

IMPORTANT MEDICAL DEVICE SAFETY INFORMATION
Medtronic MiniMed Paradigm Insulin Infusion Pump

May 11, 2007

Re: Reminder to Avoid Exposing Medtronic MiniMed Insulin Pumps to Strong Magnetic Fields

Dear Customer:

If your insulin pump is exposed to strong magnetic fields, the pump may exhibit over-delivery that could potentially result in severe hypoglycemia. As stated in the product labeling you must avoid exposing your pump to strong magnetic fields such as MRI.

Recently, we have become aware of three potential cases outside of Canada where direct exposure of the pump to Magnetic Resonance Imaging (MRI) has resulted in damage to the component that monitors and controls the movement of the motor used in Medtronic MiniMed Paradigm insulin infusion pumps. Although the pumps exhibited alarms as a result of this exposure, it was reported that the user overrode these alarms and continued to use the pump.

Medtronic MiniMed has always cautioned users to avoid exposing infusion pump to strong magnetic fields such as those associated with MRI machines. Until recently, all testing has indicated this exposure would result in significant pump damage and prevent Paradigm insulin pumps from delivering any insulin following this exposure. However, we are now aware that significant over-delivery of insulin can occur following exposure to strong magnetic fields.

In light of this new information, we are reminding pump users that you should not expose your pump to strong magnetic fields such as those generated by MRI equipment. **YOUR PUMP MUST BE REMOVED AND KEPT OUTSIDE THE PROCEDURE ROOM IF YOU ARE UNDERGOING MRI.**

If the pump is damaged by exposure to a high strength magnetic field, the pump will typically provide multiple and frequent alarms such as "motor error" alarms (especially after rewind), A35 alarms, A43 alarms and "no delivery" alarms. In addition, the pump will no longer provide "low reservoir" alerts, and the actual volume in the reservoir will be less than the "insulin remaining" amount displayed on the pump's status screen. If you suspect the pump may have been exposed to MRI or another very strong magnetic field, or you observe any of these alarms or unusual displays, please discontinue use of the pump immediately and contact Medtronic Minimed at **1-800 Minimed, (1-800-646-4633)**, for further assistance.

Please note that Paradigm insulin infusion pumps have undergone extensive testing with devices such as airport metal detectors, electronic article surveillance equipment and cellular phones and we have confirmed that exposure to these devices will not adversely affect pump operation.

Please feel free to contact your Medtronic Diabetes support team at 1-800-284-4416 if you have any questions regarding this letter or with any other questions you might have regarding our products.

Sincerely,

Medtronic of Canada Ltd.