Using the CARES Framework

A Clinical Guide to Advanced Diabetes Devices and Closed-Loop Systems

What is CARES?

The **CARES framework** was designed by diabetes researchers to better understand the differences and benefits of the various automated insulin delivery (AID) systems. This five-step framework asks pertinent questions designed to compare, understand, and ultimately choose the right AID therapy for users.

Scan to learn more information

t:slim X2 Insulin Pump with Control-IQ technology
vs. MiniMed 780G[1]

TANDEM Diabetes Care

Medtronic

Calculate	How does the algorithm calculate insulin delivery?
Adjust	How can insulin delivery be adjusted?
Revert	When will the system default to open loop (no automation)?
Educate	What are the critical education points?
Sensor/ Share	What are the key aspects of the systems' sensor and sharing capabilities?

1.Panther™ Diabetes Technology Deciphered.™ 23 May 2023, https://www.pantherprogram.org/device-comparison

Calculate

How does the algorithm calculate insulin delivery?

	Tandem	Medtronic
BASAL AUTOMATION	✓ Basal rate modulates when the 30-minute predicted glucose is outside of the treatment range and is calculated using a metabolic target	✓ Auto basal is calculated based on TDI delivery from past 2-6 days
BASAL AUTOMATION TREATMENT VALUES* / TARGET GLUCOSE	6.25-8.9 mmol/L 6.25-6.7 mmol/L 7.8-8.9 mmol/L	5.5, 6.1 or 6.7 mmol/L
BOLUS AUTOMATION	✓ Automatic Correction Bolus uses 30-minute predicted glucose value to deliver a 60% correction dose when expected to be ≥ 10.0 mmol/L†	✓ Auto-correction bolus Uses current and past glucose trends to determine dose and delivers if glucose > 6.7 mmol/L and at maximum "auto basal" delivery
BOLUS CORRECTION TARGET	6.1 mmol/L	6.7 mmol/L

0:05 PM
14 Nov
235 u
22
18
14
10
6
2
6.7 mmol/L
3 HRS
2.1 u
BOLUS

Control-IQ Technology and How it Works

Control-IQ technology **predicts glucose levels 30 minutes ahead** and automatically adjusts insulin every 5 minutes.

Helps Prevent Lows
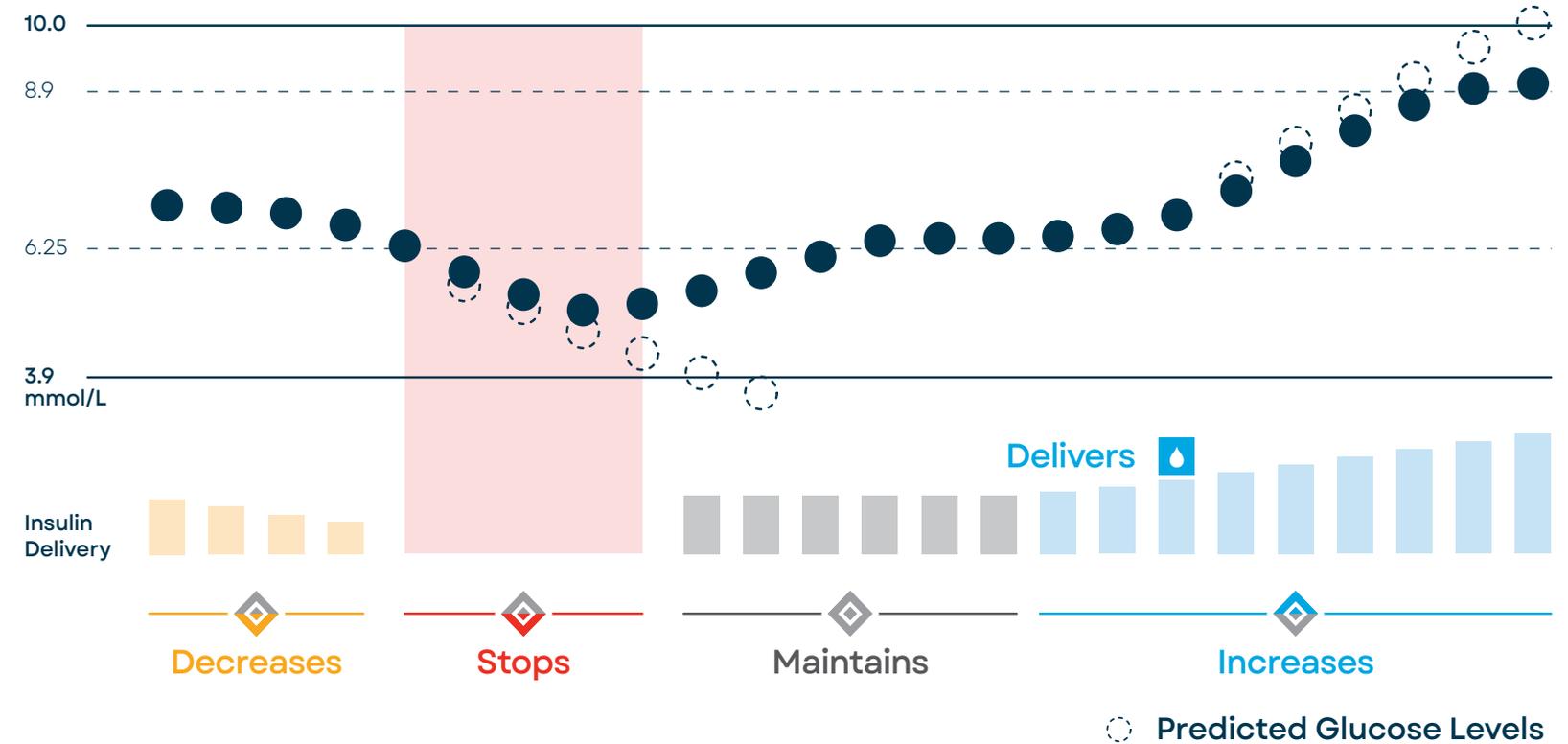Decreases or stops basal insulin if sensor glucose is predicted to be low.

Helps Prevent Highs
Increases basal insulin and delivers automatic correction boluses† (🔵) if sensor glucose is predicted to be high.

Scan to see how
Control-IQ technology works

10.0

8.9

6.25

3.9
mmol/L

Insulin
Delivery

Delivers 🔵

Decreases   **Stops**   **Maintains**   **Increases**

Predicted Glucose Levels

How Do You Treat High Glucose?

○ Increase Basal Insulin

○ Give a Correction Bolus

✓ **Control-IQ technology does both!**

Adjust

How can insulin delivery be adjusted?

Tandem

MODIFIABLE INSULIN SETTINGS THAT IMPACT AUTOMATION	
✓	Basal Rate
✓	Correction Factor
✗	Active Insulin Time
✗	Correction Target

EXTENDED BOLUS ✓

EDIT CALCULATED BOLUS DOSE ✓

SPECIAL FEATURES

Sleep Activity
Changes treatment values
to 6.25-6.7 mmol/L

Exercise Activity
Changes treatment values
to 7.8-8.9 mmol/L

Mide
diagnosed 2012

Medtronic

✗	Basal Rate
✗	Correction Factor
✓	Active Insulin Time
✗	Correction Target

✗

✗

Temp Target
Changes algorithm target
to 8.3 mmol/L

Control-IQ Technology Aims to Increase the Time Spent in Range between 3.9-10.0 mmol/L

Sleep Activity

Sets a lower range of treatment values (6.25-6.7 mmol/L) without delivering automatic correction boluses.[†] This feature is designed to achieve glucose levels of approximately 6.1-6.7 mmol/L during a fasting state.

Who may benefit from Sleep Activity all day?

+ Those wanting basal modulation to occur with the tighter range of treatment values
+ People not wanting automatic correction boluses[†]
+ Users willing to give manual corrections as necessary

Sleep Schedule during the night

Sleep Schedule all day

HELPFUL TIP

Automatic correction boluses[†] may be more helpful in certain situations as opposed to basal modulation only.

Consider the following when setting a Sleep Schedule to optimize start and stop times:

+ Start Sleep 1-2 hours after the last snack or meal
+ Stop Sleep prior to waking
+ Turn Sleep off during times of high stress or growth spurts

Exercise Activity

Sets a higher range of treatment values (7.8-8.9 mmol/L) that are designed to accommodate the likely natural drop in glucose during and following exercise.
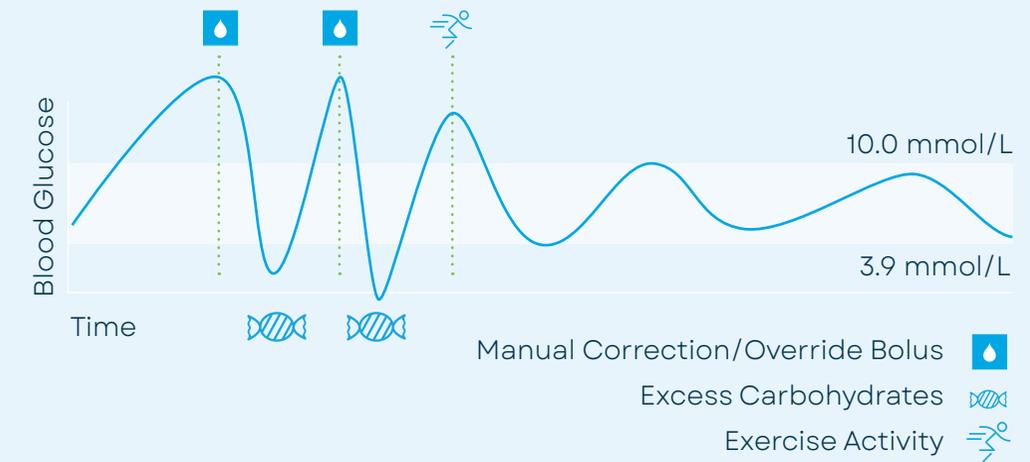
Alternative uses for additional hypoglycemia protection:

+ Intermittent fasting
+ NPO for medical procedure
+ Nausea or vomiting
+ Hypoglycemia unawareness
+ Fear of hypoglycemia
+ Those who are older or at high-risk
+ Alcohol consumption

EXERCISE STARTED

HELPFUL TIP

Turn on Exercise Activity as a temporary reset for glycemic variability and ease off the rollercoaster

Blood Glucose

Time

10.0 mmol/L

3.9 mmol/L

Manual Correction/Override Bolus

Excess Carbohydrates

Exercise Activity

Revert

When will the system default to open loop (no automation)?

Tandem

No CGM data ≥ 20 min

(Defaults to Personal Profile settings and Control-IQ technology automatically resumes when CGM‡ connection is restored)

Flashing yellow light and **Out of Range** alert notify the user that safety conditions may need attention.

OUT OF RANGE ALERT

Transmitter out of range for 20 min.

CLOSE

Medtronic

Safe-Basal
(static basal rate determined by the system without glucose-dependent adjustment)

Possible triggers include:
+ System concerns about sensor accuracy
+ Max/min delivery constraints
+ Loss of CGM data

Manual Mode
(no automation)

Possible triggers include:
+ Triggered after four hours in Safe-Basal mode

# Today's doses shouldn't be based on yesterday's activities.

Control-IQ technology

Customize insulin dosing using an alternate Personal Profile.

Up to six Personal Profiles can be created to personalize anticipated changes in insulin requirements.

+ Illness
+ Steroids
+ Menstruation
+ Vacation
+ Summer Camp

Personal Profiles

Pump Settings

Mon-Fri   OFF

Long Run   ON

Medication   OFF
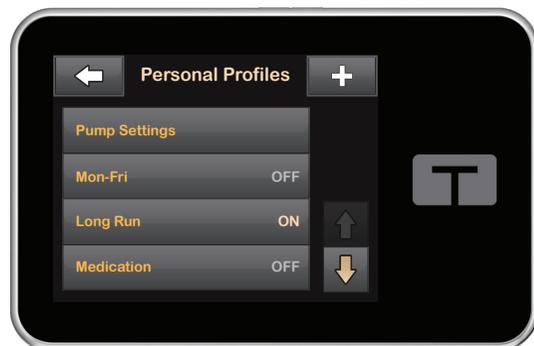
Today

10 AM	
11 AM	**Mon-Fri** Personal Profile
12 PM	
1 PM	
2 PM	
3 PM	
4 PM	
5 PM	**Long Run** Personal Profile
6 PM	

Personal Profile	Mon-Fri	Long Run
Basal Rate	0.8 units	0.4 units
Carb Ratio	9 grams	9 grams
Correction Factor	2.2 mmol/L	4.4 mmol/L

Doses are for illustrative purposes only.

Educate

What are the critical education points?

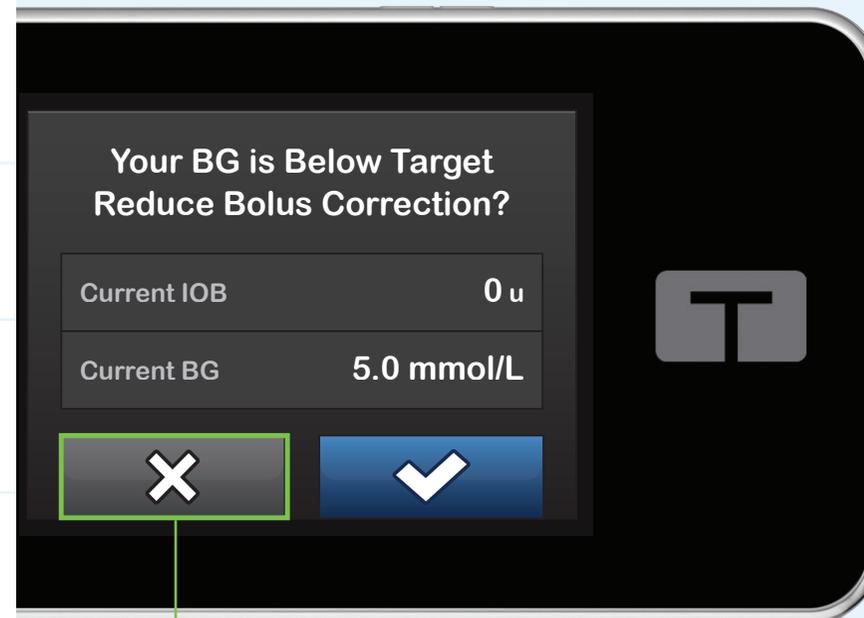|	**Tandem**		**Medtronic**
MEALTIME	For sensor glucose < 6.1 mmol/L, consider declining prompt: *"Your BG is **Below** Target **Reduce** Bolus Calculation?"*		Potential need to strengthen carb ratio
OVERNIGHT	**Sleep Activity** Schedule		For insulin sensitive users, consider setting a temp target to prevent hypoglycemia
EXERCISE	**Exercise Activity** and/or **Personal Profiles**		Temp Target
OTHER CONSIDERATIONS			+ **Unable to deliver** manual correction doses + Follow prompts for BG Required to stay in SmartGuard

Your BG is Below Target Reduce Bolus Correction?

Current IOB	0 u
Current BG	5.0 mmol/L

✕   ✓

Consider declining prompt to reduce bolus

How to Prevent and Treat Hypoglycemia

BOLUSING TIPS

Bolus with success
Use the recommended bolus doses because additional insulin may have been delivered by the algorithm. Check insulin on board (IOB) before overriding dose recommendations.

Bolus before start of meal
If bolus is given after meal, then the algorithm may have increased insulin delivery and can cause hypoglycemia if bolus dose is not adjusted appropriately.

+ 30-60 min after start of meal: Deliver half of recommended bolus[1]

+ >60 min after start of meal: Deliver system-recommended correction bolus[1] only

HELPFUL TIP

The longer insulin has been suspended, the **fewer carbohydrates (5-10 g) are likely needed** to treat low glucose

Carbohydrate

15 g

5 g

Time of Insulin Suspension

Grams of Carbohydrate
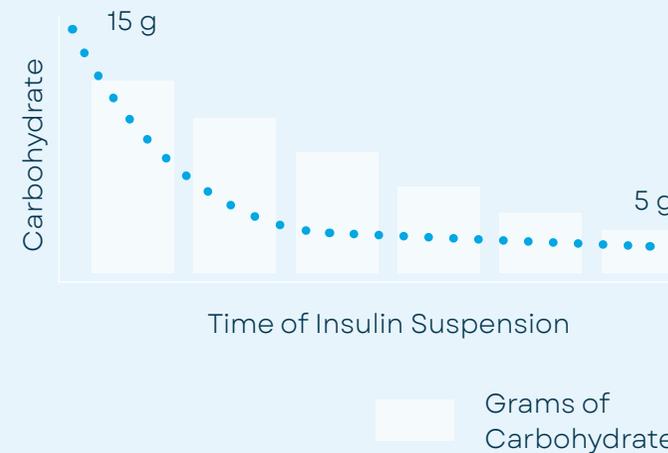
Examples of some foods and the carbs they contain.

= 5 Grapes
5 g Carbs

= 1-2 Glucose Tabs
5-10 g Carbs

= 75-125 ml of Juice
10-15 g Carbs

Amounts are approximate

Sensor/Share

What are the key aspects of the systems' sensor and sharing capabilities?

	Tandem	Medtronic
COMPATIBLE CGM	Dexcom G6	Guardian 4
SENSOR WEAR TIME	10 days	7 days
NO CALIBRATION REQUIRED	✓	⊗ Required to enter automation and as system prompts
SENSOR WARM UP TIME	2 hours	Up to 2 hours
SENSOR ACCURACY	MARD[2]§ 9%	MARD[3]§ Adults 10.6% Peds 11.6%
SHARE FEATURE	✓ Dexcom G6 Follow App	✓ CareLink Connect App

Responsible Use of Control-IQ Technology
Control-IQ technology does not prevent all high and low blood glucose events, and is not a substitute for meal boluses and active self-management of diabetes. Control-IQ technology will not be able to predict sensor glucose values and adjust insulin dosing if a user's CGM is not working properly or is unable to communicate with their pump. Users should be instructed to always pay attention to their symptoms and blood glucose levels and treat accordingly. Please visit tandemdiabetes.com/tslimX2-use for more information.

*Personal Profile settings are delivered when the 30-minute predicted glucose is within the treatment range. †If glucose values are predicted to be above 10.0 mmol/L, Control-IQ technology calculates a correction bolus using the Personal Profile settings and a target of 6.1 mmol/L and delivers 60% of that value. ‡CGM sold separately. §Mean absolute relative difference (MARD) is a statistical measure of accuracy.

References 1. Phillip M, Nimri R, Bergenstal RM, et al. Consensus Recommendations for the Use of Automated Insulin Delivery Technologies in Clinical Practice. *Endocr Rev.* 2023;44(2):254-280. doi: 10.1210/endrev/bnac022. 2. Beck RW, Riddlesworth T, et al. Effect of Continuous Glucose Monitoring on Glycemic Control in Adults with Type 1 Diabetes Using Insulin Injections – The DIAMOND Randomized Clinical Trial. *JAMA.* 2017;317(4):371-378. doi: 10.1001/*jama*.2016.19975. 3.Christiansen MP, Garg SK, Brazg R, et al. Accuracy of a Fourth-Generation Subcutaneous Continuous Glucose Sensor. *Diabetes Technol Ther.* 2017;19(8):446-456. doi: 10.1089/dia.2017.0087.

Important Safety Information: The t:slim X2 insulin pump with Control-IQ technology (the System) consists of the t:slim X2 insulin pump, which contains Control-IQ technology, and a compatible continuous glucose monitor (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 people requiring insulin. The t:slim X2 insulin pump can be used solely for continuous insulin delivery and as part of the System. When used with a compatible CGM, the System can be used to automatically increase, decrease, and suspend delivery of basal insulin based on CGM sensor readings and predicted glucose values. The System can also deliver correction boluses when the glucose value is predicted to exceed a predefined threshold. The pump and the System are indicated for use in individuals six years of age and greater. The pump and the System are intended for single user use. The pump and the System are indicated for use with U-100 insulin only. The System is intended for the management of Type 1 diabetes.

WARNING: Control-IQ technology should not be used by anyone under the age of six years old. It should also not be used in users who require less than 10 units of insulin per day or who weigh less than 25 kilograms.

The System is not indicated for use in pregnant women, people on dialysis, or critically ill users. Do not use the System if using hydroxyurea.

Users of the pump and the System must: be willing and able to 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 t:slim X2 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.

TANDEM Diabetes Care

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