Think Biosolution

Accuracy of Heart Rate, Heart Rate Variability and Respiratory Rate Using QuasaR™ Device

---

June 2019

Abstract

Background

The QuasaR™ remote patient monitoring platform (RPM) designed to help patients continuously track their health at home and in a clinical setting. The QuasaR™ is an end to end RPM platform, which includes the QuasaR™ device, App, HIPAA compliant cloud, dashboard, analytics, and REST APIs for integration. The QuasaR™ device is a wearable biometric tracking device that sits on the patient's chest (upper sternum) and is held in position with a strap. The QuasaR™ device also measures additional parameters such as the type of movement, number of steps per unit time, core body temperature, and GPS based location. The QuasaR™ platform's continuous monitoring dashboard reports the biometric and movement parameters on a timeline and can automatically tag medically significant events, such as a sudden rise in heart rate.

Objective

In this validation study, we compare the accuracy of the biometric signals derived from QuasaR™ device with an FDA approved medical device. For this study, the QuasaR™ device measures a continuous color PPG, which can then be post-processed to derive biometric parameters such as heart rate (HR), heart rate variability (HRV), and respiratory rate (RR) while the subject is at rest.

Methods

In this study, we did experiments on six healthy volunteers with the IR LED set at a brightness corresponding to 5.5 ohms. For each healthy volunteer, we measured the data three times.

Results

We analyzed ten subjects (7 men and 3 women) for this study. Their mean age is 34 years, and the mean weight is 74 kg, height of 159 cm. The subjects also had a wide range of skin color i.e., Fitzpatrick skin color range 1-V (I-VI is the total range) and body type (fat % from 6-28%).

For these ten subjects at rest we collected 15 sets of readings using the QuasaR™ device as mentioned in the above section. The measured heart rate (average = 76.3 BPM, minimum = 63.3 BPM, maximum = 94.5 BPM), heart rate variability (RMSSD) (average = 121.52 ms, minimum = 43.2 ms, maximum = 247.3 ms) and respiratory rate (average = 15, minimum = 6, maximum = 17) is correlated with the gold standard instrument method.

Conclusions

QuasaR™ can measure all three biometric parameters, heart rate, heart rate variability, and respiratory rate with clinical accuracy.

Introduction

Remote patient monitoring is becoming a critical part of telehealth. According to a survey published by Accenture in HIMSS 18, the consumer use of wearables in the US for health purposes has grown from 9% in 2014 to 33% in 2018 [1-9]. The study also found that this rapid growth was fuelled by consumers' demand for wearables to play a more active role in managing their health.

The benefits of integrating wearables with Electronic Medical Records (EMR) was also highlighted in a recent report from BCC Research, which predicts the global market for wearable medical devices to grow from $8.8 Billion in 2018 to $30 Billion by 2023. The report suggests that the three primary benefits of wearable medical devices include the ability of a physician to remotely monitor their patients, make informed decisions with continuous biometric data, and expand the reach of patient care to geographically isolated areas.

Large telehealth companies are currently partnering with fitness tracking and smart-watch brands to address the early adopter market. For example, American Well's Apple Heart Study uses data collected from Apple Watch to identify irregular heart rhythms, including those from potentially serious heart conditions such as atrial fibrillation.

Fuelled by the popularity of wrist-band based wearable companies, other wearable companies have introduced FDA approved and EMR compatible medical devices to be used in a hospital or at home. Companies such as Vitalpatch and Biotricity use single-lead ECG based devices, whereas Snap40, Valdic, and CouldDX use optical PPG combined with single-lead ECG based instruments to track one or more biometric parameters in clinical settings.

A 12-lead ECG is the gold standard signal that is used for monitoring HR and HRV. Single-lead ECG technology can also measure heart rate (HR) and heart rate variability (HRV) accurately, however miniaturizing and integrating them with fabrics in the apparel for regular use at an affordable price is a challenge. PPG sensors are less invasive (does not require electrical leads to touch the body) and therefore allow the subject to move freely. Besides, additional biometric parameters such as respiratory rate and blood oxygen saturation can be derived from PPG sensors. In this study, we aim to establish the accuracy of the color PPG sensor that can do multiple parameter tracking but has the accuracy of a single-lead ECG sensor.

Pulse/ HR is defined as the number of times the heart beats per minute and heart rate variability (HRV) is defined as the amount of variance between each consecutive heartbeat. HR is widely used in the assessment of cardiac health, such as predicting myocardial infarctions, and HRV is used in the study of the autonomic nervous system. In an exercise stress test, HR combined with speed is used to compute predictors like heart rate-running speed index, which can then be used to track and therefore improve the cardiac endurance of athletes. HRV, as a function of time, is used to determine if an athlete is overtraining. When the patient is not moving, both HR and HRV can be reliably measured using an optical sensor technology called photoplethysmogram i.e. where the variation of transmissivity and/or reflectivity of light is measured through the tissue as a function of arterial pulsation [10]–[12], followed by different signal post-processing approaches [10]–[14]. The wavelength under consideration varies from near-infrared (NIR) [10] to red or green [11] and even white flashlight [15] for fingertip based sensor systems. The accuracy in measuring HR and HRV using PPG based approaches can be affected by a variety of factors including, movement and skin color [16]–[18].

Respiratory rate (RR) is defined as the number of times you breathe per minute and is widely used to predict respiratory dysfunction and circulatory health of an individual in clinical settings. In sports medicine, RR is seldom

used as it is difficult to measure when the subject is moving. However, RR as a function of exercise intensity, can be used to distinguish between aerobic and anaerobic regimens. Measurement of RR in clinical settings typically consists of capnography, where the change in concentration or partial pressure of carbon dioxide is measured in exhaled respiratory gases, or pneumography, where the movement is measured as a change in pressure [19], [20]. Other less accurate ways of measuring RR include electrophysiological measurements analogous to electrocardiography (ECG) [21] or PPG [10]–[12], [22].

In Section II we first discuss the various experimental devices and then in Section III we discuss in details the experimental methods of how we record the data using the QuasaR™ device and compare it with a fingertip based Nonin Pulse Oximeter. This is followed by Section IV where we discuss the results and validate the performance of QuasaR™ device with Nonin Pulse Oximeter. In Section V we summarise current findings and discuss future work.

II. Experimental Device

A. QuasaR™ device

The QuasaR™ device is built using a custom PCB based and has the following components, a color sensor made by AMS, 9DoF MEMS sensor, MCU, Bluetooth module, power management IC, human body temperature sensor, GPS system. The color sensor with a red and an infrared LED on either side of it at a distance of 12.5mm is used as the sensor module. In "Continuous Monitoring" mode, the QuasaR™ device captures data for 300 seconds (5 minutes), and the color sensor is set up to capture at 30 frames per second. During these 300 seconds, the IR LED is kept ON, and the brightness is adjusted using a varistor set at 5.5 kOhms as default. The QuasaR™ device is further enclosed in a 3D printed plastic enclosure and is held in position using a chest-strap. The device is shown in Figure. 1.

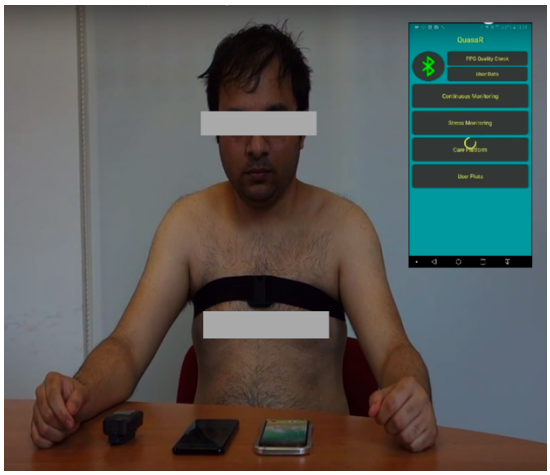

Fig. 1. QuasaR™ device and strap system

B. Gold Standard Devices

To compare the accuracy of the measurements, we have simultaneously measured the HR and HRV using the FDA approved Nonin Connect 3240 Wireless Finger Pulse Oximeter (Nonin Connect App). The subjects were made to

breathe at either 10, 15, or 20 breaths per minute by using a visual cue configured on the Breath Ball Desktop App for MacBook Air.

III. Experimental Method

A. Participants and Recruitment

Random selection of 6 subjects who volunteered to be part of the study from within the office space of the National Digital Research Centre (NDRC), Dublin 8, provides us with a convenient sample. Of the 6 healthy subjects, 66.66% (n=4) were men, and the mean age was 34 years. The participants had an average weight of 74 kg, average height of 159 cm. All subjects were accepted for testing except those under the with skin type VI on the Fitzpatrick scale. Body type was not a criterion for exclusion from the study. Exclusion criteria include refusal to give voluntary written informed consent for GRPR. Testing was done in a room with ambient lighting and temperature.

B. Experimental Setup

The goal of this study is to determine the accuracy of the QuasaR™ device. This study involved subjects sitting still with QuasaR™ device strapped onto their chest with a QuasaR™ strap for up to 6 minutes for each reading. The device first records for five minutes and then calculates the HR, HRV, and RR. HR and HRV are computed once every second whereas RR is computed once every 5 minutes.

Simultaneously the subject wore a Nonin Connect 3240 Wireless Finger Pulse Oximeter clipped on the index finder for the same length of time. The subjects also breathed at either 10, 15 or 20 breaths per minutes by using a visual cue configured on the Breathe Ball Desktop App for MacBook Air.

During this study, one of the authors helped the subject position the sensor module, and set up the strap such that enough vertical pressure was applied on the sensor module by adjusting the elastic chest-belt. For each subject three readings were taken.

IV. Results and Discussions

We will first visually compare the results between the QuasaR™ device (In Green) and Nonin Connect 3240 Wireless Finger Pulse Oximeter (In Red). Since we derive both the HR and HRV from the time-series peak to peak distance (as detailed in our previous whitepaper – "Measurement of Color PPG Using QuasaR™ Device"), so a high co-relation in HR between the QuasaR™ device and the FDA approved Nonin Connect 3240 automatically ensures a high co-relation in the HRV as well.

(A)

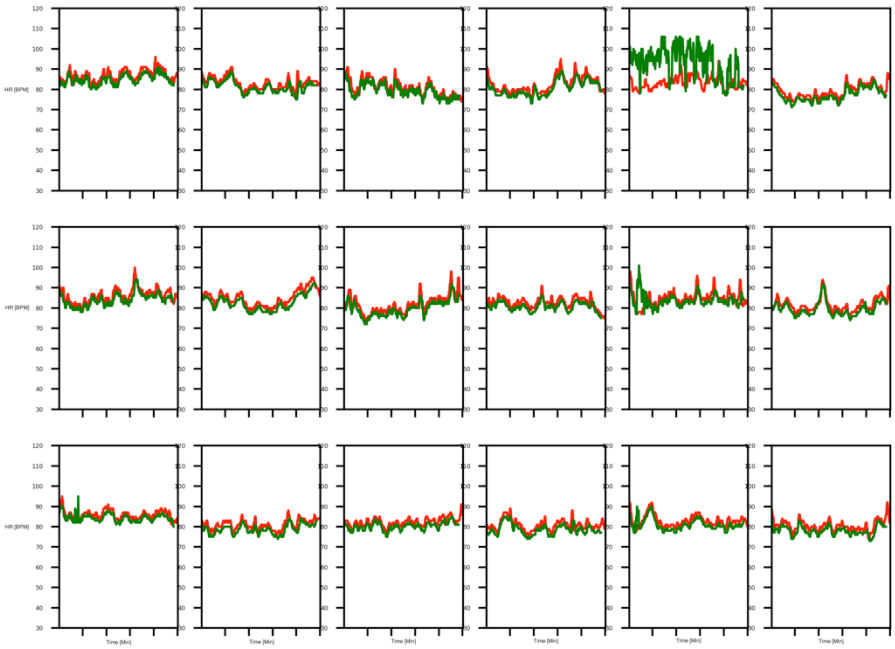

Fig 2. HR compared between QuasaR™ device (In Green) and Nonin Connect 3240 Wireless Finger Pulse Oximeter (In Red)

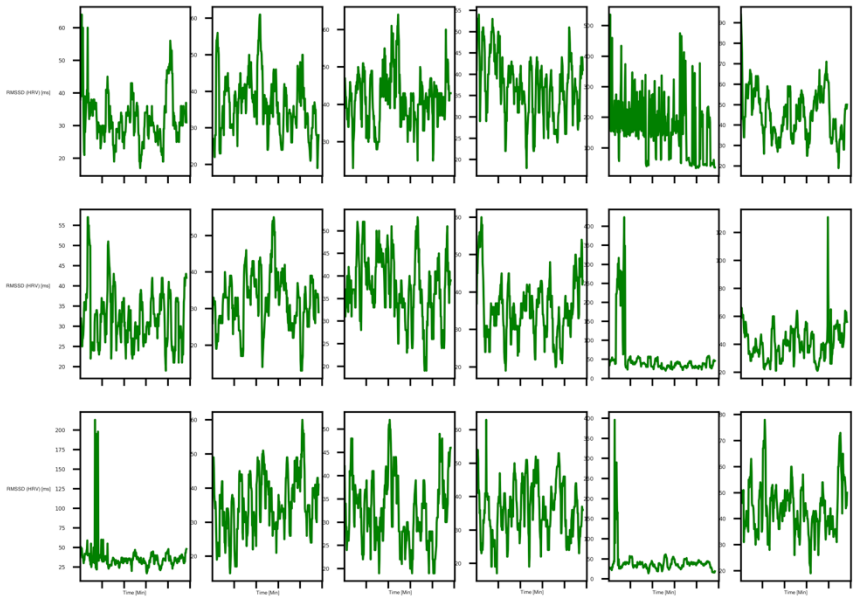

Fig 3. HRV from QuasaR™ device (In Green)

Subject	Reading	RR (Input)	RR (Computed)
1	1	10	9
1	2	10	9
1	3	15	14
1	4	15	14
1	5	20	18
1	6	20	18
1	7	10	9
1	8	15	14
1	9	15	14
1	10	15	14
1	11	20	18
1	12	20	18
1	13	10	9
1	14	10	9
1	15	15	13
1	16	15	14
1	17	20	18
1	18	20	18

Table 1. RR from QuasaR™ device compared to the readings given as input from the Breathe Ball Desktop App.

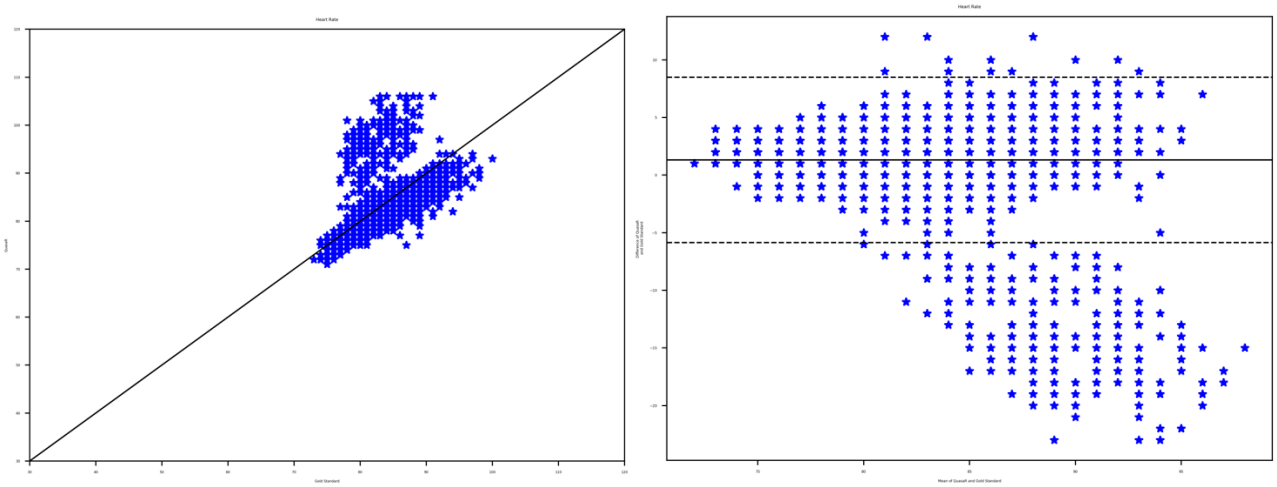

Fig 4. Correlation (Left) and Bald Altman plots (Right) for HR from QuasaR™ device compared to the Nonin Connect 3240 Wireless Finger Pulse Oximeter.

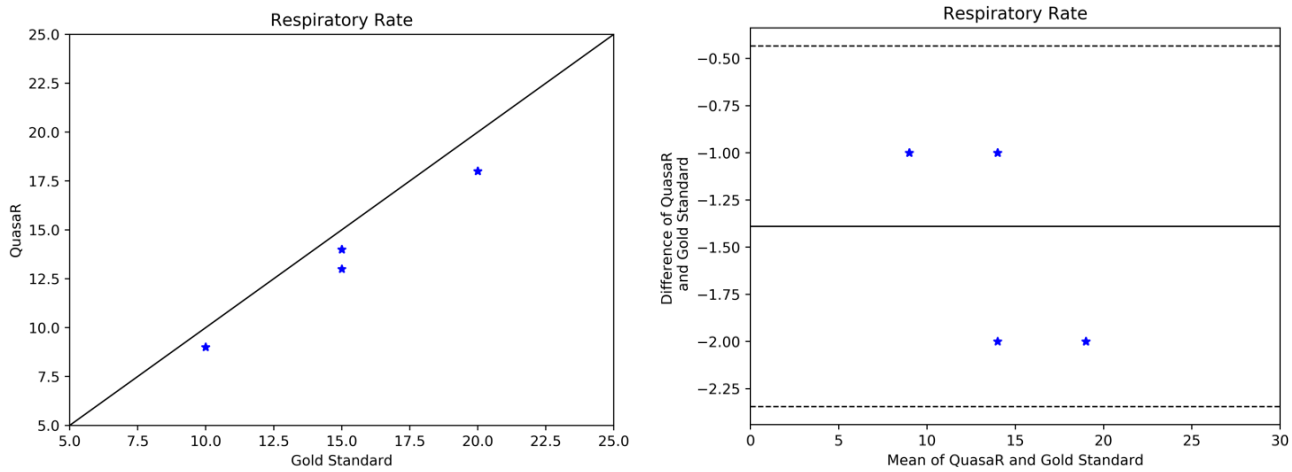

Fig 5. Correlation (Left) and Bald Altman plots (Right) for RR from QuasaR™ device compared to the readings given as input from the Breathe Ball Desktop App.

V. Conclusion

In this work, we study how accurately our QuasaR™ device can measure three biometric parameters i.e., HR, HRV (RMSSD) and RR from continuous color PPG. The QuasaR™ device is a vital part of the QuasaR™ RPM designed to help patients continuously track their health at home and a clinical setting.

An initial eye-balling of the results in Fig.1. shows the strong co-relation in the time-series data obtained using the QuasaR™ device and the Nonin Connect 3240 Wireless Finger Pulse Oximeter. Further statistical analysis in Fig 4. shows that the QuasaR™ device is within 0.25 standard deviation of the Nonin Connect 3240 Wireless Finger Pulse Oximeter while measuring HR.

Since HR and HRV are both computed from the same peak to peak distance time-series, we know that a strong co-relation in HR will correspond to a strong co-relation in HRV. However, further studies could be executed with a single lead ECG such as the Polar Chest strap to independently establish this claim. An initial eye-balling of the results in Fig.3. show the HRV varies from 0-60 ms for most stable results. In the case of instability it can jump to 300-400 ms range.

Statistical analysis in Fig 5. shows that RR measured with the QuasaR™ device is within 0.5 standard deviations of the RR recommended by the Breathe Ball Desktop App. Since there can be a slight human error in following the Breathe Ball Desktop App's breathing instructions, the results are inferior compared to the HR.

REFERENCES

1. W. Song, H. Yu, C. Liang, Q. Wang, and Y. Shi, "Body monitoring system design based on android smartphone," in *Information and Communication Technologies (WICT), 2012 World Congress on*. IEEE, 2012, pp. 1147–1151.
2. Kinsa smart thermometer. [Online]. Available: https://kinsahealth.com/
3. A. Al-Ali and M. E. Kiani, "Pulse oximeter monitor for expressing the urgency of the patient's condition," 2003, US Patent 6,542,764.
4. J. Achten and A. E. Jeukendrup, "Heart rate monitoring," *Sports medicine*, vol. 33, no. 7, pp. 517–538, 2003.
5. E. Jonathan and M. Leahy, "Investigating a smartphone imaging unit for photoplethysmography," Physiological Measurement, vol. 31, no. 11, p.N79, 2010.
6. J. Takacs, C. L. Pollock, J. R. Guenther, M. Bahar, C. Napier, and M. A. Hunt, "Validation of the fitbit one activity monitor device during treadmill walking," Journal of Science and Medicine in Sport, vol. 17, no. 5, pp. 496–500, 2014.
7. Fitbit. [Online]. Available: https://fitbit.com/
8. W. Lee, Y. M. Chae, S. Kim, S. H. Ho, and I. Choi, "Evaluation of a mobile phone-based diet game for weight control," *Journal of telemedicine and telecare, vol. 16, no. 5, pp. 270–275, 2010.*
9. J. Tran, R. Tran, and J. R. White, "Smartphone-based glucose monitors and applications in the management of diabetes: an overview of 10 salient "apps" and a novel smartphone-connected blood glucose monitor," *Clinical Diabetes*, vol. 30, no. 4, pp. 173–178, 2012.
10. P. Rolfe, "In Vivo Near-Infrared Spectroscopy," *Annual Review of Biomedical Engineering*, vol. 2, no. 1, pp. 715–754, Aug. 2000.
11. N. G. Roald, "Estimation of Vital Signs from Ambient-Light Non- Contact Photoplethysmography," Ph.D. dissertation, Norwegian University of Science and Technology, 2013.
12. T. Tamura, Y. Maeda, M. Sekine, and M. Yoshida, "Wearable photo-plethysmographic sensors-past and present," *Electronics*, vol. 3, no. 2, pp. 282–302, 2014.
13. W. G. Zijlstra, a. Buursma, and W. P. Meeuwsen-van der Roest, "Absorption spectra of human fetal and adult oxyhemoglobin, deoxyhemoglobin, carboxyhemoglobin, and methemoglobin," *Clinical Chemistry*, vol. 37, no. 9, pp. 1633–1638, 1991.
14. T. force of the European Society of Cardiology, the North American Society of Pacing, and Electrophysiology, "Heart rate variability standards of measurement, physiological interpretation, and clinical use," *European Heart Journal*, vol. 17, pp. 354–381, 1996.
15. Instant heart rate by azumio. [Online]. Available: http://www.azumio.com/s/instantheartrate/index.html
16. H. Y. Wu, M. Rubinstein, E. Shih, J. Guttag, F. Durand, and W. Freeman, "Eulerian video magnification for revealing subtle changes in the world," *ACM Transactions on Graphics*, vol. 31, no. 4, pp. 1–8, 2012.
17. C. F. Poets and V. a. Stebbens, "Detection of movement artifact in recorded pulse oximeter saturation." *European journal of pediatrics*, vol. 156, no. 10, pp. 808–11, Oct. 1997.
18. R. Stojanovic and D. Karadaglic, "A led-led-based photoplethysmography sensor," *Physiological Measurement*, vol. 28, no. 6, pp. N19–N27, 2007.
19. T. Yilmaz, R. Foster, and Y. Hao, "Detecting vital signs with wearable wireless sensors." *Sensors (Basel, Switzerland)*, vol. 10, no. 12, pp. 10 837–62, Jan. 2010.
20. E. a. Simoes, R. Roark, S. Berman, L. L. Esler, and J. Murphy, "Respiratory rate: measurement of variability over time and accuracy at different counting periods," *Archives of disease in childhood*, vol. 66, no. 10, pp. 1199–1203, 1991.
21. Dan Wu, Ping Yang, Guan-Zheng Liu, and Yuan-Ting Zhang, "Auto- matic estimation of respiratory rate from pulse transit time in normal subjects at rest," in *Proceedings of 2012 IEEE-EMBS International Conference on Biomedical and Health Informatics*, vol. 25, no. Bhi. IEEE, Jan. 2012, pp. 779–781.
22. W. Verkruysse, L. O. Svaasand, and J. S. Nelson, "Remote plethysmo- graphic imaging using ambient light." *Optics Express*, vol. 16, no. 26, pp. 21 434–21 445, 2008.
23. U. Rubins, V. Upmalis, O. Rubenis, D. Jakovels, and J. Spigulis, "Real- time photoplethysmography imaging system," *IFMBE Proceedings*, vol.

