

# Journal of Visualized Experiments

## Patient Directed Recording of a Bipolar Three-Lead Electrocardiogram Using a Smartwatch with ECG Function --Manuscript Draft--

Article Type:	Invited Methods Article - JoVE Produced Video
Manuscript Number:	JoVE60715R2
Full Title:	Patient Directed Recording of a Bipolar Three-Lead Electrocardiogram Using a Smartwatch with ECG Function
Section/Category:	JoVE Medicine
Keywords:	Smartwatch, smart device, Electrocardiogram, bipolar ECG, multichannel ECG, Einthoven ECG
Corresponding Author:	Alexander Samol Johannes Wesling University Hospital Minden, GERMANY
Corresponding Author's Institution:	Johannes Wesling University Hospital
Corresponding Author E-Mail:	Alexander.Samol@muehlenkreiskliniken.de
Order of Authors:	Alexander Samol Kristina Bischof Blerim Luani Dan Pascut Marcus Wiemer Sven Kaese
Additional Information:	
Question	Response
Please indicate whether this article will be Standard Access or Open Access.	Standard Access (US\$2,400)
Please indicate the <b>city, state/province, and country</b> where this article will be <b>filmed</b> . Please do not use abbreviations.	Minden, North-Rhine-Westphalia, Germany

**TITLE:**

Patient Directed Recording of a Bipolar Three-Lead Electrocardiogram Using a Smartwatch with ECG Function

**AUTHORS AND AFFILIATIONS:**

Alexander Samol<sup>1</sup>, Kristina Bischof<sup>1</sup>, Blerim Luani<sup>1</sup>, Dan Pascut<sup>1</sup>, Marcus Wiemer<sup>1</sup>, Sven Kaese<sup>1</sup>

<sup>1</sup>Department of Cardiology and Critical Care Medicine, Johannes Wesling University Hospital, Ruhr University Bochum, Minden, Germany

**Corresponding Author:**

Alexander Samol (alexander.samol@muehlenkreiskliniken.de)

**Email Addresses of Co-authors:**

Kristina Bischof (kristina.bischof@muehlenkreiskliniken.de)

Blerim Luani (blerim.luani@muehlenkreiskliniken.de)

Dan Pascut (danliviu.pascut@muehlenkreiskliniken.de)

Marcus Wiemer (marcus.wiemer@muehlenkreiskliniken.de)

Sven Kaese (sven.kaese@muehlenkreiskliniken.de)

**KEYWORDS:**

smartwatch, smart device, electrocardiogram, bipolar ECG, multichannel ECG, Einthoven ECG

**SUMMARY:**

We describe a protocol for the patient-directed registration of a three lead bipolar electrocardiogram by a smartwatch that functions identically to the Einthoven leads from standard electrocardiograms. This enables patients to record electrocardiograms on their own immediately after the onset of symptoms.

**ABSTRACT:**

Cardiac arrhythmias and cardiovascular diseases are a major public health problem in developed countries. A major goal in preventive medicine is the reduction of cardiovascular death by early detection of atrial fibrillation (AF), which may cause stroke, or early detection of life-threatening myocardial ischemia in acute coronary syndrome. Detection of arrhythmia is often challenging if symptoms occur when patients have no chance for immediate electrocardiogram (ECG) diagnostic testing, or if the observation time period is short or an immediate visit to their doctor is not possible. Smartwatches and other wearable devices are able to record a single lead ECG recording, but a single lead ECG is often not sufficient for diagnosis of cardiovascular disorders. Even diagnosis of AF can be difficult with only information from a single lead bipolar ECG. Some smart devices use photoplethysmography for detection of cardiac rhythm, but this technique can only give indirect hints of the underlying cardiac rhythm, is prone to interferences, and cannot be used for detection of myocardial ischemia. A three-lead bipolar ECG like the Einthoven leads used in regular ECGs can add useful information concerning arrhythmia detection or even diagnosis of other cardiovascular diseases like ischemia. Therefore, we describe a protocol for

the patient-directed recording of an Einthoven three-lead ECG using a smartwatch.

## **INTRODUCTION:**

Smartwatches or other so-called “wearable devices” show increasing popularity and a steeply rising daily use in Western countries. Nearly 80% of US-Americans own a smartphone and more than 10% have a smartwatch<sup>1</sup>. Due to a photoplethysmographic sensor using LED-light and photodiodes, some smartwatches can record pulse frequency and irregularities<sup>1</sup>. This feature enables the detection of arrhythmias, especially AF, with high diagnostic accuracy<sup>2,3</sup>. For authentic ECG arrhythmia detection, portable, handheld, and wearable ECG devices have been developed to enable smartphone-assisted ECG recordings. Nevertheless, these devices allow patient-activated recording of electrocardiograms only if the patients’ compliance for carrying the ECG device is extremely high<sup>4-7</sup>.

Thus, the optimal tool for a patient’s medical surveillance would be a smart device for daily use. Some last generation smartwatches enable a single-lead ECG recording comparable to bipolar lead Einthoven I from a standard 12-channel ECG using the backside of the watch as the positive and the crown as the negative electrode<sup>8</sup>. ECG recording is patient-controlled and activated if symptoms occur. Thereafter, an application creates a PDF document for further analysis by a healthcare professional. Nevertheless, using only a single-lead ECG for discrimination of P waves for diagnosis of sinus rhythm is sometimes insufficient<sup>9</sup> for detection of the P wave and often multiple ECG leads are required<sup>5</sup>. In addition, multichannel ECG recording is mandatory for diagnosis of most acute or chronic structural heart diseases like myocardial infarction (MI), pulmonary embolism, or signs of acute heart failure,.

More than 100 years ago, Einthoven developed a method for recording of a bipolar three-channel ECG<sup>10</sup>. This three-channel ECG offers the opportunity to identify the electrical heart axis and possibly the myocardial ischemia as well, especially in inferior regions of the myocardium<sup>11</sup>. Therefore, in clinical daily practice bipolar Einthoven leads I-III are essential parts of the 12-lead ECG and enable heart rhythm determination or detection of myocardial ischemia.

Early diagnosis and especially early treatment of myocardial infarction has improved substantially during recent decades. Nevertheless, especially early after the onset of symptoms, many patients hesitate to contact professional help. Thus, first medical contact and initiation of adequate treatment is often delayed<sup>12</sup>. Registration and transmission of a patient-directed ECG early after the onset of symptoms might accelerate specific treatment and thus enable a better patient outcome<sup>7</sup>. Until now, ischemia detection by smart devices is limited, because mainly single-lead (Einthoven I), or as in our study, maximal three-lead (Einthoven I-III) ECGs can be recorded, which only represent a limited area of the myocardium.

Several studies used patient-directed devices like portable ECG recorders, smartphones, and very recently smartwatches, for detection of AF in heart patients<sup>1,2,5,9</sup>. The Apple Heart Study and the WATCH AF trial used the photoplethysmographic LED-light sensor of the smartwatch for detection of an irregular or variable pulse, which correlates with arrhythmia like AF<sup>1,2</sup>. Insufficient signal quality was the limiting factor in these trials, leading to a high dropout rate<sup>2</sup>. Another

smartwatch trial used photoplethysmography for AF detection, but also showed reduced diagnostic accuracy compared to regular ECGs<sup>13</sup>.

The detection of AF by the registration of pulse irregularities is the limiting factor of photoplethysmography, because heartbeat variabilities due to extra systoles or sinus arrhythmia may also cause pulse irregularities. Thus, recording of an ECG by a smartphone or smartwatch may increase the sensitivity and specificity of arrhythmia detection. Several smartphone compatible devices can record a bipolar single-lead ECG simulating Einthoven lead I<sup>5,9</sup>. In one study, a bipolar smartphone ECG device was used for AF screening<sup>9</sup>. In this trial, a small voltage of P waves in lead I led to incorrect AF determination, a limitation when only a single-lead ECG is available<sup>9</sup>. ECG devices for AF screening were also tested in hospitalized patients on cardiologic and geriatric wards<sup>5</sup>. Diagnostic accuracy of the automated algorithms was only suboptimal and additional 12-lead ECGs were often mandatory. Most of these devices have the limitation of only one ECG lead recording (Einthoven I), which is not always sufficient to ensure arrhythmia or repolarization detection.

Only one small case series of five patients demonstrated that a conventional 12 lead ECG is recordable by a conventional bipolar smartphone device after modification for unipolar lead recordings with ECG tabs and wires with alligator clips<sup>4</sup>. They showed ECG recordings with good signal quality, but the limiting factor is the need for device modifications that complicates patient-directed self-ECG recording.

In contrast, we performed the first study for recording an ECG with a smartwatch with the three bipolar Einthoven leads as a proof of concept in healthy subjects. We were able to show a high grade of consistency between the smartwatch leads and the Einthoven leads from a standard ECG using the following simple protocol.

## **PROTOCOL:**

This study was performed according to the Declarations of Helsinki and approved by the Ethics Committee of the Aerztekammer Westfalen-Lippe (reference number 2019-456).

### **1. Study**

1.1. Instruct subjects on how to use the smartwatch for proper ECG recording.

### **2. Recording of a standard 12-lead ECG by a common device**

2.1. Use a common ECG device for standard ECG recording.

2.2. Adjust the paper running speed to 50 mm/s.

2.3. Perform the ECG recording after a 5 min resting period in a supine position.

2.4. Place the right arm electrode near the right shoulder.

2.5. Place the left arm electrode near the left shoulder.

2.6. Place the right leg electrode near the right ankle.

2.7. Place the left leg electrode near the left ankle.

2.8. Place the V1 electrode in the fourth intercostal space at the right parasternal line.

2.9. Place the V2 electrode in the fourth intercostal space at the left parasternal line.

2.10. Place the V3 electrode between V2 and V4.

2.11. Place the V4 electrode in the fifth intercostal space at the midclavicular line.

2.12. Place the V5 electrode in the fifth intercostal space at the anterior axillary line.

2.13. Place the V6 electrode in the fifth intercostal space at the mid-axillary line.

2.14. Record a standard 12-lead ECG with the standard ECG device.

NOTE: The patient should not move during the ECG recording in order to prevent ECG artifacts.

### **3. Recording of Einthoven leads I-III by a smartwatch with ECG function**

3.1. Record smartwatch ECGs directly after recording the standard ECGs.

3.2. Enable the application of the smartwatch for ECG recordings. A 30 s ECG will be recorded directly after proper skin contact with the smartwatch.

3.3. Record Einthoven I by placing the back of the smartwatch on the left wrist and the right index finger on the crown (**Figure 1A**).

3.4. Record Einthoven II by placing the back of the smartwatch on the left lower abdomen and the right index finger on the crown (**Figure 1B**).

3.5. Record Einthoven III by placing the back of the smartwatch on the left lower abdomen and the left index finger on the crown (**Figure 1C**).

NOTE: The right and left index finger should not contact the skin of the left wrist or left lower abdomen for adequate ECG recording. The patient should not move during the ECG recording in order to prevent ECG artifacts.

#### 4. Analysis of the ECGs

4.1. Recorded smartwatch ECGs are digitally stored using the smartphone app.

4.2. Use the “send PDF to your doctor” function to create a PDF document of every single smartwatch ECG lead. Print the digital smartwatch ECG on paper for comparison with the standard ECG on printed paper.

4.3. Classify all recorded smartwatch ECGs as of moderate signal quality if at least three consecutive QRS-complexes show noise-free signal quality and there are no artifacts in the isoelectric lines between QRS-complexes.

4.4. Classify smartwatch ECGs as of good signal quality if at least ten QRS-complexes show noise-free signal quality and there are no artifacts in isoelectric lines between QRS-complexes.

#### 5. Statistical analysis

5.1. Perform statistical analysis using IBM SPSS Statistics.

NOTE: Categorical variables are shown as absolute numbers and percentages. Continuous variables are presented as mean  $\pm$  standard deviation. Differences of metric outcome variables were assessed by one way repeated analysis of variance (ANOVA) and paired t-test. In case of binary variables, the  $\chi^2$ -test was used.

#### REPRESENTATIVE RESULTS:

In a cohort of 100 healthy subjects (66 female) we investigated the feasibility of our smartwatch recording protocol. The subjects’ characteristics are shown in **Table 1**. After a short tutorial all volunteers managed the ECG recording procedure with the smartwatch. All 300 smartwatch ECGs were useable for further analysis with at least adequate signal quality for diagnostics purposes. Of the total ECGs, 277 (92%) were of good quality and 23 (8%) of moderate signal quality. Three blinded cardiologists were asked to assign the smartwatch ECGs to the corresponding Einthoven leads in each subject. They correctly assigned 288 (96%) smartwatch ECGs to the corresponding Einthoven lead I, II, and III from the 12-lead ECG (range from 93%–97%). All blinded cardiologists assigned the ECGs from eighty-nine participants (89%) correctly to the corresponding Einthoven leads. A comparison of the single-leads to the corresponding Einthoven leads is shown in **Figure 2**. Assignment errors occurred in 11 volunteers. In five of these subjects more than one cardiologist assigned the single-lead ECGs incorrectly to the corresponding Einthoven leads. Fleiss kappa analysis showed moderate interrater reliability (kappa = 0.437;  $p < 0.001$ ). The intraclass correlation coefficient was 0.703. All assignment errors were made in subjects with comparable amplitudes and morphologies in the two smartwatch ECGs or the corresponding standard ECG leads. At least one ECG lead was assigned correctly in all participants by all the cardiologists. All assignment errors were made in the ECGs with good signal quality. Thus, there was no correlation between the quality of the ECG recordings and correct assignment. Assignment errors occurred

in statistically older subjects ( $46 \pm 10$  vs.  $37 \pm 11$  years; mean  $\pm$  SD). No other subject parameter listed in **Table 1** was associated with an incorrect assignment.

#### **FIGURE AND TABLE LEGENDS:**

**Figure 1: Recording positions of the smartwatch for the three Einthoven leads.** (A) Recording of Einthoven lead I between the left arm wrist and the right index finger. (B) Recording of Einthoven lead II between the left lower abdominal region and the right index finger. (C) Recording of Einthoven lead III between the left lower abdominal region and the left index finger.

**Figure 2: Comparison of a typical standard ECG with Einthoven I–III leads (black ECG curves) to the smartwatch ECGs (red ECG curves).** Despite a different writing speed of 50 mm/s of the black ECG curves from the standard ECG and 25 mm/s of the red ECG curves of the smartwatch ECGs, the morphologies of the three channels are clearly identical.

**Table 1: Subject characteristics.** BSA = body surface area; BMI = body mass index; HR = heart rate; lead I = Einthoven lead I; lead II = Einthoven lead II; lead III = Einthoven lead III.

#### **DISCUSSION:**

Smart devices like smartphones and smartwatches are increasingly used in daily life and medical care<sup>1</sup>. These new devices and apps may have a significant impact on health awareness of the population, but their effective use needs to be tested in studies<sup>8</sup>. To the best of our knowledge, our group was the first to develop this method of single-lead ECG recordings corresponding to the conventional Einthoven ECG leads I–III using a smartwatch<sup>14</sup>.

An important part in the protocol for patient-directed ECG recording is sufficient instruction on the use of the smartwatch and the corresponding app. Patients need to be instructed where to place the back of the watch on the wrist of the left arm or left lower abdomen and the index finger of the left or right hand on the crown of the smartwatch. For optimization of smartwatch ECG quality, the user should be advised to not move during ECG recording in order to prevent ECG artifacts. Further, the index finger should not contact the wrist or abdomen. In addition, smartwatch ECG recording should be performed in a supine position, similar to standard ECG recordings. If patients detect insufficient ECG quality of the recorded ECG due to artifacts, optimization of skin contact may improve the signal quality. After a short tutorial, all of our 100 participants were able to perform the three-lead ECG recordings on their own by positioning the smartwatch in the required positions. Therefore, wider use of a smartwatch for patient-directed three-lead ECG recording may be feasible in the population at large after a short tutorial. This training may be performed by a short video clip or illustrated manual, for example. Our study cohort was middle-aged and may be more familiar with smart devices than older subjects. Therefore, in a cohort of older patients an appropriate use of a smartwatch for ECG recordings might be challenging due to difficulties in the use of the device or the app, the different positioning of the smartwatch, and a potential inability to lie still in a supine position due to comorbidities like Parkinson's disease. One recent study compared two handheld ECG devices and showed that approximately 7% of cardiology patients and 21.4% of geriatric patients did not manage correct use of the device<sup>5</sup>.

The quality of all the recorded smartwatch ECGs was sufficient for further evaluation. Good signal quality was found in 92% and moderate signal quality in 8% of smartwatch ECGs. Of our smartwatch ECGs, 96% were correctly assigned to the corresponding Einthoven leads I-III from 12-channel standard ECGs by all blinded cardiologists. Morphological and quantitative ECG parameters like P wave, QRS complex, and T wave of the smartwatch recordings were highly comparable to the corresponding standard ECG leads. Assignment errors occurred in older subjects, but physiognomic parameters and physical aspects like sex or electrical heart axis did not influence the correct ECG assignment. In older patients, assignment errors were not due to insufficient signal quality but were caused by comparable ECG morphologies in two of the three leads.

A limitation of the technology and protocol used our study is that several steps are required for recording a three-lead smartwatch ECG. The complexity of positioning the smartwatch and right or left index finger on the watch as well as the correct application of the required app may impede widespread use in the general population. Further, the smartwatch used in our study also requires use of a smartphone from the same company. Thus, this smartwatch cannot be used in combination with other commercially available smartphones or smart devices.

A limitation of our protocol is that we only performed a visual comparison of the recorded smartwatch leads with the standard ECGs. Until now, we have not developed a computer-based algorithm for comparison of the smartwatch bipolar ECGs with the standard Einthoven leads recorded by a standard ECG device. So far, we could only record Einthoven leads I-III with the smartwatch. Due to this, we could only record ECGs of a limited area of the heart encompassing the inferior and anterolateral myocardium. In addition, we have not performed measurements in patients with heart diseases. The use of patient-directed smartwatch ECG recordings in the wider population might improve and accelerate diagnosis of acute cardiac diseases and shorten duration to medical contact. Of note, users and patients should be reminded that smartwatch ECG recording does not replace a standard 12-lead ECG during a doctor's visit.

An advantage of the smartwatch is that patients with documented or presumed AF can carry them in daily life. Other smart devices for bipolar ECG recording need to be carried in addition to a smartphone, which may limit their wider use in the population. Multichannel smartwatch ECG recording may optimize monitoring heart rhythm in patients if the P waves cannot sufficiently be detected in lead I. Broad deployment of smartwatches for AF detection may improve medical treatment for this group of patients, because 25% of all strokes are caused by AF, which is the most frequent rhythm disorder in Western populations<sup>1</sup>. Further, many individuals are unknowingly at risk: in 18% of AF-related strokes, AF was diagnosed for the first time after the stroke<sup>1</sup>.

Recent studies<sup>1,2</sup> demonstrated good accuracy of smartwatch AF detection based on photoplethysmography. The Apple Heart Study recorded pulse disorders by smartwatch photoplethysmography as a surrogate marker for the detection of AF<sup>1</sup>. The authors demonstrated that the smartwatch reliably recorded pulse disorders for unmasking



asymptomatic AF<sup>1,9</sup>. The WATCH AF trial also used a smartwatch with photoplethysmography for AF detection<sup>2</sup>. This trial also showed a very high accuracy for AF detection by a smartwatch<sup>2</sup>. However, a limitation of the used algorithm was a high failure rate due to restricted signal quality<sup>2</sup>. An additional study with the smartwatch photoplethysmography technique confirmed the ability to record AF but also demonstrated reduced quality of AF detection compared to a standard ECG device<sup>13</sup>. A major limitation of the applied photoplethysmography in these studies is that pulse irregularities are used as a surrogate marker for AF detection. Cardiac extra systoles can also cause pulse disorders, which may be incorrectly interpreted as AF and therefore impede adequate AF detection. Therefore, the technique of smartwatch bipolar ECG recording may enhance the accuracy of detection of heart rhythm disorders compared to the smartwatch photoplethysmography technique. These true single-lead ECG recordings can be performed by several handheld electrocardiogram devices as additional tools for smartphones. One of these devices can record Einthoven lead I and showed a high sensitivity and specificity for AF detection in community-based AF screening<sup>9</sup>. Incorrect positive AF detection was caused by reduced P wave voltage in the only available lead Einthoven I<sup>9</sup>. An additional trial studied several one-lead ECG handheld devices for screening of AF in cardiologic and geriatric patients in hospital units<sup>5</sup>. This trial offered restricted diagnostic accuracy of the device algorithms and that supplemental 12-lead ECG recordings needed to be performed to increase diagnostic accuracy. A limitation of the one-lead ECG devices is that only Einthoven lead I can be applied, which impedes sufficient P wave detection. Further, these devices are used as an additional tool to a smartphone, which may limit wider use in the population, as the user must carry the ECG device in addition to the smartphone.

An advantage of the smartwatches is that they are worn like a normal watch, which may be useful in integrating these devices in daily life. This may contribute to a wider use of these smartwatches in the population, which may increase patient-directed ECG recording. Compared to the photoplethysmography of the older smartwatches and the single-lead ECG devices for smartphones, true bipolar three-lead ECG recording by the smartwatch in our study may improve detection of cardiac arrhythmias and myocardial ischemia as more ECG data are available. Our smartwatch ECG protocol may improve patient-directed AF detection and therefore optimize oral anticoagulation treatment of these patients, which in turn may decrease AF-related stroke rates. In addition, smartwatch ECG recordings may optimize the early detection of myocardial ischemia by the patients themselves, which may lead to improved initiation of adequate treatment and outcome in myocardial infarction<sup>15</sup>. Studies demonstrate that 75% of MI patients contact emergency medical services more than one hour after the onset of symptoms<sup>12</sup>. Studies showed that a delay between symptom onset and medical contact occurred because patients did not recognize that symptoms were caused by a heart disease or believed that the symptoms were harmless<sup>12</sup>. In this subgroup of MI patients, use of smartwatch ECG recording by the patients themselves may contribute to earlier detection of myocardial ischemia and diminish the time patients take to initiate medical contact, subsequently improving the treatment and outcome of MI.

Because our study evaluated the feasibility of recording a three-lead smartwatch ECG in healthy subjects, further studies should evaluate the feasibility of smartwatch ECG recordings in patients

with cardiac disease. These studies should examine whether the three-lead smartwatch ECG recordings (Einthoven I-III) actually improve the detection of cardiac arrhythmia compared to a single-lead ECG recording (Einthoven I) and a 12-lead ECG from a standard device. The comparison of the diagnostic accuracy of the three-lead smartwatch ECG recordings should be performed in patients with AF, atrial flutter, and premature supraventricular contractions.

#### ACKNOWLEDGMENTS:

This research received no external funding. We thank Lisa Tiedemann, Ester Krist and Tobias Anke for technical support.

#### DISCLOSURES:

The authors have nothing to disclose.

#### REFERENCES:

1. Turakhia, M. P. et al. Rationale and design of a large-scale, app-based study to identify cardiac arrhythmias using a smartwatch: The Apple Heart Study. *American Heart Journal*. **207**, 66–75 (2019).
2. Dorr, M. et al. The WATCH AF Trial: SmartWATCHes for Detection of Atrial Fibrillation. *JACC Clinical Electrophysiology*. **5** (2), 199–208 (2019).
3. Hochstadt, A. et al. Continuous heart rate monitoring for automatic detection of atrial fibrillation with novel bio-sensing technology. *Journal of Electrocardiology*. **52**, 23–27 (2019).
4. Baquero, G. A., Banchs, J. E., Ahmed, S., Naccarelli, G. V., Luck, J. C. Surface 12 lead electrocardiogram recordings using smart phone technology. *J of Electrocardiology*. **48** (1), 1–7 (2015).
5. Desteghe, L. et al. Performance of handheld electrocardiogram devices to detect atrial fibrillation in a cardiology and geriatric ward setting. *Europace*. **19** (1), 29–39 (2017).
6. Samol, A. et al. Prevalence of unknown atrial fibrillation in patients with risk factors. *Europace*. **15** (5), 657–662 (2013).
7. Nigolian, A., Dayal, N., Nigolian, H., Stettler, C., Burri, H. Diagnostic accuracy of multi-lead ECGs obtained using a pocket-sized bipolar handheld event recorder. *Journal of Electrocardiology*. **51** (2), 278–281 (2018).
8. Foster, K. R., Torous, J. The Opportunity and Obstacles for Smartwatches and Wearable Sensors. *IEEE Pulse*. **10** (1), 22–25 (2019).
9. Lau, J. K. et al. iPhone ECG application for community screening to detect silent atrial fibrillation: a novel technology to prevent stroke. *International Journal of Cardiology*. **165** (1), 193–194 (2013).
10. Einthoven, W., Fahr, G., De Waart, A. On the direction and manifest size of the variations of potential in the human heart and on the influence of the position of the heart on the form of the electrocardiogram. *American Heart Journal*. **40** (2), 163–211 (1950).
11. Burch, G. E. History of precordial leads in electrocardiography. *European Journal of Cardiology*. **8** (2), 207–236 (1978).
12. Leslie, W. S., Urie, A., Hooper, J., Morrison, C. E. Delay in calling for help during myocardial infarction: reasons for the delay and subsequent pattern of accessing care. *Heart*. **84** (2), 137–141 (2000).

- 397 13. Tison, G. H. et al. Passive Detection of Atrial Fibrillation Using a Commercially Available  
398 Smartwatch. *JAMA Cardiology*. **3** (5), 409–416 (2018).
- 399 14. Samol, A. et al. Recording of Bipolar Multichannel ECGs by a Smartwatch: Modern ECG  
400 Diagnostic 100 Years after Einthoven. *Sensors (Basel)*. **19** (13) (2019).
- 401 15. Avila, C. O. Novel Use of Apple Watch 4 to Obtain 3-Lead Electrocardiogram and Detect  
402 Cardiac Ischemia. *Permanente Journal*. **23** (2019).
- 403

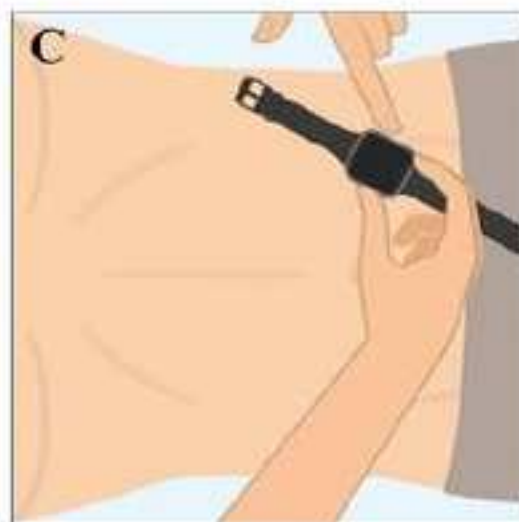
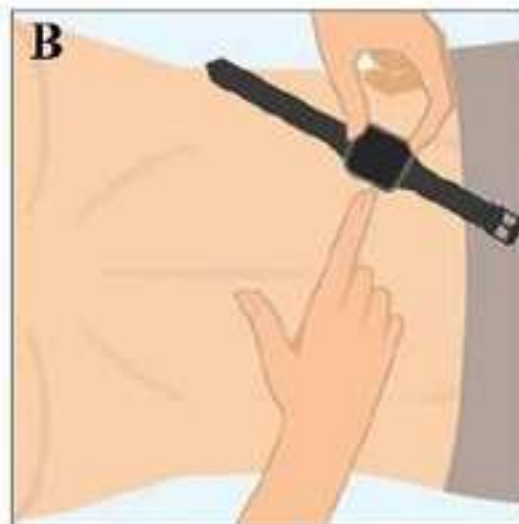


Figure 2



	<b>all</b>	<b>male</b>	<b>female</b>	<b>p</b>
<b>Size (cm)</b>	171±19	176±32	169±6	0.053
<b>Weight (kg)</b>	74±14	83±14	69±11	<0.001
<b>BSA (m<sup>2</sup>)</b>	1.86±0.26	1.98±0.36	1.79±0.15	0.001
<b>BMI (kg/m<sup>2</sup>)</b>	24.5±4.1	25.0±4.0	24.3±4.1	0.396
<b>Age (years)</b>	38±12	38±10	38±13	0.933
<b>QRS axis (°)</b>	51±31	42±35	56±29	0.040
<b>HR 12 lead ECG (bpm)</b>	71±12	72±11	70±13	0.420
<b>HR lead I (bpm)</b>	71±11	72±9	70±11	0.301
<b>HR lead II (bpm)</b>	72±11	73±10	71±11	0.372
<b>HR lead III (bpm)</b>	72±11	74±10	70±11	0.096

Name of Material/Equipment	Company	Comments/Description
Apple Watch Series 4	Apple	Smartwatch with bipolar ECG function
IBM SPSS Statistics	IBM	version 25 for Mac
MAC 5500	GE Healthcare	Standard 12 channel ECG device

# **A method for patient directed recording of a bipolar three-lead electrocardiogram using a smartwatch with ECG function**

## **Response to Editor**

We are very thankful for your constructive and helpful review. In the revised version we have improved the content in accordance with your comments:

1. Please take this opportunity to thoroughly proofread the manuscript to ensure that there are no spelling or grammar issues.

**We proofreaded the manuscript and checked the grammar.**

2. Please obtain explicit copyright permission to reuse any figures from a previous publication. Explicit permission can be expressed in the form of a letter from the editor or a link to the editorial policy that allows reprints. Please upload this information as a .doc or .docx file to your Editorial Manager account. The Figure must be cited appropriately in the Figure Legend, i.e. "This figure has been modified from [citation]."

**All figures were produced by our own, no permissions are warranted.**

3. Please remove the embedded figure(s) from the manuscript. All figures should be uploaded separately to your Editorial Manager account.

**All figures were removed from the manuscript file and uploaded separately.**

4. Please remove the embedded Table from the manuscript. All tables should be uploaded separately to your Editorial Manager account in the form of an .xls or .xlsx file.

**All tables were removed from the manuscript file and uploaded separately.**

5. Each figure must be accompanied by a title and a description after the Representative Results of the manuscript text.

**Figure legends were modified.**

6. Please do not abbreviate journal titles for references.

**We modified the reference list.**

7. Please check the Standard Access or Open Access box in Author License Agreement (page 1).

**Author license agreement was modified and has already been sent to your Journal.**

8. Step 1.2: Please write this step in the imperative tense.

**Step was written in imperative tense.**

9. 4.3: Please write this step in the imperative tense.

**Step was written in imperative tense.**

10. 4.4: Please write this step in the imperative tense.



Step was written in imperative tense.

11. Figure 2: Please add a short description of the figure in Figure Legend.

A short description was added.

### Response to Reviewer #1

#### Manuscript Summary:

The authors describe a novel use of an existing commercially available smartwatch device to acquire ambulatory EKG data.

The authors demonstrate a proof of useability of the apple watch in acquiring 3 lead EKG data which is novel and valuable to the scientific and commercial community

#### Major Concerns:

the paper is well written and describes a novel approach to improved data acquisition of more detailed EKG data from ambulatory patients

the extent and use of this technology will be inherently limited due to the number and complexity of steps required to acquire the EKG data; additionally, similar limitations exist with this use of the technology compared other commercially available EKG acquisition devices since it is essentially using the same equipment

This limitation was clarified in the Discussion section on page 6, second paragraph.

authors can further elaborate on the limitations to the use of this technology and the number of steps that may be required in allowing this device to create actionable data

This limitation was clarified in the Discussion section on page 6, second paragraph.

authors can go further in describing more far reaching uses and aspirational uses of wearable devices in the detection and treatment of disease

A paragraph was added in the Discussion section on page 7, last paragraph.

#### Minor Concerns:

typo on line 322 (trial and trail)

We apologize this typo. It was corrected to "trial".

## Response to Reviewer #2

### Manuscript Summary:

In this manuscript the authors suggest a method of using a common smartphone device with an ability to record a single Lead I ECG tracing to record a 3 Einthoven leads ECG. Quality and accuracy of the recordings are presented and are assessed by means of a blinded assignment of each lead to its corresponding lead on a standard 12 lead ECG.

### Major Concerns:

Line 189: Please provide measures of agreement between cardiologists on the assignment of ECGs, and measures of agreement between individual cardiologist to the actual assignment (using a weighted kappa or an Intraclass correlation coefficient as appropriate).

Measures of agreement were added in the Representative Results section on page 4, lines 206 and 207.

Line 194: Was there any correlation between Tracings quality and malassignment of ECG by the cardiologists?

We did not observe this correlation, this was added in the Representative Results section on page 4 lines 210 and 211.

Table 1: As there is no statistical methods paragraph, how were p values calculated? Consider adding a statistical paragraph to the methods.

A statistical paragraph was added on page 4 line 184 to 190.

General remark: As the main advantage of a 3 lead ECG is identifying the abnormalities in rhythm that are difficult to recognize on a one lead recording, I believe that mere assignment of Smartwatch recorded ECG tracing to a normally rerecorded 12 ECG is not enough to show the utility of this novel approach. For this experiment I would suggest adding measurements that are dependent on identifying small waves on the ECG such as the PR, QRS and QT interval lengths and comparing them with measurements derived from "normal" ECG tracings. Also interesting will be to see if the above measurements are closer to the "real" measurements from the 12 lead ECG when using 3 leads tracings rather than a single lead I tracing.

We totally agree with this reviewer, we just performed a qualitative analysis of Einthoven lead recordings from healthy subjects by blinded cardiologists showing a high grade of correct allocation in limb leads. An easy quantitative analysis of R-amplitude by counting the millimetres of Amplitude in the single lead recordings and comparing this amplitude to the standard lead ECGs was used by the cardiologist for correct allocation. The standard ECG recording speed in Germany for 12-channel-ECG is 50mm/s and the Apple Watch recording speed is 25mm/s, thus easy quantitative analysis comparing durations of QRS-complex, T-wave, etc., is not feasible. Also, the Apple Health App offers actually no tools for automatic measurements of amplitudes and durations. Therefore our recorded data are not sufficient to answer these quantitative questions, a new study is warranted with 12-channel ECG recordings in a paper speed with 25mm/s for manually comparative measurements of these parameters.

Also, as you mentioned in the manuscript, the main use of a 3 lead ECG

would be to better diagnose arrhythmias, hence I would add to the discussion part a suggestion for a future follow up study where one would assess the ability of the 3 lead ECG to identify arrhythmias in patients with known arrhythmias such as sinus arrhythmia, multiple APBS, atrial flutter and atrial fibrillation and comparing the diagnostic accuracy to a standard 12 lead and "regular" single lead I ECG.

This topic is now discussed on page 7 least paragraph.

Minor Concerns:

Line 51: Consider adding a reference to: Continuous heart rate monitoring for automatic detection of atrial fibrillation with novel bio-sensing technology. J Electrocardiol. 2019 Jan - Feb;52:23-27. doi: 10.1016/j.jelectrocard.2018.10.096.

This reference was added.

Lines 71-76: As the 3 Einthoven lead are not very sensitive to Acute MI/Ischemia I would focus less on ischemia detection and more on arrhythmia detection.

This limitation was clarified on page 1 line 76 to 78.

## ARTICLE AND VIDEO LICENSE AGREEMENT

Title of Article:	A method for patient directed recording of a bipolar three channel ECG using an Apple Watch series 4
Author(s):	Alexander Samol, Kristina Bischof, Blerim Luani, Dan Pascut, Marcus Wiemer and Sven Kaese

Item 1: The Author elects to have the Materials be made available (as described at <http://www.jove.com/publish>) via:

☒ Standard Access

☐ Open Access

Item 2: Please select one of the following items:

☒ The Author is **NOT** a United States government employee.

☐ The Author is a United States government employee and the Materials were prepared in the course of his or her duties as a United States government employee.

☐ The Author is a United States government employee but the Materials were NOT prepared in the course of his or her duties as a United States government employee.

### ARTICLE AND VIDEO LICENSE AGREEMENT

1. **Defined Terms.** As used in this Article and Video License Agreement, the following terms shall have the following meanings: **"Agreement"** means this Article and Video License Agreement; **"Article"** means the article specified on the last page of this Agreement, including any associated materials such as texts, figures, tables, artwork, abstracts, or summaries contained therein; **"Author"** means the author who is a signatory to this Agreement; **"Collective Work"** means a work, such as a periodical issue, anthology or encyclopedia, in which the Materials in their entirety in unmodified form, along with a number of other contributions, constituting separate and independent works in themselves, are assembled into a collective whole; **"CRC License"** means the Creative Commons Attribution-Non Commercial-No Derivs 3.0 Unported Agreement, the terms and conditions of which can be found at: <http://creativecommons.org/licenses/by-nc-nd/3.0/legalcode>; **"Derivative Work"** means a work based upon the Materials or upon the Materials and other pre-existing works, such as a translation, musical arrangement, dramatization, fictionalization, motion picture version, sound recording, art reproduction, abridgment, condensation, or any other form in which the Materials may be recast, transformed, or adapted; **"Institution"** means the institution, listed on the last page of this Agreement, by which the Author was employed at the time of the creation of the Materials; **"JoVE"** means MyJoVE Corporation, a Massachusetts corporation and the publisher of The Journal of Visualized Experiments; **"Materials"** means the Article and / or the Video; **"Parties"** means the Author and JoVE; **"Video"** means any video(s) made by the Author, alone or in conjunction with any other parties, or by JoVE or its affiliates or agents, individually or in collaboration with the Author or any other parties, incorporating all or any portion

of the Article, and in which the Author may or may not appear.

2. **Background.** The Author, who is the author of the Article, in order to ensure the dissemination and protection of the Article, desires to have the JoVE publish the Article and create and transmit videos based on the Article. In furtherance of such goals, the Parties desire to memorialize in this Agreement the respective rights of each Party in and to the Article and the Video.

3. **Grant of Rights in Article.** In consideration of JoVE agreeing to publish the Article, the Author hereby grants to JoVE, subject to **Sections 4** and **7** below, the exclusive, royalty-free, perpetual (for the full term of copyright in the Article, including any extensions thereto) license (a) to publish, reproduce, distribute, display and store the Article in all forms, formats and media whether now known or hereafter developed (including without limitation in print, digital and electronic form) throughout the world, (b) to translate the Article into other languages, create adaptations, summaries or extracts of the Article or other Derivative Works (including, without limitation, the Video) or Collective Works based on all or any portion of the Article and exercise all of the rights set forth in (a) above in such translations, adaptations, summaries, extracts, Derivative Works or Collective Works and (c) to license others to do any or all of the above. The foregoing rights may be exercised in all media and formats, whether now known or hereafter devised, and include the right to make such modifications as are technically necessary to exercise the rights in other media and formats. If the "Open Access" box has been checked in **Item 1** above, JoVE and the Author hereby grant to the public all such rights in the Article as provided in, but subject to all limitations and requirements set forth in, the CRC License.

## ARTICLE AND VIDEO LICENSE AGREEMENT

4. **Retention of Rights in Article.** Notwithstanding the exclusive license granted to JoVE in **Section 3** above, the Author shall, with respect to the Article, retain the non-exclusive right to use all or part of the Article for the non-commercial purpose of giving lectures, presentations or teaching classes, and to post a copy of the Article on the Institution's website or the Author's personal website, in each case provided that a link to the Article on the JoVE website is provided and notice of JoVE's copyright in the Article is included. All non-copyright intellectual property rights in and to the Article, such as patent rights, shall remain with the Author.

5. **Grant of Rights in Video – Standard Access.** This **Section 5** applies if the "Standard Access" box has been checked in **Item 1** above or if no box has been checked in **Item 1** above. In consideration of JoVE agreeing to produce, display or otherwise assist with the Video, the Author hereby acknowledges and agrees that, Subject to **Section 7** below, JoVE is and shall be the sole and exclusive owner of all rights of any nature, including, without limitation, all copyrights, in and to the Video. To the extent that, by law, the Author is deemed, now or at any time in the future, to have any rights of any nature in or to the Video, the Author hereby disclaims all such rights and transfers all such rights to JoVE.

6. **Grant of Rights in Video – Open Access.** This **Section 6** applies only if the "Open Access" box has been checked in **Item 1** above. In consideration of JoVE agreeing to produce, display or otherwise assist with the Video, the Author hereby grants to JoVE, subject to **Section 7** below, the exclusive, royalty-free, perpetual (for the full term of copyright in the Article, including any extensions thereto) license (a) to publish, reproduce, distribute, display and store the Video in all forms, formats and media whether now known or hereafter developed (including without limitation in print, digital and electronic form) throughout the world, (b) to translate the Video into other languages, create adaptations, summaries or extracts of the Video or other Derivative Works or Collective Works based on all or any portion of the Video and exercise all of the rights set forth in (a) above in such translations, adaptations, summaries, extracts, Derivative Works or Collective Works and (c) to license others to do any or all of the above. The foregoing rights may be exercised in all media and formats, whether now known or hereafter devised, and include the right to make such modifications as are technically necessary to exercise the rights in other media and formats. For any Video to which this **Section 6** is applicable, JoVE and the Author hereby grant to the public all such rights in the Video as provided in, but subject to all limitations and requirements set forth in, the CRC License.

7. **Government Employees.** If the Author is a United States government employee and the Article was prepared in the course of his or her duties as a United States government employee, as indicated in **Item 2** above, and any of the licenses or grants granted by the Author hereunder exceed the scope of the 17 U.S.C. 403, then the rights granted hereunder shall be limited to the maximum

rights permitted under such statute. In such case, all provisions contained herein that are not in conflict with such statute shall remain in full force and effect, and all provisions contained herein that do so conflict shall be deemed to be amended so as to provide to JoVE the maximum rights permissible within such statute.

8. **Protection of the Work.** The Author(s) authorize JoVE to take steps in the Author(s) name and on their behalf if JoVE believes some third party could be infringing or might infringe the copyright of either the Author's Article and/or Video.

9. **Likeness, Privacy, Personality.** The Author hereby grants JoVE the right to use the Author's name, voice, likeness, picture, photograph, image, biography and performance in any way, commercial or otherwise, in connection with the Materials and the sale, promotion and distribution thereof. The Author hereby waives any and all rights he or she may have, relating to his or her appearance in the Video or otherwise relating to the Materials, under all applicable privacy, likeness, personality or similar laws.

10. **Author Warranties.** The Author represents and warrants that the Article is original, that it has not been published, that the copyright interest is owned by the Author (or, if more than one author is listed at the beginning of this Agreement, by such authors collectively) and has not been assigned, licensed, or otherwise transferred to any other party. The Author represents and warrants that the author(s) listed at the top of this Agreement are the only authors of the Materials. If more than one author is listed at the top of this Agreement and if any such author has not entered into a separate Article and Video License Agreement with JoVE relating to the Materials, the Author represents and warrants that the Author has been authorized by each of the other such authors to execute this Agreement on his or her behalf and to bind him or her with respect to the terms of this Agreement as if each of them had been a party hereto as an Author. The Author warrants that the use, reproduction, distribution, public or private performance or display, and/or modification of all or any portion of the Materials does not and will not violate, infringe and/or misappropriate the patent, trademark, intellectual property or other rights of any third party. The Author represents and warrants that it has and will continue to comply with all government, institutional and other regulations, including, without limitation all institutional, laboratory, hospital, ethical, human and animal treatment, privacy, and all other rules, regulations, laws, procedures or guidelines, applicable to the Materials, and that all research involving human and animal subjects has been approved by the Author's relevant institutional review board.

11. **JoVE Discretion.** If the Author requests the assistance of JoVE in producing the Video in the Author's facility, the Author shall ensure that the presence of JoVE employees, agents or independent contractors is in accordance with the relevant regulations of the Author's institution. If more than one author is listed at the beginning of this Agreement, JoVE may, in its sole

## ARTICLE AND VIDEO LICENSE AGREEMENT

discretion, elect not take any action with respect to the Article until such time as it has received complete, executed Article and Video License Agreements from each such author. JoVE reserves the right, in its absolute and sole discretion and without giving any reason therefore, to accept or decline any work submitted to JoVE. JoVE and its employees, agents and independent contractors shall have full, unfettered access to the facilities of the Author or of the Author's institution as necessary to make the Video, whether actually published or not. JoVE has sole discretion as to the method of making and publishing the Materials, including, without limitation, to all decisions regarding editing, lighting, filming, timing of publication, if any, length, quality, content and the like.

12. **Indemnification.** The Author agrees to indemnify JoVE and/or its successors and assigns from and against any and all claims, costs, and expenses, including attorney's fees, arising out of any breach of any warranty or other representations contained herein. The Author further agrees to indemnify and hold harmless JoVE from and against any and all claims, costs, and expenses, including attorney's fees, resulting from the breach by the Author of any representation or warranty contained herein or from allegations or instances of violation of intellectual property rights, damage to the Author's or the Author's institution's facilities, fraud, libel, defamation, research, equipment, experiments, property damage, personal injury, violations of institutional, laboratory, hospital, ethical, human and animal treatment, privacy or other rules, regulations, laws, procedures or guidelines, liabilities and other losses or damages related in any way to the submission of work to JoVE, making of videos by JoVE, or publication in JoVE or elsewhere by JoVE. The Author shall be responsible for, and shall hold JoVE harmless from, damages caused by lack of sterilization, lack of cleanliness or by contamination due to


the making of a video by JoVE its employees, agents or independent contractors. All sterilization, cleanliness or decontamination procedures shall be solely the responsibility of the Author and shall be undertaken at the Author's expense. All indemnifications provided herein shall include JoVE's attorney's fees and costs related to said losses or damages. Such indemnification and holding harmless shall include such losses or damages incurred by, or in connection with, acts or omissions of JoVE, its employees, agents or independent contractors.

13. **Fees.** To cover the cost incurred for publication, JoVE must receive payment before production and publication of the Materials. Payment is due in 21 days of invoice. Should the Materials not be published due to an editorial or production decision, these funds will be returned to the Author. Withdrawal by the Author of any submitted Materials after final peer review approval will result in a US\$1,200 fee to cover pre-production expenses incurred by JoVE. If payment is not received by the completion of filming, production and publication of the Materials will be suspended until payment is received.

14. **Transfer, Governing Law.** This Agreement may be assigned by JoVE and shall inure to the benefits of any of JoVE's successors and assignees. This Agreement shall be governed and construed by the internal laws of the Commonwealth of Massachusetts without giving effect to any conflict of law provision thereunder. This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together shall be deemed to be one and the same agreement. A signed copy of this Agreement delivered by facsimile, e-mail or other means of electronic transmission shall be deemed to have the same legal effect as delivery of an original signed copy of this Agreement.

A signed copy of this document must be sent with all new submissions. Only one Agreement is required per submission.

### CORRESPONDING AUTHOR

Name:	Alexander Samol		
Department:	Department of Cardiology and Critical Care Medicine		
Institution:	Johannes Wesling University Hospital Minden		
Title:	MD		
Signature:		Date:	08/31/2019

Please submit a **signed** and **dated** copy of this license by one of the following three methods:

1. Upload an electronic version on the JoVE submission site
2. Fax the document to +1.866.381.2236
3. Mail the document to JoVE / Attn: JoVE Editorial / 1 Alewife Center #200 / Cambridge, MA 02140



612542.6 For questions, please contact us at [submissions@jove.com](mailto:submissions@jove.com) or +1.617.945.9051.



# Signature Certificate

Document Ref.: FY3YI-SUDRW-6Z26E-YFDCL

Document signed by:

	<p><b>Alexander Samol</b></p> <p>Verified E-mail: alexander.samol@muehlenkreisklinike n.de</p> <p>IP: 5.146.154.17      Date: 31 Aug 2019 09:46:20 UTC</p>	<p><i>Alexander Samol</i></p> 
---	--	---

Document completed by all parties on:  
31 Aug 2019 09:46:20 UTC

Page 1 of 1



Signed with PandaDoc.com

PandaDoc is the document platform that boosts your company's revenue by accelerating the way it transacts.

