

Supporting diabetes management to help improve health and lives

Introducing Dexcom ONE+ Continuous Glucose Monitoring System



Sponsored spokesperson
of Dexcom.

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Foreword

Abbreviations

CGM	Continuous glucose monitoring
isCGM	Intermittent scanning continuous glucose monitoring
rtCGM	Real-time continuous glucose monitoring
T1D	Type 1 diabetes
T2D	Type 2 diabetes
SMBG	Self monitoring of blood glucose



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It is estimated there are 4.3 million people are living with diabetes in the UK, and an additional 850,000 people are as yet undiagnosed, equating to around 1 in 14 people in total.¹ Juvenile Diabetes Research Foundation (JDRF) data serve to highlight that approximately 400,000 people are now living with type 1 diabetes, including around 29,000 children.²

Diabetes is a serious condition which, if undiagnosed or poorly managed, can have far reaching effects on a person's physical and emotional wellbeing. There is a well-evidenced need to provide and support holistic diabetes care in order to achieve optimal outcomes for people living with diabetes and their families.^{3,4} Achieving appropriate glycaemic levels is an essential part of this holistic approach to care.

In terms of measuring glucose levels, we have thankfully seen the progression from the days of urinalysis to the timelier intermittent finger-prick blood glucose testing. In recent years, we have seen further advances in diabetes technology to include the development and use of wearable continuous glucose monitoring (CGM) devices for interstitial glucose measurement. CGM systems allow for a fuller picture of glucose levels, predictions of the direction of glucose levels, and alarms to alert the user to episodes of hypoglycaemia and/or hyperglycaemia. This can be done automatically by real-time CGM

(rtCGM) or through active scanning via intermittently scanned CGM (isCGM). Clinical trial data and real-world studies have consistently provided evidence to support the use of CGM, with significant benefits in terms of improved HbA1c and time in range, less hypoglycaemia/diabetic ketoacidosis, and improved quality of life.⁵⁻¹² In response to this evidence base, NICE guidance has been updated to recommend offering CGM to all people with type 1 diabetes (T1D)¹³ and to certain cohorts of people with type 2 diabetes (T2D).¹⁴ NHS England estimates that 80% of people with T1D are now using CGM, but access to this technology can still vary widely.¹⁵

Typically, diabetes technology has been perceived as the domain of specialist diabetes teams, but with the expansion in eligibility, there are now many people with diabetes who are completely managed within primary care and who should now be offered CGM. As a result, there is an increasing need for primary care professionals to have an awareness of eligibility, and how to initiate and provide ongoing support for CGM

use. The appropriate use of CGM can help reduce care inequities and variation by enabling access to care to those unable to travel, unable to self-manage their diabetes, those with learning disabilities, or possibly those relying on third-party care.

We can look forward to potentially better diabetes related outcomes, but it is important to remember that technology is the enabler and not the panacea for improved diabetes care. It is imperative that the foundations of technology use remain in the education of the person with diabetes and the healthcare professional. This booklet has been developed to describe the functionality and use of the rtCGM device Dexcom ONE in meeting the needs of healthcare professional education and to signpost to resources to support the person with diabetes.

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Introduction

General glucose monitoring plays a role in the diagnosis of diabetes and is an essential part of diabetes management. Avoidance of hypoglycaemia in type 1 diabetes (T1D) and type 2 diabetes (T2D) with insulin requires the consideration of contextual factors such as eating and exercise.¹ Additionally, for those with T2D, long, unnoticed prolonged hyperglycaemic episodes are critical risk factors for long term complications requiring medical intervention or even intensive care.²

Historically, people living with diabetes have had to rely on self-monitoring

via finger pricks, with some success for improving HbA1c levels.¹ For T2D however, self-monitoring blood glucose (SMBG) only leads to slightly better glycaemic control in the short term, with no significant long-term improvements.³ Self-monitoring for both T1D and T2D can be perceived as a burden and has been associated with impaired mental health, diabetes-related distress, and a lack of engagement.^{1,4}

The burden of self-monitoring can be overcome with the use of continuous glucose monitoring (CGM). 2022 NICE guidance recommends offering CGM



Burden of self monitoring blood glucose with finger pricks

Impaired mental health

Diabetes-related distress

Lack of engagement



systems to adults and children with T1, and to certain groups of adults with T2 on multiple daily insulin injections.⁵⁻⁷ The guidance includes recommendations for both real-time CGM (rtCGM) and intermittently scanned CGM (isCGM). However, research suggests that HbA1c is improved, the time spent in range (3.9 - 10.0 mmol/L) is higher, time below range and hypoglycaemia distress is lower for people using rtCGM.⁸⁻¹¹

The Dexcom ONE+ real-time Continuous Glucose Monitoring system

is a smart and easy-to-use diabetes management tool,[†] continuously measuring glucose levels within the interstitial fluid, and displaying sensor readings on a smartphone[†] or receiver without finger pricks[‡] or scanning.^{12,13*} Dexcom CGM not only demonstrates improved clinical outcomes, such as lower HbA1c, but has also been seen to improve overall wellbeing, treatment satisfaction and hypoglycaemic confidence, along with a reduced fear of hypoglycaemia and diabetes distress.¹⁴⁻¹⁹

*Results obtained with Dexcom G7 study, which shares similar features and usability

† For a list of compatible devices, visit www.dexcom.com/compatibility

‡ If your glucose alerts and readings from the Dexcom ONE+ do not match symptoms or expectations, use a blood glucose meter to make diabetes treatment decisions

Importance of tackling diabetes

In the UK, it is now estimated that for the first time, 4.3 million people are living with diabetes, and an additional 850,000 people are as yet undiagnosed, equating to around 1 in 14 people in total.²⁰ The NHS spends at least £10 billion a year on diabetes, accounting for 10% of its entire budget. Approximately 80% of this total is spent on complications associated with diabetes.²¹

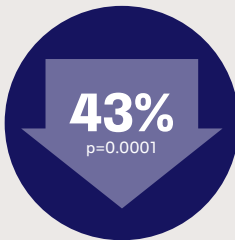
There is an exponential relationship between higher HbA1c and diabetes complications, meaning finding treatment options for reducing HbA1c is of great concern.¹⁸ rtCGM has been shown to reduce HbA1c levels especially in people living with diabetes with higher HbA1c levels at study start, those at the higher risk of diabetes complications.²²

The burden of living with diabetes

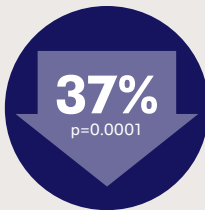
Diabetes therapy and prognosis are highly dependent on self-management. Self-management of diabetes includes keeping track of administering insulin, maintaining healthy lifestyle habits such as diet and exercise, and instigating proper foot care.¹ Despite self-monitoring of blood glucose showing improvements in HbA1c, this constant self-management can be seen as a burden and can negatively affect mental health.¹

In fact, high levels of negative affect and greater variability in negative affect have been associated with higher glucose levels, higher rates of hyperglycaemia, and greater time out of glucose level range, while higher variability in positive affect was related to higher

Lower risk for each 1 percentage point HbA1c reduction:^{2,24}



Amputation
or PVD Death



Microvascular
Complications



Diabetes-
Related Death



Myocardial
infarction

Intensive glucose control from the time of diagnosis is essential to maximize reduction of risk for the long-term complications^{25,26}

rates of hypoglycaemia.²³ Similarly, in adolescents, positive affect was associated with in-range glucose levels, reduced odds of very low glucose, and reduced daily blood glucose variability.²⁷

Maintaining optimal quality of life and preventing acute and long-term complications of diabetes requires not only monitoring of glucose but also contextual factors such as mental health, self-care, and sleep.¹

rtCGM systems are a convenient and accurate way to receive a complete picture of the glucose level with a simple glance at a screen mitigating diabetes worry and distress. Within just 3 months of using Dexcom CGM, improvements in psychosocial outcomes and improved HbA1c were reported for people with T1D and T2D. These improvements included less diabetes distress and hypoglycaemia fear, as well as greater treatment satisfaction.^{15,19,28}

These early improvements in glycaemic control in the first few months of CGM use²⁹ can have beneficial long-term effects by reducing complications related to diabetes.^{24,25}

CGM allows a person living with diabetes to visualise the impact of medication, food and exercise on glucose levels, allowing for behavioural innovations and better adherence to treatment.³⁰

Engagement

Patient engagement with self-monitoring is essential for successful management of diabetes. Unfortunately, engagement can be quite low, with one study reporting a rate of only 57.6% using SMBG.⁴

Factors associated with reducing engagement with self-monitoring included a longer course of diabetes and



the use of oral anti-diabetic agents.⁴ Poor engagement in people with a long course of diabetes may be explained by a negative perception of diabetes as this is seen to affect self-management.^{4,31} For children and their parents, reasons for not regularly monitoring glucose included the cost of strips and glucometers, the fear of pain and injection, psychological frustration, lack of availability of information to deal with high readings, no motivation, and challenges in finding appropriate and safe places to perform self-monitoring of blood glucose.³²

A general desire to avoid thinking about glucose values and diabetes is a considerable obstacle to self-monitoring; people living with diabetes who are highly avoidant have lower self-monitoring frequency.³³ Furthermore, the degree of avoidance of diabetes and the view that self-monitoring is pointless both significantly impacted how often self-monitoring of glucose data was shared to clinicians.³³

It was found that HbA1c was reduced by 0.46% in those using a Dexcom CGM sensor more than 70% of the time, while there was no significant change if used less than 70%.¹⁵ Dexcom CGM systems have high patient engagement rates of around 70 - 90%, underlining the added convenience of Dexcom CGM systems.^{14-16,34}

Guidance on use of CGM



Display devices sold separately. For a list of compatible smart devices, please visit www.dexcom.com/compatibility

Previous NICE guidance only recommended CGM technology for adults with T1D under certain circumstances. More recently, the NICE committee have agreed that there is enough evidence in key outcomes, such as HbA1c, time in range, and severe or nocturnal hypoglycaemia, to demonstrate that CGM provides clinical benefits over standard self-monitoring of blood glucose in T1D and T2D.^{5,7} Updated NICE guidance, published in March 2022, now **recommends** the use of rtCGM and isCGM for adults and children living with T1D, and to **consider** rtCGM next to isCGM for T2D in intensive insulin therapy for the first time.⁵⁻⁷

The guidance emphasises the need to use shared decision making when choosing a CGM device according to the individuals needs and preferences⁵⁻⁷

Factors to consider include accuracy of the device, the need for predictive alerts or alarms, access to appropriate software, the need for calibration, fear of hypoglycaemia, and body image concerns.⁵⁻⁷

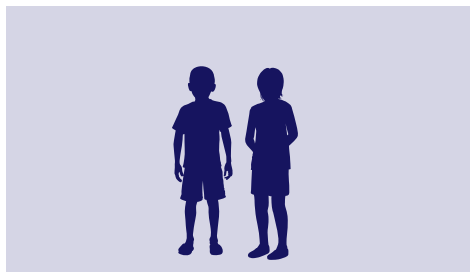
Nevertheless, research has shown that people living with diabetes have improved HbA1c, spend a greater time in range, and have lower hypoglycaemia distress when using rtCGM compared to isCGM.⁸⁻¹¹

All people with diabetes should be advised that they will still need to take capillary blood glucose measurements if their symptoms do not match their CGM measurements, although this may be less often than with self-monitoring.^{5,7} All key information on CGM must be included in the structured education programme provided by clinicians and people should be empowered to use CGM devices.⁵⁻⁷



NICE recommendations for adults with diabetes

- Recommendation to offer adults with T1D a choice of rtCGM or isCGM based on their preferences and needs⁵
- Offer rtCGM as an alternative to isCGM for adults with insulin treated T2D if it is available for the same or lower cost⁷
- Only offer CGM to T2D if any of the following apply:⁷
 - They have recurrent hypoglycaemia or severe hypoglycaemia
 - They have impaired hypoglycaemia awareness
 - They have a condition or disability (including a learning disability or cognitive impairment) that means they cannot self-monitor their blood glucose by capillary blood glucose monitoring but could use an isCGM device (or have it scanned for them)
 - They would otherwise be advised to self-measure at least 8 times a day



NICE recommendations for children with diabetes

- Offer rtCGM to all children and young people with T1D, before isCGM, alongside education to support them, their families and their carers to use it⁶
- Only offer isCGM to children (>4 years) who are unable to use rtCGM or show a clear preference for isCGM⁶

Meet Chris, who has type 1 diabetes



Not a real patient, for illustrative purposes only

Profile

Chris is an insurance broker and an assistant coach for his local football club. Intermittently scanning his blood glucose monitor takes up time in his day where he could be working, which is frustrating for Chris. He would like to play football on the weekends but is often tired and worries about having a hypoglycaemic episode if he doesn't scan frequently enough. He tries his best to manage his diabetes with intermittent scanning and insulin but the burden of this interferes with his work and social life, and as a result Chris struggles with his mental health.

Age 34 years old

Height 5' 10"

BMI 22

Current diabetes management isCGM, insulin aspart injection at mealtimes, insulin glargine at night

Medical history Estimated 175 days spent recovering from hypoglycaemic episodes*

Other health conditions Difficulty sleeping

*Based on figures from Juvenile Diabetes Research Foundation, 2022

Meet Carol, who has type 2 diabetes and takes insulin



Not a real patient, for illustrative purposes only

Profile

Carol is a receptionist who enjoys gardening and spending time with her young grandchildren. She finds it difficult to be regularly active and has struggled to maintain a healthy weight over the years. Carol manages her diabetes with diet and exercise, insulin, and finger prick tests, but this leaves her fingers sore and makes it harder to type on a keyboard. Managing her diabetes is distressing and she does not test her blood sugar as often as she should leading to uninformed insulin dosing. Carol is worried about the future and her health long term.

Age 58 years old

Height 5' 4"

BMI 29

Current diabetes management Diet and exercise, finger-prick tests, insulin glargine injection once a day

Medical history Difficulty managing weight

Benefits of Dexcom CGM

Dexcom has been producing rtCGM systems since 2004, and all Dexcom systems use rtCGM technology.

Better quality of life by providing peace of mind

For those using blood glucose monitoring or isCGM, rtCGM provides an alternative for accurate, automated glucose monitoring without the need for fingerpricks* and scanning, for people with diabetes using insulin.

Transitioning to a Dexcom CGM

system been shown to significantly improve subjective well-being and treatment satisfaction, in comparison with conventional therapy.¹⁵ For people living with T1D for over 10 years, rtCGM use reportedly contributed to hypoglycaemic confidence, improved overall wellbeing, and reduced diabetes distress.^{15,19}

People with diabetes using Dexcom CGM had a lower fear of hypoglycaemia than those using fingerpricks¹⁵

Trusted accuracy, reliability, and clinical relevance

Dexcom CGM systems demonstrate consistent sensor accuracy, even in instances where glucose levels are rapidly rising or falling, which should give users high device confidence and facilitate persistent use.^{1,12,13,35} Greater user satisfaction with accuracy is linked to better adherence, more confident and intensive insulin adjustments, improvements in quality of life, reduced reliance on self-monitoring of blood glucose, and may reduce alarm fatigue.³⁶

Simple monitoring of glucose levels

Using a Dexcom CGM system can improve glycaemic control, which is particularly important for younger people with diabetes.³⁷ For young children aged 2 to <8 years old with T1D, percentage time in hypoglycaemia was significantly reduced when using

a Dexcom CGM compared to blood glucose monitoring (by 2.8%).³⁸ Time spent in range (3.9 - 10.0 mmol/L) for 14 to 24 year-olds with T1D using a Dexcom CGM system was greater than for standard blood glucose monitoring (43% vs 35%).³⁹ For adults already using isCGM, time spent in range was higher when using a Dexcom CGM system (59.6% vs 51.9%),⁸ and for older adults (60+ years), time spent in range was 8.8% higher using an rtCGM system than standard blood glucose monitoring.⁴⁰

Dexcom CGM systems remove the need for intermittent scanning or finger pricks* and can help users manage their diabetes by automatically monitoring when their glucose levels are in range, below or above, delivering the full picture of their glucose readings. When using Dexcom Clarity,[†] an 8.4% increased time in range has been shown when users engaged with all the Clarity

Benefits of Dexcom rtCGM



These statements are supported by the articles referenced in this handbook. Statements are comparisons to SMBG.

features, such as web-based reports and automated notifications.⁴¹

Dexcom Clarity helps prepare users for conversations with clinicians by giving access to key metrics and reports, which they can share with their healthcare team. The in-app Clarity Card has been designed to help users stay motivated as they see how small changes can transform into long-term

wins. Dexcom Clarity (Professional) also helps healthcare professionals by consolidating their patient's diabetes data in one place, delivering automated reports at a glance, and allows consultations to take place virtually as well as in person. This flexibility allows for more efficient time management when healthcare professionals have limited appointment time per person.

*If your glucose alerts and readings from the Dexcom ONE+ do not match symptoms or expectations, use a blood glucose meter to make diabetes treatment decisions

† Results obtained with Dexcom G7 study, which shares similar features and usability

‡ An internet connection is required while uploading to Dexcom Clarity. For full detailed instructions always refer to the Dexcom Clarity user guide

CGM can boost the benefits of exercise

Physical activity can help improve glycaemic control, reduce glycaemic variability, and reduce insulin resistance.⁴² One of the strongest barriers preventing people with T1D from incorporating physical activity into their daily lives is fear of hypoglycaemia.⁴² Even mild-to-moderate exercise can increase insulin sensitivity for the following 11 to 16 hours and lead to late-onset or nocturnal hypoglycaemia.⁴²

A rtCGM system provides real-time observation of glucose levels allowing users to quickly detect glycaemic changes that occur during physical activity and its recovery phase.⁴²

The use of rtCGM and its progress curves offer the possibility to avoid

hypoglycaemia or to react to it at an early stage, especially for people with T1D who are regularly physically active.⁴² The use of CGM systems can help predict further glycaemic courses and consider the influences of sport on glucose levels.⁴² The simplicity of CGM can help motivate people with diabetes to undertake more physical exercise, which in turn further improves glycaemic control and variability.⁴² One randomised clinical trial with inadequately controlled T2D participants showed using rtCGM for three days per month for 12 weeks resulted in increased physical activity and an additional 1% reduction in HbA1c.⁴³



Introduction to Dexcom ONE+



The Dexcom ONE+ Continuous Glucose Monitoring system is a smart, effective and easy-to-use diabetes management tool for people with diabetes ages two years and older.^{*,14,16,44,45} Dexcom ONE+ uses a small wearable sensor to measure and send real-time glucose values wirelessly to a compatible smart phone[†] or receiver, eliminating the need for painful finger pricks[‡] or active scanning. The app or receiver displays trend arrows to show the speed and direction glucose levels are heading and the customisable alerts indicate whenever glucose levels fall outside of pre-set high and low levels, making treatment decisions easier. There is an option to delay the first high alert. This has been designed to make the high alert even more actionable and relevant for the person living with diabetes. The delay first alert enables users to delay their first high alert for a specific amount of time and only activates if the reading is still at or above the designated alert setting. That specific amount of time can be set from 15 minutes up to 4 hours. If the glucose level goes up and comes back down within this amount of time, the high

alert will not trigger, and this may help to prevent alarm fatigue.

Dexcom ONE+ makes diabetes management easier, empowers users to take control of their diabetes and allows better understanding of how food and exercise affect glucose levels:[§]

- With Event Entry, users can log in their food intake, exercise sessions and insulin injections, helping them better understand their glucose patterns⁴⁶
- Real-time readings with just a glance at the Dexcom ONE+ smartphone app[†] or receiver
- Diabetes management with zero fingerpricks,[‡] scanning or calibrations
- Glucose readings the user can trust^{*,12,13}
- Customisable low and high alerts
- Flexible options for sensor location, convenient, and discreet
- Accurate and easy to use^{*,12,13,46}
- 30 minute warm-up time
- Share and follow with up to 10 followers
- Waterproof [¶]1,46

* Results obtained with Dexcom G7 study, which shares similar features and usability

† For a list of compatible devices, visit www.dexcom.com/compatibility

‡ If your glucose alerts and readings from the Dexcom ONE+ do not match symptoms or expectations, use a blood glucose meter to make diabetes treatment decisions

§ Compared with SMBG

¶ Dexcom ONE+ is waterproof to a depth of 2.4M for up to 24 hours

Using Dexcom ONE+

How is it applied?

The sensor is placed on the abdomen or back of the arm, avoiding bones, irritated skin, tattoos, and areas that get bumped easily. For children aged 2-6, the sensor can additionally be placed on the upper buttock.

To apply the Dexcom ONE+ sensor, the user should wash their hands and clean the sensor site with an alcohol wipe before following the steps below.



- 1** Unscrew the cap of the Dexcom ONE+ applicator, taking care not to touch the inside of the applicator



- 2** Press and hold applicator firmly against skin (1) and then push button (2)
Once applied, remove applicator.



- 3** Rub gently around the patch 3 times and gently press on top of sensor for 10 seconds



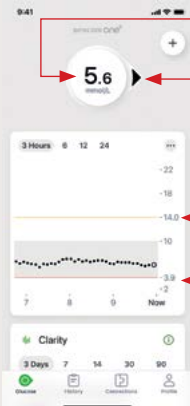
- 4** **OPTIONAL**
Apply overpatch, using tab to peel off coloured liner. Rub around overpatch to secure

How is it used?

Once communication is confirmed with the transmitter, a 30-minute sensor warmup will start, after which the first reading will appear on the read-out device (receiver or app). The sensor measures glucose readings from the interstitial fluid every 5 minutes, which are transmitted to the Dexcom ONE+ read-out device. The app will also store summary reports of glucose information over the last 3, 7, 14, 30 and 90 days, and can be used to identify trends in glucose patterns. The Dexcom ONE+ receiver will store and allow review of up to 30 days data.

What's on prescription?

Sensors for the Dexcom ONE+ system last for 10 days and can be ordered by prescription on the National Health Service (NHS) if the user is eligible as per local criteria; pharmacies can order through pharmaceutical wholesalers. Users will need to order three sensors per month. Once used, the applicator must be disposed of appropriately in the sharps bin which can be ordered by the user through their pharmacy.



Sensor Reading
The number is your reading, updated automatically every 5 minutes.

Trend Arrow
Shows where your glucose is heading and at what pace.

Trend Graph
Shows the history of your readings (last 3, 6 or 24 hours).

High and Low Alert Levels
Optional and customisable high and low glucose alerts.



Scan the QR code to watch videos on how to set up the app and apply the sensor



What's next for Chris and Carol?



Chris' fear of hypoglycaemia during and after exercise and Carol's lack of self-monitoring has caused enough stress to motivate them to talk to their GPs. They each expressed that their anxiety about controlling their diabetes has become overwhelming and asked what their options are.

Carol's GP suggested Dexcom ONE+ technology to avoid routine fingerpricks* and to provide continuous information on her glucose levels, providing insight to help her with dietary management.

Since Chris is already using isCGM, his GP recommends Dexcom ONE+ to ensure real-time tracking of glucose levels with customisable alarms during exercise to reduce the burden of intermittently scanning and worry about hypoglycaemia.

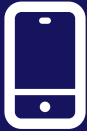
What would you choose for Chris and Carol?

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NICE guidance now recommends the use of real-time continuous glucose monitoring (rtCGM) for adults and children living with T1D and to be considered for T2D on intensive insulin treatment⁵⁻⁷



The Dexcom ONE+ real-time Continuous Glucose Monitoring System makes diabetes management easier,^{*} measuring glucose levels automatically in real time and displaying them on your patient's smartphone[†] or receiver



Compared to self-monitoring and intermittent scanning CGM (isCGM), Dexcom CGM use has been shown to be associated with improved glycaemic control, increased time spent in optimal glucose range, and improved HbA1c levels^{14,16,17}



rtCGM use reportedly contributed to hypoglycaemic confidence, improved overall wellbeing, reduced diabetes distress, and high rates of treatment satisfaction^{15,17-19}



Use of rtCGM and its progress curves offer the possibility to avoid hypoglycaemia or to react to it at an early stage for physically active people⁴²

^{*}Compared to SMBG.

[†]For a list of compatible devices, visit www.dexcom.com/compatibility.