DIABETES MANAGEMENT WITH CONTINUOUS GLUCOSE MONITORING

HEALTHCARE PROFESSIONAL GUIDE

Guardian™ Connect System & CareLink™ Reports
Includes: Interpretation, Alert Guidelines & Trend Management
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This guide is based on “A Guide to Personal Continuous Glucose Monitoring for the MiniMed™ 640G System” and was adapted for Personal Continuous Glucose Monitoring with the Guardian™ Connect System. The authors would like to thank the following reviewers for their valuable comments and suggestions that helped to improve the original guide:

Oliver Schnell: Prof. Dr. Executive Member of the Managing Board of the Forschergruppe Diabetes e.V., Helmholtz Center, Munich, Germany. Dana Korine-Patt: Clinical Dietitian & Diabetes Educator Maccabi Healthcare Foundation, Israel. Carine de Beaufort: MD, Pediatric Consultant, Clinique Pédiatrique de Luxembourg. Guest professor UZ Brussels, Belgium. Ragnar Hanas: MD, PhD, Assoc. Prof. Department of Pediatrics, NU Hospital Group, Uddevalla and Sahlgrenska Academy, Gothenburg University, Gothenburg, Sweden. Kirsten Nørgaard: MD, DMSc, MHPE Specialist in Endocrinology, Medical Leader of the DiaCon-group Hvidovre University Hospital, Denmark.
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 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 App screen of the mobile device 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 of the app 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™ System Software you will also have on-demand access to the 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.

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. **Guardian™ Connect 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 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 CareLink™ System software allows the information from the Guardian™ Connect App to be downloaded and displayed on reports. These reports will help you and your patient to 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™ 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.

   In addition to that, the patient can invite up to five Care Partners 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 software. In addition to that they can elect to receive SMS messages for patient’s 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. **Guardian™ Connect System is 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 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.

* Range: up to 20 feet (6.1 meter) between transmitter and mobile device.
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 is increasing worldwide.\(^4\)
- 2 in 3 adults cannot achieve optimal HbA\(_{1c}\) levels\(^5\)
- 1 in 4 children have HbA\(_{1c}\) levels ≥ 9.5 and 13 % of children show early signs of increased risk of blindness\(^5,6\)

There is an urgent need to improve self-management, glycaemic control & reduce complication rates and costs.\(^7,8\)

The Problem
SMBG is frequently done less often than recommended\(^9\), 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 HbA\(_{1c}\) values, hospital admission rate, and increased annual direct medical costs.\(^13-16\)

CGM for Better Diabetes Management
CGM can improve glycaemic control, reduce severe hypoglycaemia, and improve quality of life.\(^17-23\)
Guardian\(^\text{TM}\) Connect empowers the patients to take action when needed, with the following options to:
- view glucose values on their phone discretely
- receive alerts for hyper- and hypoglycaemia for patients and caregivers
- record insulin, carbohydrates, exercise and medication
- upload data and enable the patient’s care team to analyze the reports and to jointly develop an action plan.
Managing Multiple Daily Injection (MDI) Patients with CGM

When utilising 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 as to not overcorrect and administer 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 usually perform SMBG and are unaware of the phenomena. By having CGM data, Guardian™ Connect will alert to the early glucose rise post meal, and a patient might wish to correct this by bolusing with insulin. As early correction boluses rarely correct the excursion but usually cause insulin stacking and hypoglycemia, you 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, increase the insulin to carb ratio and/or inject the pre-meal bolus earlier.

2. **Insulin stacking** – There is a 30-120 minute turnaround time for bolus injection to affect glucose levels. Thus, unless in a ketosis situation – recommend to the patient to pace correction boluses 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 alarm 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 12. 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 bars should be done. Also review dosing of 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 10 days before consultations.

5. **Timing and frequency of calibrations** – The Guardian™ Connect system monitors the sensor readings throughout the day to ensure the sensor glucose readings remain accurate. In some cases, the system may require to calibrate the sensor more frequently if it detects the accuracy could be improved. “Calibrate Now” alerts may occur more frequently than every 12 hours to maintain the accuracy of the sensor. Suggest a regular calibration schedule that will work for the patient and most importantly, recommend calibrating before bedtime. 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 avoid additional requests for calibration.
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: Low 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 each 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 one react to Alert on Low depends on the settings. The way and the time a 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 than that 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 pre-set 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 pre-set 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.

The patient will receive an Urgent Low Sensor Glucose Alert that sounds at maximum level when their sensor glucose value reaches or falls below 3.0 mmol/L, even if the audio override feature is turned off.

See page 23 for considerations when determining initial Low Settings.
High settings are intended to notify 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: High 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 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 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™ System software 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™ Report Sensor & Meter Overview**
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 pre-set 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 set at 10.0 mmol/L (180 mg/dL) the reaction of a patient needs to be different instead of an alert when the High Limit is set at 13.8 mmol/L (250 mg/dL).

Alert Before High

The Guardian™ Connect System triggers an Alert on High before the pre-set 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 pre-set 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 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>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.\textsuperscript{21} 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.

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

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

<table>
<thead>
<tr>
<th>TREND ARROWS</th>
<th>BOLTADJUSTMENTS GUIDELINES USING TREND ARROWS</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>
</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.
USING ON-SCREEN DATA TO MAKE THERAPY ADJUSTMENTS

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>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™ System software generates easy-to-read reports that allows you to quickly assess control and fine-tune therapy. Guardian™ Connect data will be uploaded automatically to CareLink™ Personal software.* 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™ System software 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 behaviour and pointing out opportunities to improve.

Methodology for Interpretation

While there is no single preferred approach to CareLink™ report 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™ System software in their daily practice.

This four Step methodology describes how you could use CareLink™ System software to optimise your patient’s diabetes therapy:

- **PREPARATION & CARELINK™ SYSTEM SETTINGS**
  - Define CareLink™ System 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)

- **PATIENT BEHAVIOUR**
  - Encourage the good (or positive) behaviour
  - Avoid focusing too much on therapy outcomes
  - Determine data quality and behaviour issues
    - e.g. “Does the patient eat without giving a bolus?”

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

- **OPTIMISE THERAPY**
  - 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™ System software only shows data from the device. Discuss with your patient what happened at that time (stress, special situations, etc.)

* The mobile device must be connected to the Internet.
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?
Adherence Report* and Sensor and Meter Overview (Statistics section)

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

* 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.

**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 hypoglycaemia).
- Encourage continuous CGM use.

**IMPORTANT** 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.
Sensor and 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.

**Notes**
THERAPY OUTCOME – IDENTIFICATION OF CHALLENGES

Sensor and Meter Overview (Graph data) – cont.

Average how many carbohydrates are eat per meal

Average SG values before (pre-meal) and after (post-meal) a bolus
Overnight and meal buckets to see patterns surrounding bedtime, wake up, and meal times
To get this overview your patient has to enter MEAL EVENTS into the App

Notes
This report shows you all daily details for several days in a row (SG values and information that were entered into the App).

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

Is the patient 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
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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**Reach the Target**
- Document the challenges
- Suggest adjustment of device settings and/or therapy?
- Discuss adjustment and concrete implementation with the patient.
- Propose 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>Off</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>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>0:00</td>
<td>Off</td>
<td></td>
<td>x</td>
<td></td>
</tr>
</tbody>
</table>

**Auto Calibration**
- --

**Calibration Reminder**
- On

**Calibration Reminder Time**
- 1:00

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* 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.

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**Notes**

Enter all insulin units, and continue to upload to CareLink until next visit.
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.

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

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.

**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**

**CONSIDERATIONS**

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

**STEP 2: LOW LIMIT**

- **Can be set from 2.8 to 5 mmol/L (50 to 90 mg/dL) in increments of 0.2 mmol/L (5mg/dL)**

**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 before Low</th>
<th>Alert on Low</th>
<th>Rate Alert</th>
</tr>
</thead>
<tbody>
<tr>
<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>Time before Low must also be set.</td>
<td></td>
<td>Can be used as indicator for missed boluses</td>
</tr>
<tr>
<td>Time can be set from 10 - 60 minutes in 5 min increments</td>
<td></td>
<td>Fall 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>

**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**

- **Time before alert repeats after cleared if condition still exists**
- **One setting applies to all low alerts**

**CONSIDERATIONS**

- Default of 20 minutes generally appropriate.

The patient will receive an Urgent Low Sensor Glucose Alert that sounds at maximum level when their sensor glucose value reaches or falls below 3.0 mmol/L, even if the audio override feature is turned off.
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**

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

**CONSIDERATIONS**

Use one time segment for entire 24 hour period

**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)

**CONSIDERATIONS**

Start at 13.8 mmol/L (250 mg/dL) once high alerts are turned on

Decrease the limit as glucose control improves and hyperglycaemia decreases

Alternatively may use CareLink™ System data to determine initial setting

If patient reports too many alerts, increase the limit coupled with therapy adjustments

**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>■ Off at initiation</td>
<td>■ Can be used as indicator for missed boluses</td>
</tr>
<tr>
<td>■ Time can be set from 10 – 60 minutes in 5 min increments</td>
<td>■ Turn On after initial insulin adjustments have been made to improve control</td>
<td>■ Rise Limit can be set to alert</td>
</tr>
<tr>
<td></td>
<td>■ Adjust high limit as needed</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>

**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 †† or ††† to alert patients 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

One setting applies to all high alerts

Allows time for insulin to take effect and high glucose to decrease

Can be set from 5 minutes to 3 hours

**CONSIDERATIONS**

Set at 2 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 mg/dL</td>
<td>On</td>
<td>____ min</td>
<td>On</td>
<td>![Alert on Low]</td>
</tr>
<tr>
<td>___ - ___</td>
<td>____ mmol/L mg/dL</td>
<td>Off</td>
<td></td>
<td>Off</td>
<td>![Fall Alert]</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 mg/dL</td>
<td>On</td>
<td>____ min</td>
<td>On</td>
<td>![Rise Alert]</td>
</tr>
<tr>
<td>___ - ___</td>
<td>____ mmol/L mg/dL</td>
<td>Off</td>
<td></td>
<td>Off</td>
<td>![Rise Alert]</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: ____________________________
Prescriber Signature: ____________________________ Date: ____________________________
GUARDIAN™ CONNECT PATIENT TRAINING CHECKLIST

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.

PATIENT TRAINING CHECKLIST
GUARDIAN™ CONNECT SYSTEM

Patient name: __________________________
HCP name: ____________________________
Date: ________________________________

Please complete the following learning content prior to the start with the Guardian™ Connect System and provide me with a copy of the certificate of completion (no later than _______________):

Module “Introduction to CGM”
- What is CGM?
- Controlling Diabetes
  - Controlling Blood Glucose
  - Counting Carbohydrates
  - Fat & Protein
- Overview Guardian™ Connect System
- Sensor Glucose & Blood Glucose
- Managing expectations

Module “Before start with CGM”
- Recap CGM
- The keys to success
- Days in the life with CGM
- Getting the most out of it
- Quiz (Passing score 80%)

Module “How to start the system”
- Get an overview/Preparation before start
- Sensor insertion
- Setting up alerts/Starting the system
- Calibration/Information in display/Interaction with the App
- Inviting Care Partners

Please complete the following learning content within the first days with the Guardian™ Connect System and provide me with a copy of the certificate of completion (no later than _______________):

Module “Take control of hypoglycaemia”
- Hypoglycaemia
- Insulin Dose
- Glucose Trends
- Low Glucose Alerts
- Quiz (Passing score 80%)

Please complete the following learning content within the 2nd week with the Guardian™ Connect System and provide me with a copy of the certificate of completion (no later than _______________):

Module “Take control of hyperglycaemia”
- Hyperglycaemia
- Insulin Dose
- Glucose Trends
- High Glucose Alerts
- Quiz (Passing score 80%)

Module “Take control of your glucose values”
- CGM information on home screen (glucose graphs)
- Using CGM (how to use different glucose graphs)
- Using CareLink™ Personal Software
- Quiz (Passing score 80%)


Comments

1. accent colours should only be used for the key takeout of the header not the complete headline (McCann, Donna)
2. why is this not an A? (McCann, Donna)
3. five (5) Note: Style is to spell out numerals 0-9 and then write in numbers 10 and over (McCann, Donna)
4. icons should not be in accent colours. Please change all instances of this (McCann, Donna)
5. as above (McCann, Donna)
6. icons should not be in accent colours (McCann, Donna)
7. no accent colours for icons (McCann, Donna)
8. no accent colours for icons (McCann, Donna)
9. Four (McCann, Donna)
10. no accent colours for icons (McCann, Donna)
11. use AU english spelling - analyse (McCann, Donna)
12. icon colour (McCann, Donna)
13. accent colour use is for key takeaways - otherwise use bold - blue (McCann, Donna)
14. as above (McCann, Donna)
15. should not use & in headers (McCann, Donna)
16. as above (McCann, Donna)
17. as above - and (McCann, Donna)
18. Effra is the only font used! (McCann, Donna)
19. as above (McCann, Donna)
20. why is the 1800 number not on here? (McCann, Donna)