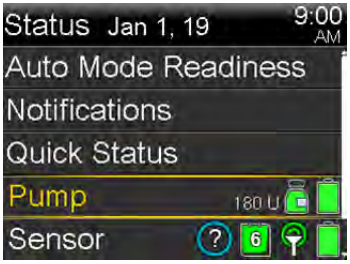
Note: Be aware that using a longer Backlight time causes your pump to use more battery power. When your pump battery is low, the timeout for the backlight on your pump screen is automatically reduced.

Where is my pump status screen?

1. Press ◎ and select Status to go to the Status screen.

   The Status screen appears.



2. From the Status screen, you can select the type of status information you want to view. For example, to see a quick status of your pump and recent insulin deliveries, go to Quick Status. For details, see *Status screens, on page 50*.

My pump is asking me to enter my settings

Certain pump errors can clear your settings and return them to their factory default values. This also happens if you intentionally clear your settings. Do not clear your settings unless directed to do so by your healthcare professional.

If you have saved your settings using the Save Settings option, you can restore them using the Restore Settings option. If you restore your settings, ensure the restored settings match the settings prescribed most recently by your healthcare professional.

The Startup Wizard appears automatically when your pump restarts. The wizard tells you to enter the following information. Have the following values ready when you begin:

- Time format, time, and date
- Active insulin time
- Basal patterns

After you enter your pump settings, you have the option of entering the following Bolus Wizard settings:

- Carb ratio
- Insulin sensitivity factor
- BG target

To enter your pump settings:

1. Select your language, and then select **Next** to go to each new screen.
2. When the Select Time Format screen appears, select a **12 Hour** or a **24 Hour** time format.
3. When the Enter Time screen appears, adjust the setting to the current time. If you are using a 12-hour clock, be sure to specify AM or PM.
4. When the Enter Date screen appears, adjust the **Year**, **Month**, and **Day** to the current date.
5. When the Active Insulin Time screen appears, enter the **Duration**.

   For details, see *About active insulin, on page 96*.
6. Enter the End time and the Rate for your first basal rate. You can enter more basal patterns after you complete the startup wizard.

   For details, see *Adding a new basal pattern, on page 67*.

   After you complete your basal pattern, a screen appears for you to review your basal information.
7. A screen appears and tells you to set up the Bolus Wizard settings. Do one of the following:
   - Select **Yes** to continue to enter your settings, and then continue to the next section.
   - Select **No** if you do not want to enter your Bolus Wizard settings. A message appears to confirm the startup is complete. Select **OK** to continue to use your pump.

To enter your Bolus Wizard settings:

1. When your pump shows a list of settings for the Bolus Wizard feature, make sure you have the values you need before you continue.

2. When the Carb Ratio screen appears, enter your carb ratio by entering the End time and the ratio. You can adjust your carb ratio at any time.

   For details, see *Changing your carb ratio, on page 94*.

3. When the Sensitivity screen appears, enter your insulin sensitivity factor by entering the End time and the mg/dL per unit. You can adjust your insulin sensitivity factor at any time.

   For details about entering insulin sensitivity factors, including how to set multiple time periods, see *Changing your insulin sensitivity factor, on page 95*.

4. When the BG Target screen appears, enter your BG Target range by entering the End time and your Lo (low) and Hi (high) values. You can adjust your BG Target ranges at any time.

   For details, see *Changing your Bolus Wizard BG target, on page 95*.

5. A message appears to confirm the startup is complete. Select **OK** to continue to use your pump.

Troubleshooting sensor issues

My pump cannot find the sensor signal

If your pump cannot find the sensor signal after 30 minutes of normal use, the Lost sensor signal alert appears. Follow the instructions on the pump screen to troubleshoot the issue, as described in the following steps:

Note: If the Alert Silence option is on and a glucose alert occurs, the notification light begins to flash and the Sensor alert occurred alert appears, but no explanatory text is shown. All silenced alerts are shown with explanatory text in the Alarm History screen.

1. Move your pump closer to your transmitter and select **OK**. It can take up to 15 minutes for your pump to find the sensor signal.

   If your pump still cannot find the sensor signal, the Possible signal interference alert appears.

2. Make sure you are away from any electronic devices that might cause interference, such as cellular phones that are not paired with the MiniMed 770G System and other wireless devices, and select **OK**.

If your pump does not find the sensor signal within 15 minutes after you selected OK, the Check connection alert appears.

3. Ensure the transmitter and sensor connection is secure, and then select **OK**.

   The "Check sensor insertion" message appears.

4. If your sensor is fully inserted, select **Yes** and skip to step 7.
5. If your sensor is not fully inserted, select **No**. A Change sensor alert appears.
6. Select **OK** and change your sensor.
7. If you selected **Yes** and your pump still cannot find the sensor signal after 15 minutes, or if your sensor graph displays "Sensor signal not found. See User Guide," call 24-Hour Technical Support for assistance.

Calibration not accepted

Calibration not accepted alert occurs when one of the following happens:

- System was unable to use the BG meter readings you entered to calibrate your sensor.
- System rejects two calibrations in a row from the same sensor.
- The transmitter was unable to receive the calibration BG meter readings from the pump due to failed sensor signal.

For details on when and how to calibrate your sensor, see *Calibrating your sensor, on page 204*.

Why does the SmartGuard suspend icon on my Home screen appear gray?

The SmartGuard suspend icon appears gray  on the Home screen when either the Suspend on low or Suspend before low feature is unavailable. The SmartGuard suspend features may be unavailable due to the following conditions:

- A suspend event has occurred recently.

  After a Suspend before low or Suspend on low event occurs, there is a period of time when the suspend functionality is unavailable. This time will vary depending on whether or not you respond to the suspend event. Typically, the suspend features will be unavailable for 30 minutes after your basal insulin delivery is resumed. For details, see *When Suspend before low is unavailable, on page 181* or *When Suspend on low is unavailable, on page 184*.

- No sensor glucose (SG) values are available.

  SG values may be unavailable because:

  - Sensor calibration is required.

    For details on when and how to calibrate your sensor, see *Calibrating your sensor, on page 204*.

  - Your pump has lost connection to the sensor.

    Move your pump closer to the sensor. For more details, see *My pump cannot find the sensor signal, on page 288*.

  - The SG value received was outside the expected range and was not displayed.

    Select **OK** to clear the alert. If the issue continues, you may need to replace the sensor.

If the issue persists, call 24-Hour Technical Support for assistance.

15

Maintenance

15 Maintenance

Cleaning your pump

CAUTION: Never use organic solvents, such as lighter fluid, nail polish remover, or paint thinner to clean your pump. Never use lubricants with your pump. When you clean your pump, be sure to keep the reservoir compartment dry and away from moisture. When you clean your pump with organic solvents, it can cause the pump to malfunction and result in minor injury.

Make sure you have the following supplies ready for cleaning your pump: three or four small, clean, soft cloths, a mixture of water with a mild detergent, clean water, 70% alcohol, and a few clean cotton tips and cotton balls.

To clean your pump:

1. Dampen a cloth with water mixed with a mild detergent.
2. Using the cloth, wipe the outside of the pump.
3. Dampen a clean cloth with water and wipe to remove any detergent residue.
4. Dry with a clean cloth.
5. Wipe your pump with a 70% alcohol wipe.
6. Using a dry clean cotton tip, remove any battery residue from the battery cap.
7. Using a dry clean cloth, remove any battery residue from the battery compartment opening.

Cleaning your transmitter

Always refer to your transmitter user guide for instructions on cleaning the transmitter.

Storing your pump

Storage mode lets you safely place your pump in storage while not in use.

Note: If you place your pump in storage mode, it is important to insert a new AA battery for 8 to 12 hours every six months to ensure that the internal battery does not discharge to a deep discharge. A battery that is deeply discharged may experience decreased performance.

WARNING: After placing your pump in storage mode, do not rely on active insulin tracked in the pump when making new Bolus Wizard calculations. Storage mode clears active insulin. Inaccurate Bolus Wizard calculations could result in inaccurate insulin delivery, and serious injury.

To place your pump in storage mode:

1. Remove the AA battery from the pump. For details, see *Removing the battery, on page 39*.

   Note: When you remove the battery, your pump issues an Insert Battery alarm for 10 minutes or until you place your pump into storage mode.

2. Press and hold ↩ until your screen turns off.

   CAUTION: Never expose the pump to temperatures below -4°F (-20°C) or above 122°F (50°C) while it is in storage without a battery. Storing your pump in temperatures outside of this range can damage your pump.

To wake your pump from storage mode:

1. Insert a new AA battery into your pump. For details, see *Inserting the battery, on page 38*.

   A Pump Error message appears.

2. Select **OK**.

   Your pump displays a Power Loss alarm.

3. Select **OK**.

   The Time & Date screen appears.

4. Enter the current **Time**, **Time Format**, and **Date**.

5. Select **Save**.

   Your pump displays an Active Insulin Cleared alert.

6. Select **OK**.

   Make sure that all of your settings, such as basal rate, are set as desired. If you need to, reapply your last saved settings by using the Restore Settings option as instructed in *Restoring your settings, on page 163*.

7. You must repeat the pairing process for your transmitter and meter. For transmitter details, see *Pairing your pump and transmitter, on page 199*. For meter details, see *Pairing your pump and meter, on page 134*.

Storing your transmitter

Always refer to your transmitter user guide for instructions on storing your transmitter.

Pump disposal

Contact 24-Hour Technical Support for information on proper disposal of the MiniMed 770G insulin pump. Always follow local laws and regulations for the disposal of medical devices.

16

Product specifications and safety information

16 Product specifications and safety information

This chapter provides detailed product specifications and safety information.

Product specifications

Alarm and alert escalation

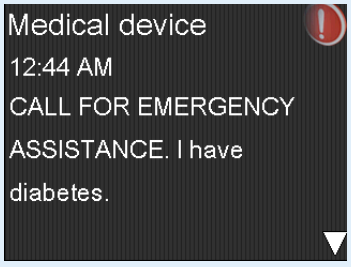
The following alerts may escalate to a siren if not cleared:

- Alert before high
- Alert before low
- Alert on high
- Alert on low
- Basal delivery resumed
- BG not received
- Calibration not accepted
- Calibrate now
- Change sensor
- Check connection
- Lost sensor signal
- No calibration occurred
- Possible signal interference
- High SG
- Rise Alert
- Sensor expired
- Sensor signal not found
- Low SG XX mg/dL (XX represents 50 mg/dL or below)
- Sensor updating
- Transmitter battery depleted

For alerts that escalate to a siren, the pump will begin to siren if the alert is not cleared in 10 minutes. Before the siren occurs, your pump will beep, vibrate, or both, depending on your audio settings.

Minutes	Audio	Audio and vibration	Vibration
0	Audio	Audio and vibrate	Vibrate
1	Audio	Audio and vibrate	Vibrate
2	Audio	Audio and vibrate	Vibrate
3	Audio	Audio and vibrate	Vibrate
4	Audio	Audio and vibrate	Vibrate
5	Audio	Audio and vibrate	Vibrate
6	Audio and vibrate	Audio and vibrate	Audio and vibrate
7	Audio and vibrate	Audio and vibrate	Audio and vibrate
8	Audio and vibrate	Audio and vibrate	Audio and vibrate
9	Audio and vibrate	Audio and vibrate	Audio and vibrate
10	Siren and vibrate	Siren and vibrate	Siren and vibrate

Note: The Medical device alarm sirens immediately when this screen appears.



Altitude range

- Pump operating range is from 10.2 psiA (70.33 kPa) to 15.4 psiA (106.18 kPa)
- Storage range is from 7.2 psiA (49.64 kPa) to 15.4 psiA (106.18 kPa)

Audio frequency

The following table lists the various audible tones and their corresponding frequencies:

Tone name	Frequency
Alarm	1655 Hz followed by 3310 Hz
Alternate Alarm	1850 Hz
Siren (escalated alarm)	1655 Hz, followed by 3310 Hz
Alert	934 Hz
High Sensor Glucose	1312 Hz, followed by 1410 Hz, 1500 Hz, 1619 Hz, 1722 Hz
Low SG	1722 Hz, 1619 Hz, 1500 Hz, 1410 Hz, 1312 Hz
Lost SG	1485 Hz, followed by 1395 Hz, 1320 Hz, 1395 Hz
Message tone	1655 Hz
Reminder tone	934 Hz
Fill tubing tone	1850 Hz
Bolus delivery cancellation tone	1485 Hz, followed by 1655 Hz and 1485 Hz
Loading complete tone	934 Hz
Reservoir loading in progress tone	1850 Hz
Easy Bolus activation	1045 Hz
Easy Bolus step 1 increment	1175 Hz
Easy Bolus step 2 increment	1320 Hz
Easy Bolus step 3 increment	1395 Hz
Easy Bolus step 4 increment	1570 Hz
Easy Bolus step 5 increment	1760 Hz

Backlight

Type	LED (Light-emitting Diode)
Time out	15 seconds (default), 30 seconds, one minute, three minutes
Time out when battery is low	15 seconds (default), 30 seconds

Basal delivery

Delivery rate range	0 to 35 units per hour or the Max Basal Rate amount, whichever is lower.
Max Basal Rate default	2 units per hour
Basal patterns	Maximum of 8 patterns. Each pattern covers a 24-hour period and can have up to 48 rates. Rates are set in 30-minute increments.
Basal pattern names	Fixed names: Basal 1, Basal 2, Basal 3, Basal 4, Basal 5, Workday, Day Off, Sick Day
Increments	• 0.025 units per hour for basal amounts in the range 0 to 0.975 units • 0.05 units per hour for basal amounts in the range 1 to 9.95 units • 0.1 units per hour for basal amounts of 10 to 35 units

BG Target

Maximum targets	8
Range	60 to 250 mg/dL
Default value for High blood glucose (BG) targets and Low BG targets	None

Note: Auto Mode uses a fixed BG Target of 150 mg/dL.

BG meter value

The most recent BG value received from the meter. If you are using an Accu-Chek Guide Link meter, this value appears on the Home screen when the Sensor feature is off. This value also appears in the Bolus Wizard screen when setting up a bolus.

Expiration	12 minutes
Range	20 to 600 mg/dL

Bolus delivery

Bolus Speed options	• Standard: 1.5 units/minute • Quick: 15 units/minute
Bolus programming increments	• 0.025 units • 0.05 units • 0.1 units
Fluid delivered/stroke	• 0.25 µL (microliter) for 0.025 unit pump stroke • 0.5 µL for 0.05 unit pump stroke • 2.0 µL for 0.2 unit pump stroke

Bolus Wizard feature default settings

Item	Default	Limits	Increments
Carb units	grams	-	-
Insulin to carb ratio	None	1–200 g/u	0.1 g/u for 1–9.9 g/u; 1 g/u for ratios of 10 g/u to 200 g/u
Insulin Sensitivity Factor	None	5–400 mg/dL	1 mg/dL
BG Target	None	60–250 mg/dL	1 mg/dL
Active Insulin Time	4 hours	2 to 8 hours	15 minutes

Bolus Wizard feature specifications

There are four different formulas the Bolus Wizard feature uses to estimate a bolus, depending on your current BG. The following formulas apply only when the carb units are in grams.

1. If your current BG is greater than your High BG Target, the Bolus Wizard feature subtracts active insulin from the BG correction estimate, then adds this to the food estimate to get the total bolus estimate. However, if the result of subtracting active insulin from BG correction estimate is a negative number (less than zero), the total bolus estimate is based only on the food estimate.

(food estimate) (correction estimate)

$$\text{total bolus estimate} = \frac{A}{B} + \frac{C - D}{E} - \text{active insulin}$$

where: A = food (grams)
B = carb ratio
C = current BG
D = High BG Target
E = insulin sensitivity

Food estimate:

Carb grams ÷ Carb ratio = Units of insulin

Correction estimate:

(Current BG - High BG Target) ÷ Insulin sensitivity - Active insulin = Units of insulin

Total bolus estimate:

Food estimate + Correction estimate = Units of insulin

2. If your current BG is less than your Low BG Target, the Bolus Wizard feature adds the BG correction estimate to the food estimate to get the total bolus estimate.

(food estimate) (correction estimate)

$$\text{total bolus estimate} = \frac{A}{B} + \frac{C - D}{E}$$

where: A = food (grams)
B = carb ratio
C = current BG
D = Low BG Target
E = insulin sensitivity

Food estimate:

Carb grams ÷ Carb ratio = Units of insulin

Correction estimate:

(Current BG - Low BG Target) ÷ Insulin sensitivity = Units of insulin

Total bolus estimate:

Food estimate + Correction estimate = Units of insulin

3. If your current BG is within your High or Low BG Target, the total bolus estimate is based only on the food estimate.

$$\text{total bolus estimate} = \text{(food estimate)} = \frac{\text{food (grams)}}{\text{carb ratio}}$$

Food estimate:

Carb grams ÷ Carb ratio = Units of insulin

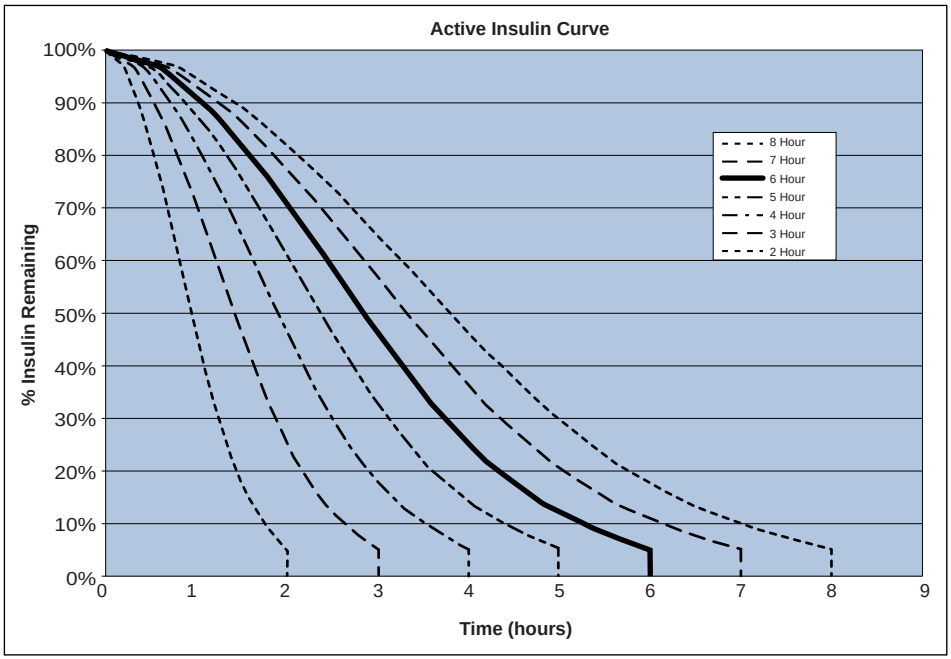
Note: When the current BG is below the Low BG Target, an active insulin amount is not considered in the Bolus Wizard feature calculations.

Total bolus estimate = Food estimate

4. If you do not enter a BG, the total bolus estimate is based only on the food estimate.

Following are some notes about using the Bolus Wizard feature:

- If a Dual Wave bolus is less than the estimate due to the Max Bolus limit or a change that you make, the Square portion is reduced first.
- Based on the Active Insulin Time setting you choose, your pump keeps track of how much insulin is still active in your body. This is shown as Active Insulin or Act. Insulin on the Home screen, Bolus screen, Manual Bolus screen, Preset Bolus, and Daily History screens. This prevents stacking of insulin, and lowers the chances of hypoglycemia.
- The Bolus Wizard feature may utilize your current BG measurement, carbohydrate consumption, and active insulin to calculate your estimated bolus.
- The following Active Insulin Curve represents how long a bolus of insulin lowers your glucose after the bolus is given. The percentage of insulin remaining lowers at varying rates depending on how long the insulin is active in your body.



Graph adapted from Mudaliar and colleagues, Diabetes Care, Volume 22, Number 9, Sept. 1999, page 1501.

Carb ratios

Maximum ratio settings	Range
8	1 to 200 grams/unit

Delivery accuracy

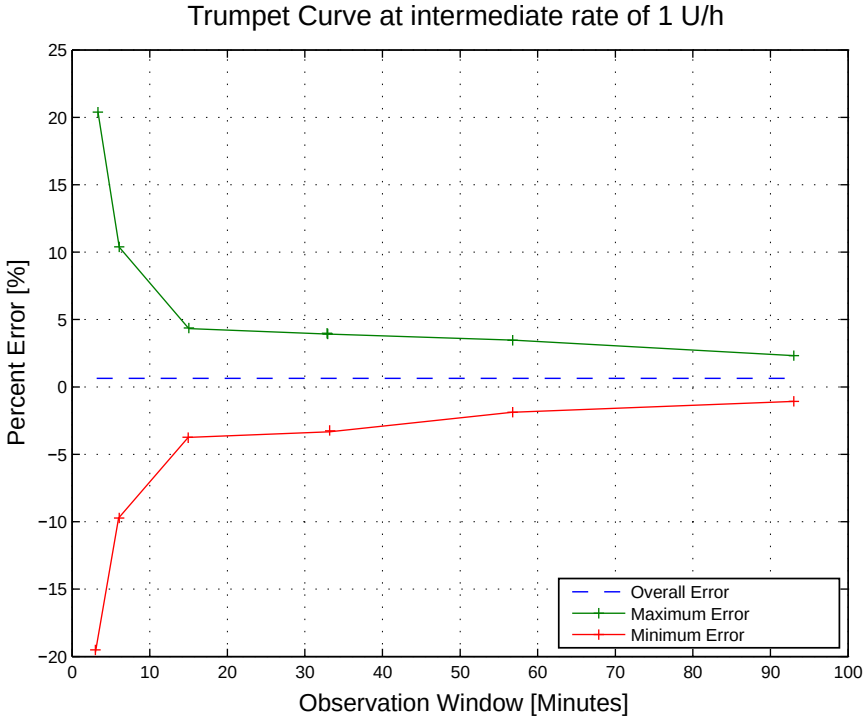
- For a basal rate of 1.0 U/h, the delivery accuracy is ±5%.

  For a basal rate of 0.025 U/h, the delivery accuracy is ±10%.

  Delivery accuracy for bolus volumes < 0.1 unit is ±20% and delivery accuracy for bolus volumes ≥ 0.1 unit is ±5%.

- All Normal boluses are delivered within 16 minutes, 41 seconds ±3 seconds at Standard rate (25 units, at 1.5 units per minute), and within 1 minute, 41 seconds ±3 seconds at Quick rate (25 units, at 15 units per minute).

- The maximum infusion pressure generated and the occlusion threshold pressure using a 3.0-mL reservoir is 13.15 psi (90.67 kPa). The average resulting bolus volume generated upon clearing the occlusion is 0.0112 mL (equivalent to 1.12 units of U-100 insulin).
- The following image is a representative delivery accuracy curve. The Trumpet Curve represents the maximum percentage change from the expected insulin dosage for a given time interval, known as the observation window, during the infusion of insulin. The upper curve corresponds to positive changes, and the lower curve corresponds to negative changes.



Easy Bolus feature

The Easy Bolus feature lets the user set up and deliver a Normal Bolus when the pump is in Sleep Mode. This is done using ∧ and with the help of audio and vibration cues.

Audio mode range	0 to 20 increments or Max Bolus limit, whichever comes first

Vibrate mode range	0 to 20 increments or Max Bolus limit, whichever comes first
Default step size	0.1 unit
Adjustable step size	0.1 to 2 units per increment up to Max Bolus limit

Environmental conditions

The MiniMed 770G insulin pump system is designed to withstand most conditions encountered in your daily life. For more details about environmental conditions, such as exposure to magnetic fields and radiation, waterproof capabilities, and extreme temperatures, see *User safety, on page 7*.

- Pump storage temperature range without a AA battery is from -4°F (-20°C) to 122°F (50°C).
- Pump operating temperature range is from 41°F (5°C) to 104°F (40°C).
- Operating air pressure range is from 10.2 psi (700 hPa) to 15.4 psi (1060 hPa).
- Storage air pressure range is from 7.2 psi (496.4 hPa) to 15.4 psi (1060 hPa)
- Relative humidity (RH) range during operation is from 20% to 90%.
- RH range during storage is from 5% to 95%.

Essential performance

In the specified environmental conditions, the insulin pump maintains essential performance of the following functionalities:

- Delivery accuracy
- Occlusion detection
- Empty reservoir detection
- Detection of power loss
- Pump therapy status
- Notification annunciation and display

Filling the infusion set and cannula

- The cannula can be filled from 0.025 units to 5.1 units, in increments of 0.025 units.
- The standard fill rate is 1.5 units per minute.

The quick fill rate is 15 units per minute.

- When filling the tubing, a warning occurs at 30 units. A second warning occurs at 40 units instructing you to rewind the pump.
- Insulin used to fill the infusion set is recorded in the Daily History.

Infusion pressure

The maximum infusion pressure and occlusion pressure are 25 psi (172.4 kPa).

Insulin delivery default settings

Bolus settings

Item	Default setting	Limits	Increments
Bolus Wizard feature:	Off	-	-
Easy Bolus feature:	Off	-	-
Easy Bolus step size:	0.1 U	0.1 U to 2 U	-
Bolus increment:	0.10 U	0.025 U 0.05 U 0.10 U	-
Dual/Square bolus:	Off	-	-
Max bolus:	10 U	0 to 25 U (per single bolus)	-
Bolus BG Check Reminder:	Off	0:00 to 5:00	0:30

Basal settings

Item	Default setting	Limits	Increments
Max Basal Rate	2 U/h	0–35 U/h	0.025 U for 0.025–0.975 U/h 0.05 U for 1.00–9.95 U/h 0.1 U for rates of 10.0 U/h or more
Basal Rate	0.000 U/h	0.000 U/h to Max Basal Rate setting	0.025 U for 0.025–0.975 U/h 0.05 U for 1.00–9.95 U/h 0.1 U for rates of 10.0 U/h or more
Temp Basal Type	Percent	Percent, Rate	N/A
Temp Basal Percent	100%	0–200%	5%
Temp Basal Rate	Current basal rate	0.0 U/hr to Max Basal Rate	0.025 U for 0.025–0.975 U/h 0.05 U for 1.00–9.95 U/h 0.1 U for rates of 10.0 U/h or more

Insulin sensitivity factor

Maximum settings	8
Default	None. Insulin sensitivity is set during Startup of the Bolus Wizard feature.
Range	5 to 400 mg/dL/unit

Note: The insulin sensitivity factor only applies while the pump is in Manual Mode.

Low Reservoir reminder

The values are based on amount shown, not actual amount.

Alert range	Increment	Default value
First reminder occurs at 5 to 50 units. Second reminder occurs at 50 percent of the remaining specified amount. The second reminder is automatic and cannot be changed by the user.	1 unit	20 units

Max Bolus

Range	0 to 25 units
Default	10 units

Normal bolus

Range is 0.025 to 25 units of insulin, and limited by the Max Bolus setting.

Occlusion detection

When occlusion is detected, the Insulin flow blocked alarm occurs. The occlusion alarm is triggered by an average of 2.23 units of missed insulin (standard bolus) or 1.97 units of missed insulin (quick bolus). The MiniMed 770G insulin pump is intended for use with U-100 insulin. This table shows occlusion detection for four different situations when using U-100 insulin.

Rate	Minimum time before alarm	Average time before alarm	Maximum time before alarm
bolus delivery (10 units at standard speed)	71 seconds	95 seconds	136 seconds
bolus delivery (10 units at quick speed)	9 seconds	10 seconds	14 seconds
basal delivery (1.0 u/h)	2.00 hours	2.50 hours	3.80 hours
basal delivery (0.025 u/h)	123.38 hours	142.03 hours	178.33 hours

Note: Certain factors, such as ambient temperature changes or the presence of air in the infusion set or the reservoir, can delay an occlusion alarm.

Percent temp basal

The default value is 100 percent of basal programming. For example, if you program six units of basal per day, the default temp basal will be six units per day.

Range	0 to 200%
Default	100% of basal programming
Increment	5%

Program safety checks

A single fault condition will cause the pump to suspend insulin delivery. Maximum infusion with a single fault condition is 0.2 units.

Pump dimensions

The pump dimensions in inches are no greater than 3.78 length x 2.11 width x 0.96 depth.

The pump dimensions in centimeters are no greater than 9.60 length x 5.36 width x 2.44 depth.

Pump memory

User settings and pump history are stored in non-volatile memory which will retain data. The memory size will hold 90 days of pump history before it becomes full and has to be written over. The viewable history on the pump is 30 days. This information can be accessed on the History screen.

Pump weight

The mass of the insulin pump without battery and consumables is less than 106 grams.

Sensor default settings

High sensor settings			
Item	**Default setting**	**Limits**	**Increments**
High SG alert limit	250 mg/dL	100 to 400 mg/dL	5 mg/dL
Alert before high	Off	-	-

High sensor settings			
Item	**Default setting**	**Limits**	**Increments**
Alert on high	Off	-	-
Time before high	15 minutes	5 to 30 minutes	5 minutes
Rise Alert	Off	-	-
Rise Limit	Two up arrows	• 1 up arrow (1 mg/dL/min) • 2 up arrows (2 mg/dL/min) • 3 up arrows (3 mg/dL/min) • Custom limit (1.0 to 5.0 mg/dL/min)	
High Snooze	1 hour	5 minutes to 3 hours	5 minutes

Low sensor settings			
Item	**Default setting**	**Limits**	**Increments**
Low SG alert limit	60 mg/dL	50 to 90 mg/dL	5 mg/dL
Suspend before low	Off	-	-
Suspend on low	Off	-	-
Alert before low	Off	-	-
Alert on low	Off	-	-
Low Snooze	20 minutes	5 minutes to 1 hour	5 minutes
Resume basal alert	Off	-	-

Auto Mode settings			
Item	**Default setting**	**Limits**	**Increments**
Auto Mode	Off	-	-
Auto Mode BG alert	On	-	-

Wireless communication

The MiniMed 770G insulin pump communicates using Bluetooth wireless technology.

FCC notice

This device complies with the United States Federal Communications Commission (FCC) and international standards for electromagnetic compatibility. This device complies 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. These standards are designed to provide reasonable protection against excessive radio frequency interference, and prevent undesirable operation of the devices from unwanted electromagnetic interference.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Decrease the distance between the transmitter and the insulin pump to 6 feet (1.8 meters) or less.
- Decrease the distance between the meter and the insulin pump to 6 feet (1.8 meters) or less.
- Increase the separation between the transmitter and the device that is receiving/emitting interference.

IMPORTANT: Do not change or modify the internal RF transmitter or antenna unless expressly approved by Medtronic Diabetes. Doing so could interfere with your ability to operate the equipment.

Note: Harmful interference is defined by the FCC as follows. Any emission, radiation or induction that endangers the functioning of a radio navigation service or of other safety services or seriously degrades, obstructs or repeatedly interrupts a radio communications service operating in accordance with FCC rules.

IEC60601-1-2:4th Edition notice

IEC60601-1-2:4th Edition; Special EMC Precautions for Medical Electrical Equipment

1. Special Precautions regarding Electromagnetic Compatibility (EMC): This body worn device is intended to be operated within a reasonable residential, domestic, public or work environment, where common levels of radiated "E" (V/m) or "H" fields (A/m) exist; such as cellular phones that are not paired with the MiniMed 770G System, Wi-Fi, Bluetooth wireless technology, electric can openers, microwave and induction ovens. This device generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the provided instructions, may cause harmful interference to radio communications.
2. Portable and mobile RF communications equipment can affect Medical Electrical Equipment as well. If you encounter RF interference from a mobile or stationary RF transmitter, move away from the RF transmitter that is causing the interference.

IEC60601-1-2:4th Edition; 5.2.1.1

The MiniMed 770G insulin pump should not be used adjacent to other electrical equipment. If adjacent use becomes necessary, the MiniMed 770G insulin pump should be observed to verify normal system operation.

Guidance and manufacturer's declaration

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The MiniMed 770G insulin pump is intended for use in the electromagnetic environment specified below. The customer or the user of the MiniMed 770G insulin pump should make sure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions Test: 47 CFR Part 15, Subpart C Section 15.247/FCC Part 15 Subpart B Section 15.109	• 6 dB and 99% Bandwidths: Complies • Maximum Output Power: Complies • TX Spurious Emissions: Complies • Power Spectral Density: Complies • Radiated Emission & Band edge: Complies	The MiniMed 770G insulin pump must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	
RF emissions CISPR 11 (2009)+A1	Complies Group 1 Class B	The MiniMed 770G insulin pump is suitable for use in aircraft and in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RTCA DO 160G (2010) 20.5 and 21.5	Complies	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The MiniMed 770G insulin pump is intended for use in the electromagnetic environment specified below. The customer or the user of the MiniMed 770G insulin pump should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2, 60601-1-2	±8 kV contact ±2, 4, 8, 15 kV air	±8 kV contact ±2, 4, 8, 15 kV air	For use in a typical domestic, commercial, or hospital environment.
Conducted disturbances induced by RF fields	3 Vrms 150 kHz to 80 MHz 6 Vrms ISM bands between 150 kHz to 80 MHz	Not applicable	Requirement does not apply to this battery powered device.
Electrical fast transient/ burst IEC 61000-4-4	±2 kV 100 kHz repetition frequency	Not applicable	Requirement does not apply to this battery powered device.
Surge IEC 61000-4-5	Line to Line: ±0.5 kV, ±1 kV Line to Ground: ±0.5 kV, ±1 kV, ±2 kV	Not applicable	Requirement does not apply to this battery powered device.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
Voltage dips, short interruptions, and voltage variations on power supply lines IEC 61000-4-11	0% U_T; 0.5 cycle (at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°) 0% U_T; 1 cycle (at 0°) 70% for 25/30 cycles (at 0°) 0% for 250/300 cycles	Not applicable	Requirement does not apply to this battery powered device.
Power frequency (50/60 Hz) electromagnetic field IEC 61000-4-8, IEC 60601-1-2	30 A/m (continuous field at 60 seconds)	30 A/m 400 A/m per IEC 60601-2-24: 1998	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Proximity fields from RF wireless communications equipment IEC 61000-4-3	IEC 60601-1-2;2014, Table 9	IEC 60601-1-2:2014, Table 9	For use in a typical domestic, commercial, or hospital environment.
Note: *U_T is the a.c. mains voltage prior to application of the test level.*			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The MiniMed 770G insulin pump is intended for use in the electromagnetic environment specified below. The customer or user of the MiniMed 770G insulin pump should assure that it is used in such an electromagnetic environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Radiated RF IEC 61000-4-3 IEC 60601-1-2	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the MiniMed 770G insulin pump, including cables, than the recommended separation distance of 12 inches (30 cm). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Note: *The table is per IEC (EN) 60601-1-2 Edition 4.*			

Icon glossary

For a definition of the symbols displayed on the device and package labels, please see www.medtronicdiabetes.com/symbol-definitions.

17

670G Performance Data and Technical Information

17 670G Performance Data and Technical Information

I. Performance data for users 14 years old and older

A. Device performance for users 14 years and older

The MiniMed 670G System can automatically increase or decrease insulin delivery when informed by continuous glucose monitoring (CGM) values; however, the user must still calculate and administer meal boluses. Previous clinical studies that did not involve the MiniMed 670G System have shown that other integrated insulin pump and CGM systems may provide better diabetes management, compared with multiple daily injections or with the pump alone. Some studies also suggest that when you pair pump therapy with the information provided by the sensor, it may significantly improve HbA1C levels without increasing the risk of hypoglycemia.[1, 2, 3]

The MiniMed 670G System also features SmartGuard technology with different types of diabetes management. There are two levels of SmartGuard technology:

- The first level of SmartGuard technology automatically suspends insulin when the sensor reaches a preset low limit or before the low limit is reached, referred to as Suspend on low and Suspend before low, respectively. When a

1 Bergenstal RM, Tamborlane WV, Ahmann A, et al. Effectiveness of sensor-augmented insulin-pump therapy in type 1 diabetes [STAR3 Study]. N Engl J Med.2010;363:311–320.

2 Battelino T, Conget I, Olsen B, et al. The use and efficacy of continuous glucose monitoring in type 1 diabetes treated with insulin pump therapy [SWITCH study]. Diabetologia. 2012 Dec;55(12):3155-62. doi: 10.1007/s00125-012-2708-9. Epub 2012 Sept 11.

3 Bergenstal RM, Klonoff DC, Bode BW, et al. Threshold-based insulin-pump interruption for reduction of hypoglycemia [ASPIRE in-home study]. N Engl J Med. 2013;369(3):224-232.

Suspend on low event occurs, you can choose to continue to keep insulin suspended, or you can choose to resume insulin delivery. When a Suspend before low occurs, insulin delivery will automatically resume when the sensor glucose (SG) levels recover. The Suspend on low and Suspend before low features are optional features available when the system is in Manual Mode.

- The second level of SmartGuard technology automatically calculates insulin dose using CGM data, referred to as Auto Mode. The Auto Mode feature can automatically increase or decrease the amount of insulin delivered based on sensor values. Elevated SG readings result in increased delivery rates and decreased SG values result in decreased insulin delivery rates.

During Auto Mode operation, the user must deliver meal boluses by entering the estimated amount of carbohydrates for meals at the time they are eaten. Failure to deliver meal boluses in association with meals during Auto Mode operation can result in significant post meal hyperglycemia.

Since adjustments to insulin delivery rates when the system is in Auto Mode are based on SG readings, it is critical to monitor blood glucose (BG) values using a home glucose meter regardless of whether the system is operating in the Manual Mode or the Auto Mode. If these home glucose meter measurements indicate hypoglycemia or hyperglycemia, you must follow your physician's instruction for treating these conditions and you should not rely on the MiniMed 670G System to automatically restore your glucose levels to normal.

The SmartGuard technology contains two insulin delivery suspend options: Suspend on low and Suspend before low. The Suspend on low was previously evaluated and is currently available on commercially available pumps (MiniMed 530G Pump and MiniMed 630G Pump).

The Suspend before low feature was evaluated for safety in a multi-center, single-arm, in-clinic study. Study subjects included persons aged 14 to 75 years diagnosed with type 1 diabetes mellitus who were on pump therapy at the time of screening. A total of 71 subjects were subjected to hypoglycemic induction, followed by an observation period. For hypoglycemic induction, the target was set to 65 mg/dL, using the rate of change basal increase algorithm. Suspend before low was activated with the Low Limit setting for Suspend before low ON set to 65 mg/dL, and the subject was observed with frequent sample testing (FST) for a

maximum of 19 hours. The observation period included the suspension period, the insulin resumption period, and if applicable, an insulin resuspension after insulin delivery resumed.

Five adverse events were reported during the study. Four adverse events were neither device nor procedure related. One adverse event was procedure related.

Data from this in-clinic study demonstrated that the Suspend before low feature is safe to use. Study success criteria, as defined in the protocol, were met (i.e. there were no device related serious adverse events, no diabetic ketoacidosis events related to the Suspend before low feature, and no unanticipated adverse device effects).

The second level of SmartGuard technology was evaluated under a pivotal, single-arm, multi-center, home and hotel study in subjects with type 1 diabetes on insulin pump therapy. Study subjects included persons aged 14 to 75 years diagnosed with type 1 diabetes mellitus for two years or more that had used pump therapy for more than 6 months prior to screening. Study subjects had an HbA1C value of less than 10.0% at the time of screening.

This study consisted of a 2-week run-in phase and a 3-month study phase. A total of 124 subjects used the MiniMed 670G System in Manual Mode only first, before transitioning to Auto Mode during the study phase. In addition to system use at home, the study phase included a 6-day and 5-night hotel stay during which subjects underwent daytime and nighttime FST for a total of approximately 24 hours. Subjects were allowed to eat as they normally would, and participated in a daily exercise or activity regimen for a minimum of 4 hours per day, spread throughout the day, during the hotel stay. Two of the 124 subjects did not participate in a hotel stay. One of these two subjects withdrew from the study.

The MiniMed 670G System was used for 12,389 patient days. No serious adverse events, diabetic ketoacidosis (DKA), or severe hypoglycemia were reported during the study. Compared to Manual Mode use during the run-in phase, use of the system was associated with a higher percentage of SG values within the range of 71–180 mg/dL and lower percentage of SG values in the low and high glucose ranges. A change in mean A1C from 7.4 ± 0.91 (median 7.3) at the start of the study to 6.9 ± 0.61 (6.8) at the end of the study was observed. This observation was associated with a modest increase in the mean total daily dose of insulin (47.5 baseline to 50.9) and mild increase in mean weight (76.9 baseline to 77.6).

CAUTION: Note that since this study did not include a control group, no claims regarding effectiveness can be made. However, the study does support that the device is relatively safe for use.

Device related adverse events reported during the different phases of the pivotal trial are listed in the following table.

Table A-1: Device Related Adverse Events

Event	Run-In Period	Study Period
Severe hyperglycemia	5	12
Hyperglycemia	0	6
Skin irritation	3	0
Irritation on sensor site	0	1
Rash	0	1

The following table shows the time spent per day in specific glucose ranges during the run-in and study phases by all subjects.

Table A-2: Time Spent in Specific Glucose Ranges During the Run-In and Study Phases by All Subjects

Glucose Range (mg/dL)	Run-In Phase Time in Glucose Range Mean ±SD	Study Phase Time in Glucose Range Mean ±SD
≤50	12.8 mins ± 14.5 mins	7.7 mins ± 7.6 mins
≤60	35.2 mins ± 31.2 mins	19.9 mins ± 14.8 mins
≤70	1 hr 18.6 mins ± 55.3 mins	42.9 mins ± 25.4 mins
70–180	14 hrs 54.4 mins ± 3 hrs 1.4 min	16 hrs 2.2 mins ± 2 hrs 35.6 mins
>180	6 hrs 2.1 mins ± 2 hrs 52.7 mins	5 hrs 20.7 mins ± 1 hr 46.9 mins
>250	1 hr 30.4 mins ± 1 hr 32.3 mins	1 hr 12.1 mins ± 52.6 mins
>300	29.6 mins ± 51.7 mins	21.1 mins ± 22.2 mins
>350	8.9 mins ± 20.7 mins	6.1 mins ± 8.35 mins

The following table shows the range of changes in HbA1C observed in the study and indicates the number of subjects that demonstrated each type of change in HbA1C observed.

Table A-3: Number of Subjects with Change in HbA1C at Different Baselines

HbA1C Change Range	Number of Subjects (% of Subjects) with Change in A1C				
Baseline A1C (%)	Decrease >1%	Decrease 0 to 1%	No Change	Increase 0 to 1%	Increase >1%
5% ≤ A1C < 6%	0 (0.0%)	1 (0.8%)	0 (0.0%)	3 (2.4%)	0 (0.0%)
6% ≤ A1C < 7%	1 (0.8%)	20 (16.1%)	5 (4.0%)	11 (8.9%)	0 (0.0%)
7% ≤ A1C < 8%	8 (6.5%)	34 (27.4%)	1 (0.8%)	9 (7.3%)	0 (0.0%)
8% ≤ A1C < 9%	11 (8.9%)	12 (9.7%)	1 (0.8%)	0 (0.0%)	0 (0.0%)

Table A-3: Number of Subjects with Change in HbA1C at Different Baselines					
HbA1C Change Range	**Number of Subjects (% of Subjects) with Change in A1C**				
Baseline A1C (%)	**Decrease >1%**	**Decrease 0 to 1%**	**No Change**	**Increase 0 to 1%**	**Increase >1%**
9% ≤ A1C < 10%	6 (4.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Overall	26 (21.0%)	67 (54.0%)	7 (5.6%)	23 (18.5%)	0 (0.0%)

The following table shows the number of subjects that spent a specific range of time per day in specific glucose ranges during the study phase.

Table A-4: Number of Subjects that Spent a Certain Time Range in Each Glucose Range During the Study Phase								
Time Range	**Number of Subjects (% of Subjects) in the Glucose Range (mg/dL) Indicated**							
	≤50	**≤60**	**≤70**	**70 to 180**	**>180**	**>250**	**>300**	**>350**
0 to 15 mins	105 (84.7%)	58 (46.8%)	12 (9.7%)	0 (0.0%)	0 (0.0%)	8 (6.5%)	66 (53.2%)	112 (90.3%)
15 to 30 mins	16 (12.9%)	43 (34.7%)	33 (26.6%)	0 (0.0%)	0 (0.0%)	16 (12.9%)	31 (25.0%)	6 (4.8%)
30 to 45 mins	3 (2.4%)	12 (9.7%)	29 (23.4%)	0 (0.0%)	0 (0.0%)	24 (19.4%)	12 (9.7%)	6 (4.8%)
45 mins to 1 hr	0 (0.0%)	10 (8.1%)	25 (20.2%)	0 (0.0%)	0 (0.0%)	17 (13.7%)	6 (4.8%)	0 (0.0%)
1 to 4 hr	0 (0.0%)	1 (0.8%)	25 (20.2%)	0 (0.0%)	34 (27.4%)	58 (46.8%)	9 (7.3%)	0 (0.0%)
4 to 8 hr	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	83 (66.9%)	1 (0.8%)	0 (0.0%)	0 (0.0%)
8 to 12 hr	0 (0.0%)	0 (0.0%)	0 (0.0%)	12 (9.7%)	7 (5.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
12 to 16 hr	0 (0.0%)	0 (0.0%)	0 (0.0%)	38 (30.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
16 to 20 hr	0 (0.0%)	0 (0.0%)	0 (0.0%)	70 (56.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
20 to 24 hr	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (3.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

The following table shows the average amount of time spent in Auto Mode per day.

Table A-5: Time Spent in Auto Mode at Different Glucose Ranges during the Study Phase	
Glucose Range (mg/dL)	**Study Phase Time in Glucose Range Mean±SD (95% CI)**
≤50	4.8 mins ± 4.6 mins (4.0 mins, 5.6 mins)
≤60	13.2 mins ± 10.1 mins (11.4 mins, 15.0 mins)
≤70	29.9 mins ± 18.8 mins (26.6 mins, 33.2 mins)
70 to 180	13 hrs 50.3 mins ± 3 hrs 1.4 mins (13 hrs 18.1 min, 14 hrs 22.5 mins)
>180	4 hrs 5.2 mins ± 1 hr 5.0 mins (3 hrs 53.7 mins, 4 hrs, 16.8 mins)
>250	44.8 mins ± 24.9 mins (40.4 mins, 49.2 mins)
>300	9.3 mins ± 7.6 mins (8.0 mins, 10.7 mins)
>350	1.7 mins ± 2.0 mins (1.3 mins, 2.0 mins)
All	18 hrs 25.4 mins ± 2 hrs 44.4 mins (17 hrs 56.2 mins, 18 hrs 54.7 mins)

The pivotal clinical trial of the MiniMed 670G System suggested that the system was safe; however, this trial had a number of limitations which included the following:

- The study involved a relatively small number of patients.

- There was no control group for comparison purposes.
- The amount of time the system was used in the Manual Mode was much shorter than the time it was programmed to the Auto Mode. Additionally, for each subject, the study period lasted only three months.

Due to these limitations, the results of the clinical trial must be interpreted with caution and you should understand that your individual results when using the MiniMed 670G System may be significantly different from those of the subjects who participated in the trial.

B. Guardian Sensor (3) Performance for 14 years old and older

CGM performance

The use of the Guardian Sensor (3) with the Guardian Link (3) transmitter enables CGM technology. The transmitter transmits SG values calculated by the real-time algorithm to a primary display device, allowing you to monitor your SG values.

Clinical study description

The performance of the Guardian Sensor (3) was evaluated in a clinical study.[4] This inpatient (in-clinic) and outpatient (at home) study included subjects 14 to 75 years in age. The study design was a multi-center, prospective single-sample correlational design without controls.

All subjects were assigned to treatment. Three sensors were worn at the same time by each subject.

Each subject was instructed to wear two real-time CGM systems in the abdomen area:

- One Guardian Sensor (3) connected to the Guardian Link (3) transmitter, which transmitted to the insulin pump (for display purposes only).
- One Guardian Sensor (3) connected to the Guardian Connect transmitter which transmitted to the Guardian Connect app, a standalone CGM display device.

Each subject was also instructed to wear another Guardian Sensor (3) in the arm area that was connected to a blinded glucose sensor recorder (GSR).

4 Medtronic Inc., A Performance Evaluation of the Enlite™ 3 Glucose Sensor to Support a Full 168 hours (7 Days) of Use, CER292DOC/F. Oct 2016.

The SG data collected by the blinded GSRs were retrospectively processed through the real-time CGM algorithm. This is the same algorithm used in the Guardian Connect and pump CGM systems. Thus all data is representative of real-time sensor usage.

The CONTOUR NEXT LINK 2.4 Wireless Meter was the study meter used for all calibrations in this study, and was the only meter evaluated with the Guardian Sensor (3) CGM systems. The sensor has not been tested with other meters. Therefore, the performance with other BG meters may differ from the performance with the CONTOUR NEXT LINK 2.4 Wireless Meter described below.

FST was performed on days 1, 3, and 7 over the life of the sensor. Reference blood (plasma) glucose values were obtained with a Yellow Springs Instrument (YSI) Glucose Analyzer every 5 to 15 minutes. During the FSTs, the subjects were instructed to calibrate the sensors once every 12 hours, or as requested by the display device. During home use (outside the clinic), subjects were instructed to calibrate both sensors 3 or 4 times spread throughout the day.

A total of 93 subjects previously diagnosed with type 1 or 2 diabetes were enrolled in the study, and 88 subjects participated in at least one day of FST. The overall number of subjects that participated in FST procedures on days 1, 3, and 7 were 88, 87, and 79, respectively. During each FST period, subjects with an established insulin sensitivity ratio and insulin carbohydrate ratio underwent a hypoglycemic challenge and a hyperglycemic challenge to evaluate performance at high and low glycemic ranges.

During the study, subjects were instructed to continue with their current diabetes regimen (including glucose monitoring with their own meter when appropriate) independent of their use of the study devices. The insulin pumps were not used to infuse insulin, and neither of the two real-time CGM systems nor the blinded GSR system was used to manage diabetes during this study. The study meter was used for confirmation of alerts, treatment decisions, and sensor calibrations.

Results

Sensor accuracy

The following information highlights the Guardian Sensor (3) performance from 88 subjects only during FST.

Mean absolute relative difference, by number of daily calibrations

Table B-1 shows the sensor accuracy measured by the mean absolute relative difference (MARD). MARD represents the average relative difference (regardless if positive or negative) between the SG values and the paired BG values measured by YSI.

Table B-1: SG MARD Versus YSI (within YSI glucose ranges).

YSI glucose ranges (mg/dL)	Abdomen Insertion Site				Arm Insertion Site			
	Calibration every 12 hours		Calibration 3 or 4 times a day		Calibration every 12 hours		Calibration 3 or 4 times a day	
	Number of paired SG-YSI	MARD (%)	Number of paired SG-YSI	MARD (%)	Number of paired SG-YSI	MARD (%)	Number of paired SG-YSI	MARD (%)
Overall	12090	10.55	11664	9.64	10526	9.09	10771	8.68
<40*	12	17.03	11	16.41	7	17.24	7	17.24
40–60*	353	7.96	324	7.53	335	6.44	349	6.42
61–80*	1445	9.44	1403	8.81	1345	7.76	1372	7.44
81–180	6505	9.94	6342	9.33	5644	8.64	5795	8.35
181–300	3277	10.00	3114	8.57	2766	8.58	2785	7.95
301–350	366	9.63	341	8.13	308	9.09	338	8.27
351–400	117	9.58	114	8.56	111	8.47	115	8.23
>400	15	10.85	15	10.92	10	10.71	10	11.44

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

Note: SG Readings are within 40-400 mg/dL.

Percent agreement, by number of daily calibrations

In Tables B-2 through B-9, the agreement of the SG values to paired YSI values was assessed by calculating the percentage of YSI values that were within 15%, 20%, 30%, 40% and greater than 40% of the paired SG values. For readings less than or equal to 80 mg/dL, the absolute difference in mg/dL between the SG and paired YSI values was calculated.

Results are shown for defined SG ranges when calibrating every 12 hours and calibrating three or four times a day for sensors.

Table B-2: Overall agreement (%) of SG-YSI paired points within SG ranges on FST Days 1, 3, and 7; Calibration every 12 hours, Abdomen.

SG ranges (mg/dL)	Number of paired SG-YSI	Percent of YSI within 15/15% of SG (%)	Percent of YSI within 20/20% of SG (%)	Percent of YSI within 30/30% of SG (%)	Percent of YSI within 40/40% of SG (%)	Percent of YSI greater than 40/40% of SG (%)
Overall	12090	76.6	85.7	94.3	97.3	2.7
≥40–60*	781	57.7	73.2	90.7	96.9	3.1
>60–80*	1350	76.1	83.4	93.4	96.8	3.2
>80–180	6769	76.5	85.3	93.5	96.5	3.5

Table B-2: Overall agreement (%) of SG-YSI paired points within SG ranges on FST Days 1, 3, and 7; Calibration every 12 hours, Abdomen.

SG ranges (mg/dL)	Number of paired SG-YSI	Percent of YSI within 15/15% of SG (%)	Percent of YSI within 20/20% of SG (%)	Percent of YSI within 30/30% of SG (%)	Percent of YSI within 40/40% of SG (%)	Percent of YSI greater than 40/40% of SG (%)
>180–300	2833	80.8	90	97.1	98.9	1.1
>300–350	286	86.4	95.1	99.7	100	0
>350–400	71	93	100	100	100	0

* For reference range ≤80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: SG Readings are within 40–400 mg/dL.

Table B-3: Agreement (%) of SG paired points within SG ranges on FST Day 1; Calibration every 12 hours, Abdomen.

SG ranges (mg/dL)	Number of paired SG-YSI	Percent of YSI within 15/15% of SG (%)	Percent of YSI within 20/20% of SG (%)	Percent of YSI within 30/30% of SG (%)	Percent of YSI within 40/40% of SG (%)	Percent of YSI greater than 40/40% of SG (%)
Overall	4294	65.3	76.6	89.5	94.7	5.3
≥40–60*	278	46.8	61.9	83.5	94.2	5.8
>60–80*	474	61	71.7	88	93.5	6.5
>80–180	2443	64.9	75.4	87.6	93.2	6.8
>180–300	985	71.6	83.8	95.5	98.5	1.5
>300–350	90	82.2	95.6	100	100	0
>350–400	24	91.7	100	100	100	0

* For reference range ≤80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: The overall number of available paired SG-YSI points on FST Day 1 was from 88 subjects. SG Readings are within 40–400 mg/dL.

Table B-4: Overall agreement (%) of SG-YSI paired points within SG ranges on FST Days 1, 3, and 7; Calibration 3 or 4 times a day, Abdomen.

SG ranges (mg/dL)	Number of paired SG-YSI	Percent of YSI within 15/15% of SG (%)	Percent of YSI within 20/20% of SG (%)	Percent of YSI within 30/30% of SG (%)	Percent of YSI within 40/40% of SG (%)	Percent of YSI greater than 40/40% of SG (%)
Overall	11664	80.6	88.9	95.9	98.2	1.8
≥40–60*	686	60.2	75.1	92	98.1	1.9
>60–80*	1303	78.7	85.7	93.5	96.7	3.3
>80–180	6549	79.9	88.5	95.7	98	2
>180–300	2782	86.4	93.5	98	99.4	0.6
>300–350	279	92.5	97.8	99.6	100	0
>350–400	65	95.4	100	100	100	0

* For reference range ≤80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: SG Readings are within 40–400 mg/dL.

Table B-5: Agreement (%) of SG paired points within SG ranges on FST Day 1; Calibration 3 or 4 times a day, Abdomen.

SG ranges (mg/dL)	Number of paired SG-YSI	Percent of YSI within 15/15% of SG (%)	Percent of YSI within 20/20% of SG (%)	Percent of YSI within 30/30% of SG (%)	Percent of YSI within 40/40% of SG (%)	Percent of YSI greater than 40/40% of SG (%)
Overall	4136	71.4	81.9	92.3	96.3	3.7

Table B-5: Agreement (%) of SG paired points within SG ranges on FST Day 1; Calibration 3 or 4 times a day, Abdomen.						
SG ranges (mg/dL)	**Number of paired SG-YSI**	**Percent of YSI within 15/15% of SG (%)**	**Percent of YSI within 20/20% of SG (%)**	**Percent of YSI within 30/30% of SG (%)**	**Percent of YSI within 40/40% of SG (%)**	**Percent of YSI greater than 40/40% of SG (%)**
≥40–60*	247	50.2	64.4	84.6	95.5	4.5
>60–80*	429	66.2	73.9	86.5	92.8	7.2
>80–180	2353	70.6	81.4	91.8	95.5	4.5
>180–300	988	78.6	89.1	97.2	99.5	0.5
>300–350	97	88.7	96.9	100	100	0
>350–400	22	100	100	100	100	0
* For reference range ≤80 mg/dL, agreement was based on 15/20/30/40 mg/dL.						
Note: The overall number of available paired SG-YSI points on FST Day 1 was from 88 subjects. SG Readings are within 40–400 mg/dL.						

Table B-6: Overall agreement (%) of SG-YSI paired points within SG ranges on FST Days 1, 3, and 7; Calibration every 12 hours, Arm.						
SG ranges (mg/dL)	**Number of paired SG-YSI**	**Percent of YSI within 15/15% of SG (%)**	**Percent of YSI within 20/20% of SG (%)**	**Percent of YSI within 30/30% of SG (%)**	**Percent of YSI within 40/40% of SG (%)**	**Percent of YSI greater than 40/40% of SG (%)**
Overall	10526	82.5	90.3	96.3	98.7	1.3
≥40–60*	520	77.1	86.9	96	99.6	0.4
>60–80*	1238	88.2	92.5	96.4	99	1
>80–180	5957	80.3	88.5	95.5	98.2	1.8
>180–300	2495	85	93.2	98	99.4	0.6
>300–350	256	90.6	96.9	100	100	0
>350–400	60	90	93.3	100	100	0
* For reference range ≤80 mg/dL, agreement was based on 15/20/30/40 mg/dL.						
Note: SG Readings are within 40–400 mg/dL.						

Table B-7: Agreement (%) of SG-YSI paired points within SG ranges on FST Day 1; Calibration every 12 hours, Arm.						
SG ranges (mg/dL)	**Number of paired SG-YSI**	**Percent of YSI within 15/15% of SG (%)**	**Percent of YSI within 20/20% of SG (%)**	**Percent of YSI within 30/30% of SG (%)**	**Percent of YSI within 40/40% of SG (%)**	**Percent of YSI greater than 40/40% of SG (%)**
Overall	3390	74.7	84.2	93.2	97.8	2.2
≥40–60*	168	60.1	73.2	90.5	98.8	1.2
>60–80*	339	75.5	79.4	88.8	97.3	2.7
>80–180	2017	73.2	83.1	92	97	3
>180–300	760	80.5	90.8	98.2	99.6	0.4
>300–350	91	84.6	93.4	100	100	0
>350–400	15	60	73.3	100	100	0
* For reference range ≤80 mg/dL, agreement was based on 15/20/30/40 mg/dL.						
Note: The overall number of available paired SG-YSI points on FST Day 1 was from 82 subjects. SG Readings are within 40–400 mg/dL.						

Table B-8: Overall agreement (%) of SG-YSI paired points within SG ranges on FST Days 1, 3, and 7; Calibration 3 or 4 times a day, Arm.						
SG ranges (mg/dL)	**Number of paired SG-YSI**	**Percent of YSI within 15/15% of SG (%)**	**Percent of YSI within 20/20% of SG (%)**	**Percent of YSI within 30/30% of SG (%)**	**Percent of YSI within 40/40% of SG (%)**	**Percent of YSI greater than 40/40% of SG (%)**
Overall	10771	84.3	91.6	97.3	99.1	0.9
≥40–60*	503	77.1	87.5	96.6	99.6	0.4
>60–80*	1291	89.3	93.4	97.7	99.1	0.9
>80–180	6076	82	90	96.7	98.7	1.3
>180–300	2569	87	94.4	98.3	99.7	0.3
>300–350	271	94.8	98.5	100	100	0
>350–400	61	95.1	96.7	100	100	0
* For reference range ≤80 mg/dL, agreement was based on 15/20/30/40 mg/dL. **Note:** SG Readings are within 40–400 mg/dL.						

Table B-9: Agreement (%) of SG-YSI paired points within SG ranges on FST Day 1; Calibration 3 or 4 times a day, Arm.						
SG ranges (mg/dL)	**Number of paired SG-YSI**	**Percent of YSI within 15/15% of SG (%)**	**Percent of YSI within 20/20% of SG (%)**	**Percent of YSI within 30/30% of SG (%)**	**Percent of YSI within 40/40% of SG (%)**	**Percent of YSI greater than 40/40% of SG (%)**
Overall	3591	76.8	86	95	98.5	1.5
≥40–60*	162	62.3	75.3	91.4	98.8	1.2
>60–80*	346	76.3	81.5	92.8	97.4	2.6
>80–180	2108	75.1	85	94.2	98	2
>180–300	869	81.8	91	97.7	99.9	0.1
>300–350	93	92.5	96.8	100	100	0
>350–400	13	84.6	84.6	100	100	0
* For reference range ≤80 mg/dL, agreement was based on 15/20/30/40 mg/dL. **Note:** The overall number of available paired SG-YSI points on FST Day 1 was from 83 subjects. SG Readings are within 40–400 mg/dL.						

Agreement when the CGM system reads "Below 40 mg/dL" or "Above 400 mg/dL"

The real-time CGM systems display glucose values between 40 mg/dL and 400 mg/dL. It displays "Below 40 mg/dL" when the SG value detected is below 40 mg/dL. It displays "Above 400 mg/dL" when the SG value detected is above 400 mg/dL. Tables B-10, B-11, B-12, and B-13 illustrate the number and percentage of the paired YSI values in different BG levels when the CGM system displays "Below 40 mg/dL" (LOW) or "Above 400 mg/dL" (HIGH).

Table B-10: The number and percentage of YSI values collected when CGM displays "Below 40 mg/dL" (LOW); Calibration every 12 hours.								
				YSI (mg/dL)				
CGM Display	Insertion Site	CGM-YSI pairs	<55	<60	<70	<80	>80	Total
LOW	Abdomen	Cumulative, n	42	77	139	150	4	154
		Cumulative %	27%	50%	90%	97%	3%	100%
	Arm	Cumulative, n	17	35	67	74	1	75
		Cumulative %	23%	47%	89%	99%	1%	100%

Table B-11: The number and percentage of YSI values collected when CGM displays "Below 40 mg/dL" (LOW); Calibration 3 or 4 times a day.								
				YSI (mg/dL)				
CGM Display	Insertion Site	CGM-YSI pairs	<55	<60	<70	<80	>80	Total
LOW	Abdomen	Cumulative, n	33	64	108	119	4	123
		Cumulative %	27%	52%	88%	97%	3%	100%
	Arm	Cumulative, n	18	35	66	72	1	73
		Cumulative %	25%	48%	90%	99%	1%	100%

Table B-12: The number and percentage of YSI values collected when CGM displays "Above 400 mg/dL" (HIGH); Calibration every 12 hours.								
				YSI (mg/dL)				
CGM Display	Insertion Site	CGM-YSI pairs	<340	<320	<280	<240	>240	Total
HIGH	Abdomen	Cumulative, n	8	9	9	9	0	9
		Cumulative %	89%	100%	100%	100%	0%	100%
	Arm	Cumulative, n	8	8	9	9	0	9
		Cumulative %	89%	89%	100%	100%	0%	100%

Table B-13: The number and percentage of YSI values collected when CGM displays "Above 400 mg/dL" (HIGH); Calibration 3 or 4 times a day.								
				YSI (mg/dL)				
CGM Display	Insertion Site	CGM-YSI pairs	<340	<320	<280	<240	>240	Total
HIGH	Abdomen	Cumulative, n	8	9	9	9	0	9
		Cumulative %	89%	100%	100%	100%	0%	100%
	Arm	Cumulative, n	8	8	8	8	0	8
		Cumulative %	100%	100%	100%	100%	0%	100%

Concurrence of SG and YSI values

Tables B-14 through B-21 show, for each SG range, the percentage of concurring data points where the paired YSI values were in different BG ranges.

Table B-14: Overall concurrence of YSI values and SG readings using SG ranges on FST Days 1, 3, and 7; Calibration every 12 hours, Abdomen

Percent of matched pairs in each YSI glucose range for each SG range (mg/dL)												
SG ranges (mg/dL)	**Number of paired SG-YSI**	**YSI Glucose Range (mg/dL)**										
		<40	**≥40–60**	**>60–80**	**>80–120**	**>120–160**	**>160–200**	**>200–250**	**>250–300**	**>300–350**	**>350–400**	**>400**
A) <40	154	0.0% (0/0)	50.0% (77/154)	47.4% (73/154)	2.6% (4/154)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
B) ≥40–60	781	1.2% (9/781)	30.7% (240/781)	57.2% (447/781)	10.6% (83/781)	0.3% (2/781)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
C) >60–80	1350	0.2% (3/1350)	8.3% (112/1350)	60.1% (811/1350)	29.2% (394/1350)	2.1% (28/1350)	0.1% (2/1350)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80–120	2953	0.0% (0/0)	0.0% (1/2953)	6.3% (185/2953)	73.0% (2157/2953)	18.2% (537/2953)	2.0% (60/2953)	0.4% (13/2953)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120–160	2784	0.0% (0/0)	0.0% (0/0)	0.1% (2/2784)	8.8% (245/2784)	67.7% (1885/2784)	20.3% (565/2784)	2.8% (79/2784)	0.3% (8/2784)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160–200	1875	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.1% (2/1875)	10.0% (188/1875)	60.2% (1128/1875)	28.2% (529/1875)	1.5% (28/1875)	0.0% (0/0))	0.0% (0/0)	0.0% (0/0)
G) >200–250	1382	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.3% (4/1382)	8.0% (111/1382)	61.1% (844/1382)	28.1% (389/1382)	2.3% (32/1382)	0.1% (2/1382)	0.0% (0/0)
H) >250–300	608	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.3% (2/608)	10.9% (66/608)	61.2% (372/608)	25.5% (155/608)	2.1% (13/608)	0.0% (0/0)
I) >300–350	286	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	1.0% (3/286)	19.9% (57/286)	55.2% (158/286)	22.4% (64/286)	1.4% (4/286)
J) >350–400	71	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	1.4% (1/71)	29.6% (21/71)	53.5% (38/71)	15.5% (11/71)
K) >400	9	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	11.1% (1/9)	77.8% (7/9)	11.1% (1/9)

Table B-15: Concurrence of YSI values and SG readings using SG ranges on FST Day 1; Calibration every 12 hours, Abdomen

Percent of matched pairs in each YSI glucose range for each SG range (mg/dL)												
SG ranges (mg/dL)	**Number of paired SG-YSI**	**YSI Glucose Range (mg/dL)**										
		<40	**≥40–60**	**>60–80**	**>80–120**	**>120–160**	**>160–200**	**>200–250**	**>250–300**	**>300–350**	**>350–400**	**>400**
A) <40	71	0.0% (0/0)	38.0% (27/71)	57.7% (41/71)	4.2% (3/71)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
B) ≥40–60	278	2.2% (6/278)	23.0% (64/278)	55.8% (155/278)	18.7% (52/278)	0.4% (1/278)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
C) >60–80	474	0.4% (2/474)	12.0% (57/474)	47.7% (226/474)	34.8% (165/474)	4.6% (22/474)	0.4% (2/474)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80–120	1071	0.0% (0/0)	0.1% (1/1071)	4.6% (49/1071)	66.6% (713/1071)	23.4% (251/1071)	4.5% (48/1071)	0.8% (9/1071)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120–160	978	0.0% (0/0)	0.0% (0/0)	0.1% (1/978)	8.3% (81/978)	58.4% (571/978)	26.8% (262/978)	5.9% (58/978)	0.5% (5/978)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)

Table B-15: Concurrence of YSI values and SG readings using SG ranges on FST Day 1; Calibration every 12 hours, Abdomen												
Percent of matched pairs in each YSI glucose range for each SG range (mg/dL)												
SG ranges (mg/dL)	**Number of paired SG-YSI**	**YSI Glucose Range (mg/dL)**										
		<40	**≥40–60**	**>60–80**	**>80–120**	**>120–160**	**>160–200**	**>200–250**	**>250–300**	**>300–350**	**>350–400**	**>400**
F) >160–200	662	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.3% (2/662)	9.1% (60/662)	52.6% (348/662)	35.3% (234/662)	2.7% (18/662)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200–250	515	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	6.2% (32/515)	56.3% (290/515)	33.8% (174/515)	3.3% (17/515)	0.4% (2/515)	0.0% (0/0)
H) >250–300	202	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	9.4% (19/202)	55.0% (111/202)	32.2% (65/202)	3.5% (7/202)	0.0% (0/0)
I) >300–350	90	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	20.0% (18/90)	54.4% (49/90)	23.3% (21/90)	2.2% (2/90)
J) >350–400	24	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	4.2% (1/24)	37.5% (9/24)	50.0% (12/24)	8.3% (2/24)
K) >400	1	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	100.0% (1/1)
Note: The overall number of available paired SG-YSI points on FST Day 1 was from 88 subjects.												

Table B-16: Overall concurrence of YSI values and SG readings using SG ranges on FST Days 1, 3, and 7; Calibration 3 or 4 times a day, Abdomen.												
Percent of matched pairs in each YSI glucose range for each SG range (mg/dL)												
SG ranges (mg/dL)	**Number of paired SG-YSI**	**YSI Glucose Range (mg/dL)**										
		<40	**≥40–60**	**>60–80**	**>80–120**	**>120–160**	**>160–200**	**>200–250**	**>250–300**	**>300–350**	**>350–400**	**>400**
A) <40	123	0.0% (0/0)	52.0% (64/123)	44.7% (55/123)	3.3% (4/123)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
B) ≥40–60	686	1.3% (9/686)	31.6% (217/686)	57.0% (391/686)	9.9% (68/686)	0.1% (1/686)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
C) >60–80	1303	0.2% (2/1303)	8.1% (106/1303)	63.4% (826/1303)	26.2% (342/1303)	1.9% (25/1303)	0.2% (2/1303)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80–120	2864	0.0% (0/0)	0.0% (1/2864)	6.5% (186/2864)	74.5% (2133/2864)	17.5% (502/2864)	1.3% (36/2864)	0.2% (6/2864)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120–160	2681	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	9.0% (241/2681)	69.9% (1874/2681)	19.1% (512/2681)	1.8% (49/2681)	0.2% (5/2681)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160–200	1820	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.1% (2/1820)	10.3% (188/1820)	63.6% (1157/1820)	24.9% (454/1820)	1.0% (19/1820)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200–250	1314	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.5% (7/1314)	8.5% (112/1314)	65.3% (858/1314)	24.6% (323/1314)	1.1% (14/1314)	0.0% (0/0)	0.0% (0/0)
H) >250–300	652	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.3% (2/652)	11.3% (74/652)	63.5% (414/652)	22.9% (149/652)	2.0% (13/652)	0.0% (0/0)
I) >300–350	279	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	17.9% (50/279)	59.5% (166/279)	21.1% (59/279)	1.4% (4/279)

Table B-16: Overall concurrence of YSI values and SG readings using SG ranges on FST Days 1, 3, and 7; Calibration 3 or 4 times a day, Abdomen.

Percent of matched pairs in each YSI glucose range for each SG range (mg/dL)												
SG ranges (mg/dL)	**Number of paired SG-YSI**	**YSI Glucose Range (mg/dL)**										
		<40	**≥40–60**	**>60–80**	**>80–120**	**>120–160**	**>160–200**	**>200–250**	**>250–300**	**>300–350**	**>350–400**	**>400**
J) >350–400	65	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	18.5% (12/65)	64.6% (42/65)	16.9% (11/65)
K) >400	9	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	11.1% (1/9)	77.8% (7/9)	11.1% (1/9)

Table B-17: Concurrence of YSI values and SG readings using SG ranges on FST Day 1; Calibration 3 or 4 times a day, Abdomen.

Percent of matched pairs in each YSI glucose range for each SG range (mg/dL)												
SG ranges (mg/dL)	**Number of paired SG-YSI**	**YSI Glucose Range (mg/dL)**										
		<40	**≥40–60**	**>60–80**	**>80–120**	**>120–160**	**>160–200**	**>200–250**	**>250–300**	**>300–350**	**>350–400**	**>400**
A) <40	62	0.0% (0/0)	37.1% (23/62)	58.1% (36/62)	4.8% (3/62)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
B) ≥40–60	247	2.4% (6/247)	21.5% (53/247)	58.7% (145/247)	17.0% (42/247)	0.4% (1/247)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
C) >60–80	429	0.2% (1/429)	12.6% (54/429)	52.0% (223/429)	30.3% (130/429)	4.4% (19/429)	0.5% (2/429)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80–120	1014	0.0% (0/0)	0.1% (1/1014)	5.3% (54/1014)	70.7% (717/1014)	20.4% (207/1014)	3.1% (31/1014)	0.4% (4/1014)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120–160	973	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	9.1% (89/973)	61.6% (599/973)	24.8% (241/973)	4.0% (39/973)	0.5% (5/973)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160–200	633	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.3% (2/633)	10.7% (68/633)	56.7% (359/633)	30.3% (192/633)	1.9% (12/633)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200–250	497	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.2% (1/497)	7.8% (39/497)	64.6% (321/497)	26.4% (131/497)	1.0% (5/497)	0.0% (0/0)	0.0% (0/0)
H) >250–300	224	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	12.9% (29/224)	58.0% (130/224)	23.7% (53/224)	5.4% (12/224)	0.0% (0/0)
I) >300–350	97	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	19.6% (19/97)	59.8% (58/97)	18.6% (18/97)	2.1% (2/97)
J) >350–400	22	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	27.3% (6/22)	63.6% (14/22)	9.1% (2/22)
K) >400	1	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	100.0% (1/1)

Note: The overall number of available SG-YSI points on FST Day 1 was from 88 subjects.

Table B-18: Overall concurrence of YSI values and SG readings using SG ranges on FST Days 1, 3, and 7; Calibration every 12 hours, Arm.

Percent of matched pairs in each YSI glucose range for each SG range (mg/dL)												
SG ranges (mg/dL)	**Number of paired SG-YSI**	**YSI Glucose Range (mg/dL)**										
		<40	**≥40–60**	**>60–80**	**>80–120**	**>120–160**	**>160–200**	**>200–250**	**>250–300**	**>300–350**	**>350–400**	**>400**
A) <40	75	2.7% (2/75)	44.0% (33/75)	52.0% (39/75)	1.3% (1/75)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)

Table B-18: Overall concurrence of YSI values and SG readings using SG ranges on FST Days 1, 3, and 7; Calibration every 12 hours, Arm.												
Percent of matched pairs in each YSI glucose range for each SG range (mg/dL)												
SG ranges (mg/dL)	Number of paired SG-YSI	YSI Glucose Range (mg/dL)										
		<40	≥40–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
B) ≥40–60	520	1.0% (5/520)	41.9% (218/520)	51.7% (269/520)	5.4% (28/520)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
C) >60–80	1238	0.2% (2/1238)	9.2% (114/1238)	70.3% (870/1238)	20.0% (247/1238)	0.4% (5/1238)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80–120	2722	0.0% (0/0)	0.1% (3/2722)	7.5% (203/2722)	74.0% (2014/2722)	17.7% (481/2722)	0.8% (21/2722)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120–160	2348	0.0% (0/0)	0.0% (0/0)	0.1% (3/2348)	9.2% (215/2348)	70.4% (1652/2348)	18.0% (423/2348)	2.3% (54/2348)	0.0% (1/2348)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160–200	1614	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.1% (2/1614)	9.4% (151/1614)	64.7% (1044/1614)	24.8% (400/1614)	0.9% (14/1614)	0.2% (3/1614)	0.0% (0/0)	0.0% (0/0)
G) >200–250	1212	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.6% (7/1212)	6.8% (83/1212)	63.9% (774/1212)	27.3% (331/1212)	1.4% (17/1212)	0.0% (0/0)	0.0% (0/0)
H) >250–300	556	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.2% (1/556)	9.4% (52/556)	65.1% (362/556)	23.9% (133/556)	1.4% (8/556)	0.0% (0/0)
I) >300–350	256	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	18.0% (46/256)	56.6% (145/256)	24.6% (63/256)	0.8% (2/256)
J) >350–400	60	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	3.3% (2/60)	16.7% (10/60)	66.7% (40/60)	13.3% (8/60)
K) >400	9	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	11.1% (1/9)	55.6% (5/9)	33.3% (3/9)

Table B-19: Concurrence of YSI values and SG readings using SG ranges on FST Day 1; Calibration every 12 hours, Arm.												
Percent of matched pairs in each YSI glucose range for each SG range (mg/dL)												
SG ranges (mg/dL)	Number of paired SG-YSI	YSI Glucose Range (mg/dL)										
		<40	≥40–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
A) <40	54	3.7% (2/54)	29.6% (16/54)	64.8% (35/54)	1.9% (1/54)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
B) ≥40–60	168	1.8% (3/168)	22.0% (37/168)	64.3% (108/168)	11.9% (20/168)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
C) >60–80	339	0.6% (2/339)	11.2% (38/339)	58.1% (197/339)	29.2% (99/339)	0.9% (3/339)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80–120	895	0.0% (0/0)	0.3% (3/895)	6.6% (59/895)	69.8% (625/895)	21.6% (193/895)	1.7% (15/895)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120–160	803	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	10.0% (80/803)	64.6% (519/803)	21.4% (172/803)	4.0% (32/803)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160–200	549	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.2% (1/549)	8.9% (49/549)	61.4% (337/549)	28.1% (154/549)	1.5% (8/549)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)

Table B-19: Concurrence of YSI values and SG readings using SG ranges on FST Day 1; Calibration every 12 hours, Arm.

Percent of matched pairs in each YSI glucose range for each SG range (mg/dL)												
SG ranges (mg/dL)	**Number of paired SG-YSI**	**YSI Glucose Range (mg/dL)**										
		<40	**≥40–60**	**>60–80**	**>80–120**	**>120–160**	**>160–200**	**>200–250**	**>250–300**	**>300–350**	**>350–400**	**>400**
G) >200–250	355	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.3% (1/355)	7.9% (28/355)	63.9% (227/355)	27.0% (96/355)	0.8% (3/355)	0.0% (0/0)	0.0% (0/0)
H) >250–300	175	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	10.9% (19/175)	65.7% (115/175)	21.1% (37/175)	2.3% (4/175)	0.0% (0/0)
I) >300–350	91	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	20.9% (19/91)	52.7% (48/91)	24.2% (22/91)	2.2% (2/91)
J) >350–400	15	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	13.3% (2/15)	33.3% (5/15)	53.3% (8/15)	0.0% (0/0)
K) >400	1	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	100.0% (1/1)	0.0% (0/0)	0.0% (0/0)

Note: The overall number of available paired SG-YSI points on FST Day 1 was from 82 subjects.

Table B-20: Overall concurrence of YSI values and SG readings using SG ranges on FST Days 1, 3, and 7; Calibration 3 or 4 times a day, Arm.

Percent of matched pairs in each YSI glucose range for each SG range (mg/dL)												
SG ranges (mg/dL)	**Number of paired SG-YSI**	**YSI Glucose Range (mg/dL)**										
		<40	**≥40–60**	**>60–80**	**>80–120**	**>120–160**	**>160–200**	**>200–250**	**>250–300**	**>300–350**	**>350–400**	**>400**
A) <40	73	2.7% (2/73)	45.2% (33/73)	50.7% (37/73)	1.4% (1/73)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
B) ≥40–60	503	1.0% (5/503)	45.9% (231/503)	48.3% (243/503)	4.8% (24/503)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
C) >60–80	1291	0.2% (2/1291)	8.9% (115/1291)	72.3% (933/1291)	18.4% (237/1291)	0.3% (4/1291)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80–120	2756	0.0% (0/0)	0.1% (3/2756)	7.0% (194/2756)	75.9% (2092/2756)	16.5% (456/2756)	0.4% (11/2756)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120–160	2442	0.0% (0/0)	0.0% (0/0)	0.1% (2/2442)	9.3% (228/2442)	71.4% (1743/2442)	18.0% (439/2442)	1.2% (30/2442)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160–200	1588	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.1% (2/1588)	9.4% (150/1588)	66.3% (1053/1588)	23.5% (373/1588)	0.6% (9/1588)	0.1% (1/1588)	0.0% (0/0)	0.0% (0/0)
G) >200–250	1246	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.5% (6/1246)	7.4% (92/1246)	65.7% (818/1246)	25.1% (313/1246)	1.4% (17/1246)	0.0% (0/0)	0.0% (0/0)
H) >250–300	613	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.2% (1/613)	8.6% (53/613)	65.1% (399/613)	24.6% (151/613)	1.5% (9/613)	0.0% (0/0)
I) >300–350	271	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	16.2% (44/271)	59.8% (162/271)	23.2% (63/271)	0.7% (2/271)
J) >350–400	61	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	4.9% (3/61)	11.5% (7/61)	70.5% (43/61)	13.1% (8/61)

Table B-20: Overall concurrence of YSI values and SG readings using SG ranges on FST Days 1, 3, and 7; Calibration 3 or 4 times a day, Arm.												
Percent of matched pairs in each YSI glucose range for each SG range (mg/dL)												
SG ranges (mg/dL)	Number of paired SG-YSI	YSI Glucose Range (mg/dL)										
		<40	≥40–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
K) >400	8	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	62.5% (5/8)	37.5% (3/8)

Table B-21: Concurrence of YSI values and SG readings using SG ranges on FST) Day 1; Calibration 3 or 4 times a day, Arm.												
Percent of matched pairs in each YSI glucose range for each SG range (mg/dL)												
SG ranges (mg/dL)	Number of paired SG-YSI	YSI Glucose Range (mg/dL)										
		<40	≥40–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
A) <40	54	3.7% (2/54)	29.6% (16/54)	64.8% (35/54)	1.9% (1/54)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
B) ≥40–60	162	1.9% (3/162)	25.3% (41/162)	61.7% (100/162)	11.1% (18/162)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
C) >60–80	346	0.6% (2/346)	11.6% (40/346)	61.3% (212/346)	25.7% (89/346)	0.9% (3/346)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80–120	899	0.0% (0/0)	0.3% (3/899)	6.3% (57/899)	74.0% (665/899)	18.2% (164/899)	1.1% (10/899)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120–160	878	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	10.0% (88/878)	67.0% (588/878)	21.0% (184/878)	2.1% (18/878)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160–200	571	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.2% (1/571)	9.3% (53/571)	62.3% (356/571)	27.3% (156/571)	0.9% (5/571)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200–250	427	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.2% (1/427)	8.2% (35/427)	62.5% (267/427)	27.6% (118/427)	1.4% (6/427)	0.0% (0/0)	0.0% (0/0)
H) >250–300	202	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	9.9% (20/202)	59.9% (121/202)	26.7% (54/202)	3.5% (7/202)	0.0% (0/0)
I) >300–350	93	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	16.1% (15/93)	59.1% (55/93)	22.6% (21/93)	2.2% (2/93)
J) >350–400	13	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	15.4% (2/13)	7.7% (1/13)	76.9% (10/13)	0.0% (0/0)
K) >400	0	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
Note: The overall number of available paired SG-YSI points on FST Day 1 was from 83 subjects.												

Percent agreement post calibration

The agreement of the SG values to paired YSI values was assessed for every 2-hour period post sensor calibration. For readings less than or equal to 80 mg/dL, the absolute difference in mg/dL between the SG and paired YSI values was calculated.

Tables B-22 and B-23 show the percent agreement rates post calibration for sensors inserted into the abdomen. Performance when sensors are inserted in the arm is at least comparable to results when sensors are inserted in the abdomen.

Table B-22: Agreement rates for every 2-hour period post calibration period; Calibration every 12 hours, Abdomen.

		Percent Agreement (%)				
Time after calibration	**Number of paired SG-YSI**	**Percent of SG within 15/15% of YSI**	**Percent of SG within 20/20% of YSI**	**Percent of SG within 30/30% of YSI**	**Percent of SG within 40/40% of YSI**	**Percent of SG greater than 40/40% of YSI**
0–2 hours	2999	85	92.6	97.8	99.6	0.4
2–4 hours	2667	75.1	85.9	95.3	98.8	1.2
4–6 hours	2138	71.4	82	92.7	97.6	2.4
6–8 hours	1521	77.6	88.4	97	99.3	0.7
8–10 hours	1523	84.2	91.1	97.6	99.3	0.7
10–12 hours	1242	79.8	89.5	96.3	98.6	1.4

* For reference range ≤80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: SG Readings are within 40–400 mg/dL.

Table B-23: Agreement rates for every 2-hour period post calibration; Calibration 3 or 4 times a day, Abdomen.

		Percent Agreement (%)				
Time after calibration	**Number of paired SG-YSI**	**Percent of SG within 15/15% of YSI**	**Percent of SG within 20/20% of YSI**	**Percent of SG within 30/30% of YSI**	**Percent of SG within 40/40% of YSI**	**Percent of SG greater than 40/40% of YSI**
0–2 hours	4585	87	93.5	98.1	99.7	0.3
2–4 hours	3949	80.7	89.9	96.7	99	1
4–6 hours	2856	78.7	87.6	95.5	98.5	1.5
6–8 hours	227	74.9	86.3	96.9	99.6	0.4
8–10 hours	35	82.9	85.7	91.4	94.3	5.7
10–12 hours	12	91.7	91.7	91.7	100	0

* For reference range ≤80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: SG Readings are within 40–400 mg/dL.

Trend accuracy

Tables B-24 through B-25 show, for each SG rate-of-change range (indicated on display by number of arrows), percentage of SG-YSI paired values that fell into different YSI rate-of-change ranges. The tables show the trend accuracy for sensors inserted into the abdomen. Performance when sensors are inserted in the arm is at least comparable to results when sensors are inserted into the abdomen.

Table B-24: Trend accuracy; Calibration every 12 hours, Abdomen.							
	Percent of Matched Pairs-in Each YSI Rate-of-Change Range for Each SG Rate-of-Change Range						
	YSI Rate-of-Change Ranges (mg/dL/min)						
SG Rate-of-Change Range (mg/dL/min)	**Number of Paired SG-YSI**	**<-2**	**[-2, -1]**	**[-1, 0]**	**[0, 1]**	**[1, 2]**	**>2**
A) <-2	162	38.3% (62/162)	40.1% (65/162)	20.4% (33/162)	0.6% (1/162)	0.6% (1/162)	0.0% (0/162)
B) [-2, -1]	1001	4.8% (48/1001)	39.9% (399/1001)	51.3% (514/1001)	3.7% (37/1001)	0.3% (3/1001)	0.0% (0/1001)
C) [-1, 0]	5960	0.5% (30/5960)	3.8% (228/5960)	77.6% (4627/5960)	17.1% (1020/5960)	0.8% (49/5960)	0.1% (6/5960)
D) [0, 1]	3517	0.2% (7/3517)	0.5% (18/3517)	25.7% (903/3517)	63.4% (2231/3517)	9.3% (326/3517)	0.9% (32/3517)
E) [1, 2]	1059	0.1% (1/1059)	0.4% (4/1059)	4.5% (48/1059)	37.9% (401/1059)	48.6% (515/1059)	8.5% (90/1059)
F) >2	391	0.0% (0/391)	0.0% (0/391)	2.8% (11/391)	7.4% (29/391)	40.9% (160/391)	48.8% (191/391)

Table B-25: Trend accuracy; Calibration 3 or 4 times a day, Abdomen.							
	Percent of Matched Pairs-in Each YSI Rate-of-Change Range for Each SG Rate-of-Change Range						
	YSI Rate-of-Change Ranges (mg/dL/min)						
SG Rate-of-Change Range (mg/dL/min)	**Number of Paired SG-YSI**	**<-2**	**[-2, -1]**	**[-1, 0]**	**[0, 1]**	**[1, 2]**	**>2**
A) <-2	159	39.0% (62/159)	39.6% (63/159)	19.5% (31/159)	0.6% (1/159)	1.3% (2/159)	0.0% (0/159)
B) [-2, -1]	967	5.1% (49/967)	38.7% (374/967)	51.9% (502/967)	4.0% (39/967)	0.3% (3/967)	0.0% (0/967)
C) [-1, 0]	5753	0.5% (28/5753)	4.0% (228/5753)	77.5% (4456/5753)	17.2% (990/5753)	0.8% (46/5753)	0.1% (5/5753)
D) [0, 1]	3387	0.2% (8/3387)	0.5% (18/3387)	26.5% (898/3387)	62.5% (2118/3387)	9.3% (316/3387)	0.9% (29/3387)
E) [1, 2]	1024	0.0% (0/1024)	0.2% (2/1024)	5.0% (51/1024)	38.8% (397/1024)	47.5% (486/1024)	8.6% (88/1024)
F) >2	374	0.0% (0/374)	0.0% (0/374)	2.4% (9/374)	8.0% (30/374)	42.8% (160/374)	46.8% (175/374)

Precision

Precision of the system was evaluated by comparing the results from two separate sensors worn in the abdomen on the same subject at the same time. A total of 83 subjects provided 30,350 paired SG-YSI measurements, with a mean Percent Absolute Relative Difference (PARD) of 9.07% with a coefficient of variation (%CV) of 6.5%.

Though precision in the arm has not been specifically assessed, arm vs. arm and arm vs. abdomen is likely comparable to the abdomen precision based on internal evaluation by Medtronic.

Sensor life

After the first successful calibration, 72.3% of sensors worn operated more than six days and up to the full seven days of wear (144 to 168 hours). The mean functional sensor life for sensors worn in the abdomen insertion site over the course of the study was 144.2 hours, with a median functional life of 167.6 hours.

The mean functional sensor life for sensors worn in the arm insertion site over the course of the study was 146.1 hours, with a median functional life of 167.9 hours.

Safety

There were no moderate or severe device-related or procedure-related adverse events, device-related or procedure-related serious adverse events, or unanticipated adverse device effects through seven days of use.

C. Alert performance for users 14 years and older

The CGM system enables your device to display SG readings, glucose trend arrows, glucose trend graphs, and SG alerts (for example, High and Low Limit Threshold alerts, High and Low Predictive alerts, and Rise and Fall rate-of-change alerts).

The high and low limit alerts (Threshold alerts) let the user know when the SG is at or above the high limit or at or below the low limit. Using only a high or low limit alert may reduce the number of false alerts, but does not provide a warning before reaching a high or low limit.

Predictive alerts notify users that their SG level may soon reach a high or low limit setting. Users may select how early they would like to be notified before their SG level reaches a high limit setting. The earliest warning is 30 minutes before reaching a high limit setting, but users can reduce the amount of warning down to 5 minutes. Users will receive a warning approximately 30 minutes prior to when their SG level is predicted to reach their low limit setting. In general, the earlier the warning, the more time a user will have to react to a potential high or low limit setting, but this also increases the potential for false alerts.

A predictive alert is simply an estimation of a future SG level compared to the high or low limit setting. If the predicted SG value is above the high limit or below the low limit, then a predictive alert is sounded even though the current SG level has not crossed the high or low limit. The predicted SG level is calculated using the current SG level, the derivative of previous SG readings (the trend or slope of the SG readings) and the amount of early warning duration the user selects.

The device will always alert the user when the CGM system reads that the user is below 50 mg/dL, regardless of the high threshold, low threshold, or predictive alerts that the user sets.

Glucose TRUE Alert Rate

The glucose true alert rate is the rate at which the BG confirmed that the CGM alert was triggered correctly. For example:

True Threshold Hypoglycemic alert rate alerted when the CGM system read that the user was below the low threshold and the user's BG was actually below that low threshold.

True Threshold Hyperglycemic alert rate alerted when the CGM system read that the user was above the high threshold and the user's BG was actually above that high threshold.

True Predictive Hypoglycemic alert rate alerted when the CGM system predicted that the user would reach below the low threshold and the user's BG was actually below that low threshold within 15 or 30 minutes.

True Predictive Hyperglycemic alert rate alerted when the CGM system predicted that the user would reach above the high threshold and the user's BG was actually above that high threshold within 15 or 30 minutes.

The true alert rate is important because it is necessary that users be notified when their BG is low (or high) so that they can correct the low (or high) BG. A high true alert rate indicates that when the CGM system says that their glucose values are, or will reach a specified threshold, the user's BG is likely to be at or approaching that threshold.

For example, per the following table, the low glucose alerts would have correctly indicated that the user was below (i.e. threshold only), or predicted to reach below the threshold (i.e. predictive only) or both (predictive and threshold) 66.9%, 52.7%, or 58.3% of the time within 30 minutes (or 66.9%, 47.7%, or 55.2% of the time within 15 minutes) when the user had BG values lower than 70 mg/dL for a sensor inserted in the abdomen.

Table C-1: Glucose TRUE Alert Performance using Calibration every 12 hours							
		Glucose TRUE Alert Rate					
mg/dL	Insertion Site	Threshold Only		Predictive Only		Threshold & Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
50	Abdomen	25.0%	25.0%	15.2%	12.3%	18.2%	16.2%
	Arm	36.8%	36.8%	21.9%	16.7%	26.1%	22.4%
60	Abdomen	53.5%	51.9%	40.7%	37.1%	46.2%	43.4%
	Arm	69.0%	67.8%	47.5%	45.6%	55.1%	53.5%
70	Abdomen	66.9%	66.9%	52.7%	47.7%	58.3%	55.2%
	Arm	77.4%	75.3%	57.4%	54.5%	65.6%	63.0%
80	Abdomen	69.3%	69.3%	57.8%	51.1%	62.2%	58.2%
	Arm	77.5%	76.4%	59.9%	53.0%	66.5%	61.9%
90	Abdomen	75.1%	74.4%	64.0%	58.5%	67.9%	64.3%
	Arm	74.9%	74.9%	69.0%	63.2%	71.3%	68.0%
180	Abdomen	93.7%	92.8%	70.5%	66.9%	78.0%	75.4%
	Arm	92.9%	92.9%	68.0%	63.2%	76.5%	73.7%
220	Abdomen	91.9%	91.9%	68.9%	66.3%	76.6%	74.8%
	Arm	92.2%	92.2%	65.7%	62.2%	74.5%	72.2%
250	Abdomen	90.2%	90.2%	64.0%	60.1%	72.5%	69.8%
	Arm	91.4%	91.4%	62.0%	59.8%	71.1%	69.6%
300	Abdomen	81.3%	81.3%	57.8%	54.0%	65.4%	62.7%
	Arm	81.9%	80.6%	51.7%	49.7%	61.2%	59.3%

Glucose FALSE Alert Rate

The glucose false alert rate is the rate at which the BG did not confirm that the CGM alert was triggered correctly. For example:

False Threshold Hypoglycemic alert rate alerted when the CGM system read that the user was below the low threshold but the user's BG was actually above that low threshold.

False Threshold Hyperglycemic alert rate alerted when the CGM system read that the user was above the high threshold but the user's BG was actually below that high threshold.

False Predictive Hypoglycemic alert rate alerted when the CGM system predicted that the user would be below the low threshold but the user's BG was actually above that low threshold within 15 or 30 minutes.

False Predictive Hyperglycemic alert rate alerted when the CGM system predicted that the user would be above the high threshold but the user's BG was actually below the high threshold within 15 or 30 minutes.

The false alert rate is important because it is necessary that users be correctly notified when their BG is low (or high) so that they can correct the low (or high) BG. A low false alert rate indicates that when the CGM system says that their glucose values are, or will reach a specified threshold, the user's BG is likely to be at or approaching that threshold.

For example, per the following table, the high glucose threshold alerts would have incorrectly indicated that the user was above (i.e. threshold only), or predicted to reach above the threshold (i.e. predictive only), or both (threshold and predictive) 6.30%, 29.5%, or 22% of the time within 30 minutes (or 7.2%, 33.1%, or 24.6% of the time within 15 minutes) when the user had BG less than 180 mg/dL for a sensor inserted in the abdomen.

Table C-2: Glucose FALSE Alert Performance using Calibration every 12 hours

		Glucose FALSE Alert Rate					
mg/dL	Insertion Site	Threshold Only		Predictive Only		Threshold and Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
50	Abdomen	75.0%	75.0%	84.8%	87.7%	81.8%	83.8%
	Arm	63.2%	63.2%	78.1%	83.3%	73.9%	77.6%
60	Abdomen	46.5%	48.1%	59.3%	62.9%	53.8%	56.6%
	Arm	31.0%	32.2%	52.5%	54.4%	44.9%	46.5%
70	Abdomen	33.1%	33.1%	47.3%	52.3%	41.7%	44.8%
	Arm	22.6%	24.7%	42.6%	45.5%	34.4%	37.0%
80	Abdomen	30.7%	30.7%	42.2%	48.9%	37.8%	41.8%
	Arm	22.5%	23.6%	40.1%	47.0%	33.5%	38.1%
90	Abdomen	24.9%	25.6%	36.0%	41.5%	32.1%	35.7%
	Arm	25.1%	25.1%	31.0%	36.8%	28.7%	32.0%
180	Abdomen	6.30%	7.20%	29.5%	33.1%	22.0%	24.6%
	Arm	7.10%	7.10%	32.0%	36.8%	23.5%	26.3%
220	Abdomen	8.10%	8.10%	31.1%	33.7%	23.4%	25.2%
	Arm	7.80%	7.80%	34.3%	37.8%	25.5%	27.8%
250	Abdomen	9.80%	9.80%	36.0%	39.9%	27.5%	30.2%
	Arm	8.60%	8.60%	38.0%	40.2%	28.9%	30.4%
300	Abdomen	18.8%	18.8%	42.2%	46.0%	34.6%	37.3%
	Arm	18.1%	19.4%	48.3%	50.3%	38.8%	40.7%

Glucose Correct Detection Rate

Glucose Correct Detection Rate is the rate that the device alerted when it should have alerted. For example, the BG was below the hypoglycemic threshold, or above the hyperglycemic threshold, and the device sounded an alert.

Glucose detection rates are important because it is necessary that users be notified when their BG is low (or high) so that they can correct the low (or high) BG. A high glucose correct detection rate indicates that users can have confidence that they will be notified by the device if their BG is low or high.

For example, per the following table, the threshold alert, the predictive alert, or both (threshold and predictive) notified the user 64%, 76%, or 76% of the time within 30 minutes (or 64%, 68%, or 68% within 15 minutes) when the user had BG less than 50 mg/dL for a sensor inserted in the abdomen.

Table C-3: Glucose Correct Detection Alert Performance using Calibration every 12 hours

		Glucose Correct Detection Rate					
mg/dL	Insertion Site	Threshold Only		Predictive Only		Threshold & Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
50	Abdomen	64.0%	64.0%	76.0%	68.0%	76.0%	68.0%
	Arm	66.7%	66.7%	95.2%	71.4%	95.2%	76.2%
60	Abdomen	83.3%	82.1%	94.0%	88.1%	94.0%	89.3%
	Arm	86.3%	83.6%	98.6%	94.5%	98.6%	97.3%
70	Abdomen	90.5%	90.5%	94.2%	89.8%	94.2%	92.0%
	Arm	90.2%	88.6%	92.7%	90.2%	93.5%	91.9%
80	Abdomen	87.2%	87.2%	93.6%	87.2%	93.6%	89.9%
	Arm	89.0%	88.4%	94.8%	86.6%	95.9%	92.4%
90	Abdomen	91.1%	88.7%	94.6%	89.5%	95.7%	92.2%
	Arm	91.7%	90.4%	96.9%	91.7%	97.8%	95.6%
180	Abdomen	93.1%	91.4%	96.6%	93.4%	96.9%	95.4%
	Arm	93.2%	92.2%	98.1%	94.2%	98.7%	96.4%
220	Abdomen	90.1%	89.2%	94.8%	93.5%	95.3%	94.4%
	Arm	90.1%	89.2%	96.1%	93.6%	96.1%	95.6%
250	Abdomen	81.5%	80.9%	96.5%	91.3%	96.5%	93.6%
	Arm	80.9%	79.6%	96.7%	90.8%	96.7%	91.4%
300	Abdomen	75.3%	75.3%	95.3%	92.9%	95.3%	94.1%
	Arm	74.4%	71.8%	93.6%	89.7%	93.6%	89.7%

Glucose Missed Detection Rate

The Missed Detection Rate is the rate that the device did not alert when it should have. For example, the BG was below the hypoglycemic threshold, or above the hyperglycemic threshold, and the device did not sound a threshold or predictive alert.

Missed detection rates are important because it is necessary that users be notified when their BG is low (or high), so that they can correct the low (or high) BG. A low missed detection rate indicates that users can have confidence that they will be notified by the device if their BG is low or high.

For example, per the following table, the threshold alert, predictive alert, or both alerts (threshold and predictive) did not sound 36%, 24%, or 24% of the time within 30 minutes (or 36%, 32%, or 32% within 15 minutes) when the user had BG less than 50 mg/dL for a sensor inserted in the abdomen.

Table C-4: Glucose Missed Detection Alert Performance using Calibration every 12 hours

		Glucose Missed Detection Rate					
mg/dL	Insertion Site	Threshold Only		Predictive Only		Threshold & Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
50	Abdomen	36.0%	36.0%	24.0%	32.0%	24.0%	32.0%
	Arm	33.3%	33.3%	4.8%	28.6%	4.8%	23.8%
60	Abdomen	16.7%	17.9%	6.0%	11.9%	6.0%	10.7%
	Arm	13.7%	16.4%	1.4%	5.5%	1.4%	2.7%
70	Abdomen	9.5%	9.5%	5.8%	10.2%	5.8%	8.0%
	Arm	9.8%	11.4%	7.3%	9.8%	6.5%	8.1%
80	Abdomen	12.8%	12.8%	6.4%	12.8%	6.4%	10.1%
	Arm	11.0%	11.6%	5.2%	13.4%	4.1%	7.6%
90	Abdomen	8.9%	11.3%	5.4%	10.5%	4.3%	7.8%
	Arm	8.3%	9.6%	3.1%	8.3%	2.2%	4.4%
180	Abdomen	6.9%	8.6%	3.4%	6.6%	3.1%	4.6%
	Arm	6.8%	7.8%	1.9%	5.8%	1.3%	3.6%
220	Abdomen	9.9%	10.8%	5.2%	6.5%	4.7%	5.6%
	Arm	9.9%	10.8%	3.9%	6.4%	3.9%	4.4%
250	Abdomen	18.5%	19.1%	3.5%	8.7%	3.5%	6.4%
	Arm	19.1%	20.4%	3.3%	9.2%	3.3%	8.6%
300	Abdomen	24.7%	24.7%	4.7%	7.1%	4.7%	5.9%
	Arm	25.6%	28.2%	6.4%	10.3%	6.4%	10.3%

II. Performance data for users ages 7 through 13

D. Device Performance data for users ages 7 through 13

The SmartGuard technology has two levels that include 1) the Suspend on low and Suspend before low features that automatically suspends insulin based on the CGM system and 2) Auto Mode that automatically calculates insulin dosing using the CGM system. A study was performed to evaluate for safety in a multi-center, single-arm, home and hotel clinical investigation. Study subjects included persons

aged 7 to 13 years of age diagnosed with type 1 diabetes mellitus and who were on pump therapy for more than 6 months prior to screening. All study subjects had an HbA1C less than 10.0% at the time of screening.

The first level of SmartGuard technology included evaluation of the "Suspend before low" feature. A total of 105 subjects were asked to exercise in an in-clinic setting, in order to lower blood sugars sufficiently to trigger Suspend before low. Activation was followed by an observation period to ensure subject safety. The target for Suspend before low was set to 65 mg/dL. Subjects underwent FST for a maximum of 12 hours, which included the exercise period, insulin suspension, and approximately 4 hours after resumption of insulin delivery (which may also have included insulin resuspension).

Data from this in-clinic study demonstrated that the Suspend before low feature is safe to use. Study success criteria, as defined in the protocol, were met (i.e. there were no device related serious adverse events, no diabetic ketoacidosis events related to the Suspend before low feature, and no unanticipated adverse device effects).

The second level of SmartGuard technology was the evaluation of Auto Mode, which was accomplished during the 3-month study phase. A total of 105 subjects first used the MiniMed 670G System in Manual Mode (approximately 2 weeks during the run-in phase and 1 additional week at the start of the study phase), before transitioning to Auto Mode at specific points in time during the study phase. The timing of the transition to Auto Mode was based on the scheduling of a 6-day and 5-night hotel or house stay during the study phase. At the hotel or house, subjects underwent daytime and nighttime FST for a total of approximately 24 hours. Subjects were allowed to eat as they normally would, and participated in a daily exercise or activity regimen for a minimum of 4 hours per day, spread throughout the day. All subjects participated in a hotel or house stay and finished the study. During this study, the MiniMed 770G System was used for over 15,353 patient days (including the 2-week run-in phase and the 3-month study phase) without any reported device-related serious adverse events, such as severe hypoglycemia or diabetic ketoacidosis. Compared to Manual Mode used during the run-in phase, use of Auto Mode was associated with reduction in mean SG values, an increase within the range of 71 to 180 mg/dL, and a lower percentage of glucose values in the hyperglycemic and hypoglycemic ranges. There was a significant reduction in mean HbA1c from 7.9±0.8 (median 7.9) at the start of study

to 7.5±0.6 (median 7.5) at the end of study. There was a small change in mean total daily dose of insulin/kg (0.8±0.2 baseline to 0.9±0.2 end of study) and modest increase in weight. Weight gain would also be expected for pediatric patients 7 to 13 years of age as part of the normal growth process.

CAUTION: Note that since this study did not include a control group, no claims regarding effectiveness can be made. However, the study does support that the device is relatively safe for use.

Of the 203 adverse events reported through the end of the study period, 39% (N=80) were classified as device related. Of the 80 device-related adverse events, 65 were glycemic events (hyperglycemia, severe hyperglycemia, and severe hyperglycemia with ketosis) and 14 were related to skin issues (cellulitis, skin infection at the infusion set site, infection at the sensor insertion site, pump site infection on lower abdomen, eczema, and skin irritation). Five adverse events were classified as procedure related (these included neurocardiogenic syncope, headache, and angioedema) and two of the adverse events (hyperglycemia and skin irritation) were classified as both device and procedure related.

There were 104 reports of severe hyperglycemia and there was no diabetic ketoacidosis while on the MiniMed 670G System during the study. The majority of these severe hyperglycemic events (77/104) were mild in intensity. Ketone levels were available for 102 of the 104 severe hyperglycemia episodes and the majority of ketone levels (83/104) were low (10.8–27 mg/dL).

One severe hyperglycemic event was associated with an emergency room visit, however, the ER visit was primarily due to concurrent acute gastroenteritis.

Of the 62 device related episodes of severe hyperglycemia, 51 were believed to be due to infusion set issues such as occlusion, bent cannula or cannula pull out. These issues are typically seen in relatively high rates in the pediatric population (causes provided in Table D-1 and Table D-2). Unlike insulin pump therapy which may or may not have alerts associated with infusion set failure, the MiniMed 670G System has fixed alarms (high alerts) that serve as an additional mitigation for subjects.

Table D-1: Run-In Period Severe Hyperglycemia:	
Cause	**Total**
Infusion set change	9
Occlusion Alarm	3
Infusion set fell out	2
Bent or Kinked Cannula	1
Total	15

Table D-2: Study Period Severe Hyperglycemia:	
Cause	**Total**
Infusion set change	28
Occlusion Alarm	12
Infusion set fell out	7
Bent or Kinked Cannula	5
Infusion set change or safe basal	3
Safe basal	2
Suspend before low suspension	1
Automatic & manual suspensions	1
Unclipped infusion set	1
Internal Battery Connector Resistance	1
Manual suspension and safe basal	1
Total	62

The following table shows the time spent per day in specific glucose ranges during the run-in and study phases by all subjects.

Table D-3: Time Spent in Specific Glucose Ranges During the Run-In and Study Phases by All Subjects		
Glucose Range (mg/dL)	**Run-In Phase**	**Study Phase**
	Time in Glucose Range (min) Mean±SD	**Time in Glucose Range (min) Mean±SD**
≤50	12.2±16.9	7.8±7.3
≤60	32.3±32.7	20.3±14.2
≤70	68.3±55.4	43.1±23.6
70–180	808.6±163.5	936.2±110.4
>180	563.1±184.3	460.7±110.5
>250	191.0±111.5	148.4±74.1
>300	68.1±54.8	53.7±39.4
>350	23.0±24.9	17.4±17.1

The following table shows the ranges of changes in HbA1C observed in the study and indicates the number of subjects that demonstrated each type of change in HbA1C observed.

Table D-4: Number of Subjects with Change in HbA1C at Different Baselines					
HbA1C Change Range	Number of Subjects (% of Subjects) with Change in A1C				
Baseline A1C (%)	Decrease >1%	Decrease 0 to 1%	No Change	Increase 0 to 1%	Increase >1%
5% ≤ A1C < 6%	0(0.0%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
6% ≤ A1C < 7%	0(0.0%)	1(1.0%)	0(0.0%)	9(8.6%)	0(0.0%)
7% ≤ A1C < 8%	3(2.9%)	22(21.0%)	6(5.7%)	16(15.2%)	0(0.0%)
8% ≤ A1C < 9%	9(8.6%)	21(20.0%)	3(2.9%)	4(3.8%)	0(0.0%)
9% ≤ A1C < 10%	4(3.8%)	6(5.7%)	0(0.0%)	0(0.0%)	0(0.0%)
Overall	16(15.2%)	50(47.6%)	9(8.6%)	30(28.6%)	0(0.0%)

The following table shows the number of subjects that spent a specific range of time in specific glucose ranges during the study phase.

Table D-5: Number of Subjects that Spent a Certain Time Range in Each Glucose Range During the Study Phase						
Time Range	Number of Subjects (% of Subjects) in the Glucose Range (mg/dL) Indicated					
	≤50 mg/dL	≤60 mg/dL	≤70 mg/dL	70 to 180 mg/dL	>180 mg/dL	>250 mg/dL
0 to 15 mins	93(88.6%)	41(39.0%)	13(12.4%)	0(0.0%)	0(0.0%)	1(1.0%)
15 to 30 mins	10(9.5%)	46(43.8%)	23(21.9%)	0(0.0%)	0(0.0%)	1(1.0%)
30 to 45 mins	2(1.9%)	12(11.4%)	24(22.9%)	0(0.0%)	0(0.0%)	4(3.8%)
45 mins to 1 hr	0(0.0%)	3(2.9%)	23(21.9%)	0(0.0%)	0(0.0%)	2(1.9%)
1-4 hr	0(0.0%)	3(2.9%)	22(21.0%)	0(0.0%)	2(1.9%)	83(79.0%)
4-8 hr	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	54(51.4%)	14(13.3%)
8-12 hr	0(0.0%)	0(0.0%)	0(0.0%)	5(4.8%)	49(46.7%)	0(0.0%)
12-16 hr	0(0.0%)	0(0.0%)	0(0.0%)	54(51.4%)	0(0.0%)	0(0.0%)
16-20 hr	0(0.0%)	0(0.0%)	0(0.0%)	45(42.9%)	0(0.0%)	0(0.0%)
20-24 hr	0(0.0%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)

The following table shows the average amount of time spent in Auto Mode per day.

Table D-6: Time Spent in Auto Mode at Different Glucose Ranges during the Study Phase	
Glucose Range (mg/dL)	Study Phase Time in Glucose Range (min) Mean±SD
≤50	5.0±4.0
≤60	14.0±9.0
≤70	31.2±16.8
70–180	797.0±142.2
>180	321.9±59.2
>250	84.2±32.4
All	1150.1±132.9

The pediatric pivotal clinical trial of the MiniMed 670G System suggested that the system was safe; however, this trial had a number of limitations which included the following:

- The study involved a relatively small number of patients.
- There was no control group for comparison purposes.
- The amount of time the system was used in the Manual mode was much shorter than the time it was programmed to the Auto Mode.
- Additionally, for each subject, the study period lasted only three months.

Due to these limitations, the results of the clinical trial must be interpreted with caution and you should understand that your individual results when using the MiniMed 670G System may be significantly different from those of the subjects who participated in the trial.

E. Guardian Sensor (3) Performance in users ages 7 to 13

CGM performance

The use of the Guardian Sensor (3) with the Guardian Link (3) transmitter enables CGM technology. The transmitter transmits SG values calculated by the real-time algorithm to a primary display device, allowing you to monitor your SG values.

Clinical study description

The performance of the Guardian Sensor (3) was evaluated in a clinical study.[5] This in-patient (in-clinic) and outpatient (at home) study included subjects 7 to 13 years in age. The study design was a multi-center, prospective single sample correlational design without controls.

All subjects were assigned to treatment. Each subject was instructed to wear two Guardian Sensor (3) sensors in the abdomen or buttock.

- One Guardian Sensor (3) connected to the Guardian Connect Transmitter, which transmitted to the Guardian Connect app, a standalone CGM display device.
- One Guardian Sensor (3) connected to the Guardian Link (3) transmitter, which served as a glucose sensor recorder (GSR, transmitter and recorder for sensor-integrated pump systems).

5 Medtronic Inc., A Performance Evaluation of the Enlite™ and Enlite™ 3 Glucose Sensor to Support Use in Children; CEP249 Data From Subjects 7-13 Years of Age 10703807DOC. November 2017.

The SG data collected by the blinded GSRs were retrospectively processed through the real-time CGM algorithm. This is the same algorithm used in the Guardian Connect and pump CGM systems. Thus all data is representative of real-time sensor usage.

The CONTOUR NEXT LINK 2.4 Wireless Meter was the study meter used for all calibrations in this study, and was the only meter evaluated with the Guardian Sensor (3) CGM systems. The sensor has not been tested with other meters. Therefore, the performance with other BG meters may differ from the performance with the CONTOUR NEXT LINK 2.4 Wireless Meter described below.

FST was performed on day 1, 3, or 7 for 6 hours each, over the life of the sensor. Reference blood (plasma) glucose values were obtained with a YSI Glucose Analyzer every 5 to 15 minutes. During the FSTs, the subjects were instructed to calibrate the sensors once every 12 hours, or as requested by the display device. During home use (outside the clinic), subjects were instructed to calibrate both sensors three to four times spread throughout the day.

The overall number of subjects that participated in FST procedures on day 1, 3, or 7 were 21, 13, and 10 respectively.

During the study, the meter was used for confirmation of alarms, treatment decisions, and sensor calibrations.

Results

Sensor accuracy

The following information highlights the Guardian Sensor (3) performance from 50 subjects (7 to 13 years old) wearing the Guardian Link (3) Transmitter that served as a glucose sensor recorder (GSR, transmitter and recorder for sensor-integrated pump systems and the Guardian Connect Transmitter, which transmitted to the Guardian Connect app, a standalone CGM display device) during FST.

Mean absolute relative difference, by number of daily calibrations

Table E-1 shows the sensor accuracy measured by the MARD. MARD represents the average relative difference (regardless if positive or negative) between the SG values and the paired BG values measured by YSI.

Table E-1: SG MARD Versus YSI (within YSI glucose ranges)								
YSI Glucose Ranges (mg/dL)	Abdomen Insertion Site				Buttock Insertion Site			
	Calibration every 12 hours		Calibration 3 or 4 times a day		Calibration every 12 hours		Calibration 3 or 4 times a day	
	Number of Paired SG-YSI	MARD (%)	Number of Paired SG-YSI	MARD (%)	Number of Paired SG-YSI	MARD (%)	Number of Paired SG-YSI	MARD (%)
Overall	733	10.46	710	9.84	710	9.14	686	8.79
40-60*	4	19.16	2	31.9	7	5.43	7	3.61
61-80*	20	10.59	18	8.54	34	10.85	28	7.86
81-180	378	11.59	367	11.04	393	9.63	374	8.99
181-300	290	8.76	282	8.4	255	7.92	253	8.56
301-350	32	7.11	32	5.63	15	4.64	18	7.67
351-400	9	8.59	9	5.57	6	5.05	6	3.01
* For YSI reference range ≤80 mg/dL, the differences in mg/dL are included instead of percent difference (%). Note: SG Readings are within 40-400 mg/dL.								

Percent agreement, by number of daily calibrations

In Tables E-2 through E-9, the agreement of the SG values to paired YSI values was assessed by calculating the percentage of YSI values that were within 15%, 20%, 30%, 40%, and greater than 40% of the paired SG values. For readings less than or equal to 80 mg/dL, the absolute difference in mg/dL between the SG and paired YSI values was calculated.

Results are shown for defined SG ranges when calibrating every 12 hours and calibrating three or four times a day for sensors.

Table E-2: Agreement (%) of SG-YSI paired points within YSI glucose ranges on FST Days 1, 3, and 7; Calibration every 12 hours, Abdomen						
YSI Glucose Ranges (mg/dL)	Number of Paired SG-YSI	Percent of SG Within 15/15% of YSI	Percent of SG Within 20/20% of YSI	Percent of SG Within 30/30% of YSI	Percent of SG Within 40/40% of YSI	Percent of SG greater than 40/40% of YSI
Overall	733	78.9	87.7	95.9	98.9	1.1
≥40-60*	4	50	50	75	100	0
>60-80*	20	70	80	90	95	5
>80-180	378	74.1	83.1	92.9	98.1	1.9
>180-300	290	83.1	93.1	100	100	0
>300-350	32	100	100	100	100	0
>350-400	9	100	100	100	100	0
* For glucose ranges ≤80 mg/dL, agreement was based on 15/20/30/40 mg/dL. Note: SG readings are within 40-400 mg/dL.						

Table E-3: Agreement (%) of SG-YSI paired points within YSI glucose ranges on FST Day 1; Calibration every 12 hours, Abdomen						
YSI Glucose Ranges (mg/dL)	**Number of Paired SG-YSI**	**Percent of SG Within 15/15% of YSI**	**Percent of SG Within 20/20% of YSI**	**Percent of SG Within 30/30% of YSI**	**Percent of SG Within 40/40% of YSI**	**Percent of SG greater than 40/40% of YSI**
Overall	403	81.9	90.6	96.5	99	1
≥40-60*	2	100	100	100	100	0
>60-80*	11	63.6	72.7	90.9	100	0
>80-180	196	75.5	84.2	93.4	98	2
>180-300	160	86.9	97.5	100	100	0
>300-350	27	100	100	100	100	0
>350-400	7	100	100	100	100	0
* For glucose ranges ≤80 mg/dL, agreement was based on 15/20/30/40 mg/dL.						
Note: The overall number of available paired SG-YSI points on FST Day 1 was from 16 subjects. SG readings are within 40-400 mg/dL.						

Table E-4: Agreement (%) of SG-YSI paired points within YSI glucose ranges on FST Days 1, 3, and 7; Calibration 3 or 4 times a day, Abdomen						
YSI Glucose Ranges (mg/dL)	**Number of Paired SG-YSI**	**Percent of SG Within 15/15% of YSI**	**Percent of SG Within 20/20% of YSI**	**Percent of SG Within 30/30% of YSI**	**Percent of SG Within 40/40% of YSI**	**Percent of SG greater than 40/40% of YSI**
Overall	710	81.7	90	97.2	99.4	0.6
≥40-60*	2	0	0	50	100	0
>60-80*	18	83.3	88.9	94.4	94.4	5.6
>80-180	367	74.9	84.5	95.1	99.2	0.8
>180-300	282	88.3	96.5	100	100	0
>300-350	32	100	100	100	100	0
>350-400	9	100	100	100	100	0
* For glucose ranges ≤80 mg/dL, agreement was based on 15/20/30/40 mg/dL.						
Note: SG readings are within 40-400 mg/dL.						

Table E-5: Agreement (%) of SG-YSI paired points within YSI glucose ranges on FST Day 1; Calibration 3 or 4 times a day, Abdomen						
YSI Glucose Ranges (mg/dL)	**Number of Paired SG-YSI**	**Percent of SG Within 15/15% of YSI**	**Percent of SG Within 20/20% of YSI**	**Percent of SG Within 30/30% of YSI**	**Percent of SG Within 40/40% of YSI**	**Percent of SG greater than 40/40% of YSI**
Overall	372	83.9	92.2	97.3	99.5	0.5
>60-80*	9	77.8	88.9	100	100	0
>80-180	182	76.9	86.3	94.5	98.9	1.1
>180-300	147	89.1	98	100	100	0
>300-350	27	100	100	100	100	0
>350-400	7	100	100	100	100	0
* For glucose ranges ≤80 mg/dL, agreement was based on 15/20/30/40 mg/dL.						
Note: The overall number of available paired SG-YSI points on FST Day 1 was from 15 subjects. SG readings are within 40-400 mg/dL.						

Table E-6: Agreement (%) of SG-YSI paired points within YSI glucose ranges on FST Days 1, 3, and 7; Calibration every 12 hours, Buttock

YSI Glucose Ranges (mg/dL)	Number of Paired SG-YSI	Percent of SG Within 15/15% of YSI	Percent of SG Within 20/20% of YSI	Percent of SG Within 30/30% of YSI	Percent of SG Within 40/40% of YSI	Percent of SG greater than 40/40% of YSI
Overall	710	84.8	92.3	96.8	98.6	1.4
≥40-60*	7	100	100	100	100	0
>60-80*	34	70.6	79.4	94.1	100	0
>80-180	393	80.9	89.8	94.9	97.5	2.5
>180-300	255	91	96.9	99.6	100	0
>300-350	15	100	100	100	100	0
>350-400	6	100	100	100	100	0

* For glucose ranges ≤80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: SG readings are within 40-400 mg/dL.

Table E-7: Agreement (%) of SG-YSI paired points within YSI glucose ranges on FST Day 1; Calibration every 12 hours, Buttock

YSI Glucose Ranges (mg/dL)	Number of Paired SG-YSI	Percent of SG Within 15/15% of YSI	Percent of SG Within 20/20% of YSI	Percent of SG Within 30/30% of YSI	Percent of SG Within 40/40% of YSI	Percent of SG greater than 40/40% of YSI
Overall	335	78.8	87.2	93.7	97	3
>60-80*	19	52.6	63.2	89.5	100	0
>80-180	178	71.9	82.6	89.9	94.4	5.6
>180-300	133	91	96.2	99.2	100	0
>300-350	3	100	100	100	100	0
>350-400	2	100	100	100	100	0

* For glucose ranges ≤80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: The overall number of available paired SG-YSI points on FST Day 1 was from 14 subjects. SG readings are within 40-400 mg/dL.

Table E-8: Agreement (%) of SG-YSI paired points within YSI glucose ranges on FST Days 1, 3, and 7; Calibration 3 or 4 times a day, Buttock

YSI Glucose Ranges (mg/dL)	Number of Paired SG-YSI	Percent of SG Within 15/15% of YSI	Percent of SG Within 20/20% of YSI	Percent of SG Within 30/30% of YSI	Percent of SG Within 40/40% of YSI	Percent of SG greater than 40/40% of YSI
Overall	686	84.7	92.7	97.1	99.1	0.9
≥40-60*	7	100	100	100	100	0
>60-80*	28	85.7	89.3	100	100	0
>80-180	374	82.4	90.4	95.7	98.4	1.6
>180-300	253	87.4	96	98.4	100	0
>300-350	18	83.3	94.4	100	100	0
>350-400	6	100	100	100	100	0

* For glucose ranges ≤80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: SG readings are within 40-400 mg/dL.

Table E-9: Agreement (%) of SG-YSI paired points within YSI glucose ranges on FST Day 1; Calibration 3 or 4 times a day, Buttock						
YSI Glucose Ranges (mg/dL)	Number of Paired SG-YSI	Percent of SG Within 15/15% of YSI	Percent of SG Within 20/20% of YSI	Percent of SG Within 30/30% of YSI	Percent of SG Within 40/40% of YSI	Percent of SG greater than 40/40% of YSI
Overall	311	80.7	90.4	95.5	98.7	1.3
>60-80*	13	69.2	76.9	100	100	0
>80-180	159	77.4	86.8	92.5	97.5	2.5
>180-300	131	87	96.2	98.5	100	0
>300-350	6	50	83.3	100	100	0
>350-400	2	100	100	100	100	0
* For glucose ranges ≤80 mg/dL, agreement was based on 15/20/30/40 mg/dL.						
Note: The overall number of available paired SG-YSI points on FST Day 1 was from 13 subjects. SG readings are within 40-400 mg/dL.						

Agreement when CGM reads "Below 40 mg/dL" or "Above 400 mg/dL"

The real-time CGM systems display glucose values between 40 mg/dL and 400 mg/dL. It displays "Below 40 mg/dL" when the SG value detected is below 40 mg/dL. It displays "Above 400 mg/dL" when the SG value detected is above 400 mg/dL. Tables E-10 through E-13 illustrate the number and percentage of the paired YSI values in different BG levels when the CGM system displays "Below 40 mg/dL" (LOW) or "Above 400 mg/dL" (HIGH).

Table E-10: The number and percentage of YSI values collected when CGM displays "Below 40 mg/dL" (LOW); Calibration every 12 hours								
CGM Readings	Insertion Site	CGM-YSI pairs	<55	<60	<70	<80	>80	Total
LOW	Abdomen	Cumulative, n	2	2	2	2	0	2
		Cumulative %	100%	100%	100%	100%	0%	
	Buttocks	Cumulative, n	3	4	7	7	1	8
		Cumulative %	38%	50%	88%	88%	13%	

Table E-11: The number and percentage of YSI values collected when CGM displays "Below 40 mg/dL" (LOW); Calibration 3 or 4 times a day								
CGM Readings	Insertion Site	CGM-YSI pairs	<55	<60	<70	<80	>80	Total
LOW	Abdomen	Cumulative, n	0	0	0	0	0	0
		Cumulative %	0%	0%	0%	0%	0%	
	Buttocks	Cumulative, n	3	4	6	6	1	7
		Cumulative %	43%	57%	86%	86%	14%	

Table E-12: The number and percentage of YSI values collected when CGM displays "Above 400 mg/dL" (HIGH); Calibration every 12 hours								
CGM Readings	Insertion Site	CGM-YSI pairs	>340	>320	>280	>240	<240	Total
HIGH	Abdomen	Cumulative, n	0	0	0	0	0	0
		Cumulative %	0%	0%	0%	0%	0%	
	Buttocks	Cumulative, n	0	0	0	0	0	0
		Cumulative %	0%	0%	0%	0%	0%	

Table E-13: The number and percentage of YSI values collected when CGM displays "Above 400 mg/dL" (HIGH); Calibration 3 or 4 times a day.								
CGM Readings	**Insertion Site**	**CGM-YSI pairs**	**>340**	**>320**	**>280**	**>240**	**<240**	**Total**
HIGH	Abdomen	Cumulative, n	0	0	0	0	0	0
		Cumulative %	0%	0%	0%	0%	0%	
	Buttocks	Cumulative, n	0	0	0	0	0	0
		Cumulative %	0%	0%	0%	0%	0%	

Concurrence of SG and YSI values

The following tables show the percentage of concurring SG readings with FST reference values.

Table E-14: Overall concurrence of YSI values and SG readings using YSI ranges on FST Days 1, 3, and 7; Calibration every 12 hours, Abdomen												
YSI Glucose Ranges (mg/dL)	**Percent of Matched Pairs-in Each SG Glucose Range for Each YSI Glucose Range**											
	Number of Paired SG-YSI	**SG (mg/dL)**										
		<40	**≥40–60**	**>60–80**	**>80–120**	**>120–160**	**>160–200**	**>200–250**	**>250–300**	**>300–350**	**>350–400**	**>400**
B) ≥40-60	6	33.3% (2/6)	33.3% (2/6)	0.0% (0/0)	33.3% (2/6)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
C) >60-80	20	0.0% (0/0)	10.0% (2/20)	55.0% (11/20)	35.0% (7/20)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80-120	124	0.0% (0/0)	4.8% (6/124)	13.7% (17/124)	66.1% (82/124)	15.3% (19/124)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120-160	169	0.0% (0/0)	0.0% (0/0)	0.6% (1/169)	21.3% (36/169)	62.1% (105/169)	15.4% (26/169)	0.6% (1/169)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160-200	160	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	1.9% (3/160)	25.0% (40/160)	64.4% (103/160)	8.8% (14/160)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200-250	151	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	1.3% (2/151)	40.4% (61/151)	56.3% (85/151)	2.0% (3/151)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
H) >250-300	64	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	32.8% (21/64)	64.1% (41/64)	3.1% (2/64)	0.0% (0/0)	0.0% (0/0)
I) >300-350	32	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	40.6% (13/32)	59.4% (19/32)	0.0% (0/0)	0.0% (0/0)
J) >350-400	9	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	88.9% (8/9)	11.1% (1/9)	0.0% (0/0)

Table E-15: Overall concurrence of YSI values and SG readings using YSI ranges on FST Day 1; Calibration every 12 hours, Abdomen											
YSI Glucose Ranges (mg/dL)	**Percent of Matched Pairs-in Each SG Glucose Range for Each YSI Glucose Range**										
	Number of Paired SG-YSI	**SG (mg/dL)**									
		<40	**≥40–60**	**>60–80**	**>80–120**	**>120–160**	**>160–200**	**>200–250**	**>250–300**	**>300–350**	**>350–400**	**>400**
B) ≥40-60	4	50.0% (2/4)	50.0% (2/4)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
C) >60-80	11	0.0% (0/0)	18.2% (2/11)	45.5% (5/11)	36.4% (4/11)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)

Table E-15: Overall concurrence of YSI values and SG readings using YSI ranges on FST Day 1; Calibration every 12 hours, Abdomen

YSI Glucose Ranges (mg/dL)	Percent of Matched Pairs-in Each SG Glucose Range for Each YSI Glucose Range											
	Number of Paired SG-YSI	SG (mg/dL)										
		<40	≥40–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
D) >80-120	50	0.0% (0/0)	6.0% (3/50)	8.0% (4/50)	62.0% (31/50)	24.0% (12/50)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120-160	94	0.0% (0/0)	0.0% (0/0)	1.1% (1/94)	19.1% (18/94)	58.5% (55/94)	20.2% (19/94)	1.1% (1/94)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160-200	95	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	2.1% (2/95)	17.9% (17/95)	69.5% (66/95)	10.5% (10/95)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200-250	83	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	1.2% (1/83)	27.7% (23/83)	68.7% (57/83)	2.4% (2/83)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
H) >250-300	34	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	44.1% (15/34)	52.9% (18/34)	2.9% (1/34)	0.0% (0/0)	0.0% (0/0)
I) >300-350	27	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	37.0% (10/27)	63.0% (17/27)	0.0% (0/0)	0.0% (0/0)
J) >350-400	7	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	100.0% (7/7)	0.0% (0/0)	0.0% (0/0)

Note: The overall number of available paired SG-YSI points on FST Day 1 was from 16 subjects.

Table E-16: Overall concurrence of YSI values and SG readings using YSI ranges on FST Days 1, 3, and 7; Calibration 3 or 4 times a day, Abdomen

YSI Glucose Ranges (mg/dL)	Percent of Matched Pairs-in Each SG Glucose Range for Each YSI Glucose Range											
	Number of Paired SG-YSI	SG (mg/dL)										
		<40	≥40–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
B) ≥40-60	2	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	100.0% (2/2)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
C) >60-80	18	0.0% (0/0)	0.0% (0/0)	61.1% (11/18)	38.9% (7/18)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80-120	120	0.0% (0/0)	3.3% (4/120)	15.8% (19/120)	67.5% (81/120)	13.3% (16/120)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120-160	162	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	17.9% (29/162)	64.8% (105/162)	16.7% (27/162)	0.6% (1/162)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160-200	161	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	1.2% (2/161)	25.5% (41/161)	65.2% (105/161)	8.1% (13/161)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200-250	145	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	1.4% (2/145)	42.8% (62/145)	53.8% (78/145)	2.1% (3/145)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
H) >250-300	61	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	32.8% (20/61)	65.6% (40/61)	1.6% (1/61)	0.0% (0/0)	0.0% (0/0)
I) >300-350	32	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	37.5% (12/32)	62.5% (20/32)	0.0% (0/0)	0.0% (0/0)
J) >350-400	9	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	55.6% (5/9)	44.4% (4/9)	0.0% (0/0)

Table E-17: Overall concurrence of YSI values and SG readings using YSI ranges on FST Day 1; Calibration 3 or 4 times a day, Abdomen

YSI Glucose Ranges (mg/dL)	Percent of Matched Pairs-in Each SG Glucose Range for Each YSI Glucose Range											
	Number of Paired SG-YSI	SG (mg/dL)										
		<40	≥40–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
C) >60-80	9	0.0% (0/0)	0.0% (0/0)	55.6% (5/9)	44.4% (4/9)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80-120	46	0.0% (0/0)	2.2% (1/46)	10.9% (5/46)	67.4% (31/46)	19.6% (9/46)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120-160	85	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	16.5% (14/85)	60.0% (51/85)	22.4% (19/85)	1.2% (1/85)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160-200	91	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	2.2% (2/91)	16.5% (15/91)	70.3% (64/91)	11.0% (10/91)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200-250	76	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	1.3% (1/76)	27.6% (21/76)	68.4% (52/76)	2.6% (2/76)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
H) >250-300	31	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	38.7% (12/31)	58.1% (18/31)	3.2% (1/31)	0.0% (0/0)	0.0% (0/0)
I) >300-350	27	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	29.6% (8/27)	70.4% (19/27)	0.0% (0/0)	0.0% (0/0)
J) >350-400	7	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	57.1% (4/7)	42.9% (3/7)	0.0% (0/0)

Note: The overall number of available paired SG-YSI points on FST Day 1 was from 15 subjects.

Table E-18: Overall concurrence of YSI values and SG readings using YSI ranges on FST Days 1, 3, and 7; Calibration every 12 hours, Buttock

YSI Glucose Ranges (mg/dL)	Percent of Matched Pairs-in Each SG Glucose Range for Each YSI Glucose Range											
	Number of Paired SG-YSI	SG (mg/dL)										
		<40	≥40–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
B) ≥40-60	11	36.4% (4/11)	63.6% (7/11)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
C) >60-80	37	8.1% (3/37)	24.3% (9/37)	43.2% (16/37)	24.3% (9/37)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80-120	156	0.6% (1/156)	5.1% (8/156)	9.0% (14/156)	75.6% (118/156)	9.6% (15/156)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120-160	170	0.0% (0/0)	0.0% (0/0)	2.9% (5/170)	16.5% (28/170)	67.6% (115/170)	12.9% (22/170)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160-200	144	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	16.0% (23/144)	75.7% (109/144)	8.3% (12/144)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200-250	130	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	2.3% (3/130)	38.5% (50/130)	56.2% (73/130)	3.1% (4/130)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
H) >250-300	49	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	40.8% (20/49)	53.1% (26/49)	6.1% (3/49)	0.0% (0/0)	0.0% (0/0)
I) >300-350	15	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	33.3% (5/15)	60.0% (9/15)	6.7% (1/15)	0.0% (0/0)
J) >350-400	6	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	50.0% (3/6)	50.0% (3/6)	0.0% (0/0)

Table E-19: Overall concurrence of YSI values and SG readings using YSI ranges on FST Day 1; Calibration every 12 hours, Buttock

YSI Glucose Ranges (mg/dL)	Number of Paired SG-YSI	Percent of Matched Pairs-in Each SG Glucose Range for Each YSI Glucose Range										
		SG (mg/dL)										
		<40	≥40–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
B) ≥40-60	4	100.0% (4/4)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
C) >60-80	22	13.6% (3/22)	27.3% (6/22)	31.8% (7/22)	27.3% (6/22)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80-120	68	1.5% (1/68)	11.8% (8/68)	13.2% (9/68)	58.8% (40/68)	14.7% (10/68)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120-160	74	0.0% (0/0)	0.0% (0/0)	6.8% (5/74)	23.0% (17/74)	56.8% (42/74)	13.5% (10/74)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160-200	76	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	18.4% (14/76)	72.4% (55/76)	9.2% (7/76)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200-250	67	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	3.0% (2/67)	19.4% (13/67)	73.1% (49/67)	4.5% (3/67)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
H) >250-300	27	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	44.4% (12/27)	48.1% (13/27)	7.4% (2/27)	0.0% (0/0)	0.0% (0/0)
I) >300-350	3	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	100.0% (3/3)	0.0% (0/0)	0.0% (0/0)
J) >350-400	2	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	50.0% (1/2)	50.0% (1/2)	0.0% (0/0)

Note: The overall number of available paired SG-YSI points on FST Day 1 was from 14 subjects.

Table E-20: Overall concurrence of YSI values and SG readings using YSI ranges on FST Days 1, 3, and 7; Calibration 3 or 4 times a day, Buttock

YSI Glucose Ranges (mg/dL)	Number of Paired SG-YSI	Percent of Matched Pairs-in Each SG Glucose Range for Each YSI Glucose Range										
		SG (mg/dL)										
		<40	≥40–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
B) ≥40-60	11	36.4% (4/11)	63.6% (7/11)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
C) >60-80	30	6.7% (2/30)	10.0% (3/30)	50.0% (15/30)	33.3% (10/30)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80-120	144	0.7% (1/144)	1.4% (2/144)	7.6% (11/144)	80.6% (116/144)	9.7% (14/144)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120-160	164	0.0% (0/0)	0.0% (0/0)	1.8% (3/164)	16.5% (27/164)	67.1% (110/164)	14.0% (23/164)	0.6% (1/164)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160-200	140	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	14.3% (20/140)	75.0% (105/140)	10.7% (15/140)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200-250	127	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	1.6% (2/127)	42.5% (54/127)	51.2% (65/127)	4.7% (6/127)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
H) >250-300	53	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	41.5% (22/53)	39.6% (21/53)	17.0% (9/53)	1.9% (1/53)	0.0% (0/0)
I) >300-350	18	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	38.9% (7/18)	38.9% (7/18)	22.2% (4/18)	0.0% (0/0)
J) >350-400	6	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	16.7% (1/6)	83.3% (5/6)	0.0% (0/0)

Table E-21: Overall concurrence of YSI values and SG readings using YSI ranges on FST Day 1; Calibration 3 or 4 times a day, Buttock												
YSI Glucose Ranges (mg/dL)	Percent of Matched Pairs-in Each SG Glucose Range for Each YSI Glucose Range											
	Number of Paired SG-YSI	SG (mg/dL)										
		<40	≥40–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
B) ≥40-60	4	100.0% (4/4)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
C) >60-80	15	13.3% (2/15)	0.0% (0/0)	40.0% (6/15)	46.7% (7/15)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80-120	56	1.8% (1/56)	3.6% (2/56)	12.5% (7/56)	66.1% (37/56)	16.1% (9/56)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120-160	68	0.0% (0/0)	0.0% (0/0)	4.4% (3/68)	25.0% (17/68)	57.4% (39/68)	13.2% (9/68)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160-200	72	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	15.3% (11/72)	75.0% (54/72)	9.7% (7/72)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200-250	64	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	1.6% (1/64)	29.7% (19/64)	62.5% (40/64)	6.3% (4/64)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
H) >250-300	31	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	45.2% (14/31)	29.0% (9/31)	22.6% (7/31)	3.2% (1/31)	0.0% (0/0)
I) >300-350	6	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	50.0% (3/6)	50.0% (3/6)	0.0% (0/0)	0.0% (0/0)
J) >350-400	2	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	50.0% (1/2)	50.0% (1/2)	0.0% (0/0)
Note: The overall number of available paired SG-YSI points on FST Day 1 was from 13 subjects.												

Percent Agreement Post Calibration

The agreement of the SG values to paired YSI values was assessed for every 2-hour period post sensor calibration. For readings less than or equal to 80 mg/dL, the absolute difference in mg/dL between the SG and paired YSI values was calculated.

Tables E-22 through E-25 show the percent agreement rates post calibration for sensors inserted into the abdomen and buttock.

Table E-22: Agreement rates for every 2-hour period post calibration period; Calibration every 12 hours, Abdomen						
Time after calibration	Number of paired YSI-sensor points	Percentage (%) Agreement				
		±15% (±15 mg/dL)	±20% (±20 mg/dL)	±30% (±30 mg/dL)	±40% (±40 mg/dL)	>±40% (±40 mg/dL)
0–2 hours	224	84.4	93.3	98.7	99.6	0.4
2–4 hours	181	77.9	85.1	94.5	98.3	1.7
4–6 hours	145	72.4	84.1	94.5	98.6	1.4
6–8 hours	77	74	83.1	97.4	100	0
8–10 hours	52	80.8	82.7	86.5	96.2	3.8
10–12 hours	54	81.5	94.4	100	100	0

Table E-23: Agreement rates for every 2-hour period post calibration; Calibration 3 or 4 times a day, Abdomen						
Time after calibration	Number of paired YSI-sensor points	Percentage (%) Agreement				
		±15% (±15 mg/dL)	±20% (±20 mg/dL)	±30% (±30 mg/dL)	±40% (±40 mg/dL)	>±40% (±40 mg/dL)
0-2 hours	360	83.3	90.8	97.8	99.4	0.6
2-4 hours	174	83.9	92.5	98.3	100	0
4-6 hours	53	75.5	90.6	98.1	100	0
6-8 hours	64	73.4	82.8	96.9	100	0
8-10 hours	36	75	77.8	83.3	94.4	5.6
10-12 hours	23	87	95.7	100	100	0

Table E-24: Agreement rates for every 2-hour period post calibration period; Calibration every 12 hours, Buttock						
Time after calibration	Number of paired YSI-sensor points	Percentage (%) Agreement				
		±15% (±15 mg/dL)	±20% (±20 mg/dL)	±30% (±30 mg/dL)	±40% (±40 mg/dL)	>±40% (±40 mg/dL)
0–2 hours	196	81.6	94.9	96.4	98.5	1.5
2–4 hours	195	78.5	85.1	92.8	96.9	3.1
4–6 hours	157	87.9	91.1	99.4	99.4	0.6
6–8 hours	76	96.1	100	100	100	0
8–10 hours	45	97.8	100	100	100	0
10–12 hours	41	82.9	95.1	97.6	100	0

Table E-25: Agreement rates for every 2-hour period post calibration period; Calibration 3 or 4 times a day, Buttock						
Time after calibration	Number of paired YSI-sensor points	Percentage (%) Agreement				
		±15% (±15 mg/dL)	±20% (±20 mg/dL)	±30% (±30 mg/dL)	±40% (±40 mg/dL)	±40% (±40 mg/dL)
0–2 hours	314	81.8	92.4	95.9	98.1	1.9
2–4 hours	195	79.5	88.2	96.4	100	0
4–6 hours	70	94.3	95.7	100	100	0
6–8 hours	52	94.2	100	100	100	0
8–10 hours	37	100	100	100	100	0
10–12 hours	18	94.4	100	100	100	0

Trend accuracy

Tables E-26 through E-29 show, for each SG rate-of-change range (indicated on display by number of arrows), percentage of SG-YSI paired values that fell into different YSI rate-of-change ranges. The tables show the trend accuracy for sensors inserted into the abdomen or buttock.

Table E-26: Trend Accuracy; Calibration every 12 hours, Abdomen							
SG Rate Ranges (mg/dL/min)	Percent of Matched Pairs-in Each YSI Rate Range for Each SG Rate Range						
	YSI (mg/dL/min)						
	Numbered of Paired SG-YSI	<-2	[-2, -1]	[-1, 0]	[0, 1]	[1, 2]	>2
<-2	19	47.4% (9/19)	47.4% (9/19)	0.0% (0/19)	5.3% (1/19)	0.0% (0/19)	0.0% (0/19)
[-2, -1]	107	2.8% (3/107)	31.8% (34/107)	60.7% (65/107)	3.7% (4/107)	0.9% (1/107)	0.0% (0/107)
[-1, 0]	276	0.7% (2/276)	5.8% (16/276)	71.7% (198/276)	21.0% (58/276)	0.7% (2/276)	0.0% (0/276)
[0, 1]	209	0.0% (0/209)	1.0% (2/209)	22.5% (47/209)	62.2% (130/209)	13.9% (29/209)	0.5% (1/209)
[1, 2]	98	0.0% (0/98)	0.0% (0/98)	1.0% (1/98)	37.8% (37/98)	59.2% (58/98)	2.0% (2/98)
>2	23	0.0% (0/23)	0.0% (0/23)	4.3% (1/23)	8.7% (2/23)	30.4% (7/23)	56.5% (13/23)

Table E-27: Trend Accuracy; Calibration 3 or 4 times a day, Abdomen							
SG Rate Ranges (mg/dL/min)	Percent of Matched Pairs-in Each YSI Rate Range for Each SG Rate Range						
	YSI (mg/dL/min)						
	Numbered of Paired SG-YSI	<-2	[-2, -1]	[-1, 0]	[0, 1]	[1, 2]	>2
<-2	17	41.2% (7/17)	47.1% (8/17)	5.9% (1/17)	5.9% (1/17)	0.0% (0/17)	0.0% (0/17)
[-2, -1]	105	2.9% (3/105)	32.4% (34/105)	60.0% (63/105)	3.8% (4/105)	1.0% (1/105)	0.0% (0/105)
[-1, 0]	273	0.4% (1/273)	6.2% (17/273)	72.5% (198/273)	20.1% (55/273)	0.7% (2/273)	0.0% (0/273)
[0, 1]	199	0.5% (1/199)	0.5% (1/199)	22.6% (45/199)	63.3% (126/199)	12.6% (25/199)	0.5% (1/199)
[1, 2]	98	0.0% (0/98)	0.0% (0/98)	2.0% (2/98)	36.7% (36/98)	59.2% (58/98)	2.0% (2/98)
>2	17	0.0% (0/17)	0.0% (0/17)	5.9% (1/17)	11.8% (2/17)	41.2% (7/17)	41.2% (7/17)

Table E-28: Trend Accuracy; Calibration every 12 hours, Buttock							
SG Rate Ranges (mg/dL/min)	Percent of Matched Pairs-in Each YSI Rate Range for Each SG Rate Range						
	YSI (mg/dL/min)						
	Numbered of Paired SG-YSI	<-2	[-2, -1]	[-1, 0]	[0, 1]	[1, 2]	>2
<-2	35	37.1% (13/35)	45.7% (16/35)	17.1% (6/35)	0.0% (0/35)	0.0% (0/35)	0.0% (0/35)
[-2, -1]	83	7.2% (6/83)	31.3% (26/83)	59.0% (49/83)	2.4% (2/83)	0.0% (0/83)	0.0% (0/83)
[-1, 0]	272	0.0% (0/272)	4.8% (13/272)	69.9% (190/272)	21.7% (59/272)	2.9% (8/272)	0.7% (2/272)
[0, 1]	199	0.0% (0/199)	0.5% (1/199)	22.1% (44/199)	60.8% (121/199)	15.6% (31/199)	1.0% (2/199)
[1, 2]	97	0.0% (0/97)	0.0% (0/97)	4.1% (4/97)	36.1% (35/97)	54.6% (53/97)	5.2% (5/97)
>2	23	0.0% (0/23)	0.0% (0/23)	0.0% (0/23)	26.1% (6/23)	34.8% (8/23)	39.1% (9/23)

Table E-29: Trend Accuracy; Calibration 3 or 4 times a day, Buttock							
SG Rate Ranges (mg/dL/min)	Percent of Matched Pairs-in Each YSI Rate Range for Each SG Rate Range						
	YSI (mg/dL/min)						
	Numbered of Paired SG-YSI	<-2	[-2, -1]	[-1, 0]	[0, 1]	[1, 2]	>2
<-2	31	41.9% (13/31)	38.7% (12/31)	19.4% (6/31)	0.0% (0/31)	0.0% (0/31)	0.0% (0/31)
[-2, -1]	83	7.2% (6/83)	32.5% (27/83)	56.6% (47/83)	3.6% (3/83)	0.0% (0/83)	0.0% (0/83)

Table E-29: Trend Accuracy; Calibration 3 or 4 times a day, Buttock							
SG Rate Ranges (mg/dL/min)	Percent of Matched Pairs-in Each YSI Rate Range for Each SG Rate Range						
	YSI (mg/dL/min)						
	Numbered of Paired SG-YSI	<-2	[-2, -1]	[-1, 0]	[0, 1]	[1, 2]	>2
[-1, 0]	261	0.0% (0/261)	5.0% (13/261)	71.6% (187/261)	21.1% (55/261)	2.3% (6/261)	0.0% (0/261)
[0, 1]	194	0.0% (0/194)	0.5% (1/194)	22.2% (43/194)	62.9% (122/194)	13.4% (26/194)	1.0% (2/194)
[1, 2]	94	0.0% (0/94)	0.0% (0/94)	4.3% (4/94)	36.2% (34/94)	56.4% (53/94)	3.2% (3/94)
>2	22	0.0% (0/22)	0.0% (0/22)	0.0% (0/22)	22.7% (5/22)	36.4% (8/22)	40.9% (9/22)

Precision

Precision of the system was evaluated by comparing the results from two separate sensors worn on the same subject at the same time.

Data from two sensors worn at the same time for 11 subjects, both inserted in the abdomen, provided 772 pairs of CGM measurements, with a mean PARD during the study of 7.83% and a coefficient of variation (%CV) of 5.7%.

Data from two sensors worn at the same time for 18 subjects, one inserted in the abdomen and one in the buttock, provided 1302 pairs of CGM measurements, with a mean PARD during the study of 11.33% and a coefficient of variation (%CV) of 7.8%.

Data from two sensors worn at the same time for 10 subjects, both inserted in the buttock, provided 695 pairs of CGM measurements, with a mean PARD during the study of 10.93% and a coefficient of variation (%CV) of 8.1%.

Sensor life

After the first successful calibration, 64.3% of sensors worn in the abdomen operated more than six days and up to the full seven days of wear (144 to 168 hours). The mean functional sensor life for sensors worn in the abdomen insertion site over the course of the study was 122.1 hours, with a median functional life of 128.4 hours.

After the first successful calibration, 81.3% of sensors worn in the buttock operated more than six days and up to the full seven days of wear (144 to 168 hours). The mean functional sensor life for sensors worn in the buttock insertion site over the course of the study was 142.7 hours, with a median functional life of 158.1 hours.

Safety

There were no moderate or severe device-related or procedure-related adverse events, device-related or procedure-related serious adverse events, or unanticipated adverse device effects through seven days of use.

F. Alert performance for user ages 7 through 13

The CGM system enables your device to display SG readings, glucose trend arrows, glucose trend graphs, and SG alerts (for example, High and Low Limit Threshold alerts, High and Low Predictive alerts, and Rise and Fall rate-of-change alerts).

The high and low limit alerts (Threshold alerts) let the user know when the SG is at or above the high limit or at or below the low limit. Using only a high or low limit alert may reduce the number of false alerts, but does not provide a warning before reaching a high or low limit.

Predictive alerts notify users that their SG level may soon reach a high or low limit setting. Users may select how early they would like to be notified before their SG level reaches a high limit setting. The earliest warning is 30 minutes before reaching a high, but users can reduce the amount of warning down to 5 minutes. Users will receive a warning approximately 30 minutes prior to when their SG level is predicted to reach their low limit setting. In general, the earlier the warning, the more time a user will have to react to a potential high or low, but this also increases the potential for false alerts.

A predictive alert is simply an estimation of a future SG level compared to the high or low limit setting. If the predicted SG value is above the high limit or below the low limit, then a predictive alert is sounded even though the current SG level has not crossed the high or low limit. The predicted SG level is calculated using the current SG level, the derivative of previous SG readings (the trend or slope of the SG readings) and the amount of early warning duration the user selects.

The device will always alert the user when the CGM system reads that the user is below 50 mg/dL, regardless of the high threshold, low threshold, or predictive alerts that the user sets.

Glucose TRUE Alert Rate

The glucose true alert rate is the rate at which the BG confirmed that the CGM alert was triggered correctly. For example

True Threshold Hypoglycemic alert rate alerted when the CGM system read that the user was below the low threshold and the user's BG was actually below that low threshold.

True Threshold Hyperglycemic alert rate alerted when the CGM system read that the user was above the high threshold and the user's BG was actually above that high threshold.

True Predictive Hypoglycemic alert rate alerted when the CGM system predicted that the user would reach below the low threshold and the user's BG was actually below that low threshold within 15 or 30 minutes.

True Predictive Hyperglycemic alert rate alerted when the CGM system predicted that the user would reach above the high threshold and the user's BG was actually above that high threshold within 15 or 30 minutes.

The true alert rate is important because it is necessary that users be notified when their BG is low (or high) so that they can correct the low (or high) BG. A high true alert rate indicates that when the CGM system says that their glucose values are, or will reach a specified threshold, the user's BG is likely to be at or approaching that threshold.

For example, per the following table, when wearing the sensor in the abdomen, the low glucose alerts would have correctly indicated that the user was below (i.e. threshold only), or predicted to reach below the threshold (i.e. predictive only), or both (predictive and threshold) 44.4%, 28.6%, or 36.4% of the time within 30 minutes (or 44.4%, 14.3%, or 27.3% of the time within 15 minutes) when the user had BG values lower than 70 mg/dL.

Table F-1: Glucose TRUE Alert Performance using Calibration every 12 hours

		Glucose TRUE Alert Rate					
mg/dL	Insertion Site	Threshold Only		Predictive Only		Threshold & Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
50	Abdomen	33.3%	33.3%	12.5%	12.5%	18.2%	18.2%
	Buttock	25.0%	25.0%	11.1%	11.1%	16.7%	16.7%
60	Abdomen	25.0%	25.0%	8.3%	8.3%	12.5%	12.5%
	Buttock	60.0%	60.0%	25.0%	16.7%	35.3%	29.4%
70	Abdomen	44.4%	44.4%	28.6%	14.3%	36.4%	27.3%
	Buttock	60.0%	60.0%	36.8%	26.3%	40.7%	33.3%
80	Abdomen	33.3%	33.3%	31.6%	15.8%	32.3%	22.6%
	Buttock	61.1%	61.1%	46.2%	38.5%	51.2%	46.5%

Table F-1: Glucose TRUE Alert Performance using Calibration every 12 hours							
		Glucose TRUE Alert Rate					
mg/dL	Insertion Site	Threshold Only		Predictive Only		Threshold & Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
90	Abdomen	55.0%	55.0%	46.2%	30.8%	47.7%	38.6%
	Buttock	70.8%	70.8%	58.3%	44.4%	62.5%	53.6%
180	Abdomen	78.4%	78.4%	66.2%	66.2%	70.5%	70.5%
	Buttock	83.3%	81.3%	64.3%	62.9%	70.6%	68.8%
220	Abdomen	87.5%	87.5%	60.0%	57.8%	68.2%	66.7%
	Buttock	75.0%	75.0%	51.0%	49.0%	58.3%	56.9%
250	Abdomen	81.3%	81.3%	53.1%	46.9%	63.0%	58.7%
	Buttock	73.3%	73.3%	41.2%	35.3%	50.0%	45.7%
300	Abdomen	77.8%	77.8%	44.4%	44.4%	55.6%	55.6%
	Buttock	57.1%	57.1%	31.3%	31.3%	38.1%	38.1%
Note: Given the small sample size of data available in the low range, the alert performance in the 50 mg/dL and 60 mg/dL should be interpreted with caution and may not reflect actual use performance.							

Glucose FALSE Alert Rate

The glucose false alert rate is the rate at which the BG did not confirm that the CGM alert was triggered correctly. For example:

False Threshold Hypoglycemic alert rate alerted when the CGM system read that the user was below the low threshold but the user's BG was actually above that low threshold.

False Threshold Hyperglycemic alert rate alerted when the CGM system read that the user was above the high threshold but the user's BG was actually below that high threshold.

False Predictive Hypoglycemic alert rate alerted when the CGM system predicted that the user would be below the low threshold but the user's BG was actually above that low threshold within 15 or 30 minutes.

The false alert rate is important because it is necessary that users be correctly notified when their BG is low (or high) so that they can correct the low (or high) BG. A low false alert rate indicates that when the CGM system says that their glucose values are, or will reach a specified threshold, the user's BG is likely to be at or approaching that threshold.

For example, per the following table, when wearing the sensor in the abdomen, the high glucose threshold alerts would have incorrectly indicated that the user was above (i.e. threshold only), or predicted to reach above the threshold (i.e.

predictive only), or both (threshold and predictive) 21.6%, 33.8%, or 29.5% of the time within 30 minutes (or 21.6%, 33.8%, or 29.5% of the time within 15 minutes) when the user had BG less than 180 mg/dL.

Table F-2: Glucose FALSE Alert Performance using Calibration every 12 hours

		Glucose FALSE Alert Rate					
mg/dL	Insertion Site	Threshold Only		Predictive Only		Threshold & Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
50	Abdomen	66.7%	66.7%	87.5%	87.5%	81.8%	81.8%
	Buttock	75.0%	75.0%	88.9%	88.9%	83.3%	83.3%
60	Abdomen	75.0%	75.0%	91.7%	91.7%	87.5%	87.5%
	Buttock	40.0%	40.0%	75.0%	83.3%	64.7%	70.6%
70	Abdomen	55.6%	55.6%	71.4%	85.7%	63.6%	72.7%
	Buttock	40.0%	40.0%	63.2%	73.7%	59.3%	66.7%
80	Abdomen	66.7%	66.7%	68.4%	84.2%	67.7%	77.4%
	Buttock	38.9%	38.9%	53.8%	61.5%	48.8%	53.5%
90	Abdomen	45.0%	45.0%	53.8%	69.2%	52.3%	61.4%
	Buttock	29.2%	29.2%	41.7%	55.6%	37.5%	46.4%
180	Abdomen	21.6%	21.6%	33.8%	33.8%	29.5%	29.5%
	Buttock	16.7%	18.8%	35.7%	37.1%	29.4%	31.2%
220	Abdomen	12.5%	12.5%	40.0%	42.2%	31.8%	33.3%
	Buttock	25.0%	25.0%	49.0%	51.0%	41.7%	43.1%
250	Abdomen	18.8%	18.8%	46.9%	53.1%	37.0%	41.3%
	Buttock	26.7%	26.7%	58.8%	64.7%	50.0%	54.3%
300	Abdomen	22.2%	22.2%	55.6%	55.6%	44.4%	44.4%
	Buttock	42.9%	42.9%	68.8%	68.8%	61.9%	61.9%

Note: Given the small sample size of data available in the low range, the alert performance in the 50 mg/dL and 60 mg/dL should be interpreted with caution and may not reflect actual use performance.

Glucose Correct Detection Rate

Glucose Correct Detection Rate is the rate that the device alerted when it should have alerted. For example, the BG was below the hypoglycemic threshold, or above the hyperglycemic threshold, and the device sounded an alert.

Glucose detection rates are important because it is necessary that users be notified when their BG is low (or high) so that they can correct the low (or high) BG. A high glucose correct detection rate indicates that users can have confidence that they will be notified by the device if their BG is low or high.

For example, per the following table, when wearing the sensor in the abdomen, the threshold alert, the predictive alert, or both (threshold and predictive) notified the user 100%, 100%, or 100% of the time within 30 minutes (or 100%, 100%, or 100% within 15 minutes) when the user had BG less than 50 mg/dL.

Table F-3: Glucose Correct Detection Alert Performance using Calibration every 12 hours

		Glucose Correct Detection Rate					
mg/dL	Insertion Site	Threshold Only		Predictive Only		Threshold & Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
50	Abdomen	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
	Buttock	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
60	Abdomen	50.0%	50.0%	50.0%	50.0%	50.0%	50.0%
	Buttock	100.0%	100.0%	100.0%	66.7%	100.0%	100.0%
70	Abdomen	80.0%	80.0%	80.0%	40.0%	80.0%	80.0%
	Buttock	85.7%	85.7%	85.7%	71.4%	85.7%	85.7%
80	Abdomen	66.7%	66.7%	83.3%	50.0%	83.3%	66.7%
	Buttock	85.7%	85.7%	85.7%	78.6%	85.7%	85.7%
90	Abdomen	91.7%	91.7%	91.7%	66.7%	91.7%	91.7%
	Buttock	86.4%	86.4%	90.9%	72.7%	95.5%	86.4%
180	Abdomen	95.1%	95.1%	100.0%	100.0%	100.0%	100.0%
	Buttock	97.5%	95.0%	100.0%	100.0%	100.0%	100.0%
220	Abdomen	92.6%	85.2%	96.3%	88.9%	96.3%	88.9%
	Buttock	95.7%	95.7%	100.0%	95.7%	100.0%	100.0%
250	Abdomen	77.8%	77.8%	88.9%	83.3%	88.9%	83.3%
	Buttock	68.8%	62.5%	100.0%	93.8%	100.0%	100.0%
300	Abdomen	80.0%	80.0%	100.0%	90.0%	100.0%	90.0%
	Buttock	60.0%	60.0%	100.0%	100.0%	100.0%	100.0%

Note: Given the small sample size of data available in the low range, the alert performance in the 50 mg/dL and 60 mg/dL should be interpreted with caution and may not reflect actual use performance.

Glucose Missed Detection Rate

The Missed Detection Rate is the rate that the device did not alert when it should have. For example, the BG was below the hypoglycemic threshold, or above the hyperglycemic threshold, and the device did not sound a threshold or predictive alert.

Missed detection rates are important because it is necessary that users be notified when their BG is low (or high), so that they can correct the low (or high) BG. A low missed detection rate indicates that users can have confidence that they will be notified by the device if their BG is low or high.

For example, per the following table, when wearing the sensor in the abdomen, the threshold alert, predictive alert, or both alerts (threshold and predictive) did not sound 0%, 0%, or 0% of the time within 30 minutes (or 0%, 0%, or 0% within 15 minutes) when the user had BG less than 50 mg/dL.

Table F-4: Glucose Missed Detection Alert Performance using Calibration every 12 hours

		Glucose Missed Detection Rate					
mg/dL	Insertion Site	Threshold Only		Predictive Only		Threshold & Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
50	Abdomen	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
	Buttock	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
60	Abdomen	50.0%	50.0%	50.0%	50.0%	50.0%	50.0%
	Buttock	0.0%	0.0%	0.0%	33.3%	0.0%	0.0%
70	Abdomen	20.0%	20.0%	20.0%	60.0%	20.0%	20.0%
	Buttock	14.3%	14.3%	14.3%	28.6%	14.3%	14.3%
80	Abdomen	33.3%	33.3%	16.7%	50.0%	16.7%	33.3%
	Buttock	14.3%	14.3%	14.3%	21.4%	14.3%	14.3%
90	Abdomen	8.3%	8.3%	8.3%	33.3%	8.3%	8.3%
	Buttock	13.6%	13.6%	9.1%	27.3%	4.5%	13.6%
180	Abdomen	4.9%	4.9%	0.0%	0.0%	0.0%	0.0%
	Buttock	2.5%	5.0%	0.0%	0.0%	0.0%	0.0%
220	Abdomen	7.4%	14.8%	3.7%	11.1%	3.7%	11.1%
	Buttock	4.3%	4.3%	0.0%	4.3%	0.0%	0.0%
250	Abdomen	22.2%	22.2%	11.1%	16.7%	11.1%	16.7%
	Buttock	31.3%	37.5%	0.0%	6.3%	0.0%	0.0%
300	Abdomen	20.0%	20.0%	0.0%	10.0%	0.0%	10.0%
	Buttock	40.0%	40.0%	0.0%	0.0%	0.0%	0.0%

Note: Given the small sample size of data available in the low range, the alert performance in the 50 mg/dL and 60 mg/dL should be interpreted with caution and may not reflect actual use performance.

III. Performance data for users 2 through 6 years old

G. Device Performance data for users ages 2 through 6

The SmartGuard technology has two levels that include the 1) Suspend on low and Suspend before low that automatically suspends insulin based on CGM and 2) Auto mode that automatically calculates insulin dosing using CGM. A study was performed to evaluate for safety in a multi-center, single arm, clinical investigation. Study subjects included persons aged 2 to 6 years of age diagnosed with type 1

diabetes mellitus and who were on pump therapy for more than 90 days prior to screening. All study subjects had an HbA1C less than 10.0% at the time of screening visit.

For the first level of SmartGuard technology, the "Suspend before low" feature, subjects 2-6 years of age were set up but did not participate in frequent sample testing.

For this study, there were 47 subjects in the 2-6 year old cohort that entered the run-in phase. During the run-in phase, 1 subject withdrew. Therefore, 46 subjects in the 2-6 year old cohort entered the study-phase. The second level of SmartGuard technology, the "Auto Mode" feature, was evaluated during the 3-month study phase. Subjects 2-6 years of age are not required to participate in a hotel study. Instead, they will participate in an out-of-home study for 5 consecutive days, 4-6 hours per day. During that 5 day period, subjects should engage in significant activity/exercise. Such activities could include utilizing gym play areas appropriate for toddlers and young children, swimming, and playground games. Evidence of geographic location and exercise/activity will be documented by daily photograph. In addition, investigational center staff will be present daily for the 4-6 hours of exercise during the 5 day period.

During this study, the MiniMed 670G System data was collected for subjects 2-6 years old and was used for over 6697 patient days prior to Run-In + Run-In + Study periods) without any reported device-related serious adverse events, such as severe hypoglycemia or diabetic ketoacidosis. Compared to Manual Mode used during the Run-In phase, use of Auto Mode was associated with reduction in mean sensor glucose values, an increase within the range of 71 to 180 mg/dL and a lower percentage of glucose values in the hyperglycemic and hypoglycemic ranges. There was a significant reduction in mean HbA1c from 8.0±0.9% median 8.1) at the baseline to 7.5±0.6 (median 7.5) at the end of study. There was a small change in mean total daily dose of insulin/kg (0.8±0.1 baseline to 0.8±0.2 end of study) and modest increase in weight. Weight gain would also be expected for pediatric patients 2-6 years of age as part of the normal growth process.

CAUTION: Note that since this study did not include a control group, no claims regarding effectiveness can be made. However, the study does support that the device is relatively safe for use.

Of the 138 adverse events reported through the end of the study period, 39% (N=54) were classified as device related, including glycemic events (severe hyperglycemia) and skin issues (abscess, dermatitis, skin infection at the infusion set site and skin irritation). Of the 54 device-related adverse events, 49 were severe hyperglycemia events that were thought to be device related. There were no procedure related events.

There were 86 reports of severe hyperglycemia and there was no diabetic ketoacidosis while on the MiniMed 670G System during the study. The majority of these severe hyperglycemic events (81/86) were mild in intensity. Ketone levels were available for 83 of the 86 severe hyperglycemia episodes and the majority of ketone levels (57/86) were low (0.6–1.5 mmol/L).

Of the 49 device related episodes of severe hyperglycemia, 46 were believed to be due to infusion set issues such as occlusion, bent cannula or cannula pull out. These issues are typically seen in relatively high rates in the pediatric population (causes provided in Table G-1 and Table G-2). Unlike insulin pump therapy which may or may not have alerts associated with infusion set failure, the MiniMed 670G System has fixed alarms (high alerts) that serve as an additional mitigation for subjects.

Table G-1. Run in Period Severe Hyperglycemia:

Cause	Total
Infusion set change	9
Occlusion alarm	0
Infusion set fell out	0
Bent or Kinked Cannula	0
Total	9

Table G-2. Study Period Severe Hyperglycemia

Cause	Total
Infusion set change	29
Occlusion alarm	3
Infusion set fell out	2
Bent or Kinked Cannula	1
Infusion set change or safe basal	1
Safe basal	1
Suspend before low suspension	1
Automatic & manual suspensions	1
Total	39

The following table shows the time spent per day in specific glucose ranges during the run-in and study phases by all subjects.

Table G-3: Time Spent in Specific Glucose Ranges During the Run-In and Study Phases by All Subjects		
Glucose Range (mg/dL)	**Run-In Phase**	**Study Phase**
	Time in Glucose Range (min) Mean±SD	**Time in Glucose Range (min) Mean±SD**
≤50	7.5±8.8	7.4±6.5
≤60	22.4±20.2	21.4±13.6
≤70	51.9±37.7	49.7±23.7
>70–180	797.6±191.6	915.5±134.8
>180	590.5±211.1	474.8±142.6
>250	210.6±136.0	153.5±85.4
>300	75.0±70.8	53.5±41.2
>350	23.9±30.8	16.6±16.4

The following table shows the ranges of changes in HbA1C observed in the study and indicates the number of subjects that demonstrated each type of change in HbA1C observed.

Table G-4: Number of Subjects with Change in HbA1C at Different Baselines					
HbA1C Change Range	**Number of Subjects (% of Subjects) with Change in A1C**				
Baseline A1C (%)	**Decrease >1%**	**Decrease 0 to 1%**	**No Change**	**Increase 0 to 1%**	**Increase > 1%**
5% ≤ A1C<6%	-	-	-	-	-
6% ≤ A1C<7%	0(0.0%)	0(0.0%)	0(0.0%)	6(13.0%)	0(0.0%)
7% ≤ A1C<8%	2(4.3%)	7(15.2%)	0(0.0%)	4(8.7%)	0(0.0%)
8% ≤ A1C<9%	4(8.7%)	11(23.9%)	1(2.2%)	2(4.3%)	0(0.0%)
9% ≤ A1C<10%	5(10.9%)	2(4.3%)	0(0.0%)	0(0.0%)	0(0.0%)
Overall	11(23.9%)	20(43.5%)	1(2.2%)	12(26.1%)	0(0.0%)
Note: For the blank cells (-), there are no subjects age 2-6 with a baseline A1C in this category.					

The following table shows the number of subjects that spent a specific range of time in specific glucose ranges during the study phase.

Table G-5: Number of Subjects that Spent a Certain Time Range in Each Glucose Range During the Study Phase								
Time Range	**Number of Subjects (% of Subjects) in the Glucose Range (mg/dL) Indicated**							
	≤ 50 mg/dL	**≤ 60 mg/dL**	**≤ 70 mg/dL**	**70 to 180 mg/dL**	**> 180 mg/dL**	**> 250 mg/dL**	**>300 mg/dL**	**>350 mg/dL**
0 to 15 mins	41 (89.1%)	17 (37.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.2%)	11 (23.9%)	28 (60.9%)
15 to 30 mins	4 (8.7%)	21 (45.7%)	8 (17.4%)	0(0.0%)	0(0.0%)	2(4.3%)	5 (10.9%)	9 (19.6%)
30 to 45 mins	1(2.2%)	5 (10.9%)	16 (34.8%)	0(0.0%)	0(0.0%)	1(2.2%)	7 (15.2%)	6 (13.0%)
45 mins to 1 hr	0(0.0%)	2(4.3%)	12 (26.1%)	0(0.0%)	0(0.0%)	1(2.2%)	6 (13.0%)	2(4.3%)
1-4 hr	0(0.0%)	1(2.2%)	10 (21.7%)	0(0.0%)	3(6.5%)	34 (73.9%)	17 (37.0%)	1(2.2%)

Table G-5: Number of Subjects that Spent a Certain Time Range in Each Glucose Range During the Study Phase								
Time Range	Number of Subjects (% of Subjects) in the Glucose Range (mg/dL) Indicated							
	≤ 50 mg/dL	≤ 60 mg/dL	≤ 70 mg/dL	70 to 180 mg/dL	> 180 mg/dL	> 250 mg/dL	>300 mg/dL	>350 mg/dL
4-8 hr	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	18 (39.1%)	7 (15.2%)	0(0.0%)	0(0.0%)
8-12 hr	0(0.0%)	0(0.0%)	0(0.0%)	3(6.5%)	22 (47.8%)	0(0.0%)	0(0.0%)	0(0.0%)
12-16 hr	0(0.0%)	0(0.0%)	0(0.0%)	25 (54.3%)	3(6.5%)	0(0.0%)	0(0.0%)	0(0.0%)
16-20 hr	0(0.0%)	0(0.0%)	0(0.0%)	17 (37.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
20-24 hr	0(0.0%)	0(0.0%)	0(0.0%)	1(2.2%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

Table G-6: Time Spent in Auto Mode at Different Glucose Ranges during the Study Phase	
Glucose Range (mg/dL)	Study Phase Time in Glucose Range (min) Mean±SD
≤ 50	6.2±5.4
≤ 60	18.1±11.4
≤ 70	42.4±19.8
70–180	805.1±139.8
>180	371.9±106.1
>250	107.7±56.5
>300 mg/dL	32.3±23.9
>350 mg/dL	7.7±7.5
All	1219.4±93.0

The pediatric pivotal clinical trial of the 670G suggested that the system was safe; however, this trial had a number of limitations which included the following:

- The study involved a relatively small number of patients.
- There was no control group for comparison purposes.
- The amount of time the system was used in the Manual mode was much shorter than the time it was programmed to the Auto mode.
- Additionally, for each subject, the study period lasted only three months.

Due to these limitations, the results of the clinical trial must be interpreted with caution and you should understand that your individual results when using the 670G system may be significantly different from those of the subjects who participated in the trial.

H. Guardian Sensor (3) Performance in users ages 2 through 6

CGM performance

The use of the Guardian Sensor (3) with the Guardian Link (3) transmitter enables CGM technology. The transmitter transmits sensor glucose values calculated by the real-time algorithm to a primary display device, allowing you to monitor your sensor glucose values.

Clinical study description

The performance of the Guardian Sensor (3) was evaluated in a clinical study[6]. This in-patient (in-clinic) and outpatient (at home) study included subjects 2 to 6 years in age. The study design was a multi-center, prospective single sample correlational design without controls.

All subjects were assigned to treatment. Each subject was instructed to wear two Guardian™ Sensor (3) sensors in the abdomen and/or buttock.

1. One Guardian Sensor (3) connected to the Guardian Connect Transmitter, which transmitted to the Guardian Connect app, a standalone CGM display device.
2. One Guardian Sensor (3) connected to the Guardian Link (3) transmitter, which served as a glucose sensor recorder (GSR, transmitter/recorder for sensor integrated pump systems).

The sensor glucose data collected by the blinded GSRs were retrospectively processed through the real-time CGM algorithm. This is the same algorithm used in the Guardian™ Connect and pump CGM systems. Thus, all data is representative of real-time sensor usage.

The CONTOUR®NEXT LINK 2.4 Wireless Meter was the study meter used for all calibrations in this study, and was the only meter evaluated with the Guardian Sensor (3) CGM systems. The sensor has not been tested with other meters. Therefore, the performance with other blood glucose meters may differ from the performance with the CONTOUR NEXT LINK 2.4 Wireless Meter described below.

Subjects aged 2-6 years old will be randomly assigned to which day to come in for the FST but may have their parents choose the area for sensor placement.

Frequent Sample Testing (FST) was performed on day 1, 3, or 7, for 6 hours each, over the life of the sensor. Reference blood (plasma) glucose values were obtained with a Blood Glucose Meter (BGM) or Yellow Springs Instrument (YSI®) Glucose

6 Medtronic Inc., A Performance Evaluation of the Enlite™ and Enlite™ 3 Glucose Sensor to Support Use in Children; CEP249 Data From Subjects 7-13 Years of Age 10901316DOC. May2019.

Analyzer every 5 to 15 minutes. During the FSTs, the subjects were instructed to calibrate the sensors once every 12 hours, or as requested by the display device. During home use (outside the clinic), subjects were instructed to calibrate both sensors three to four times spread throughout the day.

The overall number of subjects that participated in FST procedures on day 1, 3, or 7 were 6, 7, and 8, respectively.

During the study, the meter was used for confirmation of alarms, treatment decisions and sensor calibrations.

Results

Sensor accuracy

The following information highlights the Guardian Sensor (3) performance from 21 subjects (2 to 6 years old) wearing the Guardian Link (3) Transmitter that served as a glucose sensor recorder (GSR, transmitter/recorder for sensor-integrated pump systems and the Guardian Connect Transmitter, which transmitted to the Guardian Connect app, a standalone CGM display device) during FST.

Mean absolute relative difference, by number of daily calibrations

Table H-1 shows the sensor accuracy measured by the mean absolute relative difference (MARD). MARD represents the average relative difference (regardless if positive or negative) between the sensor glucose (SG) values and the paired blood glucose values measured by YSI (or BGM).

Table H-1: SG MARD Versus YSI or BGM (within YSI glucose ranges)

YSI Glucose Ranges (mg/dL)	Abdomen Insertion Site				Buttock Insertion Site			
	Calibration every 12 hours		Calibration 3 or 4 times a day		Calibration every 12 hours		Calibration 3 or 4 times a day	
	Number of Paired SG-YSI	Mean Absolute Relative Difference (%)	Number of Paired SG-YSI	Mean Absolute Relative Difference (%)	Number of Paired SG-YSI	Mean Absolute Relative Difference (%)	Number of Paired SG-YSI	Mean Absolute Relative Difference (%)
Overall	62	10.7	62	10.96	195	10.1	159	10.05
40-60*	-	-	-	-	2	21.5	2	23
61-80*	1	7	1	7	12	14.76	12	11.51
81-180	26	10.12	26	10.12	99	10.72	78	11.54
181-300	30	11.9	30	11.98	73	7.09	60	6.03
301-350	5	6.73	5	9.46	8	6.63	7	7.5
351-400	-	-	-	-	1	7.71	-	-

Table H-1: SG MARD Versus YSI or BGM (within YSI glucose ranges)								
YSI Glucose Ranges (mg/dL)	Abdomen Insertion Site				Buttock Insertion Site			
	Calibration every 12 hours		Calibration 3 or 4 times a day		Calibration every 12 hours		Calibration 3 or 4 times a day	
	Number of Paired SG-YSI	Mean Absolute Relative Difference (%)	Number of Paired SG-YSI	Mean Absolute Relative Difference (%)	Number of Paired SG-YSI	Mean Absolute Relative Difference (%)	Number of Paired SG-YSI	Mean Absolute Relative Difference (%)

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

Note: SG Readings are within 40-400 mg/dL.

Note: For the blank Cells (-), there are no paired points in this reference range.

Percent agreement, by number of daily calibrations

In Tables H-2 through 9, the agreement of the SG values to paired YSI (or BGM) values were assessed by calculating the percentage of SG values that were within 15%, 20%, 30%, 40% and greater than 40% of the paired YSI (or BGM) values. For readings less than or equal to 80 mg/dL, the absolute difference in mg/dL between the SG and paired YSI (or BGM) values were calculated.

Results are shown for defined YSI (or BGM) ranges when calibrating every 12 hours and calibrating three or four times a day for sensors.

Table H-2: Agreement (%) of SG-YSI (or BGM) paired points within YSI (or BGM) glucose ranges on Frequent Sample Testing (FST) Days 1, 3, and 7; Calibration every 12 hours, Abdomen

YSI Glucose Ranges (mg/dL)	Number of Paired SG-YS	Percent of SG Within 15/15% of YSI	Percent of SG Within 20/20% of YSI	Percent of SG Within 30/30% of YSI	Percent of SG Within 40/40% of YSI	Percent of SG Within >40/40% of YSI
Overall	62	72.6	85.5	96.8	100	0
≥40-60*	-	-	-	-	-	-
>60-80*	1	100	100	100	100	0
>80-180	26	80.8	88.5	96.2	100	0
>180-300	30	60	80	96.7	100	0
>300-350	5	100	100	100	100	0
>350-400	-	-	-	-	-	-

*For glucose ranges ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: Sensor glucose readings are within 40-400 mg/dL.

Note: For the blank Cells (-), there are no paired points in this reference range.

Table H-3: Agreement (%) of SG-YSI (or BGM) paired points within YSI (or BGM) glucose ranges on Frequent Sample Testing (FST) Day 1; Calibration every 12 hours, Abdomen

YSI Glucose Ranges (mg/dL)	Number of Paired SG-YS	Percent of SG Within 15/15% of YSI	Percent of SG Within 20/20% of YSI	Percent of SG Within 30/30% of YSI	Percent of SG Within 40/40% of YSI	Percent of SG Within >40/40% of YSI
Overall	11	72.7	100	100	100	0

Table H-3: Agreement (%) of SG-YSI (or BGM) paired points within YSI (or BGM) glucose ranges on Frequent Sample Testing (FST) Day 1; Calibration every 12 hours, Abdomen

YSI Glucose Ranges (mg/dL)	Number of Paired SG-YS	Percent of SG Within 15/15% of YSI	Percent of SG Within 20/20% of YSI	Percent of SG Within 30/30% of YSI	Percent of SG Within 40/40% of YSI	Percent of SG Within >40/40% of YSI
≥40-60*	-	-	-	-	-	-
>60-80*	-	-	-	-	-	-
>80-180	1	100	100	100	100	0
>180-300	10	70	100	100	100	0
>300-350	-	-	-	-	-	-
>350-400	-	-	-	-	-	-

*For glucose ranges ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: Sensor glucose readings are within 40-400 mg/dL.

Note: For the blank Cells (-), there are no paired points in this reference range.

Table H-4: Agreement (%) of SG-YSI (or BGM) paired points within YSI (or BGM) glucose ranges on Frequent Sample Testing (FST) Days 1, 3, and 7; Calibration 3 or 4 times a day, Abdomen

YSI Glucose Ranges (mg/dL)	Number of Paired SG-YS	Percent of SG Within 15/15% of YSI	Percent of SG Within 20/20% of YSI	Percent of SG Within 30/30% of YSI	Percent of SG Within 40/40% of YSI	Percent of SG Within >40/40% of YSI
Overall	62	71	83.9	98.4	100	0
≥40-60*	-	-	-	-	-	-
>60-80*	1	100	100	100	100	0
>80-180	26	80.8	88.5	96.2	100	0
>180-300	30	60	80	100	100	0
>300-350	5	80	80	100	100	0
>350-400	-	-	-	-	-	-

*For glucose ranges ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: Sensor glucose readings are within 40-400 mg/dL.

Note: For the blank Cells (-), there are no paired points in this reference range.

Table H-5: Agreement (%) of SG-YSI (or BGM) paired points within YSI (or BGM) glucose ranges on Frequent Sample Testing Day 1; Calibration 3 or 4 times a day, Abdomen

YSI Glucose Ranges (mg/dL)	Number of Paired SG-YS	Percent of SG Within 15/15% of YSI	Percent of SG Within 20/20% of YSI	Percent of SG Within 30/30% of YSI	Percent of SG Within 40/40% of YSI	Percent of SG Within >40/40% of YSI
Overall	11	72.7	100	100	100	0
>60-80*	-	-	-	-	-	-
>80-180	1	100	100	100	100	0
>180-300	10	70	100	100	100	0
>300-350	-	-	-	-	-	-
>350-400	-	-	-	-	-	-

Table H-5: Agreement (%) of SG-YSI (or BGM) paired points within YSI (or BGM) glucose ranges on Frequent Sample Testing Day 1; Calibration 3 or 4 times a day, Abdomen

YSI Glucose Ranges (mg/dL)	Number of Paired SG-YS	Percent of SG Within 15/15% of YSI	Percent of SG Within 20/20% of YSI	Percent of SG Within 30/30% of YSI	Percent of SG Within 40/40% of YSI	Percent of SG Within >40/40% of YSI

*For glucose ranges ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: Sensor glucose readings are within 40-400 mg/dL.

Note: For the blank Cells (-), there are no paired points in this reference range.

Table H-6: Agreement (%) of SG-YSI (or BGM) paired points within YSI (or BGM) glucose ranges on Frequent Sample Testing (FST) Days 1, 3, and 7; Calibration every 12 hours, Buttock

YSI Glucose Ranges (mg/dL)	Number of Paired SG-YS	Percent of SG Within 15/15% of YSI	Percent of SG Within 20/20% of YSI	Percent of SG Within 30/30% of YSI	Percent of SG Within 40/40% of YSI	Percent of SG Within >40/40% of YSI
Overall	195	81.5	88.7	97.4	98.5	1.5
≥40-60*	2	50	50	50	100	0
>60-80*	12	75	83.3	91.7	91.7	8.3
>80-180	99	78.8	85.9	97	98	2
>180-300	73	84.9	93.2	100	100	0
>300-350	8	100	100	100	100	0
>350-400	1	100	100	100	100	0

*For glucose ranges ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: Sensor glucose readings are within 40-400 mg/dL.

Table H-7: Agreement (%) of SG-YSI (or BGM) paired points within YSI (or BGM) glucose ranges on Frequent Sample Testing (FST) Day 1; Calibration every 12 hours, Buttock

YSI Glucose Ranges (mg/dL)	Number of Paired SG-YS	Percent of SG Within 15/15% of YSI	Percent of SG Within 20/20% of YSI	Percent of SG Within 30/30% of YSI	Percent of SG Within 40/40% of YSI	Percent of SG Within >40/40% of YSI
Overall	93	71	83.9	96.8	97.8	2.2
≥40-60*	1	100	100	100	100	0
>60-80*	10	70	80	90	90	10
>80-180	46	63	78.3	95.7	97.8	2.2
>180-300	31	77.4	90.3	100	100	0
>300-350	4	100	100	100	100	0
>350-400	1	100	100	100	100	0

*For glucose ranges ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: Sensor glucose readings are within 40-400 mg/dL.

Table H- 8: Agreement (%) of SG-YSI (or BGM) paired points within YSI (or BGM) glucose ranges on Frequent Sample Testing (FST) Days 1, 3, and 7; Calibration 3 or 4 times a day, Buttock

YSI Glucose Ranges (mg/dL)	Number of Paired SG-YS	Percent of SG Within 15/15% of YSI	Percent of SG Within 20/20% of YSI	Percent of SG Within 30/30% of YSI	Percent of SG Within 40/40% of YSI	Percent of SG Within >40/40% of YSI
Overall	159	84.3	88.7	96.2	97.5	2.5
≥40-60*	2	50	50	50	50	50

Table H- 8: Agreement (%) of SG-YSI (or BGM) paired points within YSI (or BGM) glucose ranges on Frequent Sample Testing (FST) Days 1, 3, and 7; Calibration 3 or 4 times a day, Buttock						
YSI Glucose Ranges (mg/dL)	**Number of Paired SG-YS**	**Percent of SG Within 15/15% of YSI**	**Percent of SG Within 20/20% of YSI**	**Percent of SG Within 30/30% of YSI**	**Percent of SG Within 40/40% of YSI**	**Percent of SG Within >40/40% of YSI**
>60-80*	12	75	91.7	100	100	0
>80-180	78	78.2	83.3	93.6	96.2	3.8
>180-300	60	93.3	95	100	100	0
>300-350	7	100	100	100	100	0
>350-400	-	-	-	-	-	-
*For glucose ranges ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL. **Note:** Sensor glucose readings are within 40-400 mg/dL. **Note:** For the blank Cells (-), there are no paired points in this reference range.						

Table H-9: Agreement (%) of SG-YSI (or BGM) paired points within YSI (or BGM) glucose ranges on Frequent Sample Testing Day 1; Calibration 3 or 4 times a day, Buttock						
YSI Glucose Ranges (mg/dL)	**Number of Paired SG-YS**	**Percent of SG Within 15/15% of YSI**	**Percent of SG Within 20/20% of YSI**	**Percent of SG Within 30/30% of YSI**	**Percent of SG Within 40/40% of YSI**	**Percent of SG Within >40/40% of YSI**
Overall	70	74.3	81.4	94.3	97.1	2.9
≥40-60*	1	100	100	100	100	0
>60-80*	10	80	90	100	100	0
>80-180	37	59.5	70.3	89.2	94.6	5.4
>180-300	19	94.7	94.7	100	100	0
>300-350	3	100	100	100	100	0
>350-400	-	-	-	-	-	-
*For glucose ranges ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL. **Note:** Sensor glucose readings are within 40-400 mg/dL. **Note:** For the blank Cells (-), there are no paired points in this reference range.						

Agreement when CGM reads “Below 40 mg/dL” or “Above 400 mg/dL"

The real-time CGM systems display glucose values between 40 mg/dL and 400 mg/dL. It displays “Below 40 mg/dL” when the SG value detected is below 40 mg/dL. It displays “Above 400 mg/dL” when the SG value detected is above 400 mg/dL. Tables H-10 through H-13 illustrate the number and percentage of the paired YSI (or BGM) values in different blood glucose levels when the CGM system displays “Below 40 mg/dL” (LOW) or “Above 400 mg/dL” (HIGH).

Table H-10: The number and percentage of YSI (or BGM) values collected when CGM displays 'Below 40 mg/dL' (LOW); Calibration every 12 hours.								
CGM Readings	**Insertion Site**	**CGM-YSI pairs**	**<55**	**<60**	**<70**	**<80**	**>80**	**Total**
LOW	Abdomen	Cumulative, n	0	0	0	0	0	0
		Cumulative %	0%	0%	0%	0%	0%	0%
	Buttocks	Cumulative, n	0	0	0	0	0	0
		Cumulative %	0%	0%	0%	0%	0%	0%

Table H-11: The number and percentage of YSI (or BGM) values collected when CGM displays 'Below 40 mg/dL' (LOW); Calibration 3 or 4 times a day.								
CGM Readings	**Insertion Site**	**CGM-YSI pairs**	**<55**	**<60**	**<70**	**<80**	**>80**	**Total**
LOW	Abdomen	Cumulative, n	0	0	0	0	0	0
		Cumulative %	0%	0%	0%	0%	0%	0%
	Buttocks	Cumulative, n	0	0	0	0	0	0
		Cumulative %	0%	0%	0%	0%	0%	0%

Table H-12: The number and percentage of YSI (or BGM) values collected when CGM displays 'Above 400 mg/dL' (HIGH); Calibration every 12 hours.								
CGM Readings	**Insertion Site**	**CGM-YSI pairs**	**>340**	**>320**	**>280**	**>240**	**<240**	**Total**
HIGH	Abdomen	Cumulative, n	0	0	1	1	0	1
		Cumulative %	0%	0%	100%	100%	0%	100%
	Buttocks	Cumulative, n	0	0	0	0	0	0
		Cumulative %	0%	0%	0%	0%	0%	0%

Table H-13. The number and percentage of YSI (or BGM) values collected when CGM displays 'Above 400 mg/dL' (HIGH); Calibration 3 or 4 times a day.								
CGM Readings	**Insertion Site**	**CGM-YSI pairs**	**>340**	**>320**	**>280**	**>240**	**<240**	**Total**
HIGH	Abdomen	Cumulative, n	0	0	1	1	0	1
		Cumulative %	0%	0%	100%	100%	0%	100%
	Buttocks	Cumulative, n	0	0	0	0	0	0
		Cumulative %	0%	0%	0%	0%	0%	0%

Concurrence of SG and YSI values

The following tables show the percentage of concurring SG readings with FST reference values.

Table H-14: Overall concurrence of YSI (or BGM) values and SG readings using YSI ranges on FST Days 1, 3, and 7; Calibration every 12 hours, Abdomen												
YSI Glucose Ranges (mg/dL)	**Percent of Matched Pairs-in Each SG Glucose Range for Each YSI Glucose Range**											
	SG (mg/dL)											
	Number of Paired SG-YSI	**<40**	**≥40-60**	**>60-80**	**>80-120**	**>120-160**	**>160-200**	**>200-250**	**>250-300**	**>300-350**	**>350-400**	**>400**
B) ≥40-60	-	-	-	-	-	-	-	-	-	-	-	-

Table H-14: Overall concurrence of YSI (or BGM) values and SG readings using YSI ranges on FST Days 1, 3, and 7; Calibration every 12 hours, Abdomen

YSI Glucose Ranges (mg/dL)	Percent of Matched Pairs-in Each SG Glucose Range for Each YSI Glucose Range											
	SG (mg/dL)											
	Number of Paired SG-YSI	<40	≥40-60	>60-80	>80-120	>120-160	>160-200	>200-250	>250-300	>300-350	>350-400	>400
C) >60-80	1	0.0% (0/0)	0.0% (0/0)	100.0% (1/1)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80-120	11	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	63.6% (7/11)	36.4% (4/11)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120-160	10	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	20.0% (2/10)	60.0% (6/10)	20.0% (2/10)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160-200	11	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	18.2% (2/11)	63.6% (7/11)	18.2% (2/11)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200-250	6	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	16.7% (1/6)	0.0% (0/0)	33.3% (2/6)	50.0% (3/6)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
H) >250-300	19	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	21.1% (4/19)	47.4% (9/19)	21.1% (4/19)	5.3% (1/19)	5.3% (1/19)
I) >300-350	5	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	20.0% (1/5)	80.0% (4/5)	0.0% (0/0)	0.0% (0/0)
J) >350-400	-	-	-	-	-	-	-	-	-	-	-	-

Note: For the blank Cells (-), there are no paired points in this reference range.

Table H- 15: Overall concurrence of YSI (or BGM) values and SG readings using YSI (or BGM) ranges on FST Day 1; Calibration every 12 hours, Abdomen

YSI Glucose Ranges (mg/dL)	Percent of Matched Pairs-in Each SG Glucose Range for Each YSI Glucose Range											
	SG (mg/dL)											
	Number of Paired SG-YSI	<40	≥40-60	>60-80	>80-120	>120-160	>160-200I	>200-250	>250-300	>300-350	>350-400	>400
B) ≥40-60	-	-	-	-	-	-	-	-	-	-	-	-
C) >60-80	-	-	-	-	-	-	-	-	-	-	-	-
D) >80-120	-	-	-	-	-	-	-	-	-	-	-	-
E) >120-160	1	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	100.0% (1/1)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160-200	4	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	50.0% (2/4)	50.0% (2/4)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200-250	2	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	50.0% (1/2)	50.0% (1/2)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
H) >250-300	4	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	75.0% (3/4)	25.0% (1/4)	0.0% (0/0)	0.0% (0/0)
I) >300-350	-	-	-	-	-	-	-	-	-	-	-	-

Table H- 15: Overall concurrence of YSI (or BGM) values and SG readings using YSI (or BGM) ranges on FST Day 1; Calibration every 12 hours, Abdomen

YSI Glucose Ranges (mg/dL)	Percent of Matched Pairs-in Each SG Glucose Range for Each YSI Glucose Range											
	SG (mg/dL)											
	Number of Paired SG-YSI	<40	≥40-60	>60-80	>80-120	>120-160	>160-200l	>200-250	>250-300	>300-350	>350-400	>400
J) >350-400	-	-	-	-	-	-	-	-	-	-	-	-

Note: For the blank Cells (-), there are no paired points in this reference range.

Table H- 16: Overall concurrence of YSI (or BGM) values and SG readings using YSI (or BGM) ranges on FST Days 1, 3, and 7; Calibration 3 or 4 times a day, Abdomen

YSI Glucose Ranges (mg/dL)	Percent of Matched Pairs-in Each SG Glucose Range for Each YSI Glucose Range											
	SG (mg/dL)											
	Number of Paired SG-YSI	<40	≥40-60	>60-80	>80-120	>120-160	>160-200	>200-250	>250-300	>300-350	>350-400	>400
B) ≥40-60	-	-	-	-	-	-	-	-	-	-	-	-
C) >60-80	1	0.0% (0/0)	0.0% (0/0)	100.0% (1/1)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80-120	11	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	63.6% (7/11)	36.4% (4/11)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120-160	10	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	20.0% (2/10)	60.0% (6/10)	20.0% (2/10)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160-200	11	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	18.2% (2/11)	63.6% (7/11)	18.2% (2/11)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200-250	6	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	16.7% (1/6)	0.0% (0/0)	33.3% (2/6)	50.0% (3/6)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
H) >250-300	19	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	26.3% (5/19)	42.1% (8/19)	21.1% (4/19)	5.3% (1/19)	5.3% (1/19)
I) >300-350	5	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	20.0% (1/5)	20.0% (1/5)	60.0% (3/5)	0.0% (0/0)	0.0% (0/0)
J) >350-400	-	-	-	-	-	-	-	-	-	-	-	-

Note: For the blank Cells (-), there are no paired points in this reference range.

Table H-17: Overall concurrence of YSI (or BGM) values and SG readings using YSI (or BGM) ranges on FST Day 1; Calibration 3 or 4 times a day, Abdomen

YSI Glucose Ranges (mg/dL)	Percent of Matched Pairs-in Each SG Glucose Range for Each YSI Glucose Range											
	SG (mg/dL)											
	Number of Paired SG-YSI	<40	≥40-60	>60-80	>80-120	>120-160	>160-200	>200-250	>250-300	>300-350	>350-400	>400
C) >60-80	-	-	-	-	-	-	-	-	-	-	-	-

Table H-17: Overall concurrence of YSI (or BGM) values and SG readings using YSI (or BGM) ranges on FST Day 1; Calibration 3 or 4 times a day, Abdomen

YSI Glucose Ranges (mg/dL)	Percent of Matched Pairs-in Each SG Glucose Range for Each YSI Glucose Range											
	SG (mg/dL)											
	Number of Paired SG-YSI	<40	≥40-60	>60-80	>80-120	>120-160	>160-200	>200-250	>250-300	>300-350	>350-400	>400
D) >80-120	-	-	-	-	-	-	-	-	-	-	-	-
E) >120-160	1	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	100.0% (1/1)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160-200	4	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	50.0% (2/4)	50.0% (2/4)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200-250	2	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	50.0% (1/2)	50.0% (1/2)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
H) >250-300	4	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	75.0% (3/4)	25.0% (1/4)	0.0% (0/0)	0.0% (0/0)
I) >300-350	-	-	-	-	-	-	-	-	-	-	-	-
J) >350-400	-	-	-	-	-	-	-	-	-	-	-	-

Note: For the blank Cells (-), there are no paired points in this reference range.

Table H-18. Overall concurrence of YSI (or BGM) values and SG readings using YSI (or BGM) ranges on FST Days 1, 3, and 7; Calibration every 12 hours, Buttock

YSI Glucose Ranges (mg/dL)	Percent of Matched Pairs-in Each SG Glucose Range for Each YSI Glucose Range											
	SG (mg/dL)											
	Number of Paired SG-YSI	40	≥40-60	>60-80	>80-120	>120-160	>160-200	>200-250	>250-300	>300-350	>350-400	>400
B) ≥40-60	2	0.0% (0/0)	50.0% (1/2)	0.0% (0/0)	50.0% (1/2)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
C) >60-80	12	0.0% (0/0)	25.0% (3/12)	33.3% (4/12)	41.7% (5/12)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80-120	31	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	87.1% (27/31)	12.9% (4/31)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120-160	45	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	17.8% (8/45)	60.0% (27/45)	22.2% (10/45)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160-200	41	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	17.1% (7/41)	65.9% (27/41)	17.1% (7/41)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200-250	31	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	16.1% (5/31)	77.4% (24/31)	6.5% (2/31)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
H) >250-300	24	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	4.2% (1/24)	16.7% (4/24)	70.8% (17/24)	8.3% (2/24)	0.0% (0/0)	0.0% (0/0)
I) >300-350	8	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	62.5% (5/8)	25.0% (2/8)	12.5% (1/8)	0.0% (0/0)

Table H-18. Overall concurrence of YSI (or BGM) values and SG readings using YSI (or BGM) ranges on FST Days 1, 3, and 7; Calibration every 12 hours, Buttock

YSI Glucose Ranges (mg/dL)	Percent of Matched Pairs-in Each SG Glucose Range for Each YSI Glucose Range											
	SG (mg/dL)											
	Number of Paired SG-YSI	40	≥40-60	>60-80	>80-120	>120-160	>160-200	>200-250	>250-300	>300-350	>350-400	>400
J) >350-400	1	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	100.0% (1/1)	0.0% (0/0)

Table H-19. Overall concurrence of YSI (or BGM) values and SG readings using YSI (or BGM) ranges on FST Day 1; Calibration every 12 hours, Buttock

YSI Glucose Ranges (mg/dL)	Percent of Matched Pairs-in Each SG Glucose Range for Each YSI Glucose Range											
	SG (mg/dL)											
	Number of Paired SG-YSI	<40	≥40-60	>60-80	>80-120	>120-160	>160-200	>200-250	>250-300	>300-350	>350-400	>400
B) ≥40-60	1	0.0% (0/0)	100.0% (1/1)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
C) >60-80	10	0.0% (0/0)	30.0% (3/10)	40.0% (4/10)	30.0% (3/10)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80-120	14	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	78.6% (11/14)	21.4% (3/14)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120-160	21	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	14.3% (3/21)	47.6% (10/21)	38.1% (8/21)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160-200	19	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	31.6% (6/19)	47.4% (9/19)	21.1% (4/19)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200-250	11	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	18.2% (2/11)	72.7% (8/11)	9.1% (1/11)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
H) >250-300	12	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	8.3% (1/12)	16.7% (2/12)	58.3% (7/12)	16.7% (2/12)	0.0% (0/0)	0.0% (0/0)
I) >300-350	4	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	50.0% (2/4)	25.0% (1/4)	25.0% (1/4)	0.0% (0/0)
J) >350-400	1	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	100.0% (1/1)	0.0% (0/0)

Table H-20. Overall concurrence of YSI (or BGM) values and SG readings using YSI (or BGM) ranges on FST Days 1, 3, and 7; Calibration 3 or 4 times a day, Buttock

YSI Glucose Ranges (mg/dL)	Percent of Matched Pairs-in Each SG Glucose Range for Each YSI Glucose Range											
	SG (mg/dL)											
	Number of Paired SG-YSI	<40	≥40-60	>60-80	>80-120	>120-160	>160-200	>200-250	>250-300	>300-350	>350-400	>400
B) ≥40-60	2	0.0% (0/0)	50.0% (1/2)	0.0% (0/0)	50.0% (1/2)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)

Table H-20. Overall concurrence of YSI (or BGM) values and SG readings using YSI (or BGM) ranges on FST Days 1, 3, and 7; Calibration 3 or 4 times a day, Buttock

YSI Glucose Ranges (mg/dL)	Percent of Matched Pairs-in Each SG Glucose Range for Each YSI Glucose Range											
	SG (mg/dL)											
	Number of Paired SG-YSI	<40	≥40-60	>60-80	>80-120	>120-160	>160-200	>200-250	>250-300	>300-350	>350-400	>400
C) >60-80	12	0.0% (0/0)	25.0% (3/12)	33.3% (4/12)	41.7% (5/12)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80-120	23	0.0% (0/0)	0.0% (0/0)	8.7% (2/23)	73.9% (17/23)	13.0% (3/23)	4.3% (1/23)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120-160	36	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	11.1% (4/36)	61.1% (22/36)	27.8% (10/36)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160-200	33	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	6.1% (2/33)	72.7% (24/33)	18.2% (6/33)	3.0% (1/33)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200-250	27	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	18.5% (5/27)	70.4% (19/27)	11.1% (3/27)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
H) >250-300	19	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	10.5% (2/19)	78.9% (15/19)	10.5% (2/19)	0.0% (0/0)	0.0% (0/0)
I) >300-350	7	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	71.4% (5/7)	14.3% (1/7)	14.3% (1/7)	0.0% (0/0)
J) >350-400	-	-	-	-	-	-	-	-	-	-	-	-

Note: For the blank Cells (-), there are no paired points in this reference range.

Table H-21. Overall concurrence of YSI (or BGM) values and SG readings using YSI (or BGM) ranges on FST Day 1; Calibration 3 or 4 times a day, Buttock

YSI Glucose Ranges (mg/dL)	Percent of Matched Pairs-in Each SG Glucose Range for Each YSI Glucose Range											
	SG (mg/dL)											
	Number of Paired SG-YSI	<40	≥40-60	>60-80	>80-120	>120-160	>160-200	>200-250	>250-300	>300-350	>350-400	>400
B) ≥40-60	1	0.0% (0/0)	100.0% (1/1)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
C) >60-80	10	0.0% (0/0)	30.0% (3/10)	40.0% (4/10)	30.0% (3/10)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80-120	13	0.0% (0/0)	0.0% (0/0)	7.7% (1/13)	69.2% (9/13)	15.4% (2/13)	7.7% (1/13)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120-160	16	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	6.3% (1/16)	50.0% (8/16)	43.8% (7/16)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160-200	13	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	69.2% (9/13)	23.1% (3/13)	7.7% (1/13)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200-250	7	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	14.3% (1/7)	71.4% (5/7)	14.3% (1/7)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
H) >250-300	7	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	71.4% (5/7)	28.6% (2/7)	0.0% (0/0)	0.0% (0/0)

Table H-21. Overall concurrence of YSI (or BGM) values and SG readings using YSI (or BGM) ranges on FST Day 1; Calibration 3 or 4 times a day, Buttock												
YSI Glucose Ranges (mg/dL)	Percent of Matched Pairs-in Each SG Glucose Range for Each YSI Glucose Range											
	SG (mg/dL)											
	Number of Paired SG-YSI	<40	≥40-60	>60-80	>80-120	>120-160	>160-200	>200-250	>250-300	>300-350	>350-400	>400
I) >300-350	3	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	66.7% (2/3)	0.0% (0/0)	33.3% (1/3)	0.0% (0/0)
J) >350-400	-	-	-	-	-	-	-	-	-	-	-	-
Note: For the blank Cells (-), there are no paired points in this reference range.												

Percent Agreement Post Calibration

The agreement of the SG values to paired YSI (or BGM) values was assessed for every 2-hour period post sensor calibration. For readings less than or equal to 80 mg/dL, the absolute difference in mg/dL between the SG and paired YSI (or BGM) values was calculated.

Tables H-22 through H-25 show the percent agreement rates post calibration for sensors inserted into the abdomen and buttock.

Table H-22. Agreement rates for every 2-hour period post calibration period; Calibration every 12 hours, Abdomen						
Time after calibration	No. paired YSI-sensor points	Percentage (%) Agreement				
		± 15% (± 15 mg/dL)	± 20% (± 20 mg/dL)	± 30% (± 30 mg/dL)	± 40% (± 40 mg/dL)	> ±40% (± 40 mg/dL)
0-2 hours	20	65	85	100	100	0
2-4 hours	16	68.8	93.8	100	100	0
4-6 hours	11	90.9	90.9	100	100	0
6-8 hours	8	62.5	62.5	87.5	100	0
8–10 hours	6	100	100	100	100	0
10-12 hours	1	0	0	0	100	0

Table H-23. Agreement rates for every 2-hour period post calibration period; Calibration 3 or 4 times a day, Abdomen						
Time after calibration	No. paired YSI-sensor points	Percentage (%) Agreement				
		± 15% (± 15 mg/dL)	± 20% (± 20 mg/dL)	± 30% (± 30 mg/dL)	± 40% (± 40 mg/dL)	> ±40% (± 40 mg/dL)
0-2 hours	24	62.5	79.2	100	100	0
2-4 hours	13	61.5	92.3	100	100	0
4-6 hours	11	90.9	90.9	100	100	0
6-8 hours	8	62.5	62.5	87.5	100	0
8–10 hours	6	100	100	100	100	0
10-12 hours	*	*	*	*	*	*

Table H-23. Agreement rates for every 2-hour period post calibration period; Calibration 3 or 4 times a day, Abdomen						
Time after calibration	No. paired YSI-sensor points	Percentage (%) Agreement				
		± 15% (± 15 mg/dL)	± 20% (± 20 mg/dL)	± 30% (± 30 mg/dL)	± 40% (± 40 mg/dL)	> ±40% (± 40 mg/dL)
*There are no paired points in this reference range. So these cells are blank.						

Table H-24. Agreement rates for every 2-hour period post calibration period; Calibration every 12 hours, Buttock						
Time after calibration	No. paired YSI-sensor points	Percentage (%) Agreement				
		± 15% (± 15 mg/dL)	± 20% (± 20 mg/dL)	± 30% (± 30 mg/dL)	± 40% (± 40 mg/dL)	> ±40% (± 40 mg/dL)
0-2 hours	64	85.9	92.2	98.4	100	0
2-4 hours	60	78.3	86.7	95	96.7	3.3
4-6 hours	52	75	84.6	98.1	98.1	1.9
6-8 hours	11	90.9	90.9	100	100	0
8–10 hours	4	100	100	100	100	0
10-12 hours	4	100	100	100	100	0

Table H-25. Agreement rates for every 2-hour period post calibration period; Calibration 3 or 4 times a day, Buttock						
Time after calibration	No. paired YSI-sensor points	Percentage (%) Agreement				
		± 15% (± 15 mg/dL)	± 20% (± 20 mg/dL)	± 30% (± 30 mg/dL)	± 40% (± 40 mg/dL)	> ±40% (± 40 mg/dL)
0-2 hours	84	86.9	90.5	97.6	98.8	1.2
2-4 hours	46	87	91.3	93.5	93.5	6.5
4-6 hours	22	63.6	72.7	95.5	100	0
6-8 hours	5	100	100	100	100	0
8–10 hours	2	100	100	100	100	0
10-12 hours	*	*	*	*	*	*
*There are no paired points in this reference range. So these cells are blank.						

Trend Accuracy

Tables H-26 through H-29 show, for each SG rate-of-change range, percentage of SG-YSI (or BGM) paired values that fell into different YSI (or BGM) rate-of-change ranges. The tables show the trend accuracy for sensors inserted into the abdomen or buttock.

Table H-26. Trend Accuracy; Calibration every 12 hours, Abdomen							
SG Rate Ranges (mg/dL/min)	Percent of Matched Pairs-in Each YSI Rate Range for Each SG Rate Range						
	YSI (mg/dL/min)						
	Number of Paired SG-YSI	<-2	[-2, -1)	[-1, 0)	[0, 1]	(1, 2]	>2
<-2	2	0.0% (0/2)	50.0% (1/2)	0.0% (0/2)	50.0% (1/2)	0.0% (0/2)	0.0% (0/2)
[-2, -1)	7	14.3% (1/7)	57.1% (4/7)	0.0% (0/7)	28.6% (2/7)	0.0% (0/7)	0.0% (0/7)
[-1, 0)	6	0.0% (0/6)	33.3% (2/6)	50.0% (3/6)	16.7% (1/6)	0.0% (0/6)	0.0% (0/6)

Table H-26. Trend Accuracy; Calibration every 12 hours, Abdomen							
SG Rate Ranges (mg/dL/min)	Percent of Matched Pairs-in Each YSI Rate Range for Each SG Rate Range						
	YSI (mg/dL/min)						
	Number of Paired SG-YSI	<-2	[-2, -1)	[-1, 0)	[0, 1]	(1, 2]	>2
[0, 1]	7	0.0% (0/7)	14.3% (1/7)	14.3% (1/7)	57.1% (4/7)	0.0% (0/7)	14.3% (1/7)
(1, 2]	5	0.0% (0/5)	0.0% (0/5)	60.0% (3/5)	20.0% (1/5)	20.0% (1/5)	0.0% (0/5)
>2	3	0.0% (0/3)	0.0% (0/3)	33.3% (1/3)	33.3% (1/3)	0.0% (0/3)	33.3% (1/3)

Table 27. Trend Accuracy; Calibration 3 or 4 times a day, Abdomen							
SG Rate Ranges (mg/dL/min)	Percent of Matched Pairs-in Each YSI Rate Range for Each SG Rate Range						
	YSI (mg/dL/min)						
	Number of Paired SG-YSI	<-2	[-2, -1)	[-1, 0)	[0, 1]	(1, 2]	>2
<-2	2	0.0% (0/2)	50.0% (1/2)	0.0% (0/2)	50.0% (1/2)	0.0% (0/2)	0.0% (0/2)
[-2, -1)	7	14.3% (1/7)	57.1% (4/7)	0.0% (0/7)	28.6% (2/7)	0.0% (0/7)	0.0% (0/7)
[-1, 0)	6	0.0% (0/6)	33.3% (2/6)	50.0% (3/6)	16.7% (1/6)	0.0% (0/6)	0.0% (0/6)
[0, 1]	8	0.0% (0/8)	12.5% (1/8)	25.0% (2/8)	50.0% (4/8)	0.0% (0/8)	12.5% (1/8)
(1, 2]	4	0.0% (0/4)	0.0% (0/4)	50.0% (2/4)	25.0% (1/4)	25.0% (1/4)	0.0% (0/4)
>2	3	0.0% (0/3)	0.0% (0/3)	33.3% (1/3)	33.3% (1/3)	0.0% (0/3)	33.3% (1/3)

Table 28. Trend Accuracy; Calibration every 12 hours, Buttock							
SG Rate Ranges (mg/dL/min)	Percent of Matched Pairs-in Each YSI Rate Range for Each SG Rate Range						
	YSI (mg/dL/min)						
	Number of Paired SG-YSI	<-2	[-2, -1)	[-1, 0)	[0, 1]	(1, 2]	>2
<-2	3	66.7% (2/3)	33.3% (1/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)
[-2, -1)	8	0.0% (0/8)	62.5% (5/8)	12.5% (1/8)	12.5% (1/8)	12.5% (1/8)	0.0% (0/8)
[-1, 0)	13	0.0% (0/13)	7.7% (1/13)	30.8% (4/13)	30.8% (4/13)	23.1% (3/13)	7.7% (1/13)
[0, 1]	6	0.0% (0/6)	16.7% (1/6)	16.7% (1/6)	16.7% (1/6)	50.0% (3/6)	0.0% (0/6)
(1, 2]	7	0.0% (0/7)	0.0% (0/7)	0.0% (0/7)	42.9% (3/7)	57.1% (4/7)	0.0% (0/7)
>2	7	0.0% (0/7)	0.0% (0/7)	0.0% (0/7)	0.0% (0/7)	42.9% (3/7)	57.1% (4/7)

Table 29. Trend Accuracy; Calibration 3 or 4 times a day, Buttock							
SG Rate Ranges (mg/dL/min)	Percent of Matched Pairs-in Each YSI Rate Range for Each SG Rate Range						
	YSI (mg/dL/min)						
	Number of Paired SG-YSI	<-2	[-2, -1)	[-1, 0)	[0, 1]	(1, 2]	>2
<-2	3	66.7% (2/3)	33.3% (1/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)
[-2, -1)	8	0.0% (0/8)	62.5% (5/8)	12.5% (1/8)	12.5% (1/8)	12.5% (1/8)	0.0% (0/8)
[-1, 0)	13	0.0% (0/13)	7.7% (1/13)	38.5% (5/13)	30.8% (4/13)	15.4% (2/13)	7.7% (1/13)
[0, 1]	6	0.0% (0/6)	16.7% (1/6)	0.0% (0/6)	16.7% (1/6)	66.7% (4/6)	0.0% (0/6)
(1, 2]	7	0.0% (0/7)	0.0% (0/7)	0.0% (0/7)	42.9% (3/7)	57.1% (4/7)	0.0% (0/7)

Table 29. Trend Accuracy; Calibration 3 or 4 times a day, Buttock							
SG Rate Ranges (mg/dL/min)	Percent of Matched Pairs-in Each YSI Rate Range for Each SG Rate Range						
	YSI (mg/dL/min)						
	Number of Paired SG-YSI	<-2	[-2, -1)	[-1, 0)	[0, 1]	(1, 2]	>2
>2	7	0.0% (0/7)	0.0% (0/7)	0.0% (0/7)	0.0% (0/7)	42.9% (3/7)	57.1% (4/7)

Precision

Precision of the System was evaluated by comparing the results from two separate sensors worn on the same subject at the same time.

Data from two sensors worn at the same time for 2 subjects in the abdomen/abdomen insertion locations provided 124 pairs of CGM Measurements, with a mean Percent Absolute Relative Difference (PARD) during the study of 10.29% and a coefficient of variation (%CV) of 7.6%.

Data from two sensors worn at the same time for 2 subjects in the abdomen/abdomen insertion locations provided 124 pairs of CGM Measurements, with a mean Percent Absolute Relative Difference (PARD) during the study of 10.29% and a coefficient of variation (%CV) of 7.6%.

Data from two sensors worn at the same time for 11 subjects in the buttock/buttock insertions location provided 754 pairs of CGM Measurements, with a mean PARD during the study of 5.98% and a coefficient of variation (%CV) 4.2%.

Sensor life

After the first successful calibration, 50% of sensors worn in the abdomen operated more than six days and up to the full seven days of wear (144 to 168 hours). The mean functional sensor life for sensors worn in the abdomen insertion site over the course of the study was 142.1 hours, with a median functional life of 163.2 hours.

After the first successful calibration, 72.2% of sensors worn in the buttock operated more than six days and up to the full seven days of wear (144 to 168 hours). The mean functional sensor life for sensors worn in the buttock insertion site over the course of the study was 146.4 hours, with a median functional life of 166.8 hours.

Safety

There were no moderate or severe device-related or procedure-related adverse events, device- related or procedure-related serious adverse events, or unanticipated adverse device effects through seven days of use.

I. Alert performance for users ages 2 through 6

CGM enables your device to display sensor glucose readings, glucose trend arrows, glucose trend graphs, and sensor glucose alerts (for example, High and Low Limit Threshold alerts, High and Low Predictive alerts, and Rise and Fall rate-of-change alerts).

The high and low limit alerts (**Threshold alerts**) let the user know when the sensor glucose is at or above the high limit or at or below the low limit. Using only a high or low limit alert may reduce the number of false alerts, but does not provide a warning before reaching a high or low limit.

Predictive alerts notify users that their sensor glucose level may soon reach a high or low limit setting. Users may select how early they would like to be notified before their sensor glucose level reaches a high limit setting. The earliest warning is 30 minutes before reaching a high, but users can reduce the amount of warning time down to 5 minutes. Users will receive a warning approximately 30 minutes prior to when their sensor glucose level is predicted to reach their low limit setting. In general, the earlier the warning, the more time a user will have to react to a potential high or low, but this also increases the potential for false alerts.

A predictive alert is simply an estimation of a future sensor glucose level compared to the high or low limit setting. If the predicted sensor glucose value is above the high limit or below the low limit, then a predictive alert is sounded even though the current sensor glucose level has not crossed the high or low limit. The predicted sensor glucose level is calculated using the current sensor glucose level, the derivative of previous sensor glucose readings (the trend or slope of the sensor glucose readings) and the amount of early warning duration the user selects.

The device will always alert the user when the CGM reads that the user is below 50 mg/dL, regardless of the high/low threshold and/or predictive alerts that the user sets.

Glucose TRUE Alert Rate

The glucose true alert rate is the rate at which the blood glucose confirmed that the CGM alert was triggered correctly. For example:

True Threshold Hypoglycemic alert ratealerted when the CGM read that the user was below the low threshold and the user's blood glucose was actually below that low threshold.

True Threshold Hyperglycemic alert ratealerted when the CGM read that the user was above the high threshold and the user's blood glucose was actually above that high threshold.

True Predictive Hypoglycemic alert ratealerted when the CGM predicted that the user would reach below the low threshold and the user's blood glucose was actually below that low threshold within 15 or 30 minutes.

True Predictive Hyperglycemic alert rate alerted when the CGM predicted that the user would reach above the high threshold and the user's blood glucose was actually above that high threshold within 15 or 30 min.

The true alert rate is important because it is necessary that users be notified when their blood glucose is low (or high) so that they can correct the low (or high) blood glucose. A high true alert rate indicates that when the CGM says that their glucose values are, or will reach a specified threshold, the user's blood glucose is likely to be at or approaching that threshold.

For example, per the following table, when wearing the sensor in the Buttocks, the low glucose alerts would have correctly indicated that the user was below (i.e. threshold only), or predicted to reach below the threshold (i.e. predictive only) or both (predictive and threshold) 100%, 40%, or 57.1 % of the time within 30 minutes (or 100%, 40% or 57.1% of the time within 15 minutes) when the user had blood glucose values lower than 70 mg/dL.

Table I-1. Glucose TRUE Alert Performance using Calibration every 12 hours

		Glucose TRUE Alert Rate					
mg/dL	Insertion Site	Threshold Only		Predictive Only		Threshold & Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
50	Abdomen	N/A*	N/A*	N/A*	N/A*	N/A*	N/A*
	Buttock	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
60	Abdomen	N/A*	N/A*	0.0%	0.0%	0.0%	0.0%
	Buttock	100.0%	100.0%	25.0%	25.0%	40.0%	40.0%
70	Abdomen	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
	Buttock	100.0%	100.0%	40.0%	40.0%	57.1%	57.1%
80	Abdomen	25.0%	25.0%	16.7%	0.0%	20.0%	10.0%
	Buttock	40.0%	40.0%	33.3%	22.2%	35.7%	28.6%
90	Abdomen	50.0%	50.0%	50.0%	33.3%	50.0%	40.0%
	Buttock	100.0%	100.0%	81.8%	63.6%	88.9%	77.8%
180	Abdomen	100.0%	100.0%	80.0%	70.0%	85.7%	78.6%
	Buttock	89.7%	89.7%	84.8%	81.8%	85.7%	83.9%

Table I-1. Glucose TRUE Alert Performance using Calibration every 12 hours							
		Glucose TRUE Alert Rate					
mg/dL	Insertion Site	Threshold Only		Predictive Only		Threshold & Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
220	Abdomen	100.0%	100.0%	50.0%	50.0%	61.5%	61.5%
	Buttock	90.0%	85.0%	62.1%	55.2%	70.5%	63.6%
250	Abdomen	100.0%	100.0%	83.3%	83.3%	90.9%	90.9%
	Buttock	80.0%	73.3%	65.2%	56.5%	70.3%	62.2%
300	Abdomen	60.0%	60.0%	40.0%	40.0%	50.0%	50.0%
	Buttock	66.7%	66.7%	35.0%	30.0%	42.3%	38.5%

Note: Given the small sample size of data available in the low range, the alert performance in the 50 mg/dL and 60 mg/dL should be interpreted with caution and may not reflect actual use performance.

*There is no evaluable events in this reference range so it is N/A.

Glucose FALSE Alert Rate

The glucose false alert rate is the rate at which the blood glucose did not confirm that the CGM alert was triggered correctly. For example:

False Threshold Hypoglycemic alert ratealerted when the CGM read that the user was below the low threshold but the users blood glucose was actually above that low threshold.

False Threshold Hyperglycemic alert ratealerted when the CGM read that the user was above the high threshold but the user's blood glucose was actually below that high threshold.

False Predictive Hypoglycemic alert ratealerted when the CGM predicted that the user would be below the low threshold but the user's blood glucose was actually above that low threshold within 15 or 30 minutes.

False Predictive Hyperglycemic alert ratealerted when the CGM predicted that the user would be above the high threshold but the user's blood glucose was actually below the high threshold within 15 or 30 minutes.

The false alert rate is important because it is necessary that users be correctly notified when their blood glucose is low (or high) so that they can correct the low (or high) blood glucose. A low false alert rate indicates that when the CGM says that their glucose values are, or will reach a specified threshold, the user's blood glucose is likely to be at or approaching that threshold.

For example, per the following table, when wearing the sensor in the buttock, the high glucose threshold alerts would have incorrectly indicated that the user was above (i.e. threshold only), or predicted to reach above the threshold (i.e. predictive only), or both (threshold and predictive) 10.3%, 15.2% or 14.3% of the time within 30 minutes (or 10.3%, 18.2%, or 16.1% of the time within 15 minutes) when the user had blood glucose less than 180 mg/dL.

Table I-2. Glucose FALSE Alert Performance using Calibration every 12 hours

		Glucose FALSE Alert Rate					
mg/dL	Insertion Site	Threshold Only		Predictive Only		Threshold & Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
50	Abdomen	N/A*	N/A*	N/A*	N/A*	N/A*	N/A*
	Buttock	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
60	Abdomen	N/A*	N/A*	100.0%	100.0%	100.0%	100.0%
	Buttock	0.0%	0.0%	75.0%	75.0%	60.0%	60.0%
70	Abdomen	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
	Buttock	0.0%	0.0%	60.0%	60.0%	42.9%	42.9%
80	Abdomen	75.0%	75.0%	83.3%	100.0%	80.0%	90.0%
	Buttock	60.0%	60.0%	66.7%	77.8%	64.3%	71.4%
90	Abdomen	50.0%	50.0%	50.0%	66.7%	50.0%	60.0%
	Buttock	0.0%	0.0%	18.2%	36.4%	11.1%	22.2%
180	Abdomen	0.0%	0.0%	20.0%	30.0%	14.3%	21.4%
	Buttock	10.3%	10.3%	15.2%	18.2%	14.3%	16.1%
220	Abdomen	0.0%	0.0%	50.0%	50.0%	38.5%	38.5%
	Buttock	10.0%	15.0%	37.9%	44.8%	29.5%	36.4%
250	Abdomen	0.0%	0.0%	16.7%	16.7%	9.1%	9.1%
	Buttock	20.0%	26.7%	34.8%	43.5%	29.7%	37.8%
300	Abdomen	40.0%	40.0%	60.0%	60.0%	50.0%	50.0%
	Buttock	33.3%	33.3%	65.0%	70.0%	57.7%	61.5%

Note: Given the small sample size of data available in the low range, the alert performance in the 50 mg/dL and 60 mg/dL should be interpreted with caution and may not reflect actual use performance.

*There is no evaluable events in this reference range so it is N/A.

Glucose Correct Detection Rate

Glucose Correct Detection Rate is the rate that the device alerted when it should have alerted. For example, the blood glucose was below the hypoglycemic threshold, or above the hyperglycemic threshold, and the device sounded an alert.

Glucose detection rates are important because it is necessary that users be notified when their blood glucose is low (or high) so that they can correct the low (or high) blood glucose. A high glucose correct detection rate indicates that users can have confidence that they will be notified by the device if their blood glucose is low or high.

For example, per the following table, when wearing the sensor in the buttock, the threshold alert, the predictive alert, or both (threshold and predictive) notified the user 50.0%, 50.0% or 50.0% of the time within 30 minutes (or 50.0%, 50.0% or 50.0% within 15 minutes) when the user had blood glucose less than 60 mg/dL.

Table I-3. Glucose Correct Detection Alert Performance using Calibration every 12 hours

		Glucose Correct Detection Rate					
mg/dL	Insertion Site	Threshold Only		Predictive Only		Threshold & Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
50	Abdomen	N/A*	N/A*	N/A*	N/A*	N/A*	N/A*
	Buttock	N/A*	N/A*	N/A*	N/A*	N/A*	N/A*
60	Abdomen	N/A*	N/A*	100.0%	100.0%	100.0%	100.0%
	Buttock	50.0%	50.0%	50.0%	50.0%	50.0%	50.0%
70	Abdomen	N/A*	N/A*	N/A*	N/A*	N/A*	N/A*
	Buttock	66.7%	66.7%	66.7%	66.7%	66.7%	66.7%
80	Abdomen	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
	Buttock	40.0%	40.0%	60.0%	40.0%	60.0%	40.0%
90	Abdomen	66.7%	66.7%	100.0%	66.7%	100.0%	100.0%
	Buttock	80.0%	80.0%	90.0%	60.0%	90.0%	80.0%
180	Abdomen	84.6%	84.6%	92.3%	84.6%	92.3%	84.6%
	Buttock	100.0%	98.3%	100.0%	91.4%	100.0%	100.0%
220	Abdomen	100.0%	100.0%	100.0%	87.5%	100.0%	100.0%
	Buttock	91.7%	86.1%	97.2%	86.1%	100.0%	94.4%
250	Abdomen	100.0%	100.0%	100.0%	87.5%	100.0%	100.0%
	Buttock	84.0%	84.0%	96.0%	84.0%	96.0%	88.0%
300	Abdomen	100.0%	100.0%	100.0%	75.0%	100.0%	100.0%
	Buttock	62.5%	62.5%	100.0%	87.5%	100.0%	100.0%

Note: Given the small sample size of data available in the low range, the alert performance in the 50 mg/dL and 60 mg/dL should be interpreted with caution and may not reflect actual use performance.

*There is no evaluable events in this reference range so it is N/A.

Glucose Missed Detection Rate

The Missed Detection Rate is the rate that the device did not alert when it should have. For example, the blood glucose was below the hypoglycemic threshold, or above the hyperglycemic threshold, and the device did not sound a threshold or predictive alert.

Missed detection rates are important because it is necessary that users be notified when their blood glucose is low (or high), so that they can correct the low (or high) blood glucose. A low missed detection rate indicates that users can have confidence that they will be notified by the device if their blood glucose is low or high.

For example, per the following table, when wearing the sensor in the buttocks, the threshold alert, predictive alert, or both alert (threshold and predictive) did not sound 50.0%, 50.0% or 50.0% of the time within 30 minutes (or 50.0%, 50.0% or 50.0% within 15 minutes) when the user had blood glucose less than 60 mg/dL.

Table I-4. Glucose Missed Detection Alert Performance using Calibration every 12 hours

		Glucose Missed Detection Rate					
mg/dL	Insertion Site	Threshold Only		Predictive Only		Threshold & Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
50	Abdomen	N/A*	N/A*	N/A*	N/A*	N/A*	N/A*
	Buttock	N/A*	N/A*	N/A*	N/A*	N/A*	N/A*
60	Abdomen	N/A*	N/A*	100.0%	100.0%	100.0%	100.0%
	Buttock	50.0%	50.0%	50.0%	50.0%	50.0%	50.0%
70	Abdomen	N/A*	N/A*	N/A*	N/A*	N/A*	N/A*
	Buttock	33.3%	33.3%	33.3%	33.3%	33.3%	33.3%
80	Abdomen	0.0%	0.0%	0.0%	100.0%	0.0%	0.0%
	Buttock	60.0%	60.0%	40.0%	60.0%	40.0%	60.0%
90	Abdomen	33.3%	33.3%	0.0%	33.3%	0.0%	0.0%
	Buttock	20.0%	20.0%	10.0%	40.0%	10.0%	20.0%
180	Abdomen	15.4%	15.4%	7.7%	15.4%	7.7%	15.4%
	Buttock	0.0%	1.7%	0.0%	8.6%	0.0%	0.0%
220	Abdomen	0.0%	0.0%	0.0%	12.5%	0.0%	0.0%
	Buttock	8.3%	13.9%	2.8%	13.9%	0.0%	5.6%
250	Abdomen	0.0%	0.0%	0.0%	12.5%	0.0%	0.0%
	Buttock	16.0%	16.0%	4.0%	16.0%	4.0%	12.0%
300	Abdomen	0.0%	0.0%	0.0%	25.0%	0.0%	0.0%
	Buttock	37.5%	37.5%	0.0%	12.5%	0.0%	0.0%

Note: Given the small sample size of data available in the low range, the alert performance in the 50 mg/dL and 60 mg/dL should be interpreted with caution and may not reflect actual use performance.

*There is no evaluable events in this reference range so it is N/A.

Appendix A: End user software license agreement

End user software license agreement

End user software license agreement

NOTICE TO USER: Certain portions of software contained in this product may be covered by the GNU General Public License, Version 2 or Version 3 (“Open Source”), which can be obtained through the GNU web site at www.gnu.org/copyleft/gpl.html. The source code for any Open Source can be obtained, for a nominal fee to cover the cost of shipping and media, by contacting Medtronic MiniMed, Inc., **Director of Software Development,** 18000 Devonshire Street, Northridge, CA 91325-1219, USA, tel: +1-866-948-6633.

Glossary

Glossary

active insulin	Bolus insulin that has been delivered by the pump and is still working to lower your BG levels.
active insulin adjustment	The amount of insulin that is subtracted from your BG correction bolus to account for the active insulin that is tracked by the Bolus Wizard feature.
Active Insulin Time	A Bolus Wizard setting that lets you set the length of time that bolus insulin is tracked as active insulin.
Activity Guard	An attachment that can be used to ensure that the reservoir stays secure during activity, or when the pump is worn by a child.
alarm	An audible beep or vibration with a message to inform you that the pump is no longer delivering insulin. Alarms require immediate action.
Alarm History	A feature that stores information about recent alarms and alerts.
alert	An audible beep or vibration with a message to inform you of a situation that may require your attention.
Alert before low	An alert that occurs when you are approaching your low SG value.
Alert Limits	The values that you set to determine when low and high glucose alerts are triggered.
Alert on low	An alert that occurs when your SG value reaches or falls below your low limit.

Auto Basal	The automatically adjusted basal insulin delivered by Auto Mode based on your SG values.
Auto Mode	Auto Mode is an insulin delivery feature that automatically controls basal insulin delivery to regulate BG levels to a target SG value.
Auto Mode Bolus feature	The Auto Mode Bolus feature assists the user in calculating a recommended bolus amount based on optional carbohydrate intake and optional BG measurement. The user may enter one or both of the two optional inputs. This feature utilizes the Carb Ratio setting to compute the bolus.
Auto Suspend	An alarm that you set to suspend insulin delivery and trigger an alarm if no buttons are pressed for a specified period of time. Clearing the alarm resumes insulin delivery.
Awake mode	A state in which the pump screen is on. Unless you are actively using another screen, your Home screen appears.
basal insulin	Insulin that is continuously delivered by the pump to meet your individual insulin needs between meals and during sleep.
basal pattern	A set of one or more basal rates that covers a 24-hour period.
basal rate	The amount of continuous basal insulin that you program your pump to automatically deliver per hour.
BG	Abbreviation for blood glucose. See *blood glucose (BG)*.
BG meter	A device that measures glucose levels in the blood.
BG Targets	The high and low values to which your BG is corrected when using the Bolus Wizard feature.
Block Mode	A feature that restricts the ability to change all settings. You can still perform certain functions, such as suspending insulin delivery, reviewing history, testing your pump, or clearing alarms and alerts.
blood glucose (BG)	Glucose that is present in the blood, commonly measured by a BG meter.

Bolus BG Check reminder	A reminder that you set just after you program a bolus. The reminder tells you to check your BG when the time period that you specified has passed.
bolus insulin	Insulin used to cover an expected rise in BG levels due to carbohydrates, or to lower a high BG value down to your target range.
Bolus Speed	A feature that lets you choose the speed at which your device delivers bolus insulin.
Bolus Wizard feature	A feature that uses your individual Bolus Wizard settings to calculate an estimated bolus amount based on the BG values and carbs that you enter. These settings include Carb Ratio, Insulin Sensitivity Factor, BG Target range, and Active Insulin Time.
calibrate	The process of using a meter BG reading to calculate SG values.
Calibration reminder	Set the Calibration reminder to notify you when your next calibration is due.
cannula	Short, thin, and flexible tube placed in the tissue below the skin. Insulin is delivered through the cannula into the body.
carb ratio	The number of grams of carbohydrates covered by one unit of insulin. The carb ratio is used to calculate bolus amounts.
CGM	Abbreviation for continuous glucose monitoring. See *continuous glucose monitoring (CGM)*.
continuous glucose monitoring (CGM)	A monitoring tool that uses a glucose sensor placed below the skin to continuously measure the amount of glucose in your interstitial fluid.
correction bolus	Insulin used to lower a high BG value down to your target range.
Daily History	A feature that displays the actions that you performed using your device.
diabetic ketoacidosis (DKA)	A serious condition that occurs when the insulin levels are low, BG levels are elevated, and the body uses fat for

	energy. This process produces ketones which upset the body's acid-base balance, leading to a potentially life threatening situation.
Dual Wave bolus	A type of bolus that provides a dose of insulin delivered as a combination of a Normal Bolus followed by a Square Wave bolus.
Easy Bolus feature	A feature that lets you deliver a Normal Bolus in preset increments using only audio or vibrate confirmation.
Event Marker	A feature that lets you record events, such as BG readings, injections, carbohydrates, and exercise.
food bolus	A dose of insulin you give to cover an expected rise in glucose levels from carbohydrates.
High limit	The value you set to determine when the pump will alert you of a high SG condition.
infusion set	Tubing that connects to the reservoir on one end, and has a needle or cannula on the other end, that you insert into your body. Insulin travels from the pump through the infusion set into your body.
infusion site	The location on the body where the infusion set is inserted.
insulin sensitivity factor	The amount that BG is reduced by one unit of insulin. The insulin sensitivity factor is used to calculate correction bolus amounts.
interstitial fluid	The fluid that surrounds the cells in the body.
ISIG	The signal created by the sensor that is used to calculate your SG value. Typically used by Medtronic technical support representatives when troubleshooting.
lock	A pump feature that prevents accidental button presses.
Low limit	The value you set to determine when the pump will alert you of a low SG condition, and also used for determining if insulin delivery should be suspended.
Manual Bolus	A feature that lets you enter and deliver a dose of insulin in the amount that you have determined is necessary.

Manual Mode	Manual Mode refers to system functions other than Auto Mode. In other words, if Auto Mode is not active, the system is in Manual Mode.
Max Basal Rate	A feature that lets you set the maximum amount of basal insulin that can be delivered per hour.
Max Bolus	A feature that lets you set the maximum bolus amount that can be delivered in one dose.
meter	A term for any BG meter.
Missed Meal Bolus reminder	A reminder that a bolus was not delivered during time periods that you specify, often set around your meal times.
Normal Bolus	A type of bolus that provides an entire dose of insulin immediately.
notifications	All notifications are designed to get your attention and convey different types of information. They include alarms, alerts, reminders, and messages.
occlusion	A blockage or crimp of the cannula or tubing that prevents proper insulin flow.
piston	The part of the insulin pump that engages the reservoir and moves insulin through the tubing.
Power save mode	A state in which your pump is fully functional, but the screen goes dark to save power. You can set how long it takes for your screen to enter power save mode with the Backlight setting.
Preset Bolus	A feature that lets you set up and save a bolus for specific meals or snacks that you frequently eat or drink.
Preset Temp Basal	A feature that lets you set up and save temporary basal rates for repeated use.
reminder	A type of notification that you can set to help you remember to do something.
reservoir	The small container that you fill with insulin and insert into your delivery device.

Resume basal alert	An alert that can be set to occur when your pump has automatically resumed basal insulin delivery after a Suspend before low or Suspend on low event because your SG values have met the necessary criteria. This alert always occurs if basal insulin delivery has resumed because the two-hour maximum suspend time has elapsed.
Rewind	A feature used when you change a reservoir. It returns the piston to its start position and lets a new reservoir be placed into the pump.
Rise Alert	An alert that tells you if your SG value is rising rapidly.
sensitivity	See *insulin sensitivity factor*.
sensor (glucose sensor)	The small part of the continuous glucose monitoring system that you insert just below your skin to measure glucose levels in your interstitial fluid.
sensor glucose (SG)	Glucose that is present in the interstitial fluid and is measured by a glucose sensor.
Set Change reminder	A reminder that you can set to change your infusion set.
SG	Abbreviation for sensor glucose. See *sensor glucose (SG)*.
Sleep mode	A state in which your pump is fully functional, but the screen is dark. Your pump automatically enters sleep mode when you have not pressed any buttons for about two minutes.
SmartGuard suspend	SmartGuard suspend features include Suspend before low and Suspend on low.
SmartGuard technology	A feature that can automatically stop and resume insulin delivery based on your SG values and low limit. SmartGuard Auto Mode can automatically adjust basal insulin delivery based on SG values.
Square Wave bolus	A bolus delivered evenly over a specified time period.
Suspend before low	A feature that suspends insulin delivery when the sensor predicts the SG value is approaching your low limit.

Suspend Delivery	This feature stops all insulin delivery until you resume it. Only the basal insulin restarts when delivery is resumed.
Suspend on low	A feature that suspends insulin delivery when your SG value reaches or falls below your low limit.
Temp Basal rate (temporary basal rate)	A feature that lets you temporarily increase or decrease your current basal rate for a duration of time that you specify.
transfer guard	The plastic piece that comes attached to the reservoir. It is used to connect the reservoir to the insulin vial while the reservoir fills with insulin.
transmitter	A device that connects to a glucose sensor. The transmitter collects data measured by the sensor and wirelessly sends this data to monitoring devices.

Index

Index

B

C

D

E

F

G

H

I

L

M

N

O

P

Q

R

S

T

U

V

W

Medtronic

Medtronic MiniMed
18000 Devonshire Street
Northridge, CA 91325 USA
1 800 646 4633
+1 818 576 5555
www.medtronicdiabetes.com

M998590A011_A

MiniMed™ 770G

SYSTEM USER GUIDE

MiniMed™ 770G

Bluetooth®

MiniMed™ 770G
SYSTEM USER GUIDE

Copyright & trademarks

Bolus Wizard™, CareLink™, Dual Wave™, Guardian™, MiniLink™, MiniMed™, Mio™, Quick-set™, Silhouette™, SmartGuard™, Square Wave™, and Sure-T™ are trademarks of Medtronic MiniMed, Inc.

ACCU-CHEK and ACCU-CHEK GUIDE are trademarks of Roche.

Ascensia, the Ascensia Diabetes Care logo, and Contour are trademarks and/or registered trademarks of Ascensia Diabetes Care Holdings AG.

Tylenol™*

Wi-Fi™*

Bluetooth™*

Humalog™*

NovoLog™*

Android™*

iOS™*

Medtronic

Medtronic MiniMed
18000 Devonshire Street
Northridge, CA 91325
USA
1 800 646 4633
+1 818 576 5555
www.medtronicdiabetes.com

℞ *Only*

M998590A011_A
RF: M994838A001

REF MMT-1880

Contacts:

Africa: Medtronic South Africa and Southern Africa
Office Reception Tel: +27(0) 11 260 9300
Diabetes: 24/7 Helpline: 0800 633 7867
Sub-Sahara 24/7 Helpline: +27(0) 11 260 9490

Albania: Net Electronics Albania
Tel: +355 697070121

Argentina: Corpomedica S.A.
Tel: +(11) 4 814 1333
Medtronic Directo 24/7: +0800 333 0752

Armenia: Exiol LLC
Tel: +374 98 92 00 11
or +374 94 38 38 52

Australia: Medtronic Australasia Pty. Ltd.
Tel: 1800 668 670

Bangladesh: Sonargaon Healthcare Pvt Ltd.
Mobile: (+91)-9903995417
or (+880)-1714217131

Belarus: Zarga Medica
Tel: +375 29 625 07 77
or +375 44 733 30 99
Helpline: +74995830400

België/Belgique: N.V. Medtronic Belgium S.A.
Tel: 0800-90805

Bosnia and Herzegovina:
"Novopharm" d.o.o. Sarajevo
Tel: +387 33 476 444
Helpline: 0800 222 33
Epsilon Research Intern. d.o.o.
Tel: +387 51 251 037
Helpline: 0800 222 33

Brasil: Medtronic Comercial Ltda.
Tel: +(11) 2182-9200
Medtronic Directo 24/7: +0800 773 9200

Bulgaria: RSR EOOD
Tel: +359 888993083
Helpline: +359 884504344

Canada: Medtronic Canada ULC
Tel: 1-800-284-4416 (toll free/sans-frais)

Chile: Medtronic Chile
Tel: +(9) 66 29 7126
Medtronic Directo 24/7: +1 230 020 9750
Medtronic Directo 24/7 (From Santiago): +(2) 595 2942

China: Medtronic (Shanghai) Management Co., Ltd.
Landline: +86 800-820-1981
Mobile Phone: +86 400-820-1981
Calling from outside China: +86 400-820-1981

Colombia: Medtronic Latin America Inc. Sucursal Colombia
Tel: +(1) 742 7300
Medtronic Directo 24/7 (Landline): +01 800 710 2170
Medtronic Directo 24/7 (Cellular): +1 381 4902

Croatia: Mediligo d.o.o.
Tel: +385 1 6454 295
Helpline: +385 1 4881144
Medtronic Adriatic d.o.o.
Helpline: +385 1 4881120

Danmark: Medtronic Danmark A/S
Tel: +45 32 48 18 00

Deutschland: Medtronic GmbH
Geschäftsbereich Diabetes
Telefon: +49 2159 8149-370
Telefax: +49 2159 8149-110
24-Stdn-Hotline: 0800 6464633

Eire: Accu-Science LTD.
Tel: +353 45 433000

España: Medtronic Ibérica S.A.
Tel: +34 91 625 05 42
Fax: +34 91 625 03 90
24 horas: +34 900 120 330

Estonia: AB Medical Group Estonia Ltd
Tel: +372 6552310
Helpline: +372 5140694

Europe: Medtronic Europe S.A. Europe, Middle East and Africa HQ
Tel: +41 (0) 21-802-7000

France: Medtronic France S.A.S.
Tel: +33 (0) 1 55 38 17 00

Hellas: Medtronic Hellas S.A.
Tel: +30 210677-9099

Hong Kong: Medtronic International Ltd.
Tel: +852 2919-1300
To order supplies: +852 2919-1322
24-hour helpline: +852 2919-6441

India: India Medtronic Pvt. Ltd.
Tel: (+91)-80-22112245 / 32972359
Mobile: (+91)-9611633007
Patient Care Helpline: 1800 209 6777

Indonesia: Medtronic International Ltd.
Tel: +65 6436 5090
or +65 6436 5000

Israel: Medtronic
Tel. (orders): +9729972440, option 3 + option 1
Tel. (product support): +9729972440, option 2
Helpline (17:00 – 08:00 daily/weekends – Israel time): 1-800-611-888

Italia: Medtronic Italia S.p.A.
Tel: +39 02 24137 261
Fax: +39 02 24138 210
Servizio assistenza tecnica:
Nº verde: 800 60 11 22

Japan: Medtronic Japan Co. Ltd.
Tel: +81-3-6776-0019
24 Hr. Support Line: 0120-56-32-56

Kazakhstan: Medtronic BV in Kazakhstan
Tel: +7 727 311 05 80 (Almaty)
Tel: +7 717 224 48 11 (Astana)
Круглосуточная линия поддержки:
8 800 080 5001

Kosovo: Yess Pharma
Tel: +377 44 999 900
Helpline: +37745888388

Latin America: Medtronic, Inc.
Tel: 1(305) 500-9328
Fax: 1(786) 709-4244

Latvija: RAL SIA
Tel: +371 67316372
Helpline (9am to 6pm): +371 29611419

Lithuania: Monameda UAB
Tel: +370 68405322
Helpline: +370 68494254

Macedonia: Alkaloid Kons Dooel
Tel: +389 23204438

Magyarország: Medtronic Hungária Kft.
Tel: +36 1 889 0688

Malaysia: Medtronic International Ltd.
Tel: +603 7946 9000

Middle East and North Africa:
Regional Office
Tel: +961-1-370 670

Montenegro: Glosarij d.o.o.
Tel: +382 20642495

México: Medtronic Servicios S. de R. L. de C.V.
Tel (México DF): +(11) 029 058
Tel (Interior): +01 800 000 7867
Medtronic Directo 24/7 (from México DF):
+(55) 36 869 787
Medtronic Directo 24/7:
+01 800 681 1845

Nederland, Luxembourg: Medtronic B.V.
Tel: +31 (0) 45-566-8291
Gratis: 0800-3422338

New Zealand: Medica Pacifica
Phone: 64 9 414 0318
Free Phone: 0800 106 100

Norge: Medtronic Norge A/S
Tel: +47 67 10 32 00
Fax: +47 67 10 32 10

Philippines: Medtronic International Ltd.
Tel: +65 6436 5090
or +65 6436 5000

Россия: ООО «Медтроник»
Tel: +7 495 580 73 77
Круглосуточная линия поддержки:
8 800 200 76 36

Polska: Medtronic Poland Sp. z o.o.
Tel: +48 22 465 6934

Portugal: Medtronic Portugal Lda
Tel: +351 21 7245100
Fax: +351 21 7245199

Puerto Rico: Medtronic Puerto Rico
Tel: 787-753-5270

Republic of Korea: Medtronic Korea, Co., Ltd.
Tel: +82.2.3404.3600

Romania: Medtronic Romania S.R.L
Tel: +40372188017
Helpline: +40 726677171

Schweiz: Medtronic (Schweiz) AG
Tel: +41 (0)31 868 0160
24-Stunden-Hotline: 0800 633333
Fax Allgemein: +41 (0)318680199

Serbia: Epsilon Research International d.o.o.
Tel: +381 113115554
Medtronic Serbia D.o.o
Helpline: +381 112095900

Singapore: Medtronic International Ltd.
Tel: +65 6436 5090
or +65 6436 5000

Slovenija: Zaloker & Zaloker d.o.o.
Tel: +386 1 542 51 11
24-urna tehnična pomoč:
+386 51316560

Slovenská republika: Medtronic Slovakia, s.r.o.
Tel: +421 26820 6942
HelpLine: +421 26820 6986

Sri Lanka: Swiss Biogenics Ltd.
Mobile: (+91)-9003077499
or (+94)-777256760

Suomi: Medtronic Finland Oy
Tel: +358 20 7281 200
Help line: +358 400 100 313

Sverige: Medtronic AB
Tel: +46 8 568 585 20
Fax: +46 8 568 585 11

Taiwan: Medtronic (Taiwan) Ltd.
Tel: 02-21836000
Toll free: +886-800-005285

Thailand: Medtronic (Thailand) Ltd.
Tel: +662 232 7400

Türkiye: Medtronic Medikal Teknoloji Ticaret Ltd. Sirketi.
Tel: +90 216 4694330

USA: Medtronic Diabetes Global Headquarters
24-Hour Technical Support:
+1-800-646-4633
To order supplies:
+1-800-843-6687

Ukraine: Med Ek Service TOV
Tel: +380 50 3311898
or +380 50 4344346
Лінія цілодобової підтримки:
0 800 508 300

United Kingdom: Medtronic Ltd.
Tel: +44 1923-205167

Österreich: Medtronic Österreich GmbH
Tel: +43 (0) 1 240 44-0
24 – Stunden – Hotline:
0820 820 190

Česká republika: Medtronic Czechia s.r.o.
Tel: +420 233 059 111
Non-stop helpLine (24/7):
+420 233 059 059
Zákaznický servis (8:00 - 17:00):
+420 233 059 950

Warranty

The expected life of the MiniMed insulin pump is a maximum of 4 years. Medtronic Diabetes warrants the MiniMed insulin pump against defects in materials and workmanship for a period of 4 years from the date of purchase.

During the warranty period, Medtronic Diabetes will, at its discretion, replace (with a new or recertified pump, at Medtronic Diabetes' discretion) any defective pump or motor, subject to the conditions and exclusions stated herein. In the event that a pump replaced, the warranty period will not be extended.

This warranty is valid only if the MiniMed insulin pump is used in accordance with the manufacturer's instructions. This warranty will not apply:

- If damage results from changes or modifications made to the pump by the user or third persons after the date of manufacture.
- If damage results from use of non-Medtronic reservoirs and/or infusion sets.
- If damage results from service or repairs performed by any person or entity other than the manufacturer.
- If damage results from a *Force Majeure* or other event beyond the control of the manufacturer.
- If damage results from negligence or improper use, including but not limited to improper storage; water submersion that does not meet the instructions of the manufacture; or physical abuse, such as dropping or otherwise.

This warranty shall be personal to the original user. Any sale, rental or other transfer or use of the product covered by this warranty to or by a user other than the original user shall cause this warranty to immediately terminate. This warranty does not apply to batteries, infusion sets, reservoirs, and other accessories.

The remedies provided for in this warranty are the exclusive remedies available for any breach hereof. Neither Medtronic Diabetes nor its suppliers or distributors shall be liable for any incidental, consequential, or special damage of any nature or kind caused by or arising out of a defect in the product.

All other warranties, expressed or implied, are excluded, including the warranties of merchantability and fitness for a particular purpose.

Contents

Before you begin

First steps

Basal

Bolus

Reservoir and infusion set

Meter

History and events

Reminders

General settings

Setting up CGM

Alarms, alerts, and messages

Troubleshooting

Maintenance

Product specifications and safety information

670G Performance Data and Technical Information

Before you begin

1 Before you begin

This user guide is designed to help you understand the operation of the MiniMed 770G System with Bluetooth wireless and SmartGuard technology, our latest advancement in diabetes management. In the MiniMed 770G System, SmartGuard technology can automatically adjust insulin delivery based on your sensor glucose (SG) values. The system can be used in two modes: Manual mode and SmartGuard Auto Mode. Work closely with your healthcare professional when you start insulin pump therapy.

In this user guide, the term Auto Mode refers to the automatic control of insulin delivery. For more information, see *About SmartGuard Auto Mode, on page 219*. When your pump is not operating in Auto Mode, the term Manual Mode is used to describe its functions.

Using this user guide

This user guide contains valuable information about using your new insulin pump. To help you find the information you need, you can use the table of contents at the beginning of the user guide and the index at the end of the user guide. There is also a glossary of terms, which starts on *page 405*.

The following table describes certain terms, conventions, and concepts used in this user guide.

Convention	What it means
Select	To activate a screen item, accept a value, or initiate an action.
Select and hold	To perform an action using your pump screen, press the Select button and hold until the action is complete.

Convention	What it means
Press	To push and then release a button.
Press and hold	To push and keep pressure on a button.
Bold text	To indicate screen items and buttons. For example, "Select **Next** to continue."
X	To indicate a numeric value or name that appears differently on your pump screen.
Note	 **Note:** A note provides helpful information.
Caution	 **CAUTION:** A caution tells you of a potential hazard which, if not avoided, may result in minor or moderate injury or damage to the equipment.
WARNING	 **WARNING: A warning tells you of a potential hazard which, if not avoided, could result in death or serious injury. It may also describe potential serious adverse reactions and safety hazards.**

The MiniMed 770G System User Guide includes instructions on how to set up devices on the MiniMed 770G insulin pump. For additional instructions not included in the MiniMed 770G System User Guide, refer to the instructions for the device.

Device	For instructions see
Reservoir	Reservoir user guide
Infusion Sets	Infusion set user guide
Transmitter	Guardian Link (3) transmitter user guide
Sensor	Guardian Sensor (3) user guide

Device	For instructions see
Meter	Accu-Chek® Guide Link User's Manual

Acronyms and abbreviations

The following table defines acronyms and abbreviations used in this guide.

Acronyms and abbreviations	Definition
AST	alternate site testing
BG	blood glucose
CDC	Centers for Disease Control and Prevention
CGM	continuous glucose monitoring
CT scan	computerized tomography scan
DKA	diabetic ketoacidosis
EMC	electromagnetic compatibility
ESD	electrostatic discharge
FCC	Federal Communications Commission
FDA	U.S. Food and Drug Administration
GPS	global positioning system
ISIG	input signals, which are read from the sensor and measured in nanoamperes (nA)
IV	intravenous
MRI	magnetic resonance imaging
NiMH	nickel-metal hydride
RF	radio frequency
SG	sensor glucose
SN	serial number
TDD	total daily dose

Emergency kit

Keep an emergency kit with you at all times to make sure that you always have necessary supplies. Tell a family member, co-worker, or friend where you keep your emergency kit.

It is important that you test your blood glucose (BG) more frequently while you travel. The routine hassle of travel, including stress, changes in time zones, schedules and activity levels, meal times and types of food, can all affect your diabetes control. Be extra attentive to monitoring your BG frequently, and be prepared to respond if needed.

Your emergency kit should include these items:

- Fast-acting glucose tablets
- BG monitoring supplies
- Urine or blood ketone monitoring supplies
- Extra MiniMed infusion set and MiniMed reservoir
- Extra new AA lithium or alkaline batteries, or fully charged NiMH batteries
- Insulin syringe and rapid-acting insulin (with dosage instructions from your healthcare professional)
- Wallet card (packaged with your pump accessories)
- Adhesive dressing
- Glucagon emergency kit

WARNING: Do not use the Bolus Wizard feature to calculate a bolus for a period of time after giving a manual injection of insulin by syringe or pen. Manual injections are not accounted for in the active insulin amount. Therefore, the Bolus Wizard feature could prompt you to deliver more insulin than needed. Too much insulin can cause hypoglycemia. Consult with your healthcare professional for how long you need to wait after a manual injection of insulin before you can rely on the active insulin calculation of the Bolus Wizard feature.

WARNING: Do not use Auto Mode for a period of time after giving a manual injection of insulin by syringe or pen. Manual injections are not accounted for in Auto Mode. Therefore, Auto Mode could deliver too much insulin. Too much insulin may cause hypoglycemia. Consult with your healthcare professional for how long you need to wait after a manual injection of insulin before you resume Auto Mode.

For details on pump safety, see *User safety, on page 7*.

User safety

Indications

MiniMed 770G System

The MiniMed 770G system is intended for continuous delivery of basal insulin (at user selectable rates) and administration of insulin boluses (in user selectable amounts) for the management of type 1 diabetes mellitus in persons two years of age and older requiring insulin as well as for the continuous monitoring and trending of glucose levels in the fluid under the skin. The MiniMed 770G System includes SmartGuard technology, which can be programmed to automatically adjust delivery of basal insulin based on continuous glucose monitoring (CGM) sensor glucose values and can suspend delivery of insulin when the SG value falls below or is predicted to fall below predefined threshold values.

The Medtronic MiniMed 770G System consists of the following devices: MiniMed 770G Insulin Pump, the Guardian Link (3) Transmitter, the Guardian Sensor (3), one-press serter, and the Accu-Chek Guide Link blood glucose meter. The system requires a prescription.

The Guardian Sensor (3) has not been evaluated and is not intended to be used directly for making therapy adjustments, but rather to provide an indication of when a fingerstick may be required. All therapy adjustments should be based on measurements obtained using a blood glucose meter and not on values provided by the Guardian Sensor (3).

WARNING: Do not use the Suspend on low feature to prevent or treat low glucose. Always confirm your sensor glucose reading using your BG meter, and follow the instructions of your healthcare professional to treat low glucose. Using Suspend on low alone to prevent or treat low glucose may result in prolonged hypoglycemia.

Guardian Sensor (3)

The Guardian Sensor (3) is intended for use with the MiniMed 770G system to continuously monitor glucose levels in persons with diabetes.

The sensor is intended for single use and requires a prescription. The Guardian Sensor (3) is indicated for 7 days of continuous use.

The Guardian Sensor (3) has been studied and is approved for use in the following sensor insertion sites by persons of the following ages:

Approved Age	Sensor Insertion Site
2-13	Abdomen and Buttocks
14 and older	Abdomen and Arm

One-press Serter

The serter is used as an aid for inserting the sensor. It is indicated for single-patient use and is not intended for multiple patient use.

Guardian Link (3) Transmitter

The Guardian Link (3) Transmitter is intended for use with MiniMed 770G System. The Guardian Link (3) Transmitter powers the glucose sensor, collects and calculates sensor data, and wirelessly sends the data to the MiniMed 770G insulin pump. The Transmitter is intended for single-patient multi-use.

Accu-Chek Guide Link Blood Glucose Monitoring System

The Accu-Chek Guide Link Blood Glucose Monitoring System is comprised of the Accu-Chek Guide Link meter and the Accu-Chek Guide test strips.

The Accu-Chek Guide Link Blood Glucose Monitoring System is intended to quantitatively measure glucose in fresh capillary whole blood from the fingertip, palm, and upper arm as an aid in monitoring the effectiveness of glucose control.

The Accu-Chek Guide Link Blood Glucose Monitoring System is intended for in vitro diagnostic single-patient use by people with diabetes

The Accu-Chek Guide Link Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

This system is not for use in diagnosing or screening for diabetes mellitus and not for neonatal use.

Alternative site testing should be done only during steaty-state times (when glucose is not changing rapidly).

The Accu-Chek Guide control solutions are for use with the Accu-Chek Guide Link Blood Glucose Monitoring System to check that the meters and test strips are working together properly and that the test is performing correctly.

The Accu-Chek Guide Link Blood Glucose Monitoring System is intended to be used to wirelessly transmit glucose values to a compatible MiniMed pump with Bluetooth wireless technology through the use of Bluetooth low energy communication.

Contraindications

Pump therapy is not recommended for people whose vision or hearing does not allow recognition of pump signals and alarms.

Do not use the serter on products other than the Guardian Sensor (3). Medtronic cannot guarantee the safety or efficacy of this product if used with other products.

The reservoir is contraindicated for the infusion of blood or blood products.

Infusion sets are indicated for subcutaneous use only and not for intravenous (IV) infusion or the infusion of blood or blood products.

Insulin pump therapy is not recommended for those who are unwilling to perform at least four BG tests per day. As insulin pumps use rapid-acting insulin only, BG testing is required to help identify rapid glycemic deterioration due to insulin infusion occlusion, infusion site problems, insulin stability issues, user error, or a combination of these.

SmartGuard Auto Mode cannot be used for people who require less than eight units or more than 250 units of total daily insulin dose per day.

Pump therapy is not recommended for people who are unwilling or unable to maintain contact with their healthcare professional.

Potential risks

Risks related to insulin pump infusion set

General risks related to insulin pump infusion set may include:

- Localized infection
- Skin irritation or redness
- Bruising
- Discomfort or pain
- Bleeding
- Irritation
- Rash
- Occlusions that can interrupt insulin delivery and lead to hyperglycemia or diabetic ketoacidosis

Patients should be instructed to follow the provided user guides for insertions and care of infusion sets. If an infusion site becomes irritated or inflamed, the infusion set should be removed and another placed in a new location.

Risks related to insulin administration and pump use

Due to the use of insulin, there is risk related to the infusion of insulin and the potential interruptions of insulin delivery. These general risks may include:

- Hypoglycemia
- Hyperglycemia
- Diabetic ketoacidosis
- Seizure
- Coma
- Death

Risks related to sensor use

General risks related to sensor use may include:

- Skin irritation or other reactions
- Bruising
- Discomfort

- Redness
- Bleeding
- Pain
- Rash
- Infection
- Raised bump
- Appearance of a small "freckle-like" dot where needle was inserted
- Allergic reaction
- Fainting secondary to anxiety or fear of needle insertion
- Soreness or tenderness
- Swelling at insertion site
- Sensor fracture, breakage or damage
- Minimal blood splatter associated with sensor needle removal
- Residual redness associated with adhesive, tape, or both
- Scarring

Specific risks related to sensor use

Taking medications with acetaminophen, including, but not limited to Tylenol, fever reducers, or cold medicine, while wearing the sensor may falsely raise your SG readings. The level of inaccuracy depends on the amount of acetaminophen active in your body and may be different for each person. Always use BG meter readings to verify your glucose level before making therapy decisions, including when you could have acetaminophen active in your body. Avoid taking medications with acetaminophen while in Auto Mode. If acetaminophen is taken, use additional BG meter readings to verify your glucose levels, and consider exiting Auto Mode. Do not use these additional BG meter readings to calibrate the sensor. Always check the label of any medications to confirm whether acetaminophen is an active ingredient.

For persons two to thirteen years of age, sensor placement and insertion has been studied in the belly (abdomen) and buttocks only and is not approved for other sites.

For persons that are fourteen years of age and older, sensor placement and insertion has been studied in the belly (abdomen) and back of upper arm only and is not approved for other sites.

Specific risks related to meter use

- Do not use the meter at high hematocrit levels above 65% or low hematocrit levels below 10%.
- Not for use in diagnosis or screening of diabetes mellitus.
- Not for neonatal use.
- Abnormally high concentrations of ascorbic acid (vitamin C) resulting in blood concentrations in excess of 5 mg/dL may cause inaccurate results. If you are not sure please check with your doctor.
- Do not use the meter system to measure blood glucose in people who are experiencing cardiovascular collapse (severe shock) or decreased peripheral blood flow.
- Do not use this system during xylose absorption test.
- Not for use on critically ill patients, patients in shock, dehydrated patients, or hyperosmolar patients.
- This system has not been tested at altitudes higher than 10,150 feet.

Risks related to serter use

General risks with serter use may include skin infection around the area where the serter is used.

Risks related to the MiniMed 770G insulin pump system

General risks related to the MiniMed 770G insulin pump system may include:

- Hypoglycemia
- Hyperglycemia
- Diabetic ketoacidosis
- Seizure
- Coma
- Death

General warnings

Pump

- Do not use the pump when a flammable anesthetic mixture with air, oxygen, or nitrous oxide is present. These environmental conditions can damage your pump and result in serious injury.
- Always use the fingertip for blood samples used for calibrating the sensor while in Auto Mode. The fingertip was the only site studied for use with Auto Mode. Do not use blood samples from the palm to calibrate the sensor as this site was not studied for use with Auto Mode and the performance of the system is not known.
- Always use the values from your BG meter for treatment decisions. The MiniMed 770G system CGM does not replace a BG meter to make treatment decisions. BG values may differ from SG values. Using the SG readings for treatment decisions could lead to high or low BG.
- For MiniMed 770G System Users Ages 2-13:

  The low SG alert functionality is distinct from the automated insulin dosing function of the MiniMed 770G System. When used in Auto Mode, the MiniMed 770G System has been shown to be safe and effective for its intended use in this population. However, do not rely solely on the use of a low SG value for "Alert on Low" or "Alert before Low" for alerts set at 50 mg/dL and 60 mg/dL. A low SG alert may not reflect the user's true BG at these levels, or may not alert. Do not ignore symptoms of low glucose. Always confirm your SG readings with your BG meter, and treat according to the recommendations of your healthcare professional. Solely relying on these SG alerts and readings for treatment decisions could result in missing severe hypoglycemia (low BG) events.
- Never rely on the pump beeps or vibrations alone to navigate through the pump screens or menus. Always check your pump screen as you navigate. The pump beeps and vibrations are intended to notify you of a condition that may require attention. Relying on the pump beeps or vibrations alone to navigate can result in incorrect menu selection or settings.
- Do not use your pump if the screen appears broken or unreadable. In some instances, impact to the pump can damage the screen while the buttons continue to function. If the screen is broken or unreadable, do not press any

buttons. Remove the pump and begin using your backup insulin plan per the direction of your healthcare professional. If the pump is accidentally programmed while the screen is broken or unreadable, this could result in high or low BG levels. If your screen is damaged, contact 24-Hour Technical Support to arrange for shipment of a replacement pump.

- Only use rapid-acting U-100 insulin (Humalog and NovoLog) that has been prescribed by your healthcare professional for use with an infusion pump. Do not put any other drugs or medications inside your reservoir for use with this pump. Other drugs or medications are not intended for use with this pump. Use of other drugs or medications can cause serious injury.
- Always make sure the infusion set is disconnected from your body before you rewind your pump or fill the infusion set tubing. Never insert the reservoir into the pump while the tubing is connected to your body. Doing so could result in an accidental infusion of insulin.
- Do not insert the reservoir in the pump if you did not rewind your pump. Doing so could result in an accidental infusion of insulin.
- Do not use the MiniMed 770G insulin pump or additional system devices adjacent to other electrical equipment which may cause interference with the normal system operation. This includes mobile communication devices such as cell phones that are not paired with the MiniMed 770G System, GPS navigation systems, anti-theft systems, and any electrical equipment that has an output transmitter power greater than 1W. For more information about recommended separation distance guidelines between the insulin pump and common RF emitters, see *Guidance and manufacturer's declaration, on page 317*. The recommended separation distance between the insulin pump and common RF emitters is 12 inches. Other electrical equipment that may compromise normal system operation has been contraindicated. For more information, see *Exposure to magnetic fields and radiation, on page 24*.
- Do not unscrew or retighten the tubing connector on the reservoir while the infusion set is connected to your body. Doing so could result in an accidental infusion of insulin.

- Do not use standard Luer sets with the MiniMed 770G insulin pump. Standard Luer sets are not compatible with the pump. The MiniMed reservoirs and the MiniMed infusion sets are specifically designed for use with the MiniMed 770G insulin pump.
- Do not change or modify the MiniMed reservoir or the MiniMed infusion set unless expressly approved by Medtronic Diabetes. Modifying the devices can cause serious injury, interfere with your ability to operate the device, and void your warranty.
- Do not rely on preset pump alarms or reminders alone to prompt you to check your BG. This can cause you to forget to check your BG. Set additional reminders on other devices, such as your cell phone.
- Do not change or modify the internal RF transmitter or antenna unless expressly approved by Medtronic Diabetes. Doing so could interfere with your ability to operate the equipment.
- Do not attempt to use any transmitter other than the Guardian Link (3) transmitter with Bluetooth wireless technology (MMT-7911). "GL3" is marked on the transmitter. Only the "GL3" transmitter can communicate with the MiniMed 770G insulin pump with Bluetooth wireless technology.
- If other devices, outside those being used as part of the MiniMed 770G System, employ radio frequencies such as cell phones, cordless phones, walkie-talkies, and wireless networks, they may prevent communication between the transmitter and the insulin pump. This interference does not cause any incorrect data to be sent and does not cause any harm to your devices. Moving away from, or turning off, these other devices may enable communication. If you continue to experience RF interference, contact 24-Hour Technical Support.
- Special Precautions regarding Electromagnetic Compatibility (EMC): This body worn device is intended to be operated within a reasonable residential, domestic, public or work environment, where common levels of radiated “E” (V/m) or “H” fields (A/m) exist; such as cellular phones that are not paired with the MiniMed 770G System, Wi-Fi, Bluetooth wireless technology, electric can openers, microwave and induction ovens. This device generates, uses, and can

radiate radio frequency energy and, if not installed and used in accordance with the provided instructions, may cause harmful interference to radio communications.

- Portable and mobile RF communications equipment can affect Medical Electrical Equipment as well. If you encounter RF interference from a mobile or stationary RF transmitter, move away from the RF transmitter that is causing the interference.
- This device can generate, use, and radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. If the device does cause interference to radio or television reception, you are encouraged to try to correct the interference by one or more of the following measures:
    - Decrease the distance between the transmitter and the insulin pump to 6 feet (1.8 meters) or less.
    - Decrease the distance between the meter and the insulin pump to 6 feet (1.8 meters) or less.
    - Increase the separation between the transmitter and the device that is receiving/emitting interference.

Note: Harmful interference is defined by the FCC as follows. Any emission, radiation or induction that endangers the functioning of a radio navigation service or of other safety services or seriously degrades, obstructs or repeatedly interrupts a radio communications service operating in accordance with FCC rules.

- The safety of the MiniMed 770G System has not been studied in people with impaired kidney function. Let your healthcare professional know if you have kidney disease so you and your healthcare professional can determine if the potential benefits of using the system outweigh the risks.
- The safety of the MiniMed 770G System has not been studied in pregnant women, people with type 2 diabetes, or in people using other anti-hyperglycemic therapies that do not include insulin. Let your healthcare

professional know if any of these conditions apply to you so you and your healthcare professional can determine if the potential benefits of using the system outweigh the risks.

- The safety of using Auto Mode, Suspend before low, and Suspend on low in people who have no pump experience is not known. Auto Mode, Suspend before low, and Suspend on low should not be used if insulin pump settings have not been previously established. Insulin pump settings include basal rates, insulin to carb ratio, or insulin sensitivity factors. Always discuss with your healthcare professional before using Auto Mode, Suspend before low, or Suspend on low.

Reservoir and infusion sets

For the most current warnings, see the user guide that came with your device.

- Only use rapid-acting U-100 insulin (Humalog and NovoLog) that has been prescribed by your healthcare professional for use with an infusion pump. Do not put any other drugs or medications inside your reservoir for use with this pump. Other drugs or medications are not intended for use with this pump, and can result in serious injury.
- If insulin, or any liquid, gets inside the tubing connector, it can temporarily block the vents that allow the pump to properly prime the infusion set. This may result in the delivery of too little or too much insulin, which can cause hyperglycemia or hypoglycemia. If this occurs, start over with a new reservoir and infusion set.
- Do not reinsert the introducer needle into the infusion set. Reinsertion may cause tearing of the soft cannula, which may result in unpredictable medication flow.
- If infusing insulin, and your BG level becomes unexplainably high, or an occlusion alarm occurs, check for clogs and leaks.
- If in doubt, change the infusion set because the soft cannula may be dislodged, crimped, or partially clogged. Should any of these problems arise, make a plan with your healthcare professional for rapidly replacing insulin. Check your BG level to make sure the problem is corrected.
- Reuse of the infusion set may cause damage to the cannula or needle and lead to infection, site irritation, and inaccurate medication delivery.

- Dispose of transfer guard safely in sharps container.
- Never prime the set or attempt to free a clogged line while the set is inserted. You may accidentally inject too much medication.
- Do not put disinfectants, perfumes, or deodorants on the infusion set as these may affect the integrity of the set.
- Dispose of the infusion set and introducer needle safely, in a sharps container, after a single use. Do not clean or re-sterilize.
- Store infusion sets in a cool, dry place. Do not leave infusion sets in direct sunlight or inside a vehicle.
- Only use reservoir and infusion sets manufactured or distributed by Medtronic Diabetes. The pump has undergone extensive testing to confirm appropriate operation when used with compatible reservoirs and infusion sets manufactured or distributed by Medtronic Diabetes. We cannot guarantee appropriate operation if the pump is used with reservoirs or infusion sets offered by third parties. We are not responsible for any injury or malfunctioning of the pump that may occur in association with such use.
- Use aseptic techniques when temporarily disconnecting the set and consult your healthcare provider on how to compensate for missed medication when disconnected.
- If infusing insulin, carefully monitor your BG levels when disconnected and after reconnecting.
- Reservoir and transfer guard are sterile, non-pyrogenic, and for single use only.
- Do not clean or re-sterilize. Reuse of the reservoir may lead to insulin degradation, infection, inaccurate medication delivery, and leaks which may cause damage to the pump.
- Inaccurate medication delivery, infection, or site irritation may result from improper insertion and maintenance of the infusion site.
- If using this infusion set for the first time, do the first set-up in the presence of your healthcare professional.
- Do not leave air in the infusion set. Prime completely.
- Replace the infusion set every 48 to 72 hours according to Centers for Disease Control guidelines, or per your healthcare professional's instructions.

- If infusing insulin, do not change the infusion set just before bedtime unless you can check your BG 1 to 3 hours after insertion.
- Do not use if package has been opened or damaged.
- Ensure sterility by checking that the sterile paper and tamper-proof seal are not damaged.
- This device is sterile and non-pyrogenic unless the package has been opened or damaged. Do not use if the package has been opened or damaged. Do not use the infusion set if the tubing connector needle has been damaged.
- Do not use the infusion set for more than three days. Insulin is not labeled for more than three days of use when it is used in an infusion set. If insulin is used in the infusion set for more than three days, it may increase the risk of set occlusions and cause problems with insulin absorption, which may lead to severe hyperglycemia and DKA.
- Before insertion, clean the insertion site with isopropyl alcohol.
- Check frequently to make sure the soft cannula remains firmly in place as you may not feel pain if it pulls out. The soft cannula must always be completely inserted to receive the full amount of medication.
- Release the tubing with caution as a hard pull of the tubing can result in damage to the infusion set and introducer needle. Ensure that the infusion set is properly in place when the tubing is fully released.
- If the infusion site becomes inflamed, replace the set, and use a new site until the first site has healed. Replace the infusion set if the tape becomes loose, or if the soft cannula becomes fully or partially dislodged from the skin.
- Failure to remove trapped air from reservoir may result in inaccurate delivery of medication.
- Never point a loaded insertion device towards the body part where insertion is not desired.
- Remove the needle guard before inserting the infusion set.

Sensor and serter

For the most current warnings, see the user guide that came with your device.

- Keep the sensor away from children. This product contains small parts and may pose a choking hazard.

- Keep the serter away from children. This product contains small parts and may pose a choking hazard.
- A retractable needle is attached to the sensor and minimal blood splatter may occur. If you are a healthcare professional or caregiver, wrap sterile gauze around the sensor to minimize contact with blood. Keep as much distance as possible between you and the patient when removing the needle.
- Do not attempt to remove the sensor yourself if you suspect that the sensor is broken. While there is no evidence of a sensor breaking in a patient's body, sensor breakage can result in serious injury. Contact your healthcare professional for assistance in removing the sensor.
- Always inspect the packaging for damage prior to use. Sensors are sterile and non-pyrogenic, unless the package has been opened or damaged. Do not use the sensor if the sterile package has been opened or damaged. Use of an unsterile sensor can cause site infection.
- If bleeding continues, causes excessive pain or discomfort, or is significantly visible in the plastic base of the sensor, do the following:
    a. Remove the sensor and continue to apply steady pressure until the bleeding stops. Discard the sensor in a sharps container.
    b. Check the site for redness, bleeding, irritation, pain, tenderness, or inflammation. Treat based on instructions from your healthcare professional.
    c. Insert a new sensor in a different location.
- The one-press serter (MMT-7512) does not work the same as other Medtronic insertion devices. Failure to follow directions or using a different serter may result in improper insertion, pain, or injury.
- Keep the needle housing within sight at all times to avoid an accidental needlestick or puncture.
- Taking medications with acetaminophen while wearing the sensor may falsely raise your SG readings. The level of inaccuracy depends on the amount of acetaminophen active in your body and may be different for each person.
- Make sure the sensor is securely placed in the serter to avoid improper insertion, pain, or minor injury.

- Watch for bleeding at the insertion site (under, around, or on top of the sensor). If bleeding occurs, do the following:
    a. Apply steady pressure, using sterile gauze or a clean cloth placed on top of the sensor, for up to three minutes. The use of unsterile gauze can cause site infection.
    b. If bleeding stops, connect the transmitter (or recorder) to the sensor. If bleeding does not stop, do not connect the transmitter to the sensor because blood can get into the transmitter connector, and could damage the device.
- The sensor is designed to work with Guardian Link (3) transmitter only. It is not interchangeable with transmitters and recorders that are not compatible with the sensor. Connecting your sensor to a transmitter or recorder that is not approved for use with the sensor may cause damage to the components or inaccurate sensor glucose values.
- 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 sensor in the critically ill population is not recommended.

Transmitter

For the most current warnings, see the user guide that came with your device.

- Do not allow children to put small parts in their mouth. This product poses a choking hazard for young children.
- Do not use the tester if it comes in contact with blood. Touching blood can cause infection. Dispose of the tester according to the local regulations for medical waste disposal, or contact your healthcare professional for disposal information.
- Bleeding may occur after inserting the sensor. Always make sure that the site is not bleeding before connecting the transmitter to the sensor. Blood can get into the transmitter connector and damage the device. Discard the device if damaged. If bleeding occurs, apply steady pressure with a sterile gauze or clean cloth at the insertion site until bleeding stops. After bleeding stops, connect the transmitter to the sensor.

- Do not use the transmitter adjacent to other electrical equipment which may cause interference with the normal system operation. This includes mobile communication devices such as cell phones, GPS navigation systems, and other devices that have an output transmitter power greater than 1W. Other electrical equipment that may compromise normal system operation has been contraindicated.
- Do not change or modify the device unless expressly approved by Medtronic Diabetes. Modifying the device can cause serious injury, interfere with your ability to operate the device, and void your warranty.

Meter

For the most current warnings, see the User's Manual that came with your device.

Always use the fingertip for blood samples used for calibrating the sensor while in Auto Mode. The fingertip was the only site studied for use with Auto Mode. Do not use blood samples from the palm to calibrate the sensor as this site was not studied for use with Auto Mode and the performance of the system is not known.

Serious illness

- Capillary (fingerstick or Alternate Site) BG testing may not be clinically appropriate when peripheral flow is decreased. Shock, severe hypotension, hyperosmolar hyperglycemia, diabetic ketoacidosis, and occurrence of severe dehydration are examples of clinical conditions that may adversely affect the measurement of glucose in peripheral blood.[1, 2, 3]
- Keep out of reach of children. This kit contains small parts which could cause suffocation if accidentally swallowed.

Talk to your healthcare professional

- Before setting any Target ranges or High or Low Alerts on your meter.
- Before changing your medication based on test results.
- If your blood sugar reading is under 54 mg/dL, follow medical advice immediately.

---

1 Wickham NWR, Achar KN, Cove DH. Unreliability of capillary blood glucose in peripheral vascular disease. *Practical Diabetes*. 1986;3(2):100.

2 Atkins, S. et al. Fingerstick Glucose Determination in Shock. *Ann intern Med*. 1991;114:1020-1024.

3 Desachy A, Vuagnat AC, et al. Accuracy of bedside glucometry in critically ill patients: influence of clinical characteristics and perfusion index. *Mayo Clin Proc*. 2008;83(4):400-405.

- If your blood sugar reading is over 250 mg/dL, wash and dry your hands well and repeat the test with a new strip. If you get a similar result, call your healthcare professional as soon as possible.
- About whether Alternate Site Testing (AST) is appropriate for you.

CAUTION: Do not use Alternate Site Testing under the following conditions. Use fingertip testing in any of these cases:

- If you think your BG is low (hypoglycemia).
- When BG is changing rapidly (after a meal, insulin dose, or exercise).
- If you have hypoglycemic unawareness (lack of symptoms).
- If you get alternate site BG results that do not agree with how you feel.
- During illness or times of stress.
- If you will be driving a car or operating machinery.
- For calibration of CGM system.

AST testing should not be used for Bolus Wizard, to calibrate a device or verify a low BG level.

Consult your healthcare professional to determine if alternate site testing is right for you.

Potential Biohazard

- Always wash and dry your hands well with soap and water before and after testing, handling the meter, lancing device or test strips.
- The meter, lancing device, and lancets are for single person use. Do not share them with anyone including other family members. Do not use on multiple persons.[4, 5]
- The Accu-Chek lancing device is intended for self-testing by a single patient. It must not be used on more than one person due to risk of infection.

4 FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication: Update 11/29/2010. http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm

5 CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens (2010). http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html

- Use a new lancet each time you test because it is no longer sterile after use.
- Always dispose of test strips and lancets as medical waste or as advised by your healthcare professional. All products that come in contact with human blood should be handled as if capable of transmitting infectious diseases.

Exposure to magnetic fields and radiation

- Do not expose your pump to MRI equipment, diathermy devices, or other devices that generate strong magnetic fields (for example, x-ray, CT scan, or other types of radiation). The strong magnetic fields can cause the system to malfunction, and result in serious injury. If your pump is exposed to a strong magnetic field, discontinue use and contact 24-Hour Technical Support for further assistance.

  Magnetic fields, and direct contact with magnets, may affect the accurate functioning of your system, which may lead to health risks such as hypoglycemia or hyperglycemia.
- Do not expose your transmitter to MRI equipment, diathermy devices, or other devices that generate strong magnetic fields. Exposure to a strong magnetic field has not been evaluated and can cause the device to malfunction, result in serious injury, or be unsafe. If your transmitter is inadvertently exposed to a strong magnetic field, discontinue use and contact 24-Hour Technical Support for further assistance.
- Do not expose your sensor to MRI equipment, diathermy devices, or other devices that generate strong magnetic fields as the performance of the sensor has not been evaluated under those conditions and may be unsafe. If your sensor is inadvertently exposed to a strong magnetic field, discontinue use and contact 24-Hour Technical Support for further assistance.
- Always remove your pump, sensor, transmitter, and meter before entering a room that has x-ray, MRI, diathermy, or CT scan equipment. The magnetic fields and radiation in the immediate vicinity of this equipment can make your devices nonfunctional or damage the part of the pump that regulates insulin delivery, possibly resulting in over delivery and severe hypoglycemia.

- Do not expose your pump to a magnet, such as pump cases that have a magnetic clasp. Exposure to a magnet may interfere with the motor inside the pump. Damage to the motor can cause the device to malfunction, and result in serious injury.
- Always carry the Medical emergency card provided with your device when you are traveling. The Medical emergency card provides critical information about airport security systems and pump use on an airplane, which can help you and others. Not following the guidance on the Medical emergency card could result in serious injury.

General precautions

Always check your BG levels at least four times per day. Although the pump has multiple safety alarms, it cannot notify you if the infusion set is leaking, or the insulin has lost its effectiveness. If your BG is out of range, check the pump and the infusion set to ensure that the necessary amount of insulin is being delivered.

Waterproof capabilities

- At the time of manufacture and when the reservoir and tubing are properly inserted, your pump is waterproof. It is protected against the effects of being underwater to a depth of up to 12 feet (3.6 meters) for up to 24 hours.
- If the pump is dropped, hit against a hard object, or otherwise damaged, the waterproof characteristics of the outer casing of the pump may be compromised. If your pump has been dropped or you suspect your pump is damaged, carefully inspect your pump to ensure there are no cracks before exposing your pump to water.
- This waterproof capability rating applies only to your pump.
- If you believe that water has entered your pump or you observe any other possible pump malfunction, check your BG, and treat high BG as necessary, using an alternative source of insulin. Contact 24-Hour Technical Support for further assistance. Always contact your healthcare professional if you experience excessively high or low BG levels or if you have any questions about your care.

Electrostatic discharge

- Although the MiniMed 770G insulin pump is designed to be unaffected by typical levels of electrostatic discharge (ESD), very high levels of ESD can result in a reset of the pump's software and a pump error alarm. After clearing the alarm, verify that your pump is set to the correct date and time, and that all other settings are programmed to the desired values. The software reset could erase your previously programmed settings. Following a pump reset, Auto Mode will be unavailable for five hours to allow active insulin to be updated.
- For more information on pump alarms, see *Pump alarms, alerts, and messages, on page 244*. For more information on re-entering your pump settings, see *My pump is asking me to enter my settings, on page 286*. If you are unable to re-enter your pump settings, or otherwise believe there is a problem with your pump, contact 24-Hour Technical Support.

Extreme temperatures

Exposure to extreme temperatures can damage your device, which can adversely affect safety and effectiveness of your device. Avoid the following conditions:

- Avoid exposing your pump to temperatures above 104°F (40°C) or below 41°F (5°C). This may damage your device.
- Insulin solutions freeze near 32°F (0°C) and degrade at temperatures higher than 98.6°F (37°C). If you are outside in cold weather, wear your pump close to your body and cover it with warm clothing. If you are in a warm environment, take measures to keep your pump and insulin cool.
- Do not steam, heat, sterilize, or autoclave your pump. Exposure to high temperatures may damage your device.

Lotion, sunscreen, and insect repellent

Some skin care products, such as lotion, sunscreen, and insect repellents, can cause damage to plastics, which is a material used in your pump case. After using such products, be sure to wash your hands prior to handling your pump. If you get any skin care products or insect repellents on your pump, wipe them off as soon as possible with a damp cloth and mild soap. For instructions on cleaning your pump, see *Cleaning your pump, on page 293*.

Infusion sets and sites

Always refer to the infusion set user guide for all precautions, warnings, and instructions relating to the infusion set and your insertion sites. Not referring to the infusion set user guide can result in minor injury or damage to the infusion set.

Sensor

Always refer to the sensor user guide for all precautions, warnings, and instructions relating to the sensor. Not referring to the sensor user guide can result in minor injury or damage to the sensor.

Transmitter

Always refer to the transmitter user guide for all precautions, warnings, and instructions relating to the transmitter. Not referring to the transmitter user guide can result in minor injury or damage to the transmitter.

Meter

Always refer to the Accu-Chek Guide Link User's Manual for all precautions, warnings, and instructions relating to compatible meters. Not referring to the User's Manual can result in minor injury or damage to the meter.

Security precautions

The MiniMed 770G insulin pump system is designed with security features to help keep the system and the data secure. These security features in the insulin pump system are set in the factory and ready to use when the insulin pump is received. For example, when the pump communicates with other devices in the system, such as the BG meter, transmitter, or compatible mobile device, the data that it is sending and receiving is encrypted and protected by cyclic redundancy checks. This helps prevent other people from being able to see system data, or to interfere with insulin pump therapy.

To help keep the system secure, follow these instructions:

- Do not leave the insulin pump or the paired devices unattended.
- Do not share the pump, transmitter, or BG meter serial number.
- Do not connect the pump to any third-party devices not authorized by Medtronic.
- Do not use any software not authorized by Medtronic to control the system.

- Be attentive to pump notifications, alarms, and alerts because they may indicate that someone else is trying to connect to or interfere with the device.
- Disconnect the Blue adapter from the computer whenever it is not being used.
- Use good cyber security practices; use anti-virus software and keep computer software up to date.
- Refer to the MiniMed Mobile App User Guide for information on how to keep the compatible mobile device safe to use with the Medtronic devices.

The pump only communicates with paired devices. The short time that it takes to pair the pump with other devices is a sensitive time for security. During this time, it is possible for an unintended device to pair with the pump. While Medtronic has designed security features into the system to prevent this, to keep the system safe during pairing always follow these instructions:

- Pair the transmitter, BG meter, or the compatible mobile device with the pump away from other people and devices.
- When the transmitter successfully pairs with the pump, the green LED on the transmitter stops blinking. If the green LED on the transmitter continues to blink for several minutes or more after it is successfully paired, it may have been paired with an unintended device. See *Deleting the transmitter from your pump, on page 202* to delete the transmitter from the pump and then follow the steps to pair it again.
- After pairing the BG meter or the compatible mobile device with the pump, make sure that the BG meter or compatible mobile device indicates that pairing was successful.

Consult a healthcare professional if there are symptoms of severe hypoglycemia or diabetic ketoacidosis, or suspect that the insulin pump settings, or insulin delivery changed unexpectedly.

If there is a concern that someone else is trying to connect to or interfere with the device, stop using it and contact a local Medtronic support representative immediately.

Adverse reactions

Always refer to the sensor user guide for adverse reactions related to the sensor. Not referring to the sensor user guide can result in minor injury or damage to the sensor.

Keeping track of your system information

The serial number (SN) is located on the back of your pump. If you are using the pump clip, you need to remove the pump clip to view the serial number. It also displays in your Pump status screen. For more details on the status screens, see *Status screens, on page 50*. You will need your pump serial number if you call 24-Hour Technical Support. For future reference, enter the serial number of your pump and the purchase date in the following table:

Pump serial number and purchase date
Serial Number:
Purchase Date:

Insulin guidelines

WARNING: Never start on insulin until directed by your healthcare professional. Do not use insulin in your pump while you are practicing by either inserting an insulin filled reservoir into your pump, or connecting an insulin filled infusion set to your body. Doing so could result in an infusion of insulin, not prescribed by your healthcare professional, which may result in low or high BG.

The MiniMed 770G insulin pump has been studied with, and is intended for use with, the following rapid-acting U-100 insulins:

- U-100 NovoLog
- U-100 Humalog

The use of any other insulin in the MiniMed 770G insulin pump has not been tested and may not be appropriate for use with this device.

WARNING: Only use rapid-acting U-100 insulin (Humalog and NovoLog) in the MiniMed 770G insulin pump. Use of the incorrect insulin, or insulin with a greater or lesser concentration, may result in over delivery or under delivery of insulin. Over delivery or under delivery of insulin may result in high or low blood glucose levels. High blood glucose levels may lead to diabetic ketoacidosis. Low blood glucose levels may lead to coma or death. If you are unsure about whether you can use a specific insulin with this pump, contact your healthcare professional.

Consumables

The pump uses disposable, single-use, MiniMed reservoirs and infusion sets for insulin delivery.

WARNING: Only use reservoir and infusion sets manufactured or distributed by Medtronic Diabetes. The pump has undergone extensive testing to confirm appropriate operation when used with compatible reservoirs and infusion sets manufactured or distributed by Medtronic Diabetes. We cannot guarantee appropriate operation if the pump is used with reservoirs or infusion sets offered by third parties and therefore we are not responsible for any injury or malfunctioning of the pump that may occur in association with such use.

- Reservoirs–Use the MiniMed reservoir MMT-332A, 3.0 mL (300-unit).
- Infusion sets–Medtronic Diabetes provides a variety of infusion sets to fit your needs. Contact your healthcare professional for help in choosing an infusion set. Change your infusion set every two to three days per your infusion set manufacturer's instructions.

The following table lists the compatible infusion sets. The MMT numbers may change if other compatible infusion sets become available.

Type	MMT number
MiniMed Quick-set infusion set	MMT-386, MMT-387, MMT-394, MMT-396, MMT-397, MMT-398, MMT-399
MiniMed Silhouette infusion set	MMT-368, MMT-377, MMT-378, MMT-381, MMT-382, MMT-383, MMT-384
MiniMed Sure-T infusion set	MMT-862, MMT-864, MMT-866, MMT-874, MMT-876, MMT-884, MMT-886
MiniMed Mio infusion set	MMT-921, MMT-923, MMT-925, MMT-941, MMT-943, MMT-945, MMT-961, MMT-963, MMT-965, MMT-975
MiniMed Mio Advance infusion set	MMT-211, MMT-212, MMT-213, MMT-231, MMT-232, MMT-233, MMT-242, MMT-243, MMT-244

Additional MiniMed 770G System devices

- **Accu-Chek Guide Link meter**–the MiniMed 770G System is compatible with an Accu-Chek Guide Link meter. The meter pairs with your pump, allowing you to send BG meter readings to your pump.
- **Guardian Link (3) transmitter (MMT-7911)**–pairs with your pump for CGM. A device that connects to a glucose sensor. The transmitter collects data measured by the sensor and wirelessly sends this data to monitoring devices.
- **Guardian Sensor (3) (MMT-7020)**–used with your pump for CGM. The sensor is a small part of the CGM system that you insert just below your skin to measure glucose levels in your interstitial fluid. The sensor is a disposable, single-use, device. Only use the Guardian Sensor (3) (MMT-7020) glucose sensor with the transmitter. Do not use any other sensor. Other sensors are not intended for use with the transmitter, and will damage the transmitter and the sensor.
- **MiniMed Mobile app (MMT-6101 for Android or MMT-6102 for iOS)**–can be downloaded onto multiple compatible mobile devices from the app store, but the pump can be paired with only one compatible mobile device at any time.

Refer to the app user guide for setup and operation. This product should only be used with supported mobile devices. Refer to your local Medtronic Diabetes website for information about supported devices and operating systems.

- **Blue adapter (ACC-190)**–uploads system data to CareLink software through a USB port on your computer. Refer to the CareLink software user guide for setup and operation of the blue adapter.

Accessories

The following accessories may be used with the MiniMed 770G System.

- **Pump clip**–used to wear the pump on your belt. Also, you can use the tip of the pump clip to open the battery compartment on your pump. Refer to your pump clip user guide for instructions on using your pump clip.
- **Activity guard (ACC-1520)**–used if you are active in sports, or if a child is wearing the pump. Using the activity guard prevents the reservoir from being rotated or removed from the pump.
- **Skins**–personalize the look of the pump as decorative overlays and provide additional protection against surface scratches.

Ordering supplies and accessories

To order supplies or accessories, call 800 646 4633, +1 818 362 5958 (outside U.S.), refer to the contacts list at the beginning of this user guide, or visit our website at www.medtronicdiabetes.com.

2

First steps

2 First steps

This chapter gives you an overview of your pump so you can become familiar with the buttons and screens. Read this entire chapter to understand the basic features before using your pump to deliver insulin.

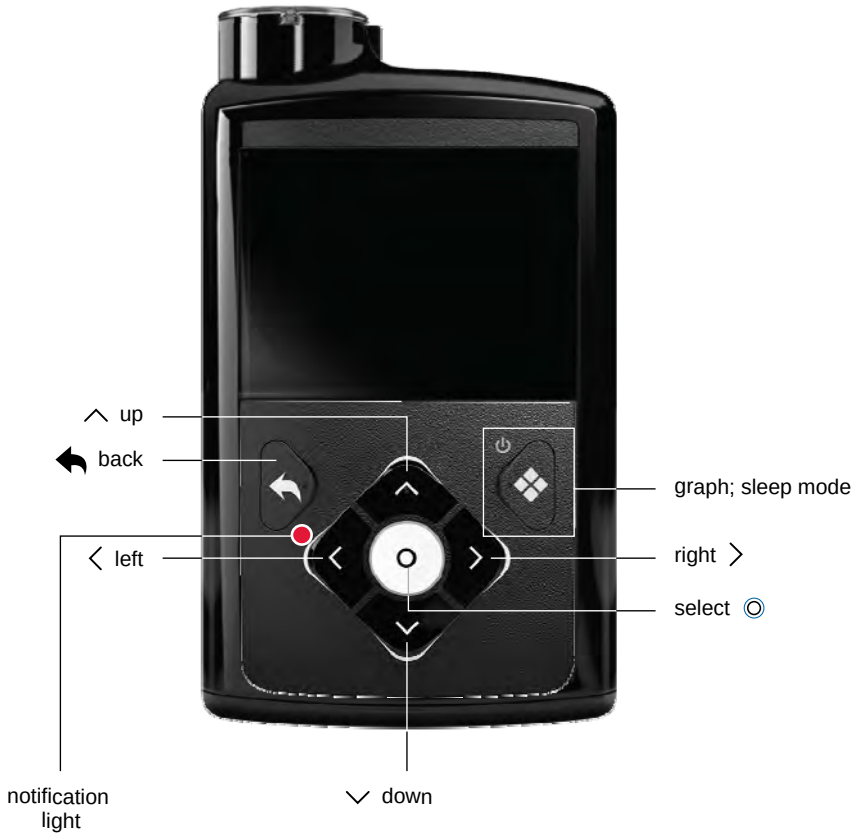
Your pump

The following illustration shows the different parts of your pump. The reservoir, with the tubing connector attached, is inserted into the reservoir compartment.

Using the buttons

CAUTION: Do not use sharp objects to press the buttons on your pump. The use of sharp objects can damage your pump.

The following picture shows the buttons and the notification light on your pump. The notification light flashes when your pump has an alarm or alert. The notification light is not visible unless it flashes.



The following table describes how to use the buttons.

To do this:	Follow these steps:
Display the menu.	From the Home screen, press the ◎ button.

To do this:	Follow these steps:
Scroll up or down a menu or list, or increase or decrease the value of a setting.	Press the ∧ or ∨ buttons.
Select an item on a screen or menu.	Press the ∧, ∨, <, or > buttons to select the desired item, and then press the ◎ button.
Enter a value into a field.	Press the ∧, ∨, <, or > buttons to select the desired field, and then press the ◎ button. The field you select flashes. Press the ∧ or ∨ buttons to enter the desired value, and then press the ◎ button.
Return to the previous screen.	Press the ↩ button.
Display the Home screen.	Press and hold the ↩ button to return to the Home screen.
Put the pump in sleep mode.	Press and hold the ❖ button for about two seconds. **Note:** ⏻ reminds you that you can press and hold ❖ to put the pump into sleep mode.
Wake up the pump.	Press any button.

About batteries

The pump requires one new AA (1.5 V) battery. For best results, use a new AA lithium (FR6) battery. The pump also accepts an AA alkaline (LR6) or a fully charged AA NiMH (HR6) nickel-metal hydride rechargeable battery.

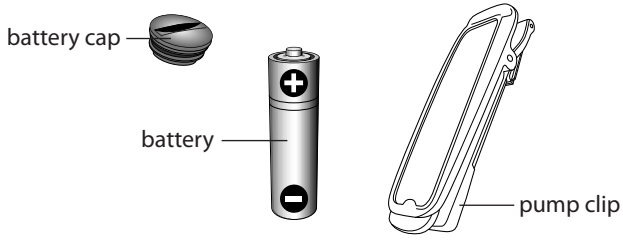
CAUTION: Do not use a carbon zinc battery in your pump. Carbon zinc batteries are not compatible with the pump. Use of carbon zinc batteries can cause the pump to report inaccurate battery levels.

Carbon zinc batteries have a short shelf life, they deteriorate rapidly in cold weather, and oxidation of the zinc wall eventually causes the contents to leak out. They will not perform as well as other battery types to power the pump and may potentially damage your pump.

Note: Do not use cold batteries because the battery life may incorrectly appear as low. Allow cold batteries to reach room temperature before you insert them in your pump.

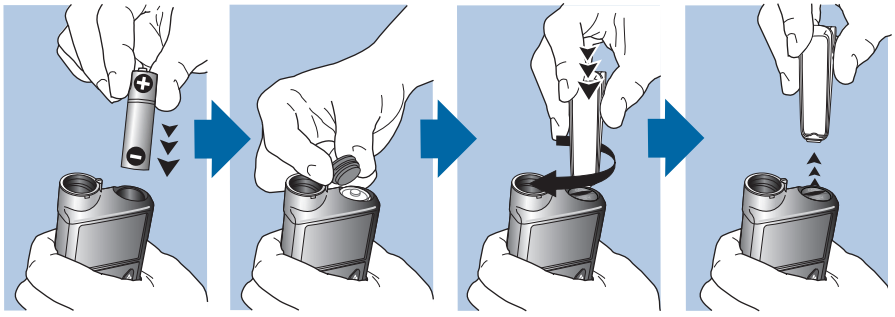
Inserting the battery

Your pump does not ship with the battery cap on. The battery cap is located in the pump box with the accessories.



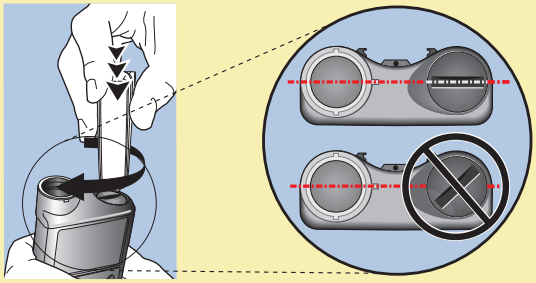
To insert the battery:

1. Insert the new or fully charged AA battery. Be sure to insert the flat end first.



2. Place the battery cap onto the pump. Use the bottom edge of the pump clip to turn the cap to the right and tighten.

CAUTION: Do not overtighten or undertighten the battery cap. Overtightening the battery cap can cause damage to your pump case. Undertightening the battery cap will prevent the pump from recognizing the new battery. Turn the battery cap clockwise until the cap is aligned horizontally with the pump case, as shown in the following example.



Note: If this is the first time you have inserted a battery in your pump, the Startup Wizard begins. For more information about the Startup Wizard, see *Entering your startup settings, on page 41*. If this is not the first time you have inserted a battery into your pump, the Home screen appears and the pump resumes your basal delivery.

Removing the battery

CAUTION: Do not remove the battery unless you insert a new battery or store the pump. Your pump cannot deliver insulin while the battery is removed. After you remove an old battery, be sure to replace it with a new battery within 10 minutes to clear the Insert battery alarm and avoid a Power loss alarm. If power loss occurs, you must re-enter your time and date settings.