User's Manual is also available electronically.

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Rev. Date: 2026-01

101-3HM312-0G0 EN



RIGHTEST™

rFree CGM

Continuous Glucose Monitoring System

User's Manual

For use with mobile App

READ THIS FIRST :

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

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Indications For Use & Statement And Advisory

Indications For Use

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

Statement And Advisory

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

Intended Benefit

- Qualitative benefits, including continuous real-time glucose monitoring for improved glycemic awareness, elimination of routine fingerstick testing to reduce pain and inconvenience, and improved treatment adherence through visualization of glucose trends.
- Quantitative benefits, supported by published clinical evidence from randomized controlled trials and international consensus:
  - HbA1c reduction of approximately 0.3 - 0.6% in adults with type 1 and type 2 diabetes using CGM compared with SMBG.
  - An increase in Time in Range (TIR) of ~10% (~2.4 hours/day) corresponding to a ~ 0.5% reduction in HbA1c, validated by meta-analysis and international consensus.
  - Associations between reduced TIR and higher risks of diabetic complications (retinopathy progression +64% per 10% decrease; microalbuminuria +40% per 10% decrease).
  - Improved detection of hypoglycemia (<70 mg/dL and <54 mg/dL) and hyperglycemia, reducing the risk of acute complications.

Potential Side Effect

Skin Irritation Reaction Caused by the Sensor Adhesive: Some individuals may be sensitive to the medical adhesive that keeps the

sensor attached to the skin. If you develop a rash around or under your sensor, remove the sensor and stop using the iFree CGM. If necessary, consult your healthcare professional.

Contraindication

- No MRI/CT/Diathermy: The iFree CGM (sensor, transmitter, and other display devices) must be removed prior to Magnetic Resonance Imaging (MRI), Computed Tomography (CT), or high-frequency electrical heat (diathermy) treatment. People who are unable or unwilling to contact their healthcare professional are not recommended to use the iFree CGM. Sufficient vision or hearing is critical for successful use of the system including effective recognition of the alerts.
- Known allergy to disinfecting alcohol or medical adhesives
- Extensive skin conditions or lesions at the site of device placement. Relevant conditions include, but are not limited to: Psoriasis, Eczema, Dermatitis Herpetiformis, severe burns or sunburns, and scars.

Safety Information

The following is a summary of safety information which must be observed before using the iFree CGM.
CONTRAINDICATION: A situation where using CGM could be harmful rather than helpful.
WARNING: A potential danger to the user.
CAUTION: A potential injury to the user or damage to the system.
NOTE: Cautionary reminders regarding operational instructions.
To minimize risks, read the following safety information before using the system. Improper use and maintenance may damage the system resulting in failure or injury to the user. It is important to understand that this safety information is not exhaustive. It is intended to ensure the safety of the user when using the system.

WHEN NOT TO USE:

- Do not use the iFree CGM if you are pregnant, on dialysis or critically ill; or on users with other implanted medical devices (e.g., a pacemaker). The system has not been evaluated for use in these populations.
- iFree CGM is contraindicated in patients with infection, edema at or near the sensor insertion site, those receiving vasoactive drug

therapy, or with impaired tissue perfusion.

- iFree CGM use is not recommended, or should be undertaken with caution, in patients with an increased risk of bleeding, known allergies to disinfectants or medical adhesives, sensitive skin, a predisposition to skin ulceration, or when the insertion site is affected by wounds, scarring, or inflammation, as these conditions may interfere with device placement and accuracy.
- iFree CGM should not be used during episodes of severe hypoglycemia (<40 mg/dL), severe hyperglycemia (>500 mg/dL), or during periods of rapid blood glucose fluctuation.
- The sensor should not be inserted into areas with tattoos, scars, or similar skin conditions.

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

WARNINGS :

Use a Blood Glucose (BG) Meter to Make Treatment Decisions under the Following Conditions:

- During the first 2-hour warmup period when you start a new sensor. You will not receive any sensor readings or alerts until your system begins to transmit data.
- If you suspect that your sensor readings may be inaccurate for any reason.
- If your sensor readings do not match what you are feeling.
- If you are experiencing symptoms that may be due to low or high blood glucose.
- If your system does not include your current glucose concentration or a glucose trend arrow.
- If you wish to confirm hypoglycemia or impending hypoglycemia as reported by the system.
- If you are experiencing rapid glucose changes (greater than 2 mg/dL per minute), the sensor readings displayed may be less accurate and less timely.

Not Receiving Urgent Alerts under the Following Conditions:

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

- When there is a system error (e.g. no glucose readings, sensor error, signal loss, etc.) or damage to the system.
- During the 2-hour sensor warm-up period.
- When the display device is out of range (6 meters/20 feet) from your transmitter; or obstacles (metal, walls, water, etc.) are between them.

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

Children or pets without adult supervision: Do not allow children or pets to play with any parts of iFree CGM without adult supervision.

Choking and Strangulation Hazard: The iFree CGM contains small components that may be dangerous if swallowed. The charging cable may pose a strangulation hazard.

⚠ **CAUTIONS :**

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

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

Avoid Skin Care Products: Do not apply skin care products such as sunscreen, moisturizer, perfume or insect repellent over the sensor insertion site or any components of the iFree CGM. Failure to comply may lead to damage of the plastic used in the iFree CGM or reduction in the stickiness of the sensor adhesive.

Do NOT Attempt to Reinsert a Sensor: If the adhesive patch

is loose or if the sensor tip is pulled out from your skin, remove the sensor and replace it with a new sensor. Sensor readings may be unreliable until a new sensor is inserted.

Do not freeze sensors. Avoid direct sunlight, extreme temperatures, and high humidity. These conditions may damage the sensor and cause inaccurate sensor readings.

DO NOT Reuse Your Sensor or Inserter: The entire Sensor kit package is sterilized and designed for single use. It is not suitable for re-sterilization. Re-sterilization of these components may result in no glucose readings and infections.

Use as Directed: The charging accessories provided with iFree CGM comply with safety regulations for medical devices. Use only these components when charging your transmitter. Otherwise, the system may be damaged or a fire hazard may be presented. Make sure access to the power adapter is not blocked and it can be easily unplugged due to the potential risk of electrical shock.

DO NOT Use If Any Component Appears to be Damaged: A damaged or cracked, sensor kit or transmitter, may compromise the integrity of the system and contribute to

infection risk.

Traveling by Air: Always check and follow flight rules and regulations before departure. Notify the security personnel of the presence of the iFree CGM and comply with requirments for pat-downs, visual inspection, and metal detectors. You must comply with any requests by airline personnel (e.g., turning off the system). Do not pass through an advanced imaging technology (AIT) body scanner (e.g., millimeter-wave scanners) or put iFree CGM components through x-ray machines since the effect of this equipment on iFree CGM has not been evaluated.

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

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

The emergency kit should contain:

• Fast-acting glucose tablets.

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

Troubleshooting: If any situation not mentioned in this user manual occurs, please contact your healthcare professional or Customer Service.

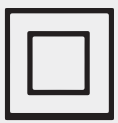
Be Careful of Electromagnetic Disturbance: Stacking equipment, or using AC power adapters, USB cables and USB chargers not provided with iFree CGM may negatively influence on electromagnetic compatibility. Stay a distance greater than 30 cm (12 inches) from any part of any portable RF communications equipment and at least 1 meter from sensitive equipment. If abnormal behavior is observed due to EM disturbances, please relocate the device accordingly.

Symbol Definitions

The following symbols apply to the iFree CGM:

	Date of Manufacture
	Manufacturer
	Input
	Importer
	Do not re-use
	Use-by date

	Temperature limit
	Keep away from sunlight
	Keep Dry
	MR Unsafe
	Type BF applied part device
	Direct current
	Alternating current

	Humidity limitation
MD	Medical Device
STERILE R	Sterilized using irradiation
SN	Serial number
	Bluetooth
	Class II Equipment
	WEEE (Discard this product according to local regulations)

	Do not use if package is damaged and consult instructions for use
	Unique device identifier
	Catalogue number
	Caution
	Consult instructions for use
	Near-field communication (NFC) scan area
	Electrical Equipment Designed Primarily for Indoor Use (Transmitter Charger Only)

IP21	Protected from touch by fingers and objects greater than 12.5 millimeters. Protected from vertical dripping water for 10 minutes
IP22	Protected from touch by fingers and objects greater than 12.5 millimeters. Protected from dripping water when tilted at 15° for 10 minutes
IP48	Protected from tools and small wires greater than 1 millimeter. Protected from immersion up to 10 feet (3.05 meter) for 30 hours

Getting To Know Your iFree CGM

Performance Features

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

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

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

Safety Features

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

These features include:

- Alerts includes visual notification, vibrations and sound, depending on your personalized settings.

- When you are out of your target glucose range, the display device alerts you.
- Display device warns you if your glucose level falls below to or below 54 mg/dL.
- Urgent alert settings at 54 mg/dL or below cannot be changed or turned off.
- Display device notifies you when a sensor has failed, expired or when there are system errors.

CGM Components

The iFree CGM consists of 3 key parts: Sensor kit, Transmitter, and display device - App installed in smartphone.



SENSOR KIT (HS312)

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



TRANSMITTER (HT312)
The transmitter wirelessly sends your glucose data from the sensor to the display device. The transmitter is rechargeable for multiple-use by a single patient.



DISPLAY DEVICES - App Installed Smartphone (iOS or Android) and Smartwatch
The display device provides sensor readings and delivers alerts of high and low glucose readings. The system can be used with a smartphone with the mobile App. You can install the iFree CGM App on your smartphone; if you use a smartwatch in conjunction, you can also view the glucose readings and trends provided by the iFree CGM App on your smartwatch.

iFree CGM App

iOS App

Android App

Accessories



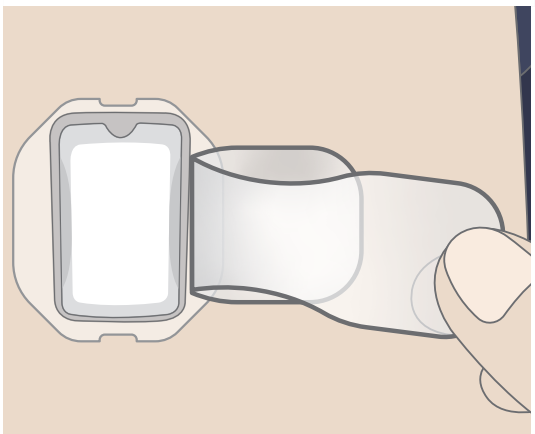
TRANSMITTER CHARGER (HC312)
A USB charging dock is included.
Note. USB cable is labeled with "iFree" for identification and are exclusively for CGM use.



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



SPLITTER (HP312)
The splitter is used for separating the transmitter, sensor base, and adhesive patch.



SENSOR PATCH (TP110)
Designed to secure continuous glucose monitoring system transmitters.

Before You Start

Install The App

iFree CGM App can be downloaded from the Google Play Store or App Store. Start by following the on-screen instructions to complete the initial setup if it is your first time using the App. The screens in this manual may look different from your App because of operating systems or updates, please use the App by following the on-screen instructions. Refer to the original user's manual of your smartphone to learn how to change relevant settings.

Before starting monitoring, please confirm the following settings below:

- **Bluetooth on and location permission agreed:** Connection between your transmitter and the App is via Bluetooth and location; you will receive sensor readings or alerts after enabling and agreeing to the App permission.
- **Notifications on:** Enable and allow notifications to show on your locked screen.
- **Keep the battery charged:** The App will continue running in background and may drain your battery. Ensure that your device has sufficient power.

- **Smartphone powered on and running:** Open the App again if you restart your smartphone.
- **Update manually:** Update the operating systems or the App automatically may change settings or shut down the App. Always update manually and verify the setting afterward.
- **Do not change the time:** You are not allowed to change time zone during the 14-day monitoring session. Changing the time or date settings during monitoring may result in gaps in the graph or hidden glucose readings.
- **Use Smartwatch in conjunction:** To install the App, use the Watch App on your mobile phone. See your watch instructions for details about installing Apps. Make sure you understand how you get notifications when the smartwatch is connected to your iFree CGM App.

iFree CGM App is only compatible with certain smartphones and operating systems, please check the official website (https://www.rightest.com/guides) or contact customer service for more information about compatible devices.

Charging The Transmitter

WARNINGS :
Not Receiving Alerts. There are no alerts when your transmitter battery is dead.

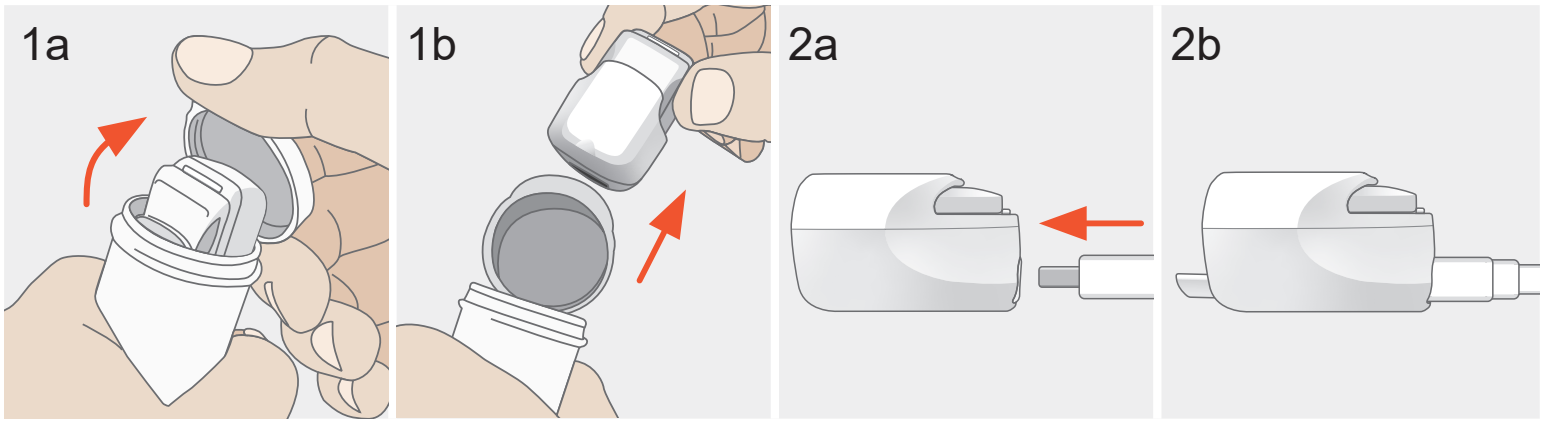
⚠ **CAUTIONS :**
Plug in to Charge. Make sure to fully charge your transmitter before you start a new monitoring session. When plugged into a standard household electrical outlet (100 - 240VAC, 50/60 Hz) with the supplied transmitter charger, the transmitter requires approximately 2 hours to fully charge.

Fully charge the transmitter every time before you start a new monitoring session to ensure data is collected from the sensor and sent to the display device during the entire monitoring session (14 days).

1. Take out your transmitter with its charger from the storage vial.
2. Connect the USB-C plug of the USB cable to the USB-C input of the charger. Slide the USB-C port inwards to lock the transmitter in position.

   NOTE:

   1. The USB cable can only be plugged in when the transmitter is secured inside its charger compartment.
   2. After the USB port is pushed inwards, the transmitter cannot be removed from the charger.

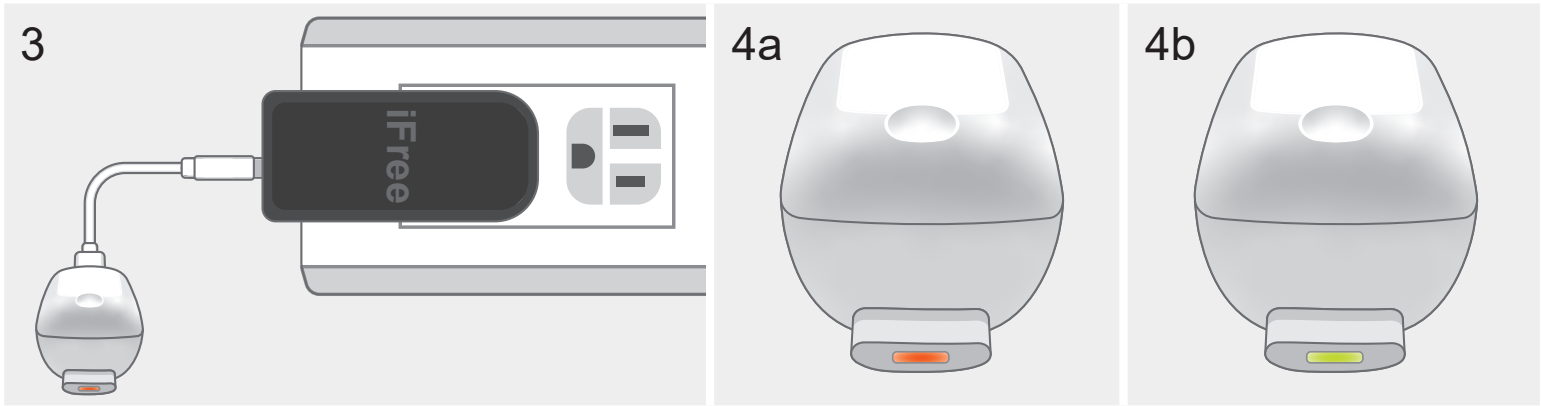


3. Plug the cable's USB plug into the USB port on the AC power adapter.
4. Plug the AC power adapter into AC wall socket (100 - 240V AC, 50/60Hz), then check LED on the charger to monitor the charging status of the transmitter.

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

NOTE:

If the LED does not light up, make sure the power adapter is connected to a power source with an output rating of 500 mA or higher. If the issue persists, try connecting to another power source or contact customer support.

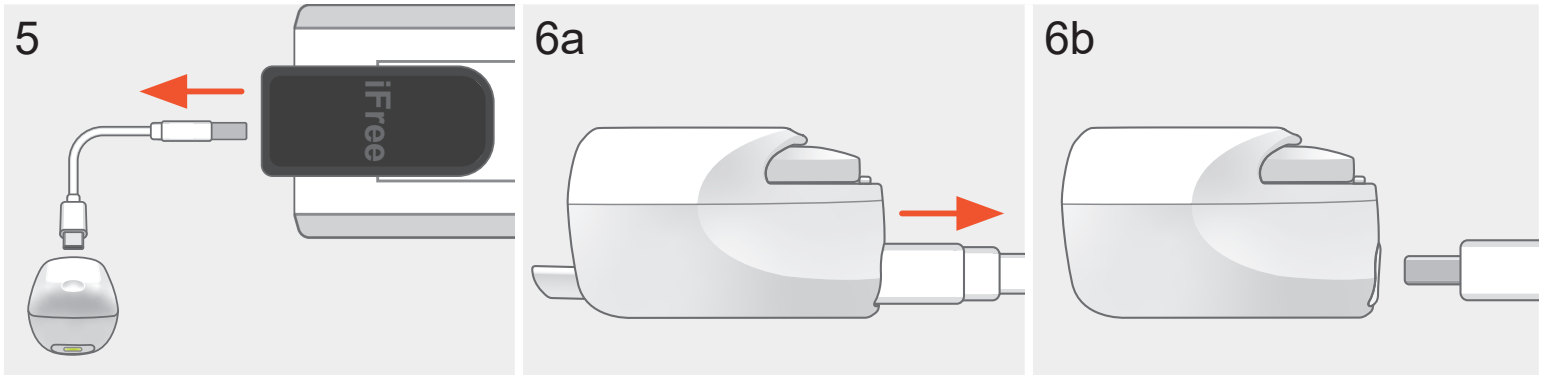


5. Unplug the cable from the AC power adapter after the transmitter is fully charged.
6. Pull the USB-C cable outwards to allow the transmitter to be removed.

NOTE:

1. The transmitter can only be removed when the USB-C port is unplugged.

2. After the transmitter is removed, the USB-C port cannot be slid inwards.

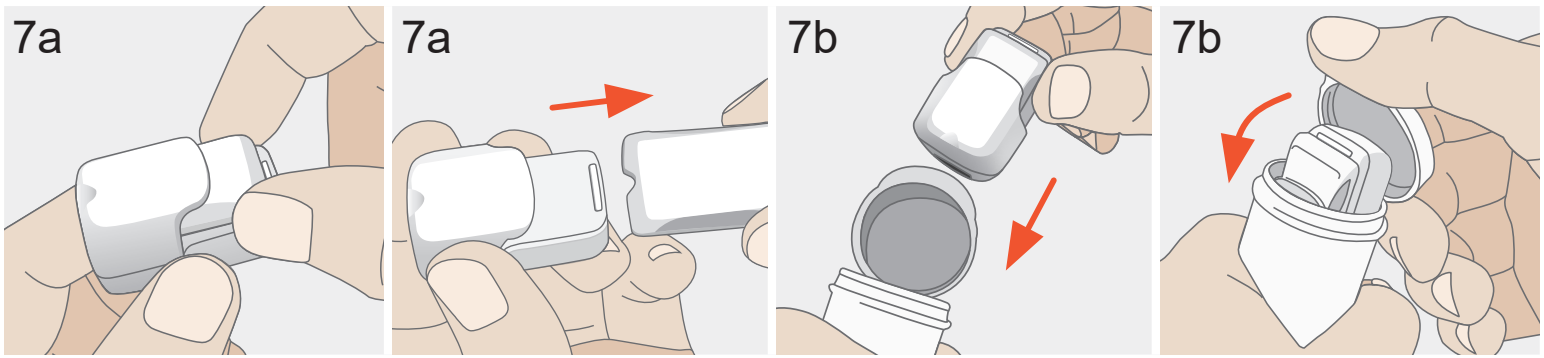


7a. To start a new monitoring session, slide the fully charged transmitter out of the charger compartment.

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

NOTE:

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



Setting Up Your iFree CGM

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

- Sensor Kit
- Transmitter
- Display device: choose App installed in smartphone
- Alcohol Wipes
- Blood Glucose (BG) Meter

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

Scan The Sensor Kit And Transmitter

⚠ **CAUTIONS :**

Scan Before Monitoring: Every time you start a new monitoring session, scan both NFC tag of the Sensor kit and the transmitter with your display device. Each Sensor kit has its unique NFC tag which is attached on the packaging. The NFC tag of the transmitter is located beneath the top plastic cover (the face without the metal components.

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

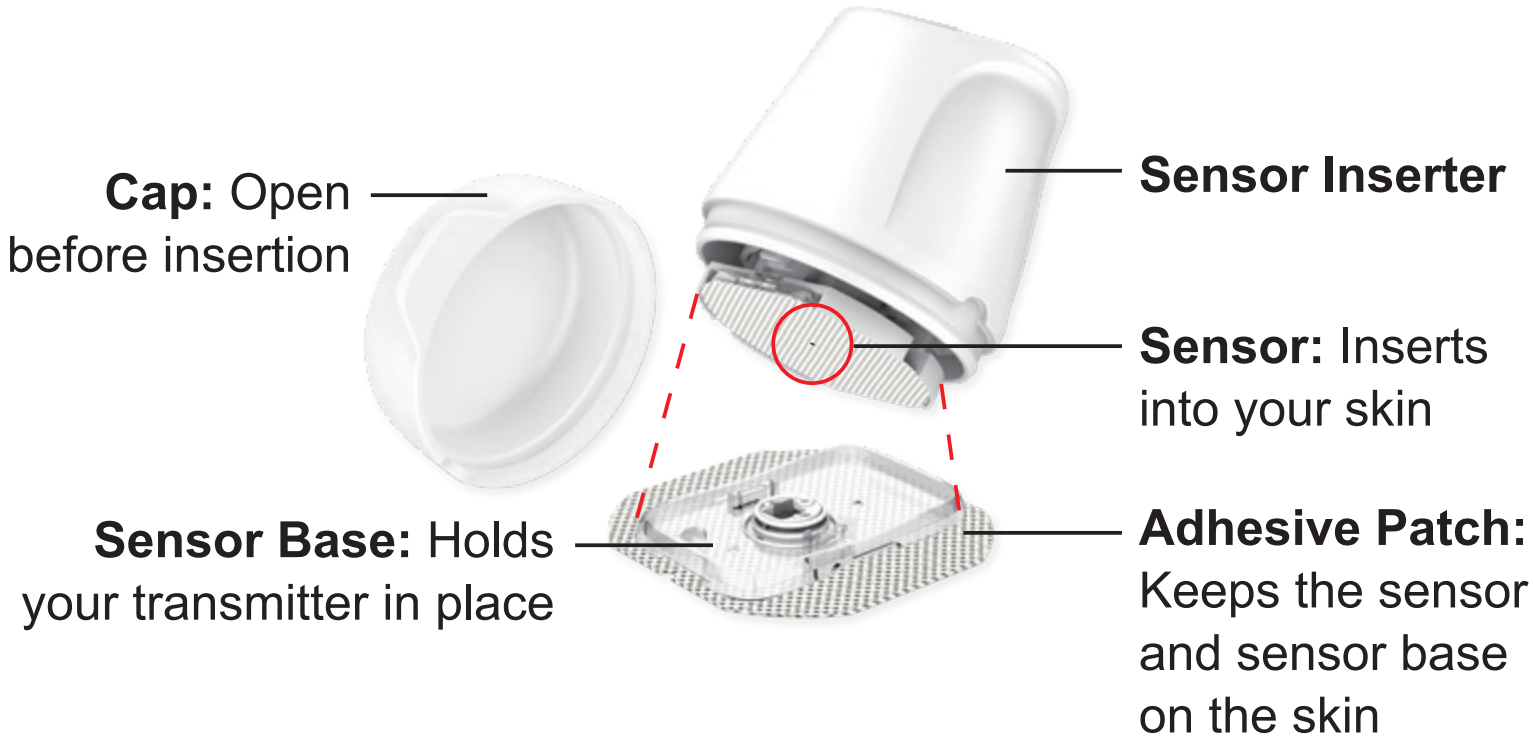
Scan The Sensor Kit And Transmitter Using The App

1. Open the App on your smartphone.
2. Tap **[Let's Start**] to start a new glucose monitoring session.
3. Tap **[Start Paring]** and hold your phone to close to the transmitter, once it scanned successfully, a checkmark (√) will appear on the screen.
4. Following the screen instructions to check the battery of the transmitter, once it scanned successfully, a checkmark (√) will appear on the screen.
5. Press **[Start Paring]** and hold your phone close to the Sensor kit, once it scanns successfully, a checkmark (√) will appear on the screen.
6. Make sure you follow the steps in the next two sections ("Apply Your Sensor" and "Attach Your Transmitter"). After installing the sensor and transmitter, click **[Connect]**.

Apply Your Sensor

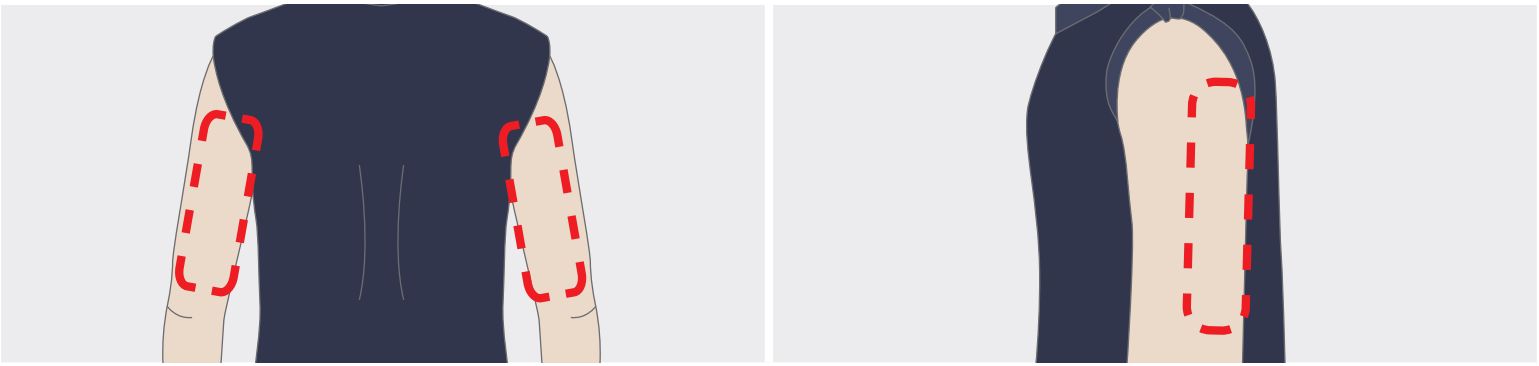
The sensor is pre-loaded inside the inserter. Before applying the sensor to your skin, familiarize yourself with the information in this section.

Overview of the Sensor Kit



CAUTIONS :

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



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



The following areas are preferable for insertion:

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

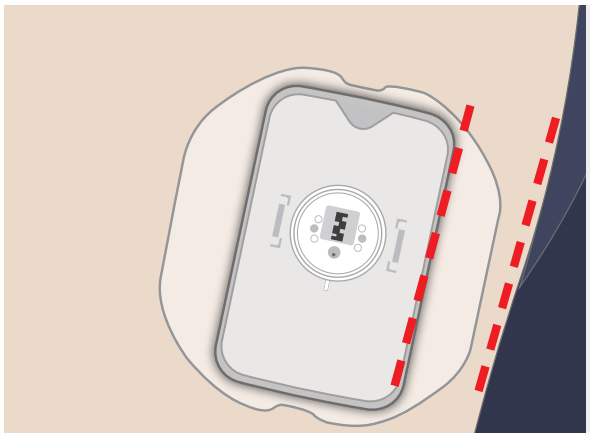


The following should NOT be selected for insertion:

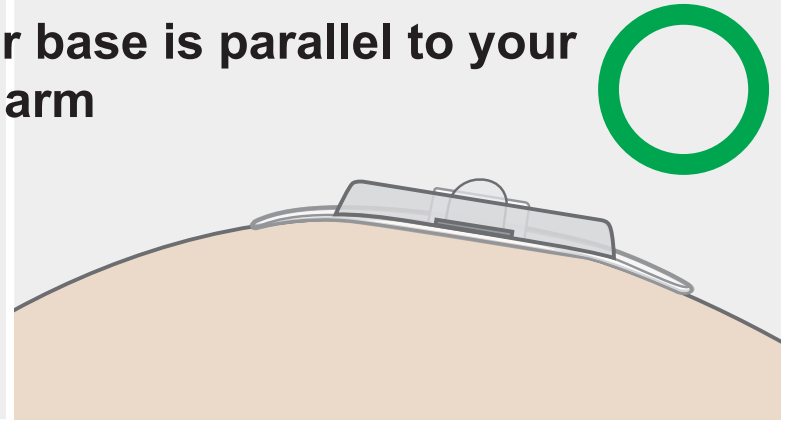
1. Any area of the body other than the back of upper arm. Placing the sensor on other areas of the body may present unknown risks.
2. Skin that is painful to touch, is higher than surrounding skin, is crusting or bleeding.
3. Areas directly over muscle, scars, moles, tattoos, irritation, stretch marks,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

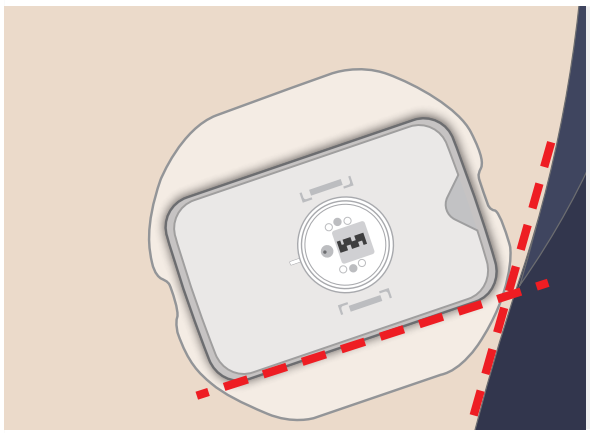
The following is not recommended for insertion:

1. Sites that are too close (less than 1 inch or 2.5 cm) to an insulin injection site or previous sensor insertion site. Placing a new sensor on the same spot will increase skin irritation or redness and could potentially lead to scabs.
2. Areas constrained by clothing or accessories and areas which experience high amounts of movement during exercise so as to avoid accidental sensor removal due to excessive sweat or body movement.

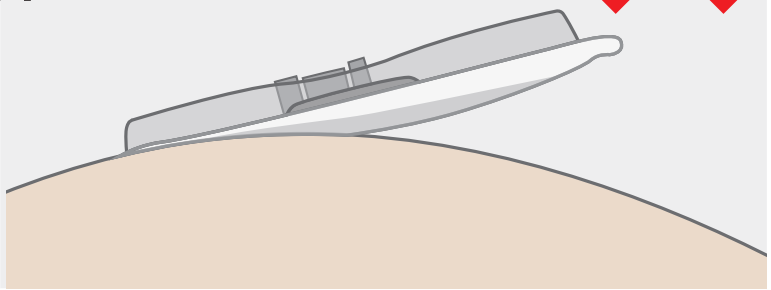


Sensor base is parallel to your upper arm





Sensor base is NOT parallel to your upper arm

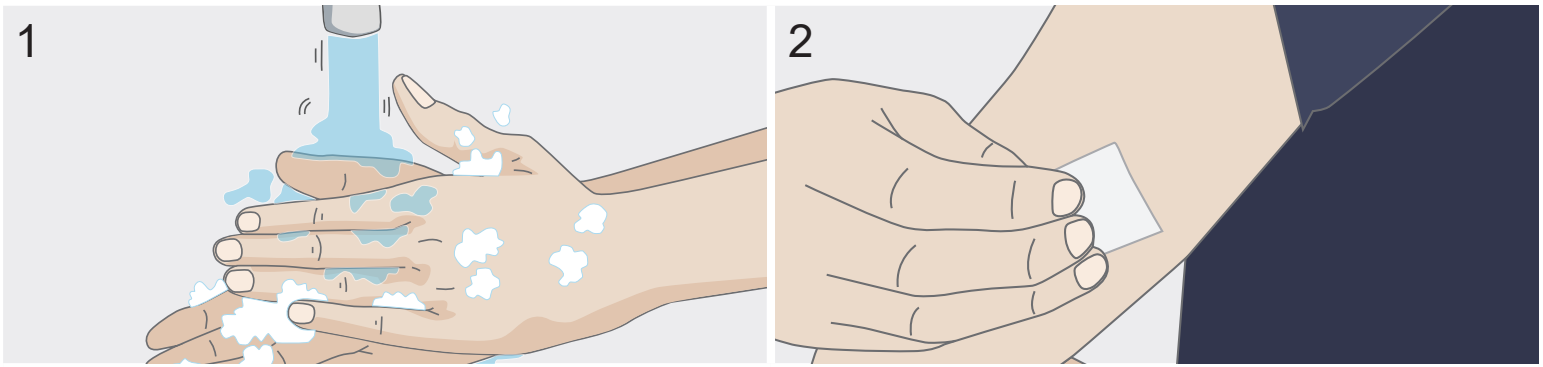


Follow these steps to Apply the sensor under your skin. Correct Application of a sensor ensure fully attachment of adhesive patch on your skin and help the sensor stay under your skin for up to 14 days.

1. Wash and dry your hands.
2. Wipe the insertion site with an alcohol wipe and wait for Approximately 2 minutes until the site has dried before getting started.

   NOTE:

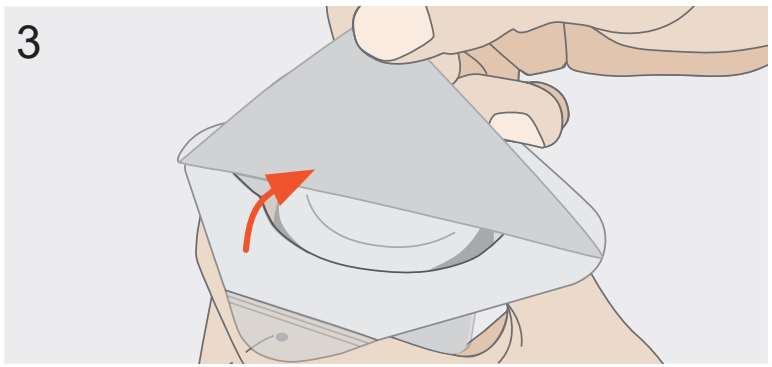
   1. Cleaning the insertion site using a plain soap, drying, and then cleaning with an alcohol wipe before insertion of a sensor helps remove any oily residue to let the sensor stick properly.
   2. If needed, consider shaving the insertion area to help the sensor stick properly.

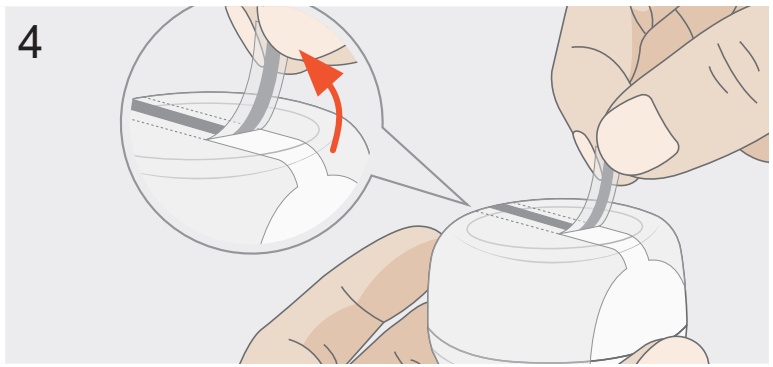


⚠ **CAUTIONS :**

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

3. Open the sensor kit package by peeling off the sealing paper completely. Take out the Sensor kit from its package and save the package until the end of the monitoring session.
4. Peel off the plastic film outside the Sensor kit.
   NOTE:
   The plastic film prevents the cap opening during transportation.



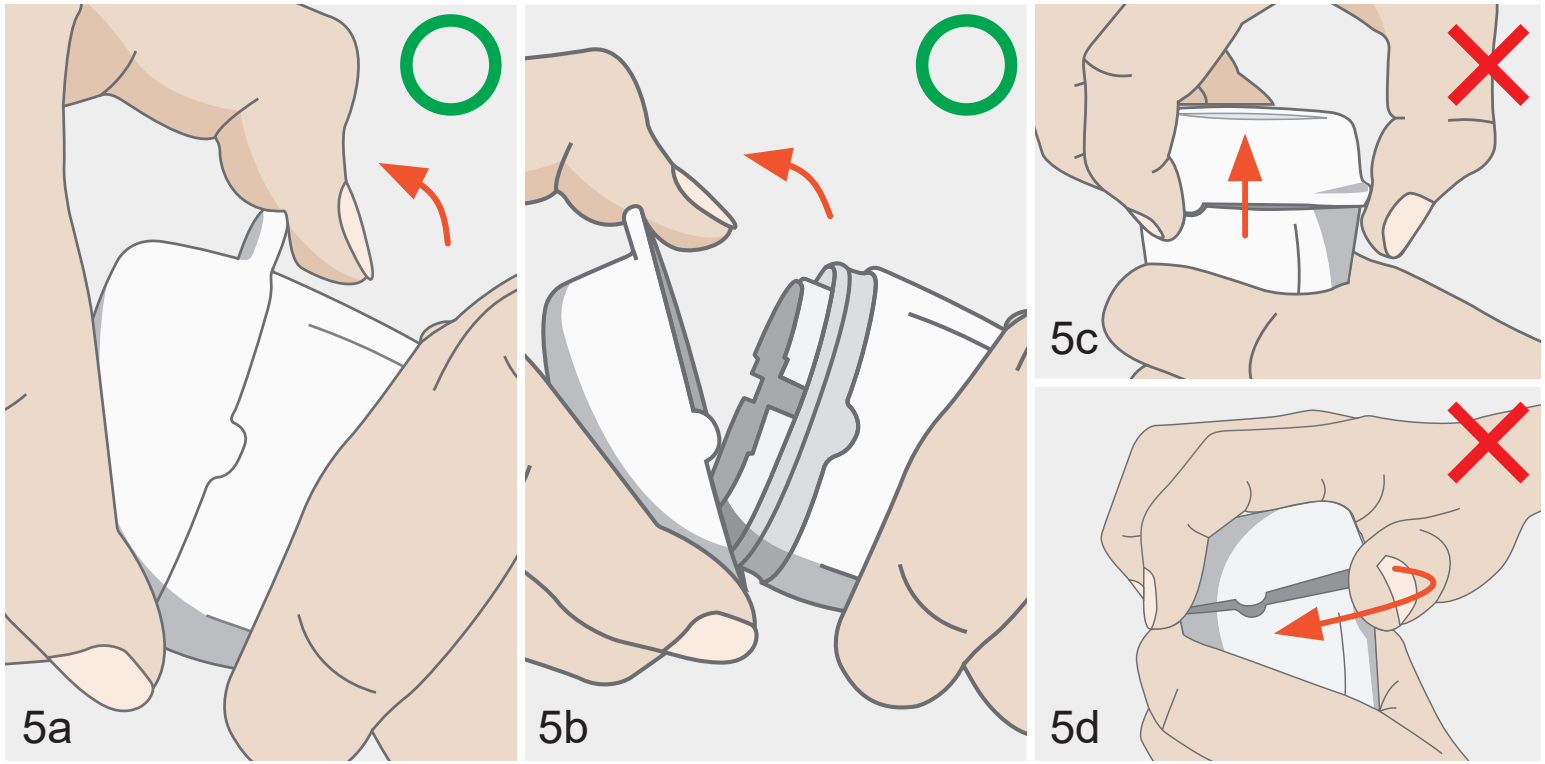


⚠ **CAUTIONS :**

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

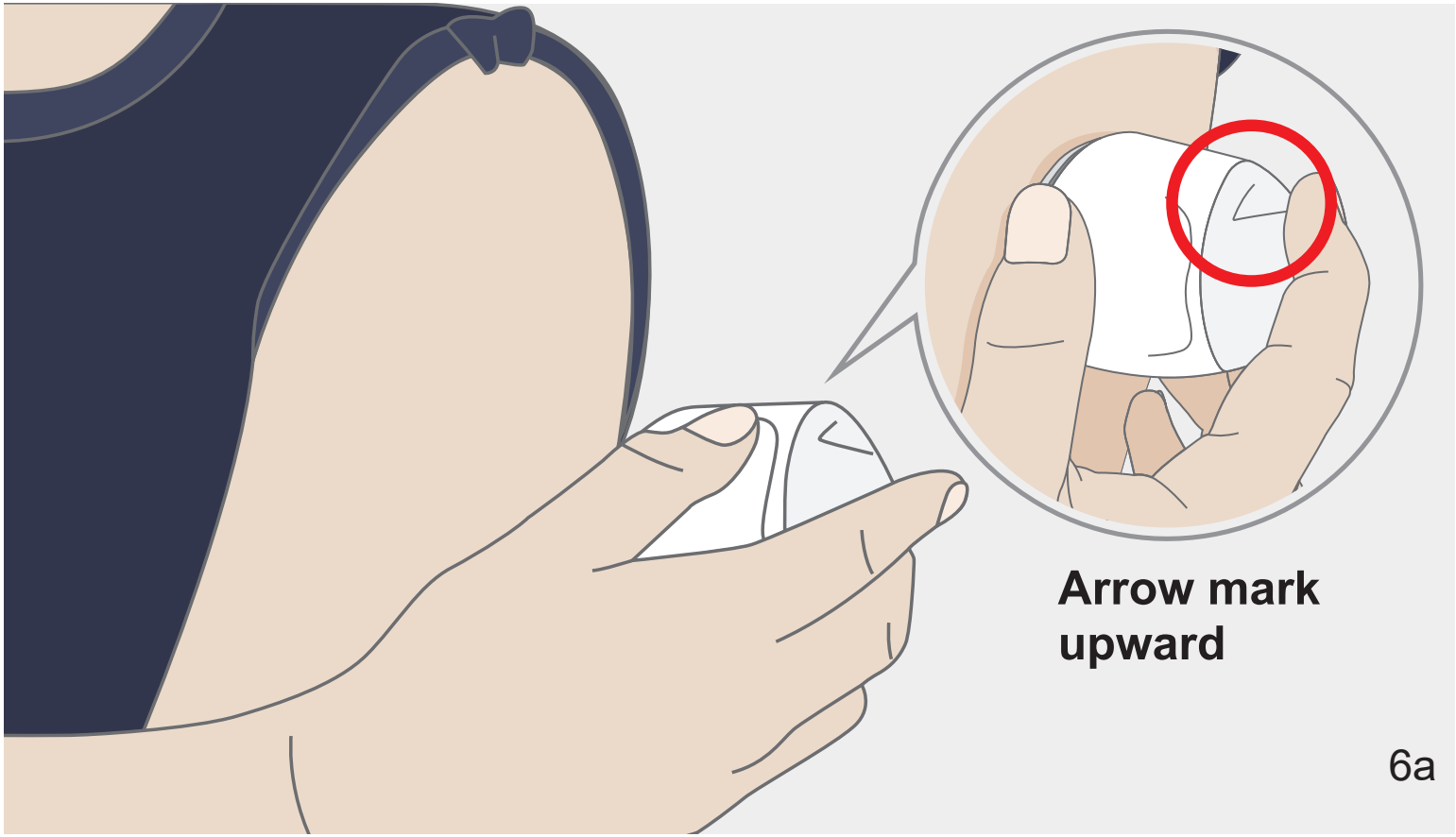
Check the Expiry Date. Discard and do NOT use the Sensor kit after the expiry date (YYYY-MM-DD) printed on the sealing paper.

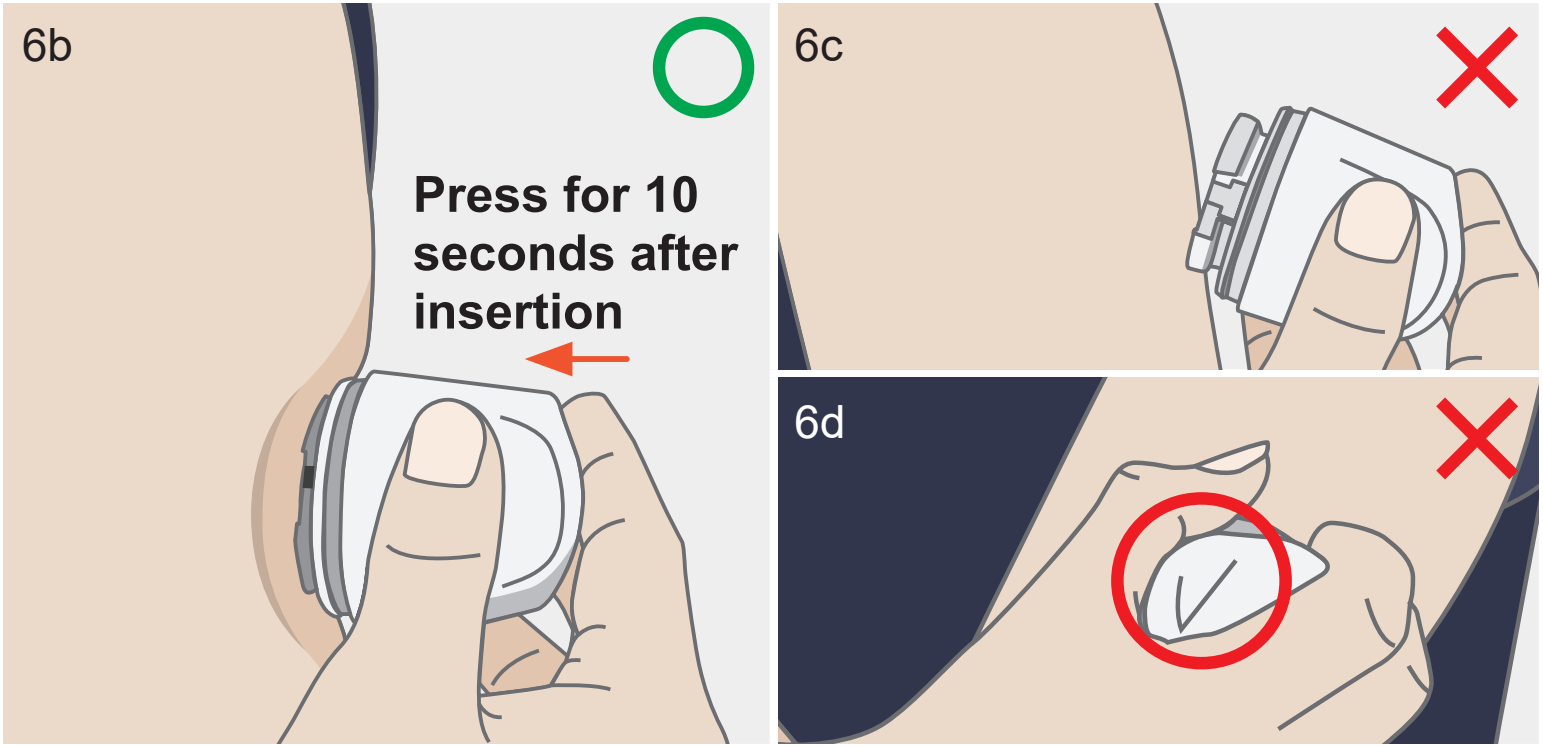
5. Open the Sensor kit cap.
   NOTE:
   The adhesive patch does not have a paper cover and is ready for Application immediately after opening the cap.



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

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





CAUTIONS :

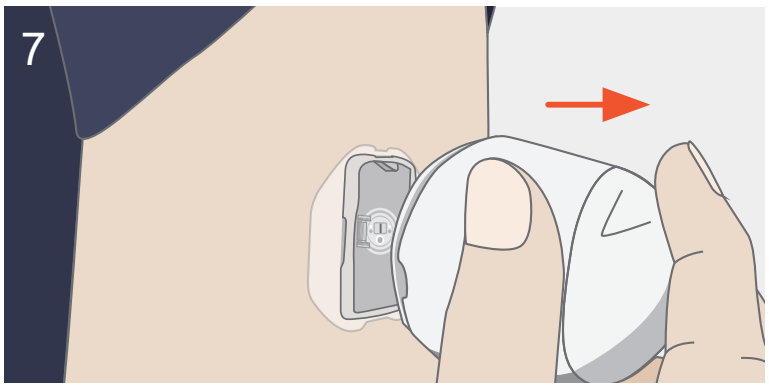
1. Apply the sensor immediately after opening its package and the cap. Otherwise, it may present an infection risk.
2. Do not push down the inserter until it is placed over the insertion site.
3. If the insertion is not successful or causes any discomfort, please consult your healthcare professional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

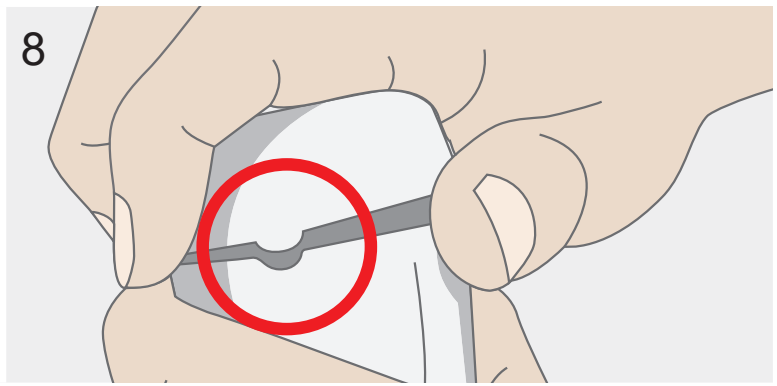
4. Do not Apply the sensor if it falls out of the inserter when opening the cap.
5. Do not Apply the inserter if it is misused or mishandled before insertion.

7. Gently move the inserter away from your insertion site.
8. Align both notches on the inserter body and the cap to reconnect them. Discard the inserter in an Appropriate puncture-proof or biohazard container according to local regulations for sharps and blood-containing components to prevent cross-contamination and ensure safety.

   NOTE:

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





⚠ **CAUTIONS :**

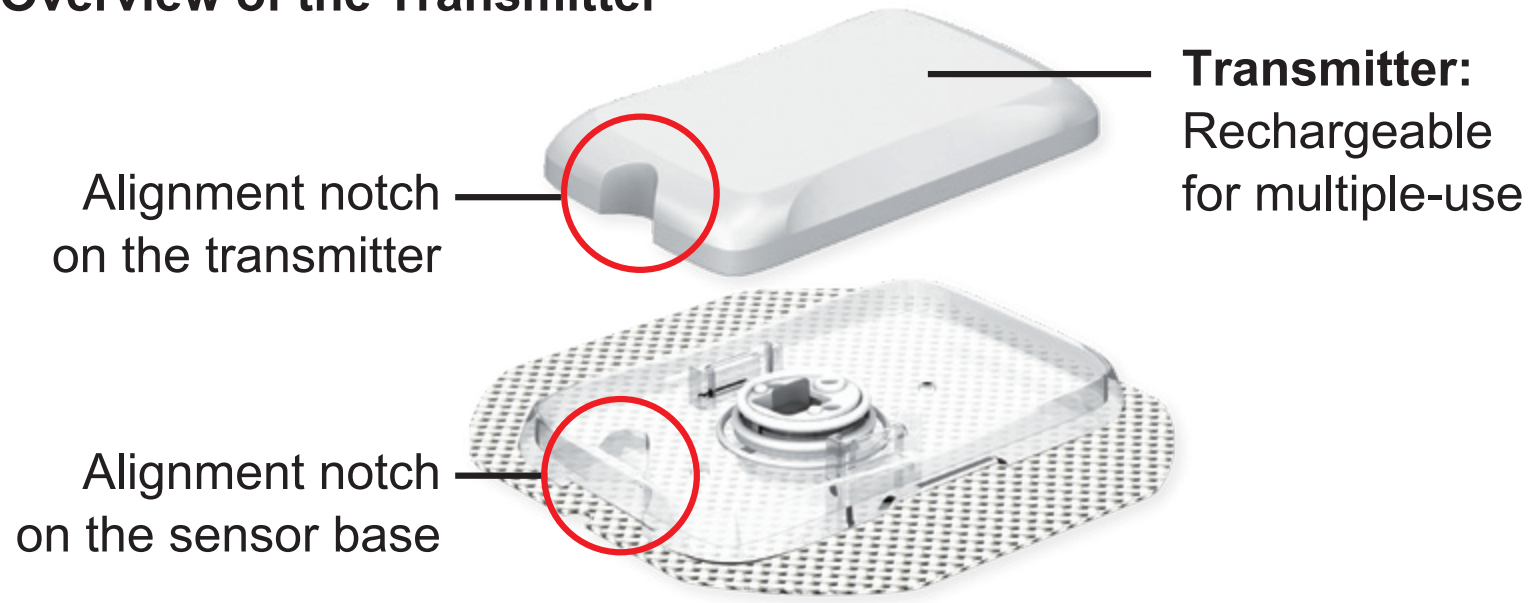
Bleeding or bruising at the insertion site under or around the sensor base after applying the sensor is extremely uncommon. If bleeding occurs or you experience high levels of discomfort, follow these steps to reduce risks:

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

Attach Your Transmitter

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

Overview of the Transmitter



Attach your transmitter after the sensor is inserted.

• Store both the transmitter and its charger in the provided storage

vial. Before attaching the transmitter, make sure it is fully charged. Do not remove your transmitter until your sensor session is over.

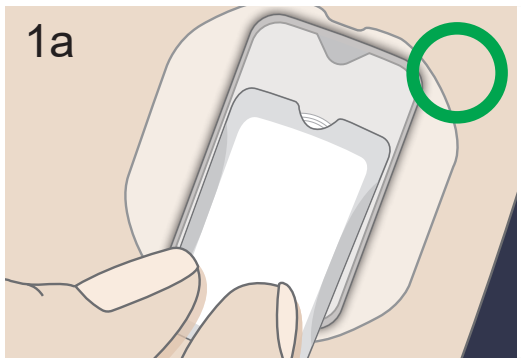
⚠ **CAUTIONS :**
Pair Before Use: Make sure the transmitter has been paired with the sensor.

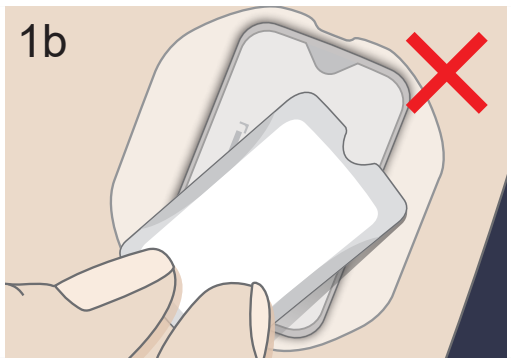
Follow these steps to attach your transmitter:

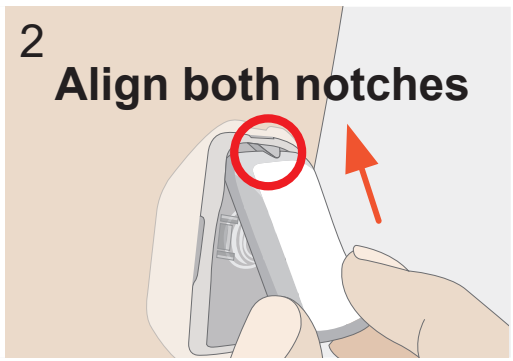
1. Align the edge of transmitter and the edge of sensor base.
2. Slide transmitter along the edge of sensor base until both notches on the sensor base and transmitter are aligned.

   NOTE:

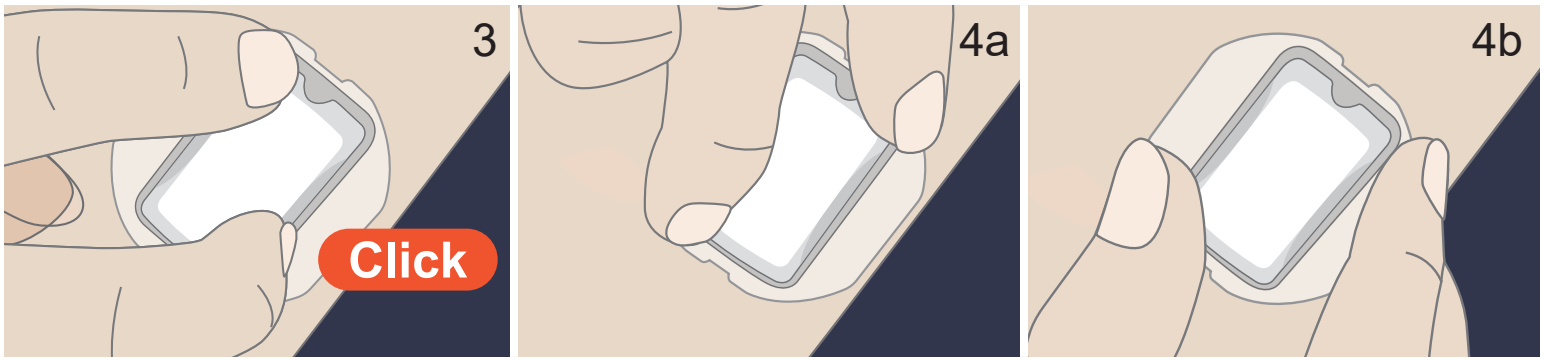
   1. After the transmitter and sensor are assembled, they are IP48 rated for water resistance (10 feet or 3.05 meter for 30 hours) and can be worn while bathing, showering, or swimming.
   2. Make sure there are no unknown substances on the sensor or sensor base to ensure maximum water resistance.







3. Press down the transmitter until it clicks into the sensor base.
   NOTE:
   Try using a mirror or asking others for assistance to attach your transmitter in the sensor base. An LED will flash when the transmitter is sucessfully connected.
4. Make sure the following sites:
   (a) All four corners of the transmitter are secured in the sensor base. (b) Adhesive patch is fully attached on your skin.



Connect Transmitter With Display Device

WARNING :
Use a Blood Glucose (BG) Meter. During the first 2-hour sensor warm-up period after you insert a new sensor, use a BG meter to make treatment decisions. You will not receive any sensor readings, or alerts until your system begins to transmit data.

WARNING :
Test Your Display Device Regularly. Test your smartphone's speaker and vibration functions regularly. If you have any doubts about it, contact a manufacturer authorized dealer for technical support.
Keep Your Display Device Close. Be sure your display device is close to your transmitter and in the same room. The maximum transmission distance is 6 meters (20 feet) with no obstructions (e.g. walls, metal, glass or water) in between. Obstructions or greater distances may cause Bluetooth signal loss and you may not receive important alerts.

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

Keep your smartphone close to you.

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

NOTE:

1. Your smartwatch only communicates with your mobile phone, not the Transmitter. You won't get alerts or sensor readings on your smartwatch unless it's connected to your mobile phone.
2. Using the smartwatch with your iFree CGM App may change how you get alerts.
3. Waking up your smartwatch updates your current glucose data from your mobile phone. There may be a brief delay before your smartwatch shows current information.

Ending A Monitoring Session

End The Monitoring Session

⚠ **CAUTIONS :**

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

Ending a Session Early: If any unexpected issues (irritation or discomfort) happen at the application site, consult your healthcare professional for further assistance to prevent serious adverse events. Follow the instructions to remove your sensor.

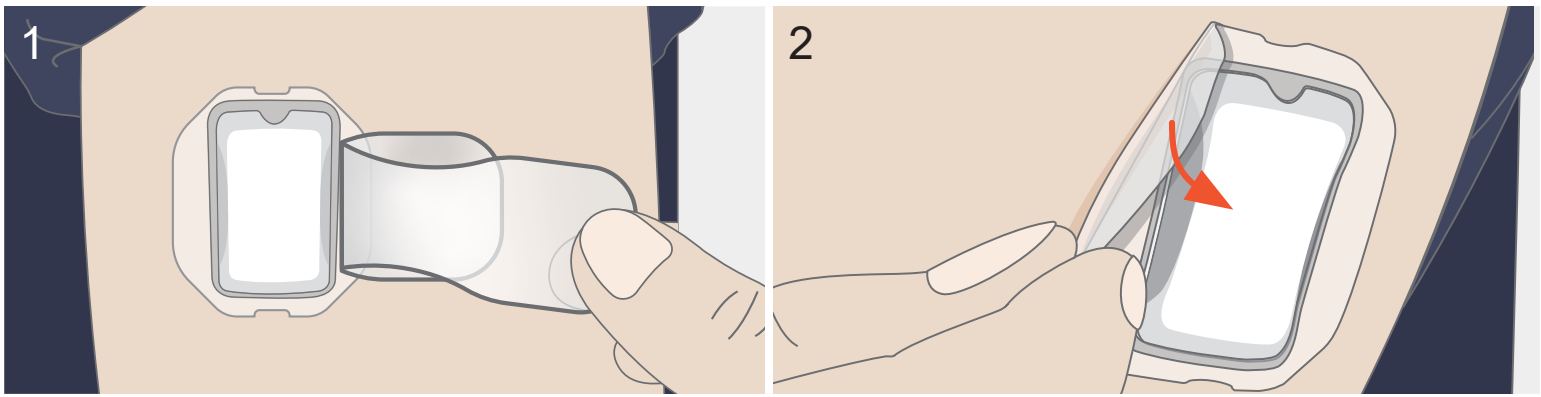
1. The monitoring session ends automatically when the sensor reaches the ends of its 14-day life, and the sensor reading will no longer be shown on the screen. A notification will pop-up to let you know the session has ended. You MUST remove or replace the currently used sensor upon receiving this notification. Press **[Remove CGM]** to confirm.
2. To end a monitoring session before receiving the notification, you can select "Stop Monitoring" from "Report". You will see a message warning you that the sensor has not yet expired. Press **[Stop anyway]** to end the session.

Sensor And Transmitter Removal

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

sensor and transmitter:

1. Press and hold the center of the transmitter with your fingers. Start by peeling off the sensor patch from the skin until the transmitter is exposed. Hold the exposed transmitter part with one hand while continuing to remove the sensor patch from the transmitter with the other hand.
2. Grip the edge of the adhesive patch and peel the sensor and transmitter off in one motion.

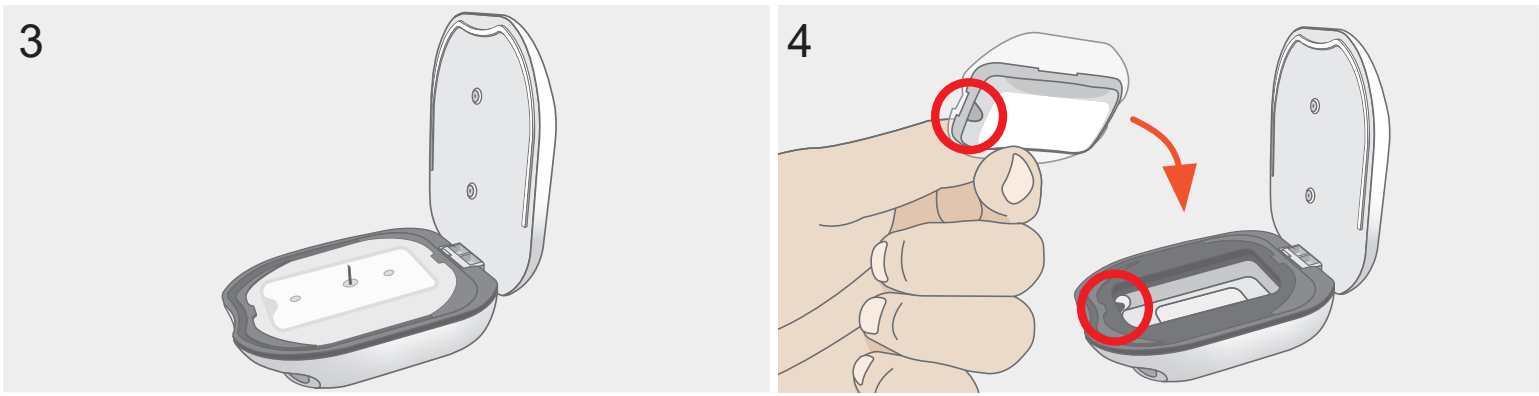


⚠ **CAUTIONS :**

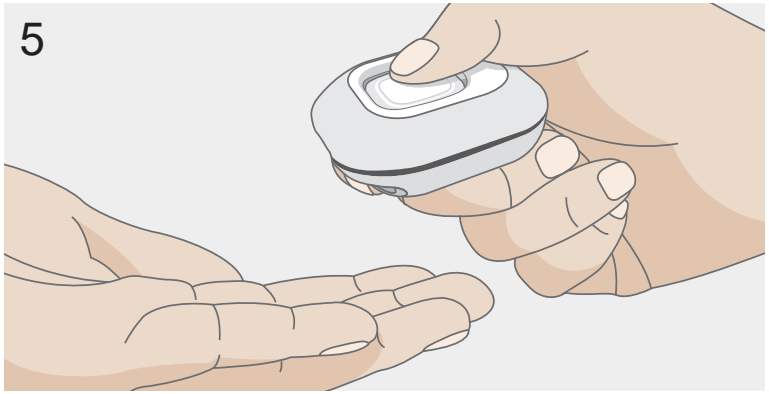
Follow the instructions to proper use of the sensor and avoid sensor breaking. If the sensor breaks under your skin, do not remove it by yourself. Contact your healthcare professional immediately for further assistance. If any symptoms of

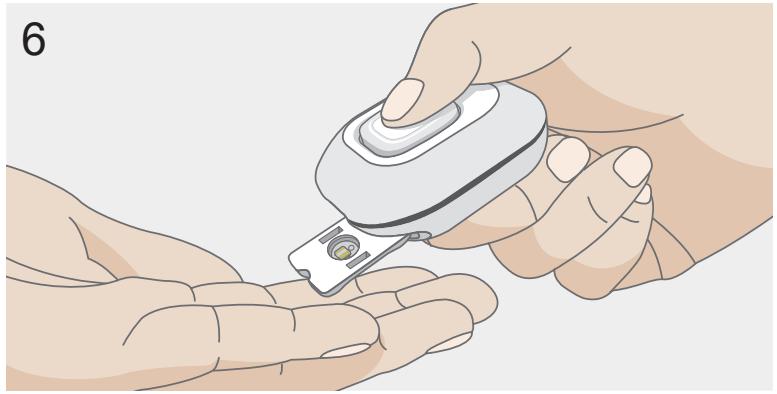
infection or inflammation (such as redness, swelling, or pain at the insertion site) occurs, visit medical facility for emergency treatment.
Any remaining adhesive residue on the skin can be removed with warm soapy water or isopropyl alcohol.

3. Open the upper cover of the splitter. Find the alignment notches of the transmitter and the splitter. Align both notches.
4. Face the transmitter into the compartment and put the the transmitter with the sensor base into the splitter.

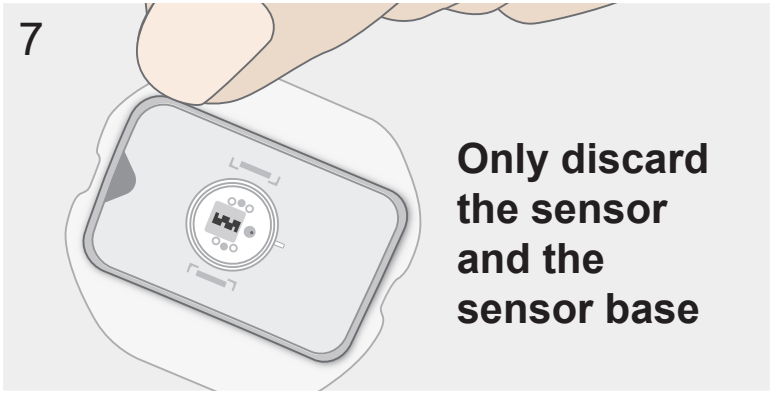


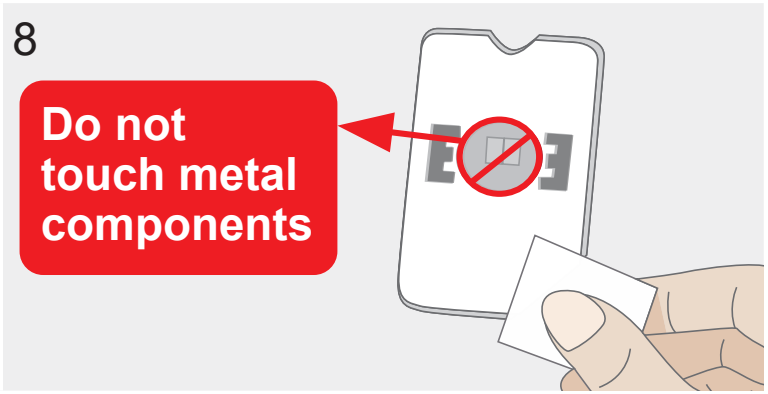
5. Close the cover and push the splitter button.
6. Tilt the splitter to drop out the transmitter.



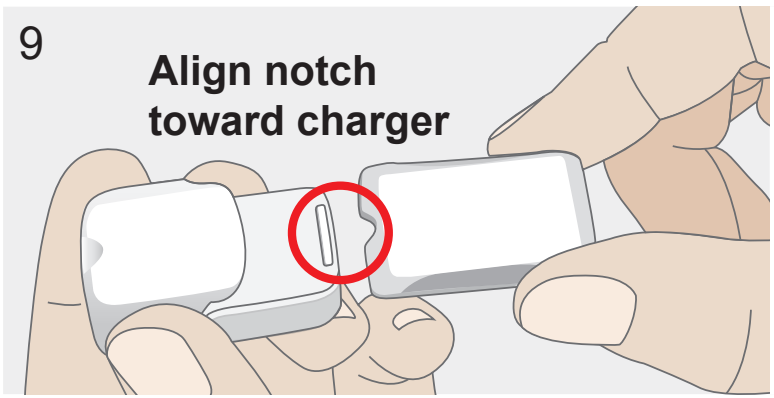


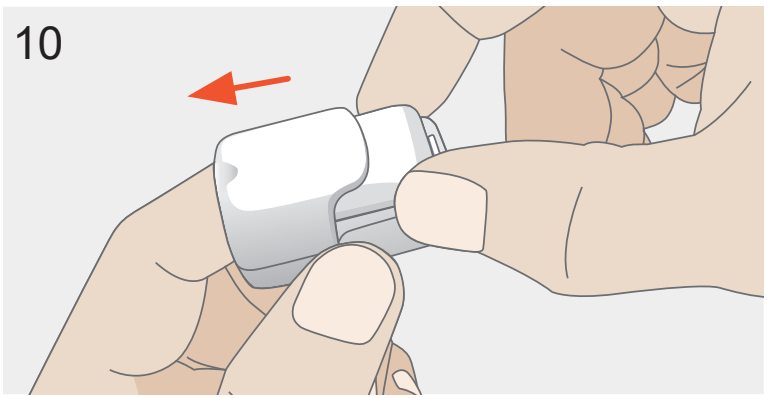
7. Keep the transmitter to use with the next sensor. Discard the sensor, sensor base and adhesive patch according to local regulations for disposal of bloodcontacting components.
   NOTE:
   Do not throw away the transmitter.
8. Always clean the bottom of the transmitter with an alcohol pad or a dry cloth and let the transmitter dry before continuing. Do not touch or scratch the metal components.
   NOTE:
   Failure to clean it may cause it to deteriorate and harden over time, resulting in malfunction.





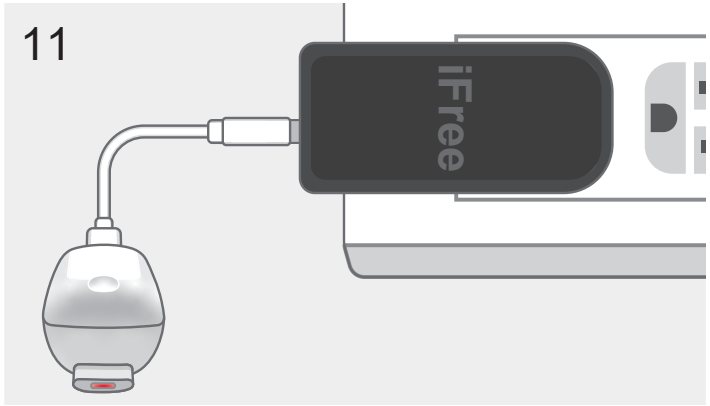
9. Hold the charger face up. Align the notch of the transmitter toward the charger's transmitter compartment with the transmitter's metal components facing down.
10. Slide the transmitter into the charger compartment.

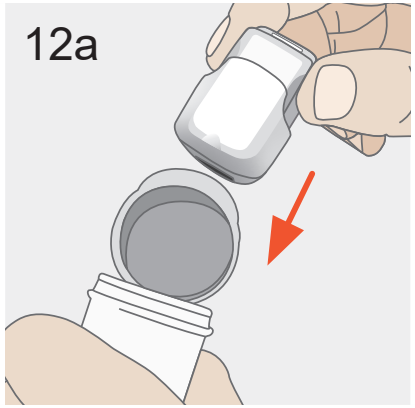


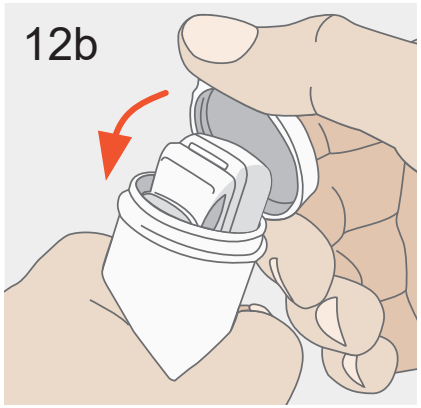


11. Follow steps 2 - 8 of CHARGING THE TRANSMITTER to charge your transmitter before its next use.
12. Store the charger with the transmitter inside in the storage vial. Cap the storage vial.

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







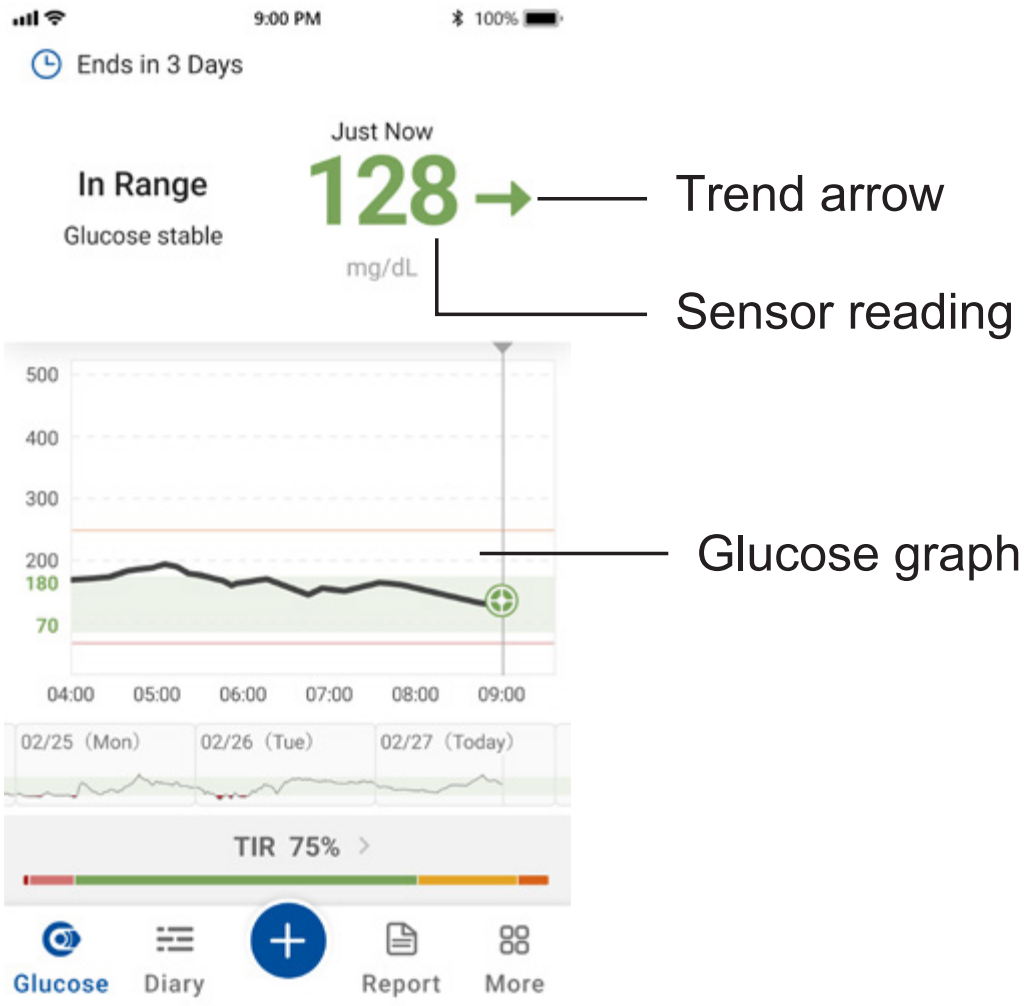
Understand Your Glucose Readings

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

Home Screen Indicator And Displays Overview

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

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

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

Direction / Arrow Color	Glucose is steady*	Glucose rising**	Glucose rising rapidly***	Glucose falling**	Glucose falling rapidly***
Orange > 250 mg/dL					
Amber 181 - 250 mg/dL					
Green 70 - 180 mg/dL					
Pink 54 - 69 mg/dL					
Red < 54 mg/dL					

Add And Access Notes

1. From the Home screen, add a note by tapping ⊕.
2. Make sure the time is correct. Select the options (Insulin, Exercise, Carbs) and follow the prompts to add a note.
3. Tap **[Done]** to save your notes.
4. Notes can be accessed, edited or deleted if you want. Tap on a note for more details.

High/Low Readings

HIGH/LOW message on your display device screen indicates the sensor reading is outside of the measuring range.

HIGH means 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.

LOW means 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.

Calibration

The calibration allows alignment between CGM readings and your BG meter values. Use specified BG meter (MAX Plus) to calibrate. When the iFree CGM needs to be calibrated (as shown in the table below), the display device will send a calibration alert. The symbol () will appear on the reminder screen, and users must follow the directions provided in the prompt.

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

Subsequent after Third	Within 24 hours after last calibration (20 to 24 hours is recommended.)	Input glucose value obtained from a blood glucose finger-stick test once.

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

1. From the calibration reminder screen, tap **[Take fingertip glucose]**.
2. Enter the exact BG value then press **[Save]**.
3. You will see a prompt from the screen. Tap **[OK]**.

NOTE:

1. Only a BG value between 40 mg/dL (2.2 mmol/L) and 500 mg/dL (27.8 mmol/L) can be used for calibration. If your BG value is significantly different from your sensor reading, it is recommended to calibrate again to avoid inaccurate readings.
2. During periods of rapid glucose change (such as after eating, insulin injection, or exercise), physiological differences between interstitial fluid and blood may cause discrepancies between the

sensor reading and the BG meter value. It is advised not to calibrate the CGM during periods of rapid glucose fluctuation to ensure calibration accuracy.

3. Perform calibration when fasting or before meals to minimize glucose fluctuation.
4. Enter the blood glucose value into the display device immediately after performing the fingertip test.
5. Do not use previously measured blood glucose values for calibration.
6. If calibration fails, wait at least 15 minutes before retrying.

Connection And Data Upload

The App can automatically upload your monitoring results to the cloud via the Internet. Refer to the original manual of your smartphone to learn how to set up a mobile network or Wi-Fi connection. Using a mobile network for internet access may incur data transmission charges. It will be charged by your mobile carrier.

Treatment Decisions

Before you start using the iFree CGM for treatment decisions, make sure you are familiar with the tips provided in this chapter and you have a good understanding of how the CGM works.

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

WARNINGS :

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

Use a Blood Glucose (BG) Meter to Make Treatment Decisions under the Following Conditions:

- During the first 2-hour warmup period when you start a new

sensor. You won't receive any sensor readings, and alerts until your system begins to transmit data.
- If you suspect that your sensor readings may be inaccurate for any reason.
- If your sensor readings do not match what you are feeling.
- If you are experiencing symptoms that may be due to low or high blood glucose.
- If your sensor readings do not include your current glucose concentration or a glucose trend arrow.
- If you wish to confirm hypoglycemia or impending hypoglycemia as reported by the sensor.
- If you are experiencing rapid glucose changes (more than 2 mg/dL per minute), the sensor readings displayed may be less accurate and not as timely.

When Not To Use Sensor Readings To Make Treatment Decisions

You must not make treatment decisions based on your sensor glucose reading in the following situations:
- You suspect that your sensor blood glucose readings may be inaccurate for any reason.

- Sensor glucose readings do not match what you are feeling.
- You are experiencing symptoms that may be due to low or high blood glucose.
- The display device shows no glucose information (e.g., an interrupt alert).
- **Glucose is Falling/Rising Rapidly.** (with upwards/downward arrow): Glucose measured in interstitial fluid may differ substantially from true blood glucose levels, particularly during rapid glucose change (e.g., after meals, insulin intake, or exercise).
- **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 or falling quickly.
- **No Current Glucose Concentration and Trend Arrow:** When there is a HIGH/LOW result, you lack enough information to make a treatment decision.

⚠ **CAUTIONS :**
Sensor Readings may be Different from BG Meter Values.
During periods of rapid change in blood glucose (e.g. after

eating, taking insulin, or exercising), you may observe differences in glucose readings between interstitial fluid and capillary blood. Due to physiological differences between different body fluids, the sensor readings may be different from fingerstick blood glucose values from BG meters. Calibration may help align the sensor readings and BG meter values. Confirm your blood glucose values with a BG meter before making treatment decisions.

Trend Arrows And Treatment Decisions

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

Trend Arrow	Treatment Decision		
	Low Glucose (< 70 mg/dL)	**Glucose in Target Range**	**High Glucose (> 250 mg/dL)**
(No Trend Arrow)	Do a fingerstick blood glucose check with your BG meter. **Do NOT** treat based on your iFree CGM.		
Double up arrow 	(All Arrow Colors) Do a fingerstick blood glucose check with your BG meter. **Do NOT** treat based on your iFree CGM.		

Trend Arrow	Treatment Decision
	Low Glucose (< 70 mg/dL)
Single up arrow 	(Pink/Red Arrow Colors) Do a fingerstick blood glucose check with your BG meter. **Do NOT** treat based on your iFree CGM.

Trend Arrow	Treatment Decision Glucose in Target Range
Single up arrow 	• 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, wait and check your glucose reading later. **Avoid "Insulin stacking"**.

Trend Arrow	Treatment Decision
	High Glucose (> 250 mg/dL)
Single up arrow 	(Orange Arrow Color) • If you are about to eat, take insulin to cover your meal. Consider increasing your dose a little since your glucose is high and rising. • If you've recently taken insulin or are about to exercise, wait and check your glucose reading later. • If you have not recently taken insulin and have finished exercise, consider adjusting your insulin correction dose upwards. **Avoid "Insulin stacking".**

Trend Arrow	Treatment Decision
	Low Glucose (< 70 mg/dL)
Horizontal arrow →	(Pink/Red Arrow Colors) Do a fingerstick blood glucose check with your BG meter. **Do NOT** treat based on your iFree CGM.

Trend Arrow	Treatment Decision Glucose in Target Range
Horizontal arrow →	• If you are about to eat, take insulin to cover your meal. • If you've recently taken insulin or are about to exercise, wait and check your sensor reading later. **Avoid "Insulin stacking"**.

Trend Arrow	Treatment Decision
	High Glucose (> 250 mg/dL)
Horizontal arrow →	(Orange Arrow Color) • If you are about to eat, take insulin to cover your meal. Consider increase your dose a little since your glucose is high. • If you've recently taken insulin or are about to exercise, wait and check your glucose reading later. • If you have not recently taken insulin and have finished exercise, consider adjusting insulin correction dose upwards. **Avoid "Insulin stacking".**

Trend Arrow	Treatment Decision
	Low Glucose (< 70 mg/dL)
Single down arrow 	(Pink/Red Arrow Colors) Do a fingerstick blood glucose check with your BG meter. **Do NOT** treat based on your iFree CGM.

Trend Arrow	Treatment Decision
	Glucose in Target Range
Single down arrow 	• 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.

Trend Arrow	Treatment Decision
	High Glucose (> 250 mg/dL)
Single down arrow 	(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, wait and check your glucose reading later. **Avoid "Insulin stacking"**.

Trend Arrow	Treatment Decision		
	Low Glucose (< 70 mg/dL)	**Glucose in Target Range**	**High Glucose (> 250 mg/dL)**
Double down arrow 	(All Arrow Colors) Do a fingerstick blood glucose check with your BG meter. **Do NOT** treat based on your iFree CGM.		

Specifications

Sensor Kit Specifications

Sensor Glucose Range	40-500 mg/dL
Sensor Use Life	up to 14 days
Shelf Life	12 months
Sensor Operation Conditions	Temperature: 5°C - 45°C (41°F - 113°F) Relative humidity: 10% - 90%
Sensor Ingress Protection Rating (when installed with a transmitter)	IP48 Protected from tools and small wires greater than 1 millimeter. Protected from immersion 10 feet (3.05 meter) for 30 hours

Storage & Transportation Conditions	Temperature: 5°C - 30°C (41°F - 86°F) Relative humidity: 10% - 90% (in a cool, dry place)
Operation and Storage Altitude	0 to 3,048 meters (0 to 10,000 ft)
Inserter Size	52.0 x 57.0 x 61.3 mm (± 0.5 mm)
Sterilization	Sterilized by radiation
Usage	Single use (disposable)

Transmitter Specifications

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

Storage & Transportation & Operation Conditions	Temperature: 5°C - 45°C (41°F - 113°F) Relative humidity: 10% - 90%
Operation and Storage Altitude	0 to 3,048 meters (0 to 10,000 ft)
Shelf Life	24 months
Battery Run Time	Up to 14 days (based on full charge)
Battery Charging Time	2 hours (via AC adapter)
Charge Cycles	52 times (equivalent to 2 years of use life)
Memory Storage	14 days of glucose data (glucose readings stored every minute)
Protection Against Electrical Shock	Type BF applied part

Ingress Protection Rating (when attached to Sensor)	IP48 Protected from tools and small wires greater than 1 millimeter. Protected from immersion 10 feet (3.05 meter) for 30 hours
Data Communication	Bluetooth 4.2 Frequency range BLE : 2402 - 2480 MHz Maximum RF output power of the product : 0 dBm System pairing: NFC pairing (RFID: 13.56 MHz)
Data Communication Range	Up to 6 meters (20 feet)

Quality of Service

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

Transmitter Charger Specifications

Charger Channel	1
Indicator	LED (Green/Orange)
Input Port	USB Type
Weight	10g (± 1.0)
Charger Dimensions	37.3 x 26.0 x 22.5 mm (± 0.5 mm)
Input	DC 5V/20 mA
Output	DC 4.2V/20 mA
Storage Conditions	Temperature: 5°C - 45°C (41°F - 113°F) Relative humidity: 10% - 90%
Operation Conditions	Temperature: 5°C - 45°C (41°F - 113°F) Relative humidity: 10% - 90%

Ingress Protection Rating	IP21 Protected from touch by fingers and objects greater than 12.5 millimeters. Protected from condensation.

Recommended Power Adapter:
Although the iFree CGM system does not include a power adapter in the product package, users are recommended to use a certified adapter that meets the required electrical safety and performance standards to ensure proper and safe charging of the device.
The following adapter model is recommended:
Manufacturer: UNIFIVE TECHNOLOGY CO., LTD.
Brand: UNIFIVE
Model: UMB305-0510
This adapter provides a stable 5V/1A output suitable for use with the transmitter charger (HC312). Users may also use alternative adapters with equivalent specifications that conform to IEC 60601-1 and relevant national safety standards.

Splitter Specifications

Splitter dimension	53.0 x 44.0 x 22.0 mm (± 0.5 mm)
Weight	12.5 g (± 0.5g)
Storage & Transportation & Operating Conditions	Temperature: 5°C - 45°C (41°F - 113°F) Relative humidity: 10% - 90%
Sheif Life	2 years

It Networks Characteristics And It Security Measures For App

iFree CGM is designed to transmit data between the transmitter and designated display devices.
iFree CGM uses the following interfaces and communication protocols:
Display Device: Bluetooth Low Energy to transmitter. TLS to data platform using cellular data or Wi-Fi. Display Device is only compatible with certain mobile devices and operating system.

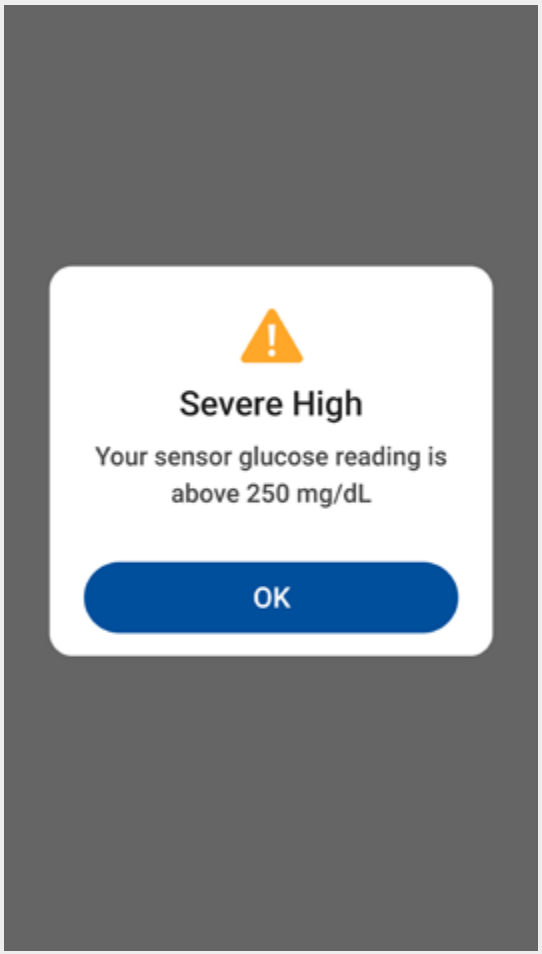
For using iFree CGM App, please check https://www.rightest.com/guides for more information about device compatibility before using the App.
Use of the iFree CGM requires user registration, and the user should follow instructions on the continuous glucose monitoring system.
Don't pair your CGM over Bluetooth in public areas.
Bluetooth pairing should be done in a private and safe location to reduce cyber risks such as eavesdropping.
In addition to the security provided by the Bluetooth Low Energy connection, communication between the transmitter and mobile applications is protected by additional levels of security and safety mitigations using an encrypted and proprietary data format. This format embeds various industry standard encryption protocols and methods to protect data, verify data integrity, and to detect and prevent data tampering.

Glucose And Signal Loss Alerts

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

- When either your display device or transmitter battery is dead.
- When your display device is turned off.
- When there is a system error (e.g., no glucose readings, sensor error, signal loss, etc.) or damage to the system.
- During the 2-hour sensor warm up period.
- When the display device is out of range (6 meters/20 feet) from your transmitter; or obstacles (metal, walls, water, etc.) are between them.

Alert settings are restored automatically after power is interrupted for less than 30 seconds.
Alert limits are restricted for any changes by the user.

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

Default Setting:

• Visual Safety Symbol (⚠) on Home Screen: Yes.

• Sound & Vibration Alert: Yes.

Editable Setting:

• Sound & Vibration can be turned ON/OFF by the user.

Alert:

- Sound & Vibration active unless turned off by user pressing the **[OK]** button on screen; or glucose is detected to fall.
- Hyper Alert will repeat every 30 minutes or until glucose level returns to the target range.

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

Default Setting:

• Visual Safety Symbol (⚠) on Home Screen: Yes.

• Sound & Vibration Alert: Yes.

Editable Setting:

• Sound & Vibration can be turned ON/OFF by the user.

Alert:

- Sound & Vibration active unless turned off by user pressing the **[OK]** button; or glucose is detected to rise.
- Low glucose alert will repeat every 30 minutes or until glucose level returns to the target range.

Screen	Event
	**Urgent Low Glucose:** Happens when glucose is at or below 54 mg/dL.

Default Setting:

• Visual Safety Symbol (⚠) on Home Screen: Yes.

• Sound & Vibration Alert: Yes.

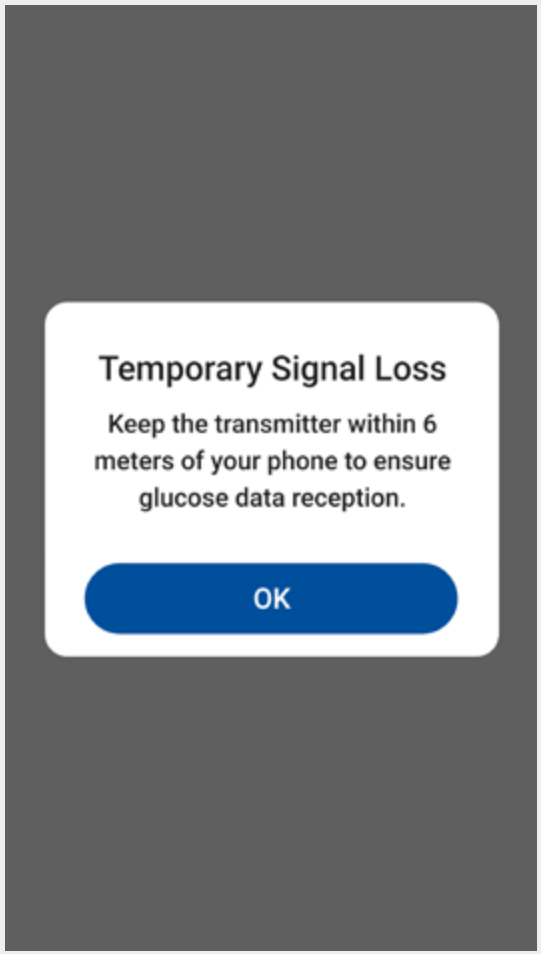
No Editable Setting:

• Sound & Vibration CANNOT be turned ON/OFF by the user.

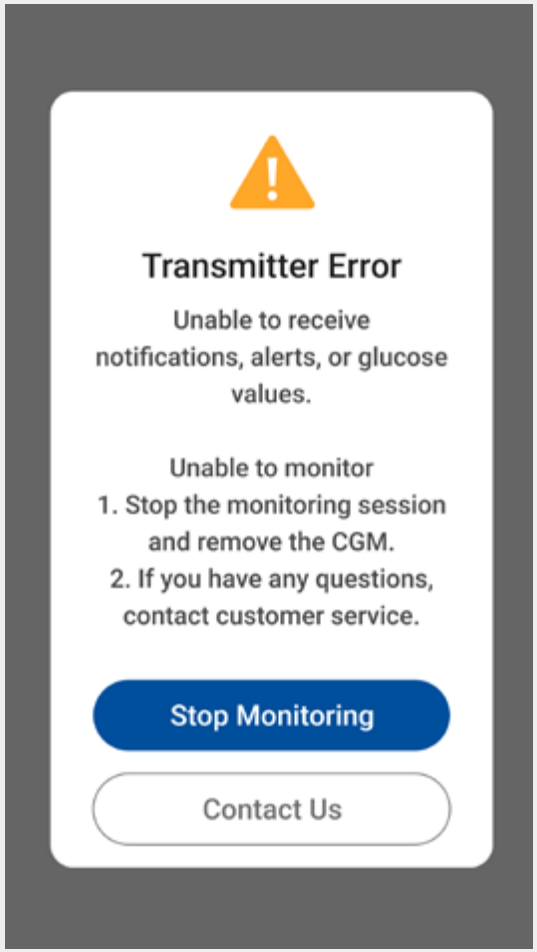
Alert:

- Sound & Vibration active unless turned off by user pressing the **[Use Fingersticks]** button; or until glucose is higher than 54 mg/dL.
- Urgent low glucose alert will repeat every 30 minutes or until glucose level returns to the target range.

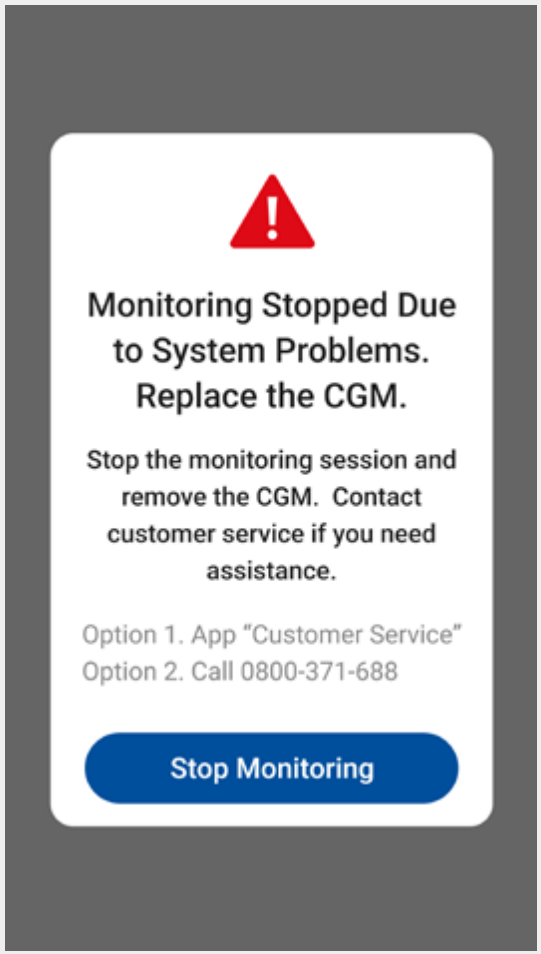
Note: If the symbol () appears, follow the prompts on the UI and perform a fingerstick blood glucose test.

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

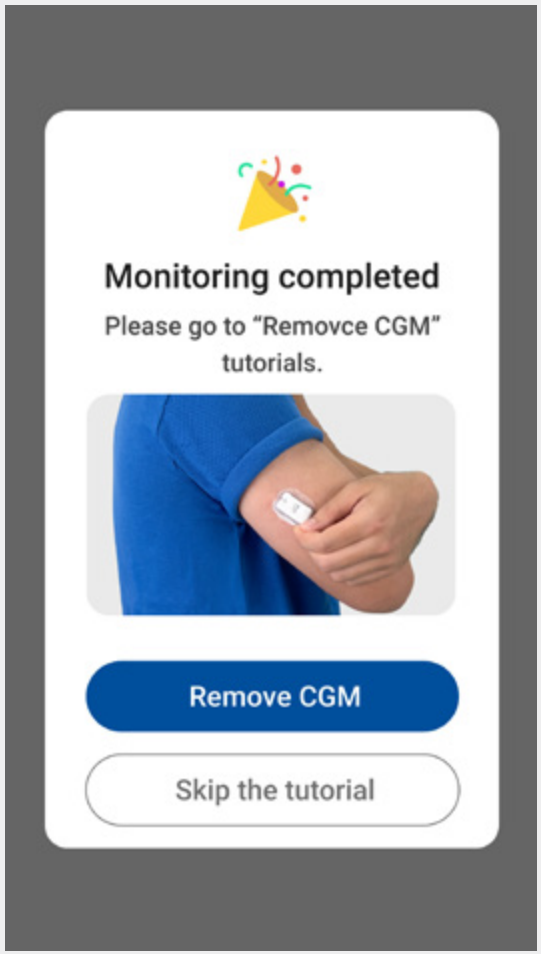
Default Setting:
• Visual message on the screen: Yes.
• Sound & Vibration Alert: Yes.
Editable Setting:
• Sound & Vibration can be turned ON/OFF by the user.
Alert:
- Displayed continuously for 5 minutes or until **[OK]** is pressed.
- System attempts to reconnect every 5 minutes even if user doesn’t press **[OK]**
- System alerts will repeat every 30 minutes.

Screen	Event
	**Transmitter Error:** Transmitter is not working.

Default Setting:
• Visual message on the screen: Yes.
• Sound & Vibration Alert: Yes.
No Editable Setting:
• Sound & Vibration CANNOT be turned ON/OFF by the user.
Alert:
- Displayed continuously for 5 minutes or until **[Stop Monitoring]** is pressed.
- System alerts will repeat every 30 minutes.

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

Default Setting:
• Visual message on the screen: Yes.
• Sound & Vibration Alert: Yes.
Editable Setting:
• Sound & Vibration can be turned ON/OFF by the user.
Alert:
- Displayed continuously for 5 minutes or until [**Stop Monitoring**] is pressed.
- System alerts will repeat every 30 minutes.

Screen	Event
	**Session is Completed:** Your sensor session has expired.

Default Setting:
• Visual message on the screen: Yes.
• Sound & Vibration Alert: Yes.
Editable Setting:
• Sound & Vibration can be turned ON/OFF by the user.
Alert:
- Displayed continuously until **[Remove CGM]** is pressed.

Customer Service

We aim to provide great service to our customers. Please review these instructions to make sure you know how to use your product correctly.

If you have any questions or encounter any issues with your product, please contact Bionime Customer Service or your authorized distributor. For any serious incident, you may also consult your local competent authority.

User's Manual is also available electronically.

- App: “More” tab > Certification > Go to eIFU
- https://www.rightest.com/guides
- Free printed copy: Order at https://www.rightest.com or contact us.
  Tel: +886 4 2369 2388 Fax: +886 4 2261 7586
  Email: info@bionime.com

Manufacturer’s declaration - Electromagnetic emissions

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

Emission test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations / flicker emissions IEC 61000-3-3	Cmpliance

Electromagnetic environment - Guidance (for home healthcare environment)
The Transmitter/Charger 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.
The Transmitter/Charger 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.

Manufacturer’s declaration - Electromagnetic immunity

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

Immunity test	IEC 60601 test level
Electrostatic discharge (ESD) IEC 61000-4-2	Contact: ± 8 kV Air ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV
Electrical fast transient / burst IEC 61000-4-4	+ 2kV for power supply lines + 1kV for input / output lines
Surge IEC 61000-4-5	+ 0.5kV, +1kV line(s) to line (s) + 0.5kV, +1kV, + 2kV line(s) to earth

Compliance level	Electromagnetic environment - Guidance (for home healthcare environment)
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%
+ 2kV for power supply lines Not applicable	Mains power quality should be that of a typical home healthcare environment.
+ 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
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
Power frequency (50, 60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz

Compliance level	Electromagnetic environment - Guidance (for home healthcare environment)
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 Transmitter/Charger requires continued operation during power mains interruptions, it is recommended that the Transmitter/ Charger be powered from an uninterruptible power supply or a battery.
30 A/m 60 Hz	The Transmitter/Charger power frequency magnetic fields should be at levels characteristic of a typical location in a typical home healthcare environment.

NOTE: UT is the a.c. mains voltage prior to application of the test level.

Manufacturer’s declaration - Electromagnetic immunity

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

Immunity test	IEC 60601 test level
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

Compliance level	Electromagnetic environment - Guidance (for home healthcare environment)
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 Transmitter/Charger 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
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

Electromagnetic environment - Guidance (for home healthcare environment)

Recommended separation distance:
$d = 1,2 \sqrt{P}$
$d = 1,2 \sqrt{P}$ 80MHz to 800 MHz
$d = 2,3 \sqrt{P}$ 800MHz to 2,7 GHz

Where P is the maximum output power rating of the transmitter in watts (W). according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Interference may occur in the vicinity of equipment marked with the following symbol: 

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

Recommended separation distance between portable and mobile RF communications equipment and Transmitter/Charger

The Transmitter/Charger 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 Transmitter/Charger can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Transmitter/Charger as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)
0,01
0,1
1
10
100

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**
0,12	0,12	0,23
0,38	0,38	0,73
1,2	1,2	2,3
3,8	3,8	7,3
12	12	23

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

Manufacturer's declaration - Electromagnetic immunity Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment (only applicable for CE regulatory)

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

Test frequency (MHz)	Band a) (MHz)	Service a)	Modulation b)
2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450,	Pulse modulation b) 217 Hz
Maximum power (W)	**Distance (m)**	**IMMUNITY TEST LEVEL (V/m)**	**Compliance LEVEL (V/m) (for home healthcare)**
2	0,3	28	28

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

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