

DVLA approves glucose sensor technology for Group 1 drivers

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For people with diabetes treated with insulin, reliable measurement of ambient glucose levels is an essential part of achieving effective self-management. Such personal monitoring has provided considerable benefits to the individual in terms of objective glycaemia awareness and the consequent means whereby insulin can be appropriately adjusted to whatever circumstances prevail. But within the diversity of these lifestyle circumstances, there is a beholden responsibility of individuals to ensure that glucose levels are sufficiently stable as not to engender risk to others under certain conditions, of which driving a vehicle on the roads is clearly a prime consideration.

To date, guidance from the DVLA has advised that insulin-treated drivers should undertake a capillary blood glucose measurement within at least 2 hours of commencing to drive, and at further 2-hour intervals as the journey continues. Capillary measurement, known to correlate well with systemic arterial blood glucose levels, has been the accepted standard for some time, but recent advances in glucose sensor technology have raised questions as to whether the new forms of continuous (Real-Time; RT-CGM) or 'flash' (FGM) glucose monitoring might be acceptable alternatives consistent within the principles of safe driving on insulin. Certainly, continuous monitoring of glucose status by RT-CGM and FGM has become increasingly popular with individuals, who have ascertained particular clinical and practical advantages over traditional finger-prick testing.

So, why has there been previous reservation by regulatory bodies to embrace either CGM or FGM? Both of these new techniques measure the interstitial fluid glucose level, which is not exactly the same as systemic arterial concentration, with an average lag time of 5–10 minutes across the plasma-interstitial gradient. Additional discrepancies can occur with physical activity and when eating itself may result in more rapid glucose changes. However, continuous monitoring does have the advantage of registering the trajectory of developing glucose change, which has to be seen as a most singularly useful indicator.

Approval with caveats

The DVLA Medical Advisory Panel on Driving and Diabetes, accountable to the Secretary of State for Transport, after grappling with this issue over a period of time, has reached the conclusion that interstitial fluid monitoring systems could be used to monitor glucose levels while driving. Draft guidance was duly developed for consultation with relevant stakeholders to obtain views on the proposed changes. The stakeholder comments on feedback were sufficiently positive to endorse the panel's proposal to recommend that both RT-CGM and FGM may be used for the purpose of monitoring

glucose levels in the context of driving. This guidance from the DVLA was officially notified by press release on 15 February 2019, and has been widely welcomed.

Although this new policy will be incorporated with future driving guidelines, it should be noted there are certain caveats. Firstly, the new guidance applies only to Group 1 drivers (car and motorcycle) and not Group 2 (bus and lorry). Secondly, drivers may still use finger-prick blood testing, should that be their current means of monitoring and their preferred choice. Thirdly, even if they are using RT-CGM or FGM, drivers must still confirm their blood glucose level by finger-prick capillary measurement if their interstitial fluid glucose level is 4.0mmol/L or below, if they are experiencing symptoms of hypoglycaemia, or if their monitoring reading is inconsistent with the symptoms they are experiencing, especially symptoms of hypoglycaemia.

In terms of accuracy and precision of measurement, continuous glucose sensor devices have improved progressively, but there is still absence of an international standard (ISO) for interstitial glucose monitoring equipment. The DVLA panel has considered how a minimum standard for such devices might be implemented. One option to determine a minimum Mean Absolute Relative Difference (MARD) of 10% has yet to be formalised and therefore considered not to be an appropriate measure at this stage. For the time being, the more familiar alternative of CE ('Conformité Européenne') marking will probably be adopted by the DVLA as the minimum regulatory standard for assessing glucose monitoring devices.

Diabetes will continue to benefit from ever-evolving new technologies, designed to improve the life and management of people with diabetes, particularly for those treated with insulin. It is evident that such innovations are readily embraced when the clinical advantages are so clearly apparent to the user, and there can be frustrations when new advances seem slow to be incorporated into current guidelines. Regulatory bodies such as the DVLA have responsibility to ensure monitoring systems are accurate and thereby safe for use within the public domain at large. It has taken due process of time for continuous glucose sensor devices to be evaluated as acceptable alternative monitoring systems, but after stakeholder consultation and careful consideration, the decision by the DVLA to approve their use, with certain cautions, for Group 1 insulin-treated drivers is most welcome.

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