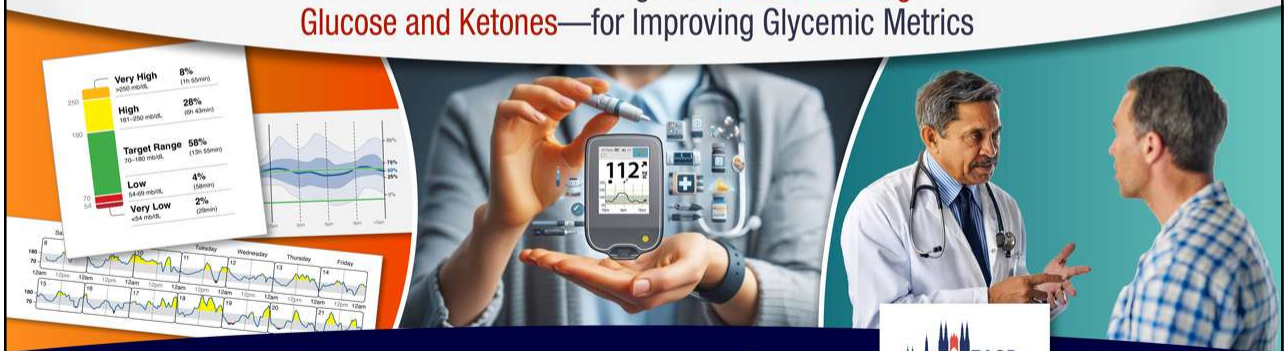
Pushing the Limits of What Sensing Can Do for T1D and T2D

Focus on Pivotal Advantages in Dual Monitoring—Glucose and Ketones—for Improving Glycemic Metrics



PROGRAM CHAIR
Stefano Del Prato, MD | University of Pisa

EASD 2026 MILAN

1

This CME-certified symposium is jointly provided by the UMASS Chan Medical School and CMEducation Resources.

Commercial Support: Supported by an educational grant from Abbott Diabetes Care

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Pushing the Limits of What Sensing Can Do for T1D and T2D

Welcome and Introduction

Stefano Del Prato, MD – Program Chair
President - Fondazione Menarini | Professor Emeritus of Endocrinology | University of Pisa | Pisa, Italy

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Pre-Program Assessment Question #1

Based on my current practice pattern, I would **initiate CGM monitoring** in the following persons with T2D who are on basal insulin and SGLT2 inhibitors and/or incretin therapy:

1) All persons with T2D who are on basal insulin and SGLT2i and/or incretin therapy
2) An overwhelming majority of such persons
3) About 50% of such persons
4) Less than 50% of such persons

4

Pre-Program Assessment Question #2

Based on my current understanding of dual sensing technology that continuously monitors glucose and ketone levels, I believe **this recently approved innovation should become an integral part of managing persons with diabetes.**

1) Very strongly agree
2) Strongly agree
3) Agree
4) Somewhat agree
5) Disagree

5

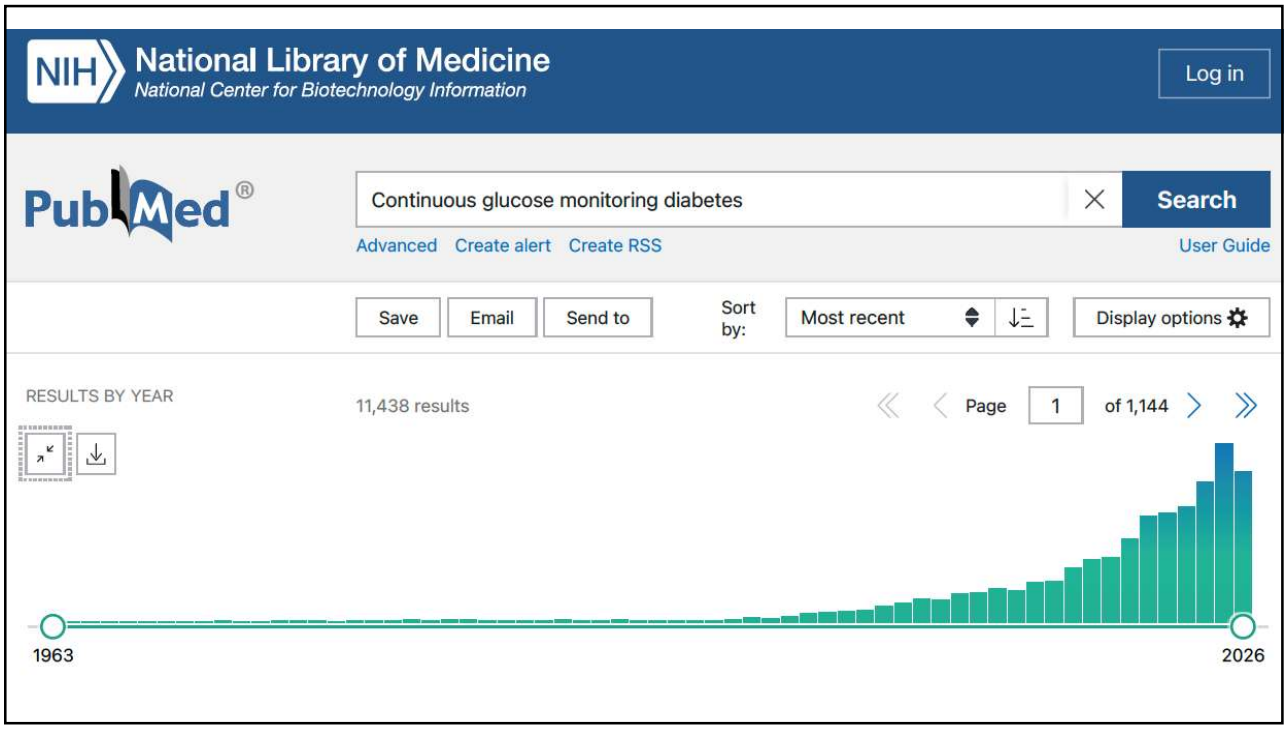
Presenter Disclosures

Advisory board -	Abbott, Amgen, Dexcom, Eli Lilly & Co., Hoffman La Roche, Innovent, Menarini, Nephris, Novo Nordisk, Structure Therapeutics, Sun Pharma
Speaking Engagements -	Abbott, Boehringer Ingelheim, Dexcom, Eli Lilly & Co., Menarini, Novo Nordisk, Sun Pharma

I may present recommendations regarding the use of drugs or devices from companies with which I have a financial relationship and I have submitted my presentation for peer-review.

- Additionally, my presentation will adhere to the following criteria:
- My recommendations will be based on data and findings from peer-reviewed sources OR in the absence of adequate peer-reviewed material, my recommendations will rely on the best available evidence-based medicine.
- Content will be fair and balanced, and if any product, specific drugs, or devices are discussed, alternate drugs or devices will also be discussed when appropriate.

6



7

7. Diabetes Technology: Standards of Care in Diabetes—2026

*American Diabetes Association Professional Practice Committee for Diabetes**

Diabetes Care 2026;49(Suppl. 1):S150–S165 | https://doi.org/10.2337/dc26-S007

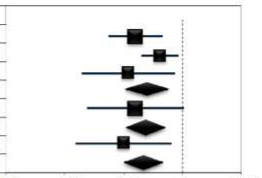
7.15 Use of CGM is recommended at diabetes onset and anytime thereafter for children, adolescents, and adults with diabetes who are on insulin therapy, **A** on noninsulin therapies that can cause hypoglycemia, **C** and on any diabetes treatment where CGM helps in management. **C** The specific CGM device and method for use should be made based on the individual's circumstances, preferences, and needs. **E**

8

The Effect of CGM vs SMBG in T2DM Insulin-Treated Patients

HbA1c

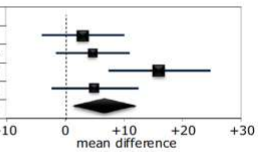
type of treatment	study	N: CGM/SMBG	mean diff.	95% CI
basal-bolus	Beck 2017	79/79	-0.40	-0.63; -0.17
basal-bolus	Yaron 2019	53/48	-0.19	-0.35; -0.03
basal-bolus	Kim 2024	52/47	-0.46	-0.86; -0.06
all basal-bolus		184/174	-0.30	-0.48; -0.13
basal	Martens 2021	105/51	-0.40	-0.81; +0.01
basal or basal-bolus		289/225	-0.31	-0.47; -0.16
mixed b or bb	Aljan 2019	49/52	-0.50	-0.91; -0.09
all insulin		338/277	-0.33	-0.48; -0.19



Heterogeneity: I^2 = 2.8%; Tau^2 = 0.0074; X^2 = 4.16 (p=0.3852)
Random Effects Model Z=-4.42 (p<0.0001)

Time in range

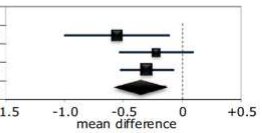
type of treatment	study	N: CGM/SMBG	mean diff.	95% CI
basal-bolus	Beck 2017	74/72	3.00	-3.98; 9.98
basal-bolus	Kim 2024	52/47	4.70	-1.57; 10.97
basal	Martens 2021	93/53	16.0	7.35; 24.65
mixed b or bb	Aljan 2019	49/52	5.00	-2.41; 12.41
all insulin		268/224	6.67	1.53; 11.81



Heterogeneity: I^2 = 50.5%; Tau^2 = 13.7373; X^2 = 6.06 (p=0.1088)
Random Effects Model Z=2.54 (p=0.0110)

Time below range

type of treatment	study	N: CGM/SMBG	mean diff.	95% CI
basal-bolus	Beck 2017	74/72	-0.56	-1.01; -0.11
basal-bolus	Kim 2024	52/47	-0.22	-0.54; 0.10
basal	Martens 2021	93/53	-0.30	-0.53; -0.07
all insulin		219/172	-0.31	-0.49; -0.14



Heterogeneity: I^2 = 0.0%; Tau^2 = 0.0; X^2 = 1.49 (p=0.4750)
Random Effects Model Z=-3.57 (p=0.0004)

Giaccari A et al ***Acta Diabetologica*** 2026;63:1385–1394

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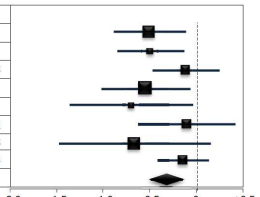
The Effect of CGM vs SMBG in T2DM Patients Not Treated With Insulin

HbA1c in non-insulin-treated pts

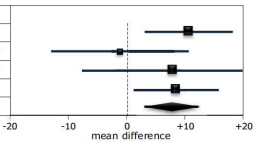
study	N: CGM/SMBG	mean diff.	95% CI
Aronson 2023	58/58	-0.50	-0.89; -0.11
Bergenstal incr. 2022	14/15	-0.49	-0.85; -0.13
Bergenstal SU 2022	17/17	-0.11	-0.47; +0.25
Cox 2020	138/40	-0.54	-1.02; -0.06
Moon 2023	15/15	-0.70	-1.36; -0.04
Price 2021	44/23	-0.10	-0.62; +0.42
Sseemondo 2022	19/20	-0.66	-1.47; +0.15
Wada 2022	49/51	-0.14	-0.41; +0.13
all non-insulin	354/239	-0.32	-0.49; -0.15



Heterogeneity: I^2 = 6,5%; Tau^2 = 0.111; X^2 = 7.49 (p=0.3799)
Random Effects Model Z=-3.71 (p=0.0002)

Time in range

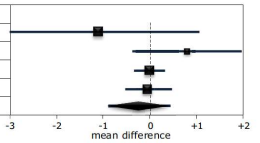
study	N: CGM/SMBG	mean diff.	95% CI
Aronson 2023	51/48	10.7	2.72; 18.68
Moon 2023	15/15	-1.10	-12.9; 10.67
Price 2021	42/19	8.00	-7,66; 23.66
Wada 2022	41/35	8.53	1.30; 15.75
all non-insulin	149/117	7.72	3.06; 12.37



Heterogeneity: I^2 = 0.0%; Tau^2 < 0,0001; X^2 = 2.74 (p=0.4342)
Random Effects Model Z=-3.25 (p=0.0012)

Time below range

study	N: CGM/SMBG	stand. mean	95% CI
Aronson 2023	51/48	-1.10	-3.17; 0.97
Moon 2023	15/15	-0.80	-0.37; 1.97
Price 2021	42/19	0.00	-0.33; 0.33
Wada 2022	41/35	-0.03	-0.53; 0.47
all non-insulin	149/117	-0.23	-0.89; 0.43



Heterogeneity: I^2 = 60.9%; Tau^2 =0.3508; X^2 = 10.22 (p=0.0369)
Random Effects Model Z=-0.67 (p=0.5015)

Giaccari A et al ***Acta Diabetologica*** 2026;63:1385–1394

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Evidence-Based Recommendations for the Use of CGM in TeDM
The Italian Guidelines

Conclusion

In conclusion, our findings support a shift in clinical practice toward the more widespread use of CGM in T2D, with regulatory frameworks and reimbursement policies needing to adapt accordingly. While further long-term studies are warranted on health outcomes and on T2D complications, current evidence strongly supports integrating CGM into the standard of care for T2D.

Giaccari A et al ***Acta Diabetologica*** 2026;63:1385–1394

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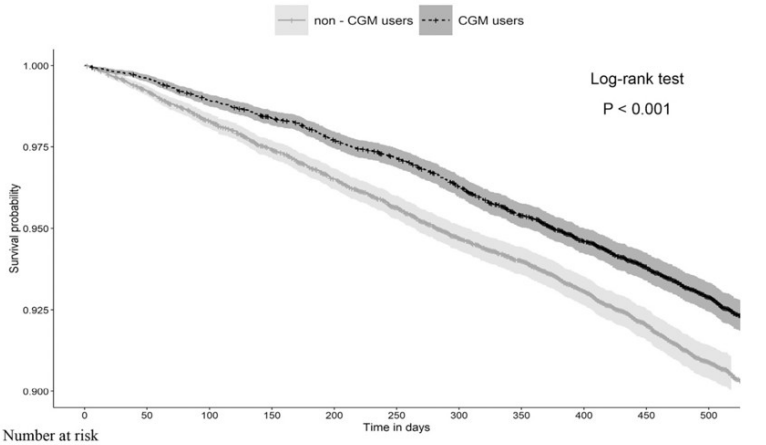
Initiation of Continuous Glucose Monitoring and Mortality in Type 2 Diabetes



Number at risk

Non – CGM users	12729	12611	12464	12317	12146	11954	11730	11472	11146	10692	9498
CGM users	12729	12679	12584	12505	12407	12322	12190	12023	11820	11471	10446

Reaven PD et al **Diabetes Technol Ther**. 2025;27:778-789

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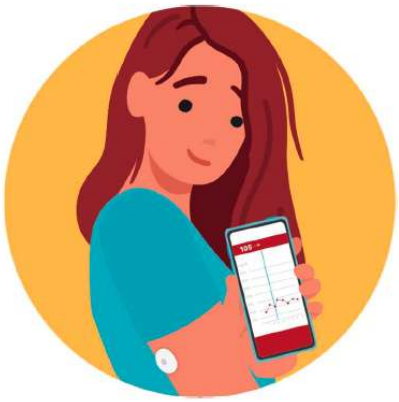
Joint ADA/EASD Consensus Report Management of Type 2 Diabetes

Place of Technology

Consensus Recommendations

- Evidence-based diabetes **technologies**, with proven benefits in people with type 2 diabetes should be considered as adjunctive tools within a comprehensive, integrated diabetes management plan and individualised based on clinical need, preference, and skill level.
- **CGM** should be considered in people living with type 2 diabetes, especially those on insulin.



Preseted at ADA 2026

American Diabetes Association. EASD European Association for the Study of Diabetes

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Initiation of Insulin Therapy Is Often Delayed

Despite uncontrolled blood sugar, **initiation of insulin therapy is often delayed**, leading to increased risk of diabetes-related complications[1-2]

3295 patients with T2D who were insulin naive[3]

~30% declined insulin treatment[3]

Only 38% of decliners eventually started insulin[3]

[1]Peyrot. ***Diabetes Care*** 2005;28:2673; [2]Hauber. ***Diabetes Care*** 2005;28:2243. [3]Hosomura. ***Diabet Med*** 2017;34:1599.

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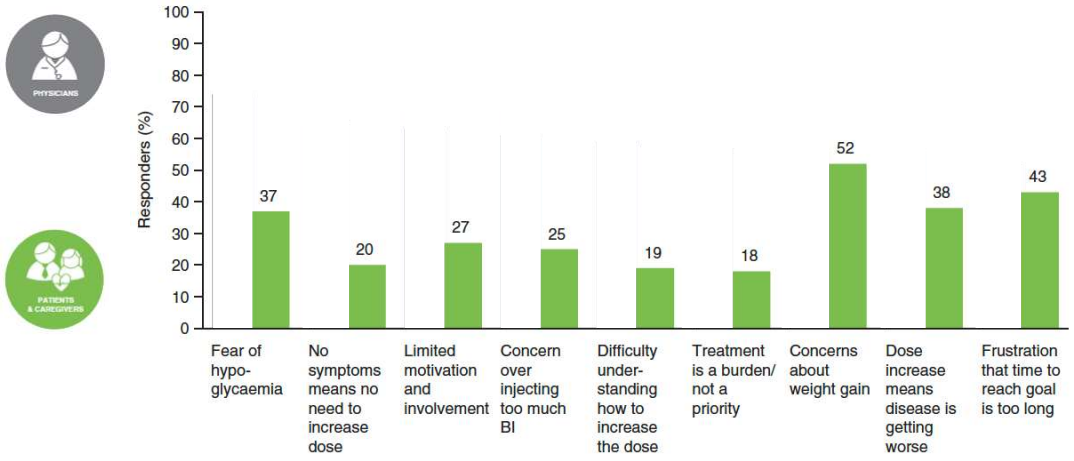
Barriers to Self-Titration Identified by HCPs and Patients



Berard L et al. ***Diabetes Obes Metab.*** 2018;20:301–308

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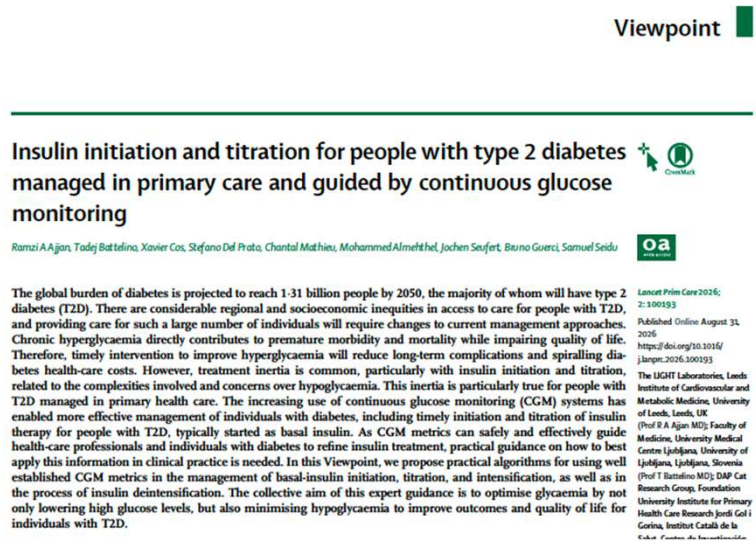
Insulin Initiation and Titration in People with T2D Guided by Continuous Glucose Monitoring: A Clinical Expert Position



Viewpoint

Insulin initiation and titration for people with type 2 diabetes managed in primary care and guided by continuous glucose monitoring

Ramzi A Ajjan, Tadej Battelino, Xavier Cos, Stefano Del Prato, Chantal Mathieu, Mohammed Almehthel, Jochen Seufert, Bruno Guerci, Samuel Seidu

The global burden of diabetes is projected to reach 1·31 billion people by 2050, the majority of whom will have type 2 diabetes (T2D). There are considerable regional and socioeconomic inequities in access to care for people with T2D, and providing care for such a large number of individuals will require changes to current management approaches. Chronic hyperglycaemia directly contributes to premature morbidity and mortality while impairing quality of life. Therefore, timely intervention to improve hyperglycaemia will reduce long-term complications and spiralling diabetes health-care costs. However, treatment inertia is common, particularly with insulin initiation and titration, related to the complexities involved and concerns over hypoglycaemia. This inertia is particularly true for people with T2D managed in primary health care. The increasing use of continuous glucose monitoring (CGM) systems has enabled more effective management of individuals with diabetes, including timely initiation and titration of insulin therapy for people with T2D, typically started as basal insulin. As CGM metrics can safely and effectively guide health-care professionals and individuals with diabetes to refine insulin treatment, practical guidance on how to best apply this information in clinical practice is needed. In this Viewpoint, we propose practical algorithms for using well established CGM metrics in the management of basal-insulin initiation, titration, and intensification, as well as in the process of insulin deintensification. The collective aim of this expert guidance is to optimise glycaemia by not only lowering high glucose levels, but also minimising hypoglycaemia to improve outcomes and quality of life for individuals with T2D.

Lancet Prim Care 2026; 2: 100193
Published Online August 31, 2026
https://doi.org/10.1016/j.lanprc.2026.100193

The LIGHT Laboratories, Leeds Institute of Cardiovascular and Metabolic Medicine, University of Leeds, Leeds, UK (Prof R A Ajjan MD); Faculty of Medicine, University Medical Centre Ljubljana, University of Ljubljana, Ljubljana, Slovenia (Prof T Battelino MD); DAP Cat Research Group, Foundation University Institute for Primary Health Care Research Jordi Gol i Gorina, Institut Català de la

Ajjan RA et al ***Lancet Prim Care***, 2026;2:100193

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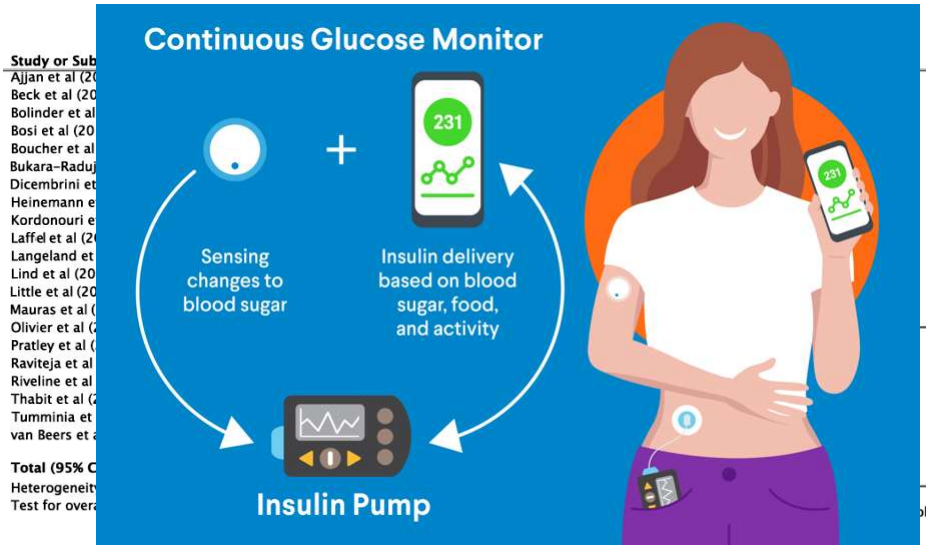
CGM Effectiveness in Maintaining Glycaemic Control Among People with T1DM: A Systematic Review of Randomised Controlled Trials and Meta-Analysis



Teo E et al ***Diabetologia*** 2022;65:604–619

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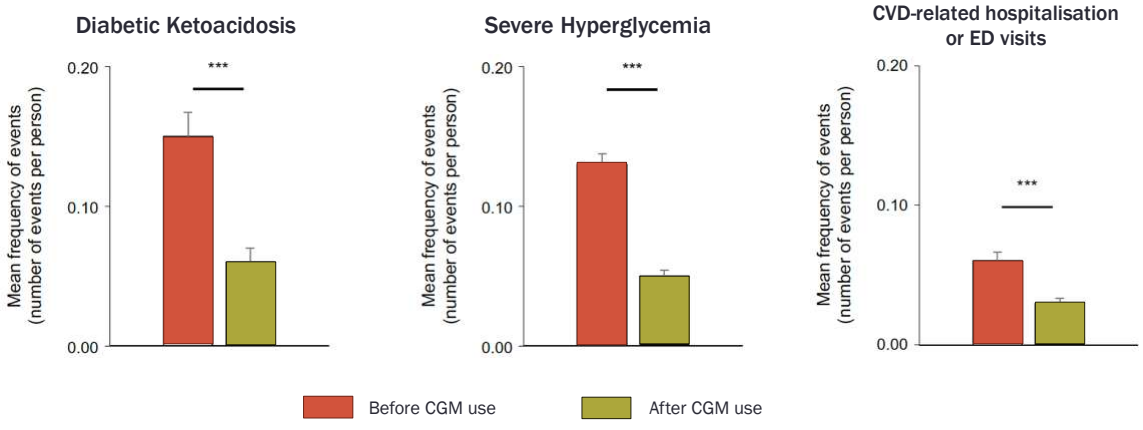
CGM and Risks of Acute and Chronic Diabetes-Related Complications in Adults with T1DM



Kim JY et al ***Diabetologia*** 2026;69:1858–1868

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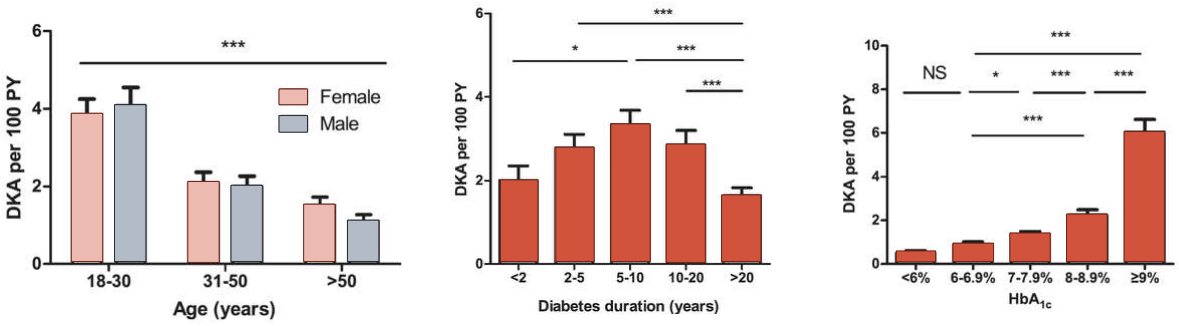
Diabetic Ketoacidosis in Adult Patients With Type 1 Diabetes: Analysis From the DPV Registry Based on 46,966 Patients



Kalscheuer H et al ***Diabetes Care*** 2019;42:e34–e36

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FDA NEWS RELEASE

FDA Authorizes First Wearable Device That Continuously Monitors Both Ketone Levels and Blood Sugar

New device can help people with diabetes detect warning signs of a dangerous complication before it becomes a medical emergency

For Immediate Release: August 25, 2026

The U.S. Food and Drug Administration today authorized the Libre Duo 10 Day Continuous Dual Glucose Ketone Monitoring System for people aged 2 years and older living with diabetes. The Libre Duo 10 Day is the first wearable device in the U.S. that continuously monitors ketone levels, and the first in the world to continuously monitor both ketones and blood sugar (glucose) together in a single device.

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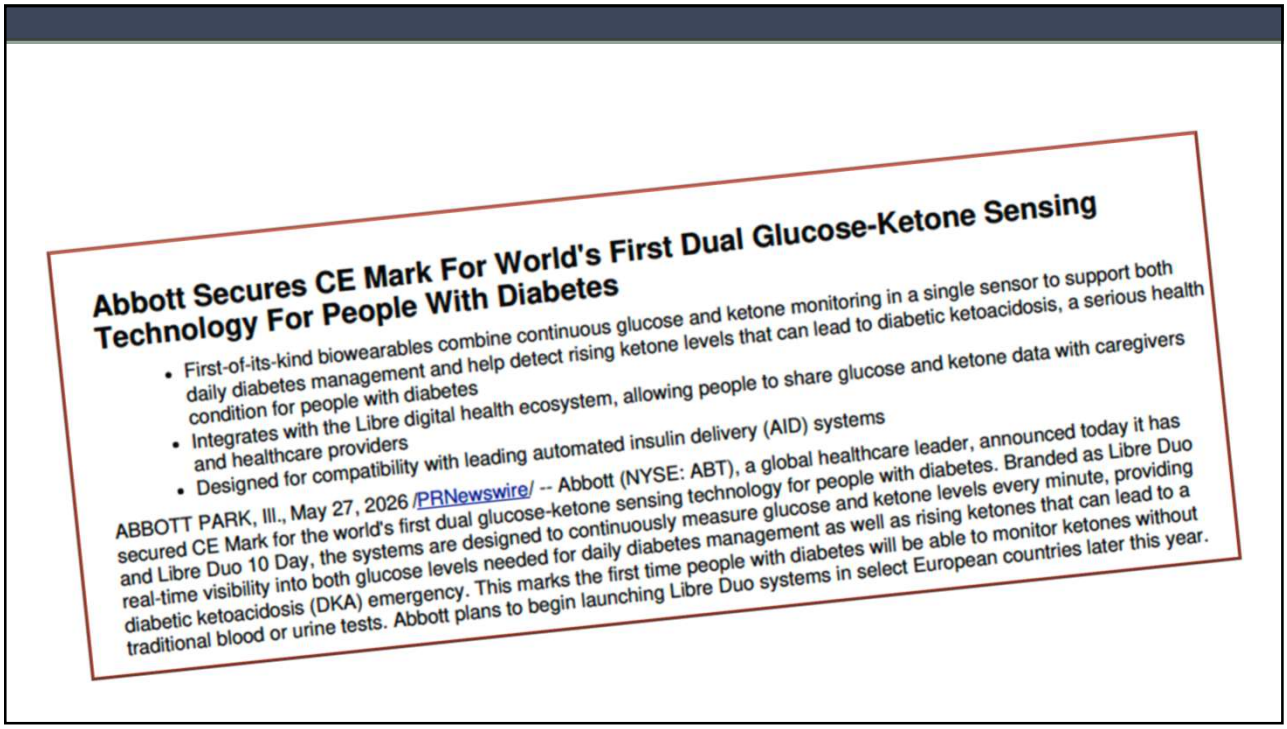

Abbott Secures CE Mark For World's First Dual Glucose-Ketone Sensing Technology For People With Diabetes

- First-of-its-kind biowearables combine continuous glucose and ketone monitoring in a single sensor to support both daily diabetes management and help detect rising ketone levels that can lead to diabetic ketoacidosis, a serious health condition for people with diabetes
- Integrates with the Libre digital health ecosystem, allowing people to share glucose and ketone data with caregivers and healthcare providers
- Designed for compatibility with leading automated insulin delivery (AID) systems

ABBOTT PARK, Ill., May 27, 2026 /PRNewswire/ -- Abbott (NYSE: ABT), a global healthcare leader, announced today it has secured CE Mark for the world's first dual glucose-ketone sensing technology for people with diabetes. Branded as Libre Duo and Libre Duo 10 Day, the systems are designed to continuously measure glucose and ketone levels every minute, providing real-time visibility into both glucose levels needed for daily diabetes management as well as rising ketones that can lead to a diabetic ketoacidosis (DKA) emergency. This marks the first time people with diabetes will be able to monitor ketones without traditional blood or urine tests. Abbott plans to begin launching Libre Duo systems in select European countries later this year.

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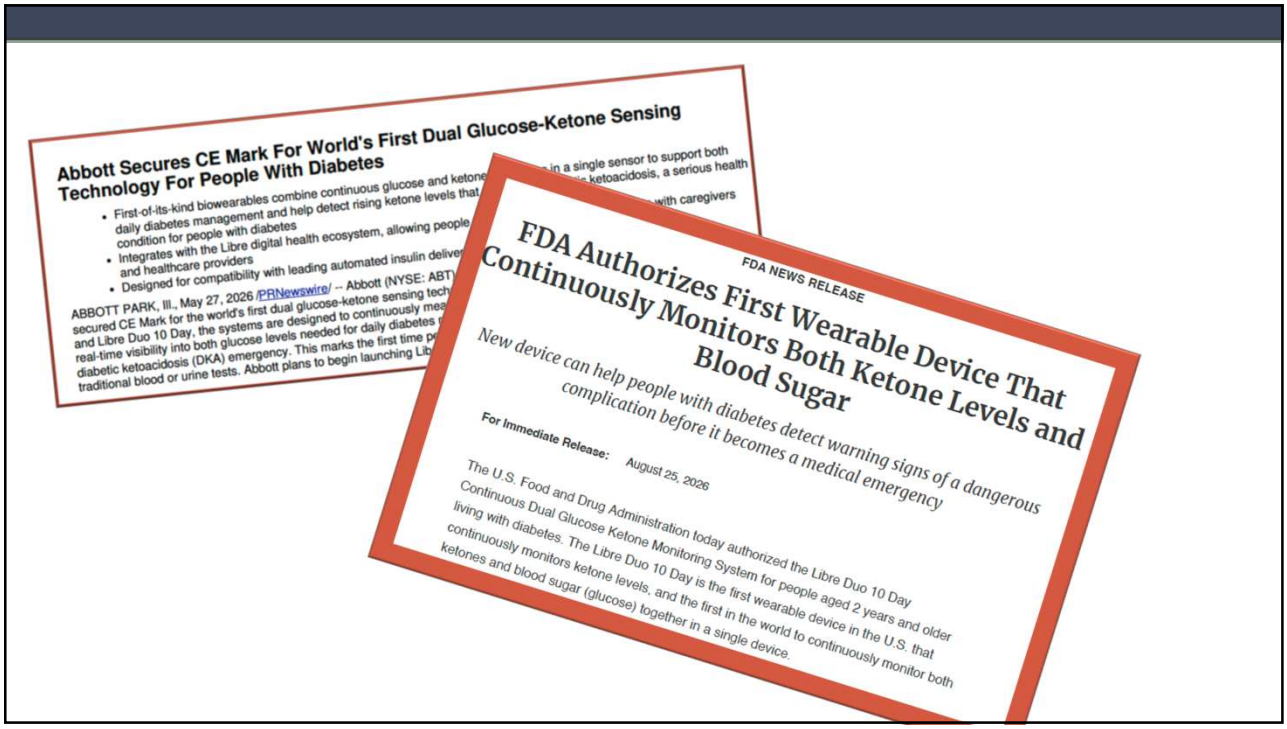

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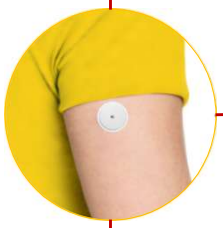
Pushing the Limits of What Sensing Can Do for T1D and T2D



- Beyond CGM: Dual Sensing Technology as the Cornerstone for DKA Prevention
- The Foundational Role of iCGM for Personalized A1c Optimization
- CGM for T2D in the Setting of Basal Insulin and SGLT2i/GLP-1 – The FreeDM2 Study

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Honorary Consultant Diabetologist, University Hospital of Derby and Burton NHS FT
Founder, Diabetes Technology Network, UK

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Beyond CGM: Dual Sensing Technology as the Cornerstone for DKA Prevention

Prof Dr Christophe De Block, MD
Head of the Dept of Endocrinology-Diabetology
Antwerp University Hospital
Full Professor, University of Antwerp
Antwerp, Belgium

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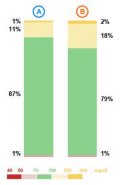
Outline



1. CGM , hybrid closed loop pumps & dual hormone pumps
2. Continuous ketone monitoring: for whom
3. Continuous ketone monitoring: current status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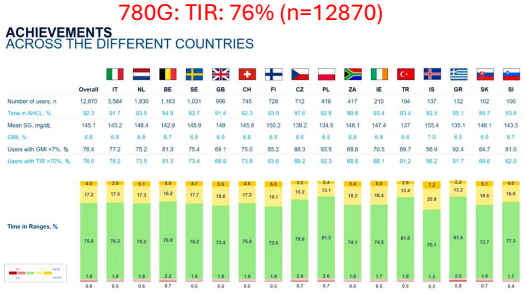
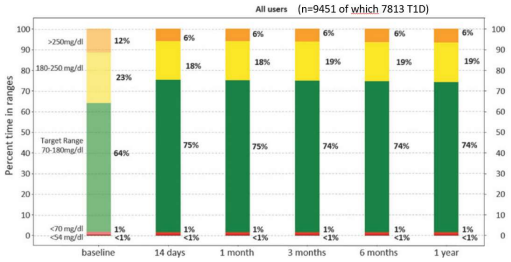
What Can We Achieve with Currently Available Hybrid Closed Loop Systems?

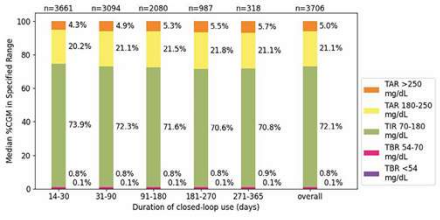
780G: TIR: 76% (n=12870)



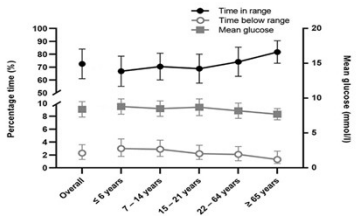
Tandem X:slim: TIR: 74% (n=9451)



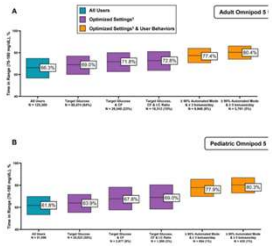
Diabeloop: TIR: 72% (n=3706)



CamAPS FX: TIR: 73%



Omnipod 5: 66-80%



Breton, Kovatchev, Diab Techn Ther 2021; Benhamou et al. DOM 2023; Amadou et al. Diabetes Care 2021; Alwan et al. J Diab Sci Technol 2025; Sawyer et al. DTT 2026

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Despite AID, Still Some Develop DKA

ESM Table 7 Evolution of acute diabetes complications and work absenteeism from 12 months before to 12 months after start of Control-IQ

	12 months before start	12 months after start	p value
Participants with			
a self-reported severe hypoglycaemic event	12.2 (9.0-16.2)	9.8 (7.0-13.6)	0.209
a hospital visit for a severe hypoglycaemic event	3.6 (2.2-5.7)	2.4 (1.3-4.3)	0.276
a hospitalisation due to a severe hypoglycaemic event	2.1 (1.1-3.9)	0.7 (0.2-2.2)	0.095
a hospital visit for diabetic ketoacidosis	2.0 (1.0-4.0)	1.6 (0.7-3.5)	0.579
a hospitalisation due to diabetic ketoacidosis	1.7 (0.8-3.5)	0.9 (0.4-2.5)	0.213
work absenteeism	12.3 (8.5-17.5)	12.9 (8.8-18.5)	0.778
Number of events per 100 patient years of			
a self-reported severe hypoglycaemic event	37.5 (21.3-65.9)	15.7 (9.7-25.3)	0.002
a hospital visit for a severe hypoglycaemic event	4.2 (2.5-7.1)	2.4 (1.3-4.4)	0.145
a hospitalisation due to a severe hypoglycaemic event	2.5 (1.3-4.8)	0.7 (0.2-2.5)	0.077
a hospital visit for diabetic ketoacidosis	2.4 (1.2-4.9)	1.7 (0.8-3.8)	0.396
a hospitalisation due to diabetic ketoacidosis	1.8 (0.8-3.9)	0.9 (0.3-2.4)	0.119
Number of days per 100 patient years of			
a hospitalisation for a severe hypoglycaemic event	5.7 (2.4-13.7)	0.8 (0.2-4.2)	0.016
a hospitalisation for diabetic ketoacidosis	5.9 (2.8-12.3)	2.4 (0.8-7.0)	0.129
work absenteeism	116.3 (42.8-315.5)	69.3 (25.4-189.2)	0.034

Data are represented as % participants or n events/days with (95% CI). Hospitalisations were validated by clinicians of each centre.

De Meulemeester et al. Diabetologia 2025; 68: 948-960

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Outline




1. CGM , hybrid closed loop pumps & dual hormone pumps
2. **Continuous ketone monitoring: for whom ?**
3. Continuous ketone monitoring: current status


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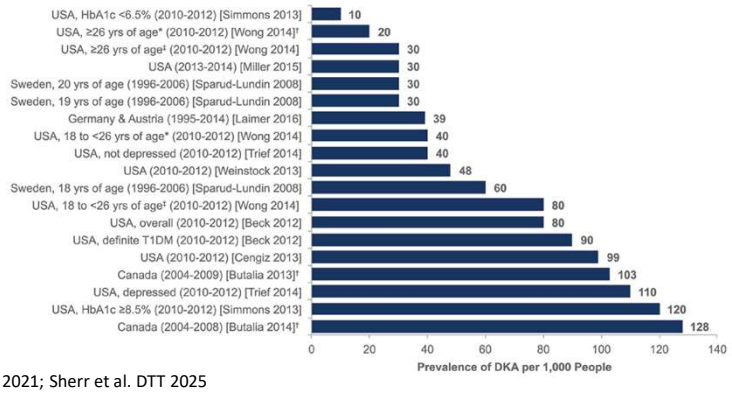
Ketosis and DKA

- Worldwide incidence of DKA varies between **8-51 cases per 1000** patient-years in T1D
- DKA is a serious, potentially life-threatening medical emergency that affects approximately **4%–8%** of adults with T1D each year. DKA occurs at the onset of T1D in up to 80% of patients
- The risk of **mortality** due to DKA in children and adolescents with T1D ranges from **0.15% to 0.3**% in developed countries, but increases from **3.4% to 13.4%** in developing countries



Nguyen et al. J Diab Sci Technol 2021; Sherr et al. DTT 2025

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Continuous Ketone Monitoring: When ?

Table 4. Scenarios Where Addition of CKM Data Might Enhance the Value of Using an AID System.

1	Failure of insulin delivery by the AID
2	Inadequate bolus dosing
3	Recurrent DKA
4	Sick days
5	Stress
6	Reduced carbohydrate intake
7	Fasting
8	High intensity exercise
9	SGLT2 inhibitor therapy
10	Pregnancy
11	Heavy alcohol intake
12	Prolonged sedentary state
13	Social isolation

Pump stop: (Attia et al. Diab Care 1998)
β-hydroxybutyrate (BHB)
after 3h > 0.4 mmol/l
after 4h > 0.6 mmol/l
after 6h > 1.0 mmol/l

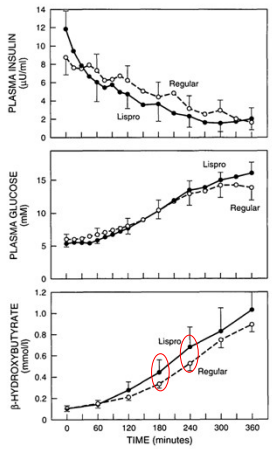

Figure 1—*Changes in plasma insulin, plasma glucose, and serum β-OHB concentrations after cessation of basal insulin infusion (time 0) in patients treated with lispro or regular human insulin.*

Nguyen et al. J Diab Sci Technol 2021

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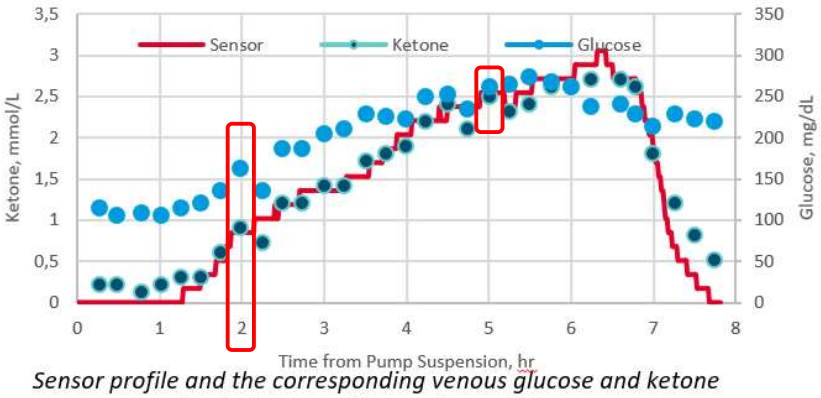
Could CKM Help in Warning People Sooner?

- This patient already had ketone levels of 1 mmol/l at a glycaemia of 160 mg/dl (8.9 mmol/l)
- At a glycaemia of 250 mg/dl (13.9 mmol/l), ketone levels were already at 2.5 mmol/l



Sensor profile and the corresponding venous glucose and ketone levels for one of the study participant

Clinical thresholds used to prompt assessment for ketones (glucose >200mg/dL (>11.1 mmol/L)) may lead to a delay in the detection of ketones.

Sherr J et al. ATTD 2024

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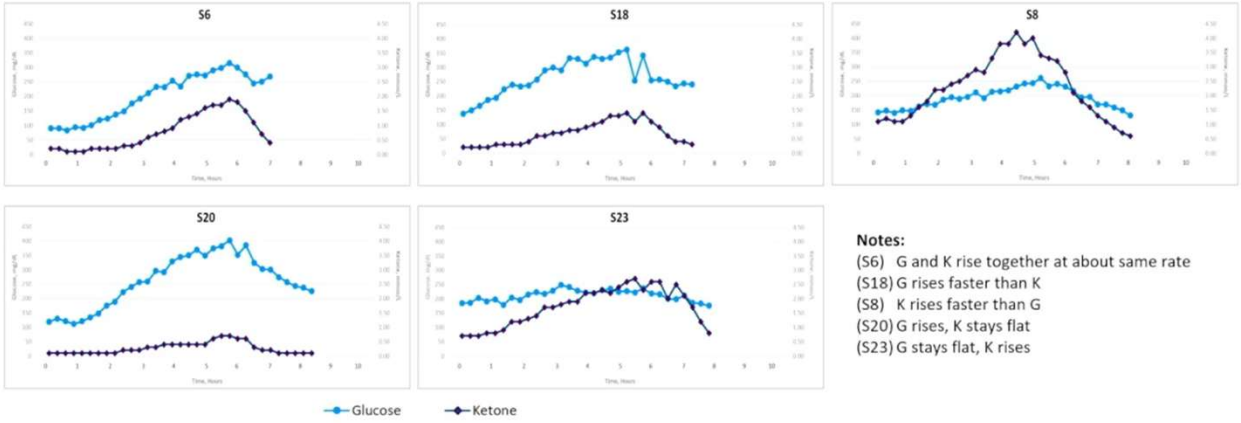
Glucose and Ketone Variability



Notes:
(S6) G and K rise together at about same rate
(S18) G rises faster than K
(S8) K rises faster than G
(S20) G rises, K stays flat
(S23) G stays flat, K rises

Data on file. Abbott Diabetes Care.

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Continuous Ketone Monitoring: When ?

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10	Pregnancy
11	Heavy alcohol intake
12	Prolonged sedentary state
13	Social isolation

- Deliberately… to lose weight
- Preoperatively … nurses are afraid of hypo and "under" bolus
- Postoperatively … after bariatric surgery
- Transition from ICU to regular ward

Nguyen et al. J Diab Sci Technol 2021

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Continuous Ketone Monitoring: When ?

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10	Pregnancy
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12	Prolonged sedentary state
13	Social isolation

- High HbA1c, socioeconomic factors (e.g., ethnic/racial minority status, psychosocial factors, and underinsurance) play a role in recurrence.

Nguyen et al. J Diab Sci Technol 2021

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Continuous Ketone Monitoring: When ?

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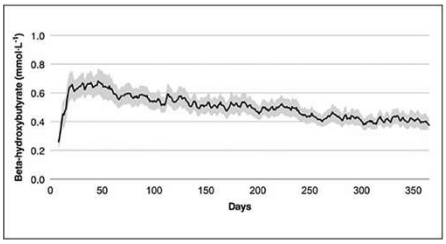

Figure 7. BHB concentrations of subjects in a very low carbohydrate diet program after one year. 349 subjects with T2D enrolled and after one year, 218 of them remained enrolled. Each day, participating subjects consumed 30 g of carbohydrates, 1.5 g/kg of protein, and fat ad lib for satiety. Mean BHB concentrations

Nguyen et al. J Diab Sci Technol 2021

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SiBio CKM — Ketosis Events (> 15 min)

	Very-low carbohydrate diet (n=72 days)	Intermittent fasting diet (n=83 days)
Ketone events ≥0.6 mmol/L		
Total number of events	53	28
Rate of events (/week)	5.2	2.4
Duration of events (min/event)	55 [25-100]	68 [39-106]
Events in 00h–06h (%)	28	14
Events in 06h–12h (%)	26	54
Events in 12h–18h (%)	23	21
Events in 18h–24h (%)	23	11
Ketone events ≥1.0 mmol/L		
Total number of events	9	8
Rate of events (/week)	0.9	0.7
Duration of events (min/event)	65 [45-115]	33 [20-80]
Events in 00h–06h (%)	22	13
Events in 06h–12h (%)	56	50
Events in 12h–18h (%)	22	25
Events in 18h–24h (%)	0	13

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Continuous Ketone Monitoring: When ?

Table 4. Scenarios Where Addition of CKM Data Might Enhance the Value of Using an AID System.

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12	Prolonged sedentary state
13	Social isolation

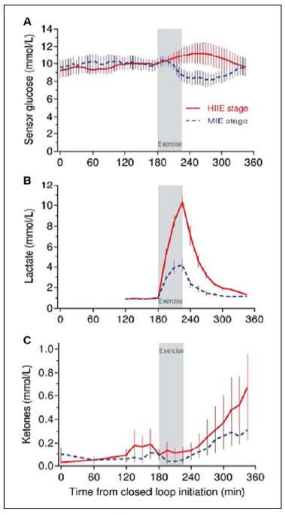

Figure 1. Biochemical profiles during CL with high-intensity exercise (HIIE) and moderate-intensity exercise (MIE) in participants with type 1 diabetes.[9]

Nguyen et al. J Diab Sci Technol 2021

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Continuous Ketone Monitoring: When ?

Table 4. Scenarios Where Addition of CKM Data Might Enhance the Value of Using an AID System.

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- Prevalence of DKA in T1D on SGLT2i varies between 1.5-4% (RR x 2.8)
- Dapa (DEPICT1), empa (EASE), sota (TANDEM1)
- DKA may not necessarily be associated with hyperglycaemia (>200 mg/dl), especially in patients using SGLT2i and/or GLP1/(GIP) receptor agonists

Nguyen et al. J Diab Sci Technol 2021

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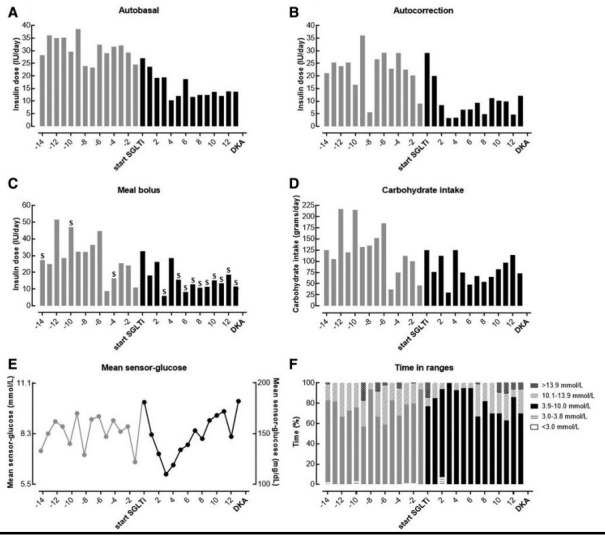
Continuous Ketone Monitoring: When ?

DKA in a person with T1D using SGLT2i and a hybrid closed loop pump (780 G)

Autobasal

Meal bolus

Sensor glc



Autocorrection

CHO intake

TIR

Visser M et al. Diab Technol Ther 2022

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Continuous Ketone Monitoring: When ?

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11	Heavy alcohol intake
12	Prolonged sedentary state
13	Social isolation

GLP-1 RA or GLP-1/GIP RA / immune checkpoint inhibitor therapy (0.2-1.4%)

Nguyen et al. J Diab Sci Technol 2021

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Outline




1. CGM , hybrid closed loop pumps & dual hormone pumps
2. Continuous ketone monitoring: for whom ?
3. **Continuous ketone monitoring: Current status**


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Real-World Ketone Testing Patterns Among People Using Freestyle Libre

Study Overview

- Data on blood ketone readings performed with the FSL reader from 89 countries from 2014 – 2024
- Ketone levels bucketed as ≤0.5 (normal) | 0.6–1.4 | 1.5–2.9 | ≥3.0 mmol/L
- 2.5 Million Ketone Tests, 135,000 patients using readers with ketone data analyzed

Key Findings

- **Most patients did not test ketones:** 92.5% of 1.7 million readers had no ketone testing performed
- **Delayed ketone testing (5 – 8 hours)** after glucose >250 mg/dL
- **Ketones rarely rechecked** within 24–72 hours even with elevated ketones
- **Elevated ketones even at lower glucose:** 12.5% had ketones ≥0.6mmol/L, while glucose <250 mg/dL

- **Elimination of testing barriers** and early identification of elevated ketone levels using CKM could prompt a patient to identify reasons for the rise in ketones (e.g., an issue with the insulin pump) or to seek early treatment
- CKM **does not require patient-prompted ketone measurement** (in contrast to fingersticks)

Bergenstal et al. DTT 2026

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Continuous Ketone Monitoring ?
An Airbag: You Rarely Need It But It Could Save Your Life

Table 5. Endpoints of Interest in CKM Trials (Numbers 2–7 Would be Randomized Controlled Trials).

	Endpoints of interest in CKM trials
1	Analytical accuracy (bias and precision) in four ketone concentrations ranges: highest range (DKA), mid-range (impending DKA), lower range (diet-induced ketosis), and lowest range (healthy controls)
2	Frequency of DKA episodes in high-risk individuals (T1D and insulin-treated T2D, use of sodium-glucose co-transporter-1 and 2 inhibitors, high-risk patients following ketogenic diets)
3	Reduction in events leading to emergency department visits or hospitalizations
4	In-hospital use during DKA resolution (length of stay, time to transition from intravenous to subcutaneous insulin, readmission rate)
5	Incremental benefit of CKM added to CGM in various clinical situations (but for statistically significant results they might require being powered with an impractically large n if the anticipated incremental benefit is small)
6	In-hospital resource use and economic analysis
7	Weight loss assisted by a CKM for a ketogenic diet
8	Patient-reported outcomes/satisfaction/user experience/user interface

- Successful integration of a CKM into an **AID** device will require **novel algorithms** based on ketone data
- Ketone-specific **alarms** for high ketone levels, predictive alarms and **trend** information will be useful features

Nguyen et al. J Diab Sci Technol 2021

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Continuous Ketone Monitoring

- The first-in-human study of a CKM device in **12 volunteers**
- Healthy participants on low carbohydrate diet over 14 days
- The electrochemical sensor used **wired enzyme** to measure β-hydroxybutyrate (BHB) (within 4 minutes)
- This sensor delivered a **linear response over the 0-8 mM range with good accuracy and stability** for **14 days**.

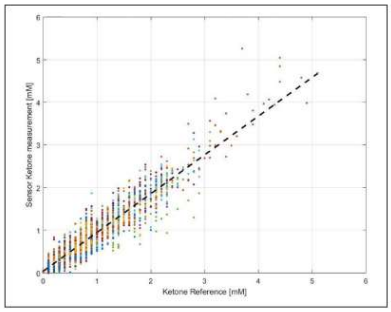

Figure 5. Plot of ISF ketone values measured by the sensors against capillary ketone strip reference measurements. Number of Paired data points is 3132.

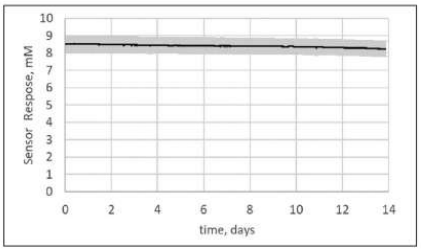

Figure 3. Change in sensor response (solid line is the mean and shaded area is 1 standard deviation of the data from 16 sensors) at 8 mM ketone held at 37°C for 14 days.

Alva et al. J Diabetes Sci Technol 2021, 15(4): 768–774

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Continuous Ketone Monitoring

- With a single **retrospective** calibration, the mean absolute difference (MAD) for BHB concentrations <1.5 mM was 0.129 mM and **91.7% of the sensor results were within ±0.3 mM** of the reference.
- For **BHB ≥1.5mM** the mean absolute relative difference **(MARD) was 14.4%.**
- However, the sensor was **not tested** in a setting with **dynamically changing** blood glucose or ketone levels.

Table 3. Accuracy of the In Vivo Interstitial Fluid Ketone Sensor Results Compared to the Capillary Ketone Strip Reference. Table Reproduced from Alva et al.[1]

Concentration range	Percentage within		Mean MAD/MARD	SD/%CV		Number of paired data points
	0.225 mM/20%	0.3 mM/30%		Between subject	Within subject	
<1.5 mM	83.4%	91.7%	0.129 mM	0.051 mM	0.029 mM	2724
≥1.5 mM	76.0%	89.7%	14.4%	5.40%	7.46%	408
Combined	82.4%	91.4%	–	–	–	3132

Accuracy and bias results for ketone concentrations <1.5 mM are in mM. SD is the standard deviation and CV is the coefficient of variation.

Alva et al. J Diabetes Sci Technol 2021, 15(4): 768–774

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The GLOW Study: Multibiomarker Sensor

- A miniaturized **near-infrared spectrometer** on a silicon photonics chip that measures optical transmittance in the interstitial fluid at up to 24 wavelengths between 1680 and 2400 nm
- Covered by a biocompatible silicone envelope
- Contains a **small coil** for wireless communication and charging, and a **micro battery**
- The size of the sensor is 3 x 0.7 x 1.5 cm (3.15 ml), mainly taken up by the size of its internal battery

De Ridder F et al. PLoS One 2024; 19 (5): e0301041

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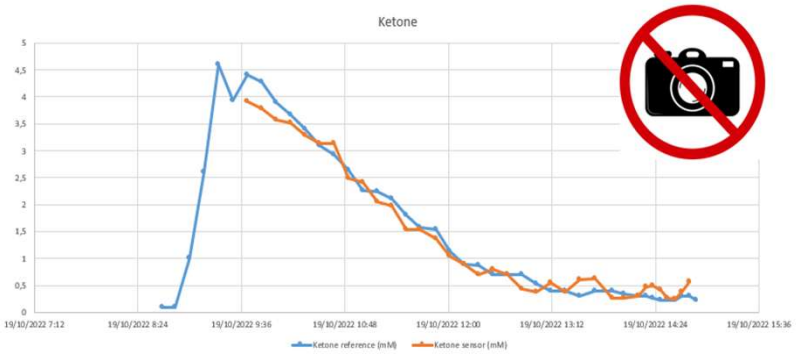
Case Study: Low Carb Diet, Keton Ester Drink

- Diabetes, low carb diet
- Hyper/hypoglycemia
  - Up to 400 mg/dl (dextrose gel)
  - Down to 40 mg/dl (pump)
- Ketones:
  - **Ketone ester to get ketones to 3.5 mM**



De Ridder F, et al. Do not photograph, unpublished data

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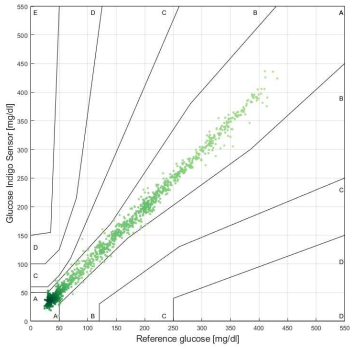
Glucose

Parkes Error Grid
Reference Method EKF Diagnostics

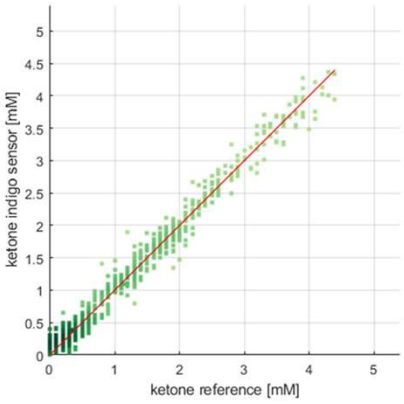


Parkes Error Grid	
% in A	98.9%
% in B	1.1%
% in C	0%
% in D	0%

Range	MAD	MARD
40-70mg/dL	6.0 mg/dL	11.8%
70-180mg/dL	7.5 mg/dL	6.5%
>180mg/dL	7.2 mg/dL	2.9%
overall	6.8 mg/dL	7.1%

Ketones

Reference method Ketone strips (GlucoMen LX B(eta)-Ketone Sensor).



Number of data points	MAD
235	0.12 mM

De Ridder F et al. PLoS One 2024; 19 (5): e0301041

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Do We Really Need CONTINUOUS Ketone Sensing or Display?

Figure 3. Proposed display for ketone sensor measurements: <0.6 mmol/L = green light and no reading; 0.6-1.0 mmol/L = yellow light with ketone level and trend arrows displayed; 1.0-1.5 mmol/L = orange light with ketone level and trend arrows displayed; >1.5 mmol/L = red light with ketone level and trend arrows displayed.

- A single up or down arrow if ketone levels are increasing or decreasing between 0.25 and 0.5 mmol/L/h
- And two trend arrows if levels are changing at more than 0.5 mmol/L/h.

Lee et al. J Diab Sci Technol 2019

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Continuous Ketone Monitoring for People with Diabetes:
International Expert Recommendations on the Application of a New Technology

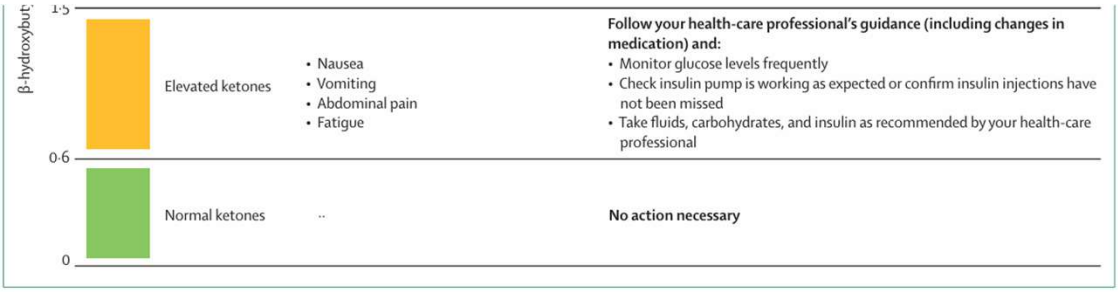

Figure 2: Template schema for developing practical recommendations on continuous ketone monitoring thresholds

Lancet Diabetes Endocrinol 2026; 14: 82–92

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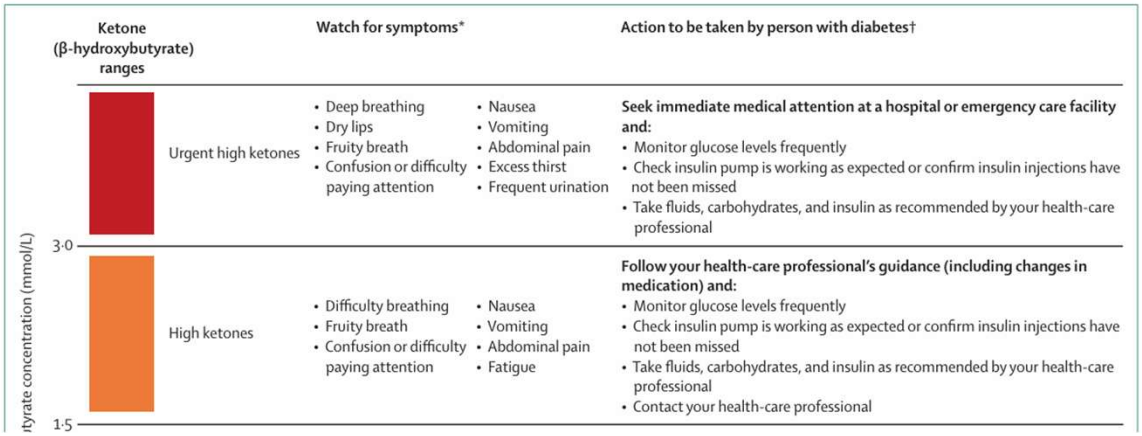
Continuous Ketone Monitoring for People with Diabetes:
International Expert Recommendations on the Application of a New Technology



Lancet Diabetes Endocrinol 2026; 14: 82–92

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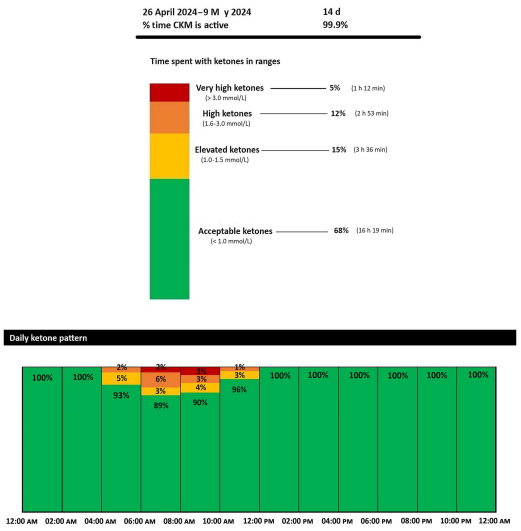
Continuous Ketone Monitoring: Reporting



First attempt: Clinical targets for CKM in T1D on SGLT2i:

- Level 1 ketosis (> 1.0 mmmol/L) should be < 3%
- Level 2 ketosis (> 1.5 mmol/L) should be < 1%

Haidar A, ATTD congress 2026

Time above 0.6, 1.0, 1.5 and 3.0 mmol/L should be reported

Diabetes Obes Metab 2024; 26, 47-58

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The Unknowns

- What is the time lag between interstitial and capillary ketones?
  - Is this "lag" variable or stable?
- Is the value of a certain BHB level the same in all conditions or do we need condition specific cutoffs (sports, low carb, illness, …)?
- What about trend arrows (rate of change of 0.4 mmol/L/hour seems reasonable)?
- Is there a temporal relationship between glucose and BHB in certain conditions?
  - Is this relationship stable ?
- Could integration of CKM data improve current AID algorithms?

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Case Study: AID – Cannula Dislodgement After Gardening, Trying to Correct with Fake Carbs

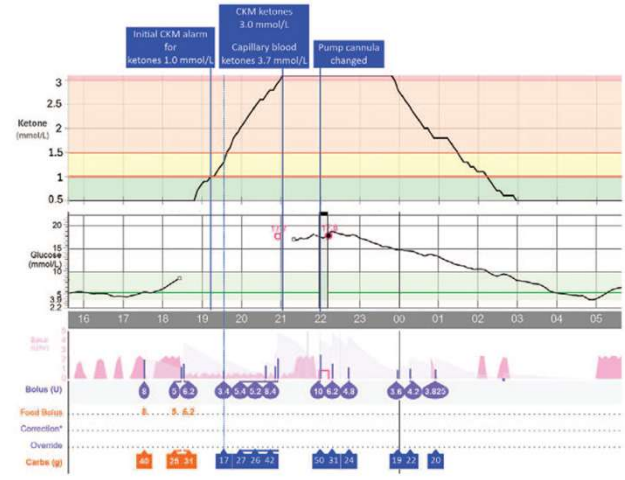

FIG. 1. Insulin delivery, continuous glucose monitor (CGM) glucose, and continuous ketone monitor (CKM) ketone data. CKM alert alarms are triggered when ketones are ≥1.0 and ≥1.5 mmol/L (red lines on the ketone graph). Under Carbs (**g**), orange boxes indicate carbohydrates in meals, and blue boxes indicate "fake carbohydrates" that are entered as a way to deliver additional insulin. Blue dotted line indicates when the "fake carbohydrates" were first entered (action to manage ketonemia).

- 55-y old man, with 53y of T1D
- HbA1c 6.9%, TIR 83%
- Last episode of DKA was during childhood
- His CGM sensor had expired
- Gardening
- Ketone sensor gave alarms
- Gave fake carbs without result
- Noticed dislodgement due to ketone alarms, fixed it and prevented hospitalisation for DKA

Kong et al. DTT 2025

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Clinical Case #1

30 year old female

Medical history	Type 1 diabetes for 20 years
Profile	• Using AID (Minimed780G): TDI: 0.6 U/kg/day • HbA1c 7.0% • TIR: 73%
Management	• Using an SGLT2i • Wore a SiBionics CKM • Well educated on capillary ketone testing in case of symptoms, CGM readings > 200 mg/dl or CKM readings > 0.6 mmol/L

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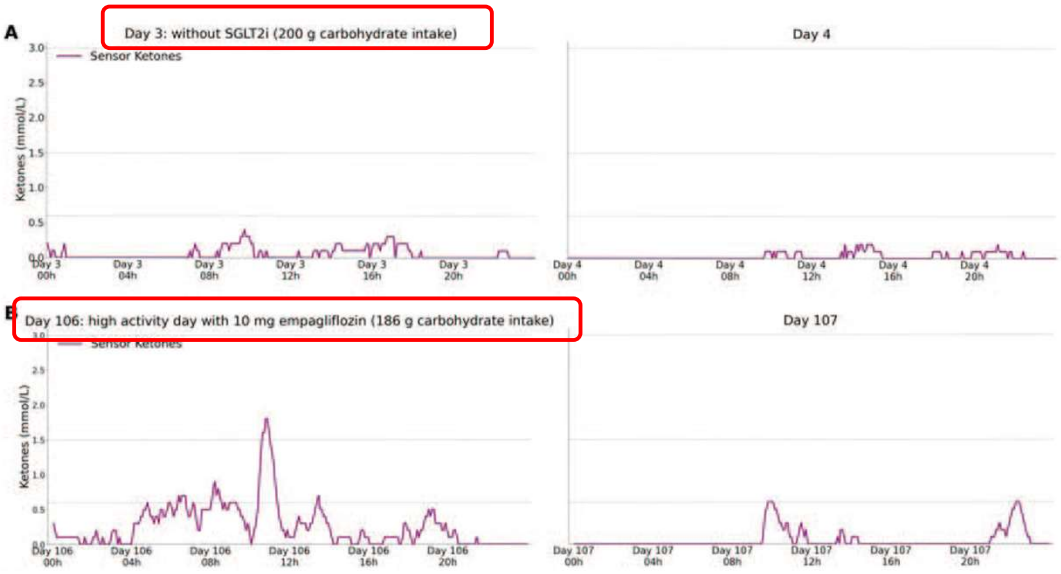
Clinical Case #1



Lawton et al. DTT 2026

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Clinical Case #1 - Question

What should the patient be advised?

1) Check tubing of AID system in case of symptoms and change it if glycemia > 250 mg/dl

2) For ketone levels > 0.6 mmol/L: drink extra water, ingest extra carbs and an insulin bolus

3) For ketone levels > 1.5 mmol/L ingest 15-30g of carbs and a large glass of water hourly, administer a bolus based on carb intake hourly and monitor ketones until < 0.6 mmol/L

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Clinical Case #1 - Answer

What should the patient be advised?

1) Check tubing of AID system in case of symptoms and change it if glycemia > 250 mg/dl
   - Should already be advised if > 200 mg/dl)

2) For ketone levels > 0.6 mmol/L: drink extra water, ingest extra carbs and an insulin bolus
   - Should be advised only if symptoms are also present

3) **For ketone levels > 1.5 mmol/L ingest 15-30g of carbs and a large glass of water hourly, administer a bolus based on carb intake hourly and monitor ketones until < 0.6 mmol/L**

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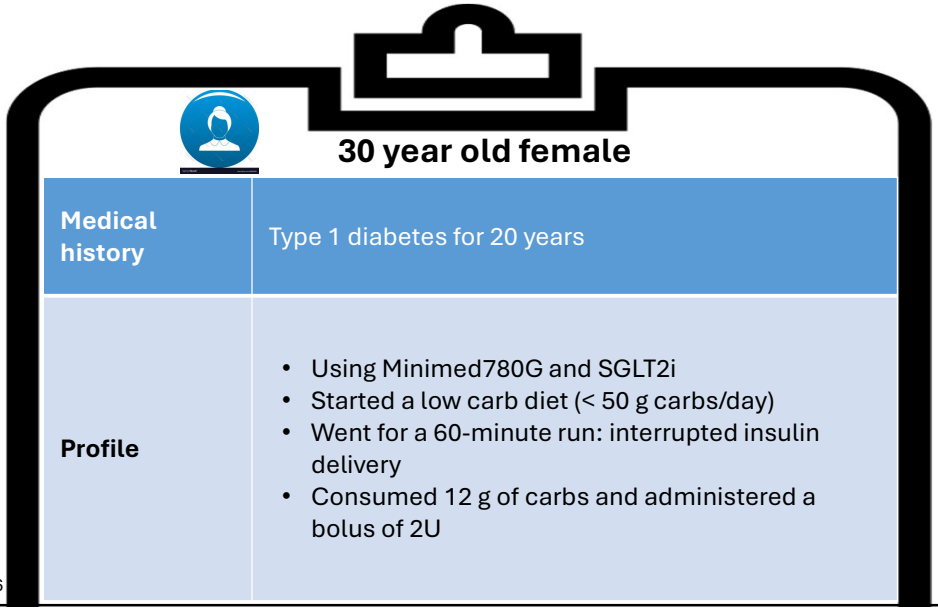
Clinical Case #2



30 year old female

Medical history	Type 1 diabetes for 20 years
Profile	• Using Minimed780G and SGLT2i • Started a low carb diet (< 50 g carbs/day) • Went for a 60-minute run: interrupted insulin delivery • Consumed 12 g of carbs and administered a bolus of 2U

Lawton et al. DTT 2026

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Clinical Case #2 - Question

- A 30-year old woman with T1D, SGLT2i, Minimed780G (temp stop during a 60-min run)
- What do you think happened to the ketone values?

1) Stayed flat (aerobic exercise)
2) Transiently rose to 0.6 mmol/L
3) Transiently rose to 2.0 mmol/L
4) Transiently rose to > 3.0 mmol/L necessitating E.R. visit for DKA protocol

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Clinical Case #2 - Answer

- A 30-year old woman with T1D, SGLT2i, Minimed780G (temp stop during a 60-min run)
- What do you think happened to the ketone values?

1) Stayed flat (aerobic exercise)
   - Stays flat if there is no insulin interruption
2) Transiently rose to 0.6 mmol/L
   - Combination of insulin interruption (increasing glucagon/insulin ratio and counterregulatroy hormone leves), low carb diet, exercise and SGLT2i use: ketone levels are expected to rise to higher levels
3) **Transiently rose to 2.0 mmol/L**
4) Transiently rose to > 3.0 mmol/L necessitating E.R. visit for DKA protocol
   - Only 1h of insulin suspension, post-exercise carb intake and bolus administration

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Clinical Case #3

30 year old female

Medical history	Type 1 diabetes for 20 years
Profile	• Using Minimed780G and SGLT2i • Started a low carb diet (< 50 g carbs/day) • Went for a 60-minute run: interrupted insulin delivery • Consumed 12 g of carbs and administered a bolus of 2U
Management	• Insulin was also manually suspended on 3 additional occasions: biking, fitness class and biking • Insulin was suspended during biking in response to a downward glucose trend readings > 0.6 mmol/L

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Lawton et al. DTT 2026

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Clinical Case #3

A 30-year old woman with T1D

- At 23h she reported fatigue, which she attributed to high amounts of physical activity (5 km run, 11 km bike ride, exercise class and again 11 km bike ride), and hunger
- Consumed 50g of carbs without administering a bolus (glucose level: 130 mg/dl)
- At 23h30: ketone levels of 1.5 mmol/L
- Following morning: symptoms of ketosis: frequent urination, increased thirst and very fatigued.
- Overnight CKM values peaked at 2.9 mmol/L

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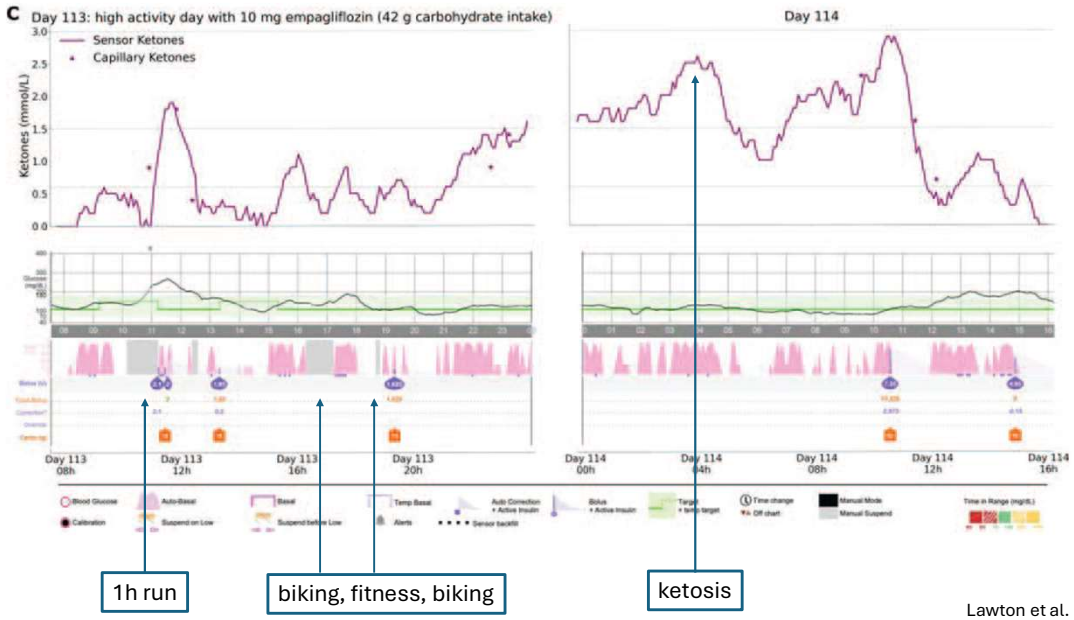

Lawton et al. DTT 2026

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Clinical Case #3 - Question

- A 30-year old woman with T1D, SGLT2i, Minimed780G, morning ketosis
- What should she do?

1) Go to the E.R.
2) Interrupt low carb diet and ingest extra carbs and additional bolus of insulin
3) Interrupt low carb diet and SGLT2i, ingest extra carbs and additional bolus of insulin

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Clinical Case #3 - Answer

- A 30-year old woman with T1D, SGLT2i, Minimed780G, morning ketosis
- What should she do?

1) Go to the E.R.
   - In well-educated people, provided with clear guidance, they can probably manage at home, rechecking CKM values and when not improving then go to the E.R.
2) Interrupt low carb diet and ingest extra carbs and additional bolus of insulin
   - This is not enough
3) **Interrupt low carb diet and SGLT2i, ingest extra carbs and additional bolus of insulin**
   - **Recheck CKM values every hour until < 1.5 mmol/L**

- **CKM enabled continuous monitoring of the recovery process, providing reassurance of treatment effectiveness as ketone levels declined**

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FDA and CE Mark Approval for Dual Sensing Technology

Abbott receives FDA OK for dual glucose-ketone sensing technology

The Libre Duo 10 Day system is a dual glucose-ketone sensing technology.

Abbott secures CE Mark for world's first dual glucose-ketone sensing technology for people with diabetes

PR Newswire
Wed, May 27, 2026 at 9:00 AM EDT • 7 min read

- First-of-its-kind biowearables combine continuous glucose and ketone monitoring in a **single sensor** to support both daily diabetes management and help detect rising ketone levels.
- **Integrates** with the Libre digital health ecosystem, allowing people to share glucose and ketone data with caregivers and healthcare providers
- Designed for **compatibility** with leading automated insulin delivery (AID) systems

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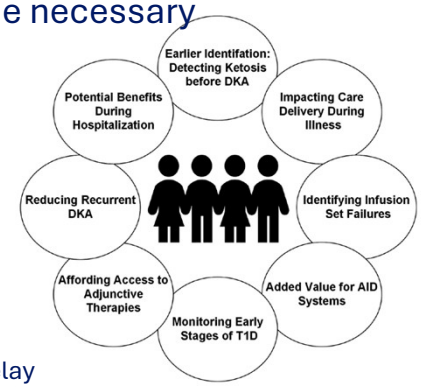
Continuous Ketone Monitoring – Is it Needed?

- CKM can act as an airbag
- Continuous display of BHB values might not be necessary
- CKM can be very helpful for some people…
  - With recurrent DKA
  - On sglt2-i (and/or incretin-based agents)
  - On low carb diet
  - For intraoperative and perioperative care:
    - Emergency surgery
    - Bariatric surgery
    - Perioperative fasting … certainly when there is surgical delay



- Future studies should address: interference, lag time

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Thank you for your attention

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The Foundational Role of iCGM for Personalized A1c Optimization

Concetta Irace, MD, PhD
Full Professor
Advanced Medical & Surgical Technology and Methodology
Dept. Of Health Science
University Magna Grecia
Catanzaro, Italy

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CGM Features For Personalized Therapy and A1c Optimization

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Classification of CGM Features

ESSENTIAL FEATURES
(i.e., features that are absolutely necessary for all patients):
- **accuracy**
- **certification**

MAJOR DRIVERS OF CHOICE
(i.e., features that address more relevant clinical issues and/or meet the needs of specific subgroup of patients):
- **approved indications of use**
- **alerts (optional, predictive, on body vibration)**
- **interoperability / integration**
- **approved application sites**
- **visualization devices**
- **transmitter removal**
- **cost of devices**

ADDITIONAL FEATURES
(i.e., features that improve patient's experience):
- **preassembled vs. non-preassembled systems**
- **other alerts (snooze, delay)**
- **device size**
- **notes entry**
- **calibration**
- **allergens**
- **interferences**
- **impermeability**

Irace et al. Diabetes Therapy 2024 15:2263-2278

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CGM Accuracy: How We Measure It

Analytical accuracy

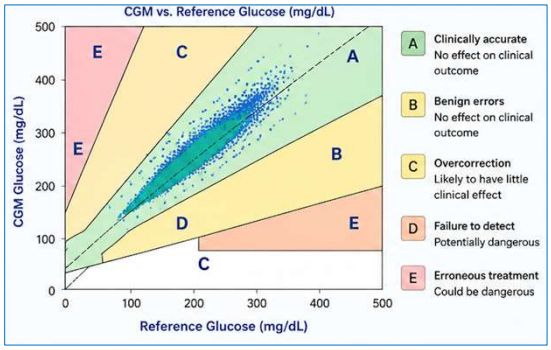
Clinical accuracy

MARD is calculated as:

$$\text{MARD}\,(\%) = \frac{1}{n}\sum_{i=1}^{n}\left|\frac{\text{CGM}_i - \text{Reference}_i}{\text{Reference}_i}\right| \times 100$$

Where:
- CGM_i = CGM glucose value
- Reference_i = reference (e.g., laboratory or SMBG) glucose value
- n = number of paired observations

MARD provides a single summary measure of accuracy across the entire glucose range.



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The Myth of MARD (Mean Absolute Relative Difference)

Limitations of MARD in the Clinical Assessment of Continuous Glucose Monitoring Data

TABLE 3. THE IMPACT C
IN HYPOGLYCEMIA (C

Case 1

Index	*SG*	*RefG*
1	50	60
2	100	90
3	150	165
4	200	210
5	250	235
6	300	280
MARD		

AVING ONE MORE POINT
AY) GLUCOSE RANGE

Case 3

SG	*RefG*	*ARD*
50	60	16.67
100	90	11.11
150	165	9.09
200	210	4.76
250	235	6.38
250	235	6.38
300	280	7.14
)		8.79

Vigersky, et al. DTT 10.1089/dia.2023.0435

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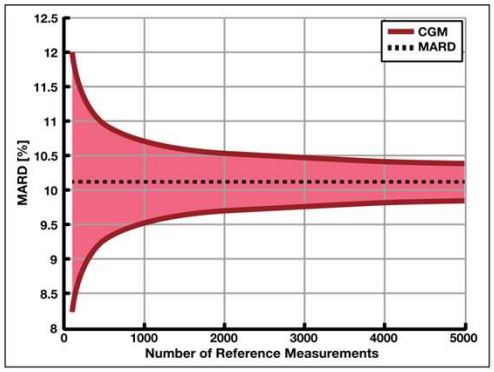
Accuracy of Flash Glucose Monitoring and Continuous Glucose Monitoring Technologies: Implications for Clinical Practice



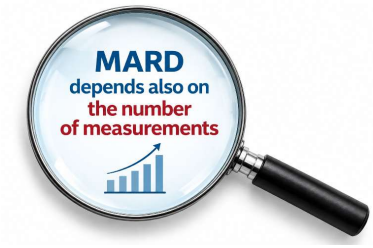


Figure 1. The impact of the number of paired points on the uncertainty of MARD: upper and lower bounds of the confidence interval with probability $\gamma = 0.95$. The constant line represents the value to which it would converge.

Ajjan RA et al. Diabetes & Vascular Disease Research 2018;15(3): 175-84

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MARD and the Rate of Change (RoC)

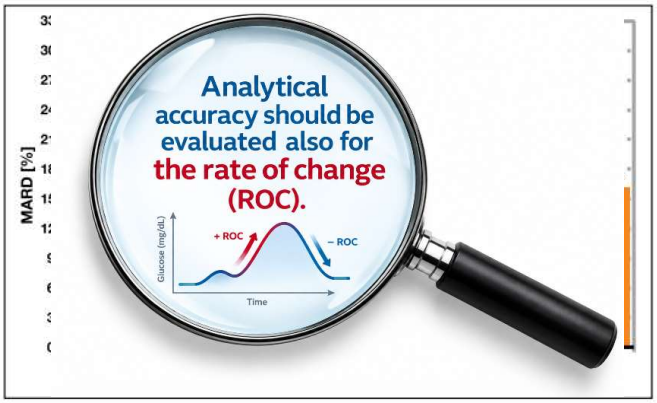

Figure 2. (adapted from Pleus et al.). At **low rate of change**, the accuracy of system A and system B does not look that different. However, with **increasing rate of change**, the superior accuracy of system B over system A becomes evident.

Ajjan RA et al. Diabetes & Vascular Disease Research 2018;15(3): 175-84

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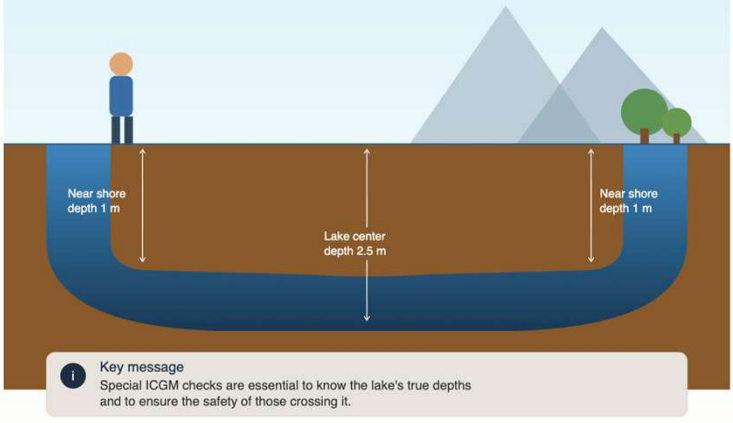
MARD and special ICGM checks

- MARD is like a person about to cross a river, knowing that the average water depth is 1.5 meters, while their own height is 2 meters
- Special ICGM checks reveal the depth is actually 1 meter near the shore but 2.5 meters at the center



Key message
Special ICGM checks are essential to know the lake's true depths and to ensure the safety of those crossing it.

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Food and Drug Administration (FDA). Classification of the Integrated Continuous Glucose Monitoring System (iCGM).

Glucose range	Performance against reference reading	Lower boundary of 95% confidence interval (CI)
<70 mg/dL mg/dL (<3.9 mmol/L)	Within ± 15 mg/dL	>85% of readings
70–180 mg/dL (3.9–10.0 mmol/L)	Within ± 15%	>70% of readings
>180 mg/dL (>10.0 mmol/L)	Within ± 15%	>80% of readings
<70 mg/dL (<3.9 mmol/L)	Within ± 40 mg/dL	>98% of readings
70–180 mg/dL (3.9–10.0 mmol/L)	Within ± 40%	>99% of readings
>180 mg/dL (>10.0 mmol/L)	Within ± 40%	>99% of readings
Across the reportable range	Within ± 20%	>87%
Overall, across all glucose measuring ranges	Within ± 20%	>87% of readings
CGM <70 mg/dL (<3.9 mmol/L) when reference > 180 mg/dL (>10.0 mmol/L)		0% of readings
CGM >180 mg/dL (>10.0 mmol/L) when reference < 70 mg/dL (<3.9 mmol/L)		0% of readings
CGM ROC > − 1 mg/dL/min when reference ROC < −2 mg/dL/min		<1% of readings
CGM ROC < −1 mg/dL/min when reference ROC > −2 mg/dL/min		<1% of readings

Abbreviations: CGM, continuous glucose monitor; CI confidence interval; ROC, rate of change.

Federal register February 18. 2022

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Received: 24 October 2024 | Revised: 9 December 2024 | Accepted: 12 December 2024
DOI: 10.1111/dom.16153

COMMENTARY

WILEY

Minimum expectations for market authorization of continuous glucose monitoring devices in Europe—'eCGM' compliance status

Chantal Mathieu MD[1] | Concetta Irace MD[2] | Emma G. Wilmot MD[3,4] | Bassil Akra PhD[5] | Stefano Del Prato MD[6] | Martin Cuesta MD[7] | Peter Adolfsson MD[8,9] | Tomasz Klupa MD[10] | Eric Renard MD[11] | Tadej Battelino MD[12,13]

Diabetes Obes Metab. 2024;1–7. https://dom-pubs.onlinelibrary.wiley.com/doi/10.1111/dom.16153?af=R

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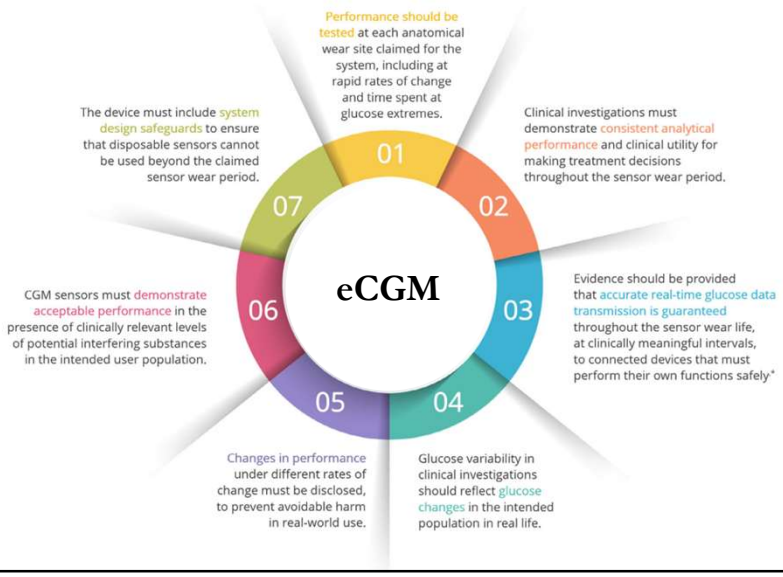
Proposed Parameters for Clinical Investigation and Device Validation



- ✓ The number of paired readings for each site should be a minimum of **2500** for younger children, and at least **10 000** for adults.
- ✓ A minimum of **8%** of paired comparator readings should be in the <70 mg/dL (<3.9 mmol/L) range and **>5%** of readings in the >300 mg/dL (>16.7 mmol/L) range.

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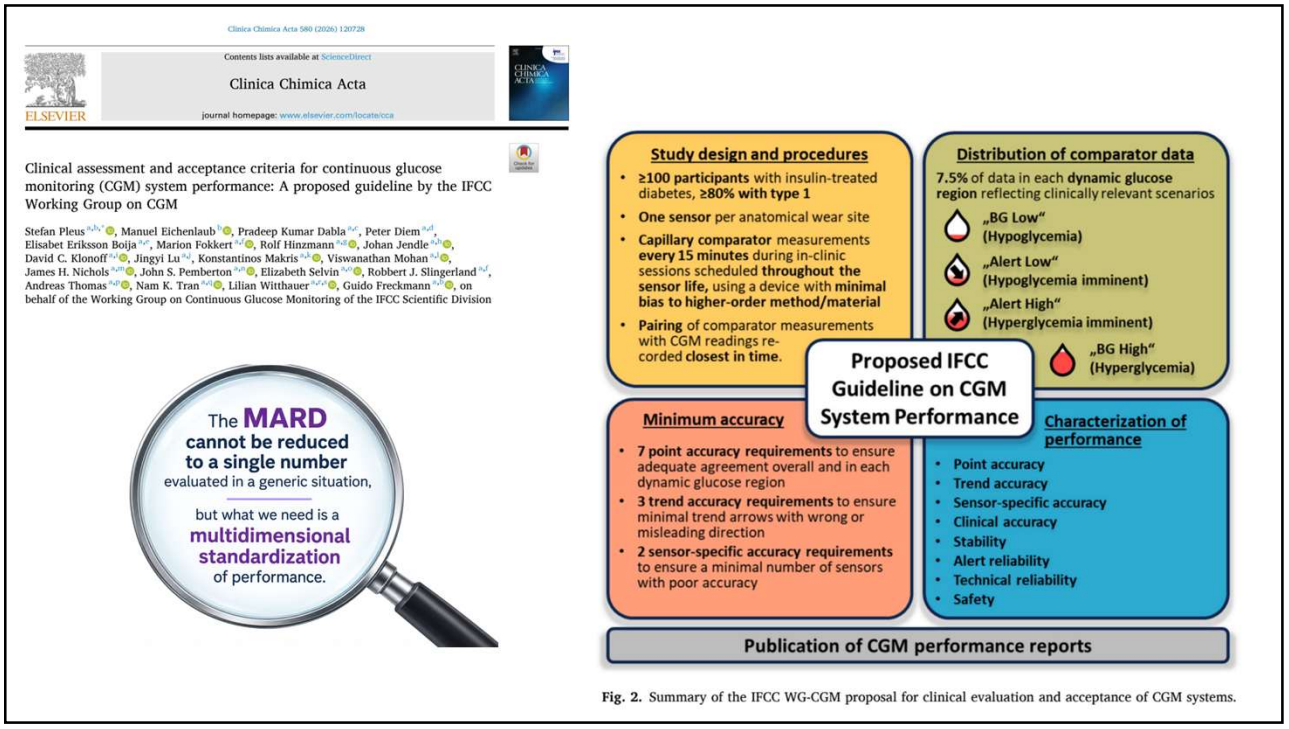

Clinica Chimica Acta 580 (2026) 120728

Contents lists available at ScienceDirect

Clinica Chimica Acta

journal homepage: www.elsevier.com/locate/cca

Clinical assessment and acceptance criteria for continuous glucose monitoring (CGM) system performance: A proposed guideline by the IFCC Working Group on CGM

Stefan Pleus, Manuel Eichenlaub, Pradeep Kumar Dabla, Peter Diem, Elisabet Eriksson Boija, Marion Fokkert, Rolf Hinzmann, Johan Jendle, David C. Klonoff, Jingyi Lu, Konstantinos Makris, Viswanathan Mohan, James H. Nichols, John S. Pemberton, Elizabeth Selvin, Robbert J. Slingerland, Andreas Thomas, Nam K. Tran, Lilian Witthauer, Guido Freckmann, on behalf of the Working Group on Continuous Glucose Monitoring of the IFCC Scientific Division

The **MARD** cannot be reduced to a single number evaluated in a generic situation, but what we need is a **multidimensional standardization** of performance.

Study design and procedures
- **≥100 participants** with insulin-treated diabetes, **≥80% with type 1**
- **One sensor** per anatomical wear site
- **Capillary comparator** measurements **every 15 minutes** during in-clinic sessions scheduled **throughout the sensor life,** using a device with **minimal bias to higher-order method/material**
- **Pairing** of comparator measurements with CGM readings recorded **closest in time.**

Distribution of comparator data

7.5% of data in each **dynamic glucose region** reflecting clinically relevant scenarios
- „BG Low" (Hypoglycemia)
- „Alert Low" (Hypoglycemia imminent)
- „Alert High" (Hyperglycemia imminent)
- „BG High" (Hyperglycemia)

Proposed IFCC Guideline on CGM System Performance

Minimum accuracy
- **7 point accuracy requirements** to ensure adequate agreement overall and in each dynamic glucose region
- **3 trend accuracy requirements** to ensure minimal trend arrows with wrong or misleading direction
- **2 sensor-specific accuracy requirements** to ensure a minimal number of sensors with poor accuracy

Characterization of performance
- Point accuracy
- Trend accuracy
- Sensor-specific accuracy
- Clinical accuracy
- Stability
- Alert reliability
- Technical reliability
- Safety

Publication of CGM performance reports

Fig. 2. Summary of the IFCC WG-CGM proposal for clinical evaluation and acceptance of CGM systems.

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Accuracy of a 15-day Factory-Calibrated Continuous Glucose Monitoring System With Improved Sensor Design

Table 2. Overall Performance by Participant Age Group Against YSI Comparator.

Participant group	Participants	Matched pairs (n)	% within ±15%/±15 mg/dL	% within ±20%/±20 mg/dL	% within ±40%/±40 mg/dL	MARD, %	MRD,%
Adults (ages 18+)	149	20 619	89.3	94.2	99.4	8.2	-2.8
Pediatric (ages 6-17)	124	7075	88.4	94.0	99.5	8.1	-4.5
Pediatric* (ages 2-5)	12	477	78.0	86.6	97.3	11.2	-0.8

*Results based on comparing with SMBG comparator.

(a).

YSI_{ref} Glucose level, mg/dL [mmol/L] [1]	% Within ± 15%/±15 mg/dL	% Within ± 20%/±20 mg/dL	% Within ± 40%/±40 mg/dL
40–50 [2.2–2.8]	92.2	97.7	100.0
51–80 [2.8–4.4]	94.1	97.6	99.4
81–180 [4.5–10.0]	81.6	89.6	98.7
181–300 [10.0–16.7]	91.8	95.4	99.8
301–400 [16.7–22.2]	95.0	97.7	99.6
401–500 [22.3–27.8]	90.8	92.0	100.0
Overall	89.3	94.2	98.3

(d).

	Adult Population			
YSI_{ref} Glucose ROC, (mg/dL/min)	No. Pair	% Within ±15%/±15 mg/dL	% Within ±20%/±20 mg/dL	% Within ±40%/±40 mg/dL
<-2	424	81.6	89.6	99.1
-2 to -1	1586	88.3	93.7	99.7
-1 to 1	14 412	90.6	95.0	99.5
1 to 2	2234	88.8	94.4	99.6
>2	1372	79.7	88.1	98.7
NA*	591	89.0	92.9	98.8

JDST 2025 10.1177/19322968251329644

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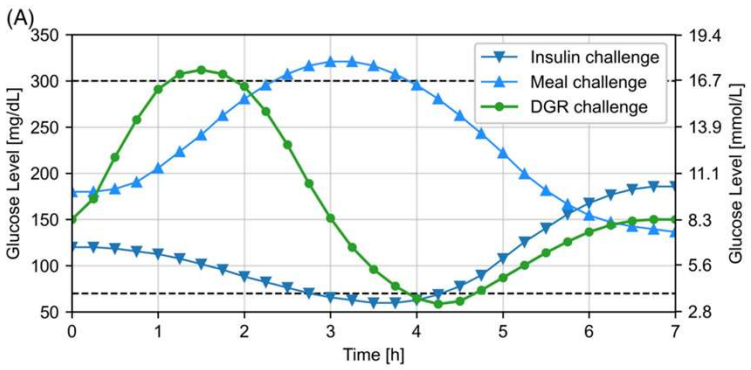
Received: 19 February 2025 | Revised: 3 April 2025 | Accepted: 14 April 2025
DOI: 10.1111/dom.16420

LETTER TO THE EDITOR

WILEY

Proposed minimum requirements for market approval of continuous glucose monitoring (CGM) systems: A viewpoint from the IFCC working group on CGM



Additional points:

- Insulin challenge
- Meal challenge
- Comparator measurement
- Alignment between EU and FDA

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Continuous Glucose Monitoring Systems in Europe: Regulatory Landscape and Certification Process Challenges Under MDR 2017/745

Concetta Irace[1] | Bassil Akra[2]

- *To enable all stakeholders to be informed about the MDs given a CE mark;*
- *To collate and process information about the MD on the market;*
- *To provide oversight of PMS and vigilance data.*

- *To determine the conformity of MD;*
- *To perform technical and clinical evaluation;*
- *To recommend CE marking.*

FIGURE 1 | Summary of the key steps for the CE marking applicable to CGM. MD, medical devices; TD, technical documentation; QMS, quality management system.

Diabetes, Obesity and Metabolism, 2026; 0:1–12
https://doi.org/10.1111/dom.71202

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European Diabetes Forum: EUDF - IDF

- EUDF calls for quality standards for CGM devices to ensure optimal performance and reliability.
- Guaranteeing the quality of Continuous Glucose Monitors in Europe – An IDF Europe position.
- Question for written answer E-004998/2025 to the Commission Ensuring quality and safety of diabetes management devices in the EU.

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The Glucose Never Lies ® Podcast

Ep 35 John Pemberton — CGM Accuracy & Study Design with Prof Othmar Moser

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CGM in Type 2 Diabetes

KEY EASD 2026 ABSTRACTS

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Association of CGM Initiation with Reduced Mortality, Macrovascular Complications, and ADE Hospitalizations Across T2D Populations

Mortality and Macrovascular Outcomes:
CGM vs No CGM at 12 and 24 Months

Outcome	12-month (95% CI)	24-month (95% CI)
All-cause mortality, HR	0.55 (0.43, 0.69)***	0.64 (0.52, 0.78)***
First macrovascular event, HR	0.74 (0.59, 0.93)*	0.75 (0.63, 0.90)**
Recurrent macrovascular events, IRR	0.65 (0.50, 0.85)**	0.64 (0.52, 0.80)***
Myocardial infarction, IRR	0.85 (0.50, 1.43)	0.75 (0.51, 1.10)
Heart failure, IRR	0.46 (0.30, 0.71)***	0.53 (0.37, 0.75)***
Peripheral artery disease, IRR	0.58 (0.32, 1.04)	0.72 (0.42, 1.21)
Stroke/TIA, IRR	0.65 (0.42, 1.00)*	0.61 (0.41, 0.91)*

*Notes: ***p<0.001, **p<0.01, *p<0.05. HR = hazard ratio; IRR = incidence rate ratio; Macrovascular composite consists of myocardial*

Impact of CGM Initiation on Acute Diabetes Event (ADE) Hospitalizations in 12 Months

Patient Group	Number of Patients	ADE Percentage Change
MDI	179,142	2.7% to 1.2% (-56%)
Basal	46,061	1.7% to 0.9% (-47%)
NIT	28,642	4.2% to 0.8% (-81%)

Seufert J, et al. EASD 2026 Guerci B, et al. EASD 2026

Conclusions

CGM initiation in adults with T2D on basal insulin therapy was associated with **significant reductions in all-cause mortality and macrovascular event occurrence.**

Regardless of using MDI, basal, or NIT, the **rate of hospitalization for ADEs also dropped following CGM initiation**.

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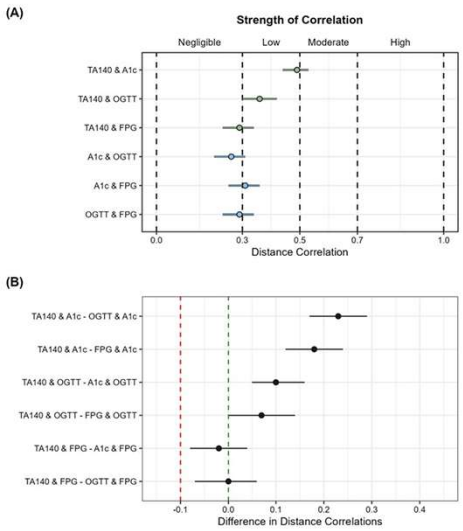
Time Above 140 mg/dL Outperforms Traditional Glycaemic Tests in Reflecting Inter-Test Alignment



Bergenstal RM, et al. EASD 2026

Conclusion

When a single metric is desired to summarize overall glycemic control, **time above 140 mg/dL provides a practical alternative to relying on A1c, OGTT or FPG alone**.

In this CGM study, **time above 140 mg/dL aligns with traditional pre-DM tests as well as, or better than, the tests align with one another**.

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Time in Tight Range is Superior to HbA1c at Assessing Early Glucose Abnormalities: Implications for Clinical Practice

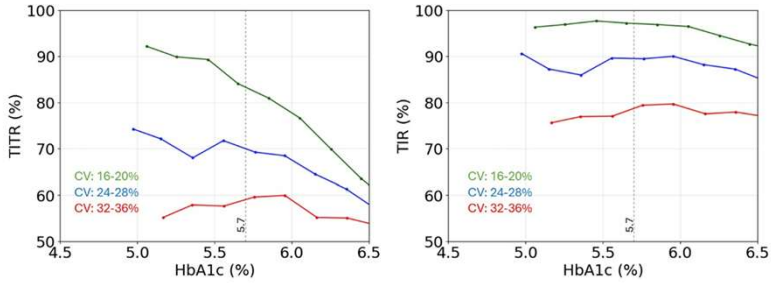

Figure 1. HbA1c associations with time in tight range (TITR; left) and time in range (TIR; right) in three glucose coefficient variation (CV) groups. TIR shows a plateau effect in the normoglycaemia and prediabetes range, until TITR.

Ajjan R, et al. EASD 2026

Conclusion

TITR demonstrates strong sensitivity in the prediabetes range, while TIR is unable to identify individuals with early dysglycaemia.

In those with high CV, indicating abnormal glucose metabolism, TITR decreases, while uGMI and HbA1c can remain in the normal glycaemic range.

Taken together, **TITR is superior to TIR, HbA1c and uGMI at assessing early/mild glucose abnormalities**.

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Conclusions

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CGM for T2D in the Setting of Basal Insulin & SGLT2/GLP-1 The FreeDM2 Study

Dr Emma Wilmot
Associate Professor
University of Nottingham
Honorary Consultant
University Hospitals of Derby & Burton NHS FT
Founder, ABCD Diabetes Technology Network UK

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Disclosures

- Dr Emma Wilmot has received fees and/or honoraria from Abbott, AstraZeneca, Dexcom, Eli Lilly, Embecta, Insulet, Medtronic, Novo Nordisk, Roche, Sanofi, Sinocare, Tandem, Ypsomed and research support from Abbott, Embecta, Insulet, Novo Nordisk, Sanofi.

- The FreeDM2 study was sponsored by Abbott Diabetes Care.

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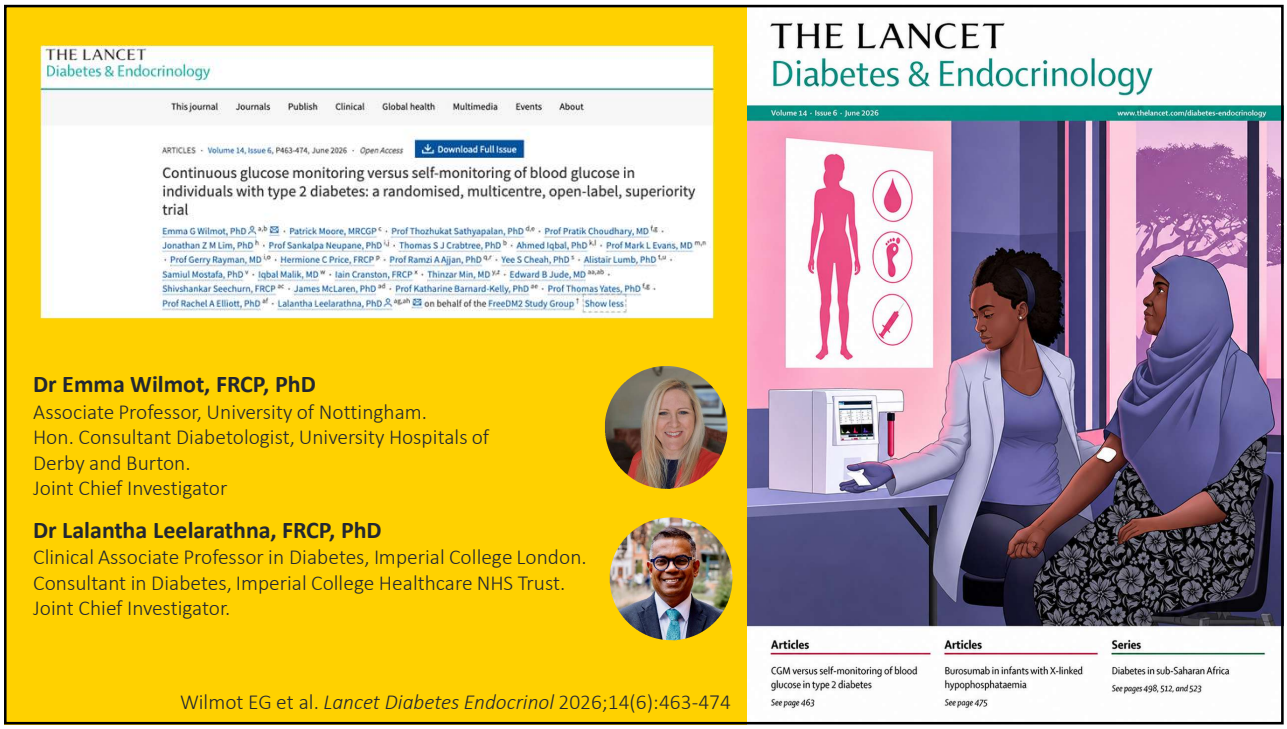

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Rationale for FreeDM2

Individuals treated with basal insulin, SGLT2i and GLP-1 RA therapy represent a **significant proportion** of those living with **T2DM**.

Despite combination therapy, many **do not** achieve **glycaemic targets**.

There is a **lack** of high quality RCT evidence supporting the use of **CGM** in people with T2DM treated with **basal insulin** combined with **modern therapies.**

Our **understanding** of **behavioral changes** associated with CGM use are limited.

Aim

To determine whether use of FreeStyle Libre 3 CGM system improves HbA1c over 32 weeks compared to SMBG in adults with suboptimal glycaemia

Wilmot EG et al. *Lancet Diabetes Endocrinol* 2026;14(6):463-474

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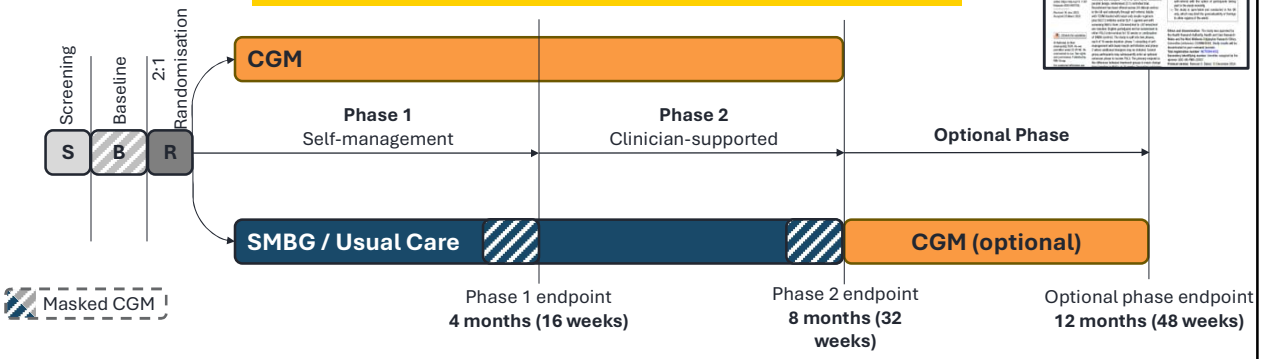
Study Design

UK study: recruitment from 24 secondary & primary care centres & nationally via self-referral.

Key inclusion criteria
- Adults with T2DM
- Basal-only insulin plus SGLT2i and/or GLP-1 or GIP/GLP-1 RA
- HbA1c ≥59 and ≤97 mmol/mol (≥7.5 and ≤11.0%)



Wilmot EG et al. *BMJ Open* 2025;15:e090154 | NCT05944432

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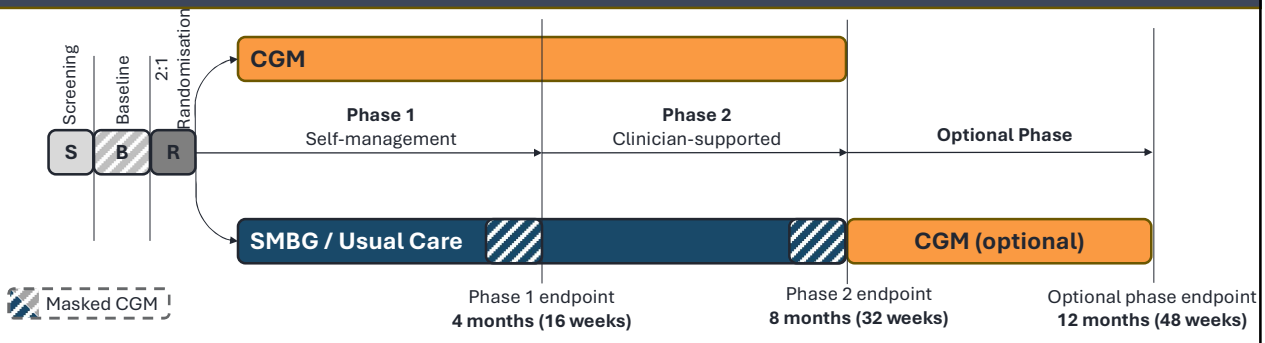
Analysis Endpoints



Primary endpoint
Between group difference in HbA1c change at 16 weeks

Key secondary endpoint
Between group difference in HbA1c change at 32 weeks

Other Secondary endpoints
- CGM metrics
- Accelerometer data
- PROMs (including GMSS, UKDDQ, HCS, HFS-II)
- Changes to insulin doses and non-insulin medications
- Safety
- Qualitative interviews

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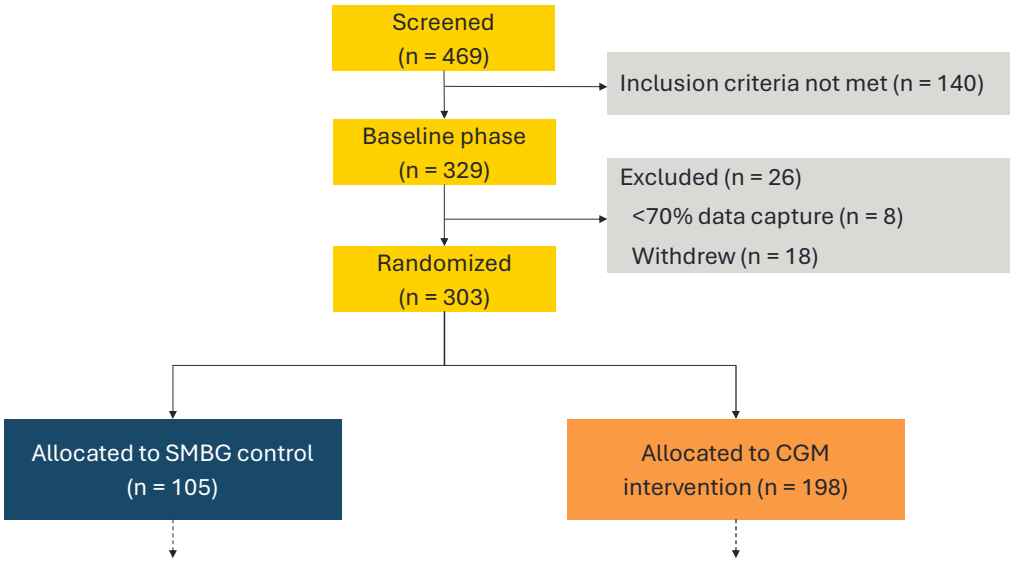
Participant Flow



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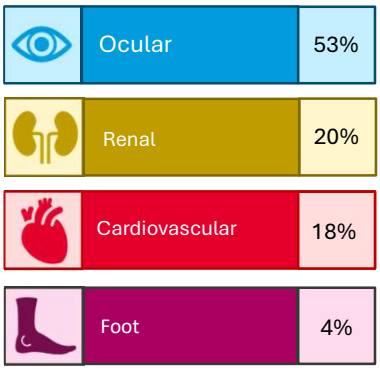
Baseline Data
Demographics and Medical History

Demographic	All (n=303)	SMBG Control (n=105)	CGM (n=198)
Age, years	60.7 ± 9.8	59.8 ± 9.1	61.2 ± 10.2
Male sex, %	67.3	68.6	66.7
BMI, kg/m^2	31.1 ± 5.6	31.3 ± 5.7	31.0 ± 5.6
Diabetes duration, years	16.7 ± 6.9	15.9 ± 7.4	17.1 ± 6.6

Mean ± SD unless stated otherwise

Diabetes related complications at baseline



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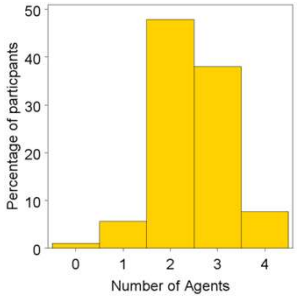
Baseline Data
Medication History

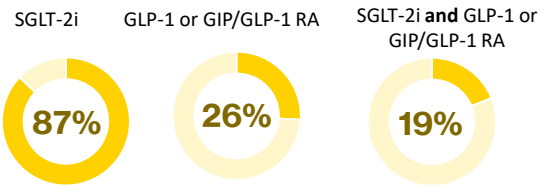
Drug class	All (n=303)	SMBG Control (n=105)	CGM (n=198)
Insulin			
Total daily insulin dose			
Units	34.1 ± 25.4	35.5 ± 32.8	33.3 ± 20.4
Units/kg	0.36 ± 0.23	0.37 ± 0.27	0.36 ± 0.21
Non-insulin medications prescribed at baseline			
SGLT-2 inhibitors, %	87	86	88
Metformin, %	86	82	88
Sulphonylureas, %	33	33	33
Incretins^, %	37	37	36

mean± SD unless stated otherwise
^includes GLP-1- based therapies plus gliptins

Number of agents



SGLT-2i combined with GLP-1- based therapy



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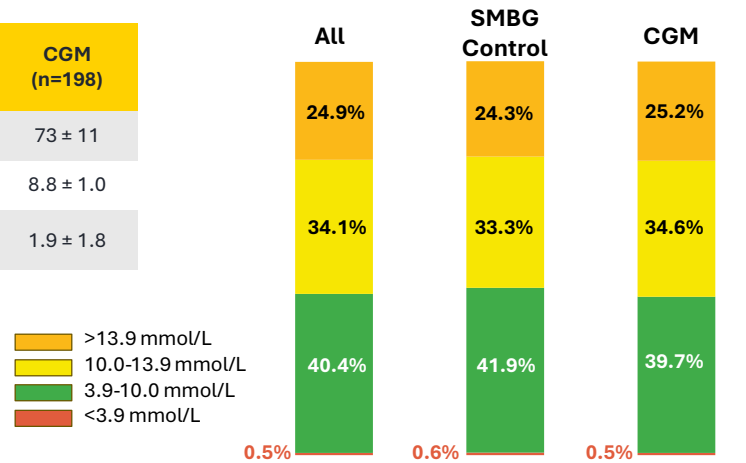
Baseline Data
Glycaemia

Parameter	All (n=303)	SMBG Control (n=105)	CGM (n=198)
HbA1c, mmol/mol	73 ± 11	73 ± 11	73 ± 11
HbA1c, %	8.8 ± 1.0	8.8 ± 1.1	8.8 ± 1.0
Daily fingerstick frequency	2.0 ± 1.9	2.1 ± 2.0	1.9 ± 1.8

mean± SD unless stated otherwise

Mean % time in glucose ranges at baseline



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CGM in Type 2 Diabetes

CHANGE IN HbA_1c
PRIMARY AND KEY SECONDARY OUTCOME

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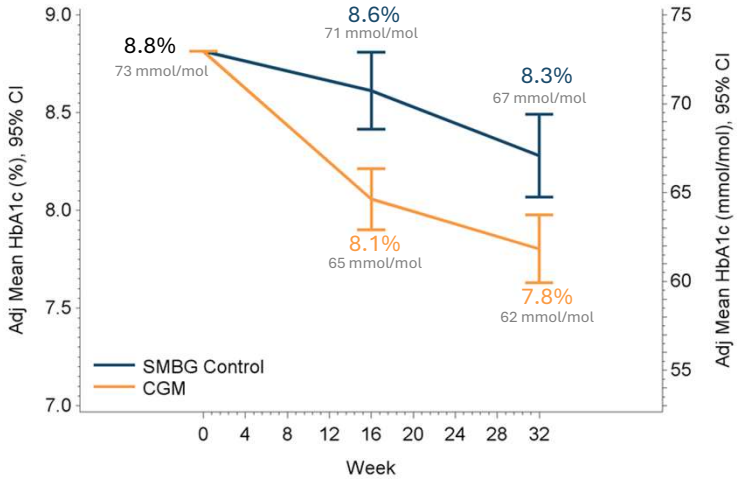
Change in HbA1c
Primary and Key Secondary Outcome

	Adjusted mean difference (95%CI)
4 months	**-0.6%** (-0.77, -0.34) [-6mmol/mol] **p<0.0001**



Treatment groups compared using a linear mixed model with baseline HbA1c as a fixed effect and site as a random effect.

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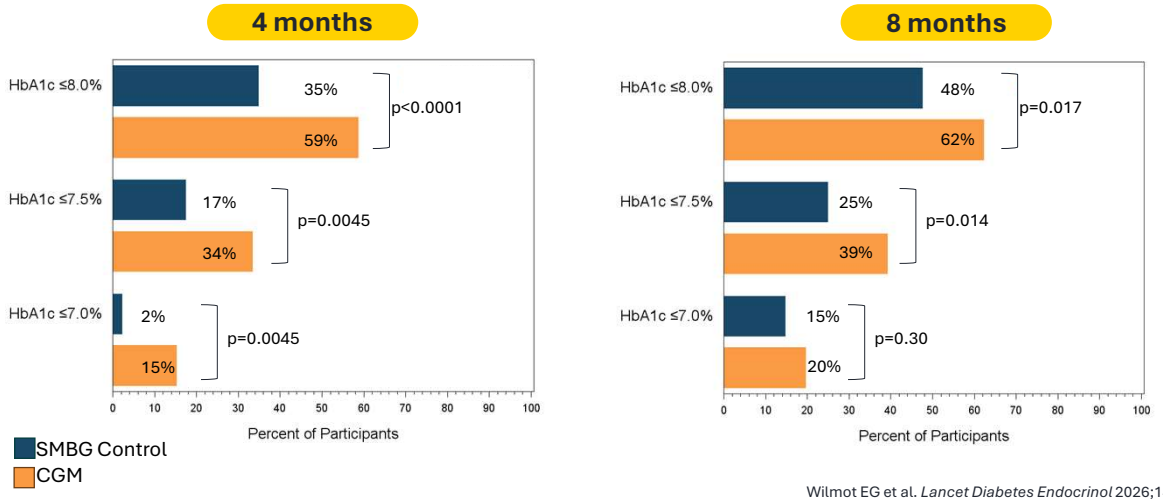
HbA1c Analysis
Achievement of argets



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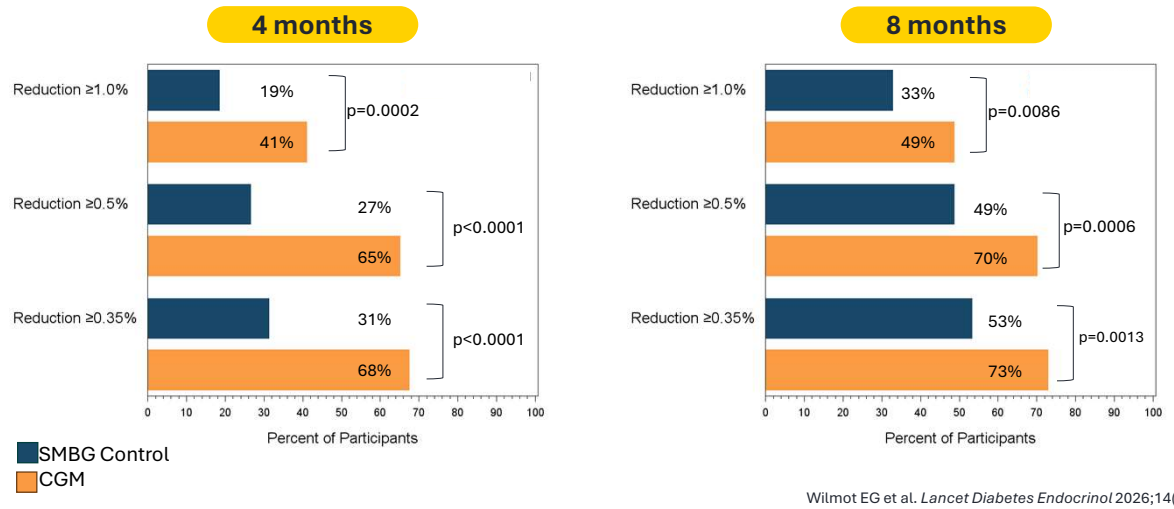
HbA1c Analysis
Magnitude of Improvements



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CGM in Type 2 Diabetes

SENSOR-BASED METRICS

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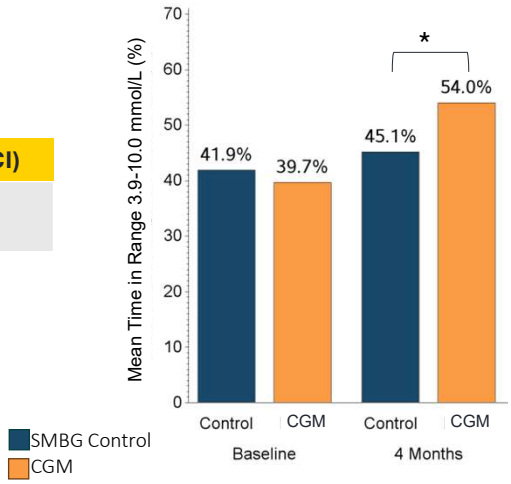
Sensor-Based Metrics
Time in Range 3.9-10.0 mmol/L (70-180 mg/dL)

	Adjusted mean difference (95%CI)
4 months	**+10.4%** (5.4, 15.4) [+2.5h/day] **p<0.0001***



*: p<0.05

Wilmot EG et al. *Lancet Diabetes Endocrinol* 2026;14(6):463-474

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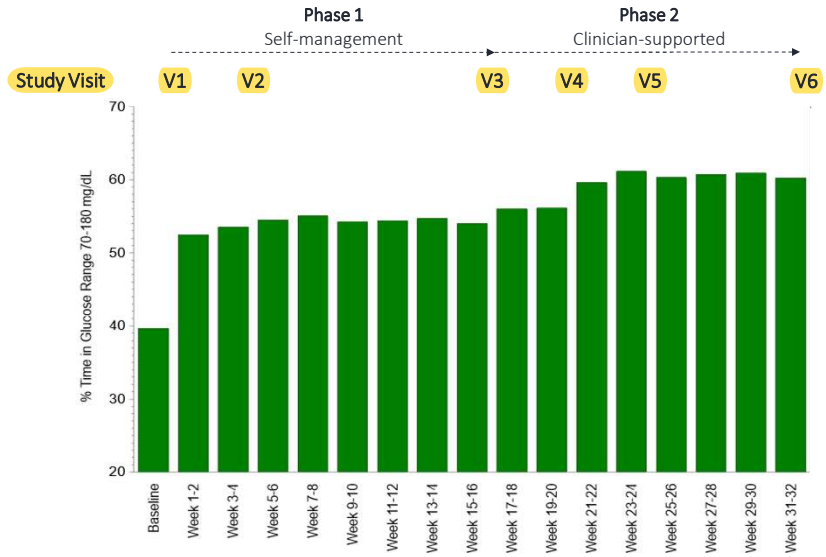
Sensor-Based Metrics
Speed of Improvements in Time in Range



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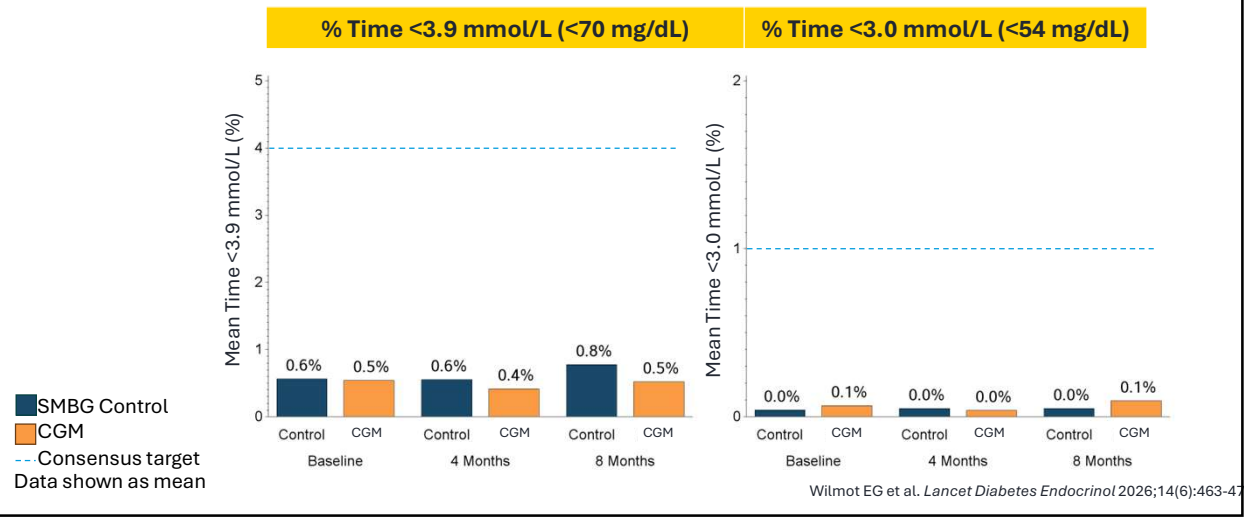
Sensor-Based Metrics
Time Below Range



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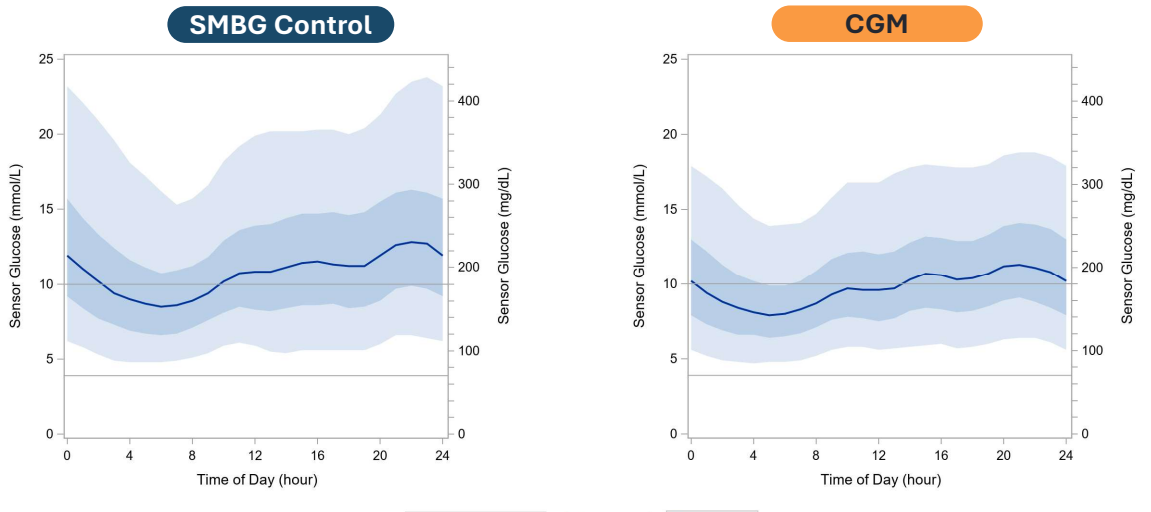
Sensor-Based Metrics
24-hour Glucose Profile at 4 Months



Wilmot EG et al. *Lancet Diabetes Endocrinol* 2026;14(6):463-4

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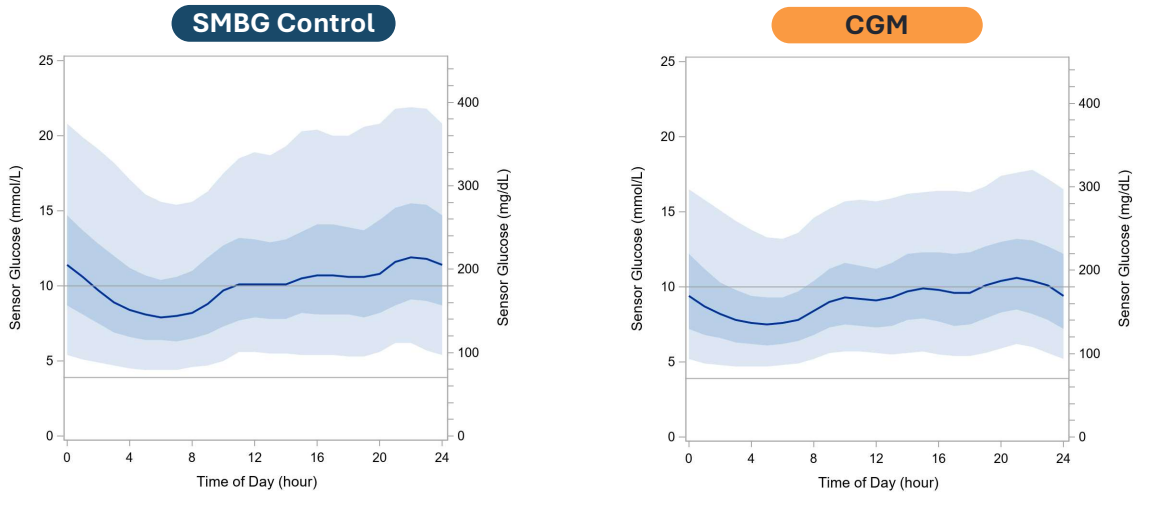
Sensor-Based Metrics
24-hour Glucose Profile at 8 Months



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CGM in Type 2 Diabetes

MEDICATION CHANGES

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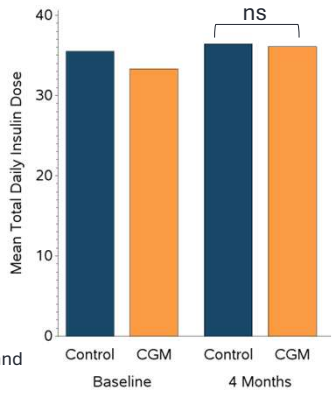
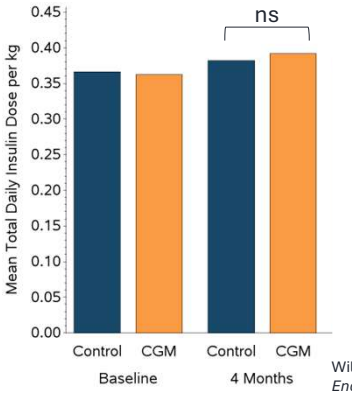
Medication Changes

Changes to Total Daily Insulin Dose

	Total daily insulin dose†, units	Total daily insulin dose†, units/kg
	4 months	4 months
Adjusted mean difference (95%CI)	-0.1 units (-2.7, 2.5) p=0.92	-0.01 units/kg (-0.03, 0.02) p=0.69





SMBG Control
CGM
ns: p≥0.05
†: Includes basal and bolus doses

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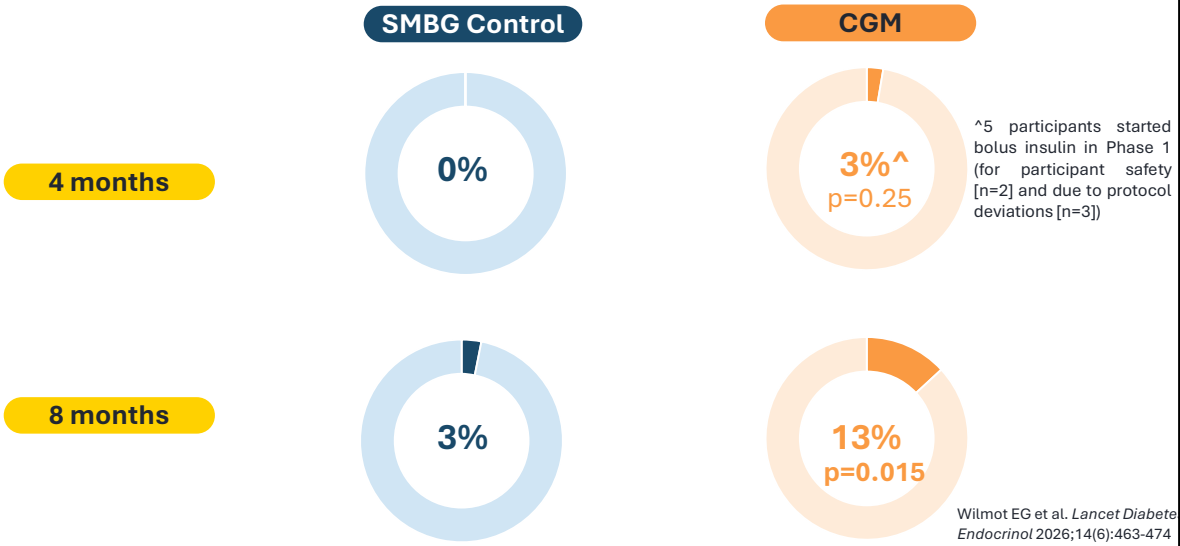
Medication Changes
% of Participants Starting Bolus Insulin



^5 participants started bolus insulin in Phase 1 (for participant safety [n=2] and due to protocol deviations [n=3])

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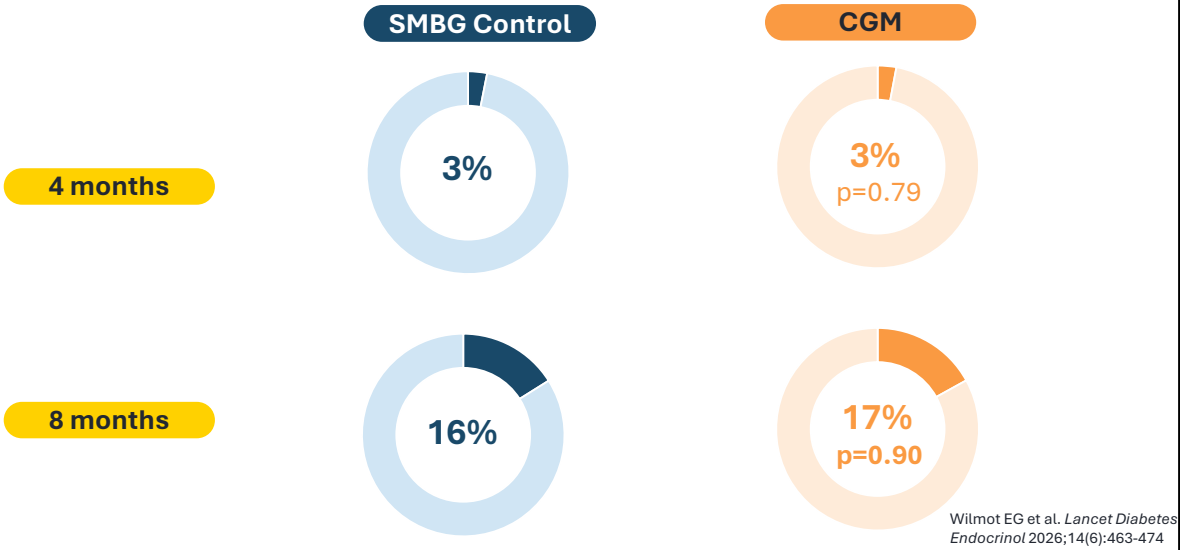
Medication Changes
% of Participants Initiating New Non-Insulin Glucose Lowering Medications



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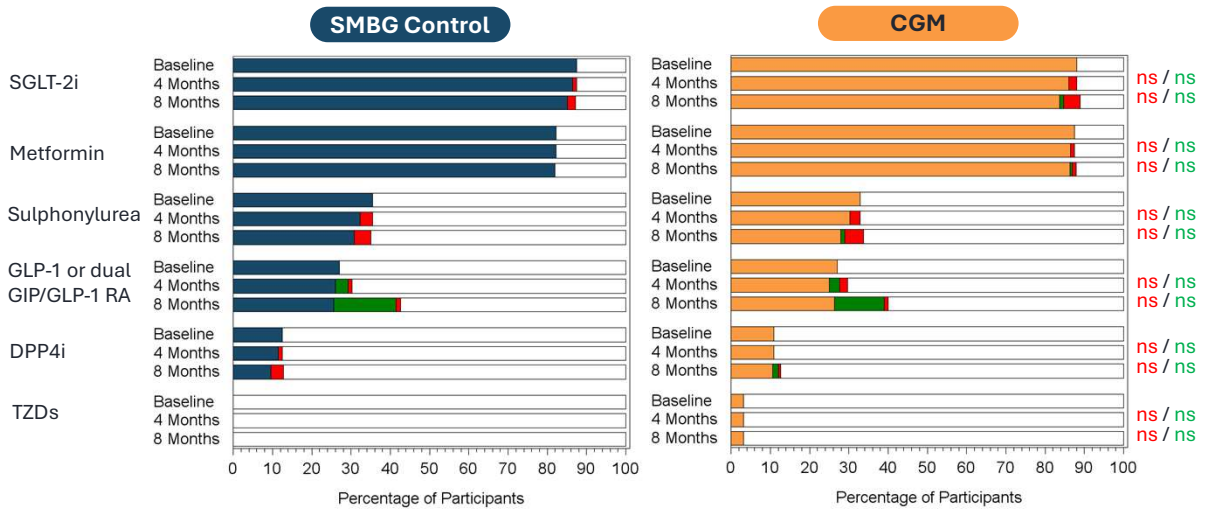
Medication Changes

No Significant Between-Group Changes in Each Non-Insulin Medication Class



ns/ns: : p≥0.05 for difference in proportion of participants stopping/starting.

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CGM in Type 2 Diabetes

PROMs AND PHYSICAL ACTIVITY

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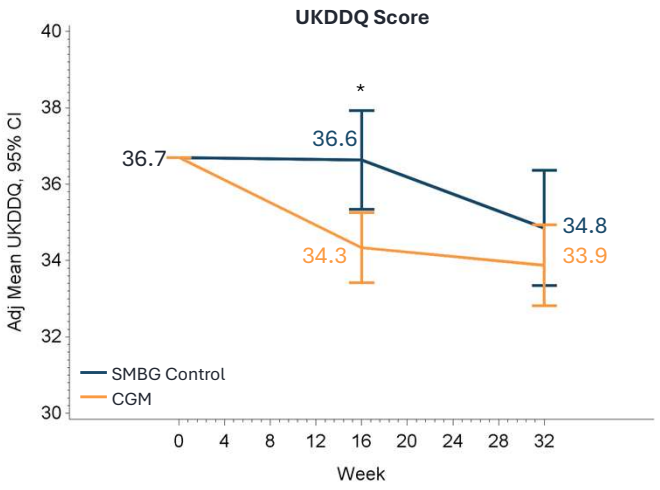
Changes to Diet
UK Diabetes & Diet Questionnaire (UKDDQ)[1]

21-item tool to assess dietary habits important in T2DM.

- Assesses frequency and type of food consumption (e.g. cakes, fruits/ vegetables, processed foods, alcohol etc).

	Adjusted mean difference (95%CI)
4 months	**-2.3** (-3.9, -0.7) **p=0.0047***
8 months	**-1.0** (-2.8, 0.9) p=0.30

Score range: 0 – 105
Lower score = better dietary habits.
*:p<0.05



1: England CY et al. *Public Health Nutr* 2017;20(2):191–9

Wilmot EG et al. *Lancet Diabetes Endocrinol* 2026;14(6):463-47

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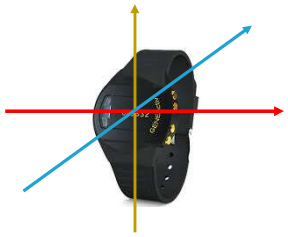
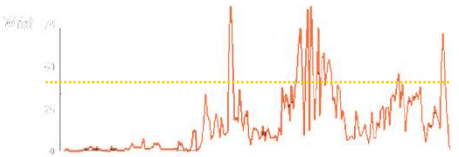
Physical Activity
Methodology

- Assessed at baseline, 16- and 32- weeks.
- GENEActiv triaxial accelerometers worn for 2-week periods.
- Metrics describing behaviours across the 24-hour day were extracted.
- 1 milligravitational unit (mg) recognised as the minimum clinically important difference (MCID)[1].





Example accelerometer trace

Prof Tom Yates
Professor in Physical Activity & Health
University of Leicester, UK

1: Rowlands A et al. *Br J Sports Med* 2021;55:814-815

Wilmot EG et al. *Lancet Diabetes Endocrinol* 2026;14(6):463-474

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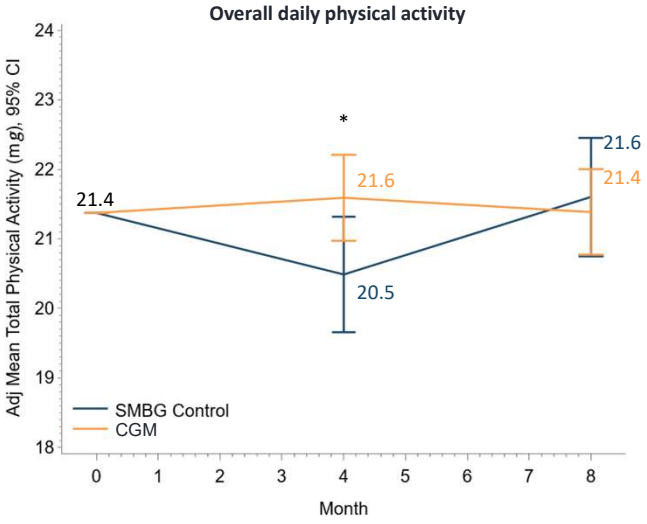
Physical Activity
Overall Daily Activity

Outcome	Month	Adjusted mean difference (95% CI)	P value
Overall daily activity, mg	4	**1.1** (0.1, 2.1)	**0.037***
	8	-0.2 (-1.3, 0.8)	0.69
Moderate-vigorous activity, min/day	4	1.4 (-3.2, 6.0)	0.54
	8	-3.5 (-8.3, 1.2)	0.14
Light-intensity activity, min/day	4	**12.1** (0.3, 23.9)	**0.045***
	8	5.5 (−6.5, 17.6)	0.37
Inactive, min/day	4	-0.4 (-16.8, 16.0)	0.96
	8	1.4 (-17.3, 20.2)	0.88

mg: milligravitational units
*: p<0.05



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PROMs & Qualitative Interviews

Outcome	Month	Adjusted mean difference (95% CI)	P value
Glucose Monitoring Satisfaction Survey,[1] total scale	4	**0.75** (0.60, 0.91)	**<0.0001***
	8	**0.69** (0.53, 0.86)	**<0.0001***
Hypoglycaemia Confidence Scale,[2] mean score	4	**0.24** (0.10, 0.37)	**0.0006***
	8	**0.17** (0.03, 0.31)	**0.018***
Hypoglycaemia Fear Survey-II,[3] mean score	4	-1.9 (-5.0 1.2)	0.23
	8	-2.0 (-5.4, 1.5)	0.27

fear
*: p<0.05

CGM group at 8 months

It makes life **more manageable**, more normal … it definitely impacts my quality of life

I've **changed how I eat**, I was snacking a lot between meals but I learned a lot about food, what food does to blood sugars …

I'm anxious about the study ending and **not having access** anymore…

Wilmot EG, et al. *Lancet Diabetes Endocrinol.* 2026

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FreeDM2 Conclusions

The use of real-time CGM by people living with T2DM on basal insulin led to a clinically and statistically **significant improvement in HbA1c** vs control at 4 and 8 months

- **Significant improvements** in **sensor-measured** glycaemia and **participant reported outcomes** were also observed.
- Improvements were achieved **without** increased hypoglycaemia.
- Improvements were observed with **self-management** and **sustained** following **clinician intervention.**

Wilmot EG et al. *Lancet Diabetes Endocrinol* 2026;14(6):463-47

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CGM in Type 2 Diabetes

CLINICAL CASES

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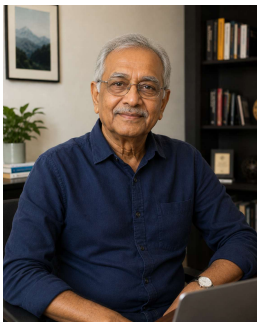
Clinical Case Study #1

75 year old male

Medical history	Type 2 diabetes for 26 years
Profile	BMI 25kg/m^2 Diabetes Tx
Management	•MF 1g BD •Empagliflozin 10mg OD •Humulin I, 22 units morning, 9 units evening •Check glucose once daily •HbA1c 8.2%



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Glucose Data: SMBG

	Pre-breakfast	Pre-lunch	Pre-dinner	Pre-bed
Sunday	11.2			
Monday	9.3			
Tuesday	8.9			
Wednesday	12.5			
Thursday	10.9			

Humulin I insulin doses are 22 units morning, 9 units in the evening. What are your recommendations for insulin titration?

1) Increase evening dose
2) Increase morning dose
3) Increase both morning and evening dose
4) Add in prandial insulin
5) No changes, more glucose data is needed

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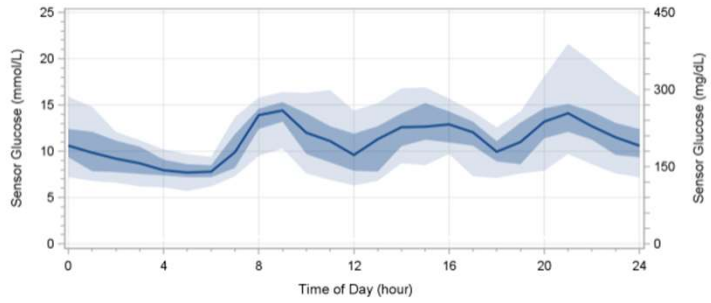
Glucose Data: CGM and SMBG

	Pre-breakfast	Pre-lunch	Pre-dinner	Pre-bed
Sunday	11.2			
Monday	9.3			
Tuesday	8.9			
Wednesday	12.5			
Thursday	10.9			



Insulin doses are 22 units morning, 9 units in the evening. Now, what are your recommendations for insulin titration?

1) Increase evening dose
2) Increase morning dose
3) Increase both morning and evening dose
4) Add in prandial insulin
5) No changes, more glucose data is needed

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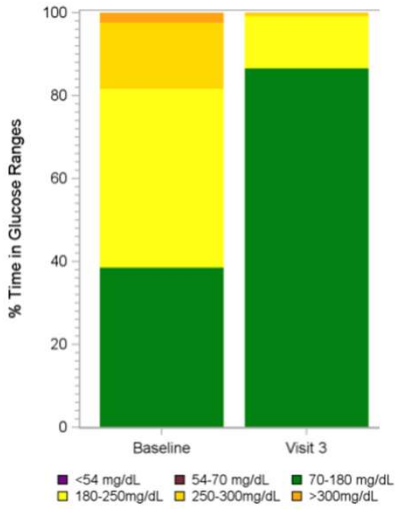
4 Month Review

- Access to CGM has altered behaviour and glycaemic outcomes
- HbA1c has improved from 8.2% to 6.4%
- Has altered diet
  - Avoiding food which spike glucose
  - Reduced portion sizes
- Looks at glucose data often – finds it useful
- Increased morning insulin by 2 units



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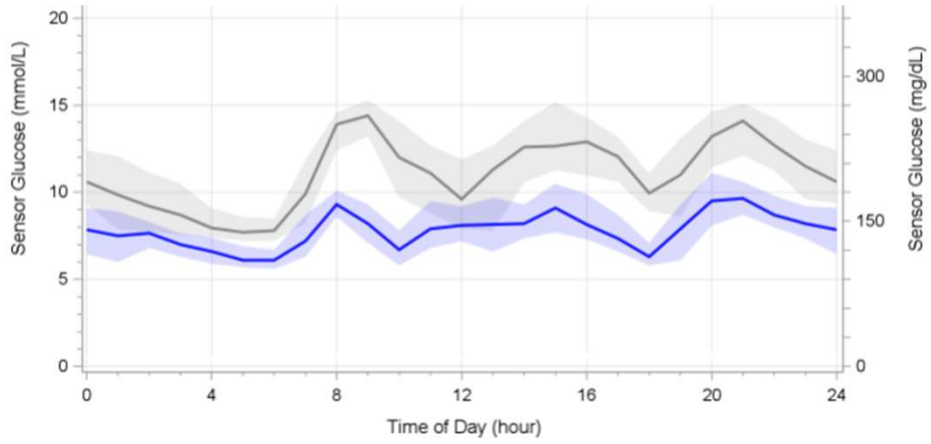
By 4 Months



TIR improved from 39 to 87%

HbA1c 6.4%

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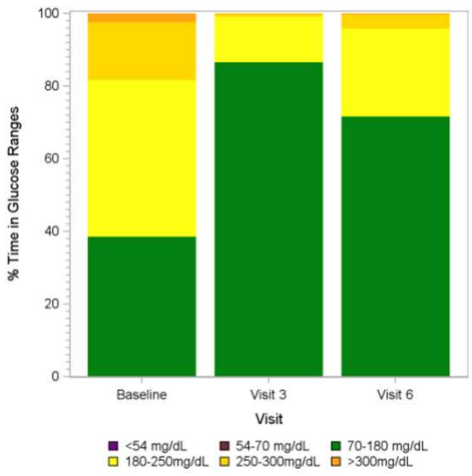
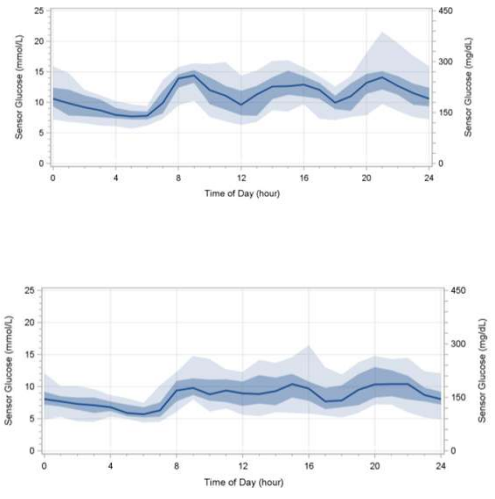
8 Months HbA1c 6.8%





HbA1c 8.2%

TIR 39%

HbA1c 6.8%

TIR 72%

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Clinical Case Study #2

52 year old female

Medical history	Type 2 diabetes, smoker
Profile	• BMI 29kg/m2 • HbA1c 9.6% (chronically elevated) • Only checks blood glucose for a few days before diabetes clinic
Management	• Humulin i 19u BD • Empagliflozin 25mg OD • Declined statin, intolerant metformin & GLP-1

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Glucose Data (HbA1c 9.6%)

	Pre-breakfast	Pre-lunch	Pre-dinner	Pre-bed
Sunday	4.9			
Monday	5.2			
Tuesday				
Wednesday	6.3			
Thursday	5.1			

Question: How will you alter the insulin dosing (Humulin i 19 units BD)?

1) Increase the morning dose
2) Increase the evening dose
3) Add in prandial insulin
4) Wait for more blood glucose data first
5) Wait and give a trial of rtCGM first

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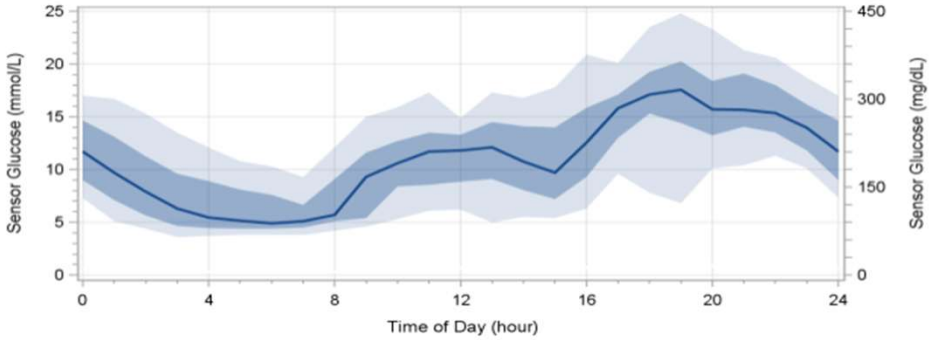
CGM Insights…

	Pre-breakfast	Pre-lunch	Pre-dinner	Pre-bed
Sunday	4.9			
Monday	5.2			
Tuesday				
Wednesday	6.3			
Thursday	5.1			



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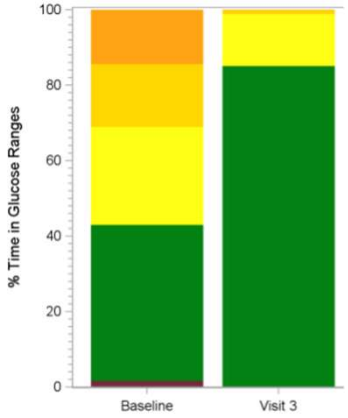
By 4 Months

- Patient used rtCGM for 4 months
- Gained insight into the impact of foods on her glucose levels
- Made changes to her diet: avoiding chocolates, sweets and eating less bread
- By 4 months she had reduced her insulin dose from 19u BD to 14u BD
- Time in Range improved from 41 to 85%
- HbA1c improved from 9.6% to 6.9%



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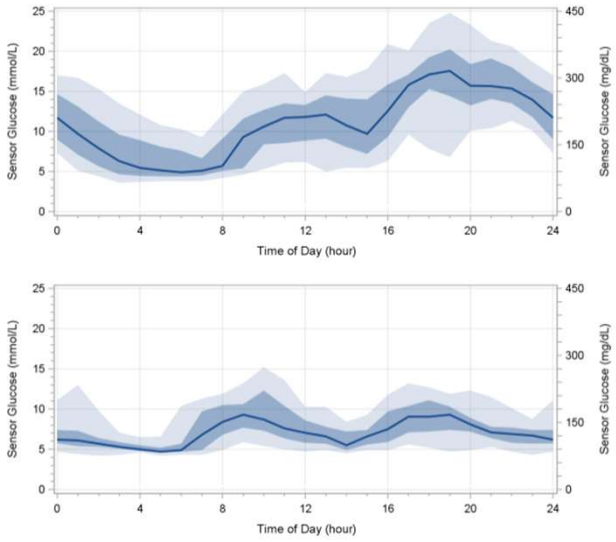
4 Months Later



HbA1c 9.6%
TIR 41%

HbA1c 6.9%
TIR 85%

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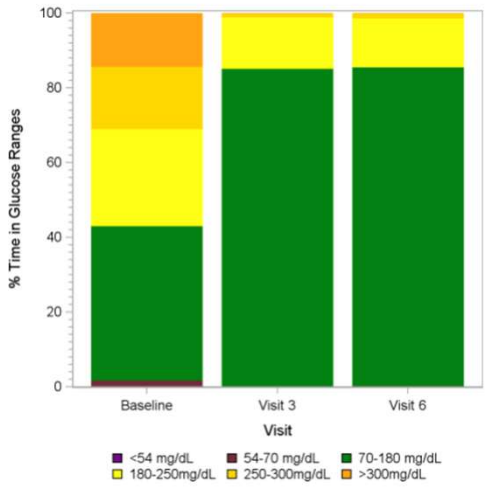
After 8 Months of rtCGM

- By 8 months she had further reduced her insulin dose to 10 units morning, 12 units at night
- Sustained improvements in dietary intake
- Time in Range 85%
- HbA1c improved
  - 9.6% at start
  - 6.9% at 4 months
  - 6.5% at 8 months
  - 6.6% at 12 months
- Weight reduced 96 to 87kg



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Conclusions

CGM in people living with T2DM improves **HbA1c**

- The visualisation of real-time CGM data supports people with diabetes to achieve better outcomes
- Access to CGM in those with T2DM remains a post code lottery
- There is a need to address the barriers to inequitable access to CGM technology

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Acknowledgements

Collaborators and Specialist Advisors

Dr Richard Bergenstal, International Diabetes Centre.
Prof Rachel Elliott, University of Manchester (Health Economics).
Prof Thomas Yates, NIHR Leicester BRC (Physical Activity).
Prof Katharine Barnard-Kelly, Barnard Health Ltd (Psychosocial analysis).
Dr Fraser Gibb, University of Edinburgh.

Participant Identification Centres

For their valuable support in identifying potential participants for this study.

Trial Steering Committee

Prof Rory McCrimmon, University of Dundee and all members of the trial steering committee.

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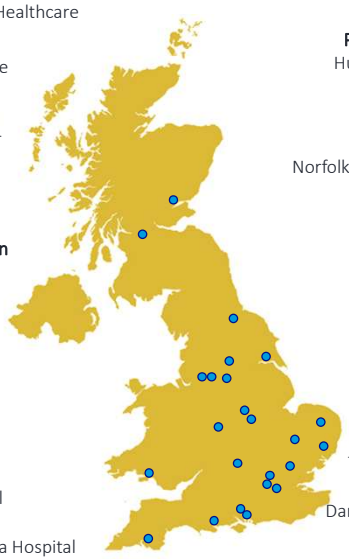

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Norfolk & Norwich Univ. Hospitals
Prof Mark Evans
Addenbrooke's Hospital
Dr Hermione Price
Southern Health
Dr Yee Cheah
King's College Hospital
Dr Samiul Mostafa
Univ. Hosp. Birmingham
Dr Iain Cranston
Queen Alexandra Hospital
Dr Edward Jude
Tameside General Hospital
Dr Shafie Kamaruddin
Darlington Memorial Hospital
Dr James McLaren
NHS Lanarkshire
Dr Shivshankar Seechurn
Northwick Park Hospital

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THANK YOU

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Post-Program Assessment Question #1

Based on my new understanding after participating in this program, I would **now initiate CGM monitoring** in the following persons with T2D who are on basal insulin and SGLT2 inhibitors and/or incretin therapy:

1) All persons with T2D who are on basal insulin and SGLT2i and/or incretin therapy
2) An overwhelming majority of such persons
3) About 50% of such persons
4) Less than 50% of such persons

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Post-Program Assessment Question #2

Based on my understanding, after participating in this program, of dual sensing technology that continuously monitors glucose and ketone levels, I now believe **this recently approved innovation should become an integral part of managing persons with diabetes**.

1) Very strongly agree
2) Strongly agree
3) Agree
4) Somewhat agree
5) Disagree

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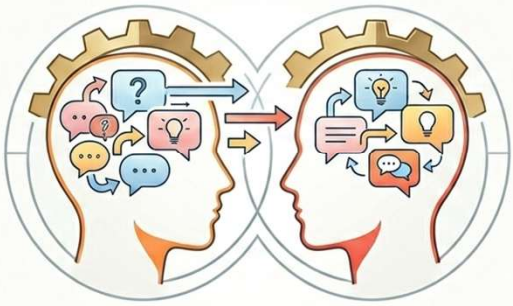
INTERACTIVE DIALOGUE SESSION



Your Questions, Perspectives, and Discussion Points

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