Medtronic

A Guide to Personal Continuous Glucose Monitoring

for the MiniMed™ 640G System

Includes Suspend Features as well as Alert and Trend Management

MiniMed™ Academia

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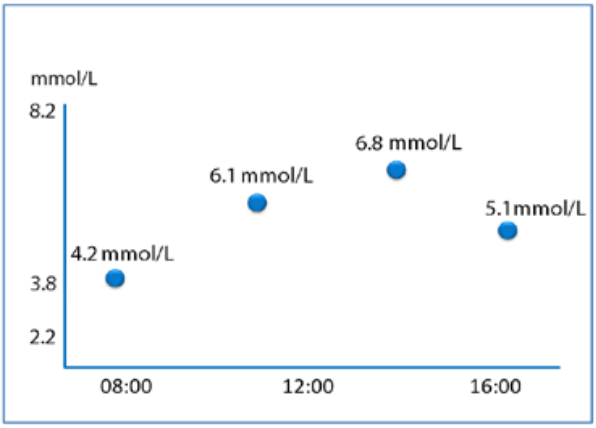
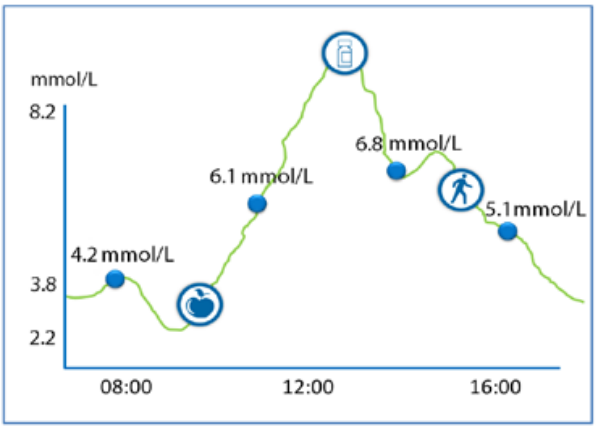
Fundamental Concepts

This guide is for healthcare professionals and will cover the continuous glucose monitoring initiation and adjustment process for those patients using the MiniMed 640G system. Continuous glucose monitoring, commonly known as CGM, is a technology that allows patients to monitor their glucose 24 hours a day and provides a more complete picture of overall glucose control.

Without CGM, healthcare professionals and patients rely upon point-in-time blood glucose (BG) readings to provide glucose information with no visibility to what is happening in between.



CGM can uncover glucose excursions such a nocturnal hypoglycemia or post prandial hyperglycemia that occurs between BG tests. This provides the opportunity to see how food, insulin, exercise and other things throughout the day effect a patient's glucose levels.



CGM data is updated every 5 minutes and displayed on the pump screen as both a sensor glucose value and a sensor tracing. Up to 288 sensor readings can be recorded each day, providing graphs and trend arrows to show the speed and direction of glucose change. Trend arrows can be particularly helpful in situations such as when a patient is getting ready to drive, sleep or perform activities where high or low glucose levels could be even more detrimental.

In addition to the visual information that CGM provides, the pump can be set to alert when glucose rises too high or falls too low. Even more important, insulin delivery can be set to suspended when glucose is approaching or has reached the low limit, helping to prevent a low glucose excursion or decrease its duration.

Pump and CGM data can be uploaded into Carelink® Therapy Management Software allowing you to readily identify glycemic trends and patterns and thus make informed decisions regarding a patient's diabetes treatment regimen.

The goal of CGM is ultimately to increase clinical efficacy while decreasing patient burden. As this guide will describe, the MiniMed 640G system provides features that continue to make advancements to meet this goal.

Fundamental Concepts

The following principles guide current CGM practice:

1. Medtronic CGM devices measure interstitial glucose, which is related to, but not the same as capillary glucose

- CGM values will usually lag behind self-monitored blood glucose (SMBG) values due to physiologic delay of glucose transfer between interstitial and blood compartments.
- Depending on the rate of change, CGM values are generally within 15%–20% of SMBG values, with greater differences during rapid rates of change. Understanding that blood glucose (BG) does not equal sensor glucose (SG) helps to set realistic expectations and emphasizes the importance of trends versus discrete values.

2. CGM is part of an integrated system that consists of four components:

- The **glucose sensor** is inserted into the subcutaneous tissue where glucose oxidase is used to measure the interstitial glucose level.
- The **transmitter** is connected to the glucose sensor and sends the sensor glucose values to the insulin pump.
- The **insulin pump** displays the sensor glucose values and trends, that is, the speed and direction that glucose values are moving. It has various alerts and suspend features that can be individualized for each patient and are discussed later in this guide. All settings and CGM data are stored in the pump.
- **CareLink™ Personal and Pro** software allows the information from the pump to be downloaded and displayed on reports. These reports will help the healthcare professional and patient make appropriate adjustments to pump and CGM settings in order to improve glucose control.

3. CGM devices are indicated for use as adjunctive to SMBG[1]

- All patient initiated treatment changes are to be based on standard SMBG tests, not the SG values.
- The CGM system is calibrated using SMBG with a glucose meter, usually 3–4 times a day for optimal results.

4. The more frequently patients use CGM, the greater improvement in glucose control[2,3]

- Encourage patients to adopt full-time use of CGM. However, patients who use CGM intermittently also benefit.
- Minimizing excessive CGM alerts upon initiation increases acceptance of the therapy.
- For those patients who use CGM intermittently, focus on times when glucose management is particularly difficult, for example, travel, illness, menstruation, or prolonged exercise.

5. MiniMed 640G with SmartGuard Technology™ allows insulin to be suspended based on glucose sensor values

- Suspending insulin delivery when glucose levels reach the pre-set low limit helps to decrease the frequency and duration of hypoglycemia.[4]
- Suspending insulin delivery even sooner - when glucose levels are predicted to be approaching the pre-set low limit – helps the patient avoid hypoglycemia by allowing glucose levels to recover before hypoglycemia occurs.[5,13]
- Once suspended, basal insulin will also be automatically resumed if and when sensor glucose levels have met the specified limits or if the maximum suspend time of two hours is reached.[5,13]

Clinical Evidence

Below is a summary of evidence for integrated insulin delivery and continuous glucose monitoring as technology advances toward a new standard of care.

Background

Managing type 1 diabetes requires constant vigilance and attention to diet, exercise, and insulin regimens, and depends on consistently delivering the right amount of insulin at the right time. Recent technological advances in insulin delivery systems and several key clinical trials have established the value of using data from continuous glucose monitoring (CGM) to guide dosing decisions and in some cases, stop insulin delivery automatically.

Although systems with fully-automated insulin delivery (the "closed loop") are not yet available, three important results have defined the new standard of care for type 1 diabetes. First, real-time CGM data, used in conjunction with insulin pump therapy, allows patients to safely reduce their A1C values compared to patients on optimally-adjusted multiple daily injection (MDI) therapy.[3] Second, allowing CGM sensor glucose values to stop the pump when hypoglycemia is detected can reduce the rate and severity of hypoglycemic events – especially those occurring at night.[4] Third, many instances of hypoglycemia can be prevented entirely if the pump is stopped by predicted (rather than actual) hypoglycemia.[5]

Better than MDI: The STAR 3 Study

The advantages of using sensor-augmented pumps (SAP) compared to MDI were established in the STAR 3 study[3] in which 485 subjects with suboptimal glycemic control were randomly assigned to continue on MDI or switch to SAP for 1 year. A1C reductions in the SAP group were rapid, clinically significant, and durable. At the end of the year, those in the SAP group had a mean reduction in A1C of 0.8 percentage points, compared to a 0.2 percentage point reduction in the MDI group ($p<0.001$), and were more than twice as likely to reach an A1C value of ≤7% ($p<0.001$). Importantly, the beneficial effect of routine CGM use was shown by the significant association between sensor use and A1C reductions ($p=0.003$). At the end of the year-long study phase, subjects assigned to MDI therapy were allowed to cross over to SAP therapy for a 6-month continuation phase.[6] Subjects who elected to switch achieved significant and sustained A1C reductions while on SAP therapy.

Mitigating Hypoglycemia: Low Glucose Suspend and Threshold Suspend

The next advance was to allow the CGM data to automatically suspend insulin delivery by the pump when a pre-set sensor glucose threshold was reached. The feature was CE marked and introduced as Low Glucose Suspend (LGS) in Europe and later as Threshold Suspend (TS) in the United States. When the feature is enabled and a sensor glucose value at or below a pre-specified value is detected, the pump stops delivering insulin for up to 2 hours if not restarted earlier by the user. The benefits of this strategy were quantified in the ASPIRE In-Home Study[4] that included 247 individuals who were prone to nocturnal hypoglycemia. After randomization to either the control group (routine SAP therapy) or the Threshold Suspend group, subjects' insulin delivery and CGM data were monitored for 3 months. Although nocturnal hypoglycemia was not eliminated in either group, the severity, duration, and rate of such events were reduced in those assigned to use the Threshold Suspend feature. The differences in each parameter were statistically and clinically significant: a 37.5% reduction in the combined severity and duration (measured as the area under the glucose concentration – time curve), and a 31.8% reduction in the weekly rate of hypoglycemic events. There was no change in A1C in either group.

The safety of automatic insulin pump suspensions lasting 2 hours was reinforced in several smaller clinical trials in Australia[7] and the United States.[8] In two separate exploratory data analyses, Agrawal and colleagues established that in routine "real world" use of pumps equipped with the LGS/TS feature, having the feature enabled was associated with significant reductions in hypoglycemia.[9,10]

Clinical Evidence

Preventing Hypoglycemia: SmartGuard™ Technology

The feasibility of hypoglycemia prevention by stopping insulin delivery in advance of predicted hypoglycemia has been established in several clinical studies involving investigational and commercially-available systems. In one study, overnight hypoglycemia (defined as one or more sensor glucose values ≤60 mg/dL (3.3 mmol/L)) occurred on 33% of control nights; this rate fell to 21% with predictive insulin pump suspension.[11] A second study involving increases in basal insulin delivery rates noted overnight hypoglycemia in 9 of 10 participants in the control arm, compared to 2 of 10 participants in the predictive pump suspension arm.[12] A third report noted that exercise-induced hypoglycemia was prevented with the predictive suspension feature in 80% of the successful experiments.[5] Medtronic's SmartGuard algorithm, available as part of the MiniMed 640G system, can automatically stop and resume insulin delivery based on sensor glucose values and pre-set low limit. In a recent user evaluation study that included over 2300 activations of the feature, in 83% of the events the pre-set low limit was not reached, suggesting that the SmartGuard algorithm can help avoiding hypoglycemia.[13]

Initiating CGM with MiniMed 640G - Low Settings

MiniMed™ 640G with SmartGuard™ can help prevent over 80% of hypoglycaemic events, without significant increase in hyperglycaemia, and is the only system clinically proven to reduce hypoglycaemia.[13] In addition, alerts can be set to notify the patient in situations when intervention is needed.

When starting a patient on CGM, you will need to determine the settings most appropriate for that patient. These settings are meant to be individualized to best meet the needs of each patient.

There are 4 steps to determine the low settings when initiating CGM:

- Step 1: Time Segments
- Step 2: Low Limits
- Step 3: SmartGuard Suspend by Sensor Options
- Step 4: Alert Options

The following further discusses each step.

Step 1: Time Segments

Multiple time segments allow you to have different settings for different times of the day. For example, you might want different settings for daytime versus nighttime; perhaps different settings for the time a child is at school day versus being at home. Up to 8 time segments can be set for a 24 hour period. Once the time segments are determined, the low limit, suspend by sensor option and the alerts are then set for each time segment.

Step 2: Low Limits

The low limit is the glucose value that you want the patient to spend no time, or at least only a minimal time, at or below. A low limit of 3.2 mmol/L (58 mg/dL) could be a good starting point for most patients during the day. You may want to consider increasing the low limit during night time hours and for those with severe hypoglycemia or hypoglycemia unawareness. Other conditions that might require more aggressive control (e.g. pregnancy) may require a decrease in the low limit.

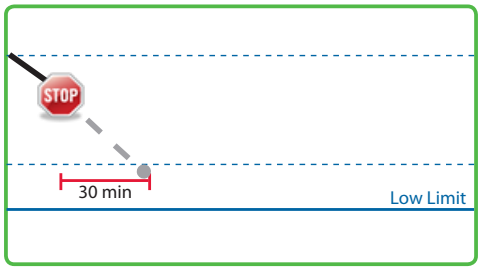
Initiating CGM with MiniMed 640G - Low Settings

Step 3: SmartGuard Suspend by Sensor Options

MiniMed™ 640G with SmartGuard™ can be set to suspend insulin delivery to both help decrease the number of hypoglycemic events and the duration and severity if and when hypoglycemia does occur. Not only will insulin delivery be suspended, but it will also be automatically resumed if glucose levels have met the specified limits. You will choose one of the following options for each defined time segment:

Option 1: Suspend before low

When *Suspend before low* is on, insulin delivery is suspended when glucose levels are predicted to be approaching the low limit in 30 minutes*.



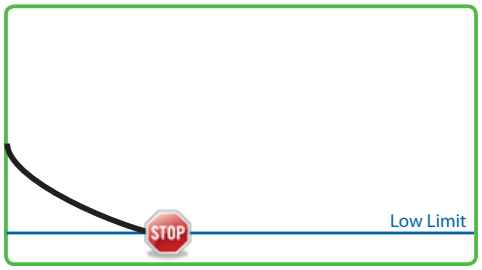
The patient may or may not choose to be alerted when this occurs. The goal of this feature is to suspend insulin delivery before glucose reaches the low threshold, helping glucose levels to recover and ideally avoid a hypoglycemic event.

When using the *Suspend before low* feature, insulin delivery can be suspended, minimizing the time spent in low possibly avoiding hypoglycemia, and insulin resumed – ideally without the patient even knowing this occurred. This can be especially appealing during the nighttime hours so that sleep is not disturbed. If the patient is awake and aware that the suspend has occurred, they can also be directed to manually resume basal insulin if the suspend occurs near a snack or meal time so a bolus can be given as needed. A blood glucose meter test should always be done to confirm glucose value before any action is taken.

The effectiveness of *Suspend before low* to avoid hypoglycemia is dependent on the severity of the drop in glucose levels. If the low limit that has been determined is reached despite insulin being suspended, the patient will always receive an alert. If that low alert is not addressed within 10 minutes, the pump will siren until cleared.

Option 2: Suspend on low

When using *Suspend on low*, insulin delivery is suspended when glucose levels reach the low limit.



The patient will always receive an alert when the *Suspend on low* occurs. If that low alert is not addressed within 10 minutes, the pump will siren and display an emergency screen until cleared.

Suspend on low may be preferred during the day for patients that are frequently interacting with their pump and monitoring their glucose levels and trends. A patient should be directed to treat with carbohydrate whenever possible. A blood glucose meter reading should always be done ` to confirm glucose value before any action is taken.

Note: Suspending insulin delivery has been shown to reduce hypoglycemia. However, you do have the option of using only alerts without any suspend feature if desired. Alert options are discussed in Step 4.

*Insulin delivery is suspended when sensor glucose is at or within 3.9 mmol/L (70 mg/dL) above the low limit and predicted to be at or within 1.1 mmol/L (20 mg/dL) above the low limit in 30 minutes.

Initiating CGM with MiniMed 640G - Low Settings

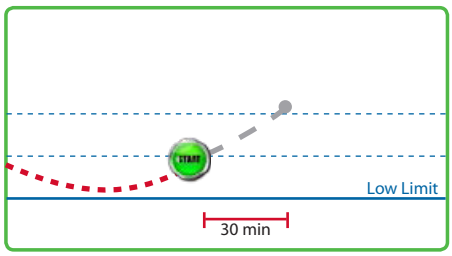
Additional SmartGuard Information

Resuming Insulin Delivery

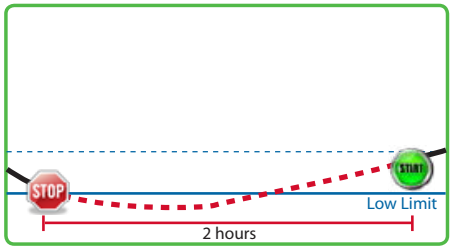
When using either *Suspend before low* or *Suspend on low*, insulin will remain suspended until basal insulin delivery is resumed due to one of the following:

1. **Manual resume:** The patient manually resumes basal insulin delivery. This can be done at any point during the suspend event.

2. **Auto resume based on SG value:** Basal insulin is automatically resumed when the sensor glucose level has risen above the low limit and is trending upward.* This can only occur after insulin has been suspended for at least 30 minutes. In a user evaluation study, the overall mean duration of insulin suspension was 56 minutes.[13]



3. **Auto resume due to 2 hour max suspend time:** The maximum time that insulin will be suspended is 2 hours. Basal insulin is automatically resumed anytime insulin delivery has been suspended for the maximum time.



Suspend Unavailable

Anytime basal resumes after a suspend event, there is a period of time when insulin will not be suspended regardless of the sensor glucose value. This time interval is 30 minutes anytime the patient has responded to the alert, insulin has been automatically resumed, or the patient has manually resumed insulin delivery. After 30 minutes, insulin delivery would again be suspended if the suspend condition exists.

In the event that the patient does not respond to the suspend message, the low limit is reached, and insulin remains suspended for the 2 hour maximum, basal insulin will be resumed and will not be suspended again for at least 4 hours. This cycle would continue for a maximum of 12 hours (two cycles) until another calibration is required or sooner if battery power is depleted. The patient may respond at any time, clear the alarm, and resume insulin delivery.

Note: SmartGuard is available in the MiniMed 640G system. See the *MiniMed 640G System User Guide* for complete information and instructions for use.

* Insulin delivery resumes when sensor glucose is at least 1.1 mmol/L (20 mg/dL) above the low limit and predicted to be more than 2.2 mmol/L (40 mg/dL) above in 30 minutes.

Initiating CGM with MiniMed 640G - Low Settings

Step 4: Alert Options

When selecting alerts, keep in mind that most patients only want to be alerted when they need to take action. Therefore, consider the following strategies when using SmartGuard:

When using ***Suspend before low*** there are two optional alerts:

- when insulin is suspended **(Alert before low)**
- when basal insulin delivery has resumed due to SG values **(Resume basal alert)**

Keep the Alert before low Off to see if hypoglycemia can be avoided by the suspension of insulin, knowing the pump will alert if the low limit is reached. It is recommended to keep the Resume basal alert Off since SG is at a safe level and no patient action is required.

When using ***Suspend on low*** there are two optional alerts:

- when sensor glucose is predicted to reach the low limit **(Alert before low)**
- when basal insulin delivery has resumed due to SG values **(Resume basal alert)**

It is recommended to keep the Alert before low turned On to prompt the patient to take action so that hypoglycemia can be avoided. It is recommended to keep the Resume basal alert turned Off since SG is at a safe level and no patient action is required. (Nevertheless, if basal delivery resumes after the maximum suspend time of two hours, the user will be alerted even if the Resume basal alert is set to Off.)

When suspend by sensor features are not used, there are two optional alerts:

- when sensor glucose is predicted to reach the low limit **(Alert before low)**
- when sensor glucose reaches the low limit **(Alert on low)**

It is recommended to keep the Alert before low turned Off at initiation in order to avoid alarm fatigue. Turn Alert on low On to prompt the patient to take action immediately.

Snooze

The low Snooze feature reminds a patient that an alert condition still exists after the initial alert has been received and cleared. For example, if the Snooze is set to 20 minutes and an Alert on low occurs, the patient can test their BG and treat with carbohydrate. They will be alerted again in 20 minutes if the sensor glucose is still below the low limit. A low snooze of 20 minutes is typically recommended.

See page 28 for considerations when determining initial Low Settings.

Initiating CGM with MiniMed 640G - Low Settings

Key Learnings from Early SmartGuard Use

Patients will need to be instructed to think differently when using SmartGuard in order to know how to handle suspend events correctly.

1. Insulin will suspend at different sensor glucose values when using *Suspend before low*. SG will always be at or within 3.9 mmol/L (70 mg/dL) above the low limit when suspend occurs, but will vary based on the rate that SG is falling (i.e. predicted to be 1.1 mmol/L [20 mg/dL] above the low limit within the next 30 mins). If falling rapidly, the sensor glucose will be higher than if falling gradually. This will be an important point for patients to understand.

2. The *Suspend before low* feature suspends insulin delivery before the glucose level reaches the low limit. Therefore, a patient should not treat with carbohydrate at the time of a *Suspend before low* event without first checking the BG, since hypoglycemia might not have been reached.

   a. If the patient confirms with a BG meter test and does decide to treat with carbohydrate, make sure they understand they need to resume the basal insulin delivery to avoid hyperglycemic rebound. It is important that patients do not both treat with carbs AND keep the basal insulin suspended when they are not hypoglycemic.

   b. If a patient reaches the low limit, they should confirm with BG meter test and treat with carbohydrate. At that point, the patient can consider resuming their basal insulin delivery based on their individual clinical situation (i.e., glucose value, active insulin, recent exercise, hypoglycemia unawareness, renal insufficiency, etc.).

   c. If a *Suspend before low* occurs at the time a routine bolus is due, for example, lunchtime, a blood glucose test should be performed, the suspend message cleared, and basal insulin manually resumed. The Bolus Wizard bolus amount should be adjusted as needed for any current glucose trend.

3. If suspend events routinely occur as evidenced by CareLink reports, consider adjustments to the pump settings.

Initiating CGM with MiniMed 640G – High Settings

High settings are intended to alert the patient if the sensor glucose is approaching or has reached the high limit, giving the patient an opportunity to respond and either prevent or reduce the severity and duration of the high excursion. These settings should be individualized for each patient, balancing the benefits of being notified and taking action while avoiding excessive alerts.

It is recommended that High Settings be Off at CGM initiation to minimize the number of alerts patient receives. Once patient is comfortable using CGM and initial insulin adjustments have been made to improve control, high alerts are added. This generally occurs 1 to 4 weeks after initiation.

There are 3 steps to determine the high settings when initiating CGM:

- Step 1: Time Segments
- Step 2: High Limits
- Step 3: Alert Options

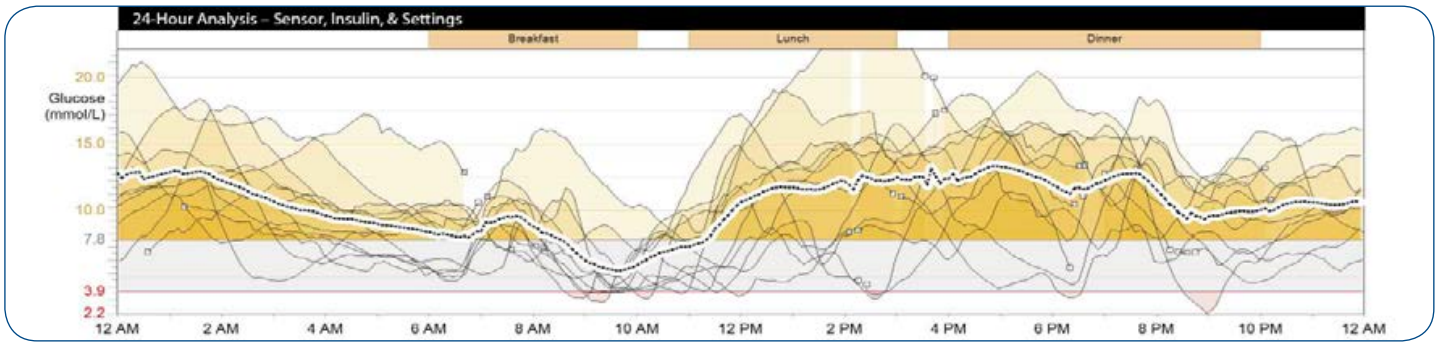
The following further discusses each step.

Step 1: Time Segments

Like the low settings, multiple time segments allow you to have different settings for different parts of the day. Up to 8 time segments can be set for a 24 hour period. Once the time segments are determined, the high limit and alerts are then set for each time segment.

Step 2: High Limit

The high limit is the glucose value at which, if reached, the patient should assess to see if additional insulin is needed. It is very important that this limit is not set too low or considered to be the same as glucose target. We recommend to start with a high limit of 13.8 mmol/L (250 mg/dL; default setting) which can be decreased as glucose control improves and hyperglycemia is reduced. CareLink is also a useful tool for determining appropriate limits individualized for a particular patient to help prevent excessive alerts. Looking at the CareLink report below and considering the amount of hyperglycemia that is occurring, a limit higher than 13.8 mmol/L (250 mg/dL) may be more appropriate until therapy adjustments are made to reduce the amount of hyperglycemia that is occurring.



Therapy Management Dashboard Sensor Overlay

Initiating CGM with MiniMed 640G – High Settings

Step 3: High Alerts

Once the time segments and high limits are determined, the alert options are as follows. Always keep in mind, it is important to avoid excessive alerts leading to patient frustration. Below you will find a description of each alert and the strategy you may want to consider when setting the high alerts:

- **Alert on high:** Alerts when sensor glucose reaches the high limit.
- **Alert before high:** Alerts when sensor glucose is predicted to reach the high limit.
  - When using Alert before high, the **Time before high** must also be set. The Time before high determines when the user will receive an Alert before high (can be between 5 and 30 minutes).
- **Rise Alert:** Alerts when sensor glucose is rising at a rapid rate. This can bet set based on the trend arrows that display on the Home screen (see page 14).

Keep all alerts turned Off at initiation. Then use either Alert before high or Alert on high. Using both may cause excessive alerts. Rise alerts are most frequently used for those patients who often miss boluses.

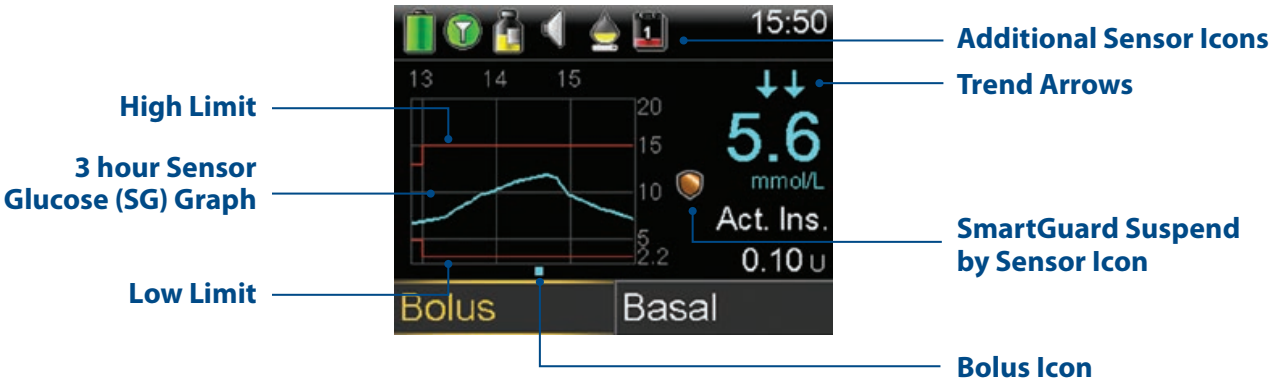
Snooze

The high Snooze feature reminds a patient that an alert condition still exists after the initial alert has been received and cleared. For example, if the Snooze is set to 1 hour and an Alert on high alert occurs, the patient will be reminded again in 1 hour if the sensor glucose is still above the high limit. Having the Snooze set for too short a time can cause repeated alerts that occur too soon and do not allow insulin that may have been taken to lower glucose levels. A high snooze of at least 2 hours is typically recommended.

See page 29 for considerations when determining initial High Settings.

Graphs and Displays

Here is an example of the CGM information that is displayed on the Home screen:



The Home screen always displays a 3 hour trend graph which helps the patient see where the SG has been and the direction it is moving. There are 6, 12 and 24 hour graphs available that can be viewed as well. The most current SG reading is displayed and updated every 5 minutes. Above the SG value are trend arrows that appear when glucose is moving at the following rates:

Trend Arrows	
↑ ↓	SG has been rising or falling by about 1 - 2 mmol/L (20-40 mg/dL) over the last 20 minutes
↑↑ ↓↓	SG has been rising or falling by about 2 - 3 mmol/L (40-60 mg/dL) over the last 20 minutes
↑↑↑ ↓↓↓	SG has been rising or falling greater than 3 mmol/L (60 mg/dL) over the last 20 minutes

Home screen during suspend by sensor event

Shown here is the Home screen during a *Suspend before low* event.

The graph will display a gold shaded area to show any time when insulin was suspended by SmartGuard.

When the SmartGuard icon is displayed, the patient knows a suspend feature is on. The icon will flash while insulin is suspended.

Using On-Screen Data to Make Therapy Adjustments

The protocol for the Juvenile Diabetes Research Foundation (JDRF) CGM study provided recommendations for insulin dose adjustments based on trend arrows.[14] The guidelines below are adapted from these recommendations.

Trend Arrows

After a patient has become comfortable responding to alarms and alerts and interpreting glucose trends, you may want to consider adding trend arrows to the insulin dose adjustments. Patients should use the Bolus Wizard® calculator using fingerstick BG values to determine the bolus insulin recommendation, and then can be instructed to consider making dose adjustments to the Bolus Wizard estimate based on the on-screen trend arrows.

If fingerstick BG is low before bed, or anytime a low alert occurs:

- Correct the low with glucose tablets.
- Check to see if there are trend arrows on the pump screen.
- Consider taking more glucose if down arrows are present.
  - For example, if 15 grams is normally used to treat a low, consider adding 5 grams glucose for 1 arrow, 10 grams for 2 arrows and 15 grams for 3 arrows.

If fingerstick BG is low before food intake:

- Do not bolus while glucose is low.
- Treat the hypoglycemia.
- After treating the hypoglycemia and the glucose is within target, calculate the bolus to cover the meal, check for trend arrows on the pump, and adjust based on the arrows using the guidelines in the table below.

If fingerstick BG is at or above target before a meal or whenever a high alert occurs:

- Check to see if there are trend arrows on the pump screen.
- Calculate your meal bolus and/or correction dose and adjust based on the trend arrows using the guidelines in the table below.

Bolus Adjustment Guidelines Using Trend Arrows	
↓	Decrease dose by 10%
↓↓ or ↓↓↓	Decrease dose by 20%
No arrows	No change in dose
↑	Increase dose by 10%
↑↑ or ↑↑↑	Increase dose by 20%

Adjustments can also be made for trend arrows when the BG is within target range. This should be initiated after the patient has experience with adjusting doses for high and low BGs using trend arrows. When BG is within target range, use the arrows to give minor correction doses and small amounts of glucose as appropriate.

As always, individual patient history should be considered with all recommended dosage adjustments.

Making Therapy Adjustments Based on CareLink Pro Reports

CareLink Pro generates easy-to-read reports that allow a healthcare professional to quickly assess control and fine-tune therapy. CareLink combines insulin pump, continuous glucose monitoring, and blood glucose meter data in one convenient place. Furthermore, CareLink reports can be a powerful tool to educate and motivate patients by emphasizing positive behavior and pointing out opportunities to improve.

Methodology for Interpretation

The 3 most frequently used reports to begin assessment are the Therapy Management Dashboard, the Sensor & Meter Overview, and the Device Settings page. While there is no single preferred approach to CareLink interpretation, here is the most commonly suggested methodology:

1. Examine patient behavior by looking at the number of BG readings, Bolus Wizard use, site changes and sensor use. Assess appropriateness of Total Daily Dose (TDD) and Basal/Bolus Ratio and Suspend events.

2. Assess the overall mean sensor glucose on the Therapy Management Dashboard, focusing on the frequency and extent of hypoglycemia and hyperglycemia excursions. Look for patterns of glycemic variability.

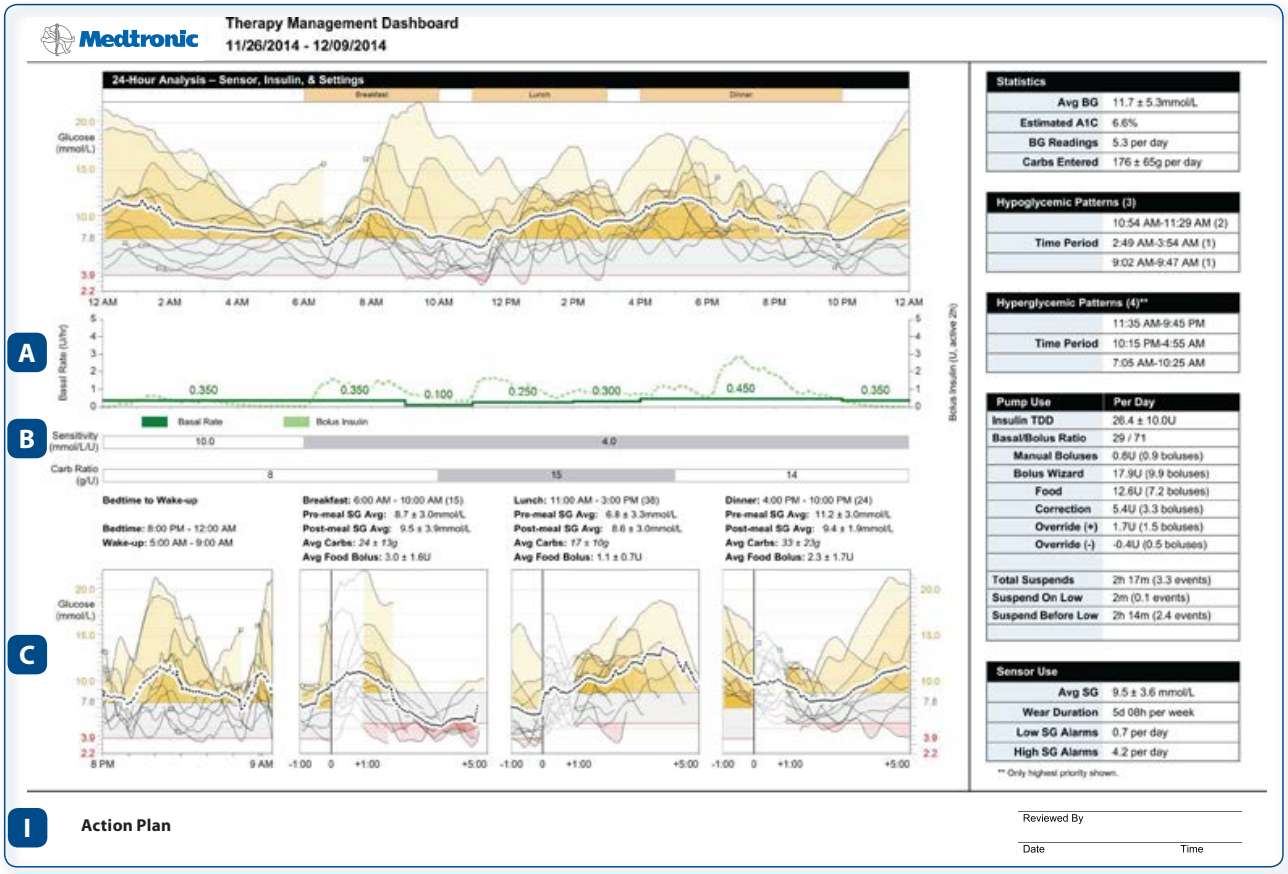
3. Use the Sensor Meter Overview report to assess timeliness of BG checks and appropriateness of carb entry and bolus activity. Look for glycemic trends as a result of bolus deliveries, and assess basal rates during periods between boluses. Consideration for adjustment in basal rates, insulin to carb ratio and insulin sensitivity factor can be deduced here.

4. Define goals, document findings and implement changes to current settings on the Device Settings report. Evaluate the results on follow up visit

The following pages discuss CareLink reports and provide guidance on using the information provided.

Reviewing the Therapy Management Dashboard

This is an introduction to the CareLink Therapy Management Dashboard. This report is generated when a minimum of five days (1440 data points) of pump and sensor data are within a reporting period.



Information Presented for Evaluation

A Insulin Profile Graph
Assess insulin profiles. How many basal rates? Are they appropriate? Is variance appropriate? Evaluate average active bolus insulin.

B Sensitivity and Carb Ratio
Evaluate insulin sensitivity and carb ratios. Are they appropriate? Consider checking carb ratio against 450 rule (450 divided by TDD) and insulin sensitivity against 1700 or 2000 rule (1700 or 2000 divided by TDD).

C Bedtime to Wake-up and Meal Sensor Overlay*
Evaluate sensor glucose from bedtime to wake-up.
Is patient within target during this time period? If not, make adjustments to overnight basal rates. Assess pre and post meal sensor variability. Is carb ratio too aggressive or does the patient need more insulin for meals? Suggestions for management can be found on page 19.

D Statistics Table
Evaluate average BG, standard deviation (SD) and assess carb counting. Suggestions for therapy adjustments related to these statistics can be found on page 19.

E Hypo- and Hyperglycemic Patterns Tables*
Evaluate hypo-and hyperglycemic patterns. Are there areas of concern? Are there extreme excursions of hypo- or hyperglycemia?

F Pump Use Table
Evaluate total daily dose of insulin. Is it appropriate based on weight and age? Assess basal to bolus ratio. Suggestions for therapy adjustments related to pump usage can be found on page 19.

G Total Suspends**
This represents the total duration of suspend events including manual suspends. Are there lengthy periods of suspends?

H Sensor Use Table
Evaluate average SG and SD. Evaluate amount of sensor wear. Evaluate number of alarms per day.

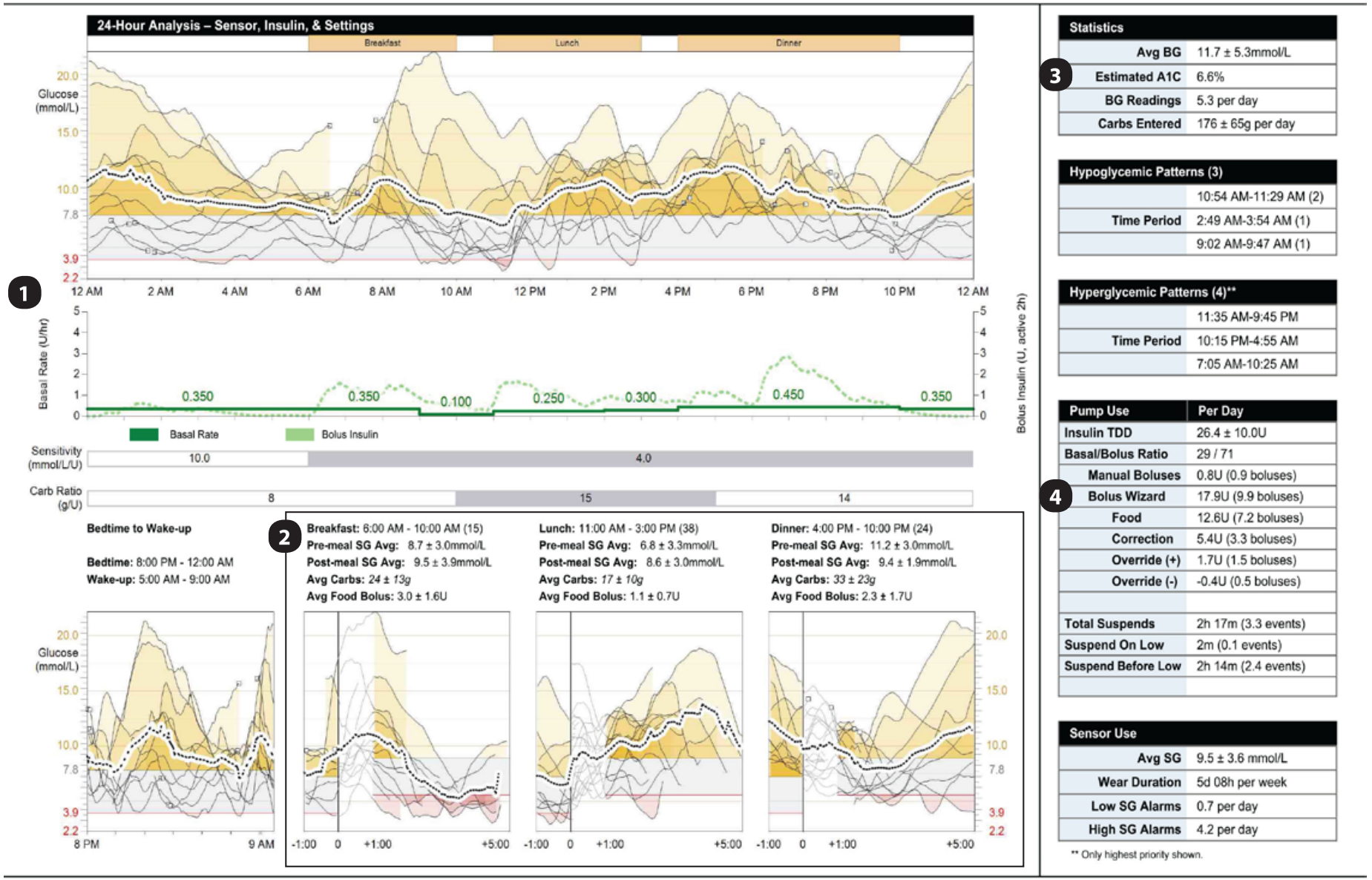
I Action Plan
Use this section to record notes for patient records, to provide comments and recommendations for patient therapy, and/or to record documentation for health insurance providers.

*Targets determined by provider during report setup.
**Total Suspends, *Suspend on low*, *Suspend before low* will be displayed if device supports this feature.

Using the Therapy Management Dashboard to Make Therapy Adjustments

CareLink should be reviewed in a systematic format. Start by looking at the Therapy Management Dashboard for a sense of overall control or areas of concern.

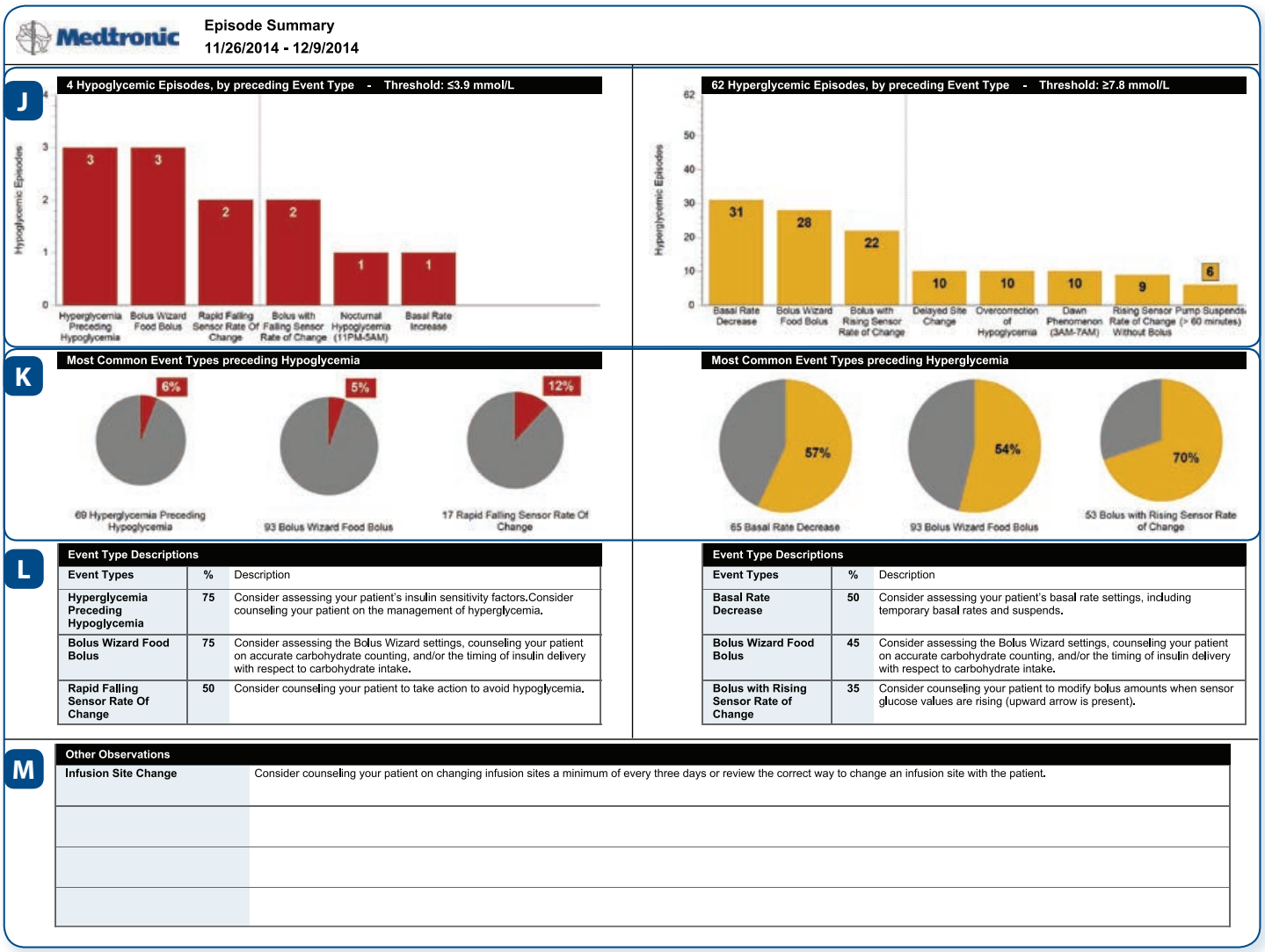
Generally, 1 to 2 therapy changes and 1 to 2 behavioral changes at a time with a follow up evaluation is appropriate.



	1 Sensor Overlay	2 Meal Sensor Overlay	3 Statistics Table		4 Pump Use Table	
	Assess mean sensor glucose (SG) variability indicated by the red shaded areas of hypoglycemia and gold shaded areas of hyperglycemia. Refer to the Hypoglycemia and Hyperglycemia Patterns under Statistics Table (3) for frequency of occurrences. Compare insulin delivery data for number and variability of basal rates, carb ratios and sensitivity, as well as insulin on board from prior boluses.	Assess pre- and post-meal with accompanying SG averages. Evaluate carb ratios, timing of meals, and patient's carb counting capability. Average of carbs is listed per meal with standard deviation (SD).	Assess average blood glucose (BG) along with standard deviation (SD). SD can be used to evaluate degree of variability. Estimated A1C is derived mathematically from SG values during the reporting period. It is not the same as a lab A1C measurement. Refer to number of BG readings per day to assess adherence issues.		Total Daily Dose (TDD) should be evaluated (consider patient's weight) along with basal/bolus ratio. Determine use of Bolus Wizard, manual boluses and allocation of insulin used for food and correction. Evaluate the number of overrides and frequency of suspends.	
			Avg BG	Standard Deviation (SD)	Basal/Bolus Ratio	Manual Boluses vs. Bolus Wizard
Acceptable behavior:	✔ None or minimal hypoglycemic events and BG is within target.	✔ Post-meal SG within 1.7-3.3 mmol/L (30-60 mg/dL) rise of Pre-meal SG.	✔ 5.6-8.9 mmol/L (100-161 mg/dL)	✔ (SD x 2) < Avg BG	✔ Bolus Ratio ≥ 50% (+/- 10%)	✔ Boluses are delivered through the Bolus Wizard.
Opportunities for improvement:	✘ Hypoglycemic patterns reflect too many low SG values. Frequent basal changes that do not provide improvement in SG average. The amount of insulin on board at night, and there is the use of many basal rates.	✘ Post-meal SG is outside of 1.7-3.3 mmol/L range, consider (30-60 mg/dL) adjusting Carb Ratios.	✘ Avg BG is not optimal.	✘ Double the SD is > Avg BG, assess for appropriate number of BG readings/day. Refer to **Sensor & Meter Overview** for daily variability.	✘ Basal insulin is significantly larger than bolus insulin. Consider adjusting basal rates or encouraging patient to bolus appropriately for meals and snacks using the Bolus Wizard.	✘ Manual boluses > Bolus Wizard activity. Assess effectiveness of manual boluses and consider counseling patient on the use of Bolus Wizard with minimal overriding.
This example:	✔ Continue to monitor with no changes to basal rates at this time. Overall, patient has bedtime and early morning hyperglycemia, post breakfast lows, and post lunch highs. Frequent snacking or correcting is seen high insulin on board. Refer to **Daily Detail** report for isolated events.	✘ Patient has trends of hypoglycemia post-meal in the mornings. Multiple causes can range from over estimating carbs versus an aggressive carb ratio. Use the **Episode Summary** report to confirm findings and adjust settings as necessary. Assess patient's knowledge on correct carb counting and consider the usage of advanced feature boluses, such as Dual or Square Wave boluses for high fat meals and slow digestion of carbohydrates.	✘ Patient requires additional insulin for lunch and dinner. Make changes to carb ratios and consider adjustments to sensitivity in follow up evaluation.	✔ Doubled standard deviation is less than Avg BG. Patient has limited variability. (SD x 2) < Avg BG.	✔ Patient boluses frequently for meals and for correction. Refer to reports such as the **Sensor & Meter Overview** or **Daily Detail** to consider making adjustments to lunch carb ratio.	✔ Patient minimally uses manual bolus. Discuss with patient reasoning for Bolus Wizard overrides.

Review of Episode Summary†

Use this report to evaluate events that precede hypoglycemic and hyperglycemic episodes. You may also use this as a "conversation map" to develop questions you may want to discuss with the patient in order to make therapy changes or provide additional education.



J Hypoglycemic/Hyperglycemic Episode Charts (22 different algorithms)*
Use this to assist in identifying and ranking events that precede hypo- and hyperglycemic episodes. There can be more than one event preceding an episode and it is possible that no events precede an episode. You may want to obtain more information from the patient about these events.

K Most Common Event Types Pie Charts (for top 3 preceding events)
Evaluate the hypo- and hyperglycemic episodes in relation to the total number of occurrences for each event during the reporting period. If < 10%, may not require evaluation.

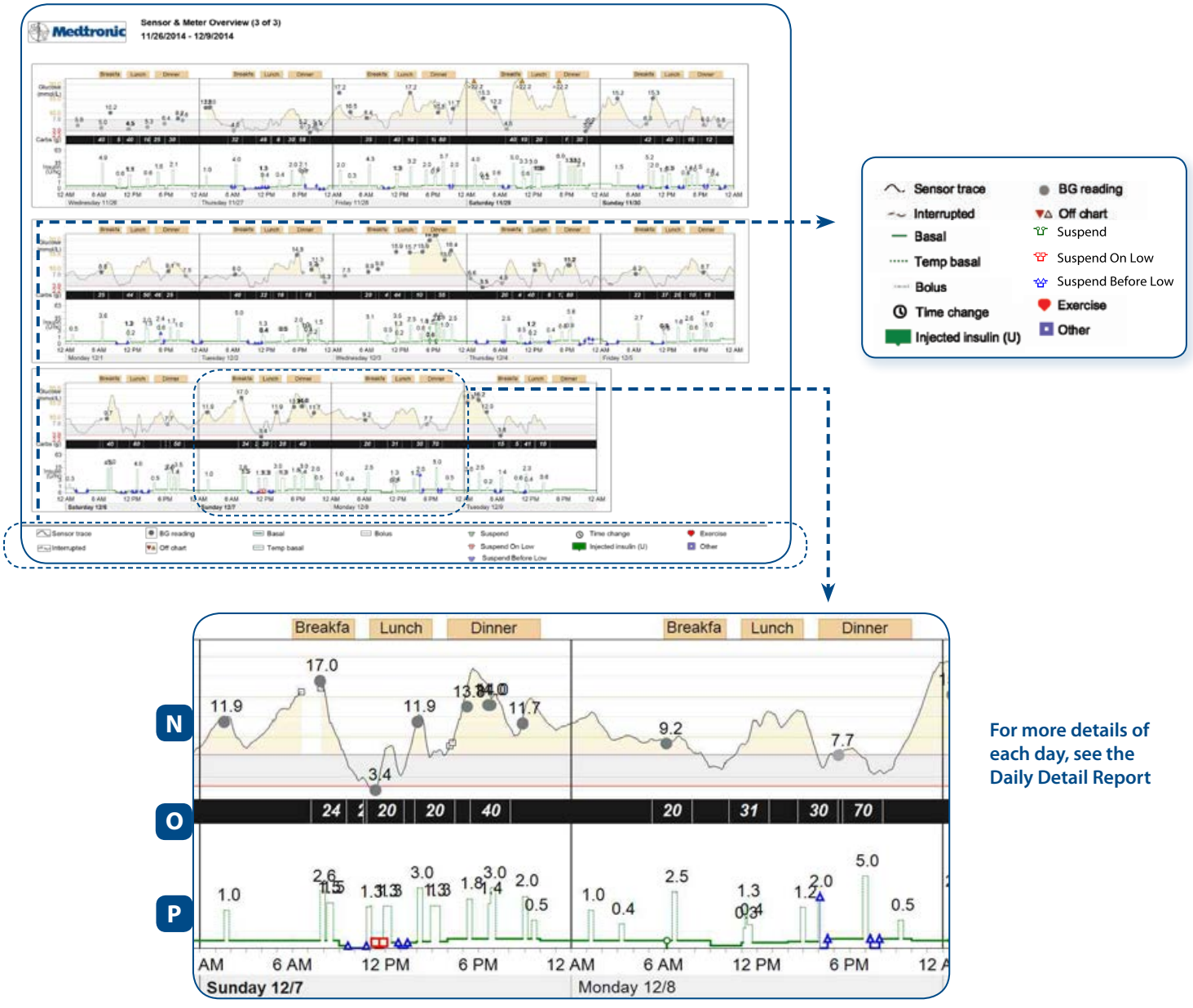
L Event Type Descriptions Table
Consider possible therapy adjustments or education related to hypo- and hyperglycemic episodes.

M Other Observations Table (6 algorithms)
Identify possible behavior changes related to pump, CGM, and/or meter usage.

*Targets determined by provider during report setup.
†To obtain the Episode Summary, a minimum of five days (1440 data points) of pump and sensor data are required.

Use of the Sensor & Meter Overview Report: Daily Snapshots

Use this report to analyze glucose levels, carbohydrate intake, and insulin delivery to assist in identifying trends.



For more details of each day, see the Daily Detail Report

N Glucose Section*

Evaluate for sensor variability and daily patterns. Are there events that are the cause of concern? Does glucose drastically change while suspended or does the patient remain suspended for too long? Did patient take carbs during *Suspend before low* that caused an excursion?

O Carbs Section

Evaluate carbohydrate intake. Is the patient eating large meals and is there insulin given for all carbohydrate entries? Assess if carb ratio is sufficient for meals.

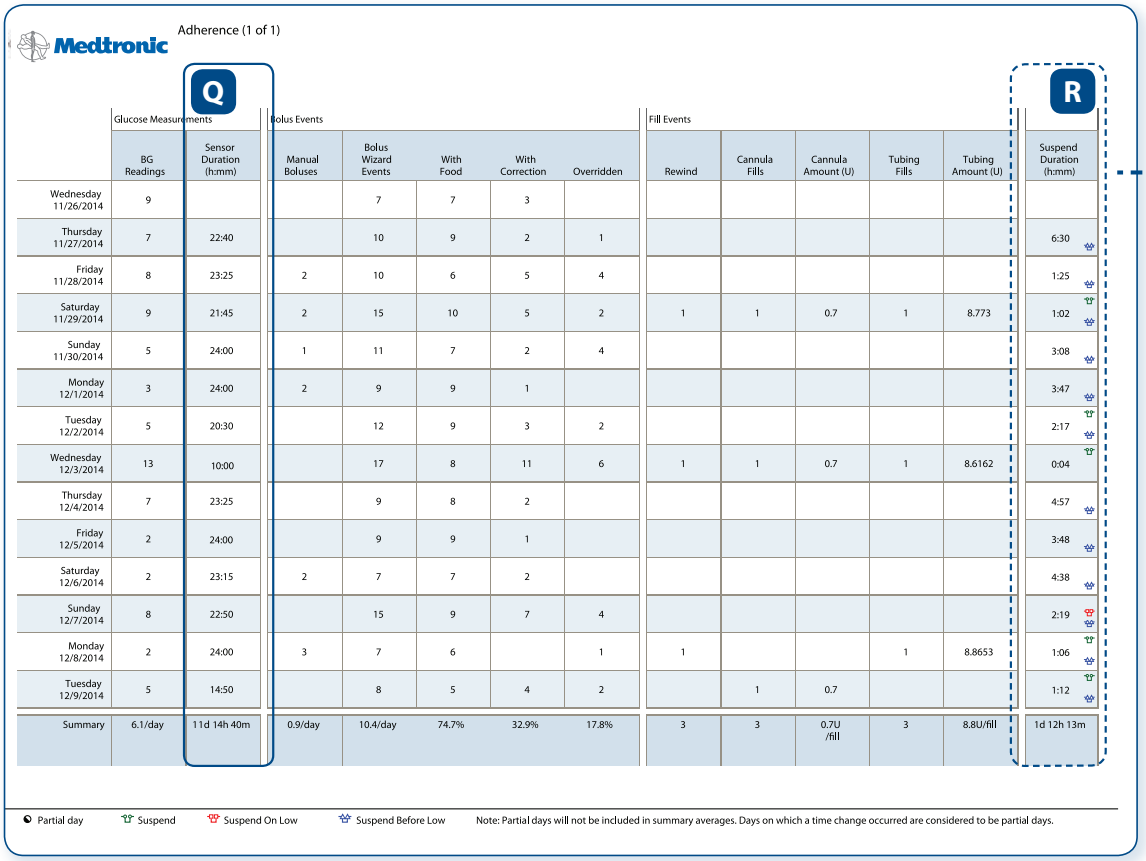
P Insulin Section

Assess insulin delivery. Could the patient be overriding the pump? Confirm your findings in the Daily Detail Report. Are there many *Suspend on low* events? Does the patient frequently manual bolus for BG post-meal?

*Targets determined by provider during report setup

Example of Adherence Report

Use this report to analyze patient behaviors.



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Adherence (1 of 1)

	Glucose Measurements		Bolus Events					Fill Events					
	BG Readings	Sensor Duration (h:mm)	Manual Boluses	Bolus Wizard Events	With Food	With Correction	Overridden	Rewind	Cannula Fills	Cannula Amount (U)	Tubing Fills	Tubing Amount (U)	Suspend Duration (h:mm)
Wednesday 11/26/2014	9			7	7	3							
Thursday 11/27/2014	7	22:40		10	9	2	1						6:30
Friday 11/28/2014	8	23:25	2	10	6	5	4						1:25
Saturday 11/29/2014	9	21:45	2	15	10	5	2	1	1	0.7	1	8.773	1:02
Sunday 11/30/2014	5	24:00	1	11	7	2	4						3:08
Monday 12/1/2014	3	24:00	2	9	9	1							3:47
Tuesday 12/2/2014	5	20:30		12	9	3	2						2:17
Wednesday 12/3/2014	13	10:00		17	8	11	6	1	1	0.7	1	8.6162	0:04
Thursday 12/4/2014	7	23:25		9	8	2							4:57
Friday 12/5/2014	2	24:00		9	9	1							3:48
Saturday 12/6/2014	2	23:15	2	7	7	2							4:38
Sunday 12/7/2014	8	22:50		15	9	7	4						2:19
Monday 12/8/2014	2	24:00	3	7	6		1	1			1	8.8653	1:06
Tuesday 12/9/2014	5	14:50		8	5	4	2		1	0.7			1:12
Summary	6.1/day	11d 14h 40m	0.9/day	10.4/day	74.7%	32.9%	17.8%	3	3	0.7U /fill	3	8.8U/fill	1d 12h 13m

Partial day Suspend Suspend On Low Suspend Before Low Note: Partial days will not be included in summary averages. Days on which a time change occurred are considered to be partial days.

Q Sensor Duration
Assess the amount of time per day the sensor is worn. Encourage and promote full 24 hour wear. Note that every 6th day a sensor change is recommended so full 24 hour wear for that day will not be expected.

R Suspend Duration
Evaluate the total amount of time the pump is suspended per day (includes manual suspend, *Suspend before low*, and *Suspend on low* events).

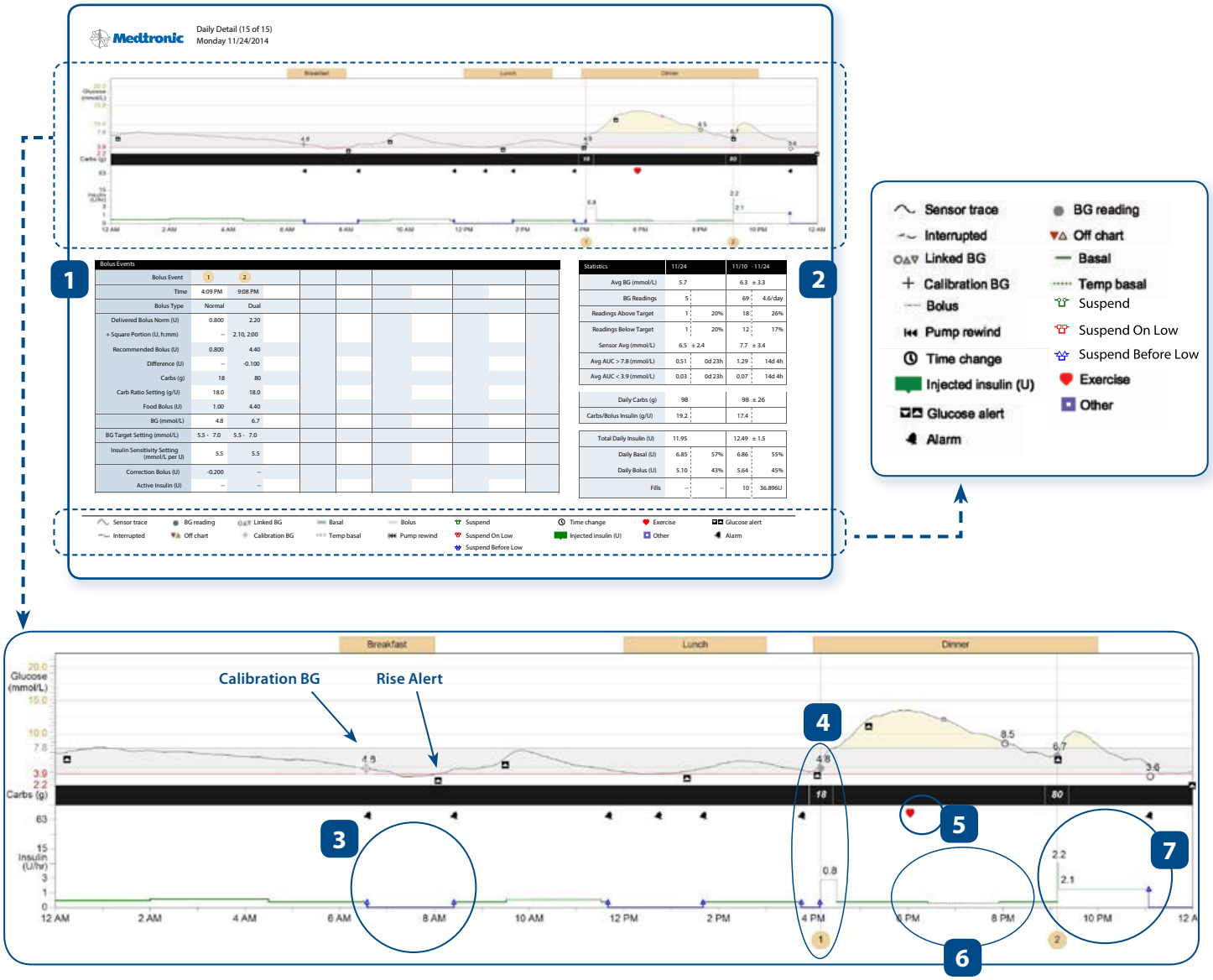
S Manual Suspend
Evaluate manual suspend events indicated by the green icon and included in the summation of total suspend duration.

T Suspend Events
Evaluate the occurrence of SmartGuard events per day. Each colored icon indicates a designated suspend event. Refer to the Sensor & Meter Overview Report or the Daily Detail Report for the frequency of each suspend event.

Suspend Suspend On Low Suspend Before Low

Review of Daily Detail Report

Use this report to look at more specific details (time, amount, type) of each bolus given as well as suspend and temp basal events.



1 Bolus Events Table

Up to 10 bolus events can be displayed. If more than 10 bolus events have occurred, the 10 largest boluses will be shown.

2 Statistics

Insulin statistics for the day's usage will be displayed in the first column and paired aside the statistics for the entire reporting period in the next column.

3 *Suspend before low* event that did not involve intervention from the patient. Auto resume of basal insulin is initiated after 2 hour suspend and a recovering sensor glucose is shown.

4 Patient manually resumed insulin delivery to bolus for snack.

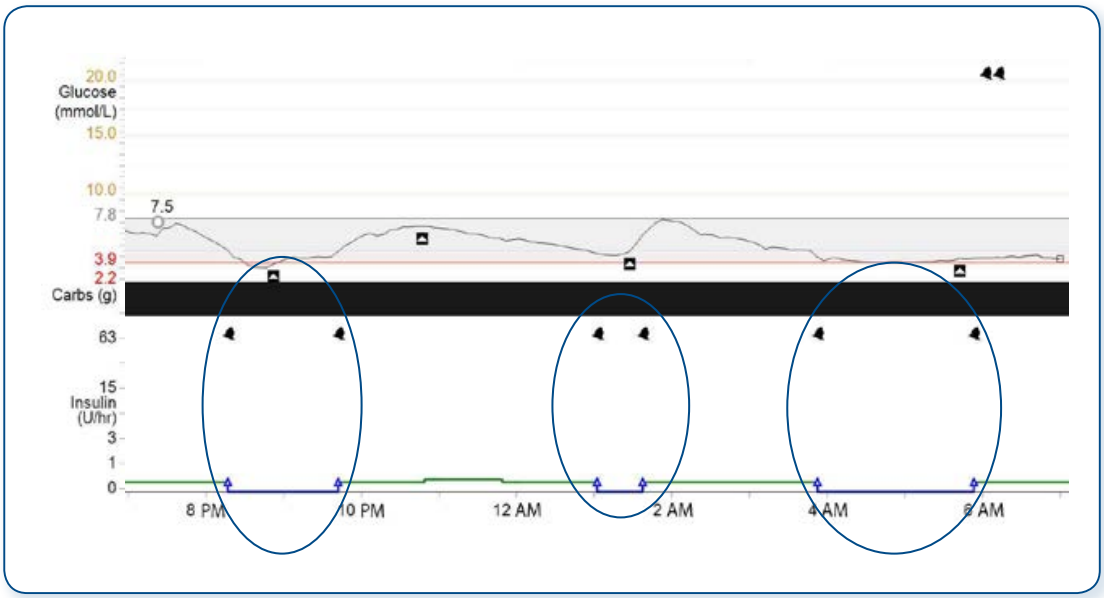
5 Exercise entered via Event Marker feature.

6 User initiated Temp Basal to accommodate exercise.

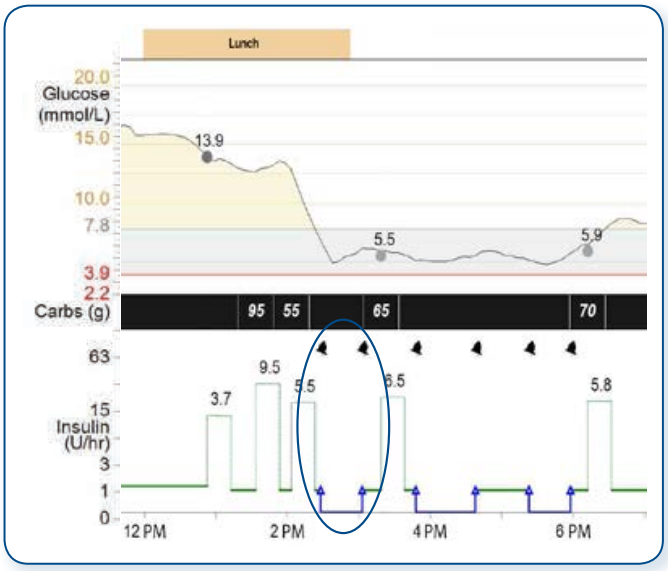
7 An example of a Dual Wave bolus for 80 gram carb meal.

Using the CareLink Pro Daily Detail Report to Identify SmartGuard

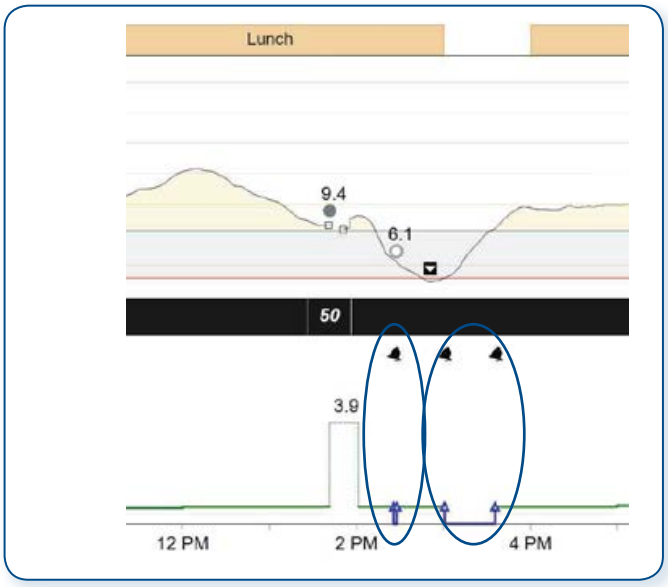
SmartGuard suspend events are indicated by the basal rate drop to 0.0 units/hour as well as a color change from green to blue or red. Detection of a *Suspend before low* event can be seen by two bells; one bell at the beginning of the event and a second bell at the end when basal insulin auto resumes. The alert when *Suspend before low* occurs can actually default to Off so it does not need to be turned Off as preferred by the patient.



Three *Suspend before low* events occurred mitigating nocturnal hypoglycemia. This patient was able to experience 12 hours without intervention for diabetes management.



Suspend before low is triggered by falling sensor glucose with auto-resume of basal approximately 30 minutes later. Another bolus for food is given and initiating another *Suspend before low*. Auto-resume of basal begins when sensor glucose levels recover. SmartGuard continues to stabilize glucose post meals, avoiding hypoglycemia.

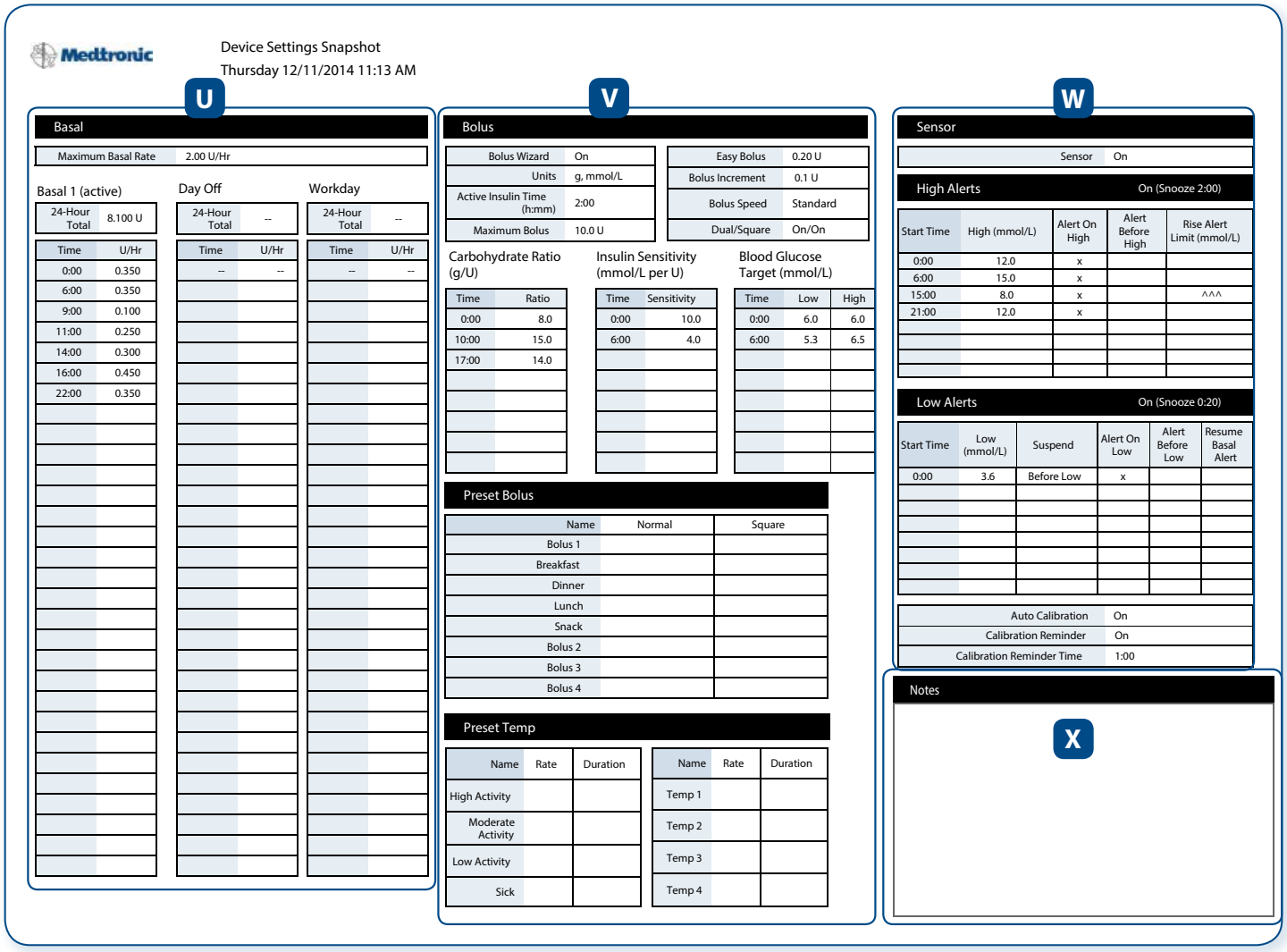


The first time *Suspend before low* occurs, patient manually resumes basal insulin. This is evident by the absence of a second bell and causes the suspend feature to be unavailable for 30 minutes. *Suspend before low* occurs again due to glucose levels approaching low limit and patient allows the suspend to continue. Insulin remains suspended for the 30 minute minimum and auto-resumes since glucose had recovered.

Sensor trace
Interrupted
Linked BG
Calibration BG
Basal
Bolus
Temp basal
Glucose alert
Alarm
Suspend
Suspend On Low
Suspend Before Low
BG reading
Off chart

Example of Device Settings Report

Use this report to evaluate insulin pump and sensor settings.



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Device Settings Snapshot
Thursday 12/11/2014 11:13 AM

U

Basal

Maximum Basal Rate	2.00 U/Hr

Basal 1 (active)

24-Hour Total	8.100 U

Time	U/Hr
0:00	0.350
6:00	0.350
9:00	0.100
11:00	0.250
14:00	0.300
16:00	0.450
22:00	0.350

Day Off

24-Hour Total	--

Time	U/Hr
--	--

Workday

24-Hour Total	--

Time	U/Hr
--	--

V

Bolus

Bolus Wizard	On
Units	g, mmol/L
Active Insulin Time (h:mm)	2:00
Maximum Bolus	10.0 U

Easy Bolus	0.20 U
Bolus Increment	0.1 U
Bolus Speed	Standard
Dual/Square	On/On

Carbohydrate Ratio (g/U)

Time	Ratio
0:00	8.0
10:00	15.0
17:00	14.0

Insulin Sensitivity (mmol/L per U)

Time	Sensitivity
0:00	10.0
6:00	4.0

Blood Glucose Target (mmol/L)

Time	Low	High
0:00	6.0	6.0
6:00	5.3	6.5

Preset Bolus

Name	Normal	Square
Bolus 1		
Breakfast		
Dinner		
Lunch		
Snack		
Bolus 2		
Bolus 3		
Bolus 4		

Preset Temp

Name	Rate	Duration
High Activity		
Moderate Activity		
Low Activity		
Sick		

Name	Rate	Duration
Temp 1		
Temp 2		
Temp 3		
Temp 4		

W

Sensor

Sensor	On

High Alerts — On (Snooze 2:00)

Start Time	High (mmol/L)	Alert On High	Alert Before High	Rise Alert Limit (mmol/L)
0:00	12.0	x		
6:00	15.0	x		
15:00	8.0	x		^^^
21:00	12.0	x		

Low Alerts — On (Snooze 0:20)

Start Time	Low (mmol/L)	Suspend	Alert On Low	Alert Before Low	Resume Basal Alert
0:00	3.6	Before Low	x		

Auto Calibration	On
Calibration Reminder	On
Calibration Reminder Time	1:00

Notes

X

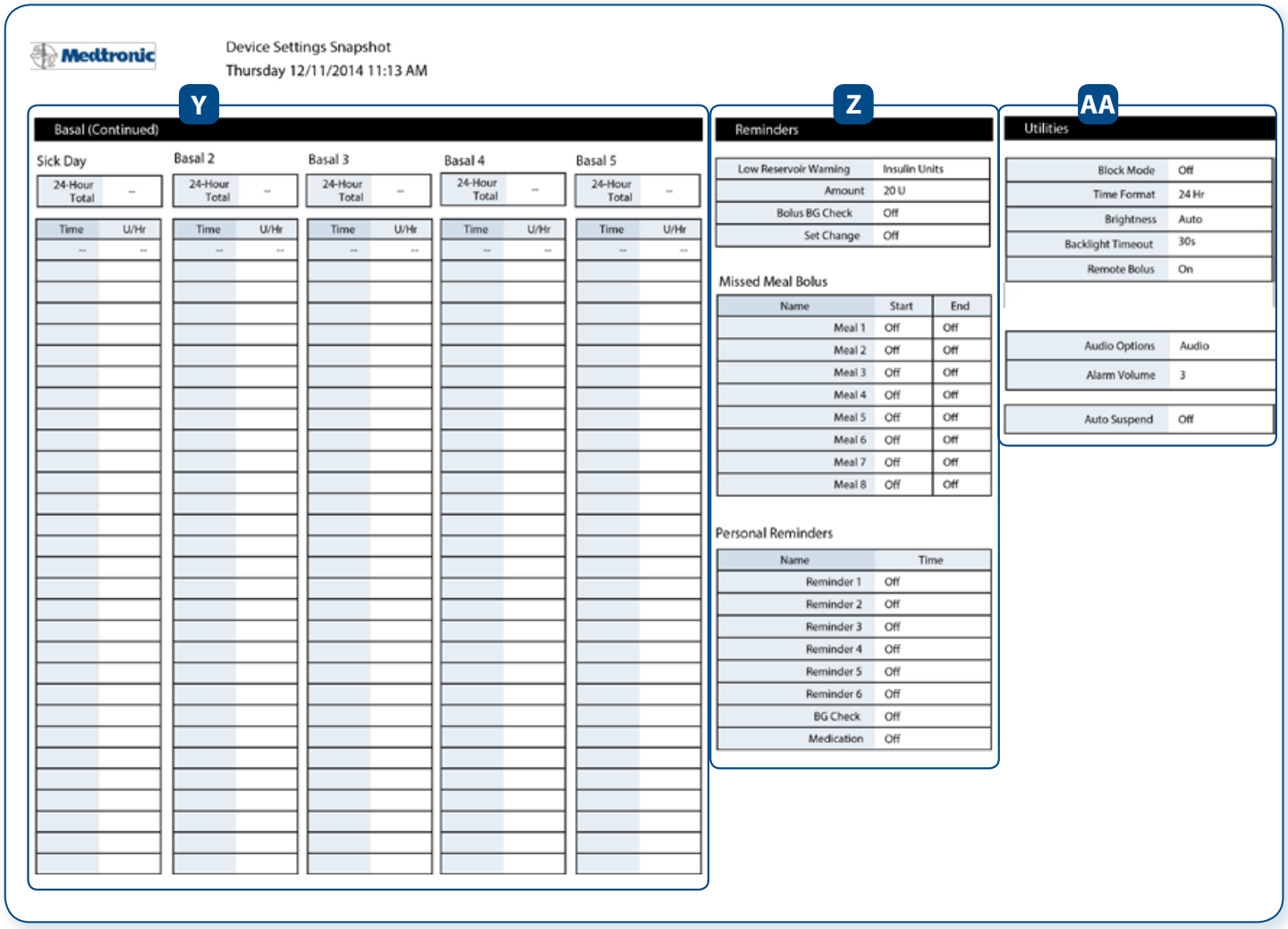
U Basal Settings
Evaluate basal settings. Is the number of basal rates appropriate or excessive? Is variance between rates appropriate?

V Bolus Settings
Evaluate bolus settings. Are they appropriate? Are the Bolus Wizard glucose targets appropriate? Is the Active Insulin time appropriate? Overall, do the settings make sense?

W Sensor Settings
Evaluate parameters of the sensor settings. Are alerts set appropriately and to the needs of the patient for proper glucose control? Assess if the timing of sensor alarms create a nuisance to the patient which prevent them from wearing the sensor.

X Notes
Use this section to make notes for patient records. No more than 1 to 2 changes are recommended at a time. Provide a copy of this page as instruction of changes for the patient. Scan or save the entire CareLink Pro report as a PDF to attach to the Patient's EMR.

Example of Device Settings Report (continued)



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Device Settings Snapshot
Thursday 12/11/2014 11:13 AM

Y

Basal (Continued)

Sick Day	Basal 2	Basal 3	Basal 4	Basal 5
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
--	--	--	--	--	--	--	--	--	--

Z

Reminders

Low Reservoir Warning	Insulin Units
Amount	20 U
Bolus BG Check	Off
Set Change	Off

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

AA

Utilities

Block Mode	Off
Time Format	24 Hr
Brightness	Auto
Backlight Timeout	30s
Remote Bolus	On
Audio Options	Audio
Alarm Volume	3
Auto Suspend	Off

Y Additional Basal Settings
These are additional basal patterns for different needs of insulin demand.

Z Reminders
These settings are turned on to assist with BG checks, and missed meal boluses. It is best practice to have the patient use reminders for proper maintenance of reservoir and infusion set changes every 2-3 days. These features are essentially useful in assisting a patient with adherence while on pump therapy.

AA Utilities
These are personalized settings set by the user according to their preference of time format, brightness, backlight timeout, and remote bolus.

Guide to CGM Initialization Settings

The following pages summarize the steps to determine initial CGM settings. Recommended settings and additional clinical considerations are provided to help individual therapy for each patient. Initial settings can be documented on the form provided (mmol/L) and given to the patients for their records. (The form is also separately available for mg/dL.)

Low Settings

These settings are intended to provide warning for the patient when the sensor glucose values are approaching or have reached the preset low limit. By using the SmartGuard™ suspend by sensor features, insulin can be automatically suspended and resumed based on the low limit. Initial settings are intended to balance safety while minimizing unnecessary alerts. Settings are individualized in all cases.

1 Determine Time Segments

- Up to 8 time segments can be set for 24 hour period
- Different low settings can be selected for each time segment

Considerations

- Start with two segments: day and night
- Consider segments for regularly occurring activity

2 Determine Low Limit for each time segment

- Can be set from 2.8 to 5 mmol/L in increments of 0.2

Considerations

- Start at 3.2 – 4.0 mmol/L
- Increase for history of hypoglycemia or hypoglycemia unawareness
- Decrease in pregnancy when tighter control is desired

3 Determine SmartGuard Suspend by Sensor option

Option 1: Suspend before Low*	Option 2: Suspend on Low	No suspend by sensor
Stops insulin delivery when sensor glucose is predicted to be approaching the low limit in 30 minutes	Stops insulin delivery when sensor glucose reaches or falls below the low limit	Alert only options used

When Suspend by sensor options are used, insulin delivery will automatically resume when SG is above the low limit and trending upward.**

Considerations

- Use *Suspend before low* during the day and night to minimize patient burden and best prevent hypoglycemia
- May prefer *Suspend on low* during the day when patient is frequently interacting with their pump

4 Options for Alerts

	Using Suspend before Low	Using Suspend on Low	Using no suspend
Alert before low	Alerts when insulin suspends	Alerts when SG is predicted to reach low limit within 30 minutes	Alerts when SG is predicted to reach low limit within 30 minutes
Alert on low	On	On	Alerts when SG reaches or falls below low limit
Resume basal alert	Alerts when basal insulin resumes based on SG	Alerts when basal insulin resumes based on SG	N/A

Considerations

- Keep optional alerts off to minimize patient burden
- Use Alert before low during the day to prompt patient involvement

Snooze

- Time before alert repeats after cleared if condition still exists
- One setting applies to all low alerts
- Allows time for patient to treat hypoglycemia and glucose to rise
- Can be set from 5 min to 1 hour

Considerations

- Default of 20 minutes generally appropriate

* Insulin delivery is suspended when sensor glucose is at or within 3.9 mmol/L (70 mg/dL) above the low limit and predicted to be at or within 1.1 mmol/L (20 mg/dL) above the low limit in 30 minutes.

** Insulin delivery resumes when sensor glucose is at least 1.1 mmol/L (20 mg/dL) above the low limit and predicted to be more than 2.2 mmol/L (40 mg/dL) above in 30 minutes.

High Settings

High alerts are intended to detect actual or impending hyperglycemia so the patient can respond and prevent or reduce the high excursion. Initial settings are intended to balance safety while minimizing unnecessary alerts. Settings are individualized cases.

It is recommended that High Settings be Off at CGM initiation to minimize the number of alerts patient receives. Once patient is comfortable using CGM and initial insulin adjustments have been made to improve control, high alerts are added. This generally occurs 1 to 4 weeks after initiation.

1 Determine Time Segments

- Up to 8 time segments can be set for 24 hour day
- Different high settings can be selected for each time segment

Considerations

- Use one time segment for entire 24 hour period

2 Determine High Limit for each time segment

- Can be set from 5.6 to 22.2 mmol/L in increments of 0.2

Considerations

- Start at 13.8 mmol/L once high alerts are turned on
- Alternatively may use CareLink data to determine initial setting
- Decrease the limit as glucose control improves and hyperglycemia decreases
- If patient reports too many alerts, increase the limit coupled with therapy adjustments

3 Options for Alerts

Alert before high	Alert on high	Rate Alert
• Alerts when high glucose is predicted to occur • Used to prevent or reduce the severity of high glucose excursion • Time can be set from 5 to 30 minutes in 5 min increments	• Alerts when SG reaches the high limit	• Alerts when SG has risen at a specified rate of change • Can be used as indicator for missed boluses • Rise Limit can be set to alert - when 1, 2 or 3 trend arrows display on the pump screen - at rate you set from 0.050 to 0.275 mmol/L/min
Considerations		
• Leave Off to decrease the burden of frequent alerts with limited perceived value • Using with Alert on high will likely result in excessive alerts • Set at 15 minutes if On	• Off at initiation • Turn On after initial insulin adjustments have been made to improve control • Adjust high limit as needed	• Leave Off to decrease the burden of frequent alerts with limited perceived value • Set at 0.220 to alert patients only of very rapid changes that may occur • If patient reports too many alerts, increase limit or turn alert Off

Snooze

- Time before alert repeats after cleared if condition still exists
- Allows time for insulin to take effect and high glucose to decrease
- One setting applies to all high alerts
- Can be set from 5 min to 3 hours

Considerations

- Set at 2 hours

Continuous Glucose Monitoring Initiation Settings

PRESCRIBER'S INSTRUCTIONS TO PATIENT

Patient Name:_____ DOB: _____ Date: _____

Low Settings:

TIME SEGMENTS	LOW LIMIT	CHOOSE SMARTGUARD™ OPTION AND ALERTS
00:00 - _____	2.8-5 mmol/L (increments of 0.2) _____ mmol/L	☐ Suspend before low Alert before low ☐ Resume basal alert ☐ OR ☐ Suspend on low Alert before low ☐ Resume basal alert ☐ OR ☐ No suspend by sensor Alert before low ☐ Alert on low ☐
_____ – _____	_____ mmol/L	☐ Suspend before low Alert before low ☐ Resume basal alert ☐ OR ☐ Suspend on low Alert before low ☐ Resume basal alert ☐ OR ☐ No suspend by sensor Alert before low ☐ Alert on low ☐
_____ – _____	_____ mmol/L	☐ Suspend before low Alert before low ☐ Resume basal alert ☐ OR ☐ Suspend on low Alert before low ☐ Resume basal alert ☐ OR ☐ No suspend by sensor Alert before low ☐ Alert on low ☐

Low Snooze: _____ minutes (5 min to 1 hour; Default setting is 20 minutes)

High Settings:

☐ **High Alerts Off at initiation. Settings below begin** _____ **(date)**

TIME SEGMENTS	HIGH LIMIT	CHOOSE HIGH ALERTS
00:00 - _____	5.6-22.2 mmol/L (increments of 0.2) _____ mmol/L OR ☐ High Alerts Off	Alert before high ☐ Time: _____ minutes (5-30min) Alert on high ☐ Rise Alert ☐ Rise Limit: ☐1 ☐2 ☐3 arrows OR ☐Custom __ mmol/L (0.050-0.275 mmol/L/min)
_____ – _____	_____ mmol/L OR ☐ High Alerts Off	Alert before high ☐ Time: _____ minutes (5-30min) Alert on high ☐ Rise Alert ☐ Rise Limit: ☐1 ☐2 ☐3 arrows OR ☐Custom __ mmol/L (0.050-0.275 mmol/L/min)
_____ – _____	_____ mmol/L OR ☐ High Alerts Off	Alert before high ☐ Time: _____ minutes (5-30min) Alert on high ☐ Rise Alert ☐ Rise Limit: ☐1 ☐2 ☐3 arrows OR ☐Custom __ mmol/L (0.050-0.275 mmol/L/min)

High Snooze: _____ minutes (5 min to 3 hours; Default setting is 1 hour)

☐ Yes, patient may adjust settings as necessary after initial use.

☐ No, it is preferred that the patient not adjust settings without consulting prescriber.

Notes (optional): _____

_____

_____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

References

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Suggested Readings

Suggested Reading

American Association of Clinical Endocrinologists Consensus Panel. AACE Consensus Statement on Continuous Glucose Monitoring. *Endocrine Practice*. 2010;(16)5:732-745.

American Diabetes Association Position Statement on Standards of Medical Care in Diabetes 2015. *Diabetes Care*. 2015;38(Suppl. 1):S33-S40.

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Notes

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