

# Guardian™ 4

Sensor User Guide





## Introduction

The Guardian™ 4 sensor is part of the Continuous Glucose Monitoring (CGM) system. The sensor converts small amounts of glucose from the interstitial fluid under the skin into an electronic signal. The system then uses these signals to provide sensor glucose (SG) values.



Sensor assembly

## Indications for use

The Guardian 4 sensor (MMT-7040) is intended for use with the Guardian 4 transmitter (MMT-7841) to monitor glucose levels in persons with diabetes where self monitoring of blood glucose (SMBG) is indicated. The sensor is designed to replace fingerstick blood glucose (BG) readings for diabetes treatment decisions.

The sensor is intended for insertion into persons ages 7 years and older. The sensor is intended for insertion into the back of the upper arm or the upper buttocks in persons ages 7 through 17 years. The sensor is intended for insertion into the back of the upper arm or the abdomen in persons ages 18 years and older.

## Contraindications

No contraindications are associated with Guardian 4 sensor use. For contraindications related to CGM, see the system user guide.

## Clinical benefits

The Guardian 4 sensor is a component of the CGM system that provides SG values. See the system user guide for the clinical benefits of systems that use the Guardian 4 sensor.

## User safety

### Warnings

Read this entire user guide before attempting to insert the Guardian 4 sensor. The one-pressserter (MMT-7512) is the onlyserter 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.

The system can replace testing except in the below situations. These are the times when you need to do a BG test before deciding what to do or what treatment decision to make as a sensor reading may not accurately reflect BG levels:

**Always use your BG meter:**

- during the first 12 hours of wearing the sensor
- when you aren't sure if your SG value is correct
- when your symptoms don't match your SG value, do not ignore symptoms that may be due to low or high glucose
- when a SG value isn't available
- when you have taken medications that contain acetaminophen (such as Tylenol®), paracetamol, or hydroxyurea as they may cause your SG to become falsely raised

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 SG readings compared to BG readings. Taking hydroxyurea while using continuous glucose monitoring can result in hypoglycemia caused by over-delivery of insulin and substantially higher SG readings in reports than actual BG 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 BG 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 SG 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. Use additional BG meter readings to confirm BG levels.

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 a local Medtronic support representative 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 may pose a choking hazard that can result in serious injury or death.

If a person different from the patient helps with inserting the

sensor:

- 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. Refer to a healthcare professional for indications on how to treat the condition.
3. Insert a new sensor in a different location.



Plastic base

For questions or concerns related to sensor use, contact a local Medtronic support representative for assistance.

For medical questions or concerns, contact a healthcare professional.

If a serious incident related to the device occurs, immediately report the incident to the manufacturer and local competent authority.

**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.

Continuous glucose monitoring is not recommended for people who are unable or unwilling to maintain contact with their healthcare professional.

Successful CGM use requires sufficient vision or hearing to allow recognition of the alerts generated by the compatible system.

## **Risks and side effects**

Keep the Guardian 4 sensor out of reach of children. The sensor may pose a choking hazard that can result in serious injury or death.

Other 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 needle was inserted
- Allergic reaction
- Fainting secondary to anxiety or fear of needle insertion
- Soreness or tenderness
- Swelling at insertion site
- Sensor fracture, breakage or damage
- Minimal blood splatter associated with sensor needle removal
- Residual redness associated with adhesive or tapes or both
- Scarring

## **Hazardous substances**

None.

## **Allergens**

None known.

## **Reagents**

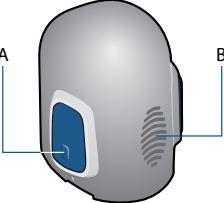
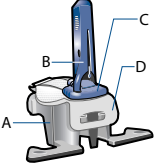
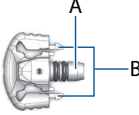

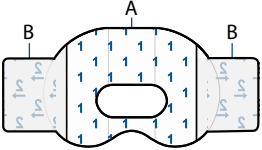
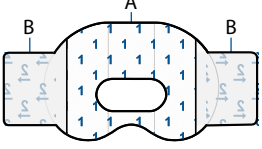
The Guardian 4 sensor contains two biological reagents: glucose oxidase, and human serum albumin (HSA). Glucose oxidase is derived from *Aspergillus niger* and manufactured to meet industry

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 cross-linked via glutaraldehyde. Approximately 3  $\mu\text{g}$  of glucose oxidase and approximately 10  $\mu\text{g}$  of HSA are used to manufacture each sensor. HSA is approved for IV infusion in humans at quantities much larger than in the sensor.

## Remove 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.

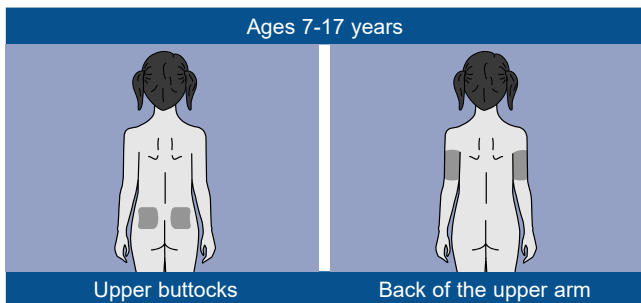
## Components

	<p><b>One-pressserter</b></p> <p>A. bump on both buttons B. thumbprint marking</p>
	<p><b>Glucose sensor assembly</b></p> <p>A. pedestal B. needle housing C. sensor D. clear liner</p>
	<p><b>Sensor base</b></p> <p>A. sensor connector B. sensor snaps</p>
	<p><b>Transmitter</b></p>
	<p><b>First piece of oval tape</b></p> <p>A. liner 1 B. liner 2</p>
	<p><b>Second piece of oval tape</b></p> <p>A. liner 1 B. liner 2</p>



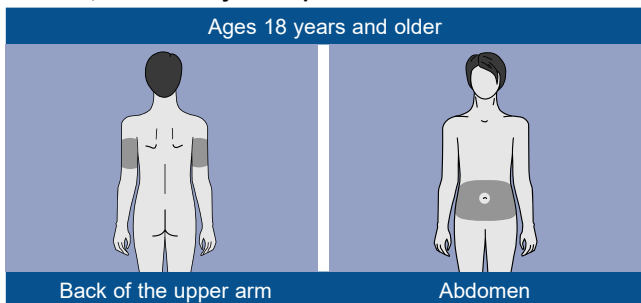
## Where to insert the sensor

Choose an insertion site for the applicable age group. Target the shaded areas, and make sure that the insertion site has a sufficient amount of fat.



Insertion on abdomen for ages 7-17 years has not been evaluated for accuracy.

**Note: Insertion onto the upper buttocks should target the top third of the buttocks area. Assistance from another person may be needed for sensor insertion into the back of the upper arm or the upper buttock. If assistance is not needed, a mirror may be helpful for self insertion.**



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

**CAUTION: Avoid the 5.0 cm (2 inch) area around the navel to help make a comfortable insertion site and to help with sensor adhesion.**

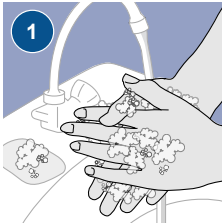
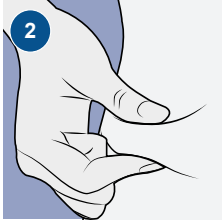
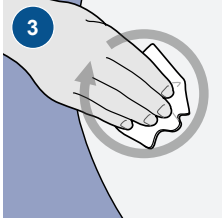
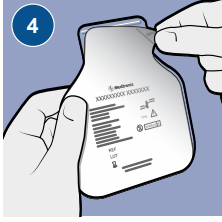
For best SG performance, and to prevent accidental sensor removal:

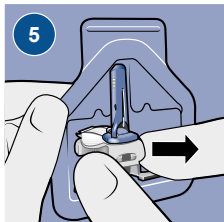
- Do not insert the sensor into muscle, tough skin, or scar tissue.
- Avoid areas that are constrained by clothing or accessories.

- Avoid areas that are located under a belt or waistband.
- 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.**

 <p>1</p>	<p>1. Wash hands thoroughly with soap and water.</p>
 <p>2</p>	<p>2. Choose an insertion site that has a sufficient amount of fat.</p>
 <p>3</p>	<p>3. Clean the insertion site with alcohol. Let the area air dry.</p>
 <p>4</p>	<p>4. Open the sensor package.</p>



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.

tucked tab



Correct



Incorrect

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



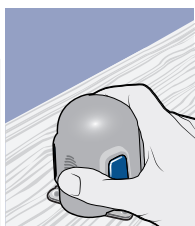
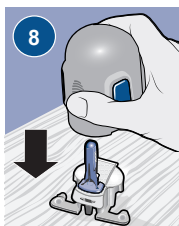
Correct



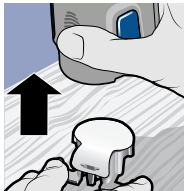
Incorrect

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

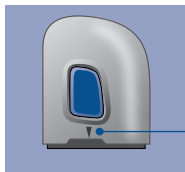
thumb on thumbprint marking



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



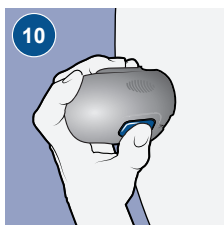
9. With either hand, place two fingers on the base of the pedestal. With the other hand, grip the inserter and pull the inserter upwards.



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

arrow

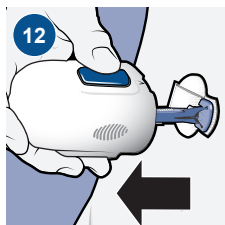
**WARNING:** Never point a loaded inserter toward any body part where insertion is not desired. An accidental button-push may cause the needle to inject the sensor in an undesired location, causing minor injury.



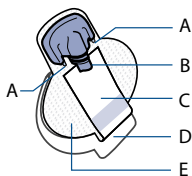
10. Place the inserter on top of the prepared insertion site.



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



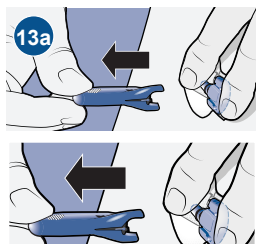
12. Lift the serter away from the insertion site. Fingers must not press the buttons while lifting the serter.



### Sensor base

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

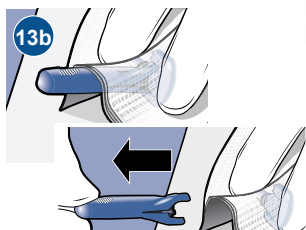
If the sensor is inserted without assistance, complete step 13a. If a person different from the patient assisted with sensor insertion, complete step 13b.



### Patient:

13. a. 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

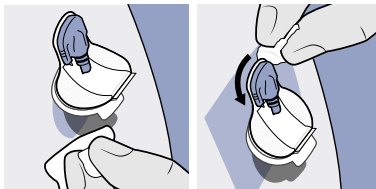


### Person different from the patient:

13. b. 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.



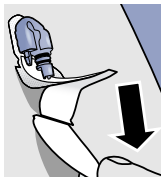
**Note:** After insertion, use of adhesive products, such as Skin Tac™, in addition to the oval tape is optional. If optional adhesive products are used, apply them to the skin under the adhesive pad prior to removing the liner. Adhesive products may also be applied to the adhesive pad or the skin around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

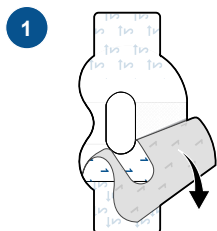


16. Untuck the adhesive tape from under the sensor connector.

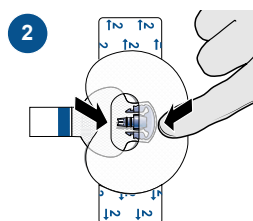


17. Straighten the sensor adhesive tab so that it lies flat against the skin.

### Applying Oval Tape

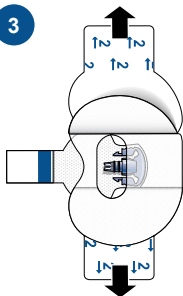


1. Remove the liner marked 1.



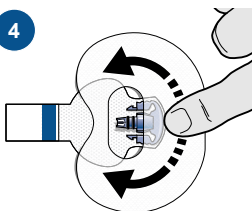
2. Apply the tape as shown and press down firmly.

3



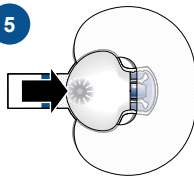
3. Remove liners marked 2 from each side.

4



4. Smooth the tape.

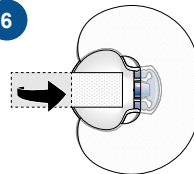
5



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



6. Cover the transmitter with the adhesive tab.

**Note:** Do not pull the tab too tightly.

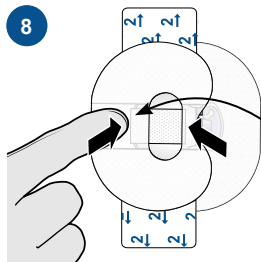


7



7. To apply a second tape, remove liner marked 1.

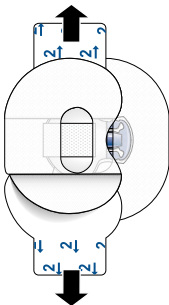
8



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

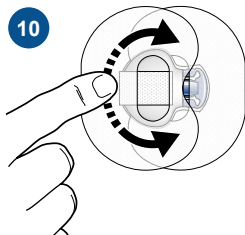
wide part of tape covers end of transmitter and skin

9



9. Remove liners marked 2 from each side.

10



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

### Cleaning

The Guardian 4 sensor is a single-use, disposable device. No cleaning or maintenance is required.

### 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 2 °C to 27 °C (36 °F to 80 °F).

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

### Disposal









Dispose of the Guardian 4 sensor into a sharps container.
















## Technical specifications

<b>Approximate dimensions</b>
3.8 x 6.7 x 5.2 centimeters (1.5 x 2.6 x 2.0 inches)
<b>Approximate weight</b>
2.80 grams (.09 ounces)

### Sensor life of use

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

Icon table	
	Use-by date
	Medical device
	Importer
	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
	Catalogue number
	Batch code

	Sterilized using irradiation
	Do not use if package is damaged
	Single sterile barrier system
	Storage temperature limit
	Open here
	Manufacturer
	Date of manufacture
	Do not resterilize
	Fragile, handle with care
	Keep dry
	Recyclable, contains recycled content
	Authorized representative in the European Community
	Conformité Européenne (European Conformity). This symbol means that the device fully complies with applicable European Union Acts.
	Magnetic Resonance (MR) unsafe
	Non-pyrogenic

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**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:**

Net Electronics Albania  
Tel.: +355 697070121

**Argentina:**

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

**Armenia:**

Exiol LLC  
Tel.: +374 98 92 00 11  
or +374 94 38 38 52

**Australia:**

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

**Bangladesh:**

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

**Belarus:**

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

**België/Belgique:**

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

**Bosnia and Herzegovina:**

"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

**Brasil:**

Medtronic Comercial Ltda.  
Tel.: +(11) 2182-9200  
Medtronic Directo 24/7:  
+0800 773 9200

**Bulgaria:**

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:**

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:**

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

**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

**Danmark:**

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

**Deutschland:**

Medtronic GmbH  
Geschäftsbereich Diabetes  
Telefon: +49 2159 8149-370  
Telefax: +49 2159 8149-110  
24-Std-Hotline: 0800 6464633

**Eire:**

Accu-Science Ltd.  
Tel.: +353 45 433000

**España:**

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

**Estonia:**

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

**France:**

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

**Hellas:**

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

**Hong Kong:**

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

**India:**

India Medtronic Pvt. Ltd.  
Tel.: (+91)-80-22112245 /  
32972359  
Mobile: (+91)-9611633007  
Patient Care Helpline:  
1800 209 6777

**Indonesia:**

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

**Israel:**

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

**Italia:**

Medtronic Italia S.p.A.  
Tel.: +39 02 24137 261  
Fax: +39 02 24138 210  
Servizio assistenza tecnica:  
N° verde: 800 60 11 22

**Japan:**

Medtronic Japan Co. Ltd.  
Medtronic Japan  
24hr. Support Line:  
0120-56-32-56  
日本: 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:**

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

**Kosovo:**

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

**Latin America:**

Medtronic, Inc.  
Tel.: 1(305) 500-9328  
Fax: 1(786) 709-4244

**Latvija:**

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

**Lithuania:**

Monameda UAB  
Tel.: +370 68405322  
Helpline: +370 68494254

**Macedonia:**

Alkaloid Kons Dooel  
Tel.: +389 23204438

**Magyarország:**

Medtronic Hungária Kft.  
Tel.: +36 1 889 0688

**Malaysia:**

Medtronic International Ltd.  
Tel.: +603 7946 9000

**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:**

Glosarij d.o.o.  
Tel.: +382 20642495

**Nederland, Luxembourg:**

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

**Norge:**

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

**Philippines:**

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

**Россия:**

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

**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:**

Medtronic Korea, Co., Ltd.  
Tel.: +82.2.3404.3600

**Romania:**

Medtronic Romania S.R.L.  
Tel.: +40 372188017  
Helpline: +40 726677171

**Schweiz:**

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

**Serbia:**

Epsilon Research International  
d.o.o.  
Tel.: +381 113115554

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

**Singapore:**

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

**Slovenija:**

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

**Slovenská republika:**

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

**Sri Lanka:**

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

**Suomi:**

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

**Sverige:**

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

**Taiwan:**

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

**Thailand:**

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

**Türkiye:**

Medtronic Medikal Teknoloji  
Ticaret Ltd. Sirketi.  
Tel.: +90 216 4694330

**Ukraine:**

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

**USA:**

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

**United Kingdom:**

Medtronic Ltd.  
Tel.: +44 1923-205167

**Vietnam:**

Medtronic Vietnam  
Tel.: +84 283 926 2000

**Österreich:**

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



# Medtronic



**Medtronic MiniMed**

18000 Devonshire Street

Northridge, CA 91325

USA

1 800 646 4633

+1 818 576 5555

[www.medtronicdiabetes.com](http://www.medtronicdiabetes.com)

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Medtronic B.V.

Earl Bakkenstraat 10

6422 PJ Heerlen

The Netherlands

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