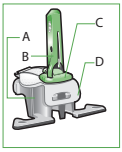
Guardian™ Sensor (3)

User Guide

Medtronic

Introduction

The Guardian™ Sensor (3) glucose sensor is part of the Continuous Glucose Monitoring (CGM) system. The sensor continuously converts tiny amounts of glucose from the interstitial fluid under the skin into an electronic signal. The system then uses these signals to provide sensor glucose values.



A. pedestal
B. needle housing
C. sensor
D. clear liner

Potential risks related to sensor use

General risks with sensor use include:

- Skin irritation or other reactions
- Bruising
- Discomfort
- Redness
- Bleeding
- Pain
- Rash
- Infection
- Raised bump
- Appearance of a small freckle-like dot where needle was inserted
- Allergic reaction
- Fainting secondary to anxiety or fear of needle insertion
- Soreness or tenderness
- Swelling at insertion site
- Sensor fracture, breakage, or damage
- Minimal blood splatter associated with sensor needle removal
- Residual redness associated with adhesive or tapes or both
- Scarring

Indications for use

The Guardian™ Sensor (3) is intended for use with compatible Medtronic systems to continuously monitor glucose levels in persons with diabetes.

The sensor is intended for single use and requires a prescription.

The Guardian™ Sensor (3) is indicated for 7 days of continuous use. For approved age ranges for use, refer to the compatible Medtronic system user guide.

Contraindications

None known.

Assistance

Department	Telephone Number
Local Medtronic support representative (calls within the United States)	800 646 4633
Local Medtronic support representative (calls outside the United States)	+1 818 576 5555
Website	www.medtronicdiabetes.com

General warnings

Read this entire user guide before attempting to insert the sensor. The one-press serter (MMT-7512) does not work the same as other Medtronic insertion devices. Failure to follow directions or using a different serter may result in improper insertion, pain, or injury.

The Guardian™ Sensor (3) was developed, and its performance evaluated, for use with the approved system only. The sensor should not be used as part of unapproved systems, as it may provide inaccurate sensor glucose readings.

The sensor is designed to work with approved transmitters only. The sensor is not interchangeable with transmitters or recorders that are not compatible with the sensor. Connecting the sensor to a transmitter or recorder that is not approved for use with the sensor may cause damage to the components or inaccurate sensor glucose values.

Refer to the compatible Medtronic system user guide for guidance on therapy decisions.

Taking medications with acetaminophen, such as Tylenol™*, fever reducers, or cold medicine, while wearing the sensor may falsely raise the sensor glucose readings. The level of inaccuracy depends on the amount of acetaminophen active in the body and may be different for each person. Always check the label of any medications to confirm whether acetaminophen is an active ingredient.

Do not expose the sensor to MRI equipment, diathermy devices, or other devices that generate strong magnetic fields as the performance of the sensor has not been evaluated under those conditions and may be unsafe. If the sensor is inadvertently exposed to a strong magnetic field, discontinue use and contact a local Medtronic support representative for further assistance.

A retractable needle is attached to the sensor, and minimal blood splatter may occur. Healthcare professionals or caregivers, wrap sterile gauze around the sensor to minimize contact with blood. Keep as much distance as possible from the patient when removing the needle.

Keep the needle housing within sight at all times to avoid an accidental needlestick or puncture.

Always inspect the packaging for damage prior to use. Sensors are sterile and non-pyrogenic, unless the package has been opened or damaged. Do not use the sensor if the sterile package has been opened or damaged. Use of an unsterile sensor can cause site infection.

This product contains small parts and may pose a choking hazard for children.

Watch for bleeding at the insertion site (under, around, or on top of the sensor).

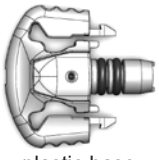
If bleeding occurs, do the following:

1. Apply steady pressure, using sterile gauze or a clean cloth placed on top of the sensor, for up to three minutes. The use of unsterile gauze can cause site infection.
2. If bleeding stops, connect the transmitter to the sensor.

   If bleeding does not stop, do not connect the transmitter to the sensor. This can allow blood to get into the transmitter connector, and could damage the device.

If bleeding continues, causes excessive pain or discomfort, or is significantly visible in the plastic base of the sensor, do the following:

1. Remove the sensor and continue to apply steady pressure until the bleeding stops. Discard the sensor in a sharps container.


plastic base

2. Check the site for redness, bleeding, irritation, pain, tenderness, or inflammation. Treat based on instructions from a healthcare professional.

3. Insert a new sensor in a different location.

For warnings on use, refer to the compatible Medtronic system user guide.

General precautions

Wash the hands with soap and water before inserting the sensor to help prevent site infection.

Wear gloves when inserting the sensor into someone else to avoid contact with patient blood.

Do not insert the sensor through tape. Inserting the sensor through tape may cause improper sensor insertion and function.

Only use alcohol to prepare the insertion site, to ensure that residue is not left on the skin.

Rotate the sensor insertion site so that sites do not become overused.

Discard used sensors and needle housings in a sharps container after each use to avoid accidental needlestick or puncture.

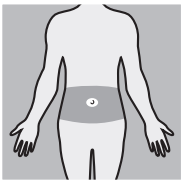
Do not clean, resterilize, or try to extract the needle from the needle housing. An accidental needlestick or puncture may occur.

Do not reuse sensors. Reuse of a sensor may cause damage to the sensor surface and lead to inaccurate glucose values, site irritation, or infection.

Where to insert the sensor

CAUTION: Avoid the 2 inch (5.0 cm) area around the navel to help ensure a comfortable insertion site and to help with sensor adhesion.

Choose an insertion site that has an adequate amount of subcutaneous fat. The Guardian™ Sensor (3) has been studied and is approved for use in the abdomen and other insertion sites. For approved age ranges for use and alternate insertion sites, refer to the compatible Medtronic system user guide.



Do not insert the sensor in muscle or areas constrained by clothing or accessories, areas with tough skin or scar tissue, sites subjected to rigorous movement during exercise, or in sites under a belt or on the waistline for best sensor performance and to avoid accidental sensor removal.

Removing the sensor

To change the sensor, disconnect the transmitter from the sensor as described in the transmitter user guide. Gently pull the sensor from the body to remove it. Place the sensor in a sharps container.

Reagents

The sensor contains two biological reagents: glucose oxidase, and human serum albumin (HSA). Glucose oxidase is derived from *Aspergillus niger* and manufactured to meet industry requirements for extraction and purification of enzymes for use in diagnostic, immunodiagnostic, and biotechnical applications. The HSA used on the sensor consists of purified and dried albumin fraction V, derived from pasteurized human serum which is cross-linked via glutaraldehyde. Approximately 3 µg of glucose oxidase and approximately 10 µg of HSA are used to manufacture each sensor. HSA is approved for IV infusion in humans at quantities much larger than in the sensor.

Storage and handling

CAUTION: Do not freeze the sensor, or store it in direct sunlight, extreme temperatures, or humidity. These conditions may damage the sensor.

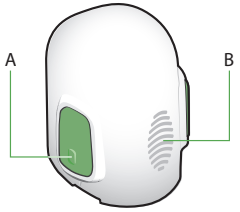
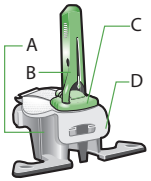
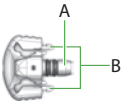
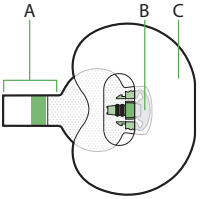
Only store sensors at room temperature between 36°F to 80°F (2°C to 27°C).

Discard the sensor after the “Use by date” indicated on the label, if the package is damaged, or the seal is broken.

Sensor life

The sensor can be used one time, and it has a maximum life of 170 hours (seven days). The 170-hour life span of the sensor begins when the sensor is connected to the transmitter.

Components

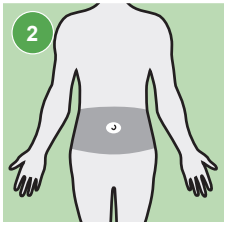
	One-press serter A. bump on both buttons B. thumbprint marking
	Glucose sensor assembly A. pedestal B. needle housing C. sensor D. clear liner
	Sensor base A. sensor connector B. sensor snaps
	Transmitter
	Tape and sensor components A. adhesive tab B. sensor base C. oval tape

Inserting the sensor

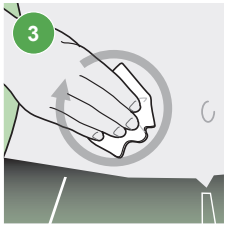
This section gives instructions to insert the sensor into the abdomen. For approved age ranges for use and alternate insertion sites, refer to the compatible Medtronic system user guide.

WARNING: Wear gloves when inserting the sensor into someone else to avoid contact with patient blood. Minimal bleeding may occur. Contact with patient blood can cause infection.

1. Wash the hands with soap and water.

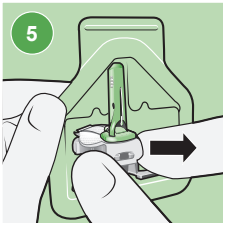


2. Choose an insertion site that has an adequate amount of subcutaneous fat. For approved age ranges for use and alternate insertion sites, refer to the compatible Medtronic system user guide.



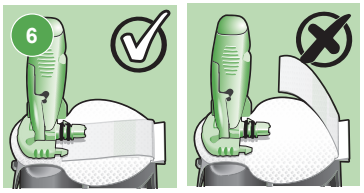
3. Clean the insertion site with alcohol. Let the area air dry.

4. Open the sensor package.

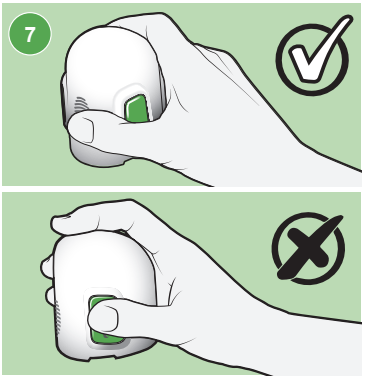


5. Hold the pedestal and remove the glucose sensor assembly from the package. Place the pedestal on a flat surface.

Note: The pedestal and glucose sensor assembly are the established definitions in the component table.



6. Make sure that the adhesive tab of the sensor is tucked under the sensor connector and sensor snaps.

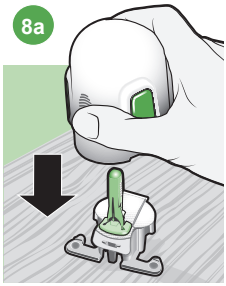


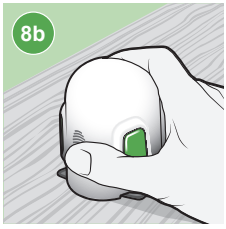
7. Holding serter correctly

Place a thumb on the thumbprint marking to hold the serter without touching the buttons.

Holding serter incorrectly

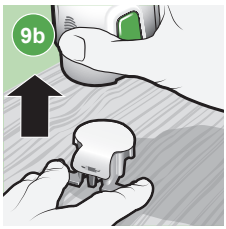
Fingers should not be touching the buttons.



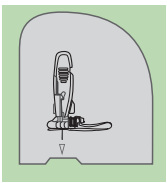


8a–8b. Grip the serter, placing a thumb on the thumbprint marking, **without holding the buttons**. Carefully push the serter down onto the pedestal until the base of the serter sits flat on the table and a click is heard.

9a. To detach the serter from the pedestal, place the thumb of one hand on the thumbprint marking and grip the serter **without touching any buttons**. With the other hand, place two fingers on the pedestal arms.

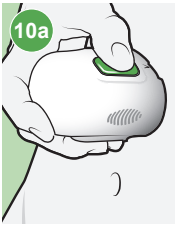


9b. Slowly pull the serter straight up without holding the buttons. Do not detach the pedestal from the serter in midair, as this might damage the sensor.



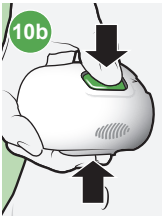
Note: The arrow on the side of the serter aligns with the needle inside the serter.

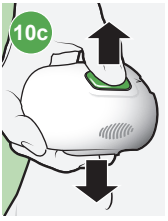
WARNING: Never point a loaded serter toward any body part where insertion is not desired. An accidental button-push may cause the needle to inject the sensor in an undesired location, causing minor injury.



10a. Hold the serter steady against the cleaned insertion site, without pushing the serter too deeply into the skin.

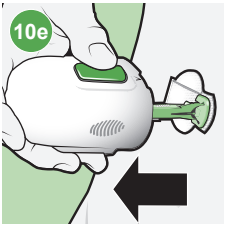
Note: Failing to hold the serter securely flat against the body during insertion may let the serter spring back after pressing the buttons, and result in improper insertion of the sensor.





10b-10c. Press and release the bump on both buttons at the same time, while holding the serter flat against the body.

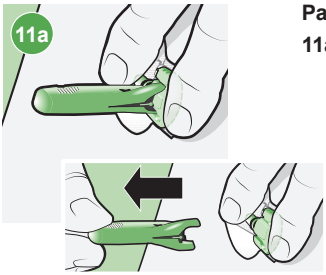
10d. Continue holding the serter flat against the body for at least five seconds to let the adhesive stick to the skin.



10e. Slowly lift the serter away from the body, making sure that the buttons are not pressed.

For patients who inserted the sensor, complete step 11a.

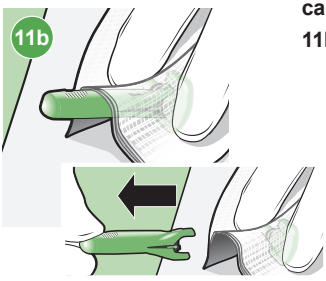
For healthcare professionals or caregivers who inserted the sensor into the patient, complete step 11b.



Patient:

11a. Gently hold the sensor base against the skin at the sensor connector and the opposite end of the sensor base. Hold the needle housing **at the top** and slowly pull straight out, away from the sensor.

OR

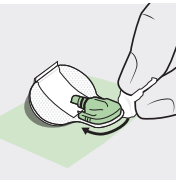


Healthcare professional or caregiver:

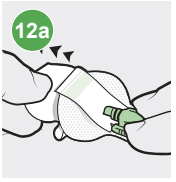
11b. Wrap sterile gauze around the sensor (as shown in image 11b). Gently hold the sensor base against the skin at the sensor connector and the opposite end of the sensor base. Hold the needle housing **at the top** and slowly pull straight out, away from the sensor.

WARNING: Watch for bleeding at the insertion site. If bleeding occurs under, around, or on top of the sensor, apply steady pressure using sterile gauze or a clean cloth placed on top of the sensor for up to three minutes. The use of unsterile gauze can cause an infection. If bleeding does not stop, remove the sensor and apply steady pressure until the bleeding stops.

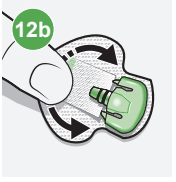
Note: Medtronic adhesives are pressure-sensitive. Pressing the adhesive against the skin ensures that the sensor remains adhered to the skin throughout the wear period.



Note: After insertion, use of adhesive products such as Skin Tac™* in addition to the tape is optional. If optional adhesive products are used, apply to the skin under the adhesive pad prior to removing the liner. It can also be applied to the adhesive pad or the skin around the sensor base. Allow the product to dry.

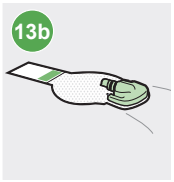


12a. Hold the sensor in place and gently remove the adhesive liner from under the adhesive pad. Do not remove the adhesive liner from the rectangular adhesive tab. This tab will be used to secure the transmitter in a later step.



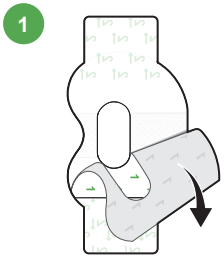
12b. Firmly press the adhesive pad against the skin to make sure that the sensor remains adhered to the skin.

13a. Untuck the adhesive tab from under the connector.

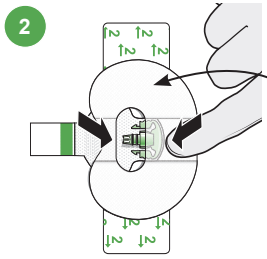


13b. Straighten the sensor adhesive tab so that it lies flat against the skin.

Applying Oval Tape

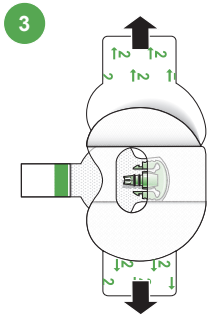


1. Remove liner 1.

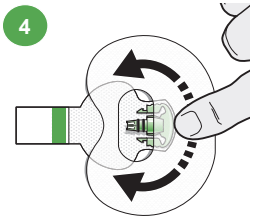


2. Apply the tape as shown and press it down firmly.

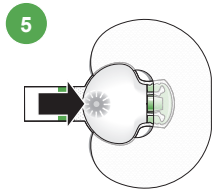
The wide part of tape covers half of the sensor base.



3. Remove the liner marked 2 from each side.

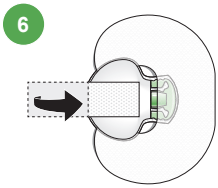


4. Smooth the tape.



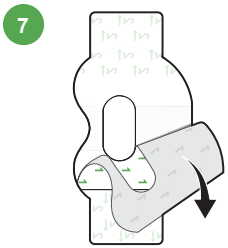
5. Connect the transmitter to the sensor.

Note: Wait for the green light on the transmitter to flash. If the green light does not flash, refer to the troubleshooting section of the transmitter user guide.

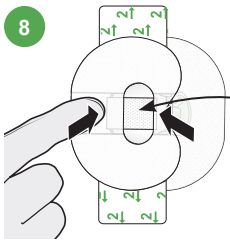


6. Cover the transmitter with the adhesive tab.

Note: Do not pull the tab too tightly.

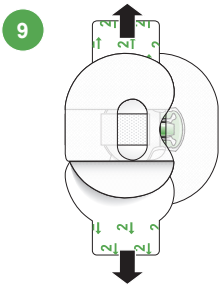


7. To apply a 2nd tape, remove liner 1.

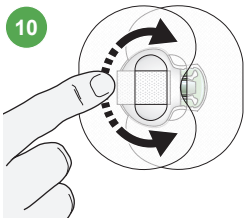


8. Apply the 2nd tape in the opposite direction to the first tape and place it on the transmitter. Press it down firmly.

The wide part of the tape covers the end of transmitter and the skin.



9. Remove the liner marked 2 from each side.



10. Smooth the tape.

Note: Be sure to regularly check the sensor site. If the device is not secure, apply an additional off-the-shelf adhesive.

11. For details on how to set up CGM, refer to the compatible Medtronic system user guide.

Icon glossary

For a definition of the symbols on the device and package labels, see www.medtronicdiabetes.com/symbols-definitions.

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