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RIGHTTEST™

Continuous Glucose
Monitoring System
(HM312)



User Manual

Use with a receiver (HR310)


READ THIS FIRST :

It is important to read the entire contents of this manual before using the RIGHTEST Continuous Glucose Monitoring System.

The instructions, warnings, precautions, safety information as well as tips contained within this manual are intended to help ensure proper use and optimal results. It is important that you read this entire manual before using the system for the first time.

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I. INDICATIONS FOR USE & STATEMENT AND ADVISORY

INDICATIONS FOR USE

The RIGHTEST Continuous Glucose Monitoring System (hereafter referred to as the "RIGHTEST CGMs") is indicated for detecting glycaemia trends and for the management of diabetes in persons age 18 to 80. It's an applied part and it is designed to replace blood glucose testing for diabetes treatment decisions. Interpretation of the RIGHTEST CGMs results shall be based on the glucose trends and several sequential readings over time. It also aids detecting episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments.

The RIGHTEST CGMs is also intended to autonomously interface with digitally connected devices. The RIGHTEST CGMs can be used alone or in conjunction with these digitally connected devices for the purpose of managing diabetes.


STATEMENT AND ADVISORY

This manual is designed to instruct all personnel responsible for the proper use and care of the RIGHTEST CGMs. All users are urged to carefully read this manual before using the system.

II. SAFETY INFORMATION

The following is a summary of safety information which must be observed before using the RIGHTEST CGMs. WARNING indicates potential danger to 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 user injury. It is important to understand that the safety information is not exhaustive. It is meant to keep the user safe while using the system.

WHEN NOT TO USE (CONTRAINDICATIONS) :

 **No MRI/CT/Diathermy:** The RIGHTEST CGMs (sensor, transmitter, Receiver and/or other receiving devices) must be removed prior to Magnetic Resonance Imaging (MRI), Computed Tomography (CT), or high frequency electrical heat (diathermy) treatment.


If you are in the serious incidents caused by the RIGHTEST product, please call local emergency service for help. Please feel free to report your incident to us and the local competent authority.

⚠️ WARNINGS :

Read This Manual First. Failure to operate the system according to the guidelines and safeguards specified in this manual could result in a hazardous condition.

DO NOT Ignore Low/High Blood Glucose Symptoms. If your glucose readings do not match what you are feeling, use your blood glucose meter; or, if needed, consult your healthcare practitioner.

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 get any sensor readings, alarm/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 you see the  symbol on your receiver display, 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 Getting Urgent Alarm/Alert. The RIGHTEST CGMs Receiver lets you know when your sensor readings drop to or below 54 mg/dL; or when your sensor reading is below 70 mg/dL and continuously falling for the following reading(s) regardless your alarm/alert settings. There are no alarm/alerts in the following situations.

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

Modification of the System is Not Allowed: Do not modify or tamper with any components or accessories of the RIGHTEST CGMs. Otherwise, you could 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: Don't put any parts of the RIGHTEST CGMs in your mouth or let children and pet play with it without adult supervision.

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

- **INTERNALLY POWERED ME EQUIPMENT.** Not Suitable for use in an OXYGEN RICH ENVIRONMENT

⚠ PRECAUTIONS :

DO NOT Use If You Are Pregnant, on Dialysis or Critically Ill. Do not use the RIGHTEST 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 in these populations.

DO NOT Use the System on Skin With Extensive Skin Changes or Diseases. Do not use the RIGHTEST CGMs on persons who have extensive psoriasis, extensive eczema, extensive scarring, or extensive tattoos; or on skin insertion sites that are dermatitis herpetiformis infected, irritated, burned or cut.

Calibration Safety: Calibration is not required if users scan sensor & transmitter codes. If necessary, calibrate your system for accurate readings. Take additional precautions when you enter your blood glucose value. Entering incorrect blood glucose values for calibration can result in inaccurate glucose readings, which may result in you missing a high or low glucose event.

Clean Before Use: Clean your hands before sensor insertion. To minimize infection risk, wipe the insertion site with an alcohol wipe, and ensure the site is dry prior to sensor insertion. This helps the sensor stay attached to your body.

Skin Irritation Reaction Caused by 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 RIGHTEST CGMs. If needed, consult your health care professional.

Avoid Skin Care Products or Insect Repellent: Do not apply skin care products such as sunscreens, moisturizer or perfume over the sensor insertion sites. Insect repellent may damage the plastic used in the RIGHTEST CGMs. Failure to comply may lead to inaccurate system performance.

Store the Sensor in a Dry Room: Store your sensor at a temperature of 5°C to 30°C (41°F to 86°F) and 10% - 90% non-condensing humidity. You can also store the sensor in the refrigerator at 5°C to 30°C (41°F to 86°F). Do NOT freeze the sensor.

DO NOT Reuse Your Inserter, and Sensor: The inserter is pre-loaded with a sensor. The entire sensor inserter package is sterilized and designed for single use. All RIGHTEST CGMs components are not suitable for re-sterilization. Reuse of these components may result in no glucose readings and infections.

Discard Sensor Inserter in an appropriate puncture-proof or biohazard container, for safety and to prevent cross-contamination.

Check sensor package. Do not use the sensor if its sterile package has been damaged or open because it may cause infection.

Use the Charger as Directed: Use only the AC power adapter, USB cable and USB charger provided with the RIGHTEST CGMs when charging your receiver and transmitter. Using different chargers or AC power adapters could damage the system or cause fire. Use USB cable only as directed, and store safely. Misuse of the USB cable can be a strangulation risk.

Do NOT Use If the Receiver is Damaged, or If It Could Fall into Water.

The receiver and accessories are enclosed without protection from the ingress of water. Do not submerge these components in water. 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 or damaged could result in electric shock or no glucose results.

Test Your Receiver Regularly. Test your receiver's speaker and vibration functions regularly. If you are in any doubt, contact a manufacturer authorized dealer for technical support.

Keep Your Receiver Close. Be sure your receiver is close to your transmitter and in the same room. The maximum transmission distance is 6 meters (20 feet) with no obstructions (e.g. wall, metal, glass or water) in between. Obstructions or longer distances may cause Bluetooth signal loss and you will not receive important alerts/alarms.

Plug in to Charge.

- Be sure to fully charge your transmitter every time you start with a new sensor. When plugged into an adapter that is connected to a standard household electrical outlet (100 to 240V AC, 50/60Hz), the transmitter battery requires approximately 2 hours to fully charge. When connected to your personal computer's USB port or USB car charger adapter, it may take a longer time.
- To best protect yourself from not getting the alarm/alerts due to a depleted battery, plug in your receiver to its charger at the end of the day and charge it up overnight.

Going Through Security Check Points. Remove all parts of the RIGHTEST CGMs before exposing it to an X-ray machine. The effect of X-rays on the system has not been evaluated.

Adequate Brightness while reading: If you have difficulty reading your receiver in bright sunlight, you may need to seek a shady location.

Symbol Definitions

III. SYMBOL DEFINITIONS

The following symbols apply to the RIGHTEST CGMs

| SYMBOL | DEFINITION | SYMBOL | DEFINITION |
|--------|---|--------|---|
| | Date of Manufacture | | Do not use if 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 | | Medical Device |
| | Method of sterilization using irradiation | | Protected from tools and small wires greater than 1 millimeter. Protected from immersion between 15 centimeters and 1 meter in depth. |

Symbol Definitions

| SYMBOL | DEFINITION | SYMBOL | DEFINITION |
|--------|---|--------|--|
| | Protected against insertion of fingers and dripping water. | | Keep Dry |
| | Protected from touch by fingers and objects greater than 12.5 millimeters. Protected from condensation. | | MR Unsafe |
| | Serial Number | | Prescription Required |
| | CE Mark with Notified Body Number | | Refer to Instruction Manual/Booklet |
| | Bluetooth | | Electrical Equipment Designed Primarily for Indoor Use (Chargers Only) |
| | Class II Equipment | | Warning/Precaution |
| | Input | | Operating Instructions; consult manual for further instructions |
| | Keep away from heat | | Near-field communication (NFC) scan area |
| | Importer | | |

Getting to Know Your RIGHTEST CGMs

IV. GETTING TO KNOW YOUR RIGHTEST CGMS

WHAT IS INCLUDED

1. SENSOR INSERTER : Designed with a pre-loaded sensor.
2. TRANSMITTER : Rechargeable for multiple-use for a single patient.
3. RECEIVER : Blood glucose information display.
4. POWER SUPPLY: AC power adapter & USB cable.
5. TRANSMITTER CHARGER : A USB charging dock for the transmitter.
6. STORAGE VIAL: Storage for the transmitter and transmitter USB charger to keep them dry.

Getting to Know Your RIGHTEST CGMs



Getting to Know Your RIGHTEST CGMs

PERFORMANCE FEATURES

The RIGHTEST CGMs is an integrated continuous glucose monitoring system (iCGM) that provides glucose readings, trends, and levels every minute. The system is comprised of three main components: (a) a Sensor, (b) a Bluetooth Transmitter and (c) a Receiver. The sensor is pre-loaded inside an Inserter. The sensor is inserted under your skin and measures your interstitial glucose level test glucose. The transmitter wirelessly sends data to the receiver.

The receiver displays glucose values and alerts users to hypoglycemia and hyperglycemia.

The RIGHTEST CGMs user-friendly features and benefits include:

- Ergonomic design of sensor inserter allows users to insert the sensor safely with just one hand.
- Easy-to-read visual glucose values and trends.
- Transmitter's powerful storage holds 14 days of glucose readings with zero data loss.
- Getting visual and audible alerts to hypoglycemia and hyperglycemia.
- Lightweight sensor and transmitter for maximum comfort.

Getting to Know Your RIGHTEST CGMs

SAFETY FEATURES

The RIGHTEST CGMs offers a number of important safety features when you use it.

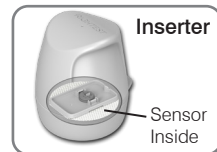
These features include:

- Receiver's alarm/alert includes visual notification, vibrations and sound, depending on your personalized settings.
- When you are out of your target glucose range, the receiver alerts you.
- Receiver warns you if your glucose level falls below 54 mg/dL; or when your sensor reading is below 70 mg/dL and continuously falling for the following reading(s).
- Urgent alert/alarm settings at 54 mg/dL or below; or below 70 mg/dL and continuously falling for the following reading(s) cannot be changed or turned off.
- Receiver notifies you when a sensor has failed, expired or when there are system errors.

Getting to Know Your RIGHTEST CGMs

THE RIGHTEST CGMS COMPONENTS

The RIGHTEST CGMs consists of 3 key parts: a Sensor, a Transmitter and a Receiver. These 3 parts are described below:



SENSOR INSERTER

The inserter is pre-loaded with a sensor and does not require user assembly. The inserter helps you place the sensor wire under your skin with ease. The sensor measures your glucose information.



TRANSMITTER

The transmitter sends your glucose data from the sensor to the Receiver. The transmitter is equipped with a rechargeable battery.



RECEIVER

The receiver displays glucose values and alerts you to hypo/hyperglycemia.

Getting to Know Your RIGHTEST CGMs

ACCESSORIES



TRANSMITTER CHARGER

A USB charger is included with your transmitter.



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 to 240V AC, 50/60 Hz).

V. BEFORE GETTING STARTED

CHARGING BASICS

Before using the system for the first time, charge the receiver for a complete charging cycle without interruption. A transmitter charger is supplied along with your transmitter package. Rechargeable transmitters must be fully charged each time you start a new monitoring session. Otherwise, your sensor will likely not remain operational until the end date of sensor wear period (14 days).

A complete charging cycle of the receiver takes about 4 hours. For the transmitter it takes about 2 hours when using the supplied USB adapter plugged into a standard household electrical outlet (100 to 240V AC, 50/60 Hz). It is recommended to use only the supplied USB cable and USB power adapter.

CHARGING THE RECEIVER

⚠ WARNINGS :

Not Getting Urgent Alarm/Alert. There are no alarm/alerts, when your receiver is turned off or its battery is dead.

⚠ PRECAUTIONS :

Use Charger as Directed. Use only the AC power adapter, USB cable and USB charger provided with the RIGHTTEST CGMs when charging your receiver and transmitter. Using different chargers or AC power adapters could damage the system or cause fire.

Plug in to Charge. To best protect yourself from not getting the alarm/alerts due to a depleted battery, plug in your receiver to its charger at the end of the day and charge it up overnight.

Before Getting Started



1. Connect the micro-USB plug of the charging cable to the USB Type C input of the receiver.

Before Getting Started



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. Alternatively, connect plug to the USB port of your computer or USB car charger adapter.

Before Getting Started

BATTERY LIFE INDICATOR ON THE RECEIVER

From the receiver display, battery level (as a percentage of full charge) and the battery status icon (charging or discharging) is displayed in the top-right corner of the screen. When the receiver is charging, you will see lightning bolt in the middle of the battery icon. The receiver utilizes an intelligent battery charging technology that prevents overcharging.



Before Getting Started

CHARGING TRANSMITTER

⚠ **WARNINGS :**

Not Getting Urgent Alarm/Alert. There are no alarm/alerts when your transmitter battery is dead.

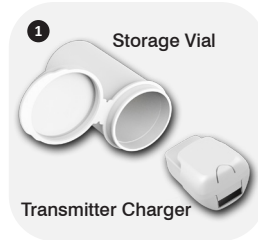
PRECAUTIONS Use only the AC power adapter, USB cable and USB charger provided with the RIGHTTEST CGMs when charging your receiver and transmitter. Using different chargers or AC power adapter could damage the system or cause fire.

Plug in to Charge. Be sure to fully charge your transmitter every time you start with a new sensor. When plugged into a standard household electrical outlet (100 to 240V AC, 50/60 Hz), the transmitter battery requires approximately 2 hours to fully charge using the transmitter charger supplied with the RIGHTTEST CGMs. When connected to your personal computer's USB port or USB car charger adapter, it may take a longer time.

Before Getting Started

It is important to charge the transmitter battery to its full charge **every time** before you begin with a new sensor to ensure data is collected from the sensor and sent to receiver during entire wear period (14 days).

1. Take out your transmitter charger from its storage vial. Hold the charger face up.



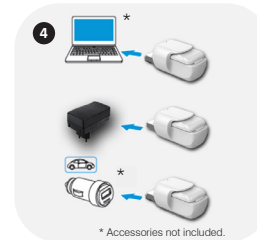
2. Make sure the alignment notch of the transmitter is facing the charger's transmitter compartment with the transmitter mark (📶) facing up. With the transmitter outer frame between your fingers, steadily slide the transmitter all the way into the compartment.



Before Getting Started



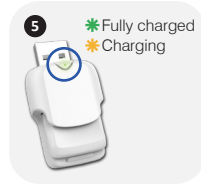
3. With the transmitter secured inside its charger compartment, turn over the charger to the back side and slide the lock button outwards.



4. Plug the charger's USB plug into the USB port on the AC power adapter supplied with the RIGHTEST CGMs, then plug the AC power adapter into the AC mains outlet (100 to 240V AC, 50/60 Hz). You can also charge your transmitter with a computer or a car charger adapter with a USB port but it may take much longer.

Before Getting Started

5. When you connect the transmitter charger to a USB power source, the LED on the charger lights up. The charge condition of transmitter battery is indicated below: a solid green (★) light means the battery is fully charged.
a solid amber (✱) light means the battery is charging.



NOTE :

If the LED doesn't light up, make sure you connect to a power source with output rating of 500 mA or higher. If this does not solve the issue, check with another power source again then contact customer support.

6. After the transmitter is fully charged, unplug the transmitter charger from the power source.

7. If you wish to take out the transmitter from its charger, or to store the transmitter charger, turn over the charger to the back side and press the lock button slightly downward, then slide the lock button all the way inward.



Set Up Your RIGHTEST CGMs

VI. SET UP YOUR RIGHTEST CGMS

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

- Sensor Inserter Package
- Transmitter
- Receiver
- Alcohol Wipes
- Your Blood Glucose (BG) Meter

PAIRING THE SENSOR AND TRANSMITTER USING NFC

⚠ PRECAUTIONS :

Scan the NFC Tags First before Connecting to the System: Each sensor has its unique code established on the tag (📱) attached on the sensor inserter package. The transmitter's code is located right beneath its top plastic cover where you see a (📱) mark. Every time you begin the use of a new sensor, scan both codes to ensure successful system connections. The system will not start if you fail to scan the codes.

The following steps describe using receiver to make a sensor-transmitter pair. If the instructions provided do not work, the receiver will display an error message.

Set Up Your RIGHTEST CGMs

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



NOTE :

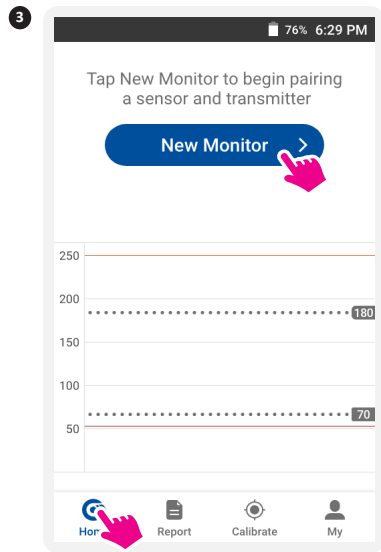
If using the receiver for the first time, follow prompts to set the date, time and your glucose target & alerts.

2



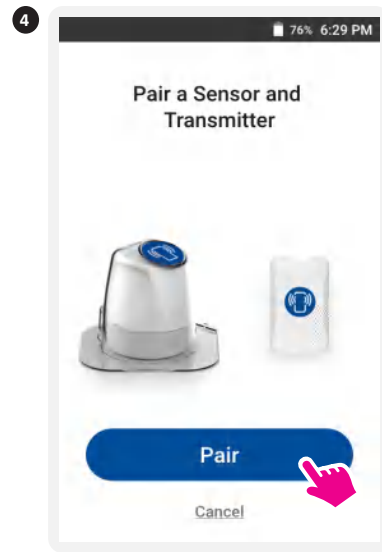
Set Up Your RIGHTEST CGMs

3. Tap **[Home]** at the bottom of your receiver screen. Then, tap **[New Monitor]** to start a new monitoring session.




Set Up Your RIGHTEST CGMs

4. When the receiver prompts you to pair the sensor & transmitter, choose **[Pair]**.



Set Up Your RIGHTEST CGMs

5. Locate the NFC panel at the top of your receiver's back cover. The center of NFC panel is engraved with a  mark.



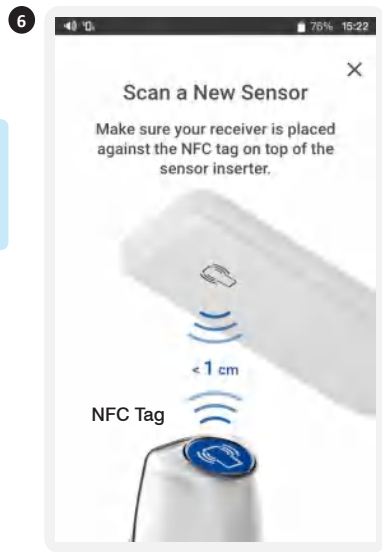
Set Up Your RIGHTEST CGMs

6. Tap the receiver's NFC panel against the  tag on top of the sensor inserter package until you hear a “beep” sound.



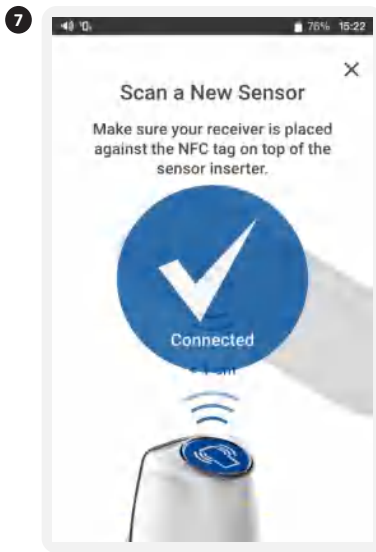
NOTE :

Be sure your receiver's NFC panel is within 1 cm (3/8") of the NFC tag/mark when you scan the codes.



Set Up Your RIGHTEST CGMs

7. Once connected, pairing confirmation is displayed as by checkmark (✓) on the receiver screen.



Set Up Your RIGHTEST CGMs

8. Tap receiver's NFC panel against the NFC mark () on the top of transmitter until you hear a "beep" sound.



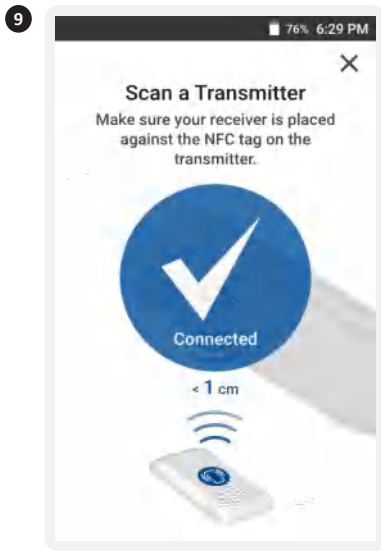
NOTE :

Be sure your receiver's NFC panel is within 1 cm (3/8") of the NFC tag/mark when you scan the codes.



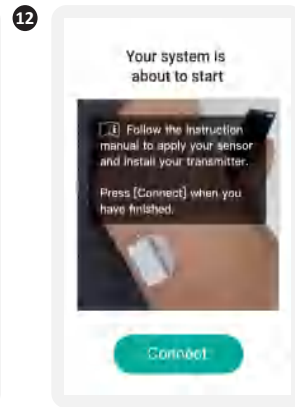
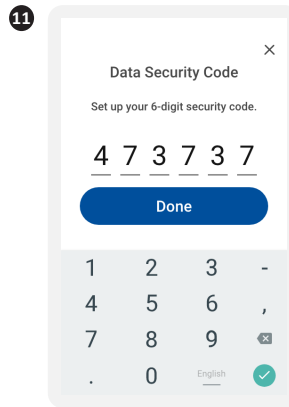
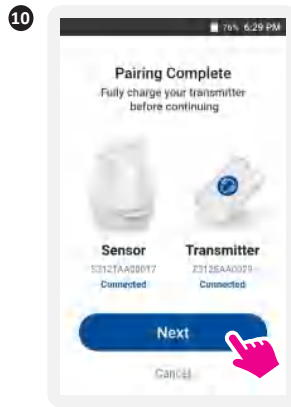
Set Up Your RIGHTEST CGMs

9. Once connected, pairing confirmation is displayed as by checkmark (✓) the screen.



Set Up Your RIGHTEST CGMs

10. When the receiver displays “Pairing Complete”, press **[Next]**.
11. You will be prompted to enter your personal security code. Then press **[Done]**.
12. Make sure you follow the step-by-step instructions in the installation guide described in the next 2 sections (“*Apply Your Sensor*” and “*Attach Your Transmitter*”). After the sensor and transmitter are installed, press **[Start Sensor]**.



Set Up Your RIGHTEST CGMs

APPLY YOUR SENSOR

⚠ PRECAUTIONS :

Clean Before Use: Clean your hands before sensor insertion. To minimize infection risk, wipe the insertion site with an alcohol wipe, and ensure the site is dry prior to sensor insertion. This helps the sensor stay attached to your body.

DO NOT Place the Sensor on Any Area of the Body other than the Upper Arm: Placing the sensor on other areas of the body has not been tested and the risks are unknown.

Select an Appropriate Sensor Insertion Site: Do NOT place the sensor on skin that is painful to touch, raised (higher than surrounding skin), crusting or bleeding; or on areas with scars, tattoos or moles. Select a skin area that stays flat during normal daily activities. Choose a site that is greater than 1 inch (2.5 cm) away from any insulin injection sites.

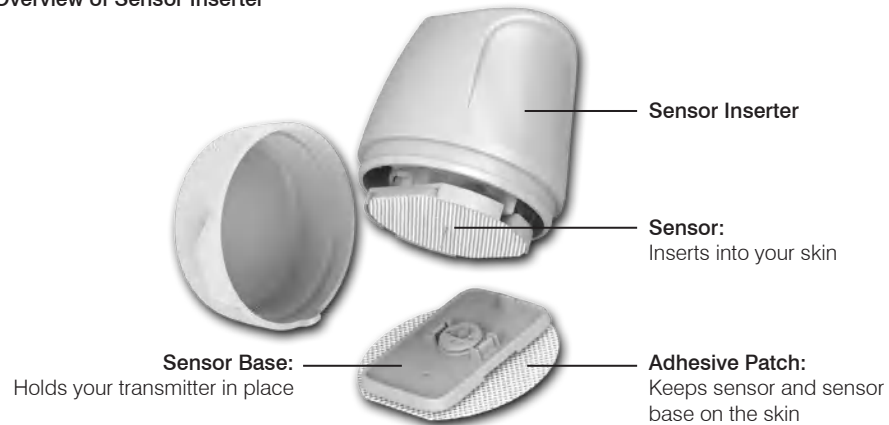
Change the Sensor Insertion Site for the Next Sensor Insertion: Placing the next sensor on the same spot will increase skin irritation or redness and could potentially lead to scabs.

Excessive Sweat or Body Movement Can Cause Your Sensor to Loosen: Remove and replace your sensor if it starts to loosen.

Set Up Your RIGHTEST CGMs

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

Overview of Sensor Inserter



Set Up Your RIGHTEST CGMs

Follow these steps to apply your Senso

1. Choose an insertion site on the **upper arm**.



NOTE :

Use a different site for the next sensor insertion.

2. Wipe the insertion site with an alcohol wipe and wait approximately for 2 minutes until the site dried out thoroughly before getting started.
3. Take out the sensor inserter from its package. Open the sensor inserter cap.
4. Place the inserter over the site and push down firmly to insert the sensor. Stay for 10 seconds to ensure the adhesive patch is fully attached to your skin.



NOTE :

Do not apply the inserter if the base falls out when opening the cap. Use a new one.
Do not apply the inserter if it is misused before the insertion. Use a new one.
Apply the inserter immediately after opening its package and cap.
Do not push down the inserter until it is placed over the insertion site.

2



3



4



Set Up Your RIGHTEST CGMs

5. Gently move the inserter away from your insertion site.
6. Make sure the sensor is securely attached to your skin.
7. Discard the inserter and its package according to local regulations.

6



Set Up Your RIGHTEST CGMs

ATTACH YOUR TRANSMITTER

⚠ PRECAUTIONS :

DO NOT Use If Any Components Appears to be Damaged or Past Its Expiration Date. A damaged or cracked inserter, sensor, transmitter, or receiver could compromise the integrity of the system or contribute to infection risk. Do not use if your sensor has past its expiration date. The sensor expiration date is in YYYY-MM-DD (Year-Month-Day) format on your Inserter Package.

DO NOT Share Your Re-chargeable Transmitter. The RIGHTEST CGMs' transmitter is rechargeable and reusable. Never share your transmitter with others. The system is a prescription-only medical device and is meant for your use only. If used by other persons, the glucose readings, report, alarms/alerts, etc., may be wrong.

Use Charger as Directed. Use only the AC power adapter, USB cable and USB charger provided with the RIGHTEST CGMs when charging your receiver and transmitter. Using different chargers or AC power adapters could damage the system or cause fire.

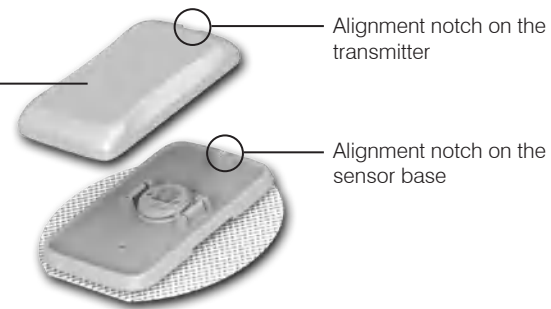
Set Up Your RIGHTEST CGMs

Plug in to Charge. Be sure to fully charge your transmitter every time you start with a new sensor. When plugged into a standard household electrical outlet (100 to 240V AC, 50/60 Hz), the transmitter battery requires approximately 2 hours to fully charge using the transmitter charger supplied with the RIGHTEST CGMs. When connected to your personal computer's USB port or USB car charger adapter, it may take much longer.

Overview of the Transmitter

Transmitter:

- Rechargeable for multiple-use



Set Up Your RIGHTEST CGMs

Attach your transmitter after you insert a sensor.

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

Follow these steps to install your Transmitter:

1. Get your transmitter.



NOTE :

Be sure your transmitter is fully charged every time you start with a new sensor.

2. If necessary, clean the transmitter with an alcohol wipe. While you do so, do not touch or scratch its metal components located at the bottom.



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.

2



Set Up Your RIGHTEST CGMs

3. Let the transmitter dry.

4. Align both notches on the sensor base and transmitter.

5. Press down the transmitter until it snaps into place.

4



5



Set Up Your RIGHTEST CGMs

CONNECT TRANSMITTER WITH RECEIVER

⚠ 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 won't get any sensor readings, alarms or alerts until your system begins to transmit data.

⚠ PRECAUTIONS :

Test Your Receiver Regularly. Test your receiver's speaker and vibration functions regularly. If you are in any doubt, contact a manufacturer authorized dealer for technical support.

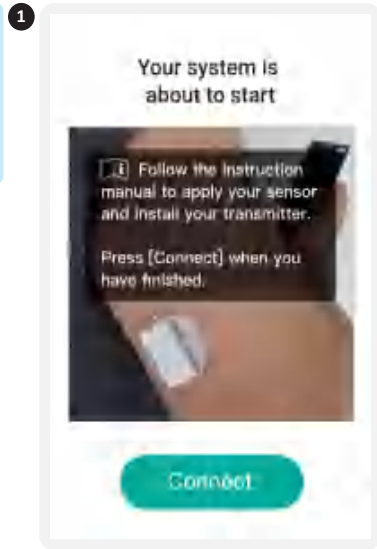
Keep Your Receiver Close. Be sure your receiver is close to your transmitter and in the same room. The maximum transmission distance is 6 meters (20 feet) with no obstructions (e.g. wall, metal, glass or water) in between. Obstructions or longer distance may cause Bluetooth signal loss and you will not receive important alerts/alarms.

Set Up Your RIGHTEST CGMs

📌 NOTE :

Make sure you go through all steps in the “*Pairing the Sensor and Transmitter using NFC*” section. Make sure that you have your sensor and transmitter installed properly before you start the following steps.

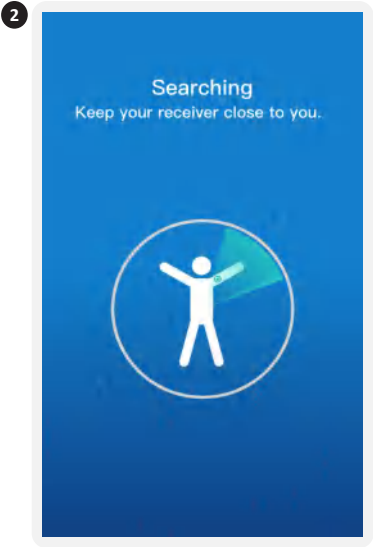
1. Make sure you have followed the installation guide described in the “*Apply your Sensor*” and “*Attach Your Transmitter*” sections. Then, when the receiver displays “Your system is about to start, press [Connect]”,



Set Up Your RIGHTEST CGMs

NOTE :
If your receiver doesn't start the search or displays a "Cannot Connect to Sensor/Transmitter Pair" message, go through the steps in the "Pairing the Sensor and Transmitter using NFC" section again. If the problem persists, refer to the troubleshooting section.

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



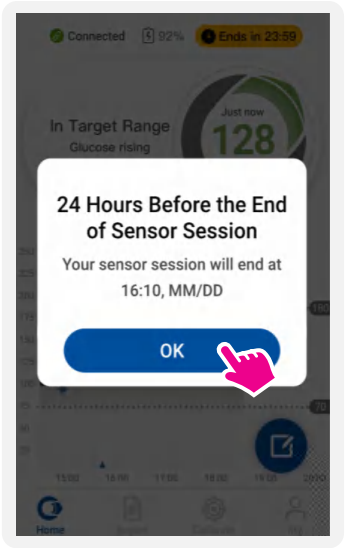
Set Up Your RIGHTEST CGMs

3. After the system is connected, the Receiver displays the warmup progress and remaining warmup time. When the warmup is completed, "Warmup" disappears from your display.



VII. ENDING A MONITORING SESSION

You will receive a “24 Hours Before the End of Sensor Session” alert on your receiver 24 hours prior to monitoring ending. Press **[OK]** to confirm you have read this alert .



Ending a Monitoring Session

END THE MONITORING SESSION

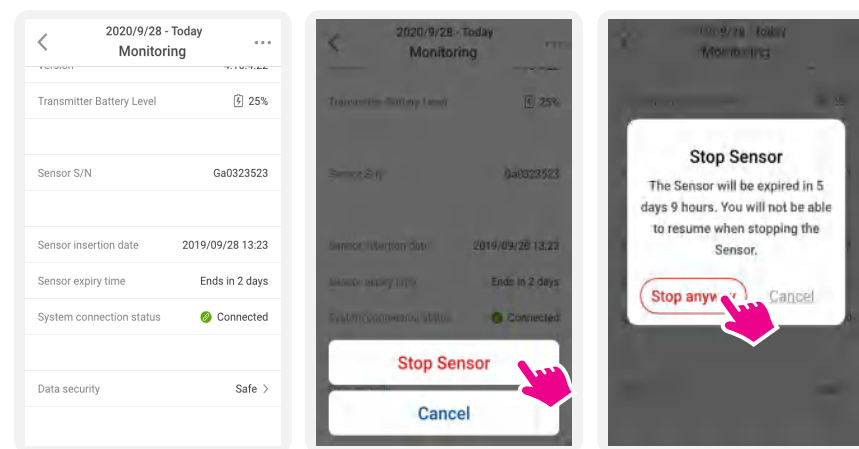
Before you remove the sensor. Either:

- Wait for the sensor to fully expire. You will receive a “Sensor Expired” alert and the session will end automatically. Press **[Done]** confirm you read this alert.



Ending a Monitoring Session

- End the monitoring session early by selecting the upper right in “My” menu. You will see a message warning you that the sensor has not expired yet. Press **[Stop anyway]** to end the session.



Ending a Monitoring Session

SENSOR AND TRANSMITTER REMOVAL

Once the session has ended, follow these steps to remove your sensor and transmitter:

1. Grip the edge of the patch attached to your skin. Slowly pull upwards to peel it off.
2. Pick up the sensor base and transmitter. Note that one edge of the base has a notch.
3. Locate a point two-thirds along the length of the base and across from the notch. Then pinch firmly at this point with your thumb and index fingers. While you do so, grip a corner of the notched edge of the sensor base with your other hand.
4. Press down firmly with both your hands to bend the base away from the transmitter.
5. The transmitter will pop out as you bend the base. You will hear a click as the transmitter detaches.
6. Discard the sensor according to local regulations.



NOTE :

Do not throw away the Transmitter. Transmitters are reusable after recharging.

Ending a Monitoring Session

1



3



4



Understand Your Glucose Readings

VIII. UNDERSTAND YOUR GLUCOSE READINGS

Your sensor glucose readings appear on your receiver display's **Home** 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 **Home** screen. It is important to understand these indicators before use. An overview of the home screen is shown below.

Understand Your Glucose Readings

Overview of Receiver Home Screen



Understand Your Glucose Readings



GLUCOSE INFORMATION

Your most recent glucose reading is displayed inside a circle with an arrow on top of the receiver screen. The arrow shows the direction of your glucose trend.

A  symbol reminds you to do a fingerstick blood glucose test before making treatment decisions.

You will see this  symbol in each of the following situations:

- Your glucose is less than 70 mg/dL regardless of your detected trend direction.
- Your glucose is rising or falling rapidly at or more than 2 mg/dL per minute.
- There is no glucose value or trend arrow (HIGH/LOW event).
- During the first 2 hour sensor warmup period.

The sensor glucose concentration reading range is 40 - 500 mg/dL. A glucose alert safety symbol ( or ) will appear in the following situations:

- When your glucose is at or higher than 250 mg/dL, and is detected to rise or remain steady.
- When your glucose is at or less than 70 mg/dL, and is detected to fall or remain steady.

Understand Your Glucose Readings

Fingerstick Check and Alerts/Message

Glucose High/Low Alerts

Glucose message

Check Blood Glucose

When you see this symbol, you must check your blood glucose value with a meter before making any treatment decisions.



Understand Your Glucose Readings

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, rouge and red) of the arrow helps identify the risk of hypoglycaemia and hyperglycaemia.

Understand Your Glucose Readings

| Direction Arrow Color | What it means | | | | |
|--------------------------|--------------------|------------------|---------------------------|-------------------|----------------------------|
| | 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 | | | | | |
| ROUGE: 54 - 69 mg/dL | | | | | |
| RED: <54 mg/dL | | | | | |

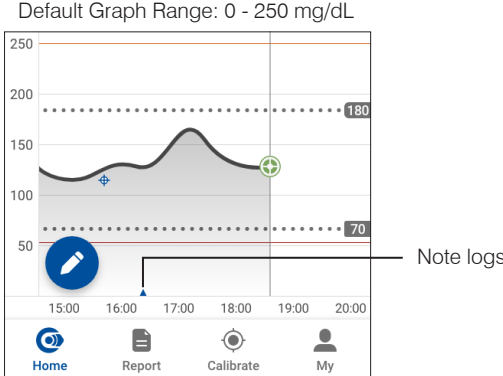
*"glucose is steady" means the glucose rate of change is in between 0 to 1 mg/dL.
**"glucose falling/rising" means the glucose rate of change is in 1 - 2 mg/dL per minute.
***"glucose falling/rising rapidly" means the glucose rate of change is at or more than 2 mg/dL per minute.

Understand Your Glucose Readings

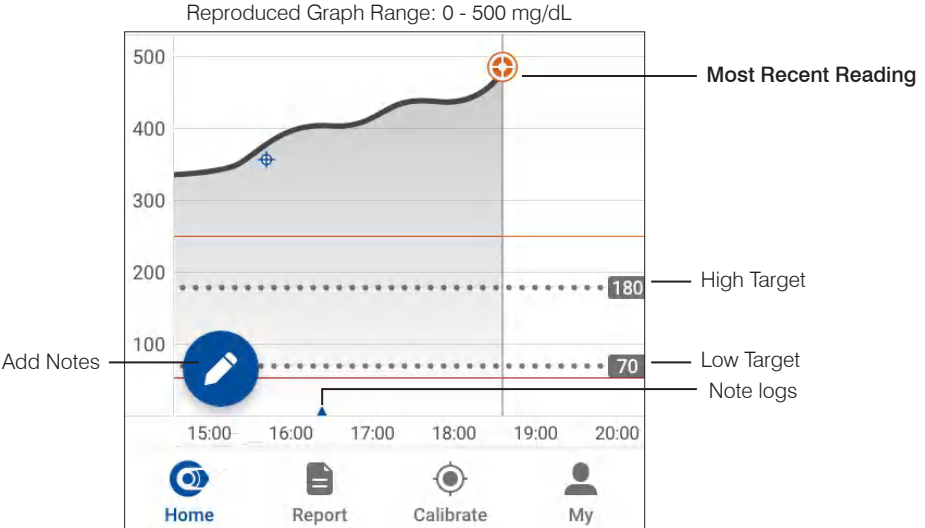
TREND GRAPH

The trend graph is displayed on the lower portion of the screen. It shows your glucose trend for the past 6 hours. The graph adds one reading every 5 minutes. The most recent data point is marked by an open-target double circle at the right end of the plot. The sensor glucose reading range is 40 - 500 mg/dL. The trend graph uses a dynamic range of 0 - 500 mg/dL. The default graph displays a range of 0 - 250 mg/dL and is able to reproduce the maximum range as required when taking actual readings.

Overview of Trend Graph




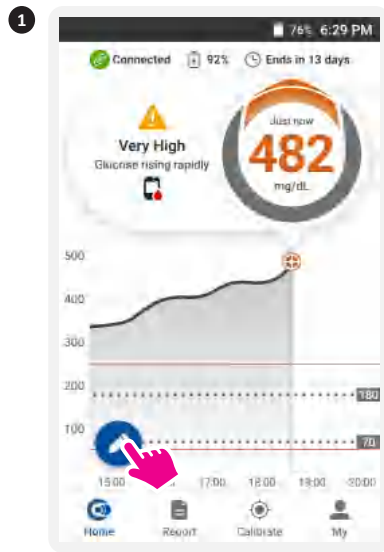
Understand Your Glucose Readings



Understand Your Glucose Readings

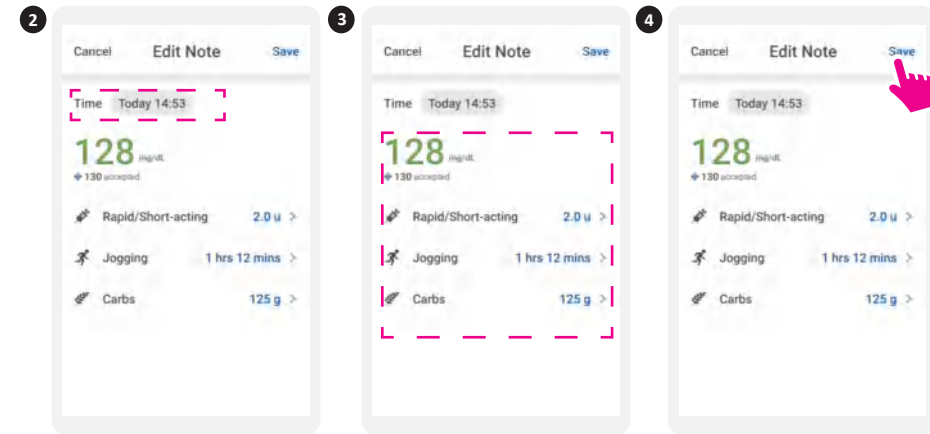
ADD NOTES

1. From the **Home** screen, add a note by tapping the  symbol in the lower right corner of the screen.



Understand Your Glucose Readings

2. Make sure the time is correct.
3. Select the options (carbs, insulin, exercise) then follow the prompts.
4. Tap to save your notes. Notes are viewable in your logbooks.

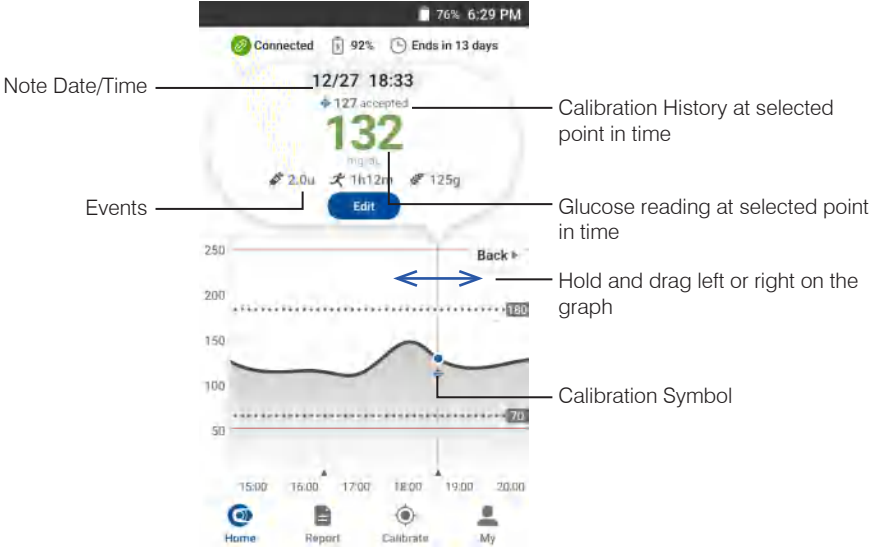


Understand Your Glucose Readings

ACCESS YOUR NOTES INFORMATION

Personal notes (insulin, meals, exercise) are marked by blue triangle on the bottom of the graph. If you performed calibration, the calibration record (if accepted) is marked with a blue target symbol and is viewable in the note. To access your sensor glucose information or to view your personal notes from anytime between the first and most recent reading, hold and drag the trend graph left or right. Note entries will be displayed on the upper portion of the receiver screen. Tap the **[Back]** button to return to the Home screen showing the most recent glucose information.

Understand Your Glucose Readings



Understand Your Glucose Readings

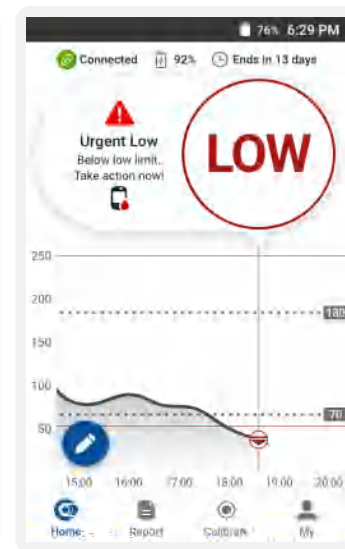
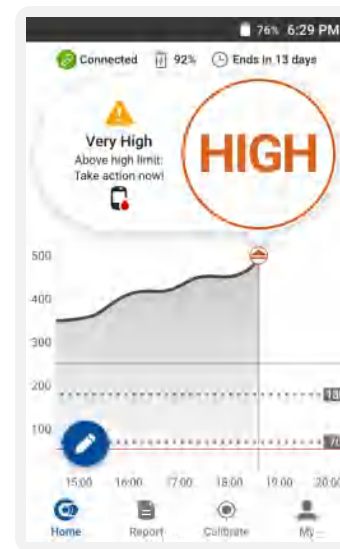
HIGH/LOW READING

If **HIGH** appears on your receiver screen, your glucose reading is above 500 mg/dL. Do a fingerstick 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 receiver screen, your glucose reading is less than 40 mg/dL. Do a fingerstick 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.

Understand Your Glucose Readings

HIGH/LOW Reading



Review Your Glucose History

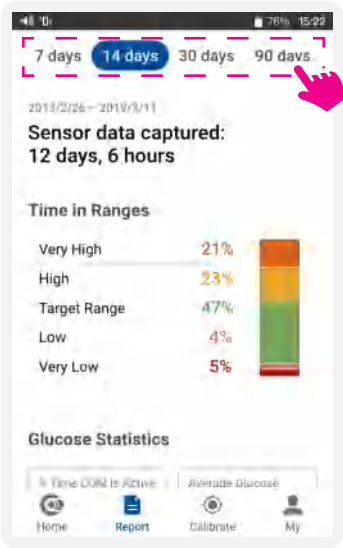
IX. REVIEW YOUR GLUCOSE HISTORY

Your receiver will record and analyze up to 90 days of glucose data using Ambulatory Glucose Profile (AGP) techniques. Make sure you have data for at least 7 - 10 days (ideally more than 14 days) to identify your glucose patterns.

The 7 days, 14 days, 30 days and 90 days result of AGP analysis can be reviewed on the **Report** page. From the **Report** screen, choose the duration of your glucose summary statistics to review on the upper portion. By pooling data from multiple days, graphs showing the 24-hour glucose level percentage and daily glucose level are shown below.

Review Your Glucose History

Glucose History



Choose a report duration from here!

Calibration (Optional)

X. CALIBRATION (OPTIONAL)

Your RIGHTEST CGMs features factory-calibration that calculated correction factors based on factory input reference values. The system does not need user calibration and you will not receive any calibration prompts from your receiver. Calibrating your RIGHTEST CGMs is optional. The calibration allows alignment between your system readings and your meter values.


⚠ WARNINGS :

DO NOT Ignore Low/High Blood Glucose Symptoms. If your glucose readings do not match what you are feeling, use your blood glucose meter or, if needed, consult your healthcare practitioner.

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 get any sensor readings, alarm/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.

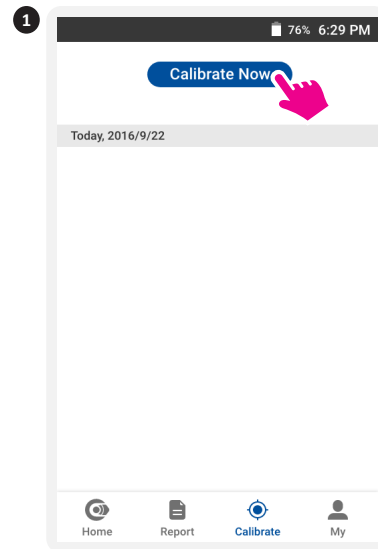
Calibration (Optional)

- 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 you see the  symbol on your receiver display, 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.

CALIBRATE

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

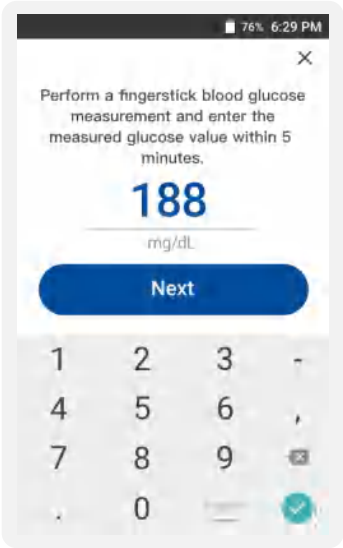
1. From the **Calibrate** screen, tap **[Calibrate Now]**.



Calibration (Optional)

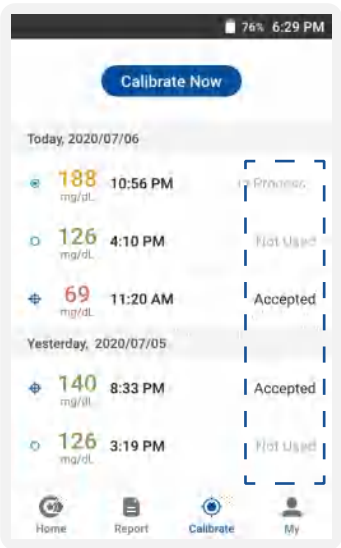
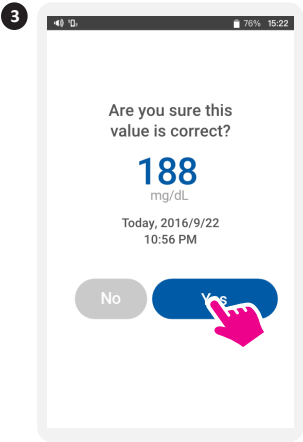
2. Enter the exact BG value then press **[Next]**. If incorrect, tap the backspace key on the numeric keypad to erase the entries then enter the correct value.

NOTE :
Make sure you enter the exact value that is measured with 5 minutes.



Calibration (Optional)

3. You will see a prompt from receiver. Tap **[Yes]** or **[No]**.
4. The messages on the right side of the **Calibrate** screen display the calibration progress and whether your entry is accepted or not.



XI. TREATMENT DECISIONS


Before you start using the RIGHTEST 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 his/her recommendation to put together a plan for making treatment decisions.
- Trace your note logs often to see how carbs, medication, exercise, illness, or stress levels impact your sensor glucose reading.

⚠ WARNINGS :

DO NOT Ignore Low/High Blood Glucose Symptoms. If your glucose readings do not match what you are feeling, use your blood glucose meter; or, if needed, consult your healthcare practitioner.


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 get any sensor readings, alarm/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 you see the  symbol on your receiver display, you must check your sensor reading with a BG meter before making any treatment decisions. Sensor readings may be less accurate and may not reflect your current glucose levels.

WHEN NOT TO USE SENSOR READINGS WHEN MAKING TREATMENT DECISIONS




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



| When to NOT Make a Treatment Decision |
|---|
| <ul style="list-style-type: none">• When you suspect that your sensor blood glucose readings may be inaccurate for any reason.• When your sensor blood glucose readings do not match what you are feeling.• When you are experiencing symptoms that may be due to low or high blood glucose.• When the Receiver displays no glucose information (e.g. an interrupt alert). |

| When to NOT Make a Treatment Decision | |
|---|---|
| <ul style="list-style-type: none">• Whenever you see this symbol on your screen, <div></div> <p>do a fingerstick blood glucose test and make treatment decisions based on that result.</p> | <p>Glucose is Falling/Rising Rapidly (with upwards/ downward pointing arrow): Glucose measured in interstitial fluid may differ substantially from blood glucose levels, particularly at times of rapid glucose change (e.g. after meals, taking insulin, or exercising).</p> <p>Low Glucose or Urgent Low Message: Sensor glucose readings may not accurately reflect your blood glucose.</p> <p>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.</p> <p>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.</p> |



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 RIGHTEST CGMs alone.**





| Trend Arrow | Treatment Decision | | |
|---|---|-------------------------|--------------------------------|
| | Low Glucose (< 70 mg/dL) | Glucose in Target Range | High Glucose (> 250 mg/dL) |
| (No Trend Arrow) | You will see  symbol. Do a fingerstick blood glucose check with your BG meter. Do NOT treat based on your RIGHTEST CGMs. | | |
| 90° upward arrow  | (All Arrow Colors) You will see  symbol. Do a fingerstick blood glucose check with your BG meter. Do NOT treat based on your RIGHTEST CGMs. | | |

| Trend Arrow | Treatment Decision | | |
|---|--|---|---|
| | Low Glucose (< 70 mg/dL) | Glucose in Target Range | High Glucose (> 250 mg/dL) |
| 45° upward arrow  | (Rouge/Red Arrow Colors) You will see  symbol. Do a fingerstick blood glucose check with your BG meter. Do NOT treat based on your RIGHTEST CGMs. | <ul style="list-style-type: none">If you are about to eat, take insulin to cover your meal. Consider increasing your dose a little since your glucose is rising.If you've recently taken insulin or are about to exercise, do nothing and check your glucose reading later. Avoid "Insulin stacking". | (Orange Arrow Color) <ul style="list-style-type: none">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, do nothing 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". |

Treatment Decisions

| Trend Arrow | Trend Arrow | | |
|---|--|--|--|
| | Low Glucose (< 70 mg/dL) | Glucose in Target Range | High Glucose (> 250 mg/dL) |
| Horizontal arrow  | (Rouge/Red Arrow Colors) You will see  symbol. Do a fingerstick blood glucose check with your BG meter. Do NOT treat based on your RIGHTEST CGMs. | <ul style="list-style-type: none"> If you are about to eat, take insulin to cover your meal. If you've recently taken insulin or are about to exercise, do nothing and check your sensor reading later. Avoid "Insulin stacking". | (Orange Arrow Color) <ul style="list-style-type: none"> 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, do nothing 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". |

Treatment Decisions

| Trend Arrow | Trend Arrow | | |
|---|--|--|---|
| | Low Glucose (< 70 mg/dL) | Glucose in Target Range | High Glucose (> 250 mg/dL) |
| 45° downward arrow  | (Rouge/Red Arrow Colors) You will see  symbol. Do a fingerstick blood glucose check with your BG meter. Do NOT treat based on your RIGHTEST CGMs. | <ul style="list-style-type: none"> If you are about to eat, take insulin to cover your meal. Consider taking a lower dose since your glucose is falling. If you've recently taken insulin or have finished exercise, eat some snacks or fast-acting carbs. | (Orange Arrow Color) <ul style="list-style-type: none"> If you are about to eat, take insulin to cover your meal. Consider taking a lower dose since your glucose is falling. If you've recently taken insulin or are about to exercise, do nothing and check your glucose reading later. Avoid "Insulin stacking". |
| 90° downward arrow  | (All Arrow Colors) You will see  symbol. Do a fingerstick blood glucose check with your BG meter. Do NOT treat based on your RIGHTEST CGMs. | | |

XII. RIGHTEST CGMS SPECIFICATIONS

SENSOR INSERTER SPECIFICATIONS

| | |
|---|--|
| Sensor Glucose Range | 40 - 500 mg/dL |
| Sensor Useful Life | up to 14 days |
| Sensor Inserter 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) | IP47 Protected from tools and small wires greater than 1 millimeter. Protected from immersion between 15 centimeters and 1 meter in depth. |
| Inserter 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) |

Specifications

TRANSMITTER SPECIFICATIONS

| | |
|---|--|
| Transmitter Size | 32.8 x 19.8 x 4.15 mm (± 0.5 mm) |
| Transmitter Weight | 3.2 g with battery (± 0.5 g) |
| Power Source | Rechargeable lithium battery (3.7V/25mAh) |
| 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) |
| Power 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 |

Specifications

| | |
|---|---|
| Ingress Protection Rating (when attached to Sensor) | IP 47 Protected from tools and small wires greater than 1 millimeter. Protected from immersion between 15 centimeters and 1 meter in depth. |
| Data Communication | Bluetooth 4.0 Frequency range BLE : 2402 ~ 2480MHz 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 Receiver connect to each other via BLE network. Quality of the connection is in accordance with the Bluetooth Specification v4.0. The RIGHTTEST CGM System is designed to accept radio frequency (RF) communications from recognized and paired display devices only.

Specifications

RECEIVER SPECIFICATIONS

| | |
|---|--|
| Dimension | 126.1 x 68.1 x 15.2 mm with battery and silicone case (±1.0 mm) |
| Weight | 145 g with battery and silicone case (± 8%) |
| Touch Screen Size | 4 inches |
| Power Source | Rechargeable lithium battery (3.7V/1150mAh) |
| Memory Storage | Up to 90 days (typical use) |
| Battery Longevity | 1 days (typical use) |
| Battery Charging Time | 4.5 hours (via AC adapter) |
| Storage Transportation & Operating Conditions | Temperature: 5°C - 45°C (41°F - 113°F) Relative humidity: 10% - 90% |
| Alarm Output | Sound Speaker; Vibration |

Specifications

| | |
|---------------------------|---|
| Data Communication | Glucose data transfer: Bluetooth 4.0 Frequency range BLE : 2402 ~ 2480MHz Maximum RF output power of the product : 2 dBm System pairing: NFC pairing (RFID: 13.56 MHz) |
| Charging Port | USB type C |
| 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°. |
| Power Supply | Input: 100 - 240V AC, 50 - 60 Hz, 0.2A Output: DC5.0V, 1.0A, 5.0W Operating temperature: 0°C ~ 45°C |

Only update authorized by Bionime Corporation is recommended. Any update from unofficial channel may bring security risk.

TRANSMITTER CHARGER SPECIFICATIONS

| | |
|----------------------|---|
| Charger Channel | 1 |
| Indicator | LED (Green/ Amber) |
| Input Port | USB Type A |
| Weight | 10 g (± 1.0) |
| Charger Dimensions | 37.3 x 26.0 x 22.5 mm (± 0.5 mm) |
| Input | DC 5V/18 ~ 20 mA |
| Output | DC 4.2V/18 ~ 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. |
|---------------------------|---|

XIII. CERTIFICATE STATEMENT

RF STATEMENT

This device has been evaluated to meet general RF exposure requirements. The device can be used in a portable exposure condition without restrictions.

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.

⚠ CAUTION :

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

Certificate Statement

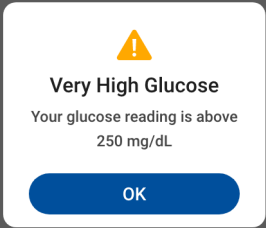

NCC STATEMENT

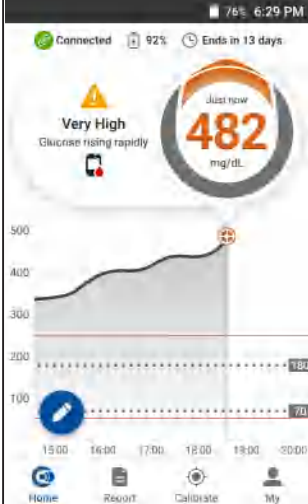

低功率電波輻射性電機管理辦法



「取得審驗證明之低功率射頻器材，非經核准，公司、商號或使用者均不得擅自變更頻率、加大功率或變更原設計之特性及功能。低功率射頻器材之使用不得影響飛航安全及干擾合法通信；經發現有干擾現象時，應立即停用，並改善至無干擾時方得繼續使用。前述合法通信，指依電信管理法規定作業之無線電通信。低功率射頻器材須忍受合法通信或工業、科學及醫療用電波輻射性電機設備之干擾。」

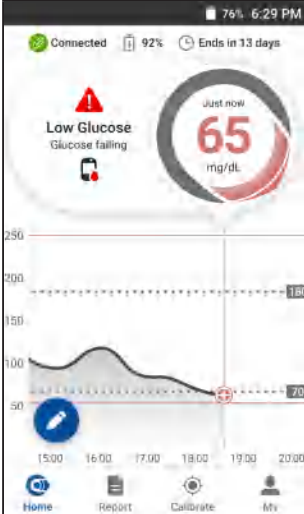

XIV. APPENDIX: ALARM/ALERTS



RECEIVER : GLUCOSE AND SIGNAL LOSS ALERTS



| Screen | Event | Visual & Sound Settings |
|---|--|---|
|  | Very High Alert happens when glucose > 250 mg/dL and is detected to rise or remain steady. | Default Setting: <ul style="list-style-type: none"> Visual Safety Symbol () on Home Screen: Yes. Sound & Vibration Alert: Yes. - Vibrates 3 times and beeps 3 times at the alarm volume following the user settings. Separated by 2s. - Sound & Vibration active unless turned off by user pressing the [OK] button on screen; or glucose is projected to fall. - Very high glucose alert will repeat every 30 minutes or until glucose level returns to the target range. Editable Setting: <ul style="list-style-type: none"> Sound & Vibration can be turned ON/OFF by the user. |

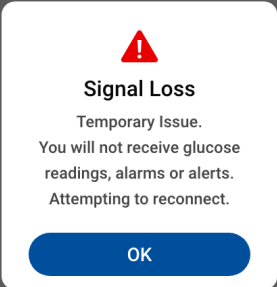
| Screen | Event | Visual & Sound Settings |
|---|--|---|
|  | Very High Alert happens when glucose > 250 mg/dL and is detected to rise or remain steady. | Default Setting: <ul style="list-style-type: none"> Visual Safety Symbol () on Home Screen: Yes. Sound & Vibration Alert: Yes. - Vibrates 3 times and beeps 3 times at the alarm volume following the user settings. Separated by 2s. - Sound & Vibration active unless turned off by user pressing the [OK] button on screen; or glucose is projected to fall. - Very high glucose alert will repeat every 30 minutes or until glucose level returns to the target range. Editable Setting: <ul style="list-style-type: none"> Sound & Vibration can be turned ON/OFF by the user. |

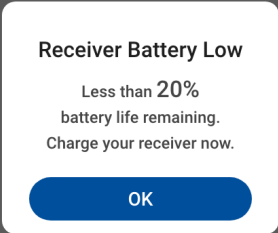
| Screen | Event | Visual & Sound Settings |
|---|--|--|
|  | Low Glucose Alert happens when glucose is between 55 - 70 mg/dL and is detected to fall or remain steady | Default Setting: <ul style="list-style-type: none"> • Visual Safety Symbol () on Home Screen: Yes. • Sound & Vibration Alarm : Yes. - Vibrates 2 times and beeps 2 times at the alarm volume following the user settings. Separated by 1s. - Sound & Vibration active unless turned off by user pressing the [OK] button; or glucose is projected to rise. - Low glucose alert will repeat every 30 minutes or until glucose level returns to the target range. Editable Setting: <ul style="list-style-type: none"> • Sound & Vibration can be turned ON/OFF by the user. |

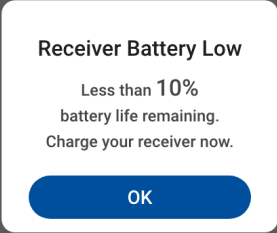
| Screen | Event | Visual & Sound Settings |
|---|--|--|
|  | Low Glucose Alert happens when glucose is between 55 - 70 mg/dL and is detected to fall or remain steady | Default Setting: <ul style="list-style-type: none"> • Visual Safety Symbol () on Home Screen: Yes. • Sound & Vibration Alarm : Yes. - Vibrates 2 times and beeps 2 times at the alarm volume following the user settings. Separated by 1s. - Sound & Vibration active unless turned off by user pressing the [OK] button; or glucose is projected to rise. - Low glucose alert will repeat every 30 minutes or until glucose level returns to the target range. Editable Setting: <ul style="list-style-type: none"> • Sound & Vibration can be turned ON/OFF by the user. |

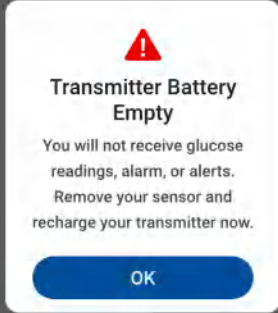
| Screen | Event | Visual & Sound Settings |
|---|--|---|
|  | Urgent Low Alarm happens when glucose is < 54 mg/dL. | Default Setting: <ul style="list-style-type: none"> Visual Safety Symbol () on Home Screen: Yes. Sound & Vibration Alarm : Yes. - Vibrates 2 times and beeps 2 times at highest alarm volume. Separated by 1/2s. - 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: <ul style="list-style-type: none"> Sound & Vibration CANNOT be turned ON/OFF by the user. |

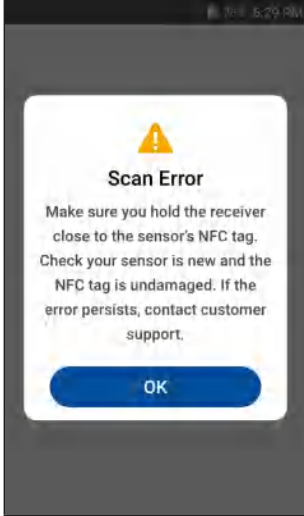
| Screen | Event | Visual & Sound Settings |
|---|--|---|
|  | Urgent Low Alarm happens when glucose is < 54 mg/dL. | Default Setting: <ul style="list-style-type: none"> Visual Safety Symbol () on Home Screen: Yes. Sound & Vibration Alarm : Yes. - Vibrates 2 times and beeps 2 times at highest alarm volume. Separated by 1/2s. - 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: <ul style="list-style-type: none"> Sound & Vibration CANNOT be turned ON/OFF by the user. |


| Screen | Event | Visual & Sound Settings |
|---|--|---|
|  <p>Signal Loss</p> <p>Temporary Issue. You will not receive glucose readings, alarms or alerts. Attempting to reconnect.</p> <p>OK</p> | Transmitter is too far from the receiver or when there is an obstacle (e.g. water, wall) in between transmitter and receiver . | <p>Default Setting:</p> <ul style="list-style-type: none"> • Visual message on the screen: Yes • Sound & Vibration Alert : Yes. <p>- Vibrates 1 time and beeps 1 time at highest alarm volume. Separated by 1s.</p> <p>- Displayed continuously for 5 minutes or until [OK] is pressed.</p> <ul style="list-style-type: none"> • System attempts to reconnect every 5 minutes even if user doesn't press [OK] • System alerts will repeat every 30 minutes. <p>Editable Setting:</p> <ul style="list-style-type: none"> • Sound & Vibration CANNOT be turned ON/OFF by the user. |

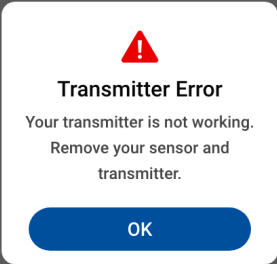
| Screen | Event | Visual & Sound Settings |
|---|---------------------------------|--|
|  <p>Receiver Battery Low</p> <p>Less than 20% battery life remaining. Charge your receiver now.</p> <p>OK</p> | Receiver battery less than 20%. | <p>Default Setting:</p> <ul style="list-style-type: none"> • Visual message on the screen: Yes. • Sound & Vibration Alert : No. |

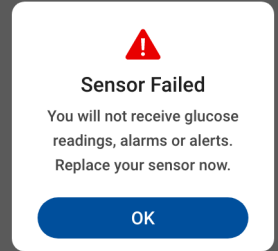
| Screen | Event | Visual & Sound Settings |
|--|---------------------------------|---|
|  <p>Receiver Battery Low</p> <p>Less than 10% battery life remaining. Charge your receiver now.</p> <p>OK</p> | Receiver battery less than 10%. | <p>Default Setting:</p> <ul style="list-style-type: none"> • Visual message on the screen: Yes • Sound & Vibration Alert : Yes. <p>- Vibrates 1 time and beeps 1 time at the alarm volume following the user settings. Separated by 1 second.</p> <p>- Displayed continuously for 5 minutes; or until [OK] pressed; or until connected to AC mains.</p> <p>- System alerts will repeat every 30 minutes.</p> <p>Editable Setting:</p> <ul style="list-style-type: none"> • Sound & Vibration can be turned ON/OFF by the user. |


| Screen | Event | Visual & Sound Settings |
|---|------------------------------------|---|
|  <p>Transmitter Battery Empty</p> <p>You will not receive glucose readings, alarm, or alerts. Remove your sensor and recharge your transmitter now.</p> <p>OK</p> | Transmitter battery less than 10%. | <p>Default Setting:</p> <ul style="list-style-type: none"> • Visual message on the screen: Yes • Sound & Vibration Alert : Yes. <p>- Vibrates 1 time and beeps 1 time at the alarm volume following the user settings. Separated by 1 second.</p> <p>- Displayed continuously for 5 minutes or until [OK] is pressed.</p> <p>- System alerts will repeat every 30 minutes.</p> <p>Editable Setting:</p> <ul style="list-style-type: none"> • Sound & Vibration can be turned ON/OFF by the user. |

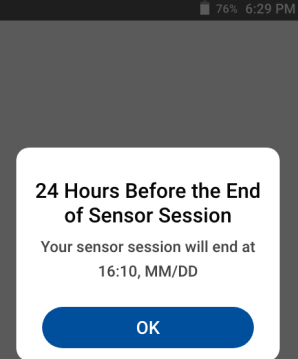
| Screen | Event | Visual & Sound Settings |
|--|---|---|
|  | <ol style="list-style-type: none">1. Receiver scan distance is too far (> 1 cm) away from the NFC tag/mark.2. When the NFC tag/mark is damaged. | <p>Default Setting:</p> <ul style="list-style-type: none">• Visual message on the screen: Yes• Sound & Vibration Alert: No. |

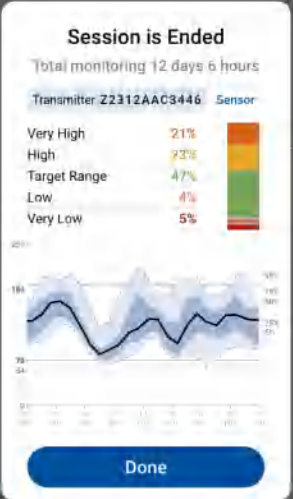
| Screen | Event | Visual & Sound Settings |
|---|---|--|
|  | <ol style="list-style-type: none">1. Transmitter is too far from the receiver or there is an obstacle (e.g. water, wall) in between transmitter and receiver.2. Transmitter battery empty. | <p>Default Setting:</p> <ul style="list-style-type: none">• Visual message on the screen: Yes• Sound & Vibration Alert : No.• [Try again] reconnection attempted Max. 10 times. |

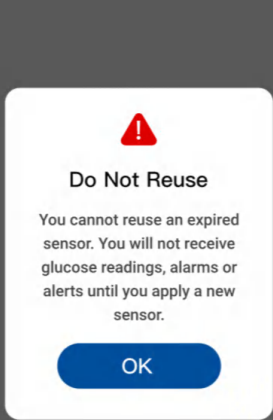
| Screen | Event | Visual & Sound Settings |
|---|-----------------------------|---|
|  <p>The screenshot shows a white dialog box on a dark grey background. At the top is a red triangle with a white exclamation mark. Below it, the text reads: "Transmitter Error", "Your transmitter is not working.", "Remove your sensor and transmitter.", and a blue "OK" button at the bottom.</p> | Transmitter is not working. | <p>Default Setting:</p> <ul style="list-style-type: none"> • Visual message on the screen: Yes • Sound & Vibration Alert : Yes. <p>- Vibrates 1 time and beeps 1 time at the alarm volume following the user settings. Separated by 1s.</p> <p>- Displayed continuously for 5 minutes or until [OK] is pressed.</p> <p>- System alerts will repeat every 30 minutes.</p> |

| Screen | Event | Visual & Sound Settings |
|---|---|---|
|  <p>The screenshot shows a white dialog box on a dark grey background. At the top is a red triangle with a white exclamation mark. Below it, the text reads: "Sensor Failed", "You will not receive glucose readings, alarms or alerts.", "Replace your sensor now.", and a blue "OK" button at the bottom. The status bar at the top shows 76% battery and 6:29 PM.</p> | The Receiver software detects a current error measured by the sensor. | <p>Default Setting:</p> <ul style="list-style-type: none"> • Visual message on the screen: Yes. • Sound & Vibration Alert: Yes. <p>- Vibrates 1 time and beeps 1 time at the alarm volume following the user settings. Separated by 1s.</p> <p>- Displayed continuously for 5 minutes or until [OK] is pressed.</p> <p>- System alerts will repeat every 30 minutes.</p> <p>Editable Setting:</p> <ul style="list-style-type: none"> • Sound & Vibration can be turned ON/OFF by the user. |

| Screen | Event | Visual & Sound Settings |
|---|---|--|
|  | Transmitter temperature is too high. Temporary Issue. Move to a cooler environment below 45°C and wait up to 3 hours. | <p>Default Setting:</p> <ul style="list-style-type: none"> • Visual message on the screen: Yes. • Sound & Vibration Alert : Yes. <p>- Vibrates 1 time and beeps 1 time at the alarm volume following the user settings. Separated by 1s.</p> <p>- Displayed continuously for 5 minutes or until [OK] is pressed.</p> <p>- System alerts will repeat every 30 minutes.</p> <p>Editable Setting:</p> <ul style="list-style-type: none"> • Sound & Vibration can be turned ON/OFF by the user. |

| Screen | Event | Visual & Sound Settings |
|---|---|---|
|  | When sensor is to be expired in less than 24 hours. | <p>Default Setting:</p> <ul style="list-style-type: none"> • Visual message on the screen: Yes. • Sound & Vibration Alert: No. |

| Screen | Event | Visual & Sound Settings |
|---|---------------------------------|---|
|  | Your sensor session is expired. | <p>Default Setting:</p> <ul style="list-style-type: none"> • Visual message on the screen: Yes. • Sound & Vibration Alert : Yes. <p>- Vibrates 1 time and beeps 1 time at the alarm volume following the user settings. Separated by 1s.</p> <p>- Displayed continuously for 5 minutes or until [OK] is pressed.</p> <p>Editable Setting:</p> <ul style="list-style-type: none"> • Sound & Vibration can be turned ON/OFF by the user. |

| Screen | Event | Visual & Sound Settings |
|---|---|--|
|  | When the Receiver software detects a sensor that has been used. | <p>Default Setting:</p> <ul style="list-style-type: none"> • Visual message on the screen: Yes • Sound & Vibration Alert : Yes. <p>- Vibrates 1 time and beeps 1 time at the alarm volume following the user settings. Separated by 1s.</p> <p>- Displayed continuously for 5 minutes or until [OK] is pressed.</p> <p>Editable Setting:</p> <ul style="list-style-type: none"> • Sound & Vibration can be turned ON/OFF by the user. |

Appendix

XV. APPENDIX: CUSTOMER INFORMATION

CUSTOMER SERVICE

We sincerely like to provide complete, considerate services to our customers. Please review all the instructions to make sure you are performing the steps correctly. If you have any questions or in case of problems with the RIGHTEST CGMs, please contact your local Bionime customer service.

If you are in the serious incidents caused by the RIGHTEST product, please call local emergency service for help. Please feel free to report your incident to us and the local competent authority.

WARRANTY

The manufacturer warrants that your RIGHTEST Receiver, 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 RIGHTEST CGMs Products.

Please complete and return the enclosed warranty card to your local Bionime affiliate.

If any of the RIGHTEST CGMs Products are exposed to a high temperature difference, please wait for 30 minutes before measurement.