Abbott Recalls the Readers used with the FreeStyle Libre, FreeStyle Libre 14 day, and FreeStyle Libre 2 Flash Glucose Monitoring Systems for Risk of Extreme Heat and Fire

On April 12, 2023, the FDA added information for patients about Abbott's April 2023 Medical Device Correction letter. If you are not experiencing problems with the Abbott provided Reader and you have the Abbott provided USB cable and power adapter, you can continue to use the Abbott provided Reader, USB cable, and power adapter.

A medical device recall means a firm's removal or correction of a medical device. In this case, the firm is correcting the product labeling and not physically removing all the readers as part of this recall.

Additional information, including recommendations, and what to do if a reader needs to be returned can be found in the What to Do section.

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

Recalled Product

- Product Name: FreeStyle Libre Flash Glucose Monitoring System, FreeStyle Libre 14 day Flash Glucose Monitoring System, FreeStyle Libre 2 Flash Glucose Monitoring System
- Product Models: all Reader serial numbers
- Distribution Dates: Beginning November 2017
- Devices Recalled in the U.S.: 4,210,785
- Date Initiated by Firm: February 13, 2023

Device Use

The FreeStyle Libre, Libre 14 day, and Libre 2 Flash Glucose Monitoring Systems are intended to provide continuous monitoring of glucose levels. These devices help people manage diabetes by detecting trends and tracking patterns in glucose levels so treatment can be adjusted as needed. They are indicated for single patient use, and require a prescription.

Reason for Recall

Abbott is recalling the FreeStyle Libre, Libre 14 day, and Libre 2 Flash Glucose Management Systems' reader devices, which use rechargeable lithium-ion batteries, may get extremely hot, spark, or catch on fire if not properly stored, charged, or used with its Abbott provided USB cable and power adapter.

This does not affect any of the FreeStyle Libre family of sensors.

The potential for overheating, spark, or fire may occur when charging the Reader with non-Abbott adapters or non-Abbott USB cables combined 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 power provided to safely charge the battery, whereas USB cables and power adapters manufactured by a third party may allow much higher power, increasing the risk of overheating, spark, or fire.

The Reader, if not properly stored, charged, or used with its Abbott provided USB cable and power adapter, may expose users to extreme heat and/or fire which can cause serious injuries or death. Additionally, users may delay or miss a critical diabetes treatment if the system cannot be used after is damaged by extreme heat or fire.

There have been 88 incidents, including at least seven reports of fires, one injury, and no deaths involving this issue.

Who May be Affected

- People who monitor their glucose levels using the FreeStyle Libre, Libre 14 day, or Libre 2 Glucose Monitoring Systems**.**
- Health care providers with patients who use FreeStyle Libre, Libre 14 day, or Libre 2 systems to monitor their glucose levels.

What to Do

On February 13, 2023, Abbott sent some users of the FreeStyle Libre family of Readers an Urgent Medical Device Correction letter.

The FDA recommends:

If you have the Abbott provided USB cable and power adapter AND you are not experiencing the problems listed below, you can continue to use the Abbott provided Reader, USB cable, and power adapter.

Stop using the FreeStyle Libre Reader and switch to a back-up method **ONLY** if you experience any of the following:

- The Reader appears damaged or cracked
- If there is visible swelling of the Reader
- If the Reader gets too hot to hold
- If the Reader is no longer able to hold a charge (for example, if it turns off unexpectedly or immediately after charging)
- You do not have the Abbott provided USB cable and power adapter (charger)

If the Reader is damaged or a replacement USB cable or power adapter (charger) are needed, call Abbott's Customer Service at 1-855-632-8658 to request a replacement.

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 USB cable and power adapter (charger). Photos are included on www.FreeStyleBattery.com (http://www.freestylebattery.com/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) to help identify Abbott cables and power adapters.
- 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 here at www.freestyle.abbott/us-en/support (http://www.freestyle.abbott/us-en/support) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
- Visit www.FreeStyleBattery.com to follow steps to perform a Reader Test to determine if your current Reader needs to be replaced

Contact Information

Users with questions about this recall should contact Abbott Customer Service at 1-855-632-8658, available 7 days a week from 8AM to 8PM Eastern Time, excluding major holidays.

Additional Resources

- Medical Device Recall Database Entry

- Company Press Release (https://abbott.mediaroom.com/Abbott-Issues-Safety-Notification-for-FreeStyle-Libre-Family-of-Readers-in-the-U-S) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) they experienced using these devices to MedWatch: The FDA Safety Information and Adverse Event Reporting Program using an online form, regular mail, or FAX.