

regarding the patient's condition such as may be obtained from an instrument (e.g., blood pressure cuff, heart monitor, etc.), the patient's chart or the patient directly. Finally, the clinician will exercise his or her medical judgment regarding changes to the therapy.

[0006] The development of new therapy management techniques thus typically rely upon a clinician's expertise, and must face the challenge of a rigorous regulation scheme as well. Taking drug delivery as an example, developments tend to occur as to a particular drug and a particular route of delivery. Even in those instances where certain changes of therapy have been automated (e.g., where the pump automatically modifies its operation in accordance with a sensor reading), the development has been isolated to a particular drug and/or required continued intensive clinician involvement to manage the system. Certainly, the nature of the focus is influenced by the need to obtain regulatory approval prior to wide-spread release of the therapy, which approval is only obtained after extensive development and testing of such unique systems. One effect of the isolated nature of development is a proliferation of unique single-use or limited-use systems, methods and/or devices, with the attendant problems of supplying and supporting each of these devices.

[0007] As set forth in greater detail below, the present disclosure sets forth an improved assembly embodying advantageous alternatives to the conventional devices and methods discussed above.

Summary

[0007a] According to a first aspect of the present invention, there is provided a therapy management development platform for facilitating development, modification, or testing of a therapy management system, the platform comprising: (i) a pump controller with a pump input/output interface coupled to the pump controller, and (ii) an interface module including an interface module controller and a module-sensor input/output interface, the module-sensor input/output interface having at least one standardized input port, at least one standardized output port and at least one standardized power connection, and the interface module controller customizably programmed to receive data from a sensor coupled to the module-sensor input/output interface and from the pump controller and to provide instructions to the pump controller to vary the operation of a pump coupled thereto according to a level of

access, wherein, when set to an initial level of access the platform provides first functionality, and when set to a second level of access the platform provides second functionality, wherein the first functionality and the second functionality relate to the use with the platform of sensors or algorithms, and wherein the variation of the operation of the pump according to the level of access is non-therapeutic in nature.

[0007b] According to a second aspect of the present invention, there is provided a method of providing therapy management development, the method comprising: providing a computerized therapy management development platform including at least (i) a pump controller including a first processor, and (ii) an interface module including a second processor and a module-sensor input/output interface and coupled to the pump controller; performing one of both of: (a) coupling a sensor-under-test to the module-sensor input/output interface; and/or (b) programming the pump controller with an algorithm-under-test; setting the computerized therapy management development platform to a first level of access to facilitate a first stage of testing of the sensor-under-test and/or the algorithm-under-test, the first level of access providing first functionality; testing one or more aspects of the sensor-under-test and/or the algorithm-under-test; setting the computerized therapy management development platform to a second level of access, in response to entry of a key or password, to facilitate a second stage of testing of the sensor-under-test and/or the algorithm-under-test, the second level of access providing second functionality; and performing additional investigation of one or more aspects of the sensor-under-test and/or the algorithm-under-test using the second functionality.

[0008] There is disclosed a method of providing therapy management development is provided. The method includes providing a therapy management development platform having a plurality of levels of functionality, the platform including a medical device capable of providing therapy management, setting the platform to a first level of access to the functionality relative to the medical device, and modifying the operation of the medical device using the platform. The method also includes receiving an indication of approval to change the level of access to the functionality of the platform to a second level of access, and setting the platform to the second level of access to the functionality of the platform in response to receipt of the indication of approval.

[0009] There is also disclosed a therapy management development platform includes a pump controller with a pump

CLAIMS

1. A therapy management development platform for facilitating development, modification, or testing of a therapy management system, the platform comprising:

(i) a pump controller with a pump input/output interface coupled to the pump controller, and

(ii) an interface module including an interface module controller and a module-sensor input/output interface, the module-sensor input/output interface having at least one standardized input port, at least one standardized output port and at least one standardized power connection, and

the interface module controller customizably programmed to receive data from a sensor coupled to the module-sensor input/output interface and from the pump controller and to provide instructions to the pump controller to vary the operation of a pump coupled thereto according to a level of access,

wherein, when set to an initial level of access the platform provides first functionality, and when set to a second level of access the platform provides second functionality,

wherein the first functionality and the second functionality relate to the use with the platform of sensors or algorithms,

and wherein the variation of the operation of the pump according to the level of access is non-therapeutic in nature.

2. The platform according to claim 1, further comprising a development toolkit having a graphical user interface to be used to customizably program the interface module controller.

3. The platform according to claim 2, further comprising a computing device, the tool kit operating on the computing device.

4. The platform according to claim 2 or claim 3, wherein the tool kit comprises a standardized library of commands.

5. The platform according to any one of claims 1 to 4, wherein the pump controller and the interface module communicate wirelessly via radio-frequency or infra-red transmitters and receivers.
6. The platform according to any one of claims 1 to 5, wherein the interface module receives an indication of a level of access associated with a geographic location, and determines if the pump controller and the interface module are disposed in the geographic location.
7. The platform according to claim 6, wherein the indication of the level of access corresponds to a stage in the testing of a pump associated with the pump controller, the stage comprising one of bench trials, animal trials, human clinical trials, and human use.
8. A method of providing therapy management development, the method comprising:
- providing a computerized therapy management development platform including at least (i) a pump controller including a first processor, and (ii) an interface module including a second processor and a module-sensor input/output interface and coupled to the pump controller;
 - performing one of both of:
 - (a) coupling a sensor-under-test to the module-sensor input/output interface; and/or
 - (b) programming the pump controller with an algorithm-under-test;
 - setting the computerized therapy management development platform to a first level of access to facilitate a first stage of testing of the sensor-under-test and/or the algorithm-under-test, the first level of access providing first functionality;
 - testing one or more aspects of the sensor-under-test and/or the algorithm-under-test;

setting the computerized therapy management development platform to a second level of access, in response to entry of a key or password, to facilitate a second stage of testing of the sensor-under-test and/or the algorithm-under-test, the second level of access providing second functionality; and

performing additional investigation of one or more aspects of the sensor-under-test and/or the algorithm-under-test using the second functionality.

9. The method according to claim 8, wherein performing one or both of (a) and (b) comprises coupling a sensor-under-test to the module-sensor input/output interface.

10. The method according to claim 9, further comprising changing the operation of a control algorithm.

11. The method according to claim 8, wherein performing one or both of (a) or (b) comprises programming the pump controller with an algorithm-under-test.

12. The method according to claim 11, wherein programming the pump controller with the algorithm-under-test comprises programming the controller using a development toolkit configured to permit a program to be written by a user through the manipulation of a GUI in combination with a library of standardized input commands, output commands, and procedure commands.

13. The method according to claim 8, wherein the sensor-under-test and/or the algorithm-under-test are being tested for integration with a commercial product already existing at the time that the testing occurs.

14. The method according to claim 8, wherein performing one or both of (a) and (b) comprises coupling a sensor-under-test to the module-sensor input/output interface, and programming the pump controller with an algorithm-under-test.

15. The method according to claim 8, further comprising setting the computerized therapy management development platform to a third level of access, in response to a second indication of approval, to facilitate a third stage of testing of the sensor-under-test and/or the algorithm-under-test, the third level of access providing third functionality different from, but possibly inclusive of, the second functionality.

16. The method according to claim 15, wherein the second indication of approval indicates regulatory approval and wherein the third functionality facilitates use of the sensor-under-test and/or the algorithm-under-test in a commercial product.

17. The method according to claim 8, wherein the interface module is customizably programmed to receive different data from the sensor-under-test, to provide different instructions to a pump controller to vary the operation of the pump, or both.

18. The method according to claim 8, wherein the indication of approval is an encryption key, the interface module programmed to change the level of access in response to receipt of the encryption key from a remote computer.

19. The method according to claim 8, wherein:

receiving the indication of approval comprises receiving an indication of approval associated with a geographic location for the pump controller and interface module; and

setting the computerized therapy management development platform to the second level of access comprises determining if the pump controller and the interface module are disposed in the geographic location, and setting the computerized therapy management development platform to the second level of access only if it is determined that the pump controller and interface module are disposed in the geographic location.

20. The method according to claim 8, wherein:

setting the computerized therapy management development platform to the first level of access comprises setting the computerized therapy management development platform to the first level of access according to a determination made by a first party, separate from a second party that modifies the operation of a medical device, that the second party has received approval from a governmental or commercial organization that oversees testing of medical devices prior to marketing to have access to the first level; and

setting the computerized therapy management development platform to the second level of access in response to receipt of the indication of approval comprises setting the computerized therapy management development platform to the second level according to a determination made by the first party that the second party has received approval from the governmental or commercial organization to proceed to the second level of access.

THERAPY MANAGEMENT DEVELOPMENT PLATFORM

Abstract

A method of providing therapy management development includes providing a therapy management development platform having a plurality of levels of functionality, the platform including a medical device capable of providing therapy management, setting the platform to a first level of access to the functionality relative to the medical device, and modifying the operation of the medical device using the platform. The method also includes receiving an indication of approval to change the level of access to the functionality of the platform to a second level of access, and setting the platform to the second level of access to the functionality of the platform in response to receipt of the indication of approval. The platform is also provided.

Fig. 9