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.....34..... dated 17/2/22 Regarding NCMDR FSCA of MiniMed™ 600 and 700 series insulin pump from (mrf: Medtronic SA).

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
Directorate General of Pharmaceutical Affairs and Drug Control
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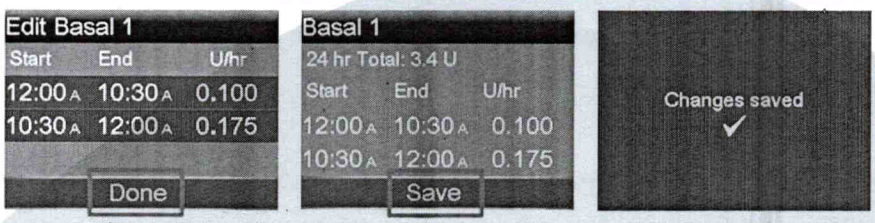
سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة والرقابة الدوائية
مسقط

Circular No. 34 **/ 2022**

16-07-1443 H

17-02-2022

Field Safety Corrective Action of MiniMed™ 600 and 700 series insulin pump from Medtronic SA

Source	NCMDR-National Center for Medical Device Reporting https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=16015
Product	MiniMed™ 600 and 700 series insulin pump.
Description	Ambulatory insulin infusion pump, electronic.
Manufacturer	Medtronic SA.
The affected products	MiniMed™ 640G: MMT-1711, MMT-1712, MMT-1751, MMT-1752; MiniMed™ 670G: MMT-1780, MMT-1781, MMT-1782, MMT-1760, MMT-1761, MMT-1762, MMT-1741, MMT-1742; MiniMed™ 720G: MMT-1809, MMT-1810, MMT-1859, MMT-1860; MiniMed™ 740G: MMT-1811, MMT-1812, MMT-1861, MMT-1862; MiniMed™ 770G: MMT-1881, MMT-1882, MMT-1892, MMT-1891; MiniMed™ 780G: MMT-1885, MMT-1886, MMT-1895, MMT-1896.
Local Agent	Mustafa Sultan Science & Industry Co LLC.
Reason	The new/replacement pump was NOT pre-programmed with the patient's basal rates or other verified settings (i.e., bolus wizard settings, sensor settings, etc.) which must be set up and saved on the pump prior to use.
Action	1. Inform impacted users of the MiniMed™ 600 and 700 series insulin pump using the enclosed letter. 2. Please refer to the attached FSN for more information. 3. Contact the local agent for remedial action.
Product Image	 The exact Basal rates shown above are for example only.
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

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

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

Kingdom of Saudi Arabia
Saudi Food & Drug Authority
Medical Devices Sector
قطاع الأجهزة الطبية

NCMDR
National Center for Medical Devices Reporting
المركز الوطني لبلاغات الأجهزة والمنتجات الطبية

NCMDR Recall

Reference Number: mdprc 005 02 22 000
Date submitted: 2/2/2022

Back

Manufacturer:	Medtronic SA
Device Type:	MiniMed™ 600 and 700 series insulin pump
Description:	Ambulatory insulin infusion pump, electronic.
Medical Device Identifier:	MiniMed™ 640G: MMT-1711, MMT-1712, MMT-1751, MMT-1752; MiniMed™ 670G: MMT-1780, MMT-1781, MMT-1782, MMT-1760, MMT-1761, MMT-1762, MMT-1741, MMT-1742; MiniMed™ 720G: MMT-1809, MMT-1810, MMT-1859, MMT-1860; MiniMed™ 740G: MMT-1811, MMT-1812, MMT-1861, MMT-1862; MiniMed™ 770G: MMT-1881, MMT-1882, MMT-1892, MMT-1891; MiniMed™ 780G: MMT-1885, MMT-1886, MMT-1895, MMT-1896.
Reason of Field Safety Corrective Action:	The new/replacement pump was NOT pre-programmed with the patient's basal rates or other verified settings (i.e., bolus wizard settings, sensor settings, etc.) which must be set up and saved on the pump prior to use.
Remedy Action:	*Inform impacted users of the MiniMed™ 600 and 700 series 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:	*47E2661373215*
SFDA Comments:	*SFDA urges all hospitals that have devices subjected to this FSCA to contact the company.*
Attachments:	*Medtronic SA.pdf*

View History

Medtronic

Field Safety Notice

MiniMed™ 600 and 700 series insulin pump

Basal Setting Programming

MiniMed™ 640G	MMT-1711, MMT-1712, MMT-1751, MMT-1752
MiniMed™ 670G	MMT-1780, MMT-1781, MMT-1782, MMT-1760, MMT-1761, MMT-1762, MMT-1741, MMT-1742
MiniMed™ 720G	MMT-1809, MMT-1810, MMT-1859, MMT-1860
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MiniMed™ 770G	MMT-1881, MMT-1882, MMT-1892, MMT-1891
MiniMed™ 780G	MMT-1885, MMT-1886, MMT-1895, MMT-1896

January 2022

Medtronic Reference: FA1216

Dear Physician, Healthcare Professional,

You are receiving this letter because our records indicate that one or more of your patients have either received a new insulin pump or a replacement insulin pump in the last 6 months. The pump your patient received was NOT pre-programmed with their basal rates or other verified settings (i.e., bolus wizard settings, sensor settings, etc.), which must be set up and saved on their pump prior to use. If the basal rate settings are intended to be set but not entered at all or if they are entered but not saved prior to pump use, it could result in an under-delivery of basal insulin. Under-delivery of insulin can potentially cause severe hyperglycemia, which may lead to life-threatening diabetic ketoacidosis (DKA). As described in the user guide, when programming basal rate settings, the patient must scroll down to select "**Done**" and then select "**Save**" on the next screen to activate the basal rate settings. If "**Save**" is not selected, then basal settings will not be set.

Serious injuries have been reported with the use of the MiniMed™ 600 series and MiniMed™ 700 series insulin pumps which may be directly attributed to not setting basal rates. In addition, one death has been reported, although a review by independent clinical experts did not directly attribute this to not setting basal rates. If basal rates are not set in the pump when they should be, it could potentially lead to those events as explained above.

ACTIONS REQUIRED BY YOU:

1) Inform impacted users of the MiniMed™ 600 and 700 series insulin pump using the enclosed letter.
2) Pass this notice on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Medtronic

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

At Medtronic, patient safety is our top priority, and we are committed to delivering safe and effective therapies. We apologize for any inconvenience this issue may cause you and we appreciate your time and attention in reading this important notification.

If you have further questions or need assistance, please contact your Medtronic representative.

Sincerely,

Erfan Al-Lababidi

Business Manager, Diabetes, APS

Enclosure:

- Pump User Letter

Medtronic

Field Safety Notice

MiniMed™ 600 and 700 series insulin pump

Basal Setting Programming

MiniMed™ 640G	MMT-1711, MMT-1712, MMT-1751, MMT-1752
MiniMed™ 670G	MMT-1780, MMT-1781, MMT-1782, MMT-1760, MMT-1761, MMT-1762, MMT-1741, MMT-1742
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MiniMed™ 780G	MMT-1885, MMT-1886, MMT-1895, MMT-1896

January 2022

Medtronic Reference: FA1216

Dear Pump User,

You are receiving this letter because our records indicate that in the last 6 months, you have either received a new insulin pump or a replacement insulin pump. We want to remind you that the pump you received was NOT pre-programmed with your basal rates or other verified settings (i.e., bolus wizard settings, sensor settings, etc.), which must be set up and saved on your pump prior to use. Please carefully review the instructions below and refer to the user guide in order to confirm that your settings have been saved and, if not, to program your insulin pump with these important settings and ensure that they are saved correctly.

Basal insulin is the "background" insulin needed throughout the day to maintain your target glucose values when you are not eating. Your basal insulin accounts for about half of your daily insulin requirements. Basal insulin delivery is an important component of your total insulin dose. If the basal rate settings are intended to be set but not entered at all or if they are entered but not saved prior to pump use, it could result in an under-delivery of basal insulin. Under-delivery of insulin can potentially cause severe hyperglycemia, which may lead to life-threatening diabetic ketoacidosis (DKA). As described in the user guide, when programming basal rate settings, you must scroll down to select "**Done**" and then select "**Save**" on the next screen to activate the basal rate settings. If "**Save**" is not selected, then basal settings will not be set.

Serious injuries have been reported with the use of the MiniMed™ 600 series and MiniMed™ 700 series insulin pumps which may be directly attributed to not setting basal rates. In addition, one death has been reported, although a review by independent clinical experts did not directly attribute this to not setting basal rates. If basal rates are not set in the pump when they should be, it could potentially lead to those events as explained above.

Medtronic

ACTIONS REQUIRED

New Users with New Device:

1. **Do not use your pump until you have consulted with your healthcare professional to determine the settings.**
2. **Program your settings as described in Steps 4 (c) and (d) below.**

Existing Users: Replacement or Upgrade devices

3. **Verify current basal rate settings**

   To check the current basal rate settings in your pump, follow the instructions on the pump user guide for your pump model.

4. **Check if the basal rate settings are present on your pump**

   If the basal rate settings are present on your pump:

   a. No action is required. For future reference, you may also save your settings to CareLink™, or write them down on a paper and keep it securely.

   If the basal rate settings are not present on your pump, please take all the following actions:

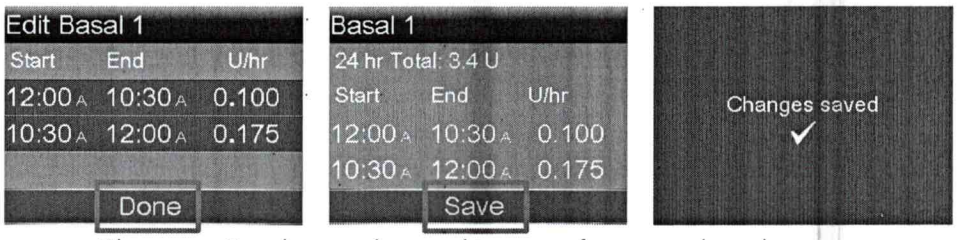
   b. Locate the settings for your pump, including basal rate settings, and consult with your healthcare professional to verify they are the most recent settings.

      i. If you cannot get in touch with your healthcare professional, but your previous settings were uploaded to CareLink™ in the past 90 days, you may log into your CareLink™ Personal, navigate to "Reports", then "Select custom range" to choose a week that had the previous pump's upload, select "DEVICE SETTINGS SNAPSHOT", and select "Generate reports". The settings should have a non-zero basal rate.

   c. Program your new or replaced insulin pump with all your verified settings. Refer to the pump user guide for detailed instructions on programming your insulin pump. If you have your settings but require assistance programming your pump, please contact our Helpline at 8002472288

Medtronic

d. As stated in the user guide, during programming the basal settings on your pump, make sure you respond to all pump screens to ensure your basal settings are saved. As shown in the screen sequence below, you **must** first scroll down to select "**Done**", and then select "**Save**" on the following screen. The settings are successfully saved when the message "**Changes saved**" is shown on the screen.



The exact Basal rates shown above are for example only.

As always, we are here to support you. If you have further questions or need assistance, please call Helpline at 8002472288

At Medtronic, patient safety is our top priority, and we are committed to delivering safe and effective therapies. We apologize for any inconvenience this issue may cause you and we appreciate your time and attention in reading this important notification.

Sincerely,

Erfan Al-Lababidi

Business Manager, Diabetes, APS