



Powered by Tidepool®



GETTING **STARTED**

GUIDE

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Introduction to the twiist™ Getting Started Guide

Welcome to the twiist Automated Insulin Delivery (AID) System powered by Tidepool®!

We are so excited you have chosen the twiist AID System! The twiist Pump features innovative technology and is the first commercial AID system to integrate an algorithm based on Tidepool Loop – which was developed by the diabetes community for the diabetes community.

We are here to support you through your training! This guide is designed to get you started through the twiist training journey. It is divided into three sections:

Part 1: twiist Foundation and Readiness to prepare you for use of the twiist AID System.

Part 2: twiist AID System Setup and Use to start your twiist AID System experience — from getting connected through day-to-day use of the system.

Part 3: twiist Training Follow-Up to set expectations on your training follow-up to help drive success.

Sequel Customer Support

Number: 877-4twiist (877-489-4478)

Website: <https://twiist.com>

Address: Sequel Med Tech, LLC., 50 Commercial St, Manchester, NH 03101

Certified twiist Trainer

Name: _____

Phone: _____

Email: _____

Ready? Let's get twiisting!

Training and Support

This Getting Started Guide provides an introduction to the basic operation and programming of your twiist AID System. It does not take the place of training. It is important to receive training so you understand how to effectively and safely use your twiist AID System. Discuss your individual training needs with your healthcare provider.



WARNING: 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.



CAUTION: 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.



Part 1: twiist Foundation & Readiness

This part of the twiist Getting Started Guide is here to help you get comfortable with the twiist AID System. It walks you through the essentials to prepare you for your twiist AID System training.

Learning Objectives:

- Review the twiist AID System Indications and Contraindications
- Review the insulins that are compatible with the twiist AID System
- Review the CGMs that are compatible with the twiist AID System
- Identify when to work with your healthcare provider
- Review considerations for using twiist during medical procedures
- Review the warnings, cautions, list of emergency supplies, and steps to take before you start setting up your system
- Detail the components of both the twiist Starter Kit and the twiist Refill Kit

Important Safety Information

For complete details of the system, including full indications, instructions for use, warnings, and cautions, please refer to the **twiist Automated Insulin Delivery System** powered by Tidepool User Guide at www.twiist.com/twiist-on-support.

Images of the device and supplies pictured throughout this Getting Started Guide may not be an exact representation and are for instructional purposes only.

The appearance of the **twiist** App and available settings may vary based on your smartphone model and operating system.

Values displayed in this Getting Started Guide are for demonstration of the **twiist AID System** features and should not be used for making therapy decisions.

Changes in equipment, software, or instructions may occur. Changes will be included in future revisions of the Getting Started Guide.

Indications For Use

twiist Alternate Controller Enabled (ACE) Pump

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.

The twiist Loop Algorithm

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 and for the management of type 2 diabetes mellitus in persons eighteen years of age and greater. The twiist Loop algorithm is intended for single-patient use and requires a prescription.



INFORMATION: Throughout this *Getting Started Guide*, *Loop* on/enabled indicates that the Loop algorithm is in use to automate basal delivery and provide bolus recommendations. *Loop* off/disabled indicates that basal delivery will follow your basal pattern and bolus recommendations will use the included Bolus Calculator.

Bolus Calculator

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).



CAUTION: The twiist AID System should not be prescribed to patients with vision, hearing, cognitive, or physical impairments that would affect their ability to use the twiist AID System.

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.



WARNING: Only use fast-acting U-100 Humalog (insulin lispro) or NovoLog (insulin aspart). Use of other concentrations or types may lead to insulin delivery errors that could cause low or high blood glucose.

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).

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.



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

FreeStyle Libre 3 Plus Sensor



INFORMATION: 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



INFORMATION: 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/compatibility](https://twiist.com/compatibility) to see what smartphones, smartwatches, and operating systems are compatible with the twiist AID System.



WARNING: Do not install Beta Updates for iOS or Android. 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.



CAUTION: 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.



CAUTION: 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.



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

Working with your Healthcare Provider

Talk with your healthcare provider before starting twiist. Together, decide which features are best for your diabetes care.

It is the responsibility of the healthcare provider and caregiver to determine if the patient is a good candidate for treatment with the twiist Automated Insulin Delivery System.

The twiist AID System does not eliminate the need for routine follow-up.

Do not adjust your therapy settings without consulting with your healthcare provider.



WARNING: 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).



CAUTION: 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.

Warnings and Cautions

Medical Advisories

MR

WARNING: The twiist Automated Insulin Delivery System is Magnetic Resonance Unsafe. Disconnect the twiist Pump before entering an MRI scan room. Do not bring your smartphone or twiist Pump into an MRI scan room. Contact with, or being in proximity to, an MRI scanner may cause the twiist Pump and smartphone to move or lead to electric shock and may result in severe injury.



WARNING: Do not expose your twiist 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 twiist AID System and leave it outside the room prior to these procedures. Failure to do so may lead to harm.



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



WARNING: 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.



WARNING: 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.



CAUTION: *twiist* Loop combined with GLP-1 agonists, SGLT-2 inhibitors, DPP-4 inhibitors or metformin has only been studied in people with Type 2 diabetes mellitus and has not been studied in people with Type 1 diabetes mellitus. The performance of *twiist* Loop in conjunction with these medications is unknown in the Type 1 patient population.

Approved Parts



WARNINGS:

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

Disposables



WARNINGS:

- 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.

Infusion Site Connection



WARNINGS:

- 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.
- 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.

Infusion Set



WARNINGS:

- Always rotate insulin infusion sites to help prevent infusion site complications like scar tissue and infection. Rotating insulin infusion sites reduces the risk of scarring. Using a site with scar tissue can lead to problems with insulin absorption or blockages that may lead to high blood glucose.
- Always follow your infusion set manufacturer instructions for infusion site insertion and care. Failure to do so may result in over or under-delivery of insulin or infection.

Contamination or Damage



WARNINGS:

- 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.



CAUTION: 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.

Cassette Fill and Prime



WARNINGS:

- 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 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.
- 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.



CAUTIONS:

- Do not fill the cassette with more than 300 U of insulin. Filling the cassette with more than 300 U may lead to pump malfunctions and interruptions of therapy.
- Do not refill previously filled cassettes. Refilling previously used cassettes may lead to pump malfunctions and interruptions of therapy.

Discontinue Use



WARNING: If the twist AID System fails to work as described within the twist AID System User Guide, stop using the system and switch to your backup insulin therapy. Using the system when it is not working as described within the twist AID System User Guide may lead to harm.



CAUTIONS:

- Stop using the pump and switch to your backup insulin delivery method in the event the pump housing is cracked, the pump button is damaged, or there is other evidence of damage to the pump. Failure to do so may lead to pump malfunctions resulting in interruption of therapy.
- Discontinue use of the system and switch to your backup insulin therapy plan if the pump fails to beep during the pump self-test.

Training and Use



WARNINGS:

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



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

Smartphone and Smartwatch



WARNINGS:

- A passcode must be enabled to use the twiist App on your smartphone or smartwatch. Your 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, Critical Alerts (iPhone), or Modes Access/Do Not Disturb Permission (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.

Travel



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



WARNINGS:

- Do not ignore how you feel or symptoms of high and low glucose. If your CGM glucose readings do not match how you feel, measure your blood glucose with a BG meter even if your CGM reading is not in the high or low range. Ignoring the symptoms of high and low glucose even when your CGM reading is not in the high or low range may lead to incorrect treatment decisions which may lead to harm.
When in doubt, get your meter out.
- FreeStyle Libre 3 Plus Sensor readings and alerts are not available during the 60 minute warm-up period or during *CGM Signal Loss*. Check your glucose using your BG meter to prevent low or high glucose.
- The Eversense 365 sensor will not provide readings during warmup, until a second calibration is successful during the initialization phase, or during CGM Signal Loss. Check your glucose using your BG meter to prevent low or high glucose.



CAUTION: 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.

Sound and Vibration



CAUTIONS:

- 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 *twiist* 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 *twiist* App notifications can be heard.

Emergency Supplies

Always keep a small supply kit nearby to help you stay prepared when you are away from home. Talk to your healthcare provider about what you should keep in your emergency supplies in addition to:

- Blood glucose monitoring supplies
- Fast-acting glucose
- Spare insulin
- Provided syringe and needle
- Unopened cassette
- Unopened infusion set
- Alcohol wipes
- Fully charged twist Pump batteries

Always order your prescription supplies in advance:

- Insulin
- CGM supplies
- Infusion Sets
- twist Cassettes

Insulin Backup Plan

Always have a backup insulin plan ready. Use your backup plan if insulin delivery stops unexpectedly or the twiist AID System is disconnected for more than 1-2 hours. Not having a backup insulin plan can cause high blood glucose or diabetic ketoacidosis (DKA). Work with your healthcare provider to ensure your backup plan is right for you.

My backup **long-acting** insulin is _____. I inject _____ units daily.
My backup **rapid-acting** insulin is _____.

I dose insulin for carbohydrates using:

☐	Insulin to Carb Ratio	1: _____
☐	Small/Medium/Large Dose	_____ / _____ / _____
☐	Set units at meals and snacks	_____ units with meals _____ units with snacks

If my glucose is **high**, I add 1 unit for every _____ over _____ mg/dL.
I can use this correction dose if it has been _____ or more hours since my last rapid-acting insulin injection.

Signs of high glucose:

- Increased thirst/dry mouth
- Frequent urination
- Headache
- Nausea or vomiting, stomach pain

Treat high glucose as directed by your healthcare provider. Check your ketones if glucose stays over 250 mg/dL for 2 hours. Make sure you have ketone testing supplies and a ketone action plan. Call your healthcare provider if you need prescriptions or to review your ketone action plan.

Call 911 or go to the emergency room if glucose is very high and any of these symptoms are present:

Nausea or vomiting, shortness of breath, confusion, or loss of consciousness.

Backup Plan: Ongoing Preparedness

- Ask about updating your insulin backup plan at routine visits
- Keep your long-acting insulin refrigerated
- Check your long-acting insulin expiration dates before use
- Replace any opened insulin vial or pen every 28 days (or per label)
- Keep a backup glucose meter

Before You Start

- ✓ Charge your smartphone daily to ensure you always have access to the twiist App.
- ✓ Your smartphone passcode feature must be enabled in order to use the twiist App.
- ✓ Ensure Bluetooth is enabled on your smartphone to allow the twiist App to communicate with the twiist Pump and CGM.
- ✓ Notifications, Critical Alerts (iPhone), or Modes Access/Do Not Disturb Permission (Android) must be enabled within your smartphone settings in order to receive notifications from the twiist App.
- ✓ Notifications provided by the twiist App are played on your iPhone at the Ringtone and Alerts volume, or on your Android at the Media volume. In order to hear and feel notifications, your smartphone volume must be turned up and Haptics or vibrate must be enabled.
- ✓ Your smartphone 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 or delete the twiist App. Therapy changes cannot be made if the twiist App is not running or is deleted.
- ✓ An internet connection (Wi-Fi or cellular) is required in order to download the twiist App, pair your twiist App and twiist Pump, receive software updates, provide data to the cloud for reporting, and for twiist insight. Only connect to trusted (secure) Wi-Fi networks.

The Continuous Glucose Monitor (CGM) in use with the system is sold separately. The CGM must be used with the twiist App on your compatible smartphone, and not the provided receiver from the manufacturer. Follow the important training and safety information that apply to your CGM device to get started.

The twiist Starter and Refill Kits

The twiist AID System is made up of several components. A few of them are disposable. There are two different kits: the Starter Kit, and the Refill Kit.

The Starter Kit

- The twiist AID System Getting Started Guide
- QR code to create your My twiist Portal account
- The twiist Pump with attached cover
- Rechargeable pump batteries (4)
- Pump battery chargers (2)
- USB charging cables (2)
- Wall power adapters with 2 USB ports (2)
- Pump clip
- twiist Cassettes (10)
- Needles (10): 27 gauge x 3/8 inch (0.40 x 10 mm)
- Syringes (10): 3 mL
- Alcohol wipes (30)
- Infusion Sets (10)

The Refill Kit

- twiist Cassettes (10)
- Needles (10): 27 gauge x 3/8 inch (0.40 x 10 mm)
- Syringes (10): 3 mL
- Alcohol wipes (30)
- Infusion Sets (10): Optional





Part 2: twiist AID System Setup and Use

This section of the Getting Started Guide provides instructions and practice activities (completed with your Certified twiist Trainer) to set up and begin using your twiist AID System.

Learning Objectives:

- Set up My twiist Portal Account
- Set up your twiist App and review the Introduction, How the App Works, and A Day in the Life modules
- Identify, set up, and become familiar with the use of the twiist AID System components (e.g., batteries and cassettes)
- Use the twiist App to pair your pump and continuous glucose monitor (CGM)
- Program your twiist *Therapy Settings*
- Start Looping! Insert your infusion set and start automated insulin delivery
- Describe the functions, notifications, and settings of the twiist App and your CGM
- Define and demonstrate daily use of the twiist AID System

About the twiist AID System

The twiist AID System:

- Automatically increases or decreases basal insulin and recommends boluses when requested by the user. It uses information from:
 - A compatible Continuous Glucose Monitor (CGM)
 - The twiist Loop algorithm
 - The twiist Pump
- Makes a calculation and can adjust insulin delivery as often as every 5 minutes. This 5-minute cycle is called a *Loop*.
- Uses the twiist App on your compatible smartphone.

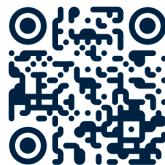


Did you know?

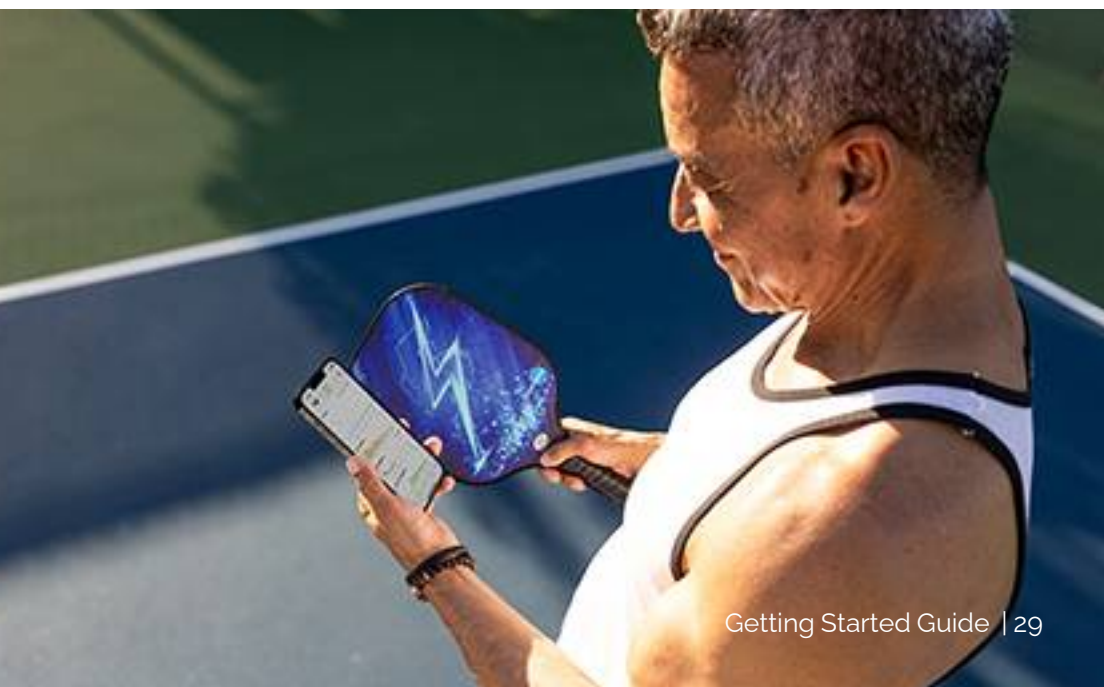
- The twiist Loop algorithm calculates insulin needs using your twiist App *Therapy Settings*, CGM data, recent insulin deliveries, and carb entries. Its unique features - like customizable carb absorption time and ability to edit carb entries - help the algorithm deliver the right insulin dosing for you.
- The twiist AID System measures each dose in order to accurately deliver insulin.

Set Up My twiist Portal Account

Perform these steps prior to training with your Certified twiist Trainer.



1. Scan the QR code to go to mytwiistportal.com and enter information to create My twiist portal account.
2. Select the **Create twiist account** button.
3. Select who will be wearing twiist and if the wearer currently has twiist.
4. Select **Save**.
5. Enter the information for the person wearing the twiist pump and create a password.
If required, enter the information for the parent or guardian.
6. Agree to the Terms of Use and **Save**.
7. Check your email for a verification message from twiist and click on the link in the email to verify your email address.
8. Sign in and continue setting up your account.



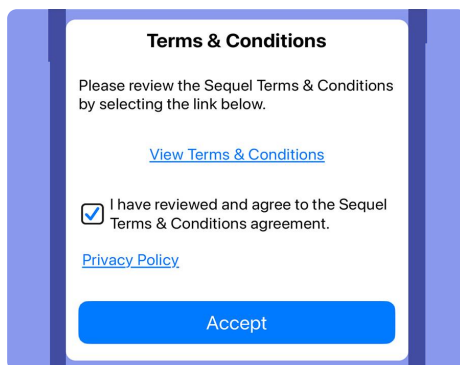
Set Up Your twiist AID System

Perform these steps prior to training with your Certified twiist Trainer.

1. Download the twiist App.



2. Open the twiist App on your smartphone.
3. Tap **Welcome**.
4. Enter your My twiist Portal Account **username** and **password**.
5. Tap **Login**.
6. Tap the **box** after you have reviewed the *Terms & Conditions*.
7. Tap **Accept**.
8. Tap **Continue** to review each of the *Welcome to the twiist AID System* and *Getting to Know the twiist AID System* modules, including:
 - Introduction
 - How the App Works
 - A Day in the Life



Plan for about 30 minutes to complete these sections which will help you feel prepared for training day. When you meet with your Certified twiist Trainer, you will go through the remainder of *Getting to Know the twiist AID System*, including pairing your twiist Pump and CGM, entering your therapy settings, and starting insulin delivery.



INFORMATION: Before proceeding, your Certified twiist Trainer will contact you to schedule an appointment to complete your twiist AID System training and setup.

Pump Batteries

Before you use your twist AID System, and each time you replace your cassette and infusion set, make sure to charge the pump batteries. The rechargeable lithium-ion batteries included with the twist AID System are designed for use with the twist Pump.

The pump batteries are charged using the provided battery charger and wall power adapter. The pump batteries typically take 6 hours or less to charge and will power the pump for 3 days (72 hours).

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



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 - A charging fault occurred. Reinsert the pump battery into the battery charger.

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



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



CAUTION: Do not use the wall power adapter if it is visibly damaged or malfunctioning. Using damaged or malfunctioning wall power adapters can result in electrical shock.

Inserting Pump Batteries

1. Insert the pump battery into the pump by aligning the metal contacts on the battery and pump. The battery can only be inserted into the pump in a single direction.

The pump will play a quick beep.



Skills to practice!

1. Insert the pump battery into the pump.
2. Practice inserting and removing the pump battery until the battery can be inserted and removed comfortably.
3. Remove the pump battery and place it into the battery charger.



twiist Cassettes

The twiist Cassette is a disposable, single-use component of the twiist™ AID System that holds up to 300 Units of fast-acting insulin, and attaches to the twiist Pump.

Attaching the twiist Cassette to the twiist Pump

The *pump-bump* and alignment ridge are features that help align the cassette with the pump during attachment.

1. Align the ridges on the pump-bump and the top of the cassette.
2. Press down gently while rotating the pump until the ridge on the pump-bump is aligned with the infusion set tubing and the pump and cassette click into place.



Removing the twiist Cassette from the twiist Pump

1. While holding the cassette still, rotate the pump until the ridges on the pump-bump and the top of the cassette are aligned.
2. Remove the cassette from the pump.



Skills to practice!

1. Attach the cassette to the pump.
2. Attach and remove the cassette from the pump until the process is comfortable and easily repeated.



WARNING: 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.



WARNING: 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.

Exciting things are ahead! Before you continue with your devices, wait for your training session with a Certified twist Trainer. The next steps are designed to be completed together during training to help ensure a safe and successful start.

Your Devices

Before pairing your twist 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.

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 or *Urgent Low Glucose* alert 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 cooldown, Pause App

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

Smartphone Permissions

The twist 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 requested permissions when prompted so the twist App works as expected.

Pairing the twiist Pump

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**.

To pair by taking a photo:

- 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**.

To pair by manually entering the PIN (iPhone):

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

To pair by manually entering the PIN (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**.

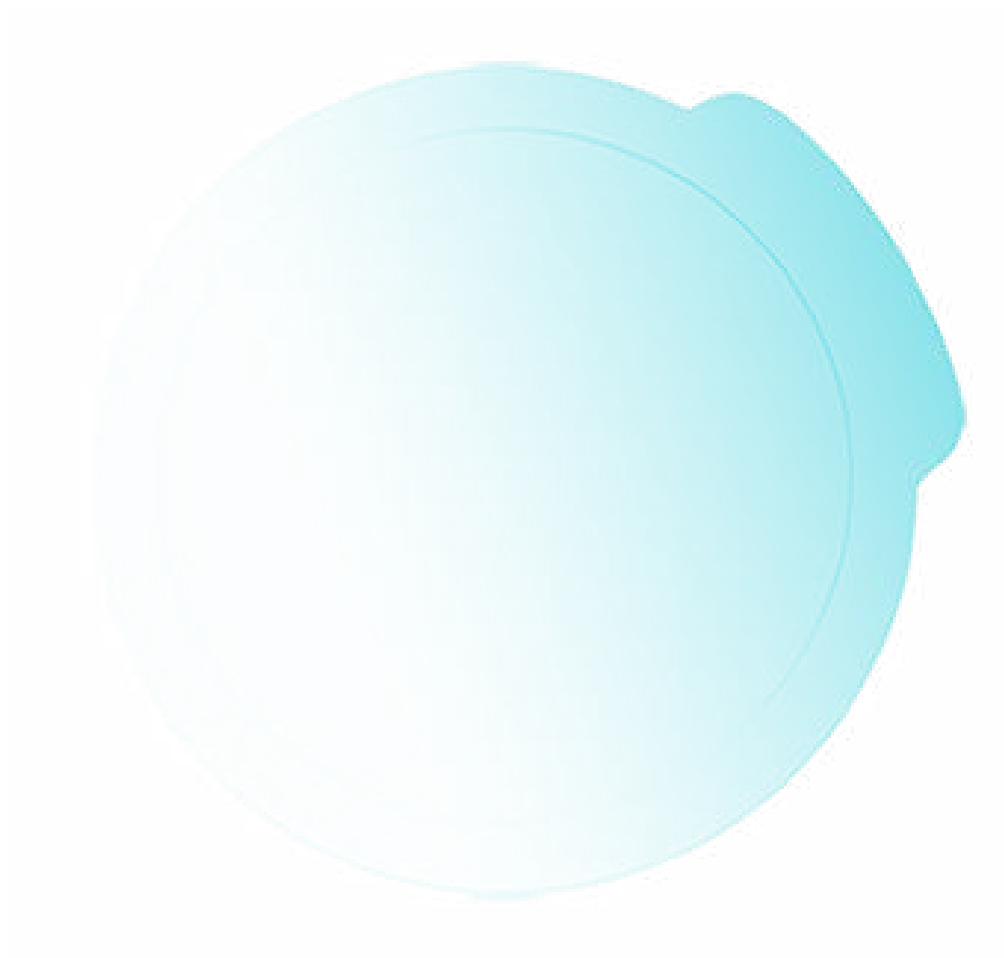


INFORMATION: If a *Limited Internet Connectivity* notice is displayed, remove and reinsert the pump battery and try to pair the pump again after joining a cellular network or a different Wi-Fi network.

Once your pump is paired, it will be included in your smartphone Bluetooth devices as the serial number shown on your pump label. Do not delete this from your smartphone Bluetooth devices.

Pump Software Update

After pairing, your pump will perform a software update. Follow the on-screen steps to complete the twiist Pump update. Keep the pump and smartphone close together and do not power off the pump or smartphone during any updates.



Pair Your CGM

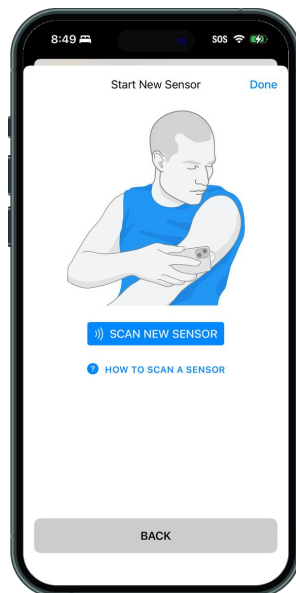
Add FreeStyle Libre 3 Plus



INFORMATION: 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. A new sensor is required.

1. Tap **Pair CGM**.
2. Tap **FreeStyle Libre 3 Plus**.
3. Clean your hands before inserting a sensor to help prevent infection.
4. Wash, clean, and dry the selected area on the back of your upper arm and apply your new sensor.
5. Tap **NEXT**.
6. Tap **SCAN NEW 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. CGM Readings will be available after setup of the twist App and the 60-minute *Sensor Warmup* period are complete.
8. Tap **OK**.

An open circle icon is displayed within the twist Loop status during sensor warmup. Refer to the FreeStyle Libre 3 Plus Sensor manufacturer instructions for instructions for proper use, safety information, and troubleshooting related to starting a new sensor.



WARNING: During the first 12 hours after starting a sensor, the  symbol will be displayed in the FreeStyle Libre 3 Plus Sensor Screen. Confirm sensor glucose readings with a fingerstick before making treatment decisions.



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

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.

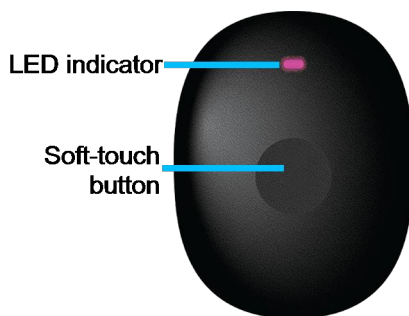
Use the Eversense 365 app to calibrate your sensor, place your smart transmitter, and configure CGM notifications.

1. Tap **Pair CGM**.
2. Tap **Eversense 365**.
The twiist App will display *Searching* for smart transmitter.

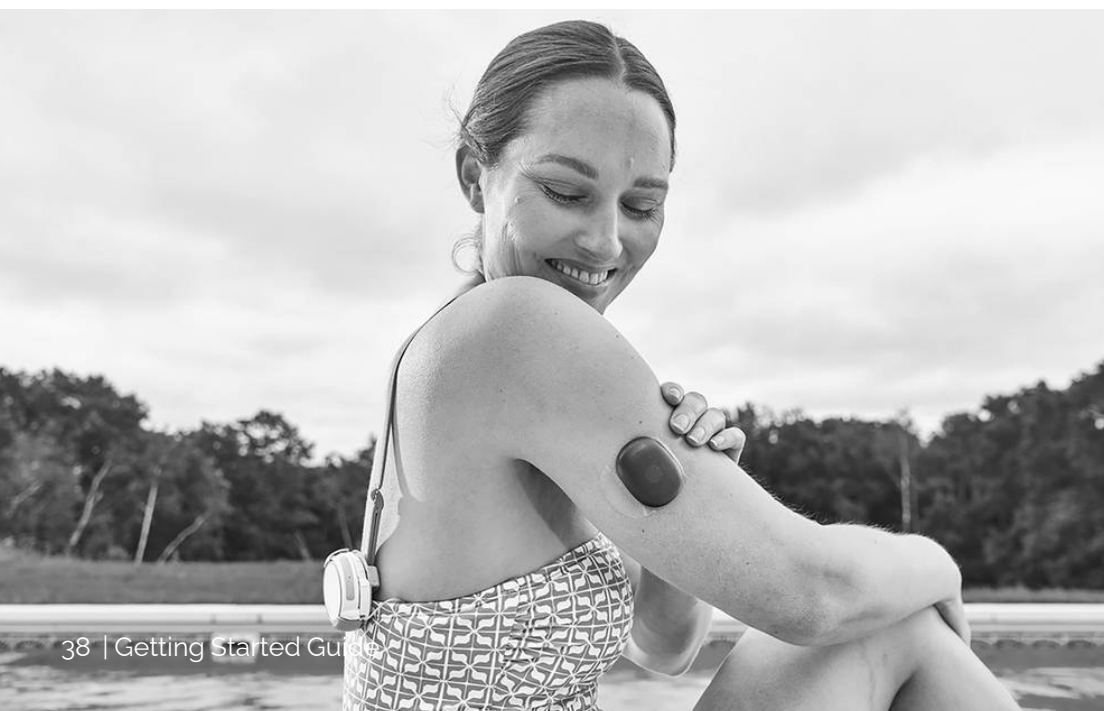
3. Tap the **Smart Transmitter Soft-touch button** three times to start pairing mode.

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

4. Tap **OK** to continue.



INFORMATION: 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.



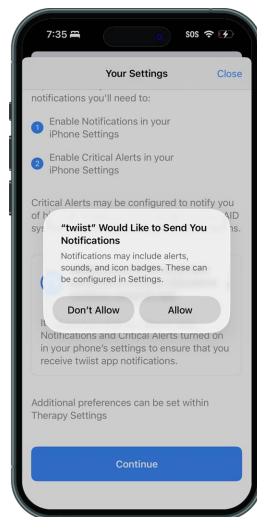
Your Settings

Notifications

It is important that you always keep smartphone Notifications, Critical Alerts (iPhone), or Modes Access/Do Not Disturb Permission (Android) turned on to ensure that you receive twist App notifications. Make sure to give access to all required permissions when prompted.



INFORMATION: Some Android Modes (such as Sleep or Work) prevent the use of selected apps while active. Ensure the twist App is included in the list of unaffected apps whenever using Android Modes.



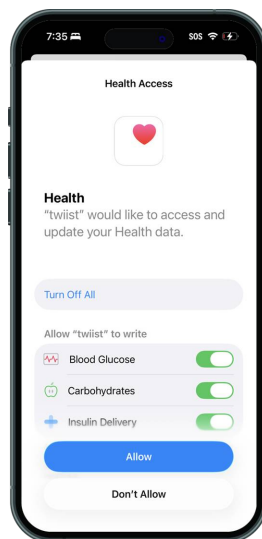
Apple Health (iPhone)

Apple Health allows you to review blood glucose, carbohydrates, and insulin delivery data, including Total Daily Dose, in the Apple Health app on your iPhone.

- 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 and insulin delivery trends
- Daily carbohydrate intake
- Total basal and bolus insulin delivered daily



Therapy Settings

Therapy settings for the twiist AID System are provided by your healthcare provider. You enter these in the twiist App with your Certified twiist Trainer. Optional settings can be entered later. See the twiist AID System User Guide for detailed information on all therapy settings.

1. Tap **Continue** and enter the therapy settings provided by your healthcare provider.
If you enter values that are higher or lower than those that are typically recommended, a caution ⚠ or warning ⚠ will display for the selected values.
2. Tap **Save Settings**.
3. Tap **Continue**.

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.



INFORMATION: Use the Apple Health app to update your glucose unit of measure when using the twiist App on your iPhone.

Glucose Safety Limit

If your glucose is predicted to be above this limit for the next three hours, the twiist AID System delivers basal and recommended bolus insulin. *Glucose Safety Limit* can be set as low as 67 mg/dL and as high as 110 mg/dL.

Correction Range

The range of glucose values you want the twiist AID System to aim for when adjusting your basal insulin and recommending boluses. *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*.

Pre-Meal Range

Temporarily lowers your *Correction Range* before a meal to impact post-meal glucose spikes. *Pre-Meal Range* can be set as low as your *Glucose Safety Limit* and as high as 130 mg/dL.

Workout Range

Temporarily raises your *Correction Range* before, during, or after physical activity to reduce the risk of low glucose events. *Workout Range* can be set as low as 87 mg/dL or your *Glucose Safety Limit*, whichever is higher, and as high as 250 mg/dL.

Carb Ratios

The number of grams of carbohydrates covered by 1 unit of insulin. *Carb Ratios* can be entered as low as 2 g/U and as high as 150 g/U in 0.1 g/U increments. The 12:00 AM carb ratio cannot be deleted.

Basal Rates

The number of units per hour you need to cover your background insulin needs. *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*. The 12:00 AM basal rate cannot be deleted.

Delivery Limits

The safety guardrails for your insulin delivery. Insulin delivery needs to be suspended to adjust these settings.

Maximum Basal Rate

Maximum Basal Rate is the maximum automatically adjusted basal rate that the twiist AID System is allowed to deliver to help reach your *Correction Range*.

Maximum Bolus

Maximum Bolus is the largest bolus amount that you can deliver at one time to cover carbs or bring down high glucose.

Insulin Model

The twiist AID System assumes insulin 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.

Insulin Sensitivities

The drop in glucose expected from 1 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. The 12:00 AM insulin sensitivity cannot be deleted.

twiist Cassette Setup

1. Gather the following supplies to set up and start therapy:

- A new cassette, infusion set, syringe and needle provided in your twiist Starter Kit
- Humalog or NovoLog U-100 insulin
- Alcohol wipes



2. Wash your hands.

3. Tap **Continue**.

4. Open a new cassette and remove it from the package.

5. Align the ridges on the pump-bump and the top of the cassette.

6. Press down gently while rotating the pump until the ridge on the pump-bump is aligned with the infusion set tubing and the pump and cassette click into place.

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



WARNING: 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.

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

8. Tap **Scan Cassette** and scan the cassette with your smartphone camera.

9. Using the picker, select your desired **Cassette Fill Volume** between 100-300 units. This should be enough insulin to last you 2-3 days.

- Priming the cassette and the 24-inch (61 cm) infusion set tubing requires up to 30 units of insulin. The insulin used to fill the cassette, no more than 300 units maximum, includes the amount for priming.
- The cassette volume displayed in the twiist Pump menu shows the reduced amount of insulin remaining in the cassette after priming is complete.
- The twiist AID System will remember your last selected cassette fill volume for future cassette changes. 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.

10. Tap **Next** to continue.

Before moving to the next step, review the **Cassette Fill Port** and **Instructions for Filling a Syringe** with your Certified twiist Trainer.



INFORMATION:

- Only use the syringe and needle provided in your twiist Starter or Refill Kit to fill your cassette with Humalog or NovoLog fast-acting U-100 insulin.
- Insert the needle straight into the filling port — do not insert the needle at an angle.
- The cassette is single fill only; do not refill the cassette once filled.



Practice with your trainer!

1. Insert an empty syringe into the filling port successfully until the process is comfortable and easily repeated.



Filling the Syringe

Allow insulin to come to room temperature and follow the manufacturer instructions for use and handling.

11. Clean the top of the insulin vial with an alcohol wipe.
12. Attach the needle to the syringe.
13. Draw air into the syringe by pulling back the plunger to the selected *Cassette Fill Volume*.
14. Insert the needle into the insulin vial and press the plunger down to inject the air into the vial.
15. Flip the insulin vial so that the vial is on top and the syringe is on the bottom, making sure the needle is below the insulin level.
16. Fill the syringe with insulin equal to the selected *Cassette Fill Volume*. Never fill your cassette with more than 300 units.
17. Tap on the syringe and press the plunger slightly to remove any visible air bubbles.
18. Pull additional insulin to reach the *Cassette Fill Volume*, if needed.
19. Tap **Next** to continue.

Filling Your Cassette

20. Fill the cassette with the amount of insulin you selected by inserting the syringe into the filling port and pushing the plunger in and holding.

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



CAUTION: Do not fill the cassette with more than 300 U of insulin. Filling the cassette with more than 300 U may lead to pump malfunctions and interruptions of therapy.

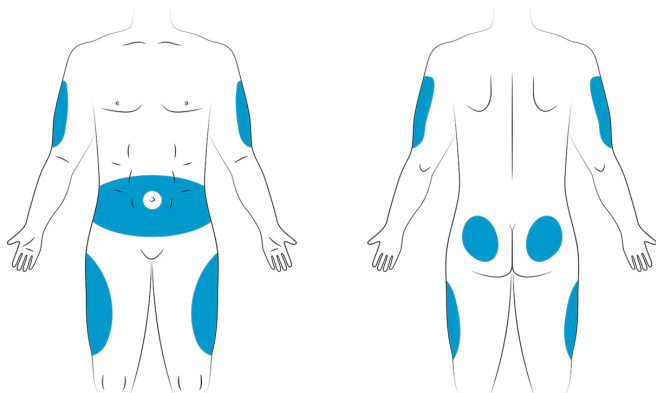
21. Remove the needle and dispose of the used needle and syringe in a sharps container.
22. Tap **Next** to continue.

Connect Infusion Set Tubing and Prime Tubing and Cassette

23. Open a new infusion set package.
24. Attach the infusion set tubing to the cassette by twisting the luer connectors together.
25. Tap **Next** to continue.
26. Tap **Start Prime** to prime the cassette and infusion set tubing.
27. Watch for drops to appear at the end of the infusion set tubing.
Drops of insulin at the end of the infusion set tubing indicate the cassette and tubing are primed.
28. Tap **Stop Prime**.
29. 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.
30. Check for leaks around the cassette and infusion set after priming. If leaks are visible, replace the cassette and infusion set tubing.

Infusion Site Selection

An infusion site can be inserted anywhere on your body where insulin would normally be injected. Absorption can vary from site to site and should be reviewed with your Certified twiist Trainer or your healthcare provider.



Infusion Set Insertion Best Practices

The twiist AID System is compatible with the infusion sets listed in the twiist AID System User Guide. Refer to infusion set manufacturer instructions for insertion and cannula fill.

Change your infusion set every 48 to 72 hours as recommended by your healthcare provider. Wash your hands with soap and water before handling a new infusion set and thoroughly clean the insertion site with an alcohol wipe to avoid infections. Using the same infusion site area often may cause scarring or lumps which affects insulin absorption. Establish a site rotation schedule to help avoid this.

When selecting your infusion site:

- Avoid areas that may constrict the site, such as the waistline, beltline, or where the body naturally bends.
- Avoid the area 2 inches (5 cm) around your belly button.
- Keep the infusion site at least 1 inch (2.5 cm) from your FreeStyle Libre 3 Plus sensor or 4 inches (10.16 cm) from your Eversense 365 sensor.
- Avoid placing the infusion site on scars, moles, stretch marks, and tattoos.
- Avoid broken skin, cuts, and scrapes.
- Keep the infusion site at least 1-2 inches (2.5 to 5 cm) from your previous infusion site.
- If your infusion site is being applied to your abdomen, stand up to fully extend your body before insertion.

Insert Infusion Site

1. Clean your infusion site with the provided alcohol wipes and let your skin air dry before applying infusion set.

Body hair can prevent the adhesive from sticking, so you may consider shaving or clipping hair at the site to provide a smooth surface for the adhesive to stick securely.

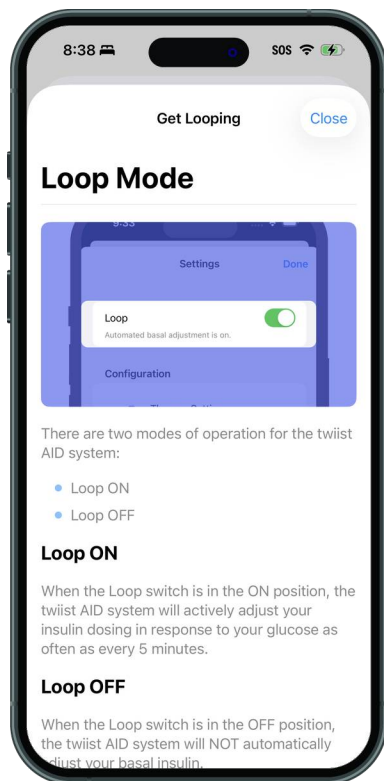
2. Insert the infusion set cannula per the manufacturer instructions.

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 twist System to automate your basal delivery.

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

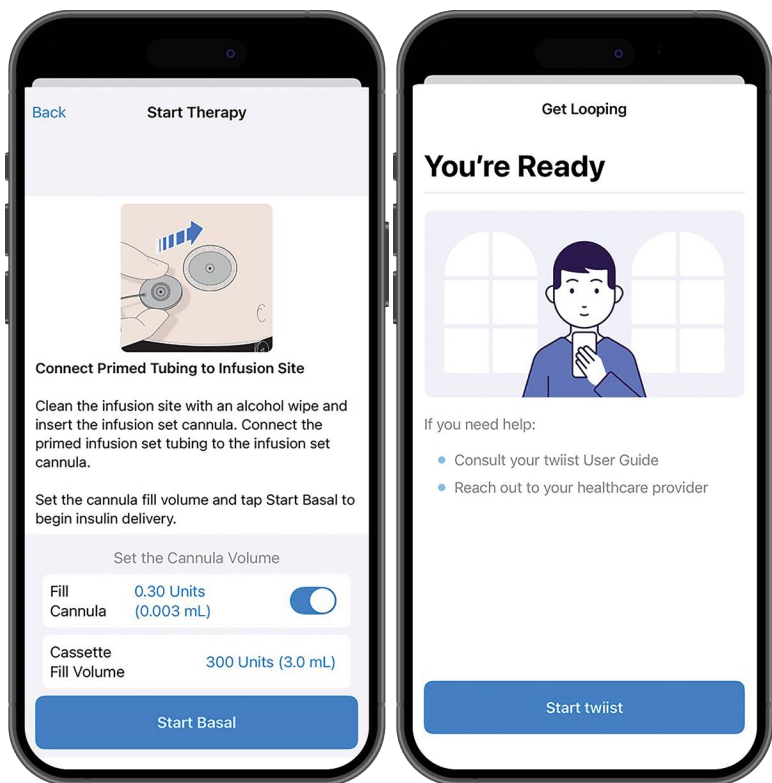
4. Tap **Continue**.



Connect Infusion Set Tubing to your Site

1. Connect the primed infusion set tubing to infusion site.
2. Tap **Fill Cannula** to select the cannula fill volume according to your infusion set manufacturer instructions.
3. Tap **Done**.
4. Verify the *Cassette Fill Volume* matches what you filled the cassette with.
5. To begin insulin delivery, tap **Start Basal**.
The pump plays the *Delivering* sound.
6. Tap **Start twist**.

If you need help, consult with your Certified twist Trainer or healthcare provider.



Now that you're Looping, **it's time to learn about the twist App!**

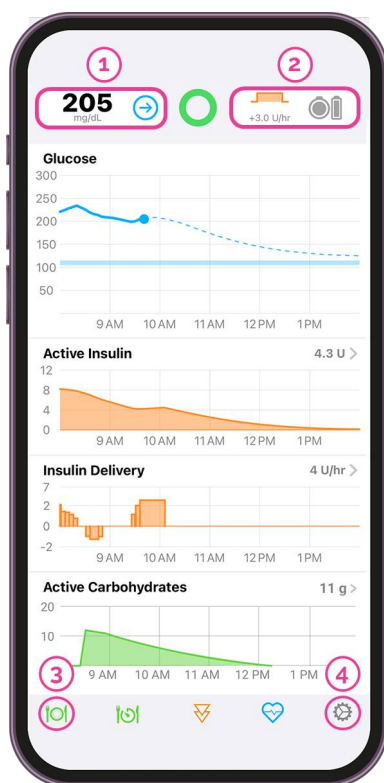
twiist App

The twiist App allows you to interact with the twiist AID System. It displays how twiist is working through icons and charts on the twiist App home screen. You can see what is happening at a glance, or you can tap the icons and charts for additional information.

The twiist App: Four Corners

Navigating the twiist App is made easier by focusing on the four corners. These are the areas you will be using the most as you manage your twiist AID System.

1. CGM Status
2. Pump Status
3. Carb Entry and Meal Bolus
4. Settings



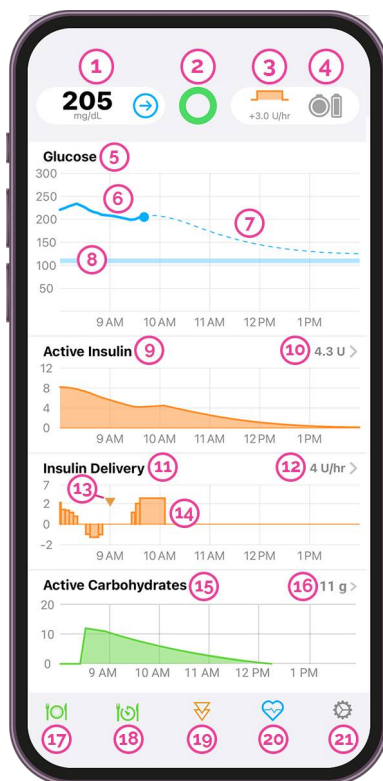
twiist App - Full Picture

Beyond the four corners, the twiist App home screen offers ways to view valuable information about your insulin delivery and take action on your insulin management.



INFORMATION: Some features of the twiist App work differently when Loop is off.

1. CGM Status
2. twiist Loop Status
3. Insulin Delivery Status
4. Pump Status
5. Glucose Chart
6. Glucose History
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



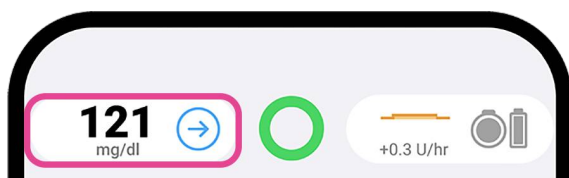
Status

Status is located along the top of the *twiist* App home screen, providing the status of your CGM, *twiist* Loop, Insulin Delivery, and your *twiist* Pump at a quick glance.

CGM Status

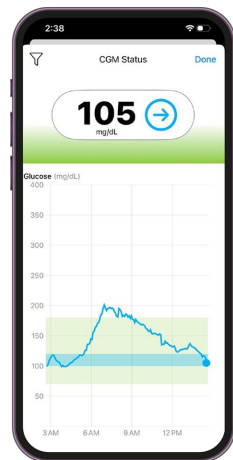
The *CGM Status* icon displays your current glucose and rate of change arrow when CGM readings are available.

Additional CGM Status icons may be displayed while your CGM is warming up, if you experience CGM signal loss, and additional scenarios. Refer to the *twiist* AID System User Guide for more information on CGM Status icons that may be displayed for your CGM.



CGM Status Screen

Tapping the CGM Status icon opens the CGM Status screen, displaying glucose data from your CGM sensor including your current glucose, glucose trend arrow, and a chart of current and past glucose readings.



Practice with your trainer!

1. Tap on the CGM Status icon to open the CGM Status screen.

The CGM Status screen may display messages along with the glucose readings or when glucose readings are unavailable. If displayed, tap the message, which provides more information.



FreeStyle Libre 3 Plus CGM Status

Some CGM Status icons are specific to the FreeStyle Libre 3 Plus Sensor. Tap the **CGM Status** icon to access the CGM Status screen.

Refer to the twiist AID System User Guide for more information on CGM Status icons that may be displayed for your FreeStyle Libre 3 Plus CGM.



Eversense 365 CGM Status

Eversense 365 includes features available only through the Eversense 365 app, including CGM calibration. Open the Eversense 365 app for additional information and follow the instructions provided to resume CGM readings.



twiist Loop Status

Loop On

When *Loop* is on, the twiist AID System will start with your scheduled basal rate and make adjustments to your basal delivery automatically. A closed circle icon is displayed within the twiist Loop Status. .



Loop makes a calculation as often as every 5 minutes to adjust your basal rates. Tap the **twiist Loop Status** icon for more information, including whether your pump is delivering insulin, and if your basal rate is being adjusted automatically.

twiist Loop Status Icons

The twiist Loop Status icons indicate how long it has been since the twiist AID System completed a *Loop*.

	<i>Loop</i> was successful within the last 5 minutes. The twiist AID System is automatically adjusting your basal delivery.
	It has been 5-15 minutes since the last successful <i>Loop</i>. The twiist AID System is automatically adjusting your basal delivery. You may be experiencing temporary CGM <i>Signal Loss</i>. Typically, this does not require user action to resolve.
	It has been more than 15 minutes since the last successful <i>Loop</i>. Basal will return to your scheduled rate until CGM readings are available or a fingerstick glucose is manually entered. You may be experiencing a problem with your CGM that requires interaction with the CGM or twiist App to resolve.
	This icon can indicate one of the following: - The pump is initializing - The twiist Pump and App are not in communication - Insulin delivery has been suspended

Loop Off

When *Loop* is off, your *twiist* Pump delivers your scheduled basal rate. The *twiist* System does not automatically adjust basal insulin delivery. An open *Loop* icon is displayed within the *twiist* Loop Status.



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 <i>twiist</i> Pump and App are not in communication Insulin delivery has been suspended

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 reading was received within the last 15 minutes.
	Your pump is working properly but it has been more than 15 minutes since your last CGM reading was received.
	This icon can indicate one of the following: The pump is initializing The <i>twiist</i> Pump and App are not in communication Insulin delivery has been suspended

Insulin Delivery Status

The *Insulin Delivery Status* icon displays whether basal insulin is being delivered at your scheduled basal rate, or if it has been reduced or increased.



Scheduled Basal



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



INFORMATION: This does not mean your basal rate is 0.0 U/hr.

Reduced Basal



A dropped icon indicates a reduction in your basal rate and will show how much the basal rate has been reduced.

Increased Basal



A raised icon indicates an increase in your basal rate and will show how much the basal rate has been increased.

Pump Status

The *Pump Status* icon displays an estimate of the insulin remaining in your cassette and the pump battery level. Selecting the right *Cassette Fill Volume* during your Cassette Changes will help ensure this status is as accurate as possible.



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



Your cassette has more than 20% insulin remaining, and your pump battery has more than 20% charge.



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



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

twiist Pump Menu

The *twiist Pump* menu is accessed by tapping the **Pump Status**  icon and displays additional information about your cassette and pump battery, including:

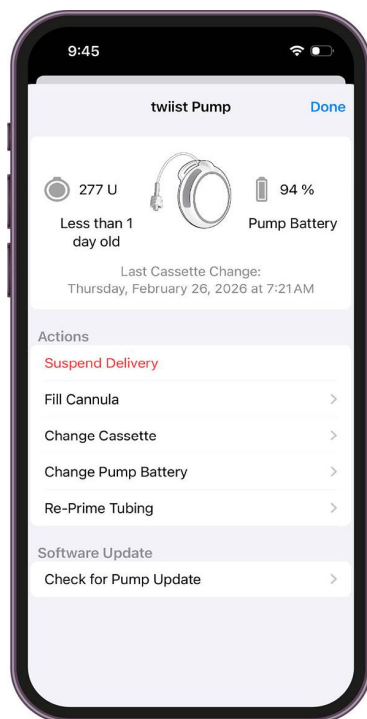
- Estimated Cassette volume remaining and cassette age
- *Last Cassette Change* date and time
- Pump battery charge remaining

From the *twiist Pump* menu you can perform the following actions:

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

For more information, refer to "[Perform a Cassette Change](#)" on page 99 or "[Change Pump Battery](#)" on page 104.

Refer to the *twiist AID System User Guide* for more information about Cannula Fill, Re-Prime Tubing, or Check for Pump Update.



Practice with your trainer!

1. What is the current pump battery charge?
2. How much insulin is estimated to be in your cassette?
3. How old is your cassette?

Suspend Insulin Delivery

1. Tap the **Pump Status** icon to open the *twiist Pump* menu.
2. Tap **Suspend Delivery**.
3. Tap **Confirm** to suspend insulin delivery.

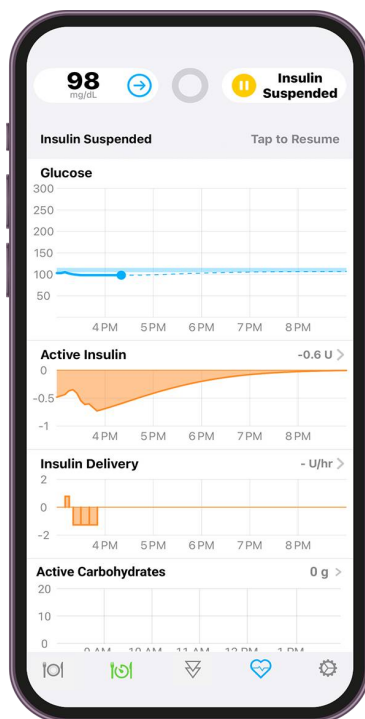
How to identify that insulin delivery is suspended:

- *twiist Loop Status* icon is gray
- Bolus buttons on the toolbar are gray
- *Insulin Suspended* is displayed in *Pump Status* and *Temporary Status Banner*
- The *Insulin Delivery Chart* displays current insulin delivery rates as – U/hr
- *twiist Pump* plays *Delivery Suspended* sound, a series of 4 descending tones



Practice with your trainer!

1. Suspend insulin delivery.
2. What sounds did you hear?
3. What do you see on the *twiist App* home screen to indicate that insulin delivery has been suspended?



Resume Insulin Delivery

There are two options to resume insulin delivery:

1. Tap the **Insulin Suspended** icon to open the *twiist Pump* menu, then tap **Resume Delivery**.
2. Tap the **Temporary Status Banner** on the *twiist App* home screen.

How to identify that insulin delivery has resumed:

- The *twiist Loop Status* icon will be green, yellow, or red
- *Insulin Delivery* and *Pump Status* icons return
- The *Insulin Delivery Chart* displays current basal rate
- The *twiist Pump* plays the *Delivering* sound, a series of 3 ascending tones



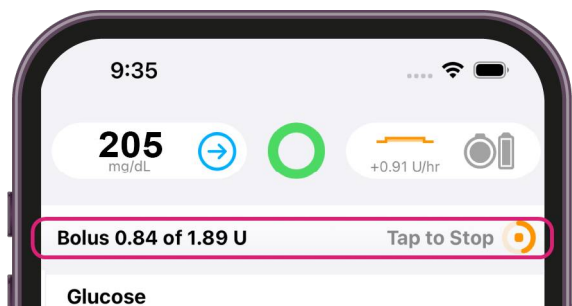
Practice with your trainer!

1. Resume insulin delivery.
2. What sounds did you hear?
3. What do you see on the *twiist App* home screen to indicate that insulin delivery has been resumed?

Temporary Status Banner

The *twiist* App may display a *Temporary Status Banner* below the *Status* icons. You will see and can interact with this banner in the following situations:

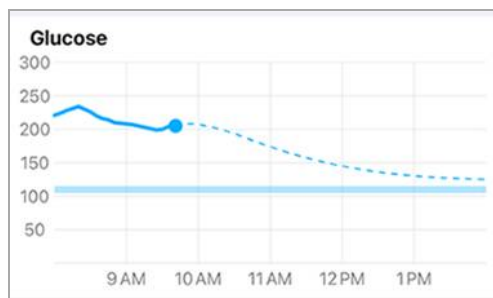
- Bolus delivery is in progress
- A temporary basal is active
- A cannula fill is in progress
- Stopping a bolus or temporary basal that is currently being delivered
- A *No Recent Glucose* message is displayed and allows you to enter a fingerstick glucose value
- To resume insulin delivery
- *Pre-Meal* or *Workout Preset* is active



Charts

Glucose Chart

The numbers along the left side of the *Glucose Chart* are glucose readings, either from a CGM or a fingerstick. The numbers along the bottom of the chart are the time of each glucose reading.



INFORMATION: The glucose prediction displayed as a light-blue dashed line on the glucose chart changes frequently and should not be used to make treatment decisions.

Correction Range is displayed on the glucose chart as a blue shaded bar, which indicates the range *Loop* aims for when adjusting your basal insulin and recommending a bolus.

Glucose History is displayed as a solid blue line on the glucose chart that indicates CGM readings over the last 60-90 minutes.

Glucose Prediction is displayed as a light blue dashed line that represents your glucose prediction for 6 hours into the future.

Current Glucose Value is displayed as the blue dot between your *Glucose History* and *Glucose Prediction*.



INFORMATION: When *Loop* is off, the twist AID System does not make or display glucose predictions.



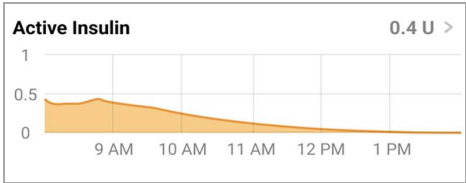
Practice with your trainer!

1. Identify your current, past, and predicted glucose values on the *Glucose Chart*.
2. Identify where your *Correction Range* is on the glucose chart and what it represents.

Active Insulin Chart

The *Active Insulin Chart* displays how much insulin has been delivered but has yet to act within your body. It displays an estimate of how much insulin is working in your body over the next few hours. It takes both basal and bolus insulin into consideration.

Your current *Active Insulin* is displayed in the upper-right corner of the active insulin chart.



Practice with your trainer!

Identify your current amount of *Active Insulin*.

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 vertical orange bars. Bars above the orange line indicate an increased basal rate, orange bars below indicate a reduced basal rate.



Boluses are displayed as orange triangles.



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



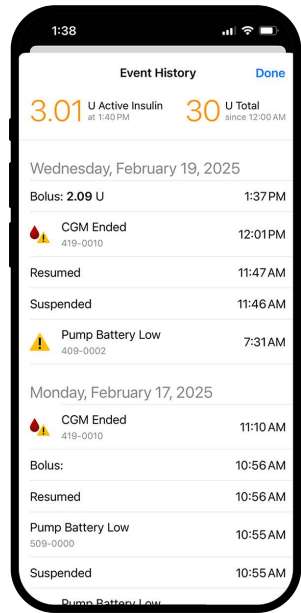
Practice with your trainer!

1. Identify your current basal delivery rate.
2. Identify if the *twiist AID System* is delivering at your programmed, an increased, or a decreased basal rate.

Event History

To see **Event History**, tap the **Active Insulin Chart** or **Insulin Delivery Chart**. The *twiist* App displays up to 14 days of event history. You can see historical events including:

- Active Insulin
- Total Units (delivered since 12:00 AM)
- Temporary Basal Rates (*Loop* off)
- Boluses (delivered or interrupted)
- Insulin delivery suspended
- Insulin delivery resumed
- Cannula Fills
- Alarms, Alerts, CGM Alerts, and Notices

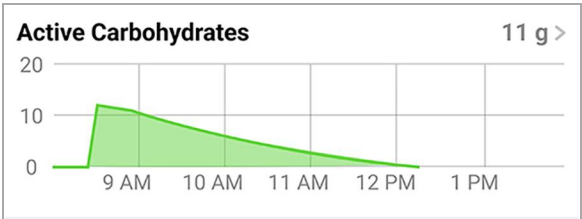


Active Carbohydrates Chart

The *Active Carbohydrates Chart* displays the carbs that you have entered into the *twiist* App and how *twiist* Loop predicts they will impact your glucose over time. Carb entry is necessary for the *twiist* AID System to make its best glucose predictions.

If you have eaten carbs that have not been entered in the *twiist* App, the system may predict that your glucose will go lower because it does not know about those carbs. Make sure to always enter your carbs when eating a meal.

Your current active carbohydrates are displayed in the upper-right corner. To view the carb entries over the past 12 hours, tap the **Active Carbohydrates Chart**.



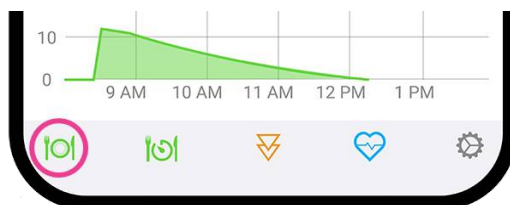
Toolbar

Located along the bottom of the screen, the *Toolbar* contains *Carb Entry*, *Pre-Meal Preset*, *Correction Bolus*, *Workout Preset*, and *twiist App Settings* options.

Carb Entry - How to Bolus for Meals

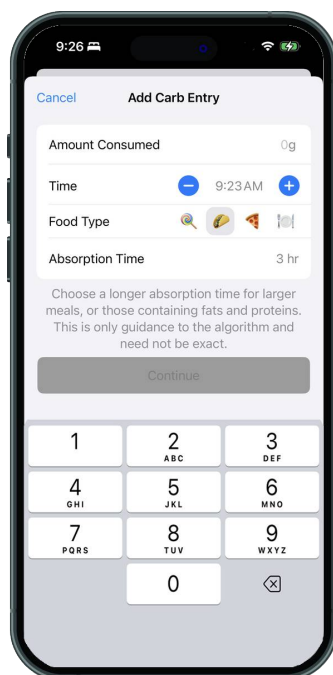
Carb entry allows the twiist AID System to make bolus recommendations, when appropriate. If you do not know the exact carb count, use your best guess.

1. Tap **Carb Entry**  to enter details about your meal.



Add Carb Entry

2. **Amount Consumed:** Enter the amount of carbohydrates you consumed, or plan to consume.
3. **Time:** Enter the time you ate, or plan to eat. You can log missed meals up to 12 hours in the past or log upcoming meals up to 1 hour in the future.
4. **Food Type/Absorption Time:** Tap to select the emoji that best matches with the estimated absorption time of the food you're consuming. The system defaults to the taco emoji, representing a 3 hour absorption time.
5. **Continue:** Tap to proceed to the *Meal Bolus* screen and review the *Recommended Bolus*.

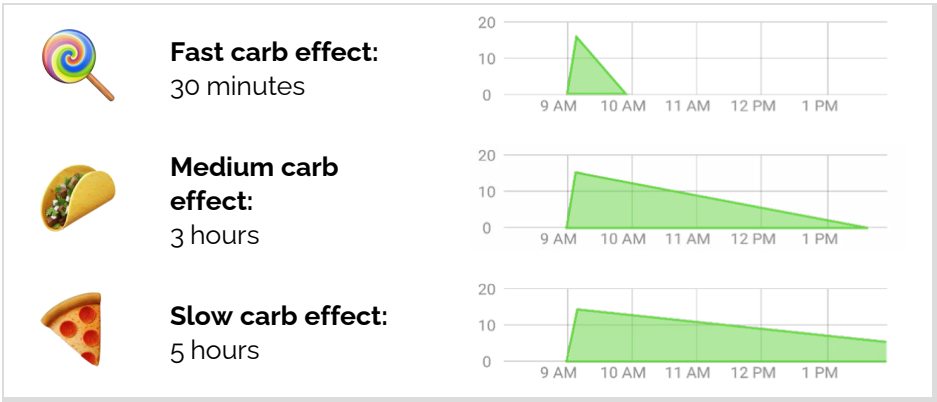


A screenshot of a smartphone screen showing the 'Add Carb Entry' form. The form has a 'Cancel' button at the top left and a 'Continue' button at the bottom. The fields are: 'Amount Consumed' with a unit of '0g', 'Time' set to '9:23 AM' with minus and plus buttons, 'Food Type' with a search icon and a taco emoji selected, and 'Absorption Time' set to '3 hr'. Below these fields is a note: 'Choose a longer absorption time for larger meals, or those containing fats and proteins. This is only guidance to the algorithm and need not be exact.' At the bottom is a numeric keypad with digits 1-9, 0, and a backspace icon.

Food Type/Absorption Time

Food Types affect glucose in different ways. Some foods may raise glucose quickly and others more slowly over time. The 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:



Choose a longer absorption time for larger meals or those containing both fats and proteins. The absorption time entered is only an estimate and does not need to be exact. If you are not sure what to choose, stick with the taco emoji.

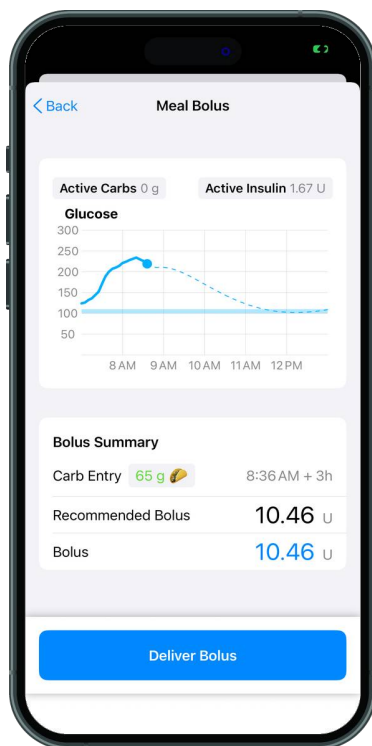


Confirm Meal Bolus

Before delivering the recommended bolus, review the following:

- Amount of carbs entered
- *Active Carbs* and *Active Insulin*
- *Carbs Entry* time
- Food Type
- Absorption Time
- *Recommended Bolus* amount

Tap the **Deliver Bolus** button when you are ready and watch the progress of your bolus delivery in the *Temporary Status Banner* on the *twiist* App home screen. You will hear the *Delivering* sound, 3 ascending tones, when the bolus delivery begins.



WARNING: Do not set the *Bolus* to be greater than the recommended value. Modifying the bolus to be greater than the recommendation can lead to glucose falling below your *Glucose Safety Limit* and may increase your risk of low blood glucose.



Practice with your trainer!

1. Tap the **Carb Entry** button and enter the carbs you are eating to see if the system recommends a meal bolus.
2. If a meal bolus is recommended, deliver the bolus.
3. If a meal bolus is not recommended, save without bolusing.

For information about deleting or editing carbs that you have entered, refer to the *twiist AID System User Guide*.

Stop Bolus Delivery

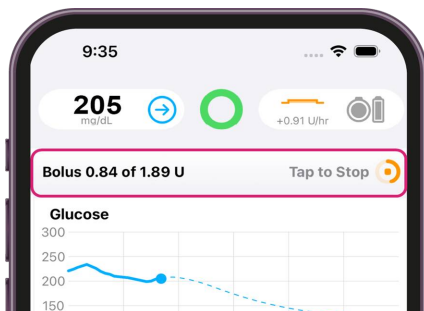
When a bolus is being delivered, its progress is shown in the *Temporary Status Banner*.

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



Practice with your trainer!

1. Describe stopping the bolus delivery.
2. Describe how you know that the bolus has stopped.
3. Stopping a bolus delivery requires confirmation.



Pre-Meal Preset

When *Loop* is on and the *Pre-Meal Preset* is enabled, the *twiist* AID System temporarily lowers your *Correction Range* to the *Pre-Meal Range* configured in your *Therapy Settings*.

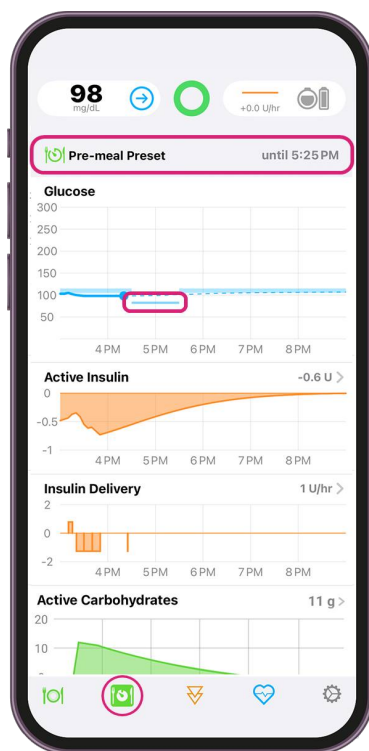
1. Tap **Pre-Meal Preset** .
2. Tap **Until I enter carbs**.

The *Pre-Meal Preset* will stay on for up to one hour, until it is canceled, or until you enter carbs, whichever occurs first.

When enabled:

- The *Temporary Status Banner* will show *Pre-Meal Preset* until 1 hour from the time activated.
- The glucose chart will show the *Pre-Meal Range*.
- The *Pre-Meal Preset* button color  on the toolbar will be inverted.

When *Loop* is off, the *twiist* AID System will not adjust your *Correction Range* or automate your basal insulin to bring you to your *Pre-Meal Range*. The *Pre-Meal Preset* button will be disabled on the toolbar.



Cancel Pre-Meal Preset

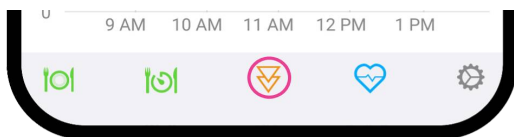
1. Tap **Pre-Meal Preset**  to cancel the *Pre-Meal Preset*.
 - The *twiist* App home screen will no longer display a *Temporary Status Banner* showing the *Pre-Meal Preset*.
 - Your *Correction Range* will be updated within the glucose chart.



Practice with your trainer!

1. Enable the *Pre-Meal Preset* and describe the items on-screen that indicate *Pre-Meal Preset* is on.
2. Cancel the *Pre-Meal Preset* by tapping the *Pre-Meal Preset* button .

Bolus Entry (Correction Bolus)

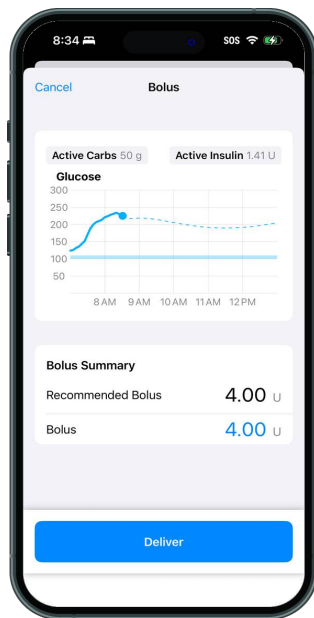


Correction Bolus

1. Tap **Bolus Entry**  to receive a recommendation for a correction bolus to bring down high glucose.
2. Before delivering the recommended bolus, review *Active Carbs* and *Active Insulin*.
3. Confirm the *Recommended Bolus* and tap **Deliver**.
 - If a bolus is not recommended, a *No Bolus Recommended* caution is displayed. Tap *Cancel* at the top of the screen to return to the twist App home screen.

When a *Correction Bolus* is being delivered:

- The *Temporary Status Banner* displays the bolus delivery in progress.
- You will hear the *Delivering* sound, 3 ascending tones, when delivery begins.



WARNING: Do not set the *Bolus* to be greater than the recommended value. Modifying the bolus to be greater than the recommendation can lead to glucose falling below your *Glucose Safety Limit* and may increase your risk of low blood glucose.

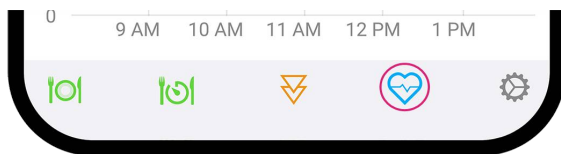


Practice with your trainer!

1. Tap **Bolus Entry**  to see if the system recommends a *Correction Bolus*.
2. If a *Correction Bolus* is recommended, deliver the bolus.

Workout Preset

When *Loop* is on and the *Workout Preset* is enabled, the twist AID System temporarily raises your *Correction Range* before, during, or after physical activity to reduce the risk of low glucose events. The twist AID System will aim for the *Workout Range* configured in *Therapy Settings*.



INFORMATION: To use the *Workout Preset* effectively, work with your healthcare provider to determine the settings that are best for you.

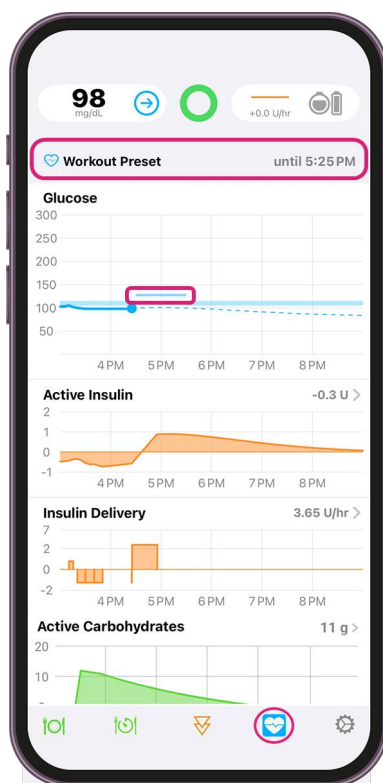
1. Tap **Workout Preset** .
2. Select how long you would like to use the *Workout Preset* for. You can keep the *Workout Preset* active for:
 - 1 hour
 - 2 hours
 - Until you choose to turn it off

When you select the *1 hour* or *2 hour* option, the *Workout Preset* automatically turns off after the selected duration.

The *Until I turn off* option requires you to turn it off when ready to resume your programmed *Correction Range* setting.

When the *Workout Preset* is active:

- The *Temporary Status Banner* displays the *Workout Preset* and its duration.
- The glucose chart displays your *Workout Range*.
- The *Workout Preset* button color  on the toolbar will be inverted.



Cancel Workout Preset

1. Tap **Workout Preset**  to cancel the *Workout Preset*.



- The twist App home screen will no longer display a *Temporary Status Banner* displaying the *Workout Preset* and its duration.
- Your *Correction Range* will be updated on the glucose chart.

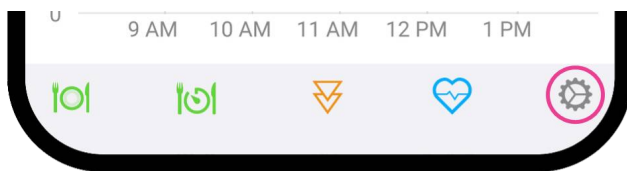


Practice with your trainer!

1. Enable the *Workout Preset* for 1 hour.
2. Identify the items on the twist App home screen that indicate *Workout Preset* is on.
3. Identify how the *Workout Preset* turns off.
4. Cancel the *Workout Preset* by tapping .



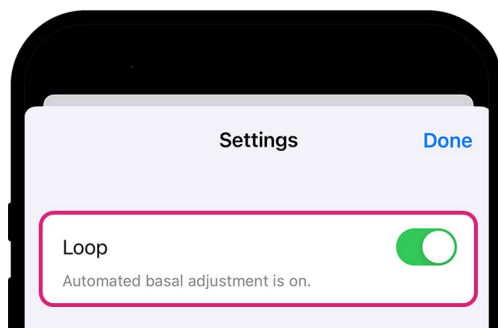
twiist App Settings



Tap **Settings**  to open the twiist App *Settings* screen where you can:

- Turn *Loop* On or Off
- Review or Edit *Therapy*, *Bolus*, or *Notification Settings*
- Review or Edit CGM settings, start a new FreeStyle Libre 3 Plus, or pair a new Eversense 365 Smart Transmitter.

Loop On or Off



When *Loop* is on, the twiist AID System automatically adjusts your basal insulin delivery based on your glucose as often as every 5 minutes.

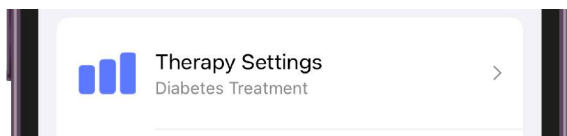
When *Loop* is off, twiist will not automatically adjust your basal insulin.

Use twiist with *Loop* Off when:

- You do not have an active CGM sensor.
- You want to take full control of your insulin dosing decisions.

Refer to the twiist AID System User Guide for more information about using twiist when *Loop* is off.

Therapy Settings



Your *Therapy Settings* are initially entered with your Certified twist Trainer and must be confirmed prior to use. Updates to therapy settings should be made with direction from your healthcare provider.

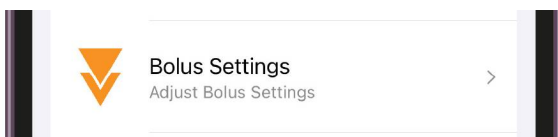
Incorrect settings may lead to low or high blood glucose.

The required therapy settings, already programmed, include:

- Glucose Unit of Measure (Android)
- Glucose Safety Limit
- Correction Range
- Pre-Meal Range
- Workout Range
- Carb Ratios
- Basal Rates
- Delivery Limits
- Insulin Model
- Insulin Sensitivities

Additional information about all therapy settings can be found in the twist AID System User Guide.

Bolus Settings

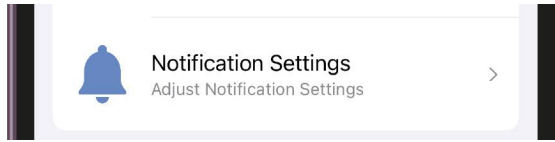


All changes to *Bolus Settings* should be made with direction from your healthcare provider.

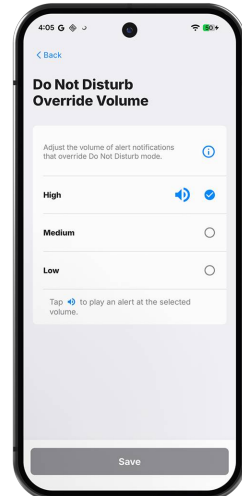
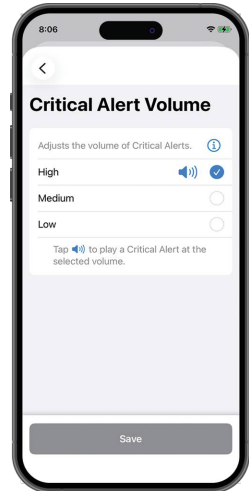
- **One-Button Bolus** - Allows you to deliver a bolus using only the twist Pump. *One-Button Bolus* is disabled by default.
- **Extended Bolus** - Allows you to deliver a bolus over an extended time to prevent a delayed increase in glucose from certain types of food. An *Extended Bolus* can only be delivered when *Loop* is off. *Extended Bolus* is disabled by default.
- **Dual Bolus** - Allows you to deliver a portion of a bolus at the time of administration and a portion over an extended period. A *Dual Bolus* can only be delivered when *Loop* is off. *Dual Bolus* is disabled by default.

For more information on delivery of a *One-Button Bolus* with your twist Pump, or *Extended* or *Dual Boluses* when *Loop* is off, refer to the twist AID System User Guide.

Notification Settings



- **Critical Alert Volume (iPhone)** - Allows you to adjust the volume your iPhone plays Critical Alerts. 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. Volume defaults to High.
- **Do Not Disturb Override Volume (Android)** - Allows you to adjust the volume your Android plays notifications delivered with Modes Access/Do Not Disturb Permission. Notifications from the twist App that are delivered with Modes Access/Do Not Disturb Permission are displayed and played at the *Do Not Disturb Override Volume* even when your Android is silenced or has Modes, such as Do Not Disturb, turned on. Volume defaults to High.

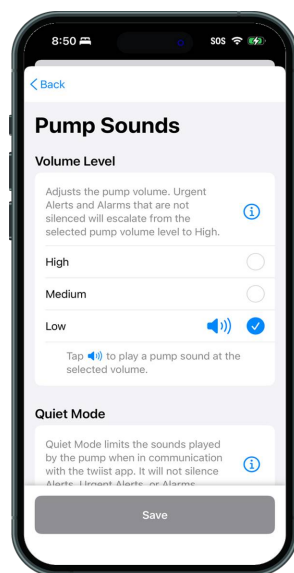


INFORMATION: Some Android Modes (such as Sleep or Work) prevent the use of selected apps while active. Ensure the twist App is included in the list of unaffected apps whenever using Android Modes.

1. Tap **Settings** .
2. Tap **Notification Settings**.
3. Tap **Critical Alert Volume (iPhone)** or **Do Not Disturb Override Volume (Android)**.
4. Select **High**, **Medium**, or **Low** volume.
5. Tap **Save**.

- **Pump Sounds** - Pump Sounds provide access to the settings for *Pump Volume Level* and *Quiet Mode*.
 - *Pump Volume Level* defaults to *Medium* and will escalate from the programmed volume level for the *Urgent Low Glucose Alert* and Alarms until silenced.
 - *Quiet Mode* limits the sounds played by the pump when in communication with the *twiist App*. The sounds for starting and stopping Basal, Temporary Basal, and Bolus delivery will be silenced.
 - *Quiet Mode* will not silence Alarms, *Urgent Low Glucose* alerts, Alerts, or CGM Alerts. *Quiet Mode* is off by default.

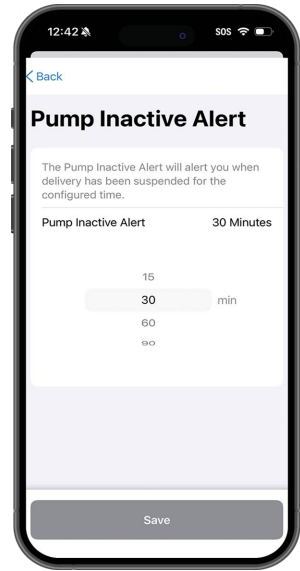
1. Tap **Settings** .
2. Tap **Notification Settings**.
3. Tap **Pump Sounds**.
4. Select **High**, **Medium**, or **Low** volume.
5. Tap **Save**.



- **Low Insulin Alert #1** - Occurs when there are 10 units of insulin remaining in your cassette. Low Insulin Alert #1 cannot be changed or turned off.
- **Low Insulin Alert #2** - Occurs when the insulin in your cassette falls below the configured volume, between 20 and 100 units. Low Insulin Alert #2 is off by default.
- **Phone Out of Range** - Alerts you when the *twiist Pump* and *twiist App* have been out of communication for the configured time. A message is displayed on the *twiist App* when communication is restored. *Phone Out of Range* is off by default.

- **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. Be sure to select a timing interval that works best for you. For your safety, the *Pump Inactive Alert* cannot be disabled, and is always played on your iPhone at the *Critical Alert Volume* or on your Android at the *Do Not Disturb Override Volume*.

1. Tap **Settings** .
2. Tap **Notification Settings**.
3. Tap **Pump Inactive Alert**.
4. Tap the time and use the picker to set to 15, 30, 60, or 90 minutes.
5. Tap **Save**.



- **Cassette Change Reminder** - Reminds you when it is time to change your cassette and can be set from 2 -3 days in 1-hour increments. *Cassette Change Reminder* is off by default.

CGM Alert Settings

Some CGM alerts cannot be modified or turned off. These alerts indicate that you are no longer receiving CGM glucose readings and include:

- CGM Ended
- Replace CGM
- Check CGM

To configure, enable, or disable optional CGM alerts:

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

CGM Alert Snooze Duration

Snooze Duration allows you to set a time for temporarily silencing a high or low glucose alert. After you acknowledge the alert, you will be notified again when the snooze duration expires, if glucose is still out of range.

1. Tap **Settings** .
2. Tap **FreeStyle Libre 3 Plus** or **Eversense 365 Settings**.
3. Tap **CGM Alerts**.
4. Tap **High/Low Glucose Alert** and adjust the *Snooze Duration*.

Alert Name	Description
Urgent Low Glucose	Defaults to 15 minutes. Cannot be changed or turned off.
Low Glucose	When the Low Glucose Alert is enabled, CGM Alert Snooze is always On. Defaults to 15 minutes. Configurable duration between 15 minutes - 2 hours in 5 minute increments.
High Glucose	When the High Glucose Alert is enabled, CGM Alert Snooze is always On. Defaults to 1 hour. Configurable duration between 15 minutes - 4 hours in 5 minute increments.

Target Range Setting

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

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

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

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

Pump Button

The pump button allows you to:

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

Now that your settings are configured, **let's learn more about twiist AID System Alarms, Alerts, and Notices!**



Alarms, Alerts, and Notices

The twiist AID System provides alarms, alerts, and notices for your information and safety.

If your iPhone Ringtone and Alerts volume 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 twiist App may not be played or heard.



INFORMATION: Some Android Modes (such as Sleep or Work) prevent the use of selected apps while active. Ensure the twiist App is included in the list of unaffected apps whenever using Android Modes.

Check your smartphone for twiist App notifications if you are in an environment where you cannot hear or feel vibration from your smartphone or hear the pump sounds. Alert and alarm settings are unaffected by power loss.

For a list of the sounds made by the twiist App and Pump, refer to the twiist AID System User Guide.

Notifications are displayed within the twiist App with the following priority:

1. Alarms
2. Alerts
3. Notices



INFORMATION: The *Urgent Low Glucose* alert is prioritized above all other alerts.

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/Do Not Disturb Permission (Android)

Alarms

- Alarms suspend insulin delivery and require immediate attention. Check your glucose and take the appropriate action to treat highs or lows.
- When an alarm occurs, the *twiist* App plays the *Alarm* sound at your iPhone Ringtone and Alerts volume or Android Media volume, and displays a message with the Alarm  icon followed by the alarm name.
- If the alarm has not been dismissed within 5 minutes, it will repeat and play as a Critical Alert (iPhone) or notification with Modes Access/Do Not Disturb Permission (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*. The *Alarm* sound repeats on your pump every 15 seconds and increases the pump volume level every 5 minutes until the maximum *Pump Volume Level* is reached.
- Alarms that have been dismissed and have not been resolved will occur again after 15 minutes.
- If the *twiist* App and Pump are out of communication, Alarm sounds will play on the pump immediately.
- For more information about *Alarms*, refer to the *twiist* AID System User Guide.

Alarm Name	Description	What to do
Cassette Empty	There is not enough insulin remaining in the cassette to continue delivery.	Disconnect tubing from your infusion site and follow steps to <i>"Perform a Cassette Change"</i> on page 99.
Cassette Error	The cassette is not operating correctly and insulin delivery has been suspended.	Disconnect tubing from your infusion site. Monitor your glucose. Follow on-screen instructions to resolve with your current cassette or perform a cassette change.

Alarm Name	Description	What to do
Cassette Not Attached	The cassette is not properly attached to the pump.	Disconnect tubing from your infusion site. Monitor your glucose. Follow on-screen instructions to resolve with your current cassette or perform a cassette change.
Line Blocked	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.	Disconnect tubing from your infusion site. Monitor your glucose and check your ketones. Pay attention to discomfort at the infusion site which may indicate the cannula is bent or kinked. Replace your infusion site if no kinks can be seen in the tubing. Follow on-screen instructions to resolve with your current cassette or perform a cassette change.
Pump Battery Empty	Your pump battery does not have enough charge to continue delivery and needs to be replaced with a fully charged battery.	Disconnect tubing from your infusion site. Follow on-screen instructions to resolve with your current cassette or perform a cassette change.
Pump Error	Your pump has experienced a problem and cannot deliver insulin. Insulin delivery may have been affected.	Disconnect tubing from your infusion site. Monitor your glucose. Follow on-screen instructions to resolve with your current cassette or perform a cassette change.

Alerts

Alerts display information about the twiist AID System. Alerts do not suspend insulin delivery, but should be addressed as soon as possible.

When an alert occurs, the twiist App plays the *Alert* sound and displays a message with an Alert ⚠️ icon 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.

**INFORMATION:** Some Android Modes (such as Sleep or Work) prevent the use of selected apps while active. Ensure the twiist App is included in the list of unaffected apps whenever using Android Modes.

For your safety, some alerts will be played as a Critical Alert (iPhone) or notification with Modes Access/Do Not Disturb Permission (Android).

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

**INFORMATION:** If the twiist App and Pump are out of communication, alert sounds will play on the pump at the selected *Pump Volume Level*.

The following list is not comprehensive. Refer to the twiist AID System User Guide for a complete list of *Alerts*.

Alert Name	Description	What to do
Cassette Low	10 U of insulin remaining in your twiist Cassette.	Prepare to perform a Cassette Change.
Check Pump and Cassette	The twiist AID System has detected the pump is too close to a magnet, or the cassette is not properly attached.	Move your pump away from any magnets that it may contact, including MagSafe smartphone cases and accessories and wireless earbuds with magnetic cases. Ensure cassette is properly attached.

Alert Name	Description	What to do
Interrupted Bolus	Insulin delivery was stopped when a bolus was in progress.	You may not get as much insulin as you intended. Check your glucose and determine if an additional bolus is required.
No Communication	The twiist App and Pump have not communicated in 7 hours.	Move your smartphone closer to your pump so communication can be restored.
Pump Battery Low	10% or less pump battery charge remaining.	Prepare to perform a battery change.
Pump Inactive	Insulin delivery has been suspended for at least the amount of time set in the Pump Inactive Alert setting. Default is 30 minutes.	Resume insulin delivery.
Reattach Cassette	The cassette is not properly attached to the pump and self-test cannot begin.	Remove the cassette from the pump and reattach. The self-test will begin.

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  icon followed by the name of the CGM alert. Most CGM alert sounds are played at your iPhone Ringtone and Alerts volume or Android Media volume. CGM alerts, with the exception of the *Urgent Low Glucose*, are only played on your smartphone.



INFORMATION: If the *twiist* App and Pump are out of communication, the *Urgent Low Glucose* alert sounds will play on the pump at the selected *Pump Volume Level*.

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

The *Urgent Low Glucose* alert is displayed with higher priority than all other alerts and plays the *Urgent Low Glucose* sound. The *Urgent Low Glucose* alert is always delivered as a Critical Alert (iPhone) or notification with Modes Access/Do Not Disturb Permission (Android). After 5 minutes, the *Urgent Low Glucose* alert repeats on your smartphone and will play on your pump at the *Pump Volume Level*. 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.



INFORMATION: For your safety, some CGM alerts will be played as Critical Alerts (iPhone) or notifications with Modes Access/Do Not Disturb Permission (Android).

The following list is not comprehensive. Refer to the *twiist* AID System User Guide for a complete list of *CGM Alerts*.

Alert Name	Description	What to do
CGM High Glucose	Your CGM glucose is above the level you have set in your CGM High Glucose Alert setting.	Confirm with fingerstick. Treat your high glucose as advised by your healthcare provider.

Alert Name	Description	What to do
CGM Low Glucose	Your CGM glucose is below the level you have set in your CGM Low Glucose Alert setting.	Confirm with fingerstick. Treat your low glucose as advised by your healthcare provider.
CGM Ended	Your sensor has ended and needs to be replaced.	Tap OK to dismiss the CGM alert. FreeStyle Libre 3 Plus: 1. Tap the CGM Status. A <i>Start New Sensor</i> message displays. 2. Tap Yes and follow instructions. Eversense 365: 1. Contact your healthcare provider to schedule a sensor replacement.
CGM Signal Loss	CGM has not communicated with the twiist Pump for the amount of time set in the Signal Loss Alert setting. CGM readings and alerts are unavailable, and twiist <i>Loop Status</i> may show red or yellow circle icon.	Make sure your twiist Pump and sensor are within communication range.
Urgent Low Glucose	Your CGM Sensor reading is at or below 55 mg/dL.	Confirm with fingerstick. Treat your low glucose as advised by your healthcare provider.

Eversense 365 CGM Alerts

The Eversense 365 app has programmable Low Glucose and High Glucose Alerts, separate from the *twiist* App. Alerts in the Eversense 365 app can be set to different values than the *twiist* App, which may result in duplicated or extra notifications. Discuss your personalized settings and how to configure CGM alerts with your healthcare provider.



INFORMATION: The Eversense 365 Low Glucose alert cannot be disabled.

On-Body Smart Transmitter Vibrations

The Eversense 365 smart transmitter vibrates when an alert occurs. The vibration pattern cannot be changed, but the repeat interval can be changed for some alerts. View the Eversense 365 User Guide for details.

Notices

Notices provide information about the status of the *twiist* AID System, and do not affect insulin delivery. CGM and Loop notices are displayed to keep you informed about your CGM and your automated insulin delivery. Refer to the *twiist* AID System User Guide for a list of *Notices*.



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Additional Instructions and Resources

Sleep

Before Sleeping

Before you go to sleep, check the icons on your *twiist* App home screen to ensure the *twiist* AID System is working properly and is all set for use.

Make sure *Loop* is on and:

- Your *twiist* Pump is delivering insulin
- Your smartphone is charging or has enough battery to last through the night
- Your *twiist* Pump has enough battery charge
- Your *twiist* Cassette has enough insulin

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



CAUTION: Do not perform a cassette change just before bedtime if you will not be able to check your blood glucose 1-2 hours after inserting a new infusion site.



Sleep Schedule

The *Sleep Schedule* allows you to set different *High* and *Low Glucose* alert values during a specified time of the day and can only be enabled when the *High* or *Low Glucose* alerts are turned on. The *Sleep Schedule* is off by default.

To turn on the Sleep Schedule:

1. Tap **Settings** .
2. Tap **FreeStyle Libre 3 Plus** or **Eversense 365 Settings**.
3. Tap **CGM Alerts**.
4. Tap **Sleep Schedule**.
5. Tap **Enable Sleep Schedule** to turn on or off.
6. Select start and end times for your sleep schedule.
7. Tap **Low Glucose Sleep Value** and use the picker to select a value.
8. Tap **High Glucose Sleep Value** and use the picker to select a value.
9. Tap **Save**.

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



Safety and Sick Days

High Blood Glucose and Ketones – 250 mg/dL (13.9 mmol/L) or greater

The twiist AID System automatically increases insulin delivery as often as every 5 minutes in response to high or rising CGM glucose levels. Ketones can form quickly when infusion sites fail, which increases your risk of developing diabetic ketoacidosis (DKA).

Early symptoms of DKA include:

- Unusual thirst or very dry mouth
- Frequent urination

Other symptoms that can appear:

- Nausea, vomiting, abdominal pain
- Fruity odor on breath
- Confusion
- Rapid breathing
- Fatigue
- Flushed skin

If your glucose has been over 250 mg/dL (13.9 mmol/L) for 2 hours or more, check your ketone levels.

If ketones are negative, you may consider:

- Drinking non-carbohydrate fluids to keep yourself hydrated.
- Delivering a correction bolus through your twiist Pump.
- Rechecking glucose and ketones in 2 hours.
 - If ketones are positive: consider following the steps for positive ketones.
 - If your blood glucose is still over 250 mg/dL (13.9 mmol/L), consider changing the infusion set and giving a *Correction Bolus* with the new infusion set.
- Rechecking glucose and ketones 2 hours after infusion set change. If glucose is above 250 mg/dL contact your physician.
- If you are vomiting at any time or feel drowsy, call 911.

If ketones are positive, you may consider:

- Calling 911 if you have vomiting at any time or feel drowsy.
- Drinking non-carbohydrate fluids to keep yourself hydrated.
- Changing your infusion set and delivering a *Correction Bolus* through your pump.
- Rechecking glucose and ketones in 2 hours.
 - If your blood glucose is still over 180 mg/dL, continue to give a *Correction Bolus* with the new infusion set every 2 hours until glucose is below 180 mg/dL (10 mmol/L).
 - If your blood glucose is still over 250 mg/dL, contact your diabetes care team.



WARNING: 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.



WARNING: 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).

Troubleshooting Frequent Hyperglycemia

Check your *twiist App Settings* with your healthcare provider:

- Is *Loop* on and adjusting your insulin delivery?
- Is your *Correction Range* set so that *twiist* is working to get your glucose where you want it to be?
- Is your *Workout Preset* enabled while you are not working out or while not needed?
- Is your *Carb Ratio* set so that *twiist* knows the number of grams of carbs covered by one unit of insulin?
- Is your *Insulin Sensitivity* set so *twiist* knows the drop in glucose you will experience from one unit of insulin?

Check Infusion Site and tubing:

- Is there an interruption of insulin delivery?
- Has your insulin been exposed to extreme temperatures, or is it expired?
- Did the cannula slip out of your skin?
- Do you see blood at the infusion site?
- Is there redness, drainage, or signs of infection around the cannula?
- Is your tubing connected or leaking?
- Is the cannula bent or is there discomfort at the site?
- Are you receiving frequent *Line Blocked* alarms?
- Is your cannula fill amount correct?

*Check the Event History in the **twiist** App and/or the Tidepool report data:*

- Did you deliver a large enough bolus to cover your meal?
- Did you set the absorption time correctly for the food that you're eating?
- Have you told the **twiist** AID system about all the carbs you've eaten?
- Have you skipped meal boluses at meal times?
- Is your CGM working correctly? Are CGM readings and rate of change arrows displayed within the **twiist** app?

Assess any recent lifestyle changes:

- Have there been changes to the time, types, or portions of foods that you have been eating?
- Has the amount or intensity of physical activity decreased?
- Have you experienced a recent increase in stress?
- Have you had a recent illness or infection? Are you recovering from an injury?
- Have there been changes in the amount or quality of sleep that you have been getting?
- Have you experienced any recent low glucose events?
- Have you started taking any new medications or made any changes to medications you are taking?



WARNING: If you are experiencing nausea, vomiting, diarrhea, or fatigue for greater than 2 hours, contact your healthcare provider immediately.

Low Blood Glucose – 70 mg/dL (3.9 mmol/L) or less

The twiist AID System reduces or stops insulin delivery in response to low or falling CGM glucose levels. The twiist AID System cannot prevent all instances of low glucose.

Always have a source of fast-acting glucose available to take action if your glucose is low. You may need to treat with fewer carbs than you are used to – twiist has likely decreased or stopped insulin delivery already by adjusting your basal delivery.

Signs and symptoms of low blood glucose:

- Feeling shaky
- Being nervous or anxious
- Sweating, chills, and clamminess
- Irritability or impatience
- Confusion
- Fast heartbeat
- Feeling lightheaded or dizzy
- Hunger
- Nausea
- Color draining from the skin (pallor)
- Feeling sleepy
- Feeling weak or having no energy
- Tingling or numbness in the lips, tongue, or cheeks
- Headaches
- Coordination problems
- Nightmares or crying out during sleep
- Seizures



WARNING: Treat hypoglycemia (low glucose) or its symptoms right away. Delaying treatment can lead to severe hypoglycemia, which may prevent you from swallowing food or fast-acting glucose. Untreated, hypoglycemia can cause loss of consciousness, seizure, or death. If loss of consciousness or inability to swallow occurs: pause insulin delivery, call 911, and administer glucagon as directed by your healthcare provider.

Troubleshooting Frequent Hypoglycemia

Check settings with your healthcare provider:

- Is *Loop* on and adjusting your insulin delivery?
- Is your *Correction Range* set so that *twiist* is working to get your glucose where you want it to be?
- Does your insulin sensitivity result in the desired drop in glucose from 1 unit of insulin?
- Does your carb ratio setting reflect the correct amount of carbs that are covered by 1 unit of insulin?

Assess meals and snacks:

- Are you over estimating the amount of carbs you're entering when entering bolus details for a meal?
- Are you modifying the recommended bolus or manually setting a specific bolus amount?
- Did you consume alcohol?

Assess physical activity:

- Has the amount or intensity of physical activity increased?
- Are you using the Workout Preset to raise your *Correction Range*?
- Are you consuming carbs when you are active and entering them into the *twiist* AID system?

Sick Day Management

Always discuss sick day management with your healthcare provider and follow their guidance for your individual needs.

Make a sick day plan with your healthcare provider that includes:

- When to call your doctor (e.g., in most cases, if you are vomiting or have diarrhea more than 3 times over 24 hours or have had a fever over 101° for 24 hours)
- How often to check your blood glucose
- What foods and fluids to consume during your illness
- How and when to adjust your insulin or oral medication
- If and when to check for ketones
- What over-the-counter medicines should be used for colds, flu, etc. Some can affect your blood sugar or interact with your usual medications

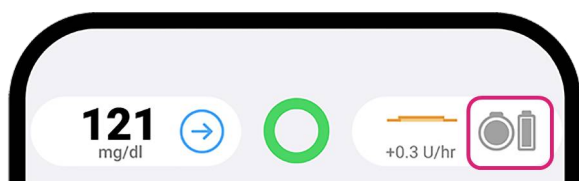
Always consult your healthcare provider when experiencing low or high glucose and sick days and follow your healthcare team guidelines.

Perform a Cassette Change

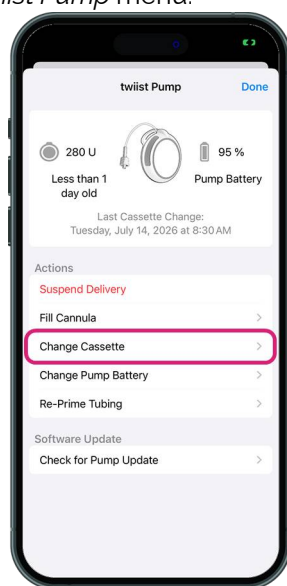
A *twiist Cassette Change* is a step-by-step process for changing out your cassette and supplies to restart delivery. A cassette change will need to be completed after 72 hours (3 days) or when the cassette is empty, whichever comes first. The *twiist* AID System provides on-screen, step-by-step instructions to complete a cassette change. Do not jump ahead of the *twiist* App.



WARNING: Do not fill cassettes before you intend to use them. Filling cassettes before you intend to use them may result in spoilage or changes to insulin potency or purity and may lead to harm.



1. Tap the **Pump Status**  icon to access the *twiist Pump* menu.
2. Tap **Change Cassette**.
3. Gather the following supplies:
 - A charged pump battery
 - A new cassette, infusion set, syringe and needle provided in your *twiist* Starter Kit
 - Humalog or NovoLog U-100 insulin
 - Alcohol wipes
4. Tap **Start Cassette Change**.
5. Tap **Confirm** to suspend insulin delivery.
The pump plays the *Delivery Suspended* sound.
6. Disconnect the infusion set tubing from your infusion site.
7. Remove the infusion site and dispose.
8. Tap **Next**.



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

10. Remove the cassette from the pump and dispose of the used cassette and infusion set tubing.

The screen advances automatically.

11. Remove the battery from the pump and insert it into the battery charger.

12. The twist App will display *Searching for Pump*.

13. Insert a charged battery (green indicator on the battery charger) into the pump.

The twist App advances automatically.

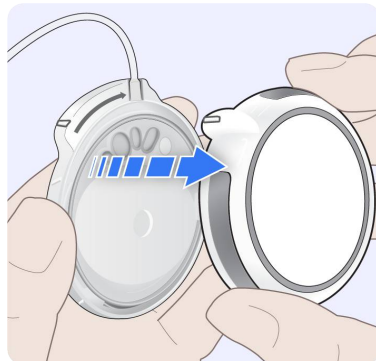
14. Wash your hands with soap and water before opening sterile supplies.

15. Open a new cassette and remove it from the package.

16. 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.



WARNING: 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.

17. Align the ridges on the pump-bump and the top of the cassette.

18. Press down gently while rotating the pump until the ridge on the pump-bump is aligned with the infusion set tubing and the pump and cassette click into place.

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

20. Tap **Scan Cassette** and position the QR code on the cassette inside the green box.



21. Using the picker, select your desired **Cassette Fill Volume**. The *Cassette Fill Volume* is how much insulin you will use to fill your syringe.
- Priming the cassette and the 24-inch (61 cm) infusion set tubing requires up to 30 units of insulin. The insulin used to fill the cassette, no more than 300 units maximum, includes the amount for priming.
 - The cassette volume displayed in the twiist Pump menu shows the reduced amount of insulin remaining in the cassette after priming is complete.
 - The twiist AID System will remember your last selected cassette fill volume for future cassette changes. 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.
22. Tap **Next** to continue.



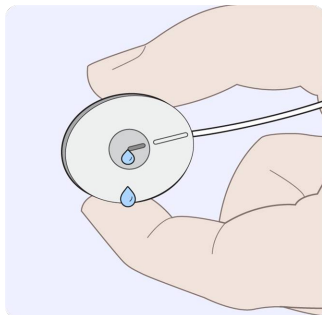
WARNING: Do not fill or prime the cassette and infusion set tubing while connected to your infusion site. Connecting the infusion set tubing during filling and priming may lead to unintended over-delivery of insulin which may result in low blood glucose.

23. Fill your cassette using room temperature insulin, following the manufacturer instructions for use and handling:
 - Clean the top of the insulin vial with an alcohol wipe.
 - Attach the needle to the syringe.
 - Fill the syringe with air, pulling the plunger out to the selected *Cassette Fill Volume*.
 - Insert the needle into the insulin vial and inject the air.
 - Fill the syringe with insulin equal to the selected *Cassette Fill Volume*. Never fill your cassette with more than 300 units.
 - Tap on the syringe to remove any visible air bubbles and tap **Next** to continue.
 - Insert the needle into the cassette filling port. Do not force the needle.
 - Push down and hold syringe plunger to fill the cassette. If you cannot press the syringe plunger, remove the needle and try inserting again.



CAUTION: Do not fill the cassette with more than 300 U of insulin. Filling the cassette with more than 300 U may lead to pump malfunctions and interruptions of therapy.

- Keep holding the plunger down as you remove the needle and dispose of the used needle and syringe in a Sharps Container and tap **Next** to continue.
24. Open a new infusion set package.
 25. Attach the infusion set tubing to the cassette by twisting the luer connectors together and tap **Next** to continue.
 26. Prime the cassette and infusion set tubing:
 - Tap **Start Prime**. A series of *Busy Beeps* are played by the pump as priming occurs.
 - Watch for drops to appear at the end of the infusion set tubing, which indicates if the cassette and tubing are primed.
 - Tap **Stop Prime**.
 - Tap **Yes** to confirm that priming is complete.

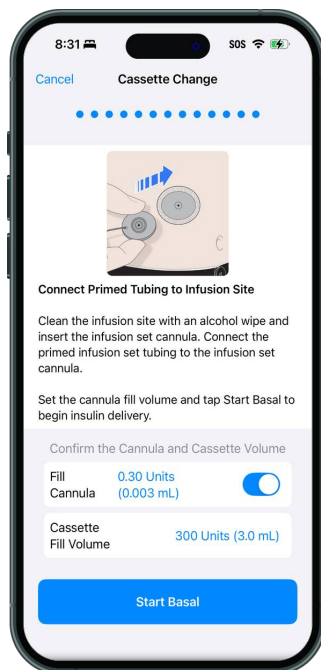


- If you tap *No*, you are returned to the prime steps. Tap *Resume Prime* to continue.
- If you do not stop priming, the pump will automatically stop and a *Prime Stopped* notice is displayed.

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

28. Choose your infusion site and start basal.

- Clean the infusion site with an alcohol wipe and allow to dry.
- Insert the infusion set cannula per the manufacturer instructions.
- Connect the primed infusion set tubing to the infusion site and route the infusion set tubing to avoid kinks.
- 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 and tap **Done** to continue.
- Confirm the *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 and tap **Done** to continue.
- To begin insulin delivery, tap **Start Basal**. The pump plays the *Delivering* sound and basal delivery will start.



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



CAUTION: 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.

Change Pump Battery

A battery change may be done without a full cassette change. If a battery that was not fully charged was used to begin insulin delivery during your last cassette change, you may need to change the battery only.

1. Gather the required supplies:
 - A fully charged pump battery
 - Your *twiist* Pump
2. Tap the **Pump Status**  icon to access the *twiist* Pump menu.
3. Tap **Change Pump Battery**.
4. Obtain a fully charged pump battery.
5. Tap **Start Battery Change** and follow the on-screen instructions.



Line Blocked Alarm

A *Line Blocked* alarm is the result of insulin being blocked from delivery due to a kink in the infusion set tubing or a kink in the cannula under your skin.



CAUTION: 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.

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.



WARNING: 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.

3. Test for ketones. Check your blood glucose and treat highs and lows as advised by your healthcare provider.

If a Line Blocked alarm occurs:

1. **Resolve with Current Cassette.**
2. Disconnect the infusion set tubing from the infusion site when investigating or resolving a *Line Blocked* alarm.
3. Check the infusion set tubing for kinks or bends, including the tubing from the cassette. Never pull or bend the tubing tightly at the cassette. Sometimes repositioning your body can correct the flow of insulin.

If the Line Blocked alarm occurs again while wearing the same cassette, perform the following steps:

1. **Resolve with Current Cassette.**

2. Disconnect the infusion set tubing from the infusion site when investigating or resolving a *Line Blocked* alarm.
3. Check the infusion set tubing for kinks or bends, including the tubing from the cassette. Never pull or bend the tubing tightly at the cassette. Sometimes repositioning your body can correct the flow of insulin.
4. Change infusion site only. Consider the infusion site you are choosing. Avoid scar tissue, where your body naturally bends, and areas where clothing may be tight over the site. Site rotation is important for optimal insulin absorption and to avoid scarring when a site is overused. Once the site is changed, select **Fill Cannula**. Then tap **Start Basal**.

Repeated Line Blocked alarms after troubleshooting using the same cassette may indicate the blockage is associated with the infusion site. A full Cassette Change is recommended.

1. Initiate the **Change Cassette** from the *twiist Pump* menu, following the on-screen instructions to complete the process.
2. When placing the new infusion site, consider the infusion site you are choosing. Avoid scar tissue, where your body naturally bends, and areas where clothing may be tight over the site. Site rotation is important for optimal insulin absorption and to avoid scarring when a site is overused.
3. Consider how you manage your infusion set tubing. Never pull or bend the tubing tightly at the cassette as it may restrict insulin delivery.

Your twiist AID System Therapy Settings

It is important to write down your *Therapy Settings*. Use this sheet to keep track of your therapy settings. All changes to therapy settings should be made with direction from your healthcare provider. Refer to "*Therapy Settings*" on page 40 for more information.

Glucose Safety Limit:

_____ mg/dL

Correction Range:

12am - _____ mg/dL

_____ - _____ mg/dL

_____ - _____ mg/dL

_____ - _____ mg/dL

Carb Ratios:

12am - _____ g/Unit

_____ - _____ g/Unit

_____ - _____ g/Unit

_____ - _____ g/Unit

Basal Rates:

12am - _____ Unit/hour

_____ - _____ Unit/hour

_____ - _____ Unit/hour

_____ - _____ Unit/hour

Maximum Basal Rate:

_____ Unit/hour

Maximum Bolus:

_____ Units

Insulin Model:

☐ Fast-Acting Adults

☐ Fast-Acting Children

Insulin Sensitivities:

12am - _____ mg/dL/Unit

_____ - _____ mg/dL/Unit

_____ - _____ mg/dL/Unit

_____ - _____ mg/dL/Unit

Resources

Contact Sequel Customer Support to obtain a replacement in the event a component stops working as expected.

For detailed instructions and additional support information, refer to the twist AID System User Guide and the resources available on the twist Support website

www.twiist.com/twiist-on-support.



Everyday Reminders:

- Suspend and disconnect your twist Pump when swimming and bathing.



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

- Avoid contact with insect repellents containing DEET, skin care products, or sunscreens.
- Keep the cassette or pump cover on when cleaning. Water splashes are okay, but do not immerse the pump in water.
- Cover the pump when stored.



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

Symbols

The following symbols provide information required for safe use of the twist AID System.

Symbol	Definition	Symbol	Definition	Symbol	Definition	
	Read instructions prior to use.		Do not use if package is damaged		Temperature limit	
R _x Only	Prescription use only		Sterile		Humidity limit	
	Single use only		Sterilized using ethylene oxide		Pressure limit	
	Material may be recycled		Sterilized using irradiation		Separate collection for electrical and electronic equipment waste.	
	Manufacturer		Non-pyrogenic	 	Indicates a potential hazard. Obey all safety messages that follow this symbol.	
	Date of Manufacture		Keep dry			
	Expiration date		Keep away from sunlight	 	Magnetic Resonance Unsafe – Items should not enter an MRI scanner room.	
	Lot code		Type BF Applied Part			
	Catalog number		Direct Current required			
	Serial number		Recycle lithium-ion batteries			

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Magnetic Resonance Unsafe Card



WARNING: The twiist Automated Insulin Delivery System is Magnetic Resonance Unsafe. Disconnect the twiist Pump before entering an MRI scan room. Do not bring your smartphone or twiist Pump into an MRI scan room. Contact with, or being in proximity to, an MRI scanner may cause the twiist Pump and smartphone to move or lead to electric shock and may result in severe injury.

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



Magnetic Resonance Unsafe

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

Distributed by:

Sequel Med Tech, LLC.

50 Commercial Street

Manchester, NH 03101

+1 877-489-4478

Keep this card with you while using the system.



Magnetic Resonance Unsafe

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

Distributed by:

Sequel Med Tech, LLC.

50 Commercial Street

Manchester, NH 03101

+1 877-489-4478

Keep this card with you while using the system.



Part 3: twiist Training Follow-Up Plan

Follow-up training with your Certified twiist Trainer drives long-term success with the twiist AID System. Your Certified twiist Trainer will follow up with you post-training at an agreed upon time to check your progress and cover additional twiist System features. Work with your Certified twiist Trainer to list your follow-up topics in the space below.



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