

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 Pump User:

You are receiving this letter because our records indicate that you may use one of the above-referenced MiniMed™ Mio™ Advance infusion set model numbers. The intent of this notice is to update the soft cannula insulin fill volume recommended in the user guide for all MiniMed™ Mio™ Advance infusion set models. The soft cannula is the MiniMed™ Mio™ Advance infusion set component that delivers insulin below the skin.

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 your MiniMed™ Mio™ Advance infusion sets, you will find a 1-page insert inside shipper boxes calling your attention to this matter. This is not a product recall and does not affect any other Medtronic MiniMed infusion set brands.

What you 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.

If you have further questions or need assistance, please call our support line at Tel No: 01 511 1444.

Medtronic

Medtronic Ireland Limited

Block 3090-3094

Lake Drive

Citywest Business Campus

Dublin

DN24 XN47

www.medtronic.ie

Tel: 01 511 1400

Fax: 01 807 7220



Sincerely,

Keith Taverner

Regulatory Affairs Manager UK & Ireland