الجمهوريــة اللبنـانيــة

وزارة الصحــة العـامــة

المديــر العـــام

جانب شركة Prime Medical

الموضوع: إشعار بمتابعة جهاز طبي

Paradigm pumps

الجهاز المعني بالمتابعة:

- Paradigm pumps
- Trade Mark: Medtronic Diabetes
- Local Representative: Prime Medical

بناء على التوصية الصادرة عن الشركة المصنعة والتي تشير الى وجود خلل في عمل الصنف المذكور اعلاه، نرجو منكم متابعة هذه النشرة مع جميع الجهات المعنية.

مرفق ربطاً:

- التوصية الصادرة عن الشركة المصنعة

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مديـر عـام الصحة

د. وليد عمـار

![Medtronic]

Urgent Field Safety Notice

Paradigm Pump Modes MMT-511, MMT-512, MMT-712, MMT-712E, MMT-515, MMT-715, MMT-522, MMT-722, MMT-722K, MMT-523, MMT-723, MMT-723K, MMT-554, and MMT-754: Recommendations regarding use of Paradigm Pump

Paradigm Pump Models MMT-554 and MMT-754 (VEO): Recommendations for Graph settings in Low Glucose Suspend mode

27 March 2013

Medtronic Reference: FA562

Dear Healthcare Professional:

At Medtronic, we are committed to continually evaluating and improving the quality and reliability of our products and services. Through our monitoring system, we have learned about potential issues and we would like to inform you about these and provide recommendations regarding the usage of our pumps.

Medtronic is informing directly patients for which we have contact details. **Because Medtronic does not have your patients' records on file, we kindly ask you to inform Paradigm pump users using the enclosed letter.**

1. LOOSE DRIVE SUPPORT CAP

The insulin pump's drive support cap holds the pump motor in place and allows the motor's piston to press against the reservoir to deliver insulin.

Some customers have experienced a loose drive support cap, and in rare cases the cap may stick out from the bottom of the reservoir compartment. This condition can occur when the insulin pump is damaged due to impact with a hard surface (for example if it is dropped). We have one report of a customer who attempted to push the drive support cap back into place while attached to the insulin pump. This resulted in unintended delivery of insulin and associated severe hypoglycemia.

A normal insulin pump and an insulin pump with a loose drive support cap are shown in the pictures below.
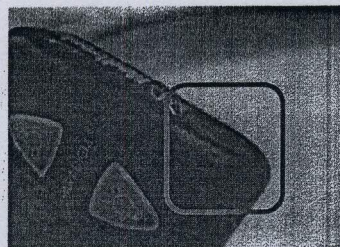
Normal Drive Support Cap-
Cap slightly indented

Loose Drive Support Cap-
Cap sticking out

Below are the recommendations that we are providing to patients:

- *Regularly examine your pump especially after a shock or drop on a hard surface.*
- *If the drive support cap is sticking out, as shown in the photo above, **do not press on this portion of the pump and discontinue use of the pump.***

2. WATER DAMAGE

As explained in the pump user guide, exposure to water may result in pump alarm, damage of the pump's internal electronics or cause the buttons to stop working. Although it is unlikely that water damage will occur if an insulin pump is splashed or briefly dunked, it should not be immersed in water.

Below are the recommendations that we are providing to patients (same recommendations as in the pump user guide)

To swim or participate in other water activities, always disconnect from your Paradigm pump, and reconnect after water play.

If you accidentally submerge your insulin pump in water, dry the pump quickly using a soft, clean towel and verify that it is working properly by selecting Self-test from the insulin pump's Utilities Menu. If you believe that water has entered your insulin pump or you observe any other possible insulin pump malfunction, please check your blood glucose, treat high blood glucose (if necessary) with an injection and contact your help line or representative for further assistance.

3. SENSOR GRAPH Timeout.

This information applies only to Paradigm VEO (MMT-554 and MMT-754) pump users who are also using Medtronic Continuous Glucose Monitoring and have the Low Glucose Suspend feature enabled.

The factory default setting for Sensor Graph timeout is set to 2 minutes. If the Sensor Graph timeout is set to "NONE" it can prevent the auto-resume of basal delivery 2-hours after a Low Glucose Suspend event, which can result in elevated blood glucose values. This will only happen if the pump user goes to the Sensor Graph screen during a Low Glucose Suspend event, and leaves that screen displayed.

Below are the recommendations that we are providing to patients.

- *Do not change the Sensor Graph timeout setting to "NONE."*
- *If you are using the Low Glucose Suspend feature and have changed the Sensor Graph timeout setting to "NONE," please follow the steps below to reset it now.*
    1. *Go to the Sensor Menu*
    2. *Select Edit Settings, Press ACT*
    3. *Select Graph Time Out, Press ACT*
   4. *Select 2, 4 or 6 minutes (do not select "NONE"), Press ACT*

The Competent Authority of your country has been notified of this action.
This notice needs to be passed on all those who need to be aware within your organization.

We deeply apologize for any disruption this may cause your practice. Please know, patient safety is our top priority. Feel free to contact us Salehiya Trading Establishment Tel #: 00 966 1 46469554 if you have any questions or concerns. We appreciate your time and attention to this important notification, and thank you for continuing to put your trust in Medtronic.

Sincerely,

Lina Haffar
Business Manager, Middle East
Medtronic Diabetes

Enclosure: - Letter: Dear Paradigm Insulin Pump Use
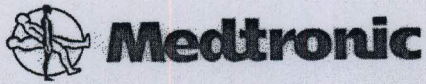
Medtronic

Dear Paradigm Insulin Pump User:

At Medtronic, we are committed to continually evaluating and improving the quality and reliability of our products and services. Through our monitoring system, we have learned about potential issues and we would like to inform you about these and provide recommendations regarding the usage of our pumps.

1. Loose Drive Support Cap

The pump is designed to withstand occasional drops or bumps, however when this happens it is recommended to check the pump for cracks or damage. We have learned about some users having experienced issues with the drive support cap of the pump (see picture below) and we want to proactively inform our customers how to avoid experiencing similar challenges. The pump's drive support cap holds the pump motor in place and allows the motor's piston to press against the reservoir to deliver insulin

In rare cases, the cap may stick out from the bottom of the reservoir compartment. This condition can occur when the pump is damaged due to impact with a hard surface (for example if it is dropped). If the loose drive support cap is pressed on it could result in the unintended delivery of additional insulin.
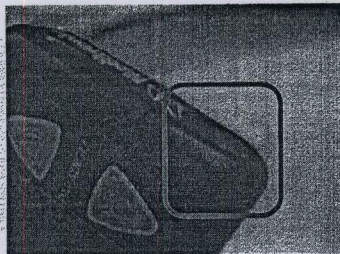
Normal Drive Support Cap-
Cap slightly indented

Loose Drive Support Cap-
Cap sticking out

Recommendations:
- *Regularly examine your pump especially after a shock or drop on a hard surface.*
- *If the drive support cap is sticking out, as shown in the photo above, **do not press on this portion of the pump and discontinue use of the pump.***

2. Water Damage

We also would like to reiterate our recommendations regarding pump's exposure to water. As explained in the pump user guide, exposure to water may result in pump alarm, damage of the pump's internal electronics or cause the buttons to stop working. Below is a copy of the relevant part of the user guide that we ask you to take good note of.

To swim or participate in other water activities, always disconnect from your Paradigm pump, and reconnect after water play.

If you accidentally submerge your insulin pump in water, dry the pump quickly using a soft, clean towel and verify that it is working properly by selecting Self-test from the insulin pump's Utilities Menu. If you believe that water has entered your insulin pump or you observe any other possible insulin pump malfunction, please

check your blood glucose, treat high blood glucose (if necessary) with an injection and contact your help line or representative for further assistance.

3. **Sensor Graph Timeout.**
   This information applies <u>only</u> to Paradigm VEO (MMT-554 and MMT-754) pump users who are also using Medtronic Continuous Glucose Monitoring and have the Low Glucose Suspend feature enabled.

Your Paradigm Veo insulin pump allows you to set the number of minutes to display the Sensor Graph before returning to the home screen.

The factory default setting for Sensor Graph timeout is set to 2 minutes. If the Sensor Graph timeout is set to "NONE" it can prevent the auto-resume of basal delivery 2-hours after a Low Glucose Suspend event, which can result in elevated blood glucose values. This will only happen if you go to the Sensor Graph screen during a Low Glucose Suspend event, and leave that screen displayed.   When this happens, the pump will beep 3 times every 15 minutes to remind you that insulin delivery has been suspended. All other alarms will function normally, but basal delivery will not resume as long as the Sensor Graph screen is displayed.

Recommendations:
- *Do not change the Sensor Graph timeout setting to "NONE."*
- *If you are using the Low Glucose Suspend feature and have changed the Sensor Graph timeout setting to "NONE," please follow the steps below to reset it now.*

   1. *Go to the Sensor Menu*
   2. *Select Edit Settings, Press ACT*
   3. *Select Graph Time Out, Press ACT*
   4. *Select 2, 4 or 6 minutes (do not select "NONE"), Press ACT*

We have notified your healthcare professional with this same information. Please contact us at Salehiya Trading Establishmen Tel #: 00 966 1 46469554 if you have any questions or concerns or need a replacement pump.

We appreciate your time and attention to this important notification, and your continued trust in Medtronic.

Sincerely,

Lina Haffar

Business Manager, Middle East

Medtronic Diabetes