



WARNING: If you receive a critical error on your pump, the following screen displays and the pump sirens.



Immediately disconnect from your insulin pump and discontinue use. Contact your local representative for assistance.

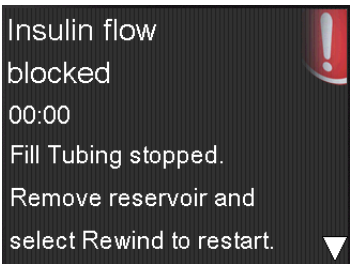
Remember, your body still needs insulin while your pump is removed. It is important that you consult your healthcare professional to determine an alternate method of receiving insulin while your pump is removed.

Alarms

An alarm warns you that the pump detected something that prevents insulin from being delivered. It is important that you respond to an alarm.



WARNING: Do not ignore your pump when it has an alarm because all insulin delivery is stopped, which may lead to high blood glucose and ketoacidosis.



When an alarm occurs:

Display: The pump displays a notification with a red icon and instructions.

Notification light: The red notification light blinks twice, followed by a pause, in a continuous repeating pattern. The notification light is shown in *Using the buttons, on page 20*.

Audio: Depending on your Audio Options settings, the pump emits an alarm tone, a continuous three-pulse-and-pause vibration pattern, or both the alarm tone and vibration.

You must resolve the underlying problem that triggered the alarm. In most cases, you clear an alarm by pressing  and then you make a selection. In some cases, however, clearing the alarm does not fix the underlying problem. The alarm repeats until the underlying problem is fixed.

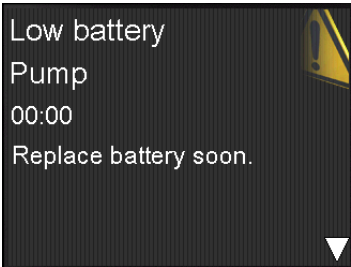
If you do not respond to an alarm, after ten minutes the alarm tone escalates to a loud emergency siren. For more information, see *Alarm and alert escalation*, on page 247.

Alerts

An alert makes you aware of a situation that may require your attention. An alert is less serious than an alarm.

When an alert occurs:

Display: The pump displays a notification with a yellow icon and instructions.



Notification light: The red notification light on your pump blinks once, followed by a pause, then blinks once again in a continuous repeating pattern. The notification light is shown in *Using the buttons*, on page 20.

Audio: Depending on your Audio Options settings, the pump either beeps or vibrates in a continuous three-pulse-and-pause pattern, or does both.

To clear an alert, press  and then make a selection. If you do not respond to an alert, the pump beeps every five minutes or every fifteen minutes, depending on the alert. Some alerts will also escalate to a loud emergency siren after ten minutes. For more information, see *Alarm and alert escalation*, on page 247.



Note: If an alert occurs when you are in a screen other than the Home screen, the alert message may appear after you return to the Home screen.

Messages

A message informs you about the status of your pump or if you need to make a decision.

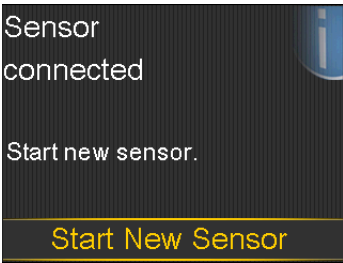
When a message occurs:

Display: The pump displays a notification with a blue icon and instructions.

Notification light: Does not illuminate or blink.

Audio: Depending on the message, the pump emits a message tone, an alert tone, or no tone. Depending on your Audio Options settings, you may hear a tone, feel a one-pulse-only vibration, or hear a tone and feel a vibration.

You clear the message by pressing  and make a selection.



Pump alarms, alerts, and messages

The following table lists the most common or serious alarms, alerts, and messages related to your pump. The table also explains the meaning, consequences, and the reasons why these notifications appear, and provides steps for problem resolution.

Title and text	Explanation	Next steps
Active Insulin cleared Any Active Insulin amount has been cleared.	An alarm has cleared your active insulin amount. Your active insulin amount is now at 0 units.	• Select OK to clear the alarm. • The active insulin tracked prior to pump restart is not included in new Bolus Wizard calculations. Consult your healthcare professional for how long you need to wait after active insulin is cleared before you can rely on the active insulin calculation of your Bolus Wizard • You can check Daily History for the time and amount of your last bolus. For more information, see <i>Daily History</i>, on page 121.

Title and text	Explanation	Next steps
Auto Suspend Insulin delivery suspended. No buttons pressed within time set in Auto Suspend.	You have not pressed any buttons during the time specified in the Auto Suspend settings.	• To clear the alarm and resume basal insulin delivery, select Resume Basal. • Check your BG and treat as necessary.
Battery failed Insert a new AA battery.	The pump battery does not have enough power.	• Select OK to clear the alarm. • Remove the old battery and insert a new AA battery. For details, see <i>About batteries</i>, on page 21.
Battery not compatible. See User Guide.	The battery that you inserted into the pump is not compatible.	• To clear the alarm, remove the incompatible battery. • Insert a new AA battery. For compatible battery types, see <i>About batteries</i>, on page 21.
Bolus not delivered. Bolus entry timed out before delivery. If bolus intended, enter values again.	Bolus values entered, but bolus was not delivered within 30 seconds.	• Select OK to clear the alert. • If bolus delivery was intended, check your BG, re-enter bolus values and deliver bolus.
Bolus stopped Cannot resume bolus or cannula fill. XX.XXX of YY.YYY U delivered. ZZ.ZZZ U not delivered. If needed, enter values again.	The battery power was exhausted while a bolus or Fill Cannula was in progress.	• Note the amount of insulin not delivered. • Replace the AA battery. • Select OK to clear the alarm. • Deliver the remaining bolus amount if needed.

Title and text	Explanation	Next steps
Cannot connect device This device is incompatible with your pump. See User Guide.	• You may be trying to connect a device that is not compatible with your pump. • You are trying to connect a transmitter to your pump but another transmitter is already wirelessly connected to your pump.	• Select OK to clear the alert. • Check the list of devices that are compatible with your pump in <i>Optional devices, on page 14</i>. • If you are replacing your transmitter, make sure that you first delete the old transmitter from your pump before you try to connect your new transmitter. Only one transmitter can be connected to your pump. For details, see <i>Deleting the transmitter from your pump, on page 181</i>.
Check settings Startup Wizard settings complete. Check and set up your other settings.	Some settings have been cleared or reverted to factory default values.	• Select OK to clear the alert. • Review any settings that you have not already set in Startup Wizard and re-enter the values, if necessary.
Critical pump error Delivery stopped. Pump not working properly. Stop using pump. Remove infusion set from body. Consider other insulin treatment. See User Guide.	Your pump has encountered a critical error.	The pump is not able to deliver insulin. Remove your infusion set and stop using your pump. • Consider another form of insulin delivery. • Check your BG, and treat as necessary. • Write down the error code that appears on the alarm screen. • Call your local representative for assistance with your pump.

Title and text	Explanation	Next steps
Delivery limit exceeded Delivery stopped. Check BG. See User Guide for more information.	You have attempted to deliver more insulin than expected based on your Max Bolus and Max Basal settings.	• Check your BG. • Select Resume Basal. • Check Bolus History and reevaluate your need for insulin. • Continue to monitor your BG.
Fill Cannula? Select Fill to fill cannula or select Done if not needed.	You had the Fill Cannula screen displayed for 15 minutes.	• To proceed and fill the cannula, select Fill. • If you do not need to fill the cannula, select Done to skip this process.
Insert battery Delivery stopped. Insert a new battery now.	The battery was removed from the pump.	• Insert a new AA battery. • The alarm clears when you insert a new battery. • The pump powers off after 10 minutes unless you insert a new battery.

RELEASED

Title and text	Explanation	Next steps
Insulin flow blocked Check BG. Consider injection and testing ketones. Change reservoir and infusion set.	Your pump has detected that the basal or bolus insulin flow was blocked.	• Check your blood glucose. Consider checking ketones and take an injection if needed. • Remove your infusion set and reservoir. • Select Rewind to start the new reservoir process using a new infusion set and reservoir. If a bolus delivery was in progress when the alarm occurred: • Check the Daily History screen for the amount of bolus already delivered before the pump alarmed. • Consider delivering remaining bolus, if the bolus insulin was not included in an insulin injection.

RELEASED

Title and text	Explanation	Next steps
Insulin flow blocked Check BG. Consider injection and testing ketones. Estimated 0 U insulin in reservoir. Change reservoir and infusion set.	Your pump has detected that the insulin flow was blocked and there is no insulin in the reservoir.	• Check your blood glucose. Consider checking ketones and take an injection if needed. • Remove your infusion set and reservoir. • Select Rewind to start the new reservoir process using a new infusion set and reservoir. If a bolus delivery was in progress when the alarm occurred: • Check the Daily History screen for the amount of bolus already delivered before the pump alarmed. • Consider delivering remaining bolus, if the bolus insulin was not included in an insulin injection.

RELEASED

Title and text	Explanation	Next steps
Insulin flow blocked Fill Cannula stopped. Remove infusion set from body. Change reservoir and infusion set.	Your pump has detected the insulin flow was blocked while filling the cannula.	• Check your blood glucose. Consider checking ketones and take an injection if needed. • Remove your infusion set and reservoir. • Select Rewind to start the new reservoir process using a new infusion set and reservoir. If a fill cannula was in progress when the alarm occurred: • Check the Daily History screen for the amount of bolus already delivered before the pump alarmed. • Consider delivering remaining bolus, if the bolus insulin was not included in an insulin injection.

RELEASED

Title and text	Explanation	Next steps
Insulin flow blocked Fill Tubing stopped. Remove reservoir and select Rewind to restart.	Your pump has detected the insulin flow was blocked while filling the tubing. Possible connection issue between the tubing and reservoir.	- Remove the reservoir and select Rewind to restart the fill tubing process. - Disconnect tubing from reservoir. - Be sure tubing is not crimped or bent. - Continue following the steps displayed on the pump using the same infusion set and reservoir. - If this alarm occurs again, use a new infusion set. If a fill tubing delivery was in progress when the alarm occurred: - Check the Daily History screen for the amount of bolus already delivered before the pump alarmed. - Consider delivering remaining bolus, if the bolus insulin was not included in an insulin injection.
Loading incomplete Remove reservoir and select Rewind to restart loading.	You pressed  after loading began.	- Remove the reservoir to start again. - Select Rewind and follow the on-screen instructions.
Low battery Pump Replace battery soon.	The battery in the pump is low on power.	- Select OK to clear the alert. - Replace the AA battery as soon as possible. Otherwise, insulin delivery stops, and the Replace Battery Now alarm occurs. - If the pump is delivering a bolus or filling the cannula, wait until delivery is complete to replace battery.

Title and text	Explanation	Next steps
Low reservoir XX hours remaining. Change reservoir. or: XX units remaining. Change reservoir.	Your reservoir is low on insulin, according to the number of hours or units set in the Low Reservoir Reminder.	• Select OK to clear the alert. • Change the reservoir soon. • If you do not change the reservoir after you receive this alert, you will receive a second Low reservoir alert when the insulin level reaches half of your original alert amount. For more details, see <i>Low Reservoir reminder</i>, on page 132.
Manage settings error Delivery stopped. Backup settings cleared from Manage Settings. Current settings are working properly. Select OK to restart. See User Guide.	A pump error has occurred, and you need to restart your pump. Your backup settings have been lost, but your current settings are unchanged.	• Select OK to restart your pump. Your current settings are unchanged. Only your backup settings are lost. • When the pump restarts, follow instructions on the pump display. • If the pump was delivering a bolus or filling the cannula, check Daily History and evaluate your need for insulin. • Consider saving your current settings. For details, see <i>Saving your settings</i>, on page 142.
Max Fill reached 3X.X U. Did you see drops at the end of tubing?	You have exceeded the number of units expected to fill the tubing. By now, insulin should be at the end of the tubing.	• If you see drops at the end of the tubing, select Yes. • If you do not see drops, select No. • Follow instructions displayed on the pump.

Title and text	Explanation	Next steps
Max Fill reached 4X.X U. Remove reservoir and select Rewind to restart New Reservoir procedure.	You have exceeded the number of units expected to fill the tubing. By now, insulin should be at the end of the tubing.	• Remove the reservoir. • Check if you still have insulin in the reservoir. If you do, you can continue using the same reservoir. • Select Rewind to restart the new reservoir procedure.
No reservoir detected Rewind before loading reservoir.	There is no reservoir in the pump or the reservoir is not properly locked into place.	• Select Rewind. • Ensure that your reservoir is filled with insulin. • When prompted, ensure that your reservoir is inserted and properly locked into place.
Power error detected Delivery stopped. Record your settings by uploading to CareLink or write your settings on paper. See User Guide.	The internal power source in your pump is unable to charge. Your pump is operating on the AA battery only.	• Select OK to clear the alert. • Check your BG and treat as necessary. • Record your settings as soon as possible because your AA battery may not last long. • Call your local representative for assistance with your pump.
Power loss AA battery was removed for more than 10 min or power was lost. Select OK to re-enter time and date.	Your pump battery has been out for more than ten minutes, and your pump has lost power. You must reset your time and date.	• Select OK to go to the Time & Date screen. • Enter the current time, time format, and date.

Title and text	Explanation	Next steps
Pump error Delivery stopped. Current settings cleared. Pump restart needed. Select OK to restart and then re-enter your settings. See User Guide.	Your pump encountered an error and will restart. Your pump settings will return to factory default values.	• When the pump restarts, follow instructions on the pump display. • After restart, check settings and re-enter values as needed. • If you recently saved backup settings in Manage Settings, use Restore Settings. • If the pump was delivering a bolus or filling the cannula, check Daily History and reevaluate your need for insulin. • If this alarm recurs frequently, write down the error code displayed on the alarm screen (you can also find it in your Alarm History) and contact your local representative for assistance with your pump.
Pump error Delivery stopped. Settings unchanged. Pump restart needed. Select OK to restart. See User Guide.	A pump error has occurred, you need to restart your pump.	• Select OK to restart your pump. • If the pump was delivering a bolus or filling the cannula, check Daily History and reevaluate your need for insulin. • If this alarm recurs frequently, write down the error code displayed on the alarm screen (you can also find it in your Alarm History) and contact your local representative for assistance with your pump.

Title and text	Explanation	Next steps
Pump error Delivery stopped. Settings unchanged. Select OK to continue. See User Guide.	Your pump encountered an error but a restart is not necessary. The issue is resolved. Your settings are not changed.	• Select OK to resume basal delivery. • If the pump was delivering a bolus or filling the cannula, check Daily History and reevaluate your need for insulin. • If this alarm recurs frequently, write down the error code displayed on the alarm screen (you can also find it in your Alarm History) and contact your local representative for assistance with your pump.
Pump restarted Delivery stopped. Settings unchanged. Select OK to continue. See User Guide.	Your pump has encountered a problem and has restarted. Your settings have not been changed.	• Select OK to continue. • If the pump was delivering a bolus or filling the cannula, check Daily History and re-evaluate your need for insulin. • If this alarm recurs frequently, write down the error code displayed on the alarm screen (you can also find it in your Alarm History) and contact your local representative for assistance with your pump.
Replace battery Battery life less than 30 minutes. To ensure insulin delivery, replace battery now.	Battery life is low and will be exhausted within 30 minutes.	• Select OK to clear the alert. • Replace the AA battery.

Title and text	Explanation	Next steps
Replace battery now Delivery stopped. Battery must be replaced to resume delivery.	Insulin delivery has stopped due to low power. Battery was not replaced after the Low battery Pump alert.	Replace the battery immediately to resume insulin delivery. For details, see <i>Removing the battery</i> , on page 23.
Reservoir estimate at 0 U To ensure insulin delivery, change reservoir.	Your reservoir level is estimated at 0 units.	• Select OK to clear the alert. • Change the reservoir now.
Resume bolus? XXX of YYY U delivered. Resume delivery of ZZZ U?	A normal bolus delivery has been interrupted because the pump battery was removed. If it is within 10 minutes since this interruption, you can resume this bolus.	• Check the message to see how much of the bolus was actually delivered. • To cancel remaining amount of bolus, select Cancel. • To resume remaining amount of bolus, select Resume.
Resume Dual bolus? XX of YY U delivered. Resume delivery of ZZ U for XX:XX hr?	The Square portion of Dual Bolus delivery has been interrupted. If it is within 10 minutes since this interruption, you can resume this bolus.	• Check the message to see how much of the Dual Wave bolus was actually delivered. • To cancel remaining amount of bolus, select Cancel. • To resume remaining amount of bolus, select Resume.

Title and text	Explanation	Next steps
Resume Dual bolus? XX of YY U delivered. Resume delivery of ZZ U now, and AA U Square for XX:XX hr?	The Now portion of a Dual Wave bolus delivery has been interrupted because the pump battery was removed. If it is within 10 minutes since this interruption, you can resume this bolus.	• Check the message to see how much of the Dual Wave bolus was actually delivered. • To cancel remaining amount of bolus, select Cancel. • To resume remaining amount of bolus, select Resume.
Resume Square bolus? XX of YY U delivered for XX:XX hr. Resume delivery of ZZ U for XX:XX hr?	The Square Wave bolus delivery was interrupted. If it is within 10 minutes since this interruption, you can resume this bolus.	• Check the message to see how much of the Square Wave bolus was actually delivered. • To cancel remaining amount of bolus, select Cancel. • To resume remaining amount of bolus, select Resume.
Stuck button Button pressed for more than 3 minutes	The pump has detected that a button has been pressed for an unusually long time.	• Select OK to clear the alarm. • If this alarm occurs again, contact your local representative for assistance with your pump. If you are unable to clear the alarm: • Consider another form of insulin, because your pump is not delivering insulin. • Check your BG and treat as necessary. • Contact your local representative for assistance with your pump.

Title and text	Explanation	Next steps
Wrong key pressed Try again	Wrong button selected while unlocking the pump.	• Select OK to clear the alert. • Try to unlock the pump. Select the highlighted key when prompted. For more information, see <i>Unlocking your pump, on page 26.</i>

CGM (sensor) alarms, alerts, and messages

The following table lists the most common or serious alarms, alerts, and messages related to your sensor glucose readings, as well as the status of your transmitter and sensor. The table also explains the meaning, consequences, and the reasons why these notifications appear, and provides steps for problem resolution.

Title and text	Explanation	Next steps
Alert before high Sensor glucose approaching High Limit. Check BG.	Your SG value is approaching your specified high limit.	• Select OK to clear the alert. • Check your BG. • Follow instructions from your healthcare professional and continue to monitor your BG.
Alert before low Sensor glucose approaching Low Limit. Check BG.	Your SG value is approaching your specified low limit.	• Select OK to clear the alert. • Check your BG. • Follow instructions from your healthcare professional and continue to monitor your BG.
Alert on high XXX mg/dL High sensor glucose. Check BG.	Your SG value is at or above your specified high limit.	• Select OK to clear the alert. • Check your BG. • Follow instructions from your healthcare professional and continue to monitor your BG.

Title and text	Explanation	Next steps
Alert on low XXX mg/dL Low sensor glucose. Check BG.	Your SG value is at or below your specified low limit.	• Select OK to clear the alert. • Check your BG. • Follow instructions from your healthcare professional and continue to monitor your BG.
Alert on low XXX mg/dL Low sensor glucose. Insulin delivery suspended since XX:XX. Check BG.	Your SG value is at or below your specified low limit, and the pump has suspended insulin delivery due to a Suspend on low or Suspend before low event.	• Select OK to clear the alert. • Check your BG. • Follow instructions from your healthcare professional and continue to monitor your BG.
Basal delivery resumed Basal delivery resumed at XX:XX after suspend by sensor. Check BG.	Your pump is resuming basal insulin delivery after a Suspend on low or Suspend before low event occurred.	• Select OK to clear the alert. • Check your BG. • Follow instructions from your healthcare professional and continue to monitor your BG.
Basal delivery resumed Low settings change caused basal to be resumed at XX:XX. Check BG.	Your pump is resuming basal insulin delivery after a Suspend before low or a Suspend on low event occurred, because you have turned off the Suspend before low or the Suspend on low feature.	• Select OK to clear the alert. • Check your BG. • Follow instructions from your healthcare professional and continue to monitor your BG.

Title and text	Explanation	Next steps
Basal delivery resumed Maximum 2 hour suspend time reached. Check BG.	Your pump is resuming basal insulin delivery two hours after a Suspend before low or Suspend on low event occurred.	• Select OK to clear the alert. • Check your BG. • Follow instructions from your healthcare professional and continue to monitor your BG.
Basal delivery resumed Maximum 2 hour suspend time reached. SG is still under Low limit. Check BG.	Your pump is resuming basal insulin delivery two hours after a Suspend before low or Suspend on low event occurred.	• Your pump has resumed basal insulin delivery; however, your SG value is still at or below your low limit. • Select OK to clear the alert. • Check your BG. • Follow instructions from your healthcare professional and continue to monitor your BG.
BG not received Place pump close to transmitter. Select OK to resend BG to transmitter.	The transmitter was unable to receive the calibration BG meter readings from the pump.	• Move your pump and transmitter closer together. • Select OK. Your pump tries again to send your BG to your transmitter for sensor calibration.

Title and text	Explanation	Next steps
Calibrate now Check BG and calibrate sensor.	A BG meter reading is needed immediately to calibrate your sensor so that you can continue receiving sensor glucose readings.	• Take a BG meter reading and enter for calibration. After you receive a Calibrate now alert, it takes up to 15 minutes after you calibrate for your pump to receive SG values. For details, see <i>Calibrating your sensor</i>, on page 183. • If you are unable to calibrate now, you can use the Snooze feature. Set the desired time, and select Snooze. If you do not calibrate before the Snooze time is up, the Calibrate Now alert occurs again.
Calibration not accepted Recheck BG and calibrate sensor.	Your system was unable to use the BG meter readings you entered to calibrate your sensor.	• Wash and dry hands thoroughly. See <i>Guidelines for calibrating</i>, on page 186. • Enter a new BG meter reading for calibration as instructed in <i>Calibrating your sensor</i>, on page 183. If you receive a Calibration not accepted alert on your second calibration, a Change sensor alert occurs. • Call your local representative if you have questions.

Title and text	Explanation	Next steps
Cannot find sensor signal Disconnect and reconnect transmitter, then select OK. Notice if transmitter light blinks.	The pump has not received a signal from the transmitter.	• Disconnect and reconnect your transmitter and sensor. • See if the light on your transmitter blinks when connected to the sensor. You may need this information for troubleshooting later. • Select OK. Your pump searches for your sensor. If your pump receives a signal from your sensor, you do not need to do anything else. If your pump does not receive a signal from the sensor, another message appears to let you know.
Change sensor Insert new sensor and Start New Sensor.	You selected No in the Check sensor insertion message, indicating that your sensor is not fully inserted.	• Select OK to clear the alert. • Change your sensor. For details, see your sensor user guide. • After you change your sensor, refer to <i>Starting the sensor, on page 182</i>.
Change sensor Second calibration not accepted. Insert new sensor.	This alert occurs when you receive two Calibration not accepted errors in a row.	• Select OK to clear the alert. • Change your sensor. For details, see your sensor user guide.
Change sensor Sensor not working properly. Insert new sensor.	Sensor signal is no longer reliable.	• Select OK to clear the alert. • Change your sensor. For details, see your sensor user guide.

Title and text	Explanation	Next steps
Check connection Ensure transmitter and sensor connection is secure, then select OK.	The pump fails to detect the transmitter and is unable to receive sensor signal.	• Select OK to clear the alert. • If your sensor is fully inserted, select Yes. If your sensor is not fully inserted, select No. • If your sensor was not fully inserted, insert a new sensor. • If you still cannot connect your sensor, see <i>My pump cannot find the sensor signal</i>, on page 234.
Lost sensor signal Move Pump closer to transmitter. May take 15 minutes to find signal.	Transmitter signal has not been received for 30 minutes during or after initialization.	• Move your pump closer to your transmitter. It can take up to 15 minutes for your pump to start communicating with your transmitter. • Select OK to clear the alert.
Low battery transmitter Recharge transmitter within 24 hours.	The battery in the transmitter needs to be recharged within 24 hours.	• Select OK to clear the alert. • Recharge your transmitter as soon as possible.
Medical device CALL FOR EMERGENCY ASSISTANCE. I have diabetes.	Your pump is suspended due to low SG, and you have not responded to the alarm within 10 minutes.	• Select Dismiss. • Immediately call for emergency assistance.

Title and text	Explanation	Next steps
No calibration occurred Confirm sensor signal. Calibrate by XX:XX.	The transmitter was unable to receive the calibration BG meter readings from the pump.	• Select OK to clear the alert. • Check the status bar on your pump to ensure that your pump has a signal from your sensor. If there is no sensor signal, see <i>My pump cannot find the sensor signal, on page 234</i>. • Calibrate again by the time shown on the pump screen to ensure you continue SG monitoring.
No calibration occurred Confirm sensor signal. Check BG again to calibrate sensor.	The transmitter was unable to receive the required calibration BG from the pump. Calibration is required by the system for SG values to resume. "Calibration required" appears on your sensor graph.	• Select OK to clear the alert. • Take another BG meter reading and calibrate again.
Possible signal interference Move away from electronic devices. May take 15 minutes to find signal.	There may be interference from another electronic device that is affecting the communication between your pump and transmitter.	• Move away from other electronic devices. It can take up to 15 minutes for your pump to start communicating with your transmitter. • Select OK to clear the alert.

Title and text	Explanation	Next steps
Rise Alert Sensor glucose rising rapidly.	Your SG value has been rising as fast or faster than your preset Rise Alert Limit.	• Select OK to clear the alert. • Monitor trend and glucose level. • Follow instructions from your healthcare professional.
Sensor alert occurred Check Alarm History for silenced alerts.	Sensor alert occurred when Alert Silence is on.	• Select OK to clear the alert. • Check the Alarm History screen to see which alerts were silenced. For more information about accessing the Alarm History screen, see <i>Alarm History</i>, on page 122. • Select the alert to open the Alarm Detail screen. • Take action based on the selected alert.
Sensor connected If new sensor, select Start New. If not, select Reconnect.	The transmitter has detected that you have connected a sensor. The pump needs to know if this is a new sensor or if you have reconnected your old sensor.	• If you have connected a new sensor, select Start New Sensor. • If you have reconnected a sensor you have been using, select Reconnect Sensor. • In either case, a "warm-up" messages appears on your Home screen, and you are prompted to calibrate your sensor. Your pump starts receiving your SG values again after the two-hour initialization is complete.
Sensor expired Insert new sensor.	The sensor has been used for 6 days (144 hours). It has reached the end of its useful life.	Change your sensor. For details, see your sensor user guide.

Title and text	Explanation	Next steps
Sensor signal not found Did transmitter light blink when connected to sensor?	The pump has still not received a signal from the transmitter.	When you reconnected the transmitter to the sensor, did you see a blinking green light on the transmitter? • Select Yes or No and follow the instructions on the screen.
Sensor signal not found See User Guide.	After multiple attempts, the pump failed to detect the transmitter and is unable to receive sensor signal.	• Select OK to clear the alert. • Repeat the connection process. Remove the transmitter from the sensor for about ten seconds, and then reconnect it to the sensor. • It can take up to 15 minutes for your pump to find the sensor signal. • Move your pump closer to your transmitter to improve reception. • Make sure you are away from any electronic devices that might cause interference, such as cellular phones and other wireless devices. • If your pump still cannot find the sensor signal, call your local representative for assistance.
SG value not available If problem continues, see User Guide.	The sensor signals are either too high or too low.	• Select OK to clear the alert. • You do not need to change the sensor. If the alert persists, test your transmitter with the tester. Refer to your transmitter user guide for instructions on testing the transmitter.

Title and text	Explanation	Next steps
Suspend before low Delivery stopped. Sensor glucose approaching Low Limit. Check BG.	Your SG value is falling. Insulin delivery is suspended according to your Suspend before low setting and your SG is approaching your specified low limit.	• Select OK to clear the alert. • Check your BG. If necessary, treat your BG as directed by your healthcare professional.
Suspend on low Delivery stopped. Sensor glucose XXX mg/dL. Check BG.	Your SG value is at or below the low limit you specified.	• Select OK to clear the alert. • Check your BG. If necessary, treat your BG as directed by your healthcare professional.
Transmitter battery depleted Recharge transmitter now.	The battery in the transmitter needs to be recharged. SG values are not recorded or transmitted until you recharge transmitter.	• Select OK to clear the alert. • Recharge your transmitter.

CareLink alert and message

The following table lists the most common or serious alarms, alerts, and messages related to CareLink. The table also explains the meaning, consequences, and the reasons why these notifications appear, and provides steps for problem resolution.

Title and text	Explanation	Next steps
Connect Device? Device with SN <XXXXXXXXXX> is trying to connect to your pump. Allow connection?	The CareLink USB software is attempting to connect to your pump in preparation for data download.	• Select Yes to allow connection, only if you are expecting or performing a data download. • Select No to deny connection. If no selection is made, the screen will timeout after 30 seconds and will automatically reject the request.
Download slow Insulin delivery not affected. CareLink download may take longer than usual. Select OK to continue. See User Guide.	The download of pump data is taking longer than expected. Data will not be affected.	• Select OK to clear the alert. • Wait for the data to finish downloading. • If problem still persists or if there is no progress in download, call your local representative for assistance.

RELEASED

13

troubleshooting

RELEASED

RELEASED

Troubleshooting

This chapter contains procedures and information to help you understand and address conditions that might occur with your pump.

For a list of alarms, alerts, and messages that may appear on your pump, see *Pump alarms, alerts, and messages, on page 202*.

Troubleshooting pump issues



WARNING: If you receive a critical error on your pump, the following screen displays and the pump sirens.



Immediately disconnect from your insulin pump and discontinue use. Contact your local representative for assistance.

Remember, your body still needs insulin while your pump is removed. It is important that you consult your healthcare professional to determine an alternate method of receiving insulin while your pump is removed.

What is a Check Settings alarm?

This alarm occurs when a condition causes your pump to reset to factory settings. You see this alarm after your pump guides you through re-entering the Startup Wizard settings.

The Check Settings alarm is letting you know that other settings may have been cleared or reverted to factory default values. Review any settings that you have not already set in Startup Wizard and re-enter the values, if necessary.

My pump is asking me to rewind



WARNING: 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, which may cause low BG.

You always rewind your pump when changing the reservoir. Rewinding returns the piston in the reservoir compartment to its starting position. It is normal for your pump to ask you to rewind anytime you must remove and replace the reservoir, such as when resolving an Insulin Flow Blocked alarm or addressing a problem loading the reservoir.

I dropped my pump



Caution: 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.

Do the following:

1. Check that all connections are still tightly in place.
2. Check the display, button area, and pump case for cracks or damage.
3. Check the infusion set, including the tubing connector and tubing for cracks or damage.
4. Review the status screen, basal rates and other pump settings.
5. Perform the Self Test procedure by going to:

Menu > Utilities > Self Test

For details, see *Self Test*, on page 145.

- 6. If the Self Test does not complete successfully, or if you are concerned about your pump, call your local representative for assistance and check your BG.

I cannot get to the Manage Settings screen

If you go to Menu > Utilities > Manage Settings, a message appears telling you that the feature is not normally accessible and to consult your user guide. To access the Manage Settings screen:

- 1. **Menu > Utilities > Manage Settings**
- 2. Simultaneously press and hold > and ⬅ for about two seconds. The Manage Settings screen appears. For more information, see *Managing your pump settings*, on page 142.

My pump display times out too quickly

Your pump display times out after 15 seconds by default in order to conserve battery power. You can increase this setting up to three minutes. Go to **Menu > Utilities > Display Options**, and then adjust the Backlight setting as desired. For more information, see *Display Options*, on page 141.



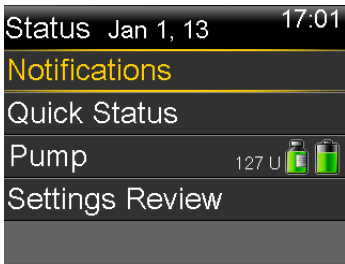
Note: Be aware that using a longer Backlight time causes your pump to use more battery power. When your pump battery is low, the timeout for the backlight on your pump screen is automatically reduced.

Where is my pump status screen?

- 1. To go to the Status screen, highlight and select the status bar at the top of your Home 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 31*.

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 guides you through entering the following information. Be sure to have these values ready when you begin.

- Time format, time, and date
- Carb unit
- Active Insulin Time

- Basal patterns

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

- Carb ratio or Exchange ratio
- Insulin sensitivity factor
- BG target

To enter your pump settings:

1. Begin entering your settings by selecting your language. Click **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 Select Carb Unit screen appears, select **Grams** or **Exchanges** as the unit your pump uses to display carbohydrate information.
6. When the Active Insulin Time screen appears, enter the **Duration**.
For details, see *About active insulin, on page 71*.
7. Enter your first basal rate by entering the End time and the Rate. You can enter more basal patterns after you complete the startup wizard.
For details, see *Adding a new basal pattern, on page 42*.
After you complete your basal pattern, a screen appears to allow you to review your basal information.
8. When the message appears asking if you want to setup the Bolus Wizard settings, do one of the following:
 - Select **Yes** to continue entering your settings, then continue to the next section.
 - Select **No** if you do not want to enter your Bolus Wizard settings. A message appears letting you know that your settings are complete. Select **OK** to continue using your pump.

To enter your Bolus Wizard settings:

1. When your pump shows a list of settings for the Bolus Wizard, make sure you have the values you need before continuing.
2. Depending on the Carb Unit you set earlier, either the Carb Ratio or the Exch Ratio screen appears. Enter your carb ratio or exchange ratio by entering the End time and the Rate. You can adjust your carb or exchange ratio at any time.

For details, see *Changing your carb or exchange ratio, on page 69*.

3. When the Edit 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 70*.

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

For details, see *Changing your Bolus Wizard BG target, on page 70*.

A message appears confirming that your setup is complete.

5. Select **Next** to display the Home screen, and continue using your pump.

Troubleshooting sensor issues

My pump cannot find the sensor signal

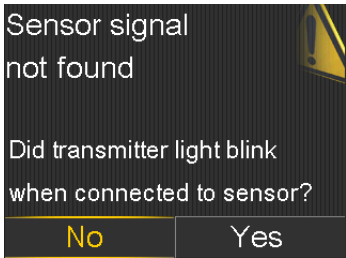
If your pump cannot find the sensor signal after you connect your sensor and transmitter, follow the instructions on the pump screen to troubleshoot the issue as described below.

If your pump finds the sensor signal at any time during troubleshooting, your pump beeps or vibrates, and "Warm up" appears on your sensor graph. It can take up to two hours for your sensor to warm up.



Note: If you are using Alert Silence and currently have all sensor alerts silenced, your pump does not display the troubleshooting screens. Any glucose alerts you received are displayed in the Alarm History screen.

1. Make sure your setup meets the following requirements:
 - Your transmitter is fully charged.
If both lights on the charger are off, your transmitter is fully charged. For details, see your transmitter user guide.
 - You have only one transmitter connected to your pump.
Delete the current transmitter that is connected to your pump before continuing. For details, see *Deleting the transmitter from your pump, on page 181*.
 - Your transmitter is placed next to your pump.
 - Your transmitter is reconnected to the pump, if your pump has been recently reset. For details, see *Wirelessly connecting your pump and transmitter using Auto Connect, on page 175*.
 - The Airplane Mode is turned off on your pump.
 - You have applied the tape correctly, as instructed in the sensor user guide.
2. Disconnect the transmitter from the sensor for at least 10 seconds.
3. While the light on the transmitter is blinking, reconnect the transmitter with the sensor to restart communication and select **OK** on the pump to acknowledge the alert.
4. Depending on whether the light blinked when you connected the transmitter to the sensor, select **Yes** or **No** on your pump and do one of the following:



- If the transmitter light did not blink, you need to charge your transmitter. When your transmitter is charged, start your sensor. For details, see *Starting the sensor, on page 182*.
 - If your transmitter light blinked, but you still have no sensor signal, continue to the next step.
5. 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.
 6. If your pump still cannot find the sensor signal, make sure you are away from any electronic devices that might cause interference, such as cellular phones and other wireless devices, and select **OK**.
 7. If you have gone through all the troubleshooting steps on your pump screen, and your pump still cannot find the sensor signal, or if your sensor graph displays "Sensor signal not found. See User Guide," call your local representative 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 183*.

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

The SmartGuard suspend by sensor icon appears gray  on the Home screen when either the Suspend on low or Suspend before low feature is unavailable. The 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 159* or *When Suspend on low is unavailable, on page 162*.

- No SG values are available.

SG values may be unavailable because:

- Your pump is in Airplane Mode.

For more information, see *Airplane Mode, on page 137*.

- Sensor calibration is required.

For details on when and how to calibrate your sensor, see *Calibrating your sensor, on page 183*.

- 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 234*.

- The sensor glucose 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 your local representative for assistance.

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14

■ maintenance

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Maintenance

Read your warranty statement included with your pump for information about what is covered during your warranty period.

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 cleaning your pump, be sure to keep the reservoir compartment dry and away from moisture.

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 for disinfection.
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 allows you to 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 recharge the internal power source.



WARNING: Active insulin is now cleared. Any active insulin tracked prior to the pump entering storage mode is not included in any new Bolus Wizard calculations.

Placing your pump in storage mode:

1. Remove the AA battery from the pump. For details, see *Removing the battery*, on page 23.



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: Store your pump at room temperature. While in storage, the pump should never be exposed to temperatures above 35°C (95°F).

Waking your pump from storage mode

1. Insert a new AA battery into your pump. For details, see *Inserting the battery*, on page 22.

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 143*.

Storing your transmitter

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

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15

product specifications and safety information

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Product specifications and safety information

This chapter provides detailed product specifications and safety information.

Product specifications

This section provides detailed information on product specifications.

Alarm and alert escalation

The following alerts may escalate to a siren:

- Alert before high
- Alert before low
- Alert on high
- Alert on low
- Basal delivery resumed
- BG not received
- Calibration not accepted
- Calibrate now
- Cannot find sensor signal
- Change sensor
- Check connection
- Lost sensor signal
- No calibration occurred
- Possible signal interference
- Rise Alert
- Sensor expired
- Sensor signal not found
- SG value not available
- Suspend before low (only if Alert before low is on)
- Transmitter battery depleted

Minutes from alarm or alert	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.

Altitude range

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

Audio frequency

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

Tone name	Frequency tolerance (+/- 1%)
Alarm	1655 Hz followed by 3310 Hz
Alternate Alarm	1850 Hz
Siren (escalated alarm)	1655 Hz, followed by 3310 Hz
Alert	934 Hz

Tone name	Frequency tolerance (+/- 1%)
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 BG targets and Low BG targets	None

BG meter value

The most recent BG value received from the meter. If you are using a compatible Bayer 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 (or exchange) ratio	None	1–200 g/u (0.075–15.0 u/exch)	0.1 g/u for 1–9.9 g/u; 1 g/u for ratios of 10 g/u to 200 g/u (0.001 u/exch for 0.075–0.099 u/exch; 0.01 u/exch for 0.10–9.99 u/exch; 0.1 u/exch for 10–15 u/exch)
Insulin Sensitivity Factor	None	5–400 mg/dL	1 mg/dL
BG Target	None	60–250 mg/dL	1 mg/dL
Active Insulin Time	6 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)

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

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 between or equal to your High or Low BG Target, the total bolus estimate is based only on the food estimate.

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

Food estimate:

Carb grams ÷ Carb ratio = Units of insulin



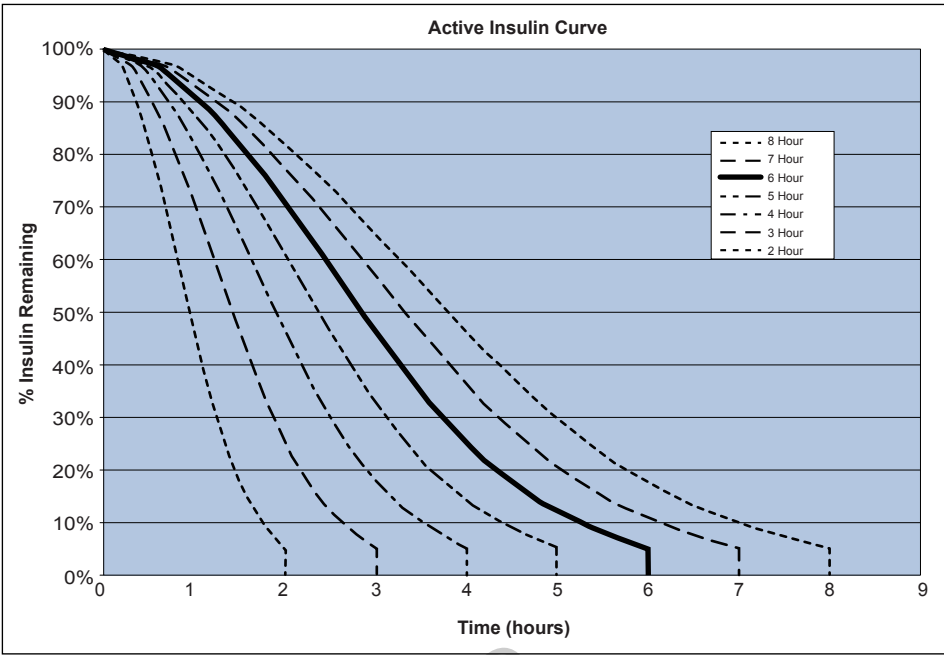
Note: When the current BG is below the Low BG Target, an active insulin amount is not considered in the Bolus Wizard feature calculations.

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:

- 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. Ins. 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.
- Active Insulin Curve



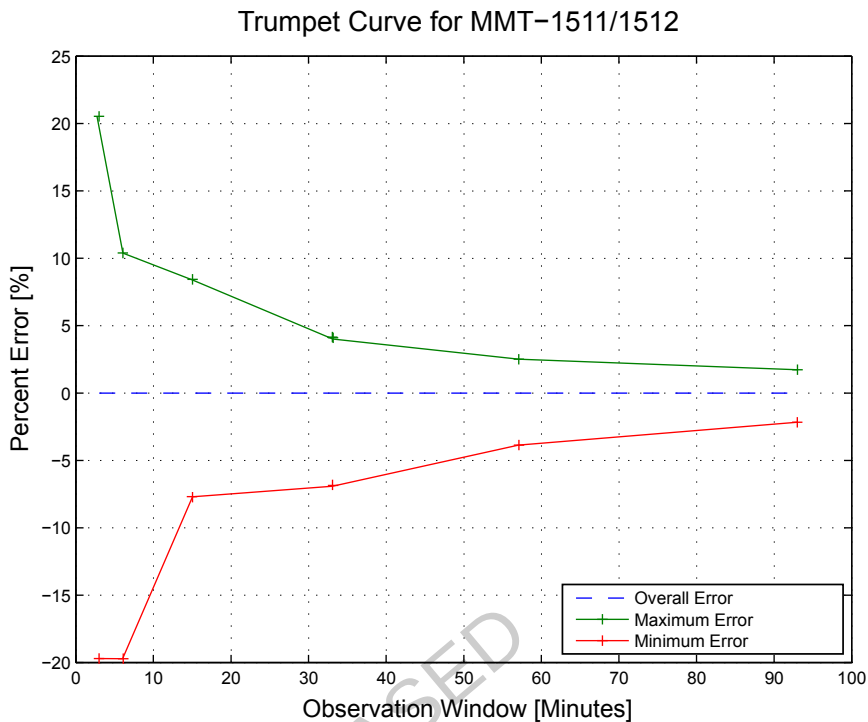
Graph adapted from Mudaliar and colleagues, Diabetes Care, Volume 22, Number 9, Sept. 1999, page 1501.

Carb ratios

Maximum ratio settings	Range
	1 to 200 grams/unit
8	0.075 to 15 units/exch

Delivery accuracy

- Delivery accuracy: $\pm 5\%$.
- All Normal boluses are delivered within 50 minutes ± 3 seconds at Standard rate (75 units, at 1.5 units per minute), and within 5 minutes ± 3 seconds at Quick rate (75 units, at 15 units per minute).
- The maximum infusion pressure generated and the occlusion threshold pressure is 86.12 kPa (12.49 psi). The bolus volume generated is 0.01225 mL.
- The following is a representative delivery accuracy curve.



Easy Bolus

Allows user to set up and deliver a Normal Bolus when the pump is in Sleep Mode. This is done using the ^ 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

- Pump operating temperature range is from 5°C (41°F) to 40°C (104°F).
- Air pressure range is from 10.2 psi to 15.4 psi (700 hPa to 1060 hPa).

- Operating humidity range of the case: 20% to 90%.
This requirement exceeds IEC 60601-1, subclause 7.9.3.1 (30% to 75%).

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, and thereafter at every 10 units.
- Insulin used to fill the infusion set is recorded in the Daily History.

Infusion pressure

The maximum infusion pressure and occlusion pressure is 86.12 kPa (12.49 psi).

Insulin delivery default settings

Bolus settings

Item	Default setting	Limits	Increments
Bolus Wizard feature:	Off	-	-
Easy bolus:	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 75 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.
Range	5 to 400 mg/dL/unit

Low Reservoir reminder

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

Alert type	Alert range	Increment	Default value
Time	First reminder occurs at 2 to 24 hours. Second reminder occurs one hour before empty. The second reminder is automatic and cannot be changed by the user.	30 min	8 hours
Units	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 75 units
Default	10 units

Normal bolus

Range is 0.025 to 75 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 pump is intended for use with U100 insulin. This table shows occlusion detection for four different situations when using U100 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



Percent temp basal

The default value is 100 percent of basal programming.

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 MMT-1512 pump dimensions in inches are approximately 2.1 width x 3.34 length x 0.96 depth.

The MMT-1512 pump dimensions in centimeters are approximately 5.3 width x 8.5 length x 2.44 depth.

The MMT-1712 pump dimensions in inches are approximately 2.1 width x 3.78 length x 0.96 depth.

The MMT-1712 pump dimensions in centimeters are approximately 5.3 width x 9.6 length 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. This means that at any time the user can review a maximum of 90 days of history.

Pump weight

The mass of the MiniMed 640G insulin pump (MMT-1512) is approximately 91.9 grams.

The mass of the MiniMed 640G insulin pump (MMT-1712) is approximately 95.7 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	-	-
Alert on high	Off	-	-
Time before high	15 minutes	5 to 30 minutes	5 minutes
Rise Alert	Off	-	-
Rise Limit	Two up arrows	• 1up 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

Low sensor settings			
Item	Default setting	Limits	Increments
Resume basal alert	Off	-	-

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Guidance and manufacturer's declaration

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The MiniMed 640G insulin pump is intended for use in the electromagnetic environment specified below. The customer or the user of the MiniMed 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(a)(2)/RSS-210 FHSS– DAOO-705, DTS-KDB 558074, ANSI C63.4, RSS-Gen, FCC Part 15 Section 15.109, Class B/ANSI c63.4 (2009)	• 6 dB and 99% Bandwidths: Pass • Maximum Output Power: Pass • TX Spurious Emissions: Pass • Power Spectral Density: Pass	The MiniMed insulin pump must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions EN55011 (2009)+A1	Class B	The MiniMed insulin pump is suitable for use 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	
ARIB STD-T66	Complies	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The MiniMed 640G insulin pump is intended for use in the electromagnetic environment specified below. The customer or the user of the MiniMed 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	±8 kV contact ±15 kV air	±30 kV air (<5% relative humidity)	For use in a typical domestic, commercial, or hospital environment.
Electrical fast transient/ burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	Not applicable	Requirement does not apply to this battery powered device.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Not applicable	Requirement does not apply to this battery powered device.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle	Not applicable	Requirement does not apply to this battery powered device.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	400 A/m (continuous field at 60 seconds) 4000 A/m (short duration at 3 seconds)	400 A/m 4000 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical 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 640G insulin pump is intended for use in the electromagnetic environment specified below. The customer or user of the MiniMed insulin pump should assure that it is used in such an electromagnetic environment.			
Immunity Test	IEC 60601 Level	Compliance Level	Electromagnetic Environment Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the MiniMed insulin pump, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

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Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The MiniMed 640G insulin pump is intended for use in the electromagnetic environment specified below. The customer or user of the MiniMed insulin pump should assure that it is used in such an electromagnetic environment.			
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 800 MHz	10 V/m 80 MHz to 800 MHz	Recommended separation distance $d = [12/E_{ref}]\sqrt{P}$ 80 MHz to 800 MHz
	10 V/m 800 MHz to 2.5 GHz	10 V/m 800 MHz to 6 GHz	$d = [23/E_{ref}]\sqrt{P}$ 800 MHz to 6 GHz Where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a , should be less than the compliance level in each frequency range ^b . Interference may occur in the vicinity of equipment marked with the following symbol: 
Note: At 80 MHz and 800 MHz, the higher frequency range applies. Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption, and reflection from structures, objects and people. Note: The table is per IEC (EN) 60601-1-2 Edition 3.			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity
The MiniMed 640G insulin pump is intended for use in the electromagnetic environment specified below. The customer or user of the MiniMed insulin pump should assure that it is used in such an electromagnetic environment.
^aField strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcasts and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the MiniMed insulin pump is used exceeds the applicable RF compliance level above, the insulin pump should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the MiniMed insulin pump. ^bOver the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

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Recommended separation distances between the MiniMed 640G insulin pump and common household radio transmitters			
Household RF Transmitter	Frequency	Recommended Separation Distance (meter)	Recommended Separation Distance (inch)
Telephones			
Cordless Household	2.4 GHz	0.3	12
Cordless Household	5.8 GHz	0.3	12
TDMA-50 Hz (cell phone)	1.9 GHz	0.3	12
TDMA-50 Hz (cell phone)	800 MHz	0.3	12
PCS (cell phone)	1.9 MHz	0.3	12
DCS (cell phone)	1.8 MHz	0.3	12
GSM (cell phone)	900 MHz	0.3	12
GSM (cell phone)	850 MHz	0.3	12
CDMA (cell phone)	800 MHz	0.3	12
Analog (cell phone)	824 MHz	0.3	12
CDMA (cell phone)	1.9 MHz	0.3	12
WiFi Networks			
802.11b	2.4 GHz	1	39.5
802.11g	2.4 GHz	1	39.5
802.11n	2.4 GHz	1	39.5
Bluetooth 500 kb/s	2.4 GHz	0.1	3.93
ZigBee 250 kb/s	2.4 GHz	0.1	3.93

Recommended separation distances between portable and mobile RF communications equipment and the MiniMed 640G insulin pump		
The insulin pump is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the MiniMed insulin pump can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MiniMed insulin pump as recommended below, according to the maximum output power of the communications equipment.		
Rated maximum output power of transmitter (W)	Separation distance according to the frequency of transmitter (m)	
	80 MHz to 800 MHz $d=1.2\sqrt{P}$	800 MHz to 6 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.23
0.1	0.38	0.73
1	1.2	2.3
10	3.8	7.3
100	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.		
Note: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.		
Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		

Wireless communication

Quality of service

The CGM transmitter and MiniMed insulin pump are associated as part of an 802.15.4 network for which the pump functions as the coordinator and the CGM transmitter as an end node. In an adverse RF environment the MMT-1512/1712 pump will assess channel changing needs based on "noise" levels detected during

an energy scan. The pump will perform the energy scan if after 10 minutes no CGM transmitter signal has been received. If the channel change occurs the pump will send beacons on the new channel.

The CGM transmitter will initiate a channel search when beacon detection fails on the associated channel. The search will be conducted across all five channels. When the beacon is located the transmitter will rejoin on the identified channel. Upon re-association any missed packets (up to 10 hours) will be transmitted from the CGM transmitter to the pump.

In normal operation the CGM transmitter will transmit a packet every 5 minutes and retransmit the packet if the data is corrupted or missed.

Radio frequency (RF) communications specifications

Utilizes the IEEE 802.15.4 protocol with the proprietary data format.

Pump frequency	2.4 GHz; proprietary Medtronic protocol; range up to 1.8 meters (6 feet).
Maximum output power (EIRP)	-1.59 dBm
Operating frequencies	2420 MHz, 2435 MHz, 2450 MHz, 2465 MHz, 2480 MHz
Bandwidth	5 MHz which is allocated channel bandwidth per the IEEE protocol

Data security

The MiniMed 640G insulin pump is designed to only accept radio frequency (RF) communications from recognized and linked devices (you must program your pump to accept information from a specific device).

The MiniMed 640G system ensures data security via proprietary means and ensures data integrity using error checking processes, such as cyclic redundancy checks.

Icon table

Follow instructions for use	
Manufacturer	
Date of manufacture (year - month)	
Use by (year - month)	
Catalogue number	
Device serial number	
Storage temperature range	
Storage humidity range	
Magnetic Resonance (MR) unsafe	
Type BF equipment (protection from electrical shock)	
Radio communication	
Pump: Protected against the effects of continuous immersion in water (12 feet or 3.6 meters for 24 hours).	IPX8
Signifies compliance with Australian EMC, EME and Radio communications requirements	
Signifies compliance with Industry Canada EMC and Radio communications requirements	IC
This symbol means that the device fully complies with MDD 93/42/EEC (NB 0459) and R&TTE Directive 1999/5/EC.	

appendix a: end user software license agreement

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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.

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Glossary

active insulin	Bolus insulin that has been delivered by the pump and is still working to lower your blood glucose 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.
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.
Airplane Mode	A feature that temporarily stops your device from communicating wirelessly.
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 sensor glucose 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 sensor glucose value reaches or falls below your low limit.
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 <i>blood glucose</i> .
BG Targets	The high and low values to which your blood glucose is corrected when using the Bolus Wizard.
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)	Refers to glucose (sugar) that is present in the blood, commonly measured by a blood glucose meter.
blood glucose meter	A device that measures glucose levels in the blood.
Bolus BG Check reminder	A reminder that you set just after you program a bolus. The reminder notifies you to check your blood glucose when the time period that you specified has passed.
bolus insulin	Insulin used to cover an expected rise in glucose levels from carbohydrates, or to lower a high blood glucose 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	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 blood glucose reading to calculate sensor glucose values.
Calibration reminder	A reminder you can set to let you know 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.
carb unit	The unit of measure for carbohydrates, either grams (g) or exchanges (exch).
CGM	Abbreviation for continuous glucose monitoring. See <i>continuous glucose monitoring</i> .
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 blood glucose value down to your target range.
Daily History	A feature that displays the actions that you performed using your device.
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™	A feature that lets you deliver a Normal Bolus in preset increments using only audio or vibrate confirmation.
Event Marker	A feature that allows you to record events, such as blood glucose readings, injections, carbohydrates, and exercise.

exchange ratio	The number of insulin units that are needed to cover 1 carbohydrate exchange. The exchange ratio is based on your individual needs and is used to calculate bolus amounts.
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 sensor glucose 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 blood glucose 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 sensor glucose 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 of a low sensor glucose condition, and also used for determining if insulin delivery should be suspended.
Manual Bolus	A feature that allows you to enter and deliver a dose of insulin in the amount that you have determined is necessary.
Max Basal Rate	A feature that allows you to set the maximum amount of basal insulin that can be delivered per hour.
Max Bolus	A feature that allows you to set the maximum bolus amount that can be delivered in one dose.
meter	A term for any blood glucose 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 by changing the Backlight setting.
Preset Bolus	A feature that allows you to set up and save a bolus for specific meals or snacks that you frequently eat or drink.
Preset Temp Basal	A feature that allows you to set up and save temporary basal rates for repeated use.
Rate alert	An alert that notifies you if your sensor glucose value has been rising or falling faster than the Rise Limit or Fall Limit that you have set.
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 sensor glucose values have met the necessary criteria. This alert will always occur if basal insulin delivery has resumed because the two hour maximum suspend time has elapsed.

Rewind	A feature used when changing a reservoir. It returns the piston to its starting position and allows a new reservoir to be placed into the pump.
sensitivity	See <i>insulin sensitivity factor</i> .
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)	Refers to glucose (sugar) 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 <i>sensor glucose</i> .
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™	A feature that can automatically stop and resume insulin delivery based on your sensor glucose values and low limit.
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 sensor glucose 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 sensor glucose value reaches or falls below your low limit.
Temp Basal Rate (temporary basal rate)	A feature that allows you to 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 filling the reservoir 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.

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index

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Index

A

- accessories 15
- active insulin
 - about 71
 - adjustment 71
 - clearing settings 144
 - Home screen 26
 - injection warning 71
 - viewing amount 27
- Active Insulin cleared alert 202
- Active Insulin Time
 - about 66
 - changing 71
- Airplane Mode
 - setting up 138
 - status bar 29
 - using 137
- Alarm History 122
- alarms
 - about 199
 - audio options 201
 - Auto Suspend 203
 - Battery failed 203
 - Battery not compatible 203
 - Bolus not delivered 203
 - Bolus stopped 203
 - CGM 216
 - Critical pump error 204
 - Delivery limit exceeded 205
 - emergency siren 201
 - Fill Cannula? 205
 - Insert battery 205
 - Insulin flow blocked 206, 207, 208, 209
 - Loading incomplete 209
 - Manage Settings error 210
 - Max Fill reached 210, 211
 - No reservoir detected 211
 - notification light 200
 - overview 200
 - pump 202, 225
 - Pump error 212, 213
 - Pump restarted 213
 - red icon 200
 - Replace battery 213
 - Replace battery now 214
 - sensor 216
 - siren 201
 - Stuck button 215
- Alert before high SG setting 156
- Alert before low
 - about 160
 - summary screen 120
- Alert on high SG setting 156
- Alert on low
 - about 163
 - summary screen 120
- Alert Silence 193
- alerts
 - about 199
 - Active Insulin cleared 202
 - audio options 201
 - BG not received 218
 - Calibrate now 219
 - Calibration not accepted 219
 - Cannot connect device 204

Cannot find sensor signal 220
CGM 216
Change sensor 220
Check connection 221
Check settings 204
Download slow 226
Lost sensor signal 221
Low battery Pump 209
Low battery transmitter 221
Low reservoir 210
No calibration occurred 222
notification light 201
overview 201
Possible signal interference 222
pump 202, 225
Reservoir estimate 214
Rise alert 223
sensor 216
Sensor alert occurred 223
Sensor expired 223
Sensor signal not found 224
SG value not available 224
silencing 193
Transmitter battery depleted 225
yellow icon 201
areas, for inserting infusion set 103
arrows, trend 192
audio
 options 33
 settings 138
 silencing 193
 vibrate 29
auto connect 175
Auto Suspend alarm 203
awake mode 34

B

backlight
 battery use 21
 setting up 141
basal
 about 39
 current delivery 52

daily delivery amount 118
delivery 39
history 117, 118
Home screen 26
Max Basal Rate 41
patterns 41
Preset Temp basal rate 49
rate 39
settings 40
summary 117
Temp Basal 47
basal patterns
 about 42
 adding 46
 changing 46
 deleting 46
 example 42
battery
 about 21
 alarm 203, 205, 213, 214
 alert 209
 belt clip 23
 compartment location 19
 disposal 23
 inserting 22
 removing 23
 replacing 22
 status bar icon 28
 types 21
Battery failed alarm 203
Battery not compatible alarm 203
belt clip
 part number 15
 remove battery cap 23
BG
 Home Screen 26
 sensor calibration 185
BG meter readings
 average 119
 manual high 120
 manual low 120
 meter high 120
 meter low 119
 summary 119

BG not received alert	218
BG target	
Bolus Wizard	66
setting up	70
Block Mode	
status bar	31
using	139
blood glucose	
Home screen	26
sensor calibration	185
bolus	
about	59
daily delivery amount	118
delivery speed	63
history	117, 118
increment setting	63, 64
Max bolus	62
reminders	131
setting delivery speed	63
settings	62
summary	117, 118
types	59
Bolus BG Check reminder, about	130
bolus deliveries	
about	59
Bolus Wizard	61, 65
delivery rate	63
Dual Wave	79
Easy Bolus	62, 82
Manual Bolus	61, 75
Max Bolus setting	62
Normal bolus	73, 75
options	61
Preset Bolus	61, 85
resume message	214, 215
Square Wave	76
stopping	88
types	59
Bolus not delivered alarm	203
Bolus stopped alarm	203
bolus types	
DualWave	60
examples	60
Normal	59
Square Wave	60
Bolus Wizard	
Active Insulin Time	66
BG target	66
Carb ratio	65
Dual Wave	79
Exchange ratio	65
High BG warning	72
injection warning	71
Insulin Sensitivity Factor	65
Low BG warning	72
Max Bolus Exceeded warning	73
Normal bolus	73
Square Wave	77
warnings	72
calibrate	
error	220, 221
sensor	183
when to	186
Calibrate now alert	219
calibration	
guidelines	186
icon	30
Calibration not accepted alert	219
Calibration reminder	133
Cannot connect device alert	204
Cannot find sensor signal alert	220
cannula alarm	205
carb ratio	69
Carb Units	140
CareLink Personal Software	124
Change sensor alert	220
Check connection alert	221
Check settings alert	204
cleaning	
pump	241
transmitter	242

clearing
 active insulin 144
 pump settings 143
Connect Device message 226
connecting pump, transmitter
 automatically 175
 manually 178
connection, failure 178
Consumable
 infusion set 13
 reservoir 13
continuous glucose monitoring
 about 151
 airplane mode 137
 alarms 216
 alerts 216
 calibrating sensor 183
 connecting pump, transmitter 175
 examples 164
 High Settings 156
 home screen 152
 Low Settings 157
 messages 216
 sensor feature, turning on 167
 sensor glucose reading 191
 sensor graph 191
 settings 155
correction estimate 251, 252
Critical pump error 204

D

Daily History 121
date
 changing 148
 Startup Wizard 24
delivery
 stop bolus 33
 suspend all 33
Delivery limit exceeded alarm 205
Download slow alert 226
Dual Wave 60
 about 79
 Bolus Wizard 79

example 60
Manual bolus 81
resume message 214, 215
setting up 79

E

Easy bolus
 about 82
 Manual bolus 84
 setting up 83
 step size 83
electromagnetic emissions 262
Electromagnetic environment 267, 268
electromagnetic immunity 263
emergency
 kit 4
 siren 201
emergency kit 4
emissions 262
event markers
 about 124
 blood glucose 125
 exercise 125
 food 125
 injection 125
 setting up 124
exchange ratio 69

F

Fill Cannula? alarm 205
food estimate 251, 252, 253

G

glucose alerts, silencing 193
graph, sensor 191

H

High BG, Bolus Wizard warning 72
High Limit SG setting 156
High Settings
 about 156
 entering 167

history	
about	117
menu	33
pump settings, viewing	145
summary	117
Home Screen	
about	26
active insulin amount	26
basal delivery	26
blood glucose reading	26
bolus delivery	26
CGM, with	152
display	21
sensor glucose	152
sensor glucose reading	152
sensor graph	152
sensor status icons	152
status bar	26
time	26
trend arrows	152
I	
icons	
Home Screen	28
sensor status	152
SmartGuard	155, 159, 162
suspend by sensor	155
infusion set	
about	93
best insertion sites	103
disconnect Quick-set	107
fill cannula alarm	205
fill tubing	101
inserting	103
reconnect Quick-set	107
reservoir alarm	209
reservoir and tubing	33
reservoir removal	93
rotating sites	104
setting up	93
type	13
Insert battery alarm	205
inserting	
infusion set	103
reservoir	99
sensor	181
insulin	
basal	39
basal patterns	41
bolus	59
flow blocked alarm	206, 207, 208, 209
icon	29
Max Fill reached alarm	210, 211
settings	33
insulin delivery	
Block Mode	139
resuming	54, 163, 174
stopping	54, 88
suspending	54, 139, 158, 161
Insulin flow blocked	
alarm	206, 207, 208, 209
Insulin Sensitivity Factor	
about	65
setting up	70
ISIG	
view	124
L	
language	
changing	141
starting	24
light, red	200
Loading incomplete alarm	209
Lost sensor signal alert	221
Low battery Pump alert	209
Low battery transmitter alert	221
Low BG, Bolus Wizard warning	72
Low limit	158
Low Reservoir	
alert	132, 210
reminder	132
Low Settings	
about	157
entering	171
examples	164

M

- maintenance 241
- Manage Settings error alarm 210
- managing, pump settings 142
- Manual bolus
 - Dual Wave 81
 - Easy bolus 84
 - Normal bolus 75
 - Square Wave 78
- Max Basal
 - alarm 205
 - rate 40
- Max Basal Rate
 - setting 41
- Max Bolus
 - alarm 205
 - exceeded 73
 - setting 62
 - warning 63
- Max Fill reached alarm 210, 211
- Menu screen
 - about 32
 - accessing 32
 - audio options 33
 - display 21
 - event markers 33
 - history 33
 - insulin settings 33
 - reminders 33
 - reservoir and tubing 33
 - sensor settings 33
 - suspend delivery 33
 - utilities 33
- messages
 - about 199
 - audio options 202
 - blue icon 202
 - CGM 216
 - Connect Device 226
 - continuous glucose monitoring 216
 - overview 202
 - pump 202, 225
 - Resume bolus 214

- Resume Dual bolus 214, 215
- Resume Square bolus 215
- sensor 216
- Sensor connected 223
- Missed Meal Bolus reminder 131
- modes
 - Block 139
 - power 34
- mute alerts 193

N

- No calibration occurred alert 222
- No reservoir detected alarm 211
- Normal bolus
 - about 73
 - Bolus Wizard 73
 - delivery 73
 - example 60
 - Manual bolus 75
 - resume message 214
- notification light 200, 201
- notifications 31

O

- ordering supplies 15

P

- patterns, basal
 - about 42
 - adding 46
 - changing 46
 - copying 46
 - deleting 46
 - example 42
- personal reminder 129
- Possible signal interference alert 222
- power save mode 34
- Preset Bolus
 - about 85
 - changing 86
 - deleting 86
 - delivering 87

- Dual Wave 85
- renaming 86
- setting up 85
- Square Wave 85
- Preset Temp Basal rate
 - about 40
 - starting 51
- Preset Temp basal rate
 - about 49
 - editing 50
 - managing 49
 - setting up 49
- previous screen 21
- pump
 - alarms 202, 225
 - alerts 202, 225
 - buttons 20
 - cleaning 241
 - connecting, transmitter 175, 178
 - connection status 29
 - deleting, transmitter 181
 - messages 202, 225
 - navigation 24
 - notification light 20
 - overview 19
 - parts illustration 19
 - rewinding 94
 - settings 232
 - storing 242
 - unlocking 26
- Pump error alarm 212, 213
- Pump restarted alarm 213
- pump settings
 - clearing 143
 - managing 142
 - restoring 143
 - saving 142
 - specifications 247
 - viewing history 145

Q

- quick status 31

- Quick-set infusion set
 - disconnecting 107
 - reconnecting 108

R

- rate, basal
 - about 39
 - Preset Temp 40
 - Temp 40, 47
- rate of change arrows 152
- red light 200, 201
- reminders
 - about 129
 - Bolus BG Check 130
 - Calibration 133
 - Low Reservoir 132
 - Menu screen 33
 - Missed Meal Bolus 131
 - Personal 129
 - Set Change 133
- remote bolus 62, 112
- Replace battery alarm 213, 214
- reservoir
 - about 93
 - compartment image 19
 - inserting 99
 - Loading incomplete alarm 209
 - Low Reservoir alert 210
 - Max Fill reached alarm 210, 211
 - Menu screen 33
 - No reservoir detected alarm 211
 - ordering 15
 - plunger rod 97
 - removal 93
 - Reservoir estimate at 0 U 214
 - setting up 93
 - transfer guard 97
 - type 13
- Reservoir estimate alert 214
- restoring, pump settings 143
- Resume basal alert 163, 164
- Resume bolus message 214
- Resume Dual bolus message 214, 215

Resume Square bolus message	215	Missed Meal Bolus	131
resuming suspended delivery	54, 163, 174	New Reservoir	95
return to previous screen	21	Personal reminder	129
RF communications	267, 268	Preset Bolus Setup	86
Rise Alert		Preset Temp Setup	50
responding to	223	Select Time Format	24
SG setting	157	Self Test	146
summary screen	120	Sensitivity	70
Rise Limit SG setting	157	Sensor Demo	147
		Sensor Glucose Review	122
		Sensor Settings	167
		Set Change	133
		Summary	117
		Suspend Delivery	54
		Temp Basal	48
		Time and Date	148
		Welcome screen	24
		scroll bar	21, 34
		select	21
		sensor	
		airplane mode	137
		alarms	216
		alerts	216
		BG not received alert	218
		calibrating	183, 186
		calibration alert	219
		calibration icon	30
		connecting, transmitter	182
		disconnecting, transmitter	187
		expired alert	223
		feature, turning off	187
		feature, turning on	167
		graph	152
		inserting	181
		life icon	30
		messages	216
		pair	175, 178
		removing	187
		settings	33, 167
		signal alert	220
		starting	182
		status icons	152

S

saving	
power	34
pump settings	142
screen	
Active Insulin Time	71
Airplane Mode	138
Alarm History	122
Audio Options	139
Auto Suspend	139
Basal Pattern Setup	46
BG Check	130
BG Target	70
Block Mode	140
Bolus Increment	64
Bolus Speed	64
Bolus Wizard Setup	66, 71
Carb Ratio	69
Carb Unit	140
Display Options	141
Dual/Square Wave	77
Easy Bolus	83
Enter Date Screen	25
Enter Time	25
Event Markers	124
Exchange Ratio	69
Fill Cannula	106
Fill Tubing	102
Home Screen	26, 152
Language	24, 141
Low Reservoir	133
Manual bolus	75
Max Bolus	63

summary 120
trend arrows 152
wireless connection 175, 178
Sensor alert occurred
 responding to 223
Sensor connected message 223
Sensor Demo 146
Sensor expired alert 223
sensor glucose
 arrows 192
 graph 191
 high settings 156
 history 191
 low settings 157
 review 122
 rise alert 223
 sensor alert occurred 223
sensor graph
 about 191
 trend arrows 192
Sensor signal not found alert 224
serial number, pump 12
Set Change reminder 133
settings
 basal 40
 bolus 62
 Bolus Wizard 65
 CGM 155
 low SG 157
 product specifications 247
 startup 24
 troubleshooting 229
SG average 120
SG Std. Dev. 120
SG value not available alert 224
silencing alerts 193
siren 201
sleep mode 35
SmartGuard
 about 152
 icon 155, 159, 162
 summary 121

Square Wave 60
 about 76
 Bolus Wizard 77
 example 60
 Manual bolus 78
 resume message 214, 215
 setting up 76
starting
 sensor 182
Startup Wizard
 about 24
 re-entering settings 232
 using 24
status bar
 about 28
 Airplane Mode 29
 audio mode 29
 battery 28
 Block Mode 31
 CGM, with 152
 CGM, without 26
 Connection icon 29
 icons 28
 insulin amount 29
 sensor calibration 30
 sensor life 30
 time 26
status screens
 about 31
 notifications 31
 pump 31
 quick status 31
 sensor 31
 settings review 32
stopping
 bolus 88
 insulin delivery 54
storage mode 242
Stuck button alarm 215
summary screen
 about 117
 basal 118
 BG meter readings 119
 bolus 118

- overview 118
- total carbs 118
- total daily dose 118
- viewing 117
- supplies, ordering 15
- Suspend before low
 - about 158
 - examples 164, 165, 166
 - unavailable 159
- suspend by sensor
 - icon 155
- Suspend on low
 - about 161
 - examples 166
 - unavailable 162
- suspended delivery, resuming
 - automatically 163
 - manually 54, 174
- suspending insulin delivery 54, 139, 158, 161

T

- temp basal rate
 - about 47
 - percent 47
 - preset 40
 - rate 47
 - starting 48
 - types 47
- Time before high SG setting 156
- time, current changing 148
- transmitter
 - communication 29
 - connecting, pump 175, 178
 - deleting, from pump 181
 - signal alert 220
- Transmitter battery depleted alert 225
- trend arrows 192
- troubleshooting 229
- tubing
 - filling 101
 - image 19
 - Max Fill reached alarm 210, 211

U

- unavailable
 - Suspend before low 159
 - Suspend on low 162
- unlocking 26
- utilities 33

V

- viewing history, pump settings 145

W

- wireless connection
 - automatic 175
 - failure 178
 - manual 178

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