**Wireless Diabetes Management System**

**Paradigm® 512 and Paradigm® 712 Insulin Pumps, and Paradigm Link™ Blood Glucose Monitor**

Integrated, “intelligent” pump and glucose monitor systems can enhance and simplify diabetes management, making insulin dosing more accurate and convenient for many diabetes patients.

**Product Description**

In July 2003, Medtronic MiniMed introduced the Paradigm® 512 insulin pump and Paradigm Link™ blood glucose monitor system, the industry’s first diabetes management system using wireless technology to automate the exchange of blood sugar values between a meter and a pump, and recommend more accurate insulin dosages to patients.

In October 2003, the company introduced the Paradigm® 712 insulin pump and Paradigm Link™ blood glucose monitor system, which incorporates all of the capabilities of the Paradigm 512 model, and holds a larger (3ml) reservoir. The larger pump reservoir is well suited for people who use more than 50 units of insulin per day. Patients requiring more insulin include children, young adults, insulin-resistant Type 1 and Type 2 patients, and women with gestational diabetes.

Medtronic MiniMed’s new “intelligent” pump systems simplify two important steps in diabetes management – blood sugar (glucose) monitoring and insulin delivery. The Paradigm Link monitor (powered by BD Logic™ Technology) automatically transmits a patient’s glucose value to a Paradigm 512 or Paradigm 712 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.

Both Paradigm 512 and Paradigm 712 pumps contain a Bolus Wizard calculator, which 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 calculator will make a dosing recommendation based upon a blood glucose reading, carbohydrate entry, or both. The calculator also 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.

Without this integrated system, many diabetes patients mentally calculate the amount of insulin required, 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.
KEY FEATURES

Paradigm 512 and 712 Insulin Pumps

- **Wireless Communication Capability:** Paradigm pumps automatically receive 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 is the smallest full-featured pump available. It measures only 2.0” x 3.0” x 0.8” and weighs 106.5 grams with a full reservoir. The Paradigm 712 is small and lightweight, measuring 2.0” x 3.6” x 0.8” and weighing 108.2 grams with a full 3ml reservoir.

- **Safety:** Paradigm platform insulin pumps conduct millions of safety checks each day. Programmable block options prevent tampering by small children.

- **Reservoir:** The Paradigm 512 pump reservoir utilizes a 176 unit reservoir, meeting the needs of most customers. The Paradigm 712 pump holds either a 176 unit reservoir or a 300 unit reservoir for patients who require more than 50 units of insulin per day.

- **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 Paradigm 512 or Paradigm 712 pump.

- **Speed:** The Paradigm Link monitor provides accurate blood glucose readings in five seconds¹ and automatically transmits a glucose reading to a Paradigm 512 or Paradigm 712 pump.

- **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 pain². BD Ultra-Fine™ 33 Lancets have a diameter 30 to 40 percent smaller than most other lancets.¹

- **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.¹

- **Memory Function:** The Paradigm Link monitor’s memory stores up to 250 blood glucose values and 250 insulin records,¹ which are entered manually by the user.

- **Download Function:** The Paradigm Link monitor can be used to download a Paradigm 512 or Paradigm 712 pump data to a personal computer using a special USB or serial cable.
Paradigm 512 and 712 Insulin Pumps (Cont’d)

- **Battery Powered:** Paradigm platform insulin pumps use a single AAA alkaline battery.

- **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.

Paradigm Link Blood Glucose Monitor (Cont’d)

- **Battery Powered:** The Paradigm Link monitor uses a single 3-volt coin cell battery.

Future Data Management Capabilities

Upon FDA clearance of Medtronic MiniMed's ParadigmPAL™ software, Paradigm 512 and Paradigm 712 users will be able to program pump settings from a computer and easily upload this information to their pumps using the Paradigm Link monitor.

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. This new integrated 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. Paradigm 512 and Paradigm 712 pumps are developed and manufactured by Medtronic MiniMed. The Paradigm Link monitor has been co-developed by Medtronic MiniMed and BD.

Obtaining Paradigm 512/712 Pumps and Paradigm Link Blood Glucose Monitor

Pump therapy 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.

1BD Logic™ Owner’s Guide.
2When used with BD Ultra-Fine™ 33 Lancets and BD™ Lancet Device. Data is on file at BD.

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