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Stay Between the Lines

DEXCOM | G4 PLATINUM

CONTINUOUS GLUCOSE MONITORING SYSTEM

USER'S GUIDE

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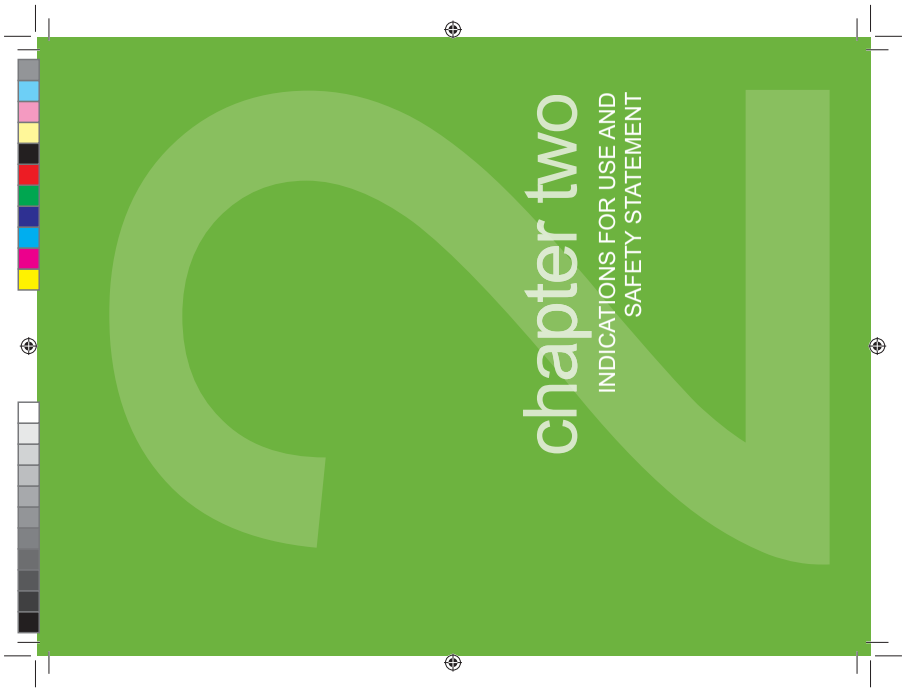

chapter two
INDICATIONS FOR USE AND
SAFETY STATEMENT

CHAPTER 2: INDICATIONS FOR USE AND SAFETY STATEMENT

2.1 INDICATIONS FOR USE

The Dexcom G4 PLATINUM Continuous Glucose Monitoring System is a glucose monitoring device indicated for detecting trends and tracking patterns in persons **(age 18 and older)** with diabetes. The system is intended for single patient use and requires a prescription.

The Dexcom G4 PLATINUM System is indicated for use as an adjunctive device to complement, not replace, information obtained from standard home glucose monitoring devices.

The Dexcom G4 PLATINUM 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 Dexcom G4 PLATINUM System results should be based on the trends and patterns seen with several sequential readings over time.

2.2 IMPORTANT USER INFORMATION

Please review your product instructions before using your continuous glucose monitoring system. Contraindications, warnings, precautions, cautions, and other important user information can be found in your product instructions. Discuss with your healthcare professional how you should use your sensor trend information to help manage your diabetes. Your product instructions contain important information on troubleshooting your system and on the performance characteristics of the device.

2.3 CONTRAINDICATIONS

- Remove the Dexcom G4 PLATINUM Sensor, Transmitter, and Receiver before Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, or diathermy treatment. The Dexcom G4 PLATINUM System has not been tested during MRI or CT scans or with diathermy treatment. The magnetic fields and heat could damage the device so that it might not display sensor glucose readings or provide alerts, and you might miss a low or high blood glucose value.
- Taking medications with acetaminophen (such as Tylenol) while wearing the sensor may falsely raise your sensor glucose readings. The level of inaccuracy depends on the amount of acetaminophen active in your body and may be different for each person.

2.4 WARNINGS

- Thoroughly review the training materials included with your CGM system before using the Dexcom G4 PLATINUM CGM System. Incorrect use might lead to you misunderstanding the information provided by your system, or might affect system performance, and you might miss a low or high blood glucose value.
- Do not use the Dexcom G4 PLATINUM System for treatment decisions, such as how much insulin you should take. The Dexcom G4 PLATINUM System does not replace a blood glucose meter. Always use the values from your blood glucose meter for treatment decisions. Blood glucose values may differ from sensor glucose readings. Using the sensor glucose readings for treatment decisions could lead to low or high blood glucose value.
- Do not ignore symptoms of high and low glucose. If your sensor glucose readings do not match your symptoms,

measure your blood glucose with a blood glucose meter even if your sensor is not reading in the high or low range, so you do not miss a low or high blood glucose value.

- Calibrate at least once every 12 hours. Calibrating less often than every 12 hours might cause sensor glucose readings to be inaccurate, and you might miss a low or high blood glucose value.
- Sensors may 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 at **1.877.339.2664 or 1.858.200.0200.**
- The Dexcom G4 PLATINUM System **is not approved for use** in children or adolescents, pregnant women or persons on dialysis.
- It is not known how different conditions or medications common to the critically ill population may affect the performance of the system. Therefore, the use of this system in the critically ill population is not recommended.
- Sensor placement and insertion **is not approved** for sites other than the belly (abdomen).
- If your transmitter or receiver case is damaged/cracked, do not use it. This could create an electrical safety hazard or malfunction, which might cause electrical shocks.
- Store the sensor at temperatures between 36° F - 77° F for the length of the sensor's shelf life. You may store the sensor in the refrigerator if it is within this temperature range. The sensor should not be stored in a freezer. Storing the sensor improperly might cause the sensor

glucose readings to be inaccurate, and you might miss a low or high blood glucose value.

2.5 PRECAUTIONS

- Before opening the sensor package, wash your hands with soap and water, and let them dry. You may contaminate the insertion site and suffer an infection if you have dirty hands while inserting the sensor.
- Before inserting the sensor, clean the skin with a topical antimicrobial solution, such as isopropyl alcohol, and allow to dry. This may help prevent infection. Do not insert the sensor until the cleaned area is dry so the sensor adhesive will stick better.
- Change the site where you place the sensor with each insertion. Using the same site too often might not allow the skin to heal, and might cause scarring or skin irritation.
- Avoid inserting the sensor in areas that are likely to be bumped, pushed or compressed or areas of skin with scarring, tattoos, or irritation as these are not ideal sites to measure glucose. Insertion in those areas might affect sensor performance, and you might miss a low or high blood glucose value.
- Avoid injecting insulin or placing an insulin pump infusion set within 3 inches of the sensor. The insulin might affect sensor performance, and you might miss a low or high blood glucose value.
- Do not use the sensor if its sterile package has been damaged or opened. Using an unsterile sensor might cause infection.
- To calibrate the system, enter the exact blood glucose value that your blood glucose meter displays within 5 minutes of a

carefully performed blood glucose measurement. Entering incorrect blood glucose values or blood glucose values from more than 5 minutes before entry might affect sensor performance, and you might miss a low or high blood glucose value.

- Do not calibrate if your blood glucose is changing at a significant rate, typically more than 2 mg/dL per minute. Do not calibrate when your receiver screen is showing the rising single arrow or double arrow, which indicates that your blood glucose is rising 2-3 mg/dL/min or more than 3 mg/dL/min. Also, do not calibrate when your receiver screen is showing the falling single arrow or double arrow, which indicates that your blood glucose is falling 2-3 mg/dL/min or more than 3 mg/dL/min. Calibrating during significant rise or fall of blood glucose may affect accuracy of sensor glucose readings.
- The system accuracy may be affected when your glucose is changing at a significant rate (e.g., 2-3 mg/dL/min or more than 3 mg/dL each minute), such as during exercise or after a meal.
- The transmission range from the transmitter to the receiver is up to 20 feet without obstruction. Wireless communication does not work well through water so the range is much less if you are in a pool, bathtub, or on a water bed, etc. Types of obstruction differ and have not been tested. If your transmitter and receiver are farther than 20 feet apart or are separated by an obstruction, they might not communicate or the communication distance may be shorter and you might miss a low or high blood glucose value.
- Keep the USB port cover on the receiver closed whenever the USB cable is not attached. If water gets into the

USB port, the receiver could become damaged and stop displaying readings or providing alerts, and you might miss a low or high blood glucose value.

- Do not use alternative blood glucose site testing (blood from your palm or forearm, etc.) for calibration. Alternative site blood glucose values may be different than those taken from a fingerstick blood glucose value and may not represent the timeliest blood glucose value. Use a blood glucose value taken only from a fingerstick for calibration. Alternative site blood glucose values might affect sensor performance, and you might miss a low or high blood glucose value.
- Do not discard your transmitter. It is reusable. The same transmitter is used for each session until you have reached the end of the transmitter battery life.
- The Dexcom G4 PLATINUM Sensor, Transmitter, and Receiver are not compatible with the SEVEN/SEVEN PLUS Transmitter and Receiver. Different generations will not connect with each other and will not work. Also make sure to use the correct version of Dexcom Studio with your system.

2.6 CAUTION

U.S. (Federal) law restricts the sale of the Dexcom G4 PLATINUM System to sale by or on order of a physician.

chapter fourteen

TECHNICAL INFORMATION

CHAPTER 14: TECHNICAL INFORMATION

14.1 DEVICE PERFORMANCE CHARACTERISTICS

NOTE: We recommend that you review the information in this chapter with your healthcare provider to understand how well the Dexcom G4 PLATINUM System performs.

The Dexcom G4 PLATINUM System (the System) uses a glucose sensor to continuously measure and monitor your glucose levels. The sensor is "calibrated" using a commercially available blood glucose meter; and once calibrated the System reports glucose readings up to every 5 minutes. The System was evaluated in a clinical study in which System readings were compared to blood glucose values to assess its performance and how well the System readings compare to a laboratory test method that measures blood glucose values. Additionally, subjects performed self-monitoring blood glucose meter tests at home to assess the System performance in real use environment.

Although the performance characteristics of the System are presented in the following, there is no commonly accepted statistical approach for capturing performance of continuous glucose monitors (CGMs), such as the Dexcom G4 PLATINUM System.

Clinical Study Overview

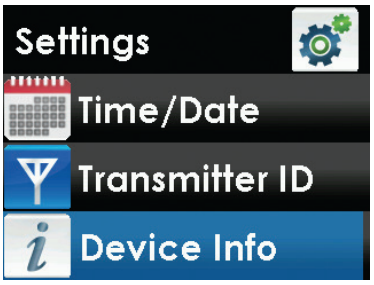
The System performance was evaluated in two separate prospective clinical studies: the **Original** Receiver Software Study (**SW10050**) and the **Software 505** Receiver Software Study (**SW10505**). Differences between the studies include the number of subjects enrolled, the number of Systems worn by each participant, the SMBG meter used, and the number of clinic days each subject participated in during the study. An overview of each study is provided below. Both sets of study data are presented in the tables that follow and are labeled as **Original** Study or **Software 505** Study from this point forward.

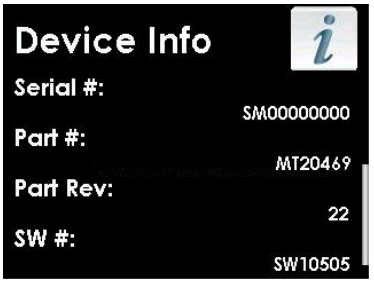
The **Original** Study enrolled 72 subjects, and the **Software 505** Study enrolled 51 subjects. All subjects had Type 1 or Type 2 diabetes mellitus, and required insulin or oral medication to manage their diabetes. In the **Original** Study, 83% of subjects had Type 1 diabetes, and 17% of subjects had Type 2 diabetes. In the **Software 505** Study, 86% of subjects had Type 1 diabetes, and 14% of subjects had Type 2 diabetes. Both studies included subjects greater than 18 years of age.

CHECKING YOUR RECEIVER SOFTWARE VERSION

You can check your receiver for information about your CGM system at any time.

1. From the Settings menu, press the **UP** or **DOWN** button to scroll to "Device Info."
2. Press the **SELECT** button. Information about your sensor session and system will show.
3. Scroll down to see:
   - Serial Number
   - Part Number
   - Part Revision
   - Software Number
   - Software Revision
4. Press the **LEFT** button to return to the Settings menu.





Subjects in both studies used the System for seven days. In the **Original** Study, thirty-six subjects each wore 2 sensors; in the **Software 505** Study, all subjects wore 1 sensor only. Throughout the 7-day wear period, the sensor was calibrated with an average of 2 fingersticks per day (approximately once every 12 hours). In the **Original** Study, subjects used the LifeScan® OneTouch® Ultra®2 meter and in the **Software 505** Study, subjects used Bayer's CONTOUR® NEXT USB meter.

In the **Original** Study, all subjects were evaluated in a controlled clinic environment on all three clinic days: Day 1, Day 4, and Day 7 of the 7-day wear period. In the **Software 505** Study, subjects were evaluated in one of the three clinic days so there are fewer data samples than in the **Original** Study. While using the System in the clinic, subjects had their blood glucose measured every 15 minutes with a reliable laboratory method, the Yellow Springs Instrument 2300 STAT Plus™ Glucose Analyzer. This instrument is referred to as the “YSI.” Readings from the System were reported every 5 minutes and paired with YSI values in order to characterize how well the System readings agreed with laboratory standard blood glucose results. The remainder of the study took place at home, and the System performance was also paired with the comparative meter results, referred to as the “SMBG.”

Table 1. System Agreement to YSI within CGM Glucose Ranges

CGM Glucose Range [1] (mg/dL)	Study[2]	Number of paired CGM-YSI	Percent within 15/15% YSI	Percent within 20/20% YSI	Percent within 30/30% YSI	Percent Greater than 40/40% YSI
Overall	Original	9152	71%	82%	92%	3%
	Software 505	2263	86%	93%	98%	1%
40-60	Original	512	67%	78%	88%	6%
	Software 505	120	89%	94%	98%	0%
61-80	Original	781	73%	85%	94%	2%
	Software 505	226	91%	96%	99%	0%
81-180	Original	3853	67%	78%	91%	3%
	Software 505	738	84%	92%	98%	1%
181-300	Original	2784	72%	84%	93%	4%
	Software 505	798	86%	93%	98%	1%
301-350	Original	775	82%	91%	97%	2%
	Software 505	229	86%	94%	98%	1%
351-400	Original	447	74%	84%	91%	5%
	Software 505	152	80%	92%	97%	0%

[1] CGM readings are within 40-400 mg/dL, inclusive.

[2] Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

Agreement Relative to YSI

Agreement between the System and blood glucose values is characterized using paired System and YSI values. The System and YSI results were compared by pairing the YSI blood glucose value to a System glucose reading that occurred immediately after the YSI was collected.

The agreement of the System to blood glucose value was assessed by calculating the percentage of System readings that were within 15%, 20%, 30% and greater than 40% of the YSI values. For readings less than or equal to 80 mg/dL the absolute difference in mg/dL between the two glucose results was calculated. For values greater than 80 mg/dL the absolute percent difference (%) from the YSI values was calculated. The percentages of total readings within 15 mg/dL or 15%, 20 mg/dL or 20%, 30 mg/dL or 30% or greater than 40 mg/dL or 40% were then calculated in Table 1. Table 1 is categorized within CGM glucose ranges. When you see a CGM reading on your receiver, this table shows you how likely that reading matches your blood glucose level (measured by YSI in the study).

Original Study (SW10050): The total number of data pairs considered in the analysis was 9152. Of these, 82% of the System readings fall within ± 20 mg/dL of the YSI blood glucose values ≤ 80 mg/dL and within ± 20% of YSI blood glucose values > 80 mg/dL.

Software 505 Study (SW10505): The total number of data pairs considered in the analysis was 2263. Of these, 93% of the System readings fall within ± 20 mg/dL of the YSI blood glucose values ≤ 80 mg/dL and within ± 20% of YSI blood glucose values > 80 mg/dL.

Table 2. Number and Percentage of YSI Values When CGM Readings are "Low" or "High"

CGM Readings	Study[1]	CGM-YSI pairs	YSI mg/dL < 55	< 60	< 70	< 80	≥ 80	Total
"LOW"	Original	n	66	84	123	142	13	155
		Cumulative Percent	42%	54%	79%	92%	8%	
	Software 505	n	11	16	17	18	0	18
		Cumulative Percent	61%	89%	94%	100%	0%	

CGM Readings	Study[1]	CGM-YSI pairs	YSI mg/dL > 340	> 320	> 280	> 240	≤ 240	Total
"HIGH"	Original	n	189	220	238	246	2	248
		Cumulative Percent	76%	89%	96%	99%	1%	
	Software 505	n	40	43	45	45	0	45
		Cumulative Percent	89%	96%	100%	100%	0%	

[1] Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

Agreement When CGM Reads "LOW" or "HIGH"

The System reports glucose readings between 40 and 400 mg/dL. When the System determines the glucose reading is below 40 mg/dL, it displays "LOW" in the Receiver Status Box. When the Dexcom G4 PLATINUM System determines that the glucose level is above 400 mg/dL, it displays "HIGH" in the Receiver Status Box. Because the System does not display glucose values below 40 mg/dL or above 400 mg/dL, the comparisons to the actual blood glucose levels (as determined by the YSI analyzer) when CGM is classified as "LOW" or "HIGH" are included separately in Table 2. The table includes the numbers and the cumulative percentages when YSI values were less than certain glucose levels (for "LOW"), and when YSI values were greater than certain glucose levels (for "HIGH").

Original Study (SW10050): When the System displayed "LOW" (155 occasions), 92% (142 out of 155) of the YSI values were less than 80 mg/dL, and only 79% (123 out of 155) of the YSI values were less than 70 mg/dL. When the System displayed "HIGH" (248 occasions), 99% (246 out of 248) of the YSI values were greater than 240 mg/dL, and 96% (238 out of 248) of the YSI values were greater than 280 mg/dL.

Software 505 Study (SW10505): When the System displayed "LOW" (18 occasions), 100% (18 out of 18) of the YSI values were less than 80 mg/dL, and 94% (17 out of 18) of the YSI values were less than 70 mg/dL. When the System displayed "HIGH" (45 occasions), 100% (45 out of 45) of the YSI values were greater than 240 mg/dL, and 100% (45 out of 45) of the YSI values were greater than 280 mg/dL.

Table 3-A. Concurrence of CGM Readings and YSI Values (Original Study)

CGM (mg/dL)	YSI (mg/dL) Row percentage of matched pairs in each CGM glucose range											Number of Paired CGM-YSI
	< 40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	> 400	
< 40	6%	48%	37%	7%	1%	0%	0%	0%	0%	0%	0%	155
40-60	4%	49%	36%	11%	1%	0%	0%	0%	0%	0%	0%	512
61-80	0%	22%	51%	24%	1%	0%	0%	0%	0%	0%	0%	781
81-120	0%	2%	17%	66%	13%	1%	0%	0%	0%	0%	0%	1706
121-160	0%	0%	1%	25%	60%	13%	2%	0%	0%	0%	0%	1492
161-200	0%	0%	0%	2%	28%	53%	16%	2%	0%	0%	0%	1240
201- 250	0%	0%	0%	0%	3%	21%	51%	21%	3%	1%	0%	1181
251- 300	0%	0%	0%	0%	0%	4%	19%	49%	24%	3%	0%	1018
301- 350	0%	0%	0%	0%	0%	0%	3%	28%	51%	16%	1%	775
351- 400	0%	0%	0%	0%	0%	0%	3%	10%	43%	38%	7%	447
> 400	0%	0%	0%	0%	0%	0%	1%	6%	21%	57%	15%	248

Table 3-B. Concurrence of CGM Readings and YSI Values (Software 505 Study)

CGM (mg/dL)	YSI (mg/dL) Row percentage of matched pairs in each CGM glucose range											Number of Paired CGM-YSI
	< 40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	> 400	
< 40	6%	83%	11%	0%	0%	0%	0%	0%	0%	0%	0%	18
40-60	2%	74%	22%	3%	0%	0%	0%	0%	0%	0%	0%	120
61-80	0%	19%	68%	13%	0%	0%	0%	0%	0%	0%	0%	226
81-120	0%	0%	19%	72%	8%	1%	0%	0%	0%	0%	0%	347
121-160	0%	0%	0%	17%	72%	11%	0%	0%	0%	0%	0%	246
161-200	0%	0%	0%	0%	25%	59%	16%	0%	0%	0%	0%	286
201- 250	0%	0%	0%	0%	0%	16%	70%	13%	1%	0%	0%	376
251- 300	0%	0%	0%	0%	0%	2%	16%	61%	14%	7%	0%	281
301- 350	0%	0%	0%	0%	0%	0%	2%	28%	59%	10%	1%	229
351- 400	0%	0%	0%	0%	0%	0%	0%	4%	47%	45%	5%	152
> 400	0%	0%	0%	0%	0%	0%	0%	0%	20%	38%	42%	45

Concurrence of System and Laboratory Reference

Tables 3-A and 3-B are categorized by ranges of CGM glucose readings. This table describes, for each range of CGM glucose readings, what percentage of paired YSI values were in the same glucose range (shaded) or in glucose ranges above and below the paired CGM readings. For example, based on the **Software 505** Study, when CGM readings are within 81 to 120 mg/dL, you can expect your blood glucose levels are within 81 to 120 mg/dL 72% of time.

Accuracy Relative to YSI

Accuracy between matched pairs was also estimated by calculating the percent difference between the System reading and the YSI value. For example, if the YSI value is 100 mg/dL and the System reading is 90 mg/dL, a 10% difference between the System and the YSI is reported. The System and YSI values were compared by pairing the System reading that fell immediately after the YSI value was collected.

In the example above, the System reading is less than the YSI value, so the percent difference reading is negative. The mean percent difference is the average of all positive and negative percent differences between the two devices; it tells you if the System reads higher or lower on average than the YSI within each glucose range.

Another estimate used to show the accuracy of the System is the absolute percent difference. The absolute percent difference tells you the percent difference or "distance" between the System and YSI values, but does not tell you whether the System is reading, on average, higher or lower than the YSI laboratory standard. The mean absolute percent difference is the average "distance" (regardless if positive or negative) between System readings and YSI values.

Accuracy measures in differences for both the **Original** and **Software 505** Studies are based on 9152 and 2263 paired glucose results, respectively; the data are summarized in Table 4. Table 4 is categorized within CGM glucose ranges.

Original Study (SW10050): Overall, on average, the System reads 2.9% different (Mean Percent Difference) than the reference and 13.3% absolute different (Mean Absolute Difference) than the reference values. The Median Percent Difference shows that half of the time the System reads 1.7% or less than the YSI blood glucose values and the Median Absolute Percent Difference shows that half of the time the System reads about 9.8% or less than the YSI blood glucose values.

Software 505 Study (SW10505): Overall, on average, the System reads 2.5% different (Mean Percent Difference) than the reference and 9.0% absolute different (Mean Absolute Difference) than the reference values. The Median Percent Difference shows that half of the time the System reads 2.4% or less than the YSI blood glucose values and the Median Absolute Percent Difference shows that half of the time the System reads about 7.0% or less than the YSI blood glucose values.

Table 4. System Difference to YSI within CGM Glucose Ranges

CGM Glucose Ranges[1] (mg/dL)	Study[2]	Number of Paired CGM-YSI	Mean Percent Difference	Median Percent Difference	Mean Absolute Percent Difference	Median Absolute Percent Difference
Overall	Original	9152	2.9%	1.7%	13.3%	9.8%
	Software 505	2263	2.5%	2.4%	9.0%	7.0%
*40-60	Original	512	-10.0	-8.2	13.5	9.7
	Software 505	120	-3.3	-2.1	6.9	4.8
*61-80	Original	781	-2.4	-0.4	11.4	8.6
	Software 505	226	0.8	1.4	6.7	5.4
81-180	Original	3853	4.8%	3.0%	13.8%	9.8%
	Software 505	738	3.9%	4.1%	9.6%	8.2%
181-300	Original	2784	2.1%	0.0%	11.9%	9.2%
	Software 505	798	0.6%	0.4%	8.0%	6.1%
301-350	Original	775	3.8%	2.8%	9.8%	7.9%
	Software 505	229	4.1%	3.4%	8.0%	5.8%
351-400	Original	447	10.4%	7.7%	12.8%	9.1%
	Software 505	152	7.2%	6.3%	9.2%	7.2%

[1] CGM readings are within 40 to 400 mg/dL, inclusive.

[2] Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

* For CGM ≤ 80 mg/dL, the difference and absolute difference in mg/dL are included instead of percent differences (%).

Low and High Glucose Alerts

The ability of the System to detect high and low glucose levels is assessed by comparing System results to YSI results at low and high blood glucose levels and determining if the alert may have sounded. The System and YSI values were compared by pairing the System reading that occurred immediately after the YSI value was collected. We suggest that you ask your doctor what alert settings would be best for you.

The Low Glucose Alert

Estimates of how well the adjustable Low Glucose Alert performs are presented in Table 5.

Hypoglycemia Alert Rate

The Alert Rate shows how often the alert is right or wrong. The True Alert Rate is the % of time the device alarmed when the blood glucose level was at or below the alert setting within 15 minutes before or after the device alarmed. The False Alert Rate is the % of time the device alarmed when the blood glucose level was above the alert setting within 15 minutes before or after the device alarmed.

For example, if you set the Low Glucose Alert to 70 mg/dL and your alarm sounds, how often can you expect your blood sugar to actually be low? Based on the **Original** Study, if your alarm sounds, you can expect your blood sugar to be below 70 mg/dL approximately 79% of the time and not be below 70 mg/dL approximately 21% of the time within the 15 minute period before or after your alarm sounds. Based on the **Software 505** Study, if your alarm sounds, you can expect your blood sugar to be below 70 mg/dL approximately 92% of the time and not be below 70 mg/dL approximately 8% of the time within the 15 minute period before or after your alarm sounds.

Hypoglycemia Detection Rate

The Detection Rate shows how often the device recognizes and alerts you to an episode of hypoglycemia or how often it misses such an event. The Hypoglycemia Detection Rate is the % of time the blood glucose level was at or below the alert setting and device alarmed within 15 minutes before or after the blood glucose was at or below the alert settings. The Hypoglycemia Missed Detection Rate is the % of time the blood glucose was at or below the alert setting, but the device did not alarm within 15 minutes before or after the blood glucose was at or below the alert setting.

For example, if you set the Low Glucose alert to 70 mg/dL, how often will your alarm alert you if your blood glucose goes below 70 mg/dL? Based on the **Original** Study, if your blood sugar goes below 70 mg/dL, you can expect your alarm to sound 83% of the time and not to sound approximately 17% of time within the 15 minute period before or after your blood sugar goes below 70 mg/dL. Based on the **Software 505** Study, if your blood sugar goes below 70 mg/dL, you can expect your alarm to sound 91% of the time and not to sound approximately 9% of time within the 15 minute period before or after your blood sugar goes below 70 mg/dL.

Table 5. Hypoglycemic Alert Evaluation

Hypoglycemic Alert Level (mg/dL)	Study[1]	True Alert Rate	False Alert Rate	Hypoglycemia Detection Rate	Hypoglycemia Missed Detection Rate
55	Original	50%	50%	71%	29%
	Software 505	71%	29%	68%	32%
60	Original	64%	36%	75%	25%
	Software 505	85%	15%	83%	17%
70	Original	79%	21%	83%	17%
	Software 505	92%	8%	91%	9%
80	Original	87%	13%	86%	14%
	Software 505	95%	5%	90%	10%
90	Original	90%	10%	89%	11%
	Software 505	96%	4%	94%	6%

[1] Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

The High Glucose Alert

Estimates of how well the adjustable High Glucose Alert performs are presented in Table 6.

Hyperglycemia Alert Rate

The Alert Rate shows how often the alert is right or wrong. The True Alert Rate is the % of time the device alarmed when the blood glucose level was at or above the alert setting within 15 minutes before or after the device alarmed. The False Alert Rate is the % of time the device alarmed when the blood glucose level was below the alert setting within 15 minutes before or after the device alarmed.

For example, if you set the High Glucose alert to 200 mg/dL and your alarm sounds, how often can you expect your blood sugar to actually be high? Based on the **Original** Study, if your alarm sounds, you can expect your blood sugar to be at or above 200 mg/dL approximately 92% of the time and not be above 200 mg/dL approximately 8% of the time within the 15 minute period before or after your alarm sounds. Based on the **Software 505** Study, if your alarm sounds, you can expect your blood sugar to be at or above 200 mg/dL approximately 96% of the time and not be above 200 mg/dL approximately 4% of the time within the 15 minute period before or after your alarm sounds.

Hyperglycemia Detection Rate

The Detection Rate shows how often the device recognizes and alerts you to an episode of hyperglycemia or how often it misses such an event. The Hyperglycemia Detection Rate is the % of time the blood glucose level was at or above the alert setting and the device alarmed within 15 minutes before or after the blood glucose was at or above the alert settings. The Hyperglycemia Missed Detection Rate is the % of time the blood glucose was at or above the alert setting, but the device did not alarm within 15 minutes before or after the blood glucose was at or above the alert setting.

For example, if you set your High Glucose alert to 200 mg/dL, how often will your alarm alert you if your blood glucose goes at or above 200 mg/dL? Based on the **Original** Study, if your blood sugar goes above 200 mg/dL, you can expect your alarm to sound 97% of the time and not to sound approximately 3% of time within the 15 minute period before or after your blood sugar goes above 200 mg/dL. Based on the **Software 505** Study, if your blood sugar goes above 200 mg/dL, you can expect your alarm to sound 98% of the time and not to sound approximately 2% of time within the 15 minute period before or after your blood sugar goes above 200 mg/dL.

Table 6. Hyperglycemic Alert Evaluation

Hyperglycemic Alert Level (mg/dL)	Study[1]	True Alert Rate	False Alert Rate	Hyperglycemia Detection Rate	Hyperglycemia Missed Detection Rate
120	Original	95%	5%	98%	2%
	Software 505	98%	2%	100%	0%
140	Original	94%	6%	97%	3%
	Software 505	97%	3%	99%	1%
180	Original	92%	8%	97%	3%
	Software 505	97%	3%	99%	1%
200	Original	92%	8%	97%	3%
	Software 505	96%	4%	98%	2%
220	Original	91%	9%	95%	5%
	Software 505	94%	6%	98%	2%
240	Original	91%	9%	94%	6%
	Software 505	93%	7%	95%	5%
300	Original	82%	18%	86%	14%
	Software 505	86%	14%	90%	10%

[1] Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

Table 7. Percentage of System Readings[1] within YSI Values with Data Stratified in 2-Hour Increments after Calibration

Time from Calibration	Study[2]	Number of paired CGM-YSI	Percent within 15/15% YSI	Percent within 20/20% YSI	Percent within 30/30% YSI	Percent greater than 40/40% YSI
0-2 hours	Original	1929	78%	88%	96%	2%
	Software 505	469	93%	97%	99%	0%
2-4 hours	Original	1516	69%	81%	91%	4%
	Software 505	389	90%	97%	99%	0%
4-6 hours	Original	1547	69%	79%	91%	5%
	Software 505	383	85%	91%	97%	2%
6-8 hours	Original	1520	68%	79%	92%	3%
	Software 505	380	79%	90%	97%	2%
8-10 hours	Original	1555	71%	82%	92%	4%
	Software 505	347	83%	92%	98%	0%
10-12 hours	Original	1068	65%	77%	91%	4%
	Software 505	295	80%	90%	98%	0%
12-14 hours	Original	17	65%	76%	82%	12%
	Software 505	0	--	--	--	--

[1] CGM readings are within 40 to 400 mg/dL, inclusive.

[2] Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

Calibration Stability

The System must be calibrated every 12 hours. To demonstrate performance of the System over a 12-hour calibration period, Systems were evaluated to verify that performance remains consistent over the 12-hour calibration period. Systems were evaluated in 2-hour increments after calibration. Performance was estimated at each 2-hour interval and stratified by glucose values by calculating the percentage of System readings within 15 mg/dL or 15%, 20 mg/dL or 20%, 30 mg/dL or 30%, 40 mg/dL or 40% and greater than 40 mg/dL or 40% of the YSI values in Table 7.

Table 8. Sensor Stability (Accuracy[1] over Time)

Day of Wear	Study[2]	Number of paired CGM-YSI	Mean Absolute Percent Differences	Median Absolute Percent Differences	Percent within 15/15% YSI	Percent within 20/20% YSI	Percent within 30/30% YSI	Percent greater than 40/40% YSI
Day 1	Original	3023	16.7%	13.2%	59%	71%	86%	6%
	Software 505	680	10.7%	7.9%	77%	84%	96%	2%
Day 4	Original	3108	11.4%	8.2%	77%	87%	95%	2%
	Software 505	777	8.0%	6.4%	89%	96%	99%	0%
Day 7	Original	3021	11.9%	8.9%	76%	87%	95%	2%
	Software 505	806	8.5%	7.2%	90%	97%	99%	0%

[1] CGM readings are within 40 to 400 mg/dL, inclusive.

[2] Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

Sensor Stability

Sensors can be worn for up to 7 days. To verify sensor performance over time, 72 subjects were evaluated with the **Original** System across the 7-day wear period while 50 subjects were evaluated with the **Software 505** System across the 7-day wear period. Performance was estimated by calculating the percentage of System readings within 15 mg/dL or 15%, 20 mg/dL or 20%, 30 mg/dL or 30% , 40 mg/dL or 40% and greater than 40 mg/dL or 40% of the YSI values at the beginning (Day 1), middle (Day 4) and end (Day 7) of the System lifecycle. The average and median of the absolute percent differences are included in Table 8 showing consistent accuracy and sensor stability over the 7-day life of the sensor.

Precision of System Readings

In the **Original** Study, 36 subjects wore two Systems. This was to look at how similarly two Systems function on the same subject (sensor precision). Precision was evaluated by comparing the glucose readings from the two Systems worn on the same subject at the same time. Results showed that System readings from the two sensors generally agreed with each other within 9% (absolute percent difference) with a 7% coefficient of variation. Only one System was worn in the **Software 505** Study so precision data was not collected in this study.

Sensor Life

Sensors may be worn for up to 7 days (168 hours). To estimate how long a sensor will work over 7 days, 108 sensors were evaluated with the **Original** Study to determine how many days/hours of readings each sensor provided. Ninety-four percent (94%) of the sensors lasted until Day 7 (145-168 hours). There were 6 (6%) sensors that ended early, four of which lasted more than 3 days.

For the **Software 505** Study, 51 sensors were evaluated to determine how many days/hours of readings each sensor provided. Ninety-eight percent (98%) of the sensors lasted until Day 7 (145-168 hours). There was 1 (2%) sensor that ended early, which lasted until day 5 of the sensor wear.

Table 9. Number of Readings Provided by Each Sensor Over 7-Days

% of Total Possible Readings Provided	Study[1]	Total Readings Provided (Min-Max)	% of Systems Providing that Number of Readings
0-25%	Original	167-491	2%
	Software 505	0	0%
26-50%	Original	719-914	4%
	Software 505	856-856	2%
51-75%	Original	1267-1267	1%
	Software 505	1253-1253	2%
76-100%	Original	1811-1992	94%
	Software 505	1497-1992	96%

[1] Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

Table 10. System Readings Within Wear Days

Statistic	Study[1]	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	All Days[2]
Mean	Original	98%	98%	98%	98%	97%	99%	95%	97%
	Software 505	98%	99%	98%	98%	96%	99%	97%	98%
Median	Original	100%	100%	100%	100%	100%	100%	100%	100%
	Software 505	99%	100%	100%	100%	100%	100%	100%	100%
STD	Original	5%	3%	9%	8%	10%	3%	11%	8%
	Software 505	3%	2%	8%	11%	15%	2%	13%	9%

[1] Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

[2] A total of 108 sensors were included with the **Original** Study and 51 sensors were included with the **Software 505** Study.

Number of Readings Provided

The System is capable of providing a reading up to every 5 minutes, or up to 288 readings per day. For a variety of reasons, the System may not display a glucose reading and readings are “skipped.” Table 9 estimates the number of readings you can expect to receive from the System over the entire 7-day period after calibration. For the **Original** Study, 94% of Systems provided between 1,811 and 1,992 valid glucose readings (or more than 75% of the expected number of readings). Adjusted within each system wear-day, the **Original** System provided an average of 97% of all expected glucose readings (288) as seen in Table 10.

For the **Software 505** Study (SW10505), 96% of Systems provided between 1,497 and 1,992 valid glucose readings (or more than 75% of the expected number of readings). Adjusted within each system wear-day, the **Software 505** System provided an average of 98% of all expected glucose readings (288) as seen in Table 10.

Table 11. CGM System Agreement to SMBG within CGM Glucose Ranges

CGM Glucose Ranges[1] (mg/dL)	Study[2]	Number of paired CGM-SMBG	Percent within 15/15% SMBG	Percent within 20/20% SMBG	Percent within 30/30% SMBG	Percent greater than 40/40% SMBG
Overall	Original	7508	69%	81%	94%	2%
	Software 505	2992	77%	87%	96%	1%
40-60	Original	731	75%	84%	92%	4%
	Software 505	221	73%	80%	87%	7%
61-80	Original	968	78%	86%	95%	1%
	Software 505	336	77%	85%	95%	1%
81-180	Original	3141	65%	78%	93%	2%
	Software 505	1362	74%	85%	96%	1%
181-300	Original	1960	68%	81%	94%	3%
	Software 505	826	80%	90%	97%	1%
301-350	Original	450	77%	88%	98%	1%
	Software 505	161	83%	93%	99%	0%
351-400	Original	258	75%	85%	95%	2%
	Software 505	86	90%	93%	98%	1%

[1] CGM readings are within 40 to 400 mg/dL, inclusive.

[2] Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

Agreement and Accuracy Relative to SMBG

During the study, agreement between the System and blood glucose values is also characterized using paired System and SMBG results. The System and SMBG values were compared by pairing the comparative SMBG value to a System glucose reading that occurred immediately after the SMBG was collected. These results characterize the performance subjects expect during real-time use of the System in their daily diabetes management when comparing the System readings to their home blood glucose meter results.

Table 11 is categorized within CGM glucose ranges. For readings less than or equal to 80 mg/dL the absolute difference in mg/dL between the two glucose results was calculated. For values greater than 80 mg/dL the absolute percent difference (%) from the SMBG values was calculated. The percentages of total readings within 15 mg/dL or 15%, 20 mg/dL or 20%, 30 mg/dL or 30%, 40 mg/dL or 40% or greater than 40 mg/dL or 40% were then calculated. For example, if the CGM reads 100 mg/dL, it is between 81-180 mg/dL range and you can expect the CGM readings to be within 20% of the SMBG values 78% of the time for the **Original** System and 85% time for the **Software 505** System.

Table 12. CGM System Difference to SMBG within CGM Glucose Ranges

CGM Glucose Ranges[1] (mg/dL)	Study[2]	Number of Paired CGM-SMBG	Mean Percent Difference	Median Percent Difference	Mean Absolute Percent Difference	Median Absolute Percent Difference
Overall	Original	7508	-0.4%	-1.4%	14.0%	11.0%
	Software 505	2992	-2.6%	-2.7%	11.3%	8.6%
*40-60	Original	731	-9.3	-8.0	11.7	8.0
	Software 505	221	-10.3	-6.0	13.0	8.0
*61-80	Original	968	-1.0	1.0	10.7	8.0
	Software 505	336	-4.0	-2.0	10.1	7.0
81-180	Original	3141	1.4%	0.0%	14.2%	11.0%
	Software 505	1362	-2.6%	-3.1%	11.4%	8.9%
181-300	Original	1960	-0.7%	-2.8%	13.0%	10.3%
	Software 505	826	-1.4%	-2.0%	9.5%	7.4%
301-350	Original	450	-0.7%	-2.6%	10.5%	8.6%
	Software 505	161	-0.0%	0.0%	8.3%	6.0%
351-400	Original	258	5.0%	3.0%	11.9%	8.6%
	Software 505	86	3.9%	3.2%	8.1%	6.7%

[1] CGM readings are within 40 to 400 mg/dL, inclusive.

[2] Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

* For CGM ≤ 80 mg/dL, the differences in mg/dL are included instead of percent differences (%).

Table 12 is categorized within CGM glucose ranges. Overall, the System in the **Original** Study reads, on average, 0.4% lower (Mean Percent Difference) than SMBG values and 14.0% absolute different (Mean Absolute Percent Difference) than the SMBG values. The Median Percent Difference shows that half of the time the System reads -1.4% or less than the SMBG values and the Median Absolute Percent Difference shows that half of the time the System reads about 11.0% or less different than SMBG values.
Overall, the System in the **Software 505** Study reads, on average, 2.6% lower (Mean Percent Difference) than SMBG values and 11.3% absolute different (Mean Absolute Percent Difference) than the SMBG values. The Median Percent Difference shows that half of the time the System reads lower in 2.7% or less

than the SMBG values and the Median Absolute Percent Difference shows that half of the time the System reads about 8.6% or less different than SMBG values.

Adverse Events

No serious adverse events or device-related serious adverse events occurred during either study. Mild or very slight skin irritation, such as erythema or edema, occurred in low frequency around the adhesive area. No infection, bruising, or bleeding occurred at the sensor needle insertion area or the adhesive area.