



SPECIAL CONSIDERATIONS ASSESSMENT GUIDE

A supplement to the Guide for the MiniMed™ 670G
system with SmartGuard™ Technology

Medical Education

Medtronic

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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	
Assess	Actions to Consider
Aerobic Exercise ■ If experiencing lows ■ If lows persist even with use of Temp Target – OR – spontaneous exercise	Use Temp Target (8.3 mmol/L or 150 mg/dL) ■ Start 1-2 hours before activity ■ Stop 1-2 hours after activity ▪ May need longer Temp Target (possibly overnight) or carb replacement for intense or long duration. ■ Consider suspending pump for at least part of exercise time. ■ Consider supplemental carbs as needed if activity is unplanned or glucose is < 8.3 mmol/L (150 mg/dL). ■ 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 counter productive and result in lows during exercise. Coach patient on behaviour change.
Anaerobic Exercise ■ If experiencing highs ■ If experiencing lows	■ Test BG more frequently and consider giving correction doses as recommended by the system. ■ Use Temp Target during and after exercise.
Disconnecting and Suspending for Sports / Activity ■ If disconnecting for < 4 hours ■ If disconnecting for ≥ 4 hours	■ Suspend pump ■ If lost sensor alerts occur, use Airplane Mode to prevent alerts ▪ Note: to use Airplane Mode you need to exit Auto Mode ■ 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) ■ Reconnect, Turn Auto Mode ON, follow prompts to re-enter Auto Mode Note: Assess glucose hourly to determine basal insulin replacement needs

SITUATIONS REQUIRING SPECIAL CONSIDERATION

HIGH A1C PRIOR TO STARTING SMARTGUARD™ AUTO MODE

Assess	Actions to Consider
A1C prior to starting Auto Mode - If > 9% (75 mmol/mol) - If experiencing persistent highs, lows, and / or multiple exits in Auto Mode	- 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

Assess	Actions to Consider
Total Daily Dose If < 8 units / day	- Keep in Manual Mode with Suspend before low ON - Transition to Auto Mode as insulin requirements increase $\geq$ 8 units / day
Auto Mode Exits If Min Delivery exits occur due to endogenous insulin secretion	- Use Manual Mode with Suspend before low - Transition to Auto Mode when endogenous insulin subsides

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.

GROWTH SPURTS / WEIGHT INCREASE / PUBERTY

Assess	Actions to Consider
Glycaemia, 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

Assess	Actions to Consider
Glucose If patient is regularly waking with glucose over 8.3 mmol/L (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

Assess	Actions to Consider
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 individualised plan. - Adjust timing and amount of carb entry when delayed food absorption is anticipated.

RENAL FUNCTION

Assess	Actions to Consider
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 [176 µmol/l]).	

SICK DAYS

Assess	Actions to Consider
Glucose - If glucose is consistently < 5.5 mmol/L (100 mg/dL) - If glucose is consistently high	- Use Temp Target (8.3 mmol/L or 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

Assess	Actions to Consider
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 hypoglycaemia.

POST-PARTUM

Assess	Actions to Consider
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 stabilise. - Set low alert ≥0.6 mmol/L (10 mg/dL) higher than it was set pre-pregnancy. - Initiate Auto Mode once TDD and insulin requirements stabilise.
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 minimise maternal burnout. Re-set Temp Target every 12 hrs as needed.

WARNING: The safety of the MiniMed™ 670G system has not been studied in pregnant women. Auto Mode target of 6.7 mmol/L (120 mg/dL) may not be appropriate for pregnancy.

SITUATIONS REQUIRING SPECIAL CONSIDERATION

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

Assess	Actions to Consider
Type of Sedation - If patient is conscious during procedure - If patient is sedated during procedure	- Continue SmartGuard™ 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 SmartGuard™ Auto Mode with the Temp Target (8.3 mmol/L or 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 hypoglycaemia.

HOSPITALISATIONS

Assess	Actions to Consider
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 SmartGuard™ Auto Mode use. - Follow hospital guidelines - Discontinue SmartGuard™ Auto Mode and / or pump therapy until patient is able to safely manage device.
Medications If medications that alter glycaemia 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 stabilise. - Re-initiate SmartGuard™ Auto Mode 5 to 6 days after insulin doses return to baseline to reduce risk of hypoglycaemia.
Insulin injections If an insulin injection has been given, consider type and duration of action	Exit SmartGuard™ Auto Mode for the duration of insulin action time. - Short or rapid acting: Utilise Manual Mode with Suspend before low and programmed basal rates. - Intermediate or long-acting: Utilise 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

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.

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