

Why does a test result  
from one meter differ  
from another?



Comparing Accuracy  
of Meter Measurements  
*from One Brand to Another*

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# Meter Accuracy Comparing Meter Measurements

**FAQ:** How can two (2) blood glucose meters (marketed by different manufacturers) produce readings that are not the same from the same blood sample? Does this make one reading more accurate than the other?

**Answer:** Yes, different meters can produce results that are not the same using the same blood sample.

No, this does not mean that one result is more accurate than the other.

## The reasons for this are as follows.

1. All blood glucose meters have to meet the requirements of published standards issued by ISO (International Standards Organization) and CLSI (Clinical and Laboratory Standards Institute). The primary standard is ISO 15197: In Vitro Diagnostic Test Systems-Requirements for Blood Glucose Monitoring Systems for Self Testing in Managing Diabetes Mellitus. The ISO standard references CLSI standards for specific tests.
2. The accuracy requirements for the blood glucose monitoring system (meters and test strips) as stated in ISO 15197 is this:

***Ninety five percent (95%) of the individual glucose results shall fall within  $\pm 0.83$  mmol/L (15 mg/dL) of the results of the manufacturers measurement procedure at glucose concentrations  $<4.2$  mmol/L ( $<75$  mg/dL) and within  $\pm 20\%$  at glucose concentrations  $\geq 4.2$  mmol/L ( $\geq 75$  mg/dL).***

## How does this answer the FAQ?

The accuracy of the system is determined by a clinical study using 100 blood samples at interval glucose concentrations ranging from  $< 50$ mg/dL to over 400 mg/dL.

### Example 1

If the manufacturers reference measurement is 70 mg/dL this means that the meter measurements are considered accurate if they fall within  $\pm 15$  mg/dL of 70mg/dL or in the range of 55mg/dL to 85mg/dL

If meter A produces a measurement of 60mg/dL and meter B measures 80 mg/dL, then both are in the acceptable range and meet the accuracy requirement

### Example 2

If the manufacturer's reference measurement is 150 mg/dL, this means that the meter measurements are considered accurate if they fall within  $\pm 20\%$  of 150mg/dL or in the range of 120mg/dL to 180mg/dL.

If meter A produces a measurement of 135mg/dL and meter B measures 160mg/dL, then both are in the acceptable range and meet the accuracy requirement.

Each manufacturer has met the System Accuracy requirement as part of its testing to be cleared for marketing. In the System Accuracy testing a distribution of blood glucose readings will result at the various glucose concentration levels for one manufacturers system. This is the same for other manufacturers system. Because of the range of acceptable readings for the accuracy requirement, identical readings from two different meters on the same blood sample may not happen.