

FIELD SAFETY NOTIFICATION INCORRECT RISE ALERT INSTRUCTIONS

MiniMed™ 630G Insulin Pump: MMT-1714K, MMT-1714KRP

5 March 2020

Dear Valued Customer:

You are receiving this letter because our records indicate you may be using a MiniMed™ 630G insulin pump that included incorrect instructions on how to confirm that Rise Alerts are disabled in your pump. These incorrect instructions were sent as a Release Note with the MiniMed™ 630G insulin pumps distributed in Canada between November 2019 and February 2020.

Because your safety is our top priority, we are making you aware of the correct instructions and some recommended precautions.

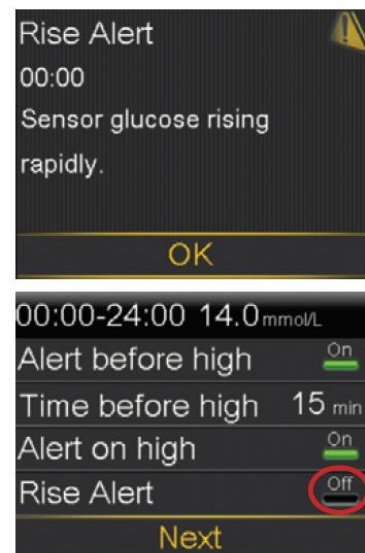
The insulin pump model can be found on the bottom of your pump and the model number can be found on the back of your pump.

Insulin Pump Model	Model Number
MiniMed™ 630G Insulin Pump	MMT-1714K MMT-1714KRP

Actions required:

Please confirm Rise Alerts are disabled on your pump.
 To disable Rise Alerts, follow these instructions:

1. Go to the high settings Setup screen.
 - a. **Menu > Sensor Settings > High Settings > Setup.**
2. Select **Edit**.
3. Press **O** four times to view settings.
4. Confirm that **Rise Alert** is off.
5. Select **Next**.
6. Repeat for each time segment.
7. Select **Done**, then select **Save**.



Rise Alert
On/Off



INCORRECT RISE ALERT INSTRUCTIONS

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The Rise Alert in your pump contains a software calculation error which uses a sensor glucose value that is 10 times greater than the correct value due to a conversion error. As a result, this alert is triggered earlier than the user settings. This makes the Rise Alert trigger at values that do not require alerts. The Rise Alerts do not directly affect insulin therapy.

Precautions recommended for all patients:

1. The Rise Alert feature is disabled from the factory. Medtronic recommends that you confirm that the Rise Alert feature is disabled on your pump and that you do not enable the Rise Alert feature.
2. Confirm your blood glucose levels with your Blood Glucose Meter (BGM), please continue to monitor over time.

At Medtronic, patient safety is our top priority, and we are committed to delivering safe and effective technologies of the highest quality and reliability possible. We appreciate your time and attention in reading this important notification.

As always, we are here to support you. If you have further questions or need assistance, please call our 24-Hour Technical Support team at: 1.800.284.4416.

Additional Information:

Health Canada has been notified of these actions. As is standard practice, any adverse events or quality problem experienced with the use of this product should be reported to Medtronic at 1.800.284.4416.

Sincerely,

Lisa Armour

For

Isabelle Gerges

Director, Quality