

Guardian[®] Link

Transmitter



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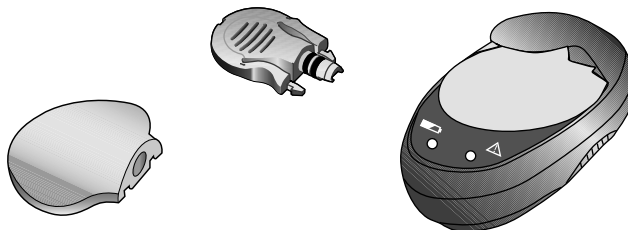
Non-stop helpLine (24/7):

+420 233 059 059

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+420 233 059 950

The Guardian® Link transmitter is a component of the continuous glucose monitoring system for the MiniMed® 630G insulin pump. The transmitter collects data from the Enlite® glucose sensor. The transmitter then wirelessly sends the data to the insulin pump.



Guardian Link transmitter kit components

A complete Guardian Link transmitter kit includes the following components:

- Guardian Link transmitter (MMT-7763)
- Watertight Tester (MMT-7726)
- Charger (MMT-7715)
- One-press senter (MMT-7512)

Indications for use

The Medtronic MiniMed Guardian Link transmitter is indicated for use as a component of select Medtronic continuous glucose monitoring and sensor-enabled pump systems. It processes, stores and transmits glucose sensor values to data collection and display devices. The Guardian Link transmitter is not intended to function as a stand-alone device and is for single-patient use.

The Guardian Link transmitter system includes the Guardian Link transmitter (MMT-7763), charger (MMT-7715), watertight tester (MMT-7726), and One-press senter (MMT-7512).

Contraindications

Do not expose your transmitter to MRI equipment, diathermy devices, or other devices that generate strong magnetic fields. If your transmitter is inadvertently exposed to a strong magnetic field, discontinue use and contact the 24 Hour HelpLine for further assistance.

Warnings

- Always refer to the Enlite Sensor User Guide for all precautions, warnings, and instructions relating to the sensor. Not referring to the Enlite 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 poses a choking hazard for young children.
- Do not change or modify the device unless expressly approved by Medtronic Diabetes. Modifying the device can cause serious injury, interfere with your ability to operate the device, and void your warranty.
- Do not use the tester if it comes in contact with blood. Touching blood can cause infection. Dispose of the tester according to the local regulations for medical waste disposal, or contact your healthcare professional for disposal information.
- 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. If bleeding occurs, apply steady pressure with a sterile gauze or clean cloth at the insertion site until bleeding stops. After bleeding stops, connect the transmitter to the sensor.
- Contact the 24 Hour HelpLine if you experience any adverse reactions associated with the transmitter or sensor. Adverse reactions can cause serious injury.

Precautions

- 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. 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. A wet transmitter can damage the sensor.
- Do not clean the o-rings on the tester. Cleaning the o-rings can damage the tester.

Exposure to magnetic fields and radiation

- Do not expose your transmitter to MRI equipment, diathermy devices, or other devices that generate strong magnetic fields (for example, x-ray, CT scan, or other types of radiation). The strong magnetic fields can cause the device to malfunction. If your transmitter is exposed to a strong magnetic field, discontinue use and contact the 24 Hour HelpLine for further assistance.

X-rays, MRIs, diathermy devices, and CT scans

- Always remove your sensor and transmitter before entering a room that has x-ray, MRI, diathermy, or CT scan equipment. This equipment has strong magnetic fields that can cause the device to malfunction. If your sensor or transmitter is exposed to a strong magnetic field, discontinue use and contact the 24 Hour HelpLine for further assistance.
- Always carry the Emergency Card provided with your device when you are traveling. The Emergency Card provides critical information about airport security systems, and using your transmitter on an airplane, that can help you and others. Not following the guidance on the Emergency Card could result in serious injury.

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 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.
- These standards are designed to provide reasonable protection against excessive radio frequency interference, and prevent undesirable operation of the devices from unwanted electromagnetic interference.
- 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. 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 harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment 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.
- This device can generate, use, and radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. If the device does cause interference to radio or television reception, you are encouraged to try to correct the interference by one or more of the following measures:

- 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 device that is receiving/ emitting interference.
- If other devices that employ radio frequencies are in use, such as cell phones, cordless phones, and wireless networks, they may prevent communication between the transmitter and the insulin pump. This interference does not cause any incorrect data to be sent and does not cause any harm to your devices. Moving away from, or turning off, these other devices may enable communication. If you continue to experience RF interference, please contact the 24 Hour HelpLine.
- Do not change or modify the internal RF transmitter or antenna unless expressly approved by Medtronic Diabetes. Doing so could interfere with your ability to operate the equipment.

IEC60601-1-2:2007; 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, WiFi, Bluetooth, 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 as well. If you encounter RF interference from a mobile or stationary RF transmitter, move away from the RF transmitter that is causing the interference.

Assistance

Medtronic MiniMed provides a 24 Hour HelpLine for assistance. The HelpLine is staffed with representatives who are trained in the set-up and operation of your CGM system. When calling the HelpLine, please have your pump serial number available. Your pump serial number is listed on the back of your device and the 24 Hour HelpLine phone number is listed on the bottom of your device.

Department	Telephone number
24 Hour HelpLine (calls within the United States)	800 646 4633
24 Hour HelpLine (calls outside the United States)	+1 818 576 5555
Web site	www.medtronicdiabetes.com

Charger

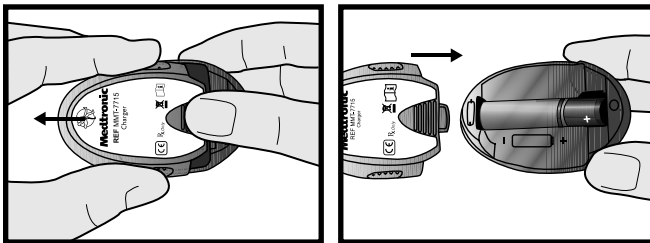
The transmitter contains a non-replaceable, rechargeable battery that you can recharge as needed with the charger. The charger has a green light that shows the charging status and a red light that communicates any problems during charging. If you see a red light, see the Troubleshooting section. The charger needs 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

To install a battery in the charger:

- 1 Push the battery cover in and slide it off (as shown in the following illustration).
- 2 Insert a new alkaline AAA 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.

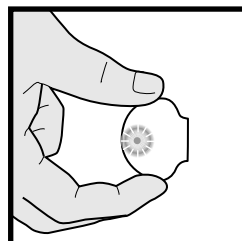
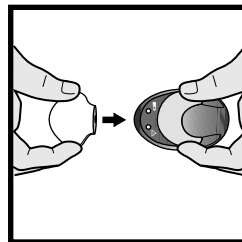


Charging the transmitter

Caution: Always charge the transmitter before inserting your sensor. A depleted transmitter does not function. A fully charged transmitter works at least six days without recharging. A depleted transmitter can take up to one hour to recharge.

To charge the transmitter:

- 1 Connect the transmitter to the charger by lining it up, flat side down, with the charger. Push the two components together fully.
- 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 charger's green light 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 will flash for about five seconds and then turn off.



Inserting the sensor

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

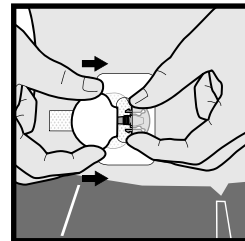
Connecting the transmitter to the sensor

Before proceeding, have your pump user guide available.

To connect the transmitter to the sensor:

- 1 After the sensor is inserted, consult your senter user guide for details on applying the required overtape.
- 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 until the sensor's flexible 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, the green light on the transmitter will flash within 10 seconds.
- 5 If the transmitter light does not flash, disconnect the transmitter from the sensor, wait for several seconds and then reconnect. If the transmitter light still does not flash, charge the transmitter.
- 6 When the transmitter light flashes green when connected to the sensor, use your pump to start the sensor. For more instructions, see your pump user guide.
- 7 After the transmitter successfully sends sensor data to the pump, attach the sensor's adhesive tab to the transmitter.
- 8 Follow the instructions that appear on the pump screen or follow the instructions in your pump user guide.

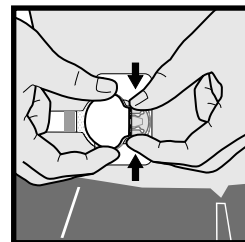


Disconnecting the transmitter from the sensor

Before proceeding, have your pump user guide available.

To disconnect the transmitter from the sensor:

- 1 Carefully remove any occlusive dressing from the transmitter and sensor.
- 2 For the Enlite sensor, 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 your thumb and forefinger.
- 4 Gently pull the transmitter away from the sensor.
- 5 Follow the instructions that appear on the pump or follow the instructions in your pump user guide.



Removing the sensor

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

Bathing and swimming

After the transmitter and sensor are connected, they form a waterproof seal to a depth of 8 feet (2.4 meters) for up to 30 minutes. You can shower and swim without removing them. No occlusive dressing or overtape is needed.

Watertight Tester

The tester is used to test the transmitter to make sure it is working. It is also used as a required component for cleaning the transmitter. Properly connecting the tester to the transmitter will ensure that fluids do not come in contact with the transmitter's connector pins. Fluids can cause connector pins to corrode and affect the transmitter's performance.

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

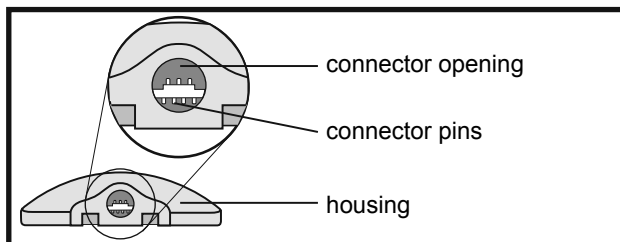
The tester can be used for one year. If you continue to use the tester for more than one year, the transmitter's connector pins could be damaged, because the tester cannot continue to provide a waterproof seal. For instructions on how to check the connector pins, see *Inspecting the transmitter connector pins, on page 8*.

Caution: Only use the tester with the transmitter. Do not use any other test plug. Other test plugs are not intended for use with the transmitter, and can cause the device to malfunction.



Inspecting the transmitter connector pins

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



Look inside the transmitter's connector opening 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 pump. Contact the 24 Hour HelpLine. It may be time to replace your transmitter.

Also look for moisture inside the connector opening. If you see any moisture, 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.

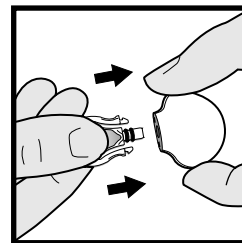
Connecting the tester for testing or cleaning

Before proceeding, have your pump 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 within 10 seconds.



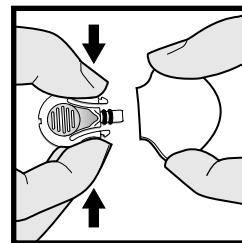
- 3 To test the transmitter, check the sensor icon on the pump to ensure that the transmitter is sending a signal (see your pump user guide).
- 4 To clean the transmitter, see *Cleaning the transmitter*, on page 9.
- 5 After testing or cleaning, disconnect the tester from the transmitter.

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

The transmitter is a single-patient use device and not intended for multi-patient use.

Caution: Do not discard the transmitter in a medical waste container or otherwise subject it to incineration. The transmitter contains a battery that may explode upon incineration.

Note: The tester is a required component for cleaning the transmitter. For details, see *Watertight Tester*, on page 8.

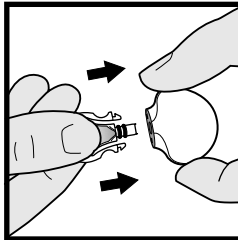
Always clean the transmitter after each use.

To clean the transmitter, you will need the following materials: Ivory® liquid soap, a softbristled toddler toothbrush, a container, 70% isopropyl alcohol, and a few clean, dry cloths. You can find these supplies at Walmart, Target, or <http://www.amazon.com/>.

Warning: Do not use the device if you see 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 the 24 Hour HelpLine and discard the device according to local regulations for battery disposal (nonincineration), or contact your healthcare professional for disposal information.

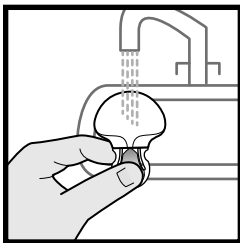
To clean the transmitter:

- 1 Wash your hands thoroughly.
- 2 Attach the tester to the transmitter.

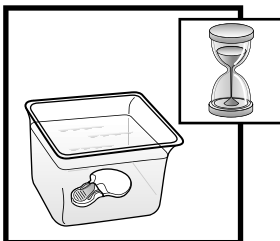


- 3 If optional occlusive dressing or overtape was used and there is adhesive residue on the transmitter, see *Removing adhesive residue*, on page 13.

- 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.



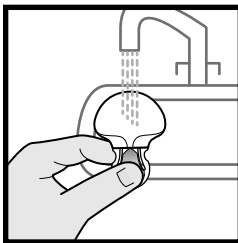
- 5 Prepare a mild liquid soap solution using 1 teaspoon (5 milliliters) of Ivory® liquid soap per 1 gallon (3.8 liters) of room temperature tap water.
- 6 With tester still attached, submerge the transmitter in the mild liquid soap solution and soak for one minute.



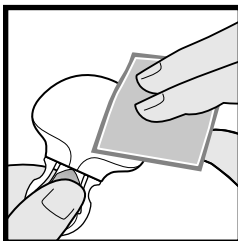
- 7 Holding the tester, brush the entire surface of the transmitter using a soft-bristled toddler toothbrush. Make sure to brush all hard-to-reach areas until visibly clean.



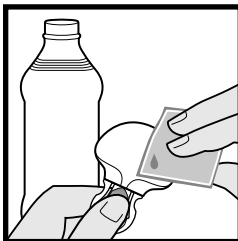
- 8 Rinse the transmitter under running room temperature tap water for at least one minute, and until all visible liquid soap is gone.



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

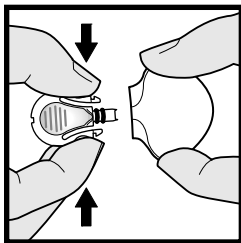


- 10 Holding the tester, wipe the transmitter with 70% isopropyl alcohol.



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

12 Disconnect the tester from the transmitter.



Removing adhesive residue

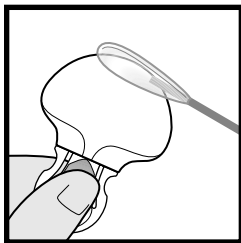
You may need to perform this procedure only if you have used optional occlusive dressing, which may leave adhesive residue on the transmitter. If you visually inspect the transmitter and see adhesive residue on it, follow the instructions below.

To remove adhesive residue, you will need the following materials: Detachol® medical adhesive remover and cotton swabs. You can buy Detachol at <http://www.amazon.com/>, <http://www.medtronicdiabetes.com> or by calling 800 646 4633.

Note: *During testing, Medtronic MiniMed used Detachol 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 Holding the tester, saturate a cotton swab in the Detachol solution and gently rub the adhesive residue on the transmitter until it is fully removed.



- 3 Continue with the cleaning procedure. See *Cleaning the transmitter*, on page 9 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.

Caution: Dispose the charger according to the local regulations for battery disposal (non-incineration), or contact your healthcare professional for disposal information. The charger may explode upon incineration.

To clean the charger:

- 1 Wash your 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.

Troubleshooting

The following table contains troubleshooting information for the transmitter, charger, and tester. For more information about troubleshooting, see your pump user guide.

Problem	Likely Cause(s)	Resolution
You connected the transmitter to the charger and no lights came on.	The transmitter connector pins are damaged or corroded. Your charger battery has no power.	<ol style="list-style-type: none">1 Check the transmitter connector pins for damage or moisture. For more information about your connector pins, see <i>Inspecting the transmitter connector pins</i>, on page 8. If the pins are damaged or corroded, contact the 24 Hour HelpLine. It may be time to replace your transmitter.2 If there is no damage to the connector pins, replace the battery in the charger. For instructions on replacing your charger battery, see <i>Installing a battery in the charger</i>, on page 5.
During charging, the flashing green light on the charger turns off and you see a flashing red light on the charger.	Your charger battery is low on power.	Replace the battery in the charger. For instructions on replacing your charger battery, see <i>Installing a battery in the charger</i> , on page 5.

Problem	Likely Cause(s)	Resolution
During charging, the flashing green light on the charger turns off and you see a series of quick flashing red lights on the charger.	Your transmitter is low on power.	<ol style="list-style-type: none"> 1 Charge the transmitter continuously for one hour. If flashing does not stop, proceed to step 2. 2 Charge the transmitter continuously for eight hours. If flashing does not stop, call the 24 Hour HelpLine. It may be time to replace your transmitter.
During charging, a mix of quick and long flashing red lights appear on the charger.	Your charger <i>and</i> your transmitter are low on power.	<ol style="list-style-type: none"> 1 Replace the battery in the charger. For instructions on replacing your charger battery, see <i>Installing a battery in the charger, on page 5</i>. 2 Charge the transmitter continuously for one hour. If flashing does not stop, proceed to step 3. 3 Charge the transmitter continuously for eight hours. If flashing does not stop, call the 24 Hour HelpLine. It may be time to replace your transmitter.
The green light on the transmitter does not flash when you connect it to the sensor.	<p>Your transmitter is not fully connected.</p> <p>Your transmitter is low on power.</p> <p>Your sensor is not properly inserted into your body.</p>	<ol style="list-style-type: none"> 1 Disconnect the transmitter from the sensor. 2 Wait for five seconds and reconnect them. If the green light still does not flash, proceed to step 3. 3 Fully charge the transmitter. If the green light still does not flash, proceed to step 4. 4 The sensor may not be properly inserted into your body. Insert a new sensor.
The green light on the transmitter does not flash when you connect it to the tester.	<p>Your transmitter is low on power.</p> <p>Your transmitter is not fully connected.</p>	<ol style="list-style-type: none"> 1 Check the connection between the transmitter and the tester. If the green light still does not flash, proceed to step 2. 2 Fully charge the transmitter. 3 Test the transmitter with the tester again. If you still do not see the green light flash, call the 24 Hour HelpLine. It may be time to replace your transmitter.

Problem	Likely Cause(s)	Resolution
<p>Your transmitter battery does not last for six days.</p>	<p>Your transmitter is not fully charged when you connect it to the sensor.</p> <p>The transmitter and pump frequently lose wireless connection.</p>	<ol style="list-style-type: none"> 1 Fully charge the transmitter before connecting it to the sensor. If the transmitter battery still does not last for six days, proceed to step 2. 2 Move away from any device that can cause RF interference. For more information on RF interference, see <i>Radio Frequency (RF) communication, on page 3</i>. 3 Make sure your pump and your transmitter are located on the same side of your body to minimize any RF interference. If your fully charged transmitter battery continues to lose power before a full six days, call the 24 Hour HelpLine. It may be time to replace your transmitter.
<p>Your transmitter has lost connection with your pump.</p> <p>Note: <i>An alarm or alert occurs and a message appears when your transmitter has lost connection with your pump.</i></p>	<p>Your pump is out of range.</p> <p>There is RF interference from other devices.</p>	<ol style="list-style-type: none"> 1 Move away from any device that can cause RF interference. For more information on RF interference, see <i>Radio Frequency (RF) communication, on page 3</i>. If your transmitter is still not communicating with your pump, proceed to step 2. 2 Make sure your pump and your transmitter are located on the same side of your body to minimize any RF interference. If your transmitter is still not communicating with your pump, call the 24 Hour HelpLine for assistance.

Storing the devices

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. Although not required, you may store the transmitter on the charger. If you are storing the transmitter on the charger, you must disconnect and reconnect the charger and the transmitter at least once every 60 days.

Disposal

Discard the transmitter according to local regulations for battery disposal, or contact your healthcare professional for disposal information.

Specifications

Biocompatibility	Transmitter: Complies with EN ISO 10993-1
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Applied parts	Transmitter Sensor
Operating conditions	Transmitter temperature: 23 °F to 113 °F (-5 °C to 45 °C) Caution: 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). This can cause the device to malfunction. Transmitter relative humidity: 5% to 95% with no condensation Transmitter pressure: 8.9 psi to 15.4 psi (61.36 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
Storage conditions	Transmitter temperature: -13 °F to 131 °F (-25 °C to 55 °C) Transmitter relative humidity: 10% to 100% with condensation Transmitter pressure: 8.9 psi to 15.4 psi (61.36 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
Battery	Uses one new AAA battery to charge the transmitter.
Transmitter frequency	2.4 GHz, 2M65G1D modulation, less than 1mW ERP
Maximum output power (EIRP)	-0.63 dBm (865 µW)
Radio Frequency (RF) communications	Pump to transmitter frequency: 2.4 GHz; proprietary Medtronic protocol; range up to 6 feet (1.8 meters) Utilizes the IEEE 802.15.4 protocol with proprietary data format Operating frequency: 5 frequencies are used: 2420, 2435, 2450, 2465, and 2480 MHz Bandwidth: 5 MHz, which is allocated channel bandwidth per IEEE protocol
Transmitter expected service life	The transmitter expected service life is 1 year depending on patient usage

Guardian Link wireless communication

Quality of service

The Guardian Link transmitter and the MiniMed 630G insulin pump are associated as part of an 802.15.4 network for which the pump functions as the coordinator and the transmitter as an end node. In an adverse RF environment the pump will assess channel changing needs based on "noise" levels detected during an energy scan. The pump will perform the energy scan if after 10 minutes no CGM transmitter signal has been received. If the channel change occurs the pump will send beacons on the new channel.

The Guardian Link transmitter will initiate a channel search when beacon detection fails on the associated channel. The search will be conducted across all five channels. When the beacon is located the transmitter will rejoin on the identified channel. Upon re-association any missed packets (up to 10 hours) will be transmitted from the transmitter to the pump.

In normal operation the transmitter will transmit a packet every 5 minutes and retransmit the packet if the data is corrupted or missed.

Data security

The MiniMed 630G insulin pump is designed to only accept radio frequency (RF) communications from recognized and linked devices (you must program your pump to accept information from a specific device).

The MiniMed 630G insulin pump and system components (meters and transmitters) ensure data security via proprietary means and ensures data integrity using error checking processes, such as cyclic redundancy checks.

Guidance and manufacturer's declaration

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The transmitter is intended for use in the electromagnetic environment specified below. The customer or the user of the transmitter should make sure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The transmitter must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	The transmitter is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The transmitter is intended for use in the electromagnetic environment specified below. The customer or the user of the transmitter should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 2 kV, ± 4 kV, ± 8 kV Air ± 2 kV, ± 4 kV, ± 6 kV Indirect	± 2 kV, ± 4 kV, ± 8 , ± 22 kV Air ± 2 kV, ± 4 kV, ± 6 kV Indirect	For use in a typical domestic, commercial, or hospital environment.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Not applicable	Requirement does not apply to this battery powered device.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not applicable	Requirement does not apply to this battery powered device.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	$< 5\% U_T$ ($> 95\%$ dip in U_T) for 0.5 cycle	Not applicable	Requirement does not apply to this battery powered device.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The transmitter is intended for use in the electromagnetic environment specified below. The customer or the user of the transmitter should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	400 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical domestic, commercial, or hospital environment.

Note: U_T is the a.c. mains voltage prior to application of the test level.


Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The Guardian Link is intended for use in the electromagnetic environment specified below. The customer or user of the Guardian Link should assure that it is used in such an electromagnetic environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The Guardian Link is intended for use in the electromagnetic environment specified below. The customer or user of the Guardian Link should assure that it is used in such an electromagnetic environment.

<p>Radiated RF IEC 61000-4-3</p>	<p>3 V/m 80 MHz to 2.5 GHz</p>	<p>10 V/m 80 MHz to 6 GHz</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Guardian Link than the recommended separation distance calculated from the equation applicable to the frequency of the RF transmitter.</p> <p>$d = 0.35\sqrt{P}$ 80 MHz to 800 MHz</p> <p>$d = 0.70\sqrt{P}$ 800 MHz to 6 GHz</p> <p>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).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^a, should be less than the compliance level in each frequency range^b.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
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Note: At 80 MHz and 800 MHz, the higher frequency range applies.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption, and reflection from structures, objects and people.

- a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcasts and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Guardian Link is used exceeds the applicable RF compliance level above, the Guardian Link should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Guardian Link.
- b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the transmitter

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

Rated maximum output power of transmitter (W)	Separation distance according to the frequency of transmitter (m)		
	150 kHz to 80 MHz Not applicable	80MHz to 800MHz $d = 0.35 \sqrt{P}$	800MHz to 6.0GHz $d = 0.70 \sqrt{P}$
0.01	Not applicable	0.035	0.07
0.1	Not applicable	0.11	0.22
1	Not applicable	0.35	0.7
10	Not applicable	1.1	2.2
100	Not applicable	3.5	7

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.

Note: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note: 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.

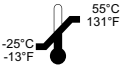











The remedies provided for in this warranty are the exclusive remedies available for any breach hereof. Neither Medtronic MiniMed nor its suppliers or distributors shall be liable for any incidental, consequential, or special damage of any nature or kind caused by or arising out of a defect in the product.

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.

Icon Table

	Serial number
	Catalogue or model number
(1x)	One per container/package
	Date of manufacture
	Manufacturer
	Follow instructions for use (appears blue on label)
	Consult instructions for use

	Storage temperature range
	Radio communication
	Configuration or unique version identifier
	Degree of protection against electric shock: Type BF applied part
IP48	Transmitter: Protected against the effects of continuous immersion in water (8 feet (2.4 meters) immersion for 30 minutes).
	Storage humidity range
R_x Only	Prescription only
	Magnetic Resonance (MR) Unsafe: keep away from magnetic resonance imaging (MRI) equipment
	RF device distributed in Australia
CE 0459	Marking of Conformity: This symbol means the device fully complies with MDD 93/42/EEC (NB 0459).
IC	RF device distributed in Canada
	Authorized representative in the European community
	Fragile, handle with care
	Keep dry
	Recycle cardboard, paper, plastic packaging supplies and unwanted written material.
	WEEE Initiative: DO NOT THROW IN TRASH. Recycle device according to local disposal requirements.

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