



Medtronic, Inc.
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Urgent Medical Device Safety Notification

Dear Medtronic 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 a potential safety issue relating to our Paradigm insulin infusion pumps.¹ As always, please feel free to contact our support team at 1-800-646-4633, 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). 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-
Cap slightly indented



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.

¹ The model numbers of the pumps that may be affected by these issues are MMT-522, MMT-522K, MMT-722, MMT-722K, MMT-523, MMT-523K, MMT-723, MMT-723K, MMT-551, and MMT-751.

We have notified your healthcare professional about this potential safety issue. 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,

A handwritten signature in black ink, appearing to read "James R. Dabbs". The signature is fluid and cursive, with a prominent initial "J" and "D".

Jim Dabbs
Vice President, Quality
Medtronic Diabetes