



Student's Medical Device

Tandem Mobi

An automated insulin delivery system to manage diabetes that is fully controllable via a mobile app.





!

IMPORTANT!

The student will need to keep their smartphone with them throughout the day so they can:

- Check blood sugar levels and adjust their insulin delivery
- Access the internet to count carbohydrates
- Text a caregiver to confirm carb counts or insulin doses

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Show this document to a school representative

If you have questions about this student's insulin pump, please contact their parent or guardian at:





Important Safety Information: RX ONLY.

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. If your CGM readings do not match your symptoms or expectations, use a blood glucose meter to make diabetes management decisions. 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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