minimed

Simplera Sync

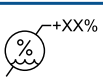
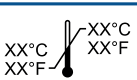
A component of the
MiniMed 780G system

Sensor Instructions for Use

M058081C001_4

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

	Non-ionizing electromagnetic radiation

Introduction

The Simplera Sync sensor (MMT-5120) with Bluetooth® wireless technology is a component of the MiniMed™ 780G 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 the MiniMed 780G system.

The Simplera Sync sensor does not require calibration.

Intended use

The Simplera Sync sensor is intended for use with the MiniMed 780G system to monitor glucose levels for the management of diabetes.

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. However, some sensors may not survive the full wear period for a variety of reasons. Please be prepared to replace the sensor during the grace period to ensure sensor glucose values continue to be monitored.

The Simplera Sync sensor is not intended to be used directly to make therapy adjustments while the MiniMed 780G 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 has been studied and is approved for use in the systems, insertion sites, and ages listed in the following table.

System	Approved Age	Sensor Insertion Site
Simplera Sync	7 years and older	Arm

Intended target population

The intended target population for the Simplera Sync sensor includes children and adolescents ages 7-17 years, and adults ages 18 years and older who are responsive to insulin delivered subcutaneously.

Contraindications

No contraindications are associated with Simplera Sync sensor use. For information on contraindications associated with the MiniMed 780G system, see the system user guide.

User safety

WARNING: For persons under the age of 18 years, the Simplera Sync sensor is not approved to make treatment decisions in Manual mode. Use the SmartGuard feature with Auto Correction On as much as possible when using the MiniMed 780G system with the Simplera Sync sensor.

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 system operation. For more information on electrical equipment that may cause interference with normal system 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 system if you are pregnant or critically ill. Since the system has not been studied in these populations, the impact of medications common to these conditions on system performance is unknown and the system 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 Medtronic and your local applicable 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 Simplera Sync sensor performs measurements and estimates blood glucose concentration, and wirelessly communicates glucose information to the MiniMed 780G system.

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

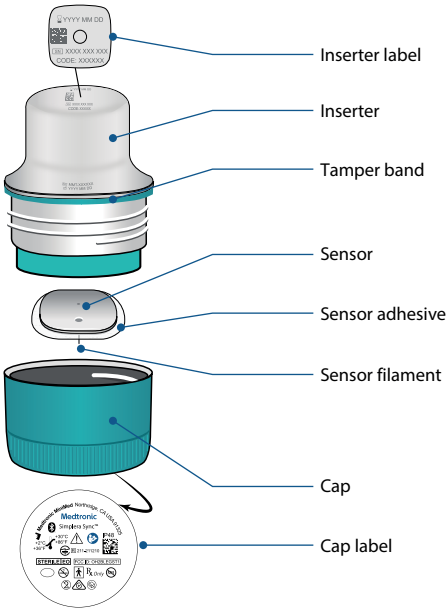
The Simplera Sync sensor contains nickel in stainless steel.

Reagents

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

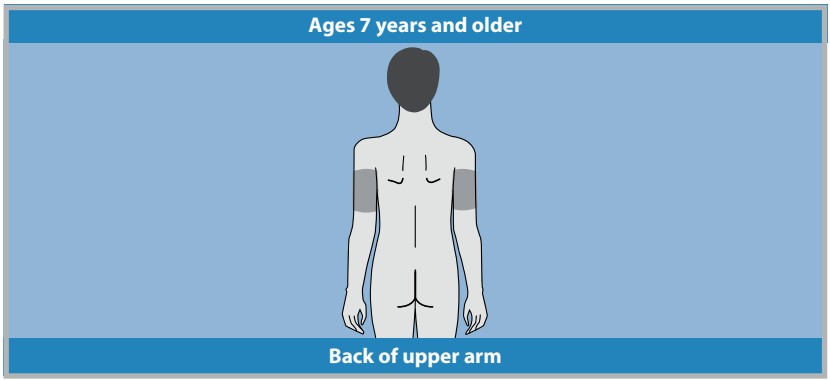
Glucose oxidase is derived from **Aspergillus niger** and manufactured to meet industry requirements for extraction and purification of enzymes for use in diagnostic, immunodiagnostic, and biotechnical applications. The HSA used in the Simplera Sync sensor consists of purified and dried albumin fraction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

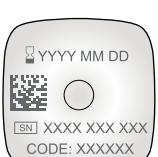


Insertion on abdomen and buttocks are not recommended.

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 the MiniMed 780G system.

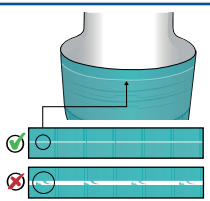
Note: The SN and CODE label is also on the inside of the Simplera Sync sensor box lid.

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.

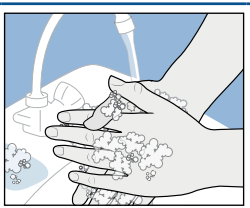
3



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.

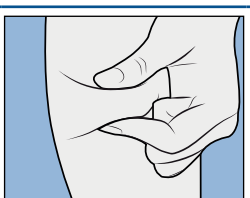
4



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

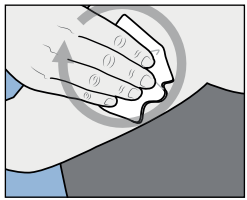


Choose an insertion site that has a sufficient amount of fat. For insertion sites see *Where to insert the Simplera Sync sensor, page 12*.

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

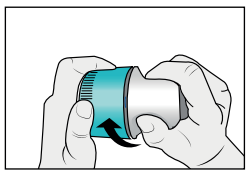
- muscle, tough skin, or scar tissue
- areas that are constrained by clothing or accessories
- areas subjected to rigorous movement during exercise

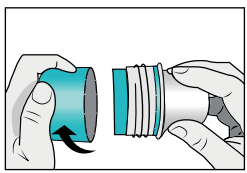
6



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

7



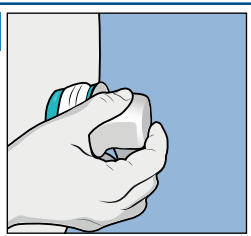


Unscrew the cap from the inserter, breaking the tamper band.

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

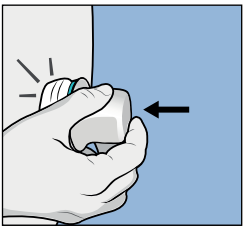
Insertion

8



Place the inserter on top of the prepared insertion site.

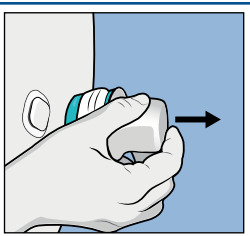
9



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

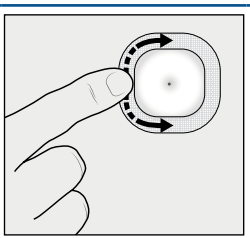
After insertion

10



Gently pull the inserter straight from the body.

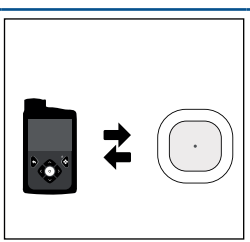
11



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 the MiniMed 780G system.

Note: The SN and CODE are required to pair the sensor with a compatible display device. For details on how to pair the Simplera Sync sensor with the MiniMed 780G system, see the MiniMed 780G 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 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 ensures 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 authority 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)	-4.45 dBm (0.36 mW)
Effective isotropic radiated power (EIRP)	-2.30 dBm (0.59 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
Sensor glucose assay method	Enzymatic amperometric electrochemical sensor
Sensor glucose measurement range	50 to 400 mg/dL (2.8 to 22.2 mmol/L)
Sensor power source	2 silver oxide batteries
Sensor data	At least 2 days
Sensor memory	At least 2 days (glucose values stored every 5 minutes)
Sensor operating frequency	2.402 to 2.480 GHz BLE
Modulation	Gaussian Frequency-Shift Keying (GFSK)
Sensor transmission range	Minimum of 20 feet (6.09 m) line of sight in free-air
Sensor dimensions	1.128 × 1.128 × 0.188 in (2.865 × 2.865 × 0.477 cm)
Sensor 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 MiniMed 780G system user guide for performance data.

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 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

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REF MMT-5120

℞ *Only*

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