# The 3rd **Generation** Real-Time **CGM System**

# GlucoMen® iCan

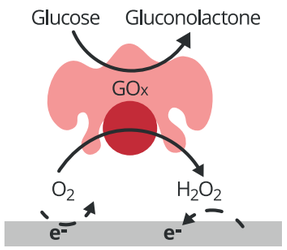
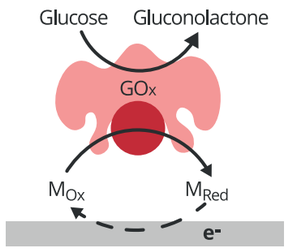
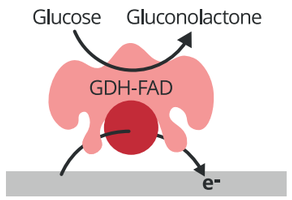

Take Your **Time**
Live **in Range**

glucomen-ican.com

A.MENARINI
diagnostics

# The 3rd Generation System

GlucoMen® iCan

| 1st Generation | 2nd Generation | 3rd Generation |
|---|---|---|
| | | **GDH-FAD Based Technology** |
|  |  |  |
| Use oxygen ($O_2$) as the electron transfer medium in combination with a high operating voltage | Use artificial redox agents as the electron transfer media in combination with lower operating voltages | **Direct electron transfer via modified Glucose Dehydrogenase** |
| ✓ Vulnerable to interference from electrochemically active endogenous and exogenous chemicals<br>✓ Vulnerable to oxygen interference when tissue $O_2$ levels go down | ✓ Less interfered by oxidizable chemicals as compared to 1st generation sensors<br>✓ Less interfered by oxygen concentration as compared to 1st generation sensors | ✓ Limited susceptibility to interference from oxidizable chemicals<br>✓ Immune to oxygen interference |

| | | | |
|---|---|---|---|
| **Reaction** | $O_2$ / $H_2O_2$ oxidoreduction | Mediated oxidoreduction | **Direct electron transfer** |
| **Enzyme** | Glucose Oxidase (GOx) | Glucose Oxidase (GOx) | **Modified Glucose Dehydrogenase-FAD (GDH-FAD)** |
| **Interferant** | Acetaminophen, $O_2$ | Ascorbic Acid, $O_2$ | **No interference from Acetaminophen, Ascorbic Acid, and $O_2$** |

## High Accuracy: 8.71% overall MARD

## Interference Resistance

No Interference from Acetaminophen, Ascorbic Acid (Vitamin C), and $O_2$

## 15-Day Effective and Comfortable Wear Life


## Full-Featured App

# High **Accuracy**

**8.71%**
overall MARD

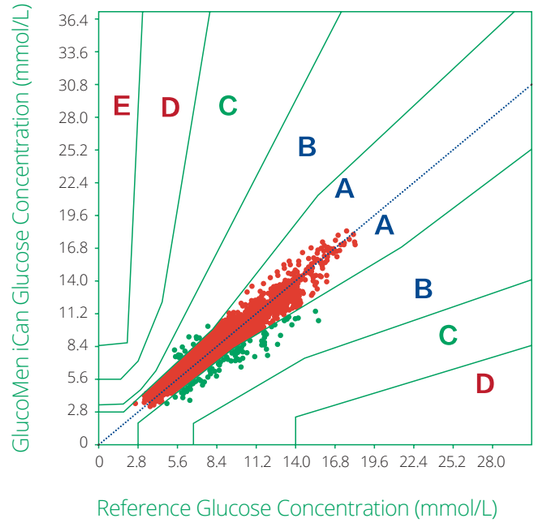
## Confirmed **Sensor Accuracy** Across Multiple Glucose Ranges

| YSI glucose level, mmol/L | % within ±0.83 mmol/L or 15% | % within ±1.11 mmol/L or 20% | % within ±1.67 mmol/L or 30% | % within ±2.22 mmol/L or 40% | MAD, mmol/L or MARD,% | Matched pairs |
|---|---|---|---|---|---|---|
| **<3.9** | 94.74 | 100.00 | 100.00 | 100.00 | 0.55 | 39 |
| **3.9-10.0** | 83.64 | 93.00 | 98.69 | 99.56 | 8.94 | 1,143 |
| **10.0-13.9** | 85.38 | 93.99 | 98.96 | 100.00 | 7.99 | 383 |
| **>13.9** | 92.23 | 97.09 | 99.03 | 100.00 | 6.14 | 103 |
| **Overall** | 84.83 | 93.65 | 98.80 | 99.70 | **8.71** | 1,668 |

**YSI**, Yellow Springs Instrument; **MAD**, mean absolute difference is provided for glucose levels <3.9 mmol/L, and is expressed as mmol/L; **MARD**, mean absolute relative difference is provided for glucose levels ≥3.9 mmol/L, and is expressed as %.

## **Clinical Accuracy**
1,668 data pairs, **100%** fell **in zones A+B**

### Consensus Error Grid*




| | Count | Prop | 95%CI |
|---|---|---|---|
| A | 1,559 | 93.47% | (92.18%, 94.55%) |
| B | 109 | 6.53% | (5.45%, 7.82%) |
| C | 0 | 0.00% | |
| D | 0 | 0.00% | |
| E | 0 | 0.00% | |
| A+B | **1,668** | 100% | (99.77%, 100.00%) |

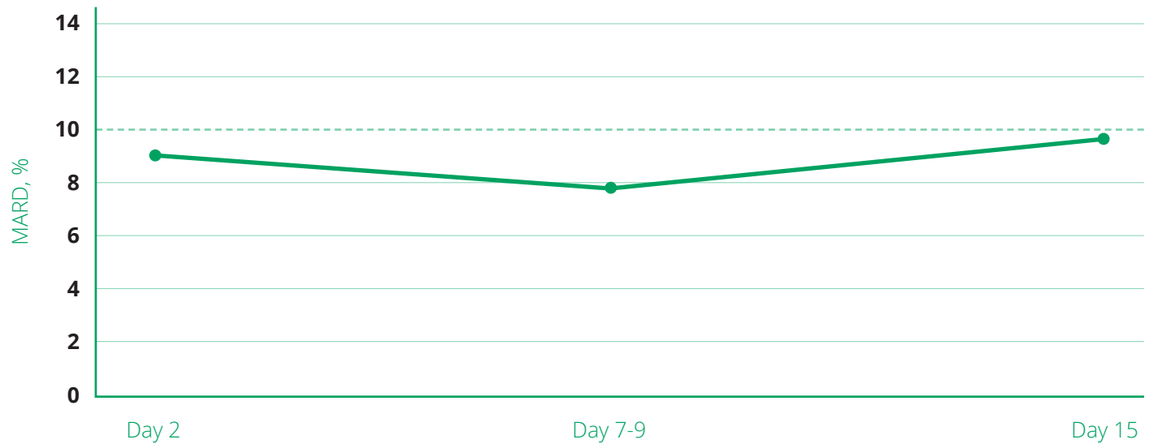
**A:** no effect on clinical action; **B:** little or no effect on clinical outcome; **C:** likely to affect clinical outcome; **D:** could have significant medical risk; **E:** could have dangerous consequences.

* Consensus Error Grid for Type 1 Diabetes

For Self-Monitoring of Blood Glucose (SMBG) meters **EN ISO 15197:2015** requires 99% of all data pairs to be located in Zones A+B.

## Demonstrated **Single Digit MARD** **Stability** Over 15 Day Wear Life

**15**



# Interference **Resistance**


No Clinically Relevant Effect Observed With **Ascorbic Acid**

| BG range (YSI), mmol/L | Δ MAD, mmol/L | Δ MARD, % |
|---|---|---|
| **<3.9** | -0.17 | |
| **3.9-10.0** | | -1.1 |
| **>10.0** | | -1.7 |
| **Overall** | | -1.6 |

Stop Negative Influence by:

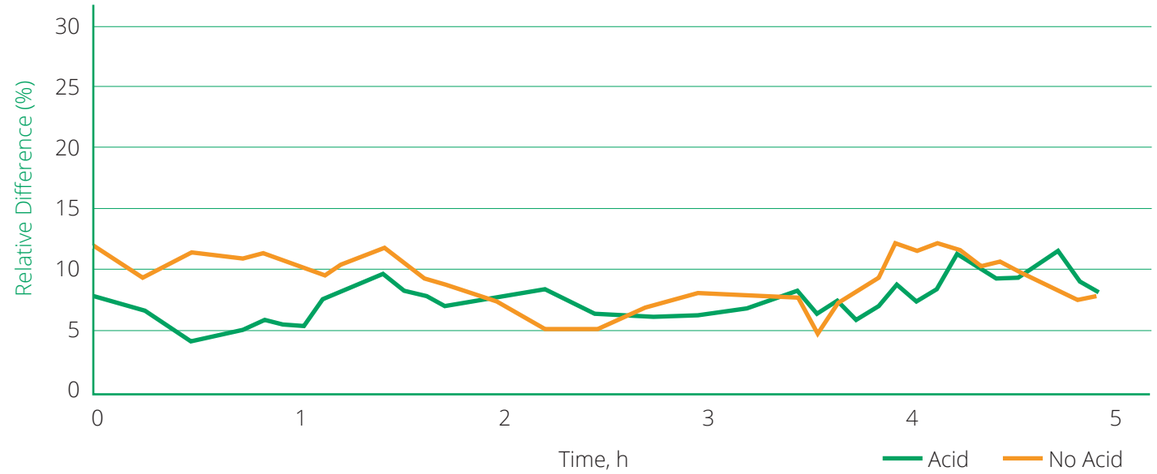
**Acetaminophen**
**Oxygen** ($O_2$)
**Ascorbic Acid** (Vitamin C)

No Clinically Relevant Effect Observed With Moderate **Physical Exercise**

| BG range (YSI), mmol/L | Δ MAD, mmol/L | Δ MARD, % |
|---|---|---|
| **<3.9** | -0.04 | |
| **3.9-10.0** | | -1.2 |
| **>10.0** | | -1.7 |
| **Overall** | | -1.3 |

**GlucoMen iCan** relies on a modified GDH-FAD enzyme sensor which **overcomes the issues related to oxygen limitation.**

iCan vs YSI MARD: With and Without **Ascorbic Acid**

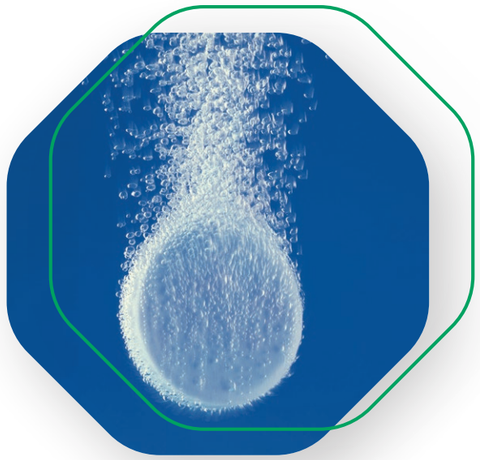



## Why Ascorbic Acid?

**Ascorbic Acid** is one of the most commonly taken **OTC / GSL vitamin supplements.**

**Vitamin C is a strong antioxidant** that inactivates free radicals and can be oxidized at the surface of electrochemical strips/sensors, producing electrons that increase the measured current, leading to overestimated glucose readings.*

**GlucoMen iCan relies on a low operating voltage sensor which overcomes this issue.**



* Cho J, Ahn S, Yim J, Cheon Y, Jeong SH, Lee SG, Kim JH. Influence of Vitamin C and Maltose on the Accuracy of Three Models of Glucose Meters. Ann Lab Med. 2016 May;36(3):271-4. doi: 10.3343/alm.2016.36.3.271. PMID: 26915620; PMCID: PMC4773272.

# High **Wearability**

# **15-Day**
## **Effective** and **Comfortable** Wear Life

**Pricing**
**Calibrating**
**Scanning**

Demonstrated
**Effective Sensor Wear Life**

Mean Sensor Wear Life:
**exceeds 14 Days**

| | Indicator | Per Protocol Set (n=57 subjects) |
|---|---|---|
| **Sensor Wear Life [Days]** | Sensors (missing) | 114 (0) |
| | Mean (SD) | 14.75 (1.29) |
| | Median | 15.00 |

SD, standard deviation

Nearly All Sensors (>99%) Operating Effectively
**at Day 15**

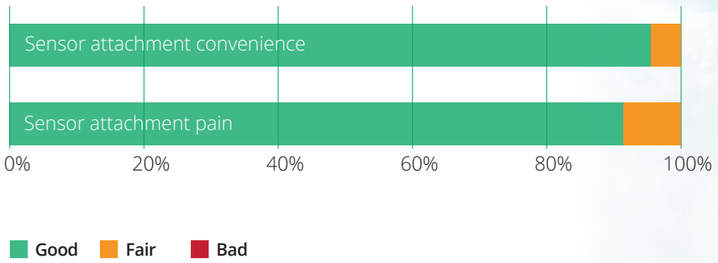
| | Indicator | Per Protocol Set (n=57 subjects) |
|---|---|---|
| **Effective Sensors measured at Day 15** | Effective Sensors (%) | 107 (99.07%) |
| | Ineffective Sensors (%) | 1 (0.93%) |
| | Total Sensors (missing) | 108 (0) |

**IP28 Rating**
Waterproof to 2.5 meters
for up to 2 hours

**Small & Light Sensor**
32 mm width, 5.7 mm thickness
5.2 g weight

**Hypoallergenic Tape**
Colophony, PVC, Latex, IBOA certified free

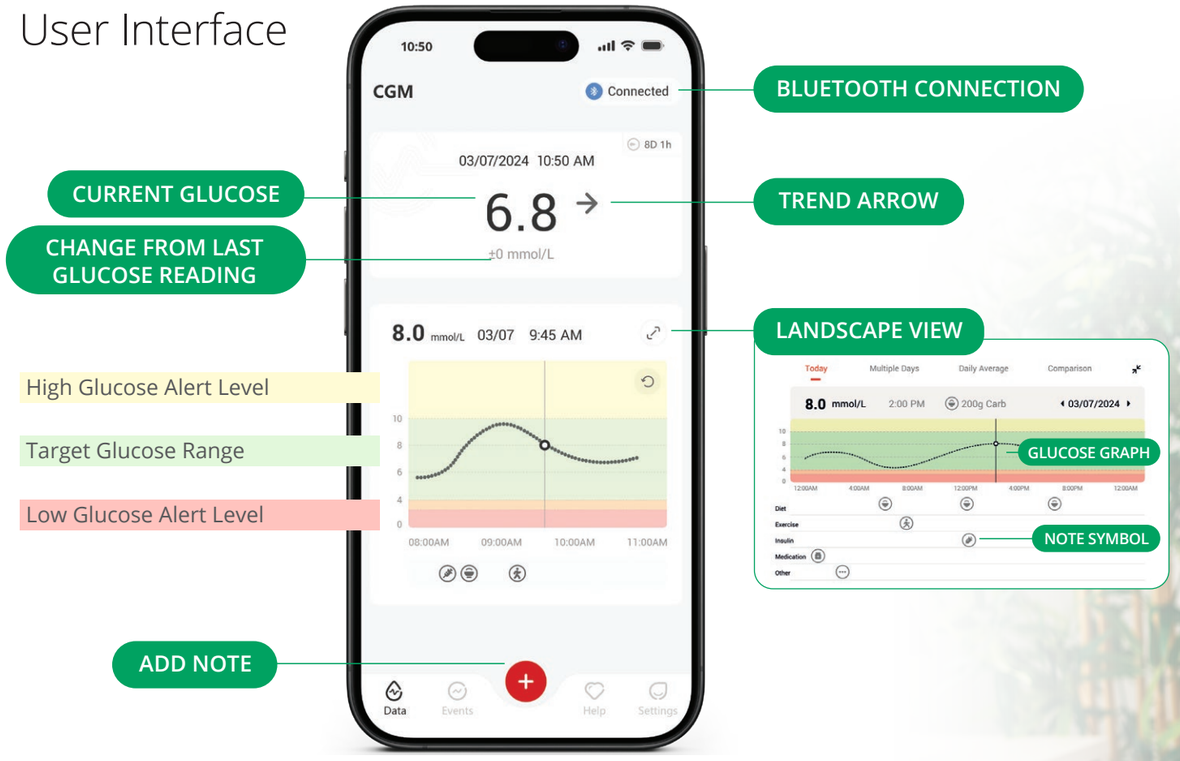
Patient Reported
Feedback Confirms
**Day 1 Comfort and Convenience**




| Good | Fair | Bad |
|---|---|---|
| 94.74% (54) | 5.26% (3) | 0.00% (0) |
| 91.23% (52) | 8.77% (5) | 0.00% (0) |

# Full-Featured **App**

## Seamless Readability and Optimized Display with an Intuitive User Interface

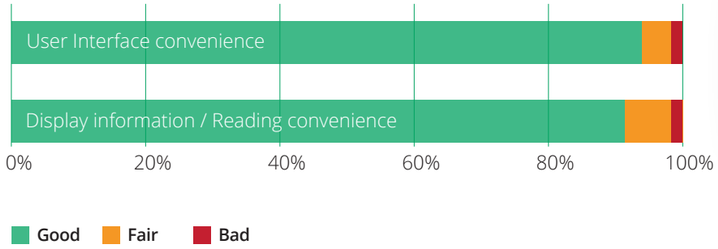



- Detailed **Trend Arrows** (7 modes)
- **Multiple Day** View
- **AGP** and Exclusive **Graph Report**
- Customizable high/low glucose **real-time Alerts**
- Available in more than **20 languages** (changeable at any time)
- Compatible with a **wide range of smartphones**
- In-App **Video Tutorials**

Stable Real-time Bluetooth Transmission

**3-minute real-time data update**
(7,200 glucose readings over 15 Days)

## Validated by Users: **15 Days** of Convenient Experience




| Good | Fair | Bad |
|---|---|---|
| 92.98% (53) | 5.26% (3) | 1.76% (1) |
| 91.23% (52) | 7.02% (4) | 1.75% (1) |

## Simple to Connect with Caregivers and HCPs

### iCan Reach App

- **Reach partner receives the same view & alerts as user**
- **Reach HCP can receive data from 10 active users**

iCan Reach

Available on the App Store
GET IT ON Google Play
EXPLORE IT ON AppGallery

iCan App

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# GlucoMen® iCan

## TECHNICAL SPECIFICATIONS

### GlucoMen iCan Sensor

**Sensor glucose assay method:** Amperometric electrochemical sensor

**Sensor glucose result range:** 2.0 mmol/L – 25.0 mmol/L

**Sensor life:** Up to 15 days

**Shelf life:** Up to 18 months

**Transmitter battery type:** 1 non-serviceable, non-rechargeable button cell inside the transmitter, DC 1.5 V

**Data Communication Range:** 6 meters (20 ft) unobstructed

**IP Rating:** IP28 (waterproof: 2.5 meters x 2 hours)

**Storage and transport temperature:** 2°C to 30°C (36°F to 86°F)

**Storage and transport humidity:** 10% - 90% Relative humidity

**Operating temperature:** 10°C to 42°C (50°F to 108°F)

**Operating humidity:** 10% - 90% Relative humidity

### The iCan CGM APP operation environment minimum requirements:

**Platform:** Android 8.1 and above, iOS 14.1 and above

**Bluetooth version:** Bluetooth 5.0

**Memory:** 1 GB and above

**CPU:** Main frequency 1.4 GHz and above

**Screen:** No less than 12 cm (4.7 inches)

**Resolution:** No less than 1280x720

**Storage capacity:** No less than 500 MB

**Network:** WLAN (Wireless Local Area Network) or cellular network (4G and above), as well as Bluetooth function

**Note:** For the complete list of technical specifications, please refer to the **GlucoMen iCan User Guide.**

"I can start wearing the **GlucoMen iCan** on my tummy from **age 2!**"


**References:**
Data on file, Sinocare Meditech

This content is intended for Healthcare Professionals only.
Prescribing Information for GlucoMen iCan CGM System may be found at **glucomen.com**

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