



# Single-lead portable ECG devices: Perceptions and clinical accuracy compared to conventional cardiac monitoring

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## Abstract

**Introduction:** Portable ECG devices are widely available yet there are limited data on their accuracy, physician and patient perceptions, and ease of use. The purpose of this study was to evaluate the accuracy of 4 single-lead portable ECG devices compared to a conventional 3-lead hospital cardiac monitor and to assess physician and patient perceptions of portable ECG devices.

**Methods:** Twenty consecutive hospitalized patients were provided 4 portable ECG devices for 30 second cardiac rhythm recording. ECG rhythm strips from the portable ECG devices were interpreted by a group of 5 physician reviewers. The reviewers then compared the portable ECG device rhythm strips to simultaneously recorded hospital cardiac monitor rhythm strips to determine physician preference. A cardiac electrophysiologist interpreted ECG rhythm strips from the hospital cardiac monitor as the “gold standard.” Rhythm interpretations of the portable ECG devices and the hospital cardiac monitor were analyzed to evaluate clinical accuracy. Patient perceptions were evaluated by a 20-item questionnaire.

**Results:** There was less than 50% concordance of portable ECG device rhythm strips with the hospital cardiac monitor (when uninterpretable rhythm strips were included). Physicians usually preferred interpreting ECGs from hospital cardiac monitors compared to portable ECG devices. Manufacturer instructions were insufficient to allow patients to operate portable ECG devices in a limited time. Most patients felt comfortable using a portable ECG device if prescribed by a physician.

**Conclusion:** Portable ECG devices may be a reasonable option for long-term rhythm surveillance in select patients. Widespread use of these devices cannot be endorsed unless improvements in their accuracy are properly addressed.

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## Keywords:

Portable ECG device; Accuracy; Perception; Cardiac monitor; Arrhythmia

## Introduction

Conventional methods of arrhythmia diagnosis include 12-lead electrocardiogram (ECG), Holter monitor, cardiac event monitor, and loop recorders [1]. Portable ECG devices to monitor cardiac rhythm are now widely available for both patient and physician use. These devices are battery-operated, self-contained, handheld, leadless recorders with built-in displays. These devices vary in method of operation although all work via skin contact on the palm or chest, functioning as a single lead. Devices can record 30-second rhythm measurements or may function as continuous monitors upon patient trigger. Devices have an internal

memory card or cloud-based storage for immediate review or future analysis of multiple rhythm recordings. Depending on the device, the number of stored rhythm episodes ranges from 24 to >400. Data transmission is also device specific, occurring by a cable to a personal computer or using wireless Internet.

The United States Food and Drug Administration (FDA) has approved several portable ECG devices for direct sale to patients. Some of the benefits of a portable ECG device, as stated by one manufacturer [AliveCor, San Francisco, CA, USA], include low cost, portability, ease of use, utility in post-procedure monitoring, and self-reassurance [2]. Despite the widespread availability and increasing adoption of portable ECG devices by physicians and patients, there are limited data on their accuracy, physician and patient perceptions, and ease of use. The purpose of this study was two-fold: to evaluate the accuracy of 4 portable ECG

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devices compared to a conventional hospital cardiac monitor, and to assess physician and patient perceptions of portable ECG devices.

**Materials and methods**

This was a prospective, single center, cross-sectional study comparing quality and accuracy of 4 single-lead portable ECG devices (Device #1: Shenzhen Creative Industry Co., Easy ECG Monitor, PC-80A [Shenzhen, China]; Device #2: Beijing Choice Electronic Technology Co., Handheld ECG Monitor, MD-100B [Beijing, China]; Device #3: AliveCor, Heart Monitor, iPhone 4 model [San Francisco, CA, USA]; Device #4: Omron Corp., Portable ECG Monitor, HCG-801 [Lake Forest, IL, USA]) to a 3-lead conventional hospital cardiac monitor (Dräger, Infinity Acute Care System [Telford, PA, USA]). Supplemental information about the portable ECG devices may be found in Appendix A and photos of the portable ECG devices may be found in Figs. 2–5. The study also determined patient perceptions of the portable ECG devices via a questionnaire shown in Fig. 1. Twenty patients were enrolled in the study. Patient demographics are provided in Table 1. All patients provided written consent under a clinical protocol approved by the Rush University Medical Center Institutional Review Board.

Inclusion criteria for this study were literate, English speaking patients connected to a hospital cardiac monitor on a general medical floor, cardiac intensive care unit, or medical intensive care unit. Exclusion criteria were patients unable to independently hold a portable ECG device. Patients were selected consecutively and provided a written overview of the study. Upon consent, patients were advised to minimize movement and rest their arms on a tray table while using each portable ECG device. A written summary of instructions and pictorial representations of proper use (adapted from original manufacturer instructions) for each portable ECG device were provided to each patient. Patients were provided 3 minutes to operate each device and if unable to operate a device properly, an additional 3 minutes was provided. If after 6 minutes the patient was unable to operate a device properly, a demonstration was provided. Thirty-second rhythm strips were simultaneously recorded on the portable ECG device and the hospital cardiac monitor to enable comparison during identical time periods. The 4 portable ECG devices were used in the same sequential order for each of the 20 patients. Eighty total portable ECG device rhythm strips and 80 total hospital cardiac monitor rhythm strips were recorded in this study. High quality examples of rhythm strips from the portable ECG devices and the hospital cardiac monitor may be found in Figs. 6–10. After using the 4 portable ECG devices, each patient was provided a questionnaire assessing their perceptions of the portable ECG devices.

A cardiac electrophysiologist performed rhythm interpretation and ECG signal quality assessment of only the 80 hospital cardiac monitor strips (our “gold standard”). Two attending cardiologists, two internal medicine hospitalists, and one cardiology fellow (henceforth referred to as “reviewers”) each performed rhythm interpretation and ECG signal quality

1. Which device did you prefer?  
1      2      3      4
2. Which device was easiest to use?  
1      2      3      4
3. Would you purchase one of these devices?  
Yes                      No
4. Which one?  
1      2      3      4
5. Would you be comfortable using this if prescribed by a physician?  
Yes      No
6. Would you purchase one on your own?  
Yes      No
7. Which device would you purchase on your own?  
1      2      3      4
8. Do you have an interest in technology?  
Yes      No
9. How would rate the quality of device 1?  
Very Good      Good      Barely Acceptable      Poor      Very Poor
10. How would rate the quality of device 2?  
Very Good      Good      Barely Acceptable      Poor      Very Poor
11. How would rate the quality of device 3?  
Very Good      Good      Barely Acceptable      Poor      Very Poor
12. How would rate the quality of device 4?  
Very Good      Good      Barely Acceptable      Poor      Very Poor
13. Which device was most difficult to use?  
1      2      3      4
14. If you had to carry one of these devices with your for 30 days, which one would you select?  
1      2      3      4
15. Would you be comfortable using this if prescribed by a physician?  
Yes      No
16. Do you have an interest in technology?  
Yes      No
17. Do you have Wi-Fi (wireless Internet) in your home?  
Yes      No
18. Have you ever used a Holter monitor or cardiac event monitor?  
Yes      No
19. If Yes to the above question, which do you prefer to use?  
A. Holter monitor or cardiac event monitor  
B. One of the devices you used today
20. What is your highest level of education?  
A. High School  
B. College  
C. Graduate Level

Fig. 1. Patient questionnaire completed after use of portable ECG devices.

assessment of the portable ECG device rhythm strips (400 total portable ECG device rhythm strips). ECG signal quality was determined by consideration of baseline sway, artifact, and interpretability. The reviewers were not provided the hospital cardiac monitor strips for comparison until rhythm interpretation

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