

11 March 2021

URGENT – Product Defect Correction

Sensor Glucose Values with Use of Hydroxyurea Medication Enhanced Enlite™ Sensor (MMT-7008) and Guardian™ Sensor 3 (MMT-7020)†

TGA Reference: RC-2021-RN-00677-1

ARTG: 313740, 313741

Dear Valued Customer:

You are receiving this letter because our records indicate you may be using an Enhanced Enlite™ or Guardian™ Sensor 3 continuous glucose monitoring (CGM) sensor. If you are actively taking a medication named **Hydroxyurea**, used to treat some cancers and sickle cell anemia, your sensor could present inaccurate sensor glucose (SG) readings. Because your safety is our top priority, we are making you aware of this issue and important actions. Consult your healthcare professional if you are taking Hydroxyurea and using a CGM. Medtronic has not received any complaints or reports of patient harm or injuries due to this issue.

Explanation of issue:

Hydroxyurea is used to treat certain diseases, such as cancer and sickle cell anemia. Hydroxyurea is also known by other names, such as hydroxycarbamide, Hydrea™, Droxia™, and Siklos™. Hydroxyurea use results in higher SG readings compared to blood glucose (BG) readings and may result in the following:

- Hypoglycemia caused by over-administration of insulin
- Inaccurate graphs or missed alarms and alerts
- Delay to or loss of sensor-enabled insulin suspension (sensor-enabled insulin pump use only)
- SG readings in CareLink™ reports being substantially higher than BG readings

What you should do:

- Do not use continuous glucose monitoring (CGM) while taking hydroxyurea.
- Only use your BG meter to monitor glucose levels while taking hydroxyurea.
- Consult with your healthcare professional if you are taking hydroxyurea and using CGM.
- When using an insulin pump system, disable the CGM feature by going to the sensor settings. Refer to the user guide that came with your insulin pump for instructions.
- Always check the label of any medication to confirm with your healthcare professional whether hydroxyurea or hydroxycarbamide is an active ingredient.

What Medtronic is doing:

Medtronic is working to update instructions for use of CGM sensors to include warnings about use of CGM while taking Hydroxyurea.

Additional Information:

Medtronic is initiating this action in consultation with the Therapeutic Goods Administration.

Local contact details:

At Medtronic, patient safety, awareness and customer satisfaction are our top priorities. We apologize for any inconvenience this issue may cause you and appreciate your time and attention in reading this important notification.

As always, we are here to support you. If you have further questions or need assistance, please call our Global Help line at: 1800-777-808.

Best Regards,



Frederick Wu

Associate Post Market Vigilance Specialist | Quality and Regulatory Affairs

Medtronic

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† Includes these variants for Enlite™ sensors (MMT-7008A, MMT-7008B, MMT-7008C, MMT-7008D) and Guardian™ Sensor 3 sensors (MMT-7020LA, MMT-7020LB, MMT-7020LPA, MMT-7020A, MMT-7020B, MMT-7020GA, MMT-7020Y, MMT-7020YL, MMT-7020C5, MMT-7020D5, MMT-7020C1, MMT-7020D1)

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Acknowledgement Form

**Sensor Glucose Values with Use of Hydroxyurea Medication
Enhanced Enlite™ Sensor (MMT-7008) and Guardian™ Sensor 3 (MMT-7020)†
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To assist us in this corrective action, please complete and sign this Acknowledgement Form.

By signing this acknowledgement form, I confirm that I have read and understood the URGENT – Product Correction Notification regarding Sensor Glucose Values with Use of Hydroxyurea Medication dated March 2021

Please complete the form and email to rs.anzrecalls@medtronic.com to the attention of Recalls

Customer Name: _____

Customer Signature: _____

Date: _____

Telephone: _____

Email: _____

For questions, contact our Global Help line at: 1800-777-808.