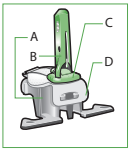
Guardian™ Sensor (3)

User Guide

Medtronic

Introduction

The Guardian™ Sensor (3) glucose sensor is part of your Continuous Glucose Monitoring (CGM) system. The sensor continuously converts tiny amounts of glucose from the interstitial fluid under your skin into an electronic signal. Your 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 sensor is a component of Medtronic Continuous Glucose Monitoring Systems and is indicated for continuously monitoring glucose levels in persons with type 1 diabetes. The sensor is

indicated for use as an adjunctive device to complement, not replace, information obtained from standard blood glucose monitoring devices.

The sensor is indicated for:

- Ages 2 or older when used as part of a system with Guardian Connect
- Ages 2 or older when used as a part of a system with the MiniMed 640G insulin pump
- Ages 7 or older when used as part of a system with the MiniMed 670G insulin pump

The indication for children under the age of 18 is limited to those who are supervised by a caregiver. The caregiver must be at least 18 years of age.

Contraindications

None known.

Assistance

Please contact your local representative for assistance. Refer to the Medtronic Diabetes International Contacts list at the end of this user guide for contact information.

General warnings

The Guardian™ Sensor (3) is only intended to be used by patients (aged 2 years and older) with type 1 diabetes.

Health care professionals and consumers should be aware about the limitations of available scientific evidence for use of this device in any other groups of patients who require diabetes management.

Nevertheless it would not be unreasonable to allow the clinical data derived from type 1 diabetes to be adduced to other forms of diabetes which are truly insulin dependent or deficient, including severe insulin deficient secondary diabetes, and some with cystic fibrosis related diabetes, where the achievement of adequate glycaemic control may benefit from continuous glucose monitoring or continuous subcutaneous insulin infusion.

During times of rapidly changing glucose (more than 0.1 mmol/L (2 mg/dL) per minute), interstitial fluid glucose levels as measured by the Guardian™ Sensor (3) may not accurately reflect blood

glucose levels. Under these circumstances, check the Sensor glucose readings by conducting a fingerstick test using a blood glucose meter.

In order to confirm hypoglycaemia or impending hypoglycaemia as reported by the Guardian™ Sensor (3), conduct a fingerstick test using a blood glucose meter.

Do not ignore symptoms that may be due to low or high blood glucose. If you have symptoms that do not match the Guardian™ Sensor (3) reading or suspect that your reading may be inaccurate, check the reading by conducting a fingerstick test using a blood glucose meter. If you are experiencing symptoms that are not consistent with your glucose readings, consult your health care professional.

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 sensor is designed to work with approved transmitters only. It prevents connection with transmitters and recorders that are not compatible with the sensor. Connecting your sensor to a transmitter or recorder that is not approved for use with the sensor may cause damage to the components. Refer to your system user guide for a list of compatible products.

Do not make therapy decisions based on sensor glucose values because sensor glucose and blood glucose (BG) values may differ. If your sensor glucose is low or high, or if you feel symptoms of low or high blood glucose, do the following prior to making therapy decisions. Confirm your blood glucose with your meter using a fingerstick blood sample.

Taking medications with acetaminophen or paracetamol, including, but not limited to Panadol™*, fever reducers, or cold medicine, while wearing the sensor may falsely raise your sensor glucose readings. The level of inaccuracy depends on the amount of acetaminophen or paracetamol active in your body and may be different for each person. Always use BG meter readings to verify your glucose level before making therapy decisions, including when you could have acetaminophen or paracetamol active in your body. Always check the label of any medications to confirm whether acetaminophen or paracetamol is an active ingredient.

Do not expose your 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 your sensor is inadvertently exposed to a strong magnetic field, discontinue use and contact your local representative for further assistance.

A retractable needle is attached to the sensor and minimal blood splatter may occur. If you are a healthcare professional or caregiver, wrap sterile gauze around the sensor to minimize contact with blood. Keep as much distance as possible between you and 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).

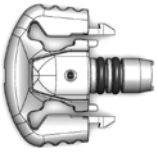
If bleeding occurs, do the following:

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 (or recorder) to the sensor.

   If bleeding does not stop, do not connect the transmitter to the sensor because blood can 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 your healthcare professional.
3. Insert a new sensor in a different location.

General precautions

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

Individuals under the age of 18 may require supervision for sensor insertion.

Wear gloves when inserting the sensor into someone other than yourself 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.

The sensor must be calibrated, at a minimum, every 12 hours throughout the life of the sensor. For better sensor performance, it is recommended that you calibrate your sensor three or four times each day at regular times throughout the day, such as before meals and before bed.

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.

Potential risk

For the use with the MiniMed 640G system, sensor placement and insertion has been studied in the belly (abdomen) and upper arm only and is not approved for other sites.

For the use with the MiniMed 670G system, sensor placement and insertion has been studied in the belly (abdomen) only and is not approved for other sites.

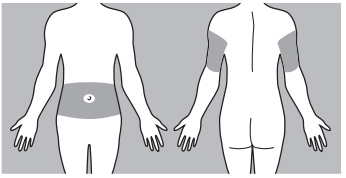
Where to insert the sensor

CAUTION: Make sure the sensor site is at least 2.5 cm (1 inch) away from the insulin pump infusion site or manual injection site. And when replacing the sensor, select a new site that is at least 2.5 cm (1 inch) away from the previous site to allow the area to heal. Any scarring or hardening of the tissue can

cause inaccurate insulin delivery or sensor performance.

CAUTION: Avoid the 5.0 cm (2 inch) 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. Shown here are the best body areas (shaded) for sensor insertion.



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

When you are ready to change your sensor, disconnect the transmitter from the sensor as described in your transmitter user guide. Gently pull the sensor from your 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 2 °C to 27 °C (36 °F to 80 °F).

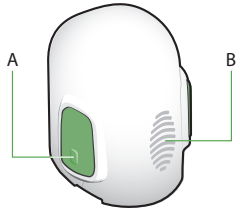
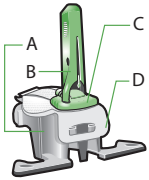
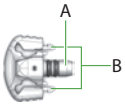
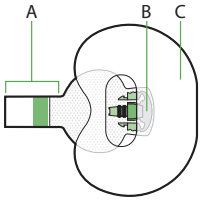
Discard sensor after the “Use by date” indicated on the label, if the

package is damaged, or the seal is broken.

Sensor life of use

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.

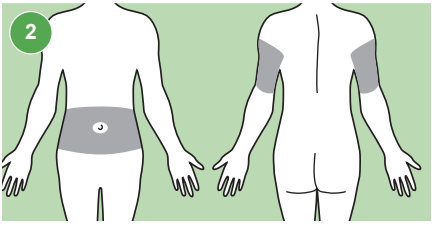
Components

	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
	Compatible transmitter
	Tape and sensor components A. adhesive tab B. sensor base C. oval tape

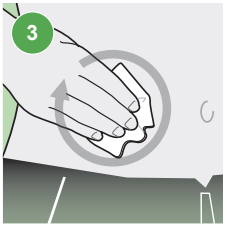
Inserting the sensor

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

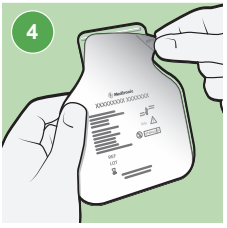
1. Wash your hands.



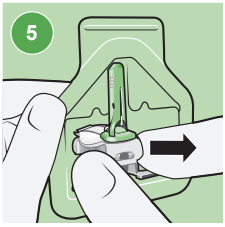
2. Choose an insertion site on the abdomen or the upper arm that has an adequate amount of fat.



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

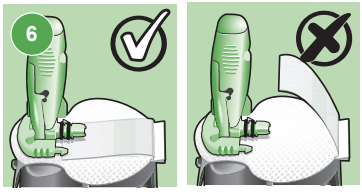


4. Open the sensor package.

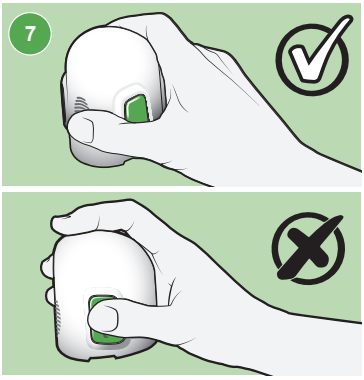


5. Hold the pedestal and remove the glucose sensor assembly from the package. Place the pedestal on a flat surface.

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.

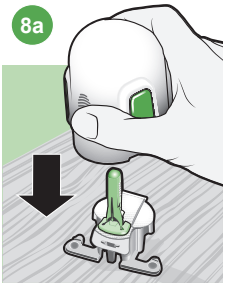


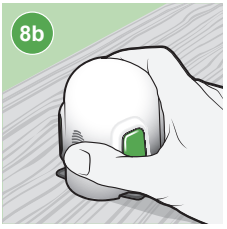
7. Holding serter correctly

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

Holding serter incorrectly

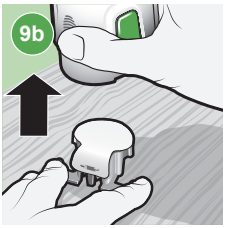
Your fingers should not be touching the buttons.



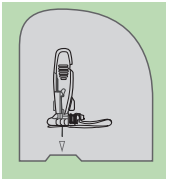


8a–8b. Grip the serter, placing your thumb on the thumbprint marking, **without holding the buttons**. Carefully push the serter down onto the pedestal until the base of the serter sits flat on the table and you hear a click.

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 your other hand, place two fingers on the pedestal arms.

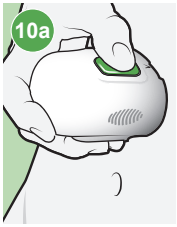


9b. Slowly pull the serter straight up without holding the buttons. Do not detach the pedestal from the serter in midair, as this might damage the sensor.



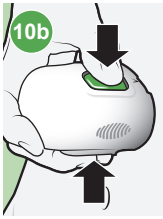
Note: The arrow on the side of the serter aligns with the needle inside the serter.

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.



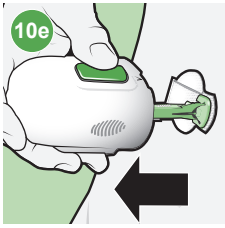
10a. Hold the serter steady against your cleaned insertion site, without pushing the serter too deeply into your skin.

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



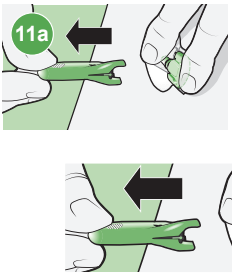
10b-10c. Press and release the bump on both buttons at the same time, while holding the serter flat against your body.

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



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

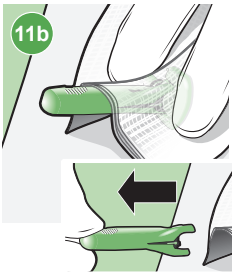
If you inserted the sensor into yourself, complete step 11a. If you are a healthcare professional or caregiver who inserted the sensor into a patient, complete step 11b.



Patient:

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

OR

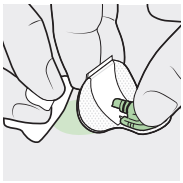


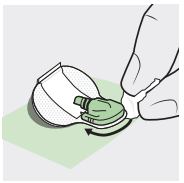
Healthcare professional or caregiver:

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 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.

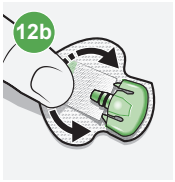
Note: Medtronic adhesives are pressure-sensitive. Pressing the adhesive against the skin ensures that the sensor remains adhered to the skin throughout the wear period.





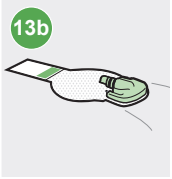
Note: After insertion, use of adhesive products such as Skin Tac™ in addition to the tape is optional. If optional adhesive products are used, apply to the skin under the adhesive pad prior to removing the liner. It can also be applied to the adhesive pad or the skin around the sensor base. Allow for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

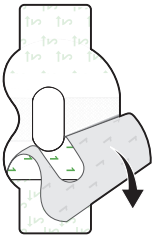
13a. Untuck the adhesive tab from under the connector.



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

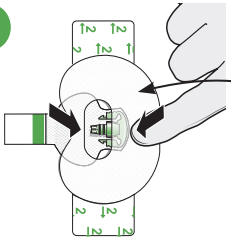
Applying Oval Tape

1



1. Remove liner marked 1.

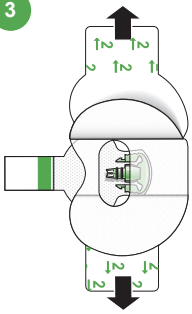
2



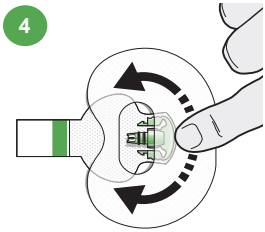
2. Apply the tape as shown and press down firmly.

Wide part of tape covers half of sensor base.

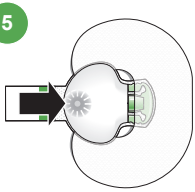
3



3. Remove liner marked 2 from each side.

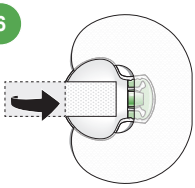


4. Smooth the tape.



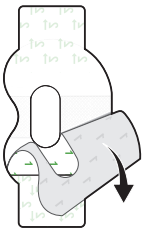
5. Connect the transmitter to the sensor.

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



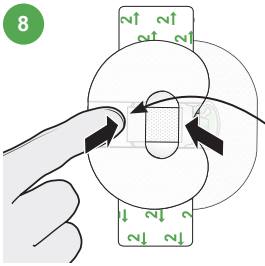
6. Cover the transmitter with the adhesive tab.

Note: Do not pull the tab too tightly.



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

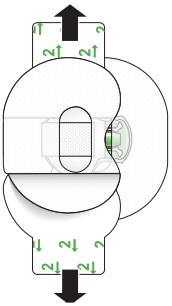
8



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

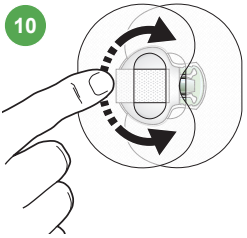
Wide part of tape covers end of transmitter and skin.

9



9. Remove liner marked 2 from each side.

10



10. Smooth the tape.

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

11

11. For details on how to enter your sensor settings into your pump or mobile device, refer to the corresponding user guide.

Icon table

	Use by date
	Do not reuse
(1x)	One sensor per container/package
(5x)	Five sensors per container/package
(2x)	Two tapes per package
(10x)	Ten tapes per package
	Consult instructions for use
REF	Catalogue or model number
LOT	Batch code
STERILE R	Sterilized using irradiation
	Temperature limit
	Open here
	Manufacturer
	Do not resterilize
	Fragile, handle with care
	Keep dry
	Recycle cardboard, paper, plastic packaging supplies and unwanted written material.
EC REP	Authorized representative in the European Community.
	Magnetic Resonance (MR) unsafe: keep away from magnetic resonance imaging (MRI) equipment.
	Non-pyrogenic - Does not contain endotoxins.
	Specific warnings or precautions not found on the label exist, for which the IFU should be consulted.
	Do not use if package is damaged

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