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Accuracy Performance of the EasyMax NG System

Introduction

- The accuracy of the system was assessed per EN ISO 15197:2013 standard, Requirements for in vitro Glucose Monitoring Systems for Self-Testing in Managing Diabetes Mellitus.
- Capillary blood from at least 100 subjects diagnosed with diabetes was obtained at one external diabetes clinic. These results were compared to reference values obtained by using the glucose-dehydrogenase reference method adjusted to give plasma like results.

I. ACCURACY

Method

Testing was performed using 3 lots EasyMax NG glucose test strips. Three EasyMax NG blood glucose meters were assigned for testing with three lots of blood glucose test strips.Each subject performs two tests for each strip lot.

Per the ISO standard, blood glucose meter results must lie within the following ranges for each meter tested as stated in the table below:

95% of the individual glucose results shall fall within ± 0.83 mmol/L (± 15 mg/dL) of the results of the reference measurement at glucose concentrations <5.55 mmol/L (<100 mg/dL) and within ± 15% at glucose concentrations ≥5.55 mmol/L (≥100 mg/dL). Moreover at least 99% of individual glucose results shall fall within zones A and B of the Consensus Error Grid [3].

Three meters and three strip lots were used and 103 subjects were involved on clinical accuracy evaluation. Because of missed stability criterion described in ISO 15197, only 100 subjects test results were analysised.

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Results

The EasyMax NG blood glucose test lots were analyzed by linear regression and are summarized in the following table.

N=200	Regression
Lot1: 082123802	y = 1.04 x – 3.20
Lot2: 082123803	y = 1.05 x – 4.62
Lot3: 082123804	y = 1.02 x – 2.26

The lot demonstrates excellent correlation with all values near the optimum value of 1.00.
The test glucose concentration range for the samples included in evaluation is 32-512mg/dL.

The minimum system accuracy performance criteria in ISO15197:2013 is :

1. 99 % of individual glucose measured values shall fall within zones A and B of the Consensus Error Grid (CEG) for type 1 diabetes.
2. 95 % of the measured glucose values shall fall within either ± 0,83 mmol/l (±15 mg/dl) of the average measured values of the reference measurement procedure at glucose concentrations < 5,55 mmol/l (<100 mg/dl) or within ± 15 % at glucose concentrations ≥ 5,55 mmol/l (≥100 mg/dl).

The following table shows the summary of Clarke error grid analysis and EasyMax NG fulfill the requirement of ISO15197:2013.

N=200	Percentage of results within zones A and B
Lot1: 082123802	100%
Lot2: 082123803	100%
Lot3: 082123804	100%

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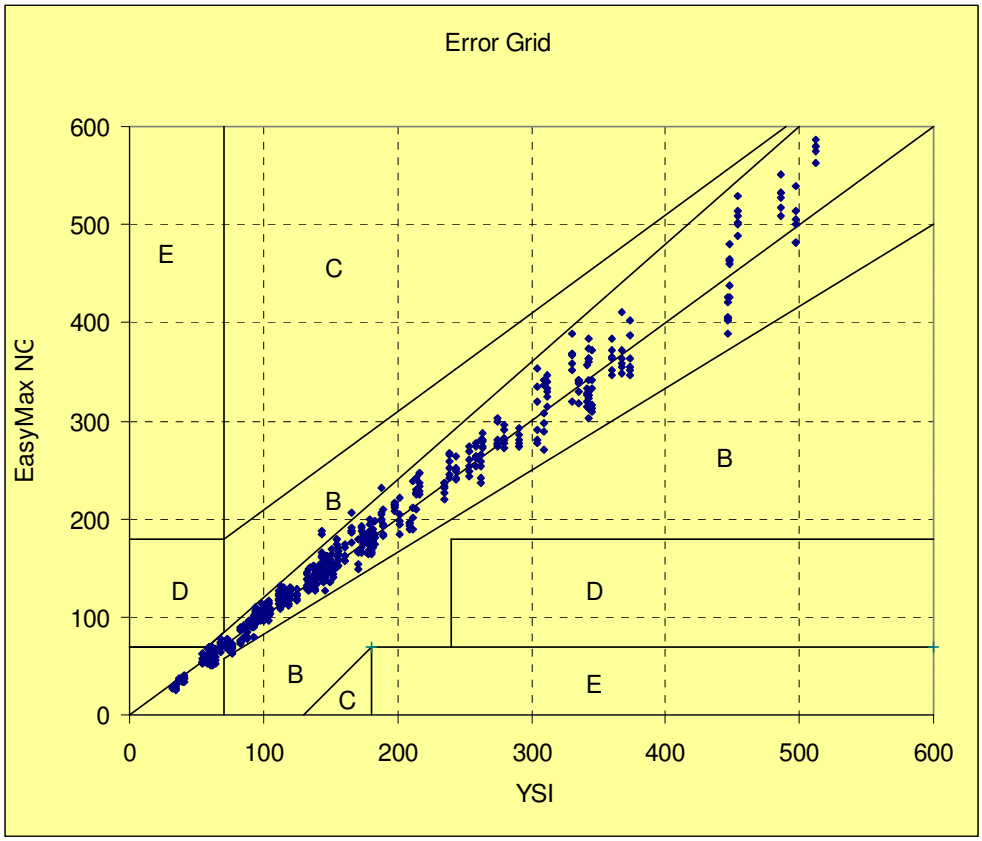
The minimum acceptable accuracy for results produced by a glucose monitoring system shall be as follows:

Ninety-five percent (95%) of the individual glucose results shall fall within ± 15 mg/dL of the results of the manufacturer`s measurement procedure at glucose concentrations of ＜100 mg/dL and within ± 20% at glucose concentration ≧100mg/dL.

N=200	Combined system accuracy	Criteria of ISO 15197:2013 met?
Lot1: 082123802	196 / 200 (98.0%)	YES
Lot2: 082123803	196 / 200 (98.0%)	YES
Lot3: 082123804	195 / 200 (97.5%)	YES

Summary of error grid analysis



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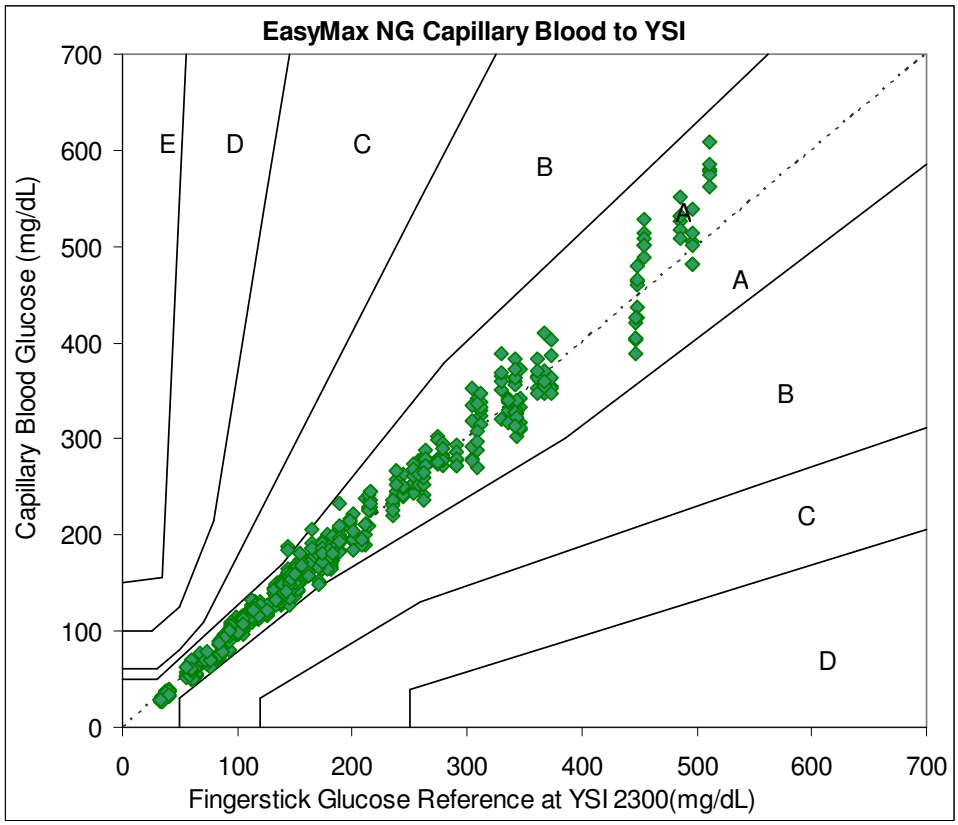

CONCLUSION

The EasyMax NG Glucose Monitoring System be with the tested test strip lots complies with the system accuracy criteria of ISO 15197:2013

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