DTN-UK statement on the assessment of accuracy for CGM systems

DTN-UK is acutely aware of the challenges that DTN-UK members and commissioners are facing in the assessment of accuracy and performance of novel continuous glucose monitoring (CGM) devices coming into the UK market, as well as those already available. Our focus is to ensure that people with diabetes have access to cost-effective CGM devices that have demonstrated sufficient accuracy when assessed appropriately (ideally in published, peer-reviewed studies) for us to be confident that they are safe.

There are currently no universally accepted standards for how the accuracy of CGM devices should be assessed to obtain CE marking, leading to the potential for significant variability in the accuracy and safety of devices carrying a CE mark. Expert groups in Europe and the USA have proposed guidance on how accuracy should be assessed[1-4]. Regulatory bodies are also considering this area, but changes in regulatory requirements are likely to take time and are not anticipated in the near future.

In order to ensure the safety of people with diabetes, DTN-UK recommends the use of CGM devices that meet eCGM³ criteria, or those which have met the US FDA pre-market standards for efficacy and safety for a Class III medical device. Other devices can be used, as long as they can demonstrate that their accuracy has been assessed appropriately and found to be sufficient. This applies especially when CGM is being used in automated insulin delivery systems or for glucose measurement in drivers of group 2 vehicles.

While an improved regulatory framework is awaited, DTN-UK are extremely grateful to the Diabetes Specialist Nurse (DSN) Forum who have developed some very helpful CGM comparison charts. These charts are updated regularly and provide both clinicians and funders with a summary of which systems have demonstrated sufficient accuracy following appropriate assessment. The charts are available via the DSN forum website.

References

1. Freckmann G, Pleus S, Eichenlaub M, et al. Recommendations on the Collection of Comparator Measurement Data in the Performance Evaluation of Continuous Glucose Monitoring Systems. J Diabetes Sci Technol. 2025 May 6:19322968251336221. doi: 10.1177/19322968251336221.

2. Pleus S, Eichenlaub M, Eriksson Boija E, et al. Working Group on Continuous Glucose Monitoring of the IFCC Scientific Division. Proposed minimum requirements for market approval of continuous glucose monitoring (CGM) systems: A viewpoint from the IFCC working group on CGM. Diabetes Obes Metab. 2025 Jul;27(7):4039-4042. doi: 10.1111/dom.16420. Epub 2025 Apr 28.

3. Mathieu C, Irace C, Wilmot EG, et al. Minimum expectations for market authorization of continuous glucose monitoring devices in Europe-'eCGM' compliance status. Diabetes Obes Metab. 2025 Mar;27(3):1025-1031. doi: 10.1111/dom.16153. Epub 2024 Dec 26.

4. Pemberton JS, Andrews RC, Barnard-Kelly K et al. International clinical opinion on transparency, standardisation, and calibration alignment in the performance evaluation of systems for continuous glucose monitoring. Diabetes Obes Metab. 2026 Jan;28(3):1–15. DOI: 10.1111/dom.70460.Epub 2026 Jan 26.

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