OMNIPOD Automated Insulin Delivery System Instructions

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Contents

INSTRUCTIONS FOR USE

1. Download user's device to 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).
- 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's Target Glucose (6.1, 6.7, 7.2, 7.8, 8.3 mmol/L) for adaptive basal rate.
- **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 it REVERTS to manual mode

- System may revert to Automated Mode: Limited (static basal rate determined by 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. 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 hypoglycaemia with 5-10g carb to avoid rebound hyperglycaemia and WAIT 15 min before re-treating to give glucose time to rise.
- **Infusion site failure:** Check ketones and replace Pod if hyperglycaemia persists (e.g. 16.7 mmol/L for > 90 min) despite correction bolus. Give syringe injection for ketones.

S | SENSOR/SHARE characteristics

- Dexcom G6 which requires 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 dat

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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 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 optimising system use, bolus behaviors and bolus doses.

STEP 1 BIG PICTURE (PATTERNS)

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

Is the person using the CGM and Automated Mode?

% 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

SCAN TO VIEW:
pantherprogram.org/ skin-solutions

Automated Mode %: _____
If <90%, assess why:
Emphasise 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 optimise 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 CHO added)?
—>If not, ASSESS for missed meal boluses

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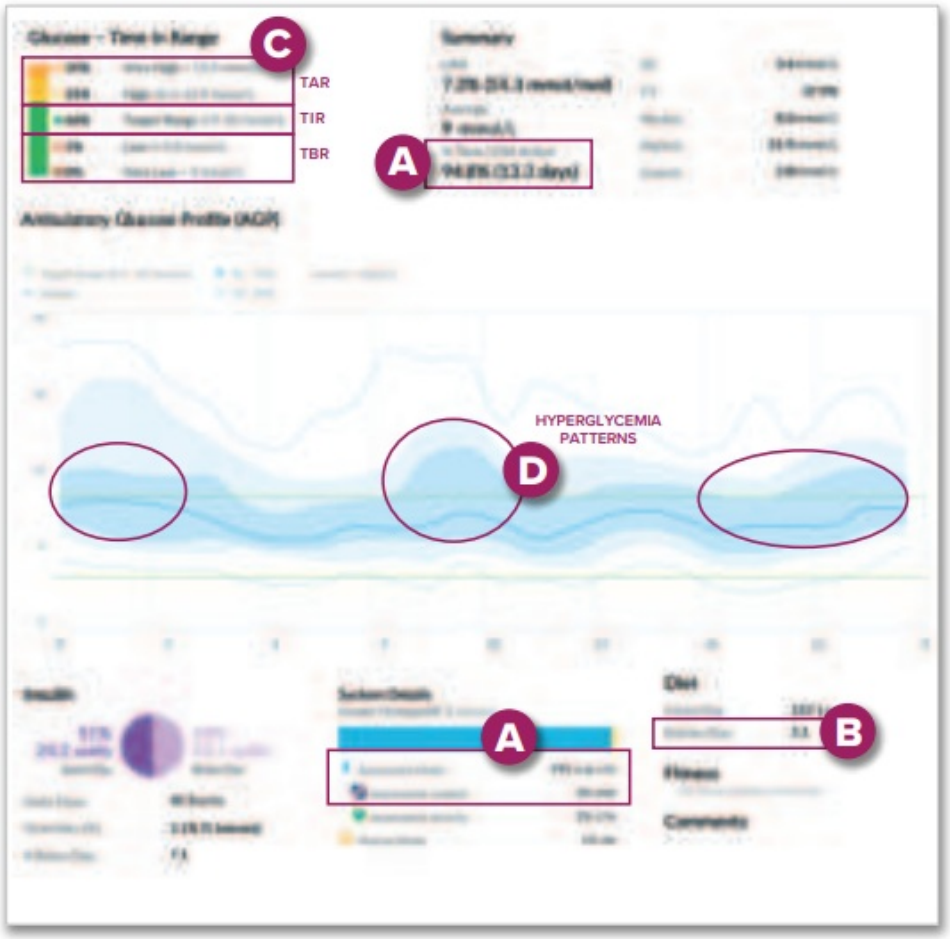
1. The goal of this therapy review is to increase Time in Range (3.9-10.0 mmol/L) while minimising Time Below Range (< 3.9 mmol/L)
2. Is the Time Below Range more than 4%? If **YES,** focus on reducing patterns of **hypoglycaemia** If **NO,** focus on reducing patterns of **hyperglycaemia**



C is the user meeting Glycemic Targets?

Time in Range (TIR) _____Goal is >70%
3.9-10.0mmol/L “Target Range”

Time Below Range (TBR) _____Goal is <4%

< 3.9 mmol/L "Low" + "Very Low"

Time Above Range (TAR) _____Goal is <25%
>10.0 mmol/L "High" + "Very High"

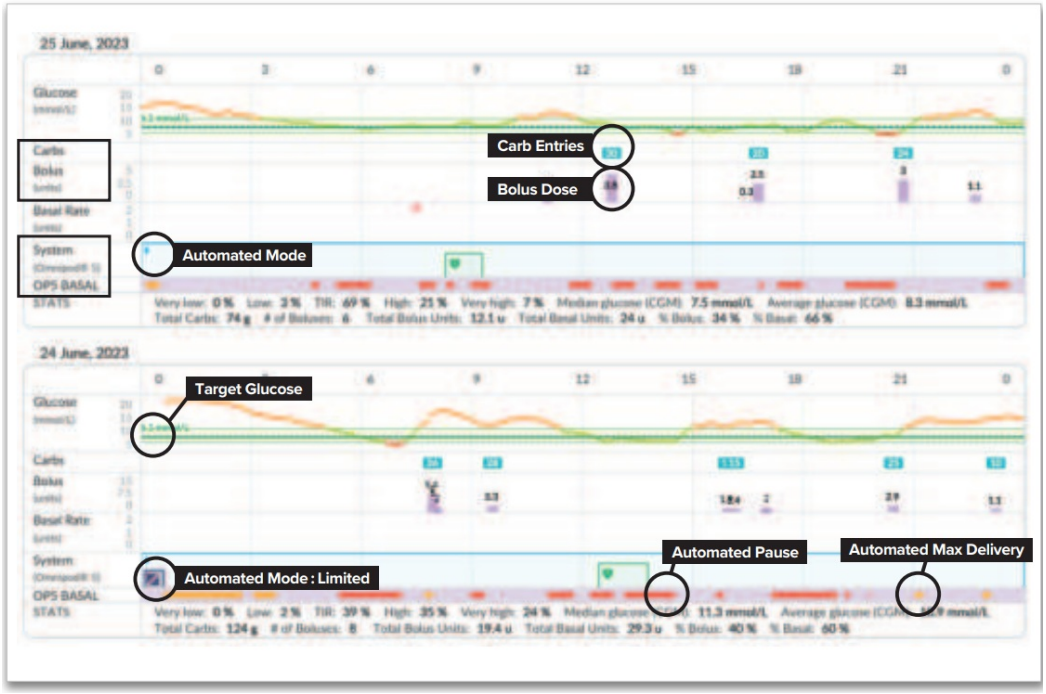
D What are their patterns of hyperglycemia and/or hypoglycemia?
Ambulatory Glucose Profile compiles all data from reporting period into one day; shows median glucose with the blue line, and variability around the median with the shaded ribbons. Wider ribbon = more glycemic variability.

Identify the overall patterns by primarily focusing on the dark blue shaded area.
Hyperglycemia patterns: (eg: high glycemia at bedtime)

_____
_____
Hypoglycemia patterns:
_____
_____

STEP 2 SMALL PICTURE (REASONS)

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 hyperglycaemia pattern.

Is the **hypoglycaemia** 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 **hyperglycaemia** 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 co

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

STEP 3 PLAN (SOLU

Hypoglycemia		**Hyperglycemia**
SOLUTION	**PATTERN**	**SOLUTION**
Raise Target Glucose (algorithm ta rget) overnight (highest is 8.3 mmol /L)	Fasting / Overnight 	Lower Target Glucose overnight (lo west is 6.1 mmol/L)
Assess carb counting accuracy, bol us 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 m eals) 	Assess if meal bolus was missed. If yes, educate to give all meal boluses prior to eating. Assess carb counting accuracy, bolus timing, an d meal composition. Strengthen I:C Ratios by 10-20% (e.g. from 1:10g t o 1:8g)
If due to bolus calculator overrides, educate user to follow the bolus cal culator and avoid overriding to give more than recommended. There m ay be a lot of IOB from AID that use r is not aware of. Bolus calculator fa ctors in IOB from increased AID wh en calculating correction bolus dos e.	Where low glucose follows high glu cose 	

Weaken correction factor by 10-20 % (e.g. from 3mmol/L to 3.5 mmol/L) if hypos 2-3 hours after correction bolus.	Where high glucose follows low glucose 	Educate to treat mild hypoglycaemia with fewer grams of carbs (5-10g)
Use the Activity feature 1-2 hours before exercise begins. Activity feature will temporarily reduce insulin delivery. It can be used during times of increased risk of hypoglycaemia. 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 3 mmol/L to 2.5 mmol/L)

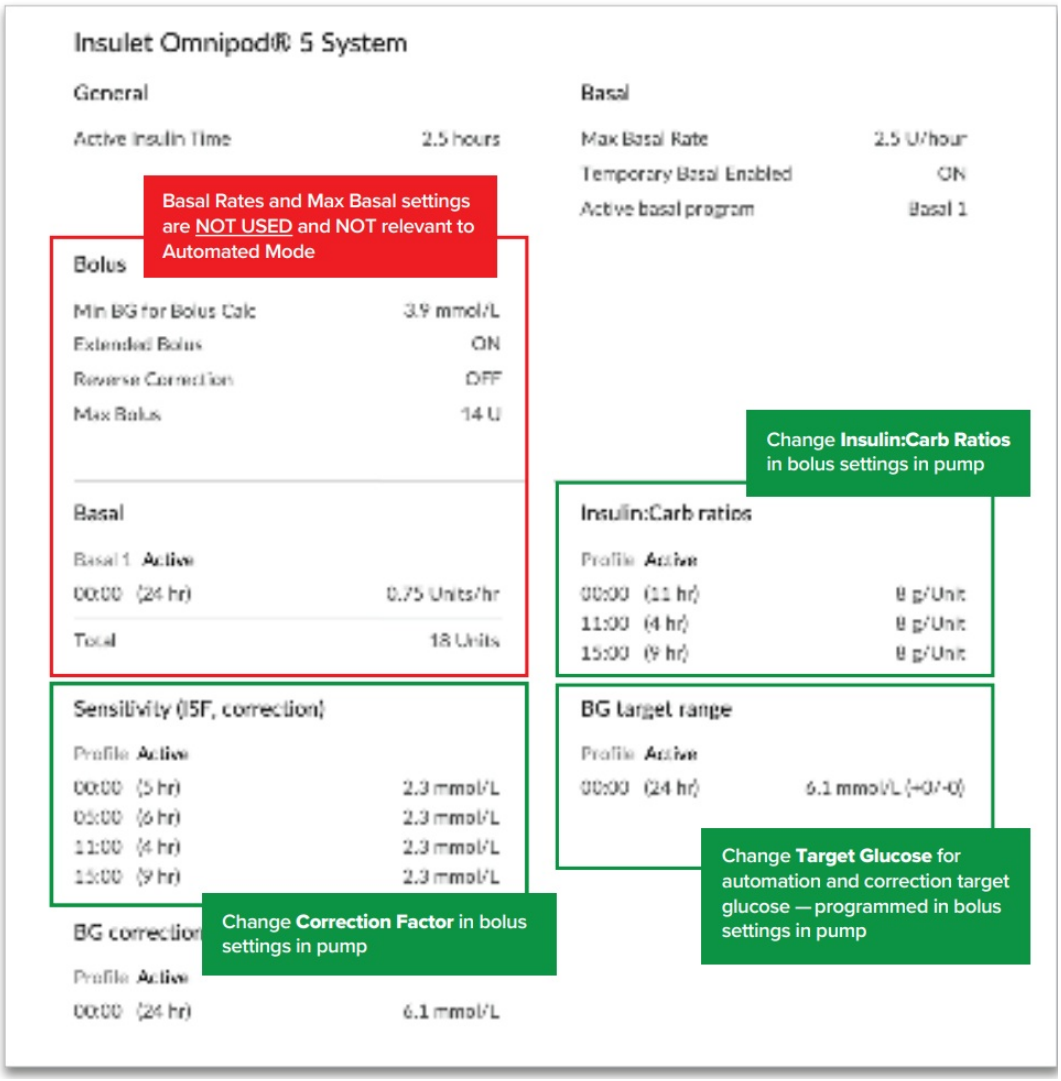
STEP 3 PLAN (SOLUTIONS) …continued

ADJUST insulin pump settings and EDUCATE.**

Most impactful insulin dose settings to change:

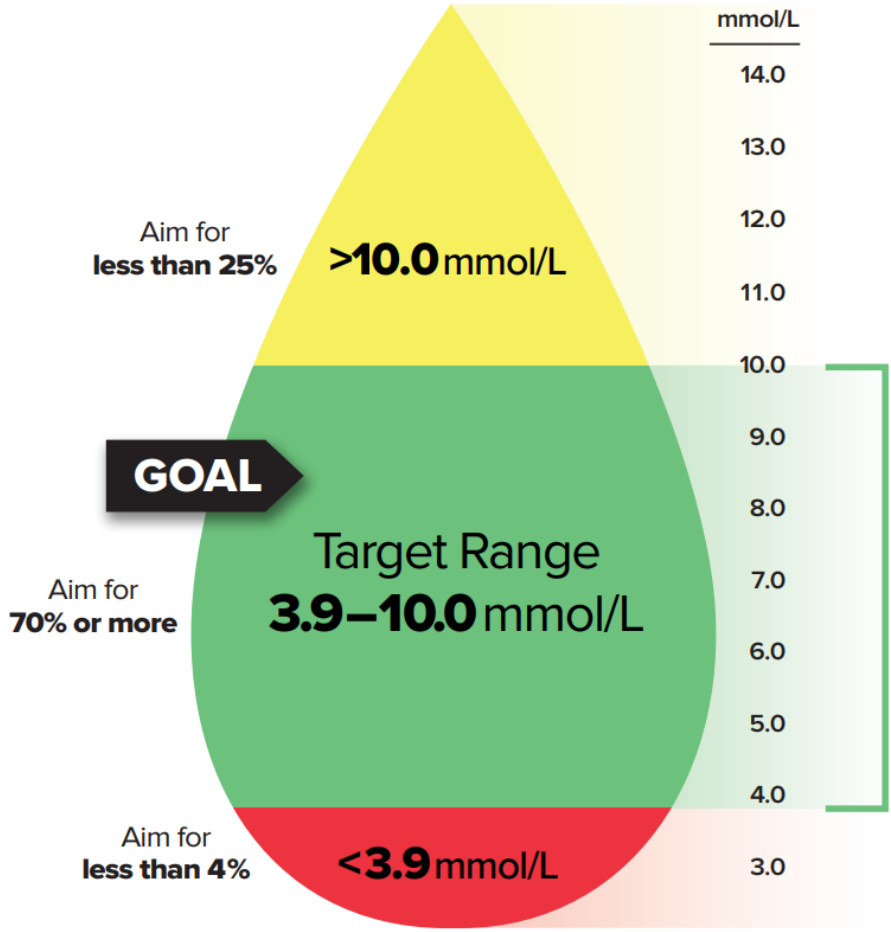
1. Target Glucose (for adaptive basal rate) Options: 6.1, 6.7, 7.2, 7.8, 8.3 mmol/L Can program di!erent targets for di!erent times of day
2. I:C Ratios It is common to need stronger I:C Ratios with AID
3. Correction Factor & Active Insulin Time These will only influence bolus calculator doses; has no impact on automated insulin To change settings, tap the main menu icon in top-left corner of Omnipod 5 controller: —> Settings —> Bolus

BEFORE making changes to insulin delivery settings, please confirm insulin settings within the user's Omnipod 5 controller.



AFTER VISIT SUMMARY

Great job using Omnipod 5



Using this system may 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

- **HYPERGLYCAEMIA >16.7 mmol/L for 1-2 hours?** Check ketones first!

If ketones, give syringe 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 rate.
- **Give correction boluses for hyperglycaemia:** Tap Use CGM in bolus calculator to add glucose value and trend into bolus calculator.
- **Treat mild hypoglycaemia with 5-10g carb to avoid rebound hyperglycaemia** 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 hypoglycaemia 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.

SCAN TO VISIT
PANTHERprogram.org

Have questions about the Omnipod 5?
omnipod.com
Omnipod customer support
0800 011 6132

Have questions about your CGM?
dexcom-intl.custhelp.com
Dexcom customer support
0800 031 5761
Dexcom technical support
0800 031 5763

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Documents / Resources

	OMNIPOD Automated Insulin Delivery System [pdf] Instructions Automated Insulin Delivery System, Insulin Delivery System, Delivery System, System

References

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- Omnipod | Insulin Pump Therapy, Simplified
- Diabetes Technology. Deciphered. | PANTHER Program
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