November 24, 2025

Urgent Medical Device Correction
FreeStyle Libre 3 and FreeStyle Libre 3 Plus Sensors

Reference: ADC FA1002-2025
Communication from Manufacturer

Dear Pharmacy Customer,

We're reaching out to you about an issue that may affect your patients using **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 U.S.

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 wrong 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.

Actions to be taken

1. **Check your inventory**

   Initiate this Urgent Medical Device Correction to remove potentially impacted sensors from your inventory and return to your wholesaler using the normal return process. This Urgent Medical Device Correction only involves sensors from the lots listed below.

72081-01 FreeStyle Libre 3 Sensor Kit Impacted Lots

T60003054	T60003092	T60003159	T60003374	T60003434	T60003547
T60003085	T60003099	T60003160	T60003375	T60003507	T60003564
T60003088	T60003113	T60003271	T60003391	T60003534	T60003628
T60003089	T60003136	T60003284	T60003426	T60003546	T60003646

78768-01 FreeStyle Libre 3 Plus Sensor Kit Impacted Lots

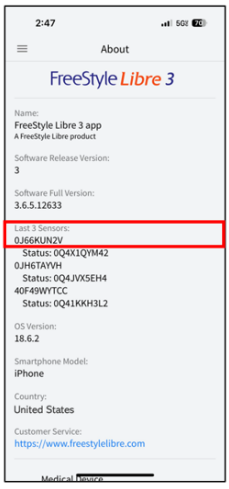
T60002984	T60003366	T60003455	T60003492	T60003560	T60003592
T60002994	T60003369	T60003460	T60003494	T60003562	T60003596
T60002995	T60003377	T60003470	T60003496	T60003563	T60003601
T60002996	T60003378	T60003471	T60003497	T60003567	T60003611
T60003007	T60003379	T60003473	T60003498	T60003568	T60003617
T60003009	T60003384	T60003478	T60003518	T60003570	T60003618
T60003010	T60003398	T60003479	T60003542	T60003573	T60003619
T60003138	T60003400	T60003480	T60003543	T60003575	T60003631
T60003243	T60003404	T60003481	T60003544	T60003576	T60003639
T60003255	T60003446	T60003488	T60003550	T60003585	T60003641
T60003348	T60003449	T60003490	T60003552	T60003589	T60003683
T60003352	T60003454	T60003491			

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

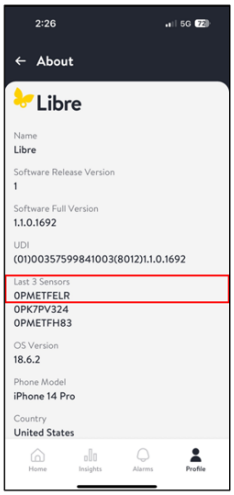
Patients wearing a FreeStyle Libre 3 sensor or a FreeStyle Libre 3 Plus sensor can find the serial number in the app or reader. The serial number can also be found on the label on the bottom of the sensor applicator or carton. (If patients are using a sensor with a connected insulin delivery device, they can refer to the connected insulin delivery device user manual on how to locate the sensor serial number.)

FreeStyle Libre 3 app



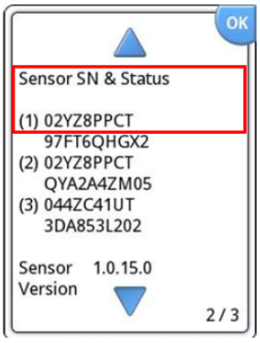
In the app, from the Main Menu select About Screen and locate sensor serial number under "Last 3 Sensors"

Libre app



In the app, from the bottom Menu select Profile > About, locate sensor serial number under "Last 3 Sensors"

FreeStyle Libre 3 Reader



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

Sensor Carton

Sensor Applicator label

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 / FreeStyle Libre 3 Plus sensors, please call Abbott Customer Service at 833-815-4273, available 7 days a week, 8 a.m. to 8 p.m. Eastern time, excluding holidays.

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