Important Drug Recall Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC25-024-CG
December 5, 2025

Re: *An FDA Early Alert - FreeStyle Libre 3 Sensors – Several Model*

Dear provider, below please find valuable information regarding a resent FDA alert issued for several models of the FreeStyle Libre 3 Sensors.

FDA Early Alert: *The FDA has become aware of a potentially high-risk issue.*

The FDA is aware that Abbott Diabetes Care has issued a letter to distributors, health care providers, and affected customers recommending certain glucose monitor sensors be removed from where they are used or sold:

- 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.

RECOMMENDATIONS

1. **For Patients:**

   a. Determine if your current or unused sensor(s) are affected by visiting **www.freestylecheck.comExternal Link Disclaimer** and selecting "CONFIRM SENSOR SERIAL NUMBER." You will need to locate your sensor serial number to determine if your sensor is affected.

      i. If you are wearing a FreeStyle Libre 3 and FreeStyle Libre 3 Plus sensor, you can find the serial number in the app or reader. The serial number can also be found on the label on the bottom of the sensor applicator or carton. (If you are using a

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sensor with a connected insulin delivery device, please refer to the connected insulin delivery device user manual on how to locate the sensor serial number.)

b. If you are currently wearing or have a FreeStyle Libre 3 or FreeStyle Libre 3 Plus sensor that has been confirmed as potentially affected on **www.FreeStyleCheck.comExternal Link Disclaimer** or by a customer service representative, immediately discontinue use and dispose of the affected sensor(s).

c. You can request a replacement for any potentially affected sensor(s) on **www.FreeStyleCheck.comExternal Link Disclaimer**. Select "CONFIRM SENSOR SERIAL NUMBER" and enter a valid serial number. If your sensor is potentially impacted, you will be instructed to enter your contact information so a replacement product can be sent to you at no cost.

d. Use a blood glucose meter or the built-in meter in your FreeStyle Libre 3 Reader to make treatment decisions when your sensor readings don't match your symptoms or expectations.

2. **For Health Care Providers:**

a. Inform your patients of this issue. Please instruct your patients to visit **www.FreeStyleCheck.comExternal Link Disclaimer** to confirm if their sensors are impacted. Abbott Diabetes Care has provided a patient letter to use with your patients.

b. If your patient is currently wearing or has a FreeStyle Libre 3 or FreeStyle Libre 3 Plus sensor that has been confirmed as potentially affected on **www.FreeStyleCheck.comExternal Link Disclaimer** or by a customer service representative, have them immediately discontinue use and dispose of the affected sensor(s).

c. Patients can request a replacement for any potentially affected sensor(s) on **www.FreeStyleCheck.comExternal Link Disclaimer**. They can select "CONFIRM SENSOR SERIAL NUMBER" and enter a valid serial number. If their sensor is potentially impacted, they will be instructed to enter their contact information so a replacement product can be sent to them at no cost.

d. 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 don't match symptoms or expectations.

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e. If applicable, your sales representative will contact you with instructions to dispose of your impacted samples. You will receive sample replacements.

3. **For Distributors , Wholesalers & Pharmacies:**

a. Inform your customers of this Urgent Medical Device Correction and have impacted sensors returned to you under your normal return process.

b. Check your inventory for sensors from affected lots, remove them from inventory, and return them using the normal return process. Review your inventory to identify existence of recalled products.

c. Expect patients to visit your pharmacy to deliver recalled products and prepare your pharmacy staff on how to handle the situation.

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FDA U.S. FOOD & DRUG ADMINISTRATION

Early Alert: Glucose Monitor Sensor Issue from Abbott Diabetes Care

This communication is an FDA Early Alert. *The FDA has become aware of a potentially high-risk issue. The FDA will keep the public informed and update this web page as significant new information becomes available.*

Affected Product

The FDA is aware that Abbott Diabetes Care has issued a letter to distributors, health care providers, and affected customers recommending certain glucose monitor sensors be removed from where they are used or sold:

- 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 the Full list of affected lots please refer to:

https://www.fda.gov/media/189900/download?attachment

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 to Do

Patients should verify if their sensors are impacted and immediately discontinue use and dispose of the affected sensor(s).

On November 24, 2025, Abbott Diabetes Care sent all affected customers a letter recommending the following actions:

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- **For Patients:**
  - Determine if your current or unused sensor(s) are affected by visiting **www.freestyliecheck.comExternal Link Disclaimer** and selecting "CONFIRM SENSOR SERIAL NUMBER." You will need to locate your sensor serial number to determine if your sensor is affected.
    - If you are wearing a FreeStyle Libre 3 and FreeStyle Libre 3 Plus sensor, you can find the serial number in the app or reader. The serial number can also be found on the label on the bottom of the sensor applicator or carton. (If you are using a sensor with a connected insulin delivery device, please refer to the connected insulin delivery device user manual on how to locate the sensor serial number.)
  - If you are currently wearing or have a FreeStyle Libre 3 or FreeStyle Libre 3 Plus sensor that has been confirmed as potentially affected on **www.FreeStyleCheck.comExternal Link Disclaimer** or by a customer service representative, immediately discontinue use and dispose of the affected sensor(s).
  - You can request a replacement for any potentially affected sensor(s) on **www.FreeStyleCheck.comExternal Link Disclaimer**. Select "CONFIRM SENSOR SERIAL NUMBER" and enter a valid serial number. If your sensor is potentially impacted, you will be instructed to enter your contact information so a replacement product can be sent to you at no cost.
  - Use a blood glucose meter or the built-in meter in your FreeStyle Libre 3 Reader to make treatment decisions when your sensor readings don't match your symptoms or expectations.
- **For Health Care Providers:**
  - Inform your patients of this issue. Please instruct your patients to visit **www.FreeStyleCheck.comExternal Link Disclaimer** to confirm if their sensors are impacted. Abbott Diabetes Care has provided a patient letter to use with your patients.

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- Patients can request a replacement for any potentially affected sensor(s) on **www.FreeStyleCheck.comExternal Link Disclaimer**. They can select "CONFIRM SENSOR SERIAL NUMBER" and enter a valid serial number. If their sensor is potentially impacted, they will be instructed to enter their contact information so a replacement product can be sent to them at no cost.

- 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 don't match symptoms or expectations.

- Your sales representative will contact you with instructions to dispose of your impacted samples. You will receive sample replacements.

- **For Distributors and Wholesalers:**

  - Inform your customers of this Urgent Medical Device Correction and have impacted sensors returned to you under your normal return process.

  - Check your inventory for sensors from affected lots, remove them from inventory, and return them using the normal return process.

The FDA is currently reviewing about this potentially high-risk device issue and will keep the public informed as significant new information becomes available.

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