Dexcom

URGENT: MEDICAL DEVICE CORRECTION NOTIFICATION - Dexcom ONE+ iOS App versions 1.5 to 1.6 – Mandatory Update
US-MF-000010694 – UDI: 00386270004307

Description of the Problem:
A software error was identified within app versions 1.5 to 1.6 that can cause the app display to flicker sequentially through previous estimated glucose values (EGVs) and trend arrows before displaying the current EGV and trend arrow with the potential to delay glucose alarms/alerts. This may occur when the app display is brought to the foreground on a smart device, after having been run for a period of time in the background. You're using an older version of the Dexcom ONE+ iOS app, which may not function as intended due to this issue.

Risk to Health:
If a user is unaware that a glucose value or trend arrow displayed by the app is not updated or if a user does not receive a prompt alert, there is potential for the missed detection of a hyperglycemic (high glucose) or hypoglycemic (low glucose) event, or for a treatment decision to be made based on incorrect information. Through 13 March, 2026, 4 complaints have been received globally, which have been confirmed to be associated with this issue. Of those, there have been no serious injuries.

Required Customer Action:
Updating from app versions 1.5-1.6 to the most current version is mandatory and you will not be able to use app versions 1.5 to 1.6 after April 30, 2026. Update your app now to continue using the app:

1. Tap **Update App** to go to the app store
2. Install the latest Dexcom ONE+ iOS app version
3. Open the Dexcom ONE+ iOS app

If you need assistance, contact Technical Support.
Global: Find local Technical Support contact information at Dexcom.com

Adverse reactions or quality problems experienced with the use of these products should be reported to the National Competent Authority in your area.

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