

Computer-aided Assessment of Glucose

ICD-10 Coordination and Maintenance Committee Fall Update - September 2025

Glytec LLC Presenters:

- Deborah Dean, Chief Government & Strategic Growth Officer
- Donald Fetterolf, MD, MBA, FACP

Glytec History and Device

- Developed by Dr. Bruce Bode and Robby Booth.
- Current product configuration is “Glucommander®”.
- Device is an advanced electronic glucose/glycemic management software device that integrates into inpatient workflows to reduce glycemic variation, i.e., FDA Software as a Medical Device (SaMD).
- Product has been available for more than 10 years.
- FDA 510K medical device clearance granted 8/4/2017.
- No significant serious adverse events have occurred, although there have been several medical device alerts since 2017, mostly related to minor issues that were addressed through corporate corrective and preventive actions.

Background: Hospital Glycemic Management

- High prevalence of diabetes and glucose control needs presents major issues for hospital patient management.
- Traditional paper-based tools result in significant hypo- and hyperglycemic clinical adverse events.
- Comprehensive medical literature supports the value of aggressive glycemic control.
- Glycemic control is recognized as a major failure of health care delivery and has recently been the focus of the CMS Hospital Inpatient Quality-Reporting (IQR) Program.
- A significant solution will be the successful use of SaMD programs.
- Glucommander® has seen widespread use and results published in the medical literature.

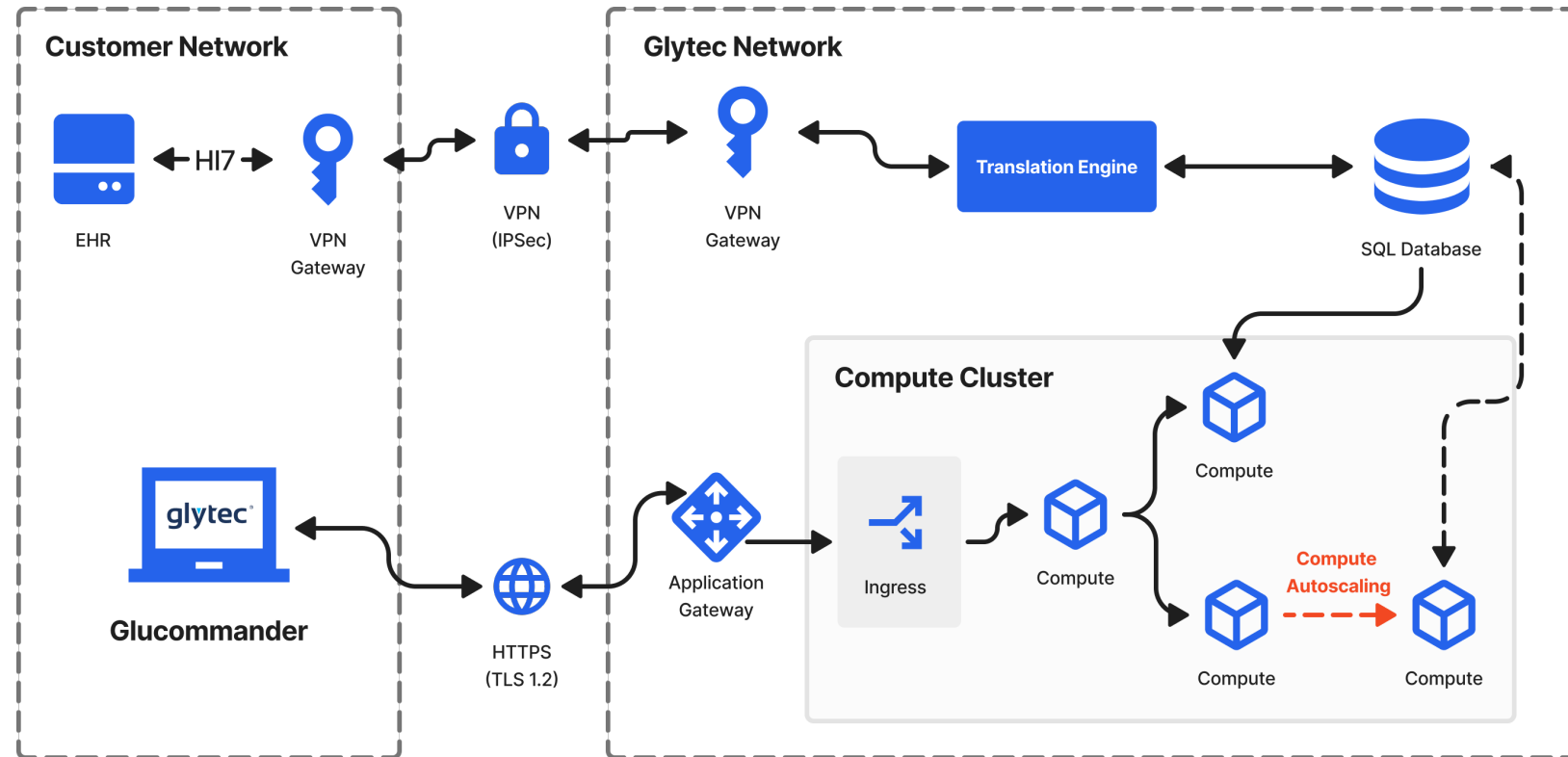
Technology Review

- Glucommander® glycemic management software device is an FDA-cleared, HITRUST*-certified solution designed to maintain blood glucose in hospitalized patients.
- Integrated directly within clinical workflows through seamless integration with EMR, laboratory interface systems (LIS), and pharmacy systems.
- Supports clinicians' care delivery by determining insulin dosing based on key inputs, preprogrammed guidelines, lab results, and predictive needs to produce smooth glycemic control through optimized care and insulin dosing.
- Facilitates administrative management of patients via floor-level, committee-level, hospital-level, and system-level analytic outputs.

*Health Information Trust Alliance

Network Architecture

- ✓ Secure site-to-site VPN tunnel using IPSec for integrations
- ✓ HL7v2.0 translation is processed in a real-time data flow from the EHR
- ✓ The application is delivered through a scalable, redundant platform
- ✓ Access to the application is provided through a secure HTTPS connection using TLS 1.2



Integrating Glucommander® into Care Delivery

- “Glucosurveillance” is a hospital data-based alert system.
- Patients are selected for the Glytec insulin titration program based on:
 - The need for ongoing glycemic management.
 - Patients identified through the Glucosurveillance feature for patient safety.
- A physician's order for the Glytec insulin titration program is required to enter patients into the system.
- Enter the patient's demographic and medical information into the system.
- Lab values are electronically transmitted, or clinicians can use "dual entry" to add the glucose value, and the Glucommander® will titrate the insulin amount.
- The program identifies insulin dosing, frequency, and usage, and monitors clinical data within the medical record to analytically develop the course of care.
- The versatility to support intravenous insulin and subcutaneous insulin administration allows the program to be adopted in critical care areas and expanded at risk patients throughout the hospital.

Description

- Product installed and linked into hospital systems, integrated into a direct EMR interface, and connects with lab, pharmacy, local insulin delivery devices, etc. Clinical training is needed, but graphics are intuitive.
- Supports a dynamic patient care environment by combining SaMD algorithms, hospital guidelines, and supplemental patient demographic and clinical information.
- Suitable for clinical management of all patients on IV or SQ insulin, diabetic/nondiabetic patients (CABG, CVA, pregnant patients), various locations (ICU/floor), and other variables (pediatric patients).
- Ongoing workflow determines feedback to clinicians and provides predictive insulin dosing, with appropriate safety controls and overrides.
- Comprehensive analytics with real-time dashboards, comparative analysis, and benchmarking to monitor performance.
- Coders would locate the use of this product in progress notes or nursing notes.

Seamless EHR Integration & Interoperability

Glucommander® is built for deep, secure integration.

- ✓ Real-time, bi-directional data exchange with Epic, Cerner, and other leading electronic health records (EHRs)
- ✓ Smart-on-FHIR *login + SmartClick launch enables frictionless workflow inside the EHR
- ✓ Supports interfaces for ADT, LIS, MAR, Orders, Nutrition, and BAR
- ✓ Secure point-to-point Virtual Private Network (VPN) tunnels for HL7v2 transactions—validated and normalized before entry

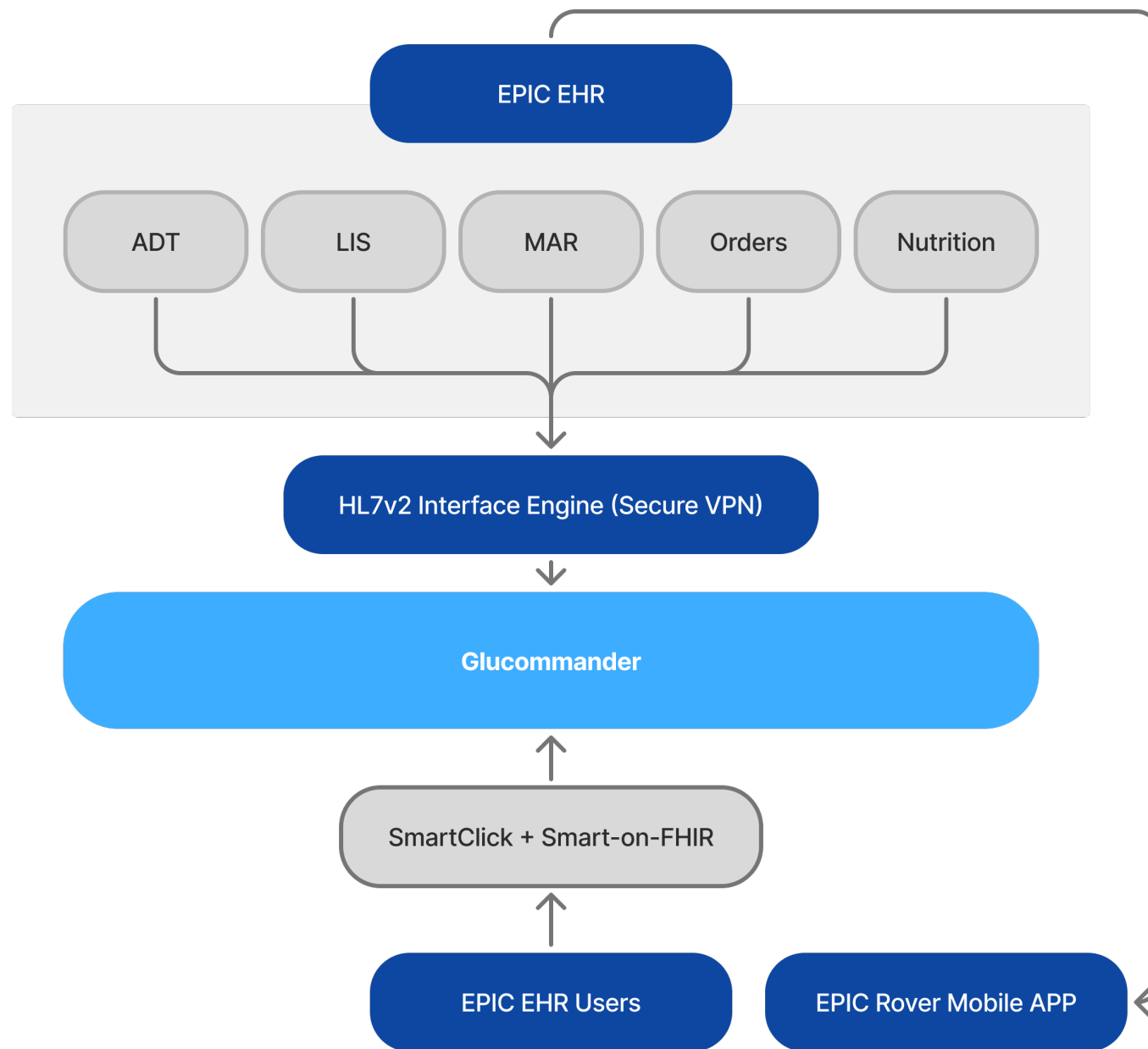
ADT = Admission, Discharge, Transfer

LIS = Laboratory Information System

MAR = Medication Administration Record

BAR = Billing Account Record

FHIR=Substitutable Medical Applications and Reusable Technologies on Fast Healthcare Interoperability Resources



Glucommander® Demo Sample Clinical View

Components Include

- Patient demographics
- Insulin dosing rate
- Target Range set
- Recent glucoses
- Anion gap
- Insulin sensitivity estimate
- Time until next insulin dose

Other Screens Show

- Patient setup and integration
- Target range set up
- Subcutaneous dosing regimens



Statistics

- The software has been installed at over 350 inpatient hospitals in the United States, and in 2024 was operational in 285 hospitals.
- In 2024, the program was used in 126,183 unique inpatient admissions in these 285 hospitals.
- Percentage of patients with Medicare in all admissions where the product was used = 54%
- Across our client base, Glucommander® IV was utilized for insulin dosing and glycemic management in 30% of all ICU admissions. An additional 25–30% of inpatient clients requiring IV or SubQ insulin therapy were managed using Glucommander®.
- This data reflects consistent clinical integration of Glucommander® in various inpatient acuity levels.

Benefits of Reporting the Use of Glucommander®

- Enables tracking of the scope and value of SaMD in glycemic control.
- Accelerates uptake and use of effective medical technology.
- Improves the healthcare technology ecosystem for Medicare beneficiaries and underserved populations.
- Adds value across multiple domains in the medical care system.
 - Clinical care quality outcomes and patient safety
 - Utilization management
 - Operations management and reduction in operating overhead
 - Intangible/social benefits

Conclusions

- The prevalence of glucose-related diseases and the novel use of insulin have led to an increased need for inpatient glycemic control that supports clinicians in effective management.
- The CMS mandates on the collection and public reporting of hyper/hypoglycemic electronic clinical quality measures (eCQMs) provide opportunities for clinical outcome improvement.
- Electronic glycemic management systems have proven to be an effective intervention that supports improved clinical outcomes.
- The goal is to facilitate hospital integration of these programs in the patient care workflows. Promoting the delivery of both optimized insulin management and evidence-based clinical management strategies.

Closing

- In short, adoption of an ICD-10-PCS code for addressing the use of this particular software device will engage the use of real-time, patient-specific, evidence-based knowledge at the point of care, integrated with medical care workflows to optimize management of patients using continuous improvement tools.

Thank you