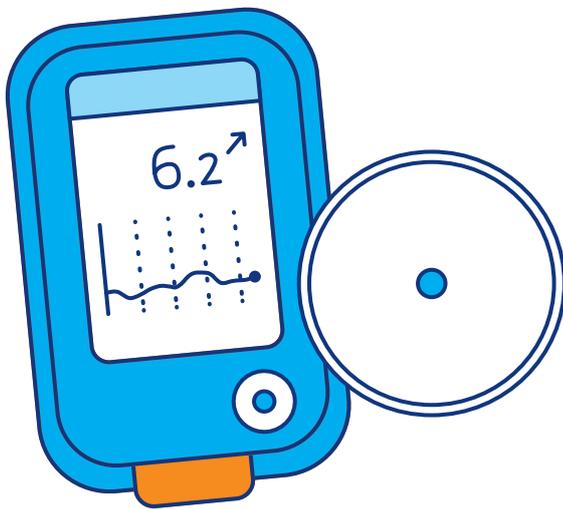


Diabetes UK Consensus Guideline for Flash Glucose Monitoring

Date published September 2017



Introduction	3
Our recommendations	4
Overview	5
Who is flash glucose monitoring suitable for?	5
What is the clinical evidence for flash glucose monitoring?	6
What does flash glucose monitoring offer people with diabetes?	6
The role of healthcare professionals	10
Key points for funders and providers in the NHS	11
Further information	12
Appendices	13
References	15

Introduction

Flash glucose monitoring (Flash GM) is a new technology that has recently been made available on the NHS Drugs Tariff. This means in principle it is available to people with diabetes in the UK on NHS prescription. It is important that healthcare professionals and local health decision makers are aware of the new technology so that they can make sure that people with diabetes have access to Flash GM in their local area.

.....
“We are lucky to be able to afford the Libre, it has made a huge difference to my daughter’s lifestyle and her diabetes care. It’s a travesty that those who can’t afford it don’t have access to such a life changing technology.”

Emma, mother of a child with Type 1 diabetes
.....

We have developed these recommendations for the use of Flash GM in the NHS, jointly with other diabetes organisations representing people with diabetes and clinicians. We recognise that there is need for further research and audit to determine a full picture of the benefits and limitations of the technology to the NHS and people with diabetes. These recommendations are based on the best currently available clinical and scientific evidence as well as experiences from people living with diabetes using this technology.

These guidelines cover:

- Which patient groups would benefit from Flash GM.
- How healthcare professionals can support patients to get optimum use of this technology.
- Considerations for health service funders and providers when making decisions on funding for specific patients and patient groups.



Our recommendations

Flash glucose monitoring is a major advance over routine finger prick glucose monitoring. It is easier, quicker and less painful. The density of data and the ability to follow trends in glucose levels, which are not available from less frequent blood glucose testing, has been shown to help patients improve glucose control and reduce hypoglycaemia.

- Flash GM can be used alongside routine finger prick testing to check their blood glucose levels. It can also be used as a management tool to obtain a more detailed picture of an individual's glucose profile.
- Flash GM devices should be made available to any adult or child with Type 1 diabetes and to people with other forms of diabetes when intensive insulin therapy becomes necessary because of severely reduced pancreatic function.
- The short term use of Flash GM by healthcare professionals as a management tool, sometimes referred to as troubleshooting, can help someone who is having difficulties in achieving their personalised treatment target, someone who is troubled by frequent hypoglycaemia, hyperglycaemia or both.
- Flash GM would not be appropriate in those who have completely and irreversibly lost their hypoglycaemia awareness, which means they cannot recognise when their glucose levels are low. Continuous glucose monitoring (CGM) devices which provide alarms are more appropriate in these patients.
- People who have recently developed hypoglycaemia unawareness could use Flash GM, with the support of their healthcare professional team, 'to troubleshoot', which may help stabilise their blood glucose levels and re-establish their hypo awareness.
- Ongoing funding for Flash GM sensors should be made available on the condition the person demonstrates active management of their glucose levels or progress towards achieving and maintaining their personalised treatment target. This should be assessed at least annually.
- People who use Flash GM should have a good understanding of intensive insulin therapy and how to self-manage their diabetes. The completion of a structured diabetes education programme, as recommended by NICE, is highly recommended.
- It is essential that people using Flash GM have education to make sure they can best use the information the system provides to improve management of their glucose levels. Healthcare professionals will also need training on how to interpret the information on glucose trends in relation to patients' daily living and in insulin dose adjustment.
- The use of Flash GM should be audited in order to get a fuller assessment of longer term benefits and better understand its wider value.
- Flash GM should not be considered as an alternative to continuous glucose monitoring for those who meet the CGM criteria.
- People who use Flash GM will still need access to test strips and meters for use in certain circumstances. For example currently Driving and Vehicle Licensing Agency (DVLA) regulations stipulate that people should use finger prick testing of glucose levels before driving.
- Once Flash GM device(s) are on the NHS Prescriptions Authority Drug Tariff, local health decision makers should make sure that Flash GM readers and sensors are listed in the local formulary.

Overview

Blood glucose monitoring is a key part of diabetes self-management. More frequent glucose monitoring has been associated with improved diabetes control and, therefore a lower risk of complications including eye, kidney and nerve damage². NICE recommends that people with Type 1 diabetes test their glucose levels between four and 10 times a day^{3,4}. NICE also advises that people with Type 2 diabetes on insulin or glucose lowering medication are also supported to monitor blood glucose levels⁵. This currently involves using a lancet to draw blood from the fingertip which requires specialised equipment for their disposal. The process is painful, time consuming, inconvenient and a significant barrier to optimised glucose control.

Flash GM offers a novel method for glucose monitoring for people with diabetes.

A sensor, the size of a £2 coin, is worn on the arm. It has a very fine sensing electrode (roughly the thickness of two human hairs) which is automatically inserted just under the skin when the user applies the sensor to the skin. Readings can be obtained for 14 days providing the sensor remains in place (Figure 1). The sensor measures interstitial fluid glucose levels, which correlate with blood glucose levels. Measurements are taken by scanning the sensor with a handheld reader or compatible mobile phone. (Figure 2)

Flash GM can transform the way diabetes is treated, managed and monitored by providing more information to a person than finger prick tests and can help to engage people with diabetes in their care and potentially improve outcomes.



Figure 1 A flash glucose sensor when worn on a person's arm

Who is Flash GM suitable for?

Flash GM is suitable for adults and children who use insulin to manage their diabetes, principally those with Type 1 diabetes using multiple daily injections or an insulin pump. It would also be suitable for patients with other types of diabetes when intensive insulin therapy becomes necessary because of severely reduced pancreatic function.

Flash GM is not the appropriate tool for those who have completely and irreversibly lost their hypoglycaemia awareness, which means they cannot recognise when their glucose levels are dangerously low. In this instance continuous glucose monitoring (CGM) which provides alarms is more appropriate, as highlighted in NICE guidance for people with Type 1 diabetes³ (Appendix 1).

Flash GM can also be used as a management tool for short-term troubleshooting investigations into someone's glucose levels where they're having difficulty managing their condition.

.....
"I was having problems with high and low glucose levels, with symptoms too, despite the blood glucose meter saying I was in target range. The Flash has helped resolve these issues."

Linda, adult living with Type 2 diabetes
.....

Short-term use can help identify clinical issues regarding management of blood glucose. For example, helping to optimise diabetes self-management on current regimes, such as whether someone using a basal-bolus regimen would benefit from an insulin pump.

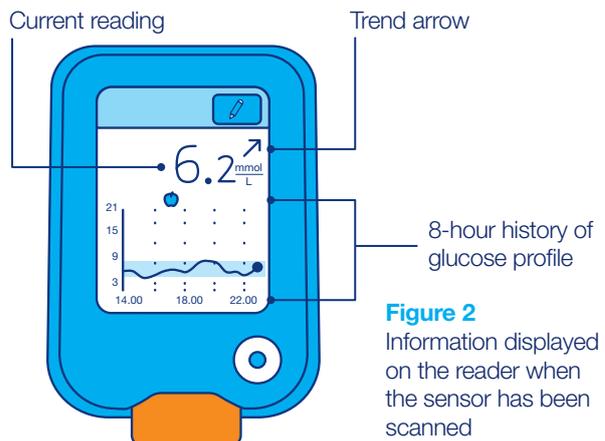


Figure 2 Information displayed on the reader when the sensor has been scanned

What is the clinical evidence for flash glucose monitoring?

Flash GM has been shown to safely improve time in target glucose range, reduce hypoglycaemia and hyperglycaemia, and improve HbA1c^{1, 6, 7, 8}.

NICE have developed a Med Tech briefing for the FreeStyle Libre flash glucose monitor⁹. The briefing provides a description of the system and a review of the current evidence.

The main adverse events are skin reactions in a minority of users and dislodging of sensors. In terms of accuracy, it has a similar accuracy to real-time continuous glucose monitors which are currently on the market (Dexcom G4 and G5, Medtronic Enlite)¹⁰.

What does Flash GM offer people with diabetes?

Flash GM has a number of benefits that can improve people's diabetes clinical outcomes over and above glucose testing. The technology provides data to support someone's self management of their condition and can improve their quality of life. It can:

- 1 Reduce the need for painful, stressful and inconvenient finger prick glucose monitoring.**
- 2 Help people to better manage their diabetes and engage people in self-management of their condition.**
- 3 Enable fine tuning of insulin and so reduce hypoglycaemia and increases time in target range**
- 4 Improve HbA1c.⁶**

1 Reduce the need for painful, stressful and inconvenient finger prick glucose monitoring

Self-monitoring of glucose levels is a core part of how people with diabetes manage the condition. However, finger prick tests are painful, inconvenient and can be a barrier to optimising glucose control. Unlike finger-prick monitoring, Flash GM is discreet to use, significantly reduces the need for finger prick tests, and is very often accepted when finger pricking is rejected⁷. It may also be beneficial to people with diabetes who have learning difficulties or have a fear of needles. The sensor can be scanned through layers of clothing, and does not need multiple pieces of equipment or for the individual to dispose of test strips and lancets. Flash GM is popular amongst parents and children as they see it as tool to help overcome some of the difficulties of painful finger pick testing and reduces the burden of self-management.

.....
"My son is very active, he does judo, tennis, football, cricket, swimming and helps to walk the family dog too. At school he is physically and mentally active. No day is ever the same. The flash device has allowed my son his freedom and independence to test. The arrows are the most important for us, at six years old my son can read his levels and immediately understand how to take care of himself. We have a better understanding of how to manage his diabetes with his active lifestyle, so he can join in and experience a 'normal' childhood."

Sam, mother of a child with Type 1 diabetes
.....

Flash glucose monitoring can be particularly useful for people who struggle to perform finger prick tests regularly. For instance, car mechanics who have dirty hands and struggle to get them clean enough to perform a finger prick test, teachers, shop workers and healthcare professionals who find performing finger prick tests challenging during the course of the working day.

People with diabetes have reported how Flash GM supports them to carry on with their daily lives, (sports, work, performances, and exercise) with greater ease and confidence.

Some people with diabetes, can be unwilling to perform finger prick blood glucose checks due to pain, inconvenience, and unwillingness to be open about their diabetes. This is especially so in children and young people which can lead to immense tensions within the family.

.....
“It is difficult to stress the horror we went through at the beginning of diagnosis when my daughter had to finger prick all the time. She thoroughly hated it. It was the worst time. She would scream, cry, run away from us and hide. It was just beyond awful. There are no words to describe the incredible positive difference the flash monitoring can make.”

Mother of a child with Type 1 diabetes

.....

Flash GM can help reduce anxiety around hypos and hyperglycaemic events. For instance when parents are concerned about night-time hypoglycaemia in their child, scanning the sensor is far more convenient and less intrusive than a finger-prick test in the middle of the night. This aspect of using the flash monitor improves the quality of life not just for the user, but for the carer of those with diabetes.

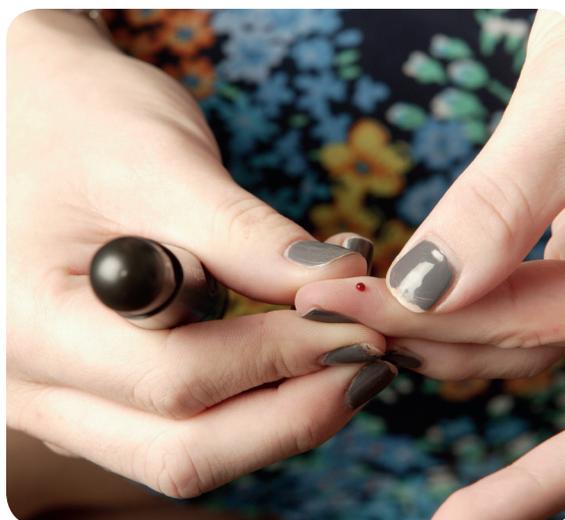
Right Finger prick testing can be painful and inconvenient

Increased testing has been shown to improve clinical outcomes, but people with diabetes don't always test as often as recommended by NICE guidance. The Flash GM system has been shown to increase the frequency with which patients check their glucose levels^{7,9}. For instance, in the Impact study which assessed the use of Flash GM in people with Type 1 diabetes, patients became much more engaged in checking their glucose levels whilst reducing their use of test strips. The number of scans at six months averaged 15 per day, and finger prick tests fell from an average 5.5 to 0.5 per day⁷.

Although Flash GM devices can reduce the frequency of finger prick monitoring they don't completely remove the need for them. Finger prick tests are still needed:

- during times of rapidly changing glucose levels when interstitial fluid glucose levels may not accurately reflect blood glucose levels
- to meet Driving and Vehicle Licensing Authority requirements¹¹ ([Appendix 2](#))
- when scanned glucose results do not correspond with the user's symptoms
- to use the bolus calculator function
- where the reader indicates a low glucose reading.

People who use a Flash GM monitor will therefore need a supply of test strips in order to finger prick test in the circumstances listed above.



2 Helps people to better manage their diabetes and engages people in self-management of their condition

In addition to enabling people to check their glucose levels more frequently, Flash GM also provides more detailed information on glucose levels compared with finger-prick glucose monitoring.

Flash GM allows people to better adjust insulin, food intake and activity related to the current test result, what has happened immediately before (as shown on the glucose profile), and what is predicted to happen as shown by the trend arrow (Figure 2). This information is considerably more valuable than a one off blood glucose result (Figure 3).

“Without having a clear picture of what my glucose levels are doing, I’m essentially poking around in the dark. Even with a finger prick test, it’s a moment in time rather than a direction. Flash gives an interactive way of managing my diabetes. I can watch things unfolding and react accordingly. I am now trying to avoid the events rather than avoiding recording the events. It takes away the stress and guesswork around testing and management of the condition.”

Mike, who’s living with Type 1 diabetes

The flash reader presents the user with data; glucose levels, trends and an overview of the data, displayed as an ambulatory glucose profile (AGP).



Figure 3
The information on the Flash GM (left) is considerably more valuable than a one off blood glucose result on a traditional meter (below).



The AGP helps to identify glucose patterns, the effects of insulin doses, meal times, and exercise. It also shows patterns of hypoglycaemia, hyperglycaemia, and glucose variability and helps to adjust daily and longer-term management. The AGP data can be downloaded onto the user’s computer and shared with healthcare professionals (Figure 4).

“My son’s consultant is happy to look at his Libre data profile to see how we can improve his levels. They interpret the graphs together and it’s great to see them both so enthusiastic to improve my son’s diabetes management. He’s even arranged a Skype appointment to discuss the graphs in between clinic appointments to look at more ways to improve his glucose levels.”

Fiona, mother of teenager living with Type 1 diabetes for three years

The Flash GM reader tells someone what percentage of the time their glucose levels are in their target range across the day. Increasing time in target leads to lower HbA1c⁸.

The directional arrows and data profiles on scanned glucose levels can help users to understand the trajectory of their glucose levels rather than just having a spot reading. This enables on-going education by showing, in almost real-time, the effect of certain foods or behaviours on glucose levels. This helps the user easily identify and adjust for a hypo or hyperglycaemic event reducing their glucose variability. There is increasing evidence that reduced glucose variability decreases the risk of developing complications¹.

“Using the Libre has completely changed my relationship with monitoring my blood sugar. I have had diabetes for 30 years so this had become normalised. Using the Libre meant I developed a new curiosity about what was happening with my blood sugars – it became an interest rather than a stress. I am more engaged with taking care of my diabetes therefore I am doing a better job. I actually find using the Libre fun. I could never have said that about test strips.”

Marie, adult with Type 1 diabetes

Flash GM gathers overnight data, as long as the sensor is scanned at least once every eight hours. This helps to identify night-time hypos, the dawn phenomenon and other periods of hyperglycaemia, provides a person with diabetes a retrospective review of their glucose levels.

Flash GM gives the complete glucose profile whereas the information from blood glucose monitoring will be limited by the number of overnight tests the patient is willing to do. If on the other hand there is a need to check on the glucose level at night it is quicker and easier for someone to perform a scan than a blood test; and for a parent there is no need to wake the child to get a glucose reading.

Glucose pattern insights

13 September – 10 October (28 days)
 LOW-GLUCOSE ALLOWANCE SETTING: Medium
 MEDIAN GOAL SETTING: 8.6mmol/L (A1c: 7.0% or 53mmol/mol)

Estimated A1c **5.8% or 40 mmol/mol**

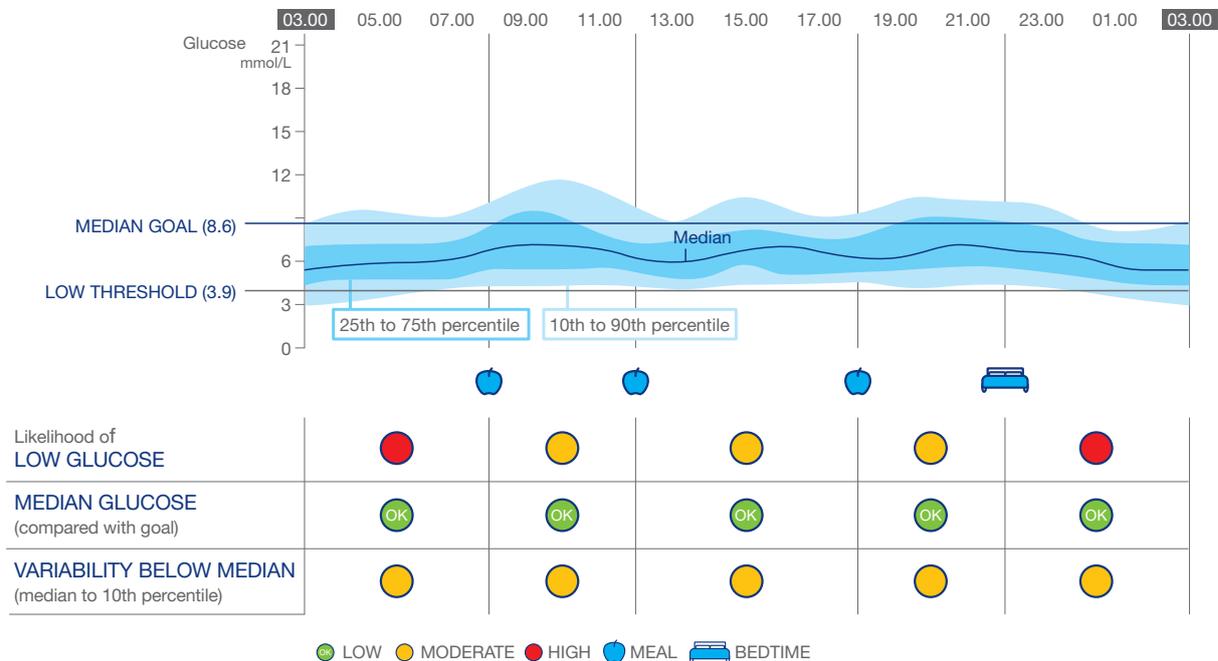


Figure 4
 Ambulatory glucose profile (AGP)
 produced from a Flash GM
 device download

3 Enable fine tuning of insulin to reduce hypoglycaemia and increases time in target range

Hypoglycaemia is a significant barrier to achieving tight glucose control. In its mild form it can be a nuisance, but moderately severe hypoglycaemia can significantly interfere with work and social activities and severe hypoglycaemia can lead to fits and loss of consciousness, injury and in rare cases to death. Not surprisingly people with diabetes are fearful of hypoglycaemia. The Impact study in Type 1 diabetes showed that users opted to scan their flash glucose sensor frequently, on average 15 times a day, which had a very significant 38% reduction in hypoglycaemia and increase in glucose time in target⁷. The same was the case in the 'Replace' study in patients with Type 2 diabetes where more frequent use of the sensor and frequent scanning was associated with a 43% reduction in hypoglycaemia⁸.

Using Flash GM also allows people with diabetes to closely monitor their glucose levels, especially after meals when glucose levels are likely to rise and fall before the next blood test is performed. It has been firmly established that tight glycaemic control in people with diabetes is associated with a significant reduction in serious long-term diabetes related complications. Achieving tight glycaemic control risks more frequent hypoglycaemic events². The ability to quickly check glucose levels on average hourly during the day seems key to limiting hypoglycaemia. Most people are reluctant to finger prick test this frequently⁷.

4 Improve HbA1c

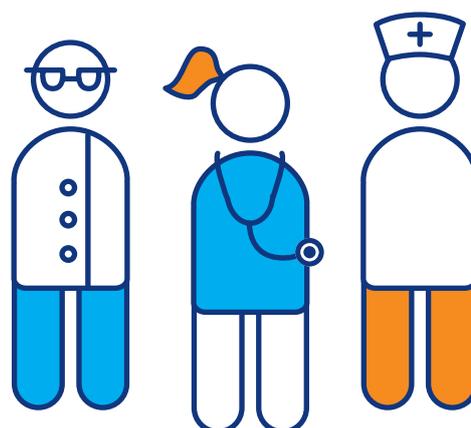
Use of Flash GM has been associated with an improvement in HbA1c in a study in children and young people with Type 1 diabetes and in an observational report of real clinic use¹.

The use of the flash glucose sensor, the FreeStyle Libre, by children and adolescents (aged 4–17 years) with Type 1 diabetes was found to be safe and effective. It was shown to be superior to conventional self-monitoring of blood glucose for time in target range, reduced HbA1c and improved treatment satisfaction^{6,10}.

The role of healthcare professionals

Healthcare professionals working with people with diabetes will need to understand how to use and interpret flash glucose data, so they can understand the AGP and use it as part of the care planning discussion with the patient.

We believe an integrated package of care should include ongoing education for people with diabetes on how best to interpret and use glucose test results in the day-to-day management of their diabetes. Many current Flash GM users are self-taught on how to interpret the data that the device presents. It is essential that people using Flash GM have education to make sure they can best use the information the device provides to improve management of their glucose levels. Healthcare professionals will also need training on how to interpret the information on glucose trends in relation to people's daily living and in insulin dose.



Key points for health service funders and providers

Flash GM technology benefits people as it allows them to monitor more frequently, better understand their glucose levels and helps them make day-to-day decisions about the management of their condition. This has been associated with an improved HbA1c, less glucose variability and reduced hypoglycaemia which is likely to reduce the risk of developing distressing and expensive diabetic complications. People report a better quality of life and a reduction in stress and anxiety when using Flash GM^{1,12,13}.

This better management of diabetes can help reduce the risk of admission to accident and emergency department to be treated for severe hypoglycaemic events or diabetic ketoacidosis.

People with diabetes have looked at the costs and benefits for themselves. Those who can afford it have chosen to fund themselves as they have found the benefits to outweigh the costs. Unless available to all patients who could potentially benefit, the less affluent may be deprived of an important means of helping them better engage in their diabetes care.

.....
“It does cost a lot so we made a fair deal that we will only fund the flash if she scans regularly and reacts to what the readings tell her. There’s no point having the technology if you’re not going to engage with it.”

Angela, mother to a 13-year-old girl with Type 1
.....

The need for regular review of use and outcomes

To make sure that NHS funding for Flash GM is cost effective, we propose that funding is conditional on the basis that the person has demonstrated active management of their glucose levels or progress towards achieving and maintaining their personalised treatment target. This should be assessed at least annually.

For some people there are practical issues which may affect their use of the device. Some people may develop skin reactions to the adhesive. In some, the sensors may not stick adequately and are easily dislodged which can be costly. Some individual sensors may provide inaccurate results which is why it is important to do occasional finger prick tests to confirm the result. Faulty sensors can be currently returned to the manufacturer for free replacement.

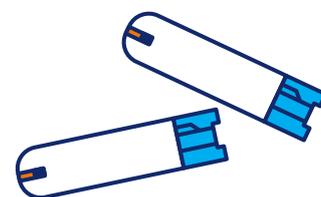
Audit

We recommend that in order to measure the effect of Flash GM on shorter and longer-term clinical outcomes, and cost benefits, its use should be audited.

Test strips

We know that people with diabetes can experience restrictions in number of test strips they are prescribed and budget constraints is often a reason given to people to explain the restriction¹⁴. Flash GM allows people to test as many times as needed, without the costs of using test strips and lancets. However there are specific circumstances that still require people to check their glucose levels by using a finger prick test.

People who use Flash GM should still have access to test strips on prescription, however the number of test strips that they will need would be reduced.



Structured education

Attendance at a structured education course supports improved self-management. The offer of Flash GM alongside education could potentially help commissioners and health care professionals to increase uptake of diabetes education courses.

Use as a management tool – ‘troubleshooting’

Flash GM can be used for short-term troubleshooting investigations into someone’s glucose levels where they’re having difficulty managing their condition. It should be noted that the reader can’t be wiped so a new one would be required for each new patient.

CGM and Flash GM

Flash GM should not be considered as an alternative to continuous glucose monitoring (CGM) for those who meet the guidance and criteria for the use of CGM in people with Type 1 diabetes, as set out clearly in NICE guidance^{3,4,5,15} and our position statement¹⁶. Flash GM is different from CGM devices in that it only provides data on demand and, as such, is unable to provide alerts – it has no alarm feature and so is not suitable for individuals who have a complete lack of hypo awareness.

Flash GM is not a less expensive alternative for CGM, rather the different technologies have different uses for specific groups in particular circumstances.

Further information

[National Institute for Health and Care and Excellence Med tech innovation briefing](#)⁹



Appendices

Appendix 1: Flash GM vs Continuous Glucose Monitoring (CGM)

Flash GM does not provide real-time continuous glucose monitoring. There are differences between the two systems that make one more appropriate than the other, depending on the needs of the person. The main differences are summarised in the table below.

Flash GM	Continuous Glucose Monitoring (CGM)
Uses a sensor to measure glucose in interstitial fluid	Uses a sensor to measure glucose in interstitial fluid
Sensor records every minute and stores interstitial glucose levels every 15 minutes and when the user scans the sensor.	Sensors records and stores interstitial glucose levels every five minutes.
Sensor must be scanned in order to get the latest reading along with a trace from the last eight hours readings to a reader.	Automatically transmits readings to the receiver every five minutes. Display shows the latest reading along with a trace from the last three hours (Dexcom).
To be able to detect when the glucose level is too low or too high the sensor must be scanned – there are no alerting alarms.	Alarms can be set to alert the user that their glucose levels are too low or too high.
Licensed for adults and children over the age of four years old.	Licensed for adults and children over the age of two years old.
Does not require finger prick calibration.	Requires twice daily calibration with a finger prick reading.

Appendix 2: Driving

Flash GM and CGM systems measure interstitial fluid glucose concentration and not blood. The DVLA currently stipulates that drivers must monitor their blood glucose levels, with test strips and a meter, within two hours of driving and every two hours whilst driving ¹¹.

Acknowledgments

We would like to thank the following people for their time, expertise and enthusiasm in the development of these guidelines:

Professor Gerry Rayman

Consultant Physician and Diabetologist (CHAIR)

Marian Blokpoel

Parent of child using Flash GM

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Simon O'Neill

Director Health Intelligence at Diabetes UK

Gavin Thomson

Policy and Campaigns Support Manager at Diabetes UK – Scotland

Nick Thrower

Diabetes Voice Diabetes UK

Dr Emma Wilmot

Consultant Diabetologist, Chair ABCD Insulin Pump Network UK

Thank you to all the children, parents, and adults living with diabetes who have contributed their experiences to these guidelines.

This document has endorsement from the following organisations:

Association of British Clinical Diabetologists (ABCD)

Diabetes Inpatient Specialist Nurses UK Group (DISN UK Group)

INPUT Patient Advocacy

Juvenile Diabetes Research Foundation (JDRF)

Primary Care Diabetes Society (PCDS)

Declarations of interest

Claire Neely organises trials to support people to use the FreeStyle Libre at the Kingston Hospital Foundation.

Professor Rayman was an investigator in the Replace study and has received speaker's fees from Abbott and Diabetes UK.

Dr Emma Wilmot has received personal fees from Abbott, Dexcom and Medtronic.

INPUT receives web advertising fees from Abbott and other diabetes medtech companies.

A number of members of the working group use the Flash GM, which they self-fund.

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