BRIEF SUMMARY: INSULIN PUMP THERAPY MEDTRONIC MINIMED INSULIN INFUSION PUMPS
(Paradigm™, Paradigm 512 and Model 508)

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 Insulin Pump is indicated for the continuous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin.

CONTRAINDICATIONS
Pump therapy is not recommended for people who are unwilling or unable to perform a minimum of four blood glucose tests per day and to maintain contact with their healthcare professional.

Successful operation of the Insulin Pump requires good vision and hearing. While features exist to help facilitate pump usage, Medtronic MiniMed does not recommend the use of this product by individuals whose impaired vision or hearing does not allow full recognition of the pump signals and alarms.

WARNINGS/PRECAUTIONS/ADVERSE EVENTS
Insulin pump therapy uses only regular (short-acting) insulin; therefore, any interruption in the delivery of insulin (due to infusion set clogs, leaks, loss of insulin potency, or pump malfunction) may result in hyperglycemia (high blood glucose) within two to four hours and, subsequently, the rapid onset of diabetic ketoacidosis (DKA) within four-to-ten hours. The onset of stress or illness (caused by infection or an emotional event) can result in a rise of blood glucose levels and the development of DKA. Act quickly to respond to abnormal blood glucose. Notify your healthcare professional of low blood glucose requiring assistance or of high blood glucose, or of an increased frequency in low or high blood glucose. If your insulin delivery is interrupted for any reason, you must be prepared to replace the missed insulin immediately. Always carry an “emergency Kit” of insulin and syringes or pens, BG test strips and meter, and urine ketone test strips in case you develop a problem with your pump and your insulin delivery is stopped or in case of high blood glucose. You should check for urine or blood ketones whenever your blood glucose is elevated above 250 mg/dl (13.7 mmol/L) and take an insulin injection. Establish a plan with your healthcare professional for rapidly identifying and treating hyperglycemia, to prevent the onset of DKA and possible hospitalization.

The management of diabetes has also been associated with an increase in the incidence of hypoglycemia (low blood glucose). Never go to bed with a blood glucose value below your target level. Blood glucose tests should be performed before driving a car, because hypoglycemia may have serious consequences.

For proper insertion techniques, follow the advise of your healthcare professional and the Instructions for Use included with the product. Change your infusion site every 2 to 3 days, according to your healthcare profession’s suggestions, and according to the Instructions for Use, which accompany the infusion sets and reservoirs. Check the amount of insulin remaining in your reservoir at least once a day. Infection at the infusion site is a risk of pump therapy. Check the infusion site often for redness, irritation and inflammation.

For the Paradigm pump, use only the Paradigm reservoir and Paradigm infusion sets. The reservoir and infusion sets are specifically designed for use with the Paradigm pump. Use of non-Paradigm reservoirs and/or infusion sets with the Paradigm pump may reduce pump accuracy and hinder occlusion detection. For the Model 508 pump, use only non-Paradigm reservoirs and infusion sets with your pump. Do not modify your pump reservoir or pump infusion set. Do not put any other drugs/medications inside your reservoir to use with the pump. Only insulin that has been prescribed by your physician can be used in the pump. Do not use any lubricants on the pump mechanism.

If you are going to have an X-ray, CT scan, MRI or any other type of radiation therapy, TAKE YOUR PUMP AND REMOTE CONTROL OFF, and remove them from the treatment area. Do not use hot air to dry your pump. This may damage your pump’s internal electronics. This device generates, uses, and can radiate radio frequency energy and, if installed and used in accordance with the instruction, may cause harmful interference to radio communications.

BRIEF SUMMARY: MEDTRONIC MINIMED 407C INFUSION PUMP

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 407C infusion pump is indicated for infusion of medication labeled for subcutaneous administration, at set and variable rates, for therapies including chemotherapy, antibiotic therapy, and controlled analgesia.

CONTRAINDICATIONS
This device is contraindicated for use with medications that have not been labeled for subcutaneous administration.

WARNINGS/PRECAUTIONS/ADVERSE EVENTS
Infection at the infusion site is a risk of pump therapy, but risk of infection may be minimized by good site preparation and the frequent changing of infusion sets. Practice aseptic technique when inserting infusion sets, and check the infusion site often for redness, irritation and inflammation. Rotate the infusion site each time you change the infusion set to ensure proper absorption of the medication. Avoid using an infusion site that will be irritated by clothing and accessories or by rigorous movement and stretching due to exercise. If the site becomes sore, red, or swollen, contact a health care professional to find out if the set has to be changed. Follow the advice of a health care professional and the Instructions for Use included with the product regarding proper insertion techniques.

Successful operation of the Medtronic MiniMed pump requires both visual and auditory acuity. While features exist to help facilitate pump usage, Medtronic MiniMed does not recommend the use of this product by individuals whose impaired vision or hearing does not allow full recognition of the pump signals and alarms.

Check the amount of medication remaining in the reservoir at least once a day even if the Low Reservoir Alert is on. Always check for leaks after changing the reservoir and infusion set. Wrap a tissue around the Luer connection between the reservoir and infusion set and check for moisture.

Rx Only
Medtronic MiniMed
The Medtronic MiniMed pump is watertight, but it should not be deliberately submerged in liquids. If the reservoir area becomes wet, dry it completely within 10 minutes. Do not use hot air to dry your pump. This may damage your pump’s internal electronics. Wet reservoirs should not be placed in the pump. Continued exposure of the reservoir area to liquids, including water or medication, can corrode the mechanism.

Do not expose the medication to extreme changes in temperature. Refer to medication labeling. Use only 3.0ml reservoirs identified “for use with MiniMed pumps.” Other manufacturer’s reservoirs can deliver the wrong amount of medication. Do not use any lubricants on the pump mechanism.

If you are going to have an X-ray, CT scan, MRI or any other type of radiation therapy, TAKE YOUR PUMP OFF and remove it from the treatment area.

If you live in a cold, dry climate, protect your pump from Electrostatic Discharge (ESD), which can cause your pump to alarm. Using the leather case can help protect your pump from ESD.

**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 it’s 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.

Rx Only

Medtronic MiniMed