t:slim X2

Insulin Pump

WITH Control-IQ TECHNOLOGY

Training Manual

for Professional Educators

TANDEM™ Diabetes Care

SOFTWARE VERSION:
CONTROL-IQ 7.6

MMOL/L

This manual is designed to educate you on the features and functions of the t:slim X2™ insulin pump with Control-IQ™ technology, also referred to in this manual as the "System." This training manual is for use by professional educators to train end users of the System. This training manual is not intended to be distributed to end users and is not meant to replace the t:slim X2 insulin pump with Control-IQ technology user guide. This training manual provides step-by-step illustrative instructions that you should follow sequentially when training an end user on how to properly operate, manage, and care for their System. Look for special content boxes, which highlight useful tips and important Notes that may help end users interact with the System. For more comprehensive information on the System, please refer to the t:slim X2 insulin pump with Control-IQ technology user guide. If end users have questions or need further clarification on their pump use, they should be instructed to ask their healthcare provider or contact their local customer support service.

You should instruct all end users that they MUST NOT deliver insulin with their t:slim X2 insulin pump with Control-IQ technology until they have received training.

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CHAPTER 1

Getting Started

Important Safety Information

The t:slim X2 insulin pump with Control-IQ technology (the System) consists of the t:slim X2 insulin pump, which contains Control-IQ technology, and a compatible continuous glucose monitor (CGM, sold separately). The t:slim X2 insulin pump is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in people requiring insulin. The t:slim X2 insulin pump can be used solely for continuous insulin delivery and as part of the System. When used with a compatible CGM, the System can be used to automatically increase, decrease, and suspend delivery of basal insulin based on CGM sensor readings and predicted glucose values. The System can also deliver correction boluses when the glucose value is predicted to exceed a predefined threshold. The pump and the System are indicated for use in individuals six years of age and greater. The pump and the System are intended for single user use. The pump is indicated for use with NovoRapid, Admelog (Canada Only), or Humalog U-100 insulin.

WARNING: Control-IQ technology should not be used by anyone under the age of six years old. It should also not be used in users who require less than 10 units of insulin per day or who weigh less than 25 kilograms.

The System is not indicated for use in pregnant women, people on dialysis, or critically ill users. Do not use the System if using hydroxyurea. Users of the pump and the System must: be willing and able to use the insulin pump, CGM, and all other system components in accordance with their respective instructions for use; test blood glucose levels as recommended by their healthcare provider; demonstrate adequate carb-counting skills; maintain sufficient diabetes self-care skills; see healthcare provider(s) regularly; and have adequate vision and/or hearing to recognize all functions of the pump, including alerts, alarms, and reminders. The t:slim X2 pump and the CGM transmitter and sensor must be removed before MRI, CT, or diathermy treatment. Visit tandemdiabetes.com/safetyinfo for additional important safety information.

Pump Overview

The t:slim X2 insulin pump with Control-IQ technology uses touchscreen technology. To activate and interact with the System, the user should use the pad of their finger to quickly and lightly tap on the screen.

Do not use a fingernail or other object to interact with the screen. It will not activate the screen or its functions. A soft-tipped stylus may be used on the touchscreen.

Quick Tip: Fingers should be clean and dry. Oily or damp fingers may interfere with activation of the screen.

Alert: Turn screen off and position the screen away from the skin when worn under clothing.

Pump Terminology

Basal
Basal is a slow, continuous delivery of insulin, which keeps blood glucose (BG) levels stable between meals and during sleep. It is measured in units per hour (units/hour).

Blood Glucose
BG is the level of glucose in blood, measured in millimoles per liter (mmol/L).

Bolus
A bolus is a quick dose of insulin that is usually delivered to cover meals or an elevated BG. There are several types of boluses that can be delivered by the System, including food, correction, extended, and quick boluses.

Cannula
Insulin is delivered through the cannula, the part of the infusion set that is inserted under the skin.

Carbs
Carbohydrates (carbs) are the sugars and starches in food that the body breaks down into glucose and uses as an energy source. Carbs are measured in grams.

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

Continuous Glucose Monitor
CGM systems sense glucose in the interstitial fluid at regular intervals.

Control-IQ
Control-IQ technology is a feature of the t:slim X2 insulin pump that automatically adjusts insulin delivery rates and amounts in response to readings from a continuous glucose monitor (CGM).

Correction Bolus
A correction bolus is given to correct elevated BG.

Correction Factor
A correction factor is the amount that BG is lowered by one unit of insulin. Also known as the insulin sensitivity factor (ISF).

Extended Bolus
An Extended Bolus is delivered over a period of time. It is intended for times when the user has a high-fat meal or a meal spread out over a long period of time.

Glucose Target
Glucose target is a specific blood glucose goal; it's an exact number, not a range. When a BG or CGM value is entered in the t:slim X2 pump bolus calculator, the calculated insulin bolus will be adjusted up or down as needed to attain this target.

Grams
Grams are a unit of measurement used to measure carbohydrates.

Insulin Duration
Insulin duration is the amount of time that insulin is active and available in the body after a bolus has been delivered. This also relates to the calculation for insulin on board.

Insulin on Board (IOB)
IOB is the insulin that is still active (has the ability to continue to lower the BG) in the body after a bolus has been delivered. In addition, when Control-IQ technology is active, basal modulations will be incorporated into insulin on board.

Load
Load refers to the process of removing, replacing, and filling a new cartridge and infusion set.

Personal Profile
A Personal Profile is a personalized group of settings that defines the delivery of basal and bolus insulin within specific time segments throughout a 24-hour period.

Quick Bolus
A Quick Bolus is a way to deliver a bolus (using the Quick Bolus button) by following beep/vibration commands without navigating through or viewing the t:slim X2 insulin pump screen.

Temporary Basal Rate (Temp Rate)
Temp Rate is used to increase or decrease the current basal rate for a short period of time to accommodate special situations, such as exercise or illness. The programmed basal rate is represented as 100%, with percentages greater or less than 100% representing how much more or less insulin is delivered compared with the basal rate. A 120% temp rate, for example, represents 20% more insulin than the regular basal rate.

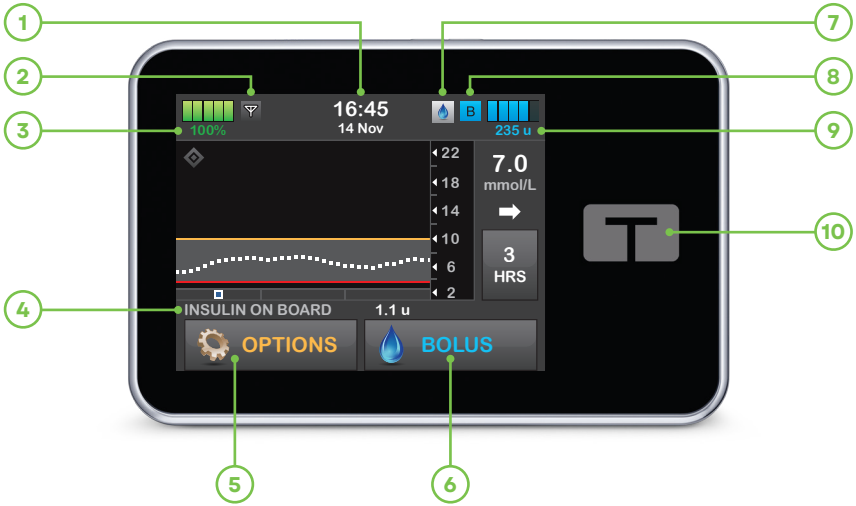
Unit
A unit is the increment of measurement for insulin.

USB Cable
USB is the abbreviation for universal serial bus. The cable connects into the micro-USB port on the t:slim X2 insulin pump with Control-IQ technology.

Control-IQ Lock Screen

1. **Alert Icon:** Indicates a reminder, alert, or alarm is active behind the screen lock
2. **USB Port:** Charge the t:slim X2 insulin pump battery. Close the cover when not in use.
3. **Control-IQ Technology Status:** Indicates the status of Control-IQ technology
4. **Control-IQ Activity Status:** Indicates an Activity has been enabled
5. **CGM Graph:** Visual view of data from the continuous glucose monitor with bolus icons below the graph
6. **1–2–3:** Unlocks pump screen
7. **CGM Graph Shading:** Red shading indicates Control-IQ technology is, or was, delivering 0 units of insulin for the period indicated
8. **Screen On/Quick Bolus Button:** Turns on the t:slim X2 insulin pump screen or programs a Quick Bolus (if activated)
9. **LED Indicator:** Illuminates when the t:slim X2 insulin pump is connected to a power supply and functioning properly
10. **Cartridge Tubing:** Tubing attached to the cartridge
11. **Tubing Connector:** Connects the cartridge tubing to the infusion set tubing

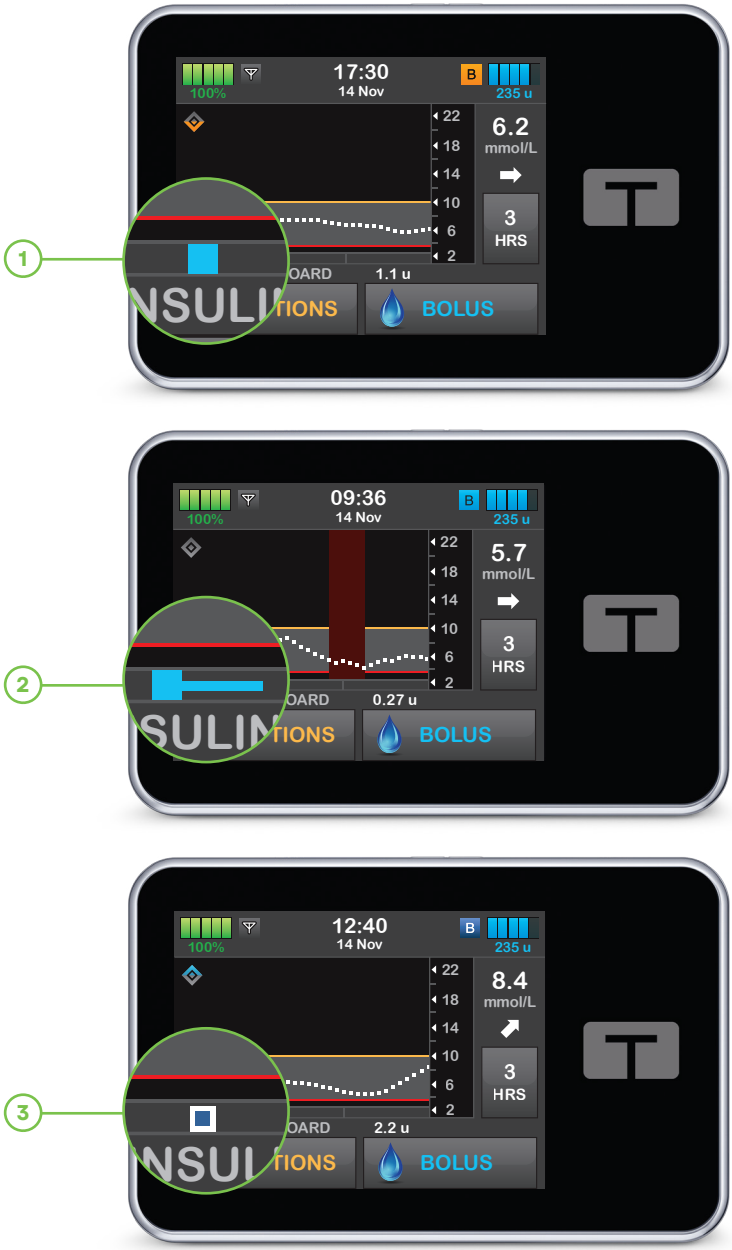
Control-IQ Home Screen



1. **Time and Date Display:** Displays the current time and date
2. **Antenna:** Indicates communication status between pump and transmitter
3. **Battery Level:** Displays the level of battery power remaining. When connected for charging, the charging icon (lightning bolt) will display
4. **Insulin on Board:** Indicates the amount and time remaining for any active IOB

   ⚑ **Note:** The IOB time remaining is not displayed when Control-IQ technology is enabled due to variability of insulin delivery when automatically responding to CGM values.
5. **Options:** Stop/Resume insulin delivery, load cartridge, manage My Pump, My CGM, Activity and Device Settings, program a Temp Rate, and view History
6. **Bolus:** Program and deliver a bolus
7. **Active Bolus Icon:** Indicates an active bolus
8. **Status:** Displays current pump settings and insulin delivery status
9. **Insulin Level:** Displays the current amount of insulin in the cartridge
10. **Tandem logo:** Returns to the Home screen

Bolus Icons


1
17:30
14 Nov
100%
B
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6.2
mmol/L
3
HRS
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18
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10
6
2
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5.7
mmol/L
3
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0.27 u
BOLUS
3
12:40
14 Nov
100%
B
235 u
8.4
mmol/L
3
HRS
2.2 u
BOLUS

Note: After a bolus has been delivered, you will see a blue square icon on the bottom of your CGM graph. The icon will move along to the left as time passes, like the CGM graph timeline. There are three types of icons that you might see, depending on the type of bolus delivered.

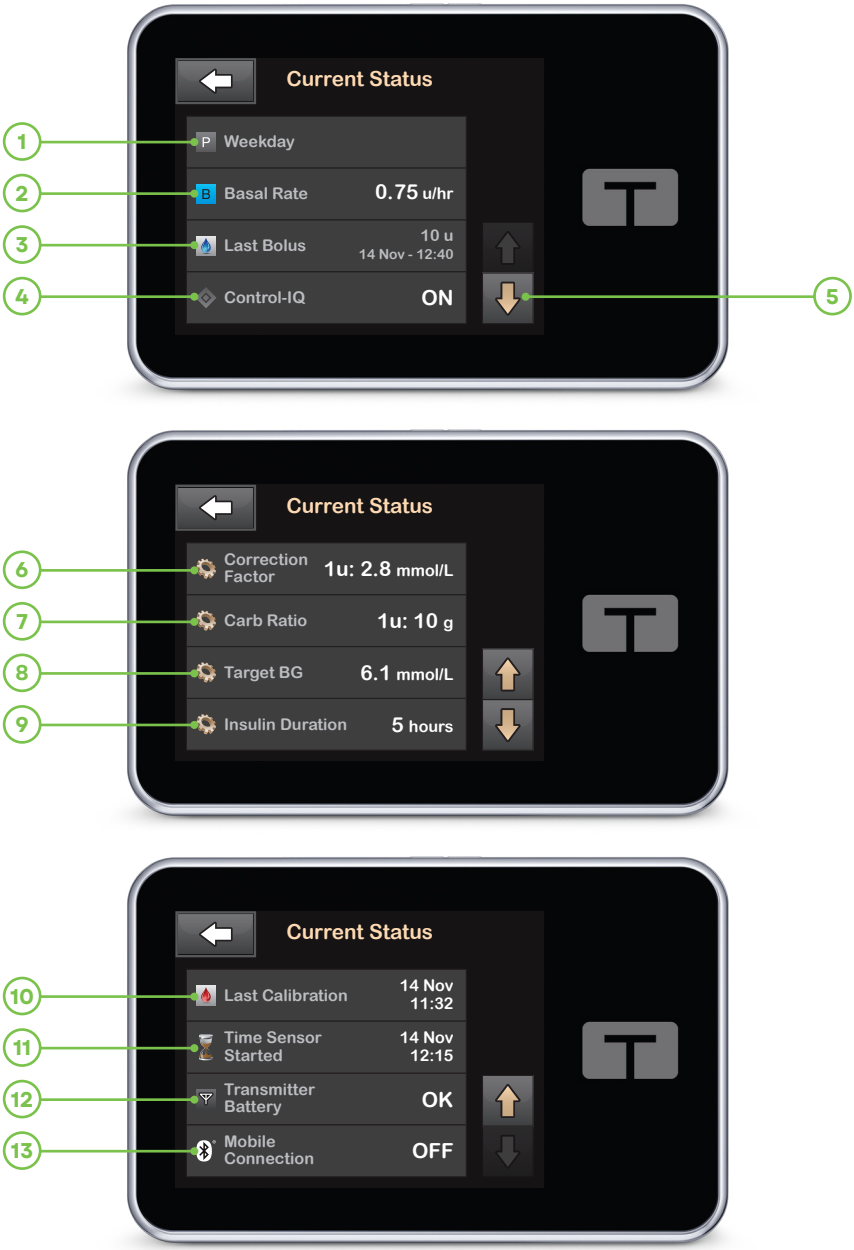
1. Standard/Correction Bolus
2. Extended Bolus
3. Control-IQ technology Automatic Correction Bolus

Pump Back Side

1. **t:slim X2 Cartridge:** A sinlge-use disposable cartridge can hold up to 300 units (3.0 mL) of insulin.
2. **Vent Holes:** Vent holes help the pump function correctly. It is important that these vents remain uncovered.

Precaution: When choosing third-party pump cases or stickers, do not cover the six vent holes on the back of the pump

Status Screen

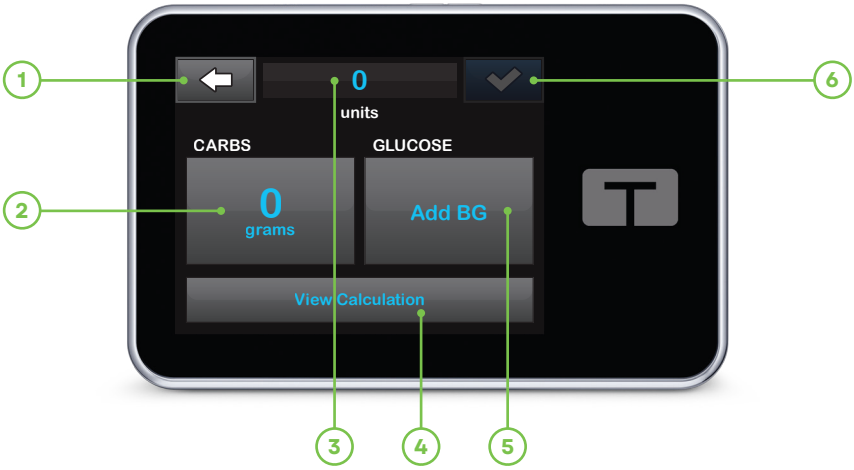


⚑ **Note:** The Current Status screen can be accessed from the Lock screen and the Home screen by tapping the insulin level symbol.

⚑ **Note:** No changes can be made from this screen.

1. Profile: Displays current active Personal Profile
2. Basal Rate: Displays current basal rate or Temp Rate in units/hour
3. Last Bolus: Displays the amount, date, and time of last bolus
4. Control-IQ Status: Displays the Control-IQ technology status
5. Up/Down Arrow: Indicates there is more information
6. Correction Factor: Displays current correction factor used to calculate bolus
7. Carb Ratio: Displays current carb ratio used to calculate bolus for food
8. Target BG: Displays current BG target used to calculate bolus
9. Insulin Duration: Displays current insulin duration used to calculate insulin on board
10. Last Calibration: Displays date and time of last calibration
11. Time Sensor Started: Displays date and time of last time sensor started
12. Transmitter Battery: Displays transmitter battery status
13. Mobile Connection: Displays whether the mobile connection is turned on or off, whether a mobile device is paired with the pump, and if so whether the mobile device is actively connected to the pump. The mobile connection may not yet be available in your region.

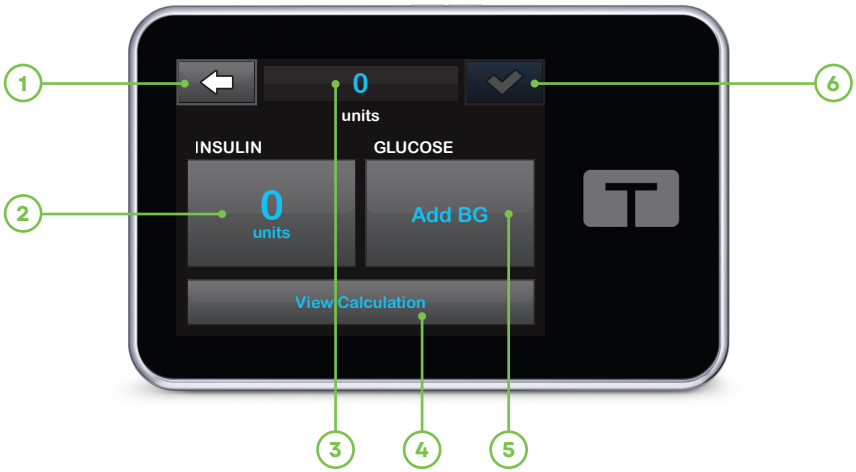
Bolus Screen Using Grams



1. : Returns to the Home screen
2. CARBS: Enter grams of carbohydrate
3. Units: Displays total units calculated
4. View Calculation: Displays how the insulin dose was calculated using the current settings
5. GLUCOSE: Enter BG level
6. : Moves to next step

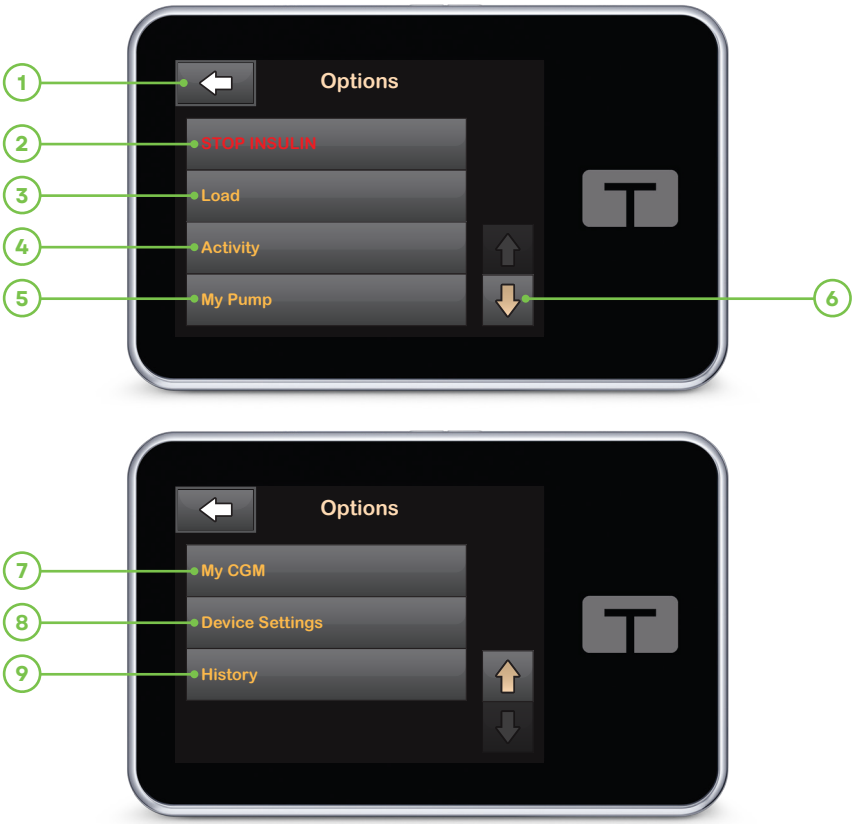
Note: Use of blue text may relate to bolus delivery activity.

Bolus Screen Using Units



1. : Returns to the Home screen
2. **INSULIN:** Enter units of insulin
3. **Units:** Displays total units calculated
4. **View Calculation:** Displays how the insulin dose was calculated using the current settings
5. **GLUCOSE:** Enter BG level
6. : Moves to next step

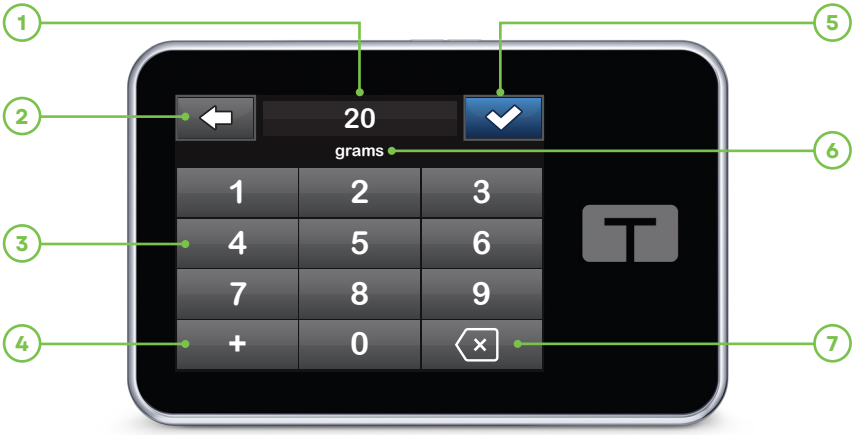
Options Screen



1. : Returns to the Home screen
2. STOP INSULIN: Stops insulin delivery. If insulin delivery is stopped, RESUME INSULIN will be displayed.
3. Load: Change Cartridge, Fill Tubing, Fill Cannula, and Site Reminder
4. Activity: Exercise, Sleep, Sleep Schedules, and Temp Rate
5. My Pump: Personal Profiles, Control-IQ, Alerts & Reminders, and Pump Info
6. Up/Down Arrow: Indicates that there is more information
7. My CGM: STOP/START SENSOR, Calibrate CGM, CGM Alerts, Transmitter ID, and CGM Info
8. Device Settings: Display Settings, Bluetooth Settings, Time and Date, Sound Volume, and Security PIN
9. History: Pump History (Displays historical log of pump events) and CGM History (Sessions and Calibrations, Alerts and Errors, and Complete)

⚑ **Note:** Orange text relates to t:slim X2 insulin pump setup or delivery settings.

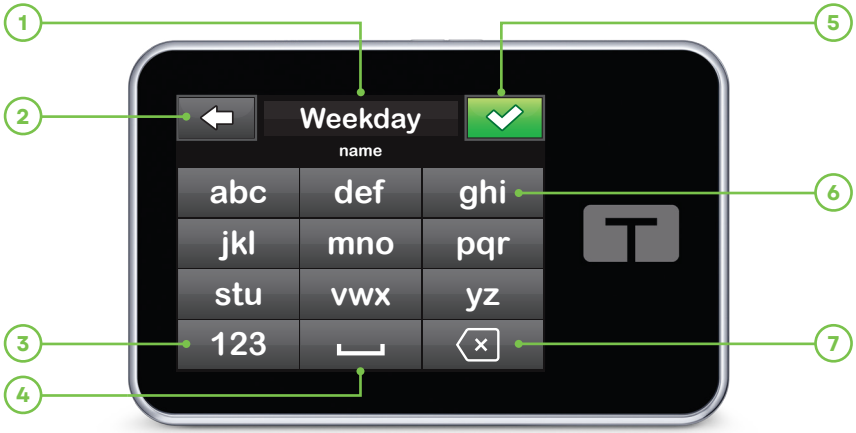
Number Keypad



1. Value Entered
2. : Returns to previous screen
3. Keypad Numbers
4. : Allows numbers to be added on gram keypad screen (if in units, this displays as a decimal point)
5. : Completes task and saves information entered
6. Units/Grams: Value of what is entered
7. : Deletes last number entered

Quick Tip: To change an existing number, begin by tapping the numbers on the keypad to override the current value.

Letter Keypad



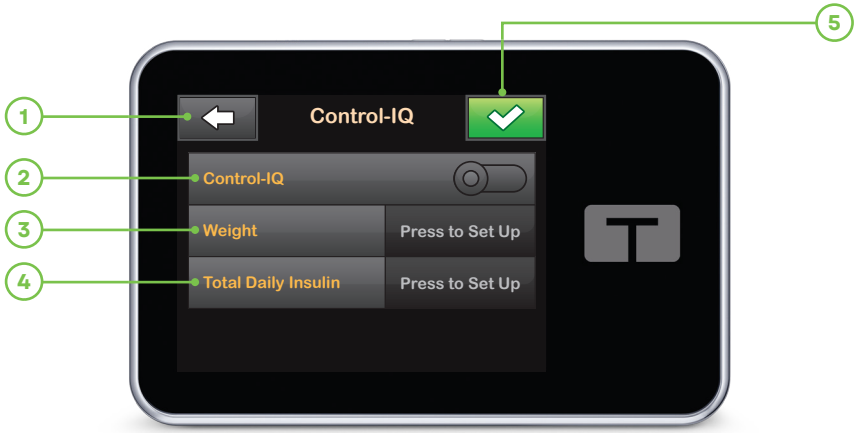
1. Name of Profile
2. : Returns to previous screen
3. **123:** Changes keypad mode from letters (ABC) to numerals (123)
4. : Enters a space
5. : Saves entered information
6. **Letters:** Tap once for first letter displayed, two quick taps for middle letter, and three quick taps for third letter
7. : Deletes last letter or number entered

Quick Tip: If changing an existing name, begin by tapping the letters on the keypad to enter new text. The maximum number of characters is 16.

My Pump Screen

1. : Returns to the **Options** screen
2. **Personal Profiles:** A group of settings that defines basal and bolus delivery
3. **Control-IQ:** Turn on/off Control-IQ technology and enter required values
4. **Alerts & Reminders:** Pump Reminders and Pump Alerts
5. **Pump Info:** t:slim X2 pump serial number and other technical information

Control-IQ Screen



1. : Returns to previous screen

   Note: If this is the first time using the t:slim X2 insulin pump with Control-IQ technology, the user must first begin an active sensor session before using Control-IQ technology. Control-IQ technology is turned off by default and will begin working once it is turned on and there is an active sensor session.

2. Control-IQ: Turns Control-IQ technology on or off

3. Weight: Press to set up Weight

   Note: Weight should be representative of what the user weighs when they start the system. Weight can be updated when they visit their healthcare provider.

4. Total Daily Insulin: Press to set up Total Daily Insulin

5. : Saves entered information

   Note: If Total Daily Insulin (TDI) is not known, the user should speak with their healthcare provider to get this value.

For full detailed instructions on items in this chapter, please refer to the Introduction, Important Safety Information, and Getting to Know Your t:slim X2 Insulin Pump chapters in the Control-IQ technology user guide.

Charging the Pump

The t:slim X2 insulin pump with Control-IQ technology is powered by an internal lithium polymer rechargeable battery. Included with the System are accessories for charging from AC wall outlets. Upon receipt of the t:slim X2 insulin pump with Control-IQ technology, the user should charge it using the AC charger long enough to ensure a full charge, then plug in for a few minutes every day or two to keep the battery optimally charged. Battery life depends on use (for example, screen-on time can be shortened to extend battery life).

1. Plug the AC charger into a grounded AC electrical outlet.

2. Plug the USB cable into the AC charger and the other end into the micro-USB port on the t:slim X2 insulin pump with Control-IQ technology. The screen is illuminated.

Note: When the pump is plugged in, the following are signs that it is charging:
- An illuminated screen
- An audible alert
- An illuminated LED (edge around the **Screen On/Quick Bolus** button)
- A vibrating alert
- A charge symbol (lightning bolt) on the battery level indicator appears

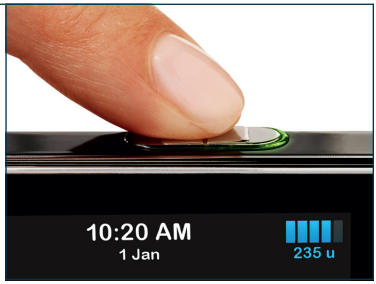
Quick Tip: Tandem Diabetes Care recommends periodically checking the battery level indicator, charging the System for a short period of time every day (10-15 minutes), and also avoiding frequent full discharges.

Turning On Pump Screen

1. Press **Screen On/Quick Bolus** button.

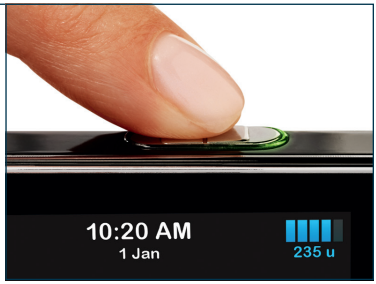
✓ The Lock screen is displayed. Once unlocked, the Home screen or the last screen that was viewed is displayed.

⚑ **Note:** The Screen On/Quick Bolus button can also be used to turn the screen off.

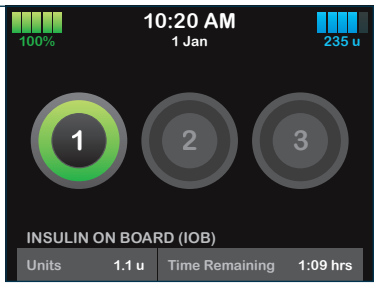


Unlock Pump Screen

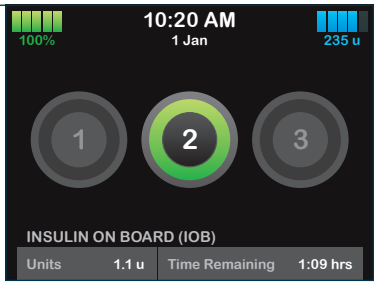
1. Press **Screen On/Quick Bolus** button.



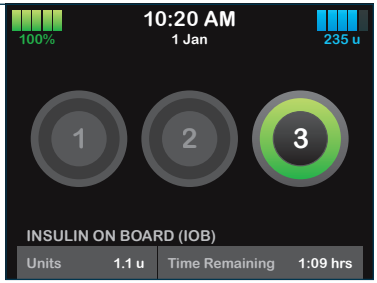
2. Tap **1**.



3. Tap **2**.



4. Tap 3.



✓ The pump screen is now unlocked. The last screen that was viewed is displayed.

Note: The user must tap 1-2-3 in sequential order, or they will have to begin again to unlock the pump screen. The screen will turn off after three accidental screen taps.

Selecting a Language

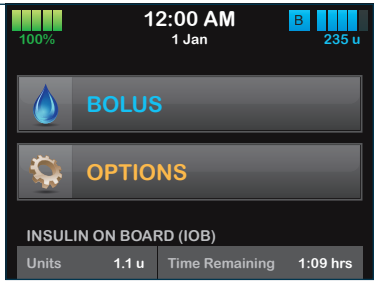
The Language Selection screen displays when the user unlocks the pump screen for the first time, or when they unlock the screen after turning the pump off.

1. Tap the circle next to the language the user wants to display. Tap the **Down** Arrow to see additional language selections.

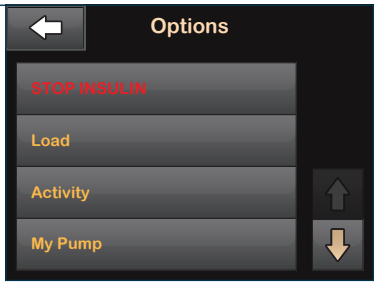
2. Tap to save the selection and continue with pump setup.

Edit Time

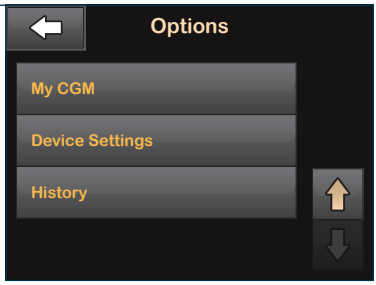
1. From the Home screen, tap OPTIONS.



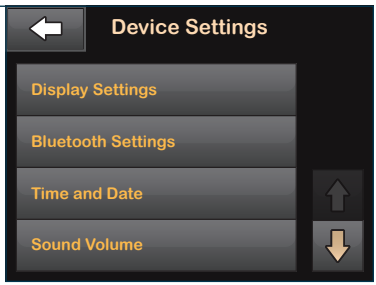
2. Tap Down Arrow.



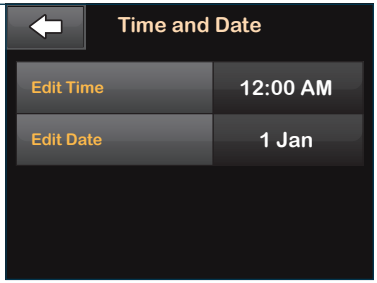
3. Tap Device Settings.



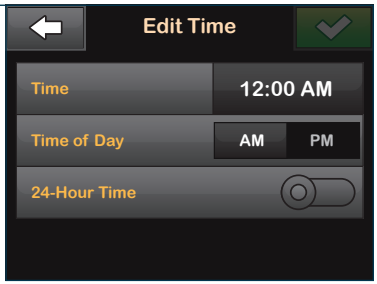
4. Tap Time and Date.



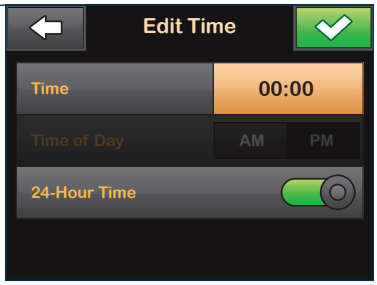
5. Tap **Edit Time**.



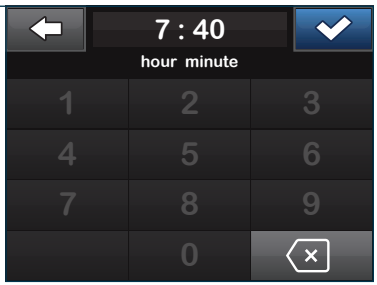
6. Tap **24-Hour Time**.



7. Tap **Time**.



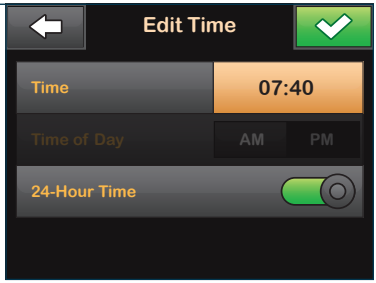
8. Using the on-screen keypad, enter the hour and minute values. Verify and tap .



9. Verify the correct time is set and tap .

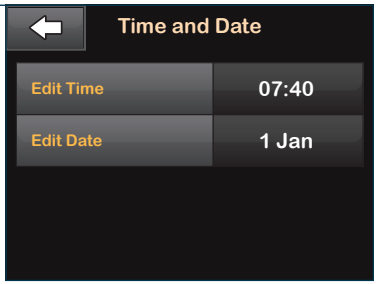
✓ The SETTING SAVED screen is displayed.

⚑ **Note:** The orange highlighted area indicates a recent change made to a setting.

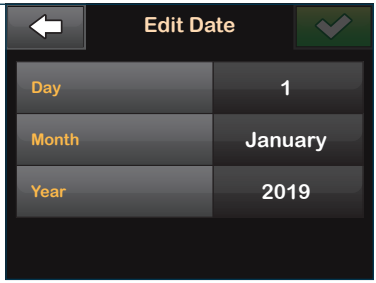


Edit Date

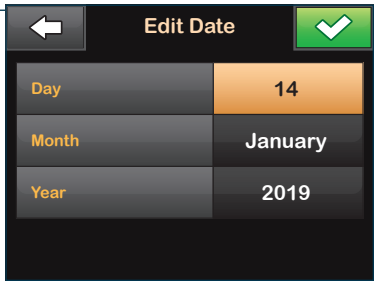
1. From the Time and Date screen, tap **Edit Date**.



2. Tap **Day**. Using the on-screen keypad, enter the current day and tap .



3. Tap **Month**.

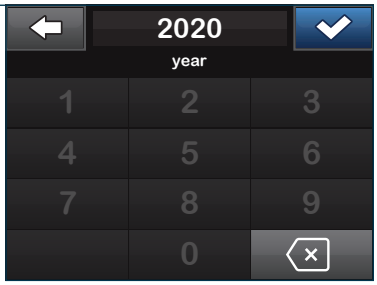


4. Find and tap current month. Use Up/Down Arrows to view months not displayed.

✓ Once a value is selected, the pump will return to the previous screen.

5. Tap **Year**.

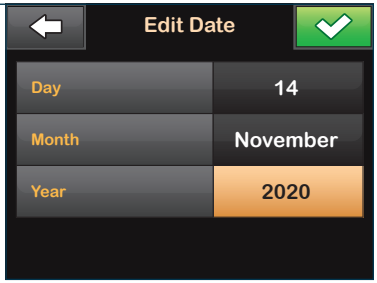
6. Using the on-screen keypad enter the current year and tap .



7. Verify the correct date is set and tap .

✓ The SETTING SAVED screen is displayed.

⚑ **Note:** Setting the correct time and date on the t:slim X2 insulin pump with Control-IQ technology is very important to ensure that the settings reflect the user's insulin needs and generate accurate software reports.

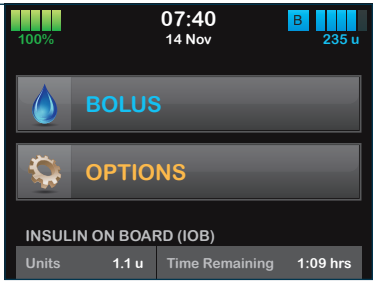


Sound Volume and Display Settings

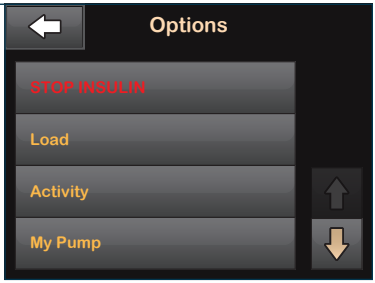
Sound Volume can be personalized for button taps on the Keypad, Bolus, Quick Bolus, Fill Tubing, Reminders, Pump Alarms, Pump Alerts, and CGM Alerts. Options for Sound Volume include high, medium, low, and vibrate.

Display Settings allow for personalization of the Screen Timeout.

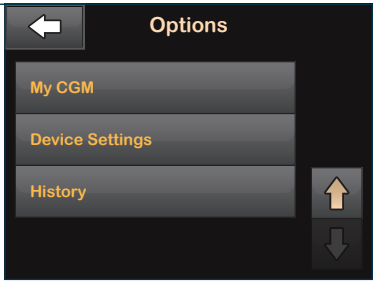
1. From the Home screen, tap OPTIONS.



2. Tap the Down Arrow.

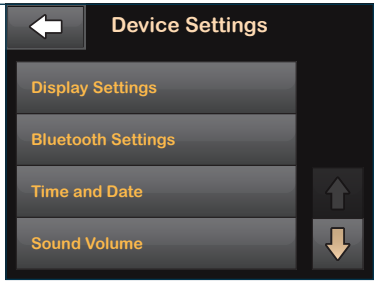


3. Tap Device Settings.



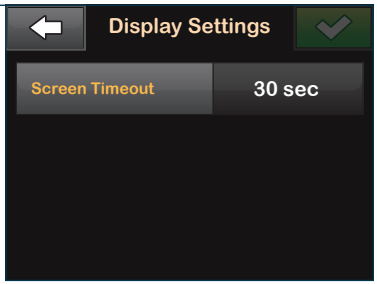
For Screen Timeout

1. Tap **Display Settings**.



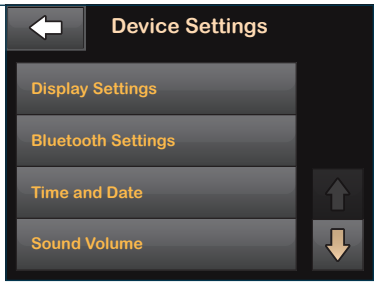
2. Tap **Screen Timeout** and select desired option.

✓ Once a value is selected, the pump will return to the previous screen to complete setup.



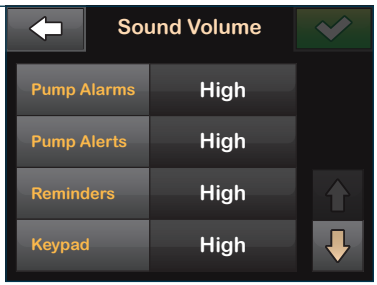
For Volume Options

1. Tap **Sound Volume**.



2. Tap desired function and select desired option.

✓ Once a value is selected, the pump will return to the previous screen to complete setup.



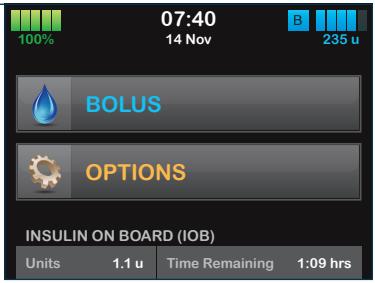
Notes

CHAPTER 2

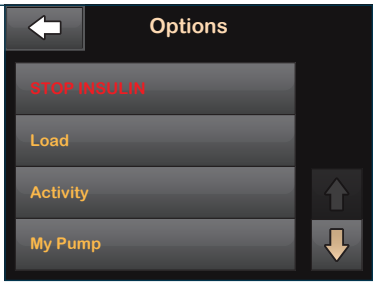
My CGM

Entering the Transmitter ID

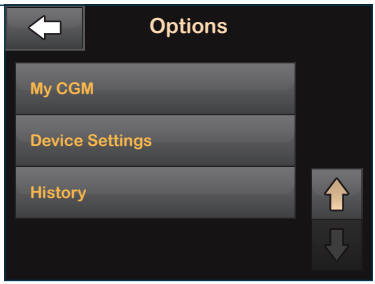
1. From the Home screen, tap OPTIONS.



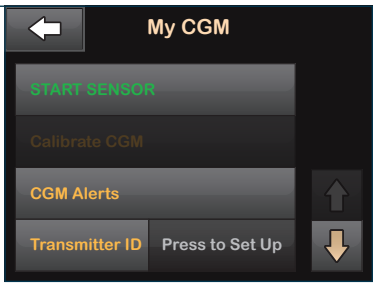
2. Tap Down Arrow.



3. Tap My CGM.

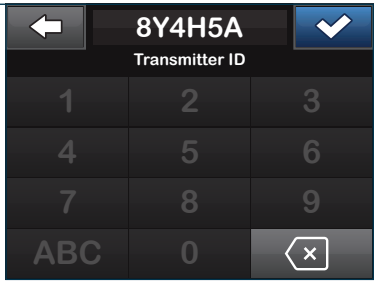


4. Tap Transmitter ID.

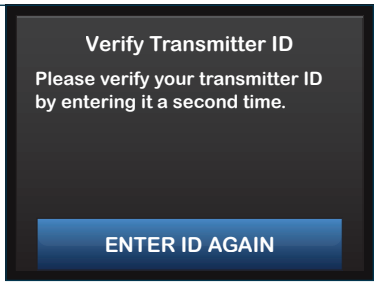


5. Enter the six-character transmitter ID (found on the bottom of the transmitter).

6. Tap .

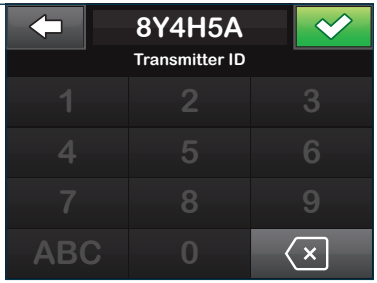


7. Tap ENTER ID AGAIN to verify transmitter ID.



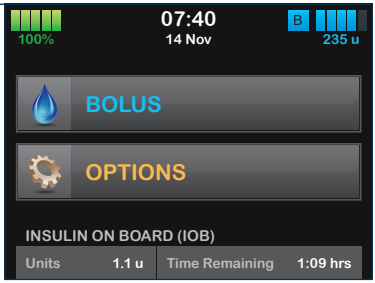
8. Enter the six-character transmitter ID again and tap .

✓ The SETTING SAVED screen is displayed.

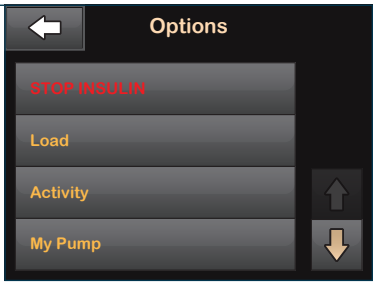


Starting a Sensor Session

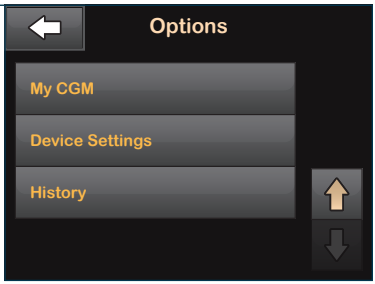
1. From the Home screen, tap OPTIONS.



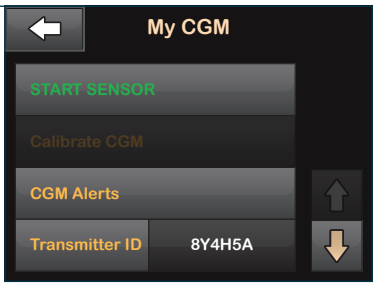
2. Tap Down Arrow.



3. Tap My CGM.

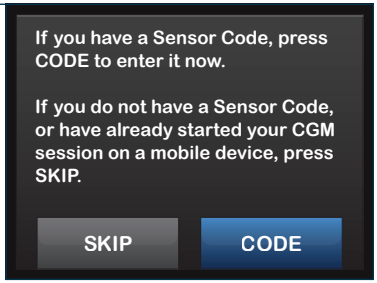


4. Tap START SENSOR.

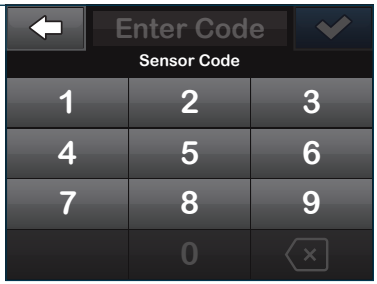


5. Tap **CODE**.

   ⚑ **Note:** If a sensor session is already in progress with a CGM smartphone app, tap SKIP instead of entering a code.

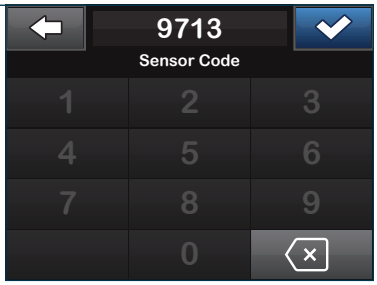


6. Enter the four-digit sensor code (found on the bottom of the applicator on the adhesive strip).



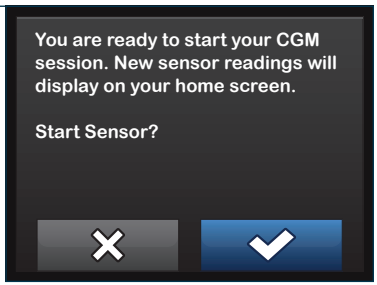
7. Tap ✓.

✓ The CODE CONFIRMED screen is displayed.



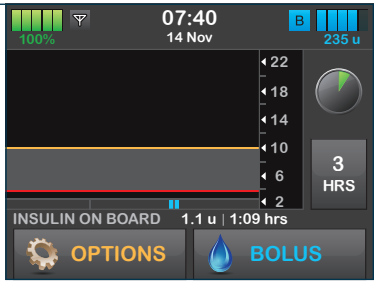
8. Tap ✓ to start sensor session.

✓ The SENSOR STARTED screen is displayed.



9. The two-hour warm up period starts.

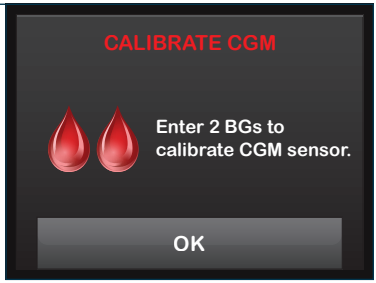
   Note: A graph of the user's CGM values will appear on the pump screen. Tap the Trend Graph Time (HRS) to change the timeline of the graph. The default setting is 3 HRS. The user can select: 1 HR, 3 HRS, 6 HRS, 12 HRS, or 24 HRS.



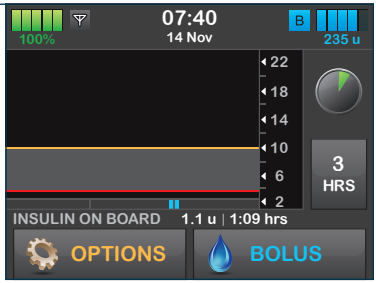
Calibrating the Sensor

Note: If the Sensor Code is entered when starting a sensor session, calibration of the Dexcom G6 sensor is not requested. However, if the Sensor Code is not entered and **SKIP** is chosen when starting a new sensor session, the CALIBRATE CGM screen will appear two hours after the sensor session begins; enter two separate BG values from a BG meter

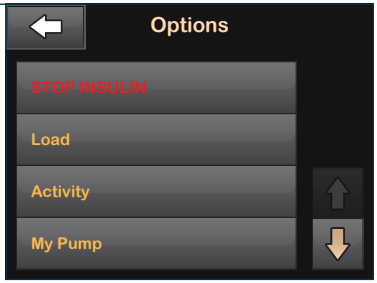
1. If the user sees this prompt, tap **OK**.



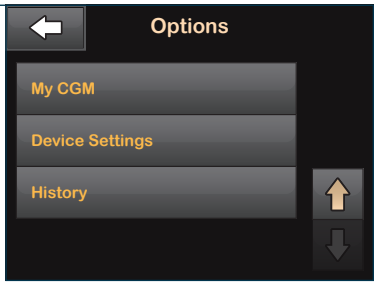
2. To calibrate the sensor, tap **OPTIONS**.



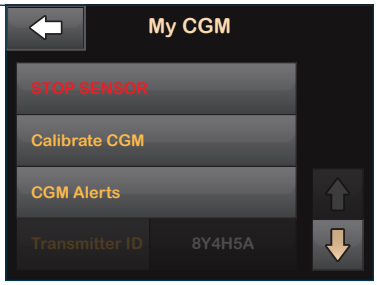
3. Tap Down Arrow.



4. Tap My CGM.

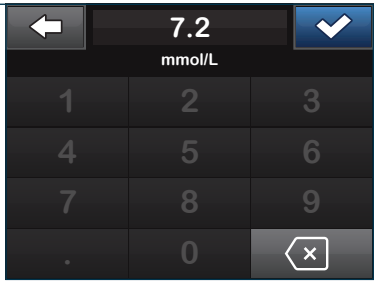


5. Tap Calibrate CGM.



6. Enter BG reading from meter into keypad.

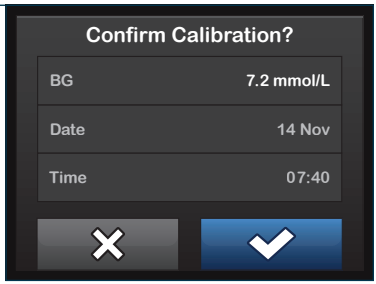
7. Tap ✓.



8. Tap ✓ to confirm calibration.

✓ The CALIBRATION ACCEPTED screen is displayed.

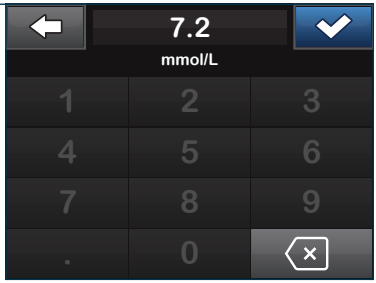
⚑ **Note:** Many functions of the t:slim X2 insulin pump with Control-IQ technology include confirmation screens. Confirmation screens are an important part of the safety feature of the System. Please confirm that the information is correct before changing settings or delivering a bolus.



9. Repeat with a second BG value and tap ✓.

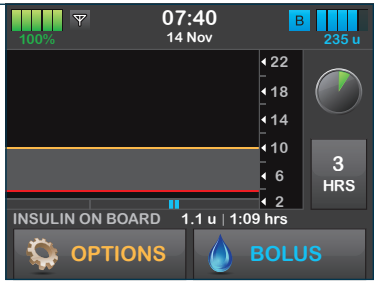
✓ The CALIBRATION ACCEPTED screen is displayed.

⚑ **Note:** A Trend Arrow will appear below the current CGM value. The direction of the arrow estimates the direction and rate of change of the user's CGM values.

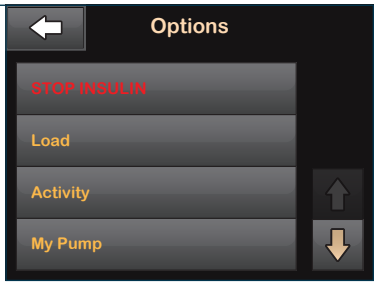


Setting Up CGM Alerts

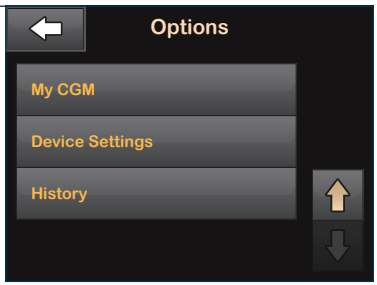
1. From the Home screen, tap OPTIONS.



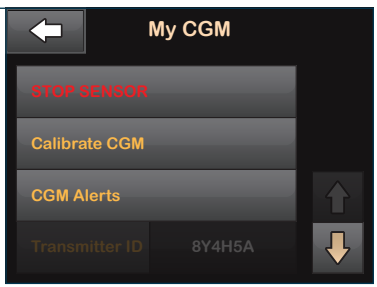
2. Tap Down Arrow.



3. Tap My CGM.

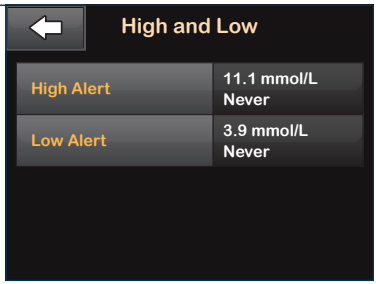


4. Tap CGM Alerts.



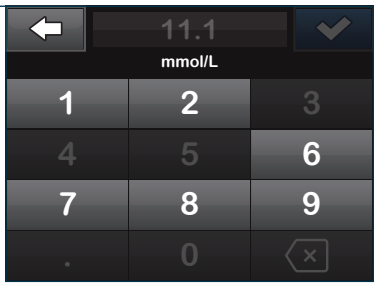
5. Tap **High and Low**.

6. To set the High Alert, tap **High Alert**.

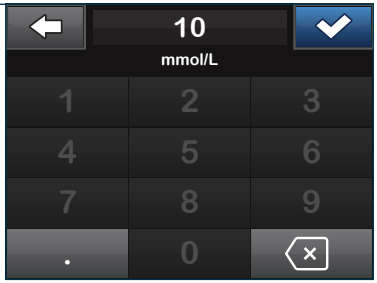


7. Tap **Alert Me Above**.

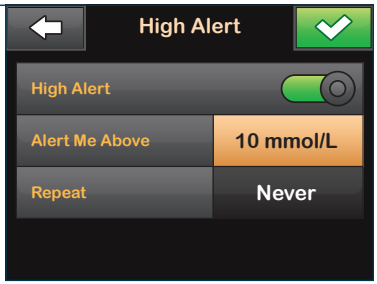
8. Using the on-screen keypad, enter the value above which the user wants to be notified.



9. Tap .

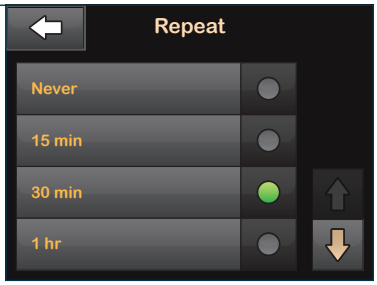


10. If the user wants the High Alert to repeat, tap **Repeat**.



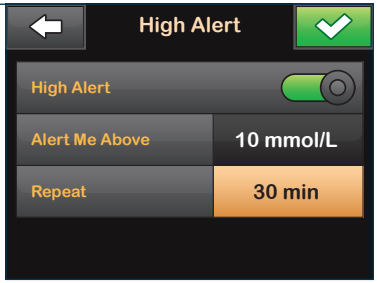
11. To select the repeat time, tap the time the user wants the Alert to sound again. Use the up and down arrows to view all Repeat options.

✓ Once a value is selected, the pump will return to the previous screen.



12. Tap .

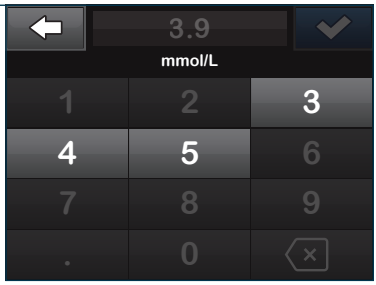
✓ The SETTING SAVED screen is displayed.



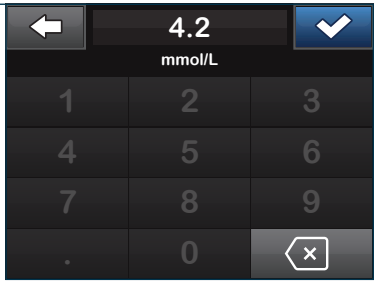
13. To set the Low Alert, tap **Low Alert**.

14. Tap **Alert Me Below**.

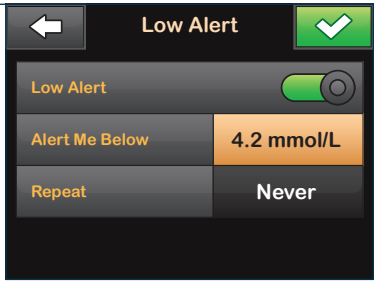
15. Using the on-screen keypad, enter the value below which the user wants to be notified.



16. Tap .

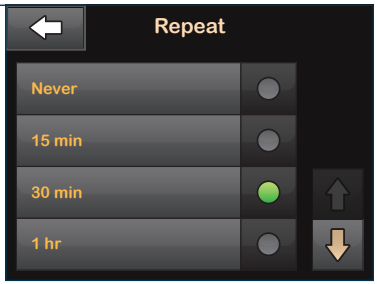


17. If the user wants the Low Alert to repeat, tap **Repeat**.



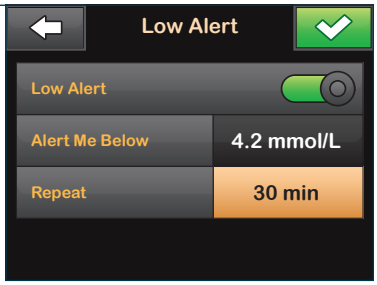
18. To select the repeat time, tap the time the user wants the Alert to sound again. Use the up and down arrows to view all Repeat options.

✓ Once a value is selected, the pump will return to the previous screen.

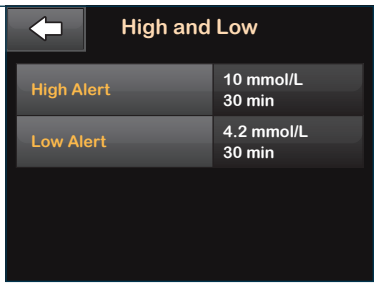


19. Tap .

✓ The SETTING SAVED screen is displayed.

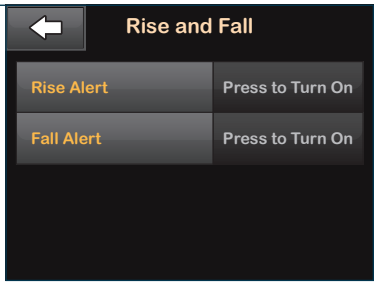


20. Tap to get to the CGM Alerts menu.

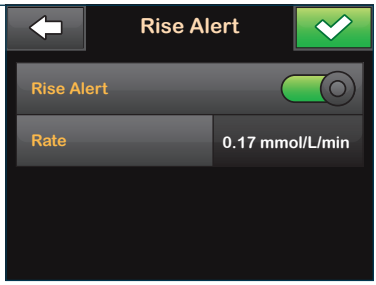


21. Tap **Rise and Fall**.

22. Tap **Rise Alert**.

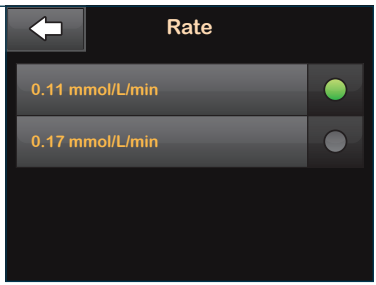


23. Tap **Rate**.



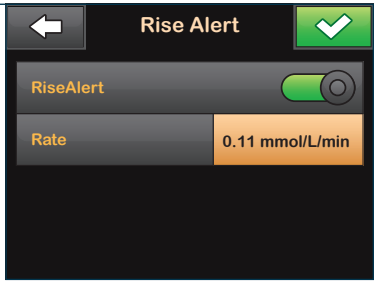
24. Select the rate of CGM rise the user wants to be notified of.

✓ Once a value is selected, the pump will return to the previous screen.

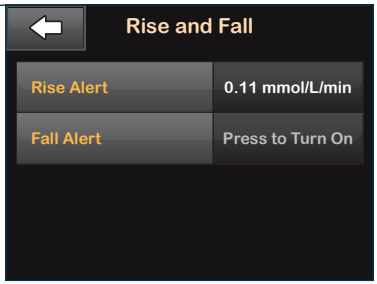


25. Tap .

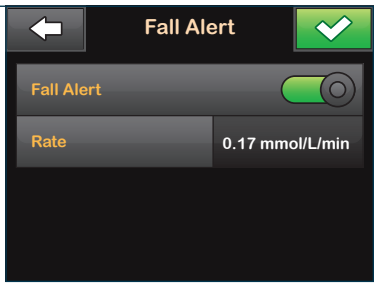
✓ The SETTING SAVED screen is displayed.



26. Tap **Fall Alert**.

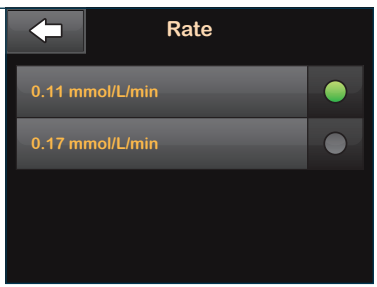


27. Tap **Rate**.



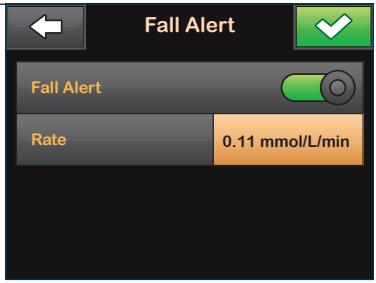
28. Select the rate of CGM fall the user wants to be notified of.

✓ Once a value is selected, the pump will return to the previous screen.



29. Tap ✓.

✓ The SETTING SAVED screen is displayed.



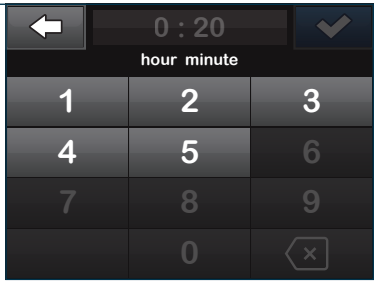
30. Tap ← to get to the CGM Alerts menu.

31. Tap **Out of Range**.

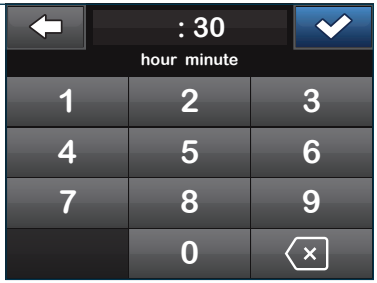
32. To change the time, tap **Alert Me After**.

⚠ Alert: The CGM is providing the data that Control-IQ technology needs to make predictions to suspend insulin delivery. The CGM Out of Range Alert defaults to on to notify the user within 20 minutes if their CGM is disconnected from their pump.

33. Using the on-screen keypad, enter the time after which the user wants to be Alerted.

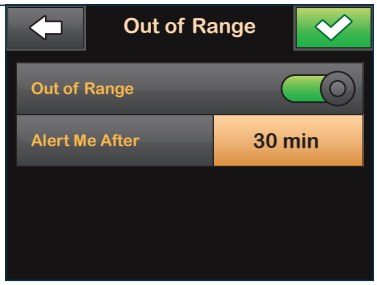


34. Tap .



35. Tap .

✓ The SETTING SAVED screen is displayed.



For full detailed instructions on items in this chapter, please refer to the Getting to Know Your CGM System, CGM Overview, CGM Settings, Setting CGM Alerts, and Start or Stop a CGM Sensor Session chapters in the Control-IQ technology user guide.

Notes

CHAPTER 3

Insulin Delivery Settings

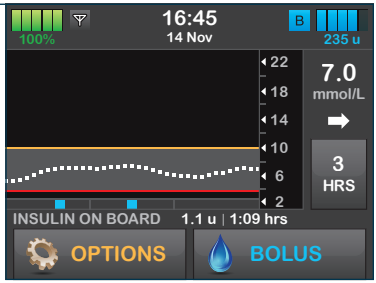
Basal Limit

The Basal Limit setting allows the user to set a limit to the basal rate that is set in the Personal Profiles, as well as the amount of insulin that will be delivered when using a Temp Rate.

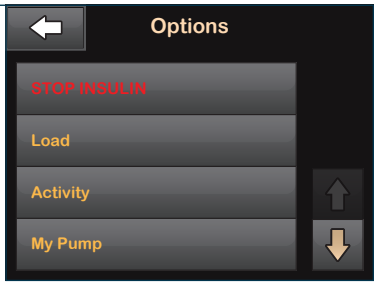
The user may be unable to set any basal rates or temp basal rates that exceed the Basal Limit. The user can set their Basal Limit from 0.2 to 15 units per hour. The user should work with their healthcare provider to set the proper Basal Limit.

⚑ **Note:** If the user is setting their Basal Limit after they have set any of their Personal Profiles, the user cannot set their Basal Limit lower than any of their existing basal rates.

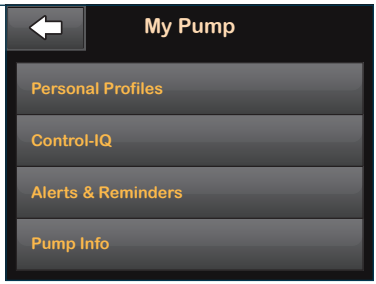
1. From the Home screen, tap OPTIONS.



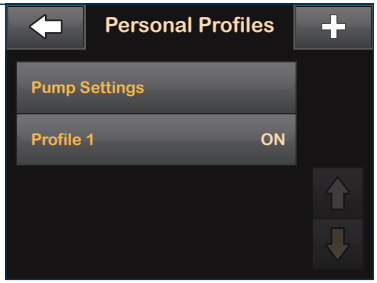
2. Tap My Pump.



3. Tap Personal Profiles.

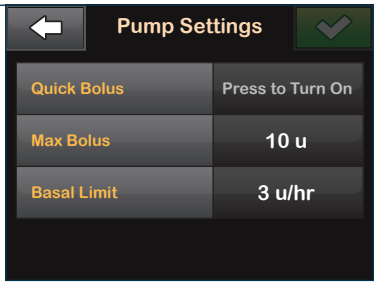


4. Tap **Pump Settings**.

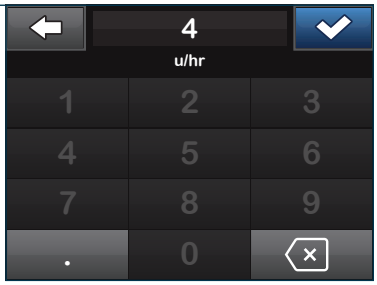


5. Tap **Basal Limit**.

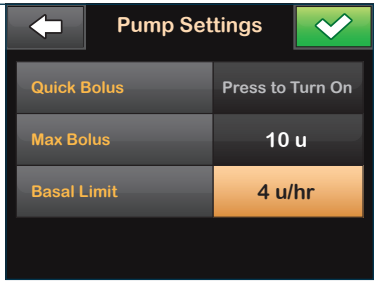
Note: The default Basal Limit is 3 units per hour. If the user is updating their pump from a version that did not previously have the Basal Limit setting, the Basal Limit will be set to a value two times the highest basal rate setting in their pump.



6. Using the on-screen keypad, enter a Basal Limit amount that is between 0.2 – 15 units. Tap .

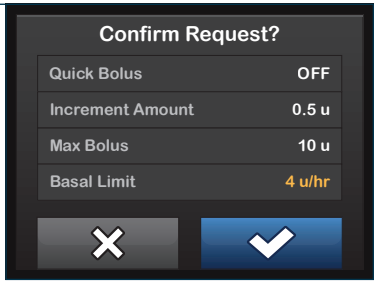


7. Review the Basal Limit value and tap .



8. Confirm settings.
   - Tap ✓ if entered data is correct.
   - Tap ✕ to make changes.

✓ The SETTING SAVED screen is displayed.



9. Tap the **Tandem logo** on the face of the pump to return to the Home screen.

For full detailed instructions on items in this chapter, please refer to the Getting Started chapter in the Control-IQ technology user guide.

Personal Profile Overview

A Personal Profile is a group of settings that define the basal and bolus delivery within specific time segments throughout a 24-hour period. Each profile can be personalized with a name. Within a Personal Profile, the following can be set:

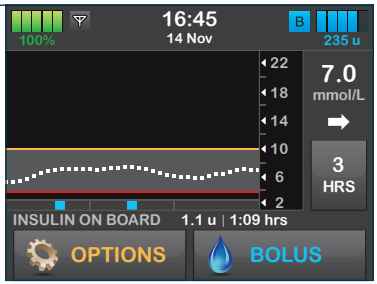
- Timed Settings: Basal Rate, Correction Factor, Carb Ratio, and Target BG.
- Bolus Settings: Insulin Duration and Carbohydrates setting (On/Off).

The first time segment starts at 00:00 (24 hour clock) or 12:00 AM (Midnight). Basal Rate, Correction Factor, Carb Ratio, and Target BG are set for each segment.

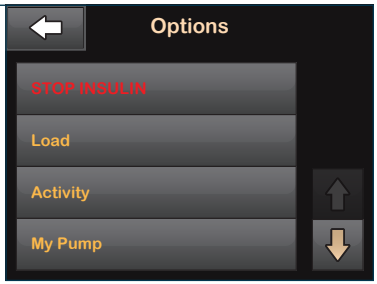
⚑ **Note:** Up to six different Personal Profiles can be created and up to 16 different time segments can be set in each Personal Profile.

Creating a New Profile

1. From the Home screen, tap **OPTIONS**.

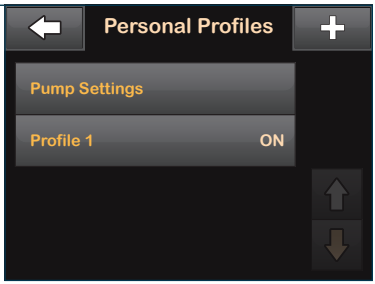


2. Tap **My Pump**.



3. Tap **Personal Profiles**.

4. Tap + to create a new profile.

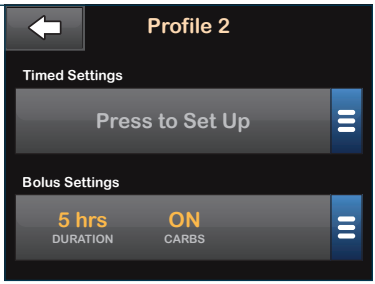


5. Using the on-screen keypad, enter a profile name (up to 16 characters) and tap ✓.

   ⚑ **Note:** Refer to the Getting Started section for instructions on using the on-screen keypad.

6. Tap **Press to Set Up** to begin setting insulin delivery settings.

   ⚑ **Note:** Once the Personal Profile has been created, the settings must be programmed.



Programming a New Profile

Note: Data entered will affect insulin delivery. Make sure all information is entered correctly.

1. Tap **Basal**.

   Note: The first time segment will start at 00:00 or 12:00 AM (Midnight).

2. Using the on-screen keypad, enter the desired basal rate and tap ✓.

   Note: The t:slim X2 insulin pump delivers insulin at basal rates as low as 0.1 unit/hour.

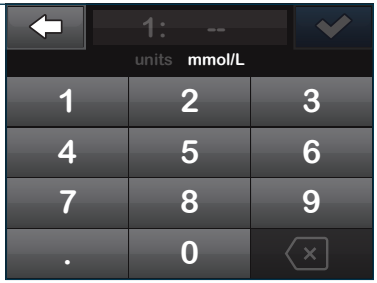
   Note: Always confirm that the decimal point placement is correct.

3. Tap **Correction Factor**.

   Note: The orange highlighted area indicates a recent change was made to a setting.

4. Using the on-screen keypad, enter the desired correction factor and tap ✓.

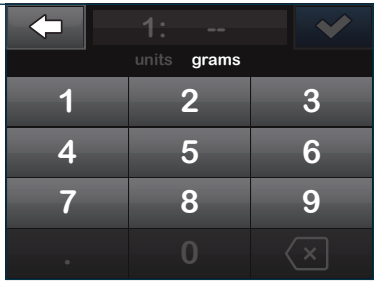
   Note: Enter the mmol/L that 1 unit of insulin will lower BG.



5. Tap **Carb Ratio**.

6. Using the on-screen keypad, enter the desired insulin-to-carbohydrate ratio and tap ✓.

   ⚑ **Note:** Enter the grams of carbohydrate to be covered by 1 unit of insulin.



7. Tap **Target BG**.

8. Using the on-screen keypad, enter the desired BG target and tap ✓.

9. Review entered values and tap ✓.

10. Confirm settings.

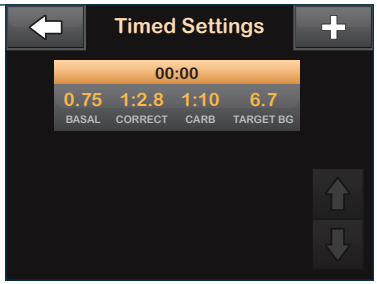
- Tap ✓ if entered data is correct.
- Tap ✗ to make changes.

11. Tap ← to set the Bolus settings.

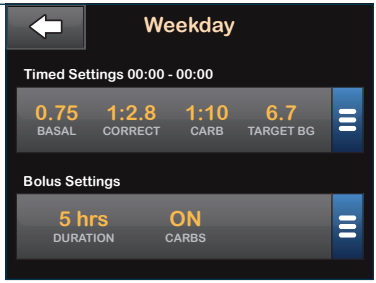
- OR -

Tap + to create additional time settings.

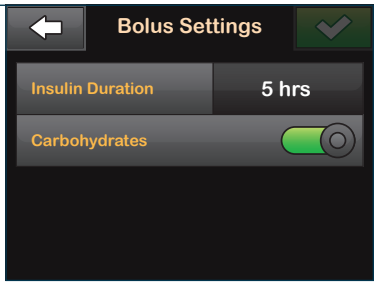
⚑ **Note:** Any settings defined in the previous time segment are copied and appear in the new time segment. Tap on each setting to edit as needed.



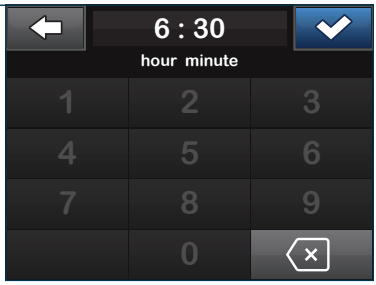
12. Tap the **Bolus Settings** panel.



13. Tap **Insulin Duration**.

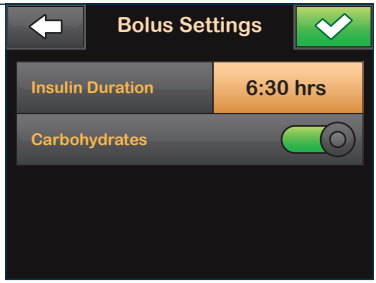


14. Using the on-screen keypad, enter the desired time for the duration of insulin action and tap ✓.

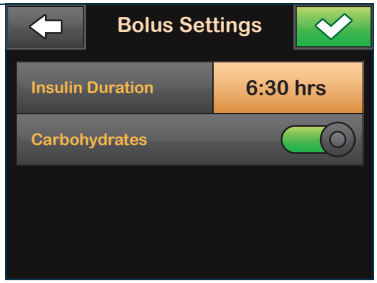


15. Tap **Carbohydrates** to activate and use the carb ratio when calculating boluses.

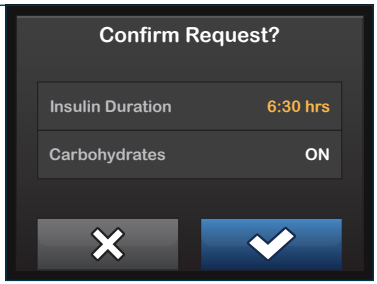
    ⚑ **Note:** The Carbs setting must be on in order to use Control-IQ technology.



16. Tap .



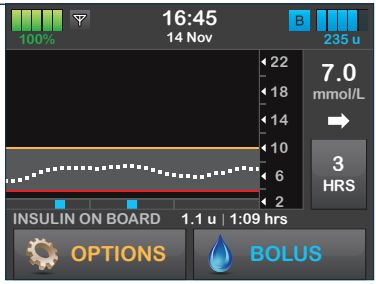
17. Confirm settings.
    - Tap if entered data is correct.
    - Tap to make changes.



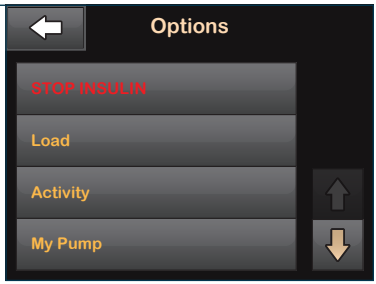
18. Tap the **Tandem logo** on the face of the pump to return to the Home screen.

Edit an Existing Profile

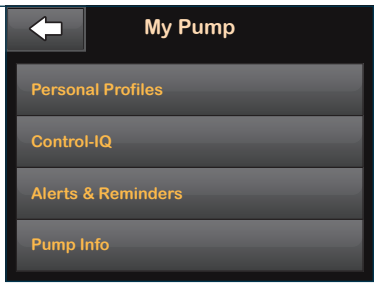
1. From the Home screen, tap **OPTIONS**.



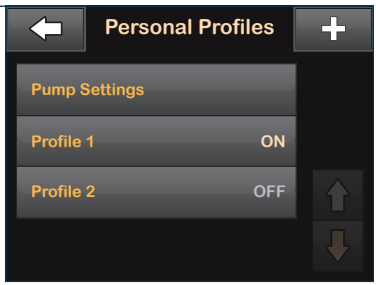
2. Tap **My Pump**.



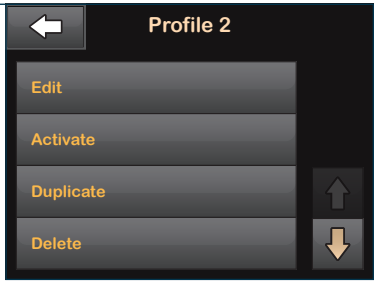
3. Tap **Personal Profiles**.



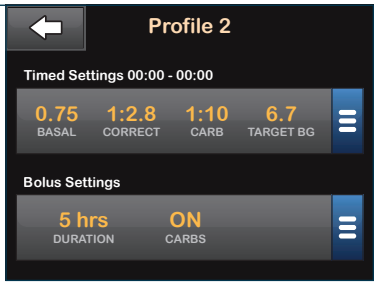
4. Tap the name of the Personal Profile to edit.



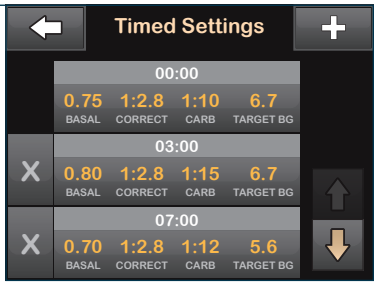
5. Tap **Edit**.



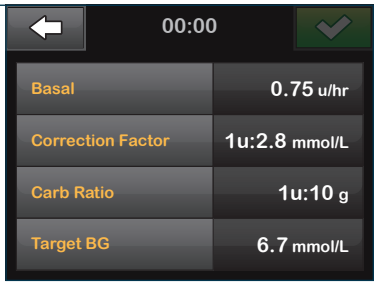
6. Tap **Timed Settings** panel.



7. Tap the desired time segment to be edited.



8. Tap **Basal**, **Correction Factor**, **Carb Ratio**, or **Target BG** to make changes as needed and use the on-screen keypad to enter desired changes. Tap ✓.



9. View recent changes and, if correct, tap ✓.

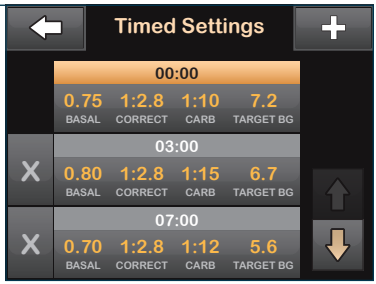
10. Confirm settings.

- Tap ✓ if entered data is correct.
- Tap ✕ to make changes.

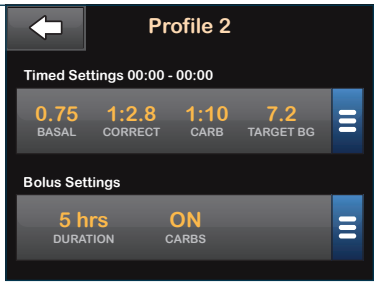
11. Tap ← after editing all of the time segments.

Note: Edit other time segments within the Timed Settings by tapping on them and using the same method described above.

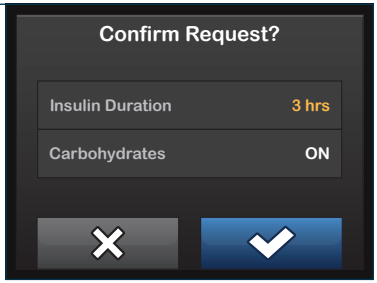
Note: To delete a time segment:
- Tap on the X to the left of the time segment
- Tap ✓ to confirm



12. Tap the **Bolus Settings** panel to change DURATION or CARBS as needed. Use the on-screen keypad to enter desired changes. Tap ✓.



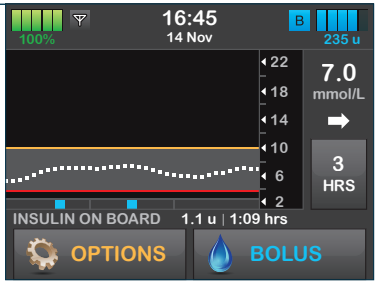
13. Confirm settings.
    - Tap ✓ if entered data is correct.
    - Tap ✕ to make changes.



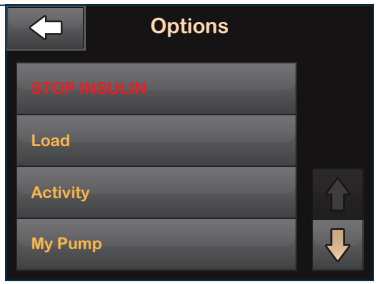
14. Tap the **Tandem logo** on the face of the pump to return to the Home screen.

Duplicate an Existing Profile

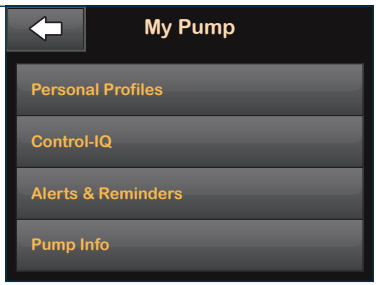
1. From the Home screen, tap **OPTIONS**.



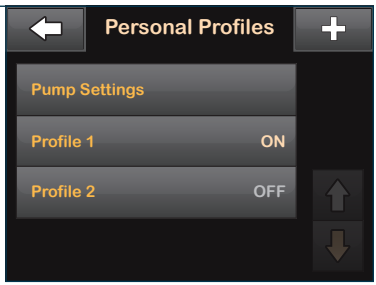
2. Tap **My Pump**.



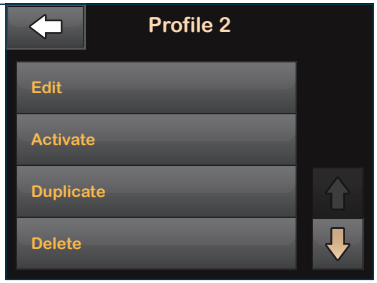
3. Tap **Personal Profiles**.



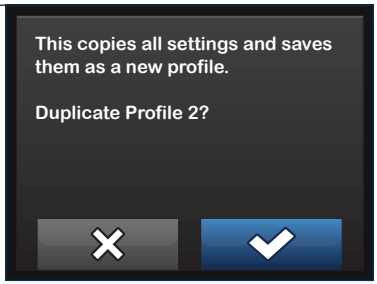
4. Tap the name of the Personal Profile to duplicate.



5. Tap **Duplicate**.



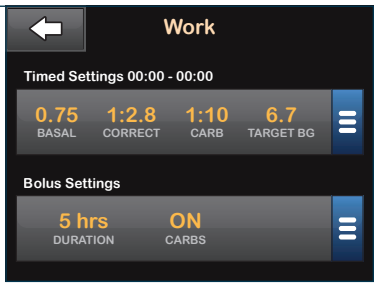
6. Confirm profile to duplicate by tapping .



7. Using the on-screen keypad, enter the name (up to 16 characters) for the new profile and tap .

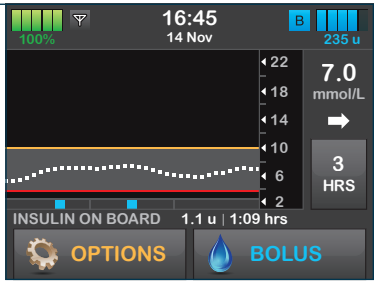
✓ The PROFILE DUPLICATED screen is displayed. A new Personal Profile will be created with the same settings as the profile copied.

8. Tap the **Timed Settings** or **Bolus Settings** panel to make changes to the new profile.

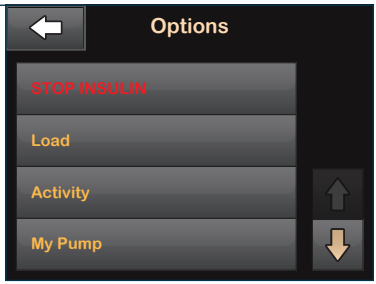


Activate, Delete, or Rename a Profile

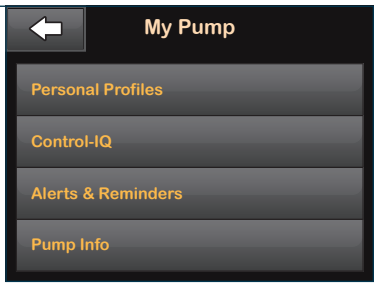
1. From the Home screen, tap OPTIONS.



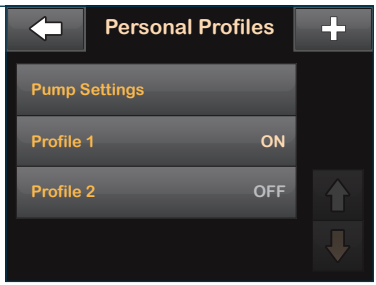
2. Tap My Pump.



3. Tap Personal Profiles.



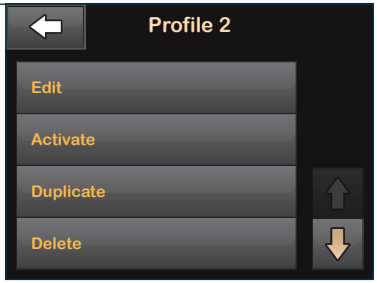
4. Tap the name of the Personal Profile.



To Activate Profile

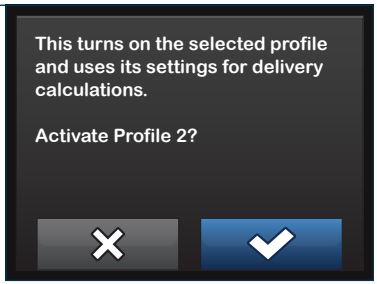
1. Tap **Activate**.

   Note: If the Activate option is disabled, then the profile is already activated. If the user has only one profile defined, they do not need to activate it (that profile is automatically activated).



2. Tap ✓.

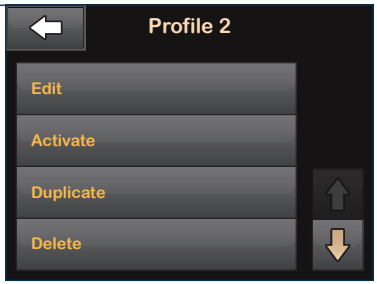
✓ The PROFILE ACTIVATED screen is displayed.



To Delete a Profile

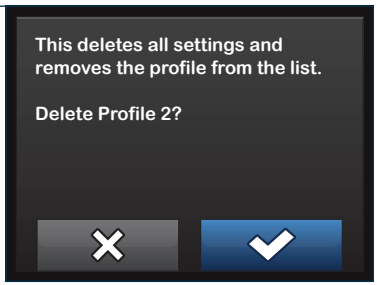
1. Tap **Delete**.

   Note: The Delete option is disabled for an active profile. The user cannot delete a profile until they have activated another profile.



2. Tap ✓.

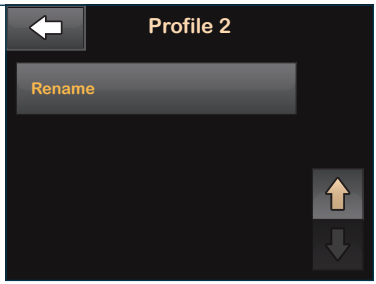
✓ The PROFILE DELETED screen is displayed.



To Rename a Profile

1. Tap **Down Arrow**.

2. Tap **Rename**.

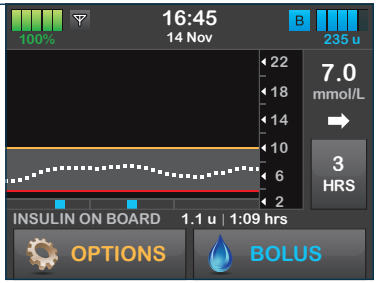


3. Using the on-screen keypad, rename the profile name (up to 16 characters) and tap .

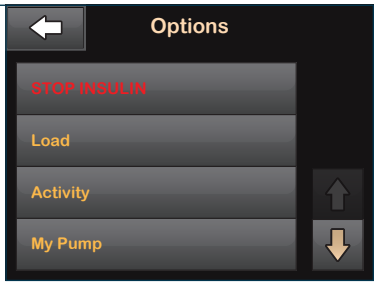
4. Tap the **Tandem logo** on the face of the pump to return to the Home screen.

Setting a Temp Rate

1. From the Home screen, tap **OPTIONS**.

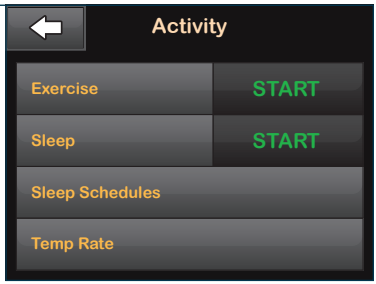


2. Tap **Activity**.

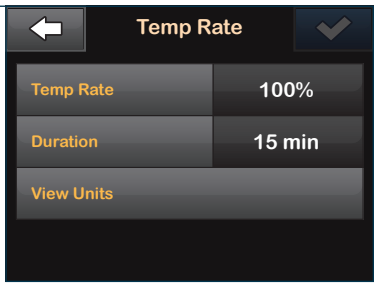


3. Tap **Temp Rate**.

   Note: Temp Rates are not available while Control-IQ technology is turned ON. To enable a temp rate turn Control-IQ technology OFF.

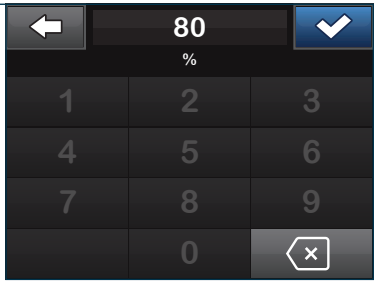


4. Tap **Temp Rate** again.

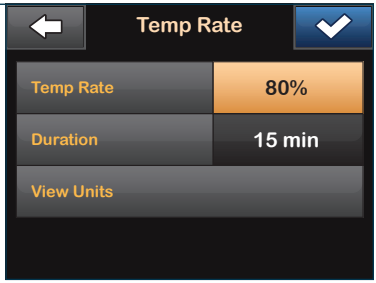


5. Using the on-screen keypad enter desired percentage. Tap ✓.

   Quick Tip: Current rate is 100%. An increase is greater than 100%, and a decrease is less than 100%.



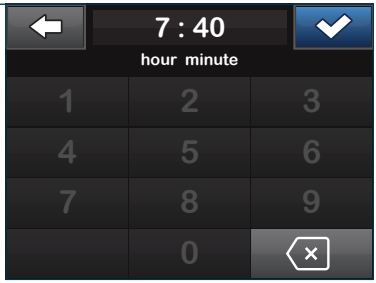
6. Tap **Duration**.



7. Using the on-screen keypad, enter desired length of time for Temp Rate. Tap ✓.

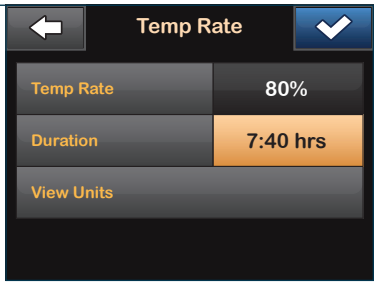
   Note: Duration can be set from a minimum of 15 minutes to a maximum of 72 hours.

   Note: Tap **View Units** to see the actual units to be delivered.

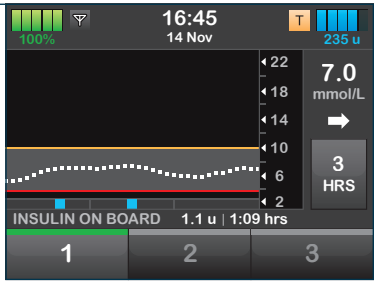


8. Verify settings and tap ✓.

✓ The TEMP RATE STARTED screen is displayed.



9. The Lock screen will be displayed with the icon indicating a Temp Rate is active.

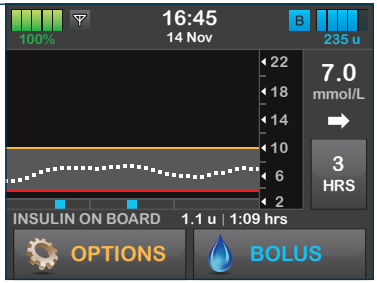


⚑ **Note:** If a Temp Rate is currently active, the status of insulin delivery displays T in an orange square. If a Temp Rate of 0% is currently active, the status of insulin delivery displays T in a red square.

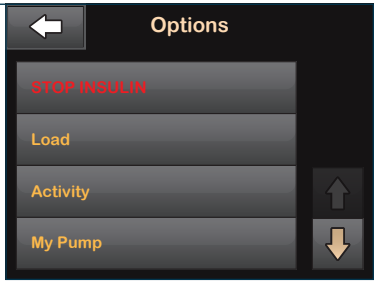
⚑ **Note:** To stop Temp Rate at any time, tap **OPTIONS**, tap **Activity** and then tap **X** to the right of Temp Rate. A confirmation message will be displayed. Tap ✔.

Stop Insulin Delivery

1. From the Home screen, tap **OPTIONS**.



2. Tap **STOP INSULIN**.

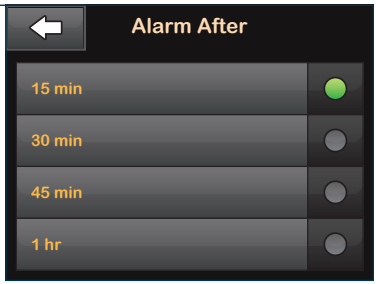


3. To change the Resume Pump Alarm setting, tap the panel in the middle of the screen. Otherwise, skip to step 5 to accept the default setting.

4. Select the time you would like the resume pump alarm to display.

✓ The pump returns to the confirmation screen.

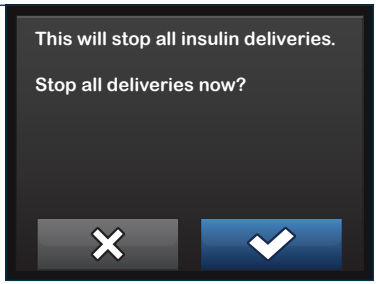
Quick Tip: The pump will save the new alarm time, unless the pump has been reset, in which case the default setting will be used.



5. Tap ✓.

✓ The All Deliveries Stopped screen is displayed before returning to the Home screen.

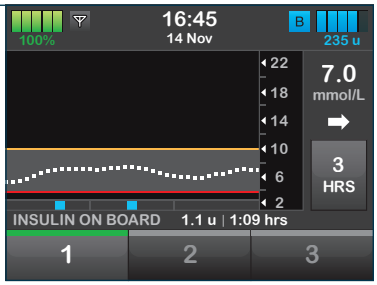
Note: If you manually stop insulin delivery, you must manually resume insulin delivery. Control-IQ technology does not automatically resume insulin if you decide to stop it manually.



Resume Insulin Delivery

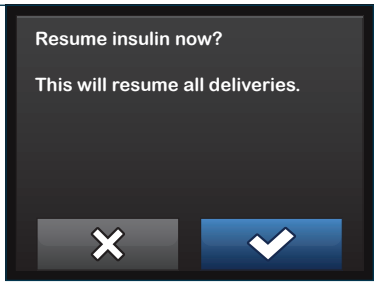
1. Press the **Screen On/Quick Bolus** button once.

2. Tap **1-2-3** to unlock the screen.



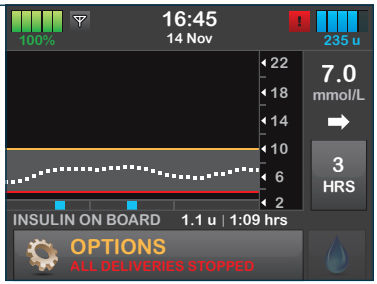
3. Tap ✓.

✓ The RESUMING INSULIN screen is displayed

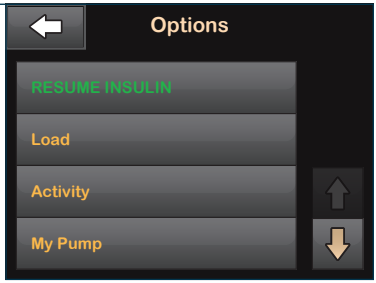


Or

1. From the Home screen, tap **OPTIONS**.

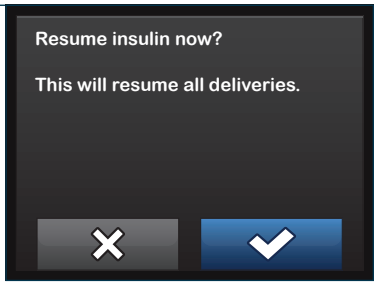


2. Tap **RESUME INSULIN**.



3. Tap .

✓ The RESUMING INSULIN screen is displayed



CHAPTER 4

Load

Fill and Load a Cartridge

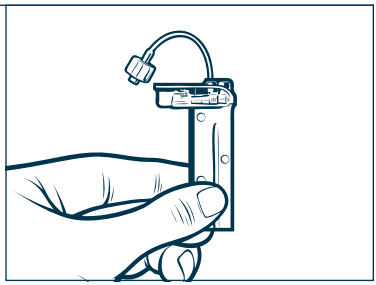
Note: Before beginning, make sure the user has the following items:
- One unopened, disposable, sterile, single-use cartridge
- One vial of room temperature, rapid-acting insulin
- 3.0 mL syringe and fill needle, filled with the desired amount of insulin
- Alcohol prep swab
- One new infusion set

Quick Tip: Avoid changing an infusion set before going to bed or the user will not be able to test their BG one to two hours after a new set is placed.

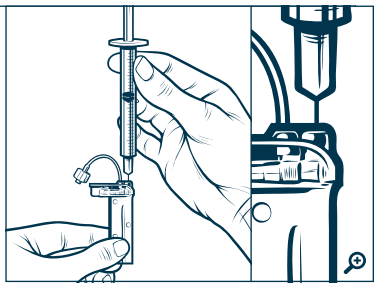
Note: Once in use, do not disconnect the connection between the cartridge tubing and the infusion set tubing. If the connection comes loose, disconnect the infusion set from the site on the body before tightening to avoid unintentional insulin delivery.

Fill the Cartridge

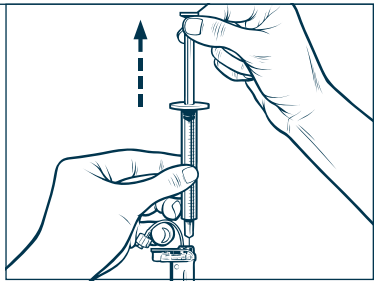
1. Remove a new cartridge from the pouch.



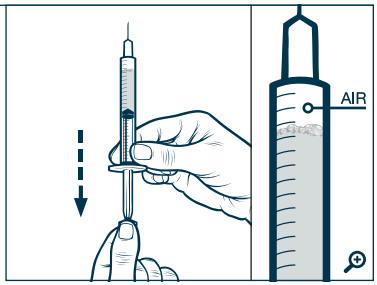
2. After filling the syringe with insulin, hold the cartridge upright and insert the needle of the filled syringe into the white fill port on top of the cartridge.



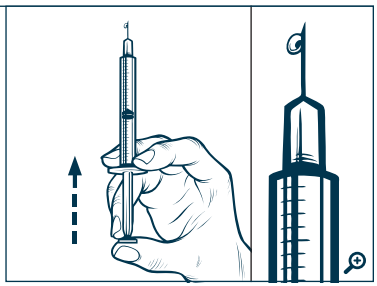
3. Keeping the syringe and cartridge vertical and the needle inside the fill port, pull back on the plunger to remove air.



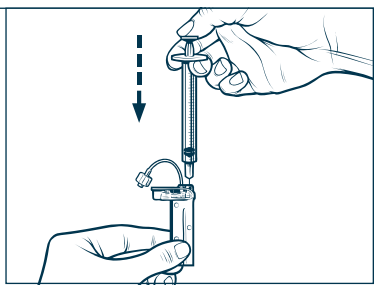
4. Turn the syringe upright and pull down on the plunger. Flick the barrel to make sure that any air bubbles rise to the top.



5. Remove the syringe from the cartridge and remove air by pressing on the plunger until the user sees a drop of insulin at the tip of the needle.

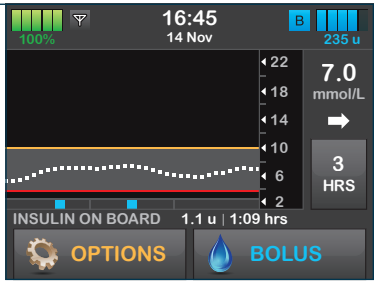


6. Reinsert the needle into the fill port on the cartridge, and slowly press the plunger to fill the cartridge with insulin. When the cartridge is filled, maintain pressure on the plunger while removing the needle.

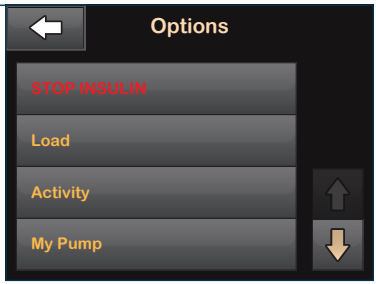


Load the Cartridge

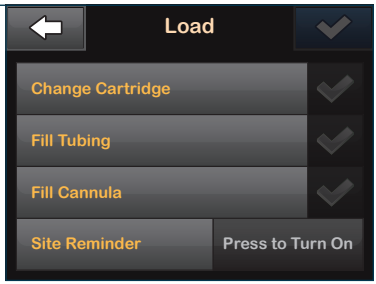
1. From the Home screen, tap **OPTIONS**.



2. Tap **Load**.

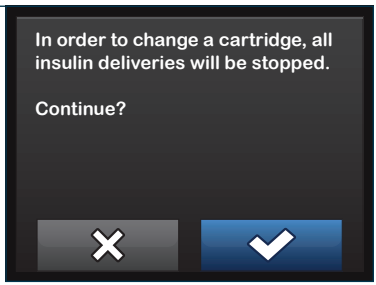


3. Tap **Change Cartridge**.



4. A screen will display that all insulin deliveries will be stopped. Tap ✓.

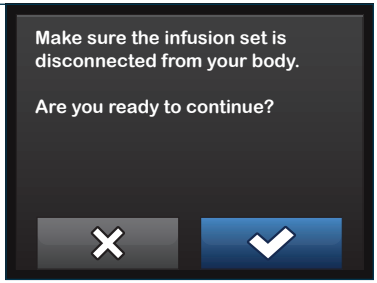
✓ The All Deliveries Stopped screen is displayed.



⚑ **Note:** This screen will not be displayed if this is the first time loading a new cartridge and you have not started actively pumping.

5. Disconnect the infusion set from the body and tap ✓ to continue.

✓ The PREPARING FOR CARTRIDGE screen is displayed.

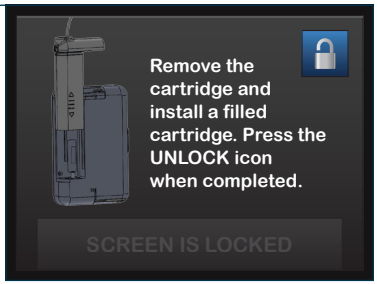


6. Remove the used cartridge and install the filled cartridge. Tap the UNLOCK icon when completed.

Quick Tip: If needed, place the cartridge removal tool or the edge of a coin in the slot at the bottom of the cartridge and twist to aid in cartridge removal.

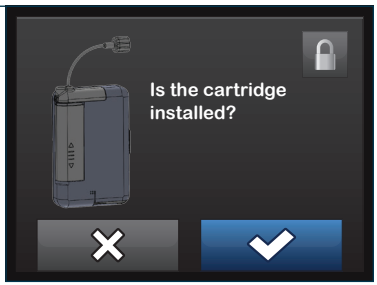
Note: To install a filled cartridge, place the bottom of the cartridge at the end of the pump, make sure it is lined up on the guide tracks, and push on the circular fill port to slide the cartridge until the user feels it click into place.

Note: Always dispose of used components such as cartridges, syringes, needles, infusion sets, and CGM sensors following healthcare provider's instructions. Wash hands thoroughly before and after handling System components.

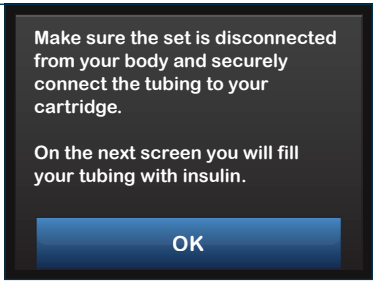


7. Tap ✓.

✓ The DETECTING CARTRIDGE screen is displayed, followed by the CARTRIDGE CHANGED screen.



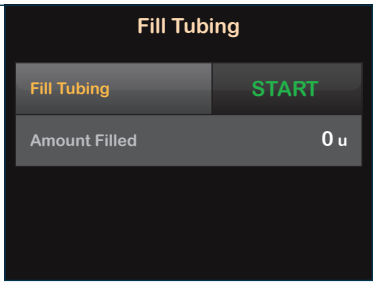
8. Tap **OK**.



9. Tap **START**.

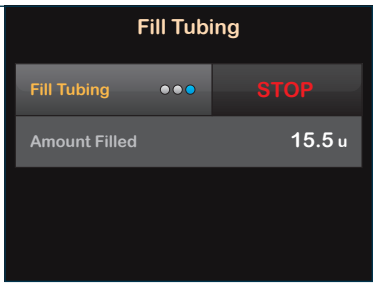
✓ The STARTING FILL screen is displayed.

⚑ **Note:** The minimum amount of insulin required to fill tubing after a cartridge change is 10 units.

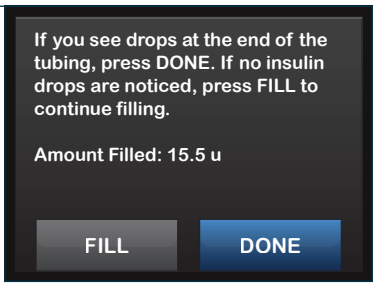


10. Tap **STOP** once three drops of insulin are seen at the end of the tubing.

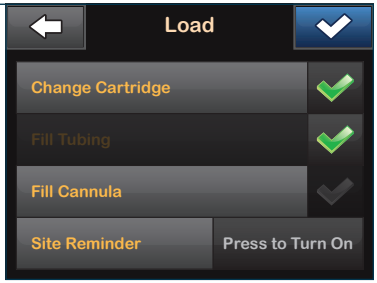
✓ The STOPPING FILL screen is displayed, followed by the DETECTING INSULIN screen.



11. Verify that drops are seen and tap **DONE**.

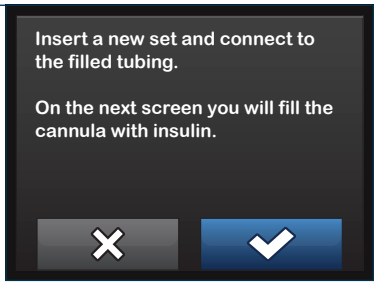


12. Fill Tubing is complete. Ensure that there are no leaks from the tubing connections. Tap **Fill Cannula**.

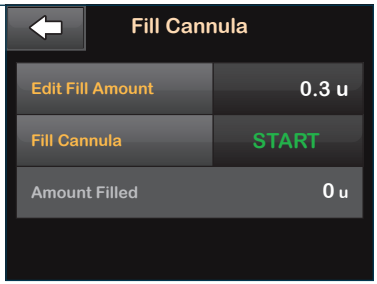


13. Insert a new infusion set and connect filled tubing to site, then tap ✓.

Note: Refer to the infusion set instructions for proper insertion.



14. Tap **Edit Fill Amount** if the user wants to change it. Otherwise, tap **START** and skip the next two steps.

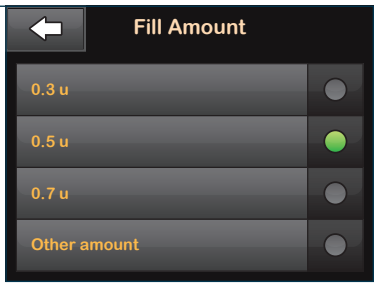


15. Select amount needed for cannula fill.

✓ Once a value is selected, the pump will return to the previous screen.

Note: Refer to the infusion set instructions for proper cannula fill amount.

Note: If the amount needed is not listed, tap **Other amount** and use the on-screen keypad to enter a value between 0.1 to 1.0 units.

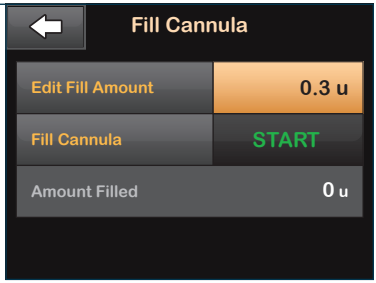


16. Tap START.

✓ The STARTING FILL screen is displayed.

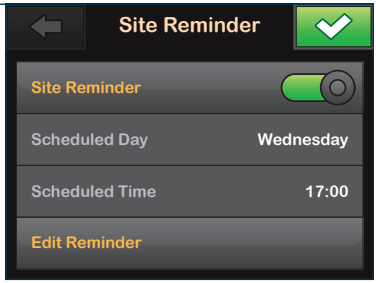
✓ After fill is complete, the STOPPING FILL screen is displayed.

Quick Tip: Avoid changing an infusion set before going to bed or the user will not be able to test their BG one to two hours after a new set is placed.

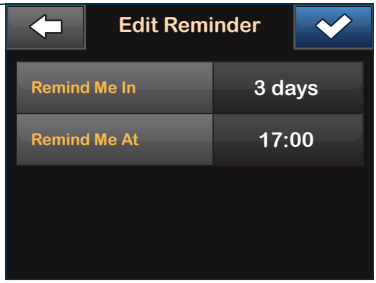


17. Review settings and tap Edit Reminder if settings need to be changed. Otherwise, tap ✓ if correct and skip the next six steps.

Note: Reminder is set to three days by default.



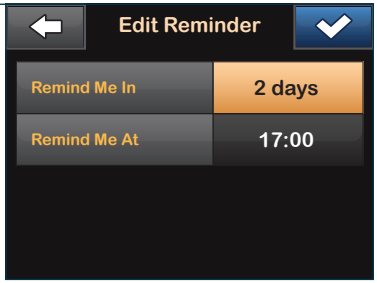
18. Tap Remind Me In.



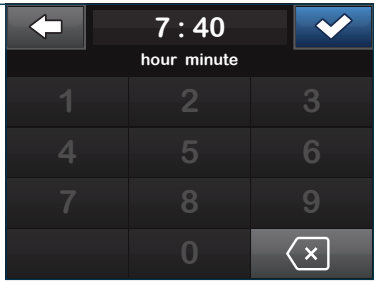
19. Select the number of days.

✓ Once a value is selected, the pump will return to the previous screen.

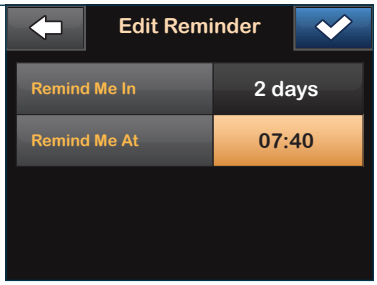
20. Tap **Remind Me At.**



21. Use the on-screen keypad to enter time and tap .

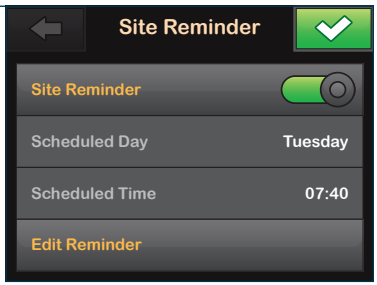


22. Tap .



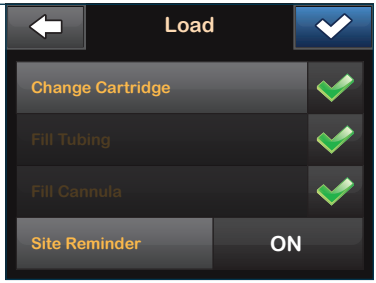
23. Verify Site Reminder is set correctly and tap .

✓ The SETTING SAVED screen is displayed.



24. Tap ✓.

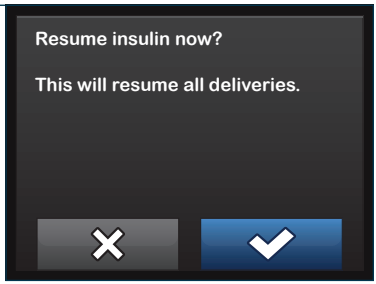
✓ A reminder to test BG in one to two hours is displayed.



25. Tap ✓.

✓ The RESUMING INSULIN screen is displayed.

⚑ **Note:** If this is the first time using the t:slim X2 insulin pump with Control-IQ technology and a Personal Profile has not been defined, a screen will notify the user that a profile must be activated to resume insulin. Tap **CLOSE**.



For full detailed instructions on items in this chapter, please refer to the Infusion Site Care and Loading Cartridge chapter in the Control-IQ technology user guide.

CHAPTER 5

Bolus

Bolus Overview

A bolus is a quick dose of insulin that is usually delivered to cover food eaten or an elevated BG.

After entering grams of carb or units of insulin needed for food, and/or entering a BG value, tap **View Calculation** to see how the delivery amount was calculated.

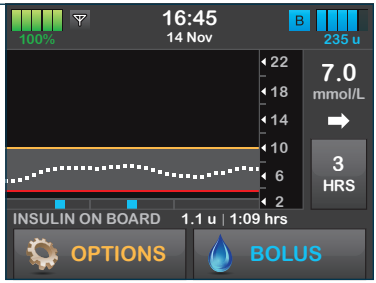
⚑ **Note:** The t:slim X2 pump with Control-IQ technology will deliver boluses between 0.05 and 25 units.

⚑ **Note:** An Incomplete Bolus Alert will be displayed if bolus programming is not completed within 90 seconds.

⚑ **Note:** Turn off the pump screen by tapping the **Screen On/Quick Bolus** button. Position the screen away from the skin before placing the pump back in its case or in any pocket/clothing to prevent unintentional interactions with the touchscreen.

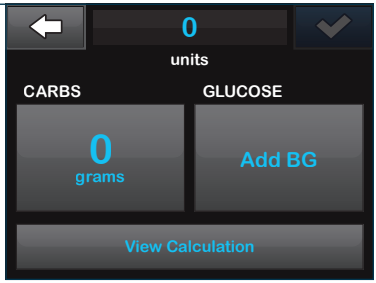
Food Bolus Using Grams

1. From the Home screen, tap **BOLUS**.

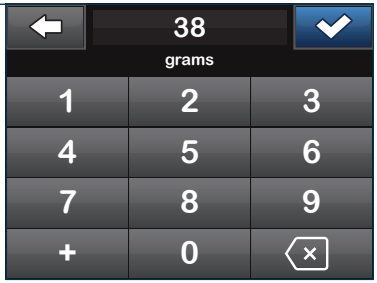


2. Tap **0 grams** on the left side of the screen.

   ⚑ **Note:** If this area reads "units," the carb feature is turned off in the active profile.

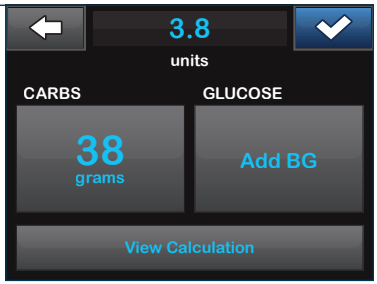


3. Using the on-screen keypad, enter grams of carbohydrate and tap ✓.



Note:
- To add multiple carb values, enter the first value, tap plus and then enter the second value. Continue until done and tap equal.
- To clear the value entered and start over, tap ⌫.

4. Tap ✓ to confirm the units of insulin to be delivered.



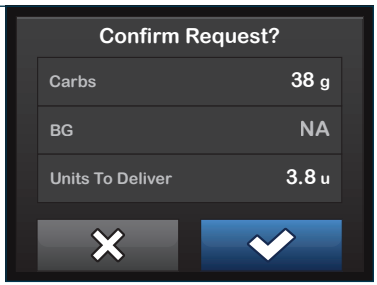
Note: Tap the displayed units calculated to override the amount.

Note: When administering a Food Bolus, it is recommended that the user enter a BG value whenever possible.

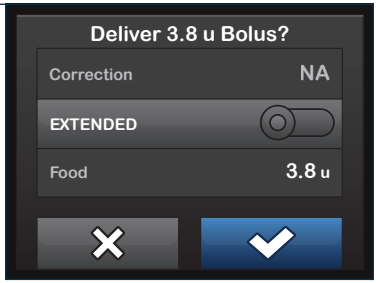
Note: If certain advanced features are being used, the current Dexcom G6 CGM reading may auto-populate to the bolus calculator. Please see the user guide for more information.

5. Confirm settings.

- Tap ✓ if entered data is correct.
- Tap ✕ to make changes.



6. Tap ✓.



✓ The BOLUS INITIATED screen is temporarily displayed.

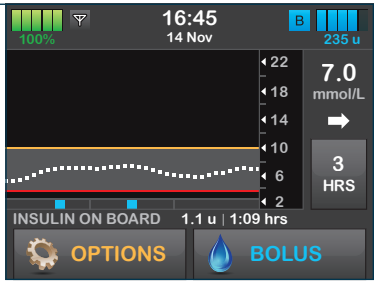
✓ After the bolus delivery is complete, an icon displays below the CGM graph (reference page 96).

⚑ **Note:** If the Control-IQ feature suspends insulin delivery during a Food Bolus, the remainder of the bolus WILL be delivered before all insulin delivery is stopped.

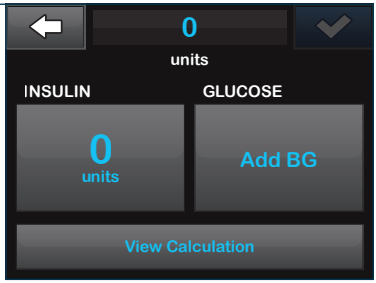
Food Bolus Using Units

⚑ **Note:** If bolusing using a carb ratio, refer to the previous section Food Bolus Using Grams. Always confirm that the decimal point placement is correct.

1. From the Home screen, tap **BOLUS**.

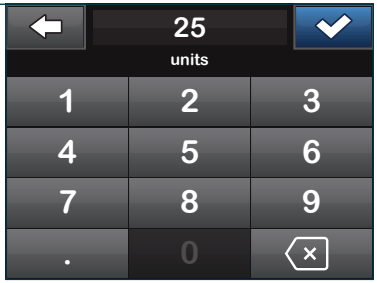


2. Tap **0 units** on the left side of the screen.



3. Using the on-screen keypad enter desired units of insulin. Tap ✓.

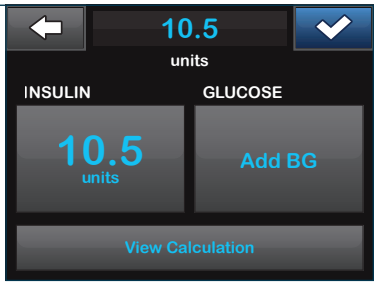
   ⚠ **Alert:** Always confirm that the decimal point placement is correct.



4. Tap ✓ to confirm the units of insulin to be delivered.

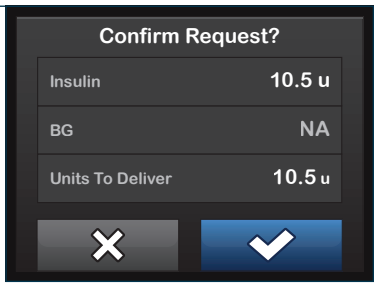
   ⚑ **Note:** When administering a Food Bolus, it is recommended that the user enter a BG value whenever possible.

   ⚑ **Note:** If certain advanced features are being used, the current Dexcom G6 CGM reading may auto-populate to the bolus calculator. Please see the user guide for more information.



5. Confirm settings.

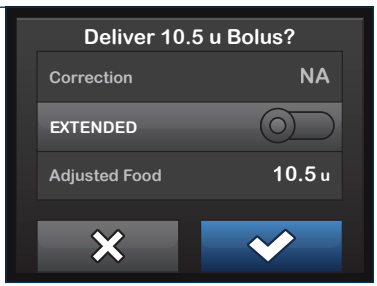
   - Tap ✓ if entered data is correct.
   - Tap ✕ to make changes.



6. Tap ✓.

✓ The BOLUS INITIATED screen is is temporarily displayed.

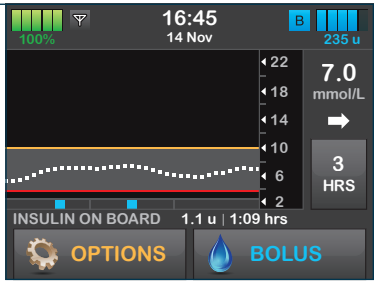
✓ After the bolus delivery is complete, an icon displays below the CGM graph.



⚑ **Note:** If the Control-IQ feature suspends insulin delivery during a Food Bolus, the remainder of the bolus WILL be delivered before all insulin delivery is stopped.

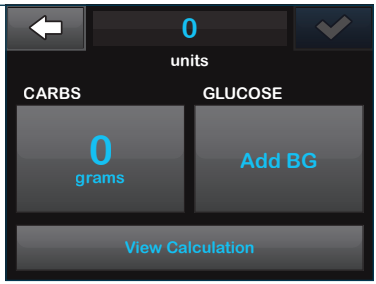
Correction Bolus

1. From the Home screen, tap **BOLUS**.



2. Tap **Add BG**.

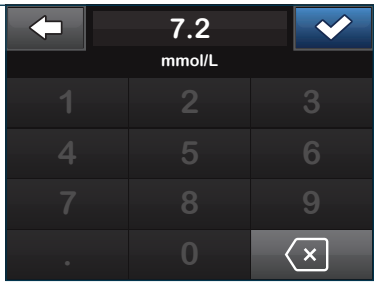
   Note: If certain advanced features are being used, the current Dexcom G6 CGM reading may auto-populate to the bolus calculator. Please see the user guide for more information.



3. Using the on-screen keypad, enter BG value and tap ✓. Alternatively, the user can enter the current CGM value, then tap ✓.

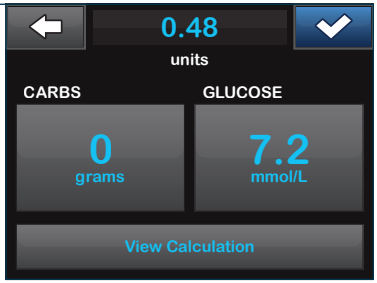
   Note: Once the checkmark is tapped, the BG value is saved in the pump history whether or not a bolus is delivered.

   Note:
   - If BG is above Target BG, the pump offers to calculate and add a correction bolus.
   - If BG is below Target BG, a message screen advises to reduce bolus calculation.
   - If BG is at Target BG, it will return to the Bolus screen with no recommended bolus amount for correction.



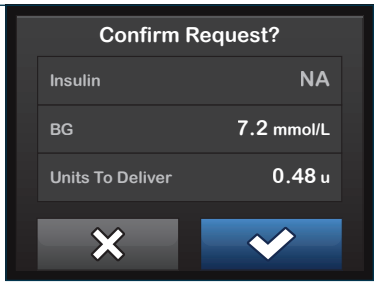
4. Tap ✓ to confirm the units of insulin to be delivered.

   ⚑ **Note:** Tap the displayed units calculated to override the amount.



5. Confirm settings.

   - Tap ✓ if entered data is correct.
   - Tap ✕ to make changes.

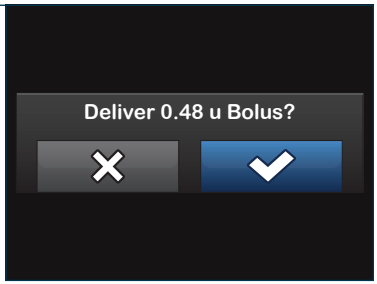


6. Tap ✓.

✓ The BOLUS INITIATED screen is is temporarily displayed.

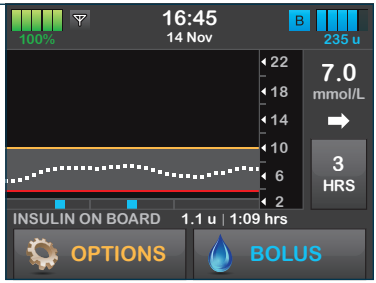
✓ After the bolus delivery is complete, an icon displays below the CGM graph.

⚑ **Note:** If the Control-IQ feature suspends insulin delivery during a bolus, the remainder of the bolus WILL be delivered before all insulin delivery is stopped.

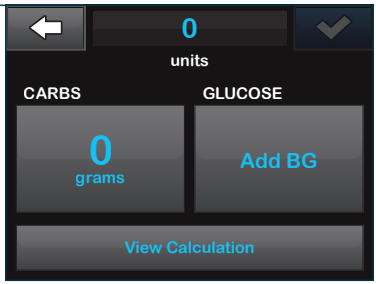


Extended Bolus

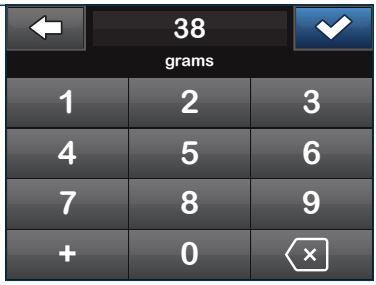
1. From the Home screen, tap **BOLUS**.



2. Tap **0 grams** (or **0 units**) on the left side of the screen.

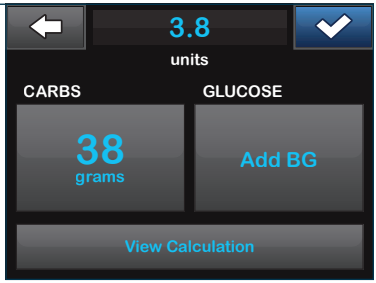


3. Using the on-screen keypad enter grams of carbohydrate (or units of insulin). Tap ✓.

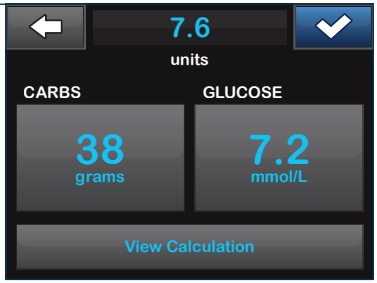


4. If desired, tap **Add BG** and using the on-screen keypad enter BG value. Tap ✓.

   ⚑ **Note:** If certain advanced features are being used, the current Dexcom G6 CGM reading may auto-populate to the bolus calculator. Please see the user guide for more information.

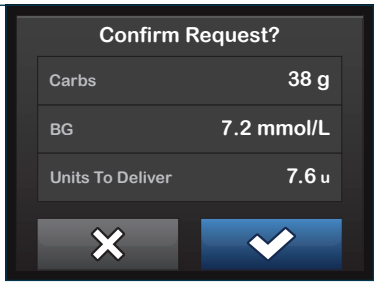


5. Tap ✓ to confirm the units of insulin to be delivered.

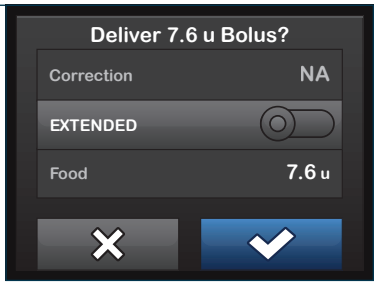


6. Confirm settings.

   - Tap ✓ if entered data is correct.
   - Tap ✕ to make changes.



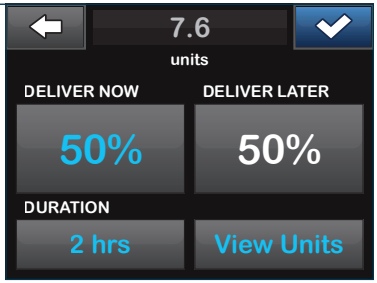
7. Tap **EXTENDED** to turn on the extended bolus, then tap ✓.



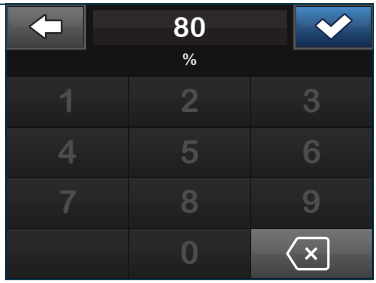
8. Tap **50%** under DELIVER NOW to adjust the percentage of the Food Bolus that is to be delivered immediately.

   Note: The percentage value for DELIVER LATER is automatically calculated by the pump. The default is 50% NOW and 50% LATER. The default for DURATION is two hours.

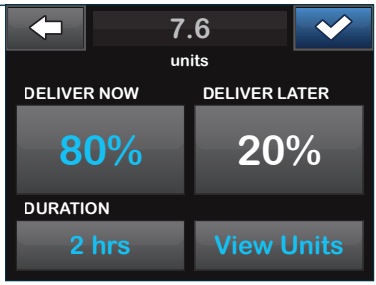
   Note: A Correction Bolus will always be given in the DELIVER NOW portion.



9. Use the on-screen keypad to enter the percentage of the bolus to DELIVER NOW and tap ✓.

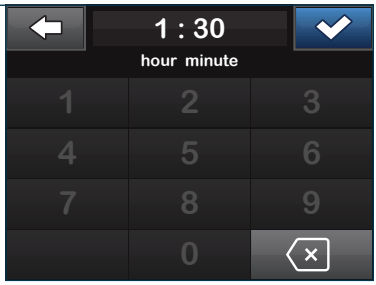


10. Tap **2 hrs** under DURATION.



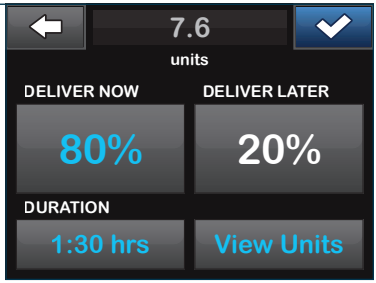
11. Use the on-screen keypad to adjust the length of time the bolus is to be delivered, then tap ✓.

    ⚑ **Note:** If Control-IQ technology is turned on, extended boluses are limited to 2 hours. Please see the user guide for more information.



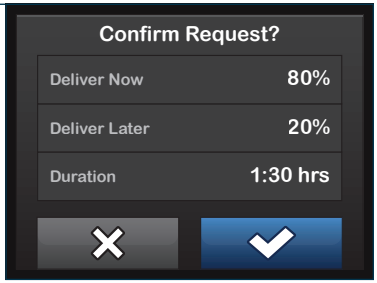
12. Tap ✓.

    ⚑ **Note:** Tap **View Units** to display the breakdown of units to be delivered now versus later.



13. Confirm settings.

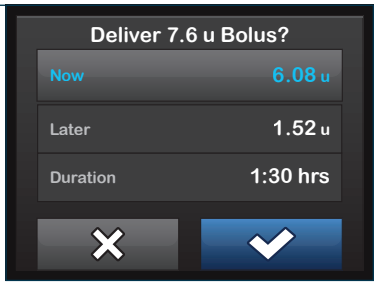
    - Tap ✓ if entered data is correct.
    - Tap ✕ to make changes.



14. Verify settings and tap ✓.

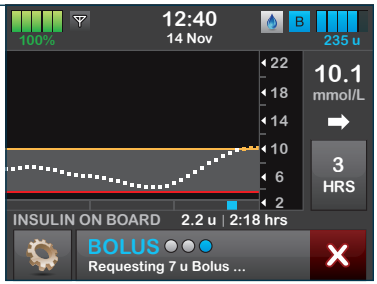
✓ The BOLUS INITIATED screen is is temporarily displayed.

✓ After the bolus delivery is complete, an icon displays below the CGM graph.



15. After the bolus delivery is complete, an icon displays below the CGM graph.

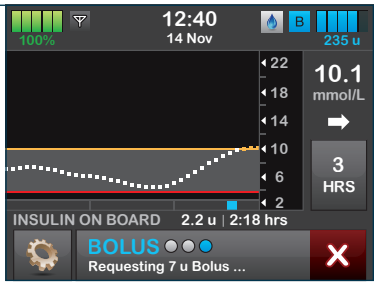
    Note: If the Control-IQ feature suspends insulin delivery during a Food Bolus, the remainder of the bolus WILL be delivered before all insulin delivery is stopped.



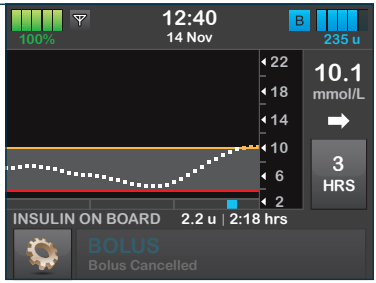
Cancel or Stop a Bolus

If Delivery HAS NOT Started

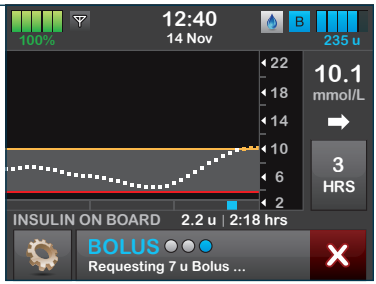
1. Tap the ✕ to cancel the bolus.



2. The BOLUS option will remain inactive while a bolus is being canceled.

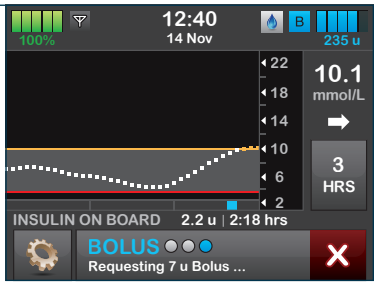


3. Once cancellation is complete, the BOLUS option will become active again on the Home screen.

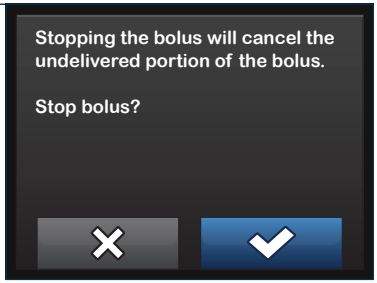


If Delivery HAS Started

1. Tap the ✕ to stop delivery.



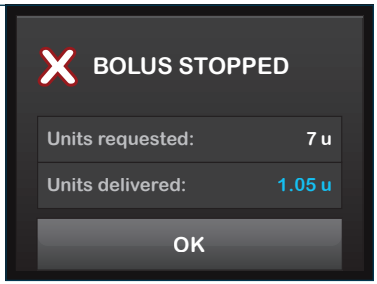
2. Tap ✓.



3. Units requested and delivered are shown. Tap OK.

✓ The CGM graph displays the amount of bolus insulin actually delivered for the bolus event. A bolus icon displays below the CGM graph.

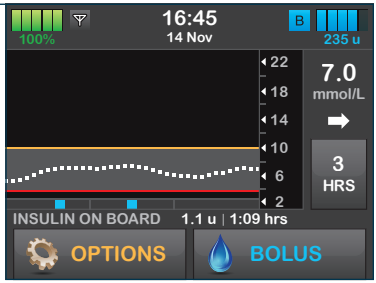
⚑ **Note:** When the Control-IQ feature needs to suspend insulin during a bolus delivery, the bolus will be completed then the insulin will be completed.



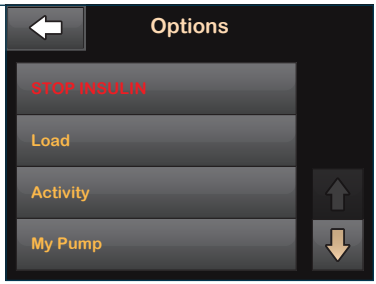
For full detailed instructions on items in this chapter, please refer to the Manual Bolus chapter in the Control-IQ technology user guide.

Quick Bolus Setup

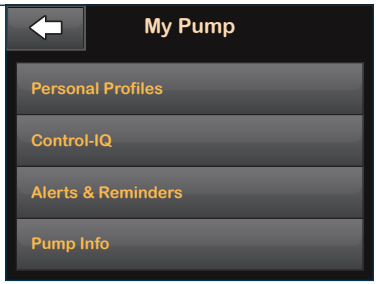
1. From the Home screen, tap OPTIONS.



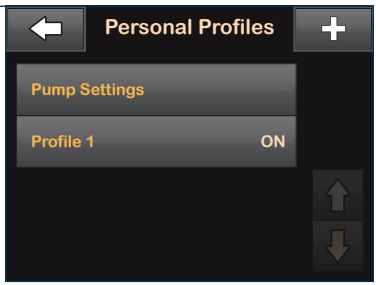
2. Tap My Pump.



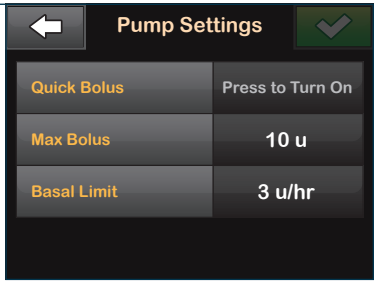
3. Tap Personal Profiles.



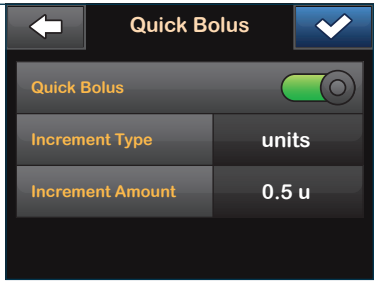
4. Tap Pump Settings.



5. Tap **Quick Bolus** to turn on.

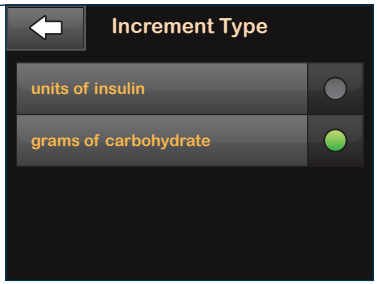


6. Tap **Increment Type**.

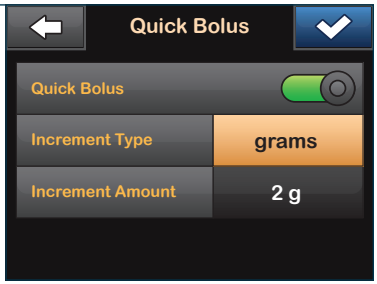


7. Tap **units of insulin** or **grams of carbohydrate**.

✓ Once a value is selected, the pump will return to the previous screen.



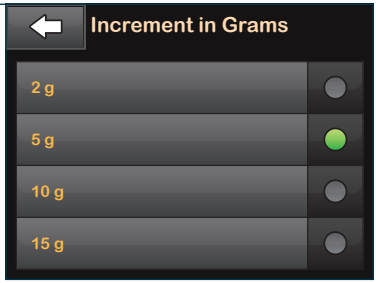
8. Tap **Increment Amount**.



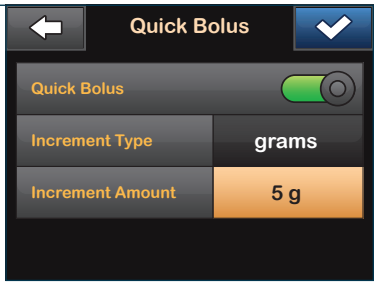
9. Select the preferred increment amount.

✓ Once a value is selected, the pump will return to the previous screen.

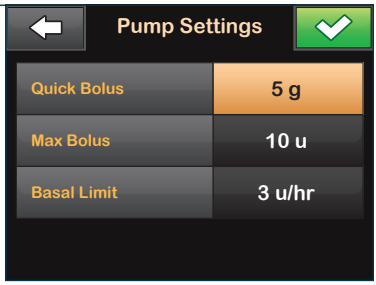
⚑ **Note:** The increment amount is added with each press of the Quick Bolus button when delivering a Quick Bolus.



10. Verify settings and tap ✓.



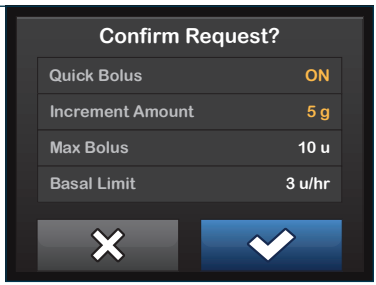
11. Review settings and tap **Max Bolus** and/or **Basal Limit** if settings need to also be changed. Otherwise, tap ✓.



12. Confirm settings.

- Tap ✓ if entered data is correct.
- Tap ✕ to make changes.

✓ The SETTING SAVED screen is displayed.



13. Tap the **Tandem logo** on the face of the pump to return to the Home screen.

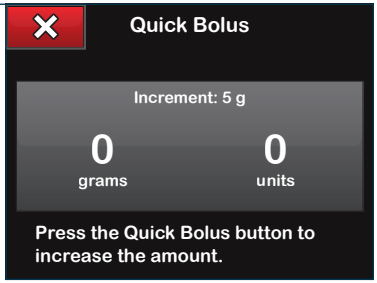
Quick Bolus

⚠ Precaution: When the Quick Bolus feature is first used, the user should always look at the screen to confirm correct programming until they are comfortable with this feature.

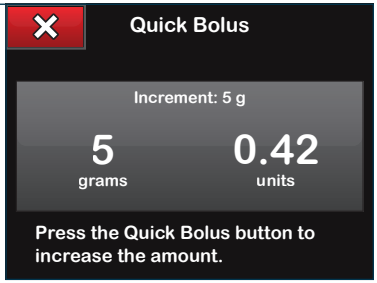
1. Press and hold **Quick Bolus** button for about two seconds. The Quick Bolus screen will appear. Listen for two beeps (if Sound Volume is set to beep) and feel for two vibrations.

2. Press **Quick Bolus** button for each increment until desired amount is reached. The pump will beep/vibrate for each button press.

   ⚑ **Note:** If the user wants to cancel the bolus and return to the Home screen, tap **X** on the screen.



3. Wait a few seconds for the pump to beep/vibrate back for each increment pressed to confirm desired amount.



4. After the beeps/vibrations, press and hold **Quick Bolus** button for about two seconds to deliver the bolus.

✓ The BOLUS INITIATED screen is is temporarily displayed.

✓ After the bolus delivery is complete, an icon displays below the CGM graph.

⚑ **Note:** If more than 10 seconds have passed with no input, the Quick Bolus will be canceled and never delivered.

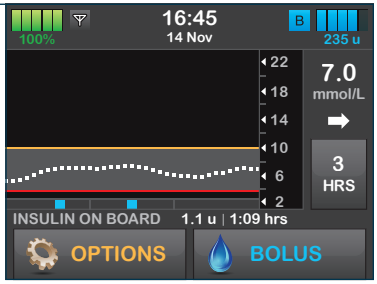
⚑ **Note:** The t:slim X2 insulin pump will beep and vibrate during a Quick Bolus if a button olume is set. It will only vibrate if the vibrate option is selected.

⚑ **Note:** If the Control-IQ feature suspends insulin delivery during a Quick Bolus, the remainder of the bolus will be delivered before all insulin delivery is stopped.

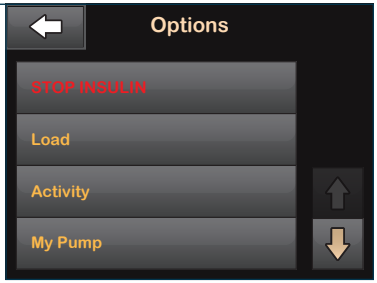
Max Bolus

The Max Bolus setting allows the user to set a limit to the maximum insulin delivery amount for a single bolus. To adjust the Max Bolus setting, follow these steps.

1. From the Home screen, tap **OPTIONS**.

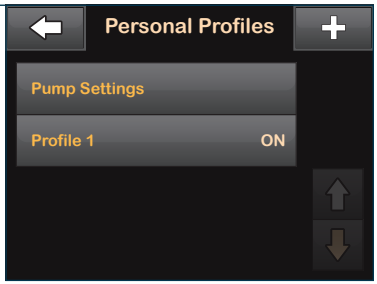


2. Tap **My Pump**.



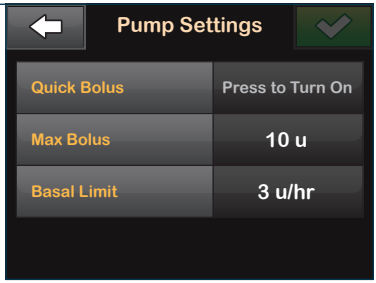
3. Tap **Personal Profiles**.

4. Tap **Pump Settings**.



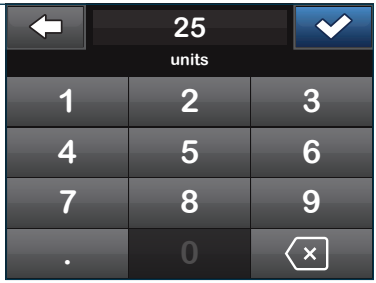
5. Tap Max Bolus.

   ⚑ **Note:** The default setting is 10 units, but can be set to any value between 1 to 25 units.

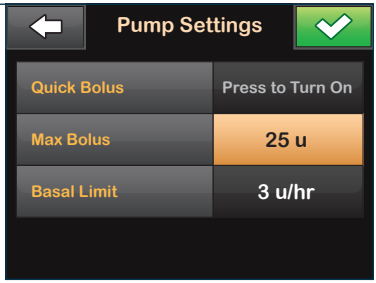


6. Using the on-screen keypad, enter the desired amount for maximum bolus (1 to 25 units) and tap ✓.

   ⚑ **Note:** If the user sets the Max Bolus to 25 units and a bolus larger than 25 units is calculated using the user's carb ratio or correction factor, after the bolus is delivered a reminder screen will appear. The option of delivering the remaining amount of the bolus up to an additional 25 units will be given.



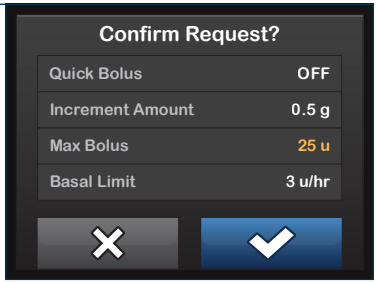
7. Review the Max Bolus value and tap ✓.



8. Confirm settings.

   - Tap ✓ if entered data is correct.
   - Tap ✕ to make changes.

✓ The SETTING SAVED screen is displayed.



9. Tap the **Tandem logo** on the face of the pump to return to the Home screen.

Notes

CHAPTER 6

Control-IQ Technology

Control-IQ Overview

Control-IQ technology is a feature of the t:slim X2 insulin pump that automatically adjusts insulin delivery rates and amounts in response to CGM readings.

The t:slim X2 pump can be used with or without Control-IQ technology enabled. The following sections describe how Control-IQ technology works and how it responds to CGM values while the user is awake, sleeping, and exercising.

⚠ Precaution: The user must continue to take boluses to cover food eaten or to correct a high glucose value. Read all Control-IQ technology instructions before activating Control-IQ technology.

⚑ **Note:** The treatment values used by Control-IQ technology are not customizable.

⚑ **Note:** Before activating a Temp Rate, the user must turn off Control-IQ technology.

⚑ **Note:** The Insulin On Board Time Remaining is not displayed when Control-IQ technology is enabled due to the variability of insulin delivery when automatically responding to CGM values. The IOB units will always be displayed on the Home and Lock screens.

Explanation of Icons

If the user has a CGM session active and is using Control-IQ technology, they may see the following additional icons on the pump screen:

Symbol	Meaning
	Control-IQ technology is enabled but not actively increasing or decreasing basal insulin delivery.
	Control-IQ technology is increasing basal insulin delivery.
	Control-IQ technology is decreasing basal insulin delivery.
	Control-IQ technology has stopped basal insulin delivery.
	The Sleep Activity is enabled.
	The Exercise Activity is enabled.
	Control-IQ technology is delivering an automatic correction bolus.
	Control-IQ technology is delivering an automatic correction bolus.
	Control-IQ technology is increasing basal insulin delivery.
	Control-IQ technology is decreasing basal insulin delivery.
	Basal insulin is programmed and being delivered.
	Basal insulin delivery is stopped and a basal rate of 0 u/hr is active.

How Control-IQ Technology Works

The Control IQ feature is designed to increase the time that is spent in the glucose target range of 3.9-10 mmol/L by predicting glucose levels 30 minutes in advance and increasing, decreasing or suspending basal insulin and delivering automated correction boluses.

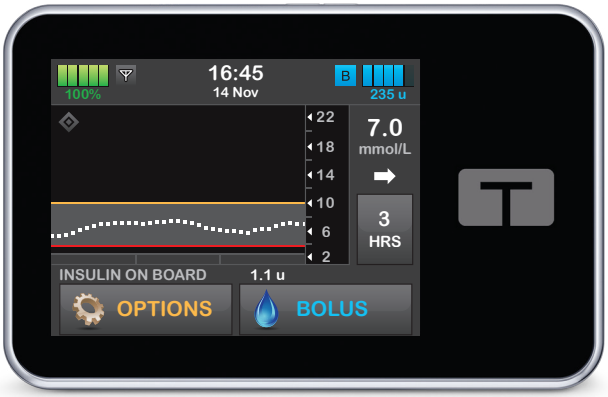
		Delivers an automatic correction bolus if sensor glucose is predicted to be above 10.0 mmol/L
10.0		
		Increases basal insulin delivery if sensor glucose is predicted to be above 8.9 mmol/L
8.9		
		Maintains active Personal Profile settings
6.25		
		Decreases basal insulin delivery if sensor glucose is predicted to be below 6.25 mmol/L
3.9 mmol/L		
		Stops basal insulin delivery if sensor glucose is predicted to be below 3.9 mmol/L

Control-IQ Technology on the Screen

Control-IQ Technology Status Icon

When Control-IQ technology is on, the CGM Trend Graph displays a diamond icon in the top left corner. This icon uses different colors to communicate information about how Control-IQ technology is operating.

When Control-IQ technology is on but not active (i.e. insulin is being delivered normally), the diamond icon is gray as depicted below. Regardless of the color, the icon always appears in the same place.



Exercise and Sleep Icons

When Exercise or Sleep is turned on, the respective icon displays in the same place on the screen, since they can never be active at the same time. The following image shows the Exercise icon active on the CGM Trend Graph screen.

CGM Trend Graph Insulin Delivery Suspended

Portions of the CGM Trend Graph that display a red band in the background indicate the times when Control-IQ technology was delivering 0 units/hour. Each dot on the CGM graph represents a five-minute increment.

Basal Status Icons

There are several basal status icons that display in different Colors, each of which communicates information about how Control-IQ technology is operating.

Automatic Correction Bolus Status Icon

When Control-IQ technology is on and delivering an automatic correction bolus, an icon displays to the left of the basal status icon (the manual bolus icon displays in the same place on the screen).

Note: The text BOLUS followed by an ellipsis displays below the CGM graph. The Control-IQ text appearing below BOLUS indicates that there is an automatic correction bolus being delivered by Control-IQ technology. The amount of the bolus is also displayed.

Activity Settings

When Control-IQ technology is turned on the user can choose to activate the Sleep Activity or the Exercise Activity to help the System adjust the automated insulin dosing settings.

Control-IQ Technology With No Activity Setting Enabled

The CGM treatment range of Control-IQ technology with no Activity enabled is 6.25-8.9 mmol/L. This range is wider than the Sleep and Exercise Activity ranges to account for the variability of factors that affect CGM values while people are awake and not exercising.

Control-IQ Technology During Sleep Activity

The CGM treatment range of Control-IQ technology during the Sleep Activity is 6.25-6.7 mmol/L. This range is smaller than the target range with no Activity enabled since there are fewer variables that affect CGM values while the user is sleeping. During the Sleep Activity, Control-IQ technology will not deliver automatic boluses.

Control-IQ Technology During Exercise Activity

During Exercise Activity, Control-IQ technology uses the target CGM range 7.8-8.9 mmol/L. This target range is smaller and higher than the target range with no Activity enabled to accommodate the likely natural drop in glucose following exercise.

Required Settings

Required Personal Profile Settings

In order to use Control-IQ technology, the following Personal Profile settings must be configured:

- Basal Rate
- Correction Factor
- Carb Ratio
- Target BG
- Carbohydrates turned on in Bolus Settings

Required Control-IQ Technology Pump Settings

In addition to the required Personal Profile settings, there are two values specific to Control-IQ technology that must be set. These are:

- Weight
- Total Daily Insulin

These values may be updated when the user visits their healthcare provider.

The Total Daily Insulin value is used by Control-IQ technology to calculate the maximum insulin delivery rate and to maintain a safe and effective increase in insulin dose. An estimate of the Total Daily Insulin should be entered. Include all types of insulin (basal and bolus) delivered in a 24-hour period. The user should consult their healthcare provider if they need assistance estimating their insulin requirements.

⚑ **Note:** Once the user has used Control-IQ technology, it will maintain and use the actual total insulin delivered, including the adjustments made to basal and all types of boluses while using the System. It is important to update the Total Daily Insulin setting in the Control-IQ screen when the user visits their healthcare provider. This value is used for the 2-hour maximum insulin alert.

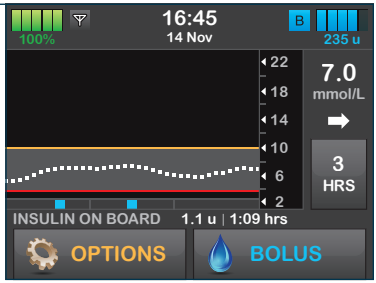
Recommended Control-IQ Technology Pump Settings

Although the Sleep Activity can be started and stopped manually, it is recommended that the user schedule it. This chapter explains how to do both. The following settings are required to create Sleep Schedules:

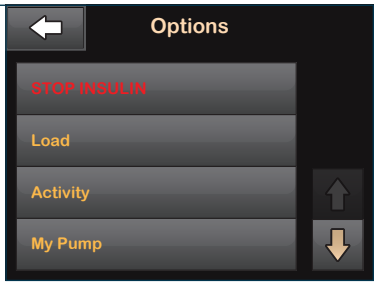
- Selected Days
- Start Time
- End Time

Setting Up Control-IQ Technology

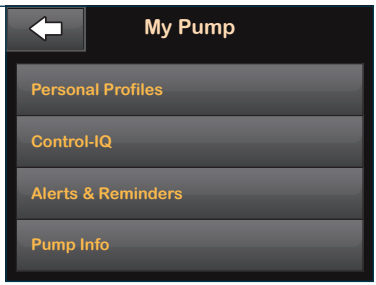
1. From the Home screen, tap **OPTIONS**.



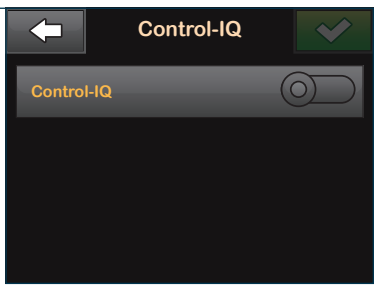
2. Tap **My Pump**.



3. Tap **Control-IQ**.



4. Tap **Control-IQ** to turn the feature on.

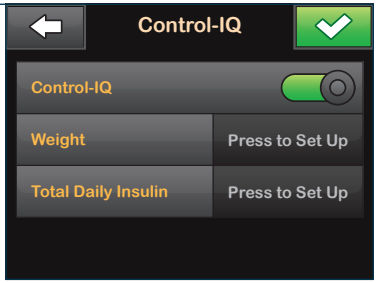


Note: If an active Temp Rate or Extended Bolus is active when you turn Control-IQ technology on, you will be notified that if you continue the Temp Rate or Extended Bolus will be stopped.

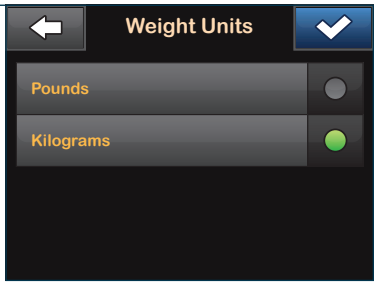
Quick Tip: The active Personal Profile must have CARBS turned on in order to turn on the Control-IQ feature. A CGM session must be running to use the Control-IQ feature.

5. Tap **Weight**.

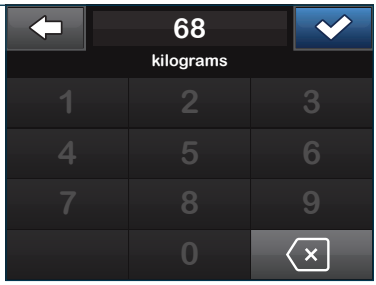
   ⚑ **Note:** Control-IQ technology cannot be enabled unless the user's weight is entered.



6. Select the preferred unit of measure and tap ✓.



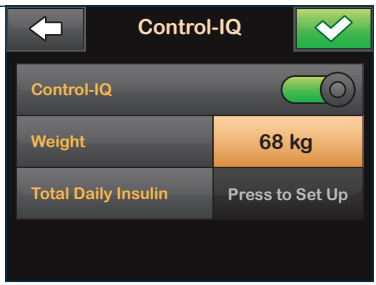
7. Use the on-screen keypad to enter the user's weight, then tap ✓.



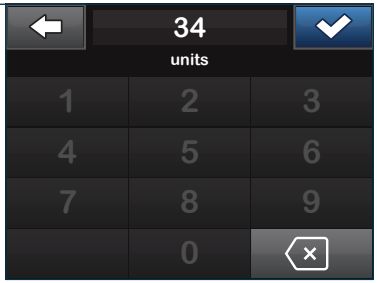
8. Tap **Total Daily Insulin**.

   ⚑ **Note:** Control-IQ technology cannot be enabled unless total daily insulin is entered.

   ⚑ **Note:** Total Daily Insulin should be an estimate of total basal and bolus insulin the user requires in a 24-hour period.

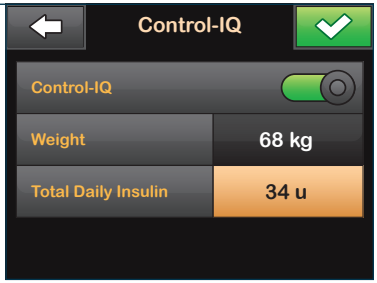


9. Use the on-screen keypad to enter the average daily insulin use in units, then tap .



10. Review settings and tap .

✓ The SETTING SAVED screen is displayed.



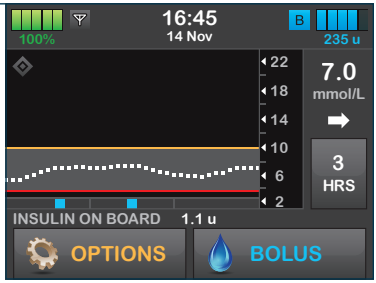
11. Tap the **Tandem logo** on the face of the pump to return to the CGM Home screen.

Setting a Sleep Schedule

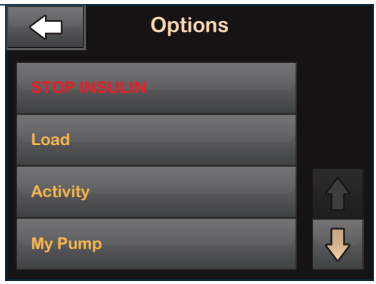
⚑ **Note:** If the user manually starts Sleep before a Sleep Schedule begins, it does not impact the scheduled wake time. Sleep will end as scheduled, unless manually stopped.

⚑ **Note:** If Exercise is active at the time a Sleep Schedule begins, the Sleep Schedule will not enable. However, once Exercise is disabled, the Sleep Schedule will start automatically.

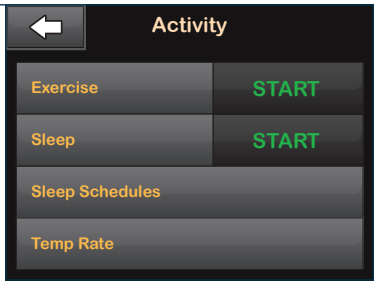
1. From the Home screen, tap OPTIONS.



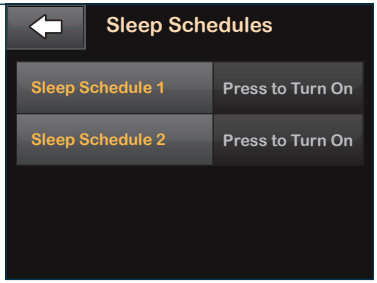
2. Tap Activity.



3. Tap Sleep Schedules.



4. Select which Sleep Schedule to configure.

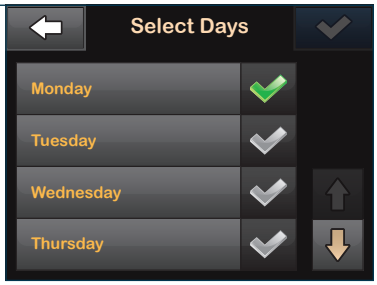


5. Tap **Selected Days**.

Note: By default, only the current day of the week is initially selected, according to the day of the week set on the pump.

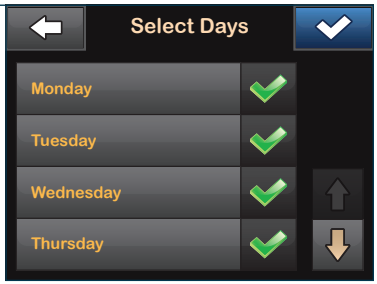
6. Tap the checkmark to the right of each day of the week that should be included in the Sleep Schedule. Tap the **Down Arrow** to see more days of the week.

Note: When a checkmark is green, the corresponding day of the week is active. To deactivate a day, tap the associated checkmark again so that it turns gray.



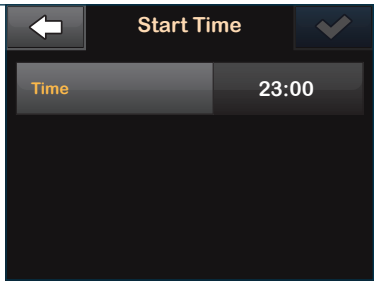
7. Tap .

Note: If no days are selected, the schedule is set to off and the remaining Sleep Schedule settings are not displayed. The remaining instructions do not apply to an incomplete schedule.

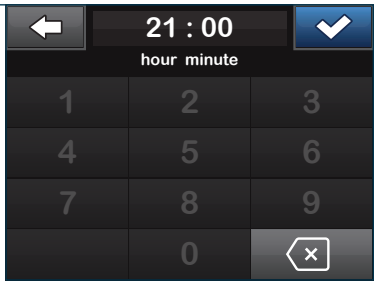


8. Tap **Start Time**.

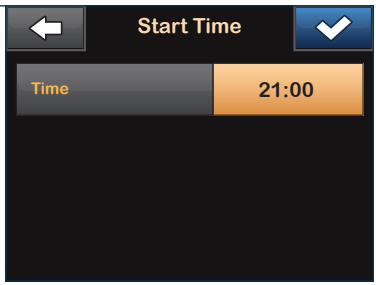
9. Tap **Time**.



10. Enter the time the user would like the Sleep Schedule to start by entering the number(s) for the hour followed by the minutes. Tap ✓.

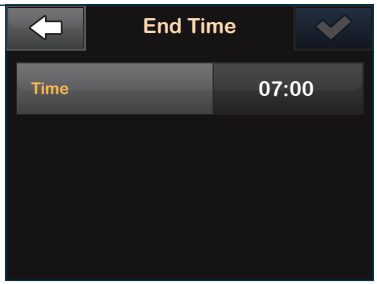


11. Tap ✓.

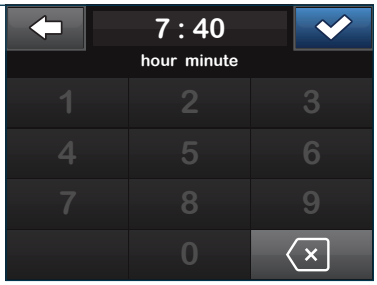


12. Tap **End Time**.

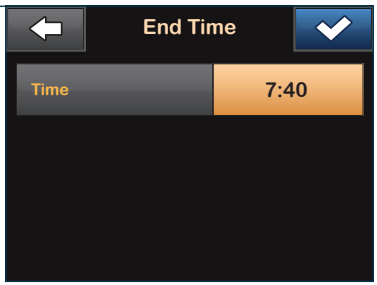
13. Tap **Time**.



14. Enter the time the user would like the Sleep Schedule to end and tap ✓.



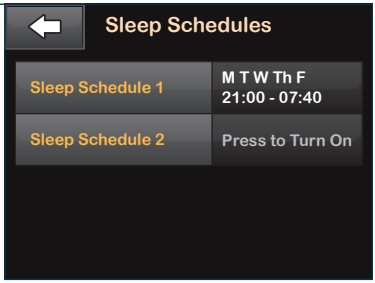
15. Tap ✓.



16. Tap .

✓ The SETTING SAVED screen is displayed

17. When done configuring sleep, tap to return to the Activity screen or tap the Tandem logo to return to the Home screen.

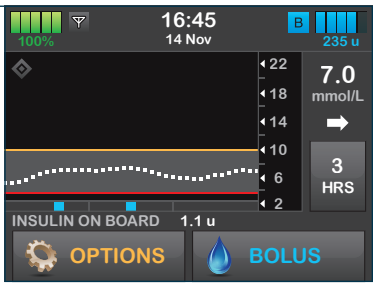


Manually Start or Stop Sleep

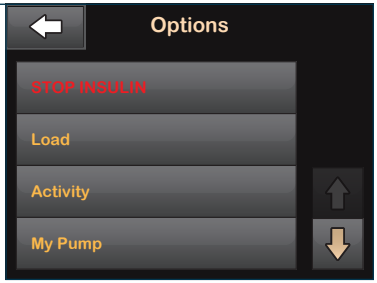
In addition to scheduling Sleep, Sleep can be manually started and/or stopped. Sleep time determines when Control-IQ technology, if enabled, switches to the Sleep Activity. Control-IQ technology must be on and a CGM session must be active to start Sleep.

Manually Start Sleep

1. From the Home screen, tap OPTIONS.

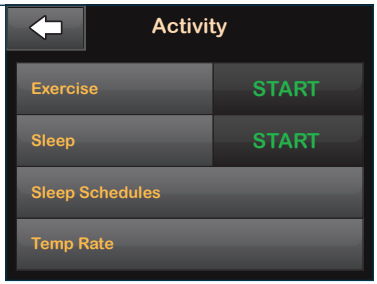


2. Tap **Activity**.



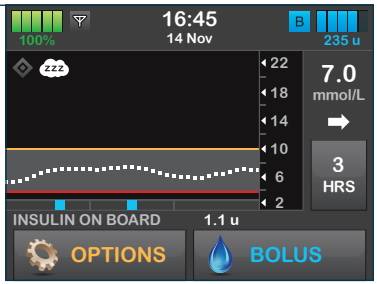
3. Tap the **START** text next to Sleep.

✓ A SLEEP STARTED screen is displayed and the Sleep icon is displayed on the Home screen.

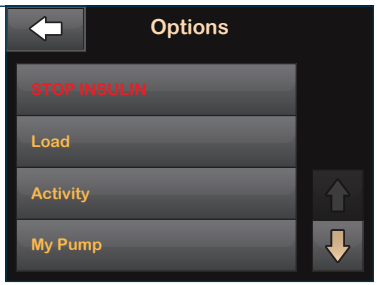


Manually Stop Sleep

1. From the Home screen, tap **OPTIONS**.

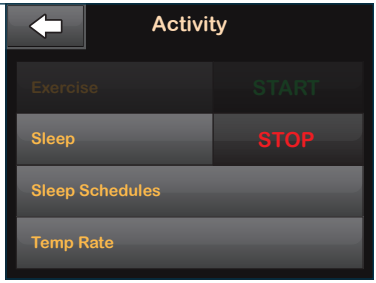


2. Tap **Activity**.



3. Tap the **STOP** text next to Sleep.

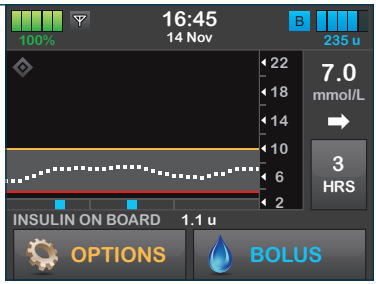
✓ A SLEEP STOPPED screen is displayed and the Sleep icon is removed from the Home screen.



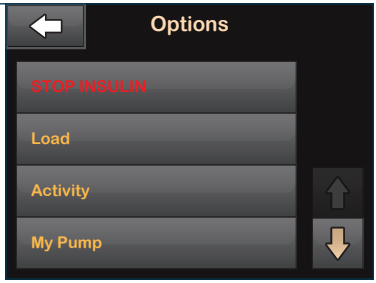
Manually Start or Stop Exercise

Start Exercise

1. From the Home screen, tap **OPTIONS**.

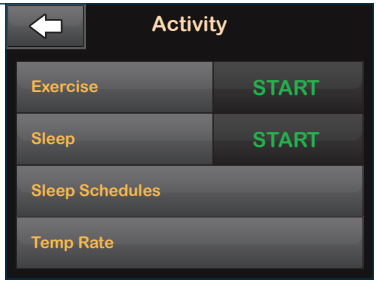


2. Tap **Activity**.



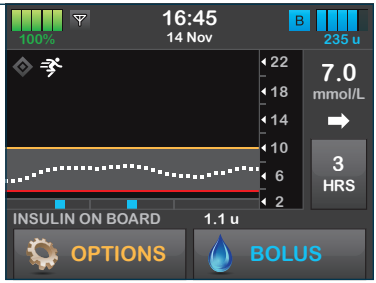
3. Tap the **START** text next to Exercise.

✓ A EXERCISE STARTED screen is displayed and the Exercise icon is displayed on the Home screen.

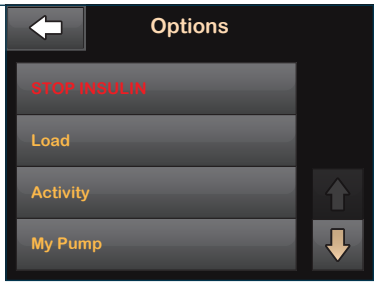


Manually Stop Exercise

1. From the Home screen, tap **OPTIONS**.

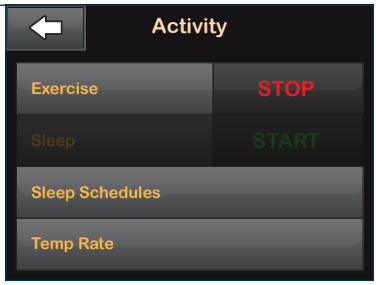


2. Tap **Activity**.



3. Tap the **STOP** text next to Exercise.

✓ A EXERCISE STOPPED screen is displayed and the Exercise icon is removed from the Home screen.



For full detailed instructions on items in this chapter, please refer to the Control-IQ Technology Important Safety Information, Getting to Know Control-IQ Technology, Introduction to Control-IQ Technology, and Configure and Use Control-IQ Technology chapters in the Control-IQ technology user guide.

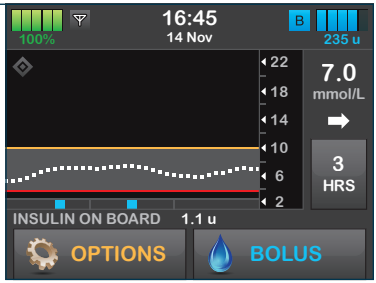
Notes

CHAPTER 7

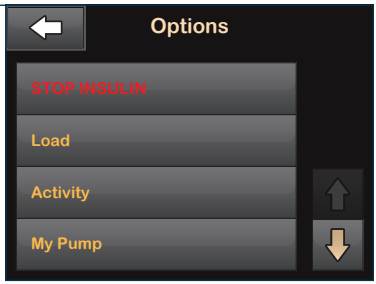
Pump Features

Pump History

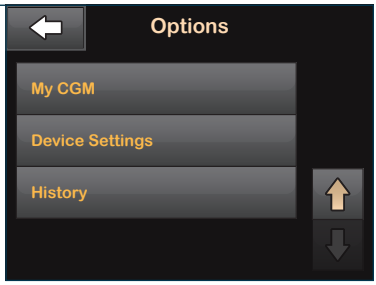
1. From the Home screen, tap OPTIONS.



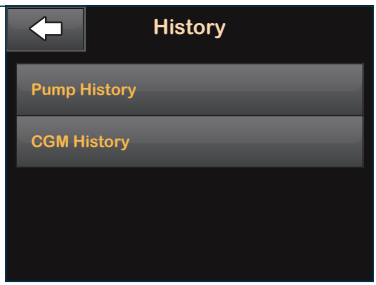
2. Tap the Down Arrow.



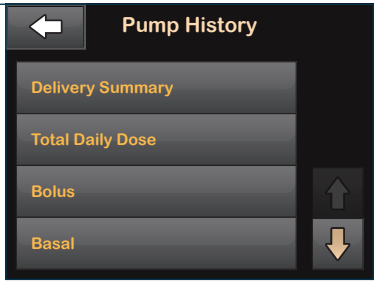
3. Tap History.



4. Tap Pump History.



5. Tap desired option.



Quick Tip:

- Delivery Summary breaks down total insulin delivery by basal and bolus types, into units and percentages. It can be viewed by the selected time period of Today, 7 Day, 14 Day, and 30 Day Average.
- Bolus, Basal, Load, BG, Alerts and Alarms, Control-IQ and Complete are categorized by date. The event details in each report are listed by time.

6. Tap the **Tandem logo** on the face of the pump to return to the Home screen.

Alerts and Reminders

The t:slim X2 pump with Control-IQ technology has customizable reminders:

- Low BG: Notifies the user to retest their BG after a low BG value is entered.
- High BG: Notifies the user to retest their BG after a high BG value is entered.
- After Bolus BG: Notifies the user to test their BG a selected time period after a bolus has been delivered.
- Missed Meal Bolus: Notifies the user of a possible Missed Meal Bolus based on the time period selected.

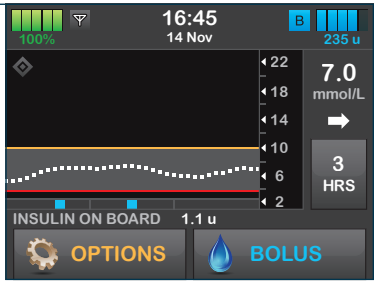
Reminders sound with a series of three-step tones at the volume/vibration selected in Sound Volume settings. They repeat at regular intervals until acknowledged.

The t:slim X2 pump with Control-IQ technology has two customizable Alerts:

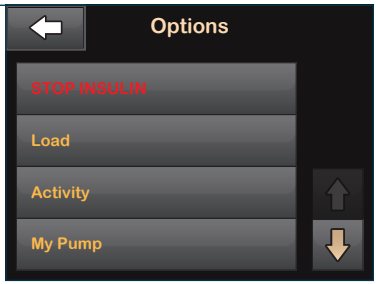
- Low Insulin: Alerts when insulin in the cartridge reaches the set low amount (10-40 units).
- Auto-Off: Alerts if no pump activity has occurred within the set time period (5-24 hrs).

Alerts sound with two series of three-step tones at the volume/vibration selected in Sound Volume settings. They repeat at regular intervals until acknowledged.

1. From the Home screen, tap OPTIONS.



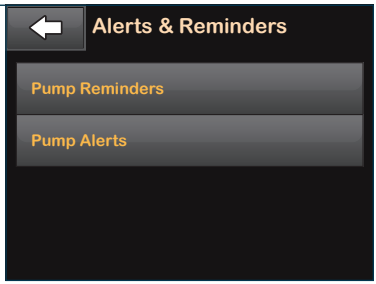
2. Tap My Pump.



3. Tap Alerts & Reminders.

For Reminders

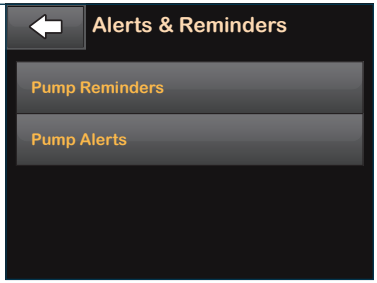
1. Tap Pump Reminders.



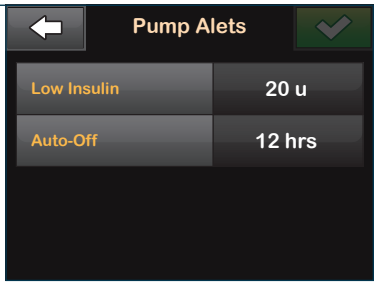
2. Tap desired option and complete setup.

For Alerts

1. Tap **Pump Alerts**.



2. Tap desired option and complete setup.



For full detailed instructions on items in this chapter, please refer to the Start, Stop, or Resume Insulin, t:slim X2 Insulin Pump Information and History, t:slim X2 Insulin Pump Reminders, and User Settable Alerts and Alarms chapters in the Control-IQ technology user guide.

Notes

CHAPTER 8

Alerts and Technical Support

Alerts

The t:slim X2 insulin pump will sound or vibrate for some of the following reasons:

- Control-IQ Technology: High, Low
- Incomplete: Bolus, Cartridge Change, Fill Cannula, Fill Tubing, Temp Rate, Setting
- Max: Basal, Bolus, Hourly Bolus, Insulin
- Low: Insulin, Power
- Out of Range

Alerts sound with two series of three-step tones or two vibrations depending on the volume/vibrate setting selected in Sound Volume. They repeat at regular intervals until acknowledged. Alerts do not escalate and do not stop insulin delivery.

Alarms

The t:slim X2 insulin pump alarms are preset and trigger automatically. Some of these alarms include:

- Resume Pump
- Shutdown
- Empty Cartridge
- Cartridge Error
- Occlusion
- Auto-Off (user settable)

Alarms are for potential interruption of insulin delivery.

Alarms sound with three series of three-step tones or three vibrations depending on the volume/vibrate setting selected in Sound Volume. If not acknowledged, alarms escalate to highest volume and vibration. Alarms repeat at regular intervals until the condition that caused the alarm is resolved. Alarms will stop insulin delivery.

Malfunction

- Malfunction alarms are preset and triggered automatically.

- Malfunction alarms indicate the need for the user to contact their local customer support service.
- Malfunctions sound with three series of three-step tones at the highest volume and three vibrations. They repeat at regular intervals until acknowledged. Malfunctions cannot be resolved.

Hazards

- Keep small parts away from children.
- Avoid exposing the System to electromagnetic radiation or magnetic resonance imaging (MRI).
- Supervise children and use the Security PIN to avoid accidental insulin delivery. For full detailed instructions on how to turn the Security PIN on or off, please refer to the Control-IQ technology user guide.
- Carry a backup plan and supplies at all times for use in the event of an unexpected interruption in insulin delivery.

Customer Technical Support

If the user has questions or needs further clarification on their pump use, they should contact their local customer support service.

Quick Tip: The Customer Technical Support phone number, pump serial number, and warranty information can be found on the back of the t:slim X2 insulin pump or in the pump info menu.

For full detailed instructions on items in this chapter, please refer to the t:slim X2 Insulin Pump Alerts, t:slim X2 Insulin Pump Alarms, t:slim X2 Insulin Pump Malfunction, and Control-IQ Technology Alerts chapters in the Control-IQ technology user guide.

Notes

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