



URGENT MEDICAL DEVICE CORRECTION
Malfunction 12 – Vibe Motor
Tandem Mobi Insulin Pump

October 6, 2025

The purpose of this letter is to advise you that Tandem Diabetes Care is voluntarily initiating an Urgent Medical Device Correction for Tandem Mobi insulin pumps using pump software versions 7.6.0.1, 7.6.0.3, or 7.7.0.1. Some of these pumps may experience a false motor failure, where the pump incorrectly detects a problem with the vibration motor. This false detection can cause the pump to be inoperable. You are receiving this letter because our records indicate you may be using one of the affected Tandem Mobi insulin pumps, which includes software that is impacted.

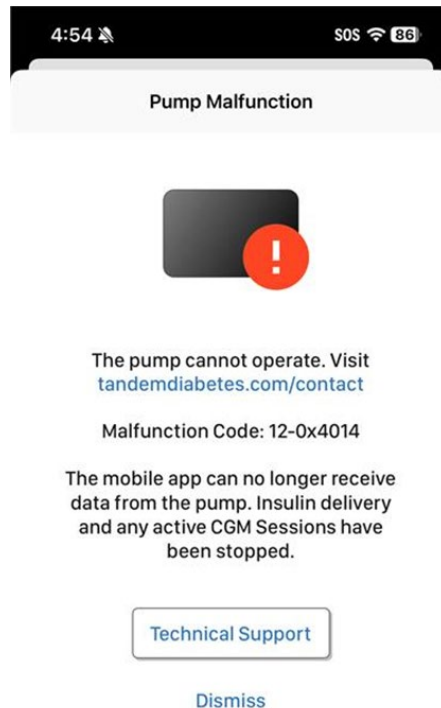
If you receive this Urgent Medical Device Correction notice, it is important to acknowledge receipt of this notice by completing the online form available at the following link or by using the QR code below:

<https://campaign.tandemdiabetes.com/FCA-Malfunction-12>



What is the potential issue?

In addition to enunciating 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).



Tandem has determined that your Tandem Mobi insulin pump is operating with a software version that may incorrectly detect a motor issue, known as a false motor failure. This 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. Please contact Tandem Diabetes Care Customer Technical Support (CTS) via phone at 1-877-801-6901 or email at Techsupport@tandemdiabetes.com for further assistance.

Risk

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.

There have been 281 adverse events reported and 4 reported injuries. There have been no reports of death.

Recommended Actions

1. 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.
2. Tandem **recommends that you 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.
3. 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 Article](#) 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 guide.

https://www.tandemdiabetes.com/docs/default-source/user-guide/user-guide-tandem-mobi-control-iq-7-9-mgdl-en-us-aw1014938.pdf?sfvrsn=872fc4d7_10

4. If you receive a Malfunction 12 alert:
 - a. Promptly acknowledge it by pressing "Silence Alarm".
 - b. Contact Tandem at 1-877-801-6901 or Techsupport@tandemdiabetes.com for further assistance.
 - c. Switch to your backup method of insulin delivery as directed by your physician.
 - d. Regularly check your blood sugar to ensure you are not having unexpectedly high or low readings.
5. 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.
6. As requested above, please complete the online form acknowledging receipt of this notice.

If you experience any adverse reactions or quality problems with the use of our products, please email Techsupport@tandemdiabetes.com or call Tandem Diabetes Care Customer Support at 1-877-801-6901. Our team is available 24/7/365.

Alternatively, you can also utilize the FDA's MedWatch Adverse Event Reporting program either online (www.fda.gov/medwatch/report.htm), by regular mail, or by fax (1-800-332-0178).

We appreciate your time and attention to this important notification.

Thank you for being a part of the Tandem family.

Sincerely,

Tandem Diabetes Care

Frequently Asked Questions (FAQs)

1. What extra precautions should I take?

Regularly check your blood sugar to ensure you are not having unexpectedly high or low readings.

2. What is an Urgent Medical Device Correction?

According to the FDA, a correction means the repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a product without its physical removal to some other location.

3. Why are you not physically recalling these Tandem Insulin Pumps?

By updating the pump software on your Tandem Mobi insulin pump, this incorporates quality improvements made to the pump software that mitigates the potential issue.

4. How many Tandem Pumps are affected?

Any Tandem Mobi insulin pump running software version 7.7.0.1 or earlier.

5. What can be the potential risk?

This issue will stop insulin delivery and terminate communication between the insulin pump and the 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.

6. Has there been any serious injury or death related to this potential risk?

Serious injury might occur only if the user does not acknowledge the malfunction alarm if this issue occurs.

7. I haven't had any problems yet. Do I need to worry about my pump?

Even if you haven't experienced this issue, Tandem recommends updating to the latest software that includes these quality improvements.

8. What solution is Tandem offering to affected customers?

Your Tandem Mobi insulin pump is eligible for a software update that includes a software change. The latest software can be downloaded remotely from within the Tandem Mobi Mobile App (mTDU). Once logged in to the app, tap "Settings" and then "Pump" to view software updates available to you. Visit [Tandem's How to Update Article](#) 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 guide.

9. How do I know what software version my pump is?

You can check your software version within the Mobi Mobile App. Select Settings> Pump > Pump Info. If your App says anything other v7.9.0.2 you should update your software.

To learn more about how to check your software version, visit [How to Check Mobi Software](#) article.

10. How will Tandem address this in the future to avoid similar problems?

While your Tandem Mobi insulin pump is functioning as intended, we have already implemented a software change which is designed to further reduce potential risk to the user. The latest software can be downloaded remotely from within the Tandem Mobi Mobile App (mTDU). Once logged in to the app, tap “Settings” and then “Pump” to view software updates available to you. Step-by-step instructions can be found by clicking the following link:

<https://www.tandemdiabetes.com/support/software-updates/how-to/tandem-mobi/update>

11. Is there any training required to update to the latest software?

The following software updates will require training by the pump users:

v7.6 to v7.9.0.2:	G7 compatibility and CIQ+ training
v7.7 to v7.9.0.2:	CIQ+ training

12. How do I get the new software for my pump?

The latest software can be downloaded remotely from within the Tandem Mobi Mobile App (mTDU). Once logged in to the app, tap “Settings” and then “Pump” to view software updates available to you. Step-by-step instructions can be found by clicking the following link:

<https://www.tandemdiabetes.com/support/software-updates/how-to/tandem-mobi/update>

Note: When updating your Mobi pump software, always follow all security precautions and instructions provided to you in the Tandem Mobi user guide.

13. What do I do if I experience an adverse event or problem?

If you experience any adverse reactions or quality problems with the use of our products, please call Tandem Diabetes Care Customer Technical Support at 1-877-801-6901 or email Techsupport@tandemdiabetes.com. Our team is available 24/7/365. Alternatively, you can also utilize the FDA’s MedWatch Adverse Event Reporting program either online (www.fda.gov/medwatch/report.htm), by regular mail or by fax (1-800-332-0178). As always, if you are having a medical emergency, call 911.