minimed

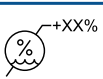
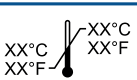
Simplera Sync

Sensor Instructions for Use

M058082C003_2

Icon table

LOT	Batch code
	Bluetooth® wireless technology or Bluetooth® enabled
REF	Catalogue number
	Date of manufacture (DoM)
	Do not re-use
	Do not use if package is damaged and consult instructions for use
(5x)	Five per container/package
	Follow instructions for use
	Fragile, handle with care
IP48	Protected against effects of continuous immersion in water at a depth of 8 feet (2.4 meters) for up to 30 minutes
	Keep dry
MR	Magnetic Resonance (MR) Unsafe

	Manufacturer
	Non-pyrogenic
(1x)	One per container/package
	Recyclable, contains recycled content
	Single sterile barrier system
	Sterilized using ethylene oxide
	Humidity upper limit
	Temperature limits
	Type BF applied part
	Use-by date
	Caution: consult instructions for use for important warnings or precautions not found on the label
	Serial number

MD	Medical device
CODE: XXX-XXX	Sensor pairing code
	Contains human blood or plasma derivatives
	Contains biological material of human origin
UDI	Unique Device Identifier
	Country of manufacture (and Date of manufacture when a date appears beside)
	Do not re-sterilize
	Manufacturing site
	Importer
$\mathrm{R_x}$ *Only*	Requires prescription in the USA
FCC ID	Complies with United States regulations for RF devices
	Do not dispose of this product in unsorted municipal waste stream

Introduction

The Simplera Sync sensor (MMT-5120) with Bluetooth® wireless technology is a component of a compatible Medtronic automated insulin dosing (AID) system.

The Simplera Sync 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.

Indications for use

The Simplera Sync sensor is a continuous glucose monitor (CGM) intended for use with compatible Medtronic automated insulin dosing (AID) Systems to monitor glucose levels for the management of diabetes.

The Simplera Sync 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 Simplera Sync sensor.

The Simplera Sync sensor is indicated for persons 7 years and older for insertion in arm.

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

The Simplera Sync sensor can be used one time and has a life of up to 6 days, followed by a grace period of 24 hours. During the grace period, the sensor will continue to work as it did during the first 6 days, to allow the patient to change their sensor more flexibly.

The Simplera Sync sensor is indicated for the management of diabetes in persons ages 7 years and older.

Intended users

The Simplera Sync sensor is intended for personal use by individuals to assist in the management of their diabetes, or for use by parents/caregivers who assist these individuals with diabetes management.

Contraindications

No contraindications are associated with Simplera Sync sensor use.

Intended clinical benefits

Although the Simplera Sync sensor does not provide any therapy or treatment, the continuous glucose information provided by the sensor used in combination with a compatible Medtronic insulin pump can aid in diabetes management.

User safety

Warnings and precautions

Read this entire user guide before attempting to insert the Simplera Sync sensor. The inserter portion of the sensor does not work the same way as other Medtronic insertion devices. The sensor is not inserted the same way as other Medtronic sensors. Failure to follow directions may result in improper insertion, pain, or injury.

Do not use the Simplera Sync sensor adjacent to other electrical equipment that may cause interference with normal sensor operation. For more information on electrical equipment that may cause interference with normal sensor operation, see *Exposure to magnetic fields and radiation, page 10*.

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 inaccurate or missed alerts, and substantially higher sensor glucose readings in reports than actual blood glucose readings. 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.

Always consult a healthcare professional before using sensor glucose values to make treatment decisions if a medication that contains acetaminophen or paracetamol is taken while wearing the sensor. Medications that contain acetaminophen or paracetamol can falsely raise sensor glucose readings. The level of inaccuracy depends on the amount of acetaminophen or paracetamol active in the body and can differ for each person. Falsely elevated sensor readings can result in over-administration of insulin, which can cause hypoglycemia. Medications that contain acetaminophen or paracetamol include, but are not limited to, cold medicines and fever reducers. Check the label of any medications being taken to see if acetaminophen or paracetamol is an active ingredient. Use additional blood glucose meter readings to confirm blood glucose levels.

Always examine the Simplera Sync sensor box for damage. If the sensor box is open or damaged, examine the sensor for damage. If the sensor is visibly damaged, discard the device to avoid possible contamination.

Do not use the Simplera Sync sensor if any part of the device is damaged. If the device is damaged, discard the device to avoid possible contamination.

Do not use the Simplera Sync sensor if the tamper band is broken, damaged, or missing from the device. The sensor is sterile and non-pyrogenic unless the device is damaged. If the tamper band is broken, damaged, or missing from the device, the sensor and the needle can be exposed to contamination. A sensor and needle exposed to contamination can cause site infection if inserted into the body.

Do not use the Simplera Sync sensor if the cap label is broken, damaged, or missing from the device. The sensor is sterile and non-pyrogenic unless the device is damaged. If the cap label is broken, damaged, or missing from the device, the sensor and the needle can be exposed to contamination. A sensor and needle exposed to contamination can cause insertion site infection if inserted into the body.

Do not unscrew or remove the Simplera Sync sensor cap until the device is ready to be used. Do not remove the cap and store the device for future use. The sensor is sterile and non-pyrogenic unless the cap is removed from the device or the tamper band is broken. If the cap is not on the device or the tamper band is broken, the sensor and the needle can be exposed to contamination. A sensor and needle exposed to contamination can cause site infection if inserted into the body.

Do not remove the cap and place it back on the device. Placing the cap back on the device could cause damage to the needle, prevent a successful insertion, and cause injury.

Do not change or modify the Simplera Sync sensor. Changing or modifying the sensor can result in improper insertion, pain, or injury.

Do not let children hold the Simplera Sync sensor without adult supervision. Do not let children put any part of the sensor in their mouth. This product poses a choking hazard for young children that can result in serious injury or death.

Do not use the Simplera Sync 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.

Watch for bleeding at the insertion site on top of the Simplera Sync sensor. If bleeding occurs, apply steady pressure with a sterile gauze pad or clean cloth placed on top of the sensor for up to three minutes. If bleeding continues, is significantly visible on top of the sensor, or if there is excessive pain or discomfort after insertion, follow these steps:

1. Remove the Simplera Sync sensor and continue to apply steady pressure until the bleeding stops.
2. Dispose of the Simplera Sync sensor. See *Disposal, page 21*.
3. Check the insertion site for redness, bleeding, irritation, pain, tenderness, or inflammation. If there is redness, bleeding, irritation, pain, tenderness, or inflammation, contact a healthcare professional.
4. Insert a new Simplera Sync sensor in a different location.

Some skin care products, such as sunscreens and insect repellents, can damage the Simplera Sync sensor. Do not allow skin care products to touch the sensor. Wash hands after using skin care products before touching the sensor. If any skin care products touch the sensor, immediately wipe the sensor with a clean cloth.

Serious incident reporting

If a serious incident related to the device occurs, immediately report the incident to a healthcare professional. Serious incidents may include death, temporary or permanent serious decline in health, or a serious public health threat. Immediately report any serious incident to the manufacturer and local competent authority.

Exposure to magnetic fields and radiation

Do not expose the Simplera Sync sensor to Magnetic Resonance Imaging (MRI) equipment, diathermy devices, or other devices that generate strong magnetic fields (for example, CT scan, or other types of radiation). Exposure to strong magnetic fields can cause the sensor to malfunction, result in serious injury, or be unsafe.

IEC 60601-1-2; Special EMC Precautions for Medical Electrical Equipment

1. Special Precautions regarding Electromagnetic Compatibility (EMC): This body worn device is intended to be operated within a reasonable residential, domestic, public or work environment where common levels of radiated "E" (V/m) or "H" fields (A/m) exist, such as cellular phones, Wi-Fi™*, Bluetooth wireless technology, electric can openers, microwave and induction ovens. This device generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the provided instructions, may cause harmful interference to radio communications.
2. Portable and mobile RF communications equipment can affect medical electrical equipment. If you encounter RF interference from a mobile or stationary RF transmitter, move away from the RF transmitter that is causing the interference.
3. Be careful when using the Simplera Sync sensor closer than 12 in (30 cm) to portable radio frequency (RF) equipment or electrical equipment. If the sensor must be used next to portable RF equipment or electrical equipment, observe the sensor to verify correct system operation. Degradation of the performance of the sensor could result.

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.

Risks

General risks with Simplera Sync sensor use include the following:

- 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 filament fracture, breakage, or damage
- Minimal blood splatter associated with sensor needle removal
- Residual redness associated with adhesive or tapes or both
- Scarring

Allergens

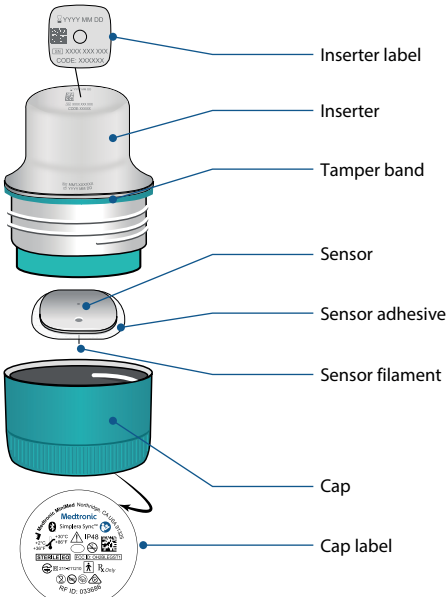
The Simplera Sync sensor contains nickel in stainless steel.

Reagents

The Simplera Sync sensor contains two biological reagents: glucose oxidase, and human serum albumin (HSA).

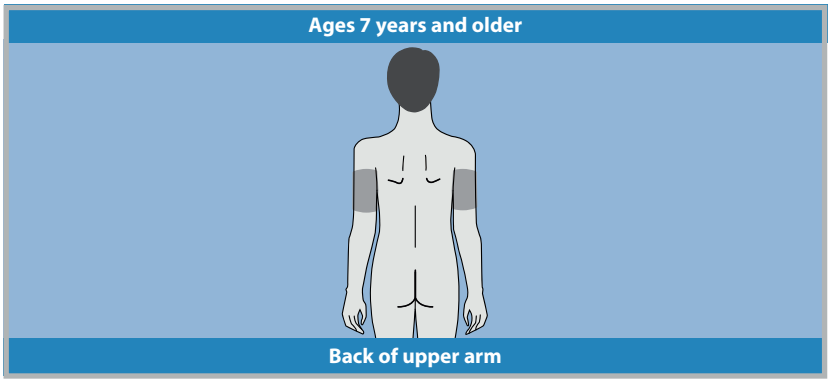
Glucose oxidase is derived from **Aspergillus niger** and manufactured to meet industry requirements for extraction and purification of enzymes for use in diagnostic, immunodiagnostic, and biotechnical applications. The HSA used in the Simplera Sync sensor consists of purified and dried albumin fraction 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.

Simplera Sync sensor device components



Where to insert the Simplera Sync sensor

The images that follow show insertion sites for ages 7 years and older. Target the shaded areas shown in the image, and make sure that the insertion site has a sufficient amount of fat.

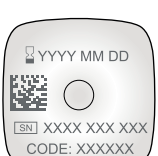


Insertion on abdomen and buttocks are not recommended.

Inserting the Simplera Sync sensor

Preparing for insertion

1



The inserter label is on the top of the inserter.
Before insertion, perform the following steps:

- Inspect the expiration date. Do not use an expired Simplera Sync sensor.
- Make note of the serial number (SN) and the CODE. Both numbers will be used later to pair the sensor with a compatible insulin pump.

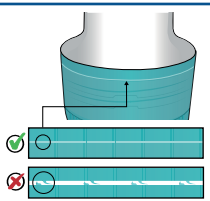
Note: The SN and CODE label is also on the inside of the Simplera Sync sensor box lid.

2

Inspect the cap label for damage before insertion.

Note: Do not use the Simplera Sync sensor if the cap label is damaged or missing from the cap.

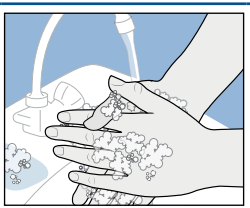
3



Inspect the tamper band to make sure that it is not broken, damaged, or missing from the device.

Note: Do not use the Simplera Sync sensor if the tamper band is broken, damaged, or missing.

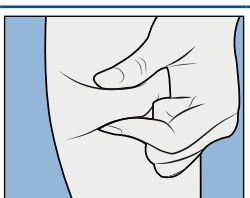
4



Wash hands thoroughly with soap and water.

Note: Wear gloves when inserting the Simplera Sync sensor into another person to avoid accidental contact with patient blood. Minimal bleeding can occur.

5

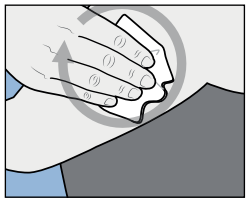


Choose an insertion site that has a sufficient amount of fat. For insertion sites see *Where to insert the Simplera Sync sensor, page 12*.

For the best sensor performance, and to avoid accidental sensor removal, do not insert the Simplera Sync sensor into the following areas:

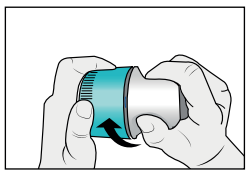
- muscle, tough skin, or scar tissue
- areas that are constrained by clothing or accessories
- areas subjected to rigorous movement during exercise

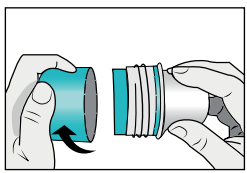
6



Clean the insertion site with alcohol. Allow the insertion site to air dry.

7



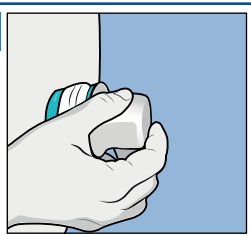


Unscrew the cap from the inserter, breaking the tamper band.

Note: Do not use the Simplera Sync sensor if the tamper band is broken, damaged, or missing from the device.

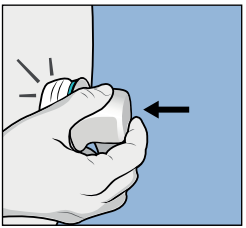
Insertion

8



Place the inserter on top of the prepared insertion site.

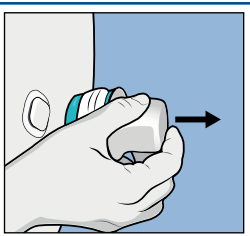
9



Press the inserter firmly against the body until there is a click.

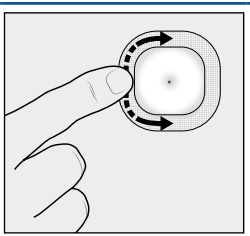
After insertion

10



Gently pull the inserter straight from the body.

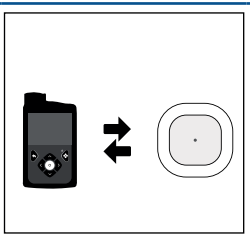
11



Smooth down the sensor adhesive with a finger to ensure the sensor stays on the body for the entire duration of use.

Note: Use over-the-counter tape if desired for additional adhesion.

12



Pair the Simplera Sync sensor with a compatible insulin pump.

Note: The SN and CODE are required to pair the sensor with a compatible display device. For details on how to pair the sensor with a compatible insulin pump, see the compatible Medtronic AID system user guide.

Bathing and swimming

While on the body, the sensor is protected against continuous immersion in water at a depth of 8 ft (2.4 m) for up to 30 minutes. Shower and swim without removing the sensor.

Removing the Simplera Sync sensor

To remove the Simplera Sync sensor:

1. Gently peel the sensor adhesive away from the body.
2. Dispose of the Simplera Sync sensor in accordance with all local laws and regulations. For additional information, see *Disposal, page 21*.

Simplera Sync sensor wireless communication

Quality of service

The Simplera Sync sensor connects to a compatible display device via a Bluetooth low-energy technology network. The sensor sends glucose data and compatible Medtronic AID system-related alerts to the compatible display device, which verifies the integrity of received data after wireless transmission. The quality of the connection is in accordance with the Bluetooth Specification v4.2.

Data security

The Simplera Sync sensor is designed to only accept radio frequency (RF) communications from a recognized and linked compatible display device. The sensor must be paired with the display device before the display device accepts information from the sensor.

The compatible mobile device ensure data security via encryption of all transmitted data and data integrity via cryptographic message authentication checks.

Traveling by air

The Simplera Sync sensor is safe for use on commercial airlines.

FCC notice

The Simplera Sync sensor complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

IMPORTANT: Do not change or modify the internal RF transmitter or antenna unless expressly approved by Medtronic Diabetes. Doing so could interfere with your ability to operate the equipment.

Guidance and manufacturer's declaration

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions CISPR 11	CISPR 11 Group 1, Class B	The transmitter uses RF energy only for system communications. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
Immunity Test	**IEC 60601-1-2 Test Level**	**IEC 60601-1-2 Compliance Level**	**Electromagnetic Environment Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2, ±4, ±8, ±15 kV air	±8 kV contact ±2, ±4, ±8, ±15 kV air	For use in a typical domestic, commercial, or hospital environment.
Power frequency magnetic field IEC 61000-4-8	30 A/m	30 A/m	For use in a typical domestic, commercial, or hospital environment.
Proximity magnetic fields IEC 61000-4-39, Table 11	IEC 60601-1-2, Table 11	IEC 60601-1-2, Table 11	For use in a typical domestic, commercial, or hospital environment.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
Immunity Test	**IEC 60601-1-2 Test Level**	**IEC 60601-1-2 Compliance Level**	**Electromagnetic Environment Guidance**
Proximity fields from RF wireless communications equipment	IEC 60601-1-2, Table 9	IEC 60601-1-2, Table 9	For use in a typical domestic, commercial, or hospital environment. Portable and mobile RF communications equipment should be used no closer to any part of the transmitter than the recommended separation distance of 12 in (30 cm). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF electromagnetic fields IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	
Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption, and reflection from structures, objects and people.			

Radiated power

Effective radiated power (ERP)	-9.45 dBm (0.12 mW)
Effective isotropic radiated power (EIRP)	-7.30 dBm (0.19 mW)

Maintenance

Operation

Operating temperature range	36 °F to 104 °F (2 °C to 40 °C)
Air pressure range	10.2 psi to 15.4 psi (70.33 kPa to 106.17 kPa)
Operating relative humidity (RH) range	15% to 95%

Specifications

Biocompatibility	Sensor: Complies with EN ISO 10993-1
Applied parts	Sensor Type BF applied part
Operating conditions	Sensor temperature: 36 °F to 104 °F (2 °C to 40 °C) Sensor relative humidity: 15% to 95% with no condensation Sensor pressure: 10.2 psi to 15.4 psi (70.33 kPa to 106.17 kPa)
Storage conditions	Sensor temperature: 36 °F to 86 °F (2 °Cto 30 °C) Sensor relative humidity: up to 95% with no condensation Sensor pressure: 10.2 psi to 15.4 psi (70.33 kPa to 106.17 kPa) **CAUTION:** Do not freeze the Simplera Sync sensor, or store it in direct sunlight, extreme temperatures, or high humidity. These conditions may damage the device.
Sensor glucose measurement range	50 to 400 mg/dL
Duration of use	Up to six days of CGM followed by a grace period of 24 hours
Operating frequency	2.4 GHz band, Bluetooth wireless technology (version 4.2)
Effective radiated power (ERP)	1.53 mW (1.85 dBm)
Effective isotropic radiated power (EIRP)	2.51 mW (4.00 dBm)
Operating range	Minimum of 20 ft (6.09 m) line of sight in free-air
Sensor device approximate dimensions	2.366 x 2.366 x 2.919 in (6.009 x 6.009 x 7.414 cm)
Sensor device approximate weight	2.56 ounces (72.5 g)

Sensor approximate dimensions	1.128 x 1.128 x 0.188 in (2.865 x 2.865 x 0.477 cm
Sensor approximate weight	0.16 ounces (4.6 g)

Storage

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

Room temperature storage range	36 °F to 86 °F (2 °C to 30 °C)
Relative humidity (RH) storage range	Up to 95% relative humidity

Simplera Sync sensor life of use

The Simplera Sync sensor can be used one time and has a life of up to six days, followed by a grace period of 24 hours. During the grace period, the sensor will continue to work as it did during the first six days, to allow the patient to change their sensor more flexibly.

CAUTION: Do not use the sensor if there is a sudden rise in sensor temperature. When operating the sensor in air temperatures of 104 °F (40 °C), under certain fault conditions, the temperature of the sensor may briefly rise up to 121 °F (50 °C). If there is a sudden rise in temperature or the sensor becomes hot or uncomfortable, remove and discard the sensor.

Disposal

Disposal requirements for electronic equipment, batteries, sharps and potential biohazardous materials differ based on location. Confirm disposal requirements for electronic equipment, batteries, sharps, and potential biohazardous materials with local laws and regulations.

The used inserter contains a needle which has been in contact with blood or other bodily fluids.

The used sensor contains a battery and has been in contact with blood or other bodily fluids. Disposal of the battery in any receptacle that could be exposed to extreme heat may cause the battery to ignite and result in serious injury.

Do not dispose of any component of this product with household waste or recyclables.

Dispose of the inserter and sensor in accordance with local laws and regulations.

Open Source Software (OSS) disclosure

This document identifies the Open Source Software that may be separately called, executed, linked, affiliated, or otherwise utilized by this product. Such Open Source Software is licensed to users subject to the terms and conditions of the separate software license agreement for such Open Source Software. Use of the Open Source Software shall be governed entirely by the terms and conditions of such license. The source/object code and applicable license for the Open Source Software can be obtained at the following site: www.medtronicdiabetes.com/ossnotices.

Performance data

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

Assistance

Department	Telephone number
24-Hour Technical Support (calls within the United States)	+1 800 646 4633
24-Hour Technical Support (calls outside the United States)	+1 818 576 5400
Website	www.medtronicdiabetes.com

For definitions of the symbols displayed in the Simplera Sync sensor and package labels, see www.medtronicdiabetes.com/symbols-definitions.

Medtronic

Medtronic MiniMed
18000 Devonshire Street
Northridge, CA 91325
USA
1 800 646 4633
+1 818 576 5555
www.medtronicdiabetes.com

RF: 033686

REF MMT-5120

℞ *Only*

M058082C003_2
2025-07-31

M058082C003

minimed

Simplera Sync

Sensor Instructions for Use

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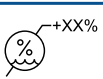
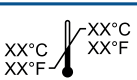
Icon table

LOT	Batch code
	Bluetooth® wireless technology or Bluetooth® enabled
REF	Catalogue number
	Date of manufacture (DoM)
	Do not re-use
	Do not use if package is damaged and consult instructions for use
(5x)	Five per container/package
	Follow instructions for use
	Fragile, handle with care
IP48	Protected against effects of continuous immersion in water at a depth of 8 feet (2.4 meters) for up to 30 minutes
	Keep dry
MR	Magnetic Resonance (MR) Unsafe

	Manufacturer
	Non-pyrogenic
(1x)	One per container/package
	Recyclable, contains recycled content
	Single sterile barrier system
	Sterilized using ethylene oxide
	Humidity upper limit
	Temperature limits
	Type BF applied part
	Use-by date
	Caution: consult instructions for use for important warnings or precautions not found on the label
	Serial number

MD	Medical device
CODE: XXX-XXX	Sensor pairing code
	Contains human blood or plasma derivatives
	Contains biological material of human origin
UDI	Unique Device Identifier
	Country of manufacture (and Date of manufacture when a date appears beside)
	Do not re-sterilize
	Manufacturing site
	Importer
$\mathrm{R_x}$ *Only*	Requires prescription in the USA
FCC ID	Complies with United States regulations for RF devices
	Do not dispose of this product in unsorted municipal waste stream

Introduction

The Simplera Sync sensor (MMT-5120) with Bluetooth® wireless technology is a component of a compatible Medtronic automated insulin dosing (AID) system.

The Simplera Sync 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.

Indications for use

The Simplera Sync sensor is a continuous glucose monitor (CGM) intended for use with compatible Medtronic automated insulin dosing (AID) Systems to monitor glucose levels for the management of diabetes.

The Simplera Sync 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 Simplera Sync sensor.

The Simplera Sync sensor is indicated for persons 7 years and older for insertion in arm.

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

The Simplera Sync sensor can be used one time and has a life of up to 6 days, followed by a grace period of 24 hours. During the grace period, the sensor will continue to work as it did during the first 6 days, to allow the patient to change their sensor more flexibly.

The Simplera Sync sensor is indicated for the management of diabetes in persons ages 7 years and older.

Intended users

The Simplera Sync sensor is intended for personal use by individuals to assist in the management of their diabetes, or for use by parents/caregivers who assist these individuals with diabetes management.

Contraindications

No contraindications are associated with Simplera Sync sensor use.

Intended clinical benefits

Although the Simplera Sync sensor does not provide any therapy or treatment, the continuous glucose information provided by the sensor used in combination with a compatible Medtronic insulin pump can aid in diabetes management.

User safety

Warnings and precautions

Read this entire user guide before attempting to insert the Simplera Sync sensor. The inserter portion of the sensor does not work the same way as other Medtronic insertion devices. The sensor is not inserted the same way as other Medtronic sensors. Failure to follow directions may result in improper insertion, pain, or injury.

Do not use the Simplera Sync sensor adjacent to other electrical equipment that may cause interference with normal sensor operation. For more information on electrical equipment that may cause interference with normal sensor operation, see *Exposure to magnetic fields and radiation, page 10*.

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 inaccurate or missed alerts, and substantially higher sensor glucose readings in reports than actual blood glucose readings. 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.

Always consult a healthcare professional before using sensor glucose values to make treatment decisions if a medication that contains acetaminophen or paracetamol is taken while wearing the sensor. Medications that contain acetaminophen or paracetamol can falsely raise sensor glucose readings. The level of inaccuracy depends on the amount of acetaminophen or paracetamol active in the body and can differ for each person. Falsely elevated sensor readings can result in over-administration of insulin, which can cause hypoglycemia. Medications that contain acetaminophen or paracetamol include, but are not limited to, cold medicines and fever reducers. Check the label of any medications being taken to see if acetaminophen or paracetamol is an active ingredient. Use additional blood glucose meter readings to confirm blood glucose levels.

Always examine the Simplera Sync sensor box for damage. If the sensor box is open or damaged, examine the sensor for damage. If the sensor is visibly damaged, discard the device to avoid possible contamination.

Do not use the Simplera Sync sensor if any part of the device is damaged. If the device is damaged, discard the device to avoid possible contamination.

Do not use the Simplera Sync sensor if the tamper band is broken, damaged, or missing from the device. The sensor is sterile and non-pyrogenic unless the device is damaged. If the tamper band is broken, damaged, or missing from the device, the sensor and the needle can be exposed to contamination. A sensor and needle exposed to contamination can cause site infection if inserted into the body.

Do not use the Simplera Sync sensor if the cap label is broken, damaged, or missing from the device. The sensor is sterile and non-pyrogenic unless the device is damaged. If the cap label is broken, damaged, or missing from the device, the sensor and the needle can be exposed to contamination. A sensor and needle exposed to contamination can cause insertion site infection if inserted into the body.

Do not unscrew or remove the Simplera Sync sensor cap until the device is ready to be used. Do not remove the cap and store the device for future use. The sensor is sterile and non-pyrogenic unless the cap is removed from the device or the tamper band is broken. If the cap is not on the device or the tamper band is broken, the sensor and the needle can be exposed to contamination. A sensor and needle exposed to contamination can cause site infection if inserted into the body.

Do not remove the cap and place it back on the device. Placing the cap back on the device could cause damage to the needle, prevent a successful insertion, and cause injury.

Do not change or modify the Simplera Sync sensor. Changing or modifying the sensor can result in improper insertion, pain, or injury.

Do not let children hold the Simplera Sync sensor without adult supervision. Do not let children put any part of the sensor in their mouth. This product poses a choking hazard for young children that can result in serious injury or death.

Do not use the Simplera Sync 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.

Watch for bleeding at the insertion site on top of the Simplera Sync sensor. If bleeding occurs, apply steady pressure with a sterile gauze pad or clean cloth placed on top of the sensor for up to three minutes. If bleeding continues, is significantly visible on top of the sensor, or if there is excessive pain or discomfort after insertion, follow these steps:

1. Remove the Simplera Sync sensor and continue to apply steady pressure until the bleeding stops.
2. Dispose of the Simplera Sync sensor. See *Disposal, page 21*.
3. Check the insertion site for redness, bleeding, irritation, pain, tenderness, or inflammation. If there is redness, bleeding, irritation, pain, tenderness, or inflammation, contact a healthcare professional.
4. Insert a new Simplera Sync sensor in a different location.

Some skin care products, such as sunscreens and insect repellents, can damage the Simplera Sync sensor. Do not allow skin care products to touch the sensor. Wash hands after using skin care products before touching the sensor. If any skin care products touch the sensor, immediately wipe the sensor with a clean cloth.

Serious incident reporting

If a serious incident related to the device occurs, immediately report the incident to a healthcare professional. Serious incidents may include death, temporary or permanent serious decline in health, or a serious public health threat. Immediately report any serious incident to the manufacturer and local competent authority.

Exposure to magnetic fields and radiation

Do not expose the Simplera Sync sensor to Magnetic Resonance Imaging (MRI) equipment, diathermy devices, or other devices that generate strong magnetic fields (for example, CT scan, or other types of radiation). Exposure to strong magnetic fields can cause the sensor to malfunction, result in serious injury, or be unsafe.

IEC 60601-1-2; Special EMC Precautions for Medical Electrical Equipment

1. Special Precautions regarding Electromagnetic Compatibility (EMC): This body worn device is intended to be operated within a reasonable residential, domestic, public or work environment where common levels of radiated "E" (V/m) or "H" fields (A/m) exist, such as cellular phones, Wi-Fi™*, Bluetooth wireless technology, electric can openers, microwave and induction ovens. This device generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the provided instructions, may cause harmful interference to radio communications.
2. Portable and mobile RF communications equipment can affect medical electrical equipment. If you encounter RF interference from a mobile or stationary RF transmitter, move away from the RF transmitter that is causing the interference.
3. Be careful when using the Simplera Sync sensor closer than 12 in (30 cm) to portable radio frequency (RF) equipment or electrical equipment. If the sensor must be used next to portable RF equipment or electrical equipment, observe the sensor to verify correct system operation. Degradation of the performance of the sensor could result.

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.

Risks

General risks with Simplera Sync sensor use include the following:

- 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 filament fracture, breakage, or damage
- Minimal blood splatter associated with sensor needle removal
- Residual redness associated with adhesive or tapes or both
- Scarring

Allergens

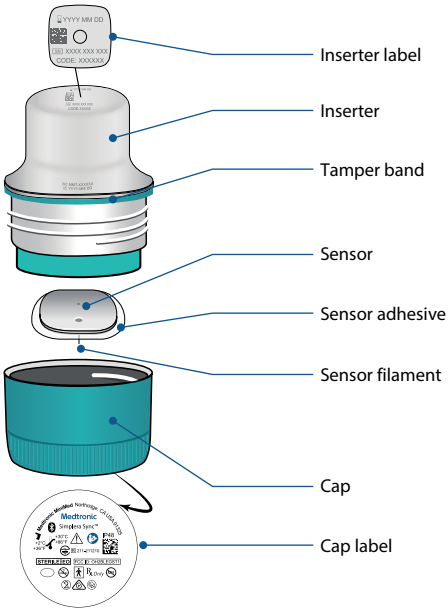
The Simplera Sync sensor contains nickel in stainless steel.

Reagents

The Simplera Sync sensor contains two biological reagents: glucose oxidase, and human serum albumin (HSA).

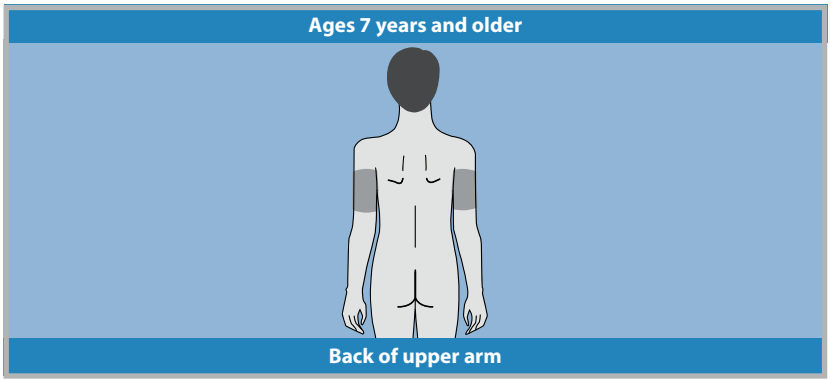
Glucose oxidase is derived from **Aspergillus niger** and manufactured to meet industry requirements for extraction and purification of enzymes for use in diagnostic, immunodiagnostic, and biotechnical applications. The HSA used in the Simplera Sync sensor consists of purified and dried albumin fraction 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.

Simplera Sync sensor device components



Where to insert the Simplera Sync sensor

The images that follow show insertion sites for ages 7 years and older. Target the shaded areas shown in the image, and make sure that the insertion site has a sufficient amount of fat.

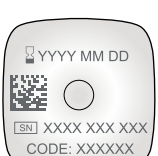


Insertion on abdomen and buttocks are not recommended.

Inserting the Simplera Sync sensor

Preparing for insertion

1



The inserter label is on the top of the inserter.
Before insertion, perform the following steps:

- Inspect the expiration date. Do not use an expired Simplera Sync sensor.
- Make note of the serial number (SN) and the CODE. Both numbers will be used later to pair the sensor with a compatible insulin pump.

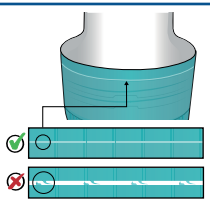
Note: The SN and CODE label is also on the inside of the Simplera Sync sensor box lid.

2

Inspect the cap label for damage before insertion.

Note: Do not use the Simplera Sync sensor if the cap label is damaged or missing from the cap.

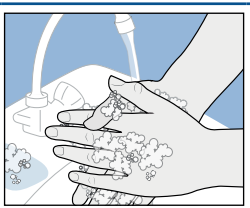
3



Inspect the tamper band to make sure that it is not broken, damaged, or missing from the device.

Note: Do not use the Simplera Sync sensor if the tamper band is broken, damaged, or missing.

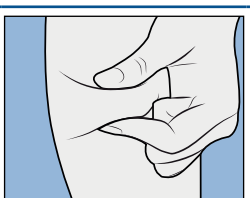
4



Wash hands thoroughly with soap and water.

Note: Wear gloves when inserting the Simplera Sync sensor into another person to avoid accidental contact with patient blood. Minimal bleeding can occur.

5

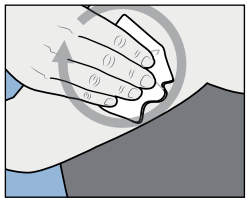


Choose an insertion site that has a sufficient amount of fat. For insertion sites see *Where to insert the Simplera Sync sensor, page 12*.

For the best sensor performance, and to avoid accidental sensor removal, do not insert the Simplera Sync sensor into the following areas:

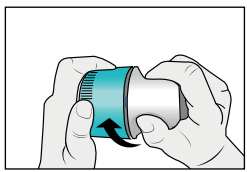
- muscle, tough skin, or scar tissue
- areas that are constrained by clothing or accessories
- areas subjected to rigorous movement during exercise

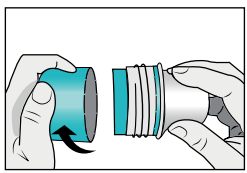
6



Clean the insertion site with alcohol. Allow the insertion site to air dry.

7



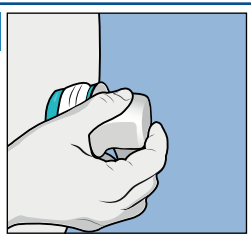


Unscrew the cap from the inserter, breaking the tamper band.

Note: Do not use the Simplera Sync sensor if the tamper band is broken, damaged, or missing from the device.

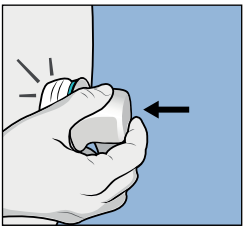
Insertion

8



Place the inserter on top of the prepared insertion site.

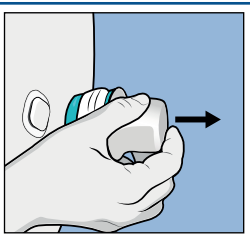
9



Press the inserter firmly against the body until there is a click.

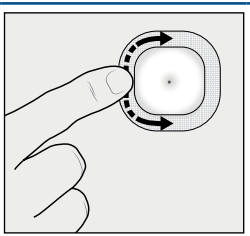
After insertion

10



Gently pull the inserter straight from the body.

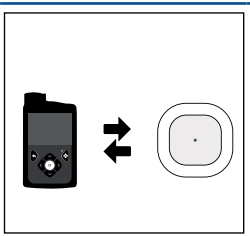
11



Smooth down the sensor adhesive with a finger to ensure the sensor stays on the body for the entire duration of use.

Note: Use over-the-counter tape if desired for additional adhesion.

12



Pair the Simplera Sync sensor with a compatible insulin pump.

Note: The SN and CODE are required to pair the sensor with a compatible display device. For details on how to pair the sensor with a compatible insulin pump, see the compatible Medtronic AID system user guide.

Bathing and swimming

While on the body, the sensor is protected against continuous immersion in water at a depth of 8 ft (2.4 m) for up to 30 minutes. Shower and swim without removing the sensor.

Removing the Simplera Sync sensor

To remove the Simplera Sync sensor:

1. Gently peel the sensor adhesive away from the body.
2. Dispose of the Simplera Sync sensor in accordance with all local laws and regulations. For additional information, see *Disposal, page 21*.

Simplera Sync sensor wireless communication

Quality of service

The Simplera Sync sensor connects to a compatible display device via a Bluetooth low-energy technology network. The sensor sends glucose data and compatible Medtronic AID system-related alerts to the compatible display device, which verifies the integrity of received data after wireless transmission. The quality of the connection is in accordance with the Bluetooth Specification v4.2.

Data security

The Simplera Sync sensor is designed to only accept radio frequency (RF) communications from a recognized and linked compatible display device. The sensor must be paired with the display device before the display device accepts information from the sensor.

The compatible mobile device ensure data security via encryption of all transmitted data and data integrity via cryptographic message authentication checks.

Traveling by air

The Simplera Sync sensor is safe for use on commercial airlines.

FCC notice

The Simplera Sync sensor complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

IMPORTANT: Do not change or modify the internal RF transmitter or antenna unless expressly approved by Medtronic Diabetes. Doing so could interfere with your ability to operate the equipment.

Guidance and manufacturer's declaration

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions CISPR 11	CISPR 11 Group 1, Class B	The transmitter uses RF energy only for system communications. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
Immunity Test	**IEC 60601-1-2 Test Level**	**IEC 60601-1-2 Compliance Level**	**Electromagnetic Environment Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2, ±4, ±8, ±15 kV air	±8 kV contact ±2, ±4, ±8, ±15 kV air	For use in a typical domestic, commercial, or hospital environment.
Power frequency magnetic field IEC 61000-4-8	30 A/m	30 A/m	For use in a typical domestic, commercial, or hospital environment.
Proximity magnetic fields IEC 61000-4-39, Table 11	IEC 60601-1-2, Table 11	IEC 60601-1-2, Table 11	For use in a typical domestic, commercial, or hospital environment.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
Immunity Test	**IEC 60601-1-2 Test Level**	**IEC 60601-1-2 Compliance Level**	**Electromagnetic Environment Guidance**
Proximity fields from RF wireless communications equipment	IEC 60601-1-2, Table 9	IEC 60601-1-2, Table 9	For use in a typical domestic, commercial, or hospital environment. Portable and mobile RF communications equipment should be used no closer to any part of the transmitter than the recommended separation distance of 12 in (30 cm). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF electromagnetic fields IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	
Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption, and reflection from structures, objects and people.			

Radiated power

Effective radiated power (ERP)	1.85 dBm (1.53 mW)
Effective isotropic radiated power (EIRP)	4.00 dBm (2.51 mW)

Maintenance

Operation

Operating temperature range	36 °F to 104 °F (2 °C to 40 °C)
Air pressure range	10.2 psi to 15.4 psi (70.33 kPa to 106.17 kPa)
Operating relative humidity (RH) range	15% to 95%

Specifications

Biocompatibility	Sensor: Complies with EN ISO 10993-1
Applied parts	Sensor Type BF applied part
Operating conditions	Sensor temperature: 36 °F to 104 °F (2 °C to 40 °C) Sensor relative humidity: 15% to 95% with no condensation Sensor pressure: 10.2 psi to 15.4 psi (70.33 kPa to 106.17 kPa)
Storage conditions	Sensor temperature: 36 °F to 86 °F (2 °Cto 30 °C) Sensor relative humidity: up to 95% with no condensation Sensor pressure: 10.2 psi to 15.4 psi (70.33 kPa to 106.17 kPa) **CAUTION:** Do not freeze the Simplera Sync sensor, or store it in direct sunlight, extreme temperatures, or high humidity. These conditions may damage the device.
Sensor glucose measurement range	50 to 400 mg/dL
Duration of use	Up to six days of CGM followed by a grace period of 24 hours
Operating frequency	2.4 GHz band, Bluetooth wireless technology (version 4.2)
Effective radiated power (ERP)	1.53 mW (1.85 dBm)
Effective isotropic radiated power (EIRP)	2.51 mW (4.00 dBm)
Operating range	Minimum of 20 ft (6.09 m) line of sight in free-air
Sensor device approximate dimensions	2.366 x 2.366 x 2.919 in (6.009 x 6.009 x 7.414 cm)
Sensor device approximate weight	2.56 ounces (72.5 g)

Sensor approximate dimensions	1.128 x 1.128 x 0.188 in (2.865 x 2.865 x 0.477 cm
Sensor approximate weight	0.16 ounces (4.6 g)

Storage

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

Room temperature storage range	36 °F to 86 °F (2 °C to 30 °C)
Relative humidity (RH) storage range	Up to 95% relative humidity

Simplera Sync sensor life of use

The Simplera Sync sensor can be used one time and has a life of up to six days, followed by a grace period of 24 hours. During the grace period, the sensor will continue to work as it did during the first six days, to allow the patient to change their sensor more flexibly.

CAUTION: Do not use the sensor if there is a sudden rise in sensor temperature. When operating the sensor in air temperatures of 104 °F (40 °C), under certain fault conditions, the temperature of the sensor may briefly rise up to 121 °F (50 °C). If there is a sudden rise in temperature or the sensor becomes hot or uncomfortable, remove and discard the sensor.

Disposal

Disposal requirements for electronic equipment, batteries, sharps and potential biohazardous materials differ based on location. Confirm disposal requirements for electronic equipment, batteries, sharps, and potential biohazardous materials with local laws and regulations.

The used inserter contains a needle which has been in contact with blood or other bodily fluids.

The used sensor contains a battery and has been in contact with blood or other bodily fluids. Disposal of the battery in any receptacle that could be exposed to extreme heat may cause the battery to ignite and result in serious injury.

Do not dispose of any component of this product with household waste or recyclables.

Dispose of the inserter and sensor in accordance with local laws and regulations.

Open Source Software (OSS) disclosure

This document identifies the Open Source Software that may be separately called, executed, linked, affiliated, or otherwise utilized by this product. Such Open Source Software is licensed to users subject to the terms and conditions of the separate software license agreement for such Open Source Software. Use of the Open Source Software shall be governed entirely by the terms and conditions of such license. The source/object code and applicable license for the Open Source Software can be obtained at the following site: www.medtronicdiabetes.com/ossnotices.

Performance data

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

Assistance

Department	Telephone number
24-Hour Technical Support (calls within the United States)	+1 800 646 4633
24-Hour Technical Support (calls outside the United States)	+1 818 576 5400
Website	www.medtronicdiabetes.com

For definitions of the symbols displayed in the Simplera Sync sensor and package labels, see www.medtronicdiabetes.com/symbols-definitions.

Medtronic

Medtronic MiniMed
18000 Devonshire Street
Northridge, CA 91325
USA
1 800 646 4633
+1 818 576 5555
www.medtronicdiabetes.com

REF MMT-5120

℞ *Only*

M058081C003_2
2025-07-31

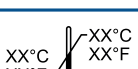
M058081C003

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 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 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 limits

	Open here
	Manufacturer
	Country of manufacture (and Date of manufacture when a date appears beside)
	Date of manufacture (DoM)
	Do not re-sterilize
	Fragile, handle with care
	Keep dry
	Recyclable, contains recycled content
	Magnetic Resonance (MR) Unsafe
	Non-pyrogenic
$\mathrm{R_x}$ *Only*	Requires prescription in the USA

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).

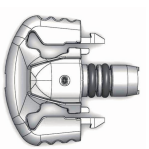
If bleeding occurs, do the following:

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 a healthcare professional. Serious incidents may include death, temporary or permanent serious decline in health, or a serious public health threat. Immediately report any serious incident to the manufacturer and local competent 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

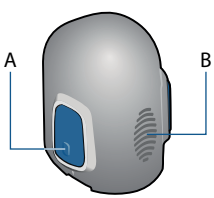
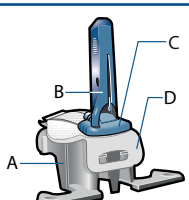
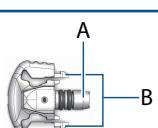
The Guardian 4 sensor contains two biological reagents: glucose oxidase, and human serum albumin (HSA). Glucose oxidase is derived from Aspergillus niger and manufactured to meet industry requirements for the

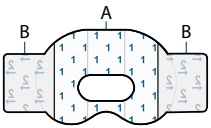
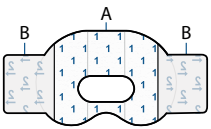
extraction and purification of enzymes for use in diagnostic, immunodiagnostic, and biotechnical applications. The HSA used on the sensor consists of purified and dried albumin fraction V derived from pasteurized human serum, which is crosslinked via glutaraldehyde. Approximately 3 µg of glucose oxidase 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** 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**

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

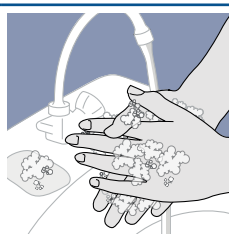
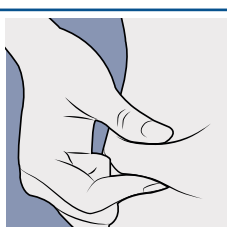
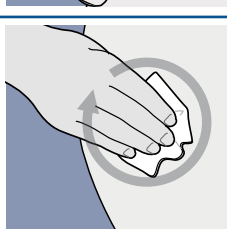
Note: Assistance will likely be needed for sensor insertion into the back of the upper arm. Some users find it difficult to insert the sensor into their arm by themselves.

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

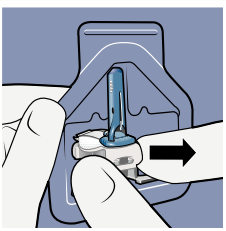
WARNING: Always wear gloves when inserting the sensor into another person to avoid contact with patient blood. Minimal bleeding may occur. Contact with patient blood may cause infection.

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.

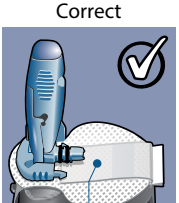
5



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

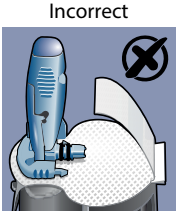
6

Correct



tucked tab

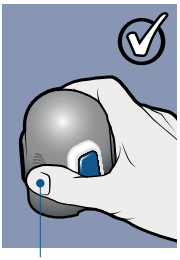
Incorrect



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

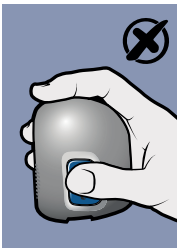
7

Correct



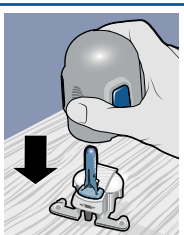
thumb on thumb-print marking

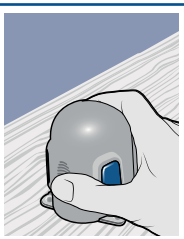
Incorrect



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

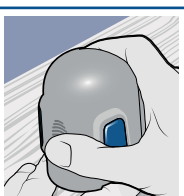
8

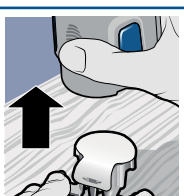




Push the serter down onto the pedestal until the base of the serter sits flat on the table and there is a click.

9





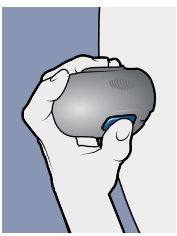
With either hand, place two fingers on the base of the pedestal. With the other hand, grip the serter and pull the serter upwards.

arrow

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

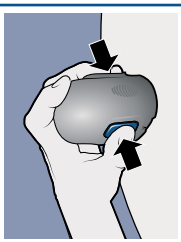
WARNING: Never point a loaded serter toward any body part where insertion is not desired. An accidental button-push may cause the needle to inject the sensor in an undesired location, causing minor injury.

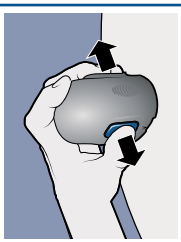
10



Place the serter on top of the prepared insertion site.

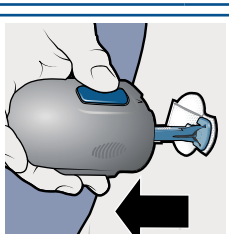
11



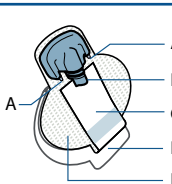


Press and release both serter buttons at the same time. Continue to hold the serter on top of the insertion site for five seconds or more to let the adhesive stick to the skin.

12



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

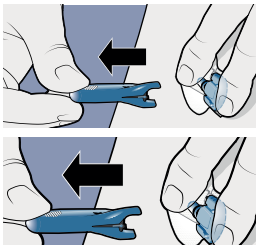


Sensor base

A. sensor snaps
B. sensor connector
C. adhesive tab
D. adhesive liner
E. adhesive pad

If the sensor is inserted without assistance, complete step 13a. If a healthcare professional or caregiver assisted with sensor insertion, complete step 13b.

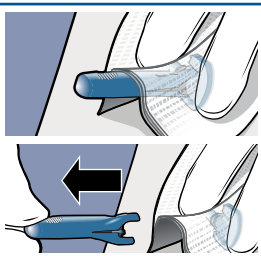
13a



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.

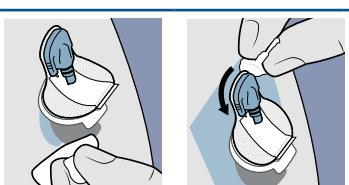
OR

13b



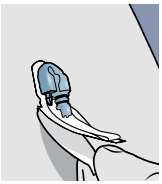
Healthcare professional or caregiver:
Wrap sterile gauze around the sensor. Hold the sensor base against the skin at the sensor connector and the opposite end of the sensor base. Hold the needle housing at the top and pull away from the sensor.

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.



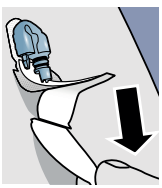
Note: After insertion, use of adhesive products, such as Skin Tac™, in addition to the oval tape is optional. If optional adhesive products are used, apply them to the skin under the adhesive pad prior to removing the liner. Adhesive products may also be applied to the adhesive pad or the skin around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

14



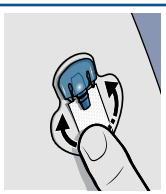
Remove the adhesive liner from under the adhesive pad. Pull the liner away from the sensor, staying close to the skin. Do not pull on the sensor when you remove the liner.

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.



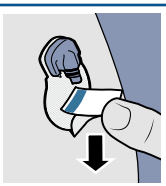
Note: If the sensor base moves, hold the sensor base down.

15



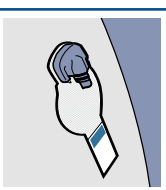
Firmly press the adhesive pad against the insertion site to confirm that the sensor base remains on the skin.

16



Untuck the adhesive tape from under the sensor connector.

17



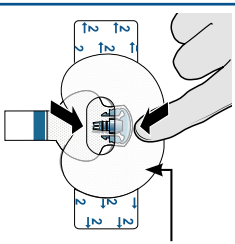
Straighten the sensor adhesive tab so that it lies flat against the skin.

Applying Oval Tape

1

Remove the liner marked 1.

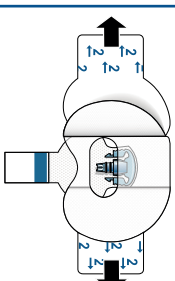
2



wide part of tape covers half of sensor base

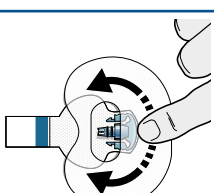
Apply the tape as shown and press down firmly.

3



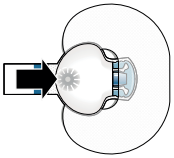
Remove liners marked 2 from each side.

4



Smooth the tape.

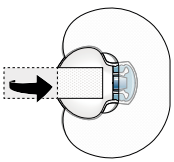
5



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



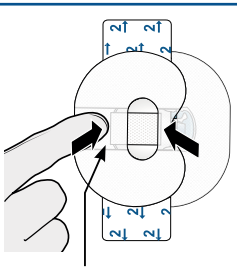
Cover the transmitter with the adhesive tab.

Note: Do not pull the tab too tightly.

7

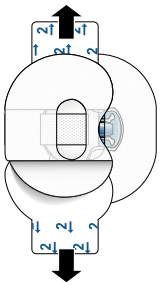
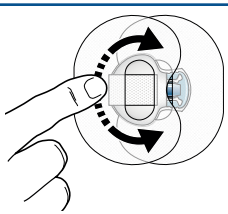
To apply a second tape, remove liner marked 1.

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)

Table 1. Product specifications

Biocompatibility	Transmitter: Complies with EN ISO 10993-1
Applied parts	Transmitter Sensor Type BF applied part
Operating conditions	Transmitter temperature: 32 °Fto 113 °F(0 °C to 45 °C) **CAUTION:** When operating the transmitter on a tester in air temperatures greater than 106 °F (41 °C), the temperature of the transmitter may exceed 109 °F(43 °C). Transmitter relative humidity: 10% to 95% with no condensation Transmitter pressure: 8.4 psi to 15.4 psi (57.60 kPa to 106.17 kPa) Charger temperature: 50 °F to 104 °F (10 °C to 40 °C) Charger relative humidity: 30% to 75% with no condensation
Storage conditions	Transmitter temperature: -4 °F to 131 °F (-20 °C to 55 °C) Transmitter relative humidity: up to 95% with no condensation Transmitter pressure: 8.4 psi to 15.4 psi (57.6 kPa to 106.17 kPa) Charger temperature: 14 °F to 122 °F (-10 °C to 50 °C) Charger relative humidity: 10% to 95% with no condensation
Battery life	Transmitter: Seven days of CGM immediately following a full charge. Charger: The charger uses one new AAA battery to charge the transmitter.

Table 1. Product specifications (continued)

Transmitter frequency	2.4 GHz band, Bluetooth® wireless technology (version 4.0)
Effective radiated power (ERP)	0.06 mW (-12.05 dBm)
Effective isotropic radiated power (EIRP)	0.1 mW (-9.9 dBm)
Operating range	Up to 6 feet (1.8 m) in free-air
Transmitter expected service life	The transmitter expected service life is one year depending on patient usage.

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.

Medtronic

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