Abbott Issues Voluntary Medical Device Correction For A Small Number Of FreeStyle Libre® 3 Sensors In The U.S.

- This voluntary medical device correction impacts a small subset of FreeStyle Libre 3 sensors from among those within three lots in the U.S. only
- Consumers can visit www.FreeStyleConfirm.com to see if their sensors are affected and to get a replacement at no charge
- No other FreeStyle Libre family of products or countries are impacted

ABBOTT PARK, Ill., July 24, 2024 – Abbott has initiated a voluntary medical device correction for a small number of FreeStyle Libre® 3 sensors distributed in the United States during the first half of May 2024.

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.

Internal testing determined that some of the sensors from among three lots may provide incorrect high glucose readings, which if undetected may pose a potential health risk for people living with diabetes and can lead to incorrect treatment decisions, such as taking insulin when not required.

This issue affects only a small subset of FreeStyle Libre 3 sensors from among those within the following three lot numbers:

- T60001948
- T60001966
- T60001969

If consumers have FreeStyle Libre 3 sensors from other lots, there is no need to take action and they can continue to use their sensors. There is no impact for users who live outside of the U.S. or use other FreeStyle Libre products (FreeStyle Libre 14 day, FreeStyle Libre 2, or FreeStyle Libre 2 Plus).

How to Identify Lot or Serial Number

If the sensor is still in the package, the lot and serial number (identified as “SN”) can be found on the bottom of the carton’s packaging.

If the sensor is currently in use or may have already been used, the serial number can be displayed within the FreeStyle Libre 3 app or reader. More detailed instructions on locating the serial number can be found by visiting www.FreeStyleConfirm.com.

Checking if the Sensor is Affected

If the consumer’s product lot number is listed above, they need to visitwww.FreeStyleConfirm.com, select “Confirm Sensor Serial Number,” and enter their serial number to confirm whether their sensor is affected by this voluntary medical device correction. Consumers wearing an affected FreeStyle Libre 3 sensor should immediately discontinue use and dispose of any affected sensors in their possession. If the consumer’s sensor is impacted they will need to enter their contact information so Abbott can send them a replacement sensor at no charge.

"We sincerely regret the disruption this may have on our customers," said Jared Watkin, executive vice president of Abbott’s diabetes care business. "We’re actively working with the U.S. Food and Drug Administration and distributors, as well as providing information to affected customers, who will receive replacements at no charge as quickly as possible."

Consumers are instructed to conduct a fingerstick test using any blood glucose meter if they experience symptoms that do not match the sensor glucose reading or suspect the reading may be inaccurate. The built-in blood glucose meter in the FreeStyle Libre 3 reader may be used to check glucose at any time.

Consumers can visit www.FreeStyleConfirm.com to learn more or call customer service at 1-833-815-4273, available seven days a week from 8 a.m. to 8 p.m. Eastern Time, excluding holidays.

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 www.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.

For further information: Abbott Media: Katie Walker, Katie.Walker@Abbott.com; Lindsy Delco, Lindsy.Delco@Abbott.com; Abbott Financial: Mike Comilla. Michael.Comilla@Abbott.com

Additional assets available online:

