

URGENT: MEDICAL DEVICE RECALL

Guardian™ 4 sensor accuracy issue

November 2023

Dear Valued Customer:

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 internally that the test system overseeing a portion of sensor assembly malfunctioned during the production of some sensor LOTs; this means some sensors may not have been tested properly and could potentially measure sensor glucose inaccurately. We've reviewed and updated our internal controls to avoid this issue going forward.

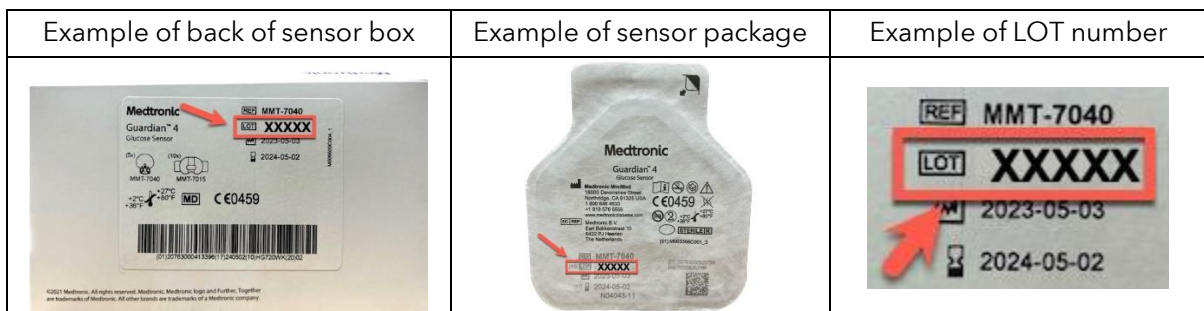
The MiniMed™ 780G system

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.

Actions:

To 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 box or sensor Package.



3. Check your sensor LOT number(s) on our website at medtronicdiabetes.com/LOT, or in the list below to see if your sensors are impacted.

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- a. **If your LOT number(s) ARE NOT impacted**, you can continue to use your sensors.
IMPORTANT: Please read to the end of this letter for steps to acknowledge you have received and read this letter.
 - b. **If your LOT number(s) ARE impacted, do not use these sensors** and request free replacement sensors by completing the web form at medtronicdiabetes.com/G4S-form, contacting 24-Hour Technical Support at 800-646-4633, option 1, or email rs.customerexperience@medtronic.com.
 - 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.
4. 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.
 5. Dispose of all impacted sensors.

Additional Information:

Please acknowledge that you have read and understood this notification and have followed the actions listed in this letter by completing and returning the attached confirmation form.

Adverse reactions or quality problems experienced with this product may also be reported to FDA's MedWatch Adverse Event Reporting program:

- Submit online: www.fda.gov/medwatch/report.htm
- Submit by regular mail or fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-332-0178.

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 us at 800-646-4633, option 1.

Sincerely,



Julio Salwen

Vice President, Quality
Medtronic Diabetes

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If your LOT number is on this list, visit [medtronicdiabetes.com/LOT](https://www.medtronicdiabetes.com/LOT) or call 24- Hour Technical support at 800-646-4633, option 1 to request free replacement sensors. Please dispose of the impacted sensors after you request your replacements.

Product Name	Product REF Number	Impacted LOT Numbers
Guardian™ 4 sensors	MMT-7040A	HG72BC, HG72CQQ, HG73VB7, HG73VC8, HG73VFT, HG73WFR, HG7441E, HG745F9, HG7486X, HG74AJ1, HG74SUR, HG74T9Q, HG74U36, HG78LMS, HG79Y9U
	MMT-7040MA	HG74460