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Electronic physiologic and subjective data acquisition in home-dwelling heart failure patients: An assessment of patient use and perception of usability

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ABSTRACT

Background: The current approach to the outpatient management of heart failure involves patients recollecting what has happened to them since their last clinic visit. But patients' recollection of their symptoms may not be sufficiently accurate to optimally manage their disease. Most of what is known about heart failure is related to patients' diurnal symptoms and activities. Some mobile electronic technologies can operate continuously to collect data from the time patients go to bed until they get up in the morning. We were therefore interested to evaluate if patients would use a system of selected patient-facing devices to collect physiologic and subjective state data in and around the patients' period of sleep, and if there were differences in device use and perceptions of usability at the device level

Methods: This descriptive observational study of home-dwelling patients with heart failure, between 21 and 90 years of age, enrolled in an outpatient heart failure clinic was conducted between December 2014 and June 2015. Patients received five devices, namely, body weight scale, blood pressure device, an iPad-based subjective states assessment, pulse oximeter, and actigraph, to collect their physiologic (body weight, blood pressure, heart rate, blood oxygen saturation, and physical activity) and subjective state data (symptoms and subjective states) at home for the next six consecutive nights. Use was defined as the ratio of observed use over expected use, where 1.0 is observed equals expected. Usability was determined by the overall System Usability Scale score.

Results: Participants were 39 clinical heart failure patients, mean age 68.1 (SD, 12.3), 72% male, 62% African American. The ratio of observed over expected use for the body weight scale, blood pressure device, iPad application, pulse oximeter and actigraph was 0.8, 1.0, 1.1, 0.9, and 1.9, respectively. The mean overall System Usability Scale score for each device were 84.5, 89.7, 85.7, 87.6, and 85.2, respectively.

Conclusions: Patients were able to use all of the devices and they rated the usability of all the devices higher than expected. Our study provides support for at-home patient-collected physiologic and subjective state data. To our knowledge, this is the first study to assess the use and usability of electronic objective and subjective data collection devices in heart failure patients' homes overnight.

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1. Introduction

The current approach to the outpatient management of heart failure combines patients' retrospective self-reports of symptoms and activity with a physical examination and laboratory results during a routine office visit [1]. Clinicians expect that patients will accurately recall significant changes in symptoms and activity since the last clinic visit. Unfortunately, there is a great deal of variability in patient's self-reports and in subjective assessment instruments [2]. Recall is, many times, not veridical with past events and it may be especially difficult for patients with heart failure because of the prevalence of mild cognitive impairment due to both heart failure itself [3] and advancing age [4]. Thus, retrospective objective and

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subjective information recalled at clinic visits may not provide the accurate, complete, and detailed information that clinicians require for the optimal management of their patients.

Until recently, methods to improve patient-collected data have been limited to recordings entered into logs and diaries maintained by the patient between clinic visits. This situation has changed with the introduction of mobile electronic technologies that are capable of collecting, storing, and transmitting physiologic and subjective state data from patients' homes. Diurnal remote patient monitoring devices [5,6] have shown improved patient outcomes. [7–9]. Mobile technologies that can be used at home have the potential to dramatically improve the information that clinicians have available to them when making clinical decisions.

Most of what is known about heart failure is related to patients' diurnal symptoms and activities; for example, the New York Heart Association Functional Classification (NYHA) is predominately a daytime system. Little is known about what happens to patients with heart failure during the night, yet many patients with heart failure present to the emergency department at night [10]. Some mobile electronic technologies can operate continuously to collect data from the time patients go to bed until they get up in the morning. These data can fill in a vital clinical information gap regarding heart failure as a disease, if patients can and will use selected devices to collect the data.

We were therefore interested to evaluate if patients would use a system of selected patient-facing devices (devices intended to be used by patients to collect clinical information in non-clinical settings) to collect physiologic and subjective state data in and around the patients' period of sleep. Additionally, we were interested to see if there were differences in device use and perceptions of usability at the device level, and so collected quantitative data from patients by asking them to complete the System Usability Scale [11]. The research questions are: (1) Will patients recruited under normal clinic operating conditions use selected patient-facing devices to collect physiologic and subjective state data at home overnight? (2) Will patients trained under normal clinical operating conditions report the devices used at home overnight to be usable? To our knowledge, researchers have not quantitatively assessed the use and usability of patient-facing electronic devices for collecting objective and subjective data in homes overnight for patients with heart failure.

2. Methods

2.1. Setting and participants

This descriptive observational study was conducted between December 2014 and June 2015 in a United States Military Health System (MHS) heart failure clinic. The institutional review board (IRB) of affiliated university and institution for research approved this study.

Patients were included for consideration if they had a clinical diagnosis of heart failure, were between 21 and 90 years of age, and able to operate study devices. All New York Heart Association Functional Classification (NYHA) patients were eligible to participate. Patients who were unable to operate the devices, by virtue of limited cognitive ability as determined by the patient's clinician were excluded from consideration. Based on the literature, we sought to recruit at least 37 participants in order to have an 85% power to detect a 10-point difference in usability scores at medium effect size, 0.5 [12 p. 157]. The participants were all retirees and their families. The MHS population and care have been shown to be similar to the general population [13–16].

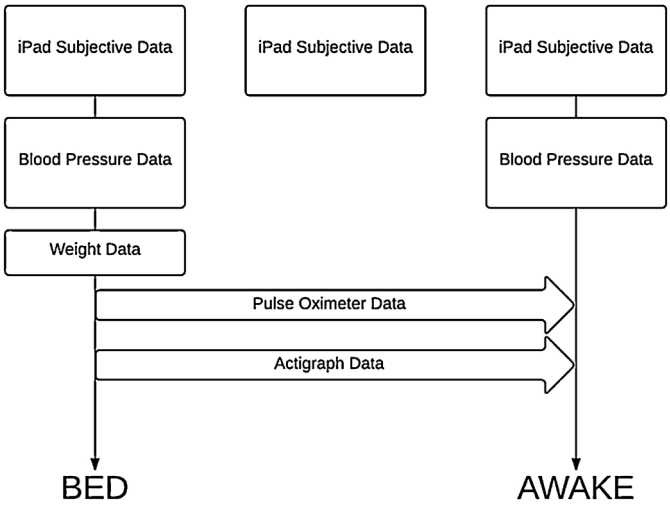


Fig. 1. Graphical representation of patient data collection tasks.

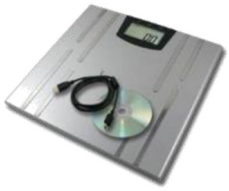
2.2. Procedure

The study was designed to be congruent what occurs in clinic. The lead author approached patients in the examination room before their clinician encounter, showed the patient the devices and described the purpose of the study, and obtained informed consent. Enrollment, device training and device issue took place in the clinic at the time of the patients' scheduled visit. The lead author trained patients for up to one hour on how to use the electronic devices selected to collect physiologic data (body weight scale, blood pressure device, pulse oximeter, and actigraph) and subjective state data (an iPad-based subjective state assessment) so that all the enrolled patients knew how to wear and to use the devices, shown in Table 1. Patients were then issued devices to collect their physiologic and subjective state data at home for the next six consecutive nights.

Patients were asked to use the scale once at night when preparing for bed; to use the blood pressure device twice daily, once before going to bed and once when getting up; the iPad at least twice each day, once at bedtime and upon awakening, and when getting up. The lead author asked patients to wear the pulse oximeter and the actigraph all night, which the lead author expected to be 8 h. The sequence of data collection is graphically illustrated in Fig. 1. Patients were contacted by telephone after the first night and asked if they had questions. Seven days after enrollment, patients came back to the heart failure clinic to return the devices and completed the System Usability Scale for each device. When patients returned the equipment the lead author asked patients to complete a 10-item System Usability Scale (SUS) survey for each device. To minimize potential ordering effects, the presentation order of device questionnaires was pre-determined by generating five-number sets of random numbers from 1 to 5, each representing one device. Sets of 5 SUS questionnaires were placed in sealed envelopes marked with the study numbers in sequential order, each envelope contained questionnaires presented in random order according to the generated table of numbers. When patients returned equipment, the received the envelope matching their respective enrollment number, at which time they completed and returned the surveys.

The device-collected data were downloaded using device-specific software, cleaned using the R statistical language, and uploaded to the MySQL study database. All devices met Protected Health Information (PHI) and Personal Identifiably Information (PII) requirements. All data use was Health Insurance Portability and Accountability Act (HIPAA) compliant.

Table 1
Selected patient-facing device for collecting physiologic and subjective state data at home overnight.

Device	Description	Patient Instructions
 American Weigh Scales (AWS) Bioweigh USB Body Fat Scale	The device is capable of recording up to 365 daily measurements for an individual patient. The device measures weight in a range from 0 to 330 lbs. (0–150 kg) and operates on two AAA batteries	Weigh once in the evening
 Omron 10 Series+ Blood Pressure Monitor (Model BP791IT)	The device measures blood pressure by the oscilometric method, and has a pressure reading accuracy of ±3 mmHg or 2%, and pulse reading accuracy ±4%. It operates on 4 1.5 V AA batteries, and is capable of storing 100 measurements	Take blood pressure in the evening before going to bed, and again when getting up for the day
 Nonin WristOx2 model 3150	The device was configured to collect blood oxygen saturation at 30 Hz. Blood oxygen saturation was calculated as a 4-pulse moving average, and reported every 1-s	Put on the device when going to bed and take the device off when they get up
 ActiSleep+ actigraph monitor	Micro-electro-mechanical system based accelerometer, collects triaxial movement at 30 Hz; raw data processed using ActiLife version 6.11.5. Data were recorded as an interval average of 30 measures reported every 1-s; wear time was validated using the algorithm developed by Choi and Liu [19] and non-wear segments were removed	Put on the device when going to bed and take the device off when they get up; may wear continuously if desired
 iPad-based Subjective State assessment application	Participants were presented with a list of 10 symptom statements, and asked rate their degree of agreement using a three-point scale	Use the application in the evening before going to bed, at night if they awaken with a change in symptoms, and again when getting up for the day

2.3. Data collection devices

We selected six clinical variables based on their clinical and prognostic value in patients with heart failure, namely, body weight [17], systolic and diastolic blood pressure [18], heart rate, blood oxygen saturation [18], physical activity [17], and subjective symptom [17]. To collect these data, we selected the following FDA-approved patient-facing electronic devices to measure and record variables. Devices were selected for their ability to accurately record physiologic data.

Patients measured body weight using the American Weigh Scales (AWS) Bioweigh USB Body Fat Scale. Patients weighed themselves each evening before going to bed.

Patients measured blood pressure using the Omron 10 Series+ Blood Pressure Monitor (Model BP791IT). Patients measured blood pressure twice daily, once when going to bed and when getting up in the morning.

Patients measured heart rate and blood oxygen saturation using the Nonin WristOx2 model 3150 pulse oximeter. The pulse oximeter was configured to automatically record when placed on the patient's finger. Patients put the device on when going to bed, wore it continuously overnight, and took it off when they got up.

Patients measured physical activity using the ActiSleep+ actigraph monitor; a micro-electro-mechanical system based accelerometer that collects triaxial movement data at a rate of 30 Hz. Patients wore the device on their wrist overnight. Wear time was validated using the algorithm developed by Choi and Liu [19]; segments calculated as non-wear segments were removed. We created a physical activity threshold to separate normal daily physical activity from low physical activity, such as what occurs during sleep, by averaging a convenience sample of 30-min segments of normal activity and dividing the grand mean of vector magnitudes by four.

Patients collected symptoms and subjective states data using a custom-built iPad-based application that presented patients with a list of 10 symptom statements and recorded their responses (Fig. 2). We implemented symptom and subjective state prompts for the iPad-based application developed from signs and symptoms common to patients with heart failure [20]. The ten subjective statements were: I am more short of breath than usual; I am in more pain than usual; I feel my heart beating fast; I feel more tired than usual; my feet are more swollen than usual; I feel sicker than usual; I am more unhappy than usual; I have less appetite than usual; I am confused; and I feel alone. Degree of agreement was on a 3-point scale: "no" = 0, "a little" = 1, or "a lot" = 11. This scoring system was devised to permit rapid visual decoding of the score. The scores were summed and an overall score was calculated. A score between 1 and 10 indicates that the patient was experiencing at least one symptom. A score equal to, or greater than 11 indicates that the patient was experiencing one or more significant symptoms. The patients were asked to use the iPad-based subjective state application when going to bed, if they awoke during the night, and when they got up in the morning. The iPad-based subjective state application collected time-stamped, scored entries for each patient and displayed the score to the nearest hour in which the symptom was experienced.

It is important to note that while the variables were selected for the clinical and prognostic value in the management of patients with heart failure; the data collected in this study were not used clinically. Device use was operationalized as the number of measurements recorded by each device (observed) over the number of expected measurements for each respective device (expected). The ratio of observed over expected (O/E) device use, where 1.0 is observed equals expected, was recorded as use for each device per patient. The expected use was defined for each device. A day's use of a device was defined as each day the device recorded any data; the mean days used was the number of days used divided by six days. We report the device use and usability scores separately as device means, and the use and usability of the system of selected devices as grand means.

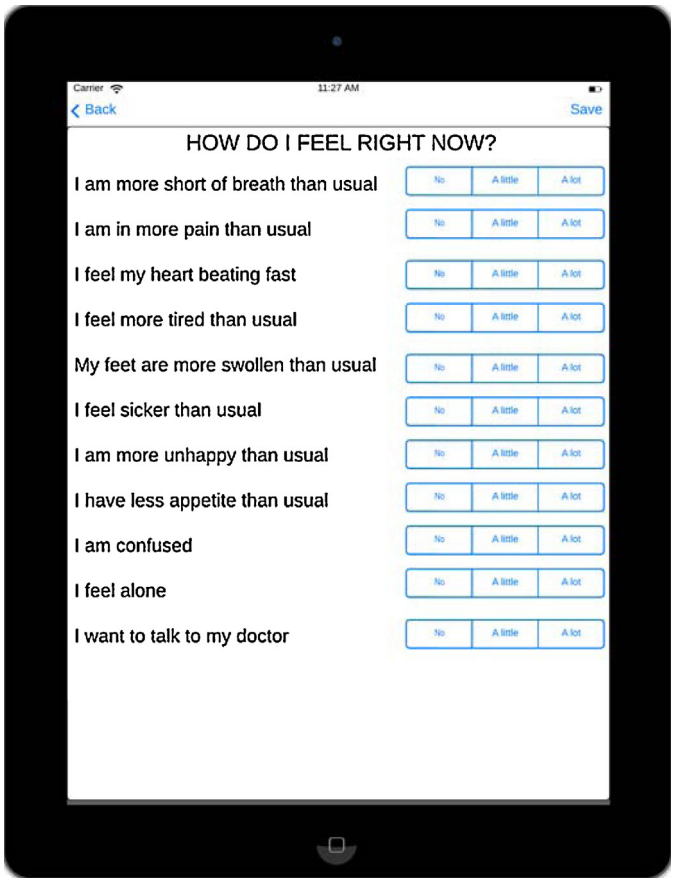


Fig. 2. iPad-based subjective assessment application.

Table 2
Items from the system usability scale.

1. I think that I would like to use this system frequently
2. I found the system unnecessarily complex
3. I thought the system was easy to use
4. I think that I would need the support of a technical person to be able to use this system
5. I found the various functions in this system were well integrated
6. I thought there was too much inconsistency in this system
7. I would imagine that most people would learn to use this system very quickly
8. I found the system very cumbersome to use
9. I felt very confident using the system
10. I needed to learn a lot of things before I could get going with this system

Note: item responses are marked on a Likert scale anchored by 1 = "strongly disagree", 3 = "neutral" and 5 = "strongly agree".

2.4. System usability scale

Usability was operationalized as the overall System Usability Scale score as described by Brooke [11]. The System Usability Scale, developed by John Brooke [11] is a validated 5-point Likert scale instrument anchored on either end by "1 = strongly disagree" and "5 = strongly agree" for each of ten items that measured the usability concepts. Raw scores are transformed resulting in scores between 0 and 100 with a global average of 68 ± 12.5; it has high reliability (Cronbach's alpha 0.85–0.90) [21]. Items from the System Usability Scale are shown in Table 2.

Table 3
Description of patient sample.

n	39
Age mean (SD)	68 (12)
Gender n (%)	
Male	28 (72%)
Female	11 (28%)
Race/ethnicity n (%)	
African American	24 (62%)
Caucasian	15 (38%)
Other	0 (0%)
NYHA functional class n (%)	
I	10 (26%)
II	22 (56%)
III	7 (18%)

2.5. Statistical methods

We assessed significance of device use by comparing O/E ratio to the hypothetical mean of 1.0 using Student's *t*-test. Further, we assessed significance of overall System Usability Scale [11] by applying Student's *t*-test against a hypothetical mean score of 68, based on the literature [22]. Inter-rater agreement of raw system usability scores was assessed by calculating the Intraclass Correlation Coefficient (ICC) with 95% confidence intervals [23]. Statistical tests were calculated using R version 3.1.3 (Comprehensive R Archive Network, http://cran.r-project.org) with the significance probability threshold set at $p < 0.05$.

3. Results

Patients were recruited from December 2014 to May 2015; we screened 58 patients, 16 of whom declined participation. The reasons patients gave for not participating were that they were not interested, it was too much work, and that they were in a hurry to leave the clinic. Ultimately, 42 patients enrolled, one patient died, one withdrew, and one person did not return the equipment; the competed sample consisted of 39 patients. The demographics of the patients are presented in Table 3.

The device use is shown in Table 4. Patients reported no device failures during the study. The least used device was the body weight scale, 5 days (4, 5). Furthermore, these results reflect only 24 patients; 15 patients did not use the scale and were not included in the mean days used result. The mean use of the blood pressure device, iPad-based subjective state application, and oximeter were approximately the same, 6 days (5, 6), 6 days (5, 6), and 6 days (5, 6), respectively, although their range of days did differ. The actigraph was used the most days; mean 6 days (6, 6).

The ratio of observed use to expected use (O/E) is significantly less than expected for the scale, O/E 0.8, $P < 0.001$. The observed use did not differ significantly from the expected use for the blood pressure device, iPad-based subjective state application, and oximeter, O/E 1.0, 1.1, and 0.9, respectively. The actigraph was used twice as much as expected, O/E 1.9, $P < 0.001$.

After the devices were returned, each participant was given the System Usability Scale (SUS) for each device (Table 5). The SUS measured the participant's perception of the usability of the device. We were also interested in how correlated the participant's scores were for each device. The SUS grand mean score was 86.9 (CI = 84.8, 90.0) and the ICC grand mean score was 0.73 (CI = 0.56, 0.90). For each device, the SUS mean score and the ICC score was: scale, 84.5 (77.3, 91.6), 0.66 (0.46, 0.87), respectively; blood pressure device, 89.7 (85.8, 93.6), 0.79 (0.64, 0.93), respectively; iPad-based subjective state application 85.7 (80.8, 90.6), 0.70 (0.51, 0.89), respectively; pulse oximeter 87.6 (83.5, 91.7), 0.61 (0.61, 0.92), respectively; and actigraph 85.2 (79.8, 90.7), 0.68 (0.50, 0.88), respectively. All the SUS and ICC scores were significantly different from what would be expected by chance, $p < 0.0001$.

We were also interested in whether the severity of illness affected the patient usability scores. Table 6 shows the O/E ratios and SUS scores by device, and further divided by NYHA class. There were no significant differences in the O/E use by device and NYHA class. There was a consistently significant SUS difference across all devices between NYHA class II and III patients. The class III patients found the devices significantly easier to use than the class II patients, $p < 0.05$. The grand mean SUS scores, by NYHA classification I, II, and III, were 87.6 (82.7, 92.6), 83.1 (79.3, 86.8), and 95.1 (92.7, 97.4) respectively. This class II vs. class III difference in SUS was also significant when comparing across all devices, $p < 0.001$.

4. Discussion

Overall, we found that, other than the scale, patients were able to use mobile electronic devices to measure, store, and transmit nocturnal physiologic and subjective state information and they found them highly usable. Patient-facing information reflecting the patient's status at home can be important for clinicians' understanding of patients' wellbeing at home [24]. A number of paper-based instruments have been developed to collect subjective patient-generated data, but they vary in terms of which symptoms they assess, number of assessment items, and time range over which patients report; they are not very accurate [2].

Patients with heart failure who used body weight and symptom diaries experienced better clinical outcomes after six months compared to matched controls [25]. However, in this study, 15 patients did not use the study-provided body weight scale. This may be due in part to patients using their own scale rather than the study scale to measure body weight. There were no significant differences in age, gender balance, race/ethnicity composition, or NYHA functional class distribution between those patients who used the body weight scale and those who did not. Among those who used the scale, it had the lowest mean days used, the lowest O/E ratio, the lowest SUS score, and the correlation of its SUS scores was the second lowest in the study. There are a number of factors that may have affected the scale's low use and usability. The scale required user setup with each use and this may have made it inconvenient. Because the operation of the scale required users to bend down to activate the device, the scale may also have been affected by some patient's physical limitations, e.g., obesity, limited flexibility, or impaired balance. Furthermore, some patients expressed concern about falling when engaging in this activity, and so declined to use the scales provided. Another explanation may be patients with heart failure many times do not fully appreciate the risks associated with weight gain, and so adhere poorly to weight monitoring recommendations [26].

The blood pressure device was used as expected given that it had the highest usability user agreement. When examining difference between NYHA classes in terms of use and usability scores. There was no significant difference for use, but there was a significant difference in usability score between NYHA class II and class III patients, with class III patients rating devices higher. Anecdotally, most patients were experienced in manual home blood pressure monitoring. This familiarity may be the reason for the high usability score and usability agreement.

The pulse oximeter used was less than expected, but not significantly less so. It had the fourth highest usability, and ranked lowest in terms of consistency of agreement. When comparing NYHA class patients, there was no significant difference for use ratio between classes, but there was a significant difference in system usability score between class II and III, with the highest scores provided by class III patients. Most patients indicated familiarity with the pulse

Table 4
Patient device use.

Episodic data collection	Days used mean (95% CI)	Range	Average measurements taken			
			Observed	Expected	O/E[a]	p-value
Body weight scale[b]	5 (4, 5)	2–6	5	6	0.8	<0.001
Blood pressure device	6 (5, 6)	1–6	12	12	1.0	0.77
iPad-based subj states	6 (5, 6)	0–6	14	12	1.1	0.16
Continuous data collection	**Days used mean (95% CI)**	**Range**	**Time used (h)**			
			Observed	Expected	O/E[a]	p-value
Pulse oximeter	6 (5, 6)	3–6	44	48	0.9	0.05
Actigraph[c]	6 (6, 6)	2–6	93	48	1.9	<0.001

[a] The ratio of observed over expected (O/E) device use where 1.0 is observed equals expected.
[b] The results are based on the 24 patients who used the body weight scale.
[c] Three patients used a Zephyr device for activity; they are not included in these results.

Table 5
Overall usability score mean and 95% confidence interval (CI), and intraclass correlation coefficient and 95% confidence interval.

Device	Mean (95% CI)	ICC (95% CI)
Body weight scale	84.5 (77.3, 91.6)	0.66 (0.46, 0.87)
Blood pressure device	89.7 (85.8, 93.6)	0.79 (0.64, 0.93)
iPad-based subjective states	85.7 (80.8, 90.6)	0.70 (0.51, 0.89)
Pulse oximeter	87.6 (83.5, 91.7)	0.61 (0.61, 0.92)
Actigraph	85.2 (79.8, 90.7)	0.68 (0.50, 0.88)
Grand Mean	86.9 (84.8, 90.0)	0.73 (0.56, 0.90)

oximeter from their clinic visits. Many patients expressed curiosity about, and interest in, continuous recording of blood oxygen saturation. Nearly a quarter of patients had been diagnosed with sleep apnea. Additionally, since shortness of breath is a common heart failure symptom [20], patients may place a higher value on collecting this data due to symptom familiarity.

The actigraph was the most used device; it ranked fourth in its overall usability, but third in usability across patients. Observed use did not differ significantly between patients with different NYHA classifications, except for class II and class III patients where there was a significant difference between usability scores. The high use score is attributable to patients simply putting on the wristband and not being required to do anything else. Patients often said that they did not understand the purpose of the actigraph, but they were nonetheless willing to wear it.

The iPad-based subjective state assessment application delivered and recorded subjective state assessment, and was used more than expected. It ranked third in usability and second in consistency of agreement of usability. There was no significant relationship between patient NYHA classification and use; however, there was a significant difference in usability between class II and class III patients. The results suggest that patients are willing to use the device to report symptoms that are present at bedtime, that occur during the night, and that are present upon awakening.

One of the goals of this study was to determine if patients could use these devices at night so that we could collect nocturnal information. Although much is known about daytime heart failure, there is little objective information about nocturnal heart failure. We found that patients were able to use these devices at night and were able to collect high quality nocturnal heart failure information.

A study limitation is that this was a sample of convenience, which may affect generalizability of the results. During the course of this study, little changed in the heart failure clinic from which patients were recruited and there were no patient interventions that might have affected the results of this study. Over two-thirds of the clinic patients contacted agreed to participate and, apart from three patients, all completed the study. The reasons patients gave for not participating were that they were not interested, it was too much work, and that they were in a hurry to leave the clinic. On the other hand, although many studies of patient-facing devices used in patient's homes have high dropout rates (50%) we had a minimal dropout rate [27]. In other words, similar to other studies like this one, most patients agreed to use the devices and they used them the entire time of the study. Other limitations include that we did not collect data regarding patients' experience or comfort with technological devices, we did not collect patients' prior knowledge related to mobile devices, and we did not assess the subjective patient

Table 6
Comparison of mean use observed-expected ratio (O/E) and overall system usability scores (SUS) across devices by New York Heart Association functional classifications (NYHA).

Device	NYHA class	N	O/E mean (95% CI)	SUS mean (95% CI)
Body weight scale	I	6	0.8 (0.6, 1.0)	81.3 (66.0, 96.5)*
Body weight scale	II	12	0.8 (0.7, 1.0)	80.6 (69.8, 91.4)**
Body weight scale	III	5	0.8 (0.7, 0.9)	97.0 (90.3, 100.0)
Blood Pressure	I	10	1.0 (0.8, 1.3)	91.5 (82.3, 100.0)
Blood Pressure	II	20	0.9 (0.8, 1.1)	87.1 (81.9, 92.2)**
Blood Pressure	III	7	1.4 (0.3, 2.4)	96.1 (91.1, 100.0)
Subj states app	I	10	1.1 (0.9, 1.2)	86.8 (77.8, 95.7)
Subj states app	II	20	1.2 (1.0, 1.4)	82.8 (75.8, 89.9)**
Subj states app	III	7	0.9 (0.5, 1.2)	93.6 (85.6, 100.0)
Pulse Ox	I	10	1.0 (0.7, 1.2)	88.3 (80.5, 96.0)
Pulse Ox	II	20	0.9 (0.7, 1.0)	85.0 (79.2, 90.8)**
Pulse Ox	III	7	0.9 (0.7, 1.1)	96.1 (90.9, 100.0)
Actigraph	I	10	2.1 (1.5, 2.7)	90.3 (81.6, 98.9)
Actigraph	II	18	1.7 (1.3, 2.1)	79.8 (71.8, 87.7)**
Actigraph	III	6	2.3 (1.5, 3.2)	92.5 (85.1, 99.9)

* I vs III, $p < 0.05$.
** II vs. III, $p < 0.05$.

responses since the study was only designed to assess patients' ability to use the iPads. Finally, we also recognize the small sample size renders the sub-analysis of NYHA classification exploratory rather than definitive.

In conclusion, we found that patients with heart failure in this particular study were able to use mobile electronic devices in their homes at night to collect clinical data relevant to the management of their disease. To our knowledge, no study has assessed the in-home, nocturnal use and usability of electronic objective and subjective data collection devices with patients who have heart failure.

Conflict of interest

The authors do not have any conflicts of interest.

Disclaimer

The opinions or assertions contained herein are solely those of the author/speaker and are not reflecting the opinions or positions of the Department of Defense or the Uniformed Services University of the Health Sciences. All devices met Protected Health Information (PHI) and Personal Identifiably Information (PII) requirements. WRNMMC IRB Protocol number 400924-4.

Contributorship

All the authors provided substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; they assisted in drafting the article or revising it critically for important intellectual content; and they provided final approval of the version to be published.

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Prior presentations

None.

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