

AlgoDx Receives FDA Clearance for Sepsis Detection Software

Stockholm, Sweden and Boston, MA – August 20th, 2024.

AlgoDx, a leading medical AI company with EU and UK-approved ML-based software for sepsis prediction in commercial use, today announced that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for its sepsis detection software using a proprietary algorithm, NAVOY CDS®. This milestone marks a major step forward in AlgoDx's expansion into the U.S. market.

NAVOY CDS® is a software as a medical device (SaMD) designed to support clinicians in identifying sepsis in hospitalized patients, including the Emergency Department. By leveraging routinely collected vital parameters, the software analyzes patient data to provide early warnings of sepsis, a life-threatening condition, enabling healthcare providers to initiate timely interventions.

“Receiving FDA clearance for NAVOY CDS® is a testament to our team’s dedication and expertise in developing cutting-edge medical device software for healthcare,” said Andreas Macura, Chief Product Officer at AlgoDx. “We believe that NAVOY CDS® has the potential to significantly improve patient outcomes by enabling earlier detection and treatment of sepsis.”

Dr. Enrico Petrillo, Brigham and Women’s Hospital Director of International Research and Strategic Initiatives, faculty Harvard Medical School, Executive Director of Network Medicine Global Alliance, and Chairman of the Board AlgoDx added, “This FDA clearance is a pivotal moment for AlgoDx as we expand our presence in the United States. It validates our commitment to developing innovative technologies that address critical healthcare challenges. We look forward to bringing NAVOY CDS® to health systems nationwide.”

Sepsis is the leading cause of in-hospital mortality worldwide, accounting for approximately 35% of all hospital deaths. Sepsis is a life-threatening condition caused by an extreme immune system response to an infection. It is a medical emergency that can lead to organ failure and death. Early detection and treatment are crucial for improving a patient’s chance of surviving sepsis. AlgoDx’s solutions offer the potential to improve sepsis care by providing healthcare providers with a powerful tool to identify patients at risk in the Emergency Department as well as other hospital wards.

About AlgoDx

AlgoDx is an AI digital health company that enables physicians and healthcare providers to use data-driven solutions to deliver better patient outcomes and reduce costs. AlgoDx is committed to developing innovative decision-support tools, including artificial intelligence and machine learning, to provide insights and predict acute complications. AlgoDx's main offering focuses on sepsis, a medical condition with high mortality rates and significant financial and social impact.

<https://www.algodx.com>.

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