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RIGHTEST
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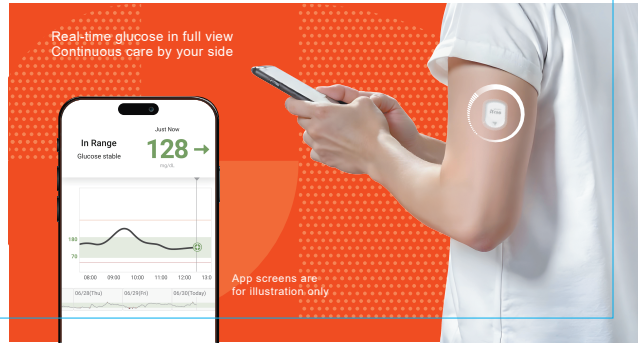
RIGHTEST™

Free2 CGM

CONTINUOUS GLUCOSE MONITORING SYSTEM

User's Manual

15-DAY WEAR
CALIBRATION-FREE



READ THIS FIRST:

It is important to read the entire contents of this manual before using the RIGHTEST iFree 2 Continuous Glucose Monitoring System. The instructions, warnings, precautions, safety information and tips contained within this manual are intended to ensure proper use and optimal results. Discuss the best way to use your RIGHTEST iFree 2 CGM with your healthcare professional. Failure to operate the system according to the guidelines and safeguards specified in this manual may present risks. If your glucose readings do not match your symptoms or how you are feeling, check your blood glucose level with a blood glucose meter and consult a healthcare professional if necessary.

Indications For Use & Statement And Advisory

Indications For Use

The RIGHTEST iFree 2 Continuous Glucose Monitoring System (hereafter referred to as the "iFree 2 CGM") is indicated for detecting glycemic trends and for the management of diabetes in persons aged 18 and older. It is designed to replace fingerstick blood glucose testing for diabetes treatment decisions. Interpretation of the iFree 2 CGM results is based on the glucose trends and several sequential readings over time. It also aids in detecting episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments.

Indications

For adults 18 years and older with type 1 or type 2 diabetes who use insulin or other diabetes medications requiring regular glucose monitoring.

Statement And Advisory

This manual is designed to instruct all personnel responsible on the proper use and care of the iFree 2 CGM in non-professional environments. All users are encouraged to read this manual carefully before using the system.

Intended Benefit

Based on established clinical evidence for CGM technology, the following potential benefits may be achieved through continuous glucose monitoring:

- Qualitative benefits, including continuous real-time glucose monitoring that supports improved glycemic awareness, reduction of routine fingerstick testing to reduce pain and inconvenience, and improved treatment adherence through visualization of glucose trends.
- Quantitative benefits, supported by published clinical evidence on CGM technology from randomized controlled trials and international consensus:
  - Clinical studies of CGM technology have demonstrated reductions in HbA1c of approximately 0.3 - 0.6% in adults with type 1 and type 2 diabetes compared with SMBG.
  - Use of CGM systems has been associated with an increase in Time in Range (TIR) of approximately 10% (~2.4 hours/day), corresponding to an approximate 0.5% reduction in HbA1c, as reported in meta-analyses and international consensus publications.
  - Published evidence has reported associations between reduced

TIR and increased risk of diabetic complications (e.g., retinopathy progression and microalbuminuria).
- Continuous glucose monitoring enables improved detection of hypoglycemia (<3.9 mmol/L and <3.0 mmol/L) and hyperglycemia compared with intermittent SMBG measurements.

Potential Side Effect

Skin Irritation Reaction Caused by the Sensor Adhesive: Some individuals may be sensitive to the medical adhesive that keeps the sensor attached to the skin. Skin reactions such as redness, bleeding, inflammation, bruising, or itching may occur at the sensor insertion site. Remove the sensor if these occur while wearing it; if they occur after removal, monitor the site and consult your healthcare professional if symptoms persist or worsen. If necessary, consult your healthcare professional.

Contraindication

- Known allergy to disinfecting alcohol or medical adhesives.
- Extensive skin conditions or lesions at the site of device placement. Relevant conditions include, but are not limited to: Psoriasis, Eczema, Dermatitis Herpetiformis, severe burns or sunburns, and scars.

- **No MRI/CT/Diathermy:** The iFree 2 CGM (sensor, transmitter and/or other display devices) must be removed prior to Magnetic Resonance Imaging (MRI), Computed Tomography (CT), or high frequency electrical heat (diathermy) treatment. People who are unable or unwilling to contact with their healthcare professional are not recommended to use the iFree 2 CGM. Sufficient vision or hearing is critical for successful use of the system including effective recognition of the alerts.
- DO NOT Use If You Are Pregnant, on Dialysis or Critically Ill. Do not use the iFree 2 CGM if you are pregnant, on dialysis or critically ill; or on users with other implanted medical devices (e.g., a pacemaker). The system has not been evaluated for use in these populations.
- iFree 2 CGM is contraindicated in patients with infection, edema at or near the sensor insertion site, those receiving vasoactive drug therapy, or with impaired tissue perfusion.
- iFree 2 CGM use is not recommended, or should be undertaken with caution, in patients with an increased risk of bleeding, known allergies to disinfectants or medical adhesives, sensitive skin, a predisposition to skin ulceration, or when the insertion site is affected by wounds, scarring, or inflammation, as these conditions may interfere with device placement and accuracy.

- iFree 2 CGM should not be used during episodes of severe hypoglycemia (<2.2 mmol/L), severe hyperglycemia (>27.8 mmol/L), or during periods of rapid blood glucose fluctuation.
- The sensor should not be inserted into areas with tattoos, scars, or similar skin conditions.

Safety Information

The following is a summary of safety information which must be observed before using the iFree 2 CGM. WARNING indicates potential danger to the user. PRECAUTION indicates potential injury to the user or damage to the system. To minimize risks, read the following safety information before using the system. Improper use and maintenance may damage the system resulting in failure or injury to the user. It is important to understand that this safety information is not exhaustive. It is intended to ensure the safety of the user when using the system.

If you experience serious incidents caused by the use of the iFree 2 CGM, contact your local emergency services for help. Please report the incident to Bionime Corporation and the local competent authority.

⚠ **WARNINGS:**

Use a Blood Glucose (BG) Meter To Make Treatment Decisions Under The Following Conditions:

- During the 1-hour warmup period when you start a new sensor. You will not receive any sensor readings, or alerts until your system begins to transmit data.
- If you suspect that your sensor readings may be inaccurate for any reason.
- If your sensor readings do not match what you are feeling.
- If you are experiencing symptoms that may be due to low or high blood glucose.
- If your system does not include your current glucose concentration or a glucose trend arrow.
- If you wish to confirm hypoglycemia or impending hypoglycemia as reported by the system.
- If you are experiencing rapid glucose changes (greater than 0.1 mmol/L per minute), the sensor readings displayed may be less accurate and less timely.

Not Receiving Urgent Alerts under the Following Conditions:

- When either your display device or transmitter battery is

dead.

- When your display device is turned off.
- When there is a system error (e.g., no glucose readings, sensor error, signal loss, etc.) or damage to the system.
- During the 1-hour sensor warm-up period.
- When the display device is out of range (6 meters/20 feet) from your transmitter; or obstacles (metal, walls, water, etc.) are between them.

Modification of the System is Not Permitted: Do not modify or tamper with any components or accessories of the iFree 2 CGM. Do not use any component of the iFree 2 CGM with any product not included in this system. Otherwise, you may damage the integrity of the system and put yourself at risk especially when you have a severe low or high glucose event.

Children or pets without adult supervision: Do not allow children or pets to play with any parts of iFree 2 CGM without adult supervision.

Choking Hazard: The iFree 2 CGM contains small components that may be dangerous if swallowed.

Strangulation hazard: The charging cable may pose a strangulation hazard.

⚠ **PRECAUTIONS:**

Calibration Safety: Calibrating the iFree 2 CGM is optional. If you choose to calibrate, use only fingerstick blood glucose values to ensure accuracy. Entering incorrect values, or using blood glucose readings obtained from alternate sites, may result in inaccurate sensor readings and could lead to missed high or low glucose events.

Skin Irritation Reaction Caused by the Sensor Adhesive: Some individuals may be sensitive to the medical adhesive that keeps the sensor attached to the skin. If you develop a rash around or under your sensor, remove the sensor and stop using the iFree 2 CGM. If necessary, consult your healthcare professional.

Avoid Skin Care Products: Do not apply skin care products such as sunscreen, moisturizer, perfume or insect repellent over the sensor insertion site or any components of the iFree 2 CGM. Failure to comply may lead to damage of the plastic used in the iFree 2 CGM or reduction in the stickiness of the sensor adhesive.

Do NOT Attempt to Reinsert a Sensor: If the adhesive patch is loose or if the sensor tip is pulled out from your skin, remove

the sensor and replace it with a new sensor. Sensor readings may be unreliable until a new sensor is inserted.

Do not freeze sensors. Avoid direct sunlight, extreme temperatures, and high humidity. These conditions may damage the sensor and cause inaccurate sensor readings.

DO NOT Reuse Your Sensor or Inserter: The entire Sensor Kit package is sterilized and designed for single use. It is not suitable for re-sterilization. Re-sterilization of these components may result in no glucose readings and infections.

Charging Direction: The charging accessories provided with iFree 2 CGM comply with safety regulations for medical devices. Use only these components when charging your transmitter. Otherwise, the system may be damaged or a fire hazard may be presented. Make sure access to the power adapter is not blocked and it can be easily unplugged due to the potential risk of electrical shock.

DO NOT Use If Any Component Appears to be Damaged: A damaged or cracked sensor kit or transmitter may compromise the integrity of the system and contribute to infection risk.

Traveling by Air: Always check and follow flight rules and

regulations before departure. Notify the security personnel of the presence of the iFree 2 CGM and comply with requirments for pat-downs, visual inspection and metal detectors. You must comply with any requests by airline personnel (e.g., turning off the system). Do not pass through an advanced imaging technology (AIT) body scanner (e.g., millimeter wave scanners) or put iFree 2 CGM components through x-ray machines since the effect of this equipment on iFree 2 CGM has not been evaluated.

Changing Time Zone Is Not Permitted: You are not allowed to change time zone during the 15-day monitoring period. Changing the time or date settings during monitoring may result in gaps in the graph or hidden glucose readings.

Keep an Emergency Kit with You: Make sure necessary supplies are always available. Let your family, co-workers, or friends know where the emergency kit is.

The emergency kit should contain:

- Fast-acting glucose tablets.
- Blood glucose monitoring supplies.
- Insulin syringe and rapid-acting insulin (with dosage instructions from your healthcare professional).

• Adhesive dressing.
• Glucagon emergency kit.

Troubleshooting: If any situation not mentioned in this user manual occurs, please contact your healthcare professional or Customer Service.

Be Careful of Electromagnetic Disturbance: Stacking equipment, or using USB cables and chargers not provided with iFree 2 CGM may negatively influence on electromagnetic compatibility. Stay a distance greater than 30 cm (12 inches) from any part of any portable RF communications equipmentand and at least 1 meter from sensitive equipment. If abnormal behavior is observed due to EM disturbances, please relocate the device accordingly.

Symbol Definitions

	Date of manufacture		Use-by date
	Manufacturer		Do not re-use

SN	Serial number		Importer
	Direct current	LOT	Batch code
	Caution		Temperature limitation
	Humidity limitation	MR	MR Unsafe
MD	Medical device		Keep away from sunlight
	Keep dry	REF	Catalogue number
UDI	Unique device identifier		
STERILE R	Sterilized using irradiation		
	Type BF applied part device		

EU REP	Authorized representative in the European Community
	Do not use if the package is damaged
	Discard this product according to local regulations
	Operating Instructions; consult manual for further instructions
IP21	Protected from touch by fingers and objects greater than 12.5 millimeters. Protected from vertical dripping water for 10 minutes.
IP22	Protected from touch by fingers and objects greater than 12.5 millimeters. Protected from dripping water when tilted at 15° for 10 minutes.
IP48	Protected from tools and small wires greater than 1 millimeter. Protected from immersion 10 feet (3.05 meter) for 30 hours.

Getting To Know Your iFree 2 CGM

Performance Features

The iFree 2 CGM provides glucose readings, trends, and levels every minute.

The iFree 2 CGM has user-friendly features and benefits including:

- Ergonomic design of sensor inserter allows users to insert the sensor safely with just one hand.
- Easy-to-read visual glucose values and trends.
- Powerful transmitter storage holds 15 days of glucose readings with zero data loss.
- Visual and audio alerts for hypoglycemia and hyperglycemia.
- Lightweight sensor and transmitter for maximum comfort.

Safety Features

The iFree 2 CGM offers a number of important safety features when you use it.

These features include:

- Alerts includes visual notification, vibrations and sound, depending on your personalized settings.
- When you are out of your target glucose range, the display device alerts you.
- Display device warns you if your glucose level falls below to or below 3 mmol/L.
- Urgent alert settings at 3 mmol/L or below cannot be changed or turned off.
- Display device notifies you when a sensor has failed, expired or when there are system errors.

CGMs Components

The iFree 2 CGM consists of 3 key parts: a sensor kit, transmitter and display device.

SENSOR KIT
Sensor kit contains with a pre-loaded sensor inside the inserter and does not require user assembly. The inserter helps you place the sensor under your skin with ease. The sensor measures your interstitial glucose level.

TRANSMITTER
The transmitter wirelessly sends your glucose data from the sensor to the display device. The transmitter is rechargeable for multiple-use by a single patient.

DISPLAY DEVICE - APP INSTALLED SMARTPHONE (iOS or Android) and SMARTWATCH
The display device provides sensor readings and delivers alerts of high and low glucose readings. The system can be used with a smartphone with the mobile App. You can install the iFree CGM App on your smartphone; if you use a smartwatch in conjunction, you can also view the glucose readings and trends provided by the iFree CGM App on your smartwatch.

Accessories

TRANSMITTER CHARGER (With Cable)
A USB charging dock is included.
Note: Both the USB cable and AC power adapter are labeled with "iFree 2" for identification and are exclusively for CGM use.

STORAGE VIAL
The vial is used for storage of transmitter to keep them dry.

SPLITTER
The splitter is used for separating the transmitter, sensor base and adhesive patch.

SENSOR PATCH (TP110)
Designed to secure continuous glucose monitoring system transmitters.

Before You Start

Install The Mobile App

iFree CGM App can be downloaded from the Google Play Store or App Store. Start by following the on-screen instructions to complete the initial setup if it is your first time using the App. The screens in this manual may look different from your App because of operating

systems or updates, please use the App by following the on-screen instructions. Refer to the original user's manual of your smartphone to learn how to change relevant settings.
Before starting monitoring, please confirm the following settings below:

- **Bluetooth on and location permission agreed:** Connection between your transmitter and the App is via Bluetooth and location; you will receive sensor readings or alerts after enabling and agreeing to the App permission.
- **Notifications on:** Enable and allow notifications to show on your locked screen.
- **Keep the battery charged:** The App will continue working in background and keep draining your battery, make sure to keep the power sufficient.
- **Smartphone powered on and running:** Open the App again if you restart your smartphone.
- **Update manually:** Update the operating systems or Applications automatically may change settings or shut down the App. Always update manually and verify the setting afterward.
- **Do not change the time:** You are not allowed to change time zone during the 15-day monitoring session. It may result in gaps in the graph or hidden glucose readings.

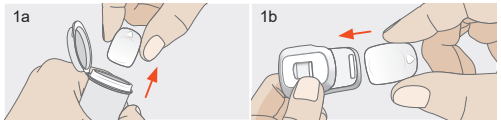
iFree CGM App is only compatible with certain smartphones and operating systems, please check the official website or contact customer service for more information about compatible devices.

⚠ **WARNINGS:**
Not Receiving Alerts. There are no alerts when your transmitter battery is dead.

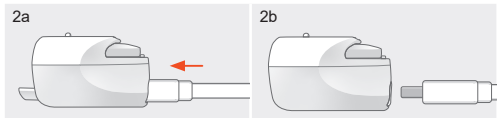
⚠ **PRECAUTIONS:**
Plug in to Charge. Make sure to fully charge your transmitter before you start a new monitoring session. When plugged into a standard household electrical outlet (100 - 240VAC, 50/60 Hz) with the supplied transmitter charger, the transmitter requires approximately 3 hours to fully charge.

Charging The Transmitter

Fully charge the transmitter every time before you start a new monitoring session to ensure data is collected from the sensor and sent to the display device during the entire monitoring session (15 days).
1. Take out your transmitter from the storage vial.

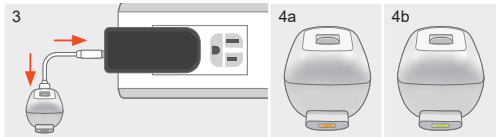


2. Connect the USB-C Plug of the USB cable to the USB-C input of the charger. Slide the USB-C port inwards to lock the transmitter in position.
   NOTE: The USB cable can only be plugged in when the transmitter is secured inside its charger compartment. After the USB port is pushed inwards, the transmitter cannot be removed from the charger.



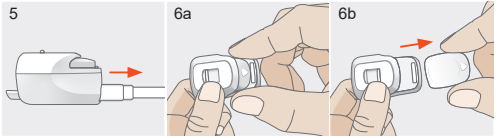
3. Plug the cable's USB plug into the USB port on the AC power adapter.

4. Plug the AC power adapter into AC wall socket (100 - 240V AC, 50/60 Hz), then check LED on the charger to monitor the charging status of the transmitter. A solid orange (✱) light means the battery is charging. A solid green (✱) light means the battery is fully charged.
   NOTE: If the LED does not light up or flashing, make sure the power adapter is connected to a power source with an output rating of 500 mA or higher. If the issue persists, try connecting to another power source or contact Customer Service.



5. After the transmitter is fully charged, pull the USB-C cable outwards to allow the transmitter to be removed.
   NOTE: The transmitter can only be removed when the USB-C port is unplugged. After the transmitter is removed, the USB-C port cannot be slid inwards.

6. To start a new monitoring session, slide the fully charged transmitter out of the compartment.



7. To store the transmitter, put it back into the storage vial and cap the storage vial.
NOTE: Always seal the transmitter in the storage vial when not in use.

Setting Up Your iFree 2 CGM

Before setting up your iFree 2 CGM, make sure you have everything you need:

• Sensor Kit • Transmitter • Display device • Alcohol Wipes
• Blood Glucose (BG) Meter

Note. When using Blood Glucose (BG) Meter, please refer to the Blood Glucose (BG) Meter manual.

Scan The Sensor Kit And Transmitter

⚠ **PRECAUTIONS:**
Scan Before Monitoring: Every time you start a new monitoring session, **scan both QR Code of the sensor kit and the transmitter with your display device**. Each sensor kit has its unique QR Code which is attached on the sealing paper. The QR Code of the transmitter is on the back (with the face of the metal components.)

The following steps describe how to start a monitoring session. If you are unable to start a monitoring session please contact Customer Service.

1. Open the App on your smartphone.
2. Tap **[Let's Start]** to start a new glucose monitoring session.
3. Scan the Sensor Kit using the built-in scanner, once it scanned successfully, a checkmark (√) will appear on the screen.
4. Scan the QR Code from the back of the transmitter, once it scanned successfully, a checkmark (√) will appear on the screen.
5. Following the screen instructions to check the battery of the

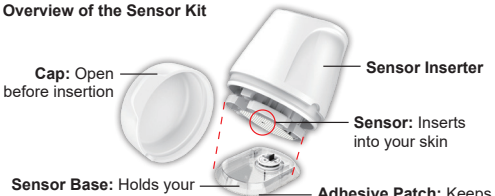
transmitter until the light turns green. Once it scanned successfully, a checkmark (√) will appear on the screen.

6. Make sure you follow the steps in the next two sections ("Apply Your Sensor" and "Attach Your Transmitter"). After installing the sensor and transmitter, click **[Connect]**.

Apply Your Sensor

The sensor is pre-loaded inside the inserter. Before applying the sensor to your skin, familiarize yourself with the information in this section.

Overview of the Sensor Kit



PRECAUTIONS:
The circle indicates where the sensor needle is located during inserting. Do not touch this area against any part of your body where you do not want to insert a sensor.

Choose an insertion site on the back of upper arm where there is an adequate amount of subcutaneous fat.

The following areas are preferable for insertion:

1. Skin that stays flat during normal daily activities (without bending or folding).
2. An area unlikely to be bumped, pushed, or lain on while sleeping.

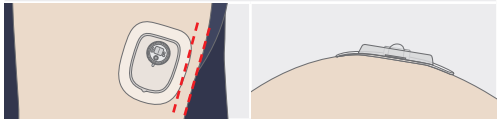
The following should NOT be selected for insertion:

1. Any area of the body other than the back of upper arm.
2. Skin that is painful to touch, is higher than surrounding skin, is crusting or bleeding.
3. Areas directly over muscle, scars, moles, tattoos, irritation, stretch marks, bones, or lumps.

The following is not recommended for insertion:

1. Sites that are too close (less than 1 inch or 2.5 cm) to an insulin injection site or previous sensor insertion site.
2. Areas constrained by clothing or accessories and areas which experience high amounts of movement during exercise so as to avoid accidental sensor removal due to excessive sweat or body movement.

Sensor base is parallel to your upper arm. Follow these steps to apply the sensor under your skin. Correct application of a sensor ensure fully attachment of adhesive patch on your skin and help the sensor stay under your skin for up to 15 days.

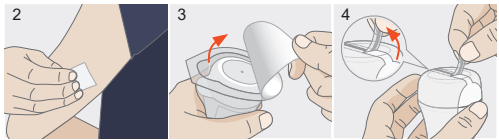


1. Wash and dry your hands.
2. Wipe the insertion site with an alcohol wipe and wait for approximately 2 minutes until the site has dried before getting started.
   NOTE: Cleaning the insertion site using a plain soap, drying, and then cleaning with an alcohol wipe before insertion of a sensor helps remove any oily residue to let the sensor stick properly. If needed, consider shaving the insertion area to help the sensor stick properly.

3. Open the seonsor kit package by peeling off the the sealing paper completely. Take out the Sensor Kit from its package and save the package until the end of the monitoring session.

PRECAUTIONS:
Check the Package. Do not insert the sensor if the sterile package is damaged, broken, or unsealed before you open the package, due to infection risks.
Check the Expiry Date. Discard and do NOT use the Sensor Kit after the expiry date (YYYY-MM-DD) printed on the sealing paper.

4. Peel off the plastic film outside the Sensor Kit.
NOTE: The plastic film prevents the cap opening during transportation.



5. Open the sensor kit cap.
NOTE: The adhesive patch does not have a paper cover and is ready for application immediately after opening the cap.

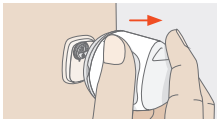
6. Place the inserter over the desired site and push down firmly to insert the sensor.
Keep pressing for 10 seconds to ensure the adhesive patch is fully attached to your skin.
NOTE: Rotate the arrow mark upward when positioning the inserter to ensure the sensor is secure and comfortable during the wear period. If you are having difficulty inserting the sensor onto the back of your upper arm by yourself, ask someone to help you or use a mirror for assistance.

PRECAUTIONS:

1. Apply the sensor immediately after opening its package and the cap. Otherwise, it may present an infection risk.
2. Do not push down the inserter until it is placed over the insertion site.
3. If the insertion is not successful or causes any discomfort, please consult your healthcare professional and use a new sensor.
4. Do not apply the sensor if it falls out of the inserter when opening the cap.
5. Do not apply the inserter if it is misused or mishandled before insertion.

7. Gently move the inserter away from your insertion site.
   NOTE: A temporary skin pressure mark may be visible after removal of the inserter due to the application of pressure during insertion. This is normal and typically resolves within a short period of time.
8. Align both notches on the inserter body and the cap to reconnect them. Discard the inserter in an appropriate puncture-proof or biohazard container according to local regulations for sharps and blood-containing components to prevent cross-contamination and

ensure safety.
NOTE: Cap the used sensor inserter immediately after use to avoid needle punching during discarding it or when sensor inserter is mistakenly taken by children.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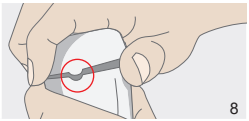
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PRECAUTIONS:

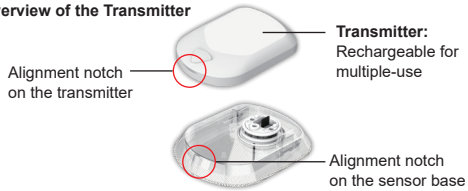
Bleeding or bruising at the insertion site under or around the sensor base after applying the sensor is extremely uncommon. If bleeding occurs or you experience high levels of discomfort, follow these steps to reduce risks:

1. Remove the sensor base and adhesive patch. Place sterile gauze or a clean cloth on the bleeding site and apply steady pressure for three minutes or until the bleeding stops.
2. Inspect the site for redness, ongoing bleeding, irritation, pain, tenderness, or inflammation, and contact a healthcare

professional for further assistance.

3. Use a new sensor kit and choose another suitable location for reapplication. If the sensor breaks off under the skin, contact a healthcare professional for further assistance.

Overview of the Transmitter



Attach Your Transmitter

⚠ **PRECAUTIONS:**

DO NOT Share Your Rechargeable Transmitter. The transmitter is rechargeable and reusable. Never share your transmitter with others. The system is intended for use by a single individual only. If used by other persons, glucose

readings, reports, alerts, etc., may be wrong.

Attach your transmitter after the sensor is inserted.

- Store the transmitter in the storage vial. Before attaching the transmitter, make sure it is fully charged. Do not remove your transmitter until your sensor session is over.

⚠ **PRECAUTIONS:**

Pair Before Use: Make sure the transmitter has been paired with the sensor.

Follow these steps to attach your transmitter:

1. Align the edge of transmitter and the edge of sensor base. Slide transmitter along the edge of sensor base until both notches on the sensor base and transmitter are aligned.
   NOTE: After the transmitter and sensor are assembled, they are IP48 rated for water resistance (10 feet or 3.05 meter for 30 hours) and can be worn while bathing, showering, or swimming. Make sure there are no unknown substances on the sensor or sensor base to ensure maximum water resistance.
2. Press down the transmitter until it clicks into the sensor base.
   NOTE: Try using a mirror or asking others for assistance to attach

your transmitter in the sensor base. An LED will flash when the transmitter is sucessfully connected.

3. Make sure the following instructions:
   (a) All four corners of the transmitter are secured in the sensor base.
   (b) Adhesive patch is fully attached on your skin.

⚠ **NOTE:**
STEP 1: Please ensure that the transmitter is securely attached to the sensor base.
STEP 2: Please "press the pressure-sensitive adhesive patch for 10 seconds daily" to ensure proper adhesion.

Connect Transmitter With Display Device

⚠ **WARNING:**
Use a Blood Glucose (BG) Meter. During the 1-hour sensor warm-up period after you insert a new sensor, use a BG meter to make treatment decisions. You will not receive any sensor readings, alerts until your system begins to transmit data.

⚠ **WARNING:**
Keep Your Display Device Close. Be sure your display device is close to your transmitter and in the same room. The maximum transmission distance is 6 meters (20 feet) with no obstructions (e.g., walls, metal, glass or water) in between. Obstructions or greater distances may cause Bluetooth signal loss and you may not receive important alerts.

1. Make sure you have followed the steps in the "Apply Your Sensor" and "Attach Your Transmitter" sections. When the screen displays "Confirmation", press **[Connect]**.
   NOTE: Make sure you have installed your sensor and transmitter before you start the following steps.
2. Your smartphone will automatically search for your transmitter. Keep your smartphone close to you.

3. After the system is connected, the screen will display a warmup progress bar. When the warmup is completed, "Warmup" will disappear from your display.

NOTE:

1. Your smartwatch only communicates with your mobile phone, not the Transmitter. You won't get alerts or sensor readings on your smartwatch unless it's connected to your mobile phone.
2. Using the smartwatch with your iFree CGM App may change how you get alerts.
3. Waking up your smartwatch updates your current glucose data from your mobile phone. There may be a brief delay before your smartwatch shows current information.

Ending A Monitoring Session

End The Monitoring Session

PRECAUTIONS:

Do Not Reuse. Reuse of a sensor, sensor base or adhesive patch may cause infection or irritation.

Ending a Session Early: If any unexpected issues (irritation or discomfort) happen at the application site, consult your healthcare professional for further assistance.

1. The monitoring session ends automatically when the sensor reaches the ends of its 15-day life and the sensor reading will no longer be shown on the screen. A notification will pop-up to let you know the session has ended. You MUST remove or replace the sensor currently in use when you receive this notification. Press **[Remove CGM]** to confirm.
2. To end a monitoring session before receiving the notification, you can select "Stop Monitoring" from "Report". You will see a message warning you that the sensor has not yet expired. Press **[Stop anyway]** to end the session.

Sensor And Transmitter Removal

Do not remove your transmitter until your sensor session is over. Once the session has ended, follow these steps to remove your sensor and transmitter:

1. Grip the edge of the adhesive patch and peel the sensor and transmitter off in one motion.

PRECAUTIONS:

Follow the instructions for proper use of the sensor to avoid

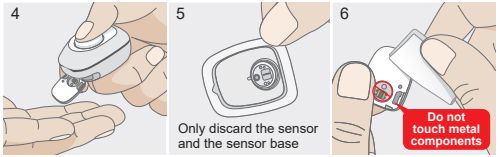
sensor breaking.
If the sensor breaks under your skin, do not remove it by yourself. Contact your healthcare professional immediately for further assistance. If any symptoms of infection or inflammation (such as redness, swelling, or pain at the insertion site) occurs, visit medical facility for emergency treatment.
Any remaining adhesive residue on the skin can be removed with warm soapy water or isopropyl alcohol.

2. Open the splitter upper cover and put the used transmitter into the splitter, then close the cover.
3. Push the splitter button.

4. Tilt the splitter out to drop out the transmitter.
5. Keep the transmitter to use with the next sensor. Discard

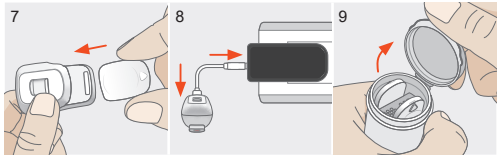
the sensor, sensor base and adhesive patch according to local regulations for disposal of blood-contacting components.
NOTE: Do not throw away the transmitter.

6. Always clean the bottom of the transmitter with an alcohol wipe and let transmitter dry before continuing. Do not touch or scratch the metal components.
NOTE: Failure to clean it may cause it to deteriorate and harden over time, resulting in malfunction.



7. Hold the charger face up. Align the transmitter toward the charger's transmitter compartment with the transmitter's metal components facing down, and slide the transmitter into the charger compartment.
8. Follow steps 2 - 7 of CHARGING THE TRANSMITTER to charge your transmitter before its next use.

9. Store the transmitter inside in the storage vial.

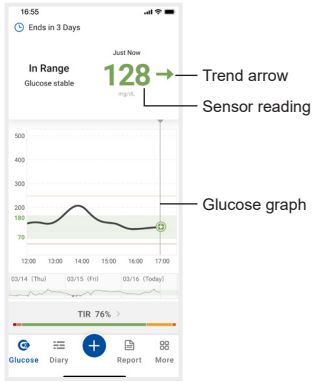


Understand Your Glucose Readings

Home Screen Indicator And Displays Overview

Your glucose information (e.g., reading, glucose graph, trend arrow indicating rates and direction of glucose change, etc.) is displayed on the screen of your display device.
It is important to understand these indicators before use.

Overview of Monitoring Screen



Glucose Trend Arrow And Arrow Color

There are 5 different trend arrows reflecting your glucose readings and how fast they are changing. The color (orange, amber, green, pink and red) of the arrow helps identify the risk of hypoglycaemia and hyperglycaemia.

* "Glucose is steady" means the glucose rate of change is between 0 and 0.06 mmol/L per minute.

** "Glucose falling/rising" means the glucose rate of change is 0.06 - 0.1 mmol/L per minute.

*** "Glucose falling/rising rapidly" means the glucose rate of change is 0.1 mmol/L per minute or more.

High/Low Readings

HIGH means your glucose reading is above 27.8 mmol/L.
Do a blood glucose test with a BG meter. If you also get a HIGH result (> 27.8 mmol/L) from the meter test, contact your healthcare practitioner immediately.
LOW means your glucose reading is less than 2.2 mmol/L. Do a blood glucose test with a BG meter. If you also get a LOW result (< 2.2 mmol/L) from the meter test, contact your healthcare practitioner immediately.

Calibration

The iFree 2 CGM is factory-calibrated and does not require manual calibration. However, manual calibration is optional and can be performed to align the sensor readings with your BG meter values. If you choose to calibrate, take a fingerstick measurement from your BG meter (MAX PLUS) then enter the value according to the following steps:

1. From the Calibrate screen, tap **[Calibrate]**.
2. Enter the exact BG value then press **[Save]**.
3. You will see a prompt from the screen. Tap **[OK]**.

NOTE: During periods of rapid glucose change (such as after eating, insulin injection, or exercise), physiological differences between interstitial fluid and blood may cause discrepancies between the sensor reading and the BG meter value. It is advised not to calibrate the CGM during periods of rapid glucose fluctuation to ensure calibration accuracy.

The recommended calibration time is immediately after the 1-hour warm-up is completed. Use a fingertip blood glucose value measured within 5 minutes for calibration.

To obtain the best correction results:

- Calibrate when fasting or before a meal.
- Use only fingertip blood glucose measurements.
- Enter the value immediately after completing the test.
- Do not use previous blood glucose results.
- If calibration fails, wait 15 minutes before trying again.

Connection And Data Uploading

The App can automatically upload your monitoring results to the cloud via the Internet.
Refer to the original manual of your smartphone to learn how to set up a mobile network or Wi-Fi to connect to the Internet. Using a mobile network to connect to the Internet may be charged for data transmission. It will be charged by your mobile carrier.

Treatment Decisions

Before you start using the iFree 2 CGM for treatment decisions, make sure you are familiar with the tips provided in this chapter and you have a good understanding of how the system works.

- Continue to use your blood glucose meter for treatment decisions until you are comfortable with the information you receive.
- Getting familiar with the system could take days, weeks, or even months.
- Work with your healthcare practitioner and follow their recommendations to put together a plan for making treatment decisions including insulin dosing, based on the glucose values provided by the system, to avoid improper timing or incorrect insulin dosage.
- Check your notes to see how carbs, medication, exercise, illness, and stress levels impact your blood glucose readings.

⚠ **WARNINGS:**
DO NOT Ignore Low/High Blood Glucose Symptoms. If your glucose readings do not match how you are feeling, perform a test with a blood glucose meter. Consult your healthcare professional if necessary.

Use a Blood Glucose (BG) Meter To Make Treatment Decisions Under The Following Conditions:

- During the 1-hour warmup period when you start a new sensor. You won't receive any sensor readings, and alerts until your system begins to transmit data.
- If you suspect that your sensor readings may be inaccurate for any reason.
- If your sensor readings do not match what you are feeling.
- If you are experiencing symptoms that may be due to low or high blood glucose.
- If your sensor readings do not include your current glucose concentration or a glucose trend arrow.
- If you wish to confirm hypoglycemia or impending hypoglycemia as reported by the sensor.
- If you are experiencing rapid glucose changes (more than 0.1 mmol/L per minute), the sensor readings displayed may be less accurate and not as timely.

When Not To Use Sensor Readings To Make Treatment Decisions

You must not make treatment decisions based on your sensor glucose reading in the following situations:

- You suspect that your sensor blood glucose readings may be inaccurate for any reason.
- Sensor glucose readings do not match what you are feeling.
- You are experiencing symptoms that may be due to low or high blood glucose.
- The display device shows no glucose information (e.g., an interrupt alert).
- Glucose is Falling/Rising Rapidly (with upward/downward arrow): Glucose measured in interstitial fluid may differ substantially from true blood glucose levels, particularly at times of rapid glucose change (e.g., after meals, taking insulin, or exercising).
- Low Glucose or Urgent Low Message: Sensor glucose readings may not accurately reflect your blood glucose.
- No Glucose Trend Arrow: During the 1-hour warmup period when you start a new sensor, the system cannot tell you if your glucose is rising quickly or falling quickly.
- No Current Glucose Concentration and Trend Arrow: When there is a HIGH/LOW result, you don't have enough information to make a treatment decision.

⚠ **PRECAUTIONS:**
Sensor Readings may be Different from BG Meter Values.
During periods of rapid change in blood glucose (e.g., after eating, taking insulin, or exercising), you may observe differences in glucose readings between interstitial fluid and capillary blood. Due to physiological differences between different body fluids, the sensor readings may be different from fingerstick blood glucose values from BG meters.
Confirm your blood glucose values with a BG meter before making treatment decisions.

Trend Arrows And Treatment Decisions

Trend arrows show the direction and rate of change of your glucose to give you an idea of where your glucose is going. The following table gives you some ideas on how you may use the arrows when considering your treatment.

Trend Arrow	Treatment Decision		
	Low Glucose (< 3.9 mmol/L)	Glucose in Target Range	High Glucose (> 13.9 mmol/L)
(No Trend Arrow)	Do a fingerstick blood glucose check with your BG meter. Do NOT treat based on your iFree 2 CGM.		
Double up arrow 	(All Arrow) Do a fingerstick blood glucose check with your BG meter. Do NOT treat based on your iFree 2 CGM.		

Trend Arrow	Treatment Decision		
	Low Glucose (< 3.9 mmol/L)	Glucose in Target Range	High Glucose (> 13.9 mmol/L)
Single up arrow 	(Pink/Red Arrow) Do a fingerstick blood glucose check with your BG meter. Do NOT treat based on your iFree 2	• If you are about to eat, take insulin to cover your meal. Consider increasing your dose a little since	(Orange Arrow) • If you are about to eat, take insulin to cover your meal. Consider increasing your

	CGM.	your glucose is rising. • If you've recently taken insulin or are about to exercise, wait and check your glucose reading later. Avoid "Insulin stacking".	dose a little since your glucose is high and rising. • If you've recently taken insulin or are about to exercise, wait and check your glucose reading later. • If you have not recently taken insulin and have finished exercise, consider adjusting your insulin correction dose upwards. Avoid "Insulin stacking".

Trend Arrow	Treatment Decision		
	Low Glucose (< 3.9 mmol/L)	Glucose in Target Range	High Glucose (> 13.9 mmol/L)
Horizontal arrow →	(Pink/Red Arrow) Do a fingerstick blood glucose check with your BG meter. Do NOT treat based on your iFree 2 CGM.	• If you are about to eat, take insulin to cover your meal. • If you've recently taken insulin or are about to exercise, wait and check your sensor reading later. Avoid "Insulin stacking".	(Orange Arrow) • If you are about to eat, take insulin to cover your meal. Consider increasing your dose a little since your glucose is high. • If you've recently taken insulin or are about to exercise, wait and check your glucose reading later. • If you have not recently taken insulin and have finished exercise, consider adjusting insulin correction dose upwards. Avoid "Insulin stacking".

Trend Arrow	Treatment Decision		
	Low Glucose (< 3.9 mmol/L)	Glucose in Target Range	High Glucose (> 13.9 mmol/L)
Single down arrow 	(Pink/Red Arrow) Do a fingerstick blood glucose check with your BG meter. Do NOT treat based on your iFree 2 CGM.	• If you are about to eat, take insulin to cover your meal. Consider taking a lower dose since your glucose is falling. • If you've recently taken insulin or have finished exercise, eat some snacks or fast-acting carbs.	(Orange Arrow) • If you are about to eat, take insulin to cover your meal. Consider taking a lower dose since your glucose is falling. • If you've recently taken insulin or are about to exercise, wait and check your glucose reading later. Avoid "Insulin stacking".

Trend Arrow	Treatment Decision		
	Low Glucose (< 3.9 mmol/L)	Glucose in Target Range	High Glucose (> 13.9 mmol/L)
Double down arrow 	(All Arrow) Do a fingerstick blood glucose check with your BG meter. Do NOT treat based on your iFree 2 CGM.		

Specifications

Sensor Kit Specifications

Sensor Glucose Range	2.2 - 27.8 mmol/L
Sensor Use Life	up to 15 days
Shelf Life	18 months
Sensor Operating Conditions	Temperature: 5°C - 45°C (41°F - 113°F) Relative humidity: 10% - 95%

Sensor Ingress Protection Rating (when installed with a transmitter)	IP48 Protected from tools and small wires greater than 1 millimeter. Protected from immersion 10 feet (3.05 meter) for 30 hours
Storage & Transportation Conditions	Temperature: 5°C - 30°C (41°F - 86°F) Relative humidity: 10% - 90% (in a cool, dry place)
Operating and Storage Altitude	0 to 3,048 meters (0 to 10,000 ft)
Inserter Size	52.0 x 60.0 x 61.1 mm (± 0.5 mm)
Sterilization	Sterilized by radiation
Usage	Single use (disposable)

Transmitter Specifications

Transmitter Size	24.96 x 18.14 x 4.4 mm (± 0.3 mm)
Transmitter Weight	2.4 g with battery (± 0.5g)
Power Source	Rechargeable lithium battery (3.7V) 18mAh
Operating Conditions	Temperature: 5°C - 45°C (41°F - 113°F) (During pairing and wearing period.) Relative humidity: 10% - 95%
Operating and Storage Altitude	0 to 3,048 meters (0 to 10,000 ft)
Battery Run Time	Up to 15 days (based on full charge)
Charging Time	3 hours (via AC adapter)
Protection Against Electrical Shock	Type BF applied part

Storage & Transportation Conditions	Temperature: -20°C - 40°C (-4°F - 104°F) Relative humidity: 10% - 95%
Memory Storage	15 days of glucose data (glucose readings stored every minute)
Ingress Protection Rating (when attached to Sensor)	IP48 Protected from tools and small wires greater than 1 millimeter. Protected from immersion 10 feet (3.05 meter) for 30 hours
Data Communication	Bluetooth 4.2 Frequency range BLE: 2402 - 2480 MHz Maximum RF output power of the product: 0 dBm System activation: NFC pairing (RFID: 13.56 MHz)

Data Communication Range	Up to 6 meters (20 feet)

Quality of Service
The transmitter and display device connect to each other via BLE network. Connection quality is in accordance with the Bluetooth Specification v4.2. The iFree 2 CGM System is designed to accept radio frequency (RF) communications from recognized and paired display devices only.

Transmitter Charger Specifications

Charger Channel	1
Indicator	LED (Green/Orange)
Input Port	USB-C
Weight	10.1 g (± 0.5 g)
Charger Dimensions	38.1 x 25.8 x 24.2 mm (± 0.5 mm)

Input	DC 5V/35 mA
Output	DC 4.2V/18 mA
Storage Transportation Conditions	Temperature: -10°C - 50°C (14°F - 122°F) Relative humidity: 10% - 95%
Operation Conditions	Temperature: 10°C - 40°C (50°F - 104°F) Relative humidity: 30% - 75%
Ingress Protection Rating	IP21 Protected from touch by fingers and objects greater than 12.5 millimeters. Protected from vertical dripping water for 10 minutes.
Operating and Storage Altitude	0 to 3,048 meters (0 to 10,000 ft)

Recommended Power Adapter: The transmitter Charger's AC POWER ADAPTER and the receiver's AC POWER ADAPTER have identical electrical specifications. Although the iFree 2 CGM system does not include a power adapter in the transmitter set's product package, users are recommended to use the receiver's AC POWER ADAPTER to ensure proper and safe charging of the device.
Manufacturer: UNIFIVE TECHNOLOGY CO., LTD.
Brand: UNIFIVE
Model: UMBE305-0510

This adapter provides a stable 5V/1A output suitable for use with the transmitter charger. Users may also use alternative adapters with equivalent specifications that conform to
IEC 60601-1 and relevant national safety standards.

Splitter Specifications

Splitter dimension	44.1 x 31.0 x 22.1 mm (± 0.5 mm)
Weight	12 g (± 0.5g)
Storage condition	Temperature: 5°C - 45°C (41°F - 113°F) Relative humidity: 10% - 95%
Operation condition	Temperature: 5°C - 45°C (41°F - 113°F) Relative humidity: 10% - 95%

IT Networks Characteristics And IT Security Measures For App And Receiver

iFree CGM is designed to transmit data between the transmitter and designated display devices.
iFree CGM uses the following interfaces and communication protocols:
Display Device: Bluetooth Low Energy to transmitter. TLS to data platform using cellular data or Wi-Fi. Display Device is only compatible with certain mobile devices and operating system.
For using iFree CGM App, please check https://www.rightest.com/guides for more information about device compatibility before using the App.
Use of the iFree CGM requires user registration, and the user should follow instructions on the continuous glucose monitoring system.
Don't pair your CGM over Bluetooth in public areas.
Bluetooth pairing should be done in a private and safe location to reduce cyber risks such as eavesdropping.
In addition to the security provided by the Bluetooth Low Energy connection, communication between the transmitter and mobile applications is protected by additional levels of security and safety mitigations using an encrypted and proprietary data format. This format embeds various industry standard encryption protocols and methods to protect data, verify data integrity, and to detect and prevent data tampering.

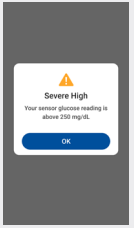
Appendix

Glucose And Signal Loss Alerts

There are delayed or no alerts in the following situations. When not in the following situations, alerts will happen in 5 seconds.

- When either your display device or transmitter battery is dead.
- When your display device is turned off.
- When there is a system error (e.g., no glucose readings, sensor error, signal loss, etc.) or damage to the system.
- During the 1-hour sensor warm-up period.
- When the display device is out of range (6 meters/20 feet) from your transmitter; or obstacles (metal, walls, water, etc.) are between them.

Event - Hyper Alert
Happens when glucose is higher than the set target range and is detected to rise or remain steady.



Visual & Sound Settings - Default Setting:
- Visual Safety Symbol (⚠) on Home Screen: Yes.
- Sound & Vibration active unless turned off by user pressing the **[OK]** button on screen; or glucose is detected to fall.
- High glucose alert will repeat every 30 minutes or until glucose level returns to the target range.

Editable Setting:
- Sound & Vibration can be turned ON/OFF by the user.

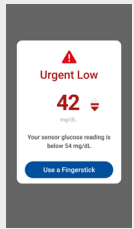
Note: If the symbol (🩸) appears, follow the prompts on the UI and perform a fingerstick blood glucose test.

Event - Hypo Alert
Happens when glucose is lower than set target range and is detected to fall or remain steady.

Visual & Sound Settings - Default Setting:
- Visual Safety Symbol (⚠) on Home Screen: Yes.
- Sound & Vibration Alert: Yes.
- Sound & Vibration active unless turned off by user pressing the **[OK]** button; or glucose is detected to rise.
- Low glucose alert will repeat every 30 minutes or until glucose level returns to the target range.

Editable Setting:
- Sound & Vibration can be turned ON/OFF by the user.

Note: If the symbol (🩸) appears, follow the prompts on the UI and perform a fingerstick blood glucose test.



Event - Urgent Low Alert
Happens when glucose is at or below 3 mmol/L.

Visual & Sound Settings - Default Setting:
- Visual Safety Symbol (⚠) on Home Screen: Yes.
- Sound & Vibration Alert: Yes.
- Sound & Vibration active unless turned off by user pressing the **[Use a Fingerstick]** button; or until glucose is higher than 3 mmol/L.
- Urgent low glucose alert will repeat every 30 minutes or until glucose level returns to the target range.

Editable Setting:
- Sound & Vibration CANNOT be turned ON/OFF by the user.

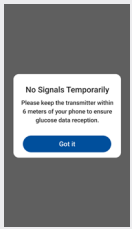
Note: If the symbol (🩸) appears, follow the prompts on the UI and perform a fingerstick blood glucose test.

Event - Upcoming Urgent Low
Happens when glucose may drop below 3 mmol/L within the next 20 minutes.

Visual & Sound Settings - Default Setting:
- Visual Safety Symbol (⚠) on Home Screen: Yes.
- Sound & Vibration Alert: Yes.
- Sound & Vibration active unless turned off by user pressing the **[OK]** button; or until the system determines that the readings will not drop below 3 mmol/L within the next 20 minutes.
- Upcoming urgent low alert will repeat every 30 minutes or until the system determines that the readings will not drop below 3 mmol/L within the next 20 minutes.

Editable Setting:
- Sound & Vibration can be turned ON/OFF by the user.

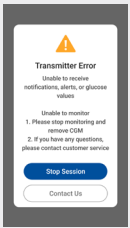
Note: If the symbol (🩸) appears, follow the prompts on the UI and perform a fingerstick blood glucose test.



Event - Signal Loss
Transmitter is too far from the display device or when there is an obstacle (e.g., water, wall) in between the transmitter and display device.

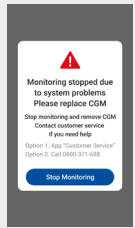
Visual & Sound Settings - Default Setting:
- Visual message on the screen: Yes
- Sound & Vibration Alert: Yes.
- Displayed continuously for 5 minutes or until **[Got it]** is pressed.
- System attempts to reconnect every 5 minutes even if user doesn't press **[Got it]**
- System alerts will repeat every 30 minutes.

Editable Setting:
- Sound & Vibration can be turned ON/OFF by the user.



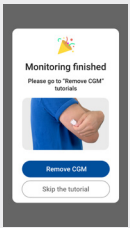
Event - Transmitter Error
Transmitter is not working.

Visual & Sound Settings - Default Setting:
• Visual message on the screen: Yes
• Sound & Vibration Alert: Yes.
- Displayed continuously for 5 minutes or until **[Stop Session]** is pressed.
- System alerts will repeat every 30 minutes.



Event - Sensor Fail
The system detects a current error measured by the sensor.

Visual & Sound Settings - Default Setting:
• Visual message on the screen: Yes.
• Sound & Vibration Alert: Yes.
- Displayed continuously for 5 minutes or until **[Stop Monitoring]** is pressed.
- System alerts will repeat every 30 minutes.



Event - Session is Completed
Your sensor session has expired.

Visual & Sound Settings - Default Setting:
• Visual message on the screen: Yes.
• Sound & Vibration Alert: Yes.
- Displayed continuously for 5 minutes or until **[Remove CGM]** is pressed.

Customer Service

We aim to provide great service to our customers. Please review these instructions to make sure you know how to use your product correctly. If you have any questions or encounter any issues with your product, please contact Bionime Customer Service or your authorized distributor.

User's Manual is also available electronically.

● App: “More” tab > Certification > Go to eIFU
● https://www.rightest.com/guides
● Free printed copy: Order at https://www.rightest.com or contact us.

Tel: +886 4 2369 2388
Fax: +886 4 2261 7586
Email: info@bionime.com

Manufacturer’s declaration-electromagnetic emissions
The Transmitter/Charger is intended for self-use by the user in the electromagnetic environment (for home healthcare) specified below. The customer or the user of the Transmitter and Charger should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment-guidance (for home healthcare environment)
RF emissions CISPR 11	Group 1	The Transmitter and Charger uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Transmitter and Charger is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Compliance	

Manufacturer's declaration-electromagnetic immunity			
The Transmitter and Charger is intended for self-use by the user in the electromagnetic environment (for home healthcare) specified below. The customer or the user of the Transmitter and Charger should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environmentguidance (for home healthcare environment)**
Electrostatic discharge (ESD) IEC 61000-4-2	Contact: ± 8 kV Air: ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV	Contact: ± 8 kV Air: ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/ burst IEC 61000-4-4	+ 2 kV for power supply lines, + 1 kV for input/ output lines	+ 2 kV for power supply lines Not applicable	Mains power quality should be that of a typical home healthcare environment.

Surge IEC 61000-4-5	+ 0.5 kV, + 1 kV line(s) to line(s), + 0.5 kV, + 1 kV, + 2 kV line(s) to earth	+ 0.5 kV, + 1 kV line(s) to line(s) Not applicable	Mains power quality should be that of a typical home healthcare environment.
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage dips: 0% UT; 0,5 cycle 0% UT; 1 cycle 70% UT; 25/30 cycles Voltage interruptions: 0% UT; 250/300 cycle	Voltage dips: 0% UT; 0,5 cycle 0% UT; 1 cycle 70% UT; 25 cycles Voltage interruptions: 0% UT; 250 cycles	Mains power quality should be that of a typical home healthcare environment. If the user of the Transmitter and Charger requires continued operation during power mains interruptions, it is recommended that the Transmitter and Charger be powered from an uninterruptible power supply or a battery.

Power frequency (50, 60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz	Transmitter and Charger power frequency magnetic fields should be at levels characteristic of a typical location in a typical home healthcare environment.

NOTE: UT is the a.c. mains voltage prior to application of the test level

Manufacturer's declaration-electromagnetic immunity			
The Transmitter and Charger is intended for self-use by the user in the electromagnetic environment (for home healthcare) specified below. The customer or the user of the Transmitter and Charger should assure that it is used in such and environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environmentguidance (for home healthcare environment)**
Conducted RF IEC 61000-4-6	3 Vrms: 0,15 MHz - 80 MHz 6 Vrms: in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80% AM at 1 kHz	3 Vrms: 0,15 MHz - 80 MHz 6 Vrms: in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80% AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the Transmitter and Charger including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz - 2,7 GHz 80% AM at 1 kHz	10 V/m 80 MHz - 2,7 GHz 80% AM at 1 kHz	Recommended separation distance: d = 1,2√P d = 1,2√P 80MHz to 800 MHz d = 2,3√P 800MHz to 2,7 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Recommended separation distance between portable and mobile RF communications equipment and the Transmitter and Charger

The Transmitter and Charger are intended for use in an electromagnetic environment (for home healthcare) in which radiated RF disturbances are controlled. The customer or the user of the Transmitter and Charger can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Transmitter and Charger as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz d =1,2 √P	80 MHz to 800 MHz d =1,2 √P	800 MHz to 2,7 GHz d =2,3 √P
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Manufacturer's declaration-electromagnetic immunity
Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

The Transmitter is intended for use in the electromagnetic environment (for home healthcare) specified below. The customer or the user of the Transmitter and Charger should assure that it is used in such an environment.

Test frequency (MHz)	Band[a] (MHz)	Service[a]	Modulation[b]	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)	Compliance LEVEL (V/m) (for home healthcare)
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n	Pulse modulation[b] 217 Hz	2	0.3	28	28

NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50% duty cycle square wave signal.

Manufacturer's declaration-electromagnetic immunity
Test specifications for
ENCLOSURE PORT IMMUNITY to proximity magnetic fields

The Transmitter is intended for use in the electromagnetic environment (for home healthcare) specified below. The customer or the user of the Transmitter and Charger should assure that it is used in such an environment.

Frequencies	Test Level [A/m]	Modulation	Dwell time [s]	Compliance LEVEL [A/m] (for home healthcare)
13.56 MHz	7.5	Pulse modulation[(a)] 50 kHz	3	7.5[(b)]

NOTE:
(a) The carrier shall be modulated using a 50% duty cycle square wave signal.
(b) r.m.s., before modulation is applied.

Device Performance Characteristics

The performance characteristics of the iFree 2 CGM system, including accuracy, were evaluated through two clinical studies to assess consistency over time and agreement with the laboratory reference method (YSI 2300). The system demonstrated a MARD within 8.4 - 8.8% under clinical use conditions when compared with the laboratory reference method.
Performance data are shown in mg/dL based on the original test reports and are for technical reference only, not for treatment decisions.

Regression analysis of the Sensors vs. YSI reference
Study A

Slope	0.936
Intercept	+11.00 mg/dL
Correlation	0.913
N	9736
Range	40 - 500 mg/dL
Overall mean bias	-1.67 md/dL
Mean Absolute Relative Difference (MARD)	8.8%

Study B

Slope	0.955
Intercept	+3.66 mg/dL
Correlation	0.946
N	5499
Range	40 – 500 mg/dL
Overall mean bias	+2.19 md/dL
Mean Absolute Relative Difference (MARD)	8.4%

Sensor accuracy for all results vs. YSI reference
Study A

Sensor accuracy results for glucose concentrations	Within ± 15 mg/dL (within ± 0.8 mmol/L)	Within ± 20 mg/dL (within ± 1.1 mmol/L)	Within ± 40 mg/dL (within ± 2.2 mmol/L)
< 70 mg/dL	263/282 (93.3%)	274/282 (97.2%)	282/282 (100.0%)
70 - 180 mg/dL	Within ± 15%	Within ± 20%	Within ± 40%
	4837/5936 (81.5%)	5407/5936 (91.1%)	5894/5936 (99.3%)
> 180 mg/dL	Within ± 15%	Within ± 20%	Within ± 40%
	4944/5655 (87.4%)	5310/5655 (93.9%)	5629/5655 (99.5%)
Sensor accuracy results for all results	Within ± 20 mg/dL (within ± 1.1 mmol/L) and within ± 20% of reference		
	10965/11873 (92.4%)		

Study B

Sensor accuracy results for glucose concentrations	Within ± 15 mg/dL (within ± 0.8 mmol/L)	Within ± 20 mg/dL (within ± 1.1 mmol/L)	Within ± 40 mg/dL (within ± 2.2 mmol/L)
< 70 mg/dL	361/377 (95.8%)	361/377 (95.8%)	377/377 (100.0%)
70 - 180 mg/dL	Within ± 15%	Within ± 20%	Within ± 40%
	2891/3525 (82.0%)	3220/3525 (91.3%)	3521/3525 (99.9%)
> 180 mg/dL	Within ± 15%	Within ± 20%	Within ± 40%
	1391/1597 (87.1%)	1486/1597 (93.0%)	1597/1597 (100.0%)
Sensor accuracy results for all results	Within ± 20 mg/dL (within ± 1.1 mmol/L) and within ± 20% of reference		
	5033/5499 (91.5%)		

Sensor accuracy over wear duration vs. YSI reference
Study A

	Beginning (Day 1)	Early Middle (Day 5)	Late Middle (Day 10)	End (Day 14)
Within ± 20 mg/dL (within ± 1.1 mmol/L) and within ± 20% of reference	92.9%	95.0%	90.5%	92.2%
Mean Absolute Relative Difference (%)	8.5%	8.1%	9.5%	9.3%

Study B

	Beginning (Day 1)	Early Middle (Day 5)	Late Middle (Day 10)	End (Day 14)
Within ± 20 mg/dL (within ± 1.1 mmol/L) and within ± 20% of reference	95.6%	95.6%	86.2%	90.7%
Mean Absolute Relative Difference (%)	7.6%	7.3%	10.1%	8.9%