

GLUCOWATCH[®] G2

AUTOMATIC GLUCOSE BIOGRAPHER

and

AUTOSENSORS

PATIENT INFORMATION

CAUTION: U.S. federal law restricts the GlucoWatch[®] G2™ Biographer and AutoSensors to sale by or on the order of a physician.

WARNING: This device is not designed to replace your regular blood glucose meter. The GlucoWatch G2 Biographer must be used with your blood glucose meter. Together, they can give you more information about glucose levels. You and your health care team may be able to use this information to manage your diabetes better.

IMPORTANT: Before you use the GlucoWatch G2 Biographer, you must do 2 things:

- Read the *User's Guide* provided in the Starter Kit
- Complete an Introductory Training Program located in the *User's Guide*

1

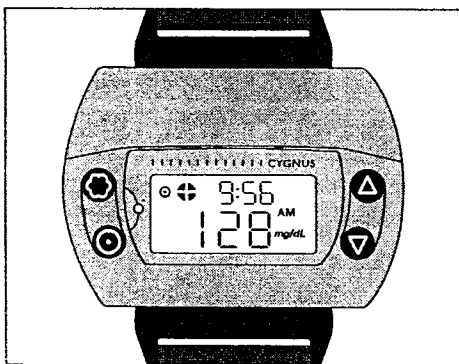
This product information sheet does not replace a complete reading of the *User's Guide*. If you have questions or need another copy of the *User's Guide*, please call our Customer Service Department. The toll-free phone number is 1-866-GLWATCH (1-866-459-2824).

What is the GlucoWatch G2 Biographer?

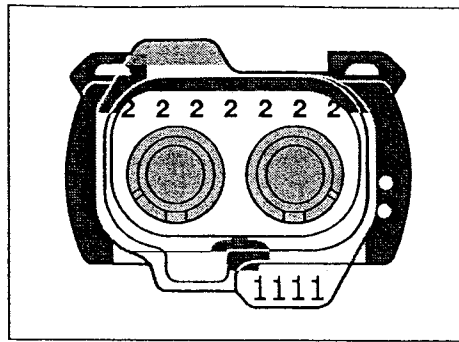
The Biographer is a glucose monitoring device that is worn like a watch. Glucose readings are taken noninvasively through your skin. The Biographer provides automatic glucose readings every 10 minutes for up to 13 hours at a time.

The G2™ Biographer consists of 2 main parts:

- The **Biographer**: the watch-like device that measures glucose.



The **AutoSensor**: a plastic part that snaps into the Biographer and sticks to your skin. Each AutoSensor provides up to 13 hours of readings. The AutoSensor must be replaced every time you wear the Biographer.



How does the GlucoWatch G2 Biographer work?

An extremely low electric current pulls glucose through the skin. The glucose is collected in 2 gel discs that are part of the AutoSensor. Then an electrode in the AutoSensor measures the glucose.

- Each glucose reading is stored in memory and the readings can be viewed with the touch of a button
- The Biographer compares each 10-minute reading with High and Low Alert levels that you and your health care team select
- The Biographer sounds an alarm if glucose readings are:
 - Below the Low Alert level
 - Above the High Alert level
 - Declining towards the Low Alert level

What is the GlucoWatch G2 Biographer used for?

The Biographer detects trends and tracks patterns in your glucose levels. The Biographer can be used during your normal daily routine (while awake or asleep) at home or at work. The frequent readings provided by the Biographer may help you manage your diabetes better.

2

The Biographer is meant for use by adults (aged 18 and older) with diabetes. This is because, so far, the Biographer has been studied only in adults.

Can I use GlucoWatch G2 Biographer readings in the same way I use finger-stick test results?

No. The Biographer is designed to help detect trends and patterns in your glucose levels. Most Biographer readings are similar to finger-stick test results taken around the same time. But some Biographer readings will differ from finger-stick tests. This difference can be important for proper treatment.

Managing diabetes means that you must make treatment decisions every day. Unfortunately, these decisions can sometimes cause problems. For example, too much insulin can result in low glucose levels and not enough can result in high glucose levels.

When it is time to make an important decision, the Biographer should not be used as a substitute for a finger-stick test. The Biographer must be used with finger-stick blood testing. Then you can make the best treatment decisions and reduce the chance of problems.

How can I use GlucoWatch G2 Biographer readings to help manage my diabetes better?

The Biographer makes frequent glucose monitoring easier. With the Biographer you can see the trends and patterns in your glucose levels. For example, you can see your glucose levels rising after meals. This can help you and your health care team identify ways to improve your diabetes management.

The Biographer can also alert you when your glucose levels are too high or too low. These situations may be hard to identify with finger-stick testing alone.

Remember that Biographer readings can sometimes be different from finger-stick test results. You must not rely on the Biographer to alert you every time your glucose is too high or too low. Never ignore symptoms that may be due to low blood glucose or high blood glucose.

When should I wear the GlucoWatch G2 Biographer?

You should discuss when to wear the Biographer with your health care team. You and your health care team may decide that you should wear the Biographer:

- Every day, if you often have problems with high or low glucose levels
- At night, when changes in glucose levels are hard to detect
- On days when your normal routine is disrupted, for example, when you're especially busy or traveling
- When you need more information to help solve problems

You should change the place where you apply the Biographer to your skin each time you wear it. The low-level electric current used by the Biographer may cause some skin irritation (redness and/or itching) after use. These symptoms should disappear within a few days if you do not put the Biographer back on the same place on your arm. If irritation continues, talk to your doctor.

When do I need to use a regular blood glucose meter?

You must use a regular home blood glucose meter:

- To calibrate the Biographer each time you use a new AutoSensor. To calibrate, you must do a blood glucose test and then enter the results into the Biographer. Everyone's skin is different. Your skin is also different from site to site and even day to day. Calibration adjusts the Biographer for the skin site you have chosen.
- To confirm the Biographer readings in certain circumstances that are described in the warnings section below.
- To monitor your blood glucose level as directed by your doctor. Since the Biographer is not designed to replace your regular blood glucose meter, never change how often you do finger-sticks without first talking with your doctor.

Important safety warnings about using the GlucoWatch G2 Biographer

- Do not ignore symptoms that may be due to low blood glucose or high blood glucose. The Biographer may not detect every instance that your glucose levels are too high or too low. If you have symptoms that do not match the Biographer readings, use your regular blood glucose meter to check the Biographer results.
- Do not change your treatment decisions based only on results from the Biographer. For example, some people use a blood glucose test result to help determine an insulin dose before each meal. This is often called a sliding scale. If you use a sliding scale, be sure to confirm the Biographer reading with your regular blood glucose meter to make sure you take the right amount of insulin.

- Do not make fundamental changes in your treatment program without talking to your health care team. Serious illness or accidents may result.
- Remember that Biographer readings can differ from finger-stick test results. When it is time to make an important decision, the Biographer should not be used as a substitute for a finger-stick test. The Biographer must be used with finger-stick blood testing. Then you can make the best treatment decisions and reduce the chance of problems.

Precautions to make sure you use the GlucoWatch G2 Biographer correctly

- Always do the calibration step carefully. Entering the right number is important for accurate results. Follow the instructions for using your regular blood glucose meter. If you question the reading from your regular meter that you plan to use for calibration, repeat the blood glucose test.
- Be sure to set the Low Alert level 10 to 20 mg/dL above the blood glucose level that you want to make sure is detected. For example, if you want to detect a level of 60 mg/dL, you should set the Low Glucose Alert between 70 and 80 mg/dL. Otherwise, the Biographer may miss some low blood glucose events and the alarm will not sound.
- Always check the last few readings in the Biographer memory to see the current trend in your glucose levels. One reading cannot tell you how fast your glucose levels are changing. If you question the Biographer results, confirm the Biographer readings with your regular blood glucose meter.
- Do not place the Biographer at any site where you have skin irritation left from a prior use. The Biographer should only be placed on sites with normal, healthy skin. Avoid sites with skin abnormalities such as eczema, cuts, sunburn, or scarring. Skin irritation may be worse than normal.
- Patients with suspected allergies to medical adhesives should consult their health care professional before using the Biographer.
- Do not use an expired AutoSensor. Check the expiration date on the package label before use.
- Do not share your Biographer with another person. This will help prevent spreading infections.

How do I use the GlucoWatch G2 Biographer?

Be sure to read the *User's Guide* included in your Starter Kit for full instructions. You should also refer to the video and *Quick Reference Guide* included in your Starter Kit. Here are the basic steps:

- Snap a new AutoSensor into the Biographer.
- Put the Biographer onto your arm and press the Start button. This begins a 2-hour warm-up period.
- After the warm-up period, calibrate the Biographer using the result of a blood glucose test with your regular meter.
- After calibration, the Biographer will give you a glucose reading every 10 minutes for up to 13 hours. After 13 hours the Biographer will stop glucose monitoring.
- The Biographer checks each reading for any sign of a technical problem that might cause a reading to be inaccurate. If a problem is detected, the reading

is skipped. The word **SKIP** will appear on the Biographer display, but monitoring will continue.

- Certain problems (for example, dislodging the Biographer from your skin) can cause the system to shut off glucose monitoring completely.

The **Troubleshooting** section of your *User's Guide* provides more details on what can cause a skipped reading or an unexpected shut off.

What else will I need to use the GlucoWatch G2 Biographer?

In addition to the items included in your Starter Kit, you will need:

- **A regular blood glucose meter** to calibrate the Biographer, plus the other supplies you normally use for testing
- **An alcohol wipe** to clean your skin before putting on the Biographer
- **A razor** to remove excess hair that may prevent good contact between the AutoSensor and your skin

What can I do about the skin irritation caused by the GlucoWatch G2 Biographer?

Most people have mild to moderate skin irritation after wearing the Biographer. Occasionally blisters may result from friction between the skin and the Biographer. People with sensitive skin may get more redness or itching. However, following a few simple steps can help reduce the amount of skin irritation you get.

- Rotate wear sites on your arms
- Keep irritated skin clean and dry
- Avoid scratching irritated areas
- Protect irritated areas from the sun
- Use lotion on irritated skin after removing the Biographer

If skin irritation is not getting better after 1 week, consult a health care professional.

Care and storage of the AutoSensors

- Before use, AutoSensors should generally be stored in a refrigerator (2°C to 8°C [36°F to 46°F]). Do not store AutoSensors in the freezer. If needed, AutoSensors can be stored at room temperature (below 25°C or 77°F) for up to 1 month. AutoSensors stored at room temperature must be used within 1 month.
- Avoid long periods of storage at high temperatures. Do not store the AutoSensors in your car.
- Do not use an expired AutoSensor. Check the expiration date on the package label before use.
- Use an AutoSensor immediately after opening the pouch it comes in. Do not store AutoSensors in open pouches.
- Check the gel collection discs in the AutoSensor for any spots or areas of different color. The gel collection discs should have a uniform but cloudy appearance and are normally white to gray with a slight yellow tint. Do not use the AutoSensor if you see any spots or discoloration.
- Dispose of used AutoSensors the same way you get rid of used blood glucose test strips.

Limitations of the GlucoWatch G2 Biographer

- It takes time for the Biographer to collect and measure your glucose. As a result, each Biographer reading corresponds to blood glucose values from about 15 minutes earlier. This 15-minute lag time can be important when your glucose levels are falling rapidly. Keep lag time in mind as you select your Low Alert level.
- If you are perspiring, you may get skipped readings. After you stop perspiring the Biographer will usually begin monitoring again. Very high levels of perspiration may cause the Biographer to stop monitoring completely. The alarm will sound if perspiration causes a skipped reading or a shut off. Remember that perspiration can be one of the symptoms of low blood glucose.
- Bumping or jarring the Biographer may also cause skipped readings or a shut off.
- The Biographer alarm may be difficult to hear if there is a lot of background noise. The alarm may also be difficult to hear at night if:
 - You are a heavy sleeper
 - You have difficulty with your hearing
 - The Biographer is under a pillow or blanket

The alarm will stay on and beep faster and faster until you press a button to shut it off.
- Never immerse your Biographer in water. Your Biographer is splash resistant, not waterproof. This means you can wear it in the rain or while washing your hands. You should not wear the Biographer while showering, bathing, or swimming. **3**
- The Biographer has been studied only in adults (aged 18 and older). Studies have included over 1,400 uses of the Biographer by hundreds of people with diabetes. No change was seen in accuracy or skin irritation during the studies. No studies have yet been done for longer than 6 weeks.
- The Biographer readings may be affected by some hospital tests that use high electromagnetic equipment. This includes x-rays and MRI tests.
- The medicines tolazamide or dopamine may affect the Biographer readings. Tolazamide is a pill sometimes used for Type 2 diabetes. Dopamine is given by injection for heart failure or shock. Ask a member of your health care team if you are uncertain if you are taking either of these medications.

Target glucose values for people with diabetes

Your own target glucose values should be determined with your health care team. If your glucose readings are frequently too low or too high, consult your health care team.

Your regular blood glucose meter gives test results that are either:

- **Whole blood** glucose values, or
- **Plasma** glucose values

All meters use whole blood to begin the test. The difference comes with how the result is calculated. Check the instructions for your meter to find out what kind of values it gives.

The Biographer readings are based on the finger-stick test result you use to calibrate the Biographer. This means that if your meter gives whole blood glucose values, the Biographer readings will also be whole blood values. If your meter gives plasma glucose values, the Biographer readings will be plasma glucose values.

Target glucose levels for people with diabetes depend on what type of result your meter and the Biographer provide. **TABLE I** below shows the general targets suggested by the American Diabetes Association.¹

TABLE I	If your regular meter provides whole blood glucose values:	If your regular meter provides plasma glucose values:
Before meals:	80-120 mg/dL	90-130 mg/dL
At bedtime:	100-140 mg/dL	110-150 mg/dL

Ensuring the accuracy of your GlucoWatch G2 Biographer readings

- The *User's Guide* includes directions for how to test your Biographer to make sure it is working correctly. Two types of tests can be done: the System Check and the Quality Control (QC) Test.
 - The System Check tests to make sure your Biographer is operating properly. Run a System Check before using your Biographer for the first time and then once before using the first AutoSensor from a new box. Also run a System Check if the Biographer is dropped or damaged in any way.
 - The QC Test checks the AutoSensors. Conduct a QC Test if you suspect that the AutoSensors have been exposed to extreme temperatures. Also run a QC Test if you have trouble calibrating the Biographer or if you question a series of Biographer readings.

The *User's Guide* explains how to do these tests.

- The accuracy of the Biographer depends on the accuracy of the blood glucose test used for calibration. Be sure to check your blood glucose meter and test strips according to the instructions. Your doctor may also want to check your meter against a standard lab test from time to time.
- If you question the finger-stick reading that you plan to use for calibration, repeat the finger-stick test.
- If you question a Biographer reading, use your regular blood glucose meter to do a finger-stick test. Keep in mind that Biographer readings correspond to blood glucose values from about 15 minutes earlier.

HEALTH CARE PROFESSIONAL INFORMATION

This section is meant for health care professionals. If you are a patient with diabetes, please read the Patient Information first. If you have questions about the Health Care Professional Information, ask a member of your health care team.

Health Care Professionals: Please read the Patient Information for the Warnings, Precautions, and Limitations. Patients must be able to use a standard blood glucose meter accurately before using the GlucoWatch® G2™ Biographer. Each patient must complete an Introductory Training Program (located in the *User's Guide*) before using the device. In addition, some patients may need further training on how to use the Biographer. The training needs of each patient should be assessed by the health care professional before prescribing this device. **4**

The GlucoWatch G2 Automatic Glucose Biographer qualifies for waived status under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

INTENDED USE

The GlucoWatch G2 Biographer is a glucose monitoring device indicated for detecting trends and tracking patterns in glucose levels in adults (aged 18 and older) with diabetes. This device is intended for use by patients at home and in health care facilities.

The Biographer is indicated for use as an adjunctive device to supplement, not replace, information obtained from standard home glucose monitoring devices.

The Biographer is indicated for use in the detection and assessment of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments, which may minimize these excursions. Interpretation of Biographer results should be based on the trends and patterns seen with several sequential readings over time.

OTHER IMPORTANT INFORMATION

- The device is for prescription use only.
- The device provides supplemental information that is not a replacement for blood glucose results obtained from standard home glucose monitoring devices.
- Changes in insulin therapy should not be made based solely on the Biographer results. Interpretation of Biographer results should be based on the trends and patterns seen with several sequential readings over time.
- The Biographer works differently than standard blood glucose meters (see Testing Principle Section). As a result, individual Biographer readings can differ substantially from blood glucose measurements taken at approximately the same time. These individual differences can be somewhat unpredictable and should be taken into account when interpreting results (see Performance Characteristics Section).
- Performance of the device can vary from use to use (ie, day 1 versus day 2) as well as within an individual 13-hour monitoring period.
- Mild to moderate skin irritation occurs in many patients.
- Skipped readings and unexpected shut offs may occur due to excessive perspiration, jarring, or dislodging of the device from the skin. **6**
- Performance of this device has been studied only in patients aged 18 and older.

Patients should be advised of when and how often to use the Biographer. Decisions about how to use the

Biographer in a patient's diabetes management program should take into account the patient's ability to operate the device correctly and to understand device limitations. The patient must also be willing to accept the mild to moderate skin irritation that can result from use of the Biographer.

The Biographer is appropriate for daytime and/or nighttime use on a routine, periodic, or situational basis.

- Routine use (ie, daily) should be considered for patients making frequent therapy adjustments based on glucose monitoring results and for patients subject to frequent problems with hypoglycemia and/or hyperglycemia
- Periodic use (ie, weekly) should be considered for patients with more stable glucose levels or simpler therapy regimens
- Situational use (ie, during a change in therapy) can be helpful in addressing specific treatment or educational issues with certain patients

The Biographer is designed to help your patients identify trends and patterns in their glucose levels. Biographer readings, although accurate most of the time, may occasionally differ significantly from finger-stick test results and therefore must be used with finger-stick blood testing. Using Biographer results solely could result in improper and potentially harmful treatment decisions.

In many instances, the Biographer is able to alert your patient to a hypo- or hyperglycemic episode. Remember, however, that Biographer results may occasionally differ significantly from finger-stick results, and that the magnitude of trending patterns may not always be registered by the Biographer. The Biographer should not be depended on as the sole source of information concerning these episodes.

INDIVIDUALIZATION OF TREATMENT

The decision to prescribe the GlucoWatch G2 Biographer should take into consideration the motivation and knowledge level of the patient and the patient's ability to understand the Warnings, Precautions, and Limitations described in this Product Information Sheet.

Carefully review target glucose values and the planned treatment program with each patient before advising the patient on when and how often to use the Biographer. Any change in treatment based on the alert capabilities of the Biographer should take into account any hearing difficulties the patient may have and the possibility that the Biographer may not detect all episodes of hypoglycemia or hyperglycemia.

A patient logbook is available to document the use plan and record results. A download terminal and software package (the GlucoWatch® Analyzer) is also available to facilitate interpretation of results.

While routine daily use may be appropriate for some patients, other approaches might include the following:

- Use on days when the patient's normal routine is disrupted (for example, during particularly busy periods or while traveling)
- Frequent use during periods of dose adjustment or other therapy transitions and then periodic (perhaps weekly) use for detailed profiles of glucose levels

- Regular use for several days to detect underlying problems in patients with higher than expected hemoglobin A_{1c} results relative to the patient's standard blood glucose testing results
- Nighttime use to investigate the causes of nocturnal or fasting hypoglycemia or hyperglycemia
- Educational use to show patients the effects of different dietary choices and activity levels

Detection of hyperglycemia and hypoglycemia

A trade-off exists between sensitivity and the frequency of alerts to which the patient must respond. The Low Glucose Alert level should generally be set 10 to 20 mg/dL above the level at which detection of low blood glucose is required. The alert level that is chosen for an individual patient should take into account any history of hypoglycemia unawareness, the rate at which the patient's glucose levels drop, and the activity level of the patient. Both the Low Glucose Alert level and the High Glucose Alert level can be easily changed as appropriate.

The specifics of the alert situation provide useful information for deciding how to respond to an alert. For example, in clinical trials the lower the Biographer reading the greater the probability that the subject was actually hypoglycemic based on the comparative blood result. When deciding how to respond to an alert, patients should be advised to consider symptoms they may be experiencing, the time since their last meal and insulin injection, and their current activity levels.

TESTING PRINCIPLE

The GlucoWatch G2 Biographer works through a process called reverse iontophoresis. This process allows the Biographer to collect glucose samples through intact skin by application of an extremely low electric current.

When current is applied, glucose molecules are pulled through the skin by charged molecules (positive and negative ions) and their surrounding medium—water. The ions migrate to gel collection discs placed at the anode (+) and cathode (-) in a single-use AutoSensor. The glucose molecules are then collected in these discs for analysis.

The gel collection discs contain the enzyme glucose oxidase. As glucose enters the discs, it reacts with the glucose oxidase in the gel to form hydrogen peroxide. A biosensor in contact with each gel collection disc detects the hydrogen peroxide generating an electronic signal. The Biographer uses a calibration value entered by the patient to convert the signal into a glucose measurement.

Calibration is performed with a standard blood glucose meter after a warm-up period of 115 minutes (about 2 hours). The Biographer will then complete a reading every 10 minutes for up to 13 hours. The result is a time-averaged measurement of glucose levels over the preceding 20 minutes.

Each reading is compared to adjustable Low and High Glucose Alert levels. If a reading is beyond either of these levels, an audible alarm will sound. The Down Alarm will sound if the glucose level is dropping such that the Low Glucose Alert level may be reached in the next 20 minutes.

PERFORMANCE CHARACTERISTICS

GlucoWatch G2 Biographer readings were compared to blood glucose (BG) tests performed twice per hour. Blood glucose was measured using the Hemocue® photometer, a point-of-care system that provides lab-quality results. Subjects in these studies were 18 years of age or older with either Type 1 or Type 2 diabetes requiring treatment with insulin. 85 subjects participated with each subject wearing up to 2 Biographers.

Detection of trends and patterns in glucose levels

The Biographer readings closely matched the direction and speed of changes reflected in the blood glucose data. The median correlation coefficient was 0.87.

The clinical utility of detecting trends and patterns in glucose levels is seen with an analysis of the alert capabilities of the device. It is important to set the alert levels in a conservative fashion. Thus, the Low Glucose Alert level should be set above the level at which detection of low blood glucose is required, and the High Glucose Alert level should be set below the level at which detection of high blood glucose is required.

For the Low Glucose Alert, results were analyzed using a definition of hypoglycemia as a BG measurement of 70 mg/dL or below on the home BG meter. At a Low Glucose Alert level of 80 mg/dL, 77% (126/164) of the events of hypoglycemia were detected by the Biographer (see TABLE II). In addition, the Biographer correctly identified the absence of hypoglycemia on 78% (1995/2559) of the occasions when BG was greater than 70 mg/dL. Greater detection of hypoglycemia can be obtained by setting the Low Glucose Alert level higher.

TABLE II	BG ≤70 mg/dL	BG >70 mg/dL
Biographer reading ≤80 mg/dL or Down Alert sounded due to projection that levels might reach 80 mg/dL within 20 minutes	126	564
Biographer reading >100 mg/dL	38	1995
Total	164	2559

Based on earlier studies, BG monitoring twice per day would have detected 19% of hypoglycemic events; BG monitoring four times per day, 39%. Thus, use of the Biographer to supplement standard BG monitoring can improve detection of hypoglycemia.

The Biographer can also improve detection of hyperglycemia. Postprandial hyperglycemia was common in an earlier home-use study. Out of 974 evaluable postmeal periods, 456 (47%) had a postprandial BG level of greater than 200 mg/dL and 238 (24%) had a postprandial BG level of greater than 250 mg/dL. None of these hyperglycemic events would be detected with standard premeal BG testing alone.

To assess Biographer detection of hyperglycemia, results were analyzed using a definition of BG ≥240 mg/dL. At a High Glucose Alert level of 180 mg/dL, 78% (212/272) of the events of hyperglycemia were detected by the Biographer (see TABLE III). In addition, the Biographer correctly identified the absence of hyperglycemia on 81% (1975/2437) of the occasions when BG was less than 240 mg/dL.

TABLE III	BG ≥240 mg/dL	BG <240 mg/dL
Biographer reading ≥180 mg/dL	212	462
Biographer reading <180 mg/dL	60	1975
Total	272	2437

Agreement between individual GlucoWatch G2 Biographer readings and blood glucose test results

Different methods were required to evaluate the performance of this noninvasive device than those used to assess standard BG monitoring systems. Typically, a single capillary whole blood sample is the source for glucose measurements by 2 comparative systems: the investigational device and a standard laboratory analyzer.

In studies of the Biographer, the time-averaged transdermal glucose readings were compared to capillary BG readings taken at specific time points. These differences in sample source, timing of readings, and comparison systems all impact the interpretation of study results.

Blood glucose measurements were taken at specific times so that they could be paired with Biographer readings for analysis. Agreement was analyzed using all the paired glucose measurements. For each data pair, the difference between the Biographer reading and the BG measurement was calculated as a percentage of the BG value.

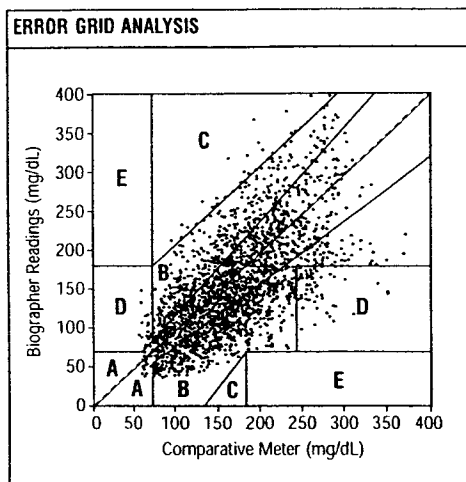
Regression analysis was used to characterize the relationship (slope and intercept) between the Biographer readings (dependent variable) and the comparative BG measurements (independent variable). Deming linear regression was used to account for variability in the comparative measurements.

The paired point results are summarized in TABLE IV.

TABLE IV	
Paired glucose measurements	2665
Mean absolute difference	24.5%
Deming regression slope (95% confidence interval)	0.92 (0.89, 0.96)
Deming regression intercept (95% confidence interval)	4.5 mg/dL (-0.9, 9.7)

Substantial variability was observed in the difference between individual Biographer readings and the paired comparative BG measurements. This can be seen in the correlation plot below.

Correlation plot of GlucoWatch G2 Biographer readings versus BG measurements
(N=2665 Paired Points)



Some of the variability in agreement is related to the differences in sample source, timing of readings, and accuracy of the comparative devices. However, analyses have indicated that performance of the Biographer can vary from use to use (ie, day 1 versus day 2) and within an individual 13-hour monitoring period.

The amount of variability was analyzed by looking at the percentage of Biographer readings falling within 20% and within 30% of the comparative BG measurement (or within 20 mg/dL in the low BG range). Results are shown in TABLE V.

BG range (mg/dL)	# of paired points	% within 20%*	% within 30%*
Overall	2665	52%	69%
41-80	238	55%	55%
81-120	680	54%	71%
121-240	1489	52%	70%
>240	258	47%	64%

* For the low glucose range (41-80 mg/dL) the value shown is the percent within 20 mg/dL.

The Clarke Error Grid was used to assess the clinical relevance of the differences between the Biographer readings and the comparative BG measurements.² The Error Grid divides a correlation plot into 5 zones (see TABLE VI).

Results in zones A and B are considered clinically acceptable while results in zones C, D, and E are potentially dangerous and therefore clinically significant errors. The Error Grid zones are labeled on the correlation plot.

Zone	Description	
A	Clinically accurate, would lead to correct treatment decisions	≤20% difference versus comparative BG measurement*
B	Would lead to benign decisions or no treatment	>20% difference versus comparative BG measurement
C	Would lead to overcorrection of normal glucose levels	
D	Would lead to failure to detect and treat high or low glucose levels	
E	Would lead to erroneous treatment decisions	

* Also includes all points where both measurements are in the hypoglycemic range (≤70 mg/dL).

The percent of Biographer readings within the clinically acceptable zones (A and B) was 95%. No points were in the erroneous treatment zone (E).

To assess the clinical relevance of Biographer performance at high and low glucose levels, the Error Grid results were stratified by BG range. TABLE VII shows the overall distribution of points by Error Grid zone along with stratified results by four BG ranges.

BG range (mg/dL)	# of paired points	A+B	A	B	C	D	E
Overall	2665	95%	51%	43%	1%	4%	0.0%
41-80	238	76%	47%	30%	0.0%	24%	0.0%
81-120	680	99%	54%	45%	1%	Not applicable	
121-240	1489	98%	52%	47%	2%		0.0%
>240	258	77%	47%	30%	0.8%	22%	0.0%

95% of the Biographer readings were in the clinically acceptable zones (A and B). Four percent (4%) of Biographer readings fell into zone D. Most of the zone D results occurred in the low range when the Hemocue BG was below 70 mg/dL and the Biographer reading was greater than 70 mg/dL. This type of low-range zone D error has also been seen with standard home BG meters.³

Precision of GlucoWatch G2 Biographer readings

Precision was estimated by comparing readings from 2 Biographers worn simultaneously at different skin sites. TABLE VIII shows the median within individual results.

Average Biographer reading (mg/dL)	# of individuals	# of paired points	Median standard deviation	Median (range) percent coefficient of variation
Overall	55	2541	15 mg/dL	11% (5%, 35%)
41-80	35	218	9 mg/dL	14% (3%, 31%)
81-120	50	706	12 mg/dL	12% (0%, 37%)
121-240	54	1393	14 mg/dL	9% (4%, 26%)
>240	29	224	23 mg/dL	8% (1%, 34%)

The variability between paired Biographer readings increases as a function of glucose range. All covariances for each individual were <37%, both overall and within each glucose range. Note that this experimental method includes additional sources of variability compared to the standard precision study in which repeated measurements are made from a single sample of capillary blood.

Skin irritation and extended wear

Most subjects experienced mild to moderate skin irritation (erythema and edema) at the extraction and adhesive sites after use of the device. Erythema, classified as strong or intense, was seen in less than 10% of the extraction and adhesive sites. Strong edema was seen in less than 1% of the extraction and adhesive sites. The irritation was temporary and resolved within a few days. There was no indication of contact sensitization.

An extended wear study was conducted with an earlier version of the device in which subjects (n=15) wore the Biographer daily for 6 weeks. Four in-clinic accuracy studies were completed on days 1, 15, 30, and 43. No significant changes were observed in any accuracy measure or in skin irritation scores during the 6-week study period.

Patients should be advised to rotate wear sites for the device. The Biographer should not be applied to any site where visible irritation remains from a previous use. Irritated skin sites should be kept clean, dry, and protected from the sun. Over-the-counter topical hydrocortisone products or other lotions can be used after removing the Biographer.

Skipped readings and unexpected shut off of glucose monitoring

The GlucoWatch G2 Biographer automatically analyzes each glucose reading to ensure that the device is operating properly. If a problem is identified, the glucose reading is skipped and the word **SKIP** appears on the Biographer display. Approximately 21% of readings were skipped.

If a problem is identified with the Biographer leading to be used for calibration, the calibration process must be repeated. Approximately 8% of Biographer uses required more than one calibration attempt. Infrequently (1% of Biographer uses) the calibration process was unable to be completed.

Certain problems (eg. heavy perspiration) can cause the Biographer to discontinue glucose monitoring before the end of the 13-hour monitoring period. Approximately 16% of Biographer uses ended with an unexpected shut off of monitoring. Individualization of the wearing schedule for each patient may result in a lower occurrence of unexpected shut offs.

Even with skipped readings and unexpected shut offs, the Biographer provided an average of 55 glucose

readings (out of a maximum of 76) per use.

8

Selection of calibration blood glucose meters

As part of each use, the GlucoWatch G2 Biographer must be calibrated with the results of a finger-stick BG test performed with a standard home meter. This calibration step accounts for variability in skin permeability both between users and between different skin sites on each user. Any inaccuracy in the calibration BG test will affect the accuracy of all the readings provided by the Biographer during that use period.

Clinical trials with an earlier version of the device have included an assessment of calibration of the Biographer using results from 4 home glucose meters: the One Touch® Profile®, the Accu-Chek® Advantage®, the Precision QID®, and the Glucometer Elite®. No significant difference in the accuracy of the Biographer was seen based on calibration with the results from these 4 meters. However, some home meters are designed to provide results in plasma-equivalent units rather than whole-blood measurements. If the Biographer is calibrated with a meter that provides results in plasma units, the glucose readings provided by the Biographer will also be in plasma units.

Tolazamide and dopamine

Bench-top experiments have shown that both tolazamide (but not other sulfonylureas) and dopamine (when used therapeutically but not at normal blood levels) have the potential to be extracted through the skin and could possibly interfere with the biosensor used in the GlucoWatch G2 Biographer. This is related to the size, charge, and lipid solubility of these 2 molecules.

Decreasing blood levels of tolazamide or dopamine following calibration could cause Biographer readings to be lower than the actual BG levels. If tolazamide or dopamine blood levels increase during the monitoring period, the Biographer readings may be higher than the actual BG levels. No clinical studies have been conducted to investigate this potential interaction.

Electromagnetic compatibility

Standard bench-top tests have not detected any evidence of interference in the operation of the GlucoWatch G2 Biographer due to electromagnetic fields created by other devices or equipment. However, these tests do not fully simulate all possible electromagnetic effects of procedures such as radiographs or magnetic resonance imaging. Clinical

judgment should be used when deciding if the Biographer should be removed before performing such procedures.

SPECIFICATIONS

The *User's Guide* includes complete specifications. Select specifications follow.

- **Power supply:** 1 alkaline or rechargeable nickel metal hydride AAA battery.
- **Result range:** 40 mg/dL to 400 mg/dL (2.2 mmol/L to 22.2 mmol/L). Out of range results will sound the alarm and the display will show **<40 mg/dL or >400 mg/dL**.
- **Calibration range:** 41 mg/dL to 279 mg/dL (2.3 mmol/L to 15.5 mmol/L).
- **Memory:** Storage capacity of >8,500 data points, including test results, event codes, or error messages (oldest reading deleted first).

References: 1. American Diabetes Association. Standards of medical care for patients with diabetes mellitus. *Diabetes Care*. 2000;23:S32-S42. 2. Clarke WL, et al. Evaluating clinical accuracy of systems for self monitoring of blood glucose. *Diabetes Care*. 1987;10:622-628. 3. Brunner GA, et al. Validation of home blood glucose meters with respect to clinical and analytical approaches. *Diabetes Care*. 1998;21:585-590.

Hemocue is a registered trademark of Aktiebolaget Leo (Helsingborg, Sweden); One Touch and Profile are registered trademarks of Johnson & Johnson (New Brunswick, NJ); Accu-Chek and Advantage are registered trademarks of Roche Diagnostics GmbH (Mannheim, Germany); Precision QID is a registered trademark of MediSense Inc. (Waltham, MA); Glucometer Elite is a registered trademark of Bayer Corp. (Elkhart, IN).

If you have any questions, please call our Customer Service Department toll free at 1-866-GLWATCH (1-866-459-2824).

The GlucoWatch G2 Biographer, AutoSensors, other components, and their use are protected under one or more of the following U.S. Patents: 5,730,714, 5,735,273, 5,771,890, 5,827,183, 5,954,685, 6,023,629, 6,141,573, 6,144,869, 6,180,416, 6,201,979, 6,233,471, 6,298,254, 6,299,578, 6,309,351, 6,326,160, 6,341,232, 6,356,776, 6,370,410, Des 437,603. Other patents pending. Refer to box label for Terms and Conditions and use restrictions.



A map of the G2 Biographer displays

You can reach most of the screens of the GlucoWatch® G2™ Biographer by simply pressing the **Up** or **Down** buttons repeatedly. In cases you get lost, simply refer to the map of the screens of the Biographer system on the other side of this page to determine where to go next.



Tip: To return to the time and date screen at any point:

- Press the **Start** button and the time and date display will reappear.
- OR
- Don't press any buttons for 30 seconds. In most situations, the time and date display will reappear automatically.

GLUCOWATCH® G2™

AUTOMATIC GLUCOSE BIOGRAPHER

USER'S GUIDE



References: 1. Data on file, Cygnus, Inc., Redwood City, CA. 2. American Diabetes Association. Standards of medical care for patients with diabetes mellitus. Diabetes Care. 2000; 23:1337-542.

DESIGNED BY
CYGNUS

Manufactured by
Cygnus, Inc.
4800 Faber Place Drive
Redwood City, CA 94061

June 1999

Printed in U.S.A.

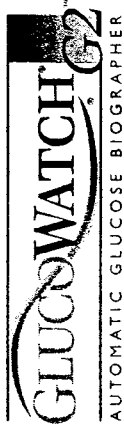
AW214101

55

56

0110054

AW 2241-01 Rev A
Effective 6/21/02
ECN # 9455



User's Guide

2

This pocket holds a Product Information sheet that contains important information, including warnings and precautions. A new Product Information sheet will be included inside each new box of GlucoWatch* AutoSensors. Check each new Product Information sheet for new information about using your GlucoWatch* G2™ Biographer.

Serial number: Write the Serial number from your Biographer here. _____

Reference number: Write the Reference number from your Biographer here. _____

Passcode number: Write the Passcode number you receive after completion of the Introductory Training Program Questionnaire here. _____

Important Operating Instructions

Be sure to read this entire booklet. It provides complete instructions for operating and maintaining your GlucoWatch G2 Biographer.

For 24-hour product support, contact our Customer Service Department toll free at 1-866-GLWATCH (1-866-459-2824).

3

01-0055

Read me first for important instructions on getting started with the G2 Biographer

A new kind of freedom for millions of people with diabetes

Congratulations! By choosing the GlucoWatch® G2™ Automatic Glucose Biographer, you've taken an important step toward better diabetes management. The GlucoWatch G2 Automatic Glucose Biographer is a glucose monitoring device that takes readings noninvasively through your skin, providing automatic glucose readings for up to 13 hours at a time. There are 2 main parts to the GlucoWatch G2 Biographer: the Biographer, the watch-like device that measures glucose, and the AutoSensor, that snaps into the Biographer and sticks to the skin, which provides glucose readings and must be replaced every time you wear the Biographer.

The G2™ Biographer can provide a more complete picture of your glucose levels. The Biographer can be used during your normal daily routine (while awake or asleep) at home or at work. These frequent automatic readings detect trends and track patterns in glucose levels, which can help you to manage your diabetes better.

Be aware that the Biographer readings can sometimes be different than finger-stick test results. When it is time to make an important decision, such as insulin dose determination, you should confirm that reading with your home blood glucose meter. While the Biographer is intended to supplement—not replace—conventional monitoring, it does provide more information about your glucose levels than was ever practical before.

To get started using the GlucoWatch G2 Automatic Glucose Biographer, you'll need to review the *Introductory Training Program* chapter of this *User's Guide* and complete the questionnaire located at the end of the chapter. After calling the toll-free number 1-866-GLWATCH (1-866-459-2824) with your answers, you will be given your individual passcode number that is needed to activate your Biographer for the first time. Detailed instructions on activating the Biographer can be found in Chapter 2 of this guide.

You will need a fully charged nickel metal hydride (NiMH) AAA battery to activate the Biographer. It will take roughly 3 hours to charge, so we suggest charging the batteries while you read the *Introductory Training Program* chapter. Detailed instructions on charging the batteries can be found in Chapter 2 of this guide.

Your GlucoWatch® G2™ Biographer Starter Kit, which includes this booklet, provides everything you need to know about the GlucoWatch G2 Biographer. Watch the videotape for an easy-to-follow run-through on the use and operation of your Biographer.

If you have any questions please visit our Web site www.glucowatch.com or call our Customer Service Department toll free at 1-866-GLWATCH (1-866-459-2824).

Contents at a glance

Chapter 1.

Introductory Training Program

Why is it necessary to complete the *Introductory Training Program*?..... 1.1

A review of some basic concepts about blood glucose..... 1.2

What is the G2 Biographer?..... 1.3

How does the G2 Biographer work?..... 1.4

What is the G2 Biographer used for?..... 1.4

Alerting you to changes in your glucose levels..... 1.5

What are some important considerations when using the G2 Biographer?..... 1.6

How is the G2 Biographer different from finger-stick blood glucose meters?..... 1.7

Understanding the lag time concept..... 1.9

How do G2 Biographer readings compare to blood glucose values?..... 1.10

How does lag time contribute to differences between G2 Biographer readings and finger-stick readings?..... 1.12

How much of a difference should I expect to see between G2 Biographer readings and finger-stick readings?..... 1.14

How important are the differences between G2 Biographer readings and finger-stick tests?..... 1.14

What do the different zones mean?..... 1.15

Working the G2 Biographer into your daily routine..... 1.16

Introductory Training Program Questionnaire..... 1.21

Precautions and warnings..... 1.24

Chapter 2.

The Basics

What's in your Starter Kit?..... 2.2

Charging the batteries..... 2.3

Battery life..... 2.6

The back of your G2 Biographer..... 2.7

Turning the G2 Biographer on..... 2.9

Inserting a battery into the G2 Biographer..... 2.9

Entering a passcode..... 2.10

The front of your G2 Biographer..... 2.11

Setting the time and date..... 2.13

Getting to the time and date screen..... 2.13

Setting the current time and date..... 2.13

Practice putting on your G2 Biographer and fastening the band..... 2.15

Choosing a wear site for your G2 Biographer..... 2.16

Changing the watchband.....	2.18
Setting an Event marker.....	2.20
Running a System Check.....	2.21
Power-save mode.....	2.23
Activating the power-save mode.....	2.23
Power levels.....	2.24
Chapter 3. Time to Monitor	
Before monitoring.....	3.1
Basic steps for getting started.....	3.2
A look at the AutoSensor.....	3.3
Removing the AutoSensor from the pouch.....	3.3
Using the AutoSensor Press.....	3.6
Connecting the AutoSensor.....	3.7
Cleaning the wear site.....	3.7
Removing protective liner 2.....	3.7
Before putting on the G2™ Biographer.....	3.9
Putting on the G2 Biographer.....	3.10
Starting the warm-up period.....	3.11
Problems that can occur during the warm-up period.....	3.12
Functions that can be entered or changed during the warm-up period.....	3.13
Checking how much time is left in the warm-up period.....	3.13
When is it time to calibrate?.....	3.14
If your calibration value isn't accepted.....	3.15
How to tell that the G2 Biographer is calibrated.....	3.15
Problems that can occur while the G2 Biographer completes the first internal measurement.....	3.15
Reasons for failed calibrations.....	3.16
Checking on the status of the G2 Biographer.....	3.18
Viewing your glucose readings.....	3.20
Stopping monitoring.....	3.21
Removing the G2 Biographer.....	3.21
Ensuring the accuracy of your G2 Biographer readings.....	3.22
Chapter 4. Using the Glucowatch® G2™ Biographer Alert System	
The Alarm Clock feature.....	4.3
To set the alarm clock.....	4.3
To disable the alarm clock.....	4.4
The High Glucose Alert.....	4.4
Changing the High Alert level.....	4.5
The Low Glucose Alert.....	4.6

5

Changing the Low Alert level.....	4.6
The Down Alert.....	4.8
The Hypoglycemia/Perspiration Alert.....	4.9
Frequency of alerts.....	4.10
Chapter 5. Troubleshooting	
How the G2 Biographer identifies potential problems.....	5.1
When the G2 Biographer skips a reading.....	5.2
Codes for a skipped reading.....	5.2
When glucose measurement stops unexpectedly.....	5.3
Codes for problems that stop glucose measurements unexpectedly.....	5.4
Recalibrating the G2 Biographer.....	5.5
For a voluntary recalibration.....	5.6
For a forced recalibration.....	5.7
Conducting a Quality Control Test on your AutoSensors.....	5.8
Chapter 6. Special Functions	
Changing the G2 Biographer settings.....	6.1
Understanding the beep.....	6.1
Understanding the Alert option.....	6.2
Changing the settings.....	6.4
Entering the SET MODE.....	6.4
Selecting a language.....	6.4
Selecting units of measurement for glucose: mg/dL or mmol/L.....	6.4
Selecting a 12-hour (AM/PM) or 24-hour clock format.....	6.5
Selecting day/month or month/day format.....	6.5
Selecting the beep.....	6.5
Selecting the Alert option.....	6.5
Saving the settings.....	6.5
Chapter 7. Additional Information	
Caring for and storing your G2 Biographer.....	7.1
Skin care tips.....	7.2
Codes for problems with the G2 Biographer's memory.....	7.3
Resetting your G2 Biographer.....	7.4
Questions and answers.....	7.4
Testing principle.....	7.5
Specifications.....	7.9
Warranty information.....	7.10
Warnings and precautions.....	7.12
Index.....	7.14
A map of G2 Biographer displays.....	7.17



*Why is it necessary to complete the
Introductory Training Program?*

Using new technology, the GlucoWatch® G2™ Biographer gives you more information about your body's glucose levels than you've ever had before. It's important to understand what this information means and how to use this information so that you and your diabetes care team can continue to work toward improving your diabetes control.

The Introductory Training Program is designed to review basic concepts about blood glucose patterns and to provide you with important information about the G2™ Biographer.

The Introductory Training Program answers questions about the following topics:

- What is the GlucoWatch G2 Biographer?
- How does the Biographer work?
- What is the Biographer used for?
- What are some important considerations when using the Biographer?
- How is the Biographer different from finger-stick blood glucose meters?

Warning:

This device is not designed to replace your regular blood glucose meter. The GlucoWatch G2 Biographer must be used with your blood glucose meter. Together, they can give you more information about glucose levels. You and your health care team may be able to use this information to manage your diabetes better.

**A review of some basic concepts
about blood glucose**

What makes your blood glucose go up and down?

Everyone's blood glucose levels go up and down a little throughout the day, but if you're a person with diabetes, these ups and downs can have important consequences. They can make you feel bad and eventually cause serious health problems.

What can cause glucose levels to go up?	What can cause glucose levels to go down?
Stress	Diabetes medicines
Illness	Insulin
Eating food	Exercise

People with diabetes need to balance the "ups" and the "downs" to help stabilize blood glucose levels throughout the day and night.

How do changes in blood glucose make you feel?

When your blood glucose is too high...

- You may feel sleepy, thirsty, or grumpy
- You may experience blurred vision
- You may feel the need to urinate often

6

When your blood glucose is too low...

- You may feel dizzy, shaky, sweaty, or confused
- You may experience changes in your vision

7

It's often hard to tell one set of feelings from the other; you just know that you don't feel good! That's why it's helpful to have a tool that gives you more information about whether you are "too high" or "too low."

Before, the only way to check your own glucose levels was with a blood glucose meter. The GlucoWatch® G2™ Biographer can help you know more about ups and downs in your glucose levels to help you meet your glucose goals.

What are good target glucose goals?

You will need to work with your diabetes care team to determine your specific target glucose goals. These goals may change depending on certain conditions, such as pregnancy, your overall health, and the type of blood glucose meter you use.

Ask your diabetes care team to help you set goals that are right for you...

- Before meals
- 1 or 2 hours after meals
- Before/after exercise
- At bedtime
- During the night

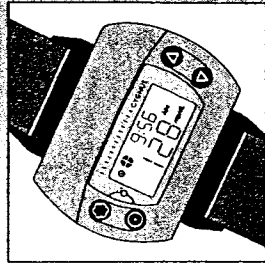
What is the G2 Biographer?

The G2™ Biographer is a glucose monitoring device that is worn like a watch and helps detect trends and track patterns in your glucose levels. Glucose readings are taken noninvasively through the skin. The Biographer provides automatic glucose readings for up to 13 hours at a time.

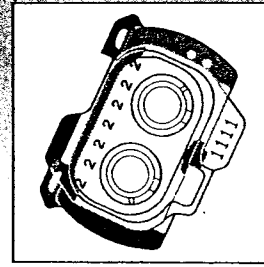
The GlucoWatch G2 Biographer has 2 main parts:

Biographer

This is the device that measures glucose. It is worn on the forearm like a watch.



Biographer



AutoSensor

AutoSensor

This is a plastic part that snaps into the Biographer and sticks to the skin. Each AutoSensor provides up to 13 hours of readings and must be replaced every time the Biographer is worn.

How does the G2 Biographer work?

- **The GlucoWatch® G2™ Biographer attracts, collects, and measures glucose**
An extremely low electric current pulls glucose through the skin. The glucose is collected in 2 gel discs in the AutoSensor. An electrode in the AutoSensor measures the glucose
- **The G2™ Biographer keeps track of glucose readings**
Each glucose reading is stored in memory. Readings can be viewed with the touch of a button
- **The Biographer allows you to set personal glucose alert levels**
Before using the Biographer, you and your diabetes care team need to establish High and Low Alert levels. The Biographer compares each 10-minute reading with these preprogrammed High and Low Alert levels
- **The Biographer sounds an alarm if glucose readings are:**
 - Below the Low Alert level
 - Above the High Alert level
 - Likely to drop below the Low Alert level in the next 20 minutes
 - Followed by perspiration when previously in the Low or Down Alert level

8

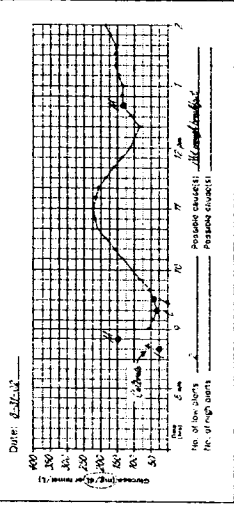
What is the G2 Biographer used for?

Detecting trends and tracking patterns in your glucose levels
The Biographer detects trends and tracks patterns in your glucose levels. The Biographer can be used during your normal daily routine (while awake or asleep) at home or at work. The frequent readings provided by the Biographer may help you manage your diabetes better. By identifying trends and patterns in your glucose levels, you and your diabetes care team can determine whether your current treatment program is the best one for you.

1.4

01-0060

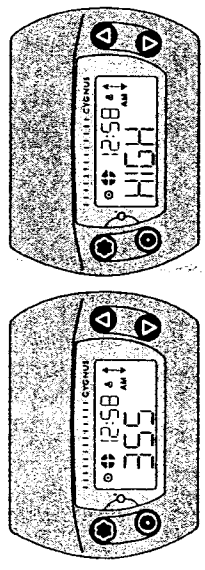
Sample monitoring period



Alerting you to changes in your glucose levels

The Biographer can alert you if your glucose readings are not within your preset target range. If your glucose goes above or below your High or Low Alert level, the Biographer will beep and alternately flash your glucose reading with the word **HIGH** or **LOW**.
It can also alert you when your glucose levels are likely to drop below the Low Alert level in the next 20 minutes. The Biographer will beep and alternately flash your glucose reading with the word **DOWN**.

The Alert feature can help keep you informed of important changes in your glucose that you otherwise may not have been aware of.



Example of the High Glucose Alert

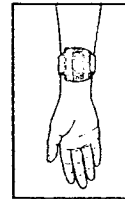
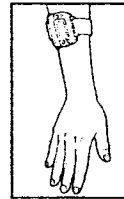
The G2 Biographer is meant for use by adults (aged 18 and older) with diabetes. This is because the Biographer has so far only been studied in adults.

9

1.5

What are some important considerations when using the G2 Biographer?

- There are a number of important factors you should consider:
- A warm-up period of nearly 2 hours is required each time you use the Glucowatch® G2™ Biographer. You will not get glucose readings during the warm-up period. The G2™ Biographer must remain securely fastened to your forearm during both the warm-up and monitoring periods. You cannot shower, bathe, or swim during the 2-hour warm-up period because you will be wearing the Biographer during this time
 - Perspiration may cause skipped readings. Very high levels of perspiration may cause the Biographer to stop monitoring completely. The alarm will sound if perspiration causes a skipped reading or a shut-off. Remember that perspiration can be one of the symptoms of low blood glucose
 - The Biographer should never be immersed in water. The Biographer is splash resistant, not waterproof. This means the Biographer should not be worn while showering, bathing, or swimming
 - Hearing the Biographer alarm can be difficult if there is too much background noise, if the Biographer is under a pillow or blanket, or for someone with hearing loss. In these situations, the alarm will stay on and beep faster and faster until a button is pressed to shut it off
 - Because of the way the Biographer measures glucose through your skin, you may experience some effects on your skin. The low-level electric current may cause some skin irritation (redness, itching, and/or small blisters) after use. Symptoms generally disappear within a few days, but may linger longer for some people. If you wear the Biographer frequently, you may have several spots of irritation at any one time, especially if you have very fair or sensitive skin
 - You must change the place that you wear the Biographer each time. Do not place it on any site where skin is irritated from an earlier wearing. The Biographer should only be placed on sites with normal, healthy skin. Avoid sites with skin abnormalities such as eczema, cuts, sunburn, or scarring
 - Persons with substantial hair on their arms will need to remove the hair. To avoid a "patchy" look, some users prefer to remove the hair from the entire forearm. This should be done at least 24 hours before wearing the Biographer. Otherwise, any skin irritation that occurs may be worse than normal



You may wear the Biographer on either side of your arms

10

- Irritated skin can be treated by applying lotion after using the Biographer. Over-the-counter hydrocortisone preparations may reduce any itching or inflammation
- The Biographer has been studied only in adults (aged 18 and older). Studies have included over 1,400 uses of the Biographer by hundreds of people with diabetes. No change in accuracy or skin irritation was seen during these studies. No studies have yet been done for longer than 6 weeks.**

How is the G2 Biographer different from finger-stick blood glucose meters?

The Biographer works very differently from finger-stick blood glucose meters. Understanding all of these differences is essential for proper use of the Biographer.

A blood glucose meter:	The GlucoWatch G2 Biographer:	This difference is important because:
Measures glucose in blood	Measures glucose collected through skin	Skin glucose levels can be a little different from blood glucose levels. They may not get as high or as low
Uses a drop of blood from your finger	Uses fluid collected through the skin on your arm	Glucose levels can be different between the finger and arm, especially during times of rapid change, like after meals
Tells you your present glucose level	Tells you your average glucose level measured during the last two 10-minute readings	It causes a delay (known as "lag time") between blood glucose levels and Biographer readings
Gives you one reading at a time	Provides automatic readings as often as every 10 minutes for up to 13 hours	With frequent and automatic readings, you can track the trends and patterns in your glucose levels

12

Understanding the lag time concept

As you learned earlier, the Biographer automatically monitors your glucose levels every 10 minutes for up to 13 hours.

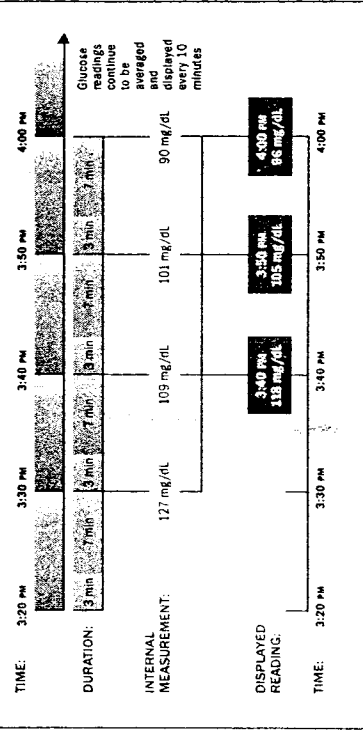
13

Biographer readings are different than readings from a regular blood glucose meter. Biographer readings involve a concept called "lag time." This means that each Biographer reading corresponds to a blood glucose value from about 15 minutes earlier (exact lag times may vary from patient to patient).

Lag time results from the fact that the Biographer initially averages the glucose values of two 10-minute periods. Each 10-minute period includes 3 minutes for glucose collection and 7 minutes for glucose measurement. At the end of each 10-minute cycle, the Biographer provides a time-averaged glucose reading.

This 15-minute lag time can be important when your glucose levels are falling rapidly. Keep lag time in mind as you select your Low Alert level.

A "running average" of glucose levels is kept to provide readings as frequently as every 10 minutes



How is the G2 Biographer different from finger-stick blood glucose meters? (continued)

GlucoWatch® G2™ Biographer readings should not be used in the same way as finger-stick results. The G2™ Biographer is designed to help detect trends and track patterns in your glucose levels. Most Biographer readings are similar to finger-stick test results taken around the same time. But some Biographer readings will differ from finger-stick tests. This difference can be important for proper treatment.

Managing diabetes means that you must make treatment decisions every day. Unfortunately, these treatments can sometimes cause problems. For example, too much insulin can result in low glucose levels, and not enough can result in high glucose levels.

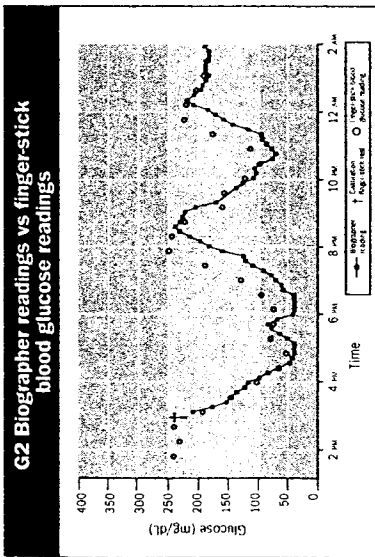
When it is time to make an important decision, such as changing your insulin dose, the Biographer should not be used as a substitute for a finger-stick test. The Biographer must be used together with finger-stick blood testing. Then you can make the best treatment decisions and reduce the chance of problems.

IMPORTANT: Always check the last few readings in the Biographer memory to see the current trends in your glucose levels. One reading cannot tell you how quickly your glucose levels are changing. A trend arrow (↑) or (↓) will help you determine whether you are going up or down. If you question the Biographer results, be sure to confirm the Biographer readings with your regular blood glucose meter.

How do G2 Biographer readings compare to blood glucose values?

In clinical studies, GlucoWatch® G2™ Biographer readings were compared to blood glucose values obtained using finger-stick tests performed once or twice per hour. To compensate for lag time, finger-stick measurements were taken about 15 minutes before G2™ Biographer readings.

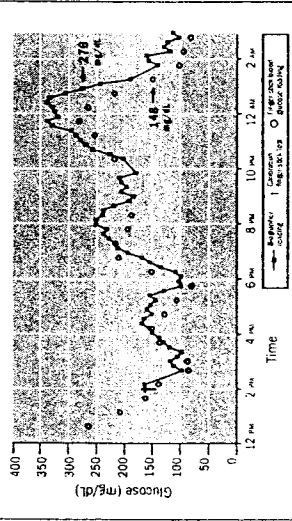
The graph below shows an example of clinical study results. Biographer readings are connected by lines, while finger-stick test results are shown as individual circles.



As you can see, the glucose trend seen with the Biographer closely matched the results obtained from finger-stick testing. However, some individual Biographer readings differed quite a bit from finger-stick tests taken around the same time.

Because of lag time, this difference will be greater when your glucose levels are changing. On the graph below, a finger-stick test result was 148 mg/dL when the Biographer reading was 276 mg/dL. However, the next 3 Biographer readings were 245 mg/dL, 190 mg/dL, and 141 mg/dL, showing that glucose levels were dropping rapidly.

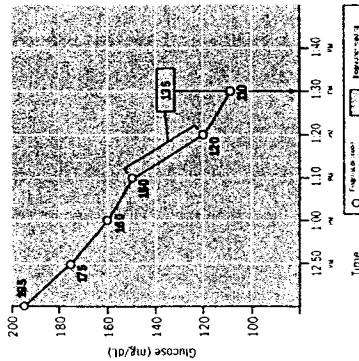
Differences in timing can result in large differences in values (G2 Biographer readings vs finger-stick readings)



How does lag time contribute to differences between G2 Biographer readings and finger-stick readings?

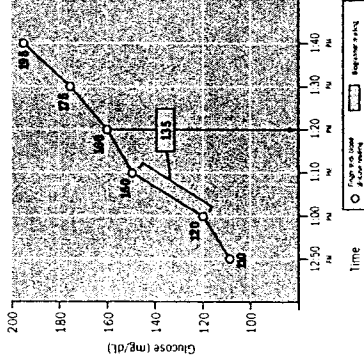
Glucowatch® G2™ Biographer readings and finger-stick blood glucose readings differ most when your glucose levels are changing rapidly, such as after eating or when you are taking rapid-acting insulin. This is due to lag time. The graphs below give examples of how, depending on your current glucose trend, lag time can cause G2™ Biographer readings to differ from finger-stick readings.

Example 1: Falling Glucose



In Example 1, the Biographer reported a reading of 135 mg/dL (the average of 150 mg/dL and 120 mg/dL) at 1:30 PM. However, because of lag time, the blood glucose level when taken with a finger-stick test was 110 mg/dL.

Example 2: Rising Glucose



In Example 2, the Biographer reported a reading of 135 mg/dL (the average of 120 mg/dL and 150 mg/dL) at 1:20 PM. However, because of lag time, the blood glucose level when taken with a finger-stick test was 160 mg/dL.

To properly account for lag time, you should always look at the past few glucose readings in order to determine the speed and direction that your glucose level is changing. If you look at only one glucose reading, you will not necessarily know how your glucose level is changing.

It is also important to take lag time into account when choosing a Low Alert level. Choosing alert levels is discussed in more detail on page 4.6.

What do the different zones mean?

Zone	Which means	% of Biographer readings
A	Accurate. Biographer within 20% of finger-stick test result (or both measurements below 70 mg/dL)	51% (1,389 out of 2,665)
B	Acceptable. Difference greater than 20% but Biographer reading would not lead to a bad decision	43% (1,115 out of 2,665)
C	Might cause "over-correction" of normal glucose levels. Finger-stick test result in normal range, but Biographer reading is high or low	1% (32 out of 2,665)
D	Failure to detect a high or low glucose level. Biographer reading in the normal range, but finger-stick test result is high or low	4% (113 out of 2,665)
E	Treatment error could occur. Biographer reading high when finger-stick test is low, or Biographer reading is low when finger-stick test is high	0% (0 out of 2,665)

Biographer readings were found to be accurate (Zone A) or acceptable (Zone B) 95% of the time. This shows that, despite differences between individual Biographer readings and finger-stick test results, the Biographer still provides you with a great amount of reliable information regarding your glucose levels.

How much of a difference should I expect to see between G2 Biographer readings and finger-stick readings?

It is best to look at the percentage difference between GlucoWatch® G2™ Biographer readings and finger-stick readings rather than the actual difference in units of measure. For example, a difference of 40 mg/dL is a 50% difference when your glucose level is 80 mg/dL, but it is only a 10% difference when your glucose level is 400 mg/dL.

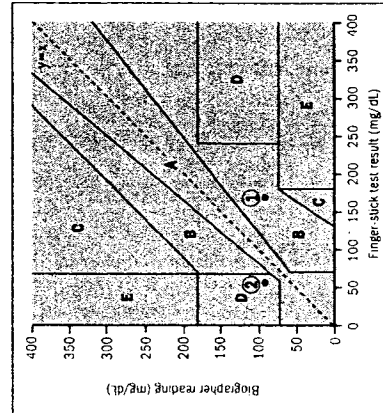
In a clinical study¹ comparing 2,665 G2™ Biographer readings with finger-stick readings, 85 people with diabetes wore 2 Biographers at the same time. The average percentage difference between the Biographer and finger-stick test results was 24.5%. About 3 in 10 Biographer readings were different from finger-stick test results by more than 30%.

How important are the differences between G2 Biographer readings and finger-stick tests?

Diabetes experts developed a grading system in the 1980s, when home blood glucose monitoring first became popular. Glucose readings from 2 different systems are plotted on one graph; the "paired point" intersection will fall into 1 of 5 different zones. Each zone is "graded" as to its clinical significance.

The graph below shows 2 different Biographer readings compared to corresponding finger-stick readings:

- ① — Biographer reading = 100 mg/dL; Finger-stick test result = 160 mg/dL. Difference = 60 mg/dL (Zone = B).
- ② — Biographer reading = 100 mg/dL; Finger-stick test result = 65 mg/dL. Difference = 35 mg/dL (Zone = D).



1.14

**Working the G2 Biographer
into your daily routine**

How can the GlucoWatch® G2™ Biographer be used to help improve diabetes management?

You and your diabetes care team can look at trends and patterns in your glucose levels over a period of time and determine the effects of meals, exercise, stress, sleep, and medications on your diabetes control.

While wearing the G2™ Biographer, you will be able to learn about your glucose levels at times you might not normally check your blood (for example, while sleeping, driving, or after meals).

Once the Alert levels are set appropriately, the Biographer can help detect low or high glucose events that you might not be aware of with regular finger-stick testing alone.

IMPORTANT: Be sure to select the High and Low Alert levels carefully, in consultation with your health care team. When deciding on a Low Alert level, be sure to choose a number 10 mg/dL to 20 mg/dL above the blood glucose level that you want to detect. Example: To detect a level of 60 mg/dL, set the Low Alert level at 70 mg/dL or 80 mg/dL. Otherwise, the Biographer may miss some low blood glucose events and the alarm will not sound.

How can the Biographer be used to help improve diabetes management if you take insulin?

The Biographer can help detect trends and track patterns in glucose levels to help your diabetes care team decide whether changes in your insulin regimen are needed. For example, Biographer readings may be helpful in deciding if your long-acting or basal insulin treatment is right for you. However, the Biographer is not meant to be the only source of information to determine whether you need to adjust your insulin dose on a given day.

For example, some people use a blood glucose test result to determine an insulin dose before each meal. This is often called a sliding scale or an insulin algorithm. If you use this method, be sure to confirm the Biographer reading with your regular blood glucose meter to make sure that you take the right amount of insulin.

IMPORTANT: Do not make fundamental changes in your treatment program without first talking to your health care team. Serious illness or accidents may result.

When is the best time to wear the Biographer?

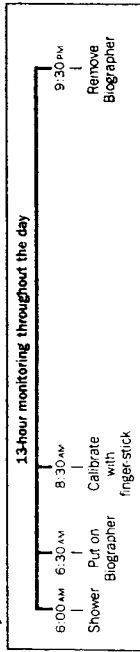
The Biographer can be worn anytime during your normal daily routine (while awake or asleep) at home or at work. It's important that you consult your diabetes care team about when to wear the Biographer. Together, you may decide that you should wear the Biographer:

- Every day, if you often have problems with high or low glucose levels
- At night, when changes in glucose levels are hard to detect
- Any day when your normal routine is disrupted (for example, when you are busier than usual or traveling)
- Whenever you need more information to help solve problems
- When a change has been made in your treatment program

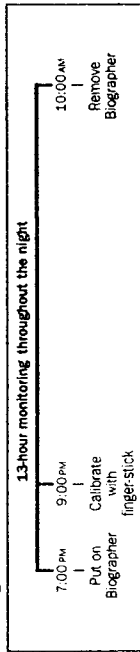
Working the G2 Biographer into your daily routine (continued)

The GlucoWatch® G2™ Biographer offers you the flexibility to obtain dozens of glucose readings...

Day...



...or night



How many glucose readings will the G2™ Biographer provide?

Each AutoSensor provides up to 13 hours of readings. The maximum number of readings possible with each AutoSensor is 76.

The Biographer checks each reading for signs of technical problems that might cause inaccurate readings. If a problem is detected, the reading is skipped. The word **SKIP** will appear on the Biographer display, but monitoring will continue. Things that can cause skipped readings include:

- Bumping the Biographer suddenly
 - Rapid temperature changes (for example, going into an air-conditioned building after being outside on a hot day)
 - Excessive perspiration
- Certain problems (for example, dislodging the Biographer from your skin) can cause the system to shut off glucose monitoring completely.

Even though some Biographer readings are skipped, you will still be able to see trends and patterns in your glucose levels. See the sample graph on page 1.5 for an example. If you look at this graph carefully, you will notice that the readings at 10:00 AM, 10:40 AM, and 12:10 PM were skipped. Despite these skipped readings, it is still easy to see the trends and patterns in your glucose levels.

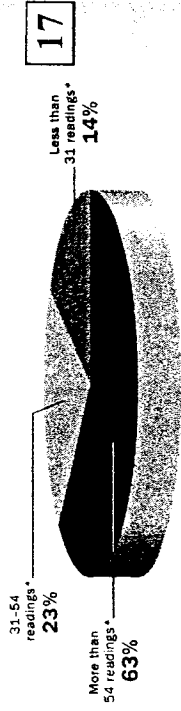
1.18

Studies have shown that:

- About 21% of readings are skipped
- The Biographer shuts off early about 16% of the time
- On average, the Biographer provides about 55 glucose readings (out of a possible 76 readings) per AutoSensor

Below is a graph showing the number of readings obtained per AutoSensor during a clinical study² of 85 people with diabetes.

16



*Per AutoSensor.

Your experiences may be different. Your lifestyle, as well as when you wear the Biographer, can affect the number of readings you get. You should discuss your expectations with your diabetes care team. Together, you can plan the best way to use the Biographer in your unique situation.

When should a regular blood glucose meter be used?

A regular home blood glucose meter **must** be used in the following situations:

- To calibrate the Biographer each time a new AutoSensor is used
- To confirm the Biographer readings in certain circumstances
- To monitor your blood glucose as directed by your diabetes care team. Since the Biographer is not designed to replace your regular blood glucose meter, never change how often you do finger-stick tests without first talking with your diabetes care team

Introductory Training Program Questionnaire

INSTRUCTIONS: Please check the box next to the correct statement for each of the questions below. There is only one correct answer for each question. Then call in your answers at 1-866-GLWATCH (1-866-459-2824).

After completion, you will be given a passcode number. Please write that number on the inside front cover of this User's Guide. You will need the passcode number to activate the Biographer.

1. What is the GlucoWatch G2 Biographer?

- a. A watch-like device that requires a finger-stick every time I want a glucose reading
- b. A noninvasive device that gives me automatic glucose readings for up to 13 hours after a finger-stick for calibration

2. How does the Alert feature of the Biographer work?

- a. The Biographer sounds an alarm if my glucose reading is above the High Alert level, below the Low Alert level, or likely to drop below the Low Alert level in the next 20 minutes
- b. The Biographer sounds an alarm only if I need to take insulin

3. What's the difference between the Biographer and standard blood glucose meters?

- a. The Biographer reads a glucose sample that is taken through the skin, not from whole blood
- b. The Biographer reads the glucose level in blood plasma

4. What will a Biographer reading tell me?

- a. The Biographer reading tells me my glucose level from about 15 minutes earlier
- b. The Biographer reading tells me my average glucose reading for the whole day

5. What is the Biographer used for?

- a. The Biographer detects trends and tracks patterns in my glucose levels
- b. The Biographer replaces my regular blood glucose meter

6. The Biographer may be a good choice for me if...

- a. I seldom or never test my glucose
- b. I find it difficult to test my blood glucose as often as my diabetes care team wants me to

Working the G2 Biographer into your daily routine (continued)

Why do you need to calibrate the GlucoWatch® G2™ Biographer?

Calibration adjusts the G2™ Biographer for the selected skin site. Everyone's skin is different. Your skin may be different from site to site and even from day to day.

To calibrate, you will need to do a finger-stick test with your regular meter and enter the result into the Biographer. Follow the instructions for using your regular blood glucose meter and always do the calibration step carefully. Entering the right number is important for accurate results.

If you question the reading from your regular meter that you plan to use for calibration, repeat the blood glucose test.

It may take more than one try to calibrate the Biographer. This will require doing additional finger-stick tests. In clinical studies, the calibration step had to be redone about 8% of the time (1 out of 12). Occasionally, the Biographer will not calibrate at all.

When do you need to confirm a Biographer reading?

You will need your regular blood glucose meter to confirm the Biographer readings in certain circumstances.

- If you have symptoms that may be due to low blood glucose or high blood glucose, do not ignore them
- The Biographer may not detect every instance when glucose levels are too high or too low
- If you have symptoms that do not match the Biographer readings, use your regular blood glucose meter to check the Biographer results

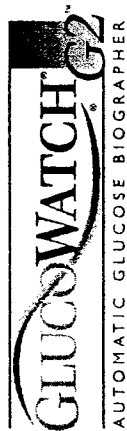
IMPORTANT: Remember that you should not make any immediate changes in your daily therapy or take an insulin injection based only on results from the Biographer.

Introductory Training Program Questionnaire (continued)

13. **When setting the glucose target ranges and Alert levels for the Biographer I should...**
- a. Decide on the settings together with my diabetes care team
 - b. Change the settings whenever I change my daily routine
14. **To calibrate the Biographer, I must...**
- a. Perform a fingerstick test with my regular blood glucose meter and enter the result into my Biographer
 - b. Use a special test solution
15. **A 2-hour warm-up period is required...**
- a. Only the first time I use the Biographer
 - b. Every time I use the Biographer

Call in your answers toll free
at 1-866-GLWATCH (1-866-459-2824).

7. **What can help reduce any skin irritation caused by the GlucoWatch® G2™ Biographer?**
- a. Changing the spot on my forearm where I wear the G2™ Biographer each time I put it on
 - b. Wearing the Biographer in exactly the same place I wore it before
8. **When is it critical to confirm the results from the Biographer with a regular blood glucose meter?**
- a. If I get a Biographer reading that is higher than the Biographer reading I had at the same time yesterday
 - b. If I'm having symptoms that do not match the results from my Biographer
9. **During an average wear cycle, how many readings can I expect from one AutoSensor?**
- a. 76
 - b. 55-60. The Biographer might shut off early 16% of the time
10. **What can cause the Biographer to skip a reading?**
- a. Three identical glucose readings in a row
 - b. Perspiration, bumping, or data inconsistencies
11. **What's the appropriate level at which to set the Low Alert level?**
- a. At 10 mg/dL to 20 mg/dL above the glucose level that I want to be detected
 - b. At the lowest glucose level I've ever reached
12. **What part of the Biographer needs to be changed at each wearing?**
- a. The AutoSensor
 - b. The Alert settings



In this section, you will learn how to assemble your Biographer and get it ready for its first use. The Biographer is very easy to use, but there are some important steps you must do before starting to monitor your glucose levels.

The basic steps for getting started:

- Charge the batteries (pages 2.3–2.5)
- Insert a charged battery (page 2.9)
- Enter the passcode number (page 2.10)
- Set the time and date (pages 2.13–2.14)
- Practice putting the Biographer on your forearm (page 2.15)
- Change the watchband if needed (pages 2.18–2.19)
- Run a System Check (pages 2.21–2.22)

Be sure you have all the items supplied in your Starter Kit before assembling your Biographer.

Precautions and warnings

Precautions:

- Always check the last few readings in the GlucoWatch® G2™ Biographer memory to see the current trend in your glucose levels. One reading cannot tell you how fast your glucose levels are changing. If you question the Biographer results, confirm the G2™ Biographer readings with your regular blood glucose meter.
- Be sure to set the Low Alert level (0 mg/dL to 20 mg/dL) about the blood glucose level that you want to make sure is detected. For example, if you want to detect a level of 60 mg/dL, you should set the Low Alert level between 70 mg/dL and 80 mg/dL. Otherwise, the Biographer may miss some low blood glucose events and the alarm will not sound.

Warnings:

- Do not ignore symptoms that may be due to low blood glucose or high blood glucose. The Biographer may not detect every instance that your glucose levels are too high or too low. If you have symptoms that do not match the Biographer readings, use your regular glucose meter to check the Biographer results.
- Do not change your treatment decisions based only on results from the Biographer. For example, some people use a blood glucose test result to help determine an insulin dose before each meal. This is often called a "sliding scale." If you use a sliding scale, be sure to confirm the Biographer reading with your regular blood glucose meter to make sure you take the right amount of insulin.
- Do not make fundamental changes in your treatment program without talking to your health care team. Serious illness or accidents may result.
- Remember that Biographer readings can differ from finger-stick test results. When it is time to make an important decision, the Biographer should not be used as a "substitute" for a finger-stick test. The Biographer must be used with finger-stick blood testing. Then you can make the best treatment decisions and reduce the chance of problems.
- Patients with suspected allergies to medical adhesives should consult their health care professional before using the Biographer.

18

19

20

21

What's in your Starter Kit?

Check to make sure you have the following:

- 1 GlucoWatch® G2™ Biographer
- 1 System Check Sensor (already in place on back of the Biographer)
- 1 battery door
- 2 rechargeable nickel metal hydride (Ni-MH) AAA batteries
- 1 Ni-MH battery charger with adapter plug
- 2 watchbands (one already attached to the Biographer)
- 1 AutoSensor Press
- 1 Instructional Videotape
- 1 Quick Reference Guide
- 1 Product Information Sheet
- 1 Personal Glucose Biography
- 1 GlucoWatch G2 Biographer User's Guide

Charging the batteries

Before using your G2™ Biographer for the first time, you must charge the Ni-MH (AAA) batteries in the battery charger. This takes 3 hours, so you will have plenty of time to read through this manual and watch the video included in your Starter Kit. **You will need one freshly charged battery each time you put on your Biographer.**

22

Caution:

Do not attempt to charge any other type of battery in your charger. It could be dangerous if you do. The charger is designed for use with Ni-MH batteries only.

The Ni-MH battery:

- Provides the primary power source for the Biographer
 - Recharges the internal lithium battery (it provides backup power)
- For more information about the life of your Ni-MH batteries and backup power for your Biographer, see page 2.6.



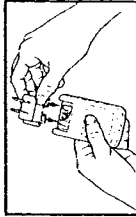
Tip: If you need more Ni-MH batteries, call Customer Service at 1-866-GLWATCH (1-866-499-2824) for assistance.

Note: The charger will not charge batteries that are below 41°F or above 113°F (below 5°C or above 45°C). The battery charger will measure battery temperature and start charging only when the batteries are within this range.

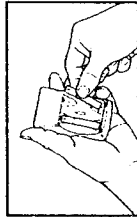
The charger must be used indoors only and protected from moisture. Periodically clean the battery contacts with a clean, dry cloth. Do not use any solvents or chemicals on the battery contacts.



Tip: You can watch the instructional video while you wait for the batteries to charge.



Step 1



Step 2

Charging the batteries (continued)

Follow these simple steps to charge the batteries:

Step 1: Attach the adapter plug to the charger. It may take some force to put these 2 pieces together.

Step 2: Place the batteries in the battery slots of the charger. (Follow the diagram on the charger so that the batteries are inserted correctly.)

Step 3: Plug the charger directly into a convenient wall outlet.

New Ni-MH batteries may not fully charge the first time. Therefore, when charging Ni-MH batteries for the first time, it is **highly recommended** that you check the charger after 30 minutes. At this time, if the charge indicates that it is finished, restart the charge by either unplugging the battery charger and plugging it back into the wall outlet or removing the batteries and reinserting them back into the charger.

The batteries should be fully charged in 3 hours. Each slot in the charger has a red LED cell to indicate the status of the battery.

Type of LED signal	This means that
Solid light	The battery is charging
Slowly flashing light	The battery is ready for use in the GlucoWatch® G2™ Biographer
Rapidly flashing light	The battery: <ul style="list-style-type: none"> • was placed in upside down OR • can no longer be charged and needs to be replaced
No flashing light	The battery is not completely inserted

Caution:

Do not use an extension cord with your charger.

Battery life

Your GlucoWatch® G2™ Biographier runs on 1 rechargeable nickel metal hydride (Ni-MH) AAA battery. It also contains 1 internal backup lithium battery. A built-in power-save mode conserves battery life.

Rechargeable Ni-MH battery: With each new monitoring period, you must use a fresh (new or recharged) Ni-MH battery (see page 2.4 for recharging instructions).

If necessary, you can substitute an alkaline AAA battery for a Ni-MH battery.

Note: Never put an alkaline battery in the charger you get with your G2™ Biographier.

Caution:

Do not use any other type of rechargeable battery in your Biographier.

Internal backup lithium battery: Saves the date, time, and glucose readings in memory while the Ni-MH battery is being charged. By itself, the lithium battery can only maintain the memory for about 2 days. The main power source (the Ni-MH battery) constantly recharges the backup lithium battery.

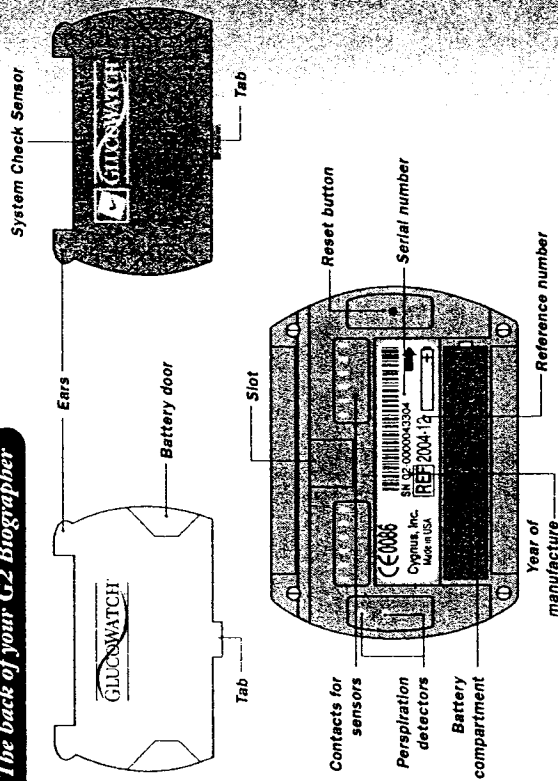
If the backup lithium and Ni-MH battery are both depleted, you will lose all memory storage of your glucose readings as well as the date and time. Always insert a freshly charged or new AAA battery before and after each monitoring period.



Tip: To preserve data stored in your Biographier

- Replace the Ni-MH battery every week, even if the Biographier is not being used

The back of your G2 Biographier



System Check Sensor: This is in place on the back of the Biographier when you receive it, but must be removed to insert the battery and AutoSensor. Put the System Check Sensor back in place when running a System Check (more on page 2.21).

Important: Do not discard the System Check Sensor or the battery door!

You will need the System Check Sensor to test the electronics of the Biographier.

The back of your G2 Biographer (continued)

Battery compartment: Holds the rechargeable Ni-MH battery.

Battery door: This clear part snaps onto the GlucoWatch® G2™ Biographer when it is not in use. The battery door keeps the battery in place and protects the back of the G2™ Biographer.

Perspiration detector: Measures perspiration (sweat)—too much sweat can cause skipped glucose readings, triggering the alarm and **SKIP** message (more on page 5.3).

Reset button: Resets the Biographer when the batteries (both main and backup) have run down.

Contacts for sensors: Provide electrical connection to the sensors.

Slot: Connection point for the AutoSensor and System Check Sensor.

Turning the G2 Biographer on**Inserting a battery into the G2 Biographer**

You will need to insert 1 freshly charged Ni-MH (AAA) battery into your Biographer for each 13-hour glucose monitoring period. The procedure for inserting a battery is simple:

Step 1: Remove the System Check Sensor, battery door, or AutoSensor by lifting both ears at the same time.

Step 2: Put a freshly charged Ni-MH battery in the battery compartment. Make sure the orientation of the battery matches the drawing on the label.

If necessary, you can substitute an alkaline AAA battery for an Ni-MH battery.

Step 3: Wait approximately 20 to 30 seconds.

Step 4: Your Biographer will respond in 1 of 3 ways:

- The Biographer will "wake up", the display will flash **WAIT, CODE** will appear in the upper display area, and --- (4 dashes) in the lower display.

What to do next: Follow the steps below for entering a passcode. You will only need to do this step the first time you use your new Biographer.

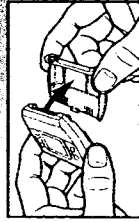
- The Biographer will "wake up," the display will flash **WAIT**, and the correct time and date display will reappear.

What to do next: Insert a new AutoSensor or run a System Check, following the normal procedures.

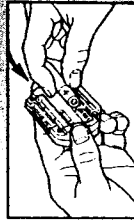
- The Biographer will "wake up" with *all* elements on the display illuminated, the display will flash **WAIT**, then the time and date screen will default to "1:01" and "12:00." This means the backup battery needs to recharge. It will recharge itself automatically.

What to do next: Follow the steps for setting the time and date on page 2.13.

24



Step 1



Step 2

25

Turning the G2 Biographer on (continued)

Entering a passcode

- Step 1:** Press and hold the **On** button until the --- (4 dashes) are replaced by **000** (3 zeros).
- Step 2:** Use the **Up** or **Down** button to replace the flashing zero with the number from your user passcode.
- Step 3:** Press the **Change** button so the next zero flashes. Repeat until all numbers are entered (from right to left).
- Step 4:** Press the **Start** button to confirm the passcode. The date and time screen should appear.

Note: If you entered the wrong passcode, the display will return to CODE- ---. You can attempt to enter the passcode again. If you continue to have problems, contact Customer Service toll free at 1-866-GLWATCH (1-866-459-2824).



Tip: To remove the battery

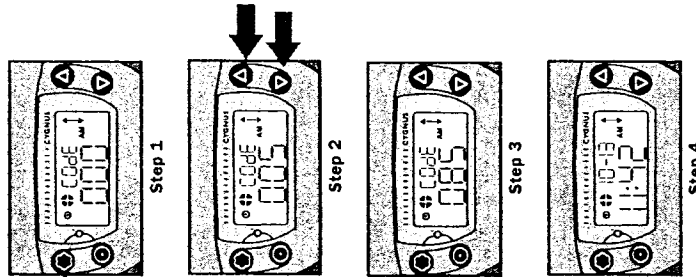
- Press gently on either end of the battery. The other end will pop up so that you can pick up the battery and remove it.

Caution:

Do not touch the battery compartment connectors with your fingers or any other objects. You may bend or break the connectors that hold the battery in place.

Note: Immediately after putting in a new battery, the lower display may show a code beginning with "M" followed by a number. This indicates a problem with the memory of the GlucoWatch® G2 Biographer. See page 7.3 for an explanation of these codes or contact Customer Service toll free at 1-866-GLWATCH (1-866-459-2824).

26

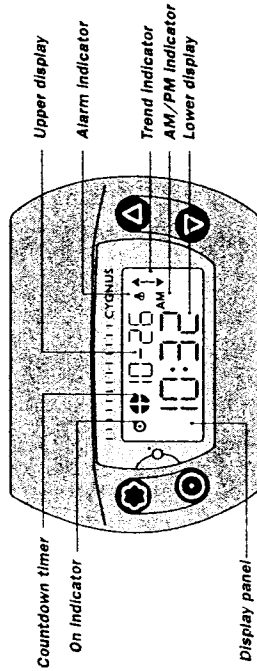


The front of your G2 Biographer

Study the following diagrams to become familiar with your G2 Biographer.

Display panel

includes 2 displays of information, the upper display and the lower display. The displays will appear once you insert a battery.



Note: The Countdown timer, On indicator, and Trend indicator are not displayed when you power up your Biographer. The Alarm indicator will be displayed only if you have set a personal alarm.

- On Indicator:** Displays during the warm-up and 13-hour monitoring periods. Also displays during the System Check and QC Test. Flashes when the low-level electric current is being applied to your skin in order to collect glucose. It stops flashing when the Biographer is measuring the glucose that was collected.
- Alarm indicator:** Displays if you have entered a personal reminder alarm.
- Trend Indicator:** If the current reading is higher or lower than the previous reading by a specified amount, an up or down arrow displays along with the glucose result.
- AM/PM Indicator:** Displays unless 24-hour clock is selected.

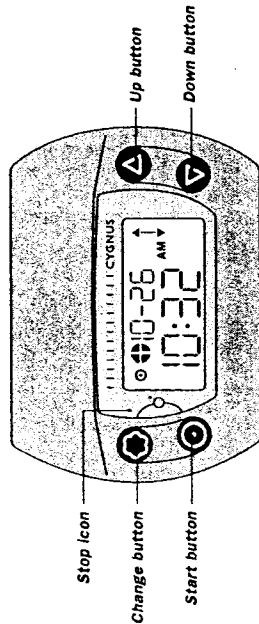
The front of your G2 Biographer (continued)

Countdown timer: Displays only after the GlucoWatch® G2™ Biographer has been successfully calibrated. Shows the time remaining before the next glucose reading.

Time to next reading:

⬆ 7½ to 10 minutes	⬆ 2% to 5 minutes
⬇ 5 to 7½ minutes	⬇ 2% minutes or less

Function buttons
provide options for programming screen settings.



- Ⓞ **Change button:** Signals to the G2™ Biographer that you wish to change something; press to turn off alarms.
- Ⓞ **Start button:** Turns on glucose monitoring; confirms choice of options; returns to time/date display. This is your "Home" button.
- Ⓞ **Up and Down buttons:** Scroll through glucose readings in memory or through functions; enters calibration blood glucose values.
- Ⓞ **Stop icon:** Reminds you to press both the Ⓞ Change and Ⓞ Start buttons simultaneously to shut off monitoring (see page 3.21).

Setting the time and date

Refer to the map of Biographer displays on page 7.17 of this guide.

(A) Getting to the time and date screen

Step 1: Insert an Ni-MH battery and then replace the battery door so the battery doesn't fall out.

Step 2: You will see the word **WAIT** flashing. Then the time and date screen with time on the lower display and date on the upper display.

Example:
To change the time and date from 12:00 on Jan. 1 to 11:42 on Oct. 13:

(B) Setting the current time and date

To set the current time and date:

Step 1: Start at the time and date screen. If necessary, press the Ⓞ Start button to return to the time and date screen.

Note: The 4 numbers on the lower display may be flashing if you have pressed the Reset button or your backup lithium battery has been depleted. The Biographer will not perform a System Check, a QC Test, or start monitoring until the time and date are set.

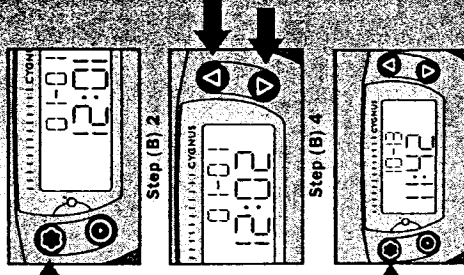
Step 2: Press and hold the Ⓞ Change button until you see the number at the far right flashing.

Step 3: Release the Ⓞ Change button.

Step 4: Press the ⬆ Up or ⬇ Down button to select the correct number for the minutes.

Step 5: Press the Ⓞ Change button until you see the second number from the right flashing. Select the correct number to finish the minutes.

Step 6: Repeat the process until you have entered the correct hour. Press the Ⓞ Change button.



Steps (B) 5 and (B) 6

Setting the time and date (continued)

Step 7: You will now be prompted to enter the year, even though the year will not normally be displayed. Press the **Up** or **Down** button to select the correct year.

Step 8: Press the **Change** button. You will now be prompted to enter the **month** and **day**. Press the **Up** or **Down** button to select the correct month and day.

Step 9: Check to make sure you entered the correct numbers. If you notice an error at this point, simply continue to press the **Change** button until the digit you want to correct flashes. Press the **Start** button to start the clock.

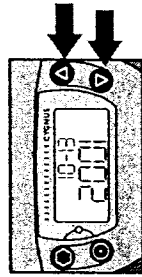
Note: If you prefer time and date in 24-hour format, see the instructions on page 6.5.

It's important to set an accurate time and date.

The GlucoWatch® G2™ Biographer stores the time and date for each glucose measurement taken. While the monitoring function is turned on, you cannot change the time and date.

Tip: For fast entry of time and date

- Press and hold the **Change** button until the far right digit flashes
- Simply press and hold the **Up** or **Down** button. The Biographer will scroll through numbers at high speed and you can enter the digit you want.
- When you follow this procedure, the Biographer automatically moves from the right digit to the left digit so you can enter the next number in a sequence



Step (B) 7

Practice putting on your G2 Biographer and fastening the band

It's a good idea to practice putting on your G2™ Biographer and fastening the band ahead of time. Practice **before** you attach an AutoSensor to the Biographer.

Step 1: Insert the battery door in the back of your Biographer.

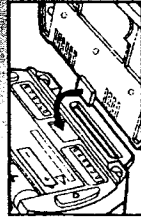
- Place the tab into the slot
- Snap the ears down onto the Biographer

Step 2: Carefully position the Biographer approximately 2 inches from your wrist.

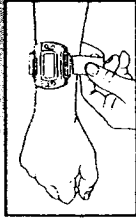
Step 3: Feed the strap through the D-ring (see diagram on page 2.18).

Step 4: Pull the strap to tighten the band.

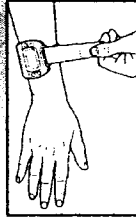
Step 5: Join the 2 Velcro® pieces together to fasten.



Step 1



Step 3



Step 4

Tip: Practice placing your Biographer at different places on your forearms. Determine which size band fits at each site. Wear your Biographer around the house for play, and to work to decide where you feel most comfortable wearing it, before you actually use it to monitor your glucose.

27

Velcro is a registered trademark of Velcro Industries B.V.

Caution: Each time you wear the Biographer

- Choose a different place on your wrist or forearm.
- Make sure there is no irritation remaining from previous warnings. It generally takes about a week for skin to recover from the effects of low-level currents. (For details on managing skin irritation resulting from wearing the Biographer, see page 7.2.)
- Make sure your Biographer is never immersed in water; the Biographer is splash-resistant but not waterproof.
- Do not fasten the watchband too tightly. Blisters may occur due to friction between the skin and the Biographer.
- Place the Biographer only on sites with normal, healthy skin. Avoid sites with skin abnormalities such as eczema, cuts, sunburn, or tanning.

Choosing a wear site for your G2 Biographer

Feel free to wear the GlucoWatch® G2™ Biographer on either your inner or outer forearm. Make sure that the appropriately sized watchband is attached to the G2™ Biographer. Your Starter Kit includes 2 bands—one size should be right for you.

28

29



- Tip:** To ensure firm contact between your skin and the Biographer, your skin must be
- Clean and dry—no lotions, perfumes, or medications.
 - Free of excess hair—important for firm contact of AutoSensor with skin.


You may want to wear the Biographer on the inner surface of your arm, where there is less hair to remove. If you are planning to wear the Biographer over several days, consider shaving the whole forearm at once to avoid a “patchy” look as you change wear sites.

It's best to remove hair at least 24 hours before placing the Biographer on your arm.

To minimize skin irritation, do not shave the site and apply the Biographer on the same day. An electric razor may be less irritating than a traditional razor.


Make sure you are comfortable and your hands can move freely

The right way



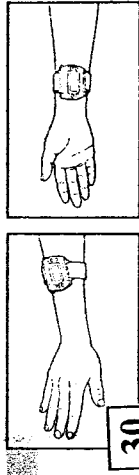
Wrist moves freely and comfortably (Biographer should be at least 2 inches from your wrist).

The wrong way



Wrist movement is restricted (Biographer is too close to your wrist).

Recommended wear sites

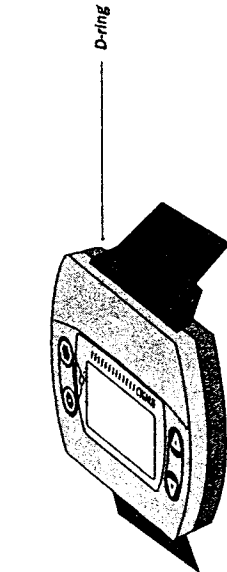


You may wear the Biographer on either side of your forearm. Use of the Biographer on other sites (eg, upper arm, legs) has not been studied.

Changing the watchband

You may need to change the band on your GlucoWatch® G2™ Biographer, depending on the size of your wrist or where you position it on your forearm. (You will need to change wear sites daily; see page 2.16 for details.)

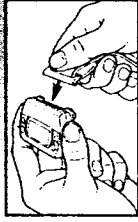
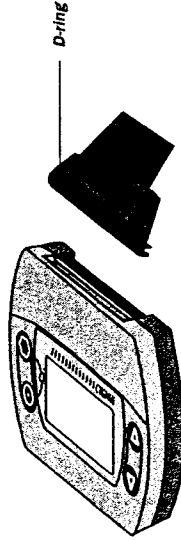
A standard-size band comes attached to your G2™ Biographer. If this band does not fit, you can replace it with the additional watchband that is included in your Starter Kit.



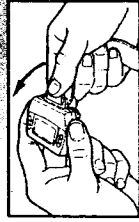
Then, attach the new band.

Step 1: Place the groove in the plastic D-ring over the metal rod on the Biographer with the band pointing downward.

Step 2: Rotate the D-ring upward until you hear it snap in place. It should now be firmly attached.



Step 1



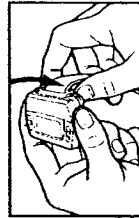
Step 2

First, disconnect the band that is in place.

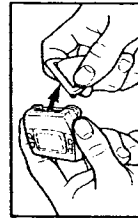
Step 1: Hold the Biographer with the band at a right angle to the watch face.

Step 2: Press your thumb on the outside of the D-ring and your index finger on the inside.

Step 3: Rotate your thumb and finger in a clockwise motion to "peel" the band off the Biographer. This may require a lot of force.



Step 1



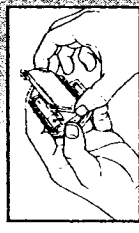
Steps 2 and 3

Running a System Check

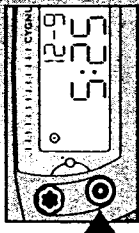
Note: You must set the time and date before running the System Check. See page 2.13 for instructions.

Your Starter Kit includes a special System Check Sensor to make sure that your Biographer is operating properly. Be sure to run a System Check before using your Biographer for the first time and then once before using the first AutoSensor from a new box. You should also run a System Check if the Biographer is dropped or damaged in any way. Here's how:

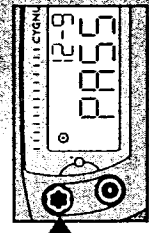
- Step 1:** Handling the System Check Sensor by the ears, connect it to the Biographer. (You must have a charged Ni-MH battery in place.) Make sure you're using the System Check Sensor and not an AutoSensor or the battery door.
- Step 2:** Press and hold the **Start** button for a few seconds until the **On** indicator appears on the display and you hear 2 beeps. The System Check will take about 10 seconds to complete.
- Step 3:** At the end of the test, the alarm will sound and the lower display will show either **PASS** or **FAIL**. Press the **Change** button to confirm that you have heard the alarm.



Step 1



Step 2



Step 3

Setting an Event marker

The Event marker allows you to keep a running record of certain events each day. By using this option, you can see how your day-to-day activities are affecting your glucose levels. You can enter an event any time the GlucoWatch® G2™ Biographer is on.

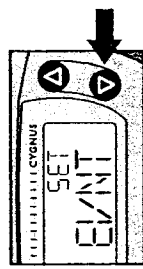
Event options

- MEAL = Breakfast, lunch, or dinner
- SNAC = Between-meal snack
- INJ = Insulin injection
- SLEEP = Went to bed
- WAKE = Woke up
- EXER = Exercise
- ILL = Illness

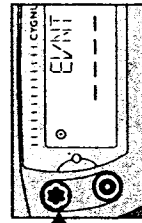
Note: An Event marker is stored just like a glucose reading and can be viewed whenever you are checking your glucose trends. You should enter events as they occur. The G2™ Biographer will record the time and date. Once an event is entered, it cannot be deleted.

To set an Event marker:

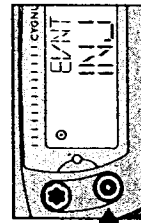
- Step 1:** From the time and date display, press the **Down** button twice. You should see **SET EVNT**.
- Step 2:** Press and hold down the **Change** button until you see **EVNT** and **----** flashing.
- Step 3:** Press the **Down** button until the display screen shows the event you want.
- Step 4:** Press the **Start** button to record the event.
- Step 5:** Your Biographer will return to the time and date display automatically.



Step 1



Step 2



Step 4

Running a System Check (continued)

Step 4: If the display shows **PASS**, press the **Start** button to return to the time and date display. If the display shows **FAIL**, the System Check Sensor may not have been seated properly in the GlucoWatch® G2™ Biographer or the G2™ Biographer may be damaged. You may run another System Check (press the **Start** button to return to the time and date display) or call Customer Service for assistance.

The System Check Sensor should be able to be used many times. If the System Check Sensor is lost or damaged, call Customer Service at 1-866-GLWATCH (1-866-459-2824) for assistance.

Tip: If the display shows **FAIL** or **OFF/READ**, squeeze the System Check Sensor firmly against the Biographer and redo the test (beginning with Step 2). A small gap between the System Check Sensor and the Biographer could be causing a disruption in the electrical connection.

Power-save mode

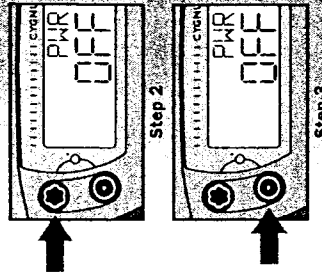
The Biographer conserves energy with a power-save mode. You can shut off the display and function buttons when the Biographer won't be used. This will keep the internal memory going for as long as possible.

Note: It's best to start with a fully charged Ni-MH battery. This will help keep your backup lithium battery charged when you want to keep your Biographer in the power-save mode for more than 1 or 2 days. Be sure to put the battery door onto the Biographer so that the battery stays in place.

Activating the power-save mode

- Step 1:** From the time and date display, press the **Down** button 9 times. The screen should display **PWR** and **OFF**.
- Step 2:** Hold down the **Change** button until the word **OFF** starts flashing.
- Step 3:** Press the **Start** button and the Biographer will turn off. You are now in the power-save mode.

To deactivate the power-save mode and turn the Biographer back on, remove and replace the battery as described on page 2.9.





Power-save mode (continued)

Power levels

Biographer: the various levels of power

When the Ni-MH (AAA) battery is getting low, the alarm will sound and you will see a **bAT** message in the upper display. This means that the GlucoWatch® G2™ Biographer can no longer make glucose readings but there's enough energy to operate other functions. You must change the Ni-MH battery before you start monitoring.

If the battery begins to get low during a monitoring session, monitoring will stop and the lower display will flash **OFF** alternating with **bAT**, then **bAT** will flash on both the upper and lower displays. You will have to change the Ni-MH battery and start over with a new AutoSensor. This means you will have to begin another 2-hour warm-up period.

Your G2™ Biographer also has a power-save mode. The display will be off, but the Biographer will save previous glucose values as well as the date and time of the readings. You can put the Biographer into the power-save mode manually, or it will go into the power-save mode automatically, approximately 6 hours after the **bAT** message appears.

If the Biographer stays in the power-save mode for more than 1 week (with a fully-charged Ni-MH battery in place), both the backup lithium and Ni-MH batteries will completely discharge, all operations will stop (including the clock), and stored readings will be lost.

Before monitoring

When you are ready to begin monitoring your glucose with the Biographer, check to make sure you have:

- Attached the correct size watchband for the site you intend to use
- Inserted a freshly charged battery
- Prepared your skin site (see page 2.16)
- Test strips for your glucose meter
- Set the correct date and time (see pages 2.13–2.14)

You will need:

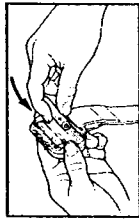
- An AutoSensor
- The AutoSensor Press

Note: Remember that the Biographer will require a 2-hour warm-up period before you can calibrate it. You must use a regular blood glucose meter during this time to measure your blood glucose. You cannot bathe, shower, or swim once the Biographer is attached to your arm, nor can you move the Biographer once you have attached it to a wear site.

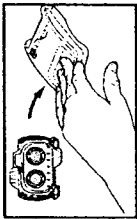
Basic steps for getting started

Your GlucoWatch® G2™ Biographer is easy to use, but it is important that you prepare correctly before starting to monitor. Here are the basic steps for getting started:

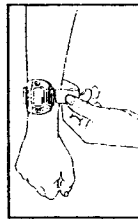
- Step 1:** Insert 1 Ni-MH (AAA) battery into the G2™ Biographer (see page 2.9).
- Step 2:** Place the AutoSensor into the AutoSensor Press and remove protective liner 1. Insert the AutoSensor into the back of the Biographer (see pages 3.3–3.7).
- Step 3:** Remove protective liner 2, then put the Biographer on your arm and press the Start button. This begins a 2-hour warm-up period (see pages 3.7–3.11).
- Step 4:** After the warm-up period, calibrate the Biographer. You will need to do a finger-stick with your regular blood glucose meter and enter this result into the Biographer (see page 3.14).
- Step 5:** After calibration, the Biographer will give you a glucose reading as frequently as every 10 minutes for up to 13 hours. After 13 hours, the Biographer stops glucose monitoring (see page 3.21).



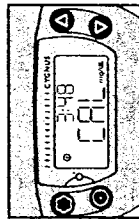
Step 1



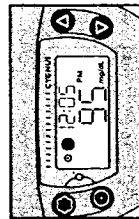
Step 2



Step 3



Step 4



Step 5

A look at the AutoSensor

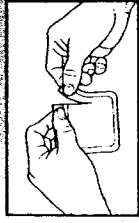
Removing the AutoSensor from the pouch

- Step 1:** Tear open the pouch by pulling on one of the labeled tabs.
- Step 2:** Gently handling the AutoSensor, remove it from the pouch.

Caution:

- Before use, AutoSensors should generally be stored in a refrigerator (36°F to 46°F [2°C to 8°C]). Do not store AutoSensors in the freezer. If needed, AutoSensors can be stored at room temperature (below 77°F or 25°C) for up to 1 month. AutoSensors stored at room temperature must be used within 1 month.
- Use AutoSensors immediately after opening the pouch. Do not store AutoSensors in open pouches.
- Do not use an expired AutoSensor. Check the expiration date on the package label before use. AutoSensors expire at the end of the month indicated.
- Check the gel collection discs in the AutoSensor for any spots or areas of different color. The gel collection discs should have a uniform but "cloudy" appearance and are normally white to gray with a slight yellow tint. Do not use the AutoSensor if you see any spots or discoloration.

To remove the AutoSensor



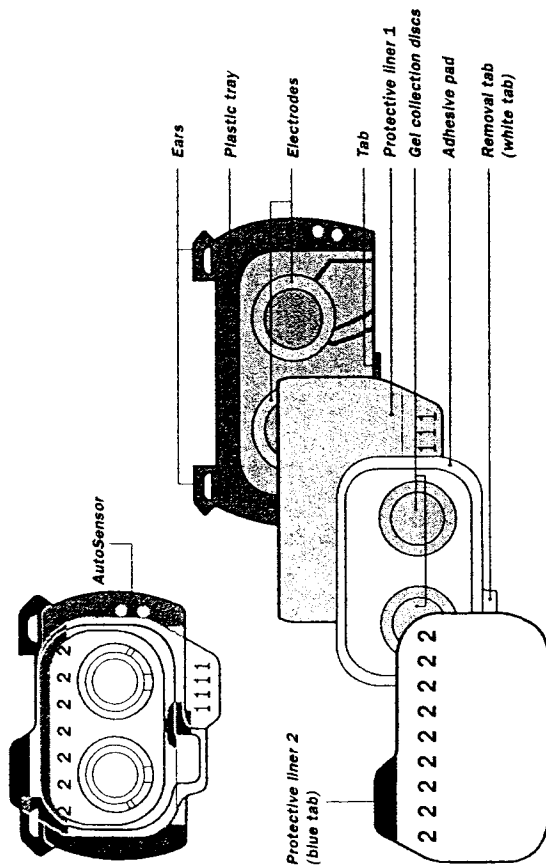
Step 1



Step 2

A look at the AutoSensor (continued)

Use a new AutoSensor each time you wear the GlucoWatch® G2™ Biographer.



Adhesive pad: Contains glucose collection discs in an adhesive plastic holder with protective liners. **Do not remove the adhesive pad.**

Protective liner 1: In between the electrodes and the adhesive pad. Pulls out so pad sticks to electrode surface.

Protective liner 2: On the top of the adhesive pad. The **blue tab** peels off so the AutoSensor sticks to your forearm.

Gel collection discs: Collect glucose and store enzymes that produce the chemical reactions needed to obtain glucose readings.

Removal tab: The **white tab** on the AutoSensor, used to help remove the Biographer from your forearm after glucose monitoring.

Plastic tray: Holds electrodes and adhesive pad. The ears and tab on the plastic tray help you snap the AutoSensor into the G2™ Biographer.

Electrodes: Send tiny electric currents into the skin that pull glucose through the skin and into a gel collection disc. The glucose interacts with enzymes in the gel and produces an electronic signal. The electrodes then measure the signal that is produced and the Biographer converts it into a blood glucose value.

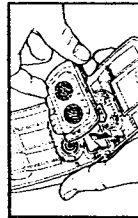
Using the AutoSensor Press

Using the AutoSensor Press is a critical step in obtaining accurate readings. Proper use of the Press helps ensure that the gel collection discs in the adhesive pad are firmly pressed onto the electrodes.

- Step 1:** Open the lid of the AutoSensor Press. Place the AutoSensor—gel collection discs facing upward—into the Press. There are 2 pegs in the Press that fit through the holes in the AutoSensor. The liner with the row of 1s on it will hang out of the back of the press.
- Step 2:** Gently bring the lid of the AutoSensor Press down. Holding the AutoSensor Press by its sides, remove protective liner 1 on the AutoSensor by pulling the tab labeled with 1s through the opening at the hinged end of the Press. **Do not squeeze the lid while attempting to remove liner 1.** Discard the liner.
- Step 3:** Firmly close the Press so that the lid and the base touch. **Hold closed for a full 10 seconds.**
- Step 4:** Open the lid of the Press and remove the AutoSensor.

Caution:

Do not skip these important directions. Be sure to use the AutoSensor Press every time you use a new AutoSensor. Skipping this step may cause faulty readings. Do not directly press the adhesive pad onto the electrodes with your fingers.



Step 1



Step 2



Step 3

Connecting the AutoSensor

- Step 1:** Remove the System Check Sensor or battery door if you have not already done so.
- Step 2:** Place the tab of the AutoSensor into the slot on the back of the GlucoWatch® G2™ Biographer.
- Step 3:** Holding the AutoSensor with your thumb and forefinger, snap each ear into place. A click lets you know the AutoSensor is properly seated.

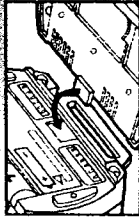
Cleaning the wear site

- Refer to pages 2.16–2.17 for a review of how to choose and prepare an appropriate wear site.
- Once you have chosen a wear site, take a minute to clean the skin at the site:
- Use an alcohol swab (or soap and water) to remove any dead skin, oils, or lotion from the skin surface
 - Allow time for the skin to dry; then remove protective liner 2 with the blue tab from the AutoSensor as described below

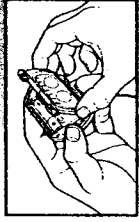
Removing protective liner 2

- Do not remove protective liner 2 until you are ready to put on the G2™ Biographer. To remove protective liner 2, pull the blue tab and peel off the protective liner. **Do not pull the white removal tab!**
- This uncovers the adhesive that makes the Biographer stick to your arm
 - Discard the liner

To connect the AutoSensor

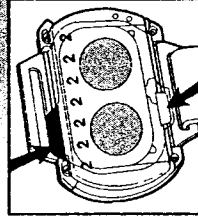


Step 2



Step 3

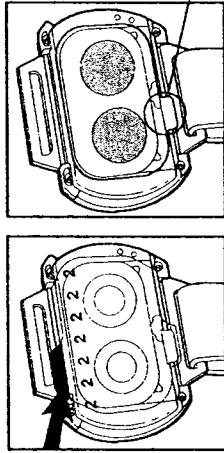
Pull here



Do not pull here

Before putting on the G2 Biographer

Inspect the back of the GlucoWatch® G2™ Biographer before you attach it to your arm. Make sure that the white removal tab is still attached. After removing protective liner 2, the back of the G2™ Biographer should look like this:



Caution:

Check to make sure the AutoSensor has the white removal tab. Do not remove the white removal tab before use. Do not use the AutoSensor if the white removal tab is missing.

Before putting the Biographer on your arm, review the instructions on choosing and preparing the wear site on pages 2.16-2.17.

Removing protective liner 2 (continued)

Caution:

- Don't touch the surface with your fingers or other objects after removing protective liner 2 if removed.
- Check to make sure the AutoSensor has the white removal tab. Do not remove the white tab before use. Do not use the AutoSensor if the white removal tab is missing.
- Check the gel collection discs for any spots or areas of different color. The gel collection discs should have a uniform but cloudy appearance. The gel collection discs are normally white to grey with a slight yellow ring. Do not use the AutoSensor if you see any spots or discoloration.

Putting on the G2 Biographer

Holding the GlucoWatch® G2™ Biographer by the edges:

Step 1: Check to make sure the display face is right side up.

Carefully place the G2™ Biographer onto the selected wear site.

Step 2: Press firmly on the Biographer. Pressing ensures that the adhesive on the AutoSensor makes a firm bond with your skin.

Caution:

Make sure the AutoSensor sticks to your skin. If the AutoSensor does not stick, you may have accidentally removed the entire adhesive pad. Start over with a new AutoSensor.

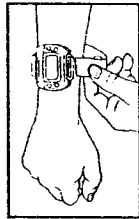
Step 3: Feed the strap through the D-ring.

Step 4: Pull the strap to tighten the band, making sure that the adhesive does not pull away from your skin.

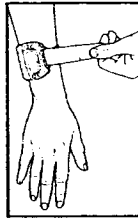
Step 5: Join the 2 Velcro pieces together to fasten.



Step 2



Step 3



Step 4

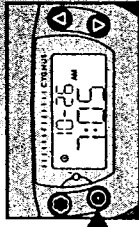
Starting the warm-up period

The Biographer requires a 2-hour warm-up period before you can calibrate it and begin the 13-hour monitoring period. To calibrate, you must do a finger-stick blood glucose test and then enter the results into the Biographer. Everyone's skin is different. Your skin is also different from site to site and even day to day. Calibration adjusts the Biographer for the skin site you have chosen (see page 3.14).

To start the warm-up period, press and hold the Start button until you hear 2 beeps. The On indicator will now appear on the display.

Note: If you have done a System Check and have gotten a FAIL result, the Biographer will not let you begin glucose monitoring. When you press the Start button, the display will show FAIL again. Do the System Check again until you get a PASS result (see page 2.22) or call Customer Service for help.

Although you will not get any glucose readings during the warm-up period, you may get certain alert messages. You can also perform most of the programming functions described in chapters 4 and 6 during this period.



33

Tip: Fasten the watchband securely

- Although the adhesive on the AutoSensor keeps the Biographer in place, the band provides extra security
- If the Biographer moves while you are wearing it, some glucose measurements may have to be skipped or monitoring may automatically shut off
- Be sure to check the band tightness periodically; if the band feels too loose or too tight, adjust as needed.

Fastening the watchband too tightly may lead to blisters due to friction between skin and the Biographer

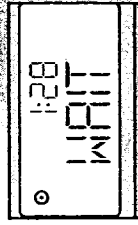
Functions that can be entered or changed during the warm-up period

There are several functions you can enter or change while the Biograph[®] is warming up. You can:

- Set the alarm clock (see page 4.3)
- Enter Event markers (see page 2.20)
- Change the High or Low Alert levels (see pages 4.5–4.7)
- Change the language, glucose units, clock format, or alert set up (see pages 6.4–6.5)

Checking how much time is left in the warm-up period

You can check the status of your Biograph[®] at any time by pressing the **⏻** Down button once. The lower display will read **WAIT**, while the upper display alternately flashes between **STAT** and the time remaining in the warm-up period. When there are approximately 25 minutes left in the warm-up period, you should move to a controlled environment and limit any vigorous activity that might rattle or bump the Biograph[®]. This will make it easier for the Biograph[®] to calibrate.



Problems that can occur during the warm-up period

Under certain circumstances, the GlucoWatch[®] G2[™] Biograph[®] may shut off during the first 5 minutes of the warm-up period. You will see one of the following on the display panel:

Flashing OFF message alternating with

VOLT: Indicates a problem with the electrical connection between the AutoSensor and the skin. This may be due to:

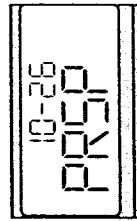
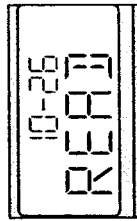
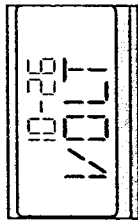
- 1) Too much hair at the site.
Solution: Pick a better wear site. You may need to use a new AutoSensor if the adhesive is not sticky enough.
- 2) Failure to remove protective liner **2**, which exposes the adhesive on the AutoSensor.
Solution: Review the instructions on page 3.7 and try starting over with the same AutoSensor once you've removed the protective liner.
- 3) Removing the AutoSensor from its pouch too soon. This can cause the gel collection discs to dry out.
Solution: Start over with a new AutoSensor.

READ: Indicates that the AutoSensor isn't seated properly. This can result if the AutoSensor isn't correctly snapped into the back of the Biograph[®] or if protective liner **1** was not removed.
Solution: Start over with a new AutoSensor.

Alarm sounds and display flashes

PRSP: Indicates the G2[™] Biograph[®] has detected perspiration. This display can only occur after 45 minutes of the warm-up period have elapsed. The Biograph[®] will alert you to this situation only if you have selected the **ALL** or **PRSP** modes, as continued perspiration may interfere with calibration.

Solution: Try to move to a cooler, less humid environment. The Biograph[®] will automatically suppress the calibration alarm if conditions are not appropriate; the Biograph[®] will wait until you've stopped perspiring before sounding the calibration alarm. However, if perspiration continues for a long period, the Biograph[®] will shut down completely (see **Codes for a skipped reading**, page 5.2).



When is it time to calibrate?

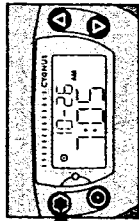
At the end of the 1-hour 55-minute warm-up period, the GlucoWatch® G2™ Biographer will perform a series of internal checks to see if conditions are right for calibration. The G2™ Biographer will NOT prompt you to enter a calibration value if conditions are not optimal for calibration. After 10 minutes, the Biographer will check again to see if conditions are right for calibration. When the conditions are right for calibration, an alarm will sound. When this occurs:

- Step 1:** Press the **Change** button to shut off the alarm.
- Step 2:** You will see a flashing **CAL** message and the timer on the upper display will count down from 5 minutes. Within the next 5 minutes, measure your blood glucose using a regular blood glucose meter and enter your finger-stick reading into the Biographer. Your finger-stick reading must be between 41 mg/dL and 279 mg/dL (2.3 mmol/L and 15.5 mmol/L).
- Step 3:** Press and hold the **Change** button until the **CAL** message is replaced by 3 zeros.
- Step 4:** Use the **Up** or **Down** button to replace the flashing zero with the number from your finger-stick test.
- Step 5:** Press the **Change** button so the next zero flashes, and repeat until all numbers are entered (from right to left).
- Step 6:** Press the **Start** button to confirm the calibration. Press the **Start** button again to return to the time and date display.

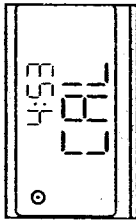
Note: The Biographer will not sound an alarm to enter a calibration value if:

- You are perspiring
- There is not a strong signal coming through your skin
- The Biographer was bumped or moved on your arm in the past 20 minutes
- Your skin temperature recently changed by more than 1°F or 0.55°C

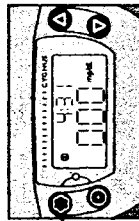
35



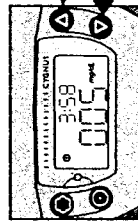
Step 1



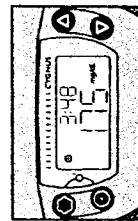
Step 2



Step 3



Step 4



Step 5

If your calibration value isn't accepted

The GlucoWatch® G2™ Biographer will not be able to use a calibration value outside of the range of 41 mg/dL to 279 mg/dL (2.3 mmol/L to 15.5 mmol/L). If you try to enter a value outside of this range, the G2™ Biographer will display either <40 alternating with **LOW** or >280 alternating with **HIGH**. The Biographer has not accepted your calibration value. When conditions are right for calibration, the alarm will sound again to let you know it is time to reattempt to calibrate your Biographer. Remember, your low or high blood glucose situation should be addressed immediately. Contact a health care professional for assistance if necessary.

How to tell that the G2 Biographer is calibrated

Over the 1.5 minutes after the calibration value is entered (Step 6, page 3.14) the Biographer completes an internal measurement matched to your finger-stick reading. When this internal measurement is completed, the Countdown timer will appear on the display and **2 triple beeps** will sound to confirm that the Biographer is calibrated. Automatic glucose monitoring is now under way! Ten minutes after the Countdown timer appears, the Biographer will record its first glucose reading.

Problems that can occur while the G2 Biographer completes the first internal measurement

If the Biographer is not able to complete the internal measurement, you will not hear the 2 triple beeps and the Countdown timer will not appear. The Biographer will record the reason for the failure to calibrate as well as the calibration value that was entered.

When the Biographer determines that conditions are right for calibration an alarm will sound.

Proceed to Step 1 on page 3.14.



Tip: You do not have to enter a calibration value when the Biographer prompts you. For example, if you do not have your blood glucose meter handy at the time the alarm sounds, simply turn off the alarm and wait 10 minutes for the next calibration period. This process will repeat every 10 minutes until you successfully enter a calibration value.

Problems that can occur while the G2 Biographer completes the first internal measurement (continued)

Note: If you accidentally input the wrong value, press and hold the **Change** button until you see 3 zeros on the lower display. Enter the new calibration value in the same way you entered the first one. Remember to press the **Start** button to confirm the calibration value you entered.

If you accidentally exit the CAL screen before entering your blood glucose value, press the **Start** button to return to the time and date display. Then press the **Down** button once and you will see STAT CAL on the display. Press and hold the **Change** button until you see 3 zeros on the lower display, then enter the calibration value. Remember to press the **Start** button to confirm the calibration value you entered.

Reasons for failed calibrations

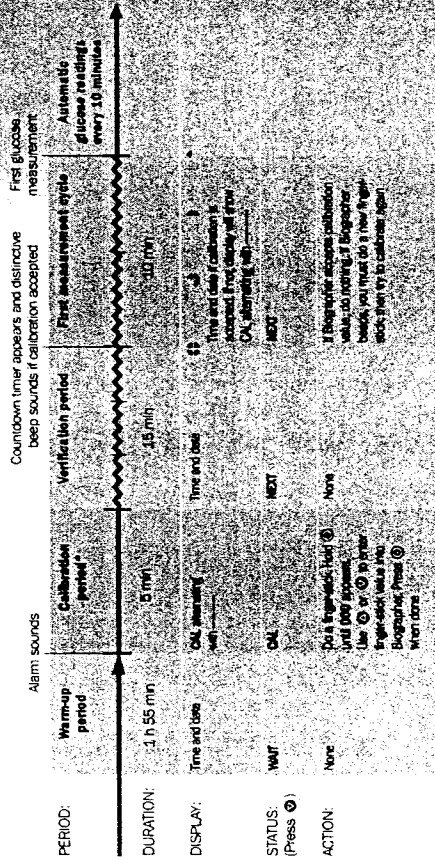
Calibration may be unsuccessful if the GlucoWatch® G2™ Biographer is not getting a strong enough signal, if you are perspiring or if the temperature is changing too rapidly.

You can see the reason for the failed calibration by pressing the **Up** button once. This display will read SKIP and either DATA, TEMP, PRSP, or COLD. These codes are explained on pages 5.2 and 5.3. If you press the **Up** button again, you will see CAL and the calibration value you tried to enter.

You can continue trying to calibrate the G2™ Biographer every 10 minutes for up to 4 calibration attempts. After 4 failed calibration attempts, the Biographer will automatically shut off. You can stop monitoring (see page 3.21) and try to start again with a new AutoSensor at a new site on your arm.

The chart on the next page summarizes the different phases of the first internal measurement (eg, warm-up, calibration, verification, and glucose monitoring functions).

Biographer stages leading to glucose monitoring



Note: For calibration, blood glucose must be between 41 mg/dL and 279 mg/dL (2.3 mmol/L and 15.5 mmol/L).

*If calibrating when the alarm sounds is not convenient, just wait for the next calibration period.



- Tip:** To reduce problems during the critical 1.5-minute period in which the Biographer completes the first internal measurement:
- Be sure to use the AutoSensor Press. Using the Press is important for getting a strong signal. Firmly close the Press and hold closed for 10 seconds.
 - Do not remove protective liner 2 from the AutoSensor until you are ready to put on the Biographer. Removing protective liner 2 too soon can cause the gel collection discs to dry out. This can prevent the Biographer from getting a strong signal.
 - Do not place the Biographer at any site where you have skin irritation left from a prior use. Reusing a site too soon can prevent the Biographer from getting a strong enough signal. You may want to wait as long as 2 weeks before going back to the same site.
 - Use the status check function (see page 3.13) to see how much time remains in the warm-up period. About 1.5 to 20 minutes before calibration, stop vigorous activity and move indoors if possible. Avoid jarring your arm or perspiring. Get your blood glucose monitoring supplies ready.
 - After entering your blood glucose value, try to stay indoors and avoid vigorous activity and perspiration.
 - If you have tried unsuccessfully 2 or more times to calibrate your Biographer, you may wish to skip a calibration entry. Wait 15 minutes (ie, skip the next calibration entry) for your blood glucose to stabilize before entering a new calibration value. Remember, you must use a new finger stick measurement for each calibration attempt.

Checking on the status of the G2 Biographer

At any time, you can press the **⏻** Down button to check the status of the GlucoWatch® G2™ Biographer. The word **STAT** will appear briefly in the upper display, and the lower display will show one of the following codes:

Code	This means
OFF	The warm-up process has not been started. See page 3.11 for instructions on how to start monitoring.
WAIT	The G2™ Biographer is warming up. The upper display will show the amount of time remaining in the warm-up period. The time will appear in hours and minutes until the last hour, then in minutes and seconds.
CAL	You can enter a calibration value into the Biographer now. The upper display will show the time remaining in the CAL period.
NEXT	A calibration value has been entered into the Biographer. If the ⏻ Countdown timer appears on the display, calibration is complete and glucose monitoring is under way. The upper display will show the time remaining until the next reading.

Viewing your glucose readings

Ten minutes after the **⏸** Countdown timer appears, the GlucoWatch® G2™ Biographer will record its first glucose reading.

Checking your most recent reading

From the time and date display, press the **⬆** Up button. You will see the most recent glucose measurement on the lower display. The upper display will alternate between the time and date of the measurement. If the glucose measurement triggered an alert, the measurement will alternate with the alert code: **HIGH**, **LOW**, or **DOWN**. If your glucose is low or dropping and you are perspiring, the display will read **PRSP** alternating with **LOW**.

A trend arrow will appear if the glucose measurement is 9 mg/dL (0.5 mmol/L) above or below the previous reading.

Checking earlier readings

The G2™ Biographer stores over 8,500 data points, including test results, event markers, and error messages. At any time, you can review as many readings as you like to determine your individual pattern of glucose changes and to chart your progress in controlling diabetes.

To see earlier readings, scroll backward by pressing the **⬅** Up button. Press and hold the **⬅** Up button to move quickly through the memory. When you reach the end of the stored data, you'll see a screen labeled **END**.

To return to the time and date screen, press the **⏹** Start button or wait 30 seconds until the time and date appear automatically.

Stopping monitoring

You can stop glucose monitoring at any time if you feel an unusual amount of discomfort or if you need to remove the Biographer. To stop glucose monitoring press both the **⏹** Start button and the **⏸** Change button at the same time.

When you stop glucose monitoring, you will no longer see the **⏹** On indicator or the **⏸** Countdown timer in the upper left corner of the display panel.

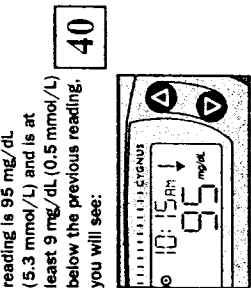
The word **OFF** will appear in the lower display alternating with the word **STOP**. The alarm will also sound. Press the **⏸** Change button to stop the alarm and then press the **⏹** Start button to return to the time and date display.

*Note: If the Biographer is worn beyond 13 hours after calibration, it will automatically stop glucose monitoring. You will see a flashing **OFF** alternating with **END**. Press the **⏹** Start button to return to the time and date. The clock and memory functions will continue to operate.*

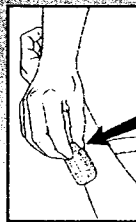
When you stop glucose monitoring, you MUST replace the used AutoSensor before you can monitor again!

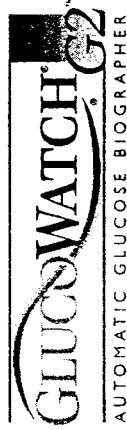
Removing the G2 Biographer

The adhesive that makes the AutoSensor stick to your arm is quite strong. The AutoSensor has a special white tab at the bottom right corner for easier removal. Remove the Biographer by first lifting up the white tab (see page 3.9 for illustration) and then slowly peeling the Biographer off your arm.



Example: If your glucose reading is 95 mg/dL (5.3 mmol/L) and is at least 9 mg/dL (0.5 mmol/L) below the previous reading, you will see:





Your Biographer has an Alarm Clock feature that can alert you once a day of special events (see page 4.3). It can also be programmed to alert you if your glucose levels are above or below certain target levels. It is important that you discuss where to set these alert levels with your diabetes care team. When you receive your Biographer, the Low Alert will be set at 100 mg/dL (5.6 mmol/L) and the High Alert at 240 mg/dL (13.3 mmol/L). You may wish to be alerted of additional events, such as each time you perspire or each time your Biographer records a reading. There are 3 alarm modes available: **MOST**, **ALL**, and **PRSP** (perspiration). The Biographer comes preset in the **MOST** alarm mode, but you can change this setting by following the instructions on page 6.5. The chart on the following page summarizes the differences between each alarm mode.

Ensuring the accuracy of your Biographer readings

In order to get the most accurate readings from your GlucoWatch® G2™ Biographer, follow these recommendations:

- Run a System Check:
 - Before using the G2™ Biographer for the first time
 - Every time you open a new box of AutoSensors
 - If the Biographer is dropped or potentially damaged in any way
- Before use, AutoSensors should generally be stored in a refrigerator (36°F to 46°F [2°C to 8°C]). Do not store AutoSensors in the freezer. If needed, AutoSensors can be stored at room temperature (below 77°F or 25°C) for up to 1 month. AutoSensors stored at room temperature must be used within 1 month
- If you suspect that the AutoSensors may have been exposed to extreme temperatures, conduct a Quality Control (QC) Test before using them (see pages 5.8–5.12)
- Always use the AutoSensor Press before attaching an AutoSensor to the Biographer. **Press for a full 10 seconds**
- The accuracy of the Biographer depends on the accuracy of the blood glucose test used for calibration. Be sure to check your regular blood glucose meter and test strips according to the instructions. Your doctor may also want to check your meter against a standard lab test from time to time
- If you question the finger-stick reading that you plan to use for calibration, repeat the finger-stick test
- If you question a Biographer reading, use your regular blood glucose meter to do a finger-stick test. Keep in mind that Biographer readings correspond to blood glucose values from about 15 minutes earlier
- If you question a series of Biographer readings during a 13-hour period, do not use another AutoSensor from the same box without running both a System Check on the Biographer and a QC Test on one of the remaining AutoSensors

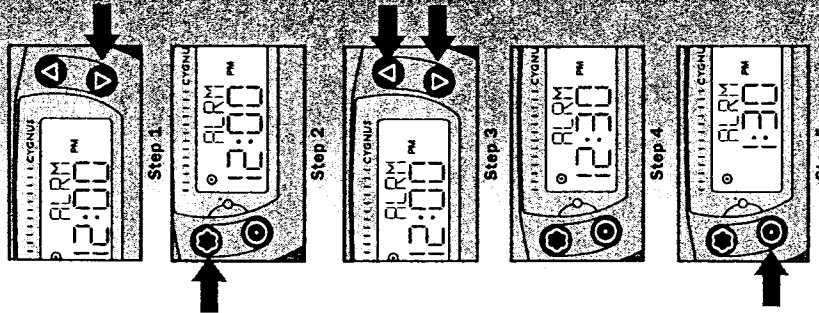
The Alarm Clock feature

The GlucoWatch® G2™ Biographer can be set to sound an alarm once a day to remind you of special events (for example, taking long-acting insulin or checking your blood glucose level with your meter). The G2™ Biographer will emit short, double beeps continuously until you turn the alarm off by pressing the **Change** button.

To set the alarm clock:

- Step 1:** From the time and date display, press the **Down** button 3 times until you see the word **ALRM** in the upper display and 12.00 in the lower display.
- Step 2:** Hold down the **Change** button until the far right digit begins flashing.
- Step 3:** Use the **Up** and **Down** buttons to set the correct number. Press the **Change** button to move to the next digit.
- Step 4:** Repeat Step 3 until all digits are set correctly to the time you want the alarm to sound.
- Step 5:** Check to make sure numbers are correct; then press the **Start** button to store the value.
- Step 6:** Press the **Start** button to return to the time and date display.

Example:
To set the alarm clock to sound at 1:30 PM:



Event	Display	Will alert when set to:	
		MOST	ALL
Alarm Clock		Yes	Yes
Glucose less than 40 mg/dL (<2.2 mmol/L)	<40 mg/dL/LOW (<2.2 mmol/L/LOW)	Yes	Yes
Glucose less than preset Low Alert level	###/LOW	Yes	Yes
Glucose dropping toward Low Alert level	###/DOWN	Yes	Yes
Glucose within target range	##*	No	Yes
Glucose above preset High Alert level	###/HIGH	Yes	Yes
Glucose greater than 400 mg/dL (>22.2 mmol/L)	>400 mg/dL/HIGH (>22.2 mmol/HIGH)	Yes	Yes
Perspiration preceded by a LOW or DOWN alert	PRSP/LOW	Yes	Yes
Perspiration during warm-up period	PRSP	No	Yes
Perspiration during monitoring period	SKIP/PRSP	No	Yes
Change in skin temperature	SKIP/TEMP	No	Yes
Skin temperature too cold (<72°F or <22°C)	SKIP/COLD	No	Yes
Biographer cannot compute glucose due to inconsistency in signal coming through skin	SKIP/DATA	No	Yes
Low-level electric current not passing through skin correctly	SKIP/VOLT	No	Yes

represents a numeric glucose value that is displayed. A discussion of the reasons the Biographer may skip readings can be found in Chapter 5: Troubleshooting.

Alarm Clock feature (continued)

To disable the alarm clock:

- Step 1:** From the time and date display, press the **Down** button 3 times until you see the word **ALRM** in the upper display and the time in the lower display.
- Step 2:** Press the **Change** button to remove the **Alarm** indicator from the display.

Note: If you store your Biographer without an AAA battery for more than 2 days, the alarm clock will need to be reset.

The High Glucose Alert

To help you reduce high blood glucose, your GlucoWatch® G2™ Biographer has a built-in High Glucose Alert. The alert sounds when your glucose level rises above a preset limit. The alert beeps more and more frequently until you press the **Change** button. The G2™ Biographer displays the glucose reading alternating with the word **HIGH**.

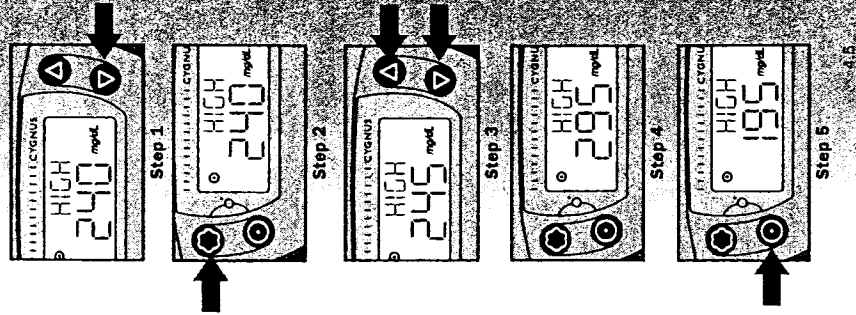
Because it takes time for glucose levels to drop after treating hyperglycemia, the High Glucose Alert will **only** sound at the next reading in 10 minutes if the Biographer's alarm mode has been set to **ALL** (see page 6.2). Otherwise, the High Glucose Alert will sound again in **40 minutes** if your glucose remains above your High Alert level.

Changing the High Alert level

When you receive your new Biographer, the High Alert level is preset at 240 mg/dL (13.3 mmol/L). Based on your individual needs, you and your health care team may decide to change the setting for the High Glucose Alert. Here's how to do it:

- Step 1:** From the time and date display, press the **Down** button 4 times until you see the word **HIGH** in the upper display.
- Step 2:** Hold down the **Change** button until the far right digit begins flashing.
- Step 3:** Use the **Up** and **Down** buttons to set the correct number. Press the **Change** button to move to the next digit.
- Step 4:** Repeat Step 3 until all digits are set correctly.
- Step 5:** Check to make sure numbers are correct; then press the **Start** button to store the value.
- Step 6:** Press the **Start** button to return to the time and date display.

Example: To change your High Alert level to 195 mg/dL (10.8 mmol/L):



The Low Glucose Alert

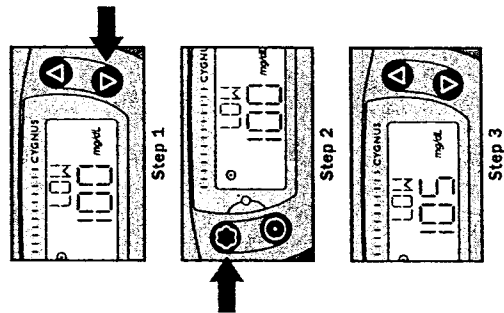
Your GlucoWatch® G2™ Biographer can also help you reduce the risk of low blood glucose with a built-in Low Glucose Alert. The G2™ Biographer sounds an alert to let you know that your glucose level has passed the preset limit set by you and your health care team. The alert beeps more and more frequently until you press the **Change** button. The Biographer displays the glucose reading alternating with the word **LOW**.

Because it takes about 15 minutes for glucose levels to rise after treating hypoglycemia (with carbohydrates), the Low Glucose Alert will only sound at the next reading in 10 minutes if the Biographer's alarm mode has been set to **ALL** (see page 6.2). Otherwise, the Low Glucose Alert will sound again in **20 minutes** if your glucose remains below your Low Alert level.

Changing the Low Alert level

When you receive your new Biographer, the Low Glucose Alert is preset at 100 mg/dL (5.6 mmol/L). Based on your individual needs, you and your health care team may decide to change the setting. Just follow these steps:

- Step 1:** From the time and date display, press the **Down** button 5 times until you see the display that says **LOW**.
- Step 2:** Hold down the **Change** button until the digit on the right begins flashing.
- Step 3:** Use the **Up** and **Down** buttons to set the correct digit. Press the **Change** button to move to the next digit.



Step 4: Repeat Step 3 until all digits are set correctly.

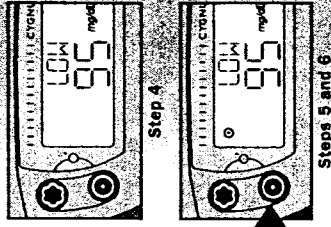
Step 5: Check to make sure numbers are correct, then press the **Start** button to store the values.

Step 6: Press the **Start** button again to return to the time and date display.

Caution:

Be sure to set the Low Alert level 10 mg/dL to 20 mg/dL above the blood glucose level that you want to make sure is detected. For example, if you want to detect a level of 80 mg/dL, you should set the Low Glucose Alert between 70 mg/dL and 80 mg/dL. Otherwise the Biographer may miss some low blood glucose events and the alarm will not sound.

Note: Your Biographer can read glucose levels between 40 mg/dL and 400 mg/dL (2.2 mmol/L and 22.2 mmol/L). Readings outside of this range will trigger a High or Low Glucose Alert. Those readings will appear on the Biographer display as <40 mg/dL (<2.2 mmol/L) or >400 mg/dL (>22.2 mmol/L). You can set your individual alert levels anywhere in between these values.



If the glucose level that you want to detect is...	Set the Low Glucose Alert of the Biographer at...
45 mg/dL	55-65 mg/dL
55 mg/dL	65-75 mg/dL
65 mg/dL	75-85 mg/dL
75 mg/dL	85-95 mg/dL

The Down Alert

The GlucoWatch® G2™ Biographer will automatically alert you if your glucose is dropping at a rate that might result in a Low Glucose Alert within the next 20 minutes. This allows you to evaluate and treat for potential hypoglycemia before your glucose gets too low. The G2™ Biographer displays the glucose reading alternating with the word **DOWN**. The ↓ trend arrow will also appear on the display.

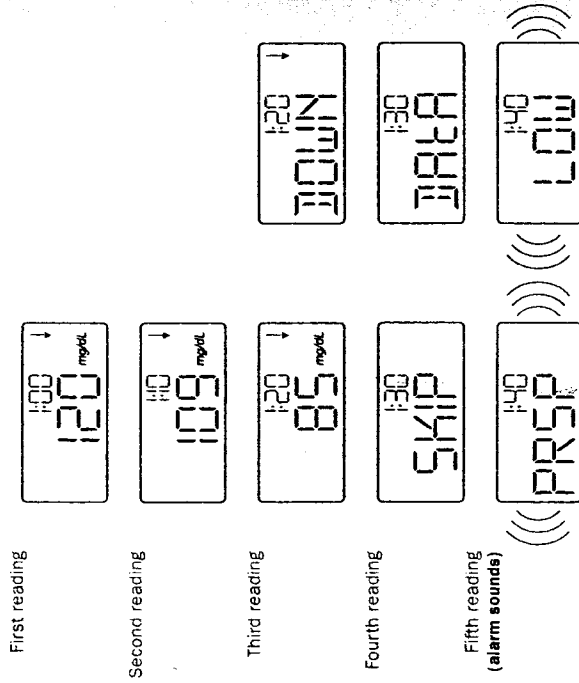
Caution:

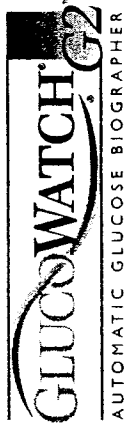
Remember that Biographer readings can sometimes be different from finger-stick test results. You must not rely on the Biographer to alert you every time your glucose is too high or too low. Never ignore symptoms that may be due to low blood glucose or high blood glucose.

The Hypoglycemia/Perspiration Alert

Perspiration can be an early symptom of hypoglycemia, or a rapid drop in glucose. The Biographer will sound an alarm if it detects perspiration and your last reading read **DOWN** or **LOW**. The display will read **PRSP** followed by **LOW**. The glucose reading will be skipped.

Here is an example of the Hypoglycemia/Perspiration Alert with the Low Glucose Alert set below 85 mg/dL:





How the G2 Biographer identifies potential problems

Frequency of alerts

The GlucoWatch® G2™ Biographer will not alert you every time it records glucose levels above or below your preset alert levels, or glucose levels that are dropping. To keep distractions to a minimum, the G2™ Biographer will alert you the first time this occurs and then periodically thereafter if the condition persists.

Alert reading	Frequency of beep	Duration
LOW	The Biographer will alert you the first time it gets a LOW reading, then every 20 minutes	It will continue to alert you every 20 minutes for as long as your glucose stays below your preset Low Alert level
HIGH	The Biographer will alert you the first time it gets a HIGH reading, then every 40 minutes	It will continue to alert you every 40 minutes for as long as your glucose stays above your preset High Alert level
DOWN	The Biographer will alert you the first time it gets a DOWN reading, then every 20 minutes	It will continue to alert you every 20 minutes for as long as your glucose level continues to drop

Note: If you have selected ALL for your alert option (see pages 6.2 and 6.5), the Biographer will sound 2 beeps every 10 minutes. However, if the Biographer is alerting you to out-of-range glucose levels, the beep will become more and more persistent.

41

42

43

Throughout the warm-up and 13-hour monitoring periods, your Biographer constantly checks to make sure the system is operating properly. When the Biographer is reading your glucose levels, 3 types of problems may arise:

Problem 1: The Biographer skips one or more glucose readings, but continues with the next scheduled reading.

Problem 2: The Biographer skips 18 consecutive readings in a 3-hour period, requiring it to be recalibrated. The previous calibration is cancelled and the Countdown timer disappears. The Biographer will then sound an alarm and the display will read CAL/END. Perform a finger-stick test when prompted (the display will read SET/CAL) and enter the blood glucose value in the same way you entered your original calibration value. The Biographer will not report any glucose readings until this new calibration value is accepted.

Problem 3: The Biographer unexpectedly stops monitoring. The Biographer alert will sound. To begin monitoring again, you must replace the AutoSensor and start over. (You must redo the warm-up and calibration steps.)

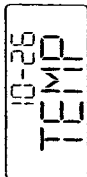
Note: When your Biographer stops monitoring unexpectedly, an alarm will always sound. When the Biographer skips a measurement due to excessive perspiration, an alarm will only sound if you have selected PRSP or ALL as the alarm option, or if the perspiration comes within 30 minutes of a LOW or DOWN alert. If the Biographer skips a measurement for any other reason, you will hear an alert only if you have selected ALL as the alarm option (see page 5.4 for a summary of OFF codes).

When the G2 Biographer skips a reading

Some conditions (such as too much perspiration or rapid temperature changes) may cause the GlucoWatch® G2™ Biographer to skip a reading. If this happens, you will see a **SKIP** message alternating with an identifying code. Try to correct the condition as soon as possible. The G2™ Biographer will attempt to take another reading in 10 minutes.

Codes for a skipped reading

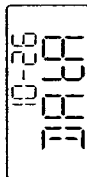
Any sudden change in skin temperature can prevent a reliable reading. Did you start out in a warm building, then go outside on a cold day? Did you just get into a car that's been in the sun?



Your skin temperature is too cold. Try covering the Biographer with your sleeve, a sweater, or a jacket.



Inconsistencies in results suggest that the current glucose value may not be reliable. This can occur if the Biographer is bumped, if you are moving your arm excessively, or if your glucose level is changing rapidly (eg, after meals).




Tip: If you have 4 or more **SKIP DATA** messages in a row, you may want to recalibrate the Biographer. See page 5.5 for details.



A reading can't be completed because the perspiration detector discovered an excessive amount of sweat. If the Biographer skips too many readings due to perspiration during the 13-hour monitoring period, it will stop monitoring.

If perspiration occurs within 30 minutes of a **LOW** or **DOWN** alert or if you have selected the **PRSP** or **ALL** alarm option, an alarm will sound. If the alarm sounds due to **PRSP**:

- Press the  Change button to silence the alarm
- Consider the possibility that your perspiration may be due to low blood glucose (hypoglycemia). Test your blood glucose with your regular blood glucose meter or, if necessary, contact a health care professional



Tip: If readings are frequently skipped due to perspiration, try wearing the Biographer further up your forearm. Since many people perspire more heavily near their wrists, this may reduce skipped readings.

When glucose measurement stops unexpectedly

If a problem occurs that is serious enough to shut down the glucose monitoring function, an alarm will sound and the display will flash **OFF** alternating with an identifying code. To begin monitoring again, remove and discard the AutoSensor. **Connect a new AutoSensor and start over** (see directions on page 3.6–3.7). You will need to repeat the 1-hour 55-minute warm-up period. If the problem occurs frequently or you can't get the Biographer to start up again, call our Customer Service Department toll free at 1-866-GLWATCH (1-866-459-2824).

Codes for problems that stop glucose measurements unexpectedly

OFF will flash alternating with one of the following codes:

Code	This means	Your next step
VOLT	<p>The GlucoWatch® G2™ Biographer has reached the high voltage limit for safe use. This means there's an inadequate electrical connection between the AutoSensor and your skin. This can happen if:</p> <ul style="list-style-type: none"> • There's too much hair • The adhesive bond is broken between the G2™ Biographer and the skin • The gel collection discs have dried out • The protective liner 2 has not been removed 	<p>Try to determine what happened before you start monitoring again with a new AutoSensor</p>
PRSP	<p>The perspiration detector found too much sweat on too many readings. Too much perspiration makes continued glucose readings unreliable. Remember that perspiration can be caused by low blood glucose</p>	<p>Remove the Biographer and allow the back of the Biographer to dry. After you have cooled down and are no longer perspiring, you may begin monitoring again with a new AutoSensor</p>
READ	<p>The Biographer can't measure the signal produced by the reaction of glucose in the gel collection discs. Several things could cause this to happen:</p> <ul style="list-style-type: none"> • The protective liner 1 has not been removed • The AutoSensor may not be properly seated on the back of the Biographer • There's a poor connection between the AutoSensor and the contacts on the back of the Biographer • There could be a small amount of water between the AutoSensor and the contacts • Four calibration attempts have been made without success • The AutoSensor Press was not used 	<p>Try to determine what happened before you start monitoring again with a new AutoSensor. Make sure that you have snapped the AutoSensor correctly onto the Biographer</p>

Recalibrating the G2 Biographer

A new calibration value can be entered into the Biographer during any 5-minute calibration period (the first 5 minutes of each 10-minute cycle). There are 2 situations in which you might want or need to recalibrate the Biographer.

A voluntary recalibration: You may want to recalibrate your Biographer if you discover that you made a mistake when entering your calibration fingerstick value, if your readings are inconsistent with your physical symptoms, or if you have done a fingerstick test and want to enter a new calibration value. When you recalibrate voluntarily, the Biographer continues to monitor your glucose based on your original calibration value until the new calibration value is accepted. The ⚡ Countdown timer will flash while the Biographer tries to confirm the new calibration value. If the new calibration value is NOT accepted, the Biographer will continue to report readings based on the original calibration, the alarm will sound, and the ⚡ Countdown timer will appear (but not flash). If the new calibration value IS accepted, 2 triple beeps will sound to confirm the new calibration value.

44

A forced recalibration: If 3 hours of consecutive SKIP messages are recorded, the Biographer will force you to recalibrate. An alarm will sound and the display will read CAL/END. The ⚡ Countdown timer will disappear and the Biographer will revert to an uncalibrated state.

45

Note: If a problem occurs during this critical period, the Biographer will sound an alarm and you will need to repeat the recalibration procedure. The Biographer will not provide any glucose readings until recalibration is completed successfully.

Recalibrating the G2 Biographer (continued)**For a voluntary recalibration:**

- Step 1:** Press the **⏻** Down button 6 times until the display reads **SET CAL**.
- Step 2:** After a couple of seconds the display will change to either
- **WAIT** on the lower display with 5 minutes or less remaining on the upper display
- OR
- **CAL** alternating with ---- mg/dL or mmol/L on the lower display with 5 minutes or less remaining on the upper display
- Step 3:** If the display reads **WAIT**, simply wait to do your finger-stick reading until the time remaining reaches 0:00 and the calibration period begins. The display will change to **CAL** alternating with ---- mg/dL or mmol/L on the lower display with 5 minutes or less remaining on the upper display.

Note: The GlucoWatch® G2™ Biographer will not automatically return to the time and date from the WAIT display. The alert will not sound when the calibration period begins. You will need to keep an eye on the time remaining so you will know when to do the calibration.

- Step 4:** Test your blood glucose level using a finger-stick and any regular blood glucose monitoring system. Enter the value into the G2™ Biographer. **Follow the instructions on page 3.14, beginning with Step 2.**
- Step 5:** Remember to press the **⏻** Start button twice to confirm the calibration value and return to the time and date display.
- Step 6:** Fifteen minutes after you enter the calibration value, the Biographer completes an internal measurement matched to your finger-stick reading. The **⚡** Countdown timer will flash on the display. The **⚡** Countdown timer will stop flashing after the Biographer measurement is completed and matched to your finger-stick reading. If calibration was successful, the Biographer will sound 2 triple beeps.

For a forced recalibration:

- Step 1:** Turn off the alarm and activate the calibration screen by pressing and holding the **⏻** Change button.
- Step 2:** The display will change to **CAL** alternating with ---- mg/dL or mmol/L on the lower display with 5 minutes or less remaining on the upper display.

Follow the instructions on page 5.6 for a voluntary recalibration, beginning with Step 4.

Conducting a Quality Control Test on your AutoSensors

The Quality Control (QC) Test helps you ensure that your glucose readings are as accurate as possible.

- Conduct a QC Test if you suspect that the AutoSensors have been exposed to extreme temperatures
- If you question a series of GlucoWatch® G2™ Biographer readings during a 13-hour period, do not use another AutoSensor from the same box without running both a System Check on the G2™ Biographer and a QC Test on one of the remaining AutoSensors
- If you are unable to successfully calibrate the Biographer, you may want to check one of the remaining AutoSensors by running a QC Test. It will take 50 minutes to complete the QC Test. Before you conduct the QC Test, make sure that you have the following items:
 - Your Biographer with a fully charged Ni-MH (AAA) battery
 - The AutoSensor Press
 - A new AutoSensor
 - A new tube of QC Test Solution
 - A new QC Test Well with adhesive label



Tip: To order QC Test materials

- QC Test Solution and Wells are available in a separate kit. If you're having trouble obtaining a QC Test Kit, call Customer Service for assistance at 1-866-GLWATCH (1-866-459-2824)

To conduct the test, follow these steps:

- Step 1:** Remove the AutoSensor from its pouch. Go to page 3.6 and follow the procedure for using the AutoSensor Press.



Step 1

Step 2: Connect the AutoSensor to the Biographer, but leave protective liner 2 in place (see page 3.7).

Step 3: From the time and date display, press the **Down** button 8 times. The display will read **QC MODE**.

Step 4: Press and hold the **Change** button until **QC** appears on the upper display and **OFF** flashes on the lower display.

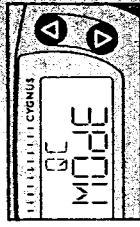
Step 5: Use the **Up** or **Down** button until **ON** flashes on the lower display.

Step 6: Press the **Start** button to begin the test. **WAIT** will appear in the lower display and the time remaining (20:00, or 20 minutes) will appear in the upper display.

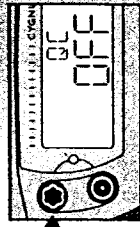
Note: You can set the Biographer down on either side during the 20-minute WAIT Period.

Step 7: After 20 minutes, the alarm will sound. The lower display will now read **GLUC** (glucose) and the upper display will show the time reset to 5 minutes. Press the **Change** button to confirm that you have heard the alarm.

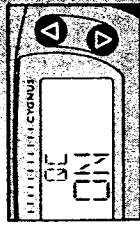
During this 5-minute period, you need to complete Steps 8 through 12.



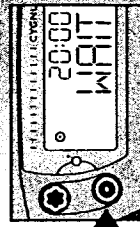
Step 3



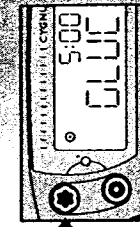
Step 4



Step 5



Step 6



Step 7

Conducting a QC Test (continued)

Step 8: Remove protective liner **2** from the AutoSensor by pulling the blue tab and peeling off the liner.

Step 9: Place the QC Test Well on the AutoSensor, making sure that the inside of the Well faces down and that the flat portion of the Well covers the entire surface of the 2 Gel collection discs. Press firmly around the edges of the QC Test Well to ensure good contact with the AutoSensor.

Step 10: Snap the top off of the tube of QC Test Solution.

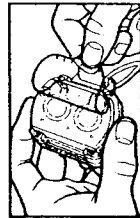
Step 11: Squeeze the solution into the hole in the QC Test Well. Make sure the QC Test Well is full. It may help to tilt the GlucoWatch® G2™ Biographer while filling the Well to prevent air bubbles.

Step 12: Place the adhesive label over the hole in the QC Test Well to prevent leaking. Leave the G2™ Biographer face down for the rest of the QC Test.

After the 5-minute period ends, a new 25-minute countdown period begins.

Step 13: After 25 minutes, the alarm will sound. (The alarm will sound earlier if an error occurs during the test.) Turn the Biographer over and press the **Change** button to confirm that you have heard the alarm.

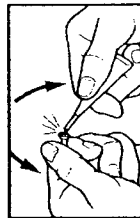
Note: The QC Test Solution is a glucose solution that will not harm the skin or clothing.



Step 8



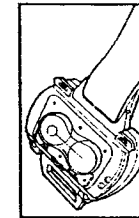
Step 9



Step 10





Step 11



Step 12

Step 14: Compare the readout on the display to the value printed on the QC Test box to determine the results of the test.

If the display reads	This means	Your next step:
<p>QC on the upper display with a numeric value on the lower display</p> 	<p>The test has been completed.</p>	<p>Compare the value shown on the lower display with the value printed on the QC Test box</p> <ul style="list-style-type: none"> If the displayed value is equal to or greater than the value on the box, you can begin glucose monitoring by removing the used AutoSensor and QC Test Well and inserting a new AutoSensor from the same box If the displayed value from the QC Test is below the value printed on the QC Test box, the box of AutoSensors should not be used for glucose monitoring
<p>QC on the upper display and ERR on the lower display</p> 	<p>An error was encountered during the QC Test (for example, a change in temperature or dropping the GlucoWatch® G2 Biographer)</p>	<p>Start the test over again with a new AutoSensor, tube of QC Test Solution, and QC Test Well</p>

Step 15: Press the **Start** button to return to the time and date display.

Caution:

If your QC Test value is below the value printed on the box, the box of AutoSensors should not be used. If this happens you should call Customer Service for assistance, or returning the failed box of AutoSensors.

GLUCOWATCH[®] G2

AUTOMATIC GLUCOSE BIOGRAPHER

- You can set many GlucoWatch[®] G2[™] Biographer functions to suit your personal preferences. You learned how to set the alarm clock and how to change the High and Low Glucose Alert settings in Chapter 4. This section explains how you can also:
- Change the language, units of glucose measurement, clock settings, and date settings
 - Turn on and off the low beeping sound that the G2[™] Biographer makes when the buttons are pressed
 - Select how you are alerted to glucose readings and other situations
- As you read this section you can follow along with the **Map of Biographer Displays** on page 7.17 of this *User's Guide*.

Changing the G2 Biographer settings

You can change the default settings for your Biographer to be just right for you. The settings that can be changed are shown in the following table.

Item	Choices	Default setting (US)
Language	See page 6.4	English
Glucose unit	mg/dL or mmol/L	mg/dL
Clock	12 hour or 24 hour	12 hour
Date	day/month or month/day	month/day
Keys (beep)	ON or OFF	ON
Alert option	MDST, ALL, or PRSP	MOST

Understanding the beep

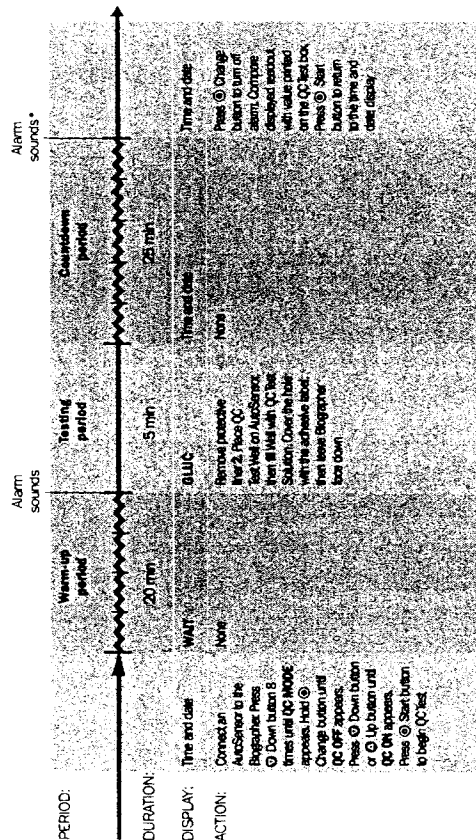
The Biographer has been preset to **ON** to sound a beep whenever a button is pressed. Changing this setting to **OFF** eliminates these beeps. This does **not** eliminate the alerts.

Conducting a QC Test (continued)

Step 16: Remove and discard the AutoSensor and QC Test Well.

Note: The AutoSensor, tube of QC Test Solution, and QC Test Well used for the QC Test cannot be reused. If you did not place the QC Test Well and QC Test Solution onto the AutoSensor before the end of the 5-minute application period, you will need to use a new AutoSensor and restart the test.

QC Test Timeline



* The alarm will sound earlier if an error occurs during the test.

Understanding the Alert option

46 Your GlucoWatch[®] G2™ Biographer will always alert you to the following circumstances:

- If your glucose readings are above or below the alert levels you select with your diabetes care team (HIGH or LOW)
- If your glucose readings are dropping and might go below the Low Alert level in the next 20 minutes (DOWN)
- If the G2™ Biographer reads LOW or DOWN within 30 minutes of perspiration being detected (PRSP/LOW)
- Any type of unexpected shut-off (OFF)

47

When the Biographer alert option is set to **MOST**, you will hear a beep in these circumstances only. The Biographer has 2 other alert settings: **PRSP** and **ALL**.

When the Biographer is set to **PRSP**, you will hear a beep for all of the circumstances listed above, as well as for every skipped reading due to perspiration. This is useful because perspiration may be an early symptom of hypoglycemia. You may wish to use this feature if perspiration is often a symptom of low glucose for you.

When the Biographer is set to **ALL**, you will hear a beep for all of the circumstances listed above, including every skipped reading due to perspiration, as well as:

- Each time a new glucose reading is available (every 10 minutes)
- At the end of each 13-hour monitoring period
- When a reading is skipped for reasons other than perspiration

The Biographer beeps and what they mean

Description of sound	What the sound means
2 beeps	Indicates that you've pressed the Start button for a System Check or to start the warm-up period. If you've selected ALL , this sound indicates that a new glucose reading is available
A beep that becomes more and more frequent (until you press the Change button)	<p>48</p> <p>Indicates it is time to calibrate your Biographer:</p> <ul style="list-style-type: none"> • Calibration value not accepted • 18 consecutive SKIP messages, causing the Biographer to require recalibration • An unexpected shut off of glucose monitoring has occurred <p>OR</p> <p>Indicates a potentially serious condition:</p> <ul style="list-style-type: none"> • Low glucose • High glucose • Low glucose possible in the next 20 minutes • Low or dropping glucose followed by perspiration <p>50</p> <p>If you've selected PRSP, it could also indicate:</p> <ul style="list-style-type: none"> • You are perspiring too much for glucose to be measured. The reading will be skipped <p>If you've selected ALL, it could also indicate the following conditions:</p> <ul style="list-style-type: none"> • A skipped glucose reading • The end of the 13-hour monitoring period
2 triple beeps	Calibration has been successfully completed.
Double beep that repeats continuously (until you press the Change button)	Calibration has been successfully completed. Indicates it is the time you set the Alarm Clock feature to sound

49

Changing the settings

Refer to the map of GlucoWatch® G2™ Biographer displays on page 7.17 of this User's Guide.

(A) Entering the SET MODE

Step 1: Start at the time and date display. Press the **Down** button 7 times.

Step 2: You should now see **SET** and **MODE**.

Step 3: Hold the **Change** button until you see **LANG** on the upper display and **ENGL** on the lower display.

(B) Selecting a language

Step 1: The **LANG** screen will appear and **ENGL** will start flashing. Press the **Up** or **Down** button to move through choices until the language you want appears:

- ENGL = English
- SVEN = Swedish
- PORT = Portuguese
- NL = Dutch
- ESPN = Spanish
- ITAL = Italian
- DEUT = German
- FRAN = French
- DAN = Danish
- SUOM = Finnish
- NOR = Norwegian
- PLSK = Polish
- CES = Czech
- MGYR = Hungarian

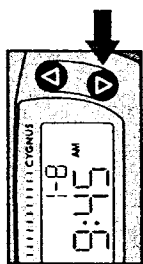
Step 2: Press the **Change** button to move to the next subject.

(C) Selecting units of measurement for glucose: mg/dL or mmol/L

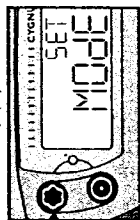
Step 1: You should see the **GLUC** screen with a flashing **---** **mg/dL** or **---** **mmol/L**.

Step 2: Press the **Up** or **Down** button to select **mg/dL** or **mmol/L**.

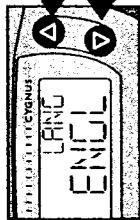
Step 3: Press the **Change** button to move to the next subject.



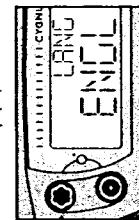
Step (A) 1



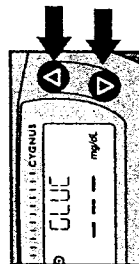
Step (A) 2



Step (B) 1



Step (B) 2



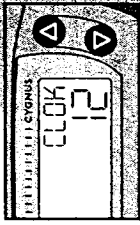
Step (C) 1

(D) Selecting a 12-hour (AM/PM) or 24-hour clock format

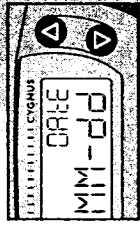
Step 1: You should see the **CLOCK** screen with a flashing **12** or **24**.

Step 2: Press the **Up** or **Down** button to select the clock you want.

Step 3: Press the **Change** button to move to the next subject.



Step (D) 1



Step (E) 1

(E) Selecting day/month or month/day format

Step 1: You should see the **DATE** screen with a flashing **MM-dd** (month/day) or **dd-MM** (day/month).

Step 2: Press the **Up** or **Down** button to select the option you want.

(F) Selecting the beep

Step 1: You should see the **KEYS** screen with a flashing **ON** or **OFF**.

Step 2: Press the **Up** or **Down** button to select the option you want.

(G) Selecting the Alert option

Step 1: You should see the **ALRM** screen with a flashing **MOST**, **ALL**, or **PRSP**.

Step 2: Press the **Up** or **Down** button to select the option you want.

(H) Saving the settings

Step 1: Press the **Change** button to confirm all of your choices.

Step 2: Press the **Change** button again to return to the time and date screen.



Caring for and storing your G2 Biographer

Your GlucoWatch® G2™ Biographer is simple to use and easy to maintain. Generally, all it takes to keep it in good working order are careful handling and regular cleaning. Just follow these easy guidelines for maintaining your G2™ Biographer:

Keep it clean

Use a damp cloth to clean the surface of the Biographer when needed. Do not use alcohol or try to clean the connectors.

Store it carefully

- If you expect that you won't use your Biographer for a week or more, insert a new or freshly charged Ni-MH (AAA) battery and put the Biographer into the power-save mode (see page 2.23). Store your Biographer with the battery door in place
- Before use, AutoSensors should generally be stored in a refrigerator (36°F to 46°F [2°C to 8°C]). Do not store AutoSensors in the freezer. If needed, AutoSensors can be stored at room temperature (below 77°F or 25°C) for up to 1 month. AutoSensors stored at room temperature must be used within 1 month

Handle it gently

Dropping or bumping the Biographer can damage the electronics. Rough handling can also disrupt the connection with the skin. If this happens, glucose monitoring may shut off.

Avoid prolonged exposure to extremes in temperature or humidity

Do not store the Biographer or the AutoSensors in your car.

Keep it dry

Never immerse your Biographer in water. Permanent damage is likely to result if water or other liquids get inside of the Biographer. Your Biographer is splash-resistant, not waterproof.

Caution:

Do not take the GlucoWatch® G2™ Biographer apart. You could damage sensitive parts and your results could be inaccurate. Taking the G2™ Biographer apart will also invalidate the warranty.

Skin care tips

After wearing your Biographer, you may notice:

- Two red and slightly bumpy circular patches on your skin where the gel collection discs were
- A slight red mark from the edges of the Biographer
- Occasional blisters, which may result from friction between the skin and the Biographer

You may also experience some itching. These symptoms should disappear within a week. They can be minimized by:

- Rotating wear sites
- Keeping skin clean and dry
- Avoiding scratching
- Protecting from the sun
- Using a lotion **after** removing the Biographer

Some people have sensitive skin and may experience severe redness or itching after wearing the Biographer.

Caution:

If any irritation does not improve after 1 week, consult your physician. Patients with suspected allergies to medical adhesives should consult their health care professional before using the Biographer.

Codes for problems with the G2 Biographer's memory

Three types of memory errors may occur with your Biographer. The following table identifies these errors and explains what you should do next should such an error occur.

Codes	This means	Your next step
Upper display reads ERR and lower display reads M1	An error has occurred with the Biographer's memory causing stored glucose readings to be lost	Press the Start button to return to the Time and Date display to resume glucose monitoring as normal. If this error occurs frequently, call Customer Service
Upper display reads ERR and lower display reads M2 OR Upper display shows the time and date and the lower display flashes ERR and M2	A potential error has occurred with the Biographer's settings or memory of your High and Low Alert levels	Insert a freshly charged Ni-MH (AAA) battery. Reset the Biographer. Re-enter all of the Biographer settings (see pages 6.4–6.5) and your High and Low Alert levels (see pages 4.5–4.7). If the error message displays again, contact Customer Service immediately
Upper display reads ERR and lower display reads M3 OR Upper display shows the time and date and the lower display flashes ERR and M3	An error has occurred with the Biographer's operating system	Replace the current battery with a freshly charged Ni-MH battery. Reset the Biographer. If the error message displays again, contact Customer Service immediately

Questions and answers

Note: A glucose monitoring program should be conducted under the guidance of your diabetes management team. Always consult a member of your diabetes care team before making changes in your treatment program.

The following pages provide answers to frequently asked questions about home glucose monitoring and the Biographer. If you have a question that's not covered here, consult a member of your diabetes care team or call our Customer Service Department toll free at 1-866-GLWATCH (1-866-459-2824).

Q. Why should I test my glucose (sugar) levels?

No doubt your diabetes care team has explained the importance of keeping your blood sugar level under control. Your Biographer helps you determine your degree of control by monitoring your glucose levels. The test results provide a good picture of how diet, exercise, and medication are affecting your diabetes.

Test results can also indicate whether your diabetes has changed in ways that might require an adjustment in your treatment plan.

Q. Should my test results always be the same?

No. Results may vary, depending on your diet, activity level, and the time of day. These variations provide useful clues about your condition and how well your treatment program is working.

With the help of your diabetes care team, you can determine your own personal target glucose values, as well as what an unusually high or low reading is for you. In most cases, your results should stay within the range you determine.

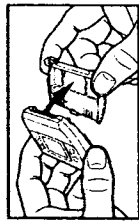
Resetting your G2 Biographer

If you have received an M2 or M3 error message (see page 7.3) or if you need to clear your stored data, you must reset your GlucoWatch® G2™ Biographer.

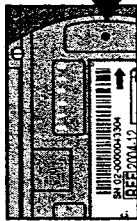
To reset, follow these steps:

- Step 1:** Remove the System Check Sensor, battery door, or the AutoSensor from the back of the G2™ Biographer.
- Step 2:** Insert a fully charged Ni-MH battery.
- Step 3:** Press the tip of a pencil or a narrow object into the Reset button on the back of the Biographer.
- Step 4:** Put the System Check Sensor, battery door, or the AutoSensor back on the Biographer. After it is reset, the Biographer will take a few seconds to return to the original time and date screen.
- Step 5:** See page 2.1.3 to reset the correct time and date.

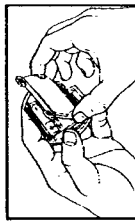
Note: Once the Reset button has been pushed, the Biographer will erase all customized settings and stored data. You will have to reset your alert levels and other preferences. See pages 4.3–4.7 and 6.4–6.5.



Step 1



Step 2



Step 3



Step 4

Questions and answers (continued)

Q What steps can I take to ensure that my readings are accurate?

- Run a System Check:
 - Before using the GlucoWatch® G2™ Biographer for the first time
 - Every time you open a new box of AutoSensors
 - If the watch is dropped or potentially damaged in any way
- Before use, AutoSensors should generally be stored in a refrigerator (36°F to 46°F [2°C to 8°C]). Do not store AutoSensors in the freezer. If needed, AutoSensors can be stored at room temperature (below 77°F or 25°C) for up to 1 month. AutoSensors stored at room temperature must be used within 1 month
- If you suspect that the AutoSensors may have been exposed to extreme temperatures, conduct a Quality Control (QC) Test before using them (see page 5.8)
- Always use the AutoSensor Press before attaching an AutoSensor to the G2™ Biographer. Press for a full 10 seconds
- Do not use an expired AutoSensor. Check the expiration date on the package label before use
- Use the AutoSensor immediately after opening the pouch. Do not store AutoSensors in open pouches
- Check the gel collection discs in the AutoSensor for any spots or areas of different color. The gel collection discs should have a uniform but “cloudy” appearance and are normally white to gray with a slight yellow tint. Do not use the AutoSensor if you see any spots or discoloration
- The accuracy of the Biographer depends on the accuracy of the blood glucose test used for calibration. Be sure to check your blood glucose meter and test strips according to the instructions. Your doctor may also want to check your meter against a standard lab test from time to time
- If you question the finger-stick reading that you plan to use for calibration, repeat the finger-stick test

- If you question a Biographer reading, use your regular blood glucose meter to do a finger-stick test. Keep in mind that Biographer readings correspond to blood glucose values from about 15 minutes earlier
- If you question a series of Biographer readings during a 13-hour period, do not use another AutoSensor from the same box:
 - Without running both a System Check and
 - A QC Test on one of the remaining AutoSensors

Q What if my glucose readings are consistently high for my own diabetes control plan?

A Your goal is to keep the amount of glucose in your blood as close to normal as possible. Normal, low, and high glucose values for your treatment plan should be determined with your diabetes care team. If your glucose readings remain consistently high, contact your health care team.

Q What are the target glucose values associated with well-controlled diabetes?

- Your own target glucose values should be determined by your health care team. If your glucose readings are frequently too low or too high, consult your health care team.
- Your regular blood glucose meter gives test results that are either:
- **Whole blood** glucose values, or
 - **Plasma** glucose values
- All meters use whole blood to begin the test. The difference comes with how the result is calculated. Check the instructions for your meter to find out what kind of values it gives.
- The Biographer readings are based on the finger-stick test result you use to calibrate the Biographer. This means that if your meter gives whole blood glucose values, the Biographer readings will also be whole blood values. If your meter gives plasma glucose values, the Biographer readings will be plasma values.

Questions and answers (continued)

Target glucose levels for people with diabetes depend on what type of result your meter and the GlucoWatch® G2™ Biographer provide. The table below shows the general targets suggested by the American Diabetes Association.⁷

	If your regular meter provides whole blood glucose values:	If your regular meter provides plasma glucose values:
Before meals:	80–120 mg/dL	90–130 mg/dL
At bedtime:	100–140 mg/dL	110–150 mg/dL

Q. With the G2™ Biographer, my glucose measurement is different than the reading I get at the same point in time with my regular blood glucose meter. Why is that?

Remember that it takes time for the Biographer to collect and measure glucose. **Each glucose reading from your Biographer actually reflects what your finger-stick reading would have been approximately 15 minutes earlier.** Blood glucose values can change rapidly, especially after you've eaten. So the lag time between the readings produced by the Biographer and your regular blood glucose meter is one explanation for the difference.

The source of the glucose can also affect your measurements. Glucose values differ depending on whether they are based on a blood sample taken from capillary blood (via a finger-stick), interstitial fluid* (via the Biographer), or venous blood (usually drawn from a vein in the arm during a lab test). So the values do not match precisely. Recent research also indicates that glucose in blood taken from alternate sites (for example, the arm, abdomen, or thigh) differs from finger-stick glucose, especially after meals, exercise, or an insulin dose. Finally, the accuracy of the Biographer depends on the accuracy of the blood glucose test used for calibration and for a comparison with Biographer readings. The Biographer has only been tested when calibrated with finger-sticks, not alternate-site glucose values. Be sure to check your blood glucose meter and test strips according to the instructions. Your doctor may also want to check your meter against a standard lab test from time to time. Be sure to perform the calibration procedure carefully (see page 3.14).

*Interstitial fluid is the fluid between the cells in the skin.

The Biographer pulls glucose contained in interstitial fluid through the skin so it can be measured.

Testing principle

How the Biographer measures glucose levels

The GlucoWatch G2 Biographer works through a process called reverse iontophoresis. This process allows the Biographer to collect glucose samples through intact skin by application of an extremely low electric current.

The battery inside the Biographer generates an electric field that pulls glucose molecules through the skin and then into the gel collection discs that are part of the AutoSensor, which is worn on the back of the Biographer next to the skin. The AutoSensor serves as the contact between the Biographer and your skin, conducting the electric current.

When current is applied, glucose molecules are pulled through the skin by charged molecules (positive and negative ions) and their surrounding medium, water. The ions migrate to the anode (+) and cathode (-) of the extracting electrodes that surround the gel collection discs in the AutoSensor. The glucose molecules are then collected in these discs for analysis.

The gel collection discs contain the enzyme glucose oxidase (GOx). As glucose enters the discs, it reacts with the GOx in the gel to form hydrogen peroxide. This reaction produces an electrochemical signal.

Biosensors surrounding the gel collection discs detect and measure this signal. The Biographer uses the calibration value to convert the signal to display your glucose levels.

The Biographer contains a built-in audible alarm to notify you of potentially dangerous glucose conditions. This, as well as many other features of the system, can be programmed according to your individual needs.

Both the electronics and the programmable software are built into an application-specific integrated circuit (ASIC) chip contained within the Biographer. The electrodes used to extract and sense glucose are screen-printed on a translucent plastic sheet that is part of the AutoSensor. Silver-based electrodes are used for extraction and platinum electrodes are used for sensing.

01-0111

Specifications

- Power supply:** 1 alkaline or rechargeable nickel metal hydride (Ni-MH) AAA battery
- Battery life:** 15 hours of use (13 hours of monitoring) per charge. Each Ni-MH battery can be charged approximately 500 times
- Result range:** 40 mg/dL to 400 mg/dL (2.2 mmol/L to 22.2 mmol/L). Out-of-range results will sound the alarm and the display will show <40 mg/dL or >400 mg/dL
- Calibration range:** 41 mg/dL to 279 mg/dL (2.3 mmol/L to 15.5 mmol/L)
- Display type:** Liquid crystal
- Case:** Drip-proof, IPX1 rating
- Dimensions:** 1.70" x 2.43" x .65"
- Operating temperature range:** 68°F to 104°F (20°C to 40°C) skin temperature
- Operating humidity range:** 0% to 90% relative humidity (noncondensing)
- Memory:** Storage capacity of over 8,500 data points, including test results, event codes, or error messages (oldest reading deleted first)
- Current:** 0.3 milliamps per square centimeter during iontophoresis
- Maximum applied voltage:** 16 volts DC
- Normal operating voltage range:** 4 to 5 volts DC

Warranty information

1-Year Limited Warranty
 Cygnus warrants to the original purchaser that the GlucoWatch® G2™ Biographer Starter Kit will be free from defects in materials and workmanship for a period of one (1) year from the date of purchase. During the stated 1-year period, Cygnus shall replace at no charge any component of the Starter Kit that is found to be defective. Proof of purchase shall be required as a condition for any replacement. This limited warranty shall not apply to defects caused by abuse, accident, alteration, misuse, or neglect by the purchaser. This limited warranty is the only warranty given by Cygnus and does not apply to the Cygnus AutoSensor or any other Cygnus product used separately or in conjunction with components of the GlucoWatch G2 Biographer Starter Kit.

Disclaimer

THIS LIMITED WARRANTY IS EXPRESSLY MADE IN LIEU OF ANY AND ALL OTHER WARRANTIES EXPRESSED OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. CYGNUS DISCLAIMS ALL CONSEQUENTIAL DAMAGES.

Warnings and precautions

Warnings

- Do not ignore symptoms that may be due to low blood glucose or high blood glucose. The GlucoWatch® G2™ Biographer may not detect every instance that your glucose levels are too high or too low. If you have symptoms that do not match the G2™ Biographer readings, use your regular blood glucose meter to check the Biographer results
- Do not change your treatment decisions based only on results from the Biographer. For example, some people use a blood glucose test result to help determine an insulin dose before each meal. This is often called a "sliding scale." If you use a sliding scale, be sure to confirm the Biographer result with your regular blood glucose meter to make sure you take the right amount of insulin
- Do not make fundamental changes in your treatment program without talking to your health care team. Serious illness or accidents may result
- Remember that Biographer readings can differ from finger-stick test results. When it is time to make an important decision, the Biographer should not be used as a "substitute" for a finger-stick test. The Biographer must be used with finger-stick blood testing. Then you can make the best treatment decisions and reduce the chance of problems

Precautions

- Always do the calibration step carefully. Entering the right number is important for accurate results. Follow the instructions for using your regular blood glucose meter. If you question the reading from your regular meter that you plan to use for calibration, repeat the blood glucose test
- Be sure to set the Low Alert level 10 mg/dL to 20 mg/dL above the blood glucose level that you want to make sure is detected. For example, if you want to detect a level of 60 mg/dL, you should set the Low Glucose Alert between 70 mg/dL and 80 mg/dL. Otherwise, the G2 Biographer may miss some low blood glucose events and the alarm will not sound
- Always check the last few readings in the Biographer memory to see the current trend in your glucose levels. One reading cannot tell you how fast your glucose levels are changing. If you question the Biographer results, confirm the Biographer readings with your regular blood glucose meter
- Do not place the Biographer at any site where you have skin irritation left from a prior use. The Biographer should only be placed on sites with normal, healthy skin. Avoid sites with skin abnormalities such as eczema, cuts, sunburn, or scarring. Skin irritation may be worse than normal.
- Do not use an expired AutoSensor. Check the expiration date on the package label before use
- Do not share your Biographer with another person. This will prevent spreading infections
- The Biographer readings may be affected by some hospital tests that use high electromagnetic equipment. This includes x-rays and MRI tests
- The medicines tolazamide or dopamine may affect Biographer readings. Tolazamide is a pill sometimes used for type 2 diabetes. Dopamine is given by injection for heart failure or shock. Ask a member of your health care team if you are uncertain if you are taking either of these medications

Accuracy
 tips to ensure accurate readings, 3.22, 7.6, 7.8
 versus blood glucose, 7.7, 7.8

Adhesive pad, 3.4, 3.5

Alarm clock
 disabling the alarm clock, 4.4
 setting the alarm clock, 4.3

Alerts (see Alerts)

Alerts
 at calibration, 3.15
 DOWN alert, 4.8
 due to perspiration, 5.3
 hypoglycemia/perspiration alert, 4.9
 for shut offs, 3.12
 for skipped readings, 5.2
 frequency of alerts, 4.10
 selecting alert levels, 4.5-4.7
 setting the high alert, 4.5
 setting the low alert, 4.6
 understanding alerts, 1.4, 4.4, 6.2, 6.3

AM/PM Indicator, 2.11

AutoSensor
 connecting to the Biographer, 3.7
 description of, 2.16, 3.3-3.5
 removing from the pouch, 3.3
 removing protective liner 1, 3.2, 3.6
 removing protective liner 2 (blue), 3.2, 3.7
 storage instructions, 3.3, 3.22, 7.1
 using the white removal tab, 3.5, 3.7, 3.9

Beeps, 6.1, 6.3
 for alerts
 DOWN, 4.8
 HIGH, 4.4
 LOW, 4.6
 PRSP/LOW, 4.9
 for ending monitoring
 END/CAL, 5.1
 OFF/STOP, 3.21
 for event markers
 EXER, 2.20
 ILL, 2.20
 MEAL, 2.20
 SET EVNT, 2.20
 SLEEP, 2.20
 SNAC, 2.20
 WAKE, 2.20
 for memory errors
 ERR/M1, 7.3
 ERR/M2, 7.3
 ERR/M3, 7.3
 for skipped readings
 SKIP/COLD, 5.2
 SKIP/DATA, 5.2
 SKIP/TEMP, 5.2
 SKIP/PRSP, 5.3
 for stopping monitoring
 OFF/STOP, 3.21
 for unexpected shut-offs
 OFF/PRSP, 5.4
 OFF/READ, 5.4
 OFF/VOLT, 5.4
 when battery is low
 BAT, 2.24
 when changing the settings
 ALRM, 6.5
 CLOK, 6.5
 DATE, 6.5
 GLUC, 6.4
 KEYS, 6.5
 LANG, 6.4
 SET MODE, 6.4
 when checking the status
 STAT/CAL, 3.18
 STAT/NEXT, 3.18
 STAT/OFF, 3.18
 STAT/WAIT, 3.18
 when conducting a Quality Control Test
 GLUC, 5.9
 QC ERR, 5.11
 QC MODE, 5.9
 WAIT, 5.9

Displays—Cont'd

when running a System Check
 FAIL, 2.21, 2.22
 PASS, 2.21, 2.22

Events
 setting of, 2.20
Finger-stick test, II, 1.8, 1.20, 3.14, 5.5, 7.7, 7.8
Gel collection discs, 1.4, 3.3-3.5, 7.6, 7.9

Glucose readings
 checking current reading, 3.20
 checking stored readings, 3.20

Glucose units, 6.4

Interstitial fluid, 7.8

Iontophoresis, 7.9

Lag time, 1.7, 1.9, 1.12, 1.13, 7.8

Memory errors, 7.3

Storage, 3.20

On indicator, 2.11

Passcode, 2.10

Perspiration detector, 2.7

Power levels, 2.24

Power-save mode, 2.23, 7.1

Protective liner 1, 3.2, 3.5, 3.12

Protective liner 2, 3.2, 3.5, 3.7, 3.9, 3.12

Quality Control (QC) Test
 how to, 5.8-5.12
 interpreting results, 5.11
 solution, 5.10
 when to, 3.22, 5.8
 forced recalibration, 5.5, 5.7
 voluntary recalibration, 5.5, 5.6
 when to, 5.2, 5.5

Reference number, 2.7

Removal tab
 description of, 3.4, 3.5
 during AutoSensor preparation, 3.7-3.9
 during Biographer removal, 3.22

Reset button, 2.7

Reset mode, 7.4

Serial number, 2.7

Settings
 alert option, 6.2, 6.5
 beeps, 6.1, 6.3, 6.5
 date, 6.5
 defaults, 6.1
 glucose units, 6.4
 keys, 6.5

Calibration (also see Recalibration)
 Bi range to calibrate, 3.14, 3.15, 3.17, 7.10
 how to, 3.14, 3.15, 3.17, 3.18
 recalibration procedure, 3.14, 3.15, 5.5-5.7
 troubleshooting, 3.14-3.16, 5.5-5.7
 voluntary recalibration, 5.5, 5.6

Codes (see Displays)

Countdown timer, 2.11, 2.12, 3.15, 3.17, 5.5
 when it flashes, 5.6

Customer service, II

Date
 setting date, 2.13, 2.14, 6.5

Displays
 during calibration
 CAL/...., 3.14, 3.16
 LOW, 3.15
 HIGH, 3.15

Change, 2.12

Down, 2.12

Reset, 2.7

Start, 2.12

Up, 2.12

Calibration (also see Recalibration)
 Bi range to calibrate, 3.14, 3.15, 3.17, 7.10
 how to, 3.14, 3.15, 3.17, 3.18
 recalibration procedure, 3.14, 3.15, 5.5-5.7
 troubleshooting, 3.14-3.16, 5.5-5.7
 voluntary recalibration, 5.5, 5.6

Codes (see Displays)

Countdown timer, 2.11, 2.12, 3.15, 3.17, 5.5
 when it flashes, 5.6

Customer service, II

Date
 setting date, 2.13, 2.14, 6.5

Displays
 during calibration
 CAL/...., 3.14, 3.16
 LOW, 3.15
 HIGH, 3.15

Battery
 description of, 3.6
 use of, 3.2, 3.6, 3.19

Battery backup lithium, 2.6

Rechargeable nickel metal hydride (Ni-MH) AAA
 inserting into the Biographer, 2.9
 power levels, 2.24
 recharging, 2.3, 7.10
 removing from the Biographer, 2.10

Battery charger
 during calibration
 attaching the adapter plug, 2.4
 description of, 2.4, 2.5
 inserting a battery, 2.9

Battery compartment, 2.8

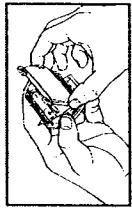
Battery door
 attaching to the Biographer, 2.15, 7.1
 description of, 2.8



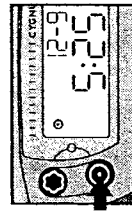
2

Running a System Check

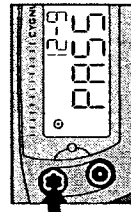
Caution: You must insert a freshly charged battery in the battery compartment each time you put on your Biographer.



Step 1: Make sure the System Check Sensor is connected to your GlucoWatch[®] G2[™] Biographer.



Step 2: Press and hold the **Start** button until the **On** indicator on the display appears and you hear 2 beeps.



Step 3: Your G2[™] Biographer will run the System Check. After about 10 seconds, the alarm will sound and the lower display will show **PASS** or **FAIL**. Press the **Change** button to confirm that you have heard the alarm.

Step 4: If the display shows **PASS**, press the **Start** button to return to the time and date display. If the display shows **FAIL**, the System Check Sensor may not have been properly seated. Reseat the System Check Sensor and run another System Check or call Customer Service at 1-866-GLWATCH.

NEED HELP? Visit our Web site: www.glucowatch.com or call Customer Service toll free: 1-866-GLWATCH (1-866-459-2824)

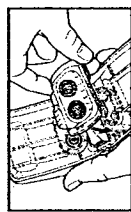
Connecting the AutoSensor

Step 1: Remove the System Check Sensor, battery door, or used AutoSensor from the back of the GlucoWatch G2 Biographer if you have not already done so.

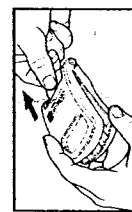


Step 2: Gently handling the AutoSensor, remove it from its pouch.

Caution: Check the gel collection discs for any spots or areas of different color. The gel collection discs should have a uniform but cloudy appearance. The gel collection discs are normally white to gray with a slight yellow tint. Do not use the AutoSensor if you see any spots or discoloration.



Step 3: Open the lid of the AutoSensor Press. Place the AutoSensor—adhesive pad side up—into the AutoSensor Press. There are 2 pegs in the Press that fit through the holes in the AutoSensor. The liner labeled with the row of 1s will hang out of the back of the Press.



Step 4: Gently bring the lid of the AutoSensor Press down. Holding the sides, remove protective liner 1 on the AutoSensor.

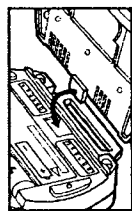
NEED HELP? Visit our Web site: www.glucowatch.com or call Customer Service toll free: 1-866-GLWATCH (1-866-459-2824)

by pulling the tab labeled with 1s through the opening at the hinged end of the Press. Do not squeeze the lid while attempting to remove liner 1. Discard the liner.



Step 5: Firmly close the Press so that the lid and the base touch. Hold closed for a full 10 seconds.

Step 6: Open the lid and remove the AutoSensor.



Step 7: Connect the AutoSensor to the Biographer by placing the tab on the AutoSensor into the slot on the back of the Biographer and holding the AutoSensor with your thumb and forefinger to snap it into place. A click lets you know the AutoSensor is properly seated.

Caution: Do not skip these important directions. Be sure to use the AutoSensor Press. Skipping this step may cause faulty readings. Do not directly press the adhesive pad onto the electrodes with your fingers.



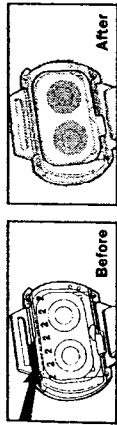
Manufactured by: Cygnum, Inc., 400 Penobscot Drive, Redwood City, CA 94063
AW2242-00 May 2002
©2002 Cygnum, Inc. Printed in U.S.A.

3
NEED HELP? Visit our Web site: www.glucowatch.com or call Customer Service toll free: 1-866-GLWATCH (1-866-459-2824)

Putting on the G2 Biographer

Step 1: Before putting on your GlucoWatch® G2™ Biographer, check to make sure that you have the correct watchband attached. Also, clean your skin with an alcohol swab and make sure to let your skin dry.

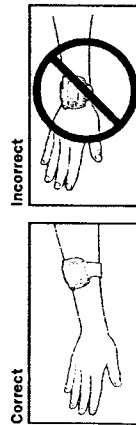
Step 2: Remove protective liner 2 from the AutoSensor by pulling the blue tab. Do not pull the white removal tab!



Step 2

Caution: Check to make sure the AutoSensor has the white removal tab. Do not remove the white tab before use. Do not use the AutoSensor if the removal tab is missing.

Step 3: Place the G2™ Biographer onto the selected wear site (on either your inner or outer forearm at least 2 inches from your wrist).



Step 3

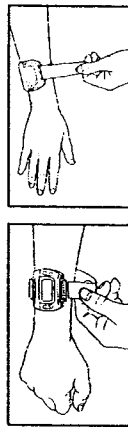
Step 4: Press firmly on the Biographer, so that the adhesive on the AutoSensor makes a firm bond with your skin.



Step 4

Caution: Remember, do not touch the sticky surface of the AutoSensor. Also, put on your Biographer immediately; otherwise, the gel collection discs on the AutoSensor may dry out.

Step 5: Feed the watchband through the D-ring and then pull the strap to tighten the band. Join the 2 Velcro® pieces together to fasten.

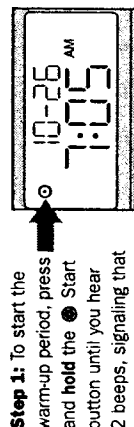


Step 5

Caution: Do not fasten the watchband too tightly. Blisters may occur due to friction between skin and the Biographer.

Starting monitoring

The GlucoWatch G2 Biographer requires a 2-hour warm-up period before you can calibrate it and begin monitoring.



Step 1

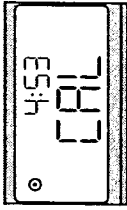
Step 1: To start the warm-up period, press and hold the Start button until you hear 2 beeps, signaling that the warm-up period has begun. The On indicator will now appear on the display.

Step 2: After the warm-up period, the alarm sounds to let you know that it's time to calibrate your Biographer.

Velcro is a registered trademark of Velcro Industries S.V.

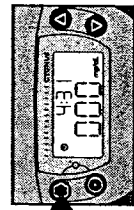
Press the Change button to shut off the alarm.

Step 3: You will see a flashing CAL message. Within the next 5 minutes, measure your blood glucose using a regular meter and enter your finger-stick reading into the Biographer.



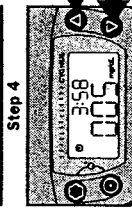
Step 3

Note: When you calibrate your Biographer, your blood glucose value must be between 41 mg/dL and 279 mg/dL.



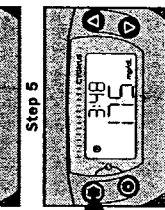
Step 4

Step 4: Press and hold the Change button until the CAL message is replaced by 3 zeros.



Step 5

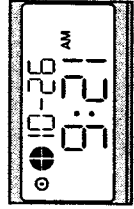
Step 5: Use the Up or Down button to replace the flashing zero with the number from your finger-stick test.



Step 6

Step 6: Press the Change button so the next zero flashes and repeat until all numbers are entered (from right to left).

Step 7: Press the Start button to confirm the calibration. Press the Start button again to return to the time and date display.



Step 8

Step 8: Over the next 15 minutes, the Biographer completes an internal measurement matched to your finger-stick reading. When this internal measurement is completed, the Countdown timer will appear on the display. Automatic glucose monitoring is now under way.

Checking earlier readings

Press the Up button to scroll backward through your glucose readings. Press and hold the Up button to move quickly through memory.

Stopping monitoring

Press both the Start button and the Change button at the same time. The On indicator and the Countdown timer will disappear from the upper display. OFF alternating with STOP will appear in the lower display and an alarm will sound. Press the Change button to stop the alarm. Press the Start button to return to the time and date display.

When you stop glucose monitoring, you must replace the used AutoSensor before you can monitor again!