DS5 Sensor

User Guide

M050862C001_1

Exclusively for Clinical Investigation.

CAUTION: Investigational device. Limited by United States Law to investigational use.

Medtronic

Introduction

The DS5 sensor is designed to detect, measure, store the interstitial glucose signal, and sensor diagnostic data throughout the duration of sensor wear. At the end of the study, the sensor is removed from the patient and the stored data is downloaded using a personal computer (PC) download application.

Indications for use

The DS5 sensor is intended to communicate with a compatible download utility to record glucose information.

The DS5 sensor is intended for single-patient, single-use only.

All components of the DS5 sensor are disposable. The sensor is pre-loaded into the disposable inserter.

Contraindications

No contraindications are associated with the DS5 sensor use.

User safety

Warnings and precautions

Read this entire user guide before attempting to insert the DS5 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 DS5 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” on page 3.

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. 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 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 DS5 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 DS5 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 DS5 sensor if the device is dropped (inside or outside of the customer box). If the sensor is dropped, return the sensor to the clinical site.

Do not use the DS5 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 DS5 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 site infection if inserted into the body.

Do not unscrew or remove the DS5 sensor cap until the device is ready to be used. Do not remove the cap and place it back on the device. 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 change or modify the DS5 sensor. Changing or modifying the sensor can result in improper insertion, pain, or injury.

Do not let children hold the DS5 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 DS5 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 DS5 sensor and continue to apply steady pressure until the bleeding stops.
2. Dispose of the DS5 sensor. See "Disposal" on page 15.
3. Check the 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 DS5 sensor in a different location.

Some skin care products, such as sunscreens and insect repellents, can damage the DS5 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.

Report any adverse reactions associated with the DS5 sensor to 24-Hour Technical Support. Adverse reactions can cause serious injury.

Exposure to magnetic fields and radiation

Do not expose the DS5 sensor to Magnetic Resonance Imaging (MRI) equipment, diathermy devices, or other devices that generate strong magnetic fields (for example, x-ray, CT scan, or other types of radiation). Exposure to strong magnetic fields has not been evaluated and can cause the sensor to malfunction, result in serious injury, or be unsafe.

IEC 60601-1-2: 4th Edition; Special EMC Precautions for Medical Electrical Equipment

- 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.
- 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.
- Be careful when using the DS5 sensor closer than 30 cm (12 in) 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.
- The essential performance (EP) of the DS5 sensor is to measure and transmit to a monitoring device the sensing device's signal value(s) within the sensor's accuracy requirements under the specified use conditions outlined in the DS5 system user

guide and for the duration of the expected service life. If the sensor experiences electromagnetic disturbances, either no or incorrect data may be transmitted. In such situations, refer to the operation, maintenance, and troubleshooting instructions within the applicable user guides. If the sensor is damaged contact 24-Hour Technical Support for assistance.

Risks

General risks with DS5 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

The DS5 sensor contains 15µg Dexamethasone Acetate (DXAC). If you are sensitive to dexamethasone acetate or are concerned that you may be sensitive to dexamethasone acetate, please consult your health care provider or study personnel prior to using the device.

Hazardous substances

For materials information such as compliance with European Union (EU) Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), EU Restriction of Hazardous Substances (RoHS), and other product stewardship program requirements, please visit http://www.medtronic.com/productstewardship.

Allergens

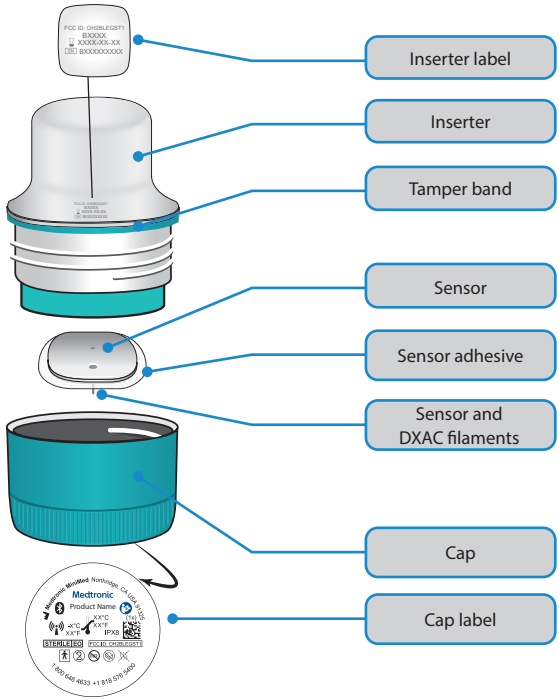
The DS5 sensor contains nickel in stainless steel.

Reagents

The DS5 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 DS5 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.

DS5 sensor device components



Where to insert the DS5 sensor

The images that follow show insertion sites for ages 2-17 years, and ages 18 years and older. Choose an insertion site for the applicable age group. Target the shaded areas shown in the image, and make sure that the insertion site has a sufficient amount of fat.

Ages 2-17 years

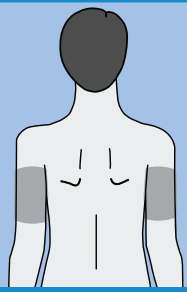
Back of upper arm

Upper buttock

Insertion on abdomen for ages 2-17 years has not been evaluated for accuracy.

Note: Insertion into 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.

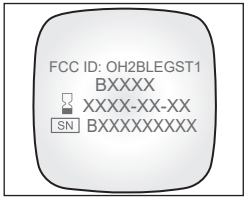
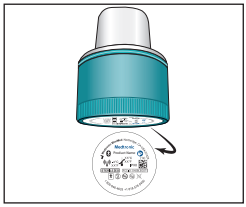
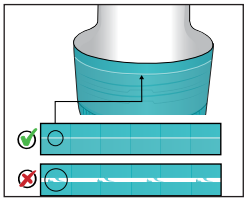
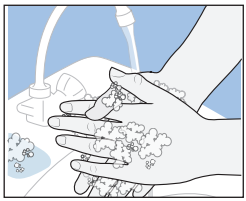
Ages 18 years and older

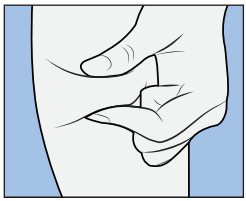
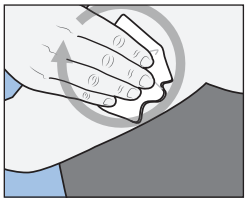
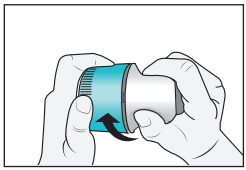
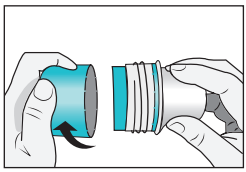


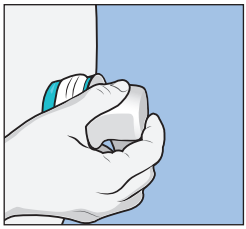
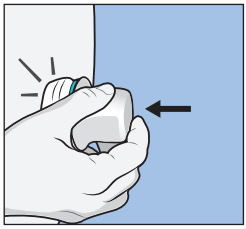
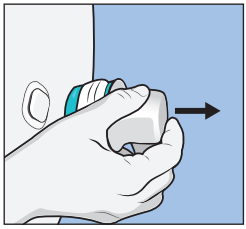
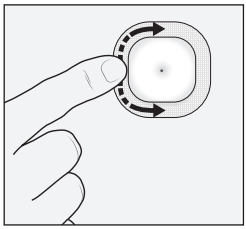
Back of upper arm

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

Inserting the DS5 sensor

1		The inserter label is on the rim of inserter. **1.** Before insertion, inspect the expiration date. Do not use an expired DS5 sensor.
2		**2.** Inspect the cap label for damage before insertion. **Note:** Do not use the DS5 sensor if the cap label is damaged or missing from the cap.
3		**3.** Inspect the tamper band to make sure that it is not broken, damaged, or missing from the device. **Note:** Do not use the DS5 sensor if the tamper band is broken, damaged, or missing from the device.
4		**4.** Wash hands thoroughly with soap and water. **Note:** Wear gloves when inserting the DS5 sensor into another person to avoid accidental contact with patient blood. Minimal bleeding can occur.

5		**5.** Choose an insertion site that has a sufficient amount of fat. For insertion sites see "Where to insert the DS5 sensor" on page 6. For the best sensor performance, and to avoid accidental sensor removal, do not insert the DS5 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		**6.** Clean the insertion site with alcohol. Allow the insertion site to air dry.
7	 	**7.** Unscrew the cap from the inserter, breaking the tamper band. **Note:** Do not use the DS5 sensor if the tamper band is broken, damaged, or missing from the device.

8		**8.** Place the inserter on top of the prepared insertion site.
9		**9.** Press the inserter firmly against the body until there is a click.
10		**10.** Gently pull the inserter straight out from the body.
11		**11.** Smooth down the sensor adhesive with a finger to ensure the sensor stays on the body for the entire duration of wear. **Note:** Use over-the-counter tape if needed for additional adhesion.

Bathing and swimming

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

Removing the DS5 sensor

To remove the DS5 sensor:

1. Gently peel the sensor adhesive away from the body.
2. Dispose of the DS5 sensor in accordance with all local laws and regulations. For additional information, see "Disposal" on page 15.

DS5 sensor wireless communication

Quality of service

The DS5 sensor connects a compatible download utility via a Bluetooth low-energy technology network. The quality of the connection is in accordance with the Bluetooth Specification v4.2.

Data security

The DS5 sensor is designed to accept radio frequency (RF) communications from a compatible download utility. The sensor must be paired with the download utility before the download utility accepts information from the sensor.

The download utility ensures data security via proprietary means and data integrity using error checking processes, such as cyclic redundancy checks.

Traveling by air

The DS5 sensor is safe for use on commercial airlines. Because travel rules are subject to change, it is advisable to check with the Transportation Safety Administration (TSA) before traveling. Do not go through the x-ray screening while wearing the sensor. Instead, ask for an alternative screening method.

FCC notice

This device 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.
Harmonic emissions	Not applicable	
Voltage fluctuations/ flicker emissions	Not applicable	

Guidance and manufacturer's Declaration-Electromagnetic Immunity			
Immunity Test	**IEC 60601-1-2:2020 Test Level**	**IEC 60601-1-2:2020 Compliance Level**	**Electromagnetic Environment Guidance**
Electrostatic discharge (ESD)	±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.
Conducted disturbances induced by RF fields	3 Vrms 150 kHz to 80 MHz 6 Vrms ISM bands between 150 kHz to 80 MHz	Not applicable	Requirement does not apply to this battery powered device.
Electrical fast transient/ burst	±2 kV 100 kHz repetition frequency	Not applicable	Requirement does not apply to this battery powered device.
Surge	Line to Line: ±0.5 kV, ±1 kV Line to Ground: ±0.5 kV, ±1 kV, ±2 kV	Not applicable	Requirement does not apply to this battery powered device.
Note: U_1 is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's Declaration-Electromagnetic Immunity			
Immunity Test	**IEC 60601-1-2:2020 Test Level**	**IEC 60601-1-2:2020 Compliance Level**	**Electromagnetic Environment Guidance**
Voltage dips, short interruptions, and voltage variations on power supply lines	0% U_T; 0.5 cycles (at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°) 0% U_T; 1 cycle (at 0°) 70% for 25/30 cycles (at 0°) 0% for 250/300 cycles	Not applicable	Requirement does not apply to this battery operated device.
Power frequency (50/60 Hz) magnetic field	30 A/m	30 A/m	For use in a typical domestic, commercial, or hospital environment.
Proximity fields from RF wireless communications equipment	IEC 60601-1-2:2020, Table 9	IEC 60601-1-2:2020, Table 9	For use in a typical domestic, commercial, or hospital environment.
Enclosure port immunity to proximity magnetic fields in the frequency range 9 kHz to 13.56 MHz	IEC 60601-1-2:2020, Table 11	IEC 60601-1-2:2020, Table 11	For use in typical domestic, commercial, or hospital environment.
Note: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's Declaration-Electromagnetic Immunity			
Immunity Test	**IEC 60601-1-2:2020 Test Level**	**IEC 60601-1-2:2020 Compliance Level**	**Electromagnetic Environment Guidance**
Radiated RF	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	10 V/m 80 MHz to 6 GHz 80% AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the transmitter than the recommended separation distance of 30 cm (12 in). 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: 
Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption, and reflection from structures, objects and people.			

Maintenance

The lights on the transmitter are intended for engineering use only and do not indicate proper operation of the sensor. The LED lights should not be used to make decisions about sensor life, function, or operation.

Operation

Operating temperature range	36°F to 104°F (2°C to 40°C)
Air pressure range	700 hPa to 1060 hPa (10.2 psi to 15.4 psi)
Operating relative humidity (RH) range	15% to 95%

Storage

CAUTION: Do not freeze the DS5 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

DS5 sensor life of use

The DS5 sensor can be used one time and has a maximum life of 410 hours (17 days + 2 hours). The 410-hour life span of the sensor begins within 30 minutes after insertion.

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

Return the DS5 sensor to the clinical site conducting the study.

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: http://www.ouah.org/ogay/hmac/.

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 DS5 sensor and package labels, see www.medtronicdiabetes.com/symbols-definitions.

Icon Table

	Follow instructions for use
	Non-ionizing electromagnetic radiation
	Do not re-use
	Magnetic Resonance (MR) unsafe
	Do not use if package is damaged and consult instructions for use
	Type BF applied part
	Caution: Federal law restricts this device to sale by or on the order of a physician
	Single sterile barrier system
	Do not re-sterilize
IP48	Protected against effects of continuous immersion in water at a depth of 8 feet (2.4 meters) for up to 30 minutes
	Non-pyrogenic
	Sterilized using ethylene oxide
	Temperature limits
	Humidity upper limit
	Caution: consult instructions for use for important warnings or precautions not found on the label
	Complies with ANZ radiocommunications requirements
	Contains a medicinal substance
	Catalogue number
	Batch code
	Date of Manufacture and Manufactured in the United States
	Use-by date
	Date of manufacture (DoM)





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