



# LEADING THE WAY

for You & Your Patients with  
Continuous Glucose Monitoring



# THE NEW STANDARD

## CGM, THE NEW STANDARD IN GLUCOSE MONITORING

A study by the Juvenile Diabetes Research Foundation showed that using a Continuous Glucose Monitoring (CGM) system, such as the Dexcom™ SEVEN® PLUS, for at least 6 days a week can lead to significant decreases in A1c and can provide a greater ability to reach the ADA recommended goal of 7% without increasing hypoglycemia.<sup>1</sup> CGM can help your patients achieve their glycemic goals.

<sup>1</sup>JDRF Continuous Glucose Monitoring Study Group, *N Engl J Med.* 2008; 359 (14): 1464-1476

## INSURANCE COVERAGE BY MAJOR CARRIERS

As a result of the widespread recognition of the value CGM brings in improving diabetes control, the nation's largest insurance companies, such as Aetna® and UnitedHealthcare®, are now providing coverage.\*

*\*Individual payer policies and criteria apply. Dexcom can provide information on current coverage policies and criteria.*



 **Dexcom**<sup>®</sup>  
**seven+PLUS**  
continuous glucose monitoring system



*Actual sizes shown*

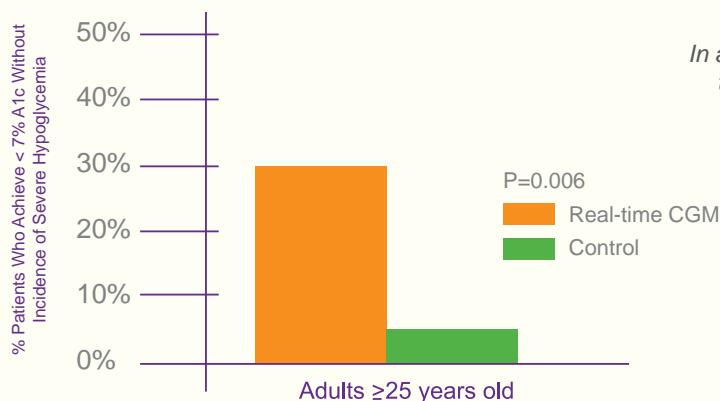
SMART with diabetes.  
Makes SENSE.  
SIMPLE for you.

# SMART WITH DIABETES

## HELP WITH HYPOGLYCEMIA

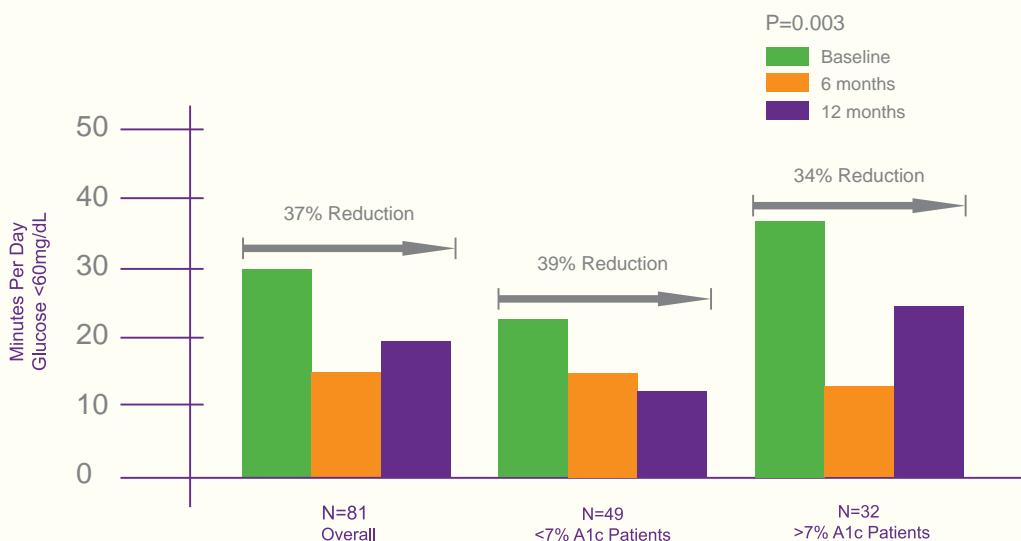
The DCCT and other studies highlight the benefit of tight glycemic control in people with type 1 and type 2 diabetes.<sup>2</sup> The challenge continues to be achieving this tight control without increasing the incidence of hypoglycemia. By displaying the direction and rate of glucose change, CGM provides greater insight than just a glucose value at a single point in time. With real time glucose trends and alerts, your patients can respond proactively before their glucose drops too low. CGM is the tool that helps your patients achieve tight control.<sup>1</sup>

### CGM helps more adults get to A1c Goals (<7%) without severe hypoglycemia<sup>1</sup>



In a recent JDRF study, more adults were able to achieve the ADA target A1c goal without incidence of severe hypoglycemia (<50mg/dL) when using CGM.<sup>1</sup>

### CGM use proven to sustain hypoglycemia reduction for 12 months<sup>4</sup>



Over the 12 months of the JDRF study, CGM reduced time spent in the hypoglycemic range (<60 mg/dL) for subjects with a high A1c and those with well-controlled A1c, demonstrating that CGM can be beneficial for patients across all spectrums of glycemic control.<sup>3,4,6</sup>

## ACCURACY WHERE IT MATTERS MOST

A common side effect of intensive diabetes management is hypoglycemia. Hypoglycemia can not only be debilitating and have deleterious consequences but can diminish counterregulatory hormone response and induce hypoglycemia unawareness, resulting in a cycle of hypoglycemia and an increased risk of subsequent severe hypoglycemia. Even with the use of insulin pumps and long-acting insulin analogs, significant nocturnal hypoglycemia is common.<sup>7</sup>

### CGM Performance in the Hypoglycemia Range\*

CATEGORY	DEXCOM SEVEN® PLUS	FREESTYLE NAVIGATOR®	MEDTRONIC PARADIGM® REAL-TIME REVEL™
Accuracy in the Hypo Range (Mean ARD% < 70 mg/dL)	27%	35.7% <sup>+</sup>	Not reported <sup>++</sup>
CGM Performance in the Hypo Range (% of readings within 20mg/dL vs. YSI between 40-80 mg/dL range)	73.3%	65.9%	68%
Overall Accuracy (Mean ARD%)	15.9%	12.8%	19.7%
% Readings Within 20 mg/dL between 40-80 mg/dL	Day 1: 73.2% <sup>+++</sup> Day 4: 75.5% <sup>+++</sup> Day 7: 69.2% <sup>+++</sup>	Not Reported	First 60 hours: 62-82%* After 60 hours: 39%*

\*Based on manufacturer user's guides. Dexcom SEVEN PLUS, 2008. FreeStyle Navigator, 2008. Medtronic Paradigm REAL-Time Revel, 2009.

<sup>+</sup>Weinstein RL, et al. Diabetes Care, 2007;30(5):1125-3110.

<sup>++</sup>Medtronic only reports overall Mean ARD data.

<sup>+++</sup>Dexcom SEVEN PLUS Summary of Safety and Effectiveness Data (SSED), 2008.

**EXCELLENT ACCURACY IN THE HYPOGLYCEMIA RANGE**  
With its excellent performance in the hypoglycemia range, the SEVEN PLUS can help reduce the fear of hypoglycemia.

**DURABLE PERFORMANCE**  
Performance in the hypoglycemia range you can trust for up to 7 days.

With Dexcom's unique severe hypoglycemia alarm at 55mg/dL, excellent performance in the hypoglycemia range and consistent accuracy over time, the SEVEN PLUS is leading the way in providing your patients reliable glucose information when it matters most.

## NOT ALL CGMs ARE CREATED EQUAL - It's All About The Technology

Dexcom's ability to deliver accurate performance drives from our historical roots in developing long-term implantable sensor technology. Core to this are:

- Sensor Geometry and Membrane Technology**

Dexcom's round platinum electrode along with a multi-layered membrane technology results in a sensor that delivers reliable performance, accuracy in the hypoglycemia range, and contributes to minimum lag time.<sup>8</sup>

- The SEVEN PLUS Algorithm**

A smart algorithm that intelligently adapts to changes in the sensor over time, processes sensor data with minimal lag time, and allows for calibration during rapid rates of change without compromising accuracy.<sup>5</sup>

## THE ONLY CGM THAT MATTERS IS THE ONE PATIENTS WILL WEAR

### Calibration - 1st and Only CGM System That Allows You to Calibrate at Any Rate of Change (ROC)<sup>5</sup>

All CGMs require calibration. Other systems warn against calibration during glucose fluctuations and restrict patients to calibrate only during times of stable blood glucose.\* The SEVEN family of products offers consistent performance, even during rapid rates of glucose change. Unlike other CGM systems, the Dexcom system does not impose restrictions on when to calibrate.\* When calibrated during rapid rates of change, overall performance remains consistent<sup>5</sup> (see table below). By letting patients calibrate on their own terms, the SEVEN PLUS allows you to train patients with fewer rules and increase patient adherence so they can see the optimal outcomes from on-going sensor use.<sup>4</sup>

Accuracy versus Rate of Change During Calibration<sup>5</sup>

Absolute Value of ROC <sup>5</sup> (mg/dL/min)	$\geq 2$	1-2	0-1	Overall
<b>Mean ARD (95% CI)</b>	<b>13.8</b> (9.6-19.6)	<b>14.6</b> (11.8-17.8)	<b>14.3</b> (12.8-16.7)	<b>14.3</b> (10.6-18.3)
<b>Median ARD (95% CI)</b>	<b>9.2</b> (6.4-17.0)	<b>12.9</b> (10.3-15.7)	<b>11.5</b> (10.2-13.6)	<b>11.6</b> (7.2-15.6)
<b>Number (%) of paired sensor-meter values</b>	<b>291</b> (6.8)	<b>986</b> (23.1)	<b>2,987</b> (70.1)	<b>4,264</b> (100)

CATEGORY	DEXCOM SEVEN® PLUS	FREESTYLE NAVIGATOR®	MEDTRONIC PARADIGM® REAL-TIME REVEL™
<b>Calibration</b>	No ROC restrictions*	Do not calibrate during ROC; during sleep; during meals/exercise*	Do not calibrate during ROC*

\*Based on manufacturer user's guide: Dexcom SEVEN PLUS, 2008; FreeStyle Navigator, 2008; Medtronic Paradigm REAL-Time Revel, 2009.

### Lag Time - Take the Guesswork Out

Lag time is a reality for all sensors. SEVEN PLUS has overcome the challenge of minimizing CGM lag time. The time difference between when changes in blood glucose appear in the SEVEN PLUS CGM data, known as lag time, has been shown to be 5 minutes on average.<sup>8</sup> With a short lag time and excellent accuracy in the hypoglycemia range, the SEVEN PLUS can provide the alert when you cross a threshold and avoid the nuisance alerts used by other sensors to predict hypoglycemia.

CATEGORY	DEXCOM SEVEN® PLUS	FREESTYLE NAVIGATOR®	MEDTRONIC PARADIGM® REAL-TIME REVEL™
<b>Average Lag Time</b>	5 minutes <sup>8</sup>	14 minutes <sup>+</sup>	Not Reported in User Guide 21 minutes <sup>9++</sup>

+ FreeStyle Navigator Users Guide, 2008.

++Based on the Guardian® RT.

## PERFORMANCE YOU CAN COUNT ON

Approved by the FDA for up to 7 days of wear, our sensors not only offer a long sensor life but have the highest percentage that last up to the limit of labeled use.\* This provides added performance, value and less hassle, all the while providing the robust information you need to manage your patients' diabetes.

CATEGORY	DEXCOM SEVEN® PLUS	FREESTYLE NAVIGATOR®	MEDTRONIC PARADIGM® REAL-TIME REVEL™
<b>Sensor Duration (up to indicated use)</b>	<b>89%*</b> (up to 168 hours or 7 days)	<b>83%*</b> (up to 108 hours or 4.5 days)	<b>55%*</b> (up to 72 hours or 3 days)

\*Based on manufacturer user's guide: Dexcom SEVEN PLUS, 2008; FreeStyle Navigator, 2008; Medtronic Paradigm REAL-Time Revel, 2009.



2001-2003

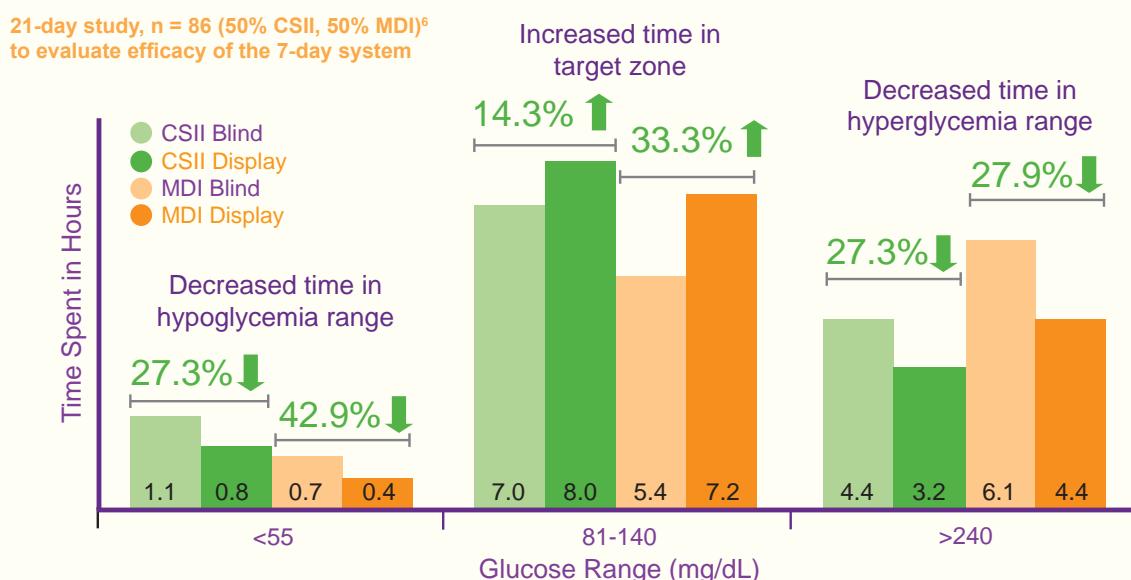
3 generations of long-term implantable sensors developed

# MAKES SENSE

## CGM & MDI

Patients who inject insulin (MDI patients) and those who infuse insulin (CSII patients) have similar needs. Both can have problems with hypoglycemia, nocturnal hypoglycemia, and fear of hypoglycemia. CGM can detect hypoglycemia no matter how insulin is delivered. Both patients have issues with hyperglycemia, in particular post meal highs. CGM detects hyperglycemia in both patients who inject and infuse insulin, providing information that is actionable to all those who use rapid acting insulin.<sup>1,6,10-14</sup>

Yet, CGM continues to be associated for use with continuous subcutaneous insulin infusion (CSII / insulin pumps) even though **patients on MDI may benefit just as significantly** from its use as do those on insulin pumps.<sup>12,15,16</sup> As the chart below illustrates with CGM use, time spent in target zone significantly improved in both groups.



## PATIENTS WHO COULD BENEFIT FROM CGM

A growing body of research is showing that CGM can provide short- and long-term clinical benefits to a wide group of patients.<sup>1,2,4,6,10,11,13,17-19</sup>

	Clinical Problem	Patient Profile	CGM Studies	SEVEN PLUS Benefits
	Frequent Hypoglycemia	Patient greatly fears hypoglycemia and worries about going low	Reduce occurrence of hypoglycemia while reducing A1c <sup>2</sup>	Hypo-Safety-Alarm is a 2nd line of awareness, particularly at night
	Glycemic Variability	A1c may be at goal, but large glucose fluctuation throughout the day and at increased risk of hypoglycemia	Current research indicates the need to consider glucose variability as well as A1c when assessing overall glycemic control <sup>17</sup>	Increased awareness of the speed and direction of glucose by using the trend graph, arrows and ROC alerts to help patients act more proactively
	High A1cs	Unable to achieve ADA A1c standard of care despite focused efforts	Several Randomized Controlled Trials (RCTs) with baseline A1c>7% have shown significant decrease in A1c with addition of CGM to any intensive insulin regimen <sup>3,4</sup>	SEVEN PLUS helps to pinpoint excursions to minimize time spent in hyperglycemia

# SIMPLE FOR YOU



The **smallest sensor** needle on the market compared to other CGM brands.<sup>20</sup>

## THE LEADER IN SENSOR TECHNOLOGY



**Current Glucose Level**  
updates every 5 minutes

**Trend-Arrows** tell you where your glucose is headed and how fast it is moving

**Trend Screen Views**  
with options of 1, 3, 6, 12, and 24 hours of continuous glucose information

**Glucose Trend-Wave**  
shows you where you've been

**Customizable Low Glucose Alert**  
notifies you when you are going low

**Customizable High Glucose Alert**  
notifies you when you are going high

## Easy to use. Simple to train.

See why Dexcom received the highest ratings with **72%** of physicians who indicated their likelihood to recommend or prescribe a SEVEN PLUS to their patients<sup>21</sup>



**2007-2008**

SEVEN System (Gen 2) launched | 1st and only 7 day sensor  
Introduction of OPENCHOICE™ | Development of 3 key partnerships

**86%** of patients on the Dexcom SEVEN PLUS are satisfied or very satisfied with their system<sup>22</sup>

	FEATURES	BENEFITS TO YOU
 <b>Sensor</b>	<ul style="list-style-type: none"> <li>Proprietary coated membrane based on implantable technology</li> <li>Ultra-sensitive electrode</li> <li>Round and flexible</li> </ul>	<ul style="list-style-type: none"> <li>The only sensor approved for up to 7 days use.</li> <li>Delivers excellent performance in the hypoglycemia range giving you the accuracy that matters when you need it the most.</li> <li>Comfortable, body-friendly and small, translating into the sensor your patients will wear.</li> </ul>
 <b>Transmitter</b>	<ul style="list-style-type: none"> <li>Small and sleek</li> <li>Wireless and water-resistant</li> <li>Built-in transmitter power</li> </ul>	<ul style="list-style-type: none"> <li>Discretion and comfort for your patients.</li> <li>Lets your patients do the things they want without restrictions.</li> <li>No batteries to buy or manage makes it simple for your patients.</li> </ul>
 <b>Receiver</b>	<ul style="list-style-type: none"> <li>Wide screen display</li> <li>Safety net</li> <li>Multiple trend screens</li> </ul>	<ul style="list-style-type: none"> <li>Up to 23%<sup>23</sup> wider viewable screen compared to other CGM brands, makes it easy for patients to read their trends and know where they're going.</li> <li>The only CGM on the market with an integrated and automatic 55mg/dL safety net to catch critical moments.</li> <li>Ability to view glucose trend screens on demand.</li> </ul>

## ONE DEVICE, TWO MODES, YOU DECIDE

Your patients rely on you for the best diabetes treatment. The SEVEN PLUS provides you with the simplicity of one device with the option of two modes, enabling you to choose the right mode for the right patient.

### Blinded Mode

In Blinded Mode, your patient will not see glucose values or trending information; no alerts and alarms activated. This will allow you to capture up to 7 days' of your patients' unadulterated glucose profiles for review and analysis. In the JDRF study, hypoglycemia detected in 7 days of blinded wear was predictive of subsequent hypoglycemia risk.<sup>4</sup>

### Unblinded Mode

In Unblinded Mode, your patients will see glucose values, trends and rate of change arrows as they occur in real-time, giving your patients the ability to proactively detect hypo- and hyperglycemic events. This gives you the ability to understand your patient's self-management and decision-making skills to help coach them to improved outcomes.



# LOOKING BEYOND

## DEXCOM IS THE SENSOR OF CHOICE

Our roots in sensor development, proprietary membranes and unique algorithms make us a preferred provider of CGM sensors for many of the key diabetes research projects and partnerships worldwide.

### Partnerships

Joining Dexcom in our commitment to improving the lives of those with diabetes through innovation, we have formed partnerships with Animas® Corporation, a Johnson & Johnson company focused on insulin delivery products such as the OneTouch® Ping® glucose management system, and Insulet Corporation, the leader in tubeless insulin pump technology with its OmniPod® Insulin Management System.

We are the first to develop a CE Marked in-vivo, Automated Blood Glucose Monitoring System in collaboration with Edwards Lifesciences for use in the critical care environment.\* The Edwards GlucoClear™ Glucose Monitoring System was launched in Europe in 2009 and Dexcom has begun work on the next generation glucose sensor.

\*CE Marked, not available for sale in the US.



### "Closing the Loop" Diabetes Projects

Dexcom is involved in multiple diabetes trials conducted by various academic and research institutions. Through the development of an automated system to dispense insulin based on continuous real time changes in blood sugar levels, these efforts aim to improve the lives of those with diabetes. Dexcom is a proud participant and a supplier of the CGM technology being used in the JDRF Artificial Pancreas Project as well as the European AP@Home project.

### Investigator-initiated Research

Dexcom is experienced in protocol design and review related to CGM use. In addition to our "professional use platform" for healthcare professionals to engage in "blinded" mode, we also offer a dedicated team that supports the use of our technologies for clinical research. All this and more is why Dexcom CGM technologies are being implemented on a global basis for clinical research as a platform for both blinded and unblinded CGM.

Since our humble beginnings, we have stayed focused and committed to developing state-of-the-art sensors. We are the only commercial company that is fully dedicated to this goal. In fact, 100% of our resources are dedicated to continuous glucose monitoring systems.

See for yourself what sets us apart and experience the Dexcom Difference.

EXPERIENCE THE  
DEXCOM DIFFERENCE  
TODAY

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2010 & Beyond

Continuing our focus on state-of-the-art sensor technologies



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#### SAFETY STATEMENT:

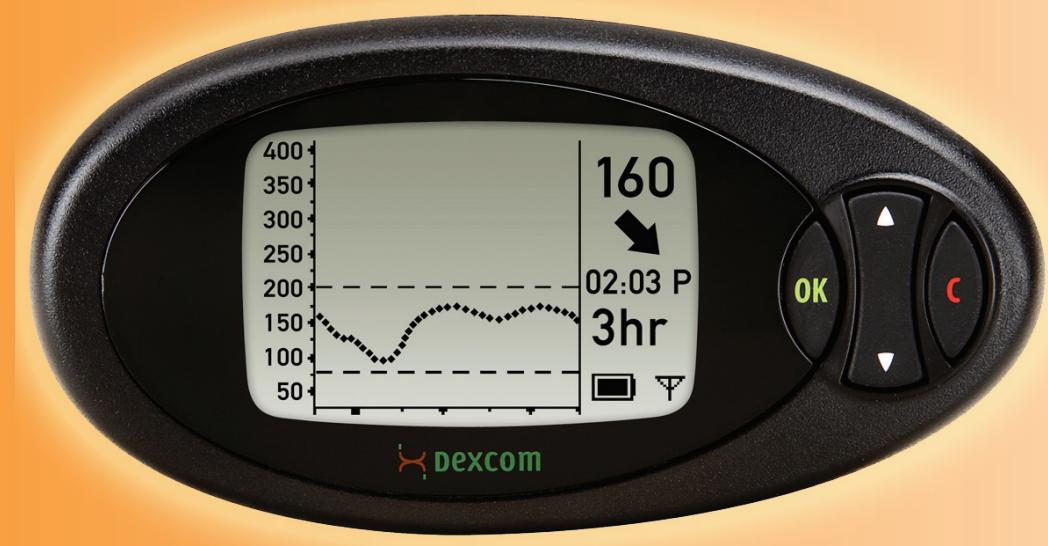
**INDICATION FOR USE** The SEVEN PLUS Continuous Glucose Monitoring System is a glucose-monitoring device indicated for detecting trends and tracking patterns in adults (**age 18 and older**) with diabetes. The SEVEN PLUS System is intended for use by patients at home and in health care facilities. The device is for prescription use only. The SEVEN PLUS Continuous Glucose Monitoring System is indicated for use as an adjunctive device to complement, not replace, information obtained from standard home glucose monitoring devices. The SEVEN PLUS Continuous Glucose Monitoring System aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments, which may minimize these excursions. Interpretation of the SEVEN PLUS System results should be based on the trends and patterns seen with several sequential readings over time. **CONTRAINDICATIONS** The SEVEN PLUS System must be removed prior to Magnetic Resonance Imaging (MRI). Use of acetaminophen-containing medications while the SEVEN Sensor is inserted may affect the performance of the device. **WARNINGS** This device is not designed to replace a blood glucose meter. The SEVEN PLUS must be used with a blood glucose meter. Treatment decisions should not be based solely on results from the SEVEN PLUS. You must confirm with a blood glucose meter before making therapeutic adjustments. Symptoms related to low or high blood glucose levels should not be ignored. If you have symptoms of low or high glucose, use your blood glucose meter to check the SEVEN PLUS results. You should update the SEVEN PLUS' calibration every 12 hours at a minimum. The performance of the SEVEN PLUS System when calibrated less frequently than every 12 hours has not been studied. Sensors fracture on rare occasions. If a sensor breaks and no portion of it is visible above the skin, do not attempt to remove it. Seek professional medical help if you have symptoms of infection or inflammation—redness, swelling or pain—at the insertion site. If you experience a broken sensor, please report this to our Technical Support department. The SEVEN and SEVEN PLUS Systems are **not approved for use** in children or adolescents, pregnant women or persons on dialysis. The safety and effectiveness of the SEVEN and SEVEN PLUS Systems have not been evaluated for sensor probe insertion sites other than the skin of the **abdomen**. **PRECAUTIONS** Always wash hands with soap and water before opening the Sensor package. After opening the package, avoid touching the adhesive area. Before inserting the Sensor, always clean the skin at the Sensor insertion location with a topical antimicrobial solution such as isopropyl alcohol. Do not apply the Sensor until the cleaned area is dry. Establish a rotation schedule for choosing each new Sensor location. Avoid Sensor locations that are constrained by clothing, accessories, or subjected to rigorous movement during exercise. Avoid injecting insulin or placing an insulin pump infusion set within 3 inches of a Sensor. The Sensor is sterile in its unopened, undamaged package. Do not use any Sensor if its sterile package has been previously damaged or opened. For OpenChoice Calibration you must enter the exact fingerstick reading that your blood glucose meter displays. Enter all fingerstick readings for calibration within 5 minutes. Entering incorrect fingerstick readings that occurred more than 5 minutes ago will affect device performance.

Please note, the performance characteristics section of the SEVEN PLUS User's Guide has changed to reflect the recent study done. The overall results of the trial showed that SEVEN PLUS System will provide you more continuous glucose readings, and you should expect more of your Sensors to provide data for the entire 7-day use period. Note that the data described in the Performance Section also showed a difference from the SEVEN PLUS to the original SEVEN device in performance in the low glucose region (40-80 mg/dL). Our study showed that at 50 mg/dL blood glucose, the device reported glucose to be as high as 64 mg/dL and at 80 mg/dL blood glucose; the device reported glucose to be as high as 90 mg/dL. Because the performance of the SEVEN PLUS System varies from the original, it is important that you assess how the new generation device performs for you, especially in the low range. You should review the performance of this device with your healthcare provider to understand how well the SEVEN PLUS System performs.

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- <sup>21</sup> Dexcom survey of physicians attending the 2010 American Diabetes Association Convention, June 2010 (n=118).
- <sup>22</sup> Dexcom Customer Satisfaction Evaluation, April 2010.
- <sup>23</sup> Physical measurements of screen (left to right): Dexcom 2", Abbott Navigator 1.625", Medtronic Paradigm REAL-Time Revel 1.8125".

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