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ARKRAY BLOOD Glucose Monitoring Systems (BGMS): Ease of Use and Accuracy

This booklet provides an overview of studies presented at medical meetings in 2014 through 2016 on ARKRAY USA, Inc. blood glucose meters and strips. The studies are divided into two categories: accuracy and ease of use. Specific ARKRAY USA products used in these studies are:

+ GLUCOCARD® Vital™
+ GLUCOCARD® 01
+ GLUCOCARD® Shine
+ GLUCOCARD® Expression™
+ Assure® Platinum
+ Assure® Prism multi
+ Assure® Lance Plus

What is ISO 15197:2013 and how does it relate to accuracy?

ISO 15197:2013 specifies requirements for in vitro glucose monitoring systems that measure glucose concentrations in capillary blood samples, for specific design verification procedures and for the validation of performance by the intended users. These systems are intended for self-measurement by lay persons for management of diabetes mellitus. These standards are proposed guidelines from an independent organization that puts forth international guidelines (not to be confused with the FDA).

The ISO 15197:2013 has been accepted in Europe and as of May 2016 must be implemented by all Blood Glucose Meter Manufacturers for those markets. To date, the FDA has not accepted the ISO 15197:2013 guidelines for blood glucose meter accuracy and still adheres to the ISO 15197:2003 guidelines for meter accuracy.

Requirements for ISO 15197:2013 accuracy performance are as follows:

**Accuracy for Glucose Concentrations < 100 mg/dL**
- 95% of results must fall within ± 15 mg/dL

**Accuracy for Glucose Concentrations ≥ 100 mg/dL**
- 95% of results must fall within ±15%

Currently, all BGMS sold in the United States are required to pass the following ISO 15197:2003 standards:

**Accuracy for Glucose Concentrations < 75 mg/dL**
- 95% of results must fall within ± 15 mg/dL

**Accuracy for Glucose Concentrations ≥ 75 mg/dL**
- 95% of results must fall within ± 20%

What is ease of use?

Ease of use, also referred to as usability, measures the effectiveness, efficiency and satisfaction with which specified users achieve specified goals in particular environments. In the case of BGMS, ease of use usually refers to a user’s ability to operate the device and the user’s level of overall satisfaction with the device.
Accuracy of the Assure® Prism multi as it relates to the ISO 15197:2013 Requirements in the Monitoring of Diabetes Mellitus

Julie Walker, RN, BSN, PHN; Patricia Gill, BA, MLT; and John Gleisner, BS, PhD

Background
Blood Glucose Monitoring Systems (BGMS) are used to monitor and regulate blood glucose levels in diabetes mellitus. The gold standard in measuring the accuracy of BGMS is the ISO 15197:2013. System accuracy performance criteria are defined as 95% of BGMS values at <100 mg/dL must be within ±15 mg/dL of the reference analyzer results, and for samples with glucose concentrations ≥100 mg/dL, 95% of BGMS values need to be within 15% of the reference analyzer results. In addition, 99% of all results are required to fall within A and B zones of the Consensus Error Grid.

Purpose
Demonstrate that the Assure® Prism multi meets the ISO 15197:2013 accuracy performance requirements.

Methods
Three lots of Assure® Prism multi test strips were evaluated for performance and bias comparison (n=600 data points). Reference values were obtained using the YSI Model 2300 Analyzer. Data was analyzed using the minimum system accuracy performance criteria published in the ISO 15197:2013.

Results
99.5% of the <100 mg/dL samples (n=191/192) were within ±15 mg/dL, thus meeting the 95% accuracy criteria. 99.0% of the ≥100 mg/dL samples (n=403/408) fell within the pre-determined 15% which met the 95% performance criteria. All data were within the A and B zones of the Consensus Error Grid. Overall bias was 0.16% (average of all three lots) demonstrating strong agreement between the Assure Prism multi and YSI reference analyzer results. Good linear regression was demonstrated.

Conclusion
Data acquired on the Assure® Prism multi met the ISO 15197:2013 system accuracy performance criteria.
Performance Comparison of the Assure® Platinum and EvenCare® G2™ Blood Glucose Monitoring Systems Against the ISO 15197:2013 Accuracy Criteria

Julie Walker, RN, BSN, PHN; Patricia Gill, BA, MLT; and John Gleisner, PhD

Background
Blood Glucose Monitoring Systems (BGMS) are used in the management of diabetes. ISO 15197:2013 is an accepted standard for measuring the accuracy of BGMS which requires 95% of results within ±15mg/dL of the reference analyzer at glucose concentrations <100mg/dL and within ±15% of reference analyzer at glucose concentrations ≥100mg/dL. Furthermore, 99% of results need to be within the A and B zones of the Consensus Error Grid.

Objective
This study compared the performance of the Assure® Platinum and EvenCare® G2™.

Methods
Two lots of test strips for each BGMS were evaluated side-by-side at ARKRAY Factory with the same study participants. Blood samples were drawn from the fingertip of confirmed diabetics (n=120) by laboratory professionals. Reference values were obtained using the YSI Model 2300 Analyzer. Data was evaluated against the accuracy boundaries of the ISO 15197:2013 Standard, and Consensus Error Grid.

Results
Assure® Platinum demonstrated 100.0% of <100mg/dL samples (8/8) were within ±15mg/dL and 97.3% of ≥100 mg/dL samples (109/112) fell within ±15%. Overall bias was -2.8% and correlation coefficient (r) = 0.98. For EvenCare® G2™, 87.5% of <100mg/dL samples (7/8) gave values ±15mg/dL and 92.0% of ≥100mg/dL samples (103/112) fell within ±15%. Overall bias was 2.2% and correlation coefficient (r) = 0.98. All data for the Assure® Platinum and EvenCare® G2™ were within the A and B zones of the Consensus Error Grid.

Conclusion
Assure® Platinum results fell within ISO 15197:2013 accuracy boundaries while EvenCare® G2™ results did not meet the accuracy boundaries of the ISO 15197:2013 Standard.

EvenCare and G2 are trademarks or registered trademarks of Medline.
Performance Comparison of the Assure® Platinum and EvenCare® G3 Blood Glucose Monitoring Systems Against the ISO 15197:2013 Accuracy Criteria

Julie Walker, RN, BSN, PHN; Patricia Gill, BA, MLT; and John Gleisner, PhD

Background
Blood Glucose Monitoring Systems (BGMS) are used in managing diabetes and preventing microvascular complications. ISO 15197:2013 is an accepted standard for measuring the accuracy of BGMS which requires 95% of results within ±15mg/dL of the reference analyzer at glucose concentrations <100mg/dL and within ±15% of reference analyzer at glucose concentrations ≥100mg/dL. Furthermore, 99% of results need to be within the A and B zones of the Consensus Error Grid.

Objective
This study compared the performance of the Assure® Platinum and EvenCare® G3.

Methods
Two lots of test strips for each BGMS were evaluated side-by-side at ARKRAY Factory with the same study participants. Blood samples were drawn from the fingertip of confirmed diabetics (n=120) by laboratory professionals. Reference values were obtained using the YSI Model 2300 Analyzer. Data was evaluated against the accuracy boundaries of the ISO 15197:2013 Standard, and Consensus Error Grid.

Results
Assure® Platinum demonstrated 100.0% of <100mg/dL samples (4/4) were within ±15mg/dL and 95.7% of ≥100 mg/dL samples (111/116) fell within ±15%. Overall bias was 2.3% and correlation coefficient (r) = 0.97. For EvenCare® G3, 100.0% of <100mg/dL samples (4/4) provided values ±15mg/dL and 94.8% of ≥100mg/dL samples (110/116) fell within ±15%. Overall bias was 1.6% and correlation coefficient (r) = 0.98. All data for the Assure® Platinum and EvenCare® G3 were within the A and B zones of the Consensus Error Grid.

Conclusion
Assure® Platinum results fell within ISO 15197:2013 accuracy boundaries while EvenCare® G3 results did not meet the accuracy boundaries of the ISO 15197:2013 Standard.
EvenCare is a trademark or registered trademark of Medline.

16TH DIABETES TECHNOLOGY MEETING.
NOVEMBER 10–12, 2016. BETHESDA, MD.

Performance of the Assure® Platinum Blood Glucose Monitoring System for Multi-Resident Use in the Long Term Care Setting Against the ISO 15197:2013 Accuracy Criteria

Julie Walker, RN, BSN, PHN; Patricia Gill, BA, MLT; and John Gleisner, BS, PhD

Objective

The purpose of this study is to determine in ongoing trending studies the performance of the Assure® Platinum Blood Glucose Monitoring System (BGMS) against accuracy boundaries of ISO 15197:2013. This standard requires that 95% of BGMS results be within ±15mg/dL of the reference analyzer at glucose concentrations <100mg/dL and within ±15% of the reference analyzer at glucose concentrations ≥100mg/dL. Furthermore, 99% of all results are required to be within the A and B zones of the Consensus Error Grid.

Methods

Fingerstick testing was performed by trained laboratory professionals from subjects with diabetes (n=240) on eight lots of Assure® Platinum test strips at the ARKRAY Factory, Inc. in Minneapolis, MN. Reference values were obtained by using the YSI Model 2300 Analyzer. The data was analyzed against the accuracy boundaries of the ISO 15197:2013 Standard and the percentage of the results in the A plus B zones of the Consensus Error Grid.

Results

100% of the results <100mg/dL (35/35) were within ±15mg/dL of the YSI and 99.5% of the results ≥100mg/dL (204/205) fell within the ±15% of the YSI. All data were within the A and B zones of the Consensus Error Grid. The overall bias to YSI was -1.9%. The correlation coefficient was (r) = 0.98 which demonstrates a strong linear relationship between Assure® Platinum and the YSI reference method.

Conclusion

The data acquired on the Assure® Platinum BGMS by laboratory professionals was within the accuracy boundaries of the ISO 15197:2013 Standard.

ISO 15197:2013 guidelines

<table>
<thead>
<tr>
<th>Assure Platinum</th>
</tr>
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<tbody>
<tr>
<td>Overall Bias</td>
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<table>
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<th>ISO 15197:2013 guidelines</th>
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</thead>
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<tr>
<td>&lt;100 mg/dL Within ±15 mg/dL</td>
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<tr>
<td>n = 35</td>
</tr>
<tr>
<td>35</td>
</tr>
<tr>
<td>≥100 mg/dL Within ±15%</td>
</tr>
<tr>
<td>n = 205</td>
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<tr>
<td>204</td>
</tr>
</tbody>
</table>

99.5%

Julie Walker, RN, BSN, PHN; Patricia Gill, BA, MLT; and John Gleisner, PhD

Background
Blood Glucose Monitoring Systems (BGMS) are a critical tool used in the management of diabetes. The gold standard in measuring the accuracy of BGMS in the testing of diabetes mellitus is known as the ISO 15197:2013. The level of accuracy of the BGMS results in the ability to regulate an individual’s blood glucose levels. According to the ISO 15197:2013, system accuracy performance criteria is defined as 95% of the BGMS results falling within ±15 mg/dL of the reference analyzer results with glucose concentrations less than 100 mg/dL. For samples with glucose concentrations ≥100 mg/dL, 95% of the BGMS results need to be within 15% of the reference analyzer results. Furthermore, 99% of all results are required to be in the A and B zones of the Consensus Error Grid.

Purpose
The objective of this study is to demonstrate whether the GLUCOCARD® Shine aligns with the ISO 15197:2013 BGMS accuracy performance requirements.

Methods
Two lots of GLUCOCARD® Shine blood glucose test strips were evaluated for performance and bias comparison (n=240 data points). The samples were collected from the fingertip of confirmed diabetics by trained personnel at the ARKRAY Factory, Inc. in Minneapolis, MN. Reference values were obtained using the YSI Model 2300 Analyzer. The data was analyzed using the minimum system accuracy performance criteria published in the ISO 15197:2013.

Results
The results showed that 100% of the <100 mg/dL samples (13/13) were within ±15 mg/dL, thus meeting the 95% accuracy criteria. 99.1% of the ≥100 mg/dL samples (n=225/227) fell within the pre-determined 15% which met the 95% performance criteria. All data were within the A and B zones of the Consensus Error Grid. The overall bias was –2.7% demonstrating strong agreement between the GLUCOCARD® Shine and YSI reference analyzer results, which is considered the gold standard glucose assay for BGMS studies. The correlation coefficient (r) = 0.98 demonstrates a strong linear relationship between the YSI reference method and the meter results.

Conclusion
The data acquired on the GLUCOCARD® Shine met the ISO 15197:2013 system accuracy performance criteria, the most stringent BGMS requirement in the monitoring of diabetes mellitus.
Accuracy of a Blood Glucose Monitoring System (BGMS) as it relates to the ISO 15197:2013 Requirements in the Management of Diabetes Mellitus

Julie Walker, RN, BSN, PHN; Patricia Gill, BA, MLT; and John Gleisner, BS, PhD

Objective
The purpose of this study was to demonstrate that GLUCOCARD® Shine meets the ISO 15197:2013 BGMS accuracy performance requirements.

Methods
Three lots of GLUCOCARD® Shine test strips were analyzed for performance and bias comparison (n=104 data points). Samples were collected from the fingertip of confirmed diabetic subjects by trained personnel at the ARKRAY Factory, Inc. in Minneapolis, MN. Reference values were obtained using the YSI Model 2300 Analyzer. Data was analyzed using the system accuracy performance criteria published in the ISO 15197:2013.

Results
Results revealed that 100% of <100 mg/dL samples (n=66) were within ±15 mg/dL meeting the 95% accuracy criteria. 99.0% of the ≥100 mg/dL samples (n=97/98) fell within the pre-determined 15%, meeting the 95% performance criteria. All data were within the A and B zones of the Consensus Error Grid. Overall bias was -1.3% demonstrating strong agreement between the GLUCOCARD® Shine and YSI reference analyzer results. Correlation coefficient (r) = 0.99 demonstrated a strong linear relationship between the YSI reference method and BGMS results.

Conclusion
Data acquired on the GLUCOCARD® Shine meets the ISO 15197:2013 system accuracy performance criteria.
Evaluation of a Blood Glucose Monitoring System (BGMS) in Comparison to Global Accuracy Performance Requirements

Julie Walker, RN, BSN, PHN; Patricia Gill, BA, MLT; and John Gleisner, BS, PhD

Objective

The purpose of this study was to demonstrate that the GLUCOCARD® Vital™ meets the global BGMS accuracy performance requirements of 95% of results within ±15 mg/dL for glucose samples <100 mg/dL and 95% of results within 15% for glucose samples ≥100 mg/dL.

Methods

Three lots of GLUCOCARD® Vital™ test strips were analyzed for performance and bias comparison (n=104 data points). Samples were collected from the fingertip of confirmed diabetic subjects by trained personnel at the ARKRAY Factory, Inc. in Minneapolis, MN. Reference values were obtained using the YSI Model 2300 Analyzer. Data was analyzed using the accuracy performance criteria of 95% of results within ±15 mg/dL for glucose samples <100 mg/dL and 95% of results within 15% for glucose samples ≥100 mg/dL.

Results

Results revealed that 100% of <100 mg/dL samples (n=6/6) were within ±15 mg/dL meeting the 95% accuracy criteria. 99.0% of the ≥100 mg/dL samples (n=97/98) fell within the pre-determined 15%, meeting the 95% performance criteria. All data were within the A and B zones of the Consensus Error Grid. Overall bias was 0.5% demonstrating strong agreement between the GLUCOCARD® Vital and YSI reference analyzer results. Correlation coefficient (r) = 0.98 demonstrated a strong linear relationship between the YSI reference method and BGMS results.

Conclusion

Data collected and analyzed on the GLUCOCARD® Vital™ meets the global accuracy performance criteria of 95% of results within ±15 mg/dL for glucose samples <100 mg/dL and 95% of results within 15% for glucose samples ≥100 mg/dL.
Assessment of the GLUCOCARD® 01 Compared to the Global Accuracy Performance Criteria
Julie Walker, RN, BSN, PHN; Patricia Gill, BA, MLT; and John Gleisner, BS, PhD

Background
Blood Glucose Monitoring Systems (BGMS) are an important monitoring tool to support the management of blood glucose levels for individuals with diabetes mellitus. The global BGMS accuracy performance criteria includes 95% of results within ±15 mg/dL for glucose samples <100 mg/dL and 95% of results within 15% of reference for glucose samples ≥100 mg/dL. In addition, 99% of the results need to fall within the A and B zones of the Consensus Error Grid.

Purpose
The purpose of this study was to demonstrate that the GLUCOCARD® 01 meets the global BGMS accuracy performance criteria.

Methods
Three lots of GLUCOCARD® 01 test strips were analyzed for performance and bias comparison (n=104 data points). Samples were collected from the fingertip of confirmed diabetic subjects by trained personnel. Reference values were obtained using the YSI Model 2300 Analyzer. Data was analyzed using the accuracy performance criteria of 95% of results within ±15 mg/dL for glucose samples <100 mg/dL and 95% of results within 15% for glucose samples ≥100 mg/dL.

Results
100% of <100 mg/dL samples (n=7/7) were within ±15 mg/dL meeting the 95% accuracy criteria. 96.0% of the ≥100 mg/dL samples (n=93/97) fell within the pre-determined 15% meeting the 95% performance criteria. All data were within the A and B zones of the Consensus Error Grid. The overall bias was -1.8% and the correlation coefficient (r) 0.98. The data demonstrates a strong linear relationship between the YSI reference method and BGMS results.

Conclusion
GLUCOCARD® 01 meets the global accuracy performance criteria.
**User Performance of the GLUCOCARD® Shine against the ISO 15197:2013 Accuracy Criteria**

*Julie Walker RN BSN PHN, Danielle Maher BS, Patricia Gill BA MLT, and John Gleisner BS PhD*

**Background**

Blood Glucose Monitoring Systems (BGMS) are important tools used in the management of diabetes mellitus. Proper management of diabetes leads to the prevention of micro and macrovascular complications. The ISO (International Organization for Standardization) 15197:2013 is an accepted standard for the accuracy of BGMS. The accuracy boundaries of ISO 15197:2013 require 95% of BGM results to be within ±15mg/dL of the reference analyzer at glucose concentrations <100mg/dL and within ±15% of the reference analyze at glucose concentrations ≥100mg/dL. Furthermore, 99% of all results are required to be within the A and B zones of the Consensus Error Grid.

**Purpose**

The objective of this study is to determine in ongoing trending studies if the GLUCOCARD® Shine continues to provide results that are within the accuracy boundaries of the ISO 15197:2013 Standard.

**Methods**

Finger stick testing was performed by non-professional subjects with diabetes (n=24) on one lot of GLUCOCARD® Shine at the ARKRAY Factory, Inc. in Minneapolis, MN. Reference values were obtained by using the YSI Model 2300 Analyzer. The data was analyzed against the accuracy boundaries of the ISO 15197:2013 Standard and the percentage of the results in the A plus B zones of the Consensus Error Grid.

**Results**

100% of the results <100mg/dL (2/2) were within ±15mg/dL of the YSI and 95.5% of the results ≥100mg/dL (21/22) fell within the ±15% of the YSI. All data were within the A and B zones of the Consensus Error Grid. The overall bias to YSI was -5.1%. The correlation coefficient was (r) = 0.99, which demonstrates a strong linear relationship between GLUCOCARD® Shine and the YSI reference method.

**Conclusion**

The data acquired on the GLUCOCARD® Shine by users was within the accuracy boundaries of the ISO 15197:2013 Standard.

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**Table 1:**

<table>
<thead>
<tr>
<th>GLUCOCARD® Shine</th>
<th>ISO 15197:2013 guidelines</th>
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<tbody>
<tr>
<td><strong>&lt;100 mg/dL</strong></td>
<td>Within ±15 mg/dL</td>
</tr>
<tr>
<td>n = 2</td>
<td></td>
</tr>
<tr>
<td><strong>≥100 mg/dL</strong></td>
<td>Within ±15%</td>
</tr>
<tr>
<td>n = 22</td>
<td>21</td>
</tr>
<tr>
<td></td>
<td>95.5%</td>
</tr>
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</table>
Performance of the GLUCOCARD® Shine by Health Care Professionals against the ISO 15197:2013 Accuracy Criteria

Julie Walker RN BSN PHN, Danielle Maher BS, Patricia Gill BA MLT, and John Gleisner BS PhD

Background
Blood Glucose Monitoring Systems (BGMS) are important tools used in the management of diabetes mellitus. Proper management of diabetes leads to the prevention of micro and macrovascular complications. The ISO (International Organization for Standardization) 15197:2013 is an accepted standard for the accuracy of BGMS. The accuracy boundaries of ISO 15197:2013 require 95% of BGM results to be within ±15mg/dL of the reference analyzer at glucose concentrations <100mg/dL and within ±15% of the reference analyzer at glucose concentrations ≥100mg/dL. In addition, 99% of all results are required to be within the A and B zones of the Consensus Error Grid.

Purpose
The objective of this study is to determine in ongoing trending studies if the GLUCOCARD® Shine when used by health care professionals continues to provide results that are within the accuracy boundaries of the ISO 15197:2013 Standard.

Methods
Finger stick testing was performed by laboratory professionals on individuals with diabetes (n=24) with one lot of GLUCOCARD® Shine at the ARKRAY Factory, Inc. in Minneapolis, MN. Reference values were obtained by using the YSI Model 2300 Analyzer. The data was analyzed against the accuracy boundaries of the ISO 15197:2013 Standard and the percentage of the results in the A plus B zones of the Consensus Error Grid.

Results
100% of the results <100mg/dL (2/2) were within ±15mg/dL of the YSI and 95.5% of the results ≥100mg/dL (21/22) fell within the ±15% of the YSI. All data were within the A and B zones of the Consensus Error Grid. The overall bias to YSI was -3.6%. The correlation coefficient was (r) = 0.99, which demonstrates a strong linear relationship between GLUCOCARD® Shine and the YSI reference method.

Conclusion
The data acquired on the GLUCOCARD® Shine by laboratory professionals was within the accuracy boundaries of the ISO 15197:2013 Standard.
Performance Comparison of the GLUCOCARD® Shine and Fora® G30 Against the ISO 15197:2013 Accuracy Criteria

Julie Walker RN BSN PHN, Danielle Maher BS, Patricia Gill BA MLT, and John Gleisner BS PhD

Background
Blood Glucose Monitoring Systems (BGMS) are a critical component to managing diabetes and are instrumental in preventing microvascular complications. ISO 15197:2013 is an accepted standard for assessing the accuracy of BGMS. The accuracy boundaries of this standard require 95% of BGM results to be within ±15mg/dL of the reference analyzer at glucose concentrations <100mg/dL and within ±15% of the reference analyzer at glucose concentrations ≥100mg/dL. Furthermore, 99% of all results are required to be within the A and B zones of the Consensus Error Grid.

Purpose
This study compared the performance of the GLUCOCARD® Shine to the Fora® G30.

Methods
Three lots of test strips were evaluated for performance for each BGMS at ARKRAY Factory, Inc. All testing was conducted under the same IRB approved protocol and used the same group of participants. To further reduce variables samples were drawn directly from the fingertip of confirmed diabetics (n=104) by laboratory professionals. Reference values were obtained using the YSI Model 2300 Analyzer. The data was analyzed against the accuracy boundaries of the ISO 15197:2013 Standard and the Consensus Error Grid.

Results
For GLUCOCARD® Shine 100.0% of the results <100 mg/dL (6/6) were within ±15 mg/dL and 99.0% of the results ≥100mg/dL (97/98) fell within ±15%. Overall bias was -1.3% and the correlation coefficient was (r) =0.99. For Fora® G30 only 85.7% of the results <100 mg/dL (6/7) were within ±15 mg/dL and 95.9% of the results ≥100mg/dL (93/97) fell within ±15%. Overall bias was 0.5% and the correlation coefficient was (r) =0.97. All Data for both BGMS were within the A and B zones of the Consensus Error Grid. GLUCOCARD® Shine had only one result outside the 2013 accuracy boundaries while Fora® G30 had 5 outside of the boundaries.

Conclusion
GLUCOCARD® Shine had better performance than Fora® G30 when assessed against the ISO 15197:2013 accuracy boundaries.
Performance of the GLUCOCARD® Shine in Alternative Site Testing Against the ISO 15197:2013 Accuracy Criteria

Julie Walker RN BSN PHN, Danielle Maher BS, Patricia Gill BA MLT, and John Gleisner BS PhD

Background

Blood Glucose Monitoring Systems (BGMS) are important tools used in the management of diabetes mellitus. Proper management of diabetes leads to the prevention of micro and macrovascular complications. It is important that an adequate blood drop is produced when evaluating a blood glucose reading. Fingersticks are the most widely accepted method for obtaining a blood drop; however, there are situations where Alternative Site Testing (AST) may be desirable. The ISO (International Organization for Standardization) 15197:2013 is an accepted standard for the accuracy of BGMS. The accuracy boundaries of ISO 15197:2013 require 95% of BGM results to be within ±15mg/dL of the reference analyzer at glucose concentrations <100mg/dL and within ±15% of the reference analyzer at glucose concentrations ≥100mg/dL. Furthermore, 99% of all results are required to be within the A and B zones of the Consensus Error Grid.

Purpose

The objective of this study is to determine if the GLUCOCARD® Shine provides results that are within the accuracy boundaries of the ISO 15197:2013 Standard when performed on an alternate site (palm).

Methods

AST was performed by confirmed diabetics (n=23) on one lot of GLUCOCARD® Shine at the ARKRAY Factory, Inc. in Minneapolis, MN. Reference values were obtained using the YSI Model 2300 Analyzer. The data was analyzed against the accuracy boundaries of the ISO 15197:2013 Standard and the percentage of the results in the A plus B zones of the Consensus Error Grid.

Results

100% of the results <100mg/dL (2/2) were within ±15mg/dL of the YSI and 95.2% of the results ≥100mg/dL (20/21) fell within the ±15% of the YSI. All data were within the A and B zones of the Consensus Error Grid. The overall bias to YSI was +1.5% and the correlation coefficient was (r) = 0.96, which demonstrate a strong linear relationship between GLUCOCARD® Shine and the YSI reference method.

Conclusion

The data acquired on the GLUCOCARD® Shine by users through AST was within the accuracy boundaries of the ISO 15197:2013 Standard.
Performance Comparison of the GLUCOCARD® Shine and the Contour® Next Against ISO 15197:2013 Accuracy Criteria

Julie Walker, RN, BSN, PHN; Patricia Gill, BA, MLT; Danielle Maher, BS; John Gleisner, BS, PhD

Objective
This study compared the performance of the GLUCOCARD® Shine to the Contour® Next.

Methods
Three lots of test strips were evaluated for performance for each BGMS at ARKRAY Factory, Inc. All testing was conducted under the same IRB approved protocol and used the same group of participants. To further reduce variables, samples were drawn directly from the fingertip of confirmed diabetics (n=104) by laboratory professionals. Reference values were obtained using the YSI Model 2300 Analyzer. The data was evaluated against the accuracy boundaries of the ISO 15197:2013 Standard and the Consensus Error Grid.

Results
The GLUCOCARD® Shine demonstrated that 100.0% of the <100 mg/dL samples (6/6) were within ±15 mg/dL and 99.0% of the ≥ 100mg/dL samples (97/98) fell within ±15%. Overall bias was -1.3% and the correlation coefficient was (r) = 0.99. For the Contour® Next, 100.0% of the <100 mg/dL samples (7/7) gave values that were within ±15 mg/dL and 100.0% of the ≥ 100mg/dL samples (97/97) fell within ±15%. Overall bias was -2.1% and the correlation coefficient was (r) = 0.99. All data for both BGMS were within the A and B zones of the Consensus Error Grid.

Conclusion
The GLUCOCARD® Shine and Contour® Next had equivalent performance when assessed against the ISO 15197:2013 boundaries.
Performance Comparison of the GLUCOCARD® Shine and the Accu-Chek® Aviva Against ISO 15197:2013 Accuracy Criteria

Julie Walker, RN, BSN, PHN; Patricia Gill, BA, MLT; Danielle Maher, BS; John Gleisner, BS, PhD

**Objective**

This study compared the performance of the GLUCOCARD® Shine to the Accu-Chek® Aviva against accuracy boundaries of ISO 15197:2013. This standard requires that 95% of BGM results be within ±15mg/dL of the reference analyzer at glucose concentrations <100mg/dL and within ±15% of the reference analyzer at glucose concentrations ≥100mg/dL. Furthermore, 99% of all results are required to be within the A and B zones of the Consensus Error Grid.

**Methods**

Three lots of test strips were evaluated for performance for each BGMS at ARKRAY Factory, Inc. All testing was conducted under the same IRB approved protocol and used the same group of participants. To further reduce variables, samples were drawn directly from the fingertip of confirmed diabetics (n=104) by laboratory professionals. Reference values were obtained using the YSI Model 2300 Analyzer. The data was evaluated against the accuracy boundaries of the ISO 15197:2013 Standard and Consensus Error Grid.

**Results**

For GLUCOCARD® Shine, 100.0% of the <100mg/dL sample results (6/6) were within ±15mg/dL and 99.0% of the ≥100mg/dL samples (97/98) fell within ±15% of the reference YSI. Overall bias was -1.3% and the correlation coefficient was (r) =0.99. For the Accu-Chek® Aviva, 100.0% of the <100mg/dL samples (5/5) gave values that were within ±15mg/dL and 99.0% of the ≥100mg/dL samples (98/99) fell within ±15% of the reference. Overall bias was -1.3% and the correlation coefficient was (r) = 0.99. All data for both BGMS were within the A and B zones of the Consensus Error Grid.

**Conclusion**

The GLUCOCARD® Shine and the Accu-Chek® Aviva had equivalent performance when assessed against the ISO 15197:2013 accuracy boundaries.

---

**ISO 15197:2013 guidelines**

<table>
<thead>
<tr>
<th>GLUCOCARD Shine</th>
<th>Accu-Chek Aviva</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall Bias</td>
<td>-1.3%</td>
</tr>
<tr>
<td>N= 104</td>
<td>N= 104</td>
</tr>
<tr>
<td>r= 0.99</td>
<td>r= 0.99</td>
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</table>

<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;100 mg/dL</td>
<td>≥100 mg/dL</td>
</tr>
<tr>
<td>n = 6</td>
<td>n = 98</td>
</tr>
<tr>
<td>Within ±15 mg/dL</td>
<td>Within ±15%</td>
</tr>
<tr>
<td>100%</td>
<td>97%</td>
</tr>
</tbody>
</table>

Accu-Chek is a trademark or registered trademark of Roche.
Performance of the GLUCOCARD® Vital™ Blood Glucose Monitoring System against the ISO 15197:2013 Accuracy Criteria

Julie Walker, RN, BSN, PHN; Patricia Gill, BA, MLT; Danielle Maher, BS; John Gleisner, BS, PhD

Objective
The purpose of this study is to determine in ongoing trending studies the performance of the GLUCOCARD® Vital Blood Glucose Monitoring System (BGMS) against accuracy boundaries of ISO 15197:2013. This standard requires that 95% of BGMS results be within ±15mg/dL of the reference analyzer at glucose concentrations <100mg/dL and within ±15% of the reference analyzer at glucose concentrations ≥100mg/dL. Furthermore, 99% of all results are required to be within the A and B zones of the Consensus Error Grid.

Methods
Fingerstick testing was collected by trained laboratory professionals from subjects with diabetes (n=240) on eight lots of GLUCOCARD® Vital at the ARKRAY Factory, Inc. in Minneapolis, MN. Reference values were obtained by using the YSI Model 2300 Analyzer. The data was analyzed against the accuracy boundaries of the ISO 15197:2013 Standard and the percentage of the results in the A plus B zones of the Consensus Error Grid.

Results
100% of the results <100mg/dL (27/27) were within ±15mg/dL of the YSI and 99.5% of the results ≥100mg/dL (212/213) fell within the ±15% of the YSI. All data were within the A and B zones of the Consensus Error Grid. The overall bias to YSI was -1.9%. The correlation coefficient was (r) = 0.98, which demonstrates a strong linear relationship between GLUCOCARD® Vital and the YSI reference method.

Conclusion
The data acquired on the GLUCOCARD® Vital BGMS by laboratory professionals was within the accuracy boundaries of the ISO 15197:2013 Standard.

ISO 15197:2013 guidelines

<table>
<thead>
<tr>
<th>Glucose (mg/dL)</th>
<th>Required Boundaries</th>
<th>Actual Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;100 mg/dL</td>
<td>Within ±15 mg/dL</td>
<td>27/27 (100%)</td>
</tr>
<tr>
<td>≥100 mg/dL</td>
<td>Within ±15%</td>
<td>212/213 (99.5%)</td>
</tr>
</tbody>
</table>
The Evaluation of a Blood Glucose Monitoring System’s Ease of Use

Julie Walker, RN, BSN, PHN; Patricia Gill, BA, MLT; and John Gleisner, PhD

Background
It is important that a Blood Glucose Monitoring System (BGMS) is easy to use since it is a critical tool in the 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 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 Assure® Platinum BGMS.

Methods
A total of 101 subjects evaluated the Assure® Platinum BGMS by answering a questionnaire directed at Ease of Use of the device. Multiple topics were covered in the questionnaire including: Meter Set-Up; Performing a Control Solution Test; Inserting Test Strip into Meter; Removing Test Strip from Meter; Performing a Blood Glucose Test; Reading Meter Display; Checking Meter Memory and Cleaning the Meter. 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 99.0% positive rating. Performing a Control Solution Test was rated positively at 97.0%. Inserting Test Strip into Meter scored positively at 96.0% while Removing Test Strip from Meter scored a 99.0% positive rating. Performing a Blood Glucose Test was rated Very Easy/Easy/Ok by 99.0% of the subjects. Reading Meter Display scored a 98.0% positive rating. Checking Meter Memory scored a 100.0% for being Very Easy/Easy/Ok to use. Cleaning the Meter was rated positively by 99.0% of the subjects. Results are displayed in the table below.

Conclusion
The Assure® Platinum BGMS scored an overall average rating of 98.4% participants evaluating the BGMS as easy to use.

Ease of Use Questionnaire for Assure® Platinum Meter

<table>
<thead>
<tr>
<th>Ease of Use Questionnaire</th>
<th>Total</th>
<th>Very Easy</th>
<th>Easy</th>
<th>OK</th>
<th>Very Difficult</th>
<th>Difficult</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meter Set-Up</td>
<td>101</td>
<td>45</td>
<td>44.6</td>
<td>45</td>
<td>99.0</td>
<td>1</td>
<td>1.0</td>
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<tr>
<td>Performing a Control Solution Test</td>
<td>101</td>
<td>36</td>
<td>37.6</td>
<td>46</td>
<td>97.0</td>
<td>3</td>
<td>3.0</td>
</tr>
<tr>
<td>Inserting Test Strip into Meter</td>
<td>101</td>
<td>53</td>
<td>52.5</td>
<td>29</td>
<td>96.0</td>
<td>3</td>
<td>3.0</td>
</tr>
<tr>
<td>Removing Test Strip from Meter</td>
<td>101</td>
<td>65</td>
<td>64.4</td>
<td>27</td>
<td>99.0</td>
<td>1</td>
<td>1.0</td>
</tr>
<tr>
<td>Performing a Blood Glucose Test</td>
<td>101</td>
<td>55</td>
<td>54.5</td>
<td>36</td>
<td>99.0</td>
<td>1</td>
<td>1.0</td>
</tr>
<tr>
<td>Reading Meter Display</td>
<td>101</td>
<td>64</td>
<td>63.4</td>
<td>30</td>
<td>98.0</td>
<td>1</td>
<td>1.0</td>
</tr>
<tr>
<td>Checking Meter Memory</td>
<td>101</td>
<td>44</td>
<td>43.6</td>
<td>44</td>
<td>100.0</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td>Cleaning the Meter</td>
<td>101</td>
<td>45</td>
<td>44.6</td>
<td>40</td>
<td>99.0</td>
<td>1</td>
<td>1.0</td>
</tr>
<tr>
<td>Overall Average</td>
<td>98.4</td>
<td></td>
<td></td>
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</tbody>
</table>
Evaluation of the Assure® Platinum Blood Glucose Monitoring System’s Ease of Use

Julie Walker RN BSN PHN, Danielle Maher BS, Patricia Gill BA MLT, and John Gleisner BS PhD

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. The Assure® Platinum is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control, including the prevention of micro and macrovascular complications. 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® Platinum 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 96.0% 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® Platinum BGMS scored an overall positive rating of 99.2% from the non-professional healthcare users evaluating the BGMS as Very Easy to OK to use.

<table>
<thead>
<tr>
<th>Ease of Use Questionnaire</th>
<th>Total N</th>
<th>Very Easy</th>
<th>Easy</th>
<th>OK</th>
<th>Total</th>
<th>Difficult</th>
<th>Very Difficult</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>N</td>
<td>%</td>
<td>N</td>
<td>%</td>
<td>N</td>
<td>%</td>
</tr>
<tr>
<td>Removing Strip from Bottle</td>
<td>25</td>
<td>20</td>
<td>80</td>
<td>2</td>
<td>8</td>
<td>96</td>
<td>1</td>
</tr>
<tr>
<td>Inserting a Strip into Meter</td>
<td>25</td>
<td>18</td>
<td>72</td>
<td>4</td>
<td>16</td>
<td>100</td>
<td>0</td>
</tr>
<tr>
<td>Removing Test Strip from Meter</td>
<td>25</td>
<td>17</td>
<td>68</td>
<td>7</td>
<td>28</td>
<td>100</td>
<td>0</td>
</tr>
<tr>
<td>Performing a Blood Glucose Test from your Fingertip</td>
<td>25</td>
<td>20</td>
<td>80</td>
<td>3</td>
<td>12</td>
<td>100</td>
<td>0</td>
</tr>
<tr>
<td>Reading Meter Display</td>
<td>25</td>
<td>22</td>
<td>88</td>
<td>2</td>
<td>8</td>
<td>100</td>
<td>0</td>
</tr>
</tbody>
</table>

Overall Average 99.2
Evaluation of the Assure® Prism multi Blood Glucose Monitoring System’s Ease of Use  
Julie Walker RN BSN PHN, Danielle Maher BS, Patricia Gill BA MLT, and John Gleisner BS PhD

**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.

<table>
<thead>
<tr>
<th>Ease of Use Questionnaire</th>
<th>Total N</th>
<th>Very Easy</th>
<th>Easy</th>
<th>OK</th>
<th>Total</th>
<th>Difficult</th>
<th>Very Difficult</th>
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<tr>
<td></td>
<td>N</td>
<td>%</td>
<td>N</td>
<td>%</td>
<td>N</td>
<td>%</td>
<td>N</td>
</tr>
<tr>
<td>Removing Strip from Bottle</td>
<td>25</td>
<td>18</td>
<td>72</td>
<td>3</td>
<td>12</td>
<td>2</td>
<td>8</td>
</tr>
<tr>
<td>Inserting a Strip into Meter</td>
<td>25</td>
<td>19</td>
<td>76</td>
<td>2</td>
<td>8</td>
<td>4</td>
<td>16</td>
</tr>
<tr>
<td>Removing Test Strip from Meter</td>
<td>25</td>
<td>19</td>
<td>76</td>
<td>3</td>
<td>12</td>
<td>3</td>
<td>12</td>
</tr>
<tr>
<td>Performing a Blood Glucose Test from your Fingertip</td>
<td>25</td>
<td>20</td>
<td>80</td>
<td>4</td>
<td>16</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Reading Meter Display</td>
<td>25</td>
<td>22</td>
<td>88</td>
<td>1</td>
<td>4</td>
<td>2</td>
<td>8</td>
</tr>
<tr>
<td>Overall Average</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Ease of Use Comparison between the Assure® Lance Plus and the Haemolance® Plus Safety Lancets

Julie Walker RN BSN PHN, Danielle Maher BS, Patricia Gill BA MLT, and John Gleisner BS PhD

**Background**

Lancets are a necessary tool used in the blood glucose testing and management of diabetes. In order for a lancet to assist in providing a sufficient capillary blood drop for testing, it needs to be easy for the healthcare professional to use.

**Purpose**

The objective of this study was to compare the Ease of Use of the Assure® Lance Plus 25 gauge lancet to the Haemolance® Plus 25 gauge lancet by healthcare professionals.

**Methods**

A total of 8 laboratory professionals were asked to fire three Assure® Lance Plus 25 gauge lancets and three Haemolance® Plus 25 gauge lancets into a stack of laboratory pads. Each laboratory professional was then asked to compare the Assure® Lance Plus lancet to the Haemolance® Plus lancet by the following rating scale: Less Easy to Use = 0, Same = 1, or More Easy to Use = 2.

**Results**

Six of the eight participants rated the Assure® Lance Plus 25 gauge lancet More Easy to Use than the Haemolance® Plus 25 gauge lancet. One participant scored the lancets as the Same and one subject rated the Assure® Lance Plus 25 gauge lancet Less Easy to Use.

**Conclusion**

The Assure® Lance Plus 25 gauge lancet was rated More Easy to Use than the Haemolance® Plus 25 gauge lancet with an average Ease of Use rating of 1.6.

![Ease of Use Graph](image-url)
Evaluation of the Performance of Assure® Lance Plus 30G and 25G Safety Lancets
Julie Walker RN BSN PHN, Danielle Maher BS, Patricia Gill BA MLT, and John Gleisner BS PhD

Background
Safety lancets are essential in diabetes management, especially in the institutional care of residents with diabetes. In addition, safety lancets need to provide a sufficient blood drop to dose a blood glucose monitoring system (BGMS) while minimizing discomfort and preventing accidental needle sticks. Pain is often associated with the gauge of the lancet. The smallest gauge (G) lancet needed to obtain an adequate blood drop; the pain associated with the finger stick; and ease of use should be considered when selecting a lancet.

Purpose
The objective of this study was to evaluate the performance of the 30G and 25G Assure® Lance Plus Safety Lancets with respect to obtaining an adequate blood drop, level of finger stick pain and ease of use.

Methods
In one study, 15 participants were asked to perform finger sticks using the 30G and 25G Assure® Lance Plus Safety Lancets and evaluate the blood drop as sufficient/insufficient for dosing a BGMS and to compare the pain level of the 30G as less, the same or more than the 25G. The two lancets have the same construction except for the gauge of the needle and therefore the ease of use was expected to be the same. In a second study, ten participants were asked to perform a finger stick with each lancet and rate ease of use as a Yes or No.

Results
Finger sticks provided sufficient blood with (14/15) for the 30G lancet and (15/15) for the 25G lancet. The participants rated the level of pain with the 30G lancet as (10/15) less pain; (5/15) the same; (0/15) more pain than the 25G lancet. In the second study, all ten participants rated both lancets as easy to use.

Conclusion
Overall, the 30G and 25G Assure® Lance Plus Safety Lancets provided a sufficient blood sample 96.7% of the time. The 30G Assure® Lance Plus Safety Lancet was found to be less painful than the 25G Assure® Lance Plus Safety Lancet. Both lancets were found easy to use.
Background
As part of the 510k approvals process for Blood Glucose Monitoring Systems (BGMS) in self-monitoring of Diabetes Mellitus, Ease of Use criterion are 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 sugar, an individual is at risk for potential micro and macrovascular complications.

Purpose
The objective of this study was to evaluate the Ease of Use as it relates to the ARKRAY GLUCOCARD® Vital™ BGMS.

Methods
A total of 118 subjects evaluated the ARKRAY GLUCOCARD® Vital™ BGMS by answering a questionnaire directed at the Ease of Use of the device. Multiple topics were covered in the questionnaire including: Getting to know the meter system; Inserting a strip into the meter; Performing a blood glucose test; Reading meter display; Adding control solution to the test strip; Performing an AST test. The subjects were asked to rate the topics for the device as Very Easy, Easy, Ok, Difficult or Very Difficult. For evaluation purposes these topics were then grouped as Very Easy/Easy/Ok being considered positive responses and Difficult/Very Difficult as negative.

Results
The first question addressing Getting to know the meter scored a 99.2% positive rating. Inserting a strip into the meter was also rated with a 99.2% positive rating. Performing a blood glucose test was rated a Very Easy/Easy/Ok by 100% of the participants. Reading meter display scored a 99.2% positive rating. Adding control solution to the test strip scored a 95.8% for being Very Easy/Easy/Ok to use. Performing an AST was rated as Very Easy/Easy/Ok by 93.2% of the subjects. Results are displayed in the table below.

Conclusion
The ARKRAY GLUCOCARD® Vital™ BGMS scored an overall average rating of 97.7% participants considering the BGMS to be OK to Very Easy to use.

Ease of Use results for ARKRAY’s GLUCOCARD® Vital™ Blood Glucose Meter System.

<table>
<thead>
<tr>
<th>Ease of Use Questionnaire</th>
<th>Total n</th>
<th>Very Easy</th>
<th>Very Easy</th>
<th>Easy</th>
<th>Easy</th>
<th>Ok</th>
<th>Ok</th>
<th>Total</th>
<th>Difficult</th>
<th>Very Difficult</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Getting to know the meter system</td>
<td>118</td>
<td>37</td>
<td>31.4</td>
<td>61</td>
<td>51.7</td>
<td>19</td>
<td>16.1</td>
<td>99.2</td>
<td>1</td>
<td>0.8</td>
<td>0.0</td>
</tr>
<tr>
<td>Inserting a strip into meter</td>
<td>118</td>
<td>49</td>
<td>41.5</td>
<td>53</td>
<td>44.9</td>
<td>15</td>
<td>12.7</td>
<td>99.2</td>
<td>1</td>
<td>0.8</td>
<td>0.0</td>
</tr>
<tr>
<td>Performing a blood glucose test</td>
<td>118</td>
<td>48</td>
<td>40.7</td>
<td>52</td>
<td>44.1</td>
<td>18</td>
<td>15.3</td>
<td>100.0</td>
<td>0</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Reading meter display</td>
<td>118</td>
<td>55</td>
<td>46.6</td>
<td>43</td>
<td>36.4</td>
<td>19</td>
<td>16.1</td>
<td>99.2</td>
<td>1</td>
<td>0.8</td>
<td>0.0</td>
</tr>
<tr>
<td>Adding control solution to the test strip</td>
<td>118</td>
<td>40</td>
<td>33.9</td>
<td>54</td>
<td>45.8</td>
<td>19</td>
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<td>95.8</td>
<td>4</td>
<td>3.4</td>
<td>1.0</td>
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<tr>
<td>Performing an AST test</td>
<td>118</td>
<td>31</td>
<td>26.3</td>
<td>48</td>
<td>40.7</td>
<td>31</td>
<td>26.3</td>
<td>93.2</td>
<td>5</td>
<td>4.2</td>
<td>3.5</td>
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<tr>
<td>Overall Average</td>
<td>118</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>97.7</td>
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</table>
The Evaluation of a Blood Glucose Monitoring System’s Ease of Use
Patricia Gill, BA, MLT; Julie Walker, RN, BSN, PHN; and John Gleisner, PhD

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 GLUCOCARD® 01 SENSOR PLUS test strip.

Methods
A total of 150 subjects evaluated the GLUCOCARD® 01 BGMS and GLUCOCARD® 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 GLUCOCARD® 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.

Ease of Use Questionnaire Results for the GLUCOCARD® 01 BGMS and 01 SENSOR PLUS test strip

<table>
<thead>
<tr>
<th>Ease of Use Questionnaire</th>
<th>Total n</th>
<th>Very Easy</th>
<th>Easy</th>
<th>OK</th>
<th>Total</th>
<th>Difficult</th>
<th>Very Difficult</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meter Set-up</td>
<td>150</td>
<td>90</td>
<td>60.0</td>
<td>60</td>
<td>40.0</td>
<td>18</td>
<td>12.0</td>
<td>177</td>
</tr>
<tr>
<td>Inserting Test Strip into Meter</td>
<td>150</td>
<td>90</td>
<td>60.0</td>
<td>60</td>
<td>40.0</td>
<td>18</td>
<td>12.0</td>
<td>177</td>
</tr>
<tr>
<td>Removing Test Strip from Meter</td>
<td>150</td>
<td>113</td>
<td>75.3</td>
<td>29</td>
<td>19.3</td>
<td>6</td>
<td>4.0</td>
<td>128</td>
</tr>
<tr>
<td>Performing a Blood Glucose Test</td>
<td>150</td>
<td>110</td>
<td>73.3</td>
<td>37</td>
<td>25.3</td>
<td>7</td>
<td>4.7</td>
<td>154</td>
</tr>
<tr>
<td>Reading Meter Display</td>
<td>150</td>
<td>130</td>
<td>86.7</td>
<td>30</td>
<td>20.0</td>
<td>7</td>
<td>4.7</td>
<td>167</td>
</tr>
<tr>
<td>Checking Meter Memory</td>
<td>145</td>
<td>135</td>
<td>93.6</td>
<td>30</td>
<td>21.3</td>
<td>7</td>
<td>4.7</td>
<td>172</td>
</tr>
<tr>
<td>Overall Average</td>
<td>68.1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1.9</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
GLUCOCARD® Shine Blood Glucose Monitoring System (BGMS) Rates Highly Favorable in Ease of Use
Julie Walker, RN, BSN, PHN; Patricia Gill, BA, MLT; and John Gleisner, PhD

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. Items in the questionnaire are displayed in Table 1 and ease of use results in Table 2.

Conclusion
The GLUCOCARD® Shine BGMS scored an overall average rating of 98.7% participants considering the BGMS OK to Very Easy to use.

<table>
<thead>
<tr>
<th>Items in Questionnaire</th>
<th>Table 1</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Device:</strong></td>
<td></td>
</tr>
<tr>
<td>- Appearance</td>
<td></td>
</tr>
<tr>
<td>- Size</td>
<td></td>
</tr>
<tr>
<td>- Color</td>
<td></td>
</tr>
<tr>
<td>- Button size</td>
<td></td>
</tr>
<tr>
<td>- Button color</td>
<td></td>
</tr>
<tr>
<td>- Display readout size</td>
<td></td>
</tr>
<tr>
<td>- Readout visibility</td>
<td></td>
</tr>
<tr>
<td>- Reaction visibility</td>
<td></td>
</tr>
<tr>
<td>- Reaction start - procedure</td>
<td></td>
</tr>
<tr>
<td>- Warning beeps</td>
<td></td>
</tr>
<tr>
<td>- Ease of use</td>
<td></td>
</tr>
<tr>
<td>- Convenience</td>
<td></td>
</tr>
<tr>
<td>- Controls</td>
<td></td>
</tr>
<tr>
<td>- Ease of cleaning/maintenance</td>
<td></td>
</tr>
<tr>
<td>- Batteries and replacement</td>
<td></td>
</tr>
<tr>
<td>- Memory features and use</td>
<td></td>
</tr>
<tr>
<td>- Carrying or storage case</td>
<td></td>
</tr>
<tr>
<td>- Method quick reference card(s)</td>
<td></td>
</tr>
<tr>
<td>- Uncertain or no feedback</td>
<td></td>
</tr>
<tr>
<td>- Following input</td>
<td></td>
</tr>
<tr>
<td>- Missing or ambiguous prompts</td>
<td></td>
</tr>
<tr>
<td>- Unreasonable mental calculations required</td>
<td></td>
</tr>
<tr>
<td>- No query for critical input</td>
<td></td>
</tr>
<tr>
<td>- Complex command structure</td>
<td></td>
</tr>
<tr>
<td>- Ambiguous symbols or icons</td>
<td></td>
</tr>
<tr>
<td>- Flagging of procedural errors and analytical errors</td>
<td></td>
</tr>
<tr>
<td>- Unfamiliar language/coding/terminology, mnemonics, etc.</td>
<td></td>
</tr>
<tr>
<td>- Inconsistencies among forms for successive or collocated display</td>
<td></td>
</tr>
<tr>
<td>- Conventions, (e.g. color) contradictory to user stereotypes/expectations</td>
<td></td>
</tr>
<tr>
<td><strong>Test strip:</strong></td>
<td></td>
</tr>
<tr>
<td>- Size and shape</td>
<td></td>
</tr>
<tr>
<td>- Appearance</td>
<td></td>
</tr>
<tr>
<td>- Quantity of blood needed</td>
<td></td>
</tr>
<tr>
<td>- Ease of application</td>
<td></td>
</tr>
<tr>
<td>- Usefulness of warning beep</td>
<td></td>
</tr>
<tr>
<td>- Measurement time</td>
<td></td>
</tr>
<tr>
<td>- Storage, handling</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ease of Use results for GLUCOCARD® Shine BGMS</th>
<th>Table 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ease of Use</td>
<td>Very Easy</td>
</tr>
<tr>
<td>-------------</td>
<td>------------</td>
</tr>
<tr>
<td>Total</td>
<td>703 (20.1%)</td>
</tr>
</tbody>
</table>
Evaluation of the GLUCOCARD® Expression™ Blood Glucose Monitoring System’s Ease of Use

Julie Walker RN BSN PHN, Danielle Maher BS, Patricia Gill BA MLT, and John Gleisner BS PhD

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 mellitus, including the prevention of micro and macrovascular complications. 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 of the GLUCOCARD® Expression™ BGMS.

Methods
A total of 25 subjects 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”, “Understanding Audio Voice”, “Following Voice Instructions” 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 96% 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”, “Understanding Audio Voice”, “Following Voice Instructions” and “Reading Meter Display”.

Conclusion
The GLUCOCARD® Expression™ BGMS scored an overall positive rating of 99.4% from the participants evaluating the BGMS as Very Easy to OK to use.

<table>
<thead>
<tr>
<th>Ease of Use Questionnaire</th>
<th>Total N</th>
<th>Very Easy</th>
<th>Easy</th>
<th>OK</th>
<th>Total %</th>
<th>Difficult</th>
<th>Very Difficult</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>N %</td>
<td>N %</td>
<td>N %</td>
<td></td>
<td>N %</td>
<td>N %</td>
</tr>
<tr>
<td>Removing Strip from Bottle</td>
<td>25</td>
<td>20 80</td>
<td>3 12</td>
<td>1 4</td>
<td>96</td>
<td>1 4</td>
<td>0 0</td>
</tr>
<tr>
<td>Inserting a Strip into Meter</td>
<td>25</td>
<td>20 80</td>
<td>3 12</td>
<td>2 8</td>
<td>100</td>
<td>0 0</td>
<td>0 0</td>
</tr>
<tr>
<td>Removing Test Strip from Meter</td>
<td>25</td>
<td>24 96</td>
<td>0 0</td>
<td>1 4</td>
<td>100</td>
<td>0 0</td>
<td>0 0</td>
</tr>
<tr>
<td>Performing a Blood Glucose Test</td>
<td>25</td>
<td>24 96</td>
<td>0 0</td>
<td>1 4</td>
<td>100</td>
<td>0 0</td>
<td>0 0</td>
</tr>
<tr>
<td>from your Fingertip</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Understanding Audio Voice</td>
<td>25</td>
<td>24 96</td>
<td>1 4</td>
<td>0 0</td>
<td>100</td>
<td>0 0</td>
<td>0 0</td>
</tr>
<tr>
<td>Following Voice Instructions</td>
<td>25</td>
<td>24 96</td>
<td>1 4</td>
<td>0 0</td>
<td>100</td>
<td>0 0</td>
<td>0 0</td>
</tr>
<tr>
<td>Reading Meter Display</td>
<td>25</td>
<td>25 100</td>
<td>0 0</td>
<td>0 0</td>
<td>100</td>
<td>0 0</td>
<td>0 0</td>
</tr>
<tr>
<td>Overall Average</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>99.4</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Evaluation of the GLUCOCARD® Expression™ Blood Glucose Monitoring System’s Ease of Use

Julie Walker RN BSN PHN, Danielle Maher BS, Patricia Gill BA MLT, and John Gleisner BS PhD

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 mellitus, including the prevention of micro and macrovascular complications. 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 of the GLUCOCARD® Expression™ BGMS.

Methods

A total of 25 subjects 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”, “Understanding Audio Voice”, “Following Voice Instructions” 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 96% 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,” “Understanding Audio Voice”, “Following Voice Instructions” and “Reading Meter Display”.

Conclusion

The GLUCOCARD® Expression™ BGMS scored an overall positive rating of 99.4% from the participants evaluating the BGMS as Very Easy to OK to use.

<table>
<thead>
<tr>
<th>Ease of Use Questionnaire</th>
<th>Total N</th>
<th>Very Easy</th>
<th>Easy N</th>
<th>OK N</th>
<th>Total N</th>
<th>Difficult</th>
<th>Very Difficult</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>N  %</td>
<td>N  %</td>
<td>N  %</td>
<td>N  %</td>
<td>N  %</td>
<td>N  %</td>
</tr>
<tr>
<td>Removing Strip from Bottle</td>
<td>25</td>
<td>20  80</td>
<td>3  12</td>
<td>1  4</td>
<td>96  1  4</td>
<td>0  0</td>
<td></td>
</tr>
<tr>
<td>Inserting a Strip into Meter</td>
<td>25</td>
<td>20  80</td>
<td>3  12</td>
<td>2  8</td>
<td>100  0  0</td>
<td>0  0</td>
<td></td>
</tr>
<tr>
<td>Removing Test Strip from Meter</td>
<td>25</td>
<td>24  96</td>
<td>0  0</td>
<td>1  4</td>
<td>100  0  0</td>
<td>0  0</td>
<td></td>
</tr>
<tr>
<td>Performing a Blood Glucose Test</td>
<td>25</td>
<td>24  96</td>
<td>0  0</td>
<td>1  4</td>
<td>100  0  0</td>
<td>0  0</td>
<td></td>
</tr>
<tr>
<td>from your Fingertip</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Understanding Audio Voice</td>
<td>25</td>
<td>24  96</td>
<td>1  4</td>
<td>0  0</td>
<td>100  0  0</td>
<td>0  0</td>
<td></td>
</tr>
<tr>
<td>Following Voice Instructions</td>
<td>25</td>
<td>24  96</td>
<td>1  4</td>
<td>0  0</td>
<td>100  0  0</td>
<td>0  0</td>
<td></td>
</tr>
<tr>
<td>Reading Meter Display</td>
<td>25</td>
<td>25  100</td>
<td>0  0</td>
<td>0  0</td>
<td>100  0  0</td>
<td>0  0</td>
<td></td>
</tr>
</tbody>
</table>

Overall Average 99.4
Ease of Use Evaluation of the GLUCOCARD® Expression™ Audio-enabled Blood Glucose Monitoring System

Julie Walker RN BSN PHN, Danielle Maher BS, Patricia Gill BA MLT, and John Gleisner BS PhD

**Background**
A blood glucose monitoring system (BGMS) needs to be easy to use because it is a critical tool in the management of diabetes. The ability to regulate blood glucose levels reduces the risk for micro and macrovascular complications.

**Purpose**
The objective of this study was to evaluate Ease of Use of the GLUCOCARD® Expression™ audio-enabled BGMS.

**Methods**
A total of 41 subjects aged 60-89 evaluated the GLUCOCARD® Expression™ BGMS by answering a questionnaire directed at Ease of Use of the device. Topics included: Removing a Test Strip from Bottle; Inserting a Test Strip into Meter; Removing a Test Strip from Meter; Performing a Blood Glucose Test (Fingertip); Understanding Audio Voice; Following Voice Instructions 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 question addressing Meter Set-Up scored a 98.0% positive rating. Inserting a Test Strip into Meter and Removing Test Strip from Meter received a 100% favorable rating except for Inserting a Test Strip into Meter, which received a 98.0% positive score.

**Conclusion**
The GLUCOCARD® Expression™ audio-enabled BGMS scored an overall average 99.7% positive Ease of Use rating of by the subjects.

<table>
<thead>
<tr>
<th>Ease of Use Questionnaire</th>
<th>Total N</th>
<th>Very Easy</th>
<th>Easy</th>
<th>OK</th>
<th>Total</th>
<th>Difficult</th>
<th>Very Difficult</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>%</td>
<td>N</td>
<td>%</td>
<td>N</td>
<td>%</td>
<td>N</td>
</tr>
<tr>
<td>Removing Strip from Bottle</td>
<td>41</td>
<td>31</td>
<td>76%</td>
<td>6</td>
<td>15%</td>
<td>4</td>
<td>10%</td>
</tr>
<tr>
<td>Inserting a Strip into Meter</td>
<td>41</td>
<td>34</td>
<td>83%</td>
<td>4</td>
<td>10%</td>
<td>3</td>
<td>7%</td>
</tr>
<tr>
<td>Performing a Blood Glucose Test from your Fingertip</td>
<td>41</td>
<td>34</td>
<td>83%</td>
<td>7</td>
<td>17%</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Understanding Audio Voice</td>
<td>41</td>
<td>34</td>
<td>83%</td>
<td>7</td>
<td>17%</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Following Voice Instructions</td>
<td>41</td>
<td>34</td>
<td>83%</td>
<td>7</td>
<td>17%</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Reading Meter Display</td>
<td>41</td>
<td>37</td>
<td>90%</td>
<td>4</td>
<td>10%</td>
<td>0</td>
<td>0%</td>
</tr>
</tbody>
</table>

**Overall Average** 99.7%