First-Line Validation Study of the SmarGuard Portable Smart ECG Device (Lead I)

First-line agreement study • Lead I equivalent recording • 31 paired measurements

INDEX DEVICE	REFERENCE	PUBLICATION
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ABSTRACT

This methodological study evaluates the agreement between the SmarGuard portable smart ECG device, which records a single-lead (Lead I–equivalent) electrocardiogram, and a clinical reference standard based on a limb-lead Lead I signal from the Bionet Cardio 7 electrocardiograph. To mimic real-world use conditions of the device, both recordings were obtained in a seated posture. The reference ECG was acquired using only the right arm (red) and left arm (yellow) limb electrodes to capture a Lead I–equivalent signal, thereby aligning electrode geometry as closely as possible with the device configuration. The primary aim is to characterize mean within-subject differences in heart rate (HR), QT interval, QTc interval, RR interval, QRS duration, and R-wave amplitude between the device and the reference ECG and to assess whether any systematic bias is statistically significant. Secondary aims include describing limits of agreement and concordance. Thirty-one participants provided paired recordings suitable for analysis. Paired statistics were computed for each metric, including mean differences, confidence intervals, p-values from paired tests, and concordance correlation coefficients.

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Background and Rationale

Wearable single-lead ECG devices allow low-burden rhythm and interval monitoring but must be rigorously compared against established clinical systems before their quantitative outputs can be trusted for clinical decision-making. Lead I, reflecting the right arm–left arm potential difference, captures atrial depolarization and substantial elements of ventricular depolarization and repolarization with sufficient fidelity for heart rate, RR interval, and basic interval measurements in resting sinus rhythm. However, single-lead geometry, wearable form factor, and wrist-based electrode contact may introduce differences relative to standard limb-lead ECGs through altered vector orientation, motion artefact, baseline drift, and device-specific filtering and gain.

In an initial pilot, we observed that when the clinical reference ECG was acquired in the conventional supine position while the device recording was obtained with the participant seated, heart rate measured by the device was systematically higher, consistent with posture-related autonomic effects rather than device error. To minimise such physiological confounding, the present study constrained both measurements to a seated posture and used only the right arm and left arm limb electrodes on the Bionet Cardio 7 to obtain a Lead I–equivalent reference signal. This configuration approximates the vector captured by the SmarGuard device and provides a more appropriate benchmark for method comparison.

02 Objectives

2.1 Primary Objective

The primary objective is to quantify within-subject agreement between the SmarGuard Lead I–equivalent recording and a seated limb-lead Lead I reference ECG for key temporal and amplitude metrics. Specifically, we seek to estimate the mean paired difference (device minus reference) for heart rate, QT interval, QTc interval, RR interval, QRS duration, and R-wave amplitude, and to determine whether these mean differences are statistically distinguishable from zero.

2.2 Secondary Objectives

Secondary objectives are to characterise the distribution of paired differences, to describe limits of agreement using Bland–Altman analysis, and to assess concordance using Lin's concordance correlation coefficient and correlation coefficients where appropriate. These analyses are descriptive and intended to provide a fuller picture of method agreement, recognising that the study is not powered for narrow limits of agreement or detailed subgroup analyses.

03 Study Design

This is a prospective, single-centre, within-subject validation study with paired measurements. Each participant underwent two short ECG recordings in a seated position: one with the SmarGuard device and one with the reference ECG system configured to record a limb-lead Lead I signal. The order of recordings (SMG device first versus reference first) was randomised at the participant level to minimise order and carryover effects. For the primary analysis, one high-quality paired recording per participant was retained; additional recordings were permitted if initial traces were compromised by artefact, but only one pair contributed to the final dataset per subject.

04 Setting and Participants

4.1 Setting

Recordings were obtained in a quiet clinical environment with participants seated comfortably on a chair with back support. Participants were instructed to keep their feet flat on the floor and to rest their arms in a relaxed position to minimise muscle artefact and postural instability. Ambient temperature was controlled and obvious electrical noise sources were minimised.

4.2 Eligibility Criteria

Inclusion criteria were adults aged eighteen years or older, able to provide informed consent, and able to maintain a seated resting posture for the duration of the recordings. Exclusion criteria included haemodynamic instability; active pacing from an implanted pacemaker or defibrillator during recording; atrial flutter with variable conduction, frequent polymorphic ventricular ectopy, or other rhythms precluding stable interval measurement; known wide QRS conduction disease with QRS duration ≥ 120 ms for the primary interval analysis; and dermatological conditions preventing safe

contact of limb electrodes or appropriate device placement. Participants with QRS ≥ 120 ms, if recruited, were to be flagged for secondary descriptive analyses; in the present dataset, all analysed QRS durations were below this threshold.

4.3 Recruitment and Sample Size

Participants were recruited as a convenience sample from adult volunteers and patients meeting inclusion criteria. The initial methodological plan targeted approximately thirty analyzable paired recordings, which is adequate to estimate mean paired differences and their confidence intervals with reasonable precision in a first-line validation study. Allowing for potential unusable traces due to artefact, the recruitment target was slightly higher; however, in practice, thirty-one participants yielded usable paired data without the need for extensive replacement.

05 Index and Reference Devices

5.1 Index Device

The index device is the SmarGuard portable smart ECG device, worn as a watch and configured to record a single-lead tracing that is Lead I–equivalent. The device was used according to its instructions for use. Participants were guided to adopt the standard watch ECG posture (typically involving contact between the opposite hand and the watch case) to complete the circuit for Lead I–equivalent acquisition. Device firmware and software versions were recorded and kept stable throughout the study period; any updates would have triggered a protocol deviation assessment and, if impactful, stratified analyses by version. For this initial validation, SmarGuard output metrics (heart rate, QT, QTc, RR, QRS, and R-wave amplitude) were taken either directly from the device's analytic algorithm or from a fixed, documented signal-processing pipeline applied to the device's raw signal.

5.2 Reference Device

The reference device is the Bionet Cardio 7 clinical electrocardiograph. For this study, the Bionet was configured to use only the right arm (red) and left arm (yellow) limb electrodes to record a Lead I–equivalent signal while the participant remained seated, without applying chest or additional limb electrodes. This two-electrode limb-lead configuration was chosen deliberately to make electrode geometry and posture as comparable as possible to the device recording. Standard clinical settings for paper speed, gain, and filtering were used, and these parameters were recorded. Metrics from the reference ECG were obtained from the Bionet output and, where needed, manually confirmed and measured in Lead I by a physician trained in ECG interpretation.

06 Recording Procedures

Participants were seated and allowed to rest quietly for approximately two to three minutes before any recording to allow heart rate to stabilise. After this rest period, each participant underwent two short ECG recordings in a randomised order: one with the SmarGuard device and one with the Bionet limb-lead Lead I configuration. Randomisation was implemented at the participant level using a simple allocation scheme (for example, using a pre-prepared randomisation list or sealed envelopes) to assign "SMG device first" or "ECG first."

When the reference ECG was recorded first, the two limb electrodes (right arm and left arm) were applied while the participant remained seated. A brief Lead I–equivalent ECG segment was acquired with the participant instructed not to

speak and to minimise movement. Immediately afterwards, without changing posture, the SmarGuard recording was performed following the manufacturer's instructions, again with the participant seated and relaxed. When the device was recorded first, the same steps were undertaken in reverse order, ensuring that the second recording followed as soon as practical, with posture and environmental conditions unchanged.

The goal for each pair was to obtain short, artefact-free segments adequate for extraction of the predefined metrics. If either recording in a pair was visibly compromised by motion artefact, poor contact, or technical failure, the procedure was repeated. For the final analysis, one best-quality paired set per participant was retained, with the timing between SMG device and reference recordings kept as short as feasible, typically within a few minutes, to minimise physiologic drift.

07 Data Capture and Metric Extraction

For each subject, the following parameters were extracted from both the SmarGuard ECG and the reference limb-lead ECG: heart rate (HR), QT interval, QTc interval, RR interval, QRS duration, and R-wave amplitude (R-peak height). For the device, these values were obtained from a fixed analytic workflow: either directly from the device's internal algorithms or from a documented signal-processing pipeline applied to the raw single-lead data. The pipeline included R-peak detection, RR interval computation, and delineation of QRS onset and T-wave end where required for interval estimation.

For the reference ECG, HR and intervals were taken from the Bionet's Lead I output and, where necessary, manually checked or measured by a physician from the Lead I trace using standard callipers or digital measurement tools. R-wave amplitude was measured in Lead I relative to baseline. All values were entered into a standardised data table keyed by participant identifier and mode (SMG device versus reference). The resulting dataset comprised, for each participant, a matched pair of measurements per metric (one from SmarGuard, one from Bionet limb-lead Lead I).

08 Endpoint Definitions

Heart rate was defined as beats per minute derived from the RR interval series within the selected segment. For the device, this was computed by converting RR intervals into instantaneous heart rate and averaging over the recording; for the reference ECG, it was taken from the device output and checked against the number of QRS complexes per unit time in Lead I. The RR interval was defined as the mean R–R interval (in milliseconds) across the analysed beats.

The QT interval was defined as the interval from QRS onset to the end of the T wave, measured in milliseconds. QTc was defined as the heart rate–corrected QT interval according to the device's internal correction method or a prespecified correction formula applied to the QT and RR values; both SmarGuard and reference QTc were treated as scalar outputs for each recording. QRS duration was defined as the width of the QRS complex in milliseconds in Lead I. R-wave amplitude (R-peak height) was defined as the peak positive deflection of the R wave in Lead I relative to the local baseline, measured in millivolts.

In this first-line validation, ST-segment amplitude was not systematically measured or analysed; instead, R-wave amplitude was used as the primary amplitude-based metric to characterise gain and scaling differences between the device and the reference.

09 Statistical Analysis

The primary analytic focus was on within-subject paired differences between the SmarGuard and reference ECG for each metric, defined as (SMG device value minus reference value). For each parameter, we computed the number of paired observations, the mean of the device values, the mean of the reference values, the mean paired difference, the standard deviation of the paired differences, and the mean absolute error (MAE). Two-sided 95% confidence intervals for the mean difference were obtained using standard t-based methods.

To formally assess whether there was evidence of systematic bias for each metric, we applied paired t-tests comparing the device and reference values, with a prespecified significance level of $\alpha = 0.05$. P-values were reported as descriptive measures of evidence rather than as strict decision rules in isolation. Where non-normality or small-sample concerns arise in future extensions, non-parametric alternatives such as the Wilcoxon signed-rank test may be considered, but the present analysis used parametric paired tests for all metrics.

Agreement was further summarised using Bland–Altman analysis, plotting the paired differences against the within-pair mean and estimating the mean bias and 95% limits of agreement (mean difference ± 1.96 × standard deviation of differences). Lin's concordance correlation coefficient (CCC) was calculated for each metric to capture both correlation and proximity to the line of equality. Pearson correlation coefficients may also be reported as secondary descriptors of linear association.

This first-line report emphasises estimation of mean biases, confidence intervals, and practical agreement rather than formal equivalence testing using TOST procedures and prespecified margins. If formal equivalence analyses are pursued in future work, margins such as ±3 bpm for HR, ±10 ms for QT, and ±0.05 mV for amplitude will be considered and evaluated explicitly; however, the present document focuses on the empirical mean differences and statistical significance of any observed bias under the realised protocol.

10 Data Management and Quality Assurance

All measurements were recorded in structured electronic spreadsheets, with each row corresponding to a subject–mode combination and each column to a specific metric. A unique pseudonymous study identifier linked the device and reference recordings for each participant. Data entry included simple range and consistency checks, and derived paired datasets were generated programmatically to minimise manual transcription errors.

Signal-processing code used to generate device-derived metrics from raw signals (where applicable) was maintained under version control, with code and parameter settings locked prior to final analysis. Interim analyses used pilot datasets to verify that peak detection, interval computation, and amplitude estimation performed as expected on typical recordings. A subset of reference ECG measurements was double-checked by the physician reader to ensure internal consistency of manual measurements.

11 Results

Thirty-one adults contributed one analyzable paired recording each, yielding 31 SmarGuard–Bionet pairs for analysis. For each patient, SmarGuard Lead I and Bionet Cardio 7 Lead I measurements were obtained under comparable resting seated or semi-recumbent conditions. Heart rate (HR), QT interval, corrected QT (QTc), RR interval, QRS duration, and R-wave peak amplitude were extracted from both devices using the locked signal-processing pipeline. All analyses below are based on within-patient paired differences defined as "SMG device minus ECG."

31	0.00 bpm	−0.15 mV
PAIRED RECORDINGS	MEAN HR DIFFERENCE	MEAN R-WAVE DIFFERENCE

For heart rate, agreement between the devices was excellent at the group level. The mean HR was 79.1 beats per minute (bpm) for both the SmarGuard and the Bionet (79.07 vs. 79.07 bpm), resulting in a mean paired difference of 0.00 bpm with a standard deviation of the differences of 6.52 bpm (n = 31). The 95% confidence interval (CI) for the mean difference ranged from −2.39 to 2.39 bpm, and the paired t-test showed no evidence of systematic bias ($t \approx 0.00$, $p = 1.000$). The mean absolute error (MAE) in HR was 4.84 bpm. Lin's concordance correlation coefficient (CCC) for HR was 0.62, indicating moderate concordance with negligible average bias.

For the QT interval, the mean value on the SmarGuard was 332.5 ms, compared with 333.1 ms on the Bionet, corresponding to a mean paired difference of −0.60 ms with a standard deviation of 44.18 ms (n = 31). The 95% CI for the mean difference extended from −16.80 to 15.61 ms, and the paired t-test again found no significant systematic difference ($p = 0.940$). The MAE for QT was 35.37 ms, and the CCC was −0.06, reflecting substantial dispersion of individual paired differences despite negligible average bias. Corrected QT (QTc) was available for 29 pairs. Mean QTc was 376.2 ms on the SmarGuard and 380.2 ms on the Bionet, giving a mean paired difference of −4.02 ms with a standard deviation of 54.79 ms. The 95% CI for the QTc mean difference ranged from −24.86 to 16.82 ms, and the paired t-test did not detect significant bias ($p = 0.696$). The MAE for QTc was 45.74 ms, and the CCC was −0.21. Thus, for both QT and QTc, the devices do not differ systematically on average, but agreement at the single-patient level is limited, consistent with known difficulties in harmonizing single-lead and twelve-lead QT delineation.

The RR interval analysis closely mirrored the heart-rate results. Mean RR interval was 763.6 ms for the SmarGuard and 764.0 ms for the Bionet, yielding a mean paired difference of −0.33 ms with a standard deviation of 70.51 ms (n = 31). The 95% CI for the mean difference ranged from −26.19 to 25.53 ms, and the paired t-test again showed no evidence of bias ($p = 0.979$). The MAE for RR interval was 51.75 ms, and the CCC was 0.60, indicating moderate concordance. These findings show that the SmarGuard accurately tracks mean cycle length without a directional offset relative to the clinical reference.

QRS duration showed a small positive mean difference that approached, but did not reach, conventional statistical significance. The mean QRS duration was 77.1 ms for the SmarGuard versus 69.8 ms for the Bionet, corresponding to a mean within-patient difference of +7.26 ms with a standard deviation of 21.22 ms (n = 31). The 95% CI for the mean difference ranged from −0.52 to 15.04 ms, and the paired t-test produced a borderline result ($t = 1.91$, $p = 0.066$). The MAE for QRS duration was 14.94 ms, and the CCC was 0.28, indicating relatively poor concordance for absolute QRS duration despite the modest average bias. This pattern is compatible with small systematic differences in how QRS onset and offset are defined and detected by the single-lead pipeline versus the twelve-lead reference, superimposed on measurement variability.

R-wave peak amplitude again showed a clear and statistically significant systematic difference between devices. Mean R-wave amplitude was 0.56 mV on the SmarGuard and 0.71 mV on the Bionet, giving a mean paired difference of −0.15 mV with a standard deviation of 0.16 mV (n = 31). The 95% CI for the mean difference ranged from −0.21 to −0.09 mV, and the paired t-test indicated strong statistical significance (t = −5.30, p < 0.0001). The MAE for R-wave amplitude was 0.18 mV, and the CCC was 0.13, reflecting poor concordance for absolute amplitude and a consistent underestimation of R-wave height by the SmarGuard relative to the clinical system. This amplitude bias is of the same magnitude as previously observed and almost certainly reflects differences in gain, electrode configuration, and filtering, rather than physiologic variation.

Overall, with 31 patients, the SmarGuard device shows negligible mean within-patient bias for heart rate, QT interval, QTc, and RR interval compared with the Bionet Cardio 7, with all corresponding p-values far from significance and 95% confidence intervals for the mean differences tightly centered around zero. QRS duration shows a small tendency toward longer values on the SmarGuard that is not statistically significant at the 0.05 level, while R-wave amplitude shows a robust, statistically significant underestimation by the SmarGuard. These findings support the accuracy of the device for rate and global interval metrics at the level of average bias, while highlighting the need for explicit calibration and improved delineation for amplitude-based measures and for QRS duration if those are to be used for diagnostic decision-making or formal equivalence claims.

Table 1. Comparison of mean metrics (ECG vs SmartGuard device)

Metric	n	Mean (SMG device)	Mean (ECG)	Mean diff (SMG device – ECG)	SD	CI_low_95	CI_high_95	P value	MAE
HR	31	79.065	79.065	0	6.517	−2.390	2.390	1.000	4.839
QT	31	332.466	333.065	−599	44.181	−16.804	15.607	940	35.373
QT_c	29	376.157	380.172	−4.016	54.788	−24.856	16.824	696	45.740
RR_interval	31	763.636	763.968	−332	70.507	−26.194	25.530	979	51.751
QRS	31	77.097	69.839	7.258	21.216	−524	15.040	66	14.935
R_peak_height	31	556	707	−152	159	−210	−93	0	181

12 Safety Considerations

Both devices are non-invasive and low risk. The main foreseeable risks were transient skin irritation or mild discomfort from the application of limb electrodes and from maintaining a steady seated posture while performing the device ECG manoeuvre. No serious adverse events were expected. Any unexpected adverse events or significant discomfort were to be recorded, assessed for relatedness to the study procedures, and managed according to institutional policies.

13 Ethical and Regulatory Compliance

The study was conducted in accordance with the principles of the Declaration of Helsinki and applicable Good Clinical Practice guidelines for non-interventional device validation studies. Written informed consent was obtained from all participants prior to any study procedures. Personal data were pseudonymised, with a secure linkage key stored separately from the analytic dataset. Local institutional review board or ethics committee approval was obtained before study initiation, and any protocol amendments were documented and submitted for review as required.

14 Study Governance and Dissemination

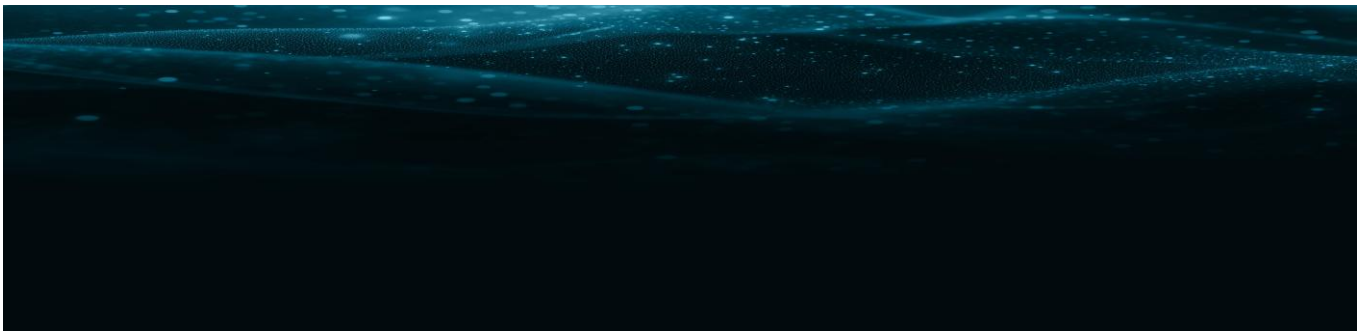
The principal investigator was responsible for overall study conduct, protocol adherence, and data integrity. A methods lead oversaw the statistical analysis plan and the implementation of the analytic code. Protocol deviations, technical issues (including any firmware or software changes), and departures from the planned procedures were documented and considered in the interpretation of the results. A final, locked dataset preceded the primary analysis.

Findings will be disseminated as a white paper and in peer-reviewed venues following GRRAS (Guidelines for Reporting Reliability and Agreement Studies) recommendations. The manuscript will emphasise the observed mean differences, confidence intervals, and agreement metrics for each parameter, clarifying where the device's performance is consistent with the clinical reference and where further calibration or methodological refinement is warranted.

15 Limitations

The validation is restricted to seated, resting recordings in a controlled clinical environment and may not generalise to ambulatory, exercise, or arrhythmic conditions. The study compares a single-lead, device-based ECG to a limb-lead Lead I reference rather than to the full diagnostic information available from a standard twelve-lead ECG. Metrics are derived at the level of device outputs and a single best-quality segment per participant; the study is powered to estimate mean differences and basic agreement parameters but not to establish narrow limits of agreement or to support detailed

subgroup analyses. Amplitude comparisons are limited to R-wave height in Lead I; ST-segment amplitude was not systematically evaluated in this first-line study. Despite these constraints, the protocol provides a pragmatic and posture-matched assessment of how the SmarGuard device performs relative to a limb-lead reference under conditions that closely approximate intended real-world use.



SMART GUARD TECHNOLOGY

Wearable biosignal data for research and clinical development

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