

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

October 2022

Medtronic Reference: FA1272

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

Dear Pump User,

We send you this letter because our records indicate that you may be using a MiniMed™ 600 series insulin pump. For your safety, we want to inform you of a potential problem with the communication method used by your pump system. Due to this problem, there is a risk that an unauthorized person might be able to change the delivery of insulin on your pump. **Medtronic has no evidence to date that an event like this has occurred on a MiniMed™ 600 series insulin pump.**

In this letter we provide instructions and actions you can take to prevent this from happening. Please carefully review the information below and follow the actions required and recommended precautions.

ISSUE DESCRIPTION



MiniMed™ 600 series
insulin pump¹



Guardian™ Link 3
transmitter



Contour® Next/Plus Link 2.4
Blood Glucose Meter



CareLink™ USB

The MiniMed™ 600 series pump communicates wirelessly with other pump system components, such as the continuous glucose monitoring (CGM) transmitter, blood glucose meter and CareLink™ USB. Medtronic has recently identified a potential problem that could allow an unauthorized person to use the communication method to change the delivery of insulin on your pump.

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

¹ Sample image. Pump screen and buttons vary by model.

Medtronic has no evidence to date that such an event has occurred. In the unlikely event that this would happen, an unauthorized person might be able to deliver too much insulin through delivery of an unintended insulin bolus or too little insulin 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 you take the actions and precautions listed below.

ACTIONS REQUIRED:

1. Turn off the "Remote Bolus" feature on your pump if it is turned on.
Note that the "Remote Bolus" feature is on by default, so you should turn off the feature even if you do not use "Remote Bolus". See Appendix: "How to Turn Off Remote Bolus Settings".
2. Conduct any linking of the pump with the transmitter, blood glucose meter or CareLink USB in a non-public place.

RECOMMENDED PRECAUTIONS:

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 Helpline to report the bolus. NOTE: Turning off the 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 the serial numbers of your pump, transmitter or blood glucose meter with anyone other than your healthcare provider or the Medtronic 24-Hour Helpline.
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.
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 Helpline if you suspect a pump setting or insulin delivery have changed unexpectedly, without your knowledge.

ADDITIONAL INFORMATION:

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

We understand this impacts your experience and we are here to support you. If you have further questions, please call our Helpline at TEL No: 01 511 1444

Sincerely,



Keith Taverner

Regulatory Affairs Manager UK & Ireland

Enclosure: Appendix "How to Turn Off Remote Bolus Settings"

Please see below pages 4,5 & 6

APPENDIX

How to Turn Off Remote Bolus Settings

Follow these steps to turn off the Remote Bolus feature:

MiniMed™ 670G Insulin Pump (MMT-1781, MMT-1782)

Note: The Remote Bolus feature is not available when in SmartGuard™ Auto Mode

1. If Auto Mode is active, Auto mode must first be deactivated to enter manual mode using the following step:

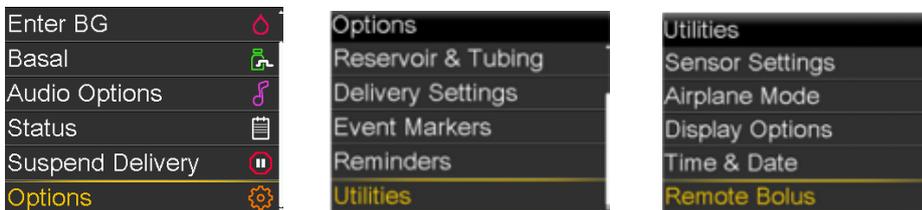
- Press Center Button () and go to the Auto Mode settings screen.

Options>SmartGuard>Auto Mode

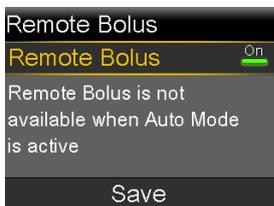


2. Select **Save**
3. In manual mode, Press Center Button () and go to the Remote Bolus screen.

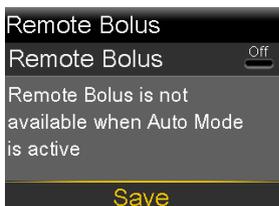
Options>Utilities>Remote Bolus



- The Remote Bolus screen appears



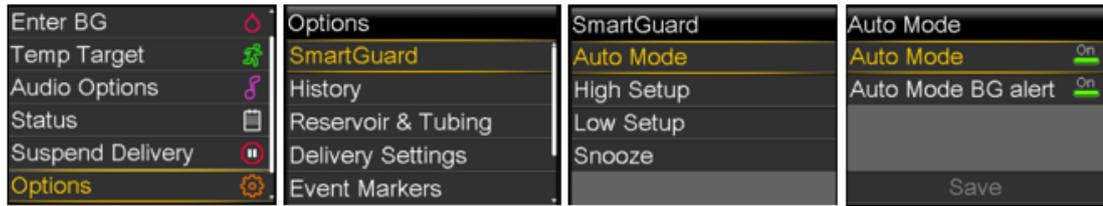
4. Select **Remote Bolus** to turn the feature off.



5. Select **Save**

- If you wish to reactivate Auto Mode, go to the Auto Mode settings screen.

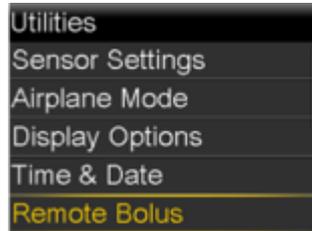
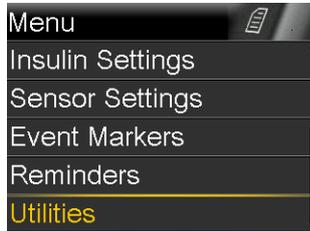
Options>SmartGuard>Auto Mode



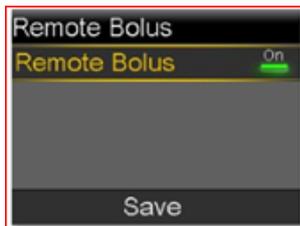
Note: Remote Bolus default setting is "ON".

1. Press Menu Button () and go to the Remote Bolus screen.

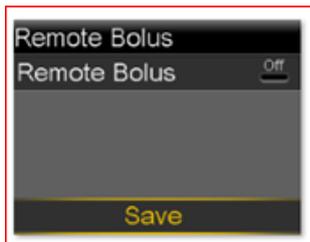
Menu>Utilities>Remote Bolus



- a. The Remote Bolus screen appears.



2. Select **Save**
3. Select **Remote Bolus** to turn the feature off



4. Select **Save**