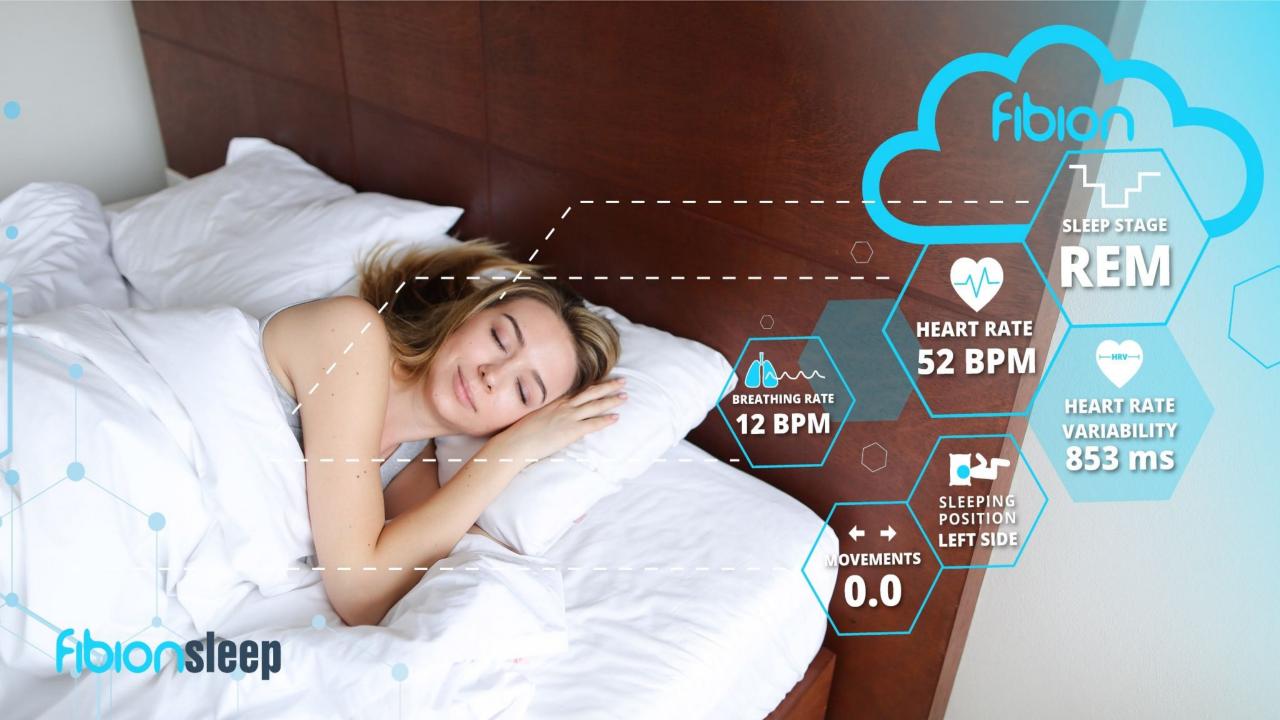
Fibion Emfit Validity and Reliability







Overview

- 1. Emfit is a contact-free, under-mattress device that utilizes ballistocardiography (BCG) to monitor sleep, heart rate variability (HRV), breathing, and movements.
- 2. Provides non-invasive and unobtrusive long-term monitoring, making it suitable for both research and clinical applications.





Key Studies Supporting Validity & Reliability (Piantino et al., 2021)

- This study proved the validity of Emfit by showing excellent agreement (ICC = 0.99) with validated actigraphy for key sleep parameters over 14 days.
- It also demonstrated reliability, with consistent results, high accuracy (88%), and better user compliance due to its non-invasive, contact-free design.

> Nat Sci Sleep. 2021 Jul 16:13:1157-1166. doi: 10.2147/NSS.S306317. eCollection 2021.

Emfit Bed Sensor Activity Shows Strong Agreement with Wrist Actigraphy for the Assessment of Sleep in the Home Setting

Juan Piantino ¹, Madison Luther ¹, Christina Reyno

Affiliations + expand

PMID: 34295199 PMCID: PMC8291858 DOI: 10.2

Abstract

assessment of rest-activity, is limited by poor comp time spent physically in the bed. A non-invasive bed actigraphy for long-term sleep assessment in the ho measurements between this sensor and a validated

Patients and methods: Thirty healthy subjects (6 to 54 years) underwent simultaneous monitoring with both devices for 14 days and filled out a daily sleep diary. Parameters included bed entry time, sleep start, sleep end, bed exit time, rest interval duration, and wake after sleep onset (WASO). The agreement between the two devices was measured using Bland-Altman plots and inter-class correlation coefficients (ICC). In addition, sensitivity, specificity, and accuracy were obtained from epoch-by-epoch comparisons of Emfit and actigraphy.

Results: Fifteen percent of the subjects reported that wearing the actigraph was a burden. None reported that using the bed sensor was a burden. The minimal detectable change between Emfit and actigraphy was 11 minutes for bed entry time, 14 minutes for sleep start, 14 minutes for sleep end, 10 minutes for bed exit time, 20 minutes for rest interval duration, and 110 minutes for WASO. Inter-class Purpose: Wrist-worn actigraphy via research-grade correlation coefficients revealed an excellent agreement for all sleep parameters (ICC=0.99, 95% CI 98-99) except for WASO (ICC=0.46, 95% CI 0.33-0.56). Sensitivity, specificity, and accuracy were 0.62, 0.93, and 0.88, respectively. Kappa correlation analysis revealed a moderate correlation between the two devices (κ =0.55, p<0.0001).

> Conclusion: Emfit is an acceptable alternative to actigraphy for the estimation of bed entry time, sleep start, sleep end, bed exit time, and rest interval duration. However, WASO estimates are poorly correlated between the two devices. Emfit may offer methodological advantages in situations where actigraphy is challenging to implement.



Source: https://pubmed.ncbi.nlm.nih.gov/34295199/

Key Studies Supporting Validity & Reliability (Zink et al., 2017)

- 1. The study demonstrated that Emfit's ballistocardiographic sensor showed a high correlation (r = 0.95) with standard ECG for beat-to-beat heart rate detection after artifact filtering.
- 2. Analysis of over **362,000 heartbeats across 93 hours**confirmed Emfit's validity and reliability for accurate, unobtrusive heart rate monitoring in patients with sleep-disordered breathing.

► Sci Rep. 2017 Oct 13;7:13175. doi: 10.1038/s41598-017-13138-0

Unobtrusive Nocturnal Heartbeat Monitoring by a Ballistocardiographic Sensor in Patients with Sleep Disordered Breathing

Matthias Daniel Zink ^{1,⊠}, Christoph Brüser ², Björn-Ole Stüben ¹, Andreas Napp ¹, Robert Stöhr ¹, Steffen Leonhardt ², Nikolaus Marx ¹, Karl Mischke ¹, Jörg B Schulz ^{3,4}, Johannes Schiefer ³

► Author information ► Article notes ► Copyright and License information PMCID: PMC5640641 PMID: 29030566

Abstract

Sleep disordered breathing (SDB) is known for fluctuating h of developing arrhythmias. The current reference for heartbelectrocardiogram (ECG). As an unobtrusive alternative, we mechanical vibrations to perform a ballistocardiography (BC algorithm for beat-to-beat cycle length detection. The aim of correlation between beat-to-beat cycle length detection by the simultaneously recorded ECG. In 21 patients suspected for S polysomnography, we compared ECG to simultaneously recorded algorithm. We analysed 362.040 heartbeats during a total of baseline heat-to-beat cycle length correlation between BCG.

Sleep disordered breathing (SDB) is known for fluctuating heart rates and an increased risk of developing arrhythmias. The current reference for heartbeat analysis is an electrocardiogram (ECG). As an unobtrusive alternative, we tested a sensor foil for mechanical vibrations to perform a ballistocardiography (BCG) and applied a novel algorithm for beat-to-beat cycle length detection. The aim of this study was to assess the correlation between beat-to-beat cycle length detection by the BCG algorithm and simultaneously recorded ECG. In 21 patients suspected for SDB undergoing polysomnography, we compared ECG to simultaneously recorded BCG data analysed by our algorithm. We analysed 362.040 heartbeats during a total of 93 hours of recording. The baseline beat-to-beat cycle length correlation between BCG and ECG was r_s = 0.77 (n = 362040) with a mean absolute difference of 15 ± 162 ms (mean cycle length: ECG 923 \pm 220 ms; BCG 908 ± 203 ms). After filtering artefacts and improving signal quality by our algorithm, the correlation increased to $r_c = 0.95$ (n = 235367) with a mean absolute difference in cycle length of 4 ± 72 ms (ECG 920 \pm 196 ms; BCG 916 \pm 194 ms). We conclude that our algorithm, coupled with a BCG sensor foil provides good correlation of beat-to-beat cycle length detection with simultaneously recorded ECG.



Source: https://pmc.ncbi.nlm.nih.gov/articles/PMC5640641/

Key Studies Supporting Validity & Reliability (Antink et al., 2020)

- 1. The study demonstrated that Emfit QS bed sensor accurately estimated beat-to-beat heart rate intervals (BBI) at night in post-surgical patients, with an average estimation error of 11.0 ms, closely matching ECG references.
- Despite lower temporal coverage in patients, the results confirmed validity and reliability of BCG-based monitoring for clinical heart rate assessment.

> IEEE J Biomed Health Inform. 2020 Aug;24(8):2230-2237. doi: 10.1109/JBHI.2020.2970298. Epub 2020 Jan 29.

Ballistocardiography Can Estimate Beat-to-Beat Heart Rate Accurately at Night in Patients After Vascular Intervention

Christoph Hoog Antink, Yen Mai, Roosa Aalto, Christoph Bruser, Steffen Leonhardt, Niku Oksala, Antti Vehkaoja

PMID: 32011272 DOI: 10.1109/JBHI.2020.2970298

Abstract

While bed-integrated ballistocardiography (BCG) has potential clinical applications such as unobtrusive monitoring of patients staying in the general bosnital ward, it has so far mainly gained

interest in the wellness domain. In this article, the potent after surgical intervention was assessed. Long-term BCG patients were performed with an EMFit QS bed sensor. In during sleep (mean duration 7.8 h). Using an iterative all cultra-short-term heart-rate-variability (HRV) parameters and root mean square of successive differences (RMSSD) reference in terms of average estimation error and templestimation error was found to be higher when full-day pudifference between healthy subjects (12.7 ms) and patier Nevertheless, temporal coverage of BBI estimation was \$ 51.7% at night) compared to the healthy sleepers (73.2% coverage (9.7% vs. 37.2%) at comparable estimation errors

PubMed Disclaimer

While bed-integrated ballistocardiography (BCG) has potential clinical applications such as unobtrusive monitoring of patients staying in the general hospital ward, it has so far mainly gained interest in the wellness domain. In this article, the potential of BCG to monitor hospitalized patients after surgical intervention was assessed. Long-term BCG recordings (mean duration 17.7 h) of 14 patients were performed with an EMFit QS bed sensor. In addition, ten healthy subjects were recorded during sleep (mean duration 7.8 h). Using an iterative algorithm, beat-to-beat intervals (BBIs) and the ultra-short-term heart-rate-variability (HRV) parameters standard deviation of NN intervals (SDNN) and root mean square of successive differences (RMSSD) were estimated and compared to an ECG reference in terms of average estimation error and temporal coverage. While the absolute BBI estimation error was found to be higher when full-day patient data was used (16.5 ms), no significant difference between healthy subjects (12.7 ms) and patient nighttime data (11.0 ms) was observed. Nevertheless, temporal coverage of BBI estimation was significantly lower in patients (39.3% overall, 51.7% at night) compared to the healthy sleepers (73.2%). This resulted in reduced HRV estimation coverage (9.7% vs. 37.2%) at comparable estimation error levels.



Source: https://pubmed.ncbi.nlm.nih.gov/32011272/

Key Studies Supporting Validity & Reliability (Kortelainen et al., 2010)

- 1. The study validated
 Emfit's ability to classify
 sleep stages by
 comparing it to
 polysomnography,
 achieving 79%
 accuracy and a kappa
 index up to 0.44.
- 2. Results confirm Emfit's validity and reliability as a low-cost, consistent method for sleep staging based on heart-beat intervals and movement detection.

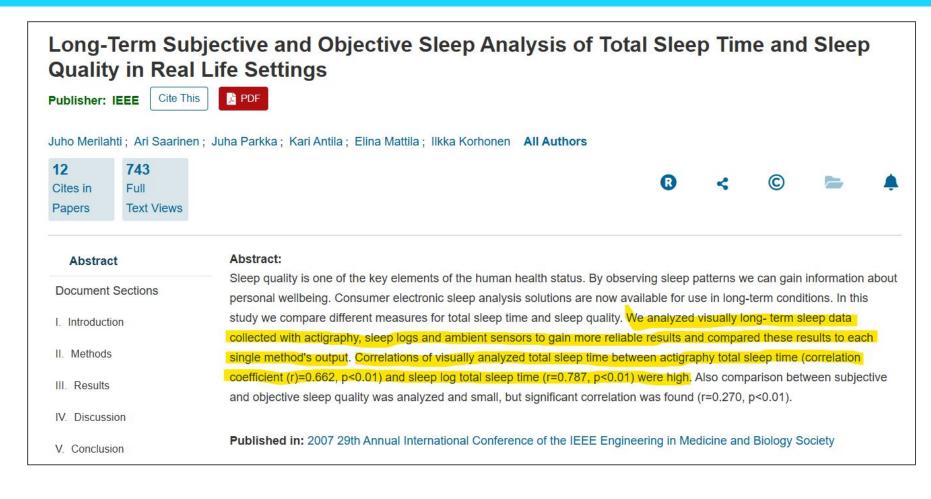




Source: https://ieeexplore.ieee.org/document/5447696

Key Studies Supporting Validity & Reliability (Merilahti et al., 2007)

- 1. This study showed that Emfit's total sleep time measurements correlated strongly with actigraphy (r = 0.662) and sleep logs (r = 0.787), confirming its validity in long-term real-world monitoring.
- Consistent long-term data collection highlighted the reliability of Emfit for sleep quality and duration assessment.

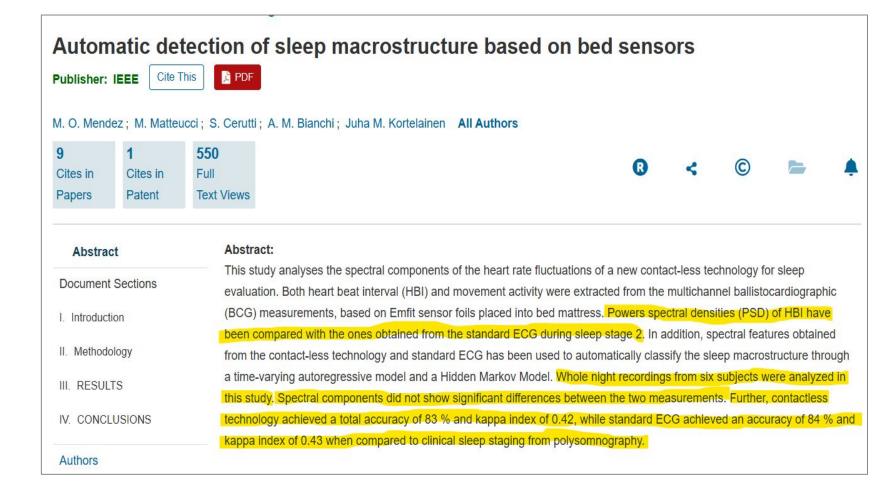




Source: https://ieeexplore.ieee.org/document/4353514

Key Studies Supporting Validity & Reliability (Mendez et al., 2009)

- 1. The study showed that Emfit's heart rate spectral components closely matched ECG results, with no significant differences, achieving 83% accuracy and a kappa index of 0.42 for sleep staging.
- 2. Whole-night recordings confirmed the validity and reliability of Emfit as a contactless tool for sleep evaluation.





Source: https://ieeexplore.ieee.org/document/5333734

Key Highlights

1. High Agreement with Gold Standards

Studies show Emfit matches closely with validated tools. For example, Piantino et al. (2021) reported an inter-class correlation coefficient (ICC) of 0.99 for key sleep parameters when compared to actigraphy, and Zink et al. (2017) found a strong correlation of $\mathbf{r} = 0.95$ between Emfit and ECG for heart rate monitoring.

2. Robust Accuracy Across Studies

Emfit has demonstrated **up to 83% accuracy** in sleep staging (Mendez et al., 2009; Kortelainen et al., 2010) and precise beat-to-beat heart rate estimation with an error margin as low as **11 ms** (Antink et al., 2020), confirming the device's validity in both healthy individuals and patient populations.

3. Reliable in Real-World & Clinical Settings

Merilahti et al. (2007) showed strong correlations between Emfit's long-term sleep data and actigraphy/sleep logs ($\mathbf{r} = \mathbf{0.662}$ and $\mathbf{r} = \mathbf{0.787}$), supporting its reliability. Consistent performance across diverse environments and long recording durations underlines Emfit's capability for **continuous**, **unobtrusive monitoring**.





Fibion Krono - New Product

Actigraphy with Advanced Light and Temperature Tracking

Circadian Rhythm & Sleep Research

Several key characteristics of the device:

- 1. 20 days of measurement on a single charge
- 2. Event marking button
- 3. Double light sensor: visible light and filtered blue light
- 4. Temperature sensor
- Watertight magnetic Micro-USB charging
- Accelerometer

A couple of research articles:

- Arguelles-Prieto, R. et al. (2019) 'Determining light intensity, timing and type of visible and circadian light from an ambulatory circadian monitoring device', Frontiers in Physiology, 10. doi:10.3389/fphys.2019.00822.
- 2. Madrid-Navarro, C.J. et al. (2019) 'Validation of a device for the ambulatory monitoring of sleep patterns: A pilot study on Parkinson's disease', Frontiers in Neurology, 10. doi:10.3389/fneur.2019.00356.

https://web.fibion.com/krono/







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