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THE sensor report

ISSUE 3/2025

WELCOME TO
THE SENSOR REPORT, ISSUE 3, 2025

The accuracy and performance of CGM sensors is a significant part of the coverage in this issue of the *Sensor Report*. Accurate measurement of blood glucose concentrations for people with T1DM or T2DM is essential for daily diabetes management, in particular for those using insulin in their treatment. The use of finger prick test by self-monitoring of blood glucose (SMBG) meters for this purpose is increasingly being replaced by CGM systems, which measure glucose levels in the interstitial fluid (ISF) and convert this reading into a close approximation of plasma-glucose levels. The widespread use of CGM technology for people with diabetes has been driven in the last decade, in part, by the availability of affordable CGM systems with proven accuracy at least as good as the majority of SMBG devices, that provide continuous readings throughout the day and overnight.[1] A wealth of RCT outcomes and real-world evidence has shown that, compared to SMBG, use of CGM systems by people with T1DM or people with T2DM on insulin or non-insulin therapies, regardless of age, results in improvements in glycemic metrics, including HbA1c, and reduced hypoglycemia during the day and overnight, with consequent improvement in patient-reported quality of life (QoL) and psychological wellbeing.[2–7] Just as important, use of CGM technology is associated with significant reductions in hospital admissions for acute diabetes events (ADEs), such as diabetic ketoacidosis (DKA) and severe hypoglycemia,[8] as well as for long-term cardiovascular and microvascular complications of diabetes.[9] Alongside their demonstrated value as stand-alone devices, CGM sensors can also be connected with continuous subcutaneous insulin infusion (CSII) pumps, as part of sensor-augmented pump (SAP) therapy, or as components of hybrid closed-loop (HCL) automated insulin delivery (AID) systems.[10]

For these reasons, it is critical that CGM devices are able to meet accuracy and performance standards that ensure that they are safe and effective. However, within Europe, the Conformité Européenne (CE) process, through which CE marks are approved for the marketing of CGM sensors, has been shown to be inadequate in ensuring CGM sensor accuracy and precision for new entrants into the healthcare market in diabetes care.[11] As detailed in our feature story in this issue of the Sensor Report, poor device accuracy of new entrants has exposed people with diabetes on insulin therapy to potential harm, prompting clinicians to raise the alarm. In the feature story and the associated coverage, we have summarized the key elements of this important topic and the surrounding issues that urge improved regulation for CGM services and other diabetes technologies. An interview with Professor Chantal Mathieu is also available to access, providing expert commentary on some of the issues and concerns that are behind the drive for improved regulation of CGM devices in Europe.

In this issue of the Sensor Report we are also able to cover the key presentations from the Advanced Treatments and Technologies in Diabetes (ATTD) conference 2025, held in Amsterdam. These include how using the FreeStyle Libre systems for people with T2DM is demonstrating improved outcomes and superior cost-effectiveness compared to SMBG at a national level, as well as enhancing QoL, for people with T2DM. The value of using the FreeStyle Libre 3 system in the management of people with diabetes in care home settings is also discussed.

The ATTD presentations also provided further support for the association between using the FreeStyle Libre systems and reductions in emergency room attendance and hospital admissions for ADEs, including for adults with T2DM on non-insulin treatment regimens. Several presentations also revealed the additional benefit that using the FreeStyle Libre systems can have in improving engagement and long-term treatment adherence for people with T2DM, compared to SMBG, leading to significant reductions in HbA1c.

A nationwide registry study in Sweden, reports on a large cohort of adults with T1DM, who switched to using the FreeStyle Libre systems having previously used real-time CGM devices. Contrary to expectations, person-reported episodes of severe hypoglycemia declined significantly after switching to the FreeStyle Libre technology, despite the absence of predictive low-glucose alarms. This suggests that user behavior and engagement may have improved with use of the FreeStyle Libre systems, leading to improved glycemic control.

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Ensuring minimum accuracy and performance standards for CGM technology in Europe – the need for eCGM compliance status

In a recent publication, authored by an international expert panel,[1] a proposal was put forward for a set of minimum performance requirements for regulatory approval of CGM devices in Europe. Meeting this minimum set of standards, as recognized by a proposed eCGM compliance status, denotes to all stakeholders, including people with diabetes, that the system has undergone a certification process beyond what is currently required for Conformité Européenne (CE) marking of a CGM device. These minimum standards are summarized in Table 1 and meeting these would mirror the standards for integrated CGM (iCGM) defined by the US Food and Drug Administration (FDA) in the United States.[2] In addition, alongside these minimum standards, the expert author group have set out a series of parameters that should apply to CGM performance testing (Table 2). These are intended to ensure that performance has been tested in clinically relevant scenarios and that all the data from these investigations is formally published or made available in publicly accessible databases. Performance data should also be presented in the instructions for use and included in the package inserts that accompany the device.

The need for an eCGM compliance status

CGM technology has been proven to be a significant intervention for people living with diabetes. Randomized controlled trials (RCTs) and real-world studies have shown that, compared to finger prick test by self-monitoring of blood glucose (SMBG), the application of CGM devices is associated with improvements in important glycemic metrics, including lowered HbA1c, and reduced hypoglycemia during the day and overnight, with consequent improvement in patient-reported quality of life (QoL) and psychological wellbeing.[3–8] Large national diabetes registries have shown that using CGM devices such as the FreeStyle Libre systems is also associated with considerable reductions in hospital admissions for acute diabetes events (ADEs), such as severe hypoglycemia and diabetic ketoacidosis (DKA),[9,10] and for long-term complications of diabetes, including stroke, acute myocardial infarction, heart failure, atrial fibrillation, peripheral vascular disease and kidney disease.[11,12] These outcomes are evident in CGM users with insulin-treated T1DM or with T2DM on insulin or non-insulin therapies.

One of the consequences of the successful and widespread adoption and integration of CGM systems in diabetes clinical practice, particularly in T1DM, is the associated risk that errors in device accuracy and performance may impact patients' safety. Although this has not happened for CGM devices which have long-standing performance records in Europe, such as the FreeStyle Libre* and FreeStyle Libre 2 and Libre 3 systems, these issues are now being reported for new entrants into the European healthcare marketplace. In 2022, concerns were raised about the CGM device chosen as the winner of a tender to supply CGM systems for insulin users in the Campania region in Italy.[13,14] Users and clinicians reported poor accuracy at low and high glucose levels, serious enough that clinicians stopped prescribing the CGM system and recommended that users returned to SMBG testing.[14] In June 2024, the Diabetes Technology Network (DTN) section of the Association of British Clinical Diabetologists (ABCD) raised concerns about a CE-marked hybrid closed-loop (HCL) system, that was associated with instances of hypoglycemia for users in an NHS England Pilot study.[15] The ABCD requested but were not able to obtain evidence to support the claimed performance of the HCL device from the manufacturers of the system.

These issues with accuracy and performance had arisen despite the devices in question being CE marked, which is a requirement for medical devices before they can be marketed in Europe. Non-adjunctive CGM systems are categorized as Class IIb medical devices with moderate to high risk. CE mark, once issued, is intended to indicate that the manufacturer of a product has met standards appropriate for Class IIb conformity in line with state-of-the-art requirements. However, current and

Table 1. Proposed minimum performance requirements for regulatory approval of CGM devices in Europe[1]

Glucose range	Performance against reference reading	Lower boundary of 95% Confidence Interval (CI)
<70mg/dL mg/dL (<3.9 mmol/L)	Within ±15 mg/dL	>85% of readings
70-180 mg/dL (3.9-10.0 mmol/L)	Within ±15%	>70% of readings
>180mg/dL (>10.0mmol/L)	Within ±15%	>80% of readings
<70mg/dL mg/dL (<3.9 mmol/L)	Within ±40 mg/dL	>98% of readings
70-180 mg/dL (3.9-10.0 mmol/L)	Within ±40%	>99% of readings
>180mg/dL (>10.0mmol/L)	Within ±40%	>99% of readings
Across all glucose measuring ranges	Within ±20%	>87% of readings
CGM <70 mg/dL (<3.9 mmol/L) when reference >180 mg/dL (>10.0 mmol/L)		0% of readings
CGM >180 mg/dL (>10.0 mmol/L) when reference <70 mg/dL (<3.9 mmol/L)		0% of readings
CGM ROC >1 mg/dL/min when reference ROC <–2 mg/dL/min		≤1% of readings
CGM ROC < –1 mg/dL/min when reference ROC >2 mg/dL/min		≤1% of readings

CGM, continuous glucose monitor; CI confidence interval; ROC, rate of change.

Table 2. Proposed parameters applicable to CGM performance testing and reporting[1]

1. Performance should be tested at each anatomical wear site claimed for the system. Meal and insulin challenges, which investigate rapid rates of change and time spent at glucose extremes, should be included in this dataset.
2. Clinical study results must demonstrate consistent analytical and clinical performance throughout the sensor wear period. The sensor is required to be tested at a minimum; at the beginning (days 1–3), middle and end of the sensor life, including periods of rapid glucose fluctuation.
3. Performance should be tested in clinical investigations that reflect glucose changes in the intended population in real life,† including glucose variability. Changes in performance under different rates of change (trend accuracy) must be disclosed as with other performance data.
4. CGM sensors must demonstrate clinically acceptable accuracy in the presence of clinically relevant levels of potential interfering substances that may be present in the intended user population, including (but not limited to), endogenous substances and metabolites, foods, dietary supplements and medications.
5. The device must include system design safeguards to ensure that disposable sensors cannot be used beyond the claimed sensor wear period.
6. Design verification and validation of a CGM system must provide evidence that secure and reliable real-time glucose data transmission is guaranteed at clinically meaningful time intervals to other connected devices intended to receive the real-time glucose data stream and perform their own functions safely.
7. Performance data must demonstrate that there are no clinically important gaps* in the availability of sensor glucose data throughout the sensor wear life, which would prevent other digitally connected devices from achieving their intended use in a safe and effective manner.
8. System design and data management specifications should provide for data privacy and cybersecurity safeguards that meet European data protection laws.
9. All data from clinical investigations must be fully disclosed in the product label, for each intended user population, at the point of marketing.
10. CGM performance should be assessed using at least three separate sensor manufacturing lots, which should be verified for regulatory purposes.

† Including in a population with a minimum 70-75% of people living with T1D to ensure performance in glucose variability. The comparator method selected should be one of laboratory grade (e.g. Yellow Spring Instruments or equivalent), with sampling component clearly documented (venous blood, arterio-venous blood, capillary blood)

* i.e., CGM data is unavailable when a treatment decision must be managed, either by the user themselves or by an enabled interconnected device. For example, an insulin dosing event, an insulin dose estimation, impending low or high glucose

proposed standards do not provide CGM evaluation criteria sufficient to guarantee that a device has been adequately assessed for safety, accuracy and performance in people with diabetes who may use the product. Notably, the need for better European Union (EU) regulation of diabetes technologies was highlighted as early as 2012.[16]

In the current EU regulatory landscape, medical device manufacturers, and the Notified Bodies that audit medical device technical data during assessment, are operating without clear guidance on how to assess the efficacy and safety of CGM devices entering the European market. The existing requirements can be interpreted very widely and may be limited to studies in which the safety and efficacy of a system have been insufficiently validated before it is awarded a CE mark. This is not the case in the United States, where minimum accuracy and performance standards for CGM are mandated by FDA iCGM requirements. The unmet need for more rigorous CGM device regulation is a focus for the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) working group on CGM,[17] with the aim to develop International Organization for Standardization (ISO) minimum standards for the accuracy of CGM devices but these will take time. In contrast, the widespread and increasing use of CGM systems in Europe is an immediate reality.

By specifying a minimum set of requirements for CGM accuracy and performance, the proposed eCGM compliance status would ensure that the necessary clinical investigations, data collection and data transparency will underpin each claim made for a candidate CGM system entering the European marketplace following conformity assessment and CE marking. This will also mean that CGM marketing approval, once achieved in one European territory, will automatically fulfil the requirements of another.[1]

*Sale of the original FreeStyle Libre system has been discontinued in EU & UK markets. In these markets, the FreeStyle Libre 2 and 3 systems are for sale, providing the same benefits as the original FreeStyle Libre system, with the added functionalities of optional Real-Time Alarms.

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Expert video on the need for eCGM compliance status

Watch an insightful video with Professor Chantal Mathieu, president of the EASD and lead author on the recent paper on minimum expectations for market authorization of CGM devices in Europe, as discussed in our Feature Story. Hear the reasons why not all CGM systems are created equal, from a European perspective, and why current Conformité Européenne (CE) marking does not follow assessment criteria sufficient to guarantee that a CGM device has been adequately evaluated for safety, accuracy and performance in people with diabetes.

Simply scan the QR code or use the link below to access this insightful video.

[https://www.springermedicine.com/cgm-performance-standards/51055324?utm_source=Abbott&utm_medium=Newsletter&utm_campaign=cgm-performance-xpert_video_Abbott-Newsletter]

Standardization of glucose measurement and reporting for continuous glucose monitoring devices

CGM systems have revolutionized diabetes self-care for people with T1DM or T2DM (see feature story), and have also underpinned the development of significant new metrics of glycemic health, based on percentage daily time in range (TIR) 3.9-10.0 mmol/L (70-180 mg/dL), time above range (TAR) Level 1 >10.0 mmol/L (>180 mg/dL), TAR Level 2 >13.9 mmol/L (>250 mg/dL) and time below range (TBR) Level 1 <3.9 mmol/L (<70 mg/dL) or TBR Level 2 <3.0 mmol/L (<54 mg/dL).[1] This has driven the evolution of diabetes health metrics aligned with real-time glycemic changes, founded in individual daily choices of a person living with diabetes.

However, CGM-derived metrics reflect the overall interpretation of a very large number of individual CGM readings, each collected by different CGM systems used by different people with diabetes. Multiple studies confirm that different brands of CGM devices provide distinctly different metrics for TIR, TAR and TBR, when worn by the same person.[2–4] The use of CGM devices in automated insulin delivery (AID) devices has raised the issue of whether different CGM devices between different AID systems may contribute to unwanted variability between systems.[5,6]

Different CGM sensors may differ in practical use as a consequence of many factors. These include different application sites, overall design and sensor detection chemistry. Differences in the sensor calibration algorithms are an important factor, since these are proprietary to different sensors and are designed to convert the raw glucose signals measured in the interstitial fluid (ISF) to CGM readings that are controlled for over- or underestimation.[7] In this context, user-calibrated CGM devices have the added element of user calibration technique, which can be variable.[8] Factory-calibrated systems do not have this issue. The choice of reference sample for calibrating system performance is also important, with differences in glucose levels between the arterial and venous compartments.[9]

These differences between the systems have led to the establishment of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) working group on CGM,[7] with the primary goal of developing a standard for the assessment of CGM system performance. Unlike the Clinical and Laboratory Standards Institute POCT05 guideline for CGM performance[10] or the US Food and Drug Administration (FDA) integrated CGM (iCGM) requirement,[11] the IFCC working group on CGM will examine the specific requirements for the collection of comparator data, with the goal of developing a standard for the assessment of CGM system performance that will apply to all CGM systems, such that readings obtained from different systems will have less variation. Ultimately, the outcome of the IFCC working group will provide for an International Organization for Standardization (ISO) minimum standards for the performance of CGM devices. The intent of these efforts is to have better alignment between CGM readings obtained by different systems, such that there is increased consistency for the application of CGM-metrics in clinical practice.

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European CE marking for CGM is limited compared to US or Australian regulations

The concerns raised in the recent proposal for an eCGM compliance status are illustrated in a 2023 review of CGM study design and outcomes as they compare between devices submitted for Conformité Européenne (CE) marking and those submitted for approval by the US Food and Drug Administration (FDA) and the Australian Therapeutic Goods Administration (TGA) processes.[1]

Accuracy of CGM devices has improved with time, as measured by mean absolute relative difference (MARD), reducing from 23% in 1990 to <10% for current CGM devices.[2] The MARD measurement (%) reflects, on average, how close the CGM readings are to the paired blood glucose samples measured by a reference method. However, submissions to the FDA and TGA for CGM device approval reveal discrepancies in the assessment criteria that result in differing

claims for the same device. For example, after reviewing all clinical data submitted for approval under the FDA iCGM process or the CE-marking process, the same CGM device claimed a MARD of 9.6% when marketed following FDA approval[1] but a MARD of 9.0% following assessment for a CE mark.[3]

Similar issues are apparent in regard of CGM sensor wear sites. Following CE marking, a CGM device was marketed in Europe as suitable for placement on the arm and abdomen for users aged ≥2 years, and on the upper buttocks for ages 2-6 years. Following iCGM assessment, the FDA did not approve the abdomen indication. These discrepancies appear to be as a consequence of the submission of a reduced subset of the available performance data for CE marking.[1] Even the indication for use in T1DM may reflect inconsistencies in approach. At least two separate devices have achieved an indication for use in people with T1DM after CE marking, following submission of data in which only 11-16% of individuals had T1DM, with no more than 14 individuals.[4,5]

In Europe, the conformity assessment for CE marking is achieved using data from a quality management system (QMS), through which the manufacturer themselves validates that the product meets EU safety and environmental requirements.[6] This information is then audited by a Notified Body, which reviews compliance with European regulatory standards but is not provided with guidance on how to assess the quality, efficacy and safety for individual devices. The Australian TGA assessment requires that clinical evidence is critically reviewed by a domain expert against a hierarchy of evidence that can include clinical trials, systematic reviews and post-marketing surveillance registries. The CE marking process requires only a 'representative sample' of data on the product to be assessed, and also accepts clinical data from a device of 'equivalence' to the CGM system being assessed. The TGA approach is more robust and also requires mandatory reporting on post-marketing data every 6 months.

These concerns regarding the CE marking process for CGM are addressed in the short term by the proposal for eCGM compliance status,[6] and in the longer-term by the outcomes from the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) working group on CGM.[7] With the continued growth in the application of CGM to improve outcomes for people living with diabetes, the need for increased regulatory oversight in the European healthcare marketplace is a considerable unmet need.

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IFCC Working Group on CGM provide feedback on the need for minimum expectations in Europe

In a Letter to the Editor following the publication of the proposal for an eCGM designation,[1,2] the International Federation of Clinical Chemistry and Laboratory Medicine Working Group (IFCC-WG) on CGM have added their voice to the call for improved regulatory standards for market authorization of CGM technologies in Europe.

As expert contributors on this issue, the IFCC-WG stated their agreement that such minimum standards are necessary to ensure safety of people with diabetes using CGM devices. They also agree that adopting the iCGM criteria would be a temporary solution to bridge the gap between the current low-bar to being awarded a CE mark and the implementation of the important work of the IFCC-WG to define and establish standardized procedures and acceptance criteria for the analytical performance of CGM technologies.[3]

In commentary on the eCGM proposal, the IFCC-WG suggested going further than the iCGM requirements currently applied by the food and drug administration (FDA) guidelines in the US. First among these is to defining specific requirements for study design, including a certain percentage of glucose readings with associated rates of change (ROC). Further design requirements would encompass rapid ROC towards both hypo- and hyperglycaemia to ensure that CGM systems are exposed to, and validated in, glycaemic situations in which accuracy is of particular importance. For example, during meal challenges or periods of planned exercise.

A second insight provided by the IFCC-WG is the need for tighter standardization of the source and origin of the reference blood sample to be analyzed, and the exact set up and analytical performance specifications that should apply to the reference analyzer. To their point, even measurements obtained with devices of the same model used at different study sites can be different.[4] In agreement with the eCGM proposals, the IFCC-WG agree that CGM manufacturers should fully disclose all clinical investigation data at the point of marketing, including these suggested additional parameters.

The call for more-rigorously defined requirements for CGM accuracy and performance, as identified by the IFCC-WG, will need the design of the CGM performance studies themselves to be made even more fit for purpose, such that even current-generation CGM sensors can be validated under more-demanding test scenarios. Finally, while acknowledging the proposed alignment with iCGM requirements to be an acceptable but temporary solution in Europe, the ultimate need is for a new International Organization for Standardization (ISO) standard for CGM technologies that will become a harmonised benchmark and mandatory for CGM accuracy assessment. This will ensure safety and provide quality assurances for individuals with diabetes.

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Insights from ATTD 2025 Annual Congress

Better outcomes and lower costs using the FreeStyle Libre system* in T2DM

This economic analysis assessed whether the FreeStyle Libre system is more cost-effective than self-monitored blood glucose (SMBG) testing in adults with suboptimally controlled T2DM on basal insulin.

A cost model was developed using real-world data from Spain to compare the FreeStyle Libre system with SMBG testing. The model included costs related to glucose monitoring, hypoglycemia, diabetic ketoacidosis (DKA), and long-term complications such as heart failure, stroke, and nephropathy. Assumptions included a 1.1% HbA1c reduction and fewer acute diabetes events (hypoglycemia down 58%, DKA down 68%) with FreeStyle Libre system use. Event rates and treatment costs were taken from published literature.

The analysis showed that annual costs per patient were €6,854 with SMBG vs. €5,076 with the FreeStyle Libre system. In a hypothetical 1,000-patient cohort, FreeStyle Libre system use could prevent over 11,000 acute and 124 chronic complications of diabetes, saving the Spanish health system nearly €1.8 million annually. Sensitivity analyses confirmed the robustness of these savings. This study demonstrates that the FreeStyle Libre system not only improves clinical outcomes but also offers a cost-efficient alternative for managing T2DM at the national level.

*Sale of the original FreeStyle Libre system has been discontinued in EU & UK markets. In these markets, the FreeStyle Libre 2 and 3 systems are for sale, providing the same benefits as the original FreeStyle Libre system, with the added functionalities of optional Real-Time Alarms.

Gomez-Peralta F, *et al.* Cost-analysis of FreeStyle Libre in T2D patients with poor glycemic control. *EPV211 / #266: ATTD 2025*, 19-22 March. [https://www.liebertpub.com/doi/epub/10.1089/dia.2024.78502.abstracts.part4b]

CGM improves both glucose control and quality of life for adults with T2DM

A six-month observational study evaluated how using CGM impacted glycemic control and quality of life among a cohort of adults with T2DM on insulin therapy in Belgium.

Following the launch of a CGM reimbursement program in Belgium, 192 adults with T2DM using multiple daily insulin (MDI) injections were offered CGM (FreeStyle Libre* or Dexcom One) systems in routine care between July 2023 and August 2024. Of these, 129 completed a six-month follow-up. Data were gathered from medical records, unblinded CGM devices, and validated questionnaires at two time points.

After six months using CGM, HbA1c levels dropped from 7.6% to 7.3% ($p<0.001$), with significant improvements in those with least-optimal glycemic control at baseline. Most participants (59%) spent over 70% of time in the target glucose range, and 95% had fewer than 4% of readings in the hypoglycemic range. Quality of life also improved significantly: participants reported reduced fear of hypoglycemia and better perceived general health. These findings underscore CGM's broader value—not only improving glucose metrics but also enhancing well-being among insulin-treated T2DM patients.

*Sale of the original FreeStyle Libre system has been discontinued in EU & UK markets. In these markets, the FreeStyle Libre 2 and 3 systems are for sale, providing the same benefits as the original FreeStyle Libre system, with the added functionalities of optional Real-Time Alarms.

De Meulemeester J, *et al.* Real-world impact of CGM on glycemic management and QoL in T2D. *EPV231 / #1154: ATTD 2025*, 19-22 March. [https://www.liebertpub.com/doi/epub/10.1089/dia.2024.78502.abstracts.part4b]

FreeStyle Libre system* reduces both HbA1c and hospital attendance in older populations with T2DM

This population-level study examined how FreeStyle Libre system use impacted glucose control and healthcare resource use in Canadian adults aged 65 years or older with T2DM not using insulin.

Researchers in Ontario, Canada, conducted a retrospective longitudinal study using administrative health data housed at IC/ES. The analysis included 1,774 adults aged over 65 who used FreeStyle Libre system between September 2019 and August 2020—273 on GLP-1 receptor agonist therapy (± oral agents) and 1,501 on oral therapies alone. The study measured changes in HbA1c and healthcare utilization before and after Libre system initiation.

Both groups saw statistically significant reductions in mean HbA1c. Emergency department (ED) visits and hospitalizations, both overall and those linked to hypoglycemia or DKA, also declined. The reductions in overall ED visits and hospitalizations were statistically significant in the oral therapy group. These results demonstrate that use of the FreeStyle Libre system can enhance glucose control and reduce the burden on healthcare systems in older adults with non-insulin-treated T2DM.

* Sale of the original FreeStyle Libre system has been discontinued in EU & UK markets. In these markets, the FreeStyle Libre 2 and 3 systems are for sale, providing the same benefits as the original FreeStyle Libre system, with the added functionalities of optional Real-Time Alarms.

Ratzki-Leewing A, *et al.* FreeStyle Libre use in Ontario among older adults with T2D on non-insulin therapies. Poster presentation at *ATTD 2025: Diabetes Congress*, 19-22 Mar 2025. [https://www.liebertpub.com/doi/epub/10.1089/dia.2024.78502.abstracts]

Stick With It: CGM Use Linked to Better GLP-1 Adherence in T2DM

This retrospective analysis explored whether consistent use of FreeStyle Libre systems could reduce the likelihood of discontinuing GLP-1 therapy among adults with T2DM on non-intensive treatment regimens.

Using U.S.-based administrative claims data from Inovalon Insights (2017–2024), researchers conducted a matched cohort study including 878 consistent FreeStyle Libre systems users and 3,512 users naïve to any CGM system. All participants were CGM-naïve at GLP-1 initiation and matched based on demographic and treatment variables. Consistent FreeStyle Libre systems use was defined as ≥80% coverage within a year. The primary outcome was discontinuation of GLP-1 therapy, marked by a ≥90-day gap.

One year after starting GLP-1 therapy, only 31.1% of consistent FreeStyle Libre system users had discontinued, compared to 48.4% of those not using CGM. Adjusted analysis showed a 45% lower risk of discontinuation among FreeStyle Libre systems users (HR: 0.55, $p<0.001$). It can be concluded that integrating the FreeStyle Libre systems into care may strengthen medication adherence and long-term glycemic control in adults with T2DM not using intensive insulin therapy.

Huang E, *et al.* Association of FreeStyle Libre CGM Utilization and GLP-1 Discontinuation: A Real-World Study. *Poster presentation at ATTD 2025: Diabetes Congress*, 19-22 March. [https://www.liebertpub.com/doi/epub/10.1089/dia.2024.78502.abstracts]

Use of the FreeStyle Libre 3 system improves engagement and lowers HbA1c in adults with T2DM

This randomized controlled trial assessed whether using the FreeStyle Libre 3 system improves both glycemic control and engagement in diabetes self-management compared to self-monitored blood glucose (SMBG).

In this U.S.-based study, 110 adults with T2DM on basal insulin or non-insulin therapies were randomized to begin either using FreeStyle Libre 3 system or continue with SMBG. The primary outcomes were HbA1c and scores on the Impact of Glucose Monitoring on Self-Management Scale (IGMSS) - a validated tool measuring capability, motivation, and opportunity for diabetes self-management. Assessments were conducted at baseline and after 3 months.

At follow-up, FreeStyle Libre 3 system users showed a significant increase in IGMSS scores (from 3.9 to 4.4, p<.001), reflecting greater engagement with their own care. HbA1c also dropped significantly from 9.2% to 8.3% (p<.001). In contrast, SMBG users showed minimal changes in engagement scores or HbA1c drop, with the latter not reaching statistical significance. These results suggest that FreeStyle Libre 3 system not only improves glycemia but also enhances the active involvement of adults with T2DM in their diabetes care, an essential factor in long-term disease management.

Soriano EC, *et al.* Impact of FreeStyle Libre 3 on glycemic control and self-management engagement: A randomized trial. *Poster presentation at ATTD 2025: Diabetes Congress*, 19-22 Mar 2025. [https://www.liebertpub.com/doi/epub/10.1089/dia.2024.78502.abstracts]

Severe hypoglycemia is reduced after switching from real-time CGM to FreeStyle Libre systems in T1DM

This real-world study evaluated changes in self-reported severe hypoglycemic events (SHEs) in adults with T1DM in Sweden after switching from real-time CGM (rtCGM) with predictive alarms to the FreeStyle Libre systems.

Researchers analyzed registry data from the Swedish National Diabetes Registry for 660 adults with T1DM who transitioned from rtCGM with predictive alarms to the intermittently scanned FreeStyle Libre systems on or after June 1, 2017. SHEs reported up to 36 months before and after the switch were assessed, with additional focus on individuals with well-controlled glycemia and HbA1c <7.5%.

Contrary to expectations, the rate of person-reported SHEs declined significantly after switching: from 11.56 to 8.90 events per 100 person-years (p=0.007). In those with HbA1c <7.5%, the reduction was even greater—from 15.01 to 10.81 events (p=0.0261). This suggests that, despite the absence of predictive alarms, user behavior and engagement may have improved with use of the FreeStyle Libre systems. The findings challenge assumptions about technology dependence and highlight the role of user adaptation in achieving better diabetes outcomes.

Levrat-Guillen F, *et al.* Self-reported severe hypoglycemia after switching from rtCGM to isCGM in T1D. *Poster presentation at ATTD 2025: Diabetes Congress*, 19-22 Mar 2025. [https://www.liebertpub.com/doi/epub/10.1089/dia.2024.78502.abstracts]

CGMrefresher

MARD alone is not sufficient to understand CGM sensor accuracy

The use of CGM technology is increasingly becoming the standard of care for the glycemic management of people with diabetes.[1,2] In addition to its impact as a stand-alone glucose monitoring system, the accuracy of CGM sensors is now sufficient for them to be a central component of automated insulin delivery (AID) systems, such that real-time glucose data collected by a CGM sensor can be used to drive insulin dose adjustment for a connected insulin pump, with limited requirement for the user to take action.

One of the most common measures to describe CGM sensor accuracy is the mean absolute relative difference (MARD) between a CGM glucose reading and capillary blood glucose reference value taken at the same time. The closer the two readings are together, the lower the percentage MARD. The use of MARD has become a shorthand for describing the clinical accuracy of CGM sensors, and it is quoted in scientific presentations and in promotional materials, as proof of accuracy, since a MARD value is a single number that is easy to understand and provides a mean to compare different CGM devices.

However, on it's own, a MARD value does not provide a full picture of CGM device performance.[3] As an average measure of accuracy, it has several disadvantages (Box 1).

Although studies on CGM sensor accuracy report MARD values in several glucose ranges, this information is not easily interpreted in the context of the overall MARD statistic.

Box 1. Disadvantages of MARD in estimation of CGM accuracy[4]

- Only a small amount of CGM data is used to calculate MARD, as it is tied to the relatively low frequency of coincident blood glucose reference measurements.
- MARD does not differentiate between whether CGM readings were above or below the comparison measurements, i.e., were biased towards higher or lower glucose.
- The direction and rates of change in glucose are not reflected in MARD values – i.e., how accurate is a CGM sensor when glucose is rising or falling, and when it is changing rapidly.
- A single MARD value is unlikely to reflect the accuracy and performance of a CGM sensor across the whole sensor wear period – which can be up to 15 days.

It is important to know that, when accuracy studies are performed, collection of fewer paired data points can generate a lower MARD than a study that collects a greater number of paired CGM and blood glucose measurements. Equally, more glucose variability during the study period will tend to generate a higher MARD, for the same average glucose level.

When looking at the overall MARD of a CGM system, it is also important to understand how many readings were collected in the hypoglycemic range, since the higher the percentage of points in the hypoglycemic range, the higher the overall MARD is likely to be.[4]

Accuracy and precision – two different measures of CGM performance

Both the analytical and clinical performance of CGM sensors is divided into two key areas: accuracy and precision. Accuracy refers to how close the CGM test values are to a blood glucose reference or sample, and precision refers to the consistency of the system, that is, how close the test results are to each other. These concepts are illustrated in Figure 1. Notably, MARD provides no information about the precision of a system. In order to better understand accuracy, precision and other dimensions of CGM performance, studies now typically use error grids that map paired readings onto zones that visualize both the accuracy of the readings as a pair and also how precise readings are for each test method.[3] The widespread access to CGM devices for people with T1DM and T2DM on insulin has led to the development of a specific error grid, the Diabetes Technology Society Error Grid,[5] with five zones for determining CGM accuracy and performance, compared to reference glucose values, along with a Trend Accuracy Matrix, to assess the performance of CGM devices when glucose is rising or falling.

In the Feature Story on page 2 of this issue of the Sensor Report, it was discussed that the CE marking process for CGM systems in Europe did not sufficiently specify how accuracy and performance studies should be designed and which key outcomes must be met before a CGM device could be awarded eCGM compliance status.[6] Equally, rather than promoting a single MARD value as testament to the accuracy and performance of a CGM system, manufacturers must disclose to healthcare professional and CGM users a complete summary of the studies against which their sensors have been evaluated prior to being given a license to market to European healthcare services. Ultimately, European regulatory agencies can be guided by adopting similar accuracy and performance standards as are mandated by the US Food and Drug Administration through their iCGM requirements.[7]

Tell us what you think!

The team at the *Sensor Report* is always keen to hear your feedback and suggestions.

Please share your feedback through this short feedback questionnaire with us.

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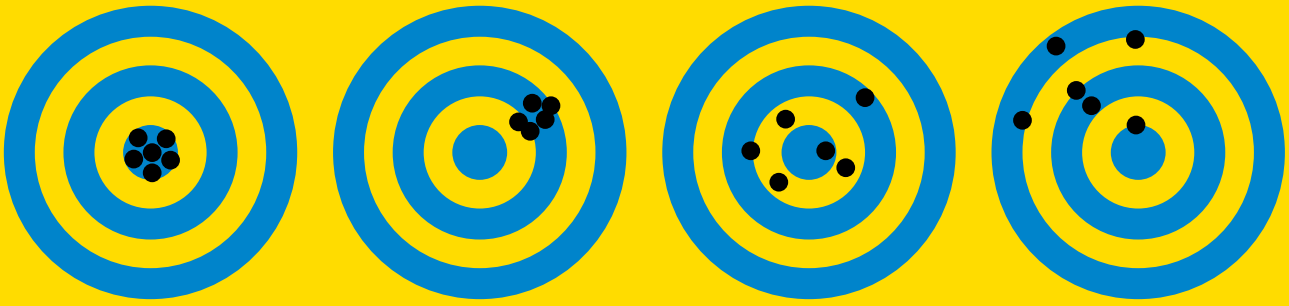
Figure 1. What do we mean by accuracy and precision of a CGM device?[3]



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