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# A pandemic response to home delivery for ambulatory ECG monitoring: Development and validation

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## ABSTRACT

In response to the COVID-19 pandemic, a protocol was designed for mail-out devices and educational materials created to teach patients how to install a device for 2 weeks of continuous ambulatory ECG monitoring. We compared data collection from two sequential patient populations; one who received standard device application in the same clinic in the months before the pandemic response, and another, who received their device by mail for self-installation. Patients received a single phone call when the device was mailed and were able to contact the manufacturer as needed for support. A total of 47 devices were assessed from each group. Each group was similar in age (70 vs 65 years), and clinical indication for monitoring. Noise signal magnitude (22.34 vs 26.28%), symptom based manual activation (10 vs 8 events) and APB/recorded hour burden measurements (37.05 vs 23.36%) were similar in both groups (all comparisons were statistically non-significant). Both groups had a similar mean of hours recorded (240.37 vs. 245.05 h). Zero patient kits were lost, and all reports were delivered. Overall, it was found that a mail-delivered home-based recording platform can be reliably used to acquire clinical data with similar data quality and patient compliance as a conventional in-clinic model for long term ambulatory ECG monitoring.

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## Introduction

Long-term ambulatory ECG monitoring devices are used for the acquisition of symptom-rhythm correlation in the assessment of rhythm related symptoms and for detection of suspected clinically relevant arrhythmias, especially atrial fibrillation or, as a surrogate atrial ectopy burden [1]. There are a variety of manufacturing systems available for such data acquisition. More recently, patch electrode systems have become available. These are available in a single, or multiple lead data acquisition configurations and allow for the reliable acquisition of continuous ECG data for up to a two-week period. Such devices are small, leadless and depending on manufacturing configurations can be mailed back to the manufacturer for refurbishment after downloaded data is uploaded to a cloud server or other interface [2]. In routine use of these devices, patients receive the device in a clinic, are educated on its use, instructed how to activate the device for symptom correlation and, also instructed how to take off the device and reapply as needed. At the time of clinic application, the skin is prepared to enhance electrode contact and the reason for obtaining the data is reviewed. In the

aggregate, the current standard application of ambulatory ECG recording devices requires expert clinical supervision, patient education and delivery of the device in an office or clinic.

The global COVID-19 pandemic has forced healthcare providers to pivot their care to telemedicine and video conferencing capabilities [3]. We wished to assess whether a similar approach could be provided for home ECG long-term telemetry data acquisition. A protocol was developed, instructional materials were created and models for internal validation were designed to answer this question. We hypothesized that the simplicity of a mail-out patch electrode long-term (14 day) ECG recording configuration should allow for reliable, entirely home-based delivery of education, service and data acquisition.

## Methods

The patient population studied was derived from a specialty neurology clinic focused on stroke management. The descriptions of both patient populations were limited to age, gender and base line rhythms.

We developed educational materials including a pamphlet and a 5 min video to educate patients on how to apply and use the device. The ordering physician met with the patient by videoconference to explain the need for long-term ECG recording data and then, notified the

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manufacturer (Icentia, Quebec, QC, Canada) to deliver the package to the patients.

Upon notification, a package was sent using regular priority postage with tracking capabilities. The package included: a single lead adhesive long term ECG recording device (CardioSTAT, Icentia, Quebec, QC, Canada), 2 sets of electrodes, the surrounding adhesive collar, a patient diary form, a pre-addressed return envelope, written instructions with diagrams as well as a contact phone number to call manufacturer for any technical support (see Fig.1). All devices were placed in a vertical orientation along the sternum (see Fig. 2) [4]. The instruction guide also included a URL reference to a 5 min video for support as needed (available at [www.cardiostat.com/support](http://www.cardiostat.com/support) (last accessed July 3, 2020)).

**Quality control**

Once an ECG recording system package was mailed to the patient, the data base entry for the tracking of the package started. By protocol, all patients received a single phone call, upon shipping to provide information regarding the device including the company’s contact information. The phone call was used to remind the patient of the role of device in management, review use and encourage prompt application. At that time, patients confirm and consent to wearing the device upon arrival. All patients were invited to phone the manufacturer if any challenges arose and the nature of the phone call was abstracted. If the recorder was not returned to the company by a specific date, the patient received their only other phone call to ensure they mailed the device back.

For comparison, a retrospective approach was used to identify a control group made up of a sequential series of patients, seen just before the pandemic response who received the same long term ECG recording device in the standard, conventional fashion with in-clinic education, skin preparation and device application were studied. Both groups were otherwise identical with respect to a physician prescribed device, and clinical location in an academic stroke clinic with the main goal being identification of atrial fibrillation in the context of concern for cardioembolic cause of stroke. All of the Holter data was reviewed and reported by the same physician. The primary outcome was noise magnitude and secondary outcome was APB burden and hours recorded. In order to express the APB burden among patients with variations in the quantity of noise signal, the amount of ectopy was normalized to the hours of

data available for analysis. This has been represented by absolute APB count per total recorded hours. The chief endpoint for purposes of comparison and validation point was:

1. The magnitude of noise on the record signal from the mailed in devices compared to the in clinic deliver devices
2. Arrhythmia related indices of atrial ectopy burden. Total atrial ectopy count was measured and expressed as: APB count per recorded hour of data acquired
3. The frequency of manual activations for symptoms
4. Hours of recorded data available

**Statistical analysis**

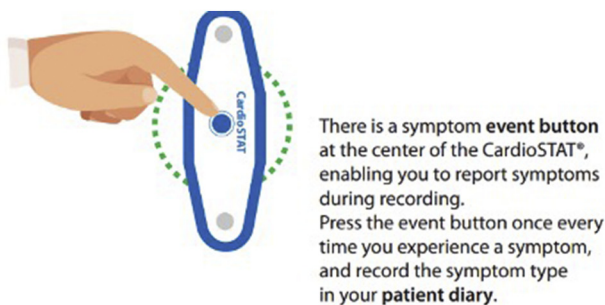
All variables were expressed as means with standard deviations (SD). Standard descriptive statistics were used to compare the two populations using a Mann Whitney U test.

**Results**

The 47 patients who received the device in the mail were compared to 47 patients in the control group. The 47 recipients with mail delivery had an average age of  $70 \pm 14.7$  years and was 49% male. The 47 patients used for the comparison control group had an average age of  $65 \pm 15$  years and was 55% male. All patients in both populations were in sinus rhythm. The two groups were not statistically different from each other.

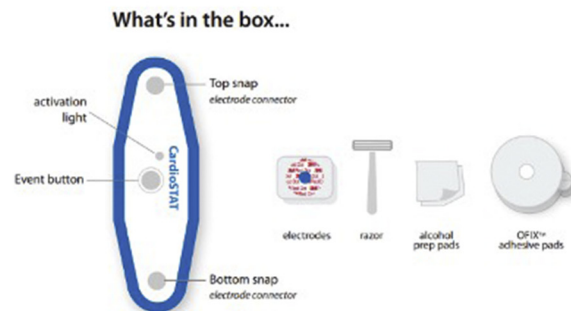
The 47 machines were sent out from March 27th to May 11th, 2020. All devices shipped out were returned and had reports delivered. Of the total shipped out, 47 were returned. Of those that were returned, 25 patients (53%) installed the devices using instructional materials given without additional assistance over the phone and 21 patients (45%) required help over the phone to install. The status of one patient (2.1%) is unknown to have required additional help. One device (2.1%) was wrongly addressed and one device (2.1%) was sent to a patient that was unaware of the test, however, both reports and devices were returned.

The magnitude of noise on mailed devices was an average of  $22 \pm 21\%$  compared to  $26 \pm 14\%$  on control group,  $U = 848, p = 0.052$ . Patients with mailed devices had an APB burden of  $37.05 \pm 95.5$  APB per



**Returning your recorder**

At the end of the test, place your CardioSTAT recorder and your Patient Diary in the pre-paid return envelope provided and send it back by post. Your results will be communicated to you by your doctor.



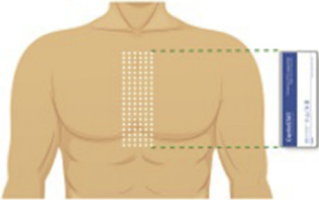
- CardioSTAT® ECG recorder
- 3M Red Dot electrodes
- Disposable razor for removing hair if required
- Alcohol prep pads
- OFIX™ adhesive disks
- Including spare parts
- Patient diary
- Safety & Use notice
- Pre-addressed return envelope



Fig. 1. From patient 2-page manual, a description of contents in mailed box and details on activation.

### 1 Prepare the skin

This step is **very important** to ensure the quality of the recording.



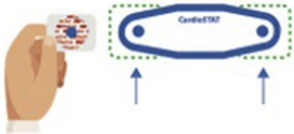
**Locate area**  
Use the CardioSTAT pouch as a guide to locate the prep area, from the lower part of your chest. *If there's a wound within the area, stop now, call your health professional.*

**Shave**  
If necessary, shave this area. Tilt the razor slightly and shave small areas at a time in the direction of hair growth. It is strongly recommended to use a clipper if available.  
*A razor is provided with your kit. Be careful, the razor is extremely sharp. To use, remove the protecting cap and tilt the razor slightly without applying too much pressure.*

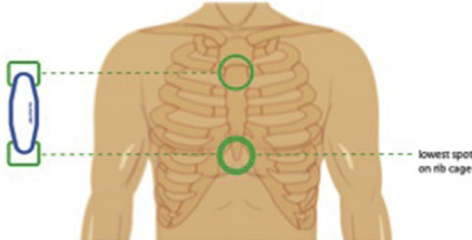
**Clean**  
Clean the area with soap and rinse thoroughly. Dry the area by rubbing with a towel from top to bottom about ten times.

### 2 Find the right spot

Snap a 3M Red Dot electrode on each side of the CardioSTAT recorder **keeping the protective film on the back of the electrodes.**




Facing a mirror, back straight, shoulders relaxed, use the recorder as a guide to locate the **top and bottom areas on your chest** where the electrodes will be applied. Place the **bottom electrode over the lowest bony spot** at the center of your rib cage (xiphoid).



If you're wearing a bra, make sure that the lower electrode is not placed directly under the frame or wire of the bra; this could cause irritation and discomfort.

Clean the skin with the alcohol prep pads, where the electrodes will be located. Use two alcohol pads per area. Do not hesitate to rub these areas more vigorously and allow the skin to dry before next step.

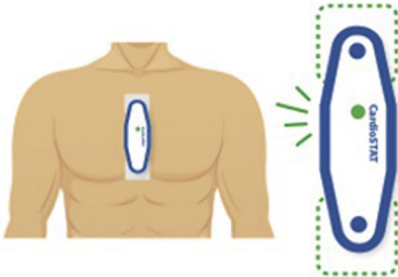
### 3 Apply



Peel off the electrode backing and stick the recorder at the location identified in Step 2. The CardioSTAT™ logo is on your left. It is important not to stretch the recorder when you apply it, or have it too loose.


The recorder should automatically activate once applied. A **solid green light** will be visible. After about 10 seconds, the green light should switch to **flashing**, indicating that the application was successful. The flashing will **stop after one minute** and recording will continue until the end of the prescribed duration.

*If the green light doesn't turn on, or if you see a red light call your health professional.*



### 4 Secure with adhesive disks

Gently **disconnect** the CardioSTAT from the electrodes using your thumb as a lever close to the metal snap. Don't tug the recorder from the center.



Peel off **one half** of the removable backing paper off the OFIX disk. Carefully overlay the disk onto the first electrode **aligning the opening** at the center of the disk with the metal contact of the electrode.


Peel off the **other half** of the backing paper from the OFIX disk and carefully press into place.

With your fingers, **smooth around the edges** of the electrode for 10 seconds to ensure proper adhesion of the OFIX disk.

Repeat the above steps to secure the other electrode.

### You're all set!

Snap the recorder back onto the electrodes. The green light will stay off.



one last thing →

Fig. 2. From patient 2-page manual, the method for applying the device.

recorded hours. Control patients were similar with respect to an APB burden of  $23.3 \pm 42.8$  APB per recorded hours,  $U = 669$ ,  $p = 0.465$ . The mean number of hours recorded for patients with mailed devices was  $240.37 \pm 78.3$  h. Control patients had a mean number of hours recorded of  $245.05 \pm 46.7$  h,  $U = 1032$ ,  $p = 0.589$ . Manual activations for symptoms occurred at an average of 10 and 8 times, respectively.

## Discussion

The main finding of this study is that a simple and effective protocol can be quickly developed to deliver home ECG recording technology in a reliable fashion with very limited involvement of healthcare professionals. Using only home printed materials, one phone call, and as-needed access to a simple video, patients can receive, apply, and record valid data for long-term ambulatory ECG recorders. Using data points such as magnitude of noise, APB burden per hour recorded, and frequency of manual activation, this study shows a non-significant statistical difference between home-based vs clinic-based application. The quality of data is commensurate with that of the patients who received their device in the clinic in a conventional format.

Our goal was to assess the least intensive intervention possible and still obtain adequate quality data. This occurred with a high patient compliance rate and limited loss to follow-up. With only one phone call, a printed instruction manual, and a pre-supplied return label, a large percentage of patients complied with the instructions and mailed back the device.

We are not aware of any prior report establishing the validity of home delivered, self-taught acquisition of ECG data in a clinical context. Our study underscores the validity of this approach with even minimal amount of contact required to reliably obtain such data. In another study, a different home delivered 7-day recording ambulatory ECG recording device was used in a trial to validate a comparison signal obtained from continuous event activated patient wearable device and also found high compliance for mailed out ECG recording devices. This study did not detail the intensity of the home ECG instruction and intervention. However, the research question required by design more intensive efforts to ensure that acquisition of Holter data was comprehensive and performed correctly [5]. Another trial using a mail-out home ECG recording device had a voluntary, more intense web-based module showing compliance to home monitoring. Unlike our study, there was no exclusive comparison between clinic and home-based application [6].

## Limitations

The patient population represents a selected group from a single stroke clinic which can give raise to possible selection and referral bias. In particular, the population studied carries psychological and clinical fears regarding stroke prevention and causation, which may influence the compliance and high response rate with minimal intervention. Whether the data can be generalized to a less clinically charged context is not known. Our comparison of the two groups is limited only to age, gender and rhythm status, no other factors were compared between the two populations. There is no reason to suspect

systematic differences between the two populations in the clinical attributes expected of the two groups studied who differ only by date of referral for monitoring. Although manual activations were preformed and were similar in both groups, detailed assessment of clinical context or even intent behind such activations is only partly available with limited patient diary methods.

## Conclusion

The global pandemic has forced the rapid development of telemedicine protocols. In this study, the development and delivery of the simple long-term home ECG monitoring protocol was effective and reliable for continuous home ambulatory ECG data acquisition. The quality of data matches clinically applied ECG monitoring devices. Using simple instructions, as well as a standard constructed single phone prompt, and as-needed contact, patients were able to properly use the device to acquire symptom–rhythm correlation and ECG recordings equivalently between home delivery and clinic application.

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