PCA 500 from QT Medical is the Only 12-Lead ECG Optimized for Pediatric Use

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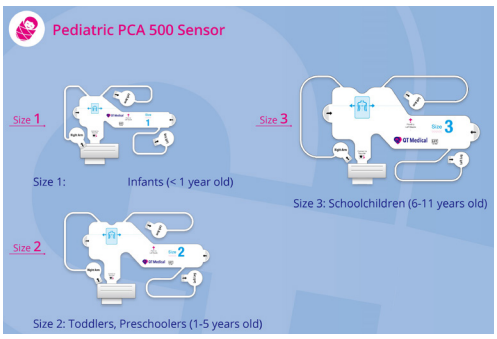
Electrocardiogram (ECG or EKG) is the most frequently used test in cardiology practice beyond the initial auscultation using a stethoscope. The standards for 12-lead resting ECG use in clinical practice were established by the American Heart Association in 1954.[1] Over the past 70 years, not only has the way how an ECG test is performed not significantly changed, but the ECG machines and the technologies have also remained relatively the same.[2]

Performing an ECG test on a pediatric patient, especially an infant, can be quite difficult. There were no ECG machines or leadwire cables designed for use on babies. The operator, an ECG technician or a bedside nurse, often have to cut the electrodes smaller to fit on the body of a baby. Doing an ECG on a baby could be a three-person operation—one person to hold the baby's arms, the second person to hold the legs, and the third person to place the electrodes. Placing the electrodes on an uncooperative baby proves to be challenging, and more manipulation of the baby is only met with more kicking and crying, leading to discomfort and distress.

Now there is a 12-lead ECG system designed and optimized for pediatric use—the PCA 500 by QT Medical.



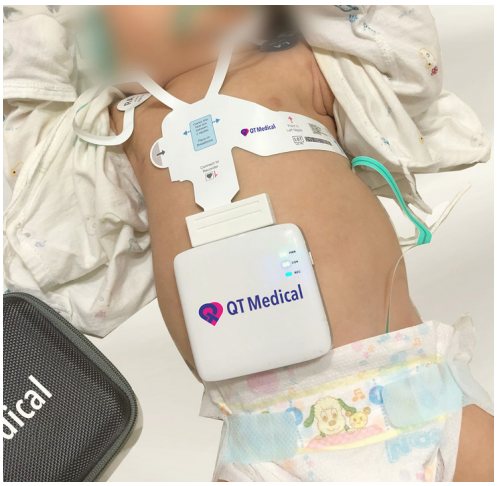
The PCA 500 was designed by a pediatric cardiologist, Dr. Ruey-Kang Chang. In his 25 years of practice, Dr. Chang has seen the significant challenges and struggles associated with getting ECG electrodes properly placed on pediatric patients. With grant funding from the National Institutes of Health (NIH), Dr. Chang's team developed a baby-friendly 12-lead ECG technology and conducted a clinical trial of 2,582 babies screening for long QT syndrome.[3] Dr. Chang founded QT Medical to commercialize this ECG platform. In a study comparing PCA 500 with Philips's flagship ECG Pagewriter TC70, it was shown that the prepositioned electrodes produced ECGs equivalent to ECGs recorded by conventional, individual electrodes when judged by three blinded cardiologists.[4] In 2022, the PCA 500 received FDA clearance for use on patients of all ages, including infants, and children.

This revolutionary product offers a digital, wireless, mobile-friendly, and cloud-based ECG management solution. With its single-use pre-positioned sensor and compact recorder, the PCA 500 is cleared by the FDA for use by both healthcare professionals and laypeople (patients or parents). Since its market launch, the PCA 500 has been widely used by: hospitals, physician offices, airlines, telehealth practices, clinics, skilled nursing facilities, and in clinical trials and schools for ECG screening of student athletes for risks associated with sudden cardiac arrest.

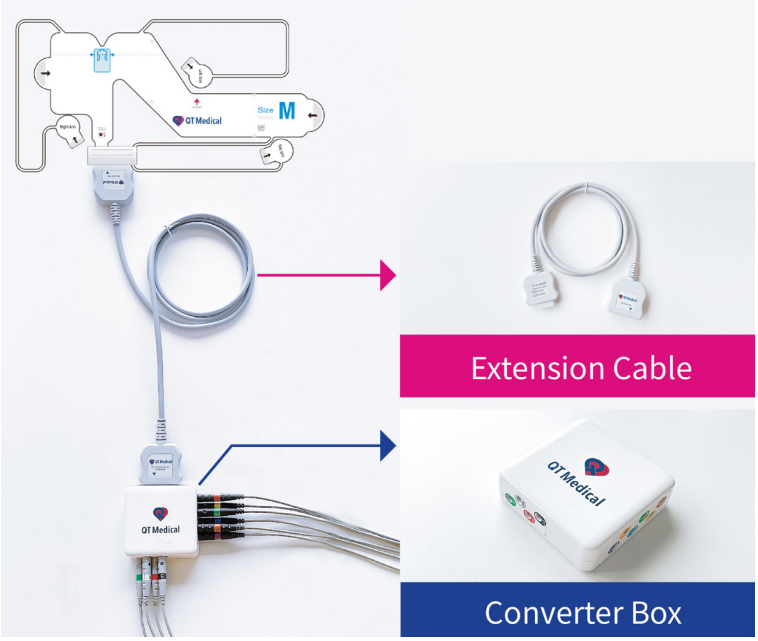
The single-use pre-positioned and preconnected electrode sensors offer many advantages. Because of its efficiency, accuracy, consistency, and lower risk of disease transmission, PCA 500 sensors can greatly streamline workflow, decrease the need for personnel training, and lower the overhead costs. The electrode sensors are available in three sizes for pediatrics—Size one for one for one-month-old to 12-months-old, Size two for ages one to five years, and Size three for ages six to 11 years. Children 12 years and older can utilize adult sensors, which are available in four sizes (S, M, L, XL).

The apparent advantages of the patented PCA 500 sensors are:

- ***Efficiency*** The proper placement of electrodes can require a significant amount of time. Then, the untangling of the leadwires and matching to each of the electrodes is cumbersome and requires additional time and patient interface. Using the PCA 500 electrode sensors eliminates the steps of matching and connecting the leadwires with electrodes and reduces the electrode placement process from 20 steps to four steps (sensor strip placement on the chest plus pulling out three limb electrodes). The electrode placement time can be reduced by over 70% using the PCA 500 sensor.
- ***Accuracy*** The sensor eliminates opportunities for lead placement errors. With its elongated asymmetric design and limb leads located in the proximity of the destined placement sites, the chance for limb leads reversals and chest leads misplacements are virtually eliminated. In fact, it would be almost impossible to reverse the limb leads or not place V1-V6 in the ordered sequence as the sensor itself would not accommodate for this placement.
- ***Consistency*** The electrode placements on the same patient will be consistent across different tests at different visits. Consistent leads placement is important in detecting early and subtle changes in the ECG.
- ***Lower Risk for Disease Transmission*** Eliminating cables, wires, and making the electrode sensor single use also helps to reduce the risk of disease transmission via ECG hardware. Previous studies have shown that ECG cables can be a source of infection outbreaks in the hospital.
- ***Minimal Training is Needed*** The PCA 500 system enables people with minimal or no training to do a standard 12-lead ECG test. This device is cleared by the FDA for use by healthcare professionals and laypeople (patients). In a study of



over 2,500 babies, more than 94% of parents were able to complete an ECG test on their own babies with only written instructions. In a study of the first 1,000 patients using the home delivery ECG testing service (Xpress ECG™), 92.9% completed their tests with good quality ECGs, and the technical failure rate was less than 2%.



The PCA 500 system is so compact and user-friendly that it can be mailed to patients for at-home ECG testing. In a study of the first 1,000 patients who used PCA 500 for at-home ECG testing, over 92% patients completed their ECG tests with a technical failure rate <2%.[5] When reviewing the results of 31 pediatric patients (mean age 13 years) who performed their own ECG tests at home, it was found that all patients had recordings suitable for clinical decision-making with 68% graded as 'excellent' 32% as 'good,'[6] 77% of patients found it 'easy' or 'extremely easy' to perform, and 80% were 'confident' or 'moderately confident' in the recording.

"We are extremely excited about the potential of the PCA 500 to improve heart health for millions of children. As a pediatric cardiologist, I know how difficult it is to get a 12-lead ECG on a child. With the PCA 500 technology, we can make ECG testing widely available and easily accessible to all children. We truly believe it will make a difference in many lives. This is the exact reason why I founded QT Medical," said Dr. Chang in an interview.

To introduce the PCA 500 to the pediatric market, QT Medical showcased its new products at the 8th World Congress of Pediatric Cardiology and Cardiac Surgery (WCPCCS) in Washington, DC, in August, 2023. It was met with very high levels of enthusiasm by nurses and cardiologists who are excited to adopt this new technology in multiple locations of care including ward and outpatient settings. Many clinicians are also planning to use the PCA 500 in telehealth practices, homecare, and for various other remote monitoring and screening applications.

QT Medical plans to announce two new initiatives at the American Academy of Pediatrics National Conference and Exhibition in October 2023. First, the Youth Xpress ECG™ screening service, in partnership with Who We Play For, a 501© organization, dedicated to preventing sudden cardiac arrest of athletes. Youth Xpress ECG is a mail delivery 12-lead ECG testing service for children aged 12-18 years old who participate in sports. The ECG results will be interpreted by expert pediatric cardiologists. Second, is the Baby Xpress ECG™, an at-home ECG screening service for infants with increased risks for long QT syndrome. In the Baby Xpress ECG service, when a baby with a prolonged QT interval is identified on the ECG, a genetic test kit will be used for collecting the baby's saliva to check for genetic mutations known for causing long QT syndrome. Long QT syndrome, occurring in one in every 2000 babies, is a known cause for sudden death (including SIDS).

QT Medical is making the patented pre-positioned ECG sensors available for use by ECG machines made by other manufacturers. The ECG sensors, called QHeart™ sensors, can be used with existing ECG machines through a cable connection (available for GE and Philips ECG machines) or a converter box (which receives banana plug inputs from the majority of existing ECG devices currently in use globally). The QHeart™ sensors can offer the same advantages of efficiency, accuracy, and consistency regardless of the ECG machine that is being used to conduct the test. QHeart™ sensors will make performing an ECG test using any ECG machines much faster, easier, and with superior signal quality.

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