iWel

IWel CG2
Continuous Glucose Monitor

User Guide

DESCRIPTION

The IWel CG2 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, delivering real-time readings on demand via a mobile application. It comprises three key components: a disposable sensor, a reusable Bluetooth transmitter, and a mobile application.

INDICAITON FOR USE

The IWel CG2 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.
- Multi-use transmitter with battery built in.
- Adhesive patch attached to transmitter.
- External arm band for the device.
- Mobile App for download.

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 not get hurt by sharp ends of sensor electrodes.
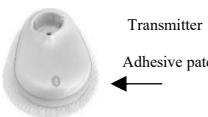
CAUTION & WARNINGS

- 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)
    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 after 10 minutes of 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 CG2 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.
- Do not use expired sensors or those with compromised packaging.
- The CG2 system is not compatible with automated insulin dosing (AID) systems.
- Dispose of used sensors in accordance with local regulations for sharp objects.
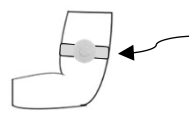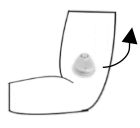
TROUBLE SHOOTING

- The app cannot detect the CG2 device and continuously searches for the sensor. Move your phone closer to the device or check the battery level of the sensor under *Settings > IWel CG2*.
- The glucose chart updates slowly on the home screen. Ensure your phone has a strong internet connection or better mobile signal.
- The timestamp for the last glucose reading is incorrect. Close and reopen the app to re-sync the timestamp with your phone's data.
- Low battery warning. Please contact your service provider for a replacement device, as the current CG2 battery is not user-replaceable.
- Sensor has detached or fallen off. Remove the device and apply a new adhesive patch along with a new sensor.
- Glucose readings appear inaccurate or unexpected. Update your fasting glucose value if you have a recent lab or fingerstick result to improve accuracy

APPLICATION STEPS

Steps	
1. Cleaning sensor application area. Select the application area as pictured on the left. Select areas with soft tissues and avoid any muscles. Clean the skin with alcohol swabs.	Upper back arm Lower front arm
2. Open transmitter package. Take out the transmitter from the package and lay it on a flat surface such a book, paper towel or tissue. Attach the adhesive patch to the bottom of the transmitter.	Transmitter Adhesive patch
3. Open sensor package. Confirm expiration date of a sensor prior to use. Gently take the sensor out from the package. Be cautious not to touch sensor needles.	Sensor
4. Place sensor into transmitter half-way. Place the sensor into the transmitter's sensor slot with needles pointing downward. Insert only half-way, where two metal side nodes are just below the edge of the transmitter's sensor slot.	
5. Place transmitter & sensor onto skin. Remove the backing of the adhesive patch in the bottom of the transmitter, place it carefully onto sensor application area onto your arm or other desired area.	Shown for front lower arm
6. Press sensor into transmitter. Press sensor gently into transmitter with thumb or palm until the top of sensor **at the same level** as the top of transmitter. Make sure don't over push.	
7. Sensor is in functional stage. Once the sensor is in place, the transmitter will blink once. It indicates sensor is functional now.	
8. Use of waterproof arm band cover. Use the customized multi-use arm band cover while taking shower for waterproof, during exercise or sleep, etc.	
9. Remove CGM after use. Remove CGM by peeling off the edge of the adhesive patch first, then pull the CGM upward from skin, until it is off completely.	
10. Replace the sensor. Simply push the sensor downward through bottom of the transmitter, place a new sensor into the slot again.	

USE OF THE MOBILE APP

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A. Download the mobile App. Search "CGMPlus" in Apple App store or Google Play, download the mobile App.	
B. Register as a user. Have your phone number ready, and follow the instructions go through the registration process. Once registered, select Yes to activate a CG2 device immediately (or No for later).	
C. CG2 set-up and activation On next screen CG2 Set Up, click on "Activate", tap on your CG2 device on the list, activation process starts. Don't turn off the phone during the activation process.	
D. Home screen Once Activation is completed, the home screen shows the last glucose read and device control on the top, glucose chart in mid-section. The connection to device lasts 3 reads, then stops automatically, until click on "Connect" again.	
E. Settings – goals & units Under Settings, complete sections including Goals & Units, add other Bluetooth devices if desired.	
F. Read glucose level Tap on "< "to open the home screen, your app is ready for use. To read glucose, just simply click "Connect" on top right box, the instant glucose reading to display on the "Glucose" box, and chart in lower section.	
G. Share data with others Click on "Share with Others" under "Settings" with your family members or health professionals. Fill out the info required, and they will be invited by email to review your data.	
H. Add relevant events Click on "+" icon in bottom of the home screen, events can be added for tracking meals, exercise, medications, stress, sleep, blood pressure, pulse, body weight etc. Bar code scanning function is available for packaged food.	

I. Charts Click on "Charts" on home screen to view Charts of Time in range, daily glucose, daily glucose average, GMI, calorie intake and exhausted for the current week and previous weeks.	
J. MyData Click on "MyData" on home screen to review all the data entered and saved with time stamps for the week and previous weeks.	
K. Activation later (optional) If a later Activation is selected during registration, the home screen will display directly. To activate the device, tap on "Settings", then IWel CG2, My CG2, click on "Activate" to go to the CG2 Set Up CG2 page for activation.	
L. Update fasting value (optional) The fasting value can be updated for better accuracy. To update the fasting glucose value, tap on Settings/CG2, My CG2, type in the fasting value, then click "Update". The system will re-calibrate immediately with the fasting value just entered.	
Record the CGM Serial # CG2-	

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

DEVICE TECHNICAL ASSISTANCE

For technical assistance, call IWel Health technical services at (855) 253-3634 or email at support@iwelhealth.com or visit website at www.iwelhealth.com

GENERAL INFORMATION

Manufacturer	Distributor	Product Purchase & Support
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