

Clinical Results and Performance Data*



EvenCare[®] G2[®] Blood Glucose Monitoring System

INTRODUCTION

The EvenCare G2 Blood Glucose Monitoring System consists of a glucose meter, test strips and control solution for the monitoring of blood glucose for individuals who have diabetes. The test strip and meter utilize electrochemical technology, based on glucose oxidase chemistry for determination of glucose levels in whole blood samples. The convenient, vial stored test strips require approximately .7 μ L of blood meaning more comfort. The alternate site testing capability allows you the option to test on the forearm, palm or fingertips.

The EvenCare G2 Monitoring System is packed with features that assist in diabetes management. Its large, easy-to-read display shows a result in only 6 seconds.

The auto code system minimizes errors and inaccurate results. Voice assistance in English or Spanish guides you through the testing process and provides you with your results. The last 300 results are stored in memory for easy review and it can provide 7, 14 and 30 day averaging. The EvenCare G2 Monitoring System accurately operates between 50-104° F in up to 85% relative humidity. Detectable glucose levels range from 20-600 mg/dL and are reliable with hematocrit ranges of 30-55%.

The clinical results and performance data contained in this report prove the reliability and accuracy of The EvenCare G2 Monitoring System.

ACCURACY

Accuracy describes how well the readings from a blood glucose testing system (meter and test strips) agree with the readings from an accepted reference system (calibrated laboratory glucose analyzer). The accuracy of the EvenCare G2 Monitoring System was assessed in 150 subjects using three different lots of test strips.

Glucose levels ranged from 37-599 mg/dL, as determined by the glucose analyzer (YSI 2300 Glucose Analyzer). The results of each lot tested were directly correlated with the readings obtained from the EvenCare G2 Monitoring System as demonstrated in the figure to the right.

PRECISION

Precision describes the low level of variation observed between multiple readings. Two different scenarios were evaluated to detect the precision of The EvenCare G2 readings; Within-Run and Between-Run tests.

The Within-Run test consisted of evaluating glucose readings of multiple samples tested in succession in glucose spiked samples (10 replicates of five spiked whole blood glucose levels each) in addition to two levels of control solution (Low and High). This test was performed over the course of one day. The Between-Run test was similar in design to the Within-Run test only performed over the course of ten days. Both of these tests utilized three different lots of test strips.

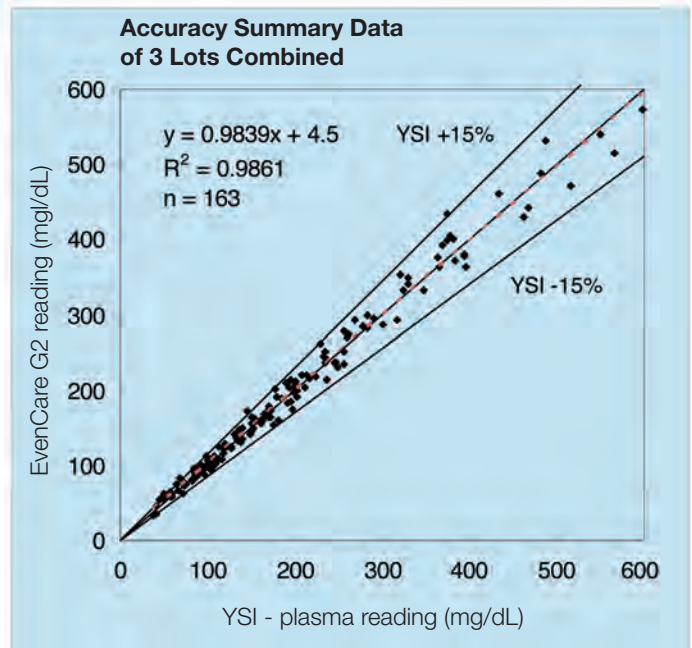
The accuracy of The EvenCare G2 Monitoring System was verified prior to the start of each test set using a calibrated YSI 2300 Glucose Analyzer.

Estimates of precision for The EvenCare G2 system were calculated to have low variability with a coefficient of variation of less than 4.3% for both the Within-Run and Between-Run testing.

HEMATOCRIT EFFECTIVE RANGE

The accuracy of detecting blood glucose can be affected by variable hematocrit levels. The specifications and accuracy for the glucose test strips were evaluated on different hematocrit levels within the normal range (30-55%). To adjust for biosensor bias, a 40% hematocrit level was selected for comparison of results.

Six different glucose concentrations ranging from 20-580 mg/dL were evaluated in combination with four concentrations of hematocrit within the normal range of 30-55%. All testing followed the methods described in the EvenCare G2 Meter user's guide. Tests were performed in the normal test mode.



EvenCare G2 glucose levels compare directly with the standardized YSI Analyzer. Minimal variability (<15%) was observed between the two methods of detection.

The results showed that at all the tested hematocrit levels, the bias due to sample hematocrit was less than +/- 19%. Very low hematocrit levels (<30%) tend to produce a larger positive bias, while very high hematocrit levels (>55%) tend to produce a larger negative bias.

The EvenCare G2 Monitoring System exhibits acceptable performance with a bias less than 19% in the normal hematocrit range of 30-55%.

TEMPERATURE/ HUMIDITY EFFECTS

Specifications for operating conditions were evaluated for the EvenCare G2 Monitoring System under varied temperatures and humidities.

The study evaluated the EvenCare G2 Monitoring System in temperatures that ranged from 10°C to 40°C (50°F to 104°F), and in humidity ranges from 40% to 90% relative humidity. Four different glucose concentrations of blood and two different glucose levels of control solution were evaluated. To adjust for biosensor bias, temperatures of 26°C (77°F) and 60% relative humidity were selected for comparison of results.

All testing followed the methods described in the package insert. Blood sample tests were performed in the normal test mode, and the control solution tests were performed in the control testing mode. The results show that the EvenCare G2 Monitoring System is qualified to be operated in temperatures that ranged from 10°C to 40°C (50°F to 104°F), and in humidity ranges from 40% to 85% relative humidity.

DRUG AND BIOLOGICAL SUBSTANCE INTERFERENCE

It is important to demonstrate the influence of some exogenous and endogenous substances with the EvenCare G2 Monitoring System. This study was conducted in order to understand the interference of glucose measurement of some medications in addition to some levels of endogenous substrates. The items tested are recommended by the Food and Drug Administration, and tested at concentrations recommended by the national committee for Clinical Laboratory Standards (CLSI EP7-A2). Summary data is provided at the right.

Main conclusions of the study were as follows:

- Triglycerides: 260 to 360 mg/dL has no significant effect on test results (normal range 36 - 165 mg/dL). Icodextrin and its metabolites (maltose, maltotriose and maltotetraose) do not significantly affect test results.
- The following will not affect test results in expected blood concentrations: ascorbic acid (Vitamin C), uric acid, or methyl-dopa.
- Therapeutic concentration of dopamine or L-dopa may affect results. People taking these drugs should not use this system to test blood sugar.
- Higher than therapeutic concentrations of acetaminophen, or glibenclamide, may affect test results. People taking higher than therapeutic concentrations should not use this system to test blood sugar levels.

ALTITUDE EFFECT

The performance of the EvenCare G2 Monitoring System was evaluated up to 10,000 feet (3048 meters).

Testing was performed on five (5) EvenCare G2 Meters using whole blood supplemented with glucose to provide samples at five different glucose ranges from 50 to 400 mg/dL.

A total of 20 tests were performed. In addition, within 5 minutes of the glucose test using the EvenCare G2 Monitoring System, the glucose level was confirmed using a calibrated laboratory reference system (YSI 2300 Glucose Analyzer). To adjust for biosensor bias, temperatures of 23°C +/- 5°C (73.4°F +/- 41°F) and 30-85% relative humidity were selected for comparison of results. Hematocrit was within the 30%-55% range.

The bias analysis indicated that the EvenCare G2 Monitoring System both at sea level and 2275 meters were within 100% of all test results (within 15-20% of the YSI reference range results).

Control solutions (Low and High) were also evaluated at similar elevations using two glucose concentrations (85 and 185 mg/dL) and under similar bias conditions. The bias analysis indicated a range from -1.4% to -0.2% with low critical values ranging from 3.4%-4.2%.

	Therapeutic Dose	Low Test Concentration	High Test Concentration
	mg/dL	mg/dL	mg/dL
Acetaminophen	1-2	1.25	20*
Amiloride	0.8	1.25	20
Ascorbic acid	0.8-1.2	1.25	20
Atenolol	4	20	20
Bilirubin	1.3	12.5	25
Cholesterol	250	250	500
Colchicine	0.2	5	20
Creatinine	1.5	1.25	20
Diclofenac	4	5	20
Dopamine	NA	5*	20*
EDTA	NA	100	1000
Galactose	NA	20	100
Gilbenclamide	0.6	5	10*
Heparin	NA	100	1000
Ibuprofen	0.5-4.2	1.25	20
Indomethacin	8	1.25	20
Ketoprofen	6	5	20
Lactose	NA	20	100
L-DOPA	NA	1.25	20*
Maltose	NA	20	100
Maltotetraose	NA	20	100
Maltotriose	NA	20	100
Methyl-Dopa	0.1-0.5	0.1	10*
Salicylic acid	15-30	12.5	50
Tetracycline	0.4	1	10
Tolbutamide	5.3-10	5	20
Triglyceride	36-165	260	360
Uric acid	7	10	20

**Asterisk indicates interference.*

The results show that there is no difference in performance and accuracy of the EvenCare G2 Meter at altitudes up to 2275 meters.

DYNAMIC RANGE

It is crucial that a glucose monitoring system be capable of measuring blood glucose levels across a wide range of values.

Testing was performed using whole blood supplemented with glucose to provide samples at eight different glucose ranges from 20 to 600 mg/dL. In order to confirm the operational range, some blood samples beyond the expected range were included. A total of 40 tests were performed at each glucose range.

In addition, within 10 minutes of the glucose test using the EvenCare G2 Monitoring System, the glucose level was confirmed using a calibrated laboratory reference system (YSI 2300 Glucose Analyzer). Three different lots of glucose test strips were evaluated.

Each test set consisted of randomly selecting one of the eight whole blood samples for analysis using both the EvenCare G2 Monitoring System and the Laboratory reference system. To adjust for biosensor bias, results from the YSI analyzer were used to calculate a bias for glucose levels (mg/dL) and percentage of results that were within the YSI range.

The bias analysis indicated that the EvenCare G2 System was within 100% of all test results (within 10-15% of the YSI reference range results).

The results also support the EvenCare G2 Monitoring System glucose reference range of 20mg/dL to 600 mg/dL by indicating display readings of LO for values lower than 20 mg/dL and HI for values higher than 600 mg/dL.

EVENCARE G2 BLOOD GLUCOSE TEST STRIPS

The EvenCare G2 Test Strip is easy to use and measures blood glucose accurately. The test strips use the enzyme glucose oxidase to convert blood glucose into an electronic charge that can be detected by the meter. When you apply blood to the end of the test strip, the blood sample is absorbed into the reaction zone. The higher the blood glucose concentration, the higher the electrical charge. The meter uses advanced biosensor technology to measure the charge (electrons) and converts the results into blood glucose levels.

Each cm² of the test strip contains the following ingredients in the appropriate concentrations listed below:

- Glucose Oxidase (A. Niger) 7.6%
- Electron Shuttle 53.3%
- Non-Reactive Ingredients 39.1%

STABILITY OF TEST STRIPS/ CONTROL SOLUTIONS

The longevity of packaged test strips and control solutions to continue to deliver consistent results were evaluated. The stability of these products was evaluated on product stored

over a 96-week period under conditions of 5°C and 30°C (41°F - 86°F) using 85% relative humidity.

Using five different blood glucose concentrations ranging from 50-400 mg/dL, the test strips (three different lots) and control solutions (Level 1 and Level 2) were evaluated for accuracy.

The assay bias for blood glucose in the test stripes ranged from -2 to 10. Similarly, assay bias for the control solutions (Low and High) ranged from -3% to 7%.

These results all fall within the acceptable limits up to 96 weeks.

QUALIFICATION OF THE EVENCARE G2 LOW AND HIGH CONTROL SOLUTIONS FOR USE WITH THE EVENCARE G2 METER

The EvenCare G2 Meter User's Manual recommends using the EvenCare G2 Low and High Control Solutions to verify the performance of the EvenCare G2 Glucose Monitoring System. A study was conducted to qualify the EvenCare G2 Control Solutions for use with the EvenCare G2 Meter.

The specifications for the EvenCare G2 Meter require that test results using the EvenCare G2 Control Solutions are within the specified range 95% of the time. The ranges for control Solutions are specified separately for each lot of test strips. The ranges specified for the strip lot used in this study were as follows: 66 to 99 mg/dL and 156 to 234 mg/dL.

All test results fell within the specified use ranges for these materials.

CONCLUSION

Extensive testing performed on the EvenCare G2 Blood Glucose Monitoring System demonstrates reliable blood glucose readings. The high degree of accuracy and precision and Medline's quality guarantee are the assurance of quality glucose monitoring care using the EvenCare G2 Blood Glucose Monitoring System.



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*Data on file.