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I. HOW TO USE THE HAND HELD COMPUTER (HHC)

Keep the HHC with your glucometer, and every time you measure your blood glucose (BG), enter your reading**.**

To do this, follow these steps:

1. Turn on the HHC by pressing the power button at the top, to the right of the word *Dell*.

2. Pull the stylus up and out from the back (top right corner).

3. Check that the time displayed on the start screen is correct. (If not, tap the time display with the stylus. Change the time by tapping the up and down arrows on the screen that appears. Then tap *OK* to return).

4. Use the stylus to tap the icon labeled *IBMF2*. (If you do not see *IBMF2,* tap *Home* or *Start* at the top left, then tap *IBMF2.)*

Illustration 1
The Hand Held Computer

Recharge the computer overnight a few times a week (about as often as you would your cell phone) by plugging the recharger cable into the charge port at the bottom of the HHC.

NOTE: Please do not use the HHC for anything except inputting BG readings. Downloading information to or saving files on the computer uses up memory. This can prevent the programs from running and providing you with accurate information.

II. IBMF2 PROGRAM

A. Overview of Program

The hand held computer (HHC) will tell you four things: your risk of experiencing hypoglycemia, your hemoglobin A1c (HbA1c), how much your blood glucose (BG) level swings between high and low, and an analysis of the specific symptoms which accompany high or low blood glucose levels in your body. Your goal is to use this information and evaluate whether it helps you to avoid severe hypoglycemia and large swings in your BG, without raising your HbA1c.

Illustration 2
IBMF2 Summary Page

The HHC will be loaded with previous readings from your glucometer. From now on, you'll need to enter all your new BG results at the time you measure them. Using the time and the BG reading, the HHC continually updates its calculations and displays the summary page (Illustration 2). This page shows:

- ***Warnings.*** At the top of the summary page you will see a warning bar with your current risk of severe hypoglycemia labeled as:
  1) Imminent Risk—Within *the next 24 hours* you have a 50% chance of having severe hypoglycemia, and immediate action is needed.
  2) High Risk—Within *the next three months* you have a 90% chance of having severe hypoglycemia.
  3) Moderate Risk—Within *the next three months* you have a 20% chance of having severe hypoglycemia.
  4) No Warning—Your risk of severe hypoglycemia is low unless something unusual happens, such as you take a lot more insulin, exercise much more, or eat much less than usual.

  The goal is to keep your risk of severe hypoglycemia at moderate or below.

- ***HbA1c Estimate***. Below and to the right of the Warnings, you'll see an estimate of HbA1c. This is a measure of your average BG that your doctor sometimes orders with blood tests. HbA1c changes slowly, so the estimate updates only once every week. The Weekly Trending box will show how your HbA1c estimate has changed over the past several weeks.

- ***Variability Index.*** At the bottom right of the summary page you will see the Variability Index, which shows the rate at which your BG swings from high to low (Low, Medium, or High). The Weekly Trending for your Variability Index is below the HbA1c estimate. This shows how much your Variability is changing over the past several weeks. You want to keep your Variability Index at *Medium* or *Low*.

- ***Enter BG***. After measuring your BG, tap the *Enter BG* button to input the BG value into the computer. First the program will ask you to rate yourself on twelve symptoms. After rating the twelve symptoms, record your BG value and then tap *OK.*

- ***Analyze.*** Each time you save a BG value in the computer, you also store information about the symptoms you were experiencing. After about two weeks, there will be enough entries for the program to analyze. Tap *Analyze* to view a list of the symptoms. The program display will indicate the probability of each symptom being associated either with high BG or low BG. By associating symptoms with your BG level, the symptoms may become like warning flags. They may warn you in time for you to take action and prevent or lessen a high or low BG episode.

- ***EXIT.*** Tap *EXIT* to leave the IBMF2 program. Then turn off the HHC by pressing the power button, to conserve the battery's power.

The reason for using the HHC is to evaluate whether the program is helping you reduce your episodes of significant or severe hypoglycemia without significantly increasing your HbA1c. Reduced BG variability would generally contribute to reduced risk for hypoglycemia.

B. Details of Program

WARNINGS

Imminent Risk of Severe Hypoglycemia

If the top of the HHC display warns that you are at "imminent risk of severe hypoglycemia," this means you have been having frequent low and variable BG readings. You are highly likely to have an episode of severe hypoglycemia in the next 24 hours. The good news is that it is possible to *limit* severe hypoglycemia even after receiving this warning, if you take appropriate steps. What will be most important during the following 24 hours will be to: a) keep your BG above 100 mg/dl, b) be more alert to any symptoms of low BG, and c) treat any low BG *immediately*. The "Imminent risk" warning will continue for at least 24 hours, or until you have avoided hypoglycemia enough that your risk level has decreased to "High."

High Risk of Severe Hypoglycemia

If the top of the HHC indicates that you are at "High risk" of severe hypoglycemia that means you have been having a lot of low BG readings. Because of these episodes, two things may have happened: first, you may no longer feel your symptoms of low BG or you may feel them later than usual, and second, your body's ability to release adrenalin and automatically recover from hypoglycemia may be reduced.

Moderate Risk of Severe Hypoglycemia

If "Moderate risk" appears, it means you have a 20% chance of experiencing severe hypoglycemia during the next three months.

No Warning of Severe Hypoglycemia

Regardless of your recent BG patterns, you are always vulnerable to severe hypoglycemia if you: take more insulin than your body needs, do a lot of non-routine exercise, or significantly reduce your carbohydrate consumption without reducing your insulin. So whenever these conditions occur or you are experiencing even mild symptoms of hypoglycemia, measure your BG more frequently. And whenever hypoglycemia symptoms occur, treat immediately.

HbA1c ESTIMATE

HbA1c is a measure of your average BG control over the past two months. The American Diabetic Association (ADA) recommendation for HbA1c is to be 7 or less. A reading of between 6.0-7.0 is considered *under control.* A reading higher than 7.0 means TAKE ACTION! In other words, if your reading is <7.0, you should be proud of it.

If your reading is >7.0 then you are at higher risk of developing long-term complications of diabetes.

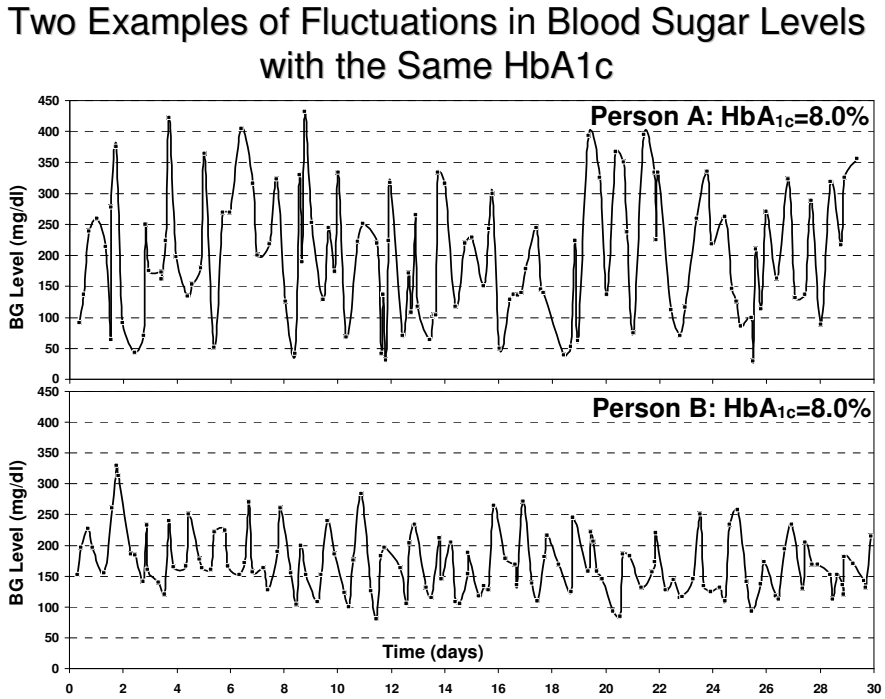
Generally speaking, if your HbA1c is >7.0 you should take significant steps to improve your BG control. Improving your BG control does *not* mean increasing the number of low BGs. It does mean *reducing* the number of times and the length of time that you have high BG. To improve your control, you may need to adjust your insulin program, reduce the number of carbohydrates you eat or increase your routine physical exercise. Talk to your diabetes health care provider and develop *a practical plan* to improve your HbA1c. Remember, HbA1c does not change rapidly. So don't look for quick changes in your HbA1c —that's why the HHC only updates it once a week.

VARIABILITY INDEX

This measures how much your BG swings from low to high and vice versa. Variable BG is a problem for three reasons. First, the more your BG changes, typically the worse you feel. Our research shows that greater BG variability is associated with feeling more depressed. Second, the more your BG varies, the more likely you are to slip down into severe hypoglycemia. Third, variable BG may contribute to the development of diabetic complications--as much or more than elevated HbA1c does.

Look at the graphs in Illustration 3. The first graph, of Person A, shows a very high Variability Index. The second graph, of Person B, shows a very low Variability Index. Both Person A and Person B have the same HbA1c. The Variability Index gives you more information about how widely your blood sugar swings between highs and lows.

Illustration 3

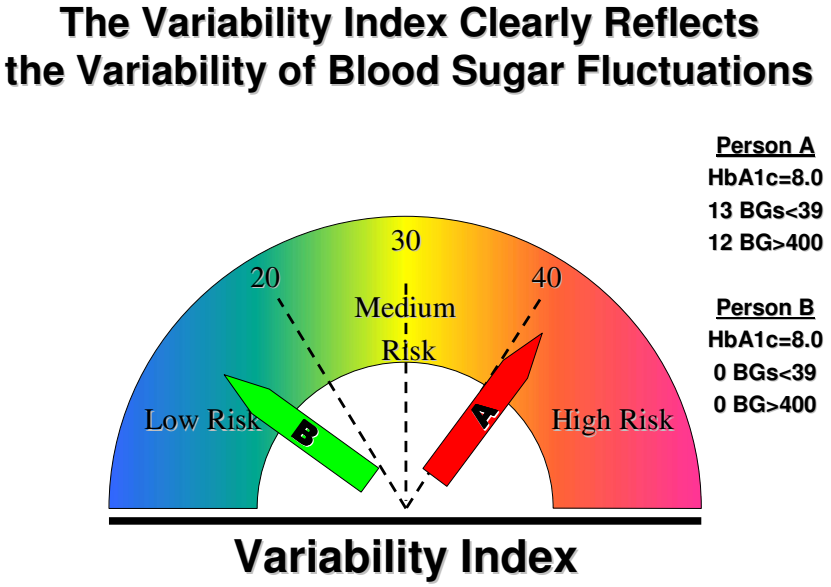


Your HHC gives you a reading of how variable your BG has been in the past week. As you can see in Illustration 4, if your BG Variability Index is below 20 that means your BG is not changing much and is at Low Risk, which is healthier for you. If your BG Variability Index is 20-39, you are at slightly higher or Medium Risk for severe hypoglycemia and possible diabetic complications. High Risk is greater than 40, which means you should talk to your health care provider about it. (The red and green pointers illustrate BG variability for Person A and Person B.)

While some peoples' BG generally changes more than others', variable BG can be due to many *overtreatment* reasons. Overtreatment reasons include: taking too much insulin, exercising too much, cutting back too much on carbohydrates when your BG goes high, or eating too many carbohydrates when your BG is low.

Like the HbA1c, the Variability Index changes slowly and updates once a week, so don't expect to see it change after working hard for a few days to curb swings.

Illustration 4



Enter BG

To enter a blood glucose value into the computer, tap the *Enter BG* button at the bottom left of the screen (see Illustration 2). The program will ask you to rate yourself on twelve symptoms. After you finish rating the symptoms, a number pad will appear in the display window. Check your blood glucose at this time. Tap in your BG reading, and then tap *OK* to save the data in the computer's memory.

The display will then return to the summary page where you can: look at information on the screen, review Weekly Trends for your HbA1c and Variability Index, analyze the symptoms and BG measurements you have recorded, or tap *Exit* to end the program.

Analyze

After you have collected about two weeks of data (BG entries) you can use the analyze button. If you tap it before this time, it will just tell you "there are not enough entries." When you have entered a minimum of four BGs per day for two weeks, you can analyze your data. Tap *Analyze*.

The screen in Illustration 5 will appear, which is identical to the screen in illustration 2 for the IBMF-1 program.

Further, the screen in Illustration 6 shows the symptom analyze screen. The program lists symptoms and, analyzes their association with low or high BG
episodes, and displays a bar graph of the symptoms.
The first number you see is 0. This appears on every page and is the baseline to which the other symptoms compare. Further, the height of the bars indicates each symptom's probability of being a high or low BG symptom (red for high and blue for low). It is possible a symptom to be associated with both low and high BG, or not associated with BG at all.

This example displays the first four symptoms of "tense/stressed," "trembling," "pounding heart," and "sweaty." By tapping *Next*, you can continue through the entire list of twelve symptoms. The bar graph will change accordingly.

You can return to the summary page by tapping *done*. Then tap *EXIT* to end the program.

When you are finished, turn the HHC off by pressing the power button. (If you do nothing, it will turn itself off after 30 seconds.)

Illustration 5
IBMF-2 Analyze Screen 1

Illustration 6
IBMF-2 Analyze Screen 2