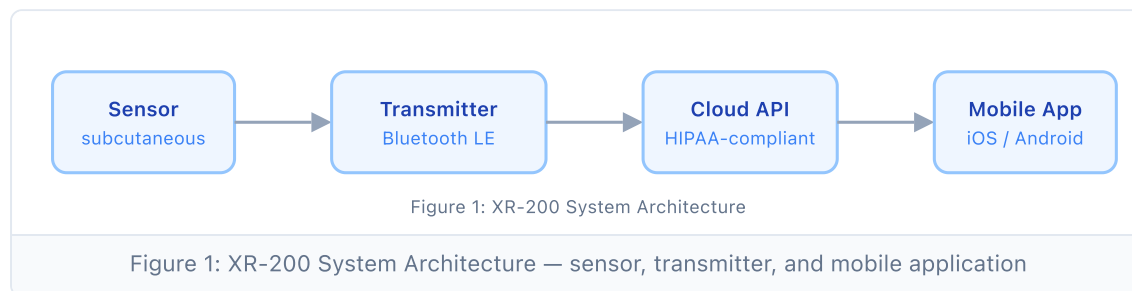


CGM Device — Technical Description

Device Overview

The XR-200 CGM system is a non-invasive wearable device for continuous glucose monitoring in adult patients with diabetes. It consists of three primary components: a subcutaneous sensor, a wireless transmitter, and a mobile application. Together they capture, transmit, and display glucose readings every five minutes over a 14-day wear period.



Sensor

The sensor is a sterile, single-use electrode inserted into the subcutaneous tissue of the upper arm using a spring-loaded applicator. It measures interstitial glucose via an electrochemical reaction with glucose oxidase. Raw signal is converted to a glucose concentration using a factory calibration algorithm; no fingerstick calibration is required during the wear period.

Key specifications:

- Wear duration: up to 14 days
- Measurement interval: every 5 minutes (288 readings per day)
- Glucose range: 40–400 mg/dL
- MARD vs. venous reference: $\leq 8.5\%$ ($\leq 10\%$ for extremes 40–60 mg/dL)

Transmitter

The reusable transmitter snaps onto the sensor and communicates with the mobile app via Bluetooth Low Energy 5.0. It also stores up to 72 hours of readings locally, ensuring continuity if the phone is out of range.

Mobile Application

The iOS and Android app displays real-time glucose values, trend arrows, and configurable high/low alarms. Glucose history is uploaded to the HIPAA-compliant cloud API every 15 minutes. A representative 24-hour glucose profile demonstrating the continuous monitoring capability is shown below.

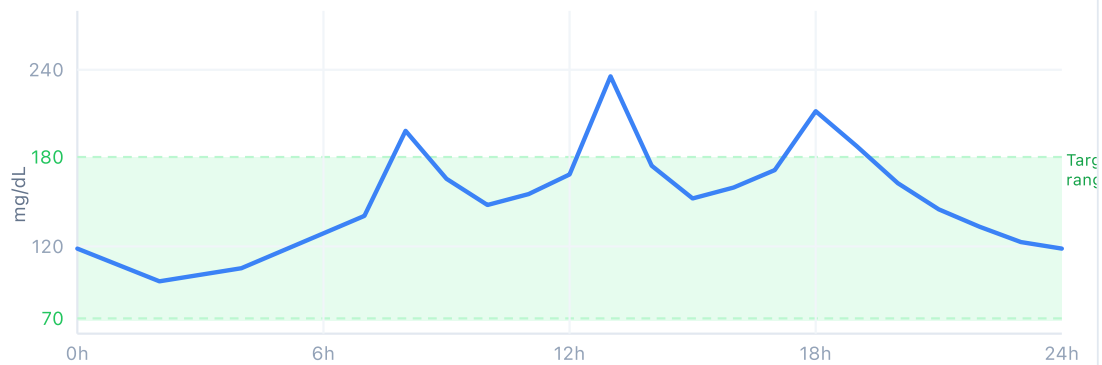


Figure 2: Representative 24-hour glucose profile — breakfast spike at 08:00, lunch at 13:00, dinner at 18:00

Figure 2: Representative 24-hour glucose profile with target range overlay (green band, 70–180 mg/dL)

Intended Use

The XR-200 is intended for use in adults (≥ 18 years) with type 1 or type 2 diabetes as a replacement for routine fingerstick glucose monitoring. It is not indicated for use in critically ill patients or those on dialysis.