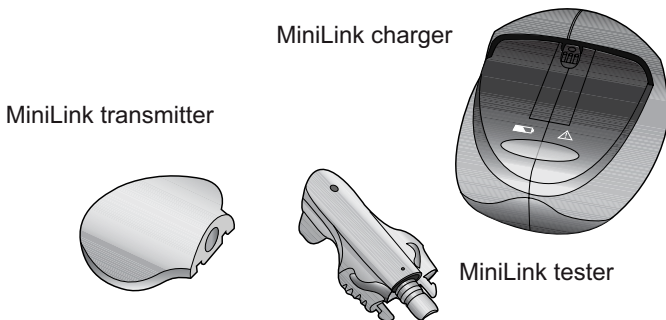


The Medtronic MiniMed MiniLink™ transmitter (MiniLink) is a component of continuous glucose sensing systems and sensor-enabled pump systems. The MiniLink powers the glucose sensor, collects glucose data, and wirelessly sends the data to a monitor. The monitor is part of a Medtronic MiniMed continuous glucose sensing system or Medtronic MiniMed sensor-enabled pump system.



## Package contents

- MiniLink transmitter
- MiniLink charger
- AAA alkaline battery
- MiniLink tester
- Occlusive dressing (10 pack)

## Indications for use

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

## Contraindications

None known.

## Warnings

Do not use the MiniLink to send glucose readings to the monitor while onboard an aircraft. Disconnect the MiniLink from the sensor while travelling on an aircraft or if interference with other transmitting devices occurs.

The sensor should be removed if redness, bleeding, pain, tenderness, irritation, or inflammation develops at insertion site, or if user experiences unexplained fever.

Occlusive dressing should be removed if irritation or reaction to the tape develops.

The sensor may create special needs regarding your medical conditions or medications. Discuss with your doctor before using the sensor.

Wait 5 minutes after sensor insertion to see if bleeding occurs at the insertion site:

- The MiniLink should not be attached to the sensor until after the bleeding has stopped.
- If bleeding persists, apply steady pressure using a sterile gauze or clean cloth at the insertion site until bleeding stops. After bleeding stops, attach the MiniLink to the sensor.
- If bleeding persists after 3 minutes, remove the sensor and discard. Insert a new sensor in a different location.

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

**Note:** The MiniLink is designed to withstand common electromagnetic interference, including airport security systems.

## Precautions

Establish a rotation schedule for choosing new sensor sites. Avoid sites that are constrained by clothing, have scar tissue, or are subject to rigorous movement during exercise.

## Telecommunications notice

This device complies with the United States Federal Communications Commission and international standards for electromagnetic compatibility. For the specific regulations and test results in your area, please contact the Medtronic 24 Hour HelpLine listed on the International Contact Card.

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 undesirable operation. Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

The MiniLink does not interfere with any radio frequency signals transmitted from outside sources. These FCC standards are designed to provide reasonable protection against excessive radio frequency interference and prevent undesirable operation of the device from unwanted electromagnetic interference.

This device receives and radiates radio frequency energy and, if installed and used in accordance with the instruction, may experience interference in its communications. In such an event, you are encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the MiniLink and/or receiving pump or monitor
- Increase the distance between the MiniLink and the device that is emitting interference
- Turn off or move other RF devices, such as the following: cell phones, cordless phones, and wireless networks.

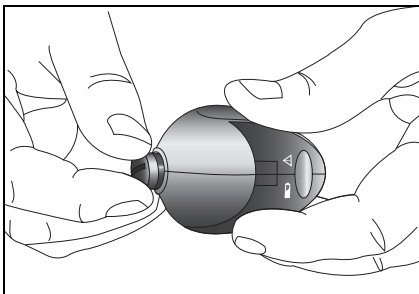
This interference will not cause any incorrect data to be sent and will not cause any harm to your pump, monitor, or MiniLink.

## MiniLink charger

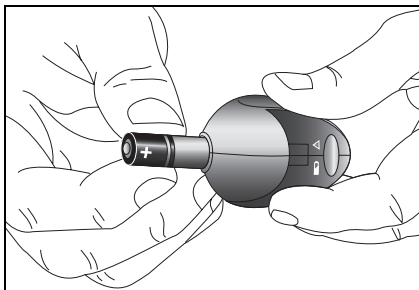
The MiniLink transmitter contains a non-replaceable, rechargeable battery so you can recharge your MiniLink as needed. Before using your MiniLink for the first time, you should charge the battery fully. To maintain a short re-charging period, charge the MiniLink after each sensor use. While the MiniLink will work more than 14 days without recharging, an empty battery can take up to 2 hours to recharge.

### Installing a new charger battery

- 1 Unscrew charger battery cap.



- 2 Insert an AAA battery with flat (-) end first and screw on charger cap.



- 3 If battery is installed incorrectly or is bad, the charger will not work when the MiniLink is attached. Repeat steps above using a new battery.

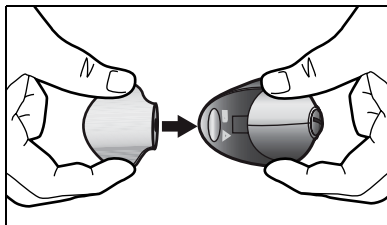
**Note:** A new AAA battery in the charger may charge the MiniLink over 40 times before it needs to be replaced.

### Charging the MiniLink

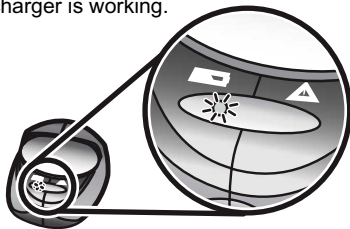
- 1 Insert the MiniLink into the charger. Line up the MiniLink connector (flat side down) with the charger and push the two components together fully.

**Note:** The charger contains green and red LEDs (lights).

- 2 When the MiniLink is first connected, the charger's green LED will blink rapidly for 1-2 seconds as charger powers on.

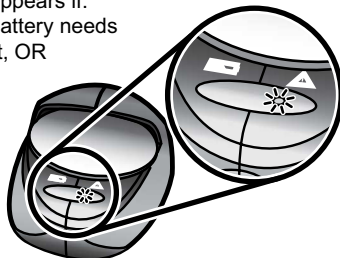


A green LED shows charger is working.



A red LED appears if:

- 1) charger battery needs replacement, OR
- 2) there is a problem with the MiniLink battery.



- 3 As the MiniLink charges, the charger's green LED will flash occasionally.



- 4 When charging is complete, the charger's green LED will turn on for 15 to 20 seconds and then turn off. Once the LED is off, disconnect the MiniLink from

the charger. A green LED inside the MiniLink will blink for about 5 seconds and then turn off. This confirms that the MiniLink is ready to use.

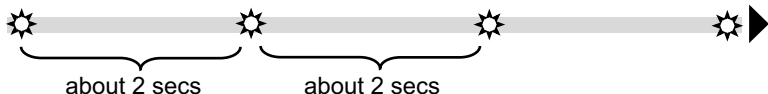
**Note:** If the green LED inside the MiniLink does not blink, re-connect the MiniLink to the charger for at least one minute. After one minute, remove the MiniLink from the charger and watch for the MiniLink to flash green. Connect to the sensor.

**Caution: If the MiniLink LED is still lit or flashing, do not connect the MiniLink to the charger.**

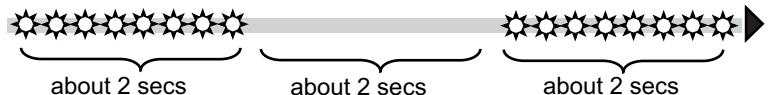
### Checking battery status

The charger's red LED will flash if the charger's internal battery is low or if the MiniLink battery is bad.

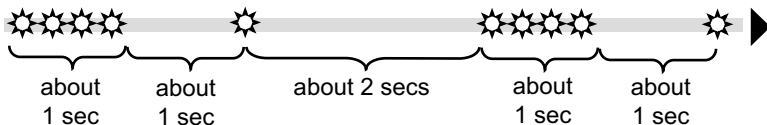
If the charger AAA battery is low, the red LED will flash once about every 2 seconds. Replace with new AAA battery.



If the MiniLink's battery is bad, the red LED on the charger will blink fast for about 2 seconds, turn off for about 2 seconds, and then repeat the cycle. Call the Medtronic Diabetes 24 Hour HelpLine.



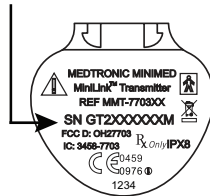
If the charger AAA battery is low AND the MiniLink battery is bad, the red LED will blink rapidly for 1 second, pause for 1 second, then blink once. After a 2 second pause, the cycle repeats. Call the Medtronic Diabetes 24 Hour HelpLine.



## Setting up the MiniLink transmitter

- 1 Find the MiniLink 7-digit serial number on the flat side of the device as shown at right. The serial number starts with "2".
- 2 Enter the serial number into your continuous glucose sensing system monitor or sensor-enabled pump. See your monitor or pump user guide for using a sensor transmitter with your system.

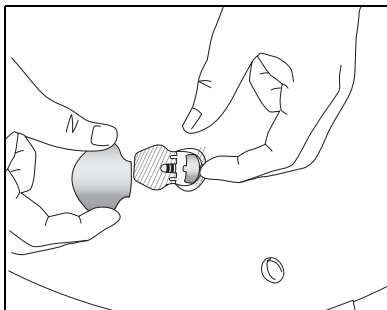
SN GT2XXXXXXM



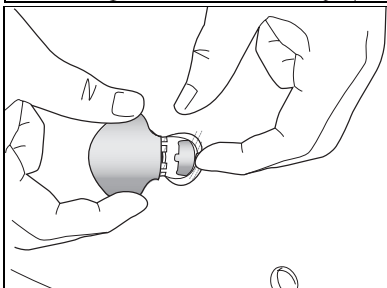
## Connecting to sensor

- 1 Follow the instructions provided with your sensor and insert the sensor before connecting the MiniLink.
- 2 Once the sensor is inserted and adhered to your body, wait 5 minutes to check for bleeding. Make sure that any bleeding has stopped (see Warnings page for details), then connect the MiniLink to the sensor.

- 3 Hold the MiniLink as shown at right. Touch the inserted sensor at back of assembly to prevent movement..
- 4 Align the MiniLink connector with the sensor connector. The MiniLink flat underside (with the label) should face the skin.



- 5 Slide the MiniLink onto the sensor. Make sure it is pushed in firmly. The flexible side arms of the sensor will “click” into notches on the underside of the MiniLink. The MiniLink will flash green for about 10 seconds with a proper connection.
- 6 The MiniLink will begin to send signals to the monitor or the pump (see your pump or monitor user guide for instructions).



**Note:** If you connect the MiniLink to a sensor that has not been inserted into your body, it will NOT flash and will NOT transmit to a monitoring device.

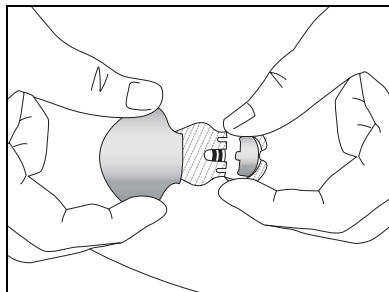
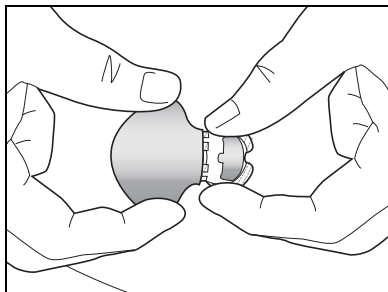
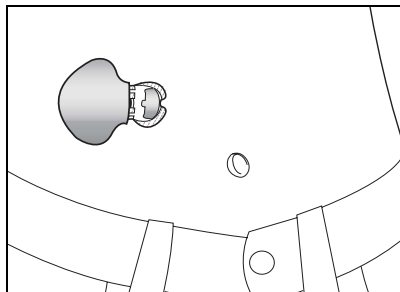
- 7 After the MiniLink successfully transmits signals to a monitor or pump, you may choose to put an occlusive dressing over the MiniLink and the sensor.

### Bathing and swimming

Once the MiniLink and sensor are connected, they form a water-tight seal to a depth of 8 feet for up to 30 minutes. You can shower and swim without removing them. **No occlusive dressing is needed.**

### Disconnecting from sensor

- 1 Hold the MiniLink as shown, and pinch the flexible side arms of the sensor between thumb and forefinger.
- 2 Gently pull the MiniLink away from the sensor assembly.

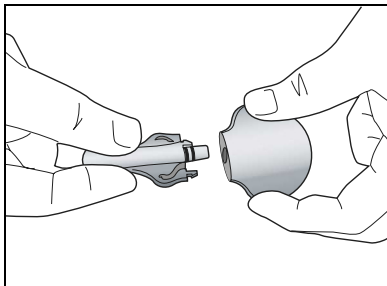


## MiniLink tester

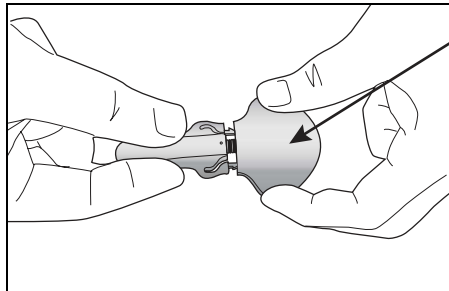
The tester is used to test the MiniLink and to make sure it is working.

### Connecting the tester

- 1 Grasp the MiniLink between the thumb and forefinger. Hold the tester body with the thumb and forefinger of the other hand. Align flat side of the tester with flat side of the MiniLink.



- 2 Plug the tester into the MiniLink. The flexible side arms of the tester will click into notches on the MiniLink underside. The MiniLink will flash green for about 10 seconds when properly connected.



#### Did the MiniLink flash?

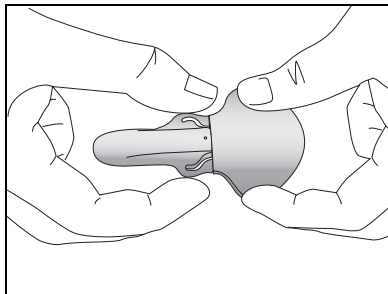
**Yes:** MiniLink is working.

**No:** Check connection.  
If still no flash, MiniLink battery needs charging OR the MiniLink is not working.  
Recharge battery (see Charger section).

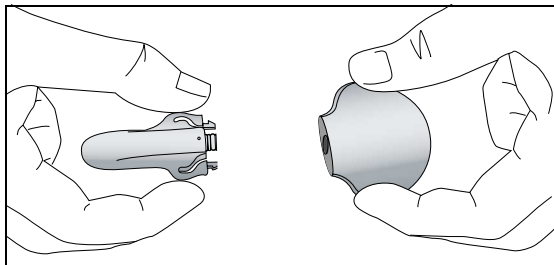
- 3 Use the pump or glucose sensing monitor to check that the MiniLink is sending a signal (see the pump or monitor user guide).

### Disconnecting the tester

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



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



**CAUTION:** To save MiniLink battery life, do NOT leave sensor or tester connected once you know the MiniLink is working.

## **Cleaning the MiniLink**

**Caution: The charger and tester units are NOT water-tight. Do NOT immerse either in water.**

### **For single-patient use**

- 1 Wash your hands thoroughly.
- 2 Dampen a clean cloth with mild liquid soap and warm water. Wipe the outside of the MiniLink.
- 3 Rinse the MiniLink under warm tap water but do NOT get water inside the connector.
- 4 Using an antibacterial hand-sanitizer (available at a local drugstore) on a clean, dry cloth, wipe down the MiniLink. Make sure to dry the inside of the connector.
- 5 Place the MiniLink on a clean, dry cloth and air dry for 2-3 minutes.

**Caution: DO NOT discard the MiniLink transmitter in a medical waste container or otherwise subject it to incineration. MiniLink contains a battery which may explode upon incineration.**

### **For multiple-patient use**

- 1 Wash your hands thoroughly.
- 2 Dampen a clean cloth with a mild liquid soap solution. Wipe the outside of the MiniLink.
- 3 Rinse the MiniLink under warm tap water but do NOT get water inside the connector.
- 4 Apply 3-4 drops of a quaternary ammonium compound disinfectant (for example, Cavicide®) on a clean, dry cloth and wipe the MiniLink.
- 5 Hold the MiniLink and rinse with 70% Isopropyl alcohol.
- 6 Place the MiniLink on a clean, dry, non-shedding cloth and air dry.
- 7 Once the MiniLink is completely dry, place it in a sealed bag labeled with the cleaning date (see label example below).

- 8 If there is any blood inside the connector, the MiniLink must be discarded. Dispose of the MiniLink according to the local regulations for battery disposal (non-incineration).

Example: Multiple-use cleaning label

Device:

Date:

Method of Decontamination:

Wash:

Disinfectant:

| <b>Specifications</b>        |                                                                                                                                                                                                                                                 |
|------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Biocompatibility</b>      | Transmitter: Complies with ISO 10993-1 for long-term body contact                                                                                                                                                                               |
| <b>Operating Conditions</b>  | Transmitter Temperature: +32° to +122° F (0° to 50° C)<br>Transmitter Relative Humidity: 10% to 95% with no condensation<br>Charger Temperature: +50° to +104° F (10° to 40° C)<br>Charger Relative Humidity: 30% to 75% with no condensation   |
| <b>Storage Conditions</b>    | Transmitter Temperature: -4° to +131° F (-20° to +55° C)<br>Transmitter Relative Humidity: 10% to 100% with condensation<br>Charger Temperature: +14° to +122° F (-10° to +50° C)<br>Charger Relative Humidity: 10% to 95% with no condensation |
| <b>Battery Life</b>          | Transmitter: 14 days of continuous sensor use immediately following a full charge<br>Charger: Completes 40 typical charging operations using a new AAA battery                                                                                  |
| <b>Transmitter Frequency</b> | 868.5 megahertz or 916.35 megahertz                                                                                                                                                                                                             |

| Icon table                                                                        |                                                                     |
|-----------------------------------------------------------------------------------|---------------------------------------------------------------------|
| <b>SN</b>                                                                         | Serial Number                                                       |
| <b>REF</b>                                                                        | Catalogue Number                                                    |
| <b>(1x)</b>                                                                       | One per container/package                                           |
|  | Date of Manufacture                                                 |
|  | Manufacturer                                                        |
|  | Fragile Product                                                     |
|  | Attention: See Instructions for use                                 |
|  | Temperature Range                                                   |
|  | CE mark by notified body as a medical device                        |
|  | CE mark as a radio transmitter under the R & TTE 95/5/EC directives |
|  | Radio communications                                                |
| <b>CONF</b>                                                                       | Configuration                                                       |
|  | Type BF Equipment (Protection from electrical shock)                |

| Icon table |                                                                                                            |
|------------|------------------------------------------------------------------------------------------------------------|
| IPX8       | MiniLink: Protected Against the Effects of Continuous Immersion in Water (8 feet immersion for 30 minutes) |

## Warranty

Medtronic MiniMed warrants the Medtronic MiniMed MiniLink to the purchaser of the product against defects in material and workmanship for a period of six (6) months and the MiniLink charger for up to six (6) months from the date of purchase.

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

This warranty is valid only if the Medtronic MiniMed MiniLink 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 MiniLink or charger by the user, or third parties, after the date of sale;
- If service or repairs are 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 fluid, physical abuse (such as dropping), or otherwise; or
- If blood or water has entered the inside of the MiniLink connector.

This warranty shall be personal to the original user. Any sale, rental or other transfer or use of the product covered by this warranty to or by a user other than the original user 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 defects in material or workmanship in the product. Neither Medtronic MiniMed nor its suppliers or distributors shall be liable for any incidental, consequential, punitive or special damages of any nature or kind caused by or arising out of a defect in the product.

All other warranties, expressed or implied, are excluded and specifically disclaimed, including, but not limited to, any warranty of merchantability or fitness for a particular purpose.

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MiniMed® is a registered trademark of Medtronic MiniMed.

MiniLink™ is a trademark of Medtronic MiniMed.

This product is covered by at least the following U.S. Patent Nos: 5,586,533; 5,954,643; 6,248,067; 6,368,141; 6,418,332; 6,809,653.

U.S., International and/or foreign patents are pending.

