

## Urgent Field Safety Notice

### MiniMed™ 600 Series Pump System Communication Issue

Notification

| Insulin Pump               | Model Number                           |
|----------------------------|--|
| MiniMed™ 640G Insulin Pump | MMT-1711, MMT-1712, MMT-1751, MMT-1752 |
| MiniMed™ 670G Insulin Pump | MMT-1761, MMT-1762, MMT-1781, MMT-1782 |

September 2022

Medtronic Reference: FA1272

[EU Manufacturer Single Registration Number \(SRN\): US-MF-000023100](#)

Dear Healthcare Institute / Health Organization / Service Provider,

You are receiving this letter because our records indicate that one or more of your patients may be using a MiniMed™ 600 series insulin pump. For your patient's safety, we want to inform you of a potential issue associated with the communication protocol used by your patient's pump system. Unauthorized access to the communication protocol on your patient's pump could compromise the pump's delivery of insulin. This letter provides actions and mitigations you and your patient should take, so please carefully review the information below and notify impacted patients of this issue.

#### **ISSUE DESCRIPTION**



MiniMed™ 600 series  
insulin pump<sup>1</sup>



Guardian™ Link 3  
transmitter



Contour® Next/Plus Link 2.4  
Blood Glucose Meter



CareLink™ USB

The MiniMed™ 600 series pump system consists of components such as the pump, continuous glucose monitoring (CGM) transmitter, blood glucose meter and CareLink™ USB device that communicate wirelessly. Medtronic has recently identified a potential issue through internal testing whereby, under specific circumstances, the communication between the components of the pump system could be compromised through unauthorized access.

<sup>1</sup> Sample image. Pump screen and buttons vary by model.

# Medtronic

For unauthorized access to occur, a nearby person other than the patient or a care partner would need to gain access to the pump at the same time when the pump is being paired with other system components. **This cannot be done over the internet.**

Medtronic has no evidence to date that such an issue has occurred. However, in the unlikely event that unauthorized access would be successful, the access could be used to deliver too much or too little insulin through delivery of an unintended insulin bolus or because insulin delivery is slowed or stopped. Too much insulin could result in hypoglycemia (low blood sugar) which can potentially lead to seizure, coma or death. Too little insulin could result in hyperglycemia (high blood sugar) which can potentially lead to diabetic ketoacidosis.

Medtronic recommends to take the actions listed below.

## **ACTIONS REQUIRED BY HEALTHCARE INSTITUTES, HEALTH ORGANIZATION, SERVICE PROVIDER:**

1. Ensure patients turn off the "Remote Bolus" feature on their pump if it is turned on.  
Note that the "Remote Bolus" capability is on by default, patients should take this action even if they have never used this feature. See Appendix: "How to Turn Off Remote Bolus Settings" of the attached Pump User Letter or visit our website at [www.medtronicdiabetes.com/remote-bolus](http://www.medtronicdiabetes.com/remote-bolus).
2. When programming a new pump for patients, please assist them in turning off the "Remote Bolus" feature on their pump per the instructions provided below. Your patients may also reach Medtronic online or via phone to get help.
3. Ask patients to conduct any linking of the pump with the transmitter, blood glucose meter or CareLink USB in a non-public place.

## **RECOMMENDED PRECAUTIONS FOR PATIENTS:**

1. Keep your pump and connected system components within your control at all times.
2. Be attentive to pump notifications, alarms, and alerts.
3. Immediately cancel any boluses you or your care partner did not initiate, monitor blood glucose levels closely and reach out to Medtronic 24-Hour Technical Support to report the bolus. NOTE: Turning off Remote Bolus feature will ensure no Remote Bolus is possible.
4. Disconnect the USB device from your computer when you're not using it to download pump data.
5. DO NOT confirm remote connection requests or any other remote action on the pump screen unless it is initiated by you or your care partner.



6. DO NOT share your pump's or devices' serial numbers.
7. DO NOT accept, calibrate, or bolus using a blood glucose reading you didn't initiate.
8. DO NOT connect to or allow any third-party devices to be connected to your pump

# Medtronic

9. DO NOT use any software which has not been authorized by Medtronic as being safe for use with your pump.
10. Get medical help immediately when experiencing symptoms of severe hypoglycemia or diabetic ketoacidosis.
11. Reach out to Medtronic 24-Hour Technical Support if you suspect a pump setting or insulin delivery have changed unexpectedly, without your knowledge.

## **ADDITIONAL INFORMATION:**

We understand this may impact you and your patient's experience and are here to support you. Additional information can be found at [www.medtronic.com/security](http://www.medtronic.com/security).

**The best step your patient can take now to eliminate their individual risk of unintended delivery of insulin is to permanently turn off the Remote Bolus feature on their pump.** We will continue to actively monitor the situation and are committed to sharing relevant information or actions with you and your patients in the future.

The Competent Authority of your country has been notified of this action. We are committed to continuously monitoring and improving your experience with our products and will proactively share important safety updates. If you have further questions, please contact your Medtronic Representative.

Sincerely,

Local/OU Manager

## **Enclosure:**

- Pump User Letter