

GlucoWatch® G2™ Biographer Fact Sheet

- The GlucoWatch® G2™ Biographer is the second-generation model of the GlucoWatch® Biographer device, the first and only monitoring device that provides glucose readings frequently, automatically and non-invasively.
- The GlucoWatch G2 Biographer enables individuals with diabetes to monitor glucose levels as frequently as every 10 minutes, for up to 13 hours. The frequency of the readings helps these individuals, their physicians and caregivers make better-informed decisions regarding diet, medication and physical activities.
- The Biographer is worn like a watch. It uses an extremely low electric current to pull glucose through the skin, not from blood like standard glucose meters. The glucose is then collected and transformed into an electric signal that is converted into a glucose reading. Every reading is displayed and stored in memory, which can be reviewed at the touch of a button.
- The device consists of two integrated parts, the Biographer and the AutoSensor:
 - The Biographer calculates, displays and stores glucose readings.
 - The AutoSensor is a single-use component that collects and measures the glucose sample. It snaps into the back of the Biographer and adheres to the skin, providing up to 13 hours of automatic readings.
 - The wearer first attaches an AutoSensor to the back of the Biographer, and straps the Biographer to his or her arm. Then a two-hour warm-up period allows for accurate calibration. After the warm-up period, the wearer performs a finger-stick test using a blood glucose meter to calibrate the Biographer, which will then automatically measure, display and store glucose readings.
 - Patients can also download readings from the G2 Biographer to a personal computer with the GlucoWatch Analyzer software program. This enables patients, physicians and caregivers to print graphs, charts and statistics, change biographer settings, and send data via e-mail -- a convenient way to send glucose data before a scheduled office visit.
- Studies show 95% of G2 Biographer readings are clinically accurate or acceptable.¹
- The Biographer detects almost six times more hypoglycemia (low blood sugar) events than twice-daily finger-stick testing.²
 - In FDA clinical studies, the GlucoWatch G2 Biographer was able to detect 77% of hypoglycemic events, with a low alert level set at 80mg/dL, compared to “finger stick” monitoring detection of hypoglycemic events at a rate of 13% when done twice daily and 39% when done four times daily.³

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- The Biographer detects 13 times more hyperglycemia (high blood sugar) events than twice-daily finger-stick testing.⁴
 - The Biographer was also able to detect 78% of hyperglycemic events, with an alert level set at 180mg/dL, compared to 17% detection of hyperglycemic events with four times daily “finger stick” monitoring.⁵

- GlucoWatch® G2™ Biographer key features include:
 - Selectable high and low glucose alerts.
 - Audible alert for "predictive" notification before a pre-set low glucose value is actually encountered.
 - “Electronic Diary” which can store up to 8,500 data points.
 - Event markers can be stored in the diary to create a running record of certain events each day. By using this option, wearers can see how day-to-day activities affect glucose levels. Choices include:
 - ❖ MEAL = Breakfast, lunch, or dinner
 - ❖ SNAC = Between-meal snack
 - ❖ INJ = Insulin injection
 - ❖ SLEP = Went to bed
 - ❖ WAKE = Woke up
 - ❖ EXER = Exercise
 - ❖ ILL = Illness
 - Multiple language support in English, French, Swedish, Danish, Portuguese, Finnish, Dutch, Norwegian, Spanish, Polish, Italian, Czech, German, and Hungarian.
 - Two units of measurement are offered: mg/dL or mmol/L.

- The U.S. Food and Drug Administration (FDA) approved the use of the GlucoWatch G2 Biographer in adults in March 2002, and granted supplemental pre-market approval (PMA) for the Biographer for pediatric use in August 2002.

- The GlucoWatch G2 Biographer is not intended to replace the common "finger-stick" testing method, but is indicated as an adjunctive device to supplement blood glucose testing to provide ongoing information about glucose levels.

- The GlucoWatch G2 Biographer has a favorable safety profile. In clinical trials involving over 25,000 hours of use, the Biographer was shown to be safe and generally well tolerated.⁶ Most patients experienced temporary irritation where the GlucoWatch G2 Biographer was in contact with the skin. This usually mild irritation typically subsided within a few days. In addition, the GlucoWatch Biographer does not interact with pacemakers or other implanted devices. Studies have not detected any evidence of interference in the operation of the GlucoWatch Biographer due to electromagnetic fields created by other devices or equipment.⁷

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¹ GlucoWatch G2 Biographer Prescribing Information. Cygnus, Inc., Redwood City, Calif.

² Data on file. Cygnus, Inc., Redwood City, Calif.

³ Data on file. Cygnus, Inc., Redwood City, Calif.

⁴ Data on file. Cygnus, Inc., Redwood City, Calif.

⁵ Data on file. Cygnus, Inc., Redwood City, Calif.

⁶ Data on file. Cygnus, Inc. Redwood City, Calif.

⁷ Data on file. Cygnus, Inc. Redwood City, Calif.