



July 12, 2023

## URGENT MEDICAL DEVICE CORRECTION

### FreeStyle Libre 2 System

Dear Customer,

Our records indicate you have a FreeStyle Libre 2 Reader.

This communication only applies to people who use FreeStyle Libre 2 Sensors with a FreeStyle Libre 2 Reader. There is no impact for people who use the FreeStyle Libre 2 app with their Sensors or who use the FreeStyle Libre 14 day or FreeStyle Libre 3 systems.

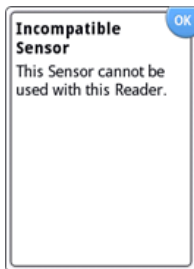
We are writing to inform you that we've recently discovered that a small number of people using FreeStyle Libre 2 Sensors have received an "Incompatible Sensor" message on their Reader when they attempt to start a new Sensor before the previous Sensor was used for the full 14-day wear time. A Sensor might not have been used for the full 14-day wear time if it fell off early. If your Sensor falls off early or you discontinue use before the end of the 14-day wear time, it is recommended to retain that Sensor until you have successfully started your next Sensor.

If you receive this "Incompatible Sensor" message on your FreeStyle Libre 2 Reader, please follow the "Actions to be Taken by Customer" below.

If you don't receive an "Incompatible Sensor" message on your Reader, you can continue to use your FreeStyle Libre 2 system.

### Actions to be Taken by Customer

If you apply a new Sensor to your arm and receive the "Incompatible Sensor" message when attempting to start it with your Reader, please follow the steps below.



#### If you still have the previous Sensor:

- Scan the previous Sensor.
  - *If it's been less than 3 hours since the previous Sensor was removed or fell off, you'll need to wait 3 hours before scanning. While you wait, please use a blood glucose*

meter to check your glucose. The FreeStyle Libre 2 Reader can be used as a blood glucose meter during this time; this functionality isn't impacted by the Incompatible Sensor message.

- You'll get a message that says "Replace Sensor"



- Scan the new Sensor on your arm – you should see the "New Sensor Starting Up" screen

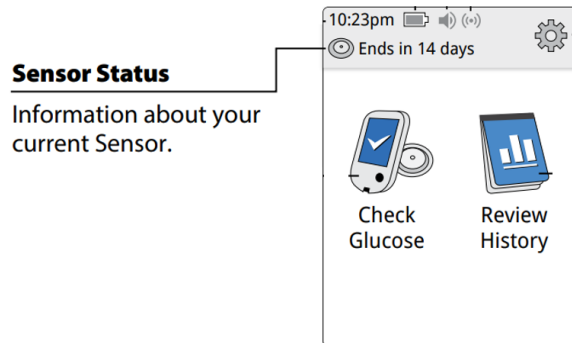


**If you no longer have the previous Sensor:**

- You can use the free FreeStyle Libre 2 app to activate the new Sensor and get your glucose data on your compatible smartphone.
  - *The new Sensor that generated the "Incompatible Sensor" error message on your Reader can still be used with the app.*
  - *If you don't yet have the app, download it from the Apple App Store or Google Play Store*
  - *To check if you have a compatible smartphone, visit: <https://www.freestyle.abbott/us-en/products/freestyle-libre-app/compatibility.html>*
- Open the FreeStyle Libre 2 app
- Follow the instructions on the app to start the Sensor on your arm
- You will be able to start your next Sensor with your Reader once a "Sensor Ended" message has been received



- You may choose to wait until the 14-day wear time for the previous Sensor has ended, at which point you may activate the new Sensor with your Reader. To see how many days are remaining on your previous Sensor, refer to the Sensor Status at the top of the Reader Home Screen.



- *Until you activate a new Sensor, please use a blood glucose meter to check your glucose. The FreeStyle Libre 2 Reader can be used as a blood glucose meter during this time; this functionality isn't impacted by the Incompatible Sensor message.*

### Potential Risk

If your previous Sensor was removed or fell off before the end of the 14-day wear time, you may be unable to start a new Sensor, and if you do not have access to another way to check your glucose levels (as required per FreeStyle Libre 2 User Manual), this could potentially result in no or delayed glucose results.

**If you are not able to scan the previous Sensor and you do not have a compatible smartphone, please contact Customer Service at 1-855-632-8658 so we may assist you further. Additionally, report any adverse reactions or quality problems experienced with the use of these products to the Customer Service team which is available 7 days a week from 8 AM to 8 PM Eastern Time, excluding holidays.** Reports may also be sent to the FDA's MedWatch Adverse Event Reporting program by completing Form FDA 3500 online at [www.FDA.gov](http://www.FDA.gov), calling 1-800-FDA-1088 or faxing to 1800-FDA-0178.

Sincerely,

Denise Reid  
Divisional Vice President  
Quality Assurance and Compliance  
Abbott, Diabetes Care

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