

MindRhythm Announces First Patient Enrolled in Pivotal Study of Novel Harmony™ Device for Rapid Detection of Stroke

CUPERTINO, CALIFORNIA, USA, June 20, 2023 /EINPresswire.com/ -- [MindRhythm](#) Inc, in partnership with Wayne State University School of Medicine in Detroit, Michigan, today announced that the first patient has been enrolled in the pivotal portion of its HeadPulse for Ischemic Stroke Detection Prehospital Study (EPISODE-VS). EPISODE-VS is designed to validate



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that the use of MindRhythm’s proprietary Harmony headset can rapidly identify large vessel occlusion (LVO) ischemic strokes in the prehospital setting to optimize triage and improve stroke outcomes.

“Stroke is the leading cause of sudden disability and the fifth leading cause of death in the US,” said John Keane, Co-Founder and CEO of MindRhythm. “Large vessel occlusions are the most severe ischemic strokes and must be treated within hours to avoid catastrophic brain damage or death,

underscoring the need to diagnose and treat stroke as quickly as possible. MindRhythm’s Harmony has been shown to accurately diagnose LVO strokes in a prehospital setting, thereby enabling direct triage to a comprehensive stroke center. We are delighted to enroll the first patient with the goal of gaining FDA clearance following the trial’s completion. Ultimately, we hope to significantly revolutionize stroke triage by providing rapid stroke identification data to expedite care and save lives.”

The pivotal portion of the EPISODE trial is expected to enroll between 200 and 250 patients, all of whom will be evaluated in the prehospital environment by paramedics/EMTs when stroke is suspected. Patients suspected of stroke will have a noninvasive headset placed to record their HeadPulse during the encounter. This knowledge is expected to aid in the triage decision of the destination hospital for stroke patients. The primary objective of the trial is to validate the sensitivity and specificity of LVO diagnosis with the Harmony device against standard of care.

“Despite recent advances in stroke care, appropriate prehospital triage and transport remain challenging. Every 40 seconds another American has a potentially debilitating stroke, and up to 30% of these strokes are large vessel occlusive (LVO) strokes requiring specialized intervention that is not available at all hospitals,” said James Paxton, MD, of Wayne State University, the

Primary Investigator of the trial. "The Harmony headset has the potential to revolutionize prehospital care by providing first responders with a noninvasive, reliable means for detecting LVO stroke that is available minutes, perhaps even hours, before conventional methods can confirm the diagnosis. Time lost is brain lost, and delays can lead to devastating injuries that may never heal. This technology is going to change lives."

In previous studies, cranial accelerometry, the primary technology used in the Harmony headset, has been shown to reliably detect LVO in hospitalized patients suspected of experiencing an ischemic stroke. MindRhythm's technology may be especially appealing to medical providers as it allows noninvasive measurement of a physiological parameter, discovered by MindRhythm, it calls the HeadPulse. Whereas previous studies assessed patients in the hospital, the EPISODE-VS trial is designed to validate device performance in the prehospital environment.

About the Harmony Headset

Harmony is a novel, noninvasive diagnostic medical device that can rapidly identify patients with Large Vessel Occlusion (LVO) strokes, the most debilitating of all stroke types. Harmony monitors a newly discovered physiology MindRhythm calls the "HeadPulse". The HeadPulse is measured by applying a highly sophisticated sensor to the patient's head, measuring minute pulsations produced by each heartbeat. The HeadPulse changes dramatically during LVO strokes, which is read by Harmony. Coupling the Harmony results with a simple clinical examination of limb weakness, the device can discriminate LVO strokes among Code Stroke patients in a matter of seconds.

About MindRhythm

MindRhythm is a medical technology company focused on preventing neurological injury. Founded by world-renowned scientific experts with significant commercialization success, MindRhythm's monitoring technology provides real-time visibility to life-threatening situations at home, prehospital, in the operating room, and on the field. MindRhythm's technology allows clinicians to intervene, optimize and manage care to prevent brain damage. Collaborating with the healthcare community, MindRhythm looks to apply a systematic approach to reducing time to treatment in strokes and monitor neurological health during recovery from injury. Together, let's save lives and improve the quality of life: <https://mindrhythm.com>

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