[0016] 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.

[0017] 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.

[0018] 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.

[0019] 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.

[0020] 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.

[0021] 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.

[0022] 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 fluid path a dispensing chamber bounded by flexible membrane material, and the reusable portion may include a fluid sensor (e.g., an acoustic volume sensor) in communication with the dispensing chamber for measuring fluid flow through the dispensing chamber. The fluid path may include a finite fluid impedance (e.g., of the types described above) downstream of the dispensing chamber so that the dispensing chamber membrane expands in response to the pumping of fluid. A resilient dispensing spring may be provided (e.g., in the reusable portion or in the dispensing chamber membrane itself) to facilitate contraction of the dispensing chamber membrane.

[0023] In order to reduce the number of components in the device, it may be advantageous to utilize certain components for more than one function. For example, in embodiments that include an acoustic volume sensor having a loudspeaker and/or a microphone, the loudspeaker may be used to produce audible alarms, while the microphone may be used to monitor operation of mechanical components such as a fluid pump (e.g., by "listening" for sounds and vibrations generated by the mechanical components). Also, in embodiments that include both a battery recharging circuit and a wireless transceiver, a single coil (e.g., a solenoid) may be included for both inductively coupling the battery recharging circuit with an external power source and conveying radio frequency signals to and from the wireless transceiver. Also, a user input (e.g., a pushbutton control) may be included to allow manual control of various functions, such as power on/off and manual actuation of the pump for such things as priming, air purging, and emergency delivery of a quantity of fluid.

[0024] It may also be advantageous to eliminate or minimize the number of user interface components supported by the housing. User interface components such as a LCD