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Executive Summary of the Thesis

L.I.F.E. sensorized garments for noninvasive and continuous respiratory monitoring: validation in different experimental conditions.

Laurea Magistrale in Biomedical Engineering - Ingegneria Biomedica

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1. Introduction

Monitoring of ventilatory parameters is of fundamental importance in the clinical practice to assess ventilation functions ant to diagnose and supervise the progression of lung and heart diseases. Laboratory instrumentation used in clinical practice is considered the gold standard to assess ventilatory functions with accurate and reliable measurements, but is not suitable to continuously monitor the state of the respiratory system of the patients in a daily-life scenario. Recently, biomedical wearable systems have gained interest and relevance as devices which allow the continuous monitoring of ventilatory and cardiac functions during daily-life activities with minimized constriction on mobility. Various solutions with different measurement principle can be used to reach this goal, and among the available solutions body surface sensors are one of the most common choices. They measure the movement of the chest wall, rib cage or abdomen through different methods and equipment [1]. For example, it is possible to use Micro-ElectroMechanical System technology (MEMS) to reconstruct the three-dimensional movement of the chest wall [2]; or again, Respiratory Inductive Plethysmography (RIP) indirectly derives the variations by measuring changes in electrical impedance between a pair of electrodes or wires incorporated into elastic bands placed around the chest and abdomen [3]. Finally, strain gauges can be used to directly measure the changes in thoracic or abdominal circumferences during breathing. These last sensors and principle of measurement are the ones employed in this thesis work.

1.1. Aim of the thesis

This study aimed to validate three wearable devices produced by L.I.F.E. Italia S.r.l. (Milano, Italy), namely Healer R1, R2 and R3, during static exercises in different body-positions and in a dynamic setup while walking on a treadmill at different velocities and inclinations.

2. Material

2.1. L.I.F.E. Healer devices

L.I.F.E. Healer R1, R2 and R3 are upper-body smart multi-parametric garments which integrate a sensor network to measure and monitor physiological signals and parameters. In particular, they record ECG (6 or 12 derivations), the ventilation mechanics on three channels, SpO2,

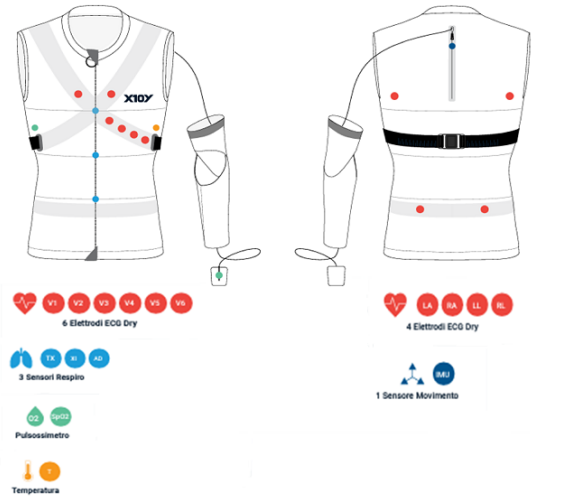

Figure 1: L.I.F.E. Healer R3 wearable device: sensor placement.

body position, body temperature and activity level. Each Healer device is connected to a Logger device plugged on the upper-back of the suit, which controls the acquisition, processing, storage and transmission of the recorded data. The structure of the L.I.F.E. Healer R3 is shown in Figure 1 as an example. For this study, only the three strain gauges sensors (with sampling frequency of 50Hz) were considered. They are positioned at the level of the thorax, xiphoid process and abdomen, as highlighted in Figure 1 by a blue dot. The three L.I.F.E. suits are produced in three different sizes (S, M and L) and in a male and female version, which differ in some structural features to better accommodate differences in anatomical features. The three L.I.F.E. devices differ, in addition to the number and position of the different sensors, by the way they fit when worn by the user. In fact, Healer R1 and Healer R3 shares the same shapes, proportions and dimensions, and are produced to be dressed in a comfortable and loose-like way; Healer R2 instead is characterized by a slim fit, resulting in a much tighter, yet comfortable fitting. Because of this, there exist little differences in the positioning and length of the three silicon strain-gauges in the three suits.

2.2. MicroQuark spirometer by COSMED

The MicroQuark spirometer produced by COSMED, coupled with the OMNIA software, has been chosen as gold standard instrument to validate the three wearable devices under test. This is a turbine-flowmeter-based spirometer, shown in Figure 2, which measures the volume of air flowing through its turbine by integrating the flow measured by the flowmeter, related to the rotation speed of the turbine. Volume or flow measurements have been acquired by the spirometer at 10Hz, the larger sampling frequency available.

Figure 2: MicroQuark spirometer by COSMED.

3. Methods

3.1. Experimental set-up

The study involved 13 healthy subjects (6 females and 7 males), and the acquisitions took place at the L.I.F.E. Italia s.r.l. headquarters in Milan. Each device has been tested with the same protocol for each Healer device, divided in static and dynamic exercises in different body-positions. During the static protocol, different exercises have been performed in different body-positions:

1. Laying
   (a) Prone: IC and SVC maneuvers
   (b) Right side: IC and SVC maneuvers
   (c) Supine: IC and SVC maneuvers
   (d) Left side: IC and SVC maneuvers
2. Sitting
   (a) IC and SVC maneuvers
   (b) Amplitude modulations
   (c) Frequency modulations
3. Standing
   (a) IC and SVC maneuvers

The dynamic protocol consisted into walking on a treadmill at different velocities (3.5 and 5km/h) and with different inclinations (flat or 12° slope). This acquisition protocol has been performed wearing one Healer device (R1, R2, R3) at time while breathing in and out through the spirometer and wearing a nose-clip.

3.2. Signal Processing

The measurement of the three strain gauges have been summed, in order to obtain the total volume dynamic of the chest wall. The total volume signal was then filtered through a LP filter with a cut-off frequency set to 1Hz. The volume signal measured by the spirometer has been oversampled from 10Hz to 50Hz in order to match the number of samples of the Healer wearable device.
The two signals were then synchronized by means of a cough stroke, a reference event induced in both measurement devices, to align the two signals and allow their further comparison. The subjects under test were instructed to perform a forced and maximal cough-stroke at the beginning and end of each exercise, which had to be produced by exaggerating the compression of the thorax and abdomen. Unfortunately, the cough-stroke in various measurements did not fulfilled all three requirements leading to some ambiguous and erroneous identification and ultimately to failure in signals synchronization, requiring in a few cases a manual identification.
Once the signals from the two instrument were synchronized, it was necessary to manage two features of the spirometer volume signal, which are the "offset error" and the integration drift. The first one is characterized by a return-to-default value event any time the spirometer does not sense any volume variation, hence non-zero flow for at least three seconds. The volume value is forcibly returned to $0mL$, resulting in a step change in the volume trace. Such an error had to be compensated by subtracting, or summing, the amplitude value before the offset step to the volume measurements after the discontinuity in volume. Regarding the integration drift, it occurs since the volume measured by the spirometer is computed by integration of the air flow through the turbine and any constant or offset summed to the flow will lead to a linear drift in the integrated volume. The source of errors can be various, ranging from leaks at the mouthpiece or steep changes in temperature and humidity of the ambient air. It has been compensated by subtracting the linear regression line computed on the minima points.
Maxima and minima points of both spirometer and Healer volume signals have been identified above and below the moving average (MA) value, computed through a MA filter on a variable temporal window of the signal. The alternation between a minimum and a maximum has been guaranteed, starting the identification from a minimum and terminating with a maximum. Ambiguous and contention cases have been solved by matching the minima (and maxima) of the Healer signal to the correspondent nearest minima (or maxima) of the gold standard spirometric volume signal. This approach helped resolving the vast majority of erroneous or indecisive breath pairings. Nonetheless in very particular cases the breaths were matched manually. A typical example of the processed signals is shown in Figure 3.
At this stage the signals have been fully processed and are guaranteed to have paired breaths, corresponding to the same respiratory events. This has been a crucial feature which allowed to compare the various parameters with a breath-by-breath logic.

3.3. Parameters extraction

Four ventilation parameters have been computed for both Healer and spirometric signals:

- Inspiratory volume V_I $[V]$ or $[mL]$: amplitude difference between the end and the beginning of the inspiratory phase of the current breath;
- Normalized inspiratory volume: normalization of each breaths by the mean amplitude of tidal breaths at rest;
- Inspiratory time T_I $[ms]$: time difference between the maximum and minimum of the same breath, hence between the end and the beginning of the inspiratory phase;
- Breathing rate f_B $[bpm]$: inverse of the time difference between two adjacent minima.

Parameters have been computed considering different sets of breaths depending on the type of exercise. In fact, the volume variation of spontaneous breaths following a large inspiration or expiration maneuver, as IC and SVC, are underestimated in the garment signal due to a slower elastic-return dynamic with respect to the one of the anatomical structures measured by the sensors. This turned out to be a systematic behaviour in the first breaths after the IC and SVC maneuvers, and for such corrupted breaths it had not been possible to compare the parameters relative to volume variations. Because of

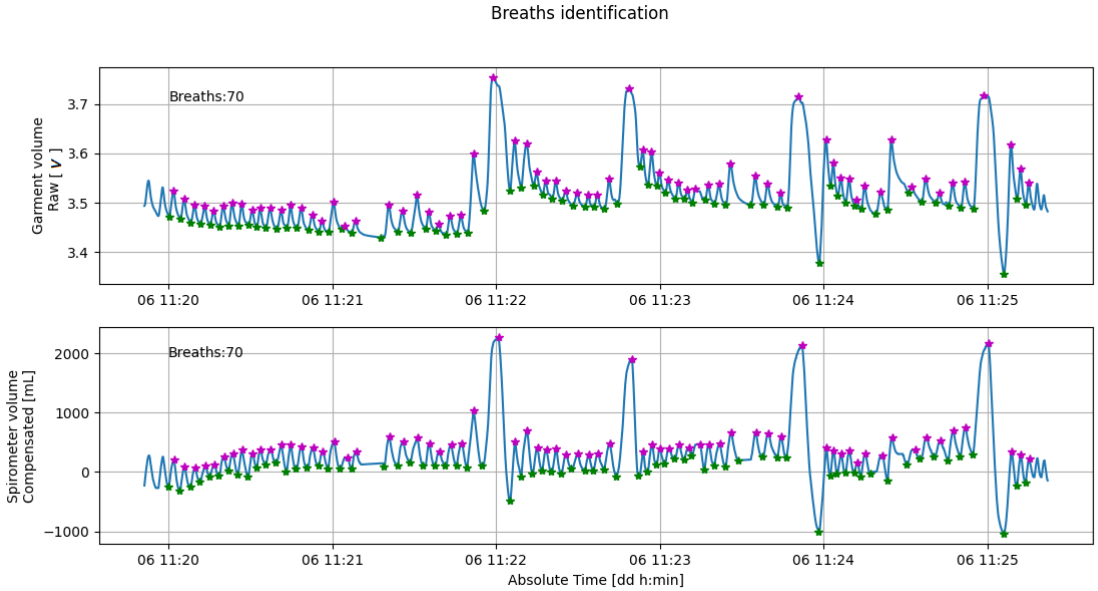

Figure 3: Breaths identification and matching: end of signal processing

such deformation in amplitude, the breaths during the maneuvers exercise have been classified into three different clusters: the spontaneous breaths before the first IC maneuver, the four inspiratory maneuvers (IC and SVC), and finally the inter-maneuver breaths. Such classification is shown in Figure 4.
Consequently, amplitude parameters are computed for spontaneous breaths during the first two minutes of exercise and for the maneuver breaths only; at the opposite, temporal parameters have been derived for all the breaths including the inter-maneuver ones since the non-ideal mechanical coupling between strain-gauges and body affected amplitudes only.

4. Results

The analysis of the results has been conducted both from a qualitative and a quantitative point of view. Scatter plots have been used to qualitatively assess the relationship of the parameters values measured by the Healer device with respect to the one measured by the spirometer. Mean Absolute Error (MAE), Mean Squared Error (MSE) and R^2 coefficients have been computed. A comparison between the estimation of these parameters is reported in 1, in which ΔV_I is estimated by quadratic regression in Healer R1 and R3 and by linear regression in Healer R2; ΔT_I and f_B are estimated by linear regression in each Healer device. Every breath has been included in these estimations. Finally a Bland-Altman analysis has been conducted to verify the concordance between the two devices.

Similar values of error have been derived when considering breaths recorded in static conditions, excluding IC and SVC maneuvers-related breaths, and in dynamic conditions. Among the parameters under analysis, respiratory rate is the one that is better estimated, with the least amount of error and the largest R^2 value. Regarding inspiratory volumes and time, it is possible to conclude that healer R2 is the most accurate between the three devices. The reason lies on the fact that Healer R2 has been designed with a slim-fit resulting more sensitive to stretch, while Healer R1 and Healer R3 are characterised by a looser-fit thus having a lower range of values.
Representing the parameters relationship for a single suit and for all the tested subjects, it has been depicted a situation in which each subject has a different regression curve. This subject-sensitive behaviour is stronger in inspiratory volumes, present in inspiratory time and almost absent when analysing respiratory rate. This led to the conclusion that a specific subject-to-subject calibration is necessary for volumes variations, while it is not necessary when monitoring inspiratory times and breathing rate.
Bland-Altman analysis described that the inspi-

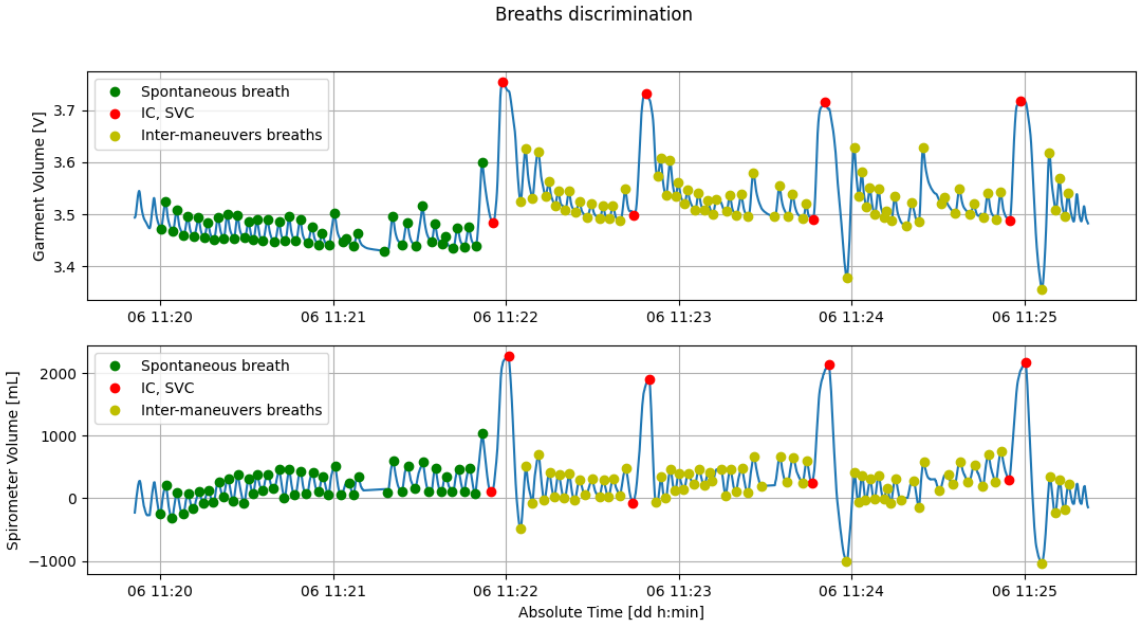

Figure 4: Breaths classification: Spontaneous breaths (green); IC and SVC maneuvers breaths (red); remaining inter-maneuvers breaths (yellow).

ratory volumes and times are moderately underestimated, with a bias proportional to the measured value. This behaviour can be attributed to the strain-gauge dynamic, inversely proportional to the amplitude of volume variation. Regarding the respiratory rate it resulted that L.I.F.E. suits do not have any bias in measuring breathing frequency, and have a small standard deviation. This appreciable result is coupled with a strange behaviour, since it appears to exist a dependency between the difference and mean of the measurements above a measured rate value. Nonetheless, it appears that the breaths taken in analysis fall, for the most part, within the concordance limits for every ventilatory parameters discussed.

This whole discussion stands for all the three breaths datasets, namely in static conditions (maneuvers excluded), dynamic conditions, or considering all the acquired breaths.

5. Conclusions

In conclusion, it has been demonstrated the necessity of a dedicated calibration for each subject when measuring volume or time inspiratory parameters. Meanwhile, if the only variable of interest is the breathing rate, a common calibration computed on the mean response of several subjects can be employed with accurate results. No significant difference exists in the responses in static or walking conditions, but in a setting in which forced maximal breathing maneuvers are required, as during a spirometric test, the volumes measured by the L.I.F.E. Healer devices resulted inaccurate and non reliable while the respiratory rate is accurately measured. In fact at maximal inspiratory and expiratory volumes, or during extreme variations of volume, the strain-gauges show an elastic-return dynamic much slower than the anatomical dynamic of expansion/compression of the chest wall. Furthermore, the strain-gauge dynamic of elastic return appeared to be inversely proportional to the amplitude of volume variation. The structural characteristic of these piezo-resistive sensors worsen the measurement of temporal and volume parameters.

Fit was found to be a determinant factor into reducing the subject-sensitive behaviour of ventilatory variables. Since L.I.F.E. Healer R2 device has been designed to be worn with a tighter fit, it shows a decreased user-variant response.

A tendency to underestimate inspiratory volumes and times has been underlined in L.I.F.E. Healer devices when compared to the COSMED gold standard. Such negative bias is also proportional to the amplitude of the

	MAE	MSE	R^2
R1: ΔV_I	0.37 ± 0.14	0.35 ± 0.26	0.81 ± 0.097
R1: ΔT_I	$0.22 \pm 0.066\ s$	$122 \pm 65\ s^2$	0.81 ± 0.13
R1: f_B	$0.71 \pm 0.23\ bpm$	$1.6 \pm 1.1\ bpm^2$	0.97 ± 0.016
R2: ΔV_I	0.17 ± 0.11	0.35 ± 0.26	0.89 ± 0.052
R2: ΔT_I	$0.19 \pm 0.073\ s$	$99.2 \pm 62.7\ s^2$	0.85 ± 0.12
R2: f_B	$0.82 \pm 0.44\ bpm$	$2.5 \pm 3.3\ bpm^2$	0.96 ± 0.039
R3: ΔV_I	0.32 ± 0.26	0.43 ± 0.97	0.80 ± 0.091
R3: ΔT_I	$0.21 \pm 0.096\ s$	$154 \pm 121\ s^2$	0.82 ± 0.10
R3: f_B	$0.79 \pm 0.39\ bpm$	$2.4 \pm 2.0\ bpm^2$	0.96 ± 0.024

Table 1: Estimation errors of normalized ΔV_I, ΔT_I and f_B computed for every L.I.F.E. Healer device considering every breath.

parameter. Even in this case, the respiratory rate has been the one having the best estimate, with almost one-to-one correspondence with the gold standard and not showing any bias. Inspiratory volumes measured by the L.I.F.E. Healer devices can not be considered in complete agreement with the gold standard, due to the large dispersion of values. On the contrary, inspiratory time and respiratory rate can be considered concordant with the one measured by the gold standard, in both static and dynamic settings.
It also appeared how the slim-fit of the L.I.F.E. Healer R2 garment, tighter than the other two suits, has been determinant for the good behaviour of the sensors, which reflected in a more subject-insensitive regression curve for both relative inspiratory volumes and inspiratory time when compared to the same behaviour of the other models.

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