iWel

IWel CGM

IWel CGS
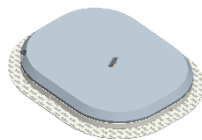*Continuous Glucose Monitor*

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:
  - o Acetaminophen (commonly found in cold medications) and
  - o Hydroxyurea (used for cancer and blood disorders)
  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.
- Warm-up period: The device begins reading immediately after activation. Readings often stabilize after the first 12 hours for a new sensor.
- 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.
- The CGS system is not compatible with automated insulin dosing (AID) systems.

TROUBLE SHOOTING

- 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 after out of range (phone is too far from the device), simply close and re-launch the app.
- The device status is showing monitoring, but no readings and plot in glucose chart, 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. Remove the device and apply a new adhesive patch along with a new sensor.
- Glucose readings appear unexpected. Update your fasting glucose value to improve accuracy if you have a recent lab or fingerstick result.

APPLICATION STEPS

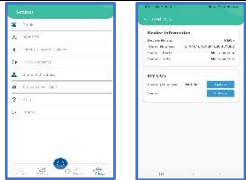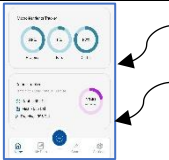| Steps	
1. Cleaning sensor application site. • Select the application site as pictured on the right. Find area with rich soft tissues and avoid direct on muscles. • Clean the skin with alcohol swabs.	Application site
2. Get the applicator ready. • Take out the applicator (sensor included inside) from 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

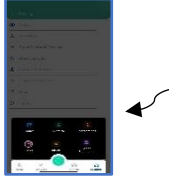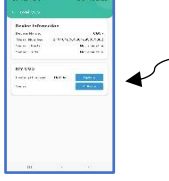|	
A. Download the mobile App. Search "CGSPlus" in Apple App store or Google Play, download the mobile App.	
B. Register through the mobile App. • Have your phone number ready, and follow the instructions go through the registration process. • Once registered, select Yes to activate a CGS device immediately (or No for later).	iWel

C. CGS activation

- Click on "Settings" on home screen.
- On the Settings screen, click on "IWel CGS" tab.
- Click on "Activate" on bottom of the screen.

D. "Setup CGS" screen to display

E. CGS activation (cont.)

- On "Setup CGS" screen, click on "Scan" to find the device.
- Your CGS device (starts with CGS or SCGM) is shown.
- Click on the device tab to connect and home screen to appear.

device   Your device

F. Home screen

- The activation process takes about a minute to complete.
- Real-time glucose reading is shown on top left continuously, and its timestamp on top right.

G. Home screen

Other functions on the home screen:
- Tracker of macro-nutrients intake
- Tracker of calorie exhaust
- Charts - analytics
- Track of wellness parameters

H. Goals and units

On "Settings" screen, the following can be personalized.
- Daily calorie goal.
- Daily goals macronutrients.
- Glucose upper and lower limits.
- Unit for body weight, temperature.

- Charts - Analytics

- Time in Range
- Daliy glucose chart (for 15 days)
- Daily glucose average
- Daily calorie intake & exhausted
- Glucose management indicator GMI

I. Setup alerts for glucose level

- Tap "Settings" on home screen.
- Click "Glucose level alert".
- Fill in high and low alert levels.
- Select alert form (s).
- Save the selections

J. Share data with others

- Tap "Settings" on home screen
- Click on "Share with Others"
- Fill out the contact info for whom you like to share glucose data with.
- They will be invited by email to review your data.

K. Track meal and exercise information

- Click on "+" icon on bottom of home screen
- Tap on "Meals" to add meal info.
- Barcode scanner is built in for scanning packaged food,
- Tap on "exercise" to add exercise info.

L. MyData

- Click on "MyData" on home screen.
- Review all the data entered and saved with timestamps for the week and previous weeks.

M. Track other events

- Click on "+" icon on bottom of the home screen
- Options to add other info including medications, notes, stress, sleep condition, blood pressure, pulse, body weight etc.

N. Update fasting value (optional)

- Click on "Settings", then tap on "IWel CGS ", then find "My CGS"
- Tap on "Update", enter your fingerstick or lab test fasting value if available,
- Tap "Save" to save the information.

Record the CGM Serial #

CGS-

Symbol	Description	Symbol	Description
IVD	In vitro diagnostic medical device	⊗	Single use
⧖	Expiration date	📖	User Instruction
🌡 30°C 2°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, call IWel CGM technical services at (855) 253-3634 or email 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 Phone: (855) 253-3634 support@iwelcgm.com www.iwelcgm.com iWel	3Sixty Biopharmaceuticals (Pty) Ltd Company Reg. No.: 2018/432238/07 23 West Street, Houghton Estate, Johannesburg, Gauteng South Africa 3sixty	**Tel:** +27 11 053-4440 +27 11 712 6039 **WhatsApp:** +27 71 209-8075 +27 63 101-0911 CGM@CDEOnline.co.za https://cdeonline.co.za/ CDE Academy