Continuous Glucose Monitoring Systems: Categories and Features

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Continuous glucose monitoring (CGM) systems fall into two categories: 1) "professional" (masked) CGM devices that patients wear without being able to see glucose values until their provider downloads and reviews the data retrospectively during an office visit and 2) personal systems affording both real-time observation of continuous data by patients and retrospective review of complete profiles by patients at home, providers in clinic, or remotely. Table 1 presents key features of the commonly used systems described below.

Professional CGM

The FreeStyle Libre Pro system (Abbott, Alameda, CA) was approved by the U.S. Food and Drug Administration (FDA) in September 2016. This system consists of the FreeStyle Libre Pro sensor and a single reader device that is kept in the health care provider's office. The sensor is applied to the back of a patient's upper arm in the provider's office and requires a 2-minute activation period. The system then records glucose levels every 15 minutes for up to 14 days. The patient has no interaction with the sensor and cannot see the glucose data. At the end of the wear period, the sensor is scanned in the health care provider's office with the reader device, and the data are uploaded to the FreeStyle LibreView software. The system has a mean absolute relative difference (MARD) accuracy of 12.3% (1). Reported as a percentage, MARD is the average of the absolute error between all CGM values and matched reference values. Lower MARD values indicate greater device accuracy.

The Medtronic iPro2 system (Medtronic, Northridge, CA) features the Enlite glucose sensor, which is wearable for up to 6 days, and the iPro2 digital recorder. Glucose readings are blinded to the patient and recorded every 5 minutes. Fingerstick blood glucose measurements are not required for calibration, but at least one blood glucose entry every 12 hours is required for system uploading. While wearing the iPro2 system, patients can document events on their smartphones via the iPro2 myLog app and simultaneously send them to the Medtronic CareLink iPro website. The information from the recorder is then uploaded to the Medtronic CareLink iPro website in the health care professional's office for analysis and therapy adjustment. With a MARD of 13.6%, the Enlite sensor is 31% more accurate than the Medtronic Sof-Sensor, which was discontinued in September 2015 (2,3).

Personal CGM

Several personal CGM systems are available in the United States for daily use by people with diabetes. The Abbott FreeStyle Libre flash CGM system received FDA approval in September 2017 for stand-alone use (i.e., not requiring

use of an insulin pump) with intermittent scanning. The system consists of the FreeStyle Libre sensor, which is wearable for up to 10 days, and the FreeStyle Libre reader. The system measures glucose levels every minute and records readings every 15 minutes. The user holds the reader over the sensor to scan the current glucose level to the reader. Both a glucose level and a trend arrow indicating direction and rate of change are displayed with each scan of the sensor. This system has a MARD of 9.7%. The sensor comes factory-calibrated, requiring no calibration by the user, and displays the most recent 8 hours of glucose data for patient review with each scan. Data history of up to 90 days can be uploaded from the reader to the FreeStyle LibreView software for evaluation by the user at home or by the health care provider with the patient during a clinic visit.

The Medtronic Enlite sensor is used with Medtronic MiniMed 530G and 630G insulin pumps. Real-time glucose data and rate-of-change trend arrows are available every 5 minutes on the pump screen, and both pumps use Medtronic SmartGuard technology, which will suspend insulin delivery for up to 2 hours when glucose levels fall below a preset threshold. The Enlite sensor requires calibration every 12 hours. The newer Guardian Sensor 3 glucose sensor and the Guardian Link transmitter are used with the Medtronic MiniMed 670G insulin pump system. Approved by the FDA in September 2016, the 670G is the first hybrid closed-loop insulin pump-CGM system to become available in the United States. The Guardian Sensor 3 may be worn for up to 7 days and is Medtronic's most accurate glucose sensor, with a MARD of 9.6% with abdominal insertion and 8.7% with arm insertion, based on three to four calibrations per day. The three Medtronic MiniMed pumps can all be downloaded to the Medtronic CareLink website for CGM data review.

Stand-alone real-time CGM systems approved for use in the United States include the Dexcom G4 Platinum, Dexcom G5 Mobile, and Dexcom G6 systems (Dexcom, San Diego, CA). The G4 Platinum and G5 Mobile systems feature the Dexcom Platinum G4/G5 sensor, which is placed by the user and can be worn for up to 7 days. Users must calibrate these systems twice daily with fingerstick blood glucose measurements. The G4 Platinum transmitter uses radio wave technology, and glucose data and trend arrows may be viewed continuously on a Dexcom G4 receiver, as well as on the Tandem t:slim (Tandem Diabetes Care, San Diego, CA) and Animas Vibe (Animas Corporation, West Chester, PA) insulin pumps. The G5 transmitter uses Bluetooth technology, and glucose data

may be viewed on the Dexcom G5 receiver, the Tandem t:slim X2 insulin pump, the Dexcom G5 Mobile App on most Apple and Android devices. The G4/G5 sensor has a MARD of 9.0% when used with devices that include the most current Dexcom software (4). The Dexcom G6 CGM system received FDA approval in March 2018. This newest sensor and transmitter system will require no calibrations or fingerstick blood glucose confirmations to make diabetes treatment decisions. The sensor may be worn for up to 10 days. A previous issue with acetaminophen interference has been resolved, and the overall MARD is 9.0% (5).

REFERENCES

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 TABLE 1
 Features of Selected CGM Systems Available in the United States

System Type	Device	Sensor Wear Duration (days)	Start- up Time (hours)	Calibration Requirements and Related Information	Frequency of Glucose Readings	MARD (%)	Software and/or Device Compatibility	Arrows
Professional CGM systems	Abbott FreeStyle Libre Pro sensor	Up to 14	1	None	Every 15 minutes	12.3	Data scanned from sensor using FreeStyle Libre Pro read- er in provider's office	NA
	Medtronic iPro2 En- lite sensor and digital recorder	Up to 6	1	None, but at least one blood glucose entry every 12 hours is required for system uploads	Every 5 minutes	13.6	Data uploaded from sensor recorder using Medtronic CareLink iPro website	NA
Personal CGM systems	Abbott FreeStyle Libre sensor and reader	Up to 10	12	None, but patients are encouraged to check their glucose with a meter if the readings do not reflect how they feel	Available every minute; auto- matically records every 15 minutes	9.7	Stand-alone; data may be uploaded from the reader in provider's office using FreeStyle LibreView software	Glucose is rising quickly (>2 mg/dL per minute) Glucose is rising (1–2 mg/dL per minute) Glucose is changing slowly (<1 mg/dL per minute) Glucose is falling (1–2 mg/dL per minute) Glucose is falling quickly (>2 mg/dL per minute)
	Dexcom Platinum G4/G5 sensor with G4 Platinum transmitter	Up to 7	2	Every 12 hours	Every 5 minutes	9.0 when used with most current Dexcom software	Stand-alone with Dexcom G4 receiver and com- patible with Animas Vibe and Tandem t:slim insulin pumps	Glucose is rapidly rising (>3 mg/dL per minute) Glucose is rising (2–3 mg/dL per minute) Glucose is slowly rising (1–2 mg/dL per minute) Glucose is steady (not increasing or decreasing >1 mg/dL per minute) Glucose is slowly falling (1–2 mg/dL per minute) Glucose is falling (2–3 mg/dL per minute) Glucose is rapidly falling (>3 mg/dL per minute)

System Type	Device	Sensor Wear Duration (days)	Start- up Time (hours)	Calibration Requirements and Related Information	Frequency of Glucose Readings	MARD (%)	Software and/or Device Compatibility	Arrows
Personal CGM systems (cont.)	Dexcom Platinum G4/G5 sensor with G5 Mobile transmitter	Up to 7	2	Every 12 hours	Every 5 minutes	9.0 when used with most current Dexcom software	Stand-alone with Dexcom G5 receiver, most Apple and Android products, and compatible with Tandem t:slim X2 insulin pump	Same as above
	Dexcom G6 sensor and trans- mitter	Up to 10	2	None	Every 5 minutes	9.0	Stand-alone with Dexcom G5 receiver and most Apple and Android products	Same as above
	Medtronic Enlite sensor and MiniLink or Guardian Link trans- mitter	Up to 6	2	Every 12 hours	Every 5 minutes	13.6	Compatible with Medtronic 530G and 630G insulin pumps	Glucose is rising at a rate of ≥3 mg/dL per minute Glucose is rising at a rate of ≥2 but <3 mg/dL per minute Glucose is rising at a rate of ≥1 but <2 mg/dL per minute Glucose is falling at a rate of ≥1 but <2 mg/dL per minute Glucose is falling at a rate of ≥2 but <3 mg/dL per minute Glucose is falling at a rate of ≥2 but <3 mg/dL per minute Glucose is falling at a rate of ≥3 mg/dL per minute
	Medtronic Guardian Sensor 3 sensor and Guardian Link 3 transmitter	Up to 7	2	Every 12 hours	Every 5 minutes	Abdominal insertion: 9.6 with 3–4 calibrations/day; 10.6 with 2 calibrations/day; Arm insertion: 8.7 with 3–4 calibrations/day; 9.1 with 2 calibrations/day	Compatible with Medtron- ic 670G hybrid closed-loop insulin pump system	Same as above