

The Pi-CON Methodology Applied: Operator Errors and Preference Tracking of a Novel Ubiquitous Vital Signs Sensor and Its User Interface

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ABSTRACT

Remote Patient Monitoring has enjoyed strong growth to new heights driven by several factors, such as the COVID-19 pandemic or advances in technology, allowing consumers and patients to continuously record health data by themselves. This does not come without its challenges, however. A literature review was completed and highlights usability gaps when using wearables or home use medical devices in a virtual environment. Based on these findings, the Pi-CON methodology was applied to close these gaps by utilizing a novel sensor that allows the acquisition of vital signs at a distance, without any sensors touching the patient. Pi-CON stands for passive, continuous and non-contact, and describes the ability to acquire vital signs continuously and passively, with limited user interaction. The preference of vital sign acquisition with a newly developed sensor was tested and compared to vital sign tests taken with patient generated health-data devices (ear thermometer, pulse oximeter) measuring heart rate, respiratory rate and body temperature. In addition, the amount of operator errors and the user interfaces were tested and compared. Results show that participants preferred vital signs acquisition with the novel sensor and the developed user interface of the sensor. Results also revealed that participants had a mean error of .85 per vital sign measurement with the patient-generated health data devices and .33 with the developed sensor, confirming the beneficial impact available when using the developed sensor based on the Pi-CON methodology.

KEYWORDS

Telehealth; remote patient monitoring; user-centered design; virtual care; vital signs; wearables; ubiquitous sensors

1. Introduction

COVID-19 unlocked the chains of telehealth and unleashed telehealth's growth, bringing digital health closer to the point of care and accelerating a paradigm shift in digital health.

Patient care is moving away from the established physician office to care at retail health clinics or virtual care at home (Meinert et al., 2018). This is in part driven by value-based care, a change from the conventional fee-for-service model, where providers get paid on the patients' health trajectory rather than the tests ordered or the amount of patient visits (Novikov et al., 2018). This new payment model was initiated by the Center for Medicare and Medicaid Services (CMS) as a result of The Affordable Care Act of 2010 with the intent to decrease healthcare cost, improve hospital readmission rates with the goal to increase population health and quality of care, while at the same time decrease cost and reduce hospital admissions and readmissions (Rambur, 2017).

Value-based care is also driven by telehealth, a platform that supports virtual care (Catalyst, 2018) by enabling higher convenience for the patient. This initiative was accelerated by the COVID-19 pandemic with the need to treat people

outside of a bricks-and-mortar healthcare facility due to limited hospital space and infection prevention precautions (Hoffman, 2020).

The growth of telehealth has also been accelerated by advancement in sensor technology, such as wearables or home use medical devices, both being part of patient-generated health data (PGHD) devices. The market has seen a massive growth with an abundance of new technology and devices, illustrated by a wearables' market size of \$7.4 billion in 2018 (Mück et al., 2019), estimated to reach \$64 billion by 2025 (Svertoka et al., 2021).

According to Catalyst (2018), the components of the telehealth umbrella include "store and forward," a capability for specialty services (such as a pharmacy) to capture and transmit patient data to another healthcare provider. mHealth is defined as allowing communication and accessing patient records via mobile devices, and "video" incorporates the capability of a patient and physician to talk live via video chat. Finally, remote patient monitoring (RPM) plays a major role in moving healthcare to the patient's home.

Originally, telehealth was intended for patients in rural areas only, but with the onset of the COVID-19 pandemic, it was opened for anyone who would like to participate (Roblyer, 2020), so all patients that benefit from health

monitoring (post-operative care, patients with acute and chronic conditions) can also participate in an RPM service. These patients, however, have to be under supervised care by a qualified physician (Aalam et al., 2021; Wicklund, 2020).

Currently, 76% hospitals in the U.S. participate in tele-health, such as communicating with patients through video (American Hospital Association [AHA], 2022), and it is estimated that 57% of U.S. medical facilities have done some type of remote patient monitoring, with the number slated to increase to around 80% within the next 2 years (Anuja Vaidya, 2022). These numbers and forecast come by no surprise due to the lifted conditions to participate in RPM, as well as the need for physicians to better monitor a patient's health in an effort to for patients to receive the maximum benefits per the value-based care system.

1.1. Background

Baumann et al. uncovered a vast amount of usability issues during RPM with their research (2019) and introduced the RPM impact usability model. It can be alarming to imagine that a patient who is admitted to a hospital with cardiac arrest, for instance, is released with an RPM kit to self-monitor vital signs at their home. This requires the patient to carry out spot-checks themselves two to three times per day (O'Malley, 2020) with a set of devices provided by the clinic, which includes devices such as a thermometer, scale, or a pulse oximeter (Madel et al., 2021).

Spot-check measurements are still common at a rate of approximately 90% in post-acute care (O'Malley, 2020), albeit PGHD devices' ability to track a patient's health continuously (Lauteslager et al., 2021; Rajbhandary & Nallathambi, 2020) to overcome the challenges with health spot-checks, such as patient compliance (Asimakopoulos et al., 2017; Gouveia & Hassenzahl, 2015; Sen et al., 2014). Table 1 provides a summary of wearables with the ability to continuously track patients' vital signs, which are defined by The Johns Hopkins Hospital as respiratory rate, heart rate and body temperature (2022). These wearables have been defined as smart rings (Cao et al., 2022; Uchida & Izumizaki, 2022), smart clothing (Molinaro et al., 2018; Scataglini et al., 2020), smart watches (Lui et al., 2022; Uchida & Izumizaki, 2022), fitness wrist bands (Guillodo et al., 2020; Miller et al., 2020; Uchida & Izumizaki, 2022), earbuds/headphones (Kumar et al., 2021; Lee et al., 2021; Uchida & Izumizaki, 2022), patches (Breteler et al., 2020; Hinde et al., 2021; Li et al., 2019), smart glasses

(Mocny-Pachońska et al., 2021) and epidermal electronics (Cui et al., 2018; Thiagarajan et al., 2022).

With performing spot-checks only, a skipped measurement or improperly positioned sensor or device might affect the treatment plan and, consequently, the patient's health result. Especially in this chosen cardiac arrest example. Cretikos et al. (2008) report that respiratory rates above 27 breaths per minute (bpm) are a leading prediction of this condition, and just over half of all patients suffering from cardiac arrest are reported to have a respiratory rate greater than 24 bpm. This shows the importance of monitoring respiratory rate when monitoring such condition, while noting that the average respiratory rate is between 8 and 16 bpm at rest for an adult (Pejović et al., 2021).

Of all vital signs, researchers agree that respiratory rate may be the most important. It may, however, also be the most neglected (Elliott, 2016). Respiratory rate is difficult to examine and is usually done by manually counting chest-wall movements (Baker et al., 2019), which is prone to errors. This demonstrates the clear need for reliable respiratory rate measurements and to rapidly spot respiratory rate changes for patients with serious health conditions, such as cardiac arrest, putting the patients at the center of their own care.

1.2. Previous work

1.2.1. Use-related-errors

A variety of user errors can impact the results amongst devices used by patients in their homes, such as a blood pressure cuff. Murakami and Rakotz (2015) published guidelines by the American Medical Association (AMA) in collaboration with John Hopkins on how to properly perform a blood pressure exam. The authors also provide examples when a blood pressure reading would be off. For instance, if the cuff is placed over the clothing, readings could be affected by up 40 mm Hg. A full bladder could impact the results by up to 15 mm Hg, and having a conversation during the exam could raise the reading by up to 15 mm Hg (all provided values are diastolic values). Additionally, Muntner et al. (2019) published similar data stating that, for instance, patients without a supported back during measurements and not having both feet on the floor during data acquisition could see an increase in their systolic reading by up to 15 mm Hg.

Cifter (2017) also focused on blood pressure exams. The researcher evaluated the design characteristics of three different blood pressure devices and reported that the actual user is often neglected in designing these devices. Cifter identified usability violations, which were rated by evaluators

Table 1. Wearables for each vital sign.

Wearable	Heart rate	Respiratory rate	Body temperature
Smart ring	Cao et al., 2022	Cao et al., 2022	Uchida & Izumizaki, 2022
Smart clothing	Scataglini et al., 2020	Molinaro et al., 2018	Scataglini et al., 2020
Smart watches	Lui et al., 2022	Lui et al., 2022	Uchida & Izumizaki, 2022
Fitness wrist bands	Guillodo et al., 2020	Miller et al., 2020	Uchida & Izumizaki, 2022
Headphones	Lee et al., 2021	Kumar et al., 2021	Uchida & Izumizaki, 2022
Patch	Hinde et al., 2021	Li et al., 2019	Breteler et al., 2020
Smart glasses	Mocny-Pachońska et al., 2021	N/A	N/A
Epidermal electronics	Cui et al., 2018	N/A	Thiyagarajan, 2022

from 0 to 4 (0 = cosmetic, 1 = minor, 2 = troublesome, 3 = major, 4 = violation of lay user safety). The most violations were identified in the “perceptible information” category with a count of 71, referring to limitations of essential information and the device not providing necessary feedback to the user to ensure proper function and operation. This is followed by “tolerance for errors” (42 violations), necessary to prevent errors as well as to provide user warnings and support. “Equitable use,” which describes the necessity to minimize the memory load of the user, counted 33 violations, followed by “simple and intuitive use” with 30 violations, demanding more intuitiveness of its operation.

Kortum and Peres (2015) used a System Usability Scale (SUS) (Lewis, 2018) to identify the usability of commonly used home use medical devices. For this study, participants selected 10 home use medical devices and rated them from 0 to 100, with 0 being the lowest and 100 being the highest score with the best usability. Oxygen masks received the highest ranking with a score of 95, and a test hormone kit received the lowest with 58.75. There was a total of 271 participants in this study and 10 ratings showed that device usability for inhalers, blood pressure monitors, thermometers, pregnancy test kits, blood glucose meters, and epinephrine injectors (EpiPen), all common home use medical devices, were limited and at the bottom end of the usability scale.

Mirel et al. (2011) reported that 54 patients (72%) experienced difficulties operating a home-use medical device. Similarly, Chaniaud et al. (2020) researched usability of two home medical devices (blood pressure monitor and pulse oximeter) by counting user errors that were made when each participant independently performed an exam. The research team observed the participants during each measurement and tallied the errors during device operation. Results showed that .77 operator errors per participant were made by the 137 study participants for the blood pressure monitor and .99 errors per participant by 147 participants for the pulse oximeter.

The usability of a glucometer was evaluated by Furniss et al. (2014) during the usage of this device for 11 days and 4 nights, where the researcher observed and interviewed oncology nurses who operated the device. The interviews revealed 19 issues related to device operations. Additionally, Rodbard (2014) described the slow pace of continuous glucose monitoring (CGM) adoption and questioned the usability and the human interface of the devices, along with the training provided for patients and clinicians. This includes sensor placement and data interpretation.

1.2.2. Technical device limitations

Majumder et al. (2017) describe in the article “Wearable Sensors for Remote Health Monitoring” technical limitations of wearables, such as battery life or the issue with managing a large amount of telemetry data collected by sensors. The authors also discuss additional issues, such as the need for the device to be aesthetically pleasing, with the ability to exchange data with other applications.

Lyons and Blandford (2018) report in their work that 46% of participants (278 instances) returned a home-use

medical device (infusion pump) to the researcher stating “it failed to work.” Additionally, in a study by Abdolkhani et al. (2019), researchers found that clinicians (Endocrinologists, Sleep Technicians, Diabetes Education, and Cardiology Technicians) who are actively involved in CGM, sleep disorders and cardiac care, did not consider the use of wearables as a part of their programs due to unknown accuracy and quality issues that could arise due to unforeseen technical device issues. The clinicians stated that data accuracy could be impacted by the patient having to self-perform the exam at home, limited program adherence due to health literacy, and limited knowledge in general.

1.2.3. Patient motivation

Li et al. (2011) stress the importance of designing devices with the patients in mind so devices can be operated without the supervision of a clinician and to ensure the patient continues to stay motivated using the device. The authors introduce user-centered design (UCD) and highlight that complying with UCD is crucial by medical device manufacturers to ensure intuitive device usage per the user needs of the device (Fouquet & Miranda, 2020). The authors highlight that design limitations and with that restricted usability could be avoided by listening to the users before and during the device’s development cycle.

During research by Gouveia and Hassenzahl (2015), health tracker usage was evaluated over a 10-month period with 256 participants, with the results that 66% of all users interacted with the downloaded application (app) for more than 2 days, 38% more than a week, and only 14% longer than 2 weeks.

Patient motivation and compliance to perform tests at home are vital to monitor the patient’s health accurately. To find out if there are ways to increase patient adherence by offering a financial incentive, Sen et al. (2014) observed the daily use of three home use medical devices for 3 months, including a 3-month follow-up period during the participants’ self-monitoring of blood glucose, blood pressure, and weight. The results of the measurements were automatically transmitted to a website once per day. After the study was completed, the research team found that participation compliance increased by including a financial incentive.

While Sen et al. attempted to find a way to increase motivation, Asimakopoulos et al. (2017) researched the main drivers that impact device usage by observing the reported usage of 34 participants and their motivation level in a 4-week period twice per week. Participants used a Fitbit or Jawbone fitness tracker and were asked to answer questions about why they chose the brand they are using and why they are using an activity tracker. They were also asked about their physical activity routines. The researcher stated that the user experience (UX) of the device app has an impact on motivation, with simplified data results (gamification) being the main reason. When usage is tracked over an extended period, it is crucial to understand the novelty effect, which is defined as the “tendency for performance to initially improve when new technology is instituted, not because of any actual improvement in learning or

achievement, but in response to increased interest in the new technology” (Ngai, 2018). In a research project by Shin et al. (2019), the novelty effect was used as a category called novelty period, with another category defined as long-term usage. The research shows that the novelty period ended after about 3 months.

Jia et al. (2018) surveyed 388 participants after they tested fitness trackers for 30 days regarding their preferred data and usability preferences. They found that heart rate monitoring was the most popular feature, with step count and electrocardiography (ECG) monitoring being mentioned as well. In terms of hardware preferences, product design received the highest ranking, followed by durability and ease of use. This demonstrates the importance of aesthetics and the need to design devices that are intuitive and easy to use.

And while Motolese et al. (2020) found a compliance rate of RPM patients to be only 30%, with technical problems and digital literacy being the driving factors, Michaud et al. (2021) studied patient compliance during an RPM initiative during COVID. The study included 46 patients that were asked to take their vitals twice a day for 2 weeks, with the findings that only 61% completed this assignment. Of all vital signs measured by the patients, an average of around 9% showed flagged values based on defined abnormal values prior to the research started. Respiratory rate showed unnormal values of around 12.1%, heart rate 6.7%, and body temperature 3.2%. A minimum of one abnormal value was obtained by 45 out of the 46 participants.

Codella et al. (2018) gathered similar data of PGHD collected by novice users, with technological issues (such as battery life), device aesthetics, and limited collected data due to inadequate patient adherence being mentioned as main apprehensions.

In a study by Lang et al. (2013), 20 cystic fibrosis patients were asked to share their experience of the “Acapella,” a home-use medical device that aids users in removing mucus from lungs after the usage for three times per day and 20 minutes per session. Upon study completion, participants reported the “real world effectiveness” of the device was missing, with the ramification that they showed less motivation using the device.

Bitterman (2011) studied how the patient’s home and surrounding environment affect device operation by pointing out that the healthcare setting is a “standardized, well regulated, accessible setting operating under close professional supervision and strict regulations” whereas the patients’ homes may be leading to improper and with that inaccurate testing. The author also highlighted that the patient’s motivation could increase if the tests were done in an environment set up as such, and not at home. Similarly, Baumann et al. (2021) report that nearly 78% of all surveyed clinicians state their concern that generated data by the patient may be inaccurate due to the patient potentially not being in a proper environment during an exam.

1.2.4. Health literacy

According to the National Adult Literacy Survey, 14% of U.S. adults are health illiterate on a below-basic level (Cutilli

& Bennett, 2009), with Rudd (2007) adding that only 12% of Americans are health literacy proficient.

This is reflected in the findings of a usability study by Reyes et al. (2018) with a multi-parameter monitor (measuring blood pressure, heart rate, SpO₂, respiration rate, and body temperature), in which the authors report that around 92% of all usability issues were related to medical abbreviations the patients were not aware of, which led to limited understanding of the results. Additionally, nearly 77% of all participants could not describe the results, which is necessary to stay compliant in virtual care at home.

Figueiredo and Chen (2020) reported on challenges with patient-generated health data and how health illiteracy affects results comprehension. The authors highlighted the need for proper manuals and tutorials to ensure intuitive use and more effective interpretation of the results. They added that it would be an ultimate need for the patients to have data recorded automatically after a set schedule, limiting user interaction.

There is an increased interest in patient monitoring, driven by COVID-19 and the increased risk of spreading viruses (Khan et al., 2020). Patient monitoring devices should be designed to not only limit the users’ contact but should be small, flexible, and hypoallergenic as well and not hinder users throughout their day (Alharbi et al., 2017; Cho et al., 2021; Majumder et al., 2017).

An additional factor that drives patient motivation to wear such devices is the need to design aesthetically pleasing devices. Perceived enjoyment and social image of wearing and using a device are affected by its looks (Hsiao & Chen, 2018; Yang et al., 2016). Patient comfort plays a significant role in patient compliance as well. Uncomfortable adhesives or smart clothing may not be tolerable for patients due to allergic reactions or general discomfort. According to Berg et al. (2018), 35% of continuous glucose monitoring patients developed at least one skin lesion due to devices attached to their bodies.

Wong et al. (2014) reported similar results where nearly half of all users (727 of 1,662) stopped wearing a glucose monitoring device after 1 year due to general discomfort (42%), with some developing a skin reaction caused by the device (18%). Finally, Jeffs et al. (2016) reported that of 192 patients that participated in wearing a monitor after Intensive Care Unit (ICU) discharge, 32% removed the sensor due to discomfort before the study was finished.

1.2.5. Non-contact tracking of vital signs

Previous research work has provided insights on the application of radar in healthcare, sleep monitoring, physical activity monitoring, and fall detection.

Kocur et al. (2017) was able to use ultra-wide band (UWB) radar to detect two persons behind a 0.5-m-thick basement wall, including also estimating the subjects’ breathing frequency, detected as 0.24 Hz and 0.12 Hz by using two receiving and one transmitting antenna. According to Russo et al. (2017), 10 bpm equals 0.16 Hz, so a respiratory rate of 7.5 Hz for one and 15 Hz for the other

subject was detected, even though one person slightly covered the other person in the way they were positioned.

In order to confirm respiratory rates estimated with UWB radar, Lai et al. (2011) conducted respiratory rate measurements simultaneously with a respiratory band for their research. The test duration was short, with 1 min each for four distances (with 0.5 m the shortest), and it only included four subjects; however, correlation coefficients were acceptable between 0.68 and 0.97, with larger sized participants showing highest accuracy.

Solberg et al. (2015) reported that radar in healthcare has mainly been used for estimating the pulse and respiration rate at a distance, typically in the context of continuous, non-contact monitoring and attempts to use UWB radar for determining blood pressure via the changes of the radius of the aorta. He reported inadequate results, however, with the UWB radar detecting signals coming from the artery walls. Furthermore, with different antenna placements, the signal was too weak to detect blood pressure as the artery wall was no longer visible.

In a study by Khan and Cho (2017), it was researched if vital signs (heart rate and respiratory rate) can be measured with radar only. An algorithm was applied to suppress the heart rate signal apart from the respiratory signal to reduce the respiratory harmonics, with the approach to point the radar toward the back side of the person.

El-Bardan et al. (2017) and Cho et al. (2015) also used UWB to estimate both radar and heart rate, with the same challenges of needing to isolate the heartbeat from the respiratory rate. Their developed algorithm has successfully been demonstrated to reduce noise and successfully extract both heart rate and respiratory rate as well.

While researchers have found Photoplethysmography (PPG) to be accurate when compared to an electrocardiogram (ECG) (Blok et al., 2021; Pietilä et al., 2017; Weiler et al., 2017), research shows mixed accuracy of remote PPG (rPPG). Sharma et al. (2019) uses rPPG to determine heart rate remotely at rest, which is compared to the results of a pulse oximeter. The author reports very accurate and promising results with an accuracy error of 2.07%. However, only seven subjects participated in this study, and the report did not mention test setup, such as the participant's distance to the camera.

van der Kooij and Naber (2019) researched how the accuracy of rPPG for various body parts compared to the values generated with a pulse oximeter with each of the 21 subjects that participated. Each test subject was recorded for about 30 s in resting, light, and moderate exercise. The team reports that heart rate accuracy is high when using the face as region of interest (ROI) during rest, with an average deviation of 2.34 bpm. The number rose to 29.75 bpm for the wrist, and for the calf to 36.83 bpm. During light exercise, the heart rate deviation was 5.91 bpm (face), 16.11 bpm (wrist), and 19.47 (calf), and for moderate exercise, deviations were even higher. Dasari et al. (2021) show similar results upon testing 140 subjects at rest for 2 min and compare results simultaneously measured with a pulse oximeter with a mean deviation of around 1 bpm.

These studies all tested short durations of vital signs recording via rPPG and will not be suitable for RPM. There are also several reported studies with limit accuracy of applying rPPG to estimate vital signs. Benedetto et al. (2019) describe their results of testing 24 participants and compared rPPG readings with the results of an electrocardiogram (ECG), showing mean deviations of 9.8 bpm compared to the ECG.

Coppetti et al. (2017) tested 108 participants by using the smartphone camera as a light source, comparing the results to an ECG measurement and reported a mean deviation of 7.08 bpm, and Cheatham et al. (2015) tested rPPG accuracy with 30 participants and compared the results with both, a heart rate belt and a pulse oximeter after a 5-min test. rPPG estimation results showed a deviation from 11.88 to 12.83 bpm as compared to the heart rate belt and between 0.59 and 17.72 bpm compared to the pulse oximeter.

In a research that was set out to compare the accuracy of ear thermometers and forehead thermometers versus rectal thermometers, which are the gold standard in body temperature determination (Wise, 2015), Teller et al. (2014) report that ear and infrared forehead thermometers returned lower readings than rectal thermometers. Their report matches with the data of Mogensen et al. (2018) that studied the accuracy of the forehead and ear thermometers compared to rectal thermometers amongst children, with the findings that ear thermometers are closer in accuracy to rectal thermometers and that forehead thermometers may not be suitable to determine temperature. Sharif Nia et al. (2022) report that measurements with an infrared forehead thermometer resulted in lower accuracy and limited precision as compared to an ear thermometer.

Nguyen et al. (2010) report good accuracy of two thermal imaging systems for fever screening, agreeing with Ge et al. (2020), who report satisfying results and encourage using infrared forehead thermometers as a screening tool. Slade and Sinha (2021) describe the options for non-contact fever screening and highlight that thermal imaging is the most preferred option; however, its accuracy could be impacted by objects that could obstruct the line of sight, such as hats, highlighting that the key to proper results is to ensure a clear line of sight.

2. The Pi-CON methodology

While this review shows that researchers have used radar and PPG in the past to estimate both heart rate and respiratory rate, it also shows the challenges of separating the heartbeat and respiration signal (Xu et al., 2021), as well as accuracy of rPPG. To eliminate these technical challenges and the above-mentioned usability issues with the goal to limit user interaction to a minimum, the Pi-CON methodology is introduced. Pi-CON is an acronym and stands for Passive, Continuous, and Non-contact. It defines a method of continuous data collection that minimizes the potential of user error, without the need to attach anything to the patient. The suggested technology to apply the Pi-CON methodology is to use a thermal camera to estimate body

temperature, ultra-wide band (UWB) radar to determine respiratory rate, and a red-green-blue (RGB) camera to estimate heart rate using rPPG.

Based on the reviewed literature and the RPM usability impact model, a sensor ("ubiquitous sensor") has been designed and developed according to the Pi-CON methodology that promises to measure a patient's vital signs contact-less and passively without any user interaction required by the patient. The sensor will also continuously detect the patient's vital signs, ensuring that adverse events are no longer missed by continuously recording data, rather than just a spot-check of vital signs, as done mostly with kits provided by hospitals participating in RPM programs.

For this research, this novel ubiquitous sensor will be used to determine if the Pi-CON methodology can increase usability and eliminate inaccurate data driven by human error (such as inaccurate data acquired due to operator error) and technical limitations of the device.

The research will answer:

- If the participant will prefer data collected with the Pi-CON methodology compared to the spot-checks taken with a PGHD device (such as the devices that come with an RPM kit)
- If a vital signs exam can be completed with less errors by using the developed sensor
- How the user interface (UI) that was developed along with the ubiquitous sensor will compare with the UI of a conventional PGHD device to increase comprehension of the results

3. Methods

To determine if the Pi-CON methodology can increase usability and eliminate inaccurate data driven by human error and technical limitations of the device, the ubiquitous sensor was developed, and the following research hypotheses (RH) were defined:

- Research Hypothesis 1 (RH1): Participants prefer using a passive and contactless method to measure heart rate, respiratory rate, and body temperature over commercially available devices.
- Research Hypothesis 2 (RH2): User-related errors made upon using the contactless ubiquitous sensor are lower in comparison to using commercially available PGHD contact devices.
- Research Hypothesis 3 (RH3): The presented results of the generated data with the ubiquitous sensor are more accepted by users since it is simple, and all the data is in one place.

3.1. Ethics approval

Approval of this study was obtained by Iowa State University's Institutional Review Board (IRB) at the Office of Research Ethics with IRB ID 22-182.

Table 2. Participants' demographics.

Age	18–24	25–34	35–44	45–54	55–64	65–74	Total
N	5	1	–	5	4	3	18

3.2. Study design

The experiment took place at two sites in the Midwest. Participants were recruited through word-of-mouth and a flyer posted in a common community location explaining the study. Because RPM is open to patients of all education levels and other demographics upon CMS removing all restrictions (Roblyer, 2020), the study was open to everybody aged 18 and above. Once a participant showed interest, the study was explained to the participants, and a consent form was provided to help them decide whether they wanted to participate.

3.3. Participants

A total of 18 participants (eight females and ten males) agreed to participate in this experiment, with five participants being between 18–24, one participant between 25–34, five participants between 45–54, four participants between 55–64, and three participants between 65–74 (Table 2). All participants signed the informed consent; none were eliminated, and none dropped out during the experiment.

3.4. Sensor design

Based on the gaps in the literature discussed above, an Internet-of-Things (IoT)-enabled sensor was developed. It enables checking vital signs of a patient without attaching a sensor, without any user input required by the patient, and by acquiring data continuously to not miss potential adverse events that would not typically be identified when the patient performs only two or three daily spot checks.

As the Pi-CON methodology suggests, the ubiquitous sensor utilizes radar, a thermal infrared camera, and an RGB camera, as those are excellent choices to estimate heart rate, respiratory rate, and body temperature due to its non-invasive nature and low cost, and due to radar's penetration capabilities (Sharma et al., 2019; Singh et al., 2011).

3.5. Sensor components

UWB radar is a specific type of radar. It provides a great range and has better penetration capabilities due to short, emitted pulses (Wang et al., 2012). It is therefore suited well for vital signs determination and estimation of a human's respiratory rate by determining chest displacement every time a person inhales (Staderini, 2002); see Figure 1. If a subject is relaxed, a chest displacement while breathing is expected to be between 4 mm and 12 mm (Cho et al., 2015). The technology operates between 3.1 GHz and 10.6 GHz, and other radars at around 60 GHz. Therefore, higher penetration capabilities can be achieved due to the higher frequency (Khan & Cho, 2017).

PPG is a non-invasive, optical technique that is commonly used due to its simplicity and high accuracy in smartphone applications and wearables by utilizing a light-Emitting Diode (LED) or Organic LED (OLED) (Allado et al., 2022; Pietilä et al., 2017; Tzafilkou et al., 2022). While plethysmography senses volume changes in different parts of the human body, such as the lungs (Criée et al., 2011), PPG uses a light source, such as an LED, to detect volume changes in our blood vessels (Kamal et al., 1989). Upon the LED or other light source emitting light, the amount reflected or transmitted (depending on the type of PPG) is detected (Yu et al., 2021), and since it is proportional to the amount of blood flowing through the blood vessels, the heart rate can be determined (Ibtehaz & Rahman, 2020).

Since the Pi-CON methodology recommends passively, contactless, and continuously estimating a human's heart rate, PPG needs to accomplish vital signs estimation from a

distance. While heart rate detection can be achieved via with PPG by using a source emitting light onto an object and the detected difference in light intensity, remote PPG, or rPPG in short, uses a derived version of PPG by pointing a camera onto an object to record the delta of pixel density between heartbeats, with ambient light emitting the light and being the source, and the forehead being the object and ROI (Mironenko et al., 2020).

The forehead is an ideal ROI due to the good accessibility of the temporal artery that runs through the forehead, its constant blood flow, and available algorithms extracting the forehead (Amelard et al., 2015; Kim et al., 2021). During every heartbeat, the heart contracts, and the blood volume increases, leading to slight color changes of the forehead. The camera can detect this change, assuming minimal motion of the person (Zou et al., 2019). This is illustrated in Figure 2.

A thermal camera is used to determine a person's body temperature from a distance by detecting thermal radiation from the surface of an object (Möllmann & Vollmer, 2007). This became a popular option after the onset of COVID-19, attempting to stop the spread of the virus (Saman et al., 2021). Thermal cameras are a safe and non-invasive technology and use an infrared detector that is added to a thermal camera to detect differences in temperatures of objects in the line of sight (Mikulska, 2006) - see Figure 2.

The forehead is also the preferred ROI to estimate the body's core temperature as it is convenient, especially for patients not cooperating with oral, rectal, or axillary methods (Somboonkaew et al., 2017). Also, with the temporal artery running through the forehead providing constant blood flow and blood being a solid indicator of the body's core temperature, emitted heat can be captured conveniently on the forehead since the blood vessels runs right below the skin surface (Kiekkas et al., 2016).

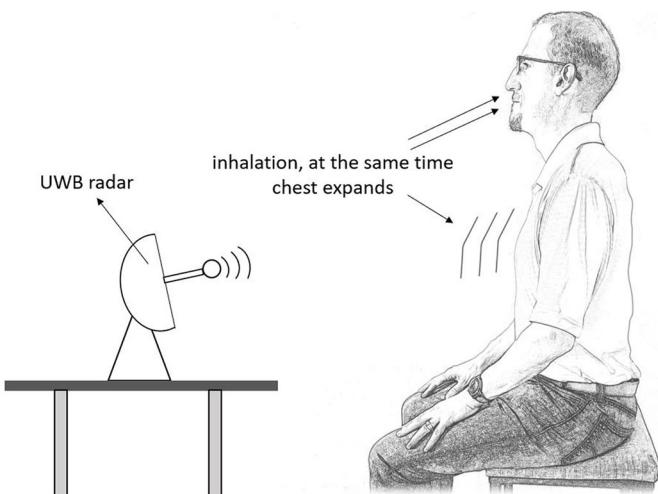


Figure 1. Radar to estimate respiratory rate.

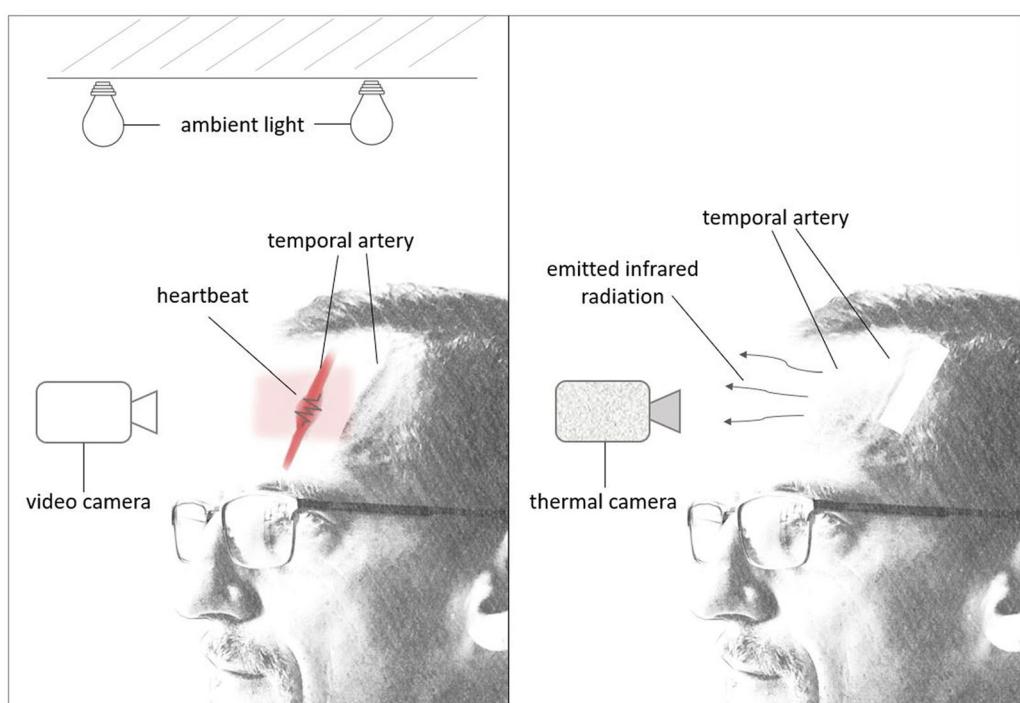


Figure 2. rPPG and thermal imaging to estimate heart rate (left) and body temperature (right).

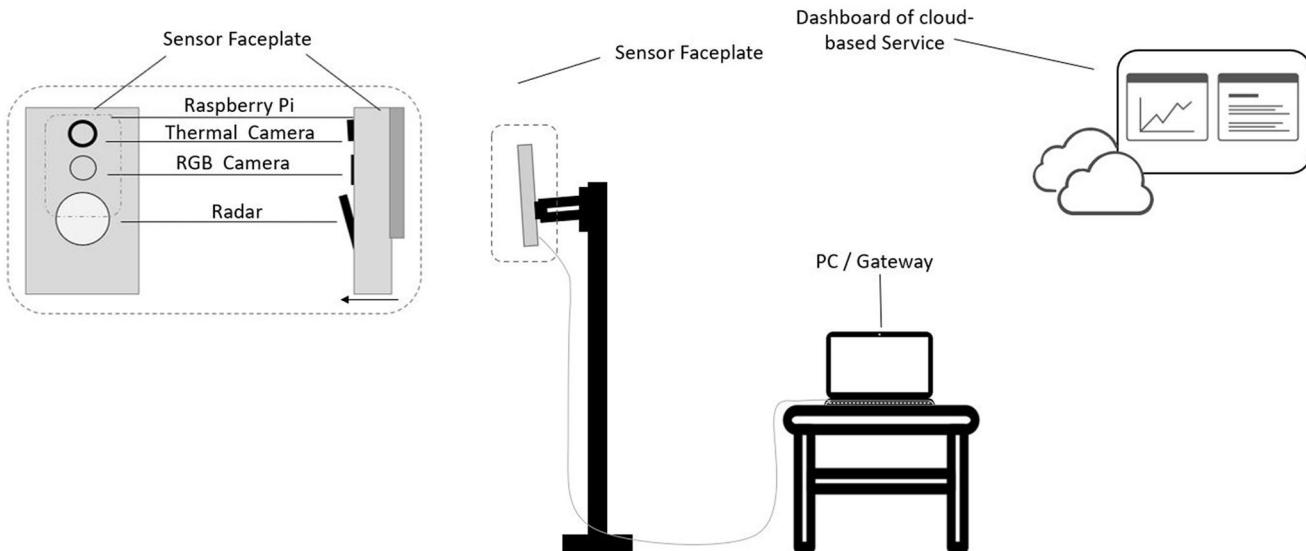


Figure 3. Sensor hardware design and setup.



Figure 4. Landing page showing first-glance results of vital signs exam.

3.6. Sensor development

The sensor firmware was written with Python 3 and ran on a Raspberry Pi 3 (The Raspberry Pi Foundation, Cambridge, United Kingdom). As the data is recorded, the data will be sent in real-time to a cloud-based solution so the data can be accessed in real-time by the patient, caregiver, or anybody else from anywhere. The chosen cloud-based service for this application is ThingsBoard (ThingsBoard, New York, NY) due to its ability to store a large amount of data and to create user-friendly UIs used as dashboards to review the health data in real-time.

Figure 3 shows the design of the ubiquitous sensor and the designed workflow. The PC on the table in the center of Figure 3 acts as a gateway and collects the telemetry (sensor-) data from the sensor faceplate. From there, the PC sends the telemetry data wirelessly as it is processed to the ThingsBoard cloud.

The moving average is calculated in the cloud once it receives the data, as it is accomplished by many wearables

(Chen et al., 2017), and displays the results as shown in Figure 4. It was the goal to develop a user interface that is intuitive and user-friendly for both experienced and novice users alike. Previous studies show that better results comprehension by the patient leads to higher engagement and motivation for device usage and RPM compliance (Asimakopoulos et al., 2017; Codella et al., 2018).

To show results in a comprehensive manner, a classification, or score, is displayed based on the data calculated displayed as moving average data, in this case “good.” The patient’s name is displayed on the top left. In this example it is hidden throughout the experiment since the participants’ identity is not shown. On the top right, an option can be found to turn off the monitor manually.

By clicking on “learn more” (next to the risk classification), the user can review the reference chart used to classify the average vital sign value (Figure 5). The Early Warning Score (EWS) is used as a reference for scoring the patients’ vital sign values. EWS is a reference database utilized to

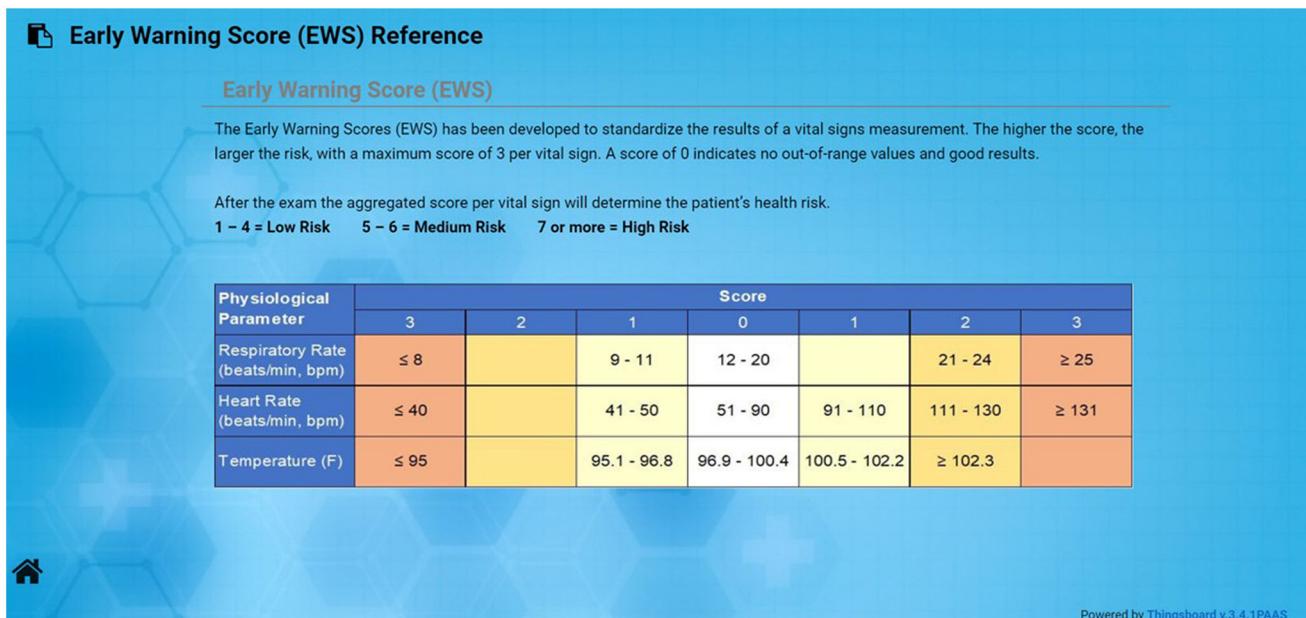


Figure 5. Out-of-range notification.

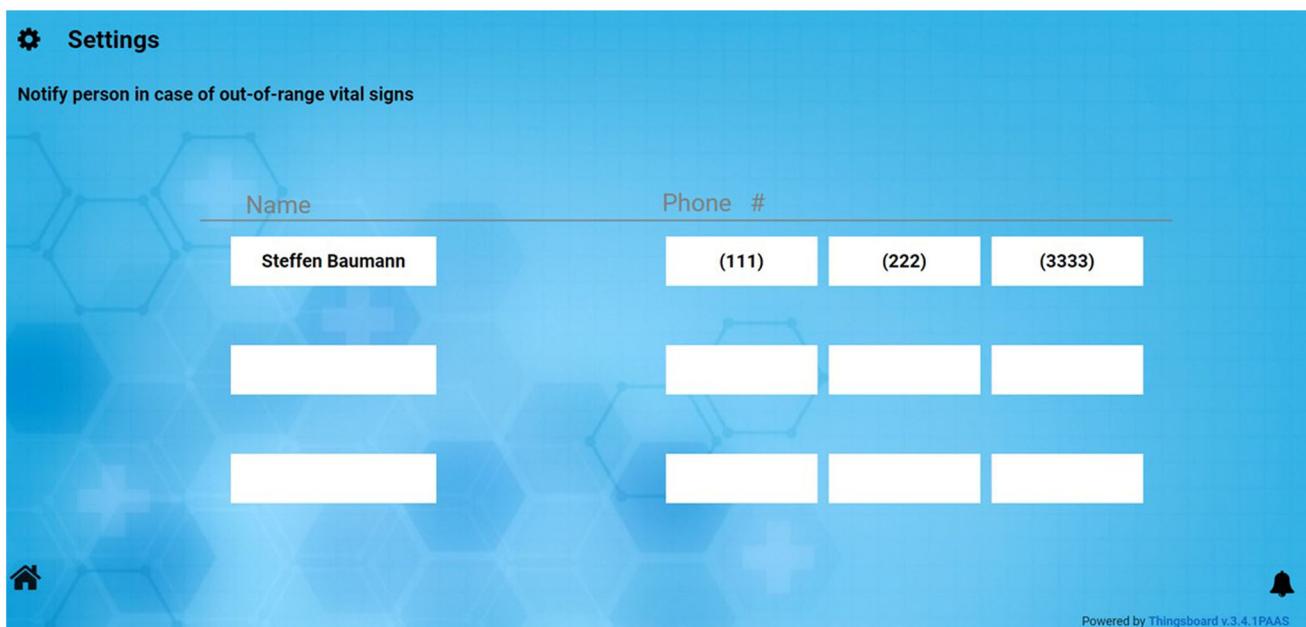


Figure 6. Early Warning Score reference.

standardize patients' vital sign results to identify if a response to treatment is taking place (Petersen, 2018).

According to the EWS (Morgan et al., 1997), the maximum score by vital sign (heart rate, body temperature, and respiratory rate) is 3. The aggregated score of all three vital signs informs the user about the risk level, with a score of 1–4 being low risk, 5–6 medium risk, and 7 or higher being high risk (Alam et al., 2015).

If there is an out-of-range value detected, the patient has the option to enter a person that should be notified if to alert and communicate about the exam (Figure 6).

The “vital signs monitor” tab in the top middle can be set to receive live data or historical view (Figure 7) and can be accessed and reviewed in real-time from anywhere. The “raw data” tab allows to study the actual acquired values during data generation also in real time (Figure 8).

3.7. Study design

As PGHD devices, the Masimo MightySat™ (Masimo, Irvine, CA) was used to determine heart rate and respiratory

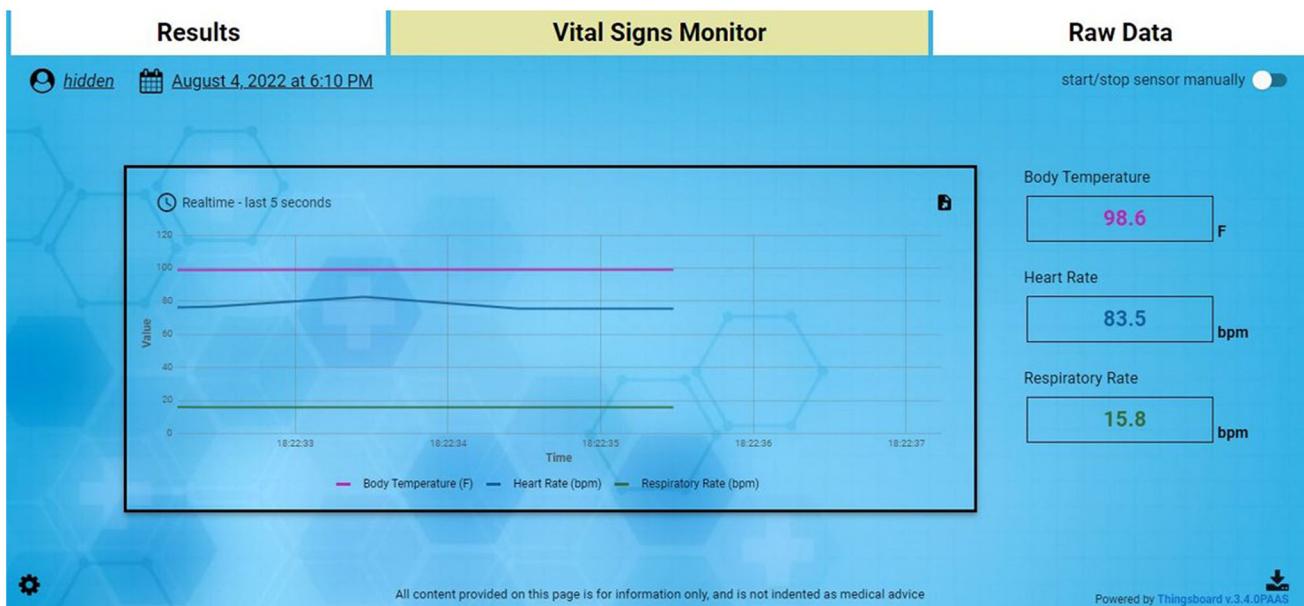


Figure 7. Vital signs monitor.

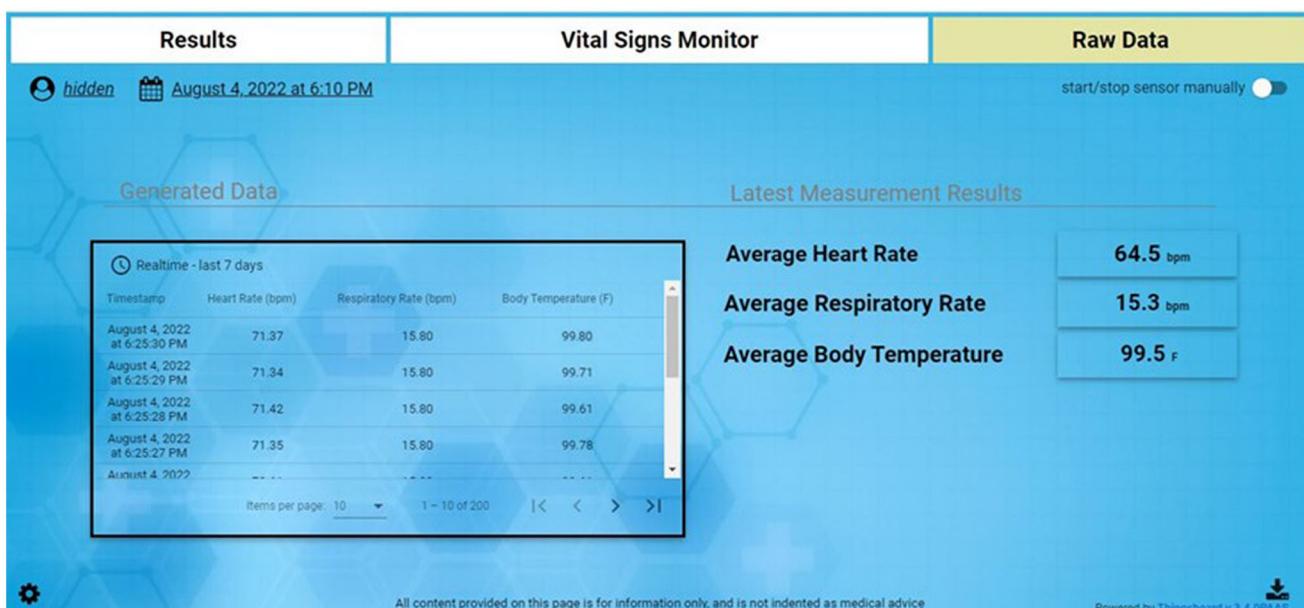


Figure 8. Raw data.

rate, and the Braun ThermoScan® 7+ (Braun Healthcare, Melsungen, Germany) to measure body temperature. Accuracy is listed as 3 bpm for heart rate and 3 bpm for respiratory rate with the Masimo MightySat™ (Masimo, 2019), and a precision of 96% for both (Cruz et al., 2021). For Braun ThermoScan® 7+, the accuracy is reported as 0.4 Fahrenheit (F) and the precision of 0.26 F (Braun, 2022). These two devices also match well with what is offered in a typical RPM kit provided by major healthcare networks (Maidel et al., 2021).

Upon arrival, each participant was asked to sit in a chair positioned in front of the sensor (Figure 9), followed by the researcher explaining the research project again and providing instructions on how to start the sessions. Both sessions

lasted 30 min. In one session, heart rate, respiratory rate, and body temperature were measured with the PGHD devices (pulse oximeter and thermometer) by the participant and immediately followed by the researcher, and in another session, the ubiquitous sensor measured the participant's vital signs, with the researcher performing manual checks throughout.

All participants were assigned a study ID. As study setup, a within-subjects design was chosen, with participants being randomly assigned to start with either of the two sessions to average out any possible carryover effects such as the “fatigue effect.” This is applied because participants may have a limited attention span by the time they get to perform their vital signs measurements (Price et al., 2015).

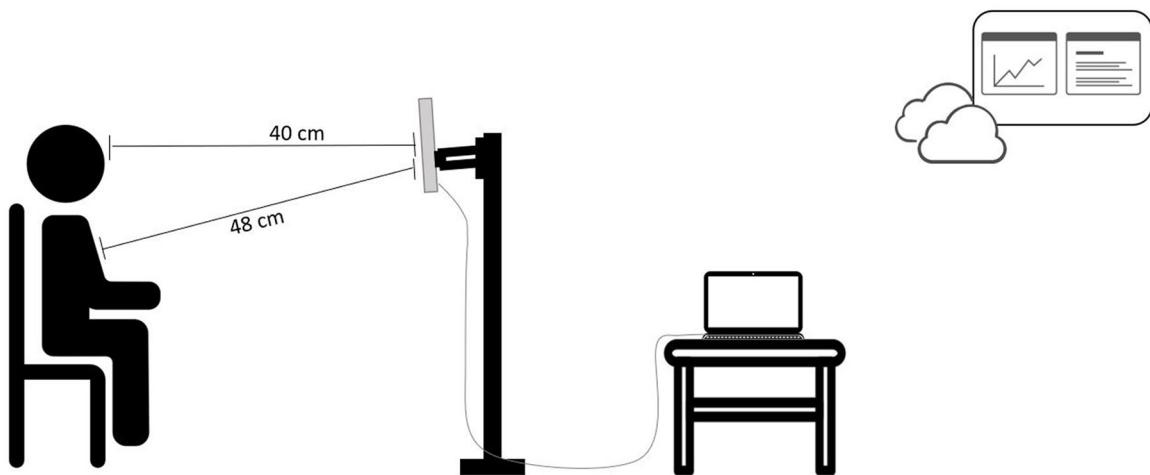


Figure 9. Experiment setup and sensor placement.



Figure 10. Vital signs measurement by participant.

In one session, the participants measured heart rate, respiratory rate, and body temperature by themselves at the beginning of the session, at the 15-min mark, and the end with the pulse oximeter and ear thermometer (Figure 10). Device operations were explained by the researcher to each participant, and the participant was encouraged to study and refer to the device's Instructions for Use (IFU) by the manufacturer before and during vital signs acquisition. The IFUs were available to the participant throughout the experiment.

Immediately after each measurement, the researcher checked the participant's heart rate by placing tips of the first and second finger on the inside of the participant's wrist and counting the heartbeats for 60 s. During these 60 s, the participant was asked to count their breaths to determine their respiratory rate. Body temperature was determined with the same ear thermometer the participant used (Figure 11). Results were recorded immediately after on the research observations sheet.

For the other session, vital signs (heart rate, respiratory rate, body temperature) were continuously acquired with the developed ubiquitous sensor (Figures 12 and 13). During this measurement, the participant was asked to sit still to reduce motion artifacts.

The Forehead Field of View (FOV) monitor (Figure 14) is visible during an exam, illustrating real-time heart rate and body temperature readings. It is located on the forehead, as both the thermal and RGB cameras were aligned and calibrated to target the forehead as a Region of Interest (ROI). Figure 15 shows the live dashboard as the data is acquired via the UIs vital signs monitor. It plots the values as the payload gets transferred to the cloud and shows the latest values to the right of the graph, similarly to a commercially available vital signs monitor. The respiratory rate does not use the forehead as ROI, but the participant's chest to estimate the respiratory rate, based on its displacement every time the participant inhales.



Figure 11. Vital signs measurements by researcher on participant.



Figure 12. Participant in front of ubiquitous sensor.

Results were recorded on the research observations sheet. Once data collection with both methods was finished, the participant was asked to review and briefly explain the data generated illustrated by the user interfaces that will be co-located in the test lab.

To determine a preference of each app, the researcher interviewed the participant about their preference. This is called “usability recall” and lasted for 30 s. This test, originally developed and coined as a “5-Second Test” (Gronier, 2016) is a cognitive ergonomics assessment. It is used to capture a user’s reactions to a UI design to get an idea of the user’s initial perception and illustrates what they were able to remember when first seeing the UI. (Gronier, 2016). Due to the nature of the available data on all provided apps, the time-window to review the UI was increased from 5 s to 30 s, with the PGHD devices app-time split into 15 s each since it was required for the user to access the Masimo MightySat™ app (Masimo Personal Health - Apps on Google Play, 2022) and Braun Family Care app (Braun Healthcare, 2021) apps, as seen in Figure 16.

3.8. Survey instrument

Upon completion of both sessions, each participant received a paper survey to record their preference of each of the two data collection methods. The survey, using a five-point Likert scale, included ten statements and yielded a Cronbach’s Alpha value of .86 (PGHD devices) and .85 (ubiquitous sensor). Participants were asked to indicate their preferred data-collection method by including questions such as “I was not bothered throughout the measurement,” “it was simple for me to perform the measurement and have my vital signs taken,” or “it required a large amount of mental effort to remember how to perform this measurement.” The survey also tested which acquisition method would help to be more compliant to RPM programs by including questions such as “taking vital signs this way, I would be following a doctor’s treatment protocol for a long period of time,” and checked the participants’ preference regarding the displayed results by including the statement “results of this measurement are easy to interpret.” Finally, the instrument tested the overall participant experience by having them rate the experience of taking vital signs with either method.

4. Results

To determine if the average rating for the ubiquitous device is significantly higher at the $\alpha = 0.05$ level of significance, we use the same methodology, a one-sided matched pairs *t*-test, to determine if participants made on average fewer operator errors with the ubiquitous sensor compared to the PGHD device for RH2. For all comparisons of RH2, we define the difference by subtracting user errors made with the PGHD device from the user errors made with the ubiquitous sensor. To define the preferences of device usage (RH1) and the user interface for results interpretation (RH3), we are subtracting participant responses of the PGHD device from participant responses of the ubiquitous sensor.

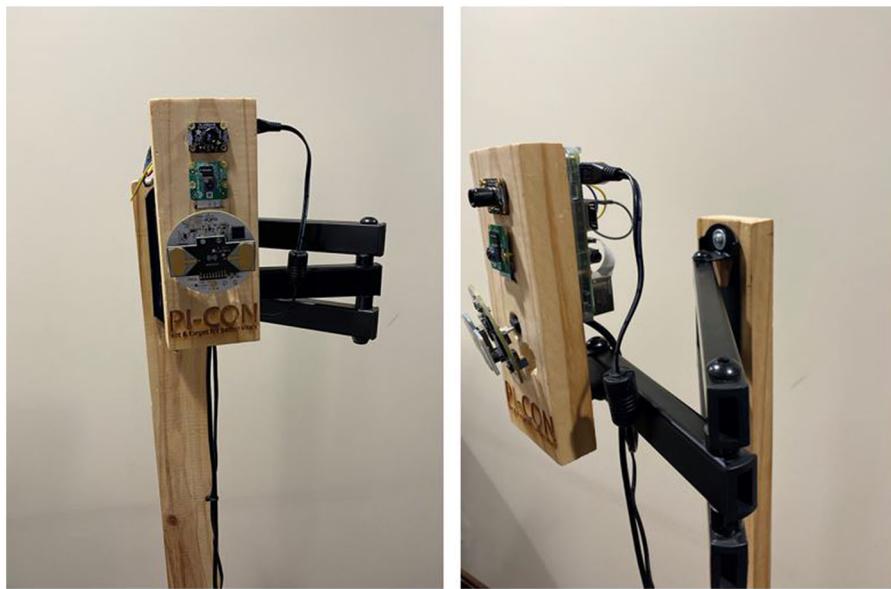


Figure 13. Developed ubiquitous sensor.



Figure 14. FOV monitor showing real-time data acquired on forehead.

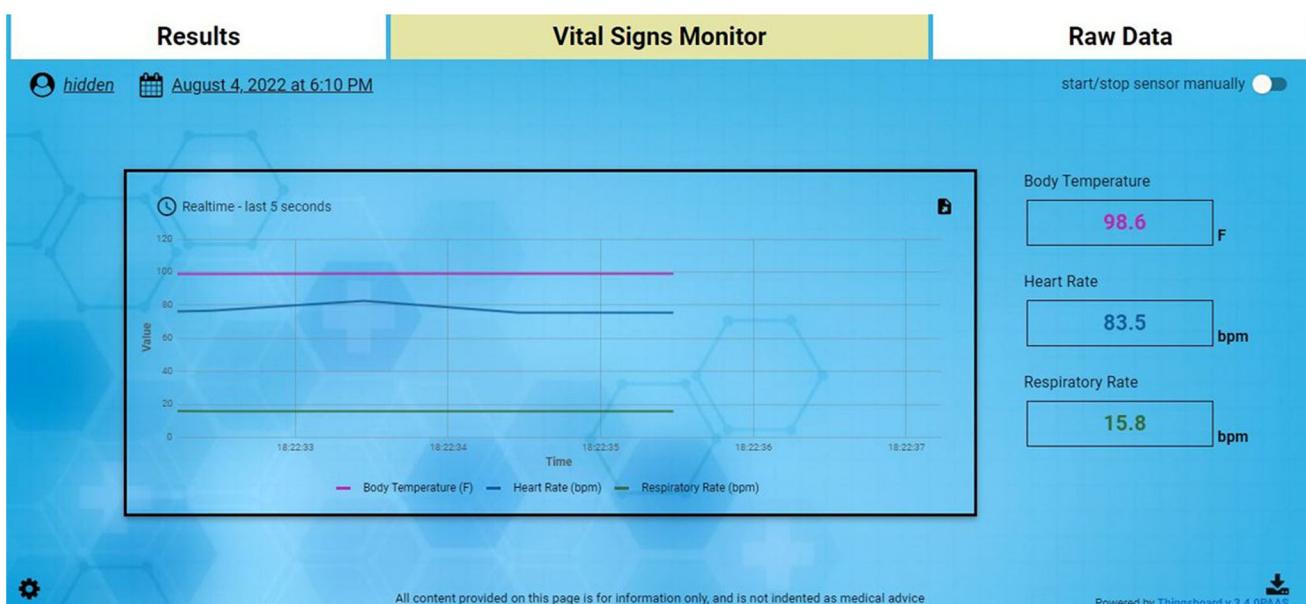


Figure 15. Vital signs monitor as live dashboard.

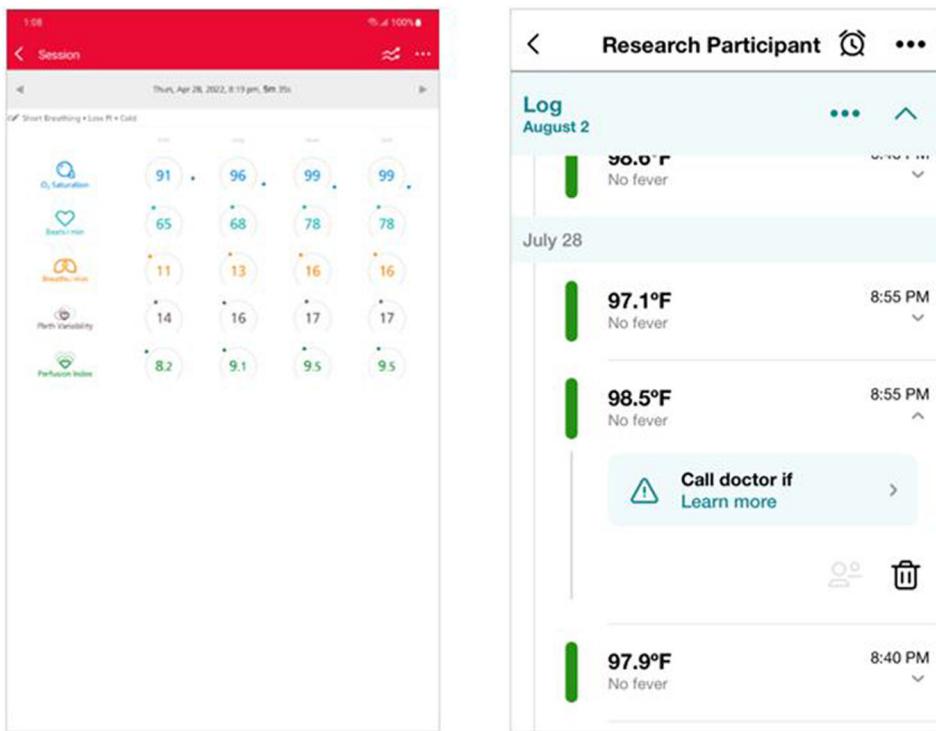


Figure 16. PGHD device apps (Masimo MightySat on the left and Braun ThermoScan® 7+ on the right).

A one-sided matched pairs t-test was used to analyze the mean difference for each case evaluated. Due to a potential lack of data normality and the small sample size ($n=18$), a Wilcoxon signed rank test was also performed in addition to the matched pairs t-test. A Wilcoxon signed rank test is a nonparametric test that does not rely on the sample means following a normal distribution, at least approximately. In all cases of the carry-out experiment, the conclusions from the Wilcoxon signed rank test was unchanged from the matched pairs t-test, i.e., to reject the null hypothesis. And while not identical, p-values from each test were of similar magnitude.

All values provided are rounded and are based on the non-rounded values provided by JASP, VS 0.16.4. (Amsterdam, Netherlands, 2018), a statistical analysis program.

RH 1: Participants prefer using a passive and contactless method to measure heart rate, respiratory rate and body temperature, over commercially available devices.

Based on participants' survey responses, the ubiquitous sensor received a mean rating score of 4.34 ($SD = .50$) compared to the PGHD device with a mean score of 3.47 ($SD = 0.77$). The average paired difference in rating scores of 0.88 ($SE = 0.21$) is significantly larger than zero, $t(17) = 4.27$, $p < 0.001$, suggesting that participants preferred the ubiquitous sensor over the PGHD device. The lower bound of a 95% one-sided confidence interval for the mean difference is 0.52.

RH 2: User-related errors made upon using the contactless ubiquitous sensor are lower in comparison to using commercially available PGHD contact devices.

We calculated the difference of errors made by each participant with both devices. If the contactless ubiquitous

sensor resulted in fewer user-related errors, as hypothesized, the average difference will be significantly larger than zero.

Respiratory Rate: The average difference in the number of errors made by participants is 0.28 ($SE = 0.24$). The results showed that the mean difference in errors is not statistically larger than zero $t(17) = 1.16$, $p = .131$. Although user errors made with the pulse oximeter, which is also capable of detecting respiratory rate, exceeded the user errors (detected motion) made with the ubiquitous sensor, the error reduction is statistically non-significant. We suspect that due to the sensitivity of the radar, participant-induced motion caused the radar signal to drop, which resulted in an error. The lower bound of a 95% one-sided confidence interval for the mean difference is -1.40.

Heart Rate: The average difference in errors made by participants measuring heart rate is 0.33 ($SE = 0.16$). This difference is statistically larger than zero $t(17) = 2.06$, $p = .027$, although the strength of evidence is weaker compared to the results for RH1. The lower bound of a 95% on-sided confidence interval for the mean difference is .05.

Body Temperature: The average difference in errors made by participants measuring body temperature is 0.44 ($SE = 0.19$). This difference is statistically larger than zero $t(17) = 2.41$, $p = .014$. The lower bound of a 95% one-sided confidence interval for the mean difference is .12.

Of the total 162 attempted vital sign measurements by the 18 participants, 45 (28%) resulted in device handling errors, ranging from struggling to get the exam started, to sensor positioning (finger/ear, hand, lens filter placement) or device malfunction (device did not turn on/off inadvertently). Of those, 35 (22% overall) resulted in not receiving a reading at all due to the error made by the participant.

Only four participants completed all exams without an error, implying that the remaining 14 participants, or 78%, made at least one error. The mean error per participant is .85 ($SD = .81$), with the pulse oximeter (measuring heart rate and respiratory rate) mean error per participant being .75 ($SD = .84$) and the ear thermometer being 1.06 ($SD = .73$). The mean error per patient with the ubiquitous sensor (due to motion) is .33 ($SD = .64$).

51% of all errors were made while taking the first measurement. Participants generally improved with measurements two and three, although 7% of all errors still occurred with the third measurement, showing that these types of tests do require a learning-curve, but errors continue to happen even if users felt more comfortable performing the tests themselves. Only two participants referred to the IFUs before or during the experiment.

A major contributor to inaccurate results is motion (Patel et al., 2019) when using a pulse oximeter, but there were no issues recorded as the participants did well following instructions given prior to the exam.

RH 3: The presented results of the generated data with the ubiquitous sensor are more accepted by the users since it is simple, and all the data is in one place.

The ubiquitous sensor received a mean rating score of 4.39 ($SD = .70$) compared to the PGHD device with a mean score of 3.56 ($SD = 1.04$). The average paired difference received a score of 0.833 ($SE = 0.25$) and is significantly larger than zero, $t(17) = 3.39$, $p = .002$, suggesting that participants prefer the ubiquitous sensor over the PGHD device. The lower bound of the one-sided 95% confidence interval for the mean difference is 0.41.

The qualitative data shared by the participants shows that 17% of all participants preferred the UIs of the PGHD devices (Figure 17), 56% preferred the developed UI of the ubiquitous sensor, while 28% were indifferent. These

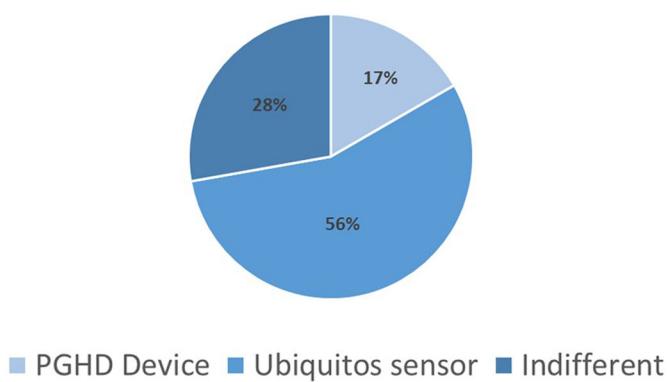


Figure 17. Preference of PGHD UI vs ubiquitous sensor UI.

participants had no preference as they focused solely on the results.

The main reasons for preferring the UI of the ubiquitous sensor were the ability to display a wealth of data in a very organized manner. One participant mentioned “it’s very organized – there’s not much thinking required, you just look” while for others the classification (Good or Low Risk) stood out right away with one participant stating, “the Good indicator is a plus, first thing I noticed, and the first thing people should see.” The drawbacks mentioned by many regarding the PGHD apps were that the data was labeled at a very minimum, acceptable ranges were either missing or it showed too much data that was perceived as “confusing.” One user compared the UI of the ubiquitous sensor with the health chart on a mobile phone and mentioned that it reminded her of “MyChart” (Epic Systems Corporation, Verona, WI). Only one user commented on the display polarity of the ubiquitous sensor UI and wondered why the background was blue and not white.

Six participants (33%) specifically stated they did not understand the information provided by the pulse oximeter, and none had similar feedback for the ubiquitous sensor UI.

4.1. RPM usability impact model & usability concerns

During the interviews, participants shared their experience and opinions about using PGHD devices. The information was collected, quantified, and categorized per the four pillars of the RPM usability impact model listed on the left of Figure 18, which are patient characteristics, technical device limitations, patient compliance to RPM and device placement on body.

4.1.1. Patient characteristics

Figure 19 refers to one participant (6%) who stated he could not have a wearable attached to his body due to his work as a contractor. 22% of all participants felt uncomfortable in their technical skill set regarding the ability to setup their device or addressing firmware issues with their home use medical device that they had to manage in the past. While they did not know how to address the issue, their physician office helped, which was commented with the statement “this requires yet another trip.”

While 33% of all participants stated they did not understand the results of the pulse oximeter, it became apparent during the discussions that 17% of all participants are health illiterate and did not know what they were looking at based on their responses, such as “I’m not sure what I’m reading –

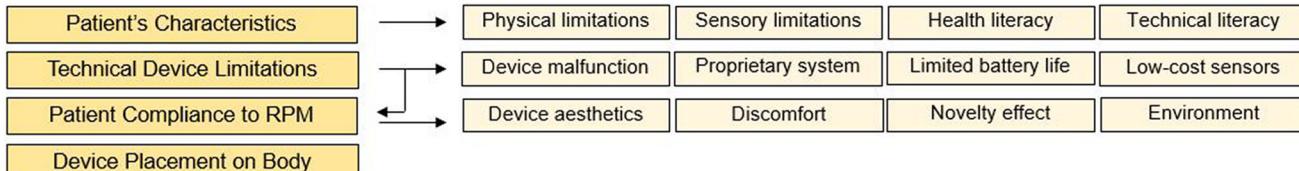


Figure 18. RPM usability impact model.

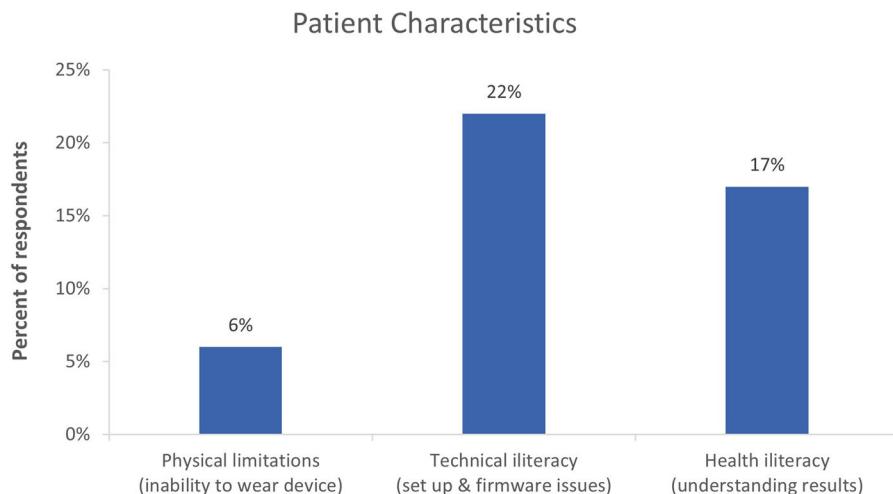


Figure 19. Patient characteristics.

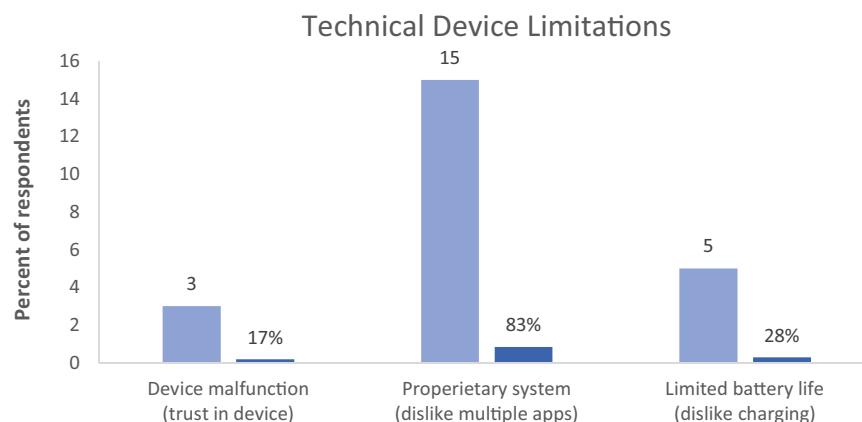


Figure 20. Technical device limitations.

I usually just listen to my doctor and trust him/her,” or “I’m sure everything is there that should be there.”

4.1.2. Technical device limitations

17% mentioned that they do not trust the accuracy of the devices (Figure 20), and 83% stated they would not want to look at different apps for their results due to proprietary technology and isolated content. This became also transparent during the usability recall of the experiment, where most of the participants reported the efficiency and organization of the ubiquitous sensor UI, showing all three vital signs in one application. Most participants preferred to have all data in one app for the reasons of speed and provided comments such as “the faster I get the results the better” or simplicity. One participant stopped wearing his wearable because it became too “bothersome” to look up step count and heart rate since he used different apps for both.

Additionally, 28% of participants are bothered by the fact that the wearable needs constantly charged, as it is “just one more thing to do” and “requires a new routine.”

4.1.3. Patient compliance

Figure 21 illustrates that 11% mentioned that device aesthetics is their reason for not owning a wearable, and that 28% of participants are bothered by having something attached to their body, with four additional participants taking off the wearable at night, making sleep tracking no longer an option.

When asked if a wearable has been used in the past or is currently used, 44% of participants responded with using a wearable at some point, with four of participants also sharing that they use a home use medical device. Two participants regularly use a continuous positive airway pressure (CPAP) device and two others a blood glucose monitoring system. Of these 44% (eight participants) that have used a wearable or home use medical device in the past, 22% (four participants) used to own a wearable, but stopped using it (as highlighted by the novelty effect), and the other remaining 22% claim they have used the wearable regularly for the past 3 months or more. For the participants who do not own or use a wearable, the reason for not owning one was that they simply never thought about it, do not want to

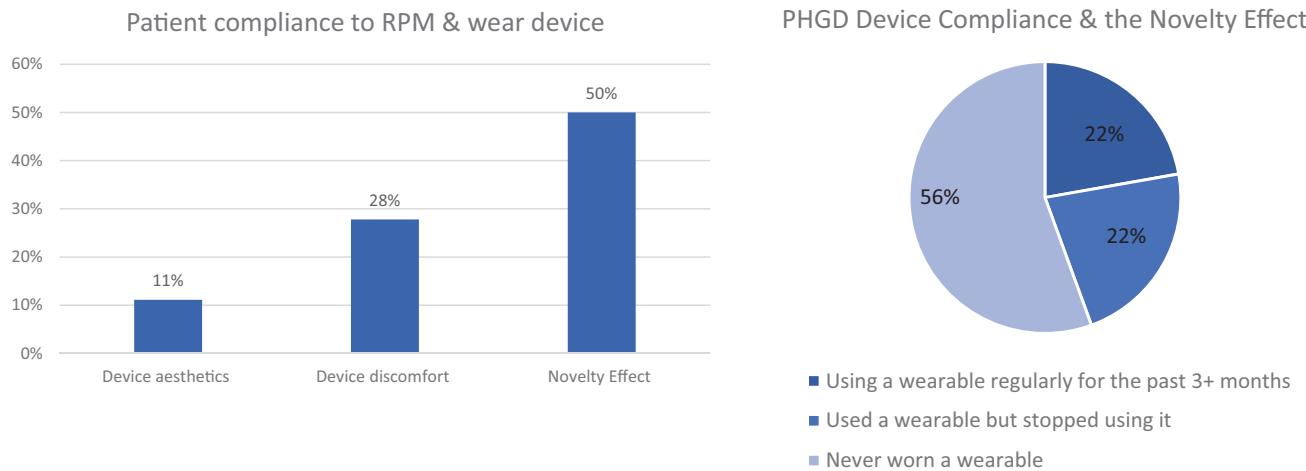


Figure 21. Patient compliance to use PGHD device.

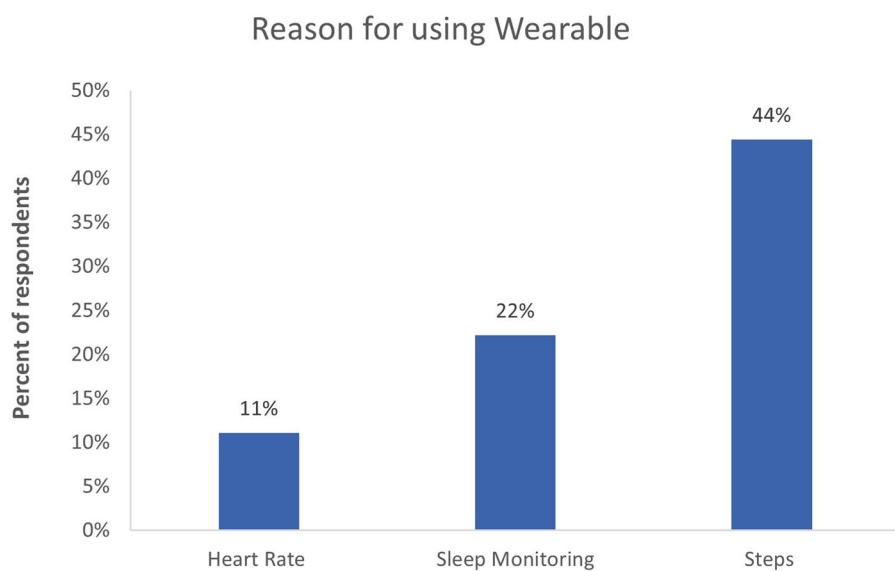


Figure 22. Reasons for using wearable.

spend the money, and they are bothered by its aesthetics. One participant mentioned that wearables are too disruptive, even after attempting to turn off all reminders and notifications, so therefore stopped using it.

4.1.4. Device placement on body

22% of participants stated their worries about proper device placement and the impact it could have on treatment decisions. This came up when asked if they feel they would be compliant to an RPM program, with the participants stating concerns about starting out with an error or a wrong habit during vital signs measurements and that they would not know to correct it. One participant shared an experience with the usage of his blood glucose monitoring system and stated it is not user-friendly, as placement of the device is challenging, and usage is cumbersome due to the need to “swipe over phone to save data every 8 hours.” He concluded by saying that if this is neglected, there may be 8 hours of data that is lost.

4.1.5. Reasons for using wearable

Of the eight participants who currently use or have used a wearable, all of them utilize the steps tracking feature. Four participants use or have used a wearable for tracking sleep, and only two participants to track heart rate (Figure 22). Two participants each stated the need for diet tracking and notifications as main reasons they own a wearable.

4.1.6. Familiarity with terminology

56% participants were familiar with telehealth after attempting to define the term. Many thought they responded with the correct definition but connected it to phone consults only. While only 33% participants were familiar with the term “wearable,” only 11% had heard of the term remote patient monitoring before (Figure 23). This data could be a contributing factor and explains why some participants cannot imagine participating in an RPM program. The awareness level, general market acceptance and adoption is still at its early stages.

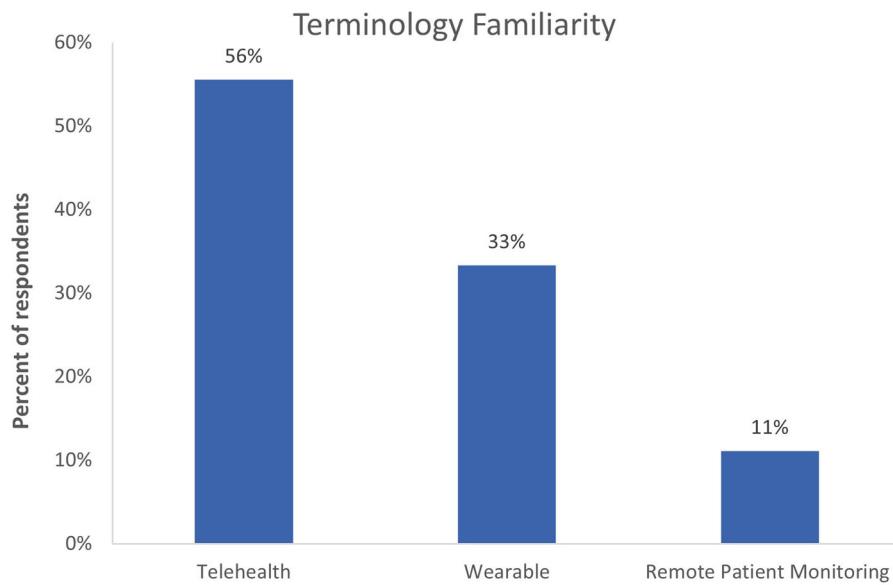


Figure 23. Terminology familiarity.

Table 3. Summary of participant's RPM concerns.

	%
Patient characteristics	
Physical limitations (inability to wear device)	6
Technical literacy (set up & firmware issues)	22
Health literacy (understanding results)	17
Technical device limitations	
Device malfunction (trust in device)	17
Proprietary system (dislike multiple apps)	83
Limited battery life (dislike charging)	28
PHGD device compliance impacted by novelty effect	
Have used a wearable at some point	44
Using a wearable regularly for the past 3+ months	22
Used a wearable but stopped using it	44
Never worn a wearable	56
Patient compliance to wearing device	
Device aesthetics	11
Device discomfort	28
Novelty Effect	50
Device placement on body	22
Miscellaneous	
Data privacy concerns	11
Prefer continuous monitoring and richer data	94
Terminology familiarity	
Telehealth	56
Wearable	33
Remote patient monitoring	11

4.1.7. Data privacy and continued data acquisition

Lastly, only 11% of participants are concerned about data privacy, and only one participant did not see the need for continuous monitoring by stating “no, not for the general population and only for people that really need to be monitored.”

Table 3 illustrates and summarizes all quantified data that was shared by the participants during the discussions highlighting the validity of the RPM usability impact model.

5. Discussion

This research investigated if research participants prefer the usage of an omnipresent and ubiquitous vital signs monitor per the Pi-CON methodology, with the sensor continuously

acquiring vital signs in a contactless way from a distance, with little to no user interaction required by a user. It also tested the user interface of the developed sensor, comparing this to the UI of a commercially available pulse oximeter and ear thermometer, and the user errors that resulted out of operating the developed sensor and the PGHD devices.

The results demonstrate that the majority of all participants prefer vital signs acquisition with the ubiquitous sensor even though they had to sit still during data generation to suppress noise due to motion. This shows their relief of not having to worry about user errors if they start off the wrong way and therefore generate wrong data, the fact that they believe they will not be compliant throughout a prescribed timeline by their physician, or simply a relief due to higher convenience and no need to sit down and initiate an exam.

The quantitative findings of this research match well with the results reported in previous research and confirm the findings categorized in the RPM usability impact model. While this research reports that 78% of all participants had a minimum of one error during device operation, Keller et al. (2017) reported that 72% of patients had difficulties with the use of a PGHD device. User errors by participant matched also well with previous work. In regard to user errors generated by an operator, Chaniaud et al. (2020) reported a mean error of .99 errors per participant for pulse oximeters, and this research reports .75 errors per patient with the pulse oximeter. While the operator error rate for respiratory rate was not significantly higher with the pulse oximeter as compared to the respiratory rate generated by the ubiquitous sensor, it still exceeded the error rate of the ubiquitous sensor. Also, the significantly higher operator error rate for heart rate and body temperature measurements with the PGHD devices exemplify the high amount of variability that is introduced when performing vital sign measurements autonomously, without the presence of a medical professional.

Furthermore, this study confirms the need to organize data in a way so both novice users and health literate users are able to gain maximum information from the data provided. One way of accomplishing this is by scoring and classifying the results for simple results comprehension, but also providing the raw data and time series in an organized manner for users that like further information. In the work by Reyes et al. (2018), 76.6% of the study subjects were not able to interpret the results on the monitor the researchers tested. In this research, however, only six users (33%) stated they did not understand the results. This shows a trend of disinterest by the user if results are not understood.

As a limitation, it should be noted that the Masimo MightySatTM was chosen as PGHD device to determine the participants' respiratory rate, despite a reported accuracy of 3 bpm (Masimo, 2019), and other devices capable of determining respiratory rate at a better accuracy rate, such as a capnograph, reporting an accuracy of 1 bpm (van Loon et al., 2018).

6. Conclusion

This research set out to study usability issues when using a PGHD device without the assistance of a medical professional. It evaluated participants' preference of using a novel sensor developed according to the Pi-CON methodology, including its user interface, versus a PGHD device and its user interface, and compared the amount of operator errors when using the ubiquitous sensor compared to a PGHD device.

While the value-based care model will continue to shift care closer to the patient, including the use of PGHD devices by patients or their caregiver (Atreja et al., 2018), there is still trepidation of fully adopting this technology amongst clinicians, and also patients.

Rodbard (2014) stated that the adoption of remotely monitoring a patient's condition is slow to market, and Abdolkhani et al. (2019) confirmed that utilization of PGHD devices in a clinical setting is still low due to many quality and accuracy challenges, mainly driven by technical limitations of the devices. And Codella et al. (2018) identified challenges of patient-generated health data via RPM programs related to the data collection by non-trained medical professionals. Besides technological challenges, such as battery life, the authors also noted that the research on PGHD is "spare and fragmented" and identified limited sensor reliability, devices not being attractive enough, limited personalized data for the user, or simply the collected data not being complete due to limited patient compliance as main reasons.

Trust in the devices is necessary, also by the patient. During discussions with participants in this research, it became apparent that there is a gap in familiarity with telehealth-related terminology, showing this development is still in its infant stages. 17% of all research participants stated they do not "trust the technology" and 22% do not have trust in themselves when it comes to device operation and sensor placement.

6.1. Future research

The Pi-CON methodology could be expanded to estimate blood pressure readings without a cuff by using Pulse Transit Time (PTT) that estimates blood pressure by determining the time it takes for a pulse wave to travel from one arterial site to another (Liu et al., 2016). Pi-CON could also be applied to a room with multiple persons to acquire vital signs of every patient, for instance, in a nursing home. By applying machine learning, noise due to motion could be surpassed, allowing patients to move freely without worrying about signal loss or noise.

Disclosure statement

No potential conflict of interest was reported by the author(s).

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