



Abbott Diabetes Care



IMPORTANT: MEDICAL DEVICE CORRECTION
Precision XceedPro Blood Glucose and β -Ketone Monitoring System

March 18, 2013

Dear Valued Customer,

This letter contains important information for users of the Precision XceedPro Blood Glucose and β -Ketone Monitoring System. Please review the information carefully.

Abbott Diabetes Care (ADC) has become aware of the following issues:

1. A small number of Precision XceedPro Blood Glucose Test Strips lots produce control solution results out of range and higher than expected percentage Coefficient of Variation and Standard Deviation with controls. This issue does not affect patient blood glucose or β -ketone results, as confirmed through our internal testing of retained strips and performance monitoring program.
2. Precision XceedPro Monitors with serial numbers beginning with "KC" do not fully support a subset of the following barcode types: Interleaved 2 of 5 (1 2 of 5), Code 128 and Code 39. As stated in label copy, if you cannot scan a barcode using the barcode scanner, the data entry keypad on your Precision XceedPro Monitor allows you to manually enter identification numbers and letters.

ADC has a firmware update to the Precision XceedPro Monitor to address these issues. If you have seen these problems and would like to schedule the update, please contact us at ADCTechnicalSupport@abbott.com or call 1-877-529-7185, and press the pound (#) key to connect with an Abbott Diabetes Care Representative.

You may continue to use the Precision XceedPro Blood Glucose and β -Ketone Monitoring System to test patients and test with controls. It is important to compare control solution results to the ranges stated on the test strip insert included with each lot.

We want to assure you that our first priority is you, our customer. We sincerely apologize for any inconvenience this may cause. We appreciate that you have chosen Abbott Diabetes Care as your partner for hospital blood glucose management.

Should you have any questions, please contact Technical Support at 1-877-529-7185, and press the pound (#) key or your Abbott Diabetes Care Representative.

Sincerely,

Quality Assurance and Compliance

Abbott Diabetes Care

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