



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

USER GUIDE

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 The twist automated insulin delivery system is Magnetic Resonance Unsafe. Disconnect your twist pump before entering an MRI scan room. Do not bring your smartphone or twist pump into an MRI scan room. Contact with, or being in proximity to, an MRI scanner may cause the twist pump and smartphone 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.



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Keep this card with you while using the system.



Magnetic Resonance Unsafe

This person has a twist™ automated insulin delivery system. Do not enter an MRI scanner room or a Magnetic Resonance system. Doing so may result in injury.

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Keep this card 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 table describes the conventions 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 twist app or on the pump the operator interacts with.

Convention	Description
<i>Italic Text</i>	Italic text is used to emphasize: • Words or phrases that appear on the twist app screen. • Parts or features of the system. • Sounds played by the system. • Headings, cross-references, table captions

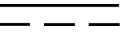
Symbols

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 Only	Prescription use only

Symbol	Definition
 	Magnetic Resonance Unsafe – Items should not enter an MRI scanner room.
	Single use only
	Material may be recycled
	Manufacturer
	Date of Manufacture

Symbol	Definition
	Expiration date
	Lot code
	Catalog number
	Serial number
	Do not use if package is damaged
	Sterile
	Sterilized using ethylene oxide

Symbol	Definition
	Sterilized using irradiation
	Non-pyrogenic
	Keep dry
	Keep away from sunlight
	Type BF Applied Part
	Direct Current required

Symbol	Definition
	Recycle lithium-ion batteries
	Separate collection for electrical and electronic equipment waste.
	Temperature limit
	Humidity limit
	Pressure limit

Symbol	Definition
	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.
	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.

Clinical language 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.

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

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

The twiist AID system includes twiist *Loop*. Throughout this user guide, the twiist *Loop* algorithm is referred to as *Loop*.

 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.

The twiist app screen appearance and settings will vary based on your smartphone model and operating system.

The twiist AID system supports the display of glucose values in mg/dL and mmol/L.

All glucose values in this user guide are displayed in mg/dL.

[*mg/dL to mmol/L conversion*](#)

1 mg/dL = 0.0555 mmol/L

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

Please visit www.twiist.com for the latest version of the user guide.

Important User Information

Read all instructions before use of the twist AID system including:

- This user guide
- Instructions from your infusion set manufacturer
- Instructions from your CGM manufacturer.

The following items must be understood prior to using the twist AID 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.

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.

For more information, visit www.twiist.com/twiist-on-support or contact Sequel Customer Support, available 24 hours a day, 7 days a week. *See "Sequel Customer Support" on page 265.*

Working with your Healthcare Provider

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

Only your healthcare provider should assist with the adjustment of your therapy settings.

Consult with your healthcare provider before using the twiist AID system to determine which features are appropriate for your use.

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
- Fully charged pump battery

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, available for iPhone and Android, 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 (AID) System may also be referred to as the *twiist* AID system.

The *twiist* AID system also delivers bolus insulin to cover meals or lower blood glucose.

The *twiist* automated insulin delivery system includes *twiist Loop*, 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, app, CGM, and optional smartwatch communicate using Bluetooth.

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

When your smartphone is on and within Bluetooth range of the pump, the *twiist* app will also display insulin dosing, and optional glucose information including CGM readings, a rate of change indicator, and a glucose trend graph.

A smartwatch can be used with the *twiist* AID system when in communication with the *twiist* app on your smartphone.

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

Basal delivery continues even when communication between the pump and *twiist* app is interrupted.

The twist pump contains volume measurement hardware, pump actuation hardware, and electronics. The twist pump is powered by a rechargeable battery designed specifically for use with the twist pump.

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, 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 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 twist 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 twist app. *Loop* cannot be enabled when a CGM is not in use.

You must be trained before using the twist AID system. If you have not received training, contact Sequel Customer Support.

What Is Loop?

The twist automated insulin delivery system includes twist *Loop* for optional automated basal insulin adjustment.

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

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

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

- Your Settings
- Your CGM readings
- Recent insulin deliveries
- Recent carb entries



The twist AID system adjusts your basal insulin by pulling together information about your glucose from your CGM, insulin from your twist pump, 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 help reduce high and low glucose and work to keep you in your *Correction Range*.

The twist AID system makes a calculation as often as every 5 minutes.

This 5 minute cycle is called a *Loop*.



Keep the twist 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 adjust your basal rate whether or not your *twiist* pump and app are in communication.

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 smartphone 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 in this section. To see if another insulin that is not listed 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 time 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 iCGMs:

- Abbott FreeStyle Libre 3 Plus Sensor
- Senseonics Eversense 365

For information, product specifications, and performance characteristics about the FreeStyle Libre 3 Plus Sensor, or Eversense 365 CGM, see the user guide provided by the manufacturer.

 Product information for your CGM includes important information on how to use and interpret data from your CGM in order to make treatment decisions.

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

Compatible iCGMs are sold and provided separately.

FreeStyle Libre 3 Plus Sensor

 When used with the twiist AID system, the FreeStyle Libre 3 Plus Sensor can only be paired with the twiist AID system. A FreeStyle Libre 3 Plus Sensor that has been previously paired with the Libre app or reader cannot be paired with the twiist AID system.

Eversense 365

 The Eversense 365 smart transmitter must be paired with the Eversense 365 app on your smartphone prior to pairing with the twiist AID system. The Eversense 365 app is required for proper use of the Eversense 365 CGM.

Smartphone Compatibility

The twiist app is available for compatible iPhone and Android smartphones.

The twiist smartwatch app is supported on compatible Apple and Android smartwatches.

[Go to twiist.com](https://www.twiist.com) to see what smartphones, smartwatches, and operating systems are compatible with the twiist AID system.

It is recommended to have automatic updates enabled on your smartphone so you are always running the latest operating system version.

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

 Do not install Beta Updates for iOS or Android on your smartphone. Beta Updates may not be compatible and may prevent the twiist app from functioning as intended, which may lead to low or high blood glucose.

 Do not install apps on your smartphone from untrusted sources. Installing apps from any source other than the Apple App Store or Google Play Store may put you at risk of unintentionally installing malware, which may impact the use of the twiist app. Only install apps from the Apple App Store or Google Play 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 smartphone, discontinue use of the twiist AID system 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 apps and restore your smartphone to factory default settings.

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

Important Information about Your Smartphone

The twiist app requires permissions from your smartphone including, but not limited to:

- Bluetooth
- Camera
- Notifications
- Critical Alerts (iPhone)
- Modes Access/Do Not Disturb Permission (Android)

Give access to all required permissions when prompted so the twiist app works as expected.

 Allow Notifications and Critical Alerts (iPhone), or Modes Access (Android) for the twist app in your smartphone settings. Failure to allow these settings may lead to missed twist app notifications which may lead to high or low blood glucose.

Your smartphone includes features that may impact the use of the twist AID system, including settings that may prevent alarm and alert notifications from appearing or providing audio notification or vibration. If an alarm occurs and you do not acknowledge on your smartphone, the pump provides audio notifications.

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

- iPhone: Focus, Screen Time, and Scheduled Summary
- Android: Do Not Disturb, Modes, Digital Wellbeing, Private Space, Notification cool down, Pause App

 If Android Modes are in use, ensure the twist app is included in the list of unaffected apps.

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

- iPhone: Zoom, Bold or Larger Text, Increase Contrast, Smart or Classic Invert

- Android: Magnification, Font or Display size, Bold text, Color correction or inversion, Split screen

Important Safety Information

The following section includes important safety information related to your twist automated insulin delivery system.

Additional and repeated warnings and cautions ( or ) appear throughout this user guide where appropriate.

Warnings

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

Training and Use

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

 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.

 The twist AID system is not recommended for use by an operator with poor vision. Poor vision may prevent the correct reading of information displayed within the twist app and may lead to harm.

 Do not use the twist AID 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 265.](#)

 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.

 Do not set glucose unit of measure (Android), 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.

 Do not modify a bolus to be greater than the recommended value. Increasing the bolus may increase your risk of low 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 twist app and may result in over-delivery of insulin resulting in low blood glucose.

Backup Supplies

 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).

Disposables

 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.

Cassette Change

 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 cassette and infusion set tubing. Failure to prime the cassette and 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 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 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.

 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, re-prime the tubing or 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.

 Do not disconnect the infusion set tubing from the cassette at the luer connector. Disconnecting the infusion set tubing from the cassette at the luer connector can introduce air into the infusion set tubing which can lead to under or over delivery of insulin, which may lead to high or low blood glucose.

Line Blocked Alarm

 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.

 Only use twist 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.

Medical Procedures



The twist AID system is Unsafe. Disconnect your twist pump before entering an MRI scan room. Do not bring your smartphone or twist pump into an MRI scan room. Contact with, or being in proximity to, an MRI scanner may cause the twist pump and smartphone 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 twist AID system. CGM readings being used by the system may be inaccurate in these cases, meaning the twist 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.



Do not expose your twist AID 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 twist AID 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* AID system. If you need to stop insulin delivery or remove your diabetes devices 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* AID system if you are taking GLP-1 agonists or SGLT-2 inhibitors, metformin or DPP-4. The *twiist* AID system has not been tested in populations using additional diabetes medications and the performance of the system in conjunction with these medications is unknown.

 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* AID 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* AID 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* AID 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.

 Avoid using the *twiist* AID 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* AID system including your *twiist* pump and compatible CGM. This can cause severe burns on the body.

Location of Use

 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 twist 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.

Sharp Objects/Small Parts

 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.

Approved Parts

 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.

Discontinue Use

 If the twist AID 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.

Maintenance and Troubleshooting

 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.

Smartphone

 Avoid using accessibility features on your smartphone. Using accessibility features on your smartphone may affect the ability to view the twist app which could lead to harm.

 Avoid using Modes on your Android smartphone. Using Modes that restrict the twist app may lead to missed twist app notifications, or prevent the use of the twist app, which may lead to harm.

 Do not install Beta Updates for iOS or Android on your smartphone. Beta Updates may not be compatible and may prevent the twist app from functioning as intended, which may lead to low or high blood glucose.

 A passcode must be enabled on your smartphone to use the *twiist* app. Your smartphone 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.

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

 Allow Notifications and Critical Alerts (iPhone), or Modes Access (Android) for the *twiist* app in your smartphone settings. Failure to allow these settings may lead to missed *twiist* app notifications which may lead to high or low blood glucose.

 Your smartphone should not be used with the *twiist* AID system if your smartphone:

- 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 smartphone under these conditions may result in harm.

Smartwatch

 A passcode must be enabled on your smartwatch to use the *twiist* smartwatch app. Your smartwatch passcode prevents unauthorized changes to insulin delivery, which may lead to low or high blood glucose. Your passcode should not be shared with unauthorized operators.

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.

General Use

⚠ 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.

⚠ 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 use the pump when swimming. Immersing your pump in water may lead to pump malfunctions resulting in interruption of therapy.

⚠ 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.

⚠ 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.

⚠ 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.

⚠ Dispose of used components, including, but not limited to cassettes, syringes, needles, and infusion sets 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 *Check Pump and Cassette* alert, or 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.

 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.

 Avoid using the *twiist* AID 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* AID 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.

 Avoid using the *twiist* AID 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* AID 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.

⚠ 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.

Sound and Vibration

⚠ Disconnect your smartphone 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 twist app notifications.

⚠ Prolonged noise or vibration may interfere with the ability of the pump to continue delivery and trigger an alarm.

⚠ Set your iPhone Ringtone and Alerts or Android Media volume to be louder than your surroundings so twist app notifications can be heard.

Clean Technique

⚠ 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.

Cybersecurity

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

Battery and Charging

 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.

Travel

 Do not expose your twist 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 twist 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.

CGM Safety Information

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

CGM Warnings and Cautions

 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.

FreeStyle Libre 3 Plus

 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.

 Choose a FreeStyle Libre 3 Plus Sensor 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.

 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.

 Your FreeStyle Libre 3 Plus Sensor and twist 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.

 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 healthcare professional to understand how long Vitamin C is active in your body.

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

 If a FreeStyle Libre 3 Plus Sensor breaks inside your body, call your healthcare provider.

 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.

Eversense 365

 The Eversense 365 smart transmitter is MR Unsafe and must be removed before undergoing an MRI procedure. Before you undergo an MRI procedure, tell the MRI staff that you have an Eversense 365 sensor and smart transmitter.

 Refer to the Eversense 365 instructions for use for implanted sensor MRI Safety Information.

 Close contact with direct EMI may interfere with the ability of the smart transmitter to send data to your pump. Move away from the source of EMI and check that your pump is communicating with your smart transmitter.

 Do not use your smart transmitter if it is damaged or cracked. This could create an electrical safety hazard or malfunction and could result in electrical shock.

 Antibiotics of the tetracycline class may falsely lower Eversense 365 sensor glucose readings. Do not rely on sensor glucose readings while taking tetracyclines.

 Do not insert your infusion site within 4 in (10.16 cm) of the sensor. If the insulin infusion site is within 4 in (10.16 cm) of the sensor, it may cause inaccurate glucose readings.

 The Eversense 365 CGM requires calibration with the Eversense 365 app in order to provide accurate readings. Do not use CGM readings to make treatment decisions unless you have followed the instructions to calibrate your Eversense 365 CGM.

 The Eversense 365 app provides alerts and notifications about your Eversense 365 CGM. To receive alerts and notifications from the Eversense 365 app, make sure the app is running and in communication with your smart transmitter.

 The Eversense 365 CGM will not provide readings during the 24-hour warmup phase and until a second calibration is successful during the initialization phase. During this time, you should monitor your glucose using a blood glucose meter.

 Calibrate your Eversense 365 CGM when prompted by the Eversense 365 app to maintain access to CGM readings.

 Your Eversense 365 smart transmitter and pump should be kept within 24.9 ft (7.59 m) of each other without obstructions between them or they may not be able to communicate. To help maintain communication, keep the smart transmitter and pump on the same side of your body.

 Do not wear the smart transmitter during medical X-rays or computed tomography (CT) scans. To avoid interference with results, remove the smart transmitter before undergoing medical X-ray or CT scans. Make sure your healthcare provider knows about your Eversense 365 sensor and smart transmitter.

 Charge your Eversense 365 smart transmitter daily to ensure CGM data is collected from your Eversense 365 sensor and sent to your twiist AID system and Eversense 365 app.

 The following medical therapies or procedures may cause permanent damage to the Eversense 365 sensor, particularly if used in close proximity to the device:

- Lithotripsy (Therapeutic Ultrasound) - The use of lithotripsy is not recommended for people who have an inserted sensor because the effects are unknown. Do not use lithotripsy near the sensor.
- Diathermy - Do not use diathermy on people who have an inserted sensor. Energy from the diathermy can transfer through the sensor and cause tissue damage in the insertion area.
- Electrocautery - The use of electrocautery near the inserted sensor may damage the device. Do not use electrocautery near the sensor.
- Vaccinations - Do not inject medications or vaccines in the immediate area of the sensor as the needle may cause damage to the sensor.

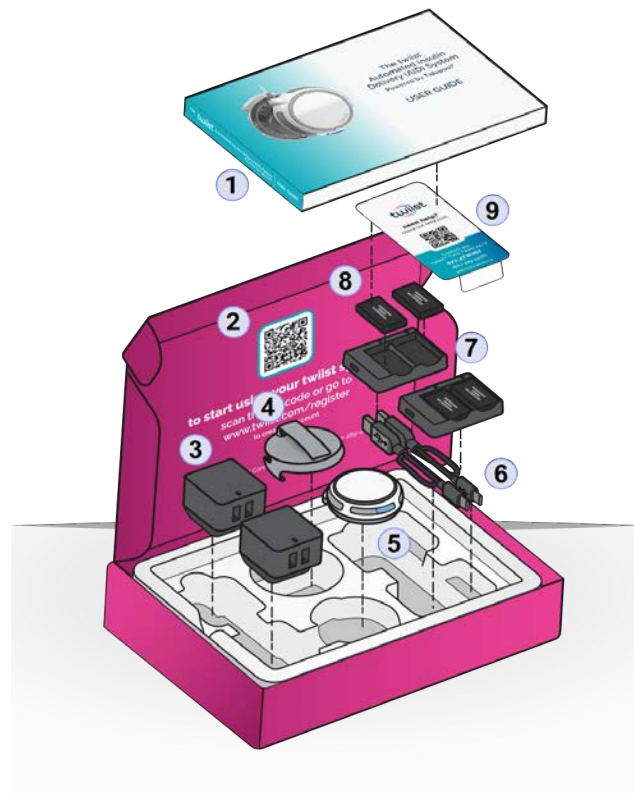
Get to Know Your twist Automated Insulin Delivery System

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

The twist AID system includes:

The twist insulin delivery system

1. The twist AID system User Guide
2. QR code to access www.twiist.com/register to create your account
3. Wall power adapter with 2 USB ports (2)
4. Pump clip
5. The twist pump with attached cover
6. USB charging cable (2)
7. Pump battery charger (2)
8. Rechargeable pump battery (4)
9. QR code to go to twiist.com for more information



Cassettes

The twist 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

Syringes, Needles, and Wipes

Additional single-use supplies are necessary to use the twist 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

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

 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.

CGM Supplies

All components and supplies for your compatible CGM are sold and shipped separately.

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 AID 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.

! Do not use the twiist AID 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 265.*

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 compatible CGM, 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 smartphone is powered off.

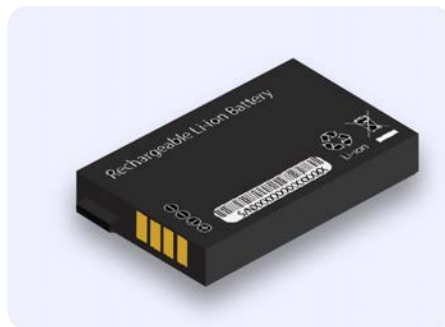
- If *Loop* is on, basal delivery will continue to be adjusted.
- If *Loop* is off, basal will be delivered at the scheduled basal rate.

The 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 can be used to deliver a *One-Button Bolus*, if enabled.

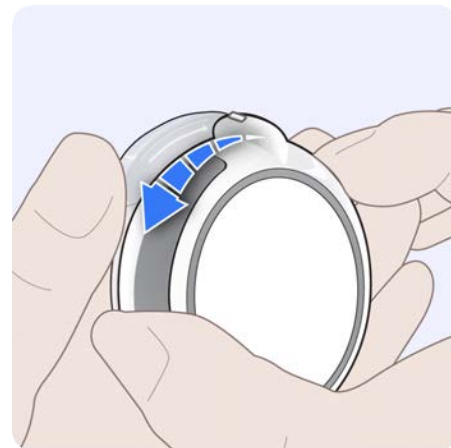
All alarm functions are maintained by the pump when the *twiist* app is not available.

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.



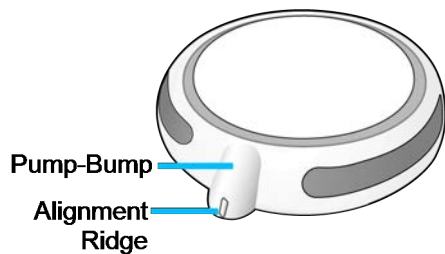
The pump is shipped with an attached cover. The cover is removed and a cassette is attached and filled during setup with your certified *twiist* trainer.

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.

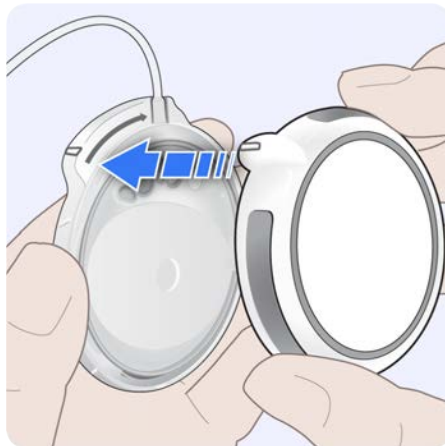


Pump-Bump

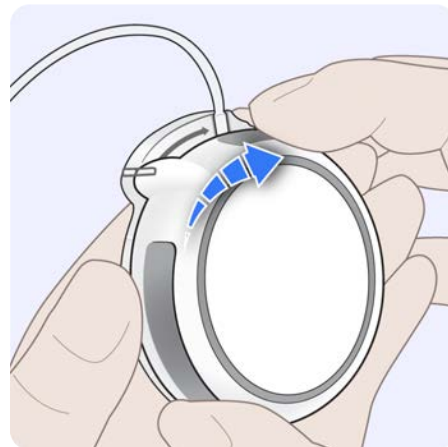
The *pump-bump* and alignment ridge are features on the pump to help align the cassette and pump when a cassette is being attached to the pump.



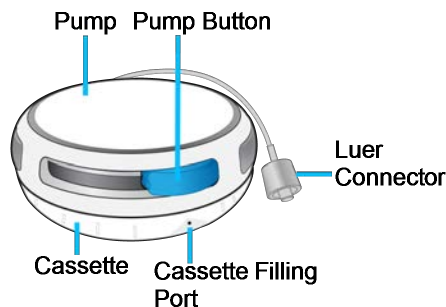
When attaching a new cassette to the pump, align the ridge on top of the *pump-bump* with the ridge on the cassette. When the ridges are aligned, turn the pump clockwise toward the infusion set tubing.



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
- Place the pump into pairing mode (when not connected to a cassette).
- Deliver a *One-Button Bolus*

The pump button can be used to confirm delivery, when the *twiist* app is not available, or you want an audio confirmation.

Press and hold the **pump button** for 3 seconds to confirm that delivery is in progress. The pump will play the *Delivering* sounds to let you know that delivery is in progress and the *Pump Inactive* sound if delivery is suspended.

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 111.](#)

The pump button can be used to deliver a *One-Button Bolus* (when enabled). [See "One-Button Bolus" on page 177.](#)

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 *Check Pump and Cassette* alert, or a false *Cassette Not Attached* alarm.

i When the system is used in a loud environment your smartphone should be kept in a clothing pocket so vibration can be felt, if enabled. Check for twist 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.

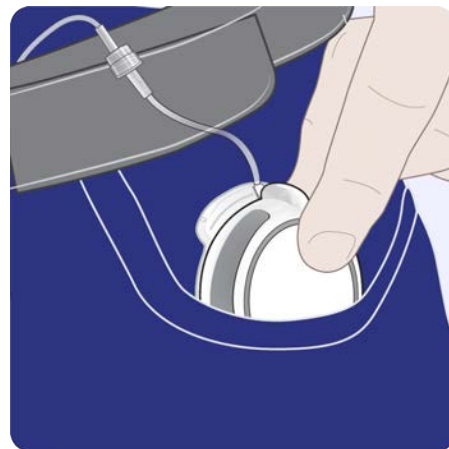
Pump Clip



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

In order for sounds to be played by the twist app, Notifications and Critical Alerts (iPhone), or Modes Access (Android), must be enabled. Keep these features enabled to make sure that sounds played by the twist app are not delayed or missed. If these features are disabled, or if your iPhone Ringtone and Alerts or Android Media volume is turned down or silenced, notifications provided by the twist app may not be played or heard.

Keep Vibration or Haptics smartphone settings enabled so twist app *Notifications* are delivered with vibration.

Sound Name	Sound Description	Sound Source	Sound Definition
<i>Quick Beep</i>	One quick beep	twiist pump	The pump battery has been inserted into the pump.
<i>Ready Beep</i>	One beep	twiist pump	The twist AID system is ready to advance to the next step.
<i>Busy Beeps</i>	One repeating beep	twiist pump	The pump self-test or prime is in progress. Wait until the pump is ready before continuing.
<i>Delivery Suspended</i>	Four descending tones	twiist pump	Insulin delivery has been suspended using the twist app.

Sound Name	Sound Description	Sound Source	Sound Definition
<i>Delivering</i>	Three ascending tones	twiist pump	• Insulin delivery has been started using the twiist app. • Insulin delivery has been confirmed using the pump button. • Bolus delivery has been started or interrupted using the twiist app. • One-Button Bolus delivery has been started using the pump button. • Temporary Basal has been started or canceled using the twiist app.
<i>Pump Inactive</i>	One extended tone	twiist pump	Pump Inactive has been confirmed using the pump button. Insulin delivery is suspended.
<i>One-Button Bolus</i>	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> .
<i>One-Button Bolus Canceled</i>	One extended tone	twiist pump	Programming a <i>One-Button Bolus</i> was not successful.

Sound Name	Sound Description	Sound Source	Sound Definition
<i>Alarm</i>	Three beeps + two beeps (2 times)	twiist app, and then twiist pump  Alarm notifications are initially played on your smartphone at your iPhone Ringtone and Alerts or Android Media volume. If the alarm has not been resolved within 5 minutes, the alarm notification will be delivered as a Critical Alert (iPhone) or with Modes Access (Android). After an additional 5 minutes, the alarm notification will repeat as a Critical Alert (iPhone) or with Modes Access (Android) and will play on your twiist pump.  If the twiist app and pump are out of communication, Alarm sounds will play on the pump immediately.	The twiist pump is in an alarm condition. Insulin delivery has been suspended. Review the alarm displayed in the twiist app for additional information.

Sound Name	Sound Description	Sound Source	Sound Definition
<i>Alert</i>	Two beeps	twiist app  Most alerts are played on your smartphone at the iPhone Ringtone and Alerts or Android Media volume. If your smartphone is silenced, or any iPhone Focus features or Android Modes are enabled, alert notifications may be missed. Some alerts work differently, for your safety, and are delivered as Critical Alerts (iPhone) or with Modes Access (Android). CGM alerts, with the exception of the <i>Urgent Low Glucose</i>, are only played on your smartphone. twiist pump  If the twiist app and pump are out of communication, <i>Alert</i> sounds play on the pump.	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
<i>Urgent Low Glucose</i>	Three beeps	twiist app, and then twiist pump  <i>Urgent Low Glucose</i> alert notifications are played on your smartphone as Critical Alerts (iPhone) or with Modes Access (Android). If the <i>Urgent Low Glucose</i> alert has not been resolved within 5 minutes, the notification will be repeated on your smartphone and will play on your twiist pump.  If the twiist app and pump are out of communication, <i>Urgent Low Glucose</i> sounds will play on the pump immediately.	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.

Smartphone Notification Settings

To ensure twiist app notifications are displayed on your smartphone, allow the following for the twiist app in your smartphone settings:

- Notifications
- Critical Alerts (iPhone)
- Modes Access (Android)

Notifications

Notifications inform you of conditions that require your attention.

Notifications from the twiist app are displayed on your smartphone lock screen, or while using other apps.

Tap the **Notification** to open the twiist app.



Critical Alerts (iPhone) and Modes Access (Android)

Critical Alerts (iPhone) or notifications delivered with Modes Access (Android) inform you of conditions that require your attention even if your smartphone is silenced, or iPhone Focus features or Android Modes are enabled.

 Some Android Modes prevent the use of selected apps while active. Ensure the twiist app is included in the list of unaffected apps whenever using Android Modes.

Critical Alerts (iPhone) or notifications delivered with Modes Access (Android) from the twiist app are played at the *Critical Alert (iPhone)* or *Do Not Disturb Override (Android)* Volume set in the twiist app.

 Allow Notifications and Critical Alerts (iPhone), or Modes Access (Android) for the twiist app in your smartphone settings. Failure to allow these settings may lead to missed twiist app notifications which may lead to high or low blood glucose.

Charge the Pump Batteries

Before you use your twist 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, USB charging cable, and wall power adapter.

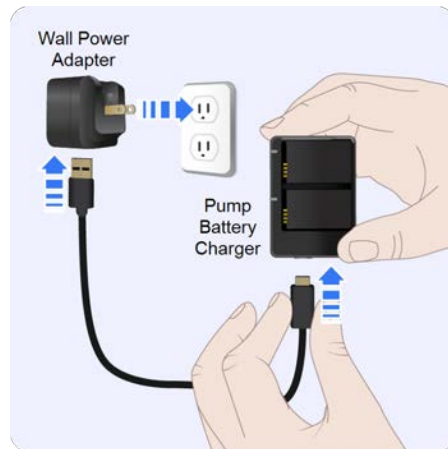
 Only use the provided wall power adapter and charging cables. Use of another wall power adapter or cables could damage the system or result in fire or burns.

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 twist AID system is compatible with the FreeStyle Libre 3 Plus and Eversense 365 to provide sensor readings through a Bluetooth connection directly to the twist pump.

When the twist AID system is used with a compatible CGM, the twist app displays your current glucose and glucose trend.

Ensure that you have reviewed this information and discussed it with your healthcare team, who can guide you in correctly using your CGM information when making treatment decisions.

For detailed instructions and important safety information, refer to instructions included with your CGM.

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.

Charge your smartphone 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 played on your smartphone at the iPhone Ringtone and Alerts or Android Media volume. In order to hear and feel notifications, your smartphone volume must be turned up and vibrate or Haptics must be enabled.
- Notifications and Critical Alerts (iPhone), or Modes Access (Android) must be enabled within your smartphone settings in order to receive notifications from the twiist app.
- Your smartphone passcode feature must be enabled in order to use the twiist app.

- Your smartphone, running the twiist app, should be kept with you at all times while using the twiist AID system. Insulin delivery will continue when your smartphone is not present.
- Do not quit the twiist app, or remove the twiist app from your smartphone. Quitting the twiist app or removing it from your smartphone 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.

 Avoid using accessibility features on your smartphone. Using accessibility features on your smartphone may affect the ability to view the twiist app which could lead to harm.

 Avoid using Modes on your Android smartphone. Using Modes that restrict the twiist app may lead to missed twiist app notifications, or prevent the use of the twiist app, which may lead to harm.

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

- 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 smartphone under these conditions may lead to harm.

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

 Allow Notifications and Critical Alerts (iPhone), or Modes Access (Android) for the twiist app in your smartphone settings. Failure to allow these settings may lead to missed twiist app notifications which may lead to high or low blood glucose.

 A passcode must be enabled on your smartphone to use the twiist app. Your smartphone 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.

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

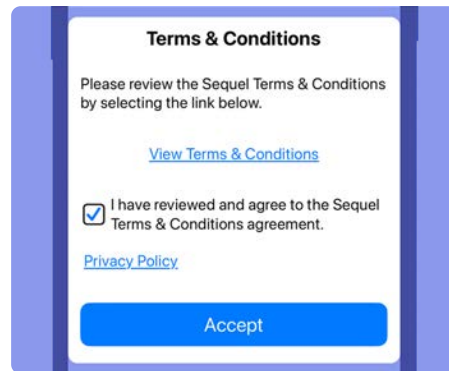
www.twiist.com/register to create your account, and download the *twiist* app from the Apple App Store or Google Play Store.



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

1. Open the *twiist* app on your smartphone.
2. Tap **Welcome**.
3. Enter your **username** and **password**.
4. Tap **Login**.

5. 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 smartphone is charged and has a Wi-Fi or cellular network connection.

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

Smartphone Permissions

The *twiist* app requires permissions from your smartphone including, but not limited to:

- Bluetooth
- Camera
- Notifications
- Critical Alerts (iPhone)
- Modes Access/Do Not Disturb Permission (Android)

Give access to all required permissions when prompted so the *twiist* app works as expected.

 Allow Notifications and Critical Alerts (iPhone), or Modes Access (Android) for the *twiist* app in your smartphone settings. Failure to allow these settings may lead to missed *twiist* app notifications which may lead to high or low blood glucose.

Pair Your *twiist* Pump

The *twiist* pump can be paired with the *twiist* app by taking a photo or by manually entering the 6-digit PIN on the pump label.

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 your pump **serial number** within *Discovered Pumps*.
5. Tap **Take Photo** or **Enter Manually**.

Take Photo:

The *twiist* app uses your smartphone camera in order to scan QR codes, such as those on your pump label and cassette.

- a. Tap **Take Photo**.

- b. Hold your smartphone 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.

- c. Tap **Connect**.

If you have an iPhone:

- d. Tap into the *Bluetooth Pairing Request* field to display the *Paste* option.
- e. Tap **Paste** to enter the pump PIN.
- f. Tap **Pair**.

Enter Manually (iPhone):

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

Enter Manually (Android):

- a. Tap in the **Pump PIN** field to display the keypad.
- b. Enter the 6-digit PIN found on the pump label and tap the check mark.
- c. Tap **Connect**.

 If a *Limited Internet Connectivity* notice is displayed, remove and reinsert the pump battery and try to pair the pump again after joining a cellular network or a different Wi-Fi network.

Pump Software Update

After pairing your pump to the *twiist* app, a pump software update is required.

1. Tap **Continue**.
2. Tap **Next**.

The *twiist* app displays the pump update progress.

3. Keep your pump close to your smartphone. Do not quit the *twiist* app, turn off your smartphone, or remove the battery from the pump during the pump software update.

After the pump software update is completed, the pump plays a *Ready Beep*.

4. Tap **Continue**.

Pair Your CGM

1. Tap **Pair CGM** and select *FreeStyle Libre 3 Plus* or *Eversense 365* to add the CGM to the *twiist* AID system or tap **Skip CGM Setup** to continue setting up your *twiist* AID system without a CGM.

If you choose not to add a CGM now, you will have an opportunity to add one once setup of your *twiist* AID system is complete.

Add FreeStyle Libre 3 Plus

When used with the *twiist* AID system, the *FreeStyle Libre 3 Plus* Sensor can only be paired with the *twiist* AID system.

Do not pair your *FreeStyle Libre 3 Plus* Sensor with 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.

1. Tap **FreeStyle Libre 3 Plus**.

Apply a New FreeStyle Libre 3 Plus Sensor

1. Clean hands prior to FreeStyle Libre 3 Plus Sensor handling and insertion to help prevent infection.
2. 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.
3. Apply your new sensor.

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

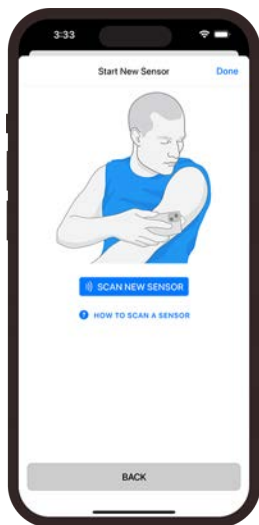
i Applying the sensor may cause bruising or bleeding. If there is bleeding that does not stop, remove the sensor and contact your healthcare provider.
 4. Put the cap back on the Sensor Applicator. Discard the Sensor Applicator according to local regulations.

5. Tap **NEXT.**

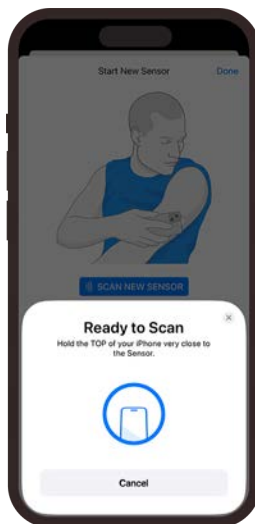


6. Tap **SCAN NEW SENSOR**.

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



7. Hold the top (iPhone) or back (Android) of your smartphone close to the sensor. Distance may vary based on the smartphone you are using.



 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.

8. Tap **OK**.

Add Eversense 365

The Eversense 365 smart transmitter must be paired and connected with the Eversense 365 app on your smartphone before pairing with the *twiist* AID system.

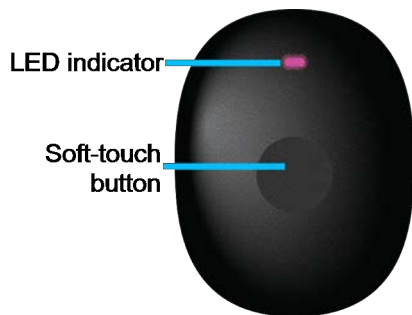
Use the Eversense 365 app to calibrate your sensor, place your smart transmitter, and configure CGM notifications.

Refer to the Eversense 365 manufacturer instructions for safety and proper use information.

1. Tap **Eversense 365**.

The *twiist* app will display *Searching* for smart transmitter.

2. Tap the **Smart Transmitter Soft-touch button** three times to start pairing mode.



The smart transmitter will blink pink to indicate it is in pairing mode.

 The smart transmitter will blink blue to indicate it is not paired and connected to the Eversense 365 app before pairing with the *twiist* AID system.

The *twiist* app will display *Pairing* followed by *Pairing Complete*.

3. Tap **OK** to continue.

Your Settings

To allow the *twiist* app to notify you of important safety information, keep smartphone Notifications and Critical Alerts (iPhone), or Modes Access (Android) enabled.

 **Allow Notifications and Critical Alerts (iPhone), or Modes Access (Android) for the *twiist* app in your smartphone settings. Failure to allow these settings may lead to missed *twiist* app notifications which may lead to high or low blood glucose.**

Share with Apple Health (iPhone)

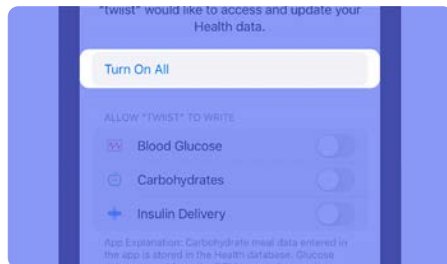
Apple Health can be used to store and review blood glucose, carbohydrate, and insulin delivery data from the *twiist* app, including *Total Daily Dose* and *Percent In Range*.

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.

! Do not set glucose unit of measure (Android), 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.

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:
 - Cassette
 - Needle and Syringe
 - Infusion Set
 - 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.
i Do not 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* are played by the pump while the pump conducts a self-test. The self-test is displayed on the twist app.
7. Wait for the self-test to complete before continuing.
8. Tap **Scan Cassette**.
9. Scan the cassette with your smartphone 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 cassette and 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 do not 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.

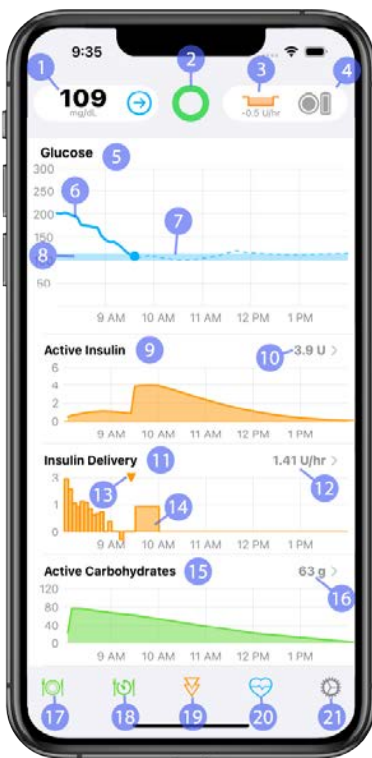
If you need help, consult with your certified *twiist* trainer or healthcare provider.

10. Tap **Start *twiist***.

How the twist App Works

The twist app shows you how the twist AID 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 twist app work differently when *Loop* is off.



1. CGM Status
2. twist Status
3. Insulin Delivery Status
4. Pump Status
5. Glucose Chart
6. CGM or fingerstick glucose readings
7. Glucose Prediction
8. Correction Range
9. Active Insulin Chart
10. Current Active Insulin
11. Insulin Delivery Chart
12. Current Basal Rate
13. Bolus Delivery
14. Basal Delivery
15. Active Carbohydrates Chart
16. Current Active Carbohydrates
17. Carb Entry and Meal Bolus
18. Pre-Meal Preset
19. Bolus Entry (Correction Bolus)
20. Workout Preset/Temporary Basal
21. 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
- View sensor glucose data
- Respond to CGM Alerts

When used with an Eversense 365 CGM:

- Pair your Eversense 365 Smart Transmitter with the **twiist** AID system
- View sensor glucose data
- Configure CGM settings
- Respond to CGM Alerts

High and *Low Glucose* alerts are configurable in the Eversense 365 and **twiist** apps. These alerts may be configured to occur at different sensor glucose values. Review *High* and *Low Glucose* alert settings in both the Eversense 365 and **twiist** apps and respond to notifications provided by both the Eversense 365 and **twiist** apps.

Target Range is configurable in the Eversense 365 and **twiist** apps. Target range may be configured to have different high and low values in the Eversense 365 and **twiist** apps, which may result in different glucose background color display and calculated time in range. Review *Target Range* settings in both the Eversense 365 and **twiist** apps and set with guidance from your healthcare provider.

 Predictive alerts provided by the Eversense 365 application are not based on predictive information provided by *Loop* and will be different than predictive information visible within the **twiist** app.

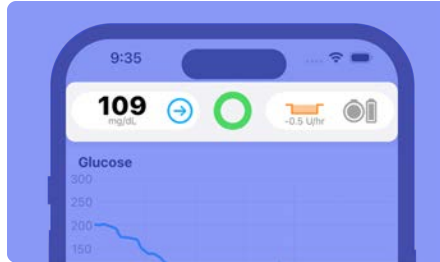
The *twiist* App Home Screen

The *twiist* app *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 *twiist* AID system.



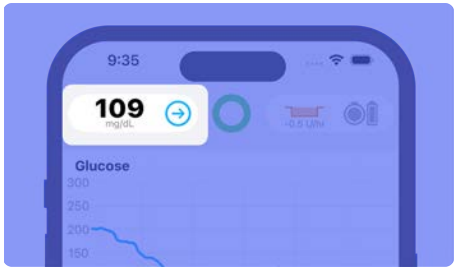
Status icons include:

- CGM Status
- *twiist* Status
- Insulin Delivery Status
- Pump Status

The *Home Screen* also displays *Temporary Status Banners*, [see "Temporary Status Banner" on page 70.](#)

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 to view additional CGM information. See "*CGM Status Screen*" on page 143.

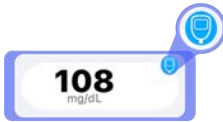
i The information displayed within the *CGM Status* icon and *CGM Status* screen depends on the CGM in use with the twist AID system.

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

	Sensor glucose is higher than 400 mg/dL.
	Sensor glucose is lower than 40 mg/dL.

Additional *CGM Status* icons may be displayed. Tap the **CGM Status** icon to see additional information.

	No CGM has been paired with your twist pump. <i>Loop</i> cannot be turned on.
	Your CGM Sensor is warming up. Tap the CGM Status for additional information about when your sensor will be ready.
	The twist AID system is connecting with your CGM.

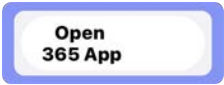
	Your CGM is not in communication with your twist pump and needs attention.
	A fingerstick glucose value  has been entered.

CGM Status with FreeStyle Libre 3 Plus Sensor

	A FreeStyle Libre 3 Plus Sensor reading is unavailable. Check again in a few minutes.
	Your FreeStyle Libre 3 Plus Sensor is too cold to give glucose readings. Check again in a few minutes.

	Your FreeStyle Libre 3 Plus Sensor is too hot to give glucose readings. Check again in a few minutes.
	Check your FreeStyle Libre 3 Plus Sensor. If it is loose from your skin, remove the sensor and start a new one. If it is applied properly, try starting the sensor again.
	A <i>Replace CGM</i> alert has occurred. See "Replace CGM" on page 220.
	A <i>CGM Ended</i> alert has occurred. See "CGM Ended" on page 214.

CGM Status with Eversense 365

	The Eversense 365 CGM needs your attention. Open the Eversense 365 app for more information.
---	--

Glucose Trend

The *Glucose Trend* displayed in the *CGM Status* displays the current direction your glucose is going, and how fast it is changing.

Glucose Trend with a FreeStyle Libre 3 Plus Sensor

	Sensor glucose is rising or falling slowly. Less than 1 mg/dL per minute.
	Sensor glucose is rising 1-2 mg/dL per minute.
	Sensor glucose is rising quickly. More than 2 mg/dL per minute.

	Sensor glucose is falling 1-2 mg/dL per minute.
	Sensor glucose is falling quickly. More than 2 mg/dL per minute.

Glucose Trend with Eversense 365

	Sensor glucose is rising or falling slowly. Less than 1 mg/dL per minute.
	Sensor glucose is rising 1-2 mg/dL per minute.
	Sensor glucose is rising quickly. Between 2-3 mg/dL per minute.
	Sensor glucose is rising very quickly. More than 3 mg/dL per minute.

	Sensor glucose is falling 1-2 mg/dL per minute.
	Sensor glucose is falling quickly. Between 2-3 mg/dL per minute.
	Sensor glucose is falling very quickly. More than 3 mg/dL 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.

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.

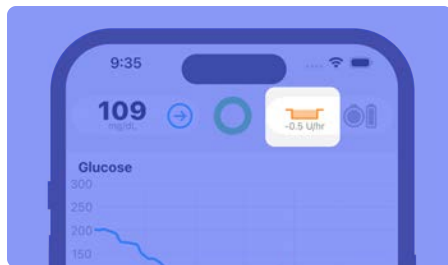
You may be experiencing temporary CGM *Signal Loss* that does not typically require user interaction to resolve.



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.

 It does NOT 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.

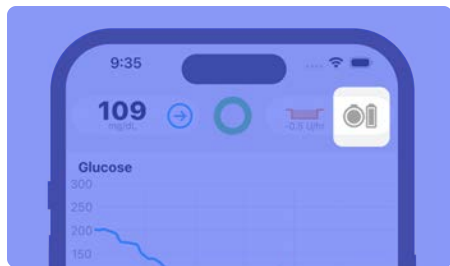
Increased Basal

 +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 twist *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.

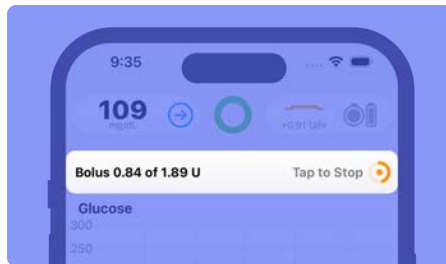


The cassette and pump battery icons are independent from each other and may show different percentages and colors.



The *Pump Status* icon will change for specific alarm conditions. [See "Alarms, Alerts, and Notices" on page 187.](#)

Temporary Status Banner



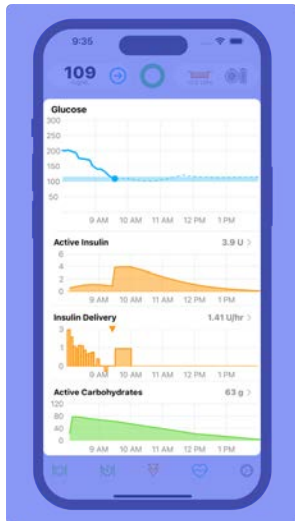
The twist app may display a *Temporary Status Banner* below the *Status* icons.

The *Temporary Status Banner* is displayed 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.
- When you have turned on a *Pre-Meal* or *Workout Preset*.
- When a *No Recent Glucose* message is displayed.
- 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. Hold your finger on the chart, and 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 readings.

Correction Range



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

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

Your *Correction Range* is typically a smaller range than your CGM Target Range, or your CGM high and low glucose alerts. Your *Correction Range* is where you want your glucose to be.

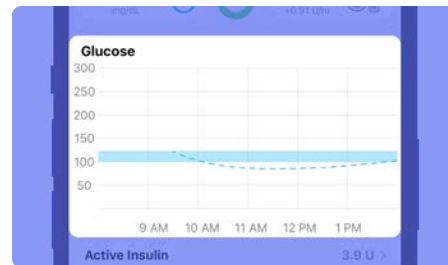
Glucose History



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

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

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

How Far Out is the Prediction?



The further out the prediction, the less accurate it is. This is because the twist 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 twist app will adjust your glucose prediction.

i The twist 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 next few loops to decide whether or not to take action.

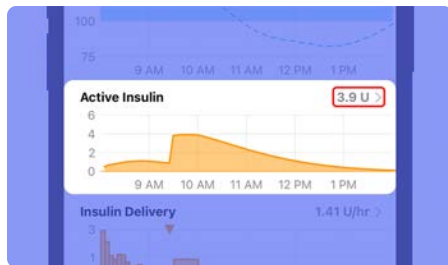
Always have a source of fast-acting glucose available to take action if your glucose is low.

When *Loop* is on, try smaller amounts of glucose to treat lows. Since the twist AID system is already adjusting your basal delivery, smaller amounts of glucose may be needed to prevent lows.

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

i When *Loop* is off, the twist 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 smartphone will allow you to see additional *Active Insulin* history.

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

If the twist AID system predicts a low soon, and your chart displays you have active insulin, you may want to keep a source of fast-acting carbs nearby to treat low glucose as advised by your healthcare provider.

If the twist 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.

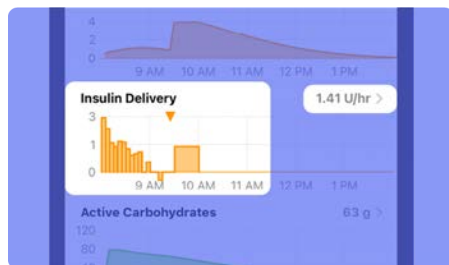
You can tap the **Bolus Entry** button at any time to see if a bolus is recommended right now.

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.

▼ Bolus deliveries are displayed as orange triangles.

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

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

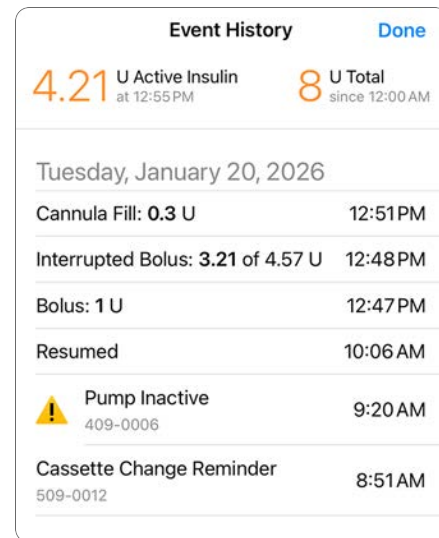
You may see frequent increases and decreases on this chart as *Loop* works to bring your glucose into your correction range.

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

Rotating your smartphone 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 are discarded.

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

Active Carbohydrates Chart



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.

Your current active carbohydrates are displayed in the top-right corner of the active carbohydrates chart.

Rotating your smartphone will allow you to see additional *Active Carbohydrates* history.

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

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

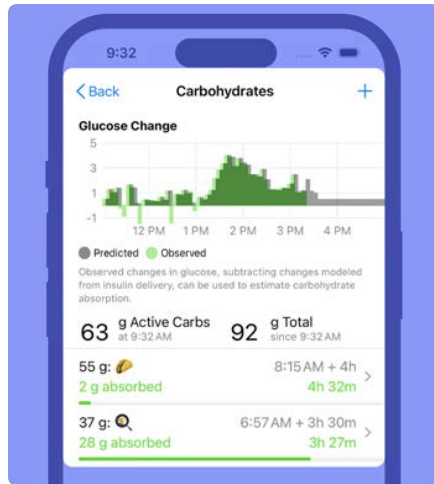
You may have enough carbs from a previous meal or snack to cover low glucose.

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

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.*

*Only when loop is on.



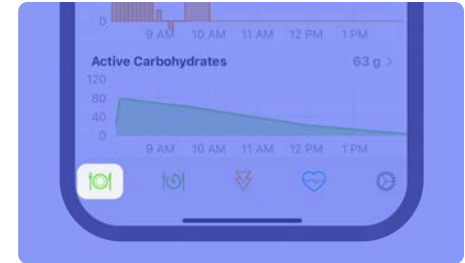
Toolbar



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.

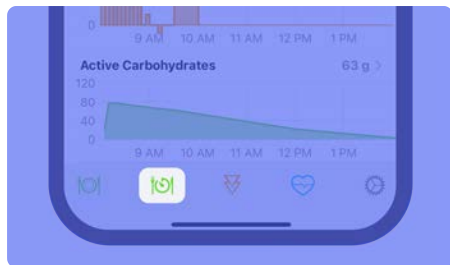
- Carb Entry
- Pre-Meal Preset
- Bolus Entry
- Workout Preset
- Settings

Carb Entry



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

Pre-Meal Preset



Pre-Meal Preset  lets you temporarily lower your **Correction Range** before a meal to reduce post-meal glucose spikes.

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

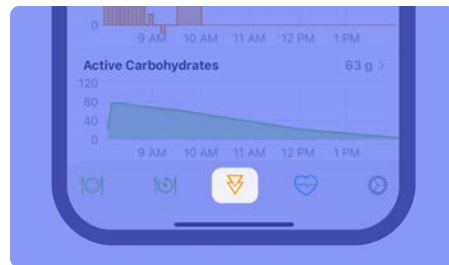
When activated, the **Pre-Meal Preset**  button color is reversed and the **Glucose Chart** is updated to show the **Pre-Meal Preset** adjustment to your **Correction Range**.

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



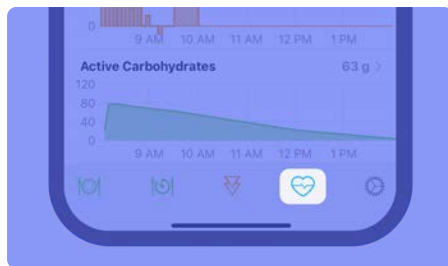
 **Pre-Meal Preset** is unavailable when **Loop** is off. The twist system will not adjust your basal insulin delivery. The **Pre-Meal Preset** button will be grayed out and cannot be selected.

Bolus Entry



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

Workout Preset



Workout Preset  lets you temporarily adjust your *Correction Range* for activity.

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

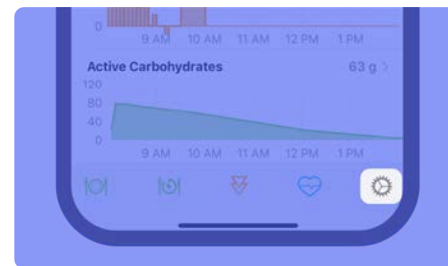
When activated, the *Workout Preset*  button color is reversed and the *Glucose Chart* is updated to show the *Workout Preset* adjustment to your *Correction Range*.

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



 *Workout Preset* is unavailable when *Loop* is off. The twist system will not adjust your basal insulin delivery. The *Workout Preset* button is used to manually set a *Temporary Basal*.

Settings

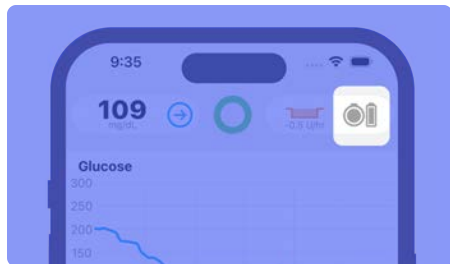


The *Settings*  button opens the *Settings Menu* to:

- Turn *Loop* On or Off
- View and edit your *Therapy Settings*, *Bolus Settings*, and *Notification Settings*
- Add a CGM
- Configure CGM Settings (when a compatible CGM has been added to the twist AID system)
- Access *Support*

Pump Menu

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

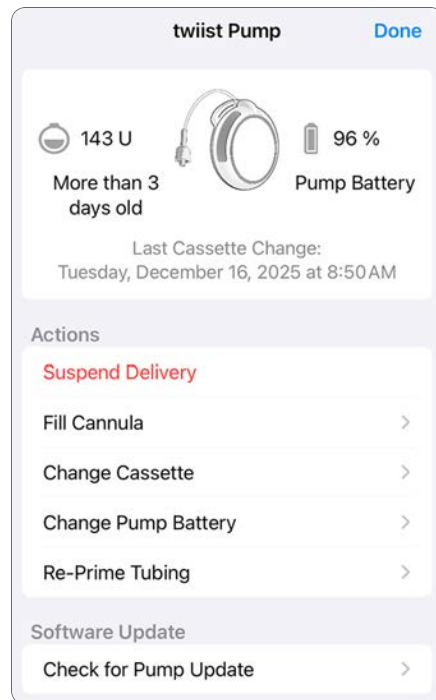


The *Pump Menu* allows you to view:

- Cassette info, including estimated volume remaining and cassette age
- Pump battery charge remaining
- *Last Cassette Change* date and time

The *Pump Menu* provides access to:

- Suspend/Resume Delivery
- Fill Cannula
- Change Cassette
- Change Pump Battery
- Re-Prime Tubing
- Check for Pump Update



Suspend Insulin Delivery

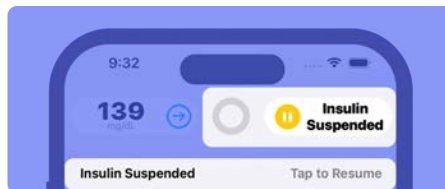
1. Tap the **Pump Status** icon to open the *Pump Menu*.
2. Tap **Suspend Delivery**.
A message is displayed asking if you are sure you want to suspend insulin delivery.
3. Tap **Confirm** to suspend insulin delivery.

The pump plays the *Delivery Suspended* sound.

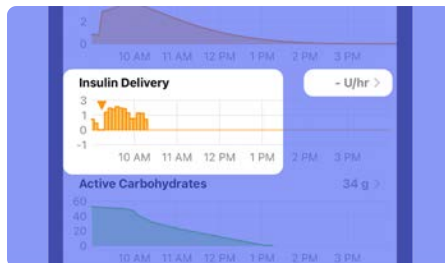
-  The pump sound will not be played when *Quiet Mode* is enabled.

How to identify that insulin delivery is suspended:

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

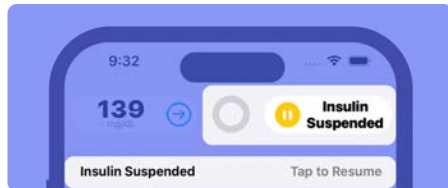


- The *Insulin Delivery Chart* displays your current insulin delivery rate as - U/hr.



Resume Insulin Delivery

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



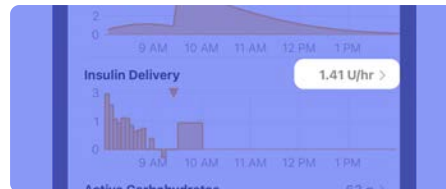
2. Tap **Resume Delivery**.
The *Home Screen* is displayed and the pump plays the *Delivering* sounds.
 The pump sound will not be played when *Quiet Mode* is enabled.

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 67.
- *Insulin Delivery Status* displays insulin delivery in progress 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.



Fill Cannula

Your infusion set cannula is filled during the cassette change process when you replace your infusion site. If you need to replace 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.

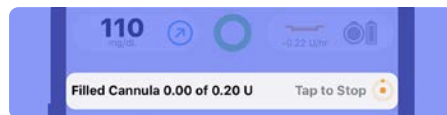
 Cannula fills are not counted towards your *Active Insulin*.

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.

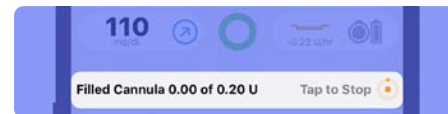
Changes to *Cannula Fill Volume* are saved for future deliveries.

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



Stop Cannula Fill

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.

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.

A *Cassette Change Reminder* can be set to remind you when it is time to change your cassette. See ["Cassette Change Reminder" on page 128](#).

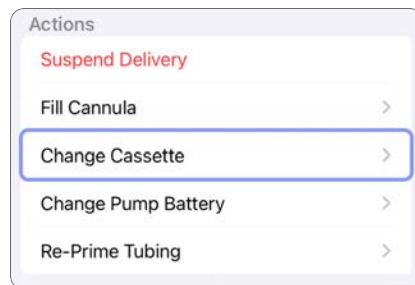
 The twist AID system provides on-screen, step-by-step instructions. Follow the instructions provided in the twist app.

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 or NovoLog U-100 insulin
- Alcohol wipes

 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 twist 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.

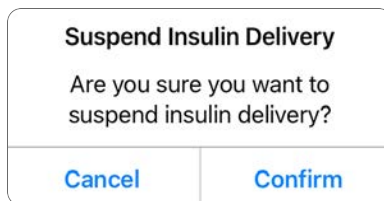
⚠ Do not use damaged cassettes or infusion sets. Using damaged cassettes or infusion sets may result in start-up failures, interruptions in therapy, topical exposure to insulin, or delivery errors leading to high or low blood glucose.

Start Cassette Change

1. Tap **Start Cassette Change**.



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

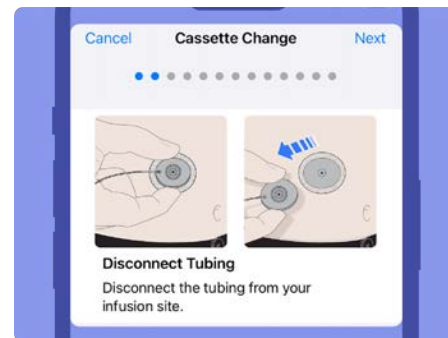


The pump plays the *Delivery Suspended* sound.

- 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. Refer to your infusion set manufacturer instructions.
2. Remove the cannula from the infusion site and dispose.
3. Tap **Next**.

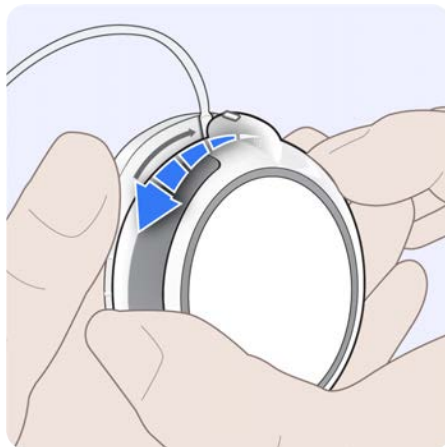


! Before removing the cassette from your pump, disconnect the infusion set tubing from your infusion site. Leaving the infusion set tubing connected may lead to unintended delivery, which may cause low blood glucose.

! Do not disconnect the infusion set tubing from the cassette at the luer connector. Disconnecting the infusion set tubing from the cassette at the luer connector can introduce air into the infusion set tubing which can lead to under or over delivery of insulin, which may lead to high or low blood glucose.

Remove and Dispose of Used Cassette

1. Holding the cassette still, rotate the pump counterclockwise until the ridges on the pump-bump and the top of the cassette are aligned.



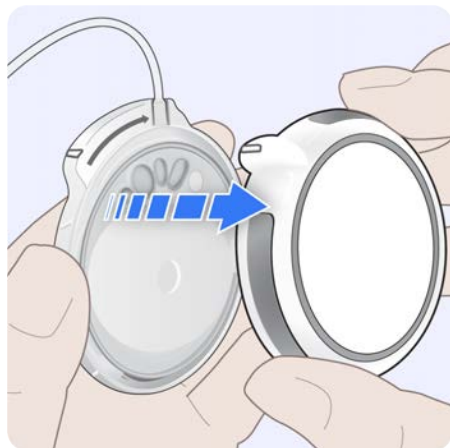
The pump plays a *Ready Beep*.

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

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.

2. Remove the cassette from the pump.



The screen advances automatically.

i It is normal to see some insulin left in the cassette.

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, including, but not limited to cassettes, syringes, needles, and infusion sets 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 twist app advances 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.

- i** 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 211.](#)



- A series of *Busy Beeps* are played by the pump while the pump conducts a self-test. The self-test is displayed on the twist app.
5. Wait for the self-test to complete before continuing.
- If you receive a *Restarting Cassette Change* message, the cassette has been removed from the pump during the cassette change process. Tap **OK** and restart the cassette change.

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

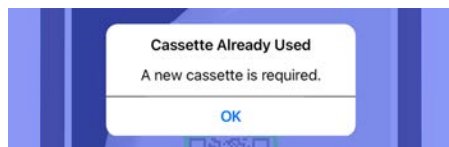
 Do not connect infusion set tubing to your infusion site before the pump completes self-test. Connecting infusion set tubing to your infusion site during self-test may lead to unintended delivery of insulin, which may lead to low blood glucose.

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.

Cassette Fill Volume

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

The twist 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**.

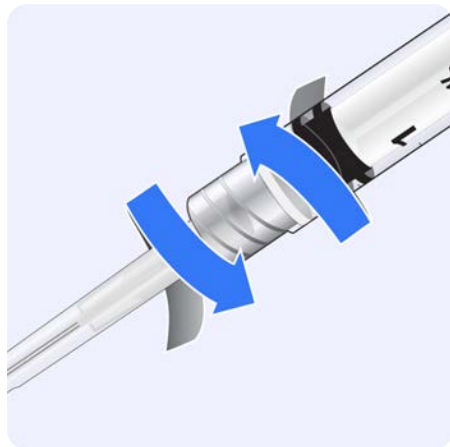
Fill the Cassette

Follow instructions from the insulin manufacturer for use and handling.

 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.

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.



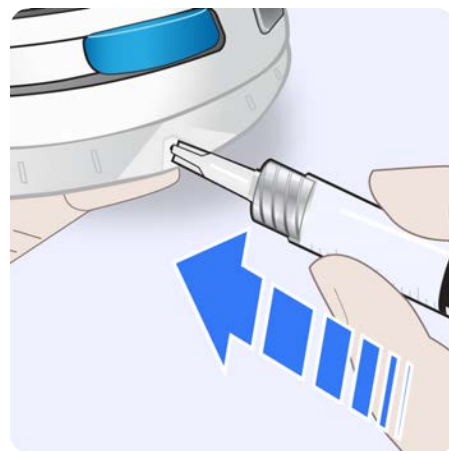
4. To fill the syringe with air, remove the cap from the needle and pull the syringe plunger out to the selected *Cassette Fill Volume*.
5. Insert the needle into the vial.
6. Inject air into the vial.

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*.



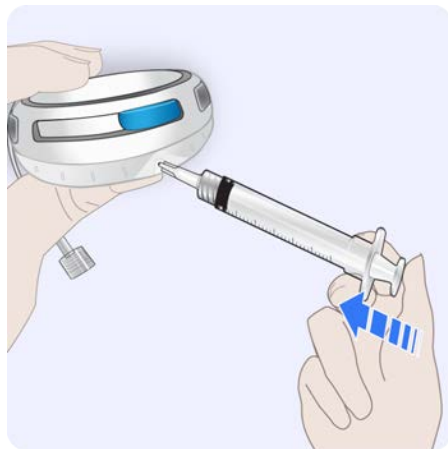
8. With the needle pointing upward, and still inserted in the vial, tap on the syringe to remove any visible air bubbles.
9. Tap **Next** to continue.

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



12. 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.



13. 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.

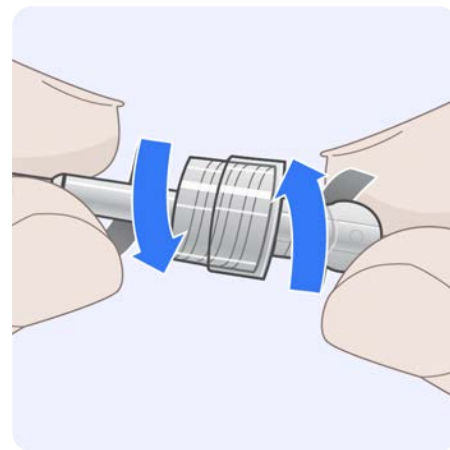
14. Tap **Next** to continue.

 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.

Prime the Cassette and Infusion Set Tubing

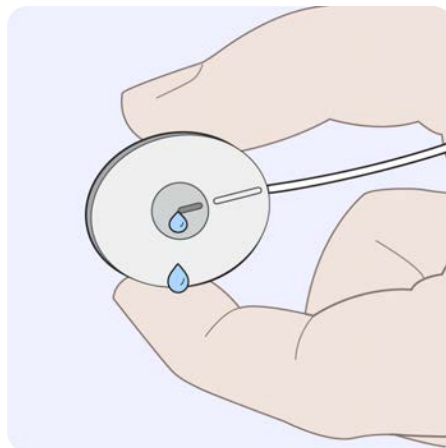
1. On the **twiist** app screen, tap **Start Prime**.



A series of *Busy Beeps* are 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.

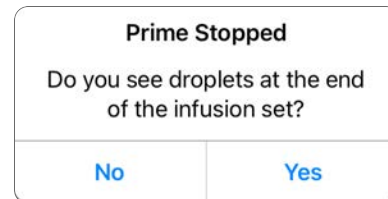


3. Tap **Stop Prime**.



A *Prime Stopped* notice is displayed.

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



Tap **No**, to return to the priming steps.

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 do not 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.

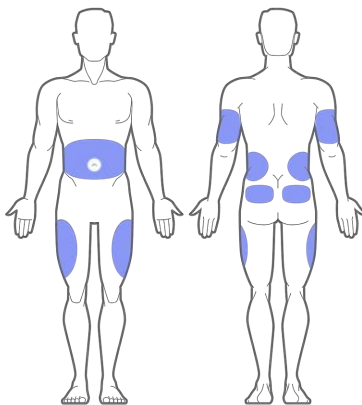
Infusion Site Selection

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 twist trainer or your healthcare 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.
- Avoid placing the infusion site on scars, moles, stretch marks, and tattoos.
- Avoid broken skin, cuts, and scrapes.

- Keep the infusion site away from your CGM
 - at least 1 inch (2.5 cm) from your FreeStyle Libre 3 Plus Sensor
 - at least 4 inches (10.16 cm) from your Eversense 365 Sensor
- Keep the infusion site at least 1 to 2 inches (2.5 to 5 cm) from your previous infusion site.

Site Rotation

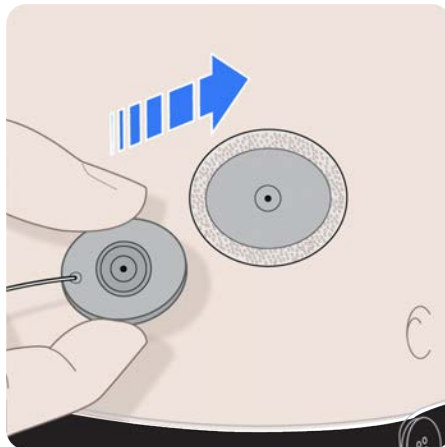
Replace your infusion set every 48 to 72 hours, or as instructed by your healthcare provider. Select a new infusion site. Using the same infusion site may cause scarring. Establish a schedule to rotate your infusion site that works best for you.

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 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.

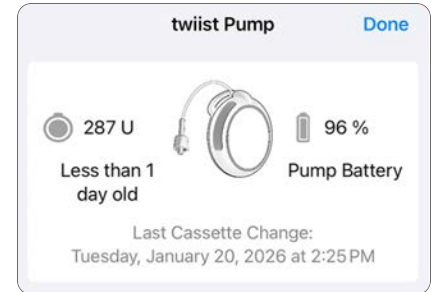
The *Home Screen* displays a *Temporary Status Banner* indicating the cannula fill is in progress.

- ! If air bubbles are present in the infusion set tubing, re-prime the tubing or 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 twist 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.

- i The volume remaining in the cassette is an estimate based on your initial cassette fill volume.



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.

Battery Change

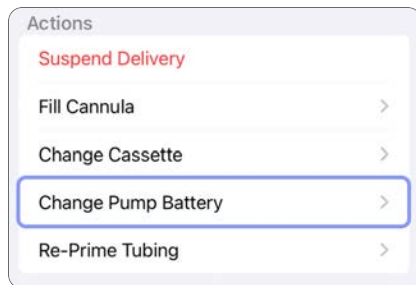
A *Battery Change* may need to be completed if a battery that was not fully charged was used to begin insulin delivery during your last *Cassette Change*.

Change Pump Battery

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



2. Tap **Change Pump Battery**.



Gather your Supplies

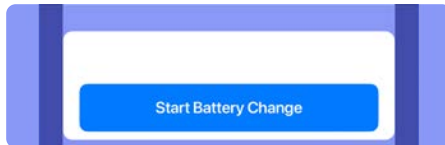
The following supplies are needed for a battery change:

- A fully charged pump battery

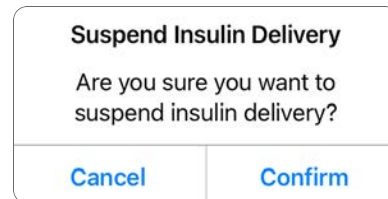
A fully charged pump battery is indicated by a green status light on the pump battery charger.

Start Battery Change

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



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



The pump plays the *Delivery Suspended* sound.

-  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.

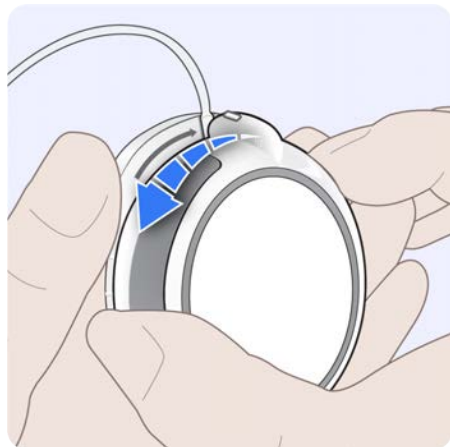
 Do not disconnect the infusion set tubing from the cassette at the luer connector. Disconnecting the infusion set tubing from the cassette at the luer connector can introduce air into the infusion set tubing which can lead to under or over delivery of insulin, which may lead to high or low blood glucose.

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.

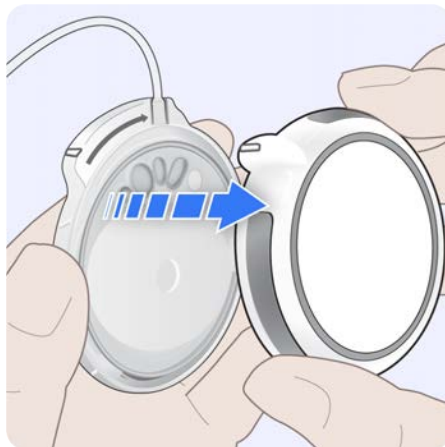
1. Holding the cassette still, rotate the pump counterclockwise until the ridges on the pump-bump and the top of the cassette are aligned.



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 twist 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 211](#) 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 *twist* app.

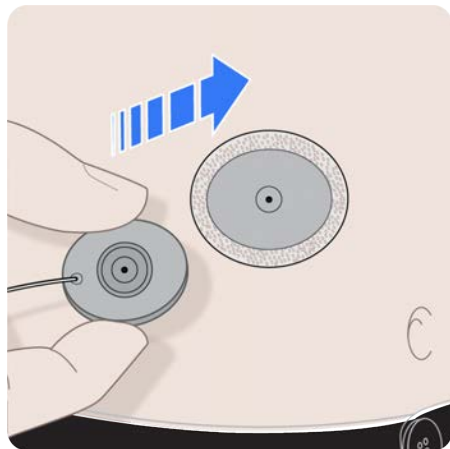
4. Wait for the self-test to complete before continuing. If you receive a *Restarting Battery Change* message, the cassette has been removed from the pump during the battery change process. Tap **OK** and restart the battery change.

! 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 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 basal delivery will start.

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

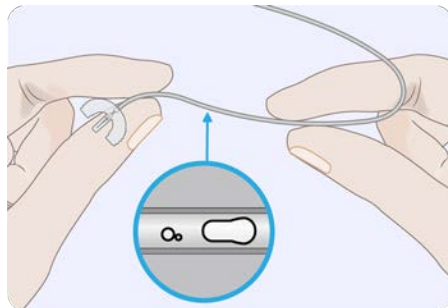
If you chose to fill the cannula, the *Home Screen* displays a *Temporary Status Banner* indicating the cannula fill is in progress.

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, re-prime the tubing or 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.

Re-Prime Tubing

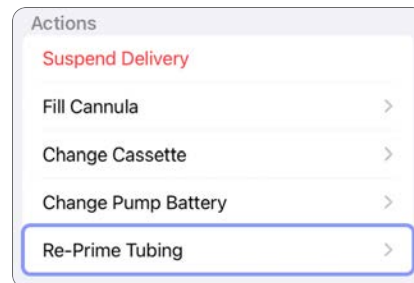
Re-Prime Tubing to remove air bubbles in your infusion set tubing.



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



2. Tap **Re-Prime Tubing**.



3. Tap **Start Prime Tubing**.
4. Tap **Confirm** to suspend insulin delivery.
The pump plays the *Delivery Suspended* sound.
 The pump sound will not be played when *Quiet Mode* is enabled.
5. Disconnect the infusion set tubing from your infusion site.

 Do not re-prime infusion set tubing while connected to your infusion site. Connecting the infusion set tubing while re-priming may lead to the unintended delivery of insulin which may result in low blood glucose.

6. Tap **Next**.
7. Confirm the tubing is disconnected and tap **Yes**.
8. On the *twist* app screen, tap **Start Prime**.



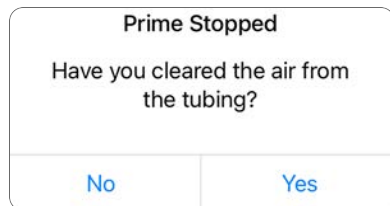
9. Use your smartphone passcode, facial recognition, or fingerprint to authenticate.
A series of *Busy Beeps* are played by the pump as priming occurs.

10. Tap **Stop Prime** when air bubbles in the infusion set tubing have been removed.



A *Prime Stopped* notice is displayed.

11. Tap **Yes** to confirm that priming is complete or tap **No**, to return to the priming steps.



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

- If you have cleared the air from the tubing, tap **Yes** to continue.
- If you have not cleared the air from the tubing, tap **No** to continue priming your cassette and infusion set tubing.

12. Check for leaks around the cassette and infusion set after priming. If leaks are visible, replace the cassette and infusion set tubing.

13. Reattach your infusion set tubing to your infusion site.

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

14. Tap **Start Basal**.

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

-  The pump 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 volume remaining in the cassette will be reduced to account for the additional volume primed.

Check for Pump Update

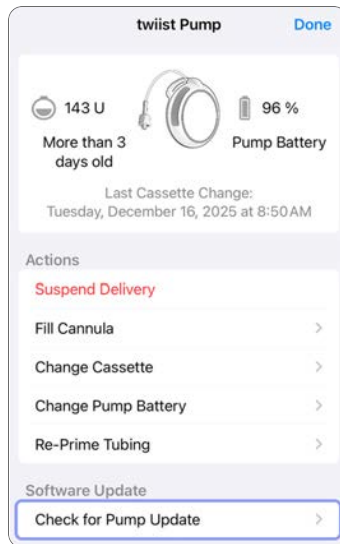
You can check to see if there is a software update available for your twist pump.

Make sure your smartphone and pump batteries are charged, and your smartphone has a Wi-Fi or cellular network connection in order to check for pump software updates.

Keep your pump close to your smartphone during pump software updates.

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

2. Tap **Check for Pump Update**.



If your pump is up to date, tap **Continue** to return to the *Home Screen*.

If a pump software update is available:

1. Tap **Continue**.
2. Disconnect your infusion set tubing from your infusion site.
3. Tap **Next** to suspend insulin delivery to continue the pump update.

The pump plays the *Delivery Suspended* sounds.

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

The twist app displays the pump update progress.

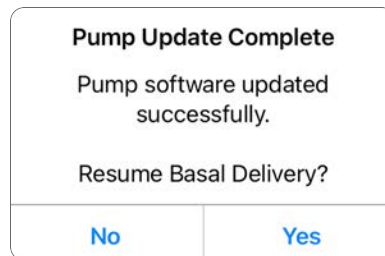
4. Keep your pump close to your smartphone. Do not quit the twist app, turn off your smartphone, or remove the battery from the pump during the pump software update.

When the pump software update is complete, a series of *Busy Beeps* will be played by the pump while the pump conducts a self-test. The self-test is displayed on the *twiist* app.

5. Wait for the self-test to complete.

 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 Pump Update Complete notice is displayed.



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

Upon resuming basal delivery, the pump plays the *Delivering* sounds.

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

Pair a New Pump

If you do not have a pump paired to the *twiist* app, you will need to pair a pump to access the Pump Menu.



Your smartphone must be connected to the internet to pair your new pump with the *twiist* app.

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 smartphone to a Wi-Fi or cellular network.

Give access to all required permissions, if prompted, so the *twiist* app works as expected.

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.
-  3. 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*.
6. Place the pump and smartphone close together and away from other wireless devices during pairing.
7. Tap **Pair Pump**.
8. Tap the **serial number** of your pump displayed within *Discovered Pumps*.
9. Tap **Take Photo** or **Enter Manually**.

Take Photo:

Use your smartphone camera to scan the QR code on your pump label.

- a. Tap **Take Photo**.

- b. Hold your smartphone 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.
- c. Tap **Connect**.

Enter Manually (iPhone):

- d. Tap in the *Bluetooth Pairing Request* field to display the *Paste* option.
- e. Tap **Paste** to enter the pump PIN.
- f. Tap **Pair**.

Enter Manually (iPhone):

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

Enter Manually (Android):

- a. Tap in the **Pump PIN** field to display the keypad.
- b. Enter the 6-digit PIN found on the pump label and tap the check mark.
- c. Tap **Connect**.
-  If a *Limited Internet Connectivity* notice is displayed, remove and reinsert the pump battery and try to pair the pump again after joining a cellular network or a different Wi-Fi network.

A Pump Software Update message is displayed.

- 10. Follow the on-screen instructions to update the pump.
- 11. After the pump update is complete, the pump plays a *Ready Beep*, tap **Continue**.

- 12. Follow the *Cassette Change* steps starting from "*Attach New Cassette to Pump*" on page 89.

Pair Your Existing Pump

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

Bluetooth Settings (iPhone)

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

1. Open iPhone **Settings**.
2. Tap **Bluetooth**.
3. Tap ⓘ next to your pump serial number.



4. Tap **Forget This Device**.
5. Tap **Forget Device** to confirm.

Your pump will be removed from the Bluetooth devices.

If you do not follow the steps to *Forget This Device*, the twist app will display a *Pump Pairing Failed* notice. Tap **OK** to dismiss the notice and follow the steps to *Forget This Device*.

Pair the Pump

Your smartphone must be connected to Wi-Fi or a cellular network in order to pair a pump.

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

Give access to all required permissions, if prompted, so the twist app works as expected.

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 smartphone 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*.
9. Tap **Take Photo** or **Enter Manually**.

Take Photo:

Use your smartphone camera to scan the QR code on your pump label.

- a. Tap **Take Photo**.
- b. Hold your smartphone 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.
- c. Tap **Connect**.

If you have an iPhone:

- d. Tap in the *Bluetooth Pairing Request* field to display the *Paste* option.
- e. Tap **Paste** to enter the pump PIN.
- f. Tap **Pair**.

Enter Manually (iPhone):

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

Enter Manually (Android):

- a. Tap in the **Pump PIN** field to display the keypad.
- b. Enter the 6-digit PIN found on the pump label and tap the check mark.
- c. Tap **Connect**.

 If a *Limited Internet Connectivity* notice is displayed, remove and reinsert the pump battery and try to pair the pump again after joining a cellular network or a different Wi-Fi network.

10. A *Pump Software Update* message is displayed.

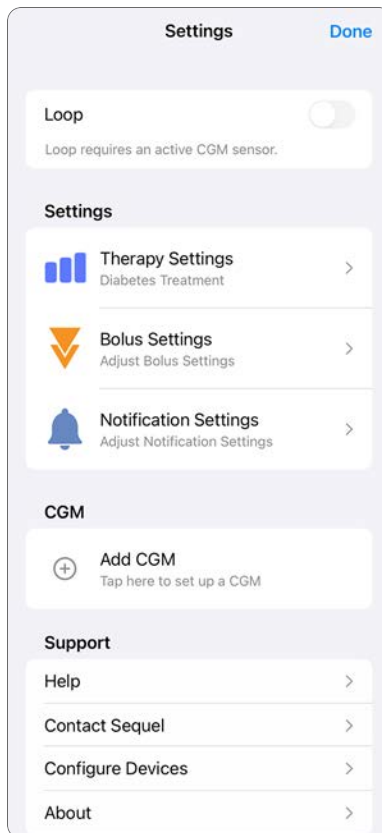
- If your pump software is up to date, tap **Continue**.
- If your pump software needs to be updated, follow the on-screen instructions to update the pump. After the pump update is complete, the pump plays a *Ready Beep*, tap **Continue**.

11. Follow the *Cassette Change* steps starting from "*Attach New Cassette to Pump*" on [page 89](#).

Settings

The **Settings**  button opens the **Settings Menu** to:

- Turn *Loop* On or Off
- View and edit your *Therapy Settings*, *Bolus Settings*, and *Notification Settings*
- Add a CGM
- Configure CGM Settings (when a compatible CGM has been added to the twist AID system)
- Access *Support*



Loop On and Off

The twist system can operate with *Loop* on or off.

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

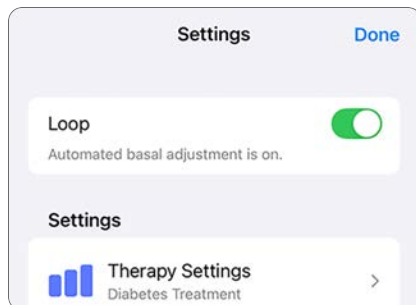
When *Loop* is **OFF**, your basal is delivered at your scheduled basal rates.

Loop is 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.

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

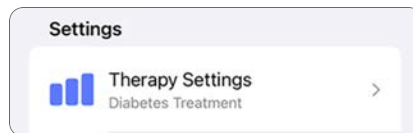
2. Tap the **Loop** toggle to turn *Loop* on or off.



Therapy Settings

Your *Therapy Settings* are initially entered during pump training with your certified twist 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*.
2. Tap **Therapy Settings**.



Values entered that are higher or lower than those that are typically recommended for most people will caution  or warn  you about the selected values.

 Do not set glucose unit of measure (Android), 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 Unit of Measure (Android)

The *twiist* AID system can display glucose in mg/dL or mmol/L. You can choose which unit of measure is used by the system.

Edit Glucose Unit of Measure

1. Tap **Settings**  on the *Toolbar*.
2. Tap **Therapy Settings**.
3. Tap **Glucose Units**.
4. Tap **mg/dL** or **mmol/L**.
5. Tap **Save**.
6. Use your smartphone passcode, facial recognition, or fingerprint to authenticate.

Use the Apple Health app to update your glucose unit of measure when using the *twiist* app on your iPhone. See "[Apple Health \(iPhone\)](#)" on page 157.

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 the *Glucose Safety 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 and as high as 110 mg/dL.

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**.
7. Use your smartphone passcode, facial recognition, or fingerprint to authenticate.

Correction Ranges

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.

The *twiist* AID system allows you to enter *Correction Ranges* in 30-minute increments, so you can set up to 48 individual *Correction Ranges* per day.

The *Correction Range* schedule starts at midnight.

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

Edit Correction Ranges

1. Tap **Settings**  on the *Toolbar*.
2. Tap **Therapy Settings**.
3. Tap **Correction Ranges**.
4. Tap the *Correction Range* you want to edit.
5. Use the picker to select a **low and high value**.
6. Tap **Save**.
7. Use your smartphone passcode, facial recognition, or fingerprint to authenticate.

Add a Correction Range

1. Tap **Settings**  on the *Toolbar*.
2. Tap **Therapy Settings**.
3. Tap **Correction Ranges**.
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**.
9. Use your smartphone passcode, facial recognition, or fingerprint to authenticate.

Delete a Correction Range

1. Tap **Settings**  on the *Toolbar*.
2. Tap **Therapy Settings**.
3. Tap **Correction Ranges**.

4. Tap **Delete**.

 You cannot delete the *Correction Range* that begins at 12:00 AM.

5. Tap the  icon next to the *Correction Range* you would like to delete.
6. Tap **Delete**.
7. Tap **Done**, when updates to *Correction Ranges* have been completed.
8. Tap **Save**.
9. Use your smartphone passcode, facial recognition, or fingerprint to authenticate.

Pre-Meal Range

Your *Pre-Meal Range* is the glucose value or range of values you want the twist 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*.

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

Your *Pre-Meal Range* can be entered as low as 67 mg/dL or your *Glucose Safety Limit*, and as high as 130 mg/dL.

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**  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**.
7. Use your smartphone passcode, facial recognition, or fingerprint 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 is in effect when you activate the *Workout Preset*.

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

Your *Workout Range* can be entered as low as 87 mg/dL or your *Glucose Safety Limit*, and as high as 250 mg/dL.

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**  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**.

7. Use your smartphone passcode, facial recognition, or fingerprint to authenticate.

Carb Ratios

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

The twist AID system allows you to enter *Carb Ratios* in 30-minute increments, so you can set up to 48 individual *Carb Ratios* per day.

The *Carb Ratio* schedule starts at midnight.

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**  on 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**.
7. Use your smartphone passcode, facial recognition, or fingerprint to authenticate.

Add a Carb Ratio

1. Tap **Settings**  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**.

9. Use your smartphone passcode, facial recognition, or fingerprint to authenticate.

Delete a Carb Ratio

1. Tap **Settings**  on the *Toolbar*.
2. Tap **Therapy Settings**.
3. Tap **Carb Ratios**.
4. Tap **Delete**.
 You cannot delete the carb ratio that begins at 12:00 AM.
5. Tap the  icon next to the carb ratio you would like to delete.
6. Tap **Delete**.
7. Tap **Done**, when updates to *Carb Ratios* have been completed.
8. Tap **Save**.

9. Use your smartphone passcode, facial recognition, or fingerprint 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 twist 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**  on 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*.
6. Use the picker to select the new *Basal Rate U/hr* value.
7. Tap **Save**.
8. Use your smartphone passcode, facial recognition, or fingerprint to authenticate.

Add a Basal Rate

1. 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**.
8. Tap **Save**.
9. Use your smartphone passcode, facial recognition, or fingerprint to authenticate.

Delete a Basal Rate

1. Tap **Settings**  on the *Toolbar*.
2. Tap **Therapy Settings**.
3. Tap **Basal Rates**.
4. Tap **Delete**.
 You cannot delete the basal rate that begins at 12:00 AM.

5. Tap the  icon next to the *Basal Rate* you would like to delete.
6. Tap **Delete**.
7. Tap **Done**, when updates to *Basal Rates* have been completed.
8. Tap **Save**.
9. Use your smartphone passcode, facial recognition, or fingerprint to authenticate.

Delivery Limits

Delivery Limits are safety guardrails for your insulin delivery, including the adjustments that the twist 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 twist AID system. When *Loop* is on, the *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. The lowest and highest this value can be set to is limited by your scheduled basal rates and your carb ratios.

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 81.](#)

1. Tap **Settings**  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**.
7. Use your smartphone passcode, facial recognition, or fingerprint 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).

Maximum Bolus can be entered as low as 1 Unit and as high as 25 Units in 1 Unit increments.

Insulin delivery must be suspended before the *Maximum Bolus* can be modified. [See "Suspend Insulin Delivery" on page 81.](#)

1. Tap **Settings**  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**.
7. Use your smartphone passcode, facial recognition, or fingerprint to authenticate.

Insulin Model

The twist 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**  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  symbol.

5. Tap **Save**.
6. Use your smartphone passcode, facial recognition, or fingerprint 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 and as high as 500 mg/dL per Unit in 1 mg/dL per Unit increments.

Edit your Insulin Sensitivities

1. Tap **Settings**  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**.
7. Use your smartphone passcode, facial recognition, or fingerprint to authenticate.

Add an Insulin Sensitivity

1. Tap **Settings**  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 an *Insulin Sensitivity* value.
7. Tap **Add**.
8. Tap **Save**.

9. Use your smartphone passcode, facial recognition, or fingerprint to authenticate.

Delete an Insulin Sensitivity

1. Tap **Settings**  on the *Toolbar*.
2. Tap **Therapy Settings**.
3. Tap **Insulin Sensitivities**.
4. Tap **Delete**.
 You cannot delete the *Insulin Sensitivity* that begins at 12:00 AM.
5. Tap the  icon next to the *Insulin Sensitivity* you would like to delete.
6. Tap **Delete**.
7. Tap **Done**, when updates to *Insulin Sensitivity* have been completed.
8. Tap **Save**.

9. Use your smartphone passcode, facial recognition, or fingerprint 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:

1. With *Loop* off, tap **Settings**  on the *Toolbar*.
2. Tap **Therapy Settings**.
3. Tap **Temporary Basal**.
4. Tap **Percent** or **Rate** to select the desired method for *Temporary Basal Adjustment*. The selection will be followed by the  symbol.
5. Tap **Save**.

To set a *Temporary Basal*, See "*Set Temporary Basal*" on page 182.

Bolus Settings

Bolus Settings allow you to adjust options for:

- One-Button Bolus
- Extended Bolus
- Dual Bolus

All changes to *Bolus Settings* should be made with direction from your healthcare provider.

1. Tap **Settings**  on the *Toolbar*.
2. Tap **Bolus Settings**.

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.

To deliver a *One-Button Bolus*, this feature must be enabled within *Bolus Settings*.

1. Tap **Settings**  on the *Toolbar*.
2. Tap **Bolus Settings**.
3. Tap **One-Button Bolus**.
4. Tap the toggle to enable or disable.
5. Tap **Save** to return to *Bolus 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 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 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.

1. With *Loop* off, tap **Settings**  on the *Toolbar*.
2. Tap **Bolus Settings**.

3. Tap **Extended Bolus** or **Dual Bolus**.
4. Tap the toggle to enable or disable the *Extended Bolus* or *Dual Bolus*.
5. Tap **Save** to return to *Bolus Settings*.

Notification Settings

Notification Settings allow you to view or adjust the following settings:

- Critical Alert Volume (iPhone)
 - Do Not Disturb Override Volume (Android)
 - Pump Sounds and Quiet Mode
 - Low Insulin Alert #1
 - Low Insulin Alert #2
 - Phone Out of Range
 - Pump Inactive Alert
 - Cassette Change Reminder
1. Tap **Settings**  on the *Toolbar*.
 2. Tap **Notification Settings**.

Critical Alert Volume (iPhone)

The *Critical Alert Volume* setting allows you to adjust the volume your iPhone will play notifications that are delivered as *Critical Alerts*.

Notifications delivered as *Critical Alerts* from the twist app are displayed and played at the *Critical Alert Volume*, even when your iPhone is silenced or Focus is enabled.

1. Tap **Settings**  on the *Toolbar*.
2. Tap **Notification Settings**.
3. Tap **Critical Alert Volume**.
Tap  for more information.
4. Select **High**, **Medium**, or **Low** volume.

To test the sound level, tap .

5. Tap **Save** to return to *Notification Settings*.

Do Not Disturb Override Volume (Android)

The *Do Not Disturb Override Volume* setting allows you to adjust the volume your Android smartphone will play notifications delivered with Modes Access.

Notifications from the twist app that are delivered with Modes Access are displayed and played at the *Do Not Disturb Override Volume* even when your Android is silenced or Do Not Disturb is turned on.

 Some Android Modes prevent the use of selected apps while active. Ensure the twist app is included in the list of unaffected apps whenever using Android Modes.

1. Tap **Settings**  on the *Toolbar*.
2. Tap **Notification Settings**.
3. Tap **Do Not Disturb Override Volume**.
4. Select **High**, **Medium**, or **Low** volume.
To test the sound level, tap .
5. Tap **Save** to return to *Notification Settings*.

Pump Sounds

Pump Sounds provide access to settings for:

- Pump Volume Level
- Quiet Mode

Volume Level

Volume Level allows you to adjust the pump volume.

1. Tap **Settings**  on the *Toolbar*.
2. Tap **Notification Settings**.
3. Tap **Pump Sounds**.
Tap  for more information.
4. Select **High**, **Medium**, or **Low** volume.
To test the sound level, tap .
5. Tap **Save** to return to *Notification Settings*.

 Alarms and Urgent Low Glucose alerts that have not been silenced will escalate from the selected pump volume level.

Quiet Mode

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

Quiet Mode is off by default.

When *Quiet Mode* is on and the twist pump and app are in communication, the following conditions apply:

Quiet Mode will not play pump sounds for changes to delivery made with the twist app including:

- Suspend or resume insulin delivery
- Start or stop bolus delivery
- Start or stop temporary basal

Quiet Mode does not silence interactions with the pump button including:

- Verify delivery
- *One-Button Bolus* programming and delivery
- Pump pairing mode

Quiet Mode never silences pump sounds played for:

- Alerts
- Urgent Low Glucose alerts

• Alarms

1. Tap **Settings**  on the *Toolbar*.
2. Tap **Notification Settings**.
3. Tap **Pump Sounds**.
Tap  for more information.
4. Tap **Enable Quiet Mode**.
5. Tap **Save** to return to *Notification 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.

1. Tap **Settings**  on the *Toolbar*.
2. Tap **Notification Settings**.
3. Tap **Low Insulin Alert #1** to view the setting.

4. Tap **Back** to return to the *Notifications Settings*.

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 system estimates 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**  on the *Toolbar*.
2. Tap **Notification 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** to return to *Notification Settings*.

Phone Out of Range Alert

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

Phone Out of Range is off by default.

1. Tap **Settings**  on the *Toolbar*.
2. Tap **Notification Settings**.
3. Tap **Phone Out of Range Alert**.

4. Tap the toggle to enable or disable.

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

5. Tap **Save** to return to *Notification 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 30 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 smartphone as a Critical Alert (iPhone) or notification with Modes Access (Android).

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

2. Tap **Notification 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** to return to *Notification Settings*.

Cassette Change Reminder

Cassette Change Reminder allows you to set a reminder time to change your cassette.

The *Cassette Change Reminder* default is off.

1. Tap **Settings**  on the *Toolbar*.
2. Tap **Notification Settings**.
3. Tap **Cassette Change Reminder**.

4. Tap **Enable Reminder** to turn on or off.
5. Use the picker to select your **Reminder Time**.
Cassette change reminder can be set from 2-3 days in 1-hour increments.
6. Tap **Save** to return to *Notification Settings*.

A *Cassette Change Reminder* notice is displayed when the *Reminder Time* has expired.

CGM

The *twiist AID* system can be used with the FreeStyle Libre 3 Plus or Eversense 365 to provide sensor glucose readings through a Bluetooth connection with the *twiist* pump.

Add CGM

The steps to *Add CGM* only need to be completed one time to add the FreeStyle Libre 3 Plus Sensor or Eversense 365 CGM features into the *twiist* app.

Add a FreeStyle Libre 3 Plus:

When used with the *twiist AID* system, the FreeStyle Libre 3 Plus Sensor can only be paired with the *twiist AID* system.

Do not pair your FreeStyle Libre 3 Plus Sensor with the Libre app or reader.

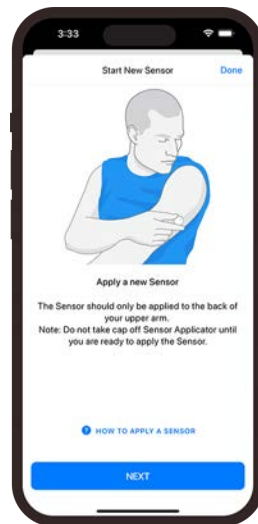
A FreeStyle Libre 3 Plus Sensor that has been previously paired with the Libre app or reader cannot be paired with the twist AID system.

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

1. Tap **Add CGM+** in the *CGM Status*, or tap **Settings**  and tap **Add CGM**.
2. Tap **FreeStyle Libre 3 Plus**.
3. Clean hands prior to FreeStyle Libre 3 Plus Sensor handling and insertion to help prevent infection.
4. 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.
5. Apply your new sensor.

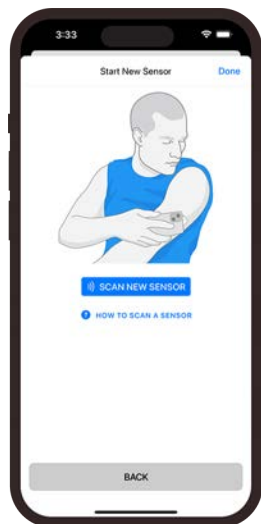
For instructions on how to apply the sensor, tap  **HOW TO APPLY A SENSOR**.



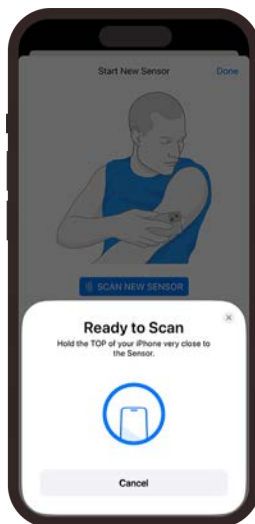
 Applying the sensor may cause bruising or bleeding. If there is bleeding that does not stop, remove the sensor and contact your healthcare provider.

6. Put the cap back on the Sensor Applicator. Discard the Sensor Applicator according to local regulations.
7. Tap **NEXT**.
8. Tap **SCAN NEW SENSOR**.

For instructions on how to scan a sensor, tap [? HOW TO SCAN A SENSOR](#).



9. Hold the top (iPhone) or back (Android) of your smartphone close to the sensor. Distance may vary based on the smartphone you are using.



[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.



10. Tap **Done**.

The *CGM Status* displays *Sensor Warmup*.



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

11. Tap the notification to open the *twiist* app.

12. Tap **OK**.

Add an Eversense 365

The Eversense 365 smart transmitter must be paired and connected with the Eversense 365 app on your smartphone before pairing with the *twiist* AID system.

Use the Eversense 365 app to calibrate your sensor, place your smart transmitter, and configure CGM notifications.

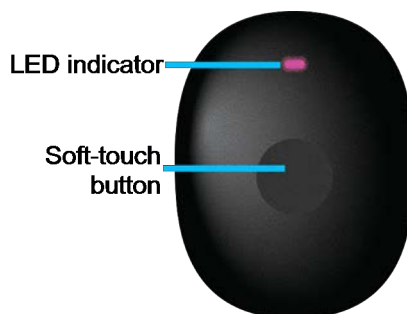
Refer to the Eversense 365 manufacturer instructions for safety and proper use information.

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

2. Tap **Eversense 365**.

The *twiist* app will display *Searching for smart transmitter*.

3. Tap the **Smart Transmitter Soft-touch button** three times to start pairing mode.



The smart transmitter will blink pink to indicate it is in pairing mode.

 The smart transmitter will blink blue to indicate it is not paired and connected to the Eversense 365 app before pairing with the *twiist* AID system.

The *twiist* app will display *Pairing* followed by *Pairing Complete*.

After pairing and connecting with the Eversense 365 smart transmitter, the *CGM Status* on the home screen may vary. Follow the instructions for the Eversense 365 CGM to make sure sensor warmup and calibrations are complete and CGM readings are available in the *twiist* AID system.

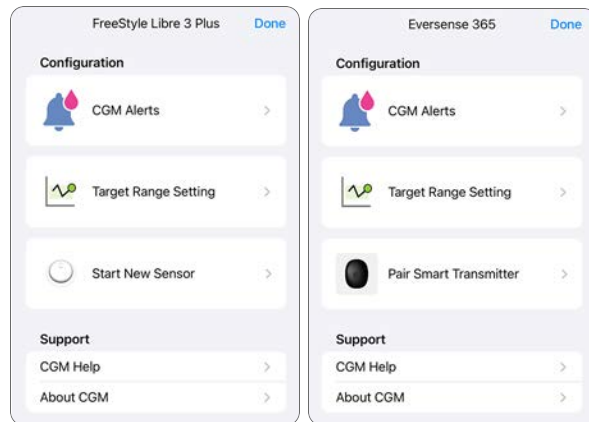
CGM Menu

1. Tap **Settings**  on the *Toolbar*.
2. Tap **FreeStyle Libre 3 Plus** or **Eversense 365 Settings**.

The contents of this menu varies based on the CGM you are using with the twist AID system.

The CGM Menu includes:

- CGM Alerts
- Target Range Setting
- Start New Sensor (FreeStyle Libre 3 Plus only)
- Pair Smart Transmitter (Eversense 365 only)
- CGM Help
- About CGM



CGM Alerts

The twiist AID system, when used with a compatible CGM, provides CGM notices and alerts.

 When the twiist AID system is used with the Eversense 365 CGM, additional notifications are provided by the Eversense 365 app.

1. Tap **Settings**  on the *Toolbar*.
2. Tap **FreeStyle Libre 3 Plus** or **Eversense 365 Settings**.
3. Tap **CGM Alerts**.

CGM Signal Loss Alert

The *CGM Signal Loss* alert notifies you when your CGM has not communicated with the twiist pump, and you can not receive CGM glucose readings or alerts.

If *Loop* is on and *CGM Signal Loss* occurs, the twiist AID system will not be able to complete a *Loop* in order to adjust basal delivery.

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 **Receive Alert after** and use the picker to select a value.
3. Tap **Save**.

Override Focus (iPhone) or *Override Do Not Disturb (Android)* is on by default. Keep this setting on to deliver *CGM Signal Loss* alerts as Critical Alerts (iPhone) or notifications with Modes Access (Android).

Urgent Low Glucose Alert

An *Urgent Low Glucose* alert notifies you when your sensor glucose reading is at or below 55 mg/dL. For your safety, the *Urgent Low Glucose* alert cannot be disabled, and is always played by your smartphone as a Critical Alert (iPhone) or a notification with Modes Access (Android).

Urgent Low Glucose Alert Snooze Duration

The *Urgent Low Glucose* alert will repeat after the *Snooze Duration* if your glucose is still at or below the urgent alert level.

The *Urgent Low Glucose Snooze Duration* is set to 15 minutes and cannot be adjusted.

Low Glucose Alert

The *Low Glucose* alert will alert you when your glucose reading falls below the configured value.

The *Low Glucose* alert is on by default, is initially set to 70 mg/dL, and can be set between 60-100 mg/dL in 5 mg/dL increments.

To change Low Glucose Alert value:

1. Tap **Low Glucose Alert**.
2. Tap **When glucose goes below** and use the picker to select a *Low Glucose Alert* value.
3. Tap **Save** to return to *CGM Alerts*.

When the *Low Glucose* alert is on, a red line is displayed on the CGM Status glucose chart at the *Low Glucose* alert value.

Low Glucose Alert Snooze Duration

The *Low Glucose* alert will repeat after the *Snooze Duration* if your glucose is still below the alert level.

The *Low Glucose Snooze Duration* is initially set to 15 minutes, but can be set between 15 min and 2 hours in 5 minute increments.

To change Low Glucose Alert Snooze Duration:

1. Tap **Snooze Duration** value and use the picker to select a value.
2. Tap **Save** to return to *CGM Alerts*.

Override Focus (iPhone) or *Override Do Not Disturb (Android)* is on by default. Keep this setting on to deliver *Low Glucose* alerts as Critical Alerts (iPhone) or notifications with Modes Access (Android).

High Glucose Alert

The *High Glucose* alert will alert you when your glucose reading rises above the configured value.

The *High Glucose* alert is on by default, and is initially set to 250 mg/dL. It can be set between 120-400 mg/dL in 10 mg/dL increments.

To change the High Glucose alert value:

1. Tap **High Glucose Alert**.

2. Tap **When glucose goes above** and use the picker to select a *High Glucose Alert* value.
3. Tap **Save** to return to *CGM Alerts*.

When the *High Glucose* CGM alert is on, an orange line is displayed on the CGM Status glucose chart at the set *High Glucose* CGM alert value.

High Glucose Alert Snooze Duration

The *High Glucose* alert will repeat after the *Snooze Duration* if your glucose is still above the alert level.

The *High Glucose Snooze Duration* is initially set to 1 hour, but can be set between 15 minutes and 4 hours in 5 minute increments.

To change High Glucose Alert Snooze Duration:

1. Tap **Snooze Duration** value and use the picker to select a value.
2. Tap **Save** to return to *CGM Alerts*.

Override Focus (iPhone) or *Override Do Not Disturb (Android)* is on by default. Keep this setting on to deliver *High Glucose* alerts as Critical Alerts (iPhone) or notifications with Modes Access (Android).

Sleep Schedule

The *Sleep Schedule* allows you to set different *High* and *Low Glucose* alert values during a specified time of the day.

The *Sleep Schedule* is off by default.

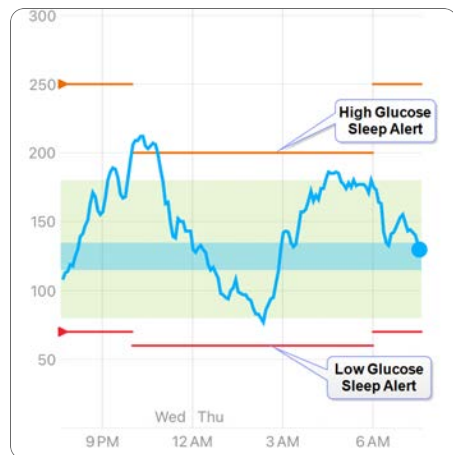
The *Sleep Schedule* can only be enabled when the *High* and *Low Glucose* alerts are turned on.

To turn on the Sleep Schedule:

1. Tap **Sleep Schedule**.
2. Tap **Enable Sleep Schedule** to turn on or off.
3. Select start and end times for your *Sleep Schedule*.
4. Tap **Low Glucose Sleep Value** and use the picker to select a value.

5. Tap **High Glucose Sleep Value** and use the picker to select a value.
6. Tap **Save** to return to *CGM Alerts*.

The CGM status screen displays your high and low glucose alert levels for your sleep schedule.



Target Range Setting

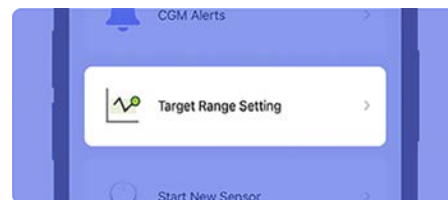
Set your *Target Range* settings with your healthcare provider. Your *Target Range* is displayed on the *CGM Status* screen glucose chart.

Your *Target Range* and current glucose readings determine the color on the *CGM Status* screen.

i When used with an Eversense 365 CGM, *Target Range* is set independently in both the twist app and Eversense 365 app. Setting different *Target Ranges* in the twist and Eversense 365 apps may result in different *Target Range* background colors being displayed.

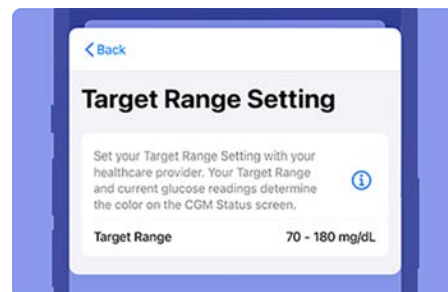
1. Tap **Settings**  on the *Toolbar*.

2. Tap **FreeStyle Libre 3 Plus Settings** or **Eversense 365 Settings**.
3. Tap **Target Range Setting**.



Tap **i** for more information.

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



5. Tap **Save** to return to the **CGM Menu**.

Target Range has a default value of 70 to 180 mg/dL and is used to calculate your time in target range.

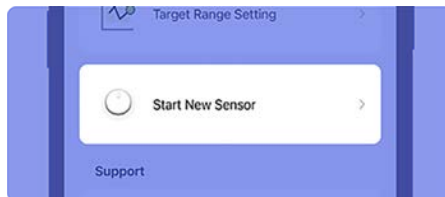
Target Range is different than your *Correction Range*. To review or edit your *Correction Range*, see ["Correction Ranges" on page 115](#).

 *Target Range* does not set glucose related CGM alert levels.

[Start a New Sensor \(FreeStyle Libre 3 Plus Only\)](#)

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

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



4. Tap **Yes** to continue.
5. Clean hands prior to FreeStyle Libre 3 Plus Sensor handling and insertion to help prevent infection.
6. 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.

7. Apply your new sensor.

For instructions on how to apply the sensor, tap  [HOW TO APPLY A SENSOR](#).

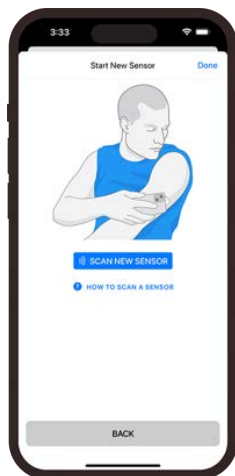


i Applying the sensor may cause bruising or bleeding. If there is bleeding that does not stop, remove the sensor and contact your healthcare provider.

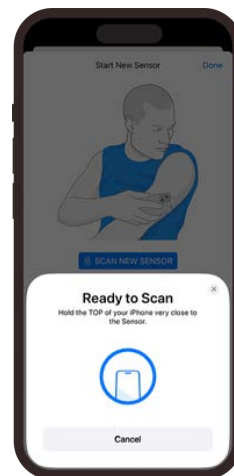
8. Put the cap back on the sensor applicator. Discard the sensor applicator according to local regulations.
9. Tap **NEXT**.

10. Tap **SCAN NEW SENSOR**.

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



11. Hold the top (iPhone) or back (Android) of your smartphone close to the sensor. Distance may vary based on the smartphone you are using.



- 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.



12. Tap **Done**.

The *CGM Status* displays *Sensor Warmup*.



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

13. Tap the notification to open the *twiist* app.

14. Tap **OK**.

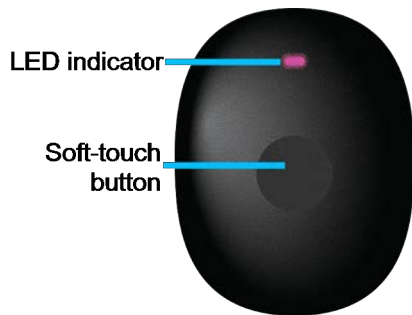
Pair Smart Transmitter (Eversense 365 Only)

The Eversense 365 smart transmitter must be paired and connected with the Eversense 365 app on your smartphone before pairing with the *twiist* AID system.

Use the Eversense 365 app to calibrate your sensor, place your smart transmitter, and configure CGM notifications.

Refer to the Eversense 365 manufacturer instructions for safety and proper use information.

1. Tap **Settings**  on the *Toolbar*.
2. Tap **Eversense 365 Settings**.
3. Tap **Pair Smart Transmitter**.
Pairing a smart transmitter will disconnect the smart transmitter you are currently using.
4. Tap **Yes** to continue.
The *twiist* app will display *Searching for smart transmitter*.
5. Tap the **Smart Transmitter Soft-touch button** three times to start pairing mode.



The smart transmitter will blink pink to indicate it is in pairing mode.

i The smart transmitter will blink blue to indicate it is not paired and connected to the Eversense 365 app before pairing with the twist AID system.

The twist app will display *Pairing* followed by *Pairing Complete*.

6. Tap **Done**.

After pairing and connecting with the Eversense 365 smart transmitter, the *CGM Status* on the home screen may vary. Follow the instructions for the Eversense 365 CGM to make sure sensor warmup and calibrations are complete and CGM readings are available in the twist AID system.

CGM Help

1. Tap **Settings**  on the *Toolbar*.
2. Tap **FreeStyle Libre 3 Plus Settings** or **Eversense 365 Settings**.
3. Tap **CGM Help**.
4. Tap any help topic to select the topic you would like to review.

Help topics include:

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

* Included when using a FreeStyle Libre 3 Plus Sensor only.

About CGM

About CGM provides information about the CGM in use with the twiist AID system.

1. Tap **Settings**  on the *Toolbar*.
2. Tap **FreeStyle Libre 3 Plus Settings** or **Eversense 365 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**  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 *Help*.

Contact Sequel

1. Tap **Settings**  on the *Toolbar*.
2. Tap **Contact Sequel** to access www.twiist.com/twiist-on-support for product support and additional resources.

Configure Devices

Configure devices provides access to:

- Delete a pump from the twiist app
 - Delete all CGM features from the twiist app
1. Tap **Settings**  on the *Toolbar*.
 2. Tap **Configure Devices**.

Delete Pump

The twist 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**  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 109*.

Delete CGM

1. Tap **Settings**  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 CGM features will be removed from the twist app.

To continue with automated insulin delivery, *see "Add CGM" on page 128*.

About

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

1. Tap **Settings**  on the *Toolbar*.
2. Tap **About**.

CGM Status Screen

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

1. Filter
2. Current Glucose
3. Glucose Trend Arrow
4. Confirm Sensor Glucose*
5. Message
6. High Glucose Alert Level
7. Glucose Readings
8. Target Range
9. Correction Range
10. Low Glucose Alert Level
11. Sensor Life*

* Included when using a FreeStyle Libre 3 Plus Sensor only.



Check Your CGM Status

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

The *CGM Status* screen displays CGM information including your current glucose, glucose trend arrow, and a chart of your current and past glucose readings.

When used with a FreeStyle Libre 3 Plus Sensor, the *CGM Status* screen will also provide information on *Sensor Warmup*, sensor errors, and sensor time remaining.

When CGM Alerts are not available, the *CGM Alerts Unavailable*  icon is displayed on the *CGM Status* screen.

Check Your CGM Glucose

The glucose chart displays glucose readings above 400 mg/dL as 400 mg/dL. For consecutive readings above 400 mg/dL, a line is displayed at 400 mg/dL. The *Current Glucose* value can be as high as 400 mg/dL.

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

 When using the Eversense 365 app, there may be times when CGM value or status does not match the Eversense 365 app.

 In the Eversense 365 app, when a sensor glucose reading is displayed in gray, without a trend arrow, and a message that says *Use BG Meter for Treatment Decisions*, this reading is not used by the *twiist* AID system. Instead, *twiist* displays *Open 365 app*.

The *twiist* AID system and Eversense 365 app receive CGM readings from the Eversense 365 smart transmitter independently. The *twiist* app may show information provided by the Eversense 365 smart transmitter up to 1 minute before the Eversense 365 app.

Your current glucose value and *Target Range* determines the background color displayed on the *CGM Status* screen.

High glucose - above 250
mg/dL

Between *Target Range* and
250 mg/dL

Glucose within your *Target
Range*

Between *Target Range* and 70
mg/dL

Low glucose - below 70 mg/dL

 When used with an Eversense 365 CGM, *Target Range* is set independently in both the *twiist* app and Eversense 365 app. Setting different *Target Ranges* in the *twiist* and Eversense 365 apps may result in different *Target Range* background colors being displayed.

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 63.](#)

CGM Messages

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

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

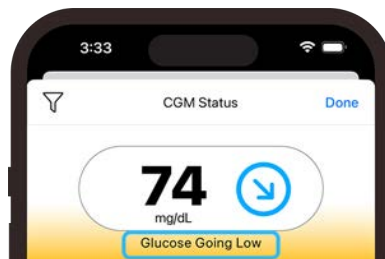
Glucose Going Low

The twist AID system is projecting that your glucose will be lower than 70 mg/dL within 15 minutes.

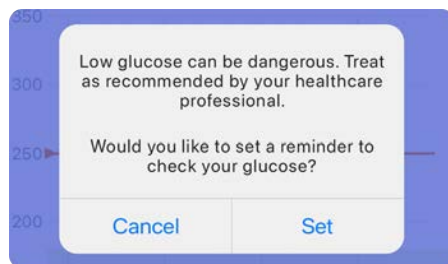
1. Tap **CGM Status**.



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**.

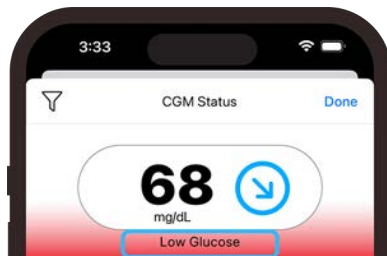
Low Glucose

Your current CGM reading is lower than 70 mg/dL.

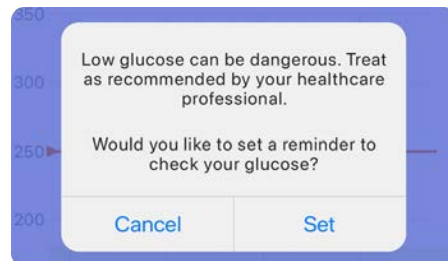
1. Tap **CGM Status**.



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**.

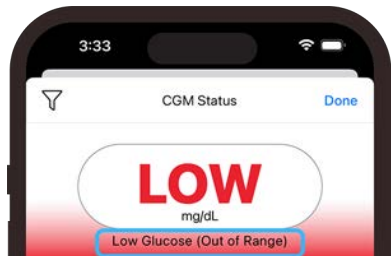
Low Glucose (Out of Range)

Your current CGM reading is lower than 40 mg/dL.

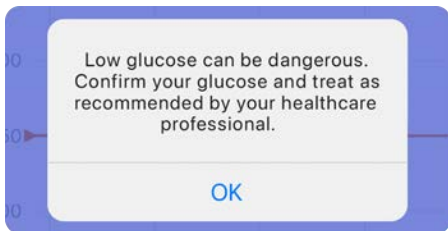
1. Tap **CGM Status**.



2. Tap the **Low Glucose (Out of Range)** message for more information.



3. Tap **OK**. Check your blood glucose with a fingerstick.



4. If you get a second *LOW* after the fingerstick, contact your healthcare provider immediately.

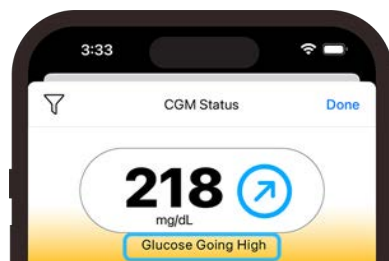
Glucose Going High

The twist AID system is projecting that your glucose will be higher than 250 mg/dL within 15 minutes.

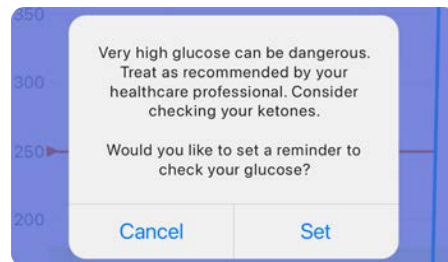
1. Tap **CGM Status**.



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**.

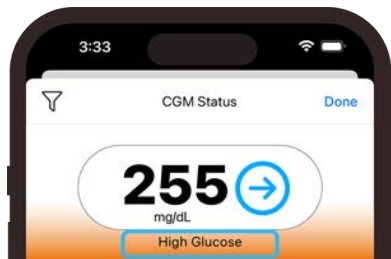
High Glucose

Your current CGM reading is higher than 250 mg/dL.

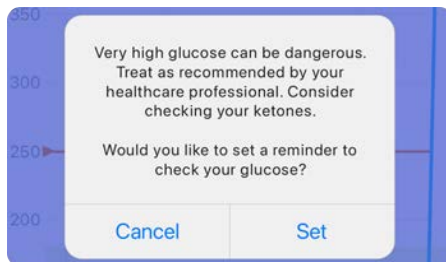
1. Tap **CGM Status**.



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**.

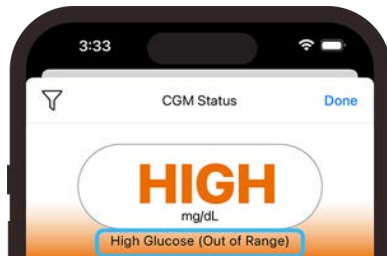
High Glucose (Out of Range)

Your current CGM reading is higher than 400 mg/dL.

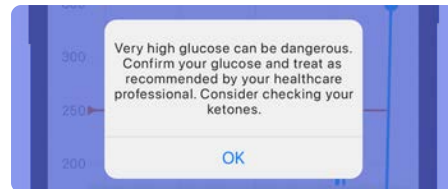
1. Tap **CGM Status**.



2. Tap the **High Glucose (Out of Range)** message for more information.



3. Tap **OK**. Check your blood glucose with a fingerstick.



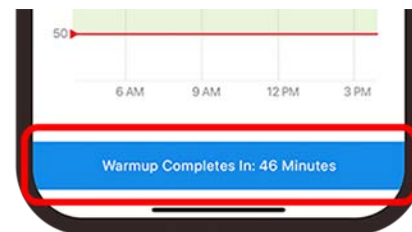
4. If you get a second **HIGH** after the fingerstick, contact your healthcare provider immediately.

Sensor Warmup

Your CGM is warming up.



When used with a FreeStyle Libre 3 Plus Sensor, tap **CGM Status** and refer to the bottom of the screen for the time remaining until **Sensor Warmup** completes.



 The **Warmup Complete** time is only displayed when used with a FreeStyle Libre 3 Plus Sensor.

When used with an Eversense 365 CGM, the Eversense 365 app will inform you when warmup is complete, and the next steps required to begin receiving CGM readings.

FreeStyle Libre 3 Plus CGM Messages

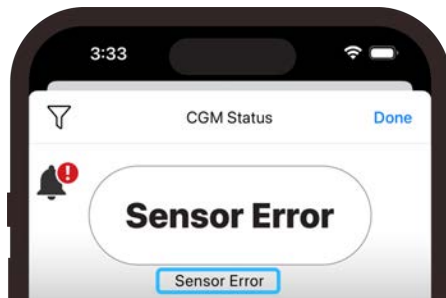
Sensor Error

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.

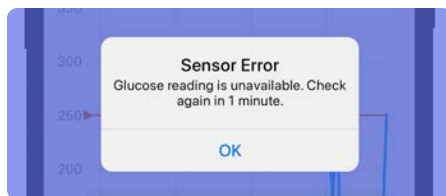
1. Tap **CGM Status**.



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.

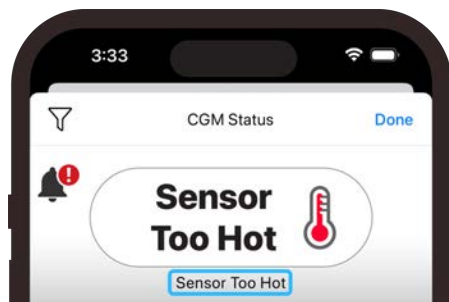
Sensor Too Hot

Your FreeStyle Libre 3 Plus Sensor is too hot to provide a glucose reading.

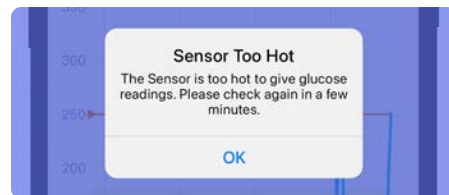
1. Tap **CGM Status**.



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.



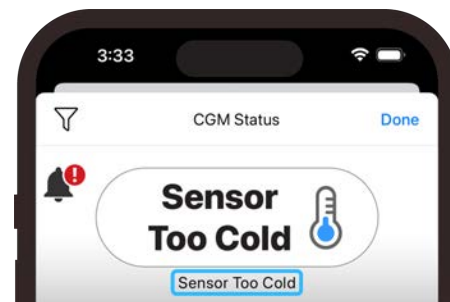
Sensor Too Cold

Your FreeStyle Libre 3 Plus Sensor is too cold to provide a glucose reading.

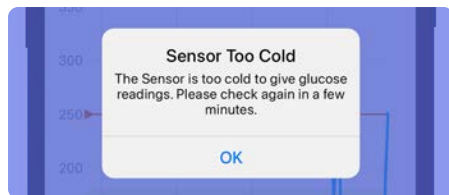
1. Tap **CGM Status**.



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.



Eversense 365 CGM Messages

Open 365 App

Your Eversense 365 CGM includes features that are only available through the Eversense 365 app, including CGM calibration.

Open the Eversense 365 app for additional information. Follow the instructions provided by the Eversense 365 app to resume receiving CGM readings.

CGM Filter Options

The glucose chart on the *CGM Status* screen can be filtered to display the *Correction Range*, *Target Range*, both, or neither.

1. Tap the **CGM Status** icon.
2. Tap the **Filter** icon.
3. Select the content to display on the glucose chart.



Confirm FreeStyle Libre 3 Plus Sensor Glucose

When the twiist AID system is used with a FreeStyle Libre 3 Plus Sensor,  is displayed on the *CGM Status* screen during the first 12 hours after starting a new FreeStyle Libre 3 Plus Sensor.

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.

When to use a Blood Glucose Meter

The twist AID system allows you to manually enter fingerstick glucose values from a blood glucose (BG) meter.

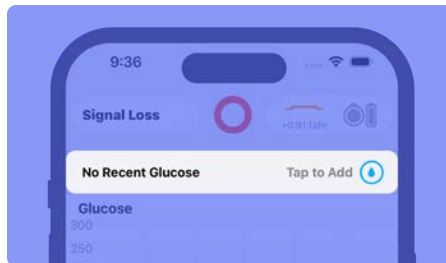
Fingerstick values should be entered:

- When no CGM has been added
- During CGM warm-up
- During CGM signal loss
- When you want to deliver a bolus but do not have recent CGM glucose data

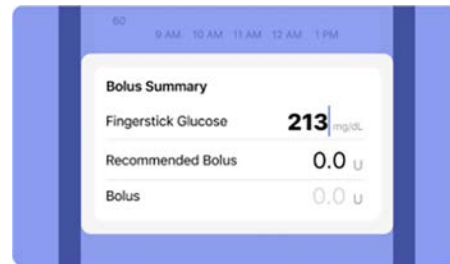
You can add a fingerstick value directly from the *Temporary Status Banner* on your *Home Screen* when *Loop* is on and no CGM data is currently available, or when you enter a meal or correction bolus.

The twist 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.

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 page 158](#) for more information.

i The twist AID system is designed to work best with CGM glucose values. Some features of automated insulin delivery may be less effective when CGM values are unavailable.

Apple Health (iPhone)

When blood glucose information is shared, you can use Apple Health to configure your blood glucose unit of measure in mg/dL or mmol/L.

Changes to your blood glucose unit of measure, made in Apple Health, are displayed within the *twiist* app.

The blood glucose unit of measure should be entered with guidance from your healthcare provider.

 Apple Health may not affect the way that glucose is displayed in applications other than the *twiist* app.

To change your blood glucose unit of measure:

1. Open the *Apple Health* app on your iPhone.
2. Tap the search icon.
3. Scroll down and tap **Vitals**.
4. Tap **Blood Glucose**.
5. Scroll down and tap **Unit**.
6. Tap **mg/dL** or **mmol/L** to select the desired unit of measure.

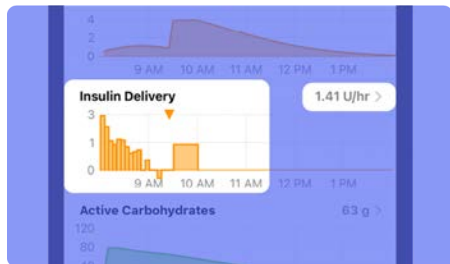
Apple Health can be used to store and review blood glucose, carbohydrate, and insulin delivery data from the *twiist* app, including *Total Daily Dose* and *Percent In Range*.

To change shared Apple Health app data:

1. Open the **Settings** app on your iPhone.
2. Tap **Apps**.
3. Tap **Health**.
4. Tap **Data Access & Devices**.
5. Tap **twiist**.
6. Choose your settings:
 - Tap **Turn Off All** to disable sharing.
 - **Turn on All** to enable sharing.
 - Tap *Blood Glucose*, *Carbohydrates*, or *Insulin Delivery* to individually enable or disable.

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 is 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* displays a scheduled, reduced, or increased basal icon depending on the adjustment to your background insulin delivery.

Bolus Delivery

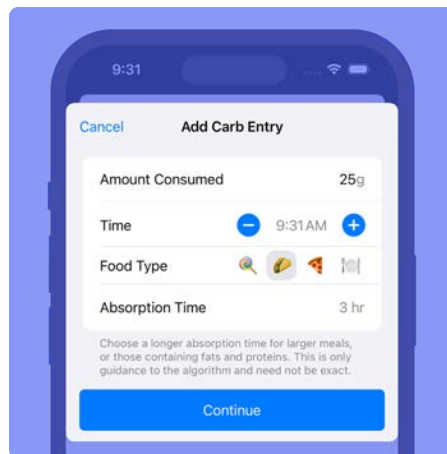
A bolus can be delivered using the *Carb Entry* or *Bolus* buttons on the *twiist* app toolbar, or directly on the pump using the *One-Button Bolus* feature.

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:

1. Tap **Carb Entry**  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.



3. 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 twist 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

 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.



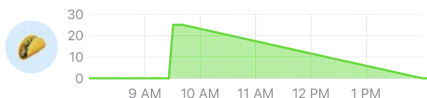
Fast carb effect: 30 minutes



Medium carb effect: 3 hours



Slow carb effect: 8 hours



5. Tap **Absorption Time**.

6. Use the picker to select an 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.

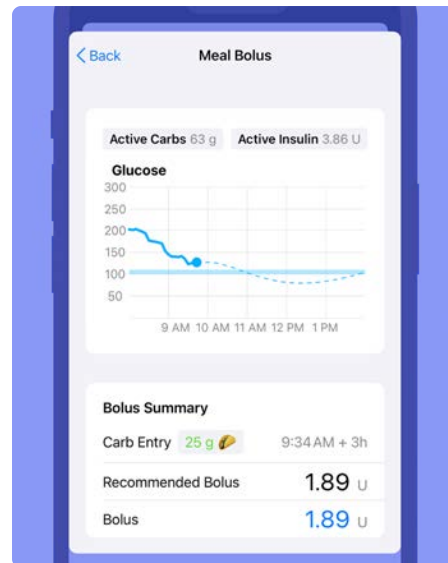
For more detailed information about how the twist AID system manages absorption time, [see "The Loop Algorithm" on page 312](#).

Confirm Bolus

7. Tap **Continue**.

8. Before delivering a bolus, review:

- *Active Carbs*
- *Active Insulin*
- *Carbs entered*
- *Food Type/Absorption Time*
- *Recommended Bolus*



! Do not modify a bolus to be greater than the recommended value. Increasing the bolus may increase your risk of low blood glucose.

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 twist 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. Use your smartphone passcode, facial recognition, or fingerprint to authenticate.

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

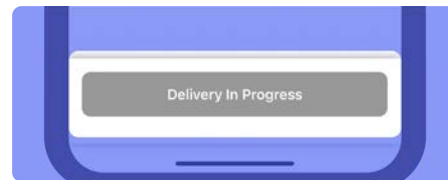
-  The pump sound will not be played when *Quiet Mode* is enabled.



A *Bolus*  icon is displayed on the *Insulin Delivery Chart* indicating that a 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.



Save without Bolusing

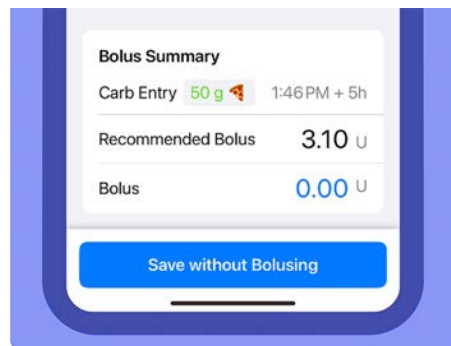
There may be times a bolus will not be recommended after carb entry. This can happen when:

- 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 twist 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.

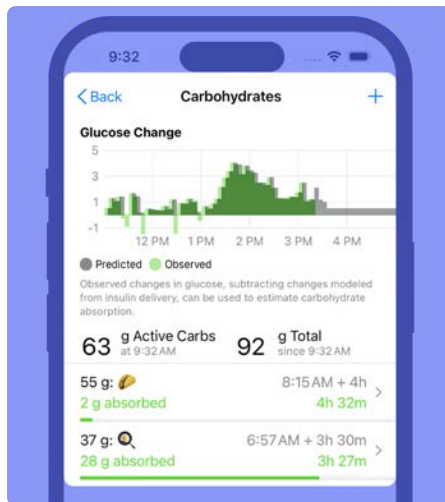
5. Once you have entered all the food types and absorption times, tap **Deliver Bolus**.

Dynamic Carbohydrate Absorption

The *Active Carbohydrates* chart displays the carbs that you entered into the twist app and how the twist AID system expects them to impact your glucose over time. This is called *Dynamic Carbohydrate Absorption*.

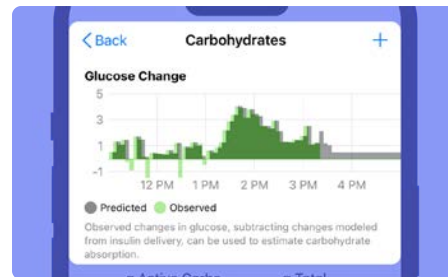
Dynamic Carbohydrate Absorption is only applicable when a CGM is paired with your twist pump and CGM readings are available.

On the *Home Screen*, tap the **Active Carbohydrates Chart** to display *Dynamic Carbohydrate Absorption* details.



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 affect the twist 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:

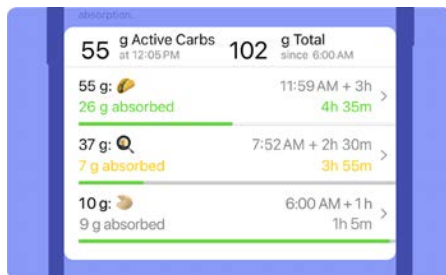
- Adjust the value of carbs entered or account for fat/protein
- Adjust absorption time
- Settings for *Insulin Sensitivity* or *Carb Ratio* may need to be adjusted
- Stress/Hormone/Exercise levels may be different than normal

If you have questions about system use, contact your healthcare provider or Sequel Customer Support. [See "Sequel Customer Support" on page 265.](#)

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.



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.

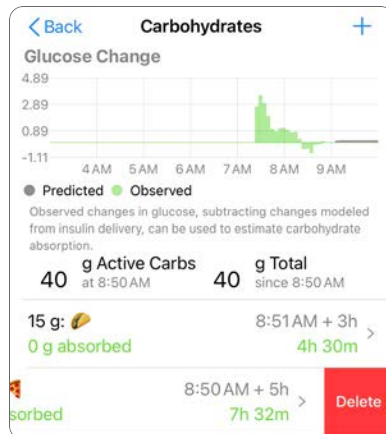
 Carbs cannot be deleted or edited when *Loop* is off.

Delete a Carb Entry

1. Tap the **Active Carbohydrates Chart**.



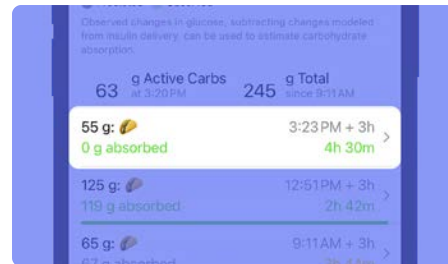
2. Swipe left on the carb entry and tap **Delete**.

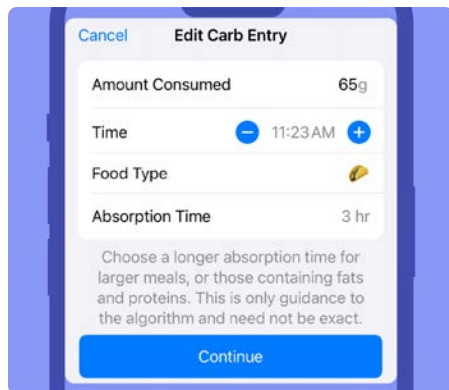


 The twist AID system will adjust your basal insulin based on your active carbohydrates. The more accurate the information you provide, the more effective it will be when it adjusts your basal to keep you within your *Correction Range*.

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.
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**.

The pump plays the *Delivering* sound.

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

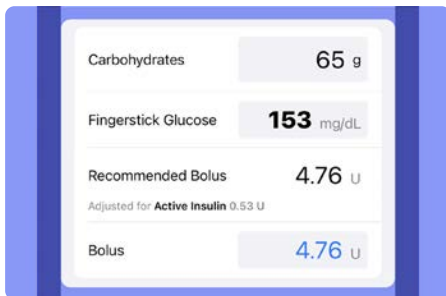
Carb Entry and Meal Bolus with Loop Off

When *Loop* is off, the twist 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. Use your smartphone passcode, facial recognition, or fingerprint to authenticate.
The pump plays the *Delivering* sound.

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

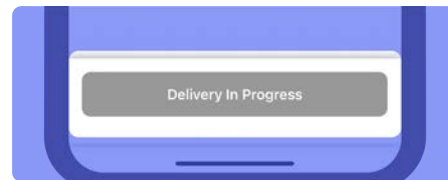
The *Home Screen* will temporarily display your fingerstick glucose value and a BG meter icon. The *Temporary Status Banner* displays the bolus delivery progress while the bolus is being delivered.



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

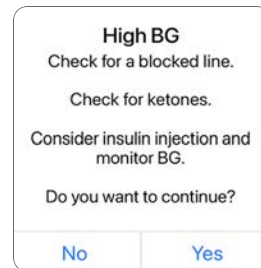


If *Delivery in Progress* is displayed instead of *Deliver Bolus*, wait until the current bolus delivery is complete before delivering another bolus.



If a fingerstick glucose value is entered that is higher than 250 mg/dL:

A *High BG* notice is displayed asking if you want to continue.

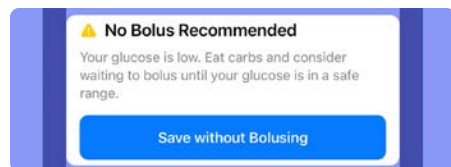


1. Before selecting **Yes** or **No**:
 - Check for a blocked line
 - Check for ketones
 - Consider insulin injection and monitor BG

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:

A *No Bolus Recommended* caution is displayed and you are given the option to **Save without Bolusing**.



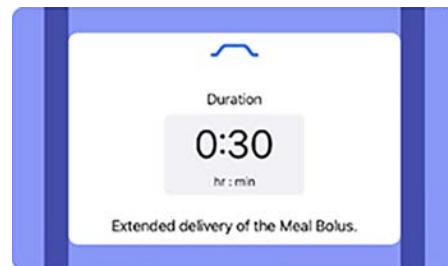
Deliver Extended Bolus

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

 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**  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 **Extended Bolus**.
7. Use the picker to adjust the *Duration* between 30 minutes and 8 hours.



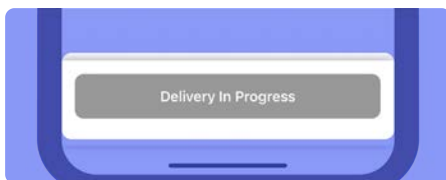
8. Tap **Done** to hide the picker.
 9. Tap **Next**.
 10. Confirm the bolus amount and tap **Deliver Bolus**.
 11. Use your smartphone passcode, facial recognition, or fingerprint to authenticate. The pump plays the *Delivering* sound, and the *Temporary Status Banner* displays the extended bolus delivery in progress.
-  The pump sound will not be played when *Quiet Mode* is enabled.



The *Bolus* icon ▼ is 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

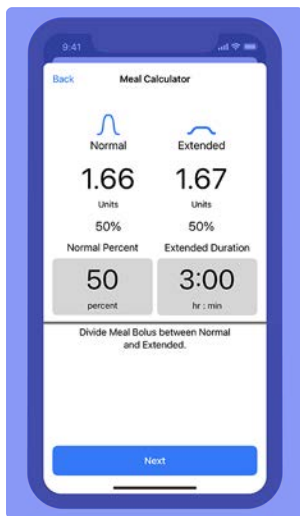
A *Dual Bolus* can only be delivered when *Loop* is off and *Dual Bolus* has been enabled in *Therapy Settings*.

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. Use your smartphone passcode, facial recognition, or fingerprint to authenticate. The pump plays the *Delivering* sound.

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

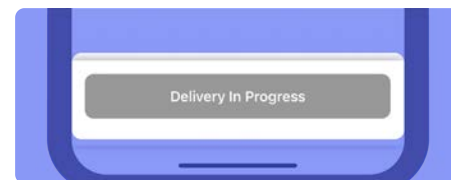
The *Temporary Status Banner* displays both the normal and extended portions of the dual bolus delivery in progress.



Two *Bolus* icons  is 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

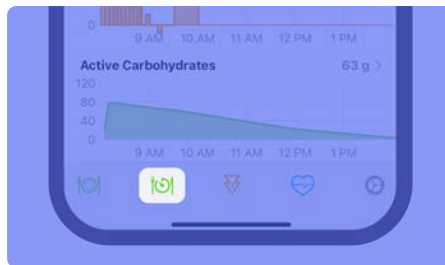
If you would like the twist AID system to temporarily lower your correction range before you begin eating to help reduce the chance of a post-meal spike, you can use the *Pre-Meal Preset*. The *Pre-Meal Preset* will stay on for up to one hour, until it is canceled, or until you enter carbs, whichever occurs first.

Using this feature before your meal tells the twist AID 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 twist 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**  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

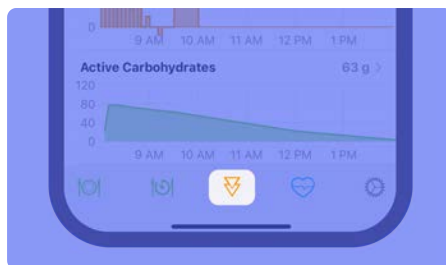
1. Tap **Pre-Meal Preset**  on the *Toolbar* to cancel the *Pre-Meal Preset*.

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)

1. When *Loop* is on, tap the **Bolus Entry**  button to receive a recommendation for a correction bolus to bring down high glucose.

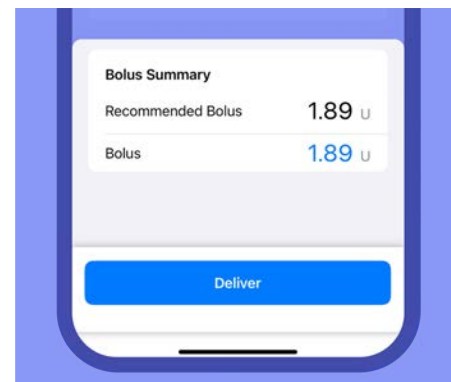


2. Before delivering a bolus, review:
 - Active Carbs
 - Active Insulin

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**.

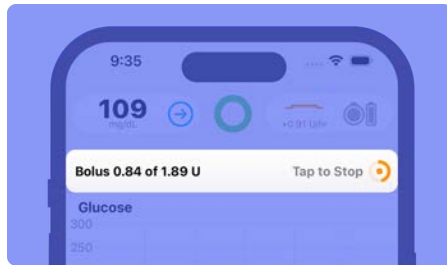
3. Confirm the *Recommended Bolus* and tap **Deliver**.



4. Use your smartphone passcode, facial recognition, or fingerprint to authenticate.

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

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



The *Bolus* icon  is 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*.



 Do not modify a bolus to be greater than the recommended value. Increasing the bolus may increase your risk of low blood glucose.

The twist 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:

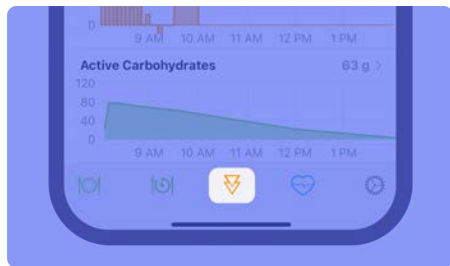
1. Tap **Enter Bolus** or tap into the *Bolus* field.
2. Using the keypad, **enter the bolus amount** you would like to deliver.
3. Tap **Done** to dismiss the keypad.
4. Tap **Deliver**.
5. Use your smartphone passcode, facial recognition, or fingerprint to authenticate.

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

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

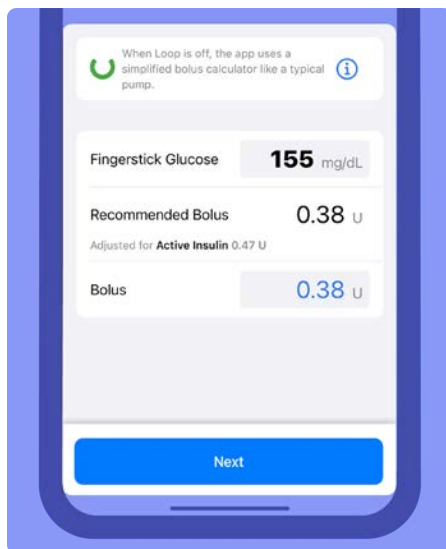
Bolus Entry (Correction Bolus) with Loop Off

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.

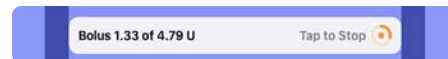


If the recommended bolus does not match the way you feel, go back to the *Home Screen* and check both your *Active Carbohydrates* and *Active Insulin*.

5. Tap **Next** to review the details of the bolus recommendation.
6. Confirm the bolus amount and tap **Deliver Bolus**.
7. Use your smartphone passcode, facial recognition, or fingerprint to authenticate.

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

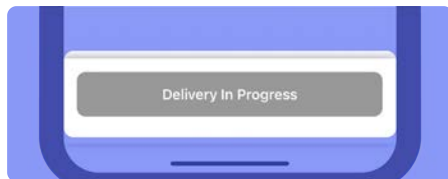
- i** The pump sound will not be played when *Quiet Mode* is enabled.



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

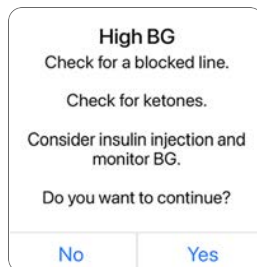


If *Delivery in Progress* is displayed instead of *Deliver Bolus*, wait until the current bolus delivery is complete before delivering another bolus.



If a fingerstick glucose value is entered that is higher than 250 mg/dL:

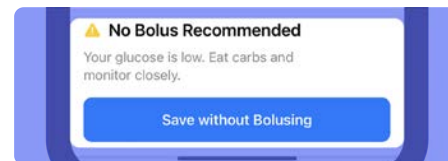
A *High BG* notice is displayed asking if you want to continue.



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:

A *No Bolus Recommended* caution is displayed and you will be given the option to **Save without Bolusing**.



Manually Enter a Bolus

1. Tap **Bolus**  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. Use your smartphone passcode, facial recognition, or fingerprint to authenticate.

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

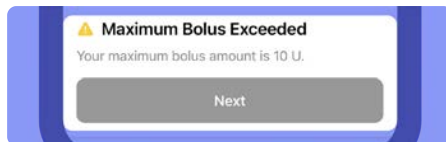
-  The pump sound will not be played when *Quiet Mode* is enabled.

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

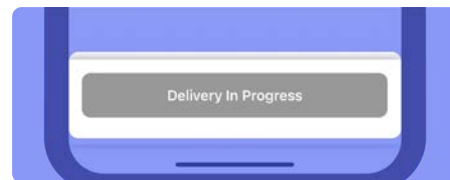


If your desired bolus value exceeds the *Maximum Bolus Limit*, a caution is displayed and you will NOT be able to proceed.

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 is 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.
 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 262.

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.

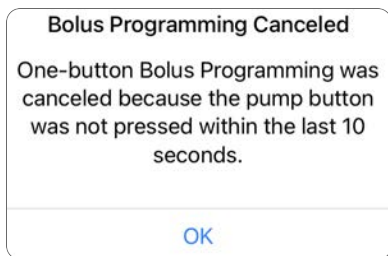
If you need to stop the bolus delivery, see "*Stop Bolus Delivery*" on the previous page.

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 262.

One-Button Bolus Programming Canceled

Bolus Programming Time Out:

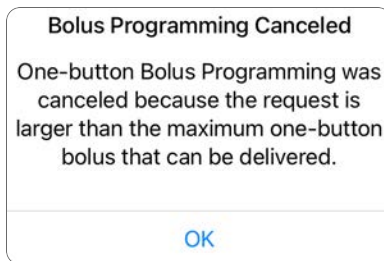
If you stop interacting with the pump during the programming of the *One-Button Bolus* and the pump plays the *One-Button Bolus Canceled* sound, the pump has timed out and canceled the *One-Button Bolus* programming. A *Bolus Programming Canceled* notice is displayed.



1. Tap **OK** to dismiss the notice.
2. Restart the *One-Button Bolus* programming and delivery.

Maximum Bolus Exceeded:

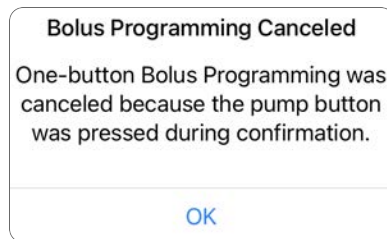
If you tried to request more than the maximum allowed bolus, the pump will play the *One-Button Bolus Canceled* sound. A *Bolus Programming Canceled* notice is displayed.



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 the *One-Button Bolus Canceled* sound 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.

Workout Preset



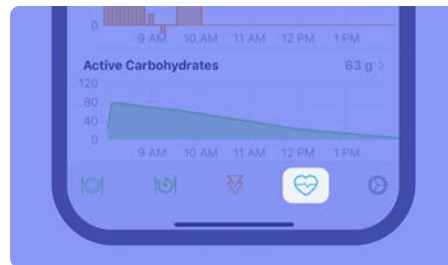
When you would like to exercise, use the *Workout Preset* to temporarily raise your *Correction Range*. The twist AID system will use your *Workout Range* to help reduce the risk of low glucose events.

i Failing to inform the twist 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.

i This feature is only available when *Loop* is on. When *Loop* is off the twist 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 182.

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*.



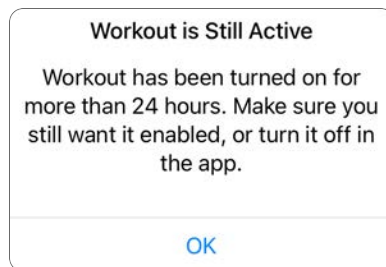
- Button color  in the toolbar will be reversed.

Although your smartphone is not required, you may want to bring it with you to monitor your glucose, and your twist 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 twist 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

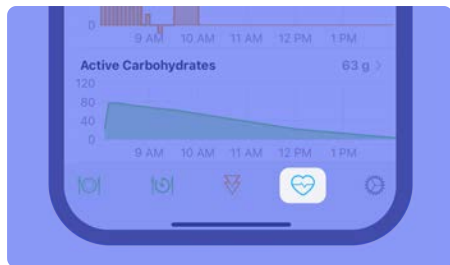
1. Tap **Workout Preset**  on the *Toolbar*.

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.

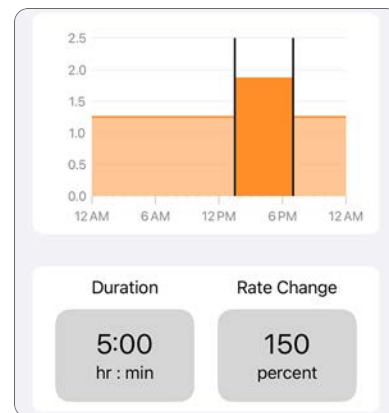


By default, a *Temporary Basal* adjusts your basal rate by allowing you to select a percentage of your basal rate for a specified duration. You can also choose to set a *Temporary Basal* by overriding your programmed rate or rates within *Therapy Settings*. See "*Temporary Basal Adjustment*" on page 122.

① When *Loop* is on, the  button on the toolbar is used to enable a *Workout Preset*, see "*Workout Preset*" on page 180.

Set Temporary Basal

1. Tap the  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.



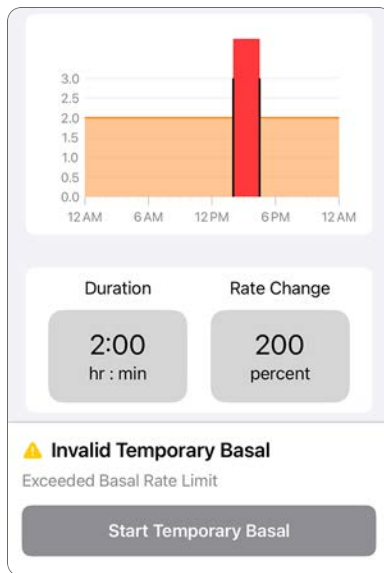
Rate adjustment will appear as percent or U/hr depending on your *Temporary Basal* adjustment setting within *Therapy Settings*.

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.

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

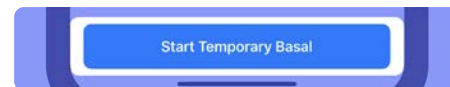
The graph displays your current scheduled basal rate or rates. The dark blue area displays the *Duration* and *Rate Change* selected.

If the *Temporary Basal* percentage causes the temporary basal to exceed the maximum basal rate, lower your percentage or modify your duration.



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**.

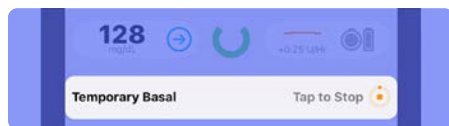
5. Review the *Temporary Basal* and tap **Start Temporary Basal**.



6. Use your smartphone passcode, facial recognition, or fingerprint 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  $+3.0 \text{ U/hr}$ basal.

The *Insulin Delivery Chart* displays a reduced or increased basal and the current basal delivery rate.



The  button on the *Toolbar* is displayed with the color reversed.



Stop Temporary Basal

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

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

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

The pump plays the *Delivering* sound.

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

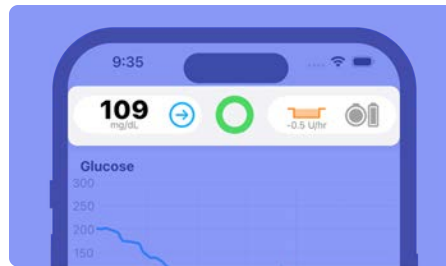
Sleeping with twist



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 twist AID system can impact your night.

Before Sleeping

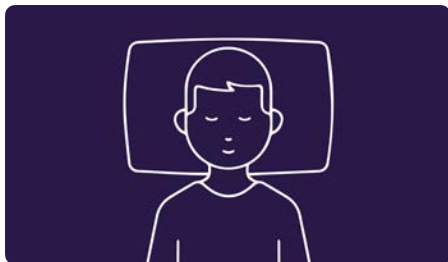


Before you go to sleep at night, check in with the twist AID system to make sure your:

- twist app *Home Screen* displays a green circle *twist Status* icon
- Smartphone has enough battery charge to last the night or is charging
- Cassette has enough insulin
- Pump has enough battery charge

- High and Low Glucose alert *Sleep Schedule* is enabled and set to the desired values.

While Sleeping



If *Loop* is on, the twist 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 twist 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 twist 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 twist AID system took while you were sleeping.

Alarms, Alerts, and Notices

The twist AID system provides alarms, alerts, and notices for your information and safety.

If your iPhone Ringtone and Alerts or Android Media volume is turned down, your smartphone is silenced, or any iPhone Focus features or Android Modes are enabled, notifications provided by the twist app may not be played or heard.

 Set your iPhone Ringtone and Alerts or Android Media volume to be louder than your surroundings so twist app notifications can be heard.

Check for twist app notifications if you are in an environment where you cannot feel vibration or hear system sounds.

The twist app displays messages with the following priority:

- Alarms
- Alerts
- Notices

 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 41](#).

For more information about configuring your smartphone for twist notifications, [see "Smartphone Notification Settings" on page 46](#).

Alarms

Alarms suspend 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*  symbol followed by the alarm name.

Alarm notifications are initially played at your iPhone Ringtone and Alerts or Android Media volume.

If the alarm has not been dismissed within 5 minutes, the alarm will repeat and play as a Critical Alert (iPhone) or notification with Modes Access (Android).

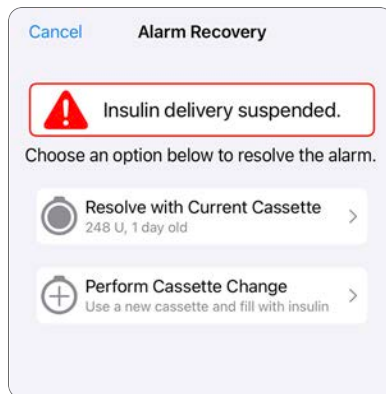
After an additional 5 minutes, the alarm notification repeats on your smartphone and will play on your twiist pump at the *Pump Volume Level* set in your twiist app *Notification Settings*. The *Alarm* sound repeats on your pump every 15 seconds and increases pump volume level every 5 minutes until the maximum *Pump Volume Level* is reached.

 If the twiist app and pump are out of communication, Alarm sounds will play on the pump immediately.

Alarms that have been dismissed and have not been resolved will occur again after 15 minutes.

For more information, refer to the details for each alarm.

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*.



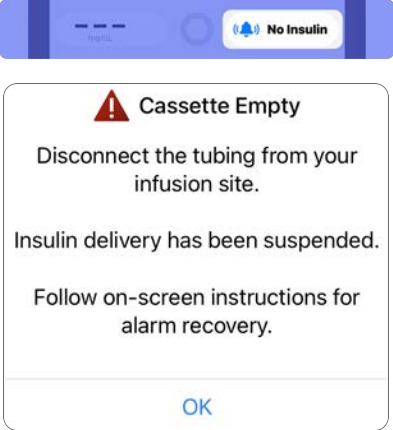
The twiist app provides information about the amount of insulin remaining and the age of the cassette to help you decide.

 Do not connect infusion set tubing to your infusion site before the pump completes self-test.

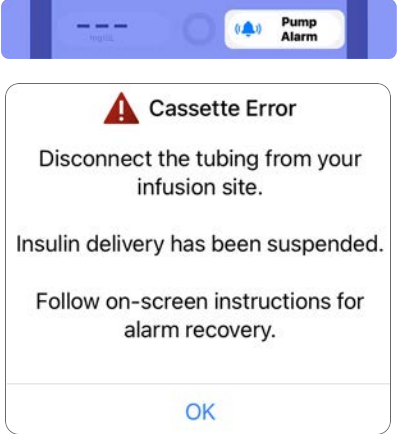
Connecting infusion set tubing to your infusion site during self-test may lead to unintended delivery of insulin, which may lead to low blood glucose.

 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.

Alarm Display  Alarm Display Disconnect the tubing from your infusion site. Insulin delivery has been suspended. Follow on-screen instructions for alarm recovery. OK	Description: There is no insulin remaining in the cassette.  The volume remaining in the cassette is an estimate and, when the cassette is removed, it is normal to see some insulin left in the cassette. What To Do: 1. Tap OK to dismiss the alarm. If the <i>Alarm</i> 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 <i>Cassette Empty</i> alarm occurs, a <i>Cassette Change</i> is required. 3. Tap Perform Cassette Change. 4. Follow the steps to complete a cassette change, starting with "<i>Gather your Supplies</i>" on page 84.
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Cassette Error

Alarm Display 	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. If the <i>Alarm</i> 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. 3. Check your blood glucose and treat highs and lows as advised by your healthcare provider.
---	---

A *Cassette Error* can be resolved with your current cassette or by performing a cassette change.

To resolve with your current cassette:

1. Tap **Resolve with Current Cassette**.
2. Make sure tubing is disconnected from your infusion site.
3. Tap **Next**.
The twiist app 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 **Start Basal**.

If a *Cassette Error* alarm is resolved with the current cassette and occurs again, perform a cassette change.

If a *Cassette Error* alarm occurs again after performing a cassette change, contact Sequel customer support.

To resolve by performing a cassette change:

1. Tap **Perform Cassette Change**.
2. Gather the supplies you need to complete a *Cassette Change*.
3. Tap **Start Cassette Change**.
4. Follow the steps to complete a *Cassette Change*, starting with "*Disconnect Infusion Site*" on page 85.

Cassette Not Attached

Alarm Display



Cassette Not Attached

Disconnect the tubing from your infusion site.

Insulin delivery has been suspended.

Follow on-screen instructions for alarm recovery.

OK

Description:

The cassette is not properly attached to the pump.



Avoid strong magnetic fields. Strong magnetic fields can trigger a *Check Pump and Cassette* alert, or a false *Cassette Not Attached* alarm.

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.
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 current cassette or by performing a cassette change.

To resolve with your current cassette:

1. Tap **Resolve with Current Cassette**.
2. Make sure tubing is disconnected from your infusion site.
3. Tap **Next**.
4. Attach the cassette to the pump.
5. Wait for the pump self-test to complete.
6. Connect the infusion set tubing to your infusion site.
7. Tap **Start Basal**.

To resolve by performing a cassette change:

1. Tap **Perform Cassette Change**.
2. Gather the supplies you need to complete a *Cassette Change*.
3. Tap **Start Cassette Change**.
4. Follow the steps to complete a cassette change, starting with *See "Disconnect Infusion Site" on page 85*.

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.

Alarm Display



Disconnect the tubing from your infusion site.

Insulin delivery has been suspended.

Follow on-screen instructions for alarm recovery.

OK

Description:

Insulin is blocked from being delivered due to a kink in your infusion set tubing or infusion site.

 The twist 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.
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.
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.

1. Tap **Resolve with Current Cassette**.
2. Make sure the infusion set tubing is disconnected from your infusion site.
3. Tap **Next**.
4. Check the cassette and infusion set tubing for kinks. Pay attention to discomfort at your infusion site which may indicate the cannula is bent or kinked. Replace your infusion site if no kinks can be seen in the tubing.
5. Tap **Next**.
The twist app performs a self-test.
6. Wait for the pump self-test to complete.
7. Route your infusion set tubing to avoid any sources of kinks that may have caused the *Line Blocked* alarm.
8. Connect the infusion set tubing to your infusion site.
If you changed your infusion site and need to fill your cannula, toggle **Fill Cannula** on and verify your cannula fill volume.
9. Tap **Start Basal**.

Perform a Cassette Change if:

- You cannot correct the blockage in your infusion set tubing.
 - Infusion set tubing is damaged.
 - You have already attempted to resolve a *Line Blocked* alarm with the current cassette and infusion set.
1. Tap **Perform Cassette Change**.
 2. Gather the supplies you need to complete a *Cassette Change*.
 3. Tap **Start Cassette Change**.
 4. Follow the steps to complete a cassette change, starting with *"Disconnect Infusion Site"* on [page 85](#).

Pump Battery Empty

Alarm Display



Pump Battery Empty

Disconnect the tubing from your infusion site.

Insulin delivery has been suspended.

Follow on-screen instructions for alarm recovery.

OK

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.

If the *Alarm* sound plays on the pump, tap **Audio OFF** to silence the alarm and tap **OK** to continue resolution steps.

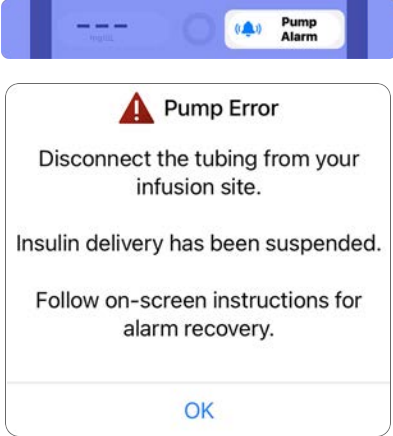
To resolve with your current cassette:

1. Tap **Resolve with Current Cassette**.
2. Gather the supplies you need to complete a *Battery Change*.
3. Tap **Start Battery Change**.
4. Follow the steps to complete a *Battery Change*, starting with "*Disconnect from Infusion Site*" on *page 99*.

To resolve by performing a cassette change:

1. Tap **Perform Cassette Change**.
2. Gather the supplies you need to complete a *Cassette Change*.
3. Tap **Start Cassette Change**.
4. Follow the steps to complete a *Cassette Change*, starting with "*Disconnect Infusion Site*" on *page 85*.

Pump Error

Alarm Display 	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. If the <i>Alarm</i> 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. 3. Check your blood glucose and treat highs and lows as advised by your healthcare provider.
---	---

A *Pump Error* can be resolved with your current cassette or by performing a cassette change.

To resolve with your current cassette:

1. Tap **Resolve with Current Cassette**.
2. Make sure the infusion set tubing is disconnected from your infusion site.
3. Tap **Next**.
The twiist app performs a self-test.
4. Wait for the pump self-test to complete.
5. Connect infusion set tubing to your infusion site.
6. Tap **Start Basal**.

If a *Pump Error* alarm is resolved with the current cassette and occurs again, perform a cassette change.

If a *Pump Error* alarm occurs again after performing a cassette change, contact Sequel customer support.

To resolve by performing a cassette change:

1. Tap **Perform Cassette Change**.
2. Gather the supplies you need to complete a *Cassette Change*.
3. Tap **Start Cassette Change**.
4. Follow the steps to complete a cassette change, starting with "*Disconnect Infusion Site*" on page 85.

Alerts

Alerts display information about the twist 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. Most *Alert* notifications are played at your iPhone Ringtone and Alerts or Android Media volume. If your smartphone is silenced, or any iPhone Focus features or Android Modes are enabled, alert notifications may be missed. For your safety, some alerts will be played as a Critical Alert (iPhone) or notification with Modes Access (Android).

If the twist app and pump are out of communication, alert sounds will play on the pump at the selected *Pump Volume Level*.

Alert sounds repeat every 15 minutes until the alert is dismissed.

When two or more alerts occur, the alerts are displayed in the twist 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.

Alert Display



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.

OK

Sounds

The pump does not play sounds for the Bluetooth Off alert.

Description:

Bluetooth is disabled on your smartphone.

When Bluetooth is disabled on your smartphone, the *twiist* app and pump cannot communicate.

Your CGM and pump will still be 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 Off* alert.

The *Home Screen* displays *Bluetooth Off* in the *CGM Status* and *Enable Bluetooth* in the *Pump Status*.

2. Enable **Bluetooth** in your smartphone 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.

Bluetooth Unavailable

Alert Display



Bluetooth Unavailable

Bluetooth access is disabled for the twist app. The app will not work successfully until Bluetooth access is enabled. You will not receive glucose readings or be able to bolus.

OK

Sounds

The pump does not play sounds for the Bluetooth Unavailable alert.

Description:

Bluetooth has been disabled for the twist app within your smartphone settings.

If Bluetooth is disabled for the twist app, the twist app and pump cannot communicate. Your CGM and pump are still in communication, and the twist AID system will continue adjusting your basal insulin delivery.

The twist app will not display glucose readings, and app notifications will not be available. You will not be able to deliver a bolus through the twist 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 twist app within your smartphone settings to receive twist app notifications and CGM readings.
3. Navigate back to the twist app.
The *CGM* and *Pump Status* icons resume displaying current status.

Cassette Low

Alert Display



Cassette Low

Cassette is low on Insulin. You may need to replace the cassette soon.

OK

Description:

The cassette has less than 10 Units of insulin remaining, or less than the number of units entered in the *Low Insulin Alert #2 Notification Setting*.



The volume remaining in the cassette is an estimate based on your initial cassette fill volume.

What To Do:

1. Tap **OK** to dismiss the alert.
2. Take the necessary steps to be prepared to perform a *Cassette Change*.

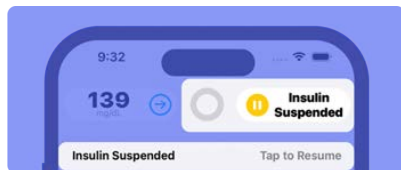
See "Cassette Change" on page 84.

Check Pump and Cassette

Alert Display  Check Pump and Cassette Keep your pump away from magnets. Make sure your cassette is properly attached. OK	Description: The twist AID system has detected the pump is too close to a magnet, or the cassette is not properly attached. These conditions can lead to a <i>Cassette Not Attached</i> alarm if they are not addressed. Check to make sure that your pump is not near any magnets and your cassette is properly attached to the pump.  Avoid strong magnetic fields. Strong magnetic fields can trigger a <i>Check Pump and Cassette</i> alert, or a false <i>Cassette Not Attached</i> alarm. What To Do: 1. Tap OK to dismiss the alert. 2. Move your pump away from any magnets that it may come into contact with, including MagSafe smartphone cases and accessories, and wireless earbuds with magnetic cases. Check to make sure the cassette is properly attached to the pump with the ridge on the pump-bump aligned with the infusion set tubing.
---	--

Interrupted Bolus

Alert Display



Interrupted Bolus

Bolus delivery has been interrupted.

OK

Sounds

The pump does not play sounds for the Interrupted Bolus alert.

Description:

Insulin delivery was suspended while a bolus delivery was in progress.

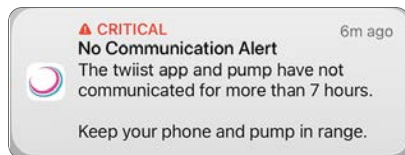
This alert is to remind you that bolus delivery was interrupted in addition to suspending your basal insulin.

What To Do:

1. Tap **OK** to dismiss the alert.
 2. Tap the **Insulin Delivery Chart** to open *Event History* and see how much of the *Interrupted Bolus* was delivered.
 3. Check your glucose to see if an additional correction or meal bolus is required and take the appropriate action.
- Insulin delivered as a result of an *Interrupted Bolus* is accounted for in a new bolus recommendation.

No Communication

Alert Display



Sounds

Smartphone: *Alert* at the configured *Critical Alert (iPhone)* or *Do Not Disturb Override (Android)* Volume.

The pump does not play sounds for the No Communication alert.

Description:

The twiist app and pump have not communicated in 7 hours.

What To Do:

1. Place your smartphone and pump close to each other to allow communication to resume.
2. Communication problems may be resolved by turning off or moving away from other wireless devices, or by restarting the *twiist* app.
3. Press and hold the **pump button** for at least 3 seconds to verify delivery is in progress.
4. If the pump plays the *Delivering* sound, delivery is in progress. If the pump plays the *Pump Inactive* sound, resume delivery with the *twiist* app.

Phone Out of Range (Communication Restored)

Alert Display



Communication Restored

Communication between the twiist app and pump was lost and has been restored.

OK

Sounds

Pump: *Alert* sound is played when not in communication with the twiist app.

Smartphone: *Alert* is played at your iPhone Ringtone and Alerts or Android Media volume when communication is restored.

Description:

The *Phone Out of Range* alert, if enabled in *Notification Settings*, plays the *Alert* sound only on the pump when your smartphone 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 smartphone.

Typically, if this alert has occurred, you have walked away from your smartphone while insulin delivery is in progress.

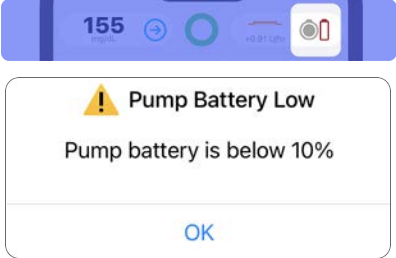
What To Do:

1. Tap **OK** to dismiss the alert. No further action is required.

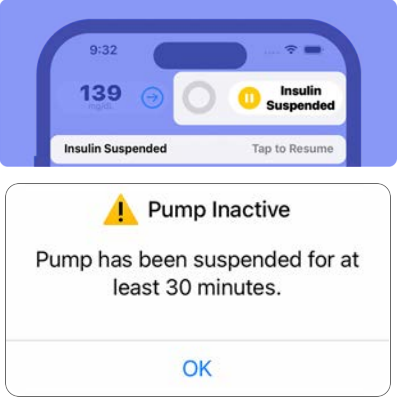
If you do not receive the message that the communication has been restored, and the pump and twiist app are within communication range, there may be another type of communication error occurring.

1. Quit and restart the twiist app.
2. If the issue persists, conduct a *Battery Change*. See "[Battery Change](#)" on page 98.
3. Move away from other wireless devices and try to establish communication between your pump and smartphone.

Pump Battery Low

Alert Display  The screenshot shows a mobile application interface. At the top, there is a blue header bar with the number '155' and several icons. Below the header, a white alert box is displayed. The alert has a yellow triangle with an exclamation mark icon and the text 'Pump Battery Low'. Below this, it says 'Pump battery is below 10%'. At the bottom of the alert box is a blue button labeled 'OK'.	Description: The pump battery has less than 10% remaining. What To Do: 1. Tap OK to dismiss the alert. 2. Take the necessary steps to prepare for a <i>Cassette</i> or <i>Battery Change</i>. <i>See "Cassette Change" on page 84.</i> <i>See "Battery Change" on page 98.</i>
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Pump Inactive

Alert Display  Sounds Smartphone: <i>Alert</i> at the configured <i>Critical Alert (iPhone)</i> or <i>Do Not Disturb Override (Android)</i> Volume.	Description: Insulin delivery has been suspended for at least the amount of time set in <i>Notification Settings</i> for the <i>Pump Inactive Alert</i>. This alert cannot be disabled and is set to 30 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 <i>Pump Inactive</i> alert therapy setting. If you are in the middle of <i>Cassette Change</i> or <i>Battery Change</i>, complete that process to resume insulin delivery. See "Cassette Change" on page 84. See "Battery Change" on page 98.
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Reattach Cassette

Alert Display  Reattach Cassette Remove cassette and reattach to continue.	Description: The cassette is not properly attached to the pump and self-test cannot begin.
	What To Do: 1. Remove the cassette from the pump and reattach. Self-test will begin.

Temporary Basal Stopped

Alert Display  Temporary Basal Stopped Temporary Basal exceeds allowable limits. OK	Description:  The <i>Temporary Basal Stopped</i> alert can only occur when <i>Loop</i> is off. The <i>Temporary Basal Stopped</i> alert will occur if a <i>Temporary Basal</i> exceeds the <i>Maximum Basal Rate</i>. What To Do: 1. Tap OK to dismiss the alert. 2. Review your glucose and active insulin. To set a new temporary basal, see "Set Temporary Basal" on page 182.
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CGM Alerts

When a CGM Sensor is used with the twist AID system, the twist app displays CGM alerts. 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. Most CGM alert sounds are played at your iPhone Ringtone and Alerts or Android Media volume. For your safety, some CGM alerts will be played as Critical Alerts (iPhone) or notifications with Modes Access (Android).

Alert sounds repeat every 5 minutes until the CGM alert is dismissed.

When CGM alerts are not available, the CGM *Alerts Unavailable*  icon is displayed on the *CGM Status* screen.

The *Urgent Low Glucose* alert is displayed with higher priority than all other alerts.

The *Urgent Low Glucose* is always delivered as a Critical Alert (iPhone) or notification with Modes Access (Android). After 5 minutes, the *Urgent Low Glucose* alert repeats on your smartphone and will play on your twist pump at the *Pump Volume Level* set in your twist app *Notification Settings*. The *Urgent Low Glucose* sound repeats on your pump every 30 seconds and increases pump volume level every 5 minutes until the maximum *Pump Volume Level* is reached.

The *Urgent Low Glucose* alert will repeat if your glucose is at or below the *Urgent Low Glucose* alert value after the 15 minute *Snooze Duration* has passed.

 If the twist app and pump are out of communication, *Urgent Low Glucose* sounds will play on the pump immediately.

CGM alerts, with the exception of the *Urgent Low Glucose*, are only played on your smartphone.

For more information, refer to the details for each CGM alert.

CGM Alert Display

CGM Ended with Loop on



CGM Ended

Your CGM has ended and Loop has been disabled.

Start a new CGM to continue receiving readings and CGM alerts.

Loop will be re-enabled once CGM readings are available.

OK

CGM Ended with Loop off



CGM Ended

Start a new CGM to continue receiving readings and CGM alerts.

OK

Description:

Your sensor has ended and needs to be replaced. 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.

For FreeStyle Libre 3 Plus:

- a. Tap the *CGM Status*.
A *Start New Sensor* message is displayed.
- b. Tap **Yes** and follow instructions from [step 5 on page 137](#).

For Eversense 365:

- a. Contact your healthcare provider to schedule a sensor replacement.

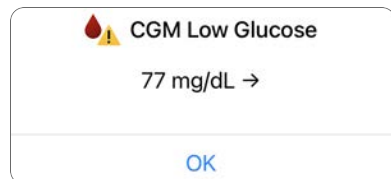
Sounds

Smartphone: *Alert* at the configured *Critical Alert (iPhone)* or *Do Not Disturb Override (Android)* Volume.

CGM High Glucose

CGM Alert Display  The image shows a simulated smartphone screen for a CGM alert. At the top, there is a red flame icon with a yellow exclamation mark inside a triangle, followed by the text 'CGM High Glucose'. Below this, the glucose level '251 mg/dL' is displayed with a small upward arrow icon. At the bottom of the screen, there is a blue 'OK' button. Sounds Smartphone: If <i>Override Focus (iPhone)</i> or <i>Override Do Not Disturb (Android)</i> is enabled, this alert is played at the configured <i>Critical Alert (iPhone)</i> or <i>Do Not Disturb Override (Android) Volume</i>.	Description: Your CGM glucose is above the level you have set in your <i>CGM High Glucose Alert</i> setting, or your <i>Sleep Schedule</i> setting, if enabled. The <i>High Glucose Alert</i> will repeat if your glucose is above the <i>High Glucose Alert</i> value after the configured <i>Snooze Duration</i> has passed. What To Do: 1. Tap OK to dismiss the CGM alert. 2. Treat your high glucose as advised by your healthcare provider.
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CGM Alert Display



Sounds

Smartphone: If *Override Focus (iPhone)* or *Override Do Not Disturb (Android)* is enabled, this alert is played at the configured *Critical Alert (iPhone)* or *Do Not Disturb Override (Android)* Volume.

Description:

Your CGM glucose is below the level you have set in your *CGM Low Glucose Alert* setting, or your *Sleep Schedule* setting, if enabled. The *Low Glucose Alert* will repeat if your glucose is below the *Low Glucose Alert* value after the configured *Snooze Duration* has passed.

What To Do:

1. Tap **OK** to dismiss the CGM alert.
2. Treat your low glucose as advised by your healthcare provider.

CGM Signal Loss

CGM Alert Display



CGM Signal Loss with Loop on



CGM Signal Loss

CGM readings and CGM alerts are not available.

Loop has not run in at least 40 minutes.

OK

CGM Signal Loss with Loop off



CGM Signal Loss

CGM readings and CGM alerts are not available.

OK

Description:

Your CGM has not communicated with the twiist pump for the amount of time set in the *CGM Signal Loss Alert* setting, and CGM readings and alerts are not available. The default alert notification time is 40 minutes.

If *Loop* is on and *CGM Signal Loss* occurs, the twiist AID system will not be able to complete a *Loop* in order to adjust basal delivery. See "*twiist Status*" on page 67.

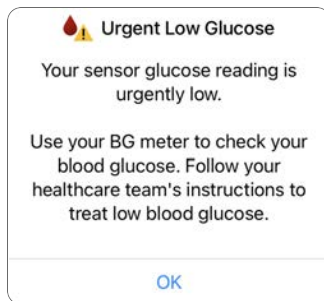
What To Do:

1. Tap **OK** to dismiss the CGM alert.
2. Make sure your twiist pump is in communication range with your FreeStyle Libre 3 Plus Sensor or Eversense 365 smart transmitter.
3. Tap the **CGM Status** icon to open the *CGM Status* screen.

Sounds

Smartphone: If *Override Focus (iPhone)* or *Override Do Not Disturb (Android)* is enabled, this alert is played at the configured *Critical Alert (iPhone)* or *Do Not Disturb Override (Android) Volume*.

Urgent Low Glucose Alert Display



Sounds

Smartphone: *Urgent Low Glucose* alert is played at the configured *Critical Alert* (iPhone) or *Do Not Disturb Override* (Android) *Volume*.

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 .

The *Urgent Low Glucose Alert* will repeat if your glucose is at or below 55 mg/dL after the 15 minute *Snooze Duration* has passed.

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 🍬 emoji.

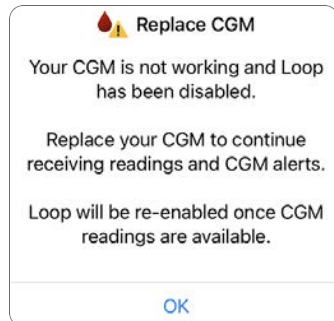
If *Loop* is off, do not deliver a bolus, and suspend your basal delivery. Do not resume basal delivery until your glucose is in your desired range.

Replace CGM

FreeStyle Libre 3 Plus Alert Display



Replace CGM with Loop on



Replace CGM with Loop off



Description:

Your FreeStyle Libre 3 Plus Sensor 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 Sensor (FreeStyle Libre 3 Plus Only)" on page 137.*

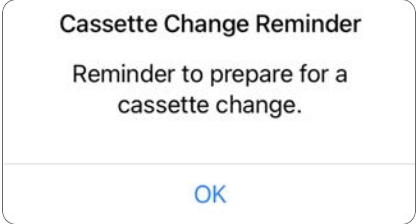
Sounds

Smartphone: *Alert* is played at the configured *Critical Alert* (iPhone) or *Do Not Disturb Override* (Android) *Volume*.

Notices and Reminders

Notices and reminders provide information about the twiist AID system, and do not affect insulin delivery. Notification sounds are played at your iPhone Ringtone and Alerts or Android Media volume. No sounds are played by the pump for notices and reminders.

Cassette Change Reminder

Notice Display 	Description: A reminder to prepare for a cassette change based on the <i>Cassette Change Reminder Notification Setting</i> . What To Do: 1. Tap OK to dismiss the notice. 2. Follow the steps to complete a cassette change. <i>See "Cassette Change" on page 84.</i>
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Internet Connection Required

Notice Display Internet Connection Required An internet connection is required before pairing. Please connect to a Wi-Fi or Cellular network. OK	Description: Your smartphone does not have an internet connection and pump pairing cannot continue.
	What To Do: 1. Tap OK to dismiss the notice. 2. Connect your smartphone to a Wi-Fi or Cellular network to continue pump pairing.

Limited Internet Connectivity

Notice Display Limited Internet Connectivity Unable to perform pump pairing. Connect to a different Wi-Fi network, or cellular network. OK	Description: Your smartphone has a limited internet connection and pump pairing cannot continue.
	What To Do: 1. Tap OK to dismiss the notice. 2. Connect your smartphone to a different Wi-Fi or cellular network to continue pump pairing.

No Communication

Notice Display  No Communication The twist app and pump have not communicated for more than 20 minutes. 3h ago	Description: Your smartphone and pump have been out of communication for more than 20 minutes. What To Do: 1. Place your smartphone and pump close to each other to allow communication to resume. 2. Communication problems may be resolved by turning off or moving away from other wireless devices, or by restarting the twist app. 3. Press and hold the pump button for at least 3 seconds to verify delivery is in progress. 4. If the pump plays the <i>Delivering</i> sound, delivery is in progress. If the pump plays the <i>Pump Inactive</i> sound, resume delivery with the twist app.
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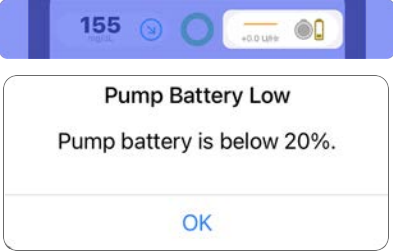
Phone Battery Low

Notice Display Phone Battery Low The phone has less than 10% battery remaining. Please connect your phone to power before starting the pump software update. OK	Description: Your smartphone has less than 10% battery remaining when starting a pump software update. What To Do: 1. Tap OK to dismiss. 2. Connect your smartphone to power before starting the pump software update. 3. Tap Next to continue with the pump software update.
--	--

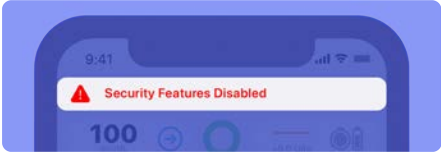
Prime Stopped

Notice Display <i>Cassette Change</i> Prime Stopped Do you see droplets at the end of the infusion set? No Yes <i>Re-Prime</i> Prime Stopped Have you cleared the air from the tubing? No Yes	Description: The <i>Prime Stopped</i> notice is displayed during <i>Cassette Change</i> or <i>Re-Prime</i> when priming has been stopped. What To Do: <i>Cassette Change:</i> • If you see drops at the end of your infusion set tubing, tap Yes to continue. • If you do not see drops, tap No to continue priming your cassette and infusion set tubing. <i>Re-Prime Infusion Set Tubing:</i> • If you have cleared the air from the infusion set tubing, tap Yes to continue. • If you have not cleared the air from the infusion set tubing, tap No to continue priming until the air is removed.
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Pump Battery Low

Notice Display  Notice Display 155 40.0 LIFE Pump Battery Low Pump battery is below 20%. OK	Description: The pump battery has less than 20% charge remaining. What To Do: 1. Tap OK to dismiss the notice. 2. Prepare for a <i>Cassette</i> or <i>Battery Change</i>. <i>See "Cassette Change" on page 84.</i> <i>See "Battery Change" on page 98.</i>
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Security Features Disabled

Notice Display  iPhone Security Features Disabled Face ID or Passcode must be enabled on your phone. Go to Settings -> Face ID & Passcode Android Security Features Disabled Biometric Unlock or Passcode must be enabled on your phone. Go to Settings → Security & Privacy	Description: Security features must be enabled on your smartphone. If security features on your smartphone are disabled, you will not be able to use the <i>twiist</i> app. Enable security features on your smartphone to continue using the <i>twiist</i> app. What To Do: 1. Navigate to your smartphone <i>Settings</i> and enable security features such as passcode, facial recognition, or fingerprint. 2. Navigate back to the <i>twiist</i> app. <i>Security Features Disabled</i> is no longer displayed on the <i>Home Screen</i>.
Sounds The <i>Security Features Disabled</i> notice does not play sounds on your smartphone.	

System Time Updated

Notice Display System Time Updated Your System time has been automatically changed. Your therapy will always follow the System time. OK	Description: Your <i>System Time</i> may be automatically updated by your smartphone when you change time zones or as a result of daylight savings time. The twist 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 twist 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 <i>Temporary Basal</i>. See "Set Temporary Basal" on page 182.
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The twist App is Closed (iPhone)

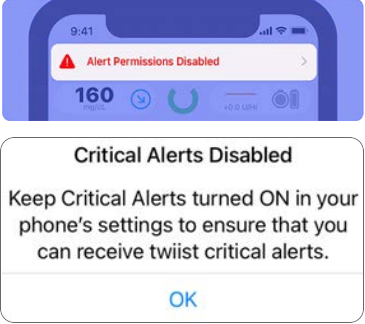
Notice Display  twiist App is Closed Tap to open app. Alarms and alerts will not be displayed until it's opened. In the future, keep the app running in the background, don't swipe it closed. now	Description: You have closed the twiist app. Closing the twiist app will result in a loss of communication with the twiist pump. Notifications from the twiist app will not be available until the app is opened. Quitting the twiist app or removing it from your iPhone will result in loss of communication with your twiist pump. What To Do: 1. Tap the notification to open the twiist app.
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Workout is Still Active

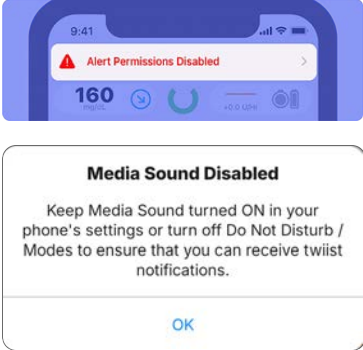
Notice Display Workout is Still Active Workout has been turned on for more than 24 hours. Make sure you still want it enabled, or turn it off in the app. OK	Description: The <i>Workout Preset</i> has been enabled for 24 hours. What To Do: 1. Tap OK to dismiss. 2. Turn off the <i>Workout Preset</i> to 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>.
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Permissions Notices

Critical Alerts Disabled (iPhone)

Notice Display 	Description: Keep Critical Alerts turned on in your iPhone settings to ensure you receive twist app notifications even when your iPhone is silenced or Focus is on. If Critical Alerts are disabled, the twist app displays a <i>Critical Alerts Disabled</i> message and the <i>Home Screen</i> displays an <i>Alert Permissions Disabled</i> warning. What To Do: 1. Tap OK to dismiss the <i>Critical Alerts Disabled</i> message. 2. Continue to "Resolve Permissions Notices" on page 236.
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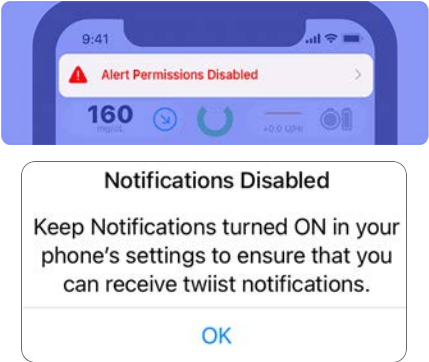
Media Sound Disabled (Android)

Notice Display  Sounds The <i>Media Sound Disabled</i> notice does not play sounds on your Android.	Description: Keep Media Sound turned on in your Android settings or disable any Android Modes to ensure you can receive twist app notifications even when your Android is silenced. If Media Sound is turned off while Modes (such as Do Not Disturb) are enabled, the twist app displays <i>Media Sound Disabled</i> and an <i>Alert Permissions Disabled</i> warning. What To Do: 1. Tap OK to dismiss the <i>Media Sound Disabled</i> message. 2. Continue to <i>"Resolve Permissions Notices" on page 236.</i>
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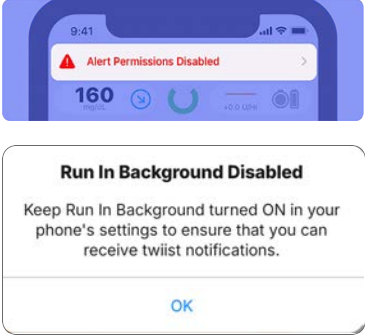
Modes Access Disabled (Android)

Notice Display Sounds The <i>Modes Access Disabled</i> notice does not play sounds on your Android.	Description: Keep Modes Access turned on in your Android settings to ensure you receive twist app notifications even when your Android is silenced, or Do Not Disturb is enabled. Some Android Modes prevent the use of selected apps while active. Ensure the twist app is included in the list of unaffected apps whenever using Android Modes. If Modes Access is disabled, the twist app displays a <i>Modes Access Disabled</i> message and the <i>Home Screen</i> displays an <i>Alert Permissions Disabled</i> warning. What To Do: 1. Tap OK to dismiss the <i>Modes Access Disabled</i> message. 2. Continue to <i>"Resolve Permissions Notices" on page 236</i>.
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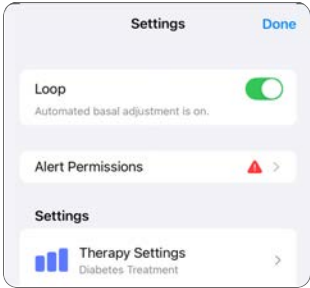
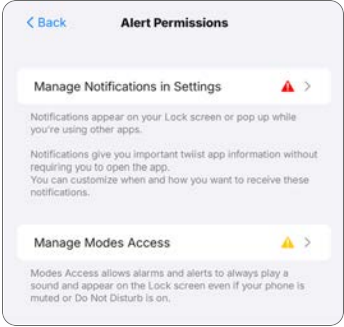
Notifications Disabled

Notice Display  Sounds The <i>Notifications Disabled</i> notice does not play sounds on your smartphone.	Description: Allow <i>Notifications</i> for the twiist app in your smartphone settings to ensure that you can receive twiist app notifications on your smartphone notification center. If <i>Notifications</i> are disabled on your smartphone, the twiist app displays a <i>Notifications Disabled</i> message and the <i>Home Screen</i> displays an <i>Alert Permissions Disabled</i> warning. What To Do: 1. Tap OK to dismiss the <i>Notifications Disabled</i> message. 2. Continue to "Resolve Permissions Notices" on page 236.
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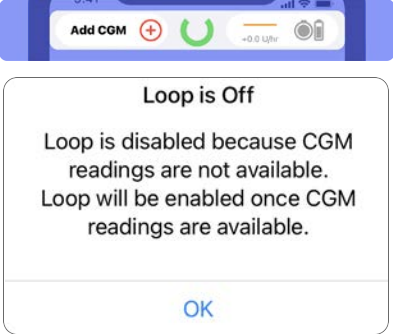
Run in Background Disabled (Android)

Notice Display  Sounds The <i>Run in Background Disabled</i> notice does not play sounds on your Android.	Description: Keep the Run in Background setting turned on in your Android settings to ensure you can receive twist app notifications in your smartphone notification center. This setting may be associated with the battery restriction setting for the twist app. If the Run in Background setting is disabled, the twist app displays <i>Run in Background Disabled</i> and an <i>Alert Permissions Disabled</i> warning. What To Do: 1. Tap OK to dismiss the <i>Run in Background Disabled</i> message. 2. Continue to <i>"Resolve Permissions Notices" on the next page.</i>
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Resolve Permissions Notices

1. Tap Settings  on the <i>Toolbar</i>.  The <i>Alert Permissions</i> setting only appears within the <i>twiist</i> app <i>Settings</i> when smartphone settings that affect notifications have been disabled. 2. Tap Alert Permissions.	
3. Tap the <i>Alert Permission</i> with the  or  icon to navigate to your smartphone settings for the <i>twiist</i> app. 4. Enable appropriate smartphone settings for the <i>twiist</i> app. 5. Navigate back to the <i>twiist</i> app to verify the  or  icons have been resolved.	iPhone  Android 

Loop is Off

Notice Display 	Description: <i>Loop</i> has been disabled because your CGM has been deleted from the <i>twiist</i> app, and CGM readings are no longer available. The <i>twiist</i> 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. Tap Add CGM and follow the steps to add FreeStyle Libre 3 Plus or Eversense 365 to the <i>twiist</i> app. 3. Check your glucose frequently, and treat your highs and lows as advised by your healthcare provider.
--	---

Loop is On

Notice Display Loop is On The system has re-enabled Loop since CGM readings are available. OK	Description: <i>Loop</i> has been re-enabled since CGM readings are available. What To Do: 1. Tap OK to dismiss the notice.
---	---

Loop is Waiting

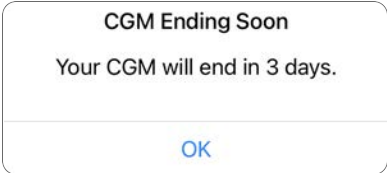
Notice Display Sensor Warmup  15:00 LPM  Loop is Waiting Loop is waiting for your Sensor Warmup to complete. Loop will be enabled once CGM readings are available. OK	Description: <i>Loop</i> is waiting for your <i>Sensor Warmup</i> to complete. Loop will be re-enabled when CGM readings are available. The twist 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.
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Timer Expired

Notice Display Timer Expired Check Glucose OK	Description: You received a reminder to check your glucose. What To Do: 1. Tap OK to dismiss the reminder. 2. Check your blood glucose and treat highs and lows as advised by your healthcare provider.
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FreeStyle Libre 3 Plus Notices

CGM Ending Soon (3 Days)

FreeStyle Libre 3 Plus Notice Display 	Description: Your FreeStyle Libre 3 Plus Sensor will end in 3 days. What To Do: 1. Tap OK to dismiss the notice. 2. Tap the CGM Status 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 FreeStyle Libre 3 Plus Sensor ends.
---	---

CGM Ending Soon (1 Day)

FreeStyle Libre 3 Plus Notice Display

CGM Ending Soon

Your CGM will end in 1 day.

OK

Description:

Your FreeStyle Libre 3 Plus Sensor will end in 1 day.

What To Do:

1. Tap **OK** to dismiss the notice.
2. Tap the **CGM Status** icon to open the *CGM Status* screen for more information.

Always make sure to have supplies available to start a new sensor when your FreeStyle Libre 3 Plus Sensor ends.

CGM Ending Soon (1 Hour)

FreeStyle Libre 3 Plus Notice Display CGM Ending Soon Your CGM will end in 1 hour. OK	Description: Your FreeStyle Libre 3 Plus Sensor will end in 1 hour. What To Do: 1. Tap OK to dismiss the notice. 2. Tap the CGM Status 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 FreeStyle Libre 3 Plus Sensor ends.
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Widgets (iPhone)

When used on an iPhone, the twist app provides widgets in order to check twist AID system status and glucose information on your iPhone home screen.

The twist app widget updates approximately every 15 minutes, but may be delayed. The widget indicates the last time the displayed information was updated.

Your iPhone limits how often widgets can be updated each day. This may result in no information being displayed, or information that is a few minutes out-of-date.

Always confirm the information displayed in the twist app widget by tapping to open the twist app. This will also refresh the information the widget displays.

Follow iPhone instructions to add a widget to your home screen.



Widgets that include the glucose chart can be configured to show between 2 and 6 hours of glucose information.

To change the chart duration:

1. Touch and hold the widget until the **Edit Widget** button is displayed.
2. Tap **Edit Widget**.
3. Tap **Chart Duration** to select.

twiist Smartwatch App

The twiist smartwatch app can be used with the twiist AID system when in communication with the twiist app on your smartphone.

This optional component provides a discreet way to view your sensor glucose and insulin information. When *Loop* is on, the pre-meal preset, workout preset, enter carbs, and deliver a bolus features are available. These features are not available when *Loop* is off.

Your smartwatch must be on and within Bluetooth (or Wi-Fi) range of your smartphone, and your smartphone must be within Bluetooth range of your pump in order for the watch to send commands to the pump.

 Your smartwatch cannot work with the twiist AID system when it is not in communication with your smartphone. All commands from the twiist smartwatch app require communication with your smartphone to reach your pump.

 A passcode must be enabled on your smartwatch to use the twiist smartwatch app. Your smartwatch passcode prevents unauthorized changes to insulin delivery, which may lead to low or high blood glucose. Your passcode should not be shared with unauthorized operators.

twiist Smartwatch App Home Screen

The twiist smartwatch app displays the *twiist Status* and *CGM Status* at the top, with buttons for Carb Entry, Pre-Meal Preset, Bolus Entry, and Workout Preset. *Settings* are not available within the twiist smartwatch app.



Pre-Meal Preset

With your smartwatch in range of your smartphone, you can enable your *Pre-Meal Preset*.

1. Tap .
2. Tap **On**.

When the *Pre-Meal Preset* is active, the button color on the twist smartwatch app will be reversed.



Cancel Pre-Meal Preset

To cancel the *Pre-Meal Preset*.

1. Tap .
2. Tap **Off**.

Workout Preset

With your smartwatch in range of your smartphone, you can enable your *Workout Preset*.

1. Tap .
2. Tap **On**.

When the *Workout Preset* is active, the button color on the twist smartwatch 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.

To decrease or increase carbs in 1 g increments, turn the smartwatch **Digital Crown** (Apple Watch), or interact with the **Digital Crown** or **Bezel** (Android Watch).

3. Tap a **Food Type** emoji to select an absorption time.
4. Tap **Continue**.



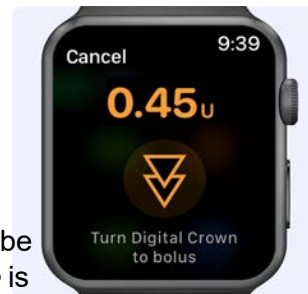
5. Tap **Save & Bolus**.



6. Turn the smartwatch **Digital Crown** (Apple Watch), or interact with the **Digital Crown** or **Bezel** (Android Watch) to deliver the bolus.

The pump plays the *Delivering* sound.

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



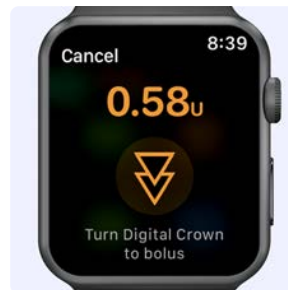
Bolus Entry (Correction Bolus)

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.
To decrease or increase the correction bolus in 0.01 U increments, turn the smartwatch **Digital Crown** (Apple Watch), or interact with the **Digital Crown** or **Bezel** (Android Watch).
3. Tap **Bolus**.



4. Turn the smartwatch **Digital Crown** (Apple Watch), or interact with the **Digital Crown** or **Bezel** (Android Watch) to deliver the bolus.



The pump plays the *Delivering* sound.

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

twiist Smartwatch App Status Screen



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

Swiping from right to left across the twiist smartwatch app home screen displays a status screen with your *Glucose Chart*.

Scroll down to view information including

- *Active Insulin*
- *Active Carbs*
- *Insulin Delivery Status*
- *Cassette Info*
- *Pump Battery Level*

Apple Watch Complications

To see your twist AID system information on your Apple Watch face, add a twist watch complication.

Follow instructions to add a complication to your Apple Watch face.

Tap the complication to open the twist app on your Apple Watch.



The watch complication updates approximately every 15 minutes, but update times may vary. Your Apple Watch limits how often complications can update each day. Exceeding Apple's update limit may cause the complication to display -- instead of your current glucose and glucose trend.

Complications vary depending on the selected Apple Watch face. Most versions of the complication include the last updated time, but small complications may not display last updated time.

Tap the complication on your Apple Watch face to open the twist app. This also refreshes the information the complication displays.

Android Watch Tiles

The *twiist* Android Watch app provides a Tile that can be added to your Android watch face for quick access to your current glucose, glucose trend, and your *twiist Loop Status*.

Follow instructions for adding a Tile to your Android Watch.



Tap the **twiist Tile** to open the *twiist* app Home Screen.



Swipe across the watch face to view the Glucose Chart, Active Insulin, Active Carbs, Net Basal Rate, Cassette Volume, and Battery Level.



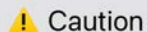
App and Pump Updates

It is recommended to have automatic updates enabled on your smartphone so you are always running the latest version of your smartphone operating system.

 Do not install Beta Updates for iOS or Android on your smartphone. Beta Updates may not be compatible and may prevent the twiist app from functioning as intended, which may lead to low or high glucose.

When twiist app updates are available, they can be installed on your smartphone directly from the Apple App Store or Google Play Store.

If you update your smartphone operating system 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 an operating system update:

- Do not rely on the twiist app for monitoring or treatment decisions.
- Contact Sequel Customer Support. *See "Sequel Customer Support" on page 265.*

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

App Updates

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

It is recommended to configure your Apple App Store and Google Play 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 smartphone settings, check the Apple App Store or Google Play Store frequently for twiist app updates.

Pump Updates

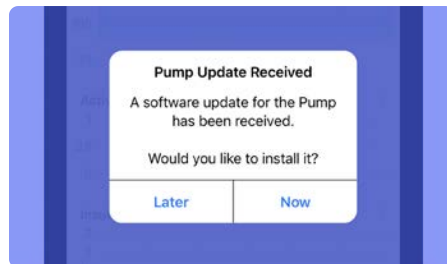
When a new version of the twist app has been installed, it will check to see if new compatible pump software is available from the cloud.

Pump software updates are sent from the twist app to the pump through Bluetooth communication.

Make sure your smartphone 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 notice is 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 will display an orange dot.



To update the pump software now:

1. Tap **Now** to display the *Pump Software Update*.
2. Disconnect the infusion set tubing from your infusion site. The twist app displays the pump update progress.

3. Keep your pump close to your smartphone. Do not quit the twist app, turn off your smartphone, or remove the battery from the pump during the pump software update.

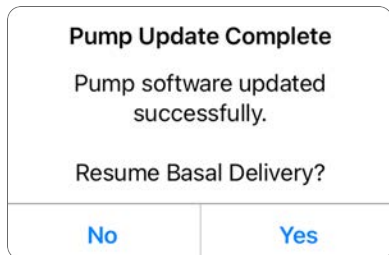
4. Tap **Next** to suspend insulin delivery and continue. Insulin delivery will be suspended.

The pump plays the *Delivery Suspended* sounds.

-  The pump sound will not be played when *Quiet Mode* is enabled.
5. When the update is complete, the pump will start a self-test. Wait for the self-test to complete.
 6. Connect the primed infusion set tubing to the infusion site.

⚠ 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 notice is displayed to inform you that the update is complete and asks if you want to *Resume Basal Delivery*.



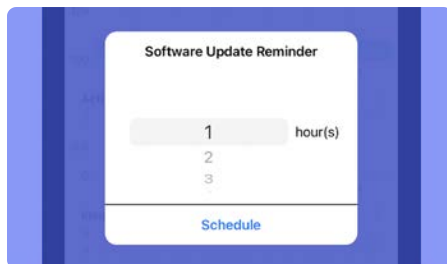
7. Tap **Yes** to resume delivery, or **No** to keep insulin delivery suspended.

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

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

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 **Install Pump Update** on the *Pump Menu* to display the pump software update information.



3. Tap **Next**.
Insulin delivery will be suspended. The pump plays the *Delivery Suspended* sounds.

-  The pump sound will not be played when *Quiet Mode* is enabled.
4. 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 notice is displayed informing you that the update is complete and asks if you want to *Resume Basal Delivery*.

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

Upon resuming basal delivery, the pump plays the *Delivering* sounds.

-  The pump sound will not be played when *Quiet Mode* is enabled.
6. 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.

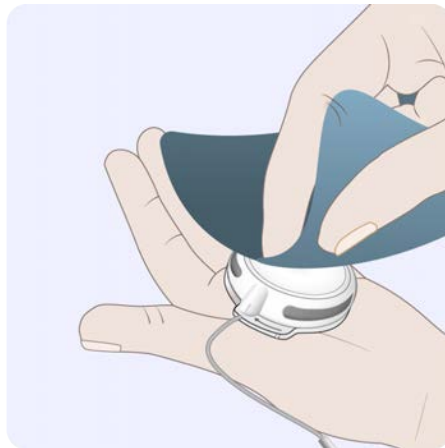
Clean the pump as needed to keep it free of dust, lint and debris or following exposure to dust or liquid contaminants.

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.

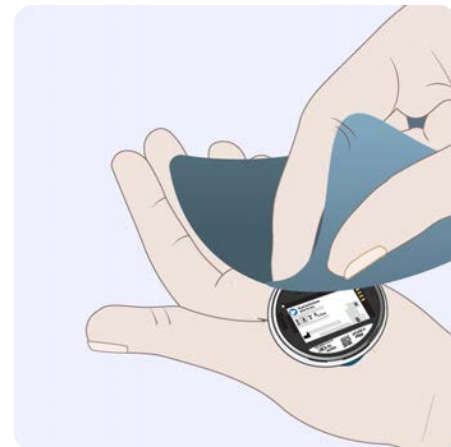
3. Thoroughly rinse the pump with water.

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.

Prepare to Travel

The twist AID system can be used while traveling on an aircraft.

Traveling with the twist AID 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.

 Do not expose your twist 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 X-ray machines and request an alternate means of screening. Your pump has been designed to withstand common electromagnetic interference including airport metal detectors.

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 in a plastic bag, protective pouch, or container.
- Place batteries in the provided pump battery charger.

FreeStyle Libre 3 Plus Sensor Lifecycle

After starting a new FreeStyle Libre 3 Plus Sensor, it will take 60 minutes before a CGM reading is available. The *CGM Status* displays *Sensor Warmup* and the *twiist Status* displays an open circle.



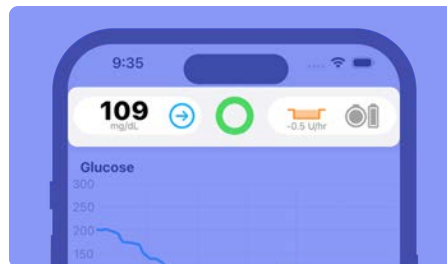
Tap the **CGM Status** icon to see how much time is remaining until the sensor is ready.

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.

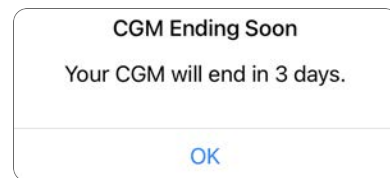
Tap **OK** to dismiss the *CGM Ready* notice.

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.

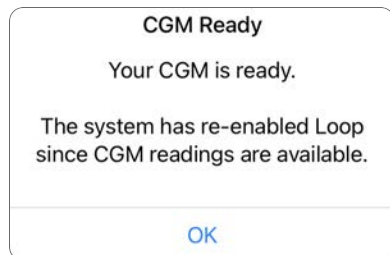
Loop will be automatically disabled.

The *CGM Status* displays *CGM Ended* and the *twiist Status* displays an open circle.



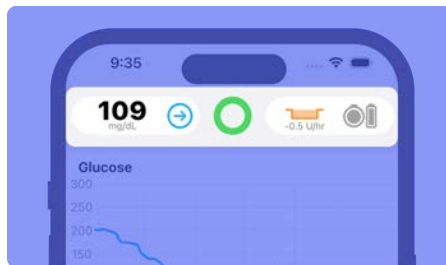
Basal insulin delivery will not automatically be adjusted until a new CGM Sensor is started, and *Sensor Warmup* is completed.

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.



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 BatteryContact Sequel Customer Support.

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

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

Can I use the system without my smartphone?

1. When the twiist pump and app are not in communication or your smartphone 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 smartphone, 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).

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 177*.

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

*Why won't my pump pair with the **twiist** app?*

- Make sure your smartphone 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 you are using an iPhone, and the pump was previously paired, you will need to forget the pump in your *Bluetooth Settings*. See "*Bluetooth Settings (iPhone)*" on page 111.

*Do you know something the **twiist** automated insulin delivery system does not?*

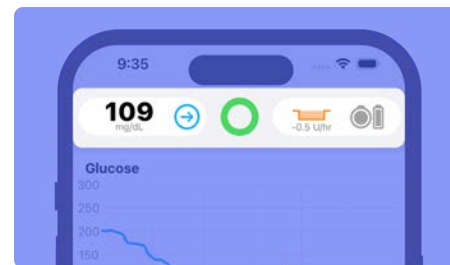


There is always a chance that you have information that the **twiist** AID system does not.

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?



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 67.

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 *twiist* Automated Insulin Delivery System Functioning Properly?*

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

 If the *twiist* AID 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.

Is Your CGM Functioning Properly?



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

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

Tap the **CGM Status** icon to monitor your CGM.

If you need replace your CGM, [see "Start a New Sensor \(FreeStyle Libre 3 Plus Only\)" on page 137.](#)

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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Refill and Replacement Parts

 Only use approved parts.

Table 1: Refills and Replacement Parts

Refills and Replacement Parts	Part Number
Pump Replacement Kit • twist pump with pump cover	DKPI-11098-001
Pump Battery Replacement Kit • Pump battery charger (3) • USB charging cable • Wall power adapter with 2 USB ports • Rechargeable pump battery (6)	DKPI-11095-001
Pump Clip Replacement Kit • Pump clip (2)	DKPI-11096-001

Refills and Replacement Parts	Part Number
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
Refill Kit with infusion sets • Cleo 90 - 24 inch (61 cm) infusion sets with 6 mm cannula (10) • Cassettes (10) • 3 mL Syringes (10) • 27 gauge x 3/8 inch (0.40 mm x 10 mm) Needles (10) • Alcohol wipes (30)	DKPI-11101-001

Technical Specifications

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 smartphone to Wi-Fi networks have already been considered by the manufacturer, connecting your smartphone 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.

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

Software Bill of Materials (SBOM)

A Software Bill of Materials (SBOM) for the twist app and pump is available upon request. The SBOM identifies the commercial, open-source, and off-the-shelf software components incorporated into the device. To request a copy, contact "*Sequel Customer Support*" on page 265.

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.

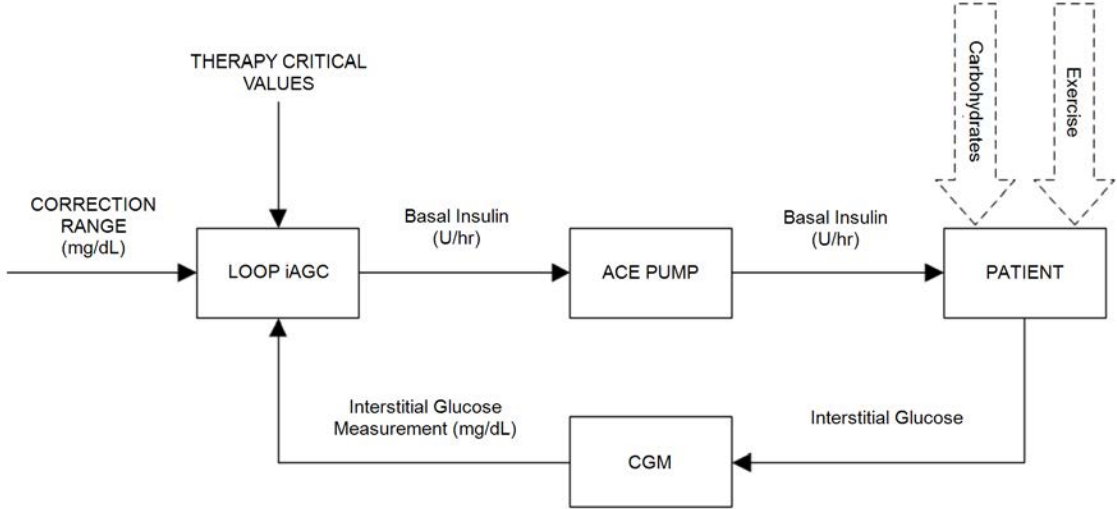


Table 2: Pump specifications

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	>45 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)

Table 4: Pump attached to cassette specifications

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

Table 4: Pump attached to cassette specifications

Pump attached to Cassette Specification Type	Details
Cannula Fill Volume	Default: -- Units Programmable from 0.10 - 0.70 Units in 0.10 Unit increments.
Cannula Fill Delivery Rate	Approximately 1.5 U/min based on the maximum cannula fill volume.

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

Table 5: Pump battery specifications

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)	1 year
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)

Table 7: Cassette specifications

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

Table 8: *twiist* App Therapy Settings

Therapy Settings	Details
Glucose Unit of Measure (Android)	mg/dL or mmol/L
Glucose Safety Limit	67-110 mg/dL Increment of 1 mg/dL

Table 8: *twiist App Therapy Settings*

Therapy Settings	Details
Correction Range	87-180 mg/dL Increment of 1 mg/dL The minimum allowed value is either 87 mg/dL or the <i>Glucose Safety Limit</i>, when the <i>Glucose Safety Limit</i> is higher than 87 mg/dL. Correction Range can be programmed at every half hour interval, as required.
Pre-Meal Range	Programmable from 67-130 mg/dL in 1 mg/dL increments The minimum allowed value is either 67 mg/dL or the <i>Glucose Safety Limit</i>, when the <i>Glucose Safety Limit</i> is higher than 67 mg/dL.
Workout Range	Programmable from 87-250 mg/dL in 1 mg/dL increments The minimum allowed value is either 87 mg/dL or the <i>Glucose Safety Limit</i>, when the <i>Glucose Safety Limit</i> is higher than 87 mg/dL.
Carb Ratios	Programmable from 2-150 g/U in 0.1 g/U increments. A different Carb Ratio can be programmed at every half hour interval, as required.
Basal Rates	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. A different Basal rate can be programmed at every half hour interval, as required.

Table 8: *twiist* App Therapy Settings

Therapy Settings	Details
Maximum Basal Rate	Min: Highest scheduled basal rate Max: Not greater than 30 U/hr and further limited to the greater of the following: • 70/ minimum of saved Carb Ratios • 6.4 x the highest programmed scheduled basal rate Increment of 0.05 U/hr
Maximum Bolus	Increment: 1 U Minimum: 1 U Maximum: 25 U
Insulin Model	Programmable for <i>Adults</i> or <i>Children</i>
Insulin Sensitivity	Programmable from 10 to 500 mg/dL/U in 1 mg/dL/U increments. A different <i>Insulin Sensitivity</i> can be programmed at every half hour interval, as required.
Temporary Basal	Default – Percent May be set to <i>Percent</i> or <i>Rate</i>  Cannot be modified when <i>Loop</i> is on.

Table 9: *twiist App Bolus Settings*

Bolus Setting	Details
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.

Table 10: *twiist App Notification Settings*

Notification Setting	Details
Critical Alert Volume (iPhone)	Default: High Options: High, Medium, Low
Do Not Disturb Override Volume (Android)	Default: High Options: High, Medium, Low

Notification Setting	Details
Pump Volume Level	Default: Medium Options: High, Medium, Low
Quiet Mode	Default: Off Options: On/Off
Low Insulin Alert #1	Default: On Options: Cannot be disabled Alert set to 10 U and cannot be modified
Low Insulin Alert #2	Default: Off Options: On/Off Alert value: 20-100 U in 5 U increments
Phone Out of Range Alert	Default: Off Options: On/Off 1-120 min in 1 min increments
Pump Inactive Alert	Default: 30 minutes Options: 15, 30, 60, 90 minutes

Notification Setting	Details
Cassette Change Reminder	Default: Disabled Options: Enable/Disable Reminder Time: programmable from 2 to 3 days in 1 hour increments

Table 11: CGM Alerts

CGM Alert Setting Ranges	Details
Urgent Low Glucose Alert	Default: 55 mg/dL Options: Cannot be modified or disabled
CGM Signal Loss Alert	Default: 40 min Options: 20, 40, 60, 90 minutes. Cannot be disabled.

Table 11: CGM Alerts

CGM Alert Setting Ranges	Details
Low Glucose Alert	Default: Enabled Options: Enable/Disable Default: 70 mg/dL Options: 60 -100 mg/dL Increment: 5 mg/dL Snooze Duration Default: 15 min Snooze Duration Options: 15 min to 2 hours in 5 min increments
High Glucose Alert	Default: Enabled Options: Enable/Disable Default: 250 mg/dL Options: 120 -400 mg/dL Increment: 10 mg/dL Snooze Duration Default: 1 hour Snooze Duration Options: 15 min to 4 hours in 5 min increments

Table 11: CGM Alerts

CGM Alert Setting Ranges	Details
Sleep Schedule	Default: Disabled Options: Enable/Disable Default Time: 10:00 AM - 6:00 PM Low Glucose Sleep Value: 60-100 mg/dL. Increment: 5 mg/dL High Glucose Sleep Value: 120-400 mg/dL, Increment: 10 mg/dL

Table 12: Accessories

Accessory	Specification
Wall Power Adapter Power	1A and 2.4A Both ports will charge the pump batteries within the specified time.
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

Table 12: Accessories

Accessory	Specification
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 13: 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.

Table 14: Basal rate delivery performance

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

Table 14: Basal rate delivery performance

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

Table 15: Basal specifications

Basal Specification Type	Details
Basal Delivery Frequency	Every 5 minutes for rates greater than or equal to 0.24 U/hr.
Basal Rate	Default: -- U/hr Minimum - 0.00 U/hr Programmable from 0.00 - configured Maximum Basal Rate (up to 30) U/hr in 0.05 U/hr increments. A different Basal Rate can be programmed at every half hour interval, as required. A basal rate of >0.00 U/hr and <0.10 U/hr is not allowed.
Temporary Basal Rate Percentage	Default: 100 percent 0 - 200 percent or Maximum Basal Rate, whichever is lower in 5 percent increments.

Table 15: Basal specifications

Basal Specification Type	Details
Temporary Basal Rate U/hr	Default: 0.00 U/hr Programmable from 0.00 U/hr - configured Maximum Basal Rate (up to 30) in 0.05 U/hr increments. A temporary basal rate of >0.00 U/hr and <0.10 U/hr is not allowed.
Temporary Basal Duration	Default: 30 minutes 30 minutes - 24 hours in 30 minute increments

Bolus Delivery

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

Table 16: Bolus accuracy 0.05 U

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

Table 17: 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 18: 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 18: 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 19: Bolus specifications

Bolus Specification Type	Details
Normal Bolus Delivery Rate	Approximately 1.70 U/min when a normal bolus is active.
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 - configured Maximum Bolus volume (25 U) in 0.01 Unit increments.
Maximum Dual Bolus	Default: 50% normal, 50% extended Normal or Extended Percentage: 5-95%, in 5% increments

Table 19: *Bolus specifications*

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

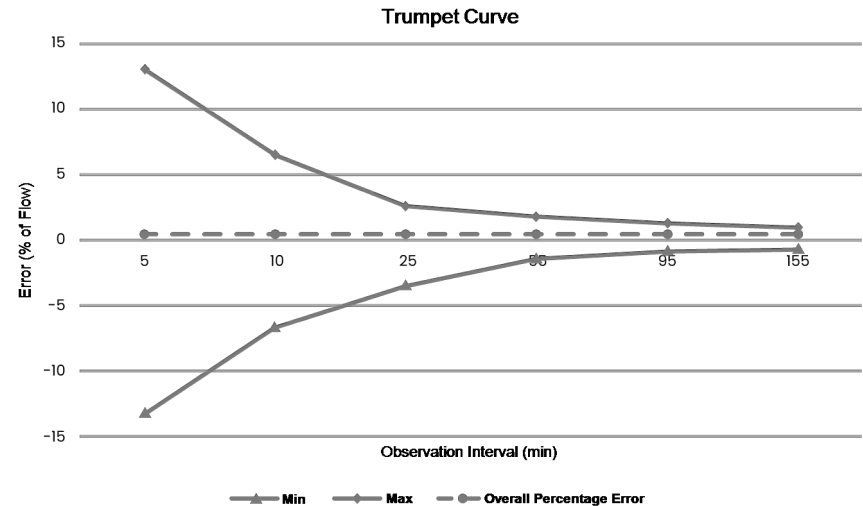
Occlusion Detection Performance

To assess occlusion detection performance and unintended bolus upon occlusion release performance, 32 pumps were tested. Sixteen of the pumps were unaged and 16 had been aged. For both aged and unaged pumps, eight pumps were tested with an unaged cassette, and eight with a cassette which underwent one year of accelerated aging. At the maximum infusion rate the bolus volume after occlusion release is no more than 0.74 units.

Table 20: Occlusion detection performance

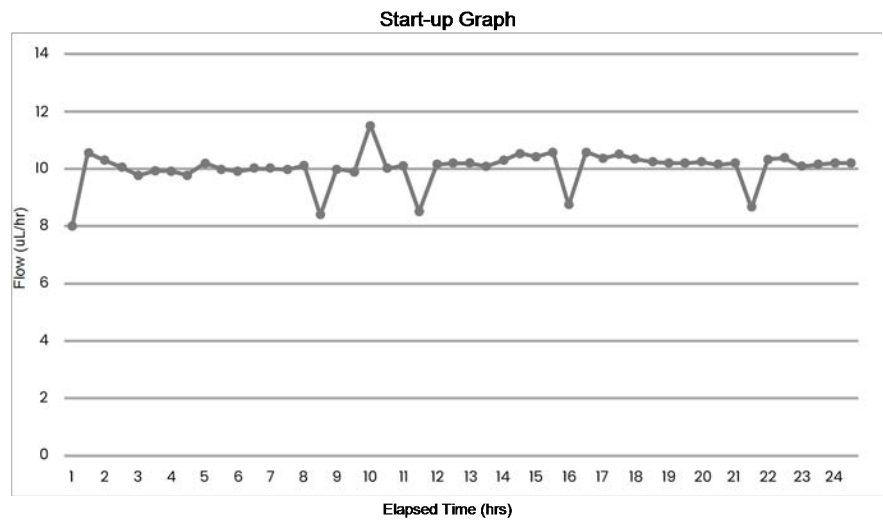
Operating Rate	Typical	Maximum
Bolus (2 Units)	00:01:52	10 minutes
Basal (1.00 U/hr)	00:19:33	3 hours
Basal (0.1 U/hr)	01:55:00	6 hours
Maximum time to detect occlusion will vary based on delivery rates. Certain factors, such as the presence of air in the infusion set can delay a <i>Line Blocked</i>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

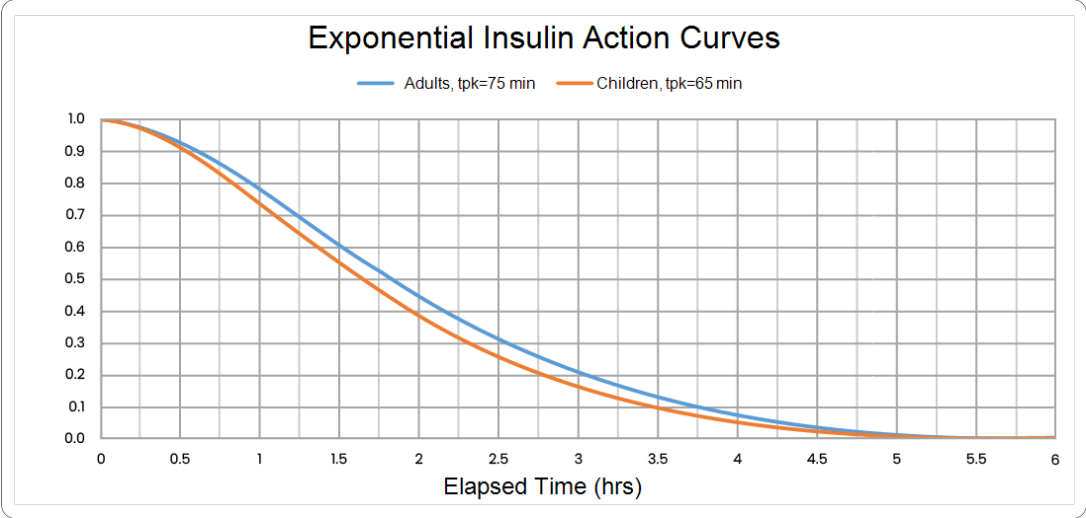


The *Start-Up Graph* shows the average flow rate over 30 minute periods. The measurements were taken at an intermediate basal rate of 1 U/hr with *Loop* off, in accordance with IEC 60601-2-24: 2012, at room temperature while delivering U-100 Humalog insulin through an extension set made of Dunn tubing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

Insulin Models

Table 21: 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 22: 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 23: Immunity test

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 2 kV, ± 4 kV, ± 6 kV, ± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV & ± 15 kV air	± 2 kV, ± 4 kV, ± 6 kV, ± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV & ± 15 kV air	Use in home healthcare environments.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 1 kHz 80% AM carrier	10 V/m 80 MHz to 2.7 GHz 1 kHz 80% AM carrier	Use in home healthcare environments, excluding near high frequency surgical equipment or near Magnetic Resonance machines.
	27 V/m 380 MHz – 390 MHz 18 Hz PM carrier	27 V/m 380 MHz – 390 MHz 18 Hz PM carrier	
	28 V/m 430 MHz – 470 MHz 1 kHz FM carrier	28 V/m 430 MHz – 470 MHz 1 kHz FM carrier	Portable and mobile RF communication equipment should be used no closer to any part of the system, including cables, than the recommended separation distance of 12 inches (30 cm).

Table 23: Immunity test

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Radiated RF IEC 61000-4-3 cont.	9 V/m 704 MHz – 787 MHz 217 Hz PM carrier	9 V/m 704 MHz – 787 MHz 217 Hz PM carrier	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
	28 V/m 800 MHz – 960 MHz 18 Hz PM carrier	28 V/m 800 MHz – 960 MHz 18 Hz PM carrier	
	28 V/m 1700 MHz – 1990 MHz 2400 MHz – 2570 MHz 217 Hz PM carrier	28 V/m 1700 MHz – 1990 MHz 2400 MHz – 2570 MHz 217 Hz PM carrier	
	9 V/m 5.1 GHz – 5.8 GHz 217 Hz PM carrier	9 V/m 5.1 GHz – 5.8 GHz 217 Hz PM carrier	

Table 23: Immunity test

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

Table 23: Immunity test

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° phase angles 0% U_T for 1 cycle 70% U_T for 25 cycles at 50 Hz, 30 cycles at 60 Hz 0% U_T for 250 cycles at 50 Hz, 300 cycles at 60 Hz	0% U_T for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° phase angles 0% U_T for 1 cycle 70% U_T for 25 cycles at 50 Hz, 30 cycles at 60 Hz 0% U_T for 250 cycles at 50 Hz, 300 cycles at 60 Hz	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 23: Immunity test

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
RFID Immunity AIM 7351731	134.2 kHz RFID fields	134.2 kHz RFID fields	AIM 7351731 testing applies to medical electrical equipment and systems. AIM 7351731 sets for test methods/levels for the electromagnetic immunity of such equipment/systems.
	13.56 MHz RFID fields 13.56 MHz RFID fields 13.56 MHz RFID fields	13.56 MHz RFID fields 13.56 MHz RFID fields 13.56 MHz RFID fields	
	433.92 MHz RFID fields	433.92 MHz RFID fields	
	860 MHz to 960 MHz RAIN RFID fields	860 MHz to 960 MHz RAIN RFID fields	
	2.4 GHz RFID fields	2.4 GHz RFID fields	
	Note: U_T is the a.c. mains voltage prior to application of the test level.		

Radio Specifications

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

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

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

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

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

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

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

- Transmit and Receive Frequency Range: 2.4 -2.5 GHz
- Effective Radiated Power: < 10 mW
- Modulation: Gaussian Frequency Shift Keying per IEEE 802.15.4-2006
- Protocol: Bluetooth Low Energy
- Effective range (smartphone/pump): 33 ft (10 m)
- Wireless Security: AES-128 encryption with Cypher-block Chaining

Quality of Service Provisions

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

The twist automated insulin delivery system supports communication between the pump and smartphone, and communication between the pump and a compatible CGM.

Quality of Service: Smartphone and twist Pump

Quality of service for Bluetooth Low Energy communication between the smartphone and paired pump includes the ability for the smartphone 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 smartphone 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 twist AID system will continue to make adjustments to your basal insulin when not in communication with the twist app. Interruption or corruption of communication between the smartphone 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 twist app will generate *No Communication* notice. See "*No Communication*" on [page 223](#).

In the absence of communication with the smartphone, alarm, urgent alert, and alert notifications will be generated by the pump. An alert can be enabled by the user if communication between the smartphone 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 twist 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 notifications) is assured at regular 1-minute intervals. If communication is lost between the twiist pump and FreeStyle Libre 3 Plus Sensor for 5-minutes, the twiist app will display an indication of *Signal Loss* on the *Home Screen*. If communication 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 communication 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.

*Quality of Service: **twiist Pump and Eversense 365 Smart Transmitter***

Quality of Service for the **twiist** pump and Eversense 365 smart transmitter wireless communications using BLE for normal operation (receiving glucose readings and notifications) at regular 5-minute intervals.

If communication is lost between the **twiist** pump and Eversense 365 smart transmitter for 10-minutes, the **twiist** app will display an indication of CGM Signal Loss on the *Home Screen*.

If communication 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 Eversense 365 smart transmitter, the last 24 hours of lost glucose data will be automatically retrieved when communication is restored. The **twiist** pump is designed to only accept Bluetooth Low Energy data from recognized and paired Eversense 365 smart transmitters. The transmission range for Bluetooth Low Energy communication is 24.9 feet (7.59 m) unobstructed. If frequent signal loss between the **twiist** pump and Eversense 365 smart transmitter occur 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 smartphone does not need to be connected to Wi-Fi in order for the pump or smartphone to function properly.

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

FreeStyle Libre 3 Plus Sensor Operating Conditions

Table 24: 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.

Table 25: FreeStyle Libre 3 Plus Sensor Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, 4 kV, 8 kV, 15 kV air	± 8 kV contact ± 2 kV, 4 kV, 8 kV, 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
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 25: 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 of the FreeStyle Libre 3 Plus Sensor requires continued battery charging during power mains interruptions, it is recommended that the system be powered from an uninterruptible power supply or a battery.
	0% U_T for 1 cycle	0% U_T for 1 cycle	
	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 25: 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 25: FreeStyle Libre 3 Plus Sensor Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 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 twist 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 twist pump and continuous glucose monitor (CGM) data.

There are three key concepts underlying the Loop algorithm:

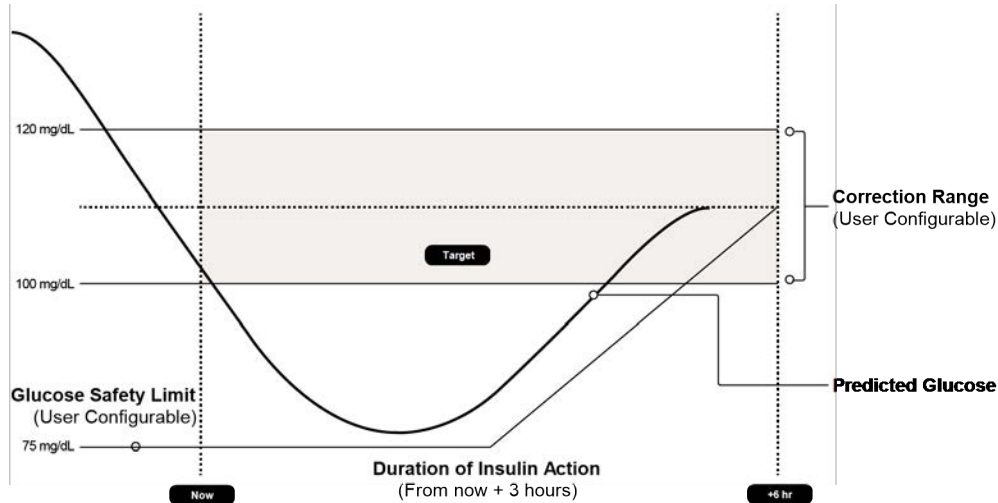
- a. The goal of the algorithm is to deliver insulin so that your predicted glucose arrives at the midpoint of your correction range at the end of insulin action time. Insulin delivery is constrained by the amount of insulin predicted to bring your predicted glucose curve no lower than the dosing safety 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 315](#) 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 26: *Loop insulin models*

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

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

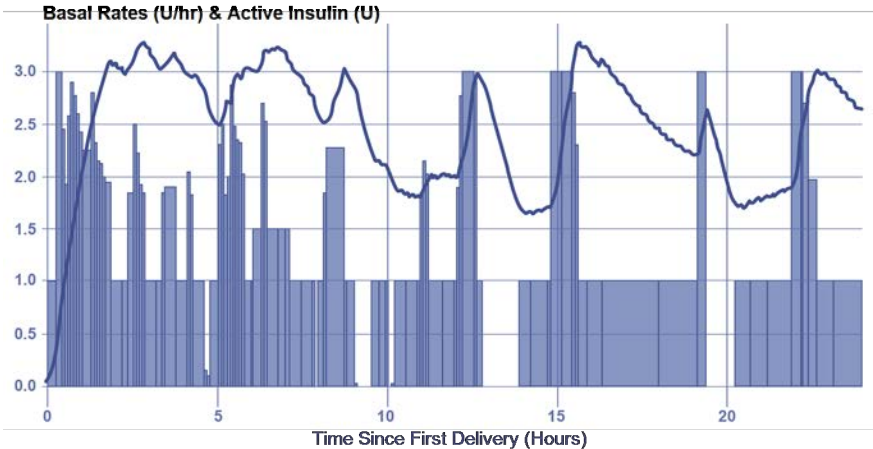
If you are coming from traditional pump therapy, you may be familiar with the duration of insulin activity being user-configurable. In Loop, this setting cannot be changed. The algorithm is considering the activity time of all of the adjustments to your basal insulin, as well as boluses.

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

 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

① 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.

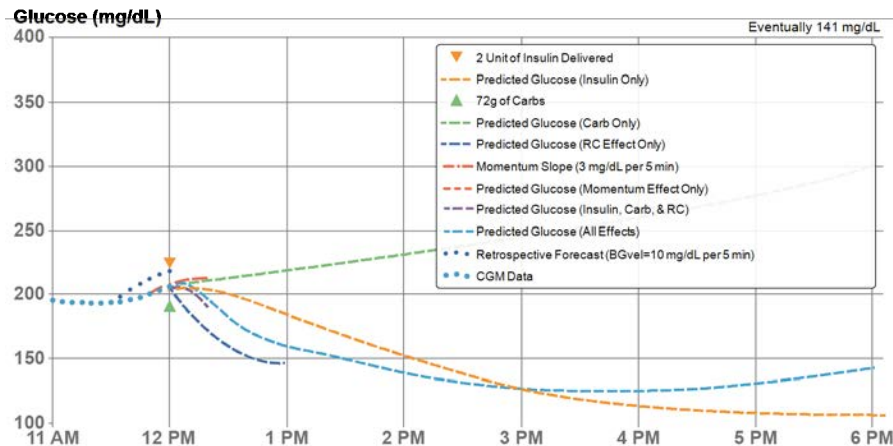
The momentum slope is then blended into the next 20 minutes of expected glucose, as predicted from the other effects (i.e., insulin, carbohydrates, and retrospective correction effects). This, in effect, makes the next 20 minutes of glucose prediction more sensitive to recent glucose trends. The blending 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 Range* value Loop is aiming for.
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 Range* value Loop is aiming for.
3. **Reduce Basal Rate to 0.00 U/hr:** If the current CGM value or any point in the predicted glucose goes below the dosing safety threshold, Loop will issue a temporary basal rate of zero units per hour, regardless of the eventual glucose.
4. **Resume Scheduled Basal Rate:** There are three situations where the Loop algorithm will resume the current scheduled basal rate.
 - a. If the eventual glucose is within the *Correction Range*, and all values in the predicted glucose are above the dosing safety threshold, then Loop will resume the current scheduled basal rate.

- b. If the eventual glucose is above the *Correction Range*, and the predicted glucose values have a temporary excursion below the *Correction Range*, but are above the dosing safety threshold, then Loop will resume the current scheduled basal rate.
- c. If the Loop algorithm does not have all of the data it needs to make a prediction, it will let the remaining temporary basal rate run its duration (maximum of 30 minutes), and then the basal rate will default back to the current scheduled basal rate, thus returning to the same therapy pattern that the user would receive using traditional insulin pump.

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

Bolus recommendations

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

 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.

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

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

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

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

Additional safety features:

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

Loop Simple Bolus Calculator (Loop off)

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

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

When Loop is off, the app uses a simplified bolus calculator like a typical pump.

Carbohydrates 60 g

Fingertick Glucose 155 mg/dL

Recommended Bolus 4.00 U

Adjusted for Active Insulin 1.91 U

Bolus 4.00 U

Next

When Loop is off, the app uses a simplified bolus calculator like a typical pump.

Fingertick Glucose 150 mg/dL

Recommended Bolus 0.55 U

Adjusted for Active Insulin 0.35 U

Bolus 0.55 U

Done

1 2 3
4 5 6
7 8 9
0

Table 27: 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 limited to intended user population		Study population limited to intended user population <i>(Ages 6 and up, settings within allowable Tidepool Loop ranges at least 90% of the time during study follow-up)</i>
	<i>New Users (Cohort A)</i>	<i>Existing Users (Cohort B)</i>	
N	606	266	175

Demographics

<i>Age</i>	16 Years (median) 1-72 Years (range)	34 Years (median) 13-76 Years (range)	23 years (mean) 6-71 (range)
<i>Sex</i>	56% Female	52% Female	56% Female
<i>Race</i>	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
<i>Education</i>	85% - Bachelor's Degree or Beyond	89% - Bachelor's Degree or Beyond	88% - Bachelor's Degree or Beyond
<i>Household Income >\$100,000</i>	71%	78%	68%

Summary Diabetes Outcomes

HbA1c at baseline (mean)	6.8%	6.3%	7.1%
HbA1c after 6 months of using DIY Loop (mean)	6.6%	6.4%	6.7%
Time in Range (70-180 mg/dL) at baseline (mean)	67%	78%	62%
Time in Range (70-180 mg/dL) 1-6 months of using DIY Loop (mean)	74%	79%	70%

Summary Safety Outcomes

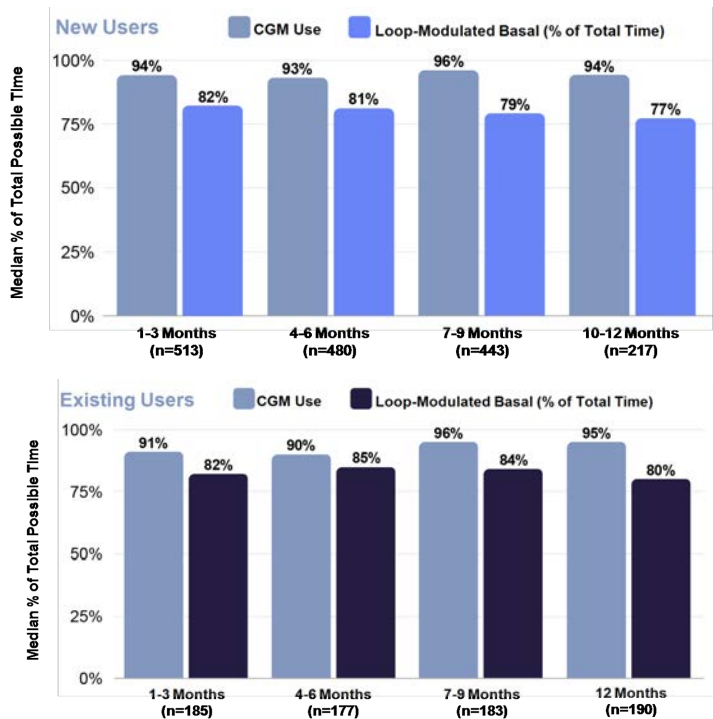
All Adverse Events	No DKA events 71 SH events	No DKA events 24 SH events	No DKA events 23 SH events
Severe Hypoglycemia (SH) during study	92% no SH from baseline to 12 months. 22.6 SH events per 100 person years compared to 181.5 events per 100 person years prior to using Loop.	95% no SH from baseline to 12 months. 14.2 SH events per 100 person years.	92% no SH from baseline to 6 months. 42.3 SH events per 100 person years compared to 192.0 events per 100 person years prior to using Loop.

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

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

3. System Intervention

The following two bar graphs show how often CGM data was available (“CGM Use”), and how often Loop 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

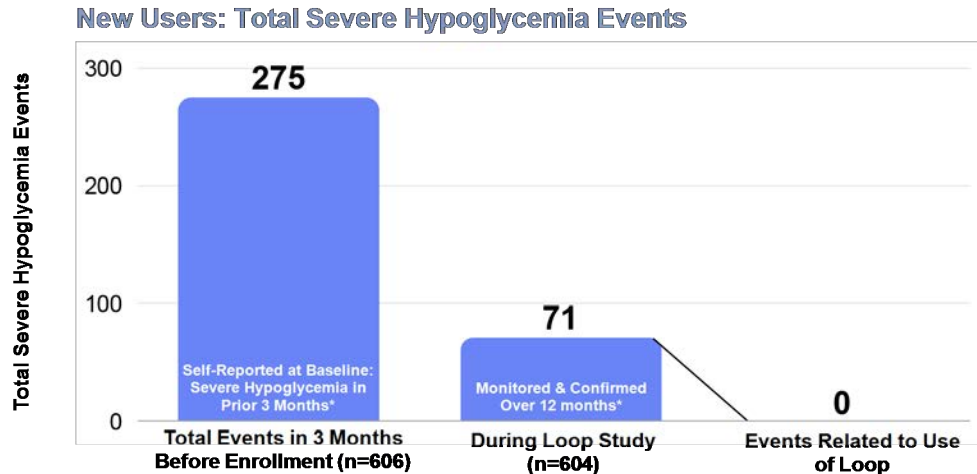
CGM and insulin dosing data were collected continuously and uploaded automatically from a study participant's own iPhone. The Tidepool Mobile app securely sent this data to Tidepool's cloud, from which it was retrieved by the Jaeb Center for Health Research and replicated in the Jaeb Center's database. 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.

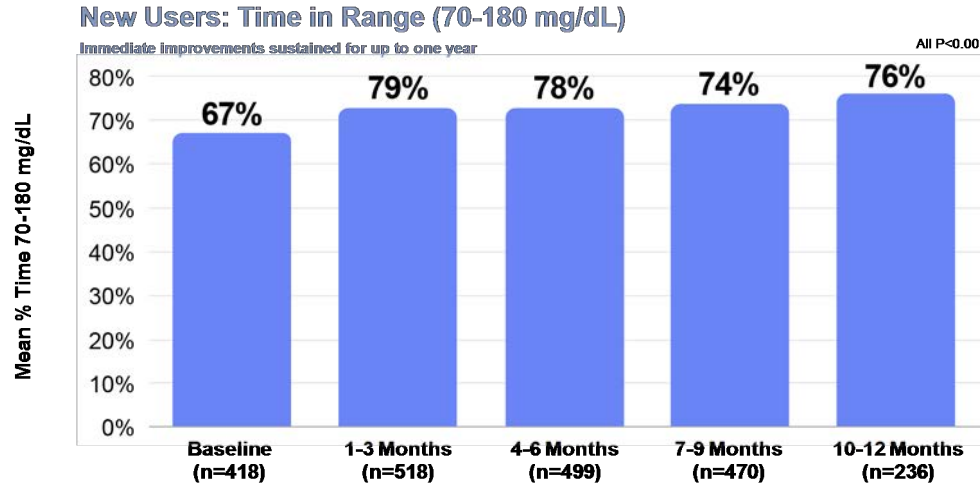
Primary Safety Analysis

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).



Primary Glycemic Outcomes

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



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

Quality of Life Outcomes

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

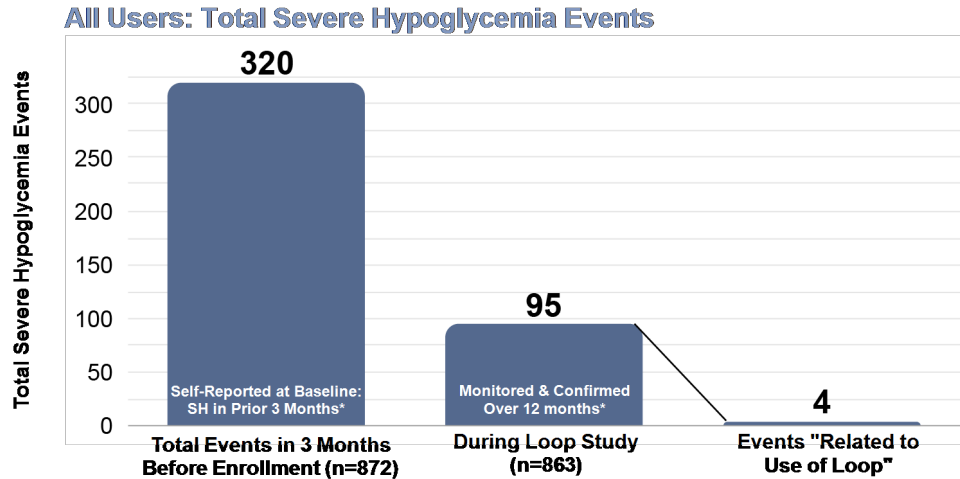
In Cohort A, statistically significant improvements were also seen with DIY Loop in the Diabetes Distress Scale – Management Burden; Fear of Hypoglycemia (Worry Scale); Hypoglycemia Confidence; and the Pittsburgh Sleep Quality Index. These validated questionnaires appear to corroborate the CGM and HbA1c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

7. Results: Cohort B (Existing Users)

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

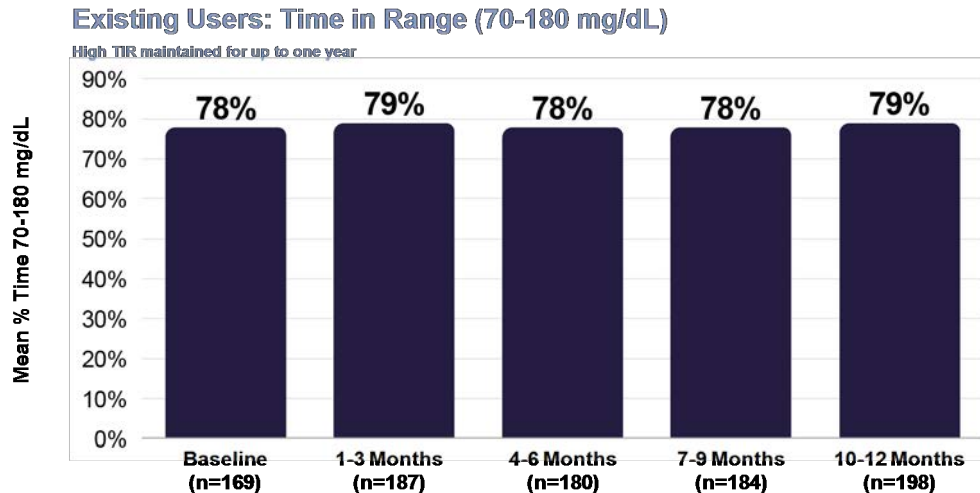
Primary Safety Analysis

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



Primary Glycemic Outcomes

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



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

Quality of Life Outcomes

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

8. Adverse events

Intended Use Population

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

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

These data show that:

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

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

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

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

Severe Hypoglycemia for Participants ≥6 Years Old

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

Severe Hypoglycemia (3 Months Prior to Baseline)				
Total # of events	84	50	2	32
# Events per participant				
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	10	5	3	2
# Events per participant				
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 ≥6 years old.

b Incidence reported per 100 person years

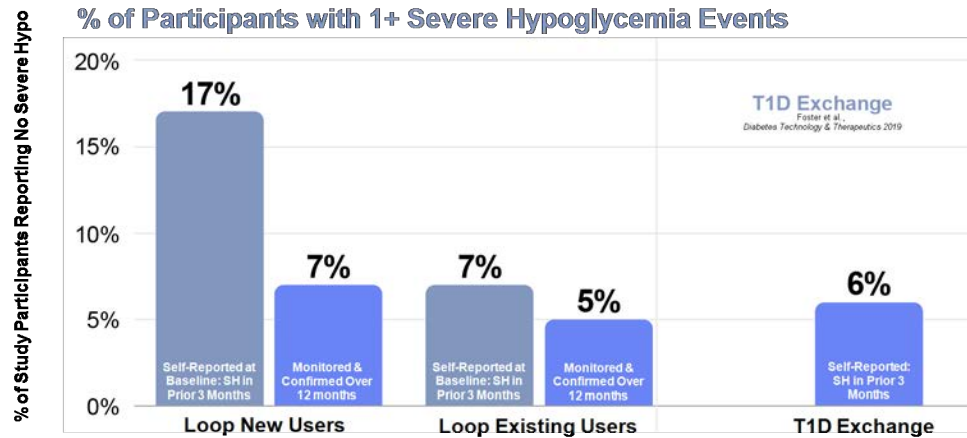
Overall Population

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 Hypoglycemia²			
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	18	11	7
# Events per participant			
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	7	5	2
# Events per participant			
0	856 (99%)	599 (99%)	257 (99%)
1	7 (<1%)	5 (<1%)	2 (<1%)

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

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

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

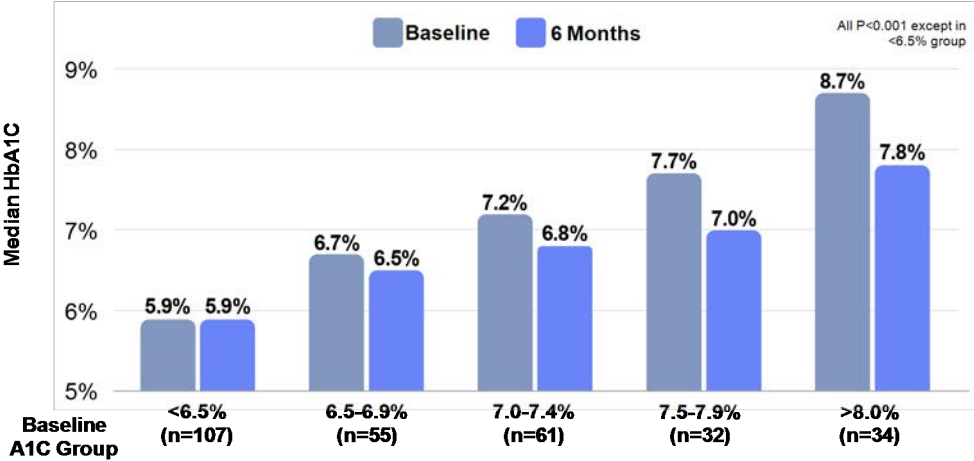
9. Conclusions

Results demonstrated that DIY Loop can be safely and effectively self-initiated and used by adults and children with type 1 diabetes for up to 12 months. With 483 person-years of data (over 175,000 person-days), this study contained more than 10x the typical amount of exposure data collected in controlled automated insulin dosing (AID) trials. There was no guidance provided to participants as to how DIY Loop was to be used, no formal customer support for troubleshooting, no training, no provision of supplies, and no prescription or required HCP involvement. Study participants initiated DIY Loop either on their own or with community-developed resources.

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

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

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



10. Applicability to the twiist automated insulin delivery system

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

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

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

GLOSSARY

A

Active Carbohydrates

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

Active Insulin

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

B

Basal

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

Battery Change

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

Battery Charger

A hardware device used to charge the pump batteries.

Blood Glucose

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

Bolus

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

C

Cannula [kan-yuh-luh]

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

Carb Absorption

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

Carb Ratio

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

Carbohydrate

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

Cassette

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

Cassette Change

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

CGM Status

An icon displayed at the top of the twist 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 twist AID system uses when helping calculate a bolus. When Loop is ON, the twist 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 twist AID system, when Loop is on, for how carbs will be absorbed, spread over an interval that is 1.5 times the selected absorption time for carbs that have been entered. Dynamic carb absorption allows for variations in actual absorption.

E

Extended Bolus

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

G

Glucose Prediction

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

Glucose Safety Limit

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

Grams

Grams are the measurement for a carbohydrate.

H

High Blood Glucose

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

I

Increased Basal

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

Infusion Set

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

Insulin

Insulin is an infused medication used to treat diabetes.

Insulin Model

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

Insulin Sensitivities

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

L

Loop

Loop is an interoperable automated 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 twist 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 twist 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.

M

Manual Bolus

Direct entry of the desired bolus volume in units.

Maximum Basal Rate

Maximum Basal Rate is the highest basal rate that can be set by the twist 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 twist AID system is allowed to set automatically.

Maximum Bolus

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

N

Normal Bolus

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

O

One-Button Bolus

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

P

Pre-Meal Range

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

Prime

The act of moving insulin from the cassette through the infusion set tubing to prepare the system for delivery or remove air. Priming is performed before the infusion set tubing is connected to the infusion site.

Pump

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

Pump-Bump

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

Pump Battery

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

Pump Cover

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

Pump Status

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

R

Reduced Basal

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

S

Scheduled Basal

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

Subcutaneous

Situated or applied under the skin.

Syringe

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

T

Temporary Basal

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

twiist App

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

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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