

Operating Description of Paradigm Link Blood Glucose Meter

The BD Paradigm Link™ Blood Glucose Meter is a handheld battery (3V) operated device intended for use in the quantitative measurement of glucose in capillary blood collected from fingertips. The Paradigm Link™ gives glucose results in just 5 seconds using a very small blood sample (0.3µL). The Paradigm Link™ has memory that stores the user's blood glucose test results and has optional features, such as mealtime averaging, to help the user and the healthcare professional manage diabetic care. The BD Paradigm Link™ Blood Glucose Meter may be used as a stand alone blood glucose meter or used in conjunction with Medtronic MiniMed External Insulin Pumps when configured for Radio Frequency (RF) telemetry. The Paradigm Link™ RF communication allows the user to automatically send a blood glucose result from the meter at the conclusion of a glucose test to the Medtronic Minimed 512 external insulin pump. The direct RF transmission of the blood glucose result from the meter to the pump reduces the potential for the user to misread or incorrectly enter the blood glucose value. In addition the Paradigm Link™ can serve as a RF communications link between the Medtronic Minimed external pump (model 511 or higher) and a PC. The user can download Paradigm Model 511 or 512 pump settings and pump data via RF telemetry using the Paradigm Link when the meter is connected to a computer via a cable.