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 ucose values, the Biographer readings will also hole blood values. If your meter gives plasma ose values, the Biographer readings will be plasma 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 Biographer readings**

- The *User's Guide* includes directions for how to test your GlucoWatch Biographer to make sure it is working correctly. Two types of tests can be done: the System Check and the QC (Quality Control) 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

is section is meant for health care professionals. .i 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 Biographer. Each patient must complete an introductory training program (provided by the manufacturer) 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.

**INTENDED USE**

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

The GlucoWatch 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 12-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.
- Performance of this device has been studied only in patients age 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 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.

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 30 mg/dL above the level at which detection of 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® 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 medi- —water. The ions migrate to gel collection discs ed at the anode (+) and cathode (-) in a single- 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 175 minutes (about 3 hours). The Biographer will then complete a reading every 20 minutes for up to 12 hours. The result is a time-averaged measurement of glucose level over the 20-minute cycle.

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 alarm will also sound if the glucose level is dropping rapidly (35% or more below the previous reading).

## PERFORMANCE CHARACTERISTICS

Four studies of similar design were conducted to ess the effectiveness of the GlucoWatch rapher in different use environments. Biographer dings were compared to blood glucose (BG) sts performed once or twice per hour. Subjects in hese studies were 18 years of age or older with either type 1 or type 2 diabetes requiring treatment with insulin. The design of these studies is summarized in **TABLE II**.

| TABLE II | Study 1 | Study 2 | Study 3 | Study 4 |
|---|---|---|---|---|
| Environment | Clinic | Home Simulated | Home Use | Home Simulated |
| Calibrating device | Hemocue® photometer[a] | One Touch® Profile® meter | One Touch Profile meter | YSI analyzer[b] |
| Comparative device | Hemocue photometer[a] | Hemocue photometer[a] | One Touch Profile meter | YSI analyzer[b] |
| Duration of use | 1 day (15 hrs) | 2 days and 1 night[c] | 5 days | 1 day (15 hrs) |
| Subjects | 221 | 120 | 111 | 28 |

[a] A point-of-care system that provides lab-quality results
[b] A standard laboratory method for measuring glucose levels
[c] Comparative BG measurements were only made during the daytime periods

**Detection of trends and patterns in glucose levels**

The GlucoWatch Biographer readings closely matched the direction and speed of changes reflected in the blood glucose data. The median correlation coefficient was approximately 0.90 in each of the 4 studies.

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 from Study 3 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 100 mg/dL, 75% (120/160) of the events of hypoglycemia were detected by the Biographer (see **TABLE III**). In addition, the Biographer correctly identified the absence of hypoglycemia on 90% (2599/2900) 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 III | BG ≤70 mg/dL | BG >70 mg/dL |
|---|---|---|
| Biographer reading ≤100 mg/dL | 120 | 301 |
| Biographer reading >100 mg/dL | 40 | 2599 |
| Total | 160 | 2900 |

Based on patient logbooks from this study, 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. Post-prandial hyperglycemia was common in the home use environment of Study 3. Out of 974 evaluable post-meal periods, 456 (47%) had a post-prandial BG level of greater than 200 mg/dL and 238 (24%) had a post-prandial BG level of greater than 250 mg/dL. None of these hyperglycemic events would be detected with standard pre-meal BG testing alone.

To assess Biographer detection of hyperglycemia, Study 3 results were analyzed using a definition of BG ≥300 mg/dL. At a High Glucose Alert level of 240 mg/dL, 86% (132/154) of the events of hyperglycemia were detected by the Biographer (see **TABLE IV**). In addition, the Biographer correctly identified the absence of hyperglycemia on 86% (2491/2906) of the occasions when BG was less than 300 mg/dL.

| TABLE IV | BG ≥300 mg/dL | BG <300 mg/dL |
|---|---|---|
| Biographer reading ≥240 mg/dL | 132 | 415 |
| Biographer reading <240 mg/dL | 22 | 2491 |
| Total | 154 | 2906 |

**Agreement between individual Biographer readings and blood glucose test results**

Different methods were required to evaluate the performance of this non-invasive 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. In addition, in the home use studies the comparative system was a home meter, which has greater variability than a standard laboratory analyzer. 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 in each study. For each data pair, the difference between the Biographer reading and the BG measurement was calculated as a percentage of the BG value.

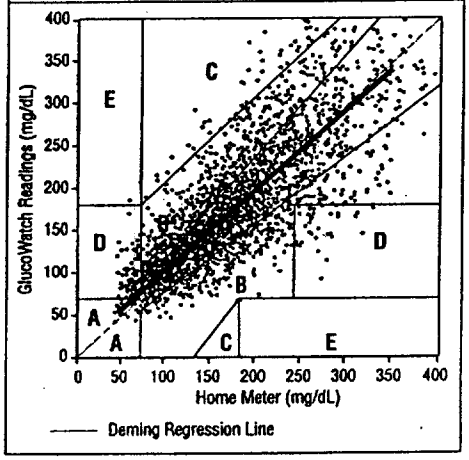
Regression analysis was used to characterize the relationship (slope and intercept) between the Biographer readings (dependent variable) and the comparative BG measurements (independent variable). Deming linear regression was used to account for variability in the comparative measurements.

The paired point results from the 4 primary effectiveness studies are summarized in **TABLE V.**

Substantial variability was observed in the differ-ce between individual GlucoWatch Biographer ngs and the paired comparative BG measure-.its. This can be seen in the correlation plot below for Study 3.

**Correlation plot of GlucoWatch Biographer readings versus home BG measurements from Study 3** (N=2966 Paired Points)

FIGURE 1




Some of the variability in agreement is related to the differences in sample source, timing of readings, and accuracy of the comparative devices. However, nalyses have indicated that performance of the rapher can vary from use to use (ie, day 1 ver-day 2) and within an individual 12-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 shown in **TABLE VI** illustrate the differences seen when using a home meter for comparison (Study 3) versus a standard laboratory analyzer (Study 4).

The Clarke Error Grid was used to assess the clinical relevance of the differences between the Biographer readings and the comparative BG measurements.[1] The Error Grid divides a correlation plot into 5 zones. (See **TABLE VII.**)

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 from Study 3.

In the 4 effectiveness studies, the percent of Biographer readings within the clinically acceptable zones (A and B) ranged from 94% to 98%. Less than 1 out of every 1,000 Biographer readings (8 out a total of 14,092 paired readings) were in the neous treatment zone (E).

assess the clinical relevance of Biographer performance at high and low glucose levels, the Error Grid results were stratified by BG range. **TABLES VIII** and **IX** show the overall distribution of points by Error Grid zone for Studies 3 and 4 along with stratified results by four BG ranges.

| TABLE V | Study 1 | Study 2 | Study 3 | Study 4 |
|---|---|---|---|---|
| Environment | Clinic | Home Simulated | Home Use | Home Simulated |
| Paired glucose measurements | 6909 | 3771 | 2996 | 416 |
| Mean absolute difference | 19% | 21% | 21% | 17% |
| Deming regression slope (95% confidence interval) | 0.93 (0.92, 0.95) | 1.00 (0.97, 1.03) | 0.95 (0.91, 0.99) | 0.94 (0.88, 1.01) |
| Deming regression intercept (95% confidence interval) | 12 mg/dL (9, 15) | 0 mg/dL (-5, 4) | 13 mg/dL (7, 18) | 8 mg/dL (-1, 17) |

**TABLE VI**

| | Study 3 | | | Study 4* | | |
|---|---|---|---|---|---|---|
| BG range (mg/dL) | # of paired points | % within 20%† | % within 30%† | # of paired points | % within 20%† | % within 30%† |
| **Overall** | **2996** | **61%** | **76%** | **420** | **71%** | **86%** |
| 40-80 | 261 | 45% | 45% | 42 | 67% | 67% |
| 81-120 | 598 | 59% | 72% | 93 | 71% | 82% |
| 121-240 | 1706 | 64% | 82% | 246 | 73% | 89% |
| >240 | 431 | 63% | 79% | 39 | 62% | 95% |

† For the low glucose range (40-80 mg/dL) the value shown is the percent within 20 mg/dL.
* For this analysis a home meter result was used for calibration and the YSI analyzer was used for comparative values.

**TABLE VII**

| 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).

| TABLE VIII | Study 3: Error Grid by Blood Glucose Range | | | | | |
|---|---|---|---|---|---|---|
| BG range (mg/dL) | # of paired points | A+B | A | B | C | D | E |
| **Overall** | **2996** | **94%** | **60%** | **34%** | **1%** | **4%** | **0.1%** |
| 40-80 | 261 | 63% | 35% | 28% | 0.4% | 36% | 0.8% |
| 81-120 | 598 | 99% | 59% | 41% | 0.7% | Not applicable | |
| 121-240 | 1706 | 98% | 64% | 35% | 2% | | 0.1% |
| >240 | 431 | 90% | 63% | 27% | 2% | 8% | 0.0% |

| TABLE IX | Study 4: Error Grid by Blood Glucose Range* | | | | | |
|---|---|---|---|---|---|---|
| BG range (mg/dL) | # of paired points | A+B | A | B | C | D | E |
| **Overall** | **420** | **98%** | **70%** | **28%** | **0.0%** | **2%** | **0.0%** |
| 40-80 | 42 | 81% | 57% | 24% | 0.0% | 19% | 0.0% |
| 81-120 | 93 | 100% | 71% | 29% | 0.0% | Not applicable | |
| 121-240 | 246 | 100% | 73% | 27% | 0.0% | | 0.0% |
| >240 | 39 | 97% | 62% | 36% | 0.0% | 3% | 0.0% |

* For this analysis a home meter result was used for calibration and the YSI analyzer was used for comparative values.

| TABLE X | | | | |
|---|---|---|---|---|
| Average Biographer reading (mg/dL) | # of individuals | # of paired points | Median standard deviation | Median (range) percent coefficient of variation |
| **Overall** | **21** | **765** | **17 mg/dL** | **10% (3%, 19%)** |
| 40-80 | 14 | 59 | 6 mg/dL | 9% (1%, 21%) |
| 81-120 | 18 | 155 | 9 mg/dL | 8% (3%, 16%) |
| 121-240 | 21 | 472 | 18 mg/dL | 10% (3%, 19%) |
| >240 | 13 | 79 | 33 mg/dL | 12% (2%, 24%) |

In Study 3, 94% 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 home meter 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]

In Study 4, when a more accurate laboratory analyzer (YSI) was used for comparison, 98% of Biographer readings were in zones A and B and 2% were in zone D. Again, most of the zone D results occurred in the low BG range.

**Precision of GlucoWatch Biographer readings**

Precision was estimated by comparing readings from 2 Biographers worn simultaneously at different skin sites by subjects (n = 21) over 3 days. The first day was in a home-simulated environment and the final 2 days were during actual home use. **TABLE X** shows the median within individual results from the ...e use period.

...variability between paired Biographer readings increases as a function of glucose range. All covariances for each individual were <25% 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 2% 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 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 ...dy period.

...nts should be advised to rotate wearing sites for ... device. The GlucoWatch Biographer should not ... 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 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. In the home use studies, approximately 20% of readings were skipped.

If a problem is identified with the Biographer reading to be used for calibration, the calibration process must be repeated. In the home use studies, approximately 20% of Biographer uses required more than one calibration attempt. Infrequently (4% of Biographer uses) the calibration process was unable to be completed. This most often occurred when subjects were unwilling to make repeated calibration attempts and chose to shut off the Biographer.

Certain problems (eg, heavy perspiration) can cause the Biographer to discontinue glucose monitoring before the end of the 12-hour monitoring period. In the home use studies, approximately 25% 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 26 to 29 glucose readings (out of a maximum of 36) per use in the home use studies.

**Selection of calibration blood glucose meters**

As part of each use, the GlucoWatch 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 have included an assessment of calibration of the Biographer using results from 4 home glucose meters: the One Touch® Profile®, the AccuChek® 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 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 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 are shown below:

- **Power supply:** 1 alkaline or rechargeable nickel metal hydride triple A 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 4,000 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.



If you have any questions, please call our Technical Services Department toll free at 1-866-GLWATCH.

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