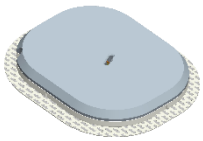
IWel CGS
Continuous Glucose Monitor

User Guide



DESCRIPTION

The IWel CGS Continuous Glucose Monitoring (CGM) System integrates an enzyme-based biosensor with a microelectronic processor to monitor glucose levels in real time within the interstitial fluid. The system reads and transmits glucose data continuously automatically, delivering real-time readings every minute via a mobile application. The entire device is disposable and for single use only.

INDICAITON FOR USE

The IWel CGS continuous glucose monitoring device (CGM) is intended for glucose monitoring in patients with Type 1, Type 2 and gestational diabetes. It is designed to support the management of diabetes. Users are encouraged to confirm the glucose readings with conventional fingerstick test prior to dosing any medications. It's suitable for use in 8 years and older diabetic population.

PRODUCT PACKAGE

- Sterile single use sensor with applicator.
- User manual

STORAGE AND HANDLING

- Store the CGM components at refrigerated or room temperature (4 to 30 ºC)
- Sensors are sterilized, don't touch the sensor electrodes with hands to avoid contamination prior to applying to the skin.
- Be cautious and not get hurt by sharp ends of sensor applicator needle shell prior to application. The needle shell will be automatically retracted once inserting process is completed.

CAUTION & WARNINGS

- Read the product instructions carefully before use.
- Do not use the adhesive patch & the device if you have sensitive or allergic skin.
- Medications may interfere with readings:
  - Acetaminophen (commonly found in cold medications) and
  - Hydroxyurea (used for cancer and blood disorders)
  - Vitamin C

  These may cause falsely elevated glucose readings. Confirm results with a fingerstick blood glucose test if necessary.
- Verify accuracy: If you suspect inaccurate or inconsistent readings, confirm with a fingerstick test before making any treatment decisions.
- Discontinue use and consult a healthcare provider if you experience discomfort at the application site, such as severe itching or pain.
- Do not use the CGS system if you are pregnant, undergoing dialysis, or critically ill.
- High-intensity exercise may loosen the sensor due to sweat or body movement.
- Do not wear the device while swimming for more than 30 mins.
- Do not use expired sensors or those with compromised packaging.
- Physical stress during sleep may lead to elevated glucose temporarily.
- The CGS system is not compatible with automated insulin dosing (AID) systems.

TROUBLE SHOOTING

- Glucose readings appear off by more than 20%. Update your fasting glucose value to improve accuracy if you have a recent lab or fingerstick result.
- The app cannot find the CGS device and continuously searches for the sensor, move your phone closer to the device.
- The device won't automatically reconnect or staying "connecting" after out of range (phone is too far from the device), simply close and re-launch the app.
- Data syncing is taking too long. The glucose data are stored in the phone's temporary cache; it may take up to a minute to re-display.
- Sensor has detached or fallen off. Replace it with a new sensor

APPLICATION STEPS

1. Cleaning sensor application site. • Select the application site as pictured on the right. Find area with rich soft tissues and avoid direct on muscles. • Clean the skin with alcohol swabs.	Application site
2. Get the applicator ready. • Take out the applicator (sensor included inside) from the package. • Make sure the sterile seal is intact. • Unscrew the bottom cover clockwise.	Unscrew the bottom cover clockwise
3. Use the applicator to insert the sensor. • Press and hold the applicator firmly against skin site until the safety guard is pushed in. • Press the trigger button on the side until a gentle trigger sound is heard.	Press & hold agsint skin Press the trigger to insert the sensor

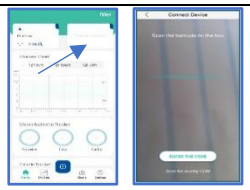
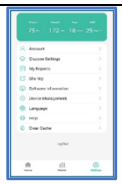
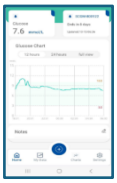
4. Left the applicator and dispose. • Leave the applicator on skin for 15 to 20 seconds to ensure the adhesive patch sticks to the skin. • Remove the applicator, screw the base back, and dispose it.	Dispose the applicator
5. Sensor is ready for activation. • Rub firmly around the sensor adhesive patch edge couple of times. • Press top of the sensor gently to ensure it sit on skin securely. • The sensor is ready for use.	The sensor is ready for activation
6. Remove CGM after use. • Remove the device by peeling off the edge of the adhesive patch first • Pull the device upward from one side, then rest of the adhesive patch.	

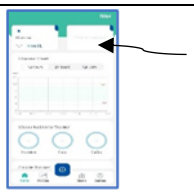
USE OF THE MOBILE APP

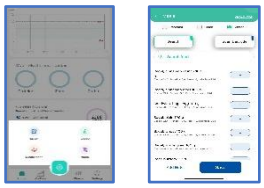
A. Download the mobile App. Search "CGMPlus2" in Apple App store or Google Play, download the mobile App.	

B. Register through the mobile App. • Have your phone number ready and follow the instructions and go through the verification process. • Once verified, fill up the simple registration form including your name and phone number.	

USE OF THE MOBILE APP (continued)

C. Connect to CGS • Tap on "Click to connect" button on top right on home screen. • Click on "Scan for nearby CGM" on bottom of Connect Device page. • Tap on the CGM matching the serial ID on sensor's bottom cap.	
E. Settings • Account & profile • Glucose settings & daily goals • My reports and sharing • Software info & device management • Help & language	
G. Home screen • Live glucose readings • Sensor status and use time left • Live glucose charts in 12, 24 hours or full view • Add simple notes	
I. Charts • Glucose related. Multi-day overlay, AGP, time in range, daily average, GMI. • Wellness related. Calorie intake and exhausted.	

D. CGS activation • The sensor is automatically connected. • Timer for the 60 minutes warm up period is displayed on top right of the home screen. • Other part of App is active.	
• Glucose settings - Set up alert limits. - Fill in fasting glucose level if available. - Regular finger stick test results can be recorded using Notes on the home screen.	
H. Home screen (cont.) Other functions on the home screen: • Tracker of macro-nutrients intake • Tracker of calorie exhaust • Charts - analytics • Mydata - events	
J. Sharing with others • Tap "Settings" on home screen • Click on "Sharing" • Fill out the contact info for whom you like to share glucose data with. • They will be invited when login to their app to view you data.	

K. Track diet • Click on "+" icon on bottom of home screen • Tap on "Meals" to add meal info. • Use built-in barcode scanner for scanning packaged food,	
L. Track exercise • Basic exercise such as steps is auto linked to Apple Health or Google Fit • Click on "+" icon on bottom of home screen to add additional exercise for tracking.	
M. MyData • Click on "MyData" on home screen. • Review all the events data entered and saved with timestamps for the use period.	
Record the CGM Serial # CGS-	

Symbol	Description	Symbol	Description
IVD	In vitro diagnostic medical device		Single use
	Expiration date		User Instruction
2°C 30°C	Store at 2-30°C		Manufacturer
LOT	Lot number		Date of manufacture
EC REP	EU authorized representative	CE	CE mark

DEVICE TECHNICAL ASSISTANCE

For technical assistance, contact IWel CGM technical services at support@iwelcgm.com or visit website at www.iwelcgm.com

GENERAL INFORMATION

Manufacturer	Distributor	Product Purchase & Support
IWel Health Inc. 740 Sprindale Drive, Suite 105 Exton, PA 19341 USA support@iwelcgm.com www.iwelcgm.com iWel		