PROTOCOL FOR HYBRID CLOSED LOOP TECHNOLOGY

Situations Requiring Special Consideration and Resource Documents

Second Edition

MiniMed™ 670G System

Medical Education

Medtronic

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**A PROTOCOL FOR HYBRID CLOSED LOOP TECHNOLOGY MINIMED™ 670G SYSTEM**

MINIMED™ 670G SYSTEM OVERVIEW

This protocol book covers the initiation, adjustment and management of type 1 diabetes using hybrid closed loop technology with the MiniMed™ 670G system. It is based on the learnings from the first year of real-world use, data, and experience of over 50,000 patients in SmartGuard™ Auto Mode.

Please note: This booklet does not cover the basics of insulin pump technology and continuous glucose monitoring (CGM) technology. It is written for clinicians with experience managing these technologies and patients using these technologies.

MiniMed™ 670G System Components

- MiniMed™ 670G Insulin Pump
- Infusion Set
- Guardian™ Sensor 3
- Guardian™ Link 3 Transmitter
- CONTOUR®NEXT LINK 2.4 Meter
  - For fingerstick blood glucose (BG) testing and calibrating the system.
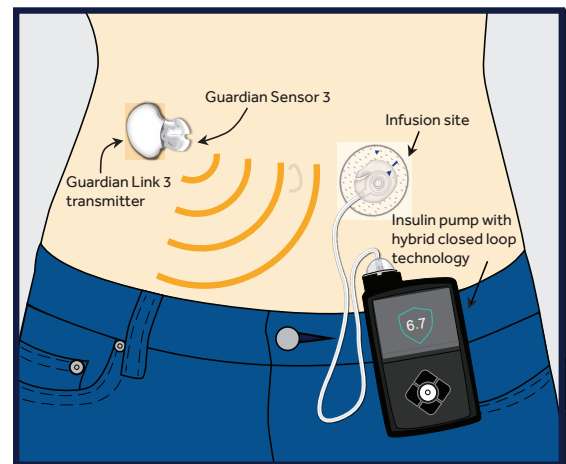
FREQUENTLY USED ACRONYMS:	
AIT: Active Insulin Time	**ISF:** Insulin Sensitivity Factor
BG: Blood Glucose	**SG:** Sensor Glucose
CGM: Continuous Glucose Monitoring	**TIR:** Time in Range
ICR: Insulin to Carbohydrate Ratio	**TDD:** Total Daily Dose

MINIMED™ 670G SYSTEM OVERVIEW

The MiniMed™ 670G system can be programmed for use as an insulin pump, a sensor-augmented pump (SAP), or a system with increasing levels of automated basal delivery and suspension. The system has two modes of operation: Manual Mode and Auto Mode.

Manual Mode / Auto Mode

Manual Mode includes all standard insulin pump and CGM features. When used with CGM, two automated SmartGuard™ features become available in Manual Mode: 1) Suspend before low with Resume basal and 2) Suspend on low with Resume basal. Both features work to minimise lows by stopping and restarting basal insulin in response to the patient's current sensor glucose (SG) value and their individualised low limit setting. The system requires at least 48 hours of insulin delivery data be collected in Manual Mode before Auto Mode can be initiated. Therefore, every patient must start MiniMed™ 670G technology in Manual Mode regardless of previous pump and CGM experience.

Auto Mode is the feature name for hybrid closed loop technology. It is controlled by a SmartGuard™ algorithm that regulates basal insulin in response to the rise and fall of real-time SG values and other parameters. Some Manual Mode settings, such as Insulin to Carbohydrate Ratios (ICR) and Active Insulin Time (AIT), are used in Auto Mode. Others, like basal rates, Insulin Sensitivity Factors (ISF) and glucose targets, are not used because they are calculated and controlled by the algorithm. Once Auto Mode is initiated, the goal is for patients to spend at least 80% of their time in Auto Mode to achieve time in range goals.

Auto Basal is the term used for basal insulin in Auto Mode. It is adjusted every five minutes based on current SG values, how far and how long SG has been away from target, how rapidly SG has been changing, the amount of insulin on board (basal and bolus), and the maximum delivery rate.

Glucose Targets are hard-set (Auto Basal to 6.7 mmol/L; Correction Boluses to 8.3 mmol/L). Auto Basal insulin adjusts every 5 minutes to target 6.7 mmol/L unless a Temp Target of 8.3 mmol/L is used. A Temp Target can be set for 30 minutes up to 12 hours anytime there is a risk or concern for lows.

Insulin Sensitivity Factor (ISF) is recalculated daily using the total daily dose (TDD) of all basal and bolus insulin.

Note: When using Auto Mode, the only two Manual Mode settings that impact bolus and basal insulin delivery are ICR and AIT. ICR has the greatest impact on glycaemia and typically needs to be strengthened once Auto Mode is initiated. Active Insulin Time has minimal impact and rarely needs to be adjusted.

EXPECTATIONS and RESPONSIBILITIES

Identifying Patients

The MiniMed™ 670G system is indicated for patients with type 1 diabetes, ages seven years and older. The MiniMed™ 670G system is contraindicated in cases where patients cannot read instructions on the pump screen, refuse to routinely check glucose, or are unwilling to count and enter carbs before eating.

Most patients transition to Auto Mode easily and are relieved to have the algorithm adjust basal insulin according to the real-time increases and decreases in glucose levels. However, it may take longer for patients who fall at extreme ends of the diabetes self-care spectrum to become comfortable and trust the system. For example:

Patients who strive for perfection with tight glycaemic control sometimes find it difficult to accept the transient highs that occur in Auto Mode as glucose gradually lowers back to target. Reviewing CareLink™ reports with these patients is particularly important so they can see if Auto Mode is resulting in more time in range with fewer lows.

Patients who do not perform basic self-care behaviours such as bolusing before eating, checking BG, or calibrating the sensor, may not be able to stay in Auto Mode enough to experience the full therapeutic benefit. For some of these patients, Auto Mode can relieve the burden of making diabetes decisions and provide motivation to complete the tasks needed for Auto Mode.

Setting Appropriate Expectations

The overarching goal is for patients to spend most of their time in Auto Mode. The system is designed with safety in mind to mitigate lows and maximise time in range (3.9-10.0 mmol/L). Therefore, when the system exits to Manual Mode, the priority is for patients to re-enter Auto Mode as quickly as possible.

One of the most important factors that leads to success when using Auto Mode is having realistic expectations. Most patients see a marked improvement in glycemia (especially overnight), less glucose variability, increased time spent in range (3.9-10.0 mmol/L), and fewer lows.[*] Improvement is seen faster in patients who are willing to accept the new concepts and implement behaviors needed for diabetes self-management.

Auto Mode Key Concepts

- The system is not fully automated
- Correction doses target 8.3 mmol/L, then Auto Basal gradually lowers SG to 6.7 mmol/L
- Frequent follow up is needed at first
- Glucose levels will not be perfect (may run higher than accustomed at first). Auto Basal will adjust to better match insulin requirements as the patient learns to use the system
- Patient Responsibilities:
  - Bolusing before eating (unless low) and counting carbs as accurately as possible
  - Calibrating 3-4 times / day (always before bed)
  - Responding to alerts and prompts (usually entering a BG) to stay in or re-enter Auto Mode
- Clinician Responsibilities:
  - Strengthening ICR as needed
  - Reviewing CareLink™ data uploads to evaluate glycemia, identify issues, make setting and / or behaviour changes (i.e., post-meal highs, lows, bolusing pre-meal, ICR is appropriate)
  - Recognising some situations (i.e., steroids, surgery) may need to be managed in Manual Mode

CareLink™ Personal data on file. Mar 2017- Sept 2018. 55,080 patients.

TRANSITIONING TECHNOLOGY TO THE MINIMED™ 670G SYSTEM

Patients can start either on pump or CGM first and transition quickly to full system use of pump with CGM. No evidence supports starting one before the other; this is usually a provider and / or patient preference. In some cases, pump and CGM technology can be started simultaneously.

The table below provides an outline of a typical pump and CGM start as patients transition from multiple daily injections (MDI) or pump technology to the MiniMed™ 670G system.

TRANSITIONING PATIENTS TO THE MINIMED™ 670G SYSTEM FROM:		
	MDI	**Pump Technology**
Initial Pump Settings (Write orders for Manual Mode)	Use standard formulas / guidelines to determine: ■ Basal rates, ICRs, ISFs, BG targets, AIT ■ Set up CareLink™ software account	Use current settings if glycaemia is acceptable: ■ If experiencing frequent excursions, re-calculate settings using standard formulas ■ Set up CareLink™ software account
Pump Start	Comprehensive training: ■ Buttons, menu navigation, infusion set insertion, Diabetic Ketoacidosis (DKA) management of lows, sick-day management, etc.	Teach new device: ■ Menus, buttons, use of Bolus Wizard™ feature, DKA management, etc. as needed.
Initial CGM Settings (Write orders for CGM)	Setting recommendations: ■ Alert on low: ON ■ Suspend before low: ON ■ All other alerts: Off	Setting recommendations: ■ Alert on low: ON ■ Suspend before low: ON ■ All other alerts: Off
CGM Start	When ready, start CGM: ■ Comprehensive training on calibration, sensor insertion, taping, trends and alerts, etc. ■ Set up CareLink™ software account	If currently using a pump: ■ Start Manual Mode & CGM simultaneously and complete comprehensive CGM training as outlined for MDI
Auto Mode Start (Write orders for Auto Mode Settings)	Recommendations: ■ Use Manual Mode at least 6-7 days and complete training before initiating Auto Mode. ■ Manual Mode settings do not have to be tightly titrated, however they should provide safe, reasonable glycaemic control with minimal risk for hypoglycaemia. ■ Consider strengthening ICR and decreasing basal rates by 10% if basal is > 50% of TDD. Assess for the following essential patient behaviours: ▪ Calibrates 3-4 times a day ▪ Gives corrections as instructed ▪ Uses pump & CGM appropriately ▪ Uploads to CareLink™ software ▪ Changes infusion site & sensor appropriately ▪ Enters carbs / boluses before eating	

Auto Mode Follow-up	Frequent follow up is recommended at first to:
	 ■ Assess patient understanding and address issues and questions.
	 ■ Review CareLink™ reports, evaluate glycaemia, system use, and need for behaviour or setting changes. (Refer to AIM Methodology page 15 for guidelines on evaluating CareLink™ data.)
	 ■ Review percent of time spent in Auto Mode (goal > 80%)
	 ■ Review time spent in range (3.9-10.0 mmol/L)
	     ▪ ≥ 70% of time for ages 14 and older
	     ▪ ≥ 65% of time for ages 7-13 yrs	

AUTO MODE INITIATION

When patients transition from their current therapy to Manual Mode, the system begins recording all insulin delivery data. If patients have been practicing during training, clear all Active Insulin prior to initiating Manual Mode, as all recorded data should be actual therapeutic values (not practice values). Auto Mode can be initiated remotely or in person.

Requirements for Auto Mode Initiation

The following requirements are needed for the system to enter Auto Mode:

- A working Guardian™ Sensor 3

- At least 8 units / day TDD

- No more than 250 units / day TDD

- A current BG entered

- Programmed ICR and AIT

- A minimum of 48 hours of insulin history in Manual Mode (starts midnight after pump start) before Auto Mode can be turned ON

Note: Auto Mode cannot initiate if the system is delivering a bolus, a temp basal is running, or the pump is suspended.

Best Practices

Below is a list of best practices to enhance Auto Mode use:

- Provide guidelines on when patients should contact your office (i.e., ketones, extreme highs or lows, illness), the product trainer, or the Medtronic Helpline

- Collect at least 6 days of Manual Mode pump and CGM data before initiating Auto Mode

- Establish a CareLink™ data downloading schedule

- Evaluate reports to assess glycemia, time in range, patient understanding and use of system, and reasons for Auto Mode exits

- Make setting adjustments and coach patient on use of system as needed

- Schedule follow-up visit

Note: Since many patients are over-basaled and under-bolused, ICRs typically need to be strengthened and basal rates lowered (10%) once Auto Mode is initiated. Individuals with A1Cs > 9% may need additional adjustments to ICR sooner and more frequently as insulin sensitivity improves.

AUTO BASAL

When using the MiniMed™ 670G system, the goal is to stay in Auto Mode as much as possible. Therefore, when the system exits Auto Mode, the patient's response should be to resolve the issue and return to Auto Mode quickly. There is a direct correlation between wearing the sensor (≥ 85% of the time), remaining in Auto Mode (≥ 80% of time), and spending more time in target (3.9-10.0 mmol/L).*

Auto Mode must be turned ON and CGM must be used with SG readings transmitting for the system to enter and stay in Auto Mode. When the pump is in Auto Mode, basal insulin can deliver either as **Auto Basal** or **Safe Basal**.

Auto Basal

When Auto Basal is delivering, a blue SmartGuard™ shield with the sensor glucose displays on the pump screen.

Blue SmartGuard™ Shield

Sensor Glucose

Active Insulin Remaining

Auto Basal is fully automated and delivers in micro-doses as often as every 5 minutes. Each dose is determined by an algorithm that regulates basal insulin using a hard-set target of 6.7 mmol/L. Auto Basal's overall objective is to keep glucose between 3.9-10.0 mmol/L (Time in Range). The algorithm accomplishes this by increasing, decreasing, stopping and restarting basal insulin as needed to coincide with the rise and fall of SG.

Auto Basal is not intended to manage significant highs, which can result from missed meal boluses or under-estimated carb intake. Highs > 8.3 mmol/L should be managed with a correction bolus (as recommended by the system) to lower glucose to the hard-set 8.3 mmol/L correction target. Auto Basal then continues to lower glucose gradually to 6.7 mmol/L (basal target). Increases in Auto Basal can be particularly beneficial in helping mitigate unnoticed highs (i.e., post meal or overnight).

A Temp Target of 8.3 mmol/L can be set for 30 minutes up to 12 hours when there is increased risk or concern for lows (i.e., exercise).
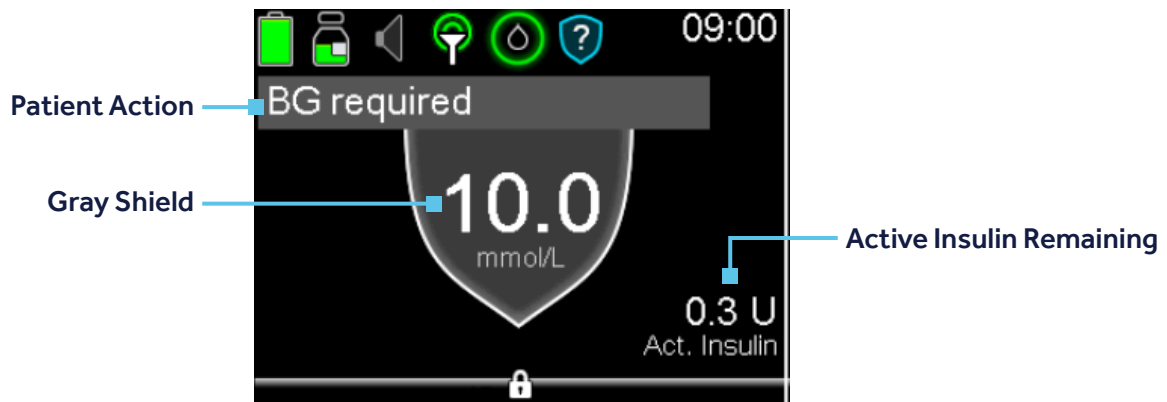

Note: In Auto Mode, the programmed Manual Mode basal rates and Max Basal settings are not used. Therefore, adjusting Manual Mode basal rates or Max Basal does not affect Auto Basal or Safe Basal delivery in any way.

SAFE BASAL

Safe Basal is a single, fixed rate of insulin that delivers in place of Auto Basal any time the algorithm determines there is an issue with the current SG reading or there is a task that needs to be completed for Auto Basal to begin delivering again (i.e., entering a BG). The purpose of Safe Basal is to provide baseline insulin and to give time for the system or patient to resolve the issue that caused the system to move from Auto Basal to Safe Basal.

When Safe Basal is delivering, a grey shield displays on the pump screen. A SG reading may or may not be displayed on the shield. If there is an action the patient can take to resolve the issue that caused the system to deliver Safe Basal instead of Auto Basal, it will show in a grey banner at the top, left of the screen.

Patient Action ——— | BG required | ——— 09:00

Gray Shield ——— 10.0 mmol/L

Active Insulin Remaining ——— 0.3 U Act. Insulin

Best Practice: Enter a BG, calibrate, and look at the pump screen before going to bed to ensure the blue colored shield is showing. If the grey shield is showing, the patient should follow the prompts on the screen and return to Auto Basal (blue coloured shield) before going to bed.

Auto Basal will change to Safe Basal if the:

1) Minimum Auto Basal amount has been delivering for 2½ hours
2) Maximum Auto Basal amount has been delivering for 4 hours
3) Sensor signal is lost, not transmitting, or not available (i.e., sensor calibration expired, sensor was changed or sensor warm-up is occurring)
4) SG differs from entered BG by ≥ 35%
5) System has detected the sensor may be under-reading

Safe Basal can deliver for a maximum of 90 minutes. If the issue is resolved within 90 minutes, Auto Basal resumes and the pump remains in Auto Mode. If the condition is not resolved, the pump exits to Manual Mode.

The system will exit directly to Manual Mode (without going to Safe Basal) if the:

1) SG has been ≥16.7 mmol/L for 1 hour
2) SG has been ≥ 13.9 mmol/L for 3 hours
3) Insulin flow blocked alarm has occurred
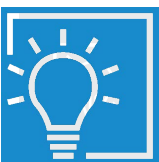
KEY LEARNING Entering a BG is usually all that is needed for the system to begin delivering Auto Basal again. This is especially important at bedtime, as entering a BG before going to bed resets the Min Delivery and Max Delivery time-limits (2½ or 4 hrs) which can help mitigate overnight exits.

AUTO MODE ALGORITHM

How Auto Basal is Determined

The 5 minute Auto Basal doses are determined using multiple factors including:

1) **Current SG:** The most recent SG reading
2) **PID Algorithm:**
   a) **Proportional:** How far SG is away from the 6.7 mmol/L target
   b) **Integral:** How long SG has been away from the 6.7 mmol/L target
   c) **Derivative:** How rapidly SG has been changing
3) **Insulin Feedback:** Total amount of active insulin (basal and bolus) on board.
4) **Auto Mode Max Delivery:** The maximum amount of Auto Basal that can be delivered over a period of time. It is recalculated every 24 hrs using fasting values and the median TDD.

The median TDD is comprised of basal and bolus insulin delivered over the last 2-6 days. It is used to update Auto Mode parameters such as Safe Basal, ISF, and Max Delivery.

In situations where the pump has been suspended or the battery has been removed for one or more days (i.e., pump vacation, ICU environment), the algorithm can look back over the last 14 days to find 2 to 6 days of TDD that meet Auto Mode requirements (page 6).

Note: The algorithm calculates Auto Basal using the above parameters; it does not learn an individual's time of day patterns or diurnal variations (i.e., dawn phenomenon).

How and When Safe Basal is Used

Safe Basal delivers at one of two rates: Safe Basal Standard or Safe Basal Low. Safe Basal Low is the more conservative rate.

The algorithm calculates Safe Basal Standard and Safe Basal Low using a percentage of the median TDD and determines which to deliver based on the following:

Safe Basal Low is selected if the algorithm determines the:

1) SG is low – OR –
2) Estimated total insulin level is high – OR –
3) Temp Target (8.3 mmol/L) is in use

If none of the above conditions exist, the system selects Safe Basal Standard.

The algorithm monitors these conditions, and if SG readings are transmitting, the system will transition between Safe Basal Standard and Safe Basal Low as needed.

FOOD & CORRECTION BOLUSES

Food Boluses

Food boluses are calculated the same as in Manual Mode, using the programmed carb ratio(s) and the number of grams entered. Bolusing pre-meal is key to maximizing time in Auto Mode. Encourage patients to bolus 5-15 minutes before eating, unless glucose is low. If a bolus is given after eating, glucose will begin to rise before the bolus is given and Auto Basal will begin to increase in an attempt to return glucose to the 6.7 mmol/L basal target. Bolusing post-meal increases the risk of post-prandial highs and / or a high followed by a precipitous drop in glucose.

Carbohydrate counting is still important for optimal post-prandial control and patients should try to count carbohydrates as accurately as possible. The increases and decreases in Auto Basal can usually handle small discrepencies in carb counting. However, the increases / decreases are not designed to accommodate large discrepancies (i.e., patient forgets to bolus for a meal or boluses for a meal and does not eat).

Correction Boluses

In Auto Mode, correction boluses are calculated using the programmed AIT, a hard-set correction target of 8.3 mmol/L and an ISF calculated by the algorithm. The ISF is recalculated every 24 hours and is based on the median TDD.

Note: Manual Mode's programmed ISF is only used in Manual Mode.

Correction boluses, in Auto Mode, are only calculated if a BG > 8.3 mmol/L is entered AND there is not enough active insulin remaining from a previous bolus to lower glucose to 8.3 mmol/L (correction target). The goal of a correction bolus is to lower highs to 8.3 mmol/L and then allow Auto Basal to lower glucose to 6.7 mmol/L (basal target). This helps mitigate lows that can occur from over-correcting highs. If a patient expresses concern that a 8.3 mmol/L target is too high, remind them that Auto Basal will continue to lower glucose.

Some patients try to lower glucose further and faster by entering carbs and bolusing for food they did not eat. Entering phantom carbs may lower glucose faster; however, it often results in lows that have to be managed with unnecessary carbs / calories. To help manage these lows, encourage patients to allow Auto Basal to gradually return glucose to 6.7 mmol/L.

Note: If down arrows are showing, patients may want to delay giving a correction bolus until glucose is stable and no longer dropping.

COMMON BOLUS BEHAVIOURS

Bolusing after eating: Typically results in post-prandial highs followed by either a low or a sustained high.

- **Post-prandial highs followed by a low:** This phenomenon occurs if there is a significant mismatch in glucose from food entering the bloodstream before insulin. In Auto Mode, if glucose rises rapidly, Auto Basal increases substantially. Increases in Auto Basal, coupled with a post-meal bolus, can result in too much insulin and cause a post-meal low.

    - Encourage pre-meal bolusing to help mitigate the issue.

- **Sustained post-prandial high:** Occurs when insufficient insulin is given, and the deficit is more than Auto Basal increases can accommodate.

    - Evaluate ICR (strengthen as needed), carb counting skills, and encourage pre-meal bolusing.

Underestimating carbs:

- Enter and bolus for additional carbs at the end of the meal.

- If > 1 hour since eating, enter current BG and give the system recommended correction bolus.

Unsure of how much will be eaten:

- Enter and bolus pre-meal for the grams they are certain they will eat.

- If additional grams are consumed, enter and bolus for additional grams as eaten. Reinforce concept that bolusing 5-15 min pre-meal (patients ≥ 7 yrs) allows for a better match of insulin and glucose entering bloodstream together and minimizes post-meal excursions.

Missing a bolus: If a bolus is forgotten and glucose is high:

- If ≤ 1 hour after eating, enter half the grams eaten and recheck BG in an hour.

    - If glucose is still high, enter current BG and give the system recommended correction bolus.

- If > 1 hour after eating, enter the BG and give the system recommended correction bolus.

Dosing for high-fat / high-protein meals: Auto Basal can usually accommodate glucose fluctuations associated with high fat / high protein meals. Dual Wave™ and Square Wave™ boluses are not available in Auto Mode.

- If post-meal lows are followed by highs, suggest entering 50%-75% of grams before eating and the entering the remainder 1-2 hours post meal. Some high-fat / high-carb meals may require all of the carbs be entered before eating with additional grams added later to help compensate for the high carb / fat content and slowed digestion of the meal.

    Note: Patients with gastroparesis may need a similar bolus strategy (i.e., 50% before / 50% after).

Bolusing more than 25 units: The maximum bolus allowed by the pump is 25 units. When a bolus exceeds 25 units, it must be given in two separate boluses.

- Enter BG and as many grams as possible without exceeding the 25 unit limit and deliver that bolus. (Ensures larger bolus is delivered in case second bolus is forgotten).

- Enter remaining grams and give second bolus.

AUTO MODE EXITS

If certain conditions occur, the system will exit Auto Mode and enter Manual Mode. When exits occur, the goal is to return to Auto Mode as soon as possible. The pump has an Auto Mode Readiness screen that can be reviewed to identify requirements that must be met and the steps that need to be taken to re-enter Auto Mode.

AUTO MODE EXITS	
Common Reasons	**Actions to Take**
■ Missed Calibration	■ Test BG and calibrate to re-start Auto Mode. **Note:** Calibrating 3-4 times a day helps to minimize this exit
■ Prolonged High SG ▪ SG ≥ 16.7 mmol/L for more than 1 hour ▪ SG ≥ 13.9 mmol/L for more than 3 hours	■ Check infusion set, check ketones, consider injection, monitor BG ■ Enter current BG to re-enter Auto Mode.
■ Auto Mode Min Delivery ▪ Min basal delivery exceeded the 2½ hour limit and Safe Basal has delivered for 1½ hours (4 hours total)	■ Enter current BG to re-enter Auto Mode ■ If low, manage with glucose, consider using less than 15 grams since little to no Auto Basal has been delivering
■ Auto Mode Max Delivery ▪ Max basal delivery exceeded the 4 hour limit and Safe Basal has delivered for 1½ hours (5½ hours total)	■ Enter current BG to re-enter Auto Mode ■ Give correction bolus as recommended by the pump
Note: Entering BG resets the Min and Max 2½ and 4 hour delivery time-limits. If BG is entered before time-limits are reached, Auto Basal will continue delivering.	
■ Sensor Algorithm Underread ▪ System has determined the sensor reading does not match the algorithm-estimated glucose	■ Enter current BG if requested by the system

Note: When the system exits Auto Mode and enters Manual Mode, the SmartGuard™ features are OFF. If the patient is staying in Manual Mode for any length of time, the Suspend before low feature should be turned ON.

■ **Suspend before low:** Automatically stops insulin delivery if SG is ≤ 3.9 mmol/L above the set low limit AND it is predicted to be within 1.1 mmol/L of the low limit in the next 30 minutes.

■ **Suspend on low:** Automatically stops insulin delivery when SG reaches or falls below the set low limit.

■ **Resume basal:** If either SmartGuard™ suspend feature is ON, Resume basal is active and basal insulin will automatically resume after it has been suspended for a minimum of 30 minutes up to 2 hours if:
 ▪ SG is ≥ 1.1 mmol/L above the set low limit AND
 ▪ SG is predicted to be ≥ 2.2 mmol/L above the low limit within the next 30 minutes. The patient can manually resume basal insulin at any time.
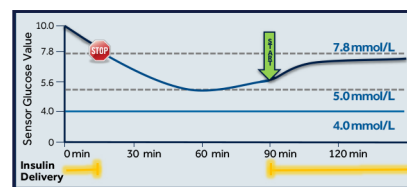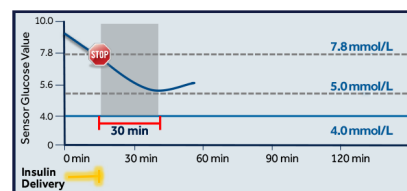
Note: SmartGuard™ suspend events cannot last > 2 hours. Therefore, basal insulin automatically resumes delivery after 2 hours regardless of the glucose value.

For more information on Manual Mode see page 38.

WARNING: Suspend before low and Suspend on low are not intended to be a treatment for low blood glucose. Having insulin suspended when glucose is low may not bring your blood glucose back to your target range for several hours. In that case, you run the risk of hypoglycaemia. Always confirm your blood glucose readings with your BG meter and manage your diabetes according to the recommendations of your healthcare professional.

ADJUSTING PUMP SETTINGS

Manual Mode Setting Adjustments

Prior to initiating Auto Mode, Manual Mode settings are adjusted using the same parameters and protocols used in traditional pump technology.

Once Auto Mode is initiated, the strategy for adjusting Manual Mode settings is to mirror Auto Mode settings as much as possible.

1) **Basal Rate Settings:** Evaluate 7 to 10 days after starting Auto Mode AND at every office visit to confirm the Manual Mode 24 hour basal total is comparable to the Auto Mode basal total.

2) **Suspend before low:** If lows occur in Manual Mode (despite the use of Suspend before low and the suspension of insulin), raise the low limit setting (eg., 3.6 mmol/L to 3.8 mmol/L).
   Note: When Auto Mode exits to Manual Mode, the basal rate that is programmed for that time of day begins to deliver regardless of the current glucose level. If the exit is the result of a Min Delivery (Auto Basal has stopped or nearly stopped for a period of time), and if the patient's glucose is low or near low when the Manual Mode basal begins, glucose may decrease further.

Strategies for Mirroring the Auto Mode 24-Hour Basal Total

Take the average daily Auto Basal total (found in Statistics section of Assessment & Progress Report) and use one of these methods:

1) Divide Auto Basal total by 24 hours and set one basal rate for Manual Mode

   - If dawn phenomenon exists, use above method and modify for dawn rise without exceeding Auto Basal's total – OR –

2) Modify current Manual Mode basal rates proportionally to ensure the sum does not exceed Auto Basal's total.

Auto Mode Setting Adjustments

Only two programmed Manual Mode settings, ICR and AIT, impact insulin delivery in Auto Mode. When evaluating these settings for Auto Mode optimisation, keep in mind:

ICR is the setting that has the <u>greatest</u> impact on glycaemia and time spent in range. It is the setting that:

- Most commonly needs to be adjusted and
- Usually needs to be strengthened (deliver more insulin)

AIT has <u>minimal</u> affect on glycaemia in Auto Mode and impacts correction dose amounts ONLY if there is active insulin remaining from a previous food or correction bolus.

- Shortening AIT decreases the length of time bolus insulin is tracked and allows the system to give larger correction doses sooner

ADJUSTING PUMP SETTINGS

Evaluating Post-Meal Excursions, Timing of Boluses, and ICR

Use the CareLink™ Weekly Review report to identify post-meal excursions and evaluate:

Post-meal Highs (> 3.3 mmol/L above pre-meal 2 hours after eating): Assess ICR, bolus timing, accuracy of carb counting, consistency of carb entry.

- **If ICR:** Lower ICR 10–20% to give more insulin

- **If Timing of Bolus:** Encourage bolusing 5-15 min pre-meal and / or add protein to meal (especially breakfast)

- **If Carb Counting:** Encourage meeting with a diabetes educator/dietitian

- **If Shaving Carbs** (common behaviour in conventional therapy to avoid lows): Stress importance of accurate carb entry and bolusing 5-15 min before eating unless low

Post-meal Lows (< 4.0 mmol/L): Assess ICR, bolus timing, accuracy of carb counting,

- **If ICR:** Increase ICR 10-20% to give less insulin

Note: Explain accurate carb entry and bolusing 5-15 min pre-meal helps with determining a most accurate ICR.

Reinforce concept of Auto Basal increasing, decreasing or stopping for small discrepancies in carb counting.

Evaluating and Adjusting Active Insulin Time

AIT is a secondary adjustment and has minimal impact on the algorithm. AIT rarely needs to be adjusted beyond the 3-4 hour recommended setting. However, it should be evaluated if lows are occurring following a correction bolus that was given within the AIT window of a previous correction bolus.

Use the CareLink™ Weekly Review report to:

1) Identify correction boluses given in Auto Mode (not Manual Mode):

- Without food – AND –

- Within Active Insulin Time of a previous correction bolus – AND –

2) Assess glucose 2 to 3 hours post-correction:

- If glucose is above the 8.3 mmol/L target: Shorten AIT 15 to 30 minutes

- If glucose is below the 8.3 mmol/L target: Lengthen AIT 15 to 30 minutes

Note: If insulin is given via injection, the Auto Mode algorithm cannot account for that dose. It is recommended that the patient exit Auto Mode before giving the injection, turn Suspend before low ON, and stay in Manual Mode for the duration of the injected insulin's action time.

WARNING: Do not use Auto Mode for a period of time after giving a manual injection of insulin by syringe or pen. Manual injections are not accounted for in Auto Mode. Therefore, Auto Mode could deliver too much insulin. Too much insulin may cause hypoglycemia. Consult with your healthcare professional for how long you need to wait after a manual injection of insulin before you resume Auto Mode.

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 glycaemia and proper use of technology (A & P Report)

I) Identify issues and their cause (Weekly Review Report)

M) Make and document setting and / or suggested behaviour changes (Device Settings Report).

Assessment and Progress (A&P) Report: Provides a synopsis of overall glycaemia and use of technology.

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.

REVIEW IN THE FOLLOWING ORDER:

1) **Statistics:** Assess technology use,

2) **Auto Mode Exits:** Evaluate frequency and reason for exits,

3) **Time in Range:** Assess time spent in, above, and below target range,

4) **Percentile Comparison:** Assess overall glycaemia. Compare to previous download.

Statistics

Statistics	(A)	(B)	
Auto Mode (per week)	97% (6d 20h)	97% (6d 19h)	1
Manual Mode (per week)	2% (04h)	3% (05h)	
Sensor Wear (per week)	98% (6d 21h)	97% (6d 18h)	2
Average SG ± SD	7.8 ± 2.5 mmol/L	7.6 ± 2.8 mmol/L	
Estimated A1C	6.5%	6.4%	
Average BG	9.3 ± 3.0 mmol/L	9.4 ± 3.9 mmol/L	
BG / Calibration (per day)	6.4 / 2.9	6.3 / 3.1	
Total daily dose (per day)	30 units	27 units	
Bolus amount (per day)	18U (60%)	17U (63%)	3
Auto Basal / Basal amount (per day)	12U (40%)	10U (37%)	
Set Change	Every 3.3 days	Every 4.0 days	
Reservoir Change	Every 3.3 days	Every 4.0 days	
Meal (per day)	6.5	6.1	
Carbs entered (per day)	159 ± 57 g	148 ± 27 g	4
Active Insulin time	2:45 hrs	2:45 hrs	5

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)

Note: Technology 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.

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)

Statistics (continued)

5) **Active Insulin Time (AIT) GOAL: Appropriately set for correction bolus to deliver enough insulin to lower glucose to the 8.3 mmol/L correction target, without stacking insulin and causing lows.**

Correcting glucose to 8.3 mmol/L and allowing Auto Basal to gradually lower it to 6.7 mmol/L may take longer than when correcting to a lower target (i.e., 5.6 mmol/L), 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: Minimise number and length of exits / Re-enter Auto Mode as soon as possible


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 (3.9-10.0 mmol/L) GOAL: ≥ 70% time for 14 yrs and older | ≥ 65% time for ages 7-13 yrs
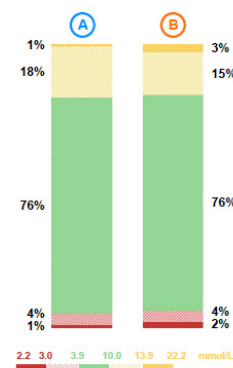
Evaluate time spent in each range:

- **Time in Range (3.9-10.0 mmol/L)**
  - If < 70% time spent in range (< 65% for 7-13 yrs), use Weekly Review report to evaluate cause of lows and highs.

- **Lows (3.1-3.8 mmol/L)**
  - 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 (< 3.1 mmol/L)**
  - If > 1% of time spent below 3.1 mmol/L, 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 minimising variability

Assess overall glycaemia 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 and 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 glycaemia, behaviour and technology 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. Emphasise importance of bolusing before eating, unless managing 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.

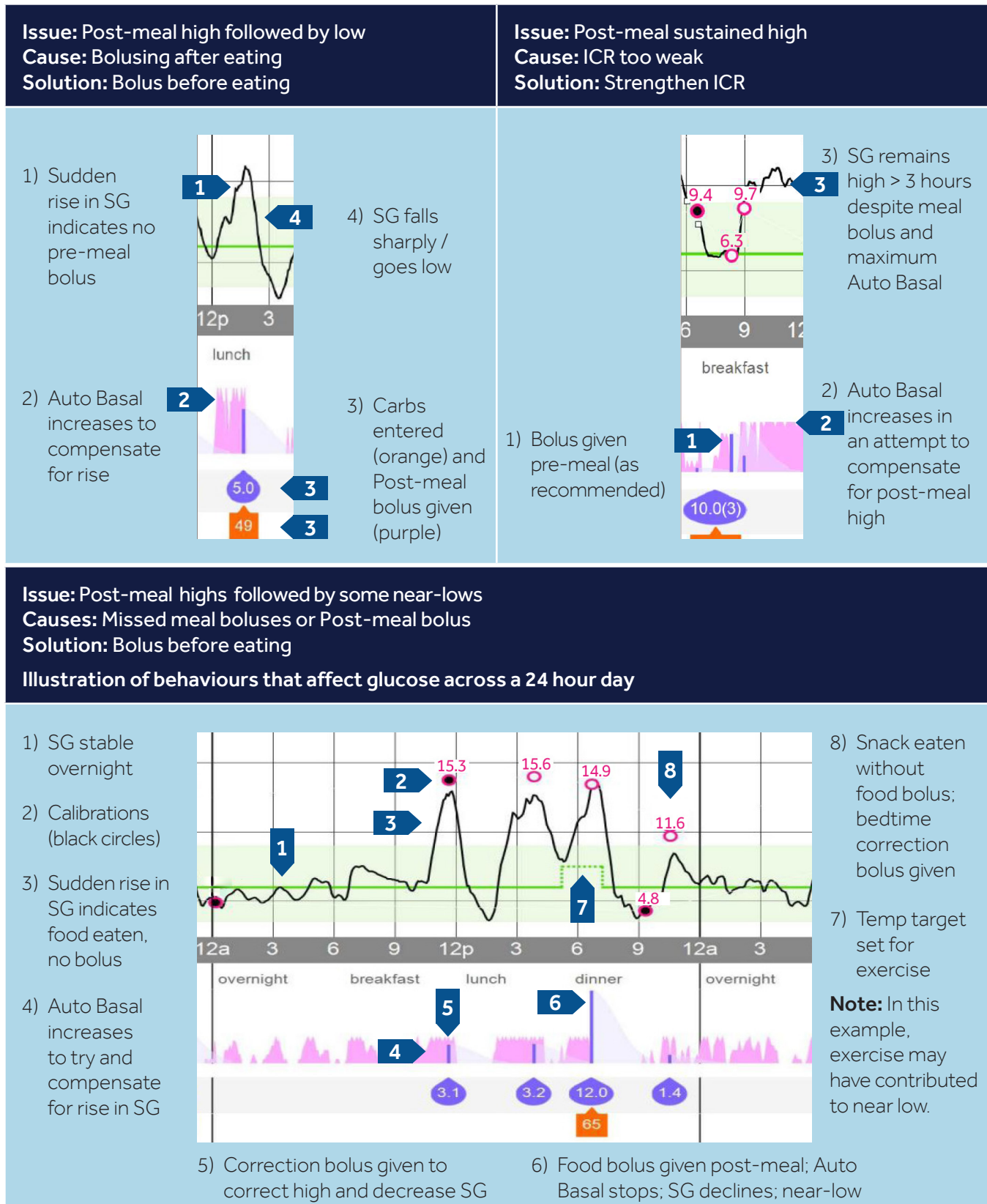- **Overnight lows:** Assess for low bedtime glucose, phantom carbs, exercise, too much correction dose or inadequate ICR with bedtime snack.

- **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 > 8.3 mmol/L.

- **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)

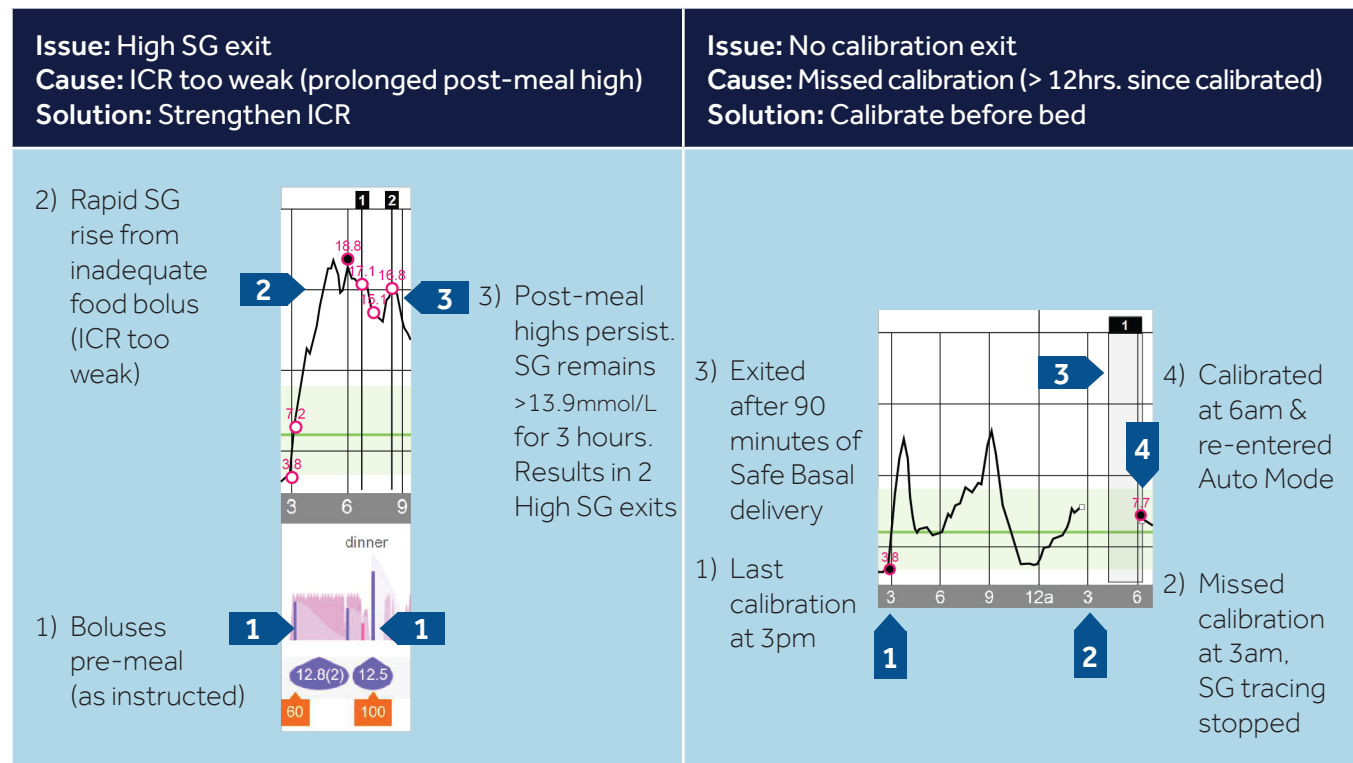Illustrations of glycaemic and behaviour issues commonly seen on Weekly Review Reports.

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

4) SG falls sharply / goes low

3) Carbs entered (orange) and Post-meal bolus given (purple)

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

3) SG remains high > 3 hours despite meal bolus and maximum Auto Basal

1) Bolus given pre-meal (as recommended)

2) Auto Basal increases in an attempt to compensate for post-meal high

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

Illustration of behaviours 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

8) Snack eaten without food bolus; bedtime correction bolus given

7) Temp target set for exercise

Note: In this example, exercise may have contributed to near low.

5) Correction bolus given to correct high and decrease SG

6) Food bolus given post-meal; Auto Basal stops; SG declines; near-low

Weekly Review Report (continued)

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

The most common exits that setting or behaviour 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

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

3) Post-meal highs persist. SG remains >13.9mmol/L for 3 hours. Results in 2 High SG exits

1) Boluses pre-meal (as instructed)

Issue: No calibration exit
Cause: Missed calibration (> 12hrs. since calibrated)
Solution: Calibrate before bed

3) Exited after 90 minutes of Safe Basal delivery

1) Last calibration at 3pm

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

2) Missed calibration at 3am, SG tracing stopped

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 > 8.3 mmol/L , give system-recommended correction bolus.

KEY LEARNINGS FOR OPTIMISING TIME IN AUTO MODE
- The most impactful setting clinicians can adjust is the ICR.
- The most impactful behaviours 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

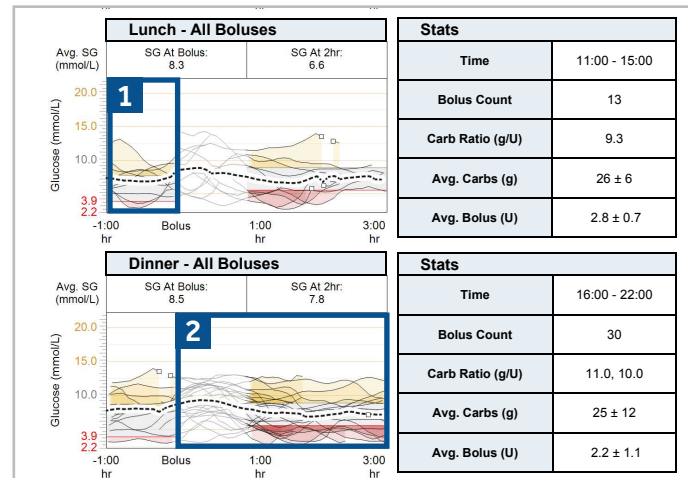This report is used to evaluate meal bolus timing issues and carb ratio effectiveness.

GOAL: Pre-meal within target / Post-meal ≤ 3.3 mmol/L 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 (> 3.3 mmol/L 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)

Lunch - All Boluses		Stats	
SG At Bolus: 8.3	SG At 2hr: 6.6	Time	11:00 - 15:00
		Bolus Count	13
		Carb Ratio (g/U)	9.3
		Avg. Carbs (g)	26 ± 6
		Avg. Bolus (U)	2.8 ± 0.7

Dinner - All Boluses		Stats	
SG At Bolus: 8.5	SG At 2hr: 7.8	Time	16:00 - 22:00
		Bolus Count	30
		Carb Ratio (g/U)	11.0, 10.0
		Avg. Carbs (g)	25 ± 12
		Avg. Bolus (U)	2.2 ± 1.1

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

SITUATIONS REQUIRING SPECIAL CONSIDERATION

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	Use Temp Target (8.3 mmol/L) ■ 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.
■ If lows persist even with use of Temp Target – OR – spontaneous exercise	■ 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. ■ 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 ■ 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 AUTO MODE

Assess	Actions to Consider
A1C prior to starting Auto Mode ■ If > 9% ■ 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 **Auto Mode Exits** ■ If Min Delivery exits occur due to endogeneous insulin secretion	■ 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 endogeneous insulin subsides

WARNING: Medtronic performed an evaluation of the MiniMed™ 670G hybrid closed loop 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 does of 8 units per day because the device requires a minimum of 8 units per day to operate safely.

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 2.8 mmol/L and 3.3 mmol/L. 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 manage according to the recommendations of your healthcare professional. Solely relying on these sensor glucose alerts and readings for management decisions could result in missing severe hypoglycaemia (low blood glucose) events.

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	■ 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 individualized plan. ■ Adjust timing and amount of carb entry when delayed food absorption is anticipated.

SITUATIONS REQUIRING SPECIAL CONSIDERATION

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 >0.11 mmol/L).	

SICK DAYS

Assess	Actions to Consider
Glucose ■ If glucose is consistently < 5.6 mmol/L ■ If glucose is consistently high	■ Use Temp Target (8.3 mmol/L). ■ 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 stabilize. ■ Set low alert ≥0.6 mmol/L 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 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 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 (8.3 mmol/L) 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 Auto Mode use. ▪ Follow hospital guidelines ▪ Discontinue Auto Mode and / or pump technology 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 stabilize. ▪ Re-initiate 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 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: Utilise Manual Mode with Suspend before low and decreased Temp Basal rates.

Notes: 1) All BG values for system checks, calibration, and dosing may 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.
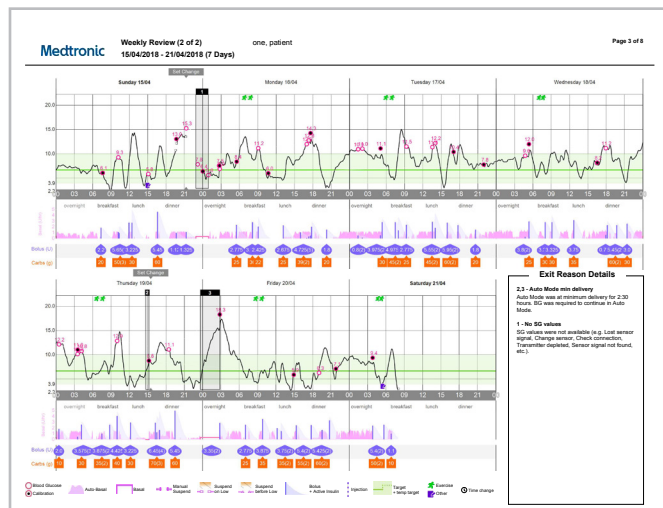
CareLink™ Software Reports

Reports containing glucose and insulin delivery data are generated by downloading MiniMed™ 670G pump and sensor data into CareLink™ software. The following pages discuss the four reports below and provide guidance on how to read the data found in each report.
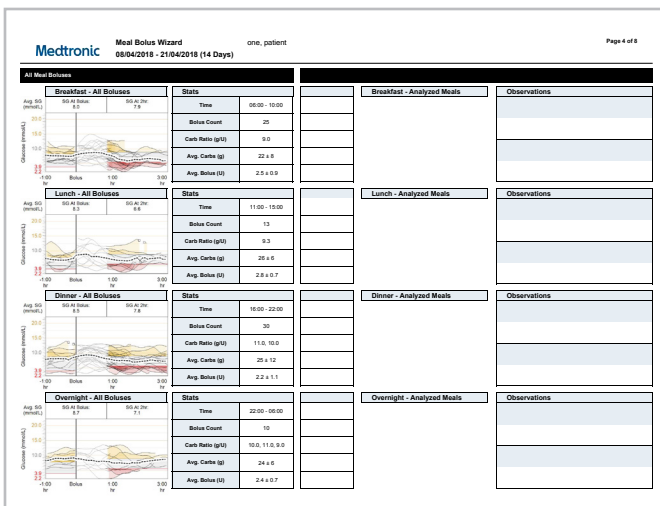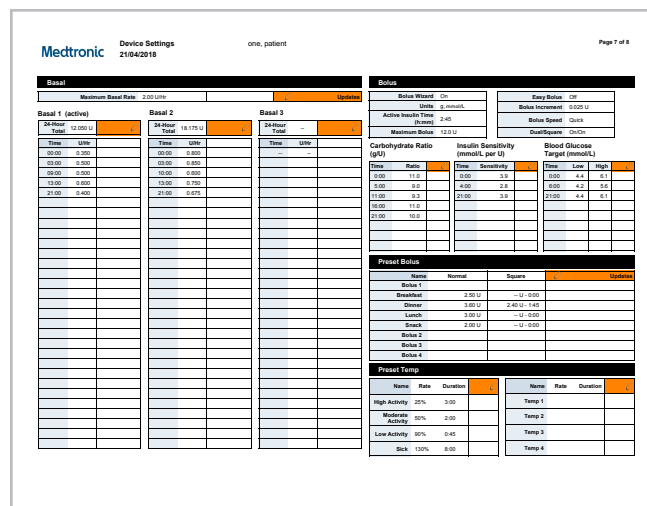
Assessment and Progress Report
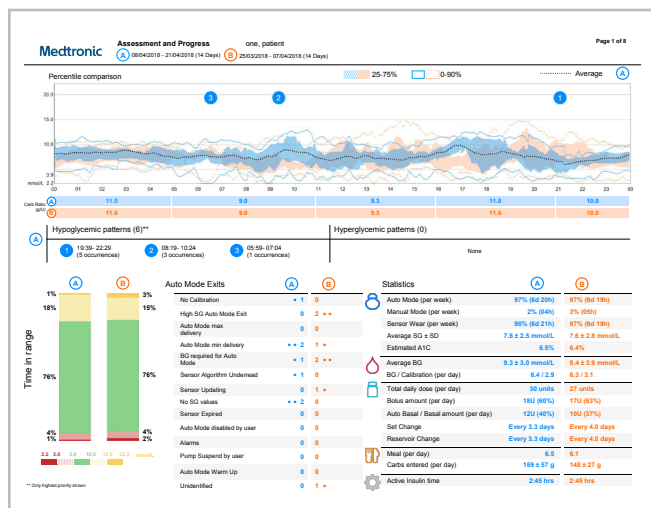
Weekly Review Report

Meal Bolus Wizard Report
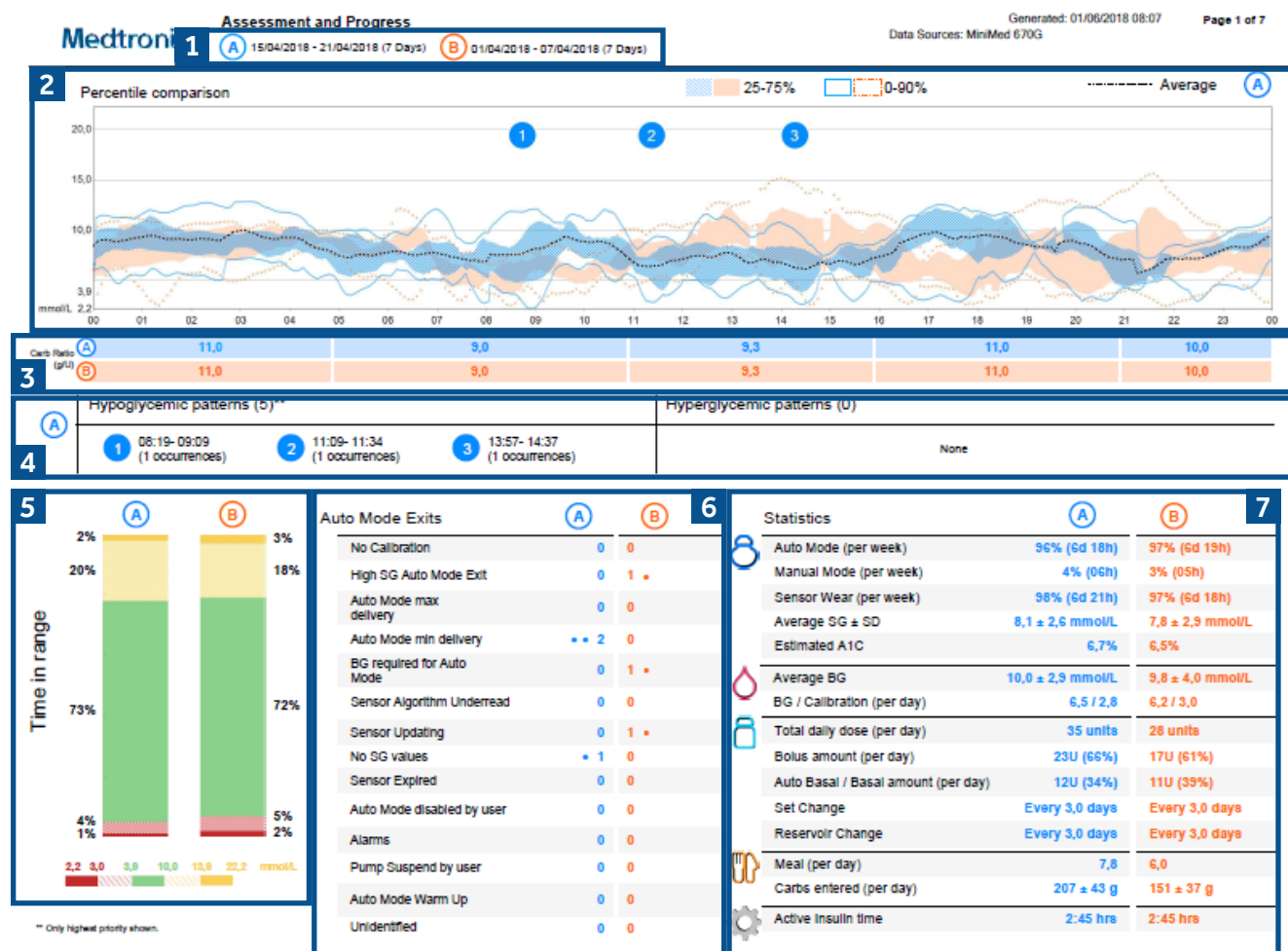
Device Settings Report

Assessment and Progress Report (7 sections)

Used to assess changes in overall glycaemia, time in Auto Mode, Auto Mode exits, Time in Range. Includes Auto Mode and Manual Mode data for reporting period.

Note: If worn without CGM, only Statistics table will have data (bottom right of report).

1   Date Ranges

All sections (except 4) can display two customisable date ranges: Range (A) and Range (B).

- Range (A): Current data - Defaults to last 14 days of data from date of download. Can be set from 1 to 90 days.
  Best Practice: Evaluate most recent 14 days of data.

- Range (B): Historical data - Defaults to 3 months prior to (A); Shows same number of days as (A) (maximum 30 days) **Best Practice**: Compare (A) to (B) to assess therapeutic progress and glycaemic improvement from last office visit or therapeutic change.

**Note:** Historical date range must be selected for (B) data to populate.

CARELINK™ ASSESSMENT AND PROGRESS REPORT

2   Percentile Comparison Chart for Ⓐ and Ⓑ

- Blue shaded area Ⓐ : depicts current interquartile data (25th to 75th percentiles); represents 50% of glucose values collected during current reporting period.
  - Blue solid lines (above and below blue shaded area) depict the 0 to 90th percentile range for Ⓐ .
- Orange shaded area Ⓑ : depicts historical interquartile data (25th to 75th percentiles); represents 50% of glucose values collected during historical reporting period.
  - Orange dotted lines (above and below orange shaded area) depict the 0 to 90th percentile range for Ⓑ .

Top 10th percentile not included as these are rarely indicative of overall glucose patterns.

Best Practice: Use graph as visual tool to show patient improvements in glycaemia.
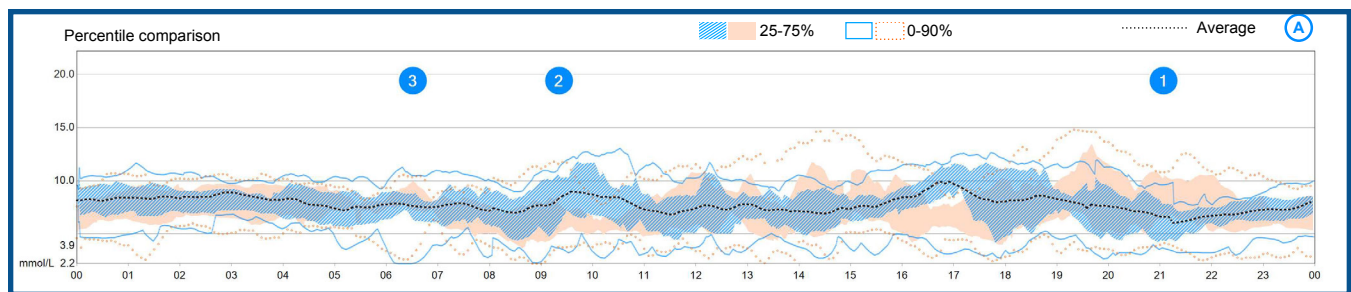
3   Carb Ratios for Ⓐ and Ⓑ

Ratios are listed and correspond with time of day programmed. Ratios less than 10 grams / unit display as a tenth of a gram.

Carb Ratio (g/U)					
Ⓐ	11.0	9.0	9.3	11.0	10.0
Ⓑ	11.0	9.0	9.3	11.0	10.0

4   Hypoglycaemic / Hyperglycaemic Patterns for Period Ⓐ

The numbered blue circles identify consistent high or low patterns; correlates with numbered circle on the Percentile Comparison Chart.

Ⓐ	Hypoglycemic patterns (6)**			Hyperglycemic patterns (0)
	① 19:39- 22:29 (5 occurrences)	② 08:19- 10:24 (3 occurrences)	③ 05:59- 07:04 (1 occurrences)	None

- Hypoglycaemic patterns identified when SG falls and stays below target for at least 30 mins.
- Hyperglycaemic patterns identified when average SG for that time period is above target.
- Number of occurrences noted beneath each time period.

5 Time in Range

Graph depicts time spent in specified glucose ranges.
Compare Ⓐ to Ⓑ to assess improvement.

GOAL: ≥ 70% of time spent in 3.9-10.0 mmol/L range (14 yrs and older)
≥ 65% of time spent in 3.9-10.0 mmol/L range (7-13 yrs)

If > 3% of time spent below 3.9 mmol/L or if > 1% of time spent < 3.1 mmol/L, evaluate ICR, AIT and patient behaviours to determine cause(s) of lows.

Note: Glucose ranges are customisable and can be adjusted in CareLink™ software.

6 Auto Mode Exits

Table shows Auto Mode Exit reasons and frequency.
Most common Auto Mode Exits are:

- No Calibration: System calibration has expired.
- High SG: ≥ 16.7 mmol/L for 1 hour or ≥ 13.9 mmol/L for 3 hours.
- Sensor Algorithm underread: System determined SG did not match estimated glucose calculated by the algorithm.
- Auto Mode max delivery: Auto Basal exceeded the 4-hour time limit + Safe Basal (1½ hour).
- Auto Mode min delivery: Auto Basal exceeded the 2½-hour time limit + Safe Basal (1½ hour).

GOAL: Limited exits. Achieve ≥ 80% of time in Auto Mode.

Auto Mode Exits	Ⓐ	Ⓑ
No Calibration	• 1	0
High SG Auto Mode Exit	0	2 • •
Auto Mode max delivery	0	0
Auto Mode min delivery	• • 2	1 •
BG required for Auto Mode	• 1	2 • •
Sensor Algorithm Underread	• 1	0
Sensor Updating	0	1 •
No SG values	• • 2	0
Sensor Expired	0	0
Auto Mode disabled by user	0	0
Alarms	0	0
Pump Suspend by user	0	0
Auto Mode Warm Up	0	0
Unidentified	0	1 •

7 Statistics

Used to assess and evaluate appropriate system use and to determine if technology goals are met.

Statistics	Ⓐ	Ⓑ	Goals / Evaluation Criteria
Auto Mode (per week)	97% (6d 20h)	97% (6d 19h)	≥ 80% of time
Manual Mode (per week)	2% (04h)	3% (05h)	≤ 20% of time
Sensor Wear (per week)	98% (6d 21h)	97% (6d 18h)	≥ 85% of time
Average SG ± SD	7.8 ± 2.5 mmol/L	7.6 ± 2.8 mmol/L	
Estimated A1C	6.5%	6.4%	
Average BG	9.3 ± 3.0 mmol/L	9.4 ± 3.9 mmol/L	
BG / Calibration (per day)	6.4 / 2.9	6.3 / 3.1	3 to 4 / day + BGs as system requests
Total daily dose (per day)	30 units	27 units	Appropriate for patient
Bolus amount (per day)	18U (60%)	17U (63%)	50 to 70% of TDD
Auto Basal / Basal amount (per day)	12U (40%)	10U (37%)	30 to 50% of TDD
Set Change	Every 3.3 days	Every 4.0 days	Every 2 to 3 days
Reservoir Change	Every 3.3 days	Every 4.0 days	
Meal (per day)	6.5	6.1	Appropriate for patient and consistent with previous carb intake
Carbs entered (per day)	159 ± 57 g	148 ± 27 g	
Active Insulin time	2:45 hrs	2:45 hrs	3-4 hrs. at initiation

CARELINK™ WEEKLY REVIEW REPORT

Weekly Review Report (3 sections)

Used to evaluate daily glucose and exits that occurred during reporting period. Up to 7days can display on a page.
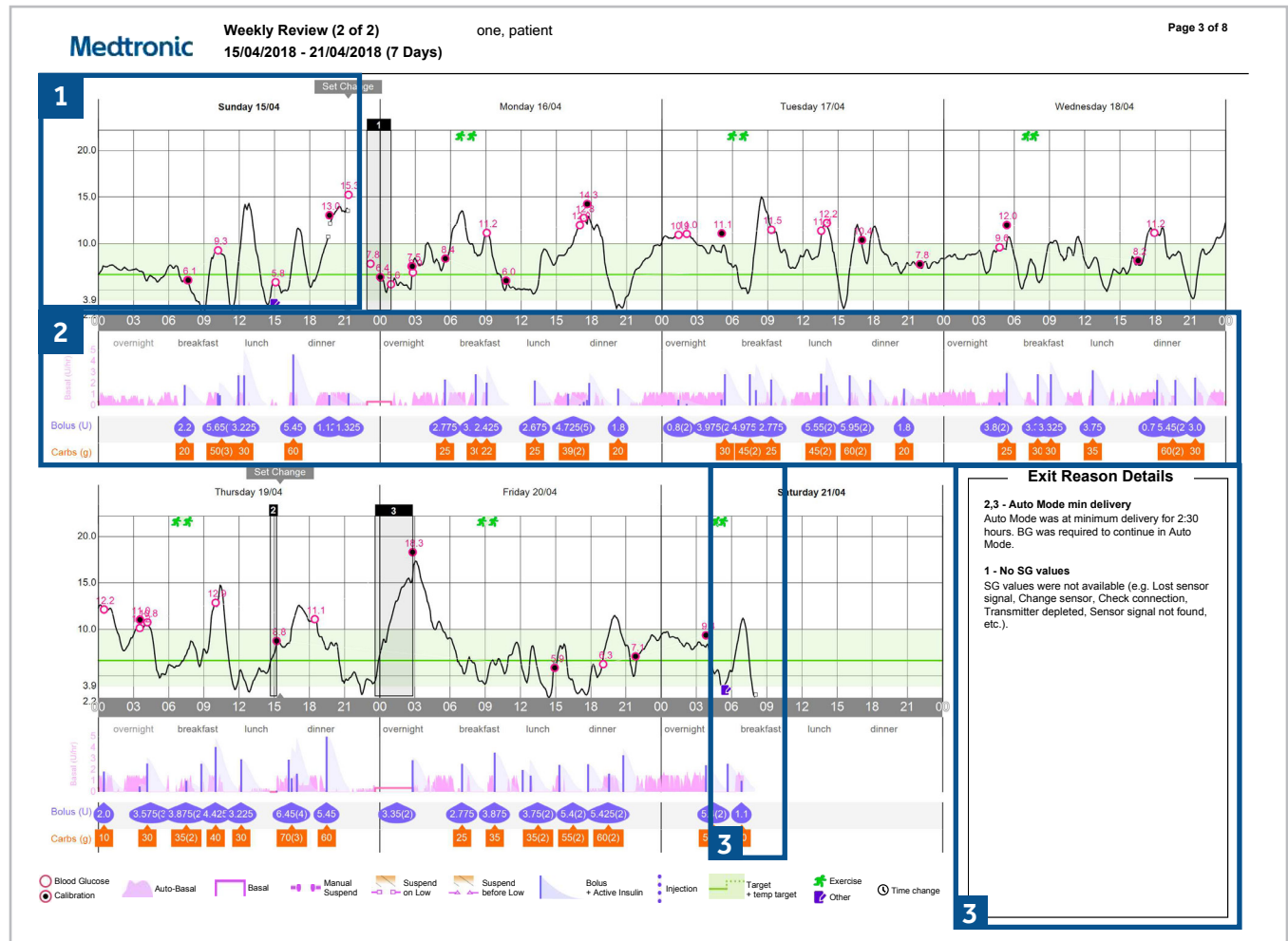
1 Glucose Section

Target range (Default 3.9-10.0 mmol/L): Green shaded band. Customisable in CareLink™ software.
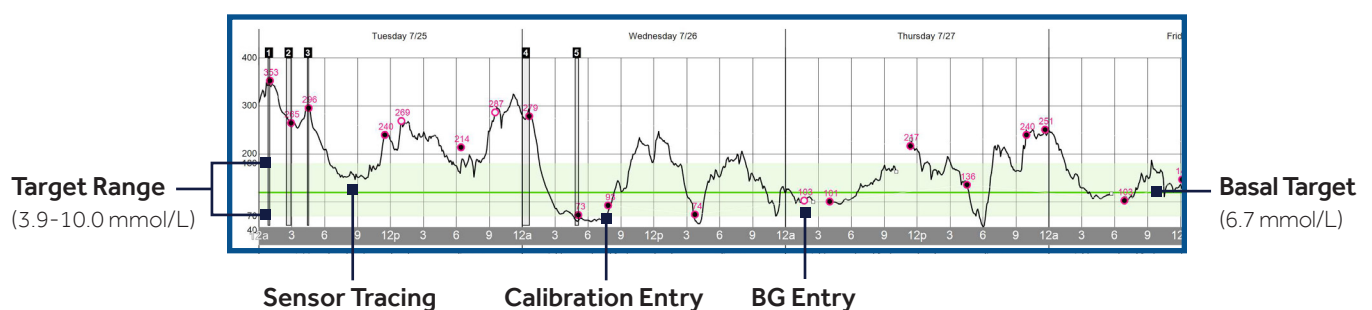
Auto Basal Target (6.7 mmol/L): Solid green line.

Temp Target (8.3 mmol/L): Dotted green line (see page 18) shifts up to 8.3 mmol/L when a temp target was used.

BG Entry: Pink circles with BG value listed above circle.

Calibration Entry: Black circles outlined in pink and BG value listed above circle.

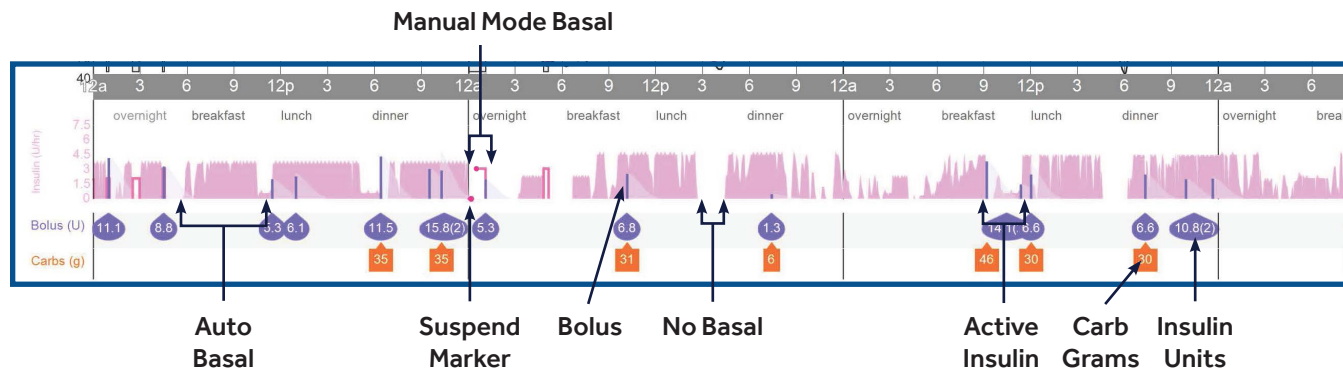**Sensor Tracing:** Solid black line running across graph.

2 Insulin Delivery Section

Auto Basal: Pink vertical spiked areas (height representative of basal amount delivered).

Manual Mode Basal Rate: Dark pink horizontal lines (height representative of basal amount delivered).

No Basal: White space indicates no Auto or Manual Mode basal insulin delivered during that time.

Labels on graph: **Manual Mode Basal**, **Auto Basal**, **Suspend Marker**, **Bolus**, **No Basal**, **Active Insulin**, **Carb Grams**, **Insulin Units**

Bolus: Purple vertical lines indicate a bolus was given (height representative of amount).

Active Insulin Time: Light purple shaded triangle attached to bolus line represents length of time & amount.

Carb Grams Entered: Orange icons with white numbers. If multiple carb entries are entered within a 3-hour period, the total grams will be shown with number of entries in parentheses.

Insulin Units Given: Purple tear-shaped icons with white numbers. If multiple boluses are entered within a 3-hour period, the total units will be shown with number of boluses in parentheses.

Suspend Markers: Break in dark pink line indicates Manual Mode basal insulin delivery suspended.

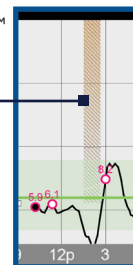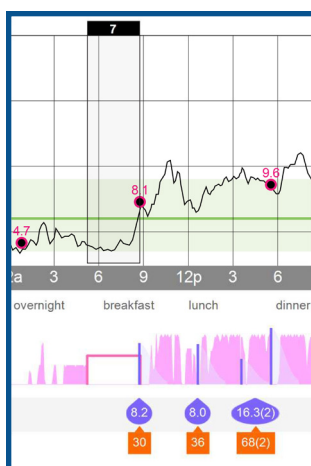**Manual suspend**   **Suspend on low**   **Suspend before low**

SmartGuard™ Suspend Event: Vertical orange shaded bars indicate Suspend before low or Suspend on low. Width of box indicates duration of suspend event.

SmartGuard™ Suspend Event

3 Exit Reason Details

Identifies type of exit and reason exit occurred. Numbers correlate with gray shaded boxes in glucose section of graph.

Exit Reason Details

1,2,3,4 - High SG Auto Mode Exit

Sensor glucose was high over 1 hour.

5 - Auto Mode min delivery

Auto Mode was at minimum delivery for 2:30 hours. BG was required to continue in Auto Mode.

6 - Sensor Expired

New sensor needed to be inserted.

7 - Sensor Algorithm Underread

BG was required to continue in Auto Mode.
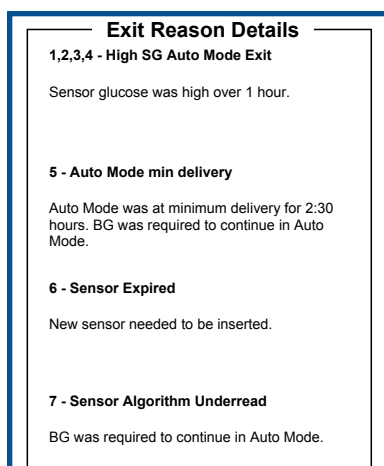
Gray shaded box marks data collected in Manual Mode to visually differentiate from Auto Mode data. At the top of a gray shaded box is a number that represents an Auto Mode exit. Reference that number in the Exit Reason Details section to understand why the patient exited.

Note: When making technology changes for Auto Mode, make sure decision is based on events that occurred in Auto Mode, not Manual Mode.

CARELINK™ MEAL BOLUS WIZARD REPORT

Meal Bolus Wizard Report

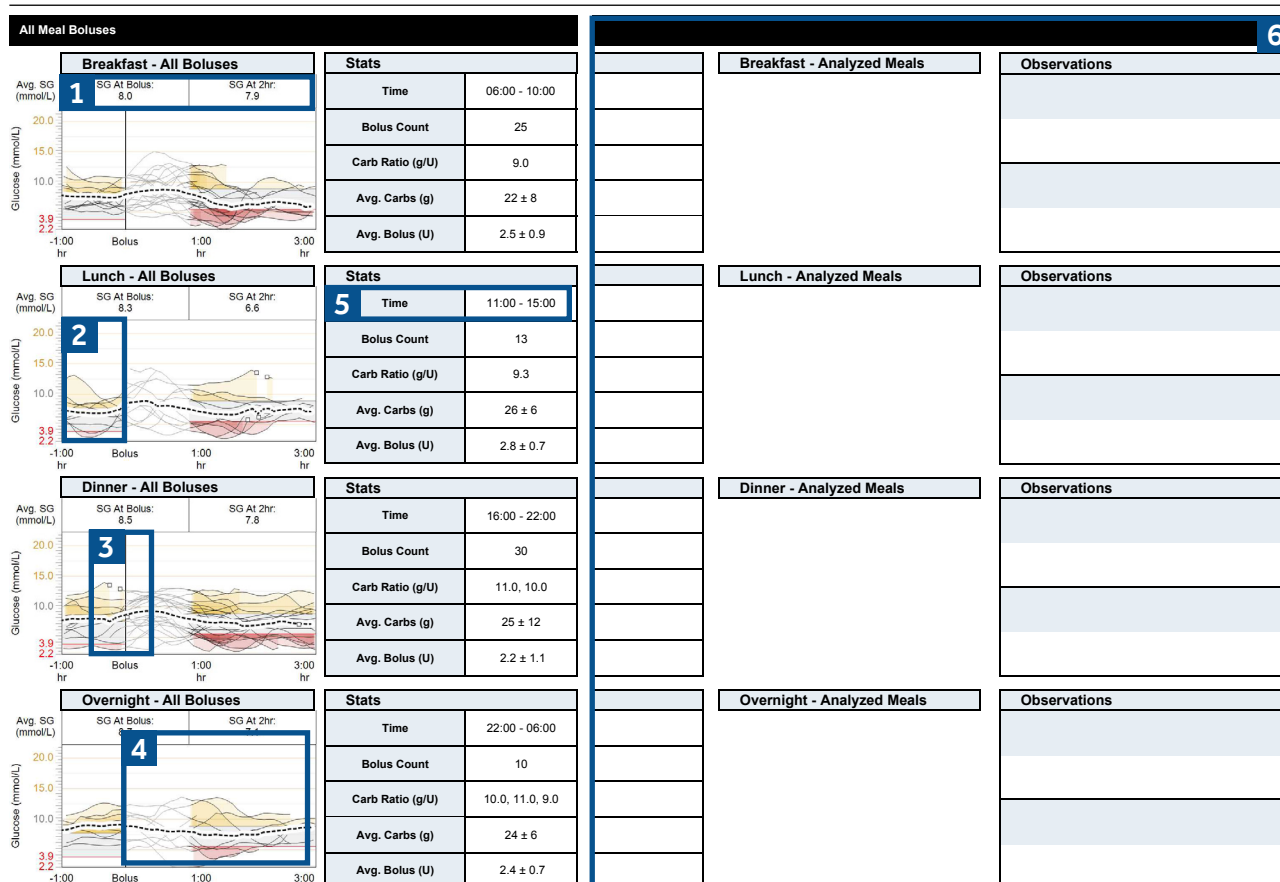Used to assess the timing of meal boluses to evaluate carb ratios and pre-and post-meal glucose levels for each meal period. Meal times can be changed to reflect each patient's meal schedule.

All Meal Boluses

Breakfast - All Boluses

1 SG At Bolus: 8.0 | SG At 2hr: 7.9

Stats	
Time	06:00 - 10:00
Bolus Count	25
Carb Ratio (g/U)	9.0
Avg. Carbs (g)	22 ± 8
Avg. Bolus (U)	2.5 ± 0.9

Lunch - All Boluses

SG At Bolus: 8.3 | SG At 2hr: 6.6

2

Stats	
5 Time	11:00 - 15:00
Bolus Count	13
Carb Ratio (g/U)	9.3
Avg. Carbs (g)	26 ± 6
Avg. Bolus (U)	2.8 ± 0.7

Dinner - All Boluses

SG At Bolus: 8.5 | SG At 2hr: 7.8

3

Stats	
Time	16:00 - 22:00
Bolus Count	30
Carb Ratio (g/U)	11.0, 10.0
Avg. Carbs (g)	25 ± 12
Avg. Bolus (U)	2.2 ± 1.1

Overnight - All Boluses

4

Stats	
Time	22:00 - 06:00
Bolus Count	10
Carb Ratio (g/U)	10.0, 11.0, 9.0
Avg. Carbs (g)	24 ± 6
Avg. Bolus (U)	2.4 ± 0.7

6

	Breakfast - Analyzed Meals	Observations
	Lunch - Analyzed Meals	Observations
	Dinner - Analyzed Meals	Observations
	Overnight - Analyzed Meals	Observations

---

1 **Pre-meal and Post-meal average glucose:**

- Average SG at time of bolus
- Average SG 2 hours after bolus

2 **Overlay of pre-meal glucose tracings for that meal period:**

Use to assess and determine if glucose was stable before bolusing. A rising glucose prior to the bolus frequently indicates the bolus was delivered after eating.

Note: Increases in glucose during early morning / pre-breakfast period may be an indication of dawn phenomenon.

3 **Bolus Line:**

This line, called time zero, marks the start of all food boluses given within the meal period, regardless of the exact time the bolus occurred. Overlaying and aligning boluses provides clarity when assessing glycaemic response to carb ratios.

4 **Post-meal glucose levels:**

Used to assess post-meal glucose up to three hours after a meal bolus. The pre-meal glucose range on this graph is set at 3.9-7.8 mmol/L.

The post-meal glucose range is set at 5.6-8.9 mmol/L, to accommodate a moderate post-prandial rise.

Note: Post-meal glucose values < 5.6 mmol/L will be shaded red and do not necessarily indicate post-meal lows.

5 **Stats:**

Shows the time range set for each meal and overnight period, the carb ratio, the average carbs entered, the average insulin units and the number of boluses given.

Note: Meal times can be changed in CareLink™ software to accommodate patient's meal schedule.

6 **Notation Section:** Used for charting observations, changes, follow-up plan, etc.

CARELINK™ DEVICE SETTINGS

Device Settings Report (1st page)

Used to review pump and CGM settings currently programmed in the pump and to note any setting changes made.

Medtronic

Device Settings
21/04/2018

one, patient

Basal   `1`

Maximum Basal Rate	2.00 U/Hr		

Basal 1 (active)

24-Hour Total	12.050 U	

Time	U/Hr	
00:00	0.350	
03:00	0.500	
09:00	0.500	
13:00	0.600	
21:00	0.400	

Basal 2

24-Hour Total	18.175 U	

Time	U/Hr	
00:00	0.800	
03:00	0.850	
10:00	0.600	
13:00	0.750	
21:00	0.675	

Basal 3

24-Hour Total	--	

Time	U/Hr	
--	--	

Bolus   `2`

Bolus Wizard	On		Easy Bolus	Off
Units	g,mmol/L		Bolus Increment	0.025 U
Active Insulin Time (h:mm)	2:45		Bolus Speed	Quick
Maximum Bolus	12.0 U		Dual/Square	On/On

Carbohydrate Ratio (g/U)			Insulin Sensitivity (mmol/L per U)			Blood Glucose Target (mmol/L)		
Time	Ratio		Time	Sensitivity		Time	Low	High
0:00	11.0		0:00	3.9		0:00	100	6.1
5:00	9.0		4:00	2.8		6:00	4.2	5.6
11:00	9.3		21:00	3.9		21:00	4.4	6.1
16:00	11.0							
21:00	10.0							

Preset Bolus   `3`

Name	Normal	Square	Updates
Bolus 1			
Breakfast	2.50 U	-- U - 0:00	
Dinner	3.60 U	2.40 U - 1:45	
Lunch	3.00 U	-- U - 0:00	
Snack	2.00 U	-- U - 0:00	
Bolus 2			
Bolus 3			
Bolus 4			

Preset Temp   `4`

Name	Rate	Duration		Name	Rate	Duration	
High Activity	25%	3:00		Temp 1			
Moderate Activity	50%	2:00		Temp 2			
Low Activity	90%	0:45		Temp 3			
Sick	130%	8:00		Temp 4			

`1` Basal

- Maximum Basal Rate setting (Manual Mode)
- Manual Mode basal patterns. Contains:
  - 24-Hour Total daily basal of the pattern
  - Start time; units / hour for each rate

Note: The word (**active**) indicates the pattern that was active at time of download.

`2` Bolus

- Active Insulin Time
- Maximum Bolus Setting
- Bolus Speed
  - Standard: 1.5 units / minute
  - Quick: delivers 15 units / minute
- Carbohydrate Ratio (start-time; g / U)
- Insulin Sensitivity Factor (start-time; mmol/L/U)
- BG Target (start-time; Low / High settings)

`3` Preset Bolus *(Manual Mode only)*

Any preset bolus delivery amounts that have been programmed for Breakfast, Lunch, Dinner, etc.

`4` Preset Temp *(Manual Mode only)*

Any Preset Temp basal rates that have been programmed for sick days, high, moderate and low activity, etc.

- Can preset rate and duration (length of time Preset Temp basal is set to deliver)
- Patient must activate Preset Temp basal each time (i.e., cannot be programed to start at a specific time each day).

CARELINK™ DEVICE SETTINGS

Device Settings Report (2nd page)

Medtronic

Device Settings
21/04/2018

one, patient

SmartGuard — 5

Auto Mode

Auto Mode	-------
Auto Mode BG Alert	-------

High Alerts — On (Snooze 2:00)

Start Time	High (mmol/L)	Alert On High	Alert Before High	Rise Alert Limit (mmol/L)
0:00	8.6	x		

Low Alerts — On (Snooze 0:20)

Start Time	Low (mmol/L)	Suspend	Alert On Low	Alert Before Low	Resume Basal Alert
0:00	3.9	Off	x		

Sensor

Sensor	On
Calibration Reminder	On
Calibration Reminder Time	1:00

Notes — 8

Basal (Continued) — 6

Basal 4		Basal 5		Workday		Day Off		Sick Day	
24-Hour Total	–	24-Hour Total	–	24-Hour Total	–	24-Hour Total	–	24-Hour Total	–
Time	U/Hr	Time	U/Hr	Time	U/Hr	Time	U/Hr	Time	U/Hr
--	--	--	--	--	--	--	--	--	--

Reminders — 7

Low Reservoir Warning	Insulin Unit
Amount	20 U
Bolus BG Check	Off
Set Change	3 days

Missed Meal Bolus

Name	Start	End
Meal 1	Off	Off
Meal 2	Off	Off
Meal 3	Off	Off
Meal 4	Off	Off
Meal 5	Off	Off
Meal 6	Off	Off
Meal 7	Off	Off
Meal 8	Off	Off

Personal Reminders

Name	Time
Reminder 1	Off
Reminder 2	Off
Reminder 3	Off
Reminder 4	Off
Reminder 5	Off
Reminder 6	Off
BG Check	Off
Medication	Off

Utilities — 9

Block Mode	Off
Time Format	12 Hr
Brightness	Auto
Backlight Timeout	180 s
Remote Bolus	On
Audio Options	Audio
Alarm Volume	5
Auto Suspend	Off

---

5 SmartGuard™

- **Auto Mode and Auto Mode BG Alerts:** "ON" by default. If off, dashes appear.
- **High Alerts:** Start Time, High limit, High Alerts (Alert On High, Alert Before High, Rise Alert Limit).
- **High Snooze:** "ON" when high alert(s) have been set. Default time: 1 hour.
  Best Practice: increase to 2 hours.
- **Low Alerts:** Start Time, Low limit, Suspend, Low Alerts (Alert On Low, Alert Before Low), and Resume Basal Alerts.
- **Low Snooze:** "ON" when low settings have been programmed. Default time: 20 minutes.

Note: "X" indicates the alert has been selected. Suspend will clarify On Low or Before Low if selected.

6 Additional Basal Settings:

Tables for the remaining five of the eight possible Manual Mode basal patterns.

7 Reminders

Customisable reminders that may be used in Manual Mode and Auto Mode to encourage behaviours that contribute to successful use of the system including:

- Low Reservoir Warning: Alerts when reservoir has a specified number of units remaining, and again when half that amount are used.
- Bolus BG Check: Reminder to test BG after meal.
- Set Change: Reminder to change infusion set on time. Can be set for 2 or 3 days.
- Missed Meal Bolus: Alerts if bolus is not delivered within a time-period that is set by patient.
- Personal Reminders: Can be programmed for any purpose.

8 Notes

Used to chart observations, behavioural issues, pump and sensor settings adjustments, and follow-up plan.

Best Practice: Provide copy of report to patient to reinforce changes, and follow up plan. Save CareLink™ report in patient's EMR.

9 Utilities

Shows personalized settings set by the user, such as time format, brightness, and backlight timeout.

FOLLOW UP ASSESSMENT GUIDE

The table below lists observations and possible questions / actions to consider during follow-up visits.

GENERAL ASSESSMENT

Observations	Questions to Ask	Possible Actions to Consider
☐ Sensor wear percentage	Is sensor wear < 85%?	▪ Review need for consistent sensor wear ▪ Address solutions for increasing sensor use
☐ Percent time in Auto Mode	Is the percent time in Auto Mode < 80%?	▪ Review Auto Mode Exits to help reduce the occurrence ▪ Explore difficulties with timely re-entry into Auto Mode
☐ Glucose levels when in Manual Mode	Are lows occurring in Manual Mode?	▪ Decrease basal rate 10-20% during the time period that lows occurred ▪ Adjust basal rates to ensure 24 hr total is comparable to Auto Basal total
	Are lows occurring in Auto Mode?	▪ Assess for phantom carbs, ensure meal bolus is given pre-meal, ICR is optimal, Temp Target is used for exercise
	Are highs occurring in Manual Mode?	▪ Increase basal rate 10-20% during the time period that highs occurred ▪ Adjust basal rates to ensure 24 hr total is comparable to Auto Basal total
	Are highs occurring in Auto Mode?	▪ Assess for post-meal bolusing (encourage pre-meal bolusing) and ICR is optimal

BOLUS ASSESSMENT

Observations	Questions to Ask	Possible Actions to Consider
☐ Post meal lows	Are lows due to timing of bolus, inappropriate ICR, inaccurate carb counting?	▪ Bolusing post-meal: Reinforce pre-meal bolusing ▪ ICR: Raise ICR 10-20% so less insulin is given ▪ Take steps needed for accurate carb counting
☐ Post meal highs	Are highs due to inadequate carb counting, bolusing post-meal, inappropriate ICR, not adding carbs when more was eaten than originally planned?	▪ Carbs: Take steps for adequate carb entry and bolusing post-meal ▪ ICR: Decrease ICR 10-20% so more bolus insulin is given ▪ Additional carbs: Encourage entering additional carbs as eaten
☐ Post correction lows	Are lows due to correction boluses given within AIT of another correction bolus?	▪ Increase AIT setting 15-30 minutes
☐ Post correction highs	Are correction boluses (given within AIT of another correction bolus) causing hyperglycaemia?	▪ Decrease AIT setting 15-30 minutes

FOLLOW UP ASSESSMENT GUIDE

OVERNIGHT ALERT ASSESSMENT
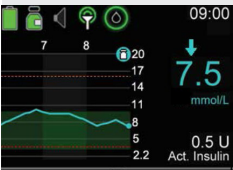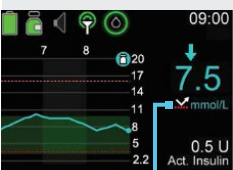
Observations	Questions to Ask	Possible Actions to Consider
☐ Nocturnal alerts	Are alerts due for calibration, Min delivery or Max delivery?	Instruct patient, before going to sleep, to: ■ Test BG and calibrate ■ Check pump for blue SmartGuard™ shield ■ Give correction (if recommended)

AUTO MODE EXIT ASSESSMENT

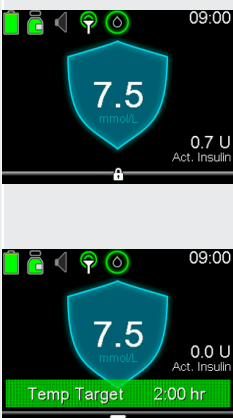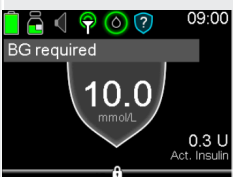| Reason for Exit	Questions to Ask	Possible Actions to Consider
☐ Missed Calibration	Are alerts occurring during the night?	■ Encourage calibrating before bedtime
	Does patient pro-actively calibrate?	■ Reinforce concept of scheduled pro-active calibrations
	Does patient know how to calibrate and that additional calibrations are sometimes needed?	■ Have patient calibrate to assess if calibrating properly
☐ High SG Auto Mode ☐ Auto Mode max delivery	Is ICR optimized?	■ Assess the need for an ICR adjustment
	Are food boluses given after eating or skipped?	■ Counsel patient on carbohydrate counting, timing of meal bolus and bolus delivery
	Are additional carbs added when consumed above what was originally estimated?	■ Ensure the additional carbs are entered and bolus given when more carbs are consumed than originally estimated
	Is BG tested and entered to assess need for correction bolus and is correction being delivered?	■ Ensure BG readings are entered for correction boluses and the boluses are being delivered
	Are exits occurring during the night?	■ Counsel patient to test BG and give recommended correction bolus at bedtime
☐ Min delivery	Is this occurring after exercise?	■ Consider using Temp Target for exercise
	Is the min delivery timeout occurring during the night?	■ Advise patient to test BG at bedtime and eat a small protein snack
☐ Auto Mode disabled by user	Why is patient turning Auto Mode OFF? (unrealistic expectations, alert fatigue, does not trust Auto Mode?)	■ Establish realistic expectations and benefits of Auto Mode ■ Use A&P report to show improved control in Auto Mode ■ Encourage use of Suspend before low when in Manual Mode

MANUAL MODE DELIVERY OPTIONS REFERENCE TABLE

This table lists the delivery options available in Manual Mode. Please see device instructions for use for complete information.

MANUAL MODE				
CGM Options	**Home Screen**	**Bolus Delivery Options**	**Basal Delivery**	**Suspend Options**
Pump without CGM	Home screen: 09:00, BG, — — — mmol/L, Active Insulin 1.0 U	▪ Bolus Wizard™ calculator: uses programmed Carb Ratio, Insulin Sensitivity, BG Target, and Active Insulin Time settings ▪ Manual bolus ▪ Remote bolus ▪ Square Wave™ and Dual Wave™ bolus ▪ Preset bolus ▪ Easy bolus	▪ Uses the programmed basal delivery settings ▪ Temporary basal rates can be manually set ▪ Preset temporary basal rates can be used	Manual Suspend
Pump with CGM	Home screen: 09:00, 7.5 mmol/L, 0.5 U Act. Insulin	▪ Bolus Wizard™ calculator: uses programmed Carb Ratio, Insulin Sensitivity, BG Target, and Active Insulin Time settings ▪ Manual bolus ▪ Remote bolus ▪ Square Wave™ and Dual Wave™ bolus ▪ Preset bolus ▪ Easy bolus	▪ Uses the programmed basal delivery settings ▪ Temporary basal rates can be manually set ▪ Preset temporary basal rates can be used	Manual Suspend
Pump with CGM, Suspend before low or Suspend on low enabled	Home screen: 09:00, 7.5 mmol/L, 0.5 U Act. Insulin *The ☑ indicates one of the SmartGuard™ Suspend features is enabled*	▪ Bolus Wizard™ calculator: uses programmed Carb Ratio, Insulin Sensitivity, BG Target, and Active Insulin Time settings ▪ Manual bolus ▪ Remote bolus ▪ Square Wave™ and Dual Wave™ bolus ▪ Preset bolus ▪ Easy bolus	▪ Uses the programmed basal delivery settings ▪ Temporary basal rates can be manually set ▪ Preset temporary basal rates can be used	▪ Manual Suspend ▪ Suspend before low ▪ Suspend on low

AUTO MODE DELIVERY OPTION REFERENCE TABLE

This table list the delivery options available in Auto Mode. Please see device instructions for use for complete information.

AUTO MODE				
CGM Options	**Home Screen**	**Bolus Delivery Options**	**Basal Delivery**	**Suspend Options**
Auto Mode (Auto Basal delivery)		■ Auto Mode Bolus impacted by Carb Ratio and Active Insulin Time Settings ■ Patient enters carb grams and BG ■ Pump may recommend bolus when BG > 8.3 mmol/L entered ■ Patient accepts or cancels bolus	■ Automatic delivery of basal insulin based on a hard set target of 6.7 mmol/L, recent insulin delivery needs, and SG values ■ May set a temporary target of 8.3 mmol/L for 30 minutes up to 12 hours	Manual Suspend
Auto Mode (Safe Basal delivery)		■ Auto Mode Bolus impacted by Carb Ratio and Active Insulin Time Settings ■ Patient enters carb grams and BG ■ Pump may recommend bolus when BG > 8.3 mmol/L entered ■ Patient accepts or cancels bolus	■ Automatic delivery of basal insulin at a fixed rate ■ If sensor signal is not transmitting or BG entry is required, will resume Auto Basal delivery when resolved or will exit Auto Mode if not resolved within 90 minutes.	Manual Suspend

Every patient must start in Manual Mode (with or without CGM) which operates similar to traditional pump technology in that:

- Basal insulin delivers evenly over each hour using the prescribed rates the patient has programmed in their pump.
- All boluses are initiated by the patient.
- Food boluses use the grams the patient enters and the programmed ICR.
- Correction boluses are based on the patient's current fingerstick reading, ISF, BG target range, and AIT.

SmartGuard™ Suspend Features with Resume Basal

When CGM is used with Manual Mode, two SmartGuard™ features become available: 1) Suspend before low with Resume Basal and 2) Suspend on low with Resume Basal. When either feature is turned ON, the system can automatically stop and restart basal insulin delivery based on SG readings and the programmed low limit setting. The features cannot be used simultaneously. **Note:** Suspend before low is recommended.

Suspend before low*: Automatically stops insulin delivery if the SG ≤ 3.9 mmol/L above the set low limit AND it is predicted to be within 1.1 mmol/L of the set low limit in the next 30 minutes. Intent: stop insulin delivery before glucose reaches set low limit. Goal: minimize the time a patient spends below 3.9 mmol/L.

Suspend before low can function without patient intervention. Insulin can be automatically suspended, a low avoided, and basal insulin automatically resumed without the patient being notified or even knowing it has occurred. The effectiveness of Suspend before low relates directly to how fast glucose is falling. If falling rapidly, a low can occur despite the suspension of insulin. If glucose reaches the set low limit, an alert will notify the patient.

Suspend on low*: Automatically stops insulin delivery if the SG reaches or falls below the set low limit. Intent: stop insulin delivery to help manage glucose from going lower. Goal: reduce time spent below 3.9 mmol/L.

An automatic safety alert triggers if SG reaches the set low limit when either suspend feature is used. If the alert is not cleared within 10 minutes, a siren alert sounds and continues to sound until cleared. If this occurs, insulin remains suspended for a minimum of 30 minutes unless the patient intervenes and manually resumes basal insulin delivery.

If the patient does not respond, the siren will continue to sound, and insulin will remain suspended until:
1) Glucose levels reach the specified parameters for the system to automatically resume basal delivery OR
2) The 2-hour suspend limit is reached.

Resume Basal: Automatically resumes basal insulin delivery from 30 minutes to 2 hours after a suspend event has occurred, if:
- SG is ≥ 1.1 mmol/L above the set low limit AND
- SG is predicted to be ≥ 2.2 mmol/L above the low limit within the next 30 minutes.

Basal insulin can be manually resumed at any time. Once resumed automatically or manually, the suspend features are not available and cannot be activated again for 30 minutes.

If glucose does not rise enough for basal insulin to automatically resume AND the patient has not responded to the alarm within 2 hours, the pump will begin to deliver the basal rate that is programmed for that time of day. Basal insulin will deliver for 4 hours, regardless of the patient's glucose level, unless the patient intervenes. SmartGuard™ Suspend features are not available during this time and the siren alarm will sound until it is cleared or the pump battery has depleted.

When Auto Mode is active, the suspend features are not needed and automatically turn OFF. If the pump exits Auto Mode, the features are not active until the patient turns them ON.

*WARNING: Suspend before low and Suspend on low are not intended to be a treatment for low blood glucose. Having insulin suspended when glucose is low may not bring your blood glucose back to your target range for several hours. In that case, you run the risk of hypoglycaemia. Always confirm your blood glucose readings with your BG meter and manage your diabetes according to the recommendations of your healthcare professional.

MINIMED™ 670G SYSTEM INITIATION SETTINGS | EXPERIENCED PUMP & CGM USERS

Prescriber's Instructions to Patient for Manual Mode and SmartGuard™ Auto Mode

Patient Name: _____ DOB: _____

MANUAL MODE — PUMP SETTINGS

☐ Transfer settings from current pump
　　OR
☐ Assess current settings and adjust as needed based on Instructions for Adjustments below
　　OR
☐ Use these basal and bolus settings:

Basal Rates	Carb Ratio	Sensitivity Factor	BG Target Ranges
12:00 AM - _____ _____ units/hour	12:00 AM - _____ _____	_____ mmol/L/unit	12:00 AM - _____ _____ - _____ mmol/L
_____ - _____ _____ units/hour	_____ - _____ _____	**Active Insulin Time**	_____ - _____ _____ - _____ mmol/L
_____ - _____ _____ units/hour	_____ - _____ _____	_____ hours 2-8 hours (15 min increments)	_____ - _____ _____ - _____ mmol/L
_____ - _____ _____ units/hour	☐ Bolus Wizard™ calculator not currently being used. Settings above have been calculated based on: Current TDD of _____ units　Total Daily Bolus _____ units		

MANUAL MODE — CGM SETTINGS

Low Settings			High Settings ☐ Use current settings and adjust as needed per patient preference		
Time Segments	**Low Limit**	**SmartGuard™ Settings**	**Time Segments**	**High Limit**	**High Alert Settings**
	2.8-5.0 mmol/L	Alert before low and Resume basal alert are available but not routinely recommended.			Alert before high and Rise Alert are available but not routinely recommended.
12:00 AM - _____	_____mmol/L	☐ Suspend before low*	12:00 AM - _____	_____mmol/L	☐ Alert on high
_____ - _____	_____mmol/L	☐ Suspend before low*	_____ - _____	_____mmol/L	☐ Alert on high
_____ - _____	_____mmol/L	☐ Suspend before low*	_____ - _____	_____mmol/L	☐ Alert on high
Low Snooze: _____min (5 min to 1 hr; Default = 20 min)			High Snooze: _____min (5 min to 3 hrs; Default = 1 hour)		

☐ If patient cannot use abdomen or buttock (ages 7-13) / abdomen or back of upper arm (ages 14 and above), I authorize use of alternate site(s) as medically necessary. Alternate site(s): _____

*Suspend before low will not automatically turn back on if pump exits Auto Mode. The patient must enable this setting when in Manual Mode.

SMARTGUARD™ AUTO MODE SETTINGS *(Adjustments made here will replace the Manual Mode settings above)*

Initiate Auto Mode on _____ (date)
Requires 48 hours (from midnight) of pump use prior to activation.

Auto Mode BG Alert: ☐ On (recommended)
　　　　　　　　　　　☐ Off
Alert must be On to receive an audio alert when a BG is required for Auto Mode. If set to Off, only a visual banner will display on screen.

Carb Ratio

☐ Use existing settings
　　OR
☐ Strengthen existing settings by 10% for more insulin
　　OR
☐ Use these Carb Ratios: 12:00 AM - _____ _____
　　　　　　　　　　_____ - _____ _____
　　　　　　　　　　_____ - _____ _____

Active Insulin Time (AIT)

☐ Use _____ hrs

Recommend 3-4 hours.

Alert on Low: ☐ On

Recommended On at 4.0 mmol/L at initiation.

INSTRUCTIONS FOR ADJUSTMENTS

Manual Mode Settings:

Basal Rates: Nocturnal, fasting/pre-meal, bedtime glucose: < 4.4 mmol/L, decrease 10-20%; if > 7.2 mmol/L (8.3 mmol/L at bedtime), increase 10-20%

Sensitivity Factor: 3 to 4 hour glucose post-correction: > 7.2 mmol/L, decrease 10–20% for more insulin; if < 4.4 mmol/L, increase 10-20% for less insulin

Manual & Auto Mode Settings: *Only Carb Ratio and Active Insulin Time affect Auto Mode use*

Carb Ratio: Post-meal glucose: > 3.3 mmol/L above pre-meal glucose, stregthen by 10% for more insulin; if lows occur, weaken by 10% for less insulin

Active Insulin Time: 2-3 hour post-correction glucose (bolus given within Active Insulin window of a previous correction bolus) > target, decrease by 15-30 minutes; if < target or lows result, increase by 15-30 minutes

CGM Settings: High and low alerts/limits can be adjusted to optimise safety and manage frequency of alerts

CALL PRESCRIBER FOR SEVERE OR RECURRING HYPOGLYCAEMIA. CALL 1800 777 808 FOR TECHNICAL ASSISTANCE.

Comments: _____

Prescriber Name: _____ Signature: _____Date:_____

Prescriber's Instructions to Patient for Manual Mode

Patient Name: _____ Date: _____ DOB: _____

Weight: _____ Current Regimen: _____

Pre-pump TDD

BASAL SETTINGS

Basal Pattern	Time	Rate	Max Basal (units/hour)
	12:00 AM - _____	_____units/hour	
	_____ - _____	_____units/hour	
	_____ - _____	_____units/hour	_____
	_____ - _____	_____units/hour	*Default: 2.0 Units*

BOLUS SETTINGS

Meal Bolus	Carb Ratio (grams/unit)		Set Dose (units)	Max Bolus (units)
	(B)	OR	(B)	
	(L)		(L)	_____
	(D)		(D)	*Default: 10 Units*

(Workspace for calculations)

Correction Bolus	ISF		Target Ranges (mmol/L)		Active Insulin Time (hours)
	12:00 AM - _____	_____ mmol/L/unit	Day	Night	
	_____ - _____	_____ mmol/L/unit			
	_____ - _____	_____ mmol/L/unit	_____ - _____	_____ - _____	_____

Insulin instructions for transition to pump:_____

_____

Comments: _____

_____
_____
_____

Instructions for adjustments

- If nocturnal, fasting/pre-meal or bedtime BG > target, increase basal 10-20%
- If nocturnal, fasting/pre-meal or bedtime BG < target, decrease basal 10-20%
- If post-meal BG > 3.3 mmol/L above pre-meal BG, **strengthen** carb ratio by 10-20%
- If post-meal lows occur, **weaken** carb ratio by 10-20%

Elevated BG: Verify trends 2-3 days before adjusting
Low BG: Consider immediate adjustment

Adjustments should be made when BGs are outside of these ranges

Fasting/pre-meal: _____ to _____mmol/L

Post-meal: _____ to _____mmol/L

Bedtime: _____ to _____mmol/L

Nocturnal: _____ to _____mmol/L

Prescriber Name: _____ Signature: _____ Date:_____

CALL PRESCRIBER FOR SEVERE OR RECURRING HYPOGLYCAEMIA. CALL **1800 777 808** FOR TECHNICAL ASSISTANCE.

MINIMED™ 670G SYSTEM CGM INITIATION SETTINGS | NEW USER

Prescriber's Instructions to Patient for Manual Mode and SmartGuard™ Auto Mode

Patient Name: _____ DOB: _____

MANUAL MODE — CGM SETTINGS

Low Settings			High Settings		
Time Segments	**Low Limit**	**SmartGuard™ Suspend Settings**	**Time Segments**	**High Limit**	**High Alert Settings**
	2.8-5.0 mmol/L	Alert before low and Resume basal alert are available but not routinely recommended.			Alert before high and Rise Alert are available but not routinely recommended.
12:00 AM - _____	_____mmol/L	☐ Suspend before low*	12:00 AM - _____	_____mmol/L	☐ Alert on high
_____ - _____	_____mmol/L	☐ Suspend before low*	_____ - _____	_____mmol/L	☐ Alert on high
_____ - _____	_____mmol/L	☐ Suspend before low*	_____ - _____	_____mmol/L	☐ Alert on high

* Suspend before low will not automatically turn back on if pump exits Auto Mode. The patient must enable this setting when in Manual Mode.

Low Snooze: _____min (5 min to 1 hr; Default = 20 min)   **High Snooze:** _____min (5 min to 3 hrs; Default = 1 hour)

SMARTGUARD™ AUTO MODE SETTINGS *(Adjustments made here will replace the Manual Mode settings above)*

Initiate Auto Mode on _____ (date)
Requires 48 hours (from midnight) of pump use prior to activation.

Auto Mode BG Alert: ☐ On (recommended)
☐ Off
Alert must be On to receive an audio alert when a BG is required for Auto Mode. If set to Off, only a visual banner will display on screen.

Carb Ratio

☐ Use existing settings
OR
☐ Decrease existing settings by 10% for more insulin
OR
☐ Use these Carb Ratios: 12:00 AM - _____ _____
_____ - _____ _____
_____ - _____ _____

Active Insulin Time

☐ Use _____ hrs

Recommend 3-4 hours.

Alert on Low: ☐ On

Recommended On at 4.0 mmol/L at initiation.

INSTRUCTIONS FOR ADJUSTMENTS

Manual Mode Settings:

Basal Rates: Nocturnal, fasting/pre-meal, bedtime glucose: < 4.4 mmol/L, decrease 10-20%; if > 7.2 mmol/L (8.3 mmol/L at bedtime), increase 10-20%

Sensitivity Factor: 3 to 4 hour glucose post-correction: > 7.2 mmol/L, decrease 10–20% for more insulin; if < 4.4 mmol/L, increase 10-20% for less insulin

Manual & Auto Mode Settings: *Only Carb Ratio and Active Insulin Time affect Auto Mode use*

Carb Ratio: Post-meal glucose: > 3.3 mmol/L above pre-meal glucose, strengthen by 10% for more insulin; if lows occur, weaken by 10% for less insulin

Active Insulin Time: 2-3 hour post-correction glucose (bolus given within Active Insulin window of previous correction bolus) > target, decrease by 15-30 minutes; if < target or lows result, increase by 15-30 minutes

CGM Settings: High and low alerts/limits can be adjusted to optimise safety and manage frequency of alerts

CALL PRESCRIBER FOR SEVERE OR RECURRING HYPOGLYCAEMIA. CALL 1800 777 808 FOR TECHNICAL ASSISTANCE.

☐   If patient cannot use abdomen or buttock , I authorise use of alternate site(s) as medically necessary.

Alternate site(s): _____

_____

_____

Comments: _____

_____

_____

Prescriber Name: _____ Signature: _____ Date:_____

LOW ALERT & ALARM SETTINGS

Low Alerts occur when an actual or impending low SG reading is detected. The intent is to notify the patient as soon as the low or potential low occurs, so the patient can respond to 1) minimise the low, or 2) manage actual lows that occur. Settings should balance safety while minimising alerts.

Settings should be individualised. Up to 8 Low Alert time segments can be programmed. The low limit can be set from 2.8-5.0 mmol/L.

ALERTS AND ALARMS	SUGGESTED	CONSIDERATIONS AND ADJUSTMENTS
Low Limit		
▪ The SG value at which the low alerts are triggered	4.0 mmol/L	▪ Set higher (4.4-5.0 mmol/L) for hypoglycaemia unaware
SmartGuard™ Suspend before low (Manual Mode)		

▪ Suspends all insulin delivery when the sensor glucose is:
  ▪ At or within 3.9 mmol/L above the low limit setting -AND-
  ▪ Predicted to reach a level that is 1.1 mmol/L above programmed low limit setting in the next 30 minutes
▪ Patient may resume insulin delivery at any time
	ON	▪ Recommendation: Turn ON as soon as patient starts sensor
		
		Note: Automatically turns OFF when pump enters Auto Mode

SmartGuard™ Suspend on low (Manual Mode)		
▪ Suspends all insulin delivery when the sensor glucose reaches or falls below programmed low limit setting ▪ Alarm sirens until patient responds ▪ Patient may resume insulin delivery at any time	OFF	▪ Set higher (4.4-5.0) low limit setting for hypoglycaemia unaware **Note:** Automatically turns OFF when pump enters Auto Mode
Alert on low		
▪ Alerts when sensor glucose reaches or falls below programmed low limit setting ▪ Automatically turned ON when either Suspend before low or Suspend on low is turned ON	ON	▪ If patient reports too many alerts, consider decreasing low limit and/or making technology adjustment
Alert before low		
▪ Alerts when low glucose is predicted to occur within 30 minutes ▪ Use to help minimise the amount of time spent low ▪ Can be programmed OFF or ON (30 minutes)	OFF	▪ Consider using with experienced CGM patients who want additional warning before a low occurs
Low Snooze		
▪ Sets amount of time patient wants to wait before being reminded that a low condition still exits ▪ Applies to all Low Alerts and SmartGuard™ Suspend features ▪ Active if one or more of the Low Alert Settings is turned ON ▪ Can be set from 5 minutes to one hour	20 minutes	▪ Default setting: 20 minutes

HIGH ALERT & ALARM SETTINGS

High Alerts occur when an actual or impending high SG reading is detected. The intent is to notify the patient so they can respond and manage or reduce the intensity and / or length of the high excursion.

Settings should be individualised. Up to 8 High Alert time segments can be programmed. The high settings can be set from 5.6-22.2 mmol/L.

ALERTS AND ALARMS	SUGGESTED	CONSIDERATIONS AND ADJUSTMENTS
High Limit		
■ The SG value at which the high alerts are triggered	13.9 mmol/L	
Alert on high		
■ Alerts when the sensor glucose has reached or risen above the sensor glucose limit	OFF	■ Alternatively may use CareLink™ data to determine initial setting ■ If patient reports too many alerts, consider increasing the setting, coupled with technology adjustment ■ As glucose control improves and hyperglycaemia decreases, consider decreasing the setting
Alert before high		
■ Alerts when high glucose is predicted to occur ■ Used to manage or reduce the severity of the high glucose excursion ■ Can be set from 5–30 minutes	OFF	■ If used, set at 15 minutes ■ Consider leaving OFF, to decrease the burden of frequent alerts with limited perceived value
Rise Rate Alert		

■ Alerts when sensor glucose has risen at a specified rate of change
■ May be used as indicator for missed boluses
■ Set only if extreme rate of change is valuable
■ Can be set to alert:
  • When 1, 2 or 3 trend arrows display on pump screen OR
  • A custom rate from 0.050-0.275 mmol/L/minute
	OFF
	
	The Rise Rate of Change alert contains a software calculation error which uses a sensor glucose value that is 10 times greater than the correct value due to a conversion error. As a result, the alerts are triggered earlier than the user settings. This makes the Rise Rate of Change alert trigger at values that do not require alerts. The Rise Rate of Change alerts do not directly affect insulin therapy. The Rise Rate of Change alert is disabled from the factory. Medtronic MiniMed recommends that you do not enable this feature.
		■ If used, consider setting at 0.220 mmol/L/minute to alert only if rapid changes in glucose occur (i..e. missed meal bolus)
		■ If patient reports too many alerts, consider turning alert OFF

High Snooze		
■ Sets amount of time patient wants to wait before being reminded a high alert condition still exits ■ Applies to all High Alerts and SmartGuard™ Suspend features ■ Can be set from 5 minutes to 3 hours ■ Active if one or more of the High Alert Settings is turned on ■ Applies to all High Alerts	2 hours	■ Default is set at 1 hour, increase to 2 hours to minimise alerts

Clinical Evidence

The pivotal trials of the MiniMed™ 670G system conducted in children ages 7-13 years (N=105, mean 10.8± 1.8 years)[1,2] and adolescents (N=30) and adults (N=94) ages 14-75 years (37.8 ± 16 years)[3,4] involved a 2-week baseline run-in phase in Manual Mode followed by a 3-month study phase with Auto Mode enabled.

Methods

The trials were conducted separately: 9 sites (8 in the US and 1 in Israel) for the 7 to 13-year-old cohort and at 10 sites (9 in the US and 1 in Israel) for the older cohort. Children had T1D for ≥ 1 year (mean 5.6 ± 2.9 years) and required ≥ 8 units of daily insulin; the older cohort had T1D for ≥ 2 years (mean 21.7 ± 14 years). All patients had an A1C < 10% and had been using pump technology for ≥ 6 months, with or without CGM, at study start.

Results

Auto Mode was used for a median [IQR] time of 80.6% [70.0-87.7%] (15,535 patient days) and 87.2% [75.0-91.7%] (12,389 patient days) by children and the older cohort, respectively. The table shows glycemic control metrics of both patient groups during the baseline run-in and study phases.

	7-13 years (N=105)		14-75 years (N=124)	
	Run-in	Study	Run-in	Study
A1C, %	7.9 ± 0.8	7.5 ± 0.6	7.4 ± 0.9	6.9 ± 0.6
Percentage of time across glucose ranges, mmol/L				
≤ 2.8	0.8 ± 1.2	0.5 ± 0.5	1.0 ± 1.1	0.6 ± 0.6
< 3.9	4.7 ± 3.8	3.0 ± 1.6	5.9 ± 4.1	3.3 ± 2.0
3.0 - 10.0	56.2 ± 11.4	65.0 ± 7.7	66.7 ± 12.2	72.2 ± 8.8
> 10.0	39.1 ± 12.8	32.0 ± 7.7	27.4 ± 13.7	24.5 ± 9.2
TDD, units/kg/day	0.8 ± 0.2	0.9 ± 0.2	0.8 ± 0.2	0.9 ± 0.3
Within-day SD of SG, mmol/L	3.2 ± 0.5	3.0 ± 0.4	2.8 ± 0.6	2.6 ± 0.4
Weight, kg	42.8 ± 13.0	44.9 ± 13.4	76.9 ± 17.9	77.6 ± 16.1

The continuous glucose monitoring (CGM) performed well with an overall mean absolute relative difference (MARD) of 11.9 ± 13.5% and 10.3 ± 9.0% when used by the children and the older cohort, respectively.

There were 82 and 28 device-related adverse events, and 121 and 117 adverse events not related to the system, in the younger cohort trial and the older cohort trial, respectively. During the run-in phase of the younger cohort trial, there was only one serious adverse event of diabetic ketoacidosis, and 4 serious adverse events in the older cohort trial. There were no episodes of severe hypoglycaemia or unanticipated device effects during the study phase of either trial.

Summary

Three months of unsupervised at-home use of the MiniMed™ 670G system was safe in children, adolescents, and adults with T1D. The CGM component of the system was accurate. Compared to the baseline run-in phase, Auto Mode control was associated with reduced glycaemic variability, greater time in the target glucose range, less exposure to lows and highs, and lowered A1C levels.

1) Data on file.
2) Buckingham BA, Shulman DI, Forlenza GP, et al., *Diabetes Technol Ther.*2018; 20: Supplement 1 A19, (Abstract 039).
3) Garg SK, Weinzimer SA, Tamborlane WV, et al. Glucose outcomes with the in-home use of a hybrid closed loop insulin delivery system in adolescents and adults with type 1 diabetes. *Diabetes Technol Ther.*2017:19(3):155-163.
4) Bergenstal R, Garg S, Weinzimer, et al. Safety of a hybrid closed loop insulin delivery system in patients with type 1 diabetes. *JAMA.* 2016;316(13):1407-1408.

Limitations

- Single-arm, nonrandomised, pre-post design with no pre-specified efficacy endpoints or control group.

- Data quantity imbalance between run-in and study phases.

- Exclusion of subjects with A1C > 10%, recent episodes of severe hypoglycaemia or recent DKA.

- The result of the clinical trial must be interpreted with caution and an individual's results when using the MiniMed™ 670G system may be significantly different from those who participated in the trial.

- Since this study did not include a control group, no claims regarding effectiveness can be made. However, the study does support that the device is relatively safe for use.

Strengths

- Multicenter, large number of subjects, both adults and adolescents

- Three months, unsupervised in-home

- CGM accuracy confirmed by i-STAT reference

- Study supports device safety

REFERENCES & SUGGESTED READING

References

1) Bergenstal R, Garg S, Weinzimer, et al. Safety of a hybrid closed-loop insulin delivery system in patients with type 1 diabetes. *JAMA*. 2016;316(13):1407-1408.

2) Garg SK, Weinzimer SA, Tamborlane WV, et al. Glucose outcomes with the in-home use of a hybrid closed-loop insulin delivery system in adolescents and adults with type 1 diabetes. *Diabetes Technol Ther*. 2017;19(3):155-163.

3) Buckingham BA, Shulman DI, Forlenza GP, et al., Glycemic outcomes during MiniMed™ 670G system use in children with T1D. *Diabetes Technol Ther*. 2018; 20: Supplement 1 A19, (Abstract 039).

Suggested Reading

- Aleppo G, Webb K. Integrated insulin pump and continuous glucose monitoring technology in diabetes care today: a perspective of real-life experience with the MiniMed™ 670G hybrid closed-loop system. *Endocr Pract*. 2018;24(7):684-692.

- Weaver K, Hirsch I. The hybrid closed-loop system: evolution and practical applications. *Diabetes Technol Ther*. 2018; 20(suppl 2):16-23.

IMPORTANT SAFETY INFORMATION

The following instructions apply to the MiniMed™ 670G System,and Carelink™Therapy Management Software.
The intent of this notice is to provide additional warnings and contraindications.
 If you have any questions, contact the Medtronic Global Helpline (1800 777 808) or your local Medtronic representative for assistance.

IMPORTANT SAFETY INFORMATION
MINIMED™ 670G SYSTEM
Contraindications

> **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.**

Insulin pump therapy is not recommended for those who are unwilling to perform at least four BG tests per day. As insulin pumps use rapid acting insulin only, BG testing is required to help identify rapid glycaemic deterioration due to insulin infusion occlusion, infusion site problems, insulin stability issues, user error, or a combination of these.
Pump therapy is not recommended for people who are unwilling or unable to maintain contact with their healthcare professional.
Pump therapy is not recommended for people whose vision or hearing does not allow recognition of pump signals and alarms.
Do not use the serter on products other than the Enlite™ sensor or Guardian™ Sensor (3). Medtronic cannot guarantee the safety or efficacy of this product if used with other products.
The reservoir is contraindicated for the infusion of blood or blood products.
Infusion sets are indicated for subcutaneous use only and not for intravenous (IV) infusion or the infusion of blood or blood products.

IMPORTANT SAFETY INFORMATION
GUARDIAN™ SENSOR (3)

General warnings
The Guardian™ Sensor (3) is only intended to be used by patients (aged 2 years and older) with type 1 diabetes.
Healthcare professionals and consumers should be aware about the limitations of available scientific evidence for use of this device in any other groups of patients who require diabetes management.
Nevertheless it would not be unreasonable to allow the clinical data derived from type 1 diabetes to be adduced to other forms of diabetes which are truly insulin dependent or deficient, including severe insulin deficient secondary diabetes, and some with cystic fibrosis related diabetes, where the achievement of adequate glycaemic control may benefit from continuous glucose monitoring or continuous subcutaneous insulin infusion.
During times of rapidly changing glucose (more than 0.1 mmol/L (2 mg/dL) per minute), interstitial fluid glucose levels as measured by the Guardian™ Sensor (3) may not accurately reflect blood glucose levels. Under these circumstances, check the sensor glucose readings by conducting a fingerstick test using a blood glucose meter.
In order to confirm hypoglycaemia or impending hypoglycemia as reported by the Guardian™ Sensor (3), conduct a fingerstick test using a blood glucose meter.
Do not ignore symptoms that may be due to low or high blood glucose. If you have symptoms that do not match the Guardian™ Sensor (3) reading or suspect that your reading may be inaccurate, check the reading by conducting a fingerstick test using a blood glucose meter. If you are experiencing symptoms that are not consistent with your glucose readings, consult your health care professional.
Do not make therapy decisions based on sensor glucose values because sensor glucose and blood glucose (BG) values may differ. If your sensor glucose is low or high, or if you feel symptoms of low or high blood glucose, do the following prior to making therapy decisions. Confirm your blood glucose with your meter using a fingerstick blood sample.
Taking medications with acetaminophen or paracetamol, including, but not limited to Panadol™*, fever reducers, or cold medicine, while wearing the sensor may falsely raise your sensor glucose readings. The level of inaccuracy depends on the amount of acetaminophen or paracetamol active in your body and may be different for each person. Always use BG meter readings to verify your glucose level before making therapy decisions, including when you could have acetaminophen or paracetamol active in your body. Always check the label of any medications to confirm whether acetaminophen or paracetamol is an active ingredient.
General precautions
Individuals under the age of 18 may require supervision for sensor insertion.
The sensor must be calibrated, at a minimum, every 12 hours throughout the life of the sensor. For better sensor performance, it is recommended that you calibrate your sensor three or four times each day at regular times throughout the day, such as before meals and before bed.
Potential risk
For the use with the MiniMed™ 670G system, sensor placement and insertion has been studied in the belly (abdomen) only and is not approved for other sites.
Panadol™* is a third party trademark.

IMPORTANT SAFETY INFORMATION
CARELINK™THERAPY MANAGMENT 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, meal times, 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 management.

For more details, please consult https://medtronic-diabetes.com.au/support/guides-and-manuals

NOTES

Medtronic