



Medtronic International, Ltd. (Singapore Branch)

(Co. Reg. No. S98FC5604C)
50 Pasir Panjang Road
#04-51
Mapletree Business City
Singapore 117384
www.medtronic.com

tel 65.6870.5300
fax 65.6482.0300

IMPORTANT FIELD SAFETY NOTIFICATION

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

9th July 2019

Dear Valued Customer:

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

Potential cybersecurity risk:

The MiniMed™ 508 insulin pump and the MiniMed™ Paradigm™ series 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 received no reports of unauthorized people changing settings or controlling insulin delivery.

ACTION REQUIRED:

We recommend you take the following precautions to minimize the potential for a cybersecurity attack:

- 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

In Singapore, for devices covered under warranty, Medtronic will voluntarily exchange the affected models as decided by patients and their physician's recommendations when the replacement stocks are available.

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™ 508 pump MiniMed™ Paradigm™ Veo™ 554/754 pumps with Software 2.5 and 2.6

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

Insulin Pump
MiniMed™ Paradigm™ Veo 554/754 with Software Versions 2.7A or greater To find the software version for the MiniMed™ Paradigm™ Veo 554/754 pumps, go to the STATUS screen: <ul style="list-style-type: none"> ▪ 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™ 620G pump MiniMed™ 630G pump 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 24-Hour Helpline at Tel: 65064874 Or 8001206276.

Alternatively, you may contact your Medtronic representative.

Sincerely,



Diana Teo
QRA Lead
SEA Region (Cluster 1)



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Customer Confirmation Form

ALL CUSTOMERS PLEASE COMPLETE THE FORM IN ITS ENTIRETY

Customer Contact Details	
Patient's Name:	
Address:	
Telephone no:	
Fax no:	
E-mail:	

Item code	Serial #	QTY (Each)

I acknowledge receipt of the MiniMed™ Paradigm™ Series Insulin Pumps Cybersecurity Concerns removal notification dated 9th July 2019, and understand the instructions provided.

Name: _____ (print) Signature: _____ Date: _____



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URGENT FIELD SAFETY NOTIFICATION

MiniMed™ 508 Insulin Pump and MiniMed™ Paradigm™ Series Insulin Pumps

Cybersecurity Concerns

4th July 2019

Attention: Risk Management Director and O.R. Materials Management

CC: The Chairman Medical Board and relevant Head of Departments

Dear Healthcare Professional:

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

Medtronic asks that you inform impacted users of the a MiniMed™ 508 insulin pump or a MiniMed™ Paradigm™ series Cybersecurity Concerns using the enclosed letter.

Potential cybersecurity risk:

The MiniMed™ 508 insulin pump and the MiniMed™ Paradigm™ series insulin pumps are designed to communicate using a wireless radio frequency (RF) with other devices such as a blood glucose meters, glucose sensor transmitters, and 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 connect wirelessly to a nearby insulin pump to change settings and control insulin delivery. This could lead to hypoglycemia (if additional insulin is delivered) or hyperglycemia and diabetic ketoacidosis (if not enough insulin is delivered).

IMPORTANT NOTE: At this time, we have received no confirmed reports of unauthorized persons changing settings or controlling insulin delivery.

ACTION REQUIRED:

we recommend the patients to 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

You may discuss with your patient on their next appointment on the option on switching to an alternative pump.

These pump models ARE vulnerable to this potential issue:

Insulin Pump	Software Versions
MiniMed™ Paradigm™ 512/712 pumps MiniMed™ Paradigm™ 515/715 pumps MiniMed™ Paradigm™ 522/722 pumps MiniMed™ 508 pump	All
MiniMed™ Paradigm™ Veo™ 554/754 pumps	Software 2.5 and 2.6

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

Insulin Pump
MiniMed™ Paradigm™ Veo 554/754 with Software Versions 2.7A or greater
To find the software version for the MiniMed™ Paradigm™ Veo 554/754 pumps, go to the STATUS screen: <ul style="list-style-type: none">▪ 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™ 620G pump MiniMed™ 630G pump MiniMed™ 640G pump MiniMed™ 670G pump

We apologize for any inconvenience this may cause. Your safety and satisfaction of your patients are our top priorities. 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 24-Hour Tel: 1800-81-6672. Alternatively, you may contact your Medtronic Representative.

Sincerely,



Diana Teo
QRA Lead
SEA Region (Cluster 1)



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Customer Contact Details	Medtronic/Distributor Contact Details
Hospital / HCP:	Name
Address:	Email Address
Telephone no:	
Fax no:	Telephone:
E-mail:	

Item code	Serial #	QTY (Each)

I acknowledge receipt of the MiniMed™ Paradigm™ Series Insulin Pumps Cybersecurity Concerns removal notification dated 4th July 2019, and understand the instructions provided.

Name: _____ (print) Signature: _____ Stamp: _____ Date: _____