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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, Cosinussº, 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 Cosinussº and thermometer pill (ICC≤0.09, p≥0.154, LoA≥1.37) and a moderate correlation between Cosinussº and inner-ear infrared (ICC=0.40, p=0.044, LoA±1.20) was observed. With individual correction both correlations were excellent (ICC≥0.84, p=0.000, LoA≤0.30). However, during and after working all correlations were poor and non-significant (ICC≤0.38, p≥0.091, LoA≥1.71). During firefighting tasks, the Cosinussº 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

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 & Sheikhzadeh, 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 (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 Cosinussº 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 Cosinussº 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, Cosinussº, 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 Cosinussº 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.

2 Materials and methods

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).

2.2 Materials

2.2.1 Cosinussº

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 55ºC. According to Cosinussº (Cosinussº, 2016) the sample frequency is 100 Hz and the accuracy is ±0.1ºC.

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 40ºC and an accuracy of ±0.1°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.

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) (Kocoglue, et al., 2002). The Braun ThermoScan® has an measurement range temperature of 35 to 42ºC with an accuracy of ±0.2ºC compared to rectal temperature measurements in an operating T_a of 10 to 40ºC (Braun GmbH, sd) (Moran-Nabarro, et al., 2018).

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 ±0.3ºC and the RH sensor has an accuracy of ±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 120ºC (Sensirion, 2010).

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 26.2 s 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 MIlenia™ 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 thermical 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.

Insert Figure 1 here

Figure 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.

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° (in one ear) and using the CorTemp® and an inner-ear IR thermometer (in other ear) as references. These concurrent validation measurement were performed in a room with a constant T_a of 20.0±2.0ºC and RH of 45.0±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±2.0ºC and RH of 45.0±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 225ºC.

The T_c of the subjects was recorded continuously using the Cosinussº (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 225ºC. The task started outdoor with a T_a of 13.0±2.0ºC, RH of 72.0±5.0% and mean wind speed of 3.2m/s. The estimated heat radiations was about 4kW/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 1, this study design is presented.

Insert table 1

Table 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	• Cosinussº • CorTemp®	-	10 minutes
	Measurement	Concurrent validity	Rest (passive sitting)	• Cosinussº • CorTemp® • Inner-ear	Once per minute	5 minutes
2	Measurement	Performance of job simulation	Periodic Preventive Medical Examination	• Cosinussº • CorTemp®	Continuously during task	15 minutes
	Cool down	-	Passive sitting and drinking water	• Cosinussº • CorTemp®	-	10 minutes
	Measurement	Performance of job simulation	Fire-extinguishing task	• Cosinussº • CorTemp®	Continuously during task	15 minutes
	Cool down	-	Passive sitting and drinking water	• Cosinussº • CorTemp®	-	10 minutes
	Dress up		*Put off suit A, put on suit B*	• *CorTemp®*		
	Acclimatization	-	Passive sitting and drinking water	• Cosinussº • CorTemp®	-	10 minutes
	Measurement	Performance of job simulation	Periodic Preventive Medical Examination	• Cosinussº • CorTemp®	Continuously during task	15 minutes
	Cool down	-	Passive sitting and drinking water	• Cosinussº • CorTemp® •	-	10 minutes
	Measurement	Performance of job simulation	Fire-extinguishing task	• Cosinussº • CorTemp®	Continuously during task	15 minutes
	Cool down	-	Passive sitting and drinking water	• Cosinussº • CorTemp® •	-	10 minutes
3	Measurement	Concurrent validity	Rest (passive sitting)	• Cosinussº • CorTemp® • Inner-ear	Once per minute	5 minutes

To test the in-vivo validity and reliability of the Cosinussº in rest (aim 1), in the concurrent validity study of stage 1 and 3 the Cosinussº was compared to the references CorTemp® and an inner-ear IR thermometer. To test the in-vivo validity and reliability of the Cosinussº during work (aim 2), in stage 2 the Cosinussº 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 Cosinussº 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.

2.4 Data analysis

Field calibration to correct the Cosinussº was explored and conducted based on both the CorTemp® and the inner-ear IR thermometer during stage 1. To correct the Cosinussº the second measurement of stage 1 was used; per subject in one ear the T_c was recorded with the Cosinussº 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 Cosinussº and CorTemp® or inner-ear thermometer was considered as the individual correction factor of the Cosinussº. 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 Cosinussº in rest (aim 1), of stage 1 and 3 the fourth concurrent validation measurement was used, including the T_c recorded with the Cosinussº, CorTemp® and inner-ear thermometer. To test the validity and reliability of the Cosinussº 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 analyzed using the paired t-test and by calculating the intraclass correlation coefficient (ICC, two-way random model). Non-parametric data were analyzed with the Wilcoxon signed rank test. The results are shown with mean or the mean difference (MD) and standard deviation (SD) (mean±SD). P-values ≤0.05 were considered statistically significant. The interpretation of the ICC: ICC<0.39 is poor, 0.40>ICC>0.59 is moderate, 0.60>ICC>0.79 is good and ICC≥0.80 is excellent (Cicchetti, 1994). The Limits of Agreement (LoA), calculated as ±1.96*SDdifference, 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).

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.

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±0.8°C with a mean SD within subjects of 0.1±0.1°C. The mean T_c recorded with CorTemp® was 37.5±0.4°C with a mean SD within subjects of 0.1±0.2°C. The mean of T_c recorded with the inner-ear IR was 36.6±0.4°C with a mean SD within subjects of 0.1±0.1°C. Individual correction (in stage 1) based on the CorTemp® resulted in an average correction factor of 1.5±0.7°C and based on the inner-ear IR of 0.6±0.6°C. In Table 2 the MD of the T_c recorded with the Cosinuss° and compared to CorTemp® and inner-ear IR are shown.

Insert Table 2 here

Table 2: Mean difference (MD) in core temperature (Tc) (°C) measurements in both suits (n=11) of Cosinuss° C-med versus reference thermometers; CorTemp® and inner-ear infrared (IR).

		Stage 1 (before working)			Stage 3 (after working)		
	Thermometer	MD±SD	[CI]	p	MD±SD	[CI]	p
Non-corrected	Cosinuss° vs CorTemp®	-0.4±0.7	[-1.84;-0.90]	0.000	-1.5±1.2	[-2.28;-0.70]	0.002
	Cosinuss° vs IR	-0.5±0.6	[-0.89;-0.07]	0.026	-0.3±1.0	[-0.97;0.30]	0.265
Corrected with CorTemp®	Cosinuss° vs CorTemp®	0.1±0.1	[0.04;0.18]	0.006	0.0±1.0	[-0.67;0.65]	0.976
	Cosinuss° vs IR	1.0±0.4	[-0.88;0.46]	0.000	1.2±1.0	[0.42;1.87]	0.006
Corrected with IR	Cosinuss° vs CorTemp®	-0.7±0.3	[-0.88;-0.46]	0.000	-0.8±0.9	[-1.38;-0.20]	0.013
	Cosinuss° vs IR	0.2±0.2	[0.11;0.32]	0.001	-0.4±1.0	[-0.28;1.00]	0.233
Non-corrected	CorTemp® vs IR	0.9±0.3	[0.67;1.12]	0.000	1.2±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 CorTem®. In stage 3, significantly high differences were found in T_c recorded with the Cosinussº and CorTemp® ($MD \geq -0.8$, $p \leq 0.013$). The Cosinussº corrected and compared to CorTemp® showed an acceptable, but non-significant mean difference with a high SD ($MD=0.0 \pm 1.0$, CI [-0.67;0.65], $p=0.976$). In Table 3 is shown the ICC for Cosinussº, CorTemp® and inner-ear IR.

Insert Table 3 here

Table 3: Intraclass correlations (ICC) and Limits of Agreement (LoA) of T_c measurements in both suits (n=11) of Cosinussº C-med versus reference thermometers; CorTemp® and inner-ear infrared (IR).

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

In stage 1 and 3, without individual correction of the Cosinussº no correlation between the Cosinussº and CorTemp® was observed and a moderate correlation was observed between Cosinussº and inner-ear with an unacceptably high LoA ($ICC=0.40$, $p=0.044$, $LoA=\pm 1.20$). The Cosinussº corrected with the CorTemp® (stage 1) resulted in an excellent correlation with an acceptable LoA compared to the CorTemp® ($ICC=0.94$, $p=0.000$, $LoA=\pm 0.20$) and a poor correlation compared to the inner-ear IR ($ICC=0.19$, $p=0.007$, $LoA=\pm 0.68$). The Cosinussº corrected with the inner-ear IR resulted in a poor correlation compared to the CorTemp® ($ICC=0.30$, $p=0.005$, $LoA=\pm 0.61$) and an excellent correlation with an acceptable LoA compared to the inner-ear IR ($ICC=0.84$, $p=0.000$, $LoA=\pm 0.30$). No correlation or a poor correlation was found between the CorTemp® and inner-ear IR thermometer ($ICC \leq 0.24$). In Figure 2, the Bland-Altman plots before working (stage 1) are shown.

Insert Figure 2 here

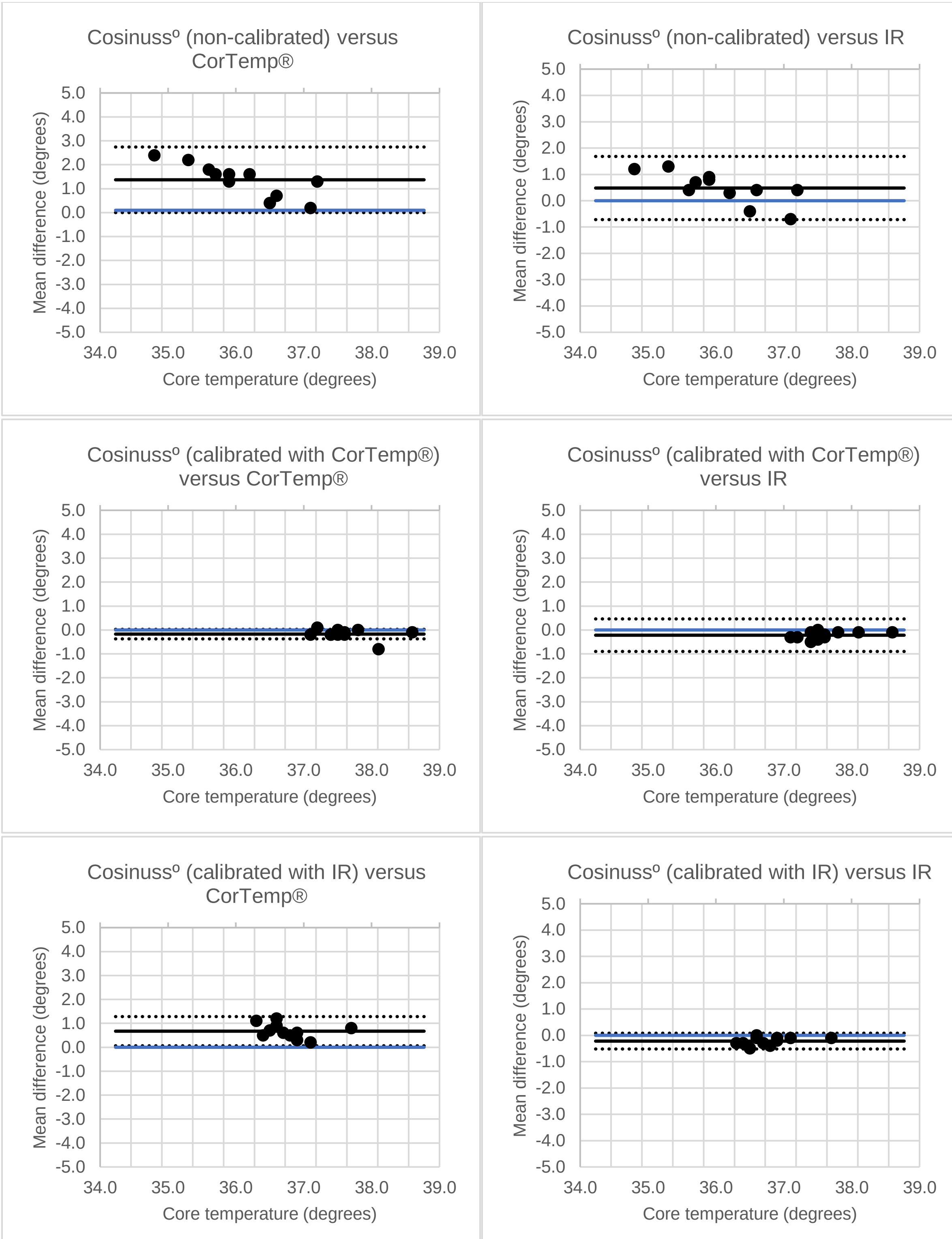

Figure 2: Bland-Altman plots of the mean core temperature versus the mean temperature difference before working (stage 1) in both suits between the non-corrected and corrected

Cosinussº 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.

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

Insert Figure 3 here

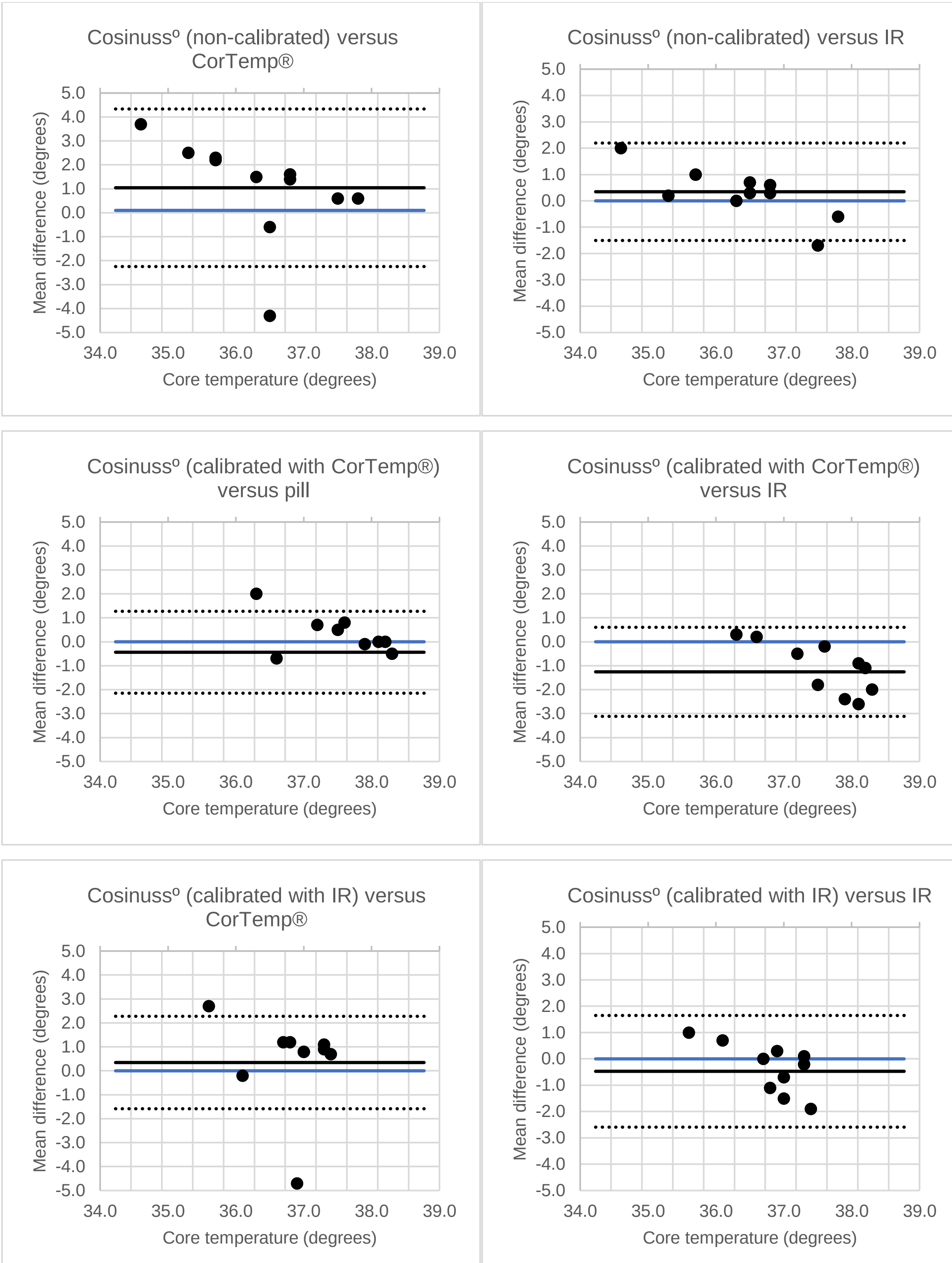

Figure 3: Bland-Altman plots of the mean core temperature versus the mean temperature difference after working (stage 3) in both suits between the non-corrected and corrected

Cosinussº 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.

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 Cosinussº was 36.1±1.1ºC (n=17). The mean T_c recorded with CorTemp® was 37.6±0.5ºC. In Table 4 the MD of the T_c recorded with the Cosinussº and compared to CorTemp® are shown.

Insert Table 4 here

Table 4: Mean difference (MD) in core temperature (Tc) (ºC) measurements in both suits (n=17) of Cosinussº C-med versus reference thermometers; CorTemp® and inner-ear infrared (IR).

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

In stage 2, the T_c recorded with the non-corrected Cosinussº differs significantly compared to the CorTemp® (MD≥-0.7, p≤0.002). The Cosinussº corrected and compared to the CorTemp® showed an acceptable, but non-significant difference (MD≤0.2, p≥0.534). In Table 5 is shown the ICC for Cosinussº and CorTemp®.

Insert Table 5 here

Table 5: Intraclass correlations (ICC) and Limits of Agreement (LoA) of Tc measurements of Cosinussº C-med versus reference thermometer; CorTemp®, in both suits.

			Stage 2 (firefighting simulation tasks)		
	n	Task	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≤0.26, p≥0.253) with unacceptable high LoA's (LoA≥2.20). Sensitivity analysis revealed similar results. In Figure 4, the Bland-Altman plots during the both realistic firefighting simulation tasks are shown.

Insert Figure 4 here

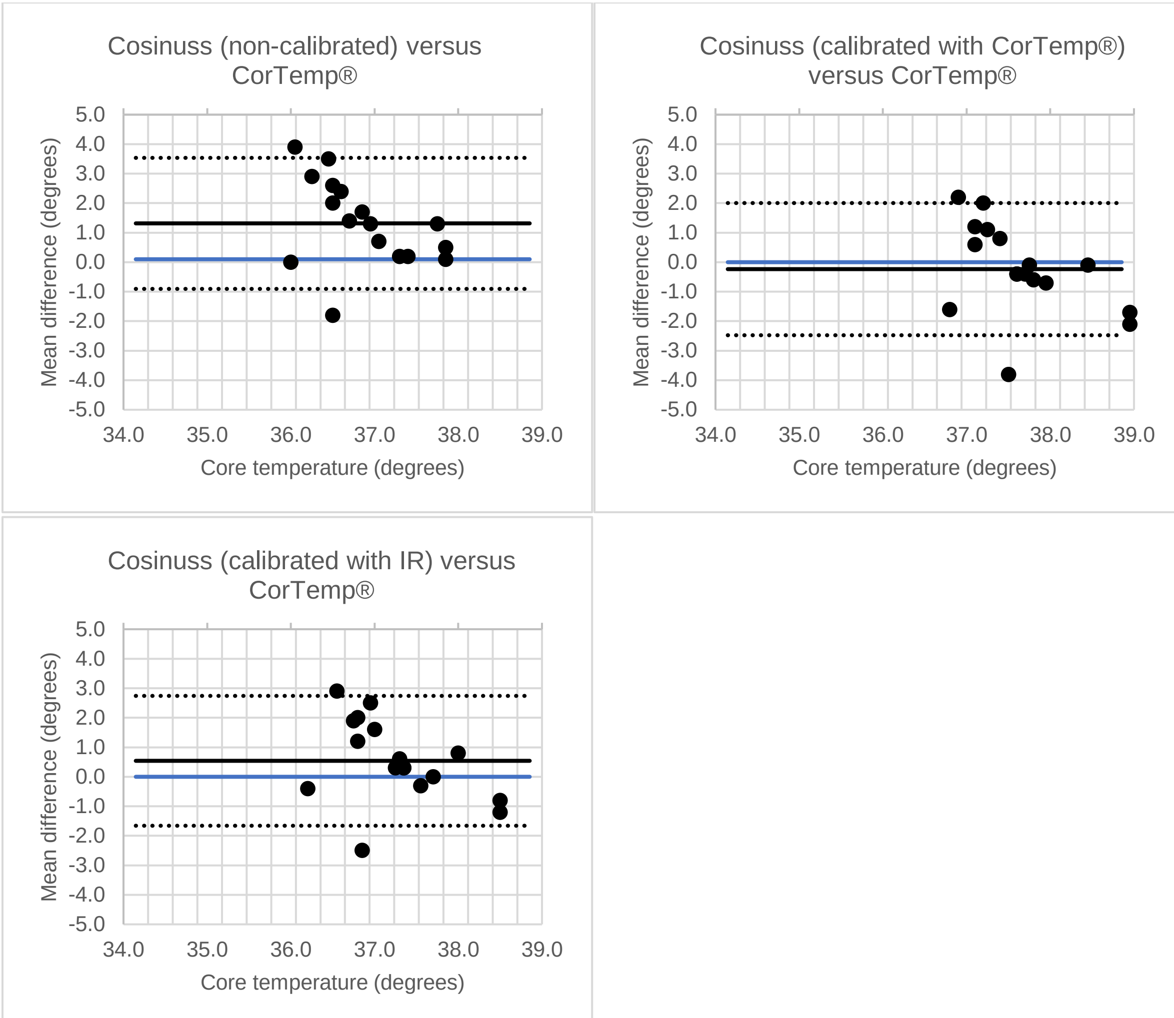

Figure 4: Bland-Altman plots of the mean core temperature versus the mean temperature difference during both firefighting simulation tasks (stage 2) in both suits between the non-corrected and corrected Cosinuss° compared to the CorTemp® with mean (black line) and upper and lower Limit of Agreement (LoA) (black dotted line) and zero-line (blue line), n=17.

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±0.14°C/minute and the mean change in T_c recorded the CorTemp® was 0.02±0.10°C/minutes. The mean T_{cli} in both suits increased with 0.4±0.4°C/minute with a mean T_{cli} of 29.7±2.1°C and the RH increased with 1.6±3.2%/minute with a mean RH of 68.4±10.8%. In Table 6 the mean T_c recorded with the Cosinuss° and CorTemp® and T_{cli} and RH per task per suit are shown.

Insert Table 6 here

Table 6: Mean and maximum core temperature (Tc) (ºC) recorded with the CorTemp® and (non-corrected) Cosinussº, temperature inside de clothing (T_{cli}) (ºC) 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® (ºC)	10	37.4±0.4	37.3±0.7	10	37.8±0.3	37.7±0.5
Mean T_c Cosinussº (ºC)	7	36.4±1.6	37.0±0.9	6	37.7±1.4	37.9±1.0
Mean T_{cli} (ºC)	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® (ºC)	10	38.1±0.5	38.4±0.6	10	38.3±0.4	38.4±0.4
Max T_c Cosinussº (ºC)	7	38.8±1.5	38.9±1.0	6	40.1±1.2	39.8±1.0
Max T_{cli} (ºC)	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 Cosinussº was 40.1ºC and with the CorTemp® 38.4ºC (both during the fire-extinguishing task). However, on average the maximum T_c recorded with the Cosinussº 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 7 the MD and ICC of the T_c recorded with the Cosinussº CorTemp®, T_{cli} and RH in both suits between the Periodic Preventive Medical Examination (PPMO) and hot fire-extinguishing task are shown.

Insert Table 7 here

Table 7: Mean difference in core temperature (Tc) (ºC) recorded with the (non-corrected) Cosinussº and the CorTemp®, temperature inside the clothing (T_{cli}) (ºC), humidity (RH) and their change (∆) between the Periodic Preventive Medical Examination (PPMO) and hot fire-extinguishing task in both suits.

	n	MD±SD	CI	p
Mean T_c CorTemp® (ºC)	21	0.4±0.4	[0.19;0.56]	0.000

Mean T_c Cosinuss° (°C)	16	0.2±0.8	[-0.21;0.67]	0.285
Mean T_{cli} (ºC)	16	3.3±1.2	[2.66;3.94]	0.000
Mean RH (%)	16	12.0±13.7	[4.39;19.59]	0.004
ΔT_c CorTemp® (°C/minute)	21	0.00±0.12	[-0.52;0.06]	0.900
ΔT_c Cosinuss° (°C/minute)	16	0.11±0.18	[0.01;0.21]	0.033
ΔT_{cli} (ºC/minute)	16	0.27±0.54	[-0.03;0.57]	0.349
∆RH (%/minute)	16	1.22±4.89	[-1.49;3.93]	0.077

During the fire-extinguishing task (stage 2), T_c recorded with the CorTemp® was significantly higher compared to the PPMO (MD=0.4±0.4°C, CI [0.19;0.56], p=0.000), as well as T_{cli} (MD=3.3±1.2°C, CI [2.66;3.94], p=0.000) and RH (MD=12.0±13.7%, CI [4,39;19.59], p=0.004). T_c recorded with the Cosinuss° 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±0.18°C/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±0.54°C/min, CI [-0.03;0.57], p=0.077). In Table 8 the MD of the T_c recorded with the Cosinuss° or CorTemp®, T_{cli} and RH per task of suit A compared to suit B are shown.

Insert Table 8 here

Table 8: Mean difference in core temperature (Tc) (ºC) recorded with the (non-corrected) Cosinuss° and the CorTemp®, temperature inside the clothing (T_{cli}) (°C), humidity (RH) and their change (∆) per (Periodic Preventive Medical Examination (PPMO) and hot fire-extinguishing) task between suit A and B.

Task		n	MD±SD	CI
PPMO	T_c CorTemp® (°C)	10	-0.3±0.8	[-0.87;0.33]
	T_c Cosinuss° (°C)	7	0.6±0.9	[-0.28;1.55]
	T_{cli} (ºC)	8	1.9±1.5	[0.47;3.27]
	RH (%)	8	4.1±15.8	[-10.6;18.69]
	ΔT_c CorTemp® (°C/minute)	10	0.01±0.17	[-0.11;0.05]

	ΔT_c Cosinussº (ºC/minute)	7	-0.04±0.09	[-0.14;0.05]
	ΔT_{cli} (ºC/minute)	8	0.63±4.51	[-4.11;5.37]
	ΔRH (%/minute)	8	-0.02±0.48	[-0.52;0.48]
Fire-extinguishing	T_c CorTemp® (ºC)	10	-0.1±0.5	[-0.53;0.31]
	T_c Cosinussº (ºC)	6	0.1±0.4	[-0.43;0.63]
	T_{cli} (ºC)	7	2.6±2.5	[0.00;5.16]
	RH (%)	7	6.5±18.6	[-13.06;26.06]
	ΔT_c CorTemp® (ºC/minute)	10	0.00±0.04	[-0.03;0.03]
	ΔT_c Cosinussº (ºC/minute)	6	0.02±0.06	[-0.06;0.09]
	ΔT_{cli} (ºC/minute)	7	0.20±4.04	[-4.81;5.21]
	ΔRH (%/minute)	7	-0.13±0.44	[-0.68;0.41]

The T_{cli} in suit B was significant higher compared to suit A (during PPMO MD=1.9±1.5ºC, CI [0.47;3.27], p=0.017, during the hot task MD=2.6±2.5ºC, CI [0.00;5.16], p=0.050) and during the PPMO no correlation was found be 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 Cosinussº (ICC≥0.74, p≤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≥0.308). Sensitivity analysis revealed similar results.

4 Discussion

The T_c of the non-corrected Cosinussº showed no correlations with the CorTemp® 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® performed once is valid over longer periods of time. Moreover, no correlation was found between the CorTemp® and inner-ear IR and no correlation or a poor correlation was found between the CorTemp® and Cosinussº 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 Cosinussº, 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). Therefor 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 Cosinussº 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 is 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 influence 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 Cosinussº, the system should be valid and reliable. The urge for individual calibration should be investigated, as well as using the Cosinussº 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 Cosinussº 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 Cosinussº is made of a thermoplastic with silicone developed to be used in ambient temperatures of -15 to 55ºC (Cosinussº, 2016), which can cause burns during long-term use in heat exposure nor is fulfilling the safety standards.

If the reliability of the Cosinussº can be improved, as part of a multivariable system (Richmond, et al., 2015) the Cosinussº 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 Cosinussº in its present form is not suitable for this.

5 Conclusion

The validity of the Cosinussº C-med was not confirmed in this study. Without individual correction, the Cosinussº 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 Cosinussº causing a movement of the sensor relative to the ear. This indicates that Cosinussº 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 Cosinussº C-med used in this study were borrowed from Cosinussº 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 Cosinussº GmbH. There is no conflict of interest.

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