

of the drug delivery device, a first communication module coupled to the one or more sensors and configured to transmit the sensor data; and a controllable element. The external computing device may include a second communication module configured to receive the sensor data from the first communication module, a processor coupled to the second communication module, and a memory coupled to the processor. The memory may store non-transitory computer-readable instructions that, when executed by the processor, cause the processor to: determine at least one of the condition or the operational state of the drug delivery device based on the sensor data, generate an instruction for controlling the controllable element of the drug delivery device based on the determination of the at least one of the condition or the operational state of the drug delivery device, and control the second communication module to transmit the instruction to the first communication module of the drug delivery device.

[0009] There is disclosed a system includes a drug delivery device and an external computing device. The drug delivery device may include 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, one or more sensors, a first communication module, and a first controller coupled to the one or more sensors and the first communication module. The first controller may be configured to use the one or more sensors to determine at least one of a condition or an operational state of the drug delivery device, and control the first communication module to transmit a communication representative of the condition or the operational state of the drug delivery device. The external computing device may include a second communication module configured to receive the communication from the first communication module, a display, a memory, and a second controller coupled to the display, the memory, and the second communication module. The second controller may be configured to control the display to display at least one of an instructional prompt or an informational prompt based on the communication from the first communication module.

[0010] According to yet another aspect of the disclosure, a method of using a system comprising a drug delivery device and an external computing device is provided. The drug delivery device may include 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, one or more sensors configured to generate sensor data, a first communication module, and a controllable element. The external computing device may include a memory and a second communication module. The method may include: (a) collecting sensor data with the drug delivery device; (b) transmitting the sensor data from the drug delivery device with

the first communication module; (c) receiving the sensor data from the drug delivery device at the external computing device with the second communication module; and (d) determining, with the external computing device, at least one of a condition or an operational state of the drug delivery device based on the sensor data; generating, with the external computing device, an instruction for controlling the controllable element of the drug delivery device based on the determination of the at least one of the condition or the operation state of the drug delivery device; and controlling the second communication module of the external computing device to transmit the instruction to the first communication module of the drug delivery device.

[0011] There is disclosed a method of using a system comprising a drug delivery device and an external computing device is provided. The drug delivery device may include a reservoir and a delivery cannula having a proximal end in fluid communication with the reservoir and a distal end to be received within a patient. The external computing device may include a memory. The method may include: (a) determining at least one of a condition or an operational state of the drug delivery device; (b) transmitting a communication representative of the condition or the operational state from the drug delivery device; (c) receiving the communication from the drug delivery device at the external computing device; and (d) processing the communication received from the drug delivery device according to information stored in the memory of the external computing device.

Brief Description of the Drawings

[0012] It is believed that the disclosure will be more fully understood from the following description taken in conjunction with the accompanying drawings. Some of the figures may have been simplified by the omission of selected elements for the purpose of more clearly showing other elements. Such omissions of elements in some figures are not necessarily indicative of the presence or absence of particular elements in any of the exemplary embodiments, except as may be explicitly delineated in the corresponding written description. None of the drawings are necessarily to scale.

[0013] Fig. 1 is a schematic diagram of a drug delivery system according an embodiment of the disclosure in communication with one or more computing devices and one or more networks;

[0014] Fig. 2 is a block diagram of a method of operating a drug delivery system according to another embodiment of the disclosure;

What is claimed is:

1. A 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;
one or more sensors configured to generate sensor data representative of at least one of a condition or an operational state of the drug delivery device;
a first communication module coupled to the one or more sensors and configured to transmit the sensor data; and
a controllable element; and
an external computing device comprising:
a second communication module configured to receive the sensor data from the first communication module;
a processor coupled to the second communication module; and
a memory coupled to the processor, the memory storing non-transitory computer-readable instructions that, when executed by the processor, cause the processor to:
determine at least one of the condition or the operational state of the drug delivery device based on the sensor data,
generate an instruction for controlling the controllable element of the drug delivery device based on the determination of the at least one of the condition or the operational state of the drug delivery device, and
control the second communication module to transmit the instruction to the first communication module of the drug delivery device.
2. The system of claim 1, the external computing device comprising a display coupled to the processor.

3. The system of claim 2, wherein the non-transitory computer-readable instructions include instructions that cause the processor to control the display to display at least one of an instructional prompt or an informational prompt based on: (i) at least one of the condition or the operational state of the drug delivery device, and (ii) information stored in the memory of the external computing device.

4. The system of any one of the preceding claims, wherein the non-transitory computer-readable instructions include instructions that cause the processor to determine

a temperature or a temperature history of the drug delivery device based on the sensor data.

5. The system of claim 4, wherein the non-transitory computer-readable instructions include instructions that cause the processor to compare the temperature or the temperature history of the drug delivery device to information stored in the memory of the external computing device to determine if the temperature or the temperature history of the drug delivery device is acceptable.

6. The system of any one of the preceding claims, wherein the non-transitory computer-readable instructions include instructions that cause the processor to determine if the drug delivery device is disposed on or against a skin of the patient based on the sensor data.

7. The system of claim 6, wherein the non-transitory computer-readable instructions include instructions that cause the processor to, in response to a determination that the drug delivery device is disposed on or against the skin of the patient, control the display to display an instructional prompt instructing a user to correctly orient the drug delivery device relative to the skin of the patient.

8. The system of any one of the preceding claims, wherein the non-transitory computer-readable instructions include instructions that cause the processor to determine an orientation of the drug delivery device based on the sensor data.

9. The system of claim 8, wherein the non-transitory computer-readable instructions include instructions that cause the processor to:

compare the orientation of the drug delivery device to information stored in the memory of the external computing device to determine if the orientation of the drug delivery device relative to a skin of the patient is acceptable, and

in response to a determination that the orientation of the drug delivery device is acceptable, control the display to display an instructional prompt instructing a user to actuate the drug delivery device.

10. The system of any one of the preceding claims, wherein the non-transitory computer-readable instructions include instructions that cause the processor to determine if the drug delivery device has been actuated by a user based on the sensor data.

11. The system of claim 10, wherein the non-transitory computer-readable instructions include instructions that cause the processor to, in response to a determination that the drug delivery device has been actuated by the user, control the display to display an instructional prompt instructing a user to wait for completion of a delivery of a medicament from the reservoir to the patient.

12. The system of any one of the preceding claims, wherein the non-transitory computer-readable instructions include instructions that cause the processor to determine if a delivery of a medicament from the reservoir to the patient has been completed based on the sensor data.

13. The system of claim 12, wherein the non-transitory computer-readable instructions include instructions that cause the processor to, in response to a determination that the delivery of the medicament from the reservoir to the patient has been completed, control the display to display an instructional prompt instructing a user to discard the drug delivery device.

14. The system of any one of the preceding claims, wherein the non-transitory computer-readable instructions include instructions that cause the processor to determine an amount of medicament remaining in the reservoir based on the sensor data.

15. The system of any one of the preceding claims, the drug delivery device comprising a removable sterile barrier disposed about the distal end of the delivery cannula, wherein the non-transitory computer-readable instructions include instructions that cause the processor to determine

if the removable sterile barrier has been removed from the distal end of the delivery cannula based on the sensor data.

16. The system of any one of the preceding claims, wherein the non-transitory computer-readable instructions include instructions that cause the processor to determine if the distal end of the delivery cannula is inserted into the patient based on the sensor data.

17. The system of any one of the preceding claims, wherein the non-transitory computer-readable instructions include instructions that cause the processor to:

generate a report representative of at least one of the condition or the operational state of the drug delivery device; and

control the second communication module to transmit the report to a remote computing device.

18. The system of claim 1, the controllable element comprising a lock that, when activated, is configured to prevent movement of at least one of: (i) a needle shield disposed about the distal end of the delivery cannula, (ii) a plunger disposed in the reservoir, or (iii) an actuator configured to trigger the drug delivery device.

19. The system of claim 1, the controllable element comprising a heating element configured to heat a medicament in the reservoir or the delivery cannula when activated.

20. The system of any one of the preceding claims, the one or more sensors comprising a temperature sensor configured to detect a temperature of a medicament within the reservoir.

21. The system of any one of the preceding claims, the one or more sensors comprising a skin contact sensor including at least one of a pressure sensor, a capacitance sensor, a resistance sensor, or an inductance sensor.

22. The system of claim 21, the skin contact sensor being mounted on a needle shield disposed about the distal end of the delivery cannula.

23. The system of any one of the preceding claims, the one or more sensors comprising an orientation sensor.

24. The system of claim 23, the orientation sensor comprising a magnetometer.

25. The system of any one of the preceding claims, the drug delivery device comprising an autoinjector.

26. The system of any one of the preceding claims, the external computing device comprising at least one of a smartphone, a smartwatch, a smart wearable device, a personal computer, a laptop computer, a smart television, a smart appliance, a smart automobile, a networked computer, or a tablet computer.

27. The system of any one of the preceding claims, the first communication module being configured to communicate with the second communication module via at

least one of Bluetooth, Bluetooth low energy, radio-frequency identification (RFID), Zigbee, Wi-Fi, or near field communication (NFC).

28. The system of any one of the preceding claim, wherein the reservoir comprises a medicament.

29. The system of claim 27, the medicament being selected from the group consisting of: TNF inhibitors, antibodies to the calcitonin gene-related peptide receptor, granulocyte colony stimulating factors, erythropoiesis stimulating agents, apelin receptor agonists, antibodies to proprotein convertase subtilisin/kexin Type 9 (PCSK9), and tissue inhibitors of metalloproteinases.

30. A method of using a system comprising a drug delivery device and an external computing device, the 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, one or more sensors configured to generate sensor data, a first communication module, and a controllable element, the external computing device comprising a memory and a second communication module, the method comprising:

- collecting sensor data with the drug delivery device;
- transmitting the sensor data from the drug delivery device with the first communication module;
- receiving the sensor data from the drug delivery device at the external computing device with the second communication module;

determining, with the external computing device, at least one of a condition or an operational state of the drug delivery device based on the sensor data;

generating, with the external computing device, an instruction for controlling the controllable element of the drug delivery device based on the determination of the at least one of the condition or the operation state of the drug delivery device; and

controlling the second communication module of the external computing device to transmit the instruction to the first communication module of the drug delivery device.

31. The method of claim 30, comprising displaying at least one of an instructional prompt or an informational prompt according to: (i) at least one of the condition or the operational state of the drug device, and (ii) information stored in the memory of the external computing device.

32. The method of claim 30 or 31, wherein the determining of the at least one of the condition or the operational state of the drug delivery device comprises determining, with the

external computing device, a temperature or a temperature history of the drug delivery device based on the sensor data.

33. The method of claim 32, comprising:

comparing the temperature or the temperature history of the drug delivery device to information stored in the memory of the external computing device to determine if the temperature or the temperature history of the drug delivery device is acceptable; and

in response to a determination that the drug delivery device has an acceptable temperature or an acceptable temperature history, displaying an instructional prompt instructing a user to dispose the drug delivery device on or against a skin of the patient.

34. The method of any one of claims 30 to 33, the determining of the at least one of the condition or the operational state of the drug delivery device comprising determining, with the external computing device, if the drug delivery device is disposed on or against a skin of a patient based on the sensor data.

35. The method of claim 34, comprising, in response to a determination that the drug delivery device is disposed on or against the skin of the patient, controlling the display to display an instructional prompt instructing a user to correctly orient the drug delivery device relative to the skin of the patient.

36. The method of any one of claims 30 to 35, the determining of the at least one of the condition or the operational state of the drug delivery device comprising determining, with the external computing device, an orientation of the drug delivery device based on the sensor data.

37. The method of claim 36, comprising:

comparing the orientation of the drug delivery device to information stored in the memory of the external computing device to determine if the orientation of the drug delivery device relative to a skin of a patient is acceptable; and

in response to a determination that the orientation of the drug delivery device is acceptable, displaying an instructional prompt instructing a user to actuate the drug delivery device.

38. The method of any one of claims 30 to 37, the determining of the at least one of the condition or the operational state of the drug delivery device comprising determining, with the external computing device, if the drug delivery device has been actuated by a user based on the sensor data.

39. The method of claim 38, comprising, in response to a determination that the drug delivery device has been actuated by the user, displaying an instructional prompt instructing a user to wait for completion of a delivery of a medicament from the reservoir to the patient.

40. The method of any one of claims 30 to 39, the determining of the at least one of the condition or the operational state of the drug delivery device comprising determining, with the external computing device, if a delivery of a medicament from the reservoir to a patient has been completed based on the sensor data.

41. The method of claim 40, comprising, in response to a determination that the delivery of the medicament from the reservoir to the patient has been completed, displaying an instructional prompt instructing a user to discard the drug delivery device.

42. The method of any one of claims 30 to 40, comprising:
generating, with the external computing device, a report representative of at least one of the condition or the operational state of the drug delivery device; and
controlling the second communication module to transmit the report to a remote computing device.

43. The method of any one of claims 30 to 42, the drug delivery device comprising an autoinjector.

44. The method of any one of claims 30 to 43, the external computing device comprising at least one of a smartphone, a smartwatch, a smart wearable device, a personal computer, a laptop computer, a smart television, a smart appliance, a smart automobile, a networked computer, or a tablet computer.

45. The method of any one of claims 30 to 44, the first communication module being configured to communicate with the second communication module via at least one of Bluetooth, Bluetooth low energy, radio-frequency identification (RFID), Zigbee, Wi-Fi, or near field communication (NFC).

46. The method of any one of claims 30 to 45, wherein the reservoir comprises a medicament.

47. The method of claim 46, the medicament being selected from the group consisting of: TNF inhibitors, antibodies to the calcitonin gene-related peptide receptor, granulocyte colony stimulating factors, erythropoiesis stimulating agents, apelin receptor agonists, antibodies to proprotein convertase subtilisin/kexin Type 9 (PCSK9), and tissue inhibitors of metalloproteinases.