PANTHERTOOL® for

OMNIPOD® 5

Automated Insulin Delivery System

INSTRUCTIONS FOR USE

1 View reports at My.Glooko.com → Set report settings to Target Range 3.9-10.0 mmol/L

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)

OVERVIEW using C|A|R|E|S Framework

C | How it **CALCULATES**

- Automated basal insulin delivery calculated from total daily insulin, which is updated with each Pod change (adaptive basal rate). The algorithm assumes that basal is ~50% TDI.
- Calculates a micro-dose of insulin every 5 min based on glucose levels predicted 60 minutes into future, aiming for the chosen target glucose. Algorithm will increase doses up to 400% to correct hyperglycemia and decrease or pause insulin delivery when predicted to drop below the target glucose.

A | What you can **ADJUST**

- Can adjust the algorithm's Target Glucose (6.1, 6.7, 7.2, 7.8, 8.3 mmol/L).
- Can adjust I:C ratios, correction factors, and active insulin time for bolus settings.
- Cannot change basal rates (programmed basal rates are not used in Automated Mode, only used in Manual Mode).

R | When it **REVERTS** to manual mode

- System may revert to Automated Mode: Limited (static basal rate determined by the system; not based on CGM value/trend) 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. User must turn Automated Mode back on after 5 minutes in Manual Mode.

E | How to **EDUCATE**

- Bolus before eating, ideally 10-15 minutes prior. Consider use of the Custom Foods feature to simplify carb counting.
- Tap Use SENSOR in bolus calculator to add glucose value and trend into bolus calculator.
- Treat mild hypoglycemia with 5-10g carbs 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. >14 mmol/L for > 2 hours) despite correction bolus. Give syringe injection for ketones.

S | **SENSOR/SHARE** characteristics

Check your country's user guide for compatible sensor availability

- Dexcom G6, G7 and FreeStyle Libre 2 Plus.
- Must use Dexcom G6 or G7 mobile app on smartphone to start sensor (cannot use Dexcom receiver or Omnipod 5 Controller).
- Can use Dexcom Share for remote monitoring of sensor data; separate Follow app required.
- Must use Omnipod 5 Controller to start FreeStyle Libre 2 Plus Sensor. No remote data sharing with FreeStyle Libre 2 Plus.

PANTHERPOINTERS® FOR CLINICIANS

1. Focus on behavior: wearing the CGM consistently, giving all boluses, etc.
2. When adjusting insulin pump settings, focus primarily on Target Glucose and I:C ratios.
3. To make the system more aggressive: lower the Target Glucose, 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).
4. Avoid overthinking the automated basal delivery. Focus on the overall Time in Range (TIR), and optimizing system use, bolus behaviors, and bolus doses.

PANTHER®
Diabetes Technology. Deciphered.

This PANTHER Program® tool for Omnipod® 5 was created with the support of Insulet

View the CGM Summary Report to assess system use, glycemic metrics, and identify glucose patterns.

A Is the person using the CGM and Automated Mode?

% Time CGM Active: _____

If <90%, discuss why:

- Problems accessing supplies/sensors not lasting the full wear period?
  → Contact sensor manufacturer 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

SCAN TO VIEW:
pantherprogram.org/skin-solutions

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 on same side of body / 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 as needed, and after 5 minutes switch mode back to Automated Mode (will not return to Automated Mode automatically)

B Is the user giving meal boluses?

Number of Diet Entries/Day? _____
Is the user giving at least 3 "Diet Entries/Day" (boluses with carbs added)?

→ If not, ASSESS for missed meal boluses

C Is the user meeting Glycemic Targets?

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

Time Below Range (TBR) _____ Goal is <4%
<3.9 mmol/L (<70 mg/dL) "Low" + "Very Low"

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

D 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.

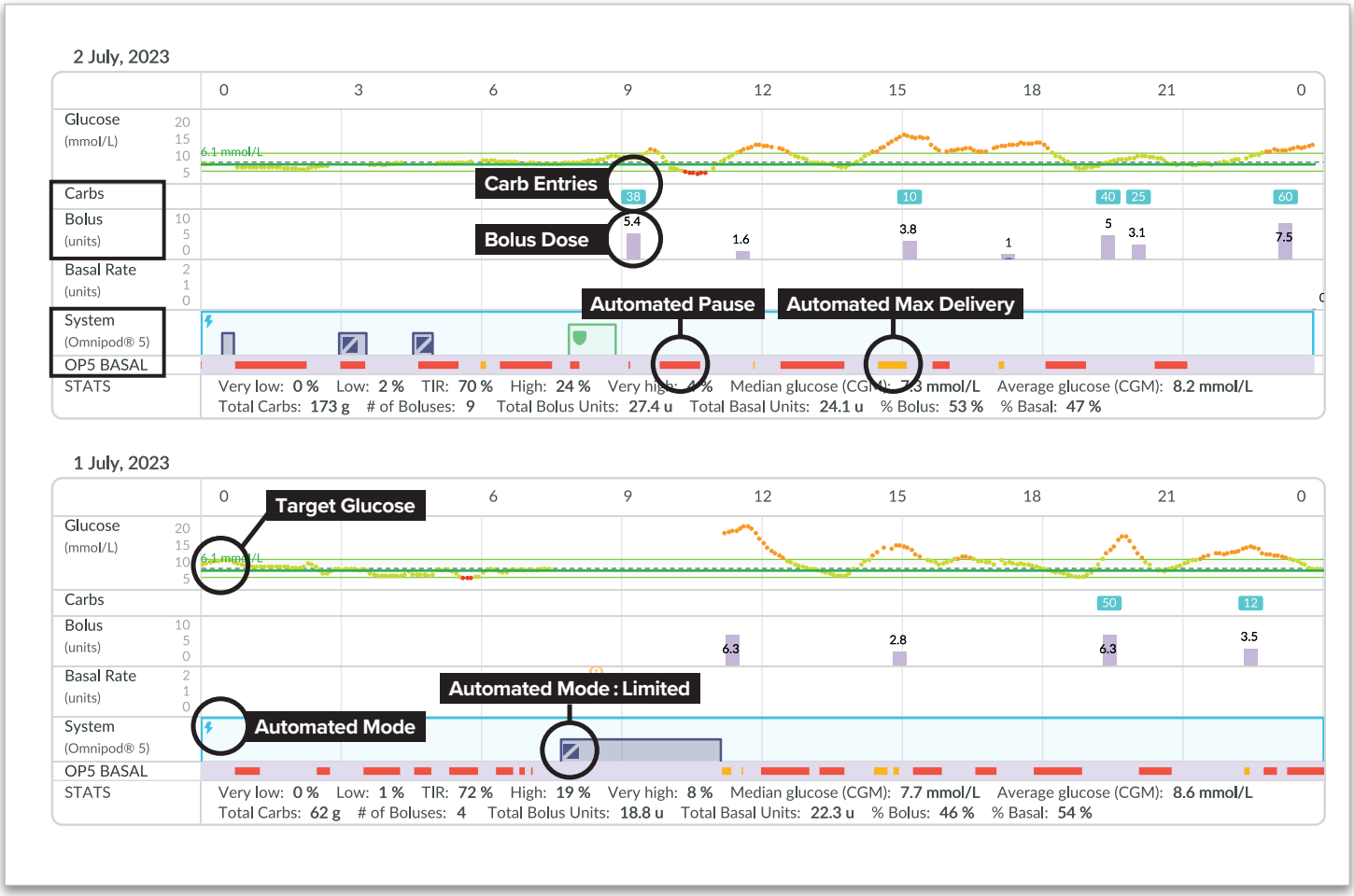
Hyperglycemia patterns: (eg: high glycemia at bedtime)

Hypoglycemia patterns:

PANTHERPOINTERS® FOR CLINICIANS

1. The goal of this therapy review is to increase Time in Range (3.9-10.0 mmol/L) while minimizing Time Below Range (<3.9 mmol/L)
2. 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.

Is the **hypoglycemia** pattern occurring:

- ☐ Fasting / Overnight?
- ☐ Around mealtime? (1-3 hours after meals)
- ☐ Where low glucose levels follow high glucose levels?
- ☐ Around or after exercise?

Is the **hyperglycemia** pattern occurring:

- ☐ Fasting / Overnight?
- ☐ Around mealtime? (1-3 hours after meals)
- ☐ Where high glucose levels follow low glucose levels?
- ☐ After a correction bolus was given? (1-3 hours after correction bolus)

Hypoglycemia		Hyperglycemia
SOLUTION	**PATTERN**	**SOLUTION**
Raise Target Glucose (algorithm target) overnight (highest is 8.3 mmol/L)	**Fasting / Overnight** 	Lower Target Glucose overnight (lowest is 6.1 mmol/L)
Assess carb counting accuracy, bolus timing, and meal composition. Weaken I:C Ratios by 10-20% (e.g. if 1:10g, change to 1:12g)	**Around mealtime** (1-3 hours after meals)  Consider use of Custom Foods feature to help simplify carb counting	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 1:10g to 1:8g)
If due to bolus calculator overrides, 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 1:2.8 mmol/L, change to 1:3.3 mmol/L) if hypoglycemia occurs 2-3 hours after a correction bolus.	**Low glucose follows high glucose** 	
	High glucose follows low glucose 	Educate to treat mild hypoglycemia with fewer grams of carbs (5-10g) and wait 15 min before re-treating to give glucose time to rise.
Use the Activity feature 1-2 hrs before exercise begins. Activity feature will temporarily reduce insulin delivery. It can be used during times of increased risk of hypoglycemia. To use Activity feature, go to Main Menu → Activity	**Around or after exercise** 	
	After a correction bolus was given (1-3 hours after correction bolus)	Strengthen correction factor (e.g. from 2.8 mmol/L to 2.2 mmol/L)

ADJUST insulin pump settings and EDUCATE.

Most impactful insulin pump settings to change:

1. **Target Glucose** Options: 6.1, 6.7, 7.2, 7.8, 8.3 mmol/L. Can program different targets for different times of day. Use the 6.1 mmol/L target for highest TIR.
2. **I:C Ratios** It is common to need stronger I:C Ratios with AID. Consider turning Reverse Correction OFF to avoid a reduction in meal bolus dose due to glucose value being below the target glucose.
3. **Correction Factor & Active Insulin Time** These are used for correction bolus doses.

Bolus settings are vital for optimal system performance to ensure the user is receiving sufficient TDI, which drives insulin automation. Ensure bolus settings are effective to optimize TIR.

To change settings, tap the main menu icon in the **Omnipod 5** App: **→ Settings → Bolus**

Extended Bolus **NOT** available in Automated Mode

Consider turning ***Reverse Correction*** OFF

Called ***Correction Factor*** in Omnipod 5 App

Basal rates and ***Max Basal Rate*** used in Manual Mode only, **NOT** used in Automated Mode. Temporary Basal Feature **NOT** available in Automated Mode.

Called ***Target Glucose*** in Omnipod 5 App

Called ***Correct Above*** in Omnipod 5 App. A correction bolus is calculated for glucose values above this value in the bolus calculator. For most aggressive bolus doses, set as the same value as target glucose.

Insulet Omnipod® 5 System

General

Active Insulin Time	2.5 hours

Basal

Max Basal Rate	2.5 U/hour
Temporary Basal Enabled	ON
Active basal program	Basal 1

Bolus

Min BG for Bolus Calc	3.9 mmol/L
Extended Bolus	ON
Reverse Correction	OFF
Max Bolus	14 U

Basal

Basal 1 Active

00:00 (24 hr)	0.75 Units/hr
Total	18 Units

Insulin:Carb ratios

Profile Active

00:00 (11 hr)	8 g/Unit
11:00 (4 hr)	8 g/Unit
15:00 (9 hr)	8 g/Unit

Sensitivity (ISF, correction)

Profile Active

00:00 (5 hr)	2.3 mmol/L
05:00 (6 hr)	2.3 mmol/L
11:00 (4 hr)	2.3 mmol/L
15:00 (9 hr)	2.3 mmol/L

BG target range

Profile Active

00:00 (24 hr)	6.1 mmol/L (+0/-0)

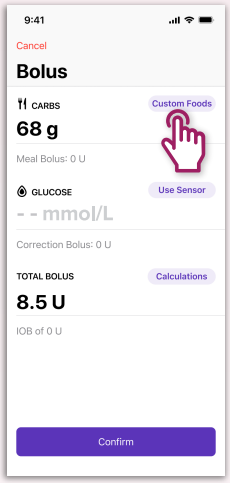
BG correction threshold

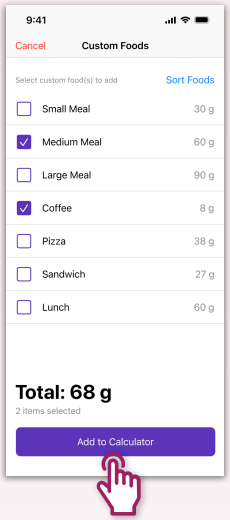
Profile Active

00:00 (24 hr)	6.1 mmol/L

ⓘ TIP: Use Custom Foods feature to simplify meal bolusing

Users can save carb amounts for common foods and/or use to save fixed carbohydrate amounts for meals (e.g., Medium Meal 60g). Consider this feature to simplify carb counting and reduce the burden of meal bolusing.





AFTER VISIT SUMMARY

Great job using Omnipod® 5!

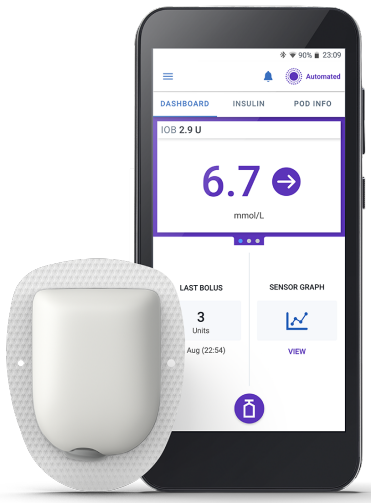
Using this system can help you achieve your diabetes goals.

The American Diabetes Association suggests aiming for **70%** of your glucose levels to be between **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 >14-15 mmol/L for 2 hours or more?** Check ketones first! If ketones are >1.0 mmol/L (mod/large on urine test), give syringe injection of insulin and replace Pod.
- **Bolus before eating,** ideally 10-15 minutes before all meals and snacks.
- **Use Custom Food feature** to help simplify carb counting. You can save common foods and/or program set carb amounts for meals (e.g., 60g for lunch).
- **Do not override the bolus calculator:** Correction bolus doses may be smaller than expected due to increased insulin delivery from the algorithm.
- **Give correction boluses for hyperglycemia:** Tap Use SENSOR in bolus calculator to add sensor glucose value and trend into bolus calculator.
- **Treat mild hypoglycemia with 5-10g carbs** to avoid rebound hyperglycemia and WAIT 15 min before re-treating to give glucose time to rise. Insulin delivery will have been suspended, 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 Restriction alarms immediately,** troubleshoot hyper/hypo, confirm CGM accuracy and switch back to Automated Mode.



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Have questions about the Omnipod® 5?
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