

Tandem Mobi System Automated App User Guide

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TANDEM MOBI SYSTEM Control-IQ Technology



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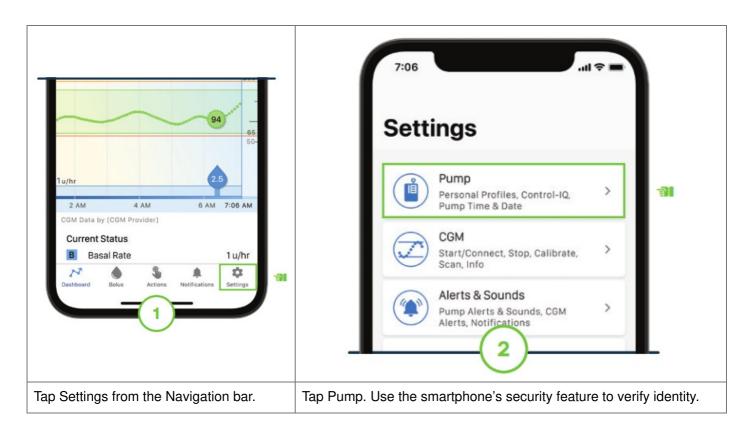
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Mobi System Automated App

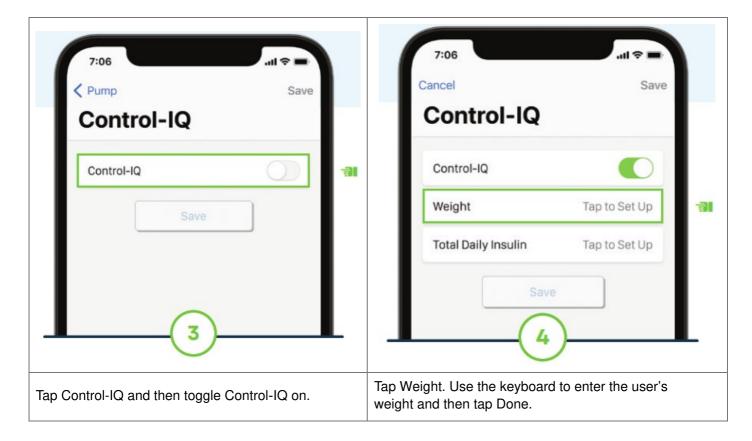
Control-IQ technology is designed to help increase time in range (70-180 mg/dL). This guide explains how to turn Control-IQ technology on, enable activities, and how the algorithm works.



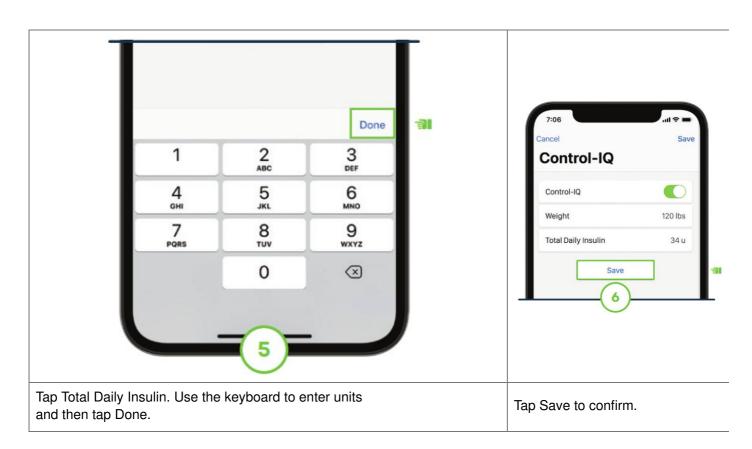
Note: These instructions are provided as a reference tool for pump users and caregivers who are already familiar with the use of an insulin pump and with insulin therapy in general. Not all screens are shown. For more detailed information on the operation of the Tandem Mobi system, please refer to the user guide.



▶ Note: To use Control-IQ technology, the pump must be integrated with continuous glucose monitoring (CGM)* and the active Personal Profile must have Carbohydrates turned on.



▶ Note: The Weight value is used by Control-IQ technology to maintain safe and effective increases and decreases in insulin dose.



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

Control-IQ technology is now enabled. See diagram on the next page to learn more about how it works.

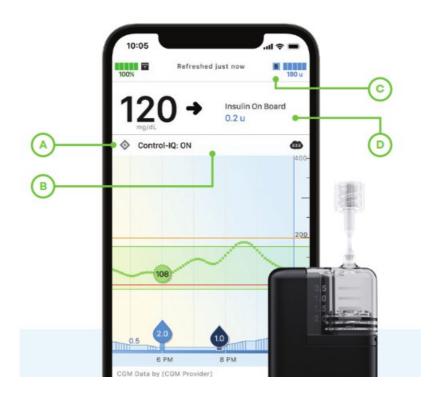
Know Your Dashboard

A Control-IQ Status A diamond icon on the left side of the Activity Bar that displays the current status of how Control-IQ technology is operating.

B Activity Bar Displays Control-IQ technology activities, Control-IQ technology status, and indicates when insulin delivery has been stopped.

C Status A square icon located to the left of the Insulin Level that displays how Control-IQ technology is adjusting basal insulin delivery.

D Insulin On Board (IOB) Time Remaining is not displayed with IOB when Control-IQ technology is enabled due to the variability of insulin delivery.





How it Works

Control-IQ technology uses CGM values to predict glucose levels 30 minutes ahead and automatically adjusts insulin every five minutes, if needed.

Control-IQ technology can decrease or stop basal insulin delivery to help prevent lows. It can also increase insulin delivery and deliver automatic correction boluses † () to help avoid highs.



Control-IQ technology includes optional settings for sleep and exercise that further adjust the range of treatment values. The following pages provide step- by-step instructions for how to enable these activities and more information about how they work.

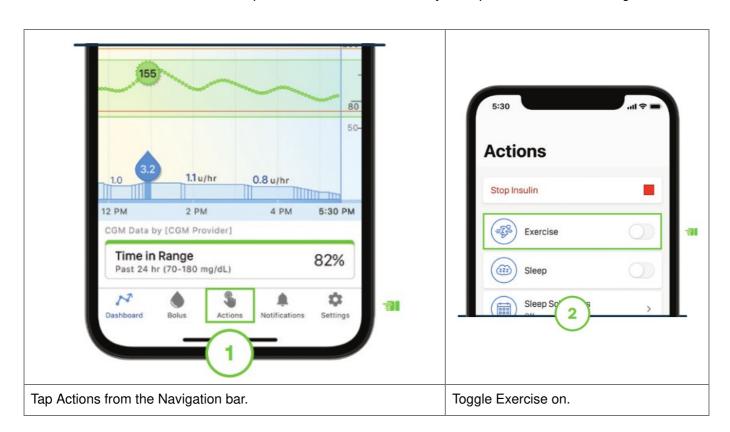
TANDEM MOBI SYSTEM Exercise Activity



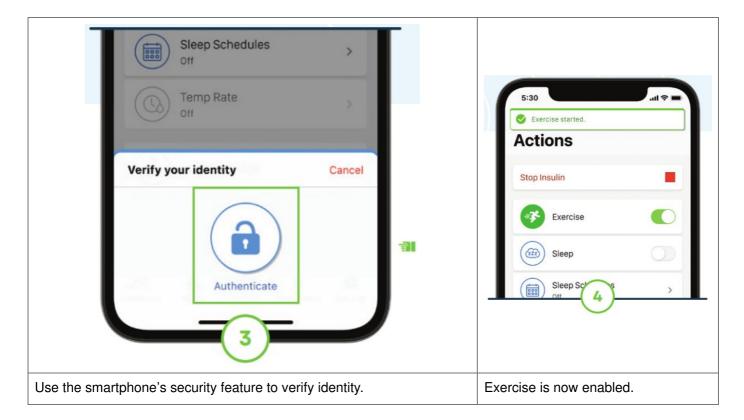
Exercise Activity can be turned on to accommodate the likely natural drop in glucose values following increased activity.



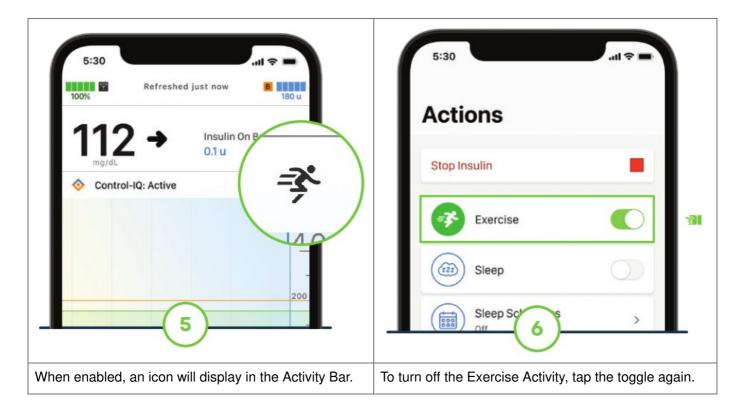
Note: These instructions are provided as a reference tool for pump users and caregivers who are already familiar with the use of an insulin pump and with insulin therapy in general. Not all screens are shown. For more detailed information on the operation of the Tandem Mobi system, please refer to the user guide.



▶ Note: In order to use Exercise or Sleep, the pump must be integrated with CGM and Control-IQ technology must be turned on.

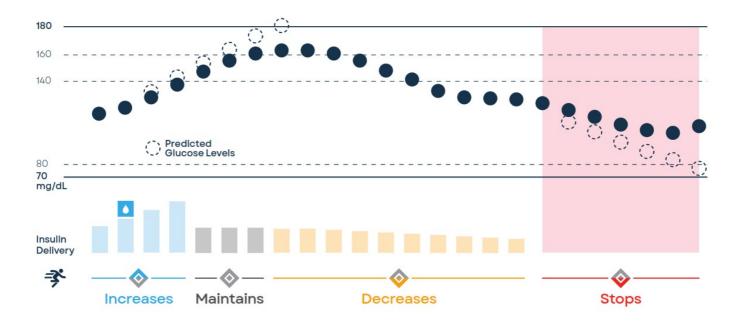


- Note: The system uses device authentication to ensure data security and patient confidentiality.
- ▶ Note: If active, the Sleep Activity will automatically be disabled if Exercise is enabled.



Go to the next page to learn how the Exercise Activity adjusts delivery.

Note: Any active Sleep Schedules will automatically start when Exercise is disabled.



How it Works

When the Exercise Activity is enabled, a tighter range of treatment values (140-160 mg/dL) is used when determining whether to increase or decrease basal insulin delivery and a predicted value of 80 mg/dL is used when determining whether to stop basal insulin delivery.

Automatic correction boluses () will be delivered up to once per hour to help avoid highs.†





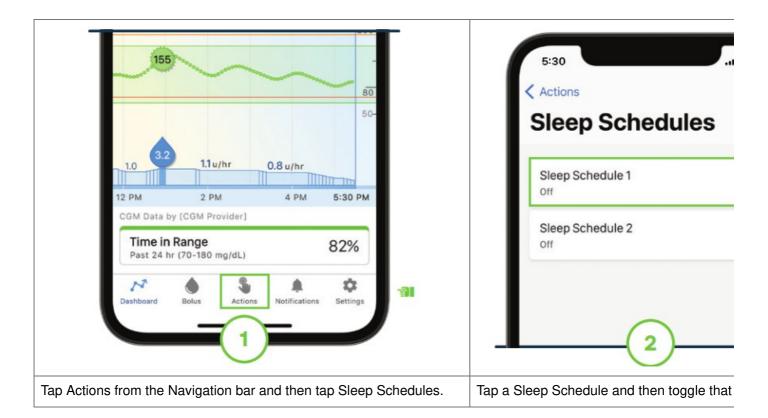
TANDEM MOBI SYSTEM Sleep Activity



Users can program the Tandem Mobi system to automatically switch into Sleep Activity. Two Sleep Schedules can be used.

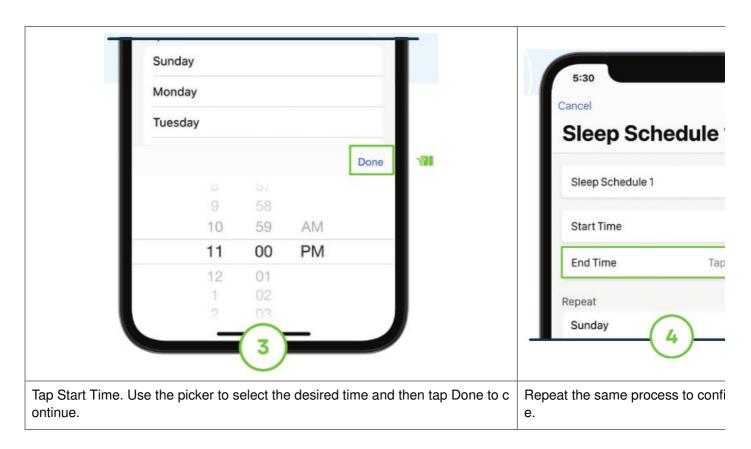


Note: These instructions are provided as a reference tool for pump users and caregivers who are already familiar with the use of an insulin pump and with insulin therapy in general. Not all screens are shown. For more detailed information on the operation of the Tandem Mobi system, please refer to the user guide.

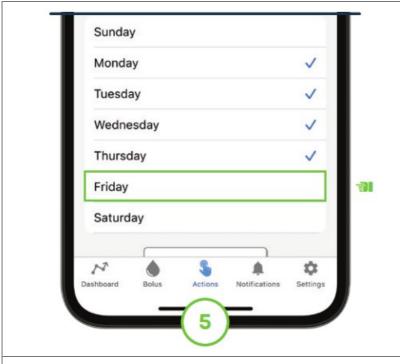


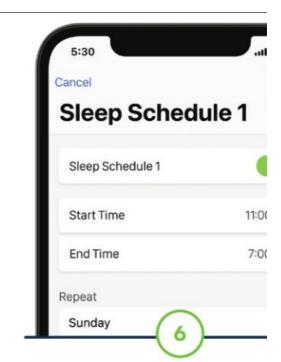
Use the smartphone's security feature to verify identity.

▶ Note: If the user does not program a Sleep Schedule, the Sleep Activity must be manually turned on and off (see next page).



Note: These times should reflect the time the user generally goes to sleep and wakes up.



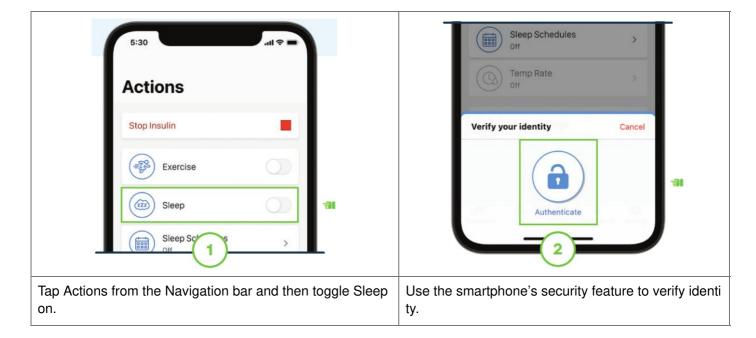


Tap each day of the week the user wants Sleep scheduled.

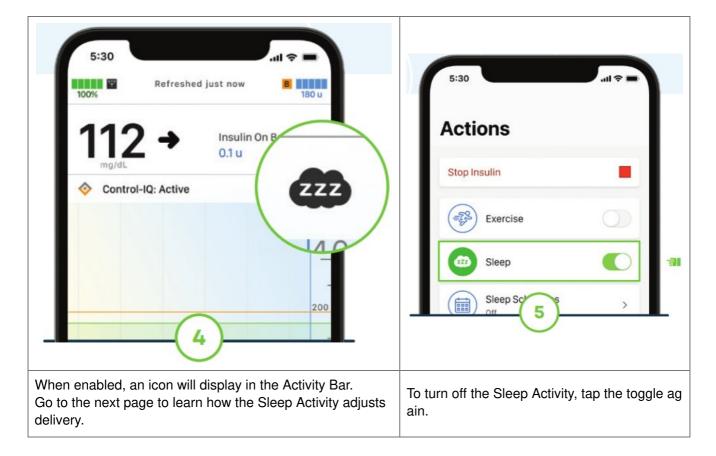
Tap Save to confirm settings and turn on the §

- Note: A blue checkmark will display next to active days in the Sleep Schedule. Tap a specific day again to deactivate it.
- Note: Two different Sleep Schedules can be programmed. If desired, repeat these steps to configure the second Sleep Schedule.

In addition to programming Sleep Schedules, the Sleep Activity can also be manually turned on and off. Follow these step- by-step instructions to learn how to enable it.



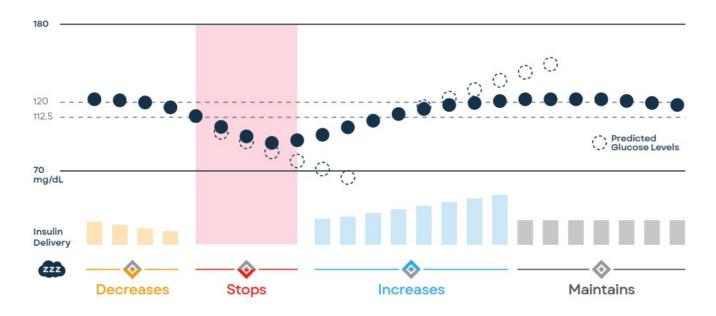
- Note: The system uses device authentication to ensure data security and patient confidentiality.
- ▶ Note: If active, the Exercise Activity will automatically be disabled if Sleep is enabled.



Configuration Settings

- ✓ To ensure that both Sleep Schedules can be saved and enabled at the same time, the two schedules cannot overlap. One or both Sleep Schedules may be disabled at any time.
- ✓ If you manually start the Sleep Activity before a Sleep Schedule begins, it does not impact the scheduled wake time
- ✓ Activities may not be enabled at the same time. If programmed, Sleep Schedules will automatically start once Exercise is disabled.
- ✓ Automatic correction boluses will not be delivered while the Sleep Activity is enabled

Pump Tip: On the Sleep Schedule screen, the day that appears at the top of the list is the current day of the week according to the Tandem Mobi system.



How it Works

When the Sleep Activity is enabled, the algorithm narrows and lowers the range of treatment values (112.5- 120 mg/dL) when determining whether to decrease, stop, or increase basal insulin delivery.

Automatic correction boluses will not be delivered while the Sleep Activity is enabled.





Need help? We have an extensive library of educational and self-help materials to help you with your pump.



https://qrco.de/bcr7Pz

Control-IQ technology does not prevent all highs and lows. You must still bolus for meals and actively manage your diabetes. Please visit <u>tandemdiabetes.com/responsible-use</u> for more info.

* CGM sold separately. † If glucose values are predicted to be above 180 mg/dL, Control-IQ technology calculates a correction bolus using the Personal Profile settings and a target of 110 mg/dL and delivers 60% of that value. Automatic correction boluses will not be delivered while the Sleep Activity is enabled.

Important Safety Information: RX ONLY. Indications for Use: Tandem Mobi system: The Tandem Mobi insulin pump with interoperable technology (the pump) is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin.

The pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices. The pump is intended for single patient, home use and requires a prescription.

The pump is indicated for use in individuals 6 years of age and greater. Control-IQ technology: Control-IQ technology is intended for use with compatible integrated continuous glucose monitors (iCGM, sold separately) and alternate controller enabled (ACE) pumps to automatically increase, decrease, and suspend delivery of basal insulin based on iCGM readings and predicted glucose values.

It can also deliver correction boluses when the glucose value is predicted to exceed a predefined threshold.

Control-IQ technology is intended for the management of Type 1 diabetes mellitus in persons 6 years of age and greater.

Control-IQ technology is intended for single patient use. Control-IQ technology is indicated for use with NovoLog or Humalog U-100 insulin.

WARNING: Control-IQ technology should not be used by anyone under the age of 6 years old. It should also not be used in patients who require less than 10 units of insulin per day or who weigh less than 55 pounds.

Control-IQ technology is not indicated for use in pregnant women, people on dialysis, or critically ill patients. Do not use Control-IQ technology if using hydroxyurea. Users of a Tandem insulin pump and Control-IQ technology must 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 Tandem 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.

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(877) 801-6901 tandemdiabetes.com

FOR USE IN THE UNITED STATES ONLY



Documents / Resources



<u>Tandem Mobi System Automated App</u> [pdf] User Guide Mobi System Automated App, System Automated App, Automated App, App

References

- Diabetes Management | Insulin Pumps | Tandem Diabetes Care
- Important Safety Information Tandem Insulin Pumps
- User Manual

Manuals+, Privacy Policy

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