DATA ACQUISTION OF BEAT-TO-BEAT VARIATION OF THE HEART RATE:

AN ECG MONITOR COMPARED TO BODYGUARD®1

by

Preston M. Criddle
Lieutenant Commander, Dental Corps
United States Navy

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CERTIFICATE OF APPROVAL

MASTER'S THESIS

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Preston M. Criddle

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Research Committee:

John Schmidt, PhD, MS
Chair, Behavioral Medicine

Sean Meehan, ~~DDS~~ DMD
CAPT, DC, USN
Dean, Naval Postgraduate Dental School

Ling Ye, DDS
LCDR, DC, USN
Chair, NPDS Research, Thesis Supervisor

Istvan Hargitai, DDS, MS
CAPT, DC, USN
Chair, Orofacial Pain Center

Nicholas Mazzeo, DDS, MS
CAPT, DC, USN
Professor, Orofacial Pain Residency Program

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RESIDENT SIGNATURE

Preston Criddle
Orofacial Pain Graduate Program
Naval Postgraduate Dental School
23 June 2017

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PRESTON M. CRIDDLE

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"DATA ACQUISTION OF BEAT-TO-BEAT VARIATION OF THE HEART RATE: AN ECG MONITOR COMPARED TO BODYGUARD®1"

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Directed by: JOHN E. SCHMIDT, Associate Professor
Naval Postgraduate Dental School

Abstract:

*Introduction***:** Heart rate is primarily influenced by the parasympathetic and sympathetic branches of the autonomic nervous system (ANS). Heart rate variability (HRV) is the variation of beats over a period of time and reflects the modulation of cardiac activity. Low HRV is associated with chronic pain and distress, which are prevalent in the military population. The Bodyguard®1 is a portable inter-beat interval (IBI) recording monitor that can record up to 14 days of ANS functional data. However, this monitor has not been tested against a traditional three lead ECG on a population with suspected ANS dysfunction.

*Purpose***:** To compare the accuracy of the Bodyguard®1 to a standard three-lead ECG.

*Methods***:** Patients referred to the Walter Reed National Military Medical Center (WRNMMC) Neurology Department for testing of ANS function were invited to participate in this study. Participants performed a series of autonomic tests while heart activity was concurrently recorded by the Bodyguard®1 and a 3-lead ECG. Data from the Bodyguard®1 and ECG were analyzed utilizing the intraclass correlation coefficient (ICC) to describe the agreement of data between devices. HRV was calculated and the level of agreement was determined using Bland Altman plots.

*Results***:** Data from 34 participants were analyzed. The ICC was 0.971, consistent for all of the autonomic tests performed. The time-domain indices of HRV of root mean square of the successive differences (RMSSD) and the standard deviation of normal heart rate intervals (SDNN) were examined using Bland Altman analysis. The absolute value of all differences in these indices between the Bodyguard®1 and the three-lead ECG was a median of 0.33 ms (IQR: 0.14 to 1.38) for RMSSD and 0.12 ms (IQR: 0.07 to 0.31) for SDNN.

*Conclusion***:** The data from the Bodyguard®1 ECG monitor is highly comparable to that of a standard three-lead ECG monitor and maybe used to accurately record heart activity for HRV clinical and research applications.

Key Words:

Heart rate variability, HRV, Bodyguard®1, Bodyguard

Introduction:

The heart does not maintain a constant resting sinus rhythm, but rather is dynamic and variable even during resting conditions [1]. Interbeat variability can be influenced by various factors to include respiration, thermoregulation, circadian rhythms, exercise, and physical and mental stress [2]. Heart rate variability (HRV) is the variation of beats over a period of time and reflects the degree to which cardiac activity is modulated to meet changing situational demands. HRV provides information regarding an individual's autonomic adaptability [3-4].

Heart rate (HR) is primarily influenced by the ANS. Parasympathetic and sympathetic systems regulate the HR through the sinoatrial node via inhibitory and excitatory influence

respectively. Although both the parasympathetic and sympathetic branches constitutively influence cardiac activity, at rest there is a predominant parasympathetic influence on HR and sudden changes in HR from beat to beat are parasympathetically mediated [5]. Sympathetic activation in response to acute physical or psychological stress is mediated by brief increases in sympathetic activity, resulting in increased HR and decreased HRV, followed by a return to the resting state when the stress is relieved [6]. The terms 'low HRV' are used to describe when the inter-beat interval (IBI) is inconsistent in variability often as a result of sympathetic reactivity to environmental stimuli. Conversely, 'high HRV' is used to describe a much more consistent IBIl pattern typically seen at rest when parasympathetic activity is dominant [7].

Chronic pain conditions may be maintained by dysregulation of autonomic function. Low HRV has been associated with chronic pain conditions to include fibromyalgia, migraine, temporomandibular disorder (TMD) as well as affective states to include, anxiety, depression and PTSD [8-11]. Low HRV is associated with increased risk of all-cause mortality; this has been proposed as a marker for disease and is a modifiable risk factor for development of post deployment –PTSD in military populations [12-13]. The use of a portable HRV device may improve identification of at risk populations for developing chronic pain, affective disorders and the management of the chronic said conditions.

The Bodyguard®1 is a commercial IBI monitor capable of recording and storing R-R interval data for up to 14 days (Firstbeat Athlete, user manual version 2.1). This device is a small (35 x 35 x 15mm: weight: 24 grams) 2-lead monitor that may be worn by individuals in their natural environment with relative ease, recording IBI data. However, HRV data from commercially available devices, such as the Bodyguard®1, may not be comparable to a standard three-lead ECG. Potential differences in algorithms for editing IBI and analysis of HRV, need to

be validated [14]. No studies were found concerning Firstbeat Bodyguard®1 validation against a standard three-lead ECG or with a population with suspected autonomic dysfunction. This non-randomized study compares the validity and reliability of interbeat data recorded using a portable IBI monitor, Bodyguard®1, versus a traditional three-lead ECG monitor for patients referred for autonomic testing.

Methods:

Subjects – This study was approved by the Walter Reed National Military Medical Center (WRNMMC) Institutional Review Board and all study procedures were performed in accordance with the ethical standards established in the 1964 Declaration of Helsinki. Thirty five consecutive patients recruited for this study were military beneficiaries. ≥ 18 year old and who were referred to WRNMMC Neurology department for autonomic testing for possible ANS dysfunction. Participants were informed about this study and were invited to participate in the study. Exclusion criteria for this investigation were ≥18 years of age, pregnancy, allergy to electrode adhesive or unwillingness to shave excessive chest hair if unable to obtain adequate electrode adhesion to the skin.

Study procedures – On the day of the study assessment and after verbal consent, an ANS dysfunction-lab technician applied the standard three-lead ECG monitor (Model 3000, Ivy Biomedical System, USA) in the Einthoven's Triangle formation on the chest and the two lead Bodyguard®1 (Firstbeat Technologies Ltd. Jyväskylä, Finland) according to the manufacturer's instructions. All patients underwent autonomic testing, with the 2 devices simultaneously monitoring HR through a series of tests to include deep breathing, Valsalva maneuvers and tilt table test [15]. For the deep breathing test, the patient laid in a supine position and breathed at a

rate of 6 breaths per minute for 1 minute. At least two separate measurements were acquired with a rest period of at least 2 minutes between each test. During the Valsalva maneuver test, the patient was in a supine position. Forced expiration against resistance was maintained at 40mmHg for 12 seconds. If a "square-wave" ("flat-topped") response was observed, the patient was tilted at a 20 degree head-up position and this procedure was repeated. The Valsalva maneuver was performed at least 2 times per patient with at least a 2 minute rest period between tests. The tilt table test was performed by applying an orthostatic load to the patient by inclining the table head at a 70 degree angle for 10 minutes followed by 10 minutes in a supine position. Beat-to-beat blood pressure monitoring was maintained during the tilt portion of this test.

Data preparation and analysis – To calculate the HRV time domain indices, the Bodyguard®1 heart activity signal was transformed in IBI using the FirstBeat Athlete software version 2.1.0.8. The ECG signal was transformed into IBI using WR TestWorks software version 2.8.2 (WR Medical Electronics Co, Maplewood MN, USA). The de-identified participant IBI data were analyzed using IGOR Pro 6 software version 6.2.2.2 (WaveMetrics, Inc., Lake Oswego OR, USA). To ensure synchronization of the data, the Bodyguard®1 IBIs and three-lead ECG was matched, removing excessive data at the beginning or end of the Bodyguard®1 data set, as the device runs continually when attached. These matched data were imported into the Nevrokard Advanced HRV analysis software, version 10.1.10, for time domain analysis (Nevrokard Kiauta, k.d., Slovenia). For this study, the time-domain HRV values of Root Mean Square of the Successive Differences between NN intervals (RMSSD) and the Standard Deviation of NN intervals (SDNN) were reported.

Statistical analysis - For the primary outcomes of RMSSD and SDNN, the agreement between the 2 devices is described using the intraclass correlation coefficient (ICC) together with 95% confidence intervals (95% CI). The absolute value of the differences between the Bodyguard®1 and the three-lead ECG are presented as the median with the interquartile range (IQR). A variation of the standard Bland Altman plot is presented for RMSSD and SDNN, in which the difference between the 2 devices are plotted versus the three-lead ECG value rather than versus the average of the 2 devices [16]. In a standard Bland Altman plot, the average of the 2 devices is used on the x-axis. Since the three-lead ECG is reported as the current gold standard for measuring HRV, the three-lead ECG outcome is used on the x-axis. The mean of these differences together with 95% CI for the differences are presented in the Bland Altman plots. Differences in RMSSD and SDNN device outcomes were compared using the Wilcoxon Signed Rank Test. Data were analyzed using IBM SPSS Statistics for Windows software (Version 22.0 Armonk NY: IBM Corp.).

Results:

Data from 104 autonomic tests were collected and matched between the Bodyguard®1 and the three-lead ECG. A total of 4 autonomic tests were removed due to inability to match and synchronize data between the 2 devices. IBI detection accuracy was evaluated by the number of missed or extra beats in the matched comparison between the devices. Missed R-waves or spurious detections were identified visually in the graphic displays in the R-R interval series. The table below describes the amount of ectopic artifact recorded under each autonomic test, with the total amount of artifact recorded being 0.0058% of the total data. (Table 1)

TABLE 1

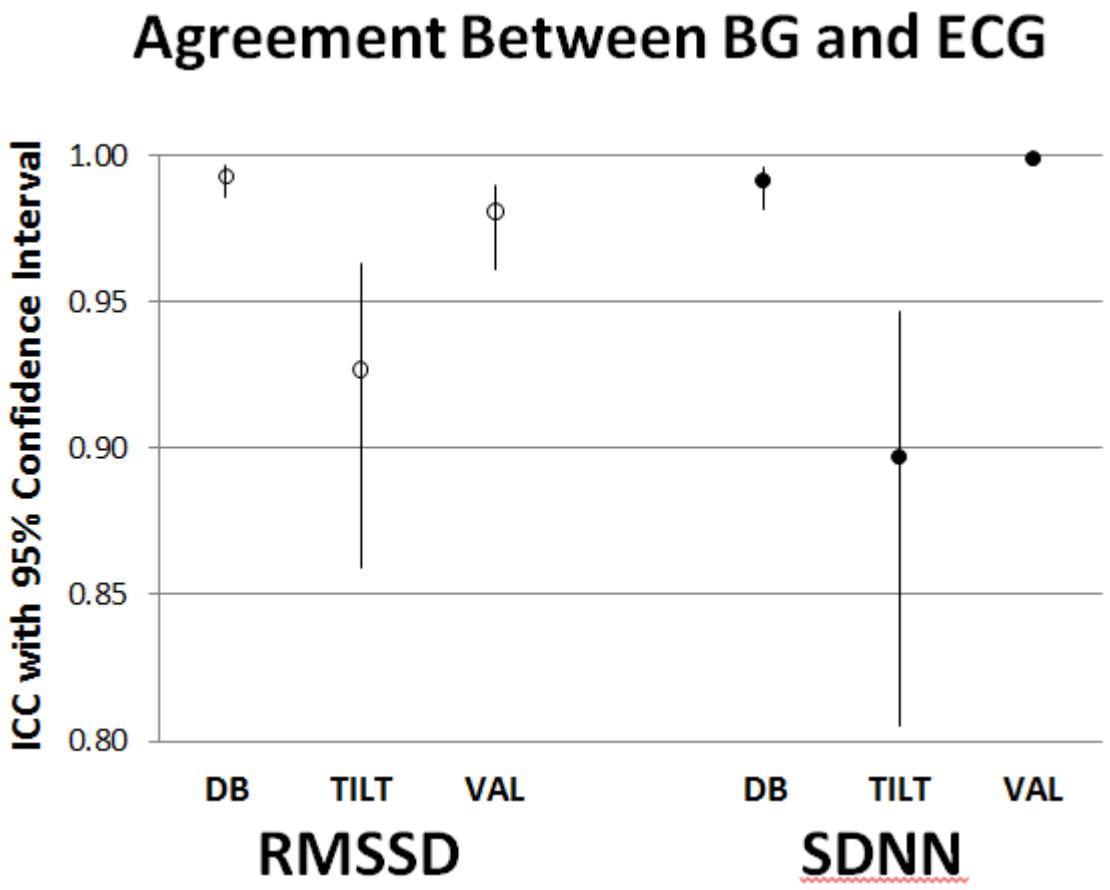
	Number of subjects with test results (n)	IBI recorded (n)	Extra beats (n)	Missing beats (n)	Total artifact (n, %)
Total all tests BG	99	102,793	305	292	597/102793 0.58%
Total all tests ECG	99	102,793	182	67	249/102793 0.24%
Total DB - BG	32	21,999	3	21	24/21999 0.11%
Total DB - ECG	32	21,999	23	19	42/21999 0.19%
Total VAL - BG	33	25,112	21	251	272/25112 1.08%
Total VAL - ECG	33	25,112	89	31	120/25112 0.48%
Total TILT – BG	34	55,682	281	20	301/55682 0.54%
Total TILT - ECG	34	55,682	70	17	87/55682 0.16%

Note * BG = Bodyguard 1, ECG = Electrocardiogram, DB = Deep Breathing, VAL = Valsalva maneuver, TILT = Tilt test

** 1 VAL, 1 TILT and 2 DB tests excluded due to inability to match data between BG and ECG

The level of agreement between the 2 devices on the time-domain HRV indices of SDNN and RMSSD was determined using ICCs. Figure 1 shows the high level of agreement between the Bodyguard®1 and the three-lead ECG with most of the ICCs near one and the lower bound of the 95% CI for the ICCs are all above 0.80 CI. According to the results of the intraclass correlation analysis regarding the agreement between Bodyguard®1 and the three-lead ECG, the HRs obtained from the Bodyguard®1 showed excellent overall clinical correlation with the reference values in all three testing conditions (ICC for RMSSD 0.971, 95% CI: 0.958-0.981; ICC for SDNN 0.963, 95% CI: 0.945-0.975).

(Fig 1)

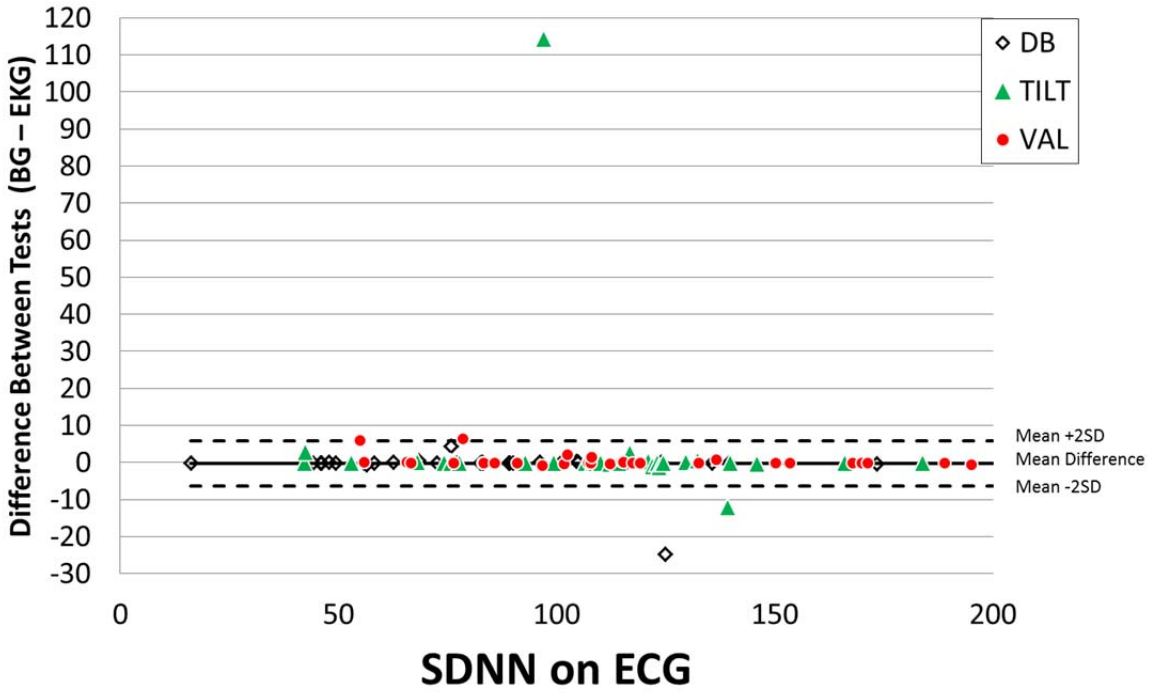


Note: RMSSD – root mean square of the successive differences in NN intervals. SDNN – standard deviation of NN intervals

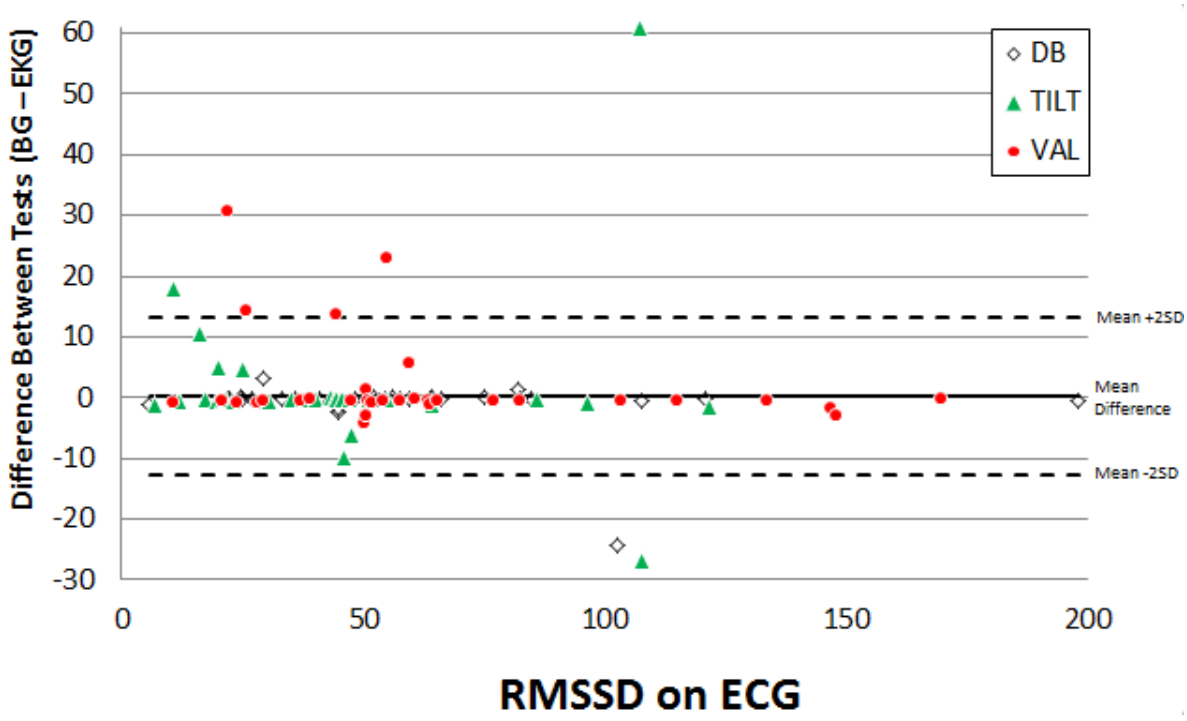
For all testing conditions, the absolute value of the difference between the Bodyguard®1 and the three-lead ECG for RMSSD had a median of 0.33ms (IQR 0.14 to 1.38) and for SDNN, the median was 0.12ms (IQR 0.07 to 0.31). Taking a closer look at device measurement bias, for the 96 tests producing RMSSD and SDNN values, the three-lead ECG value was higher than the Bodyguard®1 value 77 times while the Bodyguard®1 was higher 19 times. Overall for both RMSSD and SDNN, the three-lead ECG gave a significantly higher result ($p<0.001$). Bland

Altman plots (Figure 2A and 2B) describe the association of the error between devices with the participants' HRV as well as the agreement limits of the differences between the Bodyguard®1 and the three-lead ECG.

(Fig 2A)



(Fig 2B)



Modified Bland Altman plots the differences in SDNN (panel A) and RMSSD (panel B) between devices versus the three-lead ECG result. The mean difference and agreement limits are calculated excluding the tilt test value for one participant (green triangle at the top of the graph). This was determined to be an extreme outlier.

Discussion:

There is an emergence of portable, easy-to-use, commercially available devices for measuring IBI and assessing HRV. The utility of these devices is widespread with potential applications across the range of healthcare, physical fitness and mental health. However, validating these devices against a standard medical three-lead ECG monitor is not typically performed [17]. The purpose of this study was to validate the Bodyguard®1 against a standard

three-lead ECG monitor. We found the portable IBI recording monitor, Bodyguard®1, to be of excellent clinical significance for recording valid IBI data compared to a standard three-lead ECG monitor for patients referred for autonomic testing [18].

To assess the reliability of HRV measures calculated from the IBI data from the Bodyguard®1 compared to a standard three-lead ECG, the time domain HRV indices of SDNN and RMSSD were used. SDNN is the standard deviation of the normal IBIs measured in milliseconds and reflects the cyclic components responsible for HRV. RMSSD reflects the beat to beat variance in HR and is the primary time domain measure used to estimate vagally-mediated changes reflected in HRV. Temporal accuracy is crucial to successfully calculate the variance of a time series, such as with SDNN and RMSSD analyses. Even a single artifact can lead to errors of HRV estimates [17,19]. The Bodyguard®1 device percentage of error, determined by reviewing and identifying ectopic missed or extra beats, was extremely low at 0.0054% of the total IBIs recorded. Accuracy of HRV measurements is also determined by the sampling rate of the data acquisition system or device. The minimum suggested frequency for accurate HRV data is set at 200 Hz. More conservative guidelines suggest a sampling frequency from 500 to 1000 [20]. The Bodyguard®1 records data at a sampling frequency of 1024 Hz. There was a difference between the sampling rate frequency of the Bodyguard®1 and three-lead ECG used in this study, with the three-lead ECG sampling at 256Hz. The three-lead ECG derived HRV values were consistently higher than the Bodyguard®1 HRV values. While these differences were minimal (median difference 0.33ms), they may be due to a rounding bias associated with the lower sampling frequency of the standard three-lead ECG monitor.

The HRV time domain analyses had near identical correlation compared to the three-lead ECG with an ICC of 0.971. There was excellent agreement between the devices on the HRV

indices throughout all the autonomic challenges. The Bland Altman analyses suggest that the Bodyguard®1 can be used to accurately record IBI data and is both reliable and reproducible for collecting valid HRV analysis [21].

Low HRV has been reported in chronic pain patients with medical conditions such as fibromyalgia, migraine and TMD [8-10]. However, low HRV is also a strong indicator of poor long term outcome after adverse events in otherwise healthy individuals. In military populations presenting with low HRV prior to deployment, these personnel have a higher likelihood of developing PTSD symptoms after exposure to traumatic events [13,22]. Changes in HRV patterns may provide a sensitive and early indicator of health impairment; the presence of low HRV may indicate significant psychological distress requiring further investigation and management [23]. Monitoring ANS activity through HRV assessment in patients with chronic pain may provide further insight in this at risk population and potentially aid clinicians to improve treatment outcomes.

An overlooked factor when assessing HRV in both healthy and medically compromised patients is the individual's natural HRV 'set point'. While baseline resting HRV is associated with gender and age, an individual's set point can be strongly influenced by lifestyle (diet, exercise, substance use) and psychosocial processes (persistent stress, affective conditions) over time [24]. Limitations of this research study include the following: the subjects were relatively stationary and little movement was incorporated during IBI acquisition and the Bodyguard®1 and three-lead ECG were not time synchronized prior to data collection, making matching the IBI data difficult. Increased mobility may increase the percentage of artifact in IBI recording. It would be interesting to compare the Bodyguard®1 with a Holter monitor to validate Bodyguard®1 with natural daily movement. Previous studies have been performed with the

Bodyguard®2 device, a 1 lead monitor from FirstBeat; this device has been found to be comparable to the Holter monitor or chest belts in data acquisition [25-26].

Conclusion:

HRV assessment has become a standard technique for investigating ANS activity in the laboratory setting and within the natural environment. The goal of this study was to compare the accuracy of a small, easy to use IBI recording device (Bodyguard®1) to a standard three-lead ECG monitor. Results of this investigation suggest high level of accuracy in recording IBI under different laboratory conditions with HRV outcomes being nearly identical between the two tested devices. The use of a validated portable IBI recording device such as the Bodyguard®1 opens the door for numerous clinical and research applications in medical, mental health and basic physiological science areas.

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