

## Original Research Article

# A comparative study to evaluate the clinical utility and performance of a new hand-held mobile electrocardiogram device

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## ABSTRACT

**Background:** Electrocardiogram (ECG) is a non-invasive test which can provide clue for the presence of cardiac diseases. Simple, handheld devices, sufficiently miniaturized are useful for a widespread use. New devices, however, need to be compared with the standard ones for their performance in the real-world practice. Here in we report clinical utility of a handheld device.

**Methods:** Kardioscreen™ is a mobile and handheld device. It's been approved for safety and performance standards and it has been certified for 'Conformite Europeenne' (CE). Using this device, a comparative blinded study with a conventional and commercially available standard 12 lead ECG machine was done. 604 ECGs recorded from 302 patients with various clinical disorders were coded and analyzed by two blinded observers. A third cardiologist adjudicated the reports. The reports were then correlated for the ECG patterns generated and with the clinical diagnosis. Computer generated measurements of various durations and intervals were also analyzed and compared. Regression analysis was used to compare the values. SPSS 21 software was used to analyze the data.

**Results:** Kardioscreen device could provide recordings to diagnose including ST elevation (99%), non-ST elevation myocardial infarction (94.1%), chamber-hypertrophy (87%), conduction blocks (99%), and arrhythmias (96.4%), with good correlations with the comparator for pattern recognition. Also, computer generated measurements were significantly correlated with the comparator (R=0.96 for HR, R=0.82 for QRSd, R=0.86 for QT/QTc, R=0.76 for PR).

**Conclusions:** The Kardioscreen device is a reliable tool for electrocardiographic diagnosis of common clinical cardiac disorders.

**Keywords:** Comparison, Electrocardiography, Handheld ECG device

## INTRODUCTION

The electrocardiogram (ECG) is one of the most commonly used technologies for a quick and non-invasive diagnosis of cardiac disorders. Its availability, standardized technique of recording and broadly accepted approach to its interpretation for making a clinical

diagnosis are some important reasons for its continued popularity and utility despite its well-appreciated limitations. Many clinical guidelines issued by various American, European, and other societies of cardiologists and other care providers have placed ECG recording and reporting as a critical step in the clinical algorithms of management of various cardiac disorders especially in a

patient with chest pain to rule in or rule out an acute coronary syndrome notwithstanding its clinical caveats.<sup>1,2</sup> And, pattern recognition in an ECG by a trained clinician continues to play a critical role in the diagnostic approach; and, it scores over computer generated data. The ECG recording is standardized for a long time. The simplicity of a recording device, ease of storing, transfer and retrievability of these recordings are important developments.

### Objective

We set out to study the clinical performance of the Kardioscreen™ in the ‘real world’ scenario and compare its performance to yet another commercially available ECG recorder. Such studies are important to generate clinical confidence given the fact that the recordings are influenced by various technical characteristics. Studies have been done prior to this, on the advantages and benefits to patients when ECG based diagnosis is done by the clinician at the primary touch point.<sup>3-5</sup>

### METHODS

We studied the KardioScreen- a scalable 6 lead and 12 lead ECG recording device, designed and manufactured by iMEDRIX INC Milpitas, USA. KardioScreen works in conjunction with a mobile app residing in an Android Tablet. This device functions in two modes, 6-lead version supports limb leads and augmented leads, while the 12-lead version records like any standard 12-lead ECG instrument. The device supports ECG bandwidth from 0.05 Hz to 75 Hz, providing ECG reports just like any other hospital grade ECG device. The device and the accompanying mobile application would enable physicians to collect data in a clinically useful manner; also, it alerts lead placement error. The ECG software supports the collection of data such as the patient’s medical history, current vital signs and clinical assessment, helping to generate a comprehensive report. KardioScreen device with the accessories are shown in Figure 1.



Figure 1: KardioScreen product.

The study was a single center, blinded comparative study. KardioScreen was used and compared with 12-lead ECG device, Page writer TC-30 by Philips Healthcare.

The study was conducted at the JSS Hospital, MG Road, Mysuru, Karnataka, India, starting from 14<sup>th</sup> June 2017 to 27<sup>th</sup> October 2017 for a duration of 4 months. Ethical committee approval was obtained before the commencement of the study. Inpatients and outpatients attending cardiology center at JSS Hospital were recruited for the study, participants with age less than 12 years and pregnant woman were excluded. Thus, total of 302 subjects were recruited. Informed consent was obtained from each participant.

ECGs were recorded in a standardized way with patient in supine position after about 3 minutes of rest and during quiet breathing, consecutively using both the devices. Leads were placed on identical locations (skin marks left behind by the previous recording provided the roadmap). Patient’s clinical data were recorded too along with the ECG. All the recordings were of clinical quality traces and repeat tracings were obtained in case required. The computer-generated standard measurements including heart rate, PR, QT/QTc, QRS duration were recorded by both the machines.

The data from all the ECGs recorded using KardioScreen device is fed to a proprietary ECG analysis software, developed by M/s iMedrix Inc. USA. This software is used to generate heart rate (HR), PR, QT/QTc and QRS duration.

Comparator device, TC-30 also provided these computer-generated measurements through its own software. The two sets of data were compared for correlations.

All the ECGs were coded, by removing patient’s personal information and clinical information, and a random case number was generated. These coded ECGs records were subjected for ‘double blind review’ by two practicing cardiologists. Each cardiologist reviewed all 604 ECG records. Each reviewer reported his/her impression on every ECG recording in a systematic way. The reporting comments were recorded and tabulated for every record. These reports were further evaluated and adjudicated by another experienced cardiologist. After reviewing, the ECG reports they were de-coded and correlated for clinical diagnosis, and reviewed for visual pattern recognition on both the recording systems.

Using this final report, the number of ECG records which matched for pattern recognition comparison and computer-generated measurements between KardioScreen ECG device and Philips Page writer TC-30 were analyzed using SPSS-21 software. Statistical methods were applied using this tool to analyze the data. Percentage of acceptance, sensitivity and specificity (ECG morphology accuracy and clinical interpretation) for the KardioScreen device were calculated.

## RESULTS

302 subjects (men=202, women=100, minimum age=16 years, maximum age=91 years) participated in this study. A total of 604 ECGs were recorded using both the devices, participants distribution is tabulated in Table 1. After 'double blinded review' by two cardiologists, there were a total of 1208 reports available for analysis. Interpretation from each report were tabulated and adjudicated for further analysis.

**Table 1: Participants age and gender-based distribution.**

Age range (in years)	Men	Women	Total
11-20	8	10	18
21-30	17	10	27
31-40	15	15	30
41-50	30	18	48
51-60	34	22	56
61-70	58	11	69
71-80	32	9	41
81-91	8	5	13

Of 302 subjects, 27% were having ischemic heart disease, 20% with various rhythm abnormalities, 26% subjects with chamber hypertrophy and bundle branch blocks and 27% were normal subjects. Abnormality distribution is provided in Table 2.

**Table 2: Abnormality distribution table.**

Cardiac abnormality	Total
Ischemic heart diseases	82 (Men=60, Women=22)
Participants with rhythm abnormalities	61 (Men=39, Women=22)
Participants with other abnormalities (hypertrophy, bundle branch blocks)	78 (Men=67, Women=11)
Participants with normal ECG	104 (Men=53, Women=51)

**Table 3: Pattern matching correlation, sensitivity and specificity details between KardioScreen and TC-30.**

Clinical diagnosis and morphology correlation	R=0.92
Sensitivity	92%
Specificity	93%

Total number of records compared, N=604

ECG patterns and interpretations available from TC-30 device were considered as reference. Various ECG morphology patterns and interpretations generated from KardioScreen device were compared to that of TC-30 device. Pattern matching and morphology correlation, sensitivity, specificity of KardioScreen device were calculated. KardioScreen device reported excellent

correlation co-efficient, R=0.92 for morphology and pattern matching. The device also reported 92% sensitivity and 93% specificity, with-respect-to the comparator device, details provided in Table 3.

For analyzing computerized measurement, 192 records from each group were available for comparison. Measurements of heart rate (HR), QRS duration, PR duration, QT/QTc duration were compared. Analysis revealed a set of correlation values between the measurements obtained from two devices. Statistical methods of correlation and regression analysis techniques were used to estimate the degree of correlation using SPSS 21 software. Measurements were correlated as follows; heart rate (HR) correlation, R=0.96; QRS duration correlation, R=0.82; QT/QTc interval correlation, R=0.86 and PR interval correlation, R=0.76. Results are tabulated in Table 4.

**Table 4: Correlation ratio for computer generated measurements between KardioScreen and TC-30.**

Details	Statistics
Number of subjects	N=192
Heart rate correlation	R=0.96
QRS duration correlation	R=0.82
QT/QTc interval correlation	R=0.86
PR interval correlation	R=0.76

## DISCUSSION

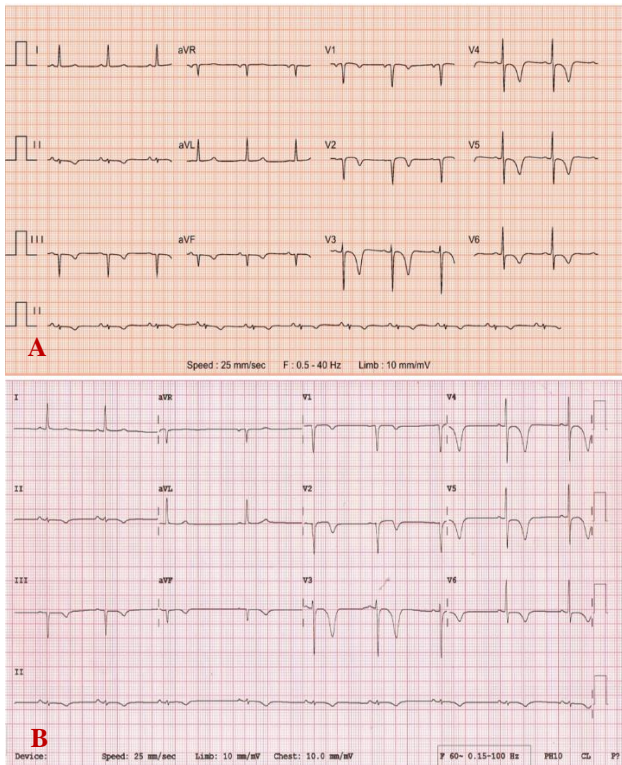
In this single centre blinded comparative clinical study, the handheld portable Kardioscreen ECG device was compared to a commercially available standard hospital grade device. Device KardioScreen was able to allow the clinical recognition of chamber hypertrophy, cardiac arrhythmia, and various ECG patterns described in patients with acute coronary syndromes.

Further, the durations and intervals, measured electronically from the electrocardiograms recorded using both the devices were compared. And a correlation coefficient of R=0.96 for HR, R=0.82 for QRS duration, R=0.86 for QT/QTc and R=0.76 for PR interval was found. This reflects the utility of the Kardioscreen device for measuring clinically useful measurements.

The pattern recognition to make ECG diagnosis by the clinicians is an accepted and well described method. The specific ECG patterns occur on the basis of electrophysiological changes produced in a diseased state. However, short comings of such an approach is well known. The variations in repolarization segment (ST-T) may misguide one, especially when diligent attention to clinical details is not given, resulting in either under-diagnosis or over-diagnosis. Indeed, with the increasing incidence of cardiovascular diseases, deployable technology to make clinical decisions should be simple and reliable. The clinical performance of the recording



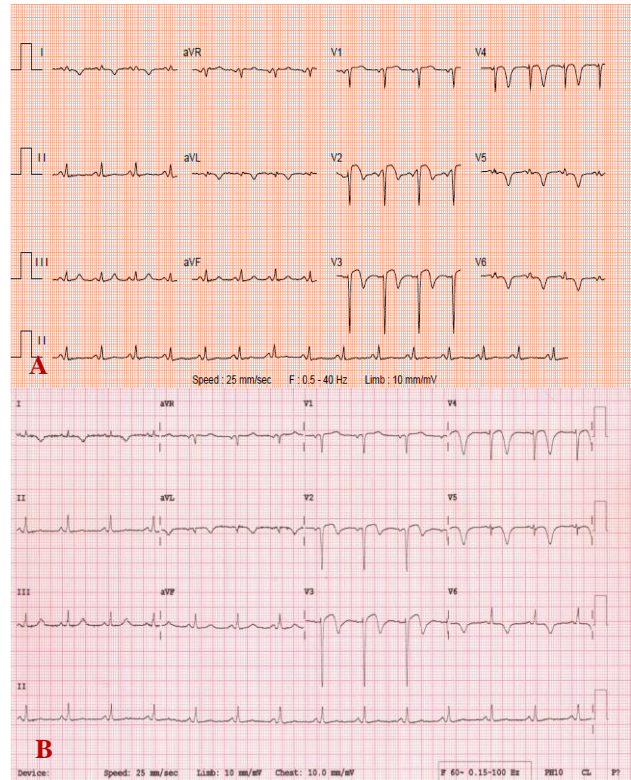
unit is a key determinant in the quality of data obtained. Importance of ECG in cardiac evaluation, especially in emergency situations, cannot be overemphasized. ECG is a good guide to make clinical and therapeutic decisions, considering many other reliable tests, may not be available as promptly as one would like. ECG recording device as a point of care technology is available for decades, though the interest in miniaturization is an exciting and welcome development. However, these new devices need to be studied in real-world applications.



Gender: Male, Age: 46 years.

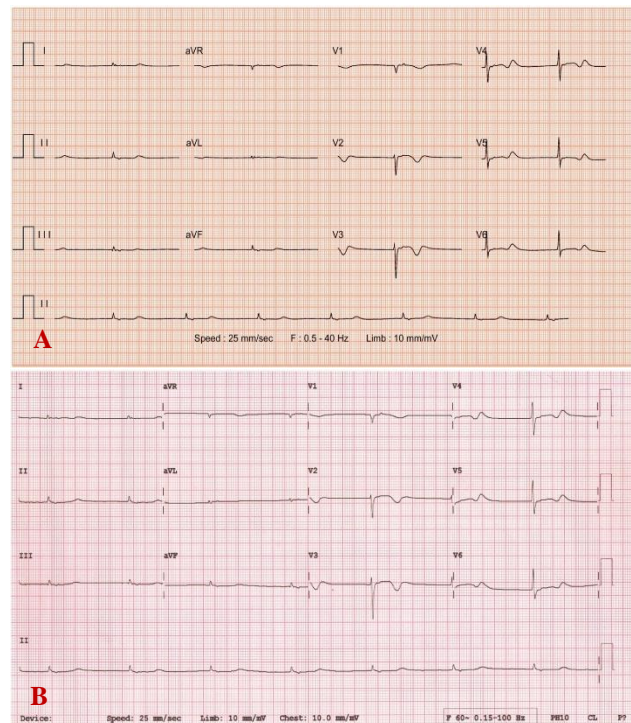
**Figure 2: Sample NSTEMI recording using (A) KardioScreen and (B) TC-30.**

604 ECGs recorded from both the devices, were coded and were interpreted independently. Further, the interpretations were adjudicated by another investigator. ECGs obtained from both the devices produced similar pattern in a recognizable way and were of clinical value. After de-coding all the ECGs, the correlations for the clinical diagnosis and variations were compared and found to be excellent. The diagnosis of Ischemic heart disease spectrum like NSTEMI and STEMI recorded on patients with those ailments was correctly picked-up as shown in Figure 2 and Figure 3. It was also noted that the diagnosis of conduction blocks, and ectopic arrhythmias as shown in Figure 4 and 5 respectively, were also correctly classified and correlated with the ECGs recorded on comparator. Previously published studies have been recently reviewed, various authors express the paucity of the clinical studies done in a systematic manner, though number of devices are reported to be satisfactory.<sup>6-8</sup>



Gender: Male, Age: 54 years.

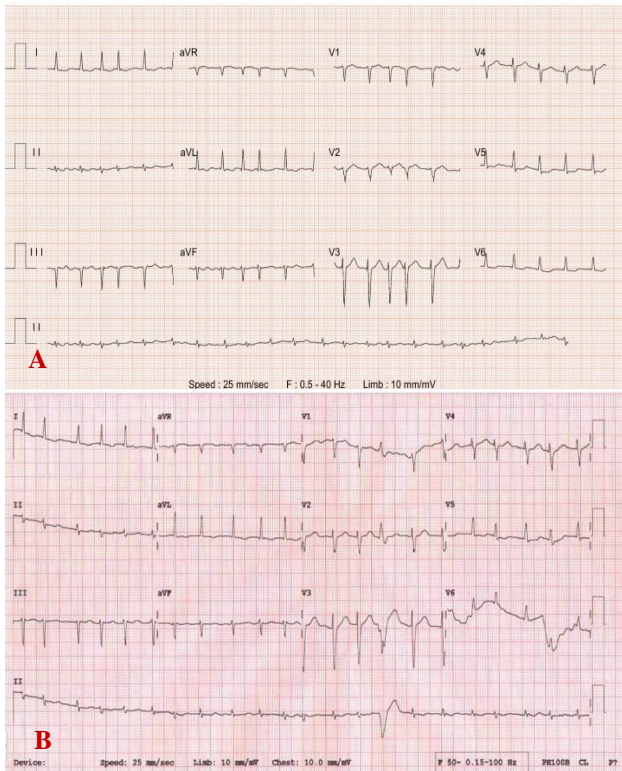
**Figure 3: Sample STEMI recording using KardioScreen (A) and TC-30 (B).**



Gender: Male, Age: 78 years.

**Figure 4: Sample conduction block, 3<sup>rd</sup> degree AV block, recording using (A) KardioScreen and (B) TC-30.**





Gender: Male, Age: 46 years.

**Figure 5: Sample arrhythmia condition, atrial fibrillation recording using (A) KardioScreen and (B) TC-30.**

The device, KardioScreen has already been tested for accuracy and performance characteristics.<sup>9</sup> It is a CE certified Class-II device. The amplitude and interval measurements were tested for 192 records, using datasets as recommended by International Common Standards for quantitative electrocardiography (CSE), which are the standardized ECG test vectors accepted globally. The device has been approved for clinical use, by the Federation of Indian Export Organizations (FIEO).

The battery-operated pocket size device, measuring 18×8 cm and device weighing less than 200 gm. It comes with an ECG cable, which can be used with standard clamps and bulbs. A rugged carry-pouch accommodates the whole unit. Making the whole solution aptly mobile, further simplicity of its use and makes it an attractive solution for field screening, office practice and easy deployment in the various departments in a hospital set-up. Single centre experience, small clinical sample and having no definite and final test like coronary angiogram in patients with acute coronary syndromes are some of the limitations of this study. However, clinician being blinded to the diagnosis and device used in the recording are the strengths. A larger sample from a multi-centric study in a real-world practice would definitely be useful.

The device KardioScreen also supports secure cloud technology, for record storage and retrieval. Authenticity and fidelity of the end-to-end transmission and storage of

the data through this cloud server have been verified, without any loss in record quality. Reports and doctor's comments can be retrieved anytime and anywhere. This feature will enable the treating medical care professionals and the remotely reviewing physician to collaborate and provide appropriate care in required clinical situations. Larger scale clinical studies including ambulance-based networking and spoke-hub model, for various varieties of electro-cardiological disorders, will further strengthen this device's utility in clinical practice.

## CONCLUSION

We conclude that, in this single centre study, the KardioScreen device was found to be a simple and useful for detecting common cardiac disorders and its accuracy is comparable to other devices used in clinical practice. The present study illustrates its utility in clinical settings.

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## REFERENCES

1. Amsterdam EA, Wenger NK, Brindis RG, Casey DE, Ganiats TG, Holmes DR, et al. 2014 AHA/ACC guideline for the management of patients with non-ST-elevation acute coronary syndromes: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol.* 2014;64(24):e139-228.
2. Kligfield P, Gettes LS, Bailey JJ, Childers R, Deal BJ, Hancock EW, et al. Recommendations for the standardization and interpretation of the electrocardiogram. *J Am Coll Cardiol.* 2007;49(10):1109-27.
3. Clemmensen P, Ripa MS, Schoos M, Terkelsen CJ, Holmvang L. Pre-hospital ECG: benefits and difficulties. Available at: <http://docplayer.net/21421294-Pre-hospital-ecg-benefits-and-difficulties.html>. Accessed on 3 June 2019.
4. Quinn T, Johnsen S, Gale CP, Snooks H, McLean S, Woollard M, et al. Effects of prehospital 12-lead

- ECG on processes of care and mortality in acute coronary syndrome: a linked cohort study from the Myocardial Ischaemia National Audit Project. *Heart*. 2014;100:944-50.
5. Daudelin DH, Sayah AJ, Kwong M, Restuccia MC, Porcaro WA, Ruthazer R, et al. Improving use of prehospital 12-lead ECG for early identification and treatment of acute coronary syndrome and ST-elevation myocardial infarction. *Circulation: Cardiovasc Quality Outcomes*. 2010;3(3):316-23.
  6. Schulman-Marcus J, Prabhakaran D, Gaziano TA. Pre-hospital ECG for acute coronary syndrome in urban India: a cost-effectiveness analysis. *BMC Cardiovasc Disorders*. 2010;10(1):13.
  7. Bansal A, Joshi R. Portable out-of-hospital electrocardiography: A review of current technologies. *J Arrhythmia*. 2018;34(2):129-38.
  8. Mehta P, Sudheer KM. Development of a Low-Cost, Portable, 12-Lead ECG machine for health-care centres across rural India. *J Med Diagn Meth*. 2013;2(120):2.
  9. Gajendra G, Shastri R. KardioScree Testing and Validation document, for clinical accuracy and morphology comparison. document number, KS1612-06-01-1P0. Internal test document from M/S iMedrix Inc. Available at: <https://www.imedrix.com/>. Accessed on 3 June 2019.

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