Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical
Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No. 40 **dated** 28/2/22 **Regarding NCMDR FSCA of MiniMed 780G insulin pump from (mrf: Medtronic MiniMed).**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DGPA&DC**
- **Director of Pharmacovigilance & Drug Information Dept, DGPA&DC**
- **Director of Drug Control Department, DGPA&DC**
- **Director of Pharmaceutical Licensing Department, DGPA&DC**
- **Director of Central Quality Control Lab., DGPA&DC**
- **Supdt. of Central Drug Information**

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control
ISO 9001:2015 CERTIFIED

ص.ب: ٣٩٣ مسقط – الرمز البريدي: ١٠٠ – هاتف: ٢٢٣٥٧١١١ – فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code : 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

Sultanate of Oman
Ministry of Health
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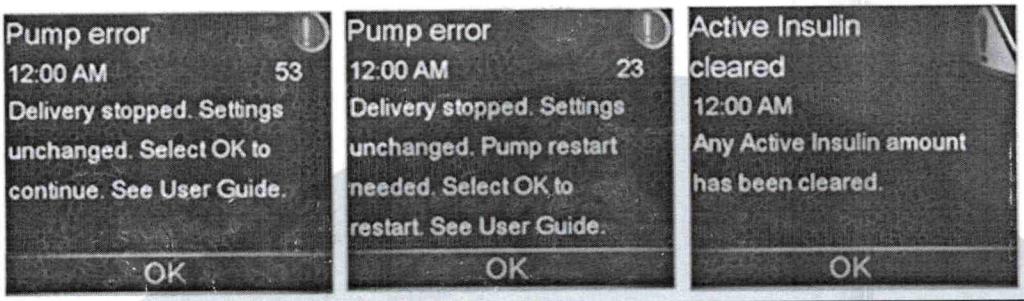
سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة والرقابة الدوائية
مسقط

Circular No. 40 / 2022

27 -07-1443 H

28 -02-2022

Field Safety Corrective Action of MiniMed 780G insulin pump from Medtronic MiniMed.

Source	NCMDR-National Center for Medical Device Reporting https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=16026
Product	MiniMed 780G insulin pump.
Description	Ambulatory insulin infusion pump.
Manufacturer	Medtronic MiniMed.
Affected	Model: MMT-1885, MMT-1886 Software version 6.5
Local Agent	Mustafa Sultan Science & Industry Co.L.L.C.
Reason	A software issue has been identified in the MiniMed 780G pump using software version 6.5 when a large bolus is delivered at quick bolus speed. Upon clearing the pump errors, the pump resets and indicates Active Insulin has been cleared, and since Active Insulin will display 0.0 units in the pump after experiencing the pump errors above, if the user is not aware of the amount of active insulin and delivers an additional bolus, there is a risk of insulin over delivery.
Action	1. Please refer to the attached FSN for more information. 2. Contact the local agent for remedial action.
	
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control contact E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL

سلطنة عمان - وزارة الصحة
المديرية العامة للصيدلة والرقابة الدوائية
SULTANATE OF OMAN - MINISTRY OF HEALTH
DIRECTORATE GENERAL OF PHARMACEUTICAL AFFAIRS & DRUG CONTROL

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ص.ب: ٣٩٣ مسقط – الرمز البريدي: ١٠٠ – هاتف: ٢٢٣٥٧١١١ – فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code : 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

NCMDR Recall

Reference Number: mdprc 015 02 22 000 Back
Date submitted: 2/10/2022

Manufacturer:	Medtronic MiniMed
Device Type:	MiniMed 780G insulin pump.
Description:	Ambulatory insulin infusion pump.
Medical Device Identifier:	Model: MMT-1885, MMT-1886 Software version 6.5
Reason of Field Safety Corrective Action:	A software issue has been identified in the MiniMed 780G pump using software version 6.5 when a large bolus is delivered at quick bolus speed. Upon clearing the pump errors, the pump resets and indicates Active Insulin has been cleared, and since Active Insulin will display 0.0 units in the pump after experiencing the pump errors above, if the user is not aware of the amount of active insulin and delivers an additional bolus, there is a risk of insulin over delivery.
Remedy Action:	Inform impacted customers of the MiniMed™ 780G insulin pump using the enclosed letter. Please refer to the attached FSN for more information.
Athorized Representative/Importer/Distributor:	Medtronic Saudi Arabia
Report Source:	NCMDR
Source Ref. Number:	226BEDDD3328A
SFDA Comments:	SFDA urges all hospitals that have devices subjected to this FSCA to contact the company.
Attachments:	Medtronic MiniMed.pdf

View History

Medtronic

Urgent Field Safety Notice
MiniMed™ 780G insulin pump: MMT-1885, MMT-1886
Pump Errors After Quick Bolus

March 2021

Medtronic reference: FA963

Dear Physician, Healthcare Professional:

You are receiving this letter because our records indicate that one of your patients may be using an affected MiniMed™ 780 series insulin pump with software version 6.5 that could present pump errors after delivering a large bolus under certain conditions. Because your patients' safety is our top priority, we are providing important actions for those patients who may have an affected insulin pump.

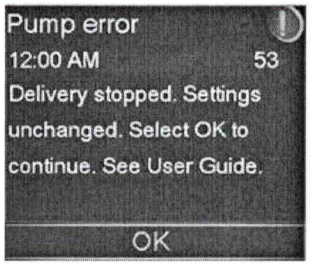
Medtronic asks that you inform impacted customers of the MiniMed™ 780G insulin pump using the enclosed letter.

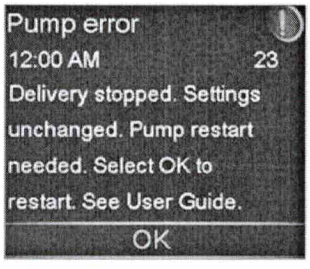
Explanation of issue:
A software issue has been identified in the MiniMed™ 780G pump using software version 6.5 when a large bolus is delivered at quick bolus speed. **These errors may occur if ALL the following conditions are met:**

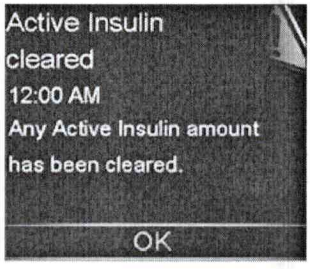
- The bolus delivery speed is programmed to "Quick" in the pump settings (default is "Standard").
- The SmartGuard™ feature is in use.
- The pump needs to be on the bolus delivery screen when an auto correction bolus is triggered. *Auto corrections are triggered when sensor glucose (SG) is running high and Active Insulin is low.*
- The bolus amount programmed to be delivered is greater than 17.1U.

  Note: This can be a single bolus greater than 17.1U or a combination of boluses totaling greater than 17.1U.

If all the above conditions are met, within 2 minutes of bolus delivery completion, the pump initiates Pump error 53, followed by Pump error 23 alarm. The following screens are presented in the pump screen:







Upon clearing the pump errors, the pump resets and indicates Active Insulin has been cleared. The pump then guides the user to resume operation in Manual Mode. The SmartGuard™ status screen

Medtronic

indicates the warm-up period has started. After approximately 5 hours, the SmartGuard™ feature will be available.

Since Active Insulin will display 0.0 units in the pump after experiencing the pump errors above, if the user is not aware of the amount of active insulin and delivers an additional bolus, there is a risk of insulin over delivery, which may result in low blood sugar (hypoglycemia) or severe hypoglycemia. In rare cases, severe hypoglycemia, if left untreated, may lead to a life-threatening situation. As of January 21, 2021, Medtronic has received no reports of serious patient harm or serious injury related to this issue.

What your patients should do:

If your patient's pump screen indicates that Active Insulin has cleared, please advise them to be aware of the following:

1. Although insulin was delivered before the error and they may have insulin on board, Active Insulin is reset to 0.0 units on the pump screen.
2. Before delivering additional boluses, check their graph or history to understand how much insulin was delivered before the error.
3. Consult with their healthcare professional about their active insulin absorption and how to plan a bolus if active insulin has been reset to 0.0.

Please advise your patients to follow these steps **if they are using Quick Bolus and require large bolus amounts while in SmartGuard™ feature:**

1. **Wait** at least 2 minutes between boluses if they need to deliver multiple boluses that exceed 17.1U in total.
2. **Consult** with their healthcare professional about setting their maximum bolus limit to 17U or less. *Note: The default setting is 10U.*

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

At Medtronic, patient safety, awareness and customer satisfaction are our top priorities. We apologize for any inconvenience this issue may cause you and your patients. We appreciate your time and attention in reading this important notification.

As always, we are here to support you. If you or your patients have further questions or need assistance, please call our Helpline at

Sincerely,

Erfan Al-Lababidi
Business Manager, Diabetes, APS

Enclosure:

- Pump User Letter

Medtronic

Urgent Field Safety Notice

MiniMed™ 780G insulin pump: MMT-1885, MMT-1886

Pump Errors After Quick Bolus

March 2021

Medtronic reference: FA963

Dear Pump User,

You are receiving this letter because our records indicate you are using a MiniMed™ 780G insulin pump with software version 6.5 that could present pump errors after delivering a large bolus under certain conditions. Because your safety is our top priority, we are making you aware of this issue and important actions.

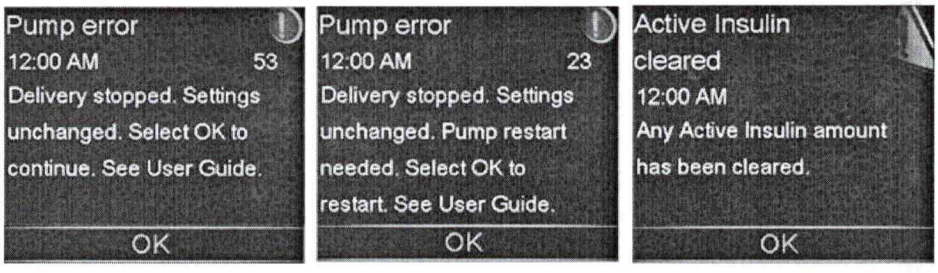
Explanation of issue:

A software issue has been identified in the MiniMed™ 780G pump using software version 6.5 when a large bolus is delivered at quick bolus speed. **These errors may occur if ALL the following conditions are met:**

- The bolus delivery speed is programmed to "Quick" in the pump settings (default is "Standard").
- The SmartGuard™ feature is in use.
- The pump needs to be on the bolus delivery screen when an auto correction bolus is triggered. *Auto corrections are triggered when sensor glucose (SG) is running high and Active Insulin is low.*
- The bolus amount programmed to be delivered is greater than 17.1U.

  Note: This can be a single bolus greater than 17.1U or a combination of boluses totaling greater than 17.1U.

If all the above conditions are met, within 2 minutes of bolus delivery completion, the pump initiates Pump error 53, followed by Pump error 23 alarm. The following screens are presented in the pump screen:



Upon clearing the pump errors, the pump resets and indicates Active Insulin has been cleared. The pump then guides the user to resume operation in Manual Mode. The SmartGuard™ status screen indicates the warm-up period has started. After approximately 5 hours, the SmartGuard™ feature will be available.

Medtronic

Since Active Insulin will display 0.0 units in the pump after experiencing the pump errors above, if the user is not aware of the amount of active insulin and delivers an additional bolus, there is a risk of insulin over delivery, which may result in low blood sugar (hypoglycemia) or severe hypoglycemia. In rare cases, severe hypoglycemia, if left untreated, may lead to a life-threatening situation. As of January 21, 2021, Medtronic has received no reports of serious patient harm or serious injury related to this issue.

What you should do:

If your pump screen indicates that Active Insulin has cleared, please be aware of the following:

1. Although insulin was delivered before the error and you may have insulin on board, Active Insulin is reset to 0.0 units on the pump screen.
2. Before delivering additional boluses, check your graph or history to understand how much insulin was delivered before the error.
3. Consult your healthcare professional about your active insulin absorption and how to plan a bolus if active insulin has been reset to 0.0.

Please follow these steps **if you're using Quick Bolus and require large bolus amounts while in SmartGuard™ feature:**

1. **Wait** at least 2 minutes between boluses if you need to deliver multiple boluses that exceed 17.1U in total.
2. **Consult** your healthcare professional about setting your maximum bolus limit to 17U or less. *Note: The default setting is 10U.*

At Medtronic, patient safety, awareness and customer satisfaction are our top priorities. We apologize for any inconvenience this issue may cause you and 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.

Sincerely,

Erfan Al-Lababidi
Business Manager, Diabetes, APS