Continuous Glucose Monitoring System Fact Sheet

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CGMS® System Gold™
Continuous Glucose Monitoring System

What is a continuous glucose monitoring system?
CGMS® System Gold™, the next-generation enhancement of the CGMS® system, is a state-of-the-art diagnostic tool used by physicians to track continuous blood sugar (glucose) patterns in people with diabetes. Comprehensive information provided by CGMS System Gold can identify erratic blood glucose fluctuations and trends, which often go unnoticed when standard HbA1c tests and finger sticks are used. The system provides additional insight to healthcare professionals, enabling them to work with their patients to make therapy, dietary and lifestyle adjustments with the goal of improving diabetes management.

CGMS System Gold provides up to 288 glucose measurements every 24 hours – 72 times more data than patients testing their blood sugars four times a day would obtain. In fact, the CGMS System Gold sensor is the only continuous glucose sensor that can measure glucose values up to 72 hours while patients go about their normal activities. The CGMS System Gold sensor is typically inserted into subcutaneous tissue in the abdominal area and worn for one to three days. A Holter-style monitor stores continuous glucose data measured by the sensor at five-minute intervals. This data can be downloaded into a computer and reports can be easily printed for retrospective analysis.

How often does a patient use the CGMS System Gold?
The CGMS System Gold is intended for occasional rather than everyday use. It is intended to be used as a supplement to, and not a replacement for, standard blood glucose monitoring. Patients can wear the CGMS System Gold as often as a healthcare professional feels it is necessary to properly evaluate and control their blood sugar patterns.

What type of information does the CGMS System Gold provide?
By downloading information from the monitor using the CGMS Solutions™ Software program, healthcare professionals are able to obtain comprehensive, glycemic profile information in easy-to-use graphs and statistical reports. This information can be used to assess diabetes management trends and make necessary treatment adjustments.

What is the value of the comprehensive information provided by the CGMS System Gold?
CGMS System Gold provides comprehensive information on glycemic patterns, which healthcare professionals can use to improve diabetes management in the patients they treat. The system can identify unhealthy blood glucose fluctuations and trends, providing significantly more information than standard finger stick readings. CGMS System Gold provides valuable glucose information often unseen by physicians, such as when glucose levels are changing, and if so, how fast and in which direction. In contrast, discrete meters only reveal a glucose value at a single-moment in time.
Do outcomes studies that demonstrate the value of continuous glucose monitoring?

Yes, more than 100 clinical references on the CGMS system have been published since the product’s introduction in 1999. Successful results from a pilot study, published in *Diabetes Research and Clinical Practice* (December 1999), indicated that patients’ HbA1c levels were reduced on an average from 9.9% to 8.8% after only five weeks using the CGMS system.¹ This improvement can dramatically reduce health complications. In fact, the pilot study’s lead investigator noted that HbA1c levels had never before been lowered so quickly. Further, therapy adjustments that led to the improvement would not have been made on the basis of intermittent finger stick readings. A 10-week follow-up demonstrated the sustainability of these results by showing that HbA1c levels remained as low or lower, without any additional intervention by the healthcare team.

Are glucose values displayed on the monitor?

No, CGMS System Gold does not display glucose values. Rather, the monitor stores data recorded by the glucose sensor, which are downloaded by a healthcare professional into a personal computer for retrospective analysis.

Must patients test their blood glucose while wearing the CGMS System Gold?

Yes, CGMS System Gold requires periodic calibration using blood glucose readings from a traditional meter. A minimum of four calibrations are recommended each day for comparison purposes.

What are the components of the CGMS System Gold?

CGMS System Gold contains two key components: a subcutaneous glucose sensor and a monitor. The sensor is inserted into the subcutaneous tissue of a patient, typically in the abdominal area. The sensor is easily inserted using the Sen-serter™, a patented insertion device. The monitor stores data recorded by the sensor, which is then downloaded into a personal computer for retrospective analysis by a healthcare professional.

How does the sensor measure glucose in interstitial fluid?

The sensor is composed of a microelectrode with a thin coating of glucose oxidase beneath several layers of biocompatible membrane. It continuously converts glucose from the patient’s interstitial fluid (liquid found between the cells of the body) into an electronic signal, the strength of which is proportional to the amount of glucose present.

How do glucose levels in blood correspond to glucose levels in interstitial fluid?

Blood glucose and interstitial fluid glucose levels are essentially equal when blood glucose is not changing rapidly. Overall, the differences between blood and interstitial fluid glucose levels do not affect the clinical utility of the continuous glucose sensor data. The differences are minor, of short duration (difference in glucose levels usually last less than 10 minutes), and because the data are analyzed retrospectively, those minor differences are negligible. In addition, the device is designed to be used as a pattern and trend recognition device rather than a discrete measurement device.

How are healthcare professionals reimbursed for using the CGMS System Gold?
Continuous glucose is reimbursed by Medicare in all fifty states and has broad private insurance reimbursement. Physicians, registered nurses, certified diabetes educators and other trained healthcare professionals using the company’s continuous glucose monitoring systems can be reimbursed using a technical code for hook-up and download (CPT Code 95250). Medicare provides reimbursement under New Technology APC code (0972), and Evaluation and Management codes can be used by physicians for patient evaluation and data interpretation during office visits.

How can a healthcare professional obtain a CGMS System Gold?
Healthcare professionals can obtain information about the CGMS system by visiting the company’s website at www.minimed.com, or by calling 1-866-MiniMed, (818) 362-5958 outside the United States.

How can patients locate a physician using a continuous glucose monitoring system?
A physician locator, which can identify physicians using continuous glucose monitoring, is expected to be available this summer on minimed.com.