Messaging: FreeStyle Libre 2 Sensors – Erroneous High Glucose Readings

[February XX, 2023]

Urgent Field Safety Notice

Product: FreeStyle Libre® 2 Sensors
Reference: ADC FA1004-2023
Communication from Manufacturer

Dear Customer:

Abbott is initiating a voluntary recall of certain FreeStyle Libre® 2 sensors from lot KTP005061. No other Abbott diabetes products are affected.

Problem / Issue

- Abbott has recently identified that certain FreeStyle Libre® 2 sensors from lot **KTP005061** may provide erroneously high glucose readings. For example, your sensor glucose reading may be high and out of your target range while your actual glucose levels may be below or within target range.

Potential Harms

- If undetected, erroneously high glucose readings can pose a potential health risk for people living with diabetes.
- Erroneously high glucose readings can lead to incorrect treatment decisions, such as taking insulin when not required.

Actions for Users

- To determine if your current sensor or any unused sensors you have are affected, please visit www.FreeStyleConfirm.com and enter your sensor serial number.
- If you are currently using the FreeStyle Libre® 2 system and are wearing an affected sensor, please immediately discontinue use. If you have symptoms that do not match the sensor glucose reading, or suspect your reading may be inaccurate, check the reading by conducting a fingerstick test using a blood glucose meter.
- You will be sent a replacement for any affected sensor(s). We will send you a mailing kit to return any affected sensor(s) to us.
- While waiting for your replacement sensor, you can continue to use sensors that are not affected and can use the built-in blood glucose meter in your FreeStyle Libre® 2 reader to check your glucose at any time.

We sincerely apologize for any inconvenience this has caused.

We have notified Medicines and Healthcare Products Regulatory Agency (MHRA), and we are implementing additional measures to address this issue.

If you have any further questions or would like to report a device fault, please call Abbott Customer Service at [### country to insert correct CS Phone #]

Sincerely,

Abbott, Diabetes Care