DIABETES MANAGEMENT
WITH GUARDIAN™ CONNECT
SYSTEM

CareLink™ Reports Includes: Interpretation, Alert Guidelines, & Trend Management

Second Edition

Medical Education
IMPORTANT SAFETY INFORMATION

The Guardian™ Connect system requires a prescription and is indicated for continuous or periodic monitoring of glucose levels in the interstitial fluid under the skin, in patients (14 to 75 years of age) with diabetes mellitus. The system is intended to complement, not replace, information obtained from standard blood glucose monitoring devices, and is not recommended for people who are unwilling or unable to perform a minimum of two meter blood glucose tests per day, or for people who are unable or unwilling to maintain contact with their healthcare professional. The system requires a functioning mobile electronic device with correct settings. If the mobile device is not set up or used correctly, you may not receive sensor glucose information or alerts. For complete details of the system and its components, including warnings, contraindications, and precautions, please consult the user guide at http://www.medtronicdiabetes.com/support/download-library/user-guides and www.medtronicdiabetes.com/importantsaftyinformation.
DIABETES MANAGEMENT FOR CONTINUOUS GLUCOSE MONITORING (CGM)
GUARDIAN™ CONNECT SYSTEM & CARELINK™ REPORTS INTERPRETATION, ALERT GUIDELINES, & TREND MANAGEMENT

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This guide is written for Personal Continuous Glucose Monitoring with the Guardian™ Connect System.

While every reasonable precaution has been taken in the preparation of this guide, the authors, sponsor and publisher assume no responsibility for errors or omissions, nor for the uses made of the materials contained herein and the decisions based on such use.

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.
This guide is for healthcare professionals (HCP) 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, HCPs 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 hypoglycemia or post prandial hyperglycemia 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.
The CGM data will be automatically uploaded from the Guardian™ Connect app into Carelink™ Personal Therapy Management Software to allow your patient to identify glycemic trends and patterns. If the Carelink™ Personal account is linked to your Carelink™ System software, you will also have on-demand access to the retrospective CGM data including the events the patient has entered into the app.

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 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 Guardian™ Connect app.
   - The Guardian™ Connect app displays the sensor glucose values and trends, along with the speed and direction to which glucose values are moving. It has various alerts features that can be individualized 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 System 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 software account of the patient with your CareLink™ System software. This will allow you to generate reports and get important insights about the diabetes management prior to the patient coming to your office.

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 at least every 12 hours. Calibrating 3-4 times a day when glucose is stable (before a meal when one or no trend arrow is present) provides optimal results.

4. **The more frequently patients use CGM, the greater improvement in glucose control**
   - Encourage patients to adopt full-time use of CGM.
   - 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.
TAKE SOME OF 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 CareLink™ Personal Therapy Management Software

Access diabetes data via automatic daily updates

Healthcare Professional Online

For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the instruction manual.
Continuous glucose monitoring (CGM) enables better diabetes management compared to self-monitoring blood glucose (SMBG)

Current Situation
Type 1 diabetes (T1D) is increasing worldwide.  
- 2 in 3 adults cannot achieve optimal A1C levels
- There is an urgent need to improve self-management, glycemic control, and reduce complication rates and costs

The Problem
SMBGs are frequently done less often than recommended, because of various individual reasons, i.e. pain, lifestyle interference, information deficits, motivational, and behavioral barriers.
Up to 75% of hyper- and hypoglycemic episodes can therefore go undetected.
Regularly missed or under-dosed injections are associated with increased A1C values, hospital admission rate, and increased annual direct medical costs.

CGM for Better Diabetes Management
Real-time CGM can improve glycemic control, reduce fear of hypoglycemia, and improve quality of life.
Guardian™ Connect System empowers the patients to take action when needed with the following options to
- View real-time glucose values on their phone discreetly
- Receive alerts for hyper- and hypoglycemia for patients and care partners
- Record insulin, carbohydrates, exercise and medication
- Receive affirmation and early detection of a missed bolus
Upload data and enable the patient’s care team to analyze the reports and to jointly develop an action plan.

*The system is intended to complement, not replace, information obtained from standard blood glucose monitoring devices. All therapy adjustments should be based on measurements obtained from standard blood glucose monitoring devices and not on values provided by the system.
Managing Multiple Daily Injection (MDI) Patients with CGM

When utilizing CGM to supplement MDI therapy, there are a few clinical expectations to consider. Certain CGM observations should be noted and reviewed with the patient for optimal experience while wearing the Guardian™ Connect System. CGM data equaling 288 values per day will be more information ever seen by the patient and will require some coaching in order to avoid overcorrecting and administering too much insulin. Additionally, proper sensor maintenance which requires calibrations every 12 hours should be reminded to the patient.

1. Overreacting to hyperglycemia curves
   Patients will need to know that peak post-meal glucose is obtained 60-90 min following a meal. This is a time when patients do not obtain SMBG and are unaware of the phenomena. By having CGM data, Guardian™ Connect System will provide insight to the early glucose rise post meal, and a patient might wish to correct this by bolusing with insulin. Early correction boluses rarely correct the excursion but usually cause insulin stacking and hypoglycemia; therefore, the HCP should explain the phenomena and the appropriate responses:
   - Wait 90 minutes post meal before administering correction boluses.
   - Prevent extremely high post-meal peaks by decreasing meal carb content, increasing the insulin (by decreasing the insulin-to-carbohydrate ratio) and/or injecting the pre-meal bolus earlier.

2. Insulin stacking
   There is a 30-120 minute activation time for bolus injection to affect glucose levels. Thus, unless in a ketosis situation, recommend to the patient to pace correction bolus injection at least 30 minutes apart and look for precipitating factors – missed bolus, fever, stress etc.

3. Overreacting to hypoglycemia alerts and alarms
   Daily hypoglycemia events are more apparent with CGM, most of them are asymptomatic. It might alert the patient to overreact, resulting in post-hypoglycemic to hyperglycemia excursion and weight gain. Patients can therefore be reassured of the different levels of hypo effects – and the appropriate responses to hypoglycemia, see page 16. Additionally a refresher course on treatment for hypoglycemia and the need for measured response with preference to the use of glucose tablets and fluids (5-15 grams) instead of meals and candy bars should be done. Also review dosing the glucose ingested (5-15 grams) according to the glucose levels, trends and circumstances (bed time, sport activity etc.).

4. Use of event markers in the Guardian™ Connect app
   This is recommended and best used before a scheduled visit or during a period of glycemic instability. Instruct the patient to use the event markers and insulin dose markers for 14 days before consultations.

5. Timing and frequency of calibrations
   The Guardian™ Connect System should be calibrated at least every 12 hours (after two initial start-up calibrations). The system may occasionally request additional calibrations to ensure accurate glucose data over the entire life of each sensor. Suggest a regular calibration alert schedule that will work for the patient and most importantly, recommend calibrating before bedtime to avoid calibration alerts at night. Other suggestions for longer sensor wear are:
   - Insert a new sensor early in the day to avoid calibration reminder alerts in the middle of the night or while sleeping.
   - The patient should ensure they have securely connected the transmitter to the sensor and taped the sensor to their body to help avoid additional requests for calibration.

Patients using the Guardian™ Connect continuous glucose monitoring system must use a compatible mobile device with the correct settings (supported operating system and Bluetooth® wireless technology enabled) and be familiar with a smartphone device.
INITIATING CGM WITH GUARDIAN™ CONNECT SYSTEM – LOW SETTINGS

LOW SETTINGS
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 individualized 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 nighttime. 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 70 mg/dL will be a good starting point for most patients during the day. Other conditions that might require more conservative control (e.g. hypoglycemia unawareness) may require a increase 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. When Alert on Low is triggered, advise your patient to react in order to avoid reaching below this limit.

**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 hypoglycemia 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 System 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 minimize the risk of a hypoglycemia or low glucose values. The Fall Alert can be set based on the trend arrows that displays on the Home screen (see page 11).

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

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 pages 19 and 20 for considerations when determining initial Low Settings.

ALERT VOLUME CONTROL

- **Alert Volume** feature lets patients increase or decrease alert volumes, independent of phone’s volume settings. The ability to control volume of alerts give patients the power to determine which need audible alerts and which can be muted in different circumstances.

- **Max Volume at Night** feature will allow set low and high alerts to play at phone’s max volume, so alerts are less likely to be missed while sleeping. In the circumstance the patient doesn’t want any audible alerts such as during meetings or tests for students.

- **Mute All Alerts** feature lets user turn off alerts for up to four hours. Normal alert settings automatically return when the chosen time expires.

An Urgent Low glucose alert will sound when the sensor glucose value reaches or falls below 55 mg/dL even if the Mute All Alerts is turned on. However, notifications for the app must be on. Urgent Low cannot be adjusted and will always be an audible alert.
INITIATING CGM WITH GUARDIAN™ CONNECT SYSTEM – HIGH SETTINGS

High settings are intended to alert the patient of actual or impending hyperglycemia 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 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.

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 a glucose target. We recommend a high limit of 250 mg/dL to start and can be decreased as glucose control improves and hyperglycemia is reduced. Carelink™ software 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 250 mg/dL may be more appropriate until therapy adjustments are made to reduce the amount of hyperglycemia that is occurring.

_Carelink™ System Assessment & Progress Report_
Step 3: High Alert Options

Once the time segment and high limit 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**
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 180 mg/dL instead of 250 mg/dL, plus consideration is given to the time relationship to meals.

**Alert before High**
The Guardian™ Connect System triggers an **Alert Before 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 System 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 minimize the risk of a hyperglycemia or high glucose values. The **Rise Alert** can be set based on the trend arrows that display on the Home screen (see page 11).

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. It will allow an early response for a missed bolus.

**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 pages 21 and 22 for considerations when determining initial High Settings.

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1 The system is intended to complement, not replace, information obtained from standard blood glucose monitoring devices. All therapy adjustments should be based on measurements obtained from standard blood glucose monitoring devices and not on values provided by the system.
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>Rate of Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>↑↓</td>
<td>One arrow signals a 1 to less than 2 mg/dL per min change in glucose</td>
</tr>
<tr>
<td>↑↑↓↓</td>
<td>Two arrows signal a 2 to less than 3 mg/dL per minute change in glucose</td>
</tr>
<tr>
<td>↑↑↑↓↓</td>
<td>Three arrows signal a 3 or greater mg/dL per min change in glucose</td>
</tr>
</tbody>
</table>
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. 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 arrow 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.
- 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</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 hypoglycemia.
- After treating the hypoglycemia 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.
- Discuss with your HCP other options for correction bolus.

**BOLUS ADJUSTMENT GUIDELINES USING TREND ARROWS**

<table>
<thead>
<tr>
<th>TREND ARROWS</th>
<th>ADJUSTMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>no arrows</td>
<td>No change in dose</td>
</tr>
<tr>
<td>↓</td>
<td>Decrease dose by 10%</td>
</tr>
<tr>
<td>↓↓</td>
<td>Decrease dose by 20%</td>
</tr>
<tr>
<td>↓↓↓ OR ↓↓↓</td>
<td>Discuss with your HCP other options for correction bolus</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>Instruction</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™ System software generates reports that allow a HCP to quickly assess control and fine-tune therapy. Guardian™ Connect data will be uploaded automatically to the CareLink™ Personal website from the app. If the patient’s CareLink™ Personal account is linked with your CareLink™ System account, you will have on-demand access to your patient’s CGM data. CareLink™ software combines continuous glucose monitoring, blood glucose meter data and the events the patient has entered into the app in one place. CareLink™ reports can be a powerful tool to educate and motivate patients by emphasizing positive behavior and identifying opportunities for improvement.

### Methodology for Interpretation

While there is no single preferred approach to CareLink™ report interpretation, here is a standard, systematic method to reviewing the reports. Choosing the correct settings in the CL report will impact the information in the report and will impact your interpretation of the report.

<table>
<thead>
<tr>
<th>A. ASSESS OVERALL GLUCOSE CONTROL</th>
<th>B. BEHAVIOR Positives &amp; Issues</th>
</tr>
</thead>
<tbody>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>A. Assess for overall control using the Assessment &amp; Progress report to evaluate:</td>
<td>B. Encourage positive behavior</td>
</tr>
<tr>
<td>• Amount of variability</td>
<td>• Identify causes for glucose patterns:</td>
</tr>
<tr>
<td>• Frequency and extent of hypo and hyperglycemia</td>
<td>• Oral medication(s) too high or incorrectly timed?</td>
</tr>
<tr>
<td>• Glucose patterns</td>
<td>• Basal insulin injection too high, too low or missed?</td>
</tr>
<tr>
<td>• Data quality frequency of BG/CGM measurements</td>
<td>• Pre-meal / Premix insulin injection too high, too low or missed?</td>
</tr>
<tr>
<td>• Timing of injection?</td>
<td>• Inconsistent activity?</td>
</tr>
<tr>
<td>• Inconsistent exercise schedule?</td>
<td>• Alcohol consumed?</td>
</tr>
<tr>
<td>• Discuss with the patient the identified behaviors or issues and define an action plan together</td>
<td>C. Confirm high and low limits on the Guardian™ Connect app are appropriate to take action†</td>
</tr>
<tr>
<td>• Document the findings, treatment strategy, and follow up plan</td>
<td></td>
</tr>
</tbody>
</table>

### Root Cause Analysis – important steps when looking for therapy results

**HYPOGLYCEMIA**
- Night-time hypoglycemia
- Hypoglycemia before meals
- Hypoglycemia after meals

**HYPERGLYCEMIA**
- Night-time hyperglycemia
- Hyperglycemia before meals
- Hyperglycemia after meals

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

**Step 1:** First take a look at the overnight period and then the periods before and after the meal

**Step 2:** Determine causes of hypoglycemic and hyperglycemic events by using the event marker in the Carelink™ reports (e.g. Insulin, Carbohydrates and Exercise)

**Step 3:** Begin a discussion with your patient to uncover issues and/or behaviors. Create an action plan of changes to make and follow up on progress.

† The system is intended to complement, not replace, information obtained from standard blood glucose monitoring devices. All therapy adjustments should be based on measurements obtained from standard blood glucose monitoring devices and not on values provided by the system.
Assessment and Progress (A&P) Report

This report provides a synopsis of overall glycemia and use of technology. You will see dates under Date Range A which represent the most recent dates of therapy. Date Range B (if selected) will contain dates prior to Date Range A used as a comparison to view the outcomes of therapy.

Note: If the A&P report indicates all therapeutic goals have been met, this may be the only report that needs to be evaluated, unless you or the patient have other concerns.

**Percentile Comparison:**
Assess overall glycemia and identify time-of-day patterns within blue shaded area. An average SG line is calculated and shown as a dotted black line in the middle. The blue shading represents 25-75% of all sensor readings. Remaining data are in 0-90% range shown within the solid blue lines. If blue area shows persistent high or low patterns, Sensor & Meter Overview reports to identify cause.

**CAUTION** Carelink™ reports show objective glucose data as well as subjective insulin and carbohydrate intake data by entering events in the Guardian™ Connect app. Please ensure patient has recorded all insulin injections and carb intake accurately before interpreting statistics. Encourage your patients to enter events in the Guardian™ Connect app.
Statistics

1. Sensor wear (per week) Goal is ≥ 85%
   - Wear Time <85%: Address reasons (i.e., tape, comfort level changing sensor, etc.) and identify solution

2. Average SG & Standard Deviation (SD)

3. Glucose Management Indicator (GMI)
   - Provides an approximate value of lab measured A1C based on average SG
   - 14 days SG data recommended when evaluating GMI

4. Coefficient of Variation (% CV)
   - Measurement of glycemic variability.
   - Better correlates with relative risk of lows
   - Stable glucose: %CV <36%
   - Unstable glucose: %CV ≥ 36%

5. Average Total Daily Insulin
   - CAUTION: Ensure accurate long acting + rapid acting insulin is entered into app before interpreting data.
   - (Total units entered for long acting + rapid acting + unspecified)

6. Average Bolus/Basal ratio
   - CAUTION: Ensure accurate rapid acting + long acting insulin is entered into app before interpreting data.
   - (Bolus is calculated on entries for rapid acting insulin. Basal is calculated on entries for long acting insulin.)
   - Goal: Bolus: 50-70% | Basal 30-50%

7. Average meals & carbs entered per day.
   - Goal: Reasonable & consistent with previous carb intake
**CARELINK™ REPORTS – ASSESSMENT AND PROGRESS (A&P) REPORT**

**Settings**

Settings of the Guardian™ Connect app can be found in two places here and on the Device Settings report.

Use the Notes section to document:
- Findings
- Setting adjustments
- Coaching
- Follow-up plan

**Meal Bolus Wizard Report**

This report is used to evaluate appropriateness of insulin dosing. Patient must log carbs and meal times for this report to generate.

**GOAL:** Pre-meal within target / Post-meal ≤ 180 mg/dL above pre-meal glucose / Boluses before eating

1. **Pre-bolus glucose:**
   - If pre-bolus glucose is rising, ensure patient is dosing pre-meal insulin 5–15 minutes before eating

2. **2-Hour Post-bolus glucose**
   - If variable, assess carb counting skills and / or inconsistent bolusing
   - If high (> 180 mg/dL post meal),
     - Oral medication(s) missed, too low, or incorrectly timed?
     - Pre-dinner insulin incorrectly timed, too low, or missed?
     - Insulin to carb ratio not optimal for pre-dinner insulin?
     - High calorie or high carbohydrate foods?
   - If low, evaluate:
     - Oral medication(s) too high or incorrectly timed?
     - Pre-meal insulin incorrectly timed or too high?
     - Meal delayed?
     - Exercise before meal?
     - Delayed digestion (high fat/high protein meal)?

---

**IMPORTANT** The information about insulin delivery is based on user entry into the Guardian™ Connect app. Therefore please ensure that the patient has recorded all insulin injections and carbohydrate intake.
This report shows you up to 14 days of sequential data on one page.

- Review consistency of SG readings and trends in this report. Always high or 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 insulin was given. Is a meal/snack and BG paired with the bolus each time?

**Daily Details Report**

- Use the Daily Details report to focus on specific days only.
- Take a closer look at the glucose levels paired to their insulin entries. Review insulin injections, meals, and physical activity.

*These images show only part of the Sensor & Meter Overview and Daily Details Reports.

**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 hypoglycemia).
- Remind patient to bolus based off of blood glucose meter values, not sensor glucose.
- Encourage continuous CGM use for a full 24 hours per day.
The following pages summarize the steps to determine initial CGM settings. Recommended settings and additional clinical considerations are provided to help individualize therapy for each patient. Initial settings can be documented on the CGM Initiation Settings form provided and given to the patients for their records.

### STEP 1: TIME SEGMENTS

- Up to 2 time segments can be set for 24 hour period
- Different low settings can be selected for each time segment

<table>
<thead>
<tr>
<th>Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start with two segments: day and night</td>
</tr>
<tr>
<td>Consider segments for regularly occurring activity</td>
</tr>
</tbody>
</table>

### STEP 2: LOW LIMIT

- Can be set from 60 to 90 mg/dL in increments of 5 mg/dL

<table>
<thead>
<tr>
<th>Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start at 70 mg/dL</td>
</tr>
<tr>
<td>Increase for history of hypoglycemia or hypoglycemia unawareness</td>
</tr>
</tbody>
</table>

### STEP 3: LOW ALERT OPTIONS

#### Alert on Low
- Alert when SG reaches the low limit

**Note:** An Urgent Low alert will sound when the sensor glucose reaches 55 mg/dL regardless of alert settings

<table>
<thead>
<tr>
<th>Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Re-evaluate within 1-2 weeks to add alert</td>
</tr>
<tr>
<td>Using with Alert on Low will likely result in excessive alerts</td>
</tr>
<tr>
<td>Set at 20 minutes if On</td>
</tr>
</tbody>
</table>

#### Alert Before Low
- Alerts when SG values are approaching Low Limit
- Time before Low must also be set
- Time can be set from 5 to 60 minutes in 5 min increments

<table>
<thead>
<tr>
<th>Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>On at initiation</td>
</tr>
<tr>
<td>Adjust low limit as needed</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>Set at ↓↓ or ↓↓↓↓ to alert patients of very rapid changes that may occur</td>
</tr>
<tr>
<td>If patient reports too many alerts, increase limit or turn Off alert</td>
</tr>
</tbody>
</table>
### LOW SETTINGS

#### SNOOZE

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

**Considerations**

Default of 20 minutes generally appropriate.

#### Alert Volume Control

- Max Volume at Night will cause low and high alerts to play at phones’ max volume, so alerts are less likely to be missed while sleeping
- Defaulted to ON at startup
- Alert volume feature allows customization of alert volume, independent of phone’s volume setting
- Mute all alerts can be selected for up to 4 hours if no audible alerts are wanted (i.e., meeting, test, etc.)

**Considerations**

Leave On so alerts are not missed while sleeping
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 need to be individualized in all cases.

**It is recommended that High Settings be Off at CGM initiation to minimize 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></th>
<th>Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Up to 2 time segments can be set for 24 hour period</td>
<td>Use one time segment for entire 24 hour period</td>
</tr>
<tr>
<td>Different high settings can be selected for each time segment</td>
<td></td>
</tr>
</tbody>
</table>

### STEP 2: HIGH LIMIT

<table>
<thead>
<tr>
<th></th>
<th>Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Can be set from 100 to 400 mg/dL in increments of 5 mg/dL</td>
<td>Start at 250 mg/dL once high alerts are turned on</td>
</tr>
<tr>
<td></td>
<td>Decrease the limit as glucose control improves and hyperglycemia decreases</td>
</tr>
<tr>
<td></td>
<td>Alternatively, may use Carelink™ data to determine initial setting</td>
</tr>
<tr>
<td></td>
<td>If patient reports too many alerts, increase the limit and couple with therapy adjustments</td>
</tr>
</tbody>
</table>

### STEP 3: HIGH ALERT OPTIONS

#### Alert Before High

<table>
<thead>
<tr>
<th></th>
<th>Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alerts when high glucose is predicted to occur</td>
<td>Leave Off to decrease the burden of frequent alerts with limited perceived value</td>
</tr>
<tr>
<td>Used to prevent or reduce the severity of high glucose excursion</td>
<td>Using with Alert on high will likely result in excessive alerts</td>
</tr>
<tr>
<td>Time can be set from 10-60 minutes in 5 min increments</td>
<td>Set at 15 minutes if On</td>
</tr>
</tbody>
</table>

#### Alert on High

<table>
<thead>
<tr>
<th></th>
<th>Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alerts when SG reaches the high limit</td>
<td>Off at initiation</td>
</tr>
<tr>
<td></td>
<td>Turn On after initial insulin adjustments have been made to improve control</td>
</tr>
<tr>
<td></td>
<td>Adjust high limit as needed</td>
</tr>
</tbody>
</table>

#### Rate Alert

<table>
<thead>
<tr>
<th></th>
<th>Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alerts when SG has risen at a specified rate of change</td>
<td>Leave Off to decrease the burden of frequent alerts with limited perceived value</td>
</tr>
<tr>
<td>Can be used as indicator for missed boluses</td>
<td>Set at ↑ or ↑↑↑ to alert patients of very rapid changes that may occur</td>
</tr>
<tr>
<td>Rise Limit can be set to alert</td>
<td>If patient reports too many alerts, increase limit or turn off alert</td>
</tr>
<tr>
<td>↑: Signals a 1 to &lt;2 mg/dL per min rise rate</td>
<td></td>
</tr>
<tr>
<td>↑↑: Signals a 2 mg/dL per min rise rate</td>
<td></td>
</tr>
<tr>
<td>↑↑↑: Signal a 3 or greater mg/dL per min rise rate</td>
<td></td>
</tr>
</tbody>
</table>
### HIGH SETTINGS

#### 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 minutes to 3 hours

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

#### Audio Override
- Defaulted to ON at startup
- Can choose to override all Low alerts, High alerts, and/or Status alerts

<table>
<thead>
<tr>
<th>Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Turn Off at initiation for High Alerts to decrease nuisance of loud audible alert if limited perceived value</td>
</tr>
<tr>
<td>Turn ON for High Alerts after initial insulin adjustments have been made to improve control</td>
</tr>
</tbody>
</table>
Use this form to document the initial CGM settings and hand-over a copy to your patient. Remind patient to use blood glucose values not sensor glucose to make therapy decisions.

### CGM INITIATION SETTINGS

Guardian™ Connect System - Continuous Glucose Monitoring

<table>
<thead>
<tr>
<th>LOW SETTINGS</th>
<th>HIGH SETTINGS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Low Limit</strong></td>
<td><strong>High Limit</strong></td>
</tr>
<tr>
<td>____ mg/dL</td>
<td>____ mg/dL</td>
</tr>
<tr>
<td>(Recommend starting at 70 mg/dL)</td>
<td>(Recommend starting at 250 mg/dL)</td>
</tr>
</tbody>
</table>

**Alert on Low**

- [ ] ON (Recommend turning ON to start)
- [ ] OFF

**Alert before Low**

- [ ] ON
- [ ] OFF (Recommend leaving OFF to start)

- **Time Before High**
  - _______ Minutes  or  _______ Hour

**Fall Alert**

- [ ] OFF (Recommend leaving OFF to start)
- [ ] ↓
- [ ] ↓↓
- [ ] ↓↓↓

**Snooze Time**

- _______ Minutes  or  _______ Hours
  (Recommend 20 minutes to start)

**Rise Alert**

- [ ] OFF (Recommend leaving OFF to start)
- [ ] ↑
- [ ] ↑↑
- [ ] ↑↑↑

**Snooze Time**

- _______ Minutes  or  _______ Hours
  (Recommend 2 hours to start)

### INSTRUCTIONS FOR ADJUSTMENTS

- [ ] Patient may adjust settings as necessary after initial use. (Recommended)
- [ ] It is preferred that the patient not adjust settings without consulting prescriber.

If patient cannot use abdomen or back of upper arms*, I authorize use of alternate site(s) as medically necessary.

Alternate site(s): ______________________________________________________________

Guardian™ Connect users will receive training by Medtronic Certified Product Trainers unless otherwise specified below:

- [ ] Prescriber’s office will facilitate product training services.
- [ ] Other: ________________________________________________________________

Prescriber name: ____________________________ Signature: ______________________________ Date: _____________

--

You can use this checklist to discuss with your patient which parts of the Guardian™ Connect Patient Training Program need to be completed before and after therapy initiation.

Please ask your local Medtronic contact person about the form in electronic format.

### Guardian™ Connect System
#### Continuous Glucose Monitoring (CGM) Training

**Patient Name:** __________________________

**Certified Product Trainer:** __________________________

**DOB:** __________________________

**Training ID:** __________________________

**End Time:** ____________ a.m. / p.m.

- **Training Start Time:** ____________ a.m. / p.m.
- **Patient checked BG prior to and after training session**

**Patient performed and demonstrated understanding of the following. Check all that apply:**

- [ ] Reviewed Getting Started with Guardian Connect System
- [ ] Completed online training videos

**CGM and Mobile Device Basics:**

- [ ] SG not the same BG. Focusing on Trends
- [ ] Setting mobile device to silent, vibrate, Do Not Disturb
- [ ] Turning on Bluetooth® communication in mobile device
- [ ] Keeping app open in background
- [ ] Reviewed all Guardian Connect system warnings
- [ ] Use BG, not SG to make therapy decisions

**Sensor Insertion and Start:**

- [ ] Selecting, preparing, and rotating sites
- [ ] Using thumbprint on one-press serter
- [ ] Inserting and taping Guardian™ Sensor 3, connecting transmitter
- [ ] Starting New Sensor on app
- [ ] Setting alerts as prescribed by healthcare professional

**Alert Settings**

- [ ] Always allowing app Notifications
- [ ] Customizing Alert Volumes, Max Volume at Night, and Mute All Alerts
- [ ] Calibration reminder

**High Settings**

- [ ] High Limit
- [ ] Alert on High
- [ ] Alert Before High / Time Before High
- [ ] Rise Alert
- [ ] Snooze Time

**Low Settings**

- [ ] Low Limit
- [ ] Alert on Low
- [ ] Alert Before Low / Time Before Low
- [ ] Fall Alert
- [ ] Snooze Time

**Calibration**

- [ ] Reviewed calibration guidelines and schedule
- [ ] Reviewed steps to calibrate sensor
- [ ] Calibration reminder

**Reading Sensor Display on App**

- [ ] Reading home screen and icons
- [ ] Reading system status icons
- [ ] Viewing sensor graphs

**Sensor Alerts**

- [ ] Reviewed common sensor alerts and icons
- [ ] Clearing and snoozing alerts

**Additional topics covered**

- [ ] Entering event markers
- [ ] Charging / storing transmitter
- [ ] Referring to [www.medtronicdiabetes.com/carelink-info](http://www.medtronicdiabetes.com/carelink-info) for help with CareLink™ software report interpretation

**CareLink™ Personal Software**

- [ ] Creating and setting up a care partner account
- [ ] Removing for X-rays, MRI, CT scan

Follow-up phone call date: __________________________

**Comments:** __________________________

**Patient Signature:** __________________________  **Date:** __________________________

**Trainer Signature:** __________________________  **Date:** __________________________
REFERENCES


