Prenosis Sepsis ImmunoScore

AI/ML software as a medical device (SaMD) for the rapid diagnosis and prediction of sepsis risk and adverse outcomes in acute care settings.

https://prenosis.com

Overview

Prenosis Sepsis ImmunoScore is the first-ever AI diagnostic tool to receive marketing authorization from the U.S. Food & Drug Administration (FDA) for sepsis. It is an Artificial Intelligence/Machine Learning (AI/ML)-based Software as a Medical Device (SaMD) intended to aid healthcare providers in the risk assessment for the presence of or progression to sepsis within 24 hours of patient assessment in the Emergency Department or hospital.

Key Features and Capabilities

The software operates by analyzing up to 22 predetermined inputs from the patient's Electronic Health Record (EHR), which include biomarkers, vital signs, and clinical data. It generates a risk score and assigns the patient to one of four discrete risk stratification categories. Critically, the Sepsis ImmunoScore has both diagnostic and predictive power, simultaneously predicting critical adverse outcomes such as in-hospital mortality, length of stay, ICU admission, mechanical ventilation placement, and vasopressor use within 24 hours.

Technology and Integration

The Sepsis ImmunoScore was built using Prenosis' Immunix precision medicine platform, which leverages a large, proprietary biobank of thousands of blood samples and clinical data. The software is designed for seamless integration directly into a hospital's existing EHR/EMR system, with the potential to utilize FHIR backend platforms for data integration. To foster clinician trust and a true clinician-AI partnership, the tool features an intuitive display that transparently explains how each of the 22 patient parameters contributed to the final sepsis score.

Use Cases and Benefits

The primary use case is to enable earlier, more accurate sepsis diagnosis and risk stratification for patients in acute care settings, allowing for faster treatment decisions and improved patient outcomes. Its use can also help hospital systems improve compliance with payer protocols, such as the federal Centers for Medicare & Medicaid Services' SEP-1 bundle.

Key Features

- First FDA-Authorized AI Diagnostic for Sepsis
- Dual Diagnostic and Predictive Power for Adverse Outcomes
- Analyzes 22 Diverse Parameters (Biomarkers & Clinical Data)
- Provides Risk Score and Four Discrete Risk Categories
- Predicts Mortality, ICU Admission, and Length of Stay within 24 Hours
- Direct EMR/EHR System Integration
- Transparent AI Display Explaining Score Calculation

Pricing

Model: enterprise

Subscription pricing varies depending on the size and needs of each client. The product is sold to hospitals and health systems through an exclusive distribution partnership with Roche Diagnostics.

Target Company Size: enterprise

Integrations

EHR/EMR Systems, FHIR-based Platforms (e.g., Aidbox)

Compliance & Certifications

FDA De Novo Marketing Authorization, FDA Class II Medical Device