



CGM Systems For Insulin Dosing Comparison Charts









Creators





The Glucose Never Lies®











Making Sense of the CGM Comparison Charts A quide to understanding the DSN Forum Continuous Glucose Monitor (CGM) Study Design Chart

What are these charts?

These charts are a simple, evidence-based guide designed to support nurses and clinicians in understanding how CGM devices have been tested for insulin dosing decisions. It focuses only on the most basic, internationally agreed-upon standards for study design. Also, the main features of CGM devices. The charts do not attempt to evaluate every design criteria and feature or detail of a CGM system.

Why create the charts?

The only eligible people for CGM according to NICE Guidance/Technology Appraisal (NG17, NG18, NG28, TA943) are those people with diabetes using insulin. This chart helps clarify:

- Which devices meet the minimum testing criteria for insulin decision-making
- Which are licensed for non-adjunctive use (i.e. insulin dosing) and which are not
- Which are available on GP prescription, even if they lack robust evaluation or approval for insulin dosing

Core Principles of the Charts

- 1. Study Design, Clinical Accuracy, and Regulatory Approval Status of CGM Systems Available in the UK
 - The chart includes only five criteria that have international agreement (<u>CLSI guideline (POCT05)</u>, <u>IFCC Working Group on CGM</u> & <u>eCGM Clinician Consensus</u>):
 - 1. Peer-reviewed publication or FDA-level review
 - 2. Testing on ≥70% of people with type 1 diabetes, to ensure the CGM system has been tested across the full glucose measurement range (typically, 2.2-22.2 mmol/L or 40-400 mg/dL)
 - 3. Meal and insulin challenges to simulate the real-world glucose rate-of-change scenarios encountered by individuals who rely on CGM systems to inform insulin dosing decisions
 - 4. Sufficient representation of low glucose readings, with 8% of readings below 4.4 mmol/L (80 mg/dL).
 - 5. Adequate representation of high glucose readings, with over 5% exceeding 16.7 mmol/L (300 mg/dL).
- 2. Excluded for Now: Factors Without Consensus (these are acknowledged as important but currently lack agreed international agreement)
 - Certain elements are not included in the scoring, such as; type of comparator glucose (e.g. capillary vs. venous vs. arteriovenous), timing of CGM-comparator pairing, etc.
- 3. Focus on Insulin Dosing Decisions
 - These charts are designed for evaluating CGMs for insulin treatment decisions. It does not evaluate CGM suitability for people who do not use insulin.
- 4. Inclusion of Devices Without Non-Adjunctive Approval
 - These devices are included because some adjunctive CGMs can be prescribed in primary care and all are available for direct purchase online. Their inclusion is intended to highlight the potential risks if they are used to guide insulin dosing.
- 5. A Low Study Design Score Does Not Mean the CGM Device is Unsafe
 - A CGM with a low study design score does not mean it is unsafe. It means the risk is unknown, for people using insulin.
- 6. Practical Features Charts: These charts only include CGM systems with non-adjunctive approval that are available on prescription by the GP (FP10) or by a Trust using the NHS Supply Chain.

Study Design, Clinical Accuracy, and Regulatory Approval Status of CGM Systems Available in the UK

Study Design Assessment and Score

The study design score (0 to 5, with higher scores = greater robustness, ordered by score then alphabet) reflects how thoroughly the CGM system has been tested across the full glucose range (typically 2.2–22.2 mmol/L or 40-400 mg/dL), including the rates of change commonly experienced by people with diabetes. This score provides insight into how likely the performance is to hold true in real-world conditions. The scoring criteria are based on testing recommendations for individuals aged 18 years and older from the 2020 Performance metrics for continuous interstitial glucose monitoring CLSI guideline (POCT05), reinforced by the IFCC Working Group on CGM & eCGM Clinician Consensus^b

Accuracy Data & Regulatory Status

The 20/20 and 40/40 metrics offers a better representation of the percentage of glucose readings that pose no risk and high risk to clinical decision-making, respectively. In contrast, the Mean Average Relative Difference (MARD) does not indicate the proportion of risk-free readings and is therefore not included.

20/20: Percentage of CGM within ±20% of the comparator blood glucose levels ≥5.5 mmol/L and within ±1.1 mmol/L (20 mg/dL) for blood levels <5.5 mmol/L.

40/40: Percentage of CGM within ±40% of the comparator blood glucose levels ≥5.5 mmol/L and within ±2.2 mmol/L (40 mg/dL) for blood levels <5.5 mmol/L.

CGM Systems (Distributor in the UK)	Peer- reviewed ^a	≥ 70% T1D	Meal & insulin challenge	≥8% of readings <4.4 mmol/L (80 mg/dL)	≥5% of readings >16.7 mmol/L (300 mg/dL)	Study design score ^b	Age range tested	N = adults	Adult 20/20 ^c	Adult 40/40°	N = Paed	Paed 20/20 ^c	Paed 40/40 ^c	CE marking for non- adjunctive ^e (age indication)	iCGM for HCL ^f	GP via FP10	NHS Supply Chain
Non-adjunctive use: Licensed for clinical decision-making including insulin dosing. Finger-prick blood glucose confirmation is not required for treatment decisions, unless symptoms do not match the CGM reading or the value and/or trend arrow is unavailable.																	
Accu-Chek SmartGuide® (ROCHE) ¹	✓	✓	✓	✓	✓	5	≥18yrs	48	91%	99%	d	d	d	√ ^J (18yrs)	x	✓	x
CareSens Air® (Spirit Healthcare) ⁹ ALLYpro (AgaMatrix) ⁹	✓	✓	✓	✓	✓	5	≥18yrs	89	94%	>99.5%	d	d	d	√ (18yrs)	×	✓	×
Dexcom G6 [™] (Dexcom) ²⁻³	✓	✓	✓	✓	✓	5	≥2yrs	159	93%	>99.5%	165	92%	>99.5%	√ (≥2yrs)	√h	x	✓
Dexcom G7™ (Dexcom) ⁴⁻⁵	✓	✓	✓	✓	✓	5	≥2yrs	316	95%	>99.5%	127	95%	>99.5%	√ (≥2yrs)	√i	×	✓
Dexcom One™ (Dexcom) ²⁻³	✓	✓	✓	✓	✓	5	≥2yrs	159	93%	>99.5%	165	92%	>99.5%	√ (≥2yrs)	×	✓	×
Dexcom One+™ (Dexcom) ⁴⁻⁵	✓	✓	✓	✓	✓	5	≥2yrs	316	95%	>99.5%	127	95%	>99.5%	√ (≥2yrs)	×	✓	×
FreeStyle Libre® 2 Plus (Abbott) ^{6,7}	✓	✓	✓	✓	✓	5	≥2yrs	148	94%	>99.5%	127	94%	>99.5%	√ (≥2yrs)	✓	✓	✓
FreeStyle Libre® 3 Plus (Abbott) ^{6,7}	✓	✓	✓	✓	✓	5	≥2yrs	148	94%	>99.5%	127	94%	>99.5%	√ (≥2yrs)	✓	✓	✓
Simplera/Simplera Sync™ (Medtronic) ⁸	✓	✓	✓	✓	✓	5	≥2yrs	160	89%	d	138	88%	d	√ (≥2yrs)	x	x	✓
Guardian™ 4 Sensor and Guardian™ 4 Link Transmitter (Medtronic) ^g	×	✓	✓	✓	✓	4	≥2yrs	153	88%	d	108	83%	d	√ (≥2yrs)	×	×	✓
TouchCare® Nano A8 (Medtrum)g	×	×	✓	d	d	1	≥14yrs	63	89%	99%	d	d	d	√ (≥2yrs)	×	×	✓
GlucoMen iCan (A. Menarini Diagnostics) ^g	×	x	d	d	d	0	≥2yrs	60	>90%	d	60	95%	>99.5%	√ (≥2yrs)	×	×	×
Linx (Microtech) ^g	×	d	d	d	d	0	≥18yrs	91	>90%	99%	d	d	d	√ (≥18yrs)	×	x	x
Adjunctive use: Not licensed for clinical decision-making. All clinical decisions must be confirmed with a finger-prick blood glucose test																	
Gluconovo® (Infinovo) ¹⁰	✓	x	x	×	x	1	≥18yrs	78	90%	99%	d	d	d	× (2yrs)	×	x	×
GlucoRx Aidex™ (GlucoRx) ¹¹	✓	×	x	×	x	1	≥18yrs	114	96%	>99.5%	d	d	d	× (≥14yrs)	×	✓	x
GS1 CGM (SiBionics) ¹²	✓	×	x	×	x	1	≥18yrs	70	92%	d	d	d	d	× (18yrs)	×	x	x
Yuwell CT3 (Urathon) ^g	x	d	d	d	d	0	≥18yrs	72	93%	d	d	d	d	× (≥14yrs)	×	✓	x
			al	al	ii ii					al	al	al	al				

93%

≥18vrs

72

Syai Tag (Syai Health Technology)g

× (≥18yrs)

Denotations

- ^a Peer reviewed in a scientific journal or assessed by the Food and Drug Administration (FDA) in the US. Both have been shown to allow comprehensive appraisal of study design by a <u>regulatory review of CGM systems</u>.

 ^b The five core criteria are taken from international recommendations published in <u>2020</u> and the five basic criteria have been reinforced by the <u>IFCC CGM working group</u> and a recent <u>European clinician consensus</u>. Several key factors, such as the glucose compartment tested (venous, arteriovenous, or capillary), the timing of comparator glucose readings, the structure of meal and challenge days, and the inclusion of conditions for, and paired reading requirements during, rapidly changing glucose levels (both rising and falling) have been identified as requiring urgent standardisation. While there is broad agreement on their importance, these aspects remain under discussion and have not yet been standardised. Consequently, they are currently omitted from the score until a formal ISO standard is established, which is actively in development by the <u>IFCC Working</u> Group on CGM.
- c Percentage of CGM within ±20/20: Percentage of CGM within ±20% of the comparator blood glucose levels ≥5.5 mmol/L and within ±1.1 mmol/L (20 mg/dL) for blood levels <5.5 mmol/L. 40/40: Percentage of CGM within ±40% of the comparator blood glucose levels ≥5.5 mmol/L and within ±2.2 mmol/L (40 mg/dL) for blood levels <5.5 mmol/L.
- d Data not available
- e CE marking for non-adjunctive use means it is approved for direct treatment decisions without requiring confirmation by fingerstick blood glucose measurements (e.g., insulin dosing, hypoglycaemia treatment, driving)
- fintegrated CGM (iCGM) status for a CGM to be permitted for use with more than one HCL system (QBJ) from the FDA is currently the most robust regulatory standard and performance criteria
- ^g Data on file and available upon request to the manufacturer or distributor
- H Dexcom G6 iCGM approval for HCL only applies for abdomen (≥2yrs) and upper buttock (2-17yrs)
- Dexcom G7 iCGM approval for HCL **only** applies for upper arm placement (≥2yrs)
- ¹ The Accu-Chek SmartGuide is not intended for insulin dosing within the first 12 hours after sensor application. According to the Mader et al. ¹ publication and the manufacturer's guidance, non-adjunctive use is only supported after initial calibration, which can occur no earlier than 12 hours post-insertion after performing a calibration routine (two finger prick blood glucose tests withing 2 hours)

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Comparison of Practical Features of Non-Adjunctive CGM Devices Available via Primary Care Prescribing Pathways

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	Accu-Chek SmartGuide (ROCHE)	CareSens Air (Spirit Health) ALLYpro (AgaMatrix)	Dexcom ONE (Dexcom)	Dexcom ONE+ (Dexcom)	FreeStyle Libre 2 Plus (Abbott) ^b	FreeStyle Libre 3 Plus (Abbott) ^b	GlucoMen iCan (A. Menarini Diagnostics)
Non-adjunctive decision making (insulin dosing)	√ (18 yrs)	√ (18 yrs)	√ (2 yrs)	√ (2 yrs)	√ (2 yrs)	√ (2 yrs)	√ (2 yrs)
Randomised control trial data	×	×	√ (G Series)	√ (G Series)	√ (Libre Series)	√ (Libre Series)	×
Hybrid closed loop (HCL) compatible	×	×	×	×	Omnipod 5 System ^a	YpsoPump mylife Loop (CamAPS Fx) ^a	×
Sensor life	14 days	15 days	10 days	10 days (12 hr grace period)	15 days	15 days	15 days
Sensor warm up time	60 mins	Up to 30 mins	120 mins	Up to 30 mins	60 mins	60 mins	120 mins
Separate transmitter	×	×	✓	×	×	×	×
Transmitter life	-	-	3 months	-	-	-	-
Smartphone app	SmartGuide	CareSens Air ALLYcgm	Dexcom ONE	Dexcom ONE+	LibreLink	Libre 3	iCan CGM
Reader available	✓	×	✓	✓	✓	✓	✓
Capillary glucose calibration (mandatory)	One time calibration routine before use as non-adjunctive. Two BG tests after 12-14 hrs	×	×	*	×	×	×
Capillary glucose calibration (Optional)	×	✓	✓	✓	×	×	×
High & low alarms	✓	✓	✓	✓	✓	✓	✓
Predictive alarms and other alarms	✓ (SmartGuide Predictions 30-min, 2 hrs & 7 hrs)	×	×	×	×	× (stand-alone) √ (HCL)	×
Smart pen data connection	×	×	NovoPen 6 & Echo Plus ▲ SoloSmart pen cap ▲	NovoPen 6 & Echo Plus A SoloSmart pen cap A	NovoPen 6 & Echo Plus	×	×
Data share HCP	ROCHE DiabeteCare	Sens365 Web ALLYpro Web	Clarity Glooko	Clarity Glooko	LibreView	LibreView	GluoLog Web
Data share friends/family app (n=)	×	Sens365 App ALLYpro App	×	Dexcom Follow (10)	LibreLinkUP (20)	LibreLinkUP (20)	iCan Reach (10)
UK approved wearable site	Back upper arm	Back upper arm	Abdomen, Back upper arm, Buttocks ⁺	Abdomen, Back upper arm, Buttocks ⁺⁺	Back upper arm	Back upper arm	Abdomen

^a iCGM approval (QBJ) from the FDA for interoperable use multiple HCL systems

^b The non-Plus version is currently available but will be discontinued before the end of 2025, therefore not included as Plus version is available at the same cost.

^{*}When using LibreLink app on smartphone. 'Scanning' still required with reader device.

[◆] via Glooko

⁻ Not applicable

⁺2-17 years old as per manufacturers' guidelines, ⁺⁺2-6 years old as per manufacturers' guidelines,

^{*** 7-17} years old as per manufacturers' guidelines.

Comparison of Practical Features of Non-Adjunctive CGM Devices Available via NHS Supply Chain Framework

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	Dexcom G6 (Dexcom)	Dexcom G7 (Dexcom)	FreeStyle Libre 2 Plus (Abbott) ^b	FreeStyle Libre 3 Plus (Abbott) ^b	Guardian 4 (Medtronic) ^b	Simplera & Simplera Sync (Medtronic)	Nano TouchCare A8 (Medtrum)		
Non-adjunctive decision making (insulin dosing)	✓ (2yrs)	√ (2yrs)	✓ (2yrs)	✓ (2yrs)	√ (2yrs)	✓ (2yrs)	√ (2yrs)		
HCL Randomised Trial data	✓	✓	X a	X a	✓	✓	x c		
Hybrid closed loop (HCL) pump compatible	Tandem t:slim x2, DANA-i & YpsoPump mylife Loop with CamAPS Fx, Omnipod 5 System	Tandem t:slim x2, Omnipod 5 System	Omnipod 5 System	YpsoPump mylife Loop (CamAPS Fx)	MinMed 780G System	MinMed 780G System (Simplera Sync)	Medtrum Nano System		
Sensor life	10 days	10 days with 12 hr grace period	15 days	15 days	7 days	7 days	14 days		
Sensor warm up time	120 mins	30 mins	60 minutes	60 minutes	120 mins	120 mins	30 mins		
Separate transmitter	✓	×	×	×	✓	×	✓		
Transmitter Life	3 months	-	-	-	12 months	-	12 months		
Smartphone app	Dexcom G6	Dexcom G7	LibreLink	Libre 3	MiniMed Mobile	Simplera (Simplera) MinMed Mobile (Simplera Sync)	EasySense		
Reader available	✓	✓	✓	✓	×	×	×		
Capillary glucose calibration (mandatory)	×	×	×	×	×	×	*		
Capillary glucose calibration (Optional)	✓	✓	×	×	✓	✓	✓		
High & low alarms	✓	✓	✓	✓	✓	✓	✓		
Predictive alarms & other alarms	√ (Urgent Low Soon)	√ (Urgent Low Soon, Delayed First High)	×	× (Stand-alone) ✓ (HCL)	✓	✓	✓		
Smart pen data connection	NovoPen 6 & Echo Plus A SoloSmart pen cap A	NovoPen 6 & Echo Plus A SoloSmart pen cap	NovoPen 6 & Echo Plus	×	InPen	InPen (Simplera)	×		
Data share HCP	Clarity Glooko	Clarity Glooko	LibreView	LibreView	CareLink	CareLink	EasyView		
Data share friends/family app (n=)	Dexcom Follow (10)	Dexcom Follow (10)	LibreLinkUP (20)	LibreLinkUP (20)	CareLink Connect (5)	CareLink Connect (5)	EasyFollow (unlimited)		
UK approved wearable site	Abdomen, Back upper arm, Buttocks ⁺	Abdomen , Back upper arm, Buttocks ⁺⁺	Back upper arm	Back upper arm	Abdomen [^] , Back upper arm ^{^+++} , Buttocks ⁺⁺⁺	Back upper arm^+++ Buttocks+++	Abdomen Back upper arm		
3:CCAA									

^a iCGM approval (QBJ) from the FDA for interoperable use multiple HCL systems

^b The non-Plus version is currently available but will be discontinued before the end of 2025, therefore not included as Plus version is available at the same cost.

^cCurrently not recommended by the paediatric (<u>BSPED and ACDC</u>) adult (<u>DTN</u>) clinical organisations in the UK due to a lack of publicly available data

^{*} When using LibreLink app on smartphone. 'Scanning' still required with reader device.

[▲] via Glooko

⁻ Not applicable

⁺ 2-17 years old as per manufacturers' guidelines.

^{++ 2-6} years old as per manufacturers' guidelines

^{*** 7-17} years old as per manufacturers' guidelines.

^{^ ≥18} years old as per manufacturers' guideline

Frequently Asked Questions

1. Is this chart relevant for all CGMs?

No. This chart is focused on CGMs used for insulin dosing. For those using CGM for lifestyle tracking or wellness, different accuracy and study requirements may apply

2. What does the Study Design Score mean?

The score (0–5) shows how well the CGM was tested across the full glucose range (typically 2.2–22.2 mmol/L or 40-400 mg/dL) in real-world conditions. A higher score means greater confidence in its accuracy for insulin dosing decisions

3. Does a low score mean the device is inaccurate?

No. It means the device has not been adequately tested in the kinds of conditions experienced by people using insulin (e.g. after a meal or during hypoglycaemia). So, it carries unknown risk, rather than proven inaccuracy.

4. Why are some CGMs listed if they are not licensed for insulin dosing?

Because these devices are available on GP prescription (FP10). Including them helps clinicians understand that, despite availability, they are not suitable for insulin decisions without adequate testing and licensing.

5. Why are MARD values not included?

MARD (Mean Average Relative Difference) is an average. It does not inform of the percentage of no risk and high-risk readings. Instead, the chart uses 20/20 and 40/40 accuracy thresholds, which better reflect risk to clinical and insulin decision-making.

6. Where do the criteria come from?

The five study design criteria are based on:

- CLSI POCT05 guidelines (2020)
- IFCC recommendations (2023)
- European consensus (2025)

7. Will the chart change as standards evolve?

Yes. The chart is reviewed bi-monthly and will evolve alongside new standards, including any formal ISO CGM accuracy standard currently in development by the IFCC Working Group

8. Who do I contact to endorse the chart or request a change to the content?

Please contact <u>dsnforumuk@gmail.com</u> for any inquiries

9. Can I copy and publish the chart without permission?

No, the chart is copyrighted. To ensure the content is accurate we ask all partners to contact to request permission to publish or use the content. This way when we update the charts, we can send you a copy (bi-monthly) of the latest chart to ensure accuracy, if we agree to the purpose of the content sharing. Please contact dsnforumuk@gmail.com for any inquiries.

10. Will the chart evolve?

Yes. The chart will continue to evolve in response to feedback, requests, and changes in the regulatory landscape. If you have suggestions or requests, please email dsnforumuk@gmail.com. All submissions will be considered by the CGM Chart Committee, although due to volume and content, we may not be able to reply individually.

11. Do you provide sessions on how to use the chart?

The chart is designed to be self-explanatory. The supporting article, podcasts, and linked resources will be sufficient for the vast majority of users. However, if you would like to request a formal session or presentation, please email dsnforumuk@gmail.com. We will let you know if this is possible and outline any associated costs.

Want to learn more?

- International recommendations:
- CLSI POCT05 guidelines (2020)
 - IFCC recommendations (2023)
 - European consensus (2025)
 - FDA iCGM Guidance
- Blogs on CGM accuracy and performance:
 - <u>Diabettech:</u> Tim Street (Member of the <u>DTN Committee</u>)
 - <u>Lies, damned lies and statistics.</u>
 <u>The art of the CGM accuracy study.</u>
 - MARD wars. More craziness in the world of CGM marketing from ATTD
 - Plain-language explainers.
 - <u>The Glucose Never Lies:</u> John Pemberton (member of the <u>IFCC</u> Working Group on CGM)
 - The Glucose Never Lies Podcast Series
 - A conversation on CGM risks, study design, and what people really need to know before choosing.
 - The Glucose Never Lies CGM Series
 - A plain-language series demystifying CGM selection and sensor risks.
- Making Sense of Sensors:
 - An article by DSN Forum