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EN

RIGHTEST®

rFree CGM

CONTINUOUS GLUCOSE MONITORING SYSTEM

User's Manual

For use with mobile App or a receiver

READ THIS FIRST :

It is important to read the entire contents of this manual before using the RIGHTEST iFree 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 iFree CGMs 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.

Contents

INDICATIONS FOR USE & STATEMENT AND ADVISORY

INDICATIONS FOR USE

The RIGHTEST iFree Continuous Glucose Monitoring System (hereafter referred to as the "iFree CGMs") is indicated for detecting glycemic trends and for the management of diabetes in persons aged 18 and older. It is an applied device designed to replace fingerstick blood glucose testing for diabetes treatment decisions. Interpretation of the iFree CGMs 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.

This system can be use with the dedicated mobile App or the receiver as display device.

STATEMENT AND ADVISORY

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

SAFETY INFORMATION

The following is a summary of safety information which must be observed before using the iFree CGMs. 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.

⚠ **CONTRAINDICATION :**

MR **No MRI/CT/Diathermy:** The iFree CGMs (sensor, transmitter, receiver 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 CGMs. Sufficient vision or hearing is critical for successful use of the system including effective recognition of the alerts.

WHEN NOT TO USE: Do not use the iFree CGMs 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.

If you experience serious incidents caused by the use of the iFree CGMs, 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 first 2-hour warmup period when you start a new sensor. You will not receive any sensor readings, alarms 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 2 mg/dL per minute), the sensor readings displayed may be less accurate and less timely.
- When you see on your display device, you must check your BG value with a BG meter before making any treatment decisions. Sensor readings may be less accurate and may not reflect your current glucose levels.

Not receiving Urgent Alarms 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 2-hour sensor warm-up period.
- If your sensor readings do not match what you are feeling.
- 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 CGMs. Do not use any component of the iFree CGMs 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 CGMs without adult supervision.

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

PRECAUTIONS :

Calibration Safety: Otherwise, only use fingerstick blood glucose values to calibrate your system for accurate readings. Entering incorrect fingerstick blood glucose values or blood glucose values taken from testing at other places can result in inaccurate glucose readings, which may result in missing a high or low glucose event.

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 CGMs. 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 CGMs. Failure to comply may lead to damage of the plastic used in the iFree CGMs 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.

Store the Sensor in a Cool and Dry Place: Store the sensor in a cool, dry place between 5°C to 30°C (41°F to 86°F) and 10 - 90% non-condensing humidity.

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.

Use as Directed: The charging accessories provided with iFree CGMs comply with safety regulations for medical devices. Use only these components when charging your receiver and 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 Put the Receiver In Contact with Water: Do not spill liquids on the receiver or submerge it in water or other liquids. If the receiver has fallen into water, do not touch it until you unplug it from any electrical outlet. Touching the receiver while it is wet may result in electric shock or no glucose results.

DO NOT Use If Any Component Appears to be Damaged: A damaged or cracked inserter, sensor, transmitter, or receiver 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 CGMs 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 CGMs components through x-ray machines since the effect of this equipment on iFree CGMs has not been evaluated.

Changing Time Zone Is Not Permitted: You are not allowed to change time zone during the 14-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 AC power adapters, USB cables and USB chargers not provided with iFree CGMs 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

The following symbols apply to the iFree CGMs:

	Date of Manufacture		Do not use if the package is damaged
	Manufacturer		Biological risks
	Authorized representative in the European Community		For single use only
	Batch/Lot Number		Type BF applied part device
	Expiry date		Direct current
	Temperature limitation		Alternating current

	Humidity limitation	MD	Medical Device
STERILE R	Method of sterilization using irradiation		Keep Dry
SN	Serial number		MR Unsafe
CE 0197	CE Mark with Notified Body Number	Rx Only	Prescription Required
	Bluetooth		Refer to Instruction Manual/ Booklet
	Class II Equipment		Warning/Precaution
	Input		Operating Instructions; consult manual for further instructions

	Keep away from heat		Discard this product according to local regulations
	Near-field communication (NFC) scan area		Importer
	Electrical Equipment Designed Primarily for Indoor Use (Chargers Only)		
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 up to 10 feet (3.05 meter) for 30 hours		

GETTING TO KNOW YOUR IFREE CGMS

PERFORMANCE FEATURES

The iFree CGMs is an integrated continuous glucose monitoring system (iCGM) that provides glucose readings, trends, and levels every minute.

The iFree CGMs 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 14 days of glucose readings with zero data loss.
- Visual and audio alerts for to hypoglycemia and hyperglycemia.
- Lightweight sensor and transmitter for maximum comfort.

SAFETY FEATURES

The iFree CGMs offers a number of important safety features when you use it.
These features include:

- Alarms and 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 54 mg/dL.
- Urgent alarm settings at 54 mg/dL 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 CGMs consists of 3 key parts: a sensor kit, transmitter and display device.

SENSOR KIT (HS312)

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

TRANSMITTER (HT312)

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.

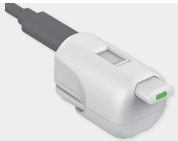
DISPLAY DEVICE - SMARTPHONE (iOS or Android) OR RECEIVER (HR310)

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 or the receiver. (Only one display device can be used at the same time.)
Receiver software version: V1.0.0.1

iOS App
software version: V1.0.0.0

Android App
software version: V1.0.0.0

ACCESSORIES



TRANSMITTER CHARGER (HC312)
A USB charging dock is included.

STORAGE VIAL
The vial is used for storage of a spare transmitter and its USB charger to keep them dry.

POWER SUPPLY (USB CABLE AND AC POWER ADAPTER)
AC power supply & USB cable for the receiver. It connects to an AC mains outlet (100-240V AC, 50/60 Hz).

BEFORE YOU START

INSTALL THE MOBILE APP

iFree CGMs Mobile 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 mobile App is via Bluetooth and location; you will receive sensor readings or alarm/alerts after enabling and agreeing to the mobile 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 mobile App again if you restart your smartphone.
- **Update manually:** Update the operating systems or mobile 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 14-day monitoring session. Changing the time or date settings during monitoring may result in gaps in the graph or hidden glucose readings.

iFree CGMs Mobile 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.

CHARGING THE RECEIVER

Before using the system for the first time, charge the receiver for a complete charging cycle without interruption. The screen displays the battery level and charging status. A complete charging cycle of the receiver takes about 3 hours. The receiver utilizes an intelligent battery charging technology that prevents overcharging.

⚠ **WARNINGS :**

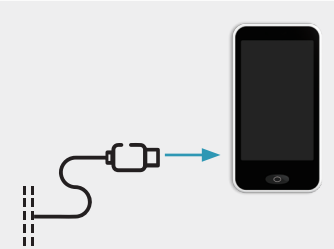
Not Receiving Alarms or Alerts. There are no alarms or alerts when your receiver is turned off or its battery is dead.

⚠ **PRECAUTIONS :**

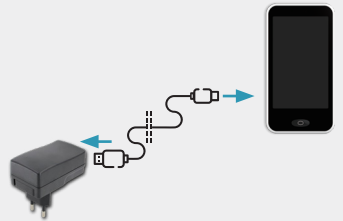
Plug In to Charge. Plug in your receiver to charge overnight to make sure you receive alarms and alerts.

Confirm Charging Status. Unstable power sources may result in the charging icon not being displayed. Check the battery charging status of the display. When plugged in and charging, the receiver will display a battery with a lightning bolt.

Do Not Operate During Charging: Operation during charging may contain risk.



1. Connect the USB-C Plug of the charging cable to the USB-C input of the receiver.



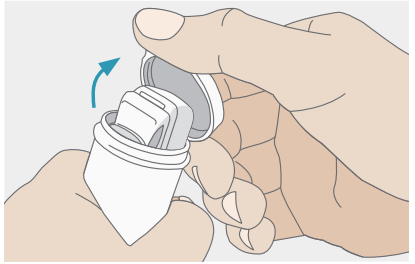
2. Connect the USB plug to the USB port of the AC power adapter supplied with your system and connect the adapter to the power source (100-240V AC, 50/60 Hz).

CHARGING THE TRANSMITTER

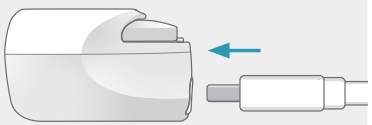
⚠ **WARNINGS :**
Not Receiving Alarms or Alerts. There are no alarm or alerts when your transmitter battery is dead.

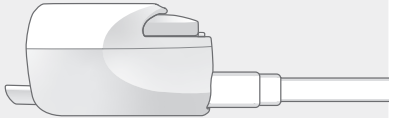
⚠ **PRECAUTIONS :**
Plug in to Charge. Make sure to fully charge your transmitter before you start a new monitoring session. When plugged into a standard household electrical outlet (100 - 240V AC, 50/60 Hz) with the supplied transmitter charger, the transmitter requires approximately 2 hours to fully charge.

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 (14 days).



1. Take out your transmitter with its charger from the storage vial.

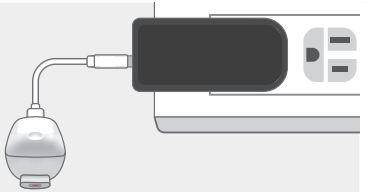




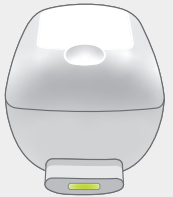
2. Connect the USB-C Plug of the charging cable to the USB-C input of the charger. Slide the USB-C port inwards to lock the transmitter in position.

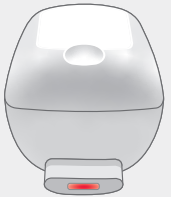
NOTE:

1. The USB cable can only be plugged in when the transmitter is secured inside its charger compartment.
2. 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.



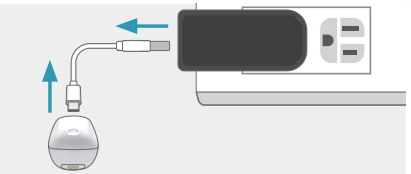


4. Plug the AC power adapter into AC wall socket (100 - 240V AC, 50/60 Hz), then check LED on the charger to monitor the charging status of the transmitter.

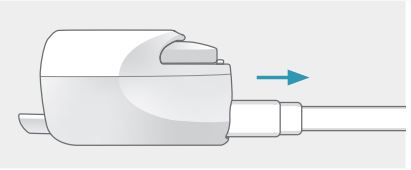
A solid red (✱) light means the battery is charging.
A solid green (✱) light means the battery is fully charged.

NOTE:

If the LED does not light up, 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 support.



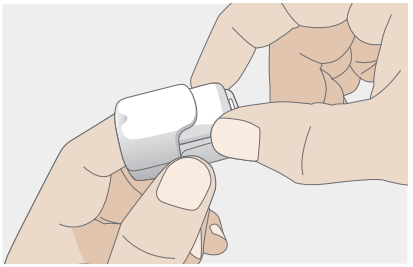
5. Unplug the cable from the power adapter after the transmitter is fully charged.

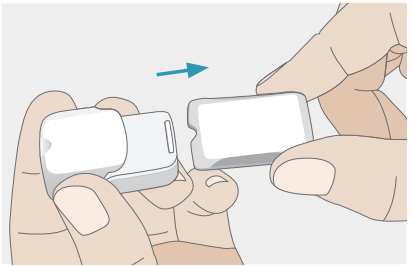


6. Pull the USB-C cable outwards to allow the transmitter to be removed.

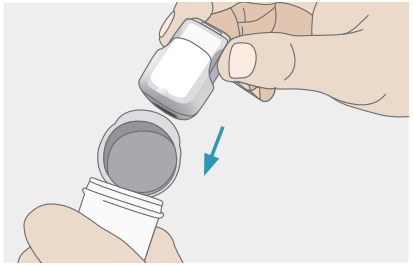
NOTE:

1. The transmitter can only be removed when the USB-C port is unplugged.
2. After the transmitter is removed, the USB-C port cannot be slid inwards.





7A. To start in a new monitoring session, slide the fully charged transmitter out of the compartment.



7B. To store the transmitter, put it back into its charger and into storage vial and cap the storage vial.

NOTE:

Always seal the transmitter and its charger in the storage vial when not in use.

SETTING UP YOUR IFREE CGMS

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

- Sensor Kit
- Transmitter
- Display device (Choose one between a smartphone with the mobile App or the receiver)
- Alcohol Wipes
- Blood Glucose (BG) Meter

SCAN THE SENSOR KIT AND TRANSMITTER

⚠ **PRECAUTIONS :**

Scan Before Monitoring: Every time you start a new monitoring session, scan both NFC tag of the Sensor Kit and the transmitter with your display device.

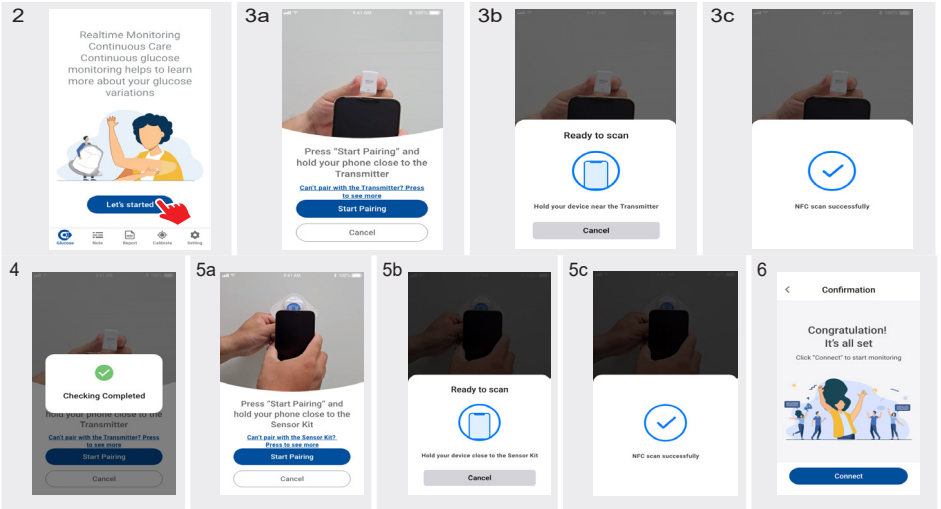
Each Sensor Kit has its unique NFC tag which is attached on the packaging. The NFC tag of the transmitter is located beneath the top plastic cover (the face without the metal components.

The following steps describe how to start a monitoring session. If you are unable to start a monitoring session by following these steps, please contact Customer Service for further assistance.

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

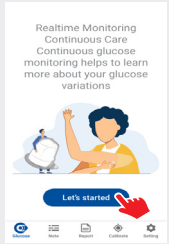
1. Open the mobile App on your smartphone.
2. Tap [Let's Started] to start a new glucose monitoring session.
3. Tap [Start Paring] and hold your phone to close to the transmitter, once it scanned successfully, a checkmark (*v*) will appear on the screen.
4. Following the screen instructions to check the battery of the transmitter, once it scanned successfully, a checkmark (*v*) will appear on the screen.
5. Press "Start Paring" and hold your phone close to the Sensor Kit, once it scanned successfully, a checkmark (*v*) 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 install the sensor and transmitter, click [Connect].

iOS

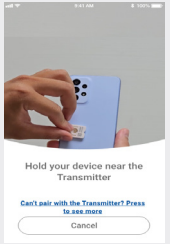


Android

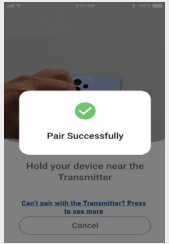
2



3a



3b



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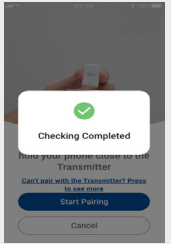
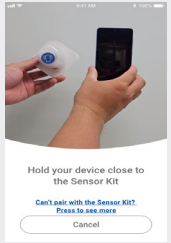
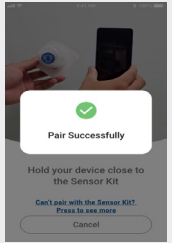


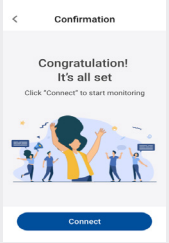
5a



5b



6



Receiver:

1. Get your receiver.

Power Button

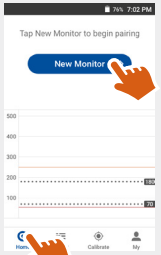
2. If your receiver is OFF, press and hold the **[Power]** button for 2 seconds to turn it ON. If your receiver is ON, press the **[Power]** button briefly to wake up the display.

NOTE :

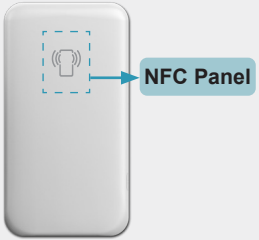
If using the receiver for the first time, follow prompts to set the date, time and your glucose targets and alerts.

NOTE :

To clean the receiver, use a soft, dry, lint-free cloth and avoid using aerosol sprays, solvents, alcohol wipes, or abrasives. Abrasive cloths, towels, paper towels, or similar items may damage the receiver and are recommended to be used for cleaning. Make sure liquid, dust, dirt, bleach, and any other substance does not get into any opening. Unplug the receiver from the USB cable and turn it off before cleaning.



3. Tap **[New Monitor]** to start a new monitoring session.

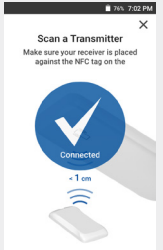


4. Locate the NFC panel on the receiver's back cover. The center of the NFC panel is engraved with a mark.

5. Scan the transmitter by touching it with the back of your receiver until you hear a beep.

NOTE :

Make sure the NFC panel is within 1 cm (3/8") of the NFC tag when you scan it.

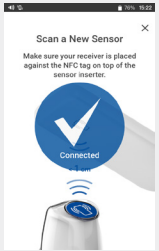


6. Once it scanned successfully, a checkmark (√) will appear on the screen to indicate that the pairing is complete.

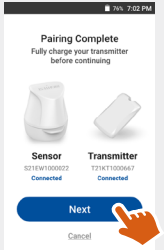
7. Scan the Sensor Kit by touching its NFC tag (on the top of package) with the back of your receiver until you hear a beep.

NOTE :

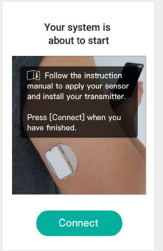
Make sure the NFC panel is within 1 cm (3/8”) of the NFC tag when you scan it.



8. Once it scanned successfully, a checkmark (√) will appear on the screen to indicate that the pairing is complete.



9. When the receiver displays "Ready to Insert", check whether the serial numbers of the sensor and the transmitter match those labeled on the package. If yes, press **[Next]**; otherwise, press **[Cancel]** and return to Step 3.



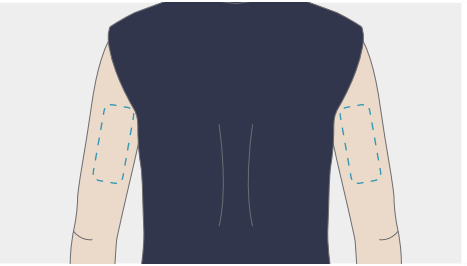
10. Make sure you follow the steps in the next two sections ("Apply Your Sensor" and "Attach Your Transmitter"). After the sensor and transmitter are installed, press **[Connect]**.

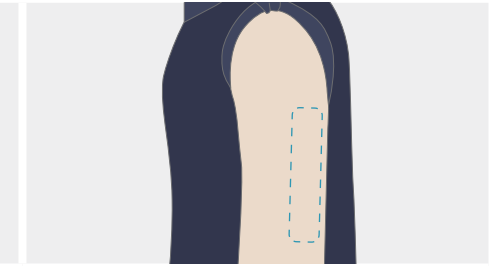
APPLY YOUR SENSOR

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.



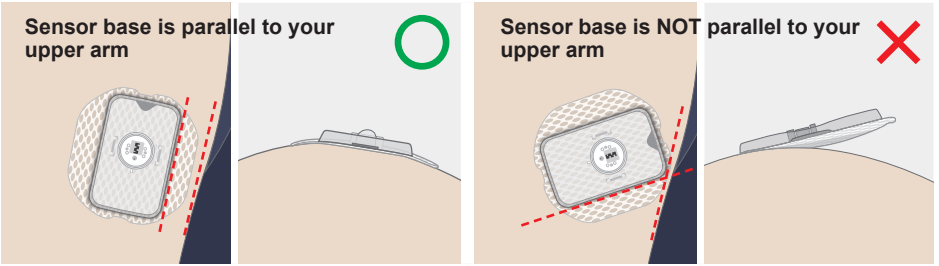


Choose an insertion site on the back of upper arm where there is an adequate amount of subcutaneous fat.

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.

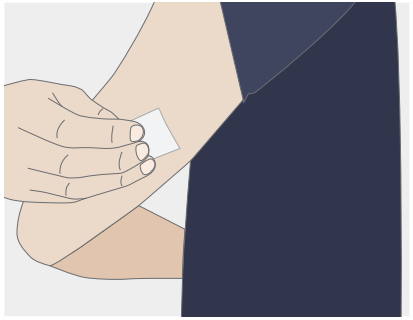
The following should NOT be selected for insertion:
1. Any area of the body other than the back of upper arm. Placing the sensor on other areas of the body may present unknown risks.
2. Skin that is painful to touch, is higher than surrounding skin, is crusting or bleeding.
3. Areas directly over muscle, 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. Placing a new sensor on the same spot will increase skin irritation or redness and could potentially lead to scabs.
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.



Follow these steps to apply the sensor under your skin.
Correctly application of a sensor ensure fully attachment of adhesive patch on your skin and help the sensor stay under your skin for up to 14 days.

1. Wash and dry your hands.

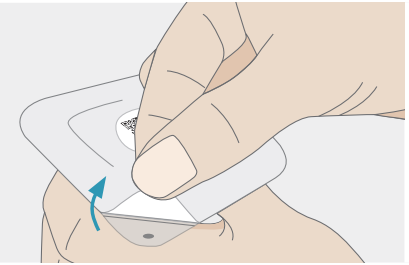


2. Wipe the insertion site with an alcohol wipe and wait for approximately 2 minutes until the site has dried before getting started.

NOTE :

1. 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.
2. If needed, consider shaving the insertion area to help the sensor stick properly.

⚠ **PRECAUTIONS :**
Clean Before Use: To minimize infection risk, wipe the insertion site with an alcohol wipe, and ensure the site is dry prior to sensor insertion.

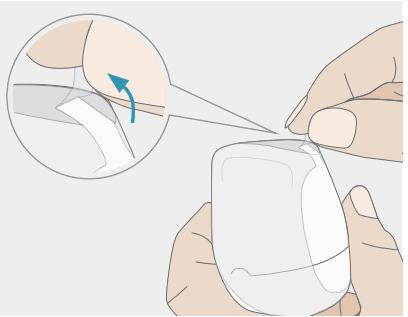


3. Open the seonsor kit package by peeling off the sealing paper completely. Take out the Sensor Kit from its package and save the package until the end of the monitoring session.

⚠ **PRECAUTIONS :**

Check the Package. Check sensor kit package before opening it. Do not insert the sensor if the sterile package is damaged, broken, or unsealed before you open the package, due to infection risks.

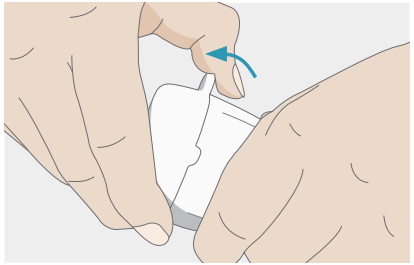
Check the Expiry Date. Discard and do NOT use the Sensor Kit after the expiry date (YYYY-MM-DD) printed on the sealing paper.



4. Peel off the plastic film outside the Sensor Kit.

NOTE :

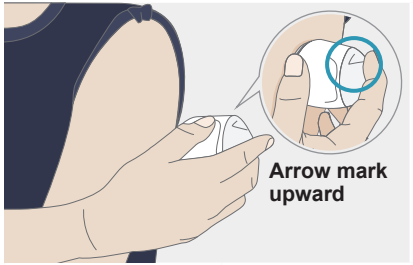
The plastic film prevents the cap opening during transportation.



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.



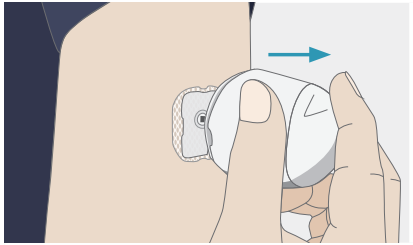
6. Place the inserter over the desired site and push down firmly to insert the sensor. Keep pressing for 10 seconds to ensure the adhesive patch is fully attached to your skin.

NOTE :

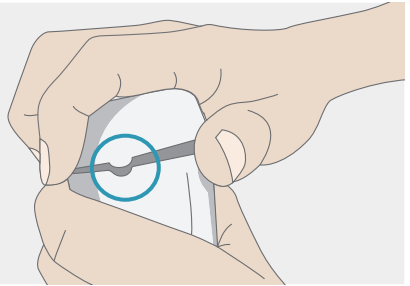
1. Rotate the arrow mark upward when positioning the inserter to ensure the sensor is secure and comfortable during the wear period.
2. If you are having difficulty inserting the sensor onto the back of your upper arm by yourself, ask someone to help you or use a mirror for assistance.

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.



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 used sensor inserter immediately after use to avoid needle punching during discarding it or when sensor inserter is mistakenly taken by children.

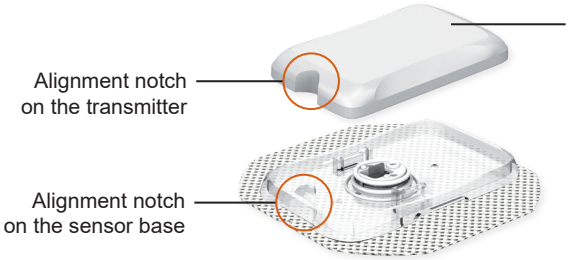
PRECAUTIONS :
Bleeding or bruising at the insertion site under or around the sensor base after applying the sensor is extremely uncommon. If bleeding occurs or you experience high levels of discomfort, follow these steps to reduce risks:

1. Place sterile gauze or a clean cloth on top of the sensor and apply steady pressure for up to three minutes. If the bleeding stops, carefully clean the blood on the sensor base before attaching the transmitter to the sensor base.
2. If the bleeding does not stop, do not connect the transmitter to the sensor since blood may enter the transmitter connector and damage the device. If bleeding continues, causes excessive pain or discomfort, or is significantly visible in the sensor base, remove the sensor and apply steady pressure until the bleeding has stopped.
3. Inspect the site for redness, bleeding, irritation, pain, tenderness, or inflammation and contact your healthcare professional for further assistance.

ATTACH YOUR TRANSMITTER

PRECAUTIONS :
DO NOT Share Your Re-chargeable Transmitter. The transmitter is rechargeable and reusable. Never share your transmitter with others. The system is a prescription-only medical device and is intended for use by a single individual only. If used by other persons, glucose readings, reports, alarms and alerts, etc., may be wrong.

Overview of the Transmitter

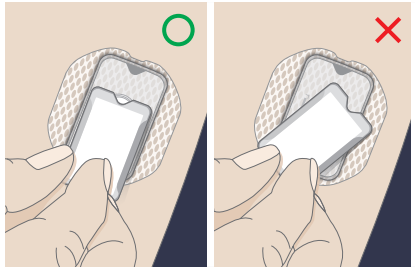


Attach your transmitter after the sensor is inserted.

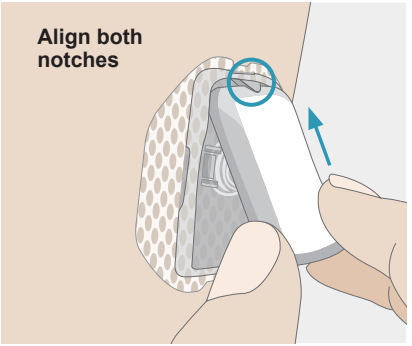
- Store both the transmitter and its charger in the storage vial provided with your iFree CGMs. Before attaching the transmitter, make sure it is fully charged. Do not remove your transmitter until your sensor session is over.

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

Follow these steps to attach your transmitter:



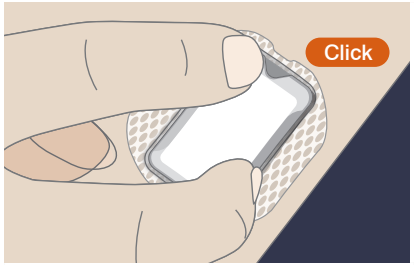
1. Align the edge of transmitter and the edge of sensor base.



2. Slide transmitter along the edge of sensor base until both notches on the sensor base and transmitter are aligned.

NOTE :

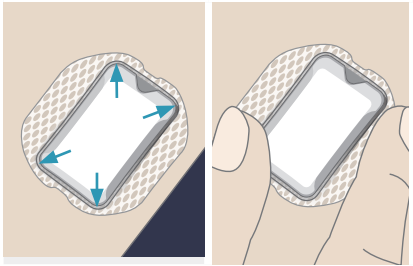
1. After the transmitter and sensor are assembled, they are IPX8 rated for water resistance (10 feet or 3.05 meter for 30 hours) and can be worn while bathing, showering, or swimming.
2. Make sure there is are no unknown substances on the sensor or sensor base to ensure maximum water resistance.



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

CONNECT TRANSMITTER WITH DISPLAY DEVICE

⚠ **WARNING :**

Use a Blood Glucose (BG) Meter. During the first 2-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, alarms or alerts until your system begins to transmit data.

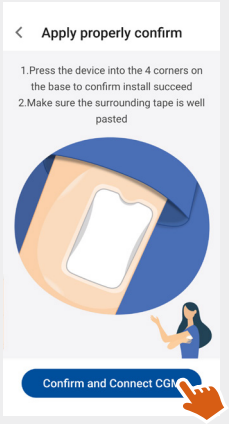
⚠ **WARNING :**

Test Your Display Device Regularly. Test your receiver's speaker and vibration functions regularly. If you have any doubts about your product, contact a manufacturer authorized dealer for technical support.

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 alarms or alerts.

DO NOT Share Your Receiver. The iFree CGMs' receiver is designed for self-use by a single patient. The system is a prescription-only medical device intended for your use only. Your receiver should not be used by others.

Mobile App:

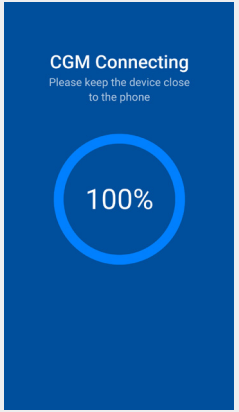


1. Make sure you have followed the steps in the "Apply Your Sensor" and "Attach Your Transmitter" sections. When the screen displays "Apply properly confirm", press **[Confirm and Connect]**.

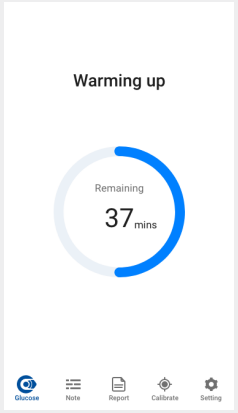
NOTE :

Make sure you go through all steps in the "Pair the Sensor and Transmitter Using NFC" section.

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.

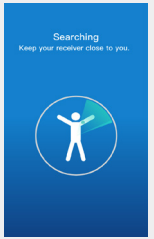


3. After the system is connected, the screen will display a warmup progress bar. When the warmup is completed, "Warmup" will disappear from your display.

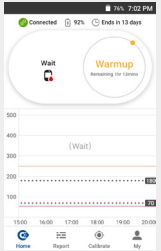
Receiver:

1. Make sure you follow the steps in the "Apply Your Sensor" and "Attach Your Transmitter". When the receiver displays "Ready to Start", press **[Connect]**.

NOTE :
Make sure you go through all steps in the "Pair the Sensor and Transmitter Using NFC" section. Make sure that you have installed your sensor and transmitter before you start the following steps.

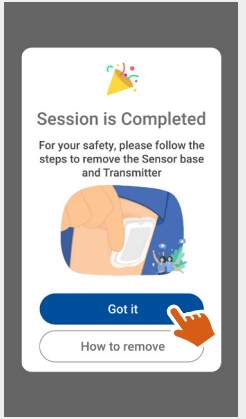


2. The receiver will automatically start searching for your transmitter. Keep your receiver close to you.

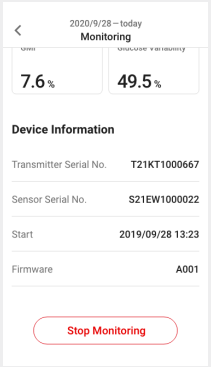


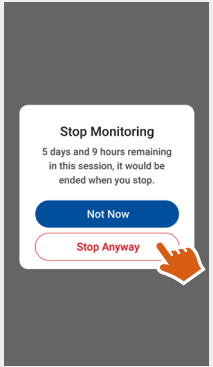
3. After the system is connected, the receiver will display a warmup progress. When the warmup is completed, "Warmup" will dissapear from your display.

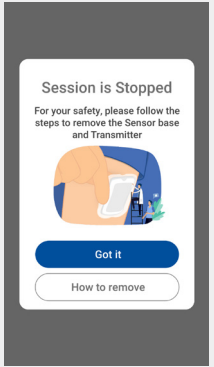
Mobile App:



The monitoring session ends automatically when the sensor reaches the ends of its 14-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 **[Got it]** to confirm.





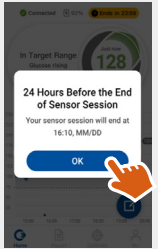


To end a monitoring session before receiving the notification, you can select "Stop Monitoring" from "Record". You will see a message warning you that the sensor has not yet expired. Press **[Stop anyway]** to end the session.

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 to prevent serious adverse events. Follow the instructions to remove your sensor.

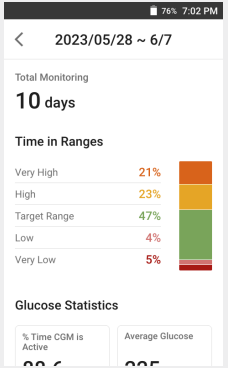
Receiver:

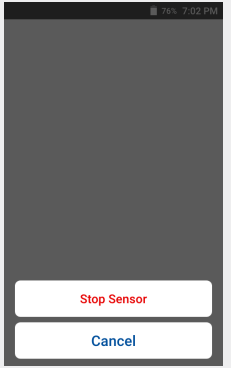


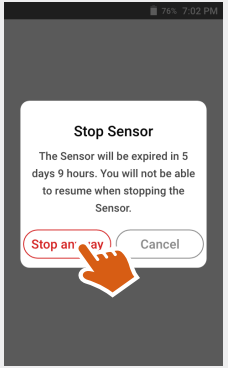
You will receive an alert on your receiver 24 hours prior to monitoring ending. Press **[OK]** to confirm you have read this alert .

The monitoring session ends automatically when the sensor reaches the end of its 14-day life and the sensor reading will no longer be shown on the receiver. 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 **[Done]** to confirm.

To end a monitoring session before receiving the "Monitoring Ends" notification, open the menu and select "Manually Stop". You will see a message warning you that the sensor has not yet expired. Press **[Stop anyway]** to end the session.

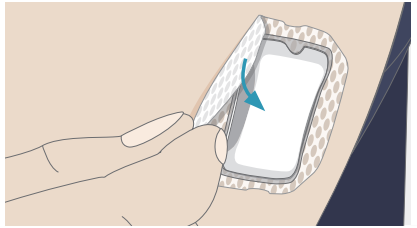






SENSOR AND TRANSMITTER REMOVAL

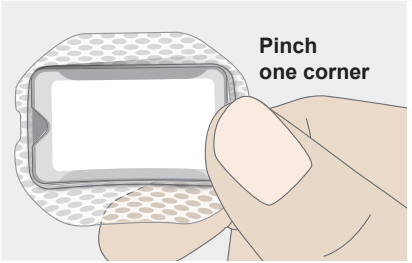
Do not remove your transmitter until your sensor session is over. Once the session has ended, follow these steps to remove your sensor and transmitter:



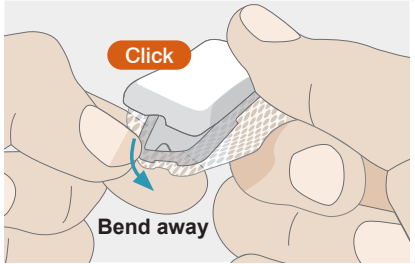
1. Grip the edge of the adhesive patch and peel the sensor and transmitter off in one motion.

⚠ **PRECAUTIONS :**

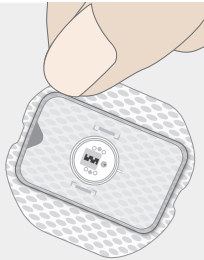
Follow the instructions to proper use of the sensor and avoid sensor wire breaking.
If the sensor wire breaks under your skin, do not remove it by yourself. Contact your healthcare professional immediately for further assistance. If any symptoms of infection or inflammation (such as redness, swelling, or pain at the insertion site) occurs, visit medical facility for emergency treatment.



2. Pinch one corner of the unnotched edge to hold the transmitter and the sensor base together.



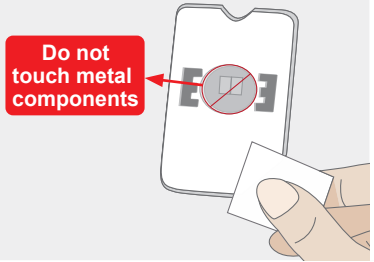
3. Bend the corner of the notched edge away until the transmitter pops out of the sensor base with a "click" sound.



Only discard the sensor and the sensor base

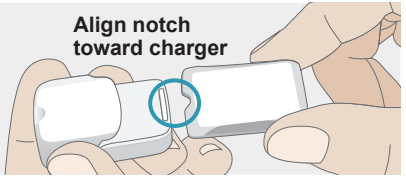
4. Keep the transmitter to use with the next sensor. Discard the sensor, sensor base and adhesive patch according to local regulations for disposal of sharps and blood-contacting components.

NOTE:
Do not throw away the transmitter. Transmitters are reusable and rechargeable.

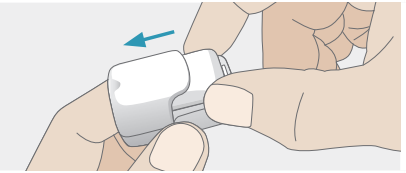


5. Always clean the bottom of the transmitter with an alcohol wipe and let the transmitter dry before continuing. Do not touch or scratch the metal components.

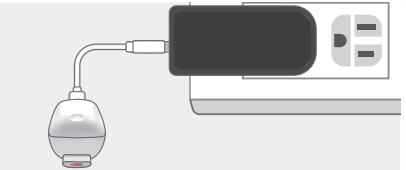
NOTE:
Wipe the bottom of transmitter with a dry cloth or an alcohol pad. Failure to clean it may cause it to deteriorate and harden over time, resulting in malfunction.



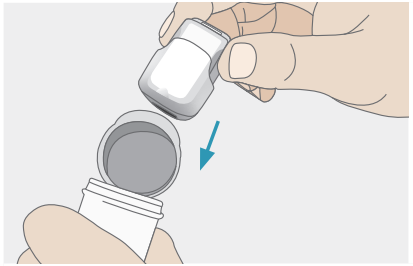
6. Hold the charger face up. Align the notch of the transmitter toward the charger's transmitter compartment with the transmitter's metal components facing down.



7. Slide the transmitter into the charger compartment.



8. Follow steps 2 - 8 of CHARGING THE TRANSMITTER to charge your transmitter before its next use.



9. Store the charger with the transmitter inside in the storage vial. Cap the storage vial.

NOTE:

Always seal the transmitter with its charger in the storage vial when they are not in use.

UNDERSTAND YOUR GLUCOSE READINGS

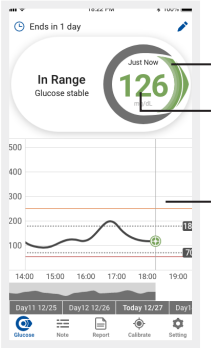
Your glucose readings appear on the receiver's screen. It is important to understand your readings.

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 your receiver's screen. It is important to understand these indicators before use. An overview of the home screen is shown below.

Overview of Monitoring Screen

Mobile App:



Receiver:

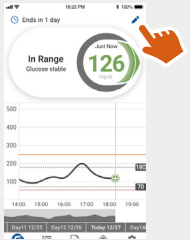
GLUCOSE TREND ARROW AND ARROW COLOR

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.

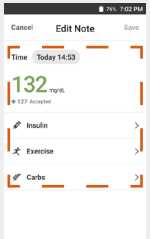
Direction / Arrow Color	Glucose is steady*	Glucose rising**	Glucose rising rapidly***	Glucose falling**	Glucose falling rapidly***
ORANGE: >250 mg/dL					
AMBER: 181-250 mg/dL					
GREEN: 70-180 mg/dL					
PINK: 55-69 mg/dL					
RED: ≤ 54 mg/dL					

* “Glucose is steady” means the glucose rate of change is between 0 and 1 mg/dL.
** “Glucose falling/rising” means the glucose rate of change is 1 - 2 mg/dL per minute.
*** “Glucose falling/rising rapidly” means the glucose rate of change is 2 mg/dL per minute or more.

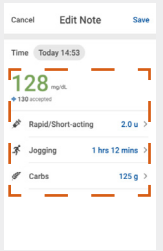
ADD AND ACCESS NOTES



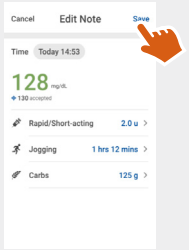
1. From the Home screen, add a note by tapping .



2. Make sure the time is correct.



3. Select the options (carbs, insulin, exercise) and follow the prompts to add a note.



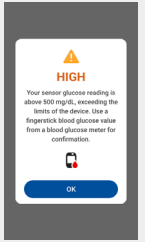
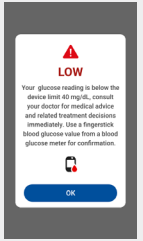
4. Tap to save your notes.

HIGH/LOW READINGS

If **HIGH** appears on your display device screen, your glucose reading is above 500 mg/dL. Do a blood glucose test with a BG meter. If you also get a HIGH result (> 500 mg/dL) from the meter test, contact your healthcare practitioner immediately.

If **LOW** appears on your display device screen, your glucose reading is less than 40 mg/dL. Do a blood glucose test with a BG meter. If you also get a LOW result (< 40 mg/dL) from the meter test, contact your healthcare practitioner immediately.

Mobile App:

	**HIGH** indicates the sensor reading is above the detection limit.
	**LOW** indicates the sensor reading is below the detection limit.

Receiver:

HIGH indicates the sensor reading is above the detection limit.

LOW indicates the sensor reading is below the detection limit.

CALIBRATION

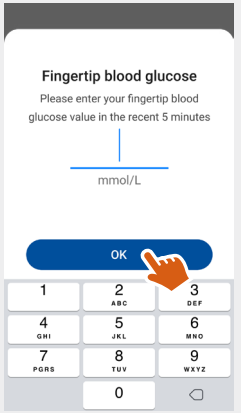
The calibration allows alignment between your system readings and your meter values. When the iFree CGMs needs to be calibrated (as shown in the table below), the display device will send a calibration alert.

Required Calibration	Timing for calibration	Action
First / Second	Immediately after warmup	Input glucose values obtained from a blood glucose meter and fingerstick twice within 5 minutes.
Third	Within 12 hours after last calibration (8 to 12 hours is recommended.)	Input glucose value obtained from a blood glucose meter and fingerstick once.
Subsequent after Third	Within 24 hours after last calibration (20 to 24 hours is recommended.)	Input glucose value obtained from a blood glucose meter and fingerstick once.

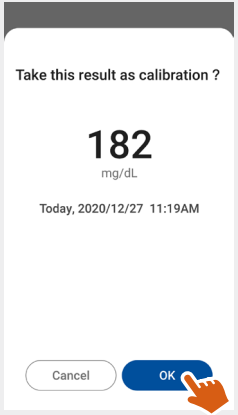
When you calibrate, take a fingerstick measurement from your BG meter then enter the value according to the following steps:

Mobile App:

1. From the Calibrate screen, tap **[Take fingertip glucose]**.



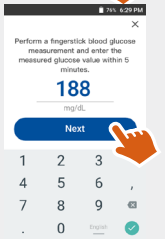
2. Enter the exact BG value then press **[OK]**.



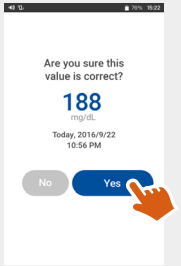
3. You will see a prompt from the screen. Tap **[OK]**.
NOTE :
Only a BG value between 40 mg/dL (2.2 mmol/L) and 500 mg/dL (27.8 mmol/L) can be used for calibration. If your BG value is significantly different from your sensor reading, it is recommended to calibrate again to avoid inaccurate readings.

Receiver:

1. From the Calibrate screen, tap **[Calibrate]**.



2. Enter the exact BG value then press **[Next]**.



3. You will see a prompt from the receiver. Tap **[Yes]**.

NOTE :

Only a BG value between 40 mg/dL (2.2 mmol/L) and 500 mg/dL (27.8 mmol/L) can be used for calibration. If your BG value is significantly different from your sensor reading, it is recommended to calibrate again to avoid inaccurate readings.

CONNECTION AND DATA UPLOADING

Mobile App:

The mobile 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 CGMs 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.
- 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 first 2-hour warmup period when you start a new sensor. You won't receive any sensor readings, alarms 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 2 mg/dL 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 upwards/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 first 2-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. Calibration may help align the sensor readings and BG meter values. 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. **NEVER make a treatment decision based on the iFree CGMs alone.**

Trend Arrow	Treatment Decision		
	Low Glucose (< 70 mg/dL)	**Glucose in Target Range**	**High Glucose (> 250 mg/dL)**
(No Trend Arrow)	Do a fingerstick blood glucose check with your BG meter. Do NOT treat based on your iFree CGMs.		
90° upward arrow 	(All Arrow Colors) Do a fingerstick blood glucose check with your BG meter. Do NOT treat based on your iFree CGMs.		
45° upward arrow 	(Pink/Red Arrow Colors) Do a fingerstick blood glucose check with your BG meter. Do NOT treat based on your iFree CGMs.	• If you are about to eat, take insulin to cover yourmeal. Consider increasing your dose a little since 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"**.	(Orange Arrow Color) • If you are about to eat, take insulin to cover your meal. Consider increasing your 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 (< 70 mg/dL)	Glucose in Target Range	High Glucose (> 250 mg/dL)
Horizontal arrow 	(Pink/Red Arrow Colors) Do a fingerstick blood glucose check with your BG meter. Do NOT treat based on your iFree CGMs.	• 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 Color) • If you are about to eat, take insulin to cover your meal. Consider increase 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 (< 70 mg/dL)	Glucose in Target Range	High Glucose (> 250 mg/dL)
45° downward arrow 	(Pink/Red Arrow Colors) Do a fingerstick blood glucose check with your BG meter. Do NOT treat based on your iFree CGMs.	• 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 fastacting carbs.	(Orange Arrow Color) • If you are about to eat, take insulinto 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"**.
90° downward arrow 	(All Arrow Colors) Do a fingerstick blood glucose check with your BG meter. Do NOT treat based on your iFree CGMs.		

SPECIFICATIONS

SENSOR KIT SPECIFICATIONS

Sensor Glucose Range	40 - 500 mg/dL
Sensor Use Life	up to 14 days
Shelf Life	12 months
Sensor Operating Conditions	Temperature: 5°C - 45°C (41°F - 113°F) Relative humidity: 10% - 90%
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 metres (0 to 10,000 ft)
Inserter Size	52.0 x 57.0 x 61.3 mm (± 0.5 mm)
Sterilization	Sterilized by radiation
Usage	Single use (disposable)

TRANSMITTER SPECIFICATIONS

Transmitter Size	32.8 x 19.8 x 4.15 mm (± 0.5 mm)
Transmitter Weight	3.2g with battery (± 0.5g)
Power Source	Rechargeable lithium battery (3.7V)
Storage Transportation & Operating Conditions	Temperature: 5°C - 45°C (41°F - 113°F) Relative humidity: 10% - 90%
Operating and Storage Altitude	0 to 3,048 metres (0 to 10,000 ft)
Battery Run Time	Up to 14 days (based on full charge)
Charging Time	2 hours (via AC adapter)
Memory Storage	14 days of glucose data (glucose readings stored every minute)
Protection Against Electrical Shock	Type BF applied part
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 pairing: 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 CGM System is designed to accept radio frequency (RF) communications from recognized and paired display devices only.

RECEIVER SPECIFICATIONS

Dimension	103.5 x 60.5 x 13.5 mm (± 0.5 mm)
Weight	86g with battery (± 5%)
Touch Screen Size	2.8 inches
Power Source	Non-replaceable, rechargeable lithium battery (3.7V)
Memory Storage	Up to 90 days (typical use)
Battery Run Time	7 days (typical use)
Battery Charging Time	3 hours (via AC adapter)
Alarm Output	Speaker; Vibration
Storage Transportation & Operating Conditions	Temperature: 0°C - 45°C (32°F - 113°F) Relative humidity: 10% - 95%
Data Communication	Glucose data transfer: Bluetooth 4.2 Frequency range BLE: 2402 - 2480 MHz Maximum RF output power of the product : 1 dBm System pairing: NFC pairing (RFID: 13.56 MHz)

Charging Port	USB-C
Wi-Fi	802.11b/g/n (2.4 GHz)
Ingress Protection Rating	IP22 Protection against insertion of fingers and objects greater than 12.5 millimeters. Protection against dripping water when tilted up to 15°
Alarm Audible Output	50 dB(A) at 100 cm (3 feet) (for high and medium priority alarms)
Mean Service time	3 year of typical use
Power Supply Specification	Input: 100 - 240V, 50/60 Hz, 0.16 - 0.12A Output: 5V DC, 1A (5.0W) Class II

Only updates authorized by Bionime Corporation are recommended. Updates from unofficial channels may present security risks.

TRANSMITTER CHARGER SPECIFICATIONS

Charger Channel	1
Indicator	LED (Green/Amber)
Input Port	USB Type
Weight	10g (± 1.0)
Charger Dimensions	37.3 x 26.0 x 22.5 mm (± 0.5 mm)
Input	DC 5V/20 mA
Output	DC 4.2V/20 mA
Storage Conditions	Temperature: 5°C - 45°C (41°F - 113°F) Relative humidity: 10% - 90%
Operation Conditions	Temperature: 5°C - 45°C (41°F - 113°F) Relative humidity: 10% - 90% Caution: When operating the transmitter on a tester in air temperatures greater than 41°C (106°F), the temperature of the transmitter may exceed 43°C (109°F)
Ingress Protection Rating	IP21 Protected from touch by fingers and objects greater than 12.5 millimeters. Protected from condensation

CERTIFICATE STATEMENT

FCC STATEMENT

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference; and (2) This device must accept any interference received, including interference that may cause undesired operation.

NOTE :

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules and Regulations. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause interference to radio frequency communications. There is no guarantee that interference will not occur in a particular installation.

Turning the equipment on and off in proximity to a radio or television will determine whether the equipment is causing interference to signal reception. If interference is present, the user is encouraged to attempt to resolve it by one or more of the following methods:

- Reorient or reposition the receiving antenna.
- Increase the separation between the equipment and the receiving device.
- Connect the equipment to a different power outlet than the receiving device.
- Consult the dealer or an experienced radio or television technician.

FCC RF Radiation Exposure Statement:

1. This device must not be co-located or operating in conjunction with any other antenna or transmitter.
2. For portable operation, this equipment complies with FCC RF radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with a minimum distance of 5 centimeters between the radiator and your body.

CAUTION :

Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

APPENDIX

GLUCOSE AND SIGNAL LOSS ALERTS

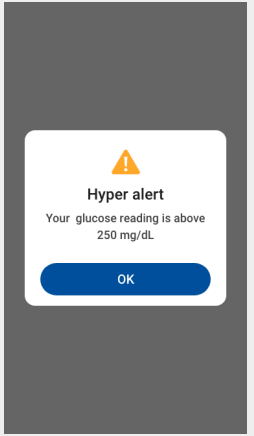
There are delayed or no alarms/alerts in the following situations. When not in the following situations, alarms/alerts will happen in 5 seconds.

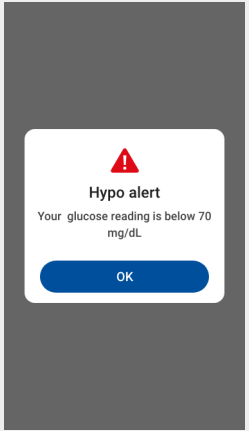
- When either your display device or transmitter battery is dead.
- When your display device is turned off.
- When there is a system error (e.g. no glucose readings, sensor error, signal loss, etc.) or damage to the system.
- During the 2-hour sensor warm-up period.
- If your sensor readings do not match what you are feeling.
- When the display device is out of range (6 meters/20 feet) from your transmitter; or obstacles (metal, walls, water, etc.) are between them.

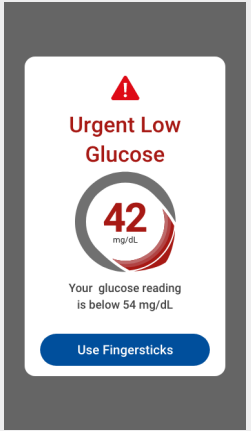
Alarms/alerts settings are restored automatically after power is interrupted for less than 30 seconds.

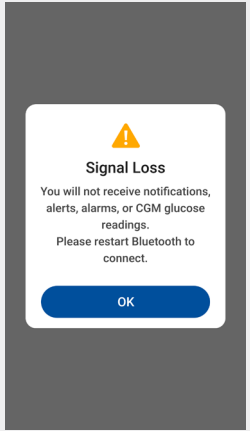
Alarms limits is restricted for any change by user.

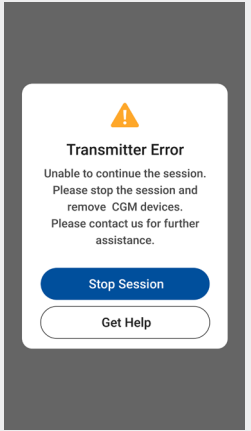
Mobile App:

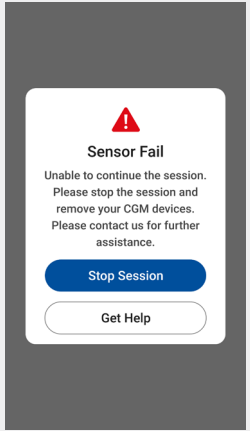
Screen	Event	Visual & Sound Settings
	**Hyper Alert** Happens when glucose is higher than the set target range and is detected to fall or remain steady.	**Default Setting:** • Visual Safety Symbol (⚠) on Home Screen: Yes. • Sound & Vibration Alert: Yes. - Sound & Vibration active unless turned off by user pressing the **[OK]** button 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.

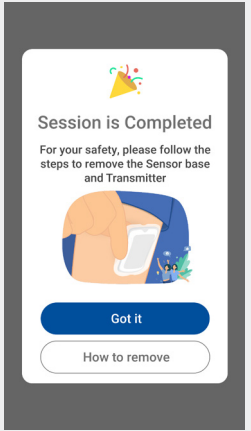
Screen	Event	Visual & Sound Settings
	**Hypo Alert** Happens when glucose is lower than set target range and is detected to fall or remain steady.	**Default Setting:** • Visual Safety Symbol (⚠) on Home Screen: Yes. • Sound & Vibration Alarm : Yes. - Sound & Vibration active unless turned off by user 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.

Screen	Event	Visual & Sound Settings
	**Urgent Low Glucose** Happens when glucose is at or below 54 mg/dL.	**Default Setting:** • Visual Safety Symbol (⚠) on Home Screen: Yes. • Sound & Vibration Alarm : Yes. - Sound & Vibration active unless turned off by user pressing the **[OK]** button; or until glucose is higher than 55 mg/dL. - Urgent low glucose alarm 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.

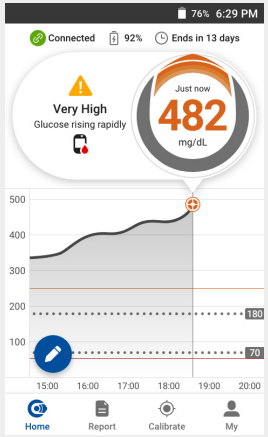
Screen	Event	Visual & Sound Settings
	Transmitter is too far from the receiver or when there is an obstacle (e.g. water, wall) in between the transmitter and receiver.	**Default Setting:** • Visual message on the screen: Yes • Sound & Vibration Alert : Yes. - Displayed continuously for 5 minutes or until **[OK]** is pressed. • System attempts to reconnect every 5 minutes even if user doesn't press **[OK]** • System alerts will repeat every 30 minutes. **Editable Setting:** • Sound & Vibration CANNOT be turned ON/OFF by the user.

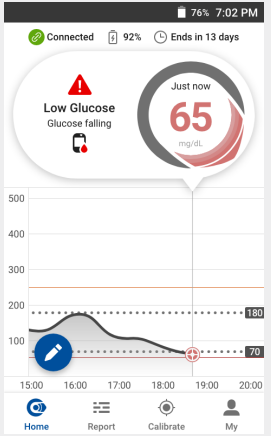
Screen	Event	Visual & Sound Settings
	Transmitter is not working.	**Default Setting:** • Visual message on the screen: Yes • Sound & Vibration Alert : Yes. - Displayed continuously for 5 minutes or until **[OK]** is pressed. - System alerts will repeat every 30 minutes.

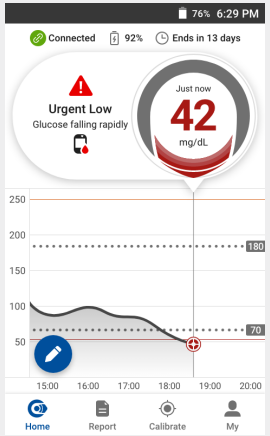
Screen	Event	Visual & Sound Settings
	The system detects a current error measured by the sensor.	**Default Setting:** • Visual message on the screen: Yes. • Sound & Vibration Alert: Yes. - Displayed continuously for 5 minutes or until **[OK]** is pressed. - System alerts will repeat every 30 minutes. **Editable Setting:** • Sound & Vibration can be turned ON/OFF by the user.

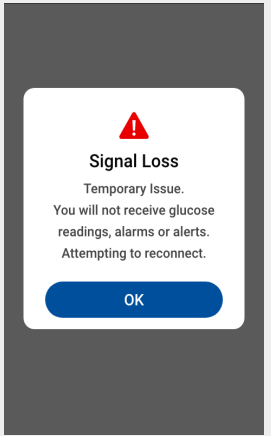
Screen	Event	Visual & Sound Settings
	Your sensor session has expired.	**Default Setting:** • Visual message on the screen: Yes. • Sound & Vibration Alert: Yes. - Displayed continuously for 5 minutes or until **[OK]** is pressed. **Editable Setting:** • Sound & Vibration can be turned ON/OFF by the user.

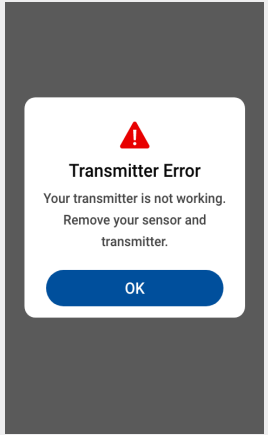
Receiver:

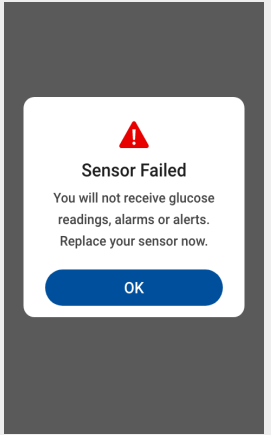
Screen	Event	Visual & Sound Settings
	**High Glucose Alert** Happens when glucose is higher than the set target range and is detected to fall or remain steady. **Alert priority** - Medium	**Default Setting:** • Visual Safety Symbol (⚠) on Home Screen: Yes. • Sound & Vibration Alert: Yes. - Sound & Vibration active unless turned off by user pressing the **[OK]** button 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.

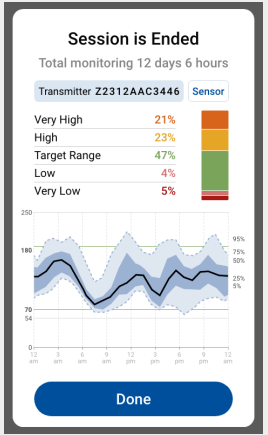
Screen	Event	Visual & Sound Settings
	**Low Glucose Alert** Happens when glucose is lower than set target range and is detected to fall or remain steady. **Alert priority** - High	**Default Setting:** • Visual Safety Symbol (⚠) on Home Screen: Yes. • Sound & Vibration Alarm : Yes. - Sound & Vibration 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.

Screen	Event	Visual & Sound Settings
	**Urgent Low Alarm** Happens when glucose is at or below 54 mg/dL. **Alert priority** - High	**Default Setting:** • Visual Safety Symbol (⚠) on Home Screen: Yes. • Sound & Vibration Alarm : Yes. - Sound & Vibration active unless turned off by user pressing the **[OK]** button; or until glucose is higher than 55 mg/dL. - Urgent low glucose alarm 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.

Screen	Event	Visual & Sound Settings
	Transmitter is too far from the receiver or when there is an obstacle (e.g. water, wall) in between the transmitter and receiver. **Alert priority** - Medium	**Default Setting:** • Visual message on the screen: Yes • Sound & Vibration Alert : Yes. - Displayed continuously for 5 minutes or until **[OK]** is pressed. • System attempts to reconnect every 5 minutes even if user doesn't press **[OK]** • System alerts will repeat every 30 minutes. **Editable Setting:** • Sound & Vibration CANNOT be turned ON/OFF by the user.

Screen	Event	Visual & Sound Settings
	Transmitter is not working. **Alert priority** - Medium	**Default Setting:** • Visual message on the screen: Yes • Sound & Vibration Alert : Yes. - Displayed continuously for 5 minutes or until **[OK]** is pressed. - System alerts will repeat every 30 minutes.

Screen	Event	Visual & Sound Settings
	The system detects a current error measured by the sensor. **Alert priority** - High	**Default Setting:** • Visual message on the screen: Yes. • Sound & Vibration Alert: Yes. - Displayed continuously for 5 minutes or until **[OK]** is pressed. - System alerts will repeat every 30 minutes. **Editable Setting:** • Sound & Vibration can be turned ON/OFF by the user.

Screen	Event	Visual & Sound Settings
	Your sensor session has expired. **Alert priority** - Low	**Default Setting:** • Visual message on the screen: Yes. • Sound & Vibration Alert : Yes. - Displayed continuously for 5 minutes or until **[Done]** is pressed. **Editable Setting:** • Sound & Vibration can be turned ON/OFF by the user.

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.

WARRANTY

The manufacturer warrants that your RIGHTEST receiver and rechargeable transmitter will be free from defects in materials and workmanship for one year from the date of purchase.
This warranty does not apply to the performance of a RIGHTEST product that has been altered, misused, tampered with or abused in any way.
This warranty applies only to the original purchaser of the iFree CGMs Products.
Please complete and return the enclosed warranty card to your local Bionime affiliate.
If any of the iFree CGMs Products are exposed to a high temperature difference, please wait for 30 minutes before measuring.

Manufacturer's declaration - Electromagnetic emissions		
The Receiver is intended for use in the electromagnetic environment (for home healthcare) specified below. The customer or the user of the Receiver should ensure 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 Receiver 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 Receiver 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	Not applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

Manufacturer's declaration - Electromagnetic immunity			
The Receiver is intended for use in the electromagnetic environment (for home healthcare) specified below. The customer or the user of the Receiver should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - Guidance (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	+ 2kV for power supply lines + 1kV for input / output lines	+ 2kV for power supply lines Not applicable	Mains power quality should be that of a typical home healthcare environment.
Surge IEC 61000-4-5	+ 0.5kV, +1kV line(s) to line (s) + 0.5kV, +1kV, + 2kV line(s) to earth	+ 0.5kV, +1kV line (s) to line (s) Not applicable	Mains power quality should be that of a typical home healthcare environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - Guidance (for 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; 30 cycles Voltage interruptions: 0% UT; 300 cycle	Mains power quality should be that of a typical home healthcare environment. If the user of the Receiver requires continued operation during power mains interruptions, it is recommended that the Receiver 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 60 Hz	The Receiver 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 Receiver is intended for use in the electromagnetic environment (for home healthcare) specified below.
The customer or the user of the Receiver should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - Guidance (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 Receiver (HR321), Receiver (HR320) including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - Guidance (for home healthcare environment)
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 metres (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 Receiver (HR321), Receiver (HR320)

The Receiver is intended for use in an electromagnetic environment (for home healthcare) in which radiated RF disturbances are controlled. The customer or the user of the Receiver can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Receiver 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 (only applicable for CE regulatory)

The Receiver is intended for use in the electromagnetic environment (for home healthcare) specified below. The customer or the user of the Receiver should ensure 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)
385	380 – 390	TETRA 400	Pulse modulation b) 18 Hz	1,8	0,3	27	27
450	430 – 470	GMRS 460, FRS 460	FM c) ± 5 kHz deviation 1 kHz sine	2	0,3	28	28

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)
710	704 – 787	LTE Band 13, 17	Pulse modulation b) 217 Hz	0,2	0,3	9	9
745							
780							
810	1700 – 1990	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0,3	28	28
870							
930							
1720	2400 – 2570	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation b) 217 Hz	2	0,3	28	28
1845							
1970							

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, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0,3	28	28
5240	5100 – 5800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0,2	0,3	9	9
5500							
5785							

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.
c) As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.