

of the medicament inside the drug delivery device may need to be raised prior to injection. While passive warming of the medication is possible, it may be desirable to hasten this process so that the user to not have to wait a significant period of time to deliver the drug. Also, onboard electronics of the drug delivery device may need to be awakened from a low-energy state to a high-energy state prior to drug delivery.

[0006] As set forth in more detail below, the present disclosure sets forth an drug delivery system embodying advantageous alternatives to existing drug delivery devices and that may address one or more of the challenges or needs mentioned above.

Summary

[0006a] According to an aspect of the present invention, there is provided a drug delivery device comprising:

a reservoir;

a delivery member having a proximal end connected or configured to be connected in fluid communication with the reservoir and a distal end configured for insertion into a patient;

a housing having an opening, the distal end of the delivery member being configured to extend through the opening in an operative state;

an adhesive for removably coupling the housing to skin of the patient;

a removable cover covering at least a portion of the adhesive;

a controllable element; and

a patient contact sensor,

wherein the drug delivery device is programmed or configured to:

(a) determine if the at least a portion of the adhesive has been exposed, and

(b) determine if the drug delivery device is in contact with the patient, then, if the drug delivery device is in contact with the patient, output a control signal to the controllable element.

[0007] ~~According to an aspect of the disclosure, There is disclosed~~ a drug delivery system includes a drug delivery device comprising a reservoir, a delivery cannula having a proximal end in fluid communication with the reservoir and a distal end to be received within a patient, and a controllable element. The drug delivery system also includes a sensor coupled to the drug delivery device and a controller coupled to the sensor as well as the controllable element. The

controller may be configured to: use the sensor to determine a condition or an operational state of the drug delivery device, and control the controllable element based on the condition or operational state of the drug delivery device.

[0008] ~~According to another aspect of the disclosure, There is disclosed~~ a drug delivery system includes a drug delivery device comprising a reservoir, a delivery cannula having a proximal end in fluid communication with the reservoir and a distal end to be received within a patient, and a controllable element. The drug delivery system also includes a memory configured to store identity information representative of at least one of an identity of the patient, an identity of the drug delivery device, or an identity of a medicament to be stored within the reservoir. Additionally, the drug delivery system includes a controller coupled to the memory and the controllable element. The controller may be configured to control the controllable element based on the identity information.

[0009] ~~According to a further aspect of the disclosure, There is disclosed~~ a method is provided of using a drug delivery device comprising a reservoir, a delivery cannula having a proximal end in fluid communication with the reservoir and a distal end to be received within a patient, a removable sterile barrier disposed about the second end of the delivery cannula, and a controllable element.

What is claimed is:

~~1. A drug delivery system comprising:~~

~~—— a drug delivery device comprising:~~

~~—— a reservoir,~~

~~—— a delivery cannula having a proximal end in fluid communication with the reservoir and a distal end to be received within a patient,~~

~~—— a housing having an opening through which the distal end of the delivery cannula can be deployed, and~~

~~—— a controllable element;~~

~~—— a first sensor configured to detect contact between the housing and the patient; and~~

~~—— a controller coupled to the first sensor and the controllable element, the controller being configured to:~~

~~—— use the first sensor to determine if the housing contacts the patient, and~~

~~—— control the controllable element if the housing is determined to contact the patient.~~

~~—— 2. The drug delivery system of claim 1, the controllable element comprising a lock.~~

~~—— 3. The drug delivery system of claim 2, the controller being configured to deactivate the lock if the housing is determined to contact the patient.~~

~~—— 4. The drug delivery system of any one of claims 2 or 3, wherein~~

~~—— the drug delivery device comprises a needle shield moveable relative to the distal end of the delivery cannula, and~~

~~—— the lock is configured to prevent movement of the needle shield when the lock is activated.~~

~~—— 5. The drug delivery system of any one of claims 2 or 3, wherein~~

~~—— the drug delivery device comprises a plunger moveable through the reservoir to discharge a medicament from the reservoir, and~~

~~—— the lock is configured to prevent movement of the plunger when the lock is activated.~~

~~6. The drug delivery system of any one of claims 2 or 3, wherein~~
~~the drug delivery device comprises an actuator configured to trigger the drug delivery device, and~~
~~the lock is configured to prevent the actuator from triggering the drug delivery device when the lock is activated.~~

~~7. The drug delivery system of any one of claims 2 or 3, comprising:~~
~~a second sensor configured to detect a temperature of a medicament within the reservoir;~~
~~and~~
~~wherein the controller is configured to:~~
~~use the second sensor to determine the temperature or temperature history of the medicament within the reservoir; and~~
~~activate the lock if the temperature or temperature history of the medicament within the reservoir is greater than or less than a target temperature or temperature range.~~

~~8. The drug delivery system of any one of claims 2, 3, or 7, comprising:~~
~~the drug delivery device comprising a removable sterile barrier disposed about the distal end of the delivery cannula;~~
~~a third sensor configured to detect movement of the removable sterile barrier; and~~
~~wherein the controller is configured to:~~
~~use the third sensor to determine whether the removable sterile barrier has been removed from the distal end of the delivery cannula;~~
~~determine if a time period has elapsed since removal of the removable sterile barrier; and~~
~~activate the lock if the removable sterile barrier has been removed from the distal end of the delivery cannula and the time period has elapsed.~~

~~9. The drug delivery system of any one of claims 2, 3, 7, or 8, comprising:~~
~~a fourth sensor configured to detect an orientation of the delivery cannula; and~~
~~wherein the controller is configured to:~~
~~use the fourth sensor to determine if the delivery cannula is oriented for delivering a medicament in the reservoir to the patient; and~~

_____ activate the lock if the delivery cannula is not oriented properly for delivering the medicament in the reservoir to the patient.

_____ 10. The drug delivery system of any one of claims 2, 3, or 7-9, comprising:

_____ a fifth sensor configured to detect an identity of the patient; and

_____ wherein the controller is configured to:

_____ use the fourth sensor to determine if the patient is an authorized patient, and

_____ activate the lock if the patient is not an authorized patient.

_____ 11. The drug delivery system of any one of claims 1 to 3, the controllable element comprising an output unit, and the controller being configured to control the output unit to notify the patient or a user that the drug delivery device can be used for drug delivery if the housing is determined to contact the patient.

_____ 12. The drug delivery system of any one of claims 1 to 3, the controllable element comprising a circuit having a low-energy state and a high-energy state, the controller being configured to switch the circuit from the low-energy state to the high-energy state if the housing is determined to contact the patient.

_____ 13. The drug delivery system of any one of claims 1 to 3, the controllable element comprising a heating element configured to heat a medicament in the reservoir or the delivery cannula when activated, the controller being configured to activate the heating element if the housing is determined to contact the patient.

_____ 14. A method for use with a drug delivery device comprising a reservoir, a delivery cannula having a proximal end in fluid communication with the reservoir and a distal end to be received within a patient, and a housing having an opening through which the distal end of the delivery cannula can be deployed, the method comprising:

_____ determining, with a first sensor, if the housing contacts the patient; and

_____ controlling a controllable element if the housing is determined to contact the patient.

~~15. The method of claim 14, the controllable element comprising a lock.~~

~~16. The method of claim 15, wherein controlling a controllable element if the housing is determined to contact the patient comprises deactivating the lock if the housing is determined to contact the patient.~~

~~17. The method of any one of claims 15 or 16, comprising:~~

~~determining, with a second sensor, a temperature or temperature history of a medicament within the reservoir; and~~

~~activating the lock if the temperature history of the medicament within the reservoir is greater than or less than a target temperature or temperature range.~~

~~18. The method of any one of claims 15-17, comprising:~~

~~determining, with a third sensor, if a removable sterile barrier has been removed from the distal end of the delivery cannula;~~

~~determining if a time period has elapsed since removal of the removable sterile barrier; and~~

~~activating the lock if the removable sterile barrier has been removed from the distal end of the delivery cannula and the time period has elapsed.~~

~~19. The method of any one of claims 15-18, comprising:~~

~~determining, with a fourth sensor, if the delivery cannula is oriented for delivering a medicament in the reservoir to the patient; and~~

~~activating the lock if the delivery cannula is not oriented properly for delivering the medicament in the reservoir to the patient.~~

~~20. The method of any one of claims 15-19, comprising:~~

~~determining, with a fifth sensor, an identity of the patient; and~~

~~activating the lock if the patient is not an authorized patient.~~

[Claim 1]A drug delivery device comprising:a reservoir;a delivery member having a proximal end connected or configured to be connected in fluid communication with the reservoir and a distal end configured for insertion into a patient;a housing having an opening, the distal end of the delivery member being configured to extend through the opening in an operative state;an adhesive for removably coupling the housing to skin of the patient;a removable cover covering at least a portion of the adhesive;a controllable element; anda patient contact sensor.wherein the drug delivery device is programmed or configured to:(a) determine if the at least a portion of the adhesive has been exposed, and(b) determine if the drug delivery device is in contact with the patient, then, if the drug delivery device is in contact with the patient, output a control signal to the controllable element.[Claim 2]The drug delivery device of claim 1, wherein the opening is formed in an exterior surface of the housing and the adhesive is disposed at the exterior surface of the housing.[Claim 3]The drug delivery device of claim 1, wherein the removable cover comprises a sheet covering the adhesive and configured for removal by the patient or a user to expose the adhesive.[Claim 4]The drug delivery device of claim 1, wherein the drug delivery device comprises a controller, the controller being programmed to output the control signal to the controllable element if (b) does not occur within a predefined time period after (a).

[Claim 5]

The drug delivery device of claim 1, wherein the drug delivery device comprises a controller, the controller being programmed to repetitively determine at predefined time intervals if the drug delivery device is in contact with the patient.

[Claim 6]

The drug delivery device of claim 1, wherein the controllable element comprises a communication unit.

[Claim 7]

The drug delivery device of claim 6, wherein the communication unit, in response to the control signal, wirelessly transmits a report to an external computing device.

[Claim 8]

The drug delivery device of claim 6, wherein the drug delivery device comprises a controller, the controller being programmed to determine (a) if drug delivery is complete, and (b) if the drug delivery device has been removed from contact with the patient, then, if (a) and (b) are determined to exist, control the communication unit to transmit a report.

[Claim 9]

The drug delivery device of claim 1, wherein the controllable element comprises a lock.

[Claim 10]

The drug delivery device of claim 9, wherein the control signal changes the lock from a locked state to an unlocked state.

[Claim 11]

The drug delivery device of claim 10, comprising a plunger configured to expel a drug from the reservoir, wherein the lock, in the locked state, prevents movement of the plunger.

[Claim 12]

The drug delivery device of claim 10, comprising a trigger button operable by the patient, wherein the lock, in the locked state, prevents operation of the trigger button by the patient.

[Claim 13]

The drug delivery device of claim 1, wherein the controllable element comprises a circuit having a low-energy state and a high-energy state, and wherein the control signal switches the circuit from the low-energy state to the high-energy state.

[Claim 14]

The drug delivery device of claim 1, wherein the controllable element comprises a heating element configured to heat a drug in the reservoir or the delivery member in response to the control signal.

[Claim 15]

The drug delivery device of claim 1, wherein the patient contact sensor comprises at least one of a capacitance sensor, a resistance sensor, and an inductance sensor.