PANTHERTOOL™ for

OMNIPOD® 5

Automated Insulin Delivery System

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)

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 (110, 120, 130, 140, 150 mg/dL) 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 to **REVERT** to open-loop

- 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 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 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 data.

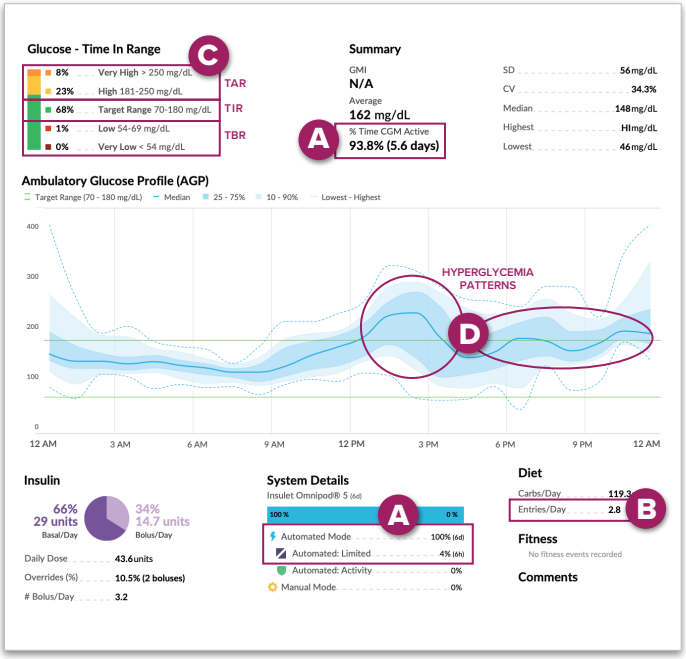
PANTHERPOINTERS™ FOR CLINICIANS

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 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.™ | danatech DIABETES TECHNOLOGY @ ADCES

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

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 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

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 CHO added)?

→If not, ASSESS for missed meal boluses

PANTHERPOINTERS™ FOR CLINICIANS

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

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) "Low" + "Very Low"

Time Above Range (TAR) _____ Goal is <25%
>180 mg/dL (>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)

_____

_____

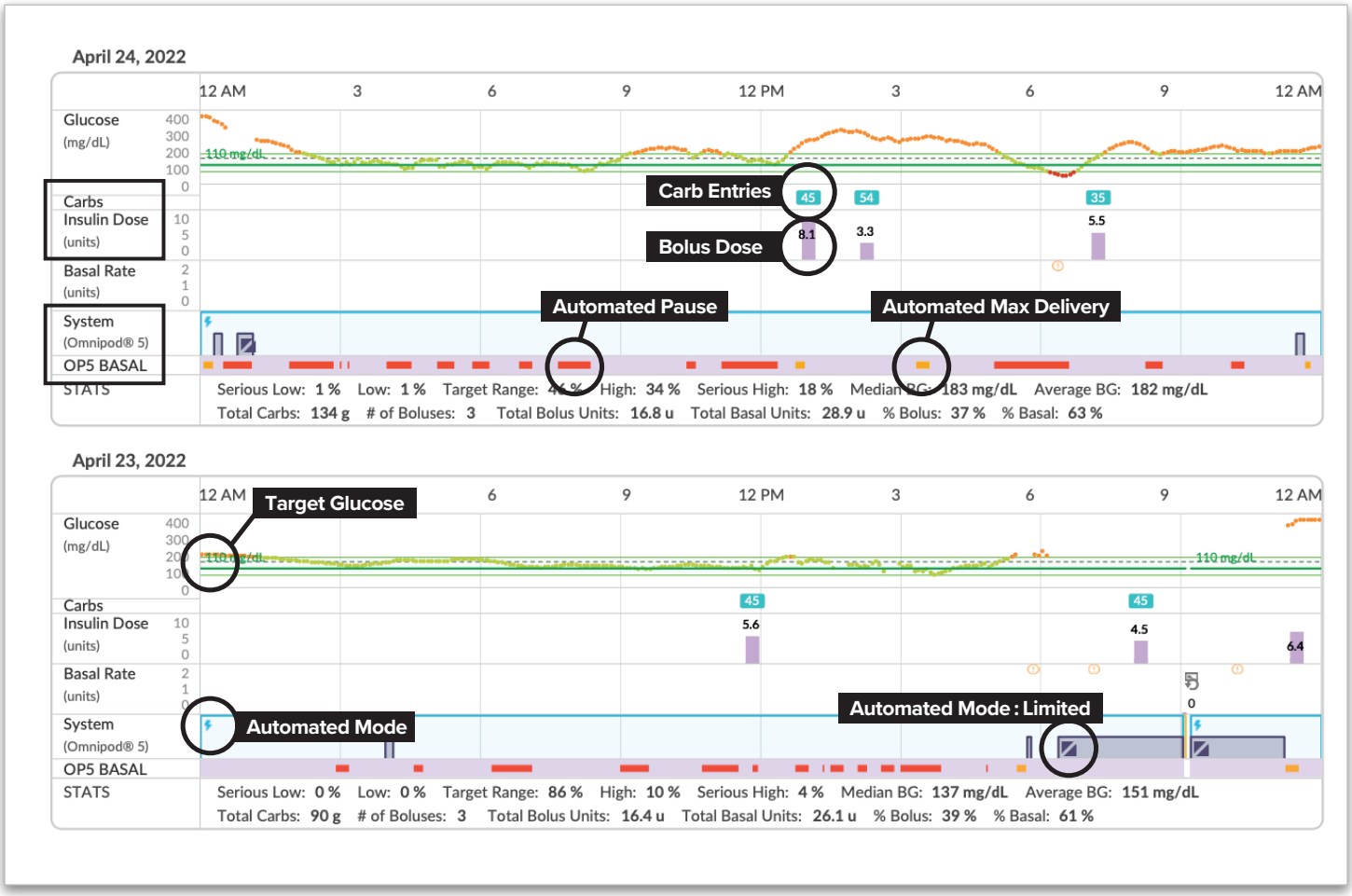
Hypoglycemia patterns:

_____

_____

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 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 SOLUTION	PATTERN	Hyperglycemia SOLUTION
Raise Target Glucose (algorithm target) overnight (highest is 150 mg/dL)	**Fasting / Overnight** 	Lower Target Glucose overnight (lowest is 110 mg/dL)
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 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 1:50, change to 1:60) if hypos 2-3 hours after correction bolus.	**Where low glucose follows high glucose**  **Where high glucose follows low glucose** 	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. 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 50 to 40)

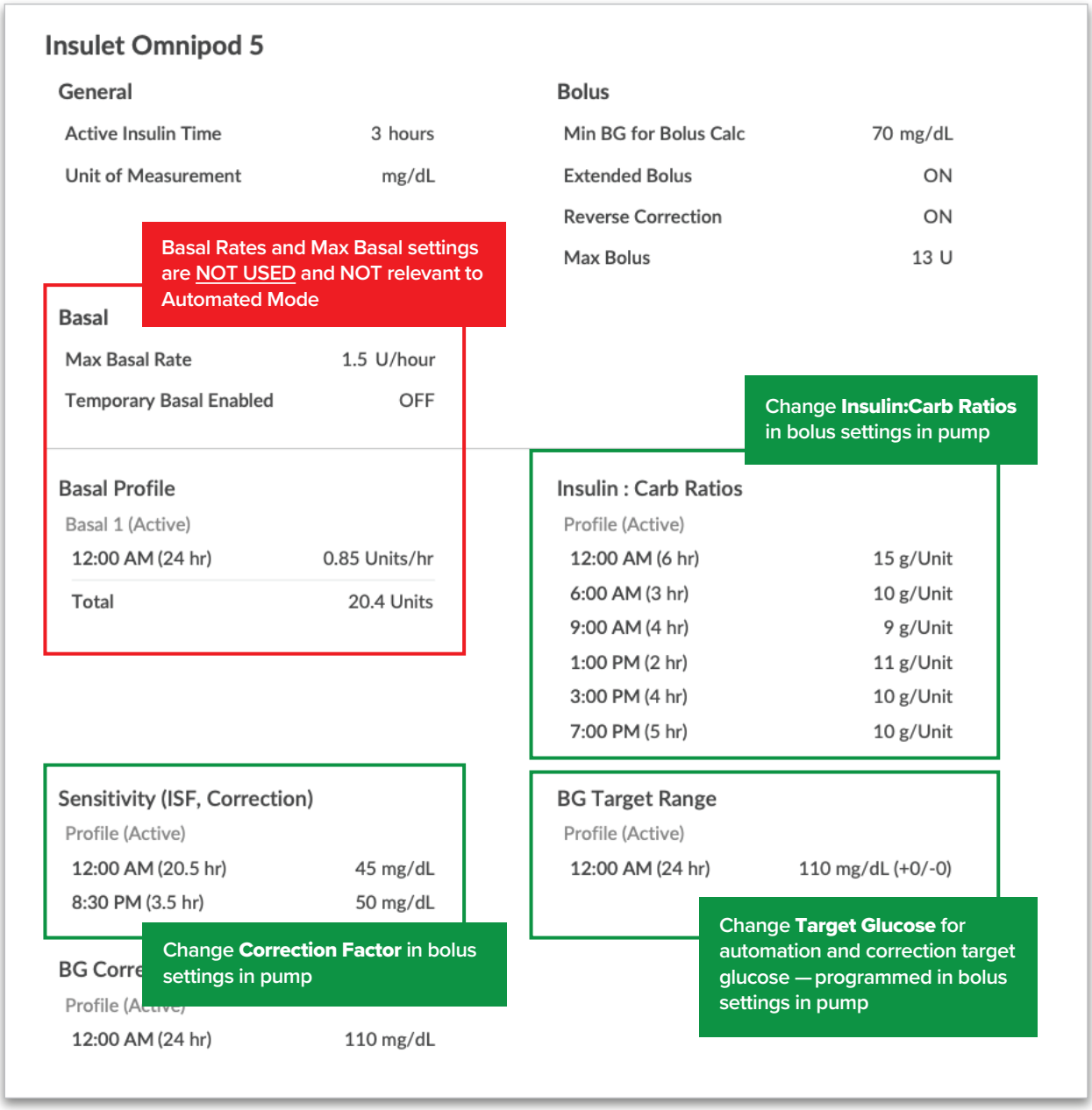
ADJUST insulin pump settings** and EDUCATE.

Most impactful insulin dose settings to change:

1. **Target Glucose (for adaptive basal rate)** 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

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

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

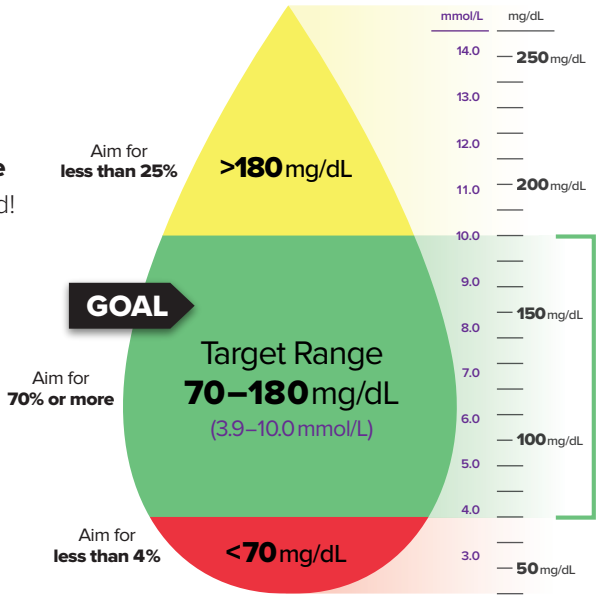


AFTER VISIT SUMMARY

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 **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 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 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 Restriction alarms immediately**, troubleshoot hyper/hypo, confirm CGM accuracy and switch back to Automated Mode.

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SCAN TO VISIT
PANTHERprogram.org

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