

Evaluation of the Assure® Prism multi Blood Glucose Monitoring System's Ease of Use

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BACKGROUND

It is critical that a Blood Glucose Monitoring System (BGMS) is easy to use since it is an important tool in the management of diabetes mellitus, including the prevention of micro and macrovascular complications. The Assure® Prism multi is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control. The "Ease of Use" consumer study is typically evaluated as part of the FDA 510(k) approval process for BGMS.

PURPOSE

The objective of this study was to evaluate the Ease of Use for the Assure® Prism multi BGMS.

METHODS

A total of 25 untrained consumers with diabetes aged 50 or older participated by performing a fingerstick self-test and answering a questionnaire directed at Ease of Use of the device and test strip. All of the subjects responded to the topics in the questionnaire which included "Removing Test Strip from Bottle", "Inserting a Test Strip into Meter", "Removing Test Strip from Meter", "Performing a Blood Glucose Test from your Fingertip" and "Reading Meter Display". The subjects were asked to rate the topics as Very Easy, Easy, OK, Difficult or Very Difficult. For evaluation purposes, these topics were grouped as Positive [Very Easy/Easy/OK] and Negative [Difficult/Very Difficult].

RESULTS

The first topic in the questionnaire, "Removing Test Strip from Bottle" received a 92.0% positive rating while all of the remaining topics received a 100% favorable report including "Inserting a Test Strip into Meter", "Removing Test Strip from Meter", "Performing a Blood Glucose Test from your Fingertip" and "Reading Meter Display".

CONCLUSION

The Assure® Prism multi BGMS scored an overall positive rating of 98.4% from the non-professional healthcare users evaluating the BGMS as Very Easy to OK to use.

Ease of Use Questionnaire	Total N	Very Easy		Easy		OK		Total	Difficult		Very Difficult	
		N	%	N	%	N	%		N	%	N	%
Removing Strip from Bottle	25	18	72	3	12	2	8	92	2	8	0	0
Inserting a Strip into Meter	25	19	76	2	8	4	16	100	0	0	0	0
Removing Test Strip from Meter	25	19	76	3	12	3	12	100	0	0	0	0
Performing a Blood Glucose Test from your Fingertip	25	20	80	4	16	1	4	100	0	0	0	0
Reading Meter Display	25	22	88	1	4	2	8	100	0	0	0	0
Overall Average								98.4				