

INSTRUCTIONS FOR USE

PANTHERTOOL™ for

MiniMed™ 780G SmartGuard™

Automated Insulin Delivery System



- 1 Upload 780G pump to CareLink™
- 2 Create reports → 2 weeks → Select:
a. Assessment and Progress; b. Weekly Review;
c. Meal Summary; and d. Device Settings
- 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 (Auto-Basal) calculated from total daily insulin and adjusted every 5 minutes based on current CGM trends
- Automated correction boluses delivered as often as every 5 min if glucose levels > 120 mg/dL (> 6.7 mmol/L) and already delivering maximum auto-basal. If the system detects glucose rise is from a meal, based on rate of change, auto-correction boluses may be stronger ("Meal Detection").

A | What you can **ADJUST**

- Can adjust algorithm target for auto-basal: 100, 110, 120 mg/dL (5.5, 6.1, 6.7 mmol/L)
- Can adjust I:C ratios and active insulin time
- Cannot change basal rates (programmed basal rates are not used by algorithm)
- Cannot adjust sensitivity factor or correction bolus target (fixed at 120 mg/dL [6.7 mmol/L] when using SmartGuard)

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

- System may revert to baseline basal delivery (static basal rate determined by algorithm, without adjustments based on CGM) due to:
 - 1) minimum or maximum insulin delivery constraints;
 - 2) loss of CGM communication with the pump;
 - 3) system concerns about sensor accuracy
- When system reverts to baseline basal, there will be a "time to exit" displayed where user must enter a BG value before this time expires or system will revert to manual mode and delivery of programmed basal rates

E | How to **EDUCATE**

- Bolus before eating, ideally 15 minutes prior to meal. Meal Detection is meant to help minimize hyperglycemia after meal boluses, it is still recommended to bolus for meals for best glucose control.
- Follow system prompts to enter BG values into the pump to stay in SmartGuard, as needed

- Sensor glucose value will auto-populate into bolus calculator and the bolus dose will be adjusted based on the CGM value and future glucose predictions
- Treat mild hypoglycemia with 5-10g carbs to avoid rebound hyperglycemia and WAIT 15 min before re-treating to give glucose values time to rise
- Check ketones if there is persistent hyperglycemia. Give syringe injection if ketone values are > 1.0 mmol/L (moderate/large in urine ketones) and change infusion set

S | **SENSOR/SHARE** characteristics

- Compatible with Guardian 3 and Guardian 4 CGM (varies by geographical region); 7-day wear for both
- Guardian 4 CGM = No routine calibration required; system may periodically request BG values which will be used to calibrate sensor as needed
- Guardian 3 CGM = Calibration required every 12 hours minimum; Calibration 3-4 times/day may improve sensor accuracy (recommended to calibrate before meals and at bedtime)
- MiniMed™ Mobile app will enable automatic uploads to CareLink; CareLink Connect app for remote data sharing

PANTHERPOINTERS™ FOR CLINICIANS

- 1 Focus on behavior: CGM use, giving all meal boluses, following system prompts to enter BG values to stay in SmartGuard
- 2 When adjusting insulin pump settings, focus primarily on Auto-Basal Target, I:C Ratios and Active Insulin Time
- 3 Consider using Auto-Basal target of 100 mg/dL (5.5 mmol/L) and Active Insulin Time of 2 hours for highest TIR, as long as TBR is < 4%
- 4 Avoid overthinking the automated insulin delivery. Focus on overall Time in Range (TIR), optimizing system use, bolus behaviors and meal bolus doses

STEP 1 BIG PICTURE (PATTERNS)

Use Assessment and Progress Report to assess system use, glycemic metrics, and identify glucose patterns.

A Is the person using the CGM and SmartGuard?

% Sensor Wear:

If <90%, discuss why:

- Problems accessing supplies/sensors not lasting 7 days?
→Contact Medtronic 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

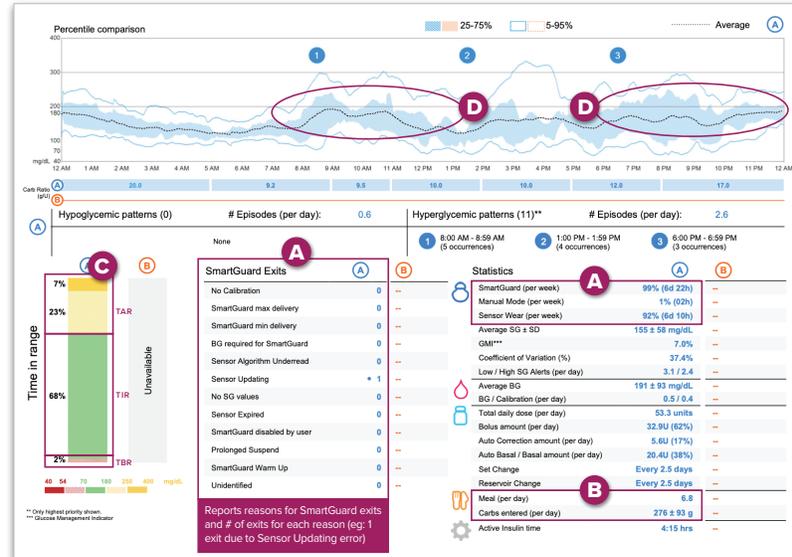


SCAN TO VIEW:
pantherprogram.org/skin-solutions

% SmartGuard:

If <90%, discuss why:

- Emphasize goal is to use SmartGuard as much as possible
- Review SmartGuard exit reasons to identify causes of exits
- See more details about SmartGuard exits in Step 2, Weekly Review



B Is the user giving meal boluses?

Number of meal boluses/day?

Is the user giving at least 4 meal boluses/day?

→If not, ASSESS for missed meal boluses

C Is the user meeting Glycemic Targets?

Time in Range (TIR) Goal is >70%

70-180 mg/dL (3.9–10.0 mmol/L)

Time Below Range (TBR) Goal is <4%

<70 mg/dL (< 3.9 mmol/L)

Time Above Range (TAR) Goal is <25%

>180 mg/dL (> 10.0 mmol/L)

D What are their patterns of hyperglycemia and/or hypoglycemia?

Percentile comparison compiles all data from reporting period into one day; shows median glucose with the black dashed line, and variability around the median with the shaded ribbons. Wider ribbon = more glycemic variability. Identify the overall patterns by primarily focusing on the blue shaded area.

Hyperglycemia patterns: (eg: high glycemia at bedtime)

Hypoglycemia patterns:

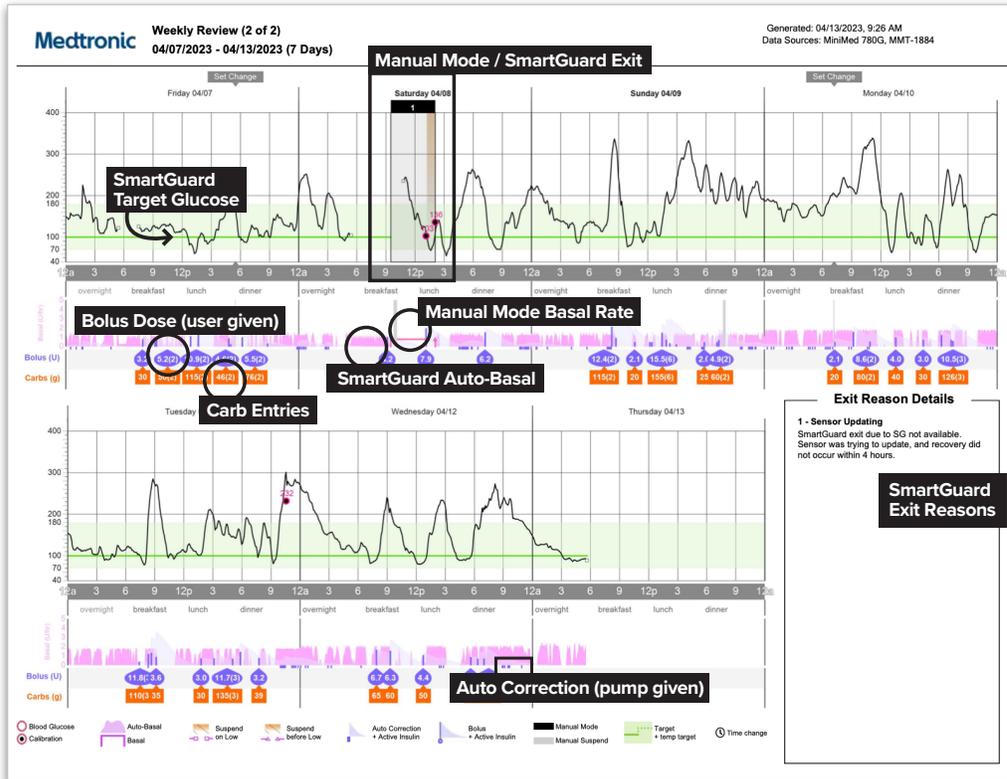
PANTHERPOINTERS™ FOR CLINICIANS

- 1 The goal of this therapy review is to increase Time in Range (70-180 mg/dL; 3.9–10.0 mmol/L) while minimizing Time Below Range (<70 mg/dL; < 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**

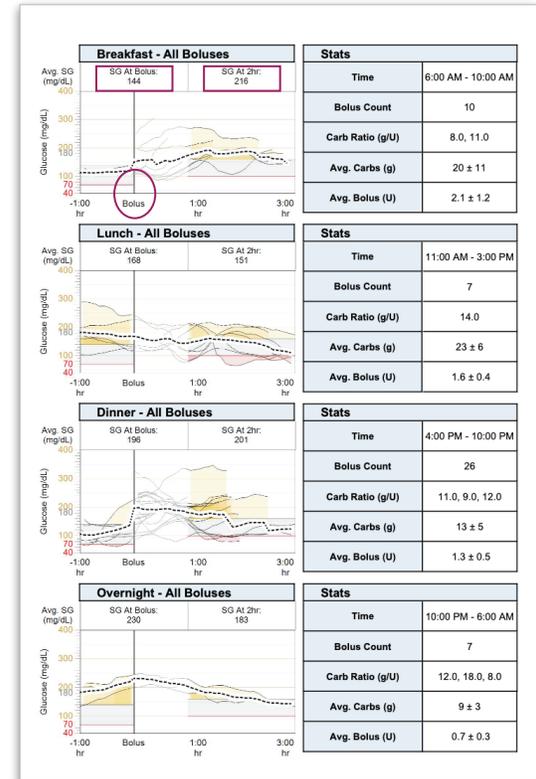
STEP 2 SMALL PICTURE (REASONS)

Use the **Weekly Review** and discussion with the user to identify the reasons for the glycemic patterns identified in STEP 1 (hypoglycemia and/or hyperglycemia). Use the **Meal Summary** and discussion with the user to more closely analyze postprandial glucose patterns.

Weekly Review



Meal Summary



Meal Summary compiles all data related to meal boluses from various time blocks together to more closely analyze postprandial glycemic patterns. The vertical line aligns all boluses within each time period to show aggregate sensor glucose values before the bolus and up to 3 hours after the bolus. Glucose trends are shown with the median glucose in the black dashed line, and variability around the median with the shaded ribbons.

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?

Hypoglycemia	PATTERN	Hyperglycemia
SOLUTION	SOLUTION	SOLUTION
<p>Increase Target Glucose (highest Auto-Basal target setting is 120 mg/dL or 6.7 mmol/L)</p> <p>Consider using Temp Target overnight if still having hypoglycemia at 120mg/dL (6.7 mmol/L) target</p>	<p>Fasting / Overnight</p> 	<p>Decrease Target Glucose (lowest option 100 mg/dL or 5.5 mmol/L)</p> <p>Decrease active insulin time by 30 min</p> <p>Consider using Target Glucose settings of 100 mg/dL (5.5 mmol/L) & Active Insulin Time of 2 hours for most aggressive automated insulin delivery</p>
<p>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)</p>	<p>Around mealtime (1-3 hours after meals)</p> 	<p>Assess if meal bolus was missed. If yes, educate to bolus for all meals. Assess carb counting accuracy, bolus timing, and meal composition. Strengthen I:C Ratios by 10-20% (e.g. from 1:10g to 1:8g)</p>
<p>Assess if lows are caused by “fake carb” boluses. Educate user to give correction boluses via the bolus calculator, following the bolus recommendation and to only give carb boluses for meals and snacks</p>	<p>Low glucose follows High glucose</p>  <p>High glucose follows Low glucose</p> 	<p>Educate to treat mild hypoglycemia with fewer grams of carbs (5-10g) and wait 15 min. after treatment before treating again</p>
<p>Use the Temp Target feature 1-2 hours before exercise begins. This will reduce insulin delivery and disable auto-correction boluses</p> <p>To use Temp Target, go to: Main Menu > SmartGuard (shield icon) > Temp Target > set duration > start</p>	<p>Around or after exercise</p> 	

ADJUST insulin pump settings and EDUCATE.

Most impactful insulin dose settings to change:

- 1. Target: 100, 110, or 120mg/dL** (5.5, 6.1, or 6.7 mmol/L) – this is the target glucose for the SmartGuard Auto-Basal
- 2. I:C Ratios** – it is common to need stronger I:C Ratios with Automated Insulin Delivery (AID)
- 3. Active Insulin Time (AIT)** – affects correction bolus calculations in bolus calculator and SmartGuard auto-corrections

NOTE: Cannot change sensitivity or basal rates when in SmartGuard. The bolus calculator does not use the sensitivity factor programmed in pump or the programmed Blood Glucose Target when in SmartGuard and it does not use the programmed basal rates when in SmartGuard.

Basal

Maximum Basal Rate	2.00 U/Hr	Updates
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Basal 1 (active)

24-Hour Total	23.450 U
Time	U/Hr
00:00	0.800
07:00	1.05

Basal 2

24-Hour Total	--
Time	U/Hr
--	--

Basal 3

24-Hour Total	--
Time	U/Hr
--	--

Bolus

Active Insulin Time (h:mm)	2:30
Maximum Bolus	10.0 U

Carbohydrate Ratio (g/U)

Time	Ratio
0:00	15.0
6:00	6.0
11:00	6.5
17:00	6.5
22:00	12.0

Insulin Sensitivity (mg/dL per U)

Time	Sensitivity
0:00	40
3:00	35
9:00	35
15:00	35
21:00	40

Blood Glucose Target (mg/dL)

Time	Low	High
0:00	120	120

Callouts:

- Blue:** To adjust Active Insulin Time, go to: Main Menu > Settings > Delivery Settings > Bolus Wizard Setup
- Red:** Max basal rate and programmed basal rates have NO impact in SmartGuard
- Green:** To adjust Insulin to Carb (I:C) Ratios, go to: Main Menu > Settings > Delivery Settings > Bolus Wizard Setup
- Purple:** Insulin sensitivity only used in MANUAL MODE. Not relevant for SmartGuard
- Purple:** This Blood Glucose Target is the correction bolus target for MANUAL MODE ONLY. Not relevant for SmartGuard.

SmartGuard

SmartGuard	On
Target	100 mg/dL
Auto Correction	On

High Alerts On (Snooze 0:20)

Start Time	High (mg/dL)	Alert On High	Alert Before High	Rise Alert Limit (mg/dL)
0:00	250	x	x	^^

Low Alerts On (Snooze 0:20)

Start Time	Low (mg/dL)	Suspend	Alert On Low	Alert Before Low	Resume Basal Alert
0:00	75	Off	x	x	

Callouts:

- Purple:** This is the auto-basal target in SmartGuard. To adjust the target, go to Main Menu > SmartGuard > Target
- Green:** Personalize CGM Alert Settings: Main Menu > Settings > Alert Settings

This is the auto-basal target in SmartGuard. To adjust the target, go to Main Menu > SmartGuard > Target

Personalize CGM Alert Settings: Main Menu > Settings > Alert Settings

Tips to reduce alarm fatigue:

- Turn OFF rise/fall alerts
- Turn OFF alert before high or low
- Set high alarm to 250 or 300 mg/dL or turn OFF
- Set high snooze to 2:00

Turn ON Suspend Before Low, so predictive low glucose suspend will be ON if in manual mode

Great job using **780G SmartGuard!**

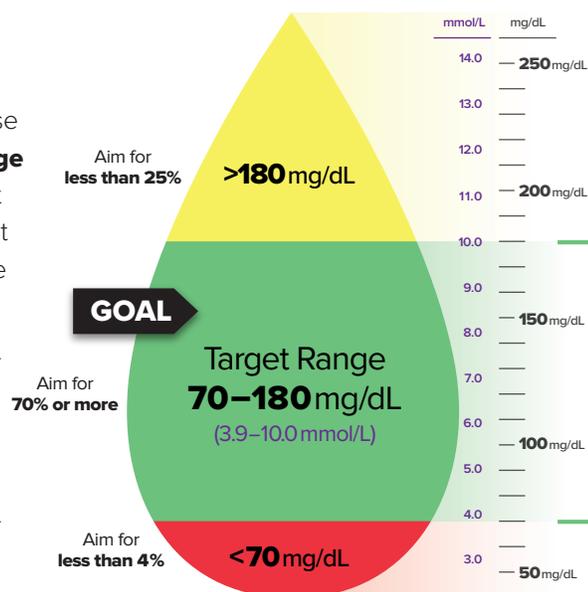
Using this system can help you achieve your diabetes goals.

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**. This is the goal for MOST people with type 1 diabetes for the best long-term health. If you are not currently meeting the goal of 70% TIR, don't be discouraged! Start from where you are and set small goals to increase your TIR. Any increase to your TIR is beneficial to your lifelong health!



REMEMBER...

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



TIPS for 780G SmartGuard

- **HYPERGLYCEMIA >300 mg/dL (>16.7 mmol/L) for 2 hours?** Check ketones first! If ketones are >1.0 mmol/L or mod/large on urine test, give syringe injection of insulin and replace your infusion set.
- **Do not enter fake carb boluses** to give more insulin than the pump recommends — this may cause hypoglycemia and more ups and downs in glucose levels.
- **Bolus before eating.** If bolusing after a meal, the user should reduce bolus or skip the bolus as system has already been increasing insulin for hyperglycemia.
- **Treat mild hypoglycemia with 5-10g carbs** to avoid rebound hyperglycemia and WAIT 15 min before re-treating to give glucose levels time to rise. Insulin delivery will have been suspended, resulting in little insulin on board when hypoglycemia occurs.
- **If disconnected** from your pump, SUSPEND insulin so the SmartGuard system counts active insulin correctly.
- **Respond to alarms to Enter BG values** into pump before “time to exit” expires to avoid SmartGuard exits.
- **Turn on “Suspend Before Low” in Low Alerts.** This will allow for the pump to suspend basal insulin if a low glucose is predicted if you are in manual mode.
- **CHANGE INFUSION SET** every 2-3 days or every 7 days if using the extended infusion set, or as needed for persistent hyperglycemia, and rotate infusion site locations.



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