CLAIMS

What is claimed is:

1. An electrotransport drug delivery device that prevents unwanted delivery of drug while in an off state when the device is powered on, the device comprising:

an anode;

a cathode;

an activation circuit configured to apply current between the anode and cathode to deliver a drug by electrotransport when the device is in an on state and not deliver drug in the off state; and

an off-current module, the module configured to automatically and periodically determine if there is a current flowing between the anode and cathode when the activation circuit is in the off state while powered on, wherein the off-current module triggers an indicator if there is a current flowing between the anode and cathode that is greater than an Output Current Off Threshold when the electrotransport drug delivery device is in an off state while powered on.

2. The device of claim 1, wherein the off-current module comprises control logic.

3. The device of claim 1, wherein the off-current module is configured to perform a device shutdown when triggering the indicator.

4. The device of claim 1, wherein the off-current module comprises firmware, software and/or hardware configured to determine if there is a potential difference between the anode and the cathode when the activation circuit is in the off state while powered on.

5. The device of claim 1, wherein the off-current module comprises software, firmware and/or hardware configured to determine if there is a change in capacitance between the anode and cathode when the activation circuit is in the off state while powered on.

6. The device of claim 1, wherein the off-current module comprises software, firmware and/or hardware configured to determine if there is a change in inductance between the anode and cathode when the activation circuit is in the off state while powered on.

7. The device of claim 1, wherein the off-current module comprises a sensing circuit that independently determines an anode voltage and a cathode voltage and compares the potential difference between the anode voltage and cathode voltage to a threshold value.

8. The device of claim 6, further including a switch connected between a reference voltage source and a sense resistor, the off-current module configured to close the switch periodically to determine the potential difference between the anode voltage and cathode voltage.

9. The device of claim 1, wherein the off-current module is configured to determine if there is a current flowing between the anode and cathode when the activation circuit is in the off state at least once per minute.

10. The device of claim 1, wherein the off-current module is configured to determine if there is a current flowing between the anode and cathode when the activation circuit is in the off state between at least once every 10 ms and once every 10 minutes.

11. The device of claim 1, wherein the off-current module is configured to wait at least 10 ms before determining if there is a current flowing between the anode and cathode when the activation circuit is in the off state

12. The device of claim 1, wherein the device has a two-part structure comprising:
an electrical module including the activation circuit and the off-current module; and
a reservoir module including the anode and the cathode and a source of drug to be delivered;
wherein the electrical module and reservoir module are configured to be combined prior to application to a patient.

13. The device of claim 11, wherein the off-current module is not enabled until the electrical module and reservoir module are combined.

14. The device of claim 1, wherein the Output Current Off Threshold is about 9 μA.

15. The device of claim 1, further comprising an Rsense resistor and an Rsense accuracy module configured to verify the accuracy of an Rsense resistance value.

16. The device of claim 1, further comprising an anode/cathode voltage difference test that measures the anode voltage and the cathode voltage using the ADC and calculates the voltage difference between the two.

17. An electrotransport drug delivery device that prevents unwanted delivery of drug while in an off state, the device comprising:
a reservoir module including: an anode, a cathode and a source of drug;
an electrical module including:

an activation circuit configured to apply current between the anode and cathode to deliver a drug by electrotransport when the device is in an on state and not in the off state; and

an off-current module, the module configured to automatically and periodically determine if there is a current flowing between the anode and the cathode greater than an Output Current Off Threshold of 9 μA when the activation circuit is in the off state while powered on;

wherein the reservoir module and the electrical module are configured to be combined before being applied to a patient.

18. A method of automatically and periodically confirming that drug will not be delivered by an electrotransport drug delivery device when the device is in an off state while powered on, the method comprising:

determining if there is a current flowing between an anode and a cathode of the electrotransport drug delivery device when the electrotransport drug delivery device is in an off state while powered on, wherein the electrotransport drug delivery device includes an activation circuit that is configured to apply current between the anode and the cathode to deliver a drug when the device is in an on state and not deliver drug in the off state; and

triggering an indicator if there is a current flowing between the anode and cathode that is greater than an Output Current Off Threshold when the electrotransport drug delivery device is in an off state while powered on, wherein triggering an indicator comprises performing a device shutdown.

19. The method of claim 18, further comprising repeating the determining step periodically while the activation circuit is in an off state.

20. The method of claim 18, further comprising repeating the determining step at least once every 10 minutes while the activation circuit is in an off state and the device is powered on.

21. The method of claim 18, wherein the Output Current Off Threshold is about 9 μA.

22. The method of claim 18, wherein determining if there is a current flowing between the anode and cathode of the electrotransport drug delivery device comprises independently determining an anode voltage and a cathode voltage and comparing the potential difference between the anode voltage and cathode voltage to the threshold value.

23. The method of claim 22, wherein the threshold voltage is 2.5 V.

24. The method of claim 22, wherein the threshold voltage is 0.85 V.

25. The method of claim 18, wherein determining if there is a current flowing between the anode and cathode of the electrotransport drug delivery device comprises independently connecting a reference voltage source and a sense resistor with each of the anode and cathode to determine the potential difference between the anode voltage and cathode voltage.

26. The method of claim 18, further comprising activating the activation circuit to enter the on state and applying current between the anode and the cathode after determining that no current above the Output Current Off Threshold is flowing between the anode and cathode while the electrotransport drug delivery device is in the off state.

27. The method of claim 18, wherein triggering the indicator comprises illuminating a light and/or sounding an alarm on the device.

28. The method of claim 18, further comprising measuring an Rsense resistance value of the electrotransport drug delivery device and verifying the accuracy of the Rsense resistance value.

29. The method of claim 18, further comprising measuring the anode voltage and the cathode voltage using an ADC and calculating the voltage difference between the two.

CLAIMS

What is claimed is:

1. A method of automatically and periodically confirming that drug will not be delivered by an electrotransport drug delivery device when the device is in an off state while powered on, the method comprising:

determining if there is a current flowing between an anode and a cathode of the electrotransport drug delivery device when the electrotransport drug delivery device is in an off state while powered on, wherein the electrotransport drug delivery device includes an activation circuit that is configured to apply current between the anode and the cathode to deliver a drug when the device is in an on state and not deliver drug in the off state; and

triggering an indicator if there is a current flowing between the anode and cathode that is greater than an Output Current Off Threshold when the electrotransport drug delivery device is in an off state while powered on, wherein triggering an indicator comprises performing a device shutdown.

2. The method of claim 1, further comprising repeating the determining step periodically while the activation circuit is in an off state.

3. The method of claim 1, further comprising repeating the determining step at least once every 10 minutes while the activation circuit is in an off state and the device is powered on.

4. The method of claim 1, wherein the Output Current Off Threshold is about 9 μA.

5. The method of claim 1, wherein determining if there is a current flowing between the anode and cathode of the electrotransport drug delivery device comprises independently determining an anode voltage and a cathode voltage and comparing the potential difference between the anode voltage and cathode voltage to the threshold value.

6. The method of claim 5, wherein the threshold voltage is 2.5 V.

7. The method of claim 5, wherein the threshold voltage is 0.85 V.

8. The method of claim 1, wherein determining if there is a current flowing between the anode and cathode of the electrotransport drug delivery device comprises independently connecting a reference voltage source and a sense resistor with each of the anode and cathode to determine the

potential difference between the anode voltage and cathode voltage.

9. The method of claim 1, further comprising activating the activation circuit to enter the on state and applying current between the anode and the cathode after determining that no current above the Output Current Off Threshold is flowing between the anode and cathode while the electrotransport drug delivery device is in the off state.

10. The method of claim 1, wherein triggering the indicator comprises illuminating a light and/or sounding an alarm on the device.

11. The method of claim 1, further comprising measuring an Rsense resistance value of the electrotransport drug delivery device and verifying the accuracy of the Rsense resistance value.

12. The method of claim 1, further comprising measuring the anode voltage and the cathode voltage using an ADC and calculating the voltage difference between the two.