INSTRUCTIONS FOR USE

- 1 Download user's device to My.Glooko.com → Set report settings to Target Range 70-180 mg/dL
- 2 Create reports → 2 weeks → Select: a. CGM Summary; b. Week View; and c. Devices
- 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)

PANTHERTOOL[™] for OMNIPOD 5



OVERVIEW using CARES Framework

C How it CALCULATES

- Automated basal insulin delivery calculated from total daily insulin, which is updated with each pod change ("adaptive basal").
- Calculates dose of insulin every 5 min based on glucose levels predicted 60 minutes into future.

A What you can ADJUST

- Can adjust the algorithm target (110, 120, 130, 140, 150 mg/dl) for adaptive basal.
- Can adjust I:C ratios, correction factors, active insulin time for bolus settings.
- Cannot change basal rates (programmed basal rates are not used in automated mode).

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

- System may revert to "Automated Mode: Limited" (static basal rate determined by system) for 2 reasons:
 - 1. If CGM stops communicating with pod for 20 min. Will resume full automation when CGM returns.
 - 2. If an "Automated Delivery Restriction" alarm occurs (insulin delivery suspended or at max delivery too long). Alarm must be cleared by user and enter manual mode for 5 min. Can turn "automated mode" back on after 5 minutes.

E How to EDUCATE

- Bolus before eating, ideally 10-15 minutes prior.
- Tap "Use CGM" in bolus calculator to add glucose value and trend into bolus calculator.
- Treat mild hypoglycemia with 5-10g carb to avoid rebound hyperglycemia and WAIT 15 min before re-treating to give glucose time to rise.
- Infusion site failure: Check ketones and replace pod if unexplained hyperglycemia persists (e.g. >300 mg/dL for > 90 min) despite correction bolus. Give syringe injection for ketones.

S SENSOR/SHARE characteristics

- Dexcom G6 which require no calibrations.
- Must use G6 mobile app on smartphone to start CGM sensor (cannot use Dexcom receiver or Omnipod 5 controller).
- Can use Dexcom Share for remote monitoring of CGM data.

PANTHER**POINTERS**[™] FOR CLINICIANS



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



When adjusting insulin pump settings, focus primarily on algorithm target and I:C ratios.



To make system more aggressive: Lower the algorithm target, encourage user to give more boluses and intensify bolus settings (e.g. I:C ratio) to increase total daily insulin (which drives the automation calculation).



Avoid overthinking the automated basal delivery. Focus on the overall Time in Range (TIR), and optimizing system use, bolus behaviors and bolus doses.





This <u>PANTHERprogram.org</u> tool for Omnipod 5 was created with the support of <u>danatech</u>. CGM Summary Report to assess system use, glycemic metrics, and identify glucose patterns.

A Is the person using the CGM consistently?

% Time CGM Active:

If <90%, discuss why:

- Problems accessing supplies/sensors not lasting 10 days?
 →Contact Dexcom for replacement sensors
- Skin problems or difficulty keeping sensor on?
 - →Rotate sensor insertion sites (arms, hips, buttocks, abdomen)
 - →Use barrier products, tackifiers, overtapes and/or adhesive remover to protect skin
- Problems with CGM-Pod connectivity?
 - Place pod and CGM on same side of body/in "line of sight" to aid the Bluetooth communication between pod and CGM

B) Is the person using Automated Mode?

Automated Mode %:

If <90%, assess why:

Emphasize goal is to use automated mode as much as possible

Automated:Limited %:

If >5%, assess why:

- Due to gaps in CGM data?
 Review device placement: wear pod and CGM in "line of sight" to optimize pod-CGM communication
- Due to automated delivery restriction (min/max delivery) alarms?
 - Educate user to clear alarm, check BG to as needed, and after 5 minutes switch mode back to Automated Mode (will not return to Automated automatically)

C) Is the user giving boluses for meals?

Is the user giving at least 3 "Diet Entries/Day" (boluses with CHO added)?

→If not, ASSESS for missed meal boluses



D 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%

 Time Below Range (TBR)

 <70 mg/dL (< 3.9 mmol/L) "Low" + "Very Low"</td>

Time Above Range (TAR)	Goal is < 25%
>180 mg/dL (>10.0 mmol/L) "Hig	h" + "Very High"

(E) What are their patterns of hyperglycemia and/or hypoglycemia?

Ambulatory Glucose Profile compiles all data from reporting period into one day; shows median glucose with the blue line, and variability around the median with the shaded ribbons. Wider ribbon = more glycemic variability.

Identify the overall patterns by primarily focusing on the dark blue shaded area.

Hyperglycemia patterns: (eg: high glycemia at bedtime)

Hypoglycemia patterns:

PANTHER**POINTERS**™ FOR CLINICIANS

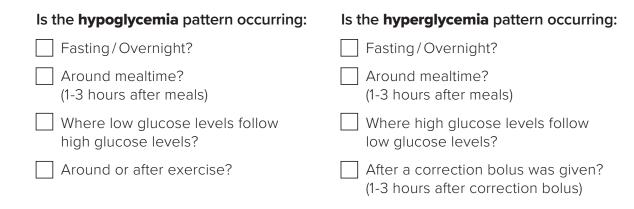


The goal of this therapy review is to increase Time in Range (70-180 mg/dL) while minimizing Time Below Range (<70 mg/dL)

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



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



Hypoglycemia		Hyperglycemia
SOLUTION	PATTERN	SOLUTION
Raise BG target (algorithm target) overnight	Fasting / Overnight	Lower BG Target overnight (lowest is 110 mg/dL)
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 the meal bolus was missed. If yes, educate on giving all meal boluses prior to eating. Strengthen I:C Ratio 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 1:50, change to 1:60) if hypos 2-3 hours after correction bolus.	 Where low glucose follows high glucose Where high glucose follows low glucose Image: State of the state of th	Educate to treat mild hypoglycemia with fewer grams of carbs (5-10g)
Use the Activity Feature 1-2 hours before exercise begins. Activity Feature will temporarily reduce insulin delivery aiming to reduce risk of hypoglycemia. To use activity feature, go to Main Menu -> Activity Feature	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)



ADJUST insulin pump settings and EDUCATE.

Most impactful insulin dose settings to change:

- 1. Target Glucose (for adaptive basal) Options: 110, 120, 130, 140, 150 mg/dL Can program different targets for different times of day
- 2. I:C Ratios It is common to need stronger I:C Ratios with AID
- 3. Correction Factor & Active Insulin Time These will only influence bolus calculator doses; has no impact on automated insulin

To change settings, tap the main menu icon ≡ in top-left corner of **Omnipod 5** app: → Settings → Bolus

General		Bolus	
Active Insulin Time	3 hours	Min BG for Bolus Calc	70 mg/dL
Unit of Measurement	mg/dL	Extended Bolus	ON
		Reverse Correction	ON
	d Max Basal settings and NOT relevant to ode	Max Bolus	13 U
Max Basal Rate	1.5 U/hour		
Temporary Basal Enabled	OFF		Change Insulin:Carb Ratios in bolus settings in pump
Basal Profile		Insulin : Carb Ratios	
Basal 1 (Active)		Profile (Active)	
12:00 AM (24 hr)	0.85 Units/hr	12:00 AM (6 hr)	15 g/Unit
Total 20.4 Ur	20.4 Units	6:00 AM (3 hr)	10 g/Unit
		9:00 AM (4 hr)	9 g/Unit
		1:00 PM (2 hr)	11 g/Unit
		3:00 PM (4 hr)	10 g/Unit
		7:00 PM (5 hr)	10 g/Unit
Sensitivity (ISF, Correction	on)	BG Target Range	
Profile (Active)		Profile (Active)	
12:00 AM (20.5 hr)	45 mg/dL	12:00 AM (24 hr)	110 mg/dL (+0/-0)
8:30 PM (3.5 hr)	50 mg/dL		
Change Sensi BG Corre in bolus setting Profile (Acuve)	tivity (ISF, Correction) gs in pump	auto pr	nge BG Target Range for omation and correction target ogrammed in bolus settings ump
12:00 AM (24 hr)	110 mg/dL		



Great job using **Omnipod 5!**

Using this system can help you achieve your diabetes goals.

The American Diabetes Association suggests aiming for **70%** of your glucose levels to be between **70-180 mg/dL** (3.9–10.0 mmol/L), called **Time in Range** or **TIR**. If you are not currently able to reach 70% TIR, don't be discouraged! Start from where you are and set smaller goals to increase your TIR. Any increase in your TIR is beneficial to your lifelong health!

REMEMBER...
Don't overthink what the Omnipod 5 is doing in the background.
Focus on what *you* can do. See helpful tips below...

TIPS for Omnipod 5

- HYPERGLYCEMIA >300 mg/dL (>16.7 mmol/L) for 1-2 hours? Check ketones first! If ketones, give <u>syringe</u> injection of insulin and replace pod.
- Bolus before eating, ideally 10-15 minutes before all meals and snacks.
- Do not override the bolus calculator: Correction bolus doses may be smaller than expected due to insulin on board from the adaptive basal.
- Give correction boluses for hyperglycemia: Tap "Use CGM" in bolus calculator to add glucose value and trend into bolus calculator.
- **Treat mild hypoglycemia with 5-10g carb** to avoid rebound hyperglycemia and WAIT 15 min before re-treating to give glucose time to rise. System will have likely suspended insulin, resulting in little insulin on board when hypoglycemia occurs.
- Wear POD and CGM on same side of body so they don't lose connection.
- Clear "Delivery Restrictions" alarms immediately, troubleshoot hyper/hypo, confirm CGM accuracy and switch back to automated mode.





Have questions about the Omnipod 5?

omnipod.com

Omnipod customer support 1-800-591-3455

Have questions about your CGM?

dexcom.com

Dexcom customer support 1-888-738-3646

Dexcom technical support **1-844-607-9398**

PANTHERprogram.org

13.0 12.0 Aim for >180 mg/dL less than 25% — **200** mg/dL 11.0 10.0 9.0 GOAL 150 ma/dL 8.0 Target Range 7.0 Aim for 70–180 mg/dL 70% or more 6.0 (3.9-10.0 mmol/L) - 100 ma/dl 5.0 4.0 Aim for <70 mg/dL less than 4% 3.0 — **50** mg/dL

mmol/L

14.0

mg/dL

- 250 ma/dL