SMARTGUARD™ AUTO MODE EXIT REASON REFERENCE GUIDE

A SUPPLEMENT TO THE PROTOCOL FOR HYBRID CLOSED LOOP TECHNOLOGY

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Auto Mode Exits are an expected occurrence with the MiniMed™ 670G system. Patients should view these as learning experiences and use them to determine ways to avoid future exits. Below are details on Auto Mode exits, as listed on the CareLink™ Assessment and Progress Report.

Exit Reason	Safe Basal?	Details	Action Required to Re-Enter Auto Mode
No Calibration occurred	Yes	Sensor requires calibration to continue providing data. This includes scheduled calibrations and diagnostic calibrations.	Enter calibration BG*
High SG Auto Mode Exit	No	System has exited Auto Mode due to: SG >16.7mmol/L for 1 hour -OR- SG >13.9mmol/L for 3 hours	1) Enter BG* 2) Deliver correction bolus, if prompted by the system. NOTE: Patient should check infusion set, check ketones and monitor BG anytime they have a high sensor glucose (SG).
Auto Mode max delivery	Yes	Auto Basal has been delivering at maximum dose for 4 hours. BG is required to reassure system that maximal basal delivery is appropriate.	Enter BG* Assess for missed boluses, accurate carbohydrate counting and adequate insulin to carb ratio (ICR).
Auto Mode min delivery	Yes	Auto Basal has been delivering at minimum dose for 2.5 hours. BG is required to reassure system that minimal basal delivery is appropriate.	Enter BG*
BG required for Auto Mode	Yes	System has concern regarding SG values and wants verification. May result from >35% difference between BG and SG.	Enter BG* If repeated alerts, encourage patient to wait at least 30 minutes before entering next BG.
Sensor Algorithm Underread	Yes	Sensor is reading lower than expected by the algorithm.	Enter BG* if requested.
Sensor Updating	Yes	Diagnostic chip in transmitter determines SG values may not be reliable.	Follow instructions on pump. Assess insertion sites and taping technique.
No SG values	Yes	System has a lost sensor.	Bring pump into range of transmitter, enter BG* if requested by the system.
Sensor Expired	Yes	Sensor has reached maximum 7-day wear time.	Change and reinitiate new sensor.

***** Blood glucose (BG) must be between 2.2-22.2mmol/L.

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Exit Reason	Safe Basal?	Details	Action Required to Re-Enter Auto Mode
Auto Mode disabled by user	No	Patient has turned Auto Mode off in their pump.	Turn Auto Mode back on (Main Menu → Options → SmartGuard → Auto Mode. Select **On**, and then **Save**)
Alarms	No	Insulin Flow Blocked.	Patient should check infusion set, check ketones and monitor BG.
	Yes	Battery issues (Battery out limit, Battery Removed, Failed Battery).	Insert new AA battery. Turn Auto Mode back on. Will require a 5-hour warm-up. Enter BG* when prompted.
	Yes	Reservoir change issues (No Reservoir Alarm, Max Fill Reached alarm, Loading Interrupted alarm).	Follow instructions on pump screen to finish loading reservoir.
Pump Suspended by user	Yes	Pump was manually suspended for at least 4 hours.	Resume delivery. Will require a 5-hour Auto Mode warm-up. Enter BG* if requested.
Auto Mode Warm Up	No	System is recalculating total daily dose (TDD).	Enter BG* when prompted.
Unidentified	No	Pump has never entered Auto Mode	No action by patient, unless prompted for BG.*
	Yes	Report is generated for a period which does not have enough history (i.e. – beginning of reporting period occurs during an exit).	No action by patient, unless prompted for BG.*
	Yes	Reason not classified into another exit.	Follow prompts of the pump screen to re-enter Auto Mode.

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IMPORTANT SAFETY INFORMATION: MiniMed™ 670G System

The 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 age seven and older requiring insulin as well as for the continuous monitoring and trending of glucose 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 monitoring (CGM) and can suspend delivery of insulin when the SG value falls below or is predicted to fall below predefined threshold values. The Guardian Sensor (3) is not intended to be used directly for making therapy adjustments, but rather to provide an indication of when a fingerstick may be required. All therapy adjustments should be based on measurements obtained using a home glucose monitor and not on values provided by the Guardian Sensor (3). For persons 7 to 13 years of age, sensor placement and insertion has been studied in the belly (abdomen) and buttock only and is not approved for other sites. For persons that are 14 years of age and older, sensor placement and insertion has been studied in the belly (abdomen) and back of upper arm only and is not approved for other sites.

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 technology is not recommended for people whose vision or hearing does not allow recognition of pump signals and alarms. Pump technology 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 www.medtronicdiabetes.ca and the appropriate user guide.

IMPORTANT SAFETY INFORMATION: CARELINK™ SOFTWARE
The CareLink™ software is intended for use as a tool to help manage diabetes. The purpose of the software is to take information transmitted from insulin pumps, glucose meters and continuous glucose monitoring systems, and turn it into CareLink™ reports. The reports provide information that can be used to identify trends and track daily activities—such as carbohydrates consumed, mealtimes, insulin delivery, and glucose readings. NOTE: CareLink™ report data is intended for use as an adjunct in the management of diabetes only and NOT intended to be relied upon by itself. Patients should consult their healthcare providers familiar with the management of diabetes prior to making changes in diabetes management plan. For more details, please consult www.medtronicdiabetes.ca and the appropriate CareLink User Guide.

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