

Guardian™ Connect

Transmitter



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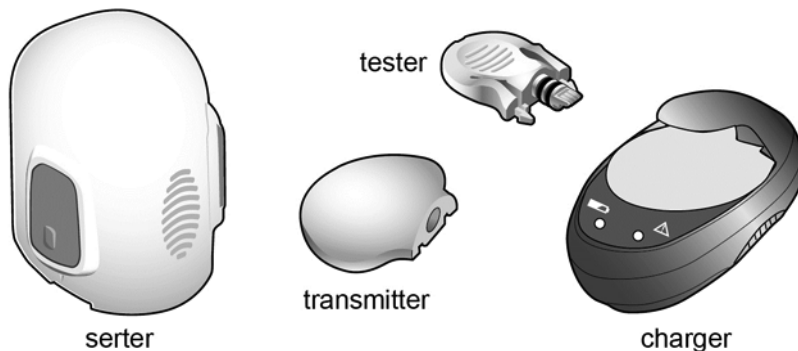
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The Guardian™ Connect transmitter is a component of the Guardian™ Connect continuous glucose monitoring (CGM) system. The transmitter is compatible only with the Guardian™ Sensor (3) glucose sensor. The transmitter receives data from the sensor. The transmitter also receives and sends data to the Guardian™ Connect app through a Bluetooth® Smart wireless connection.



Guardian Connect transmitter kit components

A complete transmitter kit includes the following components:

- Guardian Connect transmitter (MMT-7821)
- Two testers (MMT-7736)
- Charger (MMT-7715)
- One-press serter (MMT-7512)

Indications for use

The transmitter is indicated for single-patient use as a component of select Medtronic CGM 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 for further assistance.

Warnings

- Always refer to the sensor user guide for all precautions, warnings, and instructions relating to the sensor. Not referring to the 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. Discard the device if damaged. 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

- Only use the Guardian Sensor (3) (MMT-7020) glucose sensor 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 tester (MMT-7736) with the transmitter. 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.
- 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. 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.

Exposure to magnetic fields and radiation

- Do not expose your 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). The strong magnetic fields can cause the device to malfunction, and result in serious injury. If your transmitter is exposed to a strong magnetic field, discontinue use and contact the 24 Hour HelpLine for further assistance.
- 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, and result in serious injury. 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 Medical emergency card available at www.medtronicdiabetes.com/guardian-connect when you are traveling. The Medical 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 Medical 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 device 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 device. 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.
- Changes or modifications made to this equipment not expressly approved by Medtronic Diabetes could void the user's authority to operate the equipment.

For Canada only

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'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. When calling the HelpLine, please have the serial number of your device available. The 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 |
| Website | www.medtronicdiabetes.com |

Charger

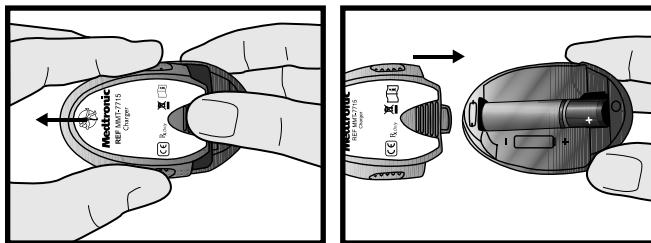
The transmitter contains a non-replaceable, rechargeable battery that you can recharge as needed with the charger. The charger has a green light that shows the charging status and a red light that communicates any problems during charging. If you see a red light, see the Troubleshooting section. The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



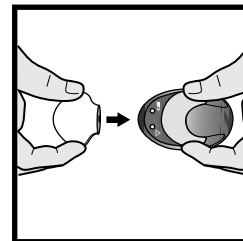
Charging the transmitter

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

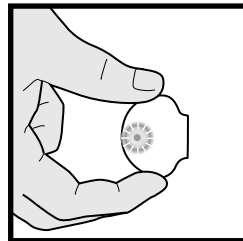
Note: Do not store the transmitter on the charger for more than 60 days. Disconnect and reconnect to the charger to re-charge again before use. If the transmitter is left on the charger for more than 60 days, the battery will be permanently damaged.

To charge the transmitter:

- 1 Push the two components together to connect the transmitter to the charger.
- 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 will flash 10 times and then turn off.



Pairing your transmitter

Always refer to the system user guide for instructions on how to pair your transmitter to your mobile device.

Inserting the sensor

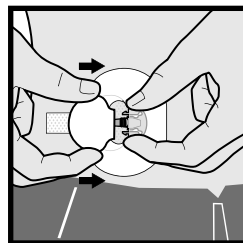
Always refer to your sensor user guide for instructions on how to insert the sensor.

Connecting the transmitter to the sensor

Before proceeding, have your system user guide available.

To connect the transmitter to the sensor:

- 1 After the sensor is inserted, consult your sensor user guide for details on applying the required tape.
- 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, the green light on the transmitter will flash 6 times.



Note: *If the transmitter does not flash, see Troubleshooting, on page 13.*

- 5 When the transmitter light flashes green after connecting to the sensor, use the app to start the sensor. For more instructions, see your system user guide.

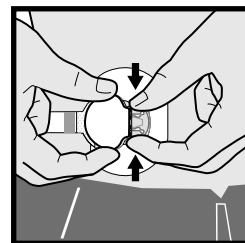
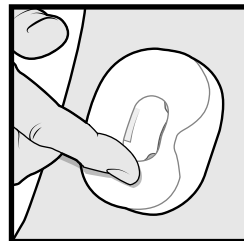
- 6 Attach the adhesive tab to the transmitter.
- 7 Refer to the sensor user guide for instructions on how to apply a second tape.
- 8 Follow the instructions that appear on the app or follow the instructions in your system user guide.

Disconnecting the transmitter from the sensor

Before proceeding, have your system user guide available.

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 your thumb and forefinger.
- 4 Gently pull the transmitter away from the sensor.
- 5 Follow the instructions that appear in the app or follow the instructions in your system 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.

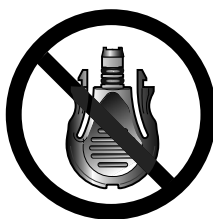
Tester

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 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.

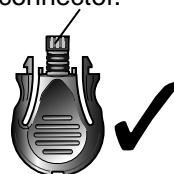
Do not twist the tester while attached to the transmitter. This will damage the transmitter.

The tester can be used for one year. If you continue to use the tester for more than one year, the connector pins inside the transmitter 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 (MMT-7736) with the transmitter. 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.

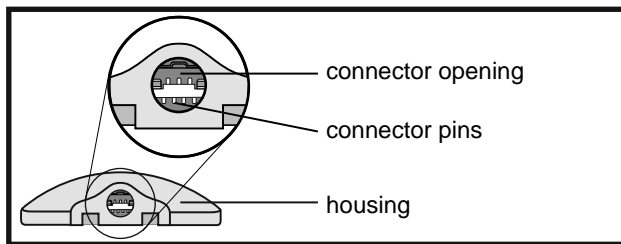


Correct tester has gold on both sides of connector.



Inspecting the transmitter connector pins

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



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 app on your compatible mobile device. 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.

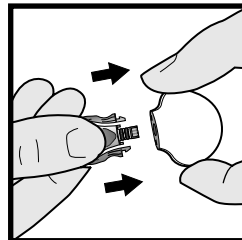
Connecting the tester for testing or cleaning

Before proceeding, have your 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.



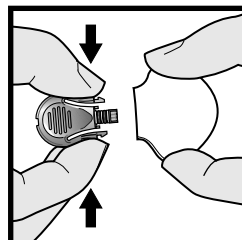
- 3 To test the transmitter, check the sensor icon in the app to ensure that the transmitter is sending a signal (see your system user guide).
- 4 To clean the transmitter, see *Cleaning the transmitter*, on page 9.
- 5 After testing or cleaning, disconnect the tester from the transmitter.

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.

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*, on page 7.

Always clean the transmitter after each use.

To clean the transmitter, you need the following materials:

- Ivory® liquid soap
- soft-bristled toddler toothbrush

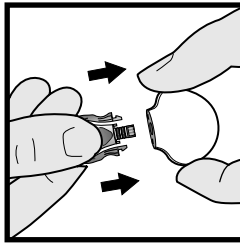
- container
- 70% isopropyl alcohol
- clean and lint-free dry cloths

You can find these supplies at Walmart, Target, or <http://www.amazon.com/>.

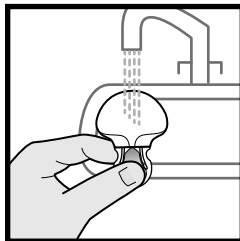
Warning: Do not use the device if you see any cracking, flaking, or damage to the housing. Cracking, flaking, or damage to the housing are signs of deterioration. Deterioration of the housing can affect the ability to properly clean the transmitter, and result in serious injury. Call the 24 Hour HelpLine and discard the device according to local regulations for battery disposal (nonincineration), or contact your healthcare professional for disposal information.

To clean the transmitter:

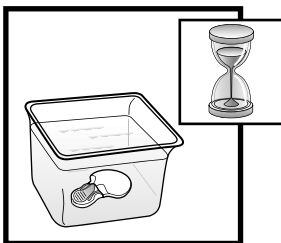
- 1 Wash your hands thoroughly.
- 2 Attach the tester to the transmitter.



- 3 If there is adhesive residue on the transmitter, see *Removing adhesive residue*, on page 12.
- 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.



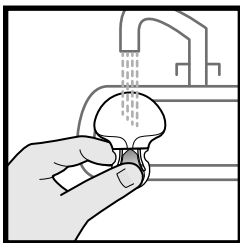
- 5 Prepare a mild liquid soap solution using 1 teaspoon (5 milliliters) of Ivory liquid soap per 1 gallon (3.8 liters) of room temperature tap water.
- 6 With the tester still attached, submerge the transmitter in the mild liquid soap solution and soak for one minute.



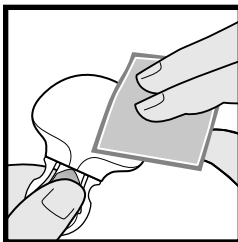
- 7 Holding the tester, brush the entire surface of the transmitter using a soft-bristled toddler toothbrush. Make sure to brush all hard-to-reach areas until visibly clean.



- 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.

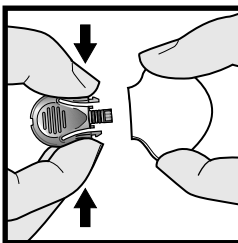


10 Holding the tester, wipe the transmitter with 70% isopropyl alcohol.



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

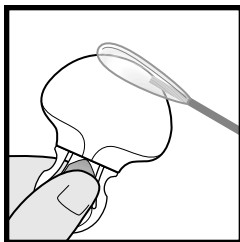
You may need to perform this procedure if there is adhesive residue present on the transmitter. If you visually inspect the transmitter and see adhesive residue on it, follow the instructions below.

To remove adhesive residue, you need 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.

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.

Warning: Dispose the charger according to the local regulations for battery disposal, or contact your healthcare professional for disposal information. The charger may ignite 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 system 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 or no battery is inserted.</p> | <ol style="list-style-type: none"> 1 Check the transmitter connector pins for damage or corrosion. 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. |
| <p>During charging, the flashing green light on the charger turns off and you see a longer 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</i>, on page 5.</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 for two seconds at a time.</p> | <p>Your transmitter is low on power.</p> | <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. |
| <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"> 1 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. 2 Charge the transmitter continuously for one hour. If the quick flashing red lights do 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. |

| 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"> 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 and connect it to the tester. If the green light still does not flash, see troubleshooting on “The green light on the transmitter does not flash when you connect it to the tester”. If the green light flashes, proceed to step 4. 4 Disconnect the transmitter from the tester, wait five minutes, and connect the transmitter to the sensor. If the green light still does not flash, proceed to step 5. 5 The sensor may not be properly inserted into your body. Remove the sensor from your body and insert a new sensor. |
| <p>The green light on the transmitter does not flash when you connect it to the tester.</p> | <p>Your transmitter is not fully connected.</p> <p>Your transmitter is low on power.</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. |
| <p>Your transmitter battery does not last for seven days.</p> | <p>Your transmitter is not fully charged when you connect it to the sensor.</p> <p>The transmitter and the app on your compatible mobile device 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 seven 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</i>, on page 3. 3 Make sure your compatible mobile device 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 seven days, call the 24 Hour HelpLine. It may be time to replace your transmitter. |

| Problem | Likely Cause(s) | Resolution |
|--|---|---|
| <p>Your transmitter has lost connection with the app on your compatible mobile device.</p> <p>Note: <i>An alert occurs and a message appears when your transmitter has lost connection with the app on your compatible mobile device.</i></p> | <p>Your compatible mobile device 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</i>, on page 3. If your transmitter is still not communicating with the app on your compatible mobile device, proceed to step 2. 2 Make sure your compatible mobile device 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 the app, 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. If the transmitter is left on the charger for more than 60 days, the battery will be permanently damaged.

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 |
| Applied parts | Transmitter Sensor |
| Operating conditions | <p>Transmitter temperature: 32 °F to 113 °F (0 °C to 45 °C)</p> <p>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)</p> <p>Transmitter relative humidity: 10% to 95% with no condensation</p> <p>Transmitter pressure: 8.4 to 15.4 psi (57.60 to 106.17 kPa)</p> <p>Charger temperature: 50 °F to 104 °F (10 °C to 40 °C)</p> <p>Charger relative humidity: 30% to 75% with no condensation</p> |

| | |
|--|--|
| Storage conditions | 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 to 15.4 psi (57.60 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 life | Transmitter: Seven days of continuous glucose monitoring immediately following a full charge Charger: The charger uses one new AAA battery to charge the transmitter |
| Transmitter frequency | 2.4 GHz band, Bluetooth Smart (version 4.0) |
| Maximum output power (EIRP) | 0.1 mW (-9.9 dBm) |
| Operating range | Up to 20 feet (6.1 meters) |
| Transmitter expected service life | The transmitter expected service life is one year depending on patient usage. |

Transmitter wireless communication

Quality of service

The transmitter and app connect via a BLE network. The transmitter sends glucose data and system related alerts to the app. The transmitter and the app verify the integrity of received data after wireless transmission. Quality of the connection is in accordance with the Bluetooth Specification v4.0.

Data security

The transmitter is designed to only accept radio frequency (RF) communications from recognized and linked devices. You must program the app to accept information from a specific transmitter. Transmitted sensitive data is encrypted to prevent unauthorized receipt or communication.

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. |

| 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 | 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 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. |
| 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. |

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

| Guidance and Manufacturer's Declaration - Electromagnetic Immunity | | | |
|---|-------------------------------|------------------|---|
| The transmitter is intended for use in the electromagnetic environment specified below. The customer or user of the transmitter should assure that it is used in such an electromagnetic environment. | | | |
| Immunity Test | IEC 60601 Level | Compliance Level | Electromagnetic Environment Guidance |
| | | | <p>Portable and mobile RF communications equipment should be used no closer to any part of the transmitter, including cables, than the recommended separation distance calculated from the equation applicable to the power of the transmitter.</p> <p>Refer to the recommended separation distance table for more information.</p> |
| Conducted RF IEC 61000-4-6 | 3 V/m 150 kHz to 80 MHz | Not applicable | Not applicable |

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

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

| Immunity Test | IEC 60601 Level | Compliance Level | Electromagnetic Environment Guidance |
|------------------------------|-----------------------------|------------------------------|---|
| Radiated RF IEC 61000-4-3 | 3 V/m 80 MHz to 6 GHz | 10 V/m 80 MHz to 6 GHz | <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>  |

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.

^aField 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 transmitter is used exceeds the applicable RF compliance level above, the transmitter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the transmitter.

^bOver 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.


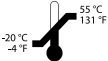










The remedies provided for in this warranty are the exclusive remedies available for any breach hereof. Neither Medtronic MiniMed nor its suppliers or distributors shall be liable for any incidental, consequential, or special damage of any nature or kind caused by or arising out of a defect in the product.

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 transmitter, charger, and senter per container/package |
| (2x) | Two testers per container/package |
|  | Date of manufacture (YYYY-MM-DD) |
|  | Manufacturer |

| | |
|---|--|
|  | Must refer to instruction manual before every use (appears blue on label). |
|  | Temperature limit |
|  | Non-ionizing electromagnetic radiation (RF communication) |
|  | Configuration or unique version identifier |
|  | Degree of protection against electric shock: Type BF applied part |
| IP48 | Transmitter: 4 is the level of protection against solid objects with a diameter above 1mm. 8 is the level of protection against the effects of continuous immersion in water [8 feet (2.4 meters) immersion for 30 minutes]. |
|  | Humidity limitation |
| R_x Only | Prescription only |
|  | 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. |
|  | Magnetic Resonance (MR) unsafe: keep away from magnetic resonance imaging (MRI) equipment |
|  | <i>Bluetooth®</i> wireless technology or <i>Bluetooth®</i> enabled |

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Ivory® is a registered trademark of The Procter & Gamble Company.

Detachol® is a registered trademark of Ferndale Laboratories Inc.



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