

HeRO NOWS Receives Breakthrough Device Status for Neonatal Opioid Withdrawal Syndrome

CHARLOTTESVILLE, VIRGINIA, USA, July 22, 2024 /EINPresswire.com/ -- [Medical Predictive Science Corporation](#) (MPSC), a company that specializes in the development of AI predictive analytics for the neonatal intensive care unit (NICU), has been granted Breakthrough Device designation by the US FDA for its HeRO NOWS device in development.

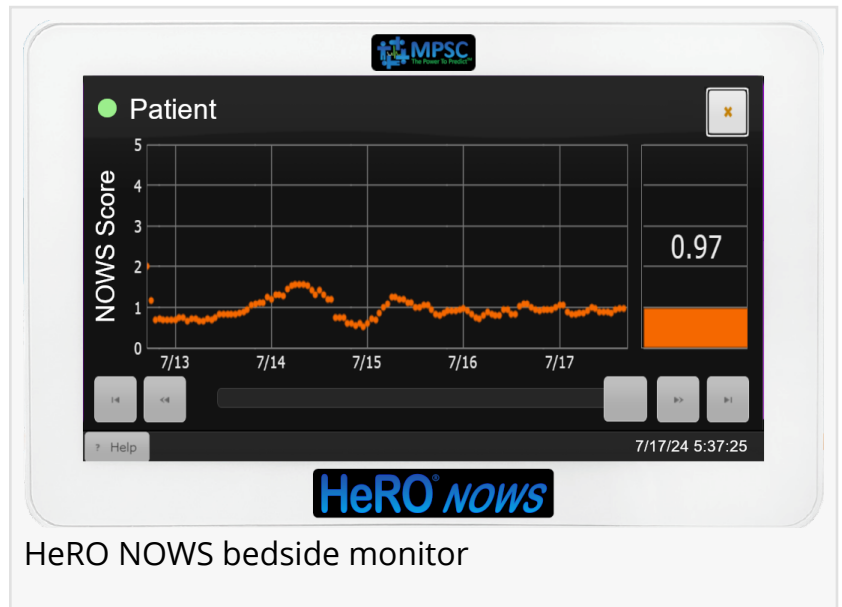
“Designation as a Breakthrough Device is a testament of our work to address unmet medical needs of the neonatal population,” said Will King, CEO of MPSC, “As the leader in AI neonatal predictive analytics, we take pride that our first of a kind HeRO platform has already saved many lives. We look forward to bringing HeRO NOWS to the market in order to continue aiding doctors and nurses to improve the lives of these most precious infants.”

What is NOWS?

Neonatal Opioid Withdrawal Syndrome (NOWS), also called neonatal abstinence syndrome (NAS), is a rising health concern affecting newborn infants exposed to opioids in utero. NOWS is a complex disorder with variable presentation and severity, yet can have lifelong consequences. Symptoms include extreme irritability, difficulty feeding, respiratory problems, and seizures. Assessment variability between clinicians and overlap with normal neonatal behavior has led to substantial ambiguity and variation in care. These challenges contribute to delays in treatment, hospital discharge, and care inequities. NOWS has seen a troubling surge in recent years, with its upward trajectory accelerated by the global pandemic.

POWS for NOWS

Building upon their expertise in vital sign analytics to detect abnormal patterns caused by neonatal sepsis, MPSC and the research team recognized similar patterns due to autonomic



dysfunction in infants with NOWS and conducted preliminary studies with promising results.

In Fall 2023, they were awarded \$3.1 million from the National Institutes of Health. The collaboration will develop a non-invasive, single-sensor device using routine pulse oximetry data as an objective tool to optimize care for the NOWS infant across hospital settings. HeRO NOWS will guide diagnosis and augment care toward improved outcomes and optimized length of stay.

About the research team

MPSC and a team of neonatal researchers at the University of Virginia Children's Hospital, Washington University in St. Louis, and the University of Alabama at Birmingham have been studying cardiorespiratory signatures of NOWS. The proposed research underscores the pressing need to better understand its pathophysiology and optimize the treatment of affected infants. As the opioid epidemic continues to evolve, targeted research like this becomes imperative in our collective endeavor to mitigate its impact on health systems and families.

About MPSC

MPSC is committed to the development of AI-based computational diagnostic and bioinformatic technologies for the healthcare industry. MPSC's technology saves lives and reduces healthcare expenditures through effective clinical diagnostic and decision support tools. These products use predictive analytical methods to make the early diagnosis of clinical illness through continuous, non-invasive patient monitoring, and to provide diagnostic information as well as decision support to the physician.

About the Breakthrough Devices Program

The FDA Breakthrough Devices Program designates certain medical devices and device-led combination products that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions.

The Breakthrough Devices Program is intended to provide patients and health care providers with timely access to medical devices by speeding up development, assessment, and review, reflecting FDA's commitment to device innovation and protecting the public health.

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