Abbott Initiates Medical Device Correction For Certain FreeStyle Libre® 3 And FreeStyle Libre 3 Plus Sensors In The U.S.

- Medical device correction impacts a subset of FreeStyle Libre 3 and FreeStyle Libre 3 Plus sensors
- Consumers can visit www.FreeStyleCheck.com to see if their sensors are affected and to get a replacement at no charge
- Abbott has identified and resolved the manufacturing issue related to this device action
- No other Libre family sensors, readers or apps are impacted

ABBOTT PARK, Ill., Nov. 24, 2025 — Abbott has initiated a medical device correction for certain FreeStyle Libre 3 and FreeStyle Libre 3 Plus sensors in the United States after internal testing determined that some sensors may provide incorrect low glucose readings.

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.

Abbott has identified and resolved the cause of the issue, which relates to one production line among several that make Libre 3 and Libre 3 Plus sensors. 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.

This action involves approximately 3 million Libre 3 and Libre 3 Plus sensors in the U.S. from that production line, about half of which are estimated to have expired or been used. Globally, Abbott has received reports of 736 severe adverse events (57 in the U.S.) and seven deaths (none in the U.S.) potentially associated with this issue.

Important Instructions for People Using Libre 3 or Libre 3 Plus Sensors

Consumers should visit www.FreeStyleCheck.com to confirm whether their sensor is potentially affected by this medical device correction. Abbott will replace any potentially affected sensors at no charge. Detailed instructions on how to check sensors and request a replacement are available on www.FreeStyleCheck.com.

If consumers are currently wearing or have a sensor that has been confirmed as potentially impacted on www.FreeStyleCheck.com or by a customer service representative, they should immediately discontinue use and dispose of it.

Consumers should use a blood glucose meter or the built-in meter in the FreeStyle Libre 3 reader to make treatment decisions when sensor readings don't match symptoms or expectations.

To learn more or get help with questions, visitwww.FreeStyleCheck.com or call Abbott's 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.

FreeStyle Libre 3 readers and mobile apps are not impacted. Additionally, no other Libre products (FreeStyle Libre 14 day, FreeStyle Libre 2, FreeStyle Libre 2 Plus, or FreeStyle Libre Pro sensors) or Abbott biowearables are impacted.

Abbott is issuing this medical device correction in other affected countries where Libre 3 and Libre 3 Plus sensors are distributed. Consumers in other countries can also visit www.FreeStyleCheck.com for more information.

About Abbott:

Abbott is a global healthcare leader that helps people live more fully at all stages of life. Our portfolio of life-changing technologies spans the spectrum of healthcare, with leading businesses and products in diagnostics, medical devices, nutritionals and branded generic medicines. Our 114,000 colleagues serve people in more than 160 countries. Connect with us at Abbott.com and on LinkedIn, Facebook, Instagram, X and YouTube.

Important Safety Information: Product for prescription only, for Important Safety Information, please visit https://www.freestyle.abbott/us-en/safety-information.html .

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