# The PROLOG Study[1]

Study Objective:

This study evaluated a new predictive low glucose suspend algorithm (PLGS), Basal-IQ™ technology. Integrated with Dexcom G6 continuous glucose monitoring (CGM) system, the t:slim X2™ insulin pump with Basal-IQ technology minimises hypoglycaemia by automatically suspending insulin. This occurs when sensor glucose is predicted to be less than 4.4 mmol/L within 30 minutes, or when sensor glucose is 3.9 mmol/L. Insulin resumes when the glucose value rises.

Inclusion Criteria:

- Diagnosis of type 1 diabetes for at least one year
- Age ≥6
- Insulin pump or multiple daily injections
- Continuous glucose monitoring (CGM) user or naïve
- No HbA1C restrictions

Study Methods:

Randomised, cross-over trial of 102 patients assigned to use either the t:slim X2 insulin pump with Basal-IQ technology or a sensor-augmented pump (SAP) at home for three weeks. After the first three weeks, participants were switched to the other therapy.
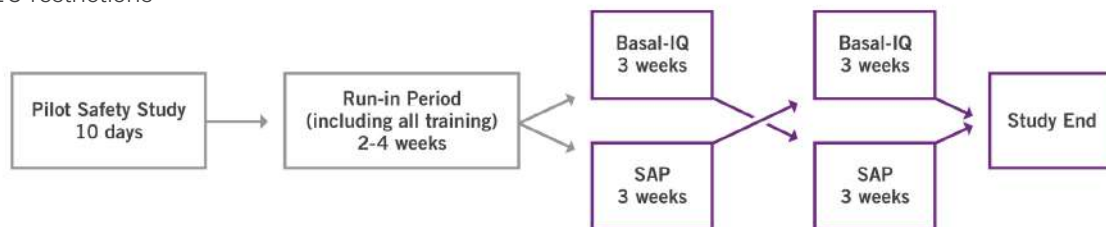
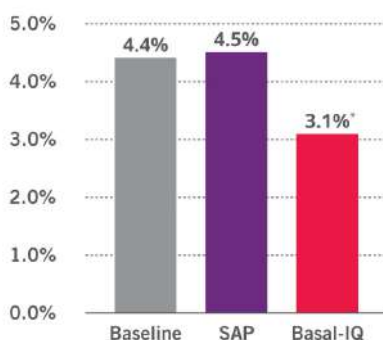# Results

Reduced Rates of Hypoglycaemia

Results showed a 31% relative reduction overall in sensor time below 3.9 mmol/L utilising Basal-IQ technology. There was a 40% relative reduction in sensor time below 3.9 mmol/L in those who experienced more hypoglycaemia during the run-in period (baseline). Reductions in hypoglycaemia were observed in all subgroups analysed, regardless of previous pump and/or CGM therapy.
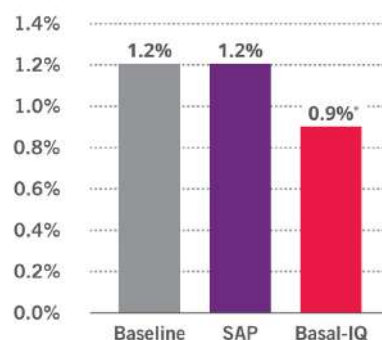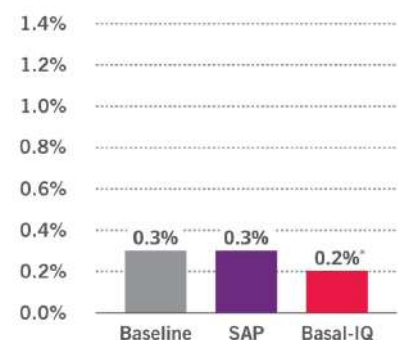
31%
Relative Reduction in sensor time below 3.9 mmol/L
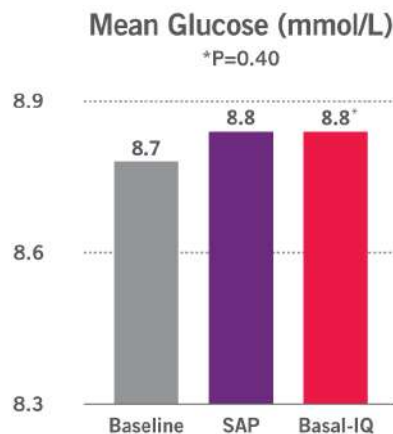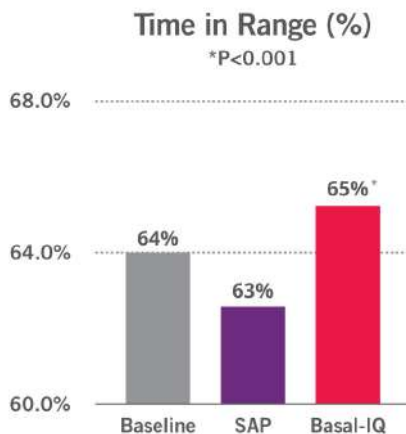
Improved Glycaemic Control

Mean time in range (3.9-10 mmol/L) improved by 2% utilising Basal-IQ technology, which equates to 30 more minutes per day of time spent in the target range. Additionally, there was no difference in the mean glucose concentration between using Basal-IQ technology and SAP. These findings are in contrast to several published studies on PLGS systems[2,3] that found an increased mean glucose and a decreased time in range. Additionally, there was a lack of rebound hyperglycaemia observed with use of Basal-IQ technology.

Time in Range (%)
*P<0.001

	Baseline	SAP	Basal-IQ
	64%	63%	65%*

Mean Glucose (mmol/L)
*P=0.40

	Baseline	SAP	Basal-IQ
	8.7	8.8	8.8*

No Evidence of Rebound Hyperglycaemia

Simple to Learn and Use

At the conclusion of the study, participants completed a System Usability Questionnaire, a tool for measuring ease of use. The t:slim X2 insulin pump with Basal-IQ technology was found to be exceptionally easy to use.

97%

Confidence
Participants felt very confident using the system

93%
thought they would like to use the system frequently

91%
thought the system was easy to use

90%
did not feel they had to learn a lot before getting started with the system

95%
did not think they would need the support of a technical person to use the system

For more information on Basal-IQ technology for the t:slim X2 insulin pump, please contact us on **1300 851 056** or at **diabetes@amsl.com.au**

amsldiabetes.com.au

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References: 1. Buckingham B, et al. PROLOG: A Randomized Clinical Trial to Assess The Efficacy of Predictive Low Glucose Suspend Versus Sensor-Augmented Pump Therapy in The Management of Type 1 Diabetes [Session #026]. Vienna, Austria: 11th Annual Advanced Technologies and Treatments for Diabetes Conference; 2018. 2. Zhong A, Choudhary P, McMahon C, et al. Effectiveness of Automated Insulin Management Features of the MiniMed® 640G Sensor-Augmented Insulin Pump. Diabetes Technol Ther. 2016;18(10):657-663. 3. Choudhary P, Olsen BS, Conget I, et al. Hypoglycemia Prevention and User Acceptance of an Insulin Pump System with Predictive Low Glucose Management. Diabetes Technol Ther. 2016;18(5):288-291. 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 hypoglycaemic event. It's recommended users always use the components of the pump system (pump, cartridges, CGM, and infusion sets) according to the applicable instructions for use and check them regularly to make sure they are functioning as expected. Users should always pay attention to their symptoms, actively monitor and manage glucose levels and treat according to their healthcare professionals' recommendations. For detailed indications for use and safety information, call AMSL Diabetes on 1300 851 056 or visit amsldiabetes.com.au © 2020 Tandem Diabetes Care, Inc. All rights reserved. Tandem Diabetes Care is a registered trademark and t:slim X2 is a trademark of Tandem Diabetes Care, Inc. Dexcom, and Dexcom G6 are registered trademarks of Dexcom, Inc. in the United States and other countries. ARTG 304681. PR-100-431 August 2020