INSTRUCTIONS FOR USE

- 1 Download user's device to tconnect.tandemdiabetes.com -> Set report settings to Target Range 70-180 mg/dL
- 2 "Save and print" reports → 2 weeks → Select: a. Dashboard; b. Therapy Timeline; c. CGM Hourly; d. Device Settings
- 3 Follow this worksheet for step-by-step guidance on clinical assessment, user education and insulin dose adjustments. STEP 1 **BIG PICTURE** (PATTERNS) → STEP 2 **SMALL PICTURE** (REASONS) → STEP 3 **PLAN** (SOLUTIONS)
- 4 Give the After Visit Summary to the Control-IQ user after visit

PANTHERTOOL[™] for

CONTROL-IQ

t:slim X2 insulin pump with Control-IQ technology



OVERVIEW using CARES Framework

C How it CALCULATES

- A hybrid closed-loop system that uses CGM glucose data to adjust the basal insulin delivery by increasing, decreasing or suspending programmed basal rates
- Algorithm targets glucose levels 112.5-160 mg/dL
- Automatic correction boluses up to once per hour, 60% of a calculated correction dose

A What you can ADJUST

- Can change basal rates, I:C ratios, correction factors
- CANNOT change active insulin time (5 hours) or correction bolus target (110 mg/dL)
- •"Exercise Activity" targets glucose 140-160 mg/dL (to reduce insulin delivery)
- •"Sleep Activity" narrows glucose target to 112.5-120 mg/dL and prevents automated correction doses overnight.

R When to **REVERT** to open-loop

The system stays in hybrid closed-loop all the time except when CGM data is not available. Users must turn off Control-IQ if they want to use temporary basal rates.

E How to EDUCATE

See PANTHER**POINTERS** below as well as EDUCATEbullets found under STEP 3.

S SENSOR/SHARE characteristics

- Dexcom G6 sensor and transmitter: 10 day sensor life, factory calibrated, can be used for diabetes management decisions without BG check.
- User can connect Dexcom transmitter to the Dexcom G6 app on a phone and share data with others using Dexcom Follow app.
- Sensor glucose levels auto-populate into bolus calculator



Focus on behavior: Wearing the CGM consistently, giving all boluses, etc.



Set the Sleep Schedule for every night.



Make sure user is bolusing before all meals and snacks.

When adjusting insulin pump settings, focus primarily on I:C ratios and correction factors.

STEP 1 **BIG PICTURE** (PATTERNS)

н	ighest Blood Glucose	Average Blood Glucose	Lowest	Blood Glucose	
	300	214	16	50	
lood Glucose Sumi	mary				
bove Target > 180	mg/dL			60% 3 times	
arget Range 70 - 1	80 mg/dL			40% 2 times	
Below Target < 70 m	ng/dL			0% 0 times	
- 21			Time in Use	96% 13 d 1:	
	01 18 ⁻	1 56	Control-IQ Set to Off CGM Inactive ¹		min. min.
Time in Range	Ģ		Control-IQ Set to Off CGM Inactive ¹ Pump Inactive ² Avg. Sleep & Exercise	0% 0% 3% 8 hrs. 40 1% 4 hrs. 37	min. min. min.
Time in Range Above Target Target Range			Control-IQ Set to Off CGM Inactive ¹ Pump Inactive ²	0% 0 3% 8 hrs. 40 r 1% 4 hrs. 37 r 8 hrs. 20 r	min. min. min.
Time in Range Above Target Target Range Below Target	45% 55% 0% <70 mg/dL 70 - 180 mg/dL 70 - 180 mg/dL	Number of Days CGM in Use	Control-IQ Set to Off CGM Inactive ³ Pump Inactive ³ Any, Steep & Exercise Daily Steep Weekly Exercise Events	0% 0 3% 8 hrs. 40 r 1% 4 hrs. 37 r 8 hrs. 20 r	min. min. min.
Time in Range Above Target Target Range Below Target Average Daily Insu	45% 55% 0% <70 mg/dL 70 - 180 mg/dL 70 - 180 mg/dL	Number of Days CGM in Use	Control-IQ Set to Off CGM Inactive ¹ Pump Inactive ² Avg. Sleep & Exercise Daily Sleep	0% 0 0 336 8 hrs. 40 1% 4 hrs. 37 6 8 hrs. 20 0 6	min. min. min. imes
Time in Range Above Target Target Range Below Target Average Daily Insu	45% 55% 0% <70 mg/dL 70 - 180 mg/dL 70 - 180 mg/dL	Number of Days CGM in Use	Control-IQ Set to Off CGM Inactive ¹ Pump Inactive ² Avg. Sleep & Exercise Daily Sleep		9% 0 3% 8 hrs. 40 1% 4 hrs. 37 8 hrs. 20



A) Is the person using the Control-IQ system?

The goal is to use Control-IQ as much as possible.

Time in Use (How often Control-IQ in use):

Aim for > 90%. If less, ASSESS why.

CGM Inactive (Time sensor not active):

Aim for < 10%. If more, ASSESS why.

Daily Sleep (For tighter glucose targets overnight)

Make sure this averages 6 hours or more per day

- →If not, check pump settings to turn on "Sleep Schedule" and select all days
- Skin problems or difficulty wearing sensor on body?
 - →Rotate sensor insertion sites (arms, hips, buttocks, abdomen)
 - →Use barrier preps, tackifiers, overtapes, or adhesive remover wipes as necessary
- Problems getting cgm data on pump?
 - →Wear pump on same side of body as CGM transmitter (to improve line of sight of Bluetooth)
 - →Carry pump with screen facing outward (away from body)

B Is the user giving meal boluses?

If food bolus is <50% total insulin, ASSESS for missed meal boluses or insufficient CHO ratios.

C) Is the user meeting Glycemic Targets?

Time in Range (TIR)	Goal is >70%
70-180 mg/dL (3.9-10.0 mmol/L) "Target	Range"

Time Below Range (TBR)	Goal is <4%
<70 mg/dL (< 3.9 mmol/L) "Below Target"	

Time Above Range (TAR) Goal is <25% >180 mg/dL (>10.0 mmol/L) "Above Target"

D What are their patterns of hyperglycemia and/or hypoglycemia?

Use CGM Hourly to understand mean CGM throughout day. Longer whiskers = more variability. Focus on the areas where the average glucose is out of target range.

Hyperglycemia patterns: (eg: high glycemia at bedtime)

Hypoglycemia patterns:

PANTHER**POINTERS**™ FOR CLINICIANS



The goal of this therapy review is to increase Time in Range (70-180 mg/dL) while minimizing Time Below Range (<70 mg/dL)

Is the Time Below Range **more** than 4%? If **YES**, focus on fixing patterns of **hypoglycemia** If **NO**, focus on fixing patterns of **hyperglycemia**

Use the **Therapy Timeline** and discussion with the user to identify causes of the glycemic patterns identified in STEP 1 (hypoglycemia or hyperglycemia).



ASSESS Bolus Behavior

Estimate # food boluses per day by counting light blue boluses with CHO amount listed (red arrows).

Do not count autocorrections ().

On average, how many food boluses are given each day? (red arrows)

Identify the predominant 1-2 causes of the hypo- or hyperglycemia pattern.

Is the hypoglycemia pattern occurring:	Is the hyperglycemia pattern occurring:
Fasting/Overnight?	Fasting/Overnight?
Around mealtime? (1-3 hours after meals)	Around mealtime? (1-3 hours after meals)
Where low glucose levels follow high glucose levels?	Where high glucose levels follow low glucose levels?
Around or after exercise?	After a correction bolus was given? (1-3 hours after correction bolus)

Hypoglycemia		Hyperglycemia
SOLUTION	PATTERN	SOLUTION
Reduce basal rates 10-20% in 1-2 hours prior to hypoglycemia	Fasting / Overnight	Make sure Sleep Schedule is turned on every night Increase basal rates 10-20% in 1-2 hours prior to hyperglycemia
Assess carb counting accuracy, bolus timing, and meal composition. Weaken I:C Ratios by 10-20% (e.g. if 1:10, change to 1:12)	Around mealtime (1-3 hours after meals)	Assess if meal bolus was missed. If yes, educate to give all meal boluses prior to eating. Assess carb counting accuracy, bolus timing, and meal composition. Strengthen I:C Ratios by 10-20% (e.g. from 1:10 to 1:8)
If due to bolus calculator over- rides: Educate user to follow the bolus calculator and avoid overriding to give more than recommended. There may be a lot of IOB from AID that user is not aware of. Bolus calculator factors in IOB from increased AID when calculating correction bolus dose. Weaken correction factor by 10- 20% (e.g. if 50, change to 60) if hypos 2-3 hours after correction bolus. This will impact both user-given and auto-correction boluses.	Where low glucose follows high glucose	Educate to treat mild hypoglycemia with fewer grams of carbs (5-10g)
Use the Exercise Activity feature 1-2 hours before exercise begins. This will temporarily reduce insulin delivery aiming to reduce risk of hypoglycemia. To use Exercise Activity, go to: Main Menu → Activity → Exercise → start	Around or after exercise	
	After a correction bolus was given (1-3 hours after correction bolus)	Strengthen correction factor (e.g. from 50 to 40). This will impact both user-given and auto-correction boluses

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ADJUST insulin pump settings and EDUCATE.

Most impactful insulin dose settings to change:

- 1. I:C Ratios It is common to need stronger I:C Ratios with AID
- 2. Correction Factor Will affect both user-given correction boluses and auto-correction doses given by the system
- 3. Basal Rates Will affect fasting glucose levels

NOTE: Cannot change Target BG (fixed at 110 mg/dL) or Active Insulin time when Control-IQ is active

1 Profile	Öptions → I	Options \rightarrow My Pump \rightarrow Personal Profiles		
Start Time	Basal Rate	Correction Factor	Carb Ratio	Target B0
Midnight	1.050 u/hr	1u:44 mg/dL	1u:11.0 g	150 mg/d
3:00 AM	1.050 u/hr	1u:44 mg/dL	1u:11.0 g	150 mg/d
6:00 AM	0.950 u/hr	1u:35 mg/dL	1u:8.0 g	110 mg/d
10:00 AM	0.950 u/hr	1u:30 mg/dL	1u:8.0 g	110 mg/d
2:00 PM	0.950 u/hr	1u:30 mg/dL	1u:7.0 g	110 mg/d
5:00 PM	1.000 u/hr	1u:30 mg/dL	1u:7.0 g	110 mg/d
9:00 PM	1.050 u/hr	1u:30 mg/dL	1u:8.0 g	150 mg/d
Calculated Total Daily Basal	23.9 units			

Alerts		Pump Settings
Alert: Auto-Off	On 16 hrs	Quick Bolus
Alert: Low Insulin	30 u	Max Bolus
Reminders		Basal Limit
Low BG	Off	Screen Timeour
High BG	Off	Options → My
		Control-IQ Settings

HYBRID CLOSED LOOP

Update "Weight" and "Total Daily insulin" on their insulin pump at each visit (used to determine max and min delivery constraints.)

uto-off Off 16 u 2.1 u/hr Pump → Control-IQ On Control IQ 130 lbs Total Daily Insulir 35 u leep Schedule 1 On Everyday 10:30 PM - 7:00 AM Off -- 11:00 PM - 7:00 AM Sleep Schedule 2 Options \rightarrow Activity \rightarrow Sleep Schedule \rightarrow Select Days \rightarrow Check all 7 days

AUTO-OFF

Consider setting "Auto-Off" to "Off".

If set to "On"-pump will suspend all insulin delivery IF the user has not pressed any buttons in the programmed time duration (i.e., 12 hours default). This may cause unnecessary/dangerous suspensions of insulin.

SLEEP SCHEDULE

Make sure Sleep Schedule is set for all seven days (to achieve tight glycemic control overnight).

EDUCATE ON BOLUS BEHAVIOR

- Do not override boluses to give more insulin than the pump recommends (may cause hypoglycemia due to automated insulin delivery).
- Bolus before eating. If bolusing after a meal, the user should reduce bolus as system has already been increasing insulin for hyperglycemia.
- Give correction boluses for hyperglycemia if recommended by the bolus calculator.

OTHER EDUCATION

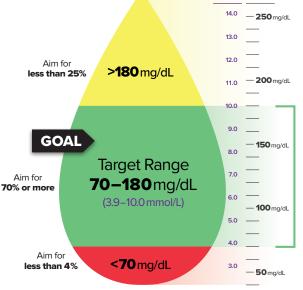
- Treat hypoglycemia with 5-10 g CHO since insulin may have been reduced/suspended for a period of time before hypoglycemia occurs.
- **Disconnecting**: If disconnected from the pump, SUSPEND insulin so Control-IQ calculate insulin-onboard accurately
- Infusion set failure: Change infusion set if unexplained persistent hyperglycemia. (i.e., >300 mg/dL for >90 min)

AFTER VISIT SUMMARY

Great job using Control-IQ!

Using systems like this can help you achieve better glucose control. Aim for more than **70%** of your CGM glucose levels to be between **70-180 mg/dL** (3.9–10.0 mmol/L). This is the goal for MOST people with type 1 diabetes. This is about the same as having an HbA1c level of 7%.





mmol/L

mg/dL

TIPS for using Control-IQ

- HYPERGLYCEMIA > 300 mg/dL (or >16.7 mmol/L) for 1.5–2 hours? Check ketones first! If ketones, give a syringe injection of insulin and turn off "Control-IQ" feature for 4 hours. Change infusion set.
- **Do not override boluses** to give more insulin than the pump recommends (may cause hypoglycemia due to automated insulin delivery).
- **Bolus before eating**. If bolusing after a meal, the user should reduce bolus as system has already been increasing insulin for hyperglycemia.
- Give correction boluses for hypergylcemia.
- **Read bolus prompts carefully**. If it states "Your BG is Below Target. Reduce Bolus Calculation?", press "NO" (or R) to get full amount of insulin for carbohydrates. Press "Yes" (or A) to subtract insulin.
- Try treating hypoglycemia with 5-10g CHO since insulin may have been reduced/suspended for a while before hypoglycemia occurs. Treating hypoglycemia with more than 5-10g may result in rebound hyperglycemia
- If disconnected from the pump, SUSPEND insulin so Control-IQ calculates insulin-on-board accurately
- Check "Auto-off" settings. Turn off or extend to 16 hours or longer.
- CHANGE INFUSION SET every 2-3 days, or as needed for persistent hyperglycemia.





Have questions about your insulin pump?

tandemdiabetes.com

Tandem customer and technical support **1-877-801-6901**

Have questions about your CGM?

dexcom.com

Dexcom customer support 1-888-738-3646

Dexcom technical support **1-844-607-8398**