Wireless Diabetes Management System

Paradigm® 512 Insulin Pump and Paradigm Link™ Blood Glucose Monitor

First integrated, “intelligent” pump and glucose monitor system enhances and simplifies diabetes management, making insulin dosing more accurate and convenient for many diabetes patients.

Product Description

Together, the Paradigm® 512 insulin pump and Paradigm Link™ blood glucose monitor form the industry’s first diabetes management system, using wireless technology to integrate an insulin pump with a blood glucose monitor. The new system simplifies two important steps in diabetes management – blood sugar (glucose) monitoring and insulin delivery.

In this intelligent system, the Paradigm Link monitor automatically transmits a patient’s glucose value to a Paradigm 512 pump using radio frequency. The pump’s Bolus Wizard™ calculator uses this blood glucose value to recommend the proper insulin dosage to diabetes patients, with the goal of keeping blood glucose levels within a healthy range.

The Paradigm 512 pump’s Bolus Wizard calculator recommends an insulin dosage based upon information pre-set in the pump by the user (target blood glucose, insulin sensitivity and insulin-to-carbohydrate ratios). The pump’s calculator will make a dosing recommendation based upon a blood glucose reading, carbohydrate entry, or both. The calculator keeps track of previous insulin dosages, remembers the times and dosage amounts delivered by the patient, and subtracts any active insulin prior to recommending a new insulin dosage to the patient. Knowing the amount of active insulin is important, as it helps patients avoid “insulin stacking,” and the common occurrence of hypoglycemia caused by delivering too much insulin. The Bolus Wizard calculator incorporates a scientific “insulin action curve” within its mathematical algorithm to recommend the insulin dosage. Medtronic MiniMed holds a pivotal patent covering bolus calculator technology.

Prior to this integrated system, many diabetes patients mentally calculated the amount of insulin needed, a complex process that can result in dosing inaccuracies and lead to less than optimal blood sugar control. By automating the delivery of a blood glucose reading, as well as an insulin dosage recommendation, this intelligent pump system can help users avoid performing complex “diabetes math,” which can be difficult and limit patient adherence.

The Paradigm Link monitor also serves as an information “conduit,” transferring data from Paradigm insulin pumps to a personal computer where users can easily review historical data stored within each device. Upon FDA clearance of Medtronic MiniMed's ParadigmPAL™ software, users will be able to program pump settings from a computer and easily upload this information to a Paradigm 512 pump using the Paradigm Link monitor.
KEY FEATURES

Paradigm 512 Insulin Pump

• **Wireless Communication Capability:** The Medtronic MiniMed Paradigm 512 pump automatically receives a blood glucose reading from the Paradigm Link monitor via radio frequency.

• **Bolus Calculator:** The Bolus Wizard calculator recommends an insulin dosage using current and target blood glucose levels, carbohydrate-to-insulin ratios, the number of carbohydrates in a meal, an insulin sensitivity factor and insulin onboard.

• **Size:** The Paradigm 512 pump is the smallest full-featured pump available. Approximately the size of a pager, it measures only 1.9” x 3.0” x 0.77” (4.39 cubic inches) and weighs less than 3.25 ounces (less than 100 grams).

• **Safety:** The Paradigm 512 pump conducts millions of safety checks each day. Programmable block options prevent tampering by small children.

• **Reservoir:** The Paradigm 512 pump reservoir has a capacity to meet the needs of most users (176 units). The compact reservoir system is easy to fill and load.

• **Water Use:** Protection against splashes or a temporary dunk in water.

• **Battery Powered:** The Paradigm 512 pump uses a single AAA alkaline battery.

• **Multiple Delivery Options:** Users can set the pump to deliver a baseline rate of insulin (basal rate) in precise 0.05 unit increments. Various delivery options, including Normal, Square™ and Dual Wave™ bolus capabilities help users better accommodate a variety of meal plans and food types.

Paradigm Link Blood Glucose Monitor

• **Wireless Communication Capability:** Co-developed by BD (Becton, Dickinson and Company) and powered by BD Logic™ technology, the Paradigm Link monitor automatically transmits a blood glucose reading to the Paradigm 512 pump.

• **Speed:** The Paradigm Link monitor provides accurate blood glucose readings in five seconds and automatically transmits a glucose reading to a Paradigm 512 pump, after information is entered by the user.

• **Comfort:** The Paradigm Link monitor uses a small blood sample (0.3 micro liters) and the thinnest lancet on the market, resulting in approximately 50 percent less pain. BD Ultra-Fine™ 33 Lancets have a diameter 30 to 40 percent smaller than most other lancets.

• **7-day/14-day & Mealtime Averaging:** The Paradigm Link monitor provides averages at seven and fourteen days, as well as four time-specific averages for adjusting insulin dosage.

• **Memory Function:** The Paradigm Link monitor’s memory stores up to 250 blood glucose values and 250 insulin records, which are entered manually by the user.

• **Download Function:** The Paradigm Link monitor can be used to download Paradigm 512 pump data to a personal computer using a special USB or serial cable.

• **Battery Powered:** The Paradigm Link monitor uses a single 3-volt coin cell battery.
Paradigm 512 Insulin Pump (Cont’d)

- **Infusion Sets:** A full range of infusion sets are available, including insertion devices which make insulin infusion set placement easy, accurate and virtually painless.

- **Color Options:** Purple, smoke, blue and clear.

- **Remote Control (optional):** Diabetes patients can use a small, hand-held remote programmer to discreetly program insulin delivery without directly accessing the pump.

First of Several Product Offerings From World Leaders in Diabetes Management

In January 2003, two world leaders in diabetes management, Medtronic MiniMed and BD (Becton, Dickinson and Company), announced a strategic relationship to develop and co-market integrated systems to simplify and improve diabetes management. The Paradigm 512 pump and Paradigm Link blood glucose monitor system represents the first of several product offerings planned by the companies. In the future, the companies intend to introduce to market a series of innovative systems to further improve the lives of people with diabetes. The Paradigm 512 pump is developed and manufactured by Medtronic MiniMed. The Paradigm Link monitor has been co-developed by Medtronic MiniMed and BD.

Obtaining the Paradigm 512 Pump and Paradigm Link Blood Glucose Monitor

The Paradigm 512 pump and Paradigm Link monitor system requires a prescription from a physician. Physicians and diabetes patients can obtain information regarding this system by calling 1-866-MiniMed (1-866-646-4633), (818) 362-5958 outside the United States, or by visiting www.minimed.com. Specific questions about the Paradigm Link monitor can be answered by BD’s Consumer Service toll-free, 24-hours a day, 7-days a week in the United States at 1-888-BDCARES (1-888-232-2737), or through their website at www.BDdiabetes.com.

For a brief statement regarding the use of Insulin Pump Therapy, see the enclosed insert.

\(^1\)When used with BD Ultra-Fine™ 33 Lancets and BD™ Lancet Device. Data is on file at BD.

\(^2\)BD Logic™ Owner’s Guide.