includes fluid management components that do not come into contact with the fluid (e.g., various valve actuators, pump actuators, and sensors that interface with the fluid path through the flexible membrane material). The reusable portion generally also includes most, if not all, of the components that would be considered reusable or non-disposable, such as, for example, a controller, an active mechanical assembly including a pump with valve and/or pump actuators and pump motor(s), one or more sensors (e.g., a fluid flow/volume sensor, a temperature sensor), one or more electrical power sources (e.g., a rechargeable battery) and related circuitry (e.g., a battery recharging circuit and a coil for inductively coupling the battery charging circuit to an external power supply), a network interface (e.g., a wireless transceiver with antenna, a wireline interface such as USB), and user interface components (e.g., a pushbutton control). The disposable portion generally includes single-use or limited-use components relating to fluid management, but may also include an integral fluid reservoir and other components, such as a backup power source, a small processor (e.g., to continue certain device operations in the event of a failure, to generate an alarm in the event of a failure, or to provide status information to the reusable portion), and/or an alarm output. The disposable portion may also include, or be configured to support, so-called "sharps" components (e.g., a cannula with cannula delivery needle and an analyte sensor) and an assembly for inserting the sharps into a patient (e.g., a cartridge that holds the sharps and an actuator for inserting the sharps). The substrate and the flexible membrane material of the disposable portion may constitute a fluidic assembly that is configured to fit within a disposable base.

[0023] In certain embodiments, the disposable portion includes a substrate having flexible membrane material thereon and incorporating therein a fluid channel, the fluid channel being part of a fluid path in the disposable portion from a reservoir port to a cannula port and including a series of regions exposed to the flexible membrane material, at least one of such regions being a valve region. The reusable portion includes a control assembly having an active mechanical assembly that interacts mechanically with the regions through the membrane material in such a manner as to achieve pumping of fluid along the fluid path, the active mechanical assembly including a valve actuator that operates on the valve region. The disposable portion may also include a pump region, and the active mechanical assembly may include a pump actuator that operates on the pump region. The series of regions may be exposed to a single flexible membrane of the flexible membrane material.

[0024] The active mechanical assembly generally includes a motor for operation of the valve actuator and/or the pump actuator under control of the control assembly. The valve actuator and the pump actuator may be interconnected by a plate for coordinated operation of the valve actuator and the pump actuator. The motor may include one or more shape-memory actuators. The motor may include a heater for operating the shape-memory actuator(s). Alternatively, the shape-memory actuator(s) may be operated through changes in electrical current passed through at least a portion of the shape-memory actuator. Multiple shape-memory actuators may be used for redundancy and/or to provide different modes of operation (e.g., a normal pumping mode and a high-powered pumping mode). The motor may include multiple shape-memory actuators of different lengths or gauges.

[0025] The disposable portion may include an integral fluid reservoir or may include a reservoir interface for coupling with a fluid reservoir. The reservoir interface may include a cannulated needle for introduction into the fluid reservoir so as to provide fluid communication between the fluid reservoir and the fluid path or may include a septum for penetration by a fluid reservoir cannulated needle so as to provide fluid communication between the fluid reservoir and the fluid path. At least one of the reusable portion and the disposable portion may include a recess for receiving the fluid reservoir. The fluid reservoir and the corresponding recess may be eccentrically shaped and/or keyed so as to prevent incorrect orientation of the fluid reservoir within the housing.

[0026] The disposable portion may be configured to support a cannulus in fluid communication with the fluid path and an analyte sensor in communication with the control assembly. Interconnection between the control assembly and the analyte sensor may be established upon engagement of the reusable portion and the disposable portion. In this regard, the control assembly may include an analyte sensor interface for direct interconnection with the analyte sensor. Alternatively, the communication path between the control assembly and the analyte sensor may include a portion of the disposable unit or may be wireless.

[0027] One challenge in such a patch-sized device is fitting all of the components into the reusable and disposable portions while also providing sufficient space for a fluid reservoir that holds a substantial amount of fluid and a pump that is capable of delivering a relatively large volume of fluid per day. Therefore, in certain embodiments of the present invention, elongated components (e.g., strips of shape-memory material and/or portions of the fluid path) may be "folded" within the housing, for example, using coil or serpentine shaped paths. One or more pulleys may be used to fit a length of shape-memory material into the housing.

[0028] Because the fluid delivery system may be used to deliver life-critical therapeutic fluids to a patient, it may be advantageous to have so-called "fail safe" operation so that a device failure will not allow fluid to be delivered to the patient at an unsafe flow rate. Therefore, certain embodiments of the present invention include a finite fluid impedance downstream of the regions so as to prevent delivery of fluid at an unsafe flow rate. The fluid impedance may be passive and/or may include a conduit. The conduit may be integral to the disposable unit (e.g., an in-molded channel) or may be a separate component, such as tubing. The conduit may have a specified minimum inside diameter (e.g., to reduce the likelihood of blockage) such that it may be necessary or desirable for the conduit to be elongated in order to achieve a desired impedance. In order to fit such an elongated conduit within the housing, the conduit may be tortuous (e.g., coiled or serpentine). For further fail safe operation, the device may operate with a non-pressurized fluid reservoir so that failure or shut-down of the pump effectively prevents further delivery of fluid to the patient.

[0029] Particularly in the context of delivering therapeutic fluid to a patient, it may be necessary or desirable to very precisely measure and control the volume of fluid delivered to the patient over time. Thus, in various embodiments of the present invention, the disposable portion may include in the