

## Messaging: FreeStyle Libre 2 Sensors – Erroneous High Glucose Readings



[February XX, 2023]

### Urgent Field Safety Notice

Product: FreeStyle Libre® 2 Sensors

Reference: ADC FA1004-2023

Communication from Manufacturer

Dear Customer:

Abbott is initiating a voluntary recall of certain FreeStyle Libre® 2 sensors from lot **KTP005061**. No other Abbott diabetes products are affected.

### Problem / Issue

- Abbott has recently identified that certain FreeStyle Libre® 2 sensors from lot **KTP005061** may provide erroneously high glucose readings. For example, your sensor glucose reading may be high and out of your target range while your actual glucose levels may be below or within target range.

### Potential Harms

- If undetected, erroneously high glucose readings can pose a potential health risk for people living with diabetes.
- Erroneously high glucose readings can lead to incorrect treatment decisions, such as taking insulin when not required.

### Actions for Users

- To determine if your current sensor or any unused sensors you have are affected, please visit [www.FreeStyleConfirm.com](http://www.FreeStyleConfirm.com) and enter your sensor serial number.
- If you are currently using the FreeStyle Libre® 2 system and are wearing an affected sensor, please immediately discontinue use. If you have symptoms that do not match the sensor glucose reading, or suspect your reading may be inaccurate, check the reading by conducting a fingerstick test using a blood glucose meter.
- You will be sent a replacement for any affected sensor(s). We will send you a mailing kit to return any affected sensor(s) to us.
- While waiting for your replacement sensor, you can continue to use sensors that are not affected and can use the built-in blood glucose meter in your FreeStyle Libre® 2 reader to check your glucose at any time.

We sincerely apologize for any inconvenience this has caused.

We have notified Medicines and Healthcare Products Regulatory Agency (MHRA), and we are implementing additional measures to address this issue.

If you have any further questions or would like to report a device fault, please call Abbott Customer Service at [### country to insert correct CS Phone #]

Sincerely,

Abbott, Diabetes Care



[February xx], 2023

### **Urgent Field Safety Notice**

Product: FreeStyle Libre® 2 Sensors  
Reference: ADC FA1004-2023  
Communication from Manufacturer

Dear Distribution Partner,

Abbott is initiating a voluntary recall of certain FreeStyle Libre® 2 sensors from lot **KTP005061**. No other Abbott diabetes products are affected.

### **Problem / Issue**

- Abbott has recently identified that certain FreeStyle Libre® 2 sensors from lot **KTP005061** may provide erroneously high glucose readings. For example, a user's sensor glucose reading may be high and out of target range while actual glucose levels may be below or within target range.

### **Potential Harms**

- If undetected, erroneously high glucose readings can pose a potential health risk for people living with diabetes.
- Erroneously high glucose readings can lead to incorrect treatment decisions, such as taking insulin when not required.

### **Actions for You**

- To determine if sensors you have are affected, please visit [www.FreeStyleConfirm.com](http://www.FreeStyleConfirm.com) and enter the sensor serial number.
- You will be sent a replacement for any affected sensor(s). We will send you a mailing kit to return any affected sensor(s) to us.
- Please communicate this issue to any customers whom you have supplied FreeStyle Libre® 2 sensors from lot **KTP005061** by forwarding the attached letter.

We have notified Medicines and Healthcare Products Regulatory Agency (MHRA), and we are implementing additional measures to address this issue.

If you have any further questions or would like to report a device fault, please call your Abbott Diabetes Care sale representative or Abbott Customer Service at [### country to insert correct CS Phone #]

Sincerely,

Abbott, Diabetes Care



[February xx], 2023

### **Urgent Field Safety Notice**

Product: FreeStyle Libre® 2 Sensors  
Reference: ADC FA1004-2023  
Communication from Manufacturer

Dear Health Care Professional,

Abbott is initiating a voluntary recall of certain FreeStyle Libre® 2 sensors from lot **KTP005061**. No other Abbott diabetes products are affected.

#### **Problem / Issue**

- Abbott has recently identified that certain FreeStyle Libre® 2 sensors from lot **KTP005061** may provide erroneously high glucose readings. For example, your patients' sensor glucose reading may be high and out of their target range while their actual glucose levels may be below or within target range.

#### **Potential Harms**

- If undetected, erroneously high glucose readings can pose a potential health risk for people living with diabetes.
- Erroneously high glucose readings can lead to incorrect treatment decisions, such as taking insulin when not required.

#### **Actions for You and Your Patients**

- To determine if you or your patients' current sensor or any unused sensors are affected, please visit [www.FreeStyleConfirm.com](http://www.FreeStyleConfirm.com) and enter the sensor serial number.
- If your patient is currently using the FreeStyle Libre® 2 system and wearing an affected sensor, please instruct them to immediately discontinue use.
- Please communicate this issue to any patients whom you have supplied FreeStyle Libre® 2 sensors from lot **KTP005061** by forwarding the attached letter.
- You or your patients will be sent replacements for any affected sensor(s), including a mailing kit to return any affected sensor(s) to us.
- While waiting for a replacement Sensor, your patients can continue to use sensors that are not affected and can use the built-in blood glucose meter in the FreeStyle Libre® 2 reader to check glucose at any time.

We sincerely apologize for any inconvenience this has caused.

We have notified Medicines and Healthcare Products Regulatory Agency (MHRA), and we are implementing additional measures to address this issue.

If you have any further questions or would like to report a device fault, please call your Abbott Diabetes Care sale representative or Abbott Customer Service at [### country to insert correct CS Phone #]

Sincerely,

Abbott, Diabetes Care



[January 27, 2023]

### **Urgent Field Safety Notice**

Product: FreeStyle Libre® 2 Sensors

Reference: ADC FA1004-2023

Communication from Manufacturer

Dear Pharmacy Partner,

Abbott is initiating a voluntary recall of certain FreeStyle Libre® 2 sensors from lot KTP005061. No other Abbott diabetes products are affected.

#### **Problem / Issue**

- Abbott has recently identified that certain FreeStyle Libre® 2 sensors from lot **KTP005061** may provide erroneously high glucose readings. For example, your customers' sensor glucose reading may be high and out of their target range while their actual glucose levels may be below or within target range.

#### **Potential Harms**

- If undetected, erroneously high glucose readings can pose a potential health risk for people living with diabetes.
- Erroneously high glucose readings can lead to incorrect treatment decisions, such as taking insulin when not required.

#### **Actions for You**

- According to our records, we have supplied you with sensors which are affected, and your current sensor inventory may contain these sensors.
- In the next few days, your local Abbott sales representative will visit your pharmacy to assist checking your inventory to identify impacted sensors. We will arrange free of charge replacement and collection of any impacted sensors.
- In the meantime, you may wish to visit [www.FreeStyleConfirm.com](http://www.FreeStyleConfirm.com) and enter the sensor serial number of the affected batch to confirm if you have any affected sensors in stock.
- If you have affected sensors, please do not dispense these and we will replace them free of charge when your local Abbott sales representative visits.
- If you have dispensed sensors from lot number KTP005061 to customers, they should also visit [www.FreeStyleConfirm.com](http://www.FreeStyleConfirm.com) and enter the sensor serial number.
- If your patient is currently using the FreeStyle Libre® 2 system and wearing an affected sensor, please instruct them to immediately discontinue use.
- Please communicate this issue to any customers whom you have supplied FreeStyle Libre® 2

sensors from lot **KTP005061** by forwarding the attached letter.

- Your customers will be sent replacements for any affected sensor(s), including a mailing kit to return any affected sensor(s) to us.
- While waiting for a replacement Sensor, your customers can continue to use sensors that are not affected and can use the built-in blood glucose meter in the FreeStyle Libre® 2 reader to check glucose at any time.

We sincerely apologise for any inconvenience this has caused.

We have notified Medicines and Healthcare Products Regulatory Agency (MHRA), and we are implementing additional measures to address this issue.

If you have any further questions or would like to report a device fault, please call your Abbott Diabetes Care sale representative call Abbott Customer Service at [### country to insert correct CS Phone #].

Sincerely,

Abbott, Diabetes Care

## Messaging: FreeStyle Libre 2 Sensors – Erroneous High Glucose Readings



[February XX, 2023]

### Urgent Field Safety Notice

Product: FreeStyle Libre 2<sup>®</sup> Sensors  
Reference: ADC FA1004-2023  
Communication from Manufacturer

Dear Customer:

Abbott is initiating a voluntary recall of certain FreeStyle Libre 2<sup>®</sup> sensors from lot KTP005061. No other Abbott diabetes products are affected.

### Problem / Issue

- Abbott has identified that you recently started a FreeStyle Libre<sup>®</sup> 2 sensor from lot **KTP005061** which may provide erroneously high glucose readings. For example, your sensor glucose reading may be high and out of your target range while your actual glucose levels may be below or within target range.

### Potential Harms

- If undetected, erroneously high glucose readings can pose a potential health risk for people living with diabetes.
- Erroneously high glucose readings can lead to incorrect treatment decisions, such as taking insulin when not required.

### Actions for Users

- To determine if your current sensor or any unused sensors you have are affected, please visit [www.FreeStyleConfirm.com](http://www.FreeStyleConfirm.com) and enter your sensor serial number.
- If you are currently using the FreeStyle Libre<sup>®</sup> 2 system and are wearing an affected sensor, please immediately discontinue use. If you have symptoms that do not match the sensor glucose reading, or suspect your reading may be inaccurate, check the reading by conducting a fingerstick test using a blood glucose meter.
- You will be sent a replacement for any affected sensor(s). We will send you a mailing kit to return any affected sensor(s) to us.
- While waiting for your replacement sensor, you can continue to use sensors that are not affected and can use the built-in blood glucose meter in your FreeStyle Libre<sup>®</sup> 2 reader to check your glucose at any time.

We sincerely apologize for any inconvenience this has caused.

We have notified Medicines and Healthcare Products Regulatory Agency (MHRA), and we are implementing additional measures to address this issue.

If you have any further questions or would like to report a device fault, please call Abbott Customer Service at [### country to insert correct CS Phone #]

Sincerely,

Abbott, Diabetes Care