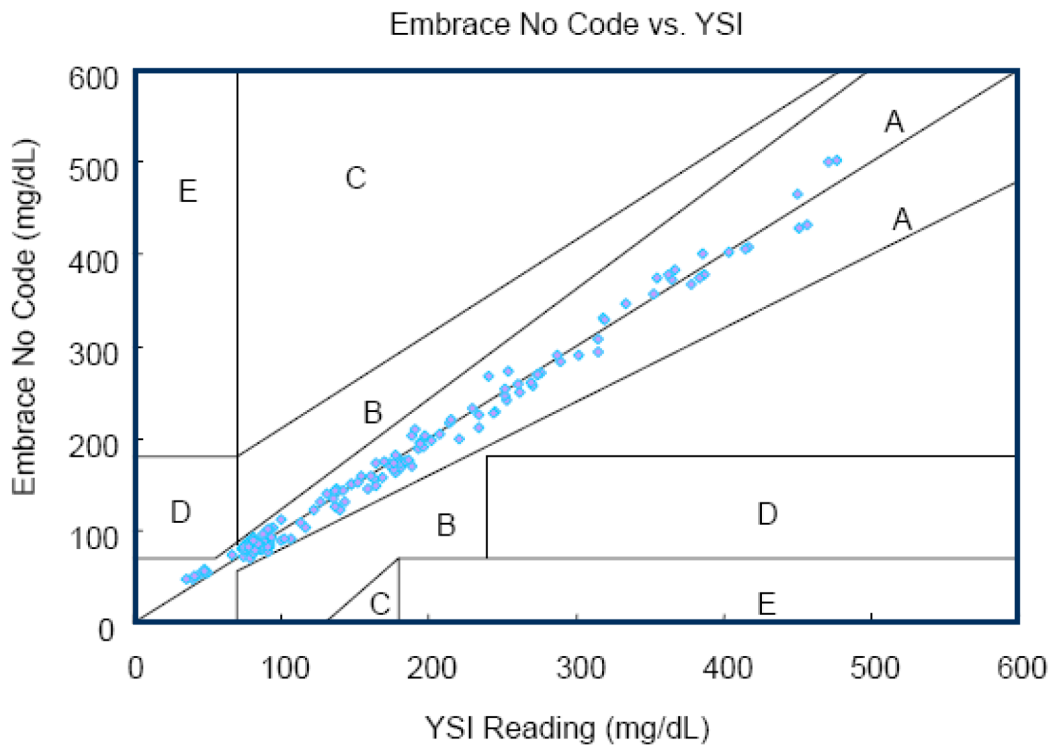


About the Study:

A study was performed to demonstrate the accuracy of the Embrace No Code Blood Glucose Management System (Embrace) compared to a clinical laboratory reference method (YSI-2300). Healthcare professionals performed the evaluation with 158 patients either with or without diabetes. Fresh capillary whole blood was tested using the Embrace system. Results were compared to YSI-2300 glucose analyzer. Data was presented in compliance with ISO 15197 standard and Error Grid Analysis.

EGA Plot and Analysis:



EGA Plot:

Clarke Error Grid Analysis plot is demonstrated:

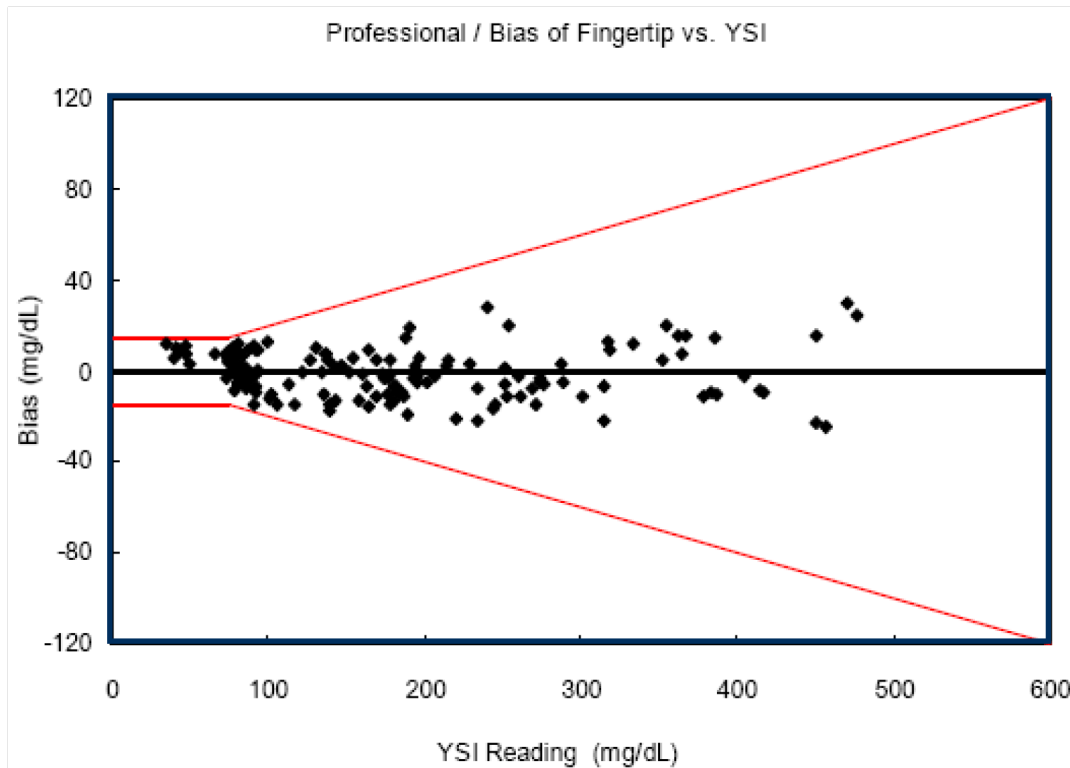
- Zone A** – glucose values deviating from the reference method by less than 20%.
- Zone B** – deviation greater than 20%, leading to benign or no treatment error.
- Zone C** – resulting in over-correcting acceptable blood glucose levels.
- Zone D** – dangerous failure to detection and treatment.
- Zone E** – erroneous treatment error.

Zone	Embrace No Code	
	No.	Ratio (%)
A	158	100
B	0	0
C	0	0
D	0	0
E	0	0
TOTAL	158	100

-continued-

Additional study details on file.

Bias Plot:



Bias	Embrace No Code		Bias	Embrace No Code	
	No.	Ratio (%)		No.	Ratio (%)
Glucose Level \geq 75 mg/dl			Glucose level < 75 mg/dl		
< 5%	87	55%	< 15 mg/dl	14	9%
5-10%	40	25%	> 15 mg/dl	0	0%
10-15%	16	10%	Sum of < 75 mg/dl	14	9%
15-20%	1	0.6%			
Sum of \geq 75 mg/dl	144	91%			
			Total	158	100%

Conclusion:

Embrace No Code Blood Monitoring System correlates with YSI-2300 analyzer over a wide range of glucose levels and meets the requirements of ISO 15197.