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RIGHTEST | iFree2 CGM CONTINUOUS GLUCOSE MONITORING SYSTEM

# USER'S MANUAL

USE WITH RIGHTEST IFREE RECEIVER

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

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## Indications For Use & Statement And Advisory

### Intended use

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

### Indications For Use

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

### Statement And Advisory

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



## Intended Benefit

Supports user awareness of glucose levels and trends, enabling informed diabetes self-management.

## Potential Side Effect

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

## Contraindication

- Known allergy to disinfecting alcohol or medical adhesives.
- The iFree 2 CGM is not recommended for insertion into skin areas affected by tattoos, scars, burns, wounds, inflammation, or extensive lesions, including psoriasis, eczema, and dermatitis herpetiformis, as these conditions may interfere with proper device placement and compromise measurement accuracy. The device

should be used with caution in patients with sensitive skin, a predisposition to skin ulceration, known allergies to disinfectants or medical adhesives, or an increased risk of bleeding, as these may affect device placement and measurement accuracy.

- **No MRI/CT/Diathermy:** The iFree 2 CGM (sensor, transmitter, and/or other display devices) must be removed prior to Magnetic Resonance Imaging (MRI), Computed Tomography (CT), or high frequency electrical heat (diathermy) treatment. People who are unable or unwilling to contact with their healthcare professional are not recommended to use the iFree 2 CGM. Sufficient vision or hearing is critical for successful use of the system including effective recognition of the alerts.
- DO NOT Use If You Are Pregnant, on Dialysis or Critically Ill. Do not use the iFree 2 CGM if you are pregnant, on dialysis or critically ill; or on users with other implanted medical devices (e.g., a pacemaker). The system has not been evaluated for use in these populations.
- iFree 2 CGM is contraindicated in patients with infection, edema at or near the sensor insertion site, those receiving vasoactive drug therapy, or with impaired tissue perfusion.
- iFree 2 CGM should not be used during episodes of severe



hypoglycemia (<2.2 mmol/L), severe hyperglycemia (>27.8 mmol/L), or during periods of rapid blood glucose fluctuation.

## Safety Information

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

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

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

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

**Not Receiving Urgent Alerts or Alerts under the Following Conditions:**

- When either your display device or transmitter battery is dead.



- When your display device is turned off.
- When there is a system error (e.g., no glucose readings, sensor error, signal loss, etc.) or damage to the system.
- During the 1-hour sensor warmup period.
- If your glucose readings do not match how you are feeling.
- When the display device is out of range from your transmitter; or obstacles (metal, walls, water, etc.) are between them; or when you are in crowded place (station, exhibition etc.).

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

**Do not allow children or pets to play with:** Do not allow children or pets to play with any parts of iFree 2 CGM.

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

⚠ **PRECAUTIONS:**

**Calibration Safety:** iFree 2 CGM is factory calibrated and ready to use after 1-hour warmup period without additional calibration by user. During monitoring session, calibrating the iFree 2 CGM is optional. If you choose to calibrate, use only fingerstick blood glucose values within 5 minutes to align the CGM readings with them. Entering incorrect values, or using blood glucose readings obtained from alternate sites, may result in inaccurate sensor readings and could lead to missed high or low glucose events.

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

**Avoid Skin Care Products:** Do not apply skin care products such as sunscreen, moisturizer, perfume or insect repellent over the sensor insertion site (less than 1 inch or 2.5 cm) or any components of the iFree 2 CGM. Failure to comply may



lead to damage of the plastic used in the iFree 2 CGM or reduction in the stickiness of the sensor adhesive.

**Do NOT Attempt to Reinsert a Sensor:** If the adhesive patch is loose or if the sensor tip is pulled out from your skin, remove the sensor and replace it with a new sensor. Sensor readings may be unreliable until a new sensor is inserted.

**DO NOT Expose to Extreme Conditions:** Avoid freezing the sensor or exposing the components to direct sunlight and environments outside the specified ranges. Exposing these components to out-of-specification conditions may damage the device and result in no or inaccurate glucose 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.

**DO NOT Use If Any Component Appears to be Damaged:** A damaged or cracked sensor kit, 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 2 CGM and comply with requirments for pat-downs, visual inspection and metal detectors. You must comply with any requests by airline personnel (e.g., turning off the system). Do not pass through an advanced imaging technology (AIT) body scanner (e.g., millimeter wave scanners) or put iFree 2 CGM components through X-ray machines since the effect of this equipment on iFree 2 CGM has not been evaluated.

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

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

**The emergency kit should contain:**

• Fast-acting glucose tablets.
• Blood glucose monitoring supplies.
• Insulin syringe and rapid-acting insulin (with dosage



instructions from your healthcare professional).
• Adhesive dressing.
• Glucagon emergency kit.

**Troubleshooting:** If any situation not mentioned in this user manual occurs, please contact your healthcare professional or Customer Service. Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

**Be Careful of Electromagnetic Disturbance:** Stacking equipment may negatively influence on electromagnetic compatibility. Stay a distance greater than 30 cm (12 inches) from any part of any portable RF communications equipment and at least 1 meter from sensitive equipment.

Avoid strong magnetic or electromagnetic radiation during monitoring session. If any abnormal behavior caused by electromagnetic interference is observed in the system, stop the monitoring session and remove the devices you are wearing.

| Symbol Definitions | | | |
|---|---|---|---|
|  | Date of manufacture |  | Use-by date |
|  | Manufacturer |  | Do not re-use |
|  | Serial number |  | Importer |
|  | Direct current |  | Batch code |
|  | Caution |  | Temperature limitation |
|  | Humidity limitation |  | MR Unsafe |
|  | Medical device |  | Keep away from sunlight |
|  | Keep dry |  | Catalogue number |
|  | Unique device identifier | | |
|  | Sterilized using irradiation | | |



| | |
|---|---|
|  | Type BF applied part device |
|  | CE Mark with number of notified body |
|  | Authorized representative in the European Community |
|  | Do not use if the package is damaged |
|  | Discard this product according to local regulations |
|  | Operating Instructions; consult manual for further instructions |
| IP21 | Protected from touch by fingers and objects greater than 12.5 millimeters.<br>Protected from vertical dripping water for 10 minutes. |
| IP22 | Protected from touch by fingers and objects greater than 12.5 millimeters.<br>Protected from dripping water when tilted at 15° for 10 minutes. |

| | |
|---|---|
| IP48 | Protected from tools and small wires greater than 1 millimeter.<br>Protected from immersion 10 feet (3.05 meter) for 30 hours. |

## Getting To Know Your iFree 2 CGM

### Performance Features

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

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

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

### Safety Features

This system detects the glucose concentration within the interstitial fluid and the blood glucose (BG) meter detects the blood glucose



concentration. Therefore, the glucose readings from this system may delay from 5 to 15 minutes comparing with blood glucose values.

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

These features include:

- Alerts include visual notification, vibrations and sound, depending on your personalized settings.
- When you are out of your target glucose range, display device alerts you.
- Display device warns you if your glucose level falls below to 3 mmol/L or to your set target value.
- Urgent alert settings at 3 mmol/L or below cannot be turned off. Some settings (such as alert volume level or temporarily switching to silent mode) can be adjusted according to your needs. However, some notification settings (such as volume level or temporarily switching to silent mode) can be adjusted to suit your needs.
- The system will still issue warnings of the urgent alert via dialog boxes and text indicators - even if notification sounds are disabled. Before changing these settings, please ensure you fully understand the risks involved.
- Display device notifies you when a sensor has failed, expired or

when there are system errors.

## CGMs Components

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




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



**TRANSMITTER**
The transmitter wirelessly sends your glucose data from the sensor to the display device. The transmitter is for single-use only.





**DISPLAY DEVICE - RECEIVER (HR510)**
The display device provides sensor readings and delivers alerts of high and low glucose readings. The system can be used with a Receiver (HR510).

## Accessories



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

## Before You Start

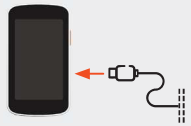
### Charging The Receiver

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 5 hours. The receiver utilizes an intelligent battery charging technology that prevents overcharging.

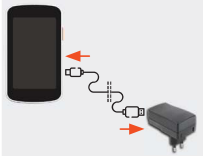
⚠ **WARNINGS:**
**Not Receiving Alerts.** There are no alerts when your receiver is turned off or its battery is dead.



⚠ **CAUTIONS:**
**Plug in to Charge.** Plug in your receiver to charge overnight to make sure you receive 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-A plug to the USB-A port of the AC power adapter supplied with your system and connect the adapter to the power source (100 - 240V AC, 50/60 Hz).

## Setting Up Your iFree 2 CGM

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

- Sensor Kit
- Transmitter
- Alcohol Wipes
- Display device: only one display device can be used at a time.
- Blood Glucose (BG) Meter: refer to the Blood Glucose (BG) Meter manual or the notifications of your display device.

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

### Scan The Sensor Kit And Transmitter Using The Receiver



⚠ **PRECAUTIONS:**
**Scan Before Monitoring:** Every time you start a new monitoring session, **scan the QR Code of the sensor kit with your display device.** Each sensor kit has its unique QR Code which is attached on the sealing paper.
Not scanning the QR Code or using incorrect QR Code or mixed using components (sensor kit and transmitter) from different packages will cause system failure or wrong glucose readings.

1. Get your receiver.
2. If your receiver is OFF, press and hold the power button for long press 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 not recommended to be used for cleaning. Make sure liquid, dust, dirt, bleach, and any other substance do not get into any opening. Unplug the receiver from the USB cable and turn it off before cleaning.

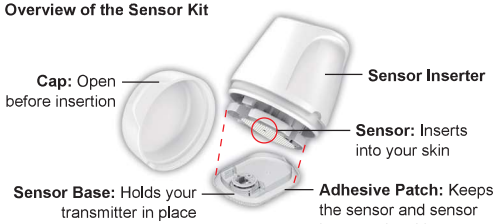
3. Tap **[New Monitoring]** to start a new monitoring session.
4. Scan the Sensor Kit using the built-in scanner, once it scanned successfully, a checkmark (√) will appear on the screen.
5. Scan the QR Code from the back of the transmitter.
6. Once it scanned successfully, a checkmark (√) will appear on the screen.
7. Following the screen instructions to turn on the battery of the transmitter.
8. Once it scanned successfully, a checkmark (√) will appear on the screen.
9. Make sure you follow the steps in the next two sections ("Apply Your Sensor" and "Attach Your Transmitter"). After installing the sensor and transmitter, click **[Connect]**.



## Apply Your Sensor

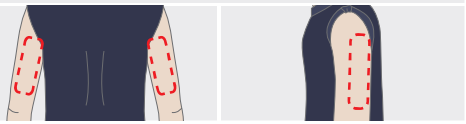
The sensor is pre-loaded inside the inserter. Before applying the sensor to your skin, familiarize yourself with the information in this section.

**Overview of the Sensor Kit**




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

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



**The following areas are preferable for insertion:**

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



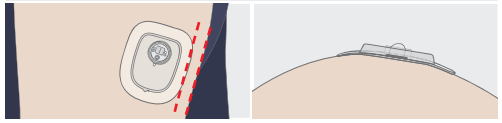
**The following should NOT be selected for insertion:**

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

**The following is not recommended for insertion:**

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

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



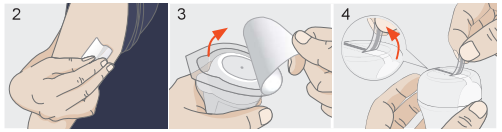
1. Wash and dry your hands.
2. Wipe the insertion site with an alcohol wipe and wait for approximately 2 minutes until the site has fully dried before getting started.
   **NOTE:** Cleaning the insertion site using a plain soap, drying, and then cleaning with an alcohol wipe before insertion of a sensor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



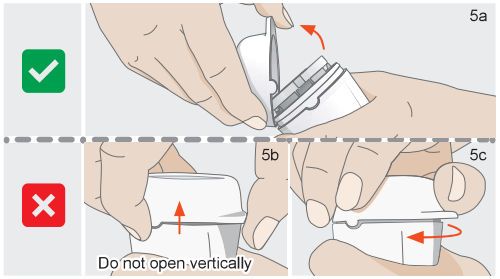
3. Open the sensor kit package by peeling off the the sealing paper completely. Take out the Sensor Kit from its package and save the package until the end of the monitoring session.

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

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



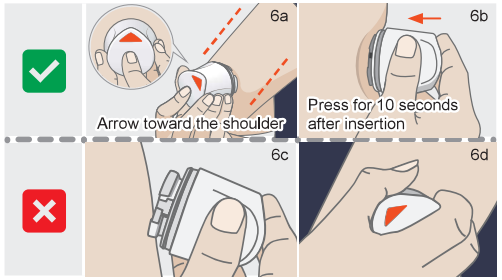
5. Open the sensor kit cap.
   **NOTE:** The adhesive patch is ready for application immediately after opening the cap.




6. Place the inserter over the desired site and push down firmly to insert the sensor. Keep pressing for 10 seconds to ensure the adhesive patch is fully attached to your skin.
   **NOTE:** Rotate the arrow mark toward the shoulder when



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



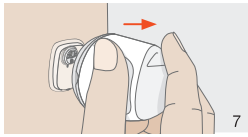
⚠ **PRECAUTIONS:**

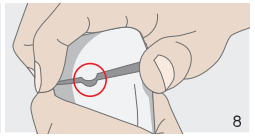
1. Apply the sensor immediately after opening its package and the cap. Otherwise, it may present an infection risk.
2. Do not push down the inserter until it is placed over the insertion site.
3. If the insertion is not successful or causes any discomfort, please consult your healthcare professional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

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



blood-containing components to prevent cross-contamination and ensure safety.
**NOTE:** Cap the used sensor inserter immediately after use to avoid needle punching during discarding it or when sensor inserter is mistakenly taken by children.


7


8

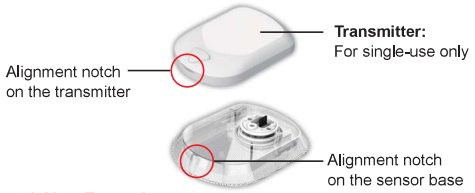
⚠ **PRECAUTIONS:**

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

1. Remove the sensor base and adhesive patch. Place sterile gauze or a clean cloth on the bleeding site and apply steady pressure for three minutes or until the bleeding stops.

2. Inspect the site for redness, ongoing bleeding, irritation, pain, tenderness, or inflammation, and contact a healthcare professional for further assistance.
3. Use a new sensor kit and choose another suitable location for reapplication. If the sensor breaks off under the skin, contact a healthcare professional for further assistance.

**Overview of the Transmitter**




## Attach Your Transmitter

Attach your transmitter after the sensor is inserted.

• Make sure the transmitter is stored in the storage vial before use. Do not remove your transmitter until your sensor session is over.



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

**Follow these steps to attach your transmitter:**

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




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

### Connect Transmitter With Display Device

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



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

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

## Ending A Monitoring Session

### End The Monitoring Session

⚠ **PRECAUTIONS:**
**Do Not Reuse.** Reuse of a sensor, sensor base, adhesive patch or transmitter may cause infection or irritation.
**Ending a Session Early:** If any unexpected issues (irritation or discomfort) happen at the application site, consult your healthcare professional for further assistance.

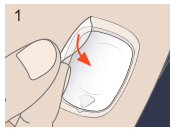
1. The monitoring session ends automatically when the sensor reaches the ends of its 15-day life and the sensor reading will no longer be shown on the screen. A notification will pop-up to let you know the session has ended. You MUST remove or replace the sensor currently in use when you receive this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

### Sensor And Transmitter Removal

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



1. Grip the edge of the adhesive patch and peel the sensor and transmitter off in one motion.
2. Discard sensor and transmitter according to local regulations for disposal of blood-contacting components.



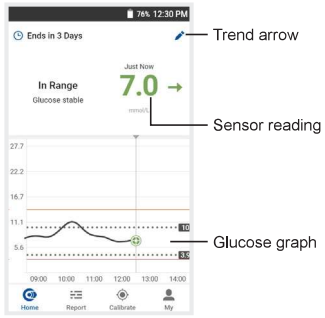

⚠ **PRECAUTIONS:**
Follow the instructions for proper use of the sensor to avoid sensor breaking.
If the sensor breaks under your skin, do not remove it by yourself. Contact your healthcare professional immediately for further assistance. If any symptoms of infection or inflammation (such as redness,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

## Understand Your Glucose Readings

### Home Screen Indicator And Displays Overview

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

**Overview of Monitoring Screen**






**Glucose Trend Arrow And Arrow Color**

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

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

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

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

| Direction / Arrow Color | Glucose is steady* | Glucose rising** | Glucose rising rapidly*** | Glucose falling** | Glucose falling rapidly*** |
|---|---|---|---|---|---|
| Orange > 13.9 mmol/L |  |  |  |  |  |
| Amber 10.1 – 13.9 mmol/L |  |  |  |  |  |
| Green 3.9 – 10.0 mmol/L |  |  |  |  |  |
| Pink 3.0 – 3.8 mmol/L |  |  |  |  |  |
| Red < 3 mmol/L |  |  |  |  |  |



## HIGH/LOW Readings

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

## Calibration

The iFree 2 CGM is factory-calibrated and does not require manual calibration. However, manual calibration is optional and can be performed to align the sensor readings with your BG meter values. Refer to the official website to obtain more information.
If you choose to calibrate, take a fingerstick measurement from your BG meter then enter the value according to the following steps:
1. From the Calibrate screen, tap **[Calibrate]**.
2. Enter a exact fingertip blood glucose value measured within 5 minutes then press **[Save]**.
3. You will see a prompt from the screen. Tap **[OK]**.

**NOTE:**

- Only BG values between 2.2 mmol/L and 27.8 mmol/L are accepted for calibration by the system. If your BG value significantly varied from your sensor reading more than 20%, wait 15 minutes before trying again.
- During periods of rapid glucose change (such as after eating, insulin injection, or exercise), physiological differences between interstitial fluid and blood may cause discrepancies between the sensor reading and the BG meter value. It is advised not to calibrate the CGM during periods of rapid glucose fluctuation to ensure calibration accuracy.

**To obtain the best results:**

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

## Connection And Data Uploading

The receiver can connect to the Internet via Wi-Fi. Follow the instructions to set up the Wi-Fi connection in **[Setting]**.



Once the Wi-Fi connection is established correctly, tap **[Upload Data]** to upload your monitoring results to the cloud.

## Treatment Decisions

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

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

⚠ **WARNINGS:**

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

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

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



0.1 mmol/L per minute), the sensor readings displayed may be less accurate and not as timely.

- If your system shows "Use Blood Glucose Meter (BGM) ".

**When Not To Use Sensor Readings To Make Treatment Decisions**

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

- You suspect that your sensor blood glucose readings may be inaccurate for any reason.
- Sensor glucose readings do not match what you are feeling.
- You are experiencing symptoms that may be due to low or high blood glucose.
- The display device shows no glucose information (e.g., an interrupt alert).
- Glucose is Falling/Rising Rapidly (with upward/downward arrow): Glucose measured in interstitial fluid may differ substantially from true blood glucose levels, particularly at times of rapid glucose change (e.g., after meals, taking insulin, or exercising).
- Low Glucose or Urgent Low Message: Sensor glucose readings may not accurately reflect your blood glucose.
- No Glucose Trend Arrow: During the 1-hour warmup period when

you start a new sensor, the system cannot tell you if your glucose is rising quickly or falling quickly.

- No Current Glucose Concentration and Trend Arrow: When there is a HIGH/LOW result, you don't have enough information to make a treatment decision.

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

## Trend Arrows And Treatment Decisions

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



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

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

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



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

| | | | |
|---|---|---|---|
| | | | consider adjusting insulin correction dose upwards. Avoid “Insulin stacking”. |

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



| | | | |
|---|---|---|---|
| | | | glucose reading later. Avoid “Insulin stacking”. |

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

## Specifications

### Sensor Kit Specifications

| | |
|---|---|
| Sensor Glucose Range | 2.2 - 27.8 mmol/L |
| Sensor Use Life | up to 15 days |

| | |
|---|---|
| Shelf Life | 18 months |
| Sensor Operating Conditions | Temperature: 5°C - 45°C (41°F - 113°F)<br>Relative humidity: 10% - 95% |
| Sensor Ingress Protection Rating (when installed with a transmitter) | IP48<br>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)<br>Relative humidity: 10% - 90% (in a cool, dry place) |
| Operating and Storage Altitude | 0 to 3,048 meters (0 to 10,000 ft) |
| Inserter Size | 52.0 x 60.0 x 61.1 mm (± 0.5 mm) |
| Sterilization | Sterilized by radiation |



| | |
|---|---|
| Usage | Single use (disposable) |

**Transmitter Specifications**

| | |
|---|---|
| Transmitter Size | 24.96 x 18.14 x 4.4 mm (± 0.3 mm) |
| Transmitter Weight | 2.4 g with battery (± 0.5g) |
| Power Source | Single use lithium battery (3.0V, 35 mAh) |
| Operating Conditions | Temperature: 5°C - 45°C (41°F - 113°F)<br>(During pairing and wearing period.)<br>Relative humidity: 10% - 95% |
| Operating and Storage Altitude | 0 to 3,048 meters (0 to 10,000 ft) |
| Battery Run Time | Up to 15 days |
| Storage & Transportation Conditions | Temperature: 5°C - 30°C<br>(41°F - 86°F)<br>Relative humidity: 10% - 90% |

| | |
|---|---|
| Usage | Single use (disposable) |
| Protection Against Electrical Shock | Type BF applied part |
| Memory Storage | 15 days of glucose data<br>(glucose readings stored every minute) |
| Ingress Protection Rating<br>(when attached to Sensor) | IP48<br>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<br>Maximum RF output power of the product: 0 dBm |
| Data Communication Range | Up to 6 meters (20 feet) |



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

## Receiver HR510 Specifications

| | |
|---|---|
| Dimension | 132.0 x 74.0 x 15.5 mm(+-0.5mm) |
| Weight | 161g with battery (±5%) |
| Touch Screen Size | 4.3 inches |
| Memory Storage | Up to 90 days (typical use) |
| Life time | Shelf life: 1 year<br>Use life: 1 year<br>Recommended recharge at least once every 3 months when not in use. |

| | |
|---|---|
| Battery Run Time | 1 day (typical use) |
| Power Source | Non-replaceable, rechargeable lithium battery |
| Battery Charging Time | < 5 hours (via USB adapter) |
| Charge Cycles | 365 rounds |
| Alert Output | Sound; Vibration |
| Data Communication | Maximum RF output power for the product: 0 dBm |
| Charging Port | USB-C |
| Storage & Transportation Conditions | Temperature: -10°C - 40°C (14°F - 104°F)<br>Relative humidity: 10 - 95% RH, non-condensing (Under 35 - 40°C can storage for 6 months.) |



| | |
|---|---|
| Operation Conditions | Temperature: 0°C - 45°C (32°F - 113°F)<br>Relative humidity: 10 - 95% RH, non-condensing |
| Wi-Fi | 802.11b/g/n (2.4 GHz) |
| Ingress Protection Rating | IP22<br>Protection against insertion of fingers and objects greater than 12.5 millimeters.<br>Protection against dripping water when tilted up to 15° |
| Alert Audible Output | 50 dB(A) at 100 cm (3 feet) (for high and medium priority alerts) |
| Power Supply Specification | Input: 100 - 240V, 50/60 Hz, 0.16 - 0.12A<br>Output: 5V DC, 1A (5.0W)<br>Class II |
| Mean Service Time | 1 year of typical use |

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

## IT Networks Characteristics And IT Security Measures For Receiver

iFree CGM is designed to transmit data between the transmitter and designated display devices.
iFree CGM uses the following interfaces and communication protocols:
Display Device: Bluetooth Low Energy to transmitter. TLS to data platform using cellular data or Wi-Fi. Display Device is only compatible with certain mobile devices and operating system.
For using iFree CGM App, please check https://www.rightest.com/guides for more information about device compatibility before using the App.
Use of the iFree CGM requires user registration, and the user should follow instructions on the continuous glucose monitoring system.
Don't pair your CGM over Bluetooth in public areas.
Bluetooth pairing should be done in a private and safe location to



reduce cyber risks such as eavesdropping.
In addition to the security provided by the Bluetooth Low Energy connection, communication between the transmitter and mobile applications is protected by additional levels of security and safety mitigations using an encrypted and proprietary data format.
This format embeds various industry standard encryption protocols and methods to protect data, verify data integrity, and to detect and prevent data tampering.

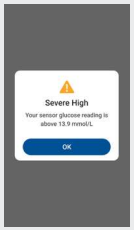
## Appendix

### Glucose And Signal Loss Alerts

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

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

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




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

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

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



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




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

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

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




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

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

**Editable Setting:**
• Sound & Vibration CANNOT be turned ON/OFF by the user.
• Users can adjust the alert volume from 10 to 100.

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





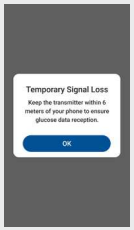

**Event - Upcoming Urgent Low**
Happens when glucose may drop below the set target value within the next 20 minutes.

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

**Editable Setting:**
• 3 mmol/L to 3.3 mmol/L is adjustable.
• Sound & Vibration can be turned ON/OFF by the user.

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

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

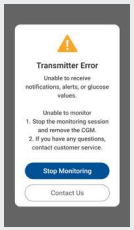



**Visual & Sound Settings - Default Setting:**
• Visual message on the screen: Yes
• Sound & Vibration Alert: Yes.
- Displayed continuously until **[OK]** is pressed.
• System attempts to reconnect every 5 minutes even if user doesn't press **[OK]**
• System alerts will repeat every 30 minutes.

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

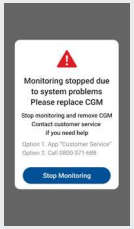


**Event - Transmitter Error**
Transmitter is not working.




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

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




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



**Event - Session is Completed**
Your sensor session has expired.




**Visual & Sound Settings - Default Setting:**
• Visual message on the screen: Yes.
• Sound & Vibration Alert: No.
- Displayed continuously until **[OK]** is pressed.

## Customer Service

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

**User's Manual is also available electronically.**

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

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

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



| Emission test | Compliance | Electromagnetic environment-guidance (for home healthcare environment) |
| --- | --- | --- |
| RF emissions CISPR 11 | Group 1 | The Transmitter/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 Transmitter/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 | Class A | |
| Voltage fluctuations/ flicker emissions IEC 61000-3-3 | Compliance | |

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



| | | | |
|---|---|---|---|
| Surge IEC 61000-4-5 | + 0.5 kV, + 1 kV line(s) to line(s), + 0.5 kV, + 1 kV, + 2 kV line(s) to earth | + 0.5 kV, + 1 kV line(s) to line(s) Not applicable | Mains power quality should be that of a typical home healthcare environment. |
| Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | Voltage dips: 0% UT; 0,5 cycle 0% UT; 1 cycle 70% UT; 25/30 cycles Voltage interruptions: 0% UT; 250/300 cycle | Voltage dips: 0% UT; 0,5 cycle 0% UT; 1 cycle 70% UT; 25 cycles Voltage interruptions: 0% UT; 250 cycles | Mains power quality should be that of a typical home healthcare environment. If the user of the Transmitter/ Receiver requires continued operation during power mains interruptions, it is recommended that the Transmitter/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 50 Hz | Transmitter/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 Transmitter/Receiver is intended for self-use by the user in the electromagnetic environment (for home healthcare) specified below. The customer or the user of the Transmitter should assure that it is used in such and environment. | | | |
| **Immunity test** | **IEC 60601 test level** | **Compliance level** | **Electromagnetic environmentguidance (for home healthcare environment)** |
| Conducted RF IEC 61000-4-6 | 3 Vrms: 0,15 MHz - 80 MHz 6 Vrms: in ISM and amateur radio bands between 0,15 MHz and 80 MHz<br><br>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<br><br>80% AM at 1 kHz | Portable and mobile RF communications equipment should be used no closer to any part of the Transmitter/ Receiver than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. |

| | | | |
|---|---|---|---|
| Radiated RF IEC 61000-4-3 | 10 V/m 80 MHz - 2,7 GHz 80% AM at 1 kHz | 10 V/m 80 MHz - 2,7 GHz 80% AM at 1 kHz | Recommended separation distance: d = 1,2√P d = 1,2√P 80MHz to 800 MHz d = 2,3√P 800MHz to 2,7 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Interference may occur in the vicinity of equipment marked with the following symbol: |

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



**Recommended separation distance between portable and mobile RF communications equipment and the Transmitter/Receiver**

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

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

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

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

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

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

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

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

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



## Device Performance Characteristics

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

**Regression analysis of the Sensors vs. YSI reference**

**Study A**

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



**Study B**

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

**Sensor accuracy for all results vs. YSI reference**
**Study A**

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



**Study B**

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

**Sensor accuracy over wear duration vs. YSI reference**

**Study A**

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



**Study B**

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