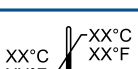
Medtronic

Guardian™ 4

Sensor User Guide

Icon table

	Use-by date
MD	Medical device
	Do not re-use
	Caution: consult instructions for use for important warnings or precautions not found on the label
(1x)	One per container/package
(5x)	Five per container/package
(2x)	Two per container/package
(10x)	Ten per container/package
	Consult instructions for use
REF	Catalogue number
LOT	Batch code
STERILE R	Sterilized using irradiation
	Do not use if package is damaged and consult instructions for use
	Single sterile barrier system
	Temperature limit

	Open here
	Manufacturer
CC	Country of manufacture
	Date of manufacture
2 STERILIZE	Do not resterilize
	Fragile, handle with care
	Keep dry
	Recyclable, contains recycled content
MR	Magnetic Resonance (MR) Unsafe
	Non-pyrogenic
Rx Only	Requires prescription in the USA
BIO	Contains biological material of human origin
	Contains human blood or plasma derivatives

UDI	Unique device identifier
FCC ID	Complies with United States regulations for RF devices

Introduction

The Guardian™ 4 sensor (MMT-7040) is part of the compatible Medtronic automated insulin dosing (AID) system. The sensor converts small amounts of glucose from the interstitial fluid under the skin into an electronic signal. The sensor uses that signal to provide sensor glucose (SG) values to a compatible Medtronic AID system.

Sensor assembly

Indications for use

The Guardian 4 sensor is intended to monitor glucose levels for the management of diabetes for persons ages 7 years and older. It is indicated for use as an adjunctive device to complement, not replace, information obtained from the standard blood glucose monitoring devices. The sensor is intended for single use and requires a prescription. The Guardian 4 sensor is indicated for **up to** 7 days of continuous use. Refer to the system user guide for treatment decisions.

The Guardian 4 sensor continuous glucose monitor (CGM) is also intended for use with Guardian 4 Transmitters and compatible Medtronic automated insulin dosing (AID) systems to monitor glucose levels for the management of diabetes.

The Guardian 4 sensor is not intended to be used directly to make therapy adjustments while the AID system is operating in manual mode. All therapy adjustments in Manual mode should be based on measurements obtained using a blood glucose meter and not on values provided by the Guardian 4 sensor.

The Guardian 4 sensor is indicated for persons 7 years and older for insertion in arm.

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

Contraindications

Refer to the system guide for contraindications associated with Guardian 4 sensor use.

User Safety

Warnings

Read this entire user guide before attempting to insert the Guardian 4 sensor. The one-press serter (MMT-7512) is the only serter approved for use with the sensor. Failure to follow directions, or the use of a different insertion device, may result in improper insertion, pain, or injury.

Do not attempt to connect a transmitter or recorder that is not compatible with the sensor. The sensor is designed to work with approved transmitters only. Connecting the sensor to a transmitter or recorder that is not approved for use with the sensor may damage the components. Refer to the system user guide for a list of compatible products.

Do not use continuous glucose monitoring if hydroxyurea, also known as hydroxycarbamide, is taken. Hydroxyurea is used to treat certain diseases, such as cancer and sickle cell anemia. Hydroxyurea use results in higher sensor glucose readings compared to blood glucose readings. Taking hydroxyurea while using continuous glucose monitoring can result in substantially higher sensor glucose readings in reports than actual blood glucose readings. For pump users, taking hydroxyurea while using continuous glucose monitoring can result in hypoglycemia caused by over-delivery of insulin.

Always check the label of any medication being taken to confirm if hydroxyurea or hydroxycarbamide is an active ingredient. If hydroxyurea is taken, consult a healthcare professional. Use additional blood glucose meter readings to verify glucose levels.

Taking medications that contain acetaminophen or paracetamol, including, but not limited to fever reducers and cold medicine, while wearing the sensor, may falsely raise sensor glucose readings. The level of inaccuracy depends on the amount of acetaminophen or paracetamol active in the body and may be different for each person. Always check the label of any medications to confirm whether acetaminophen or paracetamol is an active ingredient.

Do not expose the sensor to MRI equipment, diathermy devices, or other devices that generate strong magnetic fields. The performance of the sensor has not been evaluated under those conditions and may be unsafe. If the sensor is exposed to a strong magnetic field, discontinue use and contact 24-hour Technical support for further assistance.

Always inspect the packaging for damage prior to use. Sensors are sterile and non-pyrogenic, unless the package has been opened or damaged. If the sensor packaging is open or damaged, discard the sensor directly into a sharps container. Use of a non-sterile sensor may result in infection at the insertion site.

Do not allow children to put small parts in their mouth. This product poses a choking hazard for young children.

Do not use the Guardian 4 sensor if you are pregnant or critically ill. Since the sensor has not been studied in these populations, the impact of medications common to these conditions on sensor performance is unknown and the sensor may be inaccurate in these populations.

Healthcare professionals and caregivers:

- Always wear gloves to insert the sensor. A retractable needle is attached to the sensor. Minimal bleeding may occur.
- Cover the sensor with sterile gauze to remove the needle housing from the sensor.

Place the needle housing directly into a sharps container after sensor insertion to prevent accidental needlestick injury.

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

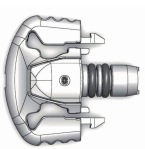
If bleeding occurs, do the following:

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 may 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 may get into the transmitter connector, and may 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.
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.



plastic base

For questions or concerns related to sensor use, contact 24-Hour Technical Support for assistance.

For medical questions or concerns, contact a healthcare professional.

Serious incident reporting

If a serious incident related to the device occurs, immediately report the incident to Medtronic and your local applicable authority.

Essential performance

The Medtronic automated insulin dosing (AID) system displays patient sensor glucose data and interprets alerts through the connected device. The essential performance of the connected sensor includes accurate sensor measurements and communication of that data to the connected device.

Precautions

Wash hands with soap and water before inserting the Guardian 4 sensor to help prevent site infection.

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. Using alcohol to prepare the insertion site makes sure that residue is not left on the skin.

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

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.

Risks and side effects

Risks related to 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 the sensor 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

Reagents

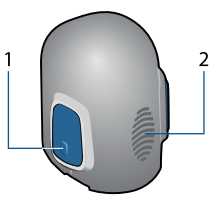
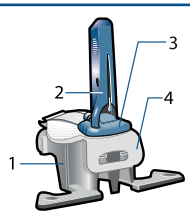
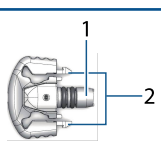
The Guardian 4 sensor contains two biological reagents: glucose oxidase, and human serum albumin (HSA). Glucose oxidase is derived from Aspergillus niger and manufactured to meet industry requirements for the extraction and purification of enzymes for use in diagnostic, immunodiagnostic, and biotechnical applications. The HSA used on the sensor consists of purified and dried albumin fraction V derived from

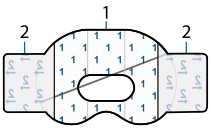
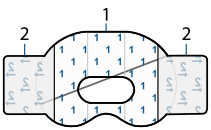
pasteurized human serum, which is crosslinked via glutaraldehyde. Approximately 3 µg of glucose oxidase and approximately 10 µg of HSA are used to manufacture each sensor. HSA is approved for IV infusion in humans at quantities much larger than in the sensor.

Removing the sensor

To change the Guardian 4 sensor, disconnect the transmitter from the sensor as described in the Guardian 4 transmitter user guide. Gently pull the sensor from the body to remove it. Discard the sensor in a sharps container.

Components

	**One-press serter** 1. bump on both buttons 2. thumbprint marking
	**Glucose sensor assembly** 1. pedestal 2. needle housing 3. sensor 4. clear liner
	**Sensor base** 1. sensor connector 2. sensor snaps
	Transmitter

	**First piece of oval tape** 1. liner 1 2. liner 2
	**Second piece of oval tape** 1. liner 1 2. liner 2

Where to insert the sensor

Choose an insertion site for the applicable age group and make sure that the site has an adequate amount of subcutaneous fat.

Ages 7-17 years

Back of the upper arm

CAUTION: Guardian 4 sensor is indicated for arm use only. Do not use Guardian 4 sensor in other sites, including the abdomen or buttocks, due to a difference in performance that could result in hypoglycemia or hyperglycemia.

Ages 18 years and older

Back of the upper arm

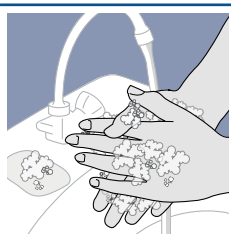
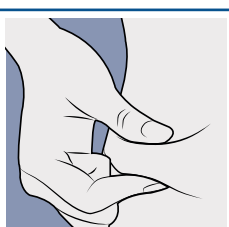
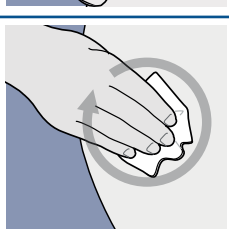
Note: Assistance will likely be needed for sensor insertion into the back of the upper arm. Some users find it difficult to insert the sensor into their arm by themselves.

For best sensor glucose performance, and to prevent accidental sensor removal:

- Do not insert the sensor into muscle, tough skin, or scar tissue.
- Avoid areas that are constrained by clothing or accessories.
- Avoid areas subjected to vigorous movement during exercise.

Inserting the sensor

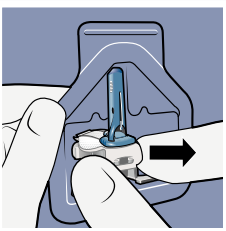
WARNING: Always wear gloves when inserting the sensor into another person to avoid contact with patient blood. Minimal bleeding may occur. Contact with patient blood may cause infection.

1		Wash hands thoroughly with soap and water.
2		Choose an insertion site that has a sufficient amount of fat.
3		Clean the insertion site with alcohol. Let the area air dry.

4

Open the sensor package.

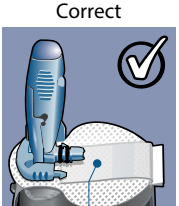
5



Hold the pedestal and remove the glucose sensor assembly from the package. Place the pedestal on a clean, flat surface such as a table.

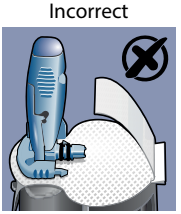
6

Correct



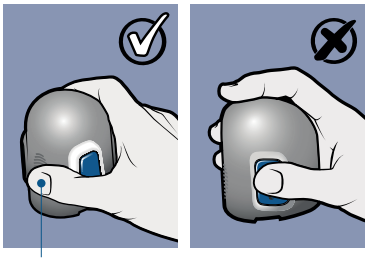
tucked tab

Incorrect



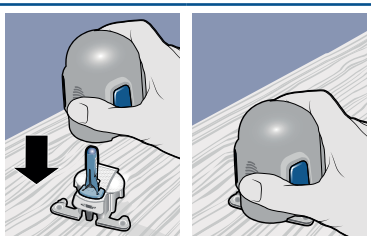
Confirm that the adhesive tab of the sensor is tucked under the sensor connector and sensor snaps.

7



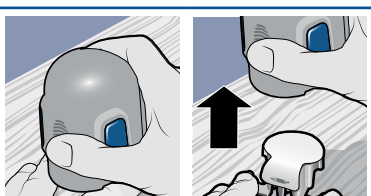
Using either hand, place a thumb on the thumbprint marking to hold the serter. Fingers must not touch the serter buttons.

8



Push the serter down onto the pedestal until the base of the serter sits flat on the table and there is a click.

9

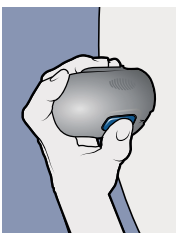


With either hand, place two fingers on the base of the pedestal. With the other hand, grip the serter and pull the serter upwards.

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

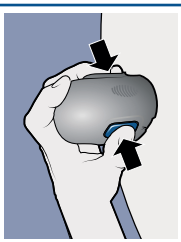
WARNING: Never point a loaded serter toward any body part where insertion is not desired. An accidental button-push may cause the needle to inject the sensor in an undesired location, causing minor injury.

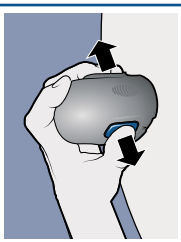
10



Place the serter on top of the prepared insertion site.

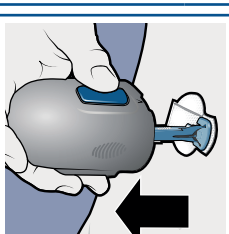
11



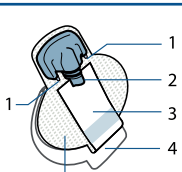


Press and release both serter buttons at the same time. Continue to hold the serter on top of the insertion site for five seconds or more to let the adhesive stick to the skin.

12



Lift the serter away from the insertion site. Fingers must not press the buttons while lifting the serter.

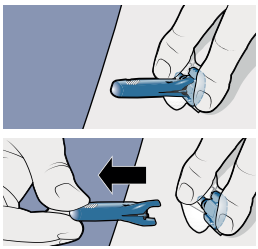


Sensor base

1. sensor snaps
2. sensor connector
3. adhesive tab
4. adhesive liner
5. adhesive pad

If the sensor is inserted without assistance, complete step 13.1. If a healthcare professional or caregiver assisted with sensor insertion, complete step 13.2.

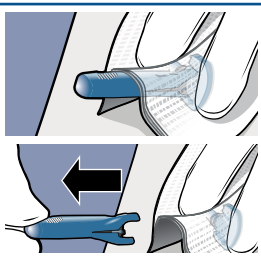
13.1



Patient:
Hold the sensor base against the skin at the sensor connector and at the opposite end of the sensor base. Hold the needle housing at the top and pull away from the sensor.

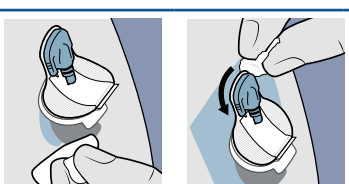
OR

13.2



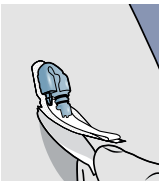
Healthcare professional or caregiver:
Wrap sterile gauze around the sensor. Hold the sensor base against the skin at the sensor connector and the opposite end of the sensor base. Hold the needle housing at the top and pull away from the sensor.

WARNING: Always 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 may cause an infection. If bleeding does not stop, remove the sensor and apply steady pressure until the bleeding stops.



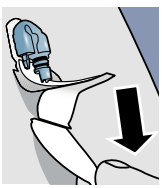
Note: After insertion, use of adhesive products, such as Skin Tac™, in addition to the oval tape is optional. If optional adhesive products are used, apply them to the skin under the adhesive pad prior to removing the liner. Adhesive products may also be applied to the adhesive pad or the skin around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

14



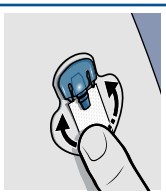
Remove the adhesive liner from under the adhesive pad. Pull the liner away from the sensor, staying close to the skin. Do not pull on the sensor when you remove the liner.

Note: Do not remove the adhesive liner from the rectangular adhesive tab. This tab will be used to secure the transmitter in a later step.



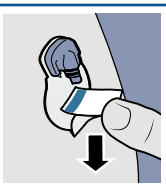
Note: If the sensor base moves, hold the sensor base down.

15



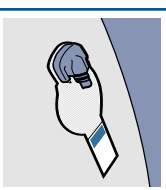
Firmly press the adhesive pad against the insertion site to confirm that the sensor base remains on the skin.

16



Untuck the adhesive tape from under the sensor connector.

17



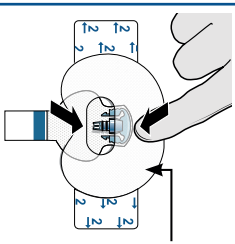
Straighten the sensor adhesive tab so that it lies flat against the skin.

Applying Oval Tape

1

Remove the liner marked 1.

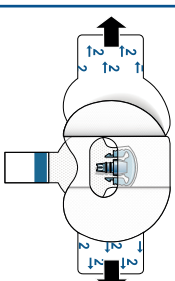
2



wide part of tape covers half of sensor base

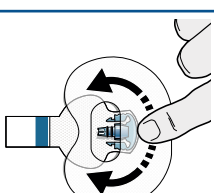
Apply the tape as shown and press down firmly.

3



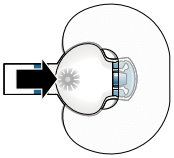
Remove liners marked 2 from each side.

4



Smooth the tape.

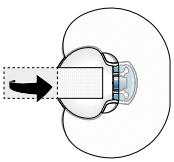
5



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 Guardian 4 transmitter user guide.

6



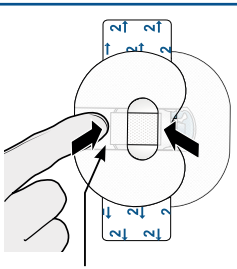
Cover the transmitter with the adhesive tab.

Note: Do not pull the tab too tightly.

7

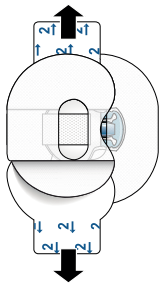
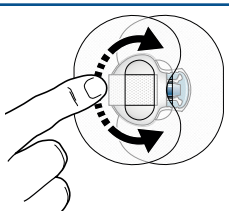
To apply a second tape, remove liner marked 1.

8



wide part of tape covers end of transmitter and skin

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

9		Remove liners marked 2 from each side.
10		Smooth the tape.

Note: For details on how to enter sensor settings into a compatible display device, refer to the system user guide.

Maintenance

Storage

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 sensor after the "Use-by date" indicated on the label, if the package is damaged, or if the seal is broken.

Disposal

Dispose of the Guardian 4 sensor into a sharps container.

Assistance

Department	Telephone Number
24-Hour Technical Support (calls within the United States)	+1 800 646 4633

Department	Telephone Number
24-Hour Technical Support (calls outside the United States)	+1 818 576 5555
Website	www.medtronicdiabetes.com

Technical specifications

Approximate dimensions
1.50 x 2.60 x 2.00 in (3.80 x 6.70 x 5.20 cm)
Approximate weight
.09 ounces (2.80 g)

Refer to the product specifications table in the Guardian 4 transmitter user guide.

Sensor life of use

The Guardian 4 sensor can be used one time and has a maximum life of **up to** 170 hours (seven days). The 170-hour life span of the sensor begins when the sensor is connected to the transmitter.

Performance data

Refer to the Medtronic automated insulin dosing (AID) system User Guide for performance data.

Icon glossary

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

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