

FDA Drug Recall

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

4/07/2023

Abbott is recalling the Readers used with the FreeStyle Libre, FreeStyle Libre 14 day, and FreeStyle Libre 2 Flash Glucose Monitoring Systems (all Reader serial numbers) because the systems' reader devices contain rechargeable lithium-ion batteries, that may swell, overheat, spark, or catch on fire if not properly stored, charged, or used with the Abbott-provided USB cable and power adapter. The U.S. Food and Drug Administration (FDA) has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries, serious health consequences, or death.

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 used in place of other blood glucose meters, are for single patient use, and require a prescription.

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

Abbott reports 206 incidents, including at least seven fires, one injury, and no deaths involving this issue. The following are the affected NDCs:

Product	NDC #
FREESTYLE LIBRE 2 READER	57599-0803-00
FREESTYLE LIBRE 14 DAY READER	57599-0002-00

On February 13, 2023, Abbott sent some users of the FreeStyle Libre family of Readers an Urgent Medical Device Correction letter. The FDA recommends patients stop using the FreeStyle Glucose Monitoring Systems and switch to a back-up method if:

- The Abbott provided USB cable and power adapter (charger) is not available
- 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, does it turn off unexpectedly or immediately after charging?)

If the Reader is damaged or a replacement USB cable or power adapter 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 adapter (charger). Photos are included on <http://www.FreeStyleBattery.com> to help identify Abbott cables and 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
- Visit www.FreeStyleBattery.com to follow steps to perform a Reader Test to determine if your current Reader needs to be replaced

For more information, please review the following press release: <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts>

Source: https://www.fda.gov/medical-devices/medical-device-recalls/abbott-recalls-readers-used-freestyle-libre-freestyle-libre-14-day-and-freestyle-libre-2-flash?utm_medium=email&utm_source=govdelivery