



Prolira Announces FDA Clearance of the DeltaScan® Brain State Monitor for Detecting Acute Encephalopathy (Acute Brain Failure), a Condition Affecting Millions of Hospitalized Patients 60 and Older

- *Acute brain failure costs the US healthcare system \$164 billion annually¹ – rivaling the cost of care for heart disease and diabetes²*
- *DeltaScan is the world’s first bedside EEG device, providing clinicians with quick and objective brain state measurements, key for timely treatment and improved outcomes*

UTRECHT, The Netherlands, March 14, 2023 – Prolira BV, a high-tech company committed to enabling early and effective treatment of patients at risk of developing acute brain failure, announced today it has received 510(k) clearance from the Food and Drug Administration (FDA) for the DeltaScan® Brain State Monitor to aid in the diagnosis of acute encephalopathy in hospitalized patients over 60 years of age. The DeltaScan Brain State Monitor provides a quick and objective measurement of acute brain failure even before symptoms appear, enabling clinicians to provide immediate treatment and help patients regain cognitive well-being.

“Managing acute encephalopathy is challenging as symptoms are often overlooked and the diagnostic approaches are largely subjective and ineffective, resulting in delayed diagnosis and treatment. This delay often leads to cognitive impairment, worse health outcomes, and increased costs,” said Dr. Frans Leijten, Head of EEG Department, UMC Utrecht, the Netherlands. “DeltaScan enables clinicians to objectively identify acute encephalopathy, which encompasses delirium, alerting us to act quickly to determine the underlying cause and appropriate interventions. It’s clear from the evidence that minimizing the duration of acute brain failure can improve outcomes.”

Each year, approximately 50% of surgical and ICU patients in the US and Europe are at risk of developing acute brain failure and delirium³, yet up to 88% of delirium cases are missed^{1,3} as the most widely used detection tools are checklist-based and subjective. Acute brain failure is caused by underlying conditions, such as post-operative infections, organ failures, and metabolic disorders. Detecting and treating acute brain failure earlier is important, as it helps prevent permanent cognitive dysfunction while decreasing hospital stays.² In the US, \$164 billion is spent annually on acute brain failure¹, rivaling costs associated with heart disease and diabetes.²

The DeltaScan Brain State Monitor is the first bedside platform designed to help clinicians objectively determine if a patient has acute brain failure even before symptoms occur by measuring polymorphic delta waves in the electroencephalogram (EEG). Nurses or technicians can easily perform a bedside measurement and obtain a clear negative or positive output in less than 5 minutes without requiring specialized personnel or complicated equipment. A large-scale clinical study of more than 400 ICU and post-operative patients (mostly 60+ of age) demonstrated a diagnostic performance of more than 85% for acute encephalopathy.⁴

“FDA clearance is a major milestone in our mission to make brain state assessments and follow-up interventions an integral part of standard practice. The uptake of DeltaScan in Europe has been strong and has allowed the company to incorporate clinician feedback into the product design, generate robust clinical evidence, and refine our commercial approach,” said Dominic Spadafore, Chief Executive Officer, Prolira. “We’re excited to bring our unique solution to the US and have developed a robust pipeline of US centers interested in our proven solution.”

About Prolira:

Prolira is a high-tech start-up that addresses a costly and growing healthcare problem: acute brain failure (acute encephalopathy and delirium), a serious response of the brain to common underlying medical conditions like post-operative infections, organ failures, and metabolic disorders. Every year, 20 million patients are at risk of acute brain failure in EU and US hospitals, which leads to long-term cognitive impairment, longer hospital stays, and increased healthcare costs. Prolira’s DeltaScan® Brain State Monitor is the world’s first EEG bedside device with a validated proprietary algorithm to support clinicians in their quest to optimize patient recovery. For more information, visit <https://us.prolira.com/>.

INVESTOR CONTACT:

Dominic Spadafore
CEO, Prolira
d.spadafore@prolira.com

MEDIA CONTACT:

Jennie Kim
SPRIG Consulting LLC
jennie@sprigconsulting.com

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2. Leslie et al, J Am Geriatr Soc, 2011 : 59(S2): S241-43
3. Marcantonio, et al. N Engl J Med 2017; 377: 1456-66
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