



CARDI•OH

Ohio Cardiovascular and Diabetes Health Collaborative



In partnership with:



Cardi-OH ECHO

*Innovations in Diabetes and
Cardiovascular Health*

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Person-Centered Language Recommendations



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The ADA and the APA recommend language that emphasizes inclusivity and respect:

- **Gender**: Gender is a social construct and social identity; use term “gender” when referring to people as a social group. Sex refers to biological sex assignment; use term “assigned sex” when referring to the biological distinction.
- **Race**: Race is a social construct that is used broadly to categorize people based on physical characteristics, behaviors, and geographic location. Race is not a proxy for biology or genetics. Examining health access, quality, and outcome data by allows the healthcare system to assist in addressing the factors contributing to inequity.
- **Sexual Orientation**: Use the term “sexual orientation” rather than “sexual preference” or “sexual identity.” People choose partners regardless of their sexual orientation; however, sexual orientation is not a choice.
- **Disability**: The nature of a disability should be indicated when it is relevant. Disability language should maintain the integrity of the individual. Language should convey the expressed preference of the person with the disability.
- **Socioeconomic Status**: When reporting SES, provide detailed information about a person’s income, education, and occupation/employment. Avoid using pejorative and generalizing terms, such as “the homeless” or “poor.”
- **Violent Language**: Avoid sayings like ‘killing it,’ ‘pull the trigger,’ ‘take a stab at it,’ ‘off the reservation,’ etc.



Continuous Glucose Monitoring

Karen Bailey, MS, RDN, LD, CDCES

Ohio University Diabetes Institute

Learning Objectives



- 1) List indications for Continuous Glucose Monitors (CGMs)
- 2) Identify candidates and strategies for successful CGM use
- 3) Describe recent device innovations in CGM
- 4) Describe insurance coverage requirements for CGM devices in Ohio

Definition of Continuous Glucose Monitors (CGM)

- A device that constantly measures glucose levels in interstitial body fluid (every one to 5 minutes, 24 hours/d). Parts include a sensor, a transmitter, and a receiver.
- rtCGM – real time CGM streams data continuously to receiver
- isCGM – intermittently scanned CGM requires transmitter to be scanned by receiver to obtain reading by user.
- Provide alerts for designated low and high glucose levels



Dexcom G6



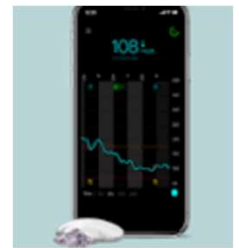
Abbot FreeStyle Libre 2



FreeStyle Libre 3



Senseonics Eversense



Medtronic Guardian

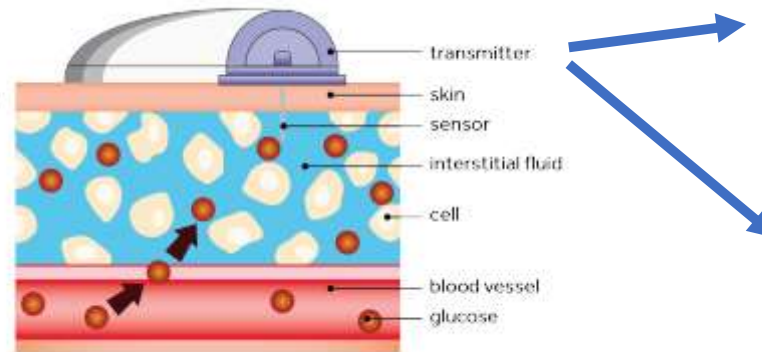
How CGMs Work

Sensor Glucose (SG) and Blood Glucose (BG)

Your glucose meter and glucose sensor measure glucose levels in two different places.

Your **BG meter** measures glucose in your blood.

The **glucose sensor** measures glucose in the fluid around the cells called **interstitial fluid**.



- Sensor is inserted most often on the abdomen or arm, depending on the device.
- Transmitter is attached to a sensor, or the transmitter and sensor are one piece, depending on the device.
- Transmitter sends the glucose level and trend data (arrows indicating direction of glucose and speed) to a receiver (smart device, receiver, or linked insulin pump, depending on the device).
- The sensor glucose will not be identical to bg, especially if bg is moving quickly, such as after a meal, insulin, or exercise. The algorithm gives a close estimate but is helpful for the user to understand this.

Professional vs Personal CGMs



Professional CGM	Personal CGM
Owned by clinic	Owned by person with diabetes
Blinded or unblinded options- for evaluation of diabetes control by provider	Unblinded (real time or scan for sg)- allows user to receive sensor data, trend and speed, receive high and low alerts designated by user
Short term use (3 to 14 days)	Long term use: the various sensors last different number of days each (7 days, up to 180 days, depending on sensor)
Insurance coverage for most with Type 1 or Type 2 diabetes	Insurance coverage for people on intensive insulin regimens or diabetes not in control.
Not compatible with insulin pumps or connected insulin pens	Compatible with insulin pumps, smartphones or connected insulin pens, depending on device

Professional CGM



	Dexcom G6 Pro	LibrePro
Blinded vs unblinded	Both	Blinded
Maximum wear time of sensor	10 days	14 days
Calibration	None	None
Downloading reports	Clarity	LibreView
Care between transmitter use	Disposable-1 time use, must attached transmitter	Disposable 1-time use, combined sensors/transmitter
Alarms for high/low glucose alerts	Yes	No
Interfering substances	Hydroxyurea	High Dose Vitamin C

ADCES Practice Paper. The diabetes care and education specialist role in CGM.

Personal CGM Comparison (FDA approved products)



	G6	Libre 2	Libre 3	Guardian Connect or Guardian 3	Eversense
Integration	T: Slim X2, Omnipod 5, InPen	Bigfoot Unity	No	Medtronic 770G, InPen	No
Display device	Smartphone or receiver	Smart phone or reader	Smartphone only	Smartphone or insulin pump	Smartphone only
Maximum wear time	10 days	14 days T-Slim pump	14 days	7 days	180 days
Warm-up time	2 hours	1 hour	1 hour	Up to 2 hours	24 hours
Calibrations required	0	0	0	At least 2/day	2/day for 21 days, then 1/day
FDA approved sites	Abdomen (ages 2+) Upper buttocks (ages 2-17)	Upper arm	Upper arm	Upper arm, abdomen Upper buttocks (ages 7-13)	Upper arm
FDA Approved for dosing (non-adjunctive indication)	Yes	Yes	Yes	No	Yes
FDA Approved ages (years)	≥2	≥4	≥4	≥2 Guardian 3 ≥14 Guardian Connect	≥18
Drug Interactions	Hydroxyurea	Vitamin C	Vitamin C	Acetaminophen, Hydroxyurea	Tetracycline antibiotics, mannitol
MARD	9%	9.2%	7.9%	9.64%	8.5%
Alarms	High, Low, Predictive	High, Low	High, Low,	High, Low, Predictive	High, Low, Predictive

ADCES Practice Paper. The Diabetes Care and Education Specialist Role in CGM. Available at: <https://www.diabeteseducator.org/practice/educator-tools/diabetes-management-tools/self->

*MARD = mean absolute relative difference. Lower MARD values indicate greater device accuracy.



Components of the Dexcom CGM

The Dexcom CGM System consists of three parts:

1. a small sensor that measures glucose levels just underneath the skin
2. a transmitter that fits onto the sensor and sends data wirelessly to your display device
3. a small receiver or compatible smart device[†] that displays real-time glucose information[†]

The Dexcom CGM also provides customizable alerts to warn the wearer of approaching glucose highs and lows.

- Dexcom G6 requires no calibration and can be used to make treatment decisions.
- It is covered by Medicare Part B (must include reader) for qualified members, Ohio Medicaid (pharmacy benefit for qualified members) and many private insurers.

Dexcom G7

- Status:

- Approved CE mark in Europe
- Pending FDA approval in USA

- Improvements:

- Improved accuracy
- Decreased size (half the size of Dexcom G6)
- Approved locations: Abdomen, Back of the arm
- Reduced Warm up period (2 hours down to 30 minutes)
- 12-hour grace period to replace expired sensors

- Compatibility:

- Meets iCGM criteria (at least 95% of glucose values s/b +/- 15 mg/dl of avg < 100 mg/dl or +/- 15% at glucose > 100 mg/dl)



<https://www.dexcom.com/g7-ce-mark>

Abbot FreeStyle Libre 2 Intermittently Scanned CGM (isCGM)



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- Abbott FreeStyle Libre 2 does not require calibration.
- Sensor and transmitter are one disposable piece.
- Sensor/transmitter is worn for 14 days.
- The FreeStyle Libre 2 allows users to enter alerts for highs and lows. The older, FreeStyle Libre 14-day wear does not have alert option.
- FreeStyle Libre 2 is covered by Medicare for qualified beneficiaries.
- Reader needs to scan the sensor for the user to see a reading. The FreeStyle Libre 3 does not require scanning and is smaller but will not include a reader.
- Users must have a smartphone with a compatible app.

Medtronic Guardian Connect and Guardian 3 CGM

Guardian Connect
CGM/app



Guardian 3
CGM/MiniMed Mobile app





- Requires calibration and decisions on treatment should be made based on fingerstick bg measure. Rechargeable transmitter. Sensors last 7 days.
- Medicare covers Guardian 3 CGM only if integrated with Medtronic insulin pump.
- Guardian Connect CGM links with InPen and smart phone app.

Senseonics Eversense E3 CGM now approved for 180-day wear.

- Must have smartphone that has the compatible app.
- Requires insertion by staff trained on sensor insertion
- Requires fingerstick calibration.
- Transmitter can be removed without ending sensor life

FDA Approved!

Eversense CGM Fully Implantable for 90 Days



1 **Make incision**
2-3 mm incision upper arm (lidscaint)

2 **Create subcutaneous pocket**
Approximately 2-5 mm below skin surface

3 **Insert sensor**
Sensor placed with custom inserter

4 **Close incision**
Steri-Stripe™ to close



Share data with provider, family/friends

CGM Device	Clinic app	Family/friends app	followers
Dexcom	Dexcom Clarity app	Dexcom Follow app	Invite up to 10 followers
Freestyle Libre	Freestyle Libre View	Freestyle Libre LinkUp	Invite up to 20 followers
Guardian Connect	Carelink	Care Partner	Invite up to 5 followers
Eversense E3	Eversense DMS Pro	Eversense Now	Invite up to 5 followers

<https://clarity.dexcom.com/professional/>
<https://www.libreview.com/>
<https://carelink.medtronic.com/>
uspro.eversensedms.com

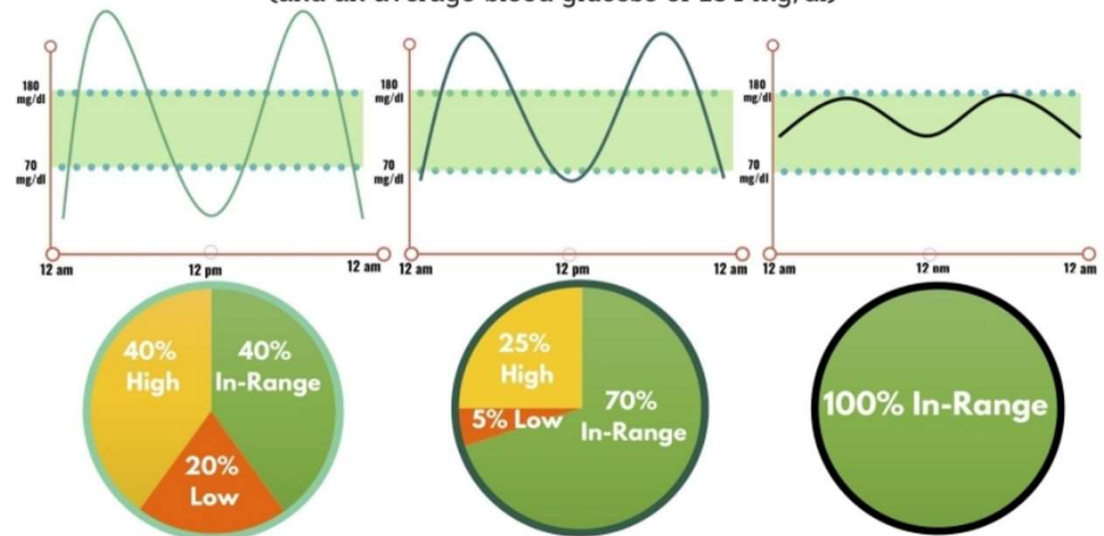
Benefits of CGM Use

- CGM gives a more complete picture of glucose fluctuations throughout the day, compared to HbA1c
- Real-time data allows users to see the effect of various foods, exercise, medications, and stress on glucose levels, even as they sleep
- Gives users alerts if sensor glucose levels are approaching highs or lows set by user
- Improves quality of life measures in people with diabetes on insulin

A1C Alone is Just Not Enough

THE MANY FACES OF A 7% A1C

(and an average blood glucose of 154 mg/dl)



<https://diatribe.org/time-range>

Who Should Be Prescribed a CGM?



Any of the following may be an indication for Personal CGM: Type 1 or Type 2 Diabetes.

- Taking multiple daily injections of insulin
- Using an insulin pump
- Frequent hypoglycemia
- Hypoglycemia unawareness
- High degree of glycemic variability
- Not achieving glucose targets



2023 Standards of Medical Care in Diabetes



Summary recommendations- individuals with diabetes should be offered a CGM if they are...

- adults on multiple daily injections or CSII (insulin pumps)
- adults on basal insulin not in target
- youths with type 1 or type 2 diabetes on multiple doses of insulin or CSII
- pregnant females with diabetes as an adjunct to pre and postprandial blood glucose monitoring

Individuals seeking CGM or their caregivers should be able to use the devices safely and the choice of device should be made based on patient circumstances, desires, and needs.

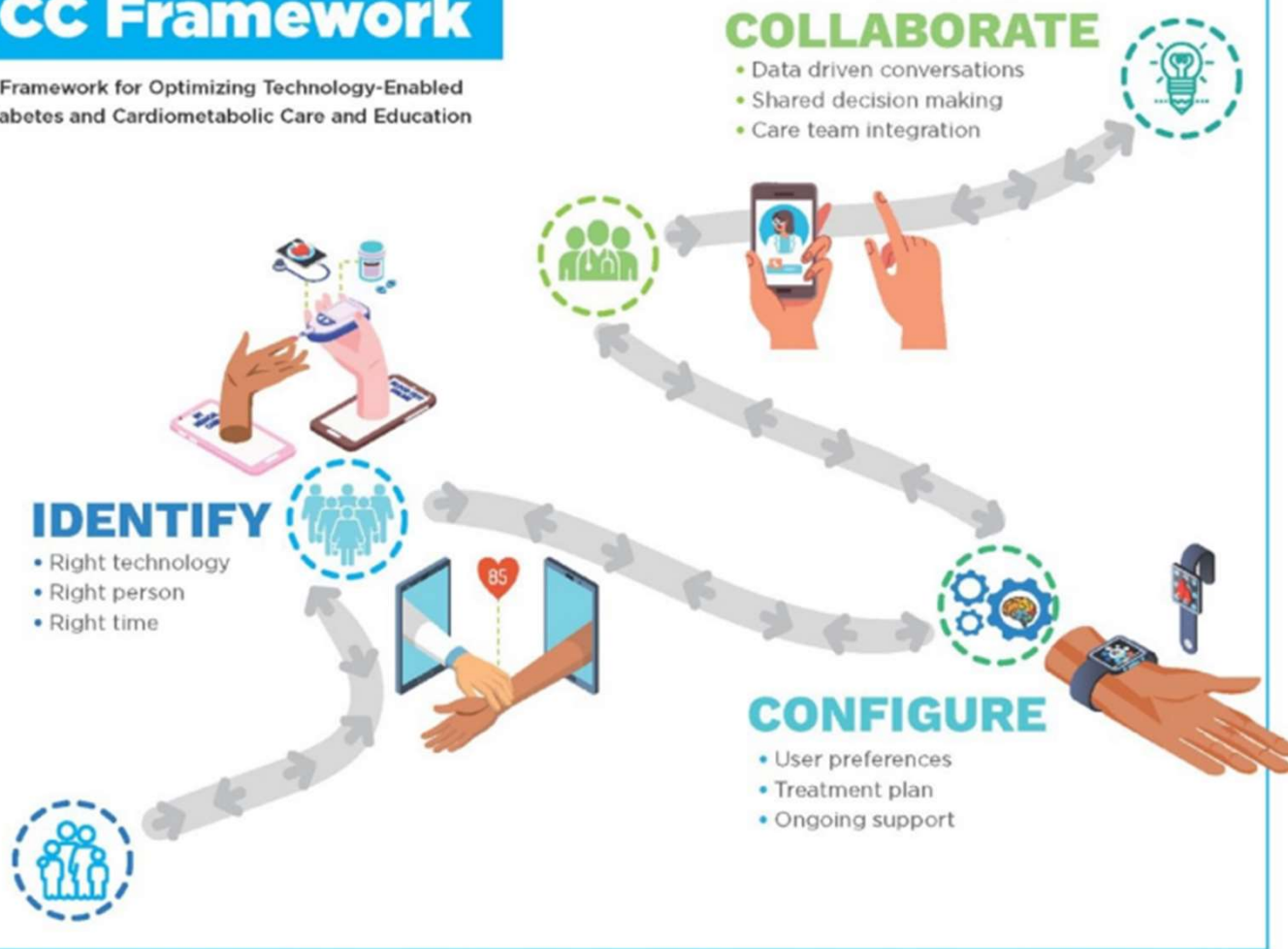
Configure: The Importance of Education & Training



“No device used in diabetes management works optimally without education, training, and follow-up.”

ICC Framework

A Framework for Optimizing Technology-Enabled Diabetes and Cardiometabolic Care and Education



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Glucose Targets Should Be Individualized



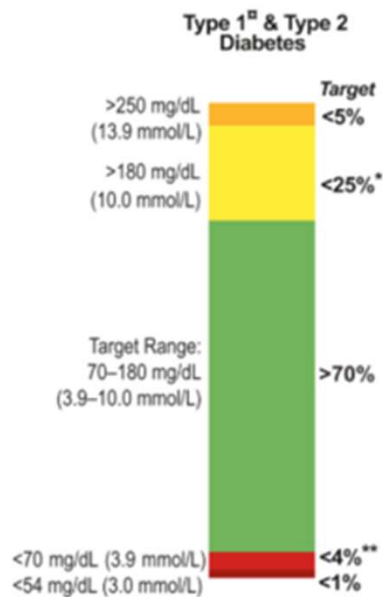
Table 1. Glucose Targets

Health Status	A1C (%)	Fasting/premeal (mg/dl)	Peak Postprandial (mg/dl)	Bedtime (mg/dl)
General Population				
Healthy*	7.0	80-130	180	*
Older Adults				
Healthy	7.5	90-130	*	90-150
Intermediate	8.0	90-150	*	100-180
Poor	8.5	100-180	*	110-200

* Targets should be individualized. Healthy refers to few comorbidities, intact cognition, and activities of daily living. Poor health indicates end-stage comorbidities, moderate-severe cognitive impairment, or requiring long-term care or dependency in two or more activities of daily living.

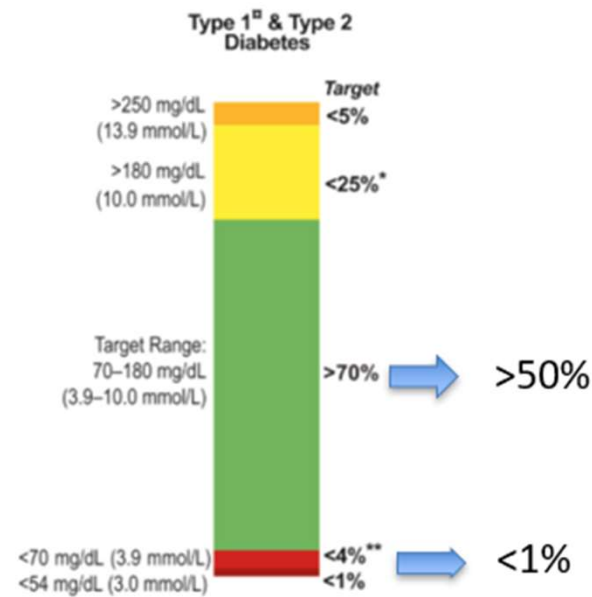
AGP (Ambulatory Glucose Profile) Targets

Interpreting CGM downloads:
Recommendations for Time in Range



Consensus on Time in Range. Diabetes Care 2019 Jun; dci190028.

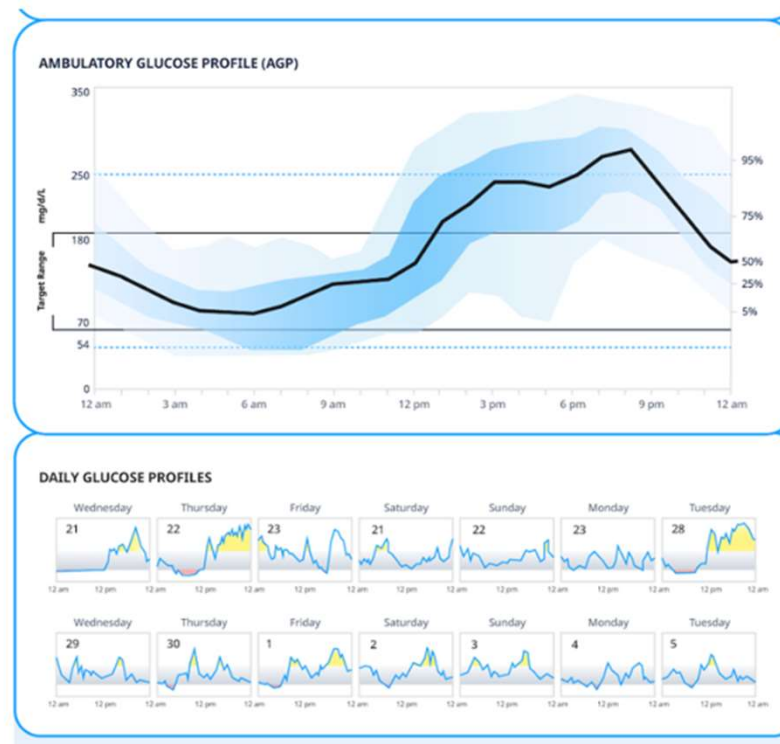
Interpreting CGM downloads:
Recommendations for Time in Range
for older individuals with comorbidities, reduced
cognitive/functional status, hypoglycemia unawareness



Consensus on Time in Range. Diabetes Care 2019 Jun; dci190028.

Interpreting CGM Downloads

Ambulatory Glucose Profile:
Help your patient detect
patterns in highs and lows over
set time period (at least 70%
CGM use over 14 days
recommended for accurate
AGP)



<https://tirhub.com/understanding-the-agp/>

CMS coverage criteria for CGM include that the patient must:

1. Have a diagnosis of diabetes, either type 1 or type 2
2. Require frequent dosing of insulin (3/day).
3. Require frequent adjustment of diabetes treatment regimen

Order must include a durable CGM receiver. Covered under Medicare Part B as durable medical supply



Ohio Medicaid coverage criteria for CGM include that patient:

Adoption of New Ohio Administrative Code Rule 5160-10-36



Has type 1 or type 2 diabetes and one or more of the following conditions:

- Frequent insulin dosing or on insulin pump
- Has HbA1c outside the target range
- Fasting or postprandial hyperglycemia
- Unexplained hypoglycemic episodes despite appropriate changes in insulin therapy
- Hypoglycemia unawareness
- Have microvascular complications
- Have a condition (ex, epilepsy) that makes hypoglycemia management difficult
- Recurrent DKA

No PA required, pharmacy benefit

References



- AACE Guide to Continuous Glucose Monitoring
<https://pro.aace.com/cgm/toolkit/cgm-device-comparison>
- <https://www.diabeteseducator.org/danatech/home>
- [Standards of Care in Diabetes – 2023. Volume 46, Issue Supplement 1](#)
- <https://www.cardi-oh.org/assets/diabetes/Cardi-OH-Beyond-the-A1C-Targets-for-Blood-Glucose-and-Methods-of-Measurement.pdf>
- <https://diabetesjournals.org/care/article/42/8/1593/36184/Clinical-Targets-for-Continuous-Glucose-Monitoring>

Product Websites:

- <https://www.ascensiadiabetes.com/eversense/why-eversense>
- <https://www.dexcom.com/en-us>
- <https://www.freestyle.abbott/us-en/home.html>
- <https://www.medtronicdiabetes.com/products/guardian-connect-continuous-glucose-monitoring-system>



Thank you!

Questions/Discussion