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URGENT FIELD SAFETY NOTICE

MiniMed™ Mio™ Advance (MMT-242, MMT-242T, MMT-242600, MMT-247, MMT-247T, MMT-247600)
User Guide Update – Soft Cannula Insulin Fill Volume

December 2018

Medtronic Reference: FA851

Dear Healthcare Provider:

The intent of this letter is to notify you that the soft cannula insulin fill volume recommended in MiniMed™ Mio™ Advance infusion set user guides has been updated.
Since Medtronic does not have your patients' records on file, we ask that you inform users of the MiniMed™ Mio™ Advance infusion set using the enclosed letter.

Explanation of Issue:
The current MiniMed™ Mio™ Advance infusion set user guide recommends that 6 mm and 9 mm soft cannulas be filled with 0.9 units (0.009 ml) of insulin after inserting a new set. The user guide is now being updated to recommend that 6 mm and 9 mm soft cannulas be filled with **0.6 units** (0.006 ml) of insulin. Reducing the soft cannula insulin fill volume to 0.6 units (0.006 ml) will reduce the risk of potential hypoglycemic events, particularly among pediatric patients.

In the interim period between now and when updated user guides are packaged with MiniMed™ Mio™ Advance infusion sets, patients will find a 1-page insert inside shipper boxes calling their attention to this matter. This is not a product recall and does not affect any other Medtronic MiniMed infusion set brands.

What your patients should do:
Fill the MiniMed™ Mio™ Advance infusion set soft cannula with insulin as follows:
6 mm: 0.6 units (0.006 ml)
9 mm: 0.6 units (0.006 ml)

At Medtronic, patient safety is our top priority, and we are committed to delivering safe and effective therapies that undergo rigorous clinical, quality, manufacturing, and regulatory controls for our customers. We appreciate your time and attention in reading this important notification.

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The Competent Authority of your country has been notified of this issue. If you have further questions or need assistance, please contact your Medtronic representative directly or via Tel no: 01 511 1444

Sincerely,
Keith Taverner
Regulatory Affairs Manager UK & Ireland

Enclosed: Ireland Dear Patient Letter FA851
Errata Sheet insert