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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. Discuss with your healthcare professional for management of the diabetes with the assistance of RIGHTEST Continuous Glucose Monitoring System. Failure to operate the system according to the guidelines and safeguards specified in this manual could result in a hazardous condition. If your glucose readings do not match what you are feeling, use your blood glucose meter; or, if needed, consult your healthcare practitioner.

CONTENTS

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 2 to 80 in home healthcare. It's an applied part and it is designed to replace fingerstick 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.

⚠ **CONTRAINDICATION :**

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.
People who are not able or not willing to contact with their healthcare professional are not recommended to use the RIGHTEST CGMs. Sufficient vision or hearing is critical for successful usage of system including effective recognition of the alerts. Do not use any component of the RIGHTEST CGMs with any product not in this system.
WHEN NOT TO USE: 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.

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 :**

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 system 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 system.
- 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. The RIGHTEST CGMs Receiver lets you know when your sensor readings drop to or below 54 mg/dL regardless your alarm/alert settings. There are no alarm 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 meters/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. All components of the RIGHTEST CGMs are not allowed to be used with any product not in this system. 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.

⚠ **PRECAUTIONS :**

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

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 healthcare 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 or any components of the RIGHTEST CGMs. Insect repellent may damage the plastic used in the RIGHTEST CGMs. Failure to comply may lead to inaccurate system performance or reduction of stickiness of sensor adhesive.

Store the Sensor in a Cool and Dry Place: Store the sensor in a cool, dry place between 5°C to 30°C (41°F to 86°F) and between 10-90% non-condensing humidity. If the temperature may be higher than 30°C (86°F), refrigerate your sensor and do NOT freeze the sensor or leave the sensor in a parked car on a hot day. Avoid direct sunlight, extreme temperatures, or humidity. These conditions may damage the sensor and cause inaccurate sensor glucose readings.

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. Re-sterilization of these components may result in no glucose readings and infections.

Use as Directed: Use only the AC power adapter, USB cable and USB charger provided with the RIGHTEST CGMs when charging your receiver and transmitter. The AC power adapter, USB cable and USB charger provided with RIGHTEST CGMs comply safety regulations for medical devices. Using different chargers or AC power adapters could damage the system or cause fire. Make sure the access to the power adapter is not blocked and it can be easily unplugged due to the potential risk of electrical shock. Misuse of the USB cable can be a strangulation risk.

Do NOT Use If It Could Fall into Water. Do not spill liquids on receiver or submerge it in water or other liquids. If the receiver has fallen into water, do not touch it until you unplug it from any electrical outlet. Touching the receiver while it is wet could result in electric shock or no glucose results.

DO NOT Use If Any Component Appears to be Damaged. A damaged or cracked inserter, sensor, transmitter, or receiver could compromise the integrity of the system or contribute to infection risk.

Traveling by Air. Always check and follow flight rules or regulations before departure. Notify the security personnel of the presence of the RIGHTEST CGMs and ask for pat-downs, visual inspection, and walk through metal detectors. You must comply any requests by airline personnel (e.g. turning off the system). **Don't pass through an advanced imaging technology (AIT) body scanner (e.g. millimeter wave scanners) or put RIGHTEST CGMs components through x-ray machines** since the effects of these equipment are not evaluated.

Not Allowed to Changing Time Zone. You are not allowed to change time zone during the 14-day of monitoring. Changing the time or date settings in the period of monitoring may result in gaps in the graph or hidden glucose readings.

Safety Information

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

- Fast-acting glucose tablets.
- Blood glucose monitoring supplies.
- Insulin syringe and rapid-acting insulin (with dosage instructions from your healthcare professional).
- Adhesive dressing.
- Glucagon™ emergency kit.

Trouble Shooting If any situation not mentioned in this user manual happens, please contact your healthcare professional or Customer Service.

Be Careful of Electromagnetic Disturbance. Stacking or collocating equipment, or using AC power adapter, USB cable and USB charger not provided with RIGHTEST CGMs may bring negative influence on electromagnetic compatibility. Stay a distance no closer than 30 cm (12 inches) to any part of any portable RF communications equipmentand at least 1 meter for sensitive equipment. If abnormal behavior is observed due to EM disturbances, please relocate the device accordingly.

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
EC REP	Authorized representative in the European Community		For single use only
LOT	Batch/Lot Number		Type BF applied part device
	Expiry date		Direct current
	Temperature limitation		Alternating current
	Humidity limitation	MD	Medical Device
STERILE R	Method of sterilization using irradiation	IP47	Protected from tools and small wires greater than 1 millimeter. Protected from immersion between 15 centimeters and 1 meter in depth.

SYMBOL	DEFINITION	SYMBOL	DEFINITION
IP22	Protected from touch by fingers and objects greater than 12.5 millimeters. Protected from dripping water when tilted at 15°.		Keep Dry
IP21	Protected from touch by fingers and objects greater than 12.5 millimeters. Protected from condensation.		MR Unsafe
SN	Serial Number	Rx Only	Prescription Required
CE 0197	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
	Discard this product according to local regulations		Importer

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 : CGM readings and 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

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

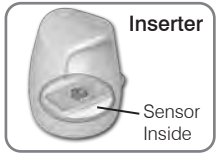
SAFETY FEATURES

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 to or below 54 mg/dL.
- Urgent alert/alarm settings at 54 mg/dL or below cannot be changed or turned off.
- Receiver notifies you when a sensor has failed, expired or when there are system errors.

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 high/low glucose readings

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 :**

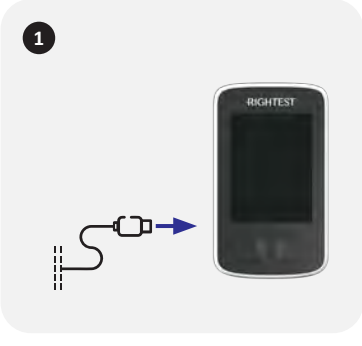
Not Getting Urgent Alarm/Alert. There are no alarm/alerts, when your receiver is turned off or its battery is dead.

⚠ **PRECAUTIONS :**

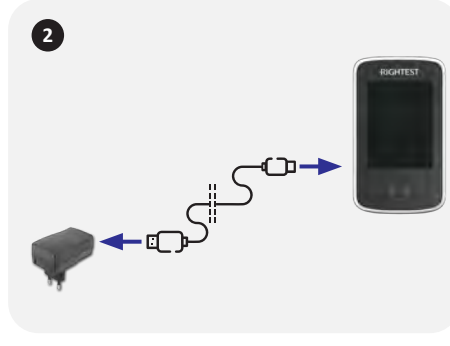
Plug in to Charge. To best protect yourself from not getting the alarm/alerts due to a depleted battery, plug in your receiver to charge at the end of the day and charge it up overnight.

Confirm Charging Status Instability of power resource may cause missing of charging icon. Check the status of charging by the battery status icon (charging or discharging) is displayed in the top-right corner of the screen. When the receiver is plugged in, you should see lightning bolt in the middle of the battery icon.

Prevent Operation during Charging Operation during charging may bring risk.



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



2. Connect the USB plug to the USB port of the AC power adapter supplied with your system, and connect the adapter to the power source.

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.

CHARGING TRANSMITTER

⚠ **WARNINGS :**

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

⚠ **PRECAUTIONS :**

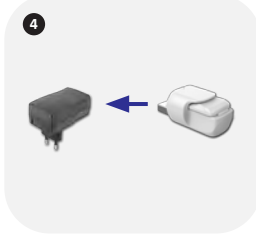
Plug in to Charge. Be sure to fully charge your transmitter every time you start with a new sensor. When plugged into a standard household electrical outlet (100 to 240V AC, 50/60 Hz), the transmitter battery requires approximately 2 hours to fully charge using the transmitter charger supplied with the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

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.

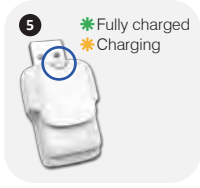
2. Make sure the alignment notch of the transmitter is facing the charger's transmitter compartment with transmitter metal components facing down. With the transmitter outer frame between your fingers, steadily slide the transmitter all the way into the compartment.

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 inot the AC mains outlet (100 to 240V AC, 50/60 Hz).

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.

VI. SET UP YOUR RIGHTEST CGMS

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

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

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 is the opposite face of its metal components. 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 monitoring session. If the instructions provided do not work, please contact Customer Service for further assistance.

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.

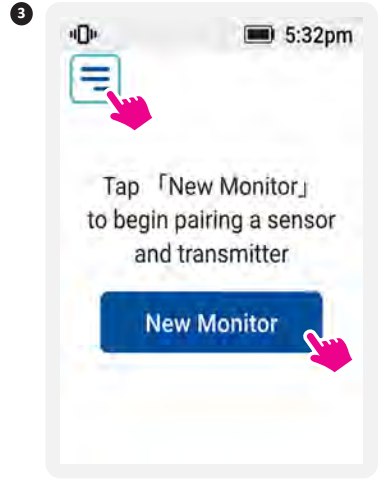
NOTE :
If using the receiver for the first time, follow prompts to set the date, time and your glucose target & alerts.

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

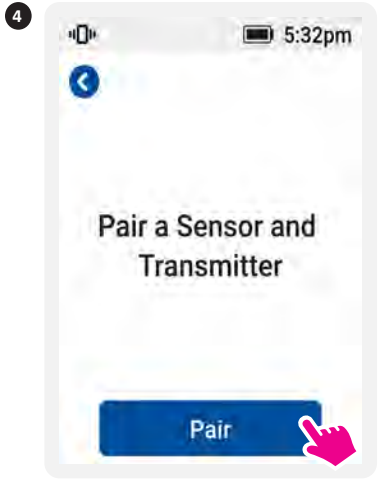
❷

Power Button

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



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



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

5

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.

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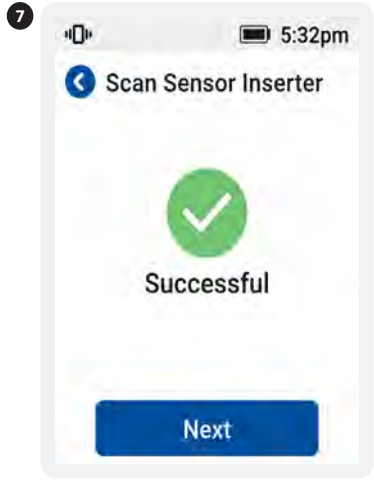
7. Once connected, pairing confirmation is displayed as by checkmark (✓) on the receiver screen.



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.

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

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Set Up Your RIGHTEST CGMs

10. When the receiver displays “Ready to Start”, check whether the serial number of the sensor and the transmitter is the same as which are labeled on the package. If yes, press **[Next]**; otherwise, press **[Cancel]** and back to Step 3.
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 **[Connect]**.

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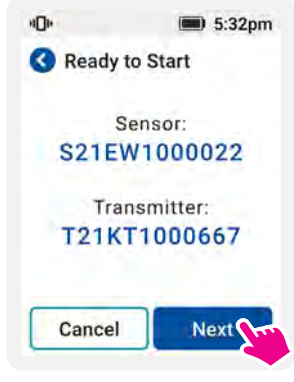

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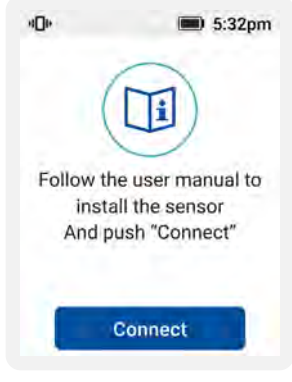

APPLY YOUR SENSOR

⚠ **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, higher than surrounding skin, crusting or bleeding; or on areas with scars, moles, tattoos, irritation, stretch marks, bones, or lumps. Select a skin area that stays flat during normal daily activities (without bending or folding) and is unlikely to be bumped, pushed, or laid on while sleeping.

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. Intense exercise or heavy work may cause the adhesive patch to loosen due to sweat or body movement.

Do not insert the sensor in muscle, areas constrained by clothing or accessories or sites subjected to rigorous movement during exercise to avoid accidental sensor removal. If the adhesive patch is loose or if the sensor tip is pulled out from your skin, the sensor reading may be unavailable or unreliable. Remove and replace the sensor if it starts to loosen, and do NOT attempt to reinsert the sensor.

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

⚠ **PRECAUTION :**

The red circle indicates where a needle comes out when inserting. Do NOT touch the region with any part of your body where is not intended to insert a sensor.

Follow these steps to apply your sensor

1. Wash your hands and wipe them with clean cloth thoroughly.
2. Choose an insertion site on the upper arm where has an adequate amount of subcutaneous fat. Wipe the insertion site with an alcohol wipe and wait approximately for 2 minutes until the site dried out thoroughly before getting started.

NOTE :
Washing insertion site using a plain soap, drying, and then cleaning with an alcohol wipe before insertion of a sensor help remove any oily residue and let the sensor stick properly. If needed, consider shaving the area for insertion to help the sensor sticks securely.

3. Open the sensor inserter package by peeling Tyvek® (the sealing paper) off completely. Take out the sensor inserter from its package and keep the package until sensor session ends. Open the sensor inserter cap.

⚠ **PRECAUTIONS :**
Check the Package. Check the package of sensor inserter before opening the package. Do NOT insert the sensor if its sterile package is damaged, broken, or unsealed before you open the package, because it may cause infection.
Check the Expiry Date. Discard and do NOT use the sensor or sensor inserter after pasting the expiry date in YYYY-MM-DD (Year-Month-Day) format labeled on Tyvek® (the sealing paper).

Set Up Your RIGHTEST CGMs

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 :
Apply the inserter immediately after opening its package and the cap.
If you find it difficult to insert the sensor into the back of your upper arm by yourself, ask others for assistance.
Do not push down the inserter until it is placed over the insertion site. If the insertion is not successful or causes any discomfort, please consult your healthcare professional and use a new sensor.
Do not apply the inserter if the sensor falls out when opening the cap and do not put the sensor back.
Do not apply the inserter if it is misused before the insertion.

2 

3 

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5. Gently move the inserter away from your insertion site. Make sure the sensor is securely attached to your skin.
6. Cap and discard the inserter in an appropriate puncture-proof or biohazard container according to local regulations for sharps and blood-containing components, for safety and to prevent cross-contamination.

5

Set Up Your RIGHTEST CGMs

PRECAUTION :

Watch for bruising or bleeding at the insertion site (under, around, or on top of the sensor and sensor base) after applying the sensor. Bleeding is uncommon and rarely happens. If there is bleeding or any discomforts, follow the instruction to prevent possible dangers.

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

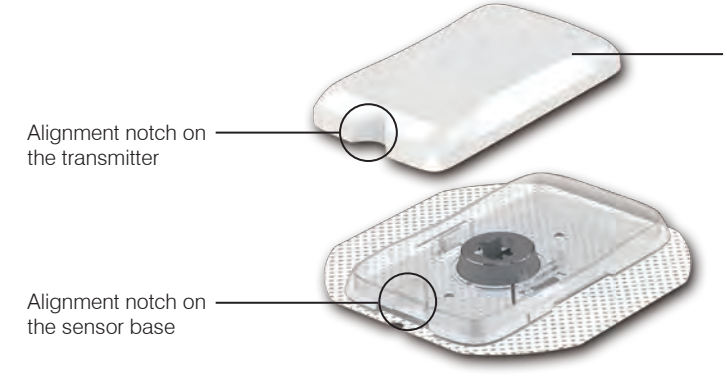
If the sensor breaks under your skin, contact your healthcare professional for further assistance.

ATTACH YOUR TRANSMITTER

⚠ **PRECAUTIONS :**
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.

Set Up Your RIGHTEST CGMs

Overview of the Transmitter



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:

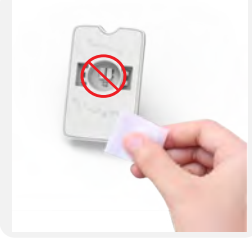
1. Get your transmitter.

> **NOTE :**
> **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.

2. Always clean bottom of transmitter with an alcohol wipe before use. 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



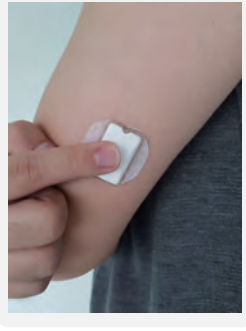
Set Up Your RIGHTEST CGMs

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.

> **NOTE :**
> After the transmitter and sensor are connected, they are water-resistant in compliance with IPX7 and can be worn while bathing, showering, or swimming. Do NOT take them deeper than 3 feet (1 meter) or immerse them longer than 30 minutes in water.

4

5



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.

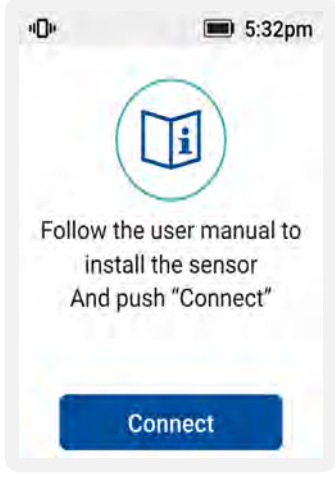
DO NOT Share Your Receiver. The RIGHTEST CGMs' receiver is designed for self-use of a single patient. Never share your receiver with others. The system is a prescription-only medical device and is meant for your use only. If used by other persons, the glucose readings, report, alarms/alerts, etc., may be wrong.

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.

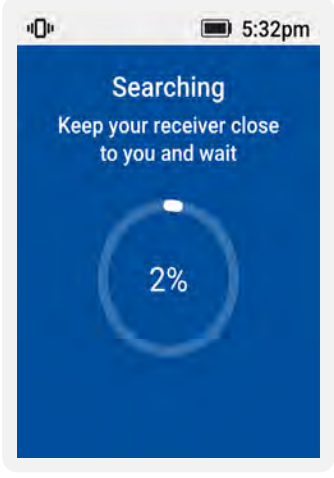
1. Make sure you have followed the installation guide described in the *"Apply your Sensor" and "Attach Your Transmitter"* sections. Then, when the receiver displays "Your system is about to start, press **[Connect]**.



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.

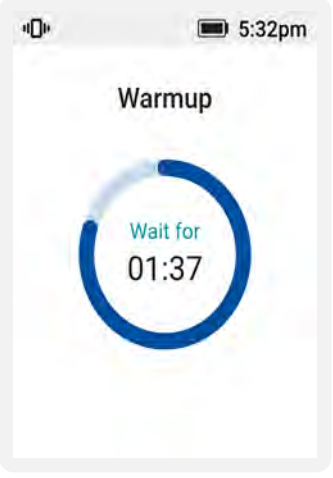
2. The receiver will automatically start searching for your sensor-transmitter pair. Keep your receiver close to you.

2



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.

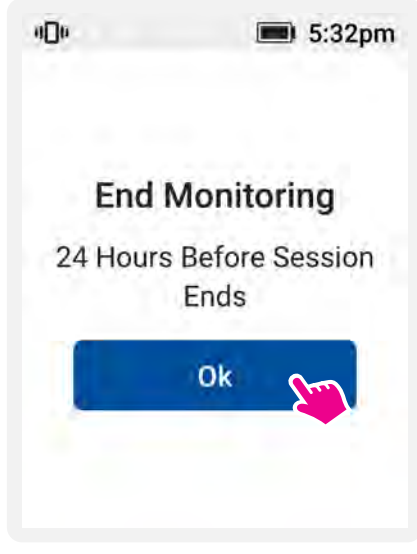
3



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

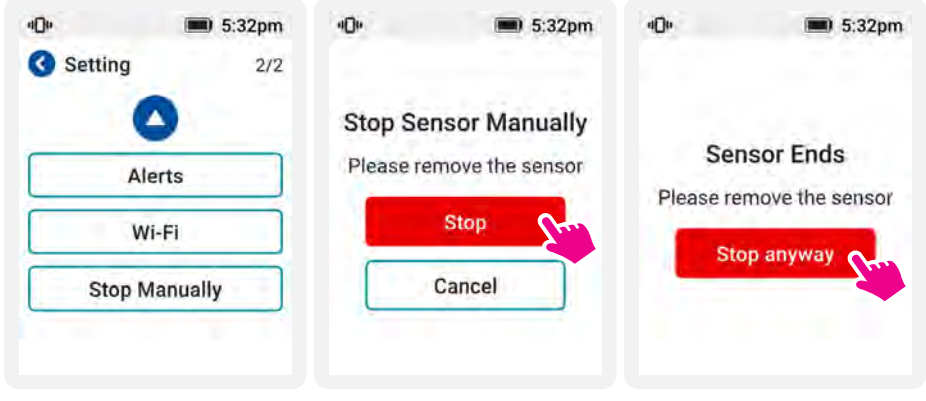
The monitoring session ends automatically when the sensor reaches its life of 14-day and the sensor reading will no longer be shown on the receiver. A “Session is Ended” notification will pop-up to let you know the session ends. You MUST remove or replace the sensor currently in use when you receive the notification of sensor expiring. Press [Done] confirm you read this alert.

⚠ **PRECAUTIONS :**

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

End Session Earlier. If any unexpected issues (irritation or discomfort) happen at the application site, consult your healthcare professional for further assistance to prevent severe results. You may follow the instruction to uninstall you sensor early under proper supervision.

If you intend to or be asked to end the monitoring session before receiving “Session is Ended” notification, you can do that 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.



SENSOR AND TRANSMITTER REMOVAL

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

1. Grip the edge of the patch attached to your skin. Slowly pull upwards to peel it off in one motion.
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 and bend the base away from the transmitter with the hand gripping the corner of the notched edge of the sensor base.
5. The transmitter will pop out as you bend the base. You will hear a click as the transmitter detaches.
6. Keep transmitter to use with next sensor. Discard the sensor, sensor base and adhesive patch according to local regulations for disposal of sharps and blood-contacting components.

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

1

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VIII. UNDERSTAND YOUR GLUCOSE READINGS

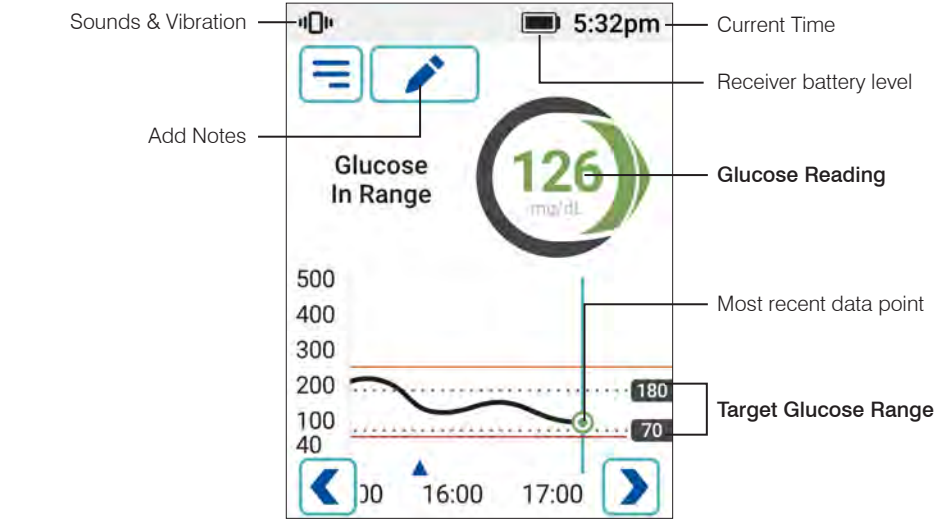
Your sensor glucose readings appear on your receiver display's **Home** screen. It is important to understand your readings.

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



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

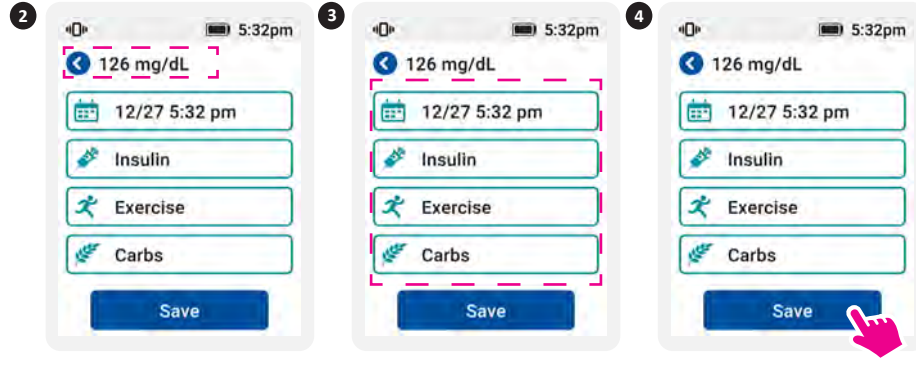
Direction / Arrow Color	What it means				
	Glucose is steady*	Glucose rising**	Glucose rising rapidly***	Glucose falling**	Glucose falling rapidly***
ORANGE: >250 mg/dL					
AMBER 181 - 250 mg/dL					
GREEN: 70 - 180 mg/dL					
ROUGE: 55 - 69 mg/dL					
RED: ≤ 54 mg/dL					

*"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.

ADD NOTES

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

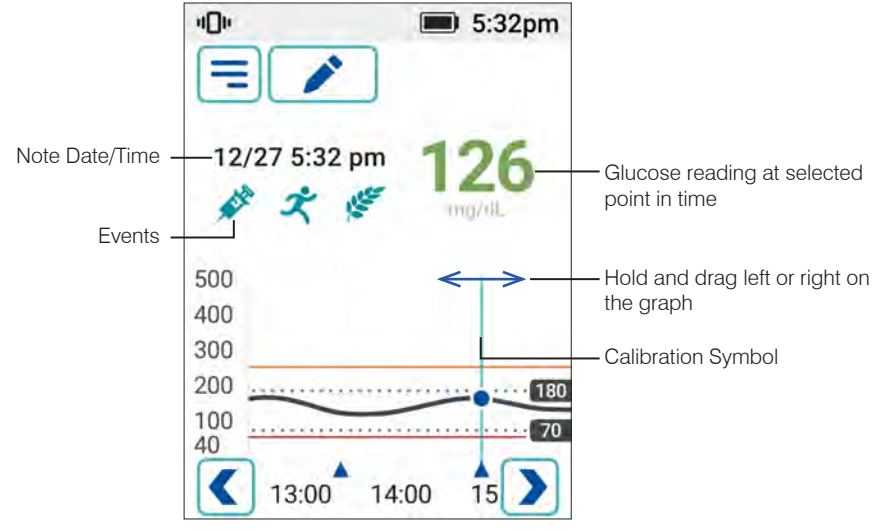
2. Make sure the time is correct.
3. Select the options (carbs, insulin, exercise) then follow the prompts.
4. Tap to save your notes. Notes are viewable in your logbooks.



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



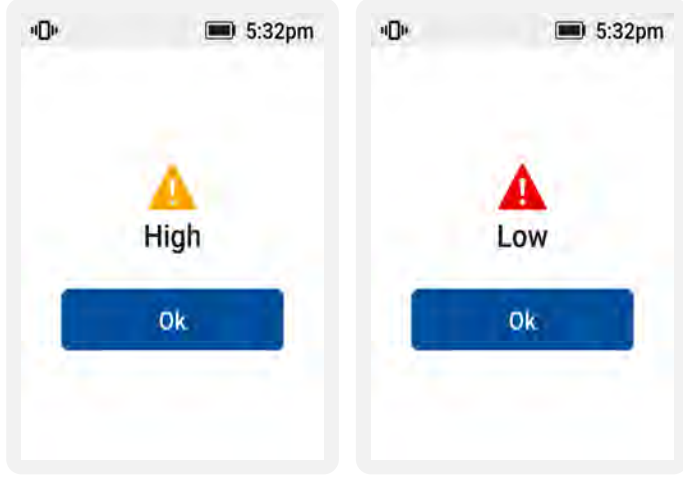
HIGH/LOW READING

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

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

Understand Your Glucose Readings

HIGH/LOW Reading



X. CALIBRATION AND Wi-Fi CONNECTION (OPTIONAL)

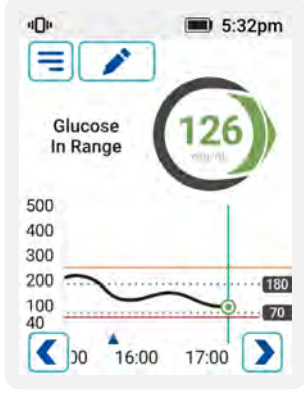
Your RIGHTEST CGMs features factory-calibration that calculated correction factors based on factory input reference values. The system does not need user calibration and you will not receive any calibration prompts from your receiver. Calibrating your RIGHTEST CGMs is optional. The calibration allows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

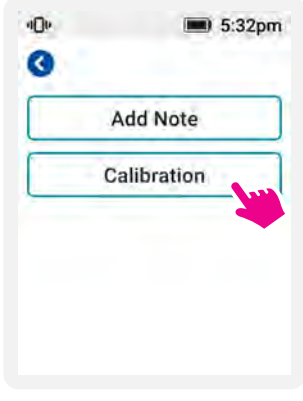
Calibration and Wi-Fi Connection(Optional)

CALIBRATE

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

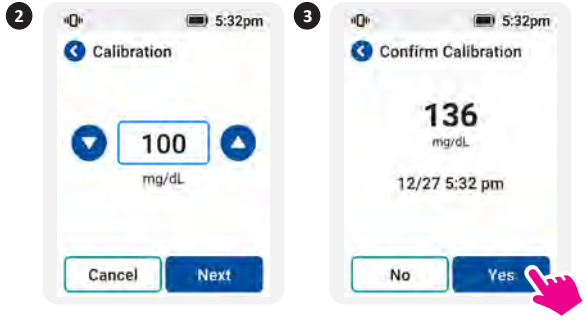
1. From the **Calibrate** screen, tap **[Calibrate Now]**.





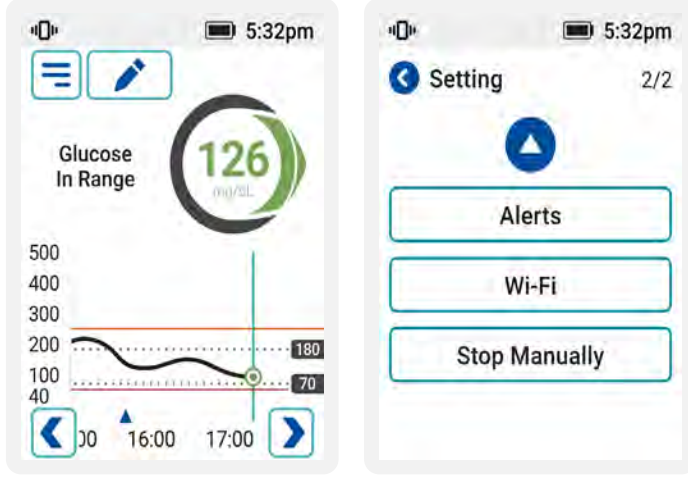
2. Enter the exact BG value then press **[Next]**. If incorrect, tap the backspace key on the numeric keypad to erase the entries then enter the correct value.
3. You will see a prompt from receiver. Tap **[Yes]** or **[No]**.

> **NOTE :**
> Make sure you enter exact fingerstick blood glucose value that is measured within 5 minutes. Only a BG value between 40 mg/dL (2.2 mmol/L) and 500 mg/dL (27.8 mmol/L) can be accepted for calibration. If your BG value is significantly different from your sensor reading, it is recommended to calibrate again to avoid inaccurate readings.



Wi-Fi CONNECTION (for HR321)

Receiver could access to internet via Wi-Fi network. Follow the instuction to set the Wi-Fi connection in Setting.



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.

Treatment Decisions

⚠ **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 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.
• When the Receiver displays no glucose information (e.g. an interrupt alert).

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

When to NOT Make a Treatment Decision
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).
Low Glucose or Urgent Low Message: Sensor glucose readings may not accurately reflect your blood glucose.
No Glucose Trend Arrow: During the first 2-hour warmup period when you start a new sensor, the system cannot tell you if your glucose is rising quickly or falling quickly.
No Current Glucose Concentration and Trend Arrow: When there is a HIGH/LOW result, you don't have enough information to make a treatment decision.

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)	Do a fingerstick blood glucose check with your BG meter. Do NOT treat based on your RIGHTEST CGMs.		
90° upward arrow 	(All Arrow Colors) 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) Do a fingerstick blood glucose check with your BG meter. Do NOT treat based on your RIGHTEST CGMs.	• 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) • 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".**

Trend Arrow	Trend Arrow		
	Low Glucose (< 70 mg/dL)	Glucose in Target Range	High Glucose (> 250 mg/dL)
Horizontal arrow 	(Rouge/Red Arrow Colors) Do a fingerstick blood glucose check with your BG meter. Do NOT treat based on your RIGHTEST CGMs.	• 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) • 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".**

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) Do a fingerstick blood glucose check with your BG meter. Do NOT treat based on your RIGHTEST CGMs.	• If you are about to eat, take insulin to cover your meal. Consider taking a lower dose since your glucose is falling. • If you've recently taken insulin or have finished exercise, eat some snacks or fast-acting carbs.	(Orange Arrow Color) • 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) 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)

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

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 RIGHTEST CGM System is designed to accept radio frequency (RF) communications from recognized and paired display devices only.

RECEIVER SPECIFICATIONS HR320 or HR321

Dimension	103.5 x 60.5 x 13.5 mm (±0.5 mm)
Weight	86g with battery (± 5%)
Touch Screen Size	2.8 inches
Power Source	Non-replaceable and Rechargeable lithium battery (3.7V)
Memory Storage	Up to 90 days (typical use)
Battery Longevity	7 days (typical use)
Battery Charging Time	3 hours (via AC adapter)
Alarm Output	Sound Speaker; Vibration
Storage Transportation & Operating Conditions	Temperature: 0°C - 45°C (32°F - 113°F) Relative humidity: 10% - 95%

Data Communication	Glucose data transfer: Bluetooth 4.0 Frequency range BLE : 2402 ~ 2480MHz Maximum RF output power of the product : 6 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°.
Mean Service time	3 year of typical use
Power Supply Specification	Input: 100-240V, 50/60Hz, 0.16-0.12A Output: 5V DC, 1A (5.0W) Class II

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

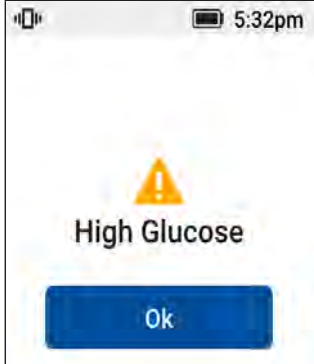
NCC STATEMENT

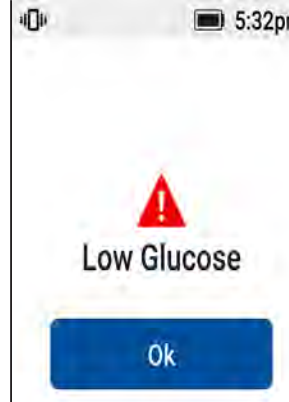
低功率電波輻射性電機管理辦法

「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

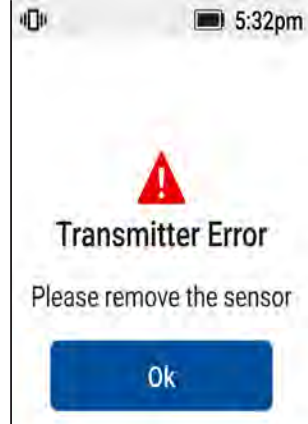
Screen	Event	Visual & Sound Settings
	**Very High Alert** happens when glucose > 250 mg/dL and is detected to rise or remain steady.	**Default Setting:** • Visual Safety Symbol ( ) on **Home** Screen: Yes. • Sound & Vibration Alert: Yes. - Vibrates 3 times and beeps 3 times at the alarm volume following 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:** • Sound & Vibration can be turned ON/OFF by the user.

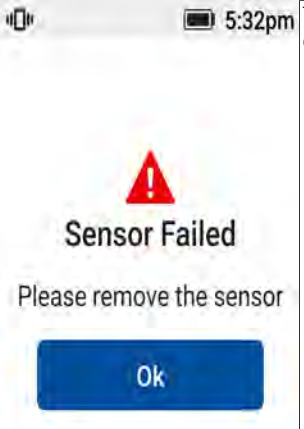
Screen	Event	Visual & Sound Settings
	**Low Glucose Alert** happens when glucose is between 55 - 70 mg/dL and is detected to fall or remain steady	**Default Setting:** • Visual Safety Symbol ( ) on **Home** Screen: Yes. • Sound & Vibration Alarm : Yes. - Vibrates 2 times and beeps 2 times at the alarm 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:** • Sound & Vibration can be turned ON/OFF by the user.

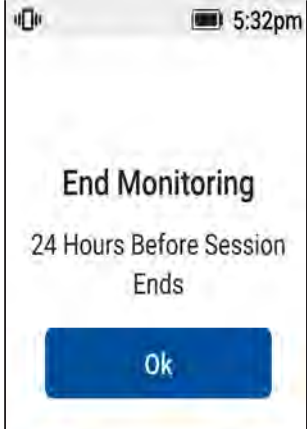
Screen	Event	Visual & Sound Settings
	**Urgent Low Alarm** happens when glucose is at or below 54 mg/dL.	**Default Setting:** • Visual Safety Symbol (⚠) on **Home** Screen: Yes. • Sound & Vibration Alarm : Yes. - Vibrates 2 times and beeps 2 times at highest alarm volume. Separated by 1/2s. - Sound & 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:** • Sound & Vibration CANNOT be turned ON/OFF by the user.

Screen	Event	Visual & Sound Settings
	Transmitter is too far from the receiver or when there is an obstacle (e.g. water, wall) in between transmitter and receiver .	**Default Setting:** • Visual message on the screen: Yes • Sound & Vibration Alert : Yes. - Vibrates 1 time and beeps 1 time at highest alarm volume. Separated by 1s. - Displayed continuously for 5 minutes or until [OK] is pressed. • System attempts to reconnect every 5 minutes even if user doesn't press [OK] • System alerts will repeat every 30 minutes. **Editable Setting:** • Sound & Vibration CANNOT be turned ON/OFF by the user.

Screen	Event	Visual & Sound Settings
	Receiver battery less than 20%.	**Default Setting:** • Visual message on the screen: Yes. • Sound & Vibration Alert : No.

Screen	Event	Visual & Sound Settings
	Transmitter is not working.	**Default Setting:** • Visual message on the screen: Yes • Sound & Vibration Alert : Yes. - Vibrates 1 time and beeps 1 time at the alarm volume following the user settings. Separated by 1s. - Displayed continuously for 5 minutes or until [OK] is pressed. - System alerts will repeat every 30 minutes.

Screen	Event	Visual & Sound Settings
	The system detects a current error measured by the sensor.	**Default Setting:** • Visual message on the screen: Yes. • Sound & Vibration Alert: Yes. - Vibrates 1 time and beeps 1 time at the alarm volume following the user settings. Separated by 1s. - Displayed continuously for 5 minutes or until [OK] is pressed. - System alerts will repeat every 30 minutes. **Editable Setting:** • Sound & Vibration can be turned ON/OFF by the user.

Screen	Event	Visual & Sound Settings
	When sensor is to be expired in less than 24 hours.	**Default Setting:** • Visual message on the screen: Yes. • Sound & Vibration Alert: No.

Screen	Event	Visual & Sound Settings
	Your sensor session is expired.	**Default Setting:** • Visual message on the screen: Yes. • Sound & Vibration Alert : Yes. - Vibrates 1 time and beeps 1 time at the alarm volume following the user settings. Separated by 1s. - Displayed continuously for 5 minutes or until [OK] is pressed. **Editable Setting:** • Sound & Vibration can be turned ON/OFF by the user.

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.

Manufacturer's declaration-electromagnetic emissions		
The Receiver(HR321), Receiver(HR320) is intended for use in the electromagnetic environment (for home healthcare) specified below. The customer or the user of the Receiver(HR321), Receiver(HR320) should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment-guidance (for home healthcare environment)**
RF emissions CISPR 11	Group 1	The Receiver(HR321), Receiver(HR320) uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Receiver(HR321), Receiver(HR320) is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Not applicable	

Manufacturer's declaration-electromagnetic immunity The Receiver(HR321), Receiver(HR320) is intended for use in the electromagnetic environment (for home healthcare) specified below. The customer or the user of the Receiver(HR321), Receiver(HR320) should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment-guidance (for home healthcare environment)**
Electrostatic discharge(ESD) IEC 61000-4-2	Contact:±8 kV Air±2 kV,±4 kV,±8 kV,±15 kV	Contact:±8 kV Air±2 kV,±4 kV,±8 kV,±15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	+ 2kV for power supply lines+1kV for input/output lines	+ 2kV for power supply lines Not applicable	Mains power quality should be that of a typical home healthcare environment.
Surge IEC 61000-4-5	+ 0.5kV, +1kV line(s) to line(s) + 0.5kV, +1kV, + 2kV line(s) to earth	+ 0.5kV, +1kV line(s) to line(s) Not applicable	Mains power quality should be that of a typical home healthcare environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance (for home healthcare environment)
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage dips: 0 % UT; 0,5 cycle 0 % UT; 1 cycle 70 % UT; 25/30 cycles Voltage interruptions: 0 % UT; 250/300 cycle	Voltage dips: 0 % UT; 0,5 cycle 0 % UT; 1 cycle 70 % UT; 30 cycles Voltage interruptions: 0 % UT; 300 cycle	Mains power quality should be that of a typical home healthcare environment. If the user of the Receiver(HR321), Receiver(HR320) requires continued operation during power mains interruptions, it is recommended that the Receiver(HR321), Receiver(HR320) be powered from an uninterruptible power supply or a battery.
Power frequency(50, 60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 60 Hz	The Receiver(HR321), Receiver(HR320) power frequency magnetic fields should be at levels characteristic of a typical location in a typical home healthcare environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Manufacturer's declaration-electromagnetic immunity			
The Receiver(HR321), Receiver(HR320) is intended for use in the electromagnetic environment (for home healthcare) specified below. The customer or the user of the Receiver(HR321), Receiver(HR320) should assure that it is used in such and environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment-guidance (for home healthcare environment)**
Conducted RF IEC 61000-4-6	3 Vrms: 0,15 MHz – 80 MHz 6 Vrms: in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 Vrms: 0,15 MHz – 80 MHz 6 Vrms: in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the Receiver(HR321), Receiver(HR320) including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance (for home healthcare environment)
Radiated RF IEC 61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	Recommended separation distance: d = 1,2 √P d = 1,2 √P 80MHz to 800 MHz d = 2,3 √P 800MHz to 2,7 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Recommended separation distance between portable and mobile RF communications equipment and the Receiver(HR321), Receiver(HR320)

The Receiver(HR321), Receiver(HR320) is intended for use in an electromagnetic environment (for home healthcare) in which radiated RF disturbances are controlled. The customer or the user of the Receiver(HR321), Receiver(HR320) can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Receiver(HR321), Receiver(HR320) as recommended below, according to the maximum output power of the communications equipment.

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

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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

The Receiver(HR321), Receiver(HR320) is intended for use in the electromagnetic environment (for home healthcare) specified below. The customer or the user of the Receiver(HR321), Receiver(HR320) should assure that it is used in such an environment.

Test frequency (MHz)	Band a) (MHz)	Service a)	Modulation b)	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)	Compliance LEVEL (V/m) (for home healthcare)
385	380–390	TETRA 400	Pulse modulation b) 18 Hz	1,8	0,3	27	27
450	430–470	GMRS 460, FRS 460	FM c) ±5 kHz deviation 1 kHz sine	2	0,3	28	28

Test frequency (MHz)	Band a) (MHz)	Service a)	Modulation b)	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)	Compliance LEVEL (V/m) (for home healthcare)
710	704–787	LTE Band 13, 17	Pulse modulation b) 217 Hz	0,2	0,3	9	9
745							
780							
810	1 700 – 1 990	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0,3	28	28
870							
930							
1 720	2 400 – 2 570	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation b) 217 Hz	2	0,3	28	28
1 845							
1 970							

Test frequency (MHz)	Band a) (MHz)	Service a)	Modulation b)	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)	Compliance LEVEL (V/m) (for home healthcare)
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0,3	28	28
5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0,2	0,3	9	9
5 500							
5 785							

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

a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.