

July 24, 2024

URGENT MEDICAL DEVICE CORRECTION FreeStyle Libre 3 Sensors

Dear Customer,

This communication only applies to people who use FreeStyle Libre 3 sensors. The FreeStyle Libre 3 system includes a sensor, reader and app. This medical device correction impacts the sensor only. The FreeStyle Libre 3 reader and app are not impacted. There is no impact for people who use FreeStyle Libre 14 day, FreeStyle Libre 2 or FreeStyle Libre 2 Plus sensors.

Abbott has recently identified a small number of FreeStyle Libre 3 sensors that may provide incorrect high glucose readings, which if undetected may pose a potential health risk for people living with diabetes.

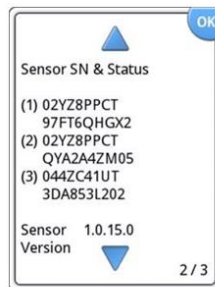
This issue affects only a small subset of FreeStyle Libre 3 sensors. To determine if your current sensor or any unused sensors you have are affected, please visit www.FreeStyleConfirm.com and select "CONFIRM SENSOR SERIAL NUMBER".

How to locate the FreeStyle Libre 3 Sensor Serial Number

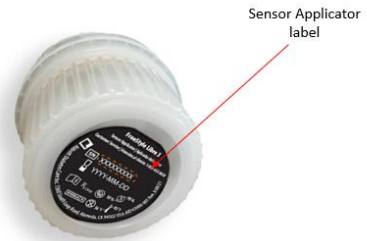
If you are wearing a Sensor, you can find the Serial number in the App or Reader. The Serial Number can also be found on the bottom of the Sensor Applicator label and carton.



In the App, from the Main Menu select About Screen



In the Reader, from the Settings Menu select System Status, then System Info



The impacted sensors are from the following 3 lots:

IMPACTED LOT NUMBERS
T60001948
T60001966
T60001969

No other FreeStyle Libre family of products are impacted.

Actions to be Taken

If you are currently using the FreeStyle Libre 3 system and are wearing an affected sensor, please immediately discontinue use, and dispose of any affected sensors in your possession.

You can request a replacement for any affected sensor(s) by visiting www.FreeStyleConfirm.com. Select “CONFIRM SENSOR SERIAL NUMBER” and enter a valid Serial Number. If your sensor is impacted, you will be instructed to enter your contact information so a replacement product can be sent to you at no cost.

If you have symptoms that do not match the sensor glucose reading or suspect your reading may be inaccurate, check the reading by conducting a fingerstick test using any blood glucose meter. The built-in blood glucose meter in the FreeStyle Libre 3 Reader may be used to check your glucose at any time.

We sincerely apologize for any inconvenience this may have caused.

Potential Risk

- If undetected, erroneously high glucose readings can pose a potential health risk for people living with diabetes.
- Erroneously high glucose readings can lead to incorrect treatment decisions, such as taking insulin when not required.

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 these sensors, please call Abbott customer service at 1-833-815-4273, available 7 days a week from 8 a.m. to 8 p.m. Eastern Time, excluding holidays.

Reports may also be sent to the FDA's MedWatch Adverse Event Reporting program by completing [Form FDA 3500](#) online at www.FDA.gov, calling 1-800-FDA-1088 or faxing to 1-800-FDA-0178.

Sincerely,

Denise Reid
Divisional Vice President
Quality Assurance and Compliance
Abbott, Diabetes Care