- 3. Enter your **username** and **password**.
- 4. Tap Login.

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- 5. Tap **Continue** to review the Welcome to the twiist AID System and the Getting to Know the twiist AID System content, including:
  - Introduction
  - How the App Works
  - · A Day in the Life

Before proceeding, your certified twiist trainer will contact you to schedule an appointment to complete your twiist automated insulin delivery system training.

#### **Your Settings**

- The twiist app will ask for the following permissions, tap Allow to enable:
  - Notifications
  - Critical Alerts
- 2. Tap Share with Apple Health and turn on the data you would like to share including blood glucose, carbohydrates, and insulin delivery data and tap Allow or tap Don't Allow.

Choosing to share data with Apple Health allows you to review blood glucose, carbohydrates, and insulin delivery data, including Total Daily Dose, in the Apple Health app on your iPhone. The therapy settings needed to use the twiist automated insulin delivery system may be programmed by your healthcare provider in advance or entered during initial setup with your certified twiist trainer.

3. Tap **Continue** and review the settings provided by your healthcare provider or enter them with your certified twiist trainer.

#### Your Devices

Before continuing:

- Make sure that your iPhone is connected to the internet.
- The Dexcom G6 app must be installed on your iPhone in order to configure a Dexcom G6 CGM.
- 1. Place the pump and iPhone close together and away from other wireless devices during pairing.

2. Pair your Dexcom G6 CGM and twiist pump using the twiist app in order to get started.

> The twiist app will ask for permission to use Bluetooth before pairing a CGM or twiist pump, tap **Allow** to enable.

If you choose to pair the pump by taking a photo, the twiist app will ask for permission to access the camera, tap **Allow** to enable.

#### Add CGM:

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- 1. Tap Add CGM.
- 2. Tap **Dexcom G6** and tap **continue**.
- 3. Tap Pair CGM.

- 4. Find and enter the **6-digit transmitter serial number** located on the transmitter box label, or on the back of the uninstalled transmitter. You can pair your transmitter by taking a photo or by entering it manually.
- 5. Tap **Take Photo** or **Enter Manually** to enter the CGM transmitter serial number.
- 6. Tap Next.
- 7. Tap **Confirm** to confirm the transmitter serial number.
- 8. Tap Open Dexcom G6 app.
- 9. Complete any required configuration within the Dexcom G6 app.
- 10. Return to the twiist app.

#### Pair Your twiist Pump

1. Insert a fully charged battery into the pump.

When the battery is inserted successfully, the pump will play a quick beep followed by a *Ready* beep and the twiist app will advance automatically. ۲

- 2. Tap Pair Pump.
- 3. Press and hold the **pump button** for approximately 5 seconds until you hear a *Ready* beep, and then release the button.
- 4. Tap on the **serial number** of your pump displayed within *Discovered Pumps*.

# To pair your pump by taking a photo:

a. Tap Take Photo.

You must allow the twiist app to access to your iPhone camera in order to pair by taking a photo.

b. Hold your iPhone above the pump so the pump label is in focus within the camera area.
When the camera has focused, a picture of the pump will be taken automatically.

The pump PIN will be copied automatically.

c. Tap Connect.

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- d. Tap **Confirm** to verify that the serial number matches the one found on the pump label.
- e. Tap in the *Bluetooth Pairing Request* field to display the *Paste* option.
- f. Tap **Paste** to enter the pump PIN.
- g. Tap Pair.

To pair your pump by manually entering the pump serial number and PIN:

a. Tap Enter Manually.

- b. Tap Connect.
- c. Tap **Confirm** to verify that the serial number matches the one found on the pump label.
- d. Using the keypad, enter the 6-digit PIN found on the pump label.
- e. Tap Pair.

#### Pump Software Update

A pump software update is required:

- 1. Tap Continue.
- 2. Tap Next.
- 3. Keep the pump close to the iPhone and do not power off the pump or iPhone during the update.
- 4. After the pump update is completed successfully, tap **Continue**.

#### **Cassette Setup**

- 1. Gather the following supplies to setup and start therapy:
  - A new cassette in unopened sterile packaging
  - Sterile 3 mL syringe and 26 gauge x 1/2 inch needle
  - A new infusion set in unopened sterile packaging
  - Humalog (insulin lispro) or Novolog (insulin aspart) U-100 fast-acting insulin
  - Alcohol wipes
- 2. Wash your hands.
- 3. Open a new cassette and remove it from the package.
- 4. Align the ridges on the pump-bump and the top of the cassette.

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5. Push down and rotate the pump clockwise so the ridge on the pump-bump is aligned with the infusion set tubing.

> A series of *Busy* beeps will be played by the pump while the pump conducts a self-test. The self-test is displayed on the twiist app.

- 6. Wait for the self-test to complete before continuing.
- 7. Scan the cassette with your iPhone camera.



- 8. Using the picker, select your desired **Cassette Fill Volume**.
- 9. Tap Next to continue.
- 10. Fill the cassette with the amount of insulin you selected.
- 11. Open a new infusion set package.
- 12. Attach the infusion set tubing to the cassette by twisting the luer connectors together.
- 13. Tap **Next** to continue.
- 14. Tap **Start Prime** to prime the infusion set tubing.
- 15. Watch for drops to appear at the end of the infusion set tubing.

Drops of insulin at the end of the infusion set tubing indicates the cassette and tubing are primed.

- 16. Tap Stop Prime.
- 17. Tap **Yes** to confirm that priming is complete.

#### Get Looping

1. Select whether you want the twiist system to automate your basal delivery.

If a CGM has not been added, you can turn Loop on later in *Settings* after a CGM has been paired..

2. Tap Continue.

Some features of the twiist automated insulin delivery system may work differently or be unavailable when *Loop* automation is off.

- 3. Connect the primed infusion set tubing to infusion site.
- 4. Tap **Fill Cannula** to select the cannula fill volume according to your infusion set manufacturer instructions.
- 5. Tap Done.

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- 6. Verify the *Cassette Fill Volume* matches what you filled the cassette with.
- 7. To begin insulin delivery, **Start Basal**.

The pump will play the *Delivering* sound.

If you need help consult your twiist user guide or reach out to your healthcare provider.

8. Tap Start twiist.

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## Notifications and Critical Alerts

In order to ensure that important information such as alerts, urgent alerts, and alarms can be displayed on your iPhone lock screen, *Notifications* must be enabled for the twiist app within your iPhone settings.

*Notifications* inform you of alert, urgent alert, or alarm conditions that require your attention.

*Critical Alerts* should be enabled to allow the twiist automated insulin delivery system to bring your attention to urgent alert and alarm conditions while your iPhone is silenced or when features including *Do Not Disturb* are enabled. Always keep *Notifications* and *Critical Alerts* turned on in your iPhone settings to ensure that you receive twiist automated insulin delivery system urgent alerts and alarms.

### Notifications

When the twiist app is running in the background, alerts, urgent alerts, and alarms will initially be displayed as *Notifications* while on the lock screen or while using other apps.





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### **Critical Alerts**

If an urgent alert or alarm is not silenced within 5 minutes, it will be displayed as a *Critical Alert*. The audio will be played at maximum volume on the pump and iPhone, and your iPhone will vibrate.

Disconnect the 1 site and inspect	cked has been suspended. tubing from the influsion for kinks. Insulin will not

## Apple Health

*Apple Health* can be used to store blood glucose, insulin, and carbohydrate data from the twiist automated insulin delivery system.

If you would like to allow this data to be stored in *Apple Health*, tap **Turn On All** in *Settings*. ۲

When you choose to share your data with Apple Health you can use the Apple Health app on your iPhone to track important information including:

- · blood glucose trends
- · daily carbohydrate intake
- total basal and bolus insulin delivered daily
- any changes to your insulin delivery trends



If you would prefer not to store this information in *Apple Health*, you can choose to leave these settings toggled off.

### Set your Blood Glucose Unit of Measure

The twiist automated insulin delivery system uses mg/dL as the default unit of measure for blood glucose.

The *Apple Health* app allows you to configure your glucose settings to set the unit of measure in mg/dL or mmol/L.

The unit of measure used for measuring blood glucose should be set with your healthcare provider after the twiist system has been set up.

To change your blood glucose unit of measure:

1. Open the *Health app* on your iPhone.

- 2. Tap Browse.
- 3. Tap Vitals.
- 4. Tap Blood Glucose.
- 5. Scroll down and tap Unit.
- Tap mg/dL or mmol/L to select the desired unit of measure.
- 7. Tap **Blood Glucose** in the upper left corner to exit after making your selection.

## How the twiist App Works

The twiist app shows you how the system is working through the icons and charts on the *Home Screen*. You can see what is happening at a glance or you can tap on the icons and charts for additional information.

Some features of the twiist app work differently when *Loop* is Off.



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- 1. CGM Status
- 2. Loop Status
- 3. Insulin Delivery Status
- 4. Pump Status/Menu
- 5. Glucose Chart
- 6. Eventual Glucose
- 7. CGM or fingerstick glucose readings
- 8. Glucose Prediction Values
- 9. Correction Range
- 10. Active Insulin Chart
- 11. Current Active Insulin
- 12. Insulin Delivery Chart
- 13. Current Basal Rate
- 14. Bolus Delivery
- 15. Basal Delivery
- 16. Active Carbohydrates Chart
- 17. Current Active Carbohydrates
- 18. Carb Entry
- 19. Pre-Meal Preset
- 20. Bolus
- 21. Workout Preset/Temporary Basal
- 22. Settings

#### Use the twiist app to:

- Manage your personal diabetes settings
- Start and stop basal insulin delivery
- Deliver a bolus for food and to bring down high glucose
- Make temporary adjustments affecting insulin delivery
- View glucose history, insulin delivery, and active carbohydrates
- Complete cassette and battery changes
- Resolve alerts, urgent alerts, and alarms

The *Home Screen* has three main areas:

- Status
- Charts
- Toolbar

## Status



The top of the *Home Screen* displays *Status* icons that provide information about the components of your system. *Status* icons include:

- CGM Status
- Loop Status
- Insulin Delivery Status
- · Pump Status/Menu

The Home Screen also displays Temporary Status Banners, see "Temporary Status Banner" on page 55.

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### CGM Status

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The *CGM Status* icon allows you to see your most recent glucose and rate of change arrow.

You can tap the CGM Status icon for additional CGM Information.

The CGM value displayed will match your Dexcom G6 app. When your CGM value is greater than 400 mg/dL, *HIGH* will be displayed. When your CGM value is lower than 40 mg/dL, *LOW* will be displayed.



Your glucose value is greater than 400.



Your glucose value is lower than 40.

When your CGM reports *HIGH* or *LOW*, check your fingerstick glucose and treat your high or low glucose.

The *Rate of Change* arrow reflects the same rate of change displayed with the Dexcom G6 app.



Your glucose is not rising or falling more than 1 mg/dL per minute. 0

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Your glucose is slowly rising at a rate of 1-2 mg/dL each minute or up to 30 mg/dL in 15 minutes.



Your glucose is rising at a rate of 2-3 mg/dL each minute or up to 45 mg/dL in 15 minutes.



Your glucose is rapidly rising at a rate of more than 3 mg/dL each minute or more than 45 mg/dL in 15 minutes.

Your glucose is slowly falling at a rate of 1-2 mg/dL each minute or up to 30 mg/dL in 15 minutes.

Your glucose is falling at a rate of 2-3 mg/dL

each minute or up to

45 mg/dL in 15

minutes.

Open Dexcom App

Open the Dexcom G6 app for more information.



A blood glucose fingerstick value 😟 has been entered.

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Your glucose is rapidly falling at a rate of more than 3 mg/dL each minute or more than 45 mg/dL in 15 minutes.

Additional *CGM Status* icons may be displayed.

Signal Loss

Your CGM is not in communication with your twiist pump and needs attention.



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No CGM has been paired with the your twiist pump. *Loop* cannot be turned on.



Connecting with your CGM.

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Do not ignore how you feel or symptoms of high and low glucose. If your sensor glucose alerts and readings do not match how you feel, measure your blood glucose with a BG meter even if your sensor is not in the high or low range. Ignoring the symptoms of high and low glucose even when your sensor is not in the high or low range may lead to incorrect treatment decisions which may lead to harm.

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When in doubt, get your meter out.

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### Loop Status

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#### When Loop in on:

When *Loop* is on, a closed circle icon is displayed within the *Loop Status*. The twiist AID system starts with your scheduled basal rate and makes adjustments to your basal delivery automatically.

Tap the **Loop Status** icon for more information, including whether your pump is delivering, and if your basal is being adjusted automatically.





*Loop* was successful within the last 5 minutes and the twiist automated insulin delivery system is automatically adjusting your basal delivery.

It has been 5-15 minutes since the last successful *Loop* and the twiist automated insulin delivery system is automatically adjusting your basal delivery.

You may be experiencing temporary signal loss. Typically, this does not require user action to resolve. It has been more than 15 minutes since the last successful *Loop*. Basal will return to your scheduled rate until



CGM values are available or a fingerstick glucose is manually entered. You may be experiencing a problem with your CGM that requires interaction with the CGM or CGM app to resolve.

This icon can indicate one of the following:

- The pump is initializing
- The twiist pump and app are not in communication
- Insulin delivery has been suspended

When *Loop* is off, an open circle icon is displayed within the *Loop Status*. Your twiist pump delivers your scheduled basal rate. The twiist system can be used with *Loop* off with or without the use of a CGM. When *Loop* is off and no CGM has been added:



 The pump is initializing

- The twiist pump and app are not in communication
- Insulin delivery has been suspended

When *Loop* is off and a CGM has been added:



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Your pump is working properly but it has been more than 15 minutes since your last CGM value was received.

You may be experiencing temporary signal loss that does not typically require user interaction to resolve.

This icon can indicate one of the following:

- The pump is initializing
- The twiist pump and app are not in communication
- Insulin delivery has been suspended

### Insulin Delivery Status



The *Insulin Delivery Status* icon has three states to show you whether basal insulin is being delivered at your scheduled basal rate, or whether your basal delivery has been reduced or increased.

#### Scheduled Basal

A solid line with a value of +0.0 U/hr indicates that your basal is being delivered at your scheduled rate.

It does <u>NOT</u> mean your basal rate is 0.0 U/hr.

#### Reduced Basal

A dropped icon indicates that your basal is reduced by the value shown.

A reduced basal rate is always indicated with a negative value such as -1.0 U/hr.

This means your basal is currently 1.0 U/hr less than your scheduled basal rate.

#### Increased Basal

A raised icon indicates that your basal is increased by the value shown.

An increased basal rate will always be displayed with a positive value such as +3.0 U/hr.

This means your basal is currently 3.0 U/hr more than your scheduled basal rate.

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### Pump Status



The *twiist Pump Status* icon shows you an estimation of how much insulin remains in your cassette, and your pump battery level.



Your cassette has more than 20% of your insulin remaining and your pump

battery has more than 20% charge.

Your cassette has less than 20% of your insulin remaining and your pump battery has less than 20% charge. Your cassette has less than 10% of your insulin remaining and your pump battery has less than 10% charge.

The cassette and pump battery icons are independent from each other and may show different percentages and colors.



Tap the **Pump Status** icon to open the *Pump Menu*. The *Pump Menu* allows you to see important pump information and suspend or resume basal insulin delivery. *See "Pump Menu" on page 79.* 

The *Pump Status* icon will change for specific alarm conditions. *See* "Alerts, Urgent Alerts, and Alarms" on page 133.

### Temporary Status Banner



The twiist app may display a *Temporary Status Banner* below the *Status* icons.

You will see and can interact with this banner in the following situations:

- Track the progress of a bolus being delivered.
- When a temporary basal is active.
- When a cannula fill is in progress.

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- When stopping a bolus or temporary basal that is currently being delivered.
- A No Recent Glucose message is displayed and allows you to add a fingerstick glucose value when CGM readings are not available.
- When insulin delivery is manually suspended.

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## Charts

The largest portion of the *Home Screen* has four charts. Here you can see your glucose and how your insulin and the carbs you have entered are working to impact your glucose.



Press and hold anywhere within the **Charts** to see more information. As you hold your finger on the chart, you can slide left and right to view data for a specific time.



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### Glucose Chart



The *Glucose Chart* shows you important information about your glucose.

- · Where it has been
- · Where it is now
- · Where you want it to be
- · Where it could be going

Press and hold the **Glucose Chart** to see individual glucose entries.

### Correction Range



Your *Correction Range* is displayed as a blue shaded bar.

Your *Correction Range* can be a single value or range of values that you (and your healthcare provider) want Loop to aim for when adjusting your basal insulin and recommending a correction bolus.

Your *Correction Range* is typically a smaller range than the high and low glucose alerts for your CGM. This is where you want your glucose to be.

### **Glucose History**



Blue dots on the *Glucose Chart* show the last 90 minutes of CGM readings or manually entered fingerstick values.

Rotating your phone will allow you to see additional glucose history.

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#### **Glucose Prediction**



A light blue dashed line on the glucose chart shows your *Glucose Prediction*. This is how the twiist AID system predicts your glucose may change over the next few hours. The twiist AID system will update this prediction as often as every 5 minutes as it works to bring your glucose into your *Correction Range*.

When *Loop* is off, no glucose predictions are made or displayed.

#### How Far Out is the Prediction?



The further out the prediction, the less accurate it is. This is because the twiist AID system will continue to make adjustments as often as every 5 minutes in an effort to reach your *Correction Range*.

If low glucose looks likely in the near future, you may want to treat with fast-acting carbs.

Entering these carbs into the twiist app will adjust your glucose prediction.

The twiist AID system cannot prevent all instances of high and low glucose.

If you see a prediction of high or low glucose over the next few hours, it is recommended that you watch the prediction as it updates over the course of the next few loops to decide whether or not to step in.

Always have a source of fast-acting glucose available to take action if your glucose is low.

When *Loop* is on, try smaller amounts of glucose to treat lows. Since the twiist AID system is already adjusting your basal delivery, smaller amounts of glucose are required to prevent lows.

Enter any rescue carbs that you eat into the twiist app so that it has the right information to help avoid rebound low or high glucose.

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### Active Insulin Chart



The Active Insulin Chart shows how much insulin has been delivered but has yet to take action within your body. This chart shows an estimation of how the insulin that has already been delivered is working in your body over the next few hours.

Your current *Active Insulin* is displayed at the top-right corner of the chart.

Press and hold the **Active Insulin Chart** to see more information about active insulin, or tap the chart for insulin delivery and history. Rotating your phone will allow you to see additional *Active Insulin* history.

Active insulin works differently with the twiist automated insulin delivery system than other insulin pumps. The twiist AID system takes into account both your bolus insulin, and your basal insulin, including any temporary adjustments to your basal delivery.

If the twiist AID system predicts a low and your chart shows you have insulin active in your bloodstream, you may want to eat fast-acting carbs to prevent low glucose. If the twiist AID system predicts a high, check your chart to see if you have enough insulin working to reduce your glucose without the need for an additional bolus.

You can tap the **Bolus Entry** button at any time to see if a bolus is recommended right now.

#### Negative Active Insulin

Autor Insults	18.3.9.1
170 110 100	
Insulin Delivery	101000
-	
100.100.000	

You may occasionally see negative values if you have less insulin active in your body than you usually have scheduled for this time. This can happen when your basal delivery has been reduced.

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### Insulin Delivery Chart



The *Insulin Delivery Chart* shows both your basal and bolus delivery history over the last few hours.

Boluses that have been delivered are presented as orange triangles.

Basal is represented as a series of orange bars related to the *Insulin Delivery Status* icon.



Dropped **——** or raised **—** orange bars within the chart show reduced or increased basal delivery.

If you are receiving your scheduled basal rate, a solid line —— will be displayed within the insulin delivery chart.

The *Insulin Delivery Chart* and the *Insulin Delivery Status* will always display how much <u>more</u> or <u>less</u> insulin is being delivered than is currently scheduled.

Your current insulin delivery rate is always displayed in the top-right corner of the insulin delivery chart.



You may see frequent increases and decreases on this chart as Loop works to bring your glucose into your correction range.

Press and hold the **Insulin Delivery Chart** to see more information, or tap the chart for more insulin delivery information.

Rotating your iPhone will allow you to see additional *Insulin Delivery* history.

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#### Event History

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Most of the information you need about your insulin delivery is visible from the *Home Screen*, but tapping the *Active Insulin* or *Insulin Delivery* charts allows you to see your event history.

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Event History	Done	
0.83 CActive Insulan 2	U Total	
Tuesday, January 30, 20	24	
Nasumed	9-28 AM	
Suspended	9/27AM	
Raset 1.5 U/hr		
1 1 Cansertie Not Attache Riem Gode 0	nd gr27AM	
Temp Basst 1.73 Lifte	9/25AM	
Terror Rosert & Thurber	a marks	

Your active insulin and total insulin delivered since midnight are displayed along with:

- delivery suspensions and resumptions
- scheduled basal rate changes
- temporary basal rate changes
- · bolus volume delivered
- interrupted boluses
- · alerts, urgent alerts, and alarms

All events displayed within *Event History* include date and time information.

The twiist app displays up to 14 days of event history.

*Event History* can only be viewed when the twiist app and pump are in communication.

When event history storage on the twiist pump reaches its maximum capacity, the oldest events will be discarded.

For additional information on carbs entered within the twiist app, blood glucose, and insulin delivery, *see "Apple Health" on page 46.* 

The twiist automated insulin delivery system saves and maintains your data when your iPhone or pump loses power.

### Active Carbohydrates Chart



This is a concept that may be new to you if you are coming from insulin injection therapy. The Active Carbohydrates Chart shows the carbs that you have entered into the twiist app and how the twiist AID system expects them to impact your glucose over time.

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The twiist AID system needs to know about all the carbs that you eat in order to update and make its best predictions about your glucose.

If you have incorrect carbohydrate details saved, the twiist AID system may not have up-to-date information.

You may have enough carbs from a previous meal or snack to cover low glucose.

If you have eaten carbs that you have not entered, the twiist AID system may predict that your glucose will go lower because it does not know about those carbs.

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You can tap the **Active Carbohydrates Chart** to see more information.

Tap the Active Carbohydrates Chart to:

- See your last 12 hours of your carb entries.
- · Enter your recent carbs.
- Edit carbs that you have entered.
- Delete carbs that were not eaten or were entered incorrectly. See "Delete or Edit Carb Entry" on page 115.

RAT	
Carbo	hydrates Delete +
Glucose Change 4.1 2.3 3 3 7 KM B KM Prediced © Observed Observed Observed Observed	0 KM 10 KM 11 AM
32 a Active Cartos	60 <sup>g Total</sup>
50-g: P 20 g absorbed	8:58.AM + 3h 4h 5m
10 gi 🔍	7:45.661 + 2h 3h 10m

Rotating your phone will allow you to see additional active carbohydrates history.

## Toolbar

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Carb Entry



to enter details about what you are

eating and to get a bolus

recommendation.

The bottom of the Home Screen displays a Toolbar with buttons for some of the most common features that you will use in the twiist app.

- Carb Entry
- Pre-Meal Preset
- Bolus Entry
- Workout Preset
- Settings

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Each of these buttons allows you to tell the twiist automated insulin delivery system important information to act on.

#### DKPI-09233-001-1.5 DRAFT

Pre-Meal Preset



If you would like the twiist AID system to temporarily lower your Correction Range before a meal to reduce post-meal glucose spikes,

use the *Pre-Meal Preset* <sup>1</sup>

Using this feature before your meal tells the twiist AID system to adjust your Correction Range to your configured Pre-Meal Range.

The Pre-Meal Preset will be in effect for up to one hour, until canceled, or carbs are entered.

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When activated, the *Pre-Meal Preset* button colors will be reversed and the *Glucose Chart* will be updated to show the adjustment to your *Correction Range* as a result of your *Pre-Meal Preset*.

Are-most Preset	
Channe	freemany 111 mg/d.
12	
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-	an line she she

Pre-Meal Preset is unavailable when Loop is off. When *Loop* is off, the twiist system does not adjust your *Correction Range* or automate your basal insulin to bring you to your *Pre-Meal Range*. You will see this button grayed out and unable to be selected.

### Bolus Entry



The Bolus Entry  $\checkmark$  button allows you to deliver a correction bolus to bring down high glucose.

### Workout Preset



If you would like the twiist AID system to temporarily adjust your *Correction Range* for activity, use the *Workout Preset* button.

Using this feature before activity tells the twiist AID system to adjust your *Correction Range* to help you meet your glucose goals during that activity.

*Workout Preset* will be in effect for the time you indicate when you activate it or until you cancel it.

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When activated, the *Workout Preset* button colors will be reversed and the *Glucose Chart* will be updated to show the adjustment to your *Correction Range* as a result of your *Workout Preset*.

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Annual Concession	and the second se

Workout Preset is unavailable when Loop is off.

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When *Loop* is off, the twiist system does not adjust your *Correction Range* or automate your basal insulin to bring you to your

*Workout Range*. The  $\bigcirc$  button is used to manually set a *Temporary Basal*.

### Settings



The Settings <sup>()</sup> button opens the Settings Menu to:

- Turn Loop On of Off
- View your Therapy Settings
- Access the twiist Pump Menu
- View your CGM Information
- View Services and Support



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## Loop On and Off

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The twiist automated insulin delivery system can operate with *Loop* automation on or off.

When the *Loop* toggle is in the **ON** position, the twiist AID system will actively adjust your basal insulin delivery in response to your glucose as often as every 5 minutes.

When the *Loop* toggle is in the **OFF** position, your basal will be delivered based on your programmed delivery rates.

*Loop* will be disabled when you do not have an active CGM session.

You may choose to turn *Loop* off to take full control of your insulin dosing decisions.

1. Tap the **Settings** <sup>(2)</sup> button on the *Toolbar*.

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2. Tap the **Loop toggle** to turn *Loop* on or off.



The twiist app will display *Communicating with Pump*.

## Therapy Settings

Your *Therapy Settings* are initially set within your prescription by your healthcare provider or entered during initial pump training, and must be confirmed prior to use. All changes to *Therapy Settings* should be made with direction from your healthcare provider.

1. Tap the **Settings** <sup>(2)</sup> button on the *Toolbar*.

Values entered that are higher or lower than those that are typically recommended for most people will

caution  $\stackrel{\frown}{\longrightarrow}$  or warn  $\stackrel{\frown}{\longrightarrow}$  you about the selected values.

2. Tap Therapy Settings.



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### Glucose Safety Limit

The *Glucose Safety Limit* can be set as low as 67 mg/dL (3.7 mmol/L) and as high as 110 mg/dL (6.1 mmol/L).

When *Loop* is on, the twiist automated insulin delivery system will deliver basal and recommend bolus insulin only if your glucose is predicted to be above this limit for the next three hours.

A Setting your glucose safety limit incorrectly may lead to insulin dosage errors, which may lead to low or high blood glucose. Your glucose safety limit should be set with direction from your healthcare provider.

#### Edit Glucose Safety Limit

- 1. Tap the **Settings** <sup>(2)</sup> button on the *Toolbar*.
- 2. Tap Therapy Settings.
- 3. Tap on Glucose Safety Limit.

# 4. Tap the current *Glucose Safety Limit* **value**.

- 5. Use the picker to edit your glucose safety limit.
- 6. Tap **Save**. Or tap *Cancel* to return to *Therapy Settings*.
- 7. Enter your iPhone passcode (or Face ID, or Touch ID) to authenticate.

### **Correction Range**

If you have used a CGM before, you are likely familiar with a glucose target range. The wide range of values such as 70-180 mg/dL (3.9 - 10 mmol/L) or 90-200 mg/dL (5.0-11.1 mmol/L) are used for your glucose notification alerts. *Correction Range* is different. Your *Correction Range* is the value or range of values used to tell the twiist AID system where you would like your glucose to be when making adjustments to your basal insulin and when recommending a bolus.

Your healthcare provider can help you choose a *Correction Range* that is right for you.

*Correction Range* can be set as low as 87 mg/dL (4.8 mmol/L) and as high as 180 mg/dL (10 mmol/L)

Setting your Correction Range incorrectly may lead to insulin dosage errors, which may lead to low or high blood glucose. Your Correction Range should be set with direction from your healthcare provider.

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#### Edit your Correction Range

- 1. Tap the **Settings** <sup>(2)</sup> button on the *Toolbar*.
- 2. Tap Therapy Settings.
- 3. Tap on Correction Range.
- 4. Tap on the *Correction Range* you want to edit.
- 5. Use the picker to select a low and high value.
- 6. Tap **Save**. Or tap *Cancel* to return to *Therapy Settings*.
- 7. Enter your iPhone passcode (or Face ID, or Touch ID) to authenticate.

#### Add a new Correction Range

- 1. Tap the **Settings** <sup>(2)</sup> button on the *Toolbar*.
- 2. Tap Therapy Settings.
- 3. Tap on Correction Range.
- 4. Tap+.

- 5. Tap the **start time** within the picker to select a start time for the new *Correction Range*.
- 6. Use the picker to select a **low** and high value.
- 7. Tap Add.
- 8. Tap **Save**. Or tap *Cancel* to return to *Therapy Settings*.
- 9. Enter your iPhone passcode (or Face ID, or Touch ID) to authenticate.

#### Delete a Correction Range

- 1. Tap the **Settings** <sup>(2)</sup> button on the *Toolbar*.
- 2. Tap Therapy Settings.
- 3. Tap on Correction Range.
- 4. Tap Delete.

You will not be able to delete the correction range that begins at 12:00 AM.

 Tap the licon next to the correction range you would like to delete. ۲

- 6. Tap Delete.
- 7. Tap Done, if needed.
- 8. Tap **Save**.
- 9. Enter your iPhone passcode (or Face ID, or Touch ID) to authenticate.

### Pre-Meal Range

Your *Pre-Meal Range* is the glucose value (or range of values) you want the twiist AID system to target in the time leading up to the first bite of your meal. This range will be in effect when you activate the *Pre-Meal Preset* button.

This will typically be <u>lower</u> than your *Correction Range*.

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Your *Pre-Meal Range* can be set as low as your *Glucose Safety Limit* and as high as 130 mg/dL (7.2 mmol/L).

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Your *Pre-Meal Range* only applies when *Loop* is on.

When *Loop* is off, the system does not adjust your *Correction Range* or automate your basal insulin to bring you to your *Pre-Meal Range*.

Setting your pre-meal range incorrectly may lead to insulin dosage errors, which may lead to low or high blood glucose. Your pre-meal range should be set with direction from your healthcare provider.

#### Edit your Pre-Meal Range

- 1. Tap the **Settings** <sup>(2)</sup> button on the *Toolbar*.
- 2. Tap Therapy Settings.
- 3. Tap on Pre-Meal Range.

- 4. Tap the current *Pre-Meal Range* value.
- 5. Use the picker to select a **low and high value**.
- 6. Tap **Save**. Or tap *Cancel* to return to *Therapy Settings*.
- 7. Enter your iPhone passcode (or Face ID, or Touch ID) to authenticate.

### Workout Range

*Workout Range* is the glucose value (or range of values) you want *Loop* to target during activity. This range will be in effect when you activate the *Workout Preset* button.

This will typically be higher than your *Correction Range*.

Your *Workout Range* can be set as low as 87 mg/dL (4.8 mmol/L) or your *Glucose Safety Limit*, whichever is higher. It can also be set as high as 250 mg/dL (13.9 mmol/L).

Your *Workout Range* only applies when *Loop* is on.

When *Loop* is off, the system does not adjust your *Correction Range* or automate your basal insulin to bring you to your *Workout Range*.

Setting your workout range incorrectly may lead to insulin dosage errors, which may lead to low or high blood glucose. Your workout range should be set with direction from your healthcare provider.

#### Edit your Workout Range

- 1. Tap the **Settings** <sup>(2)</sup> button on the *Toolbar*.
- 2. Tap Therapy Settings.

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- 3. Tap on Workout Range.
- 4. Tap the current *Workout Range* value.
- 5. Use the picker to select a low and high value.
- 6. Tap **Save**. Or tap *Cancel* to return to *Therapy Settings*.
- 7. Enter your iPhone passcode (or Face ID, or Touch ID) to authenticate.

### Carb Ratios

Your *Carb Ratio* is the number of grams of carbohydrates covered by one unit of insulin.

*Carb Ratios* can be set as low as 2 g/U and as high as 150 g/U in 0.1 g/U increments.

Setting your carb ratios incorrectly may lead to insulin dosage errors, which may lead to low or high blood glucose. Your carb ratios should be set with direction from your healthcare provider.

#### Edit Carb Ratio

- 1. Tap the **Settings** 😳 button on the *Toolbar*.
- 2. Tap Therapy Settings.
- 3. Tap on Carb Ratios.
- 4. Tap on the *Carb Ratio* you want to edit.
- 5. Use the picker to select the new *Carb Ratio* value.
- 6. Tap **Save**. Or tap *Cancel* to return to *Therapy Settings*.
- 7. Enter your iPhone passcode (or Face ID, or Touch ID) to authenticate.

#### Add a new Carb Ratio

1. Tap the **Settings** 😳 button on the *Toolbar*.

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- 2. Tap Therapy Settings.
- 3. Tap on Carb Ratios.
- 4. Tap+.
- 5. Tap the **start time** within the picker to select a start time for the new *Carb Ratio*.
- 6. Use the picker to select the new *Carb Ratio* value.
- 7. Tap **Add**.
- 8. Tap **Save**. Or tap *Cancel* to return to *Therapy Settings*.
- 9. Enter your iPhone passcode (or Face ID, or Touch ID) to authenticate.

#### Delete a Carb Ratio

- 1. Tap the **Settings** <sup>(2)</sup> button on the *Toolbar*.
- 2. Tap Therapy Settings.

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- 3. Tap on Carb Ratios.
- 4. Tap Delete.

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You will not be able to delete the carb ratio that begins at 12:00 AM.

- 5. Tap the icon next to the carb ratio you would like to delete.
- 6. Tap Delete.
- 7. Tap Done, if needed.
- 8. Tap Save.
- 9. Enter your iPhone passcode (or Face ID, or Touch ID) to authenticate.

### **Basal Rates**

Your *Basal Rate* is the units of insulin per hour (U/hr) you want to use to cover your background insulin needs.

The twiist automated insulin delivery system allows you to set

Basal Rates in 30 minute increments, so you can set up to 48 individual rates per day.

The *Basal Rate* schedule starts at midnight.

*Basal Rates* can be set with a minimum value of 0.00 U/hr and a maximum value of 30 U/hr and can be adjusted in increments of 0.05 U/hr. The basal rate is limited by the *Maximum Basal Rate* setting.

A Setting your basal rates incorrectly may lead to insulin dosage errors, which may lead to low or high blood glucose. Your basal rates should be set with direction from your healthcare provider.

#### Edit Basal Rate

- 1. Tap the **Settings** 😳 button on the *Toolbar*.
- 2. Tap Therapy Settings.

- 3. Tap on Basal Rates.
- 4. Tap on the *Basal Rate* you want to edit.
- 5. Tap the **start time** within the picker if you want to change the start time for the *Basal Rate*.
  - You will not be able to edit the basal rate that begins at 12:00 AM.
- 6. Use the picker to select the new **Basal Rate U/hr value**.
- 7. Tap **Save** or tap *Cancel* to return to *Therapy Settings*.
- 8. Enter your iPhone passcode (or Face ID, or Touch ID) to authenticate.

#### Add a new Basal Rate

- 1. Tap the **Settings** <sup>(2)</sup> button on the *Toolbar*.
- 2. Tap Therapy Settings.
- 3. Tap on Basal Rates.

4. Tap+.

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- 5. Tap the **start time** within the picker to select a start time for the new *Basal Rate*.
- 6. Use the picker to select the new **Basal Rate U/hr** value.
- 7. Tap **Add** or tap *Cancel* to return to *Basal Rates*.
- 8. Enter your iPhone passcode (or Face ID, or Touch ID) to authenticate.

#### Delete a Basal Rate

- 1. Tap the **Settings** <sup>(2)</sup> button on the *Toolbar*.
- 2. Tap Therapy Settings.
- 3. Tap on Basal Rates.
- 4. Tap Delete.
  - You will not be able to delete the basal rate that begins at 12:00 AM.

- 5. Tap the e icon next to the Basal Rate you would like to delete.
- 6. Tap Delete.
- 7. Tap Done, if needed.
- 8. Tap **Save** or tap *Cancel* to return to *Therapy Settings*.
- 9. Enter your iPhone passcode (or Face ID, or Touch ID) to authenticate.

### **Delivery Limits**

*Delivery Limits* are safety guardrails for your insulin delivery, including the adjustments that the twiist AID system can make to your basal insulin.

#### Maximum Basal Rate

Maximum Basal Rate is the maximum basal rate or temporary basal that can be set in the twiist automated insulin delivery system. When Loop is on, Maximum Basal Rate is the highest temporary rate that can be delivered automatically to help reach your correction range.

Some users choose values two to four times their highest scheduled basal rate.

Work with your healthcare provider to set a *Maximum Basal Rate* that is right for you.

A Setting your Maximum Basal Rate incorrectly may lead to insulin dosage errors, which may lead to low or high blood glucose. Your Maximum Basal Rate should be set with direction from your healthcare provider.

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Insulin delivery must be suspended before the *Maximum Basal Rate* can be modified. *See "Suspend Insulin Delivery" on page 80.* 

- 1. Tap the **Settings** <sup>(2)</sup> button on the *Toolbar*.
- 2. Tap Therapy Settings.
- 3. Tap Delivery Limits.

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- 4. Tap Maximum Basal Rate.
- 5. Use the picker to select the *Maximum Basal Rate* U/hr value.
- 6. Tap **Save**. Or tap *Cancel* to return to *Therapy Settings*.
- 7. Enter your iPhone passcode (or Face ID, or Touch ID) to authenticate.

#### Maximum Bolus

The *Maximum Bolus* setting limits the largest bolus that the twiist automated insulin delivery system will recommend or allow at one time to cover carbs (meal bolus) or bring down high glucose (correction bolus).

Setting your *Maximum Bolus* incorrectly may lead to insulin dosage errors, which may lead to low or high blood glucose. Your *Maximum Bolus* should be set with direction from your healthcare provider.

Insulin delivery must be suspended before the *Maximum Bolus* can be modified. *See "Suspend Insulin Delivery" on page 80.* 

- 1. Tap the **Settings** <sup>(2)</sup> button on the *Toolbar*.
- 2. Tap Therapy Settings.

- 3. Tap **Delivery Limits**.
- 4. Tap Maximum Bolus.
- 5. Use the picker to select the *Maximum Bolus* value in Units.
- 6. Tap **Save**. If you want to cancel, tap *Cancel* to return to *Therapy Settings*.
- 7. Enter your iPhone passcode (or Face ID, or Touch ID) to authenticate.

### Insulin Model

The *Insulin Model* sets the peak insulin activity time. The twiist automated insulin delivery system assumes that the insulin delivered is actively working to lower your glucose for 6 hours, and measures the peak insulin activity according to one of these insulin models:

 Rapid-Acting Adult: assumes peak insulin activity is at 75 minutes.

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 Rapid-Acting Child: assumes peak insulin activity is at 65 minutes.

Setting your Insulin model incorrectly may lead to insulin dosage errors, which may lead to low or high blood glucose. Your insulin model should be set with direction from your healthcare provider.

#### Edit your Insulin Model:

- 1. Tap the **Settings** <sup>(C)</sup> button on the *Toolbar*.
- 2. Tap Therapy Settings.
- 3. Tap on Insulin Model.
- 4. Tap on the **Rapid-Acting Adults** or **Rapid-Acting Children** model.

The selected model will be followed by the  $\checkmark$  symbol.

5. Tap **Save**. Or tap *Cancel* to return to *Therapy Settings*.

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

### Insulin Sensitivities

*Insulin Sensitivity* refers to the drop in glucose expected from one unit of insulin.

Insulin Sensitivities can be set as low as 10 mg/dL per Unit (0.6 mmol/L/U) and as high as 500 mg/dL per Unit (27.8 mmol/L/U) in 1 mg/dL per Unit (0.1 mmol/L/U) increments.

Setting your insulin sensitivity incorrectly may lead to insulin dosage errors, which may lead to low or high blood glucose. Your insulin sensitivity should be set with direction from your healthcare provider.

#### Edit your Insulin Sensitivities

- 1. Tap the **Settings** <sup>(2)</sup> button on the *Toolbar*.
- 2. Tap Therapy Settings.
- 3. Tap Insulin Sensitivities.
- 4. Tap on the *Insulin Sensitivity* you want to edit.
- 5. Use the picker to select a sensitivity.
- 6. Tap **Save**. Or tap *Cancel* to return to *Therapy Settings*.
- 7. Enter your iPhone passcode (or Face ID, or Touch ID) to authenticate.

#### Add a new Insulin Sensitivity

- 1. Tap the **Settings** <sup>(2)</sup> button on the *Toolbar*.
- 2. Tap Therapy Settings.
- 3. Tap on Insulin Sensitivities.
- 4. Tap+.

- 5. Tap the **start time** within the picker to select a start time for the new *Insulin Sensitivity*.
- 6. Use the picker to select a sensitivity.
- 7. Tap Add.

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- 8. Tap **Save**. Or tap *Cancel* to return to *Therapy Settings*.
- 9. Enter your iPhone passcode (or Face ID, or Touch ID) to authenticate.

#### Delete an Insulin Sensitivity

- 1. Tap the **Settings** <sup>(2)</sup> button on the *Toolbar*.
- 2. Tap Therapy Settings.
- 3. Tap on Insulin Sensitivities.
- 4. Tap Delete.

You will not be able to delete the insulin sensitivity that begins at 12:00 AM.

- 5. Tap the e icon next to the correction range you would like to delete.
- 6. Tap Delete.
- 7. Tap Done, if needed.
- 8. Tap **Save**.
- 9. Enter your iPhone passcode (or Face ID, or Touch ID) to authenticate.

### Temporary Basal Adjustment

The *Temporary Basal* and the *Temporary Basal Adjustment* setting are not available when Loop is on.

When *Loop* is off, a *Temporary Basal* can be set to increase or decrease your scheduled basal delivery. The *Temporary Basal Adjustment* setting allows you to choose percentage adjustment or an override of your set basal rate as the method to set a *Temporary Basal*.

By default, the twiist system uses a percentage adjustment.

To adjust how a temporary basal is delivered:

- 1. When *Loop* is off, tap the **Settings** to button on the *Toolbar*.
- 2. Tap Therapy Settings.
- 3. Tap Temporary Basal.
- 4. Tap the radio button next to **Percent** or **Rate** to select the desired method for *Temporary Basal Adjustment*.

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The selection will be followed by the symbol.

5. Tap **Save** or tap *Back* to cancel and return to *Therapy Settings*.

To start a *Temporary Basal*, See "Set Temporary Basal" on page 127.

### **One-Button Bolus**

*One-Button Bolus* is disabled by default and should only be enabled with direction from your healthcare provider.

In order to deliver a *One-Button Bolus*, this feature must be enabled within *Therapy Settings*.

- 1. Tap the **Settings** button on the *Toolbar*.
- 2. Tap Therapy Settings.
- 3. Tap One-Button Bolus.

- 4. Tap the toggle to enable or disable.
- 5. Tap **Save** to return to *Therapy Settings*.

For patients who do not self-manage their diabetes care, always leave the One-Button Bolus feature disabled to avoid accidental bolus delivery. Enabling the One-Button Bolus feature allows for bolus delivery without the twiist app and may result in over delivery of insulin resulting in low blood glucose.

### Extended and Dual Bolus

The *Extended Bolus* setting allows you to enable the use of a bolus delivery feature to deliver a bolus over an extended time in order to prevent a delayed increase in blood glucose from certain types of food. The *Dual Bolus* setting allows you to enable the use of a bolus delivery feature that allows some insulin to be delivered now and some over an extended period of time.

The *Extended* and *Dual Bolus* features and settings are not available when Loop is on.

The *Extended* or *Dual Bolus* features are off by default and should only be used with direction from your healthcare provider.

To enable *Extended* or *Dual Bolus* features:

- With Loop off, tap the Settings
   button on the Toolbar.
- 2. Tap Therapy Settings.
- 3. Tap Extended Bolus or Dual Bolus.
- 4. Tap the toggle to enable or disable the *Extended Bolus* or *Dual Bolus* features.

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5. Tap **Save** to return to *Therapy Settings* or tap *Back* to cancel and return to *Therapy Settings*.

### Quiet Mode

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*Quiet Mode* limits the sounds played by the twiist pump when in communication with the twiist app.

When quiet mode is on, and the twiist pump and app are in communication, pump audio will not be played in the following conditions:

- Priming
- Basal delivery is started or stopped
- Temporary basal is started or stopped
- Bolus delivery is started or stopped

*Quiet Mode* will not silence:

- interaction with the pump button, which include resuming or verifying delivery and putting the pump into pairing mode
- · one-button bolus
- alerts, urgent alerts, or alarms
- 1. Tap the **Settings** button on the *Toolbar*.
- 2. Tap Therapy Settings.
- 3. Tap Quiet Mode.
- 4. Tap the toggle to enable or disable.
- 5. Tap **Save** to return to *Therapy Settings*.

### Low Insulin Alert #1

*Low Insulin Alert #1* cannot be changed or turned off. This alert will occur when there are 10 Units of insulin remaining in your cassette.

### Low Insulin Alert #2

The *Low Insulin Alert #* 2 setting allows you to configure an additional instance of *the Low Insulin Alert* to occur between 20 and 100 Units.

To enable or disable *Low Insulin Alert* #2:

- 1. Tap the **Settings** <sup>()</sup> button on the *Toolbar*.
- 2. Tap Therapy Settings.
- 3. Tap Low Insulin Alert #2.
- 4. Tap the toggle to enable or disable.

If enabling, tap **Low Insulin Alert #2** and set the **volume** using the picker.

5. Tap **Save** or tap *Back* to cancel and return to *Therapy Settings*.

### Urgent Low Glucose Alert

The Urgent Low Glucose Alert cannot be changed or turned off. This alert will occur when your CGM reports your glucose is at or below 55 mg/dL.

### Phone Out of Range Alert

The Phone Out of Range Alert setting allows you to enable or disable an alert when the pump has been out of communication with the twiist app for a configured time.

To enable or disable *Phone Out of Range Alert*:

- 1. Tap the **Settings** <sup>(2)</sup> button on the *Toolbar*.
- 2. Tap Therapy Settings.

- 3. Tap Phone Out of Range Alert.
- 4. Tap the toggle for **Enable Phone Out of Range Alert**.

If enabling, tap **Phone Out of Range Alert** and set the alert time to 1 - 120 minutes using the picker.

5. Tap **Save** to return to *Therapy Settings* or tap *Back* to cancel and return to *Therapy Settings*.

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# Pump Menu

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To access the *twiist Pump Menu,* tap on the **Pump Status** icon.



The *Pump Menu* allows you to see the status of:

- Cassette info, including volume remaining and cassette age
- Pump battery percentage remaining

The *Pump Menu* provides access to:

- Suspend/Resume Delivery
- Fill Cannula
- Change Cassette
- Change Pump Battery
- Delete Pump



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### Suspend Insulin Delivery

- 1. Tap the *Pump Status* icon on the *Home Screen* to open the *Pump Menu*.
- 2. Tap Suspend Delivery.

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A message is displayed asking if you are sure you want to suspend insulin delivery.

3. Tap **Confirm** to suspend insulin delivery.

The pump will play the *Delivery Stopped* sound.

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

The following areas of the *Home Screen* will change:

- The Pump Status icon and Temporary Status Banner will display Insulin Suspended.
- The Loop Status icon will change to gray and, when tapped, informs you that basal delivery is suspended.
- The *Insulin Delivery Chart* will display as *U/hr*.



### Resume Insulin Delivery

1. Tap the **Temporary Status Banner** or tap the **Insulin Suspended** icon.



2. Tap Resume Delivery.

The *Home Screen* will display a *Communicating with Pump* message, and the pump will play the *Delivering* sounds.

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

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The following areas of the *Home Screen* will change:

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- The *Loop Status* will display a closed circle icon to inform you that your pump is automating your basal delivery.
- *Insulin Delivery Status* shows that you are delivering and the change from your scheduled rate.
- The *Pump Status* icon shows the pump battery and cassette info.
- The Insulin Delivery Chart will display your current basal rate.

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### Cassette Change

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*Cassette Change* is a step-by-step process for changing out your cassette and supplies to restart delivery.

A cassette change will need to be completed after 72 hours or when the cassette is empty, whichever comes first.

The twiist automated insulin delivery system provides onscreen, step-by-step instructions. Do not jump ahead of the twiist app.

#### Change Cassette

- 1. Tap the **Pump Status** icon to open the *Pump Menu*.
- 2. Tap Change Cassette.

#### Gather your Supplies

The following supplies are needed for a cassette change:

- A fully charged pump battery
- A new cassette in unopened sterile packaging
- Sterile 3 mL syringe and 26 gauge x 1/2 inch needle
- A new infusion set in unopened sterile packaging
- Humalog (insulin lispro) or Novolog (insulin aspart) U-100 fast-acting insulin
- Alcohol wipes

A Only use fast-acting U-100 Humalog (insulin lispro), or Novolog (insulin aspart). Use of other concentrations or drugs may lead to delivery errors that may lead to low or high blood glucose.

A Only use cassettes and infusion sets listed in the user guide. Failure to do so may affect accuracy or blockage detection which may lead to over or under delivery and cause low or high blood glucose.

Do not use cassettes, infusion sets, needles, or syringes that are past the expiration date on their packages. Using expired sterile components may lead to infection.

Do not use cassettes, infusion sets, needles, or syringes from previously opened or damaged sterile packaging. Use of disposable components from previously opened or damaged sterile packaging may lead to infection.

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Do not use damaged cassettes or infusion sets. Using damaged cassettes or infusion sets may result in start-up failures, interruptions in therapy, or topical exposure to insulin.

#### Start Cassette Change

1. Tap **Start Cassette Change** when you have gathered all your supplies.

> Insulin delivery must be suspended in order to conduct a cassette change.

2. Tap **Confirm** to verify that you are sure you want to suspend insulin delivery.

The pump will play the *Delivery Stopped* sound.

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

#### **Disconnect Infusion Site**

- 1. Disconnect the infusion set tubing from your infusion site.
- 2. Remove the cannula from the infusion site.
- 3. Tap Next.

Before removing the cassette from your pump, disconnect the infusion set tubing from your infusion site. Unintended delivery of medication may occur, leading to low blood glucose, if the cassette is removed from the pump before disconnecting from the infusion site.

# *Remove and Dispose of Used Cassette*

Avoid unnecessary contact with the inside of the pump and cassette which are exposed during a cassette change.

Keep dirt, lubricants, and liquids away from the inside of the pump and cassette which are exposed during a cassette change.  Holding the cassette still, rotate the pump counterclockwise until the ridges on the pump-bump and the top of the cassette are aligned.

The pump will play a *Ready* beep.

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



2. Remove the cassette from the pump.



3. Dispose of the used cassette, infusion set tubing, and infusion site.

Contact your local authorities to determine the proper method for disposal of used cassettes and infusion sets. Improper disposal of these items may result in injury to the operator and others from exposure to sharp or contaminated components.

Dispose of used components such as cassettes, syringes, needles, infusion sets, and CGM sensors following the instructions from your local authorities. Wash your hands thoroughly after handling used components.

#### Replace Pump Battery

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1. Remove the battery from the pump.



2. Insert the depleted battery into the battery charger.

3. Get a fully charged battery from the battery charger.

This is indicated by a green status light on the battery charger.



4. Insert the fully charged battery into the pump.



When the battery is inserted successfully, the pump will play a quick beep followed by a *Ready* beep and the twiist app will advance automatically.

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#### Wash your Hands

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1. Wash your hands with soap and water.



#### Attach New Cassette to Pump

- 1. Open a new cassette and remove it from the package.
- 2. Check the interface between the pump and cassette to make sure it is clean and free of fluid and debris.
- 3. To attach the cassette to the pump, align the ridges on the pump-bump and the top of the cassette.



4. Push down and rotate the pump clockwise so the ridge on the pump-bump is aligned with the infusion set tubing.



- A series of *Busy* beeps will be played by the pump while the pump conducts a self-test. The self-test is displayed on the twiist app.
- 5. Wait for the self-test to complete before continuing.

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