Flow rate accuracy

The flow rate accuracy of the pump is within ±14.5% of the programmed flow rate at 0.048-24 mL/day, 37 °C, 50% reservoir volume, and 300 meters above sea level. Measurement error, fluid volume, and changes in environmental conditions (e.g., body temperature and atmospheric pressure) all affect the flow rate. The effects of these changes on flow rate are cumulative if the conditions exist simultaneously.

Measurement error

The apparent flow rate based on clinical measurements can vary due to measurement error (e.g., syringe measurement accuracy, human error, and the volume of fluid in the extension tubing and filter).

Fluid volume

The flow rate of the pump varies slightly with the volume of fluid in the pump reservoir. The pump flow rate decreases as the reservoir volume approaches 1 mL. The pump flow rate decreases rapidly and then stops as the reservoir volume decreases from 1 mL to 0 mL. Therefore, the pump should be refilled prior to reaching 1 mL or less. Typically, the flow rate
decreases by about 4% as the volume is reduced from the half-full volume to a volume of 1 mL. The usable volume is the reservoir volume minus 1 mL (Figure 5).

Figure 5. Flow rate accuracy as a function of fluid volume in reservoir.

Environmental conditions

Body temperature
The flow rate of the pump varies with body temperature. The flow rate increases as the temperature increases above 37 °C and decreases as the temperature decreases below 37 °C (Figure 6).
**Figure 6.** Flow rate accuracy as a function of temperature (typical effect).

**Atmospheric pressure**

Patients living or traveling (e.g., airline flights, mountain climbing) at altitudes above sea level are exposed to lower atmospheric pressures. Within days of exposure to the lower pressures, the flow rate of the pump can increase and then stabilize at the higher flow rate. In circumstances where a potential increase in flow rate may pose a risk to a patient, reprogramming the infusion prescription offsets this higher flow rate (Figure 7).

In rare instances, exposure to the lower atmospheric pressure can cause the pump to deliver more than 14.5% of the programmed flow rate while the patient is exposed to the lower pressure. Consider changes in drug concentrations or changes to pump programming for patients exposed to lower pressures.
Figure 7. Flow rate accuracy as a function of altitude (typical effect).

Declaration of Conformity

Medtronic declares that this product is in conformity with the essential requirements of Directive 1999/5/EC on Radio and Telecommunications Terminal Equipment and Directive 90/385/EEC on Active Implantable Medical Devices.

For additional information, contact the appropriate Medtronic representative listed on the inside back cover of this manual.