

22 November 2021

## **URGENT – MEDICAL DEVICE RECALL**

**MiniMed™ Remote Controller MMT-503**

**TGA Reference: RC-2021-RN-02160-1**

**ARTG: 128416**

Dear Valued Patient,

You are receiving this letter because our records indicate that you may be using an optional MiniMed™ remote controller (model number **MMT-503**) with a Medtronic MiniMed™ 508 insulin pump or the MiniMed™ Paradigm™ family of insulin pumps.

Medtronic first communicated this as a Safety Alert (TGA Reference RC-2018-RN-01123-1) to some users in August 2018 with instructions on how to disable the remote bolus feature, when not in use, to protect the security of your insulin pump when using an optional remote controller which may be susceptible to a cybersecurity risk. At that time, only users whose pumps were under warranty received the recall notification. Medtronic is now expanding the notification to all users who Medtronic believes may still be using the MiniMed™ 508 insulin pump or the MiniMed™ Paradigm™ family of insulin pumps and have purchased a remote controller.

Additionally, after further review, Medtronic has determined that the potential risks associated with the MiniMed™ remote controller outweigh the benefits of its continued use. Therefore, we are providing updated instructions to further address this risk.

**You should immediately stop using and disconnect the remote controller, disable the remote feature, and return the remote controller to Medtronic.** See the Appendix attached to this letter for detailed instructions.

Please review the following issue description and instructions for disconnecting and returning your remote controller.

### **ISSUE DESCRIPTION**

The Medtronic remote controller, which uses a wireless radio frequency (RF) to communicate with your insulin pump, helps to program a set amount of insulin (or bolus) into your Medtronic pump without pressing any insulin pump buttons.



In May 2018, an external cybersecurity researcher identified a potential risk related to the MiniMed™ Paradigm™ family of insulin pumps and corresponding remote controller. The researcher's report stated that an unauthorized individual in close proximity of an insulin pump user could potentially copy the wireless RF signals from the user's remote controller (for example, while the user is in the process of delivering a remote bolus) and play those back later to deliver an additional bolus of insulin to the pump user. This could lead to potential health risks

such as hypoglycaemia if additional insulin is delivered beyond the user's insulin requirements, or hyperglycaemia if insulin delivery is suspended through a similar play back. To date, Medtronic has not received reports of any injuries resulting from this issue.

### Several Factors Must Occur for Your Pump to be Vulnerable

1. The remote option for the pump would need to be enabled. This is not a factory-delivered default, and a user must choose this option.
2. The user's remote controller ID needs to be registered to the pump.
3. The Easy Bolus™ option would need to be turned on and a bolus step size programmed in the pump.
4. An unauthorized individual would need to be in close proximity of the user, with necessary equipment to copy the RF signals activated, when the user is delivering a bolus using the remote controller.
5. The unauthorized individual would need to be in close proximity of the user to play back the RF signals to deliver a malicious remote bolus.
6. The user would need to ignore the pump alerts, which indicates that a remote bolus is being delivered.

The following list shows the Medtronic remote controllers that are impacted by this issue. Medtronic is no longer manufacturing or distributing these remote controllers.

Remote controller	Model Number Location	Serial Numbers
 <p data-bbox="427 1323 647 1413">MiniMed™ remote controller <b>MMT-503</b></p>	 <p data-bbox="730 1312 986 1406">The model # is behind the remote under the barcode</p>	<p data-bbox="1098 1227 1134 1256">All</p>

### ACTIONS REQUIRED:

#### 1. STOP USING AND DISCONNECT THE REMOTE CONTROLLER

- To disconnect the remote controller from your insulin pump, you must disable the radio frequency function and delete all remote controller IDs that are programmed into your pump. Follow the instructions in the appendix attached to this letter. The steps to disconnect the remote controller will vary by insulin pump model.

#### 2. ACKNOWLEDGE NOTIFICATION

- Visit call the Medtronic Global Help line at 1800-777-808, or complete and return the enclosed Customer Confirmation Form to acknowledge that you have read and understood this notification and to indicate your decision regarding returning the remote controller.

### 3. RETURN PRODUCT

- Prepaid return packaging will be provided for you to return the remote controller to Medtronic.

Until you disable your remote controller and disconnect it from your pump, refer to the safety precautions previously provided in the security bulletin at [medtronic.com/security](https://www.medtronic.com/security).

Please notify Medtronic of any adverse events or quality problems associated with your use of this product by calling the Medtronic Global Help line at 1800-777-808

#### **Additional Information**

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

#### **Local contact details**

At Medtronic, patient safety is our top priority, and we are committed to delivering safe and effective therapies. Thank you in advance for your patience as we work to support all our customers as quickly as possible. We appreciate your time and attention in reading this important notification. If you have any questions regarding this notification, please do not hesitate to contact the Medtronic Global Help line at 1800-777-808.

Best Regards,

#### **Frederick Wu**

Post Market Vigilance Specialist | Quality and Regulatory Affairs

#### **Medtronic**

Medtronic Australasia Pty Ltd  
2 Alma Road | Macquarie Park, NSW, 2113 | Australia  
+61 298 579 038 | +61 407 477 552  
[rs.anzpmv@medtronic.com](mailto:rs.anzpmv@medtronic.com)

## **URGENT – MEDICAL DEVICE RECALL**

### **Acknowledgement Form**

**MiniMed™ Remote Controller MMT-503**

**TGA Reference: RC-2021-RN-02160-1**

**ARTG: 128416**

To assist us in this recall action, please complete and sign this Acknowledgement Form.

*By signing this acknowledgement form, I confirm that I have read and understood the URGENT – MEDICAL DEVICE RECALL regarding the MiniMed™ Remote Controller MMT-503, dated November 2021.*

Please complete the form and email to [rs.anzrecalls@medtronic.com](mailto:rs.anzrecalls@medtronic.com) to the attention of Recalls.

Name: \_\_\_\_\_

Telephone: \_\_\_\_\_

Email Address: \_\_\_\_\_



Date: \_\_\_\_\_

Signature: \_\_\_\_\_

## **Product Return Instructions**

The following list shows the Medtronic remote controllers that are impacted by this issue. Medtronic is no longer manufacturing or distributing these remote controllers.

After signing and emailing this form to [rs.anzrecalls@medtronic.com](mailto:rs.anzrecalls@medtronic.com), call the Medtronic Global Help line at 1800-777-808 and cite the MiniMed™ Remote Controller Recall, TGA Reference RC-2021-RN-02160-1.

Remote controller	Model Number Location	Serial Numbers
 <p style="text-align: center;">MiniMed™ remote controller <b>MMT-503</b></p>	 <p style="text-align: center;">The model # is behind the remote under the barcode</p>	<p style="font-size: 24px;">All</p>