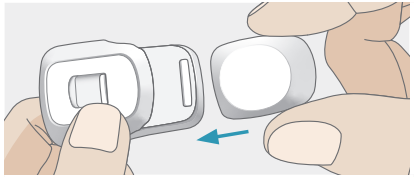
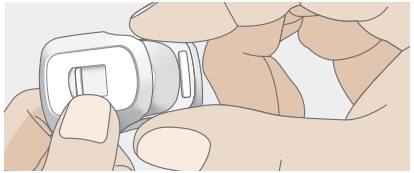
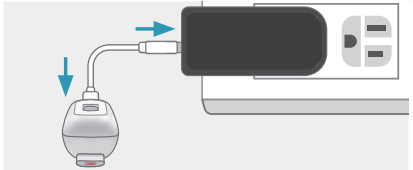


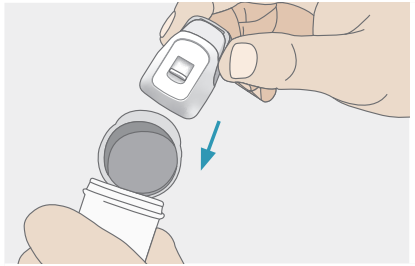
6. Hold the charger face up. Align the transmitter toward the charger's transmitter compartment with the transmitter's metal components facing down.

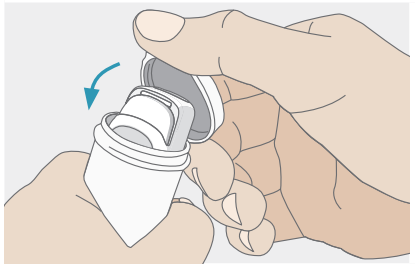


7. Slide the transmitter into the charger compartment.



8. Follow steps 2 - 7 of CHARGING THE TRANSMITTER to charge your transmitter before its next use.





9. 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 receiver'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 receiver's screen. It is important to understand these indicators before use. An overview of the home screen is shown below.

Overview of Monitoring Screen

Mobile App:

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.

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: 55-69 mg/dL					
RED: ≤ 54 mg/dL					

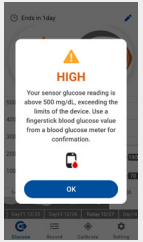
* “Glucose is steady” means the glucose rate of change is between 0 and 1 mg/dL.
** “Glucose falling/rising” means the glucose rate of change is 1 - 2 mg/dL per minute.
*** “Glucose falling/rising rapidly” means the glucose rate of change is 2 mg/dL per minute or more.

HIGH/LOW READINGS

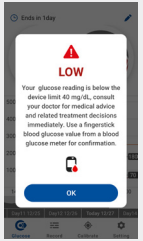
If **HIGH** appears on your display device screen, your glucose reading is above 500 mg/dL. Do a blood glucose test with a BG meter. If you also get a HIGH result (> 500 mg/dL) from the meter test, contact your healthcare practitioner immediately.

If **LOW** appears on your display device 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.

Mobile App:



HIGH indicates the sensor reading is above the detection limit.



LOW indicates the sensor reading is below the detection limit.

CALIBRATION

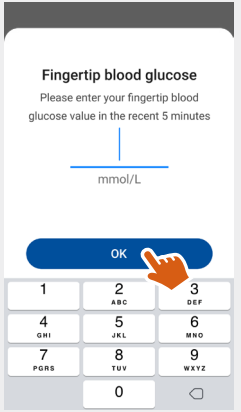
The calibration allows alignment between your system readings and your meter values. When the RIGHTEST CGMs needs to be calibrated (as shown in the table below), the display device will send a calibration alert.

Timing for calibration	Action	Remark
Immediately after warmup	Input glucose values obtained from a blood glucose meter and fingerstick once.	Make sure you enter a blood glucose value from a BG test within 5 minutes.

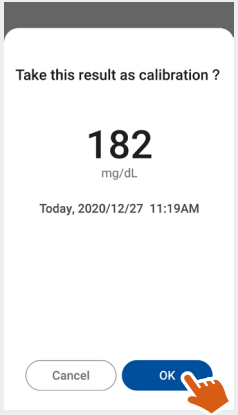
When you calibrate, take a fingerstick measurement from your BG meter then enter the value according to the following steps:

Mobile App:

1. From the Calibrate screen, tap **[Take fingertip glucose]**.



2. Enter the exact BG value then press **[OK]**.



3. You will see a prompt from the screen. Tap **[OK]**.
NOTE :
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.

CONNECTION AND DATA UPLOADING

Mobile App:
The mobile 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 to connect to the Internet. Using a mobile network to connect to the Internet may be charged for data transmission. It will be charged by your mobile carrier.

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 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 1-hour warmup period when you start a new sensor. You won't receive any sensor readings, alarms 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 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 1-hour warmup period when you start a new sensor, the system cannot tell you if your glucose is rising quickly or falling quickly.
- **No Current Glucose Concentration and Trend Arrow:** When there is a HIGH/LOW result, you don't have enough information to make a treatment decision.

⚠ **PRECAUTIONS :**

Sensor Readings may be Different from BG Meter Values. During periods of rapid change in blood glucose (e.g. after eating, taking insulin, or exercising), you may observe differences in glucose readings between interstitial fluid and capillary blood. Due to physiological differences between different body fluids, the sensor readings may be different from fingerstick blood glucose values from BG meters. 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 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.		
45° upward arrow 	(Pink/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 yourmeal. 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"**.	(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)	Glucose in Target Range	High Glucose (> 250 mg/dL)
Horizontal arrow 	(Pink/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, wait 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, 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)	Glucose in Target Range	High Glucose (> 250 mg/dL)
45° downward arrow 	(Pink/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 fastacting carbs.	(Orange Arrow Color) • If you are about to eat, take insulinto 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"**.
90° downward arrow 	(All Arrow Colors) Do a fingerstick blood glucose check with your BG meter. Do NOT treat based on your RIGHTEST CGMs.		

SPECIFICATIONS

SENSOR KIT (HS500) SPECIFICATIONS

Sensor Glucose Range	40 - 500 mg/dL
Sensor Use Life	up to 14 days
Shelf Life	12 months
Sensor Operating Conditions	Temperature: 5°C - 40°C (41°F - 104°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.
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 60.0 x 61.3 mm (± 0.5 mm)
Sterilization	Sterilized by radiation
Usage	Single use (disposable)

TRANSMITTER (HT500) SPECIFICATIONS

Transmitter Size	24.9 x 19.4 x 4.8 mm (± 0.5 mm)
Transmitter Weight	2.0 g with battery (± 0.5g)
Power Source	Rechargeable lithium battery (3.0V) 17mAh
Storage Transportation & Operating Conditions	Temperature: 5°C - 40°C (41°F - 104°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)
Charging Time	24 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)	IP47 Protected from tools and small wires greater than 1 millimeter. Protected from immersion between 15 centimeters and 1 meter in depth.

Data Communication	Bluetooth 4.2 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)
Please refer to the label on the storage vial for more device information.	
FCC ID : ADU-HM500	

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

TRANSMITTER CHARGER (HC500) SPECIFICATIONS

Charger Channel	1
Indicator	LED (Green/Amber)
Input Port	USB-C
Weight	10 g (± 1.0 g)
Charger Dimensions	37.3 x 26.0 x 22.5 mm (± 0.5 mm)
Input	DC 5V/20 mA
Output	DC 3.0V/20 mA
Storage Transportation & Operating 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
Operating and Storage Altitude	0 to 3,048 metres (0 to 10,000 ft)

CERTIFICATE STATEMENT

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.

FCC RF Radiation Exposure Statement:

1. This device must not be co-located or operating in conjunction with any other antenna or transmitter.
2. For portable operation, this equipment complies with FCC RF radiation exposure limits set forth for an uncontrolled environment.

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

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。」

APPENDIX

GLUCOSE AND SIGNAL LOSS ALERTS

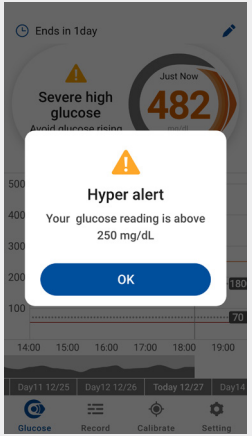
There are delayed or no alarms/alerts in the following situations. When not in the following situations, alarms/alerts will happen in 5 seconds.

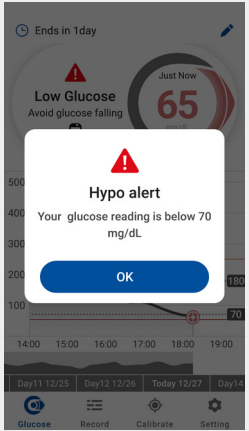
- When either your display device or transmitter battery is dead.
- When your display device is turned off.
- When there is a system error (e.g. no glucose readings, sensor error, signal loss, etc.) or damage to the system.
- During the 1-hour sensor warm-up period.
- If your sensor readings do not match what you are feeling.
- When the display device is out of range (6 meters/20 feet) from your transmitter; or obstacles (metal, walls, water, etc.) are between them.

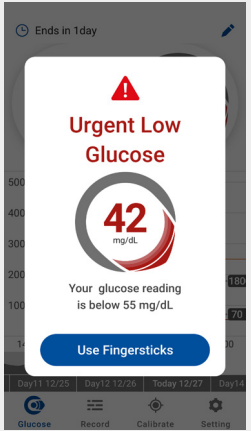
Alarms/alerts settings are restored automatically after power is interrupted for less than 30 seconds.

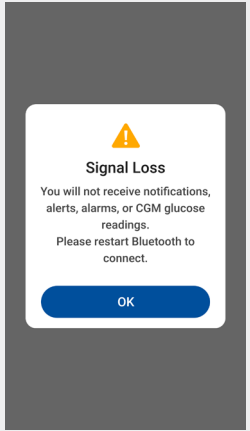
Alarms limits is restricted for any change by user.

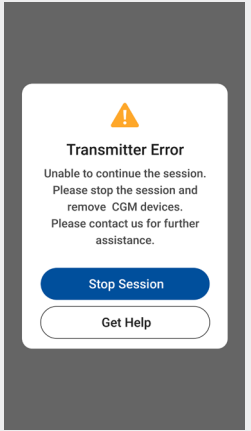
Mobile App:

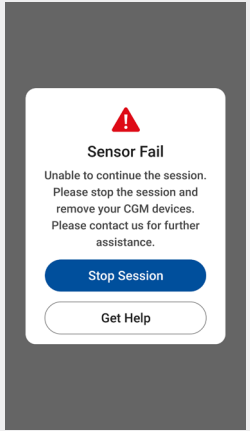
Screen	Event	Visual & Sound Settings
	**High Glucose Alert** Happens when glucose is higher than the set target range and is detected to fall or remain steady.	**Default Setting:** • Visual Safety Symbol (⚠) on Home Screen: Yes. • Sound & Vibration Alert: Yes. - Sound & Vibration active unless turned off by user pressing the [OK] button on screen; or glucose is detected to fall. - High glucose alert will repeat every 30 minutes or until glucose level returns to the target range. **Editable Setting:** • Sound & Vibration can be turned ON/ OFF by the user.

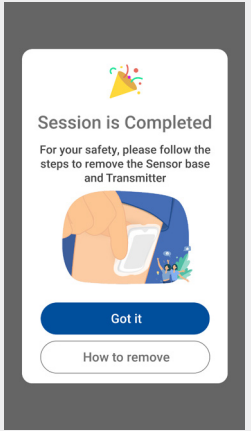
Screen	Event	Visual & Sound Settings
	**Low Glucose Alert** Happens when glucose is lower than set target range and is detected to fall or remain steady.	**Default Setting:** • Visual Safety Symbol (⚠) on Home Screen: Yes. • Sound & Vibration Alarm : Yes. - Sound & Vibration active unless turned off 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. **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. - 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 the transmitter and receiver.	**Default Setting:** • Visual message on the screen: Yes • Sound & Vibration Alert : Yes. - 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
	Transmitter is not working.	**Default Setting:** • Visual message on the screen: Yes • Sound & Vibration Alert : Yes. - 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. - 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
	Your sensor session has expired.	**Default Setting:** • Visual message on the screen: Yes. • Sound & Vibration Alert: Yes. - Displayed continuously for 5 minutes or until **[OK]** is pressed. **Editable Setting:** • Sound & Vibration can be turned ON/ OFF by the user.

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.

WARRANTY

The manufacturer warrants that your RIGHTEST receiver and 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 measuring.

Manufacturer's declaration-electromagnetic emissions		
The HT500 / HC500 is intended for use in the electromagnetic environment (for home healthcare) specified below. The customer or the user of the HT500 / HC500 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 HT500 / HC500 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 HT500 / HC500 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Compliance	

Manufacturer's declaration-electromagnetic immunity			
The HT500 / HC500 is intended for use in the electromagnetic environment (for home healthcare) specified below. The customer or the user of the HT500 / HC500 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	+ 2 kV for power supply lines, + 1 kV for input / output lines	+ 2 kV for power supply lines Not applicable	Mains power quality should be that of a typical home healthcare environment.
Surge IEC 61000-4-5	+ 0.5 kV, +1 kV line(s) to line(s), + 0.5 kV, +1 kV, + 2 kV line(s) to earth	+ 0.5 kV, +1 kV line(s) to line(s) Not applicable	Mains power quality should be that of a typical home healthcare environment.

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; 25 cycles Voltage interruptions: 0 % UT; 250 cycles	Mains power quality should be that of a typical home healthcare environment. If the user of the HT500 / HC500 requires continued operation during power mains interruptions, it is recommended that the HT500 / HC500 be powered from an uninterruptible power supply or a battery.
Power frequency (50, 60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz	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 HT500 / HC500 is intended for use in the electromagnetic environment (for home healthcare) specified below. The customer or the user of the HT500 / HC500 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 HT500 / HC500 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: $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P}$ 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 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 HT500 / HC500

The HT500 / HC500 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 HT500 / HC500 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the HT500 / HC500 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 $d = 1{,}2\sqrt{P}$	80 MHz to 800 MHz $d = 1{,}2\sqrt{P}$	800 MHz to 2,7 GHz $d = 2{,}3\sqrt{P}$
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 HT500 / HC500 is intended for use in the electromagnetic environment (for home healthcare) specified below. The customer or the user of the HT500 / HC500 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
710	704 – 787	LTE Band 13, 17	Pulse modulation b) 217 Hz	0,2	0,3	9	9
745							
780							
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0,3	28	28
870							
930							

1720	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation b) 217 Hz	2	0,3	28	28
1845							
1970							
2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0,3	28	28
5240	5100 – 5800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0,2	0,3	9	9
5500							
5785							

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.

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

The HT500 / HC500 is intended for use in the electromagnetic environment (for home healthcare) specified below. The customer or the user of the HT500 / HC500 should assure that it is used in such an environment.

Frequencies	Test Level [A/m]	Point / Window	Modulation	Dwell time [s]	Compliance LEVEL [A/m] (for home healthcare)
30 kHz (a)	8	All points on photo below	CW	3	8
134,2 kHz	65	All points on photo below	Pulse modulation (b) 2,1 kHz	3	65 (c)
13,56 MHz	7,5	All points on photo below	Pulse modulation (b) 50 kHz	3	7,5 (c)

Note:
(a) This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEALTHCARE ENVIRONMENT.
(b) The carrier shall be modulated using a 50% duty cycle square wave signal.
(c) r.m.s., before modulation is applied.

Test frequency (MHz)	Band a) (MHz)	Service a)	Modulation b)	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)	Compliance LEVEL (V/m) (for home healthcare)
2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0,3	28	28
5240	5100 – 5800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0,2	0,3	9	9
5500							
5785							

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.