



URGENT MEDICAL DEVICE CORRECTION

FreeStyle Libre Flash Glucose Monitoring System
FreeStyle Libre 14 day Flash Glucose Monitoring System
FreeStyle Libre 2 Flash Glucose Monitoring System
(All Reader Serial Numbers)

Dear Customer,

Our records indicate you are a FreeStyle Libre, FreeStyle Libre 14 day or FreeStyle Libre 2 Flash Glucose Monitoring System user. We are writing to inform you how to safely store, charge and use your Reader. The instructions included here will be included in the FreeStyle Libre 14 day and FreeStyle Libre 2 Reader User's Manual soon.

Like cell phones and many other handheld electronic devices, our Readers use lithium-ion batteries. While lithium-ion batteries are generally safe when used properly, they may present a fire hazard if they are damaged.

This notice is being communicated as a voluntary Medical Device Correction to provide information about risks associated with the lithium-ion batteries contained only in the FreeStyle Libre, FreeStyle Libre 14 day and the FreeStyle Libre 2 Readers.

We have received reports from some users regarding Reader issues, including battery swelling, and in rare cases extreme overheating which may pose a fire hazard. Our ongoing investigation has determined that using a charging cable or power adapter that was not included with your FreeStyle Libre, FreeStyle Libre 14 day or FreeStyle Libre 2 Reader may increase the risk of a fire hazard.

Risk to Health

It is important that you take the actions listed below to ensure your Reader is functioning properly and to reduce the risk of minor burns or fire.

Actions to be Taken by Customer

Please complete the actions listed here and acknowledge by clicking the link or scanning the QR code below.

[Acknowledge and Go to FreeStyleBattery.com](https://www.FreeStyleBattery.com)



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.

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 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 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.

- Take care when plugging and unplugging your yellow USB cable. Do not force or bend the end of the yellow USB cable into the Reader's USB port.

Using the Reader

- If the Reader becomes too hot to hold, immediately STOP USE and contact Customer Service about replacing your Reader, yellow USB cable, and power adapter.
- Do NOT use the Reader if you notice any signs of deterioration of the Reader (such as clouding or crazing on the display of the Reader, corroding, eroding or swelling of the plastic housing, or cracking of the plastic housing or display) or if the Reader does not turn on.
- If the Reader does not turn on after being charged or you notice a significant deterioration in battery life, contact Customer Service about replacing your Reader, yellow USB cable, and power adapter.
- If the Reader is dropped or subjected to impact and you are concerned it may be damaged, perform a Reader Test to confirm it is still working properly. See *Perform a Reader Test* section of the Reader User's Manual for instructions (or see the instructions above or at www.FreeStyleBattery.com).

Please acknowledge that you have read and understood the actions contained in this letter by clicking the link or scanning the QR code below.

[Acknowledge and Go to FreeStyleBattery.com](http://www.FreeStyleBattery.com)



If you have any further questions, please contact our Customer Care team at 1-855-632-8658. The team is available 7 days a week from 8 AM to 8 PM Eastern Time, excluding holidays.

Thank you for your attention to this important safety letter.

Sincerely,

Denise Reid
Division Vice President
Quality Assurance
Abbott, Diabetes Care