November 24, 2025

Urgent Medical Device Correction

FreeStyle Libre 3 and FreeStyle Libre 3 Plus Sensors

Reference: ADC FA1002-2025
Communication from Manufacturer

Dear Customer,

We're reaching out to you about an issue that may affect your **FreeStyle Libre 3 and FreeStyle Libre 3 Plus** sensors. This issue does not apply to any other Libre sensors, apps or readers available in the United States.

What you need to know

Abbott has recently identified that certain FreeStyle Libre 3 and FreeStyle Libre 3 Plus sensors provide incorrect low glucose readings. We learned about this through our ongoing product monitoring, where Libre 3 and Libre 3 Plus sensor users reported situations where they received incorrect low glucose readings.

Potential harm

If undetected, incorrect low glucose readings over an extended period may lead to incorrect treatment decisions for people living with diabetes, such as excessive carbohydrate intake or skipping or delaying insulin doses. These decisions may pose serious health risks, including potential injury or death, or other less serious complications. Globally as of 14-Nov-2025, Abbott has received reports of 736 severe adverse events and 7 deaths potentially associated with this issue.

Actions to be taken

This issue affects only a subset of FreeStyle Libre 3 and FreeStyle Libre 3 Plus sensors that were manufactured on one production line among several that make FreeStyle Libre 3 and FreeStyle Libre 3 Plus sensors. To determine if your current sensor or any unused sensor(s) are potentially affected, please visit www.FreeStyleCheck.com and select "CONFIRM SENSOR SERIAL NUMBER." You will need to locate your sensor serial number to determine if your sensor is potentially affected. See how to locate the sensor serial number below.

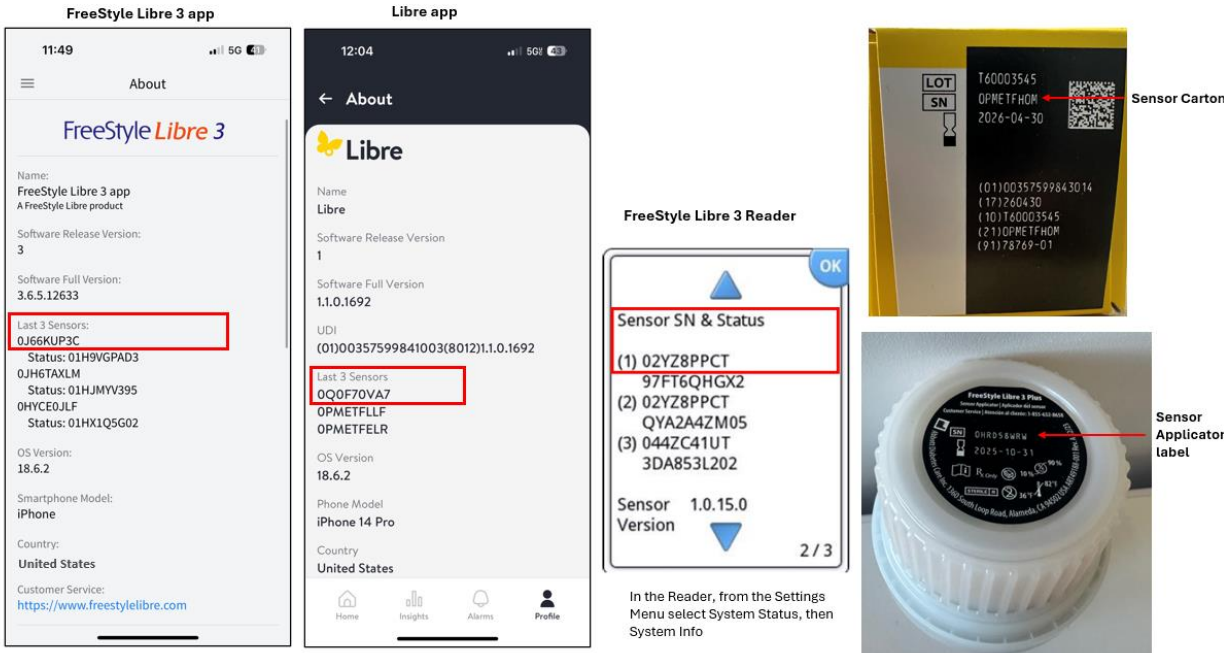
If you are currently wearing or have a FreeStyle Libre 3 / FreeStyle Libre 3 Plus sensor that has been confirmed as potentially affected on www.FreeStyleCheck.com or by a customer service representative, immediately discontinue use and dispose of the affected sensor(s).
You can request a replacement for any potentially affected sensor(s) on www.FreeStyleCheck.com. 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.

Abbott has identified and resolved the cause of the issue. The company continues to produce Libre 3 and Libre 3 Plus sensors to fulfill replacement and new orders and does not expect significant supply disruptions.

How to locate the sensor serial number

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.)



We have notified the U.S. Food & Drug Administration.

If you have additional questions or need to report any adverse reactions or quality problems experienced with the use of FreeStyle Libre 3 or FreeStyle Libre 3 Plus, please call Abbott Customer Service at 1-833-815-4273, available seven days a week from 8 a.m. to 8 p.m. Eastern Time. Agents are available 24/7 through live chat at https://www.freestyle.abbott/us-en/support/contact-us.html.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax. Complete and submit the report online at www.fda.gov/medwatch. Regular Mail or Fax: Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

Thank you for your attention to this urgent medical device correction notice. We sincerely apologize for any inconvenience this may have caused.

Sincerely,
Abbott