

06 October 2014

**URGENT FIELD SAFETY NOTICE**

**Product:** FreeStyle Libre Flash Glucose Monitoring System  
**Reference:** ADC FA1048-2014  
**Type of Action:** Field Safety Notice

Dear Health Care Professional,

Recently Abbott Diabetes Care made limited quantities of our new FreeStyle Libre System available to selected individuals, including you.

One of the safety features of the FreeStyle Libre System is the software, which is designed to disable the sensor if it identifies a possible loss of sensor power. It has come to our attention that in rare cases this disabling feature may not function correctly, and there is the potential for power loss to occur which may not be properly identified by the system.

In these instances, when a scan is completed the sensor may provide previously collected glucose values as if they are current results. If this occurs, the results produced from the scan and seen on the Reader screen may be erroneous. Erroneous results which are not recognized by the user may pose significant risks to health. It is important to note that the built-in blood glucose meter system is unaffected by this issue, and may be used to check glucose at any time.

The above issue can be easily identified as the user would see the same glucose result on the screen each time they scanned during a period of power loss. They may also notice a gap in results on the 8-hour graph on the Reader screen.

Abbott Diabetes Care has made a change to the software that has corrected this issue for all newly manufactured FreeStyle Libre Sensors. **No other Abbott Diabetes Care products are affected by this issue.**

**If you have any remaining patients who are using a FreeStyle Libre Sensor within the 14-day wear period, please communicate this issue to them by forwarding the attached letter.**

**Users of the affected product should follow the user instructions and information below:**

If any reading from a scan seems unexpected or does not seem to match the way the patient is feeling, they can use the meter and test strips to perform a blood glucose test to verify the results produced by a scan. If the problem continues, they are asked to contact Abbott Diabetes Care Customer Service at 0500 467 466. Customers are instructed to pay special attention to signs and symptoms of high and low blood sugar (hyperglycemia and hypoglycemia).

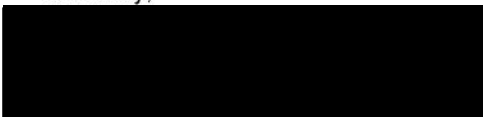
Abbott Diabetes Care has notified the Medicines and Healthcare Products Regulatory Agency (MHRA) regarding this notice.

We want to assure you that our first priority is you, our customer. We appreciate your continued support and regret any inconvenience this situation may cause.

We sincerely regret any inconvenience this situation may cause for you and your patients. We thank you for your continued support of the FreeStyle Libre System.

If you have any further questions, please call your Abbott Diabetes Care Sales Representative or Customer Service at 0500 467 466.

Sincerely,

  
Division Vice President, Quality Assurance and Compliance  
Abbott Diabetes Care