Freestyle Libre reader device

The FDA announced a consumer-level recall of Abbott's FreeStyle Libre, Libre 14 day, and Libre 2 Flash Glucose Management Systems' reader devices, which use rechargeable lithium-ion batteries. The 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.

The recall 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.

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

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.