

The twiist Automated Insulin Delivery (AID) System Powered by Tidepool®

USER GUIDE

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The twiist automated insulin delivery system is Magnetic Resonance Unsafe. Disconnect your twiist pump before entering an MRI scan room. Do not bring your iPhone or twiist pump into an MRI scan room. Contact with, or being in proximity to, an MRI scanner may cause the twiist pump and iPhone to move or lead to electric shocks and may result in severe injury.

Detach the Magnetic Resonance Unsafe card and keep with you while using the system.



Emergency Contact Information

Name
Phone Number
Healthcare Provider
Certified twiist Trainer
Pharmacy
Notes

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Conventions

The following tables describe the conventions and terminology used in this document.

Formatting Conventions

Convention	Description
Blue Text	Blue text provides a cross-reference to content in another section within this user guide.
Bold Text	Bold text is used to emphasize buttons within the twiist app or on the pump the operator interacts with.
Italic Text	 Italic text is used to emphasize: Words or phrases that appear on the twiist app screen. Parts or features of the system. Sounds played by the system. Headings, cross-references, table captions

Terminology

Term	Description
Button	Refers to a physical button or a software button displayed on a touchscreen.
lcon	A symbol displayed within the twiist app indicating an option or information, or a symbol on your pump or system packaging.
Keypad	Used to enter alpha or numeric values into the twiist app.
Picker	A tool displayed within the twiist app for selecting a value. Swipe up or down on the touchscreen to select a value.
Press	Press down on a physical button with your fingertip.

Term	Description
Press/Touch and Hold	Continue to touch an area of the touchscreen or keep pressing a physical button until the action is complete.
Select	The act of choosing from a list of options on the touchscreen.
Swipe	Place your fingertip on the touchscreen and slide your finger in a specified direction to activate a function or select a value.
Тар	Quickly and gently touch the screen with your fingertip.
Touchscreen	The display device which allows you to interact with the twiist app on your iPhone.

Symbols

Symbols are displayed on your pump, supplies, packaging, and within this user guide. These symbols provide information necessary to use the system and supplies safely.

Symbol	Definition				
(Read instructions prior to use.				
	Indicates a potential hazard. Obey all safety messages that follow this symbol.				
$R_{\!X\text{Only}}$	Prescription use only				

Symbol	Definition		Symbol	Definition
MR	Magnetic Resonance Unsafe – Items		$\sum_{i=1}^{n}$	Expiration date
	should not enter an MRI scanner room.		LOT	Lot code
(2)	Single use only		REF	Catalog number
			SN	Serial number
Ŕð	Material may be recycled		\bigcirc	
			X	Do not use if package is damaged
Manufac	anufacturer	STERILE	Sterile	
~~~	Date of Manufacture		STERILEEO	Sterilized using ethylene oxide

Symbol	Definition	Symbol	Definition
STERILE R	Sterilized using irradiation		Recycle lithium-ion batteries
XX	Non-pyrogenic	Li-ion	-
XX		X	Separate collection for electrical and
	Keep dry		electronic equipment waste.
J			Temperature limit
*	Keep away from sunlight	-⁄-	
		(%)	Humidity limit
★	Type BF Applied Part		
			Pressure limit
	Direct Current required	5	

Symbol	Definition
i	Identifies an important note about the use of the system.
	Caution - Used to notify the caregiver or patient of potential hazards. Obey all safety messages that follow this symbol.
	Warning - Used to notify the caregiver or patient of potential hazards. Obey all safety messages that follow this symbol to avoid possible injury.
(( <b>1</b> )))	Indicates generally elevated, potentially hazardous, levels of non- ionizing radiation, or to indicate equipment or systems in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment.

# About this User Guide

This User Guide provides important information about how to operate the twiist automated insulin delivery (AID) system, including step-by-step instructions to setup, manage, and care for the system.

Important warnings and cautions related to safe operation and technical information are also included in this user guide.

i Values displayed in this user guide are for demonstrating the use of the system features and should not be used to make insulin delivery decisions.

Changes in equipment, software, or instructions may occur. Changes will be included in future revisions of this user guide.

Please visit <u>www.twiist.com</u> for the latest version of the user guide.

## System Description

The twiist[™] Automated Insulin Delivery (AID) System powered by Tidepool[®] consists of the twiist pump, a twiist 300 unit (3 mL) cassette, the twiist app, and a compatible infusion set for the continuous subcutaneous (under the skin) delivery of insulin, at set and variable rates, for the management of diabetes.

The twiist automated insulin delivery system includes twiist[™] *Loop* powered by Tidepool[®], for optional automated basal delivery, when used with a compatible integrated continuous glucose monitor (iCGM).

The twiist AID system is intended for single-patient use and requires a prescription.



The twiist pump and app, *Loop*, and a compatible iCGM may be referred to as the twiist automated insulin delivery system or twiist AID system.

The twiist app provides a means of programming and controlling the pump and viewing historical data.

The twiist AID system delivers basal insulin, at a programmed rate, and bolus insulin deliveries to cover meals or lower blood glucose.

You can choose to use an Apple Watch with the twiist app.

This optional component provides a discreet way to view your sensor glucose and insulin information, enter carbs, and deliver a bolus of insulin.

The twiist pump, app, and iCGM communicate via Bluetooth. Basal deliveries are made even when the twiist pump and app are not communicating.

When your iPhone is on and within Bluetooth range of the pump, the twiist app displays insulin delivery and optional glucose information.

The twiist pump contains volume measurement hardware, pump actuation hardware, and electronics. The pump is powered by a rechargeable battery designed specifically for use with the system. Each single-use, disposable cassette can be filled with up to 300 Units (3 mL) of U-100 Humalog (insulin lispro) or Novolog (insulin aspart) and attaches to the pump. The cassette includes a luer connector, and chambers for storing, pumping, and measuring insulin, as well as valves used to control the flow of insulin.

The pump and cassette chambers actively draw up to 0.002 mL aliquots of insulin from the storage chamber in the cassette, measure the volume of each aliquot, and then deliver these aliquots into the patient. These individual measurements are used to accurately deliver insulin and detect occlusions. Insulin is infused through an attached infusion set. Cassettes and infusion sets are replaced every 48-72 hours.

The twiist system can be used for basal and bolus deliveries whether a CGM is in use or not. If a CGM is not in use, CGM readings will not be displayed by the twiist app. *Loop* cannot be enabled when a CGM is not in use.

The CGM and pump communicate via Bluetooth. The twiist app displays CGM readings, a rate of change indicator, and a glucose trend graph.

You must be trained by a healthcare provider before using the twiist AID system. If you have not received training, contact Sequel Customer Support.

#### What Is Loop?

The twiist automated insulin delivery system includes *Loop* for optional automated basal insulin adjustment. It works differently than your twiist insulin delivery system does by itself.

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

When *Loop* is on, the twiist AID system makes a prediction about your future glucose by looking at:

- Your settings
- Your CGM readings
- · Your recent insulin deliveries
- Your recent carb entries



The twiist AID system adjusts your basal insulin by pulling together information about your glucose from your CGM, insulin from your twiist pump, and details you enter about carbs you eat, plans for exercise, and the glucose correction range you are aiming for.

Your insulin delivery is adjusted in the background to reduce high and low glucose and work to keep you in your *Correction Range*. The twiist AID system makes a calculation as often as every 5 minutes. This 5 minute cycle is called a *Loop*.



Using the twiist AID system with *Loop* on is not a substitute for diabetes management.

Keep the twiist AID system informed about where you would like your glucose to be by setting your correction range. The twiist app allows you to let the system know to work a little harder to lower your glucose before a meal. This allows twiist to start adjusting for carbs you plan to eat before you consume them.

The twiist app also allows you to let the system know you want your glucose to remain elevated while you exercise or to slow down a rapidly falling glucose.

The twiist AID system can continue to make adjustments to your basal rate whether or not your twiist pump is in communication with the twiist app.

Use twiist with *Loop* off when:

- You do not have an active CGM.
- You may want to take full manual control of your insulin delivery decisions.

## Indications For Use

The twiist system is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin, ages six and above. The pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices. The twiist system is intended for single patient, home use and requires a prescription.

# Loop Indications for Use

The twiist *Loop* algorithm is intended for use with compatible integrated continuous glucose monitors (iCGMs) and the twiist alternate controller enabled (ACE) insulin infusion pump to automatically increase, decrease, and suspend delivery of basal insulin based on iCGM readings and predicted glucose values. It can also recommend, and with the user's confirmation, control the delivery of correction boluses when glucose values are predicted to exceed user configurable thresholds.

The twiist *Loop* algorithm is intended for the management of type 1 diabetes mellitus in persons six years of age and greater. The twiist *Loop* algorithm is intended for single-patient use and requires a prescription.

### Bolus Calculator Indications For Use

The twiist automated insulin delivery system includes a simple bolus calculator available when *Loop* is off. It is indicated for use for aiding the user in determining the bolus insulin dosage for management of diabetes mellitus based on consumed carbohydrates, operator entered blood glucose, insulin sensitivity, insulin to carbohydrate ratio, target glucose values, and current insulin on board.

#### Contraindications

The twiist automated insulin delivery system is not intended for anyone unable or unwilling to:

- Test blood glucose (BG) levels as recommended by their healthcare provider.
- Maintain sufficient diabetes self-care skills.
- See their healthcare provider regularly.
- Demonstrate adequate carbohydrate-counting skills (preferred, not required).

The user must not:

- · Have difficulty seeing.
- Have difficulty hearing.
- Have deficient cognitive capabilities.
- Have physical impairments which would make operating the pump or iPhone difficult.

# Compatibility Insulin

The twiist automated insulin delivery system is designed to use fast-acting U-100 insulin. The following U-100 fast-acting insulin analogs have been tested and found to be safe for use in the twiist automated insulin delivery system:

- Humalog (insulin lispro)
- Novolog (insulin aspart)

Humalog (insulin lispro) and Novolog (insulin aspart) were found to be compatible with the twiist automated insulin delivery system for 72 hours (3 days) maximum use time. Some insulin products are labeled for use in any pump that is compatible with the insulins listed above. To see if another insulin not listed above can be used, refer to section 2.2 of the prescribing information for that insulin product.

#### Cassettes

The twiist automated insulin delivery system is compatible with one cassette: the twiist cassette. This cassette was found to be compatible with the twiist automated insulin delivery system for 72 hours (3 days) maximum use times when using U-100 Humalog (insulin lispro) or Novolog (insulin aspart).

#### Infusion Sets

The twiist automated insulin delivery system is compatible with the following infusion sets:

- Contact Detach:
  - 23 inch (60 cm) FG000016-03
- Inset:
  - 23 inch (60 cm) FG000016-01
  - 32 inch (80 cm) FG000016-05
- Quick-set:
  - 43 inch (110 cm) MMT-390
  - 43 inch (110 cm) MMT-391
  - 23 inch (60 cm) MMT-392
  - 23 inch (60 cm) MMT-393
- Silhouette:
  - 23 inch (60 cm) MMT-373
- Comfort:
  - 23 inch (60 cm)
- Cleo 90:
  - 24 inch (61 cm) 21-7220-24
  - 31 inch (79 cm) 21-7221-24
  - 42 inch (107 cm) 21-7222-24
  - 24 inch (61 cm) 21-7230-24
  - 31 inch (79 cm) 21-7231-24
  - 42 inch (107 cm) 21-7232-24

Replace your infusion set every 48-72 hours, as indicated by the infusion set manufacturer, or per instruction from your healthcare provider.

### iCGMs

The twiist automated insulin delivery system is compatible with the following iCGM:

 Abbott FreeStyle Libre[®] 3 Plus Sensor

For information about the FreeStyle Libre 3 Plus Sensor product specifications and performance characteristics, refer to the user manual provided by the manufacturer. FreeStyle Libre 3 Plus Sensors are sold and shipped separately. Product information for the

FreeStyle Libre 3 Plus Sensor includes important information on how to use the FreeStyle Libre 3 Plus Sensor and interpret sensor data to make treatment decisions.

(i) The FreeStyle Libre 3 Plus Sensor can only be paired with one device. The FreeStyle Libre 3 Plus Sensor can either be paired with the twiist automated insulin delivery system, or the FreeStyle Libre 3 app, or Reader. A FreeStyle Libre 3 Plus Sensor that has been previously paired with the FreeStyle Libre 3 app or Reader cannot be paired with the twiist app.

Ensure that you have reviewed this information and discussed it with your healthcare provider, who can guide you in correctly using your FreeStyle Libre 3 Plus Sensor when making treatment decisions.

#### *iPhone Compatibility*

The twiist app requires an iPhone with version 18 or greater of the *Apple* iPhone operating system (iOS).

Do not run the twiist app on an iPhone with unauthorized modifications. In order for the twiist app to work properly, it must be used on a compatible iPhone that does not have a modified operating system (jailbroken device).

Do not install apps on your iPhone from untrusted sources. Installing apps from any source other than the App Store on your iPhone running the twiist app may put you at risk of unintentionally installing malware, which may impact the use of the twiist app. Only install apps from the App Store. Malware, or malicious software from unknown sources, is designed to damage your device and/or read your private information. The most common method for spreading malware is the use of unknown apps and unknown downloads. Malware can prevent the twiist app from functioning as intended, causing over-delivery or under-delivery of insulin, which may lead to low or high glucose.

If you believe you have malware on your iPhone, discontinue use of the twiist app and use an alternate means of insulin delivery until you are able to resolve. If you have any apps installed from unknown sources, delete the app, restore your iPhone to factory default settings and contact Sequel Customer Support.

#### Apple Watch Compatibility

The twiist app is compatible with all released versions of the Apple Watch running Apple Watch OS 10 and newer.

## Important User Information

Read all instructions in this user guide, and the instructions from your infusion set manufacturer before use of this system.

Throughout this user guide, the patient is the intended operator.

The following items must be understood prior to using the twiist automated insulin delivery system:

- The operator is able to program the system with appropriate basal rates.
- The operator is able to adjust the basal rates as instructed.
- The operator is able to deliver a bolus as instructed.
- The operator understands only approved cassettes and infusion sets may be used with the system.

- The operator is able to execute the proper procedure for changing a cassette.
- The operator is able to execute the proper procedure for resolving an alarm.

Test fingerstick glucose and take appropriate corrective action as advised by your healthcare provider in the event glucose is too high or low.

Read the instructions from your iCGM manufacturer before using the system.

If you are a new CGM user, or your symptoms do not match your CGM reading, use a BG meter to check your glucose values.

If you have read this user guide and have questions, contact Sequel Customer Support, available 24 hours a day, 7 days a week. See "Sequel Customer Support" on page 245.

## Important Information about Your iPhone

Your iPhone includes features that may impact the use of the twiist automated insulin delivery system.

Avoid the use of features that may prevent seeing or hearing notifications, including, but not limited to:

• Focus, Screen Time, and Scheduled Summary

Avoid the use of features that may alter the appearance of the twiist app such as *Accessibility* settings including, but not limited to:

• Zoom, Bold or Larger Text, Increase Contrast, Smart or Classic Invert Allow Notifications and Critical Alerts for the twiist app in your iPhone settings. Failure to allow Notifications and Critical Alerts may lead to missed twiist app notifications which may lead to high or low glucose.

Disabling *Notifications* prevents your iPhone from displaying notifications on your lock screen and playing sounds which may result in missed alarms, alerts, and notices.

Disabling *Critical Alerts* prevents your iPhone from displaying notifications and playing sounds even when your iPhone is silent or *Focus* is enabled. This may result in missed notifications for certain alarms and alerts.

# Important Pediatric User Information

It is the responsibility of the healthcare provider and caregiver to determine if the patient is a good candidate for treatment with the twiist automated insulin delivery system.

Review your device settings and features like *One-Button Bolus* to make sure they are configured appropriately. Younger users may press the pump button leading to unintentional delivery of insulin.

Children may dislodge their infusion site more frequently. Make sure infusion set tubing is secure.

## Emergency Supplies

Always have emergency supplies available. Talk to your healthcare provider about what you should keep in your emergency supplies in addition to:

- Blood glucose monitoring supplies
- Fast-acting glucose tablets
- Unopened sterile, single-use, 3 mL syringe and 27 gauge x 3/8 inch (0.40 mm x 10 mm) needle
- · Unopened cassette
- Spare insulin
- Unopened infusion set
- · Alcohol wipes

## Working with your Healthcare Provider

Clinical language contained within this user guide is used based on the assumption that you have been educated by your healthcare provider on terminology that applies to your diabetes management. Consult with your healthcare provider before using the twiist automated insulin delivery system to determine which features are appropriate for your use. Only your healthcare provider should assist with the adjustment of your therapy settings.

## Important Safety Information

The following section includes important safety information related to your twiist automated insulin delivery system. Additional and repeated warnings and

cautions ( A or ! ) appear throughout this user guide where appropriate.

## Warnings

Warnings ( ) provide information about detailed situations and the possible result of not following the guidance which could lead to death or serious injury.

#### Training and Use Warnings

Do not use the twiist automated insulin delivery system if you have not received training on appropriate use by a certified twiist trainer. Discuss your individual training needs with your healthcare provider. Failure to receive the appropriate training could result in serious injury or death.

Avoid using accessibility features on the iPhone. Using accessibility features on the iPhone may affect the ability to view the twiist app which could lead to harm. Do not use the twiist automated insulin delivery system before reading this user guide. Failure to follow the instructions provided in this user guide may result in over or under delivery of insulin, which may lead to low or high blood glucose. If you have questions about system use, contact your healthcare provider or Sequel Customer Support. See "Sequel Customer Support" on page 245.

The twiist automated insulin delivery system is not recommended for use by an operator with poor vision. Poor vision may prevent the correct reading of information displayed within the twiist app and may lead to harm. Only use fast-acting U-100 Humalog (insulin lispro) or Novolog (insulin aspart). Use of other concentrations may lead to insulin delivery errors that may lead to low or high blood glucose.

Treat symptoms of low blood glucose immediately to prevent severe low blood glucose. If not treated it could lead to loss of consciousness, seizure or death.

A passcode must be enabled on your iPhone to use the twiist app. Your iPhone passcode prevents unauthorized changes to your therapy settings or insulin delivery, which may lead to low or high blood glucose. Your passcode should not be shared with unauthorized operators. Allow Notifications and Critical Alerts for the twiist app in your iPhone settings. Failure to allow Notifications and Critical Alerts may lead to missed twiist app notifications which may lead to high or low glucose.

Your iPhone should not be used with the twiist automated insulin delivery system if your iPhone:

- · battery cannot last a full day
- · shuts down unexpectedly
- cannot be powered down or restarted
- cannot maintain Bluetooth communication
- screen, speaker, camera, or vibration motor are broken

Use of your iPhone under these conditions may result in harm.

#### Backup Supplies Warnings

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. Extended delay of insulin delivery may cause high blood glucose or diabetic ketoacidosis (DKA).

#### Location of Use Warnings

The system may affect nearby electrical devices (such as antennas or radios), including medical ones. This could cause these devices not to work properly or stop working. Keep the pump and pump battery charger away from these devices.

Retail anti-theft detectors may affect pump accuracy or trigger an alarm. Walk through retail anti-theft detectors at a normal pace, but avoid standing in them.

Portable RF communications equipment including antenna cables and external antennas may affect the communication between the twiist pump and app, or interrupt operation of the pump. Keep the pump at least 12 inches (30 cm) away from these items.

Metal detectors may affect pump accuracy or trigger an alarm. Handheld or walk through metal detectors may be used near the system, but prolonged exposure to them should be avoided. Avoid exposing your pump to temperatures below 41 °F (5 °C) or above 104 °F (40 °C). When in cold temperatures, the pump should be worn close to the body and covered in warm clothing. When in warm temperatures, take measures to keep the pump cool.

#### Disposables Warnings

Do not use damaged cassettes or infusion sets. Using damaged cassettes or infusion sets may result in start-up failures, interruptions in therapy, topical exposure to insulin, or delivery errors leading to high or low blood glucose.

- Do not use cassettes, infusion sets, needles, or syringes if:
- The expiration date on the package has passed.
- Packaging has been previously opened or damaged.

Use of disposable components that are expired or from previously opened or damaged sterile packaging may lead to infection.

#### Cassette Change Warnings

Always rotate insulin infusion sites to help prevent infusion site complications like scar tissue and infection. Rotating insulin infusion sites reduces the risk of scarring. Using a site with scar tissue can lead to problems with insulin absorption or blockages that may lead to high blood glucose.

Always follow your infusion set manufacturer instructions for infusion site insertion and care. Failure to do so may result in over or under delivery of insulin or infection.

Make sure to prime the infusion set tubing. Failure to prime the infusion set tubing may lead to a delay in the delivery of insulin resulting in high blood glucose or cause a delivery error. Do not fill the cassette with cold insulin. Filling the cassette with cold insulin may result in air bubbles forming in your cassette or infusion set tubing that may result in delivery errors that may lead to harm. Allow insulin to adjust to room temperature before filling the cassette.

Do not fill or prime the cassette and infusion set tubing while connected to your infusion site. Connecting the infusion set tubing during filling and priming may lead to the unintended delivery of insulin which may result in low blood glucose. Do not connect a filled cassette and infusion set tubing to your infusion site if the cassette is not attached to the pump. Connecting the filled cassette and infusion set tubing to your infusion site before connecting the cassette to the pump may lead to unintended insulin delivery leading to low blood glucose.

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. Damaging the inside of the pump, which is exposed while changing the cassette or battery, may affect pumping accuracy which may increase or decrease delivery and lead to low or high blood glucose.

Dirt, lubricants, or liquids may contaminate the inside of the pump while it is detached from the cassette. Contamination may affect pumping accuracy, which may increase or decrease insulin delivery causing low or high blood glucose.

Do not fill a cassette before you plan to use it. Filling a cassette before you plan to use it may result in spoilage or a change to the potency or purity of insulin, which may lead to harm. Before removing the cassette from your pump, disconnect the infusion set tubing from your infusion site. Leaving the infusion set tubing connected may lead to unintended delivery, which may cause low blood glucose.

If air bubbles are present in the infusion set tubing, perform a cassette change. Air bubbles present in the infusion set tubing may lead to under or over-delivery of insulin, which may lead to high or low blood glucose.

#### Sharp Objects/Small Part Warnings

Keep the pump, cassette, and infusion set tubing away from sharp objects. Sharp objects may damage these components which may cause delivery error and lead to harm. Pets may damage your infusion set tubing while sleeping which may lead to an interruption of insulin delivery or infection. Do not sleep with your infusion set tubing exposed if pets are present.

Do not allow children to ingest small parts, such as the pump batteries. Small parts could pose a choking hazard. If swallowed, these small parts may cause internal injury or infection.

Exposed infusion set tubing could pose a choking hazard. Keep exposed infusion set tubing out of the reach of unsupervised children.

#### Medical Procedures Warnings

The twiist automated insulin delivery system is Magnetic Resonance Unsafe. Disconnect your twiist pump before entering an MRI scan room. Do not bring your iPhone or twiist pump into an MRI scan room. Contact with, or being in proximity to, an MRI scanner may cause the twiist pump and iPhone to move or lead to electric shocks and may result in severe injury.

Never drive yourself to the emergency room if you need emergency medical care. Ask a friend or family member to take you to the emergency room or call an ambulance.

**Loop** is not indicated for use by anyone who is pregnant, on dialysis, or critically ill. It is not known how different conditions or medications used in these scenarios may affect performance of the twiist automated insulin delivery system. CGM readings being used by the system may be inaccurate in these cases, meaning the twiist AID system will not have accurate information to use for dosage recommendations. This could result in over-delivery or under-delivery of insulin, which can lead to low or high glucose.
A Do not expose your system to:

- X-ray
- Computed Tomography (CT) scan
- Magnetic Resonance Imaging (MRI)
- Positron Emission Tomography (PET) scan
- Diathermy Devices
- Electrocautery Devices
- Pacemaker/Automatic Implantable Cardioverter Defibrillator (AICD) placement or reprogramming
- Cardiac Catheterization
- Nuclear Stress Test
- Other exposure to radiation

Remove your twiist system and leave it outside the room prior to these procedures. Failure to do so may lead to harm. Always notify medical staff about your diabetes and your twiist automated insulin delivery system. If you need to stop insulin delivery or remove your CGM Sensor for a medical procedure, follow guidance from your healthcare provider about insulin missed while disconnected from your pump. Check your blood glucose before disconnection and reconnection and treat your highs and lows.

Do not use the twiist automated insulin delivery system when using hydroxyurea, a medication used in the treatment of diseases including cancer and sickle cell anemia. CGM readings being used by the system may be inaccurate while taking hydroxyurea, meaning the twiist automated insulin delivery system will not have accurate information to use for dosage recommendations. This could result in over-delivery of insulin, which can lead to low glucose. Talk to your healthcare provider about using your BG meter for treatment decisions instead.

Do not take external insulin, such as manual insulin injections or inhaled insulins, while *Loop* is on and the twiist pump is operational. The twiist automated insulin delivery system does not receive information about insulin taken outside the system. If you choose to take additional insulin with another method while *Loop* is on and the twiist pump is working, over-delivery or under-delivery of insulin may occur, which can lead to high and low glucose. Consult with your healthcare provider about how long to wait after manually taking insulin before enabling automated insulin delivery.

Do not use the twiist automated insulin delivery system if you have a condition which, in the opinion of your healthcare provider, would put you at risk. Examples of individuals who should not use the twiist automated insulin delivery system include those with uncontrolled thyroid disease, renal failure (e.g. dialysis or eGFR <30), hemophilia, or another major bleeding disorder, or unstable cardiovascular disease.

Do not use the twiist automated insulin delivery system if you are taking GLP-1 agonists or SGLT-2 inhibitors, metformin or DPP-4. The twiist automated insulin delivery system has not been tested in populations using additional diabetes medications and the performance of the system in conjunction with these medications is unknown. Avoid using the twiist automated insulin delivery system in oxygen rich environments (greater than 25% oxygen), which includes the use of supplemental oxygen and hyperbaric chambers. Exposure to oxygen rich environments could result in combustion of components of the twiist automated insulin delivery system including your twiist pump and compatible CGM. This can cause severe burns on the body.

## Therapy Settings/Bolus Delivery Warnings

When *Loop* is on, do not modify a bolus to be greater than the recommended value. Increasing the bolus can lead to increased risk of low blood glucose. Do not set glucose safety limit, correction range, pre-meal range, workout range, carb ratios, basal rates, delivery limits, insulin sensitivities, or insulin model

without direction from your healthcare provider. Incorrect settings may lead to low or high blood glucose.

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

## Discontinue Use Warnings

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.

## Line Blocked Alarm Warnings

Only use twiist cassettes with compatible infusion sets. Failure to do so may affect accuracy or blockage detection which may lead to over or under delivery and cause low or high blood glucose. Do not leave the cassette and infusion set tubing connected to your infusion site when investigating or resolving a *Line Blocked* alarm. Leaving the infusion set tubing connected during a *Line Blocked* alarm may lead to unintended delivery of insulin, which may cause low blood glucose.

## Approved Parts Warnings

Only use the provided wall power adapter and charging cables to charge your pump batteries. Use of another wall power adapter or cables could damage the system or result in fire or burns. Do not use batteries or battery chargers that were not supplied with the system. Use of batteries and battery chargers that did not come with the system may lead to unsafe operation which may lead to harm.

## Maintenance and Troubleshooting Warnings

Do not perform troubleshooting steps while the pump is connected to your infusion site. Performing troubleshooting steps while the pump is connected to your infusion site may lead to unintended delivery of insulin, which may lead to low blood glucose.

# Cautions

Cautions (!) provide information about specific scenarios and the possible outcomes that may occur as a result of failing to follow the provided guidance, which may lead to minor or moderate injury.

# Sound and Vibration Cautions

Disconnect your iPhone from audio devices such as Bluetooth headphones or speakers when you are no longer using them. Remaining connected to audio devices when they are no longer in use may lead to missed twiist app notifications.

Prolonged noise or vibration may interfere with the ability of the pump to continue delivery and trigger an alarm. Set the ringtone and alert volume on your iPhone to be louder than your surroundings so twiist app notifications can be heard.

## Clean Technique Cautions

Wash your hands and use clean technique when filling the cassette, inserting the infusion site, and connecting the infusion set tubing. Failure to do so may lead to infection.

# Battery and Charging Cautions

Replace pump batteries after four months of use. Failure to replace pump batteries after four months of use may lead to *Cassette Problem* alarms. Do not use the wall power adapter if it is visibly damaged or malfunctioning. Using a damaged or malfunctioning wall power adapter can result in electrical shock.

Surfaces of the pump battery charger may reach 131 °F (55 °C). When the device is warm to the touch avoid contacting the surfaces. Making contact with the charger while it is warm to the touch may result in burns.

Do not open, crush, heat above 140 °F (60 °C), or incinerate the pump batteries. Doing so can lead to fire, burns, or property damage.

The use of cables other than those provided or specified may result in increased radio frequency emission or decreased radio frequency immunity of the system.

## Discontinue Use Cautions

Stop using the pump and switch to your backup insulin delivery method in the event the pump housing is cracked, the pump button is damaged, or there is other evidence of damage to the pump. Failure to do so may lead to pump malfunctions resulting in interruption of therapy.

Do not use the pump when swimming. Immersing your pump in water may lead to pump malfunctions resulting in interruption of therapy.

## General Use Cautions

When a CGM is not available, there is increased risk of high and low blood glucose. Check your fingerstick glucose at least 4 times daily. Federal law restricts this device to sale by or on the order of a licensed physician. Use of this device without the training and supervision of a physician may lead to errors that result in harm.

Speak with your healthcare provider about lifestyle changes that may impact your overall insulin needs and settings, such as weight gain or loss or starting or stopping new activities.

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

Avoid strong magnetic fields. Strong magnetic fields can trigger a false *Cassette Not Attached* alarm. Check your infusion site every day for proper placement. Replace your infusion site if you notice leaks around the site. Improper placement or leaks around the site may result in under delivery of insulin resulting in high blood glucose.

Before going to sleep, check to make sure you have enough insulin in your cassette and sufficient charge remaining in your pump battery to last through the night. It is possible to sleep through, or fail to hear, a *Cassette Empty* alarm and miss a portion of your basal delivery.

Verify a One-Button Bolus by looking at the twiist app to confirm the correct bolus amount. Looking at the twiist app will ensure that you are correctly using the pump button to program the intended bolus. Do not attempt to open, modify, or repair any parts of the system. Attempting to open, modify, or repair any parts of the system could lead to unsafe operation and may lead to harm.

Make sure the time and date is set correctly on your iPhone. If the time and date is not set correctly, delivery errors may occur resulting in low or high blood glucose.

Avoid using the twiist automated insulin delivery system in high atmospheric pressure environments (above 1060 hPA), which can be found in hyperbaric chambers. Exposure to high atmospheric pressure environments can damage components of the twiist automated insulin delivery system, including your twiist pump and compatible CGM, which could result in over-delivery or under-delivery of insulin, which can lead to low or high blood glucose.

▲ Check your glucose frequently during amusement park rides, flying, hiking, skiing, snowboarding or other situations where sudden changes or extremes of air pressure, altitude, or gravity may be occurring. The atmospheric pressure in an airplane cabin can change during flight, which may affect insulin delivery. Rapid changes in altitude and gravity, such as those typically found on amusement park rides or flight takeoff and landing, can affect insulin delivery, leading to possible hypoglycemia or injury. If needed, follow your treatment instructions provided by your healthcare provider.

Avoid using the twiist automated insulin delivery system at low atmospheric pressure (below 700 hPA). Encounters with low atmospheric pressure can happen at high elevations (above 10,000 feet or 3,048 meters). Exposure to such low atmospheric pressures can damage components of the twiist automated insulin delivery system, including your twiist pump and compatible CGM, which could result in over-delivery or under-delivery of insulin, which can lead to low or high blood glucose.

## Cyber Security Cautions

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

## Travel Cautions

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 twiist pump should not 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.

# Skin Care Products Cautions

Contact with insect repellents that contain DEET, skin care products, or sunscreens can damage the pump or cassette, which may lead to leaks, pump malfunctions, or delivery interruption.

Avoid getting insect repellents, skin care products, or sunscreen on the pump or cassette. If these products do get on the cassette or pump, wipe them off immediately with a clean cloth.

# CGM Safety Information

Refer to your CGM manufacturer instructions for information on warnings and cautions associated with the use of your CGM.

# CGM Warnings

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

When in doubt, get your meter out.

The FreeStyle Libre 3 Plus Sensor contains small parts that may be choking hazards and may be dangerous if swallowed.

FreeStyle Libre 3 Plus Sensor readings and alerts are not available during the 60-minute warm up period or during *CGM Signal Loss* and will not be displayed. Check your blood glucose using your BG meter to prevent severe low or high blood glucose.

Use your blood glucose meter to make diabetes treatment

decisions when you see the symbol during the first 12 hours of wearing a FreeStyle Libre 3 Plus Sensor, if your sensor glucose reading does not match how you feel, or if the reading does not include a number.

# **CGM** Cautions

Choose a CGM insertion site that is at least 1 inch (2.5 cm) away from your insulin infusion site that is unlikely to be bumped, pushed, or slept upon, and is also away from tattoos, scarring or irritation.

Your CGM and pump should be kept within 33 ft (10 m) of each other without obstructions between them or they may not be able to communicate. To help maintain communication, keep the CGM and pump on the same side of your body. Bluetooth communication does not work well through water.

# FreeStyle Libre 3 Plus Sensor Safety Information

Taking more than 1000 mg of Vitamin C per day may falsely raise your FreeStyle Libre 3 Plus Sensor readings. This could cause you to miss a severe low glucose event. Vitamin C can be found in supplements including multivitamins and cold remedies such as Airborne[®] and Emergen-C[®]. See your health care professional to understand how long Vitamin C is active in your body. Physiological differences between the interstitial fluid and capillary blood may result in differences in glucose readings between the FreeStyle Libre 3 Plus Sensor and results from a fingerstick test using a blood glucose meter. Differences in glucose readings between interstitial fluid and capillary blood may be observed during times of rapid change in blood glucose, such as after eating, dosing insulin, or exercising.

The FreeStyle Libre 3 Plus Sensor should be removed prior to exposing it to an X-ray machine. The effects of X-rays on the performance of the sensor has not been evaluated. The exposure may damage the sensor and may impact proper function of the device to detect trends and track patterns in glucose values during the wear period. If a FreeStyle Libre 3 Plus Sensor breaks inside your body, call your healthcare provider.

FreeStyle Libre 3 Plus Sensor performance when used with other implanted medical devices, such as pacemakers, has not been evaluated.

# Get to Know Your twiist Automated Insulin Delivery System

When opening the boxes for the first time, check to make sure that all of the listed components are included.

If anything included with the twiist AID system does not work as described, contact Sequel Customer Support for a replacement.

The twiist AID system includes:

#### The twiist insulin delivery system

- 1. The twiist AID system User Guide
- 2. QR code to create your account
- 3. Rechargeable pump battery (4)
- 4. Pump battery charger (2)
- 5. USB charging cable (2)
- 6. Wall power adapter with 2 USB ports (2)
- 7. Pump clip
- 8. The twiist pump with attached cover



#### Cassettes

The twiist 3 mL cassettes are provided in individual, single-use, sterile packaging. A cassette uses a luer connector to attach to a compatible infusion set, and includes a filling port to fill the cassette with insulin.

Cassettes are sterilized using gamma radiation.

• (10) Cassettes

### Needles, Syringes, and Wipes

Additional single-use supplies are necessary to use the twiist AID system and include needles, syringes, and alcohol wipes.

- (10) 3 mL syringes
- (10) 27 gauge x 3/8 inch (0.40 mm x 10 mm) needles
- (30) Alcohol wipes

#### **Infusion Sets**

• (10) Cleo 90 - 24 inch (61 cm) infusion sets with 6 mm cannula

(i) Make sure you always have enough cassettes, infusion sets, syringes, and needles to meet your needs.

### **CGM Supplies**

All CGM components are sold and shipped separately.

- Do not use cassettes, infusion sets, needles, or syringes if:
- The expiration date on the package has passed.
- Packaging has been previously opened or damaged.

Use of disposable components that are expired or from previously opened or damaged sterile packaging may lead to infection.

Do not use damaged cassettes or infusion sets. Using damaged cassettes or infusion sets may result in start-up failures, interruptions in therapy, topical exposure to insulin, or delivery errors leading to high or low blood glucose.

# **Getting Started**

If the pump has been exposed to extremely hot or cold temperatures, allow the pump to sit at room temperature for at least an hour prior to use.

Contact Sequel Customer Support for assistance with any of the set up instructions.

Do not use the twiist automated insulin delivery system before reading this user guide. Failure to follow the instructions provided in this user guide may result in over or under delivery of insulin, which may lead to low or high blood glucose. If you have questions about appropriate use, contact your healthcare provider or Sequel Customer Support. See "Sequel Customer Support" on page 245. Do not use the twiist automated insulin delivery system if you have not received training on appropriate use by a certified twiist trainer. Discuss your individual training needs with your healthcare provider. Failure to receive the appropriate training could result in serious injury or death.

# The twiist Pump



The twiist pump, when connected to a cassette and infusion set, continuously delivers U-100 fast-acting insulin under the skin at the basal rate(s) (U/hr) set with your healthcare provider. When used with a CGM and the twiist app, basal rates will be automatically adjusted based on your insulin needs. The pump continues to deliver your basal insulin when it is not in communication with the twiist app or your iPhone is powered off.

- If *Loop* is on, your basal delivery will continue to be adjusted.
- If *Loop* is off, your basal will be delivered at the scheduled basal rate.

The twiist pump can be used to deliver a *One-Button Bolus*, if enabled. The twiist pump will continue to maintain all alarm functions when the twiist app is not available.

The twiist pump is also used to deliver a bolus of fast-acting insulin to cover carbs or bring high glucose down into your *Correction Range*. The pump is powered by a rechargeable battery designed for the twiist AID system. During a *Cassette Change*, which occurs at least every 3 days, the battery is removed from the pump and charged. A fully charged battery is inserted into the pump.



The twiist pump is shipped with an attached cover. The cover is removed and a cassette is attached and filled during setup with your certified twiist trainer. When the cover is not in use, store it in a safe, easily accessible location along with this user guide and your other system accessories. When the pump is not in use, store the pump with the cover attached.



## Pump-Bump

The *pump-bump* and alignment ridge are features on the pump to help align the cassette and pump when a cassette is being attached to the pump.



When attaching a new cassette to the pump, align the ridge on top of the *pump-bump* with the ridge on the cassette. When the ridges are aligned, turn the pump clockwise toward the infusion set tubing.



When the ridge on the *pump-bump* is aligned with the infusion set tubing, the cassette has been fully attached.



## **Pump Button**



The pump button provides the ability to:

- Confirm that delivery is in progress
- Resume insulin delivery
- Place the pump into pairing mode (when not connected to a cassette).
- Deliver a One-Button Bolus

Press and hold the **pump button** for 3 seconds to resume delivery or confirm that delivery is in progress. The *Delivering* sounds will be played by the pump to let you know that delivery is in progress.

The pump button is used to place the pump into pairing mode, in the event that it needs to be paired with the twiist app again. See "Pair Your Existing Pump" on page 99.

The pump button can be used to deliver a *One-Button Bolus* (when enabled). *See "One-Button Bolus"* on page 166.

# *How to Wear your twiist Pump*

Your twiist pump can be attached to a belt or clothing with the provided pump clip. The pump can also be placed in a clothing pocket.

In order to maximize the signal between your pump and CGM, and minimize communication interruptions, your pump and CGM should be placed on the same side of your body. The twiist logo on the pump should face away from your body.

Make sure to secure the infusion set tubing and pump to prevent them from catching on other objects.

Avoid strong magnetic fields. Strong magnetic fields can trigger a false *Cassette Not Attached* alarm. i) When the system is used in a loud environment your iPhone should be kept in a clothing pocket so vibration can be felt, if enabled. Check for twiist app notifications if you are in an environment where you cannot feel vibration or hear system sounds.

Keep the pump, cassette, and infusion set tubing away from sharp objects. Sharp objects may damage these components which may cause delivery error and lead to harm.

Pets may damage your infusion set tubing while sleeping which may lead to an interruption of insulin delivery or infection. Do not sleep with your infusion set tubing exposed if pets are present.

## Pump Clip



- 1. The pump slides into the pump clip with the pump-bump facing up.
- 2. Clip to a belt or clothing, where the pump can be firmly supported.

# In Your Pocket



Insert the pump into your pocket making sure the infusion set tubing is not pinched.

# System Sounds

The twiist app and pump play sounds to help you identify the current status of the twiist AID system.

In order to receive sounds played by the twiist app, iPhone *Notifications* and *Critical Alerts* must be enabled. Keep these features enabled to make sure that sounds played by the twiist app are not delayed or missed.

If the ringtone and alert volume is turned down, your iPhone is silenced, or *Notifications* and *Critical Alerts* are disabled, notifications provided by the twiist app may not be played or heard. Vibration for iPhone notifications are controlled in settings.

Sound Name	Sound Description	Sound Source	Sound Definition
Quick Beep	One quick beep	twiist pump	The pump battery has been inserted into the pump.
Ready Beep	One beep	twiist pump	The twiist AID system is ready to advance to the next step.
Busy Beep	One repeating beep	twiist pump	Pump is busy. Wait until the pump is ready before continuing.
			Priming the cassette and infusion set tubing is in progress.

Keep Haptics on so that Notifications are always delivered with vibration.

Sound Name	Sound Description	Sound Source	Sound Definition
Delivering	Three ascending tones	twiist pump	The twiist AID system is delivering insulin.
			Bolus delivery has been started or interrupted.
Delivery Suspended	Four descending tones	twiist pump	Insulin delivery has been suspended.
One-Button Bolus	Ascending beeps for each pump button press	twiist pump	A single ascending beep is played for each unit of insulin requested while programming a <i>One-Button Bolus</i> .
One-Button Bolus Canceled	One extended tone	twiist pump	Programming a <i>One-Button Bolus</i> was not successful.

Sound Name	Sound Description	Sound Source	Sound Definition
Alarm	Three beeps + two beeps (2 times)	<ul> <li>twiist app, and then twiist pump</li> <li>Alarm notifications are initially played based on your iPhone ringtone and alert volume.</li> <li>If the alarm has not been resolved within 5 minutes, the alarm notification will be played regardless of your iPhone volume or <i>Focus</i> settings.</li> <li>After an additional 5 minutes, the alarm notification will be repeated on your iPhone and will play on your twiist pump.</li> <li>If the twiist app and pump are out of communication, Alarm sounds will play on the pump immediately.</li> </ul>	The twiist pump is in an alarm condition. Insulin delivery has stopped. Review the alarm displayed in the twiist app for additional information.

Sound Name	Sound Description	Sound Source	Sound Definition
Alert	Two beeps	<ul> <li>twiist app</li> <li>Most alert notifications are played based on your iPhone ringtone and alert volume. If your iPhone is silenced or <i>Focus</i> is enabled, alert notifications may be missed.</li> <li>Some alerts work differently for your safety and will be played regardless of your iPhone volume or <i>Focus</i> settings.</li> <li>If the twiist app and pump are out of communication, <i>Alert</i> sounds play on the pump.</li> </ul>	The twiist AID system is in an alert condition. Review the alert displayed in the twiist app for additional information.

Sound Name	Sound Description	Sound Source	Sound Definition
Urgent Low Glucose	Three beeps	<ul> <li>twiist app, and then twiist pump</li> <li><i>Urgent Low Glucose</i> alert notifications are played even if your iPhone is silenced or <i>Focus</i> is on.</li> <li>After 5 minutes, the <i>Urgent Low</i> <i>Glucose</i> alert notification will be repeated on your iPhone and will play on your twiist pump.</li> <li>If the twiist app and pump are out of communication, <i>Urgent Low</i> <i>Glucose</i> sounds will play on the pump immediately.</li> </ul>	Review the <i>Urgent Low Glucose</i> alert displayed in the twiist app for additional information , and treat your low glucose as recommended by your healthcare provider.

# Charge the Pump Batteries

Before you use your twiist AID system, and each time you replace your cassette and infusion set, make sure you charge the pump batteries.

If the pump batteries have been exposed to extremely hot or cold temperatures, allow them to cool off/warm up for 20 minutes before charging.

The pump batteries typically take 6 hours or less to charge.

The pump batteries should be charged using the provided battery charger and wall power adapter. Only use the provided wall power adapter and charging cables. Use of another wall power adapter or cables could damage the system or result in fire or burns.

A fully charged pump battery will power the pump for 3 days (72 hours) and should be swapped each time a cassette change is completed.

Keep the pump batteries, pump battery charger, and wall power adapter clean and dry.

#### To charge the pump batteries:

- 1. Plug the USB cable into the wall power adapter and the battery charger.
- 2. Plug the wall power adapter into a wall power outlet.



3. Insert the pump batteries into the battery charger by aligning the contacts on the batteries with the contacts on the charger.



(i) Avoid touching the electrical contacts on the battery charger when the charger is connected to a power source.

The pump battery charger status light color indicates the following:

- Green The pump battery is fully charged and ready for use.
- Orange The pump battery is charging.
- Blinking Red Charging fault. The pump battery is not charging as expected.

# Continuous Glucose Monitoring (CGM)



The Abbott FreeStyle Libre 3 Plus Sensor is a disposable Continuous Glucose Monitor (CGM) that is inserted under the skin to continuously monitor glucose levels for up to 15 days.

The FreeStyle Libre 3 Plus Sensor sends readings through a Bluetooth connection directly to the twiist pump every minute. When the FreeStyle Libre 3 Plus Sensor is used with the twiist AID system, the twiist app displays your current glucose and glucose trend. The twiist app is also used to start new FreeStyle Libre 3 Plus Sensors and manage CGM alerts.

For detailed instructions and important safety information, refer to instructions included with your FreeStyle Libre 3 Plus Sensor.

# The twiist App



The twiist app displays information from your Bluetooth connected diabetes devices, including insulin data from your twiist AID system and glucose information from your CGM. In order to use the twiist app, your iPhone must be capable of:

- Establishing and maintaining a Bluetooth connection
- Providing audio and vibration feedback
- Maintaining basic operation of the display, touchscreen and camera
- Maintaining sufficient charge between charging
- i It is recommended to charge your iPhone daily to ensure you always have access to the twiist app.

Before using the twiist app the following must be understood:

- Notifications provided by the twiist app are delivered based on the ringtone and alert volume in the *Sound & Haptics* settings on your iPhone. In order to hear and feel notifications, iPhone volume must be turned up and vibrate must be enabled.
- iPhone *Notifications* and *Critical Alerts* must be enabled in order to receive notifications from the twiist app.
- The iPhone passcode feature must be enabled in order to use the twiist app.
- Your iPhone, running the twiist app, should be kept with you at all times while using the twiist AID system. Insulin delivery will continue when your iPhone is not present.

 Do not quit the twiist app, or remove the twiist app from your iPhone. Quitting the twiist app or removing it from your iPhone will result in loss of communication with the pump and will prevent modification of therapy settings. However, the pump will continue to deliver your basal insulin.

Allow Notifications and Critical Alerts for the twiist app in your iPhone settings. Failure to allow Notifications and Critical Alerts may lead to missed twiist app notifications which may lead to high or low glucose.

Avoid using accessibility features on the iPhone. Using accessibility features on the iPhone may affect the ability to view the twiist app which could lead to harm. Your iPhone should not be used with the twiist automated insulin delivery system if your iPhone:

- battery cannot last a full day
- · shuts down unexpectedly
- cannot be powered down or restarted
- cannot maintain Bluetooth communication
- screen, speaker, camera, or vibration motor are broken.

Use of your iPhone under these conditions may lead to harm.

# Set Up Your twiist AID System



The twiist automated insulin delivery system is setup using the twiist app. Use the provided QR code, or go to

#### www.twiist.com/register to

create your account, and download the twiist app from the *App Store*.

After you have installed the twiist app, follow these steps to setup your twiist AID system.

- 1. Open the twiist app on your iPhone.
- 2. Tap Welcome.



- twiist
- 3. Enter your **username** and **password**.
- 4. Tap Login.
- Tap the **box** after you have reviewed the *Terms* & *Conditions*.
- 6. Tap Accept.



- 7. Tap **Continue** to review each of the *Welcome to the* twiist AID *System* and the *Getting to Know the twiist AID System* modules, including:
  - Introduction
  - How the App Works
  - A Day in the Life

Before proceeding, your certified twiist trainer will contact you to schedule an appointment to complete your twiist AID system training and setup.

#### **Your Devices**

Before pairing your twiist pump and CGM, make sure that your iPhone is charged and connected to the internet.

Place your iPhone, CGM, and pump close together and away from other wireless devices while pairing.

#### Add CGM

- 1. Tap Add CGM.
- 2. Tap FreeStyle Libre 3 Plus.
- 3. Tap Continue.
- 4. Tap Pair CGM.

The twiist app needs to use Bluetooth to send and receive data from your diabetes devices. The twiist app will ask for permission to use Bluetooth before you can complete CGM or pump pairing.

- 5. Tap Allow to enable.
- i Refer to the FreeStyle Libre 3 Plus Sensor user manual for instructions on how to apply a new sensor.
- 6. Clean hands prior to FreeStyle Libre 3 Plus Sensor handling and insertion to help prevent infection.

- 7. Only apply the FreeStyle Libre 3 Plus Sensor to the back of the upper arm.
  - If placed in other areas, the sensor may not function properly and could give inaccurate readings.
  - Select an appropriate sensor site to help the sensor stay attached to the body and prevent discomfort or skin irritation.
  - Avoid areas with scars, moles, stretch marks or lumps.
  - Select an area of skin that generally stays flat during normal daily activities (no bending or folding).
  - Choose a site that is at least 1 inch (2.5 cm) from an insulin injection site. To prevent discomfort or skin irritation, you should select a different site other than the one most recently used.

8. Apply your new sensor.

For instructions on how to apply the sensor, tap **? HOW TO APPLY A SENSOR**.

i Applying the sensor may cause bruising or bleeding. If there is bleeding that does not stop, remove the sensor and contact your healthcare provider.

9. Put the cap back on the Sensor Applicator. Discard the Sensor Applicator according to local regulations. 10. Tap **NEXT**.



#### 11. Tap SCAN NEW SENSOR.

For instructions on how to scan a sensor, tap **HOW TO SCAN A SENSOR**.



# 12. Hold the top of your iPhone very close to the sensor.



i Refer to the FreeStyle Libre 3 Plus Sensor manufacturer instructions for troubleshooting information related to starting a new sensor. Setup of the twiist app must be complete, and the FreeStyle Libre 3 Plus Sensor must complete a 60-minute *Sensor Warmup* before glucose readings are available.

13. Tap **OK**.

### Pair Your twiist Pump and App

- 1. Tap Pair Pump.
- 2. Insert a fully charged battery into the pump.

When the battery is inserted successfully, the pump plays a *Quick Beep*.

- 3. Tap Pair Pump.
- 4. Tap the **serial number** of your pump within *Discovered Pumps*.
- (i) If your pump is not listed, press and hold the **pump button** for 5 seconds, until you hear a *Ready* beep, and then release the button.

The pump can be paired by taking a photo, or manually entering the pump serial number.

To pair your pump by taking a photo:

a. Tap Take Photo.

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

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

The pump PIN will be copied automatically.

- c. Tap Connect.
- d. Tap into the *Bluetooth Pairing Request* field to display the *Paste* option.

- e. Tap **Paste** to enter the pump PIN.
- f. Tap Pair.

#### To pair your pump manually:

- a. Tap Enter Manually.
- b. Tap Connect.
- c. Using the keypad, enter the 6-digit PIN found on the pump label.
- d. Tap Pair.

#### Pump Software Update

After pairing your pump to the twiist app, the twiist AID system will check to see if a pump software update is required.

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

#### Your Settings

To allow the twiist app to notify you of important safety information, keep iPhone *Notifications* and *Critical Alerts* enabled.

Allow Notifications and Critical Alerts for the twiist app in your iPhone settings. Failure to allow Notifications and Critical Alerts may lead to missed twiist app notifications which may lead to high or low glucose.

The twiist app will ask for permission to send you *Notifications*. Tap **Allow** to enable.

The twiist app will ask for permission to send you *Critical Alerts*. Tap **Allow** to enable.

#### Share with Apple Health

Apple Health can be used to store and review blood glucose, carbohydrate, and insulin delivery data from the twiist app, including *Total Daily Dose*.

#### Tap Share with Apple Health

and turn on the data you would like to share and tap **Allow**. If you do not want to share your data, tap **Don't Allow**. When you choose to share your data with Apple Health you can use the Apple Health app on your iPhone to track important information including:

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

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



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

#### **Therapy Settings**

Therapy settings needed to use the twiist AID system are determined by your healthcare provider and are entered during initial setup with your certified twiist trainer.

- 1. Tap **Continue** and review the settings provided by your healthcare provider or enter them with your certified twiist trainer.
- 2. Tap Save Settings.
- 3. Tap **Continue** on the *Checkpoint* screen.

#### Cassette Setup

- 1. Gather the following supplies to setup and start therapy:
  - A new cassette in unopened sterile packaging
  - Sterile syringe and needle
  - A new infusion set in unopened sterile packaging
  - Humalog (insulin lispro) or Novolog (insulin aspart) U-100 fast-acting insulin
  - Alcohol wipes
- 2. Wash your hands.
- 3. Tap Continue.
- 4. Open a new cassette and remove it from the package.
- Do not to connect the infusion set tubing to your infusion site before self-test and priming are complete.

- 5. Align the ridges on the pump-bump and the top of the cassette.
- 6. Push down and rotate the pump clockwise so the ridge on the pump-bump is aligned with the infusion set tubing.

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

- Wait for the self-test to complete before continuing.
- 8. Tap Scan Cassette.
- 9. Scan the cassette with your iPhone camera.



- 10. Using the picker, select your desired **Cassette Fill Volume**.
- 11. Tap Next to continue.
- 12. Fill the syringe with the amount of insulin you selected.
- 13. Tap **Next** to continue.
- 14. Fill the cassette with insulin.
- 15. Tap **Next** to continue.
- 16. Open a new infusion set package.
- 17. Attach the infusion set tubing to the cassette by twisting the luer connectors together.

- 18. Tap Next to continue.
- 19. Tap **Start Prime** to prime the infusion set tubing.
- 20. Watch for drops to appear at the end of the infusion set tubing.

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

#### 21. Tap Stop Prime.

22. Tap **Yes** to confirm that priming is complete.

If you tap *No*, you are returned to the prime steps. Tap *Resume Prime* to continue. If you do not stop priming, the pump will automatically stop and a *Prime Stopped* notice is displayed.

- If you see drops at the end of your infusion set tubing, tap **Yes** to continue.
- If you <u>do not</u> see drops, tap **No** to continue priming your cassette and infusion set tubing.
- 23. Check for leaks around the cassette and infusion set after priming. If leaks are visible, replace the cassette and infusion set tubing.
- 24. Choose your infusion site.

Infusion sites that are commonly used include:

- abdomen
- upper buttocks
- hips
- upper arms
- upper legs

25. Insert the infusion set cannula per the manufacturer instructions.

### Get Looping

- 1. Tap Get Looping.
- 2. Review the differences between *Loop on* and *Loop off* and tap **Continue**.
- 3. Select whether you want the twiist system to automate your basal delivery.

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

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

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

The pump plays the *Delivering* sound.

If you need help, consult with your certified twiist trainer or healthcare provider.

10. Tap Start twiist.

# How the twiist App Works

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

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



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

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

When used with a FreeStyle Libre 3 Plus Sensor:

- Start a CGM Sensor
- Configure CGM settings
- Respond to CGM Alerts

# Home Screen

The *Home Screen* has three main areas:

- · Status
- Charts
- Toolbar

# Status

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



Status icons include:

- · CGM Status
- twiist Status
- Insulin Delivery Status
- Pump Status

The Home Screen also displays Temporary Status Banners, see "Temporary Status Banner" on page 64.

### CGM Status

The *CGM Status* icon displays your current glucose and glucose trend arrow when you are connected to a CGM.



Tap the **CGM Status** icon to open the *CGM Status* screen and view additional CGM information. See "FreeStyle Libre 3 Plus Sensor Status" on page 127.

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



	Your CGM		Check your CGM	Glucose	Trend Arrow
Sensor Too Hot	Sensor is too hot to give glucose readings. Check again in a few minutes.	Check CGM	Sensor. If it is loose from your skin, remove the sensor and start a new one. If it is	$\bigcirc$	Your glucose is not rising or falling more than 1 mg/dL (0.05 mmol/L) per minute.
	Your CGM Sensor is		try starting the sensor again.		Your glucose is rising at a rate of 1-2 mg/dL (0.05-0.11 mmol/L) per minute.
Sensor Warmup	the CGM Status		A CGM Ended		
	information about when your sensor will be ready.	CGM Ended	occurred. See "CGM Ended" on page 200.		Your glucose is rising quickly at a rate greater than 2 mg/dL
	A glucose reading A Replace CGM	A <i>Replace CGM</i> alert has		(0.11 mmol/L) per minute.	
CGM Error	Check again in a few minutes.	Check again in a ew minutes.     Replace CGM     occurred. See       "Replace CGM"     on page 204.		Your glucose is falling at a rate of 1-2 mg/dL (0.05-0.11 mmol/L)	
					per minute.



Your glucose is falling quickly at a rate greater than 2 mg/dL (0.11 mmol/L) per minute.

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

When in doubt, get your meter out.

### Set your Blood Glucose Unit of Measure

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

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

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

# To change your blood glucose unit of measure:

- 1. Open the *Apple Health app* on your iPhone.
- 2. Tap Browse.
- 3. Tap Vitals.
- 4. Tap Blood Glucose.
- 5. Scroll down and tap Unit.

- Tap mg/dL or mmol/L to select the desired unit of measure.
- 7. Tap **Blood Glucose** in the upper left corner to exit after making your selection.

### twiist Status

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



#### When Loop is on:

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



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

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

You may be experiencing temporary CGM *Signal Loss*. Typically, this does not require user action to resolve. It has been more than 15 minutes since the last successful *Loop*.



You may be experiencing a problem with your CGM that requires interaction with the CGM or twiist app to resolve.

This icon can indicate one of the following:

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

#### When Loop is off:

An open circle icon is displayed within the *twiist Status*. Your twiist pump delivers your scheduled basal rate. The twiist system can be used with *Loop* off with or without the use of a CGM.

When *Loop* is off and no CGM has been added:





Your pump is working properly and insulin is being delivered at your scheduled basal rate. This icon can indicate one of the following:

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

When a CGM is not available, there is increased risk of high and low blood glucose. Check your fingerstick glucose at least 4 times daily.

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





Your pump and CGM are working properly. Insulin is being delivered at your scheduled basal rate and a CGM value was received within the last 15 minutes.

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



You may be experiencing temporary CGM *Signal Loss* that does not typically require user interaction to resolve.

This icon can indicate one of the following:

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

### Insulin Delivery Status



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

#### Scheduled Basal

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

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

#### Reduced Basal

-1.0 U/hr A dropped icon indicates that your basal is reduced by the value shown.

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

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

#### Increased Basal

+3.0 U/hr A raised icon indicates that your basal is increased by the value shown.

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

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

### Pump Status



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



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

battery has more than 20% charge.

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

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



The *Pump Status* icon will change for specific alarm conditions. *See "Alarms, Alerts, and Notices" on page 172.* 

## Temporary Status Banner



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

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

- When tracking the progress of a bolus being delivered.
- When a temporary basal is active.
- When a cannula fill is in progress.
- When stopping a bolus or temporary basal that is currently being delivered.
- When you have turned on a *Pre-Meal* or *Workout Preset*.
- When a *No Recent Glucose* message is displayed and allows you to add a fingerstick glucose value when CGM readings are not available.
- To resume insulin delivery.

# Charts

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



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



### **Glucose Chart**



The *Glucose Chart* displays important information about your glucose.

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

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

#### **Correction Range**

Glucose		Eventually 109 mg/dL				
150						
125						
100						
75 9 AM	MA OF	TLAM	12 FM	PM		

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

This is the range you want the twiist AID system to aim for when adjusting your basal insulin and recommending a bolus.

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

### **Glucose History**



A blue line on the *Glucose Chart* displays the last 90 minutes of CGM readings or manually entered fingerstick values.

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

### **Glucose Prediction**



A light blue dashed line on the glucose chart displays your *Glucose Prediction* for 6 hours into the future. The twiist AID system will update this prediction as often as every 5 minutes as it works to bring your glucose into your *Correction Range*.

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

#### How Far Out is the Prediction?



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

If low glucose looks likely in the near future, consider treating with fast-acting carbs.

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

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

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

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

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

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

#### **Eventual Glucose**

The twiist AID system will update this prediction as often as every 5 minutes as it works to bring your glucose into your *Correction Range*.

(i) When *Loop* is off, the twiist AID system does not make a glucose prediction and this information is not displayed.

### Active Insulin Chart



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

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

Touch and hold the **Active Insulin Chart** to see more information about your past and future active insulin. Rotating your phone will allow you to see additional *Active Insulin* history.

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

If the twiist AID system predicts a low and your chart displays you have insulin active in your bloodstream, you may want to eat fast-acting carbs to prevent low glucose.

If the twiist AID system predicts a high, check your chart to see if you have enough insulin working to reduce your glucose without the need for an additional bolus. You can tap the **Bolus Entry** button at any time to see if a bolus is recommended right now.

### Negative Active Insulin



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

### Insulin Delivery Chart



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

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

Basal is displayed as a series of orange bars. Bars above the orange line indicate increased basal, while bars below the orange line indicate reduced basal. Boluses that have been delivered are displayed as orange triangles.

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

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

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

Touch and hold the **Insulin Delivery Chart** to see more information.

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

### **Event History**

Tap the **Active Insulin** or **Insulin Delivery Charts** to see your event history.



- Active Insulin
- Total Units (delivered since 12:00 AM)
- Boluses (delivered or interrupted)
- Insulin delivery suspended
- · Insulin delivery resumed

- Cannula Fills
- Alarms, Alerts, and Notices
- Temporary Basal (*Loop* off only)

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

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

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

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

The twiist AID system saves and maintains your data when your iPhone or pump loses power.

### Active Carbohydrates Chart



 The concept of active carbohydrates may be new to you.

The Active Carbohydrates Chart displays the carbs that you have entered into the twiist app and how the twiist AID system expects them to impact your glucose over time.

The twiist AID system needs to know about all the carbs that you eat in order to update and make its best predictions about your glucose. Your current active carbohydrates are displayed in the top-right corner of the active carbohydrates chart.

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

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

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

# Tap the Active Carbohydrates Chart to:

- View your last 12 hours of your carb entries.
- · Enter your recent carbs.
- Edit carbs that you have entered.

• Delete carbs that were not eaten or were entered incorrectly. See "Delete or Edit Carb Entry" on page 146.



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

# Toolbar



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

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

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

# Carb Entry



The Carb Entry  $\bigcirc$  button is used to enter details about what you are eating and to get a bolus recommendation.

### **Pre-Meal Preset**



If you would like the twiist AID system to temporarily lower your *Correction Range* before a meal to reduce post-meal glucose spikes, use the *Pre-Meal Preset* O.

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

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

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



(i) Pre-Meal Preset is unavailable when Loop is off. The twiist system will not adjust your Correction Range or adjust basal insulin delivery to bring you to your Pre-Meal Range. The Pre-Meal Preset button will be grayed out and cannot be selected.

### **Bolus Entry**



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

### Workout Preset



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

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

*Workout Preset* will be in effect for the time you indicate when you activate it or until you cancel it. When activated, the *Workout Preset* button colors will be reversed and the *Glucose Chart* will be updated to show the adjustment to your *Correction Range* as a result of your *Workout Preset*.

S Workout Preset	until 10:43 AM
Glucose 312	Eventually 109 mg/dL
234	
156	-
78 9 AM 10 AM	11 AM 12 PM 1 PM

(i) Workout Preset is unavailable when Loop is off. The twiist system will not adjust your Correction Range or adjust basal insulin delivery to bring you to your Workout Range. The Workout Preset button is used to manually set a Temporary Basal.

### Settings



The Settings ⁽²⁾ button opens the Settings Menu to:

- Turn Loop On or Off
- View and edit your *Therapy Settings*
- Add a CGM
- Configure FreeStyle Libre 3
   Plus Sensor Settings (when a
   FreeStyle Libre 3 Plus Sensor
   has been added to the twiist AID
   system)
- Access Support

# Pump Menu

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



The *Pump Menu* allows you to see:

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

The *Pump Menu* provides access to:

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



# Suspend Insulin Delivery

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

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

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

The pump plays the *Delivery Suspended* sound.

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

How to identify that insulin delivery is suspended:

- The twiist *Status* icon is gray.
- *Insulin Suspended* is displayed in the *Pump Status* icon and *Temporary Status Banner*.



• The *Insulin Delivery Chart* displays your current insulin delivery rate as - *U/hr*.



# Resume Insulin Delivery

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



### 2. Tap Resume Delivery.

The Home Screen displays a Communicating with Pump message, and the pump plays the Delivering sounds.

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

How to identify that insulin delivery has resumed:

- The twiist Status icon displays a green, yellow, or red circle to inform you that basal delivery is in progress. See "twiist Status" on page 61 for more information.
- *Insulin Delivery Status* displays you are delivering and any change from your scheduled rate.
- The *Pump Status* icon displays pump battery and cassette info.



 The Insulin Delivery Chart displays your current basal rate.



# Cassette Change

*Cassette Change* is a step-by-step process for replacing your cassette and supplies to resume delivery.

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

 The twiist AID system provides on-screen, step-by-step instructions. Do not jump ahead of the twiist app.

### Change Cassette

1. Tap the **Pump Status** icon to open the *Pump Menu*.



### 2. Tap Change Cassette.



# Gather your Supplies

The following supplies are needed for a cassette change:

- A fully charged pump battery
- New cassette, infusion set, needle and syringe
- Humalog (insulin lispro) or Novolog (insulin aspart) U-100 fast-acting insulin
- Alcohol wipes
- A Only use fast-acting U-100 Humalog (insulin lispro) or Novolog (insulin aspart). Use of other concentrations may lead to insulin delivery errors that may lead to low or high blood glucose.

Only use twiist cassettes with compatible infusion sets. Failure to do so may affect accuracy or blockage detection which may lead to over or under delivery and cause low or high blood glucose.

- Do not use cassettes, infusion sets, needles, or syringes if:
- The expiration date on the package has passed.
- Packaging has been previously opened or damaged.

Use of disposable components that are expired or from previously opened or damaged sterile packaging may lead to infection.

Do not use damaged cassettes or infusion sets. Using damaged cassettes or infusion sets may result in start-up failures, interruptions in therapy, topical exposure to insulin, or delivery errors leading to high or low blood glucose.

### Start Cassette Change

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



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

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



The pump plays the *Delivery Suspended* sound.

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

### Disconnect Infusion Site

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



Before removing the cassette from your pump, disconnect the infusion set tubing from your infusion site. Leaving the infusion set tubing connected may lead to unintended delivery, which may cause low blood glucose.

# Remove and Dispose of Used Cassette

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

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



The pump plays a *Ready* beep.

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

2. Remove the cassette from the pump.



The screen will advance automatically.

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

Contact your local authorities to determine the proper method for disposal of used cassettes and infusion sets (including cannulas and inserter needles).

Improper disposal of these items may result in injury to the operator and others from exposure to sharp or contaminated components.

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

### Replace Pump Battery

Damaging the inside of the pump, which is exposed while changing the cassette or battery, may affect pumping accuracy which may increase or decrease delivery and lead to low or high blood glucose.

Dirt, lubricants, or liquids may contaminate the inside of the pump while it is detached from the cassette. Contamination may affect pumping accuracy, which may increase or decrease insulin delivery causing low or high blood glucose. 1. Remove the battery from the pump.



- 2. Insert the depleted battery into the battery charger.
- 3. Get a fully charged battery from the battery charger.

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



4. Insert the fully charged battery into the pump.



When the battery is properly inserted, the pump plays a *Quick* beep followed by a *Ready* beep and the twiist app will advance automatically.

### Wash your Hands

1. Wash your hands with soap and water before opening sterile supplies.



Wash your hands and use clean technique when filling the cassette, inserting the infusion site, and connecting the infusion set tubing. Failure to do so may lead to infection.

### Attach New Cassette to Pump

- 1. Open a new cassette and remove it from the package.
- 2. Check between the pump and cassette to make sure it is clean and free of fluid and debris.

If any moisture is visible, gently blot the interior of the pump with a dry cloth or paper towel. Make sure there is no moisture in the pump.

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

 Do not connect the infusion set tubing to your infusion site before self-test and priming are complete. 3. To attach the cassette to the pump, align the ridges on the pump-bump and the top of the cassette.



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

> If the cassette is not properly attached, a *Reattach Cassette* alert is displayed. Remove and attach the cassette to continue. *See "Reattach Cassette" on page 196* for more information.



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

5. Wait for the self-test to complete before continuing.

Discontinue use of the system and switch to your backup insulin therapy plan if the pump fails to beep during the pump self-test.

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.

### Scan Cassette

1. Tap **Scan Cassette** and position the QR code on the bottom of the cassette inside of the green box.



If you have already used the cassette, a *Cassette Already Used* message is displayed.



Tap **OK** and get a new cassette package.

# Cassette Fill Volume

1. Select your **Cassette Fill Volume**.

The twiist AID system will remember your last selected cassette fill volume.

This should be enough insulin to last you 2 to 3 days, and must be a minimum of 100 Units (1 mL) and a maximum of 300 Units (3 mL).

2. Tap Next.

### Fill the Cassette

Follow instructions from the insulin manufacturer for use and handling.

(i) Allow insulin to adjust to room temperature before filling the cassette.

1. Clean the top of the insulin vial with an alcohol wipe.

- 2. Open a new syringe and needle.
- 3. Attach the needle to the syringe luer connector by twisting until finger tight.



- 4. To fill the syringe with air, Remove the cap from the needle and pull the syringe plunger out to the selected *Cassette Fill Volume*.
- 5. Insert the needle into the vial.

- 6. Inject air into the insulin vial.
- 7. While still holding the syringe, flip the vial so it is above the syringe and slowly pull down on the plunger to fill the syringe with the selected *Cassette Fill Volume*.



8. With the needle pointing upward, and still inserted in the vial, tap on the syringe to remove any visible air bubbles.

- 9. Remove the needle from the insulin vial.
- 10. Gently insert the needle straight into the cassette filling port. Do not force the needle.



11. Push the syringe plunger down to fill the cassette. Keep holding the plunger down as you remove the needle.

If you cannot press the syringe plunger, remove the needle and try inserting again.



12. Dispose of the used needle and syringe in a *Sharps Container*. Contact your local authorities to determine the proper method for disposal of needles and syringes. Improper disposal of these items may result in injury to the operator and others from exposure to sharp or contaminated components.

13. Tap Next to continue.

Do not fill the cassette with cold insulin. Filling the cassette with cold insulin may result in air bubbles forming in your cassette or infusion set tubing that may result in delivery errors that may lead to harm. Allow insulin to adjust to room temperature before filling the cassette.

Do not fill a cassette before you plan to use it. Filling a cassette before you plan to use it may result in spoilage or a change to the potency or purity of insulin, which may lead to harm. Do not fill or prime the cassette and infusion set tubing while connected to your infusion site. Connecting the infusion set tubing during filling and priming may lead to the unintended delivery of insulin which may result in low blood glucose.

### Attach New Infusion Set Tubing

- 1. Open a new infusion set package.
- 2. Attach the infusion set tubing to the cassette by twisting the luer connectors together.



- 3. Tap Next to continue.
- (i) Once connected, do not disconnect the infusion set tubing from the cassette at the luer connector. Only disconnect infusion set tubing at the infusion site.

# Prime the Infusion Set

1. On the twiist app screen, tap **Start Prime**.



A series of *Priming* sounds will be played by the pump as priming occurs.

2. Watch for drops to appear at the end of the infusion set tubing.

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



3. Tap Stop Prime.



A *Complete Prime* message is displayed.

4. Tap **Yes** to confirm that priming is complete.



If you tap *No*, you are returned to the prime steps. Tap **Resume Prime** to continue.

If you do not stop priming, the pump will automatically stop and a *Prime Stopped* notice is displayed.



- If you see drops at the end of your infusion set tubing, tap **Yes** to continue.
- If you <u>do not</u> see drops, tap **No** to continue priming your cassette and infusion set tubing.
- 5. Check for leaks around the cassette and infusion set after priming. If leaks are visible, replace the cassette and infusion set tubing.

### Infusion Site Selection

An infusion site can be inserted anywhere on your body where insulin would normally be injected. Absorption can vary from site to site, and should be reviewed with your certified twiist trainer or your heathcare provider.

Select a site that allows you to keep the pump on the same side of your body as the CGM.

Infusion sites that are commonly used include:

- abdomen
- · upper buttocks
- hips
- upper arms
- upper legs



When selecting your infusion site:

- Avoid areas that may constrict the site, such as the waistline, beltline, or where the body naturally bends.
- Avoid the area 2 inches (5 cm) around your belly button.
- Keep the infusion site at least 1 inch (2.5 cm) from your CGM.
- Avoid placing the infusion site on scars, moles, stretch marks, and tattoos.

- Avoid broken skin, cuts, and scrapes.
- Keep the infusion site at least 1-2 inches (2.5 to 5 cm) from your previous infusion site.

### Site Rotation

Change your infusion set every 48 to 72 hours, or as instructed by your healthcare provider. Select a new infusion site. Using the same infusion site may cause scarring. Establish a schedule to rotate your infusion site that works best for you.

### Skin Adhesive

Adhesives can prevent the infusion site from slipping or being pulled out. Adhesives for your infusion site can be useful when participating in sports or exercise, and while in hot climates. Infusion set tubing can be looped and taped to the skin 1-2 inches (2.5 to 5 cm) from the infusion site.

### *Connect Tubing to Infusion Site and Start Basal*

- 1. Clean the infusion site with an alcohol wipe and allow to dry.
- 2. Insert the infusion set cannula per the manufacturer instructions.
- 3. Connect the primed infusion set tubing from the pump to the infusion site.



- 4. Route the infusion set tubing to avoid kinks.
- 5. Confirm your *Cannula Fill* volume according to your infusion set manufacturer instructions.
  - If you need to edit, tap **Fill Cannula** to open the picker and adjust the cannula fill volume.

Tap Done to continue.

6. Confirm *Cassette Fill Volume* matches what you filled the cassette with.

If you need to edit, tap **Cassette Fill Volume** to open the picker and adjust the cassette fill volume.

Tap Done to continue.

7. To begin insulin delivery, tap **Start Basal**.

The pump plays the *Delivering* sound and basal delivery will start.

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

The *Home Screen* displays a *Temporary Status Banner* indicating the cannula fill is in progress.

- The CGM Status may display Connecting with CGM to let you know your pump is reconnecting to your CGM.
- If air bubbles are present in the infusion set tubing, perform a cassette change. Air bubbles present in the infusion set tubing may lead to under or over-delivery of insulin, which may lead to high or low blood glucose.

Check your infusion site every day for proper placement. Replace your infusion site if you notice leaks around the site. Improper placement or leaks around the site may result in under-delivery of insulin resulting in high blood glucose.

The cassette volume displayed in the twiist pump menu has been reduced to account for the insulin needed to prime your cassette and infusion set tubing, and insulin that will remain in your cassette. Typically, this is around 35 units when using a 24 inch infusion set.



Pay attention to your insulin usage and adjust the cassette fill volume during your next cassette change to make sure your cassette has enough insulin to meet your needs.

# Fill Cannula

Your infusion set cannula is filled during the cassette change process when you replace your infusion site. If you need to change your infusion site for any reason, outside of cassette change, you may need to fill your cannula. Insulin delivery must be in progress to complete a cannula fill.

(i) Cannula fills are not counted towards your *Active Insulin*.

To change the cannula fill volume and deliver a cannula fill:

- 1. Tap the **Pump Status** icon to open the *Pump Menu*.
- 2. Tap Fill Cannula.
- 3. Tap **Cannula Fill Volume** to open the picker and adjust the cannula fill volume according to your infusion set manufacturer instructions.
- 4. Tap **Done** to continue.

- 5. Tap Fill Cannula.
- 6. Tap **Confirm** to deliver the cannula fill or tap **Cancel** to go back to the *Cannula Fill Volume* screen.

Changes to *Cannula Fill Volume* will be saved for future deliveries.

The *Filled Cannula* progress will be displayed on the *Temporary Status Banner*.



### Stop Cannula Fill

### To stop a cannula fill in progress:

1. Tap **Tap to Stop** on the *Temporary Status Banner*.



2. Tap **Yes** to confirm that you would like to stop the cannula fill or **No** to cancel.

# **Battery Change**

A *Battery Change* may need to be completed if a battery that was not fully charged was used to begin insulin delivery during your last *Cassette Change*.

# Change Pump Battery

1. Tap the **Pump Status** icon to open the *Pump Menu*.



2. Tap Change Pump Battery.



# Gather your Supplies

The following supplies are needed for a battery change:

• A fully charged pump battery

A fully charged pump battery is indicated by a green status light on the pump battery charger.

### Start Battery Change

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



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

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



The pump plays the *Delivery Suspended* sound.

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

### Disconnect from Infusion Site

1. Disconnect the infusion set tubing from your infusion site.

Refer to your infusion set manufacturer instructions.

#### 2. Tap Next.

Before removing the cassette from your pump, disconnect the infusion set tubing from your infusion site. Leaving the infusion set tubing connected may lead to unintended delivery, which may cause low blood glucose.

### Remove Cassette from Pump

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

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



The pump plays a *Ready* beep.

(i) The pump sound will not be played when *Quiet Mode* is enabled.
2. Remove the cassette from the pump.



The screen will advance automatically.

3. Place your cassette and infusion set tubing aside.

### Replace Pump Battery

Damaging the inside of the pump, which is exposed while changing the cassette or battery, may affect pumping accuracy which may increase or decrease delivery and lead to low or high blood glucose.

Dirt, lubricants, or liquids may contaminate the inside of the pump while it is detached from the cassette. Contamination may affect pumping accuracy, which may increase or decrease insulin delivery causing low or high blood glucose. 1. Remove the battery from the pump.



- 2. Insert the depleted battery into the battery charger.
- 3. Get a fully charged battery from the battery charger.

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



4. Insert the fully charged battery into the pump.



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

### Wash your Hands

1. Wash your hands with soap and water.



### Attach Cassette to Pump

1. Check between the pump and cassette to make sure it is clean and free of fluid and debris.

If any moisture is visible, gently blot the interior of the pump with a dry cloth or paper towel. Make sure there is no moisture in the pump.

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

- Do not connect the infusion set tubing to your infusion site before self-test is complete.
- 2. To attach the cassette to the pump, align the ridges on the pump-bump and the top of the cassette.



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

> If the cassette is not properly attached, a *Reattach Cassette* alert is displayed. Remove and attach the cassette to continue. *See "Reattach Cassette" on page 196* for more information.



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

Discontinue use of the system and switch to your backup insulin therapy plan if the pump fails to beep during the pump self-test. 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.

### *Connect Tubing to Infusion Site and Start Basal*

1. Connect the primed infusion set tubing from the pump to the infusion site.



2. Route the infusion set tubing to avoid any sources of kinks that may introduce a *Line Blocked* alarm.

If you have replaced your infusion site and need to fill your cannula, tap the **Fill Cannula** toggle and verify the *Fill Cannula* volume according to your infusion set manufacturer instructions.

3. To begin insulin delivery, tap **Start Basal**.

The pump plays the *Delivering* sound and a *Basal Delivery Started* message is displayed.

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

> If you chose to fill the cannula, the *Home Screen* displays a *Temporary Status Banner* indicating the cannula fill is in progress.

The CGM Status may display Connecting with CGM to let you know your pump is reconnecting to your CGM.

If air bubbles are present in the infusion set tubing, perform a cassette change. Air bubbles present in the infusion set tubing may lead to under or over-delivery of insulin, which may lead to high or low blood glucose.

## Pair a New Pump

Your iPhone must be connected to the internet to pair a new pump.

If your internet connection is lost while you are attempting to pair the pump, an *Internet Connection Required* notice is displayed. Tap **OK** and connect your iPhone to a Wi-Fi or cellular network.

If twiist displays a *Limited Internet Connectivity* notice, tap **OK** and connect your iPhone to a different Wi-Fi or cellular network.

If at any time your Bluetooth connection is lost while you are attempting to pair the pump, a *Bluetooth Required* message is displayed. Tap **OK** and enable Bluetooth.

- 1. Remove the pump cover by holding the pump cover in one hand and rotating the pump counterclockwise with the other hand.
- 2. Store the pump cover in a safe, easily accessible location along with this user guide and your other system accessories.
- Keep dirt, lubricants, and liquids away from the inside of the pump.
- 3. From the *Home Screen*, tap **Add Pump**.



4. Obtain a fully charged battery from the pump battery charger. This will be indicated by a green status light on the battery charger. 5. Insert the battery into the pump so the contacts on the battery are aligned with the contacts in the pump.

The pump plays a *Quick* beep followed by a *Ready* beep.

- 6. Place the pump and iPhone close together and away from other wireless devices during pairing.
- 7. Tap Pair Pump to continue.

If your pump is not discovered, Press and hold the **pump button** for approximately 5 seconds until you hear a *Ready* beep, and then release the button.

8. Tap the **serial number** of your pump displayed within *Discovered Pumps*.

To pair your pump by taking a photo:

#### 1. Tap Take Photo.

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

The pump PIN will be copied automatically.

- 3. Tap Connect.
- 4. Tap in the *Bluetooth Pairing Request* field to display the *Paste* option.
- 5. Tap **Paste** to enter the pump PIN.
- 6. Tap Pair.

A *Pump Software Update* message is displayed.

Follow the on-screen instructions to update the pump.

- 7. After the pump update is complete, the pump plays a *Ready* beep, tap **Continue**.
- 8. Follow the Cassette Change steps starting from "Attach New Cassette to Pump" on page 81.

#### To pair your pump manually:

- 1. Tap Enter Manually.
- 2. Tap Connect.
- 3. Using the keypad, enter the 6 digit PIN found on the pump label.
- 4. Tap Pair.

A *Pump Software Update* message is displayed.

Follow the on-screen instructions to update the pump.

- 5. After the pump update is complete, the pump plays a *Ready* beep, tap **Continue**.
- 6. Follow the Cassette Change steps starting from "Attach New Cassette to Pump" on page 81.

## Pair Your Existing Pump

In the event that you delete the pump from the twiist app you will need to pair to your pump again.

Your iPhone must be connected to the internet in order to pair a pump.

If at any time the internet connection is lost while you are attempting to pair the pump, an *Internet Connection Required* notice is displayed. Tap **OK** and connect to the internet.

If twiist displays a *Limited Internet Connectivity* notice, tap **OK** and connect your iPhone to a different Wi-Fi or cellular network.

If at any time your Bluetooth connection is lost while you are attempting to pair the pump, a *Bluetooth Required* alert is displayed. Tap **OK** and enable Bluetooth.

- 1. Disconnect your infusion set tubing from your infusion site.
- 2. Disconnect the cassette from the pump and remove the pump battery.
- 3. From the *Home Screen*, tap **Add Pump**.



4. Insert a pump battery into the pump.

The pump plays a *Quick* beep, followed by a *Ready* beep.

- 5. Place the pump and iPhone close together and away from other wireless devices during pairing.
- 6. Tap Pair Pump.

- 7. Press and hold the **pump button** for approximately 5 seconds until you hear a *Ready* beep, and then release the button.
- 8. Tap the **serial number** of your pump displayed within *Discovered Pumps*.

Before you can continue pairing your pump again, you need to forget the pump in your *Bluetooth Settings*.

- 9. Open iPhone Settings.
- 10. Tap Bluetooth.
- 11. Tap i next to your pump serial number.



- 12. Tap Forget This Device.
- 13. Tap Forget Device to confirm.

Your pump will be removed from the Bluetooth devices.

To pair your pump by taking a photo:

- 1. Tap Take Photo.
- 2. Hold your iPhone above the pump so the pump label is in focus within the camera area. When the camera has focused, a picture of the pump will be taken automatically.

The pump PIN will be copied automatically.

3. Tap Connect.

If you did not follow the steps to *Forget This Device*, the twiist app will display a *Pump Pairing Failed* notice. Tap OK and go back to *Step 9*.

4. Tap in the *Bluetooth Pairing Request* field to display the *Paste* option.

- 5. Tap **Paste** to enter the pump PIN.
- 6. Tap **Pair**.

A *Pump Software Update* message is displayed.

If your pump software is up to date, tap **Continue**.

If your pump software needs to be updated, follow the on-screen instructions to update the pump.

7. Follow the Cassette Change steps starting from "Attach New Cassette to Pump" on page 81. To pair your pump manually:

1. Tap Enter Manually.

#### 2. Tap Connect.

If you did not follow the steps to Forget This Device, the twiist app will display a Pump Pairing Failed notice. Tap OK and go back to Step 9.

- 3. Using the keypad, enter the 6 digit PIN found on the pump label.
- 4. Tap Pair.

A *Pump Software Update* message is displayed.

If your pump software is up to date, tap **Continue**.

If your pump software needs to be updated, follow the on-screen instructions to update the pump. 5. Follow the Cassette Change steps starting from "Attach New Cassette to Pump" on page 81.

# Settings



## Loop On and Off

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

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

When *Loop* is **OFF**, your basal will be delivered based on your scheduled basal rates.

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

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

- Tap Settings On the Toolbar.
- 2. Tap the **Loop** toggle to turn *Loop* on or off.



The twiist app will display a *Communicating with Pump* message.

## Therapy Settings

Your *Therapy Settings* are initially entered during pump training with your certified twiist trainer, and must be confirmed prior to use. All updates to *Therapy Settings* should be made with direction from your healthcare provider.

1. Tap **Settings** On the *Toolbar*.

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

caution  $\triangle$  or warn  $\triangle$  you about the selected values.

2. Tap Therapy Settings.



Do not set glucose safety limit, correction range, pre-meal range, workout range, carb ratios, basal rates, delivery limits, insulin sensitivities, or insulin model without direction from your healthcare provider. Incorrect settings may lead to low or high blood glucose.

### Glucose Safety Limit

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

When *Loop* is off, the twiist system does not make glucose predictions.

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

#### Edit Glucose Safety Limit

- 1. Tap **Settings** On the *Toolbar*.
- 2. Tap Therapy Settings.
- 3. Tap Glucose Safety Limit.
- 4. Tap the current *Glucose Safety Limit* **value**.
- 5. Use the picker to edit your glucose safety limit.
- 6. Tap **Save**. Or tap *Cancel* to return to *Therapy Settings*.
- 7. Enter your iPhone passcode (or Face ID, or Touch ID) to authenticate.

### **Correction Range**

Your *Correction Range* is the value or range of values that you want the twiist AID system to aim for when adjusting your basal insulin and recommending boluses.

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

*Correction Range* can be entered as low as 87 mg/dL (4.8 mmol/L) and as high as 180 mg/dL (10 mmol/L). The *Correction Range* cannot be set below your *Glucose Safety Limit*.

Your Correction Range is different than your CGM Target Range. This range of values is used to display your Target Range on the CGM Status screen. To review or edit your Target Range, see "Target Range Setting" on page 121.

Edit your Correction Range

- 1. Tap **Settings** ⁽²⁾ on the *Toolbar*.
- 2. Tap Therapy Settings.
- 3. Tap Correction Range.

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

#### Add a new Correction Range

- 1. Tap **Settings** to the *Toolbar*.
- 2. Tap Therapy Settings.
- 3. Tap Correction Range.
- 4. Tap+.
- 5. Tap the **start time** within the picker to select a start time for the new *Correction Range*.
- 6. Use the picker to select a **low** and high value.
- 7. Tap **Add**.

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

#### Delete a Correction Range

- 1. Tap **Settings** ⁽²⁾ on the *Toolbar*.
- 2. Tap Therapy Settings.
- 3. Tap Correction Range.
- 4. Tap Delete.
  - (i) You will not be able to delete the correction range that begins at 12:00 AM.
- 5. Tap the e icon next to the correction range you would like to delete.
- 6. Tap **Delete**.
- 7. Tap Done, if needed.
- 8. Tap Save.

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

### Pre-Meal Range

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

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

Your *Pre-Meal Range* can be entered as low as 67 mg/dL (3.7 mmol/L) or your *Glucose Safety Limit* and as high as 130 mg/dL (7.2 mmol/L).

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

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

### Edit your Pre-Meal Range

- 1. Tap **Settings** ⁽²⁾ on the *Toolbar*.
- 2. Tap Therapy Settings.
- 3. Tap Pre-Meal Range.
- 4. Tap the current *Pre-Meal Range* value.
- 5. Use the picker to select a **low** and high value.
- 6. Tap **Save**. Or tap *Cancel* to return to *Therapy Settings*.
- 7. Enter your iPhone passcode (or Face ID, or Touch ID) to authenticate.

### Workout Range

*Workout Range* is the glucose value or range of values you want *Loop* to target before, during, or after physical activity to reduce the risk of low glucose events. This range will be in effect when you activate the *Workout Preset* button.

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

Your *Workout Range* can be entered as low as 87 mg/dL (4.8 mmol/L) or your *Glucose Safety Limit* and as high as 250 mg/dL (13.9 mmol/L).

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

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

#### Edit your Workout Range

- 1. Tap **Settings** ⁽²⁾ on the *Toolbar*.
- 2. Tap Therapy Settings.
- 3. Tap Workout Range.
- 4. Tap the current *Workout Range* value.
- 5. Use the picker to select a **low** and high value.
- 6. Tap **Save**. Or tap *Cancel* to return to *Therapy Settings*.
- 7. Enter your iPhone passcode (or Face ID, or Touch ID) to authenticate.

### Carb Ratios

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

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

#### Edit Carb Ratio

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

#### Add a new Carb Ratio

- 1. Tap **Settings** ⁽²⁾ on the *Toolbar*.
- 2. Tap Therapy Settings.
- 3. Tap Carb Ratios.
- 4. Tap+.

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

#### Delete a Carb Ratio

- 1. Tap **Settings** ⁽²⁾ on the *Toolbar*.
- 2. Tap Therapy Settings.
- 3. Tap Carb Ratios.
- 4. Tap Delete.
  - (i) You will not be able to delete the carb ratio that begins at 12:00 AM.

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

### Basal Rates

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

The twiist AID system allows you to enter *Basal Rates* in 30 minute increments, so you can set up to 48 individual rates per day.

The *Basal Rate* schedule starts at midnight.

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

#### Edit Basal Rate

- 1. Tap **Settings** to the *Toolbar*.
- 2. Tap Therapy Settings.
- 3. Tap Basal Rates.
- 4. Tap on the *Basal Rate* you want to edit.
- 5. Tap the **start time** within the picker if you want to change the start time for the *Basal Rate*.
  - i You will not be able to edit the basal rate that begins at 12:00 AM.
- 6. Use the picker to select the new *Basal Rate U/hr* value.

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

### Add a new Basal Rate

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

#### Delete a Basal Rate

- 1. Tap **Settings** ⁽²⁾ on the *Toolbar*.
- 2. Tap Therapy Settings.
- 3. Tap Basal Rates.
- 4. Tap Delete.
  - i You will not be able to delete the basal rate that begins at 12:00 AM.
- 5. Tap the e icon next to the Basal Rate you would like to delete.
- 6. Tap Delete.
- 7. Tap **Done**, if needed.
- 8. Tap **Save** or tap *Cancel* to return to *Therapy Settings*.
- 9. Enter your iPhone passcode (or Face ID, or Touch ID) to authenticate.

### **Delivery Limits**

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

### Maximum Basal Rate

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

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

Work with your healthcare provider to set a *Maximum Basal Rate* that is right for you. Insulin delivery must be suspended before the *Maximum Basal Rate* can be modified. *See "Suspend Insulin Delivery" on page 74.* 

- 1. Tap **Settings** ⁽²⁾ on the *Toolbar*.
- 2. Tap Therapy Settings.
- 3. Tap Delivery Limits.
- 4. Tap Maximum Basal Rate.
- 5. Use the picker to select the *Maximum Basal Rate* U/hr value.
- 6. Tap **Save**. Or tap *Cancel* to return to *Therapy Settings*.
- 7. Enter your iPhone passcode (or Face ID, or Touch ID) to authenticate.

#### Maximum Bolus

*Maximum Bolus* is the largest bolus amount you can deliver at one time to cover carbs (meal bolus) or bring down high glucose (correction bolus).

Insulin delivery must be suspended before the *Maximum Bolus* can be modified. *See "Suspend Insulin Delivery" on page 74.* 

- 1. Tap **Settings** ⁽²⁾ on the *Toolbar*.
- 2. Tap Therapy Settings.
- 3. Tap Delivery Limits.
- 4. Tap Maximum Bolus.
- 5. Use the picker to select the *Maximum Bolus* value in Units.
- 6. Tap **Save**. If you want to cancel, tap *Cancel* to return to *Therapy Settings*.

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

### Insulin Model

The twiist AID system assumes the insulin delivered is actively working to lower your glucose for 6 hours. The peak time for that activity is different for adults and children.

- Fast-Acting Adults: assumes peak insulin activity is at 75 minutes.
- Fast-Acting Children: assumes peak insulin activity is at 65 minutes.

#### Edit your Insulin Model:

- 1. Tap **Settings** ⁽²⁾ on the *Toolbar*.
- 2. Tap Therapy Settings.
- 3. Tap Insulin Model.

4. Tap the Fast-Acting - Adults or Fast-Acting - Children model.

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

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

### Insulin Sensitivities

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

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

#### Edit your Insulin Sensitivities

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

#### Add a new Insulin Sensitivity

- 1. Tap **Settings** ⁽²⁾ on the *Toolbar*.
- 2. Tap Therapy Settings.
- 3. Tap Insulin Sensitivities.
- 4. Tap+.

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

#### Delete an Insulin Sensitivity

- 1. Tap **Settings** ⁽²⁾ on the *Toolbar*.
- 2. Tap Therapy Settings.
- 3. Tap Insulin Sensitivities.
- 4. Tap Delete.
  - i You will not be able to delete the insulin sensitivity that begins at 12:00 AM.

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

### Temporary Basal Adjustment

The *Temporary Basal Adjustment* setting allows you to choose percentage adjustment or an override of your set basal rate as the method to set a *Temporary Basal*.

*Temporary Basal* and the *Temporary Basal Adjustment* settings are not available when *Loop* is on. When *Loop* is off, a *Temporary Basal* can be entered to increase or decrease your scheduled basal delivery.

By default, the twiist system uses a percentage adjustment.

# To edit how a temporary basal is delivered:

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

The selection will be followed by the  $\checkmark$  symbol.

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

To set a *Temporary Basal*, See "Set Temporary Basal" on page 162.

### **One-Button Bolus**

*One-Button Bolus* allows you to deliver a bolus through the use of the pump only.

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

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

- 1. Tap **Settings** ⁽²⁾ on the *Toolbar*.
- 2. Tap Therapy Settings.
- 3. Tap One-Button Bolus.
- 4. Tap the toggle to enable or disable.

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

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

### Extended and Dual Bolus

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

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

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

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

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

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

### Quiet Mode

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

Quiet Mode is OFF by default.

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

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

Quiet Mode will not silence:

- · Alarms and Alerts
- Interaction with the pump button, which include resuming or verifying delivery and putting the pump into pairing mode
- · One-button bolus
- 1. Tap **Settings** On the *Toolbar*.
- 2. Tap Therapy Settings.
- 3. Tap Quiet Mode.
- 4. Tap the toggle to enable or disable.
- 5. Tap **Save**. Or tap *Back* to return to *Therapy Settings*.

### Low Insulin Alert #1

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

### Low Insulin Alert #2

*Low Insulin Alert #2* allows you to configure an additional instance of the *Low Insulin Alert* to occur when the system estimates between 20 and 100 Units of insulin remaining in your cassette.

*Low Insulin Alert* #2 will occur when the insulin in your cassette falls below the configured volume.

*Low Insulin Alert #2* is OFF by default.

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

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

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

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

### Phone Out of Range Alert

The Phone Out of Range Alert notifies you when the twiist pump and app have been out of communication for the configured time, and is displayed on the twiist app when communication is restored.

Phone out of range is off by default.

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

- 1. Tap **Settings** ⁽²⁾ on the *Toolbar*.
- 2. Tap Therapy Settings.

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

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

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

### **Pump Inactive Alert**

The *Pump Inactive* alert notifies you when delivery has been suspended for the configured time. The *Pump Inactive* alert is set to 60 minutes by default, and can be set to 15, 30, 60, or 90 minutes. For your safety, the *Pump Inactive* alert cannot be disabled, and is always played by your iPhone at the maximum notification volume, even when your iPhone is silenced or *Focus* is enabled.

# To set the *Pump Inactive Alert* time:

- 1. Tap **Settings** ⁽²⁾ on the *Toolbar*.
- 2. Tap Therapy Settings.
- 3. Tap Pump Inactive Alert.
- 4. Tap the time for *Pump Inactive Alert*.

- 5. Use the picker to set the *Pump Inactive Alert* to 15, 30, 60, or 90 minutes.
- 6. Tap **Save**.

## Add CGM

The FreeStyle Libre 3 Plus Sensor can either be paired with the twiist AID system, or the Libre app, or Reader.

A FreeStyle Libre 3 Plus Sensor that has been previously paired with the Libre app or Reader cannot be paired with the twiist app.

The steps to *Add CGM* only need to be completed one time to add the FreeStyle Libre 3 Plus Sensor features into the twiist app.

Refer to the FreeStyle Libre 3 Plus Sensor manufacturer instructions for safety and proper use information.

 Tap Add CGM in the CGM Status, or tap Settings and tap Add CGM.

- 2. Clean hands prior to FreeStyle Libre 3 Plus Sensor handling and insertion to help prevent infection.
- 3. Only apply the FreeStyle Libre 3 Plus Sensor to the back of the upper arm.
  - If placed in other areas, the sensor may not function properly and could give inaccurate readings.
  - Select an appropriate sensor site to help the sensor stay attached to the body and prevent discomfort or skin irritation.
  - Avoid areas with scars, moles, stretch marks or lumps.
  - Select an area of skin that generally stays flat during normal daily activities (no bending or folding).

- Choose a site that is at least 1 inch (2.5 cm) from an insulin injection site. To prevent discomfort or skin irritation, you should select a different site other than the one most recently used.
- 4. Apply your new sensor.

For instructions on how to



i Applying the sensor may cause bruising or bleeding. If there is bleeding that does not stop, remove the sensor and contact your healthcare provider.

- 5. Put the cap back on the Sensor Applicator. Discard the Sensor Applicator according to local regulations.
- 6. Tap **NEXT**.



7. Tap SCAN NEW SENSOR.

For instructions on how to scan a sensor, tap **?** HOW TO SCAN A SENSOR.



8. Hold the top of your iPhone very close to the sensor.



(i) Refer to the FreeStyle Libre 3 Plus Sensor manufacturer instructions for troubleshooting information related to starting a new sensor. The FreeStyle Libre 3 Plus Sensor must complete a 60-minute warm up before glucose readings are available.



9. Tap **Done** to return to the *Home Screen*.

The CGM Status displays Sensor Warmup.



The twiist app will provide a notification when the sensor is ready.

- 10. Tap the notification to open the twiist app.
- 11. Tap **OK**.

## FreeStyle Libre 3 Plus Sensor Menu

- 1. Tap **Settings** ⁽²⁾ on the *Toolbar*.
- 2. Tap FreeStyle Libre 3 Plus Settings.

Configuration  COM Alerts  COM Alerts  COM Alerts  Support  COM Help  About CGM  COM	FreeStyle Libre 3 Plus	Done
CGM Ateris	Configuration	
Target Range Setting Start New Sensor Support USM Help bout CGM	CGM Alerts	3
Support CGM Help 3 Nabout CGM 3	Target Range Setting	
Support	Start New Sensor	ā,
CGM Help >	Support	
lbout CGM	CGM Help	2
	About CGM	2

FreeStyle Libre 3 Plus Sensor Menu includes:

- CGM Alerts
- Target Range Setting
- Start New Sensor
- CGM Help
- About CGM

FreeStyle Libre 3 Plus Sensor CGM Alerts

The twiist AID system, when used with a FreeStyle Libre 3 Plus Sensor, includes CGM Alerts.

### CGM Alerts:

An *Urgent Low Glucose* alert notifies you when your sensor glucose reading goes below 55 mg/dL. For your safety, the *Urgent Low Glucose* alert cannot be disabled, and is always played by your iPhone even when your iPhone is silenced or *Focus* is enabled. A CGM *Signal Loss* alert notifies you when your FreeStyle Libre 3 Plus Sensor has not communicated with the twiist pump. The CGM *Signal Loss* alert can be customized to notify you at different times, but cannot be turned off.

During CGM Signal Loss, CGM readings and alerts are not available, the CGM Status screen will display a 49 symbol, and the *twiist Status* may show a yellow or red circle icon. See "twiist Status" on page 61.

Low Glucose and High Glucose alerts are turned on by default. They can be turned off or customized to notify you at different glucose levels. Fixed CGM alerts cannot be modified or turned off and indicate that you are no longer receiving CGM glucose readings or CGM alerts.

#### Fixed CGM alerts include:

- Replace CGM
- CGM Ended
- Check CGM

For more information on all FreeStyle Libre 3 Plus Sensor alerts, see "CGM Alerts" on page 198.

### Set FreeStyle Libre 3 Plus Sensor CGM Alerts

To set FreeStyle Libre 3 Plus CGM alerts:

- 1. Tap **Settings** ⁽²⁾ on the *Toolbar*.
- 2. Tap FreeStyle Libre 3 Plus Settings.
- 3. Tap CGM Alerts.

#### Low and High Glucose CGM Alerts

Low and High Glucose CGM alert levels are different from your *Target Range. Low* and *High Glucose* CGM alerts tell you when your glucose has passed the configured alert level. Your *Target Range* is displayed on the CGM glucose chart and is used to calculate your time in target range.

#### Low Glucose CGM Alert

The *Low Glucose* CGM alert is on by default, and is initially set to 70 mg/dL (3.9 mmol/L). It can be set between 60-100 mg/dL (3.3-5.6 mmol/L) in 5 mg/dL increments. If the *Low Glucose* CGM alert is on, you will be notified when your CGM glucose falls below the level you set.

To change the *Low Glucose* CGM alert value:

- 1. Tap Low Glucose Alert.
- 2. Tap the **When glucose goes below** value.
- 3. Use the picker to select a value.

#### 4. Tap Save.

When the *Low Glucose* CGM alert is on, a solid red line is displayed on the FreeStyle Libre 3 Plus Sensor glucose chart at the set *Low Glucose* CGM alert value. The *Low Glucose* CGM alert is played based on your iPhone ringtone and alert volume.

Turn on *Override Focus* if you want this alert to always play a sound and display on the lock screen, even if your iPhone is silenced or *Focus* is on.

#### High Glucose CGM Alert

The *High Glucose* CGM alert is on by default, and is initially set to 250 mg/dL (13.9 mmol/L). It can be set between 120-400 mg/dL (6.7-22.2 mmol/L) in 10 mg/dL increments. If the *High Glucose* CGM alert is on, you will be notified when your CGM glucose rises above the level you set.

To change the *High Glucose* CGM alert value:

- 1. Tap High Glucose Alert.
- 2. Tap the When glucose goes above value.

- 3. Use the picker to select a value.
- 4. Tap Save.

When the *High Glucose* CGM alert is on, a solid orange line is displayed on the FreeStyle Libre 3 Plus Sensor glucose chart at the set *High Glucose* CGM alert value.

The *High Glucose* CGM alert is played based on the iPhone ringtone and alert volume.

Turn on *Override Focus* if you want this alert to always play a sound and display on the lock screen, even if your iPhone is silenced or *Focus* is on.

#### CGM Signal Loss CGM Alert

The *Signal Loss* CGM alert notifies you when your CGM Sensor has not communicated with the twiist app.

The CGM *Signal Loss* alert is set to 40 minutes by default and can be set to 20, 40, 60, or 90 minutes. The CGM *Signal Loss* alert cannot be disabled.

To change the *CGM Signal Loss* alert value:

- 1. Tap CGM Signal Loss Alert.
- 2. Tap the **Signal Loss Alert** value.
- 3. Use the picker to select a value.
- 4. Tap Save.

The *CGM Signal Loss* alert is played based on the iPhone ringtone and alert volume.

Turn on *Override Focus* if you want this alert to always play a sound and display on the lock screen, even if your iPhone is silenced or *Focus* is on.

## *Target Range Setting*

Your *Target Range* will be displayed on the FreeStyle Libre 3 Plus Sensor glucose chart.

- 1. Tap **Settings** ⁽²⁾ on the *Toolbar*.
- 2. Tap FreeStyle Libre 3 Plus Settings.
- 3. Tap Target Range Setting.



4. Tap on your *Target Range* and use the picker to select a low and high *Target Range*.



#### 5. Tap **Save**.

(i) Your *Target Range* has a default value of 70 to 180 mg/dL (3.9 to 10 mmol/l) and is used to calculate your time in target range. Your *Target Range* is different than your *Correction Range*. To review or edit your Correction Range, see "Correction Range" on page 103.

 Target Range does not set glucose related CGM alert levels.

## Start a New FreeStyle Libre 3 Plus Sensor

To start a new FreeStyle Libre 3 Plus Sensor:

- 1. Tap **Settings** ⁽²⁾ on the *Toolbar*.
- 2. Tap FreeStyle Libre 3 Plus Settings.
- 3. Tap Start New Sensor.



4. Clean hands prior to FreeStyle Libre 3 Plus Sensor handling and insertion to help prevent infection.

- 5. Only apply the FreeStyle Libre 3 Plus Sensor to the back of the upper arm.
  - If placed in other areas, the sensor may not function properly and could give inaccurate readings.
  - Select an appropriate sensor site to help the sensor stay attached to the body and prevent discomfort or skin irritation.
  - Avoid areas with scars, moles, stretch marks or lumps.
  - Select an area of skin that generally stays flat during normal daily activities (no bending or folding).
  - Choose a site that is at least 1 inch (2.5 cm) from an insulin injection site. To prevent discomfort or skin irritation, you should select a different site other than the one most recently used.

6. Apply your new sensor.

For instructions on how to apply the sensor, tap **? HOW TO APPLY A SENSOR**.

- (i) Applying the sensor may cause bruising or bleeding. If there is bleeding that does not stop, remove the sensor and contact your healthcare provider.
- 7. Put the cap back on the Sensor Applicator. Discard the Sensor Applicator according to local regulations.

#### 8. Tap **NEXT**.



9. Tap SCAN NEW SENSOR.

For instructions on how to scan a sensor, tap **HOW TO SCAN A SENSOR**.



10. Hold the top of your iPhone very close to the sensor.



(i) Refer to the FreeStyle Libre 3 Plus Sensor manufacturer instructions for troubleshooting information related to starting a new sensor. The FreeStyle Libre 3 Plus Sensor must complete a 60-minute *Sensor Warmup* before glucose readings are available.



11. Tap **Done** to return to the home screen.

The CGM Status displays Sensor Warmup.



The twiist app will provide a notification when the sensor is ready.

12. Tap the notification to open the twiist app.

13. Tap **OK**.

## FreeStyle Libre 3 Plus Sensor Help

For *Help* using the FreeStyle Libre 3 Plus Sensor:

- 1. Tap **Settings** ⁽²⁾ on the *Toolbar*.
- 2. Tap FreeStyle Libre 3 Plus Settings.
- 3. Tap CGM Help.

< Back	CGM Help	Done
How to appl	y a Sensor	
How to scan	a Sensor	
Glucose Rea	idings	
CGM Alerts		
CGM Event	Log	

Help topics include:

- How to apply a Sensor
- How to scan a Sensor
- Glucose Readings
- CGM Alerts
- CGM Event Log

## FreeStyle Libre 3 Plus Sensor About CGM

About CGM provides information about the last 3 paired sensors.

- 1. Tap **Settings** ⁽²⁾ on the *Toolbar*.
- 2. Tap FreeStyle Libre 3 Plus Settings.
- 3. Tap About CGM.
- 4. When you are finished, tap **Back** or **Done**.

## Help

The *Help* feature allows you to review the following training modules:

- Introduction
- How the App Works
- A Day in the Life
- When *Loop* is Off
- 1. Tap **Settings** ⁽²⁾ on the *Toolbar*.
- 2. Tap Help.
- 3. Tap any training module to expand, and select the topic you would like to review.

Once you have selected a topic to review:

- 1. Tap **Continue** to advance through the training topics.
- 2. Tap **Back** to review the previous topic.
- 3. Tap **Close** to return to the help menu.

## **Contact Sequel**

- 1. Tap **Settings** ⁽²⁾ on the *Toolbar*.
- 2. Tap **Contact Sequel** to access the Sequel contact information or to send a message.

## **Configure Devices**

Configure devices provides access to the *Delete Pump* or *Delete CGM* functions.

- 1. Tap **Settings** ⁽²⁾ on the *Toolbar*.
- 2. Tap Configure Devices.

### Delete Pump

The twiist app can only be paired to one pump at a time. If you need to pair to a new pump, you will need to delete the existing pump.

- 1. Tap **Settings** ⁽²⁾ on the *Toolbar*.
- 2. Tap Configure Devices.
- 3. Tap Delete Pump.



- 4. Tap **Yes** to confirm or **No** to cancel.
- 5. Follow instructions to "Pair a New Pump" on page 97.

### Delete CGM

- 1. Tap **Settings** ⁽²⁾ on the *Toolbar*.
- 2. Tap Configure Devices.
- 3. Tap Delete CGM.



4. Tap **Yes** to confirm or **No** to cancel.

By confirming that you would like to delete the CGM, all FreeStyle Libre 3 Plus Sensor features within the twiist app will be removed.

To continue with automated insulin delivery, see "Add CGM" on page 115.

## About

About provides information about the twiist pump and app, hardware and software versions.

- 1. Tap **Settings** ⁽²⁾ on the *Toolbar*.
- 2. Tap About.

# FreeStyle Libre 3 Plus Sensor Status

The *CGM Status* screen displays your current glucose, glucose trend arrow, and glucose chart. This screen is automatically updated with glucose data from your sensor.



## Check Your CGM Status

Tap the **CGM Status** icon to open the *CGM Status* screen.

If you have an active FreeStyle Libre 3 Plus Sensor, the *CGM Status* screen displays additional CGM information including, your current glucose, glucose trend arrow, and a chart of your current and past glucose readings.

The *CGM Status* screen also provides information on *Sensor Warmup* time or sensor errors.



## **Confirm Sensor Glucose**

During the first 12 hours after starting a FreeStyle

Libre 3 Plus Sensor, the symbol will be displayed. Confirm sensor glucose readings with a fingerstick before making treatment decisions.

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

When in doubt, get your meter out.
## Check Your CGM Glucose

The chart displays glucose readings above 350 mg/dL as 350 mg/dL (19.4 mmol/L). For consecutive readings above 350 mg/dL (19.4 mmol/L), a line is displayed at 350 mg/dL (19.4 mmol/L). The *Current Glucose* value can be as high as 400 mg/dL (22.2 mmol/L).

(i) The current glucose value displayed on the CGM

*Status* screen will match the glucose value displayed on the twiist app home screen.

Your current glucose value determines the background color displayed on the *CGM Status* screen:

Orange	High glucose - above 250 mg/dL (13.9 mmol/L)
Yellow	Between the <i>Target Range</i> and high or low glucose level
Green	Within the Target Range

Red

Low glucose - below 70 mg/dL (3.9 mmol/L)

### Glucose Trend

The glucose trend arrow provides information about the direction your glucose is going. The glucose trend arrow displayed on the *CGM Status* screen will match the glucose trend arrow displayed in the *CGM Status* on the twiist app home screen.

For more information on glucose trend arrows, see "CGM Status" on page 58.

## CGM Messages

The *CGM Status* may display messages along with glucose readings or when sensor readings are not available.

i) When a CGM message is displayed along with a CGM reading, the background color of the message corresponds to your current CGM reading.

## **Glucose Going Low**

The FreeStyle Libre 3 Plus Sensor is projecting that your glucose will be lower than 70 mg/dL (3.9 mmol/L) within 15 minutes.

1. Tap CGM Status.



2. Tap the **Glucose Going Low** message for more information and to set a reminder to check your glucose.



### 3. Tap **Set**.



4. Use the picker to set a reminder in 15 or 30 minutes.



- 5. Tap Start.
- 6. When the reminder time has expired, a *Timer Expired* notice is displayed, tap **OK**.

### Low Glucose

Your current CGM reading is lower than 70 mg/dL (3.9 mmol/L).

1. Tap CGM Status.

68 🕥 🔿 🗕

2. Tap the **Low Glucose** message for more information and to set a reminder to check your glucose.



### 3. Tap Set.



4. Use the picker to set a reminder in 15 or 30 minutes.



- 5. Tap Start.
- 6. When the reminder time has expired, a *Timer Expired* notice is displayed, tap **OK**.

# Low Glucose (Out of Range)

Your current CGM reading is lower than 40 mg/dL (2.2 mmol/L).

1. Tap CGM Status.



2. Tap the **Low Glucose (Out of Range)** message for more information.



3. Tap **OK**. Check your blood glucose with a fingerstick.



 If you get a second LOW after the fingerstick, contact your healthcare provider immediately.

### **Glucose Going High**

The FreeStyle Libre 3 Plus Sensor is projecting that your glucose will be higher than 250 mg/dL (13.9 mmol/L) within 15 minutes.

1. Tap CGM Status.



2. Tap the **Glucose Going High** message for more information and to set a reminder to check your glucose. Consider checking your ketones.



3. Tap **Set**.



4. Use the picker to set a reminder in 1-4 hours.



- 5. Tap Start.
- 6. When the reminder time has expired, a *Timer Expired* notice is displayed, tap **OK**.

### High Glucose

Your current CGM reading is higher than 250 mg/dL (13.9 mmol/L).

1. Tap CGM Status.

255 (-)

## 2. Tap the **High Glucose**

message for more information and to set a reminder to check your glucose. Consider checking your ketones.



### 3. Tap Set.



4. Use the picker to set a reminder in 1-4 hours.



- 5. Tap Start.
- 6. When the reminder time has expired, a *Timer Expired* notice is displayed, tap **OK**.

# *High Glucose (Out of Range)*

Your current CGM reading is higher than 400 mg/dL (22.2 mmol/L).

1. Tap CGM Status.



2. Tap the **High Glucose (Out of Range)** message for more information.



3. Tap **OK**. Check your blood glucose with a fingerstick.



4. If you get a second *HIGH* after the fingerstick, contact your healthcare provider immediately.

### Sensor Warmup

The FreeStyle Libre 3 Plus Sensor is warming up.

1. Tap **CGM Status** and refer to the bottom of the screen for the time remaining until *Sensor Warmup* completes.





### Sensor Error

Your FreeStyle Libre 3 Plus Sensor runs continuous quality checks, and CGM readings have been paused. Once the sensor passes these checks, your sensor will resume CGM readings.

1. Tap CGM Status.

Sensor U

2. Tap the **Sensor Error** message for more information.



3. Tap **OK** and check again according to the duration specified in the message.



i) If you receive a Sensor Error during your first 12 hours of wearing a sensor, your body may still be adjusting to the sensor. Check your blood glucose with your blood glucose meter while you wait.

You do not need to remove your sensor.

### Sensor Too Hot

Your FreeStyle Libre 3 Plus Sensor is too hot to provide a glucose reading.

1. Tap CGM Status.



2. Tap the **Sensor Too Hot** message for more information.



3. Tap **OK** and move to a location where the temperature is appropriate and check again in a few minutes.



### Sensor Too Cold

Your FreeStyle Libre 3 Plus Sensor is too cold to provide a glucose reading.

1. Tap CGM Status.



2. Tap the **Sensor Too Cold** message for more information.



3. Tap **OK** and move to a location where the temperature is appropriate and check again in a few minutes.



## **CGM Filter Options**

**Correction Range** 

The FreeStyle Libre 3 Plus Sensor glucose chart can be filtered to display any of the following views:



### Target Range

COM Status

CGM Ends In: 14 Dave

Э

Connection Rannel

✓ Target Range

### Correction and Target Range

Glucose Readings Only





## When to use a Blood Glucose Meter

The twiist AID system allows you to manually enter fingerstick glucose values from a blood glucose (BG) meter.

Fingerstick values should be entered:

- During CGM warm-up
- During CGM signal loss
- When you want to deliver a bolus but do not have recent CGM glucose data
- When no CGM has been added

You can add a fingerstick value directly from the *Temporary Status Banner* on your *Home Screen* when *Loop* is on and no CGM data is currently available, or when you enter a meal or correction bolus. The twiist AID system can use your fingerstick values to adjust basal insulin delivery and bolus recommendations when no CGM value is available. This will occur during CGM signal loss, or while a new CGM is starting up.

1. Tap **No Recent Glucose** in the temporary status banner.



2. Enter a **Fingerstick Glucose** reading from your blood glucose meter.



After you enter a fingerstick value, a bolus may or may not be recommended. *See "Bolus Delivery" on the next page* for more information.

i The twiist AID system is designed to work best with CGM glucose. Some features of automated insulin delivery may be less effective when CGM values are unavailable.

## **Basal Delivery**

Your current basal rate is displayed on the home screen above the *Insulin Delivery Chart*.



When *Loop* is on, the twiist AID system uses your settings and current CGM glucose, as well as your *Active Carbohydrates* and *Active Insulin* to make predictions about where your glucose is going in the future. The twiist AID system makes calculations to adjust your basal as often as every five minutes in an effort to reduce high and low glucose. i If *Loop* is off, basal delivery will be delivered at your scheduled basal rates.

Your current basal rate and any increases or reductions to your basal rate made by the twiist AID system are displayed on the *Home Screen* within the *Insulin Delivery Status* and the *Insulin Delivery Chart*.

The *Insulin Delivery Status* will display a scheduled, reduced, or increased basal icon depending on the adjustment to your background insulin delivery.

## **Bolus Delivery**

A bolus can be delivered using the *Carb Entry* or *Bolus* buttons on the twiist app toolbar, or directly on the pump using the *One-Button Bolus* feature.

Monitor your glucose and consult with your healthcare provider if your glucose continues to rise following the delivery of a bolus.

## Carb Entry and Meal Bolus

When *Loop* is on, to enter carbs you have already eaten or plan to eat in order to deliver a bolus for your meal:

- Tap Carb Entry ^I○ on the *Toolbar* to enter details about what you have already eaten or plan to eat. You can also tap the Active Carbohydrates chart and +.
- 2. Tap **Amount Consumed** and enter the grams of carbs you have already eaten or plan to eat.

	P 🚥
Cancel Add Carb Entry	
Amount Consumed	<b>25</b> g
Time 😑	9:31AM 🔂
Food Type	P 4 14
Absorption Time	3 hr
Circone a longer absorption time to or those containing fats and protein guidance to the algorithm and need	r larger meals, ns. This is eng- i not be exect
Continue	

 Tap **Time** and use the picker, or tap – or + to select the time (in 10 minute increments) to enter the time you ate, or plan to eat.

> If you have eaten carbs that you have not told the twiist AID system about, go back and add those carbs so the best possible adjustments can be made.

You can log missed meals up to 12 hours into the past or log future meals up to 1 hour into the future.

4. Tap a **Food Type** emoji to select an absorption time.

### Absorption Time

i The concept of absorption time may be new to you.

Different food types can affect glucose in different ways. Some foods may raise glucose quickly and others more slowly over time.

This difference in time and effect on glucose is called *absorption time*.

You can estimate how many hours you think a food may continue to impact your glucose by selecting a food type emoji or setting the absorption time:



Fast carb effect: 30 minutes



Medium carb effect: 3 hours

Slow carb effect: 5 hours



- Tap Absorption Time. 5.
- Use the picker to select an 6. absorption time from 30 minutes to 8 hours.

Choose a longer absorption time for larger meals, or those containing fats and proteins.

This is only an estimate and does not need to be exact

For more detailed information about how the twiist AID system manages absorption time, see "The Loop Algorithm "on page 292.

## **Confirm Bolus**

#### Tap Continue. 7.

- Before delivering a bolus, 8. review:
  - Active Carbs
  - Active Insulin
  - Carbs entered
  - Food Type/Absorption Time
  - Recommended Bolus



You should not modify the bolus to be greater than the recommended value. Modifying a bolus to be greater than the recommended value can lead to glucose falling below your Glucose Safety Limit and may increase your risk of low blood glucose.

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

If a new CGM reading results in an update to your *Recommended Bolus*, a *Bolus Recommendation Updated* message is displayed. Tap **OK** and reconfirm the bolus amount.

9. Tap Deliver Bolus.

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

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

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

Bolus 1.33 of 4.79 U Tap to Stop 3

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

Insul	in Delive	ry				0.e U/hr
1						
-1	12 PM	1.PM	2 PM	3 PM	a PM	5.PM

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

-		
	Delivery In Progress	
_		

### Save without Bolusing

There may be times a bolus will not be recommended after carb entry. This can happen when:

- You have enough active insulin to cover the carbs you have entered.
- Your glucose is predicted to be below your *Correction Range*.

If your glucose is below, or predicted to go below your *Glucose Safety Limit*, the twiist AID system will not recommend a bolus and a *No Bolus Recommended* caution will be displayed. Tap **Save without Bolusing**. To save the carb entry without bolusing when a bolus is recommended:

- 1. Tap into the **Bolus** field and set the *Bolus* to **0.00 U**.
- 2. Tap Save without Bolusing.



### Bolus for Multiple Absorption Times

The twiist AID system allows you to enter one food at a time with different absorption times before delivering a bolus. Once you have entered all of the food that you intended to eat, you can then bolus for all of the carbs that you have added.

After entering your first food type and absorption time:

- 1. Tap Continue.
- 2. Tap into the **Bolus** field and set the *Bolus* to **0.00 U**.
- 3. Tap Save without Bolusing.
- 4. Repeat steps for carb entry to enter another food type and absorption time.

The twiist AID system knows about all the active carbs you have entered when it makes a bolus recommendation.

Only 1 bolus can be delivered at a time.

5. Once you have entered all the food types and absorption times, tap **Deliver Bolus**.

### Dynamic Carbohydrate Absorption

The Active Carbohydrates chart displays the carbs that you entered into the twiist app and how the twiist AID system expects them to impact your glucose over time. This is called *Dynamic Carbohydrate Absorption*.

# On the Home Screen, tap the **Active Carbohydrates Chart** to display *Dynamic Carbohydrate Absorption* details.

Delete Back Carbohydrates **Glucose Change** 7 AM MAR MAR 10 MA Predicted Observed Ved changes in gluchse, subtracting changes modeled from insulin delivery, can ne used to estimate cercolity/1.de 55 g Active Carbs g Total 102 since 6.00 JAM 55 a: 🜮 11:59 AM + 3h 4h 35m 37 g: Q 7:52 AM + 2h 30m 10 a: 🤍 6:00 AM + 60m 9 g absorbed 65m

### Glucose Change Chart

The *Glucose Change* chart at the top of the *Carbohydrates* screen displays how the entered carbohydrate may effect glucose. Observed changes in glucose, based on CGM readings, are shown in green while the effect the twiist AID system predicts the entered carbs to have on glucose are shown in gray. The predicted change compared to the observed change is called the Insulin Counteraction Effect (ICE).



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 "Sequel Customer Support" on page 245.

### **Entered Carbs**

The twiist AID system assumes that it may take up to 1.5 times longer to absorb carbs than what was entered. This gives the twiist AID system 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.

55 gractive Carbs	102 Since GOULAN
55 g: 🌮	11:59 AM + 3h
26 g absorbed	4h 35m
37 g: <b>Q</b>	7:52 AM + 2h 30m
7 g absorbed	3h 55m
10 g: 🧼	6:00 AM + 60m
9 g absorbed	65m

When carbohydrates are entered, each entry displays:

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

As carbohydrates are absorbed, each entry will also display:

- 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

### Delete or Edit Carb Entry

When *Loop* is on and carbs were logged that did not get eaten, or if information was incorrectly entered, you can delete or edit entries in the log.

1 Carbs cannot be deleted or edited when *Loop* is off.

### Delete a Carb Entry

1. Tap the Active Carbohydrates Chart.



2. On the top of the *Carbohydrates* screen, tap **Delete**.



3. Tap enext to the active carb you would like to delete.



4. Tap Delete.

### The twiist AID system will

adjust your basal insulin based on your active carbohydrates. The more accurate the information you provide, the more effective it will be when it adjusts your basal to keep you within your *Correction Range*.

### Edit a Carb Entry

- 1. Tap the Active Carbohydrates Chart.
- 2. To change a carb amount or time, tap the row of the entry you want to change.

63 g Active Carbs	92 g Total
55 g: 🌮 2 g absorbed	8:15 AM + 4h 4h 32m
37 g: 🔍	= 23 404 + 34;30m ; 71 47m

3. Within the *Edit Carb Entry* screen, tap any of the values and make the necessary edits.



4. Tap Continue.

A *Bolus* may or may not be recommended.

If a bolus is not recommended, tap **Save without Bolusing**.

If a bolus is recommended, tap **Deliver Bolus**.

## Carb Entry and Meal Bolus with Loop Off

When *Loop* is off, the twiist system can deliver a normal bolus, extended bolus, or dual bolus.

- A *Normal Bolus* delivers insulin all at once.
- An *Extended Bolus* delivers insulin over an extended period of time.

*Extended Bolus* is an advanced use feature that is disabled by default.

• A *Dual Bolus* delivers some of your bolus now as a normal bolus, and some over an extended time as an extended bolus.

*Dual Bolus* is an advanced use feature that is disabled by default.

1. Tap **Carb Entry** ^[◯] on the *Toolbar*.

- 2. Tap **Carbohydrates** and enter the amount of carbs you have already eaten or plan to eat.
- 3. Tap **Fingerstick Glucose** and enter a fingerstick glucose reading.
- 4. Tap **Done** to hide the keypad.
- 5. Before delivering a bolus, review your *Active Insulin*.

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



- 6. Tap **Next** to review the bolus details.
- 7. Tap Normal Bolus.
- 8. Tap Deliver Bolus.
- 9. Enter your iPhone passcode (or Face ID, or Touch ID) to authenticate.

The pump plays the *Delivering* sound.

i The *Delivering* sound will not be played when *Quiet Mode* is enabled. The *Home Screen* will temporarily display your fingerstick glucose value and a BG meter icon. The *Temporary Status Banner* displays the bolus delivery progress while the bolus is being delivered.



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

Insu	lin Delivery			6	.e U/hr
а					
0					
1					
	JZPM IPM	2.PM	3 PM	a PM	5.PM

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



If a fingerstick glucose value is entered that is higher than 250 mg/dL (13.9 mmol/L):

A *High BG* message will be displayed asking if you want to continue.



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

2. Select **Yes** to continue with the bolus, or **No** to exit the meal calculator.

If a fingerstick glucose value is entered that is below 70 mg/dL (3.9 mmol/L):

A *No Bolus Recommended* caution will be displayed and you will be given the option to **Save without Bolusing**.



## Deliver Extended Bolus

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

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

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

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

5. Tap Next.

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



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

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

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



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



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



## **Deliver Dual Bolus**

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

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

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

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

- 6. Review the *Bolus Details* and tap **Dual Bolus**.
- 7. Divide the *Meal Bolus* between *Normal* and *Extended* bolus types.

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

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



### 11. Tap **Next**.

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

The pump plays the *Delivering* sound.

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

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



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



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



## **Pre-Meal Preset**

If you would like the twiist AID system to temporarily lower your correction range before you begin eating so that your post-meal glucose spike is reduced, you can use the *Pre-Meal Preset*. The *Pre-Meal Preset* will stay on for up to one hour, until it is canceled, or until you enter carbs, whichever occurs first.

Using this feature before your meal tells the twiist automated insulin delivery system to adjust your basal insulin and lower your *Correction Range* to your configured *Pre-Meal Range*.

The *Pre-Meal Preset* feature is only available when *Loop* is on.

When *Loop* is off, the twiist system will not adjust your correction range or automate your basal insulin to bring you to your *Pre-Meal Range*. This button will appear grayed out on the toolbar.

1. Tap **Pre-Meal Preset** ^(S) on the *Toolbar*.



2. Tap Until I enter carbs.

## When the *Pre-Meal Preset* is active:

- Temporary Status Banner displays Pre-Meal Preset until 1 hour from the time activated.
- Your Correction Range will be updated to your Pre-Meal Range within the Glucose Chart.



• Button color in the toolbar will be reversed.

## Cancel Pre-Meal Preset

 Tap Pre-Meal Preset On the Toolbar to cancel the Pre-Meal Preset.

> The Home Screen will no longer display a Temporary Status Banner showing the Pre-Meal Preset.

Your *Correction Range* will be updated within the *Glucose Chart*.

## Bolus Entry (Correction Bolus)

 When Loop is on, tap the Bolus Entry → button to receive a recommendation for a correction bolus to bring down high glucose.



- 2. Before delivering a bolus, review:
  - Active Carbs
  - Active Insulin

## To deliver the recommended bolus:

If a new CGM reading results in an update to your *Recommended Bolus*, a *Bolus Recommendation Updated* message is displayed. Tap **OK**.

3. Confirm the *Recommended Bolus* and tap **Deliver**.



4. Enter your iPhone passcode (or Face ID, or Touch ID) to authenticate. The pump plays the *Delivering* sound, and the *Temporary Status Banner* displays the bolus delivery in progress.

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

9:35	
139 🕘	0 = 1
Bolus 0.84 of 1.89 U	Tap to Stop
Glucose	Emonumy 100 mg/dl

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



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



If a bolus is not recommended, a *No Bolus Recommended* caution is displayed. Tap **Cancel** to return to the *Home Screen*.

No Bolus Recommended	
four glucose is below or predicted to our glucose safety limit, 80 mg/dL.	go helów
Enter Bolus	

You should not modify the bolus to be greater than the recommended value. Modifying a bolus to be greater than the recommended value can lead to glucose falling below your *Glucose Safety Limit* and may increase your risk of low blood glucose.

The twiist AID system is continuously making adjustments to your basal delivery to keep you near your correction range. To enter a bolus when a bolus is not recommended:

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

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

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

## Bolus Entry (Correction Bolus) with Loop Off

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



- 2. Tap **Fingerstick Glucose** and enter a fingerstick blood glucose reading.
- 3. Tap **Done** to hide the keypad.
- 4. Before delivering a bolus, review your *Active Insulin*.

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

ingerstick Glucose	155 mg/dL
ecommended Bolus	0.38 0
lolus	0.38 (

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

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

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

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

Bolus 1.33 of 4.79 U Tap to Stop 3

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

insum benvery	ore of the
0.4	
191	CALL AND ADD ADD

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

Delivery In Progress	

If a fingerstick glucose value is entered that is higher than 250 mg/dL (13.9 mmol/L):

A *High BG* message will be displayed asking if you want to continue.



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

If a fingerstick glucose value is entered that is below 70 mg/dL (3.9 mmol/L):

A *No Bolus Recommended* caution will be displayed and you will be given the option to **Save without Bolusing**.



# Manually Enter a Bolus

1. Tap **Bolus**  $\forall$  on the *Toolbar*.

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

- 2. Tap **Bolus** to display the keypad.
- 3. Enter the desired bolus value using the keypad.
- 4. Tap **Done** to hide the keypad.
- 5. Tap Next.
- 6. Confirm the bolus amount and tap **Deliver Bolus**.
- 7. Enter your iPhone passcode (or Face ID, or Touch ID) to authenticate.

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

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

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



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

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



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



## Stop Bolus Delivery

Bolus progress will be displayed within the *Temporary Status Banner* while a bolus is being delivered. When the bolus is completed or interrupted, the *Temporary Status Banner* will not be displayed.

### To stop a bolus delivery:

1. Tap the **Temporary Status Banner**.



2. Tap **Yes** to stop the bolus.

The pump plays the *Delivering* sound.

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

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

If you need to stop a bolus and your pump and twiist app are not in communication, you will need to suspend insulin delivery. See "How do I stop insulin delivery without my twiist app?" on page 241.

## Workout Preset



When you would like to exercise, use the *Workout Preset* to temporarily raise your *Correction Range*. The twiist AID system will use your *Workout Range* to reduce the risk of low glucose events.

i Failing to inform the twiist AID system that you would like your *Correction Range* to be modified through the use of the *Workout Preset* may cause unexpected changes to your glucose to occur. About thirty minutes to an hour before you exercise, you should check your charts. Check your glucose chart to make sure your glucose is not predicted to drop in the near future, and your *Active Insulin* chart to see how much insulin is currently working to lower your glucose.

(1) This feature is only available when *Loop* is on. When *Loop* is off the twiist system will not adjust your correction range or automate your basal insulin to bring you to your *Workout Range*.

1. Tap **Workout Preset** [⇔] on the *Toolbar*.



(i) When *Loop* is off, the ↔ button on the toolbar is used to set a *Temporary Basal*, see "*Temporary Basal*" on page 162.

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

(i) To use the *Workout Preset* effectively, work with your healthcare provider to determine the settings that are best for you.

When the *Workout Preset* is active:

- Temporary Status Banner displays the Workout Preset.
- Your Correction Range will be updated to your Workout Range within the Glucose Chart.



• Button color 😌 in the toolbar will be reversed.

Although your iPhone is not required, you may want to bring it with you to monitor your glucose, and your twiist AID system, which is actively working on maintaining your *Workout Range*.



If you selected *Until I turn off*, and your *Workout Preset* is still active:

The twiist app displays a *Workout is Still Active* notice after 24 hours.



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

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

## Cancel Workout Preset

1. Tap **Workout Preset** ^{Sol} on the *Toolbar*.

The Home Screen will no longer display a Temporary Status Banner displaying the Workout Preset.

Your *Correction Range* will be updated within the *Glucose Chart*.

## **Temporary Basal**

When *Loop* is off, a *Temporary Basal* can be used to increase or decrease your basal rate temporarily, for activities such as exercise or when you are sick. Setting a *Temporary Basal* should be performed with direction from your healthcare provider.



By default, a *Temporary Basal* adjusts your basal rate by allowing you to select a percentage of your basal rate for a specified duration. You can also choose to set a *Temporary Basal* by overriding your programmed rate or rates within *Therapy Settings*. See "*Temporary Basal Adjustment*" on page 110.

(1) When *Loop* is on, the  $\bigcirc$  button on the toolbar is used to enable a *Workout Preset, see* "*Workout Preset*" on page 160.

## Set Temporary Basal

- 1. Tap the  $\bigcirc$  button on the *Toolbar.*
- 2. Use the picker to enter the **Duration** between 30 minutes and 24 hours.
- 3. Tap **Rate Change** to use the picker to select a value.

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

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

0.75				
0.50				
0.25				
12 AM 6 AM 12 P	M 6 PM 12 AI			
Duration	Rate Change			
5:00	150			
	100			

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

The graph displays your current scheduled basal rate or rates. The dark blue area displays the *Duration* and *Rate Change* selected.

If the *Temporary Basal* percentage causes the temporary basal to exceed the maximum basal rate, lower your percentage or modify your duration.

1.50	
1.25	and the second se
1.00	
0.75	
0.50	
0.25	
0.00	The state of the s
12 AM 6 AM 12	2 PM 6 PM 12 AM
12 AM 6 AM 12 Duration	PM 6 PM 12 AM Rate Change
0.00 12 AM 6 AM 12 Duration	Rate Change
22 AM 6 AM 12 Duration 2:00	Rate Change

If the *Temporary Basal* percentage causes the temporary basal to fall below the minimum deliverable basal rate, increase your percentage, or set the *Rate Change* to **0 percent**.

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



6. Enter your iPhone passcode (or Face ID, or Touch ID) to authenticate. The pump plays the *Delivering* sound.

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

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

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



The Insulin Delivery Status icon

displays a reduced -1.0 U/hr or

increased +3.0 U/hr basal.

The *Insulin Delivery Chart* displays a reduced or increased basal and the current basal delivery rate.

Insul	in Delivery				1.55 9/01	
1-	-	_			-	
-1	ARE	4 PM	5 PM	MER	7 FM	

The Solution on the *Toolbar* is displayed with the color reversed.



## Stop Temporary Basal

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

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

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

The pump plays the *Delivering* sound.

(i) The pump sound will not be played when *Quiet Mode* is enabled.
## Delivery with Pump Button

The Pump Button can be used to:

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

## Verify Insulin Delivery

The pump button can be used to verify that insulin delivery is in progress, when the twiist app is not available, or when you just want an audio confirmation.

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

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

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

## Resume Basal Insulin Delivery

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

# If delivery had been previously suspended:

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

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

1. Make sure the infusion set tubing is disconnected from the infusion site.

- 2. Remove the cassette from the pump.
- 3. Remove and reinsert the pump battery.

The pump plays a *Quick* beep followed by a *Ready* beep.

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

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

## **One-Button Bolus**

The One-Button Bolus feature is available to manually deliver a bolus directly from your pump.

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

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

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

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



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

- 2. When you have reached the number of units you would like to bolus, press and hold the **pump button** until you hear the playback start, then release the pump button.
- 3. Listen and confirm the pump plays back the number of units you entered.
- 4. If the playback is correct, press and hold the **pump button** until you hear the *Delivering* sound.

If the playback is incorrect, allow the One-Button Bolus to time out. See "Bolus Programming Time Out:" on the facing page.

The twiist app displays the *Bolus* progress with the number of units delivered out of the total units programmed.

If you need to stop the bolus delivery, see "Stop Bolus Delivery" on page 159.

If you need to stop a bolus and your pump and twiist app are not in communication, suspend insulin delivery. See "How do I stop insulin delivery without my twiist app?" on page 241.

### One-Button Bolus Programming Canceled

#### Bolus Programming Time Out:

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



- 1. Tap **OK** to dismiss the notice.
- 2. Restart the One-Button Bolus programming and delivery.

#### Maximum Bolus Exceeded:

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



- 1. Tap **OK** to dismiss the notice.
- 2. Restart the *One-Button Bolus* programming and delivery.

# Pump Button Pressed During Confirmation:

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



- 1. Tap **OK** to dismiss the notice.
- 2. Restart the *One-Button Bolus* programming and delivery.

# Sleeping with twiist



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

Let us look at how the twiist AID system can impact your night.

## Before Sleeping



Before you go to sleep at night, check in with the twiist AID system to make sure your:

- twiist app Home Screen displays a green circle twiist Status icon
- iPhone has enough battery charge to last the night or is charging
- Cassette has enough insulin
- Pump has enough battery charge

## While Sleeping



If *Loop* is on, the twiist AID system will work while you sleep to help keep you in your correction range without your intervention.

If *Loop* is off, or if you are trending low or high before bed, you may want to take additional action or monitor your glucose more closely to prevent lows and highs.

## Nighttime Checks



While the twiist AID system will continue to actively adjust basal delivery through the night, there may be times when you want to be more vigilant with your diabetes during the night, such as after a larger-than-usual dinner, an active day, or during illness.

You know your (or your loved one's) diabetes and will develop your own level of trust with the twiist AID system in your own time. You can more actively monitor as you see fit.

## **Rise and Shine**



When you wake up, you can look back over the history of the actions the twiist AID system took while you were sleeping.

## **Prepare to Travel**

The twiist AID system can be used while traveling on an aircraft. 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 fast-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 Transportation Security Administration (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.

- 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 spare 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 should not be exposed to Xray machines and request an alternate means of screening. Your pump has been designed to withstand common electromagnetic interference including airport metal detectors.

## Alarms, Alerts, and Notices

The twiist AID system provides alarms, alerts, and notices for your information and safety.

If the ringtone and alert volume is turned down, your iPhone is silenced, or *Notifications* and *Critical Alerts* are disabled, notifications provided by the twiist app may not be played or heard.

 Notifications are played based on your iPhone ringtone and alert volume.

Set the ringtone and alert volume on your iPhone to be louder than your surroundings so your twiist app notifications can be heard.

Check your iPhone for twiist app notifications anytime you are in an environment where you cannot hear or feel vibration from your iPhone, or hear the pump.

The twiist app displays messages with the following priority:

- Alarms
- Alerts
- Notices

1 The Urgent Low Glucose alert is prioritized above all other alerts.

Alert and alarm settings are unaffected by power loss.

For more information about system sounds, see "System Sounds" on page 38.

## Notifications and Critical Alerts

To ensure twiist app notifications are displayed on your iPhone lock screen, *Notifications* must be enabled within your iPhone settings.

Notifications inform you of conditions that require your attention.

*Critical Alerts* must be enabled to inform you of conditions that require immediate attention while your iPhone is silenced or when certain features are enabled.

Allow Notifications and Critical Alerts for the twiist app in your iPhone settings. Failure to allow Notifications and Critical Alerts may lead to missed twiist app notifications which may lead to high or low glucose.

### Notifications

Notifications from the twiist app are displayed on your iPhone lock screen, or while using other apps.

Tap the **notification** to open the twiist app.



### Critical Alerts

Notifications from the twiist app that require immediate attention are displayed as *Critical Alerts* on the lock screen or while using other apps.

Your iPhone plays audio at the maximum notification volume even when your phone is silenced or *Focus* is enabled.

Tap the **critical alert notification** to open the twiist app.



 Critical Alerts must be enabled to ensure CGM alerts provide audio notification.

## Alarms

*Alarms* stop insulin delivery and require immediate attention.

Check your blood glucose and treat highs and lows as advised by your healthcare provider.

When an alarm is occurring, a message is displayed with an *Alarm* A symbol followed by the alarm name.

(i) Alarm notifications are initially played based on

your iPhone ringtone and alert volume even if your iPhone is silenced or *Focus* is on.

When an alarm occurs, the pump will provide audio notification.

If the alarm has not been resolved within 5 minutes, the alarm notification will be played regardless of your iPhone volume or *Focus* settings.

After an additional 5 minutes, the alarm notification will be repeated on your iPhone and will play on your twiist pump every 15 seconds until silenced.

Silenced alarms that have not been resolved will display again after 15 minutes.

#### (i) If the twiist app and pump are out of

communication during an alarm, *Alarm* sounds will play on the pump immediately.

Alarms can always be resolved by performing a *Cassette Change*. Some alarms allow you to *Resolve with Current Cassette*, while others require you to *Perform Cassette Change*.



#### The twiist app provides

information about the amount of insulin remaining and the age of the cassette to help you decide.

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

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

### Cassette Empty



#### Sounds

iPhone: Alarm

Pump: *Alarm* is played 10 minutes after initially played on the iPhone if not silenced or resolved, and immediately when not in communication with the twiist app.

#### **Description:**

There is no insulin remaining in the cassette.

#### What To Do:

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

If the *Alarm* sound plays on the pump, tap **Audio OFF** to silence the alarm and tap **OK** to continue resolution steps.

2. Disconnect the infusion set tubing from your infusion site.

When a Cassette Empty alarm occurs, a Cassette Change is required.

- 3. Tap Perform Cassette Change.
- 4. Follow the steps to complete a cassette change, starting with "*Gather your Supplies*" on page 76.



#### Sounds

iPhone: Alarm

Pump: *Alarm* is played 10 minutes after initially played on the iPhone if not silenced or resolved, and immediately when not in communication with the twiist app.

#### **Description:**

The cassette is not operating correctly and insulin delivery has been suspended.

The amount of insulin delivered may have been affected.

#### What To Do:

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

- 2. Disconnect the infusion set tubing from your infusion site.
- 3. Check your blood glucose and treat highs and lows as advised by your healthcare provider.

A <i>Cassette Error</i> can be resolved with your current cassette or by performing a cassette change.		To resolve by performing a cassette change:		
To resolve with your current cassette:		2.	Gather the supplies you need to complete a	
1.	Tap Resolve with Current Cassette.		Cassette Change.	
2.	Make sure tubing is disconnected from your infusion site.	3. 4.	Tap <b>Start Cassette Change</b> .	
			Follow the steps to complete a Cassette Change,	
3.	Tap <b>Next</b> .		starting with "Disconnect Infusion Site" on page 77.	
	The twiist app displays <i>Communicating with Pump</i> and performs a self-test.			
4.	Wait for the pump self-test to complete.			
5.	Connect the infusion set tubing to your infusion site.			
6.	Tap <b>Start Basal</b> .			

### Cassette Not Attached



#### Sounds

iPhone: Alarm

Pump: *Alarm* is played 10 minutes after initially played on the iPhone if not silenced or resolved, and immediately when not in communication with the twiist app.

#### **Description:**

The cassette is not properly attached to the pump.

Avoid strong magnetic fields. Strong magnetic fields can trigger a false *Cassette Not Attached* alarm.

#### What To Do:

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

- 2. Disconnect the infusion set tubing from your infusion site.
- 3. Check your blood glucose and treat highs and lows as advised by your healthcare provider.

A Cassette Not Attached can be resolved with your	To resolve by performing a cassette change:	
current casselle of by performing a casselle change.	1. Tap Perform Cassette Change.	
To resolve with your current cassette:	2. Gather the supplies you need to complete a	
1. Tap Resolve with Current Cassette.	Cassette Change.	
2. Make sure tubing is disconnected from your	3. Tap Start Cassette Change.	
infusion site.	4. Follow the steps to complete a cassette change,	
3. Tap <b>Next</b> .	starting with See "Disconnect Infusion Site" on	
4. Attach the cassette to the pump.	page 77.	
5. Wait for the pump self-test to complete.		
6. Connect the infusion set tubing to your infusion		
site.		
7. Tap <b>Start Basal</b> .		

Т

### Line Blocked

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



#### Sounds

iPhone: Alarm

Pump: *Alarm* is played 10 minutes after initially played on the iPhone if not silenced or resolved, and immediately when not in communication with the twiist app.

#### **Description:**

Insulin is blocked from being delivered due to a kink in your infusion set tubing or infusion site. The twiist AID system may think it has delivered insulin that your body may not be absorbing. Charts may show large amounts of active insulin that do not reflect what you may have actually received, and your glucose prediction may be inaccurate.

#### What To Do:

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

- 2. Disconnect the infusion set tubing from your infusion site.
- 3. Test for ketones. Check your blood glucose and treat highs and lows as advised by your healthcare provider.

Resolve with the current cassette if you are able to correct the blockage in your infusion set tubing.		<ul><li>Conduct a Cassette Change if:</li><li>You cannot correct the blockage in your</li></ul>			
1. 2. 3. 4	Tap <b>Resolve with Current Cassette</b> . Make sure the infusion set tubing is disconnected from your infusion site. Tap <b>Next</b> . Check the cassette and infusion set tubing for kinks	i • I • I	infusion set tubing. Infusion set tubing is damaged. You have already attempted to resolve a <i>Line</i> <i>Blocked</i> alarm with the current cassette and infusion set.		
5.	Tap Next.The twiist app displays Communicating with Pumpand will perform a self-test.	1. 2. 3	Tap <b>Perform Cassette Change</b> . Gather the supplies you need to complete a <i>Cassette Change</i> . Tap <b>Start Cassette Change</b>		
6. 7. 8.	Wait for the pump self-test to complete. Route your infusion set tubing to avoid any sources of kinks that may have caused the <i>Line Blocked</i> alarm. Connect the infusion set tubing to your infusion site.	3. 4.	4.	4.	Follow the steps to complete a cassette change, starting with " <i>Disconnect Infusion Site</i> " on page 77.
9.	If you changed your infusion site and need to fill your cannula, toggle <b>Fill Cannula</b> on and verify your cannula fill volume. Tap <b>Start Basal</b> .				

### Pump Battery Empty

	(A) Pump Battery Empty
Pump Disconnect the	Battery Empty
infus Insulin delivery h	ion site. as been süspended.

#### Sounds

iPhone: Alarm

Pump: *Alarm* is played 10 minutes after initially played on the iPhone if not silenced or resolved, and immediately when not in communication with the twiist app.

#### **Description:**

The pump battery does not have enough charge to continue delivery. Insert a charged battery into the pump to continue delivery.

#### What To Do:

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

To resolve with your current cassette:		To resolve by performing a cassette change:	
1.	Tap Resolve with Current Cassette.	1.	Tap <b>Perform Cassette Change</b> .
2.	Gather the supplies you need to complete a <i>Battery Change</i> .	2.	Gather the supplies you need to complete a <i>Cassette Change</i> .
3.	Tap Start Battery Change.	3.	Tap Start Cassette Change.
4.	Follow the steps to complete a <i>Battery Change</i> , starting with <i>"Disconnect from Infusion Site"</i> on page 92.	4.	Follow the steps to complete a <i>Cassette</i> <i>Change</i> , starting with " <i>Disconnect Infusion Site</i> " <i>on page</i> 77.



#### Sounds

iPhone: Alarm

Pump: *Alarm* is played 10 minutes after initially played on the iPhone if not silenced or resolved, and immediately when not in communication with the twiist app.

#### **Description:**

Your pump has experienced a problem and cannot deliver insulin. The amount of insulin delivered may have been affected.

#### What To Do:

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

- 2. Disconnect the infusion set tubing from your infusion site.
- 3. Check your blood glucose and treat highs and lows as advised by your healthcare provider.

A <i>Pump Error</i> can be resolved with your current cassette or by performing a cassette change. To resolve with your current cassette:		To resolve by performing a cassette change:	
		1. 2.	Tap <b>Perform Cassette Change</b> .
			Gather the supplies you need to complete a <i>Cassette Change</i> .
2.	Make sure the infusion set tubing is	3. ₄	Tap <b>Start Cassette Change</b> .
3.	Tap <b>Next</b> .	4.	starting with "Disconnect Infusion Site" on page 77.
	The twiist app displays <i>Communicating with Pump</i> and will perform a self-test.		
4. 5. 6.	Wait for the pump self-test to complete. Connect infusion set tubing to your infusion site. Tap <b>Start Basal</b> .		

## Alerts

*Alerts* display information about the twiist AID system. Alerts do not result in the suspension of insulin delivery, but should be addressed as soon as possible.

When an alert is occurring, a message is displayed with an *Alert* symbol followed by the name of the alert. The *Alert* sounds are played based on your iPhone ringtone and alert volume. If your iPhone is silenced or *Focus* is enabled, alert notifications may be missed.

(i) Some alerts work different for your safety and are delivered regardless of your iPhone volume or *Focus* settings.

Alert sounds repeat every 15 minutes until the alert is dismissed.

(i) If the twiist app and pump are out of communication during an alert, *Alert* sounds will play on the pump immediately.

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

For more information, refer to the details for each alert.

## Basal Delivery Not Started

Alert Display	Description:
Basal Delivery Not Started Basal delivery could not be started. Try again. OK	Basal delivery could not be started. This may occur if you attempt to start basal using the pump button but the pump has insufficient information to start delivery.
Sounds iPhone: <i>Alert</i> Pump: <i>Alert</i> sound is played when not in communication with the twiist app.	<ul> <li>What To Do:</li> <li>1. Tap OK to dismiss the alert.</li> <li>2. Use the twiist app to <i>Resume Insulin Delivery</i>.</li> <li>See "Resume Insulin Delivery" on page 75.</li> </ul>

Alert Display	Description:			
9:41 Bluetooth X Enable Off X Bluetooth Glucose	Bluetooth is disabled on your iPhone. When Bluetooth is disabled on your iPhone, the twiist app cannot communicate. Your CGM and pump will still be in communication, and the twiist AID			
Bluetooth Off Bluetooth is disabled. The twiist app will not work successfully until Bluetooth is enabled. You will not receive glucose readings or be able to bolus.	system will continue adjusting your basal insulin delivery. The twiist app will not display glucose readings, and app notifications will not be available. You will not be able to deliver a bolus through the twiist app, or modify settings until Bluetooth communication is restored.			
ОК	<b>What To Do:</b> <ol> <li>Tap <b>OK</b> to dismiss the <i>Bluetooth Off</i> alert.</li> </ol>			
<b>Sounds</b> iPhone: <i>Alert</i>	The <i>Home Screen</i> displays <i>Bluetooth Off</i> in the <i>CGM Status</i> and <i>Enable Bluetooth</i> in the <i>Pump Status</i> .			
Pump: None	<ol> <li>Enable <b>Bluetooth</b> in your iPhone settings to receive twiist app notifications and CGM readings.</li> <li>Navigate back to the twiist app.</li> </ol>			
	The CGM and Pump Status icons resume displaying current status.			

### Bluetooth Unavailable



#### **Description:**

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

If Bluetooth is disabled for the twiist app, the app cannot communicate. Your CGM and pump are still in communication, and the twiist AID system will continue adjusting your basal insulin delivery.

The twiist app will not display glucose readings, and app notifications will not be available. You will not be able to deliver a bolus through the twiist app, or modify settings until Bluetooth communication is restored.

#### What To Do:

1. Tap OK to dismiss the Bluetooth Unavailable alert.

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

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

The CGM and Pump Status icons resume displaying current status.

## Interrupted Bolus

Alert Display	<b>Description:</b> Insulin delivery was suspended while a bolus delivery was in progress. This alert is to remind you that bolus delivery was interrupted in addition to suspending your basal insulin.
C Interrupted Bolus Bolus delivery has been interrupted. OK	<ul> <li>What To Do:</li> <li>1. Tap OK to dismiss the alert.</li> <li>2. Tap the Insulin Delivery Chart to open Event History and see how much of the Interrupted Bolus was delivered.</li> </ul>
<b>Sounds</b> iPhone: <i>Alert</i>	<ul> <li>3. Check to see if an additional correction or meal bolus is required and take the appropriate action.</li> <li>(i) Insulin delivered as a result of an <i>Interrupted Bolus</i> is accounted for in a</li> </ul>
Pump: None	new bolus recommendation.

### Cassette Low

Alert Display	Description:	
Au Cassette Low Cassette is low on Insulin. You may need to replace the cassette soon.	The cassette has less than 10 Units of insulin remaining, or less than the number of units entered in the <i>Low Insulin Alert</i> #2 setting.	
OK Internet	What To Do:	
	1. Tap <b>OK</b> to dismiss the alert.	
Sounds	2. Take the necessary steps to be prepared to perform a <i>Cassette</i>	
iPhone: <i>Alert</i>	Change.	
Pump: <i>Alert</i> sound is played when not in communication with the twiist app.	See "Cassette Change" on page 76.	

### No Communication

Alert Display	<b>Description:</b> The twiist app and pump have not communicated in 7 hours.
Communicated for more than 7 hours. Keep your phone and pump in range. OK	What To Do:         1. Tap OK to dismiss the alert.
<b>Sounds</b> iPhone: <i>Alert</i> Pump: None	<ol> <li>Move your iPhone closer to your pump so communication can be restored.</li> </ol>

### Phone Out of Range (Communication Restored)

#### **Alert Display**



#### Sounds

Pump: *Alert* sound is played when not in communication with the twiist app.

iPhone: *Alert* is played at your iPhone ringtone and alert volume when communication is restored.

#### **Description:**

The *Phone Out of Range* alert, if enabled in *Therapy Settings*, play the *Alert* sound on the pump when the iPhone and pump are outside of their communication range for longer than the programmed duration (1-120 minutes). When communication between the twiist app and pump is restored, the *Communication Restored* alert is displayed, and the *Alert* sound is played on your iPhone.

Typically, if this alert has occurred, you have walked away from your iPhone while insulin delivery is in progress.

#### What To Do:

1. Tap OK to dismiss the alert. No further action is required.

If you do not receive the message that the communication has been restored, and the pump and twiist app are within communication range, there may be another type of communication error occurring.

- 1. Quit and restart the twiist app.
- 2. If the issue persists, conduct a *Battery Change*. See "*Battery Change*" on page 90.
- 3. Move away from other wireless devices and try to establish communication between your pump and iPhone.

## Pump Battery Low

Alert Display	<b>Description:</b> The pump battery has less than 10% remaining.
Au A Pump Battery Low	
Pump battery has 10% remaining. ok Tructure delivery Sounds iPhone: <i>Alert</i> Pump: <i>Alert</i> sound is played when not in communication with the twiist app.	<ul> <li>What To Do:</li> <li>1. Tap OK to dismiss the alert.</li> <li>2. Take the necessary steps to prepare for a <i>Cassette</i> or <i>Battery Change</i>.</li> <li>See "Cassette Change" on page 76.</li> <li>See "Battery Change" on page 90.</li> </ul>

### **Pump Inactive**

#### **Alert Display**



#### Sounds

iPhone: *Alert* is played even if your iPhone is silenced or *Focus* is enabled.

Pump: *Alert* sound is played when not in communication with the twiist app.

#### **Description:**

Insulin delivery has been suspended for at least the amount of time set in the *Pump Inactive Alert* therapy setting. This alert cannot be disabled and is set to 60 minutes by default. Insulin is not being delivered.

#### What To Do:

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

If insulin delivery is not resumed after being dismissed, the alert will occur again based on the time set in the *Pump Inactive* alert therapy setting.

If you are in the middle of *Cassette Change* or *Battery Change*, complete that process to resume insulin delivery.

See "Cassette Change" on page 76.

See "Battery Change" on page 90.

### Reattach Cassette

Alert Display	Description:
Connect Cassette to Pump Reattach Cassette Remove cassette and reattach to continue.	The cassette is not properly attached to the pump and self-test cannot begin.
coll-tert. Was for the relief of the relief	What To Do:
Sounds	1. Remove the cassette from the pump and reattach.
iPhone: <i>Alert</i>	Self-test will begin.
Pump: <i>Alert</i> sound is played when not in communication with the twiist app.	

### Temporary Basal Stopped

#### **Alert Display**



#### Sounds

iPhone: Alert

Pump: *Alert* sound is played when not in communication with the twiist app.

#### **Description:**

The Temporary Basal Stopped alert can only occur when Loop is off.

The *Temporary Basal Stopped* alert will occur if a *Temporary Basal* (adjustment by percentage only) is in progress and the time on your iPhone is automatically adjusted, resulting in the temporary basal exceeding the *Maximum Basal Rate*.

#### What To Do:

- 1. Tap **OK** to dismiss the alert.
- 2. Review your glucose and active insulin.

Automatic time updates may require you to adjust your insulin delivery. Talk to your healthcare provider before you travel and check your blood glucose if your insulin delivery does not match your symptoms.

To set a new temporary basal, see "Set Temporary Basal" on page 162.

### CGM Alerts

When a CGM Sensor is used with the twiist AID system, alerts for the CGM Sensor will be displayed by the twiist app.

CGM alerts display information about your current glucose, CGM status, and automated insulin delivery. CGM alerts should be addressed as soon as possible.

When a CGM alert is occurring, a message is displayed with a 🂁 symbol followed by the name of the CGM alert.

The Urgent Low Glucose alert is displayed with higher priority than all other alerts.

CGM alerts, with the exception of the Urgent Low Glucose, are only played on your iPhone.

Some CGM alerts work different for your safety and are delivered regardless of your iPhone volume or *Focus* settings.

Alert sounds repeat every 5 minutes until the CGM alert is dismissed.

For more information, refer to the details for each CGM alert.

CGM Alert Display	Description: Check your CGM Sensor.
Ok         Sounds         iPhone: Alert is played even if your iPhone is silenced or Focus is on.         Pump: None	<pre>/hat To Do: Tap OK to dismiss the CGM alert. If it is loose from your skin, please remove the sensor and start a new one. If it is applied properly, try starting the sensor again.</pre>



iPhone: *Alert* is played even if your iPhone is silenced or *Focus* is on.

Pump: None

#### **Description:**

Your sensor has ended and needs to be replaced. Remove your sensor and start a new one. You will not receive CGM alerts or readings until a new sensor is started.

If *Loop* was on when you received this alert, automated insulin delivery has been disabled and insulin will be delivered at your scheduled rate. *Loop* will be re-enabled automatically once CGM readings are available.

#### What To Do:

- 1. Tap **OK** to dismiss the CGM alert.
- 2. Tap CGM Ended within the CGM Status.

A Start New Sensor message is displayed.

3. Tap **Yes** and follow instructions from *step 6 on page 122*.
#### **CGM Alert Display**



#### Sounds

iPhone: *Alert* is played based on your iPhone ringtone and alert volume.

If Override Focus is enabled, Alert is played even if your iPhone is silenced or Focus is enabled.

Pump: None

#### **Description:**

Your CGM glucose is above the level you have set in your CGM *High Glucose Alert* setting. This alert is on by default, and is initially set to 250 mg/dL (13.9 mmol/L). You will only receive one *CGM High Glucose* alert per high glucose episode.

#### What To Do:

- 1. Tap OK to dismiss the CGM alert.
- 2. Treat your high glucose as advised by your healthcare provider.

# CGM Alert Display

#### Sounds

iPhone: *Alert* is played based on your iPhone ringtone and alert volume.

If Override Focus is enabled, Alert is played even if your iPhone is silenced or Focus is enabled.

Pump: None

#### **Description:**

Your CGM glucose is below the level you have set in your CGM *Low Glucose Alert* setting. This alert is on by default, and is initially set to 70 mg/dL (3.9 mmol/L). You will only receive one *CGM Low Glucose* alert per low glucose episode.

#### What To Do:

- 1. Tap **OK** to dismiss the CGM alert.
- 2. Treat your low glucose as advised by your healthcare provider.



#### Sounds

iPhone: *Alert* is played based on your iPhone ringtone and alert volume.

If Override Focus is enabled, Alert is played even if your iPhone is silenced or Focus is enabled.

Pump: None



#### **Description:**

Your CGM is not working and needs to be replaced. Remove your sensor and start a new one. You will not receive CGM alerts or readings until a new sensor is started.

If *Loop* was on when you received this alert, automated insulin delivery has been disabled and insulin will be delivered at your scheduled rate. *Loop* will be re-enabled automatically once CGM readings are available.

#### What To Do:

- 1. Tap **OK** to dismiss the CGM alert.
- 2. Follow the instructions to "Start a New FreeStyle Libre 3 Plus Sensor" on page 122.

#### Sounds

iPhone: Alert is played even if your iPhone is silenced or Focus is on.

Pump: None

#### Urgent Low Glucose

#### Urgent Low Glucose Alert Display



#### Sounds

iPhone: *Urgent Low Glucose* is played even if your iPhone is silenced or *Focus* is on.

Pump: If not dismissed within 5 minutes, *Urgent Low Glucose* sound is played. If the twiist app and pump are out of communication, *Urgent Low Glucose* sounds will play on the pump immediately.

#### **Description:**

Your CGM Sensor reading is at or below 55 mg/dL (3.1 mmol/L).

#### What To Do:

- 1. Tap OK to dismiss the urgent alert.
- 2. Check your blood glucose and treat your low glucose as advised by your healthcare provider.

If *Loop* is on, the twiist AID system has already reduced your basal delivery because of your glucose safety limit. Eat a small snack and enter the details in *Carb Entry*.

Carbs entered to recover from low glucose should be entered with a 30 minute absorption time, using the  $\bigcirc$  emoji.

If *Loop* is off, do not deliver a bolus, and suspend your basal delivery. Do not resume basal delivery until your glucose is in your desired range.

# Notices

Notices provide information about the status of the twiist AID system, and do not affect insulin delivery.

## Critical Alerts Disabled



#### Sounds

iPhone: Notification sounds are played based on your iPhone ringtone and alert volume.

Pump: None

#### **Description:**

Keep *Critical Alerts* turned on in your iPhone settings for the twiist app to ensure you receive twiist app notifications even when your iPhone is silenced, or *Focus* is on.

If *Critical Alerts* are disabled, the twiist app displays a *Critical Alerts Disabled* message and the *Home Screen* displays an *Alert Permissions Disabled* warning.

#### What To Do:

1. Tap OK to dismiss the Critical Alerts Disabled message.

The Home Screen displays an Alert Permissions Disabled warning.

The Alert Permissions Disabled warning remains on the screen until *Critical Alerts* have been enabled.

#### To enable Critical Alerts:

- 1. Tap the **Alert Permissions Disabled** warning to open *Settings.*
- (i) Alert Permissions within the twiist app Settings only appears when Critical Alerts or Notifications have been disabled.
- 2. Tap Alert Permissions.



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



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

*Alert Permissions* is no longer displayed within *Settings*.

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

## Internet Connection Required

Notice Display	Description:
Internet Connection Required An internet connection is required before pairing. Please connect to a Wi-Fi or Cellular network.	Your iPhone does not have an internet connection and pump pairing cannot continue.
OK	What To Do:
O seconda	1. Tap <b>OK</b> to dismiss the notice.
Sounds	2. Connect your iPhone to a Wi-Fi or Cellular network to continue
iPhone: Notification sounds are played based on your iPhone ringtone and alert volume.	pump pairing.
Pump: None	

## No Communication

Notice Display	<b>Description:</b>
No Communication The twiist app and pump have not communicated for more than 20 minutes	minutes.
Keep your phone and pump in range.	What To Do:
ОК	1. Tap <b>OK</b> to dismiss.
Sounds	2. Place the iPhone and pump close to each other to allow communication to resume.
iPhone: Notification sounds are played based on your	3. Communication problems may be resolved by turning off or moving away from other wireless devices, or by restarting the twiist app.
iPhone ringtone and alert volume.	4. Press and hold the <b>pump button</b> for at least 3 seconds to verify delivery is in progress.
Pump: None	5. If the pump does not play the <i>Delivering</i> sound, change the pump battery. <i>See "Change Pump Battery" on page 90.</i>

## Notifications Disabled

## Notice Display 9:41 Alert Permissions Disabled 160 Notifications Disabled Keep Notifications turned ON in your phone's settings to ensure that you can receive twiist notifications. OK Sounds iPhone: None Pump: None

#### **Description:**

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

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

#### What To Do:

1. Tap OK to dismiss the Notifications Disabled message.

The Home Screen displays an Alert Permissions Disabled warning.

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

#### To enable Notifications:

- 1. Tap the **Alert Permissions Disabled** warning to open *Settings*.
- (i) Alert Permissions within the twiist app Settings only appears when Notifications have been disabled.
- 2. Tap Alert Permissions.



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



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

*Alert Permissions* is no longer displayed within *Settings*.

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

## Phone Battery Low at Start of Software Update

Notice Display Phone Battery Low The phone has less than 10% battery memory phone for power before starting the pump software update.	<b>Description:</b> Your iPhone has less than 10% battery remaining when starting a pump software update.
Sounds iPhone: Notification sounds are played based on your iPhone ringtone and alert volume. Pump: None	<ol> <li>What To Do:</li> <li>1. Tap OK to dismiss.</li> <li>2. Connect your iPhone to power before starting the pump software update.</li> <li>3. Tap Next to continue with the pump software update.</li> </ol>

## Prime Stopped

Notice Display	Description:
Prime Stopped Do you see droplets at the end of the infusion set? Pr	If priming is not stopped, the pump will automatically stop when priming should be complete.
aropieta at the end of the impison set. 2. When you see droplets at the end of the infusion set, tap 'Stop Prime'.	<ul> <li>What To Do:</li> <li>If you see drops at the end of your infusion set tubing tap Yes to</li> </ul>
Sounds	continue.
iPhone: Notification sounds are played based on your iPhone ringtone and alert volume. Pump: None	<ul> <li>If you do not see drops, tap No to continue priming your cassette and infusion set tubing.</li> </ul>

## Pump Battery Low

Notice Display	<b>Description:</b> The pump battery has less than 20% charge remaining.
Act Pump Battery Low Pump battery has 20% remaining.	
ОК	What To Do:
Hisufin Dolivery	1. Tap <b>OK</b> to dismiss the notice.
Sounds	2. Prepare for a <i>Cassette</i> or <i>Battery Change</i> .
Sounds	See "Cassette Change" on page 76.
iPhone: Notification sounds are played based on your iPhone ringtone and alert volume.	See "Battery Change" on page 90.
Pump: None	

## Security Features Disabled



#### **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 System Time Updated Your System time has been automatically changed. Your therapy will always follow the System time. OK

#### Sounds

iPhone: Notification sounds are played based on your iPhone ringtone and alert volume.

Pump: None

#### **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.

#### 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 AID 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 162.* 

## The twiist App is Closed

Notice Display	Description:
twist App is Closed Tap to open app. Alarms and alerts will not be displayed until it's opnened, in the future, keep the app running in the background, don't swipe it closed.	You have closed the twiist app. Closing the twiist app will result in a loss of communication with the twiist pump. Notifications from the twiist app will not be available until the app is opened.
Sounds	Quitting the twiist app or removing it from your iPhone will result in loss of communication with your twiist pump.
Phone: Notification sounds are played based on your iPhone ringtone and alert volume. Pump: None	What To Do: 1. Tap the notification to open the twiist app.

## Workout is Still Active

	-
Workout is Still Active Workout has been turned on for more than 24 hours. Make sure you still want it enabled, or turn it off in the app.	<b>Description:</b> The <i>Workout Preset</i> has been enabled for 24 hours.
ок Sounds iPhone: Notification sounds are played based on your iPhone ringtone and alert volume. Pump: None	<ul> <li>What To Do:</li> <li>1. Tap OK to dismiss.</li> <li>2. Turn off the <i>Workout Preset</i> to adjust your insulin using your <i>Correction Range</i>. Keep <i>Workout Preset</i> on to adjust your basal insulin using your <i>Workout Range</i>.</li> </ul>

# CGM and Loop Notices

CGM and *Loop* notices are displayed to keep you informed about your CGM and your automated insulin delivery.

CGM Ending Soon (3 Days)

CGM Ending Soon Your CGM will end in 3 days. Ok	<b>Description:</b> Your sensor will end in 3 days.
Sounds	What To Do: 1. Tap OK to dismiss the CGM alert.
iPhone: Notification sounds are played based on your iPhone ringtone and alert volume. Pump: None	2. Tap the <b>CGM Status</b> icon to open the <i>CGM Status</i> screen for more information.
	Always make sure to have supplies available to start a new sensor when your CGM Sensor ends.

## CGM Ending Soon (1 Day)

Notice Display CGM Ending Soon Your CGM will end in 1 day. Ok	<b>Description:</b> Your sensor will end in 1 day.
Sounds iPhone: Notification sounds are played based on your iPhone ringtone and alert volume. Pump: None	<ul> <li>What To Do:</li> <li>1. Tap OK to dismiss the CGM alert.</li> <li>2. Tap the CGM Status icon to open the CGM Status screen for more information.</li> <li>Always make sure to have supplies available to start a new sensor when your CGM Sensor ends.</li> </ul>

## CGM Ending Soon (1 Hour)

CGM Alert Display CGM Ending Soon Your CGM will end in 1 hour. Ok	<b>Description:</b> Your sensor will end in 1 hour.
Sounds iPhone: Notification sounds are played based on your iPhone ringtone and alert volume. Pump: None	<ul> <li>What To Do:</li> <li>1. Tap OK to dismiss the CGM alert.</li> <li>2. Tap the CGM Status icon to open the CGM Status screen for more information.</li> <li>Always make sure to have supplies available to start a new sensor when your CGM Sensor ends.</li> </ul>



iPhone: Notification sounds are played based on your iPhone ringtone and alert volume.

Pump: None

#### **Description:**

Your CGM is ready. CGM Readings and alerts are now available.

If *Loop* was enabled when your previous CGM ended, it is now re-enabled and the twiist AID system will automatically adjust your basal insulin delivery.

#### What To Do:

1. Tap OK to dismiss the CGM alert.

The CGM Status displays your current CGM reading and trend arrow.

2. Tap the **CGM Status** icon to open the *CGM Status* screen for more information.

## Loop is Off

### Notice Display CGM Ended Loop is Off Loop is disabled because CGM readings are not available. Loop will be enabled once CGM readings are available. OK

#### Sounds

iPhone: Notification sounds are played based on your iPhone ringtone and alert volume.

Pump: None

#### **Description:**

*Loop* has been disabled because your CGM has been deleted from the twiist app, and CGM readings are no longer available.

The twiist system is no longer automatically adjusting your basal insulin. Basal insulin is delivered at your scheduled basal rate.

#### What To Do:

- 1. Tap **OK** to dismiss the alert.
- 2. Start a new CGM Sensor. See "Start a New FreeStyle Libre 3 Plus Sensor" on page 122.
- 3. Check your glucose frequently, and treat your highs and lows as advised by your healthcare provider.

After the CGM Sensor Warmup is complete, Loop will automatically turn on.

# Loop is On

Loop is On The system has re-enabled Loop since CGM readings are available, OK	<b>Description:</b> <i>Loop</i> has been re-enabled since CGM readings are available.
<b>Sounds</b> iPhone: Notification sounds are played based on your iPhone ringtone and alert volume. Pump: None	What To Do: 1. Tap OK to dismiss.

## Loop is Waiting

#### Notice Display Sensor Warmup O Of Of Loop is Waiting Loop is Waiting for your Sensor Warmup to complete. Loop is Waiting for your Sensor Warmup to complete. Loop is waiting for your Sensor Warmup to complete. Loop is waiting for your Sensor Warmup to complete. Loop is waiting for your Sensor

#### Sounds

iPhone: Notification sounds are played based on your iPhone ringtone and alert volume.

Pump: None

#### **Description:**

*Loop* is waiting for your *Sensor Warmup* to complete. Loop will be re-enabled when CGM readings are available.

The twiist system is no longer automatically adjusting your basal insulin. Basal insulin is delivered at your scheduled basal rate.

#### What To Do:

- 1. Tap **OK** to dismiss the notice.
- 2. Check your blood glucose and treat highs and lows as advised by your healthcare provider.

After the CGM Sensor Warmup is complete, Loop will be automatically turned on. see "Loop is On" on the previous page

## Timer Expired

Notice Display	<b>Description:</b> You received a reminder from your FreeStyle Libre 3 Plus Sensor to check your glucose.
Sounds iPhone: Notification sounds are played based on your iPhone ringtone and alert volume. Pump: None	<ul> <li>What To Do:</li> <li>1. Tap OK to dismiss the reminder.</li> <li>2. Check your blood glucose and treat highs and lows as advised by your healthcare provider.</li> </ul>

# FreeStyle Libre 3 Plus Sensor Lifecycle

After starting a new FreeStyle Libre 3 Plus Sensor, it will take 60minutes before a CGM reading is available. The *CGM Status* displays *Sensor Warmup* and the *twiist Status* displays an open circle.

Sensor U Warmup

Tap the **CGM Status** icon to see how much time is remaining until the sensor is ready.

Tap the **twiist Status** icon for more information about your basal delivery and whether it is being adjusted automatically. When the new FreeStyle Libre 3 Plus Sensor is ready, a *CGM Ready* notice is displayed and *Loop* is automatically turned back on.

Tap **OK** to dismiss the *CGM Ready* notice.

The *CGM Status* displays your CGM reading and trend arrow, and the *twiist Status* displays a green closed circle icon.



The FreeStyle Libre 3 Plus Sensor provides CGM readings for up to 15 days.

CGM notices are displayed when the FreeStyle Libre 3 Plus Sensor has 3 days, 1 day, and 1 hour remaining.



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

When the CGM Sensor ends, a *CGM Ended* alert occurs.

Tap **OK** to dismiss the CGM alert.

*Loop* will be automatically disabled.

The CGM Status displays CGM Ended and the twiist Status displays an open circle.

CGM Ended

Basal insulin delivery will not automatically be adjusted until a new CGM Sensor is started, and *Sensor Warmup* is completed.

When a new CGM Sensor is started, and *Sensor Warmup* is complete, a *CGM Ready* notice is displayed. *Loop* is turned back on automatically.



Tap **OK** to dismiss the *CGM Ready* notice.

The *CGM Status* displays your CGM reading and trend arrow, and the *twiist Status* displays a green closed circle icon.



# Apple Watch Toolbar

# **Apple Watch**

You can choose to use an Apple Watch with the twiist AID system.

This optional component provides a discreet way to view your sensor glucose and insulin information. When *Loop* is on, you can use the pre-meal preset, workout preset, enter carbs, and deliver a bolus.

Your Apple Watch must be within Bluetooth range of your iPhone to work with the twiist AID system. If Bluetooth is not available, your Apple Watch will try to use Wi-Fi. Apple Watch must be on and within Bluetooth (or Wi-Fi) 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.



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

## **Pre-Meal Preset**

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

- 1. Tap 🔟.
- 2. Tap **On**.



When the *Pre-Meal Preset* is active, the button color on the Apple Watch app will be reversed.



## Cancel Pre-Meal Preset

To cancel the *Pre-Meal Preset*.

- 1. Tap 🔟
- 2. Tap **Off**.



# Workout Preset

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

- 1. Tap 🧐.
- 2. Tap **On**.



When the *Workout Preset* is active, the button color on the Apple Watch app will be reversed.



## Cancel Workout Preset

To cancel the *Workout Preset*.

- 1. Tap 😌.
- 2. Tap **Off**.



# Carb Entry and Meal Bolus

Tap *Carb Entry* to enter carbs you have already eaten or plan to eat in order to deliver a bolus for your meal.

- 1. Tap 🔍.
- 2. Tap **•** or **•** to decrease or increase carbs in 5 g increments.
- a. Turn the Apple Watch **Digital Crown** to decrease or increase carbs in 1 g increments.
- 3. Tap a **Food Type** emoji to select an absorption time.
- 4. Tap Continue.



5. Tap Save & Bolus.



6. Turn the Apple Watch **Digital Crown** to deliver the bolus.

The pump plays the *Delivering* sound.

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



# Bolus Entry (Correction Bolus)

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

- 1. Tap 🕅 .
- 2. Tap **•** or **•** to decrease or increase the correction bolus in 0.1 U increments.
- a. Turn the Apple Watch **Digital Crown** to decrease or increase the correction bolus in 0.01 U increments.
- 3. Tap Bolus.



4. Turn the Apple Watch **Digital Crown** to deliver the bolus.



The pump plays the *Delivering* sound.

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

# 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 set the twiist app as a watch face complication.

(i) The twiist app watch face complication relies on the ability to display color. Watch faces with a colored background are not supported. Tapping the complication from your watch face 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 *Event History* should display any recent changes to your glucose and insulin.

# 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.

When twiist app updates are available, they can be installed on your iPhone directly from the Apple App store.

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 caution will be displayed.



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 "Sequel Customer Support" on page 245.

Tap **Continue to App** to clear this caution 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.

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.

Make sure your iPhone and pump batteries are charged before updating your pump. If they are not, you may need to resolve a *Phone Battery Low* or *Pump Battery Low* notice before you can resume the pump update.

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 displays 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 plays the *Delivery Suspended* sounds.

- (1) 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.

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.

> 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.

- i 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. After setting a reminder, if you would like to install the pump update now:

- 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 plays the *Delivery Suspended* sounds.

- (i) 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.
- 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.

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 plays the *Delivering* sounds.

i 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*.

# **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. Make sure the pump cover or a cassette is attached to the pump before cleaning.
- 2. Clean the pump with a mixture of water and a mild soap such as dish detergent or hand soap and a damp, clean cloth.
- 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.

## 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?

- 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?

- 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 AID 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 scheduled basal insulin.
  - One-button boluses can be delivered (when enabled in *Settings*).
  - Fault detection and alarm generation is still intact.
- 2. If an alarm is occurring, 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, event history, and your current CGM glucose value to make appropriate bolus decisions.
- 4. Contact Sequel 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 plays 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. Extended delay of insulin delivery may cause 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* displays basal delivery in progress, along with other status information.

# Why won't my pump 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 9 on page 100*.

I pressed the pump button while removing the pump from the pump clip 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 166.

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 AID system does not.

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

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 *twiist Status* icon and whether it is an open or closed circle. When the *twiist Status* icon is displayed as a closed circle, *Loop* is on and insulin delivery is automated.

When the *twiist Status* icon is displayed as an open circle, *Loop* is off and insulin delivery is not automated. For more information, *see "twiist Status" on page 61.* 

If *Loop* is on, the twiist AID 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 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?

Signal Loss

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.

Tap the **CGM Status** icon to monitor your CGM.

If you need replace your CGM, see "Start a New FreeStyle Libre 3 Plus Sensor" on page 122. Is Your twiist Automated Insulin Delivery System Functioning Properly?

You can tap **Settings** to 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. I tried to scan my cassette during a cassette change and I received a *Camera Unavailable* message. What should I do?

- 1. Tap the link in the *Camera Unavailable* message to open the twiist app iPhone settings.
- 2. Tap the **Camera** toggle to enable the camera.
- 3. Return to the twiist app to restart the cassette change steps.

# Sequel Customer Support

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

- Set Up
- General use
- Maintenance
- · To report unexpected operation or events
- · To request refills or 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.

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## Warranty Information

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

## **Refill and Replacement Parts**

### (i) Only use approved parts.

Table 1: Refills and Replacement Parts

Refills and Replacement Parts	Part Number
Pump Replacement Kit <ul> <li>twiist pump with pump cover</li> </ul>	DKPI-11098-001
<ul> <li>Pump Battery Replacement Kit</li> <li>Pump battery charger (3)</li> <li>USB charging cable</li> <li>Wall power adapter with 2 USB ports</li> <li>Rechargeable pump battery (6)</li> </ul>	DKPI-11095-001
Pump Clip Replacement Kit <ul> <li>Pump clip (2)</li> </ul>	DKPI-11096-001
Refill Kit • Cassettes (10) • 3 mL Syringes (10) • 27 gauge x 3/8 inch (0.40 mm x 10 mm) Needles (10) • Alcohol wipes (30)	DKPI-11102-001

#### Table 1: Refills and Replacement Parts

Refills and Replacement Parts	Part Number
Refill Kit with infusion sets <ul> <li>Cleo 90 - 24 inch (61 cm) infusion sets with 6 mm cannula (10)</li> <li>Cassettes (10)</li> <li>3 ml. Syringes (10)</li> </ul>	DKPI-11101-001
<ul> <li>27 gauge x 3/8 inch (0.40 mm x 10 mm) Needles (10)</li> <li>Alcohol wipes (30)</li> </ul>	

# **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 IP24, indicating protection from splashing water. The pump can tolerate water splashed from any direction.

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 Sequel Customer Support:

• Substantial slowing of User Interface (UI) response

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

(i) 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 2: Pump specifications

Pump 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 3: Pump attached to cover specifications

Pump attached to Cover 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)

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	$\pm$ 20% at 0.05 U boluses and $\pm$ 5% at 25 U boluses when measured per IEC 60601-2-24.
<ul><li>Operating Conditions</li><li>Performance may exceed accuracy limits outside of the disclosed range.</li></ul>	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)

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 5: Pump battery specifications

Pump Battery 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

Pump Battery 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 6: Battery charger specifications

Battery Charger 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)

Cassette Specification	Details
Storage and Transportation Conditions	Temperatures of -25 °C (-13 °F) to 60 °C (140 °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.
Cassette Service Life	3 days
Cassette Shelf Life	1 year

twiist App Setting Ranges	Details
Glucose Safety Limit	Glucose Safety limit may be entered by your healthcare provider in advance or during initial setup with your certified twiist trainer.
	67-110 mg/dL (3.7-6.1 mmol/L)
	Increment of 1 mg/dL (0.1 mmol/L)
Correction Range	Correction Range may be entered by your healthcare provider in advance or during initial setup with your certified twiist trainer.
	87-180 mg/dL (4.8-10 mmol/L)
	Increment of 1 mg/dL (0.1 mmol/L)
	The minimum allowed value is either 87 mg/dL (4.8 mmol/L) or the <i>Glucose Safety Limit</i> , when the <i>Glucose Safety Limit</i> is higher than 87 mg/dL (4.8 mmol/L).

twiist App Setting Ranges	Details
Pre-Meal Range	Pre-Meal range may be entered by your healthcare provider in advance or during initial setup with your certified twiist trainer.
	67-130 mg/dL (3.7-7.2 mmol/L)
	Increment of 1 mg/dL (0.1 mmol/L)
	The minimum allowed value is either 67 mg/dL (3.7 mmol/L) or the <i>Glucose Safety Limit</i> , when the <i>Glucose Safety Limit</i> is higher than 67 mg/dL (3.7 mmol/L).
Workout Range	Workout range may be entered by your healthcare provider in advance or during initial setup with your certified twiist trainer.
	87-250 mg/dL (4.8-13.9 mmol/L)
	Increment of 1 mg/dL (0.1 mmol/L)
	The minimum allowed value is either 87 mg/dL (4.8 mmol/L) or the <i>Glucose Safety Limit</i> , when the <i>Glucose Safety Limit</i> is higher than 87 mg/dL (4.8 mmol/L).
Basal Rates	Basal rates may be entered by your healthcare provider in advance or during initial setup with your certified twiist trainer.
	From 0.00 U/hr to 30 U/hr or the <i>Maximum Basal Rate</i> increment, starting at 0.10, and increasing in 0.05 U/hr

twiist App Setting Ranges	Details
Basal Rate Interval	Up to 48 different Basal Rates can be programmed within a 24 hour period (a different rate every half hour).
Carbohydrate Units	Grams
Carb Ratios	Carb ratios may be entered by your healthcare provider in advance or during initial setup with your certified twiist trainer. 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).
Cannula Fill Volume	Default: Units Programmable from 0.20 - 0.70 Units in 0.10 Unit increments.
	Maximum Basal Rate may be entered by your healthcare provider in advance or during initial setup with your certified twiist trainer.
Maximum Basal Rate	Min: Highest scheduled basal rate
	Max: Not greater than 30 U/hr and further limited by the highest scheduled Basal Rate and Carb Ratios.
	Increment of 0.05 U/hr

twiist App Setting Ranges	Details
Maximum Bolus	Maximum bolus may be entered by your healthcare provider in advance or during initial setup with your certified twiist trainer. Increment: 1 U Minimum: 1 U Maximum: 25 U
Insulin Model	Insulin model may be entered by your healthcare provider in advance or during initial setup with your certified twiist trainer. Programmable for <i>Adults</i> or <i>Children</i>
Insulin Sensitivity	Insulin sensitivity may be entered by your healthcare provider in advance or during initial setup with your certified twiist trainer. Programmable pattern from 10 - 500 mg/dL/U (0.6-27.8 mmol/L/U) in 1 mg/dL/U (0.1 mmol/L/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).

twiist App Setting Ranges	Details
Temperer (Beeel	Default – Percent May be set to <i>Percent</i> or <i>Rate</i>
Temporary basar	(i) Cannot be modified when <i>Loop</i> is on.
One-Button Bolus	Default: Off Options: On/Off
Extended Bolus	Default: Off Options: On/Off Cannot be modified when <i>Loop</i> is on.
Dual Bolus	Default: Off Options: On/Off Cannot be modified when <i>Loop</i> is on.
Quiet Mode	Default: Off Options: On/Off

twiist App Setting Ranges	Details
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
Phone Out of Range Alert	Default: Off Options: On/Off 1-120 min in 1 min increments
Pump Inactive Alert	Default: 60 minutes Options: 15, 30, 60, 90 minutes

#### Table 9: 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 10: Syringe and needle specifications

Syringe and Needle Specifications	Specification
Syringe	3 mL with luer connector
Needle	27 gauge x 3/8 inch (0.40 mm x 10 mm) 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.

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

Table 11: Basal rate delivery performance

#### Table 11: Basal rate delivery performance

Rate (U/hr)	Interval	Average (U)	Minimum (U)	Maximum (U)
30 I I/br	1 hour	30.16	29.80	30.61
50 0/11	6 hours	181.05	178.94	184.46

#### Table 12: 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.

<b>Basal Specification Type</b>	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.

		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 13: Bolus accuracy 0.05 U

#### Table 14: 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 15: 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 15: 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 16: 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%, in 5% increments			

<b>Bolus Specification Type</b>	Specification Details
Manual Blood Glucose Entry	Programmable from 10 - 600 mg/dL (0.5 - 33.3 mmol/L), increments of 1 mg/dL (0.1 mmol/L).
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.

#### Table 17: Occlusion detection performance

<b>Operating Rate</b>	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 delivery rates. Certain factors, such as the presence of air in the infusion set can delay a <i>Line Blocked</i> 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 18: 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.

# twiist AID System 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 19: 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 20: 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	$\pm 2 \text{ kV}, \pm 4 \text{ kV}, \pm 6 \text{ kV}, \pm 8 \text{ kV contact}$ $\pm 2 \text{ kV}, \pm 4 \text{ kV}, \pm 8 \text{ kV}$ $\& \pm 15 \text{ kV air}$	Use in home healthcare environments.	
Radiated RF	10 V/m 80 MHz to 2.7 GHz 1 kHz 80% AM carrier 27 V/m 380 MHz – 390 MHz 18 Hz PM carrier	10 V/m 80 MHz to 2.7 GHz 1 kHz 80% AM carrier 27 V/m 380 MHz – 390 MHz 18 Hz PM carrier	Use in home healthcare environments, excluding near high frequency surgical equipment or near Magnetic Resonance machines.	
IEC 61000-4-3	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 20: Immunity test

Immunity Test	nity Test IEC 60601 Test Level Compliance Level		Electromagnetic Environment - Guidance	
	9 V/m 704 MHz – 787 MHz 217 Hz PM carrier	9 V/m 704 MHz – 787 MHz 217 Hz PM carrier		
	28 V/m 800 MHz – 960 MHz 18 Hz PM carrier	28 V/m 800 MHz – 960 MHz 18 Hz PM carrier	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the	
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	compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:	
	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 20: 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		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.	

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	$\begin{array}{c} 0\% \ U_T \ \text{for } 0.5 \ \text{cycle at } 0^\circ, \\ 45^\circ, 90^\circ, 135^\circ, 180^\circ, 225^\circ, \\ 270^\circ \ \text{and } 315^\circ \ \text{phase} \\ \text{angles} \\ 0\% \ U_T \ \text{for } 1 \ \text{cycle} \\ 70\% \ U_T \ \text{for } 1 \ \text{cycle} \\ 70\% \ U_T \ \text{for } 25 \ \text{cycles at } 50 \\ \text{Hz}, 30 \ \text{cycles } \text{at } 60 \ \text{Hz} \\ 0\% \ U_T \ \text{for } 250 \ \text{cycles } \text{at } 50 \\ \text{Hz}, 300 \ \text{cycles } \text{at } 60 \ \text{Hz} \\ \end{array}$		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.	
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.	

Table 20: Immunity test

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance		
	134.2 kHz RFID fields	134.2 kHz RFID fields			
RFID Immunity AIM 7351731	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	AIM 7351731 testing applies to medical electrical equipment and systems. AIM 7351731 sets for test methods/levels for the		
	433.92 MHz RFID fields	433.92 MHz RFID fields	electromagnetic immunity of such equipment/systems.		
	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 33 ft (10 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 Abbott FreeStyle Libre 3 Plus Sensor.

# Quality of Service: iPhone and twiist 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 pump 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 twiist AID system 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* notice. *See "No Communication" on page 209.* 

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 Abbott FreeStyle Libre 3 Plus Sensor

Quality of Service for the twiist app and FreeStyle Libre 3 Plus Sensor wireless communication using NFC (for Sensor activation) is assured when the phone is touched to the Sensor. The communication for activation takes place within 1 second. If the expected response is not received, the phone will continue to retry. Quality of Service for the twiist pump and FreeStyle Libre 3 Plus Sensor wireless communications using BLE for normal operation (receiving glucose reading and alarms) is assured at regular 1-minute intervals. If connection is lost between the twiist app and FreeStyle Libre 3 Plus Sensor for 5-minutes, the App will display an indication of Signal Loss on the home screen. If connection is lost for the user configured amount of time (between 20-90 minutes), the twiist app will notify the user.

If communication is lost between the twiist pump and FreeStyle Libre 3 Plus Sensor, the last 24 hours of lost glucose data will be automatically retrieved when the connection is restored. The twiist pump is designed to only accept Bluetooth Low Energy data from recognized and paired FreeStyle Libre 3 Plus Sensors. The transmission range for Bluetooth Low Energy communication is 33 ft (10 m) unobstructed. If the twiist pump and FreeStyle Libre 3 Plus Sensor are seeing frequent signal loss at longer distances, bring them closer together.

## 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 the internet during initial use to login to your user account, pair your iPhone with a pump, and download software updates. In the event that your pump needs to be repaired 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 pair and 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 PIN number on the pump label is required to initiate pairing between the twiist app and pump.

# FreeStyle Libre 3 Plus Technical Specifications

Table 21: FreeStyle Libre 3 Plus CGM Alerts

FreeStyle Libre 3 Plus Setting Ranges	Details
Urgent Low Glucose Alert	Default: 55 mg/dL (3.1 mmol/L) Options: Cannot be disabled
Low Glucose Alert	Default: 70 mg/dL (3.9 mmol/L) Options: 60 -100 mg/dL (3.3 - 5.6 mmol/L) Increment: 5 mg/dL (0.3 mmol/L)
High Glucose Alert	Default: 250 mg/dL (13.9 mmol/L) Options: 120 -400 mg/dL (6.7 - 22.2 mmol/L) Increment: 10 mg/dL (0.6 mmol/L)
CGM Signal Loss Alert	Default: 40 min Options: 20, 40, 60, 90 minutes

### FreeStyle Libre 3 Plus Sensor Operating Conditions

Table 22: FreeStyle Libre 3 Plus Sensor Operating Conditions

FreeStyle Libre 3 Plus Sensor Specification	Details
Operating and Storage Altitude	-1,250 ft (-381 meters) to 10,000 ft (3,048 meters)
Operating Temperature	10 °C (50 °F) to 45 °C (113 °F)
Operating and Storage Humidity	10-90% non-condensing

## FreeStyle Libre 3 Plus Sensor Immunity Testing

The FreeStyle Libre 3 Plus Sensor is intended for use in the electromagnetic environment specified below. The operator of the FreeStyle Libre 3 Plus Sensor should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test	Compliance	Electromagnetic Environment -
	Level	Level	Guidance
Electrostatic	± 8 kV contact	± 8 kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
discharge (ESD)	± 2 kV, 4 kV, 8 kV,	± 2 kV, 4 kV, 8 kV,	
IEC 61000-4-2	15 kV air	15 kV air	
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines (100 kHz frequency) ± 1 kV for signal lines (100 kHz frequency)	± 2 kV for power supply lines (100 kHz frequency) ± 1 kV for signal lines (100 kHz frequency)	Mains power quality should be that of a typical domestic, commercial, or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical domestic, commercial, or hospital environment.

 Table 23: FreeStyle Libre 3 Plus Sensor Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U _T for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	0% U _T for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	Mains power quality should be that of a typical commercial or hospital environment. If the user	
	0% U _T for 1 cycle	0% U _T for 1 cycle	<ul> <li>of the FreeStyle Libre 3 Plus Sensor requires</li> <li>continued battery charging during power main</li> <li>interruptions, it is recommended that the</li> <li>system be powered from an uninterruptible</li> <li>power supply or a battery.</li> </ul>	
	70% U _T for 25/30 cycles	70% U _T for 25/30 cycles		
	Single phase: 0% U _T for 250/300 cycles	Single phase: 0% U _T for 250/300 cycles		
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 domestic, commercial, or hospital environment.	

 Table 23: FreeStyle Libre 3 Plus Sensor Electromagnetic Immunity

 Table 23: FreeStyle Libre 3 Plus Sensor Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Magnetic; 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 domestic, commercial, or hospital environment.
Conducted RF IEC 61000-4-6	6 Vrms 150 kHz to 80 MHz	6 Vrms	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to the FreeStyle Libre 3 Plus Sensor, including cables specified by Abbott Diabetes Care. Otherwise degradation of the performance of the FreeStyle Libre 3 Plus Sensor could result.

Table 23: FreeStyle Libre 3 Plus Sensor Electromagnetic Immunity

Immunity Test	IEC 60601 Test	Compliance	Electromagnetic Environment -
	Level	Level	Guidance
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 KHz	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 KHz	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to the FreeStyle Libre 3 Plus Sensor, including cables specified by Abbott Diabetes Care. Otherwise degradation of the performance of the FreeStyle Libre 3 Plus Sensor could result.

Note:  $U_T$  is the a.c. mains voltage prior to application of the test level.

Electromagnetic immunity data obtained from FreeStyle Libre 3 User's Manual - ART49044-101_rev-A 22Nov24 2:40pm

### FreeStyle Libre 3 Plus Sensor Radio Specifications

The FreeStyle Libre 3 Plus Sensor radio has the following specifications:

• Sensor Radio Frequency: 2.402-2.480 GHz BLE; GFSK; 4.6 dBm EIRP

# 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.
- b. The algorithm is used for making and delivering basal insulin adjustments and for making correction and meal bolus recommendations, while Loop is on.
- c. The algorithm consists of four components that affect your predicted glucose curve. These components are described in detail in *Section 3 on page 295* 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 24: Loop insulin models

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

1) 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 *Fast-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**

(1) 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**

(i) 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 15 minutes of CGM readings 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 <u>all</u> 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.

(i) 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. By accounting for insulin contributions of the currently running temporary basal and the pending insulin due to the currently running temporary basal, the recommended bolus amount mitigates against the situation where the Loop app loses connectivity. This is because in instances of lost connectivity, the temporary basal rate continues to run for the full scheduled 30 minutes.
- 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.

<u>Safety feature</u>: 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*.

		Eingerstig				
Carbohydrates	60 g	Glucose	Glucose			
Fingerstick	155 mg/dL	Recommer	ded Bolus	0.55 u		
Oldcose	CONTRACT.	Adjusted for	Active Insulin	0.35 U		
Recommended Bolus 4.00 U Adjusted for Active Insulin 1.91 U		Bolus	Bolus 0.			
Bolus	4.00 u		Do			
		1	2	3		
		4 0H1	5	6 MN0		
	_	7 Pars	8 TUV	9 wxy2		
Notes 1			0	8		
#### Table 25: 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 mg/dL and Glucose Safety Limit 67-110 mg/dL). 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 li population	mited to intended user	Study population limited to intended user population ( <i>Ages 6 and up, settings within</i>
	New Users (Cohort A)	Existing Users (Cohort B)	allowable Tidepool Loop ranges at least 90% of the time during study follow-up)
Ν	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 Outo	comes		
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	<ul> <li>92% no SH from baseline to 12 months.</li> <li>22.6 SH events per 100 person years compared to 181.5 events per 100 person years prior to using Loop.</li> </ul>	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 overrode 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).



#### New Users: Total Severe Hypoglycemia Events

## **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.



#### All Users: Total Severe Hypoglycemia Events

## **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 Ad visor.

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	13	6	2	5
# Events per participant				
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  $\geq 6$  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 Months¹

	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.

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## GLOSSARY

## Α

#### **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.

#### В

#### 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 or mmol/L.

#### **Bolus**

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

## С

#### 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 insulinto-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.

#### **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.

Н

#### **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.

#### **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.

#### 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.

Μ

#### 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.

## Ν

#### **Normal Bolus**

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

0

#### **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.

Ρ

#### **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.

Т

## **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.

#### twiist Status

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

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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