Security Features Disabled

Notice Display	**Description:**
	Security features must be enabled on your iPhone. If security features on your iPhone are disabled, you will not be able to use the twiist app. Enable security features on your iPhone to continue using the twiist app.
	What To Do: 1. Navigate to your iPhone *Settings* and select **Face ID & Password**. 2. Tap **Turn Passcode On**, enter and confirm an iPhone passcode.

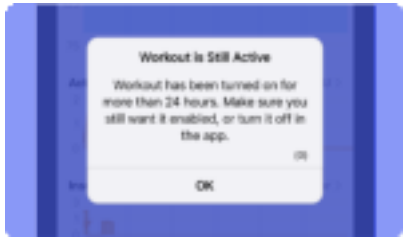
System Time Updated

Notice Display	**Description:**
	Your *System Time* may be automatically updated by your iPhone when you change time zones or as a result of daylight savings time. The twiist app will notify you when your system time has been automatically updated.
Sounds Pump: None iPhone: iPhone default notification sound on lock screen or while using a different app. No sound is played while the twiist app is displayed.	**What To Do:** 1. Tap **OK** to dismiss. Time changes can affect your therapy. Discuss traveling with your healthcare provider to determine the right treatment for you. The twiist automated insulin delivery system will deliver the basal rate for the time set on your system clock. If an adjustment needs to be made to compensate for the time change, consider setting a *Temporary Basal*. *See "Set Temporary Basal" on page 127.*

The twiist App is Closed

Notice Display	**Description:**
 **Sounds** Pump: None iPhone: iPhone default notification sound on lock screen or while using a different app.	You have closed the twiist app. Closing the twiist app will result in a loss of communication with the twiist pump. *Alarms*, *Urgent Alerts*, and *Alerts* will not be displayed, and notification sounds will not be played on the iPhone until the app is opened. Quitting the twiist app or removing it from your iPhone will result in loss of communication. **What To Do:** 1. Tap the notification to open the twiist app.

Workout is Still Active

Notice Display	**Description:**
 **Sounds** Pump: None iPhone: iPhone default notification sound on lock screen or while using a different app. No sound is played while the twiist app is displayed.	When setting up your *Workout Preset*, you selected the *Until I turn off* option. After the workout preset has been enabled for 24 hours, you will be notified that your workout is still active. **What To Do:** 1. Tap **OK** to dismiss. 2. Choose to turn off the *Workout Preset* if you would like the twiist automated insulin delivery system to adjust your insulin using your *Correction Range*, or keep your workout preset enabled if you would like the twiist automated insulin delivery system to adjust your basal insulin based on your workout range.

Apple Watch

You can choose to use an Apple Watch with the twiist automated insulin delivery system.

This optional component provides a discreet way to view your sensor glucose and insulin information. When *Loop* is on, you can also enter carbs and deliver a bolus.

Your Apple Watch must be within Bluetooth range of your iPhone to work with the twiist automated insulin delivery system. If Bluetooth is not available, your Apple Watch will try to use Wi-Fi. Apple Watch must be on and within Bluetooth (or WiFi) range of your iPhone, and your iPhone must be within Bluetooth range of your pump in order for the watch to send commands to the pump.

Apple Watch cannot work with the twiist system when out of range of your iPhone. All commands from your Apple Watch must pass through your iPhone to reach your pump.

Apple Watch Toolbar

The face of the Apple Watch app displays the *Loop Status Icon* and *CGM Status* data at the top, with four of the five *Toolbar* buttons from the twiist app. (The *Settings* button is not available on the Apple Watch.)

With your Apple Watch in range of your iPhone, you can enable your *Pre-Meal Preset* or *Workout Preset*.

Tapping *Carb Entry* or *Bolus Entry* will open more options. You can tap emoji presets to select a food type, tap into the entry fields, and you can use the up or down buttons to adjust the values or the watch's side crown wheel to dial up or down to adjust values.

Additional confirmations will appear to prevent accidental entries.

Apple Watch Status Screen

Swiping from right to left across the Apple Watch twiist app home screen opens a secondary status screen which displays your current *Glucose Chart*.

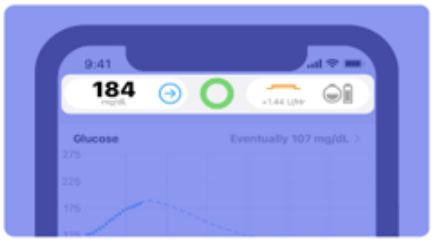
Scroll down to view information like *Active Insulin*, *Active Carbs*, *Insulin Delivery Status*, and *Cassette Info*.

To see your twiist AID system information on your Apple Watch main watch face, you can install the twiist app as a watch face complication. Tapping the complication from your primary watchface will allow you to open the twiist app on your watch.

If at any time you are uncertain about whether a command from your Apple Watch was successful, check the twiist app on your iPhone. Your charts and insulin history *Event Log* should display any recent changes to your glucose and insulin.

Before Sleeping with Loop

One of the benefits of automated basal dosing for many people with diabetes, and their loved ones, is sleeping with fewer interruptions from low and high glucose.



Before you go to sleep at night, check in with your *Home Screen* status icons to ensure the twiist automated insulin delivery system is running smoothly.

Make sure *Loop* is on and your:

- pump is delivering
- iPhone is charging or has enough battery to last the night
- pump has enough battery charge
- cassette has enough insulin

The twiist automated insulin delivery system will work while you sleep to help keep you in your correction range without your intervention.

If you are trending low or high before bed time, you may want to take additional action, or monitor more closely, to prevent highs and lows.

When *Loop* is disabled, your basal delivery will not be automatically adjusted.

App and Pump Updates

It is recommended to have *Automatic Updates* enabled on your iPhone so you are always running the latest version of Apple software.

If you update the Apple software and the version of the twiist app you are running has not been tested with the updated version, a warning will be displayed.

! Warning

If you experience issues with the twiist app due to the Apple software update:

- Do not rely on the twiist app for monitoring or treatment decisions.
- Contact Sequel customer support. *See "Customer Support" on page 195.*

Tap **Continue to App** to clear this warning and continue to the twiist app.

App Updates

Your iPhone must have a Wi-Fi or cellular network connection in order for software updates to be received.

If you receive a *Phone Battery Low* notice, your iPhone has less than 10% battery remaining.

1. Tap **OK** to dismiss.
2. Connect your iPhone to power before starting the software update.
3. Tap **Next** to continue with the software update.

It is recommended to configure your *App Store* settings so app updates are automatically installed. New versions of the twiist app will automatically be installed when they are available.

If automatic updates are disabled in your *Settings*, check the *App Store* frequently for twiist app updates.

Pump Updates

When a new version of the twiist app has been installed, it will check to see if new compatible pump software is available.

Pump updates received from the cloud are sent to the pump through Bluetooth communication.

If a pump update is available, a dialog will be displayed informing you that a pump update has been received.

You can choose to update the pump software *Now* or *Later*.

If you choose *Later*, the *pump status* icon indicates that there is a *Pump Update Required* along with an orange dot.

To update the pump software now:

1. Tap **Now** to display the *Pump Software Update.*

   The twiist app will display the pump update progress. Keep your pump close to the iPhone. Do not quit the app or power off the pump or iPhone during the update.

2. Tap **Next** to suspend insulin delivery and continue.

   Insulin delivery will be suspended.

   The pump will play the *Delivery Stopped* sounds.

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

3. When the update is complete, the pump will start a self-test. Wait for the self-test to complete.

   A message will be displayed to inform you that the update is complete and ask you to *Resume Basal Delivery*.

4. Tap **Yes** to resume delivery, or **No** to keep insulin delivery suspended.

   Upon resuming basal delivery, the pump will sound the *Delivering* sounds.

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

5. Tap **Done** on the *Pump Menu* to return to the *Home Screen.*

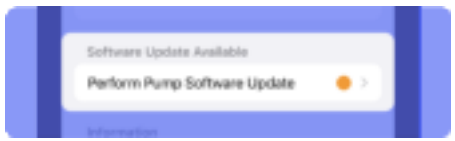
To update the pump software later:

1. Tap **Later**.
2. Using the picker, select the number of hours you would like to set the *Software Update Reminder* to and tap **Schedule**. You can choose between 1 and 24 hours.

At the scheduled time, the *Pump Update Received* message will be repeated.

You can choose to install the pump update at that time, or set an additional reminder.

1. Tap the **Pump Status** icon.
2. Tap **Perform Pump Software Update** on the *Pump Menu* to display the pump software update information.



   Insulin delivery will be suspended. The pump will play the *Delivery Stopped* sounds.

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

3. When the update is complete, the pump will start a self-test. Wait for the self-test to complete.

   A message will be displayed to inform you that the update is complete and to ask you to *Resume Basal Delivery*.

4. Tap **Yes** to resume delivery, or **No** to keep insulin delivery suspended.

   Upon resuming basal delivery, the pump will play the *Delivering* sounds.

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

5. Tap **Done** on the *Pump Menu* to return to the *Home Screen.*

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.

Clean the Pump

Dust, lint, and debris on or in the pump may have the following effects on the system:

- Decrease the water ingress protection rating.
- Interfere with the electrical connection between the pump and battery causing *Alarms* to occur.
- Cause the pump to fail self-test.
- Scrape the surface of the cassette causing leaks.

- Interfere with rotating the locking ring when connecting or disconnecting the cassette and pump.

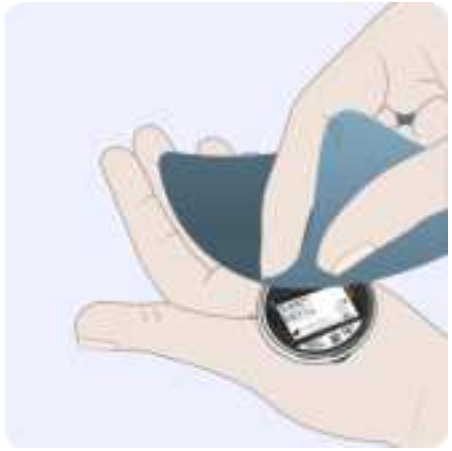
Clean the pump as needed to keep it free of dust, lint and debris or following exposure to dust or liquid contaminants.

1. Verify the pump cover or a cassette is attached to the pump before cleaning.
2. Clean the pump with water and a mild soap such as dish detergent or hand soap.

Do not place the pump in a dishwasher.

3. Thoroughly rinse the pump with water.
4. Thoroughly dry the pump with a dry cloth or paper towel.

5. Remove the pump cover or cassette.
6. If any moisture is visible, gently blot the interior of the pump with a dry cloth or paper towel.



7. Make sure there is no moisture in the pump.

   Do not rub or press on the inside of the pump.

Prepare to Travel

Traveling with the twiist automated insulin delivery system requires some planning ahead. Be sure to order supplies before your trip so that you have enough with you while you are away from home.

Keep your emergency supplies with you during trips or vacations. It may be difficult or impossible to get insulin or supplies at your destination. When you travel outside the country or for long periods of time, be sure to take extra supplies.

In addition to your *Emergency Supplies*, you should also always bring the following items:

- A prescription for both rapid-acting and long-acting insulin of the type recommended by your healthcare provider in case you need to take insulin by injection.
- A letter from your healthcare provider explaining the medical need for your insulin pump and other supplies.

It is important that you check your glucose more frequently while you are traveling. Changes in time zones, activity levels, and mealtimes can all affect your glucose.

Airport Security

Before traveling by plane, familiarize yourself with the airport security procedures and prepare your diabetes supplies for the security process and flight. Airport security checks and screening procedures may change, so review the airport website and the TSA website for travel updates before your trip. Pack your pump supplies in your carry-on luggage. Do not pack your supplies in checked luggage as it could get delayed or lost.

Airport security offers the option of requesting a visual inspection of your medical supplies rather than putting them through the X-ray. You must request this before the screening process begins.

- Your medical supplies should be in a separate bag when you approach the security officer.
- To prevent contamination or damage to your supplies, you should display, handle, and repack your own supplies during the visual inspection process.
- Notify the security agent that your pump should not be exposed to X-ray machines and request an alternate means of screening.

Visit the TSA contact center if you have any further questions or concerns.

Traveling with Spare Pump Batteries

When traveling, spare pump batteries must be protected from damage to prevent a short circuit from occurring. Spare pump batteries must be placed in carry-on baggage only. Do not transport damaged pump batteries.

Prepare alternate pump batteries for travel using one of the following methods:

- Place batteries individually within a battery case.
- Place batteries individually in a plastic bag or protective pouch.
- Place batteries in the provided pump battery charger.

⚠ Do not expose your twiist pump to X-ray screening used for carry-on and checked luggage. Newer full body scanners used in airport security screening are also a form of X-ray and your pump should not be exposed to them. Notify the security agent that your pump cannot be exposed to X-ray machines and request an alternate means of screening. Your pump has been designed to withstand common electromagnetic interference including airport metal detectors.

Frequently Asked Questions (FAQ)

My battery charger status light is blinking red when I insert the pump battery. What should I do?

1. Try reinserting the pump battery in the battery charger.
2. If the status light continues to blink red, try inserting the pump battery into the other charging bay.
3. One or more of the following components may be defective:
   - Pump Battery Charger
   - Pump Battery

   Contact Sequel Customer Support.

Why are my battery charger status light(s) not turning on when the pump batteries are inserted?

1. Verify the connections between the battery charger, USB cable, and wall power adapter are secure.
2. Verify the wall power adapter is plugged into a power source.
3. One or more of the following components may be defective:
   - USB Cable
   - Wall Power Adapter
   - Pump Battery Charger
   - Pump Battery

   Contact Sequel Customer Support.

Can I use the system without my iPhone?

1. When the twiist pump and app are not in communication or your iPhone is powered off, the following functionality is still available:
   - When *Loop* is on, the twiist automated insulin delivery system will continue to adjust basal delivery based on information from your CGM. When *Loop* is off, the twiist AID system will continue to deliver the programmed basal insulin.
   - One-button boluses can be delivered (when enabled in *Settings*).
   - Fault detection and alarm generation is still intact.
2. If your pump is alarming, disconnect the infusion set tubing from your infusion site.

3. If you cannot continue to use the pump to effectively treat your diabetes without your iPhone, switch to your backup therapy plan.

What happens if I do not hear the *Delivering* sound when I try to deliver a bolus?

1. Make sure the twiist pump and app are in communication with each other.
2. You may have *Quiet Mode* turned on in *Therapy Settings*.
3. Return to the *Home Screen* and review your active insulin, active carbohydrates, and your current CGM glucose value to make appropriate bolus decisions.
4. Contact *Customer Support* if you continue to have difficulty.

How do I stop insulin delivery without my twiist app?

If you need to suspend insulin delivery and the twiist app is not in communication with the pump:

1. Disconnect your infusion set tubing from your infusion site.
2. Remove the cassette from the pump.

   A *Cassette Not Attached* alarm is displayed and the pump will play the *Alarm* sounds.
3. Remove the battery from the pump to silence the alarm.

⚠ Always have a backup insulin therapy plan ready. A backup plan is needed if insulin delivery is stopped unexpectedly or the pump fails. Failure to have a backup insulin therapy plan may lead to delays of insulin delivery. Failure to have an alternative method of insulin delivery can lead to high blood glucose or diabetic ketoacidosis (DKA).

How do I resume insulin delivery without my twiist app?

In the event that delivery had been previously stopped:

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

If you experienced an alarm when the twiist app was not in communication with the pump:

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.
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.

My pump will not pair with the twiist app?

- Make sure your iPhone has an Internet connection.
- Make sure a fully charged battery is installed. Do not attach a cassette to the pump.
- Put the pump in Bluetooth pairing mode by pressing and holding the pump button for 5 seconds, until the pump plays a *Ready* beep.
- Select the pump serial number that matches the one located on the pump label.
- Make sure you entered the correct PIN number for pairing your pump.
- If the pump was previously paired, you will need to forget the pump in your *Bluetooth Settings*. For instructions, refer to *step 8 on page 103.*

I pressed the pump button while removing the pump from the pump clip or adhesive patch and heard a sound. Does this mean I gave myself a bolus?

No, it does not mean you gave yourself a bolus. Delivery of a *One-Button Bolus* requires you to press the pump button multiple times in order to initiate a bolus and also requires a playback before the bolus is delivered. *See "One-Button Bolus" on page 131.*

You can also check the *Home Screen* on your twiist app to see whether a bolus is delivering.

Do You Know Something the twiist automated insulin delivery system Does Not?

There is always a chance that you have information that the twiist automated insulin delivery system does not.

Perhaps you know that you are getting sick or that your activity was more strenuous than usual.

You know your body and your diabetes, but sometimes diabetes does not make sense.

In those instances, take the action you feel is necessary to keep yourself safe from the effects of low and high glucose.

Is Loop On?

You can tell if *Loop* is on based on the color of the *Loop Status* icon and whether it is an open or closed circle. When the *Loop Status* icon is displayed as a closed circle, *Loop* is on and insulin delivery is automated.

When the *Loop Status* icon is displayed as an open circle, *Loop* is off and insulin delivery is not automated. For more information, *see "Loop Status" on page 52.*

If *Loop* is on, the twiist automated insulin delivery system will continue making adjustments in an effort to bring your glucose into your *Correction Range*.

If *Loop* is off, or CGM readings are inconsistent, you will need to respond to high and low glucose according to your healthcare provider's instructions.

You may need to eat additional carbs to prevent or treat a low or take additional insulin to prevent or treat a high.

Is Your CGM Functioning Properly?

It is always a good idea to check that your devices are working as intended.

If your CGM readings do not match your symptoms or a fingerstick reading from a blood glucose meter, or if you are not getting updated readings from your CGM, your CGM may be having a problem.

You can tap the CGM Status icon and use your CGM app to calibrate, check the status of, or replace your CGM.

Is Your twiist automated insulin delivery system Functioning Properly?

If your infusion set tubing or cannula is kinked or blocked, the twiist automated insulin delivery system may think it has delivered insulin that your body may not be absorbing.

Charts will show large amounts of active insulin that do not reflect what you have actually received, and your glucose prediction will be inaccurate.

You can tap the **Settings** button on the *Toolbar* or the **Pump Status** icon to check the status of your pump, or to suspend or resume insulin delivery.

If the twiist automated insulin delivery system fails to work as described within this user guide, stop using the system and switch to your backup insulin therapy. Using the system when it is not working as described within this user guide may lead to harm.

Dynamic Carb Absorption

The twiist AID system tracks the absorption time of the entered carbohydrates based on how your glucose changes over time. This is called *Dynamic Carb Absorption*.

Tap the **Active Carbohydrates Chart** to display *Dynamic Carbohydrate Absorption* details.

The twiist AID system assumes that it may take a window of time, up to 1.5 times longer, to absorb carbs than what was entered. This gives twiist flexibility to make adjustments to your insulin delivery when the time it takes for your carbs to absorb is not exactly what you thought it would be.

The twiist AID system estimates the carbs absorbed during the time window based on your *Insulin Sensitivity*, *Carb Ratio*, your meal entry, and changes to your glucose.

When carbohydrates are entered, each entry shows:

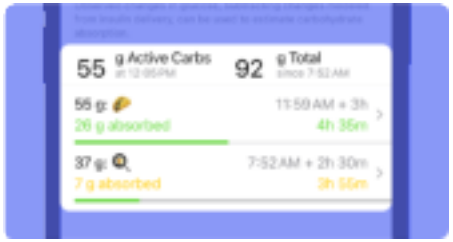
- Grams of carbs entered
- Time of entry + Absorption time

As carbohydrates are absorbed, each entry will also show:

- Grams of carbs absorbed
- A prediction for when the entered carbs will actually be absorbed.

The information within each entry may be displayed as:

- Green – carbs are absorbed within the time window
- Yellow – carbs absorbed are more than 10% above or below the entered amount
- Gray – carb absorption goes beyond the time window



Glucose Change Chart

The chart at the top of the carbohydrates screen shows the effect the twiist AID system expects carbs to have on your glucose (gray bars) compared to the actual effect, or Insulin Counteraction Effect (ICE). The gray bars represent the effects of carbs on your glucose that the twiist AID system is currently tracking. As the meal is tracked, observed carb absorption will be displayed with green bars.

If the absorption of entered carbs does not match the prediction, there may be some things to consider:

- Adjust the value of carbs entered or account for fat/protein
- Adjust absorption time
- Settings for *Insulin Sensitivity* or *Carb Ratio* may need to be adjusted
- Stress/Hormone/Exercise levels may be different than normal

If you have questions about system use, contact your healthcare provider or Sequel customer support. *See "Customer Support" on the facing page.*

Customer Support

Contact *Customer Support* for assistance with any of the following activities:

- Set Up
- General use
- Maintenance
- To report unexpected operation or events
- To request replacement parts

Replacement Parts

Discontinue use of any system component and contact Sequel Customer Support to obtain a replacement in the event a component stops working as expected.

Distributed by:

Sequel Med Tech, LLC

50 Commercial Street

Manchester, NH 03101

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www.twiist.com

Only use approved parts.

Table 2: *Replacement Parts*

Replacement Part	Part Number
Pump	DKPI-21073-006
Rechargeable Pump Battery	DKPI-70009-001
Battery Charger	DKPI-21074-006
USB Cable	DKPI-40108-001
Wall Power Adapter	DKPI-40107-001
Refill Kit	TBD
Refill Kit without infusion sets	TBD

Warranty Information

For information on your warranty, refer to the *Terms and Conditions* of your device purchase order.

Technical Specifications

This device has not been authorized as required by the rules of the Federal Communications Commission. This device is not, and may not be, offered for sale or lease, or sold or leased, until authorization is obtained.

The twiist pump, when connected to the cassette has a rating of IP28, indicating protection from continuous immersion in water. The pump can tolerate immersion to depths of up to 12 feet (3.7 m) for 1 hour.

All parts of the system are rated for continuous operation.

The twiist automated insulin delivery system has not been evaluated for use in oxygen rich environments and should not be used in areas where oxygen is in use.

The twiist pump is Internally Powered ME Equipment.

The wall power adapter is Class II non-ME Equipment.

The wall power adapter and battery charger should be kept dry and not exposed to debris.

The pump batteries should be kept dry and stored in a cool, dry environment when not in use.

The infusion set tubing and cannula are Type BF Applied Parts.

The volume of insulin delivered under single fault conditions is the greater of +/- 0.192 U or + 24/-30% of the targeted volume over the next 6 hours of delivery.

The formula to convert U/hr to mL/hr:

- 1 U/hr = 0.01 mL/hr
- 1 mL/hr = 100 U/hr (definition of U-100 is that there are 100 Units per mL of insulin)

The following are protections for over infusion and under infusion:

- Guards against the free flow of insulin from the cassette to the user.
- Self-tests to ensure the system is working.
- Alarms if a problem is found.

Though security concerns connecting your iPhone to Wi-Fi networks have already been considered by the manufacturer, connecting your iPhone to a wireless network could result in previously unidentified risks. You should watch for unexpected behavior, such as the following, and report these to *Customer Support*:

- Substantial slowing of User Interface (UI) response

Only join secure Wi-Fi networks. Unknown or public networks may not provide data security.


Contact local authorities about proper disposal of the electronic system components that contain lead and lithium ion batteries when no longer needed.

Loop, the interoperable automated glycemic controller (iAGC) utilized by the twiist automated insulin delivery system, is informed by user settings including carb ratio (g/U), insulin sensitivity (mg/dL/U), basal rate (U/hr), the patient's desired correction range (mg/dL), and interoperable continuous glucose monitor (iCGM) readings that are received every five minutes. This information is communicated to the twiist automated insulin delivery system in order to deliver the appropriate basal insulin to the patient. The patient, who is acted upon by outside factors such as the intake of carbohydrates, or exercise is monitored through the use of an interoperable continuous glucose monitor (iCGM). The iCGM glucose reading and trend information is also provided.

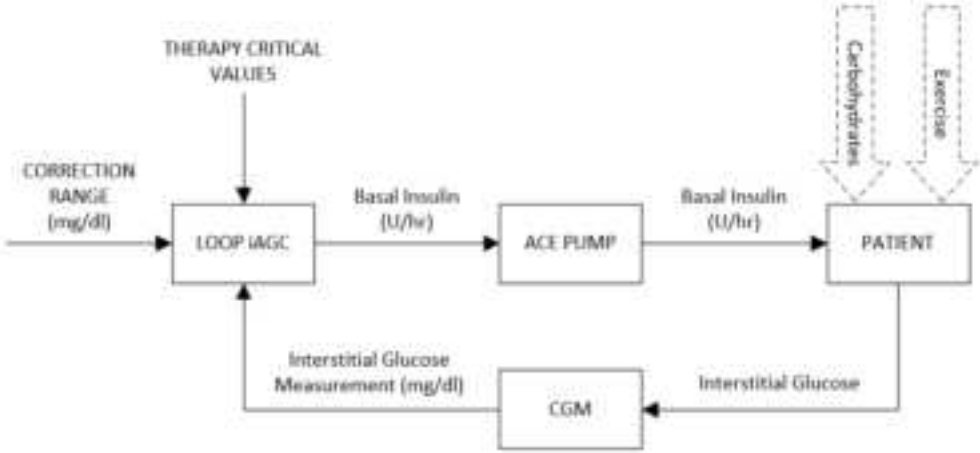


Table 3: *Pump specifications*

Pump Specification Type	Specification Details
FCC ID	2ATGA03
Cool Off/Warm Up time (after being subjected to the extremes of specified storage temperature)	1 hour
Sound Pressure Level Range for Urgent Alerts and Alarms when Fully Escalated	63.6 - 76.5 dBA (measurements taken 1 m from the device)
Pump Service Life	3 years

Table 4: *Pump attached to cover specifications*

Pump attached to Cover Specification Type	Specification Details
Storage and Transportation Conditions	Temperatures of -25 °C (-13 °F) to 70 °C (158 °F) Non-condensing humidity up to 90% Pressure of 50 kPa (7.25 psi) to 106 kPa (15.37 psi)

Table 5: *Pump attached to cassette specifications*

Pump attached to Cassette Specification Type	Specification Details
Size	5.9 cm x 5.5 cm x 1.7 cm
Mass	50 g with a filled cassette attached
Basal Accuracy	± 5% at 1 U/hr when measured per IEC 60601-2-24.
Bolus Accuracy	± 20% at 0.05 U boluses and ± 5% at 25 U boluses when measured per IEC 60601-2-24.
Operating Conditions • Performance may exceed accuracy limits outside of the disclosed range.	Temperatures of 5 °C (41 °F) to 40 °C (104 °F) Non-condensing humidity of 15% to 90% Pressure of 70 kPa (10.15 psi) to 106 kPa (15.37 psi)
Unintended Bolus Volume after Occlusion Release	No more than 0.74 units.
Maximum Infusion Pressure	≤ 43 kPa (6.24 psi)

Table 5: *Pump attached to cassette specifications*

Pump attached to Cassette Specification Type	Specification Details
Delivery Rates	Up to 105 U/hr when a normal bolus is active.
Cannula Fill Delivery Rate	1.5 U/min

Table 6: *Pump battery specifications*

Pump Battery Specification Type	Specification Details
Storage and Transportation Conditions	Pump Battery: -20 °C (-4 °F) to 45 °C (113 °F) Non-condensing humidity up to 75% Pressure of 50 kPa (7.25 psi) to 106 kPa (15.37 psi)
Cool Off/Warm Up time (after being subjected to the extremes of specified storage temperature)	20 min
Pump Battery Type	User replaceable, 300 mAh, rechargeable lithium-ion battery

Table 6: *Pump battery specifications*

Pump Battery Specification Type	Specification Details
Pump Battery Life (new fully charged)	Rate: 1.0 U/hr Runtime: 72 hr Rate: 30 U/hr Runtime: 9.5 hr (cassette volume limited)
Pump Battery Service Life (typical use)	4 months
Pump Battery Charging Temperature Range	15 °C (59 °F) to 35 °C (95 °F)

Table 7: *Battery charger specifications*

Battery Charger Specification Type	Specification Details
Battery Charger Service Life (typical use)	2 years
Storage and Transportation Conditions	Temperatures of -25 °C (-13 °F) to 70 °C (158 °F) Non-condensing humidity up to 90% Pressure of 50 kPa (7.25 psi) to 106 kPa (15.37 psi)

Table 8: *Cassette specifications*

Cassette Specification Type	Specification Details
Storage and Transportation Conditions	Temperatures of -25 °C (-13 °F) to 35 °C (95 °F) Non-condensing humidity up to 90% Pressure of 50 kPa (7.25 psi) to 106 kPa (15.37 psi)
Maximum Volume Infused under Single Fault Condition	+/- 0.192 U or +24/-30% of the next 6 hours' targeted volume
Cassette Fill Volume	Default: -- Units until programmed by the user. Programmable from 100 - 300 Units in 10 Unit increments.
Insulin Types Used	U-100 Fast-Acting Humalog (insulin lispro) U-100 Fast-Acting Novolog (insulin aspart)
Cassette Service Life	3 days
Cassette Shelf Life	1 year

Table 9: *twiist App specifications*

twiist App Setting Ranges	Specification Details
Glucose Safety Limit	Glucose Safety limit is initially set within the prescription from your healthcare provider. 67-110 mg/dL (3.7-6.1 mmol/L) Increment of 1 mg/dL
Correction Range	Correction Range is initially set within the prescription from your healthcare provider. 87-180 mg/dL (4.8-10 mmol/L) Increment of 1 mg/dL The minimum allowed value is either 87 mg/dL or the *Glucose Safety Limit*, when the *Glucose Safety Limit* is higher than 87 mg/dL.
Pre-Meal Range	Pre-Meal range is initially set within the prescription from your healthcare provider. 67-130 mg/dL (3.7-7.2 mmol/L) Increment of 1 mg/dL The minimum allowed value is either 67 mg/dL or the *Glucose Safety Limit*, when the *Glucose Safety Limit* is higher than 67 mg/dL.

Table 9: *twiist App specifications*

twiist App Setting Ranges	Specification Details
Workout Range	Workout range is initially set within the prescription from your healthcare provider. 87-250 mg/dL (4.8-13.9 mmol/L) Increment of 1 mg/dL The minimum allowed value is either 87 mg/dL or the *Glucose Safety Limit*, when the *Glucose Safety Limit* is higher than 87 mg/dL.
Basal Rates	Basal rates are initially set within the prescription from your healthcare provider. From 0.00 U/hr to 30 U/hr or the *Maximum Basal Rate* increment, starting at 0.10, and increasing in 0.05 U/hr
Carbohydrate Units	Grams
Carb Ratios	Carb ratios are initially set within the prescription from your healthcare provider. Programmable from 2-150 g/U in 0.1 g/U increments
Carb Ratio Interval	Up to 48 different Carb Ratios can be programmed within a 24 hour period (a different carb ratio every half hour).

Table 9: *twiist App specifications*

twiist App Setting Ranges	Specification Details
Cannula Fill Volume	Default: -- Units Programmable from 0.10 - 0.70 Units in 0.10 Unit increments.
Maximum Basal Rate	Maximum Basal Rate is initially set within the prescription from your healthcare provider. Min: Highest scheduled basal rate Max: Not greater than 30 U/hr, and further limited to the greater of the following: • 70/ minimum of saved *Carb Ratios* • 6.4 x the highest programmed scheduled basal rate Increment of 0.05 U/hr
Maximum Bolus	Maximum bolus is initially set within the prescription from your healthcare provider. Increment: 1 U Minimum: 1 U Maximum: 25 U

Table 9: *twiist App specifications*

twiist App Setting Ranges	Specification Details
Insulin Model	Insulin model is initially set within the prescription from your healthcare provider. Programmable for *Adult* or *Children*
Insulin Sensitivity	Insulin sensitivity is initially set within the prescription from your healthcare provider. Programmable pattern from 10 - 500 mg/dL/U in 1 mg/dL/U increments.
Insulin Sensitivities Interval	Up to 48 different Insulin Sensitivities can be programmed within a 24 hour period (a different Insulin sensitivity every half hour).
Temporary Basal	Default – Percent May be set to *Percent* or *Rate*  Cannot be modified when *Loop* is on.
One-Button Bolus	Default: Off Options: On/Off

Table 9: *twiist App specifications*

twiist App Setting Ranges	Specification Details
Extended Bolus	Default: Off Options: On/Off Cannot be modified when *Loop* is on.
Dual Bolus	Default: Off Options: On/Off Cannot be modified when *Loop* is on.
Quiet Mode	Default: Off Options: On/Off
Low Insulin Alert #1	Default: On Options: Cannot be disabled Alert set to 10 U and cannot be modified
Low Insulin Alert #2	Default: Off Options: On/Off Alert value: 20-100 U in 5 U increments

Table 9: *twiist App specifications*

twiist App Setting Ranges	Specification Details
Phone Out of Range Alert	Default: Off Options: On/Off 1-120 min in 1 min increments

Table 10: *Accessories*

Accessory	Specification
Wall Power Adapter Storage and Transportation Conditions	Temperatures of -25 °C (-13 °F) to 70 °C (158 °F) Non-condensing humidity up to 90% Pressure of 50 kPa (7.25 psi) to 106 kPa (15.37 psi)
Wall Power Adapter Service Life	2 years
USB Cable Storage and Transportation Conditions	Temperatures of -25 °C (-13 °F) to 70 °C (158 °F) Non-condensing humidity up to 90% Pressure of 50 kPa (7.25 psi) to 106 kPa (15.37 psi)
Pump Clip Service Life	2 years

Table 11: *Syringe and needle specifications*

Syringe and Needle Specifications	Specification
Syringe	3 mL with luer connector
Needle	26 gauge x 1/2 inch with luer connector

Basal Delivery

To assess basal delivery accuracy, 32 pumps were tested by delivering at minimum, intermediate, and maximum basal rates (0.1, 1.0, and 30 U/hr). Sixteen of the pumps were unaged and 16 had been aged to simulate three years of regular use. For both aged and unaged pumps, eight pumps were tested with an unaged cassette, and eight with a cassette which underwent one year of accelerated aging. Delivery accuracy was assessed by pumping insulin into a container on a scale and measuring the weight of the liquid at 1h, 6h, and 12h intervals for minimum and intermediate rates (0.1 and 1.0 U/hr) and 1h and 6h intervals for maximum rate (30 U/hr).

The following tables report the typical basal performance (average) observed, along with the lowest and highest results observed for minimum, intermediate, and maximum basal rate settings for all pumps tested.

Table 12: *Basal rate delivery performance*

Rate (U/hr)	Interval	Average (U)	Minimum (U)	Maximum (U)
0.1 U/hr	1 hour	0.12	0.09	0.17
	6 hours	0.62	0.57	0.66
	12 hours	1.22	1.16	1.31
1 U/hr	1 hour	1.02	0.98	1.09
	6 hours	6.05	5.84	6.22
	12 hours	12.07	11.73	12.33

Table 12: *Basal rate delivery performance*

Rate (U/hr)	Interval	Average (U)	Minimum (U)	Maximum (U)
30 U/hr	1 hour	30.16	29.80	30.61
	6 hours	181.05	178.94	184.46

Table 13: *Basal specifications*

Basal Specification Type	Specification Details
Number of Basal Segments	48 segments - a different Basal Rate every 30 minutes.
Basal Delivery Frequency	Every 5 minutes for rates greater than or equal to 0.24 U/hr.
Basal Rate	Rates are initially set by prescription. Default: -- U/hr Minimum - 0.00 U/hr Programmable from 0.00 - Maximum Basal Rate U/hr in 0.05 U/hr increments. A basal rate of >0.00 U/hr and <0.10 U/hr is not allowed.
Basal Rate Time	Programmable from 0.5 hr - 24 hr in 0.5 hr increments.

Table 13: *Basal specifications*

Basal Specification Type	Specification Details
Temporary Basal Rate Percentage	Default: 100 percent 0 - 200 percent or Maximum Basal Rate, whichever is lower in 5 percent increments.
Temporary Basal Rate U/hr	Default: 0.00 U/hr Programmable from 0.00 U/hr - Maximum Basal Rate in 0.05 U/hr increments. A temporary basal rate of >0.00 U/hr and <0.10 U/hr is not allowed.
Temporary Basal Duration	Default: 30 minutes 30 minutes - 24 hours in 30 minute increments

Bolus Delivery

To assess bolus delivery accuracy, 32 pumps were tested by delivering at minimum, intermediate, and maximum bolus volumes (0.05, 5.0, and 25 U). Each pump delivered 25 minimum and intermediate volume boluses and 7 maximum volume boluses interspersed during periods of active basal delivery. Sixteen of the pumps were unaged and 16 had been aged to simulate three years of regular use. For both aged and unaged pumps, eight pumps were tested with an unaged cassette, and eight with a cassette which underwent one year of accelerated aging.

Table 14: *Bolus accuracy 0.05 U*

	0.05 U Bolus Accuracy									
	<25%	25% to <75%	75% to <90%	90% to <95%	95% to <105%	105% to <110%	110% to <125%	125% to <175%	175% to 250%	>250%
Number of boluses	0/800	53/800	202/800	107/800	278/800	80/800	69/800	11/800	0/800	0/800
%of boluses	0.0%	6.6%	25.3%	13.4%	34.8%	10.0%	8.6%	1.4%	0.0%	0.0%

Table 15: *Bolus accuracy 5 U*

	5 U Bolus Accuracy									
	<25%	25% to <75%	75% to <90%	90% to <95%	95% to <105%	105% to <110%	110% to <125%	125% to <175%	175% to 250%	>250%
Number of boluses	0/800	0/800	0/800	0/800	800/800	0/800	0/800	0/800	0/800	0/800
% of boluses	0.0%	0.0%	0.0%	0.0%	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Table 16: *Bolus accuracy 25 U*

	25 U Bolus Accuracy									
	<25%	25% to <75%	75% to <90%	90% to <95%	95% to <105%	105% to <110%	110% to <125%	125% to <175%	175% to 250%	>250%
Number of boluses	0/224	0/224	0/224	0/224	222/224	2/224	0/224	0/224	0/224	0/224

Table 16: *Bolus accuracy 25 U*

	25 U Bolus Accuracy									
%of boluses	0.0%	0.0%	0.0%	0.0%	99.1%	0.9%	0.0%	0.0%	0.0%	0.0%

Table 17: *Bolus specifications*

Bolus Specification Type	Specification Details
Normal Bolus Delivery Rate	Approximately 105 U/hr
Extended Bolus Duration	Default: 30 minutes 30 minutes - 8 hr in 15 minute increments The maximum extended bolus duration is limited by the pump minimum delivery rate.
One-button Bolus Range	1-10 Units or Maximum Bolus amount, whichever is lower, in 1 Unit increments.
Bolus Range	Programmable from 0.05 U - Maximum Bolus volume in 0.01 Unit increments.
Maximum Dual Bolus	Default: 50% normal, 50% extended Normal or Extended Percentage: 5-95%

Table 17: *Bolus specifications*

Bolus Specification Type	Specification Details
Manual Blood Glucose Entry	Programmable from 10 - 600 mg/dL, increments of 1 mg/dL
Manual Carb Entry	Grams: Programmable from 1 - 250 g, 1 g increments

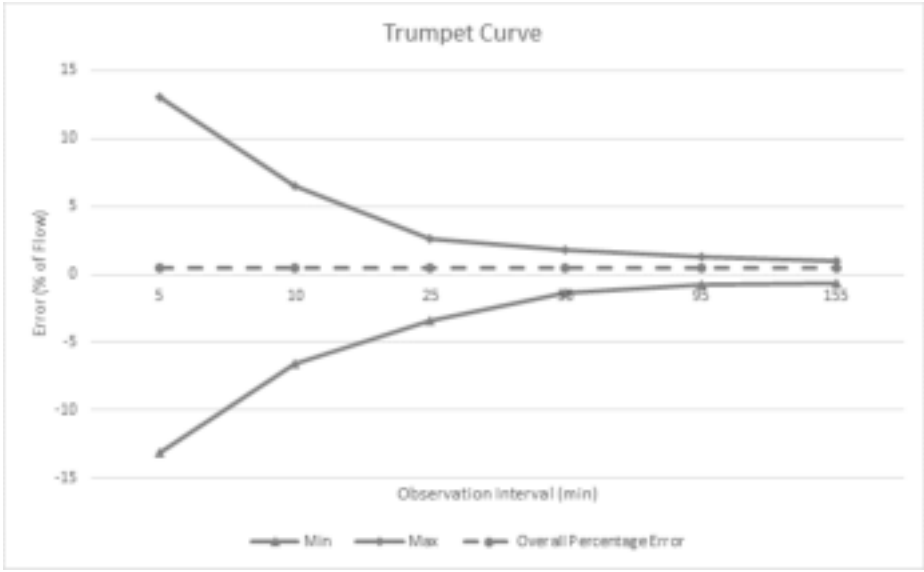
Occlusion Detection Performance

To assess occlusion detection performance and unintended bolus upon occlusion release performance, 32 pumps were tested. Sixteen of the pumps were unaged and 16 had been aged. For both aged and unaged pumps, eight pumps were tested with an unaged cassette, and eight with a cassette which underwent one year of accelerated aging. At the maximum infusion rate the bolus volume after occlusion release is no more than 0.74 units. A *Line Blocked* alarm is generated when the system reaches 43 kPa (6.24 psi).

Table 18: *Occlusion detection performance*

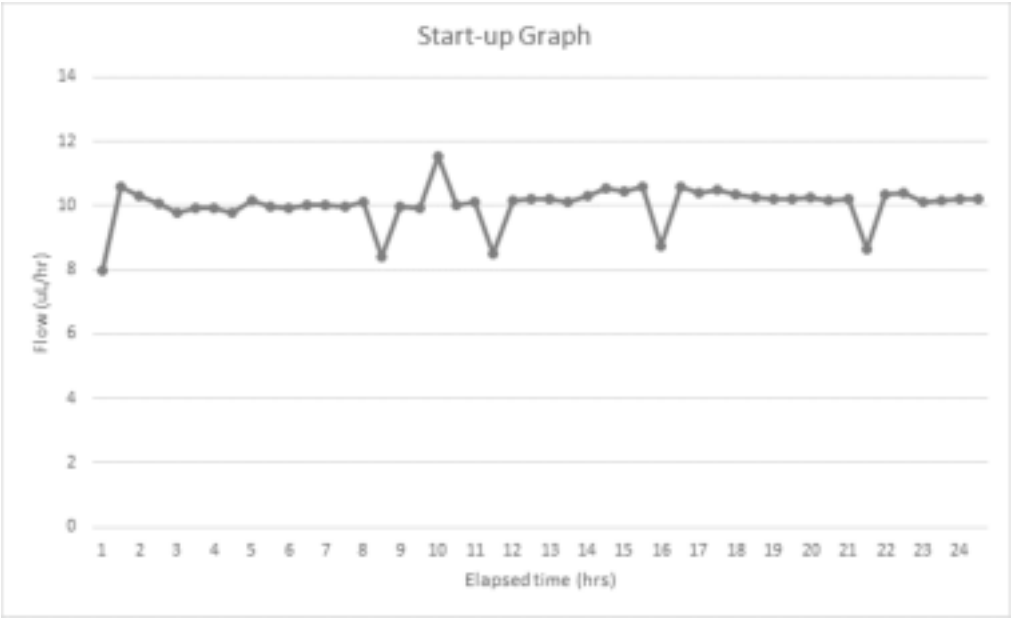
Operating Rate	Typical	Maximum
Bolus (2 Units)	00:01:52	10 minutes
Basal (1.00 U/hr)	00:19:33	3 hours
Basal (0.1 U/hr)	01:55:00	6 hours
Maximum time to detect occlusion will vary based on user-selected delivery rates. Certain factors, such as the presence of air in the infusion set can delay a *Line Blocked* alarm.		

Trumpet Curve



The *Trumpet Curve* shows the accuracy of the flow rate over a 9 hour period as a function of an averaging window. The reported overall percentage error is calculated over the full T2 time period. The data was collected at room temperature while delivering U-100 Humalog insulin, with *Loop* off, at a rate of 1 U/hr through an extension set made of Dunn tubing that is equivalent to infusion sets currently on the market. The sample interval, for calculations per equations 21, 23, and 24 in sub-clause 201.12.1.104 of IEC 60601-2-24: 2012, is taken as the nominal aliquot interval for a delivery rate of 1 U/hr.

Start-Up Graph

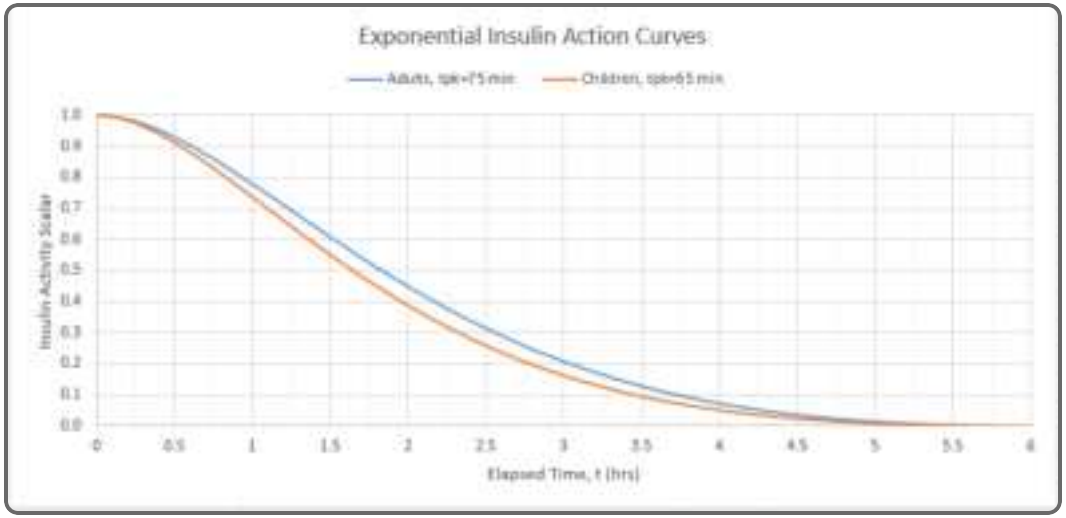


The *Start-Up Graph* shows the average flow rate over 30 minute periods. The measurements were taken at an intermediate basal rate of 1 U/hr with *Loop* off, in accordance with IEC 60601-2-24: 2012, at room temperature while delivering U-100 Humalog insulin through an extension set made of Dunn tubing that is equivalent to infusion sets currently on the market.

Insulin Models

Table 19: *Insulin Models*

Model Type	Duration (hours)	Peak Activity (min)
Adult	6	75
Children	6	65



Essential Performance

The following items are the Essential Performance of the twiist automated insulin delivery system:

- Deliver insulin to the patient per the accuracy specification.
- Stop delivery to the patient and declare an alarm in the presence of a pump fault.
- Limit bolus volumes resulting from the clearing of an occlusion to the published levels.
- Notify the patient before discontinuing the reporting of CGM data.

Emissions and Immunity Testing

The twiist automated insulin delivery system is intended for use in the electromagnetic environment specified below. The operator of the twiist automated insulin delivery system should assure that it is used in such an environment.

Table 20: *Emissions test*

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The system is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	The system is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Table 21: *Immunity test*

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/-2 kV, +/-4 kV, +/-6 kV, +/-8 kV contact +/-2 kV, +/-4 kV, +/-8 kV & +/-15 kV air	+/-2 kV, +/-4 kV, +/-6 kV, +/-8 kV contact +/-2 kV, +/-4 kV, +/-8 kV & +/-15 kV air	Use in home healthcare environments.

Table 21: *Immunity test*

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 1 kHz 80% AM carrier	10 V/m 80 MHz to 2.7 GHz 1 kHz 80% AM carrier	Use in home healthcare environments, excluding near high frequency surgical equipment or near Magnetic Resonance machines.
	27 V/m 380 MHz – 390 MHz 18 Hz PM carrier	27 V/m 380 MHz – 390 MHz 18 Hz PM carrier	
	28 V/m 430 MHz – 470 MHz 1 kHz FM carrier	28 V/m 430 MHz – 470 MHz 1 kHz FM carrier	Portable and mobile RF communication equipment should be used no closer to any part of the system, including cables, than the recommended separation distance of 12 inches (30 cm).

Table 21: *Immunity test*

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Radiated RF IEC 61000-4-3 (cont)	9 V/m 704 MHz – 787 MHz 217 Hz PM carrier	9 V/m 704 MHz – 787 MHz 217 Hz PM carrier	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
	28 V/m 800 MHz – 960 MHz 18 Hz PM carrier	28 V/m 800 MHz – 960 MHz 18 Hz PM carrier	

Table 21: *Immunity test*

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Radiated RF IEC 61000-4-3 (cont)	28 V/m 1700 MHz – 1990 MHz 2400 MHz – 2570 MHz 217 Hz PM carrier	28 V/m 1700 MHz – 1990 MHz 2400 MHz – 2570 MHz 217 Hz PM carrier	
	9 V/m 5.1 GHz – 5.8 GHz 217 Hz PM carrier	9 V/m 5.1 GHz – 5.8 GHz 217 Hz PM carrier	

Table 21: *Immunity test*

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms (6 Vrms in ISM Bands) 150 kHz to 80 MHz 1 kHz 80% AM carrier	6 Vrms 150 kHz to 80 MHz 1 kHz 80% AM carrier	Use in professional healthcare facility and home healthcare environments, excluding near high frequency surgical equipment or near Magnetic Resonance machines.
Electrical fast transient/burst IEC 61000-4-4	+/-2 kV 100 kHz repetition frequency	+/-2 kV 100 kHz repetition frequency	Mains power quality should be that of a typical professional healthcare facility and home healthcare environments.
Surge IEC 61000-4-5	± 0,5 kV, ± 1 kV line(s) to line(s)	± 0,5 kV, ± 1 kV line(s) to line(s)	Mains power quality should be that of a typical professional healthcare facility and home healthcare environments. Line to Earth surges not applicable for the system per sub-clause 7.3 of IEC 61000-4-5.

Table 21: *Immunity test*

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
	0% U_T for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° phase angles	0% U_T for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° phase angles	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T for 1 cycle	0% U_T for 1 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the system requires continued battery charging during power mains interruptions, it is recommended that the system be powered from an uninterruptible power supply or a battery.
	70% U_T for 25 cycles at 50 Hz, 30 cycles at 60 Hz	70% U_T for 25 cycles at 50 Hz, 30 cycles at 60 Hz	
	0% U_T for 250 cycles at 50 Hz, 300 cycles at 60 Hz	0% U_T for 250 cycles at 50 Hz, 300 cycles at 60 Hz	

Table 21: *Immunity test*

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
RFID Immunity AIM 7351731: 2016	134.2 kHz RFID fields	134.2 kHz RFID fields	AIM 7351731 testing applies to medical electrical equipment and systems. AIM 7351731 sets for test methods/levels for the electromagnetic immunity of such equipment/systems.

Table 21: *Immunity test*

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
RFID Immunity AIM 7351731: 2016 (cont)	13.56 MHz RFID fields 13.56 MHz RFID fields 13.56 MHz RFID fields	13.56 MHz RFID fields 13.56 MHz RFID fields 13.56 MHz RFID fields	
	433.92 MHz RFID fields	433.92 MHz RFID fields	
	860 MHz to 960 MHz RAIN RFID fields	860 MHz to 960 MHz RAIN RFID fields	
	2.4 GHz RFID fields	2.4 GHz RFID fields	
Note: U_T is the a.c. mains voltage prior to application of the test level.			

Radio Specifications

Pursuant to 47 CFR 15.21 regarding FCC rules, changes not expressly approved by the party responsible for compliance might cause harmful interference and void the FCC authorization to operate this product.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

The twiist automated insulin delivery system radio has the following specifications:

- Transmit and Receive Frequency Range: 2.4 -2.5 GHz
- Effective Radiated Power: < 10 mW
- Modulation: Direct Sequence Spread Spectrum per IEEE 802.15.4-2006
- Protocol: Bluetooth Low Energy
- Effective range (iPhone/pump): At least 3 m
- Wireless Security: AES-128 encryption with Cypher-block Chaining

Quality of Service Provisions

The twiist automated insulin delivery system is intended for use in a home healthcare environment.

The twiist automated insulin delivery system supports communication between the pump and iPhone, and communication between the pump and Dexcom G6 CGM.

Quality of Service: iPhone and Pump

Quality of service for Bluetooth Low Energy communication between the iPhone and paired pump includes the ability for the iPhone and pump to successfully transfer status, therapy commands, and alarms when in a communication range within 33 ft (10 m) during normal use. Communication will be restored in the event of interruption or corruption of communication between the iPhone and pump within 30 minutes when worn as recommended. When not in communication, the pump will deliver the last programmed therapy.

When *Loop* is on, the pump will continue to make adjustments to your basal insulin when not in communication with the twiist app. Interruption or corruption of communication between the iPhone and pump leads to interruptions in status updates and the ability to make changes to therapy parameters. If communication is interrupted for more than 20 minutes, the twiist app will generate *No Communication* notices. *See "No Communication" on page 169.*

In the absence of communication with the iPhone, alarm, urgent alert, and alert notifications will be generated by the pump. An alert can be enabled by the user if communication between the iPhone and pump has been lost for a configurable amount of time.

When other devices operating in the 2.4 GHz frequency range are transmitting or receiving within 16 in (40 cm), interruptions of communication may occur. This interference will not cause any incorrect data to be sent and will not cause any harm to the twiist automated insulin delivery system.

Quality of Service: twiist Pump and Dexcom G6 CGM

Quality of service for Bluetooth Low energy communication between the Dexcom G6 CGM and the twiist pump includes the ability to communicate with greater than 90% reliability within a distance of 20 ft (6 m) at regular 5 minute intervals, while unobstructed.

Upon reconnection, any information that was missed over the last 3 hours will be transmitted to the pump, and displayed on the iPhone. The Dexcom G6 CGM system is designed to only accept radio frequency (RF) communications from recognized and paired display devices.

The twiist automated insulin delivery system will replace the displayed sensor glucose reading with *Signal Loss* after approximately 10.5 minutes and notifies the user when communication with the Dexcom G6 CGM has been lost through the use of the *Loop status*, *Loop Failure* and *Loop Disabled* alerts..

Wi-Fi

Wi-Fi is the collection of wireless network protocols that allow devices to connect to the internet wirelessly. Wi-Fi most commonly operates on the 2.4 GHz band and is designed to coexist with other wireless protocols such as Bluetooth.

Your iPhone does not need to be connected to Wi-Fi in order for the pump or iPhone to function properly.

Your iPhone is required to be connected to an internet connection during initial use to login to your user account, get your prescription settings, pair your iPhone with a pump, and download software updates. In the event that your pump needs to be re-paired with the iPhone, or if a new pump needs to be paired with an iPhone, an internet connection is required.

The range and connection quality of a Wi-Fi network is based on many factors. A typical home Wi-Fi router operating on the 2.4 GHz band can reach up to 150 ft (46 m) indoors and 300 ft (92 m) outdoors. A Wi-Fi router operating on the 5 GHz band is more susceptible to obstruction and will typically have a slightly shorter effective range.

Do not connect to unknown or public Wi-Fi. Only connect to private networks. All data is transmitted with encryption and digital signatures to provide additional security.

Bluetooth

Bluetooth is a short-range wireless technology that is used for exchanging data between devices over short distances. Bluetooth Low Energy (LE) is designed for very low power operation on the 2.4 GHz band.

Bluetooth connectivity is required for your pump to communicate with your twiist app in order to send status and therapy information. Bluetooth connectivity is required for your pump to communicate with your CGM in order to receive CGM sensor glucose values and status. Bluetooth is enabled by default on your pump, iPhone, and CGM.

Separation distances / Operating Ranges: The nominal maximum range for Bluetooth Low Energy is < 330 ft (< 100 m)

The twiist app is designed to only detect pumps that are in Bluetooth pairing mode. The QR code or serial number on the pump label is required to initiate pairing between the twiist app and pump. The PIN number on the pump label must be entered to complete pairing between the twiist app and pump. Similarly, a QR code or PIN is required to pair to the Dexcom G6 CGM.

The Loop Algorithm

1. What is an algorithm?

An algorithm is a detailed, step-by-step process followed in order to accomplish a specific task or to solve a specific problem.

In the twiist automated insulin delivery system, the Loop algorithm uses a set of mathematical rules to predict future glucose levels and determine how much or how little to adjust basal insulin delivery in an effort to keep your glucose within your desired *Correction Range*.

The algorithm is also used to recommend bolus amounts of insulin when Loop is on.

2. Introduction to the Loop Algorithm

The Loop algorithm makes a new prediction every 5 minutes based upon your *Therapy Settings* and your most recent twiist pump and continuous glucose monitor (CGM) data.

There are three key concepts underlying the Loop algorithm:

a. The goal of the algorithm is to deliver insulin so that your predicted glucose arrives at the midpoint of your correction range at the end of insulin action time. Insulin delivery is constrained by the amount of insulin predicted to bring your predicted glucose curve no lower than the dosing safety threshold. The dosing safety threshold starts at your *Glucose Safety Limit* (shown in *Figure 3-1* as 75 mg/dL) and ends at the midpoint of your *Correction Range* (shown in *Figure 3-1* as 110 mg/dL). Your own values will vary.

a. The algorithm is used for making and delivering basal insulin adjustments and for making correction and meal bolus recommendations, while Loop is on.

a. The algorithm consists of four components that affect your predicted glucose curve. These components are described in detail in *Section 3 on page 240* and include:

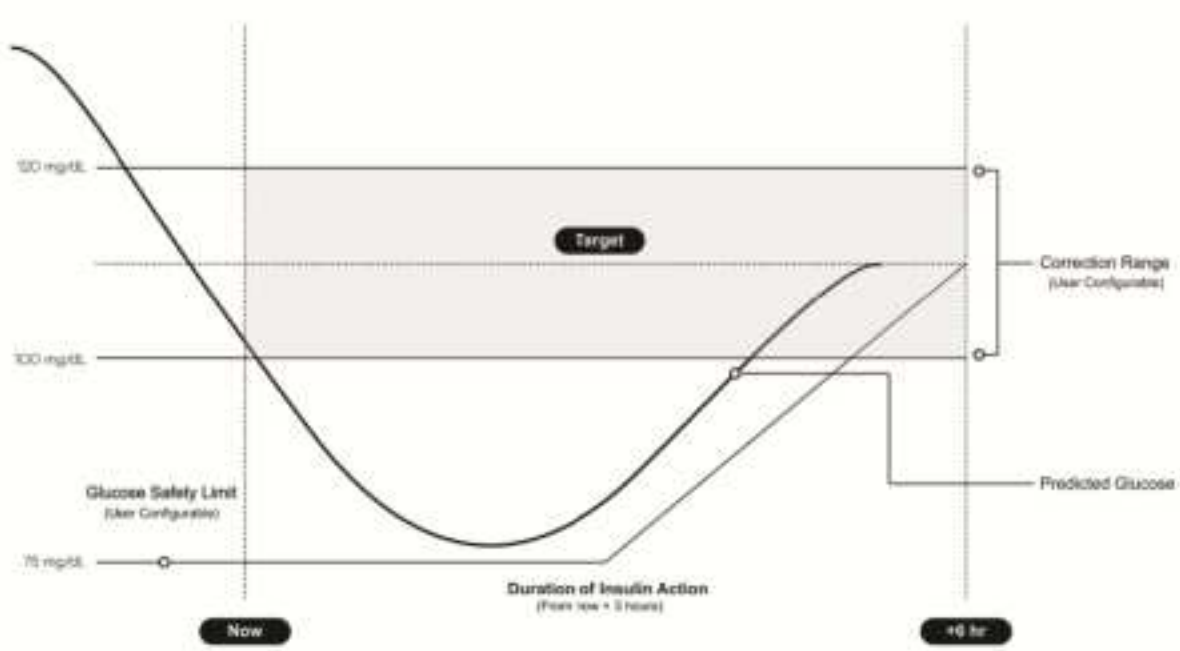
- Insulin Effect
- Carbohydrate Effect
- Glucose Momentum Effect
- Retrospective Correction Effect

Loop is based on the original diabetes community-developed and supported open source *Loop* software code that enabled insulin pump users to create a do-it-yourself automated insulin dosing system. *Figure 3-1* illustrates the Loop algorithm in its simplest form.

Loop Algorithm

The Loop algorithm is based on: Therapy Settings, Glucose Momentum and Recent History, Carbohydrates and Insulin.

Figure 3-1 *Loop algorithm*



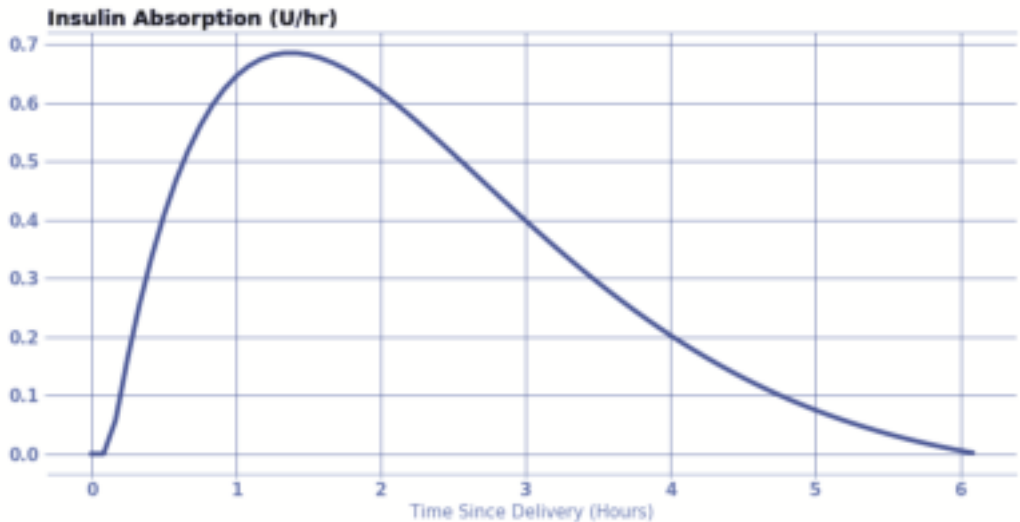
3. Components of the Loop Algorithm

The algorithm focuses on contributions from four individual effects (Insulin, Carbohydrates, Retrospective Correction, and Glucose Momentum) to recommend temporary basal rate corrections and boluses.

Insulin Effect

Fast-acting insulin takes some amount of time to impact your glucose. The insulin effect typically peaks around one hour after giving insulin and then gradually decays.

Figure 3-2 *Insulin absorption*



Loop models all fast-acting insulin with a 6-hour total activity time to account for this decay, with two models to select from in terms of where the insulin's peak activity is expected to happen:

Table 22: *Loop insulin models*

Insulin Model	Insulin Action Peak
Rapid-Acting - Adults	75 minutes
Rapid-Acting - Children	65 minutes

 The twiist automated insulin delivery system is compatible with fast-acting U-100 Humalog (insulin lispro) and Novolog (insulin aspart).

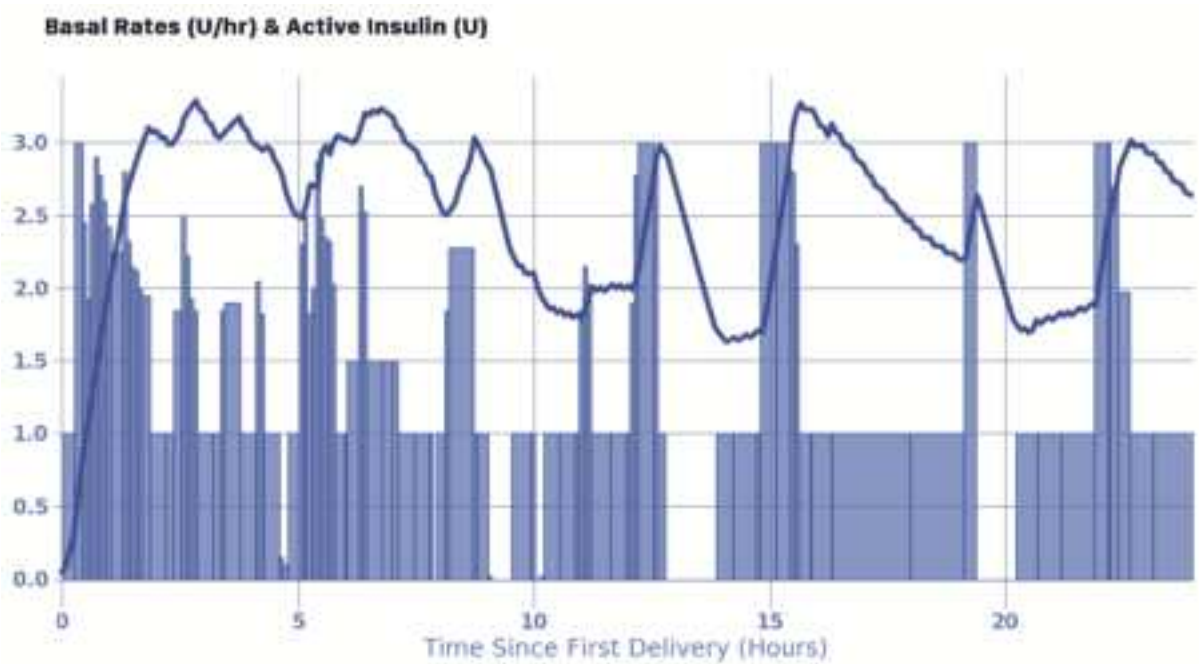
If you are coming from traditional pump therapy, you may be familiar with the duration of insulin activity being user-configurable. In Loop, this setting cannot be changed. The algorithm is considering the activity time of all of the adjustments to your basal insulin, as well as boluses.

The slightly faster absorption time for *Rapid-Acting – Children* accounts for the observed differences in absorption in children; this model was present in all versions of do-it-yourself *Loop* studied in the *Loop Observational Study* and has been preserved in Loop. Choosing the wrong model has negligible effect on the performance of the algorithm or the Loop bolus recommendation tool as the system adapts to observed changes in glucose as often as every 5 minutes when Loop is on.

The amount of insulin effect remaining, or percent of remaining *Active Insulin* after an insulin bolus is delivered, is modeled mathematically in Loop with an exponential decay curve, meaning that the effect of any insulin you receive is calculated as lessening over the next few hours.

Below is an example where Loop is setting many temporary basal rates over the course of the day. The blue bars are the temporary basal rates delivered and the blue line above is the *Active Insulin* at any given time during the day.

Figure 3-3 *Basal rates and active insulin*



Combining boluses and temporary basal rates to get total Insulin Effect

Loop combines the *Active Insulin* of all the individual boluses and temporary basal rates over the past insulin activity duration (6 hours) to predict your *Active Insulin* for the next 6 hours. Using the predicted *Active Insulin*, Loop can predict the impact to your glucose over the next 6 hours.

If Loop loses connectivity with your CGM, the pump will revert back to your scheduled basal rates. In other words, the system will fall back to traditional pump therapy within 30 minutes, given that 30 minutes is the longest temporary basal rate that Loop can enact.

Carbohydrate Effect

Carbohydrates will raise glucose, but the speed and degree to which they impact glucose depends on the type of carbohydrates. High glycemic index (GI) carbohydrates will raise glucose quickly over a shorter time, whereas low GI foods will raise glucose more slowly over a longer period. Foods like candy, juice, and fruit tend to be high GI foods, while pizza, burritos, and quesadillas are usually lower GI foods.

Because carbohydrate absorption can be quite variable, Loop has a model that dynamically adjusts the expected remaining time of carbohydrate absorption. To start with, Loop allows you to input a rough guess of how long you think the food or drink will take to absorb. Your guess is used as a middle-of-the-road estimate, and the Loop algorithm will shorten or lengthen that absorption time estimate based on the observed glucose change.

For all carbohydrate entries, Loop assumes carbohydrates will not start absorbing for 10 minutes, so there is a 10-minute period of no absorption that is modeled prior to the absorption modeled in the next sections.

Linear carbohydrate absorption

Loop takes a conservative view of how fast remaining carbohydrates will absorb. The algorithm starts out at a minimum rate of absorption based on extending the user's entered carbohydrate duration by 50%. In other words, the minimum carbohydrate absorption rate is the total number of grams of carbohydrates over 150% of your entered duration.

Using this initial minimum absorption rate, remaining carbohydrates are modeled to absorb linearly. For example, if you enter a 72 g carbohydrate meal and select an estimated absorption time of 4 hours, then Loop will predict a 12 g/hr absorption rate for the next 6 hours.

Dynamic carbohydrate absorption and the Insulin Counteraction Effect

The linear model above is modulated by an additional calculation that uses recent observed glucose data to estimate how fast carbohydrates have been absorbing. The expected change in glucose due to insulin effects alone is compared to the actual observed changes in glucose. This difference is termed the insulin counteraction effect (ICE).

The ICE is therefore a way of describing the difference between expected glucose changes based on your *Carb Entry* estimate and observed glucose changes based on your CGM information.

ICE are caused by more than just carbohydrates and can include exercise, sensitivity changes, or inaccurate insulin delivery settings (e.g., basal rate, ISF, etc.). However, since the effect of carbohydrates is significant, Loop can still make useful ongoing adjustments to its carbohydrate model by assuming that an increase in glucose is mainly carbohydrate absorption in the period following recorded meal entries.

The ICE is converted into an estimated carbohydrate absorption amount by using the current carbohydrate-to-insulin ratio and the insulin sensitivity factor at the time of the recorded meal entry.

Minimum carbohydrate absorption rate

If the estimated carbohydrate absorption of a meal entry is less than what would have been absorbed using the minimum absorption rate, then the minimum absorption rate is used instead. This is to ensure that meal entries expire in a reasonable amount of time.

Modeling remaining Active Carbohydrates

After the estimated absorbed carbohydrates have been subtracted from each meal entry, the remaining carbohydrates (for each entry) are then predicted to linearly decay or absorb using the minimum absorption rate. Loop uses this prediction to estimate the effect (*Active Carbohydrates*, or carbohydrate activity) of the remaining carbohydrates.

Retrospective Correction Effect

The retrospective correction effect allows the Loop algorithm to account for effects that are not modeled with the Insulin and carbohydrate effects, by comparing historical predictions to the actual glucose.

In addition to the modeled effects of insulin and carbohydrates, there are many other factors that affect glucose (e.g., exercise, stress, hormones, etc.). Many of these effects are active for a period of time. By observing its own prediction error, Loop can estimate the magnitude of these effects and, by assuming that they will continue for some short period of time, incorporate them into the prediction to improve the prediction accuracy.

To do this, Loop calculates a retrospective prediction with a start time of 30 minutes in the past, ending at the current time. Loop compares the retrospective prediction to the actual observed change in glucose, and the difference is summed into a velocity or rate of difference. This term is applied to the current prediction from the insulin and carb effects with a linear decay over the next hour.

Glucose Momentum Effect

The momentum effect incorporates a prediction component based on the assumption that recent glucose trends tend to persist for a short period of time.

The glucose momentum portion of the algorithm gives weight or importance to recent glucose to improve the near-future prediction. Loop estimates the slope of the last 3 continuous CGM readings (i.e., the last 15 minutes) using linear regression. Using multiple points helps filter out noise in the CGM data, while still responding to changing situations quickly. That momentum slope (M_{slope}) is the approximate or average rate of change over the last 15 minutes.

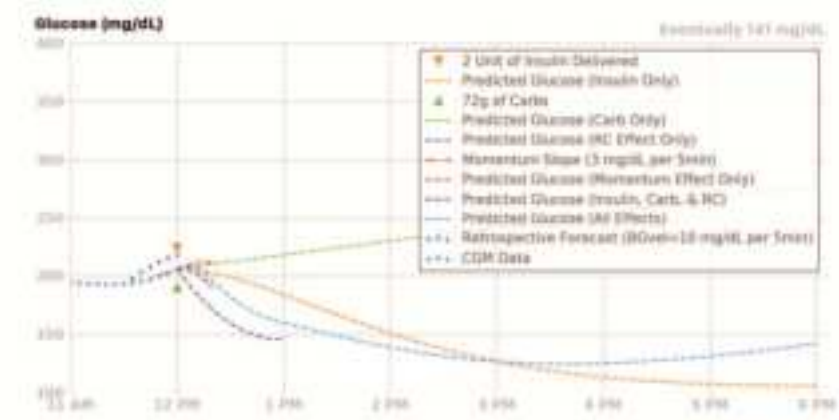
The momentum slope is then blended into the next 20 minutes of expected glucose, as predicted from the other effects (i.e., insulin, carbohydrates, and retrospective correction effects). This, in effect, makes the next 20 minutes of glucose prediction more sensitive to recent glucose trends. The blending of the recent trend slope into the next 20 minutes is weighted so that the first prediction point (5 minutes into the future) is highly influenced by the slope, and the influence of the slope gradually decays over the 20 minute time period.

Loop will not calculate glucose momentum in instances where CGM data is not continuous (i.e., there must be at least three continuous CGM readings to draw the best-fit line from). Loop will also not calculate glucose momentum when there are any CGM readings in the last 15 minutes that contain calibration points, as those may not be representative of true glucose momentum trends.

4. Predicting glucose

Each individual effect along with the combined effects are illustrated in the figure below. *Figure 3-4* shows, glucose is trending slightly upwards at the time of the prediction. Retrospective correction is having a dampening effect on the prediction (lowering the prediction curve), indicating that the recent rise in glucose was not as great as had been previously predicted in the recent past.

Figure 3-4 *Glucose predicting*



5. Insulin dosing

Dosing Safety Threshold

The dosing safety threshold is a time series that has the same duration as the insulin activity duration (i.e., 6 hours). The dosing safety threshold is equivalent to user's *Glucose Safety Limit* for the first half of the insulin activity duration (i.e., 3 hours), and then linearly increases until it reaches the midpoint of the *Correction Range* at the end of the insulin activity duration (i.e., 6 hours).

Loop calculates insulin doses (whether through the automatic implementation of temporary basal rate adjustments, or recommended as boluses) such that the predicted glucose will not result in a single future glucose value that falls below the dosing safety threshold.

The Loop algorithm calculates the amount of insulin that is required to bring each point in the predicted glucose no lower than each corresponding point in the dosing safety threshold. In other words, if Loop gave an insulin dose right now, the algorithm determines the amount of insulin needed to bring the predicted glucose to the dosing safety threshold at every point. Then the Loop algorithm selects the lowest (minimum) calculated dose of insulin over the time series. That insulin dose is then converted into a temporary basal rate when Loop is on. The dosing logic for giving automatic temporary basals when Loop is on and recommending meal and correction boluses is identical. And, the math used here is very similar to the math used to calculate bolus doses in traditional insulin pump therapy and multiple-daily injection therapy.

Possible basal dosing actions

The Loop algorithm takes one of four actions depending upon the predicted glucose and dosing safety threshold. Recall that the dosing safety threshold is derived from the *Glucose Safety Limit* and *Correction Range*. All temporary basal rate commands are issued for 30 minutes, however they may be updated (reissued) every 5 minutes. Said another way, Loop may enact a new temporary basal rate every 5 minutes. But, if communication with the pump is lost, the last issued temporary basal rate will last for at most 30 minutes before the pump reverts to the user's scheduled basal rates.

The four temporary basal actions that the Loop algorithm can implement:

1. Decrease Basal Rate: If the eventual glucose is less than the *Correction Range* and all of the predicted glucose values are above the dosing safety threshold, then Loop will issue a temporary basal rate that is lower than the current scheduled basal rate to bring the eventual glucose up to the correction target.
2. Increase Basal Rate: If the eventual glucose is greater than the upper bound of the *Correction Range* and all of the predicted glucose values are above the dosing safety threshold, then Loop will issue a temporary basal rate that is higher than the current basal rate to bring the eventual glucose down to the correction target.
3. Reduce Basal Rate to 0.00 U/hr: If the current CGM value or any point in the predicted glucose goes below the dosing safety threshold, Loop will issue a temporary basal rate of zero units per hour, regardless of the eventual glucose.
4. Resume Scheduled Basal Rate: There are three situations where the Loop algorithm will resume the current scheduled basal rate.
    a. If the eventual glucose is within the *Correction Range*, and all values in the predicted glucose are above the dosing safety threshold, then Loop will resume the current scheduled basal rate.

b. If the eventual glucose is above the *Correction Range*, and the predicted glucose values have a temporary excursion below the *Correction Range*, but are above the dosing safety threshold, then Loop will resume the current scheduled basal rate.

c. If the Loop algorithm does not have all of the data it needs to make a prediction, it will let the remaining temporary basal rate run its duration (maximum of 30 minutes), and then the basal rate will default back to the current scheduled basal rate, thus returning to the same therapy pattern that the user would receive using traditional insulin pump.

A major difference between traditional pump therapy and how Loop calculates doses is that, in traditional pump therapy, the current glucose is used to estimate a dose, whereas in the Loop algorithm, the predicted glucose and dosing safety threshold are used to calculate the corrective dose.

Bolus recommendations

When Loop is on, Loop will also recommend bolus insulin doses when the eventual glucose calculated by the algorithm is predicted to be greater than the correction target, and the *Active Insulin* and currently running temporary basal rate are not sufficient to cover the predicted excursion above the correction target.

Loop never issues a bolus command automatically. All boluses are initiated by the user. You can tap the **Bolus Entry** button at any time to see if an additional bolus is recommended.

The recommended bolus dose calculation is identical to the dose equation used to issue temporary basals with the following adjustments:

- The recommended bolus takes into account the pending insulin from the full 30-minute duration of the issued temporary basal rate, if the temporary basal rate exceeds the scheduled basal rate.
- If the recommended bolus is above the user defined maximum bolus setting, the bolus recommendation is clamped to the maximum bolus setting.

For recently saved carbohydrates where the projected carbohydrate absorption will outlast the insulin activity duration (e.g., very slow digesting meals like pizza or pasta), the Loop algorithm will inherently decrease the initial meal bolus — to prevent hypoglycemia events that often occur after these meals — by recommending only enough bolus to prevent going below the correction range. As described above, the Loop algorithm computes the recommended bolus such that predicted glucose will not dip below the dosing safety threshold. This may result in a future glucose predicted above correction range, but will prevent a hypo event shortly after the meal (as sometimes occurs for people giving a *pizza bolus* in traditional pump therapy). Loop will then later make corrections by issuing higher temporary basals. In effect, this algorithm behavior mimics traditional pump therapy of *extended* or *dual wave* bolusing, but with the benefit of added information about actual carbohydrate absorption effects and continuously updated insulin dosing decisions.

Finally, Loop checks that the result of the calculations are below the maximum single bolus the Loop user specified in their settings. If the calculated bolus is less than the maximum single bolus setting, then the recommended bolus will be displayed in the Loop bolus recommendation tool. If the calculated bolus is greater than or equal to the maximum single bolus setting, then the recommended bolus will display the maximum bolus.

Safety feature: If the current glucose, or any predicted glucose, falls below the dosing safety threshold, Loop will not return a recommended bolus. When the minimum glucose in the predicted glucose rises above the dosing safety threshold, the bolus tool will provide a recommended bolus.

Loop Bolus Recommendation Tool (LBRT) calculation (Loop on)

When you initiate a meal or correction bolus by tapping the **Carb Entry** button or the **Bolus** button, Loop recommends a dose of insulin that, after delivery, will bring your predicted glucose down to, but no lower than your dosing safety threshold.

The LBRT only makes a bolus recommendation if your predicted glucose is greater than your dosing safety threshold and the *Active Insulin* and currently running temporary basal rate are not sufficient to cover the predicted excursion above the dosing safety threshold. When Loop makes a bolus recommendation, it calculates the insulin dose that will bring your predicted glucose down to your dosing safety threshold, such that your predicted glucose never goes below your dosing safety threshold at any point in time from now through the end of duration of insulin action.

Additional safety features:

- The Loop Bolus Recommendation Tool will not provide a bolus recommendation if the CGM data or manual BG reading is more than 15 minutes old.
- If the current glucose is below the *Glucose Safety Limit* then Loop will not recommend a bolus.
- If any point in the predicted glucose, which includes the effect of the *Carb Entry*, falls below the dosing safety threshold then Loop will not recommend a bolus.

Loop Simple Bolus Calculator (Loop OFF)

The simple *Bolus Calculator* is the bolus calculator available when Loop is off.

When Loop is off, such as when you have toggled it off, or when there is no current CGM sensor session, the twiist app will use the simple *Bolus Calculator* for meal and correction boluses. The simple *Bolus Calculator* uses traditional bolus calculation like an insulin pump calculator that is based on standard, typically-used bolus calculator math like your *Carb Ratio*, *Insulin Sensitivities*, and *Maximum Bolus*.

Table 23: *Simple bolus calculator*

Simple Bolus Calculator	Loop Bolus Recommendation Tool
Considers Current Glucose (relative to Insulin Sensitivity)	Considers Glucose History, Current Glucose, and Glucose Prediction
Considers Carb Entry (relative to Carb Ratio) with a set 3-hour Absorption Time	Considers Carb Entry, Absorption Time, Active Carbs, Carb Effect
Considers Active Insulin (subtracts from recommendation)	Considers Active Insulin from Basal and Bolus Insulin
Recommends a dose of insulin to target the midpoint of your Correction Range	Recommends a dose of insulin to bring your Predicted Glucose down to, but no lower than your Dosing Safety Threshold

Clinical Study Overview

1. **Study overview and design**

   The Jaeb Center for Health Research, in collaboration with Stanford University and Tidepool, conducted an observational study to collect data on the do-it-yourself (DIY) Loop system (ClinicalTrials.gov Identifier: NCT03838900). This study collected and analyzed data on the efficacy, safety, usability, and quality of life/psychosocial effects of the DIY Loop System. The study enrolled subjects diagnosed with type 1 diabetes (T1D) who were using insulin (either pump therapy or multiple daily injections [MDI]) and currently used DIY Loop or had plans to begin using DIY Loop for insulin delivery.

2. **Demographics**

   The protocol allowed enrollment of up to 1,250 participants of any age with Type 1 diabetes with a target of at least 300 participants and a minimum of 150 as new DIY Loop users. Study participants were divided into two cohorts:

   - Cohort A: individuals new to using DIY Loop (had not started Loop or had used it for <7 days prior to enrollment)
   - Cohort B: existing DIY Loop users

   A total of 1,127 participants were enrolled into the study with 799 in Cohort A, defined as new DIY Loop users, and 328 in Cohort B, defined as existing DIY Loop users. Of the enrolled participants, 255 were determined to be ineligible resulting in 872 initiating the study with 606 participants in Cohort A and 266 in Cohort B.

Baseline Demographics and Key Outcomes

Please note: The observational study included participants that may not be part of the intended user population: < 6 years old, using Humalog or Novolog insulin only, and making use of the Tidepool Loop guardrails (Correction Range 87-180 and Glucose Safety Limit 67-110). Cohort A and Cohort B included participants who used DIY Loop settings that are not possible in Tidepool Loop. The table below summarizes these different populations.

	Study population not limited to intended user population		Study population limited to intended user population *(Ages 6 and up, settings within allowable Tidepool Loop ranges at least 90% of the time during study follow-up)*
	New Users (Cohort A)	*Existing Users (Cohort B)*	
N	606	266	175
Demographics			
Age	16 Years (median) 1-72 Years (range)	34 Years (median) 13-76 Years (range)	23 years (mean) 6-71 (range)
Sex	56% Female	52% Female	56% Female

Race	91% White, 4%Hispanic/Latinx, 2% Multiracial, 2%Asian, <1% Black	94% White, 2%Hispanic/Latinx, 2%Asian, 1% Multiracial, <1% Black	91% White, 5% Hispanic/Latinx, 2% Multiracial, 1% Asian, <1%Black
Education	85% - Bachelor's Degree or Beyond	89% - Bachelor's Degree or Beyond	88% - Bachelor's Degree or Beyond
Household Income >$100,000	71%	78%	68%
Summary Diabetes Outcomes			
HbA1c at baseline (mean)	6.8%	6.3%	7.1%
HbA1c after 6 months of using DIY Loop (mean)	6.6%	6.4%	6.7%
Time in Range (70-180 mg/dL) at baseline (mean)	67%	78%	62%

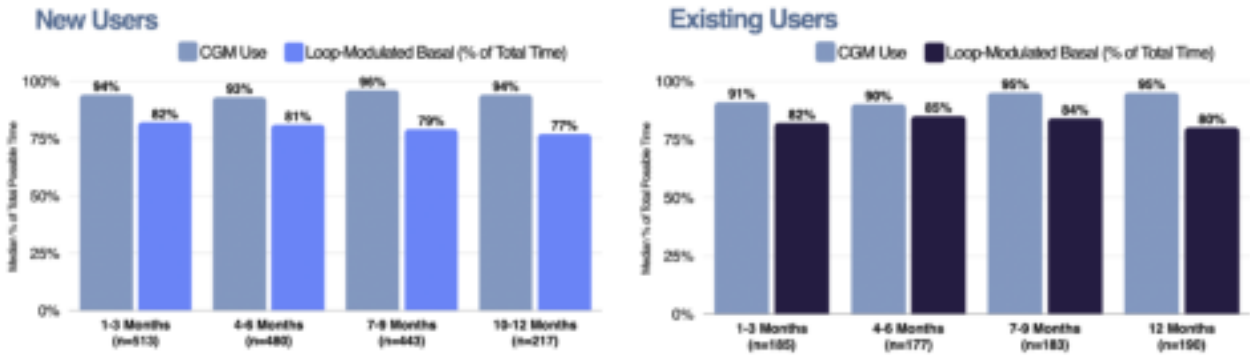
Time in Range (70-180 mg/dL) 1-6 months of using DIY Loop (mean)	74%	79%	70%
Summary Safety Outcomes			
All Adverse Events	No DKA events 71 SH events	No DKA events 24 SH events	No DKA events 23 SH events
Severe Hypoglycemia (SH) during study	92% no SH from baseline to 12 months. 22.6 SH events per 100 person years compared to 181.5 events per 100 person years prior to using Loop.	95% no SH from baseline to 12 months. 14.2 SH events per 100 person years.	92% no SH from baseline to 6 months. 42.3 SH events per 100 person years compared to 192.0 events per 100 person years prior to using Loop.

There was no required length of follow-up for study participants, however minimum exposure targets were exceeded. Due to the rolling nature of enrollment, not all participants were eligible to meet the 9 month and/or 12 month follow-ups. In Cohort A, 88% of participants (n=535/606) reached the 6-month observational time point. In Cohort B, 83% of participants (n=222/266) reached the 9-month observational time point.

A total of 483 person-years of DIY Loop exposure (over 175,000 person-days) were collected in 872 participants.

3. System Intervention

The following two bar graphs show how often CGM data was available ("CGM Use"), and how often Loop over-rode the participant's scheduled basal rate to bring the participant's glucose level into their selected Correction Range ("Loop-Modulated Basal % of Total Time") during the study period in new users (Cohort A) and existing users (Cohort B), respectively, at 1–3 months, 4–6 months, 7–9 months, and 12 months.



4. Investigational device

This observational study examined DIY Loop in real-world, unsupervised, patient-driven use, meaning no investigational device exemption was pursued from the FDA.

Tidepool Loop is based on the same algorithm as DIY Loop, with specific design changes from DIY Loop as per FDA 21 CFR 862.1356 and special controls as described in the 510(k) submission under Section 20.4.2.

5. Data collection

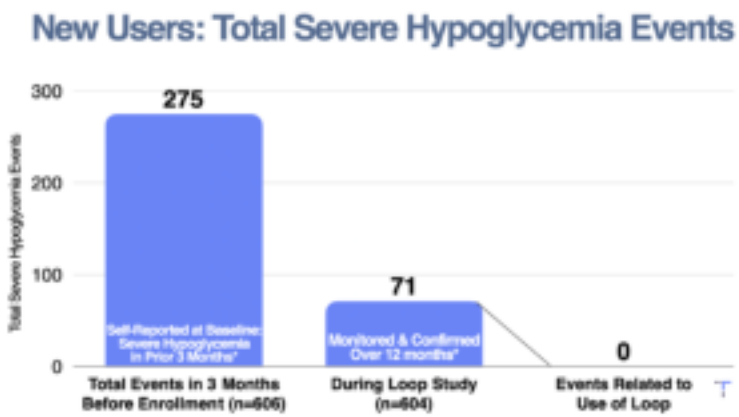
CGM and insulin dosing data were collected continuously and uploaded automatically from a study participant's own iPhone. The Tidepool Mobile app securely sent this data to Tidepool's cloud, from which it was retrieved by the Jaeb Center for Health Research and replicated in the Jaeb Center's database. Users completed weekly web-based surveys about Adverse Events (severe hypoglycemia, DKA, hospitalization) and device issues. Participants were followed for up to 12 months with general updates obtained after 3, 6 and 12 months. A fingerstick blood sample was collected for HbA1c measurement after 3 months for cohort A, and after 6 and 12 months for both cohort A and B. In addition, at three, six and 12 months, more extensive web-based surveys collected patient-reported outcomes and psychosocial/quality-of-life aspects related to Loop use. Focus groups were also completed.

6. Results: Cohort A (New Users)

A total of 314 person-years of DIY Loop exposure were collected in 606 participants. Participants had a median age of 16 years, with a range from 1–72 Years.

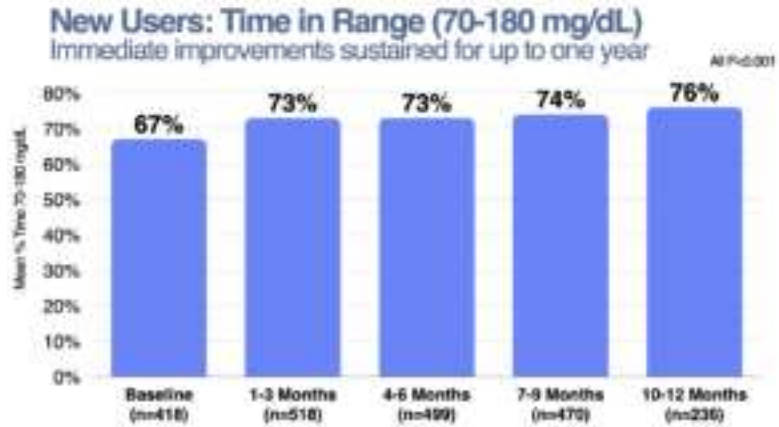
Primary Safety Analysis

92% of Cohort A participants reported no severe hypoglycemia (SH) from baseline–12 months. In the remaining 8% of participants, 71 SH events occurred in 47 participants. The overall incidence rate of SH was 22.6 events per 100 person-years, a substantially lower rate than what was reported at baseline before using DIY Loop (181.5 events per 100 person-years). No SH events were adjudicated as “Related to Loop” in Cohort A. Eleven SH events resulted in seizure or loss of consciousness, translating to an incidence rate of 3.5 events per 100 person-years. One DKA event occurred in Cohort A from baseline–12 months, resulting in a total incidence rate of 0.3 DKA events per 100 person-years; this was also a substantially lower rate than what was reported at baseline before using DIY Loop (17.2 events per 100 person-years).



Primary Glycemic Outcomes

Mean time-in-range 70–180 mg/dL (TIR) increased from 67% at baseline to 73% from 1–6 months (p<0.001). TIR increased in both adults and children, across the full range of baseline HbA1c levels, and with both high and moderate income levels.



Time <54 mg/dL and <70 mg/dL were both low at baseline (medians of 0.40% and 2.9%, respectively), but still improved during the study (p<0.001). Mean HbA1c was 6.8% at baseline and decreased to 6.6% after 6 months (P<0.001) of using DIY Loop. Multiple sensitivity analyses suggested that the results were robust and not impacted by missing data.

Quality of Life Outcomes

Study participants took eight validated questionnaires throughout the study, capturing important psychosocial and quality of life outcomes. The Insulin Dosing Systems: Perceptions, Ideas, Reflections and Expectations (INSPIRE) measures were completed by adults, parents, and children; results in Cohort A showed composite scores of 4.3 and higher out of a possible 5.0 —indicating highly positive psychosocial and quality of life outcomes associated with the use of DIY Loop. The INSPIRE questionnaires were recently qualified by the FDA through the Medical Device Development Tool program (Submission Number: Q191073).

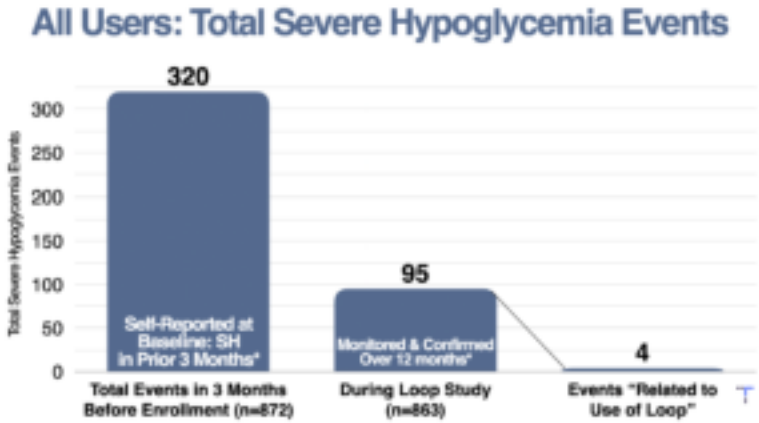
In Cohort A, statistically significant improvements were also seen with DIY Loop in the Diabetes Distress Scale – Management Burden; Fear of Hypoglycemia (Worry Scale); Hypoglycemia Confidence; and the Pittsburgh Sleep Quality Index. These validated questionnaires appear to corroborate the CGM and HbA1c metrics discussed earlier. No significant changes were observed in the Diabetes Technology Attitudes; Technology Use for Problem Solving; and the Risk Taking Survey. In Cohort A, 75% of participants said they were “very likely” (a “5” on a 1–5 scale) to recommend Loop to another person with type 1 diabetes.

7. Results: Cohort B (Existing Users)

A total of 169 person-years of DIY Loop exposure were collected in 266 participants. Participants had a median age of 34 years, with a range from 3–76 Years. Outcomes for Cohort B are descriptive and do not include p-values, as users were already on DIY Loop at baseline.

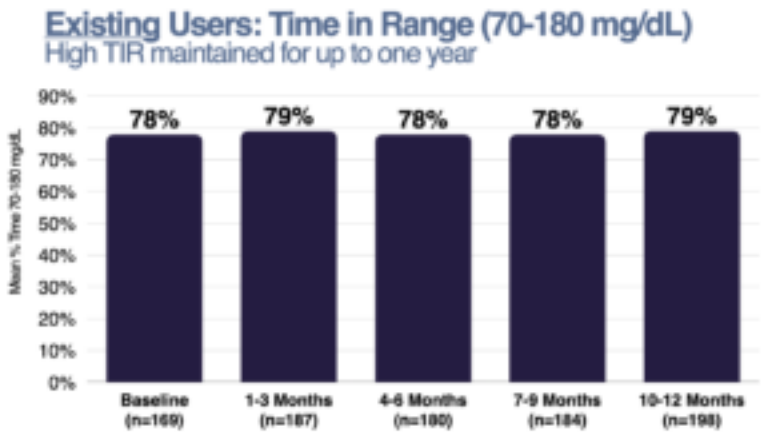
Primary Safety Analysis

95% of Cohort B participants reported no severe hypoglycemia (SH) from baseline–12 months. In the remaining 5% of participants, 24 SH events occurred over the study, resulting in an overall incidence rate 14.2 SH events per 100 person-years. Four SH events were adjudicated as “related to Loop” in Cohort B. Seven SH events resulted in seizure or loss of consciousness, translating to an incidence rate of 4.1 events per 100 person-years. No DKA events occurred in Cohort B, resulting in a total incidence rate of 0.0.



Primary Glycemic Outcomes

Mean time-in-range 70–180 mg/dL (TIR) was 78% at baseline (already using Loop) and maintained at 78%–79% from 1–12 months.



Time <54 mg/dL and <70 mg/dL were both low at baseline (medians of 0.34% and 2.6%, respectively) and remained at similar levels during the study. Mean HbA1c was 6.3% at baseline and was maintained at 6.4% at six months and 6.2% at 12 months.

Quality of Life Outcomes

INSPIRE results in Cohort B showed composite scores of 4.3 and higher out of a possible 5.0— indicating highly positive psychosocial and quality of life outcomes associated with the use of DIY Loop. Other measures of Cohort B's quality of life remained consistent from Baseline–12 months; these data were also consistent with Cohort A's results while on DIY Loop. In Cohort B, 79% of participants said they were "very likely" (a "5" on a 1–5 scale) to recommend Loop to another person with type 1 diabetes.

8. Adverse events

Intended Use Population

Severe hypoglycemic event data were specifically analyzed for the "intended use" sub-population. That population is defined as individuals in the study from both cohorts that are ≥6 years old, using Humalog or Novolog insulin only, and making use of the Tidepool Loop guardrails at least 90% of the time during study follow-up.

The table below summarizes the incidence of severe hypoglycemic events at baseline and follow-up by age group in the intended use population. Given the small sample sizes and potential lack of statistical significance for these cohorts, the Tidepool team individually analyzed each adverse event from the Observational Study of Loop in detail. Each event was reviewed both by the Jaeb Center for Health Research and by Tidepool staff, including review with Tidepool's Chief Medical Advisor.

These data show that:

(1) the majority of severe adverse events observed during the study were experienced by the minority of participants who also had at least one severe hypoglycemic event in the three months before using DIY Loop; and

(2) for those participants who reported at least one severe adverse event in the three months prior to using DIY Loop, their incident rates of severe hypoglycemic events were reduced from baseline.

(3) Across the intended use population, the incidence rate of Severe Hypoglycemia events was reduced from 192 events per 100 person-years in the 3 months prior to using DIY Loop, to 42 events per 100 person-years for the 6 months after starting on DIY Loop.

In other words, those participants who had severe hypoglycemic events before using *Loop* were more likely to continue to have SH events, but to have fewer of them.

Severe Hypoglycemia for Participants ≥6 Years Old

	Overall	6-13 Years	14-17 Years	≥18 Years
Overall	N=175	N=76	N=19	N=80
Severe Hypoglycemia (Baseline – 6 Months)				
Total # of events # Events per participant	23	11	5	7
0	161 (92%)	69 (91%)	17 (89%)	75 (94%)
1	6 (3%)	3 (4%)	0 (0%)	3 (4%)
2	7 (4%)	4 (5%)	1 (5%)	2 (3%)
≥3	1 (<1%)	0 (0%)	1 (5%)	0 (0%)
Incidence rate (per 100 person-years)	42.3	44.7	88.8	29.0

Severe Hypoglycemia (3 Months Prior to Baseline)				
Total # of events # Events per participant	84	50	2	32
0	149 (85%)	63 (83%)	17 (89%)	69 (86%)
1	12 (7%)	6 (8%)	2 (11%)	4 (5%)
2	4 (2%)	1 (1%)	0 (0%)	3 (4%)
≥3	10 (6%)	6 (8%)	0 (0%)	4 (5%)
Incidence rate (per 100 person-years)	192.0	263.2	42.1	160.0
Participants with 0 Event in the 3 Months Prior to Enrollment	N=149	N=63	N=17	N=69
Severe Hypoglycemia (Baseline – 6 Months)				

Total # of events # Events per participant	10	5	3	2
0	143 (96%)	60 (95%)	16 (94%)	67 (97%)
1	3 (2%)	1 (2%)	0 (0%)	2 (3%)
2	2 (1%)	2 (3%)	0 (0%)	0 (0%)
≥3	1 (<1%)	0 (0%)	1 (6%)	0 (0%)
Incidence rate (per 100 person-years)	21.7	23.9	63.6	9.8
Participants with ≥1 Events in the 3 Months Prior to Enrollment	N=26	N=13	N=2	N=11
Severe Hypoglycemia (Baseline – 6 Months)				
Total # of events # Events per participant	13	6	2	5

0	18 (69%)	9 (69%)	1 (50%)	8 (73%)
1	3 (12%)	2 (15%)	0 (0%)	1 (9%)
2	5 (19%)	2 (15%)	1 (50%)	2 (18%)
≥3	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Incidence rate (per 100 person-years)	154.7	163.9	218.3	130.6

a Analysis restricts to participants ≥6 years old.

b Incidence reported per 100 person years

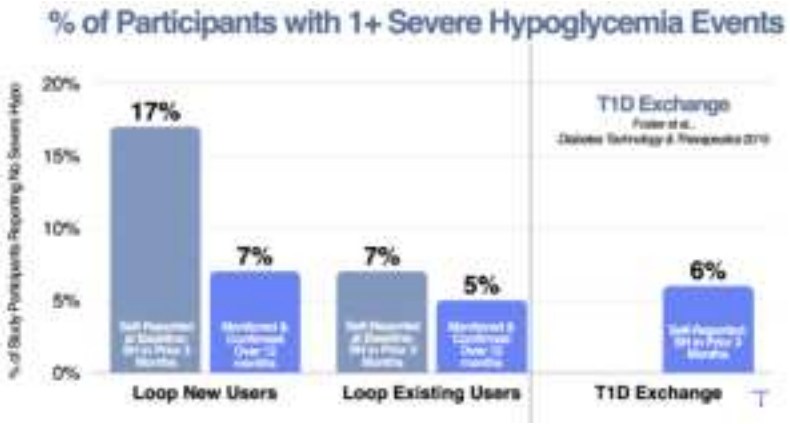
Overall Population

Because the sample size within the intended use population was small, we include data from the overall population below to provide a broader analysis of adverse event data.

Although the overall incidence rate of severe hypoglycemia in the Loop observational study was higher than in recent controlled studies of existing AID, the below data includes no exclusion criteria, whereas most previous AID studies (but not all) excluded individuals with recent severe hypoglycemia or gave investigators discretion to exclude individuals if, in the opinion of the investigator, the individual's participation would put the individual or the study at risk.

The difference could also reflect this study's frequent ascertainment of severe hypoglycemia through a weekly text prompt or differences in study design: the Loop study was real-world and virtual compared with other studies that had structured protocols with close clinical oversight of closed-loop system use by study staff (including system setup and maintenance). The difference is also possibly reflective of the high pre-study risk of this cohort for severe hypoglycemia, possibly driven by a more hyperglycemia-avoidant approach to diabetes management.

The data suggest that the use of DIY Loop was associated with a lower reported rate of severe hypoglycemia in Cohort A — over both 6-Month and 12-Month study time points — as compared to the baseline report of SH in the 3 months prior to starting Loop. The percentage of Loop users experiencing a severe hypoglycemia event within the first 3 months of the study (5%) was similar to the 6% 3-month frequency reported in the real-world T1D Exchange clinic registry (see figure below).



Tabulation of Safety Outcomes from Baseline to 12 Months[1]

	Overall N=863	Cohort A N=604	Cohort B N=259
Severe Hypoglycemia[2]			
Total # of events # Events per participant	95	71	24
0	802 (93%)	557 (92%)	245 (95%)
1	41 (5%)	31 (5%)	10 (4%)
2	14 (2%)	11 (2%)	3 (1%)
≥3	6 (<1%)	5 (<1%)	1 (<1%)
Incidence rate (per 100 person-years)	19.7	22.6	14.2
Severe Hypoglycemia Resulting in Seizure or Loss of Consciousness			

Total # of events # Events per participant	18	11	7
0	851 (99%)	595 (99%)	256 (99%)
1	8 (<1%)	7 (1%)	1 (<1%)
2	3 (<1%)	2 (<1%)	1 (<1%)
≥3	1 (<1%)	0 (0%)	1 (<1%)
Incidence rate (per 100 person-years)	3.7	3.5	4.1
Diabetes Related Hospitalizations			
Total # of events # Events per participant	7	5	2
0	856 (99%)	599 (99%)	257 (99%)
1	7 (<1%)	5 (<1%)	2 (<1%)

[1] Participants who used Loop with the IRC/FPU settings on for all of follow-up are excluded from the safety analyses. Any adverse events occurring while IRC/FPU settings were turned on are excluded.

[2] There were 4 severe hypoglycemic events in the first 6 months related to Loop that occurred in cohort B, with one of these events being associated with a seizure or loss of consciousness.

There were 7 hospitalizations during the observational study that either were or could have been diabetes related. 3 of these events were linked to a virus that presented ketones. There was no evidence or indication that the other 4 events were linked to the usage of Loop.

9. Conclusions

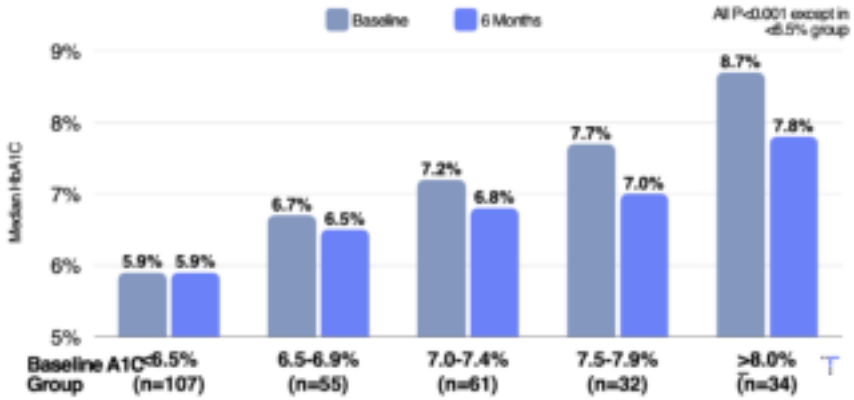
Results demonstrated that DIY Loop can be safely and effectively self-initiated and used by adults and children with type 1 diabetes for up to 12 months. With 483 person-years of data (over 175,000

person-days), this study contained more than 10x the typical amount of exposure data collected in controlled automated insulin dosing (AID) trials. There was no guidance provided to participants as to how DIY Loop was to be used, no formal customer support for troubleshooting, no training, no provision of supplies, and no prescription or required HCP involvement. Study participants initiated DIY Loop either on their own or with community-developed resources.

Time in range (TIR), which on average was already at a high level prior to starting Loop, increased further in Cohort A and was sustained in Cohort B (see figures below). TIR improved immediately after starting Loop and was sustained on average over 6 months.

The benefits of DIY Loop were seen in both adults and children, across the full range of baseline HbA1c, and with both high and moderate income levels.

New Users: No matter the A1C entering the study, almost every group saw A1C improvement on Loop



10. Applicability to the twiist automated insulin delivery system

Analysis of the study population showed that DIY Loop Study participants comprised a wide range of ages, diabetes duration, and glycemic outcomes, mirroring the intended population for Loop. Therefore, DIY Loop observational study subjects are representative of the twiist automated insulin delivery system intended use population and the study results are also representative of Loop's performance in the broader intended user population.

DIY Loop, as used in the Observational Study, is representative of the twiist automated insulin delivery system because the system design considered all known DIY Loop use problems, and the design was adapted as necessary to mitigate identified use problems, and the design was tested as part of detailed Verification and Validation Testing. The changes in the twiist automated insulin delivery system were made specifically to enhance the system's safety profile and to comply with US FDA's iAGC(interoperable Automated Glycemic Controller) requirements.

The twiist automated insulin delivery system's safety and performance are supported by the clinical data collected in the Observational Study that used DIY Loop.

GLOSSARY

A

Active Carbohydrates

Carbs that have been entered in the twiist app and how the twiist AID system expects those carbs to impact your glucose over time.

Active Insulin

Active Insulin is the amount of insulin still active in the body working to lower blood glucose, based on your basal and bolus insulin deliveries.

B

Basal

Basal or Basal Rate is the background delivery of insulin, which keeps glucose levels stable between meals and during sleep. It is measured in units per hour (U/hr).

Battery Change

A Battery Change may need to be completed if your battery is depleted but you would like to continue using the insulin remaining in your current cassette.

Battery Charger

A hardware device used to charge the pump batteries.

Blood Glucose

Also known as blood sugar or BG. Blood glucose is the level of glucose in the blood, measured in mg/dL.

Bolus

A dose of insulin taken to handle a rise in blood glucose or to cover food intake.

C

Cannula [kan-yuh-luh]

The cannula is the part of the infusion set that is inserted under the skin through which insulin is delivered.

Carb Absorption

The time it takes blood glucose to rise due to the digestion of different types of carbohydrates.

Carb Ratio

The carb ratio is the number of grams of carbohydrate that 1 unit of insulin will cover. Also known as insulin-to-carbohydrate ratio.

Carbohydrate

Carbohydrate or Carb refers to sugars, fiber, and starches that the body breaks down into glucose and uses as an energy source, measured in grams.

Cassette

A disposable component of the system that holds the insulin and attaches to the pump.

Cassette Change

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

CGM Status

An icon displayed at the top of the twiist app that allows you to see your most recent glucose and rate of change, when a CGM is in use. Tap the icon for additional information about your CGM.

Continuous Glucose Monitoring (CGM)

Continuous glucose monitoring (CGM) systems use a sensor inserted under the skin to check glucose levels. The CGM sends sensor glucose readings to a display device.

Correction Bolus

A bolus delivered to lower glucose.

Correction Range

The glucose value or range of values the twiist AID system uses when helping calculate a bolus. When Loop is ON, the twiist AID system aims for your Correction Range when adjusting your basal insulin.

D

Delivery Limits

Delivery limits consist of Maximum Basal Rate and Maximum Bolus settings.

Dual Bolus

A bolus delivered now to lower blood glucose and cover fast acting carbs, and an extended bolus used to cover carbs that take a long time to absorb. This feature is not available when Loop is on.

Dynamic Carb Absorption

A model used by the twiist AID system, when Loop is on, for how carbs will be absorbed, spread over an interval that is 1.5 times the selected absorption time for carbs that have been entered. Dynamic carb absorption allows for variations in actual absorption.

E

Extended Bolus

A bolus delivered over an extended period of time. An extended bolus is commonly used to cover foods that take a long time to absorb. This feature is not available when Loop is on.

G

Glucose Prediction

When Loop is on, your glucose prediction is displayed on the Glucose Chart based on your CGM values and rate of change, active insulin, and carbs that you have entered within the twiist app.

Glucose Safety Limit

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

Grams

Grams are the measurement for a carbohydrate.

H

High Blood Glucose

Same as high or high blood sugar. High Blood Glucose is characterized by an excess of glucose in the bloodstream. It is important to treat high blood glucose (Hyperglycemia). If left untreated, high blood glucose can lead to serious complications.

I

Increased Basal

A raised icon displayed within the Insulin Delivery Status indicating your basal rate is increased by volume displayed. Increased basal will also be displayed on the Insulin Delivery Chart.

Infusion Set

A disposable component that includes the infusion set tubing and cannula.

Insulin

Insulin is an infused medication used to treat diabetes.

Insulin Model

A mathematical system based on the assumption that insulin delivered is actively working to lower your glucose for six hours. The peak activity time is set at 75 minutes for adults or 65 minutes for children.

Insulin Sensitivities

Insulin Sensitivities refer to the drop in glucose expected from one unit of insulin.

L

Loop

Loop is an interoperable autmated glycemic controller (iAGC) that makes a prediction about your future glucose by looking at your settings, your sensor glucose, recent insulin deliveries, and recent carb entries. When Loop is enabled, the twiist AID system will adjust your basal insulin in an effort to reach your target glucose and reduce glucose highs and lows. When Loop is enabled, the twiist AID system will make a calculation as often as every 5 minutes. Each calculation cycle is called a Loop.

Loop Status

An icon displayed at the top of the twiist app that provides information about Loop, including whether your pump and CGM are working together properly. Tap the icon for additional information.

Low Blood Glucose

Same as low or low blood sugar. Low Blood Glucose is characterized by a low level of glucose in the bloodstream. It is important to treat low blood glucose (Hypoglycemia). If left untreated, low blood glucose can lead to serious complications.

Luer Connector

A twist-lock connection on a syringe or infusion set tubing that creates a leak-free seal.

M

Manual Bolus

Direct entry of the desired bolus volume in units.

Maximum Basal Rate

Maximum Basal Rate is the highest basal rate that can be set by the twiist AID system. This value represents the highest rate that can be set within Basal Rates, or the highest value that can be set during a Temporary Basal. When Loop is ON, Maximum Basal Rate is the highest temporary basal rate the twiist AID system is allowed to set automatically.

Maximum Bolus

The highest bolus amount you can delivery at one time to cover carbs or bring down high glucose.

N

Normal Bolus

A bolus delivery of insulin administered into the body all at once.

O

One-Button Bolus

A manual bolus that can be delivered directly from the pump by commanding and confirming the desired bolus volume with the pump button. A one-button bolus can be set in one unit increments up to your Maximum Bolus or 10 Units, whichever is lower.

P

Pre-Meal Range

Temporarily lowers your Correction Range before a meal to lower the impact of post-meal glucose spikes.

Prime

The process of filling the infusion set tubing with insulin.

Pump

A component of the twiist AID system that pumps insulin into your body through an attached infusion set, and wirelessly communicates with the twiist app and CGM.

Pump-Bump

Refers to the area of the pump that protrudes out from the circular shape of the pump.

Pump Battery

A battery designed for use with the twiist pump that is recharged using the provided battery charger.

Pump Cover

A clear plastic cover that attaches to the pump to protect its internal components from dust, dirt, and contamination when a cassette not in use.

Pump Status

An icon that shows an estimation of how much insulin remains in your cassette and the pump battery level. Tap the icon for additional information about how to suspend insulin delivery or complete a cassette change.

R

Reduced Basal

A dropped icon within the Insulin Delivery Status indicating your basal rate is decreased by volume displayed. Reduced basal will also be displayed on the Insulin Delivery Chart.

S

Scheduled Basal

A solid line with a value of +0.0 U within the Insulin Delivery Status indicating your basal rate is being delivered at your scheduled rate.

Subcutaneous

Situated or applied under the skin.

Syringe

A disposable component comprised of a small hollow tube used for filling your cassette. The syringe is attached to the specified needle.

T

Temporary Basal

A Temporary Basal rate is used to increase or decrease the current basal rate for a short period of time. A Temporary Basal can be set as an override of your current basal rate, or as a percentage adjustment.

twiist App

A component of the twiist AID system used to program the pump with your therapy settings, complete cassette changes, view and manage your carbs, and respond to alarms and alerts.

U

Units

Measurement used for insulin volume.

W

Workout Range

Temporarily raises your Correction Range before, during, or after a physical activity to reduce the risk of low glucose.

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