

URGENT FIELD SAFETY NOTICE

Guardian™ 4 Sensor accuracy issue

November 2023

Medtronic reference: FA1379

EU Manufacturer Single Registration Number (SRN): US-MF-000023100

Dear Pump User,

We're reaching out because you may have received Guardian™ 4 sensors that have been identified to have a potential issue. Please carefully review the information below as it provides specific actions you should take.

Issue Description:

We've found that select Guardian™ 4 sensors in specific LOTs may potentially transmit inaccurate sensor glucose readings. We identified this problem internally after we confirmed that there was an anomaly in the unique data of some impacted LOTs. Because of this, the LOTs in question were missing data, which may impact sensor accuracy. We've reviewed and improved our internal controls to avoid this issue going forward.

Impact:

If you use the MiniMed™ 780G system

If you are using an impacted Guardian™ 4 sensor with the MiniMed™ 780G system, an inaccurate sensor glucose reading may be used to determine if an auto correction or bolus is needed, which may result in over- or under-delivery of insulin, potentially resulting in hypoglycemia or hyperglycemia.



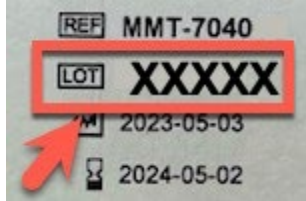
If you use the Guardian™ System

If you are using an impacted Guardian™ 4 sensor with the Guardian™ System, an inaccurate sensor glucose reading could lead to over- or under-delivery of insulin if this information is used to calculate an insulin dose, potentially resulting in hypoglycemia or hyperglycemia.

Actions:

Determine if you have sensors that are potentially impacted, please follow the steps below:

1. Gather all your Guardian™ 4 sensors.
2. Find the LOT number on the individual sensor package or sensor box.

Example of back of sensor box	Example of sensor package	Example of LOT number
		

- a. Check your sensor LOT number(s) on our website at <https://www.medtronic-diabetes.com/FA1379> or in the list below to see if your sensors are impacted.
 - a. **If your LOT number(s) ARE NOT impacted**, you can continue to use your sensors.
 - b. **If your LOT number(s) ARE impacted, do not use these sensors** and request free replacement sensors by contacting our Helpline at 0800 633 333.
 - c. **If you cannot identify the LOT number** of the sensor you are currently wearing, remove the sensor and replace your sensor with a non-impacted sensor.
3. If you only have impacted sensors remaining, call us immediately so that we can ensure you receive replacement sensors as soon as possible. You should revert to your backup plan as recommended by your healthcare professional while you await your replacement sensors.
4. Dispose of all impacted sensors.

Additional Information:

Your safety is our top priority, and we appreciate your time and attention in reading this important notification. We apologize for the inconvenience. If you have any questions, please contact our Helpline.

Sincerely,

Medtronic (Schweiz) AG

If your LOT number is on this list, contact us for replacement sensors and dispose of impacted sensors.

Manufacturer's Product Number/Catalog Number	Impacted LOT Numbers
MMT-7040C1	F1323, F1923, G0323, G1723, G2023, G2623, G2923 HG6RV7S, HG6TGNU, HG6TJ2Y, HG6TW97, HG6TWWU, HG6UNF2, HG6V8NN, HG6VB8S, HG6VNX3, HG6WNE1, HG6XFPR HG6XH54, HG6XQCG, HG6XZJX, HG6Y0W1, HG6Y3QN, HG6YEK6, HG6YFAF, HG6YFHL, HG6YJAR, HG6YJBD, HG6YNGD, HG6Z7N5, HG6ZARN, HG7038Y, HG70CW5, HG70DAM, HG70JSU HG70LRC, HG70QWA, HG71VMZ, HG72DB5, HG72G9C, HG72NV9, HG72R1P, HG72RBD, HG72SE3, HG72TPT, HG72TRV, HG72V3J, HG72ZFP, HG7340A, HG73EJX, HG73RNR, HG745SV, HG747E3, HG7480Q, HG749N6, HG74F93, HG75TSX, HG75XA1, HG76HFH, HG76RYY
MMT-7040C2	HG6RC39, HG6RXB5, HG6T4T7, HG6T8RV, HG6TJ2Y, HG6WKZU, HG6WLKS, HG6XFPR, HG6XH54, HG6XLSD, HG6XNH3, HG6Y5C6, HG6Z1X5, HG713AK, HG73EGX, HG73EJX, HG73FJP, HG73Q24, HG73QPM, HG73RNR, HG7619X, HG764J9, HG76CWC, HG77FMK
MMT-7040C3	HG6XNH3, HG73RNR
MMT-7040QC	HG6WT9A, HG6WUGE, HG73PH3
MMT-7040D1	HG6THY1, HG6V7VV
MMT-7040D2	HG6TL44