



GlucRx AiDEX™
Continuous Glucose Monitoring System (CGM)

Whitepaper

March 2022

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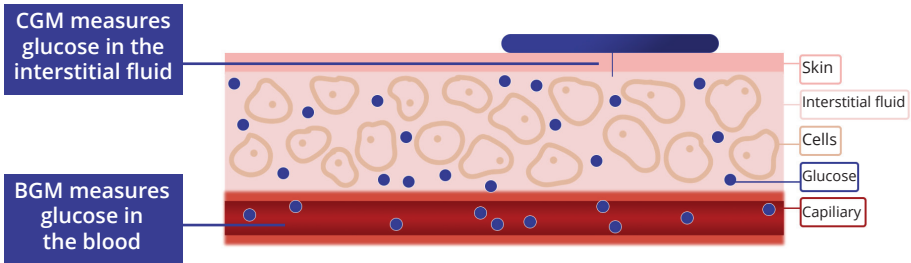


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CGM vs BGM

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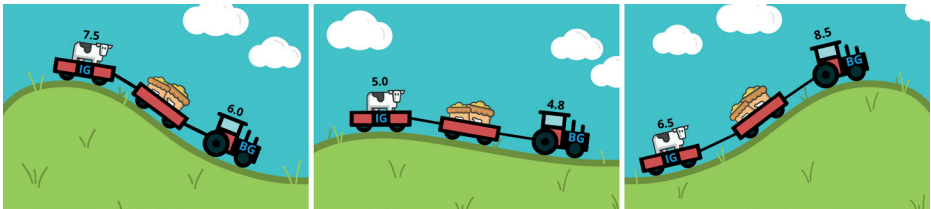
BGM (fingertip blood glucose) is a static measurement that provides an accurate instant glucose level but does not provide information about changes in glucose levels over time. In contrast, CGM (sensor glucose) is a dynamic measurement that provides information about both the current value and changes in glucose levels over time.

The primary difference is BGM measures glucose in the actual blood while CGM measures glucose in the interstitial fluid.

Interstitial fluid is found in spaces around the body's cells. It comes from substances that diffuse out of blood capillaries. One of the substances that comes out of the capillaries is glucose. Because a sensor can survive longer in the interstitial fluid versus blood, CGM sensors only penetrate under skin far enough to be in interstitial fluid.



When blood glucose level is steady, BGM and CGM have negligible difference. When blood glucose level is rapidly changing (after-meal, after-insulin or exercises), BG and CGM usually have noticeable difference.



BG - Blood Glucose IG - interstitial Glucose

The reason for this difference is because of the delay between sensor glucose change rate and current blood glucose change rate.

CGM values can be at least 15 minutes behind a reading you will get from a BGM

Evidence: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5588840/>



Why CGM?

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GlucoRx AiDEX™ is perfect for your patients for their:

Improved glycaemic control

- Track and control sugar levels with dynamic glucose information every 5 minutes, all through the day and night.
- See trends in real time so you can act earlier when sugar levels are starting to rise or drop.
- Help improve HbA1c level as you can tailor insulin doses more carefully.

Enhanced quality of life

- Eliminate finger sticks while making diabetes management decisions easier.
- Decrease manual record keeping.
- Set alarms on GlucoRx AiDEX™ when glucose levels rise or fall a certain amount so changes can be made quickly to treat or prevent highs or lows.
- Remote viewing of data, shared with family and clinicians with consent.



Increased self-management

- Fill in gaps for a better understanding of glycaemic patterns, allowing personalised care.
- Increase insight regarding food, portions, physical activity, stress, weight management and diabetes medication choices from their impact on glucose levels.
- Improve health and prevent complications of diabetes with good glucose management.



Life made easy with GlucoRx AiDEX™

 <p>No Calibration</p>	 <p>No Finger Pricks</p>	 <p>Affordable</p>
 <p>Accurate</p>	 <p>Real Time Alarms</p>	 <p>Readings every 5 Minutes</p>

Drug Tariff price: £29.95 for 1x 14 day GlucoRx AiDEX™ Sensor
Sensor Pip code: 419-6127 (includes applicator)

GlucoRx AiDEX™ CGM constantly measures and records glucose levels every 5 minutes, 24 hours a day, without any fingersticks. This dynamic data can report valuable information such as glucose level trend, direction and speed fast!



Life made easy with GlucoRx AiDEX™



Accurate enough to
replace a BG meter



Helpful Trend
Chart



Customisable Alerts
& Notifications



Comfortable &
Easy to wear



Waterproof



24/7 Monitoring



No Fingersticks



No-Scan Reading



Hi/Lo BG Alert



Specifications


Item	Subcomponent	
	Transmitter	Sensor
Model number	GRX-TRN-T01 (G7-T01)	GRX-SEN-S01 (G7-S01)
Operating temperature	5 - 40°C (41-104°F)	
Operating humidity	10-93% (non-condensing)	
Storage and transportation temperature	-20°C - 60°C	4°C - 30°C
Storage and transportation humidity	5-95% (non-condensing)	
Storage and transportation pressure	700hpa ~ 1060hpa	
Ingress protection level	IPX7	
Use life	4 Years	GRX-SEN-S01: 14 days Shelf life: 1 Year
Detection range	2.0 mmol/L-25.0 mmol/L	
Measurement accuracy	When the glucose concentration > 4.2mmoN (75mg/dL), the accuracy deviation of the sensor does not exceed ±20%; when the glucose concentration ≤4.2 (75mg/dL), the accuracy deviation does not exceed ±1mmoN (18mg/dL).	
Wireless frequency and bandwidth	Frequency: 2.402 GHz ~ 2.48 GHz Bandwidth: 1Mbps	
Wireless modulation	GFSK	
Radiated power	-2dBm	

Regulatory Conformity

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GlucoRx AiDEX™ meets the provisions of 93/42/EEC, classified according to Annex IX of this Directive Class IIa.

EC Certificate


Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)



Registration No.:	HD 1582538-1
Manufacturer:	Microtech Medical (Hangzhou) Co., Ltd No.108 Luze St., Cangqian, Yuhang District, Hangzhou, 311121, Zhejiang P.R. China
Products:	Ambulatory Insulin Infusion Pumps, Insulin Infusion Pump Reservoirs, Insulin Infusion Sets, Continuous Glucose Monitoring Systems

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II section 4 is required.

Report No.:	15065186 021
Effective date:	2021-03-31
Expiry date:	2024-04-23
Issue date:	2021-03-31



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TUV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.
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Electromagnetic immunity:
This medical device complies to IEC 60601-1-2



GlucoRx AiDEX™ Setup

This CGM includes:



Transmitter

Physically connects to the sensor and records/
uploads the glucose data automatically.



Sensor (shown with applicator)

A flexible filament that is so small, it can
barely be felt.

The tiny, flexible 14-day wear sensor is worn on the abdomen or outside/back of the upper arm. We recommend the abdomen, 3-10 cm away from the belly button, because of its thin subcutaneous fat.

GlucoRx AiDEX™ Step-By-Step Guide:

-  **1. Download the GlucoRx AiDEX™ smartphone app**
-  **2. Apply the GlucoRx AiDEX™ 14 day sensor to the arm or abdomen.**
-  **3. Apply the GlucoRx AiDEX™ transmitter to the sensor. Transmitter lasts 4 years.**
-  **4. Connect GlucoRx AiDEX™ app for data.**



Data transfer

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Glucorx AiDEX™ App

Bluetooth connect to FREE Glucorx AiDEX™ mobile app (no reader required), available to download on:

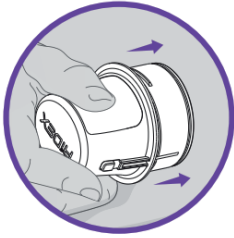


The compact and discreet transmitter (reusable and lasts 4 years) is affixed to the sensor, both applied to the skin via the applicator, automatically records and transfers readings by Bluetooth every 5 minutes (after 1 hour warmup) to your patient's iOS/Android smartphone via the Glucorx AiDEX™ App.

Compatibility list:

<https://www.glucorx.co.uk/aidex-compatibility/>





Insert Sensor



Attach Transmitter



Access Readings

GlucoRx AiDEX™ app functions:

Register Account
Login
Setup Transmitter & Sensor
User Settings
Warm Up
Calibration
Home Screen
Add Event
BG Readings
Trends
Alarms



CGM gives you a fuller picture

Gives you a CGM reading every 5 minutes, 24 hour a day

Plots data on trend graph so you can see where glucose levels have been and where they might be heading

Trend arrows show where your glucose is headed and how fast it is changing

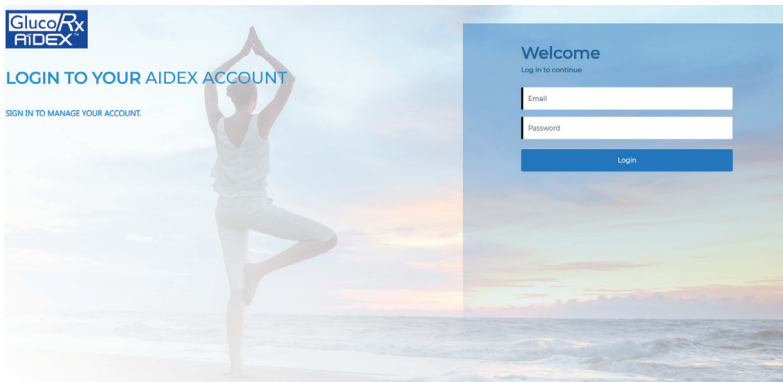
Can set high and low glucose alerts so you know if glucose is headed out of range



GlucoRx Voyager

GlucoRx AiDEX™ App is integrated with GlucoRx Voyager program, from which you can email results:

<https://grxaidex.com/auth/login>



Accuracy & Clinical evidence

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GlucoRx AiDEX™ has shown its outstanding performance in a multicenter, prospective, masked clinical study** that was conducted with 120 participants.


**Study: <https://pubmed.ncbi.nlm.nih.gov/34378432/>

Technology Report

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

Journal of Diabetes Science and Technology
1-6
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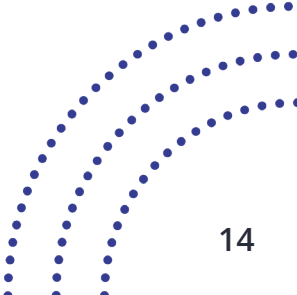
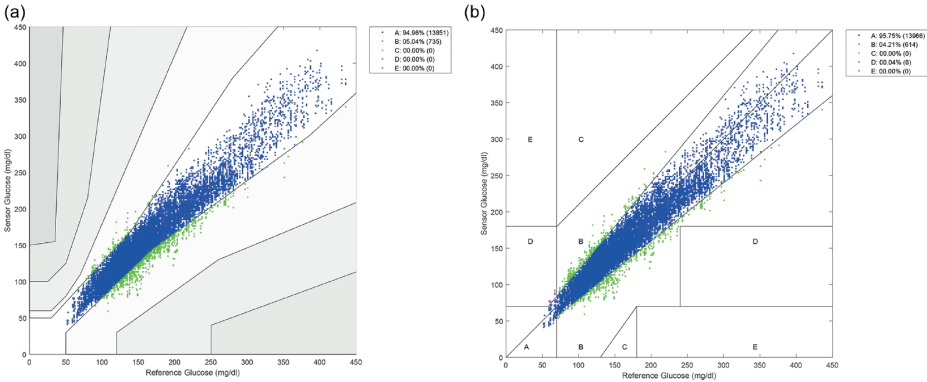
Linong Ji, MD¹, Lixin Guo, MD², Junqing Zhang, MD³, Yufeng Li, MD⁴, and Zhiyan Chen, PhD⁵ 

Abstract

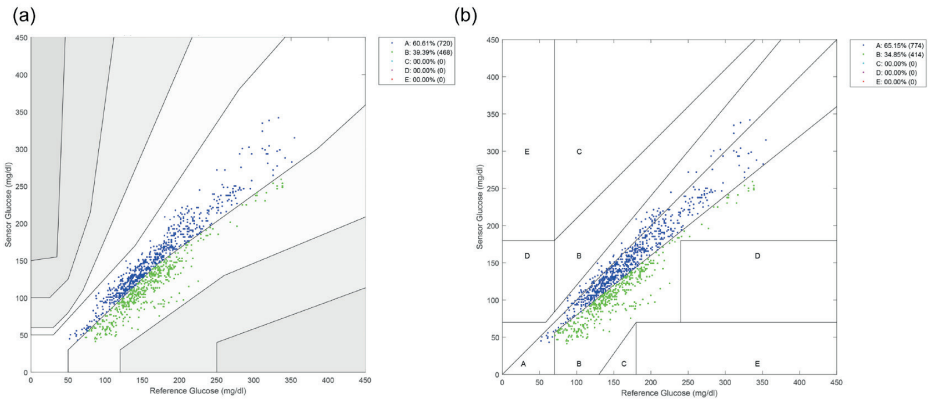
This study reports a clinical evaluation of AiDEX CGM system featuring a 14-day sensor, real-time glucose monitoring and factory-calibration. A multicenter, prospective, masked clinical study was conducted at with a total of 120 participants. Each participant wore 4 studied sensors and had one in-clinic visit for venous blood reference tests. 40 out of the 120 participants wore additional Abbott Libre sensors and performed at least 7 capillary BG tests daily for additional reference and comparison. Continuous glucose error grid analysis (CG-EGA) showed that AiDEX and Abbott Libre had good agreement with venous blood glucose, with 98.69% and 98.96% accurate readings, respectively. Overall MARD of AiDEX CGM systems was 9.08% when compared to venous blood reference and 10.1% when compared to finger capillary BG reference.



The performance of GlucoRx AiDEX™ was evaluated alongside the current market leader for Flash Monitoring. The results from both systems were plotted onto a CEG (+/-15%) and a Clarke Error Grid Analysis Chart.



Results from this study by Linong Ji et al have shown GlucoRx AiDEX™ has a system accuracy of 98.69% (venous blood glucose) and overall MARD*** of 9.08% (when compared to venous blood reference).



(*** Mean Absolute Relative Difference, is a measurement on average how far away the sensor reading is from the Blood Glucose reading over 14-day wear period).

While both systems had nearly 100% combined Zone A & B, the number was significantly lower for the market leader - a large proportion of the sensor readings have a negative bias. This demonstrates the benefit of GlucoRx AiDEX™ having a custom calibration function.



	GlucoRx AiDEX™	Market Leader
NHS Reimbursement status	Yes	Yes
Price to NHS	Sensor: £29.95 each Transmitter: Free of charge	£35.00 each
CGM	Yes	Flash - Patient must scan to get results. Sensor only stores readings for 8 hours. Patients must scan at least once every 8 hours.
Result Generation	Readings taken and stored every 5 minutes	Takes result every 60 seconds. Stores readings at 15 minute intervals, unless scanned.
Age	14+ years	4+ years
Approved site for UK	Abdomen & upper arm (we recommend abdomen for better user experience).	Upper arm only
Reusable equipment	Reusable transmitter	Throw away entire device
Warm up time	60 Minutes	60 Minutes
Wear time	14 Days	14 Days
Transmitter lifetime	4 years	14 Days
Alarms	Low, high and signal loss	Low, high and lost signal. The sensor will send a Bluetooth alert to your device if your glucose is low or high, (however you will still need to scan to see results.)
Accuracy: Overall MARD	9.08%, when compared to venous blood reference***	9.2%
Waterproof	Yes; IPX7 - 1m for up to 30 mins	Yes; 1m for up to 30 mins
Calibration	Factory calibrated and can self-calibrate if needed	Factory calibrated
Free Apps	GlucoRx AiDEX™ App	Yes
PC portal available with app	GlucoRx AiDEX™ / GlucoRx Voyager	Yes
Receiver	Use with smartphone (https://www.glucorx.co.uk/aidex-compatibility/). No dedicated reader required.	Use with smartphone (reader available)
Integration with a pump	Yes; We hope to have a hybrid closed loop system with our Equil patch pump in the future.	No information available as of March 2022.

FAQs

What size is GlucoRx AiDEX™ (sensor + transmitter when affixed on skin)?

35mm (L) x 21mm (W) x 9mm (H). This CGM is compact and comfortable to wear.

How is GlucoRx AiDEX™ powered?

There is a battery in the GlucoRx AiDEX™ sensor (14-day wear), which powers the transmitter.

How long do the sensors and transmitter last?

The GlucoRx AiDEX™ sensor lasts for 14 days. GlucoRx AiDEX™ transmitter is reusable and lasts up to 4 years.

Does this CGM work with Apple watches?

Once you download the GlucoRx AiDEX™ app on an Apple phone and if this phone is integrated with an Apple watch, then the app will appear on the watch and you should be able to see the results on your phone. You will require your phone to be nearby.

Is GlucoRx AiDEX™ waterproof?

GlucoRx AiDEX™ has a water rating of IPX7, which means it is waterproof and can withstand incidental exposure to water of up to 1 metre for up to 30 minutes. Avoid applying shower gel on the CGM adhesive pad when showering. Use an over patch to reinforce the adhesiveness if necessary. If moisture enters the gap between sensor and transmitter, detach the transmitter from the sensor to wipe and try again.

Is this device DVLA approved or is it necessary to continue finger prick testing?

As announced on 15th February 2019, Flash and Continuous Glucose Monitoring devices can now be used to take glucose readings by insulin-dependent drivers.

<https://diabetestimes.co.uk/dvla-approves-cgm-devices-for-driving-with-diabetes-28347-2/>

What is the recommended time to calibrate GlucoRx AiDEX™?

The best time to calibrate GlucoRx AiDEX™ is first thing in the morning before any food or drink is consumed (fasting state from overnight).

GlucoRx AiDEX™ at airports and scans

This CGM can be worn through airport scanners. To prevent signal loss when you put your smart phone in aeroplane mode, ensure you also enable Bluetooth. GlucoRx AiDEX™ should be completely removed before any Magnetic Resonance Imaging (MRI) scan or Computerised Tomography (CT) scan. The device is immune to mobile phone magnetic field.

Can you return and recycle the used applicators with GlucoRx AiDEX™?

GlucoRx AiDEX™ Sensor packaging can be disposed of in general waste. The Applicator which contains the needle, once used, must be discarded in a biohazardous bag or sharps box. Once the GlucoRx AiDEX™ sensor is worn and used, this should then be disposed in a biohazardous bag or sharps box. GlucoRx AiDEX™ transmitter is reusable and can last up to 4 years.

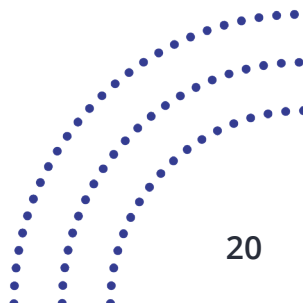
Does GlucoRx AiDEX™ sensor link to any insulin pumps?

At present GlucoRx AiDEX™ is not linked to any pump, however there are plans to have a Hybrid closed loop system with GlucoRx Equil patch pump in the future.

General troubleshooting

Restart Bluetooth then restart the GlucoRx AiDEX™ app. Remove the transmitter from sensor base and assemble them again.







GlucorRx

Quality Diabetes Care

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Life made easy with Glucor AiDEX™