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EN

RIGHTEST™

Continuous Glucose
Monitoring System



User Manual

Use with a receiver

⚠ 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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Indications for Use & Statement and Advisory

I. INDICATIONS FOR USE & STATEMENT AND ADVISORY

INDICATIONS FOR USE

The RIGHTEST Continuous Glucose Monitoring System (the RIGHTEST CGMs) is indicated for detecting glycaemia trends and for the management of diabetes in persons age 4 and older. For the younger user, the personal representative of a minor shall supervise their use with the RIGHTEST CGMs. 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 Continuous Glucose Monitoring System (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 (HR310) 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.


Safety Information

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 (HR310) 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.

Safety Information

Not Getting Urgent Alarm/Alert. The RIGHTEST CGMs Receiver (HR310) 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 2 consecutive readings (or 10 minutes) regardless your alarm/alert settings. There are no alarm/alerts in the following situations.

- When either your receiver (HR310) or transmitter battery is dead.
- When your receiver (HR310) 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 (HR310) 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

Safety Information



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.

DO NOT Use If Any Components Appear to be Damaged or Past its Expiration Date.

A damaged or cracked sensor inserter, transmitter or receiver (HR310) 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 written in YYYY-MM-DD (Year-Month-Day) format on your sensor inserter package.

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.

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.

DO NOT Place the Sensor on Any Area of the Body other than the Upper Arm or Abdomen: 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 2.5 cm (1 inch) 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.

Safety Information

PRECAUTIONS :

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, Sensor, and Single-use Transmitter (HM310): The inserter is pre-loaded with a sensor. The entire sensor inserter package is sterilized and designed for single use. HM310 transmitters are designed for single-use and are not rechargeable. 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.

DO NOT Share Your Re-chargeable Transmitter (HM312): The RIGHTEST CGMs' HM312 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, alerts/alarms, etc., may be wrong.

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 (HR310) 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 (HR310) is Damaged, or If It Could Fall into Water.

The receiver (HR310) and accessories are enclosed without protection from the ingress of water. Do not submerge these components in water. If the receiver (HR310) has fallen into water, do not touch it until you unplug it from any electrical outlet. Touching the receiver (HR310) while it is wet or damaged could result in electric shock or no glucose results.

Test Your Receiver (HR310) Regularly. Test your receiver (HR310)'s speaker and vibration functions regularly. If you are in any doubt, contact a manufacturer authorized dealer for technical support.

Interfering Substance Risks. Acetaminophen may falsely raise sensor readings to higher than they really are.

Safety Information

⚠ PRECAUTIONS :

Keep Your Receiver (HR310) Close. Be sure your receiver (HR310) 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 (HM312) every time you start with a new sensor. When plugged into an adapter that is connected to a standard household electrical outlet (100 to 240 VAC, 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 (HR310) 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 (HR310) in bright sunlight, you may need to seek a shady location.















Symbol Definitions

III. SYMBOL DEFINITIONS

The following symbols apply to the RIGHTEST Continuous Glucose Monitoring System

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	IP47	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
IP22	Protected against insertion of fingers and dripping water.		Keep Dry
IP21	Protected from touch by fingers and objects greater than 12 millimeters. Protected from condensation.		MR Unsafe
	Serial Number	Rx Only	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

RIGHTEST Continuous Glucose Monitoring System (with re-chargeable Transmitter)

1. SENSOR INSERTER: Designed with a pre-loaded sensor.

2. TRANSMITTER (HM312): Rechargeable for multiple-use.

3. Receiver (HR310): Blood glucose information display.

4. POWER SUPPLY: AC power adapter & USB cable.

5. TRANSMITTER USB CHARGER: A USB charging dock for the transmitter (HM312).

6. STORAGE VIAL: Storage for the transmitter and transmitter USB charger to keep them dry.



Getting to Know Your RIGHTEST CGMs

RIGHTEST Continuous Glucose Monitoring System (with single-use Transmitter)

1. SENSOR INSERTER: Designed with a pre-loaded sensor.
2. TRANSMITTER (HM310): Non-rechargeable transmitter for single-use.
3. Receiver (HR310): Blood glucose information display.
4. POWER SUPPLY: AC power adapter & USB cable.



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 5 minutes. The system is comprised of three main components: (a) a Sensor, (b) a Bluetooth Transmitter and (c) a receiver (HR310). The sensor is pre-loaded inside an Inserter. The sensor is inserted under your skin and measures your interstitial glucose level test glucose every 5 minutes. The transmitter will be either rechargeable or non-rechargeable as chosen by the user users' choices. The transmitter wirelessly sends data to the receiver (HR310) every 5 minutes. The receiver (HR310) 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.

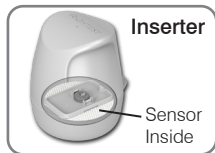
These features include:

- Receiver (HR310)'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 (HR310) alerts you.
- Receiver (HR310) 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 2 readings (or 10 minutes).
- Urgent alert/alarm settings at 54 mg/dL or below; or below 70 mg/dL and continuously falling for the following 2 readings (or 10 minutes) cannot be changed or turned off.
- Receiver (HR310) 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 (HR310). 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 (HM312/ HM310)

The transmitter sends your glucose data from the sensor to the Receiver (HR310). The HM312 transmitter is equipped with a rechargeable battery. The HM310 transmitter internal battery is non-rechargeable.



Receiver (HR310)

The receiver (HR310) displays glucose values and alerts you to hypo/hyperglycemia.

Getting to Know Your RIGHTEST CGMs

ACCESSORIES



TRANSMITTER USB CHARGER

A USB charger is included with your HM312 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 (HR310). It connects to an AC mains outlet (100 to 240 VAC, 50/60 Hz).

Before Getting Started

V. BEFORE GETTING STARTED

CHARGING BASICS

Before using the system for the first time, charge the receiver (HR310) for a complete charging cycle without interruption. If your system comes with re-chargeable transmitters (HM312), a transmitter charger is supplied along with your transmitter package. Rechargeable transmitters (HM312) 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 (HR310) takes about 4 hours. For the re-chargeable transmitter (HM312) it takes about 2 hours when using the supplied USB adapter plugged into a standard household electrical outlet (100 to 240 VAC, 50/60Hz). It is recommended to use only the supplied USB cable and USB power adapter. To ensure the best performance every day, all day, plug in your receiver (HR310) to its charger at the end of the day and charge it up overnight.

CHARGING THE Receiver (HR310)

⚠️ WARNINGS :

Not Getting Urgent Alarm/Alert. There are no alarm/alerts, when your receiver (HR310) is turned off or its battery is dead.

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 severe low or high glucose events.

⚠️ PRECAUTIONS :

Use Charger as Directed. Use only the AC power adapter, USB cable and USB charger provided with the RIGHTEST CGMs when charging your receiver (HR310) 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 (HR310) to its charger at the end of the day and charge it up overnight.

Do NOT Use If the Receiver (HR310) is Damaged, or If It Could Fall into Water. The Receiver (HR310) and accessories are enclosed without protection from the ingress of water. Do not submerge these components in water. If the receiver (HR310) has fallen into water, do not touch it until you unplug it from any electrical outlet. Touching the receiver (HR310) while it is wet or damaged could result in electric shock or no glucose results.

Before Getting Started



1. Connect the micro-USB plug of the charging cable to the micro-USB input of the receiver (HR310).

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 (HR310)

From the receiver (HR310) 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 (HR310) is charging, you will see lightning bolt in the middle of the battery icon. The receiver (HR310) utilizes an intelligent battery charging technology that prevents overcharging.



CHARGING TRANSMITTER

⚠ **WARNINGS :**

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

Modification of The System is Not Allowed: Do not modify or tamper with any components or accessories of the RIGHTEST CGMs. Only use USB charging units provided by Bionime. Otherwise, you could damage the integrity of the system and put yourself at risk especially when you have severe low or high glucose events.

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

PRECAUTIONS Use only the AC power adapter, USB cable and USB charger provided with the RIGHTEST CGMs when charging your receiver (HR310) 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 (HM312) every time you start with a new sensor. When plugged into a standard household electrical outlet (100 to 240 VAC, 50/60Hz), 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 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 (HR310) during entire wear period (14 days).

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



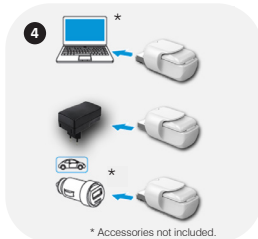
2. Make sure the alignment notch of the transmitter is facing the charger's transmitter compartment with the transmitter mark (📶) facing up. With the transmitter outer frame between your fingers, steadily slide the transmitter all the way into the compartment.



Before Getting Started



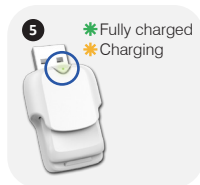
3. With the transmitter securely inside its charger compartment, turn over the charger to the back side and slide the lock button outwards.



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 240 VAC, 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 500mA 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 (HR310)
- 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 (HR310) to make a sensor-transmitter pair. If the instructions provided do not work, the receiver (HR310) will display an error message. **Every time you begin the use of a new sensor, scan the codes on both the sensor inserter package and on the transmitter.** The system will not start if you fail to scan the codes.

Set Up Your RIGHTEST CGMs

1. Get your receiver (HR310).
2. If your receiver (HR310) is OFF, press and hold the **[Power]** button for 2 seconds to turn ON.
If your receiver (HR310) is ON, press the **[Power]** button briefly to wake up its display.

 **NOTE :**

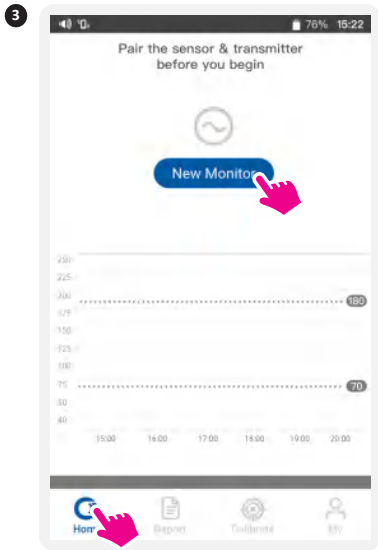
If using the receiver (HR310) for the first time, follow prompts to set the date, time and your glucose target & alerts.

2



Set Up Your RIGHTEST CGMs

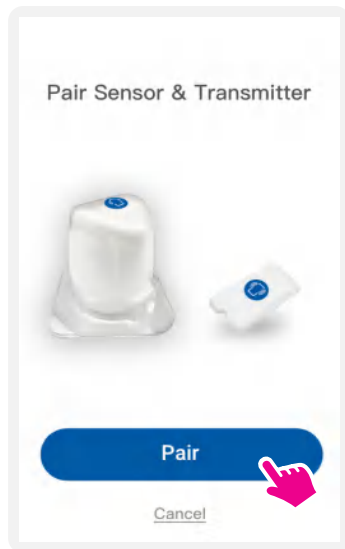
3. Tap **[Home]** at the bottom of your receiver (HR310) screen. Then, tap **[New Monitor]** to start a new monitoring session.




Set Up Your RIGHTEST CGMs

4. When the receiver (HR310) prompts you to pair the sensor & transmitter, choose **[Pair]**.

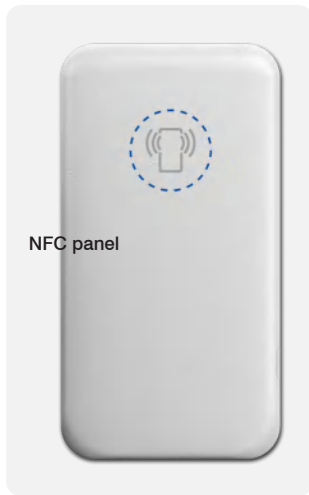
4




Set Up Your RIGHTEST CGMs


5. Locate the NFC panel at the top of your receiver (HR310)'s back cover. The center of NFC panel is engraved with a  mark.

5



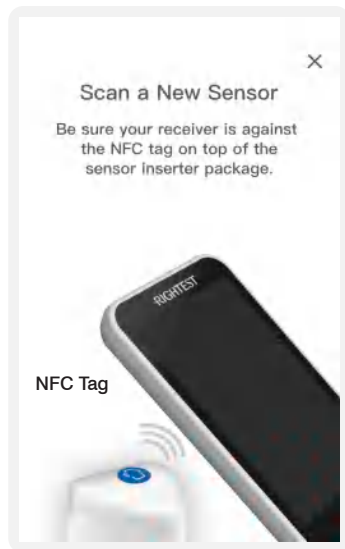
Set Up Your RIGHTEST CGMs

6. Tap the receiver (HR310)'s NFC panel against the  tag on top of the sensor inserter package until you hear a “beep” sound.

 **NOTE :**

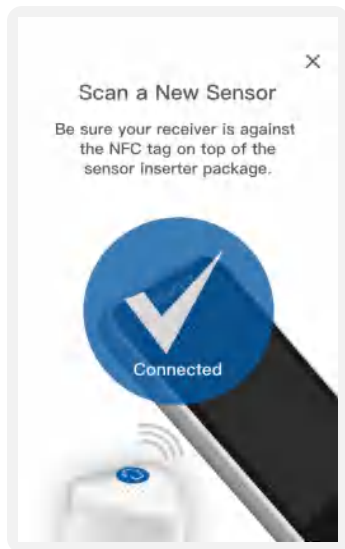
Be sure your receiver (HR310)'s NFC panel is within 1cm (3/8”) of the NFC tag/mark when you scan the codes.

6




Set Up Your RIGHTEST CGMs

7. Once connected, pairing confirmation is displayed as by checkmark (✓) on the receiver (HR310) screen.



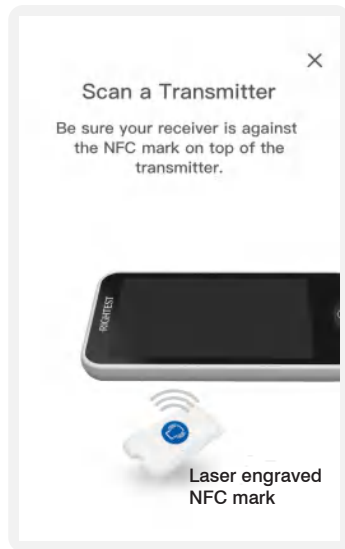
Set Up Your RIGHTEST CGMs

8. Tap receiver (HR310)'s NFC panel against the laser engraved NFC mark (📶) on the top of transmitter until you hear a “beep” sound.

 **NOTE :**

Be sure your receiver (HR310)'s NFC panel is within 1cm (3/8”) of the NFC tag/mark when you scan the codes.

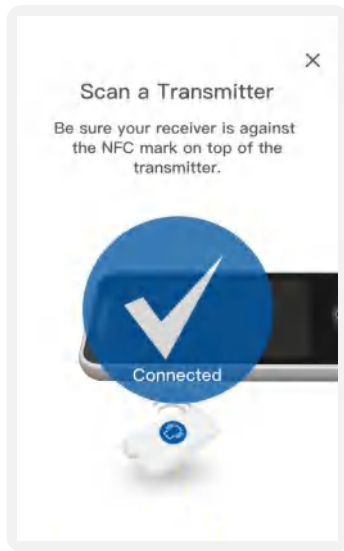
8



Set Up Your RIGHTEST CGMs

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

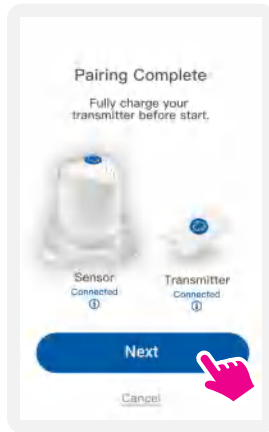
9



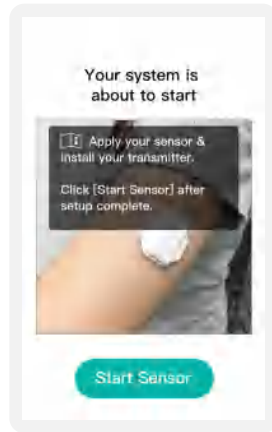
Set Up Your RIGHTEST CGMs

10. When the receiver (HR310) displays “Pairing Complete”, press **[Next]**.
11. 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]**.

10



11



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 or

Abdomen: Placing the sensor on other areas of the body has not been tested and the risks are unknown.

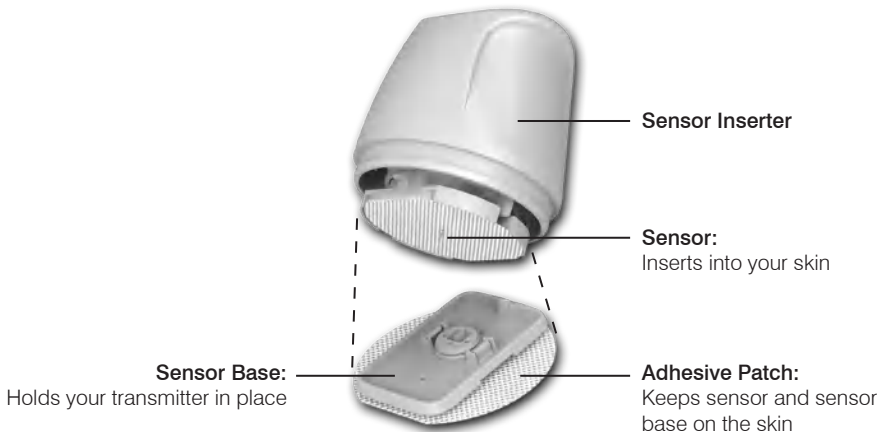
Select an Appropriate Sensor Insertion Site: Do NOT place the sensor on skin that is painful to touch, raised (higher than surrounding skin), crusting or bleeding; or on areas with scars, tattoos or moles. Select a skin area that stays flat during normal daily activities. Choose a site that is greater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

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 Sensor:

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



NOTE :

Use a different site for the next sensor insertion.

2. Wipe the insertion site with an alcohol wipe 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.



NOTE :

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. approximately for 2 minutes until the site dried out.
7. Discard the inserter and its package according to local regulations.

6



Set Up Your RIGHTEST CGMs

ATTACH YOUR TRANSMITTER

⚠ **WARNINGS :**

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

⚠ **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 (HR310) 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 (HM312). The RIGHTEST CGMs' HM312 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 (HR310) and transmitter. Using different chargers or AC power adapters could damage the system or cause fire.

Set Up Your RIGHTEST CGMs

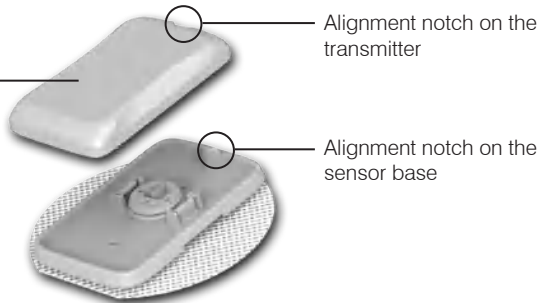
Plug in to Charge. Be sure to fully charge your transmitter (Model HM312) every time you start with a new sensor. When plugged into a standard household electrical outlet (100 to 240 VAC, 50/60Hz), the transmitter battery requires approximately 2 hours to fully charge using the transmitter charger supplied 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:

2 options available:

- HM312. Rechargeable for multiple-use
- HM310. Non-rechargeable for single-use



Set Up Your RIGHTEST CGMs

Attach your transmitter after you insert a sensor.

- If you are using the rechargeable transmitter (HM312), 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 rechargeable transmitter (HM312), make sure it is fully charged. Do not remove your transmitter until your sensor session is over.
- Single-use transmitter (HM310) has sufficient battery life to function as intended. Discard the transmitter (HM310) according to local regulations after each use.

Follow these steps to install your Transmitter:

1. Get your transmitter.



NOTE :

If using the re-chargeable transmitter (HM312), 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.

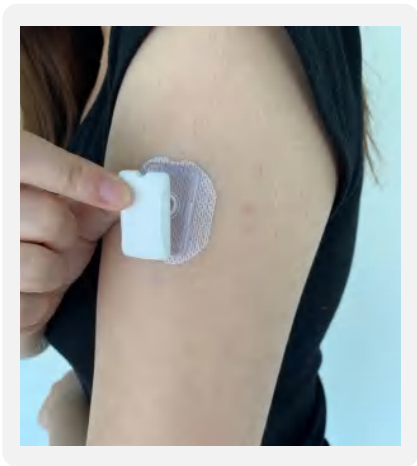
2



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



Set Up Your RIGHTEST CGMs

START SENSOR WITH THE RECEIVER (HR310)

⚠ **WARNING :**

Use a Blood Glucose (BG) Meter. During the first 2-hour sensor warm-up period when you start 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.

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 severe low or high glucose events.

⚠ **PRECAUTIONS :**

Use Charger as Directed: Use only the AC power adapter, USB cable and USB charger provided with the RIGHTEST CGMs when charging your receiver (HR310) and transmitter. Using different chargers or AC power adapters could damage the system or cause fire.

Do NOT Use If the receiver (HR310) is Damaged, or If It Could Fall into Water. The receiver (HR310) and accessories are enclosed without protection from the ingress of water. Do not submerge these components in water. If the receiver (HR310) has fallen into water, do not touch it until you unplug it from any electrical outlet. Touching the Receiver (HR310) while it is wet or damaged could result in electric shock or no glucose results.

Test Your Receiver (HR310) Regularly. Test your receiver (HR310)'s speaker and vibration functions regularly. If you are in any doubt, contact a manufacturer authorized dealer for technical support.

Set Up Your RIGHTEST CGMs

Keep Your Receiver (HR310) Close. Be sure your receiver (HR310) 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.

Plug in to Charge. To best protect yourself from not getting the alarm/alerts due to a depleted battery, plug in your receiver (HR310) to its charger at the end of the day and charge it up overnight.

Set Up Your RIGHTEST CGMs

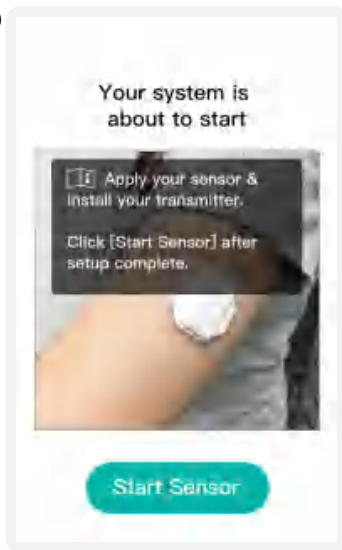


NOTE :

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 (HR310) displays “Your system is about to start, press **[Start Sensor]**”.

1



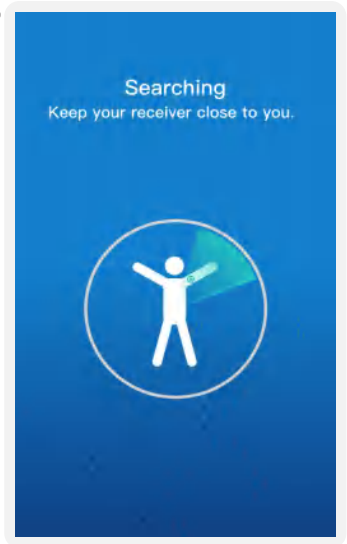
Set Up Your RIGHTEST CGMs

NOTE :

If your receiver (HR310) 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 (HR310) will automatically start searching for your sensor-transmitter pair. Keep your receiver (HR310) close to you.

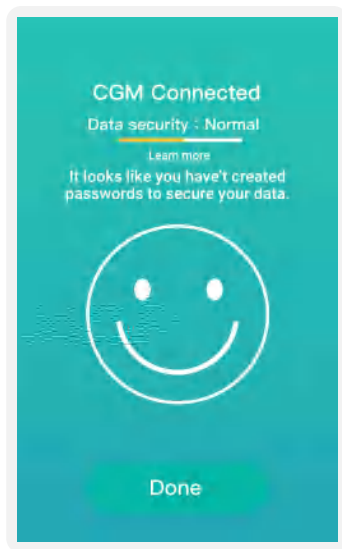
2



Set Up Your RIGHTEST CGMs

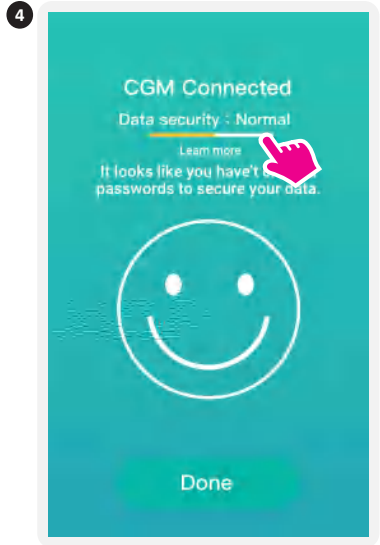
3. Wait for successful connection confirmation with a 😊 graphic.

3



Set Up Your RIGHTEST CGMs

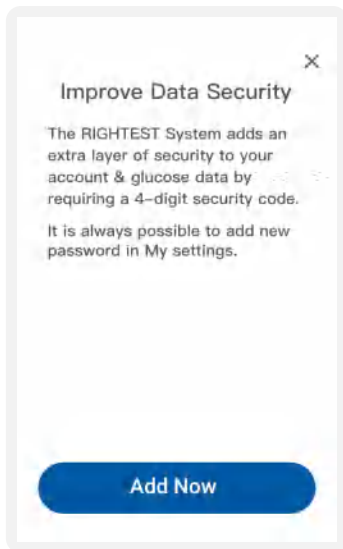
4. If you want to add a data security number press [Learn more](#). If you do not want to add a security number, then proceed to step 7.



Set Up Your RIGHTEST CGMs

5. Press **[Add Now]** to configure your 4-digit security code.

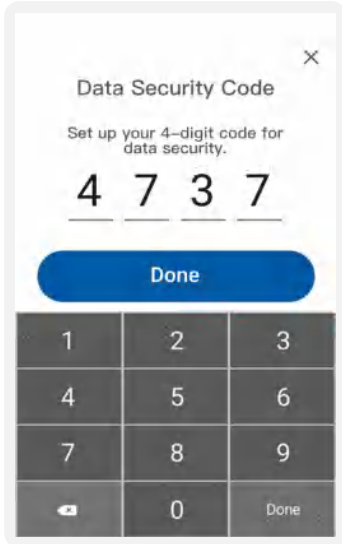
5



Set Up Your RIGHTEST CGMs

6. You will be prompted to enter your personal security code. Then press **[Done]**.

6



×

Data Security Code

Set up your 4-digit code for data security.

4 7 3 7

Done

1	2	3
4	5	6
7	8	9
⌫	0	Done

Set Up Your RIGHTEST CGMs

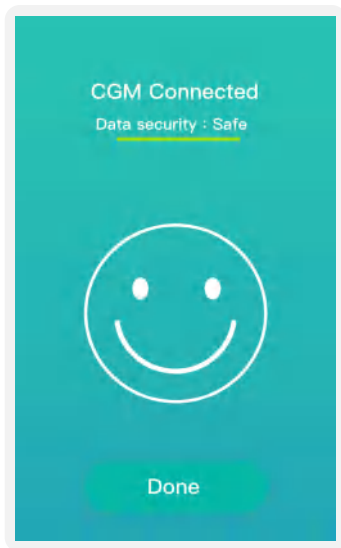
7. Press [**Done**] then wait 2 hours for the sensor warmup.

7



NOTE :

You won't get any sensor readings, alarms or alerts until your system begins to transmit data. Use a blood glucose meter to make treatment decisions during the sensor warmup.



Set Up Your RIGHTEST CGMs

8. The receiver (HR310) displays the sensor warmup progress and remaining warmup time. When the sensor warmup is complete, “Warmup” disappears from your display.

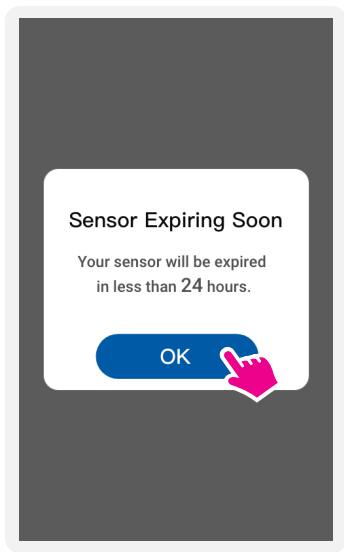


Ending a Monitoring Session

VII. ENDING A MONITORING SESSION

You will receive a “Sensor Expiring Soon” alert on your receiver (HR310) 24 hours prior to monitoring ending. Press **[OK]** to confirm you have read this alert .

Ending a Monitoring Session

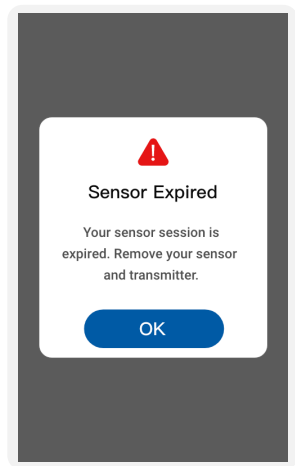


Ending a Monitoring Session

END THE MONITORING SESSION

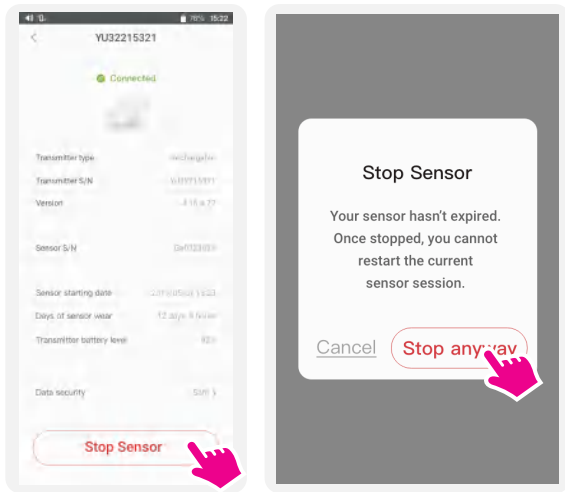
Before you remove the sensor. Either:

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



Ending a Monitoring Session

- End the monitoring session early by selecting the [Stop Sensor] option 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 a HM312 Transmitter. HM312 Transmitters are reusable after recharging. You may discard disposable HM310 transmitters.

Ending a Monitoring Session

1



3



4



Understand Your Glucose Readings

VIII. UNDERSTAND YOUR GLUCOSE READINGS

Your sensor glucose readings appear on your receiver (HR310) 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 (HR310)'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 (HR310) Home Screen


The screenshot shows the Receiver (HR310) Home Screen with the following callouts:

- Sounds & Vibration**: Points to the volume icon in the status bar.
- System connection status**: Points to the 'Connected' status and the 92% battery icon.
- Receiver (HR310) battery level**: Points to the 76% battery icon in the status bar.
- Days until sensor expiration**: Points to the 'End in 13 days' indicator.
- Glucose High/Low Alerts**: Points to the 'Very High' alert with a yellow warning icon and the text 'Glucose rising rapidly'.
- Trend Arrow**: Points to the upward-pointing arrow above the glucose reading.
- Glucose Reading**: Points to the '329 mg/dL' value.
- Transmitter level**: Points to the transmitter icon below the reading.
- Check Blood Glucose**: Points to the smartphone icon with a red drop, accompanied by the text: 'When you see this symbol, you must check your blood glucose value with a meter before making any treatment decisions.'
- Most recent data point**: Points to the orange dot on the trend line graph.
- Target Glucose Range**: Points to the dashed lines on the graph representing the target range.
- Add Notes**: Points to the blue square icon with a white note symbol.

Understand Your Glucose Readings



GLUCOSE INFORMATION

Your most recent glucose reading is displayed inside a circle with an arrow on top of the receiver (HR310) 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 projected 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 projected to rise or remain steady.
- When your glucose is at or less than 70 mg/dL, and is projected 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.

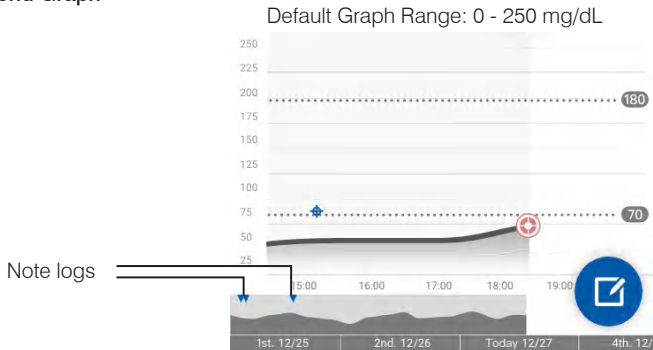
***"glucose falling/rising rapidly" means the glucose rate of change is at or more than 2 mg/dL per minute.

Understand Your Glucose Readings

TREND GRAPH

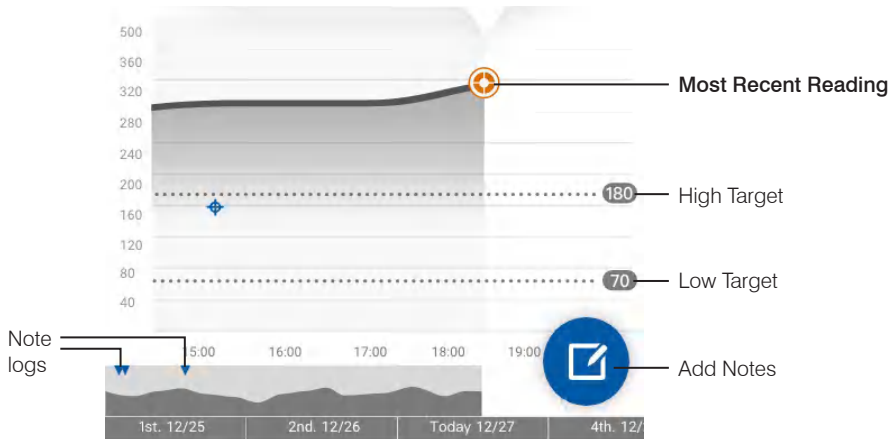
The trend graph is displayed on the lower portion of the screen. It shows your glucose trend for the past 6 hours. The graph adds one reading every 5 minutes. The most recent data point is marked by an open-target double circle at the right end of the plot. The sensor glucose reading range is 40 - 500 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

Reproduced Graph Range: 0 - 500 mg/dL



Understand Your Glucose Readings

ADD NOTES

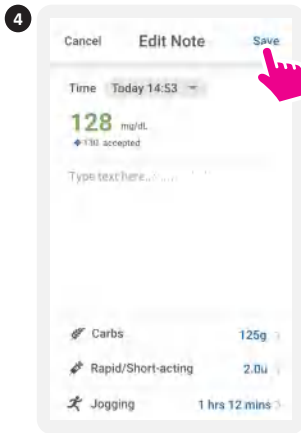
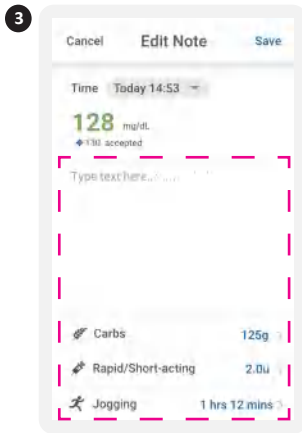
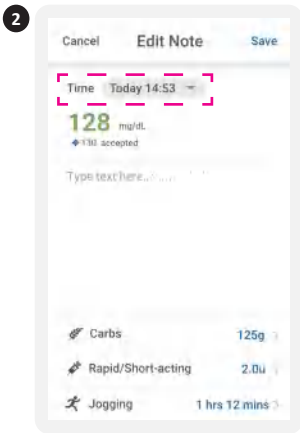
1. From the **Home** screen, add a note by tapping the  symbol in the lower right corner of the screen.

1



Understand Your Glucose Readings

2. Make sure the time is correct.
3. Select the options (carbs, insulin, exercise) then follow the prompts. You can type in other details such as meals, food or medication you take.
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 (HR310) screen. The screen will return to the **Home** screen showing the most recent glucose information after 2 minutes of non-use. Alternatively, tap the **[Back]** button.

Understand Your Glucose Readings



Understand Your Glucose Readings

HIGH/LOW READING

If **HIGH** appears on your receiver (HR310) 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 (HR310) 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

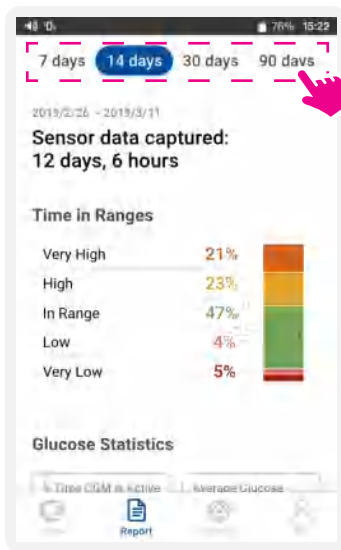
IX. REVIEW YOUR GLUCOSE HISTORY

Your receiver (HR310) 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 (HR310). Calibrating your RIGHTEST CGMs is optional. The calibration option 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.

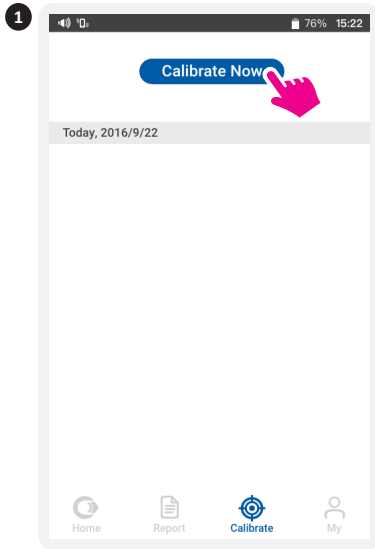
Calibration (Optional)

- 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 (HR310) 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]**.



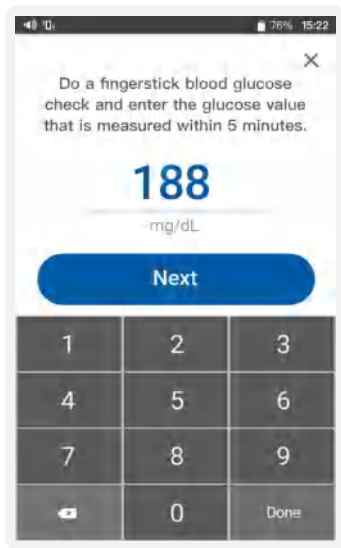
Calibration (Optional)

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 :

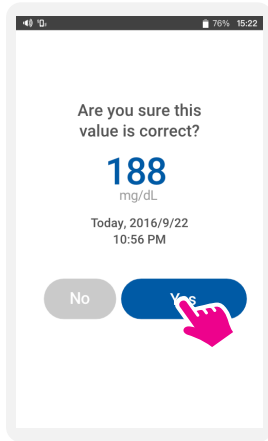
Make sure you enter the exact value that is measured with 5 minutes.



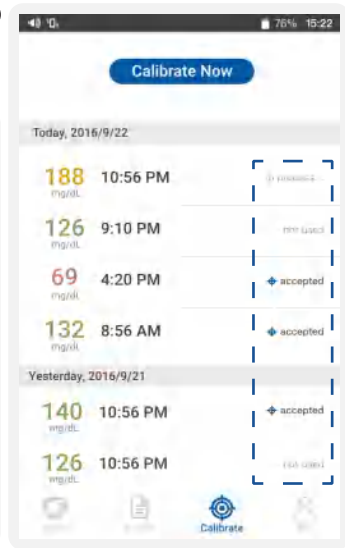
Calibration (Optional)

3. You will see a prompt from receiver (HR310). 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.

3



4



Treatment Decisions

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 (HR310) 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.

Treatment Decisions

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
• 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.
• If you have taken acetaminophen (Tylenol) medications within 6 hours of decision making.
• When the Receiver (HR310) 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,  <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>



Treatment Decisions

TREND ARROWS AND TREATMENT DECISIONS



Trend arrows show the direction and rate of change of your glucose to give you an idea of where your glucose is going. The following table gives you some ideas on how you may use the arrows when considering your treatment. **NEVER make a treatment decision based on the 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.		
0°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.		





Treatment Decisions

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.	(No Trend Arrow) <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.		

Specifications

XII. RIGHTEST CONTINUOUS GLUCOSE MONITORING SYSTEM 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 3048 metres (0 to 10,000 ft)

Specifications

Inserter Size	51.8 mm*57.0 mm*61.3 mm (+/- 0.5 mm)
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Sterilization	Sterilized by radiation
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Usage	Single use (disposable)
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Specifications

Transmitter Specifications

Model	HM312	HM310
Transmitter Size	32.8 mm x 19.8 mm x 4.15 mm (+/- 0.5 mm)	
Transmitter Weight	3.2g with battery (+/- 0.5 g)	
Power Source	Rechargeable lithium battery (3.5 ~ 4.2V/25mA)	CR 1225 Lithium Battery
Storage Transportation & Operating Conditions	Temperature: 5°C - 45°C (41°F - 113°F) Relative humidity: 10% - 90%	
Operating and Storage Altitude	0 to 3048 metres (0 to 10,000 ft)	
Battery Run Time	Up to 25 days (based on full charge)	Up to 20 days (single use)
Power Charging Time	2 hours (via AC adapter)	Non-rechargeable

Specifications

Model	HM312	HM310
Memory Storage	14 days of glucose data (glucose readings stored every 5 minutes)	14 days of glucose data (glucose readings stored every 5 minutes)
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.	
Protection Against Electrical Shock	Type BF applied part	
Data Communication	Bluetooth 4.2	
Data Communication Range	Up to 6 meters (20 feet)	

Specifications

Receiver (HR310) Specifications

Dimension	122*65*12 mm (+/- 0.5 mm)
Weight	124.5 g with battery (+/- 0.5 g)
Touch Screen Size	4 inches
Power Source	Rechargeable lithium battery; Input: 5V DC/1A
Memory Storage	Up to 90 days (typical use)
Battery Longevity	3 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
Data Communication	Glucose data transfer: Bluetooth 4.2 System pairing: NFC pairing
Charging Port	USB type C

Specifications

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 ~ 50 - 60Hz, 0.2A Output: DC5.0V, 1.0A, 5.0W Operating temperature: 0° ~ 45°
Compatible AC Power Adapter	Output: DC5.0V, 0.01-3.00 A, 15W Model: UES18LCPU-XXXXYYSPA Manufacturer: Dongguan Shilong Fuhua Electronic Co., Ltd.

Specifications

Transmitter Charger Specifications (for Transmitter model HM312)

Charger Channel	1
Indicator	LED (Green/ Amber)
Input Port	USB Type A
Weight	25 g (+/- 0.5 g)
Charger Dimensions	40*26*23 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%
Ingress Protection Rating	IP21 Protected from touch by fingers and objects greater than 12.5 millimeters. Protected from condensation.

Frequency rangeà BLE : 2402~2480MHz / RFID: 13.56 MHz

Maximum RF output power of the productà -5.37 dBm

Versions of softwareà : HR310_0.9.0.0

Versions of firmwareà : HM312_A001 / HR310_A001

Certificate Statement

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.

Certificate Statement

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

This device is compliant with Article 12 and Article 14 of the Administrative Regulations on Low Power Radio Waves Radiated Devices.

低功率電波輻射性電機管理辦法

第十二條 經型式認證合格之低功率射頻電機，非經許可，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。

第十四條 低功率射頻電機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。

前項合法通信，指依電信法規定作業之無線電通信。低功率射頻電機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。

Article 12

Without permission granted by the NCC, any company, enterprise, or user is not allowed to change frequency, enhance transmitting power or alter original characteristic as well as performance to a approved low power radio-frequency devices.

Article 14

The low power radio-frequency devices shall not influence aircraft security and interfere legal communications; If found, the user shall cease operating immediately until no interference is achieved.



The said legal communications means radio communications is operated in compliance with the Telecommunications Act.



The low power radio-frequency devices must be susceptible with the interference from legal communications or ISM radio wave radiated devices.

Appendix



XIV. APPENDIX: ALARM/ALERTS



Receiver (HR310): GLUCOSE AND SIGNAL LOSS ALERTS

Screen	Event	Visual & Sound Settings
	<p>Very High Glucose: > 250 mg/dL and when the glucose is projected to rise or remain steady.</p>	<p>Default Setting:</p> <ul style="list-style-type: none">• Visual Safety Symbol () on Home Screen: Yes• Sound & Vibration Alert : ON <p>Editable Setting:</p> <ul style="list-style-type: none">• Sound & Vibration can be turned ON/OFF by the user.

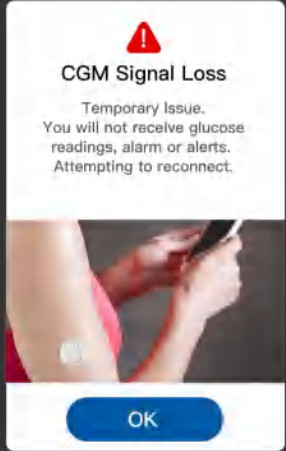
Screen	Event	Visual & Sound Settings
	<p>Low Glucose: 55 - 70 mg/dL and when the glucose is projected to fall or remain steady.</p>	<p>Default Setting:</p> <ul style="list-style-type: none"> • Visual Safety Symbol () on Home Screen: Yes • Sound & Vibration Alert : ON <p>Editable Setting:</p> <ul style="list-style-type: none"> • Sound & Vibration can be turned ON/OFF by the user.

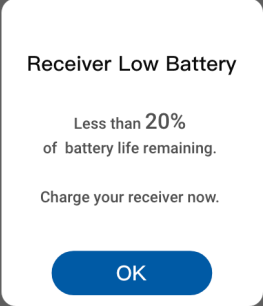
Appendix

Screen	Event	Visual & Sound Settings
	<p>Urgent Low Glucose: ≤ 54 mg/dL</p>	<p>Default Setting:</p> <ul style="list-style-type: none">• Visual Safety Symbol () on Home Screen: Yes• Sound & Vibration Alert : ON <p>Editable Setting:</p> <ul style="list-style-type: none">• NO

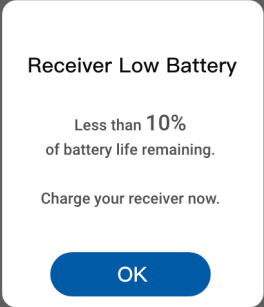
Screen	Event	Visual & Sound Settings
	<ol style="list-style-type: none"> 1. < 70 mg/dL regardless of the projected trend direction. 2. Glucose rising or falling at or more than 2 mg/dL per minute. 3. When there is no glucose value or trend arrow (High/Low). 4. During the first 2 hour sensor warmup period. 	<ul style="list-style-type: none"> • Visual glucose check symbol () on Home Screen Home Screen: Yes • Sound & Vibration Alert : ON <p><u>Editable Setting:</u></p> <ul style="list-style-type: none"> • NO


Appendix

Screen	Event	Visual & Sound Settings
	<p>Transmitter is too far from the receiver (HR310) or when there is an obstacle (e.g. water, wall) in between transmitter and receiver (HR310).</p>	<p><u>Default Setting:</u></p> <ul style="list-style-type: none">• Visual message on the screen: Yes• Sound & Vibration Alert : ON• System attempts to reconnect every 5 minutes even if user doesn't press [OK] <p><u>Editable Setting:</u></p> <ul style="list-style-type: none">• NO

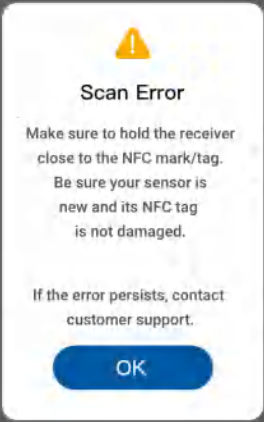
Screen	Event	Visual & Sound Settings
 A screenshot of a mobile notification screen. The background is dark gray. In the center, there is a white rounded rectangle containing the following text: "Receiver Low Battery" in bold, "Less than 20% of battery life remaining." in a smaller font, and "Charge your receiver now." in a smaller font. At the bottom of the white rectangle is a blue rounded button with the text "OK" in white. <p>Receiver Low Battery</p> <p>Less than 20% of battery life remaining.</p> <p>Charge your receiver now.</p> <p>OK</p>	<p>Receiver (HR310) battery less than 20%.</p>	<p>Default Setting:</p> <ul style="list-style-type: none">• Visual message on the screen: Yes• Sound & Vibration Alert : No


Appendix

Screen	Event	Visual & Sound Settings
 <p>Receiver Low Battery</p> <p>Less than 10% of battery life remaining.</p> <p>Charge your receiver now.</p> <p>OK</p>	<p>Receiver (HR310) battery less than 10%.</p>	<p>Default Setting:</p> <ul style="list-style-type: none">• Visual message on the screen: Yes• Sound & Vibration Alert : Yes

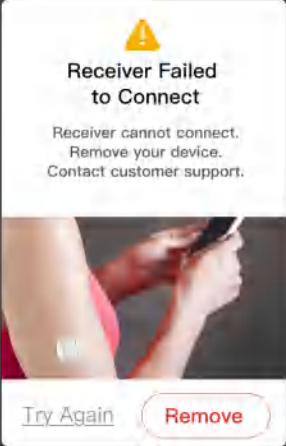
Screen	Event	Visual & Sound Settings
 <p>Transmitter Battery Empty</p> <p>You will not receive glucose readings, alarm, or alerts.</p> <p>Remove sensor and recharge your transmitter now.</p> <p>OK</p>	<p>Transmitter battery voltage less than 3.5V (10%)</p>	<p>Default Setting:</p> <ul style="list-style-type: none"> • Visual message on the screen: Yes • Sound & Vibration Alert : Yes

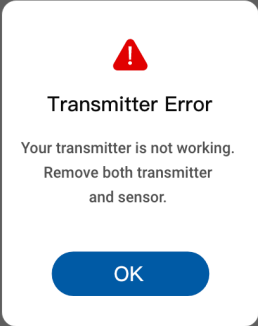
Appendix

Screen	Event	Visual & Sound Settings
	<ol style="list-style-type: none">1. Receiver (HR310) scan distance is too far (>1cm) away from the NFCtag/mark.2. When the NFC tag/mark is damaged.	<p><u>Default Setting:</u></p> <ul style="list-style-type: none">• Visual message on the screen: Yes• Sound & Vibration Alert: No

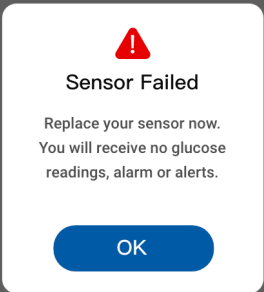
Screen	Event	Visual & Sound Settings
	<ol style="list-style-type: none"> 1. Transmitter is too far from the receiver (HR310) or there is an obstacle (e.g. water, wall) in between transmitter and receiver (HR310). 2. Transmitter battery empty. 	<p>Default Setting:</p> <ul style="list-style-type: none"> • Visual message on the screen: Yes • Sound & Vibration Alert : No • [Try again] reconnection attempted Max. 10 times.


Appendix

Screen	Event	Visual & Sound Settings
	<p>When receiver (HR310) make 10 attempts to reconnect to sensor-transmitter pair but still fails.</p>	<p>Default Setting:</p> <ul style="list-style-type: none">• Visual message on the screen: Yes• Sound & Vibration Alert : No

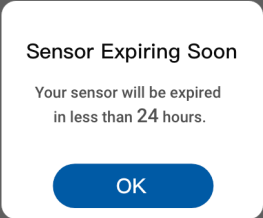
Screen	Event	Visual & Sound Settings
	Transmitter is not working.	Default Setting: <ul style="list-style-type: none">• Visual message on the screen: Yes• Sound & Vibration Alert : Yes

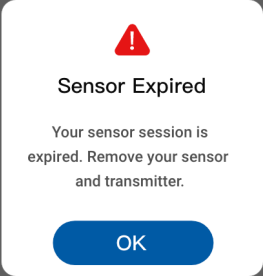
Appendix

Screen	Event	Visual & Sound Settings
	Transmitter detects a current error measured by the sensor.	Default Setting: <ul style="list-style-type: none">• Visual message on the screen: Yes• Sound & Vibration Alert: Yes

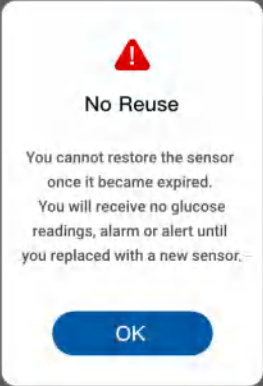
Screen	Event	Visual & Sound Settings
 <p>High Transmitter Temperature</p> <p>Temporary Issue. Move to a cooler environment below 45°C and wait up to 3 hours.</p> <p>If the problem persists remove your device and contact customer support.</p> <p>OK</p>	<p>Transmitter temperature is too high. Temporary Issue. Move to a cooler environment below 45°C and wait up to 3 hours.</p>	<p>Default Setting:</p> <ul style="list-style-type: none"> • Visual message on the screen: Yes • Sound & Vibration Alert : Yes

Appendix

Screen	Event	Visual & Sound Settings
 <p>Sensor Expiring Soon</p> <p>Your sensor will be expired in less than 24 hours.</p> <p>OK</p>	<p>When sensor is to be expired in less than 24 hours.</p>	<p><u>Default Setting:</u></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.	Default Setting: <ul style="list-style-type: none">• Visual message on the screen: Yes• Sound & Vibration Alert : Yes

Appendix

Screen	Event	Visual & Sound Settings
	When transmitter detects a sensor that has been used.	<u>Default Setting:</u> <ul style="list-style-type: none">• Visual message on the screen: Yes• Sound & Vibration Alert : Yes

Appendix

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 Continuous Glucose Monitoring System, 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 (HR310), 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.

