

Urgent Field Safety Notice

MiniMed™ Paradigm™ Series and MiniMed™ 508 Insulin Pumps

Cybersecurity Concerns

June 2019

Medtronic Reference: FA875

Dear Healthcare Professional,

You are receiving this letter because our records indicate you are following patients who may be using a Medtronic MiniMed™ Paradigm™ or MiniMed™ 508 insulin pump. Because patient safety is our top priority, we are making you aware of a potential cybersecurity risk.

Medtronic will inform users that are on file with us. Users that have been supplied directly by you, we ask that you inform these users of the MiniMed™ Paradigm Series using the enclosed letter.

Potential cybersecurity risk:

The MiniMed™ Paradigm™ and MiniMed™ 508 insulin pumps are designed to communicate using a wireless radio frequency (RF) with other devices such as a blood glucose meter, glucose sensor transmitters, CareLink™ USB devices, and remote programmers.

Security researchers have identified potential cybersecurity vulnerabilities related to these insulin pumps. An unauthorized person with special technical skills and equipment could potentially send RF signals to a nearby insulin pump to change settings and control insulin delivery. This could lead to hypoglycaemia (if additional insulin is delivered) or hyperglycaemia and diabetic ketoacidosis (If not enough insulin is delivered).

IMPORTANT NOTE: We have not received any reports of unauthorized people changing settings or controlling insulin delivery.

ACTION REQUIRED:

We recommend that patients take the following precautions:

- Keep your insulin pump and the devices that are connected to your pump within your control at all times
- Do not share your pump serial number.
- Be attentive to pump notifications, alarms, and alerts.
- Immediately cancel any unintended boluses.
- Monitor your blood glucose levels closely and act as appropriate.
- Do not connect to any third-party devices or use any software not authorized by Medtronic.
- Disconnect your CareLink™ USB device from your computer when it is not being used to download data from your pump
- Get medical help right away if you experience symptoms of severe hypoglycemia or diabetic ketoacidosis, or suspect that your insulin pump settings, or insulin delivery changed unexpectedly

These pump models ARE vulnerable to this potential issue:

Insulin Pump

MiniMed™ Paradigm™ 512/712 pumps
MiniMed™ Paradigm™ 515/715 pumps
MiniMed™ Paradigm™ 522/722 pumps
MiniMed™ Paradigm™ Veo 554/754 pumps (software 2.5 and 2.6)
MiniMed™ 508 pumps

These pump models are **NOT** vulnerable to this potential issue:

Insulin Pump

MiniMed™ Paradigm™ Veo 554/754 with software 2.7A or greater

To find the software version for the MiniMed™ Paradigm™ Veo 554/754 pumps, go to the STATUS screen:

- To open the STATUS screen, press ESC until the STATUS screen appears.
- To view more text on the STATUS screen, press the up or down arrow to scroll and view all the information.
- To exit the STATUS screen, press ESC until the STATUS screen disappears.

MiniMed™ 640G pump

MiniMed™ 670G pump

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

We are committed to patient safety and appreciate your prompt attention to this matter should a patient make you aware. Any patients who have further questions or need assistance can contact our Helpline at: 01 511 1444.

Sincerely,



Samantha Baxter
Regulatory Affairs Manager UK and Ireland

MiniMed™ Paradigm™ Series and MiniMed™ 508 Insulin Pumps Cybersecurity Concerns

June 2019

Medtronic Reference: FA875

Dear Pump User,

You are receiving this letter because our records indicate you may be using a Medtronic MiniMed™ Paradigm™ or MiniMed™ 508 insulin pump. Because your safety is our top priority, we are making you aware of a potential cybersecurity risk.

Potential cybersecurity risk:

The MiniMed™ Paradigm™ and MiniMed™ 508 insulin pumps are designed to communicate using a wireless radio frequency (RF) with other devices such as a blood glucose meter, glucose sensor transmitters, CareLink™ USB devices, and remote programmers.

Security researchers have identified potential cybersecurity vulnerabilities related to these insulin pumps. An unauthorized person with special technical skills and equipment could potentially send RF signals to a nearby insulin pump to change settings and control insulin delivery. This could lead to hypoglycaemia (if additional insulin is delivered) or hyperglycaemia and diabetic ketoacidosis (if not enough insulin is delivered).

IMPORTANT NOTE: We have not received any reports of unauthorized people changing settings or controlling insulin delivery.

ACTION REQUIRED:

For your security we recommend you take the following precautions:

- Keep your insulin pump and the devices that are connected to your pump within your control at all times
- Do not share your pump serial number.
- Be attentive to pump notifications, alarms, and alerts.
- Immediately cancel any unintended boluses.
- Monitor your blood glucose levels closely and act as appropriate.
- Do not connect to any third-party devices or use any software not authorized by Medtronic.
- Disconnect your CareLink™ USB device from your computer when it is not being used to download data from your pump
- Get medical help right away if you experience symptoms of severe hypoglycemia or diabetic ketoacidosis, or suspect that your insulin pump settings, or insulin delivery changed unexpectedly

These pump models ARE vulnerable to this potential issue:

Insulin Pump

MiniMed™ Paradigm™ 512/712 pumps
MiniMed™ Paradigm™ 515/715 pumps
MiniMed™ Paradigm™ 522/722 pumps
MiniMed™ Paradigm™ Veo 554/754 pumps (software 2.5 and 2.6)
MiniMed™ 508 pumps

These pump models are **NOT** vulnerable to this potential issue:

Insulin Pump

MiniMed™ Paradigm™ Veo 554/754 with software 2.7A or greater

To find the software version for the MiniMed™ Paradigm™ Veo 554/754 pumps, go to the STATUS screen:

- To open the STATUS screen, press ESC until the STATUS screen appears.
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MiniMed™ 640G pump
MiniMed™ 670G pump

Your safety and complete satisfaction are our top priorities. We are committed to delivering safe and effective therapies. We 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 Helpline at: 01 511 1444.

Sincerely,



Samantha Baxter
Regulatory Affairs Manager UK and Ireland