

# Guardian™ Link

Transmitter



**CAUTION: Investigational Device**

**Limited by Federal Law to Investigational Use.**



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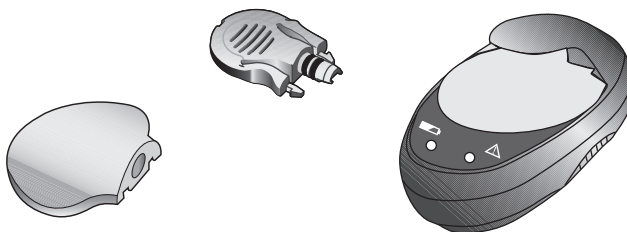
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The Guardian™ Link transmitter is a component of the continuous glucose monitoring system for the MiniMed™ 640G insulin pump. The transmitter collects data from the Enlite™ glucose sensor. The transmitter then wirelessly sends the data to the insulin 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)
- Enlite Serter (MMT-7510)

## Indications for use

The transmitter is indicated for single-patient use as a component of select Medtronic continuous glucose sensing systems and MiniMed sensor-enabled pump systems.

## 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 or your local representative for further assistance.

## Warnings

Product contains small parts and may pose a choking hazard for young children.

If the tester comes in contact with blood, the tester must be discarded. Dispose of the tester according to the local regulations for medical waste disposal.

Bleeding may occur after inserting the sensor. Make sure that the site is not bleeding before connecting the transmitter to the sensor. 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.

Refer to the Enlite Sensor User Guide for all precautions, warnings, and instructions relating to the Enlite sensor.

Contact the 24 Hour HelpLine if you experience any adverse reactions associated with the transmitter or sensor.

### **Magnetic fields**

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.

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

If you are going to have an x-ray, diathermy treatment, CT scan, MRI or other type of exposure to radiation, remove your sensor and transmitter before entering a room containing any of these equipment.

Important information about airport security systems, and using your transmitter on an airplane, can be found on the Emergency Card. Be sure to carry the Emergency Card provided with your pump when you are traveling.

### **Precautions**

Refer to the Enlite Sensor User Guide for all precautions, warnings, and instructions relating to the Enlite sensor.

Always use the Watertight Tester when cleaning the transmitter. Do not use any other test plug with the transmitter.

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

Do not allow water, or any other liquid, to come in contact with the tester when it is not connected to the transmitter. A wet tester can cause damage to the transmitter.

Do not allow the transmitter to come in contact with any liquid when not connected to a sensor or to the tester.

Do not clean the o-rings on the tester, as this can damage the o-rings.

### **Notice**

**Caution: Any changes or modifications to the devices not expressly approved by Medtronic Diabetes could interfere with your ability to operate the equipment, cause injury, and void your warranty.**

### **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 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.

**Caution: Changes or modifications to the internal RF transmitter or antenna not expressly approved by Medtronic could void the user's authority to operate this insulin delivery system.**

This device complies with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

## 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 and the 24 Hour HelpLine phone number are listed on the back 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   | <a href="http://www.medtronicdiabetes.com">www.medtronicdiabetes.com</a> |

## Charger

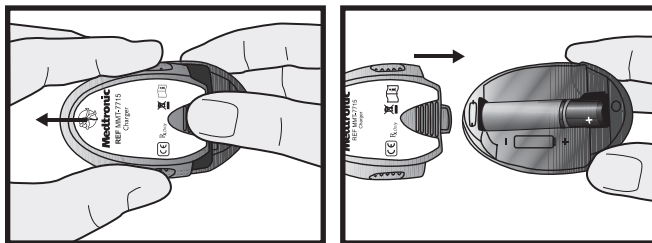
The transmitter contains a non-replaceable, rechargeable battery that you can recharge as needed with the charger. The charger has a green light that shows the charging status and a red light that communicates any problems during charging. If you see a red light, see the Troubleshooting section. The charger needs one AAA alkaline battery, size E92, type LR03 to operate.

**Note:** *A new AAA or LR-03 battery contains enough power to recharge the transmitter at least 40 times. 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 or LR-03 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.

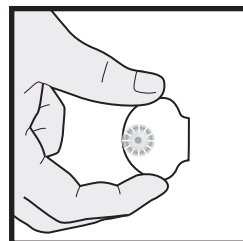
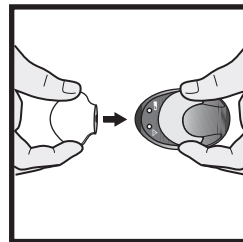


## Charging the transmitter

**Caution:** Charge the transmitter after each sensor use. A fully charged transmitter works for 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

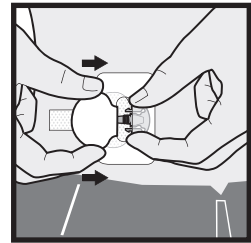
Always refer to the senter user guide for instructions on how to insert the sensor.

## Connecting the transmitter to the sensor

Before proceeding, have available your pump user guide.

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.

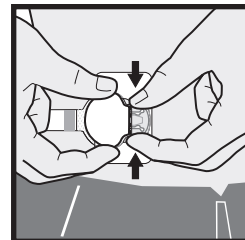


## Disconnecting the transmitter from the sensor

Before proceeding, have available your pump user guide.

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

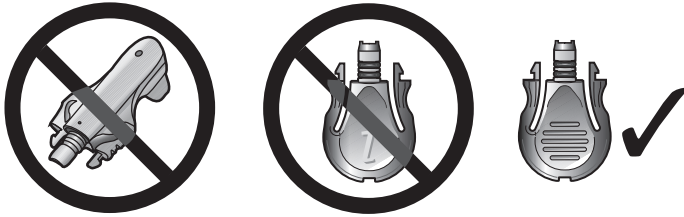
After the transmitter and sensor are connected, they form a waterproof seal to a depth of 8 feet (2.4 meters) for up to 30 minutes. You can shower and swim without removing them. No occlusive dressing is needed.

## 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.

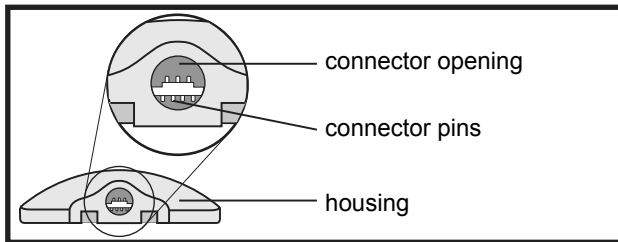
The tester can be used for one year. If you continue to use the tester for more than one year, the transmitter's connector pins could be damaged, because the tester cannot continue to provide a waterproof seal. For instructions on how to check the connector pins, see *Inspecting the transmitter connector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

**Caution:** Only use the Watertight Tester with the transmitter. Do not use any other test plug.



### **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 or your local representative. It may be time to replace your transmitter.

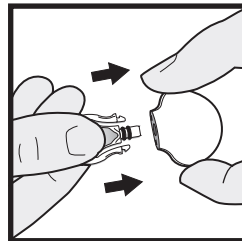
Also look for moisture inside the connector opening. If you see any moisture, allow the transmitter to dry for at least one hour. Moisture inside the connector opening could cause the transmitter to not work properly, and could cause corrosion and damage over time.

## Connecting the tester for testing or cleaning

Before proceeding, have available your pump user guide.

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.
- 3 Within five seconds, when properly connected, the green light on the transmitter flashes for about 10 seconds.
- 4 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).
- 5 To clean the transmitter, see *Cleaning the transmitter, on page 9*.
- 6 After testing or cleaning, disconnect the tester from the transmitter.

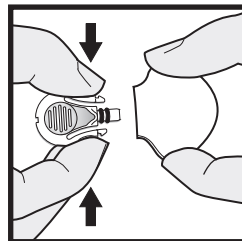


## Disconnecting the tester

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. Always clean the transmitter after each 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.

To clean the transmitter:

- 1 Attach the tester to the transmitter.

- 2 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.
- 3 Prepare a mild liquid soap solution using one (1) teaspoon of mild liquid soap per one (1) gallon of room temperature tap water.
- 4 With tester still attached, submerge the transmitter in the mild liquid soap solution and soak for one minute.
- 5 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.
- 6 Rinse the transmitter under running room temperature tap water for at least one minute, and until all visible liquid soap is gone.
- 7 Dry the transmitter and tester with a clean, dry, non-shedding cloth.
- 8 Disconnect the tester from the transmitter.
- 9 Place the transmitter and tester on a clean, dry, non-shedding cloth and air dry them completely.

## **Cleaning the charger**

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

**Caution:** The charger is **NOT** waterproof. Do **NOT** immerse in water or any other cleaning agent.

**Caution:** Dispose the charger according to the local regulations for battery disposal (non-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 2–3 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   |
|---|--|--|
| <p>You connected the transmitter to the charger and no lights came on.</p>  | <p>The transmitter connector pins are damaged or corroded.</p> <p>Your charger battery has no power.</p> | <ol style="list-style-type: none"> <li>1 Check the transmitter connector pins for damage or moisture. For more information about your connector pins, see <i>Inspecting the transmitter connector pins, on page 8</i>. If the pins are damaged or corroded, contact the 24 Hour HelpLine or your local representative. It may be time to replace your transmitter.</li> <li>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, on page 5</i>.</li> </ol> |
| <p>During charging, the flashing green light on the charger turns off and you see a flashing red light on the charger.</p>                  | <p>Your charger battery is low on power.</p>   | <p>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>.</p>  |
| <p>During charging, the flashing green light on the charger turns off and you see a series of quick flashing red lights on the charger.</p> | <p>Your transmitter is low on power.</p>   | <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 the 24 Hour HelpLine or your local representative. It may be time to replace your transmitter.</li> </ol>   |
| <p>During charging, a mix of quick and long flashing red lights appear on the charger.</p>  | <p>Your charger <i>and</i> your transmitter are low on power.</p>  | <ol style="list-style-type: none"> <li>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>.</li> <li>2 Charge the transmitter continuously for one hour. If flashing does not stop, proceed to step 3.</li> <li>3 Charge the transmitter continuously for eight hours. If flashing does not stop, call the 24 Hour HelpLine or your local representative. It may be time to replace your transmitter.</li> </ol>   |

| Problem   | Likely Cause(s)  | Resolution  |
|---|--|---|
| <p>The green light on the transmitter does not flash when you connect it to the sensor.</p> | <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"> <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. If the green light still does not flash, proceed to step 4.</li> <li>4 The sensor may not be properly inserted into your body. Insert a new sensor.</li> </ol>   |
| <p>The green light on the transmitter does not flash when you connect it to the tester.</p> | <p>Your transmitter is low on power.</p> <p>Your transmitter is not fully connected.</p>   | <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 the 24 Hour HelpLine or your local representative. It may be time to replace your transmitter.</li> </ol>   |
| <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"> <li>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.</li> <li>2 Move away from any device that can cause RF interference. For more information on RF interference, see <i>Radio Frequency (RF) communication</i>, on page 2.</li> <li>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 or your local representative. It may be time to replace your transmitter.</li> </ol> |

| Problem  | Likely Cause(s)  | Resolution  |
|--|--|---|
| Your transmitter has lost connection with your pump. | Your pump is out of range.<br>There is RF interference from other devices. | <ol style="list-style-type: none"> <li>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 2</i>. If your transmitter is still not communicating with your pump, proceed to step 2.</li> <li>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 or your local representative for assistance.</li> </ol> |

## 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.

## Specifications

|                             |   |
|-----------------------------|---|
| <b>Biocompatibility</b>     | Transmitter: Complies with ISO 10993-1 for body contact   |
| <b>Applied parts</b>        | Transmitter<br>Sensor   |
| <b>Operating conditions</b> | <p>Transmitter temperature: -5°C to 45°C (23°F to 113°F)</p> <p>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)</p> <p>Transmitter relative humidity: 5% to 95% with no condensation</p> <p>Charger temperature: 10°C to 40°C (50°F to 104°F)</p> <p>Charger relative humidity: 30% to 75% with no condensation</p> |
| <b>Storage conditions</b>   | <p>Transmitter temperature: -25°C to 55°C (-13°F to 131°F)</p> <p>Transmitter relative humidity: 10% to 100% with condensation</p> <p>Charger temperature: -10°C to 50°C (14°F to 122°F)</p> <p>Charger relative humidity: 10% to 95% with no condensation</p>  |

|                                  |  |
|----------------------------------|--|
| <b>Battery life</b>              | Transmitter: Six days of continuous glucose monitoring immediately following a full charge<br>Charger: Completes 40 typical charging operations using a new AAA alkaline battery |
| <b>Transmitter frequency</b>     | 2.4 GHz, 2M65G1D modulation, less than 1mW ERP   |
| <b>Transmitter expected life</b> | The transmitter expected life is 1 year depending on patient usage.  |

## **Guardian Link wireless communication**

### **Quality of service**

The Guardian Link transmitter and the MiniMed 640G 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.

### **Radio frequency (RF) communications specifications**

- 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 the proprietary data format.

### **Data security**

The MiniMed 640G 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 640G 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

| <b>Guidance and Manufacturer's Declaration - Electromagnetic Emissions</b>  |                   |   |
|---|-------------------|---|
| <b>The Guardian Link transmitter is intended for use in the electromagnetic environment specified below. The customer or the user of the Guardian Link should make sure that it is used in such an environment.</b> |                   |   |
| <b>Emissions Test</b>   | <b>Compliance</b> | <b>Electromagnetic Environment - Guidance</b>   |
| RF emissions<br>CISPR 11  | Group 1           | The Guardian Link must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.  |
| RF emissions<br>CISPR 11  | Class B           | The Guardian Link 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. |

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

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

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

| <b>Immunity Test</b>                                       | <b>IEC 60601 Test Level</b> | <b>Compliance Level</b> | <b>Electromagnetic Environment - Guidance</b>  |
|--|-----------------------------|-------------------------|--|
| Power frequency (50/60 Hz) magnetic field<br>IEC 61000-4-8 | 3 A/m                       | 400 A/m<br><br>4000 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.**

| <b>Immunity Test</b>          | <b>IEC 60601 Level</b>        | <b>Compliance Level</b> | <b>Electromagnetic Environment Guidance</b>  |
|-------------------------------|-------------------------------|-------------------------|--|
|                               |                               |                         | Portable and mobile RF communications equipment should be used no closer to any part of the Guardian Link, including cables, than the recommended separation distance calculated from the equation applicable to the power of the transmitter.<br><br>Refer to the recommended separation distance table for more information. |
| Conducted RF<br>IEC 61000-4-6 | 3 V/m<br>150 kHz to<br>80 MHz | Not applicable          | Not applicable   |

### 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 Level             | Compliance Level             | Electromagnetic Environment Guidance  |
|------------------------------|-----------------------------|------------------------------|---|
| Radiated RF<br>IEC 61000-4-3 | 3 V/m<br>80 MHz to<br>6 GHz | 10 V/m<br>80 MHz to<br>6 GHz | <p><math>d = 0.35 \sqrt{P}</math><br/>80 MHz to 800 MHz</p> <p><math>d = 0.70 \sqrt{P}</math><br/>800 MHz to 6 GHz</p> <p>Where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <math>d</math> is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey<sup>a</sup>, should be less than the compliance level in each frequency range<sup>b</sup>.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p>  |

**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.

<sup>a</sup>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.

<sup>b</sup>Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

| <b>Recommended separation distances between the Guardian Link and common household radio transmitters</b> |                  |  |   |
|---|------------------|--|---|
| <b>Household RF Transmitter</b>   | <b>Frequency</b> | <b>Recommended Separation Distance (meter)</b> | <b>Recommended Separation Distance (inch)</b> |
| <b>Telephones</b>   |                  |  |   |
| Cordless Household  | 2.4 GHz          | 0.3  | 12  |
| Cordless Household  | 5.8 GHz          | 0.3  | 12  |
| TDMA-50 Hz (cell phone)   | 1.9 GHz          | 0.3  | 12  |
| TDMA-50 Hz (cell phone)   | 800 MHz          | 0.3  | 12  |
| PCS (cell phone)  | 1.9 MHz          | 0.3  | 12  |
| DCS (cell phone)  | 1.8 MHz          | 0.3  | 12  |
| GSM (cell phone)  | 900 MHz          | 0.3  | 12  |
| GSM (cell phone)  | 850 MHz          | 0.3  | 12  |
| CDMA (cell phone)   | 800 MHz          | 0.3  | 12  |
| Analog (cell phone)   | 824 MHz          | 0.3  | 12  |
| CDMA (cell phone)   | 1.9 MHz          | 0.3  | 12  |
| <b>WiFi Networks</b>  |                  |  |   |
| 802.11b; 11Mbps maximum   | 2.4 GHz          | 1  | 39.5  |
| 802.11g; 54 Mbps maximum  | 2.4 GHz          | 1  | 39.5  |
| 802.11n; 11Mbps maximum   | 2.4 GHz          | 1  | 39.5  |
| Bluetooth 500 kb/s  | 2.4 GHz          | 0.1  | 3.93  |
| ZigBee 250 kb/s   | 2.4 GHz          | 0.1  | 3.93  |



### Recommended separation distances between portable and mobile RF communications equipment and the Guardian Link

The Guardian Link is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the Guardian Link users can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment and the Guardian Link 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<br>Not applicable                               | 80MHz to 800MHz<br>$d = 0.35 \sqrt{P}$ | 800MHz to 6.0GHz<br>$d = 0.70 \sqrt{P}$ |
| 0.01  | Not applicable  | 0.035                                  | 0.07                                    |
| 0.1   | Not applicable  | 0.11                                   | 0.11                                    |
| 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.

### Icon Table

|   |                                    |
|---|------------------------------------|
|    | Serial number                      |
|   | Catalogue number                   |
| (1X)  | One per container/package          |
|  | Date of manufacture (year - month) |
|  | Manufacturer                       |
|  | Follow instructions for use        |
|  | Storage temperature range          |

|   |   |
|---|---|
|   | Radio communication   |
| CONF  | Configuration   |
|  | Type BF equipment (protection from electrical shock)  |
| <b>IP48</b>   | Transmitter: Protected against the effects of continuous immersion in water (8 feet (2.4 meters) immersion for 30 minutes). |
|  | Attention: Read all warnings and precautions in instructions for use.   |
|  | Storage humidity range  |

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