



July 24, 2024

Urgent Medical Device Correction

Product: FreeStyle Libre 3 sensor
Reference: ADC FA1034-2024
Communication from Manufacturer

Dear Retail Partner,

This communication only applies to retail partners who distribute and 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.

The impacted sensors are from the following 3 lots:

IMPACTED LOT NUMBERS
T60001948
T60001966
T60001969

No other FreeStyle Libre family of products are impacted.

Abbott is asking that any inventory you have with those three lot numbers identified above be removed from inventory and returned to the wholesaler where the product was purchased so that it can be replaced at no cost.

Abbott is asking that customers currently using the FreeStyle Libre 3 system and wearing an affected sensor to immediately discontinue use of that sensor and dispose of any affected sensors in their possession.

To determine if a customer’s current sensor or any unused sensors they have are affected, please visit www.FreeStyleConfirm.com and select “CONFIRM SENSOR SERIAL NUMBER”.

Customers can request a replacement for any affected sensor(s) by visiting www.FreeStyleConfirm.com. Select “CONFIRM SENSOR SERIAL NUMBER” and entering a valid Serial Number. If their sensor is

impacted, they will be instructed to enter their contact information and we will send them replacement product at no cost to them.

If customers have symptoms that do not match the sensor glucose reading or suspect their reading may be inaccurate, they should 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 glucose at any time.

We sincerely apologize for any inconvenience this may have caused.

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,

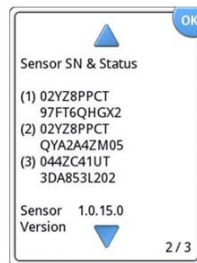
Denise Reid
Divisional Vice President
Quality Assurance and Compliance
Abbott, Diabetes Care

How to locate the FreeStyle Libre 3 Sensor Serial Number

If your customer is wearing a sensor, they 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

