Correction Bolus

۲



When *Loop* is on:

 Tap the Bolus Entry button to receive a recommendation for a correction bolus to bring down high glucose.

To deliver the recommended	
bolus:	

Barran Barningy	0.72
HELECOMENNEL DUSA	0.72
Boltan.	0.72 v
C	_
Getver	

- 2. Tap Deliver.
- 3. Enter your iPhone passcode (or Face ID, or Touch ID) to authenticate.

The pump plays the *Delivering* sound, and the *Temporary Status Banner* shows the bolus delivery in progress.

The *Delivering* sound will not be played when *Quiet Mode* is enabled.



If *Delivery in Progress* is displayed instead of *Deliver*, you will need to wait until the current bolus delivery is complete before delivering another bolus.



119

If a bolus is not recommended, a *No Bolus Recommended* caution is displayed.



When *Loop* is on, you should not modify the bolus to be greater than the recommended value.

The twiist automated insulin delivery system is making adjustments to your basal delivery to keep you near your correction range.

Modifying a bolus to be greater than the recommended value can lead to glucose falling below your *Glucose Safety Limit* and may increase your risk of low blood glucose.

To enter a bolus when a bolus is not recommended:

- 1. Tap **Enter Bolus** or tap into the *Bolus* field.
- 2. Using the keypad, **enter the bolus amount** you would like to deliver.
- 3. Tap **Done** to dismiss the keypad.
- 4. Tap Deliver.
- 5. Enter your iPhone passcode (or Face ID, or Touch ID) to authenticate.

The pump plays the *Delivering* sound, and the *Temporary Status Banner* shows the bolus delivery in progress.

The *Delivering* sound will not be played when *Quiet Mode* is enabled.

When Loop is off:

1. Tap the **Bolus Entry**[∛] button on the *Toolbar*.

- 2. Tap **Fingerstick Glucose** and enter a fingerstick blood glucose reading.
- 3. Tap **Done** to hide the keypad.

If a bolus is recommended, you will see the amount in the *Recommended Bolus* and *Bolus* fields. You can accept it, or you can enter your own *Bolus* value using the keypad that appears when you tap into the *Bolus* field.

DKPI-09233-001-1.5 DRAFT

Ų

۲

۲

120



If the recommended bolus does not match the way you feel, go back to the *Home Screen* and check both your *Active Carbohydrates* and *Active Insulin*.

4. Tap Next.

۲

۲

- 5. Review the recommended bolus and tap **Deliver Bolus**.
- 6. Enter your iPhone passcode (or Face ID, or Touch ID) to authenticate.

The pump plays the *Delivering* sound, and the *Temporary Status Banner* shows the bolus delivery in progress.

The *Delivering* sound will not be played when *Quiet Mode* is enabled.

Top to Step

Bolus 1.33 of 4.79 U

The *Bolus* icon vill be displayed on the *Insulin Delivery Chart* indicating that a bolus has been delivered.

Insul	in Delive	7				5.6 U/hr	
1							
1	12.244	1254	2 PM	3.054	4.754	SPM	

When entering fingerstick glucose, if you enter a value that is greater than 250 mg/dL, a *High BG notification* will be displayed asking if you want to continue.



- 1. Before selecting Yes or No:
 - Check for a blocked line
 - · Check for ketones
 - Consider insulin injection and monitor BG

If your glucose is below 70 mg/dL, a *No Bolus Recommended* caution will be displayed and you will be given the option to **Save without Bolusing**.

DKPI-09233-001-1.5 DRAFT

No Bolus Recommended

Your glucose is low. Eat carbs and monitor closely.

۲

Save without Balusing

Manually Enter a Bolus

Using either the *Carb Entry* or *Bolus* buttons, a manual bolus can be entered.

 Tap the Carb Entry ^I^O or Bolus ^V buttons on the *Toolbar*.

> In order to enter a bolus manually, glucose and carbohydrate values are not required.

- 2. Tap **Bolus** to display the keypad.
- 3. Enter the desired bolus value using the keypad.
- 4. Tap **Done** to hide the keypad.

- 5. Tap Next.
- 6. Confirm the bolus amount and tap **Deliver Bolus**.
- 7. Enter your iPhone passcode (or Face ID, or Touch ID) to authenticate.

The pump plays the *Delivering* sound, and the *Temporary Status Banner* shows the bolus delivery in progress.

The *Delivering* sound will not be played when *Quiet Mode* is enabled.

The *Bolus* icon will be displayed on the *Insulin Delivery Chart* indicating that a bolus has been delivered.

Insul	in Deliver	ж				1.6 U/M	21
1							
-1	12.214	1.254	2 PM	3.754	4.754	SPM	

If your desired bolus value exceeds the *Maximum Bolus Limit*, a caution will be displayed and you will <u>NOT</u> be able to proceed.

The manual bolus needs to be reduced below the *Maximum Bolus Limit*.



If *Delivery in Progress* is displayed instead of *Deliver Bolus*, you will need to wait until the current bolus delivery is complete before delivering another bolus.



DKPI-09233-001-1.5 DRAFT

122

۲

Deliver Extended Bolus

۲

An *Extended Bolus* can only be delivered when *Loop* is off and *Extended Bolus* has been enabled in *Therapy Settings*.

The Extended Bolus feature should only be used with direction from your healthcare provider.

An *Extended Bolus* can only be delivered for a meal. If a glucose correction is required, this option will not be available.

- 1. Tap on the **Carb Entry** where the button on the *Toolbar*.
- 2. Tap **Carbohydrates** and enter the amount of carbs you are planning to eat.
- 3. Tap **Fingerstick Glucose** and enter a fingerstick BG reading.
- 4. Tap **Done** to hide the keypad.

- 5. Tap Next.
- 6. Review the *Bolus Details* and tap **Set Extended Bolus**.
- 7. Use the picker to adjust the *Duration* between 30 minutes and 8 hours.



- 8. Tap **Done** to hide the picker.
- 9. Tap Next.
- 10. Confirm the bolus amount and tap **Deliver Bolus**.
- 11. Enter your iPhone passcode (or Face ID, or Touch ID) to authenticate.

The pump plays the *Delivering* sound, and the *Temporary Status Banner* shows the extended bolus delivery in progress.

The *Delivering* sound will not be played when *Quiet Mode* is enabled.



The *Bolus* icon vill be displayed on the *Insulin Delivery Chart* indicating that a bolus has been delivered.



If *Delivery in Progress* is displayed instead of *Deliver Bolus*, you will need to wait until the current bolus delivery is complete before delivering another bolus.

DKPI-09233-001-1.5 DRAFT



Deliver Dual Bolus

A *Dual Bolus* can only be delivered when *Loop* is off and *Dual Bolus* has been enabled in *Therapy Settings*.

The *Dual Bolus* feature should only be used with direction from your healthcare provider.

A *Dual Bolus* can only be delivered for a meal and should be used when you want to deliver some of your meal bolus now and some over an extended time.

1. Tap on the **Carb Entry** button on the *Toolbar*.

- 2. Tap **Carbohydrates** and enter the amount of carbs you are planning to eat.
- 3. Tap **Fingerstick Glucose** and enter a fingerstick BG reading.
- 4. Tap **Done** to hide the keypad.
- 5. Tap Next.
- 6. Review the *Bolus Details* and tap **Set Dual Bolus**.
- 7. Divide the *Meal Bolus* between *Normal* and *Extended* bolus types.

Any bolus required to lower your blood glucose (correction bolus) is always delivered as a *Normal Bolus* and cannot be allocated to the extended portion of a dual bolus.



۲

- 8. Tap on the **Normal Percent** and use the picker to adjust the *percent* between 5 and 95 percent.
- 9. Tap on **Extended Duration** and use the picker to adjust the between 30 minutes and 8 hours.
- 10. Tap **Done** to hide the picker.

124

۲

11. Tap Next.

۲

- 12. Confirm the normal and extended bolus amounts and tap **Deliver Bolus**.
- 13. Enter your iPhone passcode (or Face ID, or Touch ID) to authenticate.

The pump plays the *Delivering* sound.

The pump sound will not be played when *Quiet Mode* is enabled.

The *Temporary Status Banner* shows both the normal and extended portions of the dual bolus delivery in progress.



Two *Bolus* icons will be displayed on the *Insulin Delivery Chart* at the same time that a dual bolus has been delivered.

Mad	in Dellever				9.8.034	1.1
1 m -		*				- 11
1 A	1.440	10.000	111.414	10.04	1.044	- 6

If *Delivery in Progress* is displayed instead of *Deliver Bolus*, you will need to wait until the current bolus delivery is complete before delivering another bolus.

Delivery in Progress	

Stop Bolus Delivery

A bolus can only be stopped while the *Temporary Status Banner* is displayed. The *Temporary Status Banner* will be displayed on the *Home Screen* for the entire duration of the bolus delivery.

To stop a bolus delivery:

- 1. Tap the **Temporary Status Banner**.
- 2. Tap Yes to stop the bolus.

The pump plays the *Delivering* sound.

The pump sound will not be played when *Quiet Mode* is enabled.

If you tap **No** the bolus will continue to deliver.

DKPI-09233-001-1.5 DRAFT

If you need to stop a bolus and your pump and twiist app are not in communication, you will need to suspend insulin delivery. See "How do I stop insulin delivery without my twiist app?" on page 189.

Workout Preset



When you would like to exercise, use the *Workout Preset* to temporarily raise your *Correction Range*. The twiist AID system will use your *Workout Range* before, during, or after exercise to reduce the risk of low glucose events. Failing to inform the twiist AID system that you would like your *Correction Range* to be modified through the use of the *Workout Preset* may cause unexpected changes to your glucose to occur.

- Tap the Workout Preset button.
- Select how long you would like to use the workout preset for. You can keep the workout preset active for:
 - 1 hour
 - 2 hours
 - Until you choose to turn it off

Work with your healthcare provider to find the optimal timing and settings for your individual exercise routine. When your *Workout Range* is active, you will see a darker blue shaded correction range on your *Glucose Chart*.



You can also see that your changes are active by the

reversed *Workout Preset* button colors in the *Toolbar*.



DKPI-09233-001-1.5 DRAFT

♥

۲

126

If you selected *Until I turn off*, and your *Workout Preset* is still active 24 hours later, the twiist app will display a *Workout is Still Active* after 24 hours.



1. Tap **OK** to dismiss the notice.

If you would like your *Workout Range* to remain active, no further action is required.

If you would like to turn off the *Workout Preset*, tap the **Workout Preset** button on the *Toolbar*. This feature is only available when *Loop* is on. When *Loop* is off the twiist system will not adjust your correction range or automate your basal insulin to bring you to your *Workout Range*.

Men Loop is off, the button on the toolbar is used to set a Temporary Basal, see "Temporary Basal" below.

Temporary Basal



When *Loop* is off, the button on the *Toolbar* allows you to set a *Temporary Basal*.

Temporary Basal is a temporary adjustment to your basal rate and is typically set for activities such as exercise.

Setting a *Temporary Basal* should be performed with direction from your healthcare provider.

By default, a *Temporary Basal* adjusts your basal rate by allowing you to select a percentage of your basal rate for a specified duration. You can also choose to set a *Temporary Basal* by overriding your programmed rate or rates within *Therapy Settings*.

When *Loop* is on, the heart icon on the toolbar is used to enable a *Workout Preset*, see "Workout Preset" on the previous page.

Set Temporary Basal

1. Tap the button on the twiist app *Toolbar*.

DKPI-09233-001-1.5 DRAFT

۲

- 2. Use the picker to enter the **Duration** between 30 minutes and 24 hours.
- 3. Tap Done.

۲

4. Tap **Rate Change** to open the picker and select the value.

Rate adjustment will appear as percent or U/hr depending on your *Temporary Basal* adjustment setting within *Therapy Settings*.

When programming a *Temporary Basal* as a percent adjustment, 100% is the same basal rate as programmed. 120% means 20% more and 80% means 20% less than the programmed basal rate.

1.00 0.75 0.50 0.25 0.00	
12 AM 6 AM 1 Duration	Rate Change
5:00 hr:min	150 percent

5. Tap **Done** to hide the picker after *Duration and Rate* selection.

If the *Temporary Basal* percentage will cause the basal rate to exceed the maximum basal rate, you will need to lower your percentage or modify your duration.

1.75 1.80 1.28 1.00 0.75 0.50 0.50 0.50 0.50	
12 AM 6 AM 12 Duration	PM 6.PM 12.AM Rate Change
2:00 tr:min	170 Dercare

If the *Temporary Basal* percentage will cause the basal rate to fall below the minimum deliverable basal rate, you will need to increase your percentage, or set the *Rate Change* to **0 percent**.

6. Review the *Temporary Basal* and tap **Start Temporary Basal**.



7. Enter your iPhone passcode (or Face ID, or Touch ID) to authenticate.

The pump plays the *Delivering* sound.

The pump sound will not be played when *Quiet Mode* is enabled.

When a *Temporary Basal* is in progress, the *Home Screen* displays a *Temporary Status Banner* which allows you to:

۲

- Track the progress of the *Temporary Basal*
- Stop the Temporary Basal



The *Insulin Delivery Chart* will show reduced or increased basal and will show the rate at which basal insulin is currently being delivered.

10000	Deliver				LEEVEN
	1	-	-	-	
		100	14.000	10.004	140

The button on the *Toolbar* will be displayed with the color reversed.



Stop Temporary Basal

 Tap Temporary Basal in the Temporary Status Banner or tap the button on the toolbar.

> A message is displayed asking if you are sure you want to cancel the temporary basal.

2. Tap **Yes** to cancel the temporary basal or **No** to continue with the temporary basal.

The pump plays the *Delivering* sound.

The pump sound will not be played when *Quiet Mode* is enabled.

DKPI-09233-001-1.5 DRAFT

Delivery with Pump Button

۲

The Pump Button can be used to:

- · Verify insulin is being delivered
- · Resume basal insulin delivery
- Deliver a One-Button Bolus

Verify Insulin Delivery

The pump button can be used to verify that insulin delivery is in progress.

Press and hold the **pump button** for approximately 3 seconds.

If the pump plays the *Delivering* sound, delivery is in progress.

If the pump plays a *Ready* beep, insulin is not being delivered and additional action is required to resume insulin delivery.

Resume Basal Insulin Delivery

The following steps provide instruction on how to resume basal delivery.

If delivery had been previously suspended:

1. Press and hold the **pump button** for approximately 3 seconds until the pump plays the *Delivering* sounds.

If an alarm occurred while the twiist app and pump were not in communication:

- 1. Make sure the infusion set tubing is disconnected from the infusion site.
- 2. Remove the cassette from the pump.
- 3. Remove and reinsert the pump battery.

The pump will play a quick beep followed by a *Ready* beep.

- 4. Attach the existing cassette.
- 5. Wait for self-test to complete.
- 6. Connect the infusion set tubing to your infusion site.
- 7. Press and hold the **pump button** for approximately 3 seconds, until the pump plays the *Delivering* sounds.

When the twiist pump and app are back in communication, the *Home Screen* will display basal delivery in progress, along with other status information.

One-Button Bolus

۲

Verify you have enabled the One-Button Bolus feature in Therapy Settings.

1. Press the **pump button** for each unit of insulin you would like to deliver as a bolus.

Each time you press the pump button, the *Bolus* volume increases 1 unit and the *One-Button Bolus* sounds are played.

One-Button Bolus can be observed on the twiist app *Home Screen.*



The maximum bolus that can be delivered through the use of *One-Button Bolus* is 10 Units. This would be less if your *Maximum Bolus Delivery Limit* therapy setting is set to a lower value.

- 2. When you have reached the number of units you would like to bolus, press and hold the **pump button** until you hear the playback start, then release the pump button.
- 3. Listen and confirm the pump plays back the number of units you entered.
- 4. If the playback is correct, press and hold the **pump button** until you hear the *Delivering* sound.
- 5. The twiist app displays the *Bolus* progress with the number of units delivered out of the total units programmed.

If you need to stop the bolus delivery, see "Stop Bolus Delivery" on page 125.

One-Button Bolus Programming Canceled

If you stop interacting with the pump during the programming of the One-Button Bolus and the pump plays one long beep, the pump has timed out and canceled the One-Button Bolus programming. A Bolus Programming Canceled notice is displayed.



Tap **OK** to dismiss the notice.

You will need to restart the *One-Button Bolus* programming and delivery again.

If you tried to request more than the maximum allowed bolus, the pump will play one long beep. A *Bolus Programming Canceled* notice is displayed.



Tap **OK** to dismiss the notice.

If you press the pump button while the pump is confirming the bolus volume that you have requested, the pump will play one long beep and the bolus will be canceled. A *Bolus Programming Canceled* notice is displayed.

Bolus Programming Canceled One-button Bolus Programming was canceled because the Pump button was pressed during confirmation. (7) OK

Tap **OK** to dismiss the notice.

132

۲

Alerts, Urgent Alerts, and Alarms

The twiist automated insulin delivery system provides alerts, urgent alerts, and alarms for your safety.

Check your iPhone for alerts, urgent alerts, and alarms anytime you are in an environment where you cannot hear or feel vibration from your iPhone, or hear the pump.

iPhone sounds are controlled within your iPhone *Settings*.

The twiist app displays alarms above urgent alerts, urgent alerts above alerts, and alerts above other status notifications.

Alarm, urgent alert, and alert settings are saved in a manner that is unaffected by power loss.

Alarms can always be resolved by performing a cassette change.

The twiist automated insulin delivery system does not provide CGM high or low glucose alerts with the exception of the *Urgent Low Glucose* alert that occurs when your CGM reading has fallen below 55 mg/dL. Make sure to check your CGM app and respond to CGM alerts in order to make sure your CGM is working properly.

For more information about Alert, Urgent Alert, or Alarm sounds, see "System Sounds" on page 35.

DKPI-09233-001-1.5 DRAFT

₽

Alerts

۲

Alerts do not interrupt insulin delivery but should be addressed as soon as possible.

When an *Alert* is occurring, a message is displayed with a single, red, exclamation point **!** icon followed by the name of the alert.

Your iPhone will play the Alert sound.

When two or more alerts occur, the alerts will be displayed within the twiist app with the most recent alert first and progressing to earlier alerts as they are addressed.

۲

۲

Basal Delivery Not Started

Alert Display	Description:
Basal Delivery Not Started Basal delivery could not be started. Try again. (0) OK	Basal delivery could not be started. This may occur if you attempt to start basal using the pump button but the pump has insufficient information to start delivery.
Sounds Pump: None (when in communication with twiist app) Alert (when not in communication with the twiist app) iPhone: Alert	 What To Do: 1. Tap OK to dismiss the alert. 2. Use the twiist app to <i>Resume Insulin Delivery</i>. See "Resume Insulin Delivery" on page 80.

DKPI-09233-001-1.5 DRAFT

Bluetooth Off

۲



Description:

If Bluetooth is disabled on your iPhone, the twiist app will display a *Bluetooth Off* alert.

If Bluetooth is disabled on your iPhone, the twiist app cannot communicate with your pump, but your CGM and pump will still be in communication, and the twiist automated insulin delivery system will be able to continue adjusting your basal insulin delivery.

What To Do:

1. Tap OK to dismiss the Bluetooth Off alert.

The Home Screen will display Bluetooth Off in the CGM Status and Enable Bluetooth in the Pump Status.

- 2. Enable **Bluetooth** in your iPhone settings to receive alerts, urgent alerts, alarms, and CGM readings.
- 3. Navigate back to the twiist app.

The *Home Screen* will no longer display *Bluetooth Off* and *Enable Bluetooth* and the *CGM* and *Pump Status* icons will resume displaying current status.

)

Bluetooth Unavailable

۲

۲



Description:

Bluetooth unavailable occurs when Bluetooth has been disabled for the twiist app within your iPhone settings.

If Bluetooth is disabled for the twiist app, the app cannot communicate with your pump, but your CGM and pump will still be in communication, and the twiist automated insulin delivery system will continue adjusting your basal insulin delivery.

What To Do:

1. Tap **OK** to dismiss the *Bluetooth Unavailable Alert* message.

The Home Screen will display Bluetooth Unavailable in the CGM Status and Enable Bluetooth in the Pump Status.

- 2. Enable **Bluetooth** for the twiist app within your iPhone settings to receive alerts, alarms, and CGM readings.
- 3. Navigate back to the twiist app.

The *Home Screen* will no longer display *Bluetooth Unavailable* and *Enable Bluetooth* and the *CGM* and *Pump Status* icons will resume displaying current status.

Bolus Delivery Stopped



Cassette Low



DKPI-09233-001-1.5 DRAFT

CGM Pairing Failed



CGM Transmitter Not Found



۲

Loop Disabled

Alert Display	Description:
Dennan Age	Loop has been disabled because there has been no active CGM session for 15 minutes.
Loop Disabled Loop is disabled because there has been no active CGM Session for 15 minutes. (8) OK	The twiist system is no longer automatically adjusting your basal insulin. Basal insulin is delivered at your scheduled basal rate. Check your glucose frequently, and treat your highs and lows as advised by your healthcare provider.
Sounds	What To Do:
Dimension	1. Tap OK to dismiss the alert.
Pump: None (when in communication	2. Pair a new CGM. See "Add CGM" on page 105.
with twiist app)	When a new CGM is paired, Loop will be automatically turned on.
Alert (when not in communication with the twiist app) iPhone: Alert	A <i>Loop is On</i> notice will be displayed (<i>see "Loop is On" on page 168</i>), informing you that Loop has been re-enabled since a CGM is now connected, and the Loop <i>Status</i> icon will display a closed green circle icon. Tap OK .

Loop Failure

۲

۲



Description:

A Loop has not been successfully completed in over 20 minutes or 40 minutes.

The twiist automated insulin delivery system will deliver your basal insulin at the scheduled rate when a *Loop* has not been completed for 30 minutes.

What To Do:

- 1. Tap OK to dismiss the alert.
- 2. Check your blood glucose and take the appropriate action to treat high or low glucose.
- 3. Attempt to adjust the position of your pump in order to reestablish communication with your CGM.

Phone Out of Range

Alert Display	Description: The <i>Phone Out of Range</i> alert, if enabled in <i>Therapy Settings</i> , will play an alert sound on the pump when the iPhone and pump are outside of their communication range for longer than the programmed duration (1-120 minutes). When communication between the twiist app and pump is restored, the <i>Communication Restored</i> alert is displayed. Typically, if this alert has occurred, you have walked away from your iPhone while insulin delivery is in progress.
Sounds Pump: Alert iPhone: Alert when communication is restored	 What To Do: 1. Tap OK to dismiss the alert. No further action is required. If you do not receive the message that the communication has been restored, and the pump and twiist app are within communication range, there may be another type of communication error occurring. 1. Quit and restart the twiist app. 2. If the issue persists, conduct a <i>Battery Change</i>. See "Battery Change" on page 95. 3. Move away from other wireless devices and try to establish communication between your pump and iPhone.

Pump Battery Low



DKPI-09233-001-1.5 DRAFT

Pump Inactive



Reattach Cassette



DKPI-09233-001-1.5 DRAFT

Temporary Basal Stopped



۲

Urgent Alerts

۲

۲

Urgent Alerts do not interrupt insulin delivery, but should be addressed as soon as possible.

When an *Urgent Alert* is occurring, a message is displayed with two red exclamation point !! icons followed by the name of the urgent alert.

Your iPhone will play the urgent alert sound. The urgent alert sound will also play on the pump if you have not silenced the urgent alert within 5 minutes.

When two or more urgent alerts occur, they will be displayed within the twiist app with the most recent urgent alert first and progressing to earlier urgent alerts as they are addressed.

Loop Failure



No Communication



DKPI-09233-001-1.5 DRAFT

Urgent Low Glucose

۲



152

Alarms

۲

Alarms result in the suspension of insulin delivery and require immediate attention. Check your blood glucose and take the appropriate action to treat high or low glucose.

If you do not respond to an alarm within 5 minutes, the alarm will escalate by playing alarm sounds on the pump and will be delivered as a *Critical Alert* at maximum volume and will vibrate on your iPhone.

iPhone sounds are controlled within your iPhone Settings.

Alarm audio will repeat 15 minutes after it has been silenced unless the alarm condition is resolved. When an *Alarm* is occurring, an alarm dialog will be displayed, which includes three red exclamation point **I** icons followed by the name of the alarm.

Depending on the alarm, there may be different ways to resume insulin delivery.

Some alarms allow you to *Resolve with Current Cassette*, while others require you to *Perform Cassette Change*.



The twiist app provides information about the amount of insulin remaining and the age of the cassette to help you decide.

Choose the alarm recovery that is right for you at the time the alarm occurs.

Do not connect infusion set tubing to your infusion site before the pump completes self-test. Connecting infusion set tubing to your infusion site during self-test may lead to unintended delivery of insulin, which may lead to low blood glucose.

Do not fill or prime the cassette and infusion set tubing while connected to your infusion site. Connecting the infusion set tubing during filling and priming may lead to the unintended over delivery of insulin which may result in low blood glucose.

DKPI-09233-001-1.5 DRAFT

Cassette Empty



Cassette Error

Alarm Display	Description:	
	The cassette is not operating correctly and cannot continue to deliver insulin.	
1.1.1 Caustin Dror	The amount of insulin delivered may have been affected.	
Disconnect the fubling from your influeion alle	What To Do:	
traulin skilvery fun Benn sysperitiest	1. Tap Audio OFF to silence the alarm.	
Folios ar-screen instructions for altern numbers (i-m) Audie OFF	On the <i>Home Screen</i> , the <i>twiist Pump Status</i> displays <i>Pump Alarm</i> and the alarm icon has been updated to show the alarm has been silenced.	
Sounds	After tapping <i>Audio OFF</i> , this alarm will repeat every 5 minutes until delivery is restarted.	
Pump: No sound for 5 minutes.	2. Disconnect tubing from your infusion site.	
iPhone: Alarm	3. Check your glucose. Follow instructions from your healthcare	
in Hone. Alarm	provider to treat your glucose.	
	4. I ap OK to dismiss the alarm.	

The <i>Cassette Error</i> alarm can be resolved with your current cassette or by performing a cassette change.	To resolve the alarm by performing a cassette change:
 To resolve the alarm with your current cassette: Tap Resolve with Current Cassette. Make sure tubing is disconnected from your infusion site. Tap Next 	 Tap Perform Cassette Change. Follow the steps to complete a cassette change, starting with "Gather your Supplies" on page 82.
The twiist app displays <i>Communicating with Pump</i> and will perform a self-test.	
 Wait for pump self-test to complete. Reattach tubing to your infusion site. Tap Start Basal. 	

Cassette Not Attached



The <i>Cassette Not Attached</i> alarm can be resolved with your current cassette or by performing a cassette change.	To resolve the alarm by performing a cassette change:
 To resolve the alarm with your current cassette: Tap Resolve with Current Cassette. Make sure tubing is disconnected from your infusion site. Tap Next. Connect the cassette to the pump. Wait for pump self-test to complete. Reattach tubing to your infusion site. Tap Start Basal. 	 Tap Perform Cassette Change. Follow the steps to complete a cassette change, starting with "Gather your Supplies" on page 82.
Avoid strong magnetic fields. Strong magnetic fields can trigger the latch detect sensor within the pump causing a false <i>Cassette Not Attached</i> alarm.	

DKPI-09233-001-1.5 DRAFT

•

Line Blocked

۲

Do not leave the cassette and infusion set tubing connected to your infusion site when investigating or resolving a *Line Blocked* alarm. Leaving the infusion set tubing connected during a *Line Blocked* alarm may lead to unintended delivery of insulin, causing low blood glucose.

Alarm Display	Description: Insulin is blocked from being delivered due to a kink in your infusion set tubing or cannula.
1.1.1.1.Line Blocked Characteristic for skaring from yoar inflation site. Frankristeristicht Frankristeristicht Frankristeristicht Basie statumment Basie statum Auflei CH4	 What To Do: 1. Tap Audio OFF to silence the alarm. On the <i>Home Screen</i>, the <i>Pump Status</i> displays <i>Line Blocked</i> and the alarm icon has been updated to show the alarm has been silenced. After tapping <i>Audio OFF</i>, this alarm will repeat every 5 minutes until delivery is restarted.
Sounds Pump: No sound for 5 minutes. Alarm upon escalation. iPhone: Alarm	 Disconnect tubing from your infusion site. Check your glucose and test for ketones. Follow instructions from your healthcare provider to treat your glucose. Tap OK to dismiss the alarm.

Resolve with the current cassette if you are able to correct	Conduct a Cassette Change if:	
 Tap Resolve with Current Cassette. Make sure tubing is disconnected from your infusion site. Tap Next. Check the cassette and infusion set tubing for kinks. Tap Next. The twijst app displays Communicating with Pump and 	 You cannot correct the blockage in your infusion set tubing. Infusion set tubing is damaged. You have already attempted to resolve a <i>Line Blocked</i> alarm with the current cassette and infusion set. Tap Perform Cassette Change. 	
will perform a self-test.	2. Follow the steps to complete a cassette change, starting with " <i>Gather your</i>	
5. Wait for the self-test to complete.	Supplies" on page 82.	
6. Route your infusion set tubing to avoid any sources of kinks that may have caused the <i>Line Blocked</i> alarm.		
7. Reattach tubing to your infusion site.		
If you changed your infusion site and need to fill cannula, toggle Fill Cannula on and verify your cannula fill volume is accurate.		
8. Tap Start Basal .		

DKPI-09233-001-1.5 DRAFT

Pump Battery Empty

۲

۲



Description:

Your pump battery does not have enough charge to continue delivery. A charged battery must be inserted into the pump to continue delivery.

What To Do:

1. Tap Audio OFF to silence the alarm.

After tapping *Audio OFF*, this alarm will repeat every 5 minutes until delivery is restarted.

2. Tap **OK** to dismiss the alarm.

On the *Home Screen*, the *Pump Status* displays *Pump Battery Empty* and the alarm icon has been updated to show the alarm has been silenced.

To resolve a <i>Pump Battery Empty</i> alarm with your current cassette:	To resolve a <i>Pump Battery Empty</i> alarm by performing a cassette change:
 Tap Resolve with Current Cassette. Gather the supplies you need to complete a 	 Tap Perform Cassette Change. Gather the supplies you need to complete a
 Battery Change. Follow the steps to complete a Battery Change, 	Cassette Change. 3. Tap Start Cassette Change .
starting with "Wash your Hands" on page 98.	4. Follow the steps to complete a <i>Cassette Change</i> , starting with <i>"Wash your Hands" on page 86</i> .

Pump Error



The <i>Pump Error</i> alarm can be resolved with your current cassette or by performing a cassette change.	To resolve the alarm by performing a cassette change:
To resolve the alarm with your current cassette:	1. Tap Perform Cassette Change.
 Tap Resolve with Current Cassette. Make sure tubing is disconnected from your infusion site. Tap Next. 	2. Follow the steps to complete a cassette change, starting with <i>"Gather your Supplies" on page 82.</i>
The twiist app displays <i>Communicating with Pump</i> and will perform a self-test.	
 Wait for pump self-test to complete. Reattach tubing to your infusion site. Tap Start Basal. 	

Notices

۲

۲

Notices are displayed on the twiist app to make you aware of a situation or to continue through a process.

Bolus Recommendation Updated



Critical Alerts Disabled



166

۲

To enable Critical Alerts:

۲

۲

1. Tap the **Alert Permissions Disabled** warning to open *Settings.*

Alert Permissions within the twiist app Settings only appears when Critical Alerts or Notifications have been disabled.

2. Tap Alert Permissions.



3. Tap **Manage Critical Alerts in Settings** to navigate to the iPhone settings for the twiist app.

C Settings Alert Permissions	
Manage Notifications in Settings	2
RestRuntures appear or your lack somet or pop op while you've using other apps.	
Notifications give one important time-aga-internat antimud respecting year in super-line app. The care putchings when and how you want to income these methodizers.	
Manage Ortical Alerts in Settings	2
Deficial Alterns will always play a sound and appears the Lock scheen even if your Phone is maked in the Net Distorts is set.	1

- 4. Tap Notifications.
- 5. Tap the toggle for **Critical Alerts** to enable *Critical Alerts* for the twiist app.
- 6. Navigate back to the twiist app.

Alert Permissions is no longer displayed within *Settings*.

7. Tap **Done** to close *Settings* and return to the *Home Screen*.

DKPI-09233-001-1.5 DRAFT

Loop is On

Notice Display	Description:
Leep is On The system has re-enabled Loop since a COM is now connected.	Your previous CGM sensor session expired resulting in a <i>Loop Disabled</i> alert. After starting a new CGM sensor session, <i>Loop</i> will automatically turn back on, and a <i>Loop On</i> notice is displayed.
Sounds	
Pump: None	
iPhone: iPhone default	What To Do:
notification sound on lock	1. Tap OK to dismiss.
different app.	
No sound is played while the twiist app is displayed.	

DKPI-09233-001-1.5 DRAFT

No Communication

Notice Display	Description:
No Communication twillst App has not communicated with the twist Pump in 40 minutes. (2014) OK	If your iPhone and pump have been out of communication, the twiist app will notify you. When your twiist app has not communicated with the pump in 20 minutes, 40 minutes, 1 hour, or 2 hours, a <i>No Communication</i> notice will be displayed.
	What To Do:
Sounds	1. Tap OK to dismiss.
Pump: None	2. Place the iPhone and pump close to each other to allow communication to resume
iPhone: iPhone default notification sound on lock	 Communication problems may be resolved by turning off or moving away from other RE transmitting devices or by restarting the twijst app
screen or while using a different app.	 Press and hold the pump button for at least 3 seconds to verify delivery
No sound is played while the twiist app is displayed.	is in progress.5. If the pump does not play the <i>Delivering</i> sound, replace the pump battery.

Notifications Disabled



Description:

Keep *Notifications* turned on in your iPhone settings to ensure that you can receive twiist app notifications in your iPhone notification center.

If *Notifications* are disabled on your iPhone, the twiist app will display a *Notifications Disabled* message and the *Home Screen* will display an *Alert Permissions Disabled* warning.

What To Do:

1. Tap OK to dismiss the Notifications Disabled message.

The Home Screen will display an Alert Permissions Disabled warning.



The *Alert Permissions Disabled* warning will remain on the screen until *Notifications* have been enabled.



۲

To enable Notifications:

۲

۲

1. Tap the **Alert Permissions Disabled** warning to open *Settings*.

Alert Permissions within the twiist app Settings only appears when Notifications have been disabled.

2. Tap on Alert Permissions.



3. Tap **Manage Notifications in Settings** to navigate to the iPhone settings for the twiist app.

Cana	Auto Sectore	6
Innage	unturine e break	1.0
-		
1	Sector.	27

- 4. Tap Notifications.
- 5. Tap the toggle for **Allow Notifications** to enable *Notifications* for the twiist app.
- 6. Navigate back to the twiist app.

Alert Permissions is no longer displayed within *Settings*.

7. Tap **Done** to close *Settings* and return to the *Home Screen*.

Prime Stopped

۲

172

۲



DKPI-09233-001-1.5 DRAFT

Pump Battery Low

Notice Display	Description:
155 💿 🔿 🧫 🐽	A <i>Pump Battery Low</i> notice will be displayed when 20% of the pump battery charge is remaining.
Pump Battery Low Pump battery has 20% remaining. (2) OK	
	What To Do:
Sounds	1. Tap OK to dismiss the notice.
Pump: None2. Prepare for a Cassette or BatteriPhone: iPhone default notification sound on lock screen or while using a different app.2. Prepare for a Cassette or Batter See "Cassette Change" on page 8. See "Battery Change" on page 95.	2. Prepare for a Cassette or Battery Change.
	See "Cassette Change" on page 82.
	See "Battery Change" on page 95.
No sound is played while the twiist app is displayed.	