URGENT MEDICAL DEVICE RECALL

MiniMed™ Flex Insulin Pump

Missing Manufacturing Test Data

Product Name	Model/CFN Number	Serial Numbers
MiniMed™ Flex Insulin Pump	MMT-8072	See Appendix I

August 2026

MiniMed reference: FA1591

Dear Valued Customer,

We are writing to inform you of an important safety recall regarding your MiniMed Flex Insulin Pump. Refer to Appendix I for serial number information. Your safety and well-being are our highest priorities, and we want to make sure you have all the information you need to continue managing your diabetes safely.

Issue Description:

MiniMed identified an issue in which certain MiniMed Flex Insulin Pumps (MMT-8062) were released to customers with incomplete manufacturing testing.

Health risk:

As a result of incomplete testing, your pump may have the potential for lack of protection from moisture exposure, slow charging, disconnection with sensor or MiniMed App, reduced ability to detect occlusion, no audio or low audio volume for alarms/alerts, or insulin under-delivery. If your pump experiences these issues, it could potentially lead to delayed therapy or risk of hypoglycemia, hyperglycemia, diabetic ketoacidosis (DKA) or death.

As of August 20, 2026, three (3) complaints have been reported of pumps failing to turn on at first use, with no adverse events reported to date. This recall is being reported to the U.S. Food and Drug Administration.

Required Actions:

1. Stop using the Flex pump in your possession and revert to your back-up plan for insulin therapy.
2. Please contact us immediately at (844) 885-0259 so we can arrange to ship you a new Flex pump overnight. Upon calling, please say “Flex” when prompted to connect with an agent.

3. Please acknowledge that you've read and understood this notification and have followed the actions listed by completing and returning the confirmation form, scanning the QR code below with your phone or tablet, or by visiting https://info.medtronicdiabetes.com/FA1591 to acknowledge communication.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax as follows:

- Complete and submit the report online: www.fda.gov/MedWatch/report.htmhttp://www.fda.gov/MedWatch/report.htm or
- For Regular mail or fax: Download the form at www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

As always, we are here to support you and ensure we deliver the highest quality products possible. If you have further questions or need assistance, please call the MiniMed 24-Hour Technical Support line at 1-800-646-4633, option 1.

Sincerely,
MiniMed

Appendix I – Subject Products

Product Name	Model/CFN Number	Serial Numbers
MiniMed™ Flex Insulin Pump	MMT-8072	FB00010465
		FB00011357
		FB00011553
		FB00014455
		FB00014472
		FB00014766
		FB00014822
		FB00015700
		FB00015793
		FB00015794
		FB00015796
		FB00015797
		FB00015799
		FB00015801
		FB00015828
		FB00015839
		FB00015977
		FB00016511
		FB00018580
		FB00019307