

Abstract

Evaluating the Accuracy of an Integrated Vital Sign Measurement Wellness Device

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Abstract

Background: Wellness devices for health tracking have gained popularity in recent years. Additionally, portable and readily accessible wellness devices have several advantages when compared to traditional medical devices found in clinical environments. Building tools for patients to manage their health independently may benefit their health in the long run by improving health care providers' (HCPs) awareness of their patients' health information outside of the clinic. Increased access to portable wellness devices that track vital signs may increase how patients and HCPs track and monitor chronic conditions which can improve health outcomes. The VitalWellness is a portable wellness device that can potentially aid vital sign measuring for those interested in tracking their health.

Objective: In this diagnostic accuracy study, we evaluated the clinical performance of the VitalWellness, a wireless, compact, non-invasive device that measures four vital signs using the index finger and forehead against reference vital signs devices used in the hospital setting.

Methods: Volunteers age ≥ 18 years were enrolled to provide blood pressure (BP), heart rate (HR), respiratory rate (RR), and body temperature. We recruited volunteers with vital signs that fell within and outside of the normal physiological range, depending on the measurements they consented to undergo. A subgroup of eligible volunteers were asked to undergo an exercise test, aerobic step test and/or a paced breathing test to analyze the VitalWellness device's performance on vital signs outside of the normal physiological ranges for HR and RR. Vital signs measurements were collected with the VitalWellness device and FDA-approved reference devices. Mean, standard deviation, mean difference, standard deviation of difference, standard error of mean difference, and correlation coefficients were calculated for measurements collected; these measurements were plotted on a scatter plot and a Bland-Altman plot. Sensitivity analyses were performed to evaluate the performance of the VitalWellness device by gender, skin color, finger size, and in the presence of artifacts.

Results: We enrolled 265 volunteers in the study and 2 withdrew before study completion. The majority of volunteers were female (62%), predominately white (63%), graduated from college or post college (67%), and employed (59%). There was a moderately strong linear relationship between VitalWellness BP and reference BP ($r=0.7$, $P<.05$) and between VitalWellness RR and reference RR measurements ($r=0.7$, $P<.05$). The VitalWellness HR readings were significantly in line with the reference HR readings ($r=0.9$, $P<.05$). There was a weaker linear relationship between VitalWellness temperature and reference temperature ($r=0.3$, $P<.05$). There were no differences in performance of the VitalWellness device by gender, skin color or in the presence of artifacts. Finger size was associated with differential performance for RR.

Conclusions: Overall, the VitalWellness device performed well in taking BP, HR and RR when compared to FDA-approved reference devices and has potential serve as a wellness device. To test adaptability and acceptability, future research may evaluate

user's interactions and experiences with the VitalWellness device at home. In addition, the next phase of the study will evaluate transmitting vital sign information from the VitalWellness device to an online secured database where information can be shared with HCPs within seconds of measurement.

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KEYWORDS

wellness device; vital signs monitoring; cuffless blood pressure monitor; patient-centric; blood pressure; heart rate; health tracking

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