CLAIMS

WHAT IS CLAIMED IS:

1. A switch operated medical device, comprising:

a device switch configured to be operated by a user, which provides a switch signal to a switch input of a device controller when operated by a user;

the device controller, having said switch input operatively connected to the switch, and configured to receive the switch signal from the switch, the device controller being configured to actuate the device when the switch signal meets certain predetermined conditions; and

a switch integrity test sub circuit, which is configured to detect a fault or a precursor to a fault in the switch, whereby the controller executes a switch fault subroutine when a fault or a precursor to a fault is detected.

2. The device of claim 1, wherein the switch integrity test sub circuit is configured to check for and detect a fault or a precursor to a fault in the switch.

3. The device of claim 1, wherein the switch integrity test subcircuit is configured to test for and detect at least one fault or precursor to a fault selected from the group consisting of contamination, short circuits (including intermittent short circuits), compromised circuit components (including malfunctioning resistors, integrated circuit pins, and/or capacitors), particulates, solder balls, or combinations of two or more thereof.

4. The device of claim 1, wherein the switch integrity test subcircuit is configured to test for and detect a voltage or change in voltage in between a short between the switch input and ground, a short between the switch input and a voltage pull up, a damaged circuit resistor, contamination, corrosion or a damaged integrated circuit pin.

5. The device of claim 1, wherein the switch fault subroutine includes at least one of: activating a user alert feature, logging detection of faults or precursors to faults, deactivating the device, or one or more combinations thereof.

6. The device of claim 1, wherein the controller is configured to measure a voltage or a rate of change of voltage at the switch input and executing the switch fault subroutine when the voltage or rate of change of voltage at the switch input fails to meet one or more predetermined parameters.

7. The device of claim 1, wherein the device is an iontophoresis delivery device comprising first and second electrodes and reservoirs, at least one of the reservoirs containing therapeutic agent to be delivered by iontophoresis, the device switch being operable by the user to actuate the device controller to provide power to the electrodes and deliver the therapeutic agent from the at least one of the reservoirs.

8. The device of claim 7, wherein the therapeutic agent is fentanyl, sufentanil, an opioid agent or an analog, derivative or salt of any of the foregoing.

9. The device of claim 8, wherein the therapeutic agent is fentanyl, sufentanil, carfentanil, lofentanil, alfentanil, hydromorphone, oxycodone, propoxyphene, pentazocine, methadone, tilidine, butorphanol, buprenorphine, levorphanol, codeine, oxymorphone, meperidine, dihydrocodeinone, cocaine, or an analog, pharmaceutically acceptable salt, ester or derivative thereof.

10. The device of claim 1, wherein the predetermined conditions for actuating the device include the user activating the switch at least two times within a predetermined period of time.

11. The device of claim 1, wherein the switch input is pulled up to a high voltage when the switch is open and the switch input is a low voltage when the switch is closed.

12. A method of switch fault detection in a switch operated medical device, said device comprising:

a device switch connected to a switch input of a device controller;

the device controller comprising said switch input; and

a switch integrity test subcircuit,

said method comprising said controller:

activating the switch integrity test subcircuit;

detecting a voltage condition at the switch input; and

activating a switch fault subroutine if the voltage condition at the switch input fails to meet one or more predetermined conditions.

13. The method of claim 12, wherein the steps of activating the switch integrity test subcircuit and detecting a voltage condition at the switch input are executed continuously throughout use of the device.

14. The method of claim 12, wherein the steps of activating the switch integrity test subcircuit and detecting a voltage condition at the switch input are executed periodically throughout use of the device.

15. The method of claim 12, wherein the switch fault subroutine includes at least one of: activating a user alert feature, logging detection of faults or precursors to faults, deactivating the device, or one or more combinations thereof.

16. The method of claim 12, wherein the voltage condition is a voltage, a change in voltage or both.

17. The method of claim 12, further comprising the controller detecting the voltage at the switch input under conditions in which the voltage should be zero or nearly zero if the switch integrity is within operating norms, and activating the switch fault subroutine if the voltage is significantly higher than zero.

18. The method of claim 12, further comprising the controller detecting the voltage at the switch input under conditions in which the voltage should be equal to a pull up voltage or nearly equal to the pull up voltage if the switch integrity is within operating norms, and activating the switch fault subroutine if the voltage is significantly lower than the pull up voltage.

19. The method of claim 12, further comprising the controller detecting a change in voltage at the switch input under conditions in which the voltage is expected to fall to zero or nearly to zero after within a predetermined period if the switch integrity is within operating norms, and activating the switch fault subroutine if the voltage fails to fall to zero or nearly to zero within the predetermined period.

20. The method of claim 12, further comprising the controller detecting a change in voltage at the switch input under conditions where the voltage should rise to a pull up voltage or nearly to the pull up voltage within a predetermined period if the switch integrity is within operating

norms, and activating the switch fault subroutine if the voltage fails to rise to the pull up voltage or nearly to the pull up voltage within the predetermined period.

21. The method of claim 12, wherein the medical device is an iontophoresis delivery device comprising first and second electrodes and reservoirs, at least one of the reservoirs containing therapeutic agent to be delivered by iontophoresis, the device switch being operable by the user to actuate the device controller to provide power to the electrodes and deliver the therapeutic agent from the at least one of the reservoirs.

22. The method of claim 12, wherein the switch fault subroutine includes activating a user alert, deactivating the device, or both.

CLAIMS

What is claimed is:

1. A switch operated medical device, comprising:

a use-actuated device switch configured to be actuated by a user, which provides a switch signal to a switch input of a device controller when actuated by a user;

the device controller configured to actuate the device after the user presses the device switch at least two times within a predetermined interval, the device controller further having said switch input operatively connected to the device switch, and configured to receive the switch signal from the device switch, the device controller being configured to actuate the device after a second push of the device switch when the switch signal meets certain predetermined conditions; and

a switch integrity test sub circuit, which is configured to detect a fault or a precursor to a fault in the device switch by determining an evoked response at the switch input after release of the device switch but before the second push of the device switch, when the controller sets the switch input to one or more predetermined voltages to evoke a response, and comparing the evoked response to one or more expected values, and causing the controller to execute a switch fault subroutine when a fault or a precursor to a fault is detected.

2. The device of claim 1, wherein the switch integrity test sub circuit is configured to check for and detect a fault or a precursor to a fault in the device switch.

3. The device of claim 1, wherein the switch integrity test subcircuit is configured to test for and detect at least one fault or precursor to a fault selected from the group consisting of contamination, short circuits (including intermittent short circuits), compromised circuit components (including malfunctioning resistors, integrated circuit pins, and/or capacitors), particulates, solder balls, or combinations of two or more thereof.

4. The device of claim 1, wherein the switch integrity test subcircuit is configured to test for and detect a voltage or change in voltage in between a short between the switch input and ground, a short between the switch input and a voltage pull up, a damaged circuit resistor, contamination, corrosion or a damaged integrated circuit pin.

5. The device of claim 1, wherein the switch fault subroutine includes at least one of: activating a user alert feature, logging detection of faults or precursors to faults, deactivating the device, or one or more combinations thereof.

6. The device of claim 1, wherein the controller is configured to measure a voltage or a rate of change of voltage at the switch input and executing the switch fault subroutine when the voltage or rate of change of voltage at the switch input fails to meet one or more predetermined parameters.

7. The device of claim 1, wherein the device is an iontophoresis delivery device comprising first and second electrodes and reservoirs, at least one of the reservoirs containing therapeutic agent to be delivered by iontophoresis, the device switch being operable by the user to actuate the device controller to provide power to the electrodes and deliver the therapeutic agent from the at least one of the reservoirs.

8. The device of claim 7, wherein the therapeutic agent is fentanyl, sufentanil, an opioid agent or an analog, derivative or salt of any of the foregoing.

9. The device of claim 8, wherein the therapeutic agent is fentanyl, sufentanil, carfentanil, lofentanil, alfentanil, hydromorphone, oxycodone, propoxyphene, pentazocine, methadone, tilidine, butorphanol, buprenorphine, levorphanol, codeine, oxymorphone, meperidine, dihydrocodeinone, cocaine, or an analog, pharmaceutically acceptable salt, ester or derivative thereof.

10. The device of claim 1, wherein the switch input is pulled up to a high voltage when the device switch is open and the switch input is a low voltage when the device switch is closed.

11. The device of claim 1, wherein the switch integrity test sub circuit is configured to perform both digital and analog testing.

12. The device of claim 1, wherein the controller is configured to set the switch input to a variety of test voltages or changes in voltage when the device switch is open to test the device switch and electronic circuitry without actuating the device.

13. The device of claim 1, wherein the switch integrity test sub circuit is part of the controller.

14. A method of switch fault detection in a switch operated medical device, said device comprising:

a user-actuated device switch connected to a switch input of a device controller;

the device controller comprising said switch input and configured to actuate the device after the user presses the device switch at least two times within a predetermined interval; and

a switch integrity test sub circuit,

said method comprising said controller:

setting the switch input to one or more predetermined voltages after release of the device switch but before a second push of the device switch;

activating the switch integrity test sub circuit;

detecting a voltage condition at the switch input; and

activating a switch fault subroutine if the voltage condition at the switch input fails to meet one or more expected predetermined conditions.

15. The method of claim 14, wherein the steps of activating the switch integrity test subcircuit and detecting a voltage condition at the switch input are executed continuously throughout use of the device.

16. The method of claim 14, wherein the steps of activating the switch integrity test subcircuit and detecting a voltage condition at the switch input are executed periodically throughout use of the device.

17. The method of claim 14, wherein the switch fault subroutine includes at least one of: activating a user alert feature, logging detection of faults or precursors to faults, deactivating the device, or one or more combinations thereof.

18. The method of claim 14, wherein the voltage condition is a voltage, a change in voltage or both.

19. The method of claim 14, further comprising the controller detecting the voltage at the switch input under conditions in which the voltage should be zero or nearly zero if the switch integrity is within operating norms, and activating the switch fault subroutine if the voltage is significantly higher than zero.

20. The method of claim 14, further comprising the controller detecting the voltage at the switch input under conditions in which the voltage should be equal to a pull up voltage or nearly equal to the pull up voltage if the switch integrity is within operating norms, and activating the switch fault subroutine if the voltage is significantly lower than the pull up voltage.

21. The method of claim 14, further comprising the controller detecting a change in voltage at the switch input under conditions in which the voltage is expected to fall to zero or nearly to zero after within a predetermined period if the switch integrity is within operating norms, and activating the switch fault subroutine if the voltage fails to fall to zero or nearly to zero within the predetermined period.

22. The method of claim 14, further comprising the controller detecting a change in voltage at the switch input under conditions where the voltage should rise to a pull up voltage or nearly to the pull up voltage within a predetermined period if the switch integrity is within operating norms, and activating the switch fault subroutine if the voltage fails to rise to the pull up voltage or nearly to the pull up voltage within the predetermined period.

23. The method of claim 14, wherein the medical device is an iontophoresis delivery device comprising first and second electrodes and reservoirs, at least one of the reservoirs containing therapeutic agent to be delivered by iontophoresis, the device switch being operable by the user to actuate the device controller to provide power to the electrodes and deliver the therapeutic agent from the at least one of the reservoirs.

24. The method of claim 14, wherein the switch fault subroutine includes activating a user alert, deactivating the device, or both.

25. A switch operated medical device, comprising:

a use-actuated device switch configured to be actuated by a user, which provides a switch signal to a switch input of a device controller when actuated by a user;

the device controller configured to actuate the device after the user presses the device switch, the device controller further having said switch input operatively connected to the device switch, and configured to receive the switch signal from the device switch, the device controller being configured to actuate the device after the user pushes the device switch and when the switch signal meets certain predetermined conditions; and

a switch integrity test sub circuit, which is configured to detect a fault or a precursor to a fault in the device switch by determining an evoked response at the switch input after release of the device switch but before 400 ms, when the controller sets the switch input to one or more predetermined voltages to evoke a response, and comparing the evoked response to one or more expected values, and causing the controller to execute a switch fault subroutine when a fault or a precursor to a fault is detected.