Paradigm® REAL-Time
INSULIN PUMP AND CONTINUOUS GLUCOSE MONITORING SYSTEM

Reading the Graphs

There are two views on the pump screen: a 3 hour retrospective view graph and a 24 hr retrospective view graph. Each view is accessed by pressing ESC from the home screen. The first ESC button push brings up the 3 hour view including the actual glucose level in the bottom right corner, and any trend arrows which indicate rising or falling glucose levels.

The 3 hr graph view

- The line indicates the glucose value from your current level to 3 hours prior. You can scroll back by pressing the down arrow. A flashing scroll bar will move along the graph by your presses in increments of 5 minutes from current to past values. Small black marks at the bottom of the graph indicate boluses.
- Raising or lowering your glucose targets in the sensor setup screen will change the view on the 3 hour graph.

The 24 hour graph view

- By pressing ESC twice, you can access the graph in the 24 hour view. The black section indicates the 6 pm – 6 am time block.
- You can scroll back in this view by pressing the down arrow. The values will be shown in 20 minute increments in the 24 hour view.

Trend Arrows

- Glucose trend arrows may be seen on your pump screen.
- One arrow indicates a rise or fall over the past 15-20 minutes of approximately 1 mmol/L
- Two arrows indicates a more rapid rise or fall in the glucose level over the past 15-20 minutes of 2 mmol /L or greater.
- If no arrows are seen in the 3 hour view, your current glucose level has not fluctuated significantly over the past 20 minutes.
- *** Pictured below is a pump screen in the 3 hour view:**

Glucose Target Ranges

Trend Arrows

Hourly indicators

Actual glucose value
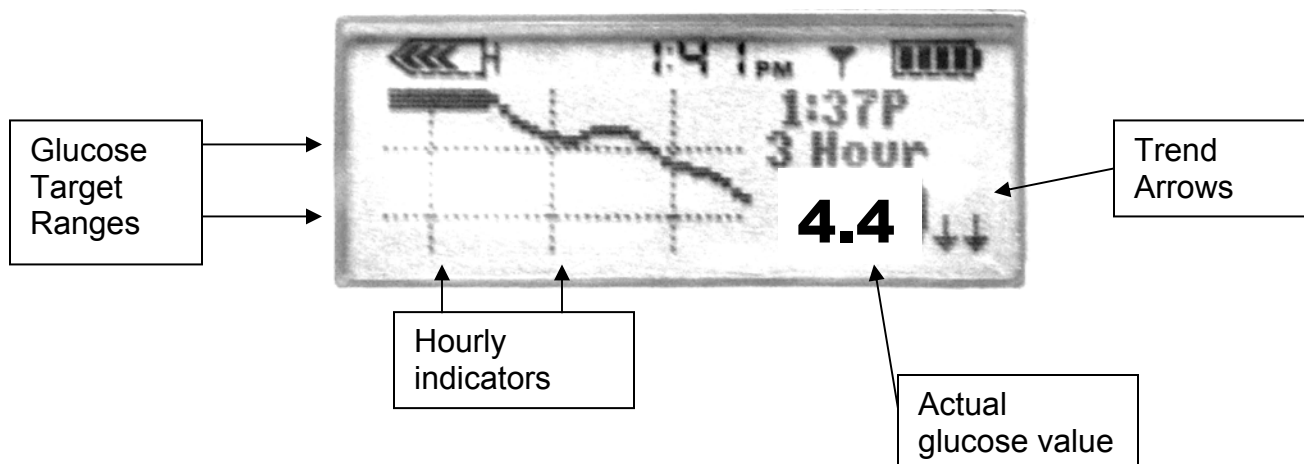
Sensor Initialization

Each time a new sensor is inserted into the body, a 2 hour initialization process must take place before glucose values are displayed on the pump.   Each sensor will function for up to 72 hours.

Sensor Initialization Programming

- Consult the Paradigm Real-Time user guide for step by step instructions for sensor site selection and insertion procedure.
- After your sensor is inserted and "New Sensor" has been initiated in the Sensor Start menu, the antenna icon should be displayed on the home screen of the pump. It will be white on a black background if the sensor function is "ON" in the pump. (See screens below)
- A few minutes after sensor start up, the antenna icon will turn black meaning that the transmitter and pump are in communication.
- You may wish to check the sensor's functioning by accessing the input signal (ISIG) in the sensor status screen by pressing ESC from the home screen 4 times. The ISIG value should be above 10 nA for adequate functioning.

Sensor Calibration

- Each new sensor will require a calibration before displaying any glucose values. An "Enter BG" alert will sound at the end of the initialization period.
- Your first glucose will be displayed about 10 minutes after the first calibration. Until a second reference calibration is entered, the glucose level displayed may not be accurate.
- You should enter 3-4 "reference" calibrations in the first 6 hours of each sensor wear. This improves the accuracy of the sensor during the remaining 72 hours.
- When a blood glucose value is entered into the Bolus Wizard you will be asked by the pump if you wish the value to be stored as a calibration.
- The BD Link™ meter automatically calibrates the sensor when a BG value is taken if the meter has been activated to communicate with the pump.
- You can choose to be alerted for an upcoming calibration and select the amount of time before the alarm sounds.
- DO NOT use sensor values displayed on your pump as calibrations.
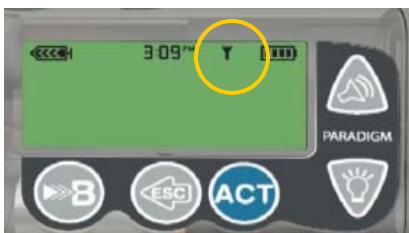
Sensor is "ON" and communicating with the pump

Sensor is "ON' but not communicating with pump.

Sensor Insertion

Every three days a new sensor will need to be inserted. Your sensor trainer will facilitate your training and can help you with your specific issues.

Sensor Initialization Checklist:

- 1 Alcohol swab
- Two IV 3000 adhesive dressings. Remove the outer packaging.
- One transmitter adhesive pad
- The Sen-Serter™ insertion device
- One sensor (check expiry date on package and remove from refrigerator 10-15 minutes prior to insertion)
- The insulin pump and transmitter

Procedure for Sensor Insertion:

1. Fit sensor into Sen-serter. Cock the Sen-serter by pushing firmly downwards on the sensor base until you hear a click
2. (Optional) You may lock the Sen-serter by turning the white button on the top end a quarter turn. This ensures it will not be released accidentally.
3. Remove the clear tape surrounding the needle. Leave the white tape with the tab in place.
4. Remove the clear needle guard from the needle.
5. Choose insertion site, lower abdomen, buttock or upper arm.
6. Clean the intended area of insertion with an alcohol swab or isopropyl alcohol in circular motion.
7. Allow skin to dry. Stretch skin slightly between the "feet" of the Sen Serter using your fingers.
8. Hold the Sen-serter on the skin at the angle indicated by the "feet" of the Sen-serter (about 45º) See below.
9. Unlock the Sen-serter if locked by turning the button a quarter turn
10. Insert the sensor by pushing slowly and firmly on the white button.
12. Hold sensor in place and remove the Sen-serter by sliding it laterally *along the body not away from the body.*
11. Remove the second layer of tape by pulling firmly on the white tab at the base of the sensor.
12. Remove the needle. You may need to pull firmly. Be sure and hold sides of sensor. Dispose of needle.
13. Connect the sensor to the transmitter. It should emit a small beep.
14. Tape the sensor site down using IV 3000. Tape the transmitter down using the transmitter adhesive tape. You may also use IV 3000 under the transmitter adhesive.
15. Go to sensor start, New Sensor ACT. Make sure the sensor function is "ON"
16. Check the Input Signal (ISIG) after 2 minutes. It will fluctuate and should stabilize within 10 – 200 nA. If it is below 10 after 5 minutes, pull the sensor out and start again with another.

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Sensor Insertion Tips

These are some additional tips for insertion of the sensor. If you continue to have difficulty contact your sensor trainer, Medtronic Diabetes nurse specialist or technical support help-line located on the back of your pump.

Dealing with the discomfort of sensor insertion
You can numb the skin prior to placing the sensor using a topical anaesthetic such as Emla™ Follow package directions for the application of the product. Ensure that you thoroughly clean off the residue of the product before cleaning the site for sensor insertion as any cream that remains on the skin will prevent the sensor adhesive from sticking.

Suggestions to prevent surface bleeding

Bleeding at the sensor site can occasionally occur. Blood at the surface of the skin though unsightly, may not be painful nor does it necessarily mean the sensor is ruined. Blood within the sensor itself can cause it to malfunction and require replacing. You will know when the sensor needs replacing due to blood because the sensor will eventually alarm calibration error as the collection of glucose is affected.

You can lower your risk of surface bleeding by choosing an area on the body with a higher degree of fatty tissue. If you are lean, using the Sen-serter may cause bleeding and you should try manual sensor insertion. If you are taking blood thinners or ASA, the sensor insertion may cause added bleeding and bruising. Discuss this with your health care provider.

Manual Sensor Insertion Procedure.

If you cant "pinch an inch" in the area you plan on inserting the sensor, manual insertion may be necessary. The below is the procedure for inserting a sensor manually:
- Find an area of tissue that you can pinch up.
- Cleanse the skin with an alcohol swab.
- Remove the sensor needle cover and clear tape surrounding the needle.
- Hold the sensor on the sides. Make sure you tip the needle to a 45° angle
- Pinch up the skin as high as possible.
- Insert the needle fully before releasing the pinch.
- Remove the introducer needle making sure to hold the sensor in place.
- Pull the white tab on the back of the sensor.
- Connect the transmitter and continue with taping and initialization

*Practice makes perfect!

Bolus Wizard & The Paradigm REAL-Time

The Bolus Wizard feature is an important part of pump therapy and continuous monitoring using the Paradigm REAL-Time. This tool can prevent un-safe"insulin stacking" cause from over-correcting high glucose. Insulin stacking can cause later hypoglycemia.

Bolus Wizard Settings
- Carbohydrate ratio
- Insulin sensitivity "correction" factor
- Target glucose ranges
- Active insulin

Understanding active insulin
After a bolus, there is a delay between when the insulin is delivered and when it affects a change in glucose levels. In addition to the insulin action, other variables may cause a delay in glucose lowering including whether there is any food being absorbed into your body, how high your glucose was for how long or even how many days your infusion set has been in. Active insulin refers to how much insulin is remaining in your system and has yet to exert its' glucose lowering effect. Depending on the rapid acting insulin type you are using, a bolus may take up to 6 or more hours to be fully used. You may feel that you want your glucose to decrease more quickly when hyperglycemic and take more insulin. The Bolus Wizard can help prevent a later hypoglycemic episode by subtracting the amount of insulin from the previous correction bolus which has yet to exert it's effect from the current correction bolus. The active insulin feature can only be used when the Bolus Wizard is "on" and set up.
** Consult your user guide for ranges and Bolus Wizard set up directions.*

Bolus Wizard and Real time glucose.
There are some key differences between standard pump therapy and pump therapy using a real time glucose display in the way that you may manage your diabetes. Firstly, having access to a glucose value every 5 minutes is a major change from the usual 4 blood glucose values per day. Secondly, having an alarm for hyperglycemia indicates the need for attention. It is important therefore to be aware that you may feel overwhelmed or reactive to the incoming information. There are a couple key pieces of information which may assist you in treating hyperglycemia:

- Use the Bolus Wizard. Set the active insulin curve with the advice of your health provider. You can evaluate the effect of your insulin action curve by testing your insulin sensitivity (correction) factor.

- When you review your glucose level on either the 3 or 24 hour views, the bolus insulin delivered will be shown as a small black marker at the bottom of the screen.

- Confirm with a finger-stick glucose prior to making diabetes treatment decisions.

Boluses
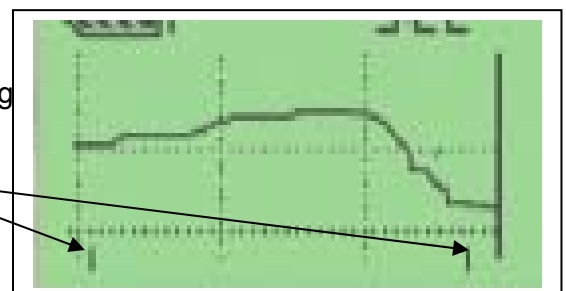
Calibrating the Paradigm REAL-Time

Calibration is necessary for the Paradigm REAL Time system's glucose monitoring function to display glucose values. It refers to the entry of finger-stick glucose into the pump. Calibrating the sensor provides a "cross-reference" between the sensor and finger-stick glucose values.

When are calibrations necessary?

Each new sensor requires early calibrations to begin sensing glucose levels. After the 2 hour initialization period, the pump will alarm "Enter BG". The first calibration should be entered as soon as possible after this first notification alarm. The first sensor reading will appear on the screen about 15 minutes after the calibration and will be the same as the level entered. What has happened is that the signal from the sensor was cross referenced with the BG entry. The next calibration will increase the accuracy of the sensor glucose therefore try and enter the second calibration within the next hour or two after the initialization is complete.

Important points about calibrating the sensor

- The minimum requirement for sensor calibration is once per 12 hours.
- The sensor will function best if it is calibrated a minimum of 3 times per day.
- The sensor should be calibrated pre-meal because glucose levels are more stable.
- Do not calibrate when your glucose is rapidly fluctuating.
- Check the sensor status screen for the time the next calibration is due to avoid any interruption in sensor functioning and alarming.
- Use only one BG meter for calibration during each sensor period of 72 hours.
- Do not use sensor values as calibrations
- Do not use alternate site testing (forearm) results as calibrations
- When the BD Link meter ID number is entered into the pump, the sensor calibrates automatically when a finger-stick glucose is performed. When you use any other brand of meter, you must enter the calibration into the pump manually. Consult your User Guide for more on how to enter a calibration manually.

Meter vs sensor glucose

When you perform a finger-stick and compare it to the sensor value, you may be surprised to see that these values are not the same. This is normal and does not mean your sensor is not accurate or functioning normally. There are several reasons for this discrepancy including the differences between the fluids being measured, the differences between the way each device converts glucose values and other technical or individual possibilities. Most of the time, the sensor and your meter will be within 2 mmol. Some of the time however, there may be a larger gap between these values such as a rapid rise in glucose or a time delay since the last calibration. It is important in these cases to enter a calibration.

* You need to verify your glucose level by finger-stick check before taking any insulin based on the sensor value and / or the way you are feeling alone. This verification is a necessary safety precaution when using the Paradigm REAL-Time

Glucose threshold alarms in the Paradigm REAL-Time

The ability of the Paradigm REAL-Time to provide an alarm when a glucose level reaches a pre-set individual threshold is one of the most exciting and anticipated features of the device. To use this feature properly, it is important to understand some of the procedures and considerations related to its' use.

Considerations for setting your glucose target thresholds
- Do you have a diminished sense of low glucose levels? If so, you may wish to set the hypoglycemia threshold higher so that your pump gives you an earlier warning.
- The narrower the margin between your glucose threshold settings, the more frequent your pump will alarm. It is up to you to decide whether the alarms are a nuisance or a comfort.
- You may wish to set the "Snooze" feature which will silence any continuous alarming at an adjustable interval. Consult the User Guide for the snooze settings.
- An alternative to the snooze feature is the raising of the hyperglycemia threshold or turning the feature off altogether.

When the threshold alarms are set, they will be displayed as horizontal dotted lines on the trend graphs. If you don't see these types of lines on the trend graph, it means that no alarms are set.

HIGH alarm

LOW alarm
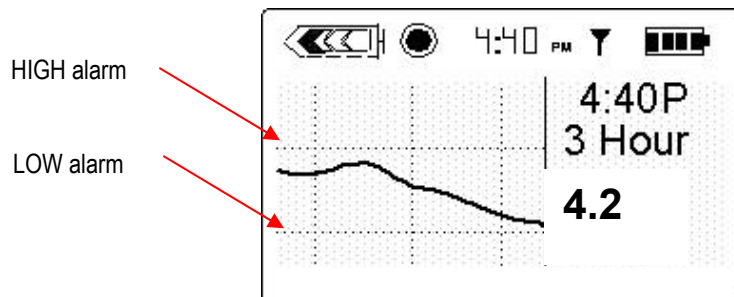
Other important points:

- Before you clear any alarm, you need to check the pump screen to see whether it is a high or low glucose alarm.

- Because there are differences between your sensor glucose and your meter blood glucose, always do a finger-stick glucose check whenever your pump alarms for a high or a low sensor glucose.

- Treatment changes should be made with advice from your healthcare provider.

CareLink online and the Paradigm REAL-Time

CareLink is a website dedicated to the viewing and storage of information stored in your Paradigm REAL-Time system. The CareLink website is available online at **http://carelink.minimed.com**. You do not need special software to use this website. Each time your pump is uploaded, the program will store your insulin use and glucose values as an individual file. You can review this file at any time. Several report types can be viewed and printed out for your evaluation or to bring to your next appointment with your health care provider.

CareLink: What you will need
In order to use the CareLink system, you require your pump, a computer with internet access, and either a BD Link with cable or a ComLink cable. You will be asked to enter your pump serial number to set up your personal folder. Each time you visit the site, you will be required to enter your personal user name and password. You may choose to provide this information to your provider so that they also can access your pump uploaded information.

Pump ⟶ Radio Frequency ▶ BD Link   PC ⟶ http://carelink.minimed.com
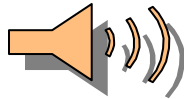
** For specific instructions consult the website*

Preparation for uploading to CareLink
You do not have to disconnect your pump to upload it to the website. Make sure that your pump is in close proximity to the BD Link meter or Com Link. Do not try and upload the pump if the battery is low or you are delivering a bolus. The first time you navigate the website, you may be directed to download a program for viewing.

View of "Meal-modal" view. Each of three meals displays several days' worth of glucose levels superimposed upon one another. Values and averages are below.
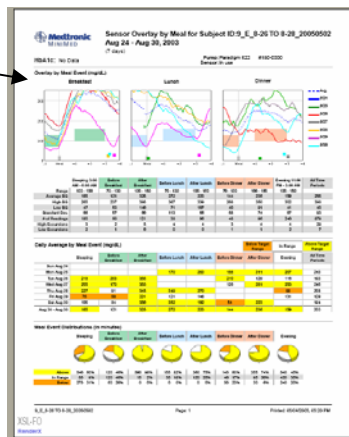
View of sensor daily detail. Several days of sensor information is superimposed. Glucose level target ranges are shown.
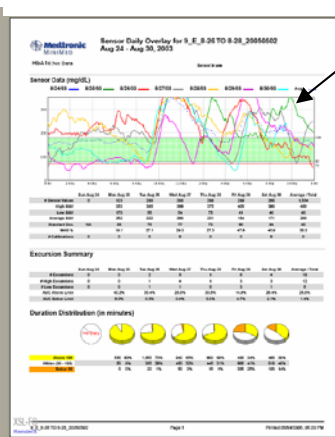
Interpretation of your CareLink Report

CareLink can help you in your diabetes management by providing insights into daily trends that are not available from the sensor graphs and bolus memory alone. Specifically, this "best look back" can help you identify the relationship between your meals and activity levels and how they affect your glucose levels.

1-2-3 Continuous Glucose Monitoring Methodology

The first time you look at the reports you may feel overwhelmed with information. Choose one or two report types which you find the most useful. Taking a systematic approach such as the following methodology may help you in evaluating your results.

- Step 1: Evaluate the overnight period
- Step 2: Evaluate the pre-meal glucose levels
- Step 3: Evaluate the post-meal glucose levels.

At each step, identify any hypoglycemic patterns first and make adjustments to correct it.

Case 1
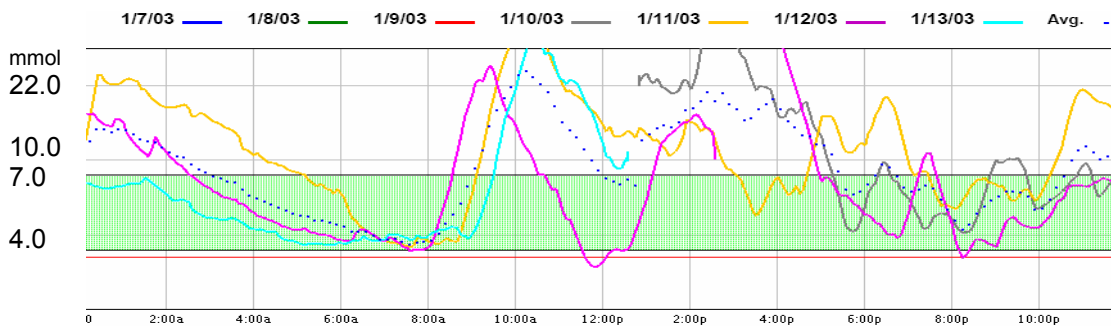
| 1/7/03 | 1/8/03 | 1/9/03 | 1/10/03 | 1/11/03 | 1/12/03 | 1/13/03 | Avg. |

Step 1: Look at the overnight period. What do you see? Look at the pattern. Does it re-occur?

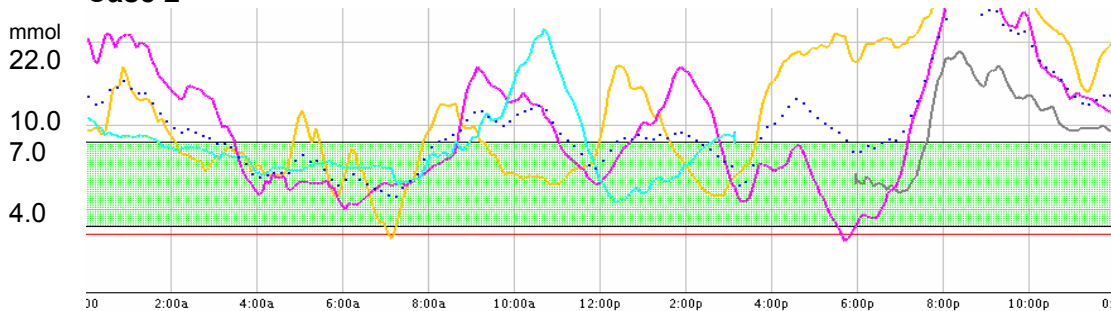**Step 2:** Look at the pre-meal values. Any hypoglycemia? Hyperglycemia?

Step 3: Look at the post-meal phase. Any hypoglycemia? Hyperglycemia?

Discussion

In this case, when we use the step-wise approach to interpretation, we can see that there is a drop in glucose levels overnight that occurs consistently over several days. Each day the drop nears the hypoglycemic threshold before breakfast. Several hours in the night are also in the hyperglycemic range on most days. Looking now at the pre-meal levels, they are in the normal to low-normal range. Lastly, evaluating the post-meal glucose, there is evidence of peaks after breakfast and lunch, but not dinner. It is important during interpretation that you evaluate all the factors leading to these results. For example, your basal rate, bolus amounts and activities during this period of time will help you in identifying areas which could affect your results. One suggestion in this case may be to raise the basal rate affecting the glucose from midnight till 3 or 4 am, and lower it in the dawn hours in order to prevent the pre-breakfast lows. It is possible that over-treating the pre-breakfast lows with too much carbohydrate may cause the post meal hyperglycemia. Evaluating the meal composition of the breakfast meal and the timing of the breakfast bolus may also help. Focusing on one or two key areas may help you evaluate the effect of any changes you decide to make based on this report.

Interpretation of your CareLink Report – Cont'd

Case 2

mmol
22.0

10.0
7.0

4.0

2:00a 4:00a 6:00a 8:00a 10:00a 12:00p 2:00p 4:00p 6:00p 8:00p 10:00p 0:0

Step 1: Look at the overnight period. What do you see? Look at the pattern. Does it re-occur?
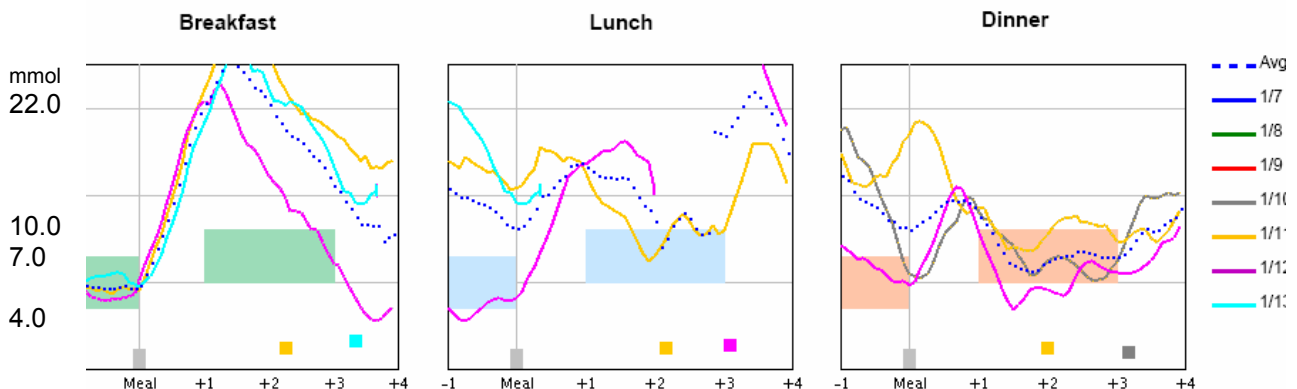
Step 2: Look at the pre-meal values. Any hypoglycemia? Hyperglycemia?

Step 3: Look at the post-meal phase. Any hypoglycemia? Hyperglycemia?

Discussion

Step 1 evaluating the overnight period reveals mainly hyperglycemia. Pre-meal glucose levels are normal most of the time with some occasional low normal values. Look at the post meal values now. There is some post meal hyperglycemia with breakfast and lunch, but it is dinner which yields the most striking post meal hyperglycemia. Possible suggestions based on this information may be to address the supper meal insulin to carb ratio or meal composition in order to evaluate whether it is the effect of the dinner meal on overnight glucose levels or overnight basal alone.

Using the Meal Modal View

Breakfast   **Lunch**   **Dinner**

mmol
22.0

10.0
7.0

4.0

Meal +1 +2 +3 +4   −1 Meal +1 +2 +3 +4   −1 Meal +1 +2 +3 +4

- - - Avg
—— 1/7
—— 1/8
—— 1/9
—— 1/10
—— 1/11
—— 1/12
—— 1/13

The meal modal view is a very useful way of determining the effectiveness of your bolus. This includes the amount and timing of your bolus amounts. The blocks shown before and after the vertical marker in each meal view indicate the glucose target range. The meal modal view shows a view of one hour pre-meal and three hour post-meal glucose levels. In the above case, the pre-meal glucose is within target before breakfast but peaks rapidly after the meal.

There are several other reports available to you. Discuss your results with your health care provider.

Sensor Troubleshooting

The below represents some of the commonly seen issues related to the sensor. You may also wish to consult your User Guide or 24 hr technical help line.

Glossary of Sensor terminology:

- Calibration Error: A system error indicating a problem with the entered blood glucose value and the sensor glucose value.
- Interstitial fluid: clear fluid found in the tissue under the skin. Where the sensor gains its glucose levels.
- ISIG: Stands for input signal, the electrical signal generated when the sensor becomes in contact with interstitial fluid. The signal can be viewed on the pump screen.
- nA: Measure of electrical current generated from a chemical reaction between interstitial glucose and the sensor.
- RF: Stands for "radio frequency" and is the way in which the transmitter and pump communicate.
- Sensor: Assembly consisting of introducer needle, tape and filament inserted under skin.

Sensor did not initialize:

Make sure sensor feature was turned "ON" in the sensor set up. Was your sensor within its' expiry date? Check the ISIG (ESC x4 for sensor status) Is the value less than 10nA? If yes, replace sensor. Check the ISIG (should be between 10 – 200+ nA.)

Problem with communication between pump and sensor

Clear the "Lost Sensor" or "Weak Signal" alarm by pressing ESC – ACT.

Check the following:

1. Check your insertion site. Is the sensor still under the skin or has it become dislodged?
2. Check the transmitter ID – is it entered correctly in the sensor set-up?
3. Check connection between sensor and transmitter. If this occurred during sensor start, did the transmitter "beep" when the sensor was connected? If not, the transmitter battery may not be working.
4. Look at the pump screen. Is there an antenna icon? If no, the sensor is not turned "on" in the sensor set-up menu
5. If the antenna is showing on the screen but has a black background there is loss of communication between devices:
   a. Check the sensor status screen (ESC x4) Was there a calibration due and not received? Any alarms or errors noted?
   b. Re-position the pump closer to the sensor and transmitter.
   c. Go to the sensor menu ➤ sensor start ➤ find lost sensor. You will be asked to re-calibrate in 15 minutes.
6. Rarely, an optical computer "mouse" or cell phone can cause a short period of interference between devices. Reposition pump away from possible interference.

* Call the technical support line if you have a recurring lost sensor alarm.

Accuracy

Terms of Reference:

Meter glucose: refers to finger-stick blood glucose. Meter BG is needed to calibrate the sensor and verify sensor values prior to making diabetes treatment decisions.

Sensor glucose: refers to the glucose level in interstitial fluid (ISF).

Blood glucose and ISF are both indicators of an overall "glycemic level" and are closely related.

There are differences between the two fluids (BG and ISF) that are normal and should be expected. It does not mean that one device is more accurate at measuring glycemic levels than the other. The following are reasons this occurs:

- Difference between ISF and BG. ISF is closer to where insulin is active in the tissues and this may affect the values shown by the pump and your meter especially when glucose levels are rapidly rising or falling.
- Device differences: Your meter and sensor use different types of calculations to provide you with a glucose value. The algorithms used aim for a discrepancy of no more than 15% separately. Used together (as in calibration procedure) the discrepancy can widen depending on:

    o **Your meter**: how accurate is your meter as compared to the lab?
    o **Your testing technique**: Are you using proper technique to avoid false readings?
    o **Your glucose level**: BG meters function differently at lower blood glucose thresholds. Your sensor relies on your meter for calibrations. Differences in meter glucose at lower thresholds can affect your sensor values.

Because managing diabetes requires serious consideration, we recommend verifying sensor values with a finger-stick glucose prior to making diabetes treatment decisions. This is a safety precaution which can help prevent any possible untoward events.

How will you know whether your values are accurate?

In general, your sensor values and BG values should differ by no more than 2 mmol/L. At higher glucose levels, this difference may seem more acceptable (9 -11mmol/L) than at lower thresholds (3.5 – 5.5mmol/L) This relates to the narrow margin of normal glucose not the functioning of the sensor. It is also one reason to verify your glucose level with any threshold alerts prior to making treatment decisions.

Rarely will both the sensor and meter have exactly the same value, however; they should be very close most of the time. It is important to adjust your expectation of glucose level measures. Have you ever tested your glucose from the same blood sample on two different meters? Using the same meter with two separate sites? If you have then you know these values are never the same. Sensor glucose values should be used along with all the other information available to you including: trend arrows, timing of your boluses, trend graphs and your BG value.