

Evaluation of the diagnostic accuracy of smartphone electrocardiogram recorder compared to standard 12 lead electrocardiography in hospital settings

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ABSTRACT

الأهداف: تقييم الدقة التشخيصية للمحقات تخطيط القلب عن طريق الهواتف الذكية مقارنة بأجهزة تخطيط القلب النموذجية المستخدمة في المستشفيات.

الطريقة: تم إجراء مقارنة مقطعية في مركز قلب مرجعي في مدينة الرياض بالمملكة العربية السعودية. خضع خلالها 403 مريض ومريضة إلى عمل تخطيط القلب باستخدام أجهزة تخطيط القلب النموذجية وعمل تخطيط القلب عن طريق الهواتف الذكية. بعد ذلك تم فحص جميع التخطيطات من قبل استشاري كهرياء القلب للتأكد من التشخيص الدقيق، وتم بعدها توزيع ما مجموعه 806 تخطيط قلب بشكل عشوائي على 6 أطباء قلب لتشخيص التخطيطات وتقييم جودتها.

النتائج: شملت هذه الدراسة 211 ذكر (52%) و192 أنثى (48%). وتضمنت تخطيطات القلب 149 تخطيط (37%) غير طبيعي. وشمل ذلك: الرجفان الأذيني والتي شكلت 46 تخطيطاً (11%)، تسارع دقات القلب والتي شملت 35 تخطيطاً (9%)، ونبضات البطين المبكرة والتي شملت 33 تخطيطاً (8%). نتج عن تحليل البيانات أن إجراء تخطيط القلب باستخدام الهاتف الذكي يملك حساسية جيدة في تشخيص نبض القلب (97.3%)، مقابل 98% في حال استخدام أجهزة تخطيط القلب النموذجية. ومع ذلك، كان أطباء القلب أكثر ثقة أثناء تحليل تخطيطات القلب النموذجية في 91% من الحالات، مقارنةً بـ 71% من تخطيطات القلب التي تم إجرائها عن طريق الهاتف الذكي.

الخاتمة: تمتلك ملحقات الهواتف الذكية المصممة لتخطيط القلب دقة جيدة في تشخيص نظم القلب.

Objectives: To evaluate Smartphone-based Electrocardiogram Recorders (S-ECG-R) diagnostic accuracy compared to standard 12 lead ECG.

Methods: A cross-sectional comparative study was conducted in a tertiary cardiac center in Riyadh, Kingdom of Saudi Arabia from December 2017 to February 2018. A total of 403 patients underwent

both standard 12 leads ECG and S-ECG-R recordings in the same time. All recordings were checked initially by an electrophysiologist to confirm the accurate diagnosis. Then, the 806 recordings were randomly distributed among 6 certified cardiologists to interpret the rhythms and to evaluate rhythms quality.

Results: In this study 211 (52%) males and 192 (48%) females were included, with a mean age of 52±18 years. Of the included rhythms, 149 (37%) were abnormal. The majority of which were atrial fibrillation 46 (11%), sinus tachycardia 35 (9%) and premature ventricular contractions 33 (8%). Analysis revealed an overall similar diagnostic sensitivity and specificity of S-ECG-R to the standard 12 lead ECG recording, sensitivity (97.3% versus (vs) 98%) and specificity (99.6% vs. 99.6%). However, cardiologists were more confident during interpreting standard ECG recordings in 91% of the recordings while in 71% of S-ECG-R recordings.

Conclusion: The ECG rhythms produced by smartphone accessory have a good diagnostic accuracy in diagnosing arrhythmias. The utility of using S-ECG-R for out-patient is to be determined.

*Saudi Med J 2019; Vol. 40 (6): 575-581
doi: 10.15537/smj.2019.6.24206*

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Received 29th November 2018. Accepted 29th April 2019.

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Several companies have tried to harness the features of smartphones to answer medical needs.¹ One emerging tool in cardiology is smartphone-based heart rhythm recorders.² The smartphone-based one lead electrocardiogram recorder (S-ECG-R) is a small tool designed as a smartphone accessory or cover. It records Electrocardiogram (ECG) data and sends this data wirelessly to the smartphone.³ It records the rhythm when users activate the application and place their fingers on the electrodes.⁴ The rhythms can be saved as a PDF file and/or be sent by email.⁴ It is a small, convenient, and lifelong ECG recorder.³ However, the diagnostic accuracy of these ECG-recording devices remains unclear, which makes cardiologists hesitant to use them for patients' healthcare despite the potential added value.⁵ The S-ECG-R may address a real clinical need when diagnosing arrhythmias when the standard 12 lead ECG or other routine recorders are unavailable, negative, or when the pattern is infrequent.⁶

Many studies have aimed to determine the usability, accuracy, and cost-effectiveness of S-ECG-R in detecting arrhythmias.^{7,8} Lau et al⁹ investigated the ability of S-ECG-R to detect atrial fibrillation; they reported a sensitivity, specificity, and overall accuracy of 98%, 97%, and 97% respectively. Similarly, the SEARCH AF study screened 1000 pharmacy customers older than 65 years with a S-ECG-R; they identified newly diagnosed atrial fibrillation (AF) in 1.5% of the screened individuals.¹⁰ The AF and atrial flutter responses after electrophysiology ablation were tested using S-ECG-R with 100% sensitivity and 97% specificity for detection of AF and atrial flutter.¹¹ Indeed, many studies have focused on S-ECG-R accuracy in detecting AF.^{9,11,12} However, other arrhythmias such as sinus tachycardia, ectopic beats, and heart blocks are also important causes of palpitation.¹³ Thus, detecting these arrhythmias could assist clinicians in identifying and treating palpitation etiology.

Saudi Arabia is the 3rd highest country in the world in term of smartphone use with an average of 1.6 smartphones per individual; this is expected to increase further.¹⁴ Surprisingly, there are no prior studies in Saudi Arabia looking at the diagnostic utility of S-ECG-R; therefore, cardiologists are still reluctant to use S-ECG-R to diagnose and monitor arrhythmias. The aim of

this study is to investigate the diagnostic accuracy of S-ECG-R in detecting the arrhythmia compared to the standard 12 leads in ECG recording. We hypothesized that S-ECG-R may provide a reasonable accuracy in detecting arrhythmias versus standard ECG.

Methods. This was a cross-sectional comparative study conducted at King Abdulaziz Medical City (KAMC), Riyadh, Saudi Arabia. The KAMC is one of the biggest tertiary healthcare centers in Saudi Arabia. Data were collected from the emergency department, outpatient ECG room, cardiac wards, and catheterization laboratory. The study was conducted between December 2017 to February 2018. S-ECG-R as well as standard ECG were performed by certified personnel at the same point of time. However, in occasions when patients' situation didn't permit true simultaneous recordings, there was a gap between recordings ranges from 5 seconds to 2 minutes.

Study participants. All adult patients undergoing standard ECG during this study period were included after giving informed written consent. We excluded patients with significant hand tremors that compromised their ability to hold the device (30 patients) as well as those with severe arm weakness or paralysis (12 patients) or amputated hands (2 patients). Subjects with a pacemaker, cardiac resynchronization therapy (CRT), or implantable cardioverter defibrillator (ICD) were excluded due to the manufacturer's instructions (10 patients).⁴

Sample size and sampling technique. The sample size was calculated using Roasoft calculator.¹⁵ At 95% confidence, 5% margin of error, and prevalence of 50%, the optimal calculated sample size was 380 patients. The ECG was recoded twice for each patient—first using the standard 12 lead ECG followed by S-ECG-R. Thus, a total of 806 ECG (403 recording using S-ECG-R, 403 recording using standard ECG) were collected. The normal-to-abnormal ECG ratios were held at 2:1 to capture the variation in both normal and abnormal rhythms. Thus, one-third of the sample was reserved for abnormal cases, and the remainder were for patients with normal rhythm. Consecutive sampling techniques were used until the sample size was reached; we enrolled all subjects who fulfilled the inclusion criteria and were willing to participate. The King Abdullah International Medical Research Center (KAIMARC) approved the study, and written informed consent form was taken from each patient.

Devices and data collection. A standard 12 lead ECG was recorded from all patients before index test

Disclosure. Authors have no conflict of interests, and the work was not supported or funded by any drug company.

recording at relatively the same time and setting to reduce time bias. The standard ECG was recorded by an ECG technician if the ECG was performed in the out-patient setting and by the patient's primary nurse if the recording was done in the emergency department or cardiac wards. A General Electric Mac 5500 EKG machine was used for all standard ECG recordings. The recording automatically captured 10 seconds of cardiac rhythms and presented them from 12 different directions using 10 leads. All ECG recordings were sent to the medical record in soft copy and were then downloaded and saved in a folder for later evaluation.

The Alivecor Kardia, San Francisco, Calif S-ECG-R was used for the smartphone recording. This is an FDA approved device that records ECG via a smartphone

accessory and transmits it wirelessly to the smartphone. The accessory is paired with iPhone and Android devices and communicates wirelessly with the Kardia app for display, analysis, and communication.² The accessory has 2 electrodes that record the difference in electrical voltage between the right and left arm; thus, it produces a lead comparable to the lead I in a standard 12 lead ECG. A single smartphone device was used to capture the ECG rhythm for all patients. Patients were given simple instructions on how to use the device—the Alivecor S-ECG-R was held with both hands to record the rhythm. The average recording time was 30 seconds except when the subjects moved their hands off of the device. This stopped recording automatically and required the patient to repeat the process. All recorded

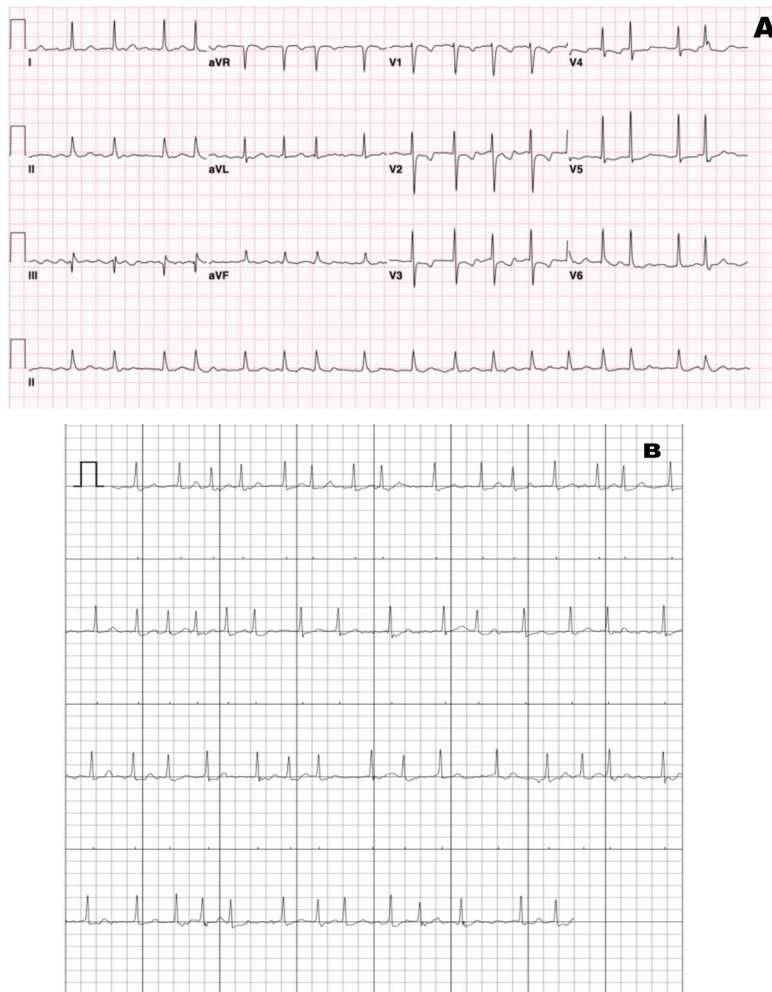


Figure 1 - Electrocardiogram (ECG) recording for 64 years old women were complaining of palpitation and was found to have atrial fibrillation with rapid ventricular response recorded with (A) Standard ECG (B) S-ECG-R. ECG - electrocardiogram, S-ECG-R - smartphone-based electrocardiogram recorders

Table 1 - Summary profile of participants.

Variables	n	(%)
Age mean \pm SD	18 \pm 52	
Age median (IQR)	55 (41,62)	
Gender		
Male	211	(52.4)
Female	192	(47.6)
Nationality		
Saudi	374	(92.8)
Non-Saudi	29	(6.80)
Source of patient		
OPD	96	(23.8)
Cardiac wards	166	(41.2)
ED	135	(33.5)
EP lab	4	(1.0)
CCU	2	(0.5)
Symptoms		
None	375	(93.1)
Shortness of Breath	9	(2.2)
Chest Pain	16	(4.0)
Dizziness	3	(0.7)
ECG rhythms diagnosis		
Normal sinus rhythm	254	(63)
Sinus bradycardia (HR below 60 bpm)	21	(5)
Sinus tachycardia (HR above 100 bpm)	35	(9)
Sinus rhythm with premature ventricular contraction/s	33	(8)
Sinus rhythm with premature atrial contraction/s	3	(1)
Atrial fibrillation	46	(11)
Atrial flutter	3	(1)
2nd degree AV block Mobitz type I	3	(1)
Supraventricular tachycardia	5	(1)

SD - standard deviation, HR - heart rate, CCU - Coronary Care Unit, EP - ElectroPhysiology laboratory, ED - Emergency Department, OPD - Out Patients Department

ECGs were sent via email with the patients' serial numbers for evaluation by an electrophysiologist who confirmed the correct diagnosis.

Rhythm interpretation sessions. After the initial phase of data collection, the 806 rhythms were equally divided via random sampling among 6 cardiologists for interpretation (board-certified physicians currently practicing with a minimum of 5 years of experience in cardiology). They were contacted through email and invited to participate voluntarily in the study. The time and place were determined for an interpretation meeting. Each cardiologist was given soft copies of the 134 recordings: half of these were standard, and the other half were S-ECG-R rhythms (Figure 1). The recordings were randomized in a way that the cardiologist who

Table 2 - Summary diagnostic accuracy.

Diagnostic accuracy indices	Standard ECG	Smartphone ECG
Sensitivity	146 (98)	145 (97.3)
Specificity	253 (99.6)	253 (99.6)
Positive predictive value	(99.30)	(99.30)
Negative predictive value	(98.80)	(98.40)
False Positive Rate	1 (.40)	1 (.40)
False Negative Rate	3 (2)	4 (2.7)
Area under the curve, 95% CI [^]	0.988 (0.97,1.00)	0.985 (0.97,1.00)
P-value*	<0.01	<0.01

*Receiver operator characteristic analysis p-value <0.05, ^Confidence Interval p-value <0.05, ECG - electrocardiogram, S-ECG-R - smartphone-based electrocardiogram recorders

Table 3 - Comparison of satisfaction and confidence with test results.

Variables	Standard ECG		S-ECG-R	
	n	(%)	n	(%)
Confidence level				
Not Confident	0	(0.00)	1	(0.20)
Slightly Confident	0	(0.00)	21	(5.20)
Moderately Confident	35	(8.70)	94	(23.30)
Very Confident	264	(65.70)	188	(46.70)
Extremely Confident	103	(25.60)	99	(24.60)
Satisfaction level				
Very Unsatisfied	0	(0.00)	3	(0.70)
Unsatisfied	2	(0.50)	19	(4.70)
Unsure	18	(4.50)	48	(11.90)
Satisfied	255	(63.40)	213	(52.90)
Very Satisfied	127	(31.60)	120	(29.80)

ECG - electrocardiogram, S-ECG-R - smartphone-based electrocardiogram recorders

read the standard ECG for a patient did not read the same S-ECG-R for that particular patient to reduce interpretation bias. For all recordings, cardiologists weren't given any clinical information about patients or recording settings. Also, automatic interpretations were electronically omitted from all recordings. Clear instructions were given that the purpose of the interpretation is find abnormal rhythm only rather than ST-T wave changes or other abnormalities other than rhythm disturbance as it is not the purpose of the study and single lead can't pick up these abnormalities compared to 12 leads ECG. For each recording, the cardiologist answered 4 questions: 1) is the rhythm normal or abnormal?; 2) what is the exact diagnosis/rhythm interpretation?; 3) how confident were they in the diagnosis; and 4) what is the level of satisfaction about the quality of the rhythms. The latter 2 were assessed on a 5-point Likert scale with 1 ranked as least and 5 as maximum.

Statistical analysis. The data was analyzed using Statistical Package for the Social Sciences Version 22.0

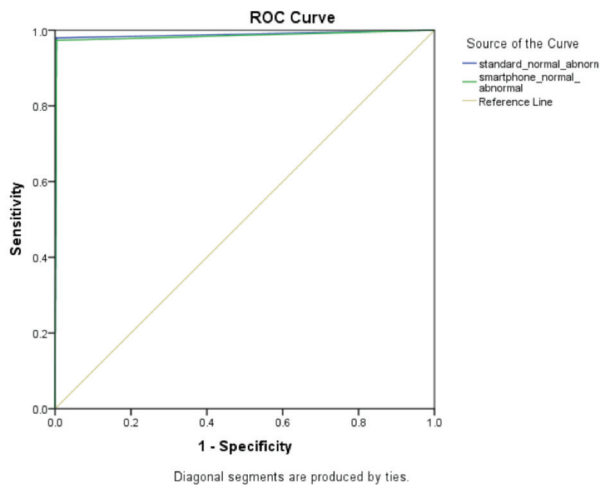


Figure 2 - Receiver operating characteristic curve for S-ECG-R and standard 12 leads ECG recordings. ECG - Electrocardiogram, S-ECG-R - Smartphone-based Electrocardiogram Recorders, ROC - Receiver Operating Characteristics Curve.

(IBM Corporation, Armonk, NY, USA). Descriptive statistics were reported in a tabular form as percentages and numbers. The diagnostic accuracy was measured using the sensitivity, specificity, positive predictive value, and negative predictive value. The level of satisfaction and confidence was assessed on a 5-point Likert scale.¹⁶ The receiver operating characteristic curve (ROC) and area under the curve were reported for both the standard and S-ECG-R. The p -value of 0.05 was considered statistically significant for all the tests.

Results. A total of 806 recordings for 403 patients were included. Nearly half were male, and the mean age was 52 ± 18 years. Most patients were asymptomatic during the recording. However, 28 (8%) of the patients complained of symptoms during recording e.g. chest pain, shortness of breath. Around two-thirds of the recorded rhythms were normal sinus rhythm 254 (63%), and 149 (37%) were abnormal. The majority of abnormal rhythms were atrial fibrillation, sinus tachycardia, and premature ventricular contractions: 46 (11%), 35 (9%), and 33 (8%) respectively (Table 1).

Analysis revealed an overall similar diagnostic metrics of S-ECG-R to standard 12 lead ECG rhythm including sensitivity (97.3% vs 98%) and specificity (99.6% vs 99.6%). The ROC analysis showed an area under the curve of 0.98 (95% CI: 0.97-1.0) and a p -value < 0.001 for both standard and S-ECG-R (Table 2, Figure 2).

Most standard ECG recordings were read with a high degree of confidence in diagnosis 364 (91%) compared to only 286 (71%) of S-ECG-R rhythms. Of the 403 patients' rhythms, suitable rhythm quality was

seen in 382 (90%) of the standard ECG recordings and 333 (82%) of the S-ECG-R rhythms. Physicians were dissatisfied with 22 (5%) of the S-ECG-R recorded rhythms and 2 (0.5%) of the standard ECG recordings.

Discussion. This study compared the diagnostic accuracy of a standard 12 lead ECG device to a novel smartphone ECG device. The results showed that both devices were comparable in terms of diagnostic accuracy of normal and abnormal rhythms. These findings support Lau et al⁹ who demonstrated that the S-ECG-R has a sensitivity and specificity of 98% and 97%, respectively. However, their study was limited to AF while the current study included both normal and various abnormal rhythms. Similarly, Haberman et al¹⁷ found an equal diagnostic accuracy for standard ECG and S-ECG-R in detecting the rate, rhythm, and atrioventricular blocks.¹⁷ Nevertheless, our analysis showed a higher diagnostic accuracy that could be explained by the strict inclusion criteria in our study. We excluded patients who could not steadily hold the accessory with both hands. Around 4% of the general population have an essential tremor suggesting that we excluded people like to have poor recording quality; this might have led to overestimation of our results.¹⁸

Paroxysmal AF is predominantly targeted by S-ECG-R studies. That's probably because it is the most common arrhythmia worldwide.¹⁹ It has an important clinical significance and is sometimes can't be diagnosed using a Holter monitor.²⁰ However, this study included the most common types of arrhythmias including AF, sinus tachycardia, sinus bradycardia, premature complexes, heart blocks, and supraventricular tachycardia. These can cause palpitation and may represent a clinical challenge.¹³ Investigating the utility and diagnostic accuracy of such devices may open the door for a new theme of diagnosing and monitoring these arrhythmia—especially those that are difficult to diagnose using other standard methods.²¹ This might reflect on the quality of care, cost, patient engagement in healthcare, and patient satisfaction.²²

This study compared S-ECG-R with standard 12 lead ECG. A drawback of S-ECG-R is that it enables the recording of lead I only, which is not always the preferred lead to diagnose arrhythmia.²³ In addition, ischemic and chambers enlargement seen in standard 12 leads ECG are most likely missed—they cannot be diagnosed from a single lead.²⁴ On the other hand, S-ECG-R allows 30 seconds of continuous recording versus 10 second with other 12 lead ECGs.

The physician confidence in diagnosis and satisfaction with any new diagnostic tool are essential for effective

integration in clinical practice. This is also related to the number of other tests requested before reaching a certain diagnosis.²⁵ Our study showed worse physician satisfaction with smartphone ECG recordings. Around 12% of the S-ECG-R rhythms (vs only 4.5% of standard ECG) were reported as “unsure” about satisfaction with the rhythm recordings quality. This could be because of several factors. Cardiologists were exposed to S-ECG-R rhythms for the first time, but they were familiar with standard ECG recordings. In addition, some rhythms were found to have artifacts in S-ECG-R. This could be because the smartphone recordings are very sensitive to hand motions and electrical noise despite the presence of 50/60 Hz filter.²⁶ In addition, some patients were nervous about the new form of ECG recording—thus they might have unintentionally pressed on the electrodes harder than needed leading to unsteady recording.²⁷ Repeated exposure to S-ECG-R recordings might cause patients and physicians to become more familiar and comfortable with this approach.

Patient satisfaction with this diagnostic test is a core factor underlying effective medical care.²⁸ Resistance to change and the use of non-standard smartphone-based medical tests are expected.²⁹ However, according to the SPEAR trial—which looked at S-ECG-R accuracy in pediatric patients in an out-patient setting—95% of the users found the device easy to use and would like to continue using it after the trial.³⁰

Numerous measures were taken at the time of study planning to overcome biases and confounders. The data collection was carried out as part of the routine practice in the hospital setting with a ratio of normal to abnormal rhythms at 2:1. This explore the comparability of the results of both the normal and abnormal rhythms. All ECG diagnoses were verified by an electrophysiologist. Additionally, the cardiologists were blinded to actual diagnosis and patients’ clinical conditions.

One limitation of the study is possible selection bias due to nonprobability sampling technique. This limitation could not be overcome because the data collection was carried out in the hospital setting; patients presenting to the ED and ward were included based on their availability during data collection sessions. The other limitation is that the cardiologists who were evaluating the soft copies of the ECG rhythms on the very first look could differentiate the difference between the ECG produced by the standard device vs S-ECG-R. This could have introduced a reporting bias on behalf of the cardiologists regarding the overall satisfaction and confidence of the results. To overcome this issue, none of the evaluators were given the same recording for each patient; thus, the ECG recording for the same patient was evaluated by 2 different cardiologists.

Patients who were very sick or not fully conscious were excluded from the study—thus, another limitation could be applicability of this tool in very sick patients. Furthermore, patients with significant hand tremors or weakness cannot hold the S-ECG device properly—this limits the use of the device in such patients.

mHeath statistics state that 93% of physicians believe that mobile health apps can improve patient’s health.³¹ Smartphones are becoming an essential component of life, and they can increase access to diagnostic tests.^{32,33} This can quicken the diagnostic process and increase patients’ satisfaction and quality of care. However, as the number of smartphones increase and become part of medical accessories and applications, care should be taken to verify their utility in health care.³⁴

In conclusion, ECG rhythms produced by smartphone accessory have a good diagnostic accuracy in diagnosing arrhythmias for tremor free patients. The use of S-ECG-R for out-patient rhythm recordings may permit diagnosing arrhythmias in selected patients when other diagnostic tools are negative. Further research is needed to evaluate S-ECG-R diagnostic accuracy in out-patient settings. Establishment and engagement in medical research to evaluate the newly evolved smartphones based medical tools is needed to build a confident judgment of these devices and therefore use them in the most appropriate settings.³⁵

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