

## **BRIEF SUMMARY**

## **MEDTRONIC MINIMED CONTINUOUS GLUCOSE MONITORING SYSTEM**

Patients should always discuss the potential risks and benefits with a physician. Product technical manual must be reviewed prior to use for detailed disclosure.

### **INDICATIONS**

The Medtronic MiniMed Continuous Glucose Monitoring System is intended to continuously record interstitial glucose levels in persons with diabetes mellitus. This information is intended to supplement, not replace, blood glucose information obtained using standard home glucose monitoring devices. The information collected by the CGMS™ system may be downloaded and displayed on a computer and reviewed by health care professionals. This information may allow identification of patterns of glucose level excursions above or below the desired range, facilitating therapy adjustments, which may minimize these excursions.

- This System is intended for prescription use only.
- Will not allow readings to be made available directly to patients in real time.
- Provides readings that will be available for review by physicians only after the entire recording interval (suggested as 72 hours).
- Is currently intended for occasional rather than everyday use, is to be used only as a supplement to, and not a replacement for, standard invasive measurement.
- Is not intended to change patient management based on the numbers generated, but to guide future management of the patient based on response to trends noticed. That is, these trends or patterns may be used to suggest when to take fingerstick glucose measurements to better manage the patient.

### **CONTRAINDICATIONS**

Successful operation of the CGMS system requires some visual and auditory acuity. Use of the CGMS system is not recommended for patients whose impaired vision or hearing does not allow full recognition of the system's signals and alarms.

### **WARNINGS/PRECAUTIONS/ADVERSE EVENTS**

Operation of the CGMS system requires the insertion of a Glucose Sensor into the skin. Infection, inflammation or bleeding at the Glucose Sensor insertion site is possible risks of glucose sensing. The Glucose Sensor should be removed if redness, pain, tenderness or swelling develop at the insertion site.

The CGMS system does not display glucose values and is intended to be used in addition to, not in place of, home glucose monitoring performed using a standard home glucose meter. During use of the CGMS system, diabetes treatment should not be modified based solely on CGMS system information.

CGMS system users should be trained to program and operate the Monitor, and respond to alarm conditions prior to attempted use of the system.

The Glucose Sensor is sterile in its unopened, undamaged package. Do not use any Glucose Sensor if its sterile package has been previously opened or damaged. Always wash hands with soap and water before opening the Glucose Sensor package. After opening the package, avoid touching any Glucose Sensor surfaces that will come into contact with the body (i.e., sensor, needle, connector adhesive surfaces and bandage). Before inserting the Glucose Sensor, always clean the skin at the sensor insertion location with a topical antimicrobial solution, such as isopropyl alcohol. After Glucose Sensor insertion, check the insertion location often for redness, bleeding, pain, tenderness and swelling, especially before going to bed in the evening and after waking up in the morning. Establish a rotation schedule for choosing each new Glucose Sensor location. Avoid sensor locations that are constrained by clothing, accessories or subjected to rigorous movement during exercise. Monitors should be placed in Shower-Paks, prior to taking a shower or engaging in other activities in which the Monitor would be expected to get wet. Do not submerge the Monitor.

Contact sports or other activities, which may damage the Monitor, should be avoided. Prior to exercising, CGMS system users should make sure that the Glucose Sensor and Monitor are securely fastened to their bodies. If the Glucose Sensor is disconnected and then reconnected again, the signals it sends to the Monitor may not be stable or accurate. The sensor may need to be recalibrated before returning to normal operation.

Users who also wear an insulin pump should make sure that the Glucose Sensor insertion site is at least two (2) inches away from the insulin infusion site. Users who inject insulin should administer injections at least three (3) inches away from the sensor insertion site.

The current and voltage signals shown in the Monitor are to be used only for finding potential problems with the CGMS system and do not indicate the current glucose value. If the Monitor shows a "NO POWER" alarm on the display for more than one hour, the glucose data and program information in the memory will be lost. If this occurs, all program information will return to the manufacturer's default settings after the batteries are replaced. Users must first reprogram the Monitor and then reinitialize and calibrate the Glucose Sensor before returning to normal operations. Using the Monitor in close proximity to strong electromagnetic sources such as a medical imaging equipment, television and radio transmitters and high voltage power lines is not recommended. Keep the Monitor in its leather case to protect against electrostatic discharges that are common in cold and dry climates.

The Monitor has been clinically tested primarily in adult Caucasian persons with Type 1 diabetes. This device has not been tested in children. Because of variations in size and the amount of body fat, performance may be different in children relative to that observed when the device is used in adults. Although the system has not been studied in other diabetic patient populations, similar results are expected. Use of the Monitor may not be applicable for patients who are not motivated to operate it, are physically unable to operate it, have unrealistic expectations about its value and do not have a good support system at home for responding to alarms.

The Monitor, Glucose Sensor and Cable and all accessories are to be used only with the CGMS system. Use of system components with other products is not recommended. Batteries should be replaced within a five (5) minute period, to avoid losing glucose data and program information in the Monitor memory.