

19 February 2014

URGENT FIELD SAFETY NOTICE

Product: FreeStyle Mini[®] and FreeStyle[®] Blood Glucose Monitoring System
Reference: ADC FA1002-2014
Type of Action: Field Safety Notice

Dear Practice Manager,

Recently, it has come to our attention that two of our older meters, FreeStyle Mini[®] and FreeStyle[®] Blood Glucose Meters, may produce erroneously low blood glucose results when using the FreeStyle Lite[®] and FreeStyle[®] Blood Glucose Test Strips. Erroneously low results that are not recognized may pose significant risks to a user's health.

No action is required if patients do not use the meters pictured below.

FreeStyle Mini[®]
Blood Glucose Meter



FreeStyle[®]
Blood Glucose Meter



If patients are currently using any of the meters pictured above, they are asked to discontinue use of their FreeStyle Mini[®] or FreeStyle[®] Blood Glucose Meter and call Abbott Diabetes Care Customer Service immediately at **0500 467 466**. When they call, Abbott will send them a new FreeStyle[®] branded meter at no charge.

Patients are being asked to dispose of their old meter in accordance with their local and state disposal regulations upon receipt of their replacement meter.

Patients with contact details on file with Abbott Diabetes Care will be notified directly of this issue. However, we also request your assistance in making users of the affected meters aware of this issue.

For patients being prescribed FreeStyle[®] Blood Glucose Test Strips, we request that you provide them with a copy of the attached patient letter.

Abbott Diabetes Care can confirm that this notice has been communicated to the required Competent Authority.

We recognize the importance of blood glucose testing for your patients, and are committed to responding quickly to requests for replacement meters.

We sincerely regret any inconvenience this situation may cause. We thank you for your continued support of the FreeStyle[®] Blood Glucose Monitoring System and Abbott Diabetes Care. If you have any further questions, please call Abbott Diabetes Care Customer Service.

Sincerely,

Joe Bugler
Director Global Clinical & EMEA Regulatory Affairs
Abbott Diabetes Care.

19 February 2014

URGENT FIELD SAFETY NOTICE

Product: FreeStyle Navigator® Continuous Glucose Monitoring System
Reference: ADC FA1002-2014
Type of Action: Field Safety Notice

Dear Valued Customer,

Recently, it has come to our attention that FreeStyle Navigator® Continuous Glucose Monitoring System (1.0 and 1.5 generation) may produce erroneously low blood glucose results when using FreeStyle Lite® and FreeStyle® Blood Glucose Test Strips. Erroneously low results that are not recognized may pose significant risks to your health.

FreeStyle Navigator® (Version 1.0 and 1.5)



If you are currently using the receiver pictured above, please take the following steps:

1. Please dispose of all test strips that are currently in your possession in accordance with your local and state disposal regulations.
2. **Call Abbott Diabetes Care Customer Service immediately at 0500 467 466.** When you call, Abbott will send you replacement FreeStyle® Blood Glucose Test Strips at no charge.
3. It is very important that you use strips only sent to you by Abbott Diabetes Care for use with your Navigator receiver when performing calibrations or testing your blood glucose levels.

Control solution should be used to check the performance of your receiver and test strips prior to calibration or blood testing. If any reading from a strip with control solution is outside the range printed on the test strip vial do not use the strips to calibrate your system.

When performing a blood glucose test with your receiver and any reading appears lower than you would expect or does not seem to match the way you are feeling, you should contact your health care provider. Pay special attention to signs and symptoms of high blood sugar (hyperglycemia).

Symptoms of high blood sugar may include: Excessive thirst, excessive urination, blurred vision, weakness, nausea, vomiting, and abdominal pain. If you are experiencing any of these symptoms or are not feeling well, contact your health care professional immediately.

4. While waiting for your replacement strips to arrive, use an alternative meter such as the FreeStyle® Freedom blood glucose meter that you may have. FreeStyle® and FreeStyle® Lite test strips when used the FreeStyle® Freedom blood glucose meter will produce accurate blood glucose results.

Abbott Diabetes Care can confirm that this notice has been communicated to the required Competent Authority.

We recognize the importance of blood glucose testing and are committed to responding quickly to our customers' needs.

We want to assure you that our first priority is you, our customer. We sincerely regret any inconvenience this situation may cause. We thank you for your continued support of the FreeStyle



Navigator® Continuous Glucose Monitoring System and Abbott Diabetes Care. If you have any further questions, please call Abbott Diabetes Care Customer Service.

Sincerely,

Joe Bugler
Director Global Clinical & EMEA Regulatory Affairs
Abbott Diabetes Care

19 February 2014

URGENT FIELD SAFETY NOTICE

Product: FreeStyle Mini[®] and FreeStyle[®] Blood Glucose Monitoring System
Reference: ADC FA1002-2014
Type of Action: Field Safety Notice

Dear Valued Customer,

Recently, it has come to our attention that FreeStyle Mini[®] and FreeStyle[®] Blood Glucose Meters may produce erroneously low blood glucose results when using FreeStyle Lite[®] and FreeStyle[®] Blood Glucose Test Strips. Erroneously low results that are not recognized may pose significant risks to your health.

No action is required if you do not use the meters pictured below.

FreeStyle Mini[®]
Blood Glucose Meter



FreeStyle[®]
Blood Glucose Meter



If you are currently using either of the meters pictured above, please take the following steps:

1. **Discontinue use of your FreeStyle Mini[®] and FreeStyle[®] Blood Glucose Meter and call Abbott Diabetes Care Customer Service immediately at 0500 467 466.** When you call, Abbott will send you a new FreeStyle[®] branded meter at no charge.

If the only meter you have available is a FreeStyle[®] or FreeStyle Mini[®] Blood Glucose Meter, do not stop testing your blood glucose. Control solution should be used to check the performance of your test strips and meter until you receive your replacement meter. However, if any reading from a strip appears lower than you would expect or does not seem to match the way you are feeling, you should contact your health care provider. Pay special attention to signs and symptoms of high blood sugar (hyperglycemia).

Symptoms of high blood sugar may include: Excessive thirst, excessive urination, blurred vision, weakness, nausea, vomiting, and abdominal pain. If you are experiencing any of these symptoms or are not feeling well, contact your health care professional immediately.

2. Upon receiving your replacement meter, please be sure to dispose of your old meter in accordance with your local and state disposal regulations.

A test strip insert is included with every carton of FreeStyle[®] and FreeStyle Lite[®] Blood Glucose Test Strips, and provides very important product information. Please read your test strip insert carefully to ensure that you are using the correct Blood Glucose Meter for your test strip type.



Abbott Diabetes Care can confirm that this notice has been communicated to the required Competent Authority.

We recognize the importance of blood glucose testing and are committed to responding quickly to our customers' needs.

We want to assure you that our first priority is you, our customer. We sincerely regret any inconvenience this situation may cause.

We thank you for your continued support of the FreeStyle Blood Glucose Monitoring System and Abbott Diabetes Care. If you have any further questions, please call Abbott Diabetes Care Customer Service at **0500 467 466**.

Sincerely,

Joe Bugler
Director Global Clinical & EMEA Regulatory Affairs
Abbott Diabetes Care

February 13, 2014

IMPORTANT: URGENT PRODUCT RECALL
FreeStyle® Blood Glucose Monitoring System

Dear Valued OmniPod® Customer,

Recently, it has come to our attention that FreeStyle® Blood Glucose Test Strips may produce erroneously low blood glucose results when using the FreeStyle® blood glucose meter built into the OmniPod® Insulin Management System. Erroneously low blood glucose results that are not recognised may pose significant risks to your health.

Please take the following steps:

1. If you are using the FreeStyle® Blood Glucose Meter built into the OmniPod Personal Diabetes Manager (PDM), **you must discontinue use of any FreeStyle® Blood Glucose Test Strips you may have** until you obtain replacement strips from Abbott Diabetes Care. To receive replacement strips at no cost contact Abbott Diabetes Care Customer Service at 0500 467 466.
2. Continue using your OmniPod Insulin Management System (OmniPod) to deliver your insulin therapy. While waiting for your replacement strips to arrive, use the FreeStyle® Freedom blood glucose meter that you may have previously received with your welcome pack. FreeStyle® test strips when used the FreeStyle® Freedom blood glucose meter will produce accurate blood glucose results.

If you would like to continue using the OmniPod system to recommend dosing, follow your OmniPod® Insulin Management System instructions for manually entering blood glucose readings.

As always, control solution should be used to check the performance of your test strips and meter until you receive your replacement test strips. If any reading from a strip appears lower than you would expect or does not seem to match the way you are feeling, you should contact your health care provider immediately. Pay special attention to signs and symptoms of high blood sugar (hyperglycemia).

Symptoms of high blood sugar may include: Excessive thirst, excessive urination, blurred vision, weakness, nausea, vomiting, and abdominal pain. If you are experiencing any of these symptoms or are not feeling well, contact your health care professional immediately.

3. Abbott Diabetes Care will provide further information when you call on the process to obtain your test strips going forward.

FreeStyle® Blood Glucose Test Strips are the only strip type that is approved for use with your OmniPod® Insulin Management System. **Please read your product information booklet and test strip insert carefully to ensure that you are using the correct test strip type for your OmniPod® Insulin Management system.** OmniPod® Insulin Management System is not labeled for use with FreeStyle Lite® Blood Glucose Test Strips.

We recognize the importance of blood glucose testing and are committed to responding quickly to customers' requests for replacement test strips.

We want to assure you that our first priority is you, our customer. We sincerely regret any inconvenience this situation may cause. If you have any further questions, please call Abbott Diabetes Care Customer Service.

Sincerely,



Kelly E. Duffy
Division Vice President, Quality Assurance and Compliance
Abbott Diabetes Care