

PRESS RELEASE Study confirms: CardioSecur's 4-electrode ECG can be used in any body position

Even in emergency situations or a home monitoring setting, results are fast and reliable with this mobile 12-lead ECG for tablet or smartphone.

Frankfurt, November 2018. The study "**Effect of Body Position on a Mobile, Vector-Derived, 12-Lead Electrocardiogram**" by the Department of Cardiology and Cardiovascular Surgery, Semmelweis University, Budapest, Hungary, has shown that a 12-lead ECG with only 4 electrodes is not affected by interference due to different body positions. This means that, using this technology, recordings can be taken in a supine, sitting or standing position without significant changes to the ECG data.

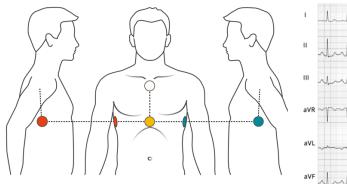
In order to achieve reliable results, standard 12-lead ECGs with 10 electrodes are usually recorded with the patient in the supine position. However, in everyday practice, this is not always possible: time and space constraints or a patient's specific disposition can mean that an ECG must be recorded in a different body position. This changes the position of the heart, which can result in divergent interpretations and thus potentially in incorrect treatment. In addition, standard technology with 10 electrodes is completely unsuitable for patients in home monitoring settings. CardioSecur, on the other hand, is a certified medical device and a validated mobile ECG system that measures 12 to 22 leads using just 4 electrodes. It is intended for a wide range of applications.

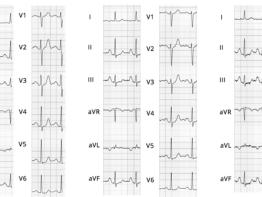
The current study examined whether body position had an effect on the ECG recordings of CardioSecur's mobile 12-lead ECG with 4 electrodes. For this purpose, the authors examined electrocardiograms recorded in supine, sitting and standing positions. They then carried out statistical evaluations of heart rate, PQ interval, QRS duration, QTc interval, P, QRS and T vectors and R and S amplitudes; and qualitative evaluations of Q waves, ST segments and T waves. The study found that there were no clinically significant changes, meaning that none of the recordings conducted in different body positions led to divergent diagnoses. This means that, unlike a standard ECG, this 12-lead ECG using 4 electrodes can be used in different body positions.

"We see this as an important advantage in favor of CardioSecur", says founder and managing director, Felix Brand. "Standard 12-lead ECGs are usually recorded in the supine position, and they also require the rather cumbersome process of correctly attaching 10 electrodes to the body. This is time-consuming and not something people without medical training can easily do." On top of this, standard ECG systems are hard to operate in mobile and emergency settings, where space is restricted. "This is where the CardioSecur ECG shines: this innovative device weighs only 50g and yet it provides fast and reliable support – no matter where the patient or user is, and regardless of the – possibly changing – body position." 12-lead ECG recordings using only 4 instead of 10 electrodes are easier and faster to perform and, above all, less susceptible to interference. The intuitive CardioSecur system even offers significant advantages for problematic patient anatomies or for private use in home monitoring settings.

For more information, visit www.cardiosecur.com







CardioSecur electrode placement locations. ©CardioSecur

Example of a 12-lead CardioSecur ECG in the lying (l.), sitting (m.), and standing (r.) positions (from study participant). ©CardioSecur

Personal MedSystems GmbH is a pioneer in digital health. The company develops mobile diagnostic ECG devices and services for private users and healthcare professionals under the name CardioSecur. **CardioSecur Active** is an innovative 15-lead, clinical-grade ECG for home use. In just a few seconds, it generates individualized feedback on changes in heart health and provides a simple recommendation on whether to visit a doctor or not. The entire system consists of a 50g light cable with only four electrodes, the free CardioSecur Active app and the user's smartphone or tablet computer. **CardioSecur Pro** is the mobile, clinical ECG solution for physicians and healthcare professionals, as well as corporate clients. Since 2018, the aviation industry standardly equips long distance aircrafts with CardioSecur Pro. Via 22 leads, CardioSecur Pro provides a 360° view of the heart and is thereby the only system that meets the European cardiology guidelines recommending evaluation of the anterior, lateral, inferior and posterior walls of the heart for infarcts.

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Effect of Body Position on a Mobile, Vector-Derived, 12-Lead Electrocardiogram

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Abstract

Background: The electrocardiogram (ECG) is a critical component of cardiovascular diagnosis. ECGs are standardly recorded in the supine position; however, due to time and space constraints as well as patient limitations, they are often performed in other positions (sitting, standing). Several studies have examined the effect of body position on electrocardiograms using various methods, body positions, and parameters, with varied results reported. This study's aim was to further evaluate the effect of body position on a mobile, vector-derived, 12-lead ECG, to determine if body position should be considered when performing an ECG.

Methods: Electrocardiograms from 39 patients were examined in the lying, sitting, and standing positions. Heart rate, PQ interval, QRS duration, QTc interval, P-, QRS-, and T-vectors, and R and S amplitudes were statistically evaluated using correlation coefficient and one-factorial Analysis of Variance (ANOVA). Changes of the Q waves, ST segments, and T waves were qualitatively evaluated.

Results: No changes of statistical or clinical significance were detected. No notable differences were seen in regard to intervals. For the vectors, a -9 degree change in the P axis with sitting, a -4 degree change in the QRS axis when standing, and a 3.8 degree increase in the T vector with change of position were seen. Negligible changes were seen in the wave amplitudes. 5/39 patients (13%) demonstrated T wave changes with change in position.

Conclusion: The results suggest that a vector-derived, 12-lead electrocardiogram can be used in different body positions without impacting key ECG parameters.

Keywords: Mobile Electrocardiogram; Vector-Derived Leads; CardioSecur 12-Lead ECG; Effect of Body Positions; Clinical ECG Diagnosis

Abbreviations

ECG: Electrocardiogram; ANOVA: Analysis of Variance; HES: Hannover EKG System

Introduction

Electrocardiographic recording allows for the non-invasive detection of cardiac ischemia and arrhythmic events, which significantly reduces patient mortality [1,2].

Standard electrocardiograms are routinely recorded in the supine position. However, patients with heart failure or respiratory insufficiency often find the supine position uncomfortable and therefore have their ECG recorded in a reclining (45°) or sitting (90°) position. Other situations such as exercise stress testing or time/space constraints also require the ECG to be recorded in a non-supine position. However, ECGs are generally submitted for analysis without an accompanying statement of the body position in which the ECG was recorded [3].

This raises the question of what effect body position has on ECG tracings, and ultimately on the clinical diagnosis. Several studies [3-9] have been performed looking at this topic. The available literature deals primarily with standard ECG lead systems and evaluates patients in a variety of settings and body positions. Mixed results have been described, with a tendency towards less effect of body position on the ECG parameters with a vector-derived ECG [7,8].

The concept of vectorcardiography was initially introduced by Frank [10] and was advanced by Dower [11] into the commonly-known EASI system [12]. The 5-electrode EASI system has been further developed into the CardioSecur ECG system (Personal MedSystems; Frankfurt, Germany) [13,14], which reduces the electrodes to four (Figure 1) and has been validated compared to a standard ECG in previous studies. The current study aimed to elaborate on the existing literature by examining the effect of body position on ECG tracings from this innovative, vector-derived ECG, to determine if it is necessary to consider the patient's body position when evaluating an ECG.

Materials and Methods

The study included 39 patients, of which 24 were male and 15 were female. The study population had an average age of 70.1 years (range: 22 - 91 years), average weight of 81.0 kg (range: 50 - 150 kg), and an average height of 168.9 cm (range: 153 - 180 cm). The patients were either ambulatory patients with chest pain or patients admitted to the cardiac care unit of the Central Hospital of the Hungarian Defence Forces in Budapest (Hungary) between December 2015 and March 2016. The primary clinical diagnoses of the participants were: acute coronary syndrome (20), chronic coronary artery disease (10), atrial fibrillation (3), pacemaker (3), dilative cardiomyopathy (1), prolonged QT syndrome (1), and valve replacement (1). Accompanying diagnoses included congestive heart failure (CHF), hypertension, diabetes mellitus, and chronic obstructive pulmonary disease (COPD), with some patients having more than one of the above diagnoses.

Each patient had three 10-second ECGs recorded in the following sequence: lying, sitting, then standing. The electrodes were not removed between readings, thereby ensuring that the position of the electrodes would not vary in the different positions. All ECGs were recorded with the above-mentioned CardioSecur ECG system, a mobile, tablet-based ECG. Electrodes were attached as depicted in figure 1. The positioning of the 4 electrodes creates a tetrahedron (Figure 1), which captures the entire heart and computes the ECG leads from 3 channels (X, Y, Z).

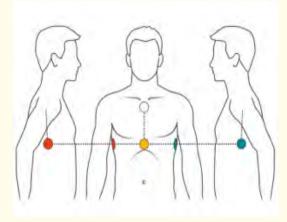


Figure 1: CardioSecur electrode placement locations.

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All ECGs were recorded with a paper speed of 25 mm/s, calibration of 1 mV/cm, and were filtered by a high-pass filter with a 0.05 Hz cut-off frequency. Automatic ECG interpretation was performed using the validated Hannover EKG System (HES) interpretation algorithm

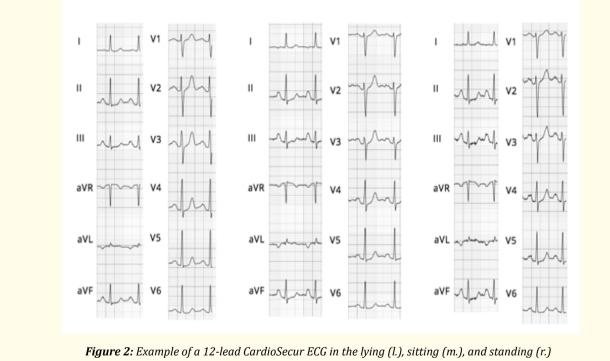
Heart rate (bpm), P vector (°), QRS vector (°), T vector (°), PR interval (ms), QRS duration (ms), and QTc interval (ms) were obtained using automatic interpretation. Outliers were re-evaluated and calculated manually when possible. The small amplitude of many ECGS, particularly of the P and T waves, made manual calculation of PR interval, P vector, and T vector difficult in certain situations. R wave amplitude (mV) in limb leads I, II and III and in the precordial lead V5 as well as the amplitude (mV) of the S wave in V1 were measured manually; the Q waves, ST segments, and T waves were qualitatively evaluated by two independent observers.

The data was analysed using descriptive statistics and reported as mean \pm standard deviation (absolute values as well as difference between body positions). Correlation coefficient (R) was used to determine the relationship between two groups (lying to sitting, lying to standing), with the supine reading serving as the reference. Analysis of variance (ANOVA) was also used to compare the three groups with each other to prove the null hypothesis of no difference between the groups (when F < F_{crit}).

Results

[15].

An example of the CardioSecur ECG in each body position is shown in figure 2 below.



positions (from study participant #14).

The absolute mean ± standard deviation and correlation coefficient (R) comparing body positions are reported below in table 1; ANO-VA results are listed in table 2, with no parameter found to be statistically significant as per one-way ANOVA. Brief findings of each parameter are reported below:

- **Heart rate:** A slight increase was seen when standing, with an average difference from lying to sitting of 2.72 bpm and lying to standing of 6.39 bpm.
- **PR interval:** The PR interval became slightly shorter when changing positions, with an average difference of -6.19 ms between lying and sitting and -7.22 ms between lying and standing. Three participants were excluded due to atrial fibrillation.
- **QRS duration:** There was a minimal change in QRS duration between body positions, with an average difference of -1.44 ms lying to sitting and -2.62 ms lying to standing.
- **QTc interval:** A slight overall increase was noted with change in position, with an average difference of 1.31 ms lying to sitting and 5.67 ms lying to standing. Outliers were manually evaluated and corrected using Bazett's formula.
- **P vector:** The P vector was lower on average when sitting than when lying and standing, with an average difference of -9° from lying to sitting and -0.911° from lying to standing. All differences of over 20° were manually evaluated. 3 patients were excluded due to atrial fibrillation and 3 other patients were excluded for reasons related to automatic interpretation (p vector unable to be measured). However, in these three cases, there was no difference of clinical significance visually observed between the body positions.
- **QRS vector:** There was a change of less than a 1° when sitting, with a slightly more negative vector when standing, as shown by the mean difference (0.743° lying to sitting, -3.95° lying to standing). All differences of over 30° were manually evaluated.
- **T vector:** An increase in the T vector was noticed with change in position, with a more pronounced increase when sitting as compared with standing: average difference between lying and sitting of 3.76° and 0.95° between lying and standing. All differences of over 20° were manually evaluated. 1 outlier was removed as automatic interpretation did not match visual inspection, but the waveforms were too small to measure manually.
- Wave amplitude (limb leads): Very little difference was seen in the amplitude of the R waves in leads I, II, and III. The most notable, though still minimal, difference was a slight overall increase in the R amplitude in lead III in the sitting position, with an average difference of 0.057 mV lying to sitting.
- Wave amplitude (precordial leads): A negligible difference was seen in the wave amplitude in the precordial leads, as represented by the R wave in V5 and S wave in V1.

	Absolute values: Lying	Absolute values: Sitting	Absolute values: Standing	Corr. (R): Lying to sitting	Corr. (R): Lying to standing
Heart rate (bpm)	70.33 ± 13.36	73.05 ± 13.28	76.72 ± 14.78	0.870	0.924
PR interval (ms)	179.39 ± 28.88	173.08 ± 27.77	172.17 ± 27.72	0.940	0.933
QRS duration (ms)	106.77 ± 23.79	105.33 ± 24.24	104.15 ± 24.46	0.987	0.985
QTc interval (ms)	448.31 ± 30.46	449.62 ± 30.03	453.97 ± 33.91	0.757	0.876
P vector (°)	63.85 ± 50.89	54.85 ± 60.19	62.94 ± 57.15	0.888	0.897
QRS vector (°)	9.38 ± 56.78	10.28 ± 60.05	5.44 ± 59.57	0.831	0.944
T vector (°)	0.5 ± 87.173	4.08 ± 89.06	1.45 ± 93.20	0.894	0.879
R Amp I (mV)	0.65 ± 0.40	0.64 ± 0.41	0.66 ± 0.42	0.960	0.952
R Amp II (mV)	0.66 ± 0.58	0.66 ± 0.60	0.65 ± 0.63	0.975	0.970
R Amp III (mV)	0.12 ± 0.57	0.18 ± 0.62	0.13 ± 0.61	0.956	0.982
R Amp V5 (mV)	1.12 ± 0.78	1.08 ± 0.79	1.13 ± 0.73	0.970	0.952
S Amp V1 (mV)	-0.80 ± 0.64	-0.80 ± 0.52	-0.87 ± 0.57	0.966	0.964

 Table 1: Absolute values (mean ± standard deviation) in each body position and correlation coefficient (R) of lying to sitting and lying to standing for all parameters.

	df	F	F _{crit}	р
Heart rate	116	2.096	3.076	0.128
PR interval	107	0.704	3.083	0.497
QRS duration	116	0.115	3.076	0.892
QTc interval	116	0.346	3.076	0.708
P vector	101	0.264	3.088	0.77
QRS vector	116	0.075	3.076	0.93
T vector	113	0.016	3.088	0.98
R Amp I	116	0.0135	3.076	0.987
R Amp II	116	0.002	3.076	0.998
R Amp III	116	0.0097	3.076	0.908
R Amp V5	116	0.043	3.076	0.958
S Amp V1	116	0.203	3.076	0.816

Table 2: ANOVA results for all measured parameters (df = total degrees of freedom, F = F ratio, Fcrit = F critical value, p = significance).

ST segments, T waves, and Q waves were qualitatively evaluated. Some minor changes were noted as described below:

- **ST segment:** There were two cases with slight ST depression compared to the supine position. No other notable changes of the ST segment were present.
- Q wave: One case showed a slight decrease in the depth of the Q wave in the sitting and standing positions, as compared to lying.
- **T wave:** 4 individuals were found to have T wave inversions when changing position.

Discussion

An ECG is typically recorded in the lying position. However, certain clinical situations (e.g. dyspnea) as well as space and time constraints often require the ECG to be recorded in an alternate position (sitting or standing). The existing literature examining the effect of body position on ECG parameters has shown conflicting results; however, a tendency towards fewer changes with a derived ECG than with a standard ECG has been seen [7,8]. Khare and Chawala [4] investigated healthy adults using standard ECG recordings and found significant changes in the mean frontal plane axis in the sitting and reclining positions, but none when standing. Nelwan., *et al.* [5] evaluated cardiac care unit patients in supine, left and right lateral, and upright positions, and found marked ECG changes (ST elevation, QRS axis shift, T wave inversion) in only 14% of patients, most notable in the left lateral position. Bergman., *et al.* [6] assessed this effect on hospitalized patients in the supine and reclining positions, reporting a QRS axis shift of more than 20° in 8 out of 58 patients, a few Q wave discrepancies, and 34% of patients with a significantly decreased voltage in V5 when sitting. Madias [3] compared standard ECGs in the supine and standing positions. He found no difference in the sums of the QRS amplitude and only slight changes in the QRS frontal plane axis. Riekkinen and Rautaharju [7] studied the effect of body position on Frank's ECG system, with negligible changes on the intervals and angles identified. Adams and Drew [8] evaluated both standard and derived ECGs and found that the derived ECGs had fewer positional QRS changes than the standard ECGs, and that significant ECG changes were found in the right- and left-lateral positions. Norgaard., *et al.* [9] found more pronounced positional changes of QRS- and ST-segment variables in the left lying position during continuous vectorcardiography monitoring. This study aimed to expand this literature by assessing these differences using the CardioSecur sys

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In general, there was a large standard deviation for all parameters, in particular for vectors, which was expected given the wide variety of cardiac diseases affecting the study population. For this reason, the intra-individual differences were also included in the analysis, which were low for all parameters as discussed in the results. Though some minor changes were seen as presented in the results above, no change was found to be of statistically significance according to one-way ANOVA (Table 2). Just as importantly, when looking at these changes from a clinical perspective, none was found to make a difference when considering the clinical consequences (e.g. the diagnosis from the ECG would not be changed due to the change in body position).

Heart rate and intervals (PRI, QRS, QTc): No notable changes were seen.

Vectors: As vector direction is dependent upon many factors, one of which being body position, a change in vector, particularly QRS vector, with body position was expected. There was a mild left-shift of the P vector when sitting (approx. 10°). It was expected that the QRS vector would display a right-shift with standing, which was not seen in this study. There was less than a +1° change from lying to sitting, with an average change in vector by approximately -4° when changing from lying to standing. There were two outliers-one of these may have been an outlier due to its overall small voltage, and the other could not be explained. A slight right-shift in T vector was noticed when sitting, with an approximate increase of 4°. There were 8 outliers-3 of these demonstrated no difference when visually evaluated and 5 were felt to be true outliers due to T wave changes associated with change in body position, which was not an unexpected finding. Though mild axis changes were seen, they were smaller than expected.

Wave amplitudes, ST segments, Q waves, T waves: No significant difference was seen in the R and S amplitude of either the limb or precordial leads with change in body position. The two cases of slight ST depression when changing position were non-specific ST segment changes and therefore would have no impact on the diagnosis stemming from the ECG. The change in depth of the Q wave in one case in the sitting and standing positions was an effect that could not be explained. However, given that the width of the Q wave was not affected, there was no impact on the overall diagnosis. 5 cases with T wave changes when changing position were identified-4 showed T wave inversions and 1 showed non-specific T wave changes, which were not unexpected findings.

Study Limitations

The study was limited by its small sample size. The studies discussed above also had a similar issue. Therefore, future studies could expand these results by including a larger sample size to increase the power.

Conclusion

In the study at hand, heart rate, PR interval, QRS duration, QTc interval, heart vectors (P, QRS and T), amplitude of the R and S waves, ST segment, T waves, and Q waves were evaluated. Minimal changes are described above; however, there were no changes found to be of clinical or statistical significance. This study therefore demonstrated the stability of a vector-derived, 12-lead ECG in various body positions, allowing for an ECG to be recorded in the lying, sitting, or standing positions without a significant change in the key ECG parameters.

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Conflict of Interest

Peter Kenedi, Jessica Thuer, David Triebl, Athar Abu Helou (intern) and Markus Riemenschneider are employed by Personal MedSystems GmbH, producer of CardioSecur. There are no additional conflicts of interest to declare.

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