Important Drug Recall Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC26-010-CG
April 29, 2026

FDA announced that, *This recall involves correcting devices, and does not involve removing them from where they are used or sold. The FDA has identified this recall as the most serious type. This device may cause serious injury or death if you continue to use it without correction. This recall was classified on November 5, 2025.*

The FDA is aware that Tandem Diabetes Care has issued an Urgent Medical Device Correction to affected customers recommending all Tandem Mobi insulin pumps with software versions 7.6.0.1, 7.6.0.3, and 7.7.0.1. be corrected prior to continued use.

RECOMMENDATIONS

1. Update your pump software as soon as possible. Be prepared with a backup method of insulin delivery.
2. You can check your software version within the Mobi Mobile App. Select Settings > Pump > Pump Info. These instructions can also be found in your user guide.
3. To learn more about how to check your software version, visit Tandem's Mobi Support Center.
4. Customers in the U.S. with adverse reactions, quality problems, or questions about this recall should contact Tandem Diabetes Care at Techsupport@tandemdiabetes.com or 1-877-801-6901.
5. Review your inventory to identify existence of recalled products.
6. Expect patients to visit your pharmacy to deliver recalled products and prepare your pharmacy staff on how to handle the situation.

Cordially,

MC-Rx Pharmacy Services Department

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Insulin Pump Correction: Tandem Diabetes Care Issues Correction for Tandem Mobi Insulin Pumps

This recall involves correcting devices, and does not involve removing them from where they are used or sold. *The FDA has identified this recall as the most serious type. This device may cause serious injury or death if you continue to use it without correction. This recall was classified on November 5, 2025.*

Affected Product

The FDA is aware that Tandem Diabetes Care has issued an Urgent Medical Device Correction to affected customers recommending all Tandem Mobi insulin pumps with software versions 7.6.0.1, 7.6.0.3, and 7.7.0.1 be corrected prior to continued use.

Affected devices:

Device Description	Catalog Number	UDI-DI
Pump, Tandem Mobi, Control-IQ	1010750	00389152075013
Pump, Tandem Mobi, Control-IQ, Replacement	1012719	00389152271910
Pump, Tandem Mobi, Control-IQ 7.6.0.3, Medicare	1013501	00389152350110
Pump, Tandem Mobi, Control-IQ 7.7	1013655	00389152365510
Pump, Tandem Mobi, Control-IQ 7.7, Replacement	1013656	00389152365619
Pump, Tandem Mobi, Control-IQ 7.7, Medicare	1013700	00389152370019
Pharmacy Kit, Starter Pack, Tandem Mobi 7.7	1014081	00389152408170

What to Do

Update your pump software as soon as possible. Be prepared with a backup method of insulin delivery.

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On October 6, 2025, Tandem Diabetes Care sent all affected customers an Urgent Medical Device Correction recommending the following actions:

- If you haven't had a Malfunction 12, continue using your Tandem pump as described in the User Guide, with added precautions as the Malfunction 12 can occur at any time.

- Update your pump software as soon as possible to access quality improvements through a free software update available to Tandem Mobi pump users. This software update is called version 7.9.0.2.
  - You can check your software version within the Mobi Mobile App. Select Settings > Pump > Pump Info. These instructions can also be found in your user guide.
  - To learn more about how to check your software version, visit Tandem's Mobi Support Center.
  - If your pump says anything other than v7.9.0.2 you should update your software.

- The latest software can be downloaded remotely from within the Tandem Mobi Mobile App. Once logged in to the app, tap "Settings" and then "Pump" to view software updates available to you. Visit Tandem's How to Update ArticleExternal Link Disclaimer for step-by-step update instructions.
  - Note: When updating your Mobi pump software, always follow all security precautions and instructions provided to you in the Tandem Mobi user guideExternal Link Disclaimer.

- If you receive a Malfunction 12 alert:
  - Promptly acknowledge it by pressing "Silence Alarm".
  - Contact Tandem at 1-877-801-6901 or Techsupport@tandemdiabetes.com for further assistance.
  - Switch to your backup method of insulin delivery as directed by your physician.
  - Regularly check your blood sugar to ensure you are not having unexpectedly high or low readings.

- Be prepared with a backup method of insulin delivery as directed by your physician, as set forth in the pump training, and as laid out in the pump user guide.

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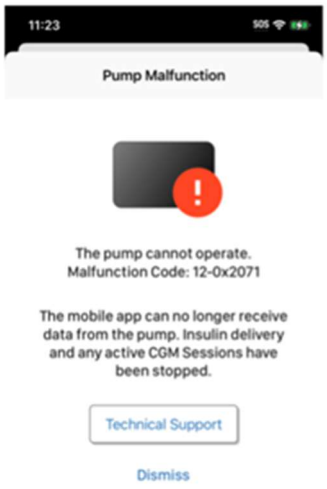
Reason for Correction

Tandem Diabetes Care stated that Tandem Mobi insulin pumps operating on affected software versions may incorrectly detect a motor issue, known as a false motor failure.
In addition to audible notifications, the Mobi insulin pump includes a vibration motor that gives tactile feedback for any alerts, alarms, or malfunctions. During normal use, the Mobi insulin pump software monitors the electric current flowing through the vibration motor during use. If the vibration motor current is detected as out of range during the pump's periodic monitoring, a malfunction of the pump is triggered to notify the user (Malfunction 12). If the pump incorrectly detects a motor issue, it can lead to the pump triggering Malfunction 12. If your Tandem Mobi pump shows Malfunction 12, insulin delivery will stop, and the pump becomes non-operational.



A Malfunction 12 will stop insulin delivery and terminate communication between the insulin pump and the Continuous Glucose Monitoring (CGM) device, as well as the Tandem Mobi mobile app. If not addressed, this could result in hyperglycemia due to the malfunction resulting in the stoppage of insulin delivery and real time CGM Estimated Glucose Values (EGVs) and CGM trends. In severe cases of hyperglycemia, the user may require hospitalization or intervention from a medical professional.

As of November 4, 2025, Tandem Diabetes Care has reported four serious injuries, and no deaths associated with this issue.

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Device Use

Tandem insulin pumps are battery-operated infusion pumps capable of both basal and bolus delivery of insulin. The pumps utilize a motor-driven mechanism to deliver insulin from within a disposable cartridge, through an infusion set, into a patient's subcutaneous tissue.

Contact Information

Customers in the U.S. with adverse reactions, quality problems, or questions about this recall should contact Tandem Diabetes Care at Techsupport@tandemdiabetes.com or **1-877-801-6901.**

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