

EMBARGOED FOR RELEASE UNTIL THURSDAY, JULY 29, 2021, AT 1:45 P.M. EDT

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**LATE-BREAKING CLINICAL TRIAL RESULTS ANNOUNCED  
AT HEART RHYTHM 2021:**

**NEW CLINICAL TRIAL FINDS HUMAN OVERSIGHT ECG MONITORS OUTPERFORM AI-DEPENDENT MONITORING**

*Results show ECG monitor is more than 200% more effective in detecting arrhythmias*

**BOSTON, MA, July 29, 2021** – Results from a new clinical trial find human-oversight dependent continuous electrocardiography (ECG) monitors to more accurately detect significant arrhythmias than mobile cardiac telemetry (MCT). Findings from this clinical trial were presented today as late-breaking science during Heart Rhythm 2021.

Cardiac arrhythmias occur when the electrical impulses that coordinate heartbeats do not work properly, which can lead to serious health issues like stroke and sudden cardiac death. In order to better identify and diagnose arrhythmias, ECG monitors and MCT allow physicians to evaluate cardiac rhythm for an extended period of time in outpatient settings.<sup>1</sup> Today, a variety of FDA-approved cardiac monitors are available, yet each differ in how the data is reviewed. Initial patient data from these monitors are interpreted by the manufacturers and third-party independent diagnostic and testing facilities before they are shared with the ordering physician for review. This study compares the accuracy of human-oversight dependent continuous ECG monitoring with algorithm-dependent MCT.

This study was conducted in an outpatient arrhythmia clinic and enrolled 50 sequential patients who simultaneously wore both a MCT and a long-term continuous ECG monitor. Of the 50 enrolled patients, four failed to wear both monitors simultaneously and were excluded from the study. Patients wore both monitors simultaneously for at least some time period (range: 1.2-14.8 days). Each study and its associated report were reviewed by two electrophysiologists and were categorized based on whether significant clinical arrhythmias were identified and correctly diagnosed.

During the simultaneous recording, significant arrhythmias were diagnosed by MCT in 11/46 patients (24%) compared to 23/46 patients by the long-term continuous ECG monitoring, a 209% increase ( $p=0.018$ ). In addition, in 12 of the 46 patients (26%), a significant arrhythmia finding was missed by MCT but was captured by long-term ECG. In two patients, AV node re-entrant tachycardia, captured by long-term ECG, was missed by MCT. In three patients, second degree AV block was unreported by MCT but captured by long-term continuous ECG monitoring. In 7/46 (15%), VT was reported by MCT, compared to 13/46 (28%) patients by long-term continuous ECG monitoring. Atrial fibrillation was documented by both types of monitors in two patients, however, long-term continuous ECG monitoring captured four additional AF episodes missed by MCT.

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<sup>1</sup> Bansal A, Joshi R. Portable out-of-hospital electrocardiography: A review of current technologies. *J Arrhythm*. 2018;34(2):129-138. Published 2018 Feb 23. doi:10.1002/joa3.12035

“Reports received from cardiac monitors greatly impact and influence clinical decisions, so accurate readings are crucial. Because every cardiac monitor employs different reporting methods to process recorded rhythms, it can be challenging for the physicians receiving and interpreting the final report. Our study set out to better understand the accuracy between two common options” said lead author Mark Willcox, MD, Alaska Heart & Vascular Institute. “We found technology, paired with key human oversight and input, proved to be the most accurate in detecting critical arrhythmias and, ultimately, helping to improve patient outcomes.”

The authors hope the results of their study will lead to further conversation into the approval process for monitoring devices and how to ensure reporting accuracy among available monitors.

**Sessions Details:**

“Late-Breaking Clinical Trials 2: Innovations: *Continuous Ecg Monitoring Versus Mobile Telemetry: A Comparison Of Arrhythmia Diagnostics Between Human And Algorithm Dependent Systems*” [Thursday, July 29, 2021 at 1:45 p.m. EST]

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About Heart Rhythm 2021

The Heart Rhythm Society's annual meeting attracts thousands of the world's finest clinicians, scientists, researchers, and innovators in the field of cardiac pacing and electrophysiology. Heart Rhythm 2021 attendees were able to determine how to participate - virtually or in-person. More than 600 international experts in the field will serve as faculty for programming that includes Daily Plenary Sessions, Late-Breaking Clinical Trials, Recorded Cases, Debates, Rhythm Theater Presentations and more, while over 100 exhibitors will showcase innovative products and services.

About the Heart Rhythm Society

The Heart Rhythm Society is the international leader in science, education, and advocacy for cardiac arrhythmia professionals and patients and is the primary information resource on heart rhythm disorders. Its mission is to improve the care of patients by promoting research, education, and optimal health care policies and standards. Incorporated in 1979 and based in Washington, D.C., it has a membership of more than 7,000 heart rhythm professionals in more than 90 countries around the world. For more information, visit [www.HRSONline.org](http://www.HRSONline.org).