Making sense of sensors: Evaluating CGM devices for safe and personalised insulin management

Amanda Williams, Bethany Kelly, Tamsin Fletcher-Salt and John Pemberton

Continuous glucose monitoring (CGM) technology has transformed diabetes management by enabling users to track their blood glucose levels at any time. As eligibility criteria have broadened, more people using insulin therapy have benefited from the improved glycaemic outcomes, safety and quality of life that CGM can bring. Diabetes specialist nurses have a major role in integrating CGM into clinical care. To help them do this safely and effectively, this article outlines a structured approach to gaining a deep understanding of how to evaluate CGM systems. For a given device, this involves assessing the robustness of study designs used during testing, interpreting its accuracy metrics, establishing its regulatory status and determining if it can meet the individualised needs of potential users. The comparison charts provided by the DSN Forum UK provide a valuable information resource to help make these decisions.

Continuous glucose monitoring (CGM) has transformed diabetes management, offering a dynamic alternative to traditional self-monitoring of blood glucose (SMBG). While SMBG provides static snapshots, CGM delivers a continuous stream of data, enabling pattern recognition, real-time response to glycaemic trends and informed insulin dosing.

As of 2025, CGM is considered standard care for all individuals with type 1 diabetes using insulin therapy, as well as for specific groups of people with type 2 diabetes in the UK. This has been made possible through guidance and approval from NICE. This article aims to demystify CGM technology, explain its regulatory context and equip diabetes nurses with the knowledge needed to evaluate CGM systems in clinical practice.

National guidelines: The clinical imperative

Recent updates from NICE emphasise the pivotal role of CGM in insulin management:

- **NG17**: All adults living with type 1 diabetes should be offered CGM (NICE, 2022a).
- **NG18**: All children and young people with type 1 diabetes should be offered CGM (NICE, 2023a).
- **NG28**: For adults living with type 2 diabetes who are on multiple daily insulin injections, intermittently scanned CGM (isCGM) should be offered to individuals experiencing recurrent or severe hypoglycaemia; those with impaired hypoglycaemia awareness; and those with disabilities or cognitive impairments that prevent them from reliably using finger-prick blood glucose monitoring but who could benefit from scanning a sensor themselves or with support (NICE, 2022b). It should also be made available to individuals advised to test their glucose levels eight or more times daily.

Furthermore, isCGM is recommended for people with insulin-treated type 2 diabetes who require assistance from a healthcare professional or care worker to monitor glucose

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Article points

1. Continuous glucose monitoring (CGM) is standard care for all individuals with type 1 diabetes and for specific groups with type 2 diabetes who are insulin treated.
2. To integrate this technology into clinical practice, a deep understanding is needed of device testing, performance metrics and regulatory distinctions.
3. The study design for testing a CGM device used for insulin dosing decisions should meet internationally accepted criteria.
4. Performance metrics are used to assess the reliability of a CGM system for safe insulin dosing.
5. Safety conformity markings in the UK, Europe and US are not equivalent.
6. The DSN Forum UK maintains an online resource to help nurses evaluate CGM devices prescribed for insulin dosing decisions.

Key words

- Continuous glucose monitoring
- Hybrid closed-loop technology
- Wearable technology

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Details can be found on page 2.

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levels, supporting greater independence and reducing the burden on care services. In settings where real-time CGM (rtCGM) is available at the same or lower cost, it may be considered as an alternative for this group.

- **TA943**: Hybrid closed-loop (HCL) systems are recommended for people living with type 1 diabetes, with national funding ring-fenced for five years to support access. Eligibility criteria include all children, and adults with an HbA_{1c} of 58 mmol/mol or above, frequent hypoglycaemia, or those who are pregnant or planning to become pregnant (NICE, 2023b). CGM is a core component of HCL therapy, where real-time glucose levels and their rate of change drive automated insulin delivery adjustments.

Table 1. Five key study design criteria for CGM accuracy: Clinical relevance and practical value.

Criterion	Explanation	Practical value in clinical use
Peer-reviewed	The study must be published in a reputable journal, ensuring transparency, peer scrutiny and scientific validity. Alternatively, reviewed by an agency that undertakes a robust assessment, such as the Center for Devices and Radiological Health, a division of the US Food and Drug Administration.	Gives nurses confidence the data is reliable and independently reviewed.
>70% participants with type 1 diabetes	The study must test the CGM during real-world scenarios, where glucose levels are actively changing due to food intake or insulin dosing.	Ensures performance results are applicable to the insulin-using population in clinical care.
Meal and insulin challenges included	The study must test the CGM during real-world scenarios, where glucose levels are actively changing due to food intake or insulin dosing.	Helps confirm the device's reliability during dynamic glucose changes, not just during stable periods.
>8% of readings <4.4 mmol/L	The CGM should be evaluated for accuracy during hypoglycaemia, when safety risks from inaccurate readings are highest.	Protects patients by ensuring the device can detect and report low glucose accurately, reducing risk of missed hypoglycaemia.
>5% of readings >16.7 mmol/L	The CGM must demonstrate accuracy during high glucose levels, where insulin decisions can lead to rapid glucose drops if based on incorrect data.	Supports safe insulin correction by confirming accuracy at high glucose values, preventing overcorrection and rebound lows.

These recommendations reflect a strong evidence base. CGM improves glycaemic outcomes, enhances safety and supports quality of life for those using insulin therapy (Maiorino et al, 2020). Furthermore, HCL systems offer additional glycaemic and quality-of-life benefits (Beck et al, 2023; Zeng et al, 2023).

Adjunctive vs. non-adjunctive use: Why it matters

Not all CGM systems are created equal. Devices fall into two main categories:

- **Adjunctive CGM**: Requires confirmation with finger-prick testing before insulin dosing.
- **Non-adjunctive CGM**: Approved for insulin dosing decisions without additional SMBG.

Understanding whether a CGM device is approved for insulin decision-making is essential. Nurses must remain vigilant when supporting people using CGM for this purpose. Currently, those using CGM for insulin dosing are all people who meet the NICE eligibility criteria (NICE, 2022a; 2022b; 2023a; 2023b).

CE and UKCA marking: Misunderstood signals

Devices sold in the UK must carry CE or UKCA marking, which confirms they meet general medical device minimum safety requirements. However, these markings do not indicate clinical accuracy or suitability for insulin dosing. In contrast, in the US, the evaluation and regulatory approval of CGM systems is overseen by the Center for Devices and Radiological Health (CDRH), a division of the Food and Drug Administration (FDA). The CDRH has established a higher standard through its "integrated CGM" (iCGM) designation and Class III (highest risk category) pre-market approval. Specifically, iCGM approval requires manufacturers to meet strict criteria for accuracy, reliability and interoperability (the ability to integrate safely with HCL and other devices; FDA, 2022).

A review of CGM regulations across Europe and the US highlights these key differences. While CE

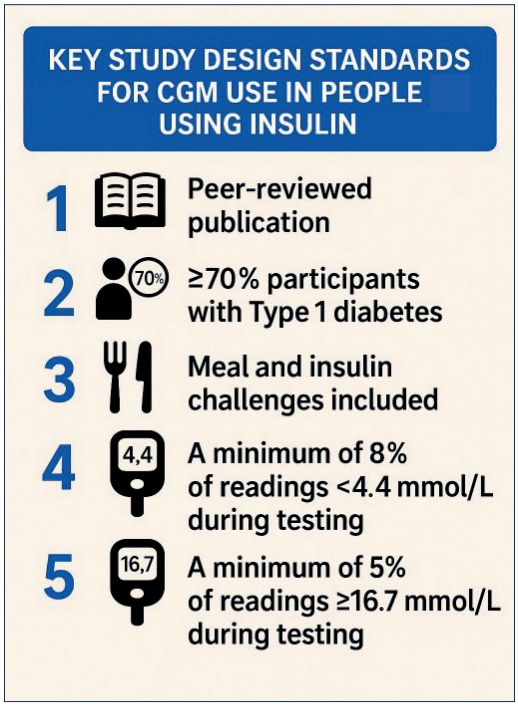

Figure 1. Key study design standards for continuous glucose monitoring use in people using insulin.

or UKCA marking is necessary for market access, it should not be interpreted as a guarantee of clinical quality. By comparison, FDA iCGM approval and Class III pre-market approvals reflect a level of clinical robustness and safety specifically suited for insulin decision-making (Pemberton et al, 2022).

This distinction is important for UK clinical teams to understand. With CGM options evolving rapidly, nurses play a critical role in supporting people with diabetes to use these devices appropriately and safely, especially when the devices are used to guide insulin dosing. In such cases, only non-adjunctive CGM systems with robust accuracy and safety data should be prescribed.

Study design: The foundation of trust

The reliability of a CGM for insulin dosing decisions depends on how it was tested. At a minimum, robust study design should meet five internationally accepted criteria (*Table 1*), first outlined in 2020 by the Clinical and Laboratory Standards Institute (CLSI, 2020). These criteria include that the data is peer-reviewed, the inclusion of more than 70% of participants with type 1 diabetes, the use of meal and insulin challenges to test device performance under real-world conditions, and evaluation across a broad glucose range, including both hypoglycaemic and hyperglycaemic episodes. These criteria have since been endorsed by both the International Federation for Clinical Chemistry (IFCC) Working Group for CGM (Freckmann et al, 2023) and a panel of clinical experts from across Europe (Mathieu et al, 2025). The checklist in *Figure 1* serves to support study design assessment.

A simple analogy helps to clarify the importance of testing a CGM device across the measurement range, typically 2.2–22.2 mmol/L: Testing a CGM device only during stable glucose levels is like test-driving a car only on a straight, empty road. We must also evaluate how it handles curves, hills and traffic, the real-world challenges of glycaemic variability.

Appendix A shows the CGM devices currently available in the UK that are licensed for insulin dosing, along with their study design score (out of 5). This score reflects the clinical relevance of the performance data for insulin dosing decisions supporting each device.

Lower scores may reflect limited testing in people who use insulin, making it harder to evaluate how well the CGM performs in this group who often experience rapid and wide fluctuations in glucose levels throughout the day.

In contrast, higher scores suggest that the device has been more thoroughly evaluated in individuals who use insulin, offering greater confidence in its performance for this group who often experience marked glucose variability. This includes situations such as rapid rises in glucose after meals without insulin coverage, or sharp declines following large correction doses, scenarios where accurate CGM readings are especially critical for safe insulin management.

Accuracy metrics: Looking beyond MARD

Once study quality for insulin users is confirmed, the next step is to interpret accuracy metrics. The most cited is mean absolute relative difference (MARD), which reflects the average variance between CGM readings and reference glucose values. A MARD under 10% is generally considered acceptable for insulin dosing (Kovatchev et al, 2009).

However, MARD is an average value and may mask clinically significant inaccuracies at the extremes of hypoglycaemia or hyperglycaemia (Heinemann et al, 2020). Nurses should be cautious when interpreting a low MARD, especially if it is presented without details about the study design, such as whether the study included people using insulin or if the testing conditions reflected real-world glucose fluctuations (see *Table 1* and *Figure 1*).

A more clinically relevant accuracy measure: The 20/20 and 40/40 metrics

The **20/20 accuracy metric** offers a clinically meaningful assessment of CGM performance by specifying how close the true blood glucose (laboratory or accurate SMBG reading) value must be to the CGM reading to consider it accurate. The thresholds depend on the CGM value:

- If the CGM reading is <5.5 mmol/L, the true blood glucose must fall within ±1.1 mmol/L (±20 mg/dL) of the CGM value.
  - For example, a CGM value of 4.5 mmol/L would be considered accurate if the reference glucose lies between 3.4 and 5.6 mmol/L.
- If the CGM reading is ≥5.5 mmol/L, the true value must fall within ±20% of the CGM value.
  - For example, if the CGM shows 10.0 mmol/L, the true glucose must be between 8.0 and 12.0 mmol/L to qualify as accurate.

A higher proportion of readings meeting the 20/20 criteria indicates stronger CGM reliability for safe insulin dosing.

The **40/40 accuracy metric** provides a broader assessment of CGM performance. It is particularly useful for identifying the percentage of readings that fall outside this threshold and could lead to inappropriate insulin dosing decisions.

- If the CGM reading is <5.5 mmol/L, the true blood glucose must fall within ±2.2 mmol/L (±40 mg/dL) of the CGM value.
  - For example, if the CGM reads 4.5 mmol/L, the paired true glucose must be between 2.3 and 6.7 mmol/L to meet the 40/40 accuracy threshold.
- If the CGM reading is ≥5.5 mmol/L, the true value must be within ±40% of the CGM reading.
  - For example, if the CGM shows 10.0 mmol/L, the matched glucose must fall between 6.0 and 14.0 mmol/L to meet the 40/40 accuracy threshold.

The 40/40 metric provides insight into the proportion of readings that fall outside this wider threshold, highlighting how many could result in problematic insulin dosing, such as mistreatment of hypoglycaemia or unnecessary correction.

Appendix A shows the percentage of CGM readings that meet the 20/20 and 40/40 accuracy agreement rates across all currently available CGM devices, along with their regulatory status (adjunctive or non-adjunctive).

It is important to note that direct comparisons between CGM systems are limited due to differences in study design. Rather than serving as a direct head-to-head comparison, *Appendix A* should be interpreted as a guide to identify which CGM systems meet clinically meaningful design standards. The five criteria used to generate the study design score (*Table 1*) provide a useful starting point, but many additional factors influence the reliability of performance data. These include whether the CGM was validated against venous or capillary blood glucose values, whether meal and insulin challenges were performed on the same day, and the number of sensor lots tested, among others (Freckmann et al, 2023; Pleus et al, 2024).

In addition, there are multiple ways to assess CGM accuracy. These include the iCGM 15/15 and 40/40 metrics, four types of error grid analyses, and assessments of trend arrows and alert performance (Pemberton et al, 2022). The IFCC Working Group is currently developing a standardised approach for evaluating CGM accuracy specifically for insulin dosing decisions (Pleus et al, 2024). This effort aims to align with ISO standards to produce internationally recognised benchmarks similar to those already used for SMBG devices (Jendrike et al, 2019).

Appraising a CGM system: A practical framework

When assessing a CGM system for someone using insulin, it is important to consider the following key factors (see *Figure 2*):

- **Study design score**: Higher scores reflect more

clinically relevant study designs involving insulin users, increasing confidence that the device will perform reliably in real-world use within this population.

- **20/20 agreement**: A higher percentage reflects a greater number of CGM readings that closely match reference values, supporting safe insulin dosing with minimal risk.
- **40/40 agreement**: A higher percentage reflects better CGM accuracy, indicating a low number that fall outside the threshold and may cause insulin dosing errors.
- **Meeting personalised patient needs**: Ensuring the CGM system supports individual lifestyle and treatment goals through key functionalities, such as reliable wear time, timely alarms and alerts, seamless app or pump integration, and compatibility with hybrid closed-loop systems.
- **Regulatory status**: The CGM device must be approved for non-adjunctive use if the patient is using it to guide insulin therapy (i.e. it must be licensed for insulin dosing decisions).

Devices that are **not approved for non-adjunctive use must never be used alone** to guide insulin dosing decisions. This has important implications in primary care, where some lower-cost CGM systems without non-adjunctive approval are still available through prescribing systems (GP via FP10; *Appendix A*).

Prescriber awareness of these regulatory distinctions may vary, highlighting the need for clear guidance to ensure patients are using clinically appropriate devices for insulin management. Additionally, the inclusion of these devices in primary care prescribing systems may warrant further consideration. NICE only recommends CGM for people with type 1 diabetes and for those with type 2 diabetes (specific criteria) who are using insulin (NICE, 2022a; 2022b; 2023a; 2023b).

Practical features: Matching tech to patient needs

After accuracy and regulation, practical usability comes into focus. Registered nurses should guide patients through options such as:

- Sensor wear time (7, 14 or 15+ days) and wear sites.
- Calibration requirements.
- Alarm and alert options with available customisation.
- Smartphone and smartpen integration.
- Compatibility with HCL systems.
- Data-sharing capabilities.

Choosing the right CGM device depends on the patient's lifestyle, preferences and clinical goals. The DSN Forum UK website (www.diabetesspecialistnurseforumuk.co.uk) provides a regularly updated comparison of CGM device study

Figure 2. Key factors to consider when assessing a continuous glucose monitoring system for someone using insulin.

designs (*Appendix A*) and their features, including those available for insulin dosing on prescription in primary care (*Appendix B*) and through the NHS Supply Chain (*Appendix C*). This resource has been officially endorsed by Breakthrough T1D and Diabetes UK.

This article does not aim to cover all available device features in detail. For the latest updates on technology and prescribing options, readers are encouraged to visit the DSN Forum website, where the DSN Forum UK team provides ongoing guidance as the landscape continues to evolve.

Hybrid closed-loop systems: The importance of CGM interoperability and accuracy

HCL systems represent a significant advancement in diabetes technology, using continuous data from CGM devices to automatically adjust insulin delivery via an algorithm and pump. With HCL therapy now recommended by NICE (2023b) for eligible individuals with type 1 diabetes, the choice of CGM within the system becomes a clinically critical decision.

iCGM: A regulatory benchmark for interoperability and accuracy

The FDA's iCGM designation provides a benchmark for CGM systems that meet high standards for accuracy, reliability and, crucially, interoperability with HCL systems. Sensors certified as iCGM (code QBJ) must meet predefined accuracy thresholds across the glucose range, maintain consistent performance over multiple sensor lots and prove their compatibility with automated insulin delivery (AID) systems (FDA, 2022).

Devices with iCGM certification are, therefore, uniquely suited to HCL use, with demonstrated accuracy under real-world conditions and a clear regulatory pathway ensuring they can safely integrate with third-party algorithms and pumps. *Appendix A* shows that the Dexcom G6 and G7, as well as FreeStyle Libre 2 Plus and Libre 3 Plus, all have iCGM (code QBJ) approval. These sensors are those used within widely adopted HCL systems, including CamAPS FX®, Tandem t:slim with Control-IQ® and Omnipod® 5 System. All of these HCL systems have multiple trials and real-world data, confirming their safety and efficacy (Phillip et al, 2023).

Medtronic: An alternative regulatory pathway with strong outcome data

Medtronic CGM systems, such as those used in the MiniMed™ 780G, are not iCGM-certified. Instead, these sensors are approved as Class III devices by the FDA. They do not meet the technical requirements for iCGM designation (including external interoperability). However, these systems are approved as part of an HCL system as they are supported by robust trial and real-world data (Phillip et al, 2023). Therefore, despite not having iCGM status, Medtronic's system remains a trusted and evidence-backed choice in HCL therapy.

TouchCare® Nano A8: Used in HCL but lacking peer-reviewed data

By contrast, the TouchCare® Nano A8 sensor (used in the Medtrum Nano HCL system) has a low study design score (*Appendix A*), and the HCL lacks publicly available trial data or peer-reviewed real-world data at the time of approval and to date. Although it has received CE marking and is available under NICE TA943 (NICE, 2023b), the absence of published clinical evidence presents challenges for clinicians seeking to assess its appropriateness and safety.

This does not suggest that the Medtrum HCL system is unsafe, but rather highlights the lack of transparent, publicly available performance data. As a result, professional bodies, including the Diabetes Technology Network UK (2024), and a joint statement from the British Society for Paediatric Endocrinology and Diabetes and the Association of Children's Diabetes Clinicians (BSPED/ACDC, 2024), have recommended caution and called for additional data.

CGM for use in people without diabetes: Proceed with caution

CGM use is expanding beyond diabetes into the wellness market, with consumers using sensors to monitor glucose trends for lifestyle and health optimisation. While there is potential benefit, first through an initial learning phase to support behaviour change, followed by a long-term accountability phase to help sustain those changes, it remains unclear whether these devices offer the level of precision needed to reliably track glucose

within tighter, normal glycaemic ranges (Oganesova et al, 2024).

In individuals without diabetes, and those with non-diabetic hyperglycaemia (NDH, previously known as pre-diabetes), glucose levels generally range between 3.3 and 10.0 mmol/L with relatively low variability. In this context, even small inaccuracies in CGM readings can result in false hypoglycaemia alerts or falsely elevated readings above the 11.1 mmol/L diagnostic threshold for diabetes. These misleading data points may cause unnecessary anxiety and lead to inappropriate dietary changes or restrictions (Oganesova et al, 2024).

The current 20/20 and 40/40 accuracy thresholds may not provide sufficient precision for individuals not living with diabetes. In this population, where glucose levels typically remain within a tighter range with little variation, a stricter standard may be more appropriate. For example, adopting a 10/10 threshold, requiring values to fall within ±0.6 mmol/L (±10 mg/dL) for readings <5.5 mmol/L, and within 10% for readings >5.5 mmol/L, could better reflect the level of accuracy needed. Additionally, using 20/20 as a threshold for identifying potentially problematic readings may offer more meaningful insights when CGM is used to support behavioural change in people not living with diabetes.

Although there is currently no consensus on the use of CGM in individuals without diabetes or those with NDH, its potential benefits are evident. However, the cost–benefit case for this use remains unclear. To move forward responsibly, it is essential to better understand the level of accuracy required in this population, and to test these expectations using robust study designs that reflect real-world conditions. While CGM may offer valuable insights, it may also carry unintended and poorly understood consequences. Meanwhile, a growing number of CE-marked CGM devices are now available for purchase online (see *Appendix A*), many of which are marketed specifically for wellness and NDH purposes.

The path forward: Regulation and quality labelling

Current CE and UKCA regulatory frameworks do not guarantee clinical accuracy of CGM systems (Pemberton et al, 2022). To address this gap, global efforts are underway, led by the IFCC Working Group on CGM (Pleus et al, 2024), to develop formal, CGM-specific accuracy standards. The goal is to establish an ISO-equivalent standard, similar to what already exists for SMBG (Jendrike et al, 2019).

A 2024 European consensus proposes a Europe-CGM (eCGM) designation for devices meeting rigorous real-world performance and transparency criteria (Mathieu et al, 2025). Such a designation would offer a short-term solution to help clinicians and people living with diabetes navigate an increasingly crowded CGM market with greater clarity and confidence, while we await the formal ISO standard.

Conclusion

Diabetes specialist nurses are at the forefront of integrating CGM into clinical care. To do this safely and effectively, we must move beyond surface-level indicators and develop a deep understanding of device testing, performance metrics and regulatory distinctions.

By using a structured approach to CGM evaluation – starting with study design, followed by performance metrics, regulatory approval status and patient-centred features – registered nurses working across primary care, secondary care, care homes and hospital settings can support personalised and evidence-based device choices.

The evolving comparison charts provided by the DSN Forum UK (https://www.diabetesspecialistnurseforumuk.co.uk), offer a valuable, regularly updated resource to help navigate the growing CGM market until a formal ISO standard is introduced, providing the community with the information necessary to evaluate efficacy and safety of CGM devices prescribed for insulin dosing decisions. ■

Contributions

AW: Design, background research, data collection, manuscript writing; BK: Data collection and manuscript review; TFS: Data collection and manuscript review; JP: Design, background research, manuscript writing, intellectual revision.

All authors were involved in the approval of the final version for publication.

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JP: Advisory Board for Roche and Abbott, and speaker payments for Abott, Dexcom and Insulet.

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Appendix A.

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

Diabetes Specialist Nurse Forum 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[c]**	**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)	×	✓	×
CareSens Air® (Spirit Healthcare)[9]	✓	✓	✓	✓	✓	5	≥18yrs	30	89%	99%	[d]	[d]	[d]	✓ (18yrs)	×	✓	×
Dexcom G6™ (Dexcom)[2-3]	✓	✓	✓	✓	✓	5	≥2yrs	159	93%	>99.5%	165	92%	>99.5%	✓ (≥2yrs)	✓[h]	×	✓
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)	×	×	✓
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]	×	×	[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)	×	×	×
Adjunctive use: Not licensed for clinical decision-making. All clinical decisions must be confirmed with a finger-prick blood glucose test																	
Gluconovo® (Infinovo)[10]	✓	×	×	×	×	1	≥18yrs	78	90%	99%	[d]	[d]	[d]	× (2yrs)	×	×	×
GlucoRx Aidex™ (GlucoRx)[11]	✓	×	×	×	×	1	≥18yrs	114	96%	>99.5%	[d]	[d]	[d]	× (≥14yrs)	×	✓	×
GS1 CGM (SiBionics)[12]	✓	×	×	×	×	1	≥18yrs	70	92%	[d]	[d]	[d]	[d]	× (18yrs)	×	×	×
Yuwell CT3 (Urathon)[g]	×	[d]	[d]	[d]	[d]	0	≥18yrs	72	93%	[d]	[d]	[d]	[d]	× (≥14yrs)	×	✓	×
Syai Tag (Syai Health Technology)[g]	×	[d]	[d]	[d]	[d]	0	≥18yrs	72	93%	[d]	[d]	[d]	[d]	× (≥18yrs)	×	×	×

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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 regulatory review of CGM systems.

[b] The five core criteria are taken from international recommendations published in 2020 and the five basic criteria have been reinforced by the IFCC CGM working group and a recent European clinician consensus. 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 IFCC Working 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)

[f] integrated 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)

[I] Dexcom G7 iCGM approval for HCL **only** applies for upper arm placement (≥2yrs)

[J] 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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Appendix B.

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

Diabetes Specialist Nurse Forum UK

	Accu-Chek SmartGuide (ROCHE)	CareSens Air (Spirit Health)	Dexcom ONE (Dexcom)	Dexcom ONE+ (Dexcom)	FreeStyle Libre 2 Plus (Abbott)[b]	FreeStyle Libre 3 Plus (Abbott)[b]
Non-adjunctive decision making (insulin dosing)	✓ (18 yrs)	✓ (18 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
Sensor warm up time	60 mins	Up to 30 mins	120 mins	Up to 30 mins	60 mins	60 mins
Separate transmitter	×	×	✓	×	×	×
Transmitter life	-	-	3 months	-	-	-
Smartphone app	SmartGuide	CareSens Air	Dexcom ONE	Dexcom ONE+	LibreLink	Libre 3
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 ▲ SoloSmart pen cap ▲	NovoPen 6 & Echo Plus	×
Data share HCP	ROCHE DiabeteCare	Sens365 Web	Clarity Glooko	Clarity Glooko	LibreView	LibreView
Data share friends/family app (n=)	×	Sens365 App	×	Dexcom Follow (10)	LibreLinkUP (20)	LibreLinkUP (20)
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

[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.

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Appendix C.

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

Diabetes Specialist Nurse Forum UK

	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	✓	✓	×[a]	×[a]	✓	✓	×[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 ▲ SoloSmart pen cap ▲	NovoPen 6 & Echo Plus ▲ 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

[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.
[c] Currently not recommended by the paediatric (BSPED and ACDC) adult (DTN) 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

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