NYRx Notice to Providers, Pharmacies, and MCOs: Early Alert – Glucose Monitor Sensor Issue from Abbott Diabetes Care

December 4, 2025

On December 2, 2025, the FDA posted an Early Alert about a letter distributed by Abbott Diabetes Care to distributors, healthcare providers, and affected customers, recommending that certain FreeStyle Libre 3 and FreeStyle Libre 3 Plus sensors be removed from distribution or sale and that customers discontinue use. These sensors have been reported to produce incorrect low glucose readings. Incorrect low glucose readings can lead to wrong treatment decisions by patients or caregivers, which can lead to serious injury or death. **As of November 14, 2025, Abbott has reported 736 serious injuries and seven deaths associated with this issue.**

Affected products include:

- FreeStyle Libre 3 Sensor
  - Model Numbers: 72081-01, 72080-01
  - Unique Device Identifiers (UDI-DI): 00357599818005, 00357599819002
- FreeStyle Libre 3 Plus Sensor
  - Model Numbers: 78768-01, 78769-01
  - Unique Device Identifiers (UDI-DI): 00357599844011, 00357599843014

For a complete list of affected lots, see the Early Alert.

FreeStyle Libre 3 readers and mobile apps are not impacted. Additionally, no other Libre products (FreeStyle Libre 14-day, FreeStyle Libre 2, FreeStyle Libre 2 Plus, or Libre Pro sensors) or Abbott biowearables are impacted.

What Providers Need to Do

- Prescribers should inform their patients of this issue and instruct them to visit www.FreeStyleCheck.com or call 1-833-815-4273 to confirm if their sensors are impacted.
- If a patient is currently wearing or has a FreeStyle Libre 3 or FreeStyle Libre 3 Plus sensor that is impacted, advise them to discontinue use and dispose of the affected product.

- Patients can request a replacement for any potentially affected sensor(s) on www.FreeStyleCheck.com.
- Patients can use a blood glucose meter or the built-in meter in the FreeStyle Libre 3 Reader to make treatment decisions when sensor readings do not match symptoms or expectations.

What Pharmacies Need to Do

- Inform patients of this Urgent Medical Device Correction and advise them to request a replacement sensor(s) from www.FreeStyleCheck.com.
- Check your inventory for sensors from affected lots, remove them from inventory, and return them using the normal return process.

What Managed Care Organizations Need to Do

Managed Care Organizations (MCOs) should be aware of the issue and prepared to advise Medicaid members and providers on how to identify affected products and obtain replacements.

Resources

- NYRx Education & Outreach Website

Contact Information

Abbott Diabetes Care

Customers in the U.S. with adverse reactions, quality problems, or questions about this recall should contact Abbott Diabetes Care at 1-833-815-4273 or https://www.freestyle.abbott/us-en/support/contact-us.html.

NYRx Education & Outreach

The NYRx Education & Outreach Call Center is available by phone at 1-833-967-7310 or by email at NYRxEO@primetherapeutics.com from 8:00 AM to 5:00 PM ET, Monday through Friday, excluding holidays.