Class 2 Device Recall MiniMed" 780G Insulin Pump, software version 6.62 OUS

Class 2 Device Recall MiniMed" 780G Insulin Pump, software version 6.62 OUS

See Related Information[22]

Date Initiated by Firm	May 27, 2026
Date Posted	July 08, 2026
Recall Status[1]	Open[3], Classified
Recall Number	Z-2698-2026
Recall Event ID	99207[23]
510(K)Number	K251032[24]
Product Classification	Alternate controller enabled insulin infusion pump[25] - **Product Code** QFG[26]
Product	MiniMed 780G Insulin Pump, REF: MMT-1885, MMT-1886, MMT-1895, MMT-1896
Code Information	UDI-DI/GTIN: A7630006392701, 00763000521554, 00763000639273, A7630006392301, 00199150035687, A7630007325603, A7630007325601, 00763000639235, A7630007325604, 00763000384289, 00763000521530, A7630007325401, 00763000521547, A7630006392601, A7630006392201, 00763000639228, 00199150035663, 00763000639266, A7630007325404, 00199150035694, 00763000442194, A7630007325403, 00763000521523. Software version 6.62
FEI Number	3003166194
Recalling Firm/ Manufacturer	Medtronic MiniMed, Inc. 18000 Devonshire St Northridge CA 91325-1219
For Additional Information Contact	Janet Cho 800-646-4633 Ext. 1
Manufacturer Reason for Recall	A software anomaly can occur when the pump is paired with the Instinct sensor. Under certain circumstances, the pump unexpectedly stops delivering insulin and displays two error messages back-to-back: Pump Error 53 followed immediately by Pump Error 23. Insulin delivery will stop which may lead to delayed therapy and an increased risk of hyperglycemia or diabetic ketoacidosis (DKA).
FDA Determined Cause [2]	Software design
Action	On 5/27/2026, field safety notices were emailed to customers who were asked to do the following: 1) Update insulin pump software to version 6.63. The update may take up to 3 hours to complete. 2) Reply to this email to confirm that you have read and understood this notification and, where applicable, completed the required action. If you have questions, contact the firm at 01923 205167
Quantity in Commerce	778
Distribution	International distribution to the countries of Spain, Great Britain, Netherlands, Italy.
Total Product Life Cycle	TPLC Device Report[27]

[1] A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about medical device recalls[28].

[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

[3] The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

510(K) Database 510(K)s with Product Code = QFG[29]

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21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/enforcement-reports
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=99207
24. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K251032
25. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=QFG
26. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=QFG
27. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=QFG
28. https://www.fda.gov/medical-devices/medical-device-recalls/what-medical-device-recall
29. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&productcode=QFG&knumber=&applicant=Medtronic%20Minimed%2C%20Inc%2E

FDA

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Ph. 1-888-INFO-FDA (1-888-463-6332)
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19. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/enforcement-reports
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=99207
24. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K251032
25. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=QFG
26. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=QFG
27. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=QFG
28. https://www.fda.gov/medical-devices/medical-device-recalls/what-medical-device-recall
29. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&productcode=QFG&knumber=&applicant=Medtronic%20Minimed%2C%20Inc%2E