Medtronic

Simplera™ Sensor

User Guide

M052537C005_1

Contacts:

Africa:
Medtronic South Africa and Southern Africa
Office Reception Tel:
+27(0) 11 260 9300
Diabetes: 24/7 Helpline:
0800 633 7867
Sub-Sahara 24/7 Helpline:
+27(0) 11 260 9490

Albania / Shqipëria:
O.E.S. Distrimed sh.p.k.
Tel.: +355 402270660

Argentina:
Corpomedica S.A.
Tel.: +(11) 4 814 1333
Medtronic Directo 24/7:
+0800 333 0752

Armenia (AM):
Exiol LLC
Tel.: +374 98 92 00 11
or +374 94 38 38 52

Australia:
Medtronic Australasia Pty. Ltd.
Tel.: 1800 668 670

Austria / Österreich:
Medtronic Österreich GmbH
Tel.: +43 (0) 1 240 44-0
24 – Stunden – Hotline:
0820 820 190

Bangladesh (BD):
Sonargaon Healthcare Pvt Ltd.
Mobile: (+91)-9903995417
or (+880)-1714217131

Belarus (BY):
Zarga Medica
Tel.: +37517 336 97 00
+37529 613 08 08
+37517 215 02 89
Helpline: +74995830400

Belgium / Belgique / België:
N.V. Medtronic Belgium S.A.
Tel.: 0800-90805

Bosnia and Herzegovina / Bosna i Hercegovina:
"Novopharm" d.o.o. Sarajevo
Tel.: +387 33 476 444
Helpline: 0800 222 33
Epsilon Research Intern. d.o.o.
Tel.: +387 51 251 037
Helpline: 0800 222 33

Brazil / Brasil:
Medtronic Comercial Ltda.
Tel.: +55 (11) 2182-9200
Atendimento Diabetes 24/7:
0800 773 9200

Bulgaria / България:
RSR EOOD
Tel.: +359 888993083
Helpline: +359 884504344

Canada:
Medtronic Canada ULC
Tel.: 1-800-284-4416 (toll free/sans frais)

Chile:
Medtronic Chile
Tel.: +(9) 66 29 7126
Medtronic Directo 24/7:
+1 230 020 9750
Medtronic Directo 24/7 (From Santiago):
+(2) 595 2942

China / 中国:
Medtronic (Shanghai) Management Co., Ltd.
Landline: +86 800-820-1981
Mobile Phone: +86 400-820-1981
Calling from outside China:
+86 400-820-1981

Colombia:
Medtronic Latin America Inc. Sucursal Colombia
Tel.: +(1) 742 7300
Medtronic Directo 24/7 (Landline):
+01 800 710 2170
Medtronic Directo 24/7 (Cellular):
+1 381 4902

Croatia / Hrvatska:
Mediligo d.o.o.
Tel.: +385 1 6454 295
Helpline: +385 1 4881144
Medtronic Adriatic d.o.o.
Helpline: +385 1 4881120

Czech Republic / Česká republika:
Medtronic Czechia s.r.o.
Tel.: +420 233 059 111
Non-Stop Helpline (24/7):
+420 233 059 059
Zákaznický servis (8:00 - 17:00):
+420 233 059 950

Denmark / Danmark:
Medtronic Danmark A/S
Tel.: +45 32 48 18 00

Estonia / Eesti:
AB Medical Group Estonia Ltd
Tel.: +372 6552310
Helpline: +372 5140694

Europe:
Medtronic Europe S.A. Europe,
Middle East and Africa HQ
Tel.: +41 (0) 21-802-7000

Finland / Suomi:
Medtronic Finland Oy
Tel.: +358 20 7281 200
Help line: +358 800 164 064

France:
Medtronic France S.A.S.
Tel.: +33 (0) 1 55 38 17 00

Germany / Deutschland:
Medtronic GmbH
Geschäftsbereich Diabetes
Telefon: +49 2159 8149-370
Telefax: +49 2159 8149-110
24-Stdn-Hotline: 0800 6464633

Greece / Ελλάδα:
Medtronic Hellas S.A.
Tel.: +30 210677-9099

Hong Kong / 香港:
Medtronic Hong Kong Medical Ltd.
Tel.: +852 2919-1300
To order supplies: +852 2919-1322
24-hour helpline: +852 2919-6441

Hungary / Magyarország:
Medtronic Hungária Kft.
Tel.: +36 1 889 0688

Iceland:
AZ Medica ehf
Tel.: +354 564 5055

India:
India Medtronic Pvt. Ltd.
Tel.: (+91)-22-48810700; 48810701
Patient Care Helpline: 1800 209 6777

Indonesia:
Medtronic International Ltd.
Tel.: +65 6436 5090 or +65 6436 5000

Ireland / Éire:
Accu-Science LTD.
Tel.: +353 45 433000

Israel / ישראל:
Medtronic Trading Ltd.
Tel.: +972-9-9724400
Tel.: (product support –
8:00-17:00): +972-9-9724489
Helpline (weekends & holidays):
1-800-611-888

Italy / Italia:
Medtronic Italia S.p.A.
Tel.: +39 02 24137 261
Fax: +39 02 24138 210
Servizio assistenza tecnica:
Nº verde: 800 60 11 22

Japan / 日本:
Medtronic Japan Co. Ltd.
24 Hr. Support Line: 0120-56-32-56
日本メドトロニック株式会社
24 時間サポートライン：0120-56-32-56

Kazakhstan / Қазақстан / Казахстан:
ТОО "Медтроник Казахстан"
Tel.: +7 727 321 13 30 (Almaty)
Круглосуточная линия поддержки:
8 800 080 5001

Kosovo / Kosova:
Yess Pharma
Tel.: +377 44 999 900
Helpline: +37745888388

Latin America / América Latina:
Medtronic, Inc.
Tel.: 1(305) 500-9328
Fax: 1(786) 709-4244

Latvia / Latvija:
RAL SIA
Tel.: +371 67316372
Helpline (9am to 6pm):
+371 29611419

Lithuania / Lietuva:
Monameda UAB
Tel.: +370 68405322
Helpline: +370 68494254

Macedonia / Македонија:
Alkaloid Kons Dooel
Tel.: +389 23204438

Malaysia:
Medtronic International Ltd.
Tel.: +603 7946 9000

Mexico / México:
Medtronic Servicios S. de R. L. de C.V.
Tel. (México DF): +(11) 029 058
Tel. (Interior): +01 800 000 7867
Medtronic Directo 24/7 (from México DF):
+(55) 36 869 787
Medtronic Directo 24/7:
+01 800 681 1845

Middle East and North Africa:
Regional Office
Tel.: +961-1-370 670

Montenegro / Crna Gora/Црна Гора:
Urion d.o.o.
Tel.: +382 20 290520

Netherlands, Luxembourg / Nederland, Luxemburg / Holland, Lëtzebuerg:
Medtronic B.V.
Tel.: +31 (0) 45-566-8291
Gratis: 0800-3422338

New Zealand:
Medica Pacifica
Phone: 64 9 414 0318
Free Phone: 0800 106 100

Norway / Norge:
Medtronic Norge A/S
Tel.: +47 67 10 32 00
Fax: +47 67 10 32 10

Philippines / Pilipinas:
Medtronic International Ltd.
Tel.: +65 6436 5090
or +65 6436 5000

Poland / Polska:
Medtronic Poland Sp. z o.o.
Tel.: +48 22 465 6934

Portugal:
Medtronic Portugal Lda
Tel.: +351 21 7245100
Fax: +351 21 7245199

Puerto Rico:
Medtronic Puerto Rico
Tel.: 787-753-5270

Republic of Korea / 대한민국:
Medtronic Korea, Co., Ltd.
Tel.: +82.2.3404.3600

Romania / România:
Medtronic Romania S.R.L
Tel.: +40 372188017
Helpline: +40 372188010

Russia / Россия:
ООО «Медтроник»
Tel.: +7 495 580 73 77
Круглосуточная линия поддержки:
8 800 200 76 36

Serbia / Srbija:
Medtronic Serbia D.o.o.
Helpline: +381 112095900

Singapore:
Medtronic International Ltd.
Tel.: +65 6436 5090
or +65 6436 5000

Slovakia / Slovenská republika:
Medtronic Slovakia, s.r.o.
Tel.: +421 26820 6942
HelpLine: +421 26820 6986

Slovenia / Slovenija:
Zaloker & Zaloker d.o.o.
Tel.: +386 1 542 51 11
24-urna tehnična pomoč:
+386 51316560

Spain / España:
Medtronic Ibérica S.A.
Tel.: +34 91 625 05 42
Fax: +34 91 625 03 90
24 horas: +34 900 120 330

Sri Lanka (LK):
Swiss Biogenics Ltd.
Mobile: (+91)-9003077499
or (+94)-777256760

Sweden / Sverige:
Medtronic AB
Tel.: +46 8 568 585 20
Fax: +46 8 568 585 11

Switzerland / Schweiz / Suisse / Svizzera:
Medtronic (Schweiz) AG
Tel.: + 41 (0) 31 868 0160
24-Stunden-Hotline: 0800 633333
Fax Allgemein: +41 (0)318680199

Taiwan / 台灣:
Medtronic (Taiwan) Ltd.
Tel.: 02-21836000
Toll Free: +886-800-005285

Thailand / ประเทศไทย:
Medtronic (Thailand) Ltd.
Tel.: +662 232 7400

Turkey / Türkiye:
Medtronic Medikal Teknoloji
Ticaret Ltd. Şirketi.
Tel.: +90 216 4694330

Ukraine / Україна:
ТОВ «Медтронік Україна»,
Лінія цілодобової підтримки:
Тел.: 0 800 508 300

United Kingdom:
Medtronic Ltd.
Tel.: +44 1923-205167

USA:
Medtronic Diabetes Global Headquarters
24-Hour Technical Support: +1-800-646-4633
To order supplies: +1-800-843-6687

Vietnam / Việt Nam:
Medtronic Vietnam
Tel.: +84 283 926 2000

Icon table

EC REP	Authorized representative in the European Community/European Union
LOT	Batch code
	Bluetooth® wireless technology or Bluetooth® enabled
REF	Catalogue number
CE0459	Conformité Européenne (European Conformity). Device fully complies with applicable European Union Acts.
	Date of manufacture (DoM)
	Do not re-use
	Do not use if package is damaged and consult instructions for use
(5x)	Five sensors per container/package
www.medtronicdiabetes.com/manuals	Follow instructions for use or electronic 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
STERILE EO	Sterilized using ethylene oxide
+XX%	Humidity upper limit
XX°C XX°F XX°C XX°F	Temperature limits
	Type BF applied part
	Use-by date

	Caution: consult instructions for use for important warnings or precautions not found on the label
SN	Serial number
MD	Medical Device
CODE: XXX-XXX	Sensor pairing code
	Contains human blood or plasma derivatives
BIO	Contains biological material of human origin
UDI	Unique Device Identifier symbol
	RF Compliance Mark (RCM) Complies with ANZ radio communications requirement
Rx *Only*	Requires prescription in the USA
CC	Country of manufacture (and Date of manufacture when a date appears beside)
2 STERILIZE	Do not re-sterilize
	Manufacturing site

	Importer

Introduction

The Simplera sensor (MMT-5100J) with Bluetooth® wireless technology is a component of the Medtronic personal continuous glucose monitoring (CGM) system.

The Simplera 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 values to the Simplera app.

Intended use

The Simplera sensor is a single-patient, single-use component of the Simplera system. It is intended to communicate with the Simplera app via Bluetooth Low Energy (BLE) to provide glucose information for diabetes management. It calculates glucose concentrations based on collected signals from the interstitial fluid and transmits glucose and device data to the mobile device.

The Simplera system is intended for use in home environments.

Indications for use

The Simplera system is a real-time continuous glucose monitoring (CGM) system indicated for the management of diabetes in persons ages 18 years and older.

The Simplera system does not require calibration and is designed to replace fingerstick BG testing for diabetes treatment decisions, unless otherwise indicated.

Interpretation of the Simplera system results should be based on the glucose trends and several sequential sensor readings over time.

Intended target population

The intended target population for the Simplera sensor includes adults ages 18 years and older.

Intended users

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

Contraindications

The Simplera sensor has no known contraindications.

Intended clinical benefits

Although the Simplera sensor does not provide any therapy or treatment, the continuous glucose information provided by the sensor used in combination with the Simplera app can aid

in diabetes management. The Simplera sensor benefits users by eliminating the discomfort associated with fingerstick glucose measurements used for calibration or confirmation of the information provided by the CGM system.

User safety

Warnings and precautions

Read this entire user guide before attempting to insert the Simplera 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 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 14*.

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 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 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 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 insertion site infection if inserted into the body.

Do not use the Simplera 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 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 nonpyrogenic 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 insertion 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 sensor. Changing or modifying the sensor can result in improper insertion, pain, or injury.

Do not let children hold the Simplera 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.

Watch for bleeding at the insertion site on top of the Simplera 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 sensor and continue to apply steady pressure until the bleeding stops.
2. Dispose of the Simplera sensor. See *Disposal, page 24*.
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 sensor in a different location.

Some skin care products, such as sunscreens and insect repellents, can damage the Simplera 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.

If a serious incident related to the device occurs, immediately report the incident to Medtronic and to the applicable competent authority with jurisdiction in their locale.

Exposure to magnetic fields and radiation

Do not expose the Simplera 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 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.

Risks

General risks with Simplera 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 sensor contains nickel in stainless steel.

Reagents

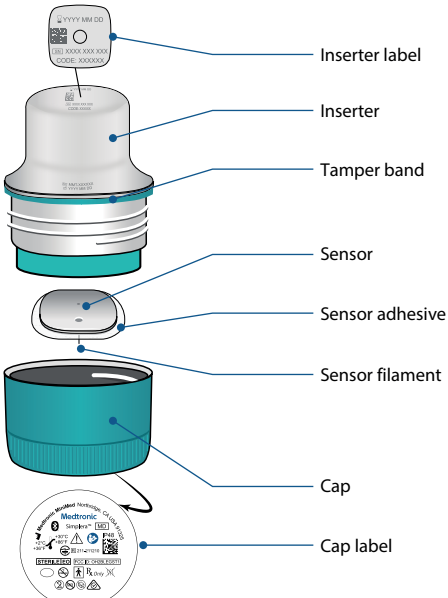
The Simplera sensor contains two biological reagents: glucose oxidase, and human serum albumin (HSA).

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 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.

Download the Simplera app

Search for and download the Simplera app from the Apple™* App Store™* or the Google Play™* store on the supported mobile device.

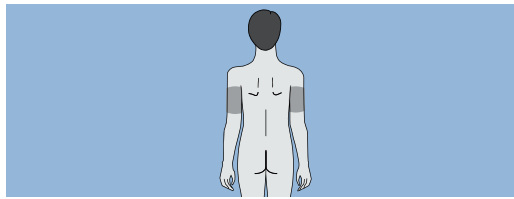
Simplera sensor device components



Where to insert the Simplera sensor

The following image shows the insertion site for ages 18 years and older. Target the shaded areas shown in the image, and make sure that the insertion site has a sufficient amount of fat.

Ages 18 years and older



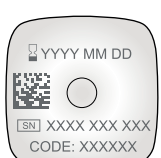
Back of upper arm

Insertion on abdomen and upper buttocks for ages 18 years and older has not been evaluated for accuracy.

Inserting the Simplera sensor

Preparing for insertion

1



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

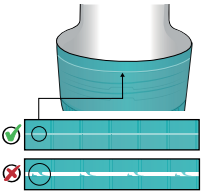
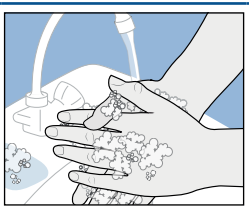
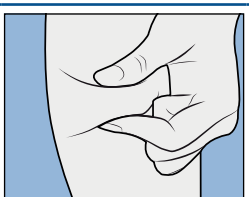
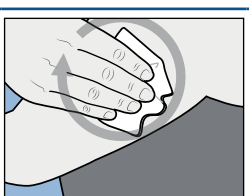
- Inspect the expiration date. Do not use an expired Simplera sensor.
- Make note of the serial number (SN) and the CODE. Both numbers will be used later to pair the sensor with the Simplera app.

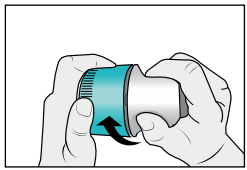
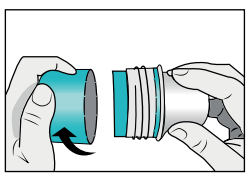
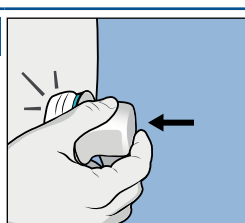
Note: The SN and CODE label is also on the inside of the Simplera sensor box lid.

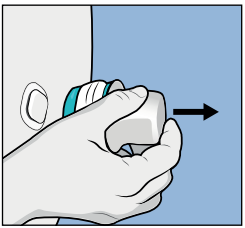
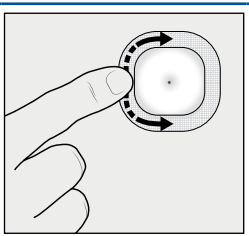
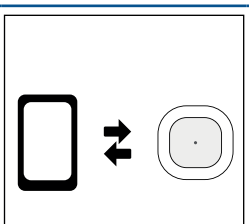
2

Inspect the cap label for damage before insertion.

Note: Do not use the Simplera 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 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 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 site see *Where to insert the Simplera sensor, page 16*. For the best sensor performance, and to avoid accidental sensor removal, do not insert the Simplera 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 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 sensor with a compatible mobile device. **Note:** The SN and CODE are required to pair the sensor with a compatible mobile device. For details on how to pair the sensor with a compatible mobile device and the Simplera app, see the Simplera 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 sensor

To remove the Simplera sensor:

1. Gently peel the sensor adhesive away from the body.
2. Dispose of the Simplera sensor in accordance with all local laws and regulations. For additional information, see *Disposal, page 24*.

Simplera sensor wireless communication

Quality of service

The Simplera sensor connects to a compatible mobile device via a Bluetooth low-energy technology network. The sensor sends glucose data and system-related alerts to the compatible mobile 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 sensor is designed to only accept radio frequency (RF) communications from a recognized and linked compatible mobile device. The sensor must be paired with the mobile device before the mobile 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 sensor is safe for use on commercial airlines.

FCC notice

The Simplera 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.

Changes or modifications not expressly approved by Medtronic could void the user's 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%
Sensor glucose measurement range	50 to 400 mg/dL

Storage

CAUTION: Do not freeze the Simplera 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 sensor life of use

The Simplera 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.

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Assistance

Contact the local representative or refer to the local Medtronic website for assistance. Refer to the Medtronic Diabetes International Contacts list in this user guide for contact information.

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

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Medtronic

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

Medtronic Puerto Rico
Operations Company
Carr 31, Km. 24.4
Juncos, Puerto Rico 00777

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