Guaranteeing the quality of CONTINUOUS GLUCOSE MONITORS in Europe – An IDF Europe position

International Diabetes Federation Europe

WHAT'S AT STAKE?

Some continuous glucose monitors (CGMs) approved for use in the EU have been found not to be fit for purpose, endangering the lives of people with diabetes (PwD).

2022

In **2022**, concerns were raised in Italy over the **poor accuracy of a CGM device at low and high glucose levels**, despite it having been approved for use in the EU through the CE marking.

2025

In 2025, the Portuguese National Authority of Medicines and Health Products, INFARMED, suspended the use of a closed loop system because of significant discrepancies in blood glucose values compared to capillary blood value.[2]

2024

In **2024**, alarm was raised in the UK about the **poor performance of another CGM**, which also lacked published efficacy and safety evidence supporting its performance.[1]

HOW ARE CGMs CURRENTLY ASSESSED IN THE EU?

The **Medical Devices Regulation (MDR)** (EU) 2017/745 and the **In Vitro Diagnostic Devices Regulation** (EU) 2017/746 govern the **manufacturing, distribution and availability of medical devices in Europe**, including essential devices used by people living with diabetes (PwD), such as blood glucose monitors (BGM) and CGMs. CGMs, classified as Class IIb medical devices, must undergo a **conformity assessment** process to obtain a **Conformité Européenne (CE) mark**.

To obtain the **CE mark**, manufacturers must implement a **quality management system (QMS)** ensuring safety, performance and regulatory compliance. The QMS must include a clinical evaluation, assessing scientific literature, clinical investigations and alternative treatments. Where no equivalent CE-marked CGM exists, a clinical investigation involving one or more humans to assess safety and performance is mandatory.

An **independent Notified Body*** (NB) is responsible for auditing the QMS and assessing the technical documentation to **verify compliance** with applicable regulatory standards.

A notified body is an organisation designated by an EU country to **assess if certain products meet safety and quality standards before they can be placed on the market and sold to consumers. The list of NBs can be found here.*

WHAT IS THE CHALLENGE?

While BGM systems assessment processes often take into account an ISO standard (15197:2013), there is currently **no device-specific guidance in the EU detailing the necessary criteria for assessing CGM device accuracy, reliability and clinical effectiveness**. The absence of standardised, CGM-specific evaluation criteria (and study designs to meet criteria) means that **manufacturers and NB are operating without a clear framework** to ensure these devices meet the highest safety and efficacy standards.

This puts the safety of PwD at risk.

For example, while the **mean absolute relative difference** (MARD) is often used as a way of measuring the performance of CGMs, in itself it is not enough to assess all relevant performance parameters.

Sources:

[1] Mathieu C, Irace C, Wilmot EG, Akra B, Del Prato S, Cuesta M, et al. Minimum expectations for market authorization of continuous glucose monitoring devices in Europe-'eCGM' compliance status. Diabetes Obes Metab. 2025 Mar;27(3):1025-31. doi: 10.1111/dom.16153. Epub 2024 Dec 26. PMID: 39726200; PMCID: PMC11802390

[2] https://www.infarmed.pt/web/infarmed/alertas-de-seguranca/-/journal_content/56/15786/10951711

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WHAT CAN BE DONE?

At **EU level**, several organisations such as IDF Europe, are **calling for a change to the MDR**, notably to strengthen EU-wide oversight and requirements for all medium to high-risk devices (at minimum class IIb) through expanding the role of EMA; mandating systematic post-market clinical follow-up; developing uniform, EU-wide standards for NBs; and using existing mechanisms to develop specific guidance on CGMs.

At **national level**, national diabetes associations and other diabetes stakeholders might require of their **national health authorities** that they **increase transparency of the approval process** by mandating the publication of all clinical data and metrics for CE-marked CGMs that receive reimbursement approval and also that they should publish real-world post-market surveillance data.

WHAT SHOULD BE KEY FEATURES OF QUALITY CGMs?

Clinical data must demonstrate **accuracy** in the intended use population in parallel against capillary blood glucose values.

Performance must be based on **clinical data** obtained throughout the **intended use population** and throughout the measuring range of the CGM.

The **clinical performance** must be validated throughout the **sensor wear period**.

The sensor must demonstrate **acceptable performance** in the presence of clinically relevant levels of potential **interfering substances**.

There should be **no gaps in the sensor data** that would prevent **connected devices** to function adequately; data transmission should provide real-time glucose readings at clinically meaningful time intervals.

The sensor must include **appropriate measures** to ensure that it cannot be **used beyond its wear period**.

Healthcare professionals and **PwD** should also be encouraged to **report** any **issues** with their devices to their national competent authority. In the EU, the **list of competent authorities** can be found here.

For more information, contact: sabine.dupont@idf-europe.org

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