Accuracy Evaluation of a New Platform of Blood Glucose Monitoring Systems With the CONTOUR® NEXT Test Strip

Bern Harrison, Daniel Brown, Mary Ellen Warchal-Windham, Holly C. Schachner,* Scott Pardo, Amy Goldy, Joan Lee Parkes

Bayer Healthcare LLC, Diabetes Care, Tarrytown, NY, USA.

Introduction

- Self-monitoring of blood glucose (SMBG) is an important part of a comprehensive diabetes management plan and helps people with diabetes improve their glycemic control.
- Accurate SMBG results are important for making informed decisions about diabetes management and treatment.

Methods

- The accuracy of the CONTOUR® NEXT platform was evaluated in multiple studies both in the laboratory and in clinical settings with healthcare professionals (HCPs) and people with diabetes.
- Accuracies were calculated for results obtained from both the laboratory and clinical studies.

Results

- User Performance Evaluation (ISO 15197, Section 8)
  - In the hands of subjects, ≥ 95% of results for all of the BGMSs met current ISO 15197:2003 accuracy criteria, and ≥ 98% of results for all of the BGMSs met proposed more stringent accuracy criteria.
  - In addition, 100% of results for all of the BGMSs were within ±0.6 mmol/L (10% glucose values), ±0.4 mmol/L (20% glucose values), and ±0.3 mmol/L (30% glucose values) of the results for the reference methods.

- Conclusions
  - Because people with diabetes use SMBG results to make diabetes management decisions, it is important for SMBG devices to be accurate.
  - Study findings showed the new platform of BGMSs utilizing the CONTOUR® NEXT test strip demonstrated consistently high levels of accuracy both in the laboratory and in the hands of people with diabetes who were naïve to the system.

References


Acknowledgments

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Introduction
Self-monitoring of blood glucose (SMBG) is an important part of a comprehensive diabetes management plan and helps people with diabetes improve their glycemic control, which in turn results in reduced complications. 6
Several regulatory agencies and organizations, including the International Organization for Standardization (ISO), have recognized the importance of accuracy and have recommended more stringent standards and guidelines for the assessment of the accuracy of SMBG devices.

A new platform of blood-glucose monitoring systems (BGMS) utilizes the CONTOUR® XT (CONTOUR® NEXT EZ) 21 (the US), the CONTOUR® NEXT LINK BGMS, the CONTOUR® NEXT USB BGMS, and the CONTOUR® NEXT BGMS ( Bayer Healthcare LLC, Diabetes Care, Tarrytown, NY, USA), consisting of a flex-resistant electrochemical glucose dehydrogenase (GOD-EDTA) enzyme in combination with a proprietary electron mediator.

The new platform includes the CONTOUR® XT BGMS (CONTOUR® NEXT EZ) 22 in the US, CONTOUR® NEXT LINK BGMS, the CONTOUR® NEXT USB BGMS, and the CONTOUR® NEXT BGMS (Bayer Healthcare LLC, Diabetes Care, Tarrytown, NY, USA).

The accuracy of the new BGMS platform was assessed in multiple studies both in the laboratory and in clinical settings with healthcare professionals (HCP) and people with diabetes.

Objective
To evaluate the performance of a new platform of BGMSs utilizing the CONTOUR® NEXT test strip in the laboratory and in the hands of users.

Methods
Study Design
The accuracy of the 4 BGMSs was evaluated in 4 laboratory studies (1 study per BGMS) based on current ISO 15197:2003 accuracy criteria and proposed more stringent accuracy criteria, including ±0.6 mmol/L and ±15%.

In each study, a total of 600 BGMS results were obtained by testing fingertip blood samples from 100 subjects in duplicate using each of 3 lots of CONTOUR® NEXT test strips.

To produce reference values for comparison, each blood sample was tested in parallel in a YSI glucose analyzer (YSI 2700 STAT PlusTM laboratory glucose analyzer, YSI Life Sciences Inc., Yellow Springs, OH, USA).

The accuracy of the 4 BGMSs was also evaluated in clinical studies (1 study per BGMS) based on current ISO 15197:2003 accuracy criteria and proposed more stringent accuracy criteria, including ±0.6 mmol/L and ±15%.

In each study, 300 BGMS results were obtained by testing capillary blood samples from 100 patients with diabetes using each of 3 lots of CONTOUR® NEXT test strips.

Assessments and Analyses
Analyses were conducted for results obtained from both the laboratory and clinical studies.

Accuracy was assessed based on current ISO 15197:2003 criteria (x* ±15% of results within ±0.6 mmol/L), the reference result for samples with glucose concentrations ≥4.2 mmol/L, and ±15% for samples with glucose concentrations <4.2 mmol/L.

Accuracy was also assessed based on proposed more stringent criteria (x* ±15% of results within ±0.6 mmol/L), the reference result for samples with glucose concentrations ≥4.2 mmol/L, and ±15% for samples with glucose concentrations <4.2 mmol/L.

In addition, accuracy was assessed based on even more stringent criteria (x* ±15% of results within ±0.6 mmol/L), the reference result for samples with glucose concentrations ≥4.2 mmol/L, and ±15% for samples with glucose concentrations ≥4.2 mmol/L.

Regression analysis was also used to compare BGMS results with YSI laboratory reference results.

Results
Analytical Performance (ISO 15197, Section 7)
In the laboratory, 100% of results for all of the BGMSs met current ISO 15197:2003 accuracy criteria, and ±15% of results for all of the BGMSs met proposed more stringent accuracy criteria.

In addition, 96% of results for all of the BGMSs were within ±0.6 mmol/L (glucose values ±0.4 mmol/L), 95% of results for all of the BGMSs were within ±0.6 mmol/L (glucose values ±1.1 mmol/L), and 97% of results for all of the BGMSs were within ±0.6 mmol/L (glucose values ±1.1 mmol/L), respectively.

Regression analysis of laboratory results demonstrated a strong correlation between YSI results and reference results for all subjects.

The r² value was 0.9692 for the CONTOUR® XT (CONTOUR® NEXT EZ) BGMS, 0.9695 for the CONTOUR® NEXT LINK BGMS, 0.9697 for the CONTOUR® NEXT USB BGMS, and 0.9690 for the CONTOUR® NEXT BGMS.

User Performance Evaluation (ISO 15197, Section 8)
In the hands of subjects, ±15% of results for all of the BGMSs met current ISO 15197:2003 accuracy criteria, and ±15% of results for all of the BGMSs met proposed more stringent accuracy criteria.

In addition, 96% of results for all of the BGMSs were within ±0.6 mmol/L (glucose values ±0.4 mmol/L), 95% of results for all of the BGMSs were within ±0.6 mmol/L (glucose values ±1.1 mmol/L), and 97% of results for all of the BGMSs were within ±0.6 mmol/L (glucose values ±1.1 mmol/L), respectively.

Regression analysis of results in the hands of subjects demonstrated a strong correlation between YSI results and reference results for all subjects.

The r² value was 0.9692 for the CONTOUR® XT (CONTOUR® NEXT EZ) BGMS, 0.9683 for the CONTOUR® NEXT LINK BGMS, and 0.9690 for the CONTOUR® NEXT USB BGMS.

In addition, 95% of results for the CONTOUR® NEXT USB BGMS and 96% of results for the CONTOUR® NEXT BGMS were within Zone A, with the remainder within Zone B (Figures 10 and 11, respectively).

Conclusions
Because people with diabetes use SMBG results to make diabetes management decisions, it is important for SMBG devices to be accurate.

Study findings showed the new platform of BGMSs utilizing the CONTOUR® NEXT test strip demonstrated consistently high levels of accuracy both in the laboratory and in the hands of people with diabetes who were naive to the system.

High levels of accuracy were seen at both lower (<4.2 mmol/L) and higher (>5.6 mmol/L) glucose ranges.

More than 99% of results in the laboratory and more than 96% of results in the hands of people with diabetes were within ±0.6 mmol/L (±15% of results) of reference results in the laboratory and ±15% of reference results in the hands of subjects.

Advanced technologies, such as highly accurate BGMSs, may enable people with diabetes to better control their glycemic control goals.

References

Acknowledgments
This study was conducted by Bayer Healthcare LLC, Diabetes Care, Tarrytown, NY, USA. Bayer Healthcare LLC, Diabetes Care, Tarrytown, NY, USA. Bayer Healthcare LLC, Diabetes Care, Tarrytown, NY, USA. Bayer Healthcare LLC, Diabetes Care, Tarrytown, NY, USA. Bayer Healthcare LLC, Diabetes Care, Tarrytown, NY, USA. Bayer Healthcare LLC, Diabetes Care, Tarrytown, NY, USA. Bayer Healthcare LLC, Diabetes Care, Tarrytown, NY, USA. Bayer Healthcare LLC, Diabetes Care, Tarrytown, NY, USA.

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Accuracy Evaluation of a New Platform of Blood Glucose Monitoring Systems With the CONTOUR® NEXT Test Strip

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Bayer Healthcare LLC, Diabetes Care, Tarrytown, NY, USA.

Introduction

- Self-monitoring of blood glucose (SMBG) is an important part of a comprehensive diabetes management plan and helps people with diabetes improve their glycemic control. A new glucose monitoring system (GMS) device provides accurate results.
- Several regulatory agencies and organizations, including the International Organization for Standardization (ISO), have revised the requirements of accuracy and have recommended more stringent standards and guidelines for the assessment of the accuracy of GMS devices.

A new platform of glucose-monitoring systems (GMSs) utilizes the CONTOUR® XT test strip (Diabetes Care, Inc., diabetescare.com) in combination with a proprietary wireless technology.

The new platform includes the CONTOUR® XT (CONTOUR® NEXT EZ in the US), the CONTOUR® NEXT LINK (BGMS), the CONTOUR® NEXT USB (BGMS), and the CONTOUR® NEXT BGMS (Hospital HealthCare LLC, Diabetes Care, Inc. diabetescare.com).

The accuracy of the new GMS platform was assessed in multiple studies both in the laboratory and in clinical settings with healthcare professional (HCP) and people with diabetes.

Objective

- To evaluate the performance of a new platform of GMSs utilizing the CONTOUR® NEXT test strip in the laboratory and in the hands of users.

Methods

Study Design

- The accuracy of the 4 GMSs was evaluated in 6 laboratory studies (1 study per GMS) based on ISO 15197:2003 accuracy criteria and proposed more stringent accuracy criteria, including ±0.6 mmol/L, and ±15%.

- In each study, a total of 600 blood samples were obtained by fingerstick or heelstick from 100 subjects in duplicate using each of 3 lots of CONTOUR® NEXT test strips.

- To produce reference values for comparison, each blood sample was tested in parallel in a YSI 2700 STAT System (YSI Inc., Yellow Springs, OH, USA) based on current ISO 15197:2003 accuracy criteria8 and proposed more stringent accuracy criteria.

- The accuracy of the 4 GMSs was evaluated in 1 clinical study (1 study per GMS) based on ISO 15197:2003 accuracy criteria and proposed more stringent accuracy criteria, including ±0.6 mmol/L, and ±15%.

- In each study, 30 patients with diabetes who were using the GMSs were enrolled.

- Blood samples from 100 subjects in duplicate using each of 3 lots of CONTOUR® NEXT test strips in the laboratory and in the hands of users.

- In addition, 90% of results for the CONTOUR® NEXT BGMS and 95% of results for the CONTOUR® NEXT USB were within Zone A, with the remainder within Zone B (Figures 1C and 1D, respectively).

Results

Analytical Performance (ISO 15197, Section 7)

- In the laboratory, 100% of results for all of the GMSs met current ISO 15197:2003 accuracy criteria, and ±0.8 mmol/L or ±15% of results for all of the GMSs met proposed more stringent accuracy criteria.

- In addition, 100% of results for all of the GMSs were within ±0.6 mmol/L, (glucose values <4.2 mmol/L), ±0.5% of results for all of the GMSs were within ±10% (2.8-4.2 mmol/L), ±0.5% of results for all of the GMSs were within ±15% (2.5-4.2 mmol/L), and ±0.6 mmol/L (≤4.2 mmol/L), or ±15% (glucose values <4.2 and ≥4.2 mmol/L), respectively (reference results Table 2).

- Regression analyses of laboratory results demonstrated a strong correlation between GMS and reference values for all patients.

- The r² value was 0.9975 for the CONTOUR® XT (CONTOUR® NEXT EZ BGMS), 0.9961 for the CONTOUR® NEXT LINK BGMS, 0.9970 for the CONTOUR® USB BGMS, and 0.9960 for the CONTOUR® NEXT BGMS.

- Parkeon-Conners Error Grid A® were generated to categorize results based on the clinical significance of differences between GMS results and YSI laboratory reference measurements.

User Performance Evaluation (ISO 15197, Section 8)

- In the hands of subjects, 94.5% of results for all of the GMSs met current ISO 15197:2003 accuracy criteria, and ±0.8 mmol/L or ±15% of results for all of the GMSs met proposed more stringent accuracy criteria.

- In addition, 100% of results for all of the GMSs were within ±0.6 mmol/L, (glucose values <4.2 mmol/L), ±0.5% of results for all of the GMSs were within ±10% (2.8-4.2 mmol/L), ±0.5% of results for all of the GMSs were within ±15% (2.5-4.2 mmol/L), ±0.6 mmol/L (≤4.2 mmol/L), or ±15% (glucose values <4.2 and ≥4.2 mmol/L), respectively (reference results Table 2).

- In the hands of subjects, GMS results showed a strong correlation with reference results and ±0.8 mmol/L or ±15% of results for all of the GMSs were within ±15% (glucose values <4.2 and ≥4.2 mmol/L), respectively (reference results Table 2).

- According to Parkeon-Conners Error Grid analysis, 100% of subject capillary fingerstick results were within Zone A for the CONTOUR® XT (CONTOUR® NEXT EZ BGMS) and the CONTOUR® NEXT LINK BGMS.

- In addition, 90% of results for the CONTOUR® NEXT USB BGMS and 95% of results for the CONTOUR® NEXT BGMS were within Zone A, with the remainder within Zone B (Figures 1C and 1D, respectively).

Conclusions

- Because people with diabetes use SMBG results to make diabetes management decisions, it is important for SMBG devices to be accurate.

- Study findings showed the new platform of GMSs utilizing the CONTOUR® NEXT test strip demonstrated consistently high levels of accuracy both in the laboratory and in the hands of people with diabetes who were naive to the system.

- High levels of accuracy were seen at both lower (<4.2 mmol/L) and higher (≥4.2 mmol/L) glucose ranges.

- More than 90% of results in the laboratory and more than 90% of results in the hands of people with diabetes were within ±0.8 mmol/L or ±15% of reference results.

- Advanced technologies, such as highly accurate GMSs, may enable people with diabetes to achieve their glycemic control goals.

References


Acknowledgments

This study was conducted by Bayer Healthcare LLC, Diabetes Care, Tarrytown, NY, USA. Editorial assistance was provided by Allison Michaelis, PhD, of MedErgy, and Thomas Wellog, PhD, of Bayer Healthcare LLC.

Table 1: Summary of Accuracy in the Laboratory (Section 7)

<table>
<thead>
<tr>
<th>GMS System</th>
<th>Glucose Concentration</th>
<th>Number of Readings Within Specified Error Limits</th>
<th>% of Readings Within Specified Error Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>CONTOUR® XT (CONTOUR® NEXT EZ)</td>
<td>-4.2 mmol/L (n = 102)</td>
<td>97 (95.1%)</td>
<td>100 (100%)</td>
</tr>
<tr>
<td>CONTOUR® NEXT LINK (BGMS)</td>
<td>-4.2 mmol/L (n = 102)</td>
<td>98 (96.1%)</td>
<td>100 (100%)</td>
</tr>
<tr>
<td>CONTOUR® NEXT USB</td>
<td>-4.2 mmol/L (n = 102)</td>
<td>100 (100%)</td>
<td>100 (100%)</td>
</tr>
<tr>
<td>CONTOUR® NEXT BGMS</td>
<td>-4.2 mmol/L (n = 102)</td>
<td>100 (100%)</td>
<td>100 (100%)</td>
</tr>
</tbody>
</table>

Table 2: Summary of Accuracy in the Hands of Subjects (Section 8, Subject vs YSI)

<table>
<thead>
<tr>
<th>GMS System</th>
<th>Glucose Concentration</th>
<th>Number of Readings Within Specified Error Limits</th>
<th>% of Readings Within Specified Error Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>CONTOUR® XT (CONTOUR® NEXT EZ)</td>
<td>-4.2 mmol/L (n = 110)</td>
<td>96 (87.2%)</td>
<td>100 (100%)</td>
</tr>
<tr>
<td>CONTOUR® NEXT LINK (BGMS)</td>
<td>-4.2 mmol/L (n = 110)</td>
<td>98 (89.1%)</td>
<td>100 (100%)</td>
</tr>
<tr>
<td>CONTOUR® NEXT USB</td>
<td>-4.2 mmol/L (n = 110)</td>
<td>100 (100%)</td>
<td>100 (100%)</td>
</tr>
<tr>
<td>CONTOUR® NEXT BGMS</td>
<td>-4.2 mmol/L (n = 110)</td>
<td>100 (100%)</td>
<td>100 (100%)</td>
</tr>
</tbody>
</table>
### Introduction

- Self-monitoring of blood glucose (SMBG) is an important part of a comprehensive diabetes management plan and helps people with diabetes improve their glycemic control, as evidence shows that recommended SMBG devices produce accurate results.
- Several regulatory agencies and organizations, including the International Organization for Standardization (ISO), have recognized the importance of accuracy and have recommended more stringent standards and guidelines for the assessment of the accuracy of SMBG devices.

A new platform of blood glucose monitoring systems (BGMS) utilizes the CONTOUR® NEXT test strip (Bayer HealthCare LLC, Diabetes Care, Tarrytown, NY, USA) consisting of a flavin adenine dinucleotide-glucose dehydrogenase (FAD-GDH) enzyme in combination with a proprietary test strip technology.

The new platform includes the CONTOUR® XT BGMS (CONTOUR® NEXT EZ in the US), the CONTOUR® NEXT LINK BGMS, the CONTOUR® NEXT USB BGMS, and the CONTOUR® NEXT BGMS (Bayer HealthCare LLC, Diabetes Care, Tarrytown, NY, USA).

- The accuracy of the new BGMS platform was assessed in multiple studies both in the laboratory and in the hands of users.

### Methods

#### Study Design

- The accuracy of the 4 BGMSs was evaluated in 4 laboratory studies (1 study per BGMS) based on current ISO 15197:2003 accuracy criteria and proposed more stringent accuracy criteria, including ±0.6 mmol/L, ±10%.
  - In each study, a total of 600 blood samples were obtained from 100 subjects in duplicate using each of 3 strips of CONTOUR® NEXT test strips.
  - To produce reference values for comparison, each blood sample was tested in parallel at a Yellow Springs Instruments (YSI Life Sciences, Inc., Yellow Springs, OH, USA) on a Yellow Springs Instruments 2300 STAT Plus™ laboratory glucose analyzer.

#### Assessments and Analyses

- Analyses were conducted for results obtained from both the laboratory and clinical study.
  - Accuracy was assessed based on current ISO 15197:2003 criteria (±5% of results within ±0.6 mmol/L), the reference result for samples with glucose concentrations ≤1.1 mmol/L, and within ±20% for samples with glucose concentrations >1.1 mmol/L.
  - Accuracy was also assessed based on proposed more stringent criteria, including ±0.6 mmol/L.

#### Regression analyses of laboratory results demonstrated a strong correlation between BGMS (Bayer HealthCare LLC, Diabetes Care, Tarrytown, NY, USA) and the Yellow Springs Instruments 2300 STAT Plus™ laboratory glucose analyzer.

#### Accuracy Evaluation of a New Platform of Blood Glucose Monitoring Systems With the CONTOUR® NEXT Test Strip

- Parkes-Consensus Error Grids were generated to categorize results based on the clinical significance of differences between BGMS results and YSI laboratory reference measurements.

### Results

#### Analytical Performance (ISO 15197, Section 7)

- In the laboratory, 100% of results for all of the BGMSs met current ISO 15197:2003 accuracy criteria, and ±8% of results for all of the BGMSs met proposed more stringent accuracy criteria.

#### In the hands of subjects, 95% of results for all of the BGMSs were within ±0.6 mmol/L, glucose values (±4.2 mmol/L), or ±10% glucose values (±4.2 and ±4.2 mmol/L), respectively of reference results (Table 2).

#### In the hands of subjects, BGMS results showed a strong correlation with YSI reference results (Table 2).

#### In addition, 95% of results for the CONTOUR® NEXT USB BGMS and 96.5% of results for the CONTOUR® NEXT BGMS were within Zone 4, with the remainder within Zone 8 (Figures 10 and 11, respectively).

#### Conclusions

- Because people with diabetes use SMBG results to make diabetes management decisions, it is important for SMBG devices to be accurate.
- Study findings showed the new platform of BGMSs utilizing the CONTOUR® NEXT test strip demonstrated consistently high levels of accuracy both in the laboratory and in the hands of people with diabetes who were naive to the system.
- High levels of accuracy were seen at both lower (<4.2 mmol/L, and <5.6 mmol/L) and higher (≥8.3 mmol/L, and ≥27.8 mmol/L) glucose ranges.

- More than 95% of results in the laboratory and more than 98% of results in the hands of people with diabetes were within ±0.6 mmol/L of reference results.

- Advanced technologies, such as highly accurate BGMS, may enable people with diabetes to reach their glycemic control goals.

### Acknowledgments

This study was conducted by Bayer Healthcare LLC, Diabetes Care, Tarrytown, NY, USA. The editorial management was provided by Elizabeth M. Parks and J. B. Wallingford, and the manuscript was reviewed by a professional medical writer for Bayer Healthcare LLC, Diabetes Care, Tarrytown, NY, USA.

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Accuracy Evaluation of a New Platform of Blood Glucose Monitoring Systems With the CONTOUR® NEXT Test Strip

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Introduction

Self-monitoring of blood glucose (SMBG) is an important part of a comprehensive diabetes management plan and helps people with diabetes improve their glycemic control.1 As a result, more regulatory standards and guidelines for the accuracy of SMBG devices have been developed.2-3

A new platform of blood-glucose monitoring systems (BGMS) utilizes the CONTOUR® NEXT test strip designed by Bayer Healthcare LLC, Diabetes Care, Tarrytown, NY, USA, consisting of a flex immunodiagnostic glucose dehydrogenase (GOD-GDH) enzyme in combination with a proprietary ion-selective electrode.

The new platform includes the CONTOUR® XT BGMS (CONTOUR® NEXT EZ in the US), the CONTOUR® NEXT LINK (BGMS), the CONTOUR® NEXT USB BGMS, and the CONTOUR® NEXT BGMS ( Bayer Healthcare LLC, Diabetes Care, Tarrytown, NY, USA).

The accuracy of the new BGMS platform was assessed in multiple studies both in the laboratory and in clinical settings with healthcare professionals (HCPs) and people with diabetes.

Objective

To evaluate the performance of a new platform of BGMSs utilizing the CONTOUR® NEXT test strip in the laboratory and in the hands of users.

Methods

Study Design

The accuracy of the new BGMS was evaluated in 4 laboratory studies (1 study per BGMS) based on current ISO 15197:2003 accuracy criteria and proposed more stringent accuracy criteria.

In each study, a total of 800 results were obtained by testing fingerprick blood samples from 100 subjects in duplicate using each of 5 sets of CONTOUR® NEXT test strips.

To produce reference values for comparison, each blood sample was tested in parallel on a Yellow Springs Instruments (YSI) 2300 STAT Plus™ laboratory glucose analyzer (YSI Life Sciences, Inc., Yellow Springs, OH, USA).

The accuracy of the new BGMS was also evaluated in 4 clinical studies (1 study per BGMS) based on current ISO 15197:2003 accuracy criteria and proposed more stringent accuracy criteria.

In each clinical study, 200 samples were obtained from patients with diabetes who were willing to participate. Blood samples were collected using the new BGMSs. The results were compared with the reference values from the YSI analyzer.

Results

Analytical Performance (ISO 15197, Section 7)

In the laboratory, 100% of results for all of the BGMSs met current ISO 15197:2003 accuracy criteria, and 98.8% of results for all of the BGMSs met proposed more stringent accuracy criteria.

In addition, 100% of results for all of the BGMSs were within ±0.6 mmol/L (glucose values <0.6 mmol/L or ≥1.1 mmol/L, or ±0.8 mmol/L for all other BGMSs were within ±0.6 mmol/L or ±1.0 mmol/L values, or ±1.1 mmol/L glucose values ±0.4 and ±0.6 mmol/L, respectively) of reference results (Table 1).

Regression analyses of laboratory results demonstrated a strong correlation between BGMS and reference results for all samples.

- The r² value was 0.9964 for the CONTOUR® XT (CONTOUR® NEXT EZ) BGMS, 0.9961 for the CONTOUR® NEXT USB BGMS, and 0.9960 for the CONTOUR® NEXT BGMS.

- The 95% confidence interval (CI) was ±0.36 mmol/L for the CONTOUR® XT (CONTOUR® NEXT EZ) BGMS, ±0.35 mmol/L for the CONTOUR® NEXT USB BGMS, and ±0.36 mmol/L for the CONTOUR® NEXT BGMS.

- The 95% prediction interval (PI) was ±0.44 mmol/L for the CONTOUR® XT (CONTOUR® NEXT EZ) BGMS, ±0.43 mmol/L for the CONTOUR® NEXT USB BGMS, and ±0.44 mmol/L for the CONTOUR® NEXT BGMS.

- The 95% limits of agreement (LOA) were ±0.44 mmol/L for the CONTOUR® XT (CONTOUR® NEXT EZ) BGMS, ±0.44 mmol/L for the CONTOUR® NEXT USB BGMS, and ±0.44 mmol/L for the CONTOUR® NEXT BGMS.

- More than 98% of results in the laboratory and more than 96% of results in the hands of people with diabetes were within ±0.6 mmol/L or ±0.8 mmol/L of reference results.

- Advanced technologies, such as highly accurate BGMSs, may enable people with diabetes to reach their glycemic control goals.

Tables 1. Summary of Accuracy in the Laboratory (Section 7.3)

Table 2. Summary of Accuracy in the Hands of Subjects (Section 8.3, Subject vs YSI)

Conclusions

Because people with diabetes use SMBG results to make diabetes management decisions, it is important for SMBG devices to be accurate.

Study findings showed the new platform of BGMSs utilizing the CONTOUR® NEXT test strip demonstrated consistently high levels of accuracy both in the laboratory and in the hands of people with diabetes who were naïve to the system.

High levels of accuracy were seen at both lower (<0.6 mmol/L) and higher (>4.2 mmol/L) glucose ranges.

- More than 95% of results in the laboratory and more than 96% of results in the hands of people with diabetes were within ±0.6 mmol/L or ±0.8 mmol/L of reference results.

- Advanced technologies, such as highly accurate BGMSs, may enable people with diabetes to reach their glycemic control goals.

References


Aknowledgments

This study was conducted by Bayer Healthcare LLC, Diabetes Care, Tarrytown, NY, USA. Final editorial changes were conducted by Don Michaels, PhD, of Wolters Kluwer, on behalf of Bayer Healthcare LLC, Diabetes Care, Tarrytown, NY, USA.

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Table 1. Summary of Accuracy in the Laboratory (Section 7.3)

Table 2. Summary of Accuracy in the Hands of Subjects (Section 8.3, Subject vs YSI)
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Introduction

- Self-monitoring of blood glucose (SMBG) is an important part of a comprehensive diabetes management plan and helps people with diabetes improve their glycemic control.
- Several regulatory agencies and organizations, including the International Organization for Standardization (ISO), have recognized the importance of accuracy and have recommended more stringent standards and guidelines for the assessment of the accuracy of SMBG devices.

A new platform of blood glucose monitoring systems (BGMS) utilizes the CONTOUR® XT test strip diagram (Bayer Diabetes Care, Tarrytown, NY, USA) consisting of a flavin adenine dinucleotide-glucose dehydrogenase (FAD-GDH) enzyme in combination with a proprietary glucose oxidase reaction.

The new platform includes the CONTOUR® XT BGMS (CONTOUR® NEXT EZ in the US), the CONTOUR® NEXT LINK BGMS, the CONTOUR® NEXT USB BGMS, and the CONTOUR® NEXT (paper HealthCare BGMS).

The accuracy of the new BGMS platform was assessed in multiple studies both in the laboratory and in clinical settings with healthcare professionals (CHPs) and people with diabetes.

Objective

To evaluate the performance of a new platform of BGMSs utilizing the CONTOUR® NEXT test strip in the laboratory and in the hands of users.

Methods

Study Design

- The accuracy of the 4 BGMSs was evaluated in 4 laboratory studies (1 study per BGMS) based on current ISO 15197:2003 accuracy criteria and proposed more stringent accuracy criteria, including ±0.6 mmol/L, and ±15%.
- In addition, 100% of results for all of the BGMSs met current ISO 15197:2003 accuracy criteria, and ±98% of results for all of the BGMSs met proposed more stringent accuracy criteria.

Results

Analytical Performance (ISO 15197, Section 7)

In the laboratory, 100% of results for all of the BGMSs met current ISO 15197:2003 accuracy criteria, and ±98% of results for all of the BGMSs met proposed more stringent accuracy criteria.

- In addition, ±3% of results for all of the BGMSs were within ±0.6 mmol/L, ±10% of results for all of the BGMSs were within ±15% (glucose values <4.2 mmol/L, ±20% of results for all of the BGMSs were within ±15% (glucose values ≥4.2 mmol/L).
- In addition, ±2.3% of results for all of the BGMSs were within ±0.6 mmol/L, ±8.7% of results for all of the BGMSs were within ±15% (glucose values <4.2 mmol/L, ±14.9% of results for all of the BGMSs were within ±15% (glucose values ≥4.2 mmol/L).

Regression analysis was also used to compare BGMS results with YSI laboratory reference measurements.

- The r² value was 0.9690 for the CONTOUR® XT (CONTOUR® NEXT EZ) BGMS, 0.9699 for the CONTOUR® XT BGMS, 0.9067 for the CONTOUR® NEXT USB BGMS, and 0.9690 for the CONTOUR® NEXT BGMS.

User Performance Evaluation (ISO 15197, Section 8)

- In the hands of subjects, ±95% of results for all of the BGMSs met current ISO 15197:2003 accuracy criteria, and ±98% of results for all of the BGMSs met proposed more stringent accuracy criteria.
- In addition, ±100% of results for all of the BGMSs were within ±0.6 mmol/L, ±15% of results for all of the BGMSs were within ±15% (glucose values <4.2 mmol/L, ±20% of results for all of the BGMSs were within ±15% (glucose values ≥4.2 mmol/L).

Conclusions

- Because people with diabetes use SMBG results to make diabetes management decisions, it is important for SMBG devices to be accurate.
- Study findings showed the new platform of BGMSs utilizing the CONTOUR® NEXT test strip demonstrated consistently high levels of accuracy both in the laboratory and in the hands of people with diabetes who were naïve to the system.
- High levels of accuracy were seen at both lower (<4.2 mmol/L) and higher (>4.6 mmol/L) glucose ranges.
- More than 90% of results in the laboratory and more than 95% of results in the hands of people with diabetes were within ±15% of reference results.
- Advanced technologies, such as highly accurate BGMSs, may enable people with diabetes to manage their glycemic control goals.

References

9. Acknowledgments

This study was conducted by Bayer Healthcare LLC, Diabetes Care, Tarrytown, NY, USA. The authors would like to acknowledge all the people who participated in this study, provided feedback, and contributed to the development of this product.

Table 1. Summary of Accuracy in the Laboratory (Section 7)

<table>
<thead>
<tr>
<th>System</th>
<th>Glucose concentration</th>
<th>&lt;4.2 mmol/L (n = 10)</th>
<th>±0.6 mmol/L (n = 40)</th>
<th>&lt;4.2 mmol/L (n = 10)</th>
<th>±0.6 mmol/L (n = 40)</th>
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<tr>
<td>CONTOUR® XT</td>
<td>g/l (mmol/L)</td>
<td>97 (6.1)</td>
<td>97 (6.1)</td>
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<td>CONTOUR® XT</td>
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Regression analysis was also used to compare BGMS results with YSI laboratory reference results.

Table 2. Summary of Accuracy in the Hands of Subjects (Section 8, Subject vs YSI)

<table>
<thead>
<tr>
<th>System</th>
<th>Glucose concentration</th>
<th>&lt;4.2 mmol/L (n = 10)</th>
<th>±0.6 mmol/L (n = 40)</th>
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<td>g/l (mmol/L)</td>
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Table 3. Comparison of Laboratory Results with YSI Reference Results

<table>
<thead>
<tr>
<th>System</th>
<th>Glucose concentration</th>
<th>&lt;4.2 mmol/L (n = 10)</th>
<th>±0.6 mmol/L (n = 40)</th>
<th>&lt;4.2 mmol/L (n = 10)</th>
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