FIND
Diagnosis for all

ACCEDE
Access to CGMs for Equity in Diabetes Management

CGM PERFORMANCE FACTSHEET

FOR PEOPLE LIVING WITH DIABETES AND HEALTHCARE PROVIDERS

Developed in collaboration with

IfDT Ulm

SA Diabetes Advocacy

Supported by

THE LEONA M. AND HARRY B. HELMSLEY CHARITABLE TRUST

UNDERSTANDING CGM PERFORMANCE: WHAT IT MEANS FOR YOU

- Why is it important to check continuous glucose monitoring (CGM) performance data as a person living with diabetes?
- What is a study?
- What is a study design?
- How do you know if the study design suits you as a person living with diabetes?
- What is mean absolute relative difference (MARD)? Why does it not reflect real-life performance?

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OBJECTIVE

The objective of this factsheet is to provide you with the tool to understand the performance data of a CGM product from the package inserts and other information sources, to support you in making an informed decision in selecting the right CGM products for you.

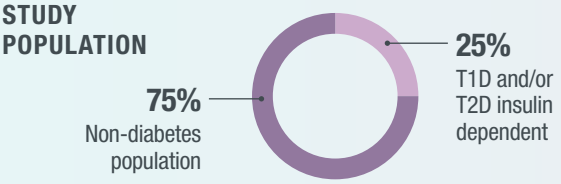
TOP TIPS

- **Always assess the study design:** only look at the CGM performance if the study population is similar to those you support, such as person with type 1 diabetes (T1D). Do not only look at MARD, it will not reflect real-life performance.
- **Comparator measurement or testing:** comparator measurements or testing is used to know what the true value of glucose was in blood, in order to understand how similar (or accurate) the CGM reading is.
- **Check if the study is published in a peer-reviewed journal:** peer review is the process where experts in the same field check a research paper for accuracy, quality, and reliability before it's published. It helps make sure the study is well-done, the results make sense, and any mistakes are caught — making the research more trustworthy.
- **Understand data points and percentage:** more data means stronger results, so check how much information the study is based on.
- **Understand dynamic glucose distribution data:** these are changing glucose levels (e.g., highs and lows), which are important to see how well CGMs respond to real-life fluctuations.
- **Understand rates of glucose change:** shows how quickly glucose levels rise or fall, helping assess if the CGM can keep up with rapid changes.
- **Consider meal and/or insulin challenges:** tests where glucose or insulin is given to see how the CGM performs under high and low blood glucose events.

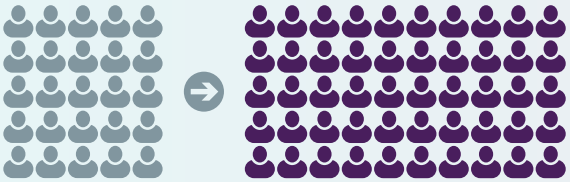
SUMMARY OF THE 6 ESSENTIAL QUESTIONS TO CHECK FOR

CGM CONFIDENCE CHECK

1. STUDY POPULATION



2. NUMBER OF PEOPLE IN THE STUDY

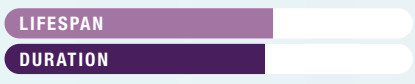


25 people
2 sensors each

50 people
1 sensor each

BETTER DATA

3. SENSOR WEAR TIME AND COMPARATOR MEASUREMENTS



Were sensor readings measured against blood glucose / other CGM readings during the entire sensor lifetime?

CGM CONFIDENCE CHECK

4. GLUCOSE DATA DISTRIBUTION

less than 8% of readings at glucose levels <4.4 mmol/L (80 mg/dL)

less than 5% of readings at glucose levels >16.7 mmol/L (300 mg/dL)

5. MEAL & INSULIN CHALLENGES

<8% of readings at glucose levels <4.4 mmol/L (80 mg/dL)

<5% of readings at glucose levels >16.7 mmol/L (300 mg/dL)

Did the sensor test rapid rates of glucose change, by introducing insulin and glucose (mealtime) challenges?

6. STUDY PUBLICATION

PEER-REVIEWED

CGM CONFIDENCE CHECK: 6 ESSENTIALS TOPICS

- This is a guideline tool (not absolute criteria). Not all six checks have to be fulfilled.
- Users should refer to local manufacturers instructions for use (IFUs) for detailed device data.
- Safety guidance: we recommend verification via finger-stick tests when trying new CGMs.

	TOPIC	QUESTION	CHECK IF...	WHY DOES IT MATTER?
1.	Study population	How many people in the study population who had T1D and/or T2D were insulin treated?	Less than 75% of people with T1D, or if people with T2D not using insulin, or people without diabetes were included	People with T1D have greater fluctuations in glucose. It is during times of glucose change and very high and low values that sensors are often most inaccurate. Having too many T2D without using insulin or people without diabetes gives the sensors an "easy ride".
2.	Number of people in the study	How many people participated in the manufacturer-sponsored study*?	At least 50 T1D/insulin-treated people participated in the manufacturer-sponsored study	For thorough studies, at least 50 (T1D / insulin treated) people are required to verify CGM performance to ensure greater power and representativeness of the study. If a study only includes a few people and/or too few data points, results can be skewed by random events. It is recommended that a study includes at least 5,500 data points from at least 50 participants, or 10,000 data points from at least 45 participants, or 15,000 data points from at least 40 participants. Justification on the number of people should be provided on request, ideally based on a calculation.
3.	Sensor wear time and comparator measurements	How long did participants wear the sensor? Were sensor readings measured against blood glucose / other CGM readings during the entire sensor lifetime?	Sensor was removed before the entire allowed wear time was finished & therefore comparator measurements were not done during the entire sensor wear time	CGM accuracy can differ at the beginning, middle and end of the sensor lifetime, often the beginning and end show worse performance. Therefore, measurements should ideally be distributed equally across the lifetime.
4.	Glucose data distribution	How many data points were in the low and high glucose range?	Low: less than 8% of readings at glucose levels <4.4mmol/l (80 mg/dL) High: less than 5% readings at glucose levels >16.7mmol/l (300 mg/dL)	International Federation of Clinical Chermistry (IFCC) guideline recommendations for CGM accuracy show that some CGMs are less accurate in the low and high glucose ranges; ideally, combinations of different glucose concentrations and rates of glucose change are covered in the study design.
5.	Meal & insulin challenges	Did the sensor test rapid rates of glucose change, by introducing insulin and glucose (mealtime) challenges (i.e. a high carb meal or a correction dose)?	Meal and insulin challenges are tested in the study	Sensor performance during rapid rates of change can be very different than during stable glucose levels, so it is important to include data from these times into the overall analysis.
6.	Study publication	Is the study published in a peer-reviewed journal?	The study has been published in a peer-reviewed journal	Peer review increases the scientific rigor of the results and also reduces the risk of bias. However, it does take time for manuscripts to be published in peer-reviewed journals, so you should not draw a final conclusion based on this reply.

* The number of participants in a study depends on who conducts the study and why. Manufacturer-sponsored studies, done to gain regulatory approval, should include at least 50 participants to ensure reliable results and detect any possible side effects. In contrast, smaller independent studies, which check how the device performs in real-world settings, can be useful even with fewer participants, as they help confirm or question the manufacturer's findings.

MAKING SENSE OF SAMPLE SIZE AND DATA RANGE

How accurate a CGM appears depends on how the study is built. Three things make the biggest difference: how many people take part, how many paired readings are collected, and whether those readings cover the full range of glucose levels — not just the steady middle ground. If a study only includes a few people (less than 50) or too few data points (less than 10,000), results can be skewed by random events. Each person's data should also show what happens across the full glucose range measured by the device. As a guide, around 8% of readings should be in the low range (below 4.4 mmol/L or 80 mg/dL), and about 5% in the very high range (above 16.7 mmol/L or 300 mg/dL). This balance helps ensure the system has been tested across real-life highs and lows, not only during stable periods.

For those who want to see more technical details — such as individual device performance, manufacturer data, and comparison metrics — these are available in the DSN Forum UK CGM Comparison Chart, which complements this factsheet.

Glossary

CGM accuracy refers to how close the readings from a continuous glucose monitor (CGM) are to your actual blood glucose levels.

MARD or mean absolute relative difference, is a number that shows how accurate a CGM is by measuring how close its readings are to actual blood glucose levels – lower MARD means better accuracy. However, this may not represent accuracy in a real-life setting.

Power of study, also known as statistical power or sensitivity is the chance that the study will find a real effect if there actually is one. A study with high power means you're less likely to miss something important. A bigger sample helps detect smaller effects more reliably.

Sample is a subset of a larger population, chosen to be representative of that population, used for research or analysis.

Study population refers to the group of people that a research study is focused on. For example: people with type 1 diabetes, people using insulin.

Abbreviations

CGM	Continuous glucose monitoring
IFCC	International Federation of Clinical Chemistry
IFU	Instructions for use
MARD	Mean absolute relative difference
PLWD	People living with diabetes
T1D	Type 1 diabetes
T2D	Type 2 diabetes

References:

1. Freckmann *et al.* Clinical Performance Evaluation of Continuous Glucose Monitoring Systems: A Scoping Review and Recommendations for Reporting https://pmc.ncbi.nlm.nih.gov/articles/PMC10658695/
2. Eichenlaub *et al.* Comparator Data Characteristics and Testing Procedures for the Clinical Performance Evaluation of Continuous Glucose Monitoring Systems https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10979680/, POCT05Ed2 | Performance Metrics for Continuous Interstitial Glucose Monitoring, 2nd Edition
3. J Pemberton *et al.* CGM accuracy: Contrasting CE marking with the governmental controls of the USA (FDA) and Australia (TGA): A narrative review Diabetes Obes Metab. 2023;1–24.
4. Stefan Pleus *et al.* Clinical assessment and acceptance criteria for continuous glucose monitoring (CGM) system performance: A proposed guideline by the IFCC Working Group on CGM, Clinica Chimica Acta, Volume 580, 2026, 120728, ISSN 0009-8981, https://doi.org/10.1016/j.cca.2025.120728.
5. DSN Forum UK CGM Comparison Chart, https://www.diabetesspecialistnurseforumuk.co.uk/new-cgm-comparison-chart

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