

Guardian[®] RT Continuous Glucose Monitoring System

– Real-time glucose readings and alarms can help patients avoid potentially dangerous high and low blood sugar fluctuations to live longer, healthier lives –

For people with diabetes, keeping blood sugar (glucose) levels within a normal range is a daily, if not hourly, challenge. Many patients are not aware of unhealthy glucose fluctuations that can damage the body because they rely upon today's standard method for daily glucose monitoring: random fingerstick measurements.

The Guardian[®] RT System continuously measures glucose levels around the clock, even while a patient sleeps. The system displays glucose values every five minutes and sounds an alarm (or vibrates) when glucose levels become too high or too low. In addition, trend reports can be viewed after information is downloaded to a computer. The system can be used by any diabetes patient (both type 1 and type 2 patients), as well as healthcare professionals who wish to assess and improve their patients' glucose control.



“Real-time” continuous glucose monitoring (CGM) is like watching a movie for the first time, after a life of seeing random snapshots from a digital camera. Viewing glucose levels every five minutes can help patients: (1) quickly take action, after confirming with a fingerstick measurement, to reduce the severity and duration of hypoglycemic (low glucose) or hyperglycemic (high glucose) episodes; (2) discover how diet, exercise, medication and lifestyle affect their glucose levels; and (3) intervene earlier to reduce the frequency and severity of glucose fluctuations. Studies have shown that by keeping glucose levels within a healthy range, diabetes patients can live longer, healthier lives.

System Components

The Guardian RT System utilizes a glucose sensor, a transmitter and a monitor. Included with the system is a docking station and therapy management software, which allows patients and healthcare professionals to download information to a computer to view trend reports and charts.

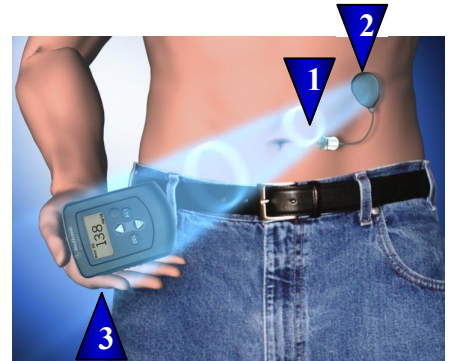
The Glucose Sensor



- ✓ The glucose sensor is a tiny electrode worn by the patient for up to 3 days.
- ✓ The sensor is easily inserted by patients, caregivers or healthcare professionals into the skin (subcutaneous tissue) using the Sen-serter[®], an automatic insertion device.
- ✓ Following a 2-hour initialization period, the sensor measures glucose levels in the interstitial fluid found between the body's cells. Interstitial fluid is where cells get oxygen and nutrients, including glucose.
- ✓ The sensor converts glucose values from interstitial fluid into an electronic signal, which represents the amount of glucose present in the blood.
- ✓ As many as 288 glucose readings are recorded by the sensor each day – nearly 100 times more information than three daily fingerstick measurements.
- ✓ Medtronic's CGMS[®] System Gold[™] utilize the same subcutaneous sensor.

2 The Transmitter

- ✓ The transmitter connects to the glucose sensor and attaches to the skin by an adhesive patch.
- ✓ Using radio frequency, the transmitter sends glucose values from the sensor to the monitor every five (5) minutes.
- ✓ The transmitter has a battery lifespan of approximately one year with near continuous sensor use.
- ✓ Since the transmitter is waterproof, patients can shower, bathe or swim while wearing both the transmitter and the sensor.



3 The Monitor

- ✓ The monitor receives continuous sensor readings from the transmitter and displays glucose values every 5 minutes.
- ✓ By sounding an alarm (or vibrating), the monitor alerts patients to potentially dangerous high or low glucose levels.
- ✓ To calibrate the system, a minimum of two meter measurements are entered into the monitor each day (every 12-hours). A fingerstick measurement is required to confirm high or low sensor values prior to making a self-management decision.
- ✓ The monitor should not be exposed to water: however, patients can easily shower or bathe without interrupting their glucose data since the monitor will receive a signal as long as it is within six feet (2 meters) of the transmitter.

4 Com-Station™ and Guardian® Solutions™ Software

- ✓ Using a docking station known as the Com-Station, patients, caregivers and healthcare professionals can download device data and personal information to a computer.
- ✓ Solutions Software simplifies analysis by organizing data into easy-to-read trend graphs, charts and tables. Reports provide visual examples so that users can see the effects of meals, exercise, insulin and medication on their glucose levels.
- ✓ Patients can print reports highlighting their glucose patterns for further analysis and discussion with their healthcare team.

