Journal of Medical Engineering & Technology

ISSN: (Print) (Online) Journal homepage: https://www.tandfonline.com/loi/ijmt20

Validation of a novel contact-free heart and respiratory rate monitor

Ofer Havakuk, Ben Sadeh, Ilan Merdler, Zeev Zalevsky, Javier Garcia-Monreal, Sagi Polani & Yaron Arbel

To cite this article: Ofer Havakuk, Ben Sadeh, Ilan Merdler, Zeev Zalevsky, Javier Garcia-Monreal, Sagi Polani & Yaron Arbel (2021): Validation of a novel contact-free heart and respiratory rate monitor, Journal of Medical Engineering & Technology, DOI: 10.1080/03091902.2021.1905896

To link to this article: https://doi.org/10.1080/03091902.2021.1905896

Published online: 13 Apr 2021.

JOURNAL OF MEDICAL ENGINEERING & TECHNOLOGY
https://doi.org/10.1080/03091902.2021.1905896

Taylor & Francis
Taylor & Francis Group

INNOVATION

Validation of a novel contact-free heart and respiratory rate monitor

Ofer Havakuk[a,b], Ben Sadeh[a,b], Ilan Merdler[a,b], Zeev Zalevsky[c,d], Javier Garcia-Monreal[c,e], Sagi Polani[c]* and Yaron Arbel[a,b,c]*

[a]Department of Cardiology, Tel Aviv Medical Center, Tel Aviv, Israel; [b]Sackler Faculty of Medicine, Tel Aviv University, Tel Aviv, Israel; [c]ContinUse Biometrics Ltd., dba Donisi Health, Tel Aviv, Israel; [d]Faculty of Engineering, Bar-Ilan University, Ramat-Gan, Israel; [e]Department of Optics, University of Valencia, Spain

ABSTRACT

There is a growing need for remote monitoring of patients due to a lack of resources and infection control. Current systems use sensors that require constant physical contact with the user, which may result in discomfort or lack of adherence. In the present study, we evaluated the accuracy of a new contact-free system to monitor heart and respiratory rate. Study participants were measured simultaneously using two devices: a contact-free optical system that measures nano-vibrations and movements (investigational device, "Gili Pro BioSensor") and a standard reference bed-side monitor, inclusive of an electrocardiogram and capnograph modules (Mindray®). Co-primary endpoints included HR and RR accuracy in subjects without active arrhythmias for HR, and for all study populations for RR (i.e., for subjects with and without active arrhythmias). Confirmatory secondary endpoints included HR scored continuously for all study populations, inclusive of subjects with arrhythmias. The present study included 115 patients who completed study procedures. Mean age was 66 ± 14.6 (range 29–93) with 60% males, 31% obese patients (i.e., BMI > 30 kg/m^2, range 17–44) and 56% measured in a chair. For the dichotomised accuracy analysis, both co-primary endpoint for HR and RR resulted in 100% accuracy (95% CI: HR 98.8–100%; RR 98.9–100%), whereas for the confirmatory secondary analysis, 99.1% of the HR measurements across subjects with and without active arrhythmias were deemed accurate (95% CI: 97.4–99.8%). The current study demonstrated over 99% accuracy in detecting heart and respiratory rate using a novel contact-free optical system.

ARTICLE HISTORY
Received 18 October 2020
Revised 26 February 2021
Accepted 15 March 2021

KEYWORDS
Vital signs; heart rate; respiratory rate; laser; camera

1. Introduction

As medical care is improved and patients live longer and with more comorbidities, there is a growing need for monitoring them. In recent years, telemedicine has become part of mainstream medical care. Current systems in place are excellent in monitoring patient's vitals, but the majority of them utilise sensors that require constant and secure physical contact with the user, which may result in discomfort and/or lack of adherence. Such sensors also increase the risk for hospital-acquired infections due to their contact-based multi-use nature – a pertinent issue amid recent public health developments (COVID-19).

In this respect, contactless monitoring solutions may offer clinicians a way to accurately measure patients' vital signs in a non-intrusive manner. In patients with chronic cardiac and respiratory conditions, small changes to heart rates (HR) and respiratory rates (RR) may signal patients at risk for an exacerbation [1–5]. In patients with infectious diseases, higher HR and RR might be additive in detecting infirmed patients in addition to infra-red temperature measurements.

Contact-free devices for vital sign monitoring have been previously described in scientific literature, and are mainly aimed at deciphering HR, RR and/or heart rate variability (HRV). The underlying technologies comprising these contact-free devices are roughly divided into three categories: camera-based systems [6], laser-based systems [7,8] and radio-frequency (RF) or Tera-Hertz (THz) based systems [9–11]. Although these technologies have gained a lot of interest amid the recent COVID-19 outbreak, the majority of them have not been validated via rigorous clinical studies or have not obtained vast regulatory clearances for measuring both HR and RR.

CONTACT Yaron Arbel yarona@tlvmc.gov.il Department of Cardiology, Tel Aviv Medical Center, 6 Weizman Street, Tel Aviv 64239, Israel
*Contributed equally.

Supplemental data for this article can be accessed here.

In this sense, this study aimed to evaluate the accuracy of a novel contact-free optical device for spot-measurement of both heart and respiratory rates (Gili Pro BioSensor, Donisi Health®). The system functions via analysis of optical signals using an image sensor (camera) alongside a coherent light source (laser). The laser is used for illuminating the inspected subject while the camera, with its optics, analyzes the time-changing spatial distribution of the statistics of the backscattered self-interference light patterns. These backscattered patterns are called secondary speckle patterns and are generated due to the unique physical properties of the laser light, that is, temporal and spatial coherences [12–14].

The aim of the present study was to validate the accuracy of the Gili Pro BioSensor compared to a standard FDA-cleared reference bed-side monitor in a myriad of subjects.

2. Methods

2.1. Study population

This prospective study included subjects admitted/visiting the cardiology ward and/or outpatient clinics for various indications. During their stay, subjects were offered to participate in this non-invasive comparative study. Subjects were screened according to the inclusion/exclusion criteria and upon eligibility confirmation, subjects have consented. The inclusion criteria included: age $\geq$ 18, hemodynamically stable as assessed by the investigator, willing and able to sign an informed consent. The exclusion criteria included: the presence of a condition that may interfere with the devices' performance during spot-measurement (e.g., nausea, vomiting, persistent coughing, tremor, mouth breathing, etc.), reflective garments (e.g., sequin, silk, or similar), or highly textured garments (e.g., fur, thick lace, shaggy wool, etc.), and parallel participation in another clinical trial. A total of 120 subjects were recruited of which 115 completed study procedures. Five patients did not complete the study due to technical difficulties with the reference device. This study was conducted at the Tel-Aviv Sourasky Medical Centre (TASMC), Israel, under IRB approval #TLV-0168-19.

2.2. Study devices

Study participants were measured simultaneously using two devices: (1) Gili Pro BioSensor (investigational device, "Gili") and (2) A standard FDA-cleared reference bed-side monitor, inclusive of a 6-lead electrocardiogram (ECG) and capnograph modules (Mindray® Benevision N1, Shenzen, China). The Gili device is a contact-free optical system consisting of an optical sensing unit controlled by a tablet. The sensing unit is placed in front of the inspected subject and captures physiological data without any physical contact. The device consists of an illuminating light source (class 1, eye-safe laser), a digital image sensor (camera), range metre and firmware to facilitate data processing (Figure 1). The system functions on the principle that subtle movements (nano movements) of a given surface (e.g., the thoracic wall) are recognised when illuminated via the light source while the device simultaneously captures the back-reflected light pattern (secondary speckle pattern) via the camera. Temporal changes in the reflected light pattern are coupled with the motions of the illuminated surface, which are affected by heart and breathing motions. Analysis of these motion-coupled light patterns during spot-measurement enables correlation of these motions with different physiological manifests (e.g., seismo/phonocardiography) of which specific vital signs, like heart and respiratory rates, can be derived [12–14].

The device captures only motion-related data. No full-scale images of the inspected subject are taken at any time via the Gili device, essentially maintaining the subject's privacy. Heart and respiratory rate values are displayed on the user interface (UI) of the mobile unit (Figure 1).

2.3. Procedure and test methods

Following the signing of the informed consent, patients were asked to sit in a chair or in a bed with the backrest raised. For comparative reference measurements, nasal tubes were placed in the patient's nostrils and accompanying ECG electrodes were placed on the patient's chest according to the manufacturer's guidelines. Patients were allowed to rest for 5 min in order to reach a physiological steady state. During this time, the reference device was turned on and allowed to stabilise, while the Gili device was adjusted to point to the left side of the patient's chest. Following the 5-min resting period, both Gili and reference devices were prompted to take a synchronised spot-measurement session of at least 3-min, essentially providing 3×60-s intervals for analysis per patient. Following completion, data was exported from both devices for offline comparison. For HR, reference ECG data were averaged across each interval. For RR, reference data was based on clinician over-scored

Figure 1. Gili Pro BioSensor. (a) Gili sensing unit, measuring 160 × 100 × 28 mm (6.3 × 4 × 1.1 inches). (b) Measurement setup. (c) User interface with heart and respiratory rates.

capnograms (COSC). Verification of reference ECG/capnogram waveform data quality was done via manual inspection by two certified cardiologists blinded to each other and to the reference device. In case of discrepancy, a third cardiologist was consulted.

2.4. Data and statistical methods

All descriptive statistics were tabulated using mean, standard deviation, minimum, median, maximum and number of observations. Categorical variables were tabulated using the number of observations and percentages.

Study endpoints were based on 60-s measured intervals. Co-primary endpoints included HR and RR scored continuously (via both reference and test measurements) in subjects without active arrhythmias for HR, and for all study populations for RR (i.e., for subjects with and without active arrhythmias). Confirmatory secondary endpoints included HR scored continuously for all study populations, inclusive of subjects with arrhythmias.

In order to compare between Gili and reference data, a logistic regression with a mixed model based on compound symmetry covariance structure as recommended via the CLSI-EP09 guideline was used [15]. In addition, Pearson correlations between reference and test were also sought.

For the co-primary endpoints, the following acceptance criteria were specified for both HR and RR:

1. Point estimate of the correlation estimated as described above is at least 0.95
2. 95% confidence interval (CI) for the slope of the regression line is wholly included in the range $1 \pm 10\%$, that is, (0.9, 1.1)
3. 95% CI for the intercept of the regression line is wholly included in the range:
   a. 0 ± 3 bpm, that is, (−3, 3), for HR in patients without active arrhythmia.
   b. 0 ± 2 breaths/min, that is, (−2, 2), for RR.

For the confirmatory secondary endpoint on HR across all study population (with and without arrhythmias), the 95% CI for the intercept of the regression line was slightly expanded to include the range of 0 ± 5 bpm, that is, (−5, 5).

Supportive analyses for the above (primary and confirmatory secondary endpoints) were performed in a descriptive manner and included: (1) Bland-Altman plots along with 95% limits of agreement (LoA) accounting for multiple within-subjects measurements, and (2) frequency distribution for the dichotomised accuracy (i.e., accurate or inaccurate) as defined above, including 95% CI estimated using logistic regression with subject random effect to account for potential within-subject dependency [16].

All statistical analyses were carried out using SAS® Version 9.4.

Table 1. Baseline demographic characteristics of subjects included in the study.

Variable	*n*
Age (years, mean ± STD)	65.9 ± 14.6
Gender (%M:F)	60:40
BMI (kg/m^2, mean ± STD)	28.3 ± 5.4
Measurement position (%Chair:Bed)	56:44

3. Results

3.1. Baseline characteristics

A total of 115 subjects completed the study procedures. Mean age was 66 ± 14.6 (range 29–93) with 60% males, 31% obese patients (i.e., BMI > 30 kg/m^2, range 17–44) and 56% measured in a chair (Table 1). In addition, the population included 13.3% of patients with an ongoing respiratory condition (of which 7.5% have COPD), 12.5% with abnormal chest shape (including barrel chest deformity; Table S1). Seventy Percent of subjects had relatively bright skin tones, 17.5% with a brown skin tone, and 12.5% with dark skin tones (Tables S2). Subjects' clothing varied in the type of garment, colour and number of layers. About half of subjects wore an undershirt or T-shirt, 24% wore a hospital gown and 18% wore a dress shirt or blouse, while a few wore sweaters (7%) (Table S3). The vast majority of subjects had only one layer of clothing (77%), though several had two layers (18%) or even three layers (5%). Lastly, 15% of measured subjects had an active arrhythmia during the measurement, of which 3% had atrial fibrillation (Afib). Details of the frequency distribution of medical history entries as evident in subjects' medical records can be found in supplemental Table S4.

3.2. Efficacy results

For the primary endpoints, a total of 294 evaluable intervals accounting for 101 subjects without an active arrhythmia were available for the HR analysis, while 340 evaluable intervals accounting for 115 subjects with and without arrhythmias were available for the RR analysis. For HR, measured values ranged between 38–100 bpm, in which the resulting regression between Gili and ECG provided a slope and intercept of 0.99 (95% CI: 0.99–1.0) and 0.51 (95% CI: 0.18–0.84), both well within the pre-specified acceptance ranges of 1 ± 10% and ±3 bpm, respectively (Figure 2(a)). Bland–Altman plot provided narrow limits of the agreement also well within the pre-specified acceptance range (Figure 2(b)).

For RR, measured values ranged between 6–34 breaths/min, with the regression line

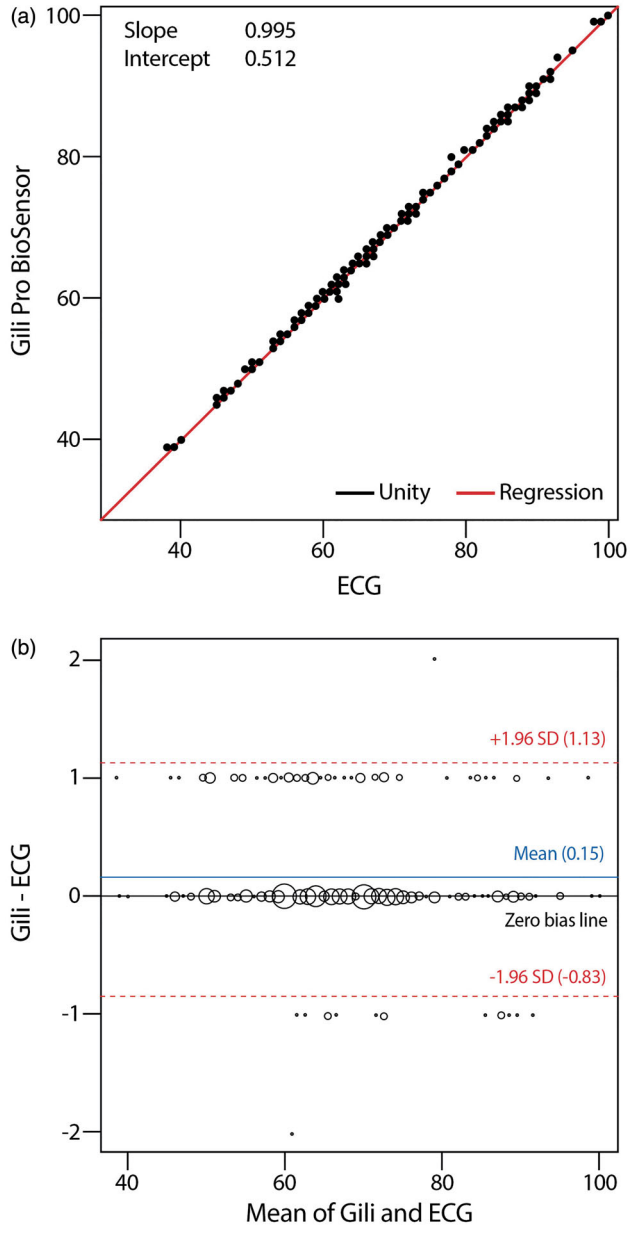

Figure 2. Scatter (a) and Bland–Altman (b) plots of comparative HR measurements (primary endpoint).

encompassing a slope and intercept of 0.99 (95% CI: 0.97–1) and 0.17 (95% CI: −0.08 to 0.42), both also well within the pre-specified acceptance ranges of 1 ± 10% and ±2 breaths/min, respectively (Figures 3(a,b)).

For the confirmatory secondary endpoint, a total of 339 evaluable intervals with and without active arrhythmias were used for HR analysis. The slope and intercept were 0.98 (95% CI: 0.97–1.0) and 1.1 (95% CI: −0.02 to 2.3), both well within the pre-specified acceptance ranges of 1 ± 10% and ±5 bpm (and even within ±3 bpm), respectively (Figures 4(a,b)).

Pearson correlation values between Gili and the reference device were $R = 0.999$ (CI: 0.998–0.999,

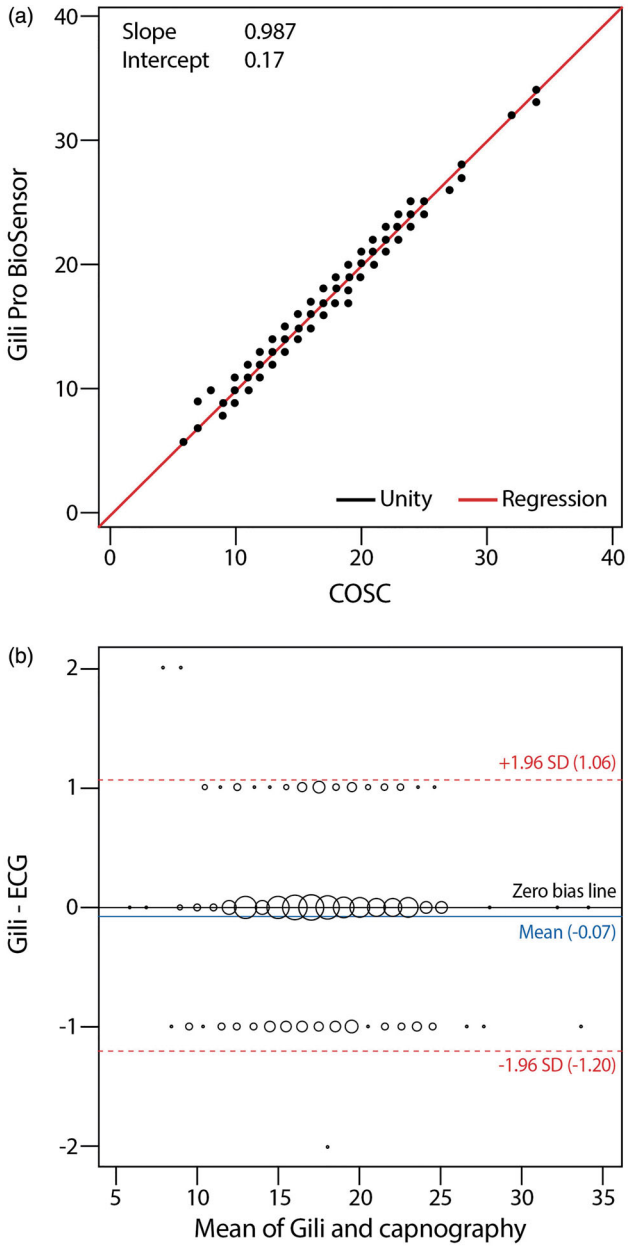

Figure 3. Scatter (a) and Bland–Altman (b) plots of comparative RR measurements (primary endpoint).

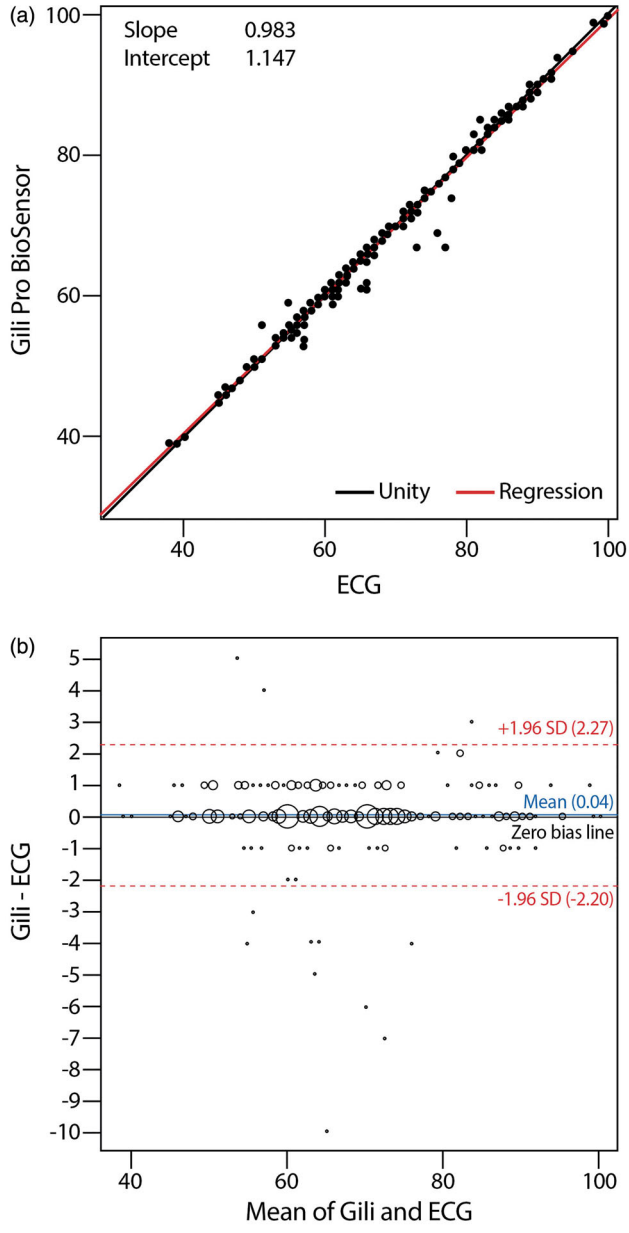

Figure 4. Scatter (a) and Bland–Altman (b) plots of comparative HR measurements inclusive of subjects with active arrhythmias (confirmatory secondary endpoint).

$p < 0.001$) for HR and $R = 0.990$ (CI: 0.986–0.993, $p < 0.001$) for RR.

For the dichotomised accuracy analysis, both co-primary endpoint for HR and RR resulted in 100% accuracy (95% CI: HR 98.8–100%; RR 98.9–100%), whereas for the confirmatory secondary analysis, 99.1% of the HR measurements across subjects with and without active arrhythmias were deemed accurate (95% CI: 97.4–99.8%).

Device accuracy was not affected by the different analysed covariates, that is, gender, BMI, clothing layers and external clothing colour, chest anatomy (including barrel-chests), respiratory conditions (including COPD), skin pigmentation (based on Fitzpatrick skin scale), history of arrhythmia, department, and subject position (sitting in a chair or in bed with the backrest raised).

No adverse events were recorded throughout the study.

4. Discussion

In the present study, we evaluated the accuracy of a non-contact optical system (Gili) to detect both heart and respiratory rates during a spot-measurement in a heterogeneous group of patients. Our study

population was representative of the general North American/European population with different skin colours, medical conditions, body habitus and age groups. By comparison, the estimated prevalence of COPD in the US varies considerably by state from <4% to >9%[17]. In addition, 15% of measured subjects had an active arrhythmia during the measurement, and 3% had Afib. By comparison, the prevalence of Afib in the general US population is estimated at <2%.[18–21]

The study met both of its primary and secondary endpoints, essentially demonstrating the ability of the non-contact optical system (Gili) to detect HR and RR accurately (i.e., >99%) during a spot-measurement when compared to the gold-standard contact-based devices (ECG and COSC). This was true in the entire population as well as in patients with arrhythmias or respiratory conditions.

As previously mentioned, contact-free devices are roughly divided into three categories: camera-based systems, laser-based systems and RF-based systems, with the latter being regulated/cleared mainly for RR measurements. The main difference between the technology underlying the investigational device and those described above is related to the fact that the latter's precision is limited by either the relatively long wavelengths used (as in RF or THz based sensors) [9,10], or the imaging resolution which is significantly affected by (a) the optics (bigger optics better resolution), (b) camera characteristics (number, size and sensitivity of pixels), (c) the distance from the object, (d) ambient conditions (e.g., lighting, noise, etc.) and (e) measurement modality [6,12]. Contrastingly, the measurement principle enabled by the investigational device's underlying technology is based on analysis of the backscattered self-interference optical signals which allow more precise localisation of the inspected signal via advanced image processing algorithms [6]. This precision is facilitated by: (a) the use of relatively short wavelengths (in which the precision is ~0.01 of the optical wavelength), (b) independence of colour of the inspected surface/tissue and ambient (lighting) conditions (as opposed to other technologies analysing relative absorption of light, for example, remote photoplethysmography), and (c) high sensitivity to motion capture enabled by the analysis of self-interference patterns (as opposed to, e.g., structured light plethysmography). The utilisation of the self-interference effect also simplifies the hardware requirements of the sensor (both physical and optical), thereby enabling the reduction of the overall price-tag of the sensor.

In medical settings, drug-resistant bacteria is a serious problem resulting in increased morbidity, mortality and costs. [22,23] They require contact precautions with gloves and gowns. There have been different ways to combat this problem with conflicting results. [24,25] In recent months, amid the COVID-19 pandemic, contact-free medical monitoring has transformed from a nice-to-have technology to a must-have technology, especially outside the clinical setting. The most prominent example includes the abundance of infra-red thermometers being used as potential screeners for symptomatic patients for purposes of "smart access-control". Additional devices, like the one proposed in this paper, may serve to provide a more holistic complementary solution for such use-cases. Such a solution may be especially relevant in highly crowded venues/transportation facilities, for example, airports, train stations, stadiums, etc.

The present technology was found to be as accurate as contact-based technologies for spot-measurement of HR and RR. However, there are important limitations that need to be considered: (1) The Gili device, in its current design, is not intended for continuous long-term patient monitoring/telemetry, which limits its use for spot-measurement purposes only. (2) Although the underlying technology of the device technically allows it to be used in different ambient and physiological conditions, the different usability related restrictions (i.e., use of improper clothing and the need to sit still during the measurement) render the device more appropriate for use in a supervised setting, or telemedicine/remote-patient monitoring so long as the user is guided as to the device's restriction via proper labelling.

In conclusion, the contact-free optical system, Gili Pro BioSensor, has been demonstrated to be equivalent to the gold standard ECG and COSC in the measurement of heart and respiratory rates. Such a capability may increase adherence of patients to being monitored due to its minimally-intrusive contact-free mode of operation.

Disclosure statement

Sagi Polani, Zeev Zalevsky, Javier Garcia-Monreal and Yaron Arbel hold equity with Donisi Health.

Funding

This study was funded by Donisi Health.

References

[1] Ohte N, Cheng CP, Little WC. Tachycardia exacerbates abnormal left ventricular-arterial coupling in heart failure. Heart and Vessels. 2003;18(3):136–141.

[2] Verma AK, Sun JL, Hernandez A, et al. Rate pressure product and the components of heart rate and systolic blood pressure in hospitalized heart failure patients with preserved ejection fraction: insights from ASCEND-HF. Clin Cardiol. 2018;41(7):945–952.

[3] Ahmed A, Ullah W, Hussain I, et al. Atrial fibrillation: a leading cause of heart failure-related hospitalizations; a dual epidemic. Am J Cardiovasc Dis. 2019;9(5): 109–115.

[4] Forleo GB, Santini L, Campoli M, et al. Long-term monitoring of respiratory rate in patients with heart failure: the Multiparametric Heart Failure Evaluation in Implantable Cardioverter-Defibrillator Patients (MULTITUDE-HF) Study. J Interv Card Electrophysiol. 2015;43(2):135–144.

[5] Gálvez-Barrón C, Villar-Álvarez F, Ribas J, et al. Effort oxygen saturation and effort heart rate to detect exacerbations of chronic obstructive pulmonary disease or congestive heart failure. JCM. 2019;8(1):42.

[6] Shafiq G, Veluvolu K. Surface chest motion decomposition for cardiovascular monitoring. Sci Rep. 2014;4: 5093.

[7] Wang C, Trivedi S, Jin F, et al. Human life signs detection using high-sensitivity pulsed laser vibrometer. IEEE Sensors J. 2007;7(9):1370–1376.

[8] Morbiducci U, Scalise L, De Melis M, et al. Optical vibrocardiography: a novel tool for the optical monitoring of cardiac activity. Ann Biomed Eng. 2007; 35(1):45–58.

[9] Pisa S, Pittella E, Piuzzi E. A survey of radar systems for medical applications. IEEE Aerosp Electron Syst Mag. 2016;31(11):64–81.

[10] Li C, Lubecke VM, Boric-Lubecke O, et al. A review on recent advances in Doppler radar sensors for noncontact healthcare monitoring. IEEE Trans Microwave Theory Techn. 2013;61(5):2046–2060.

[11] Iyer B, Garg M, Pathak NP, et al. Contactless detection and analysis of human vital signs using concurrent dual-band RF system. Procedia Eng. 2013;64:185–194.

[12] Zalevsky Z, Beiderman Y, Margalit I, et al. Simultaneous remote extraction of multiple speech sources and heart beats from secondary speckles pattern. Opt Express. 2009;17(24):21566–21580.

[13] Ozana N, Margalith I, Beiderman Y, et al. Demonstration of a remote optical measurement configuration that correlates with breathing, heart rate, pulse pressure, blood coagulation, and blood oxygenation. Proc IEEE. 2015;103(2):248–262.

[14] Zalevsky Z and Garcia J. Motion detection system and method. US patent No. 8638991; Australian Patent No. 2008278642; South Korean Patent No. 10-2010-7004615; Israeli Patent Application No. 203262; Canadian Patent Application No. 269762. 2007.

[15] CLSI. Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Third Edition. CLSI document EP09-A3. Wayne (PA): Clinical and Laboratory Standards Institute; 2013.

[16] Bland JM, Altman DG. Agreement between methods of measurement with multiple observations per individual. J Biopharm Stat. 2007;17(4):571–582.

[17] CDC-Data and Statistics-Chronic obstructive pulmonary disease (COPD). (n.d.). [cited 2021 Mar 22]. Available from https://www.cdc.gov/copd/data.html.

[18] Freedman B, Camm J, Calkins H, et al. Screening for atrial fibrillation: a report of the AF-SCREEN international collaboration. Circulation. 2017;135(19): 1851–1867.

[19] Kirchhof P, Benussi S, Kotecha D, et al. 2016 ESC Guidelines for the management of atrial fibrillation developed in collaboration with EACTS. Eur Heart J. 2016;37(38):2893–2962.

[20] Svennberg E, Engdahl J, Al-Khalili F, et al. Mass screening for untreated atrial fibrillation: the STROKESTOP Study. Circulation. 2015;131(25): 2176–2184.

[21] Atrial Fibrillation. cdc.gov. (n.d.). [Cited 2021 Mar 22]. Available from https://www.cdc.gov/heartdisease/atrial_fibrillation.htm

[22] Rosemurgy A, Whitaker J, Luberice K, et al. A cost-benefit analysis of reducing surgical site infections. Am Surg. 2018;84(2):254–261.

[23] Chiang HY, Perencevich EN, Nair R, et al. Incidence and outcomes associated with infections caused by vancomycin-resistant *Enterococci* in the United States: systematic literature review and meta-analysis. Infect Control Hosp Epidemiol. 2017;38(2):203–215.

[24] Harris AD, Pineles L, Belton B, et al. Universal glove and gown use and acquisition of antibiotic-resistant bacteria in the ICU: a randomized trial. JAMA. 2013; 310(15):1571–1580.

[25] Marshall C, Richards M, McBryde E. Do active surveillance and contact precautions reduce MRSA acquisition? A prospective interrupted time series. PLoS One. 2013;8(3):e58112.