NovaSignal is a medical technology and data company whose mission is to save lives by Unlocking the Power of Blood Flow Data.
Blood Flow in the Brain is Indicative of Overall Health

Access to real-time data can prevent disability or death. With more than 200 clinical studies published annually, indications for the use of cerebral ultrasound (also referred to as TCD) are expanding.¹
Combining robotics, artificial intelligence, and cerebral ultrasound

**NovaSignal Uniquely Captures Blood Flow Data in Real Time**

The fully-automated NovaGuide Intelligent Ultrasound is indicated to assess cerebral blood flow velocity within the major conducting arteries and veins of the head and neck, and to measure the occurrence of transient emboli signals within the bloodstream.

Robotic probe pods autonomously search, find, and display changes in cerebral blood flow in real time.
The NovaSignal Platform empowers the clinical team with critical, real-time information about cerebral blood flow to guide diagnosis and improve patient outcomes.

NovaGuide™ 2
Al-Driven, Robotic TCD Ultrasound
With cutting-edge AI and advanced robotics, the NovaGuide 2 Intelligent Ultrasound uniquely captures blood flow data in real time to identify brain illnesses and diseases that present as changes in cerebral blood flow.

NovaGuide View
Fully Connected Healthcare Experience
Offering secure, cloud-based access to dynamic exam data, NovaGuide View improves coordination of clinical teams, reduces time to intervention, and is a critical piece of the overall patient assessment.

NovaKit 2
NovaKit 2 provides required essentials to ensure exams are safe, comfortable, and personalized for each patient.

Clinical Evidence
NovaSignal is committed to advancing brain health through innovative, evidence-based solutions for patients and providers.

NovaCare
Our solution services team provides certified service and support for the NovaSignal Platform, including 24/7 remote support, IT integration, on-site servicing, loaner devices, and more.
NovaGuide™ 2 Intelligent Ultrasound

With cutting-edge AI and advanced robotics, the revolutionary NovaGuide 2 Intelligent Ultrasound uniquely captures blood flow data in real time to identify brain illnesses and diseases that present as changes in cerebral blood flow. NovaGuide 2 provides the clinical team with critical information to guide patient diagnosis and treatment.

The Only Fully Autonomous, AI-Driven, Robotic Transcranial Doppler Ultrasound System
NovaGuide™ View

A revolutionary way to improve patient care

Secure, Cloud-Based Access To Real-Time Exam Data
Amplify clinical resources to expedite patient assessment, triage, and treatment

Dynamic Data to Inform a Diagnosis
Simplify and speed report completion with access to exam-quality videos and images

An Essential Tool for Cerebral Monitoring
Remotely monitor vessel velocities and emboli count in real time, and receive notifications on key events

Full Exam History Enables Diagnostic Insights
Easily track a patient's condition over time to evaluate treatment effectiveness
Clinical Evidence

We are committed to advancing brain health through innovative, evidence-based solutions for patients and providers.

### Over 130 peer-reviewed citations covering NovaSignal’s technology

### Awarded over $25M in research grants from the DoD, NIH, and NSF

<table>
<thead>
<tr>
<th>NovaSignal Clinical Trials</th>
<th>Objective</th>
<th>Design</th>
<th># of subjects</th>
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<tr>
<td><strong>Large Vessel Occlusion</strong></td>
<td>Cerebral Blood Flow Velocity Morphology – Large Vessel Occlusion</td>
<td>To collect adequate quality data to develop an algorithmic framework for assessing cerebral vascular occlusions confirmed by standard of care Computer Tomography Angiography (CTA) imaging</td>
<td>Prospective, multi-center, multi-arm, multi-cohort</td>
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<td><strong>Traumatic Brain Injury</strong></td>
<td>Advanced Morphological Analysis of Cerebral Blood Flow for Acute Concussion Diagnosis and Return-To-Play Determination</td>
<td>To develop and evaluate an analytical platform for quantifying cerebral hemodynamic dysfunction following mild TBI and expand our medical and scientific understanding of these changes</td>
<td>Prospective, longitudinal, single-center, multi-arm, multi-cohort</td>
<td>219</td>
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<td><strong>Intracranial Bleed</strong></td>
<td>Precision Intracranial Bleed Triage and Monitoring</td>
<td>To determine if cerebral hemodynamic dysfunction can be used to rapidly classify traumatic brain injury and determine if the subject(s) are at risk of deteriorating</td>
<td>Prospective, multi-arm, multicenter, non-invasive</td>
<td>Up to 600</td>
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<tr>
<td><strong>Intracranial Pressure</strong></td>
<td>Cerebral Blood Flow Velocity Morphology for Quantification of Intracranial Pressure</td>
<td>To collect high quality cerebral blood flow velocity (CBFV) measurements to develop an algorithmic framework to determine correlation to and estimates of intracranial pressure when measured with invasive monitoring</td>
<td>Prospective, multi-center, multi cohort, non-invasive</td>
<td>Up to 540</td>
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<td><strong>PFO</strong></td>
<td>NovaGuide Intelligent Ultrasound Compared to Transthoracic Echocardiography for Detection of Right-to-Left Shunt</td>
<td>To evaluate the shunt detection rate of the NovaGuide Intelligent Ultrasound relative to standard of care diagnostic techniques (TTE, TEE, SOC TCD), and to assess the safety, accuracy and usability of the device</td>
<td>Prospective, single-arm multicenter, non-significant risk</td>
<td>Up to 150</td>
</tr>
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Awarded over $25M in research grants from the DoD, NIH, and NSF

- Over 130 peer-reviewed citations covering NovaSignal’s technology
“Integrating the NovaGuide gives clinicians a chance to look inside the brain at blood flow patterns in real time and rapidly identify physiological changes associated with neurological disorders, enabling efficient diagnosis and triage for treatment.”

Dr. Alan B. Lumsden
Medical Director and Chair of Cardiovascular Surgery
Houston Methodist DeBakey Heart and Vascular Center

**Cardiology**

**Patent Foramen Ovale (PFO)**

- The prevalence of PFO among the cryptogenic stroke population is $2^{\sim}40\%$ to $50\%$
- With 96% sensitivity and 92% specificity, TCD has been shown to detect $2X$ the number of PFOs vs TTE

**Invasive Cardiovascular Procedures**

- It is estimated that every year up to 600,000 patients in the U.S. suffer a brain injury during, or after, a cardiovascular procedure
- TCD monitoring is now recognized as a practical tool to detect intra- and periprocedural events

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Dr. Alan B. Lumsden
Medical Director and Chair of Cardiovascular Surgery
Houston Methodist DeBakey Heart and Vascular Center
NovaSignal’s solution, including the automated ultrasound and cloud application, provide unsurpassed access and accuracy for cryptogenic stroke management and PFO assessment.

Dr. Andrei V. Alexandrov
Semmes-Murphey Professor and Chairman of Neurology
University of Tennessee Memphis

800,000
Number of strokes every year in the US

#2
Stroke is the second leading cause of death globally

TCD is recognized as the standard of care at comprehensive stroke centers

70%
of subarachnoid hemorrhage patients develop vasospasm, a major complication & source of morbidity

Guidelines recommend using TCD to monitor for the development of arterial vasospasm

7

Neurology

8

6

7

9
“It is remarkable that a diagnostic machine used to study the brain could give us insight into the pathophysiology of a pulmonary disease. The benefit of using this particular system was that automated monitoring allowed providers to assess cerebral blood flow while minimizing the potential for exposure to COVID-19.”

Dr. Alex Reynolds
Neurocritical Intensivist and Asst Professor of Neurology
Icahn School of Medicine at Mount Sinai
Covering everything from basic anatomy to advanced insonation techniques, our CME courses help improve technique and ensure patients receive the best possible care.
NovaSignal is committed to providing safe and effective solutions for assessing brain health that adhere to all statutory and regulatory requirements. Our products meet FDA regulations, ISO 13485:2016 standards, and MDSAP requirements for quality management systems.

NovaSignal products and replacement parts are designed and assembled in the U.S. A rigorous internal quality management system fulfills all FDA regulations, ISO 13485:2016 standards, and MDSAP requirements. All NovaSignal products undergo meticulous quality inspections throughout manufacturing.

NovaSignal stands behind our quality by providing complementary one-year access to NovaCare expert support with the purchase of our products. Extended service agreements are available with coverage for up to 4 additional years.
REFERENCES


NovaGuide and NovaGuide 2 consist of the NovaBot and the Lucid TCD.

The Lucid TCD 2.0 is a medical ultrasound system intended for use as an adjunct to the standard clinical practices for measuring and displaying cerebral blood flow velocity within the major conducting arteries and veins of the head and neck. Additionally, the Lucid TCD measures the occurrence of transient emboli signals within the bloodstream.

The NovaBot, when used with the Lucid TCD is a medical ultrasound device which assists the user in the setup and acquisition of cerebral blood flow velocity via the patient's temporal windows.

It is intended for use as an adjunct to standard clinical practices for measuring and displaying cerebral blood flow velocity and the occurrence of transient emboli within the bloodstream.

The NovaGuide 2 intelligent ultrasound system is intended for use as an adjunct to standard clinical practices for measuring and displaying cerebral blood flow velocity and the occurrence of transient emboli within the bloodstream. NovaGuide is intended to be used by healthcare professionals qualified by training in its safe and effective use. The device is not intended to replace other means of evaluating vital patient physiological processes, is not intended to be used in fetal applications, and is not intended to be used inside the sterile field.

CAUTION: Federal (USA) law restricts this device to sale, distribution by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device.

Lucid TCD 2.0 is a new name for Lucid M1 with no significant differences in the product. NovaBot is a new name for NeuralBot with no significant differences in the product. Lucid TCD 2.0, NovaBot, NovaGuide and NovaGuide 2 are not licensed for sale in Canada.

NovaGuide View is a Medical Device Data System (MDDS) per 21 CFR 880.6310. Further, NovaGuide View is a device MDDS that contains hardware functions which only transfer, store and display medical device data or results. Per the FDA guidance on Medical Device Data Systems, Medical Image Storage Devices and Medical Image Communications Device (September 17, 2019), device MDDS remain devices under section 201(h) of the FD&C Act and FDA does not intend to enforce compliance with the regulatory controls including registration and listing, premarket review, postmarket reporting, and quality system regulation for manufacturers.

NovaGuide View is not offered for sale in Canada or the European Union.