

# Abbott Freestyle Libre

Abbott is issuing a voluntary Medical Device Correction for the below items due to reports from some users regarding Reader issues, including battery swelling, and in rare cases extreme overheating which may pose a fire hazard. Abbott's investigation has determined that using a charging cable or power adapter that was not included with the Reader may increase the risk of a fire hazard

**Date:** March 22, 2023

**URGENT!!!**

**MEDICAL DEVICE CORRECTION!!!**

**URGENT!!!**

Description	Lot # & Exp Date	NDC #	UPC #	Econo #
FREESTYLE LIBRE 2 SENSOR	ALL LOTS	57599080000	35759980000	1553874
FREESTYLE LIBRE 2 READER	ALL LOTS	57599080300	35759980300	1553890
FREESTYLE LIBRE 2 TAA READER	ALL LOTS	57599080500	35759980500	1553908
R FREESTYLE LIBRE READ*MST*TAA	ALL LOTS	57599000041	35759900041	2367860
R FREESTYLE LIBRE READ*MST*TAA	ALL LOTS	57599000041	35759900041	2394781
FREESTYLE LIBRE SENSOR 14D	ALL LOTS	57599000101	35759900101	2535193
FREESTYLE LIBRE READER KIT 14D	ALL LOTS	57599000200	35759900200	2535201
FREESTYLE LIBRE READER 14D TAA	ALL LOTS	57599000098	35759900098	2564078
FREESTYLE LIBRE 3 SENSOR	ALL LOTS	57599081800	35759981800	2638609
T FREESTYLE LIB *MST*2 READER	ALL LOTS	57599080300	35759980300	2655868
T FREESTYLE LIB*MST* 2 SENSOR	ALL LOTS	57599080000	35759980000	2655884
FREESTYLE LIBRE PRO READER	ALL LOTS	57599071687	35759971687	3599610
VA FREESTYLE LIBRE PRO SENSOR	ALL LOTS	57599071562	35759971562	3599693
FREESTYLE LIBRE SENSOR 10D	ALL LOTS	57599000019	35759900019	3734019
FREESTYLE LIBRE READER KIT	ALL LOTS	57599000021	35759900021	3734076
VA FREESTYLE LIBRE READER TAA	ALL LOTS	57599000024	35759900024	3908845
FREESTYLE LIBRE PRO READER TAA	ALL LOTS	57599000041	35759900041	3908852

**Event Description:**

Abbott is issuing a voluntary Medical Device Correction for the above items due to reports from some users regarding Reader issues, including battery swelling, and in rare cases extreme overheating which may pose a fire hazard. Abbott's investigation has determined that using a charging cable or power adapter that was not included with the Reader may increase the risk of a fire hazard.

**Consumer Information:**

Consumers should contact Abbott Customer Service at 1-855-632-8658, available 7 days a week from 8am-8pm Eastern Time excluding major holidays for more information. Consumers can also visit [www.FreeStyleBattery.com](http://www.FreeStyleBattery.com)

**Information contained in this document was provided by Abbott who is coordinating directly with the FDA.**

To determine if your Reader needs to be replaced, please answer the following questions:

#### Inspection

1. Does your Reader appear damaged or cracked?
2. Do you see any swelling of your Reader?
3. Has your Reader been too hot to hold?
4. Is your Reader no longer able to hold a charge (for example, does it turn off unexpectedly or immediately after charging?)

If you answered NO to all of the above questions and you are still concerned, perform a quick Reader Test.

Touch the Settings symbol from the Home screen, select **System Status** and then select **Reader Test**. The Reader Test will perform internal diagnostics and will allow you to check that the display, sounds, and touchscreen are working properly. For further instructions on how to perform a Reader test visit [www.FreeStyleBattery.com](http://www.FreeStyleBattery.com).

If you answered yes to any of the Inspection questions or if your Reader Test failed, please immediately discontinue use and call Customer Service to request a replacement. While you are waiting for your replacement Reader, please use an alternate method for monitoring your glucose (e.g., Freestyle LibreLink / FreeStyle Libre 2 app or a blood glucose meter).

In order to ensure that you continue to receive important information regarding your system, please visit [www.LibreView.com](http://www.LibreView.com) to create an account and connect your Reader.

#### Type of action by the Company

Abbott is updating the FreeStyle Libre 14 day and FreeStyle Libre 2 Reader User's Manuals to include the instructions below. The updated User's Manuals will be available soon on [www.FreeStyleLibre.com](http://www.FreeStyleLibre.com) through the "Support" menu.

#### Storing the Reader, Yellow USB Cable, and Power Adapter

- 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.

#### Charging the Reader

- Check the Reader's USB port and make sure it is dry and free of debris.
- Check the Abbott provided power adapter and yellow USB cable to make sure they are not damaged
- Use only the Abbott provided power adapter and yellow USB cable that came with your Reader.
- Choose a location for charging where you can easily access the power adapter and quickly disconnect it to prevent the potential risk of electrical shock.

