Interpreting Auto Mode CareLink™ Reports

AIM Methodology: AIM is a standard, systematic method used for evaluating MiniMed™ 670G CareLink™ data accurately and efficiently. AIM uses three reports to:

A) Assess glycemia and proper use of therapy (A & P Report)
B) Identify issues and their cause (Weekly Review Report)
C) Make and document setting and / or suggested behavior changes (Device Settings Report).


Note: If the A&P report indicates all therapeutic goals have been met, this may be the only report that needs to be evaluated, unless you or the patient have other concerns.

Statistics

1) Auto Mode (per week) GOAL ≥ 80%
   Spending ≥ 80% of time in Auto Mode helps patient achieve Time in Range goal
   □ In Auto Mode < 80%: Assess Sensor Wear time / reasons for Auto Mode exits

2) Sensor Wear (per week) GOAL ≥ 85%
   Wearing sensor > 85% of time increases probability of achieving ≥ 80% time in Auto Mode
   □ Wear Time < 85%: Address reasons (i.e., tape, comfort level changing sensor, etc.) and identify solution
   □ Wear Time ≥ 85% but < 80% time in Auto Mode: Review Auto Mode exits (frequency & reasons)

3) Bolus / Basal (per day) Percentage GOAL: Bolus: 50-70% | Basal: 30-50%
   □ Bolus is < 50%: Assess carb intake. Low carb intake can result in lower bolus percentage
   □ Assess Carb entry: If accurate, assess ICR

4) Carbs entered (per day) GOAL: Reasonable & consistent with previous carb intake
   □ Increased carbs: May indicate improved carb counting, diet change or phantom carbs
   □ Phantom carbs: Ask why / address issue (i.e., unrealistic expectation, insufficient food or correction bolus)

Note: Therapy effectiveness can be evaluated even if Auto Mode / Sensor Wear time are not ideal. Use Weekly Review report to identify consecutive days with most time in Auto Mode and re-run reports using only those days.
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Statistics (continued)

5) Active Insulin Time (AIT) GOAL: Appropriately set for correction bolus to deliver enough insulin to lower glucose to the 150 mg/dL correction target, without stacking insulin and causing lows.

Correcting glucose to 150 mg/dL and allowing Auto Basal to gradually lower it to 120 mg/dL may take longer than when correcting to a lower target (i.e., 100 mg/dL), but it typically results in fewer lows and more time in range.

**Recommended AIT Setting:** 3–4 hours (at initiation). Rarely needs adjusting.

**Note:** AIT only affects a correction bolus amount if there is active insulin remaining from a previous bolus.

### Auto Mode Exits

**GOAL:** Minimize number and length of exits / Re-enter Auto Mode as soon as possible

<table>
<thead>
<tr>
<th>Auto Mode Exits</th>
<th>1</th>
<th>2</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Calibraton</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>High SG Auto Mode Exit</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Auto Mode max delivery</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Auto Mode min delivery</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>BG required for Auto Mode</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Sensor Algorithm Underread</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Sensor Updation</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>BG Expired</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Auto Mode disabled by user</td>
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<td>0</td>
</tr>
<tr>
<td>Alarms</td>
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<td>0</td>
</tr>
<tr>
<td>Pump Suspend by user</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Auto Mode Warm-Up</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Unidentified</td>
<td>2</td>
<td>0</td>
</tr>
</tbody>
</table>

Fewer exits equate to more time in Auto Mode. Evaluate reasons for exits. Focus first on overnight exits and those within patient control:

- **Missed Calibration:** Coach patient to calibrate 3–4 times a day (i.e., before meals and bedtime) to help minimize overnight exits due to missed calibration.

- **High SG or Max delivery:** Coach patient to enter BG, give recommended correction dose and bolus before eating. Evaluate ICR.

**Note:** Each time a BG is entered, the Min and Max delivery times are reset. Entering a BG allows the Min and Max rate to continue to deliver for up to another (2½ and 4 hrs, respectively). This helps prevent Min and Max delivery exits.

### Time in Range (70–180 mg/dL) GOAL: ≥ 70% time for 14 yrs & older | ≥ 65% time for ages 7–13 yrs

Evaluate time spent in each range:

- **Time in Range (70–180 mg/dL)**
  - If < 70% time spent in range (< 65% for 7–13 yrs), use Weekly Review report to evaluate cause of lows and highs.

- **Lows (55–69 mg/dL)**
  - If > 3% of time in low range, ask about phantom carbs, carb counting, exercise (use of Temp Target, supplemental carbs, etc.). Evaluate ICR accuracy.

- **Lows (≤ 54 mg/dL)**
  - If > 1% of time spent below 54 mg/dL, ask about phantom carbs, carb counting, exercise (use of Temp Target, supplemental carbs, etc.). Evaluate ICR accuracy.

### Percentile Comparison

**GOAL:** Stay within target range while minimizing variability

Assess overall glycemia and identify time-of-day patterns within blue shaded area. If blue area shows persistent high or low periods, Review the Weekly Review Report to identify cause.
Weekly Review Report

Provides a review of each day’s glucose tracing, insulin delivery (basal & bolus) and carbs entered for meals and snacks (within a 3-hour time-block). Each page contains up to one week of data.

Use to:

1) Assess glycemia, behavior and therapy issues (i.e., post-meal highs, lows, frequent exits, going to bed high, waking up high)

2) Identify the cause of issues (i.e., ICR needs to be adjusted, bolus given post-meal, missed correction bolus, missed calibration, etc.)

Assess data across the days (left to right) and identify issues (i.e., high post-meal followed by a low). Look at the events that preceded the issue and could have caused the problem (i.e., bolused post-meal).

Below are common issues seen on Weekly Review Reports and their potential causes.

- **Post-meal highs or lows**: Assess ICR, missed bolus, timing of bolus and carb counting. Emphasize importance of bolusing before eating, unless treating a low or glucose is low at start of meal.

- **Overnight highs**: Assess for high bedtime glucose, inadequate ICR or bolus for dinner or bedtime snack, inaccurate carb counting, not giving recommended bolus or not bolusing for bedtime snack.

- **Overnight lows**: Assess for low bedtime glucose, phantom carbs, exercise, too much correction dose or inadequate ICR with bedtime snack.

- **Morning highs**: Assess for overnight / bedtime highs first, bedtime snack with inadequate or no bolus, morning caffeine. If issue is identified as dawn phenomenon, have patient test BG, take recommended correction dose and bolus for breakfast at least 15-20 minutes before eating.

- **Post-correction lows**: Assess changes in exercise, medications (i.e., stopped steroids) and AIT. If AIT is too short, it can cause insulin stacking that results in lows (typical AIT setting is 3-4 hours).

- **Post-correction highs**: Assess changes in medication (i.e., steroids) and TDD. If TDD is inadequate (usually caused by inconsistent bolusing), correction boluses may not lower glucose to target.

**Correction Doses and Active Insulin Time:**

- **Correction boluses** are only calculated if a BG is > 150 mg/dL.

- **AIT** impacts correction dose amounts ONLY if there is active insulin remaining from a previous bolus. AIT rarely needs to be adjusted from the suggested 3 to 4 hour initial Auto Mode setting.
Weekly Review Report (continued)

Illustrations of glycemic and behavior issues commonly seen on Weekly Review Reports.

### Issue: Post-meal high followed by low
**Cause:** Bolusing after eating  
**Solution:** Bolus before eating

1) Sudden rise in SG indicates no pre-meal bolus  
2) Auto Basal increases to compensate for rise  
3) Carbs entered (orange) and Post-meal bolus given (purple)  
4) SG falls sharply / goes low

### Issue: Post-meal sustained high
**Cause:** ICR too weak  
**Solution:** Strengthen ICR

1) Bolus given pre-meal (as recommended)  
3) SG remains high > 3 hours despite meal bolus and maximum Auto Basal

### Issue: Post-meal high followed by some near-lows
**Causes:** Missed meal boluses or Post-meal bolus  
**Solution:** Bolus before eating  

Illustration of behaviors that affect glucose across a 24 hour day

1) SG stable overnight  
2) Calibrations (black circles)  
3) Sudden rise in SG indicates food eaten, no bolus  
4) Auto Basal increases to try and compensate for rise in SG  
5) Correction bolus given to correct high and decrease SG  
6) Food bolus given post-meal; Auto Basal stops; SG declines; near-low  
7) Temp target set for exercise  
8) Snack eaten without food bolus; bedtime correction bolus given

**Note:** In this example, exercise may have contributed to near low.
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**Weekly Review Report (continued)**

**Evaluate Auto Mode Exits** (focus on exits that can be controlled by setting or behavior changes first).

The most common exits that setting or behavior modifications can help mitigate are:

- **No calibration**: Encourage calibrating 3 to 4 times a day and always before bed.
- **High SG**: Evaluate ICR. Encourage entry of all carbs, bolusing before eating, giving recommended correction boluses.
- **Auto Mode Max Delivery**: Assess ICR. Encourage entry of all carbs, bolusing before eating, giving recommended correction boluses. Each time a BG is entered, the Max delivery time-limit resets.
- **Auto Mode Min Delivery**: Occurs if no insulin has delivered for 2½ hours (i.e., stable SG, low SG, or SG is dropping). System will request a BG entry to verify sensor accuracy. Once BG is entered, the system will re-enter Auto Mode and reset Min Delivery time out limit to 2½ hours.

### Issue: High SG exit

**Cause**: ICR too weak (prolonged post-meal high)

**Solution**: Strengthen ICR

1) Boluses pre-meal (as instructed)

2) Rapid SG rise from inadequate food bolus (ICR too weak)

3) Post-meal highs persist. SG remains > 250 mg/dL for 3 hours. Results in 2 High SG exits

### Issue: No calibration exit

**Cause**: Missed calibration (>12hrs. since calibrated)

**Solution**: Calibrate before bed

1) Last calibration at 3pm

2) Missed calibration at 3am, SG tracing stopped

3) Exited after 90 minutes of Safe Basal delivery

4) Calibrated at 6am & re-entered Auto Mode

**Strategies used for reducing overnight Min and Max Delivery exits:**

- Check BG before sleep / calibrate system. (Entering BG resets Min and Max Delivery time to 2½ and 4 hours)
- If BG is on low-side of normal at bedtime, encourage a protein snack to raise glucose slightly. This should result in some basal insulin delivery and help prevent overnight Min Basal Delivery exits.
- If BG is > 150 mg/dL, give system-recommended correction bolus.

### KEY LEARNINGS FOR OPTIMIZING TIME IN AUTO MODE

- The most impactful setting clinicians can adjust is the ICR.
- The most impactful behaviors a patient can implement are bolusing for food and giving correction dose (if needed) before eating, calibrating 3 - 4 times a day, and entering a BG when requested by the system.
Meal Bolus Wizard Report

This optional report and is used to evaluate meal bolus timing issues and carb ratio effectiveness.

**GOAL:** Pre-meal within target / Post-meal ≤ 60 mg/dL above pre-meal glucose / Boluses before eating

1. **Pre-bolus glucose:**
   - If pre-bolus glucose is rising, ensure patient is bolusing 5–15 minutes before eating

2. **2-Hour Post-bolus glucose**
   - If variable, assess carb counting skills and/or inconsistent bolusing
   - If high (> 60 mg/dL above pre-meal), assess carb counting, carb ratio and bolus timing
   - If low, evaluate for over-estimating carbs, phantom carb entry, bolus timing, carb ratio, meal content (high fat / high carb)

Device Settings Report

The Device Settings report is used to:

**Confirm the safety of Manual Mode basal rates**

**GOAL:** Manual Mode basal totals should be similar to Auto Mode basal totals

Using the Assessment & Progress report, compare Manual Mode 24-hour basal total to Auto Mode basal total. If the 24-Hour basal total is higher, recalculate Manual Mode basal rates by:

- Dividing Auto Basal total by 24 hours and setting one rate
  - Using above method and modifying for dawn rise (if dawn phenomenon exists) without exceeding the Auto Basal amount – OR –
- Modifying current basal rates proportionally so that the sum does not exceed the Auto Basal amount

**Document setting changes**

Use this report to review all Manual Mode settings and document:

- Findings
- Setting adjustments
- Auto Mode coaching
- Follow-up plan