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Article

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Posted Date: February 25th, 2026

DOI: https://doi.org/10.21203/rs.3.rs-8811683/v1

Additional Declarations: Competing interest reported. Authors P.S., V.B., N.M., M.D., M.M. and T.L. are employees of Circadia Health, Inc., the manufacturer of the investigational device and sponsor of this

study. G.D.L. acts as a consultant to Circadia Health, Inc. One or more authors hold stock options in Circadia Technologies, Ltd., which licenses its technology to Circadia Health, Inc.

Validation of a Contactless Radar System for Continuous Respiratory Rate and Heart Rate Monitoring in Clinical and Simulated Use Conditions

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ABSTRACT

Continuous monitoring of respiratory rate (RR) and heart rate (HR) remains limited in post-acute and long-term care (PALTC) settings, where intermittent spot checks may delay detection of clinical deterioration. Contactless radar-based sensing offers an unobtrusive alternative suited to these environments. This study validates the performance of the C300 Monitor, a contactless frequency-modulated continuous-wave (FMCW) radar system operating at 58.0 – 61.5 GHz, for continuous RR and HR monitoring across clinical and simulated use conditions. In a clinical validation study conducted in PALTC facilities, C300-derived RR and HR were compared against carbon dioxide capnography and electrocardiography, yielding Bland-Altman limits of agreement of -1.9 to 2.7 breaths per minute for RR, and -2.9 to 2.5 beats per minute for HR, with accuracy rates of 99.8% for RR and 95.1% for HR within a $\pm$5 breaths per minute and beats per minute error margin, respectively. A complementary laboratory study evaluated system performance across representative conditions, including varying device distances, body positions, and motion scenarios. Under motion-free conditions, accuracy rates exceeded 96.3% for RR and 90.6% for HR within the same error margin, while expected system behavior was observed during patient motion or absence. Across both studies, the C300 Monitor demonstrated reliable, continuous RR and HR monitoring under conditions representative of real-world PALTC use, supporting its suitability for unobtrusive vital sign monitoring in these settings.

Keywords: Contactless vital sign monitoring; Respiratory rate monitoring; Heart rate monitoring; FMCW radar; Post-acute and long-term care; Device validation; Remote patient monitoring

Introduction

In acute care settings, such as the general hospital ward and intensive care unit, vital signs are obtained frequently, and continuous bedside monitoring is available when clinically indicated. In contrast, in post-acute and long-term care (PALTC) settings, vital signs are typically measured manually and at infrequent intervals: once or twice daily in the skilled nursing facility (SNF), or weekly in assisted living facilities. In this clinical setting, it is standard practice to record and enter vital signs into the electronic health record system manually and in batches. Apart from being time consuming, this process is prone to human error[1], and manual counting of respiratory rate (RR) in particular is well known to be unreliable[2–4]. Furthermore, intermittent vital sign checks are likely to miss clinically meaningful trends, transient abnormalities, or physiologic variability[5–7].

This low standard of monitoring in PALTC settings is misaligned with the clinical challenges faced by these facilities: patients are often frail, have multiple comorbidities, and are at elevated risk of acute or sub-acute clinical deterioration. Re-hospitalization is a well-documented and persistent problem, with approximately 23 - 30% of patients discharged to SNFs rehospitalized within 30 days[8–10], of which at least half are considered avoidable hospitalizations[11]. Quality improvement initiatives such as Interventions to Reduce Acute Care Transfers (INTERACT) indicate that early identification of patient instability is key to reducing avoidable hospitalizations[12] and multiple studies have demonstrated that continuous vital sign monitoring outside the critical care setting can result in improved patient outcomes[6,13].

Improving the standard of vital sign monitoring in the PALTC setting could lead to earlier detection of patient deterioration and enable timely clinical intervention[14]. However, the requirement for these facilities to maintain a home-like environment, combined with relatively long length-of-stay (average of 28 days in SNFs and substantially longer in assisted living settings),

limits the feasibility of conventional continuous monitoring approaches. Technologies that physically tether patients to the bed, such as electrocardiography (ECG) leads and pulse oximeters, are generally not acceptable in this context and may lead to discomfort during long-term use[15]. Wearable devices (wrist-worn or patches) are operationally impractical in high-bed-count facilities with low staff-to-patient ratios, where devices are easily misplaced, removed, or left uncharged.

Radar-based sensing offers a compelling alternative for monitoring of RR and heart rate (HR). By measuring the chest wall displacements associated with respiration and cardiac activity, radar systems can provide accurate and continuous cardiorespiratory monitoring, without the need to attach anything to the patient[16,17]. As such a monitoring system would be contactless and unobtrusive, it is particularly well suited for long-term monitoring in the the PALTC environment.

Several radar modalities have been explored for biomedical applications, including continuous-wave (CW), ultra-wideband (UWB), and frequency-modulated continuous-wave (FMCW) radar. CW radars offer high sensitivity to displacement but lack range resolution, limiting their ability to separate multiple targets. UWB radars achieve fine range resolution through the transmission of short pulses over a wide bandwidth and have been widely investigated for vital-sign monitoring; however, accurate extraction of respiratory and cardiac motion often relies on precise timing synchronization, high-speed sampling, and complex clutter suppression to distinguish physiological motion from static and dynamic environmental reflections[18]. FMCW radar provides a complementary approach by encoding range information in the beat frequency of frequency-chirped signals, enabling explicit separation of reflections from the chest wall and surrounding structures while maintaining high sensitivity to sub-millimeter displacements[16,19,20]. This combination of range discrimination and phase-based motion sensitivity makes FMCW radar particularly well suited for continuous, non-contact clinical monitoring in real-world environments where multipath and background motion are unavoidable.

Our previous work[21] evaluated the performance of a commercially available UWB radar-based respiratory monitor, the Circadia C100 Contactless Breathing Monitor (Circadia Technologies, Ltd., London, UK). It demonstrated that the C100 Monitor provides accurate RR measurements, and could effectively be used for both spot checks and continuous bedside monitoring of RR. Subsequently, the ability to monitor HR was added to the same hardware system, resulting in the C200 Monitor (no performance data published).

The present study reports a performance validation of a next-generation contactless patient monitoring system: The Circadia C300 Contactless Cardiorespiratory Monitor. In contrast to previous generations, it employs FMCW radar technology to measure both RR and HR. Clinical data were collected in a representative patient population under real-world clinical conditions. Clinical testing was complemented by an evaluation of performance in various simulated use conditions, using healthy volunteers. The C300 Monitor is FDA-cleared (K252676) and available for prescription use in healthcare settings such as the SNF. However, to date, performance validation data of this device has not been publicly reported.

Materials and Methods

Principles of FMCW Radar-based Cardiorespiratory Monitoring

Radar-based vital sign monitoring exploits the sensitivity of radio frequency signals to small periodic chest wall displacements caused by respiration and cardiac activity. These motions modulate the propagation path of the reflected signal, producing measurable phase and frequency variations that can be used to estimate RR and HR.

In an FMCW system, the transmitted signal is expressed as a linear frequency-modulated chirp:

$$s_t(t) = A_t \cos\left(2\pi f_c t + \pi \mu t^2\right), \tag{1}$$

where A_t is the transmit amplitude, f_c is the carrier frequency, and $\mu = \frac{B}{T_c}$ is the chirp slope defined by bandwidth B and chirp duration T_c. The received signal, after reflection from the thorax, is a delayed and attenuated copy of the transmitted signal:

$$s_r(t) = A_r \cos\left(2\pi f_c (t-\tau) + \pi \mu (t-\tau)^2\right), \tag{2}$$

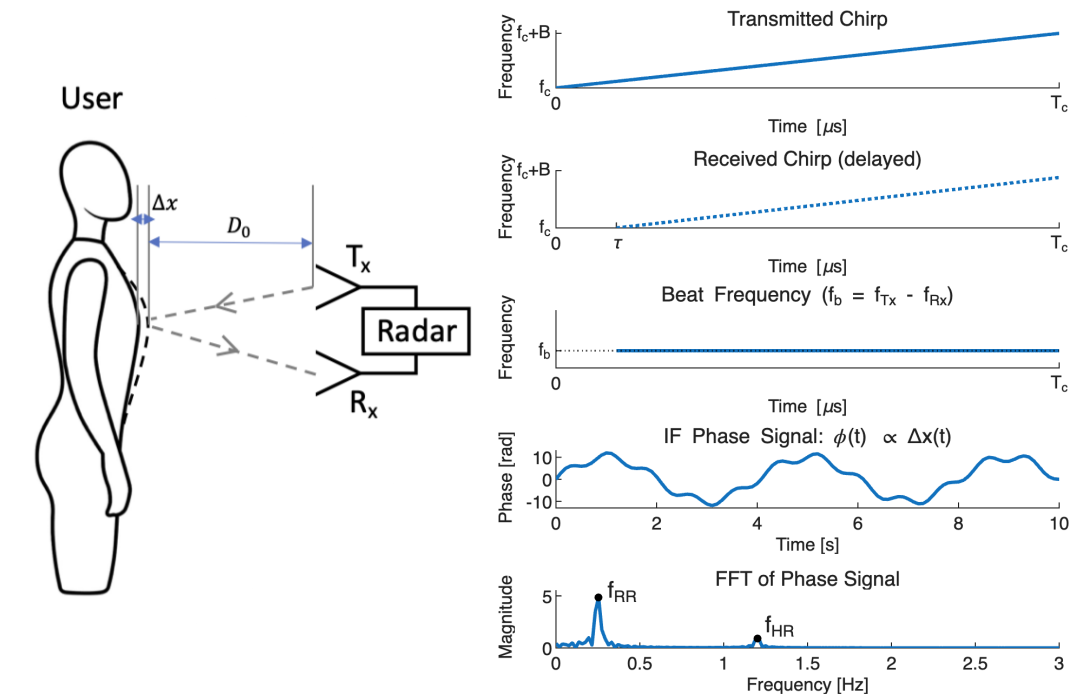
where $\tau = \frac{2D_0}{c}$ is the round-trip delay, D_0 is the distance between radar and chest surface, and c is the speed of light. After de-chirping (mixing $s_t(t)$ and $s_r(t)$), the intermediate frequency (IF) signal is obtained:

$$s_{IF}(t) = A_{IF} \cos\left(2\pi f_b t - \phi(t)\right), \tag{3}$$

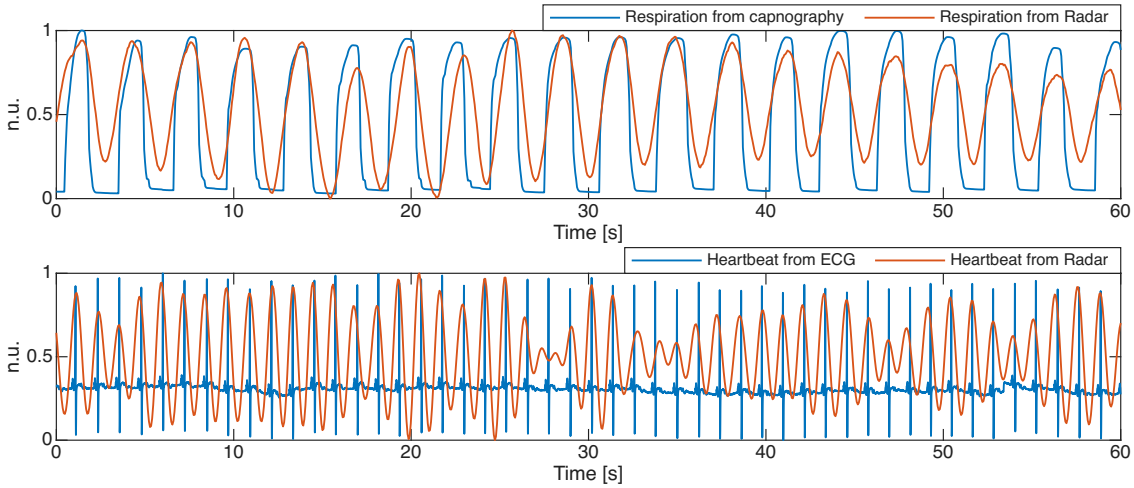
where $f_b = \mu\tau$ is the beat frequency encoding the static range, and

$$\phi(t) = \frac{4\pi}{\lambda}\Delta x(t), \tag{4}$$

is the phase term proportional to the dynamic chest displacement $\Delta x(t)$, with $\lambda = \frac{c}{f_c}$ being the wavelength. The phase domain provides sub-millimeter resolution, as a phase shift of 2π corresponds to a displacement of $\frac{\lambda}{2}$.



(a)



(b)

Figure 1. Overview of frequency-modulated continuous-wave (FMCW) radar-based cardiorespiratory monitoring. (a) Schematic illustrating FMCW radar based detection of chest displacement (Δx) for respiratory rate (RR) and heart rate (HR) monitoring. The time of flight (τ) from transmitter (Tx) to user and back to receiver (Rx) causes a delay proportional to the distance D_0 in the received chirp resulting in a fixed beat frequency. The beat frequency in the intermediate frequency (IF) signal is used to determine the user position, and the phase signal (ϕ(t)) derived from the IF signal is used to extract the chest displacement. Fast Fourier transform (FFT) of the phase signal shows the RR (f_{RR}) and HR (f_{HR}) frequencies corresponding to the user. (b) Representative respiratory (top) and cardiac (bottom) displacement waveforms derived from the radar sensor compared with reference signals, showing correspondence between radar-derived periodic motion and physiological activity used for RR and HR estimation. Adapted from Lauteslager et al.[21], licensed under CC BY 4.0.

Physiological motion of the thorax can be modeled as a superposition of respiration and heartbeat displacements:

$$\Delta x(t) = d_{\text{resp}}(t) + d_{\text{heart}}(t) = A_{\text{resp}} \sin(2\pi f_{\text{resp}} t) + A_{\text{heart}} \sin(2\pi f_{\text{heart}} t), \tag{5}$$

where $A_{\text{resp}}, f_{\text{resp}}$ and $A_{\text{heart}}, f_{\text{heart}}$ are the amplitudes and frequencies of respiration and heartbeat components, respectively. These periodic displacements induce corresponding phase modulations:

$$\phi(t) = \frac{4\pi}{\lambda} \left[A_{\text{resp}} \sin(2\pi f_{\text{resp}} t) + A_{\text{heart}} \sin(2\pi f_{\text{heart}} t) \right]. \tag{6}$$

Thus, by tracking the phase of the IF signal over time, as illustrated in Fig. 1a, periodic displacements corresponding to respiratory and cardiac motion can be simultaneously extracted.

Fig. 1b illustrates this principle using representative radar-derived displacement waveforms alongside conventional reference signals, as acquired from a human subject. The respiratory component extracted from radar measurements reflects the overall ventilatory effort, which is closely correlated with respiration as measured using carbon dioxide (CO_2) capnography. The higher-frequency component of the radar-derived displacement signal corresponds to the dominant cardiac periodicity as observed in ECG. Although radar-derived waveforms are not intended to replicate reference ECG signals on a beat-by-beat basis, their periodic structure provides sufficient information for accurate estimation of RR and HR under no-motion, resting conditions.

The C300 Monitor

The Circadia C300 Monitor is the hardware component of the FDA-cleared Circadia C300 System (K252676; Circadia Health, Inc., Los Angeles, USA), which also includes a cloud service and app (as illustrated in Fig. 2a). The Monitor comprises an FMCW radar sensor, a processor, and a communication module. The FMCW radar, operating at a frequency band of 58.0 - 61.5 GHz, is used to sense periodic motions at the surface of the patient's chest and abdomen caused by the patient's respiration and heartbeat. Proprietary algorithms, executed continuously on the device, use periodic signal variation to estimate a patient's RR and HR. Estimates are produced only if C300 signal quality criteria (i.e.: sufficient signal-to-noise ratio) are met. If data quality criteria are not met, estimates are automatically discarded to prevent inaccurate outputs during e.g. patient absence or motion. In addition to RR and HR data, the Monitor measures motion intensity, as well as presence of a person in its detection

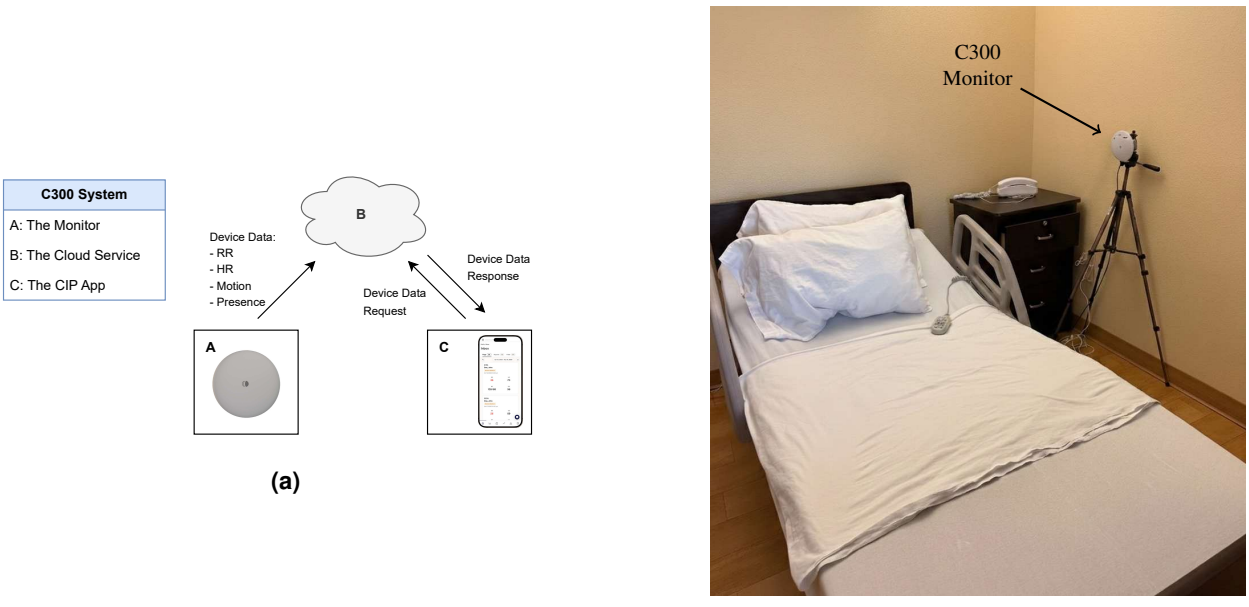


Figure 2. Description of the C300 System. (a) System architecture comprising the C300 Monitor, cloud service, and accompanying app. The C300 Monitor employs frequency-modulated continuous-wave (FMCW) radar to detect chest wall displacements and derives respiratory rate (RR), heart rate (HR), motion, and presence, which are transmitted to the cloud. The accompanying app retrieves this information and presents it to the users (healthcare professionals). (b) Picture of temporary C300 Monitor installation during the clinical study. The C300 Monitor was mounted to a tripod, placed besides the patient's bed, in a position representative of real-world deployment.

range. RR and HR data are captured at 60-second intervals, and data are transmitted via a secure Wi-Fi connection to a cloud service for storage. The accompanying app may be used to retrieve and visualize C300 Monitor data.

The Monitor may be wall-mounted or may be placed on a nightstand by the patient's bedside. The detection range (distance) of the device is configurable, and is usually set to include the range corresponding to the patient's bed. An example of a typical setup in real-world setting is shown in Fig. 2b. Unlike optical systems, the Monitor's radar signal penetrates through materials such as clothing and blankets, and is unaffected by lighting conditions. Due to the Monitor's built-in signal quality criteria (requiring periodicity and sufficient signal-to-noise ratio), no RR or HR data are produced during high-motion conditions, such as when the patient is moving around, or while a caretaker is at the bedside.

Study Design and Participants

Overview The primary validation of the C300 Monitor was carried out in an observational clinical study ('Study 1'), conducted in a real-world SNF environment, using a non-probabilistic sample of patients representative of the device's typical use population. An additional study ('Study 2') was performed under simulated use conditions with a convenience sample of healthy volunteers, to evaluate device robustness across potential confounding factors. For both study 1 (clinical conditions) and study 2 (simulated use conditions), C300 RR and HR data were compared to simultaneously obtained reference device RR and HR. Reference RR was obtained from a CO_2 capnography monitor (Capnostream 35, Medtronic Inc., Minneapolis, USA), and reference HR from a Holter ECG monitor (Faros Mobile 180 ECG Monitor, Bittium Biosignals Ltd., Kuopio, Finland).

Study 1 - Clinical Data were collected from 45 patients across multiple healthcare facilities in the United States, including skilled nursing and long-term care sites. All study procedures were conducted in accordance with the Declaration of Helsinki, and the study protocol was reviewed and approved by an independent institutional review board (Pearl IRB, Indianapolis, IN; Study ID No. 2025 - 0049). Participants were considered eligible if they were admitted to the study site and had sufficient capacity to provide informed consent. Exclusion criteria were: individuals younger than 21 years of age; those unable or with limited capacity to provide informed consent; students, prisoners, or employees of the study sponsor; and patients with dermatological conditions or skin sensitivities that could interfere with ECG electrode placement. Participants were approached directly by the investigator team at the facility where they were admitted. Eligible patients were provided with detailed information about the study, and written informed consent was obtained prior to enrollment.

Prior to each recording session, the reference devices (ECG and CO_2 capnography) were sanitized, fully charged, verified for sufficient memory, configured appropriately, and synchronized to an external time source. The C300 Monitor was synchronized automatically via its Wi-Fi connectivity.

During each recording session, the C300 Monitor was positioned on a tripod approximately 1.0 m from the participant's bedside, aligned with a direct line of sight to the chest. Participants lay supine in bed wearing their usual clothing and were instructed to minimize motion and speech. Simultaneous data from the C300 Monitor and reference devices were acquired for a continuous duration of 10 minutes.

Throughout the session, the C300 Monitor continuously recorded RR and HR and transmitted data securely to the cloud, while ECG and capnography signals were acquired in parallel as reference measurements. Upon completion of the session, ECG electrodes and nasal cannulae were removed.

Following data collection, automatically generated reference RR and HR values were manually verified for accuracy through visual inspection of CO_2 and ECG waveforms by trained personnel, who were blinded to the C300 outputs.

To determine C300 Monitor accuracy, RR and HR derived from the C300 Monitor was compared with the corresponding reference measurements.

Study 2 - Simulated Use As a secondary evaluation, a controlled study was conducted in 17 healthy volunteers with no known cardiorespiratory disorders to assess system performance under simulated use conditions representative of real-world environments. Participants were recruited from employees of the sponsor, as well as friends and family. Written informed consent was obtained from all participants prior to enrollment.

Data collection took place in a laboratory room arranged with a bed and pillow to ensure participant comfort. Across all conditions, the C300 Monitor was mounted on a tripod, oriented toward the participant's chest at a height slightly above the mattress, and connected to a local Wi-Fi network to enable continuous data transmission. Reference RR and HR measurements were obtained from CO_2 capnography and Holter ECG monitors, respectively.

Participants were monitored sequentially across nine predefined scenarios incorporating variations in device distance, body posture, occlusion, motion, and presence or absence within the radar field of view. Each condition was recorded for two minutes, with standardized one-minute transitions. Unless otherwise specified, the C300 Monitor was positioned at the default distance of 1.0 m from the participant's chest. The scenarios were designed to reflect situations commonly encountered in clinical and long-term care settings and are summarized below:

C1 *0.5 m lying still, supine*: Participant in supine position, device positioned at 0.5 m distance from bedside.

C2 *1.5 m lying still, supine*: Participant in supine position, device positioned at 1.5 m distance.

C3 *1.0 m lying still, supine*: Participant in supine position, device positioned at the default 1.0 m distance.

C4 *Absence*: No participant present in the device detection range.

C5 *Patient motion*: Participant present in bed, mimicking routine activities such as changing position, eating, stretching, speaking, or sitting up.

C6 *Lying still + bedside activity*: Participant lying supine and at rest while a second individual mimicked typical bedside care activities (e.g., feeding, bedding adjustment, taking vitals).

C7 *Lying still + blanket*: Participant lying supine, covered with a blanket.

C8 *Lying still, side facing away from device*: Participant lying on their side, facing away from the C300 device.

C9 *Absence + motion*: No participant in bed, while another individual moved through the detection range, mimicking staff activity such as cleaning or changing sheets.

Statistical Analysis

C300 RR and HR estimates were produced at 60-s intervals, or were outputted as 'NaN' by the device in case the built-in quality criteria were not met (e.g.: during patient motion or absence). No C300 data post-processing, rejection, or outlier removal was performed.

Agreement between the C300 System–derived RR and HR measurements and the corresponding reference data was evaluated using Bland–Altman analysis. Bland–Altman limits of agreement (LOA) were calculated as the mean difference (bias) between the C300 System and reference measurements $\pm$ 1.96 times the standard deviation of the paired differences, representing the 95% LOA[22]. The 95% confidence intervals (CIs) for both the bias and the LOA were also estimated[23]. As multiple measurements (up to 10, corresponding to the 10-minute measurement duration) were obtained per participant, within-subject correlation was accounted for in the estimation of the LOA and their confidence intervals, using the method described by Zou[24].

Deming regression analysis was also performed to compare the correspondence between C300 RR and HR data and reference data, by means of assessing the regression slope and intercept along with their 95% CIs.

Accuracy rate was computed as an additional metric of accuracy. C300 RR and HR accuracy rates, expressed as the proportion of measurements with an absolute error not exceeding a specified error margin (compared to reference), was calculated on a subject level. Accuracy rates were calculated using error margins of 2 breaths per minute (breaths/min) or beats per minute (beats/min), and 5 breaths/min or beats/min, for RR and HR respectively. These thresholds were selected to align with commonly reported performance metrics in the radar-based vital sign monitoring literature, thereby enabling direct

Table 1. Overview of study sample demographics. N denotes number; kg, kilogram; m, meter; BMI, body-mass index; IQR, interquartile range.

Characteristic	Property	Clinical Study (N=45)	Simulated Use Study (N=17)
Age [years]	Range	28 to 93	22 to 59
	Median (IQR)	73 (13.0)	34 (21.0)
Gender [N (%)]	Female	22 (48.9%)	5 (29.4%)
	Male	23 (51.1%)	12 (70.6%)
BMI [kg/m^2]	Range	19.3 to 41.8	19.1 to 35.0
	Median (IQR)	27.4 (8.4)	24.8 (9.3)
Race [N (%)]	American Indian or Alaska Native	1 (2.2%)	0 (0.0%)
	Asian	1 (2.2%)	6 (35.3%)
	Black or African American	11 (24.4%)	0 (0.0%)
	Native Hawaiian or Other Pacific Islander	0 (0.0%)	0 (0.0%)
	White	32 (71.1%)	11 (64.7%)
Ethnicity [N (%)]	Hispanic or Latino	6 (13.3%)	1 (5.9%)
	Not Hispanic or Latino	39 (86.7%)	16 (94.1%)

comparison with prior validation studies, and capture both stringent and clinically tolerant error margins. Aggregate mean accuracy rates across study participants were also obtained.

Apart from the accuracy and agreement analysis, RR and HR monitoring success rates were determined. These were defined as the proportion of outputted (non-NaN) C300 RR and HR minutes, respectively, in the 10-minute recording duration. It was expressed as a percentage, and calculated at the subject level, for both RR and HR.

For the simulated use evaluation (Study 2), monitoring success rates were interpreted in the context of the intended system behavior under each condition. In conditions involving participant absence from the radar field of view or substantial motion incompatible with reliable vital sign extraction, the expected monitoring success rate was zero. In these scenarios, the absence of RR and HR outputs reflects appropriate system operation rather than a performance limitation. Accordingly, monitoring success rates for such conditions were reported descriptively and were not included in aggregate performance comparisons with stationary conditions, where continuous output was expected.

Results

A summary of demographic characteristics of participants from both studies is presented in Table 1.

Study 1 - Clinical

A total of 45 patients were enrolled in the clinical evaluation. Participants ranged in age from 28 to 93 years (median 73 years, interquartile range [IQR] 13.0) and included a balanced gender distribution (22 female, 23 male). The median body-mass index (BMI) was 27.4 kg/m^2 (IQR 8.4). The clinical cohort was racially and ethnically diverse, comprising 71% White, 24% Black or African-American, 2% Asian, and 2% American-Indian participants, with 13% identifying as Hispanic or Latino. The patients suffered from a wide range of health conditions, including asthma, chronic obstructive pulmonary disease (COPD), cardiac arrhythmia's, heart failure, pacemaker, prior myocardial infarction, and other cardiovascular and respiratory disorders.

Results from the clinical study are summarized in Table 2. Following manual review of reference device data, five capnogram epochs (each corresponding to 60 seconds) and twelve ECG epochs were excluded due to uninterpretable physiological signals. A total of 445 minutes of reference RR data and 438 minutes of reference HR data were available for analysis.

Across the total recording duration, the system produced 421 minutes of valid RR data and 403 minutes of valid HR data, corresponding to monitoring success rates of 93.6% and 89.6%, respectively.

Bland–Altman analysis, while accounting for within-subject correlation, showed 95% LOA of –1.9 to 2.7 breaths/min for RR, with a mean bias of 0.4 breaths/min. For HR, the 95% LOA ranged from –2.9 to 2.5 beats/min, with a mean bias of –0.2 beats/min. Corresponding confidence intervals for bias and LOA are reported in Table 2.

Deming regression analysis yielded slopes of 0.97 for RR and 0.99 for HR, with intercepts of 0.8 and 0.3, respectively. Pearson correlation coefficients were 0.95 for RR and 1.0 for HR.

Bland–Altman and Deming regression plots are presented in Fig. 3 for RR and Fig. 4 for HR.

Accuracy rates within $\pm$2 beats/min were 89.2% for RR and 88.6% for HR. Accuracy rates within $\pm$5 beats/min were 99.8% for RR and 95.1% for HR.

Table 2. Clinical study results. N denotes number; RR, respiratory rate; HR, heart rate; min, minutes; BA, Bland-Altman; bpm, breaths or beats per minute corresponding to RR- and HR-related metrics, respectively; CI, confidence interval; r, correlation coefficient.

Category	Metric	RR	HR
Sample	N Patients	45	45
	N Reference Measurements [min]	445	438
Monitoring Efficacy	N C300 Measurements [min]	421	403
	Monitoring Success Rate	93.6%	89.6%
Bland–Altman Agreement	BA 95% Lower LoA (95% CI) [bpm]	-1.9 (-2.1, -1.7)	-2.9 (-3.2, -2.7)
	BA 95% Upper LoA (95% CI) [bpm]	2.7 (2.5, 2.8)	2.5 (2.3, 2.8)
	Within-Subject Bias (95% CI) [bpm]	0.4 (0.3, 0.5)	-0.2 (-0.4, 0.0)
Deming Regression	Intercept (95% CI)	0.8 (0.3, 1.3)	0.3 (-0.5, 1.0)
	Slope (95% CI)	0.97 (0.94, 1.0)	0.99 (0.98, 1.0)
	Pearson's r	0.95	1.00
Accuracy and Error	Accuracy Rate [$\leq$2 bpm]	89.2%	88.6%
	Accuracy Rate [$\leq$5 bpm]	99.8%	95.1%

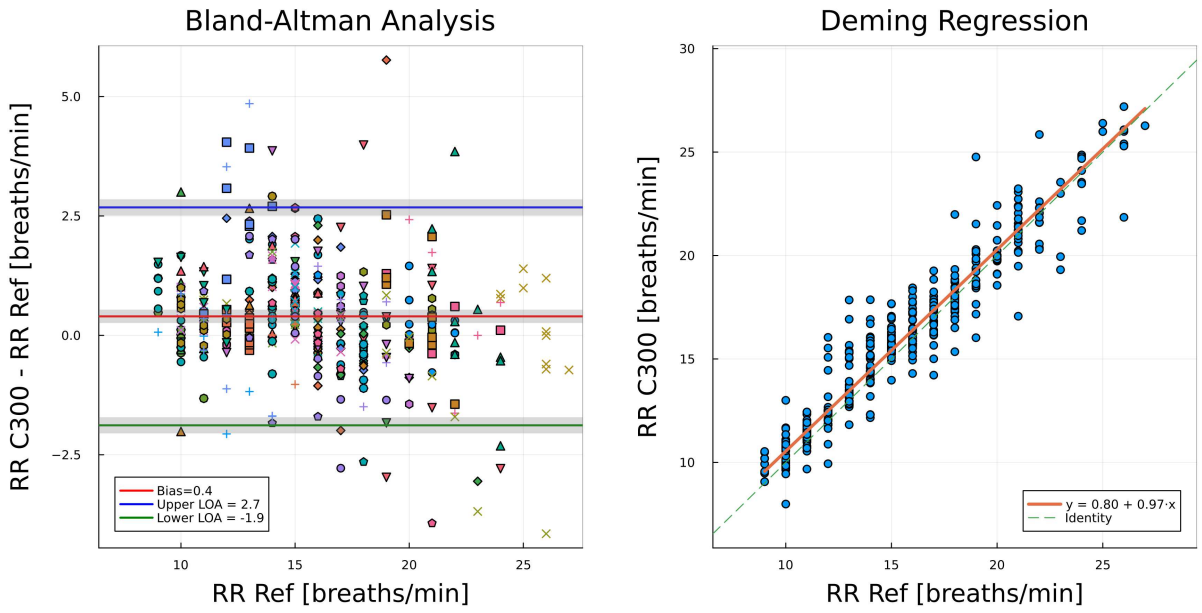


Figure 3. Bland–Altman and Deming regression analyses comparing C300 respiratory rate (RR) with reference measurements. Bland–Altman agreement results are shown on the left and Deming regression results on the right for the full patient cohort ($n = 45$). A total of 421 RR measurements (RR C300) with manually overread reference values (RR Ref) were included. In the Bland–Altman plot, the mean bias is shown as a solid red line, with upper and lower limits of agreement indicated by solid blue and green lines, respectively. Data points from individual participants are denoted by distinct markers. In the Deming regression plot, the fitted regression line is shown in orange, while the line of identity is indicated by a dashed green line. Regression parameters are provided in the figure legend.

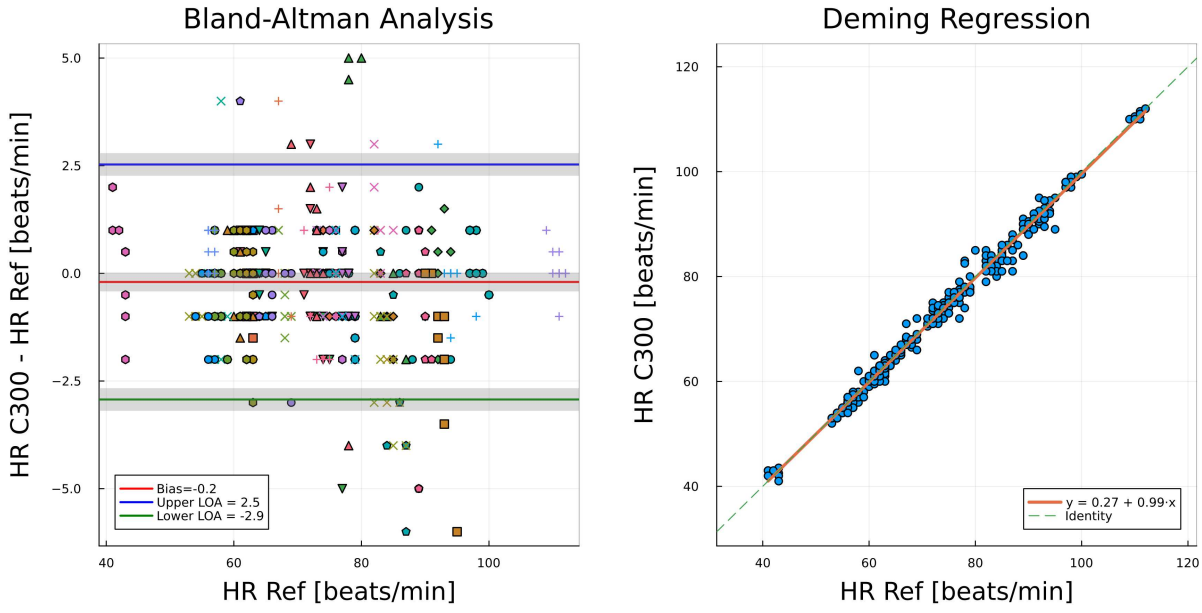


Figure 4. Bland–Altman and Deming regression analyses comparing C300 heart rate (HR) with reference measurements. Bland–Altman agreement results are shown on the left and Deming regression results on the right for the full patient cohort ($n = 43$). A total of 403 HR measurements (HR C300) with manually overread reference values (HR Ref) were included. In the Bland–Altman plot, the mean bias is shown as a solid red line, with upper and lower limits of agreement indicated by solid blue and green lines, respectively. Data points from individual participants are denoted by distinct markers. In the Deming regression plot, the fitted regression line is shown in orange, while the line of identity is indicated by a dashed green line. Regression parameters are provided in the figure legend.

Study 2 - Simulated Use

The simulated use evaluation included 17 healthy volunteers. Participants ranged in age from 22 to 59 years (median 34, IQR 21.0) and had a median BMI of 24.8 kg/m^2 (IQR 9.3). The cohort comprised 65% White and 35% Asian participants, with 6% identifying as Hispanic or Latino.

Figure 5 shows representative RR and HR time-series data from a participant enrolled in the simulated use study, illustrating the correspondence between the C300 Monitor outputs and reference measurements across different use conditions.

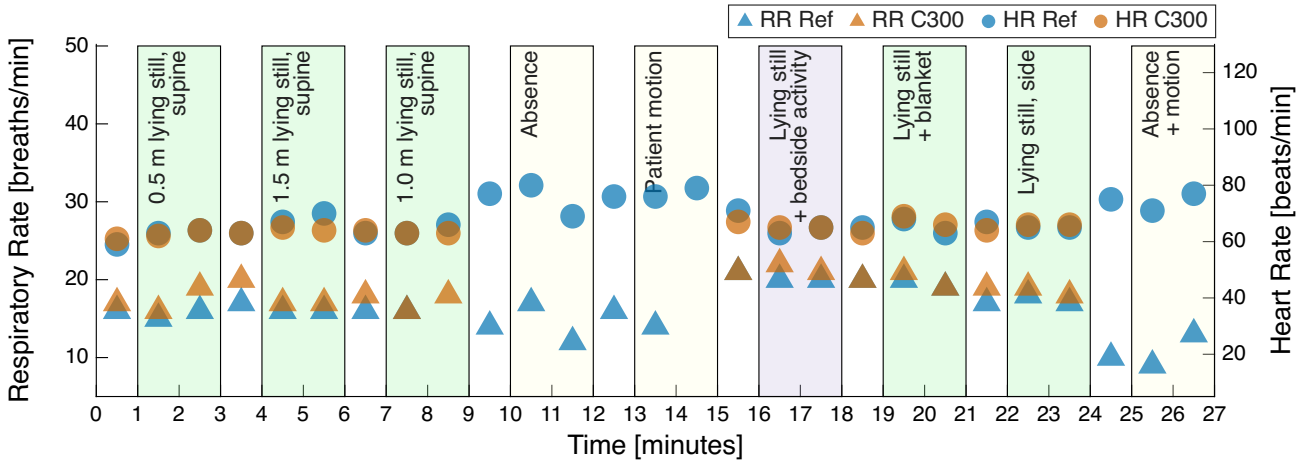


Figure 5. Respiratory rate (RR) and heart rate (HR) data from a participant enrolled in the simulated use study, showing nine different scenarios (labelled in their respective boxes), each with first minute as the transition phase, followed by two minutes of data acquired during a particular use condition. The plot with two yaxis shows reference RR data (RR Ref) from the capnogram in dark blue, C300 subject device RR (RR C300) in yellow, reference HR data (HR Ref) from the ECG data in red, and C300 subject device HR (HR C300) in light blue.

Performance results across the nine simulated use conditions are summarized in Table 3. Under stationary supine conditions (C1 – C3), the C300 Monitor achieved monitoring success rates of 91.2 – 97.1% for RR and 88.2 – 94.1% for HR across tested distances ranging from 0.5 to 1.5 m. High monitoring success was also observed under blanket coverage (C7) and side-lying orientation (C8), with RR success rates of 90.6 – 100% and HR success rates of 93.3 – 100%. During the condition involving bedside activity with the participant remaining still (C6), monitoring success rates were 93.8% for RR and 100% for HR.

No RR or HR outputs were generated during absence-only conditions (C4), participant motion (C5), or absence combined with motion (C9).

Table 3. Simulated use study results. m denotes meter; RR, respiratory rate; HR, heart rate; brpm, breaths per minute; bpm, beats per minute; N/A, not applicable.

#	Condition	Monitoring Success Rate [%]		Accuracy Rate [%]			
		RR	HR	RR		HR	
				≤2 brpm	≤5 brpm	≤2 bpm	≤5 bpm
C1	0.5 m lying still, supine	94.1	88.2	93.8	100.0	80.0	96.7
C2	1.5 m lying still, supine	97.1	94.1	100.0	100.0	84.4	90.6
C3	1.0 m lying still, supine	91.2	88.2	88.9	96.3	86.7	96.7
C4	Absence	0.0	0.0	N/A	N/A	N/A	N/A
C5	Patient motion	0.0	0.0	N/A	N/A	N/A	N/A
C6	Lying still + bedside activity	93.8	100.0	82.8	100.0	78.1	90.6
C7	Lying still + blanket	90.6	100.0	89.7	100.0	87.5	96.9
C8	Lying still, side facing away from device	100.0	93.3	96.7	100.0	78.6	100.0
C9	Absence + motion	0.0	0.0	N/A	N/A	N/A	N/A

Across conditions producing valid outputs, accuracy within ±2 beats/min ranged from 82.8 – 100% for RR and 78.1 – 87.5% for HR. Accuracy within ±5 beats/min ranged from 96.3 – 100% for RR and 90.6 – 100% for HR.

Discussion

Performance of the C300 Monitor was assessed in two separate studies for measurement of RR and HR by comparing with manually scored reference data.

In the clinical study (Study 1), the C300 Monitor achieved high monitoring success rate and low error for both RR and HR, with narrow LOAs and minimal bias relative to reference data as obtained by capnography and ECG. Strong linear associations observed in the Deming regression analysis, together with slopes near unity, indicate minimal proportional bias across the measured ranges of RR and HR. This suggests that the system maintains accuracy across both lower and higher physiological values encountered in the clinical cohort. High accuracy rates reflect robust rate estimation performance under typical resting conditions.

The simulated-use study (Study 2) complements the clinical evaluation by probing system behavior across a range of controlled scenarios designed to reflect conditions commonly encountered in clinical and long-term care environments. High monitoring success and accuracy were maintained across a range of device-to-patient distances, blanket coverage, side-lying posture, and the presence of nearby bedside activity, indicating robustness to common environmental and positioning variations encountered in care settings. Crucially, the system appropriately produced no outputs during absence and dominant-motion conditions. From a clinical safety perspective, this behavior is as important as accuracy during valid conditions. By suppressing RR and HR estimates when signal quality is insufficient, the system reduces the risk of spurious vital sign reporting and false alarms. In the context of continuous monitoring, particularly in PALTC facility environments with frequent staff movement, such conservative output logic supports clinical trust and usability.

Comparison to state of the art and validation methodology Prior work has demonstrated the feasibility of contactless respiratory and cardiac monitoring using a range of radar modalities, including continuous-wave Doppler, UWB, and FMCW approaches. A comparison of commercially available, FDA-cleared radar-based vital sign monitoring systems in the United States that have been validated in representative clinical populations is provided in Table 4. To facilitate direct comparison across systems despite differences in study design and test conditions, both Bland–Altman LOAs and accuracy rates within ±2 and ±5 breaths/min or beats/min are reported, consistent with commonly used performance metrics in the literature.

Table 4. Comparison of recent contactless radar-based vital sign monitoring systems reported in the literature. Limits of agreement and accuracy are reported as published in the respective studies. N denotes number; PPTs, participants; RR, respiratory rate; HR, heart rate; brpm, breaths per minute; bpm, beats per minute.

Company	Device	Technology	N (PPTs)	Duration [min]	Limits of Agreement		Accuracy Rate	
					RR [brpm]	HR [bpm]	RR	HR
Sleepiz AG[25,26]	Sleepiz One+	CW Doppler (24 GHz)	19[25]	20	[−0.5, 1.2]	–	100% (≤3 brpm)	–
			59 (RR); 32 (HR)[26]	–	[−1.4, 1.0]	[−2.6, 5.8]	99% (≤3 brpm)	94% (≤5 bpm)
Xandar Kardian[27]	XK300-VSA	UWB (6.5 - 8.0 GHz)	50	2 (supine)	[−1.6, 3.3]	[−10.9, 14.0]	–	–
				2 (seated)	[−2.8, 4.4]	[−14.7, 16.0]		
Neteera[28]	130H/ 131H	FMCW (122 - 123 GHz)	70	–	–	–	91.2% (≤2 brpm)	97.1% (≤5 bpm)
Circadia Health[21]	C100	UWB (6.4 - 7.8 GHz)	12	10	[−2.3, 1.7]	–	94.1% (≤2 brpm)	–
Circadia Health	C300	FMCW (58.0 - 61.5 GHz)	45	10	[−1.9, 2.7]	[−2.9, 2.5]	99.8% (≤5 brpm)	95.1% (≤5 bpm)
							89.2% (≤2 brpm)	88.6% (≤2 bpm)

The Sleepiz One+ system reported narrow LOAs for RR during prolonged sleep monitoring, highlighting the strengths of CW Doppler radar under stable nocturnal conditions[25]. Additional validation results have been reported in neurorehabilitation ward populations, including 59 patients for RR assessment and 32 patients for HR assessment[26]. An UWB-based system, the Xandar Kardian XK300-VSA, has also shown promising RR agreement under short, posture-specific recordings, though with wider heart rate LOAs and under limited evaluation durations[27]. Similarly, the Neteera FMCW system demonstrated high accuracy for both RR and HR estimation during controlled conditions, but limited details were available on used methodology[28]. While modest differences in reported accuracy exist across these systems, the absence of direct comparison studies or standardized testing conditions preclude any claims that any one system is intrinsically more accurate than another.

Beyond these commercially deployed systems, numerous radar-based systems have been reported in the literature and validated to varying extents. A substantial portion of this work originate from early-stage academic research, with performance often assessed under laboratory conditions and in non-clinical populations. Systematic reviews suggest that differences in reported performance across such studies are generally small[29], and are often less than the inter-observer variability observed in clinical spot-check measurements[30]. From a clinical standpoint, such differences in accuracy are therefore unlikely to be meaningful. Once it has been established that a radar sensor can reliably track cardiac and respiratory chest wall displacement, any discrepancies in estimated RR and HR are largely influenced by algorithmic choices, and by how non-stationary physiological signals are handled. Neither RR nor HR are strictly stationary, and differences in measurements can arise simply from how these rates are estimated. Clinicians commonly derive rates by counting discrete breaths or beats over a fixed time interval, whereas radar-based algorithms often infer rate from periodicity or frequency-domain representations. Transient physiological events, such as sighs or brief irregular breathing patterns, may therefore result in systematic differences between radar-derived estimates and manual counts. It remains unclear whether such differences are clinically relevant, or which representation better reflects a patient's underlying physiological state in continuous monitoring contexts.

In contrast, large and clinically meaningful errors may arise when monitoring systems produce erroneous outputs under non-ideal conditions, including patient motion, external periodic motion from nearby devices (e.g., fans or ventilators), bedside activity, or patient absence. These conditions are routinely encountered in real-world care settings but are frequently excluded from validation protocols. As a result, many published studies report performance under narrowly defined, highly controlled scenarios that may not reflect actual deployment environments. For radar-based systems intended for continuous and unsupervised monitoring, an application for which radar sensing is particularly well suited, robustness to such conditions is critical for both clinical performance and patient safety. The present work addresses this gap by complementing controlled clinical validation with a systematic simulated use study designed to probe performance across a range of representative real-world scenarios. Together with the inclusion of a clinically representative patient cohort, this approach shifts the focus of validation from marginal improvements in nominal accuracy toward robustness, reliability, and operational safety. They form the key prerequisites for the translation of radar-based vital sign monitoring beyond laboratory and sleep-only settings into routine clinical practice.

Limitations and future directions Although the clinical cohort was diverse, recordings were performed under resting conditions for shorter durations, and extended longitudinal deployment was not assessed. The simulated-use scenarios, while representative, cannot capture the full complexity of real-world PALTC environments over days or weeks. Future studies should evaluate long-term deployment, integration with clinical workflows, and the impact of continuous radar-based monitoring on clinical outcomes such as escalation of care, hospitalization, or mortality.

Conclusions This work demonstrates that the C300 Monitor can provide accurate and reliable contactless monitoring of RR and HR in a clinical setting, while appropriately suppressing outputs when conditions do not support valid estimation of RR and HR. The device showed strong agreement with reference standards, and clinically meaningful handling of motion and patient absence. These attributes position radar-based monitoring as a promising tool to enhance vital sign surveillance in post-acute and long-term care settings such as the skilled nursing facility, with the potential to improve early detection of patient deterioration and support timely clinical intervention.

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Additional Information

Author Contributions

T.L. and G.D.L. contributed to study design. N.M. performed data acquisition. M.D. contributed to the development of data acquisition tools. P.S. and V.B. performed the statistical analysis and interpretation of results. P.S. drafted the original manuscript. T.L. and M.M. provided project supervision. G.D.L. provided clinical oversight. T.L. and G.D.L. critically revised the manuscript. All authors reviewed and approved the final manuscript.

Funding

This research was funded by Circadia Health, Inc., the manufacturer of the investigational device and sponsor of this study. No external grant funding was received.

Competing Interests

Authors P.S., V.B., N.M., M.D., M.M. and T.L. are employees of Circadia Health, Inc., the manufacturer of the investigational device and sponsor of this study. G.D.L. acts as a consultant to Circadia Health, Inc. One or more authors hold stock options in Circadia Technologies, Ltd., which licenses its technology to Circadia Health, Inc.

Acknowledgments

The authors thank the participating patients and the staff at the participating skilled nursing facilities for their cooperation and support.

Data Availability

The data that support the findings of this study are not publicly available due to privacy and ethical restrictions, but are available from the corresponding author, upon reasonable request and subject to institutional approvals.