. The toolbox analyses the flow of big data and could finally draw conclusions using self-learning decision support systems. This decision support system can combine or summarize information from specific jobs or worker groups instead of individuals to improve the working conditions. The occupational physician could take a role in the protection of the personal data of the workers. This toolbox with workplace health promoting technologies offers a chance to open a dialogue between workers and employers about workplace improvements.

9.6 | Limitations

9.6.1 | Monitoring physical workload

The main limitation is that the workload of workers during prolonged performance of their job has not yet been investigated. In this dissertation, the focus is on the development and validation of sensor and intervention technologies to monitor balance between workload and capacity. The technologies are not yet implemented for a longer period of time to correct the balance between workload and capacity. Still, this is important to do and based on these results there needs to be additional exploration into how interventions and workplaces can be improved.

9.6.2 | Combining work-related aspects

Another limitation is the focus on only three physical aspects: posture and its related back load, energetic workload, and heat stress. To gain a more complete overview, more physical aspects need to be explored and investigated, including musculoskeletal disorders in the knees, neck and shoulders, repetitive movement of small muscles groups such as for moving



the wrist, hands and fingers, and effects of lifting and carrying. Additionally, relations between the physical, cognitive, and social work-related aspects of a job have not been explored; cognitive workload and other social aspects are not taken into consideration with these sensor technologies and interventions. Studies in this area would yield interesting information about how they are related and interact with each other, providing opportunities to solve bottlenecks more efficiently.

9.6.3 | Motivation

An observed limitation is that workers were not motivated actively to use the sensor and intervention technology. As a result, a wide range of responses of the workers to the use of the technologies was observed. Firstly, there was much diversity in the response to the interventions provided. This was particularly visible when investigating the effect of intervention of the sensor chair (Chapter 2). The subjects reacted differently to the intervening feedback signal, which was a short vibration in the seat. Some workers did improve their behaviour by reacting to the signal, but most did not respond to the signal at all and some responded for only a short period of time. These individual responses and their motivations need to be investigated in more detail (Vaughan-Johnston & Jacobson, 2020; Hermsen, et al., 2016; van der Lei, 2002), need to be taken into account when developing motivational feedback and interventions (Vaughan-Johnston & Jacobson, 2020; Hermsen, et al., 2016; van der Lei, 2002) and would help to improve the worker conscientious autonomy (Chapter 8). Second, most workers understand the advantages of these technologies and would like to use them as soon as possible. However, other workers react with resistance or complete rejection of the technologies. They create the feeling of the worker being monitored by the employer (Choi, et al., 2017; Jacobs, 2019), despite the advantages of these technologies and the worker's desire for such improvements (Spook, et al., 2019). The method of implementation is important for the acceptance of the technology, especially among workers. Workers as well as employers should be informed in an individually stimulating way.

9.7 | Lesson learned

9.7.1 | Gold standards of references

A major challenge was the selection of a reference method for all newly developed sensor systems. Not all research topics have a gold standard (as discussed in Chapter 2). Even if there is a standard, it is often not the “gold standard”, meaning it is not universally accepted (as discussed in Chapters 6 and 7). Moreover, in some cases (Chapters 6 and 7) there is a difference between the clinical and scientific standard, or the gold standards are not always



applicable to in real-life working conditions (as in Chapter 2) or rather are impractical or inappropriate (Saurabh, et al., 2014) (as in Chapter 6 and 7). This indicates the urge for alignment.

9.7.2 | Accuracy vs usability

Despite the importance of the validity and reliability of systems, these studies revealed that usability and safety are also important success factors. A technology can have a high accuracy but is unusable if it is not applicable in real-life working conditions. For example, despite its high accuracy, the mouth mask cannot be used in the workplace because it hinders communication. The breathing gas-analysing headset that has been developed does not have this drawback. Requirements of accuracy and applicability are difficult to meet in both scenarios. The breath-analysing headset is less accurate than the mouth mask version, but its applicability in real-life situations is much better because it measures in a non-obstructive and safe manner. The challenging part is finding the proper balance of accuracy and usability for each implementation scenario.

9.7.3 | Consumer health technologies

The increasing amount of commercially available health technologies is challenging. More devices become available on the market to self-monitor health parameters. Most consumer wearables are not validated (Peake, et al., 2018) and thus are not accurate enough for scientific or medical research. Still, for scientific and medical research, these self-monitoring wearables could be very useful when validated (Patel, et al., 2012). They could be used for remote monitoring of (work) behaviour or the development of health decline or diseases. Depending on the aims and proposes of the technologies, validation is of major importance (Peake, et al., 2018). These consumer health technologies could contribute to behaviour awareness, show trends to the users and provided that they achieve the minimum levels of accuracy, reliability, and usability.

9.7.4 | Human sensory system

Another challenging aspect is the human sensory system. Sensor technologies should support the worker but cannot take over the human sensory system. As stated by Christian Lous Lange *“Technology is a useful servant but a dangerous master”* (Lange, 1921). The technologies may not overrule the human sensory system, as experience and feelings and must be used as means to support the workers’ performance.

9.7.5 | Older vs younger worker

The health problems faced by the older workers in physically demanding occupations will be different compared to those among younger workers. Older workers often experience



problems as the result of working from a young age and under physically harsh conditions. In the last 50 years, many working conditions have been majorly (ergonomically) improved, resulting in lower physical workloads. Still, there are major variations in working conditions between companies and jobs. Much can be improved to optimize the workload for the body. However, it should be noted that physically demanding jobs are not necessarily unhealthy. Office workers who are physically underloaded may experience health problems due to inactivity. Sensor technologies should make the workers aware of their behaviour and should support them to find the healthiest balance for them (Wu & Wang, 2002; Kenny, et al., 2008).

9.7.6 | Ethics of technologies

Workers need to be able to respond autonomously and voluntarily to the use of workplace health-promoting technologies (Chapter 8). During the design and implementation of these technologies, the focus must not only be on user-centred design, but the ethical agenda also needs to be taken into account. The design and implementation of sensor and intervention technologies raises complex unanswered moral questions. One of them is the responsibility of the employers and other social actors, and how to handle and exercise autonomy at work (Six Dijkstra, et al., 2020). Protecting the privacy and autonomy of workers cannot be seen as stand-alone issues, but as an interplay between these values, the work context, and the responsibilities of the stakeholders. These ethical considerations need to be encountered when developing workplace health-promoting technologies, and awareness of the responsibilities of all stakeholders (including workers, employees, engineers and scientists) requires full attention. Focusing on a contextual conceptualization of the core ethical principles in the design and implementation of technologies helps to avoid compartmentalization, out-of-context generalization, and neglect of identifying responsibilities. Although it is a long iterative process in which all stakeholders need to be included in order to assess all critical ethical issues sufficiently, this process is crucial for achieving the intended goal of a technology.

9.7.7 | Interdisciplinary teams

Another lesson learned was the challenging interdisciplinary character of this project. Although the aims and goals were aligned, each discipline had its own experiences, interests, working culture, definitions, and time schedule. In order to optimize progress, it is important to align goals and expectations as detailed and as soon as possible, preferably before the start of any interdisciplinary project. This should be done not only among research disciplines, but with the whole consortium, including any involved companies.



9.7.8 | Science vs design

There is a lack of objective monitoring technologies (Netten, et al., 2011; Patel, et al., 2012; Peake, et al., 2018; Maman, et al., 2017; Vandermissen, et al., 2014; Takala, et al., 2010; Kuijper & Frings-Dresen, 2004; Verschoof, et al., 2005; Boa, et al., 2004; Aryal, et al., 2017; Pancardo, et al., 2015; Mazgoaker, et al., 2017). Product design is time-consuming which resulted in less time for scientific research and a lack of time to validate the technologies in operational working environments (TRL7). This would have provided interesting input about the uncontrolled use of these technologies and multiple work-related research topics. This is not only scientifically interesting but would also have provided interesting input about context specific issues and the optimization of the technologies. Finding the balance between science and design is a challenge. No science can exist without design, and design has no basis without science (Verkerke, et al., 2013).

9.7.9 | Reality of research

Multiple work-related aspects were covered within the SPRINT@Work project (Appendix I). More relations between physical, cognitive, and social work-related aspects could have been explored. Several interdisciplinary collaborations succeeded (de Jong, et al., 2018), as within the sensor chair study (Chapter 2) where Occupational Health investigated user experiences surrounding the implementation of sensor technologies in the workplace (Spook, et al., 2019). A portion of the study attempted to find a relation between sitting (Chapter 2) and typing behaviour as a parameter related to mental fatigue (de Jong, et al., 2018). However, the software was not working correctly during this study and the data was not usable. As is usual in research, unexpected events occur. This is the reality of research and errors such as this occur in every (interdisciplinary) project, and thus should be taken into account in the planning of the project. For this reason, the project requires a flexible and open-minded attitude of the team members.

9.8 | Future challenges

9.8.1 | Longitudinal studies

In this dissertation, multiple sensor and intervention technologies were designed (and not even all designs have reached this dissertation), explored, and studied. This dissertation stops with the validation in lab or field studies. These technologies are designed to be used to monitor (im)balances between capacity and workload. After validating each system as an objective monitoring device, these technologies can be utilized for research. The bottlenecks discovered from literature and the needs assessment (Spook, et al., 2019) can



be further investigated for solutions. An important research topic is investigating how an imbalance between workload and a worker's capacity can be prevented or solved. Therefore, subjects must be monitored in longitudinal repeated measures. Physically active workers could wear the sensor suit, headset, and core thermometer. For office workers the sensor chair and headset could be used. The workload and the internal response to this external load can be monitored and individual differences should be investigated. Based on these outcomes, interventions to adjust the workload or improve the capacity can be explored, and a healthier balance for the worker can be achieved.

9.8.2 | Awareness among stakeholders

Along with ethical considerations, awareness among and the responsibility of all stakeholders is a future challenge. In specific situations, stakeholders may not always be aware of the impact or consequences of implementing workplace health-promoting technologies, like in the case of heat stress. The stakeholders are not aware of the consequences due to a lack of knowledge about heat stress. The consequences on the workers' health are less visible in early stages and become much more severe in a later stage. To prevent health declines, workers, employers, and occupational medical staff need to recognize heat stress incidents. Next, it is important to improve the registration of heat stress incidents in the workplace (Willems, et al., 2018). Lastly, information about the diagnosis and the consequences of heat stress needs to be commonly known among all stakeholders. With these preventative measures alongside monitoring technologies, stakeholders should gain awareness of frequent and prolonged exposure to heat and to accept their responsibility in protecting workers.

9.8.3 | Personal factors

These sensor and intervention technologies focus on monitoring and optimizing the workload and work conditions. The personal factors (Figure 1.1 of Chapter 1) were not investigated due to the explorative scope of the studies. The balance between work and the private life of workers is a challenging topic. Personal factors such as lifestyle and health influence the capacity and workability of the worker (Wu & Wang, 2002). This results in work and private life becoming intertwined (van Berkel, et al., 2014) and raises ethical questions when considering scientific methods to analyse this relationship. Scientifically, it is relevant to gain a complete overview of the worker's capacity and (work)load (Varianou-Mikellidou, et al., 2019; Wu & Wang, 2002). To restore the balance between capacity and workload, lowering the workload alone might not be a solution. Instead, the worker could adjust their physical activity outside of the workplace, or the worker's capacity could be improved. The capacity could, in some cases, be improved by adjusting the lifestyle to



include more exercise, healthier food consumption, and even by limiting alcohol and tobacco intake. Companies can provide incentive to the workers by making the healthy choice an easier choice. This could also influence the lifestyle of the worker's family and thus positively affect more people than directly involved.

9.8.5 | Motivational feedback

Every worker has their own character and thus responds uniquely to feedback and motivations. The differences in individual responses are very relevant to investigate and are important to gain a remaining effect (Vaughan-Johnston & Jacobson, 2020). Additionally, the dosage of the intervention needs to be explored (Hermsen, et al., 2016; Delgadillo, et al., 2017). This information will result in knowledge regarding which type of feedback for which workers is effective, motivates the workers, and creates a long-lasting effect (Hermsen, et al., 2016; Hassan, et al., 2019; Burgers, et al., 2015). This personalized feedback should create awareness and motivate the worker to improve their working behaviour.

9.8.6 | Meaningful data

To be able to provide feedback, it is important to not just gather and present data but rather to convert it directly into a meaningful output. With an increasing flow of data, there is much information to be explored. This is challenging because combining data and drawing conclusions is still uncharted territory. Self-learning decision support systems were underexposed in this dissertation, although they are essential to combine the signals of the various sensors and derive conclusions regarding the risk factor of each worker, and which intervention can lower this risk. The decision support system will become successful if it supports the worker by making them aware of their behaviour, help the worker to interpret the data available to them and make appropriate decisions, and contributes towards successful implementation and motivation for long-term use (Spook, et al., 2019; Burgers, et al., 2015).

9.8.7 | From design to market-ready product

It is important that these workplace health-promoting technologies designed within a scientific context become market-ready products. They should become available so that workers can take advantage of the benefits they can offer. Therefore, collaborations with companies specialized in this field should be sought after. This will increase the quality of the technology and provide opportunities to put this product on the market. Currently, the proof-of-concept of the breathing gas-analysing headset is being improved into a professional prototype. This is being completed via a collaboration with a company specialized in the development of breathing gas-analysers. All designed, validated, and



reliable technologies need to be made available for the audience and optimized into a market-ready product.

9.9 | Future perspective

The life expectancy is rapidly increasing and the European population of those older than 65 years is expected to be doubled by 2060 (Koolhaas, et al., 2009; Gotmark, et al., 2018). However, the number of expected “healthy” years does not follow the same trend. Therefore in the future, a sustainable and healthy workforce will become even more and more important. More research about healthy ageing needs to be completed so that and technologies can be developed to play a more dominant role in preventing health problems.

In the future, the workplace will become smarter (Papagiannidis & Arikyan, 2020; Edirisinghe, 2019; Bootsman, et al., 2019) with the implementation of automation, internet of things, big data, artificial intelligence, and decision support systems. Mobile and wearable technologies to make humans and their equipment measurable will be critical to maintain a stable workforce and economy. Wearable technologies will be integrated in the workplace and clothing to monitor the workload continuously and in real-time (Lee, et al., 2020; Yang & Ahn, 2019; Bowen, et al., 2019).

For workers in physically demanding occupations, the technologies will focus on lowering the load on the body. Exoskeletons to support the worker and lower the workload will surely play a dominant role within many organizations. For office workers, the main challenge will remain to be achieving a balance between physical and mental load. Physical inactivity will increase and needs to be prevented or compensated for in order to prevent health problems. The 24-hours society will increase the required of technologies for remote working and wearable health promoting technologies. The human-device interaction will become more and more important, as well as the workers ability to act autonomously and the prevention of overstimulation with information.

9.10 | Conclusion

This dissertation presented new measuring systems to determine the physical workload of workers and their physiological responses in an objective, non-obstructive, and safe manner. The smart chair was useful for office workers to monitor sitting behaviour in the workplace. The validity of the sensor suit and ANN-based method for measuring working postures, movements and its related mechanical workload for physically demanding



occupations was supported. However, the usability requires improvements. The breathing gas-analysing headset to measure internal physiological responses was not yet completely validated, but its potential was supported and indicates opportunities for further professionalization and use in physically demanding occupations. The validity of the wearable, non-invasive core thermometer measuring the internal response was not confirmed but showed potential to predicting core temperature and heat storage as part of a multivariable system. Ultimately, these systems should assist the worker to achieve a balance between workload and the worker's capacity. After final design and validation steps, these sensor technologies are ready to be used to contribute to the realisation of a sustainable workforce.



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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 \geq 0.72, $p\leq$ 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 $\pm 0.2^\circ\text{C}$ 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 $0.2 \pm 0.1^{\circ}\text{C}$ ($p < 0.001$), compared to the Cosinuss[°] was $-0.44 \pm 0.19^{\circ}\text{C}$ ($p < 0.001$) and compared to tympanic IR was $-0.2 \pm 0.1^{\circ}\text{C}$. 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° and tympanic IR versus mercury thermometer: The CORTES2, Cosinuss° 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).

	MD±SD [95% CI]	P	ICC [95% CI]	p	LoA
CORTES2	0.22±0.11 [0.03;0.15]	<0.001	0.99 [0.57;1.00]	<0.001	±0.22
Cosinuss°	-0.44±0.19 [-0.56;-0.32]	<0.001	0.97 [0.13;1.00]	<0.001	±0.37
Tympanic IR	-0.21±0.13 [-0.29;-0.14]	<0.001	0.99 [0.87;1.007]	<0.001	±0.24

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 CORTES², Cosinuss° and tympanic IR are shown. Sensitivity analysis revealed non-significant differences.

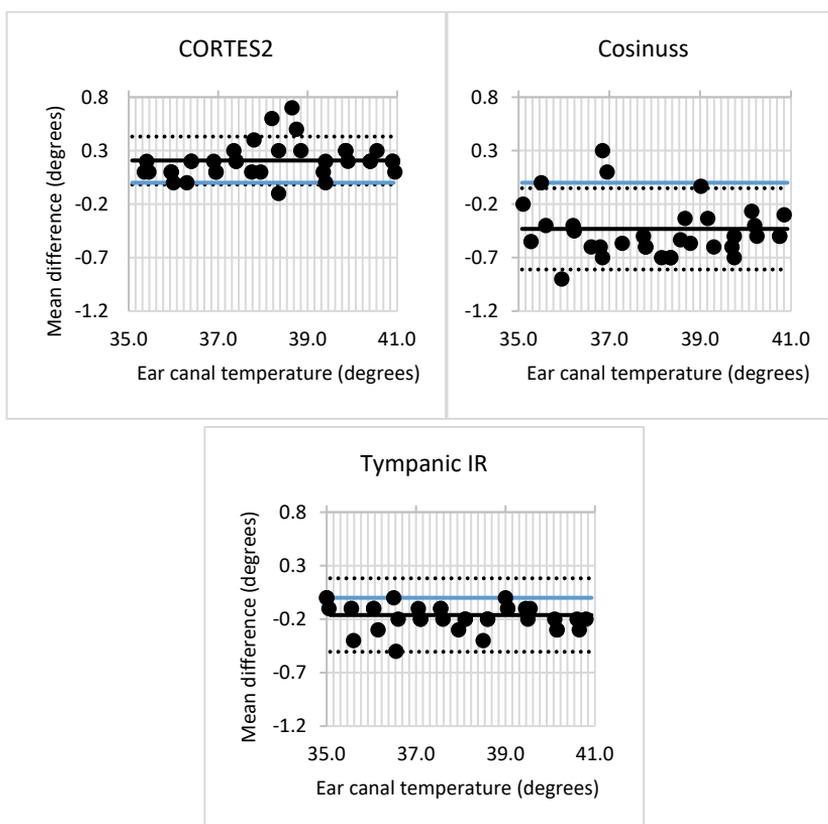


Figure I.2 | Bland-Altman plots of the mean temperature versus the mean temperature difference; CORTES² (left-side), Cosinuss° C-med (middle) and tympanic infra-red (IR) (right-side) thermometer with mean (black), upper and lower Limit of Agreement (LoA) (black dotted line) and zero-line (blue).



1.3.2 | In-vivo validity

The mean of the $CORTES^2$ was $36.7 \pm 1.2^\circ\text{C}$ (mean \pm SD) with a within-participants variation of $0.09 \pm 0.08^\circ\text{C}$. The mean calibration factor of the $CORTES^2$ was $0.0 \pm 1.1^\circ\text{C}$ (min= -1.7°C , max= 1.5°C). In Table 1.2, the mean differences and the results of the ICC analysis for the non-corrected and corrected $CORTES^2$ and Cosinuss° are shown.

The mean differences of the $CORTES^2$ are within the acceptable limit (MD= -0.1 , $p \leq 0.764$). Before calibration, a low correlation ($\text{ICC} \leq 0.20$) was observed. After calibration, high correlations ($\text{ICC} \geq 0.72$) were observed with an acceptable LoA (LoA= ± 0.39) between the $CORTES^2$ and tympanic IR. Sensitivity analysis revealed similar ICC and p-values. The Bland-Altman plots are shown in Figure 1.3.

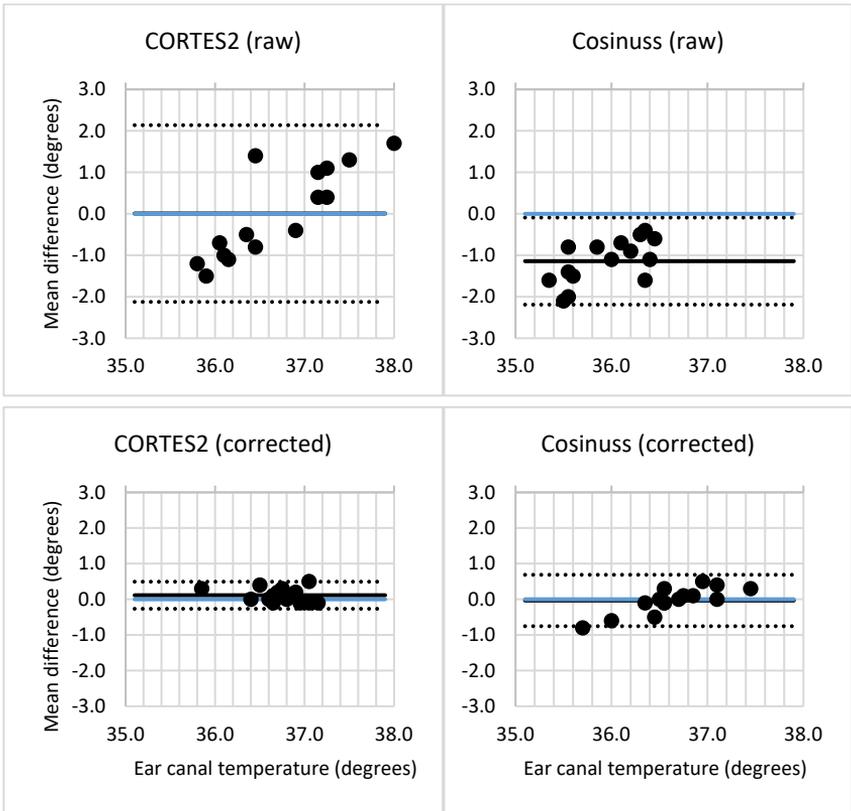


Figure 1.3 | Bland-Altman plots of the mean ear canal temperature (T_{EC}) versus the mean temperature differences; The non-corrected $CORTES^2$ (top left) and Cosinuss° (top right) and corrected $CORTES^2$ (bottom left side) and Cosinuss° (bottom right side) compared to the tympanic IR with mean and 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 1.3 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 Trellech[®], 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 $T_c=40.7\pm 1.5^\circ\text{C}$.

1.3.3 | Usability

The Cosinuss° was more flexible than 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).

1.4 | 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, therefore, only the Cosinuss° was tested in the field study.



Acknowledgments

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I.5 | Appendices

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

	MD±SD [95% CI]	p	ICC [95% CI]	p	LoA
CORTES ² (raw)	-0.09±1.10 [-0.69;0.52]	0.764	0.20 [-0.37;0.64]	0.243	±2.13
CORTES ² (corrected)	-0.11±0.2 [-0.22;0.00]	0.042	0.79 [0.44;0.93]	<0.001	±0.38
Cosinuss ^o (raw)	1.44±0.54 [1.14;1.74]	<0.001	0.07 [-0.05;0.31]	0.083	±1.05
Cosinuss ^o (corrected)	0.03±0.37 [-0.17;0.24]	0.729	0.72 [0.33;0.90]	0.001	±0.72

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^o of all participants (n=15) and the mean and max temperature (T_{air}) and relative humidity (RH) nearby the skin of the participants.

	Mean		Max	
	Sitting	Jumping	Sitting	Jumping
T _{Ec} (°C) CORTES ²	37.90±1.41	38.23±1.49	40.10±1.64	40.20±1.76
T _{Ec} (°C) Cosinuss ^o	37.46±0.77	37.42±0.74	38.90±0.78	38.80±0.77
T _{air} (°C)	27.43±0.59	28.26±0.49	28.90±0.59	29.0±0.51
RH (%)	42.98±7.42	50.30±10.88	61.70±7.42	61.60±7.32



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Appendix II

SPRINT@Work

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.

- M. de Jong, A.M. Bonvanie, J. Jolij & M.M. Lorst "Dynamics in typewriting performance reflect mental fatigue during real-life office work" – *PLoS ONE*, *accepted*.
- B. van den Berg, M. de Jong, M.G. Woldorff & M.M Lorst, "Caffeine boosts preparatory attention for reward-related stimulus information", *Journal of Cognitive Neuroscience*, *accepted*.
- C.C. Roossien, L.A. Kroops, J.B. Wempe, G.J. Verkerke, M.F. Reneman, "Can we analyze breathing gasses without a mouth mask? Proof-of-concept and concurrent validity of a newly developed breathing gasses analyzing headset". *Applied Ergonomics*, vol. 90, pp. 103266, 2021.
- Bonvanie, H. Broekhuis, E. Maeckelberghe, O. Janssen & J.C. Wortmann "Health Self-Management Applications in the Work Environment: the Effects on Employee Autonomy". *Frontiers in Digital Health*, 9:2, 2020
- C.C. Roossien, R. Heus, M.F. Reneman, G.J. Verkerke, "Monitoring core temperature of firefighters to validate a wearable non-invasive core thermometer in different types of protective clothing: concurrent in-vivo validation". *Applied Ergonomics*, vol. 83, pp. 103001, 2020.



- S. Spook, W. Koolhaas, U. Bultmann, S. Brouwer, “Implementing sensor technology applications for workplace health promotion: A needs assessment among workers with physically demanding work”. *BMC Public Health*, vol. 19, pp. 1100, 2019.
- C.C. Roossien, G.J. Verkerke, M.F. Reneman, “Patent: Instrument, system and method for use in respiratory exchange ratio measurement”, application number: EP19189792.5, 2019.
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Summary

Worldwide, the life expectancy and age of retirement are rapidly increasing, resulting in an aging workforce that often experiences a misbalance between work capacity and workload. This will negatively impact the overall well-being, workability, work performance, and safety of workers, eventually incurring high absenteeism or incapacitation costs for companies, the government, and the (working) population throughout the Netherlands and the Western World. To redeem the costs of aging and to maintain a stable workforce and economy, multiple countries have increased the age of retirement. This alone, however, will not be enough to maintain a sustainable and healthy workforce. In *Chapter 1* the focus is on how a sustainable workforce could be created and the needs of both workers and employers. To gain a sustainable workforce and healthy aging working population, a balance between work capacity and workload needs to be achieved. Physically active and office workers experience work-related health problems caused by a lowered capacity due to aging and the high or low physical demands for their jobs. The three main factors that puts workers at risks include a high mechanical workload, an internal energetic workload, and external heat exposure. Sensor technologies are very useful to continuously monitor the workload of workers, but there is a lack of sensor technologies capable of reliably measuring the workload during work without interfering with the workability. Besides, effective interventions that decrease the mismatch between capacity and workload are lacking as well. The objective of this dissertation is to develop and validate sensor technologies to monitor and improve working postures and related mechanical workload, internal energetic workload, and internal reactions to external heat exposure.

In Chapter 2, the mechanical workload of office workers is investigated. A 'smart' office chair can monitor sitting behavior and provide tactile feedback, aiming to improve sitting behavior and to prevent health problems and musculoskeletal discomfort associated with prolonged sitting. In a 12-week prospective cohort study among office workers, the sitting duration, posture, feedback signals, and musculoskeletal discomfort were measured. This study showed that the 'smart' chair was capable of monitoring sitting behavior. The feedback signal, however, led to small or insignificant changes in the sitting behavior of office workers.

In Chapter 3, monitoring the mechanical workload of physically active workers is investigated. With a 'sensor suit,' the working postures of multiple types of workers were

monitored and with an neural network the corresponding moment of the lumbar region was calculated automatically. This study observed that the sensor system showed differences in the physical load exposure of the lumbar region in coherence with perceived intensity levels and character of the work task in physically demanding occupations.

In Chapter 4 and 5 the focus is on an investigation about monitoring the energetic workload. In *Chapter 4* a patent application is presented. A headset, which analyzes breathing gasses to determine energy expenditure was developed and tested. This is the first working headset which can analyze breathing gasses without the need of a mouth mask. Unique aspects of this device include the design of the air catch-up box replacing the mouth mask, the algorithm to calculate the volume of breath flow from the nose or mouth, and the integrated wind sensor and its algorithm to eliminate influences of environmental wind. In *Chapter 5*, the validation and user experience of the proof-of-concept headset prototype is discussed. The headset that monitors the energetic workloads was used for physically active workers and was found to be more valid than heart rate monitoring alone, and more practical than indirect calorimetry with a mouth mask. The subjects preferred the headset over the mouth mask because it was more comfortable, did not hinder communication, and had a lower breathing resistance.

To be able to monitor heat exposure of physically active workers, two wearable thermometers were tested for their reliability and validity. In *Chapter 6* a study of the validity and reliability of a commercial, wearable, and non-invasive core thermometer, Cosinuss^o, during firefighting simulation tasks is presented. The core temperatures of firefighters when working in two types of protective clothing was compared. Without calibration, the accuracy of the thermometer was unacceptably low. With individual calibration, the accuracy was acceptable but was decreased when working. In *Chapter 7*, the accuracy of this wearable thermometer was evaluated and its usability explored in both a laboratory setting and in real-life working conditions. It was again concluded that, without a correction factor, the thermometer is inaccurate. With correction, the accuracy of this wearable ear canal thermometer was confirmed during rest, but not in outdoor working conditions or while wearing a helmet or hearing protection. In *Appendix 1*, the development and lab-test of an innovative wearable non-invasive core thermometer has been described. This device showed good correlations compared to the infrared thermometry used in hospital settings. However, some unrealistically high values were measured and it showed to have a lower ease of use.

In *Chapter 8*, the ethical considerations behind monitoring the workload of employees are described. The aim of the study was to address challenges by analyzing two ethical issues,

privacy and autonomy, of workers, in a real-life research setting. The results show that the protection of privacy and autonomy of workers cannot be seen as stand-alone issues; there is an interplay between these values, the work context, and the responsibilities of workers and their employer. Focusing on a contextual conceptualization of core ethical principles identified during the project helps to avoid compartmentalization, generalization, and neglect of responsibility. Developing context-specific ethics makes it possible to examine the particular implications of a certain value for a specific situation. A practical, adaptive tool for the ethical design and implementation of workplace health promotion technologies and how stakeholders can take their responsibility and support autonomy, is lacking. Engineers and scientists need to consider how the design and implementation of their technologies influence and mold the values of employers and workers and adapt their technologies to increase ethical acceptance. This interplay between design and implementation is underexposed in literature, but it is critical for the success of responsible innovations.

In *Chapter 9*, the sensor technologies and their implementation in the workplace are discussed in terms of an evaluation of the results, the relevance of these developments and proposed future research. With the data obtained from these sensor technologies, the individual physiological response on the workload can be monitored and a misbalance between workload and capacity can be prevented. After final design and validation, these sensor technologies are ready to be used to contribute towards the realization of a sustainable workforce.

Samenvatting

Wereldwijd nemen de levensverwachting en de pensioengerechtigde leeftijd snel toe. Dit heeft als gevolg een vergrijzende beroepsbevolking die vaak een disbalans tussen werkcapaciteit en werklast ervaart. Dit zal zowel het welzijn van werknemers als hun werkbaarheid, werkprestaties en veiligheid beïnvloeden en zal hoge verzuimkosten veroorzaken voor bedrijven, de overheid en de (werkende) bevolking, niet alleen in Nederland maar in heel Europa en de westerse wereld. Om de kosten van veroudering terug te dringen en een stabiele beroepsbevolking en economie te behouden, hebben meerdere landen de pensioenleeftijd verhoogd. Dit alleen zal echter niet voldoende zijn om een duurzame en gezonde beroepsbevolking in stand te houden. In *hoofdstuk 1* ligt de focus op hoe een duurzame beroepsbevolking kan worden gecreëerd en wat de behoeften zijn van werknemers en werkgevers. Om een duurzame en gezond ouder wordende beroepsbevolking te krijgen, moet een disbalans tussen werkcapaciteit en werklast worden voorkomen. Lichamelijk actieve werknemers en kantoormedewerkers ervaren werkgerelateerde gezondheidsproblemen die worden veroorzaakt door een lagere capaciteit als gevolg van veroudering en de hoge of lage fysieke belasting van hun werk. De drie belangrijkste factoren zijn een hoge mechanische belasting, interne energetische belasting en externe blootstelling aan warmte. Sensortechnologieën kunnen erg nuttig zijn om de werkdruk van werknemers continu te bewaken. Er is alleen een gebrek aan objectieve sensortechnologieën die de werkbelasting tijdens het werk kunnen valideren en betrouwbaar kunnen meten zonder de werkbaarheid te verstoren. Daarnaast ontbreken ook effectieve interventies die een onbalans verminderen. Het doel van dit proefschrift is het ontwikkelen en valideren van sensortechnologieën om de werkhoudingen en de gerelateerde mechanische werkbelasting, de interne energetische werkbelasting en interne reactie op externe blootstelling aan warmte te monitoren en te verbeteren.

In *hoofdstuk 2*, de mechanische belasting van kantoorpersoneel is onderzocht. Een "slimme" bureaustoel kan het zitgedrag monitoren en een tactiele feedback geven. Het doel van deze feedback is het zitgedrag te verbeteren en gezondheidsproblemen en musculoskeletaal ongemak als gevolg van langdurig zitten te voorkomen. In een prospectief cohortonderzoek van 12 weken onder kantoormedewerkers werden de zitduur en -houding, feedbacksignalen en musculoskeletale ongemakken gemeten. Deze studie toonde

aan dat de “slimme” stoel het zitgedrag kan monitoren. Het feedbacksignaal leidde echter tot kleine, niet-significante veranderingen in het zitgedrag van kantoormedewerkers.

In *hoofdstuk 3* de mechanische belasting van fysiek actieve werknemers is onderzocht. Met een “sensorpak” werden de werkhoudingen van meerdere typen werknemers gemonitord en met een neurale netwerk werd het corresponderende moment van het lumbale gebied automatisch berekend. Deze studie stelde vast dat het sensorsysteem verschillen vertoonde in de intensiteitsniveaus en variatie van de fysieke belasting van het lumbale gebied in samenhang met de waargenomen intensiteitsniveaus en de aard van de werktaak in fysiek veeleisende beroepen.

In *hoofdstuk 4 en 5* focust op het monitoren van de energetische belasting. In *hoofdstuk 4* een octrooiaanvraag is gepresenteerd. Er is een headset ontwikkeld en getest die ademgassen analyseert om het energieverbruik te bepalen. Dit is de eerste werkende headset die ademgassen kan analyseren zonder een mondmasker. Unieke aspecten van dit apparaat zijn het ontwerp van de box die de lucht opvangt en het mondmasker vervangt, het algoritme om het volume te berekenen uit de ademstroom uit neus of mond, en de geïntegreerde windsensor en het algoritme om invloeden van omgevingswind te elimineren. In *hoofdstuk 5*, de validiteit en gebruikerservaring van het proof-of-concept is bediscussieerd. De headset lijkt bruikbaar voor het monitoren van de ontwikkeling van de energetische belasting van fysiek actieve werknemers. De headset is meer valide dan hartslagmonitoring en praktischer dan indirecte calorimetrie met een mondmasker. De proefpersonen gaven de voorkeur aan de headset boven het mondmasker omdat deze comfortabeler was, de communicatie niet belemmerde en een lagere ademhalingsweerstand had.

Om de blootstelling aan hitte van fysiek actieve werknemers te kunnen volgen, zijn twee draagbare thermometers geïntroduceerd en onderzocht p betrouwbaarheid en validiteit. In *hoofdstuk 6* wordt een studie over de validiteit en betrouwbaarheid van een commerciële draagbare en niet-invasieve kerntemperatuur thermometer, Cosinuss^o, tijdens simulatietaken voor brandbestrijding gepresenteerd. Daarnaast is de ontwikkeling van de kerntemperatuur van brandweerlieden bij het werken in twee soorten beschermende kleding vergeleken. Zonder kalibratie was de nauwkeurigheid van de thermometer onaanvaardbaar laag. Bij individuele kalibratie was de nauwkeurigheid acceptabel, maar dit verminderde tijdens werken. In *hoofdstuk 7* werd de nauwkeurigheid van deze draagbare thermometer geëvalueerd en de bruikbaarheid onderzocht in een laboratoriumomgeving en in reële werkomstandigheden. Er werd wederom geconcludeerd dat de thermometer zonder correctiefactor onnauwkeurig is. Met correctie werd de nauwkeurigheid van deze

draagbare binnenoorthermometer bevestigd in rust, maar niet in werkomstandigheden buitenshuis of tijdens het dragen van een helm of gehoorbescherming. In *bijlage 1* is een andere draagbare, niet-invasieve kernthermometer ontwikkeld, beschreven en gevalideerd in laboratoriumomgevingen. Dit apparaat vertoonde goede correlaties vergeleken met infrarood-thermometrie die wordt gebruikt in ziekenhuisomgevingen, maar meet soms ook onrealistische hoge waarden en blijkt een lagere bruikbaarheid te vertonen.

In *hoofdstuk 8* worden de ethische overwegingen achter het bewaken van de werkbelasting van werknemers beschreven. Het doel van de studie was om twee werkgerelateerde ethische kwesties, privacy en autonomie, te analyseren in een realistische onderzoek- en werkomgeving. De resultaten laten zien dat het beschermen van de privacy en autonomie van werknemers niet als op zichzelf staande kwesties kunnen worden gezien, maar dat er een wisselwerking is tussen deze waarden, de werkcontext en de verantwoordelijkheden van werknemers en hun werkgever. Door te focussen op een contextuele conceptualisering van ethische kernprincipes die tijdens het project zijn geïdentificeerd, worden compartimentering, generalisatie en verwaarlozing van verantwoordelijkheid voorkomen. Het ontwikkelen van context-specifieke ethiek maakt het mogelijk om de specifieke implicaties van een bepaalde waarde voor een specifieke situatie te onderzoeken. Het ontbreekt aan een praktisch adaptief instrument voor het ethisch ontwerpen en implementeren van technologieën voor gezondheidsbevordering op de werkplek en aan kennis hoe belanghebbenden hun verantwoordelijkheid kunnen nemen en autonomie kunnen ondersteunen. Ingenieurs en wetenschappers moeten overwegen hoe het ontwerp en de implementatie van hun technologieën de waarden van werkgevers en werknemers beïnvloeden en vormen en moeten hun technologieën aanpassen om de ethische acceptatie te vergroten. Dit samenspel tussen ontwerp en implementatie is onderbelicht in de literatuur, maar is cruciaal voor het succes van verantwoorde innovaties.

In *hoofdstuk 9* worden de sensortechnologieën en implementatie op de werkplek besproken in termen van evaluatie van de resultaten, relevantie van deze ontwikkelingen en mogelijk toekomstig onderzoek. Met de gegevens die met deze sensortechnologieën zijn verkregen, kan de individuele fysiologische respons op de werklust worden gevolgd en kan een disbalans worden voorkomen. Na definitief ontwerp en validatie zijn deze sensortechnologieën klaar om te worden gebruikt om bij te dragen aan de realisatie van een duurzame beroepsbevolking.

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About the author



Charissa Roossien was born on August 27, 1988 and raised in Assen, the Netherlands. She holds a BEng in Mechanical Engineering and a MSc in BioMedical Engineering. In her Bachelor she did a dual internship as mechanical engineer at Pezy Product Innovation and an extra project as engineer teacher at special primary education s.b.o. de Meander. For her bachelor thesis about the development and integration of a hands-free tracheostoma valve she was awarded as best graduation thesis and won the 'OKE' price of the entrepreneurial circle of Emmen, the Netherlands. In 2010 she graduated as 'Top' (high potential) of Stenden University of Applied Sciences.

To achieve more knowledge about engineering in the medical field, she continued with the pre-master Life Science and Technology in 2010 for which she did a research about oxygen release of biomaterials for regeneration of large tissue defects and continued with the master BioMedical Engineering at the University of Groningen with minor prosthesis and implant interface technology. In 2013 she graduated with her master thesis about the optimization of a new elliptical driving mechanism for manual wheelchairs.

After her studies, Charissa started as pre-doctoral researcher at INCAS³, and continued by a collaborating PhD at INCAS³ and University Medical Center of Groningen (UMCG) about sensor technologies for sustainable employability. Halfway her PhD she combined her PhD-study with a position as lecturer and was involved in educational activities including courses about biomechanics, biomedical product design and prosthetics and orthotics and supervision of bachelor and master students from various studies and universities. During her PhD, Charissa participated in the SPRINT PhD committee. In 2018 she won the Best Poster Award at the Scientific Meeting of the Groningen Engineering Center. She did two research studies aboard at Karde AS in Oslo, Norway and Ageing lab in Jaén, Spain to investigate user involvement in the design process, intelligent data analysis, reminding technologies and self-management solutions in healthcare.

Since the start of her bachelor in Mechanical Engineering, Charissa is active in informing girls about the interesting possibilities of a technical education aiming to motivate more girls and women in IT, technology and beta science. Since 2008 she is a so-called 'role model'

for VHTO, national expertise agency for girls/women and beta/technology in the form of speed dates, guest lectures and organizing or participating in the yearly 'Girlsday' initiated by VHTO.

Charissa her motivation is to help people with useful developments. She will continue her work at the UMCG and University of Groningen in a post-doctoral career focusing on engineering and applied research and science.

Disclaimer: photo by Deborah Roffel photography

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