

Basal-IQ™ Technology: Real-World Outcomes



For Healthcare Providers

Hypoglycemia is one of the biggest concerns when managing type 1 diabetes,¹ and the occurrence of time spent below 70 mg/dL has been associated with an increased risk of subsequent severe hypoglycemic events.² Basal-IQ technology predicts glucose levels 30 minutes ahead and suspends insulin if they are expected to drop below 80 mg/dL or if a CGM reading falls below 70 mg/dL. Insulin delivery resumes as soon as sensor glucose values begin to rise.

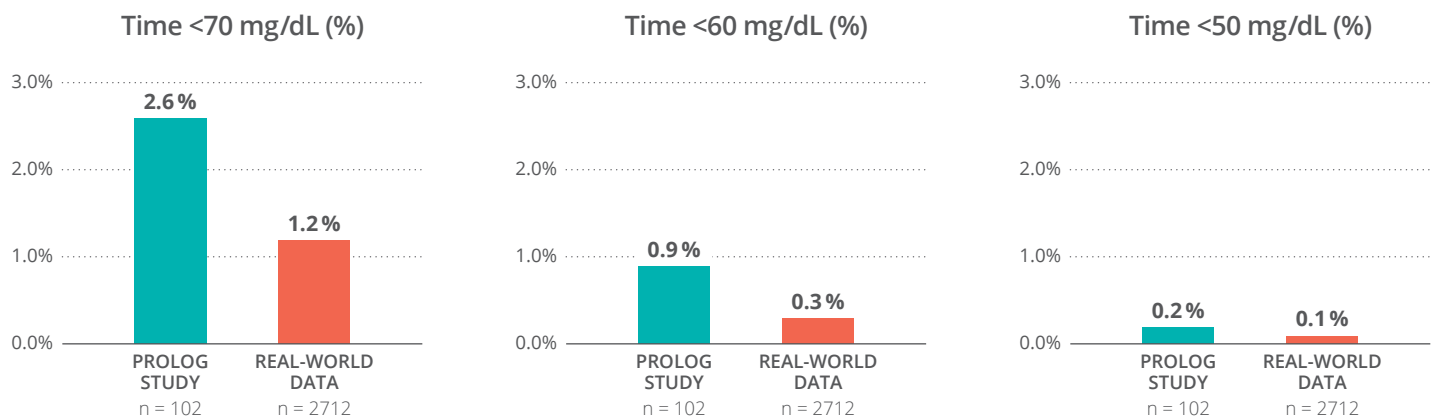
De-identified data uploaded to the t:connect® diabetes management application from August 31, 2018, to January 9, 2019, were evaluated from pump users with three consecutive weeks (n = 2,712) and six consecutive weeks (n = 1,437) of Basal-IQ technology use. This real-world data was compared to results from the PROLOG pivotal study, in which Basal-IQ technology was used for three weeks (n = 102). All results reflect median values.

*The data below has been verified by UC San Diego School of Medicine and UC San Diego Design Lab Center for Health.**

Results Three Weeks on Basal-IQ Technology

Reductions in hypoglycemia observed in real-world use

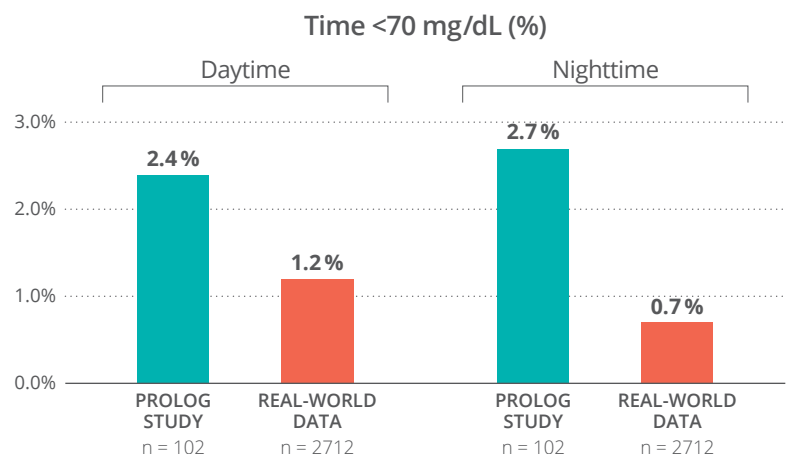
Real-world use of Basal-IQ technology demonstrated a reduction in time spent in hypoglycemia compared to outcomes observed in the PROLOG pivotal study.³



Improvements observed in rates of nocturnal hypoglycemia

Nocturnal hypoglycemia can be especially dangerous if people sleep through symptoms. Further improvements in time <70 mg/dL were seen for both the daytime (6 AM-10 PM) and nighttime (10 PM-6 AM) periods in real-world use compared to the PROLOG study.

Specific real-world values (median [quartiles]) for use over three weeks were: overall 1.16 [1.45, 2.42]; daytime 1.18 [0.44, 2.46]; nighttime 0.71 [0.07, 2.16].

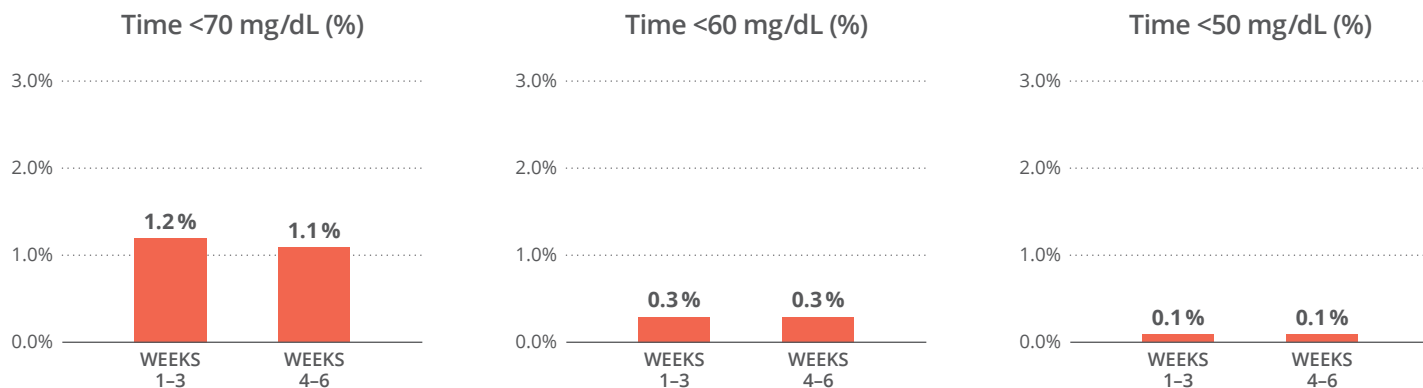


Results

Six Weeks on Basal-IQ Technology

Sustained reductions in hypoglycemia observed over six weeks

Hypoglycemia outcomes at six weeks were consistent with those seen at three weeks with real-world use of Basal-IQ technology (n = 1,437).



► Learn more about the t:slim X2 insulin pump at www.tandemdiabetescare.com/providers



Responsible Use of Basal-IQ Technology

Systems like the t:slim X2™ insulin pump with Basal-IQ technology are not substitutes for the active management of diabetes. There are common scenarios in which automated systems cannot prevent a hypoglycemic event. The Basal-IQ feature relies on current CGM sensor readings to function and will not be able to predict glucose levels and suspend insulin delivery if a patient's CGM is not functioning properly or their pump is unable to receive the CGM signal. It's recommended your patient always uses the components of the pump system (pump, cartridges, CGM, and infusion sets) according to the applicable instructions for use and checks them regularly to make sure they are functioning as expected. Patients should always pay attention to their symptoms, actively monitor and manage glucose levels, and treat according to your recommendations.



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* UC San Diego School of Medicine and UC San Diego Design Lab Center for Health were compensated by Tandem Diabetes Care, Inc. for conducting this independent analysis of de-identified t:connect data.

1. Vallis M, Jones A, Pouwer. Managing hypoglycemia in diabetes may be more fear management than glucose management: a practical guide for diabetes care providers. *Curr Diabetes Rev.* 2014;10(6):364-70. 2. Beck RW, et al. The association of biochemical hypoglycemia with the subsequent risk of a severe hypoglycemic event: analysis of the DCCT data set. *Diabetes Technol Ther.* 3. Forlenza GP, Li Z, Buckingham BA, Pinsky JE, et al. Predictive low-glucose suspend reduces hypoglycemia in adults, adolescents, and children with type 1 diabetes in an at-home randomized crossover study: Results of the PROLOG trial. *Diabetes Care.* 2019;41(10):2155-2161. doi:10.2337/dc18-0771.

The t:connect diabetes management application is intended for use by individuals with diabetes mellitus who use Tandem Diabetes Care® insulin pumps, their caregivers, and their healthcare providers in home and clinical settings. The t:connect application supports diabetes management through the display and analysis of information downloaded from Tandem Diabetes Care insulin pumps and specified blood glucose meters.

Important Safety Information: RX ONLY. The t:slim X2 insulin pump with Basal-IQ technology (the System) consists of the t:slim X2 insulin pump, which contains Basal-IQ technology, and a compatible CGM. 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 persons requiring insulin. The t:slim X2 insulin pump can be used solely for continuous insulin delivery and as part of the System. When the System is used with a compatible iCGM, Basal-IQ technology can be used to suspend insulin delivery based on CGM sensor readings. Interpretation of the System results should be based on the trends and patterns seen with several sequential readings over time. CGM also aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments. Compatible iCGM systems are intended for single patient use and require a prescription. The System is indicated for use in individuals 6 years of age and greater. The System is intended for single patient use and requires a prescription. The System is indicated for use with NovoLog or Humalog U-100 insulin. The System is not approved for use in pregnant women, persons on dialysis, or critically ill patients. For detailed indications for use and safety information, call Tandem toll-free at (877) 801-6901 or visit www.tandemdiabetes.com/safetyinfo.

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