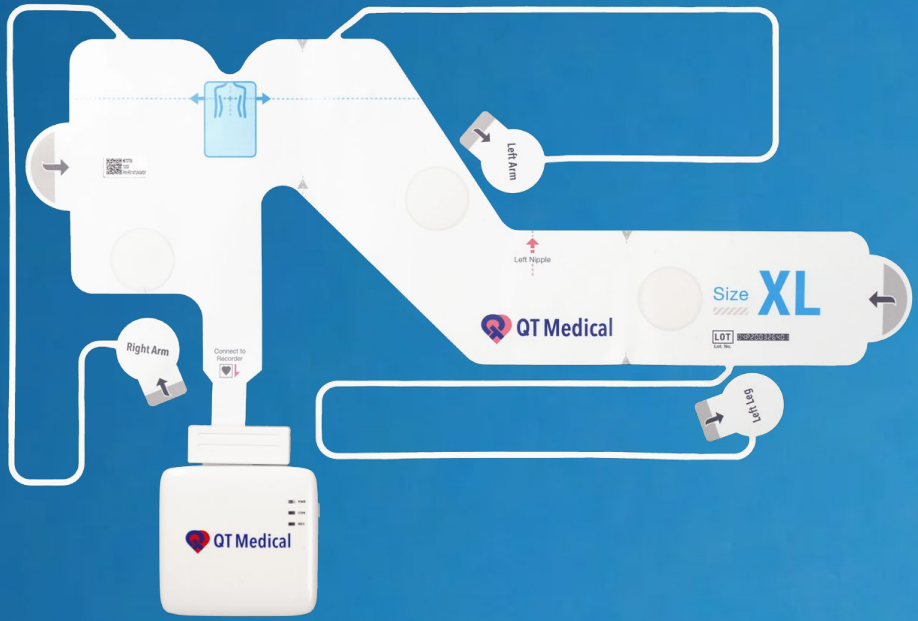
PCA 500

Optimized ECG Solution



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TECHNOLOGIES

FDA CLEARED

CE

Conventional ECG

PCA 500

A Focus on ECG Lead Improvement

The **PATENTED, PROPRIETARY 12-lead Hospital grade ELECTRODE STRIP** was designed and created by a Pediatric Chief of Cardiology (who could not get a good read on infants). This simplified (yet, highly intelligent design) proved to have *clinical equivalence to traditional 12-Lead ECG systems.

Ruey-Kang Chang, M.D, M.P.H.

CEO, QT Medical, Inc.

Chief of Pediatric Cardiology, Harbor, UCLA

Professor at UCLA Geffen School of Medicine

Principal Investigator at LA BioMed for 20 years

Traditional ECG leads

QT Medical Infant Electrode Strip powered by the QT PCA 500 recorder

*Journal of Electrocardiology 59 (2020) 126–133 Comparison of electrocardiogram quality and clinical interpretations using prepositioned ECG electrodes and conventional individual electrodes

PCA 500 | A Complete ECG Solution

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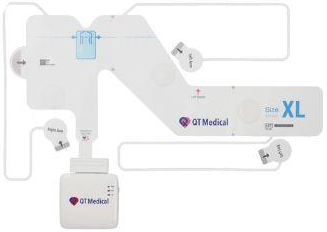


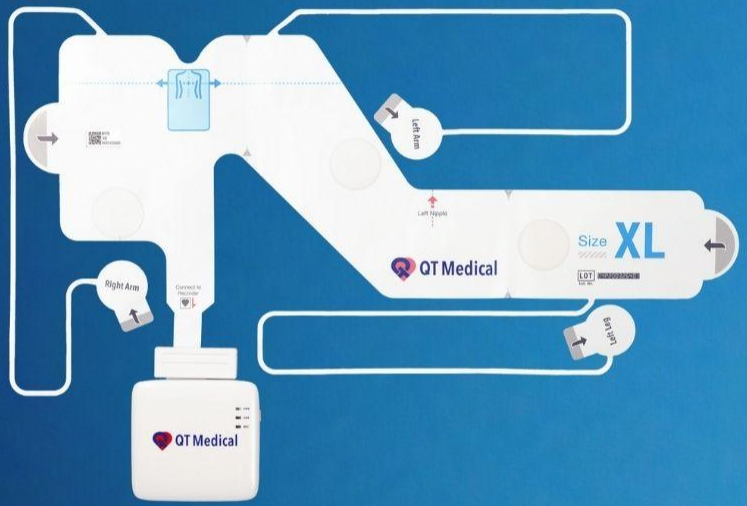
PCA 500 SENSOR

PCA 500 RECORDER

QT ECG MOBILE APP

ECGCLOUD

70% FASTER THAN A TRADITIONAL 12-LEAD ECG



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EFFICIENT

- 12 leads are pre-positioned creating a dramatically simpler application
- Streamlined the process from 20 steps to just 4 steps
- Proven so simple that patients perform at home

PATIENT SAFETY

- Reduced risk of limb lead reversal
- Reduced risk of chest lead misplacement
- No lead wires and/or cables to clean
- Reduced risk of infection

CONSISTENT

- Proven equivalent to traditional 12-lead ECGs
- 92.9% patients completed their tests with good quality ECGs, technical failure rate was less than 2%

PCA 500 Sensor

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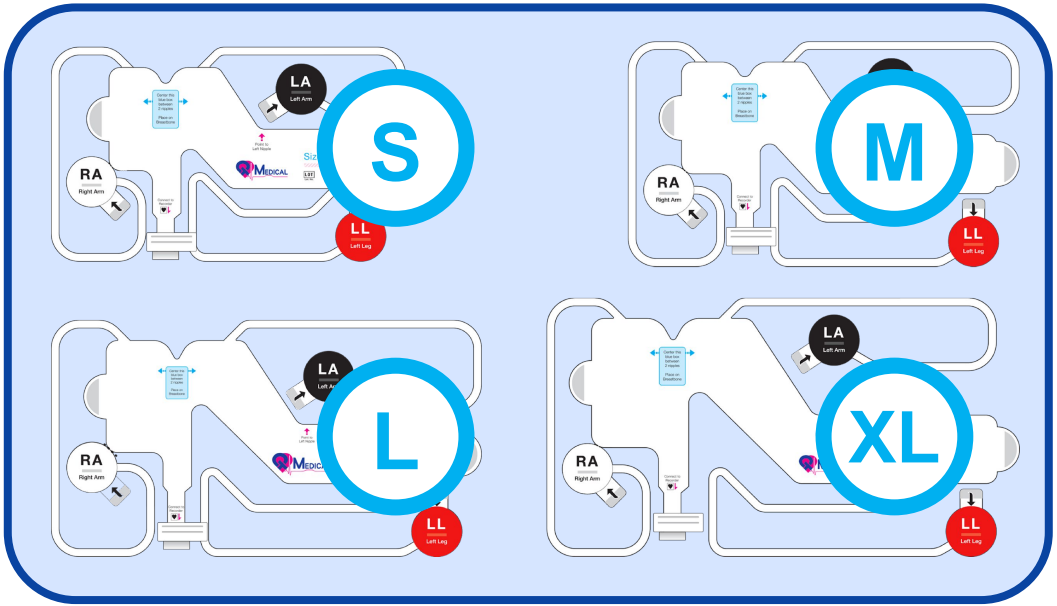
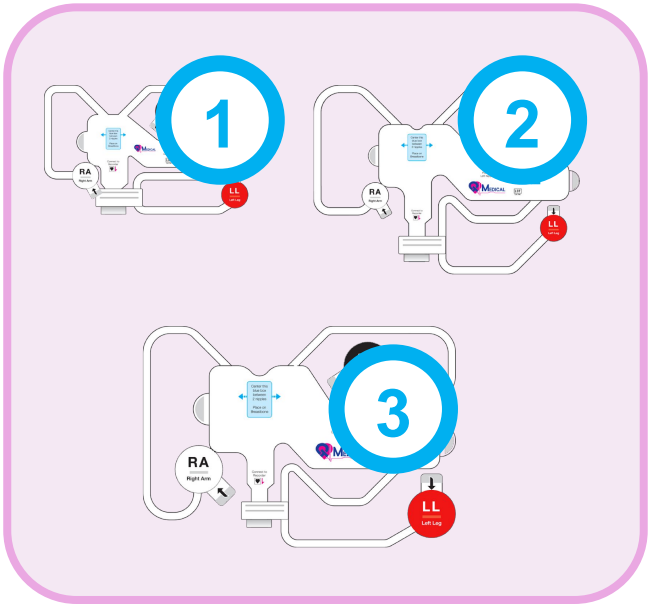
Adult



Pediatric



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PCA 500 RECORDER

COMPACT

- Compact, pocket size
- Weighs ~2.4 oz

SIMPLE

- Just one button
- Wireless connectivity via Bluetooth

SECURE

- HIPAA and GDPR compliant
- Private access from any computer, tablet or mobile device via ECGcloud
- EMR compatible

RELIABLE

- Superior signal strength
- Less noise and interference
- Low maintenance
- Overnight replacement with warranty

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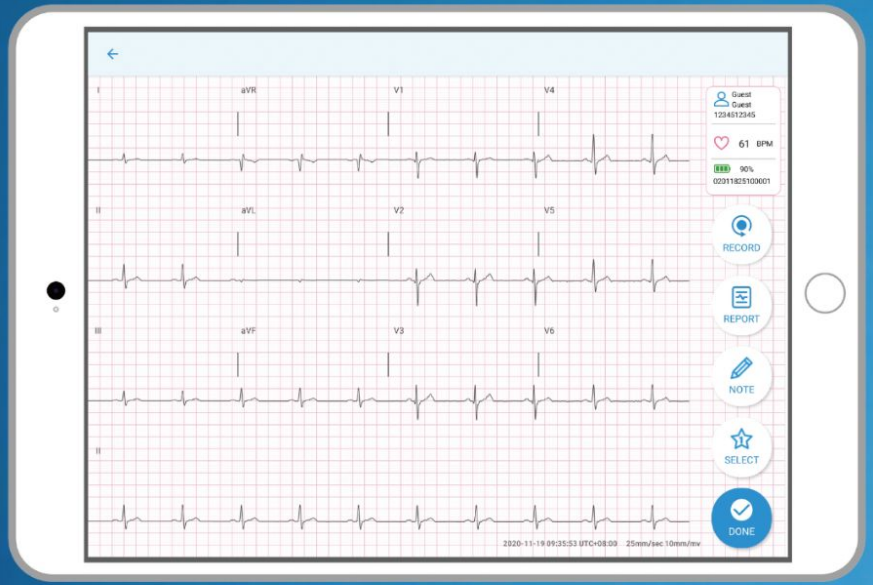
QT ECG APP



EASY TO USE

- PCA 500 Recorder connects via Bluetooth
- ECG recording automatically begins when recorder connects to Bluetooth
- Capable of recording as many 10 second segments as needed
- Wide range of smartphones and tablets supported (iOS and Android)

USABILITY FEATURES

- Computer algorithm provides preliminary interpretation
- Setting for periodic ECG recordings
- In-app tutorial
- Troubleshooting including lead-off detection
- Readings are stored until internet is present

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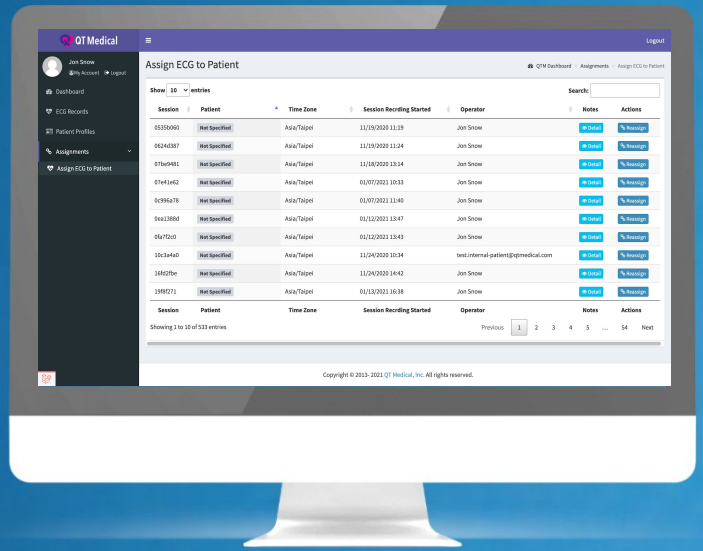
ECGcloud



FILE MANAGEMENT

- HIPAA compliant cloud storage
- Reports can be downloaded into PDF
- Patient ECG readings are filed and easy to retrieve
- API customization available for seamless EMR integration
- Patient's serial reports can be compared side-by-side

ECG REPORTING

- Preliminary interpretation algorithm
- Physician tools (e.g. calipers) and a notes section
- Customizable notifications and alerts
- Platform agnostic; only browser required

Product Specifications

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PCA 500 Recorder Specifications	
Leads	12
Recording format	10-sec standard resting 12-lead ECG
Connectivity	Bluetooth 4.0 dual mode
Output Sampling Rate	1000 Hz
Indicator	3 LEDs (power, connection, recording)
Button	1 Power button
Battery	Li-ion 3.7V, 700 mAh, rechargeable, charging time approx. 1.5 hrs from depletion to 90%
Connector	QT ECG Electrode connector
Operating Time	Approx. 300 ECGs per charge
Ingress Protection	IP22
Weight	67 g / 2.4 oz
Dimensions	72mm x 68mm x 18mm / 2.84” x 2.68” x 0.70”

PCA 500 Sensor Specifications	
Lead electrodes	10
Size	Pediatric (3) and Adult (4) Sizes
Indication of use	Single patient use
Shelf-life	3 years
Weight	<60g / 3.9 oz
Dimensions	11.42” x 13.70”
Environmental condition	41° - 86° F

Why PCA 500

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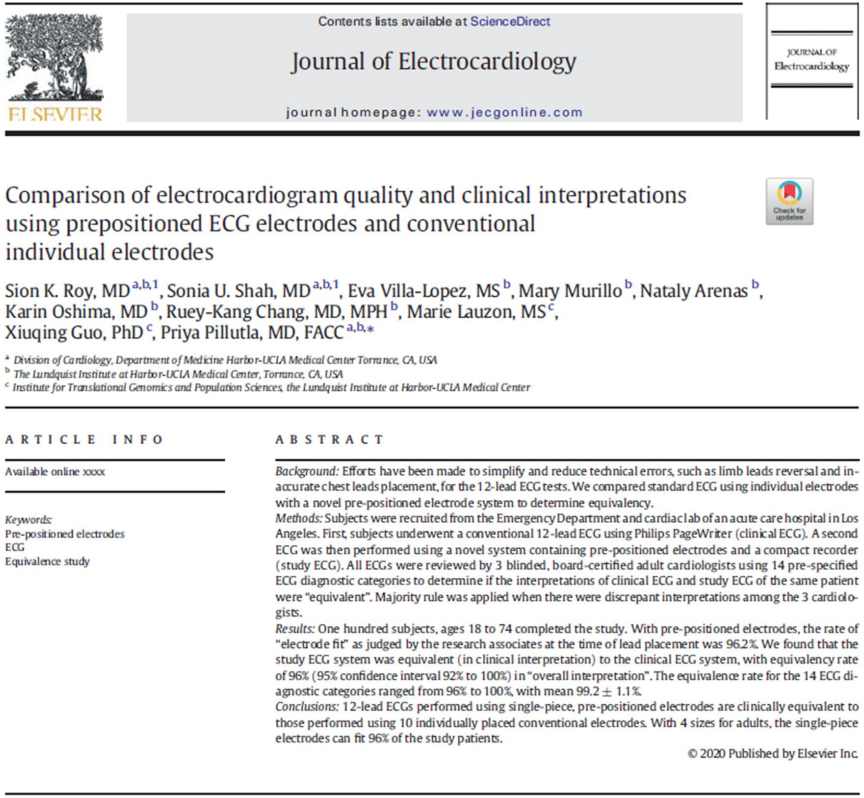
Replaces conventional machines which are large, difficult to use, and cost prohibitive

- Easy deployment & storage
- Central data collection
- Minimum training required
- 12-lead ECG provides higher sampling rate than 6-lead ECG

A network of 36 sites (and expanding) replaced their existing ECGs with PCA 500

Adult Equivalence Study

- Comparing PCA 500 with Philips PageWriter TC70
- 96% equivalence, surpassing FDA criterion of 90%
- Securing FDA clearance as professional medical standard 12-lead ECG



Contents lists available at ScienceDirect

Journal of Electrocardiology

journal homepage: www.jecgonline.com

Comparison of electrocardiogram quality and clinical interpretations using prepositioned ECG electrodes and conventional individual electrodes

Sion K. Roy, MD [a,b,1], Sonia U. Shah, MD [a,b,1], Eva Villa-Lopez, MS [b], Mary Murillo [b], Nataly Arenas [b], Karin Oshima, MD [b], Ruey-Kang Chang, MD, MPH [b], Marie Lauzon, MS [c], Xiuqing Guo, PhD [c], Priya Pillutla, MD, FACC [a,b,*]

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ARTICLE INFO

Available online xxxx

Keywords:
Pre-positioned electrodes
ECG
Equivalence study

ABSTRACT

Background: Efforts have been made to simplify and reduce technical errors, such as limb leads reversal and inaccurate chest leads placement, for the 12-lead ECG tests. We compared standard ECG using individual electrodes with a novel pre-positioned electrode system to determine equivalency.
Methods: Subjects were recruited from the Emergency Department and cardiac lab of an acute care hospital in Los Angeles. First, subjects underwent a conventional 12-lead ECG using Philips PageWriter (clinical ECG). A second ECG was then performed using a novel system containing pre-positioned electrodes and a compact recorder (study ECG). All ECGs were reviewed by 3 blinded, board-certified adult cardiologists using 14 pre-specified ECG diagnostic categories to determine if the interpretations of clinical ECG and study ECG of the same patient were "equivalent". Majority rule was applied when there were discrepant interpretations among the 3 cardiologists.
Results: One hundred subjects, ages 18 to 74 completed the study. With pre-positioned electrodes, the rate of "electrode fit" as judged by the research associates at the time of lead placement was 96.2%. We found that the study ECG system was equivalent (in clinical interpretation) to the clinical ECG system, with equivalency rate of 96% (95% confidence interval 92% to 100%) in "overall interpretation". The equivalence rate for the 14 ECG diagnostic categories ranged from 96% to 100%, with mean 99.2 ± 1.1%.
Conclusions: 12-lead ECGs performed using single-piece, pre-positioned electrodes are clinically equivalent to those performed using 10 individually placed conventional electrodes. With 4 sizes for adults, the single-piece electrodes can fit 96% of the study patients.

Pediatric Usability Study

- 2582 babies tested by parents for screening Long QT syndrome
- Randomized to parents doing the ECG or technician doing the ECG
- 94% parents completed ECG tests on their own babies

Contents lists available at ScienceDirect

Journal of Electrocardiology

journal homepage: www.jecgonline.com

Home use of a compact, 12-lead ECG recording system for newborns

Henry J. Lin [a,b,t,*], Yueh-Tze Lan [c], Michael J. Silka [d], Nancy J. Halnon [e], Eva Villa-Lopez [f], Nataly Arenas [f], Fabian Escobedo [f], Ryan Montoya [f], Sarah Valdez [f], Omid Rajabi Shishvan [g], Sandra Sedano [f], Emily H. Marr [f], Marie Lauzon [b], A.S. Moosa [h], Kimberly J. Ko [i,t], Elaine C. Shoji [j,t,u], Alexandra M. Clark [k,v], Lynne M. Smith [l,t], John Michael Criley [m,t], Wayne W. Grody [n], Yii-Der Ida Chen [b,o,p,t], Kent D. Taylor [b,o,t], Xiuqing Guo [b,o,t], Tolga Soyata [g], Jerome I. Rotter [b,o,q,t], Tingchou Chien [r], Pai Chou [r], Ruey-Kang Chang [s,t]

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ARTICLE INFO

Available online xxxx

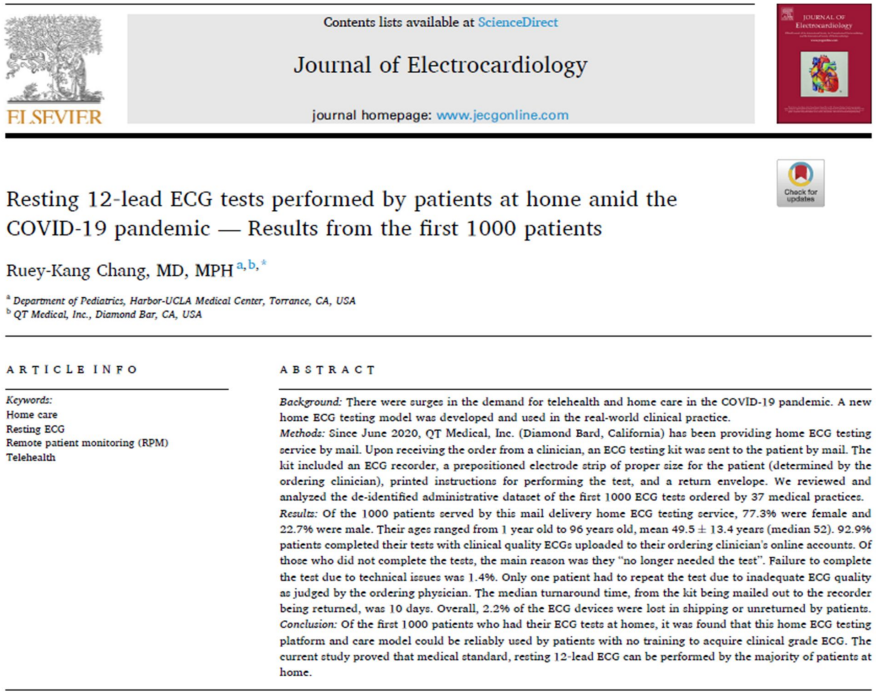
Keywords:
ECG recorder
ECG electrodes
Newborn screening

ABSTRACT

Background: An easy-to-operate ECG recorder should be useful for newborn screening for heart conditions, by health care workers – or parents. We developed a one-piece electrode strip and a compact, 12-lead ECG recorder for newborns.
Method: We enrolled 2582 newborns in a trial to assess abilities of parents to record a 12-lead ECG on their infants (2–4 weeks-old). Newborns were randomized to recordings by parents (1290) or our staff (1292 controls). Educational backgrounds of parents varied, including 64% with no more than a high school diploma.
Results: For newborns randomized to parent recorded ECGs, 94% of parents completed a 10-minute recording. However, 42.6% asked for verbal help, and 12.7% needed physical help. ECG quality was the same for recordings by parents versus staff.
Conclusions: By use of a one-piece electrode strip and a compact recorder, 87% of parents recorded diagnostic quality ECGs on their newborn infants, with minimal assistance.

Real World Evidence

- PCA 500 kits sent to 1000 patients, no training, to do their ECG tests at home
- 92.9% patients completed their tests with good quality ECGs, technical failure rate was under 2%.



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Journal of Electrocardiology

journal homepage: www.jecgonline.com

Resting 12-lead ECG tests performed by patients at home amid the COVID-19 pandemic — Results from the first 1000 patients

Ruey-Kang Chang, MD, MPH [a,b,*]

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ARTICLE INFO

Keywords:
Home care
Resting ECG
Remote patient monitoring (RPM)
Telehealth

ABSTRACT

Background: There were surges in the demand for telehealth and home care in the COVID-19 pandemic. A new home ECG testing model was developed and used in the real-world clinical practice.
Methods: Since June 2020, QT Medical, Inc. (Diamond Bard, California) has been providing home ECG testing service by mail. Upon receiving the order from a clinician, an ECG testing kit was sent to the patient by mail. The kit included an ECG recorder, a prepositioned electrode strip of proper size for the patient (determined by the ordering clinician), printed instructions for performing the test, and a return envelope. We reviewed and analyzed the de-identified administrative dataset of the first 1000 ECG tests ordered by 37 medical practices.
Results: Of the 1000 patients served by this mail delivery home ECG testing service, 77.3% were female and 22.7% were male. Their ages ranged from 1 year old to 96 years old, mean 49.5 ± 13.4 years (median 52). 92.9% patients completed their tests with clinical quality ECGs uploaded to their ordering clinician's online accounts. Of those who did not complete the tests, the main reason was they "no longer needed the test". Failure to complete the test due to technical issues was 1.4%. Only one patient had to repeat the test due to inadequate ECG quality as judged by the ordering physician. The median turnaround time, from the kit being mailed out to the recorder being returned, was 10 days. Overall, 2.2% of the ECG devices were lost in shipping or unreturned by patients.
Conclusion: Of the first 1000 patients who had their ECG tests at homes, it was found that this home ECG testing platform and care model could be reliably used by patients with no training to acquire clinical grade ECG. The current study proved that medical standard, resting 12-lead ECG can be performed by the majority of patients at home.

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Home Use PCA 500 12-lead ECG

for Arrhythmia Localization Prior to Ablation

In many patients, radiofrequency ablation is the chosen treatment for ventricular tachycardia (VT). In order to localize the origin of VT, cardiologists typically attempt to induce VT while monitoring the patient's heart with electrocardiogram (ECG) prior to ablation. However, in some patients VT cannot be induced, preventing the physician from identifying the origin. In these cases, when VT or the premature ventricular contractions (PVC) that lead to VT has not yet been documented on a 12-lead ECG, there is a much higher chance of a failed ablation. As data obtained from 1-lead and 6-lead ECG home monitors do not provide enough anatomical data to localize the PVC and conventional 12-lead ECGs were not available for patients to use by themselves, getting the needed information for localization can be especially challenging.

The PCA 500 Platform by QT Medical is a streamlined 12-lead ECG solution that allows patients to easily complete a 12-lead ECG in the comfort of their home, providing physicians with the data they need. In two patients, both with non-inducible VT and multiple failed ablations, PCA 500 was prescribed and 12-lead ECG recordings were collected, which enabled their cardiologists to localize the origin of their arrhythmia and use this knowledge to perform a successful ablation.

Two electrophysiologists, Timothy Yeh, MD, and Charles Swerdlow, MD, FACC, FAHA, FHRS, decided to use QT Medical's PCA 500 on their patients to record their arrhythmias at home. The patients were a 78-year-old male (Patient A) and a 62-year-old male (Patient B). Both patients were diagnosed with VT that persisted for six and thirteen years, respectively. Patient A had three failed ablations prior to the use of PCA 500, while Patient B had six failed ablations prior to use of the device. In all prior ablations for both patients, the arrhythmia could not be induced, leading to unsuccessful procedures. Both patients suffered from palpitations multiple times a day. In an attempt to gain the needed data to localize the PVC, Patient A used PCA 500 at home intermittently for one month prior to his fourth ablation and Patient B used PCA 500 at home intermittently for one week prior to his seventh ablation.

Both of the patients' physicians, Dr. Yeh and Dr. Swerdlow, used the 12-lead ECG data provided from PCA 500 to successfully localize the patients' PVC prior to their final ablation. Dr. Swerdlow stated that he was able to use the data collected to perform a successful ablation on Patient B, and that PCA 500 provided him with much more useful data than any other at home ECG monitors. Dr. Yeh stated that the data pinpointed the origin of the PVC. He shared this data with another electrophysiologist, who then performed fourth ablation with success. Both electrophysiologists stated that without the use of PCA 500, the final ablations for both patients may not have been successful like previous attempts due to lack of the needed data.