

**Medtronic**  
**Guardian™ 4**  
Transmitter





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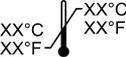
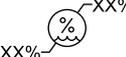
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## Icon Table

	Serial number
	Catalogue number
	Medical device
(1x)	One per container/package
	Date of manufacture
	Country of manufacture
	Manufacturer
	Temperature limit
	Non-ionizing electromagnetic radiation
	Configuration or unique version identifier
	Type BF applied part
IP48	Protected against effects of continuous immersion in water at a depth of 8 feet (2.4 meters) for up to 30 minutes
	Humidity limitation

	Fragile, handle with care
	Keep dry
	Recyclable, contains recycled content
	Do not dispose of this product in unsorted municipal waste stream
	Magnetic Resonance (MR) Unsafe
	Recharge-by date
 <b>Bluetooth</b>	Bluetooth® wireless technology or Bluetooth® enabled
<b>R<sub>x</sub> Only</b>	Requires prescription in the USA
	Consult instructions for use
	Caution: consult instructions for use for important warnings or precautions not found on the label
	Unique device identifier
<b>FCC ID</b>	Complies with United States regulations for RF devices

## **Guardian 4**

### **Introduction**

The Guardian™ 4 transmitter (MMT-7841) with Bluetooth®\*\* wireless technology is a component of the continuous glucose monitoring (CGM) system. The transmitter collects and calculates sensor data and sends the data to a compatible Medtronic automated insulin dosing (AID) system.

### **Indications for use**

The Guardian 4 transmitter is intended for use with Guardian 4 sensors and compatible Medtronic automated insulin dosing (AID) systems to monitor glucose levels for the management of diabetes.

### **Contraindications**

No contraindications are associated with Guardian 4 transmitter use.

### **User Safety**

#### **Warnings**

- Always refer to the Guardian 4 sensor user guide for all precautions, warnings, and instructions related to the sensor. Not referring to the Guardian 4 sensor user guide can result in serious injury or damage to the sensor.
- Do not allow children to put small parts in their mouth. This product may pose a choking hazard that can result in serious injury or death.
- Do not use the Guardian 4 transmitter if you are pregnant or critically ill. Since the transmitter has not been studied in these populations, the impact of medications common to these conditions on transmitter performance is unknown and the transmitter may be inaccurate in these populations.
- Do not change or modify the device unless expressly approved by Medtronic Diabetes. Modifying the device can cause serious injury, interfere with the ability to operate the device, and void the warranty.
- Do not expose the transmitter to Magnetic Resonance Imaging (MRI) equipment, diathermy devices, or other devices that generate strong magnetic fields (for example x-ray, CT scan or other types of radiation). Exposure to a strong magnetic field has not been evaluated and can cause the device to malfunction, result in serious injury, or be unsafe. If the transmitter is exposed to a strong magnetic field, discontinue use and contact 24-Hour Technical Support for further assistance.
- Do not use the tester if it comes in contact with blood. Touching blood can cause infection.
- Bleeding may occur after inserting the sensor. Always make sure that the site is not bleeding before connecting the transmitter to the sensor. Blood can get into the transmitter connector and

damage the device. Discard the device if damaged. If bleeding occurs, apply steady pressure with a sterile gauze, pad, or clean cloth at the insertion site until bleeding stops. After bleeding stops, connect the transmitter to the sensor.

- Do not discard the transmitter in a medical waste container or expose it to extreme heat. The transmitter contains a battery that may ignite and result in serious injury.
- For questions or concerns related to product use, contact 24-Hour Technical Support for assistance.
- For medical questions or concerns, contact a healthcare provider.

### **Serious incident reporting**

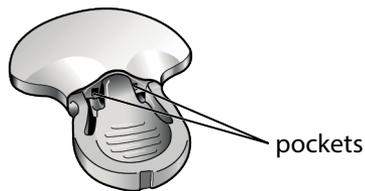
If a serious incident related to the device occurs, immediately report the incident to Medtronic and your local applicable authority.

### **Precautions**

- Do not use the transmitter adjacent to other electrical equipment that may cause interference with the normal system operation.
- Only use the Guardian 4 sensor (MMT-7040) with the transmitter. Do not use any other sensor. Other sensors are not intended for use with the transmitter and will damage the transmitter and the sensor.
- Only use the green colored tester (MMT-7736L) with the transmitter. Pockets on the transmitter are visible when connected to the tester. Do not use any other test plug. Other test plugs are not intended for use with the transmitter and will damage the transmitter and the tester.

**Figure 1.** Transmitter pockets

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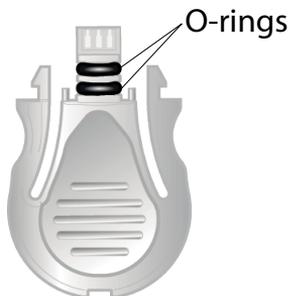


- 
- Always use the tester when cleaning the transmitter. Do not use any other test plug with the transmitter. Use of another test plug can allow water to get into the transmitter or can prevent proper cleaning. Water can damage the transmitter.
  - Do not twist the tester or sensor while attached to the transmitter. Twisting the tester or sensor will damage the transmitter.

- Do not allow the tester to come in contact with any liquid when not connected to the transmitter. A wet tester can damage the transmitter.
- Do not allow the transmitter to come in contact with any liquid when not connected to a sensor or to the tester. Moisture will damage the transmitter and a wet transmitter can damage the sensor.
- Do not clean the O-rings on the tester with any substances. Cleaning the O-rings can damage the tester.

**Figure 2.** O-rings

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## **Radio Frequency (RF) communication**

This device complies with the United States Federal Communications Commission (FCC) and international standards for electromagnetic compatibility. This device complies with Part 15 of the FCC Rules. Operation is subject to 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.

This device has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This device generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this device does cause harmful interference to radio or television reception, which can be determined by turning the device off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and the receiver.
- Decrease the distance between the transmitter and the insulin pump to 6 feet (1.8 meters) or less.

- Increase the separation between the transmitter and the equipment that is receiving or emitting interference.

**Note:** Harmful interference is defined by the FCC as follows. Any emission, radiation or induction that endangers the functioning of a radio navigation service or of other safety services or seriously degrades, obstructs or repeatedly interrupts a radio communications service operating in accordance with FCC rules.

Changes or modifications made to this equipment not expressly approved by Medtronic MiniMed could void the user's authority to operate the equipment.

## **IEC 60601-1-2 Special EMC Precautions for Medical Electrical Equipment**

1. Special Precautions regarding Electromagnetic Compatibility (EMC): This body worn device is intended to be operated within a reasonable residential, domestic, public or work environment where common levels of radiated "E" (V/m) or "H" fields (A/m) exist, such as cellular phones, Wi-Fi™\*, Bluetooth®\* wireless technology, electric can openers, microwave and induction ovens. This device generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the provided instructions, may cause harmful interference to radio communications.
2. Portable and mobile RF communications equipment can affect medical electrical equipment. If you encounter RF interference from a mobile or stationary RF transmitter, move away from the RF transmitter that is causing the interference.
3. Be careful when using the transmitter closer than 12 in (30 cm) to portable radio frequency (RF) equipment or electrical equipment. If the transmitter must be used next to portable RF equipment or electrical equipment, observe the transmitter to verify correct system operation. Degradation of the performance of the transmitter could result.
4. The essential performance (EP) of the transmitter is to measure and transmit to a monitoring device the sensing device's signal value(s) within the transmitter's accuracy requirements under the specified use conditions outlined in the system user guide and for the duration of the expected service life. If the transmitter experiences electromagnetic disturbances, either no or incorrect data may be transmitted. In such situations, refer to the operation, maintenance, and troubleshooting instructions within the applicable user guides. You may also use the tester to test if the transmitter is operating properly. If the transmitter is damaged or if it cannot communicate with the display device, contact 24-Hour Technical Support for assistance.

## **Assistance**

Medtronic provides a 24-Hour Technical Support line for assistance.

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24-Hour Technical Support (calls outside the United States)	+1 818 576 5555
Website	www.medtronicdiabetes.com

## Using the transmitter

### Components needed

- Guardian 4 transmitter (MMT-7841)
- Tester (MMT-7736L)
- Charger (MMT-7715)

**Figure 3.** Components



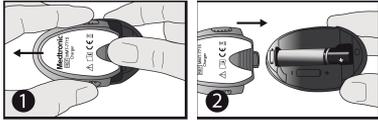
## Preparing the transmitter

The transmitter contains a non-replaceable, rechargeable battery that can recharge as needed with the charger. The transmitter needs to be charged before use. The charger has a green light that shows the charging status and a red light that communicates any problems during charging. If there is a red light, see *Troubleshooting, page 24*. The charger requires one AAA alkaline battery.

**Note:** If the battery is installed incorrectly or is low, the charger will not work. Repeat the battery installation steps using a new battery.

## Installing a battery in the charger

1. Push the battery cover in and slide it off (as shown in image 1 in step 3).
2. Insert a new AAA alkaline battery. Make sure the + and - symbols on the battery align with these same symbols shown on the charger.
3. Slide the cover back on the charger until it clicks into place (as shown in image 2 in step 3).



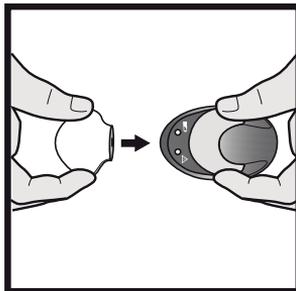
## Charging the transmitter

**CAUTION:** Always charge the transmitter before inserting the sensor. A depleted transmitter does not function. A fully charged transmitter works at least seven days without recharging. A depleted transmitter can take up to two hours to recharge.

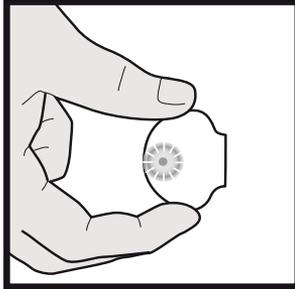
**CAUTION:** Do not store the transmitter on the charger for more than 60 days. Disconnect and reconnect it to the charger to re-charge again before use. If the transmitter is left on the charger for more than 60 days, the transmitter battery will be permanently damaged.

### To charge the transmitter:

1. Push the transmitter and the charger together to connect the transmitter to the charger. If a connection issue is experienced, wait at least 15 seconds before reconnecting the transmitter to the charger. For charging issues, see *Troubleshooting*, page 24.



2. Within 10 seconds after the transmitter is connected, a green light on the charger will flash for one to two seconds as the charger powers on. For the rest of the charging time, the green light on the charger will continue to flash in a pattern of four flashes with a pause between the four flashes.
3. When charging is complete, the green light on the charger will stay on, without flashing, for 15 to 20 seconds and then turn off.



4. After the green charger light turns off, disconnect the transmitter from the charger. The green light on the transmitter starts to flash.

## **Pairing the transmitter**

The transmitter must be paired to the system before a sensor can be used. Always refer to the system user guide for instructions on how to pair the transmitter to the system.

## **Inserting the sensor**

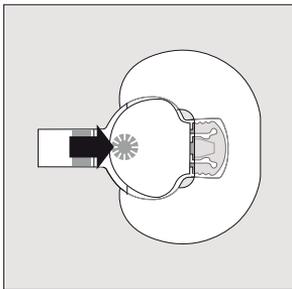
Always refer to the Guardian 4 sensor user guide for instructions on how to insert the sensor.

## **Connecting the transmitter to the sensor**

Before proceeding, have the system user guide available.

### **To connect the transmitter to the sensor:**

1. After the sensor is inserted, consult the Guardian 4 sensor user guide for details on how to apply the required tape before connecting the transmitter.
2. Hold the rounded end of the inserted sensor to prevent it from moving during connection.



3. Hold the transmitter as shown. Line up the two notches on the transmitter with the side arms of the sensor. The flat side of the transmitter should face the skin.
4. Slide the transmitter onto the sensor connector until the sensor arms snap into the notches on the transmitter. If the transmitter is properly connected, and if the sensor has had enough time to become hydrated with the interstitial fluid, the green light on the transmitter will flash 6 times.

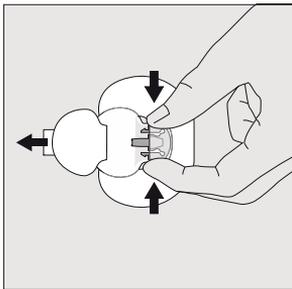
**Note:** If the transmitter does not flash, see *Troubleshooting*, page 24.

5. When the transmitter light flashes green after connecting to the sensor, use the system to start the sensor. For more instructions, see the system user guide.
6. Attach the adhesive tab of the sensor to the transmitter.
7. After the transmitter is connected, consult the Guardian 4 sensor user guide for instructions on how to apply a second tape.
8. Follow the instructions that appear on the display device or in the system user guide.

## Disconnecting the transmitter from the sensor

### To disconnect the transmitter from the sensor:

1. Carefully remove any tape from the transmitter and sensor.



2. Remove the adhesive tab from the top of the transmitter.
3. Hold the transmitter as shown, and pinch the flexible side arms of the sensor between the thumb and forefinger.
4. Gently pull the transmitter away from the sensor.

## Removing the sensor

Always refer to the Guardian 4 sensor user guide for instructions on how to remove the sensor.

## Reconnecting the transmitter to a sensor that is already inserted

The transmitter can be reconnected to the sensor currently in use. Simply connect the transmitter to the sensor that is already inserted. Select Reconnect Sensor when the display device detects the transmitter. It may take a few seconds to establish a connection when reconnecting a sensor. Reattach the adhesive tab of the sensor to the transmitter and reapply any required tape. When reconnected, the sensor goes through another warm-up period.

## Tester

The tester is used to test the transmitter to make sure it is working. The tester is also used as a required component to create a waterproof seal when cleaning the transmitter. Properly connecting the tester to the transmitter ensures that fluids do not come in contact with the connector pins inside the transmitter. Fluids can cause connector pins to corrode and affect the performance of the transmitter.

Do not twist the tester while attached to the transmitter. This will damage the transmitter.

The tester can be used for one year. If the tester is used for more than one year, the connector pins inside the transmitter can be damaged, because the tester cannot continue to provide a waterproof seal. For instructions on how to check the connector pins, see *Inspecting the transmitter connector pins*, page 18.

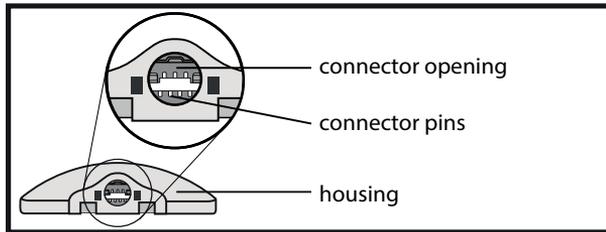
**CAUTION:** Only use the green colored tester (MMT-7736L) with the transmitter. Pockets on the transmitter are visible when connected to the tester. Do not use any other test plug. Other test plugs are not intended for use with the transmitter and will damage the transmitter and the tester.



### Inspecting the transmitter connector pins

This image is an example of how the connector pins should look for the transmitter.

**Figure 4.** Transmitter components



Look inside the connector opening of the transmitter to make sure that the connector pins are not damaged or corroded. If the connector pins are damaged or corroded, the transmitter cannot communicate with the charger or the display device. Contact 24-Hour Technical Support. It may be time to replace your transmitter.

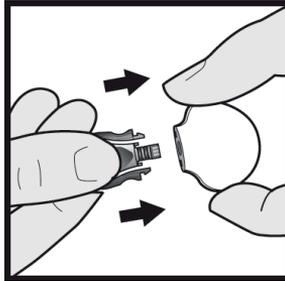
Look for moisture inside the connector opening. If any moisture is present, allow the transmitter to dry for at least one hour. Moisture inside the connector opening could cause the transmitter to not work properly and could cause corrosion and damage over time.

### Connecting the tester for testing or cleaning

Before proceeding, have your system user guide available.

### To connect the tester:

1. Hold the transmitter and the tester as shown. Line up the flat side of the tester with the flat side of the transmitter.



2. Push the tester into the transmitter until the flexible side arms of the tester click into the notches on both sides of the transmitter.

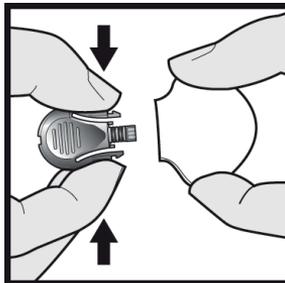
When properly connected, the green light on the transmitter flashes 6 times.

3. To test the transmitter, check the sensor icon in the display device to ensure that the transmitter is sending a signal (see your system user guide).
4. To clean the transmitter, see *Cleaning the transmitter*, page 20.
5. After testing or cleaning, disconnect the tester from the transmitter.

### Disconnecting the tester

#### To disconnect the tester:

1. Hold the transmitter body as shown and pinch the side arms of the tester.



2. With the tester arms pinched, gently pull the transmitter away from the tester.

**Note:** To save transmitter battery life, do NOT leave the tester connected after cleaning or testing.

## Cleaning the transmitter

When using the transmitter, always follow the cleaning procedure.

**WARNING:** Do not discard the transmitter in a medical waste container or expose it to extreme heat. The transmitter contains a battery that may ignite and result in serious injury.

**Note:** The tester is a required component for cleaning the transmitter. For details, see *Tester*, page 17.

**CAUTION:** Do not use an automated washer-disinfector to clean or disinfect the device. Using an automated washer-disinfector to clean or disinfect the device will cause damage to the transmitter.

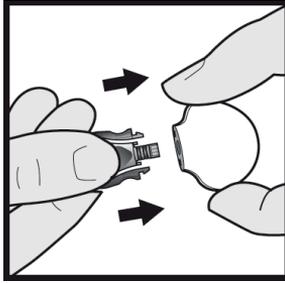
To clean the transmitter, use these materials:

- mild liquid soap
- soft-bristled toddler toothbrush
- container
- clean, lint-free dry cloths

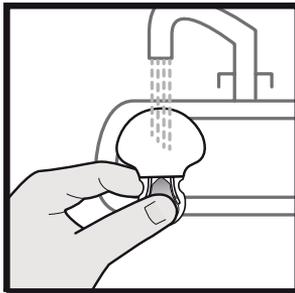
**WARNING:** Do not use the device if there is any cracking, flaking, or damage to the housing. Cracking, flaking, or damage to the housing are signs of deterioration. Deterioration of the housing can affect the ability to properly clean the transmitter and result in serious injury. Call 24-Hour Technical Support and discard the device according to local regulations for battery disposal (non-incineration), or contact your healthcare professional for disposal information.

### To clean the transmitter:

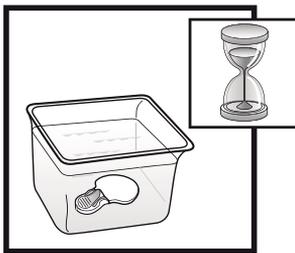
1. Wash hands thoroughly.
2. Attach the tester to the transmitter to create a waterproof seal.



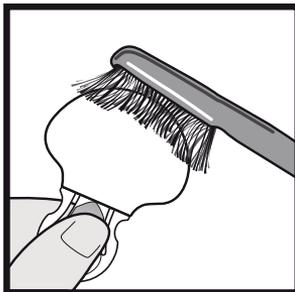
3. If there is adhesive residue on the transmitter, see *Removing adhesive residue*, page 23.
4. Rinse the transmitter under room temperature tap water for at least one minute, and until visibly clean. Make sure all hard-to-reach areas are rinsed completely.



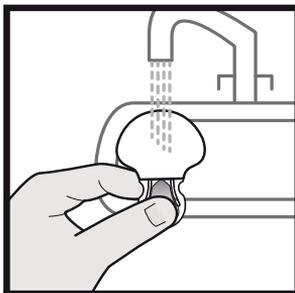
5. Prepare a mild liquid soap solution using 1 teaspoon (5 mL) of mild liquid dish soap per 1 gallon (3.8 L) of room temperature tap water.
6. With the tester still attached, submerge the transmitter in the mild liquid soap solution and soak for one minute.



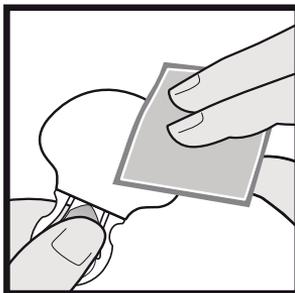
7. Holding the tester, brush the entire surface of the transmitter using a soft-bristled toddler toothbrush. Make sure to brush all hard-to-reach areas until visibly clean.



8. Rinse the transmitter under running room temperature tap water for at least one minute, and until all visible liquid soap is gone.

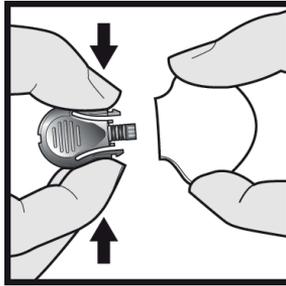


9. Dry the transmitter and tester with a clean, dry cloth.



10. Place the transmitter and tester on a clean, dry cloth and air dry them completely.

11. Disconnect the tester from the transmitter by gently squeezing the arms of the tester.



### Removing adhesive residue

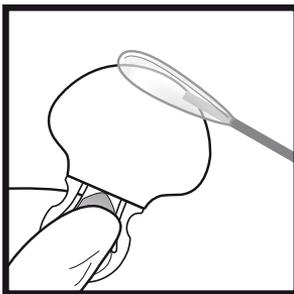
Follow these instructions if there is adhesive residue present on the transmitter.

Use cotton swabs and a medical adhesive remover such as Detachol™\*, a mineral spirit, to remove adhesive residue.

**Note:** During testing, Detachol was used to remove the adhesive residue from the transmitter. Detachol is recommended for use but may not be available in all countries.

### To remove adhesive residue:

1. Make sure the tester is attached to the transmitter.
2. Soak a cotton swab in the medical adhesive remover.
3. Hold the tester and gently rub the adhesive remover on the transmitter until the residue is removed.



4. Continue with the cleaning procedure. See *Cleaning the transmitter*, page 20 for details.

## Cleaning the charger

This procedure is for general cleaning as required, based on physical appearance.

**CAUTION:** Do not immerse the charger in water or any other cleaning agent. The charger is not waterproof. Water can damage the charger and cause the device to malfunction.

### To clean the charger:

1. Wash hands thoroughly.
2. Use a damp cloth with mild cleaning solution, such as a dishwashing detergent, to clean any dirt or foreign material from the outside of the charger. Never use organic solvents, such as paint thinner or acetone, to clean the charger.
3. Place the charger on a clean, dry cloth and air dry for two to three minutes.

## Bathing and swimming

After the transmitter and sensor are connected, they form a waterproof seal to a depth of 8 feet (2.4 m) for up to 30 minutes. Shower and swim without removing them.

## Troubleshooting

The table shown contains troubleshooting information for the transmitter, charger, and tester. For more information about troubleshooting, see the system user guide.

**Table 1.** Troubleshooting issues

<b>Problem</b>	<b>Likely Cause(s)</b>	<b>Resolution</b>
The transmitter is connected to the charger and no lights come on.	The transmitter connector pins are damaged or corroded. The charger battery has no power or no battery is inserted.	<ol style="list-style-type: none"><li>1. Check the transmitter connector pins for damage or corrosion. For more information about the connector pins, see <i>Inspecting the transmitter connector pins, page 18</i>. If the pins are damaged or corroded, contact 24-Hour Technical Support. It may be time to replace the transmitter.</li><li>2. If there is no damage to the connector pins, replace the battery in the charger. For instructions on replacing the charger battery, see <i>Installing a battery in the charger, page 14</i>.</li></ol>
During charging, the flashing green light on the charger turns off and a longer flashing red light appears on the charger.	The charger battery is low on power.	Replace the battery in the charger. For instructions on replacing the charger battery, see <i>Installing a battery in the charger, page 14</i> .
During charging, the flashing green light on the charger turns off and there is a series of quick flashing red lights on the charger for two seconds at a time.	The transmitter is low on power.	<ol style="list-style-type: none"><li>1. Charge the transmitter continuously for one hour. If flashing does not stop, proceed to step 2.</li><li>2. Charge the transmitter continuously for eight hours. If flashing does not stop, call 24-Hour Technical Support. It may be time to replace the transmitter.</li></ol>
During charging, a mix of quick and long flashing red lights appear on the charger.	The charger and the transmitter are low on power.	<ol style="list-style-type: none"><li>1. Replace the battery in the charger. For instructions on replacing the charger battery, see <i>Installing a battery in the charger, page 14</i>.</li><li>2. Charge the transmitter continuously for one hour. If the quick flashing red lights do not stop, proceed to step 3.</li><li>3. Charge the transmitter continuously for eight hours. If flashing does not stop,</li></ol>

**Table 1.** Troubleshooting issues (continued)

Problem	Likely Cause(s)	Resolution
		call 24-Hour Technical Support. It may be time to replace the transmitter.
During charging, the green light stays on and does not turn off.	The transmitter was disconnected and reconnected to the charger too quickly.	Disconnect the transmitter from the charger and wait at least 15 seconds before reconnecting to the charger.
When connected to the sensor, the green light on the transmitter does not flash.	The transmitter is not fully connected. The transmitter is low on power. The sensor is not properly inserted into the body.	<ol style="list-style-type: none"> <li>1. Disconnect the transmitter from the sensor.</li> <li>2. Wait for five seconds and reconnect them. If the green light still does not flash, proceed to step 3.</li> <li>3. Fully charge the transmitter and connect it to the tester. If the green light still does not flash, see troubleshooting on “When connected to the tester, the green light on the transmitter does not flash.” If the green light flashes, proceed to step 4.</li> <li>4. Disconnect the transmitter from the tester, wait at least five seconds, and connect the transmitter to the sensor. If the green light still does not flash, proceed to step 5.</li> <li>5. The sensor may not be properly inserted into the body. Remove the sensor from the body and insert a new sensor.</li> </ol>
When connected to the tester, the green light on the transmitter does not flash.	The transmitter is not fully connected. The transmitter is low on power.	<ol style="list-style-type: none"> <li>1. Check the connection between the transmitter and the tester. If the green light still does not flash, proceed to step 2.</li> <li>2. Fully charge the transmitter.</li> <li>3. Test the transmitter with the tester again. If you still do not see the green light flash, call 24-Hour Technical Support. It may be time to replace the transmitter.</li> </ol>

**Table 1.** Troubleshooting issues (continued)

Problem	Likely Cause(s)	Resolution
The transmitter battery does not last for seven days.	The transmitter is not fully charged when connected to the sensor. The transmitter and display device frequently lose wireless connection.	<ol style="list-style-type: none"><li>1. Fully charge the transmitter before connecting it to the sensor. If the transmitter battery still does not last for the duration of one sensor use, proceed to step 2.</li><li>2. Move away from any equipment that can cause RF interference. For more information on RF interference, see the Radio Compliance Information sheet included with the display device.</li><li>3. Make sure the display device and the transmitter are located on the same side of the body to minimize any RF interference. If your fully charged transmitter battery continues to lose power before a full seven days, call 24-Hour Technical Support. It may be time to replace the transmitter.</li></ol>
The transmitter loses connection with the display device.	The display device is out of range. There is RF interference from other devices.	<ol style="list-style-type: none"><li>1. Move away from any equipment that can cause RF interference. For more information on RF interference, see the Radio Compliance information sheet included with the transmitter. If the transmitter is still not communicating with the display device, proceed to step 2.</li><li>2. Make sure the display device and the transmitter are located on the same side of the body to minimize any RF interference. If your transmitter is still not communicating with your display device, call 24-Hour Technical Support for assistance.</li></ol>
<b>Note:</b> An alarm or alert occurs and a message appears when the transmitter has lost connection with the display device for 30 minutes.		

## Storage

Store the transmitter, charger, and tester in a clean, dry location at room temperature. If the transmitter is not in use, you must charge the transmitter at least once every 60 days.

**CAUTION:** Do not store the transmitter on the charger. If the transmitter is left on the charger for more than 60 days, the battery will be permanently damaged.

## Disposal

Do not dispose of the transmitter, charger, and tester in unsorted municipal waste stream. Dispose of the transmitter, charger, and tester according to local regulations for electronic waste disposal.

## Technical Specifications

**Table 2.** Product specifications

<b>Biocompatibility</b>	Transmitter: Complies with EN ISO 10993-1
<b>Applied parts</b>	Transmitter Sensor Type BF applied part
<b>Operating conditions</b>	Transmitter temperature: 32 °F to 113 °F (0 °C to 45 °C)  <b>CAUTION:</b> When operating the transmitter on a tester in air temperatures greater than 106 °F (41 °C), the temperature of the transmitter may exceed 109 °F (43 °C).  Transmitter relative humidity: 10% to 95% with no condensation Transmitter pressure: 8.4 psi to 15.4 psi (57.60 kPa to 106.17 kPa) Charger temperature: 50 °F to 104 °F (10 °C to 40 °C) Charger relative humidity: 30% to 75% with no condensation
<b>Storage conditions</b>	Transmitter temperature: -4 °F to 131 °F (-20 °C to 55 °C) Transmitter relative humidity: up to 95% with no condensation Transmitter pressure: 8.4 psi to 15.4 psi (57.6 kPa to 106.17 kPa) Charger temperature: 14 °F to 122 °F (-10 °C to 50 °C) Charger relative humidity: 10% to 95% with no condensation
<b>Battery life</b>	Transmitter: Seven days of CGM immediately following a full charge. Charger: The charger uses one new AAA battery to charge the transmitter.
<b>Transmitter</b>	2.4 GHz band, Bluetooth®* wireless technology (version 4.0)

**Table 2.** Product specifications (continued)

<b>frequency</b>	
<b>Effective radiated power (ERP)</b>	0.06 mW (-12.05 dBm)
<b>Effective isotropic radiated power (EIRP)</b>	0.1 mW (-9.9 dBm)
<b>Operating range</b>	Up to 6 feet (1.8 m) in free-air
<b>Transmitter expected service life</b>	The transmitter expected service life is one year depending on patient usage.

## Transmitter wireless communication

### Quality of service

The Guardian 4 transmitter and display device connect via a Bluetooth<sup>®</sup> Low Energy technology network. The transmitter sends glucose data and system-related alerts to the display device, which verifies the integrity of received data after wireless transmission. Quality of the connection is in accordance with the Bluetooth<sup>®</sup> Specification v4.0.

### Cybersecurity

The Guardian 4 transmitter is designed with cybersecurity protections to keep data secure on the device and when communicating with a compatible insulin pump or mobile app. These protections include: encryption, integrity checks, and authentication checks. The Guardian 4 transmitter uses Bluetooth<sup>®</sup> Low Energy (BLE) communication to connect to a compatible AID system.

To keep the Guardian 4 sensor and data secure, follow the security guidelines provided.

- Perform pairing with a compatible Medtronic AID system in a private location.

For questions or concerns about the cybersecurity of the Guardian 4 transmitter refer to the Assistance section within this user guide or visit [www.medtronic.com/security](http://www.medtronic.com/security). Users will be informed once the product has reached the end of life and end of support.

### Traveling by air

The transmitter is safe for use on commercial airlines. Because travel rules are subject to change, it is advisable to check your local airport security authority before traveling.

If questioned by airline personnel about the use of your device, please show them your Medical emergency card.

## Guidance and manufacturer's declaration

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR 11	CISPR 11 Group 1, Class B	The transmitter uses RF energy only for system communications. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.  <b>Note:</b> The preceding statement is required by IEC 60601-1-2 for Group 1, Class B devices. Since the transmitter is battery powered, its emissions will not be affected by the establishment power supply and there is no evidence of any issues associated with the use of the system in domestic establishments.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
Immunity Test	IEC 60601-1-2 Test Level	Max foreseeable use condition per IEC 60601-1-2	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	$\pm 8$ kV contact $\pm 2$ kV, $\pm 4$ kV, $\pm 8$ kV, $\pm 15$ kV air	$\pm 8$ kV contact $\pm 2$ kV, $\pm 4$ kV, $\pm 8$ kV, $\pm 15$ kV air	For use in a typical domestic, commercial, or hospital environment.
Conducted disturbances induced by RF fields	$3 V_{RMS}$ 150 kHz to 80 MHz $6 V_{RMS}$ ISM bands between 150 kHz to 80 MHz	Not applicable	Requirement does not apply to this battery powered device.
Electrical fast transient/burst IEC 61000-4-4	$\pm 2$ kV 100 kHz repetition frequency	Not applicable	Requirement does not apply to this battery powered device.
Surge IEC 61000-4-5	Line to Line: $\pm 0.5$ kV, $\pm 1$ kV Line to Ground: $\pm 0.5$ kV, $\pm 1$ kV, $\pm 2$ kV	Not applicable	Requirement does not apply to this battery powered device.
<b>Note:</b> $U_T$ is the a.c. mains voltage prior to application of the test level.			
Voltage dips, short interruptions, and voltage variations	$0\% U_T$ ; 0.5 cycles (at $0^\circ$ , $45^\circ$ , $90^\circ$ , $135^\circ$ , $180^\circ$ , $225^\circ$ , $270^\circ$ , and $315^\circ$ )	Not applicable	Requirement does not apply to this battery powered device.

**Guidance and Manufacturer's Declaration – Electromagnetic Immunity**

Immunity Test	IEC 60601-1-2 Test Level	Max foreseeable use condition per IEC 60601-1-2	Electromagnetic Environment Guidance
on power supply lines IEC 61000-4-11	0% $U_T$ ; 1 cycle (at 0°) 70% for 25/30 cycles (at 0°) 0% for 250/300 cycles		
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	For use in a typical domestic, commercial, or hospital environment.
Proximity fields from RF wireless communications equipment IEC 61000-4-3	IEC 60601-1-2	IEC 60601-1-2	For use in a typical domestic, commercial, or hospital environment.
<b>Note:</b> $U_T$ is the a.c. mains voltage prior to application of the test level.			
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	10 V/m 80 MHz to 6 GHz 80% AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the transmitter than the recommended separation distance of 12 in (30 cm). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:

Guidance and Manufacturer’s Declaration – Electromagnetic Immunity			
Immunity Test	IEC 60601-1-2 Test Level	Max foreseeable use condition per IEC 60601-1-2	Electromagnetic Environment Guidance
			
<b>Note:</b> These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption, and reflection from structures, objects and people.			

## Warranty

Medtronic MiniMed, Inc. (or such other legal entity as may be referred to as manufacturer on the labeling of this device “Medtronic MiniMed”) warrants the Medtronic transmitter to the purchaser of the product against defects in material and workmanship for a period of one (1) year and the charger for up to one (1) year from the date of purchase.

During the warranty period, Medtronic MiniMed will replace or repair, at its discretion, any defective transmitter or charger, subject to the conditions and exclusions stated herein. This warranty applies only to new devices. In the event a transmitter or charger is replaced, the warranty period will not be extended past its original expiration date.

This warranty is valid only if the Medtronic transmitter or charger is used in accordance with the manufacturer’s instructions. Without limitation, this warranty will not apply:

- If damage results from changes or modifications made to the transmitter or charger by the user, or third persons, after the date of purchase.
- If damage results from service or repairs performed by any person or entity other than the manufacturer.
- If damage results from a *Force Majeure* or other event beyond the control of the manufacturer.
- If damage results from negligence or improper use, including but not limited to: improper storage, submersion in water, physical abuse, (such as dropping).
- If damage results from use of the device in a manner other than according to the manufacturer’s product labeling, instructions for use, or regulatory notifications.

This warranty shall be personal to the original purchaser. Any sale, rental or other transfer or use of the product covered by this warranty to or by a user other than the original purchaser shall cause this warranty to immediately terminate. This warranty does not apply to glucose sensors and other accessories.

The remedies provided for in this warranty are the exclusive remedies available for any breach hereof. Neither Medtronic MiniMed nor its suppliers or distributors shall be liable for any incidental,

consequential, or special damage of any nature or kind caused by or arising out of a defect in the product.

All other conditions and warranties, other than mandatory statutory warranties, expressed or implied, are excluded, including the warranties of merchantability and fitness for a particular purpose.

This warranty gives the purchaser specific legal rights, and the purchaser may also have other rights that vary under local law. This warranty does not affect the purchaser's statutory rights.

## **Open Source Software (OSS) disclosure**

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The source/object code and applicable license for the Open Source Software can be obtained at the following site: [www.medtronicdiabetes.com/ossnotices](http://www.medtronicdiabetes.com/ossnotices).

## **Performance data**

Refer to the Medtronic automated insulin dosing (AID) system user guide for performance data.

## **Icon glossary**

For definitions of the symbols on the device and package labels, see [www.medtronicdiabetes.com/symbols-glossary](http://www.medtronicdiabetes.com/symbols-glossary).





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MMT-7841, MMT-7840, MMT-7920

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