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URGENT FIELD SAFETY NOTICE

Guardian™ 4 Sensor accuracy issue

November 2023

Medtronic reference: FA1379
EU Manufacturer Single Registration Number (SRN): US-MF-000023100

Dear Physician, Healthcare Professional,

We are reaching out to inform you that some of your patients may have received Guardian™ 4 sensors that have been identified to have a potential issue.
We are sharing this information with you for your awareness about the issue should your patients contact you. Please carefully review the information below.

Issue Description:

We've found that select Guardian™ 4 sensors in specific LOTs may potentially transmit inaccurate sensor glucose readings. We identified internally that some sensors of select LOTs may not have been tested properly during the manufacturing process and could potentially measure glucose inaccurately. We've reviewed and updated our internal controls to prevent this issue going forward.

Impact:

For customers using Guardian™ 4 sensor with the MiniMed™ 780G system

For your customers utilizing 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.

For customers using Guardian™ 4 sensor with the Guardian™ System

For your customers 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:

Your patients with potentially impacted LOTs received the enclosed letter with instructions on how to identify the potentially impacted LOTs. We have instructed them to stop use of these sensors and request replacement sensors. Should your patients need to wait for replacement sensors, they may revert to their backup plan and may contact you to discuss.

If your patient has received a notification that they may have received impacted sensors and you have recently made changes to their pump settings based on observed trends in their sensor data, please consider re-evaluating those changes based on new data from sensors that have been confirmed to not have been impacted in this notification and your clinical judgement.

If you have any samples of Guardian™ 4 sensors in your office or clinic, please check that the LOT numbers are not impacted on our website at https://www.medtronic-diabetes.com/FA1379_or compare them to the list of LOT numbers in the attached Patient Letter. If you have impacted sensors, discard them immediately and request replacement sensors by contacting your Medtronic representative directly or via Tel no. 01 5111 440 Option 2

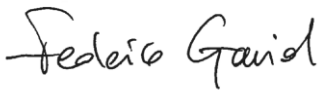
Please complete and return the enclosed Customer Acknowledgement Form even if you **do not** have unused inventory.

Additional Information:

The Competent Authority of your country has been notified of this action.

Patient 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 your Medtronic representative directly.

Sincerely,



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Enclosure:

- Patient Letter