Urgent Medical Device Safety Notification

Dear Medtronic Paradigm® Insulin Pump User:

At Medtronic we are committed to continually evaluating and improving the quality and reliability of our products and services. This letter is to notify you of two potential safety issues relating to our Paradigm insulin infusion pumps. As always, please feel free to contact our support team at 1.888.204.7616, option 1, if you have any questions regarding this letter.

1. LOOSE DRIVE SUPPORT CAP

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.

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 pump is damaged due to impact with a hard surface (for example if it is dropped). As of February 2013, we have one report of a customer who attempted to push the drive support cap back into place while attached to the pump. This resulted in unintended delivery of insulin and associated severe hypoglycemia.

A normal pump and a pump with a loose drive support cap are shown in the pictures below.

![Normal Drive Support Cap](image1)

Normal Drive Support Cap - Cap slightly indented

![Loose Drive Support Cap](image2)

Loose Drive Support Cap - Cap sticking out

**Recommendations:**
Examine your pump. If the drive support cap is sticking out, as shown in the photo above, **DO NOT PRESS ON THIS PORTION OF THE PUMP.** Please discontinue use of the pump and contact Medtronic at 1.888.204.7616, option 1, to arrange for the pump to be replaced. During this time you will need to manage your diabetes with insulin injections, per the back-up plan provided to you by your healthcare professional.

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1 The model numbers of the pumps that may be affected by these issues are MMT-511, MMT-512, MMT-712, MMT-712E, MMT-515, MMT-715, MMT-522, MMT-722, MMT-522K, MMT-722K, MMT-523, MMT-723, MMT-523K MMT-723K, MMT-554, and MMT-754.
2. WATER DAMAGE

As explained in your Medtronic insulin pump user guide, exposure to water can damage the pump’s internal electronics. Water damage may result in a pump alarm or cause the buttons to stop working. Although it is unlikely that water damage will occur if your pump is splashed or briefly dunked, you should not immerse your insulin pump in water.

**Recommendations:**
To swim or participate in other water activities, always disconnect from your pump, keep it in a safe place and reconnect after you are out of the water.

If you accidentally submerge your 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 pump’s Utilities Menu. If you believe that water has entered your pump or you observe any other possible pump malfunction, please contact us at 1.888.204.7616, option 2, for assistance with troubleshooting.

We have notified your healthcare professional about these potential safety issues. Feel free to call us if you have any questions or concerns. We appreciate your time and attention to this important notification, and your continued trust in Medtronic.

Sincerely,

Shirajul Karim  
Vice President, Quality  
Medtronic Diabetes