



# New Device Approvals

## GlucoWatch® Automatic Glucose Biographer

*This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.*

**Product Name:** GlucoWatch® Automatic Glucose Biographer  
**Manufacturer:** Cygnus, Inc.  
**Address:** 400 Penobscot Drive, Redwood City, CA 94063  
**Approval Date:** March 22, 2001  
**Approval Letter:** <http://www.fda.gov/cdrh/pdf/p990026a.pdf>

**What is it?** The GlucoWatch® Biographer is a glucose monitoring device that a patient wears like a wrist watch. Glucose measurements are taken non-invasively through the skin every 20 minutes for up to 12 hours at a time. The GlucoWatch® measurements are not intended to replace finger-stick glucose measurements, but instead should be used to detect trends and patterns in glucose levels in adults age 18 and over.

**How does it work?** After a 3-hour warm-up period, the patient calibrates (sets) the GlucoWatch® Biographer using a finger-stick measurement. After calibration, the Biographer will begin monitoring glucose values. A low level electric current pulls fluid through the skin into gel discs in the Biographer. Electrodes in the Biographer measure glucose in the collected fluid for up to 12 hours at a time. The GlucoWatch® Biographer also contains a built-in alarm that can be programmed to alert the user when results fall below pre-set low levels and above pre-set high levels.

**When is it used?** The GlucoWatch® Biographer is used with fingerstick measurements to provide additional glucose information to adults with diabetes, age 18 and over, and to their healthcare practitioners.

**What will it accomplish?** Additional glucose information may help people with diabetes and their healthcare practitioners to better manage their disease by providing more information on glucose trends and patterns than could be obtained with fingerstick glucose measurements alone.

### **When should it not be used?**

- The GlucoWatch® Biographer is a prescription device. It should not be used if it is not ordered by a physician.
- It should not be prescribed by a physician until he/she completes a formal training program.
- It should not be used until the patient successfully completes a formal training program.
- It should not be used by or for patients under 18 years of age.
- It is not a replacement for blood glucose meters. Treatment decisions should not be made or changed based on Biographer results alone.

**Additional information:** Summary of Safety and Effectiveness and labeling are available at: <http://www.fda.gov/cdrh/pdf/p990026.html>

Other:

- FDA Talk Paper: <http://www.fda.gov/bbs/topics/NEWS/2001/NEW00758.html>
- American Diabetes Association: <http://www.diabetes.org>
- National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), NIH: <http://www.niddk.nih.gov/health/diabetes/diabetes.htm>
- GlucoWatch information from NIH: <http://www.niddk.nih.gov/health/diabetes/datetime/fall00/3.htm>
- Links to all diabetic organizations & Research Centers: <http://www.niddk.nih.gov/health/diabetes/pubs/diaborgs/diaborgs.htm>