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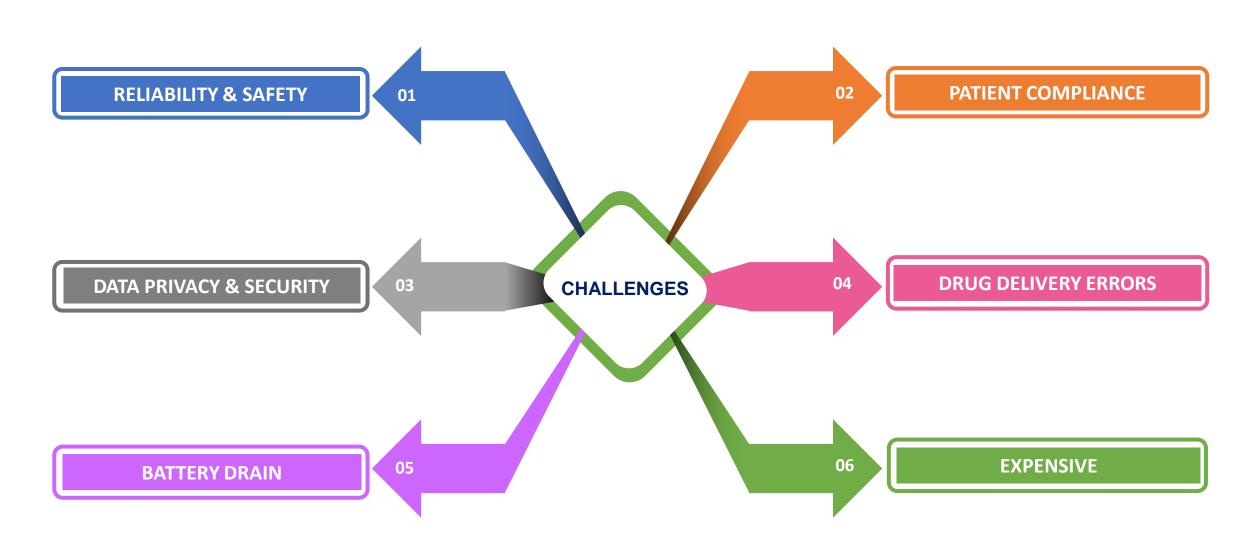
## **SUMMARY**

- Patient monitoring is a relatively well-developed area of healthcare digitalization, especially for chronic diseases such as respiratory conditions, diabetes etc. where patient responsibility for self-management and administration has been in place for decades.
- Effective remote patient management relies on digital transformation in healthcare. Digitally enabled remote healthcare enable access to clinicians, ensure prescribed therapies are administered in the right dosage and frequency, and monitor patient conditions and reactions.
- Major challenges associated with remote patient management for drug delivery systems are:
  - Reliability & Safety
  - Patient Compliance
  - Data Privacy & Security
  - Drug Delivery Errors
  - Battery Drain
  - Expensive
- Reliability & safety challenges have been addressed by Roche, Tandem, Baxter, and Smiths Medical by determining whether or not safety conditions are met by the identification code, whether or not programmed operation is within a range of acceptable parameters, and providing a system for reporting on notification, alert and alarm escalation on communication systems.
- Patient compliance challenges have been addressed by West Pharmaceutical, Closed Loop Medicine, and Portal Instruments by providing passive electronically readable information to pair and recognize the medical device, by using patient unique identifier and package unique identifiers, and determining compliance based on physical parameters, or comparing it to a reading of the physical parameter prior to the injection.
- Data privacy challenges have been addressed by YpsoMed, Nephron, and Fenwal by providing an additional encryption such as subscriber-based encryption key provision, authenticating the network packet by verifying the digital signature and public keys, and receiving commands from a server with a predetermined list of commands.
- > Drug delivery error-related challenges have been addressed by CareFusion (BECTON DICKINSON's company) by alerting healthcare professionals about drug errors using tracking engines.
- > Battery drain challenge has been addressed by Tandem by enabling effective co-ordination among devices to increase efficiency and conserve battery power.
- > Challenges posed by high cost has been addressed by Insulet Corporation by providing a drug delivery management device that can be used with many types of drug delivery devices and drugs.





# MAJOR CHALLENGES ADDRESSED BY INTERESTING PLAYERS







## **COMPANIES ADDRESSING THE CHALLENGES**

#### **COMPANIES COVERED IN THIS REPORT:**

- YPSOMED AG
- WEST PHARMA SERVICES IL LTD
- TANDEM DIABETES CARE INC
- BAXTER INTERNATIONAL INC
- SMITHS MEDICAL ASD INC
- ROCHE DIABETES CARE INC
- CLOSED LOOP MEDICINE LTD
- PORTAL INSTR INC
- INSULET CORP
- NEPHRON PHARMACEUTICALS CORP
- CAREFUSION 303 INC (A BECTON DICKINSON'S COMPANY)
- FENWALINC



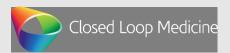




























### **01. RELIABILITY & SAFETY**

#### US20190392124A1 Controlling user access to a medical system (Publication date: 2019-12-26)

The invention addresses the challenge of controlling user access to a medical system including a body-wearable medical device such as insulin pump or continuous glucose monitor, which involves providing a controller, requesting entry of identification code, determining whether safety condition is met by medical system, and executing command if the safety condition is met.

Medical system (FIG. 1) and exemplary operational flow of a method for controlling user access and related steps are presented (Fig.2).

The operational flow starts with step S as an initial state. It is assumed that in the initial state S, the remote controller is in the locked state. It is further assumed that the medical device operates in the initial state autonomously under control of the medical device control circuit.

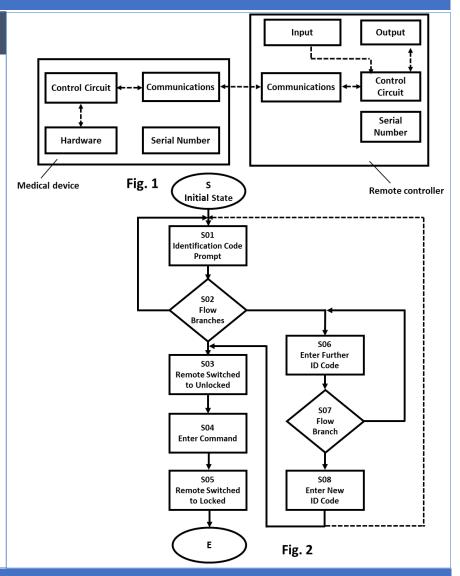
In subsequent step S01, the user is prompted by the remote controller to enter, via the remote controller input unit, the identification code or to alternatively indicate that he/she has forgotten the identification code. The transition from S to S01 may, be initiated by a corresponding user operation on the remote controller input unit.

If the identification code is entered incorrectly in step S01, the operational flow returns to step S01. If the identification code is entered correctly in step S01, the operational flow proceeds to step S03, where the remote controller is switched into the unlocked state.

In subsequent state S04, the user may enter, via the remote controller input unit, the medical device command. which is transmitted, via the remote controller communication unit, to the medical device communication unit and is subsequently executed by the medical device under control of the medical device control circuit.

The operational flow subsequently may proceed directly to step S05 or may stay in step S04 allowing the user to enter further medical device commands. In step S05, the remote controller is switched back into the locked state and the operational flow ends in step E which may correspond to step S.

If indication is provided in step S02 that the identification code is forgotten, the operational flow branches to step S06. In step S06, the user is prompted to enter further identification code, via the remote controller input unit.









### **01. RELIABILITY & SAFETY**

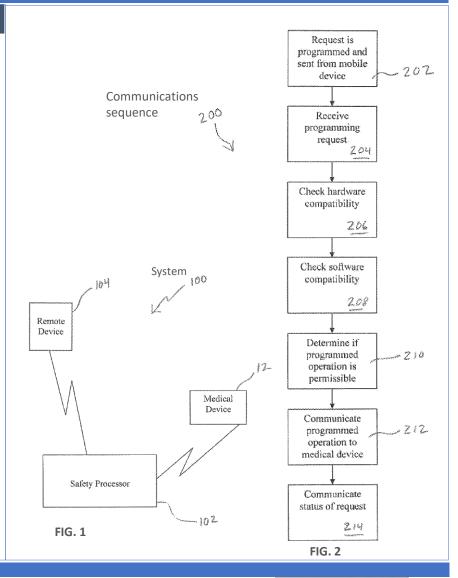
#### US9486571B2 Safety processor for wireless control of a drug delivery device (Publication date: 2016-11-08)

A processor is arranged to facilitates safe and reliable communications between remote electronic device such as a smart phone and a medical device such as an infusion pump. The processor determines whether programmed operation is within a range of acceptable parameters for facilitating operations on the medical device in an efficient manner.

FIG. 1 (#FIG. 4 in corresponding patent document) which is a schematic representation of a system for facilitating safe and reliable communications between a medical device and an electronic device, is depicted. System includes a safety processor that acts as an intermediary device between the medical device and the consumer electronic device functioning as a remote control device for the medical device.

FIG. 2 (#FIG. 6 in corresponding patent document) depicts a flowchart of a communications sequence for operating medical device with a remote control device through safety processor. At step 202, an operation request is entered into the remote control device and transmitted to the safety processor. The operation request can relate to any type of operation that could otherwise be entered using the pump user interface or a dedicated remote controller such as, for example, delivery of a bolus, delivery or modification of a basal rate, review of pump history, programming of alarms, etc. The safety processor receives the operation request at step 204. At steps 206 and 208, the safety processor reviews the compatibility of the remote device requesting the operation based on parameters stored in the safety processor memory. This can include hardware, software and/or firmware compatibility, such as whether the type of device is a device approved for use for controlling the medical device and whether the type and/or version of the software being operated on the device for making the requests is approved.

Upon confirming compatibility of the remote device hardware, software and/or firmware, at step 210 the safety processor can review the specific operation request in view of acceptable operation parameters / guidelines stored in memory to determine if the operation is permissible. For example, if the operation request is for delivery of a bolus of insulin or other medicament, the safety processor can determine, whether the size of the bolus is permissible and is being requested at an acceptable time after a previous bolus request.









### **01. RELIABILITY & SAFETY**

#### US20200023127A1 Management of infusion data methods and apparatus (Publication date: 2020-01-23)

A networked patient care system for reporting on notification and alert or alarm escalation on communication system. The server transmits infusion pump data to display device causing it to display infusion pump data.

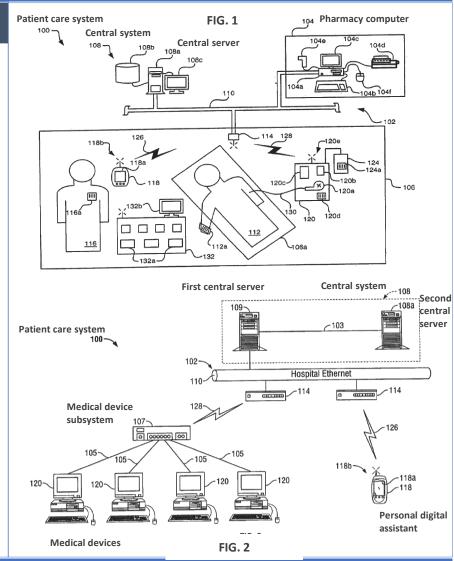
The networked patient care system includes an infusion pump communicatively coupled to a hospital network, a first server coupled to the infusion pump via the hospital network, and a second server coupled to the first server via a separate secure connection. The first server is configured to receive infusion pump data and cause the second server to store the infusion pump data in an HL 7 format to an electronic patient medical record. The first server is also configured to receive a request from a display device to access the electronic patient medical record and cause the second server to convert the infusion pump data in the electronic patient medical record to a webbased format. The first server is further configured to transmit the infusion pump data in the web-based format to the display device.

The second server is configured to determine an alarm based on the infusion pump data exceeding a threshold, and transmit the alarm, via the first server, to the infusion pump or the display device.

Via the second server, the first server is configured to receive for storage, a patient condition for relating to the infusion pump data, and transmit, via the first server, a message or a notification indicative of the patient condition to the infusion pump or the display device.

Patient care system provides a comprehensive patient safety solution for the delivery of medication. Within patient care system, software modules are provided to link together existing patient care systems using interfaces such as HL 7 interfaces.

Patient care system integrates drug delivery products with the information required to assist in ensuring safe and effective delivery of medication. The clinical decision support and accompanying alerts, alarms, warnings, and messaging of the patient care system provide a safety net of support for clinicians as they deliver patient care under increasing time and cost pressures. This information is preferably supplied through a wireless network that supplies data in a way that improves clinician workflow, making delivery of care easier.







# smiths medical

### **01. RELIABILITY & SAFETY**

US20180126067A1 Systems and methods for coordinating and controlling infusion pumps (Publication date: 2018-05-10)

A real-time embedded server system for controlling infusion pump, having networking engine for controlling their network access. The system provides relatively quick and reliable response times and handles multiple hits on the network without delays and network overloads, and controls the infusion pump in a reliable manner.

FIG. 1 depicts an example of an infusion pump system. Infusion pump includes pump control system with processor and memory programmable with selected protocols, profiles, segments of profiles, and other settings for controlling operation of pumping mechanism such as syringe and ambulatory or peristaltic type mechanisms. Infusion pump can also include control module (e.g., a user interface) for relaying commands to pump control system. Control module includes user interface utilizing operator input technology including input mechanisms, which work with display.

FIG. 2 is a block diagram of an example of a real-time embedded server. Embedded server comprises a processor and a memory. Multiple engines such as control engine, a messaging engine, an aggregation engine, and a networking engine can be implemented according to processor and memory.

While Control engine issues control commands related to operation of infusion pump, messaging engine issues messages to and receives messages from the infusion pump and aggregation engine aggregates data related to the operation of the infusion pump.

Networking engine executes the functions of network access to infusion pumps. A network couples the multiple infusion pumps and the embedded server. Networking engine provides standardized networking functions such as message forwarding, connecting, and disconnecting. The networking engine can implement any suitable protocol layers over the network. It can issue network IDs for any of the infusion pumps and itself, if needed and can also manage the addressing of the devices on the network.

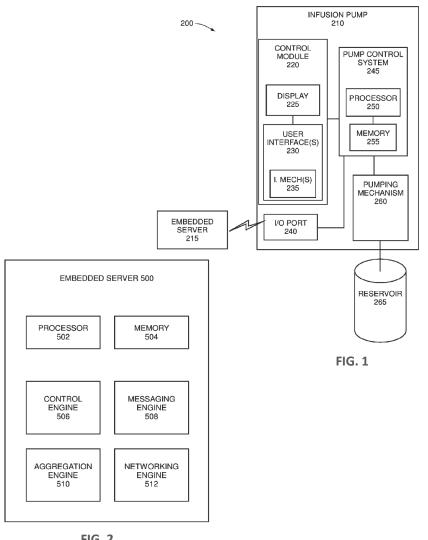


FIG. 2







#### **02. PATIENT COMPLIANCE**

#### US20190378603A1 Communication with drug delivery device (Publication date: 2019-12-12)

A portable medical device such as an autoinjector, a monitoring unit, and a communication unit configured for pairing with another device to send data of the monitoring unit; the portable medical device is packaged with a barcode or an RFID tag to enable another device to carry out the pairing.

The barcode or RFID tag may be attached to the portable medical device and is a part of packaging containing the same. The device may send, via the pairing, dynamic data from the portable medical device, such as its temperature and readiness. The communication unit may be configured to carry out the pairing based on pairing information received from another device, thereby enabling the other device to connect to a server and identify the portable medical device.

The method of monitoring a patient for compliance involves using the communication devices and obtaining data regarding usage of the medical device by the patient and sending the data to a server for compliance monitoring.

The medical devices such as an auto injector enables a computing device such as a smartphone to carry out automatic pairing, so that a connection can be made without requiring an end user to type in pairing codes. The device allows the patient to simply point a camera at the barcode and smartphone for automatically recognizing the bar code using a recognition unit and pairing with the medical device.

Once the medical device is recognized and paired with, then a second channel of communication is opened with server remotely over a network. This may use a cellular connection or locally available Wi-Fi, or an Internet connection or may directly use the IP protocol or some combination. Overall there is formed a communication route between the portable medical device and the server via the first and second communication channels respectively. Communication is established and maintained for the duration of a medical procedure such as injection of a drug.

Measurements are obtained from the medical device to track the procedure, such as duration or elapsed time of delivery of the dose, motor load data from the automatic injection device to track injection progress, back pressure, number of revolutions of the motor, rate of revolutions of the motor, etc. and obtain determinations as to whether the dose has been completed or has been interrupted before completion. Instructions for use are transmitted to the user based on real time data received from the delivery device, so that the user is told the next steps in the procedure or is given alternative instructions in the face of a malfunction etc.

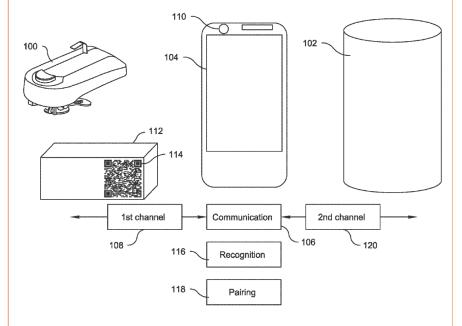


FIG. 1







### **02. PATIENT COMPLIANCE**

#### <u>US20200345299A1</u> Monitoring Patient Compliance with a Dosage Regimen (Publication date: 2020-11-05)

A computer-implemented system and method for monitoring the adherence of a patient to a dosage regimen in the package data where the package is as carton, a blister pack, a dosette box, a bottle, a tube, a syringe, a pre-filled syringe, a cartridge, a vial or a canister.

Computer-implemented method is shown in FIG. 1. The system includes a data processing device that operates in line with-program instructions stored on a RAM and executes machine learning tasks which include training a model using data from patient records stored in database(110) and/or using a trained model to classify an input data from a patient record. System also comprises patient data processing device which is a smartphone, optionally having a sensor, and connected to the smart phone via a network. System may also comprise clinician data processing device that can access the medical history of the patient, generate a prescription, amend a patient dosage regimen, place an order for medication, etc.

Computer-implemented method (Fig. 2), comprises the following steps for monitoring patient compliance with a dosage regimen:

Step 1: The data processing device receives a patient unique identifier that enables the patient to be uniquely identified and associated with a patient record including a dosage regimen.

Step 2: The data processing device receives a message including a package unique identifier and a pair of values indicating an amount of a drug administered to the patient and a time of administration of the drug.

Step 3: The data processing device identifies the drug administered to the patient using the package unique identifier. This may involve data processing device querying a database containing a list of package unique identifiers corresponding to all packages registered with the system, to enable the drug(s) contained within the package to be looked up,. The package unique identifiers enable tracking of a package at the package level, rather than the batch level. This allows system to determine exactly which drugs have been administered to the patient, i.e. at the level of individual capsules, tablets, bottles, etc.

Step 4: The data processing device stores in database the identity of the drug as determined in step 3, the time of administration of the drug and the amount of the drug administered to the patient as derived from the message received in step 2, against the record associated with the patient.

Step 5: The data processing device compares values stored in the patient record with the dosage regimen that is also stored in the patient record to calculate a compliance score indicative of the degree to which the patient has complied with the dosage regimen. It may also recommended modification to the dosage regimen based on the combination of the identity of the drug, values, and the compliance score.

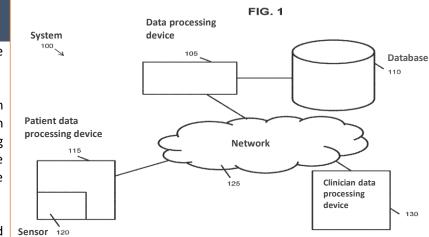
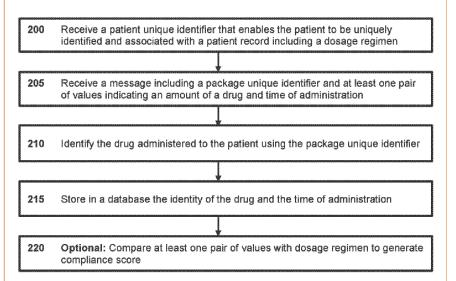


FIG. 2









### **02. PATIENT COMPLIANCE**

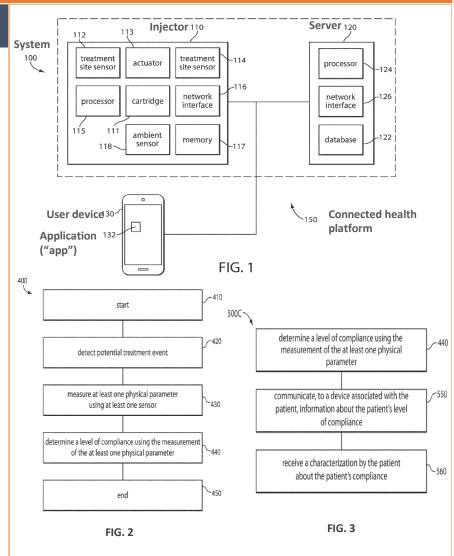
#### <u>US20180028755A1</u> Connected health platform including needle-free injector system (Publication date: 2018-02-01)

- A medical device system comprising a needle-free injection system, for monitoring patient compliance with a dosage regimen.
- A sensor in the device is configured to detect the degree of patient compliance by transmitting to a server information regarding administration of the treatment.
- The server is configured to communicate to a device associated with the patient, such as a mobile phone,.
- The system includes a network interface in communication with a third party such as a healthcare professional, wherein the server will communicate the patient's compliance in administering the treatment.
- The server is also configured to receive multiple treatment events over a period of time, determine the target level of compliance and modify the subsequent treatment based on existing level and target level of compliance.
- The needle-free injector has a base unit that communicates with the injector and the server.
- It also has a temperature conditioning unit that can change the temperature of the preloaded drug dose.

The injector collects compliance data and provides it to the server, which sends a message to a smartphone regarding the patient's compliance with the treatment regimen. The message is a reminder regarding the treatment, a question relating to the treatment, the patient's well-being, and the user's health,.

The server is further configured to receive, from the smartphone, a response to question, and stimulation for the patient to administer the treatment.

The injector uses the treatment site sensor to measure physiological parameters before, during, and/or after the treatment event. Such information is used to determine compliance, and allow, disallow, or modify a current or future treatment.









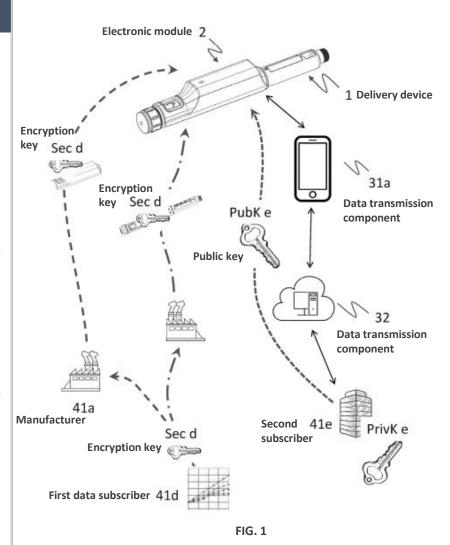
## 03. DATA PRIVACY & SECURITY

#### WO2020221707A1 Secure drug delivery data transmission (Publication date: 2020-11-05)

A medicament delivery device for delivering, administering, dispensing, injecting, or infusing substances such as insulin or hormone preparations from an electronic unit incorporated in the delivery device, and comprising a sensor for monitoring the delivery process. The electronic unit includes transmitter to transmit data items to a data subscriber, such as a manufacturer of the drug delivery device, a pharmaceutical company, a Health Care Professional (HCP), a Clinical Research Organization (CRO), a health insurance company, or the patient himself, as the primary stakeholders of an integrated healthcare data management system.

The invention is concerned with privacy and integrity of personalized protected health information when transmitted to a cloud computing facility and subsequently distributed to multiple stakeholders. The electronic unit is configured to prepare payload data comprising data items according to an allocation scheme, and to encrypt, based on an encryption key, and transmit data including the payload data. The allocation scheme and the encryption key are defined for each of multiple data subscribers. Accordingly, personalized protected health information payload data is suitably protected with generator-to-subscriber or pass-through data security measures, and any intermediary node or data server in the communication network devoid of a matching decryption key will not have access to unencrypted payload data.

The figure illustrates three distinct variants of subscriber-based encryption key provision or distribution. In a first variant (left-hand curved arrow), exemplary first data subscriber provides an encryption key to the manufacturer of electronic modules. The manufacturer then copies this key to a memory of each assembled electronic module. In a sub-variant (not shown), the manufacturer assembles electronic, or intelligent, delivery devices with embedded electronic units, in which case the key is copied to a memory of the electronic unit of the delivery device. In a second variant (center curved arrow), the encryption key of the first data subscriber is provided to a delivery device end-assembly site, where the key is copied to a machine-readable tag or label of each assembled delivery device. In a third variant (right-hand curved arrow), exemplary second subscriber provides a public key via a communication network including the data transmission components to the electronic module or, in a sub- variant (not shown), to an electronic delivery device. The three variants may be used in parallel or consecutively with one and the same auxiliary electronic device and/or data subscriber.









### 03. DATA PRIVACY & SECURITY

#### WO2020197990A1 Blockchain systems and methods for remote monitoring (Publication date: 2020-10-01)

A method of processing data from mobile medical devices such as hand-held nebulizer or pacemakers enabled with cellular radios, by using a processor, a memory, private cryptographic keys, and necessary program code for computing hash and digital signature, and forming network packet. The digital signature is generated by a private key of key signing chip onboard the mobile medical device.

The method for processing data from mobile medical devices involves:

- I) receiving a network packet from mobile medical device, containing a first digital signature and a dual payload, the first payload with anonymous data, and a second payload containing a second digital signature and hash:
- ii) authenticating the network packet by recovering the dual payload from the first digital signature using a member of a list of public keys assigned to authorized data sources;
- iii) using the same to identify a patient;
- iv) inserting the anonymous data into a record for the patient in a privacy -compliant database; and
- v) pushing the same data to a distributed ledger without any patient identification information.

Information may be added to the distributed ledger in blockchain which may be maintained to provide a history of the information added. Each added block may store a reproducible signature (ex. hash) indicative of a previous state, whereby any alteration of information will be detected because the resulting signatures in subsequent blocks would not match previously stored signatures. The records in the distributed ledger may secure trusted data by hashing the data into an ongoing chain of hash-based proof-of-work, forming a record that cannot be changed without redoing the proof-of-work.

The system of a mobile medical device for remote management of patient compliance, comprises:

- i) a processor with a RAM, linked to a data source;
- ii) a reference to predetermined network coordinates stored in the memory;
- iii) use instructions for treating a medical condition stored in the memory, and
- iv) program code executable by the processor to perform data communication operations such as a) processing signals from the data source to obtain device data; b) inserting dual payloads and device signatures into network packets, first payloads containing portions of the device data, second payloads containing hashes of the device data and device signatures; and c) pushing the network packets to the network coordinates in response to internally-generated prompts.

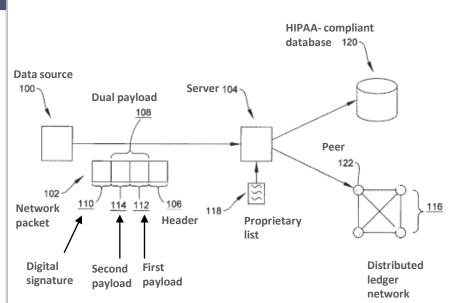


FIG. 1





### 03. DATA PRIVACY & SECURITY

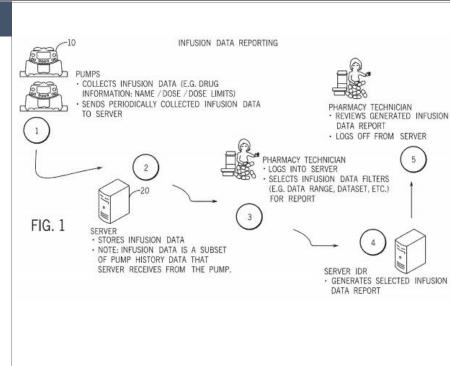
#### <u>US10306012B2</u> Secure network access to infusion pump (Publication date: 2019-05-28)

An infusion pump having improved network access security, comprising a network interface circuit configured to provide communications over a network and a communication port. The processing circuit is configured to open a communication port on the network interface circuit, transmit the infusion pump data to a server, transmit a request or receive a command from the server, and determine whether the command is on a predetermined list of commands, which are a subset of functions the infusion pump is configured to perform, process the command; and, close the communication port.

A system for communicating multiple infusion pumps and a server—with improved network security, comprises infusion pumps consisting of a network interface configured to provide a communication port and communicate over a network. The processing circuit is also configured to block commands from the server computer which are not sent in response to the request for command transmitted by the infusion pump; close the communication port on the network interface circuit, store an indication of the need to command the infusion pump in a memory, command and receive data message from an infusion pump, store the data, receive a request, transmit the command, whereby the infusion pump is commanded or controlled based on the command sent from the computer.

Fig.1, depicts a flow diagram of a system for collecting infusion data from a server. Infusion pump may be a large volume infusion pump, a patient-controlled analgesia (PCA) pump, elastomeric pump, syringe pump, enteral or parenteral feeding pump, insulin pump, etc. Infusion pump is configured to collect data, such as infusion pump programming data (e.g., user key presses), events (e.g., an alert, a notification, etc.), pump history data (e.g., any data related to pump functions) or other. Programming data can include drug name, dose, dose changes, start time, stop time, alarm information, etc.

As the pump initiates all communication requests with server, the risk of a cyberattack, such as a brute force attack, is minimized. At the same time, the protocol allows server to make commands of pump using the next command. Server may be configured to not make requests or commands on its own initiative, in keeping with a strict client/server model of communication. The pump may be configured to block commands from any server computer which are not sent in response to the request for command transmitted by the infusion pump.



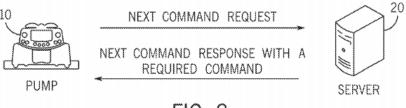


FIG. 2







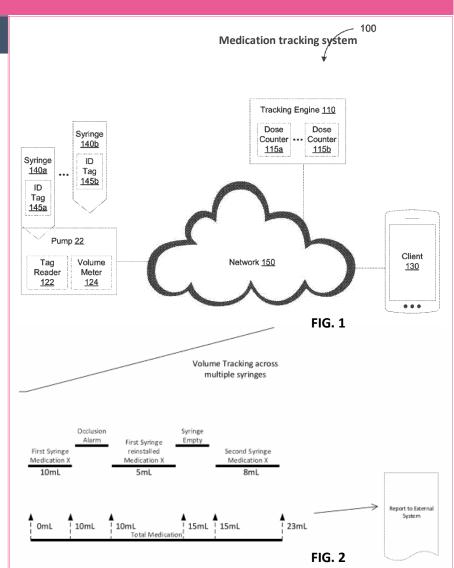
### 04. DRUG DELIVERY ERRORS

#### US20200230316A1 Medication tracking system (Publication date: 2020-07-23)

System for tracking medication delivered to patient has a data processor and memory storing instructions which when executed result in operations comprising receiving, from a volume meter at a pump, a first data on the volume of a first medication present in a first syringe inserted in the pump, which is configured to deliver the first medication to a patient; updating a first counter in response to the first medication being delivered from the first syringe or a second counter in response to the first medication as a second dose type; determining, and sending, to a mobile device, an electronic alert in response to one or more anomalies being present in the first volume of the first medication delivered to the patient.

FIG. 1 (#FIG. 1A in corresponding patent document) depicts a system illustrating a medication tracking system which includes a tracking engine, a pump and a client. These may be communicatively coupled via a network. The client may be a mobile device such as, for example, a smartphone, a tablet computer, a wearable apparatus. The pump may be a patient-controlled analgesic (PCA) pump configured to deliver a medication to a patient. The pump may also be any infusion system that is configured to deliver a substance (e.g., fluid, nutrients, medication, and/or the like) to a patient's circulatory system or epidural space via, for example, intravenous infusion, subcutaneous infusion, arterial infusion, epidural infusion, and/or the like. The pump may be configured to receive one or more syringes containing a medication such as, an opioid pain medication (e.g., morphine, hydromorphone, fentanyl, etc). For example, a first syringe containing a first medication may be inserted into the pump such that the pump may deliver the same to the patient in one or more doses including, for example, patient demand doses, clinician doses, loading doses, and/or maintenance doses. The first syringe may be removed from the pump and replaced with a second syringe containing the first medication or a second medication, for example, when a threshold quantity of the first medication remains in the first syringe, or has been delivered to the patient from the first syringe.

The tracking engine may maintain multiple counters, each of which is configured to track the volume of a medication that is delivered to a patient as a corresponding dosage type. For instance, the tracking engine may maintain a first dose counter configured to track the volume of the medication delivered as one or more maintenance doses and a second dose counter configured to track the volume of the medication delivered as patient demand doses. The tracking engine may update the first dose counter and/or the second dose counter based on an output from a volumetric device such as a volume meter. The tracking engine may detect the presence of one or more errors in the volume of a medication delivered to the patient from the first syringe and/or the second syringe. It may also detect the presence of deviations in the volume of the medication delivered as patient demand doses, clinician doses, loading doses, and/or maintenance doses. The errors may include the volume of medication delivered to the patient being greater and/or less than one or more threshold values. In response to detecting the presence of the abnormalities, the tracking engine may generate alerts as shown in FIG. 2 (#FIG. 2A in corresponding patent document), which may be sent to a medical professional associated with the client.









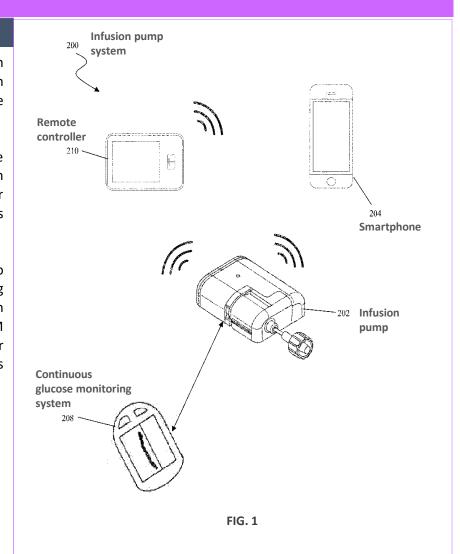
#### **05. BATTERY DRAIN**

#### US20200213946A1 Methods of wireless communication in an infusion pump system (Publication date: 2020-08-04)

Methods of establishing wireless communication in an infusion pump system including a number of components such as an infusion pump, a continuous glucose monitoring (CGM) system, multi-purpose consumer electronic device such as a smart phone or an electronic watch and a dedicated remote controller for the infusion pump. Communications among these devices can be coordinated to increase efficiency and conserve battery power.

The pump can receive glucose information from the CGM system and control commands from both the smartphone and the remote controller. The pump can also send information or receive communications from these devices such as, glucose level readings from a continuous glucose sensor. However, if both the multi-purpose consumer electronic device and the dedicated remote controller are available for communication with the infusion pump, direct communication with the infusion pump is suspended, thus saving its battery power. The dedicated remote controller has better functionality for controlling the infusion pump.

The method of coordinating the data also includes separating the data collected with the continuous glucose monitoring system into pump data that will be utilized to determine therapy parameters and non-pump data relating to the continuous glucose monitoring system that are not used to determine therapy parameters for the infusion pump; The pump data is transmitted to the infusion pump and non-pump data to the remote control device. Although the pump communicates with a monitoring device of the CGM system it can additionally communicate directly with the glucose sensor and transmitter of the CGM system. The remote controller also broadcasts for detection by the phone. The phone is always looking to detect the pump and the remote controller, which helps conserve the overall battery power of the system because the phone will generally have the largest battery.









### 06. EXPENSIVE

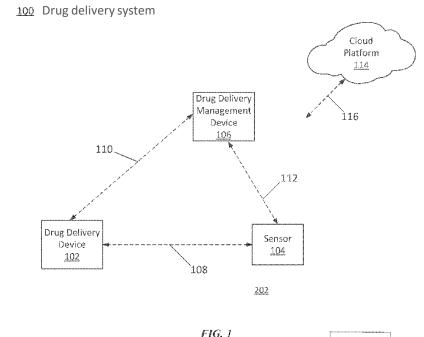
#### US20190336682A1 Code scanning for drug delivery (Publication date: 2019-11-07)

A drug delivery system that includes a drug delivery device to store and deliver a drug to a user, and a drug delivery management device that is configured to determine information relating to the drug based on an indicator coupled to a container that stores the drug and to determine a software program for controlling its operation based on the determined information relating to the drug. It reduces cost, as drug delivery system and/or drug delivery management device can be used across various drug delivery devices, drug types, and/or drug concentrations.

The drug delivery management device can be configured with different software appropriate for each different type of drug that can be loaded and used by the drug delivery management device. The different software can control the drug delivery differently for each drug type for example, by varying dosage sizes and/or times as appropriate. As a result, the need for a different type of drug delivery management device for each type of drug is no longer necessary, thereby increasing the flexibility of the drug delivery system and reducing its cost as fewer drug delivery management device stock keeping units (SKUs) are needed.

The information related to the drug can be determined using the QR code or RFID tag coupled to the container. The device provides an alarm to the user based on a determined safety issue relating to the drug such as providing an alarm to the user when the information indicates the user is not authorized to use the drug.

The drug delivery management device can include various versions of software for controlling operation of the drug delivery management device. Based on the information determined from the indicator, a particular version of software can be selected and configured for managing drug delivery operations through the drug delivery management device. The drug delivery management device can identify a particular version of software for controlling operation of the drug delivery device that is appropriate based on the information determined from the indicator. The identified software can subsequently be downloaded or provided to the drug delivery management device remotely for example, from the cloud platform. The connectivity to the cloud platforms can enable user information (e.g., patient information, drug use history, medical condition history, etc.) to be used to enable further additional configuration of the drug delivery management device.



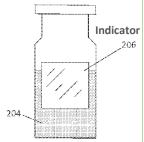


FIG. 2





# **Insulet Corporation**

## Omnipod DASH® Insulin Management System

#### Tubeless device that can provide 3 days of non-stop insulin delivery

- Wearable Pod controlled by a smartphone-like touch-screen Bluetooth®-enabled controller, minimizing the number of components to carry.
- Available through the pharmacy with no commitment or lock-in periods.
   Includes a PDM at no cost which could save you money on out-of-pocket costs and deductibles.
- Insulet Provided Glooko offers the ability to sync insulin delivery and compatible CGM data to one place for easy access for both you and your healthcare provider.
- iOS compatibility with 2 mobile apps that will allow others to remotely access and monitor insulin data.
- Product support 24/7





## **Needle-free jet injection platform**

#### Advancement in biologic administration

- Needle-free delivery system administers a narrow stream of medication, about the size of a strand of hair, through the skin in less than half a second.
- Real-time tracking and reporting sets a new standard for interactivity between patient and care teams to improve outcomes.
- Portal's game changing technology makes patient care and comfort a priority.
- Easy to use and its digital health features empower the patient to holistically manage their chronic condition interactively.





# t:slim X2<sup>™</sup> insulin pump with Control-IQ<sup>™</sup> technology

# Automated Insulin Dosing Software First to Receive New Classification by FDA

 The t:slim X2 pump is capable of remote feature updates using a personal computer.









## **Accu-Chek Combo Insulin Pump and Smart Meter**

- Full remote control over pump functionality and can deliver a bolus in a fast and discreet way.
- Automatic system status check (every three minutes and before each bolus).
- Extra safe— accurate measuring, alarm functions, key lock and fast occlusion detection.
- Integrated key lock option prevents accidental use.
- Discretion—two-way Bluetooth®wireless technology between the two devices.
- Print reports or fax or e-mail them to your healthcare provider.
- Advanced diabetes management with accompanying software solutions.





## **Adherence Technologies**

#### A multisensory-based educational and training program for West's SmartDose® platform

- Collaborating with Healthprize Technologies, Noble®, and Insight Product Development to create a multisensory-based educational and training program for West's SmartDose® platform.
- Avoids behavior and treatment complications with injection therapies.
- Works with customers and partners to optimize the experience of patients who self-inject in a way that increases affinity and fosters adherence to a treatment regimen.



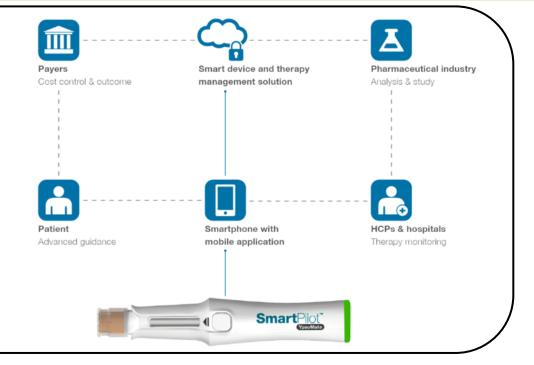






#### **SmartPilot - YpsoMate**

- Advanced patient guidance throughout the injection process
- NFC-based identification of combination product label to increase patient safety
- Compact and low-cost processing power and data storage
- Sensor miniaturisation and energy efficiency
- Network benefits of ubiquitous wireless connectivity
- Real-time tracking of injection events
  - Drug identification (incl. batch number, expiry date, etc.)
  - Injection date and time
  - · Successful injection
  - Injection interrupted
  - · Holding time deviation
- Bluetooth®-based wireless transmission of injection events to mobile application
- Injection events (date, time and result) are recorded on SmartPilot local memory for later read-outs.
- Compatible with third-party therapy management app



### The BD Intelliport™ Medication Management System



- Designed to help manage the risk of inadvertent syringe swap errors by providing real-time medication identification.
- Designed to help identify and manage the risk of possible accidental dose errors by providing realtime dose measurement.
- Features auto-documentation into the patient EMR, reducing manual documentation efforts and easing charge capture.
- Automatically identifies, measures and documents IV bolus injections all as part of the clinician's natural workflow.
- Integrates with existing hospital information systems to provide auto-documentation into the patient's EMR.







# Baxter

## **Spectrum IQ Infusion System**

Offering a simple, standardized user experience to help reduce human programming errors

- Comprehensive Approach to Safety:
  - Automatically defaults to the installed drug library and wirelessly updates the drug library, without requiring clinicians to take extra steps to use pump safety features
  - Titration error prevention enabled through a built-in Dose/Rate Change.
  - Wirelessly updates the fleet's drug library, helping ensure that programming is based on the most up-to-date drug information.
- Focus on Efficiency:
  - Built-in DeviceVue Asset Tracking Application displays both pump status and location data on a PC, tablet or smartphone .
  - Provides secondary Alarm and Alert Routing to help improve efficiency of nursing staff, and can route alarm start/stop messages to secondary Alarm Management Systems along with CQI alarm reports.
- Drug library compliance
- Protection for high-risk infusions
- · Auto-programming
- Advancing Electronic Medical Record (EMR) Integration
- Broadest range of auto-programming workflows and feature sets
- Automatically documents infusion data
- Line Check Notification technology to help clinicians visually identify that the correct medications



# smiths medical

## Medfusion® 4000 Wireless Syringe Infusion Pump

# Wireless syringe pump for reliable, accurate medication delivery to patients

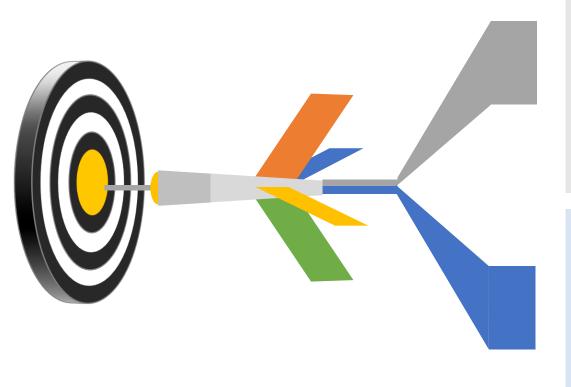
- Ability to configure care area profiles and drug protocols throughout the hospital with PharmGuard Toolbox MSS.
- Wireless connectivity to the PharmGuard® Server Software enables pump updates without physically handling the pumps.
- Smart pump technology helps reduce medication delivery errors by encouraging the use of drug libraries and identifying problem areas and trends.
- FlowSentry<sup>™</sup> monitor provides pressure sensing technology for earlier clinical intervention.
- Automatically detects various syringe types and sizes, from 1 mL to 60 mL.
- · Quick Library feature







## **RESEARCH AT UNIVERSITIES**



#### **University of Queensland**

Outcomes of a feasibility trial using an innovative mobile health programme to assist in insulin dose adjustment

Feasibility of using an innovative mobile health (mHealth) programme to assist a diabetes insulin dose adjustment (IDA) service demonstrated. Incorporating the mHealth programme for the IDA service can improve service delivery efficiencies while simultaneously improving the patient experience.

## **Grenoble Alpes University**

<u>Customization of home closed-loop insulin delivery in adult patients with</u>
<u>type 1 diabetes, assisted with structured remote monitoring: the pilot WP7</u>
<u>Diabeloop study</u>

An MPC-based algorithm (Diabeloop Artificial Pancreas system) featuring five settings designed to modulate the reactivity of regulation. Remote monitoring was ensured by expert nurses with a web platform generating automatic Secured Information Messages (SIMs) and with a structured procedure. Endpoints were glucose metrics and description of impact of monitoring on regulation parameters.





## **START-UP ACTIVITY**

## **BIOFOURMIS**

- Biofourmis' remote patient-monitoring and AI-based analytics technology, Biovitals, provides personalized predictive care.
- The AI continuously runs algorithms on the patient's profile to predict decompensation.
- Biovitals' AI-based treatment algorithms enable software-based therapeutic interventions that signal to clinicians what they should do next to intervene.
- The treatment algorithms are personalized for each patient based on machine learning, and ensure the right drug dosages and treatments for the right patient at the right time.

# NOBLE & APTAR PHARMA

- Noble and Aptar Pharma Launch AdhereIT<sup>™</sup>, a Connected Medical Device Solution for Disease Management, Adherence and Onboarding Patients
- AdhereIT<sup>™</sup> enables patients to gain control and confidence over their at-home drug delivery while easing the anxiety associated with self- injecting.
- AdhereIT<sup>™</sup> integrates with the existing software applications developed by the Digital Healthcare team at Aptar Pharma by pairing a patient's autoinjector via Bluetooth technology to their mobile phone.
- The device detects an injection event and provides real-time visual, audio and haptic feedback about whether the injection was performed correctly.



