

Disposable Sensor

User Guide



**CAUTION: Investigational
Device Limited by Federal
Law to Investigational Use**

**Exclusively for Clinical
Investigation**

Medtronic

Introduction

The DS5 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.

The DS5 sensor is preloaded into the disposable inserter.

Indications for use

The DS5 is intended to communicate with a compatible device to provide glucose information for diabetes management.

The DS5 can be used as part of a personal continuous glucose monitoring (CGM) system. It is intended for single-patient, single-use only. All components of the DS5 are disposable.

The DS5 is indicated for use by persons ages 2 years and older.

Contraindications

None known.

User Safety

Warnings and Precautions

Read this entire user guide before attempting to insert the DS5. The DS5 does not work the same as other Medtronic™ insertion devices. Failure to follow directions may result in improper insertion, pain, or injury.

Do not use the DS5 adjacent to other electrical equipment that may cause interference with the normal system operation. For more information on electrical equipment that may cause interference with the normal system operation, see *Exposure to magnetic fields and radiation, on page 2*.

Taking medications with acetaminophen, such as Tylenol™, fever reducers, or cold medicine, while wearing the DS5 may falsely raise your sensor glucose readings.

The level of sensor inaccuracy depends on the amount of acetaminophen active in your body and may be different for each person. Always check the label of any medications to confirm whether acetaminophen is an active ingredient.

Always inspect the DS5 packaging for damage prior to use. The DS5 is sterile and non-pyrogenic, unless the tamper evidence tape

has been broken. Do not use the DS5 if the device is damaged or the tamper evidence tape is broken. Use of an unsterile DS5 can cause site infection.

Do not change or modify the DS5. Changing or modifying the DS5 can result in improper insertion, pain, or injury.

Do not allow children to put the small parts in their mouth. This product poses a choking hazard for young children.

Watch for bleeding at the insertion site on top of the sensor. If bleeding occurs, apply steady pressure with a sterile gauze or clean cloth placed on top of the sensor for up to 3 minutes. If bleeding continues, causes excessive pain or discomfort, or is significantly visible on top of the sensor, follow these steps:

1. Remove the sensor and continue to apply steady pressure until the bleeding stops. Return the DS5 to the clinical site conducting the study.
2. Check the site for redness, bleeding, irritation, pain, tenderness, or inflammation. Treat based on instructions from your healthcare professional.
3. Insert a new sensor in a different location.

Some skin care products, such as sunscreens and insect repellents, can damage the DS5. Do not allow skin care products to touch the DS5. Wash hands after using skin care products before touching the DS5. If any skin care products touch the DS5, immediately wipe with a clean cloth.

If a device is dropped (inside or outside of the customer box) then it should not be used and should be returned to the clinical site.

Contact the local Medtronic support representative if you experience any adverse reactions associated with the DS5. Adverse reactions can cause serious injury.

Exposure to magnetic fields and radiation

Do not expose the DS5 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 DS5 to malfunction, result in serious injury, or be unsafe. If the DS5 is inadvertently exposed to a strong magnetic field, discontinue use and contact the local Medtronic support representative for further assistance.

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.

Risks and side effects

General risks with DS5 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
- Residual redness associated with adhesive or tapes or both
- Scarring

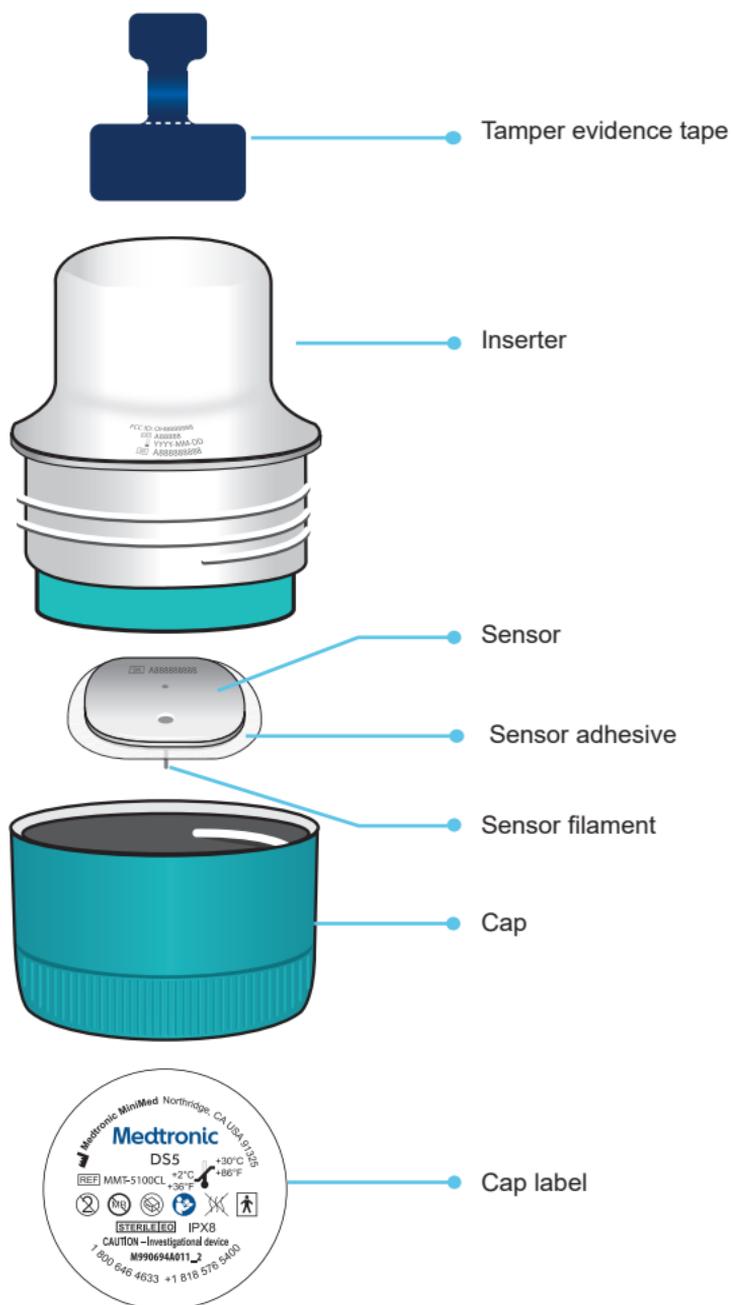
Reagents

The DS5 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 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 DS5. HSA is approved for IV infusion in humans at quantities much larger than in the DS5.

Components



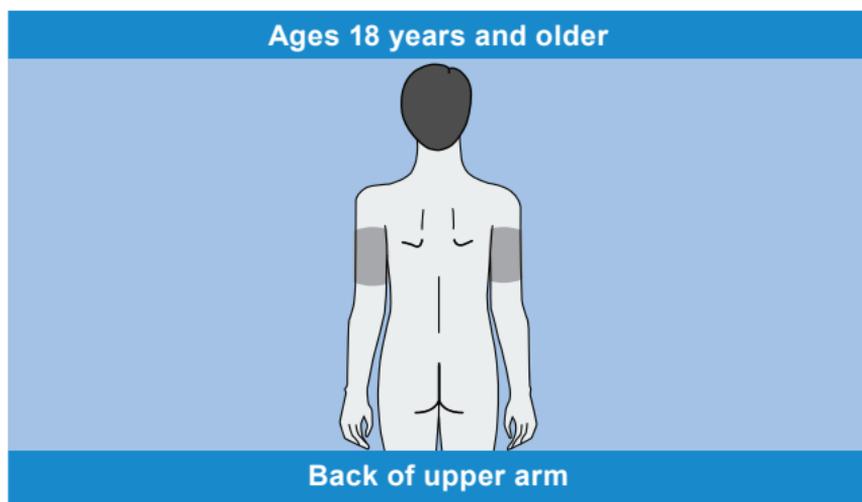
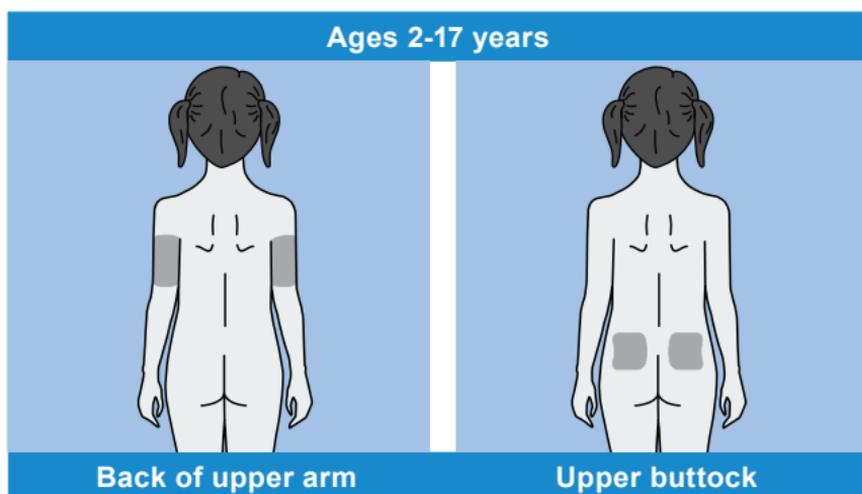
Where to insert the DS5

Choose an insertion site that has an adequate amount of fatty tissue. The DS5 is being investigated for use in particular insertion sites for specific age ranges.

DS5 insertion sites

The following table and images show the DS5 insertion sites for each age range.

Age range	DS5 insertion site
2 years to 17 years	Back of upper arm and upper buttock
18 years and older	Back of upper arm



For the best sensor performance, and to avoid accidental sensor removal, do not insert the DS5 into the following places.

- Muscle
- Areas with tough skin or scar tissue
- Areas subjected to rigorous movement during exercise
- Areas under a belt or on the waistline

Inserting the DS5

WARNING: Wear gloves when inserting the DS5 into someone other than yourself to avoid contact with patient blood.

Minimal bleeding can occur. Contact with patient blood can cause infection.

Note: Check the DS5 to make sure that the tamper evidence tape is not broken and that the label on the cap is attached securely and not torn.

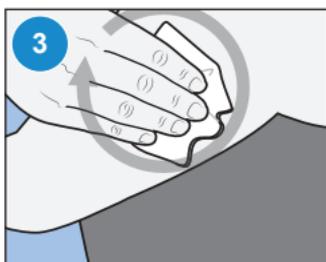
Note: Do not use an expired DS5. The use by date is on top of the inserter.



1. Wash hands thoroughly with soap and water.



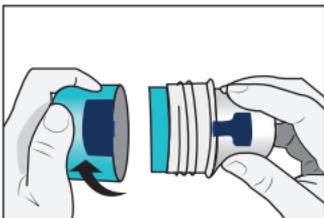
2. Choose an insertion site that has adequate fatty tissue. For insertion sites see *DS5 insertion sites*, on page 5.



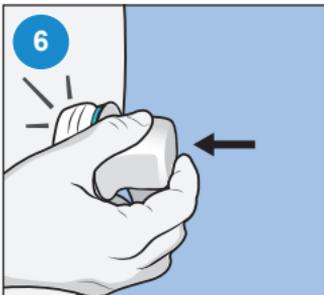
3. Clean the insertion site with alcohol. Let the insertion site air dry.



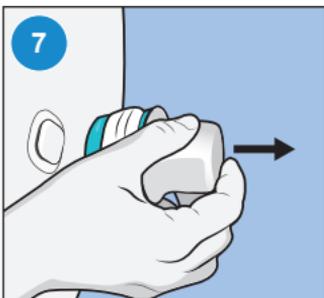
4. Unscrew the cap from the inserter, breaking the tamper evidence tape.



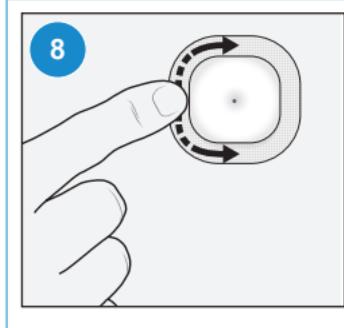
5. Place the inserter on top of the prepared insertion site.



6. Press the inserter firmly against the body until you hear a click.



7. Gently pull the inserter away from the body.



- Smooth down the sensor adhesive with your finger, to ensure the sensor stays on the body for the entire length of wear.

Note: Use over-the-counter (OTC) tape if needed for additional adhesion.

Removing the sensor

Warning: Wear gloves when removing the sensor from another person to avoid contact with patient blood. Minimal bleeding can occur. Contact with patient blood can cause infection.

Carefully peel off the sensor adhesive and the sensor from the skin.

DS5 wireless communication

Data Security

The DS5 is designed to only accept radio frequency (RF) communications from recognized devices.

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.

Traveling by air

The DS5 is safe for use on commercial airlines. Do not go through the x-ray screening. Ask for an alternative screening method.

Maintenance

Operation

The sensor has an operating temperature range from 36°F to

104°F (2°C to 40°C). The sensor has an air pressure range from 700 hPa to 1060 hPa (10.2 psi to 15.4 psi). The sensor has an operating relative humidity (RH) range of 15% to 90%.

Storage

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

Only store sensors at room temperature between 36°F to 86°F (2°C to 30°C). Do not store the sensor above its relative humidity (RH) of 95%.

Sensor life of use

The sensor is single-use only, and has a maximum life of 170 hours (7 days plus a 2 hour warm-up period). The 170 hour life span of the sensor begins within 30 minutes after insertion.

Disposal

Return the DS5 to the clinical site conducting the study.

Assistance

Department	Telephone Number
24-Hour Technical Support (calls within the United States)	+1 800 646 4633 x21009
Website	www.medtronicdiabetes.com

Icon table

For definitions of the symbols on the device and package labels, see www.medtronicdiabetes.com/symbols-definitions.

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