Medtronic MiniMed Insulin Infusion Pumps

Patients should always discuss potential risks and benefits with a physician. Please review the product manual prior to use for detailed instructions and disclosure.

Prescription Device Warning

Caution: US law restricts this device to sale by, or on the order of, a licensed physician.

Indications for use

The insulin pump is indicated for the continuous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons of all ages requiring insulin. The REAL-Time Continuous Glucose Monitoring components of the MiniMed Paradigm® REAL-Time Insulin Pump are indicated for continuous or periodic monitoring of glucose levels in the fluid under the skin, and possible low and high blood glucose episodes in persons 7 years of age or older. This information is intended to supplement, not replace, blood glucose information obtained using standard home blood glucose monitoring devices. A separate pediatric
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 an insulin pump requires good vision and hearing.

While features exist to help facilitate pump usage, Medtronic Diabetes 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 Reactions

Insulin pump therapy uses only faster-acting insulin. Therefore, any interruption in insulin delivery (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-10
hours. The onset of stress or illness (caused by infection or an emotional event) can also result in a rise of blood glucose levels and the development of DKA.

The intensive management of diabetes has also been associated with an increased 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 vehicle or operating machinery, because hypoglycemia can have serious consequences.

Establish a plan with your healthcare professional for rapidly identifying and treating both hypoglycemia and hyperglycemia, to prevent the onset of DKA and possible hospitalization. Act quickly to respond to out-of-target 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 supplies that includes insulin, syringes or pens, blood glucose 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 if appropriate.

For proper insertion techniques of your infusion set, follow the advice 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 professional’s suggestions, and according to the Instructions for Use that 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.

Use only the reservoir and infusion sets specifically designed for your pump. Use of non-Medtronic Diabetes reservoirs and/or infusion sets may reduce pump accuracy and hinder occlusion detection. Do not modify your reservoir or infusion set. Do not put any other drugs/medications inside your reservoir to use with this pump. Only insulin that has been prescribed by your physician can be used in this pump.

For information on proper sharps disposal, please visit:
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 any lubricants on the pump mechanism. Do not use hot air to dry your pump. This may damage your pump’s internal electronics.

**FCC Notice**

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.

**Medtronic MiniMed Continuous Glucose Monitoring**

Patients should always discuss potential risks and benefits with a physician. Please review the product manual prior to use for detailed instructions and
Prescription Device Warning

Caution: US law restricts this device to sale by, or on the order of, a licensed physician.

Indications for use

The Continuous Glucose Monitoring components of the MiniMed Paradigm REAL-Time Insulin Pump and Continuous Glucose Monitoring System are indicated for continuous or periodic monitoring or recording of glucose levels in the fluid under the skin, and possible low and high blood glucose episodes in persons 7 years of age or older. This information is intended to supplement, not replace, blood glucose information obtained using standard home glucose monitoring devices. A confirmatory fingerstick is required prior to treatment. Continuous Glucose Monitoring information may be downloaded and displayed on a computer and reviewed by healthcare professionals. This information may allow identification of patterns of glucose-level excursions above or below the desired range, facilitating therapy.
adjustments that may minimize these excursions. A version of this product is specifically designed for children ages 7-17.

**Contraindications**

Successful operation of the Continuous Glucose Monitoring System requires adequate vision and hearing. Use of the Continuous Glucose Monitoring System is not recommended for patients whose impaired vision or hearing does not allow full recognition of the monitor signals and alarms, or who do not have a caregiver that can perform this function for them.

**Warnings/Precautions**

The Continuous Glucose Monitoring System users should be educated to program and operate the monitor and respond to alarm conditions prior to attempted use of the system.

The current and voltage signals shown in the monitor are to be used only for finding potential problems with the Continuous Glucose Monitoring System and do not
indicate current glucose value. Infection and/or site irritation may result from improper insertion and maintenance of insertion site.

For information on proper sharps disposal, please visit:  
http://sharpsdisposal.medtronic.com/

Medtronic MiniMed Guardian®
REAL-Time Continuous Glucose Monitoring System

Patients should always discuss potential risks and benefits with a physician. Please review the product manual prior to use for detailed instructions and disclosure.

Prescription Device Warning

Caution: US law restricts this device to sale by, or on the order of, a licensed physician.

Indications for use
The Guardian REAL-Time CGM System (CSS7100) is indicated for continuous or periodic monitoring of glucose levels in the fluid under the skin, in persons 7 years and older with diabetes mellitus, for the purpose of improving diabetes management. It alerts if a glucose level falls below, or rises above, pre-set values. Values are not intended to be used directly for making therapy adjustments, but rather to provide an indication of when a meter blood glucose measurement may be required. All therapy adjustments should be based on measurements obtained using a home glucose meter and not on Guardian REAL-Time CGM System values. A version of this product is specifically designed for children ages 7-17.

**Contraindications**

Successful operation of the The Guardian REAL-Time Continuous Glucose Monitoring System requires adequate vision and hearing. Use of the The Guardian REAL-Time Continuous Glucose Monitoring System is not recommended for patients whose impaired vision or hearing does not allow full recognition of the monitor signals and alarms, or who do not have a caregiver that can perform this function for them.
Warnings/Precautions

The Guardian REAL-Time Continuous Glucose Monitoring System users should be educated to program and operate the monitor and respond to alarm conditions prior to attempted use of the system.

Read Chapter 2, “Inserting the Sensor,” in your product manual, for proper preparation of site prior to insertion. Failure to follow instructions may result in pain or injury.

Continuous Glucose Monitoring
Medtronic Diabetes CGMS® System

Patients should always discuss potential risks and benefits with a physician. Please review the product manual prior to use for detailed instructions and disclosure.

Prescription Device Warning

Caution: U.S. law restricts this device to sale by or on the order of a licensed physician.
Indications for use

The CGMS 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 healthcare professionals. This information may allow identification of patterns of glucose-level excursions above or below the desired range, facilitating therapy adjustments that may minimize these excursions. The CGMS 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 (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 adequate vision and hearing. Use of the CGMS System is not recommended for patients whose impaired vision or hearing does not allow full recognition of the monitor signals and alarms, or who do not have a caregiver who can perform this function for them.

**Warnings**

**Sensor/Sen-Serter**

Infection and/or site irritation may result from improper insertion and maintenance of insertion site.

The sensor is sterile unless package has been opened or damaged. Do not use if package has been opened or damaged.
Read Chapter 3, “The Sensor,” in the product manual for proper preparation of site prior to insertion. Failure to follow instructions may result in pain or injury.

If sensor is not securely placed in Sen-serter prior to insertion, pain or minor injury may occur.

Discard the sensor on the first day of the month indicated on the “Use Before” date on label.

Do not use sensor if temperature-limit indicator on box is black (not clear).

Never point the loaded Sen-serter toward any body part where insertion is not desired.

**Monitor**

CGMS System users should be educated to program and operate the monitor and respond to alarm conditions prior to attempted use of the system.

The current and voltage signals shown in the monitor are to
be used only for finding potential problems with the System and do not indicate the current glucose value.

**Precautions**

**Sensor**

Always wash hands with soap and water before opening the sensor package. After opening the package, avoid touching any sensor surfaces that will come in contact with the body (i.e., sensor, needle, connector adhesive surfaces and bandage).

Before inserting the sensor, always clean the skin at the sensor insertion location with a topical antimicrobial solution, such as isopropyl alcohol.

Avoid inserting sensor in locations that are constrained by clothing or accessories, or are subjected to rigorous movement during exercise.

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

When replacing sensor, select new insertion site at least two inches (5 cm) from previous site. Dispose of introducer needle safely in sharps container after single use. Do not clean or re-sterilize.

Dispose of sensor in biohazard container.

After sensor insertion, the insertion location should be checked often for redness, bleeding, pain, tenderness and swelling, especially before going to bed and after waking up. The presence of these symptoms may result in sensor removal.

The sensor should be checked periodically to ensure that it remains in place. If the sensor is disconnected and then reconnected, the signals it sends to the monitor may not be stable or accurate. The sensor may need to be recalibrated (See section titled, “Perform the Initial Calibration” in the product manual) before returning to normal operation.

Monitor
Using the monitor in close proximity to strong electromagnetic sources, such as medical imaging equipment, television and radio transmitters and high-voltage power lines, is not recommended.

Contact sports or other activities that may damage the monitor should be avoided. Prior to exercising, CGMS System users should make sure that the sensor and monitor are securely fastened to their bodies.

Monitors should be placed in a Shower-Pak™ 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.

Keep the monitor in its leather case to protect it against moisture, dirt, and debris.

Professional Continuous Glucose Monitoring Medtronic MiniMed iPro™ CGM
Patients should always discuss potential risks and benefits with a physician. Please review the product manual prior to use for detailed instructions and disclosure.

**Prescription Device Warning**

Caution: U.S. law restricts this device to sale by or on the order of a licensed physician.

**Indications for Use**

The CGMS iPro digital recorder 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 digital recorder may be downloaded and displayed on a computer and reviewed by healthcare 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.

The CGMS iPro digital recorder:
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 (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.

The glucose sensor, tester, charger, and CGMS iPro Wand are intended for use with the CGMS iPro digital recorder. The Sen-serter® device is indicated only for insertion of the Medtronic MiniMed glucose sensor.

**Contraindications**

Do not use magnetic mattress pads while wearing the CGMS
iPro digital recorder. The magnetic mattress pad will cause the digital recorder to frequently enter a transmission mode that will quickly drain the rechargeable battery and will temporarily disable data collection. Therefore, there will be sensor data gaps and the digital recorder is likely to not function for the entire 3-day duration. The magnetic mattress pad will not, however, affect the accuracy of the sensor readings that are collected, nor will it lead to any unsafe conditions.

Do not expose your digital recorder to MRI equipment or other devices that generate strong magnetic fields. If your digital recorder is inadvertently exposed to a strong magnetic field, discontinue use and contact your physician.

**Warnings**

Product contains small parts and may pose a choking hazard for young children.

**Sensor**

The glucose sensor should be removed if redness, bleeding, pain, tenderness, irritation, or inflammation develops at the
insertion site, or if you experience unexplained fever. An optional occlusive dressing should be removed if irritation or reaction to the tape develops.

The glucose sensor may create special needs regarding your patients’ medical conditions or medications. Healthcare professionals should discuss this with their patients before they use the glucose sensor.

Wait five minutes after glucose sensor insertion before setting up the CGMS iPro digital recorder with the Solutions CGMS iPro.

Make sure that the site is not bleeding before connection. If any blood gets inside the digital recorder connector, the digital recorder must be discarded. If bleeding occurs, apply steady pressure with a sterile gauze or clean cloth at the insertion site until bleeding stops. After bleeding stops, attach the digital recorder to the glucose sensor. If bleeding persists after three minutes, remove the glucose sensor and discard. Insert a new glucose sensor in a different location.
Contact your local country representative or the 24-Hour HelpLine (US) if you experience any adverse reactions associated with the digital recorder or glucose sensor.

**CGMS iPro Magnetic Wand Interference**

Do not store the CGMS iPro Magnetic Wand or any other magnet within 1.5 inches (3.8 cm) of the CGMS iPro digital recorder. Premature battery discharge may occur.

Do not place the CGMS iPro Magnetic Wand or any other magnet within 1.5 inches (3.8 cm) of the CGMS iPro digital recorder except while performing patient set-up and data download procedures. Premature battery discharge may occur.

**CGMS iPro Magnetic Wand Interference With Insulin Pumps**

Do not place the CGMS iPro Magnetic Wand directly on any insulin pump. Incorrect pump operation may occur.

Do not insert the glucose sensor with attached CGMS iPro digital recorder closer than two to three inches (5.08 - 7.62 cm).
cm) from the insulin pump. The use of the CGMS iPro Magnetic Wand may inadvertently cause incorrect operation of the pump.

**CGMS iPro Interference With PC Hard Drives**

Do not place the CGMS iPro Magnetic Wand on your PC or external hard drives, as the magnetic field may impact the integrity of the data files stored there.

**Other Electromagnetic Interference**

The CGMS iPro digital recorder is designed to withstand common electromagnetic interference, including airport security systems.