

Feasibility of monitoring heart and respiratory rates using non-wearable devices and consistency of the measured parameters: A pilot feasibility study

Kasumi Ikuta, Miya Aishima, Maiko Noguchi-Watanabe, Sakiko Fukui

Submitted to: JMIR Human Factors
on: January 20, 2024

Disclaimer: © The authors. All rights reserved. This is a privileged document currently under peer-review/community review. Authors have provided JMIR Publications with an exclusive license to publish this preprint on its website for review purposes only. While the final peer-reviewed paper may be licensed under a CC BY license on publication, at this stage authors and publisher expressly prohibit redistribution of this draft paper other than for review purposes.

Table of Contents

Original Manuscript..... 5

Supplementary Files..... 20

0..... 20

Figures 21

Figure 1..... 22

Figure 2..... 23

Figure 3..... 24

Figure 4..... 25

Figure 5..... 26

Feasibility of monitoring heart and respiratory rates using non-wearable devices and consistency of the measured parameters: A pilot feasibility study

Kasumi Ikuta^{1*}; Miya Aishima¹; Maiko Noguchi-Watanabe¹; Sakiko Fukui^{1*}

¹Department of Home Health and Palliative Care Nursing, Graduate School of Health Care Sciences Tokyo Medical and Dental University Bunkyo-Ku JP

*these authors contributed equally

Corresponding Author:

Sakiko Fukui

Department of Home Health and Palliative Care Nursing, Graduate School of Health Care Sciences

Tokyo Medical and Dental University

1-5-45

Yushima

Bunkyo-Ku

JP

Abstract

Background: As Japan is the world's fastest-aging society with a declining population, it is challenging to secure human resources for care providers. Therefore, the Japanese government is promoting digital transformation (DX) and the use of nursing care equipment, including non-wearable devices that monitor heart and respiratory rates. However, the feasibility of monitoring heart and respiratory rates with non-wearable devices and the consistency of the rates measured have not been reported.

Objective: In this study, we focus on a sheet-type non-wearable device (Safety Sheep Sensor) that has been introduced in many nursing homes. We evaluated the feasibility of monitoring heart rate (HR) and respiratory rate (RR) continuously using non-wearable devices and the consistency of the HR and RR measured.

Methods: A sheet-type non-wearable device (Safety Sheep Sensor) that measured HR and RR every minute through body vibrations was placed under the mattress of each participant. The participants in Study 1 were healthy individuals aged 20–60 years (N=21), while those in Study 2 were older individuals living in multi-dwelling houses and required nursing care (N=20). The HR was measured using standard methods by the nurse and using the wearable device (WD; Silmee Bar type Lite sensor), and RR was measured by the nurse. The primary outcome was the mean difference in HR and RR between non-wearable devices and standard methods.

Results: The mean difference in HR was -0.32 (standard deviation (SD): 3.12) in Study 1 and 0.04 (SD: 3.98) in Study 2; both differences were within the predefined accepted discrepancies (< 5 beats). The mean difference in RR was -0.98 (SD: 3.01) in Study 1 and -0.49 (SD: 2.40) in Study 2; both differences were within the predefined accepted discrepancies (3 breaths).

Conclusions: HR and RR measurements obtained using the non-wearable devices and the standard method were similar. Continuous monitoring of vital signs using non-wearable devices can aid in the early detection of abnormal conditions in older people.

(JMIR Preprints 20/01/2024:56547)

DOI: <https://doi.org/10.2196/preprints.56547>

Preprint Settings

1) Would you like to publish your submitted manuscript as preprint?

✓ Please make my preprint PDF available to anyone at any time (recommended).

Please make my preprint PDF available only to logged-in users; I understand that my title and abstract will remain visible to all users.

Only make the preprint title and abstract visible.

No, I do not wish to publish my submitted manuscript as a preprint.

2) If accepted for publication in a JMIR journal, would you like the PDF to be visible to the public?

✓ **Yes, please make my accepted manuscript PDF available to anyone at any time (Recommended).**

Yes, but please make my accepted manuscript PDF available only to logged-in users; I understand that the title and abstract will remain visible to the public.

Yes, but only make the title and abstract visible (see Important note, above). I understand that if I later pay to participate in <http://www.jmir.org/>, I will be able to make my full manuscript PDF available to the public.



Original Manuscript

Original Paper

Feasibility of monitoring heart and respiratory rates using non-wearable devices and consistency of the measured parameters: A pilot feasibility study

Abstract

Background: As Japan is the world's fastest-aging society with a declining population, it is challenging to secure human resources for care providers. Therefore, the Japanese government is promoting digital transformation and the use of nursing care equipment, including non-wearable devices that monitor heart and respiratory rates. However, the feasibility of monitoring heart and respiratory rates with non-wearable devices and the consistency of the rates measured have not been reported.

Objective: In this study, we focused on a sheet-type non-wearable device (Safety Sheep Sensor) introduced in many nursing homes. We evaluated the feasibility of monitoring heart rate (HR) and respiratory rate (RR) continuously using non-wearable devices and the consistency of the HR and RR measured.

Methods: A sheet-type non-wearable device that measured HR and RR every minute through body vibrations was placed under the mattress of each participant. The participants in Study 1 were healthy individuals aged 20–60 years (N=21), while those in Study 2 were older adults living in multi-dwelling houses and required nursing care (N=20). The HR was measured using standard methods by the nurse and using the wearable device (Silme Bar-type Lite sensor), and RR was measured by the nurse. The primary outcome was the mean difference in HR and RR between non-wearable devices and standard methods.

Results: The mean difference in HR was -0.32 (standard deviation [SD]: 3.12) in Study 1 and 0.04 (SD: 3.98) in Study 2; both differences were within the predefined accepted discrepancies (<5 beats/min). The mean difference in RR was -0.98 (SD: 3.01) in Study 1 and -0.49 (SD: 2.40) in Study 2; both differences were within the predefined accepted discrepancies (3 breaths/min).

Conclusions: HR and RR measurements obtained using the non-wearable devices and the standard method were similar. Continuous monitoring of vital signs using non-wearable devices can aid in the early detection of abnormal conditions in older people.

Keywords: heart rate; older adults; respiratory rate; non-wearable devices; vital signs

Introduction

The vital signs of older adults change with age [1,2], making it necessary to monitor them at their residences and in nursing homes [3,4]. Continuous monitoring of their heart rate (HR) and respiratory rate (RR) to obtain essential data and immediate assessment of any abnormality by medical personnel have proven successful in reducing hospitalization and mortality rates [5]. However, measuring vital signs once or twice daily for older people living at home and in nursing homes is unrealistic [6]. Moreover, the impact of COVID-19 necessitated remote monitoring of vital signs with fewer visits from medical staff to prevent infections [7].

Therefore, continuous vital sign monitoring devices that can be used without affecting daily activities must be developed.

Wearable devices (WDs), including wrist-worn devices [8], ViSi Mobile (Sotera Wireless, Carlsbad, CA, USA) [9], and health patches (VitalConnect, San Jose, CA, USA) [9], can monitor vital signs

without interfering with daily activities. Measuring vital signs continuously with a WD may improve patient comfort and safety [10–12] and reduce nurse workload [10] by reducing the number of nurse-conducted measurements. However, redness and itching are common among older adults using WDs [9] because their skin is particularly fragile and WDs come in direct contact with the skin [13]. Therefore, developing and introducing non-wearable devices (NWDs) for monitoring older patients continuously is desirable [14].

NWDs, which measure vital signs without direct patient contact, reduce older adults' feeling of restraint and awareness of being monitored as well as the workload associated with vital sign assessments for care providers. NWDs such as Highly Sensitive Fibre Optic Mattress [11,15] and office chairs [16] are being researched and developed. Verification of its use in magnetic resonance imaging as well as in medical and nursing care settings is underway [17] and has attracted widespread attention.

As Japan is the world's fastest-aging society with a declining population [18], it is challenging to secure human resources for care providers [19]. Therefore, the Japanese government is promoting digital transformation (DX) and the use of nursing care equipment, including NWDs. Many nursing homes have purchased and introduced NWDs since 2015 when the government started providing assistance payment for such devices as policy guidance [20,21]. Sheet-type NWDs, such as Safety Sheep sensors α (NJI Co., Ltd., Fukushima, Japan), NEMURI SCAN (Paramount Bed Co., Ltd., Tokyo, Japan), and Mimamoleaf (Techno Horizon Co., Ltd., Nagoya, Japan), have been developed and introduced in Japan. We focused on Safety Sheep sensors α , which is a monitoring device that has been introduced in many nursing homes [22], including 3,319 nursing homes in Japan as of December 2022. This NWD includes a highly sensitive pressure sensor placed under a mattress and does not come in contact with the individual's skin. It detects body vibrations and calculates the individual's status (lying on bed/moving on bed/getting out of bed), HR, and RR every minute. These data are displayed on a monitor at nursing homes. Care providers check these data and, if they are abnormal, can take immediate action and provide appropriate care.

However, the data from NWDs, including sheet-type NWDs, cannot be utilized by nursing homes as longitudinal data to evaluate changes in individuals accurately and provide appropriate care [23] because the consistency of the HR and RR measured by such instruments has not been evaluated yet [24]. Moreover, based on the accumulated data, it may be possible to detect deteriorating conditions during end-of-life care and unplanned hospital visits at an early stage, concentrate care on high-risk targets, and improve the quality of care using fewer personnel. Therefore, this study aimed to evaluate the feasibility of continuous HR and RR monitoring and consistency of the rates measured using the NWD.

Methods

Setting and Participants

This was a prospective, observational, and pilot feasibility study. Two studies were conducted to evaluate the feasibility of continuous HR and RR monitoring, and the consistency of the HRs and RRs was measured using an NWD (Safety Sheep sensors α). In this study, the study power was calculated based on a previous study [9], and a sample size of 20 was estimated to obtain sufficient data for analysis.

Study 1: Healthy participants

Study 1 included 22 healthy participants aged 20–60 years who were working at a company. The authors recruited participants from June 1 to June 30, 2022. Participants were excluded if they had been diagnosed with heart or respiratory disease. To maintain the privacy of the participants, their vital signs were measured in a private room in Company A. The NWD was placed under the mattress

after preparing a bed. Each participant came to the room at separate designated times for measurements.

Study 2: Older adults who needed nursing care

Study 2 included 26 older adults aged ≥ 65 years who were living in multi-dwelling houses managed by a company and required nursing care. Each multi-dwelling house had a care worker who was available for 24 h daily. Thus, older adults who required nursing care could immediately receive nursing care from their care workers. Managers working in multi-dwelling houses recruited older adults for this study from July 1 to October 30, 2022. Participants diagnosed with cardiac or respiratory disease or those with implanted medical electronic devices, such as pacemakers, were excluded. Each participant was visited at appointed dates and times, and their HR and RR were measured in their rooms.

Data collection

In this study, data were collected by two nurses: one measured the HR and RR, while the other recorded them. They waited for the participant to visit the private room at Company A in Study 1 but visited the participant's room themselves in Study 2. First, the nurses explained the purpose and methods of this study to the participants. Second, the participants lay on a bed with the NWD in place. Third, the nurse who took the measurements attached a WD to the participants' chests and asked them to rest for 5 min. The same nurse then measured the RR over 1 min and reported five sets of measurements to the recording nurse. The recording nurse documented the start time of the measurement and the number of RRs. After a 1-min break, the HR was measured using the same method. After completing the measurements, the participants were informed that the procedure was complete and the WD was removed. Finally, the participants were checked for skin abnormalities.

Measurement

Non-wearable device (NWD)

The Safety Sheep sensor α (width, 800 mm; height, 17 mm; depth, 150 mm) was used as the NWD (Figure 1) [25]. In the multi-dwelling house, this NWD was placed in all the residents' beds. The NWD comprises a sensor unit, amplifier/analog-to-digital converter unit, signal processing unit, and communication unit (Figure 2). The HR and RR are determined from heartbeat- and respiration-derived vibration waves transmitted through the device, respectively.

First, in the sensor unit, six piezoelectric elements capable of detecting minute vibrations are placed at 10-cm intervals. The vibrations generated by the participants mainly included those derived from heartbeat, respiration, and body movements. The vibration data acquired at the sensor section are converted into digital data at the amplifier/analog-to-digital converter unit. Subsequently, in the signal processing unit, HR and RR are determined from the digitally converted data (Figure 3).

Heartbeats have relatively high-frequency components and occur at periodic intervals; after passing through a high-pass filter, characteristics derived from heartbeats are extracted, and HR is detected from the intervals between the extracted characteristics. The frequency components of respiration mainly have low-frequency components and occur at relatively regular intervals; after passing through the low-pass filter, the same process used to detect HR is used to detect RR. The frequency components of body movement are mainly low-frequency components, like respiration, but often do not repeat cyclically, and the amplitude is much larger than that of respiration. Very large signals are generated simultaneously on several piezoelectric elements, distinguishing them from respiration. The determined HR and RR are sent via the communication unit and Raspberry Pi to the cloud. Care workers at the nursing homes can access the cloud server using a web application on their personal computers and view the data with a browser (Figure 2).

Measurement of vital signs by nurses

In this study, the standard method used to measure HR and RR was performed by nurses as previously described [9,10,26]. Briefly, two nurses with 20 years of experience measured the HR and RR of all participants. The nurse measured the HR by touching the participant's radial artery for 1 min, and the RR by visually observing the thoracic movement for 1 min. The nurse avoided touching the mattress while taking the measurements to eliminate interference.

Electrocardiograms and respiratory effort belts are other standard methods for measuring HR and RR; however, they are difficult to use in nursing homes staffed with only a few medical professionals [27,28]. Moreover, these contact devices have many electrodes and are not recommended for use in non-hospital settings as they cause physical restraint and discomfort in older adults [28]. Therefore, in this study, the standard method was used to ensure the safety of older adults and avoid causing discomfort.

Wearable device (WD)

A Silmee Bar-type Lite sensor (TDK Co., Tokyo, Japan; width, 64 mm; height, 96 mm; depth, 28 mm) was used as the WD to measure the HR of participants. This device could simultaneously measure electrocardiogram signals, pulse wave, acceleration, and skin temperature and was set to 125 Hz for the electrocardiograph and offline mode. This device was attached to the participants' chests at 3 cm below the collarbone using a special gel pad, and their electrocardiogram signals were measured. The HR was calculated per minute based on the time between heartbeats, which is the device output from an electrocardiogram.

HR cannot be measured visually but is preferably measured at the location of the heart. Therefore, we measured the HR both by using the WD and by manually palpating the participant's radial artery as mentioned in the previous section.

Collection of basic information

In Study 1, the following items representing basic participant information were self-reported: sex, age, height, weight, respiratory diseases, and heart diseases. In Study 2, the following data were collected from care workers in multi-dwelling houses: sex, age, height, weight, level of care needed, and diagnosis of dementia. Older adults who required nursing care were classified based on their care needs as levels 1–5. Each municipality has certified care needs according to the level of nursing care required [29,30]. Care need level 1 requires relatively low assistance, while care need level 5 requires extensive assistance with personal care.

Data analysis

The primary outcome was the mean difference between the HR and RR measured using the NWD and those measured by the nurses and the WD. We defined HR <5 beats/min and RR <3 breaths/min as the accepted mean difference before starting the study. We also defined the maximum error not leading to a change in care or observation as the criterion based on previous studies [9,31].

HR and RR data from the NWD were each compared with measurements taken by the nurses and WD at the same time point. The measured data were compared at each time point, and measurement errors were calculated. Subsequently, Bland–Altman plots were created to assess the agreement between the data measured using the NWD and those measured using the WD [32,33]. This method has been widely used in comparative studies [32,34]. We calculated the mean difference and 95% limits of agreement (LoAs) between the NWD data and manually measured data. Python (version 3.8.1; Python Software Foundation, Wilmington, DE, USA) and R statistical software (version 3.6.3; R Foundation for Statistical Research, Vienna, Austria) were used for analysis. All statistical tests were two-sided, and statistical significance was set at $P < .05$.

Ethical considerations

This study was conducted in accordance with the principles of the Declaration of Helsinki and approved by the Human Study Ethics Committee of the authors' affiliated university (approval number: M2021-374).

The participants were informed about the study aims and procedure, both verbally and in writing, and consented to participate by signing a consent form. For older adults with difficulty communicating due to dementia or other cognitive impairments, their relatives were contacted, and their proxy consent was obtained. All participants (and their family members, when needed) were informed that participation in the study was voluntary and that they could withdraw at any point. Moreover, we explained that the participants would not be disadvantaged by not participating in the study, discontinuing participation, or withdrawing their cooperation.

HR measurement using the WD required direct contact with the skin; therefore, we attempted to protect the skin by applying a protectant (PureBarrer®; Granmate Co., Chiba, Japan) before attaching the device. After the measurements, a release agent (3M™ Cavilon™ Remover; 3M, Maplewood, MN, USA) was used for careful removal.

Data Availability Statement

Data from this study are available by contacting our research team.

Results

Demographics

Twenty-two healthy individuals participated in Study 1 (Figure 4). The study population included 11 males (50%) and 11 females (50%) with a mean age of 47.0 (interquartile range [IQR]: 32.5–57) years (Table 1).

Table 1. Participants' characteristics for Studies 1 and 2

		Value
Study 1 (N=21)		
Male sex	n (%)	11 (50)
Age (years)	median (25–75%)	47 (32.5–57.0)
Body mass index (BMI; kg/m ²)	median (25–75%)	22.2 (20.6–23.9)
Study 2 (N=20)		
Male sex	n (%)	3 (15)
Age (years)	median (25–75%)	87.5 (85.0–90.5)
BMI (kg/m ²)	median (25–75%)	22.1 (20.1–23.6)
Respiratory disease	n (%)	0 (0)
Care need level 1	n (%)	7 (35)
Care need level 2	n (%)	6 (30)
Care need level 3	n (%)	6 (30)
Care need level 4	n (%)	0 (0)

Care need level 5	n (%)	1 (5)
Dementia	n (%)	12 (60)

Data are presented as median (25–75%) or n (%).

In Study 2, 26 older adults requiring nursing care were selected, of whom 20 participated (Figure 4). Three older adults did not consent, and three could not obtain consent from their families. The study population included 3 males (15%) and 17 females (85%) with a mean age of 87.5 (IQR: 85–90.5) years (Table 1). Among the participants, seven (35%) needed care level 1, six (30%) needed care level 2, six (30%) needed care level 3, and one (5%) needed care level 5. None of the participants dropped out during the study periods in Studies 1 or 2.

Technical feasibility

In Study 1, 110 HR data points (22 participants) and 110 RR data points (22 participants) were measured. The start time of HR measurement was not recorded for one participant owing to human error. Therefore, the NWD, WD, and nurse measurements for this participant could not be merged. We excluded the HR data of the participant (five data points) and included 105 data points for HR (21 participants) and 110 data points for RR (22 participants).

In Study 2, 100 data points each for HR (20 participants) and RR (20 participants) were measured. There were no missing data; therefore, 100 data points each were included for the HR (20 participants) and RR (20 participants).

Heart rate (HR)

The mean differences measured by the NWD, nurses, and WD are shown in Table 2. The mean HR in Study 1 measured by the NWD was 66.57 (standard deviation [SD]: 8.45) beats/min, the nurse measured 66.25 (SD: 8.05) beats/min, and the WD recorded 66.57 (SD: 8.45) beats/min. The mean HRs in Study 2 measured by the NWD, nurse, and WD were 64.22 (SD: 6.13), 64.18 (SD: 7.20), and 65.21 (SD: 7.84) beats/min, respectively.

Table 2. Means and differences of measurements taken using the NWD, nurse, and WD

			NWD	Nurse	WD		
			Mean (SD)	Mean (SD)	Mean (SD)	Mean difference (SD) NWD vs. Nurse	Mean difference (SD) NWD vs. WD
Study 1	HR (beats/min)	105	68.05 (6.9)	66.25 (8.05)	66.9 (8.28)	-0.32 (3.12)	0.33 (1.86)
	RR (breaths/min)	110	13.27 (7.9)	12.55 (3.27)		-0.98 (3.01)	
Study 2	HR (beats/min)	100	66.13 (5.21)	64.22 (6.13)	65.21 (7.84)	0.04 (3.98)	1.03 (4.22)
	RR (breaths/min)	100	23.22 (1.55)	15.65 (3.22)		-0.49 (2.4)	

NWD, non-wearable device; WD, wearable device; HR, heart rate; RR, respiratory rate; SD, standard deviation

The Bland–Altman plots are shown in Figure 5 and Table 3. The mean, differences, and LoAs (1.96 SD) were plotted. The y-axis in Figure 5 indicates the measurement differences and LoAs. First, the differences between NWD and nurses for 95% were within the LoAs; however, wide LoAs were observed (Study 1 (Lower LoA–Upper LoA): -6.86 to 4.90; Study 2: -7.72 to 7.80). Second, the

differences between NWD and WD for 95% were within the LoAs; however, wide LoAs were observed (Study 1: -3.42 to 4.02; Study 2: -7.20 to 9.26).

Table 3. Bland–Altman analysis for HR and RR measured using the NWD

				Difference [NWD vs. Nurses]				Difference [NWD vs. WD]			
			N	Mean	SD	Lower LoA	Upper LoA	Mean	SD	Lower LoA	Upper LoA
Study 1	HR	(beats/min)	105	-0.32	3.12	-6.86	4.90	0.33	1.86	-3.42	4.02
	RR	(breaths/min)	110	-0.98	3.01	-6.41	5.76				
Study 2	HR	(beats/min)	100	0.04	3.98	-7.72	7.80	1.03	4.22	-7.20	9.26
	RR	(breaths/min)	100	-0.49	2.40	-5.17	4.19				

NWD, non-wearable device; WD, wearable device; HR, heart rate; RR, respiratory rate; SD, standard deviation; LoA, limit of agreement

The differences in the HR measurements are presented in Table 4. Approximately 90% of the measurement differences were within five measurements in Studies 1 and 2.

Table 4. Measurement difference for NWD in Study 1 and Study 2

		Study 1		Study 2	
		NWD vs. Nurse	NWD vs. WD	NWD vs. Nurse	NWD vs. WD
		N (%)	N (%)	N (%)	N (%)
HR (beats/min)	≤2	71 (67.62)	88 (83.81)	62 (62)	62 (62)
	>2	23 (21.9)	16 (15.24)	25 (25)	22 (22)
	>5	11 (10.48)	1 (0.95)	9 (9)	12 (12)
	>10	0 (0)	0 (0)	4 (4)	4 (4)
	>15	0 (0)	0 (0)	0 (0)	0 (0)
RR (breaths/min)	≤2	81 (73.64)		84 (84)	
	>2	19 (17.27)		11 (11)	
	>5	9 (8.18)		5 (5)	
	>10	0 (0)		0 (0)	

>15 1 (0.91)

0 (0)

NWD, non-wearable devices; WD, wearable device; HR, heart rate; RR, respiratory rate

Respiratory rate (RR)

The mean differences measured by NWD, nurses, and WD are shown in Table 2. The mean RR in Study 1 measured by the NWD was 13.54 (SD: 3.31) breaths/min, and by the nurse was 12.55 (SD: 3.27) breaths/min. The mean RR in Study 2 measured by NWD was 16.14 (SD: 2.89) breaths/min, and by the nurse was 15.65 (SD: 3.22) breaths/min.

The Bland–Altman plots are shown in Figure 5 and Table 3. The mean, differences, and LoAs (1.96 SD) were plotted. The y-axis in Figure 5 indicates the measurement differences and LoAs. The differences between the data obtained from the NWD and nurses for 95% were within the LoAs. However, wide LoAs were observed (Study 1 (Lower LoA–Upper LoA): -6.41 to 5.76; Study 2: -5.17 to 4.19).

The differences in RR measurements are presented in Table 4. Approximately 90% of the measurement differences were within five measurements in Studies 1 and 2.

Discussion

This study evaluated the feasibility of monitoring HR and RR continuously using an NWD placed under the participant's mattress and measured the consistency of the rates. The consistency of the HR and RR measured was proved by the finding that the mean differences in HR and RR calculated using the NWD in healthy participants and older adults who required nursing care were within the predetermined and accepted cutoffs. Moreover, none of the participants dropped out of the study or complained of physical abnormalities. Therefore, continuous monitoring of vital signs using NWDs is feasible at residences and in nursing homes.

First, no participants dropped out or complained in this study. Although a WD can provide accurate measurements, skin redness and itching have been reported due to skin contact with the device [9]; in contrast, our study participants did not report such skin-related issues. Moreover, if participants are aware that they are being monitored, their RR may tend to be lower than normal [35]. NWDs provide a non-intrusive alternative that allows for continuous monitoring in bed without skin contact or irritation [36]. In this study, a NWD yielded HR and RR values that were close to normal values because the patients were not uncomfortable and were less likely to notice that they were being monitored.

Second, we showed the correlation of HR measured using the NWD. The mean difference in HR measured using the NWD was within the predetermined acceptable range (Study 1: -0.32 and 0.33 [nurse and WD, respectively] and Study 2: 0.04 and 1.03 [nurse and WD, respectively]). In addition, the HRs measured with the NWD and WD were similar in this study. The mean differences in HR measured using other WDs are reportedly -0.20 (SD: 5.54) [9], -1.1 (SD: 3.8) [31], and 1.8 (SD: 1.8) [37], close to those observed in this study. The device used in these previous studies was a wireless WD with electrodes attached to the anterior chest [9,31]. Although there are differences in measurement methods (i.e., direct vs. indirect contact with the skin), measurement positions (anterior chest vs. posterior back), and device systems (electrical signals of the heart vs. waves from body vibrations), the consistency in HR measurements suggests that both NWDs and WDs achieve similar accuracy. WDs can monitor an older adult's activity continuously without much discomfort [36]. Both NWDs and WDs are non-invasive and can be easily integrated into the daily lives of older adults [38]. Therefore, it is important to select the appropriate device based on the specific needs and condition of the patient.

Third, we showed the correlation of RR measured by the NWD. The mean difference in the RR measured using the NWD was within the predetermined acceptable range (Study 1: -0.98; Study 2: -0.49). The mean differences in RR measured using other WDs are -2.3 (SD: 6.8) [23] and 1.19 (3.43) [9], similar to that in this study. We observed that the NWD could measure RR almost as well as the nurses, with a low measurement error (<5 breaths/min). However, a large difference of 17 breaths/min was seen in the measurement error (5 and 22 breaths/min for the nurse and NWD, respectively), consistent with a previous study by Weenk et al., who reported a difference of 26 breaths/min [9]. In the present and previous studies, nurses assessed RR by visually observing the chest [9]. The reproducibility of the method is limited by high inter-observer variability [39], and a large difference was expected in this study. In addition, the number of events related to the reliability of bradycardic and tachycardic respiration was low in this study. Therefore, their reliability could not be evaluated. The reasons for this include the short measurement time per participant, exclusion of participants with cardiac or respiratory disease, and starting the measurement after the participants had rested for 5 min. In the future, it is necessary to conduct long-term measurements, such as overnight measurements, to evaluate events related to the reliability of bradycardic and tachycardic respiration in older adults.

The strength of our study is that we evaluated the consistency of HR and RR measured using an NWD that has already been introduced in many facilities in Japan, and suggested the possibility of improving the nursing home environment. We believe that monitoring the HR and RR of older adults safely and unobtrusively when they are in bed may help in detecting sudden changes and providing suitable care without frequent visits. NWDs reduce the number of vital sign measurements and rounds and the burden on care providers, nurses, and care workers, allowing them to concentrate on care [40]. Given the declining population and limited number of healthcare workers, devices with consistent HR and RR will help optimize the patient's environment. Therefore, we believe that NWDs can be applied in various facilities.

This study had some limitations. First, the participants were healthy or older adults without cardiac or respiratory disease. Therefore, the consistency in participants with cardiac and respiratory diseases should be examined further. Second, the measurement times for HR and RR in this study were short (5 min). When the NWD was installed at the residences and nursing homes, participants were continuously monitored while they were in bed. The disadvantages of continuous measurements, such as those taken overnight, were not considered. Third, the criterion measurement is lacking. In this study, nurse-based measurement was selected as the criterion for HR and RR as described in many studies [9,18,26]. Contact devices, such as electrocardiography, have also been used [8,9]. However, they are known to cause skin issues, such as peeling of the stratum corneum and red spots [41,42]. In this study, older adults (whose skin is typically more fragile) were recruited [13]. Therefore, we decided to use nurse-based measurement to prevent any discomfort and adverse events among the study participants. Ideally, HR and RR should have been measured using both methods. Despite these limitations, the consistency of HR and RR measured using the NWD suggests that this method may be useful for monitoring vital signs at residences and in nursing homes.

Conclusions

This study evaluated the feasibility and consistency of measuring HR and RR using an NWD placed under the mattress. The mean differences in HR and RR measured by the NWD were both within the predefined accepted discrepancies. No physical abnormalities were noted during the measurements. Therefore, we suggest using these devices at residences and in nursing homes. Safe monitoring of vital signs using NWDs is expected in the future for the early detection of abnormal conditions without inconveniencing older adults, care workers, and nurses. We believe that NWDs promote medical DX, which will enable care providers to observe conditions accurately and provide appropriate care through the data obtained from such devices.



Acknowledgments

We would like to thank all the participants in this study. We would also like to thank Ms. Kazumi Sato and Ms. Kaori Sato of NJI Co., Ltd. for their cooperation.

Author contributions: K.I., A.M., M.W., and S.F. contributed to the research idea, study design, and organization of the study. K.I. contributed to data management and statistical analysis. K.I., A.M., M.W., and S.F. contributed to the interpretation. K.I., A.M., M.W., and S.F. contributed to data acquisition. Each author has reviewed, discussed, and agreed to their individual contributions ahead of submission.

This study was supported by the Japan Society for the Promotion of Science Grants-in-Aid for Scientific Research (grant number: 21H04849, S.F.) and NJI Corporation (grant number: 21AB100084, S.F.).

Conflicts of Interest

S.F. received grant support from NJI Co., Ltd., which developed the Safety Sheep Sensor.

Abbreviations

HR: heart rate

IQR: interquartile range

LoAs: limits of agreement

NWD: non-wearable device

RR: respiratory rate

SD: standard deviation

WD: wearable device

References

1. Borský P, Holmannová D, Fiala Z, et al. Physiology of ageing. *Fyziologie stárnutí. Cas Lek Cesk*; 2022;161:11-6. PMID: 35354289.
2. Flint B, Tadi P. Physiology, Aging. In: *StatPearls*. Treasure Island (FL): StatPearls Publishing; January 4, 2023.
3. Celler BG, Sparks RS. Home telemonitoring of vital signs--Technical challenges and future directions. *IEEE Journal of Biomedical and Health Informatics*; 2015;19:82-91. doi:[10.1109/JBHI.2014.2351413](https://doi.org/10.1109/JBHI.2014.2351413)
4. Ashcraft AS, Donna CO. From nursing home to acute care: signs, symptoms, and strategies used to prevent transfer. *Geriatric Nursing*; 2014;35:316-20. doi:[10.1016/j.gerinurse.2014.06.007](https://doi.org/10.1016/j.gerinurse.2014.06.007).
5. Harris DA, Archbald-Pannone L, Kaur J, et al. Rapid telehealth-centered response to COVID-19 outbreaks in postacute and long-term care facilities. *Telemedicine Journal and E-Health*; 2021;27:102-6. doi: [10.1089/tmj.2020.0236](https://doi.org/10.1089/tmj.2020.0236)
6. Watkins T, Whisman L, Booker P. Nursing assessment of continuous vital sign surveillance to improve patient safety on the medical/surgical unit. *The Journal of Clinical Nursing*; 2016;25:278-81. doi:[10.1111/jocn.13102](https://doi.org/10.1111/jocn.13102)
7. Hollander JE, Carr BG. Virtually perfect? Telemedicine for Covid-19. *The New England Journal of Medicine*; 2020;382:1679-81. doi:[10.1056/NEJMp2003539](https://doi.org/10.1056/NEJMp2003539).
8. Kroll RR, Boyd JG, Maslove DM. Accuracy of a wrist-worn wearable device for monitoring heart rates in hospital inpatients: A prospective observational study. *Journal of Medical Internet Research*; 2016;18:e253. doi:[10.2196/jmir.6025](https://doi.org/10.2196/jmir.6025)

9. Weenk M, van Goor H, Frietman B, et al. Continuous monitoring of vital signs using wearable devices on the General Ward: Pilot study. *Journal of Medical Internet Research*; 2017;5:e91. doi:[10.2196/mhealth.7208](https://doi.org/10.2196/mhealth.7208)
10. Boatin AA, Wylie BJ, Goldfarb I, et al. Wireless vital sign monitoring in pregnant women: A functionality and acceptability study. *Telemedicine Journal and E-Health*; 2016;22:564-71. doi:[10.1089/tmj.2015.0173](https://doi.org/10.1089/tmj.2015.0173).
11. Senmao W, Ni X, Li L, et al. Noninvasive monitoring of vital signs based on Highly Sensitive Fiber Optic Mattress. *IEEE Sensors Journal*; 2020;20:6182-90. doi:[10.1364/BOE.10.005940](https://doi.org/10.1364/BOE.10.005940)
12. Zhihua W, Yang Z, Dong T. A review of wearable technologies for elderly care that can accurately track indoor position, recognize physical activities and monitor vital signs in real time. *Sensors (Basel)*; 2017;17:341. doi:[10.3390/s17020341](https://doi.org/10.3390/s17020341)
13. Russell-Goldman E, Murphy GF. The pathobiology of skin aging: New insights into an old dilemma. *The American Journal of Pathology*; 2020;190:1356-69. doi:[10.1016/j.ajpath.2020.03.007](https://doi.org/10.1016/j.ajpath.2020.03.007)
14. Ullal A, Su BY, Enayati M, et al. Non-invasive monitoring of vital signs for older adults using recliner chairs. *Health Technology*; 2021;11:169-84. doi:[10.1007/s12553-020-00503-9](https://doi.org/10.1007/s12553-020-00503-9)
15. Francesca de T, Presti DL, Carassiti M, et al. Smart mattress based on Fiber Bragg grating sensors for respiratory monitoring: a feasibility test. In: 2021 IEEE International Workshop on Metrology for Industry 4.0 & IoT (MetroInd4.0&IoT); 2021;532-37. IEEE doi:[10.1109/MetroInd4.0IoT51437.2021.9488539](https://doi.org/10.1109/MetroInd4.0IoT51437.2021.9488539)
16. Diogo P, Carvalho A, Costa FM, et al. Unobtrusive monitoring of the respiratory rate in an office desk chair with FBG sensors. In: 2021 IEEE International Workshop on Metrology for Industry 4.0 & IoT (MetroInd4.0&IoT); 2021; 177-81. IEEE. doi:[10.1109/MetroInd4.0IoT51437.2021.9488528](https://doi.org/10.1109/MetroInd4.0IoT51437.2021.9488528)
17. Rohan R, Venkadeshwaran K, Ranjan P. Recent advancements of fiber bragg grating sensors in biomedical application: A Review. *Journal of Optics*; 2024;53:282-93. doi:[10.1007/s12596-023-01134-9](https://doi.org/10.1007/s12596-023-01134-9)
18. United Nations. 2015. World Population Ageing 2015. United Nations.
19. Ministry of Health, Labour and Welfare. Dai 8 ki kaigo hoken zigyou keikaku ni motodoku kaigosityokunn no hituyousuu nituite; 2021. Available from: https://www.mhlw.go.jp/stf/houdou/0000207323_00005.html
20. Ministry of Health, Labour and Welfare. Kaigo robot no kaihatu fukyu no sokushin; 2021. Available from: <https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000209634.html>
21. Ministry of Health, Labour and Welfare. Kaigo robot to donyu sien tokubetu zigyou (Heisei 27 nendo hosei yosan); 2015. Available from: <https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000112870.html>
22. Ministry of Health, Labour and Welfare. Kaigo Robbot no kaihatu hukuuu no sokushin; 2020. Available from: <https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000209634.html>.
23. Morley JE, Caplan G, Cesari M, et al. International Survey of Nursing Home Research Priorities. *Journal of the American Medical Directors Association*; 2014;15:309-12. doi:[10.1016/j.jamda.2014.03.003](https://doi.org/10.1016/j.jamda.2014.03.003)
24. Sim I. Mobile Devices and Health. *The New England Journal of Medicine*; 2019;381:956-68. doi:[10.1056/NEJMr1806949](https://doi.org/10.1056/NEJMr1806949)
25. NJI Co., Ltd. A sensor to protect your loved ones. Available from: <https://www.anshin-hitsuji.jp/Templates/PDF/Pamphlet-English.pdf>
26. Steinhubl SR, Feye D, Levine AC, et al. Validation of a portable, deployable system for

- continuous vital sign monitoring using a multiparametric wearable sensor and personalised analytics in an Ebola treatment centre. *BMJ Global Health*; 2016;1:e000070. doi:[10.1136/bmjgh-2016-000070](https://doi.org/10.1136/bmjgh-2016-000070)
27. Patel V, Orchanian-Cheff A, Wu R. Evaluating the validity and utility of wearable technology for continuously monitoring patients in a hospital setting: systematic review. *Journal of Medical Internet Research mHealth and uHealth*; 2021;9:e17411. doi:[10.2196/17411](https://doi.org/10.2196/17411).
 28. Sun G, Matsui T, Watai Y, et al. Vital-SCOPE: design and evaluation of a smart vital sign monitor for simultaneous measurement of pulse rate, respiratory rate, and body temperature for patient monitoring. *Journal of Sensors*; 2018;1-7. doi:[10.1155/2018/4371872](https://doi.org/10.1155/2018/4371872)
 29. Takahashi S, Yonekura Y, Takanashi N, et al. Risk factors of long-term care insurance certification in Japan: a scoping review. *International Journal of Environmental Research and Public Health*; 2022;19:2162. doi:[10.3390/ijerph19042162](https://doi.org/10.3390/ijerph19042162).
 30. Ikegami N. Financing long-term care: lessons from Japan. *International Journal of Health Policy and Management*; 2019;8:462-66. doi:[10.15171/ijhpm.2019.35](https://doi.org/10.15171/ijhpm.2019.35).
 31. Breteler MJM, Huizinga E, van Loon K, et al. Reliability of wireless monitoring using a wearable patch sensor in high-risk surgical patients at a step-down unit in the Netherlands: A clinical validation study. *BMJ Open*; 2018;8:e020162. doi:[10.1136/bmjopen-2017-020162](https://doi.org/10.1136/bmjopen-2017-020162)
 32. Bland JM, Altman DG. Statistical methods for assessing agreement between two methods of clinical measurement. *Lancet*; 1986;1:307-10. doi:[10.1016/j.ijnurstu.2009.10.001](https://doi.org/10.1016/j.ijnurstu.2009.10.001)
 33. Bland JM, Altman DG. Applying the right statistics: Analyses of measurement studies. *Ultrasound in Obstetrics & Gynecology*; 2003;22:85-93. doi:[10.1002/uog.122](https://doi.org/10.1002/uog.122)
 34. Gerke O. Reporting standards for a Bland-Altman agreement analysis: A review of methodological reviews. *Diagnostics (Basel, Switzerland)*; 2020;10:334. doi:[10.3390/diagnostics10050334](https://doi.org/10.3390/diagnostics10050334)
 35. Hill A, Kelly E, Horswill MS, et al. The effects of awareness and count duration on adult RR measurements: An experimental study. *Journal of Clinical Nursing*; 2018;27:546-54. doi:[10.1111/jocn.13861](https://doi.org/10.1111/jocn.13861)
 36. Arandia N, Garate JI, Mabe J. Monitoring of vital signs in the home environment: a review of current technologies and solutions. In: *Proceedings of the 16th International Joint Conference on Biomedical Engineering Systems and Technologies (BIOSTEC 2023) - Volume 1: BIODVICES*; 2023:108–15. doi:[10.5220/0011646700003414](https://doi.org/10.5220/0011646700003414)
 37. Christina H, Cecilia GF, Haldar N, et al. Accuracy of vital signs measurements by a smartwatch and a portable health device: validation study. *Journal of Medical Internet Research*; 2020;8:e16811. doi:[10.2196/16811](https://doi.org/10.2196/16811)
 38. Olmedo-Aguirre JO, Reyes-Campos J, Alor-Hernández G, et al. Remote healthcare for elderly people using wearables: a review. *Biosensors*; 2022;12:73. doi:[10.3390/bios12020073](https://doi.org/10.3390/bios12020073)
 39. Edmonds ZV, Mower WR, Lovato LM, et al. The reliability of vital sign measurements. *Annals of Emergency Medicine*; 2002;39:233-7. doi:[10.1067/mem.2002.122017](https://doi.org/10.1067/mem.2002.122017)
 40. Fulmer T, Reuben DB, Auerbach J, et al. Actualizing better health and health care for older adults. *Health Affairs (Project Hope)*; 2021;40:219-25. doi:[10.1377/hlthaff.2020.01470](https://doi.org/10.1377/hlthaff.2020.01470)
 41. Feig, DS, Lois ED, Rosa C, et al. Continuous Glucose Monitoring in Pregnant Women with Type 1 Diabetes (CONCEPTT): A multicentre international randomised controlled trial. *Lancet*; 2017;390:2347-59. doi:[10.1016/S0140-6736\(17\)32400-5](https://doi.org/10.1016/S0140-6736(17)32400-5)
 42. Yunzhi L, An T, Lim WY, et al. Disruptive, soft, wearable sensors. *Advanced Materials*;

2020:32:1904664. doi:[10.1002/adma.201904664](https://doi.org/10.1002/adma.201904664).

Preprint
JMIR Publications

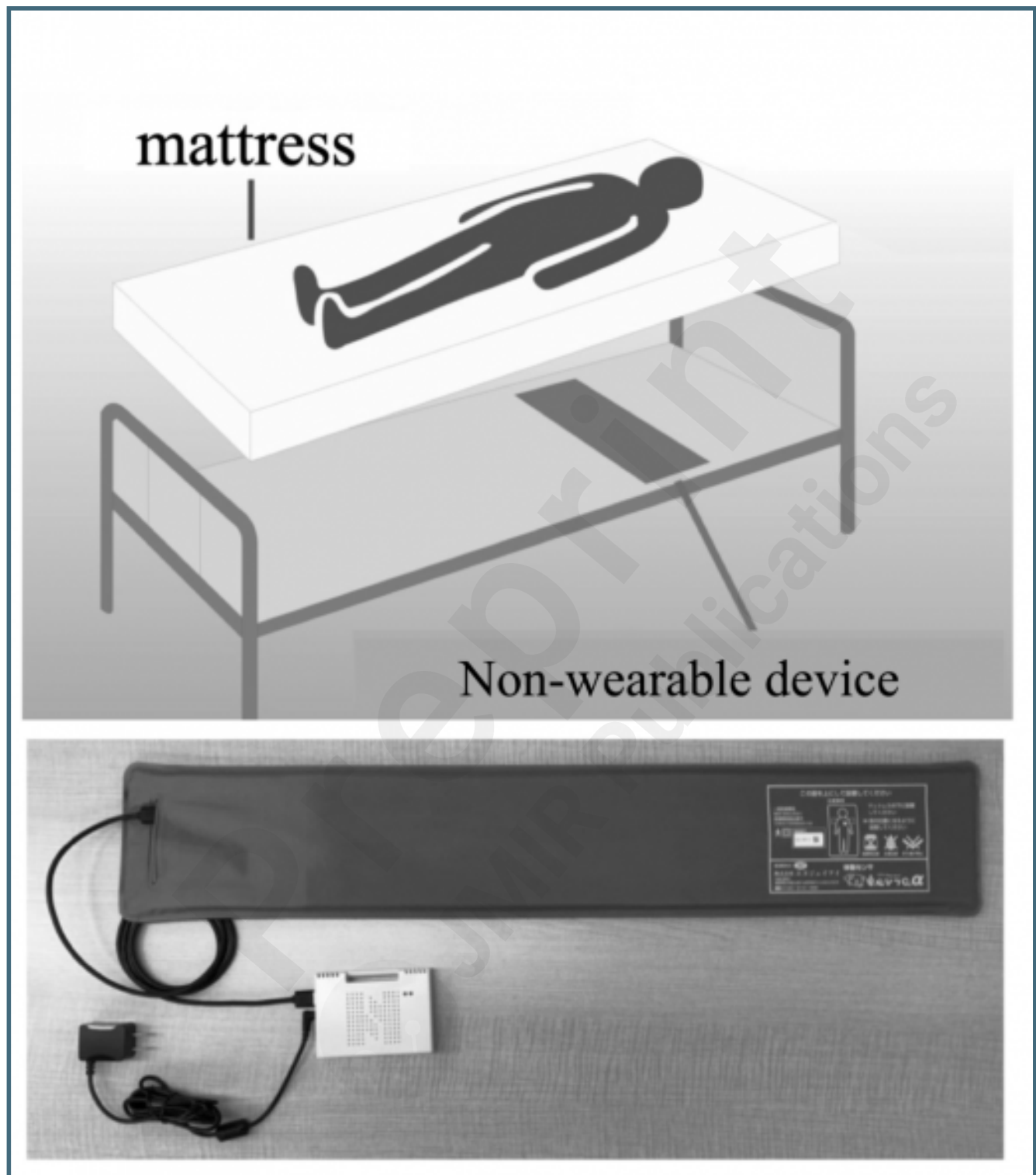
Supplementary Files

2nd a tracked-changes version manuscript.

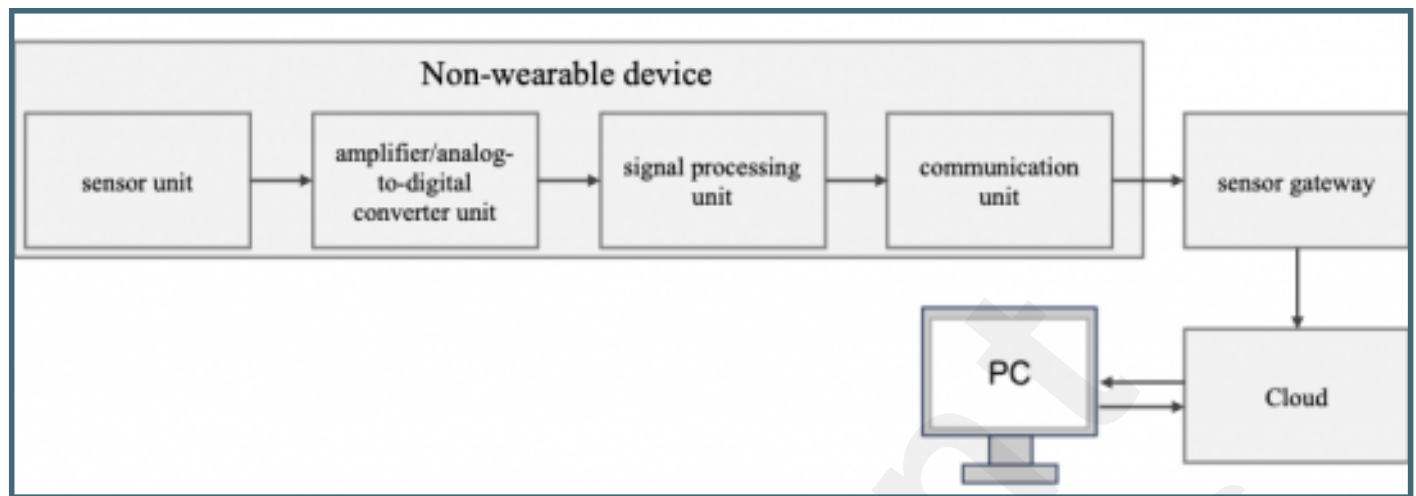
URL: <http://asset.jmir.pub/assets/26c55005eb5441407c00d80a54559dbd.docx>

Figures

Positioning of the NWD.



Comprises of Non-wearable device.



Heartbeat wave and respiratory wave.

Figure 3a. Heartbeat wave

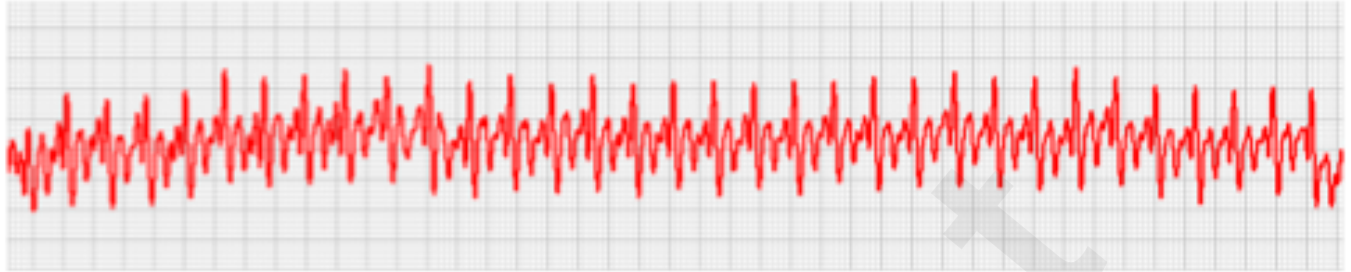
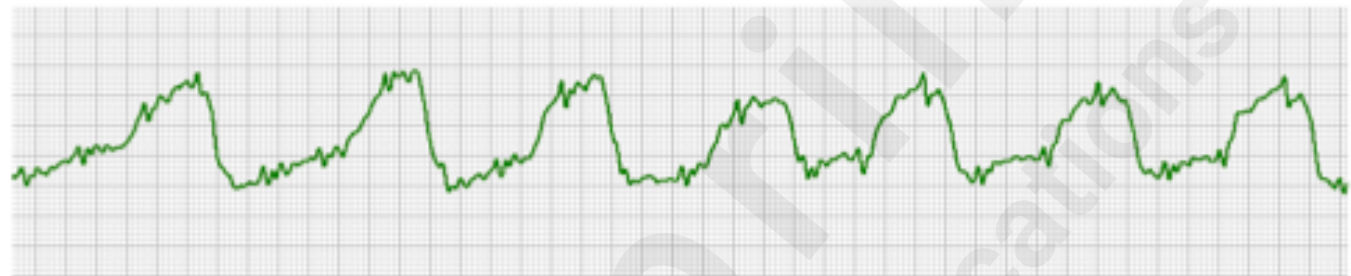
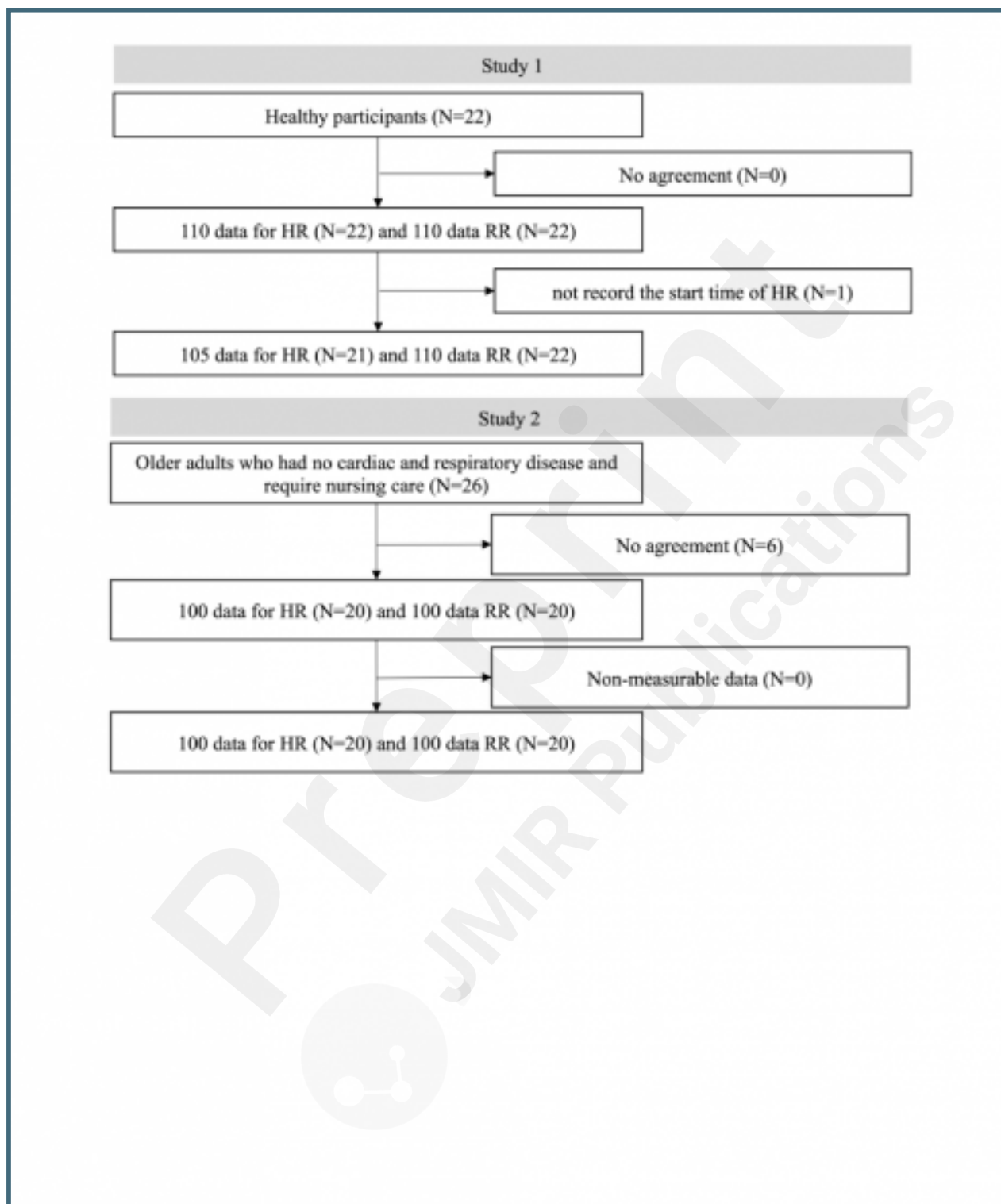


Figure 3b. Respiratory wave



Flow diagram depicting the inclusion and exclusion of study participants.



Bland–Altman plot.

