

Class I Recall – Abbott FreeStyle Libre 3 & FreeStyle Libre 3 Plus Sensors

Purpose of this communication:

We are writing to inform you that the prior Early Alert for Abbott Diabetes Care has been updated to a class I recall. Abbott previously indicated that certain FreeStyle Libre 3 and FreeStyle Libre 3 Plus sensors provide incorrect low glucose readings. 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. The FreeStyle Libre 3 Sensor (Model Numbers: 72081-01, 72080-01; UDI-DI: 00357599818005, 00357599819002) and the FreeStyle Libre 3 Plus Sensor (Model Numbers: 78768-01, 78769-01; UDI-DI: 00357599844011, 00357599843014) are included. As of January 7, 2026, Abbott has reported 860 serious injuries, and seven deaths associated with this issue.

What do I need to do?

- Please review the following Early Alert notice from the FDA [here](#).
- Notify impacted patients and to facilitate replacement, according to the guidelines issued by the manufacturer in the FDA notification in the above link.
 - Patients should verify if their sensors are impacted and immediately discontinue use and dispose of the affected sensor(s).
 - Patients are to determine if their current or unused sensor(s) are affected by visiting [CONFIRM SENSOR SERIAL NUMBER](#).
- Confirm if you have any CareCentrix patients affected by this FDA Early Alert and notify the CareCentrix Quality Department by faxing information to: 919-792-6718 Attn: Quality Department.

Thank you in advance for your cooperation and continued partnership.