DIABETES MANAGEMENT FOR CONTINUOUS GLUCOSE MONITORING:

HEALTHCARE PROFESSIONAL GUIDE

Guardian™ Connect System & CareLink™ Reports
Includes: Interpretation, Alert Guidelines & Trend Management
Patients using the Guardian Connect Continuous Glucose Monitoring System must be an existing iPhone™ user and be familiar with a smartphone device.
# TABLE OF CONTENTS

**DIABETES MANAGEMENT WITH THE GUARDIAN CONNECT™ SYSTEM**  
CONTINUOUS GLUCOSE MONITORING & CARELINK™ REPORT INTERPRETATION

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Authors</td>
<td>1</td>
</tr>
<tr>
<td>Fundamental Concepts</td>
<td>2</td>
</tr>
<tr>
<td>Guardian Connect System</td>
<td>4</td>
</tr>
<tr>
<td>Clinical Evidence</td>
<td>5</td>
</tr>
<tr>
<td>Initiating CGM with Guardian Connect - Low Settings</td>
<td>6</td>
</tr>
<tr>
<td>Initiating CGM with Guardian Connect - High Settings</td>
<td>8</td>
</tr>
<tr>
<td>Graphs and Display</td>
<td>10</td>
</tr>
<tr>
<td>Using On-Screen Data to Make Therapy Adjustments</td>
<td>11</td>
</tr>
<tr>
<td>Therapy Adjustments Based on CareLink™ Pro Reports</td>
<td>13</td>
</tr>
<tr>
<td>Patient Behaviour – Analysing Therapy Management Data</td>
<td>15</td>
</tr>
<tr>
<td>Therapy Outcome – Identification of Challenges</td>
<td>16</td>
</tr>
<tr>
<td>Therapy Outcome – What are the causes?</td>
<td>19</td>
</tr>
<tr>
<td>Therapy Optimisation – Determination of changes to therapy</td>
<td>20</td>
</tr>
<tr>
<td>Guide to CGM Initialisation Settings</td>
<td>21</td>
</tr>
<tr>
<td>Continuous Glucose Monitoring Initiation Settings Form</td>
<td>24</td>
</tr>
<tr>
<td>References</td>
<td>25</td>
</tr>
<tr>
<td>Suggested Reading</td>
<td>26</td>
</tr>
</tbody>
</table>
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This document does not contain all of the information necessary for the proper care and treatment of patients with diabetes. As such, no individual may rely on the information presented herein in forming a comprehensive treatment program or in treating any patient with diabetes. No warranties are made, expressed or implied, with regard to the contents of this work or to its applicability to specific patients or circumstances. Neither the author, sponsor, nor the publisher shall be liable for direct, indirect, special, incidental or consequential damages arising out of the use or inability to use the contents of this guide.

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Richard M. Bergenstal, MD; Bruce A. Buckingham, MD; Satish Garg, MD; Stuart A. Weinzimer, MD; Ronald Brazg, MD; Jacob Ilany, MD; Bruce Bode, MD, FACE; Timothy Bailey, MD, FACE; Stacey M. Anderson, MD; Robert Stover, MD.
This guide is for healthcare professionals and will cover the continuous glucose monitoring initiation and adjustment process for those patients using the Guardian Connect System.

Continuous glucose monitoring (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 as nocturnal hypoglycaemia or post prandial hyperglycaemia that occurs between BG readings. This provides the opportunity to see how food, insulin, exercise and other things throughout the day affect a patient’s glucose levels.

With the Guardian Connect system, CGM data is updated approximately every 5 minutes and displayed on the mobile device 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. The patient can enter events (e.g. insulin injection, meals, exercise) into the app. The event markers are visible on the Home screen to see and review the effect of activities, insulin or food intake.

In addition to the visual information that CGM provides, the Guardian Connect App can be set to alert when glucose rises too high or falls too low.
FUNDAMENTAL CONCEPTS

The CGM data will be automatically uploaded from the Guardian Connect App into Carelink™ Personal Therapy Management Software to allow your patient to identify glycaemic trends and patterns. If the CareLink Personal account is linked to your CareLink Pro Software you will also have on-demand access to the retrospective CGM data including the events the patient has entered into the app. This allows you to 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 Guardian Connect System provides features that continue to make advancements to meet this goal.

The following principles guide current CGM practice:

1. **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 the 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 emphasises 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 Guardian Connect App.
   - The Guardian Connect App displays the sensor glucose values and trends, or, the speed and direction in which glucose values are moving. It has various alerts features that can be individualised for each patient and are discussed later in this guide. All settings and CGM data are stored in the Guardian Connect App.
   - CareLink Personal and Pro software allows the information from the Guardian Connect App to be downloaded and displayed on reports. These reports will help the healthcare professional and patient make appropriate adjustments to the insulin therapy and CGM settings in order to improve glucose control. It is important to link the CareLink Personal account of the patient with your CareLink Pro software. This will allow you to generate reports and get important insights about the diabetes management prior to the patient coming to your office.
   - In addition to that, the patient can invite up to 5 Care Partner to keep them up-to-date. A Care Partner— for example parents – can see than the sensor glucose values via Web-app on any internet-enabled device by using CareLink Personal. In addition to that they can elect to receive SMS messages for patients’ alerts. This enables a Care Partner to be directly involved in the diabetes management of the patient. For this reason it is very important that a Care Partner is properly trained and is aware on how to manage glucose alerts.

3. **CGM devices are indicated for use as adjunctive to SMBG**
   - 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**
   - Encourage patients to adopt full-time use of CGM.
   - Minimising 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.
TAKE THE GUESSWORK OUT OF MANAGING DIABETES
Guardian™ Connect continuous glucose monitoring system

Check real-time glucose levels and get glucose alerts

Person with Diabetes Using Insulin Injection Therapy
Sensor + Transmitter
Bluetooth
Smartphone

Monitor remotely and receive SMS alerts
Care Partners
Online

Access diabetes data via automatic daily updates
Healthcare Provider
Online

For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use.
Continuous Glucose Monitoring (CGM) enables better diabetes management compared to self-monitoring Blood Glucose (SMBG)

Current Situation
Type 1 diabetes (T1D) is increasing worldwide.4
- 2 in 3 adults cannot achieve optimal A1c levels5
- 1 in 4 children have A1c levels ≥ 9.5 and 14 % of children show early signs of increased risk of blindness5,6
There is an urgent need to improve self-management, glycaemic control & reduce complication rates and costs.7,8

The Problem
SMBGs are frequently done less often than recommended9, because of various individual reasons, i.e. pain, lifestyle interference, information deficits, motivational, and behavioural barriers.10,11
Up to 75% of hyper- and hypoglycaemic episodes can therefore go undetected.12
Regularly missed or under-dosed injections are associated with increased HbA1c values, hospital admission rate, and increased annual direct medical costs.13-16

CGM for Better Diabetes Management
Real Time CGM can improve glycaemic control17,18, reduce fear of hypoglycaemia, and improve quality of life.19,20
Guardian Connect empowers the patients to take action when needed
- The option to view real-time glucose values on their phone discretely
- The option to receive alerts for hyper- and hypoglycaemia for patients and caregivers
- The option to record insulin, carbohydrates, exercise and medication
Optional automated data upload will enable the patient’s care team to analyse the reports and develop a personal action plan in collaboration with the patient.
The low settings are intended 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 individualised to best meet the needs of each patient.

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

**Step 1: Time Segment**

**Step 2: Low Limit**

**Step 3: Alert Options**

The following further discusses each step.

**Step 1: Time Segment**

Two time segments allow you to have different settings for day and night. For example, you might want different glucose or alert settings for daytime versus night-time. Once the time segments are determined the low limit and the alerts are then set for this time segment.

**Step 2: Low Limit**

The low limit is the glucose value that you want the patient to spend time minimally or no time below this limit. A low limit of 3.8 – 4.4 mmol/L (70 – 80 mg/dL) will be a good starting point for most patients during the day. You will want to consider increasing the low limit during night time hours for those with severe hypoglycaemia or hypoglycaemia unawareness. Other conditions that might require more aggressive control (e.g. pregnancy) may require a decrease in the low limit.

**Step 3: Low Alert Options**

When selecting alerts, keep in mind that most patients only want to be alerted when they need to take action.

**Alert on Low**

The Guardian Connect System triggers an “Alert on Low,” when the sensor glucose value reaches or falls below the low limit.

The “Alert on Low” setting can be compared to a red traffic light and your patient has to take immediate action.

How you react to “Alert on Low” depends on the settings. The way and the time your patient has to react is different. Example: If the Low Limit is set at 2.8 mmol/L (or 50 mg/dL) the reaction of your patient needs to be different instead of an alert when the Low Limit is set at 5.0 mmol/L (or 90 mg/dL).
Alert before Low

The Guardian Connect System triggers an “Alert before Low” before the Low Limit is reached. This gives your patient the opportunity to Act in advance instead of React when the low is occurring. You can compare this option to a yellow (amber) traffic light warning your patient that the light will turn red soon – or in terms of the Guardian Connect System – the low limit will be reached.

If your patient should use the “Alert before Low” you have to determine a setting for “Time before Low.” It is recommended to keep the Alert before low turned Off at initiation of these settings in order to avoid alarm fatigue. If you would like to use it for a specific situation – for example for patients with hypoglycaemia unawareness – the recommended Time Before Low is 20 minutes. That means your patient will get an “Alert before Low” 20 minutes before the Low Limit is reached.

Fall Alert

Guardian Connect triggers a Fall Alert if the Sensor Glucose is falling equal to or faster than a specified rate independently from the actual Sensor Glucose value. This allows your patient to understand how the glucose level is affected, for example – by exercise or insulin. If your patient reacts correctly, this can help to minimise the risk of a hypoglycaemia or low glucose values. The Fall Alert can be set based on the trend arrows that displays on the Home screen (see page 12).

It is recommended to keep the Fall Alert turned Off at initiation in order to avoid alarm fatigue. If you would like to use it for a specific situation – for example for patients with hypoglycaemia unawareness – the recommendation is to set the alert on two trend arrows.

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 carbohydrates. 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. The alert will be cleared when the condition no longer exists.

See page 23 for considerations when determining initial Low Settings.
INITIATING CGM WITH GUARDIAN CONNECT – HIGH SETTINGS

High settings are intended to alert the patient of actual or impending hyperglycaemia; giving the patient an opportunity to respond and either prevent or reduce the severity and duration of the high excursion. These settings should be individualised 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 minimise 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 Segment**

**Step 2: High Limits**

**Step 3: Alert Options**

The following further discusses each step.

**Step 1: Time Segments**

Like the low settings, two time segments allow you to have different settings for the day and the night. Once the time segment is determined, the high limit and alerts are then set for this 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 a high limit of 13.8 mmol/L (250 mg/dL) to start and can be decreased as glucose control improves and hyperglycaemia is reduced. CareLink is also a useful tool for determining appropriate limits individualised for a particular patient to help prevent excessive alerts. Looking at the CareLink report below and considering the amount of hyperglycaemia 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 hyperglycaemia that is occurring.

![CareLink™ Pro Report Sensor & Meter Overview](image)
Step 3: High Alert Options

Once the time segment and high limit is 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**

The Guardian Connect System triggers an "Alert on High", when the Sensor Glucose value reaches or exceeds the high limit.

You can compare the "Alert on High" with a red traffic light and your patient has to take appropriate action.

How you react to "Alert on High" depends on the HIGH settings. The way and the time the patient has to react is different. Example: If the High Limit is 10.0 mmol/L (180 mg/dL) instead of 13.8 mmol/L (250 mg/dL).

**Alert before High**

The Guardian Connect System triggers an "Alert on High" before the High Limit is reached.

This gives your patient the opportunity to act instead of react. As mentioned with the Alert before Low, you can compare this option with a yellow (amber) traffic light warning your patient that the light is about to turn red – or in terms of the Guardian Connect System – the high limit will be reached.

If your patient should use the "Alert before High", you also have to decide on the "Time before High."

It is recommended to keep the Alert before High turned Off at initiation in order to avoid alarm fatigue. If you would like to use it for a specific situation – for example for patients who are pregnant – the recommended Time before High is 15 minutes. That means your patient will get an "Alert before High" 15 minutes before the High Limit is reached.

**Rise Alert**

Guardian Connect triggers a Rise Alert if the Sensor Glucose is rising equal to or faster than a specified rate independently from the actual Sensor Glucose value. This allows your patient to understand how the glucose level is affected, for example – after a meal. If your patient reacts correctly, this can help to minimise the risk of a hyperglycaemia or high glucose values. The Rise Alert can be set based on the trend arrows that display on the Home screen (see page 12).

It is recommended to keep the Rise Alert turned Off at initiation in order to avoid alarm fatigue. If you would like to use it for a specific situation – for example for patients who are pregnant or for those patients who often miss boluses – the recommendation is to set the alert on two or three trend arrows.

**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 24 for considerations when determining initial High Settings.
Here is an example of the CGM information that is displayed on the mobile device:

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

<table>
<thead>
<tr>
<th>Arrow Pattern</th>
<th>SG Change Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>↑ ↓</td>
<td>SG has been rising or falling by about 1-2 mmol/L (20-40 mg/dL) over the last 20 minutes</td>
</tr>
<tr>
<td>↑↑ ↓↓</td>
<td>SG has been rising or falling by about 2-3 mmol/L (40-60 mg/dL) over the last 20 minutes</td>
</tr>
<tr>
<td>↑↑↑ ↓↓↓</td>
<td>SG has been rising or falling greater than 3 mmol/L (60 mg/dL) over the last 20 minutes</td>
</tr>
</tbody>
</table>
The protocol for the Juvenile Diabetes Research Foundation (JDRF) CGM study provided recommendations for insulin dose adjustments based on trend arrows. 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 fingerstick BG values to determine the bolus insulin, and then can be instructed to consider making dose adjustments 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 app screen.
- Consider taking more glucose if down arrows are present.

### FOR EXAMPLE, if a patient is normally using 15 grams:

<table>
<thead>
<tr>
<th>TREND ARROWS</th>
<th>BG</th>
<th>GLUCOSE TABLETS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Low</td>
<td>20 Grams</td>
</tr>
<tr>
<td></td>
<td>Low</td>
<td>25 Grams</td>
</tr>
<tr>
<td></td>
<td>Low</td>
<td>30 Grams</td>
</tr>
</tbody>
</table>

**If fingerstick BG is low before food intake:**
- Do not bolus while glucose is low.
- Treat the hypoglycaemia.
- After treating the hypoglycaemia and the glucose is within target, calculate the bolus to cover the meal, check for trend arrows on the app screen, and adjust based on the arrows using the guidelines in the table below.

### BOLUS ADJUSTMENT GUIDELINES USING TREND ARROWS

<table>
<thead>
<tr>
<th>TREND ARROWS</th>
<th>No change in dose</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Decrease dose by 10%</td>
</tr>
<tr>
<td>OR</td>
<td>Decrease dose by 20%</td>
</tr>
</tbody>
</table>
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 app 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**

<table>
<thead>
<tr>
<th>Arrows</th>
<th>Dosage Adjustment</th>
</tr>
</thead>
<tbody>
<tr>
<td>No arrows</td>
<td>No change in dose</td>
</tr>
<tr>
<td>↑</td>
<td>Increase dose by 10%</td>
</tr>
<tr>
<td>↑↑ OR ↑↑↑</td>
<td>Increase dose by 20%</td>
</tr>
</tbody>
</table>

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 or small amounts of glucose as appropriate.

**IMPORTANT** As always, individual patient history should be considered with all recommended dosage adjustments.
CareLink Pro generates easy-to-read reports that allow a healthcare professional to quickly assess control and fine-tune therapy. Guardian Connect data will be uploaded automatically to CareLink Personal. If the patient’s CareLink Personal account is linked with your Pro account, you will have on-demand access to your patient’s CGM data. CareLink combines continuous glucose monitoring, blood glucose meter data and the events the patient has entered into the app in one convenient place. Furthermore, CareLink reports can be a powerful tool to educate and motivate patients by emphasising positive behavior and pointing out opportunities to improve.

**Methodology for Interpretation**

While there is no single preferred approach to CareLink interpretation, here is the most commonly suggested methodology which was developed by the European CareLink Advisory Board which consists of 5 experienced HCPs who integrated CareLink in their daily practice.

This 4 Step methodology describing how you could use CareLink to optimise your patient’s diabetes therapy:

1. **PREPARATION & CARELINK™ SETTINGS**
   - Define CareLink settings
     - Glucose Target Range (threshold for low and high glucose values – not the same as therapy target)
     - Meal Times (to get information around meals)
   - Select the two most recent weeks (a patient won’t remember more than two weeks)

2. **PATIENT BEHAVIOUR**
   - Positives & Issues
     - Encourage the good (or positive) behavior
     - Prevent focusing too much on therapy outcomes
     - Determine data quality and behavior Issues
       - E.g. “Does the patient eat without giving a bolus?”

3. **THERAPY OUTCOME**
   - Identify Issues & Determine the Cause
     - Identify the therapy related issues
     - Determine a cause for each of these issues
       - What happened – what could be the reason?

4. **OPTIMISE THERAPY**
   - Define Action Plan
     - Discuss the identified issues with the patient and define together an action.
     - Document all the identified issues and agree with the patient on a treatment strategy.
     - Make sure to also discuss how to follow-up.

**NOTE** CareLink only shows data from the device. Speak with your patient what happened at that time (stress, special situations, etc.)
Root Cause Analysis – Important steps when looking for Therapy results

Focus first on hypoglycaemia and low glucose values – followed by checking the data for high glucose values and hyperglycaemia.

<table>
<thead>
<tr>
<th>HYPOGLYCAEMIA</th>
<th>HYPERGLYCAEMIA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Night-time hypoglycaemia</td>
<td>Night-time hyperglycaemia</td>
</tr>
<tr>
<td>Hypoglycaemia before meals</td>
<td>Hyperglycaemia before meals</td>
</tr>
<tr>
<td>Hypoglycaemia after meals</td>
<td>Hyperglycaemia after meals</td>
</tr>
</tbody>
</table>

Step 1: First take a look at the nights and then the periods before and after meal
Step 2: Find the reason of hypo- and hyperglycaemic events by using the event marker in the CareLink reports (e.g. Insulin, Carbohydrates and Exercise)
Step 3: What happened? What potential reason needs to be taken into consideration?
PATIENT BEHAVIOUR – ANALYSING THERAPY MANAGEMENT DATA

Adherence Report* and Sensor & Meter Overview (Statistics section)

Use these reports to analyse patient behaviors – for example BG readings per day, sensor usage and bolus frequency.

The information about insulin delivery is based on user entry into the Guardian Connect app. Therefore please ensure that patient has recorded all insulin injections.

**IMPORTANT**

- Remind the patient to check BG 3 – 4 times/day for optimal sensor performance and CGM use.
- Coach patient to bolus with all meals and/or snacks (except for carb intake to treat a hypoglycaemia.
- Encourage continuous CGM use.

* This picture shows only the part of the Adherence Report which is important when using Guardian Connect. All other columns contain only information when you are downloading a Medtronic insulin pump.
THERAPY OUTCOME – IDENTIFICATION OF CHALLENGES

Sensor & Meter Overview (Graph data)

Use this report to identify challenges – for example occurrence of hypoglycaemia or hyperglycaemia and to identify patterns.

IMPORTANT The darker the area, the more time your patient spent below and above the individual target range.

Hyperglycaemic events

Hypoglycaemic events

Notes
Average SG values before (pre-meal) and after (post-meal) a bolus.
Average how many carbohydrates are eat per meal.

<table>
<thead>
<tr>
<th>Bedtime to Wake-up</th>
<th>Breakfast: 6:00 AM - 10:00 AM</th>
<th>Lunch: 11:00 AM - 3:00 PM</th>
<th>Dinner: 4:00 PM - 8:00 PM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bedtime: 8:00 PM - 12:00 AM</td>
<td>Meals Analyzed: 12</td>
<td>Meals Analyzed: 12</td>
<td>Meals Analyzed: 22</td>
</tr>
<tr>
<td>Wake-up: 5:00 AM - 7:00 AM</td>
<td>Avg Carbs: 34g</td>
<td>Avg Carbs: 61g</td>
<td>Avg Carbs: 57g</td>
</tr>
<tr>
<td></td>
<td>Avg Insulin: -</td>
<td>Avg Insulin: -</td>
<td>Avg Insulin: -</td>
</tr>
<tr>
<td></td>
<td>Avg Carbs/Insulin: -</td>
<td>Avg Carbs/Insulin: -</td>
<td>Avg Carbs/Insulin: -</td>
</tr>
</tbody>
</table>

Sensor & Meter Overview (Graph data) – cont.

Overnight and meal buckets to see patterns surrounding bedtime, wake up, and meal times
To got this overview your patient has to enter MEAL EVENTS into the App

Notes

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This report shows you all daily details for several days in a row.

Review consistency of SG readings and of trends in this report. Are they always high or are they frequently low?

Are patients giving a bolus well after a BG has been taken or food has been eaten?

Take a look at the times a bolus was given. Is a meal/snack and BG paired with the bolus each time?

Notes

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THERAPY OUTCOME – WHAT ARE THE CAUSES?

Daily Details

- Use the Daily Details report to focus on specific days.
- Take a closer look at the glucose levels and review the Diabetes Management like Bolus and Basal insulin injection, meals and physical activity.

Notes

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**THERAPY OPTIMISATION – DETERMINATION OF CHANGES TO THERAPY**

**Reach the Target**
- Document the challenges
- Adjustment of device settings and/or therapy?
- Discuss adjustment and concrete implementation with the patient.
- No more than two or three therapy changes at the same time.
- Check whether the change brought the desired effect.

**Device Settings Snapshot Report**

<table>
<thead>
<tr>
<th>Sensor</th>
<th>On</th>
</tr>
</thead>
</table>

**High Alerts**

<table>
<thead>
<tr>
<th>Start Time</th>
<th>High (mmol/L)</th>
<th>Alert On</th>
<th>Alert Before</th>
<th>Rise Alert Limit (mmol/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0:00</td>
<td>On</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Low Alerts**

<table>
<thead>
<tr>
<th>Start Time</th>
<th>Low (mmol/L)</th>
<th>Alert On</th>
<th>Alert Before</th>
</tr>
</thead>
<tbody>
<tr>
<td>0:00</td>
<td>On</td>
<td></td>
<td>x</td>
</tr>
</tbody>
</table>

- **High & Low Alert Settings**
- **Calibration Reminder Settings**
- **Print the report and make notes for the patient**

*This picture shows only the part of the Device Setting Snapshot report which is important when using Guardian Connect. All other columns contain only information when you are downloading a Medtronic insulin pump.*
The following pages summarise 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 and given to the patients for their records.
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 and given to the patients for their records.

### STEP 1: TIME SEGMENTS

<table>
<thead>
<tr>
<th>Time Segments</th>
<th>Different low settings can be selected for each time segment</th>
</tr>
</thead>
</table>

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

### STEP 2: LOW LIMIT

<table>
<thead>
<tr>
<th>Low Limit</th>
<th>Can be set from 2.8 to 5 mmol/L (50 to 90 mg/dL) in increments of 0.2 mmol/L (5mg/dL)</th>
</tr>
</thead>
</table>

**CONSIDERATIONS**
- Start at 3.8-4.4 mmol/L (70-80 mg/dL)
- Increase for history of hypoglycaemia or hypoglycaemia unawareness
- Decrease in pregnancy when tighter control is desired

### STEP 3: LOW ALERT OPTIONS

<table>
<thead>
<tr>
<th>Alert Options</th>
<th>Alert before Low</th>
<th>Alert on Low</th>
<th>Rate Alert</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Alerts when SG values are approaching Low Limit.</td>
<td>Alerts when SG reaches the low limit</td>
<td>Alerts when SG has fallen at a specified rate of change</td>
</tr>
<tr>
<td></td>
<td>Time before Low must also be set.</td>
<td></td>
<td>Can be used as indicator for missed boluses</td>
</tr>
<tr>
<td></td>
<td>Time can be set from 5 to 30 minutes in 5 min increments</td>
<td></td>
<td>Fall Limit can be set to alert</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>↓: 1-2 mmol/L/minute</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>↓↓: 2-3 mmol/L/minute</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>↓↓↓: 3 mmol/L/minute</td>
</tr>
</tbody>
</table>

**CONSIDERATIONS**
- Leave Off to decrease the burden of frequent alerts with limited perceived value
- Using with Alert on Low will likely result in excessive alerts
- Set at 20 minutes if On
- Off at initiation
- Turn On after initial insulin adjustments have been made to improve control
- Adjust low limit as needed
- Leave Off to decrease the burden of frequent alerts with limited perceived value
- Set at ↓ or ↓↓ to alert patients of very rapid changes that may occur
- If patient reports too many alerts, increase limit or turn alert Off

### SNOOZE

<table>
<thead>
<tr>
<th>Snooze</th>
<th>Time before alert repeats after cleared if condition still exists</th>
<th>One setting applies to all low alerts</th>
<th>Can be set from 5 minutes to 1 hour</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Allows time for patient to treat hypoglycaemia and glucose to rise</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**CONSIDERATIONS**
- Default of 20 minutes generally appropriate.
High alerts are intended to detect actual or impending hyperglycaemia so the patient can respond and prevent or reduce the high excursion. Initial settings are intended to balance safety while minimising unnecessary alerts. Settings need to be individualised in all cases.

It is recommended that High Settings be Off at CGM initiation to minimise the number of alerts patient receives. Once the 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.

**STEP 1: TIME SEGMENTS**

<table>
<thead>
<tr>
<th>CONSIDERATIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use one time segment for entire 24 hour period</td>
</tr>
</tbody>
</table>

**STEP 2: HIGH LIMIT**

Can be set from 5.6 to 22.2 mmol/L (100 to 400 mg/dL) in increments of 0.2 mmol/L (5mg/dL)

<table>
<thead>
<tr>
<th>CONSIDERATIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start at 13.8 mmol/L (250 mg/dL) once high alerts are turned on</td>
</tr>
<tr>
<td>Decrease the limit as glucose control improves and hyperglycaemia decreases</td>
</tr>
<tr>
<td>Alternatively may use CareLink data to determine initial setting</td>
</tr>
<tr>
<td>If patient reports too many alerts, increase the limit coupled with therapy adjustments</td>
</tr>
</tbody>
</table>

**STEP 3: HIGH ALERT OPTIONS**

<table>
<thead>
<tr>
<th>Alert before High</th>
<th>Alert on High</th>
<th>Rate Alert</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alerts when high glucose is predicted to occur</td>
<td>Alerts when SG reaches the high limit</td>
<td>Alerts when SG has risen at a specified rate of change</td>
</tr>
<tr>
<td>Used to prevent or reduce the severity of high glucose excursion</td>
<td></td>
<td>Can be used as indicator for missed boluses</td>
</tr>
<tr>
<td>Time can be set from 5 to 30 minutes in 5 min increments</td>
<td></td>
<td>Rise Limit can be set to alert</td>
</tr>
<tr>
<td></td>
<td></td>
<td>†: 1-2 mmol/L/minute</td>
</tr>
<tr>
<td></td>
<td></td>
<td>††: 2-3 mmol/L/minute</td>
</tr>
<tr>
<td></td>
<td></td>
<td>†††: 3 mmol/L/minute</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CONSIDERATIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leave Off to decrease the burden of frequent alerts with limited perceived value</td>
</tr>
<tr>
<td>Using with Alert on high will likely result in excessive alerts</td>
</tr>
<tr>
<td>Set at 15 minutes if On</td>
</tr>
<tr>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

**SNOOZE**

<table>
<thead>
<tr>
<th>CONSIDERATIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Set at 2 hours</td>
</tr>
</tbody>
</table>

Time before alert repeats after cleared if condition still exists

One setting applies to all high alerts

Can be set from 5 minutes to 3 hours
CGM INITIATION SETTINGS

Use this form to document the initial CGM settings and hand-over a copy to your patient

LOW SETTINGS

<table>
<thead>
<tr>
<th>Time Period</th>
<th>Low Limit</th>
<th>Alert before Low</th>
<th>Time before Low</th>
<th>Alert on Low</th>
<th>Fall Alert</th>
</tr>
</thead>
<tbody>
<tr>
<td>12:00 AM - ______</td>
<td>_______ mmol/L</td>
<td>□ On</td>
<td>________ min</td>
<td>□ On</td>
<td>↓</td>
</tr>
<tr>
<td>______ - ______</td>
<td>_______ mmol/L</td>
<td>□ On</td>
<td>________ min</td>
<td>□ On</td>
<td>↓</td>
</tr>
</tbody>
</table>

Low Snooze: _________ minutes (5 minutes to 1 hour; default setting is 20 minutes)

HIGH SETTINGS

<table>
<thead>
<tr>
<th>Time Period</th>
<th>High Limit</th>
<th>Alert before High</th>
<th>Time before High</th>
<th>Alert on High</th>
<th>Rise Alert</th>
</tr>
</thead>
<tbody>
<tr>
<td>12:00 AM - ______</td>
<td>_______ mmol/L</td>
<td>□ On</td>
<td>________ min</td>
<td>□ On</td>
<td>↑</td>
</tr>
<tr>
<td>OR High Alerts Off</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>______ - ______</td>
<td>_______ mmol/L</td>
<td>□ On</td>
<td>________ min</td>
<td>□ On</td>
<td>↑</td>
</tr>
<tr>
<td>OR High Alerts Off</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

High Snooze: _________ minutes (5 minutes 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: ____________________________________________ Date: ________________________________


Suggested Reading


