

Miscoded Blood Glucose Meters Can Result in Significant Errors in Insulin Dose

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Ascensia® CONTOUR®
Blood Glucose Monitoring System
No Coding Required™



Ascensia® BREEZE®
Blood Glucose Monitoring System
No Coding Required™

ABSTRACT

Approximately 16% of people do not code their blood glucose (BG) meter to the lot of test strips they are using 1-5. Studies have shown that some miscoded meters can have median errors as great as 48%. We analyzed these studies using insulin dose algorithms to determine the error in insulin dose that would result from using miscoded meters. A Monte Carlo simulation⁶ was used to generate 'actual' and 'measured' glucose values, and insulin doses based on these values, assuming that 1U of insulin covers 50mg/dL BG. For **correctly coded meters**, the probability of insulin error of $\pm 1U$ was up to 42%; for $\pm 2U$, and $\pm 3U$ was only 2.2% and 0.02%, respectively. For **miscoded meters**, the probability of insulin error of $\pm 1U$ was up to 61%. More significantly, the probability of insulin error of $\pm 2U$ was 45%, $\pm 3U$ was 28%, $\pm 4U$ was 2.9%, and $\pm 5U$ was 0.05%. Thus, patients may be exposed to significant risks if they base their diabetes management decisions on the results of a miscoded BG meter.

INTRODUCTION

Published studies confirm that people with diabetes often fail to code, or improperly code their blood glucose meters. Improperly coded meters can produce inaccurate results, leading to inappropriate clinical decisions or treatment.¹⁻⁵

Studies were performed to determine the effect on accuracy when incorrect code numbers were used with two commonly used meter systems, the OneTouch® Ultra® (Lifescan, Inc.) and FreeStyle™ (TheraSense, Inc.). The results were compared to data obtained from correctly coded meters of the same type, the Ascensia® CONTOUR®, Ascensia® BREEZE® Systems (Bayer HealthCare), which cannot be miscoded, and to a laboratory glucose analyzer (YSI).

For Manually Coded Meters:

Miscoding can occur when a user:

1. accidentally enters the wrong code number or forgets to change the code number in the meter when using a new bottle of strips
2. forgets to insert a new code chip or code strip when using a new bottle of reagent strips

Autocoded Meters:

The Ascensia BREEZE and Ascensia CONTOUR systems **do not require you to do anything to code your meter** because they have an automatic coding feature built into them.

METHODS

To determine the errors in accuracy with miscoded meters we conducted studies as follows:

Protocols and informed consents were approved by an IRB and informed consent was obtained from all subjects.

Subjects:

- 102 (36 men and 66 women)
- Type 1 and Type 2 diabetes
- Subject Ages: 23 to 84 years

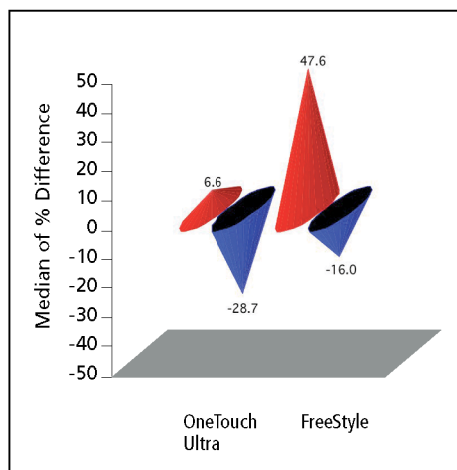
Blood Collection and Testing:

- Fresh fingerstick capillary blood used to test the CONTOUR, BREEZE, OneTouch Ultra and FreeStyle Blood Glucose Meters, laboratory glucose (YSI) and hematocrit determinations
- The blood glucose concentrations of the subjects, ranged from 48 to 462 mg/dL

RESULTS

ACCURACY: Figure 1 shows how inaccurate miscoded meters can be.

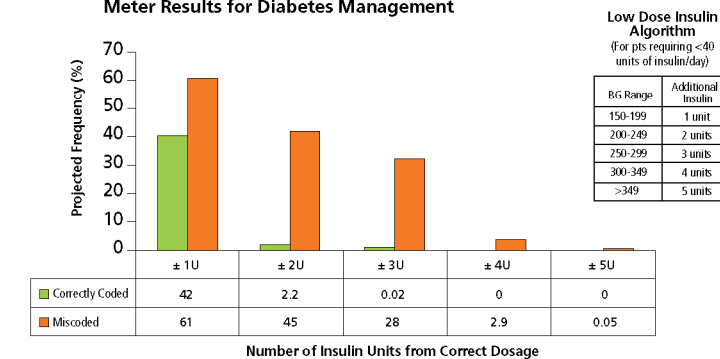
Figure 1: Medians Of The Percent Differences From Laboratory Glucose Analyzer, YSI



PROBABILITY OF INSULIN DOSE ERRORS: Figure 2

The analysis showed that for miscoded meters the probability of insulin dose error of $\pm 1U$ was up to 61%. More significantly, the probability of insulin error of $\pm 2U$ was 45%, for $\pm 3U$ was 28%, for $\pm 4U$ was 2.9%, and for $\pm 5U$ was 0.05%.*

Figure 2: Projected Errors in Insulin Doses Caused by Using Miscoded Meter Results for Diabetes Management



*Results may vary using different simulation assumptions.

CONCLUSIONS

Use of miscoded blood glucose meter results can lead to significant errors in insulin doses. Thus, patients may be exposed to increased risks if they base their diabetes management decisions on the results from a miscoded meter.

To Reduce the Risks of Inaccurate Results and Incorrect Treatment:

- People with diabetes need to be trained to properly code their meters
- Educators should check patients' meter code number during each visit
- **Best Advice:** Use a meter that cannot be miscoded such as the Ascensia® CONTOUR® or Ascensia® BREEZE®

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