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GLUCOCARD® Shine Blood Glucose Monitoring System (BGMS) rates highly favorable in ease of use

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Background: As a part of the 510(k) process for Blood Glucose Monitoring Systems (BGMS) in the monitoring of Diabetes Mellitus, Ease of Use criterion is evaluated with questionnaires following participation in the clinical trial. It is critical that a BGMS be easy to use since it is an important tool in the management of diabetes. Without the ability to regulate one's blood glucose, an individual is at risk for potential micro and macrovascular complications.

Purpose: The objective of this study was to evaluate the Ease of Use for the GLUCOCARD Shine BGMS.

Methods: A total of 100 subjects evaluated the GLUCOCARD Shine BGMS by answering a questionnaire directed at the usability of the device. A total of 35 items were evaluated on the questionnaire including 28 questions directed to the device and 7 questions to the test strip. The subjects were asked to rate the items for the device and test strip as Very Easy, Easy, Ok, Difficult and Very Difficult. For evaluation purposes these items were grouped as Very Easy/Easy/OK being considered positive responses and Difficult/Very Difficult as negative.

Results: Test results were analyzed by computing the five-scale ratings for each participant (Total 3500 = 703 + 1722 + 1028 + 47 test participants x 35 items). A total of 20.1% of participants responded that the device and test strip were very easy to use, 49.2% easy, 29.4% ok and 1.3% difficult. No participant rated the device or test strip as very difficult to use.

Conclusion: The GLUCOCARD Shine BGMS scored an overall average rating of 98.7% participants considering the BGMS Ok to Very easy to use.

Biography

John Gleisner has 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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