SPECIAL CONSIDERATIONS ASSESSMENT GUIDE

A SUPPLEMENT TO THE PROTOCOL FOR HYBRID CLOSED LOOP THERAPY
This table provides guidelines on how to assess situations that may require special consideration and possible actions to take. It was compiled based on the clinical experience of providers managing patients on the MiniMed™ 670G system. To date, there is limited published data on outcomes with the MiniMed™ 670G system in any of these conditions.

### EXERCISE

<table>
<thead>
<tr>
<th>Assess</th>
<th>Actions to Consider</th>
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<tbody>
<tr>
<td><strong>Aerobic Exercise</strong></td>
<td><strong>Use Temp Target (150 mg/dL)</strong></td>
</tr>
<tr>
<td>▪ If experiencing lows</td>
<td>▪ Start 1-2 hours before activity.</td>
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<tr>
<td>▪ If lows persist even with use of Temp Target – OR – spontaneous exercise</td>
<td>▪ Stop 1-2 hours after activity.</td>
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<td>▷ May need longer Temp Target (possibly overnight) or carb replacement for intense or long duration.</td>
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<td>▪ Consider suspending pump for at least part of exercise time.</td>
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<td>▪ Consider supplemental carbs as needed if activity is unplanned or glucose is &lt; 150 mg/dL.</td>
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<td>▪ Assess use of uncovered carbs in advance of exercise. Note: Carb loading too far in advance of exercise to raise glucose causes Auto Basal to increase which may be counterproductive and result in lows during exercise. Coach patient on behavior change.</td>
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<tr>
<td><strong>Anaerobic Exercise</strong></td>
<td>▪ Test BG more frequently and consider giving correction doses as recommended by the system.</td>
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<tr>
<td>▪ If experiencing highs</td>
<td>▪ Use Temp Target during and after exercise.</td>
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<tr>
<td>▪ If experiencing lows</td>
<td></td>
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<tr>
<td><strong>Disconnecting and Suspending for Sports / Activity</strong></td>
<td>▪ Suspend pump.</td>
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<tr>
<td>▪ If disconnecting for &lt; 4 hours</td>
<td>▪ If lost sensor alerts occur, use Airplane Mode to prevent alerts.</td>
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<tr>
<td>▪ If disconnecting for ≥ 4 hours</td>
<td>▪ Turn Auto Mode OFF to enter Manual Mode, suspend pump. (suspending ≥ 4 hrs. in Auto Mode results in a 5-hr. delay re-entering Auto Mode)</td>
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<tr>
<td></td>
<td>▪ Reconnect, Turn Auto Mode ON, follow prompts to re-enter Auto Mode.</td>
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<td><strong>Note:</strong> Assess glucose hourly to determine basal insulin replacement needs.</td>
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### SITUATIONS REQUIRING SPECIAL CONSIDERATION

#### HIGH A1C PRIOR TO STARTING AUTO MODE

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| **A1C prior to starting Auto Mode**  
- If > 9%  
- If experiencing persistent highs, lows, and / or multiple exits in Auto Mode | - Insulin to Carb Ration (ICR) may need to be adjusted soon after starting Auto Mode and multiple times thereafter as glucose toxicity and insulin sensitivity improves.  
- Use Manual Mode. Restart Auto Mode once TDD has been re-established. |

#### NEWLY DIAGNOSED

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| **Total Daily Dose**  
- If < 8 units / day | - Keep in Manual Mode with Suspend before low ON.  
- Transition to Auto Mode as insulin requirements increase ≥ 8 units / day.  
- Use Manual Mode with Suspend before low.  
- Transition to Auto Mode when endogenous insulin subsides. |
| **Auto Mode Exits**  
- If Min Delivery exits occur due to endogenous insulin secretion | |

#### GROWTH SPURTS / WEIGHT INCREASE / PUBERTY

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| **Glycemia, TIR and Bolus / Basal Ratio**  
- If not at goal | - Evaluate ICR and Auto Mode TDD. Adjust Manual Mode 24-hour basal total to ensure it does not exceed Auto Basal daily total. |

#### DAWN PHENOMENON

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| **Glucose**  
- If patient is regularly waking with glucose over 150 mg/dL | - Deliver correction bolus immediately upon waking, if recommended by the system. |

**Note:** Auto Mode delivery is based on current SG. It does not learn time-of-day patterns, as these can vary from day-to-day.

#### GASTROPARESIS

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| **Mealtime Dosing Strategy**  
- If Square Wave™ or Dual Wave™ bolus was used in Manual Mode | - Advise patient to administer a split bolus.  
- Monitor glucose to determine individualized plan.  
- Adjust timing and amount of carb entry when delayed food absorption is anticipated. |
# SITUATIONS REQUIRING SPECIAL CONSIDERATION

## RENAL FUNCTION

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| Renal Function  
   - If impaired or renal insufficiency increased | Consider extending Active Insulin Time. |

**WARNING:** The safety of the MiniMed™ 670G system has not been studied in people with impaired kidney function (defined as serum creatinine > 2 mg/dL).

## SICK DAYS

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| **Glucose**  
   - If glucose is consistently < 100 mg/dL  
   - If glucose is consistently high | Use Temp Target (150 mg/dL).  
   - Check BG every 2 hours, consider giving correction doses as recommended by the system. |
| **Ketones**  
   - If ketones are present | Notify doctor's office and follow sick-day protocol, including checking urine ketones with every void or using blood ketone meter. |
| **Food and Fluid Intake**  
   - If patient is vomiting or dehydrated | Continue Auto Mode – AND –  
   - Encourage use of sick-day protocols.  
   - Check urine ketones with every void or use blood ketone meter.  
   - Encourage hydration. |
| **Auto Mode Exits**  
   - If system exits frequently due to high glucose | Consider using Manual Mode with Suspend before low and Temp Basal rates or a Sick-Day Basal Pattern. |

## STEROIDS

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| Based on type, dose, and duration of steroid use  
   - If glucose is persistently high  
   - Once steroids are tapered | Use Manual Mode with Suspend before low and follow routine steroid protocols to adjust insulin doses.  
   - Re-initiate Auto Mode 5 to 6 days after insulin doses return to baseline to reduce risk of hypoglycemia. |

## POST-PARTUM

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| **Post-Delivery TDD**  
   **Note:** Insulin requirements decrease significantly after delivery. | Calculate and reprogram Manual Mode settings using standard formulas or use pre-pregnancy settings  
   - Use CGM with Suspend before low at least 7 days or until post-partum insulin requirements stabilize.  
   - Set low alert ≥10 mg/dL higher than it was set pre-pregnancy.  
   - Initiate Auto Mode once TDD and insulin requirements stabilize. |
| **Lows during breastfeeding or pumping** | Use Temp Target  
   - If lows continue, add uncovered carbs while breastfeeding and/or suspend pump 30-60 minutes.  
   - During cluster feeding phases, use Temp Target to minimize maternal burnout. Re-set Temp Target every 12 hrs. as needed. |
# SITUATIONS REQUIRING SPECIAL CONSIDERATION

## OUTPATIENT PROCEDURES (i.e., wisdom teeth, colonoscopy, endoscopy, mammograms)

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| **Type of Sedation**  
- If patient is conscious during procedure  
- If patient is sedated during procedure |
| - Continue Auto Mode.  
- Follow outpatient center guidelines.  
- Advise patient to be accompanied by someone who is familiar with the operation of the MiniMed™ 670G system. |
| **Length of Procedure**  
- If patient is NPO before procedure |
| - Continue Auto Mode with the Temp Target (150 mg/dL) set throughout NPO time period. Temp Target will need to be reset every 12 hours until patient is tolerating oral intake post-procedure. |
| **Electromagnetic Radiation**  
- If X-ray, MRI, CT scan will occur |
| - Always remove pump, sensor, transmitter, and meter before entering a room that has X-ray, MRI, diathermy, or CT scan equipment. The magnetic fields and radiation in the immediate vicinity of this equipment can make devices nonfunctional or damage the part of the pump that regulates insulin delivery, possibly resulting in over delivery and severe hypoglycemia. |

## HOSPITALIZATIONS

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| **Patient’s mental and physical status**  
- If patient is alert, psychologically stable, and physically able to self-manage their device or when a caretaker is present to manage the device  
- If patient is not able to self-manage |
| - Continue Auto Mode use.  
- Follow hospital guidelines.  
- Discontinue Auto Mode and / or pump therapy until patient is able to safely manage device. |
| **Medications**  
- If medications that alter glycemia are used that cause frequent Auto Mode Exits |
| - Use Manual Mode with Suspend before low for duration of medication use and for 5 to 6 days post medication until insulin requirements stabilize.  
- Re-initiate Auto Mode 5 to 6 days after insulin doses return to baseline to reduce risk of hypoglycemia. |
| **Insulin injections**  
- If an insulin injection has been given, consider type and duration of action |
| Exit Auto Mode for the duration of insulin action time.  
- Short or rapid acting: Utilize Manual Mode with Suspend before low and programmed basal rates.  
- Intermediate or long-acting: Utilize Manual Mode with Suspend before low and decreased Temp Basal rates. |

**Notes:**  
1) All BG values for system checks, calibration, and dosing must be obtained using CONTOUR®NEXT LINK 2.4 meter.  
2) For BG monitoring during and immediately after procedures, refer to the Outpatient Center / Hospital’s guidelines.
The Medtronic MiniMed™ 670G system is intended for continuous delivery of basal insulin (at user selectable rates) and administration of insulin boluses (in user selectable amounts) for the management of type 1 diabetes mellitus in persons, seven years of age and older, requiring insulin as well as for the continuous monitoring and trending of glucose. Last Modified: September 26, 2018

Managed by: Regulatory levels in the fluid under the skin. The MiniMed™ 670G system includes SmartGuard™ technology, which can be programmed to automatically adjust delivery of basal insulin based on Continuous Glucose Monitor sensor glucose values and can suspend delivery of insulin when the sensor glucose value falls below or is predicted to fall below predefined threshold values. The system requires a prescription. The Guardian™ Sensor (3) glucose values are not intended to be used directly for making therapy adjustments, but rather to provide an indication of when a fingerstick may be required. A confirmatory finger stick test via the CONTOUR®NEXT LINK 2.4 blood glucose meter is required prior to making adjustments to diabetes therapy. All therapy adjustments should be based on measurements obtained using the CONTOUR®NEXT LINK 2.4 blood glucose meter and not on values provided by the Guardian™ Sensor (3). Always check the pump display to ensure the glucose result shown agrees with the glucose results shown on the CONTOUR®NEXT LINK 2.4 blood glucose meter. Do not calibrate your CGM device or calculate a bolus using a blood glucose meter result taken from an Alternative Site (palm) or from a control solution test. It is not recommended to calibrate your CGM device when sensor or blood glucose values are changing rapidly, e.g., following a meal or physical exercise. If a control solution test is out of range, please note that the result may be transmitted to your pump when in the “Always” send mode.

**WARNING:** Medtronic performed an evaluation of the MiniMed™ 670G system and determined that it may not be safe for use in children under the age of 7 because of the way that the system is designed and the daily insulin requirements. Therefore, this device should not be used in anyone under the age of 7 years old. This device should also not be used in patients who require less than a total daily insulin dose of 8 units per day because the device requires a minimum of 8 units per day to operate safely.

Pump therapy is not recommended for people whose vision or hearing does not allow recognition of pump signals and alarms. Pump therapy is not recommended for people who are unwilling or unable to maintain contact with their healthcare professional. The safety of the MiniMed™ 670G system has not been studied in pregnant women. For complete details of the system, including product and important safety information such as indications, contraindications, warnings and precautions associated with system and its components, please consult [http://www.medtronicdiabetes.com/important-safety-information#minimed-670g](http://www.medtronicdiabetes.com/important-safety-information#minimed-670g) and the appropriate user guide at [http://www.medtronicdiabetes.com/download-library](http://www.medtronicdiabetes.com/download-library).

**WARNING:** (For MiniMed™ 670G System Users Ages 7-13): The low sensor glucose alert functionality is distinct from the automated insulin dosing function of the MiniMed™ 670G system. When used in Auto Mode, the MiniMed™ 670G system has been shown to be safe and effective for its intended use in this population. However, do not rely solely on the use of a low sensor glucose (SG) value for “Alert on Low” or “Alert before Low” for alerts set at 50 mg/dL and 60 mg/dL. A low sensor glucose alert may not reflect the user’s true blood glucose at these levels or may not alert. Do not ignore symptoms of low glucose. Always confirm your sensor glucose readings with your blood glucose meter and treat according to the recommendations of your healthcare professional. Solely relying on these sensor glucose alerts and readings for treatment decisions could result in missing severe hypoglycemia (low blood glucose) events.

**WARNING:** The safety of the MiniMed™ 670G system has not been studied in pregnant women. Auto Mode target of 120 mg/dL may not be appropriate for pregnancy. There is no commercially available CGM approved for use in pregnancy.

**WARNING:** Do not use the pump when a flammable anesthetic mixture with air, oxygen, or nitrous oxide is present. These environmental conditions can damage your pump and result in serious injury.