Abbott Issues Safety Notification For FreeStyle Libre® Family Of Readers In The U.S.

- This communication applies to the Readers used as part of the FreeStyle Libre, FreeStyle Libre 14 day, and FreeStyle Libre 2 Flash Glucose Monitoring Systems (all Reader serial numbers). This does not affect any of the FreeStyle Libre family of sensors.
- If not properly stored, charged, or used with the Abbott-provided yellow USB cable and power adapter, a potential exists for battery swelling and, in rare cases, extreme overheating, which may pose a fire hazard.
- Users should ensure they always use the Abbott-provided yellow USB cable and power adapter. Photos are included on www.FreeStyleBattery.com to help identify Abbott cables and adapters.
- The FreeStyle Libre family of Readers use lithium-ion batteries, like the kinds used in mobile phones and many other handheld electronic devices, which have the potential for battery swelling, leakage or extreme overheating.
- The Readers are safe when properly stored, charged and used only with their accompanying USB cable and power adapter, as outlined at www.FreeStyleBattery.com.

ABBOTT PARK, Ill., April 3, 2023 – Abbott initiated a voluntary medical device correction in February to emphasize instructions for its FreeStyle Libre®, FreeStyle Libre® 14 day and FreeStyle Libre® 2 Readers in the United States due to a limited number of reports worldwide (0.0017%) from users over several years that their reader's lithium-ion battery swelled, infrequently overheated or, in very rare cases, sparked or caught fire. No Readers are being physically recalled and customers can continue to use their Readers with the Abbott-provided USB cable and power adapter. The steps outlined below and at www.FreeStyleBattery.com provide guidance on how to properly store, charge and use a Reader and its accompanying USB cable and power adapter.

The Reader is a small handheld device that collects real-time glucose readings directly from a sensor worn on the back of a person's upper arm, allowing them to manage their diabetes by seeing their glucose readings on a screen. If users prefer, they can also use a compatible smartphone app [1] to receive their glucose data. To switch to the app, the user must start a new sensor.

To avoid the potential for battery swelling, leakage, extreme overheating and/or fire, Abbott recommends the following:

- Charge the reader battery by ONLY using the Abbott-supplied yellow USB cable and adapter (charger). The potential for issues may occur when charging the Reader with non-Abbott adapters or non-Abbott USB cables concurrent with misuse of the Reader and its components. Examples of misuse include exposure to liquids, damage, and introduction of foreign material into the ports.
- The Abbott-provided USB cable and power adapter limit the current to safely charge the battery, whereas third-party components may allow much higher power, increasing the risk of fire.
- DO NOT expose the Reader, power adapter or yellow USB cable to water or other liquids.
- Store the Reader between -4 °F and 140 °F.
- DO NOT place the Reader in water or other liquids.
- Avoid getting dust, dirt, blood, control solution, water, bleach, or any other substance in the test strip or USB port.
- Review the revised user guide and labeling at labeling atwww.freestyle.abbott/us-en/support.
- Visit www.FreeStyleBattery.com to follow steps to perform a Reader Test to determine if your current Reader needs to be replaced.

Abbott has been notifying customers of this matter since February through a variety of communication methods, including by email and letters. This communication to customers was done voluntarily, and the U.S. Food and Drug Administration has been informed.

Like mobile phones and many other handheld electronic devices, the FreeStyle Libre family of Readers use lithium-ion batteries, which are safe when used per instructions outlined at www.FreeStyleBattery.com.

Since FreeStyle Libre Readers launched in the U.S. in 2017, there have been no reported incidents that have caused serious adverse health consequences or death due to this issue. As previously communicated to Reader customers, if a Reader is stored, charged and used properly then risks are mitigated.

If customers have questions or want to learn how to test their Reader as well as properly store, charge and use their Reader and its USB cable and power adapter, they're encouraged to review the Perform a Reader Test section of the Reader User Manual, visit www.FreeStyleBattery.com, or contact Abbott's Customer Service at 1-855-632-8658. Customers may also contact Abbott's Customer Service if they want replacement accessories. Agents are available to help customers seven days a week from 8 a.m. to 8 p.m. Eastern Time, excluding major holidays.

This medical device correction does not affect any of the FreeStyle Libre family of sensors. For more information on how to perform a reader test and reduce risks, visit www.FreeStyleBattery.com.

Important Safety Information

Failure to use FreeStyle Libre system as instructed in labeling may result in missing a severe low or high glucose event and/or making a treatment decision, resulting in injury. If glucose alarms and readings do not match symptoms or expectations, use a

fingerstick value from a blood glucose meter for treatment decisions. Seek medical attention when appropriate or contact Abbott at 855-632-8658 or FreeStyleLibre.us for safety info.

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 115,000 colleagues serve people in more than 160 countries.

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1. The FreeStyle Libre family of apps are only compatible with certain mobile devices and operating systems. Please check our website for more information about device compatibility before using an app.

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