



Table 3-D. Concurrence of G6 CGM Readings and YSI Values by YSI Glucose Range (Pediatrics*; n=165)

CGM Glucose Range ¹ (mg/dL)	YSI glucose range (mg/dL)										
	< 40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	> 400
<40	50.0%	6.3%	1.8%	1.2%	0.1%
40- 60	50.0%	48.0%	12.5%	1.8%	0.6%	0.1%
61- 80	.	44.1%	57.1%	7.9%	0.8%	0.2%
81- 120	.	1.6%	28.6%	78.0%	12.4%	0.8%
121- 160	.	.	.	11.0%	67.3%	14.5%	1.0%
161- 200	.	.	.	0.2%	18.7%	67.6%	24.1%	3.0%	.	.	.
201- 250	0.1%	16.6%	57.8%	22.8%	3.5%	.	.
251- 300	0.1%	16.8%	56.8%	22.7%	2.7%	.
301- 350	0.3%	16.5%	57.4%	37.8%	.
351- 400	0.9%	16.0%	44.6%	20.0%
>400	0.4%	14.9%	80.0%
Total	2	127	559	1,254	1,081	955	913	570	282	74	10

* Includes pediatric subjects 6-17 years of age; no YSI measurements were taken for pediatric subjects 2-5 years of age.

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



Trend Accuracy

Trend accuracy explains how well the G6 captures the time-dependent characteristics of glucose fluctuation.

The following examples quantify G6's Trend Accuracy:

3. When the G6 CGM rate of change is rapidly rising (≥ 2 mg/dL/min), how often is reference glucose also rising? The answer is 71.3% of the time for adults and 67.1% for pediatrics.
4. When the G6 CGM rate of change is rapidly falling (≤ 2 mg/dL/min), how often is reference glucose also falling? The answer is 98.0% of the time.
5. When the G6 CGM rate of change is stable (≥ -1 mg/dL/min and ≤ 1 mg/dL/min), how often is glucose changing rapidly (≥ 2 mg/dL/min or ≤ 2 mg/dL/min)? The answer is only 1.9% of the time.

Table 4-A. Trend Accuracy Rate of Change (Adults; n=159)

CGM Rate Range (mg/dL/min)	YSI glucose range (mg/dL)						CGM-YSI Pairs (n)
	<-2	[-2,-1)	[-1,-0)	[0,1]	(1,2]	>2	
<-2	53.3%	35.0%	9.9%	1.5%	0.0%	0.2%	463
[-2,-1)	7.4%	56.9%	32.5%	2.9%	0.3%	0.0%	2,077
[-1,-0)	0.4%	9.5%	76.9%	12.5%	0.6%	0.1%	7,986
[0,1]	0.1%	1.0%	26.2%	60.6%	10.6%	1.6%	5,199
(1,2]	0.0%	0.4%	3.1%	26.8%	52.9%	16.8%	1,734
>2	0.1%	0.1%	0.8%	5.6%	22.1%	71.3%	1,367



Table 4-B. Trend Accuracy Rate of Change (Pediatrics*; n=165)

CGM Rate Range (mg/dL/min)	YSI glucose range (mg/dL)						CGM-YSI Pairs (n)
	<-2	[-2,-1)	[-1,-0)	[0,1]	(1,2]	>2	
<-2	47.9%	37.0%	12.8%	1.9%	0.0%	0.5%	211
[-2,-1)	6.6%	55.5%	33.8%	3.4%	0.6%	0.1%	686
[-1,0)	0.5%	8.9%	73.7%	15.8%	1.0%	0.0%	2,048
[0,1]	0.0%	0.8%	25.5%	62.9%	10.0%	0.8%	1,666
(1,2]	0.0%	0.4%	4.4%	35.9%	48.0%	11.4%	546
>2	0.0%	0.5%	1.7%	7.1%	23.6%	67.1%	423

** Includes pediatric subjects 6-17 years of age; no YSI measurements were taken for pediatric subjects 2-5 years of age.*



Hypoglycemia and Hyperglycemia Alerts

Low and High Glucose Alerts

The ability of the G6 to detect high and low glucose levels is assessed by comparing G6 results to YSI results at low and high blood glucose levels and determining if the alert may have sounded. The G6 and YSI values were compared by pairing the G6 reading and the YSI value within before or after 15 minutes of each other. 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 Tables 5-A and 5-B. Tables 5-A and 5-B represent the hypoglycemic alert evaluation within 15 minutes of the YSI value in the study and the hypoglycemic event evaluation within 15 minutes of each hypoglycemic alert for adults and pediatrics, respectively.

Hypoglycemic 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 results for adults in the G6 Study (Table 5-A), when your alarm sounds, you can expect your blood sugar to be below 70 mg/dL approximately 85.5% of the time and above 70 mg/dL approximately 14.5% of the time within the 15 minute period before or after your alarm sounds.

When the hypoglycemic alert rate was set at 55 mg/dL, and an alert was provided, glucose was <70 mg/dL 85% of the time within 15 minutes of the alert. (Data not presented in table.)

When the hypoglycemic alert rate was set at 60 mg/dl, and an alert was provided, glucose was <70 mg/dl 87% of the time within 15 minutes of the alert. (Data not presented in table.)



Hypoglycemic Detection Rate

The Detection 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 hypoglycemic event. The Missed Detection Rate is the % of time the device did not alarm when the blood glucose level was at or below the alert setting within 15 minutes before and after the hypoglycemic event.

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 results for pediatrics in the G6 Study (Table 5-B), when your blood sugar goes below 70 mg/dL, you can expect your alarm to sound 81.6% of the time and not to sound approximately 18.4% of time within the 15 minute period before or after your blood sugar goes below 70 mg/dL.

Table 5-A. Hypoglycemic Alert and Detection Rate Evaluations (Adults, n=159¹)

Hypoglycemic Alert Level (mg/dL)	Alerts			Detections		
	# of alerts (n)	True Alert Rate (%)	False Alert Rate (%)	# of events (n)	Correct Detection Rate (%)	Missed Detection Rate (%)
55	1,408	66.6	33.4	642	63.9	36.1
60	2,370	74.6	25.4	1,158	74.1	25.9
70	5,079	85.5	14.5	2,365	86.0	14.0
80	8,187	89.1	10.9	3,372	92.7	7.3
90	11,147	89.4	10.6	4,287	94.6	5.4

¹ All subjects were considered in the analysis; however, not all subjects experienced hypo event.



Table 5-B. Hypoglycemic Alert and Detection Rate Evaluations (Pediatrics*, n=165¹)

Hypoglycemic Alert Level (mg/dL)	Alerts			Detections		
	# of alerts (n)	True Alert Rate (%)	False Alert Rate (%)	# of events (n)	Correct Detection Rate (%)	Missed Detection Rate (%)
55	358	31.6	68.4	66	68.2	31.8
60	521	44.1	55.9	119	73.1	26.9
70	1,054	68.0	32.0	369	81.6	18.4
80	1,794	80.5	19.5	671	88.1	11.9
90	2,746	86.3	13.7	1,030	92.8	7.2

* Includes pediatric subjects 6-17 years of age; no YSI measurements were taken for pediatric subjects 2-5 years of age.

¹ All subjects were considered in the analysis; however, not all subjects experienced hypo event



The High Glucose Alert

Estimates of how well the adjustable High Glucose Alert performs are presented in Tables 5-C and 5-D. Tables 5-C and 5-D represent the hyperglycemic alert evaluation within 15 minutes of the YSI value in the study and the hypoglycemic event evaluation within 15 minutes of each hyperglycemic alert for adults and pediatrics, respectively.

Hyperglycemic 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 results for adults in the G6 Study (Table 5-C), when 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 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 hyperglycemic event. The Missed Detection Rate is the % of time the device did not alarm when the blood glucose level was at or above the alert setting within 15 minutes before and after the hyperglycemic event.

For example, if you set the High Glucose alert to 240 mg/dL and your blood sugar rises above 240 mg/dL, how often can you expect your device to correctly alarm you? Based on results for pediatrics in the study (Table 5-D), if your blood sugar was at or above 240 mg/dL, you can expect your alarm to sound approximately 90.2% of the time within 15 minutes and an alarm not to sound approximately 9.8% of the time.



Table 5-C. Hyperglycemic Alert and Detection Rate Evaluations (Adults, n=159)

Hyperglycemic Alert Level (mg/dL)	Alerts			Detections		
	# of alerts (n)	True Alert Rate (%)	False Alert Rate (%)	# of events (n)	Correct Detection Rate (%)	Missed Detection Rate (%)
120	37,061	97.5	2.5	12,664	97.6	2.4
140	32,148	97.2	2.8	11,175	96.8	3.2
180	23,424	96.6	3.4	8,455	95.2	4.8
200	19,586	96.0	4.0	7,265	93.6	6.4
220	15,689	95.6	4.4	6,143	91.2	8.8
240	12,279	94.6	5.4	5,007	88.7	11.3
300	4,211	85.9	14.1	2,095	74.8	25.2



Table 5-D. Hyperglycemic Alert and Detection Rate Evaluations (Pediatrics*, n=165)

Hyperglycemic Alert Level (mg/dL)	Alerts			Detections		
	# of alerts (n)	True Alert Rate (%)	False Alert Rate (%)	# of events (n)	Correct Detection Rate (%)	Missed Detection Rate (%)
120	11,683	97.3	2.7	3,930	97.8	2.2
140	10,113	96.2	3.8	3,388	97.7	2.3
180	6,821	93.4	6.6	2,366	94.7	5.3
200	5,190	93.3	6.7	1,874	91.2	8.8
220	4,096	90.4	9.6	1,453	91.7	8.3
240	3,068	86.9	13.1	1,093	90.2	9.8
300	1,010	77.2	22.8	374	84.8	15.2

** Includes pediatric subjects 6-17 years of age; no YSI measurements were taken for pediatric subjects 2-5 years of age.*



Sensor Stability

Sensors can be worn for up to 10 days. Performance was estimated by calculating the percentage of G6 readings within 15 mg/dL or 15% (15/15%), 20 mg/dL or 20% (20/20%), and 40 mg/dL or 40% (40/40%), of the YSI values at the beginning (Day 1, 2), middle (Day 4, 5) and end (Day 7, 10) of the G6 lifecycle. For blood glucose values less than or equal to 70 mg/dL, the absolute difference in mg/dL between the two glucose results was calculated. For values greater than 70 mg/dL, the absolute difference (%) relative to the YSI values was calculated. In addition, the mean absolute relative difference (MARD) shows the average amount the sensor readings differ from the YSI glucose. The MARD values included in Table 6-A and 6-B show consistent accuracy and sensor stability over the 10-day life of the sensor.

Table 6-A. Sensor Stability Relative to YSI (Accuracy over Time¹) (Adults; n=159)

Wear Period	Number of paired CGM-YSI	MARD (%)	Percent within 15/15% YSI (%)	Percent within 20/20% YSI (%)	Percent within 40/40% YSI (%)
Beginning	6,696	10.9	76.5	88.0	99.6
Middle	6,464	9.2	84.3	94.6	99.8
End	6,169	9.6	82.3	92.4	99.8

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



**Table 6-B. Sensor Stability Relative to YSI (Accuracy over Time)¹
(Pediatrics*; n=165)**

Wear Period	Number of paired CGM-YSI	MARD (%)	Percent within 15/15% YSI (%)	Percent within 20/20% YSI (%)	Percent within 40/40% YSI (%)
Beginning	2167	9.9	81.2	92.1	99.8
Middle	1268	9.1	83.1	93.7	99.8
End	2337	9.4	83.1	91.1	98.5

* Includes pediatric subjects 6-17 years of age; no YSI measurements were taken for pediatric subjects 2-5 years of age.

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

Sensor Life

Sensors can be worn for up to 10 days (238 hours; 240 hours less 2 hours warm-up period). To estimate how long a sensor will work over 10 days, all sensors worn were evaluated to determine how many days/hours of readings each sensor provided.

For adults, a total of 164 sensors were evaluated. Ninety-four percent (94%) of the sensors lasted through the end of the entire wear period (e.g., Day 10) (see Figure 1-A). Among the 164 sensors evaluated, 8 sensors (4.9%) had “early sensor shut-off” where the sensor algorithm would have detected sensors that did not function as intended and shut them off.

For pediatrics, a total of 210 sensors were evaluated. Seventy-seven percent (77%) of the sensors lasted through the end of the entire wear period (e.g., Day 10) (see Figure 1-B). Among the 210 sensors evaluated, 28 sensors (13.3%) had “early sensor shut-off” where the sensor algorithm would have detected sensors that did not function as intended and shut them off.



Table 7-A. Sensor Survival Rate by Wear Day (Adults; n=164)

Wear Day	Number of Sensors	Survival Rate (%)
1	162	99.4%
2	160	98.8%
3	158	98.8%
4	155	98.8%
5	154	98.1%
6	154	98.1%
7	150	96.8%
8	146	96.2%
9	144	94.9%
10	139*	93.5%

** Includes sensors that survived more than 9.5 days (228 hours) of wear.*

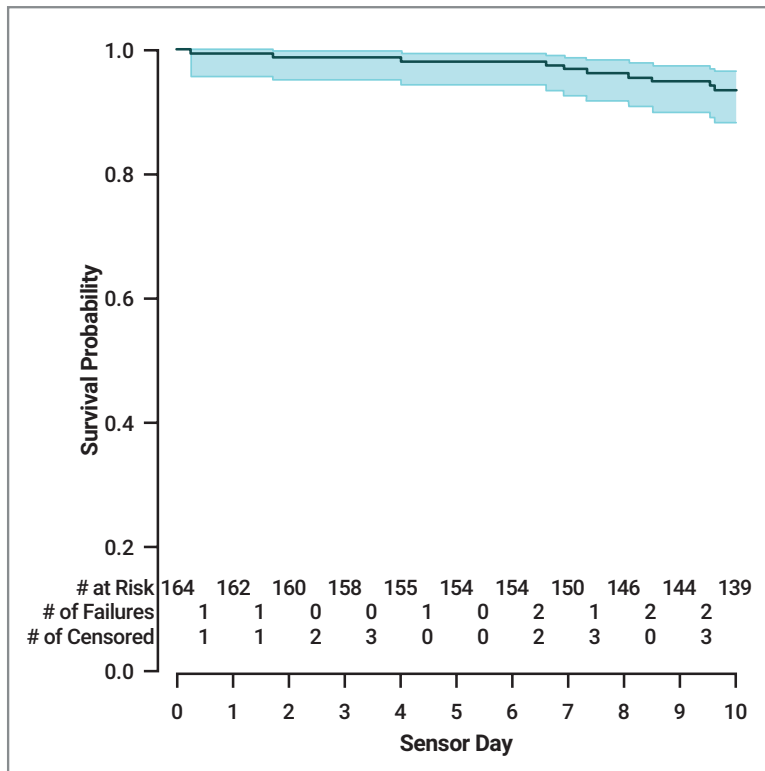


Figure 1-A. Kaplan Meier Curve of Sensor Life (Adults; N = 164)

Note: “# of Censored” refers to sensors excluded from the survival analysis due to reasons not related to the device (e.g., subject dropped out of study)



Table 7-B. Sensor Survival Rate by Wear Day (Pediatrics; n=210)

Wear Day	Number of Sensors	Survival Rate (%)
1	206	99.0%
2	204	99.0%
3	196	97.1%
4	193	95.6%
5	184	91.1%
6	175	88.6%
7	164	85.5%
8	157	83.4%
9	146	79.2%
10	142*	76.8%

** Includes sensors that survived more than 9.5 days (228 hours) of wear.*

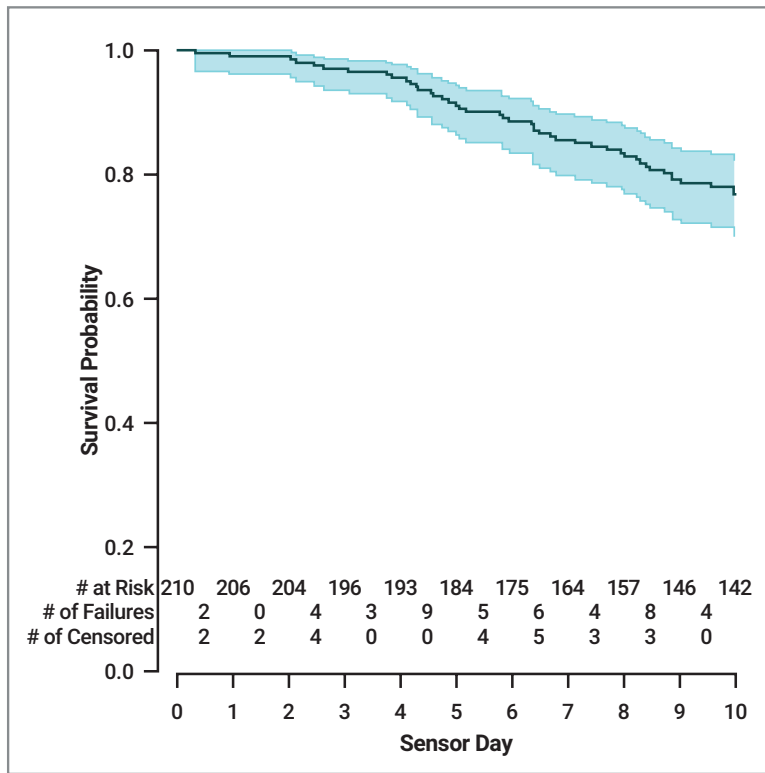


Figure 1-B. Kaplan Meier Curve of Sensor Life (Pediatrics; N = 210)
Note: “# of Censored” refers to sensors excluded from the survival analysis due to reasons not related to the device (e.g., subject dropped out of study)



Number of Readings Provided

The G6 is capable of providing a reading every 5 minutes, or up to 288 readings per day. For a variety of reasons, the G6 may not display a glucose reading and readings are “skipped.” The percentage of readings you can expect to receive from the G6 over the sensor life is 98.6%. More than 97% of the sensors captured readings at least 90% of the time. For the G6 with auto-applicator, approximately 99% of the sensors displayed reading every 5 minutes at least 90% of the time. Table 8 below describes the reading captured rate by each wear day over the sensor life.

Table 8. Reading Capture Rate by Wear Day (n=374)

Wear Day	Number of Sensors	Capture Rate (%)
1	374	97.6
2	368	98.6
3	364	98.7
4	354	98.6
5	348	98.5
6	338	98.5
7	329	98.2
8	314	97.8
9	303	97.0
10	290	96.4



Precision of System Readings

A subset of randomly selected subjects wore two Systems at the same time (n=67). This was to look at how similarly two Systems function on the same subject (sensor precision) under the same condition. Precision was evaluated by comparing the glucose readings from the two Systems worn on the same subject at the same time on the same location.

Table 9 shows that the readings from the two sensors generally agreed with each other. For adults (18+ years old) on abdomen, absolute relative difference (ARD) between the two Systems was 8.9% with coefficient of variation (CV) of 7.9%. For pediatrics (2-5 years old) on upper buttocks, paired ARD was 5.2% with CV of 4.8%.

Table 9. Precision by Wear Location

	Adults (18+ YO) Abdomen	Pediatrics (6-17 YO) Abdomen	Pediatrics (6-17 YO) Upper Buttocks	Pediatrics (2-5 YO) Upper Buttocks
CGM-CGM Matched Pairs (n)	23,019	1,255	12,230	2,638
Paired Absolute Difference (mg/dL)	14.0	14.5	16.4	9.4
Paired Absolute Relative Difference (%)	8.9	9.4	10.7	5.2
Coefficient of Variation (%)	7.9	7.6	8.5	4.8



Study 2 Overview

The purpose of the Study 2 was to assess the performance of the System with an automatic sensor applicator, which is the final G6 CGM System configuration. The automatic applicator was designed to provide more consistent sensor insertions.

The study was a prospective, multi-center, single-arm study that enrolled 76 subjects at four (4) US clinical sites. No glucose manipulations were performed in this sub-study. Subjects participated in assigned clinic sessions (Day 1, 2, 4-5, 7 and/or 10):

- Adult subjects: two (2) 12-hour clinic sessions
- Pediatric subjects 13-17 years of age: one (1) 12-hour clinic session
- Pediatric subjects 6-12 years of age: one (1) 6-hour clinic session.

The data from Study 2 was also further processed at Dexcom to assess performance of factory calibration.

Accuracy (Study 2 - Automatic Applicator)

Accuracy of the G6 is characterized by assessing its readings against blood glucose values from YSI. Accuracy of the G6 was assessed with paired G6 readings to YSI blood glucose values. For glucose value less than or equal to 70 mg/dL, the absolute difference in mg/dL between the two glucose results was calculated. For glucose value greater than 70 mg/dL, the absolute difference (%) relative to the YSI values was calculated. The percentages of total readings within 20 mg/dL or 20% over the System lifecycle and on Day 1 are provided in Table 10. The results are also presented for pediatrics and adults separately.

For example, the total number of data pairs considered in the analysis was 3,532. Of these, 92% of the System readings fall within ± 20 mg/dL of the YSI blood glucose values < 70 mg/dL and within $\pm 20\%$ of YSI blood glucose values ≥ 70 mg/dL for adults and 96% readings fall within 20/20% for pediatrics.

**Table 10. G6 Accuracy to YSI (n=62)**

Patient Population	Number of subjects	Total number of paired CGM-YSI	Percent within 20/20% YSI	Day 1 Percent within 20/20%YSI	MARD (%)
Overall	62	3,532	93.5 (89.9)	91.1	9.0
Auto-app (≥18 years)	25	2,145	91.9 (86.6)	91.0	9.8
Auto-app (6-17 years old)	37	1,387	95.8 (92.3)	91.3	7.7

Patient Comfort (Study 2 - Automatic Applicator)

Enrolled patients were asked to complete questionnaires on comfort and ease of use of the G6 with automatic applicator. The questionnaires were completed by the subjects or their parents/guardians. Subjects were asked to focus on ease or difficulty with their initial experience of sensor insertion and transmitter attachment.

Eighty-four percent (84%) of subjects felt the automatic sensor applicator was painless. All reported subjects (100%) found that the automatic applicator was easy to use and the IFU was easy to understand.

Table 11. Survey on Automated Applicator (n=76)

Question	Number of subjects (n)	Percent (95% LB)
Comfort: Painless (mild, no pain)	76	84%
Ease of use: easy (somewhat or very)	76	100%
IFU ease of use: easy (somewhat or very)	61	100%



Adverse Events

No serious adverse events (AEs) or device-related serious adverse events occurred during the studies. There was a total of 24 mild to moderate AEs which occurred during the studies (among 374 sensors). 13 of these AEs occurred due to either skin irritation, such as erythema (redness) or edema (swelling), at the sensor needle insertion area or around the adhesive area, or mild to moderate excoriation and infection.

F.2 Product Specifications

WARNING: Use of accessories, cables, adapters, and chargers other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 inches to any part of the G6 CGM system including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

WARNING: Misuse of the USB cable can present a strangulation risk.

No cleaning methods are recommended or tested for the receiver. Only wipe with a clean, dry cloth.

CAUTION: If you have difficulty reading your receiver in bright sunlight, you may need to seek a shady location.

Sensor Product Specifications

Glucose Range	40 – 400 mg/dL
Sensor Useful Life	Up to 10 days
Storage and Transport Conditions	Temperature: 36°F – 86°F Store sensors in a cool, dry place
Sterilization	Sterile by radiation



Transmitter and Receiver Product Specifications

Model	G6 Transmitter	Dexcom Receiver
Memory Storage	N/A	30 days of glucose data 7 days of tech support data
Electrical Safety Class	Internally Powered	Internally Powered
Battery Longevity (Typical)	3 months	2 days
Battery Charging Time	Non-rechargeable	3 hours
Operational Conditions	Ambient temperature is 50°F–107.6°F Humidity: 10%–95% RH	Temperature: 32°F–104°F Humidity: 15%–95% RH
Maximum Enclosure Temperature	109°F	N/A
Storage and Transport Conditions	Temperature: 32°F–113°F Humidity: 10%–95% RH	Temperature: 32°F–104°F Humidity: 10%–95% RH
Operating Altitude	-1,300 feet to 13,800 feet	-1,200 feet to 13,500 feet
Ingress Protection	IP28: Protection against insertion of large objects and immersion in water for up to 8 feet for 24 hours	IP22: Protection against insertion of large objects and vertically falling water drops
Protection Against Electrical Shock	Type BF applied part	N/A



Transmitter and Receiver Product Specifications

Model	G6 Transmitter	Dexcom Receiver
Alarm Audible Output	N/A	50 dB _{SPL} at 3 feet
TX/RX Frequencies	2.402–2.480 GHz	
Bandwidth	1.07 MHz	1.39 MHz
Maximum Output Power	1.0 mW EIRP	2.4 mW EIRP
Modulation	Gaussian Frequency-Shift Keying	
Data Rate	1 Mbps	
Data Communication Range	20 feet	

USB Charging/Download Cable* Specifications

Input/Output	5 V DC, 1A
Type	USB A to USB micro B
Length	3 feet

Power Supply/Charger Specifications

Class	II
Input	AC Input 100–240 Vac, 50/60Hz, 0.2A, 0.2A rms at 100 Vac
DC Output	5V DC, 1A (5.0 Watts)



Electromagnetic Immunity and Emissions Declaration and Guidance

The transmitter and receiver are intended for use in the electromagnetic environment specified in the next table. The customer or the user of the transmitter should ensure that it is used in such an environment.

Immunity Test	Transmitter Compliance Level	Receiver Compliance Level
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV Contact ± 15 kV Air	
Magnetic Field (50Hz) IEC 61000-4-8	30 A/m	
Electrical Fast Transient/Burst IEC 61000-4-4	N/A	± 2 kV for power supply lines
Surge IEC 61000-4-5	N/A	± 1 kV line(s) to line(s)
Voltage Dips and Interruptions IEC 61000-4-11 IEC 60601-1-11	N/A	0% 230V for 1 cycle 0% 230V for 0.5 cycle at 8 phase angles 70% 230V (30% dip in 230V) for 25 cycles 0% 230V for 250 cycles
Conducted Fields Disturbance IEC 61000-4-6	N/A	6 Vrms 150 kHz to 80 MHz
Radiated Fields Disturbance IEC 61000-4-3	10 V/m at 80 MHz to 2700 MHz (AM Modulation)	



Immunity Test	Transmitter Compliance Level	Receiver Compliance Level
Radiated and Conducted Fields Aircraft use	FAA RTCA /DO-160 edition G Section 20 Category T. Can be used on aircraft according to the directions provided by the operator of the aircraft	

Electromagnetic interference can still occur in the home health care environment as control over the EMC environment cannot be guaranteed. An interference event can be recognized by gaps in G6 readings or gross inaccuracies. The user is encouraged to try to mitigate these effects by one of the following measures:

- If the G6 reading changes by 30% or more in 5 minutes and the change does not reflect symptoms or recent actions, take a meter reading. Compare the two readings and contact Technical Support if they do not follow the 30/30 rule. The 30/30 rule is the following: If the meter shows less than 70 mg/dL, CGM should read within ± 30 points. If the meter shows 70 mg/dL and above, the CGM should read $\pm 30\%$. Example: a 202 mg/dL sensor reading and a 188 mg/dL glucose meter value = a 7% difference (this is still considered accurate). If a reading is outside of the 30/30 rule, if you want, calibrate again to more closely align your CGM and meter.
- If display device misses 20 minutes of sensor glucose data (4 readings), the Signal Loss error displays. To resolve, see Chapter 14 Troubleshooting.
- If display device shows the loading screen unexpectedly and does not display the trend screen within 3 minutes, contact Technical Support. For more information, see Chapter 14 Troubleshooting.
- If your receiver touch panel does not work for 6 minutes, contact Technical Support.



Electromagnetic Emissions Specifications

Emissions Test	Compliance
Radio Frequency Emissions CISPR 11/FCC part 15	Group 1, Class B
Radio Frequency Emissions Aircraft Use	Meets FAA RTCA /DO-160 edition G Section 21, Category M for in-cabin use.

F.3 FCC Compliance Statements

This G6 CGM transmitter and receiver comply with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may cause undesired operation

G6 Transmitter FCC ID

Transmitter Part Number	9445-02	9445-18
FCC ID	PH29588	PH29688



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Appendix G | Label Symbols

Symbols may be found on the sensor, transmitter, and receiver package labels. These symbols tell you about the proper and safe use of the Dexcom G6® Continuous Glucose Monitoring System (G6). For a listing of what they mean, see below. You may also reference the Symbols Glossary at dexcom.com/symbols.



Alternating Current



Batch/Lot Number



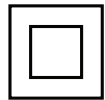
Bluetooth



Catalog Number



Caution



Class II Equipment



Consult Instructions for Use



Date of Manufacture



Direct Current



Do Not Reuse



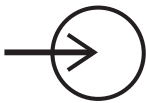
Do Not Use if Package Is Damaged



Electrical Equipment Designed Primarily for Indoor Use



Humidity Limitation



Input



IP22: Protection Against Insertion of Large Objects and Dripping Water



IP28: Protection Against Insertion of Large Objects and Immersion in Water



Keep Away from Heat



Keep Dry



Manufacturer



MR Unsafe



PN Part Number

Rx Only Prescription Required



Refer to Instruction Manual/Booklet



Serial Number



Sterile by Radiation



Temperature Limitation



Type BF Applied Part



Use By Date



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Appendix H | Alarm/Alerts Vibrations and Sounds

H.1 App: System Alerts

Screen	Default On	Default Sound	Default Vibration	Change Settings	Override Mute
	YES	Fixed Alert Beep	YES	NO	YES
	YES	Fixed Alert Beep	YES	NO	YES
	YES	Fixed Alert Beep	YES	NO	YES
	YES	Silent Alert	NO	NO	NO
	YES	Fixed Alert Beep	YES	NO	YES



Screen	Default On	Default Sound	Default Vibration	Change Settings	Override Mute
<p>Transmitter Battery Low Your transmitter battery is critically low.</p> <p>OK</p>	YES	Fixed Alert Beep	YES	NO	NO
<p>Sensor Expiring Your sensor session will end in less than 6 hours.</p> <p>You will not receive alerts, alarms, or sensor glucose readings after this time unless you replace your sensor.</p> <p>OK</p>	YES	Silent Alert	NO	NO	NO
<p>Sensor Expiring Your sensor session will end in less than 2 hours.</p> <p>You will not receive alerts, alarms, or sensor glucose readings after this time unless you replace your sensor.</p> <p>OK</p>	YES	Silent Alert	NO	NO	NO
<p>Sensor Expiring Your sensor session will end in less than 30 minutes.</p> <p>You will not receive alerts, alarms, or sensor glucose readings after this time unless you replace your sensor.</p> <p>OK</p>	YES	Fixed Alert Beep	YES	NO	NO
<p>Sensor Expired Alert Your sensor session has ended. Replace your sensor.</p> <p>OK</p>	YES	Fixed Alert Beep	YES	NO	YES



Screen	Default On	Default Sound	Default Vibration	Change Settings	Override Mute
<p>Transmitter Alert Your transmitter is not working. Pair a new transmitter.</p> <p>OK</p>	YES	Fixed Alert Beep	YES	NO	YES
<p>Transmitter Battery Low Your transmitter will expire in about 3 weeks. If you haven't already, please order a new transmitter.</p> <p>OK</p>	YES	Fixed Alert Beep	YES	NO	NO
<p>Transmitter Battery Low Your transmitter will expire in about 2 weeks. If you haven't already, please order a new transmitter.</p> <p>OK</p>	YES	Fixed Alert Beep	YES	NO	NO
<p>Low Storage The available storage on your smart device is almost full. To ensure your Dexcom CGM app functions correctly please follow these steps to free up storage: Exit this app Go to Settings > General > Usage > Manage Storage Free unnecessary storage If your smart device does not have any available storage, you will not receive any alerts, alarms, or sensor glucose readings.</p> <p>OK</p>	YES	Silent Alert	NO	NO	NO



Screen	Default On	Default Sound	Default Vibration	Change Settings	Override Mute
<p>Very Low Storage</p> <p>The available storage on your smart device is almost full. To ensure your Dexcom CGM app functions correctly please follow these steps to free up storage:</p> <p>Exit this app Go to Settings > General > Usage > Manage Storage Free unnecessary storage</p> <p>If your smart device does not have any available storage, you will not receive any alerts, alarms, or sensor glucose readings</p> <p>OK</p>	YES	Silent Alert	NO	NO	NO
<p>No Storage Error</p> <p>There is not enough available storage for the Dexcom CGM app to function correctly. Please follow these steps to free up storage:</p> <p>Exit this app Go to Settings > General > Usage > Manage Storage Free unnecessary storage</p> <p>If you do not, you will not receive any alerts, alarms, or sensor glucose readings.</p> <p>OK</p>	YES	Fixed Alert Beep	YES	NO	YES
<p>App Stopped Alert</p> <p>The Dexcom CGM app encountered a temporary error. Exit and restart the application.</p> <p>OK</p>	YES	Fixed Alert Beep	YES	NO	YES

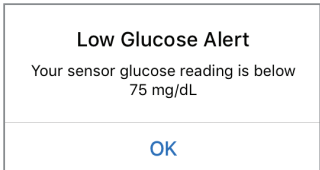
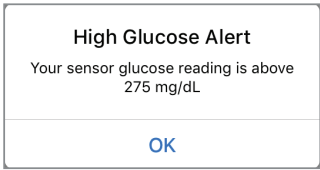
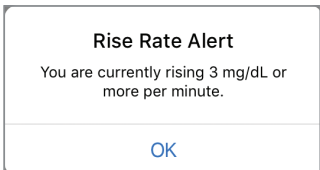


Screen	Default On	Default Sound	Default Vibration	Change Settings	Override Mute
<p>App Stopped Alert</p> <p>The Dexcom CGM app is no longer working correctly. Delete the Dexcom CGM app from this smart device. Then go to <app store> and download the Dexcom CGM app again. When you open the Dexcom CGM app again, enter your Dexcom username and password.</p> <p>OK</p>	YES	Fixed Alert Beep	YES	NO	YES

H.2 App: Glucose and No Data Alerts

Screen	Default On	Default Sound	Default Vibration	Editable Settings	Override Mute
<p>Urgent Low Glucose Alarm</p> <p>Your sensor glucose reading is below 55 mg/dL</p> <p>OK</p>	YES	Urgent Low	YES	Notify Below (default is 55 mg/dL) Repeat (default is 30 minutes) Sound (default is Urgent Low)	YES
<p>Urgent Low Soon Alert</p> <p>Act now to prevent low.</p> <p>OK</p>	YES	Urgent Low	YES	Enable/Disable (default is disabled) Repeat (default is 30 minutes) Sound (default is Urgent Low)	YES



Screen	Default On	Default Sound	Default Vibration	Editable Settings	Override Mute
	YES	Low Alert	YES	Enable/Disable (default is enabled) Notify Below (default is 80 mg/dL) Repeat (default is Never) Sound (default is Low Alert)	YES
	YES	High Alert	YES	Enable/Disable (default is enabled) Notify Above (default is 200 mg/dL) Repeat (default is Never) Sound (default is High Alert)	YES
	NO	Rise Rate	YES	Enable/Disable (default is disabled) Notify Above (default is 3 mg/dL/min) Sound (default is Rise Rate)	YES



Screen	Default On	Default Sound	Default Vibration	Editable Settings	Override Mute
	NO	Fall Rate	YES	Enable/Disable (default is disabled) Notify Below (default is 3 mg/dL/min) Sound (default is Fall Rate)	YES
	YES	Signal Loss Alert	NO	Enable/Disable Sound (default is Signal Loss Alert)	Android YES Apple NO
	YES	Signal Loss Alert	YES	Enable/Disable (default is disabled) Sound (default is Signal Loss Alert)	YES

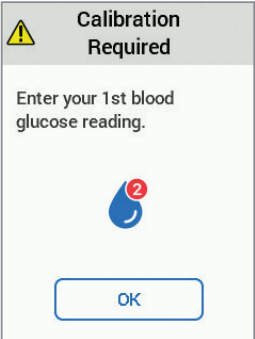
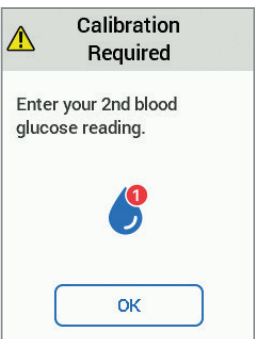
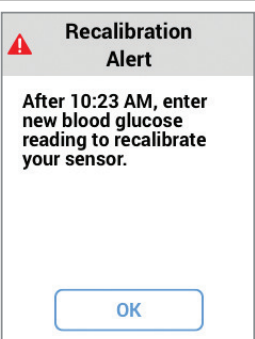
H.3 Receiver: System Alerts

No editable settings.






Screen	Default On	Default Vibration	Default Sound	Notes
<p>Low Battery</p> <p>Less than 20% of battery remaining.</p> <p>Charge receiver now.</p> <p>OK</p>	Yes	1 – 1 second vibrate	1 – 1 second medium tone beep	
<p>Sensor Warmup</p> <p>Warmup Successful Setup Complete</p> <p>Next</p>	Yes	1 – 1 second vibrate	1 – 1 second medium tone beep	Sensor warmup is done. No need to calibrate to get G6 readings.
<p>Calibration Alert</p> <p>Enter new blood glucose reading to maintain your sensor accuracy.</p> <p>Calibrate</p> <p>Dismiss</p>	Yes	Silent	Silent	






Screen	Default On	Default Vibration	Default Sound	Notes
	Yes	1 – 1 second vibrate	1 – 1 second medium tone beep	
	Yes	1 – 1 second vibrate	1 – 1 second medium tone beep	
	Yes	1 – 1 second vibrate	1 – 1 second medium tone beep	









Screen	Default On	Default Vibration	Default Sound	Notes
 Transmitter Not Found <p>Your transmitter was not found.</p> <p>Check your transmitter SN and try pairing again.</p> <p>Next</p>	Yes	1 – 1 second vibrate	1 – 1 second medium tone beep	Pairing Failed
 Sensor Failed Alert <p>Replace your sensor now.</p> <p>You will not receive alerts, alarms, or sensor glucose readings.</p> <p>OK</p>	Yes	1 – 1 second vibrate	1 – 1 second medium tone beep	First notification includes sound for: <ul style="list-style-type: none"> • Urgent Low Alarm • Urgent Low Soon Alert • Sensor Failed Alert • Transmitter Alert
 Sensor Expiring <p>Your sensor session will end in less than 23 hours.</p> <p>OK</p>	Yes	Silent	Silent	Silent Sensor Shutoff



Screen	Default On	Default Vibration	Default Sound	Notes
 Sensor Expired Alert <p>Your sensor session has ended. Replace your sensor. You will not receive alerts, alarms, or sensor glucose readings.</p> <p>OK</p>	Yes	1 – 1 second vibrate	1 – 1 second medium tone beep	Sensor Shutoff
 No Restarts <p>No alerts, alarms, or sensor glucose readings until single-use sensor replaced.</p> <p>OK</p>	Yes	1 – 1 second vibrate	1 – 1 second medium tone beep	Can't restart sensor once it has been stopped. After trying to restart, transmitter determines if sensor has been restarted and stops it if it has.
 Transmitter Battery Low <p>Your transmitter will expire in about...</p> <p>OK</p>	Yes	1 – 1 second vibrate	1 – 1 second medium tone beep	



Screen	Default On	Default Vibration	Default Sound	Notes
 Transmitter Battery Low Your transmitter battery is critically low. 	Yes	1 – 1 second vibrate	1 – 1 second medium tone beep	
 Transmitter Alert Your transmitter is not working. Replace transmitter and sensor to continue. 	Yes	1 – 1 second vibrate	1 – 1 second medium tone beep	First notification includes sound for: <ul style="list-style-type: none"> • Urgent Low Alarm • Urgent Low Soon Alert • Sensor Failed Alert • Transmitter Alert
 System Check Passed Code: xxxxx 	Yes	Silent	Silent	Recoverable error



Screen	Default On	Default Vibration	Default Sound	Notes
	Yes	1 – 1 second vibrate	1 – 1 second medium tone beep	Set time alarm

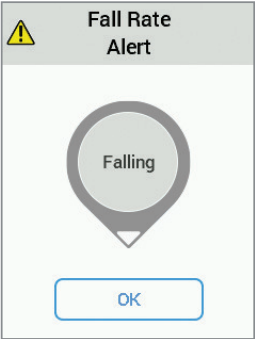
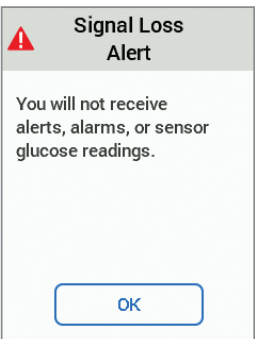
H.4 Receiver: Glucose and Signal Loss Alerts

Screen	Default On	Default Vibration	Default Sound	Editable Settings
	Yes	2 – 1/2 second vibrate, 1/2 second apart	2 – 1/2 second high tone beeps, 1/2 second apart	Can be turned on/off by the user EGV >= High alarm level value

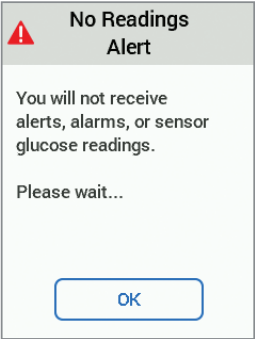
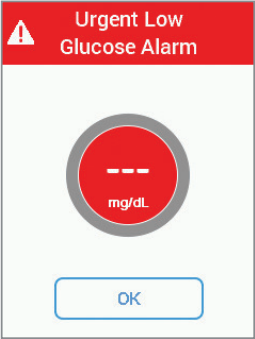


Screen	Default On	Default Vibration	Default Sound	Editable Settings
	Yes	3 – 1/3 second vibs, 1/3 seconds apart	3 – 1/3 second low tone beeps, 1/3 seconds apart	Can be turned on/off by the user EGV <= Low alarm level value
	Yes	6 vibs, progressively shorter in length	6 beeps, progressively shorter in length	Can be turned on/off by the user First notification includes sound for: <ul style="list-style-type: none"> • Urgent Low Alarm • Urgent Low Soon Alert • Sensor Failed Alert • Transmitter Alert
	No	2 – 1/2 second vibs, 1/2 second apart	2 – 1/2 second high tone beeps, 1/2 second apart	Can be turned on/off by the user



Screen	Default On	Default Vibration	Default Sound	Editable Settings
	No	3 – 1/3 second vibes, 1/3 seconds apart	3 – 1/3 second low tone beeps, 1/3 seconds apart	Can be turned on/off by the user
	Yes	1 – 1 second vibrate	1 – 1 second medium tone beep	Can be turned on/off by the user



Screen	Default On	Default Vibration	Default Sound	Editable Settings
	Yes	1 – 1 second vibrate	1 – 1 second medium tone beep	Can be turned on/off by the user
	Yes	4 – 200 ms vibrate	4 – 1/4 second low tone beeps, 1/4 seconds apart	EGV \leq 55 mg/dL First notification includes sound for: <ul style="list-style-type: none"> • Urgent Low Alarm • Urgent Low Soon Alert • Sensor Failed Alert • Transmitter alert



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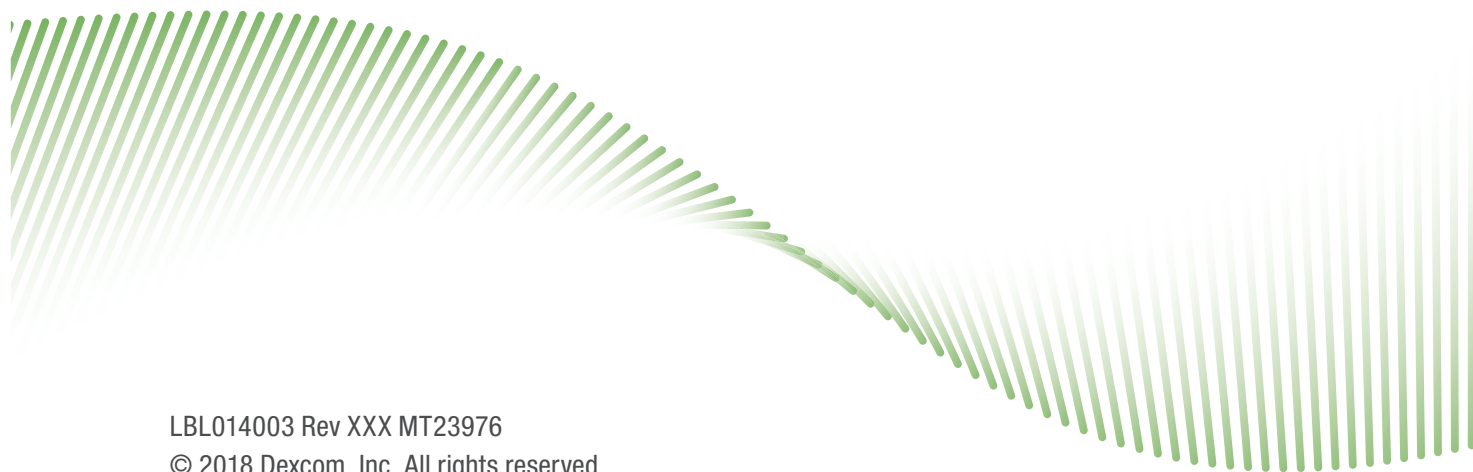
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