

Update – Prior Potential Safety Issue

Dear Medtronic Insulin Pump User:

At Medtronic, we are committed to continually evaluating and improving the quality and reliability of our products and services. We are reaching out to remind you of a prior field corrective action relating to our Paradigm insulin infusion pumps.¹ Since that communication, an updated version of your current pump is now available which has been redesigned to eliminate the potential safety issue, which we describe in more detail below. Please contact Medtronic at **1-888-204-7616** or visit <http://www.medtronicdiabetes.com/support-cap> if you are interested in having your current pump replaced with the updated version of your current pump model.

Reminder of Potential Safety Issue: LOOSE DRIVE SUPPORT CAP PROTRUDES FROM PUMP

The pump's drive support cap (pictured below) holds the pump motor in place and allows the motor's piston to press against the reservoir to deliver insulin. There have been reported incidences of this cap becoming loose, primarily in earlier generation pump designs. In rare cases, the cap may stick out from the bottom of the reservoir compartment, which can occur when the pump is damaged, for example if it is dropped. We have one report of a customer who attempted to push the cap back into place while the pump was still attached to their body. 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

Action Needed:

Examine your pump. If the drive support cap is sticking out, as shown in the photo above, **DO NOT PRESS ON IT**. Please discontinue use of the pump and contact Medtronic at 1-888-204-7616 to arrange for the pump to be replaced with the updated version of this Paradigm model pump as promptly as possible. 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. Please note your healthcare professional has also been made aware of this potential safety issue.

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

You can always report a concern to the FDA's MedWatch Adverse Event Reporting program:

Online at: <http://www.fda.gov/safety/medwatch/howtoreport/default.htm>

Report by telephone: 1-800-FDA-1088

Fax report: 1-800-FDA-0178

Should you have any questions or concerns regarding this issue please do not hesitate to contact the Medtronic 24-Hour HelpLine at 1-888-204-7616. Your safety and complete satisfaction are our first priority and we appreciate your time and attention to this important notification.

Sincerely,

A handwritten signature in blue ink that reads "James R. Dabbs". The signature is fluid and cursive, with a long horizontal stroke at the end.

Jim Dabbs
Vice President, Quality
Medtronic Diabetes

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