Physiological Data Validation of the Hexoskin Smart Textile

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Keywords: Concordance Correlation Coefficient, Intraclass Correlation Coefficient, Bland-Altman, Agreement Analysis, Cardiorespiratory.

Abstract: The aim of this study is to validate cardiorespiratory function measurement of a healthy population provided by a wearable textile during a progressive maximal exercise test. The following measurements were collected using embedded sensors to assess three variables: heart rate (HR), breathing rate (BR) and ventilation (Ve). These variables were recorded simultaneously by the wearable textile and using as a reference system for a comparison purpose. The validation was performed based on the two systems agreement estimation by calculating the intraclass correlation coefficient (ICC), the concordance correlation coefficient (CCC) and the Bland-Altman plot for each variable. Twenty-eight healthy volunteers participated in this study. Analysis of each participant under exercise condition by the two measurement systems revealed high CCC values (ρ_c between 0.91 and 0.99), no deviation from the 45° line (C_b between 0.96 and 0.99) and significant ICC values (ρ between 0.91 and 0.99, $p < 0.05$) for HR and BR. The Bland Altman plot for HR and BR indicated no deviation of the mean difference from zero and a small variability with tight agreement limits. However, the analysis of the estimated ventilation Ve of each participant revealed doubtful values for the CCC (ρ_c between 0.2 and 0.99) and ICC (ρ between 0.11 and 0.99). In summary, the Hexoskin presented good agreement for HR and BR. However, for ventilation, it is difficult to conclude from the results due to variability.

1 INTRODUCTION

Technological advances have offered new solutions to monitor and record physiological information such as heart rate, breathing rate and physical activity levels, from sensors embedded in wearable clothing.These technological solutions are growing and evolving rapidly to become new trends (Paradiso et al., 2005).

Hexoskin [1] (Carre Technlogies Inc, Quebec, Canada) is an intelligent shirt with flexible sensors sewn directly into the fabric and it is perfectly machine washable. It is embedded with several sensors: (1) Activity sensors (Figure 1 (a)), which record the movements (in three dimensions) and the acceleration of the user, (2) Respiration sensors (Figure 1 (b)), in the form of two rings present in the chest and abdominal. By analyzing the user's thoracic and abdominal breathing data, Hexoskin can calculate the number of breaths per minute and the volume of air consumed (in L/min), and (3) Heart sensors (Figure 1 (c)), in the form of electrodes, can act as an electrocardiogram ECG and deliver the heart rhythm of the intelligent textile wearer (in number of beats per minute) (Figure 1). The intelligent textile is able to measure levels of physical activity and physiological signals in real time. Using Bluetooth technology, these signals can be monitored remotely from a smart device.

The Hexoskin has been developed initially for high-level sports. However, there is a current growing interest for its use in clinical settings. Hence, the physiological data provided by the Hexoskin need to be validated. A few studies have considered such a validation. To validate the Hexoskin wearable shirt during lying, sitting, standing, and walking activities, a sample of 20 participants have been considered (Villar et al., 2015). The study revealed a low coefficient of variation and high intraclass correlation values for heart rate, breathing rate, and hip motion intensity while comparing the Hexoskin and laboratory standard devices. The magnitude of changes in

[1]http://www.hexoskin.com/

Cherif, N., Mezghani, N., Gaudreault, N., Ouakrim, Y., Mouzoune, I. and Boulay, P.
Physiological Data Validation of the Hexoskin Smart Textile.
DOI: 10.5220/0006588001500156
In *Proceedings of the 11th International Joint Conference on Biomedical Engineering Systems and Technologies (BIOSTEC 2018) - Volume 1: BIODEVICES*, pages 150-156
ISBN: 978-989-758-277-6

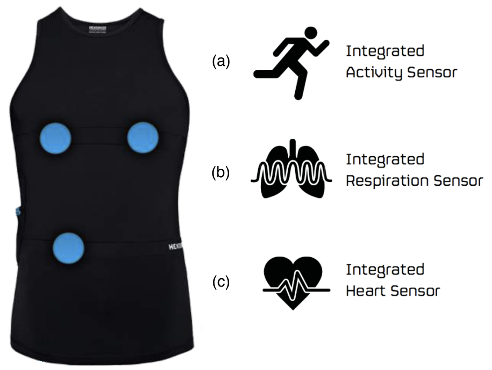

Figure 1: The Hexoskin acquisition system: (a) Activity sensor, (b) Respiration sensor and (c) Heart sensor.

tidal volume and minute ventilation from the Hexoskin closely tracked those measured by the laboratory standard method. In another study, to measure cardiorespiratory fitness, the Hexoskin has been used in a sample of 10 participants using a hiking situation during two field activities at different intensities (Montes et al., 2015). No significant differences for trail types were noted for maximal heart rate and respiratory rate. This is due to many missed data during the data collection. In a recent study, to monitor heart rate, twelve male volunteers wore the Hexoskin and Polar H7 heart rate sensor and they completed variable physical activities, using a stationary training bicycle under two different climate conditions (Al Sayed et al., 2017). The study revealed a high correlation and an absence of significant differences between the two systems in monitoring the subjects' heart rates. In another study, to investigate the validity and reliability of the Hexoskin vest for measuring respiration and heart rate, ten male elite cyclists conducted a maximal aerobic cycle ergometer test using a ramped protocol (Elliot et al., 2017). Authors conclude that the Hexoskin vest is sufficiently valid and reliable for measurements of breathing frequency and heart rate in elite athletes but the calculated minute ventilation value produces during such exercise should be used with caution due to the lower validity and reliability of this variable. Finally, the maximum oxygen uptake (VO_{2max}) has been evaluated by (Bassett Jr and Howley, 2000; Hawkins et al., 2007). This parameter, which can be defined as the maximum amount of oxygen that the body consumes during an intense effort (Howley et al., 1995), is considered as the best indicator of cardiorespiratory function. Moreover, an important parameter in determining the quality of a medical instrument is the agreement with a gold standard. These previous studies have been performed on a small sample size which can seriously limit the interpretation of the results and the validation process. In addition, in some cases (Al Sayed et al., 2017; Elliot et al., 2017), the data collection has been performed on stationary bikes which does not take into account the usual movements of the upper body.

In this study, we compared cardiorespiratory parameters from the Hexoskin against standard laboratory devices during a progressive maximal exercise test. Therefore, the purpose was to validate cardiorespiratory parameters measured simultaneously by Hexoskin and a laboratory standard devices during a progressive maximal exercise test according to BSU/Bruce ramp (Kaminsky and Whaley, 1998) protocol. More precisely, we will compare heart rate (HR) from the Hexoskin and heart rate from a reference laboratory electrocardiogram (ECG). The breathing rate (BR) and the estimated ventilation (Ve) will be compared between Hexoskin and a reference laboratory metabolic cart.

2 METHODOLOGY

2.1 Participants

Thirty healthy volunteers (18 males and 12 females) participated in the study. For 2 participants, the measurements were removed from the database due to technical issues that occurred when recording of the sensors signals that were not in the correct format. The problem was reported to Hexoskin for investigation. This gave a total of twenty-eight volunteers (17 males and 11 females, age 27.07 ± 7.25 years old, weight 73.73 ± 13.41 kg, heigh 173.12 ± 8.15 cm, Body Mass Index BMI 24.5 ± 3.44).

The study was approved by institutional ethics committees, with all subjects providing written informed consent before their participation. All participants completed a sociodemographic questionnaire and the Q-AAP + questionnaire to confirm that they were able to perform a vigorous exercise.

2.2 Data Collection

Data collection was performed at the University of Sherbrooke exercise physiology laboratory during a progressive maximal exercise test. Each participant wore the smart textile Hexoskin while they were submitted to a progressive maximal exercise test using the Cosmed Quark metabolic cart and 12 lead electrocardiogram which are considered gold standard in an exercise physiology lab.

The test was performed according to the BSU/Bruce ramp protocol (Kaminsky and Whaley, 1998), a testing protocol commonly used in clinical and research settings. The treadmill grade starts at 0% and the walking pace at 1.7 mph. Every 20 seconds, the treadmill speed increases gradually (by 0 to 0.1 mph) and/or grade increases gradually (by 0 to 0.5%). Every 3 minutes during this ramp protocol, the work rates were identical to those of the standard Bruce protocol. Ratings of perceived exertion was assessed throughout the maximum cardiorespiratory effort test using the Borg scale of 6-20 (Borg, 1982).

The recorded data (HR, BR and Ve) of the two devices were averaged every 20 seconds leading to a time series data of each variable. Figure 2 illustrates, for one participant the measurements of the heart rate (Figure 2 (a)), breathing rate (Figure 2 (b)) and ventilation (Figure 2 (c)) using the hexoskin and using the reference equipment Cosmed.

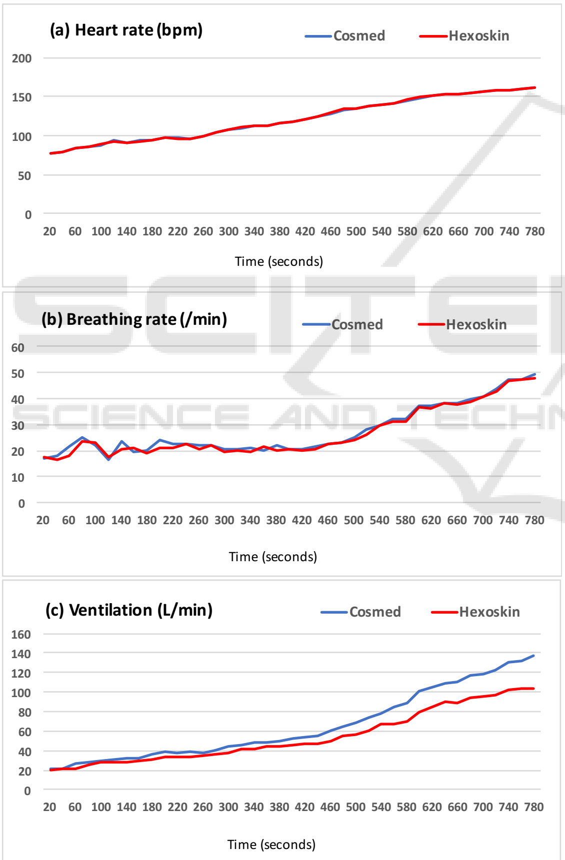

Figure 2: (a) Heart rate, (b) breathing rate and (c) ventilation measurements using the Hexoskin (red color) and using the reference equipment Cosmed (blue color) for one participant. The x-axis represents the averaged values for each variable every 20 seconds.

A preliminary analysis of the collected data shows the presence of outlier data for one participant (participant 12). Indeed the participant is muscular and when he was to run towards the end of the test, the pectorals make complex movements (bouncing) and the Hexoskin's cardiac sensors detached from the body which leading to abnormal recording (as illustrated in Figure 3. In consequence, the participant is considered as an outlier and was deleted from our database.

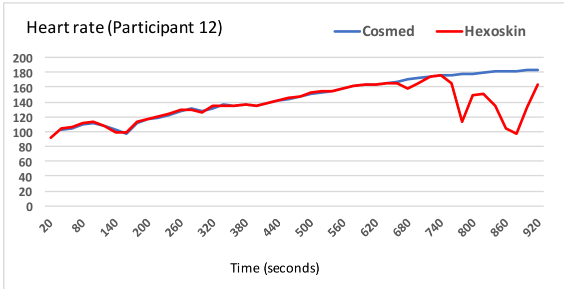

Figure 3: Heart rate curves for the Hexoskin and the laboratory reference equipment for participant 12.

2.3 Statistical Analysis for Physiological Data Validation

An important parameter in determining the quality of the wearable textile Hexoskin is the agreement with a gold standard. Agreement means the accuracy of this new measurement method (de Vet H.C.W., 1998). Several statistical methods were used to test the agreement of medical devices with quantitative results (Bland and Altman, 1983; Luiz RR, 2005).

In this study, the agreement (concordance) between the two methods of measuring Heart Rate (HR), Breathing Rate (BR) and Ventilation (Ve) were estimated by calculating the Intraclass Correlation Coefficient (ICC) and the Concordance Correlation Coefficient (CCC). The 95% confidence interval was estimated for ICC.

We also used the Bland Altman method to nuance, invalidate, or confirm the level of concordance quantified by numerical methods. Bland-Altman (Bland and Altman, 1986) is a method used to compare two measurements of the same variable. It is based on the quantification of the agreement between two quantitative measurements by studying the mean difference and constructing limits of agreement.

2.3.1 Intra-class Correlation Coefficient (ICC)

The intra-class correlation coefficient (ICC) measures the agreement and assess the reliability of medical instrument continuous outcomes. It was originally proposed by Fisher (Fisher, 1925), who suggested to use an analysis of variance with a separation of within-subject and between-subject variability. There are different forms of ICCs. Shrout and Fleiss have presented six forms of ICCs (Shrout and Fleiss, 1979) and McGraw and Wong have presented ten forms (McGraw and Wong, 1996). The ICC is defined as the following ratio,

$$\rho = \frac{\sigma_b^2}{\sigma_b^2 + \sigma_w^2} \tag{1}$$

where, σ_b^2 denotes the variance between subjects, and σ_w^2 denotes the variance within subjects. The lower the within subjects variability compared to the variability between subjects, the greater the intra-class correlation coefficient. The ICC varies between 0 and 1. When reliability is high, ICC is close to 1 and when reliability is low, ICC is close to 0. It's recommended to calculate the confidence intervals (CI) for the ICC (Shrout and Fleiss, 1979). In addition, p-values of ICC can be used to evaluate the accuracy and significance of the ICC. We consider as reliable an ICC with a p-value ≤ 0.05.

2.3.2 Concordance Correlation Coefficient (CCC)

The concordance correlation coefficient (CCC) quantifies the agreement between a new measurement method and a gold standard measurement method (Lin L, 1989; Lin and Kuei, 2000). The CCC combines measures of both precision and accuracy. Precision is measured with the correlation coefficient r. Model accuracy is evaluated with the bias correction factor C_b. A C_b equal to 1 indicates no deviation from the 45° line. The multiplication of both values gives both precision and accuracy at the same time. To be perfectly concordant, two measurement techniques have to be perfectly correlated and also provided identical measurements, i.e., situated on the 45° line through the origin.

Let $x_1 = (x_1, x_2, \ldots, x_n)$ denote the series of measurement of the Hexoskin and $y_2 = (y_1, y_2, \ldots, y_n)$ denote the series of measurement of the reference laboratory equipment for a specific participant. The CCC is defined as,

$$\rho_c = \frac{2\sigma_{12}}{\sigma_1^2 + \sigma_2^2 + (\mu_1 - \mu_2)^2} = rC_b \tag{2}$$

where μ_1 and μ_2 denote the means of each series of measurements, σ_1 and σ_2 are the corresponding variances, and σ_{12} is the covariance between the two series of measurements. The CCC takes values between -1 and 1, where these values mean respectively a perfect discordance and a perfect concordance. McBride (McBride, 2005) suggests the following descriptive scale for values of the concordance correlation coefficient:

Value of ρ_c	Strength of agreement
>0.99	Almost perfect
0.95 - 0.99	Substantial
0.90 - 0.95	Moderate
<0.90	Poor

3 RESULTS AND DISCUSSION

Experimental results were obtained using data from 28 healthy participants (as described in section 2.1). The variables of interest are the heart rate (HR), breathing rate (BR) and estimated ventilation (Ve), which were measured simultaneously by Hexoskin and a laboratory reference equipment. CCC and ICC were calculated for the three variables of interest HR, BR and Ve for each participant. Simulations were performed using packages of the open source programming language and data science environment R.

Figures 4, 5 and 6 show the frequency distribution of the obtained intra-class correlation coefficient (ICC) and concordance correlation coefficient (CCC) values from all participants.

The HR measured simultaneously for each participant by the Hexoskin and the reference laboratory equipment revealed high CCC values (ρ_c between 0.98 and 0.99), and significant ICC values (ρ between 0.98 and 0.99, $p < 0.05$) for almost all participants (Figure 4). All ICC values are in the 95% confidence interval except for one participant (participant 12) who has a low CCC (ρ_c = 0.58) and a low ICC (ρ = 0.59, p-value < 0.05).

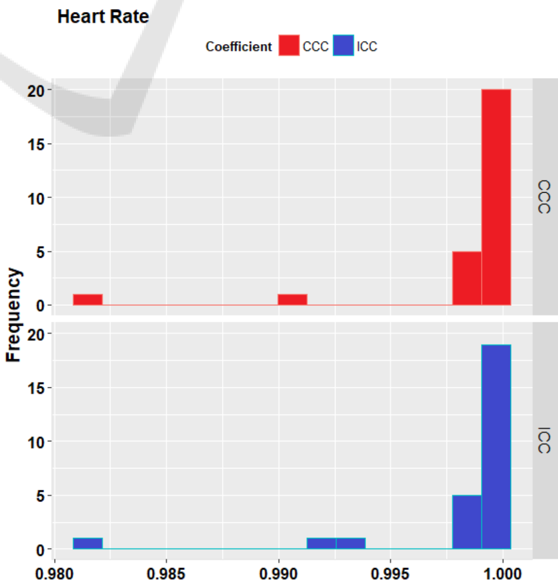

Figure 4: Histogram of the CCC and ICC values for heart rate, for all participants.

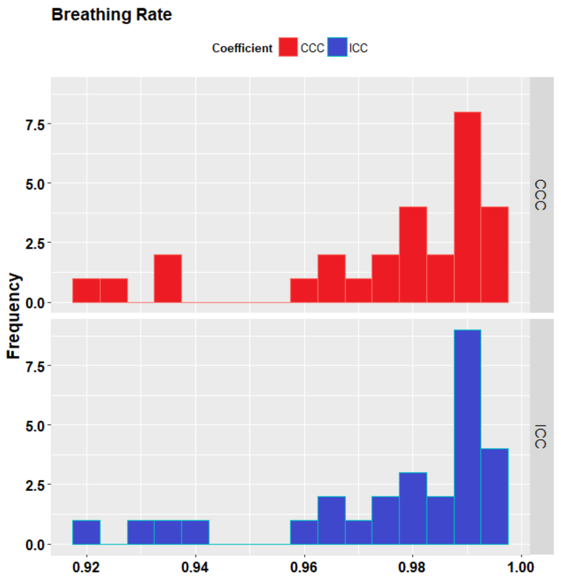

Figure 5: Histogram of the CCC and ICC values for breathing rate, for all participants.

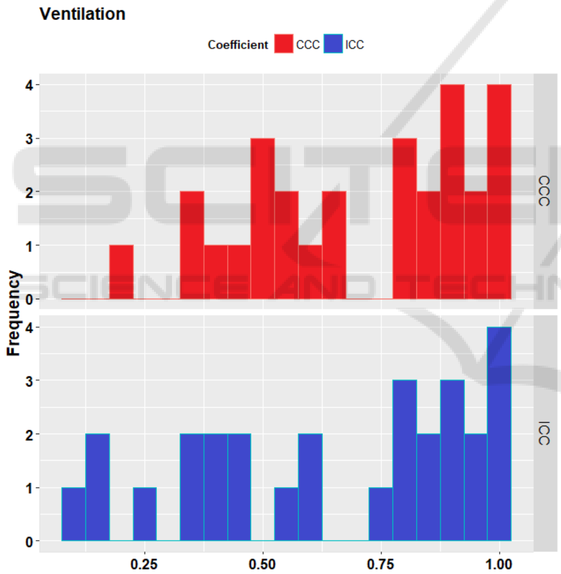

Figure 6: Histogram of the CCC and ICC values for Ventilation, for all participants.

The analysis of BR of each participant under exercise condition by the two measurement systems revealed high CCC values (ρ_c between 0.91 and 0.99) and significant ICC values (ρ between 0.91 and 0.99, $p < 0.05$) (Figure 5). All ICC values are in the 95% confidence interval.

The estimated ventilation (Ve) measured simultaneously by the Hexoskin and the laboratory reference equipment during a progressive maximal exercise test revealed doubtful values for each of the CCC (ρ_c between 0.2 and 0.99), ICC (ρ between 0.11 and 0.99) and C_b between 0.2 and 0.99 (Figure 6). It is noted that there is a significant difference between the two groups male and female in relationship to the CCC and ICC values. We observed that 8 out of 11 women (73%) had CCC values greater than 0.9, this goes to moderate to an almost perfect agreement according to the adopted scale (McBride, 2005). This can be explained by the fact that the two intelligent textiles are not made the same way for men and women.

Figure 7 shows the deviation from the 45° line. Recall that the model accuracy is evaluated with the bias correction factor C_b. A C_b equal to 1 indicates no deviation from the 45° line. Figure 7 (example 1) shows no deviation from the 45° line (C_b more than 0.99) for heart rate for one of the participants (all participants have almost the same graphs). With an average of ρ_c of more than 0.99, this corresponds to an almost perfect agreement with the scale proposed by McBride (2005). The results obtained with the numerical methods were confirmed by the Bland-Altman method. The Bland Altman results indicated no deviation of the bias (mean difference) from zero and relatively small variability with tight agreement limits.

Figure 7 (example 2) shows no deviation from the 45° line (C_b more than 0.99) for breathing rate for one of the participants (all participants have almost the same graphs). With an average of ρ_c of more than 0.97, this corresponds to a substantial agreement. The results obtained with the numerical methods were confirmed by the Bland-Altman method, the bias (mean difference) is close to 0 for all participants and the agreement limits are fairly tight. Figure 7 (example 3) shows no deviation from the 45° line for ventilation for one of the participants (female). However, example 4 (Figure 7) shows a large deviation of the 45° line for one of the participants (male).

4 CONCLUSIONS

In this study, we tested the sensor data extracted from the wearable textile Hexoskin. Specifically, we validated the cardiorespiratory variables measured with Hexoskin and with laboratory standard metabolic cart during a progressive maximal exercise test.

Using the Intraclass Correlation Coefficient, the Concordance Correlation Coefficient and the Bland Altman, we calculate the agreement between the two methods which revealed good agreement and low variability for heart rate and breathing rate. Hexoskin provides ventilation values from estimates, which is an important limitation of the Hexoskin.

The heart rate values are more accurate because they are calculated directly from the ECG signal using

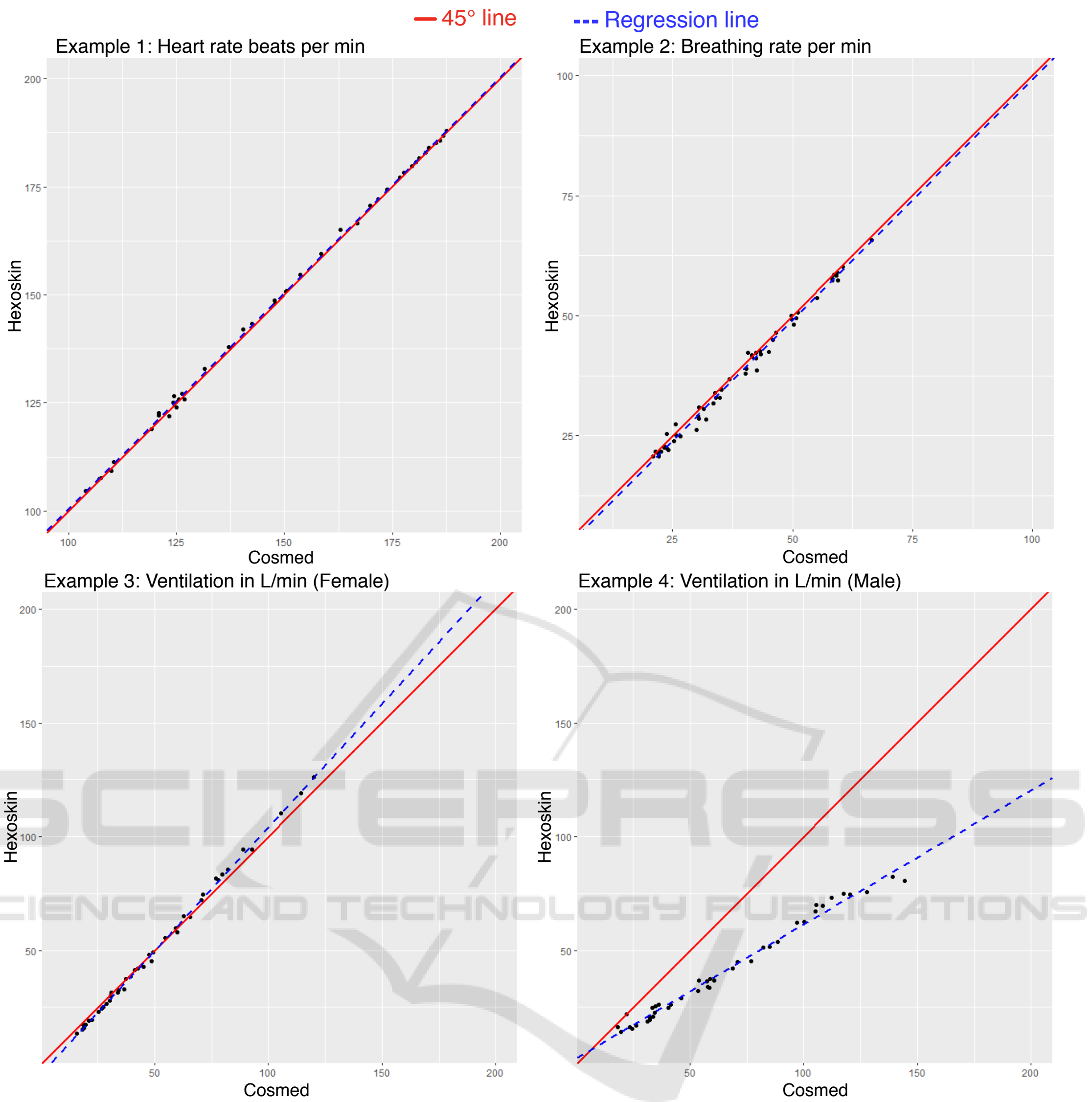

Figure 7: Graphical representation of the results of the two measurement systems for heart rate (example 1), breathing rate (example 2) and ventilation for one of the women and one of the men (examples 3 and 4). The 45° line represents the perfect match with the reference method.

the integrated electrodes. Same for the breathing rate which is calculated directly from the two integrated respiration sensors in the thoracic and abdominal levels. However, ventilation is an estimation provided using the two integrated respiration sensors.

This study confirm the good agreement for heart rate and breathing rate. However, for the ventilation, it remains difficult to conclude on the validity of Hexoskin because the results are variable.

ACKNOWLEDGEMENTS

The authors would like to thank the Natural Sciences and Engineering Research Council (NSERC), and the Canada Research Chair.

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