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The evaluation of a blood glucose monitoring system's ease of use

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Background: It is important that a Blood Glucose Monitoring System (BGMS) is easy to use since it is a critical tool in the self-management of Diabetes. The ability to regulate one's blood glucose levels decreases their risk for potential micro and macrovascular complications. As part of FDA 510(k) approval process for BGMS in the self-monitoring of Diabetes Mellitus, Ease of Use criterion is evaluated with questionnaires following participation in the clinical trial.

Purpose: The objective of this study was to evaluate the Ease of Use for the GLUCOCARD® 01 BGMS and its new 01 SENSOR PLUS test strip.

Methods: A total of 150 subjects evaluated the GLUCOCARD® 01 BGMS and 01 SENSOR PLUS test strip by 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 with the exception of one (1) subject not responding to Removing Test Strip from Meter and five (5) subjects not evaluating Checking Meter Memory. Multiple topics were covered in the questionnaire including: Meter Set-Up, Inserting a Test Strip into Meter; Removing Test Strip from Meter; Performing a Blood Glucose Test; Reading Meter Display and Checking Meter Memory. 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 question addressing Meter Set-Up scored a 98.0% positive rating. Inserting a Test Strip into Meter and Removing Test Strip from Meter consecutively received a 98.7% positive rating. Performing a Blood Glucose Test was rated Very Easy/Easy/Ok by 99.3% of the subjects. Reading a Meter Display scored a 98.7% positive rating. The Checking Meter Memory received a 95.2% positive rating. Results are displayed in Table 1 below.

Conclusion: The GLUCOCARD® 01 BGMS and 01 SENSOR PLUS test strip scored an overall average rating of 98.1% participants considering the BGMS to be Ok to Very Easy to use.

Biography

John Gleisner completed his PhD in Biochemistry from the University of Minnesota and Postdoctoral studies from the University of Iowa. His first career following graduate school was at the Virginia Mason Research Center in Seattle, WA. He later moved into industry where he is currently the Science Director at ARKRAY Factory in USA. He has spent nearly 30 years working on blood glucose system development and support. He has authored over 25 publications and holds 11 US patents.

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