

URGENT FIELD SAFETY NOTICE

Simplera™ Sensor

Label Not Completely Adhered to the Sensor Cap

Simplera™ Sensor	Model/CFN Number: MMT-5100JC1 GTIN: 20763000649580
Impacted lot number:	HG81GLZ

May 2025

Medtronic reference: FA1484

For use in countries that follow EU MDR: EU Manufacturer Single Registration Number (SRN): US-MF-000023100

Dear Medtronic Community Member,

Medtronic is contacting you regarding the Simplera™ sensor. There is the potential that Simplera™ sensors from lot **HG81GLZ**, the label may not be completely adhered or sealed to the sensor cap, which may compromise the sterility of the sensor and could potentially lead to a harm of infection.

This letter includes instructions to identify the lot number of your Simplera™ sensor. Any sensors from the impacted lot should be disposed of and Medtronic should be contacted to request replacement sensors.

Issue Description:

The cap label is used to maintain sterilization of the Simplera™ sensor, and it has product information printed on it. For some sensors in the impacted lot, the cap label may not be completely adhered to the sensor cap, which may compromise the sterility of the sensor.

Risk to Health:

An incomplete seal of the cap label to the sensor cap (Figure 1) may allow contaminants to enter the sensor and could lead to a range of minor skin infection at the insertion site to Sepsis that would require the user to receive medical treatment and hospitalization if the sensor is inserted into the body. Medtronic has not received any complaints regarding this issue.

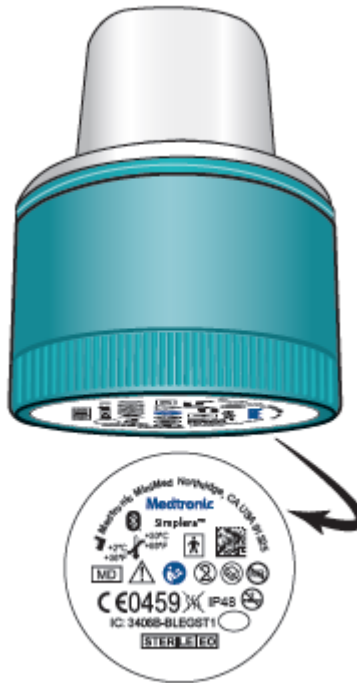


Figure 1: Cap label on the Sensor Cap

Actions Required:

- Verify if the sensors you currently have are from the impacted lot. This can be done by reading the lot number on your box, or by locating the serial number on your sensor inserter and comparing it to the list of impacted serial numbers in the online tool: <https://www.medtronic-diabetes.com/FA1484>
 - The lot number can be found on the top right corner of your Simplera™ sensor box label (Figure 2). Verify if your lot number matches: HG81GLZ.
 - The serial number can be found on the top of your inserter (Figure 3). Verify if it is from the impacted lot by entering it into this online tool: <https://www.medtronic-diabetes.com/FA1484>
- If you have a Simplera™ sensor from the impacted lot, **do not use this Simplera™ sensor** and dispose of it according to local regulations.
- Please contact our helpline/your Medtronic contact at 01923 205167 to request a replacement.

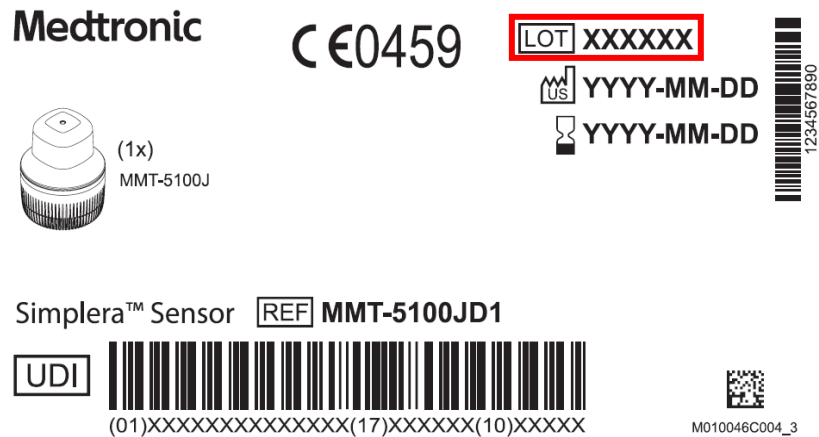


Figure 2: Lot Number on Simplera™ sensor box label

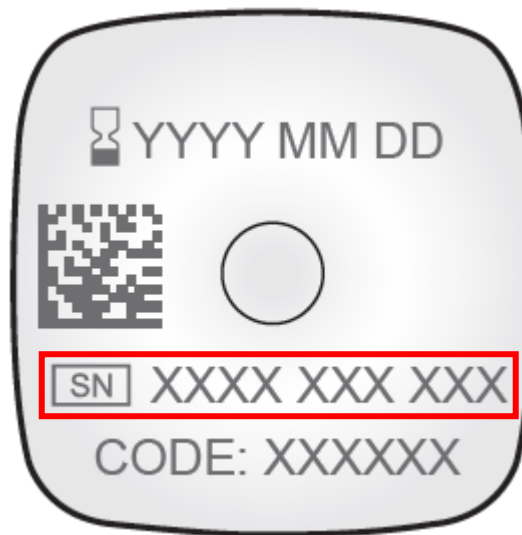


Figure 3: Serial Number on the top of the Inserter

Please acknowledge that you have read and understood this notification and have followed the actions listed in this letter, even if your sensor is unaffected, or if you do not have any sensors from the affected lot. Please complete and return the included confirmation form.



As always, we are here to support you and ensure we are delivering the highest quality products possible. If you have further questions or need assistance, please contact the Medtronic 24-Hour Technical Support line.

Sincerely,

Federico Gavioli
Sr. Vice President, International
Medtronic Diabetes

Ohad Cohen, MD
Sr. Medical Affairs Director
Medtronic Diabetes