Characterization of a PPG Wearable Sensor to Be Embedded into an Innovative Ring-Shaped Device for Healthcare Monitoring

Laura Fiorini, Filippo Cavallo, Mihail Martinelli, and Erika Rovini

Abstract Wearable sensor technologies have emerged as a revolutionary technique for real-time monitoring of physiological parameters, particularly for healthcare applications. To guarantee their use, the sensors should be embedded in everyday equipment improving their wearability. In this context, the MAX30102 wearable sensor was studied and characterized for the monitoring of the PPG signal acquired on the index finger. Heart rate (HR), heart rate variability (HRV), and oxygen saturation (SpO_2) measures were extracted from the PPG signal according to the pulse oximetry principles, by analysing the red and infrared signals detected by the LEDs embedded in the sensor. A valuation test was performed to compare the measures obtained by the MAX30102 with those achieved by two gold standard instruments used in clinical practices for cardiac and pulse oximetry measurements. The achieved results are promising, evidencing error rates lower than 2.5% for all the measures. The possibility to integrate such sensor in a ring-shaped device able to measure the vital parameters for health status monitoring can support the clinicians both in clinical and home settings for improving diagnosis, personalized treatments, and long-term monitoring.

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1 Introduction

Over the last two decades, wearable technologies, low-power electronics, Internet of Things (IoT) and communication systems are hugely improved. The demand for wearable devices has increased a lot in different fields of application, including sport and fitness, consumer electronics, games and entertainment, and particularly healthcare [1], where the use of wearable systems has become more and more common both in clinical and home settings for vital-signs monitoring [2]. Typically, wearable systems are wireless, with miniaturized sensors embedded in patches or equipment and they can be worn such as a watch, ring, and clothes to acquire data from wrist [3, 4], fingers [5], or chest [6]. These wearable sensors allow the measurement of motion and physiological parameters that can be stored, wirelessly sent to a database server, and consequently used to potentially help healthcare professionals on diagnosis, treatment, patient monitoring and prevention, also developing personalized treatment plans [7]. According to the World Population Ageing report, the population is progressively ageing, and the number of older persons is expected to double again by 2050 when it is projected to reach nearly 2.1 billion [8]. Thus, health and social care services have to be adapted to the complex care needs of an increasingly older population.

1.1 Wearable Sensors for Physiological Signals Monitoring

Wearable sensors able to measure physiological signals that can be useful for helping people in health status monitoring are recently increasing. According to the literature [9], heart rate and blood oxygen saturation are among the five traditional vital signs that have major importance to be measured to ensure clinical monitoring and allow to identifying potential health deterioration.

1.1.1 Heart Rate and Heart Rate Variability

For decades, physicians have used electrocardiograms (ECGs) to find heart-related diseases such as some forms of arrhythmias that can be caused by myocardial infarction and which in turn can lead to cardiac arrest. To avoid these consequences is required to detect the cardiac activity in the long-term and to treat all in an early stage. The ambulatory monitoring is not able to detect some rare, infrequent arrhythmias (e.g. arrhythmogenic right ventricular cardiomyopathy, long QT syndrome, hypertrophic cardiomyopathy), thus it is necessary to wear a wearable monitoring system that could not prevent normal daily activities. Some researchers have introduced system-on-chip technologies that are an integration of both analogue and digital signal processing units for ECG analysis. Izumi et al. [10] developed a system that incorporated a near field communication (NFC) module, a three-axis accelerometer,

and an ECG processor chip. This chip obtains data, processes ECG and accelerometer signals and communicate with the smartphone. Another wearable ECG monitoring system were designed in a custom T-shirt and textile belts with embedded textile electrodes. These electrodes were made from silver-based conductive yarns, and they relied on body sweat, an electrolyte medium, that improves the conductivity of the skin–electrode interface and signal quality and to avoid the use of conducting gel that can have potential toxic and irritant effect on the skin on long-term [11].

Heart rate (HR) and Heart Rate Variability (HRV) are the two most common parameters extracted from ECG to monitor the cardiac activity. HR is a standard vital sign that represents the number of beats per minute and has become a routine measurement in healthcare as well as in fitness activities. HRV represents the variation of the heart rate, meant as the time interval between two consecutive peaks R in the typical ECG signal. HR and HRV can be measured both from the ECG or from the photo-plethysmography (PPG) even if the origin of these two physiological signals and their waveforms are quite different [12]. Pulse signal derived by PPG has been proposed as an HR-related measure that can substitute it. It is produced by the increase of volume of blood pushed into the vessel caused by the alternate contraction/relaxation of the heart that results in a palpable rhythmic expansion of an artery. Strength, amplitude and regularity of pulse are additional information that can be extracted from pulse signal respect to the HR [9].

The HRV is a reflex of the autonomic nervous system (ANS) that regulates heart rate, blood pressure, breathing, galvanic skin response, and digestion. The HRV is a human psychophysiological status indicator, so it is a useful and non-invasive parameter to identify ANS imbalances, like stress, poor sleep, unhealthy diet, and lack of exercise, and it is highly correlated to the cortisol level [13], which is a physiological biomarker for stress. HRV analyses have previously been used in different studies to detect stress during mental tasks [14], high workload [15], and car driving [16], as well as for emotion recognition purpose [17].

Low HRV can be an indicator of unhealthy ANS because there is no ability to switch gears, showing more resilience and flexibility; indeed, some researches have shown a relationship between low HRV and depression or anxiety like an individual with post-traumatic stress disorder (PTSD) [18]. Differently, high HRV is typical in people who have greater cardiovascular fitness, be more resilient to stress [19] and healthy, and in case of calm and positive emotions.

1.1.2 Blood Oxygen Saturation

Blood oxygen saturation can be measured from the PPG on the basis of pulse oximetry principles reading the peripheral oxygen saturation (SpO_2). The pulse oximetry is an alternative safe, inexpensive and non-invasive method to the traditional invasive arterial blood gas (ABG) analysis.

The PPG signal is a time-varying voltage signal related to the light absorbed by the human blood and it reflects changes in arterial blood volume [20]. The Lambert–Beer's law regulates the absorption of light by a substance where a monochromatic ray

of light with I_0 intensity crosses a medium containing a light absorption substance, a part of this light is absorbed by the medium, a part is transmitted through the substance and the remaining part is reflected by the medium.

The transmitted light decreases exponentially along the way according to Lambert–Beer's law (Eq. 1):

$$I = I_0 e^{-\varepsilon(\lambda)cd} \tag{1}$$

where $\boldsymbol{I}$ denotes the intensity of light at the skin surface, $\boldsymbol{I_0}$ is the baseline intensity of light, and $\boldsymbol{e^{-\varepsilon(\lambda)cd}}$ models the arterial absorption, which depends on the extinction coefficient of the medium $\boldsymbol{\varepsilon(\lambda)}$ at the wavelength $\boldsymbol{\lambda}$, the substance concentration $\boldsymbol{c}$ that absorbs the light within the medium, and the arterial pulsating displacement $\boldsymbol{d}$. The transmittance $\boldsymbol{T}$ is the ratio between the intensity of light transmitted $\boldsymbol{I}$ and the baseline intensity of light $\boldsymbol{I_0}$ (Eq. 2):

$$T = \frac{I}{I_0} = e^{-\varepsilon(\lambda)cd} \tag{2}$$

Consequently, the absorbance A is defined as in Eq. 3:

$$A = -\ln(T) = \varepsilon(\lambda)cd \tag{3}$$

For pulse oximetry, it is assumed that the haemoglobin in the blood can be in two states only: the reduced state (Hb) and the oxyhaemoglobin state (HbO_2). Haemoglobin absorbance spectrum, indeed, changes when it bounds with oxygen, allowing the estimation of blood oxygen saturation according to the following relationship (Eq. 4):

$$SpO_2 = \frac{[HbO_2]}{[HbO_2] + [Hb]} \cdot 100\% \tag{4}$$

where $[HbO_2]$ represents the concentration of oxyhaemoglobin in the blood, while [Hb] is related to the deoxygenated haemoglobin concentration. Pulse oximetry, indeed, exploits the different light absorption spectra between Hb and HbO_2 using two different light wavelengths (i.e., $\lambda_1 = 660$ nm for the red light spectra, and $\lambda_2 = 880$ nm for near-infrared light spectra). The Hb has a higher absorption at 660 nm, whereas HbO_2 has a higher absorption at 880 nm [21].

There are two modes for measuring pulse oximetry: the transmittance or the reflectance mode. In the first case, the light-emitting diodes (LEDs) and the receiving photodiode are placed in the opposite side of the measurement site (e.g., the fingertip), and the light is absorbed from skin, bone, muscle in the body, thus it is attenuated at photodiode level. In the latter mode, differently, the LEDs and the photodiode are on the same side of the body site, offering greater flexibility of use [3].

The PPG signal is composed by the direct current (DC) component and the alternating current (AC) component. The DC component is related to the light absorption of the tissue, venous blood, and non-pulsatile arterial blood and it represents the offset of the signal. On the other hand, the AC component represents the pulsatile arterial blood and it is related to the amplitude of the signal. The SpO_2 depends on the modulation Ratio, which is calculated using the DC and AC components of both red (RED) and infrared (IR) signals according to the following equation (Eq. 5):

$$\text{Ratio} = \frac{AC_{RED}/DC_{RED}}{AC_{IR}/DC_{IR}}. \tag{5}$$

The Ratio is then converted to SpO_2 value through a linear relationship (Eq. 6), where A and B are parameters empirically identified by means of a calibration process (see par. 2.2.1):

$$SpO_2 = A - B \cdot \text{Ratio} \tag{6}$$

The normal range of oxygen carried by blood cells in healthy individuals is 95–100%. If the SpO_2 is $\leq$94%, the patient is hypoxic and needs to be treated quickly since insufficient oxygen supplies to the human body. Finally, $SpO_2 < 90\%$ represents a clinical emergency [22]. Monitoring of oxygen level is particularly important during sports activities, as well as for ambulatory monitoring in a clinical environment, and at home for long-term monitoring.

1.2 The Aim

Using PPG has some advantages but also technical limitations such as the incorrect position, partial inhibition and possible pain during a continuous acquisition with clip-fingertip pulse-oximeter. For this reason, a ring-shaped blood saturation monitoring system can be introduced as an alternative to the classical finger-tip pulse-oximeter probe being more comfortable and easy to adapt.

The aim of this work is to study and to test the ability of a prototype of a wearable physiological sensor system, to be integrated into an innovative ring-shaped device, to measure vital parameters such as blood oxygen saturation (SpO_2), heart rate (HR) and heart rate variability (HRV) extracted from the PPG signal. Additionally, the reliability of the measures is also investigated by comparing them with two gold standard devices. The ultimate goal of this wearable system is to integrate many types of sensors in a single power-saved device for physiological monitoring, which can be used daily, both in clinical and home settings.

2 Materials and Methods

In this paragraph the proposed system is described (Sect. 2.1), then a description of the two systems characterization was also proposed (Sect. 2.2). Finally, Sect. 2.3 reports a description of the analysis conducted to preliminarily validate the system thus to achieve the goal of the paper.

2.1 System Description

The module was developed by using an STM32-F103 board (STMicroelectronics), which is based on an ARM 32-bit Cortex™-M3 processor. The PPG sensor chosen is the MAX30102 (Maxim Integrated™, San Jose, CA, USA) that is controlled by means of an I^2C port. This sensor was selected because of its ultra-low power consumption, miniaturization, robust motion artefact resilience with a high Signal–Noise Ratio (SNR) and its use in similar application [23]. This sensor is placed on the first phalanx of a finger to detect HR, HRV, and SpO_2. The board size of 12.7 × 12.7 mm is compatible with its future integration in a ring-shaped sensor. During this work, the data were sent to a computer at a frequency of 100 Hz through a USB port, but in the next development, a wireless Bluetooth connection will be implemented.

As concern the operative condition, the MAX30102 works in the reflective mode (i.e., LEDs and photodetector on the same side of the finger). The sensor is composed of two LEDs (i.e., red LED with $\lambda = 660$ nm and infrared LED with $\lambda = 880$ nm), that can be managed by ranging the current from 0 to 50 mA, and the pulse width from 69 to 411 μs. In this study, the LEDs pulse width was set to 69 μs and LEDs current to 50 mA. Additionally, in order to manage the data acquisition, the data storage and the communication with a PC, a custom application was developed in C# language in Visual Studio (Microsoft Corporation, Washington, USA) (Fig. 1).

2.2 Experimental Set-Ups

Two experimental set-ups were carried out. Firstly, a bench-test was performed to calibrate the SpO_2 signal acquired from our system; then the system was finally evaluated.

2.2.1 System Characterization

Prior to validating the system, it should be calibrated in order to correlate the coefficient Ratio with the SpO_2 value acquired from the gold-standard instrument thus to create an output-input relation between SpO_2 (output) and the PPG signal (input). In

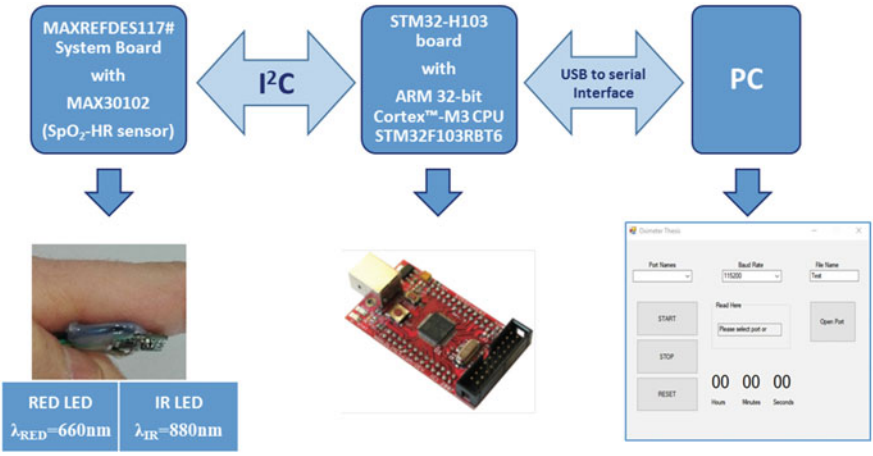

Fig. 1 System Block diagram

this work, the OXY-5 GIMA was used as reference instrument since it is commonly used as professional wireless fingertip oximeter [24]. The SpO_2 measurement range is between 35 and 99%, whereas the SpO_2 resolution is equal to ±1%. The measurement accuracy is equal to ±2% within the SpO_2 operative range 75–99%.

The user was asked to wear the proposed system on the first phalange of the index finger and the OXY-5 on the medium finger. During this test, the user was asked to stay in a rest position for 7 min breathing slowly in order to decrease the SpO_2 level from 99% (a healthy normal level) to 92% (a hypoxic level still over the dangerous level). The data from the OXY-5 was recorded every 10 s. This calibration procedure was performed four times from a young healthy no-smoked subject aged 26 years old.

2.2.2 System Evaluation

The proposed system evaluation The BioHarness™ 3 (BH3) is a chest belt capable of measuring ECG at a frequency of 250 Hz, providing also HR and HRV at a frequency of 18 Hz; it was used for research purpose in similar applications [13, 17, 25]. Even if the BH3 is not a clinical gold-standard, according to Casaccia et al. [25], the accuracy in measuring the cardiac parameters starting from the values computed on-board by the device is high. Thus, this sensor was used in this study as reference and HRV values from BH3 were measured using the preprocessed data directly provided by the device.

Differently, data from OXY-5 were recorded each 10 s, as described in the previous paragraph (see par. 2.2.1).

A total of 8 healthy subjects (5 male and 3 female subjects, mean age ± standard deviation (SD) of 25.88 ± 3.92 years old) were enrolled for this test. Prior to starting

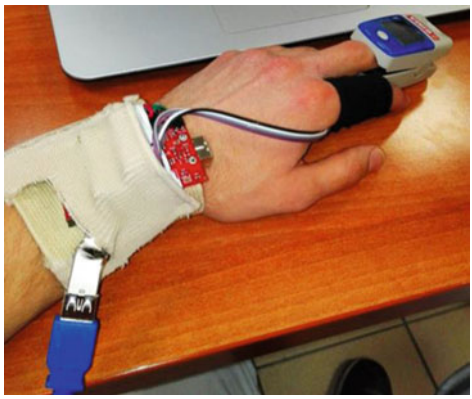

Fig. 2 The MAX30102 sensor is worn at first phalange level of index finger (similarly to a ring) whereas the commercial pulse oximeter OXY-5 is located on the medium finger-tip

the test, the users were asked to wear all the sensors at the same time. The proposed system and the OXY-5 were worn as depicted in Fig. 2, while the BH3 was appropriately worn on the chest. Then, the participants were asked to sit in front of a PC and to perform the 10-min test according to the following sequence:

1. **Relax phase**: subjects were asked to remain sitting with closed eyes for 1.5 min. No interaction between subjects and environment was allowed.
2. **Vision phase**: subjects were asked to watch a thriller film trailer for 2.5 min.
3. **Reading phase**: participants were asked to read loudly and as fast as possible for a total of 1 min.
4. **Apnoea phase**: subjects were asked to retain breath/breath slowly as long as possible for 3 min, thus to create a condition of mild hypoxia.
5. **Final relax phase**: subjects were asked to rest for 2 min with eyes closed in order to re-establish the normal physiological status.

All the trials occurred in a room with temperature and light conditions maintained constant for the entire duration. Then the data was retrieved and off-line analysed to compare the HRV, HR, and SpO_2 values simultaneously measured with the three devices over the five phases of the proposed protocol.

2.3 Data Analysis

The physiological data acquired during the two tests were analysed offline using Matlab® R2018a (MathWorks, Massachusetts, USA). The data from the MAX30102 was pre-processed. Firstly, a moving mean filter was applied to remove the trend of the signals and to correctly manage the baseline variation. Then, the values of the signal higher than the mean values plus three times the SD were removed by using the shape-preserving piecewise cubic spline interpolation. These outliers could be related to some pathologies in cardiac rhythm to the electrical conduction system - i.e.

the cardiac ectopy, ventricular extras systoles. Finally, the wavelet filter belonging to the Daubechies family ('db-45') was applied to smooth the signals and to highlight the peaks. Then, the IR-LED peaks and the RED-LED peaks were detected with the *findpeaks* Matlab function (Matlab R2018b).

Moreover, the Ratio of the direct current (DC) component and pulsatile alternating current (AC) component was computed as reported in Eq. 5 (see par. 1.1.2).

According to the relationship in Eq. 6 (see par. 1.1.2), the linear regression between the Ratio-values of MAX30102 and OXY-5 was computed for the calibration procedure, thus to link the Ratio-value with the SpO_2. Additionally, the coefficient of determination (R^2) and the root mean square error (RMSE) were calculated to evaluate the goodness of the implemented linear fitting.

As concern the system evaluation, the HR, HRV and SpO_2 were computed from the PPG signal. Particularly, the HR value was calculated by counting the peaks of the IR-LED signal over 60 s (t) (Eq. 7):

$$\mathrm{HR} = \frac{\#\mathrm{IR} - \mathrm{LED}_{\mathrm{peaks}}}{\mathrm{t}} \tag{7}$$

whereas, the HRV is measured as the mean time distance between two consecutive peaks in the IR-LED signal. HR and HRV were calculated with the IR-LED signal since it is more intense and more stable than the RED-LED one. As concern the gold standard measures, we used the ones measured directly by the devices.

HRV, HR and SpO_2 values were calculated for each phase of the protocol and for each subject. Then, the error rate (Eq. 8) and the absolute error (Eq. 9) were computed to compare and evaluate the performance of the proposed device.

$$\text{Error Rate} = \frac{(reference\ value) - (MAX30102\ value)}{(reference\ value)} \times 100\% \tag{8}$$

$$\text{Absolute Error} = |(reference\ value) - (MAX30102\ value)| \tag{9}$$

3 Results

The linear regression analysis reveals a good coefficient of determination ($R^2 = 0.80$) and a low RMSE value (RMSE = 1.14) between the Ratio values computed from the PPG signal and the SpO_2 values measured with the gold standard instruments (Fig. 3). Equation 10 reports the linear relation between the Ratio and the SpO_2 values empirically found from the calibration procedure:

$$\boldsymbol{SpO_2} = 110.87 - 36.83 \cdot \boldsymbol{Ratio} \tag{10}$$

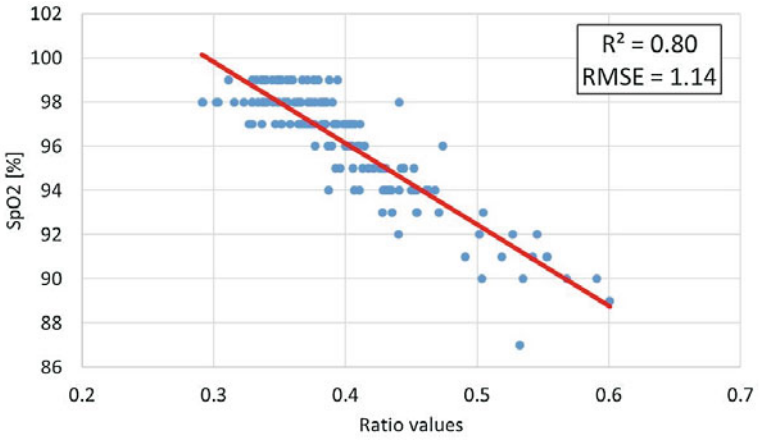

Fig. 3 Linear regression between the Ratio coefficient obtained from the PPG signal and the SpO_2 value measured with the OXY-5 GYMA

The evaluation results obtained from the analysis of HR, HRV and SpO_2 data are reported in Table 1 as the mean values and the SDs of the error rate and absolute error between MAX30102 sensor and the reference device.

Particularly, the HR values obtained from MAX30102 sensor are very similar to those obtained from the BH3 device as depicted in Fig. 4. Indeed, the error rate is below 1.44% in all phases except in the apnoea phase that it is equal to 2.54% (see Table 1).

Table 1 Means and standard deviations (SD) of HR, HRV and SpO_2 values of error rate and absolute error from all subjects divided into five phases

		Relax	Vision	Reading	Apnoea	Final relax
		Mean ± SD	mean ± SD	mean ± SD	mean ± SD	mean ± SD
HR	Error rate [%]	1.44 ± 0.79	1.30 ± 0.97	1.35 ± 1.46	2.54 ± 2.25	1.28 ± 0.91
	Absolute error [bpm]	1.00 ± 0.55	0.99 ± 0.90	1.00 ± 1.00	1.82 ± 1.49	0.94 ± 0.68
HRV	Error rate [%]	0.32 ± 0.26	0.95 ± 1.33	1.35 ± 1.78	1.17 ± 1.37	0.93 ± 0.65
	Absolute error [s]	0.003 ± 0.002	0.007 ± 0.009	0.010 ± 0.013	0.010 ± 0.012	0.008 ± 0.006
SpO_2	Error rate [%]	1.70 ± 1.38	1.45 ± 1.17	1.02 ± 0.58	1.03 ± 0.91	1.78 ± 1.42
	Absolute error [%]	1.7 ± 1.4	1.4 ± 1.2	1.0 ± 0.6	1.0 ± 0.9	1.8 ± 1.4

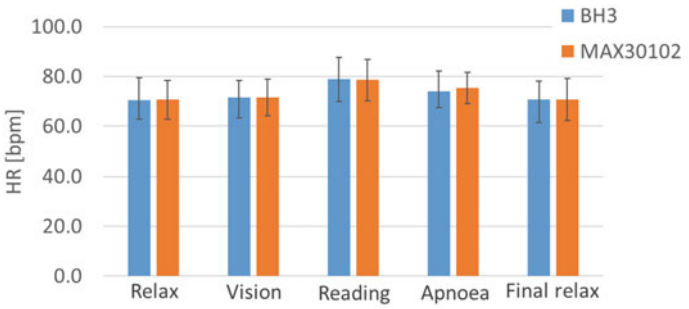

Fig. 4 Comparison of the HR values computed with the proposed device (MAX30102) and the BH3

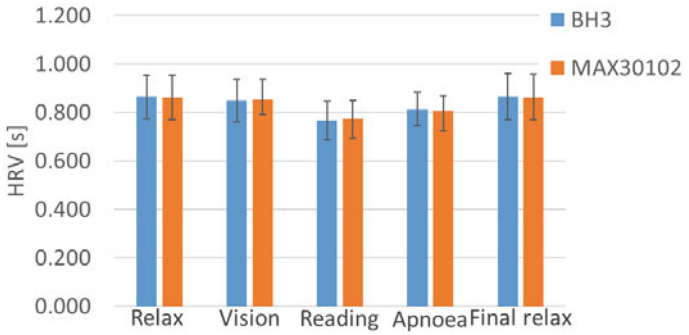

Fig. 5 Comparison of the HRV values computed with the proposed device (MAX30102) and the BH3

Also, the HRV comparison reports an error rate below 1.35% during all the five phases, and related absolute errors in the order of milliseconds. The high correlation between the measurements obtained with the two instruments is also evidenced in Fig. 5, where mean values and related SDs for HRV are reported.

As concern the comparison of SpO_2 values, the mean error rate is below 1.78% (Table 1) and the absolute error ranges between 1 and 1.8%. Figure 6 shows and compares the mean values of SpO_2 measured with the proposed system and the reference device.

4 Discussion

This work aimed at characterizing and testing a physiological sensor (i.e., MAX30102) able to measure the PPG signal from a finger for extracting and monitoring vital parameters, such as HR, HRV, and SpO_2. The preliminary results

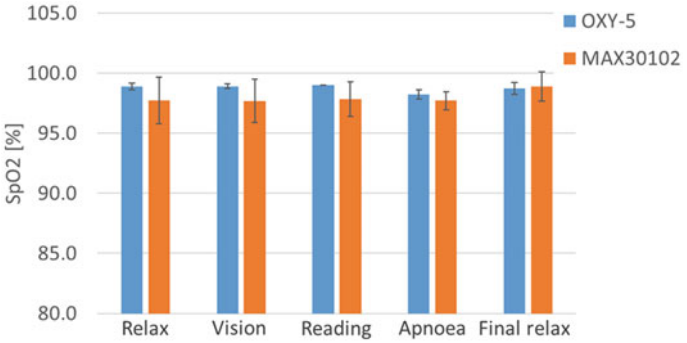

Fig. 6 Comparison of the SpO_2 values computed with the proposed device (MAX30102) and the OXY-5

presented in this paper are promising since the parameters extracted from the proposed system are comparable to those measured with the gold standard systems.

The obtained error rate is lower than 2.5% for all the measurements (Table 1) that is aligned with the state of the art. Indeed, in clinical studies, it was found that the accuracy for a single measurement of SpO_2 is 3–4% and for monitoring SpO_2 in a specific patient is about 2–3% [20]. It is worth to mention that measured HRV reports an excellent estimate error (average error rate equal to 0.94%), which is comparable with another similar work, which obtained an average normalized root-mean-square deviation (NRMSD) error equal to 2.05% [12]. Additionally, it is worth to underline that the system calibration obtained an R^2 coefficient equal to 0.8 that is comparable with another similar research [22].

The error in the measurements could be related to the light and sensor adherence, but also to the body movements that could influence the optical properties of local vessels because of the blood flow improvements. Expectably, such problems will be solved by integrating the sensor within the ring case that will be designed in order to maximize the contact area between the finger and the sensor, so reducing the amount of external light absorbed. Furthermore, the physiological measurements could be corrected by sensor fusion strategies using the MAX30102 and inertial sensors [26].

According to the preliminary results, the MAX30102 sensor has been embedded in a PCB layout and integrated into a ring-shaped sensor system where there are a microcontroller STM32, a Bluetooth module, some command buttons and a micro-B type USB port (Fig. 7). In order to reduce the motion artefact, an inertial measurement unit was also integrated into the ring. The idea to couple the measurement of physiological signals with inertial sensors lead towards a system capable of working in long-term activity monitoring with high precision and reliability. Such a system would allow the use both in clinical and home settings, to identify potential changes in people health status, including human psychophysiological assessment. Timely identification of vital parameters variations, indeed, could support the clinicians' actions on

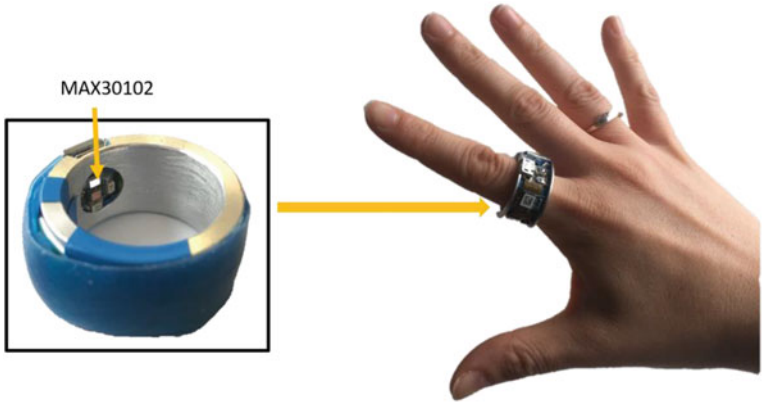

Fig. 7 MAX30102 integrated in a wireless ring-shaped device

diagnosis and treatment, developing also personalized therapy plans [27]. This application can be particularly useful for elderly and frail people that can require recurring monitoring of their physiological and motor status during their daily activities.

The main limitation of this study regards the reduced number of participants in the study, both for calibration and for validation tests. Future study should be planned to increase the number of participants obtaining a more heterogeneous dataset. Additionally, research efforts should be focused on the test of the ring-shaped device, optimizing the probe-finger coupling and the reduction of motion artefacts thus to obtain an innovative wearable physiological monitoring system. Furthermore, the acceptance of the system should be ensured, taking into account the users' needs that have to be investigated with particular attention when considering the application of the system for elderly and frail people.

5 Conclusion

The preliminary results obtained out of a comparison between our proposed system based on the MAX30102 sensor that measures SpO_2, HR and HRV parameters and two gold standard measuring the same features, namely BioHarness and OXY-5 GYMA were presented in this work. The obtained results revealed low error rate and low absolute errors yielded performance particularly comparable to the gold standards devices chosen as reference. This study is the first step to integrate the MAX30102 sensor into an innovative ring-shaped device with non-invasive sensing, local processing and feedback and communication capabilities to the user. Such system, able to measure the vital parameters of major importance for health status monitoring, can act as a reliable support system for clinicians that can use it both in clinical settings for improving the diagnosis as well as at home for long-term monitoring, favouring the development of personalized treatments.

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