

ENLITE™

Glucose Sensor



Medtronic

Indications for use

The Enlite glucose sensor (sensor) is indicated for use with Medtronic Diabetes (Medtronic) glucose sensing systems to continuously monitor glucose levels in persons age 7 or older with type 1 diabetes.

The sensor is indicated for use as an adjunctive device to complement, not replace, information obtained from standard blood glucose monitoring devices. The sensor may be used as part of a system with Guardian Connect and with iPro 2 (MMT-7745). The sensor may also be used as part of a system with the Paradigm Veo (MMT-554/MMT-754) and MiniMed 640G insulin pumps. The insulin pump system can use the sensor glucose values as an input to automatically suspend insulin delivery. The indication for children ages 7 through 17 is limited to those who are supervised by a caregiver. The caregiver must be at least 18 years of age.

Contraindications

None known.

Warnings

The Enlite glucose sensor is only intended to be used by patients (aged 7 years and older) with type 1 diabetes.

Health care professionals and consumers should be aware about the limitations of available scientific evidence for use of this device in any other groups of patients who require diabetes management.

Nevertheless, it would not be unreasonable to allow the clinical data derived from type 1 diabetes to be adduced to other forms of diabetes which are truly insulin dependent or deficient, including severe insulin deficient secondary diabetes, and some with cystic fibrosis related diabetes, where the achievement of adequate glycaemic control may benefit from continuous glucose monitoring or continuous subcutaneous insulin infusion.

During times of rapidly changing glucose (more than 0.1 mmol/L (2 mg/dL) per minute), interstitial fluid glucose levels as measured by the Enlite glucose sensor may not accurately reflect blood glucose levels. Under these circumstances, check the Sensor glucose readings by conducting a fingerstick test using a blood glucose meter.

In order to confirm hypoglycaemia or impending hypoglycaemia as reported by the Enlite glucose sensor, conduct a fingerstick test using a blood glucose meter.

Do not ignore symptoms that may be due to low or high blood glucose. If you have symptoms that do not match the Enlite glucose sensor reading or suspect that your reading may be inaccurate, check the reading by conducting a fingerstick test using a blood glucose meter. If you are experiencing symptoms that are not consistent with your glucose readings, consult your health care professional.

The Enlite Serter (Serter) does not work the same as other Medtronic insertion devices. **The Serter injects the sensor into the insertion site when the button is released**, not when the button is pressed. Be sure to read the entire Enlite Serter User Guide before attempting to insert the sensor. Failure to follow directions may result in pain or injury.

The sensor may create special needs regarding your medical conditions or medications. Bleeding, swelling, irritation or infection at the insertion site are possible risks associated with inserting the sensor and sometimes result from improper insertion and maintenance of insertion site. Discuss these conditions and medications with your doctor before using the sensor.

Taking medications with acetaminophen or paracetamol, including, but not limited to Panadol™, fever reducers, or cold medicine, while wearing the sensor may falsely raise your sensor glucose readings. The level of inaccuracy depends on the amount of acetaminophen or paracetamol active in your body and may be different for each person. Always use BG meter readings to verify your glucose level before making therapy decisions, including when you could have acetaminophen or paracetamol active in your body. Always check the label of any medications to confirm whether acetaminophen or paracetamol is an active ingredient.

Remove the sensor if you experience unexplained fevers, or develop inflammation, redness, soreness or tenderness at the insertion site. Check the insertion site often for these conditions and to ensure that the sensor is still in place. Consult your healthcare professional if these conditions persist.

This device contains an automatically retracting needle which may cause minimal blood splatter when the needle is removed from the sensor. When removing the needle from someone other than yourself, do so at arms length and pointed away from self and others. Keep device within sight at all times to avoid accidental needle stick injury.

Sensors are sterile and nonpyrogenic, unless the package has been opened or damaged. Always inspect the packaging for damage prior to use. Do not use any of the sensors if the sterile package has been opened or damaged.

Watch for bleeding at the insertion site. If bleeding occurs, do not attach the transmitter or recorder to the sensor. Apply steady pressure using a sterile gauze or clean cloth for up to 3 minutes.

If bleeding stops, attach the transmitter or recorder to the sensor.

If bleeding does *NOT* stop, DO NOT attach the transmitter or recorder to the sensor.

1. Remove the sensor and discard.
2. Check the site for redness, bleeding, irritation, pain, tenderness, or inflammation and treat accordingly.

3. Insert a new sensor in a different location.

This product contains small parts and may pose a choking hazard for young children.

Precautions

Do not reuse sensors. Reuse of the sensor may cause damage to the sensor surface and lead to inaccurate glucose values, site irritation or infection.

Always wash your hands with soap and water before opening the sensor package and handling the sensor.

Individuals under the age of 18 may require supervision for sensor insertion.

Healthcare professionals and caregivers should use universal precautions when handling the sensor. Avoid touching any sensor surfaces that will come in contact with the body—that is, the sensor, needle, adhesive surfaces and tape.

Do not insert the sensor through tape and only use alcohol to clean the insertion site. Do not use any other type of skin preps prior to insertion.

The sensor must be calibrated, at a minimum, every 12 hours throughout the life of the sensor. For better sensor performance, it is recommended that you calibrate your sensor three or four times each day at regular times throughout the day, such as before meals and before bed.

Establish a rotation schedule for choosing each new sensor site. Dispose of used sensors and introducer needles in a sharps container after a single use. Do not clean or resterilize, and do not try to extract the needle from the needle housing.

Potential Risk

For the use with the MiniMed 640G system, sensor placement and insertion has been studied in the belly (abdomen) only and is not approved for other sites.

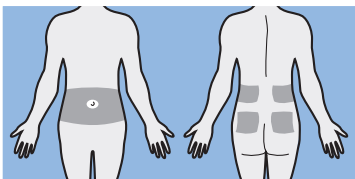
Where to insert the sensor

Refer to the Serter User Guide for instructions on inserting the sensor.

WARNING: Failure to follow directions may result in pain or injury.

CAUTION: Make sure the sensor site is at least 7.5 cm (3 inches) away from the insulin pump insertion site or manual injection site. When replacing the sensor, select a new site that is at least 5 cm (2 inches) from the previous site.

Choose an insertion site that has an adequate amount of subcutaneous fat. Shown here are the best body areas (shaded) for sensor insertion.



Do not insert the sensor in muscle or areas constrained by clothing or accessories; areas with tough skin or scar tissue; sites subjected to rigorous movement during exercise; in sites on the belt or waistline; or within 5 cm (2 inches) of the navel.

Sensor life of use

The sensor has a maximum life of 144 hours (six days). The 144-hour life span of the sensor begins when the insulin pump or monitor receives the first METER BG NOW alert.

Reagents






The sensor contains two biological reagents: glucose oxidase and human serum albumin (HSA). Glucose oxidase is derived from *Aspergillus Niger*, purified and dried according to Type VII-S guidelines and cross-linked to HSA, purified and dried albumin fraction V, derived from pasteurized human serum with gluteraldehyde. Since less than 0.4 µg of glucose oxidase and less than 0.7 µg of HSA is used to manufacture each sensor, the risks of tissue reactions and viral transmission are considered minimal.












Storage and handling

CAUTION: Do not freeze the sensor. Sensors should not be stored in direct sunlight, extreme temperatures, or humidity.

Store sensors at room temperature between +36°F to +86°F (+2°C to +30°C). If the sensor is stored in a cool environment, allow the sensor to warm to room temperature to prevent condensation. Do not store sensors at temperatures lower than +36°F (+2°C).

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

	Use by
	Do not re-use
	Consult instructions for use
	Specific warnings or precautions not found on the label exist, for which the IFU should be consulted.
	Model number

	Batch code
	Sterilized using irradiation
	Storage temperature range
	Date of manufacture
	Open here
	Manufacturer
	Nonpyrogenic
	Do not resterilize
	Do not use if package is damaged
	Magnetic Resonance (MR) unsafe: Keep away from magnetic resonance imaging (MRI) equipment.
	Signifies European technical conformity.

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