University of Nottingham
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NHS
University Hospitals of Derby and Burton
NHS Foundation Trust

CGM accuracy

Dr Emma Wilmot

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Founder, ABCD Diabetes Technology Network UK

Disclosures

- **Emma Wilmot** has received personal fees 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.

Overview

- Reflect on the CGM journey

- Key considerations with CGM accuracy
  - CE Marking
  - Study design importance
  - Limitations of MARD
  - Quality standard

- CGM Accuracy: The future

Scenario

- John comes into clinic to see you
- He has T1DM on multiple daily injections
- He is trialing a new CGM he was offered via an internet advert
- He likes it and asks you if you can make it available locally
- What is your approach?

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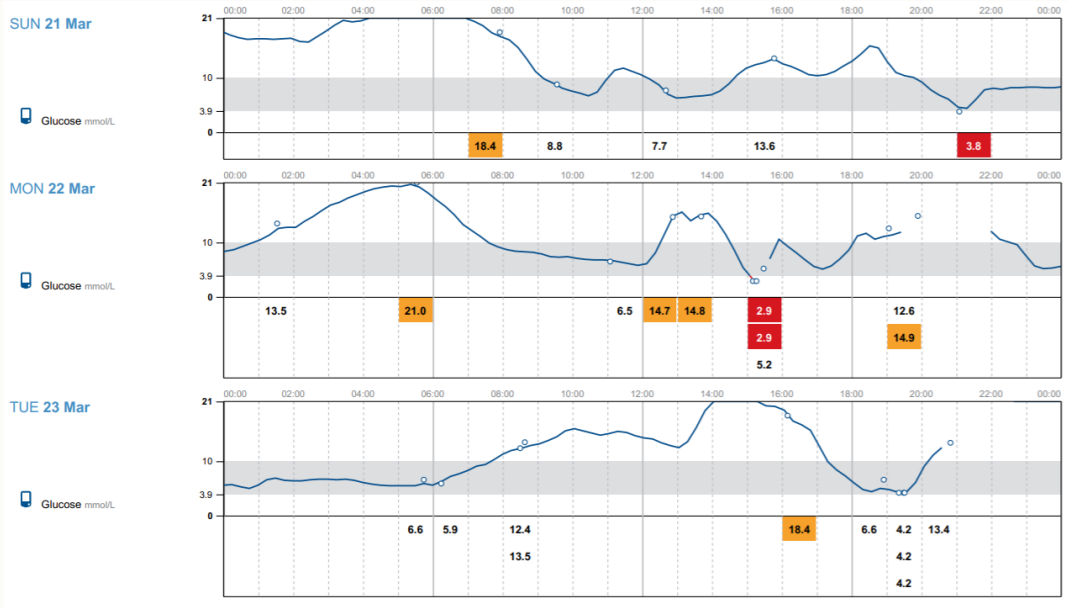
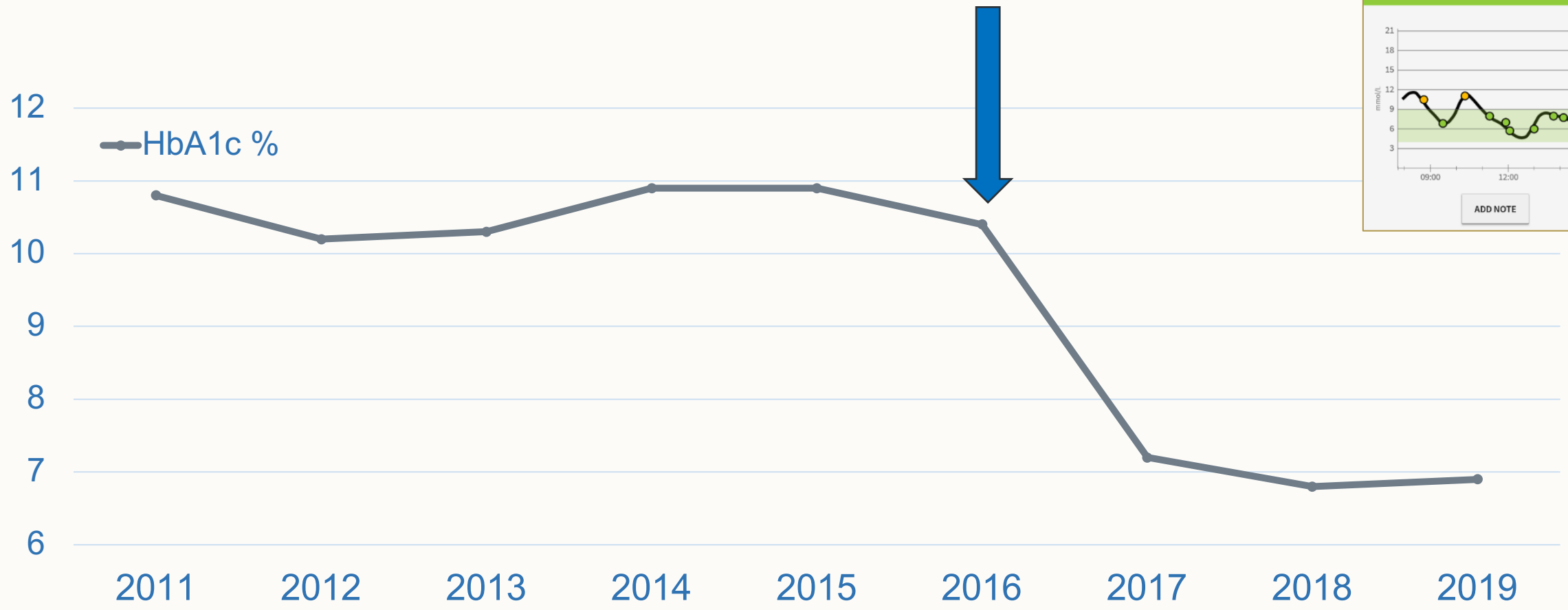
Type 1 diabetes:
The most challenging long-term condition to self-manage

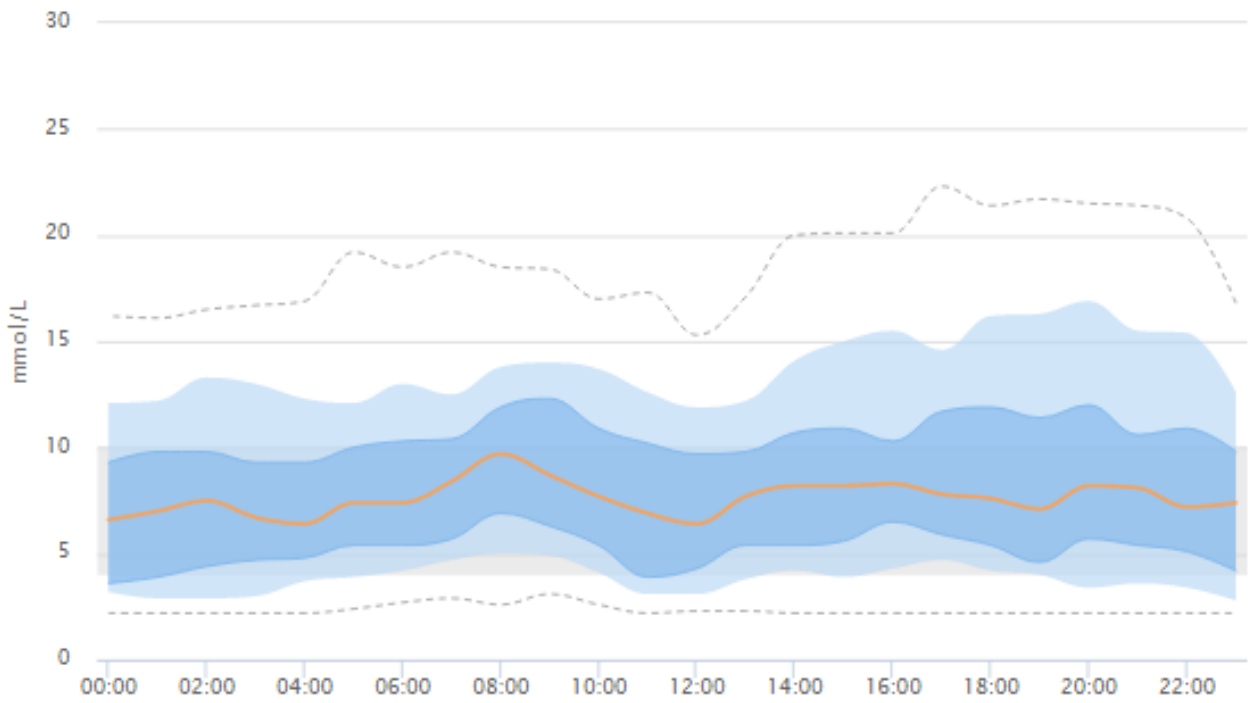
A journey with new technology

- Male with T1DM, disengaged with his diabetes
- Very high glucose levels for past 5 years
- Foot ulcers, charcot, retinopathy
- Clinic 2016 keen to re-engage in his care, rebuild confidence
- HbA1c 10.3%, not monitoring
- Between clinics started to self-fund iCGM….



HbA1c improvement





Show active basal profile

Number of values:	**5059**	Values above goal (10 mmol/L):	**1470**	Highest value (mmol/L):	**22.3** (15/08/2016 17:55)
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Period average (mmol/L):	**8.2**	Values below goal (4 mmol/L):	**669**	Standard deviation:	**3.9**

Took on a 2nd job delivering papers to be able to fund access to sensors

The Flash Glucose Monitoring Journey

2015
Flash available to self fund

2016
Impact RCT published

2017
Fight for Flash Campaign
Limited funding

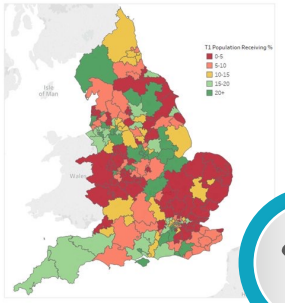
2018
Postcode lottery in access

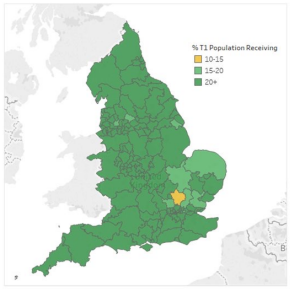
2019
NHSE national criteria launched
DTN-UK online modules

2020
1/3 of T1DM population have access
ABCD audit data published

The FreeStyle Libre reader

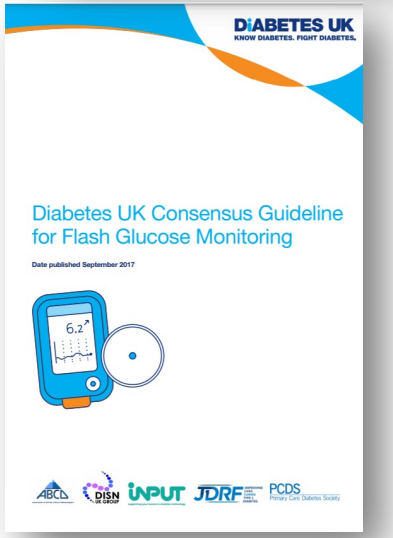

The FreeStyle Libre sensor





NHS

Flash Glucose Monitoring: National Arrangements for Funding of Relevant Diabetes Patients



Novel glucose-sensing technology and hypoglycaemia in type 1 diabetes: a multicentre, non-masked, randomised controlled trial

Jan Bolinder, Ramiro Antuna, Petronella Geelhoed-Duijvestijn, Jens Kröger, Raimund Weitgasser

https://www.diabetescare.abbott/support/manuals/uk.html
FreeStyle Libre system user guide

Real World Data

5.2 mmol/mol (0.5%) HbA1c (P<0.001)

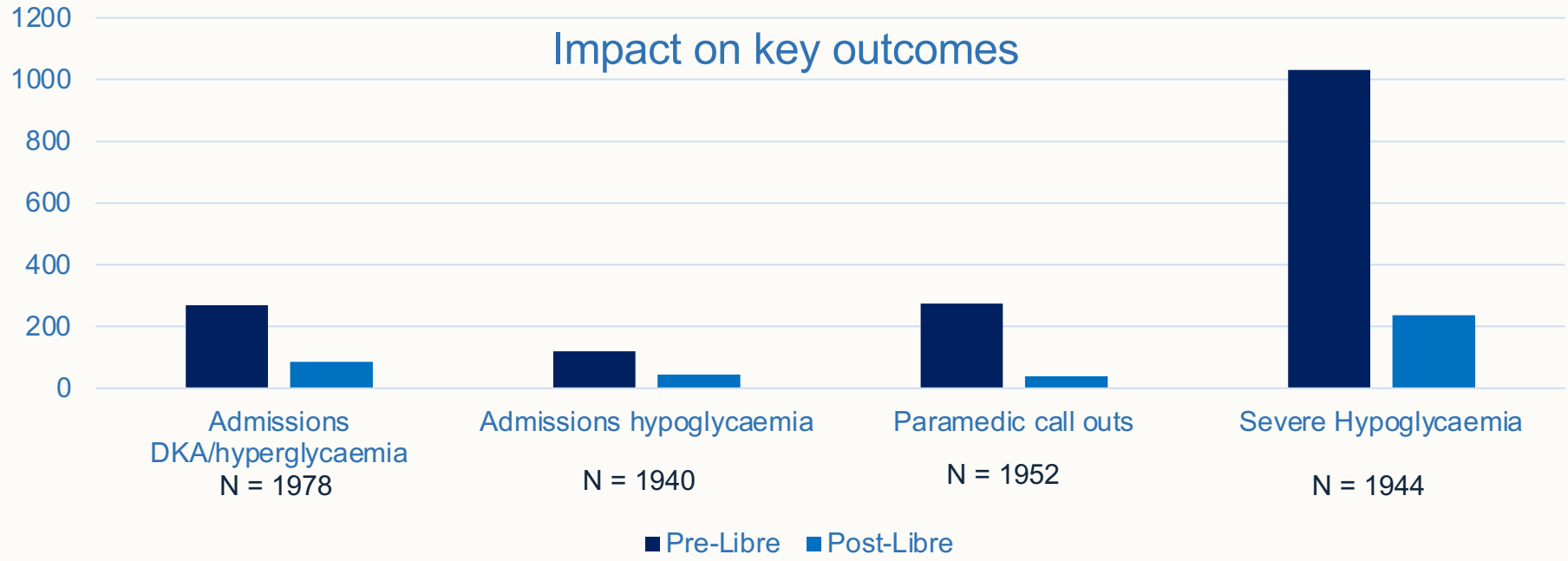
N=3182

Diabetes Care Volume 43, September 2020 2153

Effect of Flash Glucose Monitoring on Glycemic Control, Hypoglycemia, Diabetes-Related Distress, and Resource Utilization in the Association of British Clinical Diabetologists (ABCD) Nationwide Audit

Harshal Deshmukh,[1] Emma G. Wilmot,[2] Robert Gregory,[3] Dennis Barnes,[4] Parth Narendran,[5] Simon Saunders,[6] Niall Furlong,[7] Shafie Kamaruddin,[8] Rumaisa Banatwalla,[9] Roselle Herring,[10] Anne Kilvert,[11] Jane Patmore,[1] Chris Walton,[1] Robert E.J. Ryder,[12] and Thozhukat Sathyapalan[1]

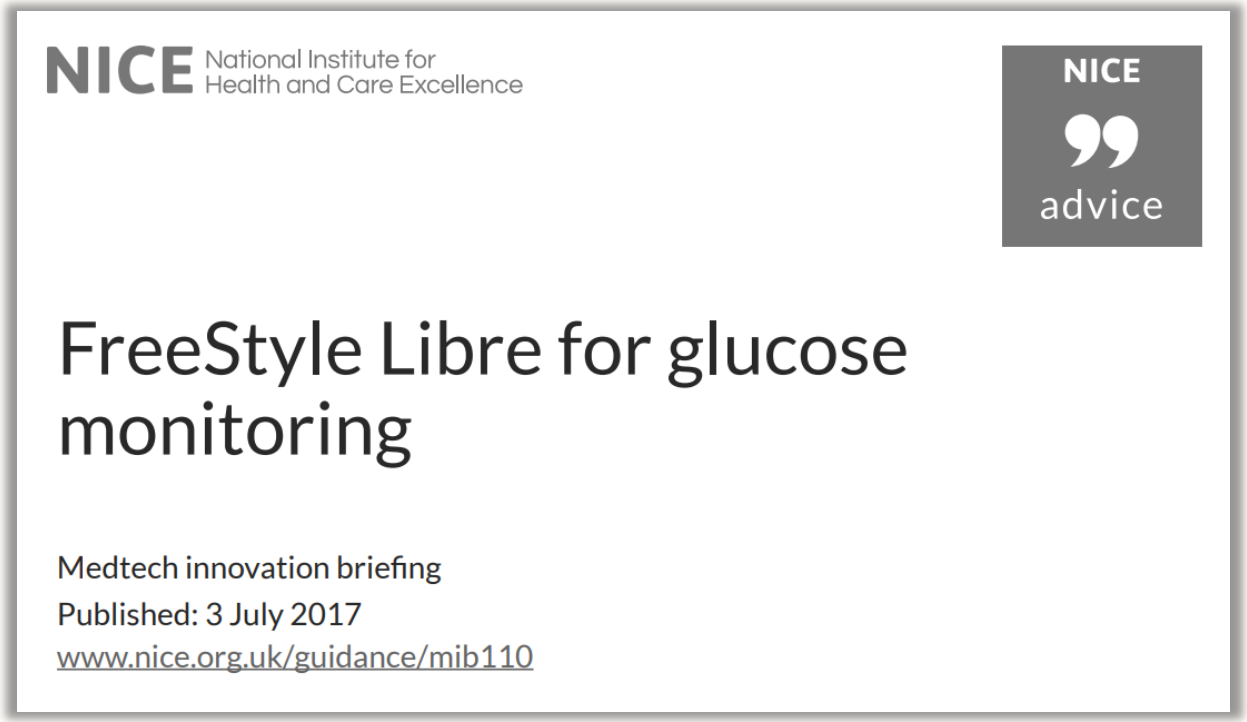
Diabetes Care 2020;43:2153–2160 | https://doi.org/10.2337/dc20-0738



Association of British Clinical Diabetologists

Deshmukh H, Wilmot EG et al. Diabetes Care 2020 15;43(9):2153-60

NICE Medtech Innovation Briefing



"There are currently no high quality, peer-reviewed randomised studies on the use of FreeStyle Libre"

https://www.nice.org.uk/advice/mib110/resources/freestyle-libre-for-glucose-monitoring-pdf-2285963268047557

Flash UK Randomised Controlled Trial

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Intermittently Scanned Continuous Glucose Monitoring for Type 1 Diabetes

L. Leelarathna, M.L. Evans, S. Neupane, G. Rayman, S. Lumley, I. Cranston, P. Narendran, K. Barnard-Kelly, C.J. Sutton, R.A. Elliott, V.P. Taxiarchi, G. Gkountouras, M. Burns, W. Mubita, N. Kanumilli, M. Camm, H. Thabit, and E.G. Wilmot, for the FLASH-UK Trial Study Group*

Flash UK

In this 8 site multi-centre randomised controlled trial FreeStyle Libre 2 led to:

- Significant improvement in HbA1c
- Less hypoglycaemia
- Improved treatment satisfaction

Cost Effectiveness

- Incremental cost-per-QALY of £4477
- For people with HbA1c >75 mmol/mol (9.0%), cost-saving

- >95% of people living with T1DM now have access to NHS funded continuous glucose monitoring

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Received: 23 July 2023 | Accepted: 18 September 2023

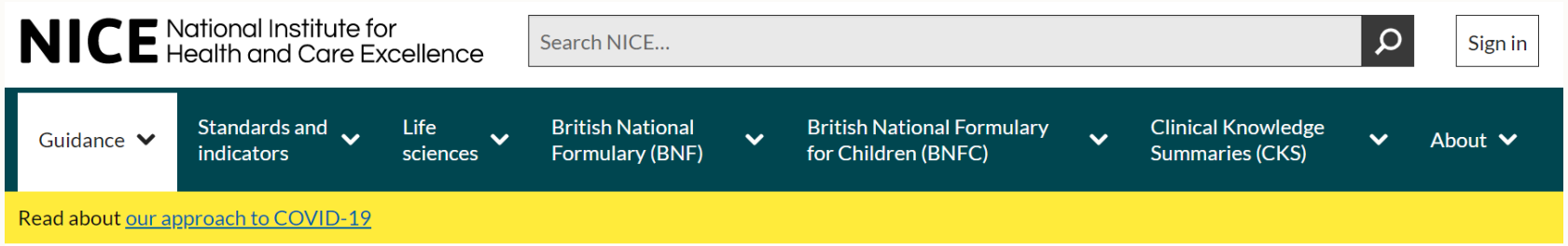
DOI: 10.1111/dme.15232

DIABETIC Medicine

RESEARCH: HEALTH ECONOMICS

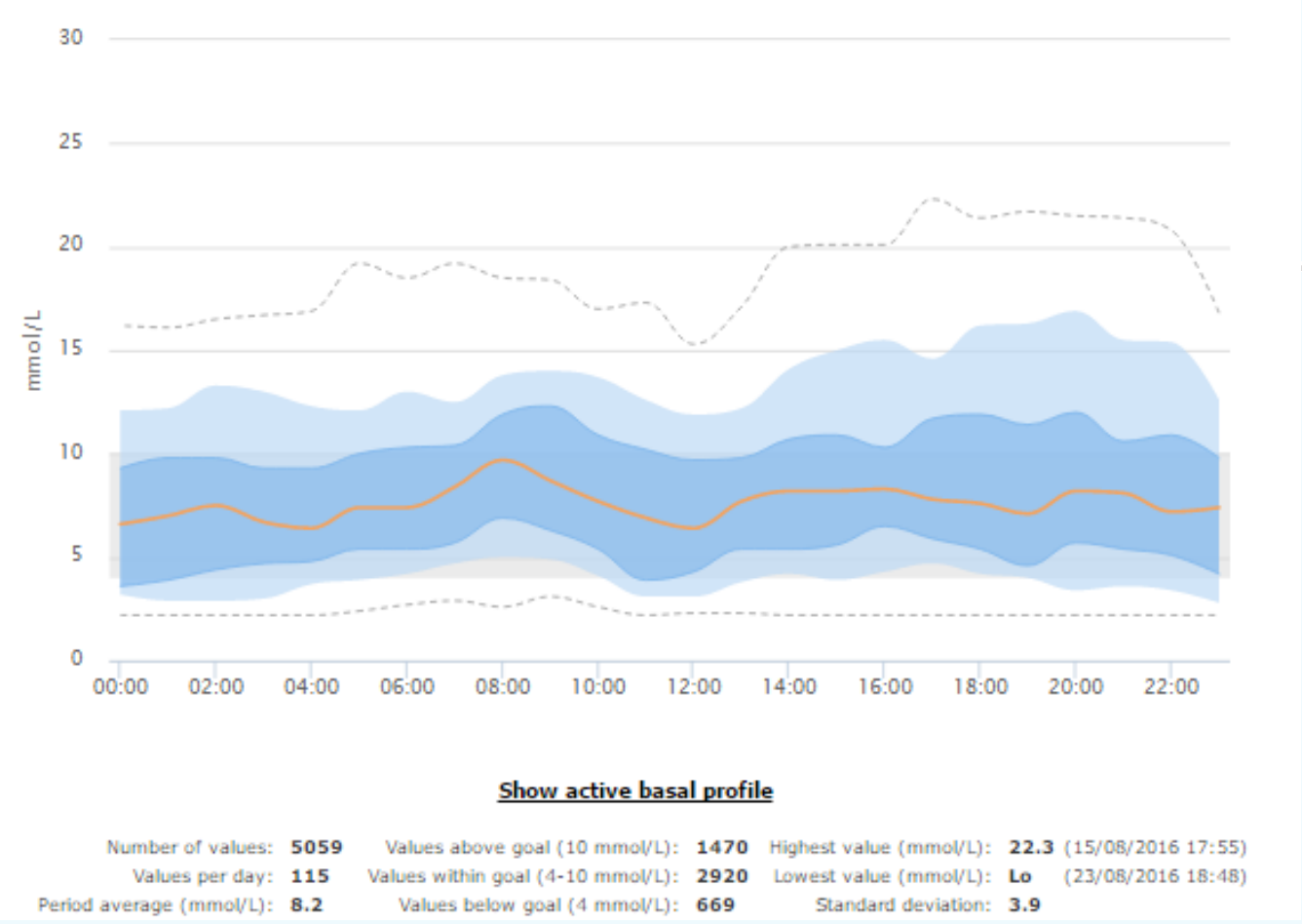
Estimating the cost-effectiveness of intermittently scanned continuous glucose monitoring in adults with type 1 diabetes in England

Rachel A. Elliott[1] | Gabriel Rogers[1] | Mark L. Evans[2] | Sankalpa Neupane[3,4] | Gerry Rayman[5] | Sarah Lumley[6] | Iain Cranston[7] | Parth Narendran[8,9] | Christopher J. Sutton[10] | Vicky P. Taxiarchi[11] | Matthew Burns[12] | Hood Thabit[13,14] | Emma G. Wilmot[15,16] | Lalantha Leelarathna[13,14] | FLASH–UK Trial Study Group



Offer adults with T1DM a choice of CGM based on **their individual preferences, needs, characteristics, & the functionality of the devices available. [2022]**

https://www.nice.org.uk/guidance/ng17



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Sensors are now standard of care for people living with Type 1 diabetes in England, UK

NICE T1 guidance: personal choice is central

Sensor accuracy

Hypoglycaemia fear,
frequency & awareness
Predictive alerts/alarms

Need for use in closed loop

Frequency sensor changes
Dexterity
Data sharing

Psychosocial factors
Impact on work
Body image concerns
Skin reactions

Smartphone access

https://www.nice.org.uk/guidance/ng17/resources/type-1-diabetes-in-adults-diagnosis-and-management-pdf-1837276469701

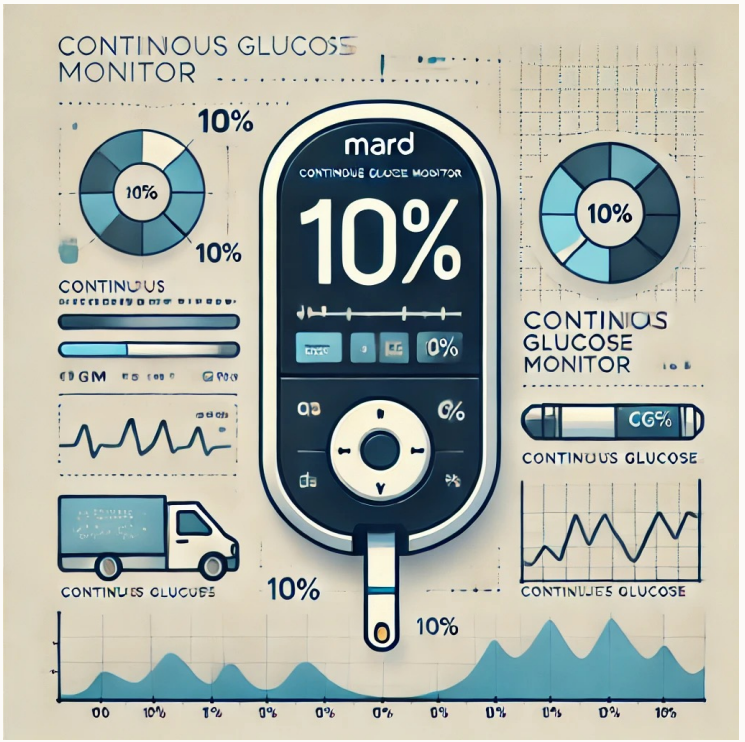
- We now have wide access to CGM in people with T1DM
- Increasing access in people with T2DM

- NICE supports choice of devices

How do we, as HCPs assess sensor accuracy??

Imagine this

“This new CGM system has a CE mark and a very accurate MARD!”



Is a CE mark an indication that the glucose sensor provides highly accurate and precise glucose readings for people living with diabetes?

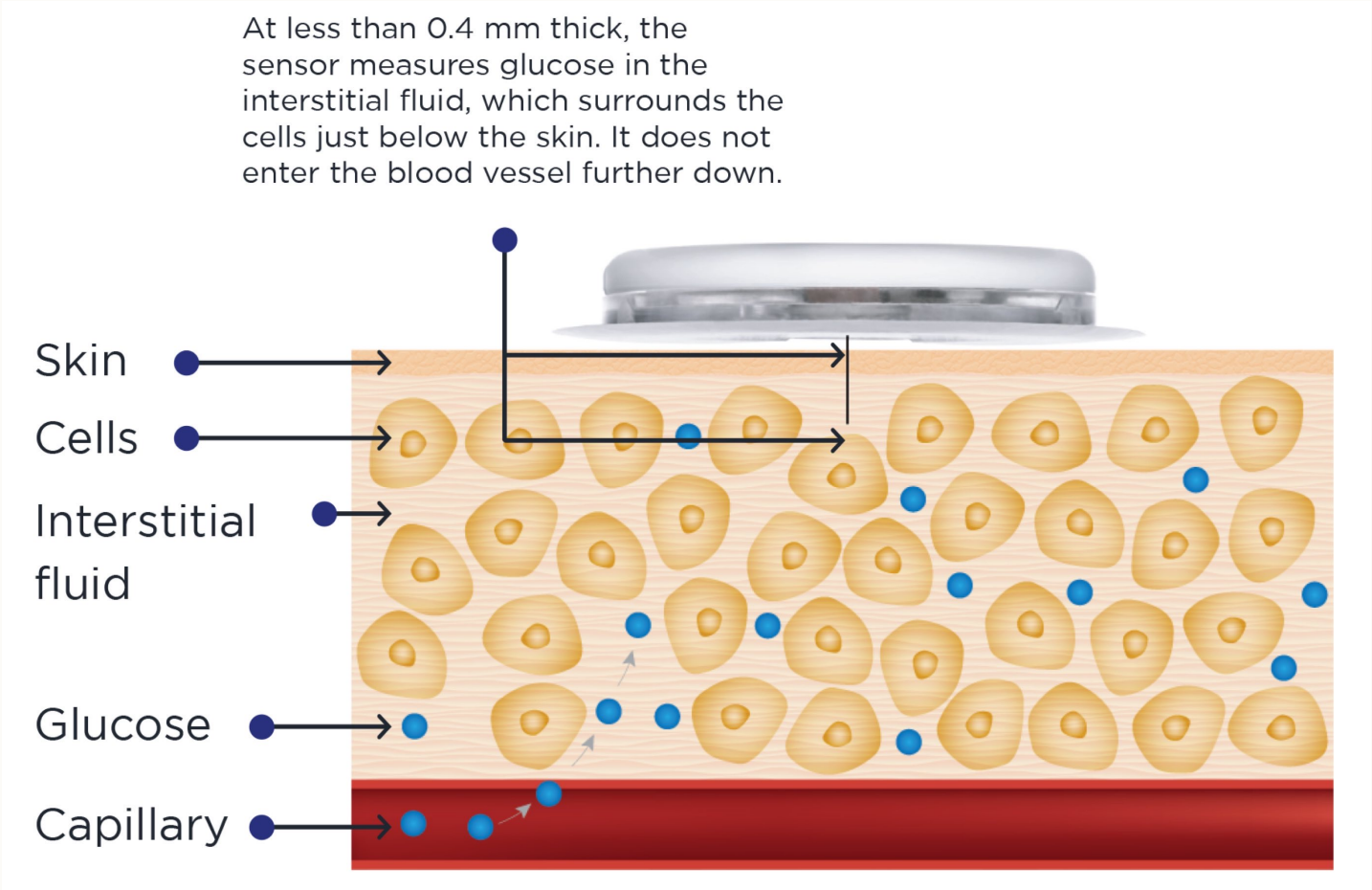
1. Yes, it must be
2. Not sure
3. I don't think so

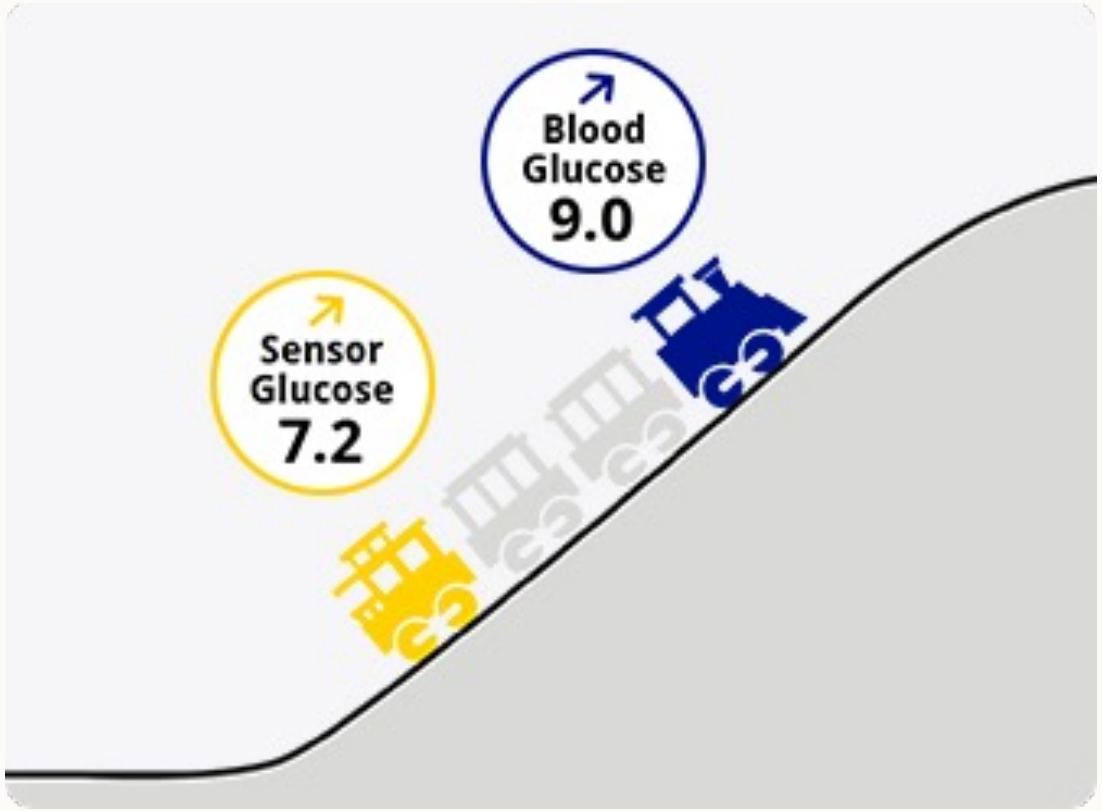
CGM systems generally report a Mean Absolute Relative Difference (MARD)

Is this metric a reliable marker of accuracy?

1. Yes, it is my go-to indicator of accuracy
2. Useful, but does not provide a full picture
3. No, it hides a multitude of sins!
4. Never heard of it

Exploring MARD

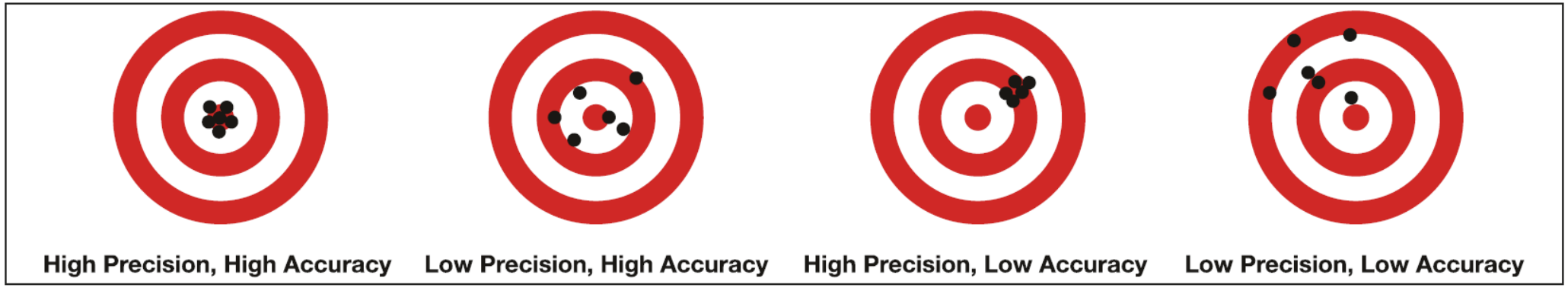



Blood
Glucose
9.0
Sensor
Glucose
7.2

Accuracy and precision

Both are critical to the analysis of glucose-sensor performance

- **Accuracy** = how close are sensor test results to the YSI reference standard
- **Precision** = how close are sensor test results to each other



- **MARD** is a metric of average accuracy, but not precision
- **Precision** can be visualised together with MARD in a consensus error grid (CEG)

CEG: Consensus error grid; MARD: Mean average relative difference; YSI: Yellow Spring Instrument

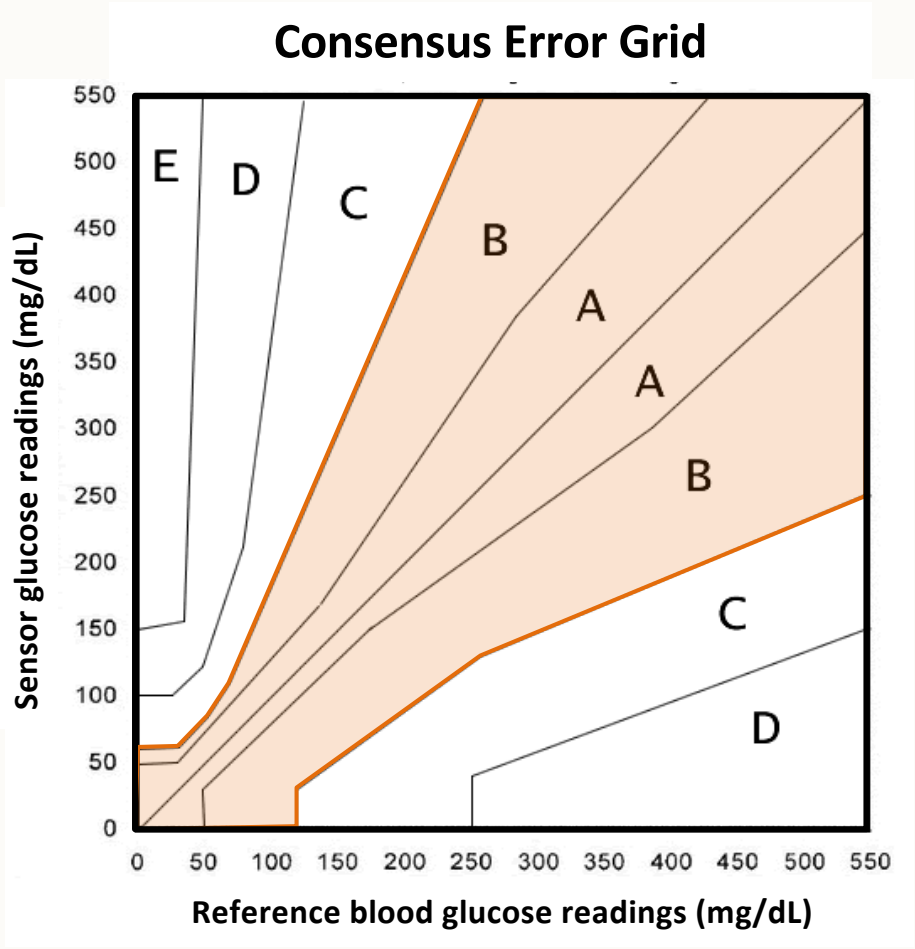
Ajjan RA, Wilmot EG et al. *Diab Vasc Dis Res.* 2018;15(3):175-184

Consensus Error Grid

- The accuracy of glucose monitors should be sufficient to exclude errors of >15%[1]
- The Consensus Error Grid is a tool for evaluating the clinical significance of inaccuracies in the measurement of glucose readings[2]

5 zones which help reflect level of risk:

- **Zone A**: No effect on clinical action (considered clinically accurate)
- **Zone B**: Altered clinical action but no or little effect on clinical outcome
- **Zone C**: Altered action, likely to affect outcome
- **Zone D**: Significant medical risk
- **Zone E**: Erroneous treatment, could have dangerous consequences



American Diabetes Association: Consensus statement on self-monitoring of blood glucose. *Diabetes Care* 1987; 10:95–99
Parkes JL, et al. *Diabetes Care* 2000; 23:1143–1148

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250mg/dl = 13.9mmol/l

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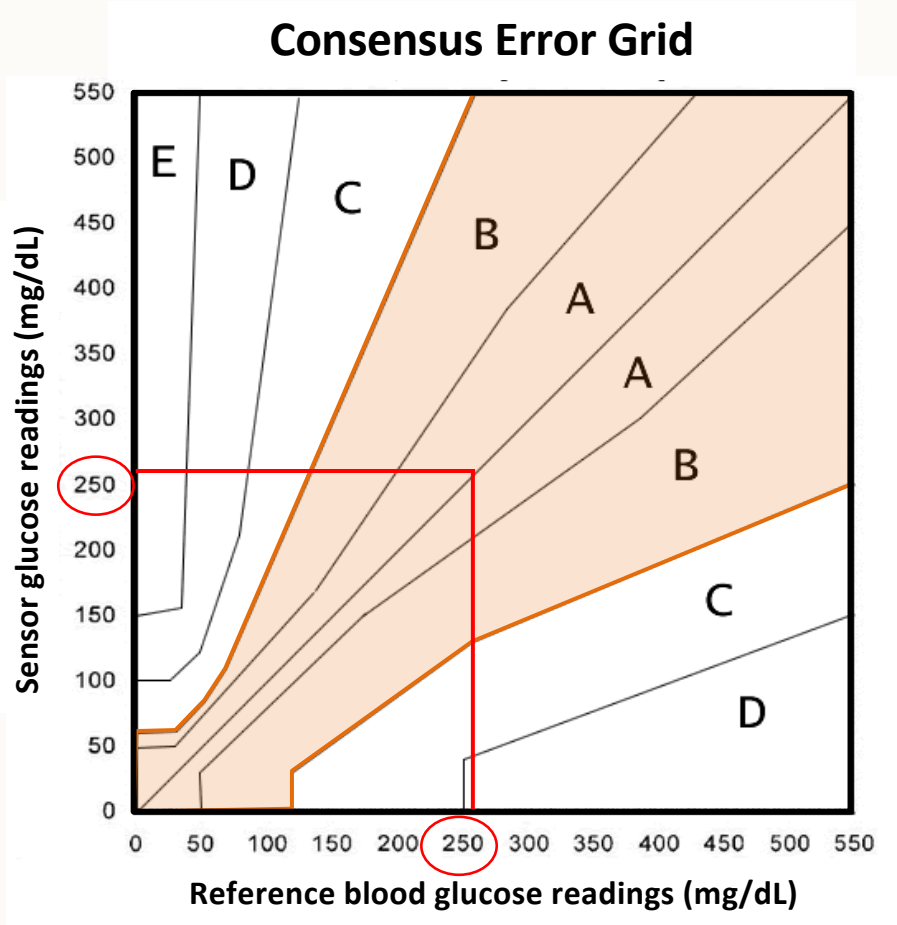

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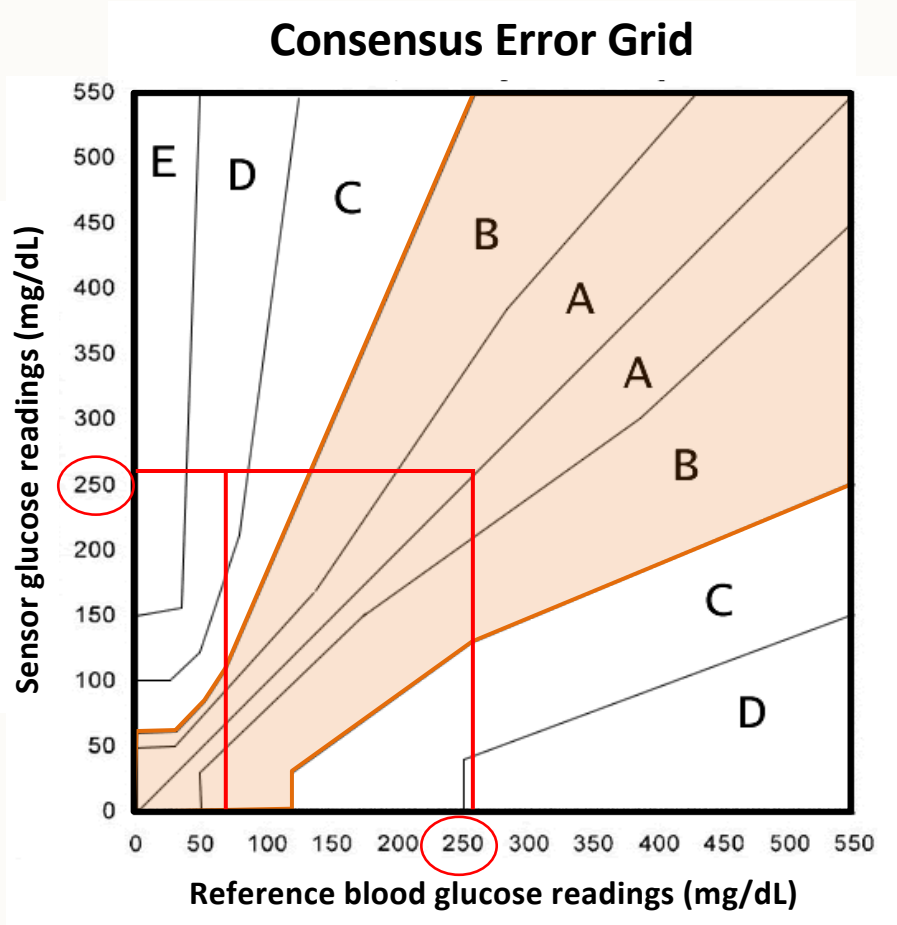

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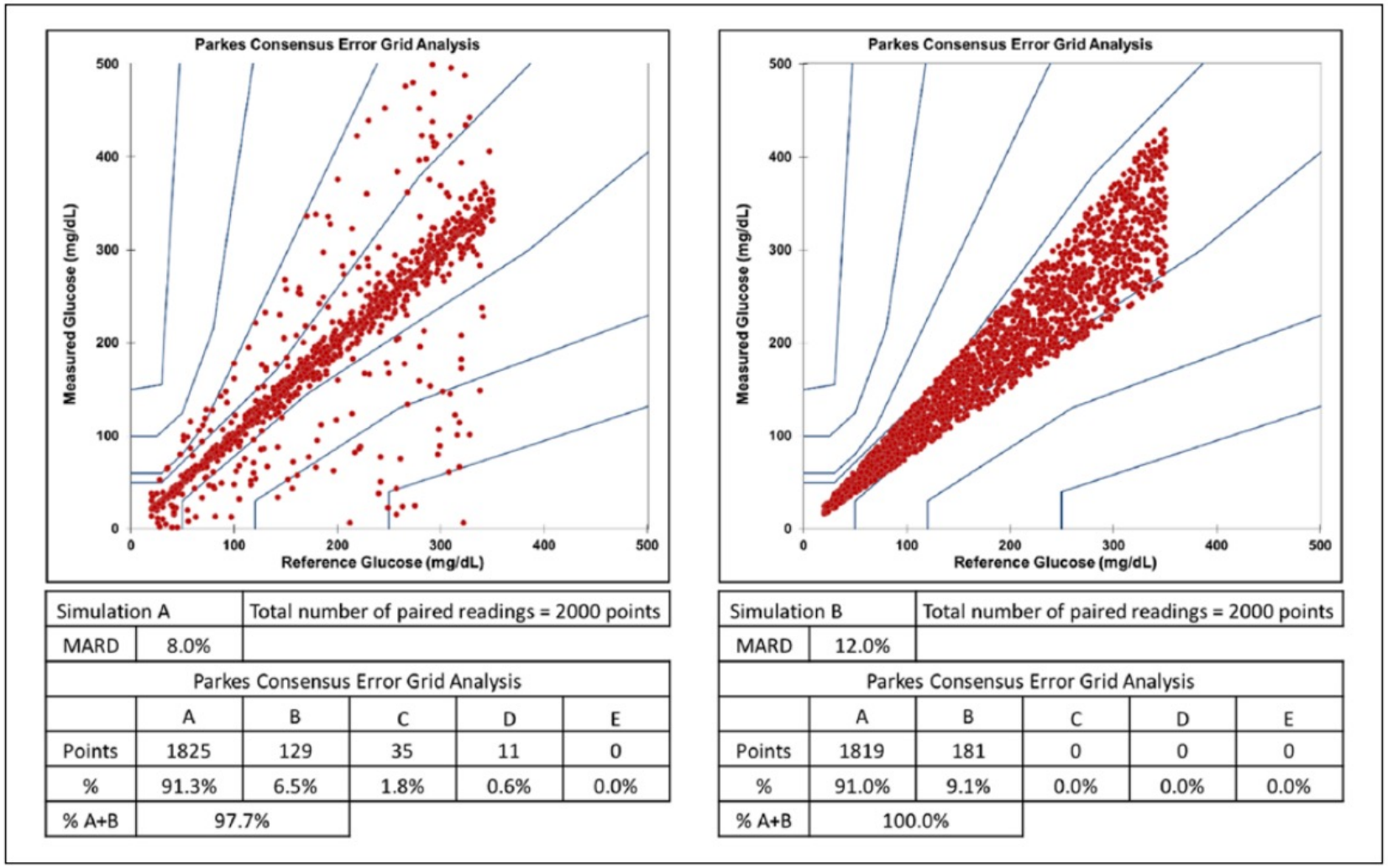
Considerations



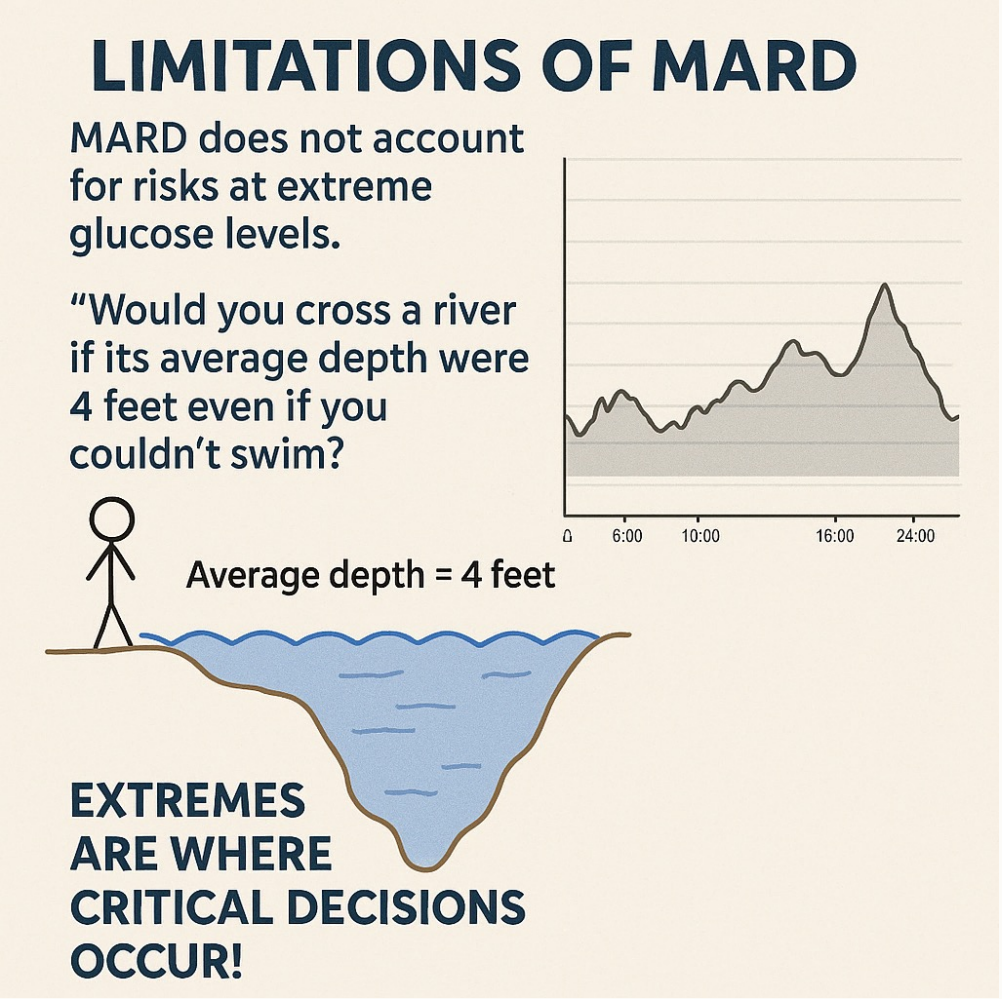
Simulation A		Total number of paired readings = 2000 points			
MARD	8.0%				
Parkes Consensus Error Grid Analysis					
	A	B	C	D	E
Points	1825	129	35	11	0
%	91.3%	6.5%	1.8%	0.6%	0.0%
% A+B	97.7%				

Simulation B		Total number of paired readings = 2000 points			
MARD	12.0%				
Parkes Consensus Error Grid Analysis					
	A	B	C	D	E
Points	1819	181	0	0	0
%	91.0%	9.1%	0.0%	0.0%	0.0%
% A+B	100.0%				

Figure 5. Comparisons of simulated test and reference glucose samples. The MARD and CEG plots of 2000 paired readings can be modelled to illustrate that different methods of analysis may generate different assessments of 'accuracy'.

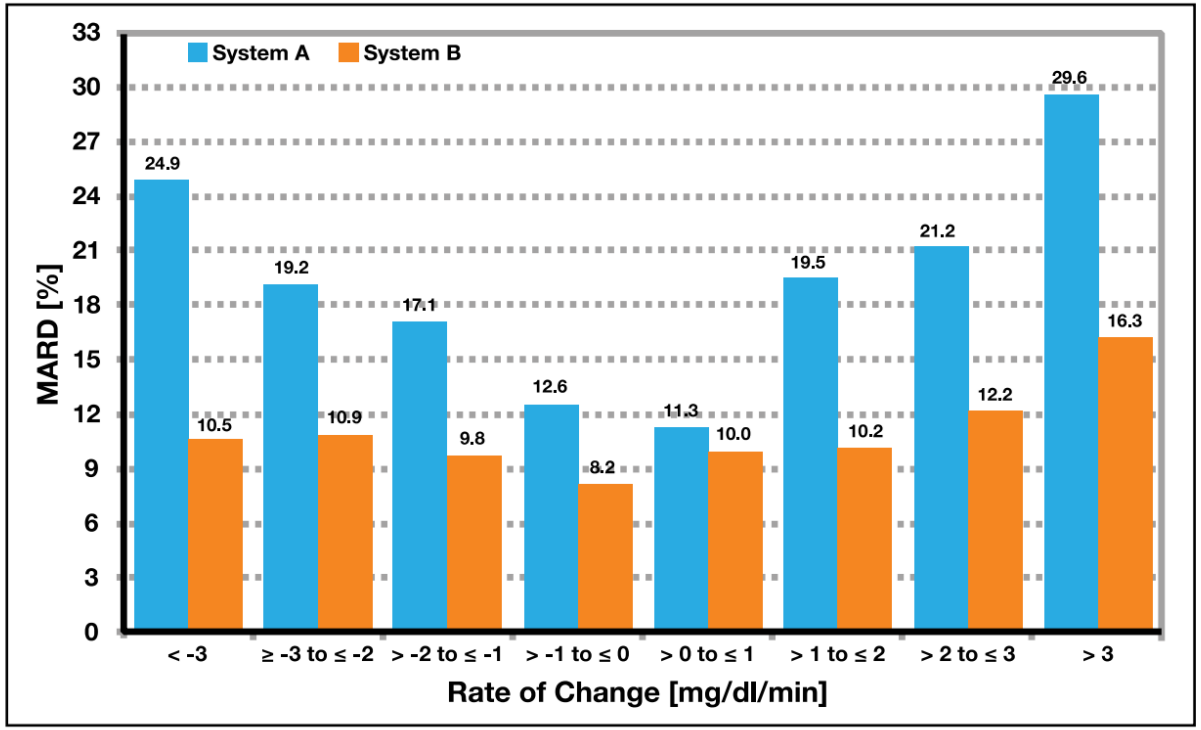
Ajjan RA, Wilmot EG et al. *Diab Vasc Dis Res.* 2018;15(3):175-184

Accuracy


LIMITATIONS OF MARD
MARD does not account for risks at extreme glucose levels.
"Would you cross a river if its average depth were 4 feet even if you couldn't swim?
0
6:00
10:00
16:00
24:00
Average depth = 4 feet
EXTREMES ARE WHERE CRITICAL DECISIONS OCCUR!

Can we rely on MARD?

- MARD is a useful measurement of accuracy of CGM systems
- The lack of universally accepted protocols for assessing MARD means that it **cannot be used in isolation as a statement of comparative accuracy**
- The objective accuracy of any glucose monitoring system is dependent on protocol used to test accuracy



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MARD

Technology Report

Journal of Diabetes Science and Technology
1–6

DOI: 10.1177/19322968211037991
journals.sagepub.com/home/dst
SAGE

Multicenter Evaluation Study Comparing a New Factory-Calibrated Real-Time Continuous Glucose Monitoring System to Existing Flash Glucose Monitoring System

Linong Ji, MD[1], Lixin Guo, MD[2], Junqing Zhang, MD[3], Yufeng Li, MD[4], and Zhiyan Chen, PhD[5]

- Study reports MARD 9.08%
- Multi-centre study in 120 participants

However….

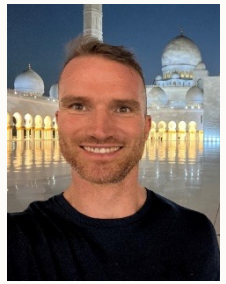
- Only 14 (11.3%) had Type 1 diabetes and 57 (49.6%) were on insulin
- No sensor day 1 data available

Linong J et al. JDST 2021

Background – The timeline

Slide courtesy of John Pemberton

May 2022
John Pemberton RD



Dr Peter Adolfsson

Jun - Dec 2022

Dr Emma Wilmot

Professor Katharine Barnard-Kelly

Dr Lalantha Leelarathna

Professor Nick Oliver

Dr Tabitha Randell

Dr Craig Taplin

Professor Pratik Choudhary

Tim Street **@Tims_Pants**
https://www.diabettech.com/

30th Dec 2022

DIABETES, OBESITY AND METABOLISM
A JOURNAL OF PHARMACOLOGY AND THERAPEUTICS

REVIEW ARTICLE

CGM accuracy: Contrasting CE marking with the governmental controls of the USA (FDA) and Australia (TGA) – A narrative review

John S Pemberton, Emma G Wilmot, Katharine Barnard-Kelly, Lalantha Leelarathna, Nick Oliver, Tabitha Randell, Craig E Taplin, Pratik Choudhary, Peter Adolfsson

First published: 30 December 2022 | https://doi.org/10.1111/dom.14962

Safe and effective?

Slide courtesy of John Pemberton

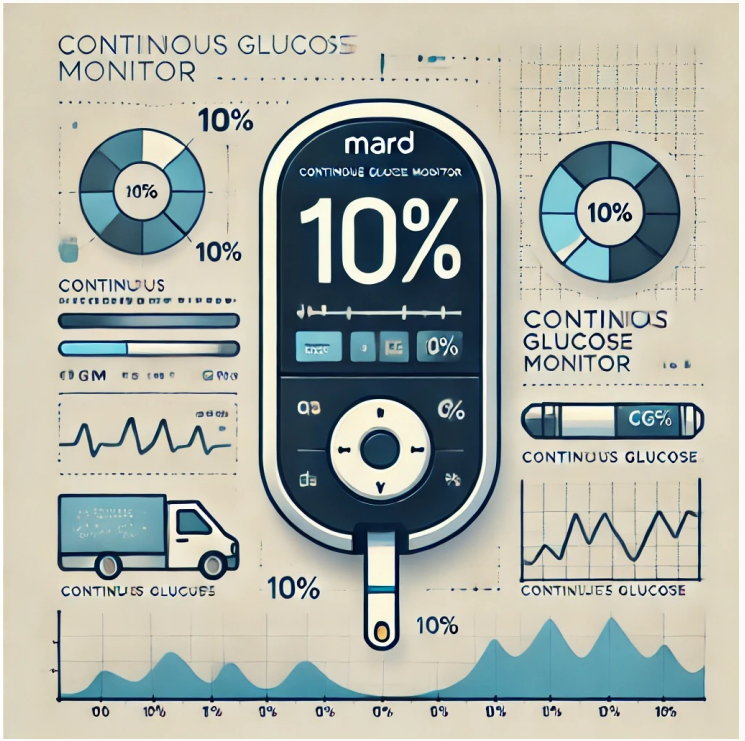
We need study design standardization

Scenario

- John comes into clinic to see you

"This new CGM system has a CE mark and a very accurate MARD!"

- He is trialing a new CGM he was offered via an internet advert
- He likes it and asks you if you can make it available locally
- What is your approach?



DSN Forum

Diabetes Specialist Nurse Forum UK

Home | *NEW* CGM comparison chart | An introduction to diabetes nursing course | Sign up page | News | Resources | What's New | Initiatives | #DSNF24 | DSN Brunches | Diabetes 101 | Contact Us

Comparison Charts

CGM Comparison Chart

An easy to understand comparison of all currently available flash and real-time CGM devices.

Download

HCL Comparison Chart

Easy to understand comparison of currently available hybrid closed loop systems.

Download

Reviewing HCL Systems

An easy to read document outlining the general principles when reviewing HCL systems and more detailed, device specific changes

Download

https://www.diabetesspecialistnurseforumuk.co.uk/charts

Key study design standards

1. Peer-reviewed publication
2. ≥70% participants with Type 1 diabetes
3. Meal and insulin challenges included
4. A minimum of 8% of readings <4,4 mmol/L during testing
5. A minimum of 5% of readings ≥16,7 mmol/L during testing

Study Design, Clinical Accuracy, and Regulatory Approval Status of CGM Systems Available in the UK

Study Design Assessment and Score

The study design score (0 to 5, with higher scores = greater robustness, ordered by score then alphabet) reflects how thoroughly the CGM system has been tested across the full glucose range (typically 2.2–22.2 mmol/L or 40-400 mg/dL), including the rates of change commonly experienced by people with diabetes. This score provides insight into how likely the performance is to hold true in real-world conditions. The scoring criteria are based on testing recommendations for individuals aged 18 years and older from the 2020 Performance metrics for continuous interstitial glucose monitoring CLSI guideline (POCT05) ,reinforced by the IFCC Working Group on CGM & eCGM Clinician Consensus[b]

Accuracy Data & Regulatory Status

The 20/20 and 40/40 metrics offers a better representation of the percentage of glucose readings that pose no risk and high risk to clinical decision-making, respectively. In contrast, the Mean Average Relative Difference (MARD) does not indicate the proportion of risk-free readings and is therefore not included.

20/20: Percentage of CGM within ±20% of the comparator blood glucose levels ≥5.5 mmol/L and within ±1.1 mmol/L (20 mg/dL) for blood levels <5.5 mmol/L.
40/40: Percentage of CGM within ±40% of the comparator blood glucose levels ≥5.5 mmol/L and within ±2.2 mmol/L (40 mg/dL) for blood levels <5.5 mmol/L.

CGM Systems (Distributor in the UK)	Peer-reviewed[a]	≥70% T1D	Meal & insulin challenge	≥8% of readings <4.4 mmol/L (80 mg/dL)	≥5% of readings >16.7 mmol/L (300 mg/dL)	Study design score[b]	Age range tested	N = adults	Adult 20/20[c]	Adult 40/40[c]	N = Paed	Paed 20/20[c]	Paed 40/40[c]	CE marking for non-adjunctive[e] (age indication)	iCGM for HCL[f]	GP via FP10	NHS Supply Chain
Non-adjunctive use: Licensed for clinical decision-making including insulin dosing. Finger-prick blood glucose confirmation is not required for treatment decisions, unless symptoms do not match the CGM reading or the value and/or trend arrow is unavailable.																	
Accu-Chek SmartGuide® (ROCHE)[1]	✓	✓	✓	✓	✓	5	≥18yrs	48	91%	99%	[d]	[d]	[d]	✓[j] (18yrs)	×	×	×
ALLYcgm (AgaMatrix)[9]	✓	✓	✓	✓	✓	5	≥18yrs	30	94%	>99.5%	[d]	[d]	[d]	✓ (18yrs)	×	×	×
CareSens Air® (Spirit Healthcare)[9]	✓	✓	✓	✓	✓	5	≥18yrs	30	94%	>99.5%	[d]	[d]	[d]	✓ (18yrs)	×	✓	×
Dexcom G6™ (Dexcom)[2-3]	✓	✓	✓	✓	✓	5	≥2yrs	159	93%	>99.5%	165	92%	>99.5%	✓ (≥2yrs)	✓[h]	×	✓
Dexcom G7™ (Dexcom)[4-5]	✓	✓	✓	✓	✓	5	≥2yrs	316	95%	>99.5%	127	95%	>99.5%	✓ (≥2yrs)	✓[i]	×	✓
Dexcom One™ (Dexcom) [2-3]	✓	✓	✓	✓	✓	5	≥2yrs	159	93%	>99.5%	165	92%	>99.5%	✓ (≥2yrs)	×	✓	×
Dexcom One+™ (Dexcom)[4-5]	✓	✓	✓	✓	✓	5	≥2yrs	316	95%	>99.5%	127	95%	>99.5%	✓ (≥2yrs)	×	✓	×
FreeStyle Libre® 2 Plus (Abbott)[6,7]	✓	✓	✓	✓	✓	5	≥2yrs	148	94%	>99.5%	127	94%	>99.5%	✓ (≥2yrs)	✓	✓	✓
FreeStyle Libre® 3 Plus (Abbott)[6,7]	✓	✓	✓	✓	✓	5	≥2yrs	148	94%	>99.5%	127	94%	>99.5%	✓ (≥2yrs)	✓	✓	✓
Simplera/Simplera Sync™ (Medtronic)[8]	✓	✓	✓	✓	✓	5	≥2yrs	160	89%	[d]	138	88%	[d]	✓ (≥2yrs)	×	×	✓
GlucoMen iCan (A. Menarini Diagnostics)[g]	×	✓	✓	✓	✓	4	≥2yrs	35	96%	>99.5%	60	95%	>99.5%	✓ (≥2yrs)	×	✓	×
Guardian™ 4 Sensor and Guardian™ 4 Link Transmitter (Medtronic)[g]	×	✓	✓	✓	✓	4	≥2yrs	153	88%	[d]	108	83%	[d]	✓ (≥2yrs)	×	×	✓
TouchCare® Nano A8 (Medtrum)[g]	×	×	✓	[d]	[d]	1	≥14yrs	63	89%	99%	[d]	[d]	[d]	✓ (≥2yrs)	×	×	✓
Linx (Microtech)[g]	×	[d]	[d]	[d]	[d]	0	≥18yrs	91	>90%	99%	[d]	[d]	[d]	✓ (≥18yrs)	×	×	×
Adjunctive use: Not licensed for clinical decision-making. All clinical decisions must be confirmed with a finger-prick blood glucose test																	
Gluconovo® (Infinovo)[10]	✓	×	×	×	×	1	≥18yrs	78	90%	99%	[d]	[d]	[d]	× (2yrs)	×	×	×
GlucoRx Aidex™ (GlucoRx)[11]	✓	×	×	×	×	1	≥18yrs	114	96%	>99.5%	[d]	[d]	[d]	× (≥14yrs)	×	✓	×
GS1 CGM (SiBionics)[12]	✓	×	×	×	×	1	≥18yrs	70	92%	[d]	[d]	[d]	[d]	× (18yrs)	×	×	×
Yuwell CT3 (Urathon)[g]	×	[d]	[d]	[d]	[d]	0	≥18yrs	72	93%	[d]	[d]	[d]	[d]	× (≥14yrs)	×	×	×
Syai Tag (Syai Health Technology)[g]	×	[d]	[d]	[d]	[d]	0	≥18yrs	72	93%	[d]	[d]	[d]	[d]	× (≥18yrs)	×	×	×

Version 1/10/25: Reviewed bi-monthly
Latest version available @ DSN Forum UK

T2 vs T1DM

GLUCOSE STATISTICS AND TARGETS

22 October 2025 - 4 November 2025 — 14 Days

Time Sensor Active: 87%

Ranges And Targets For	Type 1 or Type 2 Diabetes
Glucose Ranges Target Range 3.9-10.0 mmol/L	**Targets** % of Readings (Time/Day) Greater than 70% (16h 48min)
Below 3.9 mmol/L	Less than 4% (58min)
Below 3.0 mmol/L	Less than 1% (14min)
Above 10.0 mmol/L	Less than 25% (6h)
Above 13.9 mmol/L	Less than 5% (1h 12min)
Each 5% increase in time in range (3.9-10.0 mmol/L) is clinically beneficial.	

Average Glucose 6.6 mmol/L

Glucose Management Indicator (GMI) 6.2% or 44 mmol/mol

Glucose Variability 21.9%

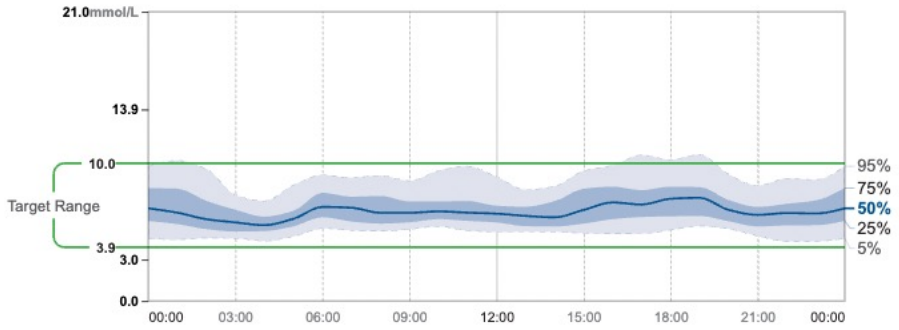
Defined as percent coefficient of variation (%CV); target ≤36%

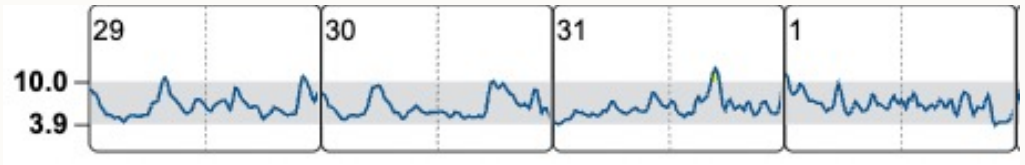
TIME IN RANGES

Very High	>13.9 mmol/L	0%	(0min)
High	10.1 - 13.9 mmol/L	3%	(43min)
Target Range	3.9 - 10.0 mmol/L	97%	(23h 17min)
Low	3.0 - 3.8 mmol/L	0%	(0min)
Very Low	<3.0 mmol/L	0%	(0min)

AMBULATORY GLUCOSE PROFILE (AGP)

AGP is a summary of glucose values from the report period, with median (50%) and other percentiles shown as if occurring in a single day.





GLUCOSE STATISTICS AND TARGETS

22 October 2025 - 4 November 2025 — 14 Days

Time Sensor Active: 85%

Ranges And Targets For	Type 1 or Type 2 Diabetes
Glucose Ranges Target Range 3.9-10.0 mmol/L	**Targets** % of Readings (Time/Day) Greater than 70% (16h 48min)
Below 3.9 mmol/L	Less than 4% (58min)
Below 3.0 mmol/L	Less than 1% (14min)
Above 10.0 mmol/L	Less than 25% (6h)
Above 13.9 mmol/L	Less than 5% (1h 12min)
Each 5% increase in time in range (3.9-10.0 mmol/L) is clinically beneficial.	

Average Glucose 10.0 mmol/L

Glucose Management Indicator (GMI) 7.6% or 60 mmol/mol

Glucose Variability 39.9%

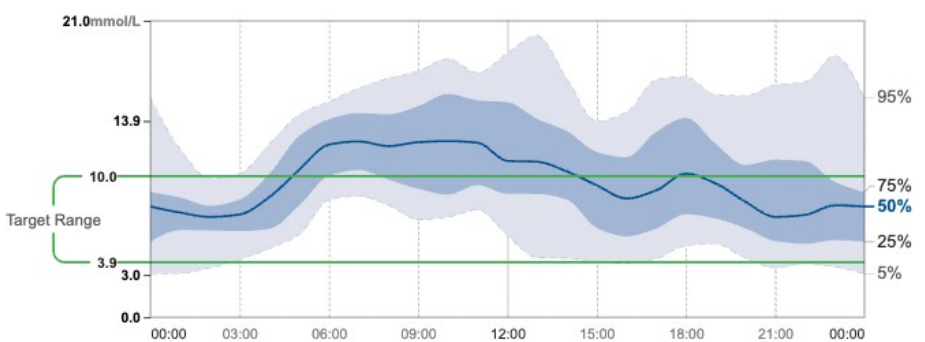
Defined as percent coefficient of variation (%CV); target ≤36%

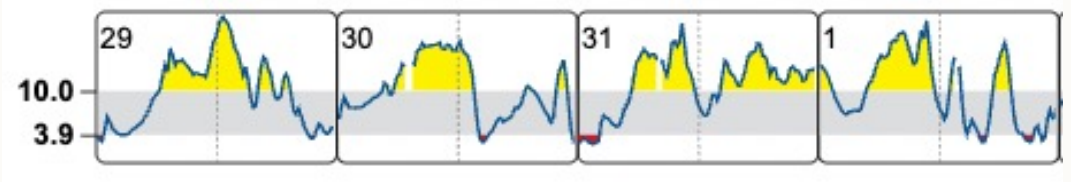
TIME IN RANGES

Very High	>13.9 mmol/L	18%	(4h 19min)
High	10.1 - 13.9 mmol/L	27%	(6h 29min)
Target Range	3.9 - 10.0 mmol/L	51%	(12h 15min)
Low	3.0 - 3.8 mmol/L	3%	(43min)
Very Low	<3.0 mmol/L	1%	(14min)

AMBULATORY GLUCOSE PROFILE (AGP)

AGP is a summary of glucose values from the report period, with median (50%) and other percentiles shown as if occurring in a single day.





Study Design, Clinical Accuracy, and Regulatory Approval Status of CGM Systems Available in the UK

Study Design Assessment and Score

The study design score (0 to 5, with higher scores = greater robustness, ordered by score then alphabet) reflects how thoroughly the CGM system has been tested across the full glucose range (typically 2.2–22.2 mmol/L or 40-400 mg/dL), including the rates of change commonly experienced by people with diabetes. This score provides insight into how likely the performance is to hold true in real-world conditions. The scoring criteria are based on testing recommendations for individuals aged 18 years and older from the 2020 Performance metrics for continuous interstitial glucose monitoring CLSI guideline (POCT05), reinforced by the IFCC Working Group on CGM & eCGM Clinician Consensus[b]

Accuracy Data & Regulatory Status

The 20/20 and 40/40 metrics offers a better representation of the percentage of glucose readings that pose no risk and high risk to clinical decision-making, respectively. In contrast, the Mean Average Relative Difference (MARD) does not indicate the proportion of risk-free readings and is therefore not included.

20/20: Percentage of CGM within ±20% of the comparator blood glucose levels ≥5.5 mmol/L and within ±1.1 mmol/L (20 mg/dL) for blood levels <5.5 mmol/L.
40/40: Percentage of CGM within ±40% of the comparator blood glucose levels ≥5.5 mmol/L and within ±2.2 mmol/L (40 mg/dL) for blood levels <5.5 mmol/L.

CGM Systems (Distributor in the UK)	Peer-reviewed[a]	≥70% T1D	Meal & insulin challenge	≥8% of readings <4.4 mmol/L (80 mg/dL)	≥5% of readings >16.7 mmol/L (300 mg/dL)	Study design score[b]	Age range tested	N = adults	Adult 20/20[c]	Adult 40/40[c]	N = Paed	Paed 20/20[c]	Paed 40/40[c]	CE marking for non-adjunctive[e] (age indication)	iCGM for HCL[f]	GP via FP10	NHS Supply Chain
Non-adjunctive use: Licensed for clinical decision-making including insulin dosing. Finger-prick blood glucose confirmation is not required for treatment decisions, unless symptoms do not match the CGM reading or the value and/or trend arrow is unavailable.																	
Accu-Chek SmartGuide® (ROCHE)[1]	✓	✓	✓	✓	✓	5	≥18yrs	48	91%	99%	[d]	[d]	[d]	✓[j] (18yrs)	×	×	×
ALLYcgm (AgaMatrix)[9]	✓	✓	✓	✓	✓	5	≥18yrs	30	94%	>99.5%	[d]	[d]	[d]	✓ (18yrs)	×	×	×
CareSens Air® (Spirit Healthcare)[9]	✓	✓	✓	✓	✓	5	≥18yrs	30	94%	>99.5%	[d]	[d]	[d]	✓ (18yrs)	×	✓	×
Dexcom G6™ (Dexcom)[2-3]	✓	✓	✓	✓	✓	5	≥2yrs	159	93%	>99.5%	165	92%	>99.5%	✓ (≥2yrs)	✓[h]	×	✓
Dexcom G7™ (Dexcom)[4-5]	✓	✓	✓	✓	✓	5	≥2yrs	316	95%	>99.5%	127	95%	>99.5%	✓ (≥2yrs)	✓[i]	×	✓
Dexcom One™ (Dexcom) [2-3]	✓	✓	✓	✓	✓	5	≥2yrs	159	93%	>99.5%	165	92%	>99.5%	✓ (≥2yrs)	×	✓	×
Dexcom One+™ (Dexcom)[4-5]	✓	✓	✓	✓	✓	5	≥2yrs	316	95%	>99.5%	127	95%	>99.5%	✓ (≥2yrs)	×	✓	×
FreeStyle Libre® 2 Plus (Abbott)[6,7]	✓	✓	✓	✓	✓	5	≥2yrs	148	94%	>99.5%	127	94%	>99.5%	✓ (≥2yrs)	✓	✓	✓
FreeStyle Libre® 3 Plus (Abbott)[6,7]	✓	✓	✓	✓	✓	5	≥2yrs	148	94%	>99.5%	127	94%	>99.5%	✓ (≥2yrs)	✓	✓	✓
Simplera/Simplera Sync™ (Medtronic)[8]	✓	✓	✓	✓	✓	5	≥2yrs	160	89%	[d]	138	88%	[d]	✓ (≥2yrs)	×	×	✓
GlucoMen iCan (A. Menarini Diagnostics)[g]	×	✓	✓	✓	✓	4	≥2yrs	35	96%	>99.5%	60	95%	>99.5%	✓ (≥2yrs)	×	✓	×
Guardian™ 4 Sensor and Guardian™ 4 Link Transmitter (Medtronic)[g]	×	✓	✓	✓	✓	4	≥2yrs	153	88%	[d]	108	83%	[d]	✓ (≥2yrs)	×	×	✓
TouchCare® Nano A8 (Medtrum)[g]	×	×	✓	[d]	[d]	1	≥14yrs	63	89%	99%	[d]	[d]	[d]	✓ (≥2yrs)	×	×	✓
Linx (Microtech)[g]	×	[d]	[d]	[d]	[d]	0	≥18yrs	91	>90%	99%	[d]	[d]	[d]	✓ (≥18yrs)	×	×	×
Adjunctive use: Not licensed for clinical decision-making. All clinical decisions must be confirmed with a finger-prick blood glucose test																	
Gluconovo® (Infinovo)[10]	✓	×	×	×	×	1	≥18yrs	78	90%	99%	[d]	[d]	[d]	× (2yrs)	×	×	×
GlucoRx Aidex™ (GlucoRx)[11]	✓	×	×	×	×	1	≥18yrs	114	96%	>99.5%	[d]	[d]	[d]	× (≥14yrs)	×	✓	×
GS1 CGM (SiBionics)[12]	✓	×	×	×	×	1	≥18yrs	70	92%	[d]	[d]	[d]	[d]	× (18yrs)	×	×	×
Yuwell CT3 (Urathon)[g]	×	[d]	[d]	[d]	[d]	0	≥18yrs	72	93%	[d]	[d]	[d]	[d]	× (≥14yrs)	×	×	×
Syai Tag (Syai Health Technology)[g]	×	[d]	[d]	[d]	[d]	0	≥18yrs	72	93%	[d]	[d]	[d]	[d]	× (≥18yrs)	×	×	×

Version 1/10/25: Reviewed bi-monthly
Latest version available @ DSN Forum UK

Meal and insulin challenges

GLUCOSE STATISTICS AND TARGETS

22 October 2025 - 4 November 2025	14 Days
Time Sensor Active:	87%

Ranges And Targets For	Type 1 or Type 2 Diabetes
Glucose Ranges Target Range 3.9-10.0 mmol/L	**Targets** % of Readings (Time/Day) Greater than 70% (16h 48min)
Below 3.9 mmol/L	Less than 4% (58min)
Below 3.0 mmol/L	Less than 1% (14min)
Above 10.0 mmol/L	Less than 25% (6h)
Above 13.9 mmol/L	Less than 5% (1h 12min)
Each 5% increase in time in range (3.9-10.0 mmol/L) is clinically beneficial.	

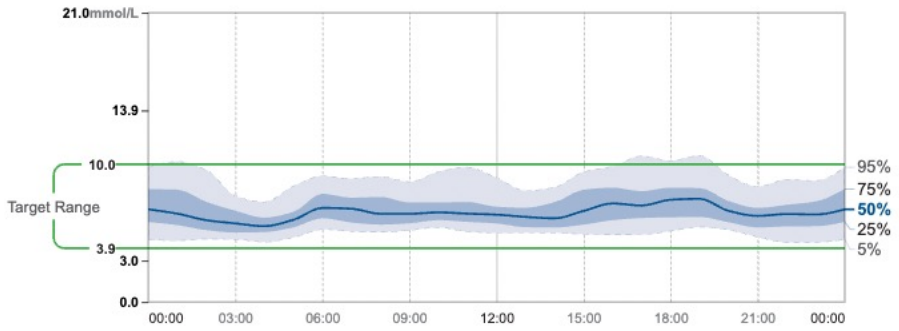
Average Glucose	**6.6** mmol/L
Glucose Management Indicator (GMI)	**6.2% or 44 mmol/mol**
Glucose Variability	**21.9%**

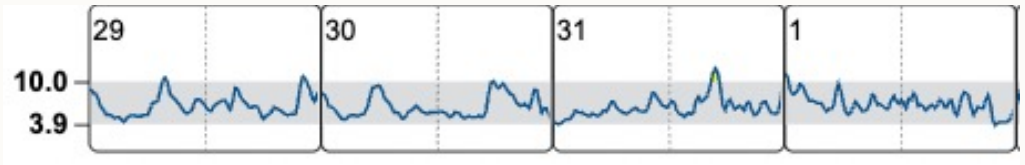
Defined as percent coefficient of variation (%CV); target ≤36%

TIME IN RANGES

AMBULATORY GLUCOSE PROFILE (AGP)

AGP is a summary of glucose values from the report period, with median (50%) and other percentiles shown as if occurring in a single day.





GLUCOSE STATISTICS AND TARGETS

22 October 2025 - 4 November 2025	14 Days
Time Sensor Active:	85%

Ranges And Targets For	Type 1 or Type 2 Diabetes
Glucose Ranges Target Range 3.9-10.0 mmol/L	**Targets** % of Readings (Time/Day) Greater than 70% (16h 48min)
Below 3.9 mmol/L	Less than 4% (58min)
Below 3.0 mmol/L	Less than 1% (14min)
Above 10.0 mmol/L	Less than 25% (6h)
Above 13.9 mmol/L	Less than 5% (1h 12min)
Each 5% increase in time in range (3.9-10.0 mmol/L) is clinically beneficial.	

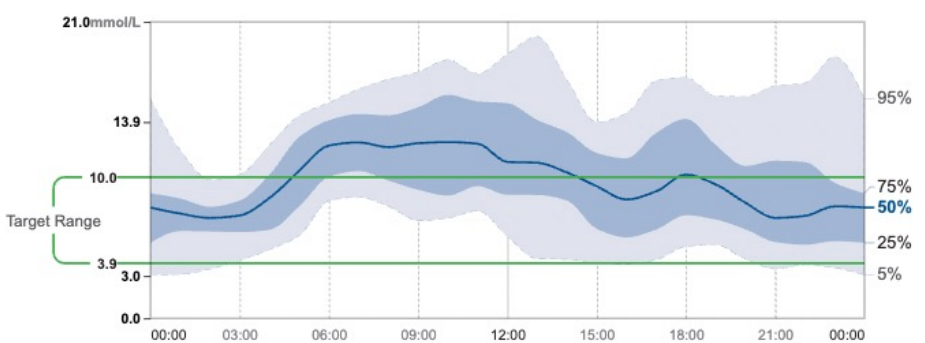
Average Glucose	**10.0** mmol/L
Glucose Management Indicator (GMI)	**7.6% or 60 mmol/mol**
Glucose Variability	**39.9%**

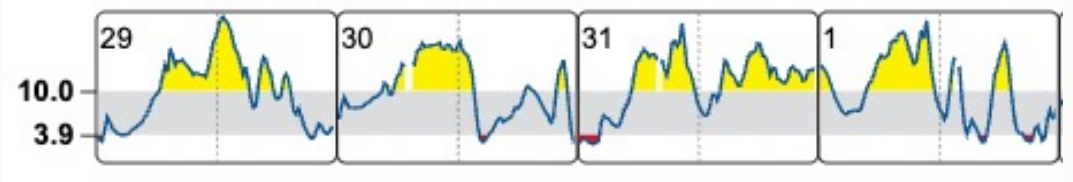
Defined as percent coefficient of variation (%CV); target ≤36%

TIME IN RANGES

AMBULATORY GLUCOSE PROFILE (AGP)

AGP is a summary of glucose values from the report period, with median (50%) and other percentiles shown as if occurring in a single day.





Study Design, Clinical Accuracy, and Regulatory Approval Status of CGM Systems Available in the UK

Study Design Assessment and Score

The study design score (0 to 5, with higher scores = greater robustness, ordered by score then alphabet) reflects how thoroughly the CGM system has been tested across the full glucose range (typically 2.2–22.2 mmol/L or 40-400 mg/dL), including the rates of change commonly experienced by people with diabetes. This score provides insight into how likely the performance is to hold true in real-world conditions. The scoring criteria are based on testing recommendations for individuals aged 18 years and older from the 2020 Performance metrics for continuous interstitial glucose monitoring CLSI guideline (POCT05) ,reinforced by the IFCC Working Group on CGM & eCGM Clinician Consensus[b]

Accuracy Data & Regulatory Status

The 20/20 and 40/40 metrics offers a better representation of the percentage of glucose readings that pose no risk and high risk to clinical decision-making, respectively. In contrast, the Mean Average Relative Difference (MARD) does not indicate the proportion of risk-free readings and is therefore not included.

20/20: Percentage of CGM within ±20% of the comparator blood glucose levels ≥5.5 mmol/L and within ±1.1 mmol/L (20 mg/dL) for blood levels <5.5 mmol/L.
40/40: Percentage of CGM within ±40% of the comparator blood glucose levels ≥5.5 mmol/L and within ±2.2 mmol/L (40 mg/dL) for blood levels <5.5 mmol/L.

CGM Systems (Distributor in the UK)	Peer-reviewed[a]	≥70% T1D	Meal & insulin challenge	≥8% of readings <4.4 mmol/L (80 mg/dL)	≥5% of readings >16.7 mmol/L (300 mg/dL)	Study design score[b]	Age range tested	N = adults	Adult 20/20[c]	Adult 40/40[c]	N = Paed	Paed 20/20[c]	Paed 40/40[c]	CE marking for non-adjunctive[e] (age indication)	iCGM for HCL[f]	GP via FP10	NHS Supply Chain
Non-adjunctive use: Licensed for clinical decision-making including insulin dosing. Finger-prick blood glucose confirmation is not required for treatment decisions, unless symptoms do not match the CGM reading or the value and/or trend arrow is unavailable.																	
Accu-Chek SmartGuide® (ROCHE)[1]	✓	✓	✓	✓	✓	5	≥18yrs	48	91%	99%	[d]	[d]	[d]	✓[j] (18yrs)	×	×	×
ALLYcgm (AgaMatrix)[9]	✓	✓	✓	✓	✓	5	≥18yrs	30	94%	>99.5%	[d]	[d]	[d]	✓ (18yrs)	×	×	×
CareSens Air® (Spirit Healthcare)[9]	✓	✓	✓	✓	✓	5	≥18yrs	30	94%	>99.5%	[d]	[d]	[d]	✓ (18yrs)	×	✓	×
Dexcom G6™ (Dexcom)[2-3]	✓	✓	✓	✓	✓	5	≥2yrs	159	93%	>99.5%	165	92%	>99.5%	✓ (≥2yrs)	✓[h]	×	✓
Dexcom G7™ (Dexcom)[4-5]	✓	✓	✓	✓	✓	5	≥2yrs	316	95%	>99.5%	127	95%	>99.5%	✓ (≥2yrs)	✓[i]	×	✓
Dexcom One™ (Dexcom) [2-3]	✓	✓	✓	✓	✓	5	≥2yrs	159	93%	>99.5%	165	92%	>99.5%	✓ (≥2yrs)	×	✓	×
Dexcom One+™ (Dexcom)[4-5]	✓	✓	✓	✓	✓	5	≥2yrs	316	95%	>99.5%	127	95%	>99.5%	✓ (≥2yrs)	×	✓	×
FreeStyle Libre® 2 Plus (Abbott)[6,7]	✓	✓	✓	✓	✓	5	≥2yrs	148	94%	>99.5%	127	94%	>99.5%	✓ (≥2yrs)	✓	✓	✓
FreeStyle Libre® 3 Plus (Abbott)[6,7]	✓	✓	✓	✓	✓	5	≥2yrs	148	94%	>99.5%	127	94%	>99.5%	✓ (≥2yrs)	✓	✓	✓
Simplera/Simplera Sync™ (Medtronic)[8]	✓	✓	✓	✓	✓	5	≥2yrs	160	89%	[d]	138	88%	[d]	✓ (≥2yrs)	×	×	✓
GlucoMen iCan (A. Menarini Diagnostics)[g]	×	✓	✓	✓	✓	4	≥2yrs	35	96%	>99.5%	60	95%	>99.5%	✓ (≥2yrs)	×	✓	×
Guardian™ 4 Sensor and Guardian™ 4 Link Transmitter (Medtronic)[g]	×	✓	✓	✓	✓	4	≥2yrs	153	88%	[d]	108	83%	[d]	✓ (≥2yrs)	×	×	✓
TouchCare® Nano A8 (Medtrum)[g]	×	×	✓	[d]	[d]	1	≥14yrs	63	89%	99%	[d]	[d]	[d]	✓ (≥2yrs)	×	×	✓
Linx (Microtech)[g]	×	[d]	[d]	[d]	[d]	0	≥18yrs	91	>90%	99%	[d]	[d]	[d]	✓ (≥18yrs)	×	×	×
Adjunctive use: Not licensed for clinical decision-making. All clinical decisions must be confirmed with a finger-prick blood glucose test																	
Gluconovo® (Infinovo)[10]	✓	×	×	×	×	1	≥18yrs	78	90%	99%	[d]	[d]	[d]	× (2yrs)	×	×	×
GlucoRx Aidex™ (GlucoRx)[11]	✓	×	×	×	×	1	≥18yrs	114	96%	>99.5%	[d]	[d]	[d]	× (≥14yrs)	×	✓	×
GS1 CGM (SiBionics)[12]	✓	×	×	×	×	1	≥18yrs	70	92%	[d]	[d]	[d]	[d]	× (18yrs)	×	×	×
Yuwell CT3 (Urathon)[g]	×	[d]	[d]	[d]	[d]	0	≥18yrs	72	93%	[d]	[d]	[d]	[d]	× (≥14yrs)	×	×	×
Syai Tag (Syai Health Technology)[g]	×	[d]	[d]	[d]	[d]	0	≥18yrs	72	93%	[d]	[d]	[d]	[d]	× (≥18yrs)	×	×	×

Version 1/10/25: Reviewed bi-monthly
Latest version available @ DSN Forum UK

Testing during hypo and hyperglycaemia

GLUCOSE STATISTICS AND TARGETS

22 October 2025 - 4 November 2025 — 14 Days
Time Sensor Active: 87%

Ranges And Targets For	Type 1 or Type 2 Diabetes
Glucose Ranges Target Range 3.9-10.0 mmol/L	**Targets** % of Readings (Time/Day) Greater than 70% (16h 48min)
Below 3.9 mmol/L	Less than 4% (58min)
Below 3.0 mmol/L	Less than 1% (14min)
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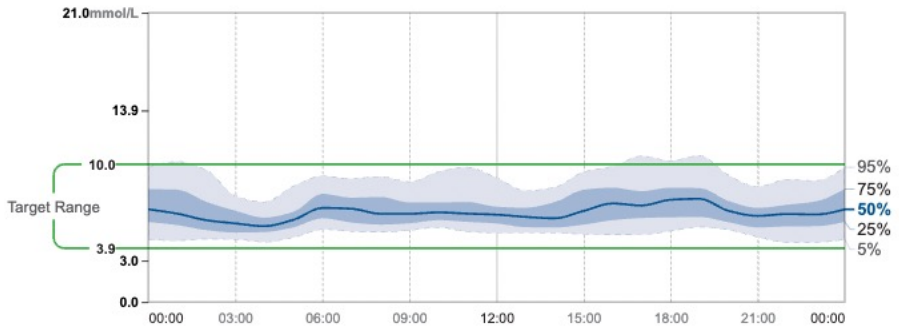
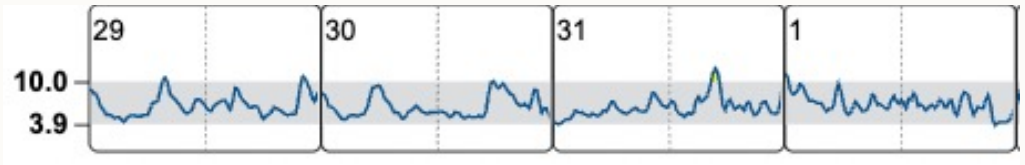
Average Glucose 6.6 mmol/L
Glucose Management Indicator (GMI) 6.2% or 44 mmol/mol
Glucose Variability 21.9%
Defined as percent coefficient of variation (%CV); target ≤36%

TIME IN RANGES

AMBULATORY GLUCOSE PROFILE (AGP)

AGP is a summary of glucose values from the report period, with median (50%) and other percentiles shown as if occurring in a single day.





GLUCOSE STATISTICS AND TARGETS

22 October 2025 - 4 November 2025 — 14 Days
Time Sensor Active: 85%

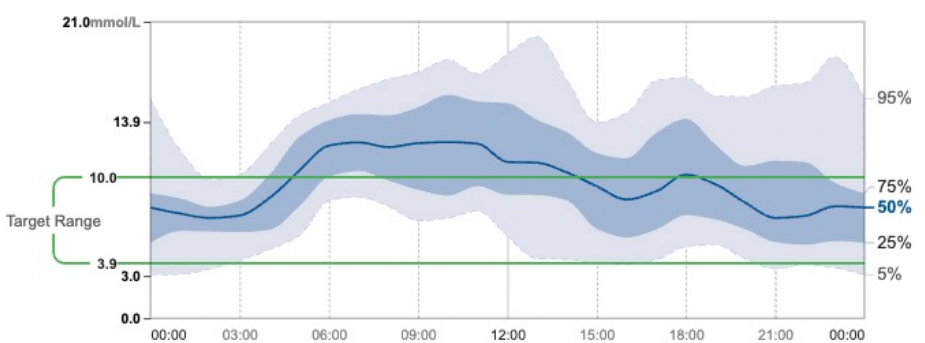
Ranges And Targets For	Type 1 or Type 2 Diabetes
Glucose Ranges Target Range 3.9-10.0 mmol/L	**Targets** % of Readings (Time/Day) Greater than 70% (16h 48min)
Below 3.9 mmol/L	Less than 4% (58min)
Below 3.0 mmol/L	Less than 1% (14min)
Above 10.0 mmol/L	Less than 25% (6h)
Above 13.9 mmol/L	Less than 5% (1h 12min)
Each 5% increase in time in range (3.9-10.0 mmol/L) is clinically beneficial.	

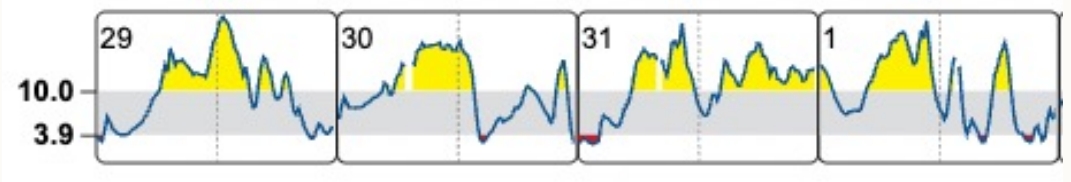
Average Glucose 10.0 mmol/L
Glucose Management Indicator (GMI) 7.6% or 60 mmol/mol
Glucose Variability 39.9%
Defined as percent coefficient of variation (%CV); target ≤36%

TIME IN RANGES

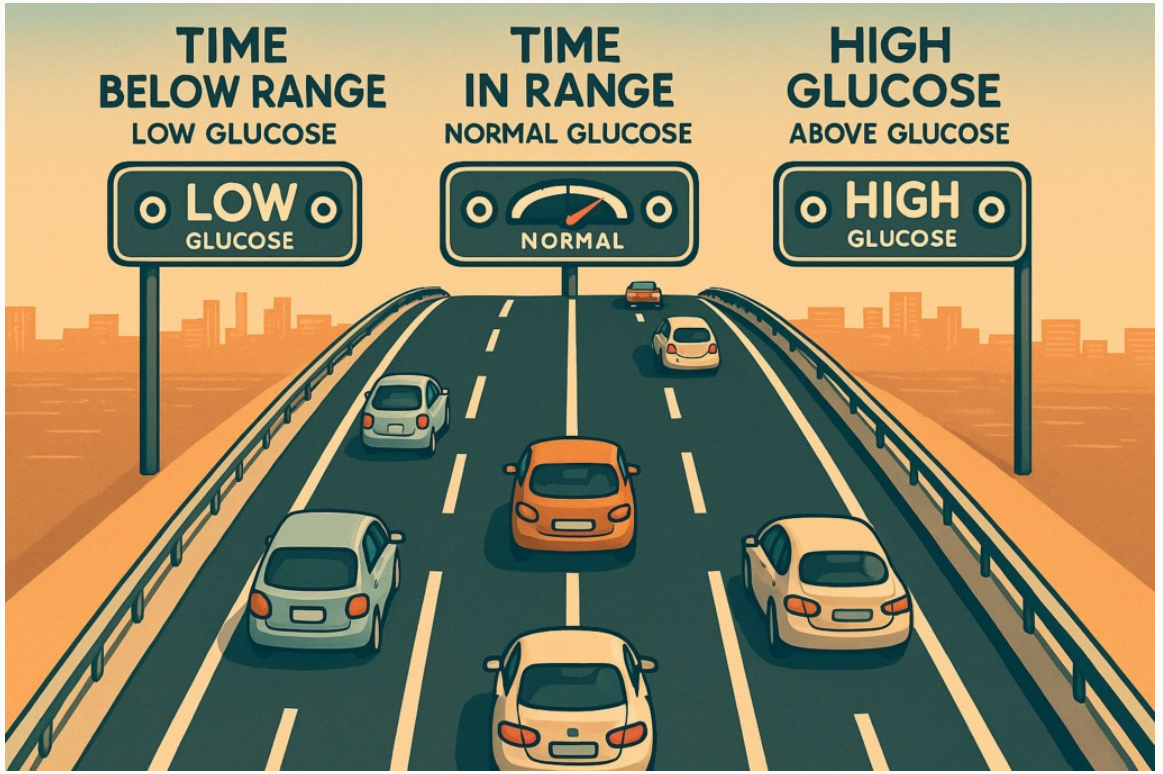
AMBULATORY GLUCOSE PROFILE (AGP)

AGP is a summary of glucose values from the report period, with median (50%) and other percentiles shown as if occurring in a single day.





Testing across the full sensor glucose



Slide courtesy of John Pemberton

Study Design, Clinical Accuracy, and Regulatory Approval Status of CGM Systems Available in the UK

	Study Design Assessment and Score The study design score (0 to 5, with higher scores = greater robustness, ordered by score then alphabet) reflects how thoroughly the CGM system has been tested across the full glucose range (typically 2.2–22.2 mmol/L or 40-400 mg/dL), including the rates of change commonly experienced by people with diabetes. This score provides insight into how likely the performance is to hold true in real-world conditions. The scoring criteria are based on testing recommendations for individuals aged 18 years and older from the 2020 Performance metrics for continuous interstitial glucose monitoring CLSI guideline (POCT05) ,reinforced by the IFCC Working Group on CGM & eCGM Clinician Consensus[b]						**Accuracy Data & Regulatory Status** The 20/20 and 40/40 metrics offers a better representation of the percentage of glucose readings that pose no risk and high risk to clinical decision-making, respectively. In contrast, the Mean Average Relative Difference (MARD) does not indicate the proportion of risk-free readings and is therefore not included. ***20/20:*** Percentage of CGM within ±20% of the comparator blood glucose levels ≥5.5 mmol/L and within ±1.1 mmol/L (20 mg/dL) for blood levels <5.5 mmol/L. ***40/40:*** Percentage of CGM within ±40% of the comparator blood glucose levels ≥5.5 mmol/L and within ±2.2 mmol/L (40 mg/dL) for blood levels <5.5 mmol/L.									
CGM Systems (Distributor in the UK)	**Peer-reviewed[a]**	**≥70% T1D**	**Meal & insulin challenge**	**≥8% of readings <4.4 mmol/L (80 mg/dL)**	**≥5% of readings >16.7 mmol/L (300 mg/dL)**	**Study design score[b]**	**Age range tested**	**N = adults**	**Adult 20/20[c]**	**Adult 40/40[c]**	**N = Paed**	**Paed 20/20[c]**	**Paed 40/40[c]**	**CE marking for non-adjunctive[e] (age indication)**	**iCGM for HCL[f]**	**GP via FP10**	**NHS Supply Chain**
Non-adjunctive use: Licensed for clinical decision-making including insulin dosing. Finger-prick blood glucose confirmation is not required for treatment decisions, unless symptoms do not match the CGM reading or the value and/or trend arrow is unavailable.																	
Accu-Chek SmartGuide® (ROCHE)[1]	✓	✓	✓	✓	✓	5	≥18yrs	48	91%	99%	[d]	[d]	[d]	✓[j] (18yrs)	×	×	×
ALLYcgm (AgaMatrix)[9]	✓	✓	✓	✓	✓	5	≥18yrs	30	94%	>99.5%	[d]	[d]	[d]	✓ (18yrs)	×	×	×
CareSens Air® (Spirit Healthcare)[9]	✓	✓	✓	✓	✓	5	≥18yrs	30	94%	>99.5%	[d]	[d]	[d]	✓ (18yrs)	×	✓	×
Dexcom G6™ (Dexcom)[2-3]	✓	✓	✓	✓	✓	5	≥2yrs	159	93%	>99.5%	165	92%	>99.5%	✓ (≥2yrs)	✓[h]	×	✓
Dexcom G7™ (Dexcom)[4-5]	✓	✓	✓	✓	✓	5	≥2yrs	316	95%	>99.5%	127	95%	>99.5%	✓ (≥2yrs)	✓[i]	×	✓
Dexcom One™ (Dexcom) [2-3]	✓	✓	✓	✓	✓	5	≥2yrs	159	93%	>99.5%	165	92%	>99.5%	✓ (≥2yrs)	×	✓	×
Dexcom One+™ (Dexcom)[4-5]	✓	✓	✓	✓	✓	5	≥2yrs	316	95%	>99.5%	127	95%	>99.5%	✓ (≥2yrs)	×	✓	×
FreeStyle Libre® 2 Plus (Abbott)[6,7]	✓	✓	✓	✓	✓	5	≥2yrs	148	94%	>99.5%	127	94%	>99.5%	✓ (≥2yrs)	✓	✓	✓
FreeStyle Libre® 3 Plus (Abbott)[6,7]	✓	✓	✓	✓	✓	5	≥2yrs	148	94%	>99.5%	127	94%	>99.5%	✓ (≥2yrs)	✓	✓	✓
Simplera/Simplera Sync™ (Medtronic)[8]	✓	✓	✓	✓	✓	5	≥2yrs	160	89%	[d]	138	88%	[d]	✓ (≥2yrs)	×	×	✓
GlucoMen iCan (A. Menarini Diagnostics)[g]	×	✓	✓	✓	✓	4	≥2yrs	35	96%	>99.5%	60	95%	>99.5%	✓ (≥2yrs)	×	✓	×
Guardian™ 4 Sensor and Guardian™ 4 Link Transmitter (Medtronic)[g]	×	✓	✓	✓	✓	4	≥2yrs	153	88%	[d]	108	83%	[d]	✓ (≥2yrs)	×	×	✓
TouchCare® Nano A8 (Medtrum)[g]	×	×	✓	[d]	[d]	1	≥14yrs	63	89%	99%	[d]	[d]	[d]	✓ (≥2yrs)	×	×	✓
Linx (Microtech)[g]	×	[d]	[d]	[d]	[d]	0	≥18yrs	91	>90%	99%	[d]	[d]	[d]	✓ (≥18yrs)	×	×	×
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Gluconovo® (Infinovo)[10]	✓	×	×	×	×	1	≥18yrs	78	90%	99%	[d]	[d]	[d]	× (2yrs)	×	×	×
GlucoRx Aidex™ (GlucoRx)[11]	✓	×	×	×	×	1	≥18yrs	114	96%	>99.5%	[d]	[d]	[d]	× (≥14yrs)	×	✓	×
GS1 CGM (SiBionics)[12]	✓	×	×	×	×	1	≥18yrs	70	92%	[d]	[d]	[d]	[d]	× (18yrs)	×	×	×
Yuwell CT3 (Urathon)[g]	×	[d]	[d]	[d]	[d]	0	≥18yrs	72	93%	[d]	[d]	[d]	[d]	× (≥14yrs)	×	×	×
Syai Tag (Syai Health Technology)[g]	×	[d]	[d]	[d]	[d]	0	≥18yrs	72	93%	[d]	[d]	[d]	[d]	× (≥18yrs)	×	×	×

Study Design, Clinical Accuracy, and Regulatory Approval Status of CGM Systems Available in the UK

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Accu-Chek SmartGuide® (ROCHE)[1]	✓	✓	✓	✓	✓	5	≥18yrs	48	91%	99%	[d]	[d]	[d]	✓[j] (18yrs)	×	×	×
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CareSens Air® (Spirit Healthcare)[9]	✓	✓	✓	✓	✓	5	≥18yrs	30	94%	>99.5%	[d]	[d]	[d]	✓ (18yrs)	×	✓	×
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FreeStyle Libre® 2 Plus (Abbott)[6,7]	✓	✓	✓	✓	✓	5	≥2yrs	148	94%	>99.5%	127	94%	>99.5%	✓ (≥2yrs)	✓	✓	✓
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Guardian™ 4 Sensor and Guardian™ 4 Link Transmitter (Medtronic)[g]	×	✓	✓	✓	✓	4	≥2yrs	153	88%	[d]	108	83%	[d]	✓ (≥2yrs)	×	×	✓
TouchCare® Nano A8 (Medtrum)[g]	×	×	✓	[d]	[d]	1	≥14yrs	63	89%	99%	[d]	[d]	[d]	✓ (≥2yrs)	×	×	✓
Linx (Microtech)[g]	×	[d]	[d]	[d]	[d]	0	≥18yrs	91	>90%	99%	[d]	[d]	[d]	✓ (≥18yrs)	×	×	×
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Yuwell CT3 (Urathon)[g]	×	[d]	[d]	[d]	[d]	0	≥18yrs	72	93%	[d]	[d]	[d]	[d]	× (≥14yrs)	×	×	×
Syai Tag (Syai Health Technology)[g]	×	[d]	[d]	[d]	[d]	0	≥18yrs	72	93%	[d]	[d]	[d]	[d]	× (≥18yrs)	×	×	×

Version 1/10/25: Reviewed bi-monthly
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Study Design, Clinical Accuracy, and Regulatory Approval Status of CGM Systems Available in the UK

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CareSens Air® (Spirit Healthcare)[9]	✓	✓	✓	✓	✓	5	≥18yrs	30	94%	>99.5%	[d]	[d]	[d]	✓ (18yrs)	×	✓	×
Dexcom G6™ (Dexcom)[2-3]	✓	✓	✓	✓	✓	5	≥2yrs	159	93%	>99.5%	165	92%	>99.5%	✓ (≥2yrs)	✓[h]	×	✓
Dexcom G7™ (Dexcom)[4-5]	✓	✓	✓	✓	✓	5	≥2yrs	316	95%	>99.5%	127	95%	>99.5%	✓ (≥2yrs)	✓[i]	×	✓
Dexcom One™ (Dexcom) [2-3]	✓	✓	✓	✓	✓	5	≥2yrs	159	93%	>99.5%	165	92%	>99.5%	✓ (≥2yrs)	×	✓	×
Dexcom One+™ (Dexcom)[4-5]	✓	✓	✓	✓	✓	5	≥2yrs	316	95%	>99.5%	127	95%	>99.5%	✓ (≥2yrs)	×	✓	×
FreeStyle Libre® 2 Plus (Abbott)[6,7]	✓	✓	✓	✓	✓	5	≥2yrs	148	94%	>99.5%	127	94%	>99.5%	✓ (≥2yrs)	✓	✓	✓
FreeStyle Libre® 3 Plus (Abbott)[6,7]	✓	✓	✓	✓	✓	5	≥2yrs	148	94%	>99.5%	127	94%	>99.5%	✓ (≥2yrs)	✓	✓	✓
Simplera/Simplera Sync™ (Medtronic)[8]	✓	✓	✓	✓	✓	5	≥2yrs	160	89%	[d]	138	88%	[d]	✓ (≥2yrs)	×	×	✓
GlucoMen iCan (A. Menarini Diagnostics)[g]	×	✓	✓	✓	✓	4	≥2yrs	35	96%	>99.5%	60	95%	>99.5%	✓ (≥2yrs)	×	✓	×
Guardian™ 4 Sensor and Guardian™ 4 Link Transmitter (Medtronic)[g]	×	✓	✓	✓	✓	4	≥2yrs	153	88%	[d]	108	83%	[d]	✓ (≥2yrs)	×	×	✓
TouchCare® Nano A8 (Medtrum)[g]	×	×	✓	[d]	[d]	1	≥14yrs	63	89%	99%	[d]	[d]	[d]	✓ (≥2yrs)	×	×	✓
Linx (Microtech)[g]	×	[d]	[d]	[d]	[d]	0	≥18yrs	91	>90%	99%	[d]	[d]	[d]	✓ (≥18yrs)	×	×	×
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Yuwell CT3 (Urathon)[g]	×	[d]	[d]	[d]	[d]	0	≥18yrs	72	93%	[d]	[d]	[d]	[d]	× (≥14yrs)	×	×	×
Syai Tag (Syai Health Technology)[g]	×	[d]	[d]	[d]	[d]	0	≥18yrs	72	93%	[d]	[d]	[d]	[d]	× (≥18yrs)	×	×	×

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40/40
Outside of this range is high risk

If your CGM reports a value below 3.9 mmol/L, it's considered accurate if the matched blood glucose is within **±2.2 mmol/L** (±40 mg/dL).

- **Example:**
  A CGM reading of **3.8 mmol/L** is on target if the true value lies between **1.6 and 6.0 mmol/L**.

If your CGM reports 3.9 mmol/L or above, it's accurate if the matched blood glucose is within **±40%** of the CGM value.

- **Example:**
  A CGM reading of **10.0 mmol/L** is on target if the actual glucose is between **6.0 and 14.0 mmol/L**.

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Dexcom G6™ (Dexcom)[2-3]	✓	✓	✓	✓	✓	5	≥2yrs	159	93%	>99.5%	165	92%	>99.5%	✓ (≥2yrs)	✓[h]	×	✓
Dexcom G7™ (Dexcom)[4-5]	✓	✓	✓	✓	✓	5	≥2yrs	316	95%	>99.5%	127	95%	>99.5%	✓ (≥2yrs)	✓[i]	×	✓
Dexcom One™ (Dexcom) [2-3]	✓	✓	✓	✓	✓	5	≥2yrs	159	93%	>99.5%	165	92%	>99.5%	✓ (≥2yrs)	×	✓	×
Dexcom One+™ (Dexcom)[4-5]	✓	✓	✓	✓	✓	5	≥2yrs	316	95%	>99.5%	127	95%	>99.5%	✓ (≥2yrs)	×	✓	×
FreeStyle Libre® 2 Plus (Abbott)[6,7]	✓	✓	✓	✓	✓	5	≥2yrs	148	94%	>99.5%	127	94%	>99.5%	✓ (≥2yrs)	✓	✓	✓
FreeStyle Libre® 3 Plus (Abbott)[6,7]	✓	✓	✓	✓	✓	5	≥2yrs	148	94%	>99.5%	127	94%	>99.5%	✓ (≥2yrs)	✓	✓	✓
Simplera/Simplera Sync™ (Medtronic)[8]	✓	✓	✓	✓	✓	5	≥2yrs	160	89%	[d]	138	88%	[d]	✓ (≥2yrs)	×	×	✓
GlucoMen iCan (A. Menarini Diagnostics)[g]	×	✓	✓	✓	✓	4	≥2yrs	35	96%	>99.5%	60	95%	>99.5%	✓ (≥2yrs)	×	✓	×
Guardian™ 4 Sensor and Guardian™ 4 Link Transmitter (Medtronic)[g]	×	✓	✓	✓	✓	4	≥2yrs	153	88%	[d]	108	83%	[d]	✓ (≥2yrs)	×	×	✓
TouchCare® Nano A8 (Medtrum)[g]	×	×	✓	[d]	[d]	1	≥14yrs	63	89%	99%	[d]	[d]	[d]	✓ (≥2yrs)	×	×	✓
Linx (Microtech)[g]	×	[d]	[d]	[d]	[d]	0	≥18yrs	91	>90%	99%	[d]	[d]	[d]	✓ (≥18yrs)	×	×	×
Adjunctive use: Not licensed for clinical decision-making. All clinical decisions must be confirmed with a finger-prick blood glucose test																	
Gluconovo® (Infinovo)[10]	✓	×	×	×	×	1	≥18yrs	78	90%	99%	[d]	[d]	[d]	× (2yrs)	×	×	×
GlucoRx Aidex™ (GlucoRx)[11]	✓	×	×	×	×	1	≥18yrs	114	96%	>99.5%	[d]	[d]	[d]	× (≥14yrs)	×	✓	×
GS1 CGM (SiBionics)[12]	✓	×	×	×	×	1	≥18yrs	70	92%	[d]	[d]	[d]	[d]	× (18yrs)	×	×	×
Yuwell CT3 (Urathon)[g]	×	[d]	[d]	[d]	[d]	0	≥18yrs	72	93%	[d]	[d]	[d]	[d]	× (≥14yrs)	×	×	×
Syai Tag (Syai Health Technology)[g]	×	[d]	[d]	[d]	[d]	0	≥18yrs	72	93%	[d]	[d]	[d]	[d]	× (≥18yrs)	×	×	×

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Paediatric considerations

Study Design, Clinical Accuracy, and Regulatory Approval Status of CGM Systems Available in the UK

Study Design Assessment and Score

The study design score (0 to 5, with higher scores = greater robustness, ordered by score then alphabet) reflects how thoroughly the CGM system has been tested across the full glucose range (typically 2.2–22.2 mmol/L or 40-400 mg/dL), including the rates of change commonly experienced by people with diabetes. This score provides insight into how likely the performance is to hold true in real-world conditions. The scoring criteria are based on testing recommendations for individuals aged 18 years and older from the 2020 Performance metrics for continuous interstitial glucose monitoring CLSI guideline (POCT05) ,reinforced by the IFCC Working Group on CGM & eCGM Clinician Consensus[b]

Accuracy Data & Regulatory Status

The 20/20 and 40/40 metrics offers a better representation of the percentage of glucose readings that pose no risk and high risk to clinical decision-making, respectively. In contrast, the Mean Average Relative Difference (MARD) does not indicate the proportion of risk-free readings and is therefore not included.

20/20: Percentage of CGM within ±20% of the comparator blood glucose levels ≥5.5 mmol/L and within ±1.1 mmol/L (20 mg/dL) for blood levels <5.5 mmol/L.
40/40: Percentage of CGM within ±40% of the comparator blood glucose levels ≥5.5 mmol/L and within ±2.2 mmol/L (40 mg/dL) for blood levels <5.5 mmol/L.

CGM Systems (Distributor in the UK)	Peer-reviewed[a]	≥70% T1D	Meal & insulin challenge	≥8% of readings <4.4 mmol/L (80 mg/dL)	≥5% of readings >16.7 mmol/L (300 mg/dL)	Study design score[b]	Age range tested	N = adults	Adult 20/20[c]	Adult 40/40[c]	N = Paed	Paed 20/20[c]	Paed 40/40[c]	CE marking for non-adjunctive[e] (age indication)	iCGM for HCL[f]	GP via FP10	NHS Supply Chain
Non-adjunctive use: Licensed for clinical decision-making including insulin dosing. Finger-prick blood glucose confirmation is not required for treatment decisions, unless symptoms do not match the CGM reading or the value and/or trend arrow is unavailable.																	
Accu-Chek SmartGuide® (ROCHE)[1]	✓	✓	✓	✓	✓	5	≥18yrs	48	91%	99%	[d]	[d]	[d]	✓[j] (18yrs)	×	×	×
ALLYcgm (AgaMatrix)[9]	✓	✓	✓	✓	✓	5	≥18yrs	30	94%	>99.5%	[d]	[d]	[d]	✓ (18yrs)	×	×	×
CareSens Air® (Spirit Healthcare)[9]	✓	✓	✓	✓	✓	5	≥18yrs	30	94%	>99.5%	[d]	[d]	[d]	✓ (18yrs)	×	✓	×
Dexcom G6™ (Dexcom)[2-3]	✓	✓	✓	✓	✓	5	≥2yrs	159	93%	>99.5%	165	92%	>99.5%	✓ (≥2yrs)	✓[h]	×	✓
Dexcom G7™ (Dexcom)[4-5]	✓	✓	✓	✓	✓	5	≥2yrs	316	95%	>99.5%	127	95%	>99.5%	✓ (≥2yrs)	✓[i]	×	✓
Dexcom One™ (Dexcom) [2-3]	✓	✓	✓	✓	✓	5	≥2yrs	159	93%	>99.5%	165	92%	>99.5%	✓ (≥2yrs)	×	✓	×
Dexcom One+™ (Dexcom)[4-5]	✓	✓	✓	✓	✓	5	≥2yrs	316	95%	>99.5%	127	95%	>99.5%	✓ (≥2yrs)	×	✓	×
FreeStyle Libre® 2 Plus (Abbott)[6,7]	✓	✓	✓	✓	✓	5	≥2yrs	148	94%	>99.5%	127	94%	>99.5%	✓ (≥2yrs)	✓	✓	✓
FreeStyle Libre® 3 Plus (Abbott)[6,7]	✓	✓	✓	✓	✓	5	≥2yrs	148	94%	>99.5%	127	94%	>99.5%	✓ (≥2yrs)	✓	✓	✓
Simplera/Simplera Sync™ (Medtronic)[8]	✓	✓	✓	✓	✓	5	≥2yrs	160	89%	[d]	138	88%	[d]	✓ (≥2yrs)	×	×	✓
GlucoMen iCan (A. Menarini Diagnostics)[g]	×	✓	✓	✓	✓	4	≥2yrs	35	96%	>99.5%	60	95%	>99.5%	✓ (≥2yrs)	×	✓	×
Guardian™ 4 Sensor and Guardian™ 4 Link Transmitter (Medtronic)[g]	×	✓	✓	✓	✓	4	≥2yrs	153	88%	[d]	108	83%	[d]	✓ (≥2yrs)	×	×	✓
TouchCare® Nano A8 (Medtrum)[g]	×	×	✓	[d]	[d]	1	≥14yrs	63	89%	99%	[d]	[d]	[d]	✓ (≥2yrs)	×	×	✓
Linx (Microtech)[g]	×	[d]	[d]	[d]	[d]	0	≥18yrs	91	>90%	99%	[d]	[d]	[d]	✓ (≥18yrs)	×	×	×
Adjunctive use: Not licensed for clinical decision-making. All clinical decisions must be confirmed with a finger-prick blood glucose test																	
Gluconovo® (Infinovo)[10]	✓	×	×	×	×	1	≥18yrs	78	90%	99%	[d]	[d]	[d]	× (2yrs)	×	×	×
GlucoRx Aidex™ (GlucoRx)[11]	✓	×	×	×	×	1	≥18yrs	114	96%	>99.5%	[d]	[d]	[d]	× (≥14yrs)	×	✓	×
GS1 CGM (SiBionics)[12]	✓	×	×	×	×	1	≥18yrs	70	92%	[d]	[d]	[d]	[d]	× (18yrs)	×	×	×
Yuwell CT3 (Urathon)[g]	×	[d]	[d]	[d]	[d]	0	≥18yrs	72	93%	[d]	[d]	[d]	[d]	× (≥14yrs)	×	×	×
Syai Tag (Syai Health Technology)[g]	×	[d]	[d]	[d]	[d]	0	≥18yrs	72	93%	[d]	[d]	[d]	[d]	× (≥18yrs)	×	×	×

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Study Design, Clinical Accuracy, and Regulatory Approval Status of CGM Systems Available in the UK

	Study Design Assessment and Score The study design score (0 to 5, with higher scores = greater robustness, ordered by score then alphabet) reflects how thoroughly the CGM system has been tested across the full glucose range (typically 2.2–22.2 mmol/L or 40-400 mg/dL), including the rates of change commonly experienced by people with diabetes. This score provides insight into how likely the performance is to hold true in real-world conditions. The scoring criteria are based on testing recommendations for individuals aged 18 years and older from the 2020 Performance metrics for continuous interstitial glucose monitoring CLSI guideline (POCT05) ,reinforced by the IFCC Working Group on CGM & eCGM Clinician Consensus[b]						**Accuracy Data & Regulatory Status** The 20/20 and 40/40 metrics offers a better representation of the percentage of glucose readings that pose no risk and high risk to clinical decision-making, respectively. In contrast, the Mean Average Relative Difference (MARD) does not indicate the proportion of risk-free readings and is therefore not included. ***20/20:*** Percentage of CGM within ±20% of the comparator blood glucose levels ≥5.5 mmol/L and within ±1.1 mmol/L (20 mg/dL) for blood levels <5.5 mmol/L. ***40/40:*** Percentage of CGM within ±40% of the comparator blood glucose levels ≥5.5 mmol/L and within ±2.2 mmol/L (40 mg/dL) for blood levels <5.5 mmol/L.									
CGM Systems (Distributor in the UK)	**Peer-reviewed[a]**	**≥70% T1D**	**Meal & insulin challenge**	**≥8% of readings <4.4 mmol/L (80 mg/dL)**	**≥5% of readings >16.7 mmol/L (300 mg/dL)**	**Study design score[b]**	**Age range tested**	**N = adults**	**Adult 20/20[c]**	**Adult 40/40[c]**	**N = Paed**	**Paed 20/20[c]**	**Paed 40/40[c]**	**CE marking for non-adjunctive[e] (age indication)**	**iCGM for HCL[f]**	**GP via FP10**	**NHS Supply Chain**
Non-adjunctive use: Licensed for clinical decision-making including insulin dosing. Finger-prick blood glucose confirmation is not required for treatment decisions, unless symptoms do not match the CGM reading or the value and/or trend arrow is unavailable.																	
Accu-Chek SmartGuide® (ROCHE)[1]	✓	✓	✓	✓	✓	5	≥18yrs	48	91%	99%	[d]	[d]	[d]	✓[j] (18yrs)	×	×	×
ALLYcgm (AgaMatrix)[9]	✓	✓	✓	✓	✓	5	≥18yrs	30	94%	>99.5%	[d]	[d]	[d]	✓ (18yrs)	×	×	×
CareSens Air® (Spirit Healthcare)[9]	✓	✓	✓	✓	✓	5	≥18yrs	30	94%	>99.5%	[d]	[d]	[d]	✓ (18yrs)	×	✓	×
Dexcom G6™ (Dexcom)[2-3]	✓	✓	✓	✓	✓	5	≥2yrs	159	93%	>99.5%	165	92%	>99.5%	✓ (≥2yrs)	✓[h]	×	✓
Dexcom G7™ (Dexcom)[4-5]	✓	✓	✓	✓	✓	5	≥2yrs	316	95%	>99.5%	127	95%	>99.5%	✓ (≥2yrs)	✓[i]	×	✓
Dexcom One™ (Dexcom) [2-3]	✓	✓	✓	✓	✓	5	≥2yrs	159	93%	>99.5%	165	92%	>99.5%	✓ (≥2yrs)	×	✓	×
Dexcom One+™ (Dexcom)[4-5]	✓	✓	✓	✓	✓	5	≥2yrs	316	95%	>99.5%	127	95%	>99.5%	✓ (≥2yrs)	×	✓	×
FreeStyle Libre® 2 Plus (Abbott)[6,7]	✓	✓	✓	✓	✓	5	≥2yrs	148	94%	>99.5%	127	94%	>99.5%	✓ (≥2yrs)	✓	✓	✓
FreeStyle Libre® 3 Plus (Abbott)[6,7]	✓	✓	✓	✓	✓	5	≥2yrs	148	94%	>99.5%	127	94%	>99.5%	✓ (≥2yrs)	✓	✓	✓
Simplera/Simplera Sync™ (Medtronic)[8]	✓	✓	✓	✓	✓	5	≥2yrs	160	89%	[d]	138	88%	[d]	✓ (≥2yrs)	×	×	✓
GlucoMen iCan (A. Menarini Diagnostics)[g]	×	✓	✓	✓	✓	4	≥2yrs	35	96%	>99.5%	60	95%	>99.5%	✓ (≥2yrs)	×	✓	×
Guardian™ 4 Sensor and Guardian™ 4 Link Transmitter (Medtronic)[g]	×	✓	✓	✓	✓	4	≥2yrs	153	88%	[d]	108	83%	[d]	✓ (≥2yrs)	×	×	✓
TouchCare® Nano A8 (Medtrum)[g]	×	×	✓	[d]	[d]	1	≥14yrs	63	89%	99%	[d]	[d]	[d]	✓ (≥2yrs)	×	×	✓
Linx (Microtech)[g]	×	[d]	[d]	[d]	[d]	0	≥18yrs	91	>90%	99%	[d]	[d]	[d]	✓ (≥18yrs)	×	×	×
Adjunctive use: Not licensed for clinical decision-making. All clinical decisions must be confirmed with a finger-prick blood glucose test																	
Gluconovo® (Infinovo)[10]	✓	×	×	×	×	1	≥18yrs	78	90%	99%	[d]	[d]	[d]	× (2yrs)	×	×	×
GlucoRx Aidex™ (GlucoRx)[11]	✓	×	×	×	×	1	≥18yrs	114	96%	>99.5%	[d]	[d]	[d]	× (≥14yrs)	×	✓	×
GS1 CGM (SiBionics)[12]	✓	×	×	×	×	1	≥18yrs	70	92%	[d]	[d]	[d]	[d]	× (18yrs)	×	×	×
Yuwell CT3 (Urathon)[g]	×	[d]	[d]	[d]	[d]	0	≥18yrs	72	93%	[d]	[d]	[d]	[d]	× (≥14yrs)	×	×	×
Syai Tag (Syai Health Technology)[g]	×	[d]	[d]	[d]	[d]	0	≥18yrs	72	93%	[d]	[d]	[d]	[d]	× (≥18yrs)	×	×	×

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Fingerprick glucose

- With CGM use this is needed:
  - To confirm hypoglycaemia
  - When sensor glucose does not match symptoms

- Some CGM systems *also need a blood glucose test confirmation* for insulin dosing – if a system does not have a “non adjunctive licence” then this means <u>finger pricks will be needed</u> to guide insulin dosing

Study Design, Clinical Accuracy, and Regulatory Approval Status of CGM Systems Available in the UK

Study Design Assessment and Score

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Accuracy Data & Regulatory Status

The 20/20 and 40/40 metrics offers a better representation of the percentage of glucose readings that pose no risk and high risk to clinical decision-making, respectively. In contrast, the Mean Average Relative Difference (MARD) does not indicate the proportion of risk-free readings and is therefore not included.

20/20: Percentage of CGM within ±20% of the comparator blood glucose levels ≥5.5 mmol/L and within ±1.1 mmol/L (20 mg/dL) for blood levels <5.5 mmol/L.

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CGM Systems (Distributor in the UK)	Peer-reviewed[a]	≥70% T1D	Meal & insulin challenge	≥8% of readings <4.4 mmol/L (80 mg/dL)	≥5% of readings >16.7 mmol/L (300 mg/dL)	Study design score[b]	Age range tested	N = adults	Adult 20/20[c]	Adult 40/40[c]	N = Paed	Paed 20/20[c]	Paed 40/40[c]	CE marking for non-adjunctive[e] (age indication)	iCGM for HCL[f]	GP via FP10	NHS Supply Chain
Non-adjunctive use: Licensed for clinical decision-making including insulin dosing. Finger-prick blood glucose confirmation is not required for treatment decisions, unless symptoms do not match the CGM reading or the value and/or trend arrow is unavailable.																	
Accu-Chek SmartGuide® (ROCHE)[1]	✓	✓	✓	✓	✓	5	≥18yrs	48	91%	99%	[d]	[d]	[d]	✓[j] (18yrs)	×	×	×
ALLYcgm (AgaMatrix)[9]	✓	✓	✓	✓	✓	5	≥18yrs	30	94%	>99.5%	[d]	[d]	[d]	✓ (18yrs)	×	×	×
CareSens Air® (Spirit Healthcare)[9]	✓	✓	✓	✓	✓	5	≥18yrs	30	94%	>99.5%	[d]	[d]	[d]	✓ (18yrs)	×	✓	×
Dexcom G6™ (Dexcom)[2-3]	✓	✓	✓	✓	✓	5	≥2yrs	159	93%	>99.5%	165	92%	>99.5%	✓ (≥2yrs)	✓[h]	×	✓
Dexcom G7™ (Dexcom)[4-5]	✓	✓	✓	✓	✓	5	≥2yrs	316	95%	>99.5%	127	95%	>99.5%	✓ (≥2yrs)	✓[i]	×	✓
Dexcom One™ (Dexcom) [2-3]	✓	✓	✓	✓	✓	5	≥2yrs	159	93%	>99.5%	165	92%	>99.5%	✓ (≥2yrs)	×	✓	×
Dexcom One+™ (Dexcom)[4-5]	✓	✓	✓	✓	✓	5	≥2yrs	316	95%	>99.5%	127	95%	>99.5%	✓ (≥2yrs)	×	✓	×
FreeStyle Libre® 2 Plus (Abbott)[6,7]	✓	✓	✓	✓	✓	5	≥2yrs	148	94%	>99.5%	127	94%	>99.5%	✓ (≥2yrs)	✓	✓	✓
FreeStyle Libre® 3 Plus (Abbott)[6,7]	✓	✓	✓	✓	✓	5	≥2yrs	148	94%	>99.5%	127	94%	>99.5%	✓ (≥2yrs)	✓	✓	✓
Simplera/Simplera Sync™ (Medtronic)[8]	✓	✓	✓	✓	✓	5	≥2yrs	160	89%	[d]	138	88%	[d]	✓ (≥2yrs)	×	×	✓
GlucoMen iCan (A. Menarini Diagnostics)[g]	×	✓	✓	✓	✓	4	≥2yrs	35	96%	>99.5%	60	95%	>99.5%	✓ (≥2yrs)	×	✓	×
Guardian™ 4 Sensor and Guardian™ 4 Link Transmitter (Medtronic)[g]	×	✓	✓	✓	✓	4	≥2yrs	153	88%	[d]	108	83%	[d]	✓ (≥2yrs)	×	×	✓
TouchCare® Nano A8 (Medtrum)[g]	×	×	✓	[d]	[d]	1	≥14yrs	63	89%	99%	[d]	[d]	[d]	✓ (≥2yrs)	×	×	✓
Linx (Microtech)[g]	×	[d]	[d]	[d]	[d]	0	≥18yrs	91	>90%	99%	[d]	[d]	[d]	✓ (≥18yrs)	×	×	×
Adjunctive use: Not licensed for clinical decision-making. All clinical decisions must be confirmed with a finger-prick blood glucose test																	
Gluconovo® (Infinovo)[10]	✓	×	×	×	×	1	≥18yrs	78	90%	99%	[d]	[d]	[d]	× (2yrs)	×	×	×
GlucoRx Aidex™ (GlucoRx)[11]	✓	×	×	×	×	1	≥18yrs	114	96%	>99.5%	[d]	[d]	[d]	× (≥14yrs)	×	✓	×
GS1 CGM (SiBionics)[12]	✓	×	×	×	×	1	≥18yrs	70	92%	[d]	[d]	[d]	[d]	× (18yrs)	×	×	×
Yuwell CT3 (Urathon)[g]	×	[d]	[d]	[d]	[d]	0	≥18yrs	72	93%	[d]	[d]	[d]	[d]	× (≥14yrs)	×	×	×
Syai Tag (Syai Health Technology)[g]	×	[d]	[d]	[d]	[d]	0	≥18yrs	72	93%	[d]	[d]	[d]	[d]	× (≥18yrs)	×	×	×

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Diabetes Specialist Nurse Forum UK

Study Design, Clinical Accuracy, and Regulatory Approval Status of CGM Systems Available in the UK

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CGM Systems (Distributor in the UK)	**Peer-reviewed[a]**	**≥70% T1D**	**Meal & insulin challenge**	**≥8% of readings <4.4 mmol/L (80 mg/dL)**	**≥5% of readings >16.7 mmol/L (300 mg/dL)**	**Study design score[b]**	**Age range tested**	**N = adults**	**Adult 20/20[c]**	**Adult 40/40[c]**	**N = Paed**	**Paed 20/20[c]**	**Paed 40/40[c]**	**CE marking for non-adjunctive[e] (age indication)**	**iCGM for HCL[f]**	**GP via FP10**	**NHS Supply Chain**
Non-adjunctive use: Licensed for clinical decision-making including insulin dosing. Finger-prick blood glucose confirmation is not required for treatment decisions, unless symptoms do not match the CGM reading or the value and/or trend arrow is unavailable.																	
Accu-Chek SmartGuide® (ROCHE)[1]	✓	✓	✓	✓	✓	5	≥18yrs	48	91%	99%	[d]	[d]	[d]	✓[j] (18yrs)	×	×	×
ALLYcgm (AgaMatrix)[9]	✓	✓	✓	✓	✓	5	≥18yrs	30	94%	>99.5%	[d]	[d]	[d]	✓ (18yrs)	×	×	×
CareSens Air® (Spirit Healthcare)[9]	✓	✓	✓	✓	✓	5	≥18yrs	30	94%	>99.5%	[d]	[d]	[d]	✓ (18yrs)	×	✓	×
Dexcom G6™ (Dexcom)[2-3]	✓	✓	✓	✓	✓	5	≥2yrs	159	93%	>99.5%	165	92%	>99.5%	✓ (≥2yrs)	✓[h]	×	✓
Dexcom G7™ (Dexcom)[4-5]	✓	✓	✓	✓	✓	5	≥2yrs	316	95%	>99.5%	127	95%	>99.5%	✓ (≥2yrs)	✓[i]	×	✓
Dexcom One™ (Dexcom) [2-3]	✓	✓	✓	✓	✓	5	≥2yrs	159	93%	>99.5%	165	92%	>99.5%	✓ (≥2yrs)	×	✓	×
Dexcom One+™ (Dexcom)[4-5]	✓	✓	✓	✓	✓	5	≥2yrs	316	95%	>99.5%	127	95%	>99.5%	✓ (≥2yrs)	×	✓	×
FreeStyle Libre® 2 Plus (Abbott)[6,7]	✓	✓	✓	✓	✓	5	≥2yrs	148	94%	>99.5%	127	94%	>99.5%	✓ (≥2yrs)	✓	✓	✓
FreeStyle Libre® 3 Plus (Abbott)[6,7]	✓	✓	✓	✓	✓	5	≥2yrs	148	94%	>99.5%	127	94%	>99.5%	✓ (≥2yrs)	✓	✓	✓
Simplera/Simplera Sync™ (Medtronic)[8]	✓	✓	✓	✓	✓	5	≥2yrs	160	89%	[d]	138	88%	[d]	✓ (≥2yrs)	×	×	✓
GlucoMen iCan (A. Menarini Diagnostics)[g]	×	✓	✓	✓	✓	4	≥2yrs	35	96%	>99.5%	60	95%	>99.5%	✓ (≥2yrs)	×	✓	×
Guardian™ 4 Sensor and Guardian™ 4 Link Transmitter (Medtronic)[g]	×	✓	✓	✓	✓	4	≥2yrs	153	88%	[d]	108	83%	[d]	✓ (≥2yrs)	×	×	✓
TouchCare® Nano A8 (Medtrum)[g]	×	×	✓	[d]	[d]	1	≥14yrs	63	89%	99%	[d]	[d]	[d]	✓ (≥2yrs)	×	×	✓
Linx (Microtech)[g]	×	[d]	[d]	[d]	[d]	0	≥18yrs	91	>90%	99%	[d]	[d]	[d]	✓ (≥18yrs)	×	×	×
Adjunctive use: Not licensed for clinical decision-making. All clinical decisions must be confirmed with a finger-prick blood glucose test																	
Gluconovo® (Infinovo)[10]	✓	×	×	×	×	1	≥18yrs	78	90%	99%	[d]	[d]	[d]	× (2yrs)	×	×	×
GlucoRx Aidex™ (GlucoRx)[11]	✓	×	×	×	×	1	≥18yrs	114	96%	>99.5%	[d]	[d]	[d]	× (≥14yrs)	×	✓	×
GS1 CGM (SiBionics)[12]	✓	×	×	×	×	1	≥18yrs	70	92%	[d]	[d]	[d]	[d]	× (18yrs)	×	×	×
Yuwell CT3 (Urathon)[g]	×	[d]	[d]	[d]	[d]	0	≥18yrs	72	93%	[d]	[d]	[d]	[d]	× (≥14yrs)	×	×	×
Syai Tag (Syai Health Technology)[g]	×	[d]	[d]	[d]	[d]	0	≥18yrs	72	93%	[d]	[d]	[d]	[d]	× (≥18yrs)	×	×	×

Version 1/10/25: Reviewed bi-monthly
Latest version available @ DSN Forum UK

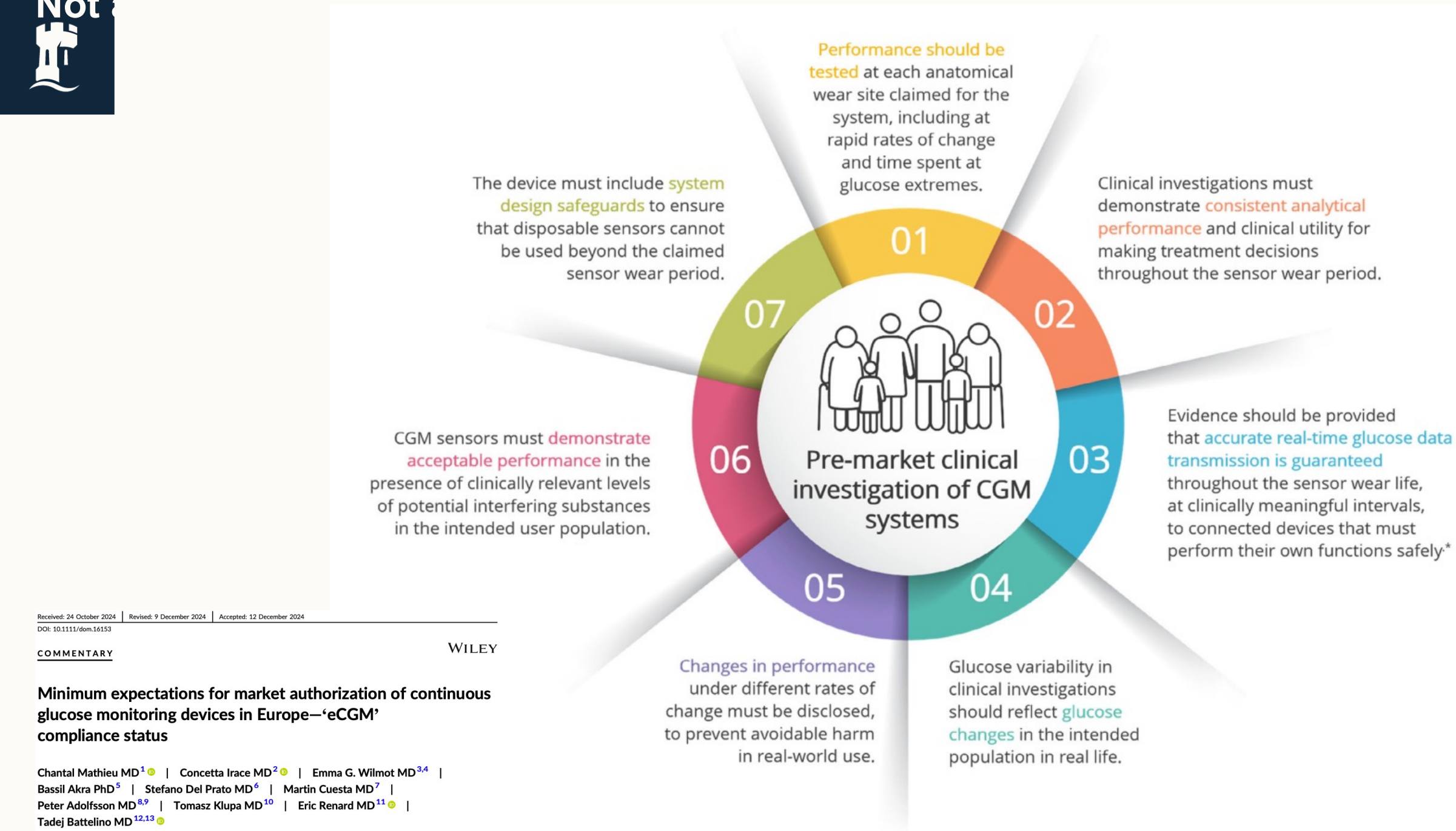
Endorsements

Breakthrough T1D™ Formerly JDRF

DISN UK GROUP

DIABETES UK
KNOW DIABETES. FIGHT DIABETES.

https://www.diabetesspecialistnurseforumuk.co.uk/new-cgm-comparison-chart



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

WILEY

COMMENTARY

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]

eCGM

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

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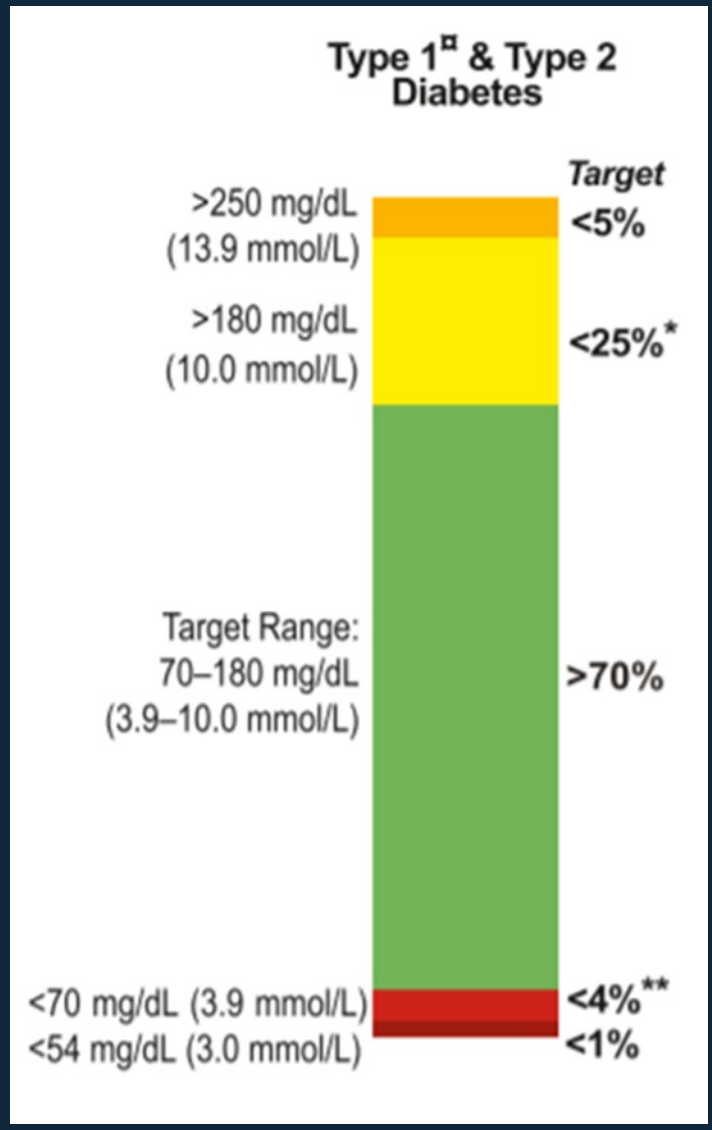
POCT05 Study Criteria:

- T1D: 70-75%
- Meal and Insulin challenges
- 8%: TBR (<70 mg/dL or 3.9 mmol/L)
- 5%: >300 mg/dL or 16.7 mmol/L

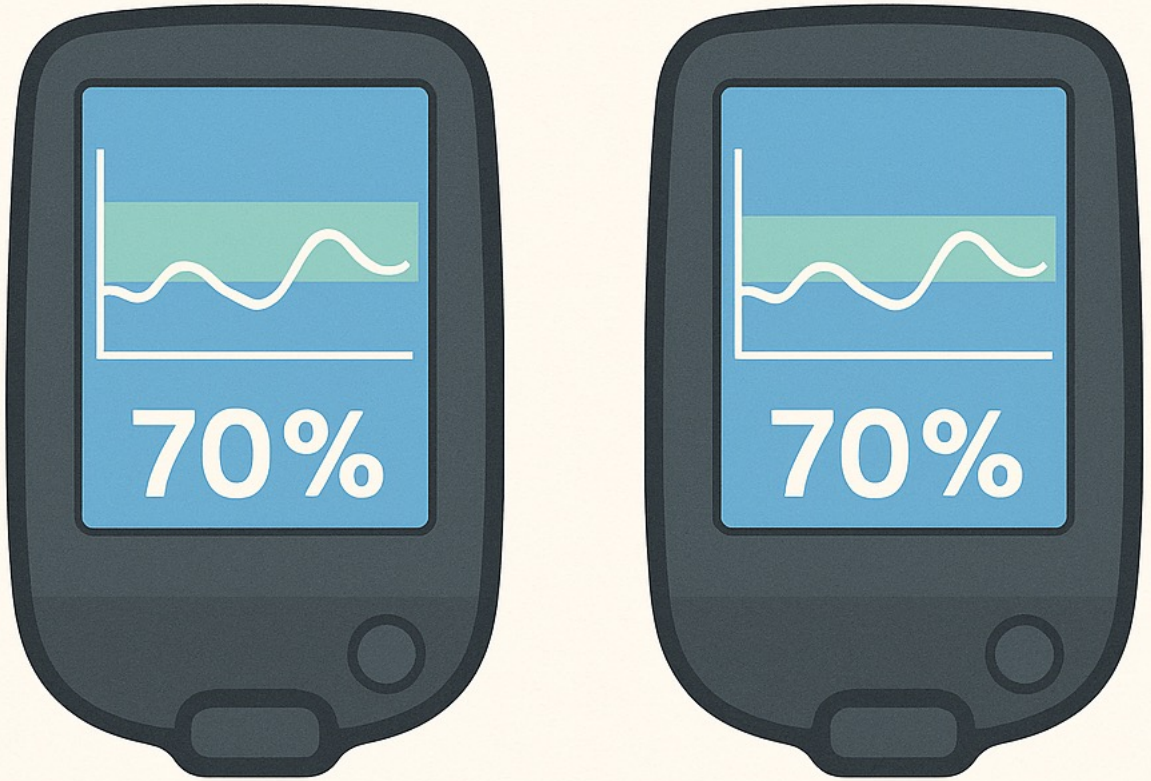
Performance Criteria:

- FDA iCGM 15/15
- FDA iCGM 40/40
- Other iCGM metrics
- Equivalent FDA Class III approval

Are all TIR equal?



Does 70% time-in-range (TIR, 3,9-10.0 mmol/L or 70-180 mg/dL) on one CGM system mean the same as 70% on another?



Diabetes Care
American Diabetes Association

A Comparative Analysis of Glycemic Metrics Derived From Three Continuous Glucose Monitoring Systems

Guido Freckmann, Stephanie Wehrstedt, Manuel Eichenlaub, Stefan Pleus, Manuela Link, Nina Jendrike, Sükrü Öter, Derek Brandt, Cornelia Haug, and Delia Waldenmaier

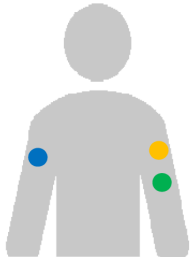
Diabetes Care 2025;48(7):1213–1217 | https://doi.org/10.2337/dc25-0129

Comparing across sensors

Objective

To analyze the **differences in continuous glucose monitoring (CGM)-derived metrics** among three current-generation systems and evaluate their i**mpact on therapeutic decision-making.**

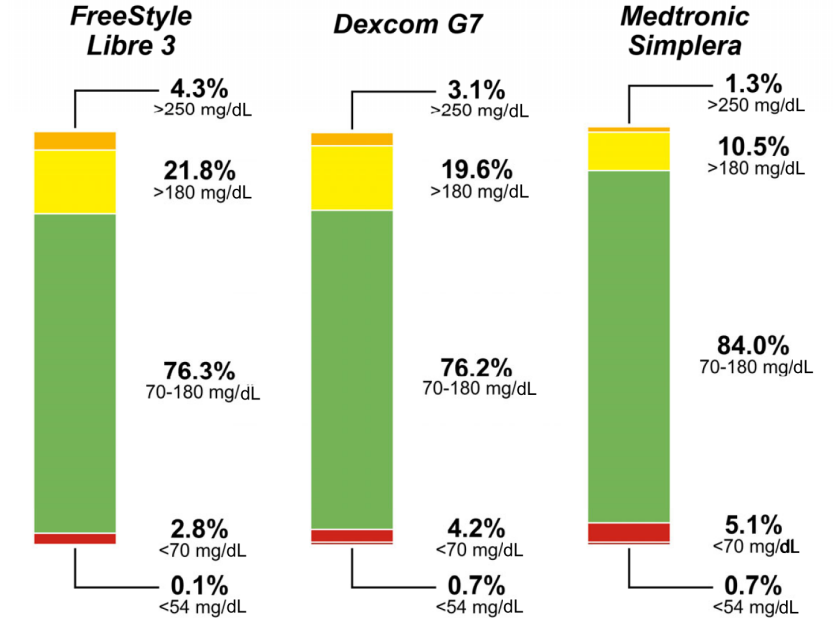
Research Design & Methods



23 adult participants, 14 days
FreeStyle Libre 3
Dexcom G7
Medtronic Simplera

CGM metrics calculated for each participant and CGM system separately

Results



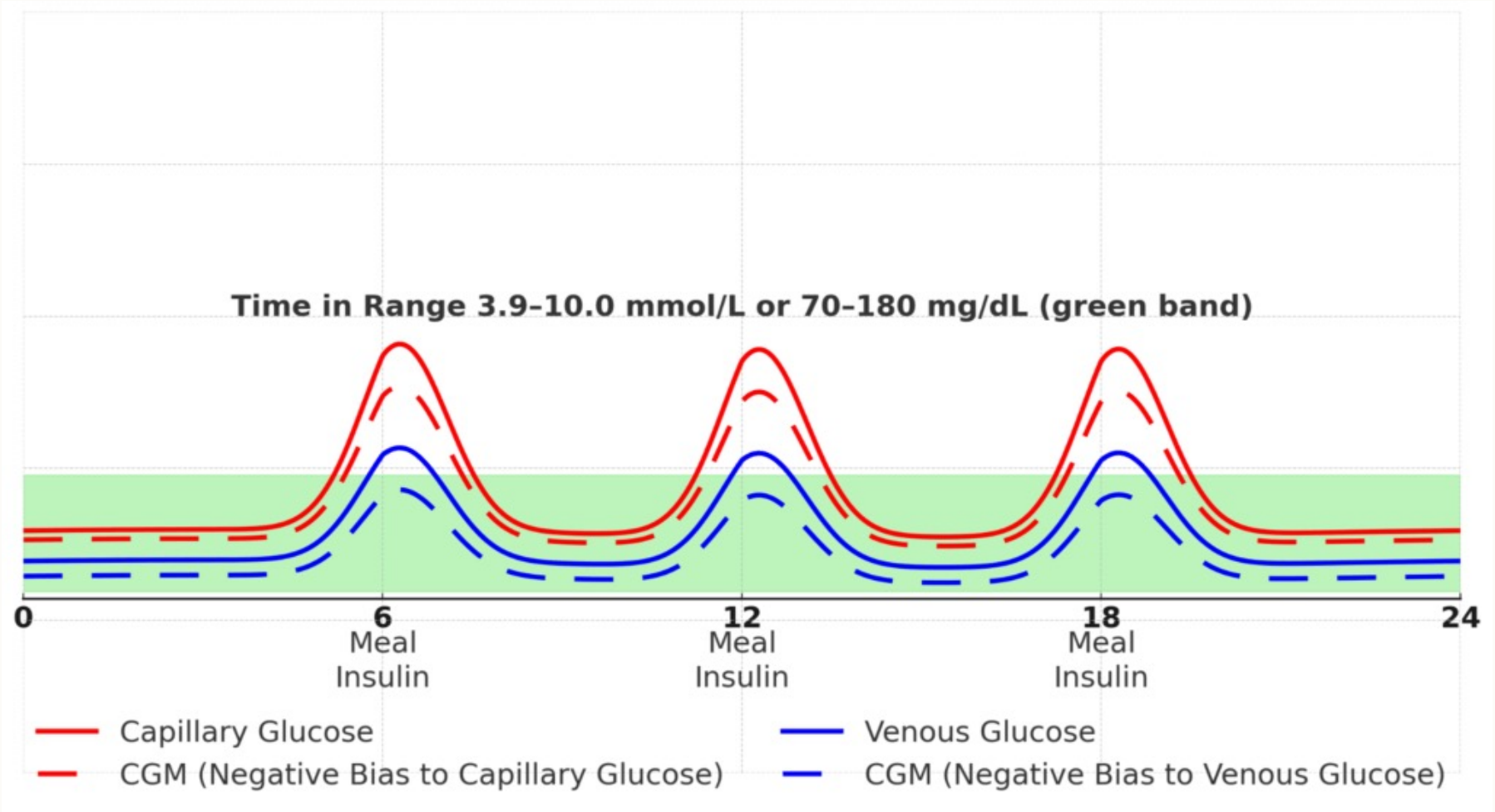
Median percentage of time in different glucose ranges across all study participants according to the different CGM systems.

- Differences in glucose profiles, resulting in **substantially different glycemic metrics** among the three systems.
- Marked intra-participant discrepancies that would have resulted in **different therapeutic recommendations**.

Conclusions

The CGM systems indicated discordant glycemic metrics that should beconsidered in diabetes the rapy. Different CGM systems should provide the same glucose readings and CGM-derived metrics when used by the same person.

Freckmann G et al. Diabetes Care. 2025;48(7):1213-1217. doi:10.2337/dc25-0129



Slide courtesy of John Pemberton

Urgent Need for Standardization in CGM Performance Assessment

John S. Pemberton,[1] Peter Adolfsson,[2,3] Emma G. Wilmot,[4,5] Pratik Choudhary,[6,7] and Othmar Moser[8,9,10]

Diabetes Care 2025;48:e126–e127 | https://doi.org/10.2337/dc25-1213

COMMENT ON FRECKMANN ET AL.

A Comparative Analysis of Glycemic Metrics Derived From Three Continuous Glucose Monitors. Diabetes Care 2025;48:1213–1217

Roy W. Beck

Diabetes Care 2025;48:e124–e125 | https://doi.org/10.2337/dc25-0920

RESPONSE TO COMMENTS ON FRECKMANN ET AL.

A Comparative Analysis of Glycemic Metrics Derived From Three Continuous Glucose Monitoring Systems. Diabetes Care 2025;48:1213–1217

Delia Waldenmaier,[1] Stephanie Wehrstedt,[1] Manuel Eichenlaub,[1] Stefan Pleus,[1] Manuela Link,[1] Nina Jendrike,[1] Sükrü Öter,[1] Derek Brandt,[2] Cornelia Haug,[1] and Guido Freckmann[1]

Diabetes Care 2025;48:e128–e129 | https://doi.org/10.2337/dci25-0071

Responses

- *"Pemberton et al. raise relevant points about the broader implications of CGM discordances for clinical care and research. The **lack of standardized performance requirements** means that patients and clinicians may **unknowingly rely on less accurate systems** in situations where accuracy is most critical, or draw conclusions from research where an outcome might be an artifact of device-specific biases."*

- *"The demand raised by Pemberton et al. **for internationally harmonized standards aligns perfectly with our conclusions**. The International Federation of Clinical Chemistry and Laboratory Medicine Working Group on Continuous Glucose Monitoring, which several of us participate in, is actively working toward standardized evaluation protocols"*

Waldenmaier D et al. *Diabetes Care* 19 September 2025; 48 (10): e128–e129.

Review Article

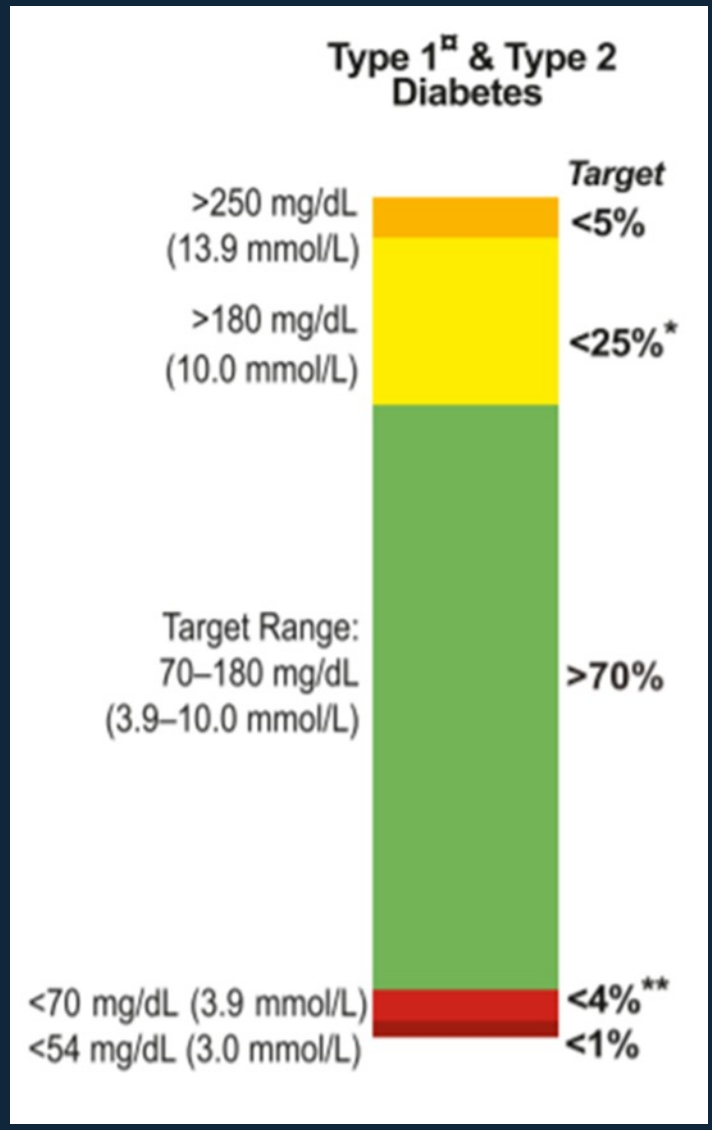
Journal of Diabetes Science and Technology
1–10

DOI: 10.1177/19322968251336221
journals.sagepub.com/home/dst
Sage

Recommendations on the Collection of Comparator Measurement Data in the Performance Evaluation of Continuous Glucose Monitoring Systems

Guido Freckmann, MD[1,2], Stefan Pleus, PhD[1,2], Manuel Eichenlaub, PhD[2], Elisabet Eriksson Boija, PhD[1,3], Marion Fokkert, PhD[1,4], Rolf Hinzmann, MD, PhD[1,5], Johan Jendle, MD, PhD[1,6], David C. Klonoff, MD, FACP, FRCP (Edin), Fellow AIMBE[1,7], Konstantinos Makris, PhD[1,8], James H. Nichols, PhD[1,9], John Pemberton, BSc, RD[1,10], Elizabeth Selvin, PhD, MPH[1,11], Nam K. Tran, PhD[1,12], Lilian Witthauer, PhD[1,13,14], and Robbert J. Slingerland, PhD[1,4]; on behalf of the Working Group on Continuous Glucose Monitoring of the IFCC Scientific Division

The future?


Type 1¤ & Type 2 Diabetes
Target
>250 mg/dL (13.9 mmol/L)
<5%
>180 mg/dL (10.0 mmol/L)
<25%*
Target Range: 70–180 mg/dL (3.9–10.0 mmol/L)
>70%
<70 mg/dL (3.9 mmol/L)
<4%**
<54 mg/dL (3.0 mmol/L)
<1%

CE Marking is not a quality standard

MARD is not a quality standard

An international standard is needed

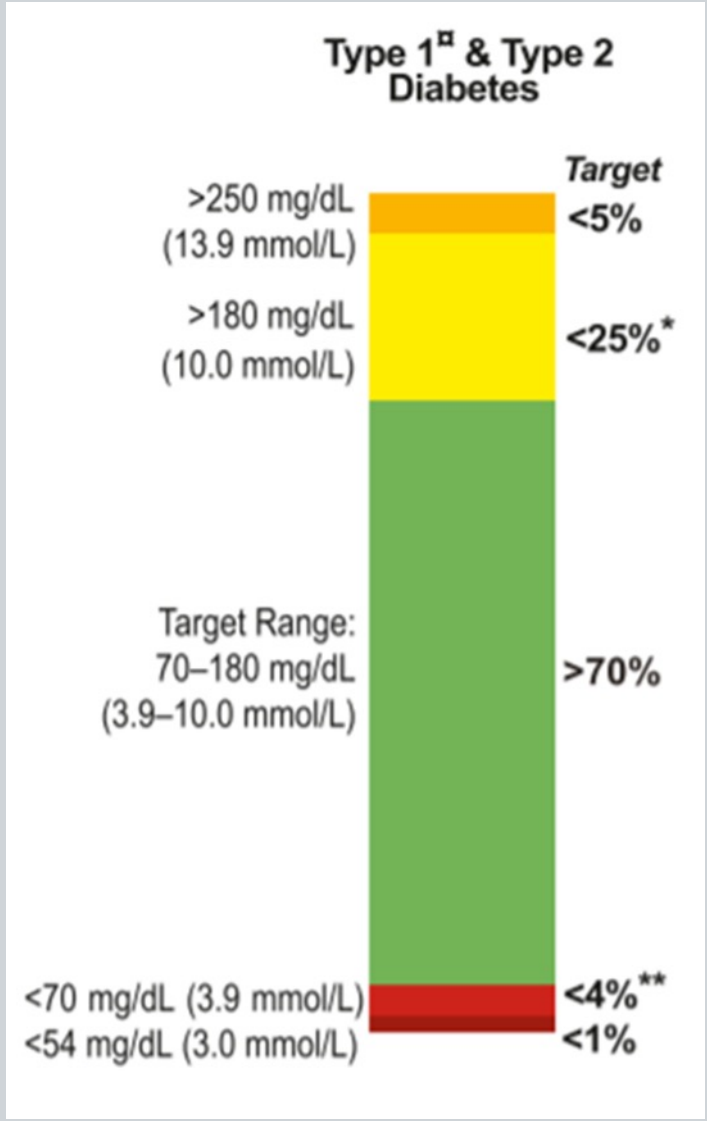
Scenario

- John comes into clinic to see you
- He has T1DM on multiple daily injections
- He is trialing a new CGM he was offered via an internet advert
- He likes it and asks you if you can make it available locally
- What is your approach?

1. Peer-reviewed publication
2. ≥70% participants with Type 1 diabetes
3. Meal and insulin challenges included
4. A minimum of 8% of readings <4,4 mmol/L during testing
5. A minimum of 5% of readings ≥16,7 mmol/L during testing

Conclusion

- Technology is improving outcomes in diabetes
- We must ensure the CGM devices that people living with diabetes have access to are a high quality
- International efforts are underway to address unmet needs



Today at 1620: FreeDM2 study results

Unlocking the Benefits of CGM in Type 2 Diabetes:

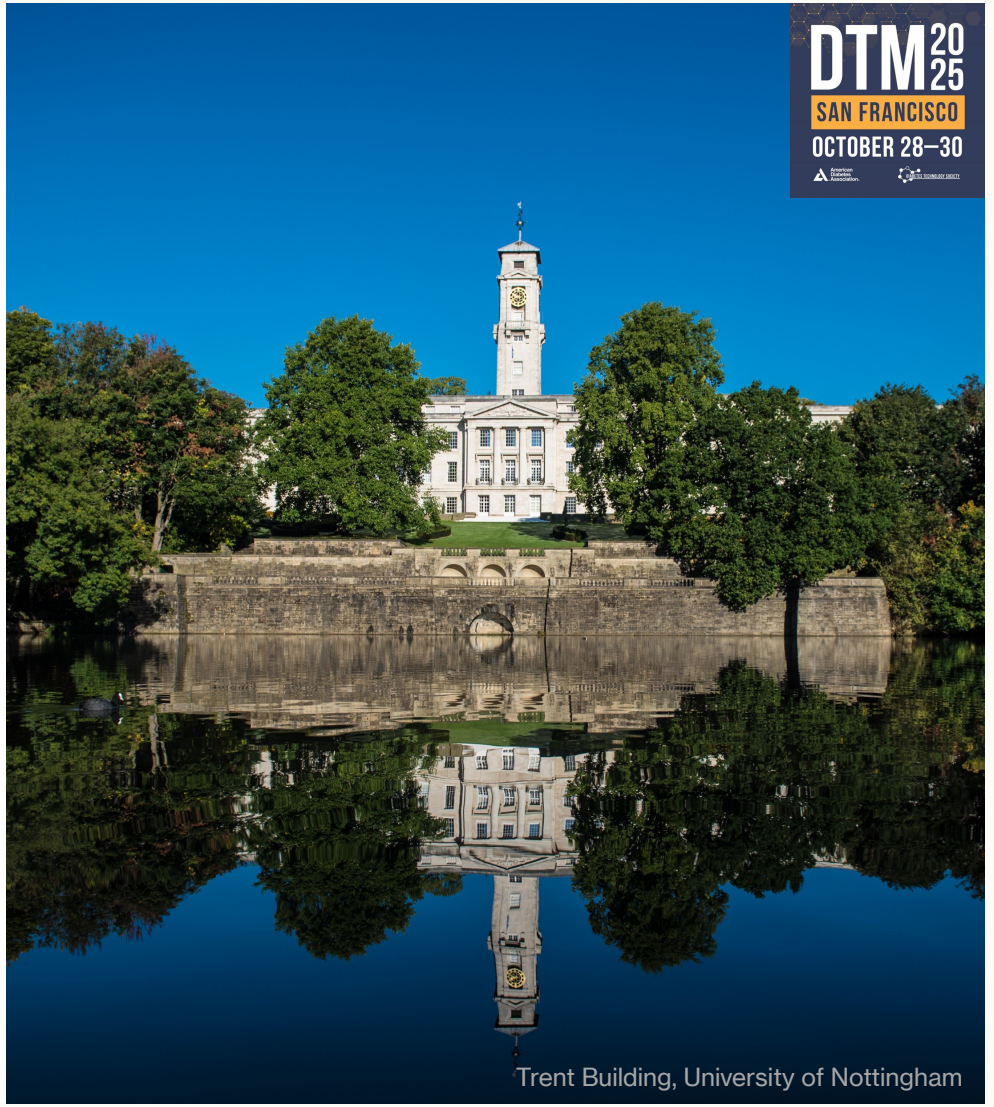
The FreeDM2 Randomised Controlled Trial

Methods
and Primary Outcome

Dr Emma G Wilmot, FRCP, PhD
Associate Professor, University of Nottingham, UK
Chief Investigator FreeDM2 RCT

Dr Lalantha Leelarathna, FRCP, PhD
Associate Professor, Imperial College London, UK
Chief Investigator FreeDM2 RCT

ClinicalTrials.gov: NCT05944432
Study sponsored by Abbott Diabetes Care



Trent Building, University of Nottingham

Thank you